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## Scope of This Report

Kvowa Kirin Co., Ltd. and its consolidated subsidiaries

\* Indication is provided in cases where the scope of reporting differs.

## Reporting Period

January to December 2022

\* The latest information at the time of publication is also included where possible.

#### Disclaimer

Statements concerning future plans and forecasts are based on information currently available to the Company and certain assumptions that the Company believes to be reasonable. Actual results and performance may differ due to various risks and uncertainties. Statements concerning ethical pharmaceuticals and products under development are not intended as advertising, promotions, or medical advice.

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## Motohiko Kawaguchi

KYOWA KIRIN Annual Report 2022

Chief Financial Officer (CFO) & Global Finance Head Managing Executive Officer, Head of Finance Department Kyowa Kirin Co., Ltd. (In charge of Corporate Communications and Procurement

## About the publication of the **Integrated Report**

Kyowa Kirin's Integrated Report is published for our shareholders, investors, and a wide range of other stakeholders. It introduces our business—both in its financial and nonfinancial aspects—as we "strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies." In producing this report, we referred to the International Integrated Reporting Framework proposed by the International Financial Reporting Standards (IFRS) Foundation and the Guidance for Collaborative Value Creation Guidance issued by Japan's Ministry of Economy, Trade and industry (METI).

Production of this report was led by the IR Group of the Corporate Communications Department, in collaboration with the Strategy Division and other departments across the organization. As head of the Corporate Communications Department, I have confirmed that the content of this report is accurate.

We hope that this report may be of use as a tool for communication with our stakeholders, leading to the creation of new shared value.



## Materiality





https://ir.kyowakirin.com/en/library/annual.html Corporate website https://www.kyowakirin.com/index.html Investors (IR) https://ir.kyowakirin.com/en/index.html Financial Results https://ir.kyowakirin.com/en/library/earnings.htm Corporate Governance Report https://ir.kyowakirin.com/en/management/governance.html Sustainability (CSR) https://www.kyowakirin.com/sustainability/index.html • ESG Data https://www.kvowakirin.com/sustainability/esq\_data/index.html



# We will deliver life-changing value that ultimately makes people smile, as a Japan-based Global Specialty Pharmaceutical (GSP) company

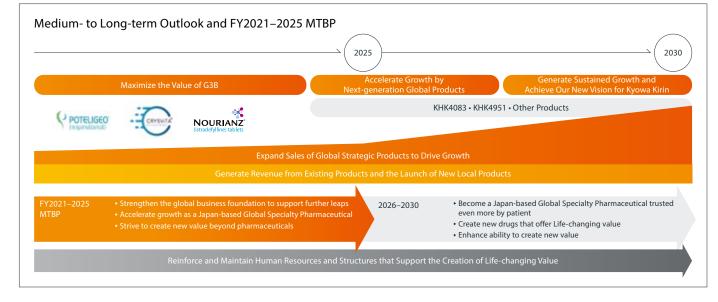
## Our medicines have the power to change lives

Our Vision for Kyowa Kirin in 2030 is to "consistently create and deliver life-changing value that ultimately makes people smile, as a Japan-based Global Specialty Pharmaceutical (GSP) company backed by a diverse team of experts with a shared passion for innovation."

In this Vision, which was formulated in 2021, "life-changing" is the word we feel most strongly about. We were inspired to include it after a patient told us how our product Crysvita changed his life. Thanks to this drug, his daily life has been transformed and he is again able to play golf,

which he enjoys even more than before. We are proud that, for many patients, Crysvita is a truly life-changing drug. Even now, the patient's smile remains etched in my memory. Talking with him impressed on me once again how our medicines have the power to change lives.

Our goal is to make even more patients smile by changing their lives for the better. Without doubt, this is what motivates us and is the overarching objective of our Creating Shared Value (CSV) Management approach. CSV Management is aimed at generating sustainable growth by creating both social and economic value. Our entire business is



underpinned by CSV Management. By creating life-changing value, we aim to solve issues faced by society through our business activities.

Bringing a new drug to market involves a daunting amount of time and effort. At times, it can be demoralizing to see the development of a drug we have being working on for so long come to a halt. However, when we look past all the problems and disappointments of the drug development process to visualize the smiles on patients' faces, we are motivated to overcome any obstacle. We want everyone in the Kyowa Kirin Group to share this feeling, and to take on new challenges without fear of failure. This thinking is embedded in the Vision.

# Update on global strategic products – the Group's growth drivers

Crysvita has seen steady growth in both the number of markets and the number of patients since its launch in 2018. In 2022, the European regulator also granted Crysvita approval for the additional indication of tumor-induced osteomalacia (TIO), bringing the life-changing value of Crysvita to even more patients. This helped Crysvita generate revenue of ¥127.1 billion in 2022, making it the Group's first product sold through proprietary channels to exceed ¥100 billion in annual revenue. As planned, sales activities for Crysvita in North America will transfer to Kyowa Kirin in spring 2023. The transition process is going smoothly and we will continue to work closely with previous distributor Ultragenyx Pharmaceutical Inc. as we establish our own sales network. In the five years since launching Crysvita, we have accumulated knowledge and evidence about how to treat X-linked hypophosphatemia (XLH), including through the use of Crysvita. Using these insights, we plan to strengthen marketing activities going forward.

Poteligeo also continues to grow steadily, especially in overseas markets. In 2022, we worked to enhance the product's visibility through promotional activities focused on patients with blood involvement.

This year, we aim to reinforce sales capabilities to further raise awareness of Poteligeo by devising new ways to utilize evidence, including data related to blood involvement.

Meanwhile, sales of Nourianz continue to rise in the US, supported by promotional activities that emphasize the drug's efficacy / safety and ease of use, as well as its different mechanism of action compared with rival products. Targeting further growth, we will continue to focus on promoting Nourianz's capabilities, while also reinforcing collaboration between sales teams in Japan and the US and effectively using digital technology.

## Strengthening the pipeline is crucial

Our pipeline includes a number of promising products. KHK4083/AMG 451 (rocatinlimab), which we are developing with Amgen Inc. for the treatment of moderate to severe atopic dermatitis, is attracting real interest in the sector, KHK7791 (tenapanor hydrochloride) is currently undergoing approval in Japan for the treatment of hyperphosphatemia in patients with chronic kidney disease on dialysis, and RTA 402 (bardoxolone methyl), a treatment for several different types of kidney disease

was, at year-end, still progressing development. Notably, we launched a Phase 3 study for KHK4083/AMG 451 (ROCKET program). This is one of our largest clinical studies to date – consisting of seven global trials – illustrating how we are pushing out all the stops to maximize the value of the product. However, we decided to discontinue global development of KW-6356 and ME-401\*, which were potential new growth drivers after our current global strategic products.

Our pipeline also includes several promising development candidates with the potential to provide life-changing value in the future. KHK4951 is an eye drop formulation of proprietary compound tivozanib, which is under development as a treatment for neovascular age-related macular degeneration (nAMD). Treating the disease often involves directly injecting drugs into the eye, but if an eye drop formulation like KHK4951 is effective, we may be able to offer a new therapy for the growing number of patients with nAMD. We are also preparing to start clinical studies of antibody drugs that incorporate our Regulgent proprietary bispecific antibody technology. We plan to have the studies up and running before the end of 2023.

## Main Development Pipeline Products

	Diseases under development*1	Planned Approval Year*2	Development status	Total addressable market*3	No. of Patients*4
KHK4083/AMG 451 rocatinlimab	Atopic dermatitis	2026/2027	Ph3 (Global)	****	16,000K
KHK4951 tivozanib	Neovascular (wet) age-related macular degeneration	TBD	Preparing for Ph2 (US and JP)	***	2,300K-
KHK7791 tenapanor	Hyperphosphatemia in patients on dialysis	2023	Filed (JP)	*	250K
KW3357 antithrombin gamma (genetical recombination)	Preeclampsia	2024	Ph3 (JP)	*	15K

- \*1 Expected indications as of the date of this report; indications may ultimately differ to expectations due status of approvals from regulatory authorities
- \*2 Expected year of first approval
- \*3 Expected total addressable market estimated by Kyowa Kirin, which is the sum of all products for the indications shown in \*1, not projected sales or the Company's targets. Colored areas represent estimates for global, and the rest are for Japan.
- ★: less than ¥50Bn, ★★: ¥50Bn-¥100Bn, ★★★: Over ¥100Bn-¥500Bn, ★★★: Over ¥500Bn-¥1Tn, ★★★★: Over ¥1Tn
- \*4 Total number of estimated patients by Kyowa Kirin. Colored areas represent in-house estimates for global, and the rest are in-house estimates for Japan.

However, we recognize that the Group needs to further expand its pipeline of new drugs to sustain growth. This is a key focus and top priority for management. That's why we will strengthen in-house basic research capabilities to identify new drug discovery targets with the potential to become life-changing medicines. We will also build a system that pushes these targets to the clinical study phase more rapidly.

In addition to these efforts in early-stage development, we urgently need to add late-stage pipeline drugs to the global pipeline. We continue to conduct due diligence and take other steps to acquire drugs under development at other companies (through in-licensing, M&As, etc.), and we are committed to actively investing in promising projects.

\* As disclosed on May 10, 2023, the Company decided to halt development in Japan of RTA 402 (bardoxolone methyl and ME-401 (zandelisib).

# Building a powerful value chain based on our unique organizational structure

Delivering medicines to patients involves various departments along the value chain – from research, development and manufacturing to quality assurance, marketing and safety monitoring. Put another way, value links these departments, and only when this value is amplified and refined through collaboration and cooperation can it become life-changing value for patients. As the Group's value chain expands worldwide, this process is becoming more complex and there is greater risk it will atrophy.

However, because of its size, Kyowa Kirin is well-placed to avoid this pitfall by linking organizations globally and organically through close communication, guided by the shared goals of our corporate vision. I believe this gives us a unique advantage over rivals.

As part of efforts to foster close communication, we continue to roll out and improve the One Kyowa Kirin (OKK) structure. OKK is a

three-dimensional matrix management structure combining a regional organization based on four regions (Japan, EMEA, North America, APAC), a global functional organization, and a product organization (product franchises). In our growth strategy for global strategic products, each product franchise leader identifies priority issues to be tackled and works with each regional and function leader to develop comprehensive optimization measures. I believe this effective, flexible organizational strategy will be a key strength supporting the creation of unique value and the Group's growth in markets worldwide.

## Kyowa Kirin is evolving to face uncertain times head-on

The operating environment surrounding pharmaceutical companies has changed dramatically since the outbreak of COVID-19. There is growing demand for even faster drug discovery and high-value-added, life-changing medicines. The current state of national finances means many countries are tightening criteria for treatment reimbursements. Pharmaceutical companies have to set out more clearly how their drugs provide value, based on even more detailed and voluminous evidence than in the past. From a long-term perspective, pharmaceutical companies may be forced to make major changes to the way they generate profits. Our pharmaceutical business, which is impacted by changes in the operating environment and industry regulations, faces considerable uncertainty. In response, we are continually working to create lifechanging value with a sense of urgency.

Failure to respond and adapt to risks arising from changes in the operating environment could have serious implications for Kyowa Kirin's survival in the future. While it is crucial to carefully analyze, predict and visualize the impact of these risks so that we can take appropriate mitigation measures, preparing for every risk is impossible. So,

when an unforeseen risk arises, we have to respond calmly and boldly, drawing on our collective expertise. This is when the true value of a company is tested.

Another powerful tool to help us respond to these changes in the operating environment will be our human resources – people with diverse values, skills, experiences and cultural backgrounds who can freely exchange opinions to devise optimal solutions. These human resources will also be key to the Group's sustained growth. With this in



We aim to adapt to risks in the operating environment that could have serious implications for Kyowa Kirin's future

mind, we are putting considerable energy into diversity initiatives. This focus on diversity also extends to board meetings, where outside officers with diverse experience add different perspectives to active discussion by the board. Their opinions are directly reflected in Kyowa Kirin's management strategies. One issue Japan currently faces is a lack of women in executive roles due to poor career opportunities. As a first step, Kyowa Kirin needs to expand the number of female management candidates, which will lead to a larger pool of potential leaders. Our goal is to increase the percentage of women in management positions to at least 18% in Japan (by 2025) and to at least 40% overseas (2030). Over the medium to long term, we want to be a company where a diverse management team of different genders and nationalities is normal, creating a dynamic culture resilient to changes in the operating environment.

INTRODUCTION

# Cultivating a corporate culture that supports Kyowa Kirin's position as a Japan-based GSP

Our employees believe that "creating new value" – a key element of our corporate philosophy – ultimately means making patients smile. I think this is why they and their colleagues choose to work at Kyowa Kirin. Our vision for 2030 is to transform Kyowa Kirin into a Japan-based Global Specialty Pharmaceutical (GSP) company with the ability to create unique life-changing value that brings a smile to patients everywhere.

To support this, all our employees worldwide have to be fully abreast of the latest technologies and trends in the pharmaceutical sector, while also widely referencing industry performance benchmarks. We also want to build a corporate culture where open-minded and curious employees energize our organization. Innovation is born in an environment where people freely communicate on a global level and embrace a wide range of different ideas and cultures. That's why we are working hard to

overhaul the Group's corporate culture through activities that overcome barriers and spur cooperation across different organizations in the Group (under the slogan KABEGOE). Our hope is that these reforms help to foster human resources with the skills and abilities to succeed at the frontline of our business worldwide.

Because of that, our efforts to create a corporate culture based on key concepts such as "patient-centric," "global," "specialized," and "life-changing value" have gained broad support across the Group.

Underpinned by this corporate culture, all Kyowa Kirin employees everywhere will be motivated to put smiles on the faces of patients, their families, and healthcare professionals, making our employees happy and fulfilled as well. In this way, we will strive to bring happiness to even more people while also creating social and economic value and maximizing the Group's corporate value. I hope we can count on your continued support as we work towards these goals.





Striving to bring happiness to more people while also creating social and economic value and maximizing corporate value

# **History of Value Creation**

# **Kirin** 1984 **Establishment of Kirin-Amgen**

company Amgen, was established for the research and development of erythropoietin. Kirin-Amgen later grew into a company that holds rights to major products with annual sales exceeding ¥1 trillion. This brought global recognition of Kirin's pharmaceutical business.



## **Establishment of** technology for producing fully human antibodies

Our researchers became the first in the world to devise Human Artificial Chromosome (HAC) technology. They succeeded in developing mice that produce fully human antibodies. This further expanded the pharmaceutical potential of antibodies.



(irin 1885

Kirin 1907 Establishment of Kirin Brewery Co., Ltd.

Kyowa 1956

Succeeded in isolating and commercializing the antitumor agent Mitomycin C



Kyowa 1949

Establishment of Kyowa Hakko Kogyo Co., Ltd. as a secondary company of Kyowa Sangyo Co., Ltd, in accordance with the Enterprise Reorganization Act



## Kirin 1988 **Promoting open** innovation

In 1988, targeting future expansion into immunology research, the Company supported the establishment of the La Jolla Immunology Institute, one of the world's leading immunology laboratories. The partnership, which continues to the present day



## 2008 **Launch of Kyowa** Hakko Kirin Co., Ltd.

## Kyowa 1951 Kyowa Hakko entered the pharmaceutical business



## Kyowa 2003 **Establishment of POTELLIGENT and BioWa**



ポテリジオ゜

KYOWA KIRIN Annual Report 2022

**2021** 

INTRODUCTION

## **▶** 2012 Launch of Poteligeo in Japan

**▶** 2013 Launch of **Nouriast in Japan** 



**2018** Launch of Fasenra in Europe, US, and Japan

▶ 2018 Launch of Crysvita in Europe and the US

Maximize product value Access to medicine

▶ 2011

▶ 2014

▶ 2018

**▶** 2019

**▶** 2019

**2020** 

▶ As of end-2022

Quality assurance and a stable supply of products

**▶** 2010

▶ 2016

**▶** 2018

**▶** 2019

**▶** 2020

**▶** 2022

Reinforcing the management infrastructure

> As part of our efforts to become a Japan-based GSP, we are maximizing the value of the Group's tangible and intangible assets through portfolio reshuffling and improvements to our management structure.

**▶** 2012

Establishment of Fujifilm Kyowa Kirin Biologics Co. Ltd., a joint venture with Fujifilm Corporation.

**▶** 2019

Kyowa Hakko Bio Co., Ltd. is transferred to Kirin Holdings Company, Limited.

▶ 2019

## Launch of the One Kyowa Kirin structure

In response to the growth of global strategic products, Kyowa Kirin launched a matrix management structure combining the regional organizations of Japan, EMEA, North America, and APAC with functional organizations that transcend regions. The close collaboration and checks and balances between the two types of organizations have made it possible to improve operational efficiency and strengthen governance.

▶ 2021 **Evolution of the** One Kyowa Kirin structure

To strengthen activities with a greater focus on patients, a product organization was added to the regional and functional organizations. We aim to further maximize the value of our global strategic products.

# To The Future

Our challenge continues into the future

# **Our Philosophy and Core Value**

**Our Philosophy** 

The Kyowa Kirin Group companies strive to contribute to the health and wellbeing of people around the world by creating new value through the pursuit of advances in life sciences and technologies.



# **Innovation**

Transform lives with passion and excitement. Challenge the status quo in all of our work.

**Core Values** 



# **Commitment to Life**

Work for the most precious presence on this planet.

Create value for patients, caregivers, healthcare professionals, and customer.



# Teamwork/Wa

One for all, all for one.

Work in diverse teams and respect each other.

Go beyond boundaries and collaborate with stakeholders.



Do the right things.

Be sincere and ethical consistently.

Make a better world through good business practices.

Kyowa Kirin will realize the successful creation and delivery of life-changing value\* that ultimately makes people smile, as a Japan-based Global Specialty Pharmaceutical company built on the diverse team of experts with shared passion for innovation.

\* Make patients smile through dramatic improvements in quality of life by identifying the unmet medical needs of people battling with medical conditions and by creating and supplying new drugs or services that help them overcome those challenges.

# **Provide** pharmaceuticals for unmet medical needs

We are focused on developing medicines for diseases where there is a clear patient need for new options. We make full use of multiple therapeutic modalities, including biotechnology such as antibody technology, and beyond, building on our Kyowa Kirin established strengths.

## **Address patient-centric** healthcare needs

We will meet the needs of patients and society by providing value across the entire patient care pathway, delivering cutting-edge science and technology, grounded in our in-depth pharmaceutical knowledge and expertise.

# Retain the trust of society

We pursue world-class product quality and operational excellence to grow our business in ways which build long-term trust with our stakeholders.



Kyowa Kirin has set qualitative and quantitative goals for the kind of company it wants to be in 2025. We are working towards these goals and our longer-term vision for the Group. We have also revised the Group's materiality, aiming to generate growth while also satisfying the demands and expectations of society.



What we mean by "new value" is value that can be shared with society, or in other words, "Creating Shared Value (CSV)."

# **Value Creation Story**

# Sources of our competitiveness

## Human capital

- Employees who share Kyowa Kirin's vision and values
- A strong, diverse **team**
- KABEGOE\* corporate culture

## Intellectual capital

- Advances in antibody technology and incorporation of various modalities
- Breakthroughs and expertise in disease science
- Integration of internal and external innovations
- \* Reforms to the Group's corporate culture launched in 2019

## **CSV Management**

Creation of social and economic value with stakeholders

Value creation in the process of delivering medicines to patients

Patient Centricity

Value creation in products, quality and distribution

Value creation to meet UMN through R&D

Management Philosophy /
Core Values

## Output

## Social value

# Continuously create and provide life-changing value



Provide new and better treatment options that meet patient expectations (new drug launches, additional indications / formulations, etc.)



Deliver essential medicines to more patients (increase number of launch markets, etc.)



Ensure stable supplies of pharmaceuticals

## Economic value

- Revenue
- Revenue growth rate
- Core operating profit
- Core operating profit ratio
- ROE







Provide pharmaceuticals for unmet medical needs

## Outcome

Achieving our vision for 2030

Address
patient-centric
healthcare
needs

Retain the trust of society

Achieving our 2030 Vision will make people facing illness smile and make our employees smile as well.











INTRODUCTION

# Materiality

Kyowa Kirin has selected materiality (key management issues) to realize its vision for 2030. As we move into 2023, the mid-point of our Medium Term Business Plan, we have reviewed the Group's materiality in light of changes in the external environment, creating a clearer link between our vision and business strategy. Going forward, the whole Group will continue to work as one to achieve our vision for 2030.

## **Topics for value creation**

Core strategies	Materiality	Related initiatives		Related SDGs
Provide	Creation of innovative drugs	A Conversation with Kyowa Kirin's R&D Executives	P21	3 GOOD HEALTH AND WELL-BEING
pharmaceuticals for unmet	Maximize product value	R&D Concept and "Our R&D Spirits"  Next-generation Drugs in	P25	AND WELL-BEING
medical needs		the Development Pipeline	P26	CENDED
	Pipeline expansion	Three Global Strategic Products	P27	5 EQUALITY
Address patient-centric	Patient advocacy	Addressing Patient-centric Healthcare Needs	P28	8 DECENT WORK AND ECONOMIC GROWTH
healthcare needs	Access to medicine	Patient Advocacy: Providing Value Beyond Pharmaceuticals	P29	9 INDUSTRY, INNOVATION AND INFRASTRUCTURE
Strengthen	DE&I			10 REDUCED INEQUALITIES
human resources and infrastructure	Talent portfolio	Human Resources	P32	17 PARTNERSHIPS FOR THE GOALS
to realize life-changing	Corporate culture			<b>***</b>
value	Digital transformation	Digital Transformation Strategy	P36	

## **Topics for value enhancement**

Core strategies	Materiality	Related initiatives	Related SDGs
Retain the	Quality assurance and a stable supply of products	Quality Assurance/ Stable Supply P4	6 SLEAN WATER AND SANITATION  7 AFFORMABLE AND GRAH BERRY
trust of society	Reducing environmental impact	Ensure a Thriving Global Environment for Future Generations P4	12 RESPONSIBLE
Strengthen	Corporate governance	Governance P4	13 CAMATE 8 15 LIFE ONLAND
human resources and infrastructure to realize life-changing	Ethics and transparency	Compliance P5 Human Rights P4	3
value	Reinforce risk management	Risk Management P5 Risk Factors P6	

# **Co-creating Value with Stakeholders**

To realize our Vision for Kyowa Kirin, we need to create both social and economic value. An essential part of this process is cooperating and collaborating with stakeholders in the value chain. We are committed to deepening relationships and co-creating value with stakeholders by engaging with them in various ways.



Stakeholders	Main engagement opportunities and frequency							
Patients, caregivers, patient communities	► Disease awareness websites ► Medical information contact center	Ongoing Ongoing						
Healthcare professionals	<ul> <li>▶ Medical websites</li> <li>▶ Disease awareness websites</li> <li>▶ Medical information contact center</li> <li>▶ Communication via MR/MSL</li> <li>▶ Publication of medical findings in journals and at conferences</li> </ul>	Ongoing Ongoing Ongoing Ongoing Ongoing						
Employees	Internal intranet  Individual interviews  Whistleblowing system  Employee engagement survey *  Basic survey on corporate culture reforms*  Wellness action surveys*  Survey on middle management support*	Ongoing Ongoing Ongoing 1 time 3 times 3 times 3 times						
Partners (Suppliers, pharmaceutical wholesalers, etc.)	► Daily operations ► Supplier briefings ► Supplier questionnaires	Ongoing 1 time 1 time						
Joint R&D partners	▶ Daily operations	Ongoing						
Shareholders / investors	► General meeting of shareholders ► Financial results briefings ► IR events (ESG, R&D) ► President IR interviews ► IR interviews by other senior managers ► IR interviews by IR team ► J.P. Morgan Healthcare Conference	1 time 4 times 2 times (77 companies in total) 29 times (115 companies in total) 18 times (222 companies in total) 131 times 1 time						
Industry associations, central and local governments, regulators / payers	▶Daily operations	Ongoing						
Local communities	▶Meetings and briefings	Ongoing						
Future generations	Disclosure of information on environmental measures  Cooperation with environmental activities by the Federation of Pharmaceutical Manufacturers'  Associations of Japan (FPMAJ) and the Japan  Pharmaceutical Manufacturers Association (JPMA)	Ongoing						

13

<sup>\*</sup> Feedback from all the above surveys is provided to employees

# **Financial Strategy**



## Motohiko Kawaguchi

Chief Financial Officer (CFO) & Global Finance Head Managing Executive Officer, Head of Finance Department Kyowa Kirin Co., Ltd.

## Building a stable earnings structure and generating sustainable growth

#### Medium Term Business Plan Progress Review

In the FY2021–2025 Medium Term Business Plan, we are targeting sustained growth and higher corporate value over the medium to long term. To measure progress, we use return on equity (ROE) as a key performance indicator (KPI). Our aim is to rapidly achieve ROE of 10% or higher so that ROE consistently exceeds the expected cost of capital. We also aim to increase ROE over the longer term. To achieve our ROE objectives, we need to continuously increase the Group's growth potential, capability to innovate, and profitability. We have selected three KPIs to measure our progress in those areas: revenue growth rate, R&D expenses ratio and core operating profit ratio.

First, let's look at the revenue growth rate (growth potential benchmark). During the five years of the Medium Term Business Plan, we are targeting average annual top-line growth of 10% or higher. We aim to do that by steadily increasing sales and maximizing the value of existing global strategic products, and by launching the next generation of strategic products. Second, the R&D expenses ratio (capability to innovate benchmark). Our goal is to expand the drug pipeline to accelerate and drive the Group's growth beyond FY2025 by consistently and actively investing in research and development, aiming for an R&D expenses ratio of 18–20%. At the same time, we will work to improve profitability by reducing the selling, general and administrative expenses ratio (profitability benchmark) of 25% or higher by FY2025, the final year of the plan.

By implementing measures to achieve these three KPIs, we aim to deliver profit growth that outpaces revenue growth in order to improve ROE over the medium to long term, supporting sustained increases in the dividend. Ultimately, our objective is to establish a stable earnings structure and generate continued growth as a Global Specialty Pharmaceutical Company (GSP).

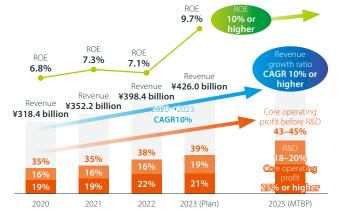
In FY2022, growth in global strategic products such as Crysvita and Poteligeo and technology out-licensing revenue drove top-line growth, supported by the yen's depreciation. We also made good progress with the roll out of our IT digital platform – which is vital to support the Group's growth as a Japan-based GSP – while also investing heavily in human resources and making preparations to transfer sales of Crysvita in North America to proprietary channels from 2023. In R&D, we pushed ahead with the development of KHK4083, a next-generation global strategic product under development with Amgen Inc. of the US. However, we decided to discontinue development of KW-6356 and joint development of ME-401 outside Japan with MEI Pharma, Inc. As a result, in terms of business plan KPIs, the revenue growth rate (CAGR, FY2020 base year) was 11.9%, the R&D expenses ratio was 15.8% and the core operating profit ratio was 21.8%, resulting in ROE of 7.1%.

In FY2023, the third year of the plan, we aim to accelerate sales of Crysvita and Poteligeo, supported by the launch of proprietary sales of Crysvita in North America and by a collaboration in the established medicines portfolio in Europe between Kyowa Kirin International plc. and Grünenthal GmbH of Germany. In R&D, we will continue to implement our strategy of creating a steady stream of

## Financial KPIs (Numerical guidance)

ROE	<b>10% or higher</b> (achieve target early / maintain or increase over the medium- to long-term)
Revenue growth rate	CAGR*1 10% or higher
R&D expenses ratio	Targeting 18–20% to support active investment
Core operating profit ratio*2	<b>25% or higher</b> by 2025
Dividend payout ratio	Targeting <b>sustained dividend hikes with 40%</b> (based on core EPS*3)

- \*1 Average growth rate over a five-year period, with FY2020 as the base year.
- \*2 Core operating profit: "Gross profit" "Selling, general and administrative expenses" "Research and development expenses" + "Share of profit (loss) of investments accounted for using equity method."
- \*3 "Core profit" ("Profit attributable to owners of parent" "Other income and expenses" (excluding impact from applicable taxes)) / average number of shares during fiscal year.



\*4 Above graph is taken from the Results Presentation FY2022, released February 7, 2023

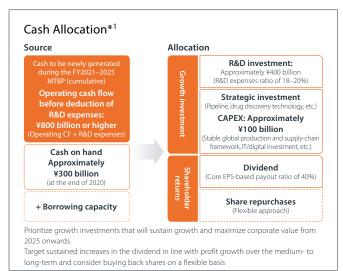
innovative new drugs. This will involve pushing ahead with the development of KHK4083, a next-generation global strategic product, KHK7791, and other products for the Japanese market, and stepping up efforts to strengthen the pipeline by developing early-stage development drugs such as KHK4951 and acquiring new pipeline products. With these initiatives, we aim to make steady progress toward the FY2025 final-year objectives in the Medium Term Business Plan by achieving our targets for FY2023 – revenue growth of 10.2%, R&D expenses ratio of 18.5%, core operating profit ratio of 20.7%, and ROE of 9.7%.

#### Cash allocation

In our five-year cash allocation plans in the FY2021–2025 Medium Term Business Plan, we assume the source of funds will be new operating cash flow of ¥800 billion or higher (before deduction of R&D expenses) generated during the plan's five years. Our top priority for cash allocation is growth investments (such as R&D, strategic investments, and capex), in order to sustain growth beyond FY2025 and maximize corporate value.

#### **R&D** investment

During the FY2021–2025 Medium Term Business Plan, we intend to continue investing heavily in R&D, based on an R&D expenses ratio of 18–20% (R&D investment as a percentage of revenue). In R&D activities, we will channel resources into the development of next-generation strategic products to maximize the value of our pipeline. We also plan to actively invest in areas that support innovation over



<sup>\*1</sup> Medium Term Business Plan (2021–25) cash allocation assumptions announced on February 4, 2021

the long term, such as multi-modality technology platforms that drive the creation of groundbreaking new treatments, aiming to consistently create new products that bring life-changing value to patients.

#### Strategic investment

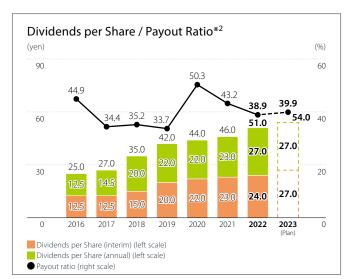
We will actively utilize external resources for strategic partnering (in-licensing, tie-ups, etc.) and M&A to tap external innovation, such as drug discovery technologies created through open innovation and new compounds for our pipeline. We are also targeting faster, sustained growth by expanding our global pipeline over the medium and long term, generating synergies with existing global strategic

## (1) In-licensing and M&A investments to reinforce the portfolio

- Development pipeline drugs (bone / mineral, hemato-oncology) that have synergies with Crysvita and Poteligeo
- Drug in-licensing leveraging the Group's strengths in each region (renal, hematology / oncology, immunology treatments)

#### (2) Investments in science and technology to cultivate new strengths

- Investments to acquire new drug discovery technologies and earlystage pipeline drugs, and to accelerate alliances and collaborations
- Venture capital (VC) investment and corporate venture capital (CVC) activities to gather information and gain market access



<sup>\*2</sup> Dividend payout ratio after 2021 is the dividend payout ratio based on core EPS
(= Profit attributable to owners of parent – Other income & expenses and impact of applicable taxes).

products, and increasing opportunities to create unique value. The Strategic Investment Review Committee, which is led by the CEO, continually considers potential targets for strategic growth investments. Priority is given to the following strategic investment projects:

In FY2022, we continued to invest in multiple VC funds as a way of increasing rapid access to the latest drug discovery technology and product information, but we also launched CVC activities to step up these efforts.

#### Capital investment (capex)

We will invest heavily to create a more competitive business structure to help us maximize the value of global strategic products. In particular, we are focusing on establishing a robust quality assurance and production system that can reliably supply safe, high-quality pharmaceuticals to patients worldwide. We also aim to rapidly establish a global business foundation that supports Kyowa Kirin's sustained growth as a Japan-based GSP. Specifically, investment will be needed to build a platform that allows us to strategically utilize IT and digital tools and to reinforce global governance and risk management functions.

In FY2022, capital investment totaled ¥24.6 billion (including intangible assets and long-term advance payments). Investment was mainly used for a new quality assurance center (Q-TOWER) equipped with the most advanced biopharmaceutical analysis equipment in Japan; a new biopharmaceutical API manufacturing facility (HB7 building) to speed up early-stage clinical studies; a new warehouse building to ensure stable supplies of products worldwide; and the rollout of a global ERP system overseas as part of efforts to reinforce the Group's IT digital platform.

When evaluating the profitability of potential investments or development projects, we mainly use two quantitative standards: net present value (NPV) and expected present value (EPV). Both standards are based on the hurdle rate (by region), which reflects the expected cost of capital (WACC) for investors. In investment decisions, we focus on whether the investment will contribute to an increase in corporate value over the medium to long term by generating returns in excess of the cost of capital.

#### Shareholder returns

In the FY2021–2025 Medium Term Business Plan, we are targeting a consolidated dividend payout ratio of 40% based on core EPS, aiming to steadily increase returns for investors by raising the dividend in line with profit growth over the medium to long term. In line with that policy, we paid an FY2022 dividend of ¥51.00 per share (dividend payout ratio of 38.9%), an increase of ¥5.00 from FY2021. In addition, we plan to raise the FY2023 dividend to ¥54.00 (dividend payout ratio 39.9%), which will be the seventh consecutive increase. We will also flexibly consider buying back shares, taking into account the share price and other factors.

To generate sustained growth and maximize corporate value as a Japan-based GSP, we will enhance the Group's growth potential, capability to innovate, and profitability in order to improve ROE over the medium to long term and support sustained increases in the dividend.

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## **Headline News**

**Topics for** Value Creation

- Creation of innovative drugs
- Maximizing product value
- Pipeline enrichment

## May 2022

Started joint research with LUCA Science Inc. on mitochondrial disease treatment with novel modality



## May 2022

Drug discovery concept identified by InveniAI LLC's platform validated in preclinical studies



## **July 2022**

Decision taken to discontinue development of Parkinson's disease treatment KW-6356

### August 2022

European Commission approves use of Crysvita for treatment of tumor-induced osteomalacia (TIO)

#### October 2022

First investment in startup through corporate venture capital (CVC) fund

#### October 2022

NDA submitted in Japan for KHK7791 for improvement of hyperphosphatemia in chronic kidney disease patients on dialysis

#### November 2022

Kyowa Kirin International plc. signs joint-venture agreement for established medicines portfolio

#### December 2022

Global Phase 3 study launched for rocatinlimab, an atopic dermatitis treatment under joint development with Amgen Inc.



#### December 2022

Decision taken to discontinue development outside Japan of ME-401, a treatment for B-cell malignancies under joint development with MEI Pharma, Inc.

#### December 2022

G-Lasta Subcutaneous Injection 3.6 mg BodyPod launched in Japan

▶ DF&I

## November 2022

Awarded gold status in the PRIDE Index 2022 (Japan) as an LGBTQ+-friendly workplace



#### March 2023

Selected as Health & Productivity Stock for second consecutive year and certified as Health & Productivity Management Outstanding Organization (White 500) for seventh consecutive year



## Patient advocacy

Access to medicine

## April 2022

Established Kyowa Kirin Group Policy for Access to Medicines (basic policy on measures to provide pharmaceuticals for unmet medical needs [UMN], improve access to medicines, ensure quality and stable supplies of medicines, and promote safety and proper use)

### May 2022

Launched virtual exhibition - Shine A Light on XLH – to coincide with International Day of Light



### September 2022

Participated in annual meeting of the European Organisation for Research and Treatment of Cancer (EORTC) and interacted with Cutaneous Lymphoma Tumours Group (CLTG), an opportunity for dialogue between specialists and patient advocacy groups

## October 2022

Hosted XLH Cafe open lecture in conjunction with World XLH Awareness Day

## February 2023

Started work on an FGF23-related hypophosphatemic rickets and osteomalacia project with Ubie Inc., which provides medical consultation support services and a medical symptom checker

**Topics for** value enhancement,

- Quality assurance and a stable supply of products
- Reducing environmental impact

### May 2022

Approved construction of new biopharmaceutical API manufacturing wing at the Takasaki Plant

#### December 2022

Approved construction of new warehouse building at the Takasaki Plant

#### December 2022

Approved installation of large-scale solar power generation system at the Ube Plant

## December 2022

New quality assurance center Q-TOWER completed at the Takasaki Plant

# **Financial Highlights**

## **Key Points**

#### Revenue

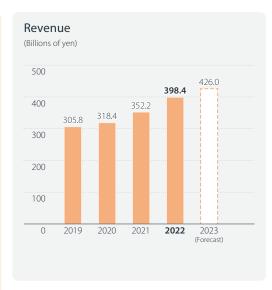
Revenue in Japan declined year on year, reflecting reductions to NHI drug prices for two consecutive years in 2021 and 2022 and the launch of rival generic products. However, revenue increased overseas, supported by steady growth for global products, especially in the US and Europe, as well as a boost from the weaker yen. Technology out-licensing revenue also grew. As a result, revenue increased ¥46.1 billion (+13.1%) year on year, and the overseas revenue ratio rose 7.2 percentage points to 61.2%.

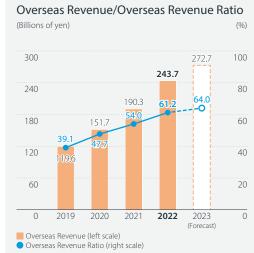
## Core Operating Profit

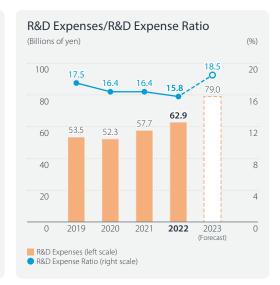
Selling, general and administrative expenses increased year on year, reflecting higher Crysvita profit-sharing expenses in North America and active investment in digital IT platforms and human resources to maximize the value of global strategic products and rapidly establish a global business base. Despite this, core operating profit increased ¥21.0 billion (+32.0%) year on year, supported by higher gross profit in line with the rise in revenue.

### Profit Attributable to Owners of Parent

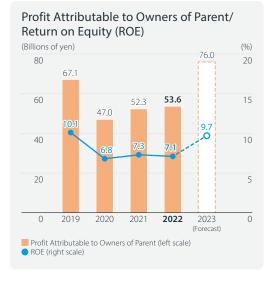
Net profit increased year on year, with the rise in core operating profit, as well as higher financial income, offsetting a rise in income taxes and an increase in other expenses due to impairment losses.

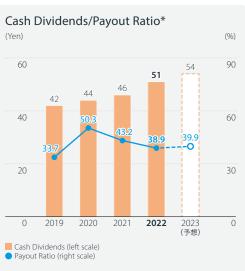












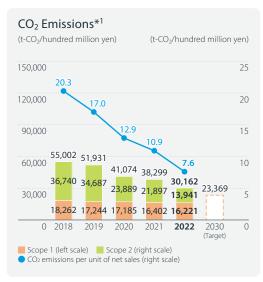
<sup>\*</sup> Dividend payout ratio after 2021 is the dividend payout ratio based on core EPS in the Medium Term Business Plan (2021–25).

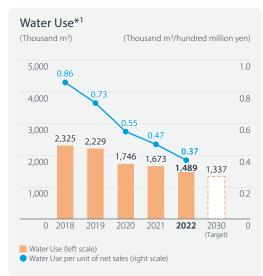
AT A GLANCE

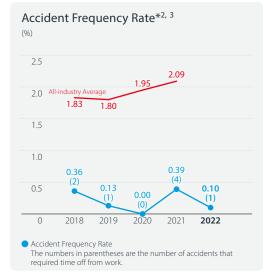
KYOWA KIRIN Annual Report 2022

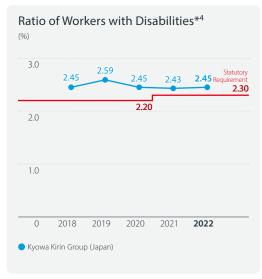
# **ESG Highlights**



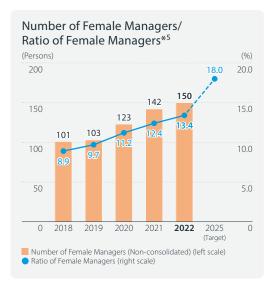




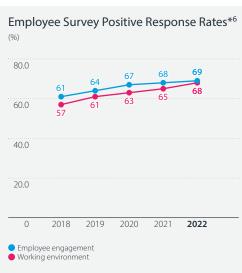












<sup>\*1</sup> Covers plants and research laboratories worldwide.

<sup>\*2</sup> Covers plants/laboratories of Kyowa Kirin/Kyowa Medex/Kyowa Hakko Bio /Kyowa Pharma Chemical in 2018, all locations of Kyowa Kirin in 2019 and 2020, and all locations in Japan and overseas plants/laboratories of the Kyowa Kirin group from 2021.

<sup>\*3</sup> The rates indicate the number of casualties from fatal lost-time accidents per million working hours.

<sup>\*4</sup> As of June each year.

<sup>\*5</sup> Covers Kyowa Kirin.

<sup>\*6</sup> Responses to each question based on 5-point scale from "very much agree" to "do not agree at all," with "very much agree" and "agree" being positive responses; positive response rates of 65% or higher are generally considered to show the strengths of a company.

# Pipeline (As of December 31, 2022)









Yantibody protein small molecule New Molecular Entity Progress with approvals in Jan-Dec 2022

## Nephrology

As of December 31, 2022

	Code Name & Generic Name < Formulation >	Mechanism of Action	Indication	ndication Area			Stage			In-House or Licensed
	code Name & Generic Name < romination>	Mechanism of Action	maication	Aled	Ph I	Ph II	Ph III	Filed	Approved	
Jan 1	KHK7580 Evocalcet <oral></oral>	Calcimimetic	Connector at the property waidings	CN/TW				$\longrightarrow$	•	Mitsubishi Tanabe Pharma
**	KHK/380 EVOCAICEL < OTAL>	Calcimimetic	Secondary Hyperparathyroidism	KR				$\longrightarrow$		WILSUDISHI TANADE PHAITHA
			Alport Syndrome	JP						
*	©RTA 402 Bardoxolone Methyl <oral></oral>	Antioxidant Inflammation Modulator	Diabetic Kidney Disease	JP						Reata
			Autosomal Dominant Polycystic Kidney Disease	JP						
8	KW-3357 Antithrombin Gamma <injection></injection>	Recombinant Human Antithrombin	Preeclampsia	JP						In-House
*	KHK7791 Tenapanor Hydrochloride <oral></oral>	NHE3 Inhibitor	Hyperphosphatemia in Patients on Dialysis	JP				$\longrightarrow$	•	Ardelyx

## Oncology

				CA WD/AF				
				CA/KR/AE				
				CN			<b></b>	
Y	KW-0761 Mogamulizumab <injection></injection>	Anti-CCR4 Humanized Antibody	Mycosis Fungoides and Sézary Syndrome	IL		$\rightarrow$		In-House
				RS		$\rightarrow$		
				KW				
			Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Allogeneic Blood Stem Cell Transplantation	JP				
8	KRN125 Pegfilgrastim <injection></injection>	Long-Acting Granulocyte Colony-Stimulating Factor	Mobilization of Hematopoietic Stem Cells into Peripheral Blood for Autologous Blood Stem Cell Transplantation	JP				Amgen-KA
			Automated Injection Device for Decreasing the Incidence of Febrile Neutropenia in Patients Receiving Cancer Chemotherapy	JP			<del></del>	
赤	©ME-401 Zandelisib <oral></oral>	PI3Kδ Inhibitor	Indolent B-cell Non-Hodgkin's Lymphoma	JP				MEI Pharma



Glossary	
Phase I Clinical Trial	Studies in small numbers of healthy people (patients in some cases) to verify safety issues including side effects.
Phase II Clinical Trial	Studies in small numbers of patients to verify effective and safe dosage and regimen.
Phase III Clinical Trial	Studies in large numbers of patients to confirm efficacy and safety in comparison with standard drugs or placebo.

<sup>\*</sup> All trials are conducted under supervision of clinical doctors and with the consent of participants.

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## Immunology/Allergy

### As of December 31, 2022

	ode Name & Generic Name <formulation></formulation>	Mechanism of Action	Indication	Area			Stage			In-House or Licensed
	ode Name & Generic Name < Formulation>	Mechanism of Action	indication	Area	Ph I	Ph II	Ph III	Filed	Approved	
	Ankylosing Spondylitis TW		TW/MY					$\longrightarrow$		
			Ankylosing Spondylitis	TH						
Y	KHK4827 Brodalumab <injection></injection>	Anti-IL-17 Receptor A Fully Human Antibody	Non-radiographic Axial Spondyloarthritis	TH						Amgen-KA
		l '	Systemic Sclerosis	JP						
			Palmoplantar Pustulosis	JP				$\rightarrow$		
Y	©KHK4083/AMG 451 Rocatinlimab <injection></injection>	Anti-OX40 Fully Human Antibody	Atopic Dermatitis	JP/NA/Europe						In-House
Y	©KK4277 <injection></injection>		Autoimmune Disease	JP	$\rightarrow$					SBI Biotech

## Central Nervous System

Y	©KHK6640 <injection></injection>	Anti–Amyloid Beta Peptide Antibody	Alzheimer's Disease	JP/Europe				Immunas Pharma	
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## Other

-								
				X-linked Hypophosphatemia (XLH)	TH			
	Y	KRN23 Burosumab <injection></injection>	Anti-FGF23 Fully Human Antibody	л-никей пурорнозрнатенна (л.с.п)	MY			In-House
				Tumor Induced Osteomalacia (TIO)	Europe			
				Treatment of Adult Patients with Chronic Immune Thrombocytopenia (ITP) Who Do Not Respond Well to	CN			
				Other Treatments, Such as Corticosteroids and Immunoglobulin	CIV			
	8	AMG531 Romiplostim <injection></injection>	Thrombopoietin Receptor Agonist	Treatment of Aplastic Anemia (AA) Which Is Refractory to Immunosuppressive Therapy or AA not Amenable to	SG			Amgen-KA
				Immunosuppressive Therapy	TH/MY			
				Aplastic Anemia Who Were Previously Untreated with	JP			
				Immunosuppressive Therapy	Asia		Ph II/Ph III	
	8	KW-3357 Antithrombin Gamma <injection></injection>	Recombinant Human Antithrombin	Disseminated Intravascular Coagulation, Congenital Antithrombin Deficiency	Europe			In-House
	*	KHK4951 Tivozanib <ophthalmic></ophthalmic>		Neovascular (wet) Age-Related Macular Degeneration	JP			In-House

# Provide pharmaceuticals for unmet medical needs

## A Conversation with Kyowa Kirin's R&D Executives



## Yoshifumi Torii

Executive Officer, Kyowa Kirin Co., Ltd. Global Research Head

## **Ernesto Aycardi**

Senior Vice President, Chief Development Officer, Kyowa Kirin, Inc. Global Development Head

Kyowa Kirin's R&D efforts are focused on creating new pharmaceuticals for unmet medical needs. In this section, Global Research Head Yoshifumi Torii and Global Development Head Ernesto Aycardi discuss how Kyowa Kirin is implementing initiatives at each stage of the R&D process to spur further advances in global R&D.



## A new global development structure

**Torii:** Ernesto, in 2022, you led the roll out of Kyowa Kirin's Global Development Organization (GDO), a globally unified development structure that builds on the integration achieved with the previous virtual Global Development Organization (vGDO). The new GDO is set to accelerate R&D decision-making at the global level, leading to qualitative improvements and productivity gains in operations. I believe this initiative will also help us realize our vision of making patients smile.

Aycardi: That's right. Existing drugs such as Crysvita and Poteligeo were developed by staff based in Japan, and also in the US, Europe, Asia and other regions, but these multiregional R&D teams used our virtual organization to collaborate. However, to step up the pace of development in our pipeline, and keeping in mind how we can serve patients globally, we decided to overhaul our organization to create a "One Team" structure that facilitates better collaboration between different regions. Under this new structure, all team members involved in projects in the pre-clinical and development stages of our pipeline have been combined into a single organization with unified management lines, replacing the previous virtual teamwork approach.

This new organization is just the first step to creating life-changing value. To accelerate value creation for patients, we have to ensure expedient, open communication from the management level right down to the project team level. Guided by one of the key tenets of "Our R&D Spirits" – This is Me, This is Our Team – we must harness the different cultural backgrounds of our regional teams to create new value for patients.

**Torii:** This transformation of the R&D organization is pivotal to enhancing the Group's global development capabilities and to realizing our vision for Kyowa Kirin. As senior managers in the R&D structure, we are firmly committed to this transformation and to promoting R&D on a global basis to achieve our vision.

## Promising new drugs in the development pipeline

Torii: Next, I would like to talk about the development pipeline. One of the management strategies in our Medium Term Business Plan for 2021–2025 aims to "Address patient-centric healthcare needs" and "Provide pharmaceuticals for unmet medical needs (UMN)." To achieve these objectives, our key mission in R&D is to drive the development of innovative pipeline drugs that provide life-changing value from the patient's perspective.

One of our next-generation development pipeline drugs is KHK4083/AMG 451 (rocatinlimab), which we are co-developing with Amgen Inc. It will be critical to achieving our vision for 2030. KHK4083/ AMG 451 is one of the largest development projects ever undertaken by Kyowa Kirin, presenting some major challenges.

**Aycardi:** This collaboration with Amgen – a company with extensive experience in the immunology and allergic disease treatment fields – will test the true value of our development capabilities under the GDO structure. It is also an excellent opportunity for our GDO to cultivate the principles of continuous improvement and learning. Patient enrollment in the Phase 3 study was suspended temporarily, but we were able to resume after detailed discussions with the regulatory authorities together with Amgen and refocus on the primary objective of providing value to patients. We are convinced this is a very valuable experience for Kyowa Kirin's future global development projects.

**Torii:** Based on my own experience, I think there is much to be learned from trial and error through actual project implementation. I think the experience will stand us in good stead for any future challenges we face delivering life-changing value to patients under the GDO structure. We need to draw on these insights from KHK4083/AMG 451 and apply them to other drugs coming through the development pipeline.

Aycardi: I agree. For example, KHK4951 (tivozanib) is under development as a treatment for neovascular age-related macular degeneration (nAMD), which is currently treated with the highly invasive method of injections directly into the vitreous humor of the eye. We aim to establish KHK4951 as a less-invasive treatment method using eye drops. We have great hopes for the project, as it aims to maximize value by putting patients at the center of drug development. A Phase 1 study in Japan was completed in 2022, and based on the data obtained, we are optimistic about the project. We also received positive feedback in discussions with key opinion leaders. We now plan to accelerate the drug's international development.

Meanwhile, KW-3357 (antithrombin gamma [recombinant human antithrombin]), which has been approved in Japan for the treatment of disseminated intravascular coagulation (DIC), is currently undergoing Phase 3 clinical trials in Japan for preeclampsia. Our aim is to develop a treatment that meets the high unmet medical needs for preeclampsia, for which no effective treatment currently exists. We see KW-3357 as a promising candidate for maximizing value in this area.

**Torii:** For our part, we need to be actively involved in developing pipeline drugs that satisfy unmet medical needs. The pre-clinical stage, as well as the development stage, is likely to be a promising area in the pipeline for satisfying unmet medical needs.



## Maximizing value by putting patients at the center of drug development

One area we are focusing on is our bispecific antibody pipeline, which we are currently preparing for Phase 1 trials. These bispecific antibodies are set to be the first drugs in our development pipeline created by proprietary Regulgent technology. We are excited to see what profile these bispecific antibodies reveal in the clinical trials, as the data will help us accelerate other pipeline drugs that use the same technology.

**Aycardi:** With the launch of the GDO structure, we can now make decisions across functions and regions more smoothly than before, which should support the rapid transition of these pipeline drugs from the pre-clinical stage to the development stage.



Combining our strengths with those of outside partners to forge new strengths



## Accelerating the creation of new value in the research stage

**Aycardi:** So far we have talked about our initiatives in the development stage. In the research stage too, I understand you are making significant progress with expanding the pipeline to support the continuous creation of life-changing value. What initiatives are you implementing?

**Torii:** For Kyowa Kirin to continue growing as an R&D-focused company, we know that we have to constantly improve the efficiency of our research setup. We are taking a whole range of steps to rapidly and consistently create "life-changing value with clear competitive advantages."

One of these is the ongoing evolution of our research organization and research management system. In 2021, we opened a new Research Unit to combine fragmented research teams, aiming to promote more dynamic, closer cooperation between technology research, disease research and open innovation. This integrated approach is allowing us to effectively manage all areas of drug discovery research, including more flexible resource allocation within the unit. Our reforms do not stop – we are making continuous improvements to management processes to further improve the efficiency of research activities.

**Aycardi:** So, many changes are underway in the research organization as well. Joined-up management systems are critical to ensure pipeline drugs transition smoothly from research into development. I look forward to continue working with you closely to build an even better R&D organization

In addition to these organizational and structural reforms, what other steps are you taking to reinforce the R&D pipeline? As members of the GDO, we have high hopes for the creation of groundbreaking pipeline drugs and their progress to the development stage.

**Torii:** Of course, we are also working on specific initiatives to strengthen the pipeline, as well as the organizational reforms.

One of our key roles in research is to actively promote open innovation. Pipeline drug KHK4083/AMG 451 is an example of this approach. The lead compound was identified through a collaboration between our US research team and the La Jolla Institute for Immunology, followed by proprietary Kyowa Kirin research that led to the discovery of the drug. This kind of approach – combining our own strengths with those of external partners to forge new strengths – will be key to driving value creation in the future.

**Aycardi:** We are seeing this not only with KHK4083/AMG 451, but also in the development of global pipeline drugs by other companies, which are increasingly relying on input from bioventure partners. Given also the growing number of different modalities in drug discovery, it is vital that Kyowa Kirin also looks to outside partners for ideas to ignite innovative drug discovery. What specific steps are you taking?

**Torii:** One example is our strong partnership with InveniAl LLC in Al-powered drug discovery. We started working with InveniAl in 2018 and are gradually seeing results, such as signals of efficacy in preclinical proof-of-concept studies for the treatment of a target disease indication. We expanded our collaboration agreement with the company in 2021 and we expect the application of Al in drug discovery to contribute to growth in our pipeline.

Another partner is Synaffix B.V. We are harnessing the company's proprietary antibody-drug conjugate (ADC) technology to identify new ADC pipeline drugs. We also continue to collaborate with Axcelead Drug Discovery Partners Inc. and xFOREST Therapeutics Co., Ltd. on small molecule drug discovery targeting RNA structures. We expect all these initiatives to yield groundbreaking pipeline drugs that progress to the development stage.

**Aycardi:** I look forward to seeing promising pipeline drugs with the potential to deliver life-changing value move into the development stage. Your work also highlights again how important it will be to continuously improve our global development capabilities so that we can deliver these new drugs to patients worldwide as quickly as possible.

In addition to the initiatives you mention, Kyowa Kirin has also launched corporate venture capital (CVC) activities. What are your objectives with CVC?

**Torii:** As an R&D-focused company targeting long-term growth, I think it is important not only to "deepen knowledge" in existing areas and technologies, but also to "explore knowledge" by developing new technologies and areas that are far removed from our own R&D. One way we are doing this is through investments in venture capital (VC) funds and CVC activities. As part of these activities, we launched a research collaboration in 2022 with LUCA Science Inc. to use its proprietary functional mitochondria therapy platform – which can isolate high-functioning mitochondria – to develop a treatment for mitochondrial disease. Currently, the only treatments available for mitochondrial disorders alleviate specific symptoms, with a definitive cure still to be found. We hope to identify innovative, life-changing pipeline drugs by combining LUCA Science's mitochondrial drug discovery platform technology with our own knowledge in disease science, accumulated from our wide-ranging experience in biopharmaceutical drug discovery.

In addition to these initiatives, we launched the Musha Shugyo Project to encourage researchers to independently seek out new challenges and establish their own research ecosystems by building internal and external networks. Under the project, researchers can nominate key team members for realizing their research, allowing them to build diverse teams of like-minded, passionate individuals to carry out research through external activities beyond the familiar walls of Kyowa Kirin's R&D facilities. We also aim to foster entrepreneurship among researchers by getting them to bring on board the necessary stakeholders themselves. Our goal is to reinvigorate Kyowa Kirin's overall research activities by drawing on experiences gained through the program.

To deliver growth over in the medium and long term, we will continue to push ahead with all these initiatives in order to consistently create life-changing value. Let's keep this momentum going!

# Creating new strengths through powerful partnerships



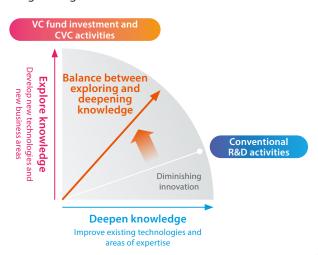








# Our approach to generating more innovations for long-term growth



Kyowa Kirin's R&D organization will continue to create life-changing value with clear competitive advantages through R&D focused on technology and disease biology, backed by open innovation that actively draws on the strengths of external partners. We will also work with a sense of urgency to rapidly deliver this life-changing value to as many people as possible living with medical conditions worldwide.

To realize the successful creation and delivery of life-changing value that ultimately makes people smile, we established "Our R&D Spirits," which sets out our vision for what each person in the global R&D organization should be and wants to be. Our R&D Spirits respects the individuality and freedom of thought of all team members, and encourages them to pursue new challenges with speed and passion. It is our roadmap for the transformation of Kyowa Kirin's R&D organization worldwide. To put this vision into practice, we have formulated a Human Resources Management Policy in R&D, which guides our efforts to develop human resources in Japan and overseas.

## Technology

Continue to evolve our antibody the possibilities of diverse modalities and building a platform that leads to innovative new therapies

## Disease Biology

Continue to provide "Only-one value drug" for unmet medical needs, while utilizing the disease science\* cultivated to date within Kvowa Kirin

\* Nephrology, Oncology, Immunology & allergy and CNS

Create Life-changing value with clear competitive advantages

### **Open Innovation (OI)**

Continue to work on collaborative research activities with academia, startups and other partners, combine with rapid access to information gained from investment in VC/CVC funds, and tap into external innovation through advanced OI activities

## **Our R&D Spirits**

Be the Best in Science

Passion for Innovation

**Every Challenge, a Step to Success** 

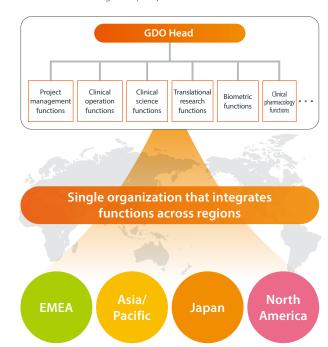
This is me. This is our team.

## TOPIC

## **Our new Global Development Organization** (GDO)

We established the Global Development Organization (GDO) in June 2022. GDO is a new global structure designed to support development projects from the pre-clinical stage, bringing together all human resources involved in development projects worldwide as "One Team."

Under GDO, development-related organizations are being integrated on a global basis along functional lines and the management of R&D teams is transitioning from a regionspecific approach to an integrated global approach. With these reforms, we will operate as a single organization – from the planning of development strategy through to operations in all regions – with the aim of speeding up decision-making to maximize value from a global perspective.



**TOPICS FOR** 

VALUE CREATION

# **Next-generation Drugs in the Development Pipeline**

## KHK4083/AMG 451 (rocatinlimab)

KHK4083/AMG 451 is an anti-OX40 fully human monoclonal antibody under global development with Amgen Inc. The initial antibody was discovered in a collaboration between Kyowa Kirin US Research and La Jolla Institute for Immunology.

OX40 is a member of the TNF receptor family and is expressed on activated T cells. OX40 binds to OX40 ligands expressed on antigenpresenting cells such as dendritic cells (cells that present fragments of invading pathogens to immune cells) and stimulates the proliferation, differentiation and survival of activated T cells, the formation of memory T cells, and increased production of a range of inflammation-related proteins called cytokines, triggering systemic and localized inflammatory responses. Patients with atopic dermatitis see increased levels of OX40-expressing T cells in their blood. The activation of T cells by the binding of OX40 to OX40 ligands is thought to be the reason for deteriorating or chronic symptoms of the condition.

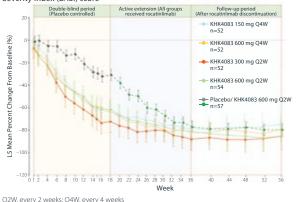
KHK4083/AMG 451 is an antibody drug that uses our fully human antibody production technology and our proprietary POTELLIGENT platform, which enhances antibody-dependent cellular cytotoxicity (ADCC). KHK4083/AMG 451 is seen as a viable treatment for atopic dermatitis because it binds to OX40 and inhibits its function by directly acting on activated T cells, reducing the number of activated T cells.

In 2021, the drug completed a Phase 2b study in patients with atopic dermatitis. Patients receiving KHK4083/AMG 451 continued to show improvement in symptoms in a 20-week off-treatment follow-up (weeks 36–56), indicating sustained efficacy. The key results of the study were published in the Lancet\* in December 2022.

In May 2022, we launched the ROCKET-IGNITE study, part of the Phase 3 ROCKET program. The program consists of six different studies, with four already underway as of the end of March 2023.

Change in I Eczema Area and Severity Index (EAS) from baseline through week 56; drug administration terminated at 36 weeks for all treatment groups. Placebo group received placebo from week 1 through week 18, 600mg of KHK4083 administered once every 2 weeks from week 18 to week 36.

## Least-squares (LS) mean percent change in Eczema Area and Severity Index (EASI) score



## KHK4951 (eye drops with tivozanib as the active ingredient)

KHK4951 is an eye drop with tivozanib as the active ingredient. Tivozanib is a proprietary VEGFR\*1 inhibitor, approved in the US and Europe as Fotivda\*2, an oral treatment for advanced renal cell carcinoma (RCC). Kyowa Kirin is developing tivozanib as a treatment for neovascular (wet) age-related macular degeneration (nAMD), in which abnormal choroidal neovascularization damages the macula, a retinal tissue. In nAMD, early detection and treatment are important, as symptom progression can lead to social blindness\*3. Currently, nAMD is mainly treated with the highly invasive method of injections of

anti-VEGF\*<sup>4</sup> inhibitor directly into the vitreous humor of the eye. Other alternative treatments have been developed, including eye drops containing small molecule compounds with VEGFR inhibitory activity as the active ingredient, but none have received approval due to lack of efficacy in clinical trials.

Through our work to develop a drug that satisfies the unmet medical needs of patients with nAMD, we have discovered a unique ophthalmic formulation that efficiently delivers active ingredient tivozanib to the posterior ocular tissues (choroid and retina). The formulation,

currently under development as KHK4951, completed a Phase 1 study in Japan in 2022. In patients with nAMD who participated in the study, there was a recognized trend of maintenance or improvement in symptoms with the ophthalmic administration of KHK4951, indicating potential as an alternative treatment to intravitreal injections. We are now preparing to conduct Phase 2 trials in Japan and the US.

<sup>\*</sup> Lancet. 2023 Jan 21; 401(10372): 204-214.

<sup>\*1</sup> VEGFR: Vascular endothelial growth factor receptor

<sup>\*2</sup> Sold by AVEO in the US and EUSA Pharma in Europe and other markets

<sup>\*3</sup> Social blindness: Refers to a degree of visual disability that hampers daily activities, such as reading; defined as a standard corrected visual acuity of 0.1 or less.

<sup>\*4</sup> VEGF: Vascular endothelial growth factor

# **Three Global Strategic Products**



## Crysvita

Crysvita is a recombinant fully human monoclonal IgG1 antibody against the phosphaturic hormone fibroblast growth factor 23 (FGF23). Developed by Kyowa Kirin, Crysvita is used to treat X-linked hypophosphatemia (XLH) and tumor-induced osteomalacia (TIO). XLH is a rare condition that causes hypophosphatemia due to a genetic mutation that results in excessive production of FGF23, a hormone produced in bone cells. The condition causes large amounts of phosphorus in the blood to be excreted in the urine and reduces phosphorus absorption in the intestinal tract. In patients with this condition, bone calcification is disturbed, preventing normal bone formation. In children, this leads to various symptoms such as bone deformity and short stature, while adults with XLH suffer from walking difficulties due to lower limb deformity, as well as bone and joint pain, muscle weakness and dental issues, leading to a material decline in patient QOL. The condition is estimated to occur in one in 20,000 people. Conventional treatments are phosphate and/or vitamin D supplements, with patients typically having to take multiple doses of medication each day. In contrast, Crysvita is injected every two weeks or every four weeks and increases reabsorption of phosphate in the kidneys in patients with XLH and TIO. Crysvita also increases production of vitamin D, which improves intestinal absorption of phosphate.

In North America, we started proprietary sales of Crysvita from April 2023. In 2022, we adjusted the scheme for the transfer of sales from Ultragenyx Pharmaceutical Inc., setting a one-year period from April 2023 during which Kyowa Kirin will receive field support from Ultragenyx. This approach will ensure a smoother transition in the North America market. In EMEA, we have continued to expand the number of markets since 2021. We plan to add more launch markets for the indication of adult XLH. In Japan, since October 2022, each branch office has a staff member responsible for disease awareness in the bone metabolism field, creating a framework that can better facilitate the provision of Crysvita to patients with XLH and TIO.

Since launch in 2018, the number of patients treated with Crysvita has increased steadily, with around 5,000 patients receiving the treatment as of December 31, 2022.

Crysvita has seen sustained growth in the five years since launch, with revenue in 2022 reaching ¥127.1 billion, making it Kyowa Kirin's first product to surpass the ¥100 billion mark. We are targeting global revenue of ¥149.1 billion in 2023.







## Poteligeo

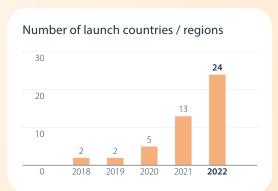


Poteligeo is the world's first therapeutic antibody to be produced using our proprietary antibody-enhancing POTELLIGENT platform. Poteligeo binds to cancer cells by targeting a molecule called CC chemokine receptor 4 (CCR4) expressed on the cell surface. It demonstrates antitumor effects by eliminating cancer cells through antibody-dependent cellular cytotoxicity (ADCC) activity, enhanced by POTELLIGENT technology. Poteligeo is currently available in Japan, the US and Europe, and we continue to increase the number of launch markets.

Poteligeo is approved for the treatment of CTCL\*. Patients with CTCL often tend to have tumors on the skin. However, in the Phase 3 MAVORIC study, Poteligeo showed evidence of particularly high efficacy in CTCL patients with cancer cells

in the blood. Based on clinical evidence gleaned from the study, we are taking steps to educate and engage physicians and patients in the US and Europe using the message, "Treat the blood. Treat the skin." In addition to extending these activities to other regions, we plan to further educate patients in the early stages of the disease about the importance of performing blood tests, thereby identifying more patients who can benefit from Poteligeo and maximizing its value. Poteligeo is currently sold in 24 countries and generated global revenue of ¥24.2 billion in 2022. We are targeting revenue of ¥29.6 billion in 2023.





# NOURIANZ\* (istradefylline) tablets

## **Nourianz / Nouriast**

Nourianz / Nouriast is a small molecule drug discovered by Kyowa Kirin for the treatment of Parkinson's disease. It has a unique adenosine A2A receptor antagonist mechanism.

Launched in Japan in 2013 and the US in 2019, Nourianz / Nouriast was approved for the indication of improving "off" episodes / "wearing-off" phenomena in Parkinson's disease patients receiving treatment with levodopa / carbidopa, the precursor to dopamine. Wearing-off phenomena occur in patients who have been taking levodopa / carbidopa – a standard treatment for Parkinson's – for several years. Over time, the efficacy of levodopa / carbidopa declines and patients start to experience wearing-off symptoms several hours after administered.

By stepping up collaboration and knowledge-sharing between our teams in Japan and the US and by using digital tools more effectively, we will continue to strengthen frontline activities to improve understanding about the importance of adenosine A2A antagonism in alleviating wearing-off phenomena. Revenue in Japan and the US totaled ¥14.6 billion in 2022 and we are targeting ¥15.0 billion in 2023.

**TOPICS FOR** 

VALUE CREATION

## **Address Patient-centric Healthcare Needs**



Danie du Plessis

Executive Vice President,
Head of Medical Affairs,
Kyowa Kirin International plc.

# Patient-centric activities in pharmaceutical companies

Health care has changed over the last number of years from disease-centred to patient-centred. Patient centricity can be simplified as integrated measures for listening to and partnering with patients, their families and carers in a respectful and compassionate way and placing improved patient well-being at the core of everything we do.

We can and should be patient-centric throughout the life cycle of the product from discovery, clinical development, pre-launch/launch, post-launch and as part of lifecycle management. Companies gather patient insights through listening to patients, families and carers about their lived experience in different settings and can use different tools to gather these insights. Implementing the learning and sharing the knowledge (internally and externally) through appropriate action is critical.

Organizations need to understand the natural history of a disease, the burden of disease, how or when a treatment can intervene to create outcomes that are meaningful to patients, and patients' tolerance for benefit-risk profiles of drugs in different diseases—all while addressing issues of access, caregiving, and quality of life among many others.

At the same time patient insights must be embedded in all data generation strategies and activities, and patients should have ready access to medical information that enables their active participation in making treatment choices. No matter how it is structured within the organization, patient engagement presents a significant challenge in a landscape of little precedent and significant regulatory oversight.

Examples of specific patient centric programs include, but are not limited to Compassionate use, Named Patient Programs and a variety of Patient Support programs.

## **Current status and challenges of Kyowa Kirin**

As part of our vision for 2030, we will meet the needs of patients and society by providing value across the entire patient care pathway, delivering cutting-edge science and technology, grounded in our in-depth pharmaceutical knowledge and expertise. Our strategy to address patient-centric healthcare needs, is to focus not only on patient advocacy but also to provide value that goes beyond pharmaceuticals. In Kyowa Kirin we define Patient Advocacy as promoting sound public understanding of medical conditions through communication and cooperation with patient and healthcare professional communities. In addition, Patient Advocacy is about making patients smile by working to address unmet medical needs through Kyowa Kirin's value chain.

To provide value that goes beyond pharmaceuticals, we focus on in depth understanding of the so-called patient journey or patient care pathway. These stages can be described as pre-diagnosis, diagnosis, treatment initiation and long-term adherence to treatment.

To have this in-depth understanding, we have started to engage with patients and patient organisations to gain insights into the lives of patients living with certain diseases so that we can work with them, their families, their carers and their treating physicians to understand how we can add value and help improve their well-being—in short, how to help them smile.

Although we have many examples in the company of patient-centric activities where we have used patient insights and of patient advocacy programs, there is always more that we can do. And we can do it much earlier in the continuum of medicines development and commercialisation.

To be truly patient-centric, we need to continue building an organisational culture, and capabilities associated with putting patients at the heart of organisational decisions—driven by an understanding of patient needs and desired outcomes.

## **Perspectives from Global Medical Affairs**

As a member of Global Medical Affairs and head of EMEA Medical Affairs, I am committed to further bolster our patient centric approach and will continuously represent the voice of our patients and of people living with specific diseases. Although all employees should have a patient-centric mindset, Medical Affairs will be the function who will continuously remind all other functions to keep the patient in the centre of what we do. We will represent people living with disease in a holistic way and not only as a patient with one disease. This is the key to transforming ourselves to one of the most patient-centred companies in the industry.

**TOPICS FOR** 

**VALUE CREATION** 

# **Patient Advocacy: Providing Value Beyond Pharmaceuticals**

## **Shine A Light on XLH Virtual Exhibition**

On May 16, 2022, International Day of Light, Kyowa Kirin International plc, the European affiliate of Kyowa Kirin, first launched the "Shine A Light on XLH" virtual exhibition across the region's Northern Cluster (UK, Ireland, Finland, Denmark, Norway and Sweden).

Created with a focus on education, support, and empowerment\*1, the Shine A Light exhibition was devised as a space where people living with X-Linked Hyperphosphatemia (XLH), a rare, genetic and progressive renal phosphate wasting disorder that causes abnormalities in the bones, muscles and joints, can read and learn more about their condition and hear firsthand from others across the XLH community who are impacted by the condition. The aim being to create a sense of community, advocacy and support.

Designed as an immersive and interactive space at the intersection of art and science the exhibition and campaign focuses on representing the impact of XLH through striking digital make-up designs, and also looks to raise awareness of XLH amongst those who may not be directly impacted by it, such as healthcare professionals, politicians, policymakers, and the media.

We know that people impacted by XLH can face a number of challenges throughout patient journey\*2, with the Shine A Light on XLH exhibition aiming to also help raise awareness of these. Some of the challenges can include:

- A lack of awareness amongst the general public which can lead to people feeling misunderstood and unheard
- A long journey to an accurate diagnosis, sometimes as a result of lower awareness of XLH amongst the healthcare community, and misdiagnosis
- Limited access to the right care and support once diagnosed
   The exhibition itself is all about the stories and lives of those 11
   individuals who we have partnered with over the last two-years in the

creation of this campaign—and we pass on our heartfelt thanks to each and every one of them.

Following the launch of the exhibition in the Northern Cluster, we now have locally approved and translated versions available in German, Italian, Spanish and French across the KKI region, alongside an English-language version available across Singapore, Australia, Korea and Thailand. To reach, support and connect the XLH community as much as we can we are also in the process of finalizing versions of the exhibition locally translated into Korean and Traditional Chinese for Rare Disease Day at the end of February, alongside exploring opportunities for localization in Japan in collaboration with our KKC colleagues.

There remains huge potential for the role and impact of the Shine A Light on XLH exhibition and we look forward to continuing to collaborate with colleagues from across the business to help reach more people and ultimately bring our core purpose – to make people smile – to life.

- \*1 Empowerment: Giving XLH patients a voice, providing support and helping them access support from the community so that they can see positive change is possible.
- \*2 Patient journey: The process of patient "behavior," "thoughts" and "feelings" from the point they recognize a change in their physical condition to when their symptoms and quality of life improve through hospital visits, medications and other treatments.



Image from the Shine A Light on XLH Virtual Exhibition

## New helpline on our Kurukotsu Hiroba microsite

"Being patient" is only a small part of the person's life that is diverse from a person to person. Thus, the patient journey and the experience of living with a condition may not necessarily be the same for patients in other countries with different healthcare systems and cultural backgrounds, even if they have the same condition. That's why Kyowa Kirin focuses on gathering feedback directly from patients around the world. In 2022, we surveyed more than 20 patients in Japan living with FGF23-related hypophosphatemia (mainly XLH and TIO) in order to understand their individual patient journeys and experiences. It became clear to us that, in Japan, which does not have an XLH-specific patient advocacy group, patients do not have sufficient access to information about their condition, leading to feelings of loneliness and social isolation due to the rarity of XLH and TIO. In addition, in the case of XLH, the mental burden is especially high for everyone impacted by the condition (patients, families, caregivers) because it requires lifelong treatment.

In an effort to address these issues, Kyowa Kirin started posting patient testimonials on Kurukotsu Hiroba – a disease awareness website for FGF23-related hypophosphatemic rickets / osteomalacia – to provide more information about the condition and to improve access to medical care. By introducing these detailed patient stories, we hope to raise awareness about FGF23-related hypophosphatemia among undiagnosed people who have had similar experiences. We also set up a counselling helpline on the website. The helpline receives a number of calls each month from people who want to consult with nurses and public health nurses about symptoms or concerns they have in an interactive format. In some cases, calls to the helpline have resulted in a visit to a specialist and a definitive diagnosis, showing how this approach can help improve access to medical care for people with rare diseases.

Separately, on World XLH Awareness Day (October 23\*3, 2022), we held an open lecture called XLH Café as part of efforts to reduce social isolation and loneliness and alleviate the mental burden of people affected by the condition. Experienced pediatric and adult specialists were on hand to provide information about the condition and we screened a video about the patient journey of an overseas patient with

\*3 This date was chosen as World XLH Awareness Day by the International XLH Alliance, with the tenth month October represented as the Roman numeral "X" and the 23rd day signifying "FGF23," a hormone related to XLH.



Kurukotsu Hiroba https://www.kurukotsu.com/

## Symposium at EORTC Annual Meeting

The annual meeting of the European Organisation for Research and Treatment of Cancer (EORTC), Cutaneous Lymphoma Tumours Group (CLTG), was held in Madrid, Spain, for three days from September 22, 2022. Kyowa Kirin International plc. made a corporate presentation and held a symposium. The meeting featured presentations related to CTCL, including reports from physicians who have used Poteligeo in clinical practice. We also held a poster presentation about the secondary analysis of data from the Phase 3 MAVORIC study of Poteligeo. In our corporate presentation, we used tablet devices to show a video with augmented reality (AR) technology to explain the pathophysiology of CTCL. Our corporate symposium included a presentation and Q&A session about the mechanism of action of Poteligeo and the management of side effects. This type of event allows us to deepen participant understanding of CTCL and Poteligeo, while also providing opportunities for meaningful discussions with key opinion leaders (KOLs) and patient advocacy groups. Feedback has been positive and we plan to continue our CTCL awareness activities.

## Seminars featuring people living with disease

At Kyowa Kirin, our vision is to continuously create life-changing value that ultimately makes patients smile. To realize our goal of "addressing" patient-centric healthcare needs," all our employees value the opportunity to learn from feedback provided by patients and their caregivers.

One way we are doing that is through regular seminars featuring people living with disease. We invited people living with cancer, chronic conditions, rare diseases and other conditions to talk directly to us about their symptoms and treatments, their thoughts and concerns, their approach to living with disease, the challenges they face, and their expectations with respect to pharmaceutical companies. The seminars are a valuable opportunity for our employees to listen to patients firsthand.

In addition to addressing clear issues faced by patients and their families, Kyowa Kirin works to identify and satisfy unmet medical needs (conditions for which there is no existing or adequate treatment method). However, many Kyowa Kirin employees have limited opportunities to directly interact with patients in their daily lives or through work. These seminars are therefore an important opportunity for them to learn from patients themselves how medical conditions impact their lives and journeys, their medical care environment, social issues, and the need for awareness-raising activities. Being closer to patient lives is a vital starting point to guide the individual behavior of our employees.

## Listening to Patients — Examples of TOPIC **Activities in EMEA Hybrid Events for all EMEA Employees**

A key area we are focusing on to realize our corporate vision is ensuring all employees have the opportunity to hear directly from the patients we serve. In 2022, Kyowa Kirin International plc. hosted a series of hybrid events for all EMEA employees featuring videos of patient stories. These stories and other feedback give us insights into what patients need, informing our decision-making and leading to the launch of patient experience programs that educate and raise awareness.



Still from a video sharing a patient's story with Kyowa Kirin Internationa plc. employees

# Strengthen human resources and infrastructure to realize life-changing value



**Wataru Murata** 

Chief People Officer (CPO) & Global Human Resources Head Senior Managing Executive Officer, Director, Human Resources Department Kyowa Kirin Co., Ltd.

At Kyowa Kirin, we see human resources as the source of innovation.

By promoting human resource strategy-based initiatives across regions and organizations for each material issue (materiality)—DE&I, talent portfolio, and corporate culture—as a leading company in ESG, we aim to not only respond to the requests of society but also to be one team of diverse healthy talents that can play an active role with a high level of engagement while working effectively to deliver life-changing value.



Sian Abel Global Head of Human Resources Business Partner Kyowa Kirin International plc

"Global Talent Management Basics for 2021–2025" describes what we want the Global HR team to achieve by 2025. Rolling out talent management measures globally in line with the Philosophy, Vision, Core Values, and business strategies of the Kyowa Kirin Group, and making the most of individuality and abilities of diverse talents across the organization, we aim to create a new corporate culture in which employees take on challenges autonomously for KABEGOE.



Takuo Hirose Global Information and Communication Technology Head Director, ICT Solution Department, Kyowa Kirin Co., Ltd.

To achieve global operational excellence and to provide new digital value, we are working on building a data platform and developing digital talent.

Under its Digital Vision 2030, by 2030, Kyowa Kirin aims to be a global specialty pharmaceutical company with originality—one that uses data to discover unmet medical needs, delivering new services, including pharmaceutical products, and creating value.

## **Human Resources**

## One Team of healthy and diverse human resources, working to realize life-changing value

## **Overall Strategy**

At Kyowa Kirin, we see human resources as the source of innovation. Believing that the collective abilities and challenges of each employee manifest themselves as value and contributions to society, the Company focuses on maximizing the abilities of individual human resources and providing opportunities for them to take on challenges.

With this in mind, we have identified DE&I, talent portfolio, and corporate culture as three material issues (materiality). As the human resources function discovering and developing healthy and diverse human resources, we will promote the "strengthening of human resources and foundations that realize life-changing value" by working on a global basis to create environments in which people can work as a unified team, to reform the organizational culture, and to foster a corporate culture, while aiming to achieve the 2030 Vision.

In ensuring to attain this purpose with certitude, we have established the Global Talent Management Basics for 2021-2025 as the vision for our human resources function. By working toward the realization of the vision, we will contribute to the promotion of the Group's management strategy. Ultimately that will enable us to create value that brings smiles to patients' faces.

## Development of talents to contribute to value creation and HR strategy to promote business strategy



## Using employee engagement surveys (Survey overview)

At Kyowa Kirin, an employee engagement survey (Global Engagement and Motivation Survey) is periodically conducted. The survey is used to identify organizational improvement issues that should be prioritized, to consider measures to revitalize the organization, and to measure their effects. As important elements for employees to maximize their abilities, in these surveys we pay particular attention to two elements: employee engagement, which is an indicator of willingness to contribute to the company, loyalty, and voluntary efforts; and employee enablement, which is an indicator of the opportunities for them to make full use of their own skills and abilities as well as of a comfortable working environment. Each function and organization formulates improvement plans based on the survey results, reflects them in action plans, and steadily implements a Plan-Do-Check-Act (PDCA) cycle.

### Key Findings of 2022 Survey (Comparison with the previous fiscal year's survey)

- Employee engagement score +1 percentage point improvement "Motivation from the company," recommendation as a good place to work," "pride in the company," etc. improved
- Employee enablement score +3 percentage points improvement "Utilization of skills and abilities" and "environment for increasing productivity" improved significantly

#### (Comparison with other companies)

• "Respect for the individual," "Leadership," "Growth opportunities," and "Education and training" are above or at the same level as the pharmaceutical company average and the global top performer average

#### (Recognized issues)

• Although both "Business processes and organizational structure" and "Resources" showed a trend of improvement compared with the previous survey, we still recognize them as issues that should be addressed on a priority basis.

### [Number of people surveyed/Response rate]

Number of people surveyed: 6,067

No. of respondents: 5,783 Response rate: 95%

#### Question categories

Employee engagement / Strategy and direction / Leadership / Quality and customer orientation / Respect for the individual / Growth opportunities / Compensation and benefits / Employee enablement / Performance management / Degree of authority and autonomy / Resources / Education and training / Cooperative framework / Business processes and organizational structure / Management philosophy and values / Code of conducts and compliance / Expectations work styles / Diversity and inclusion / Company quality culture

#### Benchmark data

Global corporate average; global average of high-performing companies, corporate average of pharmaceuticals companies, Japan corporate average, regional and country averages

## Global Talent Management Basics for 2021–2025

- Develop human resource policies aligned to the Kyowa Kirin Group's Philosophy, Vision, Core Values, and business strategy.
- We will hire people from diverse backgrounds, developing talent that will drive further innovation and contribute to value creation. In this way, we will realize our vision for bringing smiles to the faces of patients living with disease.
- We will create a new corporate culture dedicated to sustainable growth—a culture in which a wide range of people can use their personalities and abilities to the full, independently embracing challenges and overcoming obstacles.
- We will build an environment where employees feel excited about their work. To this end, we will promote competitive compensation; encourage health management; and provide opportunities and forums for increased engagement.
- By building a global database and implementing the appropriate applications, we will realize data-driven HR that supports talent management execution and productivity improvements.

#### External evaluations

- Health Management Issues 2023
- Certified Health and Productivity Management Organization 2023 (White 500)
- Platinum Kurumin
- · Eruboshi (3 stars)
- PRIDE Index 2022 (Gold)











To ensure sustainable development of the One Kyowa Kirin structure it is crucial that we discover, train, and assign next-generation leader candidates who will lead the future of each region and functions in a global context. To strategically promote global talent management, it is essential to have in place a globally common HR foundation. Under the Medium Term Business Plan that started in 2021, we are promoting the development of human resource management infrastructure while launching a variety of initiatives, such as global succession planning and a short-term overseas exchange program (Global Talent Exchange Program). By having been able to build a general HR foundation by 2022, from 2023 onwards we will leverage this foundation to empower each and every employee to take ownership of forging their careers and demonstrating their abilities, while further driving global talent management.



Global human resources Pipeline reinforcement

- ► Formulation of global succession plan
- ▶ Visualization of next-generation leader candidates and formulation of individual development plans, assignments based on those plans
- ► Short-term overseas assignment program (talent exchange between all regions)
- · Development of human resources who possess Group management perspectives and diverse values

Development of HR foundation

- ▶ Identify global key positions and their talent requirements
- ▶ Implementation of global grading
- Evaluate the size of job roles for all job-types using globally common metrics
- Globally standardize and implement talent management measures, such as hiring, development, evaluations, and promotions
- ► Formulation of leadership principles
- Principles of leadership that each Group employee is expected to demonstrate in working together to realize the Vision
- Starting from the core values of the Group, stipulate the essential elements for fostering a corporate culture
- Utilizing of hiring, development, evaluation, promotion, etc. as common global principles

- ▶ Introduction, function expansion of global human resource system (HRIS)
- Real-time global sharing of HR data to establish data-driven talent management system
- Centralized HR evaluations, career development plans, and 360degree evaluation data, implementing of mobile function

#### Japan

In the Japan region, progress was made with preparations to revise the job-based grading and remuneration system to conform to global grades, and a system introduced in April 2023. In addition to achieving talent management with the right person in the right position under the One Kyowa Kirin structure, we showed employees the importance of taking ownership of their careers. By creating job descriptions for all managerial positions and disclosing them to all employees, the Company will support each individual in finding the career they want to pursue within the Kyowa Kirin Group and in forging the desired career. We will plan and implement a variety of related initiatives while believing in such an equal relationship committed to mutual growth.

#### [Examples of related measures]

- Cultivation of a "learning culture" through efforts to improve the utilization rate of the self-development support system
- Career development support training for subordinates seen as potential leaders

#### Other regions

At each business site, a variety of learning programs have been developed for the purpose of employee skill and career development.

- EMEA: We are committed to fostering a learning culture. In addition to implementing Learning @Work Week in May 2022 and emphasizing the importance of lifelong learning through a variety of events, we provided opportunities for employees to deepen their knowledge about in-house learning opportunities and resources.
- North America: So that we are able to flexibly provide learning content in the flow of work whenever necessary, we have improved usability by actively incorporating on-demand content and mobile apps.
- APAC: We are starting discussions with all business leaders on career development frameworks and program development.

## Dialogue with the CEO/Meetups

The "overcoming barriers" corporate culture transformation initiative that started in Japan in 2019 is now being rolled out in each region under the banner KABEGOE (meaning 'overcoming barriers'). In FY2022, as part of the corporate initiatives to spread this KABEGOE culture globally, we planned a total of three Global Meetups, for which the CEO and about 10 employees from the four regions gathered online as panelists and discussed corporate culture. In each region, we had held townhall

meetings covering business topics such as financial results and pipelines with the president, but this was the first time that all four regions came together to discuss corporate culture in depth. Regardless of the role, standpoint, or affiliation, participants actively took part in conversations in which they openly shared their own experiences with KABEGOE, their thoughts on their work colleagues and patients, and the mindset and actions required to achieve the Company's vision.



**TOPICS FOR** 

Kyowa Kirin considers Diversity, Equity and Inclusion (DE&I) to be fundamental to our organization. It provides a source of innovation that drives sustainable growth. It guides our social responsibility as a J-GSP. It supports our creation of a workplace where employees can maximize their potential based on relationships of trust. It is vital to our success as we strive to create life-changing value and deliver this to patients around the world. In accordance with Our DE&I Statement, which we adopted in 2021, we have identified priority issues globally and in each region and are proactively promoting measures. As a near-term global priority, we aim to ensure that there is strong representation of women leaders in the One Kyowa Kirin structure. We have set a quantitative target of increasing the percentage of global leader roles held by women from 29% at the end of FY2021 to 40% by 2030.

Japan: Encouraging initiatives to address key issues to promote understanding that everyone is a stakeholder in DE&I

#### Unconscious bias

· Training sessions (new employees, middle management)

#### Women's empowerment

- · Mentoring program for women in management positions
- Development linked to talent management in each organization
- · Career training sessions for young people

## Support for balancing nursing care, childcare, and work

- Establishment of in-house nursery schools (Mishima area in May 2022, Takasaki area in January 2023)
- Conducting of survey on current status of nursing care

#### Workers with disabilities

- Ratio of workers with disabilities: 2.45% of Group workforce in Japan
- Joined Accessibility Consortium of Enterprises (ACE) in March 2022

#### LGBTO+

· Received Gold rating in PRIDE Index 2022, developed by voluntary organization Work with Pride

#### DE&I seminars

• Dissemination of messages from top management and holding of seminars by external experts (PRIDE Month, International Day of Persons with Disabilities)

APAC: A "melting pot" where diverse ethnicities and cultures coexist. Although DE&I-related priority issues vary depending on the country, we are actively embracing the importance of DE&I across the region.

#### Unconscious bias

- All employees received training on overcoming unconscious bias in the
- Top leaders participated in the Managing Professional Boundaries Workshop

#### Establishment of new policy

· Anti-Harassment and Anti-Discrimination Policy newly established in Singapore, training sessions provided for all employees to promote understanding

## Our DE&I Statement

At Kyowa Kirin, we embrace and proactively promote Diversity, Equity and Inclusion in the workplace as an embodiment of our Core Values.

#### Commitment to Life

Diversity, equity and inclusion in our teams enables us to reflect the people and communities we serve and be sensitive to their needs, putting patients at the heart of everything we do

#### Innovation

We believe in diversity of thought where all employees are encouraged to share fresh new ideas, are listened to and empowered to deliver innovative solutions for patients around the world

#### Integrity

We strive to create an environment where everyone has a sense of belonging and is free from any form of inequitable treatment

### Teamwork/Wa

We will build an inclusive culture that enables our employees to bring their whole, authentic selves to work, where we can grow together, feel valued and respected, and achieve our shared corporate Vision.





North America: The NA executive team and DE&I Workgroup are driving focused efforts on the execution phase of DE&I.

### Employee Resource Groups (ERGs)

· Formed three ERGs: Women's Initiative Network (WIN), embRACE (a multicultural community), and PRIDE@KKNA (LGBTQIA+)

#### **DE&I-related Events**

- Female leaders panel discussion on International Women's Day
- Breaking Bias Barriers training sessions
- CTCL Roundtable discussion about disparities in care for cancer patients
- · LGBTQIA+ Pride@Work panel discussion
- WIN-hosted book club with invited guest author forum

#### Establishment of New System

- · Added Volunteer Time Off benefit system
- Recognized Juneteenth (June 20, the emancipation of enslaved African Americans) as a company holiday
- Review of recruitment and hiring practices across all departments to encourage diverse slate of candidates

EMEA: Launched five Workstreams that created opportunities to learn through the Workstreams, celebrate key events together, and raise important topics and themes to foster a diverse, equitable, and inclusive culture.

#### Women

• Women's Accelerator Programs/Women's Resource Group Roundtable

#### Racial/Ethnicity

• Culture Awareness Week/Showcasing of religious and cultural festivals in each country via company intranet

#### LGBTO+

• Pride Week/Awareness-raising activities for gender expression and to develop employee allyship

#### Disability

· Improving in-house accessibility/Purple Light Up Day

#### Mental Health

· Mental Health Week/International Mental Health Day/ "Movember" (Mental health awareness for men)



## **Health and Productivity Management**

# Create an organization in which an active and diverse group of people can work toward driving innovation creation

The Kyowa Kirin Group Wellness Action program aims to inspire employees and those around them to pursue behavioral change to improve their own health ("wellness action"). The program helps employees reduce health risks and improve their well-being, so that they can contribute to the Company and society as a whole. The status of each measure is checked and evaluated both quantitatively and qualitatively at management strategy meetings and other meetings.

In recognition of these efforts and achievements, for the second consecutive year the Company was included in the 2023 Health and Productivity Stock Selection, having met the prescribed criteria in the Health and Productivity Management Survey conducted by the Ministry of Economy, Trade and Industry. The Company has been recognized as a certified Health and Productivity Management Organization 2023 (White 500) for the seventh consecutive year since the program was launched.

### Kyowa Kirin Group Wellness Action 2025

		Company
Reduce risks to our mental & physical health Improve the well-being	Cope with social issues*     * e.g. medical cost increase, obesity, activity qty decrease, imbalanced diets     Promotion of the Wellness     Action has a good influence on outside of the company	Enhance corporate value by improving performance of each one of us     Develop corporate culture to get over the wall through the Wellness Action

		Employees and people around us work on the Wellness Action with our own motivation & excitement					
Make employees active		Behavioral change for health					
Increase ratio of Most Effective Employees [Target in 2025] To exceed FY2020 result			Habit of exercise	Habit of meals	Habit of sleep	Non- smoking	Others
		Kyowa Kirin	Group Tale	nt Manager	nent Policy		
Employees Acting autonomously and take on the challenge Encouraging its employees to co-create new value Kirin							

#### Japan

Through Kyowa Kirin Group Wellness Action 2025, which has been established globally on a shared basis, we have also set goals for 2025 as KPIs for health management in the Japan region and are focusing on individual behavioral changes. Co-organized by the Company's health insurance association as a collabo-health\* project, a walking campaign is held twice a year with the aim of providing opportunities for physical activity and revitalizing communication. In the walking campaign in the fall of 2022, we formed teams at each business site and branch and played a parcheesi-type board game project by which the aim was to travel around the world by advancing pieces on the board in accordance with a team's participation rate and average number of steps. This event was attended by more than 3,500 people, more than 80% of the Group's employees. Furthermore, the smoking rate among our employees has remained below 5% since 2020, a decrease of more than 16 percentage points since we began measures to address this area. In addition to implementing these measures, we are also verifying the effects based on the Guidelines for Administrative Accounting of Investment in Health and Productivity Management. The positive response rate in 2022 for the "liveliness score," which measures whether people are working on Wellness Action with a feeling of motivated excitement and is one of the "ultimate health-related goals" indicators, increased by nine percentage points from the previous year to 71%.

\* "Collabo-health" refers to collaborative activities organized through coordination between corporate health insurance associations and companies to enhance the health of employees and their families.

#### APAC

We are undertaking a variety of initiatives designed to promote the mental and physical health of our employees. Specifically, in addition to holding virtual Corporate Step Challenge and walking events, webinars on World Mental Health Day, and training sessions for employees to learn how to create a healthy lifestyle, we are striving to manage the health of our employees according to the situation in each country. In 2023, we will further focus on mental health as a region-wide initiative.

Especially during the COVID-19 pandemic, we believe that these activities are not only to keep our employees healthy but also extremely important in deepening the bonds between employees and the company while realizing a healthy corporate culture and "Teamwork/Wa."





#### North America

In 2022, as a result of our activities that focused on physical and mental health, we received a silver Cigna Healthy Workforce Designation™. In addition to the easy access to fitness facilities, due to shared gyms having reopened at some work locations, we also provided, for example, free health and fitness apps, nutrition coaching programs, and health-related webinars. For Well-Being month in May, we held a Wear Green Day to raise awareness of mental health and gave our employees Mental Well-Being Day days off, which was well received. Additionally implementing a fitness challenge that recorded more than 350,000 minutes of fitness activity, recommending annual wellness exams and immunization. as part of a Healthy Self Campaign, employees from across the region are participating in a variety of initiatives, such as LLS Light the Night and Parkinson's Unity Walks.



#### **EMEA**

Since the 2020 Race to Dubai and 2021 Vendee Globe exercise projects had been well received, in 2022 we set even higher goals and took up the Rocket to the Moon challenge that aimed for the moon with a new self-care challenge. The total distance we aimed for was 384,400 km, the distance from Earth to the Moon, and 460 employees and their family members took part in running, walking, swimming, stretching, meditating, etc., and made their way to the Moon. Activities such as exercise and mindfulness were recorded from January to March, and as a result of creating teams for each region and their involvement, the Northern Cluster Northern Stars team recorded a total of 417,029 km and took the lead. Overall, by the end of this challenge, the teams had successfully completed 3,209,697 km.



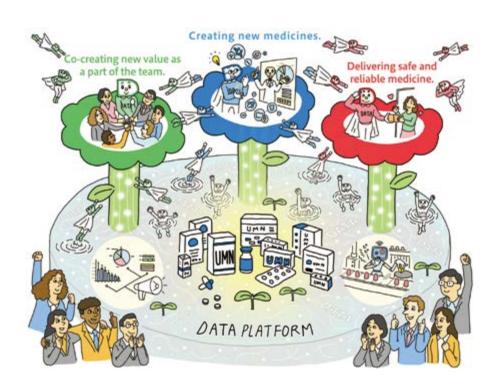
KYOWA KIRIN Annual Report 2022

# **Digital Transformation Strategy**

Continuously creating new digital-value by achieving operational excellence and reinforcing our digital transformation infrastructure

# **Digital Vision 2030**

By 2030, as a global specialty pharmaceutical company with originality, Kyowa Kirin aims to discover unmet medical needs by utilizing data to provide new services and value, including pharmaceutical products. In addition, we accumulate data obtained and created both internally and externally in a series of processes from drug discovery, production, distribution, and sales to medical professionals and patients, forming a unique data platform that is organically connected and utilized as a source for creating new value. Furthermore, we will move beyond the creation of innovative drugs to contribute broadly to maintaining and enhancing health as a member of a "team" centered on medical professionals and patients, while co-creating with various stakeholders around the data platform.



# Three Pillars of the Digital Strategy



#### 1. Achieving Operational Excellence

In support of optimizing operations at the front lines of business, we are successively building a data platform that accumulates data across the globe. Development of this data platform pursues a system that adapts to our business model and realizes operational excellence by combining elements that are best suited to particular operations in accordance with business characteristics, various functions, and the operational characteristics of different regions under the concept of "Best of Breed," which is based on active co-creation with outside entities and cloud-first.

In addition, to support new working styles in the new normal of today, we will create a secure, connected environment that enables employees to work anytime, anywhere. We will accelerate productivity gains through this digital shift in our operations.

#### 2. Transformation to a Circular Value Chain of Data

We will establish a circular value chain of data that maximizes the value of existing drugs and creates life-changing new drugs. This will work by circulating various data assets accumulated within the Company through business activities across divisions within the Group. In the future, we aim to create new solutions beyond providing pharmaceuticals, through collaboration with various stakeholders and through the use of various types of real-world data from outside the Company.

#### 3. Reinforcing Our Digital Transformation Infrastructure

Under Digital Vision 2030, with a focus on personnel and data, we will steadily advance efforts to reinforce digital talent and build a platform for data use across divisions within the Group in order to reinforce the infrastructure for promoting digital transformation.

In order to acquire and reinforce the digital talent who will support our transformation to a circular value chain of data, Kyowa Kirin will develop digital project planners, data scientists, data stewards, and other talent with the ability to lead each division and sector. At the same time, we will raise the general quality of the Company through digital literacy education targeting all employees in an approach to developing digital talent that is both "top-down" and "bottom-up."

In addition, as the entire Kyowa Kirin Group aims to realize an "environment that enables everyone to readily and securely utilize data," we will lay out standards and rules that define our vision regarding data and the specific requirements for regulations, roles, and data management.

On top of this, we will promote collaboration with external partners that possess unique technologies, and build robust digitalization promotion infrastructure that contributes to value creation that is unique to Kyowa Kirin.

KYOWA KIRIN Annual Report 2022

Digital Transformation Strategy



# **Achieving Operational Excellence**

# **Building globally optimized ICT infrastructure**

As we advance our initiatives to realize global operational excellence for each function, we are making progress in developing optimized ICT digital infrastructure across the Company in line with the three establishment principles of the Enterprise Platform for pursuing more sophisticated global management, Functional Platform for addressing requirements unique to the pharmaceutical business, and Regional Platform for supporting strategies unique to regions and operations.

# Infrastructure for supporting individual strategies and needs (differentiation by region and function)

#### **Regional Platform**

- Swiftly and flexibly address unique requirements for different countries and regions
- Marketing, Manufacturing

Japan

North America

**EMEA** 

APAC

In the Marketing sector, we promoted the transition to omni-channels for patient and other customer contact points based on a sales strategy that accounts for the business practices of each region, and completed development of digital infrastructure that is capable of providing an unprecedented customer experience and patient support.

In the Manufacturing sector, data integrity measures to ensure the provision of safe and secure pharmaceutical products and automation measures to eliminate the need for human intervention and achieve high efficiency are steadily progressing.

We are now beginning the transition to a stage where we provide new value (Life-Changing Value Creation) that combines digital tools.

# Unique infrastructure for the pharmaceutical business (optimization that accounts for industry requirements)

#### **Functional Platform**

- Realize optimized operations models for each function
- R&D, QA, PV, RA, MA

Project Management Safety Management Quality Management Regulatory Management Medical Information

#### **Document Management**

While leveraging industry best practices to their fullest extent, we are advancing digitalization in each area of business in order to upgrade those requirements and processes unique to the pharmaceutical industry into globally optimized operational processes. Consequently, we have established the infrastructure for addressing quality management platforms that support high-quality pharmaceutical provision on a global basis and for enhancing pharmaceutical commercialization management. We are also making progress on globalizing medical affairs operations and on renewing ICT infrastructure that supports more sophisticated research and development project management.

# Infrastructure for global corporate management (pursue best practices for corporate management)

#### **Enterprise Platform**

- Realize optimized operations models at the global level
- ► ERP, FP&A, HRIS

#### Security (zero-trust)

Collabo/digital workplace

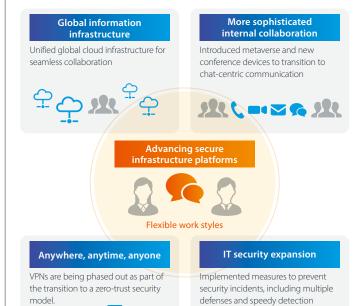
Governance, risk & control

#### Corporate management (ERP/FP&A/HRIS)

As a Japan-based Global Specialty Pharmaceutical Company, we are working to improve our corporate management infrastructure, including the enhancement of overall business management, the development of a robust security infrastructure, and the creation of a collaboration environment that accelerates hybrid work and work style reforms. The foundation for efficient management of corporate resources (people, material, and financial resources) on a global basis is now in place. In addition to people, material, and financial resources, we are also working across all divisions to develop various data utilization infrastructures for effective use of data assets and to transform into a digital-driven organization as one of the strategic pillars of digital transformation.

# Advancing secure infrastructure platforms that accelerate flexible work styles

With the spread of remote work, we have completely eliminated the on-premise environment for our internal information sharing infrastructure and portal, and completely migrated to cloud services, with the goals of promoting a cloud-based infrastructure and ensuring secure access to enable employees to work flexibly from anywhere. As a result of these efforts, we have put in place an environment that allows for seamless collaboration across the globe. In regard to new work styles under a Group-wide hybrid work policy, we realized an environment that allows employees to work from anywhere at any time by expanding online conference tools and by eliminating VPNs as part of our transition to a zero-trust security model. From a security standpoint, we are implementing measures to reduce security incidents and strengthen our response capabilities, including multiple defenses, prevention of infection in advance, and speedy detection.



New Healthcare Solutions

Improve patient outcomes through the

creation of solutions that go beyond the

provision of pharmaceuticals

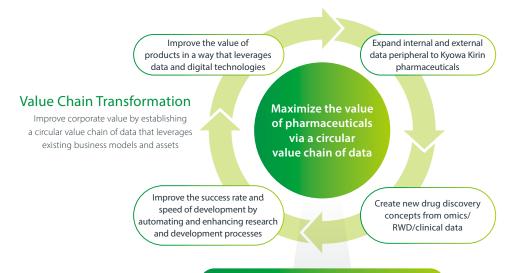
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# Digital Transformation Strategy



# **Transformation to a Circular Value Chain of Data**

We will circulate data across departments and work agilely on themes that lead to the creation of new value. We will also evolve these efforts into a system that continuously generates new themes and in which value growth based on data is deeply rooted.



# Develop new solutions through data use



Patient support

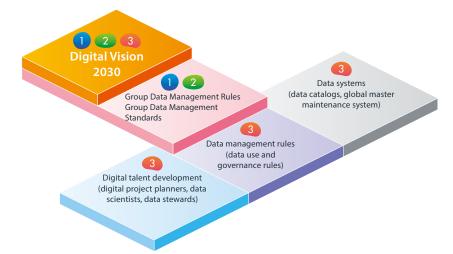
program

Digital pill /

# Foundation for Digital

# Reinforcing our digital transformation infrastructure (create human and data infrastructure to support transformation)

Under the Digital Vision 2030, we are focusing on people and data to strengthen the foundation for promoting digital transformation, and are making steady progress in developing digital human resources across departments and creating a data utilization infrastructure.



#### Data management rules and standards

In an effort to resolve issues involving data through data management activities across divisions within the Group and with the aim of realizing an "environment that enables everyone to readily and securely utilize data," the Kyowa Kirin Group laid out its vision regarding data and the specific requirements for regulations, roles, and data management.

\* Kyowa Kirin data management activities cover the entire data lifecycle (registration, recording, updating, use, and disposal)

#### Data management rules

We have defined general policies and standards for data management activities, with the aim of defining the person responsible for the data to be managed in each department and providing new value through the use of data. In addition, we have begun to develop the necessary business processes and rules related to them.

#### Digital talent development

We are developing digital talent through both a "top-down" and "bottom-up" approach in order to develop talent that can lead each business function, and to raise organizational capabilities through digital literacy education targeting all employees.

We have defined and are promoting a training program for specialized human resources, such as digital project planners who are responsible for identifying business issues based on data, solving issues and creating business innovation through digital technology, and data scientists and data stewards who promote data utilization and governance for the entire group.

#### Data systems

We are building a system to support master data management on a global basis in order to support the utilization of diverse data beyond organizational boundaries and "data governance activities" to manage utilized data as assets.

In particular, in the area of data utilization, we are also focusing on the maintenance of data catalogs to create an environment that enables safe and easy data utilization by securing the consistency of globally shared data and assigning attribute information to the data to be utilized.



# Yutaka Osawa

Representative Director of the Board, Executive Vice President

# Takashi Oyamada

Independent Outside Director

A special discussion was conducted between Yutaka Osawa,
Executive Vice President, and
Takashi Oyamada,
Independent Outside Director,
Here, they discuss about their thoughts on
Kyowa Kirin's potential and strengths as well as the Company's challenges.

## Pharmaceutical industry environment

Osawa: To ensure sustainable growth and improve corporate value over the medium-to-long term by increasing the fairness and transparency of Kyowa Kirin's corporate governance, the majority (five out of nine) of the Company's directors are independent outside directors who possess expertise and experience across a wide range of areas. These directors are expected to bring their extensive experience and knowledge to the Company's management and also supervise the business execution of directors from objective and fair standpoints. Mr. Oyamada, you have a wealth of experience in the financial industry, including as deputy president of the Mitsubishi UFJ Financial Group and president and CEO of Bank of Tokyo-Mitsubishi UFJ. This is the first time that Kyowa Kirin has appointed an independent outside director with such extensive experience in the financial industry. Two years have passed since you were appointed as an outside director, so how do you feel about Kyowa Kirin's business environment?

Oyamada: My feeling is that the environment surrounding the pharmaceutical industry and the financial industry have many points in common. These include the size of their social responsibilities and the accompanying tightness of regulations, the need to compete with major companies in the global market as well as the extent and speed of changes in industry structure. In such an environment, I feel that we need to change ourselves constantly and make innovations to improve corporate value and achieve sustainable growth. What I prize above all is Kyowa Kirin's vision. I always attend Board of Directors' meetings while paying close attention to the perspective of whether we are able to implement the Core Values that the Company holds dear, such as Commitment to Life, Innovation, Integrity, and Teamwork, at a high level in global terms to realize the vision. While I feel that Kyowa Kirin is heading in the right direction, as the environment is changing at an even faster pace, it appears to me that there are issues that will need to be addressed in terms of filling in the gaps created by change with a sense of urgency and staying ahead of the curve as a leading company.

## Kyowa Kirin Group's potential

**Osawa:** You have given us insightful opinions at Board of Directors' meetings, and it is refreshing to hear you say that the financial industry and the pharmaceutical industry have many points in common. In particular, it is also interesting to hear you say that, even in the financial industry, there is no growth without innovation.

**Oyamada:** Innovation is a process of transformation through selfdenial, and I believe that human resource diversity is an essential perspective for bringing about innovation with a sense of urgency.

The other day, I participated in a conference with outside directors of overseas regional headquarters. Some of them were from overseas mega pharmaceutical companies, and it was very meaningful to discuss with them from a global perspective. What impressed me the most was how highly they rated Kyowa Kirin's potential. The Company sometimes tends to underestimate itself in comparison to the mega pharmaceutical companies in terms of scale. However, they commented that, because of its size, Kyowa Kirin is able to make decisions quickly and respond flexibly and, what's more, if the Company was to further refine its current strengths in the field of rare diseases, it would well be able to compete globally and still be able to grow.

**Osawa:** I also attended that conference, and their opinions—gained from having experienced companies at all stages, from start-up companies to mega pharmaceutical companies, in the global market—were very informative for us and gave us confidence in the Company's potential.

In Europe and the US, it is not unusual for medium-sized pharmaceutical companies to double their market capitalization in a few years, but this is rare in Japan. As some people among them have had such experiences of success, it was very convincing.

**Oyamada:** I am really looking forward to growth in the years to come. I feel that more sophisticated risk management is the key to Kyowa Kirin's further growth. To achieve the Company's goals, appropriate risks need to be taken in important situations. It is for that reason that we must refine our risk management.

**Osawa:** I agree with you on that point. For our employees, I would like to increase the opportunities that will enable them to take risks and take on the challenges that lead to growth. The key among them would be overseas human resources. Possessing a high ability to analyze risks and to determine whether the returns would be worthwhile, they know how the probability of success is increased by controlling risks in a strategic manner. By firmly promoting exchanges with overseas personnel, I would like to improve the risk management capabilities of domestic employees and promote a change in awareness. At the same time, even if risks materialize and have a major impact on the Company, it is necessary to acquire the resilience to deal with them

# **Energizing Board of Directors' meeting discussions**

**Oyamada:** At Board of Directors' meetings, a virtuous cycle is established in which outside directors and outside Audit & Supervisory Board members express a variety of opinions, which the divisions responsible for business execution take seriously, leading to subsequent actions. In this respect, I appreciate that the recommendations of outside directors and outside Audit & Supervisory Board members are being fully reflected in management.

In contrast, as a challenge for the future, I feel that there is a lack of discussion on the direction of management from a broader perspective in response to changes in the external environment. The Board of Directors needs to discuss important global-scale themes further, such as progress in digitalization, economic security, and major changes in demographics.

A long-term perspective is also important. We should have more future-oriented discussions about the way pharmaceutical companies should be and the structure of the industry in the years ahead, with a

view to 2030 and beyond, to 2050.

To that end, I would like to see the Company establish a system to determine which proposals should be considered and discussed by the Board of Directors and which can be dealt with on the executive side, so that we can spend more time on these discussions.

**Osawa:** With regard to the organization of the agenda, I am aware of this as a challenge and have been considering it for the past few years. I would like to continue to improve the process for submitting proposals to the Board of Directors, focus more on the important issues that should be discussed at Board of Directors' meetings, and bring about an evolution in terms of process that will give us more time for discussion.

## Setting course toward materiality realization

**Oyamada:** I strongly feel the need to identify materiality. This expresses what kind of problem awareness and issue recognition the Company possesses and forms messages that should be clearly communicated to all stakeholders. Once the Company has identified its materiality, it is important to show a specific path toward how to achieve it. If there is little chance of achieving materiality, stakeholders may view it merely as a verbal commitment and even have doubts about its seriousness.

Among these areas of materiality, I am particularly interested in reducing environment impact. Companies have a great responsibility for environmental problems, and even in this pandemic many have pointed out that climate change and the destruction of nature are closely related to the spread of the virus to humans. As our philosophy states, "we contribute to the health and well-being of people around the world," I believe that we are required to face up to environmental problems that can cause illness.

**Osawa:** As you say, a rapid rise in temperature will not only lead to an increase in infectious diseases but also have a major impact on human health. For that reason, we have devised a roadmap for net-zero CO<sub>2</sub> emissions and are working toward its realization. We are switching to renewable energy at major emission sources such as plants and are



With regard to climate change and the securing of biodiversity, I would like to see Kyowa Kirin take on challenges that incorporate new perspectives unique to a pharmaceutical company

expecting to have reduced  $CO_2$  emissions by 55% by 2030 (compared with 2019). Scope 1 and Scope 2 can be reduced according to the plan, but Scope 3 represents a major issue that calls for a response across the entire value chain. Since we cannot solve this problem on our own, I believe that it will be necessary to work closely with our business partners to formulate more specific measures going forward.

**Oyamada:** While the Company is addressing climate change and the securing of biodiversity, I would like to see Kyowa Kirin take on challenges that incorporate new perspectives that are characteristic of a pharmaceutical company. In addition, the projects carried out in cooperation and collaboration with the Kirin Group are also of great significance. If progress were to be made with these kinds of efforts, I think that there will be plenty of opportunities to bring about innovation related to the Company's core business from the perspective of tackling climate change and environmental issues.



Everyone's opinions and requests are the energy source that powers our growth

# Kyowa Kirin Group's strengths and issues

**Oyamada:** It is worthy of special mention that the One Kyowa Kirin system was built and evolved with great speed to accelerate global expansion. The Company is also promoting its own operation of the direct sales force for Crysvita in North America. To survive in an increasingly harsh market environment, I believe that Kyowa Kirin's ability to transform itself represents a strength. I think it has also given employees a great deal of confidence. I also believe that the growing momentum for all employees—from the front lines overseas to all employees working in the field in Japan—to work together to build a bold and robust global value chain unique to Kyowa Kirin represents a major opportunity.

Osawa: Thank you for appreciating the speed of the Company's overseas expansion so highly. However, for the Group to become the Japanbased Global Specialty Pharmaceutical Company for which we are aiming, further acceleration will be necessary. For this purpose, we need to more actively promote our strength on the therapeutic areas we are focusing on and our research strengths externally to further raise

awareness. As our global presence grows, there will be more opportunities for attractive collaborations with various overseas companies.

Oyamada: In addition, I feel there is great potential in the area of synergies with the Kirin Group. I think there is scope for deeper delving. The Kirin Group is actively strengthening its health science fields in health and pre-symptomatic disease. Also, as part of our vision for 2030, we aim to create value beyond pharmaceuticals. Specifically, we plan to further strengthen collaboration with the Kirin Group to create innovative new value for society. Starts have been made with several projects aimed at creating synergies, and it is hoped that they will be further accelerated and that partnerships in new areas will be deepened. By doing so, I think the Company will start a chain-reaction of innovation, creating a virtuous cycle of synergy generation.

Osawa: There is still room to create synergies with the Kirin Group, and I am confident that we can make even greater contributions to society through them. However, to generate and develop synergies, we have to resolve some issues. One of those clues that can be mentioned is to further strengthen collaboration in research activities with the Kirin Group. We have accumulated a vast amount of disease-related data and knowledge about diseases, but I think there is not enough about human health science as a whole, including health and presymptomatic conditions. For its part, the Kirin Group has actively conducted research in this field and accumulated an enormous amount of data and knowledge. There remains the possibility that a comprehensive analysis of this data may generate unique ideas. In the years to come, I hope that this will lead to innovative approaches to diseases that thus far have not been explored.

Oyamada: Another issue is the lack of late-stage development projects that will lead to the next stage of growth. In this regard, I think that in the coming years Kyowa Kirin should focus more on networking with external parties and open innovation. I strongly believe that if the Company can cooperate with other companies, share knowledge, and co-create value, its corporate value will increase further and the Company will be able to move forward in a better direction.

The Company's outside directors and outside Audit & Supervisory Board members possess extensive experience and knowledge regarding alliances and networking of this kind. I understand that this is a significant added value expected of us, outside directors. If you only look inside a company, you may not notice effective networks, so I would like to see outside directors more actively involved and making more and more valuable suggestions.

Osawa: With regard to, as you said, the enhancement of late-stage development projects, the business execution side also recognizes this as a priority issue. We are considering the licensing-in of products developed by other companies that represent a good fit for Kyowa Kirin and joint developments, and in this case, I believe that building win-win relationships with partners is more important than anything else. Going forward, I would like to consider the possibility of partnering from a broader perspective.

Previously, the Company has often investigated possibilities within a limited scope, and it appears that the corporate culture of actively engaging with the outside world was weak. The information and knowledge obtained through communication with outside parties is an important factor that stimulates us and also serves as a driving force for change. Mr. Oyamada, you often advise that it is important for us to broaden our horizons and find fulcrums for applying leverage, and that even a small company is capable of achieving great results by applying leverage. Advice from an outsider's point of view remains very important to us. If we stop thinking within the company, we will not be able to come up with radical ideas and only be able to expect growth within the scope we envisioned.

It is for that very reason that advice and feedback from all our stakeholders, including shareholders and investors, are extremely valuable to us. Everyone's opinions and requests really are the energy source that powers our growth, so it would be very much appreciated if you could continue to provide us with your forthright comments and support in the years to come.

# **Ensure a Thriving Global Environment for Future Generations**

We are actively working to conserve the environment for future generations. As part of this commitment, we aim to decarbonize our company, including the value chain.

#### **Environmental Management**

Having incorporated priority environmental issues from the perspective of their impact on the sustainability of society and on the Group's business in its FY2021–2025 Medium Term Business Plan, Kyowa Kirin is setting targets for each fiscal year and implementing measures accordingly. In particular, we have positioned climate change mitigation and adaptation and water resource management as core environmental issues. As well as our annual targets, we have set mediumand long-term targets, developing a range of measures to achieve these.

We have established and are operating a governance structure for Kyowa Kirin's environmental management. The Executive Vice President has been appointed as its chief executive officer. (For details, see 'Responding to the Task Force on Climate-related Financial Disclosure (TCFD) — Governance (relating to environmental issues)' on page 44.)

In our daily environmental management activities, we operate all of our domestic plants and research laboratories in accordance with the ISO 14001 environmental management system.

#### Addressing climate change

The Kirin Group, of which Kyowa Kirin is a member, has formulated the Kirin Group Environmental Vision 2050. In its vision, the Kirin Group has set a goal of achieving net-zero greenhouse gas emissions in its entire value chain by 2050 as a "Society that has overcome climate change," a society in 2050 that we want to create together regarding climate change.

Ratio of CO<sub>2</sub> emissions by energy type and CO<sub>2</sub> emission reduction effect from introducing renewable energy (all plants and research laboratories in Japan and overseas) Approx. 53% reduction Natural gas Other 1% Steam Kerosene 26% 2019 Forecast for 2023 Starting in 2020, we have converted 100% of the electricity purchased at, in order, the Takasaki Plant, the Fuji Site, and the Ube Plant to renewable energy sources.

Kyowa Kirin has also adopted the target of reducing CO<sub>2</sub> emissions in 2030 by 55% from the 2019 level. As specific commitments related to climate change, we are committed to "Promoting early reduction of CO<sub>2</sub> emissions" through "Energy conservation" and "Expansion of renewable energy" including capital investment, and "Promoting energy conversion." Having created a road map for achieving the 2030 target, we have also set a short-term target (FY2024 CO<sub>2</sub> emissions: 51% reduction compared with 2019). Utilizing the Kirin Group as a network, we will contribute to the realization of this vision by actively developing climate change measures that leverage our business characteristics.

To promote the use of renewable energy Kyowa Kirin has been promoting the introduction of solar power generation equipment since 2011. As of the end of FY2022, such equipment is in operation at the Tokyo and Fuji research parks and at the Ube and Takasaki plants. In March 2023, we install and operate a large-scale solar power generation facility (1.47 MW) at the Ube Plant using an on-site power purchase agreement (PPA) model and are thereby planning to accelerate the reduction of  $CO_2$  emissions. In the meantime, we have been gradually introducing RE100-compliant renewable energy at the Takasaki Plant and Fuji Research Park since 2020, switching 100% of the electricity at each plant to renewable energy. In April 2023, we introduce this system at the Ube Plant, and switch 100% of the electricity used at this plant to RE100-compliant renewable energy. By introducing these renewable energy projects, of the approximately 70,900,000 kWh of annual power consumption of the Kyowa Kirin Group, approximately 60,300,000 kWh will be switched to renewable

energy with zero  $CO_2$  emissions, and the plan is for the Group's annual  $CO_2$  emissions to be reduced by approximately 53% (27,300 t).\*1 In 2021, RE100-compliant renewable energy was also introduced for the electricity (100%) of the head office.\*2

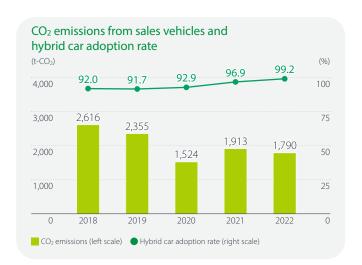
Going forward, the plan is for us to have switched to 100% renewable energy at our major business locations in Japan by 2025, and to all of our group business locations, including overseas sites and domestic branch offices, by 2030. In addition, we are considering the introduction of solar power generation facilities at our domestic plants and research laboratories as well as at our overseas plant.

Each plant and research laboratory\*3 sets its own energy intensity reduction targets for a single year, implementing measures to improve production efficiency. Although we implemented various measures to improve production efficiency, unit energy consumption in FY2022 was 2.2% higher than the previous year due to the effects of production facility enhancements and production volume increases.

Also working to reduce CO<sub>2</sub> emissions from our sales vehicles, since 2009 we have been promoting the introduction of hybrid cars for our sales vehicles (company cars) in Japan. Since FY2019, all newly introduced sales vehicles have been hybrid cars, and the hybrid car adoption rate had reached 99.2% by the end of FY2022. In addition, new information provision activities such as webbased interviews, information sessions and lectures are increasing, contributing to the reduction of CO<sub>2</sub> emissions.







KYOWA KIRIN Annual Report 2022

#### Retain the trust of society

#### Water resources management

Kyowa Kirin conducts water risk assessments (such as water shortage/water stress, flooding, and water pollution of water sources risk assessments by WRI Aqueduct and WWF Water Risk Filter) at each plant in Japan and overseas.

As a result of the assessments, we identified that the Ube Plant has a higher risk of flooding due to droughts and storm surges and that at Kyowa Kirin China Pharmaceutical Co., Ltd. (Shanghai) the risks of water shortages and flooding were greater than at other plants. In the latest local flooding simulation published by the Ministry of Land, Infrastructure, Transport and Tourism, it is assumed that the Takasaki Plant would suffer flood damage.

In response to these results, alongside soft measures such as reviewing or formulating plant BCPs for large-scale natural disasters, we are also implementing hard measures such as flood prevention measures at facilities to avoid or minimize these risks.

Under the Kirin Group Environmental Vision 2050, Kyowa Kirin is working to conserve water and protect water resources in accordance with the Kyowa Kirin Group Environmental Policy. In 2021, we reviewed our previous 2030 water consumption (water withdrawal) reduction target and set a new 2030 water withdrawal reduction target of a 40% reduction from 2019 levels. We are also setting short-term targets to achieve the 2030 target. To reduce water withdrawal, we will systematically decommission and reorganize facilities while making effective investments in equipment such air-cooled refrigeration units. As of the end of FY2022, we have achieved a 33% reduction from the 2019 level\*1 against our 2030 water withdrawal reduction target. Furthermore, to improve the efficiency of water use, each year, each plant and research

laboratory sets and manages its own water consumption intensity. In 2022, our water consumption intensity was 9.7% lower\*<sup>3</sup> than the previous year.

#### **Biodiversity**

At Kyowa Kirin, we are using our procurement activities to help protect the world's forests. Specifically, we have adopted FSC\*-certified products\*4 for materials such as company envelopes, company brochures, and cardboard product packaging. In accordance with the Kirin Group Action Plan for Sustainable Use of Biological Resources, which was revised in 2021, we continue to study applications for FSC\*-certified products. In addition to expanding their use for domestic product packaging cardboard boxes, we are considering using them for materials such as product inner boxes. We have also begun considering the use of FSC\*-certified products overseas, at business sites and for products.

As part of its activities to preserve ecosystems and ensure biodiversity, Kyowa Kirin has been working to protect water resources through its engagement in the Kirin Group's water-source preservation project since FY2007. The Takasaki and Ube plants carry out weeding, planting and tree thinning to create forest areas that provide water resources. In addition, for the seventh year running, Kirin Holdings Company, Limited has been recognized as the highest Water Security A List company by CDP, an international non-profit organization that provides an environmental data disclosure system. CDP praised the Kirin Group, of which Kyowa Kirin is a member, for its efforts in protecting water resources, evaluating river basin water risks at manufacturing sites, and for formulating and implementing strategies that reflect those risks.

Kyowa Kirin business sites also work with various local communities to preserve ecosystems, including releasing young amago trout into rivers, or protecting grasslands of Akiyoshidai in Yamaguchi Prefecture. The Fuji site continues to collaborate with local government on activities such as Shizuoka Prefecture's River Friendship Program, which organizes cleanups of local rivers, and a campaign to clean up trash from areas around Mount Fuji. Through these activities, we will continue to support local communities and raise awareness of the importance of preserving the beauty of the natural environment and protecting biodiversity.

In our research, development, and manufacturing of pharmaceutical products, we have established an in-house committee to ensure compliance with the Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms ("the Cartagena Act") and to conduct appropriate management. At the 2022 Genetically Modified Organism Committee meeting, we shared the results of audits that focused on countermeasures against leaks of experimental applications in each department.

The Kirin Group is advancing a range of initiatives in this area, including the Kirin Group Declaration of Support for Biodiversity Conservation, formulated in 2010, and the Kirin Group's Guidelines on Sustainable Sourcing of Biological Resources, formulated in 2013.

- \*1 Calculated based on FY2019 data for Kyowa Kirin Group's plants and research laboratories in Japan
- \*2 Otemachi Financial City Grand Cube, where Kyowa Kirin's head office is located, has adopted RE100-compliant electricity derived from renewable energy sources.
- \*3 Kyowa Kirin Group plants and research laboratories in Japan and plants overseas.
- \*4 Kyowa Kirin has obtained an FSC® promotion license (FSC® N003037).



#### Responding to the Task Force on Climate-related Financial Disclosures (TCFD)

Since announcing our endorsement of the TCFD recommendations in 2021, Kyowa Kirin has identified the risks and opportunities that climate change poses to our business, as well as the impacts of these risks and opportunities. We have organized our findings into four areas: governance, strategy, risk/opportunity management, and indicators and targets in line with TCFD recommendations.

#### Governance (relating to environmental issues)

Issues related to risks and opportunities in climate change, as well as environmental activity policies and results are positioned as important matters in the Group's environmental management. These issues are reported, deliberated upon, and decided by the CSR Committee, which is chaired by the Representative Director and Executive Vice President, who has the highest responsibility for overall environmental management. The content of these discussions is reported to the Board of Directors. In addition, from FY2020 we put in place a TCFD Study Team within the CSR Management Department, which is responsible for the environmental management control function. This team studies the identification and evaluation of climate change-related risks and opportunities and our response to them. We are addressing climate-related issues as part of management strategy by regularly reviewing the risks and opportunities that have been identified and reporting them to and having them brought up by the CSR Committee.

#### Strategy

We aim to achieve a world in which the average temperature increase is limited to 1.5°C or less, as outlined in the Paris Agreement. We are reviewing our climate change response based on the results of our scenario analysis of climate change-related risks and opportunities and also in the context of the Kirin Group Environmental Vision 2050. We are incorporating these findings into our business strategy and advancing measures accordingly.

As mitigation measures, to support the achievement of net-zero greenhouse gas emissions throughout the value chain by 2050, we have not only upwardly revised our 2030 CO<sub>2</sub> reduction target to a level corresponding to the Science-Based Target (SBT) 1.5°C target\* but also established a roadmap for achieving this target and set short-term targets. Having incorporated targets (CO<sub>2</sub> emission reduction achievement rate, renewable energy introduction rate, 1% reduction in energy intensity compared with the previous year, etc.) for each fiscal year in the FY2021–2025 Medium Term Business Plan, we are promoting measures, such as the early introduction and expansion of renewable energy, energy conservation, and energy conversion, and responding to the risks associated with the transition to a decarbonized society.

**TOPICS FOR** 

VALUE ENHANCEMENT

As an adaptive measure, we will formulate a Business Continuity Plan (BCP) for large-scale natural disasters. This will address the impact on global production activities arising from flooding of plant and research laboratory premises. We respond to physical risks by implementing flooding prevention measures and capital investment as required. Going forward, we will continue to minimize risk by assessing and addressing the impact throughout our supply chain.

On the other hand, an increase in the number of hay fever sufferers had led to expectations of an opportunity for the allergy drug market. However, we believe the actual impact on sales revenue will be limited. Recognizing that this will form an important point in future business strategies, we will continue to consider new developments in this field to meet medical needs based on our management philosophy.

\* Science-based corporate greenhouse gas emissions reduction targets consistent with the Paris Agreement levels

#### Risk/opportunity management

To identify risks and opportunities, we comprehensively assess—based on scenario analysis for each risk and opportunity—the expected timing and probability of occurrence, the scope and magnitude of impact, and the nature of countermeasures. We manage these risks and opportunities by identifying those that have a significant impact on business, that involve a high degree of social responsibility, or have a high probability of occurrence. We monitor and manage, on a quarterly basis, our measures to address the risks we have identified.

#### Metrics and targets

In 2021, we set a new 2030 CO<sub>2</sub> emissions reduction target of 55% reduction from 2019 levels. This is based on the SBT 1.5°C target. In addition to creating a roadmap for achieving these new targets, we have set short-term targets (2024 CO<sub>2</sub> emissions: 51% reduction compared with 2019). Incorporated into our FY2021-2025 Medium Term Business Plan, we are setting and managing annual targets for each fiscal year, while studying and developing measures to achieve them.

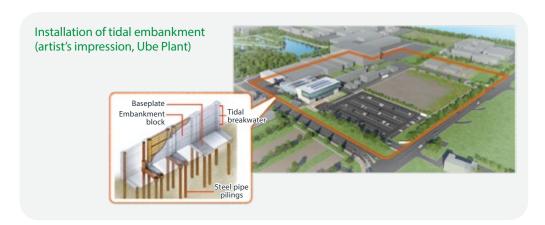
In addition, the Kirin Group has set a goal, based on the Kirin Group Environmental Vision 2050, of achieving net-zero greenhouse gas emissions for the entire value chain by 2050. As medium-term targets, the Group has upwardly revised its greenhouse gas reduction target to a 50% reduction in Scope 1 + Scope 2 and a 30% reduction in Scope 3 by 2030 compared to 2019 (approved for the SBT 1.5°C target). A target of 100% renewable energy sources for electricity consumption has been set for 2040 (RE100 member). Kyowa Kirin has developed its 2030 targets and measures in alignment with these medium- and long-term goals of the Kirin Group.

The greenhouse gas emissions in the Kyowa Kirin Group's value chain (Scope 3) are calculated by dividing them into 15 categories in accordance with the Ministry of the Environment's guidelines, which are consistent with the GHG Protocol. To achieve the Kirin Group's goal of net-zero greenhouse gas emissions for the entire value chain by 2050, we will continue to work on reducing Scope 3 emissions.

# Analysis of risks, opportunities and financial impact related to climate change

FILIK	RISK Blue: Opportunity			
Scenario classification		Climate change-related drivers with impact assessment	Potential impact	Change through response (resilience)
Transition	Policy and regulations	Carbon pricing (decarbonization, emissions trading schemes)	Small	±0
1sit		Tighter CO <sub>2</sub> emission regulations	Slight	Small
on risk	Population/economy/ geopolitics	Population growth in emerging economies/economic globalization	±0	±0
~	Community	Changing social values	Slight	±0
	Increase in average	Extreme temperature rises	Small	Small
Physical risk	temperature and change in rainfall pattern (acute)	Increased torrential rains, typhoons, and floods	Large	Slight
l a	Increase in average	Changes in hay fever patients	Medium	Medium
isk	temperature, changes in rainfall pattern (chronic)	Increased energy consumption due to increased air conditioning load	Small	Small

- Achieve 2030 target early and reduce CO<sub>2</sub> emissions
- Review workplace BCPs for major natural disasters
- Disaster preparedness of facilities



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Retain the trust of society

# **Quality Assurance/Stable Supply**

We believe that ensuring the stable supply of high-quality pharmaceuticals is vital for a pharmaceutical company.

Having the highest level of Quality and a Stable Supply of products are very important management imperatives, therefore, Kyowa Kirin is advancing various initiatives toward these priorities.

#### Capital investment in Takasaki Plant aimed at stable supply

Kyowa Kirin has two key production bases, in Takasaki City, Gunma Prefecture, and Ube City, Yamaguchi Prefecture. Primarily a base for biopharmaceuticals, the Takasaki area is home to the Bio Process Research and Development Laboratories, which develop production technologies and handle regulatory filings, and the Takasaki Plant, which manufactures and formulates bulk pharmaceuticals for investigational drugs and marketed products. Taking advantage of their geographical proximity, our teams work closely together. Such collaboration makes this location a world-class biopharmaceutical research and manufacturing base.

#### Q-TOWER completed

In 2022, the Q-TOWER that was being built at the Takasaki Plant was completed. The new Quality building is fully compliant with Japan, the United States, and European Good Manufacturing Practices (GMP). The Q-TOWER was newly constructed to carry out Quality operations relating to quality control and quality assurance, such as the testing of biopharmaceuticals and raw material quality analysis. This new quality building is equipped with the most advanced biopharmaceutical analysis equipment, including an automated colony counter, rapid microbial testing, and robot technology. As well as equipment to

automate processes and reduce manpower, such as a liquid handling system and an automated sample picking system. Also, a sterility testing isolator has been installed, helping create a laboratory that satisfies the latest global regulations. By having designed workspace areas with spatial continuity, we are providing an environment in which everyone can work healthily, creatively, and truly have an optimal workplace for fostering a positive culture.

# Construction of an active pharmaceutical ingredient manufacturing building and new warehouse building planned

In 2022, the Company decided to construct a new active pharmaceutical ingredient (API) manufacturing building and a new warehouse building at its Takasaki Plant.

Manufacturing APIs for biopharmaceuticals utilizing Kyowa Kirin's unique antibody technology and protein engineering, the new HB7 Building will be equipped with both a GMP facility to manufacture APIs for use in GMP-compliant clinical trials and a pilot facility for the scaled-up verification of manufacturing methods established in our laboratories. As both facilities have been designed to have the same single-use manufacturing equipment, and the same facility configuration can be used for everything, from the initial process development of biopharmaceutical API manufacturing to the manufacturing of investigational

APIs, it will be possible to manufacture high-mix, small-lot products in early phase development more flexibly and quickly. Moreover, it is planned to use the pilot facility to verify the continuous production system, which is new technology for biopharmaceutical APIs, as part of efforts to promote technological innovation directed at stable supply.

The new warehouse building will be constructed to accommodate the expanding supply of biopharmaceuticals (products and development). The regulatory authorities in various countries require that strict control measures be in place for the storage of pharmaceutical raw materials, drug substances, and formulations. For that reason, the new warehouse building will comply with the standards required by each regulatory authority and be capable of stably storing biopharmaceutical raw materials, drug substances, and formulations at room, cold or frozen temperatures. The building will also have a seismic isolation structure that will enable continuous product supply and the early resumption of production even in the event of a major disaster, such as an earthquake or flood. It is assumed that key facilities will be designed to protect them from any damage caused by flooding. In addition, the facility's environmental friendliness is being taken into consideration by installing a solar power generation system on the rooftop and actively adopting energy-efficient air conditioning equipment.



Q-TOWER



Rendering of the exterior of the new biopharmaceutical API manufacturing building



Biopharmaceutical drug substance production facilities

#### Building a world-class Quality Assurance (QA) system

Pharmaceuticals are products that directly affect human lives. At a pharmaceutical company, quality is the responsibility of every employee. Without robust quality and compliance, we cannot earn the trust of patients, healthcare professionals, national regulatory authorities nor that of society. Kyowa Kirin's Global QA Function confirms that various processes, including manufacturing and distribution, are conducted properly and in compliance with relevant laws and regulations. Our overall aim within the Global QA function is to always ensure the highest quality medicines are delivered to our patients that are in need.

#### Enterprise/Electronic Quality Management System (eQMS)

Since 2019, when globalization began in earnest, we have been formulating the Kyowa Kirin Group Quality Policy and the Global Quality Roadmap to 2025 while steadily strengthening our global QA system. In 2022, we completed the introduction of an enterprise/electronic quality management system (eQMS). By having introduced this system, which covers a wide range of quality assurance operations from deviation control, corrective action/preventive action (CAPA), training, document management, auditing, supplier management, and change management by means of a complete electronic process. We now have in place a platform that enables us to meet globally consistent standards as well as the requirements of relevant laws and regulations for each country

and market we serve. Aiming to build a preventive quality management system using risk-based approaches that we can confidently claim to be world-class, we have set globally integrated KPIs. While monitoring operational status in real time, we will gather and analyze vast amounts of data collected as well as engage in continuous improvement of processes and the fostering of a quality culture routinely.

#### Supply Chain Management (SCM) and other initiatives

The number of countries in which global strategic products such as Crysvita are sold is steadily increasing, and the overseas revenue ratio, which was 48% in 2020, is expected to reach 64% in 2023. In accordance with this expansion, the supply chain related to manufacturing and distribution, including outsourcing, is becoming more and more complex, and Kyowa Kirin is focusing on its management.

Kyowa Kirin's SCM Function is responsible for accurately monitoring and controlling this complex situation so that our pharmaceutical products reach the patients who need them, when they need them, and in precisely the quantity needed. To control the supply-demand balance with a high degree of precision, the SCM Function serves as a coordinator, building strong partnerships internally in particular with the quality assurance, production, and sales functions as well as externally with contract manufacturing companies and

logistics companies. At the same time, by further evolving S&OP\* initiatives, the SCM Function helps to optimize inventory levels while supporting rapid decision-making by management.

Following the disruption caused by the COVID-19 pandemic that began in 2020, transportation risks arose in 2022 due to the Russia-Ukraine conflict, but Kyowa Kirin has continued to maintain stable supplies through SCM Function-centered cooperation and response. For the Company to keep this up going forward, in addition to early anomaly detection and continuous improvement through supply chain KPI monitoring, we are planning a raft of measures designed to maintain a stable supply. These measures include building and updating stable supply Business Continuity Plans (BCPs) and the dispersing of our storage locations for APIs over multiple sites. We will also further expand measures to counter the problem of counterfeit drugs, which has become increasingly serious in recent years, and contribute to the creation of an environment in which patients can receive treatment with peace of mind.

\* Abbreviation for Sales and Operations Planning. A system that enables sales and production/ operational divisions to confirm plans and results, both in quantitative and monetary terms. S&OP ensures alignment on the optimal plan for the Company, increasing the accuracy and speed of decision making to support the achievement of the Company's financial targets.

#### Kyowa Kirin Group Quality Policy

We contribute to the health and well-being of people around the world by ensuring the highest quality commercial and clinical medicines are available and by always adhering to global quality, safety and compliance policies.

- 1. We utilize People, Process, Systems/Technology to conduct reliable and ethical activities in alignment with our compliant and effective GxP quality management system.
- 2. We maintain healthy relationships with all stakeholders and properly oversee suppliers and contractors.
- 3. We comply with all GxP global laws, guidelines and industry rules in our activities.
- 4. We utilize data and risk principles to drive decisions based on longterm outcomes, while always keeping our patients at the center of our decisions.
- 5. We foster a positive quality culture and always strive to continuously improve.

#### Global OA Structure

Four regional QAs support GxP activities within each region, and the global QA function promotes collaboration and coordination globally, while the Global Quality Head sets the overall strategy and monitors all activities.

#### Supporting Company-wide GxP activities, from research to sales



#### Launch of human rights due diligence working team

In accordance with the full-scale globalization of our business, the impact of our activities on rights-holders (those facing human rights issues) around the world is expanding. The co-creation of value with stakeholders is essential in the provision of life-changing value. In doing so, we believe that it is necessary to consider the human rights of not only our employees but also of those related to our business partners. Having launched a working team, consisting of the Strategy Division, CSR Management Department as well as the

Procurement and HR departments in 2022 to fulfill the corporate social responsibility that is respect for human rights, we are commencing initiatives with regard to human rights due diligence. Having obtained the assistance of external experts, the specified non-profit organization Caux Round Table Japan (CRT Japan), under the United Nations Guiding Principles on Business and Human Rights and based on the demands of society and the laws and regulations of each country, we are promoting the establishment of an internal system to fulfill our responsibility to respect human rights as a company. Having received multiple proposals from CRT Japan, we are progressing with them one by one. In 2022, we (1) formulated the Kyowa Kirin Group Human Rights Policy and (2) held study sessions on business and human rights and workshops to identify human rights issues (human rights due diligence workshops) for the relevant departments.

#### Formulation of the Kyowa Kirin Group Human Rights Policy

The UN Guiding Principles on Business and Human Rights require companies to formulate a human rights response policy as their responsibility and to disseminate that policy not only to their employees but also to their various other stakeholders. Previously, Kyowa Kirin had been promoting human rights initiatives in accordance with the Kirin Group Human Rights Policy. In December

2022, however, the Kyowa Kirin Group formulated its own Kyowa Kirin Group Human Rights Policy in light of changes in social conditions and demands from society. In receipt of CRT Japan's cooperation in its formulation, we subjected the Policy to repeated text brush-ups and multiple reviews, for example in human rights due diligence workshops (described below), as well as by our parent Kirin Holdings Company, Limited, chief HR officers from overseas subsidiaries, and the Group CSR Committee. With this policy as our commitment, we will promote corporate activities that respect human rights.

### Holding of human rights due diligence workshop / Kyowa Kirin initiatives designed to identify human rights issues

In August 2022, we held an online Human Rights Due Diligence Workshop for the purposes of: (1) Understanding the current situation and acquiring knowledge about business and human rights; (2) Identifying the human rights issues faced by Kyowa Kirin; and (3) Reviewing the above-mentioned Kyowa Kirin Group Human Rights Policy. (Participating departments: Strategy Division, Production Division, R&D Division, Pharmacovigilance Division, SCM Department, Corporate Communications Department, CSR Management Department, Procurement Department, HR Department).

At the workshop, opinions were exchanged on, for example, current initiatives, potential human rights themes, rights-holders, developments in the value chain (to what stages in the value chain do human rights issues apply).

With regard to the human rights issues extracted at the workshop, we confirmed the status of awareness and efforts to address issues in all Kyowa Kirin departments while the working team prioritized the human rights issues that need to be addressed and promoted initiatives. We also identified high-priority issues not only by our own evaluation but also by factoring in the level of interest from society (evaluations by specialized institutions).

#### Kyowa Kirin Group Human Rights Policy

Kyowa Kirin Group conducts its own research with high technology and unique points of view, develops and provides products in "pharmaceutical" business area, and is working on approaches to sustainable society through autonomous and responsible actions in fair and open competition. In order to realize our business philosophy "to contribute to the health and well-being of people around the world," the Group strives to continuously create life-changing value based on the Group's Core Values, having passion for innovation, teamwork of diverse brilliant personalities, and strong ethical views.



Kyowa Kirin Group Human Rights Policy

https://www.kyowakirin.com/sustainability/human\_rights\_labor\_ practices/human\_rights/index.html

# Message from Officer in Charge

#### Wataru Murata

Chief People Officer (CPO) & Global Human Resources Head Senior Managing Executive Officer, Director, Human Resources Department Kyowa Kirin Co., Ltd.



The Guiding Principles on Business and Human Rights formulated by the United Nations call for "respect for human rights" as a corporate responsibility. Moving ahead with its business to achieve its vision for 2030, the Kyowa Kirin Group must consider measures to prevent, mitigate, and remedy adverse impacts on human rights. Having formed a cross-organizational working team and received advice from outside experts while deepening our understanding of the wide range of human rights issues required of global companies, we formulated the Kyowa Kirin Group Human Rights Policy.

Positioned as the superordinate policy for all documents and norms concerning efforts to respect human rights in the Group's business activities, this policy is applicable to all the Group's officers and employees. We will also request compliance with this policy from all business partners related to the business, products and services of the Group. In addition to continuing to implement human rights due diligence based on this policy to limit adverse impacts on human rights, we will contribute to ensuring people's right to live a rich and healthy life and to live happily by engaging in the creation of positive human rights impacts.

As a Global Specialty Pharmaceutical Company (GSP), we are elevating our human rights initiatives to a global agenda while continuing to cherish consideration for those close to us whom we have always valued. We are working to create workplaces and a society free from discrimination and harassment by increasing opportunities for dialogue with each and every employee to make human rights issues their own.

By promoting such efforts, we will realize the creation of workplaces where not only our company but also our colleagues from outside the company can work in safe, secure, and healthy environments. Through Kyowa Kirin Group's growth and the achievement of our vision, we will contribute to the health and well-being of people around the world.

KYOWA KIRIN Annual Report 2022

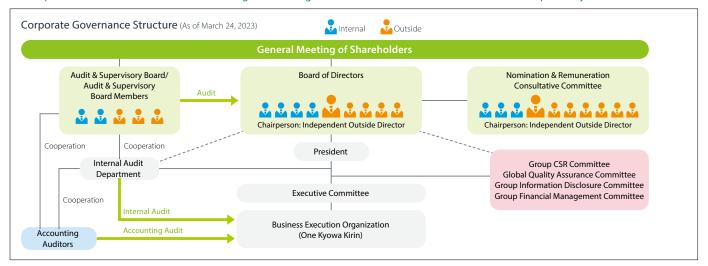
# Governance

#### **Basic Policy on Corporate Governance**

Based on our philosophy that states that "The Kyowa Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies," on its values as well as on its vision and medium-term business plans, Kyowa Kirin, as a company responsible for delivering social infrastructure, will work on the enhancement of its corporate governance. The latter will be achieved not only by ensuring transparency and fairness in decision-making to achieve sustainable growth and increase corporate value over the medium to long term but also by establishing the structures necessary for speedy and strong decision-making and the execution of management duties, and for appropriate monitoring and supervisory functions.

The Company is therefore implementing all the principles of the Corporate Governance Code.

#### A Transparent Governance Structure That Leverages the Strengths of Outside Directors and Outside Audit & Supervisory Board Members



## Outside Directors and Audit & Supervisory Board Members Independence Criteria

In connection with the requirements designed to ensure the independence of outside directors and Audit & Supervisory Board members and thereby to ensure the transparency and objectivity of their governance function as they exert proper management oversight, Kyowa Kirin has put in place and made public details of its own unique set of selection standards. To ensure independence in relation to our Group, the Company had referred to the provisions for independent outside directors and Audit & Supervisory Board members stipulated in the enforcement rules for securities listing regulations of the Tokyo Stock Exchange as well as the independent directors' nomination reference model created by the Japan Association of Corporate Directors in 2011.

## Functions of Outside Directors/ Audit & Supervisory Board Members

In order to improve the fairness and transparency of its corporate governance while ensuring the Group's sustainable growth and boosting corporate value over the medium to long term, Kyowa Kirin appoints a majority (five out of nine

directors) of independent outside directors who meet the Company's criteria for independence as outside directors.

Our outside directors have various backgrounds, expertise, and experience. They apply their wealth of experience and knowledge to the management of the Company, supervising the Company's management from an objective and fair perspective. The Company's outside Audit & Supervisory Board members apply their expertise, knowledge, and experience to auditing the Company's management from an objective and neutral standpoint, ensuring the reliability and soundness of our management.

#### **Directors and Board of Directors**

Taking into account its fiduciary duties and accountability to shareholders, the Board of Directors works diligently to realize the Company's corporate philosophy, and secure the Group's sustainable growth while increasing corporate value over the medium to long term, by establishing effective and efficient corporate governance. The Board of Directors makes decisions on significant matters pertaining to business execution by the Group. This includes the long-term

management vision, medium-term and annual business plans of the entire Group and key Group companies, as well as statutory matters. The Board of Directors is also responsible for supervising the execution of directors' duties and establishing an adequate internal control system for the entire Group. In addition to items stipulated by law and the Articles of Incorporation, the Board of Directors stipulates matters to be resolved by the Board of Directors in the Regulations of the Board of Directors and delegates other authority related to business execution to the executive officers in charge of each business operation.

With respect to the Board's composition, the maximum number of directors is 10, in accordance with the Articles of Incorporation. Upon considering the skill set—that is, knowledge, experience, capabilities and insights—necessary to become a Global Specialty Pharmaceutical Company and ensuring diversity, we established a transparent governance system, which is well-balanced as a whole. In order to ensure the effectiveness of objective management oversight, independent directors who have been appointed to the Board from outside the Company are in the majority, and the position of Board Chair is assumed by Mr. Akira Morita, who is an independent outside director. Policies and procedures for the selection of director candidates are discussed by the Nomination & Remuneration Consultative Committee and decided by the Board of Directors.

As of March 24, 2023, the Company has nine directors (including five independent outside directors; seven of whom are male and two female). In principle, the Board of Directors meets once a month to make decisions on important matters such as management policies and to supervise business execution. In FY2022, the Board of Directors met 13 times, making decisions on important matters that included the Company's management policies and supervising the execution of duties by directors.

#### Audit & Supervisory Board Members and the Audit & **Supervisory Board**

As an independent body mandated by shareholders, the Audit & Supervisory Board and its members audit the directors as they carry out their duties as means to supervising and verifying the status of establishing sound management for the Group's sustainable growth and enhancement of corporate value over the medium to long term. Leveraging the ability of full-time members to gather information within the Group as well as their independence, Audit & Supervisory Board members actively express their opinions at Board of Directors' meetings. At the same time, Audit & Supervisory Board members also strive to put in place and improve the framework used to ensure the effectiveness of auditing by each member. Furthermore, in order to better provide information to outside directors, Audit & Supervisory Board members exchange opinions with outside directors, and provide information which they have obtained through their auditing activities.

The Audit & Supervisory Board comprises persons with appropriate knowledge of finance and accounting matters. In accordance with the Company's Articles of Incorporation, the Audit & Supervisory Board has at least three members, at least half of whom are outside Audit & Supervisory Board members.

As of March 24, 2023, the Company had five Audit & Supervisory Board members (including three Outside Audit & Supervisory Board members; three of whom are male and two female).

To identify gaps between expected roles and responsibilities of the Board of Directors set forth in the "Kyowa Kirin Corporate Governance Policy" and the actual state of the Board of Directors in 2021–2022, we conducted an evaluation on the effectiveness of the Board of Directors. With respect to the evaluation of the Board's effectiveness, from the perspective of ensuring the effectiveness of governance, we identified wide-ranging issues, not limited to operational issues of the Board of Directors.

#### 1. The evaluation method for Board effectiveness in 2022

Since 2020, when the current medium-term business plan was formulated, for the purpose of identifying issues from the mid- to long-term perspective, in addition to a survey, we have conducted interviews with some officers. This year, with the aim of gathering a wider range of opinions, we increased the number of people interviewed from last year and conducted interviews with representative directors and independent outside directors. Furthermore, taking into account the results of the survey and interviews, we organized a meeting where only independent officers exchange their opinions, followed by the exchange of opinions among all directors and Audit & Supervisory Board members; and then made an evaluation.

#### 2. Results from 2022 effectiveness evaluation

Based on the evaluation score, comments in the survey and interviews, external advisor's opinion, and exchange of opinions at the Board, we concluded that the effectiveness of the Board of Directors was secured. This year, as in the previous year, we set questions for the members of the Nomination & Remuneration Consultative Committee, an advisory body to the Board of Directors, and concluded that the appropriateness of access to information as well as agenda/ deliberation are ensured.



Corporate Governance Report https://ir.kyowakirin.com/en/management/governance.html

#### 3. Achievements in addressing issues identified in the 2021 evaluation

	Issues from 2021 evaluation	Achievement
•	Advancing discussion on capital strategy	We made regular reports on the long-term product portfolio and increased opportunities to discuss growth investment direction, etc. from a medium- to long-term perspective.
6	Discussion for further strengthening risk management	The Board shared information on risk management, including what was implemented, the current risk management structure and issues, and the future plans, and had more opportunities to discuss matters from a medium- to long-term perspective.
•	Advancing discussion on sustainability	Under the theme of updating non-financial KPIs and materiality, the Board had more opportunities to discuss priorities, relationship with the business strategy, etc. We arranged opportunities that enabled the regular progress monitoring of individual sustainability-related activities and exchanges of opinions.
4	Discussion of diversity on the Board of Directors, etc.	We increased opportunities for the Nomination & Remuneration Consultative Committee to discuss the Board composition and required skills for a Global Specialty Pharmaceutical Company. We arranged opportunities for the Committee to report such discussions to the Board of Directors, and opportunities for the Board to discuss the matters.
•	Further improving operation of the Board of Directors to increase its effectiveness	The Board of Directors appropriately delegated its authority to business executives and strove to secure sufficient time for deliberations at Board meetings on important matters including various strategies.  We arranged opportunities outside the boardroom to exchange opinions, thus increasing opportunities for discussions with the business executives.

#### 4. FY2022 issues and FY2023 initiatives

Based on the evaluation results of the Board's effectiveness, we plan to implement the following measures for improvement in 2023:

	FY2022 issue	Initiatives
1	Further deepening of discussions on growth investments, etc. for mediumto long-term growth strategies	Continuing from FY2022, further deepening of discussions on capital policy, medium- to long-term growth strategy, policy for effective use of capital, review of growth investment policy in response to changes in the environment, etc.  Increase in opportunities to discuss the state of progress of strategies against the Medium Term Business Plan
2	Deepening Board of Directors' involvement to further strengthen risk management	Continuing from FY2022, with regard to risk recognition in view of medium- to long-term environmental changes, the creation of opportunities for the Board of Directors to be more deeply involved, such as intensive discussions by Board of Directors' members and the selection of the major risks across the Group
3	Discussions relating to the ideal global governance system	Creation of opportunities for discussion on governance methods to realize where the Company wants to be (GSP)
4	Further improvement of Board of Directors' operations to improve its effectiveness	Continuing from FY2022, ensuring of sufficient time for deliberations on important matters; increased opportunities for reports from departments in charge

KYOWA KIRIN Annual Report 2022

# **Management Team**

## Board Members with a Wide Array of Skills

The Board of Directors comprises diverse individuals with various skills (knowledge, experience, etc.). This is to enable the Board of Directors to fulfill its decision-making and management oversight functions appropriately and to enhance the transparency of our governance structure.

				Nomination &					Profession	onal skills				
	Name	Outside Independent	Board Chair	Remuneration Consultative Committee	Corporate management/ Business strategy	Global business	Finance, accounting and banking	Legal, governmental affairs and compliance	HR and labor	Healthcare	R&D	Production and SCM	IT/DX	Sustainability
	Masashi Miyamoto			•	•	•		•		•	•			
	Yutaka Osawa			•	•			•		•	•	•		
	Takeyoshi Yamashita			•	•	•		•		•	•		•	•
	Takeshi Minakata				•	•				•		•		
irecto	Akira Morita	•	•	•				•		•			•	
l S	Yuko Haga	•		•	•	•				•				
	Takashi Oyamada	•		Chairperson	•	•	•		•					
	Yoshihisa Suzuki	•		•	•	•					•	•	•	
	Rumiko Nakata	•		•					•	•				
7	Hiroshi Komatsu				•	•	•			•				
Board	Masaki Ueno					•	•	•						
d Members	Tomomi Yatsu	•		•			•	•						
	Mayumi Tamura	•		•	•	•	•							
	Toru Ishikura									•	•	•		•

#### Initiatives to Strengthen Governance of Executive Organization

- Established One Kyowa Kirin, a matrix management system comprising a four-unit regional dimension, a functional dimension, and a
- To strengthen the regional executive oversight function, boards of directors have been established at overseas regional operating
- · Appointment of at least two non-executive directors who possess experience in global pharmaceutical business as directors of each overseas region
- · Initiated direct exchanges of opinions between regional non-executive directors, Kyowa Kirin directors, and outside directors





(Baver, Vifor, Galenica,

Verona, Synlab)

**EMEA** 

Kyowa Kirin International plc.





(GSK, Celgine, Sanofi)



(Pfizer, AstraZeneca.

Schering-Plough, Bayer)



(Novartis, GSK,

Sterling Winthrop)



(Genzyme, Moderna,

Akcea)



Garv Zieziula (Merck, BMS, Roche, AMAG Pharmaceuticals)

**ASIA PACIFIC** Kyowa Kirin Asia Pacific Pte. Ltd.



# Expansion of CxO system Driving growth as a Japan-based GSP, the following CxOs have been appointed to assist the CEO and be responsible for improving the speed of decision-making and the strengthening of the execution system. Yutaka Osawa Takeyoshi Yamashita Masashi Miyamoto Motohiko Kawaguchi Mullick CIRO Wataru Murata Yasuo Fujii CPO CSO

#### Internal Control

Based on the fundamental principles of the internal control system of its parent company, Kirin Holdings Company, Limited, the Company steadily maintains and operates internal control systems in line with Article 362, paragraph 4, item vi of the Companies Act: "The development of systems necessary to ensure that the execution of duties by directors complies with laws and regulations and the articles of incorporation, and other systems prescribed by the applicable Ordinance of the Ministry of Justice as systems necessary to ensure the properness of operations of a Stock Company." The status of the systems' maintenance and operation was reported and confirmed by the Board of Directors on January 24, 2023.

- 1. Compliance System
- 2. System of Information Preservation and Maintenance
- 3. System for Risk Management
- 4. Effective and Efficient Performance System
- System for reporting for execution of duties and other Group internal control system
- 6. Systems related to Audit & Supervisory Board members

#### Nomination & Remuneration Consultative Committee

The Company established the Nomination & Remuneration Consultative Committee as an advisory body to the Board of Directors. Its purpose is to supplement the functions of the Board of Directors and further enhance the transparency of our governance system. The Committee deliberates and decides on the Company's nomination and remuneration from an objective and fair perspective, and reports to the Board of Directors. The Nomination & Remuneration Consultative Committee consists of 10 members, of whom the majority (7) are independent directors. The chairperson of the Committee is selected from among the independent officers.

The Nomination & Remuneration Consultative Committee deliberates and decides on proposals for policies regarding: the appointment and removal of directors, executive officers, Audit & Supervisory Board members and candidates for these officers; appointment and removal of senior directors; duties of individual directors; the policy for determining the successor of the current CEO of the Group; candidates for presidents and other key positions at individual Group companies; remuneration systems, levels, and remuneration amounts for directors, executive officers, Audit & Supervisory Board members, and for presidents and other key positions at individual Group companies. After deliberating on and deciding these matters from an objective and fair perspective, the Committee presents proposals to the Board of Directors.

#### **CEO Succession Planning**

The Nomination & Remuneration Consultative Committee conducts ongoing discussions about the selection and development of individuals who, from the perspective of KKC, would be ideally qualified for the position of CEO and reports its findings to the Board of Directors. The discussion theme includes knowledge, skills and experience needed for the role of CEO, as well as the following ideal profile of CEO, for example:

- Deep understanding of and full commitment to the Company's philosophy and core values
- Strong sense of responsibility toward society (patients) and the Company (employees)
- Determination to create value for society and to change the Company for the better
- Competence to create a future vision for the Company and penetrate it beyond national borders

# Governance as a listed subsidiary

## Ensuring management independence

- The Integration Agreement clearly states that management independence is ensured, requiring reasonable efforts to maintain Kyowa Kirin as a listed company
- M&A decisions are made solely by the Company, without the need for prior consultation with the parent company
- In accordance with the Company's own investment policy, the interest rate on loans is determined based on reasonable judgment after considering market interest rates based on the loan period, and the loan period is shortened (in principle, one month)
- Developing systems that are compatible with the revised CG Code/new market requirements

#### Decision-making process that starts with protecting minority shareholders

- Ensuring that independent outside directors are in the majority
- Directors from the parent company do not participate in resolutions when they are special interested parties
- In the event that independent outside directors do not constitute the majority
  at the time of important transactions, etc. with the parent company, the Board
  of Directors shall establish, as an advisory body to the Board of Directors, a
  Conflicts of Interest Supervisory Committee for Intercompany Transactions,
  that will consist of independent outside directors to conduct deliberations
  and considerations, and report to the Board of Directors



#### Synergies with the Kirin Group

The Kirin Group aims to become one of the world's leading CSV companies by creating value in areas ranging from food to medicine. We are the only Kirin Group company whose core business is medicine.

We believe that the management resources of the Kirin Group are extremely useful for realizing our goal of creating life-changing value. The Kirin Group's knowledge and expertise contributes greatly to our business. In production management and engineering, it helps us establish our business

foundation. In environmental conservation and supply stability, it helps us fulfill our social responsibility.

We also believe that connecting the health science field, on which the Kirin Group focuses, and the medical field, in which we are involved, offers many opportunities for us to pursue our goal of going beyond pharmaceuticals to meet society's medical needs.

#### Solving Issues around Our Own Pharmaceutical Products

- ▶ Using accumulated data, patient insights, etc.
- ► Establishing a project team for new value creation & digital transformation

## Solving Issues through Group Synergies

- Leverage opportunities created by connecting our pharmaceuticals business with the Kirin Group's the health science field.
- Incorporate synergies into intra-group projects under individual contracts



improve patients'

quality of life

Create
life-changing
value beyond
pharmaceuticals

# Basic policy on remuneration of directors and Audit & Supervisory Board Members

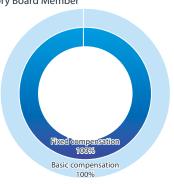
Remuneration for Directors and Audit & Supervisory Board members is designed to increase commitment to the Company's further sustainable growth and improvement in corporate value, to attract and retain suitable talent who aspire to help the Company make the leap forward to a Global Specialty Pharmaceutical Company, to motivate executives to contribute to the Company by fulfilling their respective duties as directors or Audit & Supervisory Board members and determined through a transparent and appropriate process by adopting an objective viewpoint

In order to realize this basic policy, investigations and deliberations on executives' remuneration are conducted by the Nomination & Remuneration Consultative Committee, which consists of a majority of outside directors and outside Audit & Supervisory Board members, and is chaired by an outside Director.

# Ratio of Fixed Compensation and Variable Compensation







#### Claw back provision

Kyowa Kirin has established a claw back provision that allows the Nomination & Remuneration Consultative Committee to request the return of executive director and executive officer remuneration in the case of such events as illegal acts or violations of laws and regulations.

#### **Executive Remuneration**

			Variable compensation	١				
	Fixed compensation	Short-term incentive compensation (variable)	Medium- and long-term incentive compensation (variable)					
Туре	¥	Annual Performance-Linked	Ç∰ÇÎ Share-based remuneration					
	Basic Remuneration	Bonus	Share-based remuneration with restrictions on transfer	Performance-linked, share-based remuneration (Performance Share Unit)				
Payment eligibility	Directors and Audit & Supervisory Board members	Executive directors	Ex	Executive directors				
Purpose (Incentive for Officers)	Provide remuneration commen- surate with the role and responsibilities of each officer, referencing peer company size and remuneration levels	Raise awareness toward the need to contribute to improving business performance each fiscal year	Have Directors of the Board of the Company share in the benefits and risks of share price fluctuations with the shareholders, and provide greater incentive to the directors of the Board of the Company to elevate the share price and boost corporate value	Provide incentives for achieving the Medium Term Business Plan and the sustainable enhancement of corporate value by clarifying the link between remuneration, corporate performance and the Company's stock value, and promote further value sharing with shareholders				
Payment method	Cash	Cash	Stock	Stock and cash (in roughly equal amounts)				
Payment schedule	Monthly	A certain time each year (generally April)	A certain time	e each year (generally April)				
Evaluation indicator	_	Annual targets (revenue and net profit)	_	ROE / Revenue CAGR / core operating profit ratio				
Factor for determining the amount of remuneration	Role and responsibilities	Achievement of targets (Payment rate of 0% to 200%)	Base amount determined based on basic remuneration and stock price	Base amount determined based on basic remuneration, stocl price, and achievement of targets for three consecutive fiscal years (Variation rate of 0% to 150%)				
Approximate ratio (when	1		Around 1 to 1.2					
performance targets are achieved)	1	Around 0.4 to 0.5	A	round 0.6 to 0.8				

# Remuneration\*1 by position (FY2022)

		Breakdown of Remuneration (Millions of yen)							
Position	Total Remuneration (Millions of yen)	Basic Remuneration	Annual Performance-Eligible Officers Linked Bonus*2	Share-based remuneration with restrictions on transfer*2,3	Performance-linked share-based remuneration*2	Number of Eligible Officers			
Directors (Excluding outside directors)	383	183	94	64	42	3			
Audit & Supervisory Board members (Excluding outside Audit & Supervisory Board members)	29	29	_	_	_	1			
Outside directors	84	84	_	_	_	5			
Outside Audit & Supervisory Board members	62	62	_	_	_	4			

- \*1 The above information includes one outside Audit & Supervisory Board member who retired at the end of the Ordinary General Meeting of Shareholders held last year.
- \*2 The amounts of performance-linked annual bonuses, share-based remuneration with restriction on transfer, and performance-linked share-based remuneration were recorded as expenses for the current fiscal year. As for the performance-linked share-based remuneration, both cash and non-cash portions are to be paid/provided after the relevant performance evaluation period.
- \*3 The number of restricted shares provided to executive directors in the current fiscal year was 20,397 shares (the paid-in amount per share was 3,140 yen, which is the closing price on March 24, 2022).
- \*4 The above information does not include two Directors and one Audit & Supervisory Board member who have served without pay.

# **Compliance**

Compliance at Kyowa Kirin refers to acting ethically and with integrity in a socially responsible manner, with respect to all business activities of our Group.

#### Code of Conduct and Group Policies

The Kyowa Kirin Group Code of Conduct sets forth the actions that should be taken by everyone working in the Kyowa Kirin Group. The Code of Conduct is translated into local languages and disseminated to Group companies all around the world. All executives and employees of the Group pledge to comply with the Code of Conduct. Their understanding and compliance is monitored through employee awareness surveys and other means. We also encourage all partners in our supply chain to comply with the Code of Conduct. In addition, action policies related to individual business areas have been established as the Kyowa Kirin Group Policies.

The Code of Conduct and the Group Policies are continuously reviewed in light of changes in the external environment, such as laws and regulations, as well as changes in the internal environment and any revisions must be approved by the Board of Directors.

Kyowa Kirin Group – Outline of the Relationship between the Management Philosophy and KKC Group Policies

https://www.kyowakirin.com/sustainability/index.html

#### Governance

Under the supervision of the Representative Director and Executive Vice President, the Kyowa Kirin Group has appointed a Global CSR Head and established the CSR Management Department to assist the Head in their duties. The Global CSR Head and the CSR Management Department take the leading role in compliance, formulating and implementing compliance measures on a global and regional basis in collaboration with the Regional CSR Heads\*1, who are responsible for compliance in the four regions of Japan, North America, EMEA, and APAC.

The Kyowa Kirin Group has established regional CSR committees in the four regions to discuss compliance-related activities. These committees are held on a quarterly basis to discuss the status of activities and issues that are global or specific to each region\*2. In addition, a Group CSR Committee meeting, in which all function heads and the compliance managers from each region participate, is held twice a year to deliberate on compliance strategies and action plans for the entire Group, and to report on the progress of activities during the year. The Group CSR Committee is chaired by the Company's Representative Director and Executive Vice President. Important matters discussed in these committee meetings are reported to the Board of Directors.

#### **Education and Training**

Kyowa Kirin conducts various training programs aimed at fostering a corporate culture that enables executives and employees to adapt flexibly to changes in social norms. These include group training sessions and e-learning. In 2022, individual self study and group training on integrity were conducted for all executives and employees, including contract and temporary employees (4,844 people). Other training sessions were held on topics such as anti-bribery and anti-corruption, personal information protection, and promotional codes.

Every year, we also conduct a Kirin Group-wide compliance and human rights awareness survey (4,483 people in Japan responded as the Kyowa Kirin Group in 2022) and a Kyowa Kirin Global Engagement and Motivation Survey (5,783 people in Japan and overseas responded in 2022). The results of the survey help to identify changes in employee awareness and issues that need to be addressed, and are utilized in formulating the Group's initiatives.

#### Whistleblowing System

The Kyowa Kirin Group has put in place the Compliance Line, whistleblowing system, in order to prevent, detect at an early stage and correct acts that are against the Kyowa Kirin Group Code of Conduct, as well as acts that seriously damage the brand value of the Kyowa Kirin Group. We have introduced a process under which reports concerning directors are passed directly to company auditors. On top of the strict adherence to confidentiality and a rule that those who report will not be subjected to any retaliation, steps have been taken to establish an internal and external point of contact for reporting that can be accessed by telephone, electronic and postal mail as well as online tools. Reports can also be filed anonymously. In this manner, every effort is being made to create a simple and easy reporting environment. Moreover, messages from the CEO on such topics as the importance of the Compliance Line, confidentiality and nonretaliation are sent out on a continuous basis. The point here is to ensure that employees gain a better understanding of the system through group training and e-learning and while maintaining a continuous awareness toward each point of contact for reporting. Details of the Compliance Line are readily available on the Company's website and posters displayed throughout the workplace. In 2022, the Compliance Line received a total of 26 reports in Japan and overseas. In response to Japan's revised Whistleblower Protection Act, which came into effect from June 2022, we are confirming the design and operation of our system, revising internal rules, and making continuous improvements.

Overseas subsidiaries operate local whistleblowing systems in each region. We also established and operate a global line that enables overseas subsidiaries' employees to report directly to the Group's head office in Japan in their local language.

#### **Future Initiatives**

Kyowa Kirin is strengthening its global compliance management system with the aim of becoming a global specialty pharmaceutical company. In all areas of our compliance functions (organizational structure, human resources, policies and procedures, education and training, and risk management) and of our Group Policies, the entire Group will work together to strengthen compliance in accordance with a roadmap created with the aim of establishing the ideal compliance management system for our Group.

#### Kyowa Kirin Group Code of Conduct (Summary)

#### Introduction

- 1. Purpose of this Code of Conduct
- 2. Scope of this Code of Conduct
- 3. Role of Officers
- 4. Role of Managers
- 5. Raising guestions and concerns
- 6. Prohibition of retaliation
- 7. Response to non-compliant actions with this Code of Conduct

Chapter 1. Relationship with Society

Chapter 2. Relationship with Employees

Chapter 3. Compliance with Rules

Chapter 4. Respect for Human Rights

Chapter 5. Environmental Preservation

Chapter 6. Information Management

Chapter 7. Risk Management

<sup>\*1</sup> Currently, the Global CSR Head also serves as the Regional CSR Head for Japan.

<sup>\*2</sup> In Japan, held semiannually. Important issues discussed at each Regional CSR Committee are compiled by the secretariat and reported to the Regional CSR Committee held in Japan.

Crisis Management System

# **Risk Management**

To earn the trust of its customers and society, the Kyowa Kirin Group identifies and responds appropriately to the various risks that arise in conducting its business activities.

#### Kyowa Kirin Group Risk Management

The Kyowa Kirin Group recognizes that the realization of its vision, based on its corporate philosophy will lead to sustainable growth and the enhancement of corporate value over the medium to long term. In order to safeguard its corporate value from threats, the Group engages in enterprise risk management. Through various opportunities and the taking of appropriate risks, our risk management endeavors also help create new corporate value.

#### Risk Management System

In the Kyowa Kirin Group, business functions identify risks based on changes in their internal and external environments and analyze the degree of impact of identified risks on management and the likelihood of their occurrence. After discussing and adjusting the analysis results while conversing with business functions concerning internal and external environmental changes and risk trends, the CSR Committee secretariat organizes and assesses risks by category, and identifies the principal risks. In addition to deliberating on the

appropriateness of identifying principal risks, CSR Committees monitor measures aimed at mitigating risks as well as progress while organizing and supervising the risk management of business functions. Moreover, the Group CSR Committee meets twice a year to deliberate on the Group's overall risk management strategy and action plan and monitors the status of activities during the year. Details of principal risk mitigation measures and the monitoring results discussed by the Committee are reported to the Board of Directors.

The Kyowa Kirin Group is also moving forward with the digitalization of our risk management system, having introduced an IT system for centrally managing the risks of the entire group in a database. After business functions register risk ledgers and incident information in the database, the information is shared using a workflow with divisions that support, advise, and monitor risks from specialized and company-wide risk standpoints. This enables visualization of critical risks on a risk map. In this way we are working to develop a system that enables the effective and efficient monitoring of risks.

#### Crisis Management System

We define "crises" as situations that may have a profound impact on our business and require a rapid response among those that inhibit the achievement of our management goals. In addition, we define "crisis management" as activities that minimize the impact on our business when risks evolve into crises. In the Kyowa Kirin Group, crisis management is executed autonomously by area task forces in three layers—global, regional, and local—and the Area Crisis Management Team that responds using specialized expertise. In the event that a global response is required, each crisis management team will work together to build a system to quickly reduce any impact. In addition, we repeatedly conduct global crisis BCP exercises (cyberattacks, human rights violations, pandemics, natural disasters, stable supply, etc.), which connect each region, including Japan, with our global headquarters, and work to strengthen our crisis response and business continuity systems based on worst-case scenarios. Through these exercises, we improve our response capabilities, review our risk assessment and mitigation measures, and monitor to detect any signs of risk. In this way, we aim to create a resilient organization that is able to adapt flexibly to difficult situations.



- \*1 Other regions' reports collated and presented in Japan.
- \*2 EMEA stands for Europe, Middle East and Africa







Representative Director of the Board, President and Chief Executive Officer

Masashi Miyamoto, Ph.D.

Apr. 1985 Joined Kirin Brewery Company, Limited (presently Kirin Holdings Company, Limited) Apr. 2011 Director, Regulatory Affairs Department, Pharmacovioilance and Quality Assurance

Division, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)

Mar. 2012 Executive Offices, Director, Regulatory Affairs Department, Pharmacovigilance and Quality Assurance Division, Kyowa Hakko Kirin Co, Ltd.
Jul. 2014 Executive Offices, Director, Strategic Product Portfolio Department and Regulatory Affairs Department, Pharmacovigilance and Quality Assurance Division, Kyowa Hakko Kirin

Apr. 2015 Executive Officer, Director, Strategic Product Portfolio Department, Kyowa Hakko Kirin

Mar. 2017 Director of the Board, Managing Executive Officer, Strategic Product Portfolio Department, Kyowa Hakko Kirin Co. Ltd. Apr. 2017 Director of the Board, Managing Executive Officer, Director, Corporate Strategy & Planning

Department, Kyowa Hakko Kirin Co., Ltd.

Mar. 2018 Representative Director of the Board, President, Kyowa Hakko Kirin Co., Ltd. (to present)

The Company has judged that Dr. Masashi Miyamoto is the right person to perform the deci-The Company has judged that U.C. Massani Miyalmoto is the right person to perform the deci-sion-making role on material matters of management and supervising the execution of operations as Representative Director of the Board, using his extensive experience and high level of insight regarding overall business management, to push forward various measures for CSV management and for making a leap forward to become a global specialty pharmaceutical company with his strong leadership, and to promote sustainable growth as well as efforts aimed at enhancing the corporate



Director of the Board Takeshi Minakata

Apr. 1984 Joined Kirin Brewery Company, Limited (presently Kirin Holdings Company, Limited)

Mar. 2007 Deputy General Manager, Toride Plant, Kirin Brewery Company Limited
Mar. 2009 Deputy General Manager, Production Control Department of Production Division, Kirin Brewery Company, Limited
Oct. 2010 Kirin Liaison Technical Director, Lion Nathan National Foods Pty Ltd (presently Lion Pty Ltd)

Mar. 2012 General Manager, Corporate Planning Dept., Kirin Brewery Company, Limited
Jan. 2013 Executive Officer, General Manager, Corporate Planning Department, Kirin Company,

Limited (presently Kirin Holdings Company, Limited)
Executive Officer, General Manager, Planning Dept., Kirin Brewery Company, Limited

Mar. 2015 Senior Executive Officer, Director, Corporate Strategy, Kirin Holdings Company, Limited Senior Executive Officer, General Manager, Corporate Planning Department, Kirin Company, Limited

Apr. 2016 Director and President of Myanmar Brewery Limited

Senior Executive Officer, Kirin Holdings Company, Limited Mar. 2018 President and CEO, KYOWA HAKKO BIO CO. LTD.

**TOPICS FOR** 

Mar. 2020 President and CEO, KYOWA HAKKO BIO CO. LTD. Senior Executive Officer, Kirin Holdings Company, Limited

Jan. 2022 Senior Executive Officer, in charge of Health Business Strategy, Kirin Holdings Company Limited

Oct. 1993 Professor, Faculty of Law and Economics, Chiba University
Apr. 1994 Professor, The University of Tokyo Graduate Schools for Law and Politics

Apr. 2004 Dean, Professor, Graduate School of Public Policy, The University of Tokyo
Jul. 2008 Director, Policy Alternatives Research Institute, The University of Tokyo

Jun. 2012 Emeritus Professor, The University of Tokyo (to present)

Apr. 2017 Professor, Department of Policy Studies, Tsuda University Visiting Professor, Mie University Graduate School of Medicine

Apr. 2012 Professor, Department of Political Studies, Faculty of Law, Gakushuin University

May 2013 Chair of the Board, Japan Usability Medical Information Promote Conference

Apr. 2018 Director-General, Research Institute of Science and Technology for Society, Japan Science & Technology Agency

Apr. 2014 Director-General, National Institute of Population and Social Security Research
Aug. 2014 Adjunct Professor, National Graduate Institute for Policy Studies

Mar. 2022 Director of the Board, Kyowa Kirin Co., Ltd. (to present)
Director of the Board, Senior Executive Officer, in charge of Health Business Strategy, Kirin Holdings Company, Limited (to present)

#### Reasons for Selection

The Company has judged that Mr. Takeshi Minakata is the right person to perform the decisionmaking role on material matters of management and supervising the execution of operations as Director of the Board, using his extensive experience and high level of insight regarding overall business management. He is expected to promote tight-knit cooperation with Kirin Group companies—which have diverse business platforms—with the aim of providing solutions that respond to various medical needs to facilitate people's health and well-being.

Apr. 2011 Chairman, Central Social Insurance Medical Council, Ministry of Health, Labour and Welfare

Outside Member, Administrative Council, The University of Tokyo (to present)

Mar. 2019 Outside Director of the Board, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)

Apr. 2019 Visiting Professor, Kanagawa University of Human Services (to present)
Jul. 2020 Representative Director, Next Generation Fundamental Policy Research Institute (to present)

May 2022 Data Health Operations Advisor, Health Insurance Claims Review & Reimbursement



Director of the Board

Takashi Ovamada Apr. 1979 Joined The Mitsubishi Bank, Limited (presently MUFG Bank, Ltd.)

Jan. 2006 Executive Officer, The Bank of Tokyo Mitsubishi UFJ, Ltd. (presently MUFG Bank, Ltd.)
Jun. 2009 Managing Director, The Bank of Tokyo Mitsubishi UFJ, Ltd.

KYOWA KIRIN Annual Report 2022

Member of the Board of Directors, Mitsubishi UFJ Financial Group, Inc.
May 2012 Managing Executive Officer, The Bank of Tokyo-Mitsubishi UFJ, Ltd.
May 2013 Senior Managing Executive Officer, The Bank of Tokyo-Mitsubishi UFJ, Ltd.

Jun. 2014 Representative Director, Deputy President, The Bank of Tokyo-Mitsubishi UFJ, Ltd.
Jun. 2015 Member of the Board of Directors, Representative Corporate Executive,
Deputy President and Group COO, Mitsubishi UFJ Financial Group, Inc.

Apr. 2016 Representative Director, President & CEO, The Bank of Tokyo-Mitsubishi UFJ, Ltd. Member of the Board of Directors Mitsubishi LIEI Financial Group Inc.

Jun. 2017 Senior Advisor, The Bank of Tokyo-Mitsubishi UFJ, Ltd. (to present)

Jun. 2018 Director and Vice Chair, The Japan Institute of International Affairs (to present) Dec. 2018 Outside Director, Mitsubishi Research Institute DCS Co., Ltd. (to present)

Jun. 2019 Outside Director, Mitsubishi Electric Corporation (to present)

Jun. 2019 Outside Director, Isetan Mitsukoshi Holdings Ltd. (to present)

Mar. 2021 Outside Director of the Board, Kyowa Kirin Co., Ltd. (to present)

## Reasons for Selection

Mr. Takashi Oyamada possesses an extremely high-level of knowledge on management from his long experience as a banking executive, and he has knowledge and insight into a broad range of industries based on his abundant experience in the financial sector. On the basis not only of his specialist viewpoint of the financial sector but also of his experience as a manager, the Company has judged him to be the right person to make decisions on material matters and supervise the execution of operations.

Apr. 1979 Joined ITOCHU Corporation
Apr. 2003 General Manager, Aerospace, Space and Electronics Division, ITOCHU Corporation

Jun. 2003 Executive Officer, ITOCHU Corporation

Apr. 2006 Managing Executive Officer, ITOCHU Corporation Executive Vice President and



Representative Director of the Board, Executive Vice President Yutaka Osawa

Apr. 1984 Joined Kyowa Hakko Kogyo Co., Ltd. Apr. 2007 Director, Pharmaceutical Production Development Department, Kyowa Hakko Kogyo

Oct. 2008 Director, CMC Development Department, Development Division, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)

Apr. 2009 Director, Production Planning Department, Production Division, Kyowa Hakko Kirin

Mar. 2013 Executive Officer, Director, Production Planning Department, Production Division,

Kyowa Hakko Kirin Co., Ltd. Apr. 2014 Executive Officer, Head, Production Division, Kyowa Hakko Kirin Co., Ltd.

Mar. 2017 Managing Executive Officer, Head, Production Division, Kyowa Hakko Kirin Co., Ltd.
Mar. 2018 Director of the Board, Managing Executive Officer, Head, Production Division, Kyowa Hakko Kirin Co., Ltd.

Mar. 2019 Representative Director of the Board, Executive Vice President, Kyowa Hakko Kirin Co., Ltd.

#### Reasons for Selection

The Company has judged that Mr. Yutaka Osawa has profound knowledge and a high level of insight gained through his extensive experience regarding research and development, overseas development and manufacturing, and is the right person to fully perform the decision-making role on material matters of management and supervising the execution of operations as Director of the Board, and to firmly deliver the important mission of ensuring stable supply of high quality products as a pharmaceutical company



Director of the Board Outside

Akira Morita



#### Reasons for Selection

toward reinforcing the Company's governance function and in other ways by supervising the execution of operations from an independent standpoint and reflecting in the Company's



(to present)

Services (to present)

The Corns of Section 1 Section 1 The Corns of the Corns o management the perspective of protecting the rights of general shareholders.



Director of the Board

Yoshihisa Suzuki

#### Reasons for Selection

Mr. Yoshihisa Suzuki has experience in being in charge of divisions related to aviation and electronic information and in corporate management as Representative Director and President at ITOCHU Corporation. Moreover, he also possesses experience in corporate management as President of an overseas subsidiary of the said company and Representative Director and President of a manufacturing company, and has useful knowledge and insight based on his abundant experience in Japan and abroad. The Company has judged that he is the right person to make decisions on material matters and supervise the execution of operations, and accordingly selected him as a candidate for outside director of the Board. He also has experience in activities in the business community including KEIDANREN (Japan Business Federation). The Company expects that he will provide supervision the Company's management from an independent standpoint based on his experience gained as a corporate manager and through activities in the business community.

Jun. 2012 President and CLC), JAMCO Corporation
Jun. 2016 Senior Managing Executive Officer, Member of the Board, ITOCHU Corporation
Apr. 2018 President and Chief Operating Officer (COO), Member of the Board, ITOCHU Corporation
Apr. 2020 President and Chief Operating Officer (COO), Chief Digital Officer (CDO), and
Chief Information Officer (CIO), Member of the Board, ITOCHU Corporation



Director of the Board. Senior Managing **Executive Officer** Takeyoshi

Yamashita,

Ph.D.

Apr. 1987 Joined Kirin Brewery Company, Limited (presently Kirin Holdings Company, Limited)

Apr. 2010 Director, Innovative Drug Discovery Laboratories, Research Division, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)

Apr. 2012 Director, Research Planning Department, Research Division, Kyowa Hakko Kirin Co., Ltd.

Apr. 2014 Director, Research Core Function Laboratories, Research Functions Unit, R&D Division, Kyowa Hakko Kirin Co., Ltd.

Apr. 2015 Director, Regulatory Affairs Department, Pharmacovigilance and Quality Assurance Division, Kyowa Hakko Kirin Co., Ltd. Mar. 2017 Executive Officer, Director, Regulatory Affairs Department, Pharmacovigilance and Quality

Assurance Division, Kyowa Hakko Kirin Co., Ltd. Mar. 2019 Executive Officer, Director, Corporate Strategy & Planning Department, Kyowa Hakko

Kirin Co. Ltd. Mar. 2021 Managing Executive Officer, Director, Corporate Strategy & Planning Department, Kyowa Kirin Co. Ltd.

Apr. 2022 Managing Executive Officer, Vice President Head, Strategy Division, Kyowa Kirin Co., Ltd. Mar. 2023 Senior Managing Executive Officer, President Head, Strategy Division, Kyowa Kirin Co., Ltd. Apr. 2023 Director of the Board, Senior Managing Executive Officer (to present)

#### Reasons for Selection

Mr. Takeyoshi Yamashita possesses abundant experience in management strategy, product strategy, and regulatory affairs as well as a high level of foresight from a strategic point of view. The Company has judged him to be the right person to perform a decision-making role on material matters of management and a supervisory role in the execution of operations as Director of the Board and, as a driving force behind its leaps toward becoming a GSP company, to be capable of promoting the development of the Company's global management system in an expansive manner.



Director of the Board

Yuko Haga, Ph.D.

Apr. 1989 Senior Consultant, Tokyo Office, Price Waterhouse Consultants Apr. 1991 Representative, Haga Management Consulting Office (to present)

Jun 2000 Director Link World Co. Ltd. Feb. 2010 Director, Social Welfare Corporation Fujikenikukai (to present)

Apr. 2010 Visiting Professor, Department of Policy Management, Faculty of Policy Management, Shobi University Apr. 2017 Associate Professor, Graduate School of Management, NUCB Business School
Mar. 2019 Outside Director of the Board, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co., Ltd.)

(to present)

Apr. 2020 Professor, Graduate School of Management, NUCB Business School (to present)

Jun. 2020 Outside Director, MinebeaMitsumi Inc. (to present)

#### Reasons for Selection

The Company has judged that Ms. Yuko Haga will utilize her wealth of experience in the fields of medical treatment, pursing care, and healthcare, gained from her wide-ranging activities as a management consultant, as well as her insight as a researcher in corporate strategy, and is the right person to contribute toward reinforcing the Company's governance function and in other ways by supervising the execution of operations from an independent standpoint and reflecting in the Company's management the perspective of protecting the rights of general shareholder



Rumiko Nakata

Apr. 1979 Joined Esso Sekiyu K.K. Apr. 1996 Center for Socio-Economic Research K.K.

Apr 2000 Joined Pfizer K K

Dec. 2011 Head of HR and Global Operations, Pfizer K.K.

CAO, ITOCHU International Inc.

Apr. 2007 President and CEO. ITOCHU International Inc.

Jun. 2011 Executive Vice President, JAMCO Corporation

Apr. 2021 Vice Chairman, Member of the Board, ITOCHU Corporation

Jun. 2022 Outside Director, OMRON Corporation (to present)

Mar. 2022 Outside Director of the Board, Kyowa Kirin Co., Ltd. (to present) Apr. 2022 Vice Chairman, ITOCHU Corporation (to present)

Jun 2012 President and CEO JAMCO Corporation

Mar. 2012 Corporate Officer, Pfizer K.K. Jan. 2014 Director of the Board, Corporate Officer, Pfizer K.K.

Mar. 2018 Executive Officer, in charge of Diversity & Inclusion, Mitsubishi Chemical Corporation
Apr. 2019 Managing Executive Officer, Supervising – Human Resources Department,

Mitsubishi Chemical Corporation Apr. 2020 Director of the Board, Managing Executive Officer, Supervising – Administration Department, Public Relations Department, Human Resources Department, Mitsubishi Chemical Corporation

Apr. 2022 Director of the Board, Mitsubishi Chemical Corporation

Mar 2023 Outside Director of the Board Kyowa Kirin Co. Ltd. (to present)

#### Reasons for Selection

Having consistently been in charge of human resource departments throughout her career. Ms. Rumiko Nakata possesses useful knowledge and insight regarding management based on her experience in promoting various personnel measures, such as diversity promotion and work style reform, as a director and executive officer. As she has also gained experience as a member of the Japan Association of Corporate Executives, the Company has judged her to be the right person to supervise the Company's management.

# **Audit & Supervisory Board Members Profiles/Executive Officers**



Audit & Supervisory Board Member Hiroshi Komatsu

Apr. 1986 Joined Kyowa Hakko Kogyo Co., Ltd.

Feb. 2009 CFO, Hematech, Inc.

Apr. 2012 Manager, Corporate Planning Department, Kyowa Hakko Kirin Co., Ltd. (presently Kyowa Kirin Co. Ltd.)

Apr. 2015 Deputy Director, General Affairs Department, Kyowa Hakko Kirin Co., Ltd. Apr. 2016 Deputy Director, General Affairs Department, and Leader, Corporate Secretariat Group, General Affairs Department, Kyowa Hakko Kirin Co., Ltd.

Mar. 2018 Audit & Supervisory Board Member (Full-time), Kyowa Hakko Kirin Co., Ltd. (to present)

The Company has judged that Mr. Hiroshi Komatsu has profound knowledge and insight gained through his broad range of experiences in accounting, finance, research and development, management of overseas subsidiaries, corporate planning and other areas as well as the ethical standards, fair and equal judgment required as an Audit & Supervisory Board member and is the right person to appropriately perform the duties as an Audit & Supervisory Board member of the Company Auditor by ensuring that the audit and supervisory functions are fully effective across a broad range



**Audit & Supervisory** Board Member

Tomomi Yatsu

Apr. 1983 Joined Tokyo Electron Ltd.

Oct. 1986 Joined Deloitte Touche Tohmatsu LLC

Sep. 1990 Registered as Certified Public Accountant

Oct. 2001 Joined New Tokyo International Law Office Admitted to Tokyo Bar Association

Jun. 2010 Outside Audit & Supervisory Board Member, Taiko Pharmaceutical Co.. Ltd.

Mar. 2012 Outside Audit & Supervisory Board Member, KOKUYO Co., Ltd.

Mar. 2015 Outside Audit & Supervisory Board Member, Yamaha Motor Co., Ltd Apr. 2015 Partner, TMI Associates

Jun 2016 Outside Director SMBC Nikko Securities Inc. (to present) Jun. 2017 Outside Audit & Supervisory Board Member, IHI Corporation

Mar. 2019 Outside Corporate Auditor, Kuraray Co., Ltd. (to present)
Mar. 2021 Outside Audit & Supervisory Board Member, Kyowa Kirin Co., Ltd. (to present)

Apr. 2022 Representative, Yatsu Law and Accounting Office (to present)

#### Reasons for Selection

Ms. Tomomi Yatsu is both a certified public accountant and an attorney at law. She also has an immense wealth of experience serving as outside audit & supervisory board member and outside director of corporations. The Company has deemed her to be an appropriate person capable of supervising the Company and expressing audit opinions from an independent perspective through her sophisticated knowledge and insight as an accounting and legal expert and in-depth knowledge and insight as an audit & supervisory board member of corporations.



Audit & Supervisory Board Member Toru Ishikura

Apr. 2020 Executive Officer, General Manager, Health Business Strategy Office, Corporate Strategy Department, Kirin Holdings Company, Limited Apr. 2022 Executive Officer, General Manager, Health Science Business Department, Health Science Business Division, Kirin Holdings Company, Limited

Apr. 1989 Joined Kirin Brewery Company, Limited (presently Kirin Holdings Company, Limited) Mar. 2015 General Manager, Technology Management Department, Research & Develop Division, Kirin Company, Limited (presently Kirin Holdings Company, Limited)

Mar. 2018 Executive Officer, General Manager, Research & Development Strategy Department,

Apr. 2019 Executive Officer, Vice President, Research & Development Division and General Manager

Research & Development Strategy Department, Research & Development Division,

Apr. 2015 General Manager, Research & Development Strategy Department, Research & Development Division, Kirin Company, Limited

Kirin Holdings Company, Limited
Mar. 2020 Director of the Board, KYOWA HAKKO BIO CO. LTD.

Research & Development Division, Kirin Company, Limited

Mar. 2023 Audit & Supervisory Board Member, Kyowa Kirin Co., Ltd. (to present)
Audit & Supervisory Board Member (Full-time), Kirin Holdings Company, Limited (to present)

#### Reasons for Selection

Having been involved in engineering and research and development in the Kirin Group, Mr Toru Ishikura possesses work experience and profound knowledge and insight with regard to overall Group management as well as experience of working in internal audit divisions. In Group companies, he assumed the position of General Manager of the Health Business Strategy Office in the Corporate Strategy Department in 2020 and of General Manager of the Health Science Business Department in 2022. Having successfully fulfilled those roles, the Company judges him to be someone who will be capable of appropriately performing duties in a wide range of fields as a member of the Company's



Audit & Supervisory Board Member Masaki Ueno

Apr. 1998 Joined Kirin Brewery Company, Limited (presently Kirin Holdings Company, Limited)
Mar. 2012 General Manager, Legal Department, Kirin Holdings Company, Limited Jan. 2013 General Manager, Legal Department, Kirin Company, Limited

Director of Group Legal, Kirin Holdings Company, Limited (presently Kirin Holdings Company, Limited)

Apr. 2015 Executive Officer, General Manager, Legal Department, Kirin Company, Limited,

Executive Officer, Director of Group Legal, Kirin Holdings Company, Limited

Apr. 2019 Executive Officer, General Manager, Legal Department, Kirin Holdings Company, Limited Mar. 2020 Outside Audit & Supervisory Board Member (Full-time), Kyowa Kirin Co., Ltd. (to present)

#### Reasons for Selection

The Company has judged that Mr. Masaki Ueno having long served in legal departments in the Kirin Group, he has a high level of insight and experience regarding corporate legal affairs including global M&A; and thus, together with his experience in the Corporate Strategy & Planning Department of Kirin Holdings Company, Limited, that he is a suitably qualified person with the ability of providing broad supervision of the Group and giving audit opinions based thereon.



Audit & Supervisory Board Member

Mayumi Tamura

Apr. 1983 Joined Sony Corporation (presently Sony Group Corporation)

Sep. 1991 Joined JOHNSON COMPANY, LIMITED Jul. 2002 Executive Officer, Johnson Diversey Co. Ltd. (presently CxS Corporation)

Dec. 2004 CFO, adidas Japan K.K.

Jun. 2007 Executive Officer, Senior Vice President and CFO, Seiyu KK (presently Seiyu GK)
May 2010 Executive Officer, SVP and CFO, Walmart Japan Holdings GK (presently Walmart Japan

Holdings KK) Executive Officer, SVP and CFO, Seiyu GK Jun. 2015 Outside Corporate Auditor, Honda Motor Co., Ltd.

Jun. 2017 Outside Director, Audit and Supervisory Committee Member, Honda Motor Co., Ltd. Outside Director, Hitachi High-Technologies Corporation (presently Hitachi High-Tech

Corporation) Jun. 2019 Outside Director, SHIMIZU CORPORATION (to present)

Mar. 2022 Outside Audit & Supervisory Board Member, Kyowa Kirin Co., Ltd. (to present)
Jun. 2022 Outside Director, LIXIL Corporation (to present)

#### Reasons for Selection

Ms. Mayumi Tamura has been active as Outside Audit & Supervisory Board member and outside director of companies, and also has experience in engaging in support for diversity and inclusion as a board member of an incorporated NPO. Furthermore, she possesses advance knowledge and experience gained by being in charge of finance/accounting and corporate planning at various global companies for many years, and in-depth insight as CFO. The Company has deemed her to be an appropriate person capable of supervising the Company and expressing audit opinions from an independent perspective based on such experience, knowledge and insight, and accordingly selected her as a candidate for outside Audit & Supervisory Board membe

## **Executive Officers**

Senior Managing Executive Officer Wataru Murata

Head of Human Resources Department

### Managing Executive Officers

#### Hiroshi Sonekawa

Head of Sales & Marketing Division

#### Motohiko Kawaguchi

Head of Finance Department

#### Abdul Mullick

Chief International Business Officer (CBIO)

#### Yasuo Fujii

Head of Strategy Division

## **Executive Officers**

#### Shin Inoue

Head of Kyushu Branch Sales Office. Sales & Marketing Division

#### Fumihiko Kanai

Responsible for ERP introduction, Strategy Division

#### Koichiro Ishimaru

Head of Corporate Social Responsibility Management Department

#### Yoshifumi Torii, Ph.D.

Head of R&D Division and Head of Development Unit

#### Hiroki Takamatsu

Head of Quality Assurance Division

#### **Tomohiro Sudo**

Head of Global Product Strategy Department, Strategy Division

#### Kenji Shibata, Ph.D.

Head of Internal Audit Department

#### Shoko Itagaki

Head of Corporate Planning Department, Strategy Division

# Toshiyuki Kurata

Head of Production Division

# Atsushi Matsumoto, Ph.D.

Head of Supply Chain Management Department

#### Yoshiko Mori

Head of Pharmacovigilance Division

#### Yuichi Kawasaki

Head of Product Strategy Department, Strategy Division

#### Koichi Nagano

Head of Tokyo Branch Sales Office. Sales & Marketing Division

#### Takeshi Matsushita

Head of Medical Affairs Department

# **Financial Information**

- 59 Eleven-Year Selected Financial Data
- 60 Management's Discussion & Analysis (MD&A)

We report on the financial condition and management measures of the company during the fiscal year. We also perform an assessment and analysis of corporate performance and refer to forecasts for the next fiscal year.

65 Risk Factors

Major risks concerning the performance, financial condition, etc. of the company, which may significantly affect the decisions of investors, are reported.

# WEB link

Key Financial Data

Cash Flow Data

Financial Summary

## Adoption of International Financial Reporting Standards

The Group has adopted the International Financial Reporting Standards ("IFRS") since FY2017 to enhance the international comparability of its financial reporting for the capital market, and unify the process of the Group's accounting. In addition, financial data for FY2016, the fiscal year prior to the adoption of IFRS, is reformulated and displayed in an IFRS format.

## Adoption of "core operating profit\*" (IFRS)

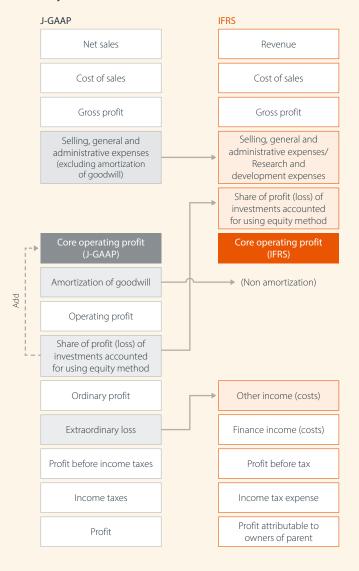
The Group has adopted "core operating profit" (IFRS) as an indicator showing recurring profitability from operating activities.

\* Gross profit – Selling, general and administrative expenses – Research and development expenses + Share of profit (loss) of investments accounted for using equity method

#### **Bio-Chemicals Business**

Following the conclusion of an agreement on February 5, 2019 in which Kyowa Kirin Co., Ltd. (the "Company") agreed to transfer 95% of the shares of its consolidated subsidiary Kyowa Hakko Bio Co., Ltd. to Kirin Holdings Company, Limited, the Bio-Chemicals business is categorized as a discontinued operation from FY2019. Accordingly, the consolidated financial statements for FY2018 have been restated to reflect the change, and from FY2019, the Group has only one reportable segment: the "Pharmaceuticals business."

# Major differences between IFRS and J-GAAP



# **Eleven-Year Selected Financial Data**

				IFRS					J-GA	AAP		IFRS
				(Millions of yen)					(Millions	of ven)		(Thousands of U.S. dollars*1)
For the Year:	2022/12	2021/12	2020/12	2019/12	2018/12	2017/12	2016/12	2015/12	2014/12	2013/12	2012/12	2022/12
Revenue*2	¥ 398,371	¥ 352,246	¥ 318,352	¥ 305,820	¥ 271,510	¥ 353,380	¥ 347,956	¥ 364,316	¥ 333,446	¥ 340,611	¥ 333,158	\$3,002,039
Gross profit*2	311,455	264,398	237,912	226,200	198.149	224,321	214,592	225,393	205,904	212,761	210.690	2,347,063
Selling, general and administrative expenses (including R&D expenses)*2	229,081	203,287	178,922	170,827	147,745	162,113	163,124	181,628	169,731	160,987	157,785	1,726,306
Core Operating Profit (J-GAAP: Operating profit)*2	86,697	65,685	59,955	59,353	50,306	57,731	39,116	43,765	36,173	51,773	52,905	653,332
Profit attributable to owners of parent	53,573	52,347	47,027	67,084	54,414	42,899	30,450	29,774	15,898	30,078	24,199	403,712
Capital expenditure and investments in intangible assets*2	30,984	22,335	34,782	22,586	13,489	20,714	33,270	20,039	29,487	35,183	27,808	233,489
Depreciation and amortization*2	18,476	19,498	20,466	18,797	16,243	22,032	23,784	23,126	23,885	21,592	20,904	139,235
R&D expenses*2	62,896	57,679	52,312	53,511	45,659	49,216	52,929	51,604	47,737	43,682	44,808	473,972
Cash Flows:	,	,	·		,	,	·	· · · · · · · · · · · · · · · · · · ·	·	,	· · · · · · · · · · · · · · · · · · ·	
Net cash provided by operating activities	¥ 48,672	¥ 86,548	¥ 39,502	¥ 53,655	¥ 56,181	¥ 64,902	¥ 66,881	¥ 66,526	¥ 19,377	¥ 56,884	¥ 59,134	\$ 366,786
Net cash provided by (used in) investing activities	(17,185)	(11,363)	252,559	(933)	(39,929)	(45,265)	(49,824)	(57,747)	16,805	(77,163)	(98,772)	(129,500
Net cash provided by (used in) financing activities	(29,032)	(28,446)	(26,003)	(47,371)	(16,501)	(18,287)	(13,871)	(14,060)	(37,184)	(12,579)	(19,189)	(218,779
Cash and cash equivalents at the end of the period	339,194	335,084	287,019	20,762	15,867	14,685	13,076	12,784	17,013	19,242	50,334	2,556,099
At Year-End:	,	,	,	·	,	,	,		·	,		
Total current assets	¥ 542,189	¥ 518,231	¥ 442,482	¥ 448,610	¥ 385,844	¥ 348,150	¥ 314,999	¥ 324,433	¥ 283,192	¥ 329,320	¥ 303,988	\$4,085,826
Total assets	939,881	921,872	801,290	784,453	741,982	708,295	683,801	720,764	719,135	719,257	679,342	7,082,749
Total current liabilities	109,825	109,129	80,749	87,530	80,459	78,409	88,072	84,823	85,182	85,076	85,774	827,622
Interest-bearing debt	21,639	20,371	17,842	17,185	2,527	2,814	7,000	4,840	4,868	6,207	5,699	163,066
Equity	762,826	737,162	698,396	678,250	649,621	616,028	577,036	614,858	605,368	595,415	555,898	5,748,501
Number of employees	5,982	5,752	5,423	5,267	7,242	7,532	7,465	7,435	7,424	7,152	7,243	_
Per Share Data:	-		<u> </u>	(Yen)					(Ye	n)		(U.S. dollars*1)
Profit attributable to owners of parent*3	¥ 99.68	¥ 97.43	¥ 87.56	¥ 124.57	¥ 99.40	¥ 78.38	¥ 55.65	¥ 54.40	¥ 29.05	¥ 54.95	¥ 44.12	\$ 0.751
Equity attributable to owners of parent	1,419.27	1,371.90	1,300.12	1,263.16	1,186.65	1,125.56	1,054.48	1,122.80	1,105.44	1,085.17	1,013.61	10.695
Cash dividends	51	46	44	42	35	27	25	25	25	25	20	0.384
Common Stock Price Range (Per share):												
High	¥ 3,515	¥ 4,240	¥ 3,060	¥ 2,594	¥ 2,478	¥ 2,227	¥ 2,098	¥ 2,321	¥ 1,510	¥ 1,256	¥ 970	\$ 26.49
Low	2,604	2,687	1,849	1,674	1,894	1,515	1,412	1,094	1,006	833	757	19.62
Stock Information (Thousands of shares):	-								-			
Number of common stock issued	540,000	540,000	540,000	540,000	576,484	576,484	576,483	576,483	576,483	576,483	576,483	_
Weighted average number of common stock issued	537,432	537,272	537,109	538,542	547,412	547,290	547,224	547,285	547,348	547,391	548,449	_
Financial Ratios:	-		. (	%, except EBITDA)					(%, except	t EBITDA)	-	
Return on assets (ROA)	5.8	6.1	5.9	8.8	7.5	6.2	4.4	4.1	2.2	4.3	3.6	_
Core operating return on assets (J-GAAP: Operating profit)*2	9.3	7.7	7.6	7.8	6.9	8.3	5.6	6.1	5.0	7.4	7.9	_
Return on equity attributable to owners of parent (ROE)	7.1	7.3	6.8	10.1	8.6	7.2	5.3	4.9	2.7	5.2	4.4	_
Ratio of equity attributable to owners of parent to total assets	81.2	80.0	87.2	86.5	87.6	87.0	84.4	85.2	84.1	82.6	81.7	_
Core operating margin (J-GAAP: Operating profit)*2	21.8	18.6	18.8	19.4	18.5	16.3	11.2	12.0	10.8	15.2	15.9	_
EBITDA* <sup>2, *4</sup> (Millions of yen)	86,392	79,793	72,974	63,750	83,421	78,220	66,981	78,018	64,101	83,190	78,160	_
Payout ratio*5	38.9	43.2	50.3	33.7	35.2	34.4	44.9	35.1	54.4	34.8	32.8	_

<sup>\*1</sup> U.S. dollar amounts are translated from Japanese yen, for convenience only, at the rate of ¥132.70=U.S.\$1, the approximate exchange rate at December 31, 2022.

<sup>\*2</sup> Figures on and after 2018 represent figures in the continued operation (Pharmaceuticals) excluding the discontinued operation (Bio-chemicals).

<sup>\*3</sup> Profit attributable to owners of parent per share is based upon the weighted average number of shares of common stock outstanding during each year.

<sup>\*4</sup> EBITDA = Profit before tax + Interest expenses + Depreciation and amortization (+ Amortization of goodwill)

<sup>\*5</sup> Under J-GAAP, consolidated dividend payout ratios are calculated using net income before the deduction of amortization of goodwill that resulted from the reverse acquisition in April 2008 (Kirin Pharma share transfer). Figures from 2021 are calculated using "Core profit" (("Profit attributable to owners of parent" – "Other income and expenses" (excluding impact from applicable taxes)) / average number of shares during fiscal year)

# **Management's Discussion & Analysis**

Figures presented in these materials have been rounded.

#### Subsidiaries Included in the Scope of Consolidation

The number of consolidated subsidiaries in the Kyowa Kirin Group stood at 39 as of December 31, 2022. Kyowa Kirin International UK NewCo Ltd. and five other companies were newly established, while Kyowa Medical Promotion Co., Ltd. and Archimedes Pharma Limited were dissolved.

#### Income

			(Billions of yen)
	2021/12	2022/12	Change
Revenue	¥352.2	¥398.4	¥46.1
Core Operating Profit	65.7	86.7	21.0
Profit attributable to owners of parent	52.3	53.6	1.2

#### **Revenue and Core Operating Profit**

The increase in revenue was the result of growth of global strategic products in North America and EMEA and a rise in revenue from technology out-licensing, despite lower revenue in Japan. The positive effect on revenue from foreign exchange was ¥30.1 billion.

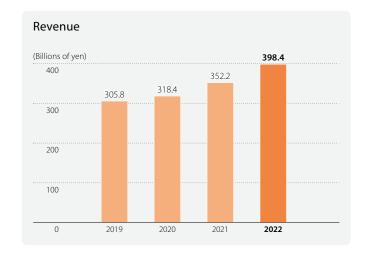
Core operating profit rose, despite increases in selling, general and administrative expenses and research and development expenses, due to higher gross profit resulting from an increase in overseas revenue and a rise in revenue from technology out-licensing. The positive effect on core operating profit from foreign exchange was ¥11.0 billion.

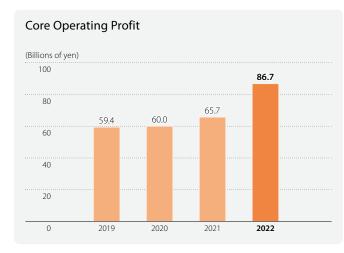
#### Profit Attributable to Owners of Parent

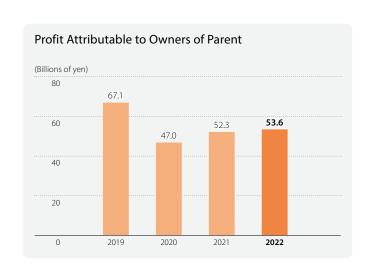
Profit attributable to owners of parent increased as a result of an increase in finance income in addition to an increase in core operating profit, despite an increase in income taxes in addition to an increase in other expenses due to increased impairment losses.

#### Revenue by Regional Controlling Company

		(Billions of yen)
2021/12	2022/12	Change
¥156.9	¥148.7	¥ (8.2)
78.8	112.6	33.8
56.1	66.9	10.8
28.4	30.1	1.8
32.1	40.1	8.0
¥352.2	¥398.4	¥46.1
	¥156.9  78.8  56.1  28.4  32.1	¥156.9 ¥148.7  78.8 112.6  56.1 66.9  28.4 30.1  32.1 40.1







#### Japan

Revenue in Japan decreased year on year due to the significant decrease in revenue from Patanol, anti-allergy eye drops, in addition to the impact of the reductions in drug price standards implemented in April 2021 and April 2022, despite the growth in sales of new product groups, such as Duvroq, a treatment for renal anemia.

- Revenue from Patanol, anti-allergy eye drops, decreased due to the release of a generic in December 2021.
- Revenue from Darbepoetin Alfa Injection Syringe [KKF] decreased due to the impact of the reductions in drug price standards and the market penetration of rival products.
- Revenue from Duvroq, a treatment for renal anemia, has been growing since its launch in August 2020.
- Revenue from ROMIPLATE, a treatment for chronic idiopathic thrombocytopenic purpura, increased due to the impact in the previous fiscal year from adjustments of shipments to distributors (June 2020 to March 2021).
- Revenue from G-Lasta, an agent for decreasing the incidence of febrile neutropenia, has been growing. The automated injection device G-Lasta Subcutaneous Injection 3.6 mg BodyPod was launched in December 2022.
- Revenue from Crysvita, a treatment for FGF23-related diseases, has been growing since its launch in December 2019

#### North America

Revenue in North America increased year on year due to the growth of global strategic products.

- Revenue from Crysvita, a treatment for X-linked hypophosphatemia, has been growing since its launch in 2018.
- Revenue from POTELIGEO, an anticancer agent, has been growing.
- Revenue from NOURIANZ™ (product name in Japan: NOURIAST), an antiparkinsonian agent, has been growing since its launch in October 2019.

#### FMF/

Revenue in EMEA increased year on year due to the growth of global strategic products.

- Revenue from Crysvita, a treatment for X-linked hypophosphatemia, has been growing as the number of countries where it has been released has been increasing since its launch in 2018. Approval for the extended indication for tumor induced osteomalacia (TIO) was acquired from the European Commission (EC) in August 2022, and sales were launched in Germany and other countries.
- Revenue from POTELIGEO, an anticancer agent, has been growing as the number of countries where it has been released has been increasing since its launch in June 2020.
- Revenue from Abstral, a treatment for cancer pain, decreased due to the impact of the market penetration of generics.

#### Asia/Oceania

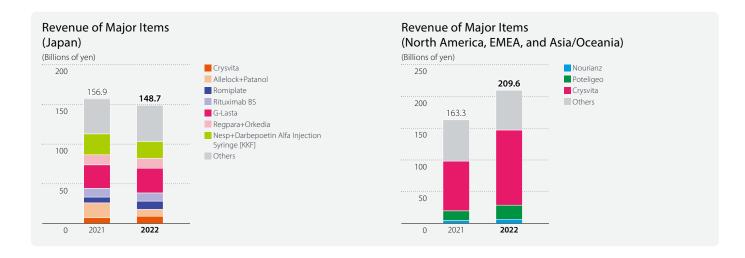
Revenue in APAC increased year on year.

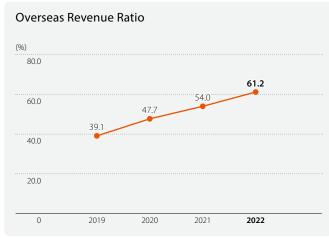
- Revenue from REGPARA, a treatment for secondary hyperparathyroidism, declined after it became subject to China's centralized governmental purchasing system\* in October 2021.
- Revenue from Gran, a neutropenia treatment drug, has been growing particularly in South Korea.
- \* Volume-Based Procurement (VBP) program that was introduced in 2018 for reducing healthcare cost in China. Even though only 2 to 5 companies are selected as suppliers through a tender, drug prices are dramatically dropped down.

#### Others

Revenue from Others increased year on year.

 Technology out-licensing increased due to the recognition of revenue of upfront payment of USD400 million over a certain period in conjunction with the conclusion of an agreement in 2021 with Amgen Inc. to jointly develop and commercialize KHK4083, anti-OX40 fully human monoclonal antibody for the treatment of atopic dermatitis, in addition to an increase in royalties revenue from AstraZeneca in relation to benralizumab.





#### Cash Flow

Cash and cash equivalents as of December 31, 2022 were ¥339.2 billion, an increase of ¥4.1 billion compared to the balance of ¥335.1 billion as of December 31, 2021. The main contributing factors affecting cash flow during the current fiscal year were as follows:

- Net cash provided by operating activities was ¥48.7 billion, compared with net
  cash provided by operating activities of ¥86.5 billion in the previous fiscal year.
  Major inflows included impairment losses of ¥18.0 billion in addition to profit
  before tax of ¥67.6 billion and depreciation and amortization of ¥18.5 billion.
  Major outflows included income taxes paid of ¥22.6 billion and decrease
  (increase) in inventories of ¥8.9 billion.
- Net cash used in investing activities was ¥17.2 billion, compared with net cash used in investing activities of ¥11.4 billion in the previous fiscal year. Major outflows included purchase of property, plant and equipment of ¥15.6 billion and purchase of intangible assets of ¥13.1 billion. On the other hand, major inflows included revenue from advance receipt from sale of investment securities of ¥4.2 billion, proceeds from redemption of bonds of subsidiaries and associates of ¥4.0 billion, and proceeds from sale of investment securities of ¥3.7 billion.
- Net cash used in financing activities was ¥29.0 billion, compared with net cash used in financing activities of ¥28.4 billion in the previous fiscal year. Major outflows included dividends paid of ¥25.3 billion.

#### **Financial Position**

#### Assets

Assets as of December 31, 2022, were ¥939.9 billion, an increase of ¥18.0 billion compared to the end of the previous fiscal year.

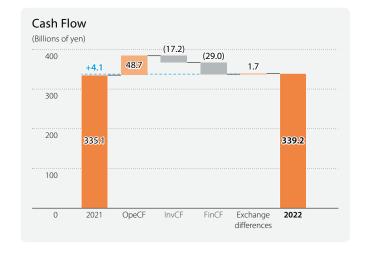
- Non-current assets decreased by ¥5.9 billion compared to the end of the previous fiscal year, to ¥397.7 billion, due mainly to impairment of intangible assets, which offset increases in property, plant and equipment and deferred tax assets.
- Current assets increased by ¥24.0 billion compared to the end of the previous fiscal year, to ¥542.2 billion, due mainly to increases in trade and other receivables and inventories.

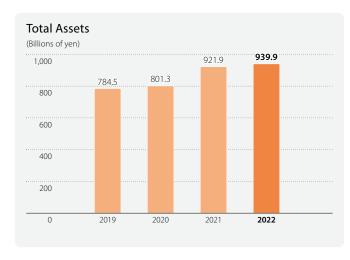
#### Liabilities

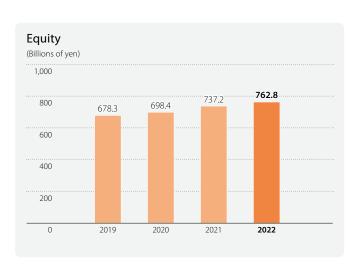
Liabilities as of December 31, 2022, were ¥177.1 billion, a decrease of ¥7.7 billion compared to the end of the previous fiscal year, due mainly to decreases in income taxes payable and contract liabilities.

#### Equity

Equity as of December 31, 2022, was ¥762.8 billion, an increase of ¥25.7 billion compared to the end of the previous fiscal year, due mainly to the recording of profit attributable to owners of parent, despite a decrease due to the payment of dividends, etc. As a result, the ratio of equity attributable to owners of parent to total assets was 81.2%, an increase of 1.2 percentage points compared to the end of the previous fiscal year.







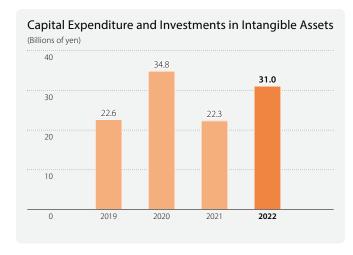
## **R&D Expenses**

R&D expenses for the fiscal year ended December 31, 2022 totaled  $\pm$ 62.9 billion, an increase of 5.2 billion from the previous fiscal year. The ratio of R&D expenses to sales for the year was 15.8%.



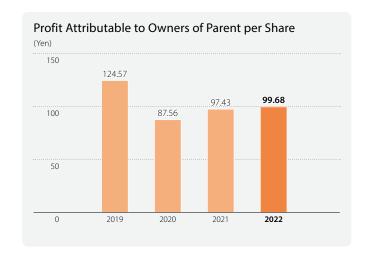
#### Capital Expenditure and Investments in Intangible Assets

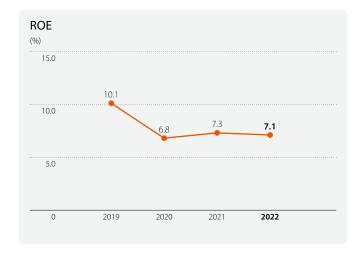
As a basic policy, Kyowa Kirin implements capital expenditure strategically, taking into account the balance with depreciation. Capital expenditure and investments in intangible assets for the fiscal year ended December 31, 2022 totaled ¥31.0 billion, a increase of ¥8.7 billion compared with the previous fiscal year. Depreciation and amortization was ¥18.5 billion, a decrease of ¥1.0 billion.

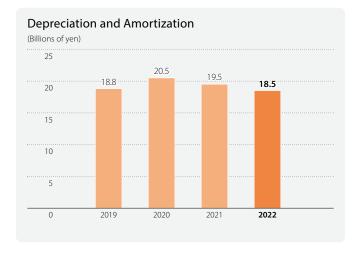


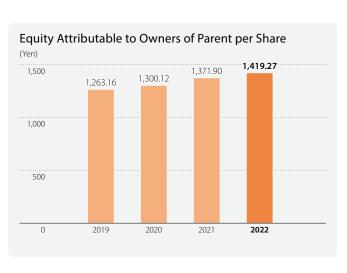
#### Per Share Data

Profit attributable to owners of parent per share for the fiscal year ended December 31, 2022 was ¥99.68, up from ¥97.43 in the previous fiscal year. Equity attributable to owners of parent per share was ¥1,419.27, compared with ¥1,371.90 in the previous fiscal year.









#### Outlook for FY2023

Consolidated financial earnings forecasts for fiscal 2023 are for revenue of ¥426.0 billion (up 6.9% compared to the current fiscal year), core operating profit of ¥88.0 billion (up 1.5%), profit before tax of ¥94.0 billion (up 39.1%), and profit attributable to owners of parent of ¥76.0 billion (up 41.9%).

- Although we expect impacts such as a reduction in drug price standards scheduled for April 2023 in Japan, revenues are expected to increase compared to the current fiscal year due to growth in the global strategic products mainly Crysvita and an increase in licensing revenue. Although we expect increases in personnel expenses and sales promotion expenses to perform our own marketing for Crysvita in North America, and increases in expenses for investment in an IT/ digital platform and human resources aimed at establishing competitive global business bases, we expect selling, general and administrative expenses to decrease as we will no longer be recording the profit share of costs for Crysvita after our own marketing begins from April. On the other hand, we are planning for significant increases in research and development expenses as a result of progress in development projects for products such as KHK4083 and KHK4951. However, we expect the increased gross profit resulting from expanded revenue will lead to higher core operating profit.
- A significant year-on-year increase is forecasted for profit before tax as a result of increased core operating profit, and a decline in other costs due to the recording of a significant amount of impairment losses in the current fiscal year.

- A year-on-year increase is forecasted for profit attributable to owners of parent despite an expected increase in income tax expense.
- Cash flows from operating activities are expected to result in a level of cash provided on par with the current fiscal year due to the recording of a large amount of impairment losses, which is a non-cash item in profit before tax in the current fiscal year, despite profit before tax being expected to increase year
- Concerning cash flows from investing activities, the Company expects a level of cash used on par with current fiscal year mainly because of proceeds from sale of investments in subsidiaries resulting from the cooperation for operating the established medicines business in Europe as a joint venture, despite an expected increase in cash used in the purchase of property, plant and equipment and intangible assets. Regarding strategic partnering, M&A and other strategic investments for acquiring R&D pipelines and drug discovery technologies, the Company will evaluate and conduct investment using a flexible approach.
- Concerning cash flows from financing activities, the Company expects net cash used to be at the same level as the current fiscal year. As regards the purchase of treasury shares and the sourcing of funds, we will remain flexible and act as appropriate for the economic and funding environment.

As a result of the above, cash and cash equivalents as of the end of fiscal 2023 are expected to be at the same level as at the end of fiscal 2022.

#### **Profit Distribution**

The Company regards the return of profits to its shareholders as one of its key management priorities.

The basis of the Company's policy regarding the distribution of profits is to pay dividends stably in light of a comprehensive consideration of factors including consolidated results and dividend payout ratio for each fiscal year, while also increasing its retained earnings for future business development and other purposes. We plan to improve our capital efficiency with regards to the purchase of treasury shares by taking a flexible approach while considering the share price in the market and other factors. The Company considers it a top priority to use internal reserve funds for investments for future growth (R&D investments, strategic investments and capital expenditures) in order to achieve sustainable growth from fiscal 2025 and maximize corporate value.

As the dividend policy, the Company set its target dividend payout ratio based on core EPS at 40% in the FY2021–2025 Medium Term Business Plan. The Company aims to ensure a stable and sustained increase in the level of dividend payment (continuous increase of dividend payments) in line with medium- to long-term growth in profits. In accordance with the above-mentioned policy, the Company paid an annual dividend from surplus of ¥51.00 per share for FY2022, an increase of ¥5.00 from the previous fiscal year and the sixth consecutive year of increase.

#### Outlook for FY2022

			(Billions of yen)
	2022/12	2023/12 (Outlook)	Year-on-year change
Revenue	398.4	426.0	27.6
Core operating profit	86.7	88.0	1.3
Profit before tax	67.6	94.0	26.4
Profit attributable to owners of parent	53.6	76.0	22.4

<sup>\*</sup> Note: These forecasts assume average exchange rates of ¥130/US\$, ¥160/British pound and ¥135/€

	2022/12	2023/12 (Outlook)	Calculation method
ROE	7.1%	9.7%	Profit / Average beginning and ending equity
Revenue growth ratio	11.9%	10.2%	Annual average growth rate with fiscal 2020 as base year
R&D expense ratio	15.8%	18.5%	Research and development expenses / Revenue
Core operating profit ratio	21.8%	20.7%	Core operating profit / Revenue

		(Yen)
	2022/12	2023/12 (Outlook)
Dividend per share (Second quarter-end)	24	27
Dividend per share (Fiscal year-end)	27	27
Dividend per share (Annual)	51	54
Dividend payout ratio*	38.9%	39.9%

<sup>\*</sup> The dividend payout ratio is based on core EPS (calculated as an indicator showing recurring profitability by dividing core profit (determined by subtracting "other income," "other expenses" and the related "income tax expense" from "profit") by the average number of shares during the period).

# **Risk Factors**

This section describes principal risks identified by the Kyowa Kirin Group as of December 31, 2022. However, the Group may face other unforeseen risks caused by changes in internal and external conditions, and risks not described here may have a negative impact on the Group's business performance and financial position. The Group defines risks as factors that could have an uncertain impact on business targets, including both threats and opportunities.

### Risks Related to Maximizing the Value of Global Strategic Products

#### ▶ Details of risks and expected main impacts

The Group is working to maximize the value of three drugs that have been positioned as global strategic products Crysvita, a treatment for X-linked hypophosphatemia, POTELIGEO, an anticancer agent, and NOURIANZ (product name in Japan: NOURIAST), an antiparkinsonian agent. The commercial activities of Crysvita in North America, which will be transferred from our partner company, Ultragenyx Pharmaceutical Inc. (Ultragenyx) in April 2023, may adversely affect the business if the transfer does not progress smoothly.

Moreover, regarding risks of global strategic products as whole, delays to sales area expansion caused by setbacks in market launch preparations, slow progress with market penetration due to difficulties in identifying potential patients, sharply lower-than-expected sales due to a shortfall in projected product prices in new markets, and impediments to stable supplies caused by quality issues, manufacturing problems and other issues, may prevent the Group from attaining its business targets.

#### ► Key mitigation measures

In preparation for maximizing the value of global strategic products, we are moving forward with measures for penetrating markets and expanding our business regions, centered on Europe and the U.S. In addition to a global management system that facilitates seamless cooperation between functions (divisions) and regions (affiliates) on a global level, the Group has appointed personnel to take responsibility for each global strategic product. This person leads a cross-function/region team that works together to draft and execute strategies to maximize the value of each product. To complete the transition in the North America smoothly, the Group partly started operations in North America from October after establishing a franchise. The preparation for the transition is proceeding smoothly based on the detailed transition scheme. The Group will receive field support from Ultragenyx for a year after the transition, allowing us to be well-prepared for risk management. Regarding issues with quality and manufacturing, key mitigation measures are outlined in the "Risks related to product quality" and "Risks related to production and stable supply."

#### Risks Related to R&D

#### ▶ Details of risks and expected main impacts

In its R&D, the Group pursues the ongoing creation of groundbreaking pharmaceutical products and has established the following strategies centered on technology, disease, and open innovation. (i) In addition to its ongoing quest to drive advances in antibody technology, the Group will build a platform for creating breakthrough drugs by making full use of diverse modalities. (ii) The Group will continue to provide "Only-one value drugs" to address diseases that currently have no effective treatment while drawing on achievements cultivated to date in disease science (in the areas of nephrology, oncology, immunology, allergies, and the central nervous system). (iii) The Group will continue to incorporate external innovation

through advanced open innovation activities, fusing collaborative research activities with academia, startups, and other partners (information gathering in the San Diego area, etc.) with early access to information by means of venture capital fund investments. However, in the process of developing new drugs over long periods of time, there may be cases where R&D has to be abandoned, for example if expected efficacy is not confirmed or for safety and other reasons, which may prevent the Group from expanding its drug pipeline and undermining growth potential and profitability.

#### ▶ Key mitigation measures

The Group is actively stepping up investments in R&D (aiming for an R&D expense ratio of 18–20%) to strengthen the pipeline of new drugs that will lead the next generation, such as global candidates. In addition, to complement proprietary research, the Group is also focusing on open innovation activities involving partners from across industry, government, and academia, including active strategic partnering (in-licensing, tie-ups, etc.) to acquire platform technologies and pipeline assets. For instance, since 2020, the Group has been collaborating with Axcelead Drug Discovery Partners Inc., a drug discovery solutions provider formed by the spinout of Takeda Pharmaceutical Company Limited's drug discovery platform business.

We aim to combine Axcelead's long-established, extensive technologies and expertise in small-molecule drug discovery with the Company's own innovative drug discovery technologies, thereby broadening the R&D pipeline with groundbreaking new compounds. The Group is also extending its R&D alliance with InveniAl LLC of the United States providing Al and machine learning applications, identifying, assessing, and optimizing novel drug discovery targets that complement the Group's proprietary next-generation antibody technology. Moreover, through investing in a venture capital fund, the Group entered into a research collaboration with LUCA Science Inc. that has a proprietary technology to isolate high functional mitochondria in 2022. The collaboration allows for the Group to research new therapeutic options based on mitochondrial drug discovery, an innovative mitochondrial modality. The Group also started Corporate Venture Capital (CVC) activities, strengthening an access to cutting-edge drug discovery technology-related information.

#### **Risks Related to Healthcare Cost-Control Policies**

#### ▶ Details of risks and expected main impacts

The trend toward tighter control of healthcare costs is increasing in Japan and elsewhere. Efforts to reform healthcare systems in various countries involve reducing prices of drugs and encouraging wider use of generic drugs. These trends may have a negative impact on the Group's business performance and financial position. In this context, while being innovative and also adequate for unmet medical needs is important to the successful reception from stakeholders outside the Company, delays to the development of further practical, ground-breaking new drugs may undermine the Group's growth potential and profitability.

#### ► Key mitigation measures

The Group closely monitors healthcare policy trends in each country, while also strategically examining measures to evaluate the value of its life-changing pharmaceuticals from various aspects so as to securely deliver them to patients. Furthermore, in post-launch price setting, the Group considers the impact on its business so that it can secure appropriate revenues to continuously creating innovative drugs, while complying with each country's systems.

#### Risks Related to Parent and Group Company Management

#### ▶ Details of risks and expected main impacts

For the Group's business as a Japan-based global specialty pharmaceutical company to grow, robust risk management for the Company and its Group companies is management's top priority. Since 2020, the Group has been working to enhance governance by launching an improvement plan with three key objectives: creating a robust quality assurance system, improving risk management, and reforming the corporate culture. In the event that these measures are not fully effective, emerging risks could result in restrictions or suspensions of production, sales and other business activities, and the loss of trust as a pharmaceutical company.

#### ► Key mitigation measures

Improving risk management aims to achieve group-wide risk management that can anticipate the future and take preventative measures. To this end, the Group holds workshops for all executives and managers at the head office, stages ongoing crisis and BCP drills across regions in Japan and overseas, and deliberates on material issues (materiality) that are both risks the Group needs to address over the medium- to long-term as well as opportunities. Through these actions, the Group is working to heighten its ability to respond to new and potential risks. Furthermore, the Group conforms to the three-line model advocated by the Institute of Internal Auditors, and has secured a system to make appropriate responses to risks. Please refer to "Risks related to product quality" for details about how we are creating a robust quality assurance system and "Risks related to human resources" for details about corporate culture reforms.

#### Risks Related to Product Quality

#### ▶ Details of risks and expected main impacts

Pharmaceutical manufacturing requires facilities (hard assets) and procedures and people (soft assets) that are compatible with good manufacturing practice (GMP). Should a GMP inspection by a national authority or an internal audit find a serious GMP issue, the regulatory authority may issue instructions for production or shipments to be suspended. In addition, if for any reason there are any concerns about the safety or quality of a product with regard to raw materials or manufacturing processes used to make the product, these may give rise to a suspension of shipments or product recall.

#### ► Key mitigation measures

The Group's quality assurance functions are centered on the Global QA Head, who reports directly to the President and collects and shares information about quality assurance activities in each region for prompt decision making. Specifically, the Global Quality Assurance Committee, regular and ad hoc Global Product Council and other quality assurance bodies discuss critical quality-related issues reported by regional head offices, evaluate quality performance at newly selected manufacturing sites, regularly assess product quality, review the activities of global taskforces established to address specific issues, and monitor issues identified in audits and progress with related response measures. The Group has also established a global, independent specialist audit unit to reinforce product quality audits within the Group and at contractors. In addition, the Group has completed introducing an electronic Quality Management System to appropriately manage and utilize large volumes of quality assurance information on a global level and to drive continuous improvements in processes and reliability. With eQMS, key quality management processes (education and training, document management, deviation, complaints, corrective and preventative actions, modifications, change control, audits, manufacturing site management, etc.) are all managed electronically.

Quality assurance divisions and safety divisions always work closely and have established a system to prevent health damage to patients by promptly evaluating impacts on patients if quality concerns arise and always consider the effect of quality in product safety monitoring.

#### **Risks Related to Production and Stable Supply**

#### ▶ Details of risks and expected main impacts

In cases where detailed, accurate demand forecasts in various regions are impossible; where it is impossible to maintain supply capacity with the Group's proprietary plants or through cooperation with contract manufacturers and other suppliers; where market supply and demand fluctuates significantly due to the supply difficulties of other companies; or in other cases, stable supplies of the Group's products could be impeded, and resulting factors such as delays in drug launch schedules or limited shipments of product could erode trust in Kyowa Kirin as a pharmaceutical company or depress revenues, among other things.

#### ► Key mitigation measures

The Group is implementing sales and operations planning (S&OP) to increase the accuracy of demand forecasting by rapidly identifying changes in product sales and needs, and to achieve a supply-demand balance and enable quick adjustments in line with business plans. The Group sets objective stable supply indicators, reviews an inventory holding policy in accordance with risks, and visualizes demand using a supply-demand planning system. In addition, to respond to spikes in demand and tight supply-demand conditions, the Group is expanding its network of contractors, investing in proprietary plants, rolling out digital technology to enhance manufacturing operational efficiency, and increasing headcount and upgrading training systems in the production and quality assurance divisions.

#### Risks Related to the Management of Suppliers and Contractors

#### ▶ Details of risks and expected main impacts

The Group enters into alliances with other companies, in the form of joint development, joint commercialization, technology partnerships and establishing joint ventures, and it also outsources operations related to the supply of raw materials, production, logistics and marketing for pharmaceuticals to other domestic and overseas suppliers. However, if the alliances and outsourcing contracts fail to deliver the expected results or are dissolved due to issues related

to human rights, legal compliance, the environment, information security at suppliers, or if there are quality issues with contracted deliverables, the Group could face difficulty securing stable supplies of the Company's products or issues in logistics and sales, which may erode trust in Kyowa Kirin as a pharmaceutical company, lower revenues, or lead to delays in new drug applications.

#### ► Key mitigation measures

The Group is seeking to conduct open, fair CSR-based procurement in line with the Kyowa Kirin Group Procurement Policy, which states its commitment to pursue CSR procurement together with suppliers to ensure stable supplies of high-quality products. To ensure that suppliers are familiar with the Group's initiatives for CSR procurement, the Group holds briefing webinar for suppliers periodically. In addition, the Supplier Code of Conduct sums up the seven areas where the Group calls for understanding and cooperation from suppliers: relationships with society, relationships with employees, compliance with rules, respect for human rights, environmental preservation, information management, and risk management. In dealing with suppliers, we have added a CSR clause, which includes compliance with the Code of Conduct, to our contracts, and the Group conducts CSR questionnaires to confirm compliance with the Supplier Code of Conduct, publishing the results. The Group also obtains risk and credit background data from external organizations and conducts supplier assessments based on objective information. The Group obtains similar information in the course of transactions as needed, and confirms with a supplier when there is any cause for concern. In addition, the Group promptly shares the risk information it obtained with relevant divisions and works together to mitigate risk, including requesting corrective action from suppliers or considering changing suppliers, as needed. Through the procurement functions and systems established in each region, the Group takes measures to reduce risks and monitors the status.

Based on Kyowa Kirin Group Human Rights Policy established in December 2022 (formerly Kirin Group Human Rights Policy), the Group also plans to promote human rights due diligence initiatives.

#### **Risks Related to Information Security**

#### ▶ Details of risks and expected main impacts

As the Group utilizes a variety of networks and information systems, the Group may experience system outages or external leaks of confidential information in the event of unauthorized system access or cyberattacks. A cyberattack on a supplier could result in damages such as the leak of confidential information of the Group or personal data, suspension of business activities, or damage to the brand. As explained in key mitigation measures for "Risks related to pandemics," the move to homeworking is improving productivity, but the number of employees using home communication environments or working alone is rising, which increases the risk of surveillance committed through network, cyberattacks, email errors, and loss of personal computers that may lead to information leaks. In addition, as cloud-based services are used more frequently, a security accident (including inaccessibility to such a service) occurred at the side of an outside service provider may directly affect the Group's business contingency.

#### ► Key mitigation measures

The Group is taking steps to upgrade information security, including technical measures to guard against cybersecurity threats that are becoming more diverse and more sophisticated each year, as well as developing playbooks that include information such as the recommended

initial response flow and procedural steps in the event of a cyber incident, to establish the system to respond to incidents. Moreover, by periodically conducting an outside evaluation driven by a standard framework for the security industry, the Group continuously improve a responsive plan formulated based on an objective risk evaluation. The Group is also taking measures to mitigate various risks, such as monitoring its business partners to verify their response to the security measures. In addition, to be better prepared to mount a rapid response and minimize damage in the event of an incident, the Group is continuously conducting crisis drills in each region to deal with ransomware and other cyberattacks. The Group is also educating employees to raise their level of information security by conducting educational seminars periodically and targeted e-mail attack drills, and raising awareness by disseminating information and precautions on preventing infection by computer viruses in accordance with the characteristics of the latest attack methods and points of attention when remote working, etc., through documentation for employees, a dedicated cybersecurity website, etc. BCP system and drills simulating limited use of cloud services will also be organized.

#### **Risks Related to Compliance**

#### ▶ Details of risks and expected main impacts

The Group is required to comply with a range of laws and regulations governing pharmaceutical R&D, manufacturing, sales, imports and exports. In addition, in the promotion of pharmaceuticals, in addition to the laws and regulations of each country, there are voluntary codes in the industry, and pharmaceutical companies are strongly requested to comply with them. Failure to comply with these laws, regulations and voluntary codes could result in sanctions that delay or suspend the development of new drugs, or restrict or suspend production, sales and other business activities, which may erode trust in Kyowa Kirin as a pharmaceutical company.

#### ► Key mitigation measures

The Group believes that compliance is not only legal compliance, but also involves promptly sensing and properly understanding the needs of society and acting ethically. We have stipulated the overall behavior expected of our officers and employees in the Kyowa Kirin Group Code of Conduct. The Company has established a system to comply with various laws and regulations and voluntary codes, and conducts ongoing education and training. The status of compliance and the progress of measures to address material issues are discussed at each regional CSR Committee meeting held semi-annually or quarterly and at the Group CSR Committee meeting held twice a year, and ongoing improvement is promoted. In addition, the Group has set up a whistleblowing hotline to prevent, quickly detect, and rectify acts that violate the Code of Conduct or significantly damage the brand value of the Group. Furthermore, the Group conducts an annual employee compliance awareness survey to identify potential risks, while working to mitigate risks in the early stages by confirming the facts of survey responses and responding accordingly. Survey results are also reported to the CSR Committee and the Board of Directors. The Group compliance enhancement project that started in 2021 is improving a framework to assess the status of efforts by each department in charge based on the various Kyowa Kirin Group Policies that supplement the Code of Conduct, and a framework of company-wide monitoring of the compliance program of each region including the global head office. Based on the monitoring and assessment results, the Group implements measures for improvement accordingly, further raising its compliance level.

#### **Risks Related to Human Resources**

#### ▶ Details of risks and expected main impacts

The Group is working to embed its global management system to encourage individuals from diverse backgrounds to demonstrate their abilities and engage in business activities in Japan and overseas. However, if the Company is unable to develop and hire personnel who will be responsible for the global management system, this may hinder the continuation of its business activities or sustainable growth.

#### ► Key mitigation measures

The Group believes people are the source of innovation. To maximize the abilities of each of its employees with diverse backgrounds and develop person and organization that challenge to innovate and continuously create new value, the Group promotes measures for the achievement of "Global Talent Management Basics for 2021–2025" created by the Human Resources Department to visualize human resources function's ideal state in 2025. Among measures taken thus far to build a global common human resources platform for promoting One Kyowa Kirin system, the Group has focused on, in specific, promoting Diversity, Equity & Inclusion (DE&I) Statement, introducing the global grading and leadership principal, building a talent management system, and promoting corporate culture reform.

As an effort to promote DE&I, the Group works on cross-regional and cross-functional measures, as well as measures to respond to region-specific challenges in order to realize strengths of teams that shine with diverse personalities. To strengthen the management system on a global basis, the Group has created succession planning for each of its global key positions and nominated next-generation leadership candidates irrespective of race, nationality, gender, or age. Going forward, to expand the pipeline of human resources, the Group will formulate individual training programs for each successor, and implement human resource development strategically by carrying out global exchange programs.

Talent review meetings that have been set up in each region will be organized by Global HR Business Partners beyond the framework of region, aiming to assign right person in the right place at a global level. As an effort to promote corporate culture reform, the Group has established Key Behavior "Overcome Barriers" (KABEGOE in Japanese). The Group is implementing activities, such as dialogues with the President and other executives and workshop, to empower all employees to overcome the barriers that divide them—all the difficulties and new challenges they face.

Through the employees' attitude survey and corporate culture surveys, the Group monitors the extent to which the above-mentioned initiatives are gaining acceptance and taking root. At the Human Resource Development Committee in which officers other than those in charge of human resources also participate, each of these measures implemented by the Human Resources Department are thoroughly discussed to allow them to be more effective. Furthermore, the Group promotes Health and Productivity Management with the aim of "realizing health and well-being" of the Group's employees, as it believes that mental and physical health is essential in order for them to maximize their capabilities to create new value.

#### **Risks Related to Pandemics**

#### ▶ Details of risks and expected main impacts

Regional outbreaks of emerging and re-emerging infectious diseases, or global pandemics, including the novel coronavirus infectious disease (COVID-19), could force the Group's head offices, plants, research laboratories and other business sites to close or cease business activities due to onsite infection clusters. Raw material suppliers may be forced to suspend

operations, and logistics may be affected. Disruptions at medical institutions and other issues could prevent the Group from ensuring stable supply of products or collecting safety information, and result in delay in the provision of product information to medical professionals and the progress of clinical studies. In addition, any impact on government authorities in each country could slow down new drug approvals and price negotiations, delaying the launch of new products. Under those conditions, the Group's business performance and financial position may be adversely affected.

#### ► Key mitigation measures

In dealing with COVID-19, the Group put the first priority on reducing the risk of infection during the phase of pandemic. The Group implemented remote working as the main mode of work, including working from home, and actively introduced web meeting tools for internal and external communication to enable employees to continue their duties. At the same time, the Group took every effort to ensure the safety of employees that need to attend work, including those in the production, R&D, and sales divisions, such as daily antigen tests, temperature checks, face masks, social distancing, divided indoor spaces and ventilation.

Based on the global policy of a hybrid working model to create innovation and promote well-being among employees, the Group attempts to boost productivity by expanding the scope of the new working styles, creating optimal customer contact points that combine in-person and digital approaches in terms of sales activities, and stepping up the pace of digitizing tasks and achieving operational excellence, while carefully tracking new case levels in each region.

#### **Risks Related to Natural Disasters**

#### ▶ Details of risks and expected main impacts

Natural disasters such as earthquakes and typhoons that may occur in various locations could lead to the closure of the Group's head offices, plants, research laboratories and business offices or halt business activities, potentially impacting progress in drug discovery research and clinical development, the stable supply of products, the collection of safety information, and the provision of product information, which may have a negative impact on the Group's business performance and financial position.

#### ► Key mitigation measures

The Group has developed a coordinated disaster prevention plan with its business sites to ensure the safety of employees and their families in the event of a disaster. Based on the plan, the Group regularly conducts safety confirmation drills and safety equipment upgrades/ checks. The Group has also developed a BCP to continue supplies, monitoring, and providing information of pharmaceuticals in the event of difficulty ensuring the continuity of normal business activities. The Group conducts BCP drills simulating a range of scenarios, including super typhoons and a massive earthquake directly under the Tokyo metropolitan area. We are working to identify issues through such drills and continuously improve our BCP.

Based on the global, all-hazard BCP guidelines established in 2021, the Group is working to enhance the business continuity framework in each region to prepare for various events. For example, the Group is planning to construct a new warehouse building with earthquake-proof construction at its Takasaki Plant (construction start scheduled for October 2023, operation start scheduled for January 2026).

#### **Risks Related to Geopolitics**

#### ▶ Details of risks and expected main impacts

Geopolitical uncertainties in multilateral relationships surrounding the Russo-Ukraine crisis and other bilateral relationships may adversely affect the Group's business activities. In Russia and Ukraine where risks have emerged, the Group does not conduct direct business operations and there are no raw material suppliers with which the Group conducts direct business, and therefore, the Group's business, including the present product supply, has not been significantly affected. However, if Russia's invasion continues for a prolonged period or expands to neighboring countries in Europe, etc., there could be an impact on the Group's business due to turmoil in the global economy and exchange rates caused by significant fluctuations in energy prices or disruptions in internet infrastructure from cyberattacks, as well as due to delays in procuring raw materials, materials and active pharmaceutical ingredients, importing and exporting, conducting clinical trials and carrying out sales activities. In addition, the safety of patients, medical institutions, and the Group's employees may also be adversely affected.

#### ► Key mitigation measures

The Group will collect information on the situation and procure raw materials, materials, and active pharmaceutical ingredients in advance when necessary, aiming to ensure stable supply appropriately. Furthermore, if the situation is worsened, the Group will work to mitigate the impact on clinical trials, procurement, supply, distribution, and employees' safety, etc.

#### **Risks Related to Climate Change**

#### ► Details of risks and expected main impacts

The occurrence of floods caused by extreme weather brought about by climate change could affect all of our business activities, including the stable supply of our products and research activities. Furthermore, in the future, the Group's brand value may decline if additional costs are incurred due to the introduction of carbon taxes or measures to comply with tighter environmental regulations, or if greenhouse gas reduction targets cannot be achieved.

#### ▶ Key mitigation measures

In addition to the impact on business activities, the Group considers the response to climate change (prevention of global warming) to be critical to bringing about a sustainable society. The Group has created a roadmap for reducing greenhouse gas emissions over the medium-to long-term, and is moving forward with an array of initiatives across the Group. In the medium term, the Group aims to accelerate the synergetic reduction of emissions of greenhouse gases by focusing on energy-saving measures and expanding the use of renewable energy. From 2020, the Group introduced RE100-certified renewable energy to its Takasaki Plant and Fuji Research Park and CMC R&D Center, switching 100% of their electric power to electricity that emits no greenhouse gases. In 2021, the Group's head office also switched 100% of its electric power to renewable energy. In 2023, an RE100-compliant renewable energy system and a large-scale solar power generation system (assumed output of 1,976,000 kWh/year) will be installed at the Ube Plant, with the solar power generation system starting operation based on an onsite PPA (Power Purchase Agreement) model. In addition, the Company has endorsed the recommendations of the Task Force on Climate-related Financial Disclosures (TCFD), and has determined the risks and opportunities that climate change poses to its businesses and their impacts. Following the recommendations of the TCFD, the Company discloses information on the following four items: governance, strategy, risk management, and metrics and targets.

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# **Corporate Data**

# Corporate Data (As of December 31, 2022)

#### Kyowa Kirin Co., Ltd.

#### **Head Office**

1-9-2, Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan Tel: 81-3-5205-7200 Fax: 81-3-5205-7182

URL: https://www.kyowakirin.com/

#### Number of Employees

Consolidated: 5,982

#### **Date of Foundation**

July 1, 1949

Paid-in Capital

¥26,745 million

## **Principal Plants**

#### Japan

Takasaki Plant (Takasaki City, Gunma) Ube Plant (Ube City, Yamaguchi)

#### Overseas

Kyowa Kirin China Pharmaceutical Co., Ltd.

### R&D Network

#### Japar

CORPORATE INFORMATION

Tokyo Research Park (Machida City, Tokyo)
Fuji Research Park (Sunto-gun, Shizuoka)
CMC R&D Center (Sunto-gun, Shizuoka)
Bio Process Research and Development Laboratories
(Takasaki City, Gunma)

#### Overseas

Kyowa Kirin, Inc. Kyowa Kirin China Pharmaceutical Co., Ltd. Kyowa Kirin Korea Co., Ltd.

## Network (As of December 31, 2022)

Name of Company	Proportion of Voting Rights Held	Share Capital (1,000)	Principal Business		
Japan					
Kyowa Kirin Frontier Co., Ltd.	100%	¥100,000	Manufacturing and sales of pharmaceuticals		
Kyowa Kirin Plus Co., Ltd.	100%	¥112,500	Insurance, wholesale and retail		
North America					
Kyowa Kirin USA Holdings, Inc.	100%	US \$76,300	Supervision and management of specific subsidiaries (U.S.A.)		
Kyowa Kirin, Inc.	100%	US \$0.2	R&D and sales of pharmaceuticals (U.S.A.)		
Kyowa Kirin Canada, Inc.	100%	CA \$0.1	Sales of pharmaceuticals (Canada)		
BioWa, Inc.	100%	US \$10,000	Out-licensing of antibody technology (U.S.A.)		
EMEA					
Kyowa Kirin International plc.	100%	£13,849	Supervision and management of specific subsidiaries (U.K.)		
Kyowa Kirin Pharmaceutical Development Limited	100%	£501	Development of pharmaceuticals (U.K.)		
Kyowa Kirin Limited	100%	£6,952	Sales of pharmaceuticals (U.K.)		
Kyowa Kirin Ireland Limited	100%	€0.1	Sales of pharmaceuticals (Ireland)		
Kyowa Kirin Pharma SAS	100%	€1,241	Sales of pharmaceuticals (France)		
Kyowa Kirin Farmacéutica, S.L.U.	100%	€216	Sales of pharmaceuticals (Spain)		
Kyowa Kirin GmbH	100%	€51	Sales of pharmaceuticals (Germany)		
Kyowa Kirin Holdings B.V.	100%	€111	Sales, licensing-in and licensing-out of pharmaceuticals (Netherlands)		
Kyowa Kirin Pharma B.V.	100%	€18	Sales of pharmaceuticals (Netherlands)		
Kyowa Kirin S.r.l.	100%	€10	Sales of pharmaceuticals (Italy)		
Kyowa Kirin AB	100%	SEK 200	Sales of pharmaceuticals (Sweden)		
Kyowa Kirin Services Ltd	100%	£0.3	Sales and development of pharmaceuticals (U.K.)		
Archimedes Pharma UK Limited	100%	£78	Sales of pharmaceuticals (U.K.)		
Kyowa Kirin Sàrl	100%	CHF 20	Sales of pharmaceuticals (Switzerland)		

Name of Company	Proportion of Voting Rights Held	Share Capital (1,000)	Principal Business
Kyowa Kirin Austria GmbH	100%	€35	Sales of pharmaceuticals (Austria)
Kyowa Kirin Farmaceutica, Unipessoal Lda.	100%	€5	Sales of pharmaceuticals (Portugal)
Kyowa Kirin Pharma s.r.o.	100%	CZK 100	Sales of pharmaceuticals (Czech Republic)
Kyowa Kirin Pharma S.R.L.	100%	RON 10	Sales of pharmaceuticals (Romania)
Kyowa Kirin Pharma FZ-LLC.	100%	AED 50	Sales of pharmaceuticals (UAE)
Kyowa Kirin International UK NewCo Ltd	100%	GBP 0	Sales of pharmaceuticals (Scotland)
Kyowa Kirin International NewCo Netherlands B.V.	100%	EUR 0.1	Sales of pharmaceuticals (Netherlands)
Kyowa Kirin International NewCo France SAS	100%	EUR 0.1	Sales of pharmaceuticals (France)
Kyowa Kirin International NewCo Germany GmbH	100%	EUR 25	Sales of pharmaceuticals (Germany)
Kyowa Kirin International NewCo Spain S.L.U.	100%	EUR 4	Sales of pharmaceuticals (Spain)
Kyowa Kirin International NewCo Italy S.r.l	100%	EUR 5	Sales of pharmaceuticals (Italy)

APAC					
Kyowa Kirin Asia Pacific Pte. Ltd.	100%	SGD 123,045	Supervision and management of specific subsidiaries and sales pharmaceuticals (Singapore)		
Kyowa Kirin China Pharmaceutical Co., Ltd.	100%	US\$ 29,800	Manufacturing and sales of pharmaceuticals (China)		
Kyowa Kirin Korea Co., Ltd.	100%	KRW 2,200,000	Sales of pharmaceuticals (Korea)		
Kyowa Kirin (Taiwan) Co., Ltd.	100%	TW \$262,450	Sales of pharmaceuticals (Taiwan)		
Kyowa Kirin (Hong Kong) Co., Ltd.	100%	HK \$6,000	Sales of pharmaceuticals (Hong Kong)		
Kyowa Kirin (Thailand) Co., Ltd.	100%	THB 100,000	Sales of pharmaceuticals (Thailand)		
Kyowa Kirin (Malaysia) Sdn. Bhd.	100%	RM 1,000	Sales of pharmaceuticals (Malaysia)		
Kyowa Kirin Australia Pty Ltd	100%	AU \$ 5,000	Sales of pharmaceuticals (Australia)		
Japan (Equity-method affiliate)					
FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.	50.0%	¥100,000	Development, manufacturing and sales of biosimilar pharmaceutic		

Note: All of the companies are consolidated subsidiaries, except FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd.

# **Investor Information (As of December 31, 2022)**

# **Stock Listing**

Tokyo

#### **Securities Code**

4151

## **Transfer Agent of Common Stock**

Sumitomo Mitsui Trust Bank, Limited 1-4-1, Marunouchi, Chiyoda-ku, Tokyo 100-8233, Japan http://www.smtb.jp/personal/agency/index.html

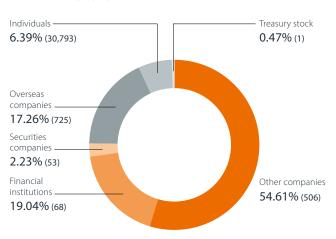
## **Number of Shares of Common Stock**

Authorized: 987,900,000 Issued: 540,000,000

#### **Number of Shareholders**

32.147

# Shareholding by Type of Investor (Number)



## **Principal Shareholders**

	Number of Shares Held (Thousands)	Percentage of Total Shares Issued (%)
Kirin Holdings Company, Limited	288,819	53.74
The Master Trust Bank of Japan, Ltd. (Trust account)	58,875	10.95
Custody Bank of Japan, Ltd. (Trust account)	27,086	5.04
State Street Bank & Trust Company 505223	9,330	1.74
SMBC Nikko Securities Inc.	7,130	1.33
State Street Bank West Client-Treaty 505234	5,114	0.95
JP Morgan Chase Bank 385781	3,361	0.63
State Street Bank & Trust Company 505025	3,308	0.62
State Street Bank & Trust Company 505103	3,164	0.59
SSBTC CLIENT OMNIBUS ACCOUNT	3,052	0.57

## Stock Price and Trading Volume



#### Total Shareholder Return (TSR)

	Past 4 years	Past 3 years	Past 2 years	Past 1 year	Current year
Kyowa Kirin Co., Ltd.	96.9%	121.6%	134.7%	151.5%	148.6%
TOPIX Total Return Index	84.0%	99.2%	106.6%	120.2%	117.2%