



Sumitomo Dainippon
Pharma

Innovation today, healthier tomorrows

Investors Meeting Presentation for FY2020 (Year ended March 31, 2021) and Revision of Mid-term Business Plan 2022

May 13, 2021

Hiroshi Nomura, President and CEO
Sumitomo Dainippon Pharma Co., Ltd.

Disclaimer Regarding Forward-looking Statements

This material contains forecasts, projections, targets, plans, and other forward-looking statements regarding the Group's financial results and other data. Such forward-looking statements are based on the Company's assumptions, estimates, outlook, and other judgments made in light of information available at the time of preparation of such statements and involve both known and unknown risks and uncertainties.

Accordingly, plans, goals, and other statements may not be realized as described, and actual financial results, success/failure or progress of development, and other projections may differ materially from those presented herein.

Information concerning pharmaceuticals (including compounds under development) contained herein is not intended as advertising or as medical advice.

Financial Results for FY2020

Financial Results for FY2020

Financial Results for FY2020 (Core Basis)



Billions of yen

	FY2019 Results	FY2020 Results	Change			FY2020 Feb. 12 forecasts
			Value	FX impact	%	
Revenue	482.8	516.0	33.2	(6.8)	6.9	515.0
Cost of sales	128.3	137.5	9.1	(0.8)	7.1	138.5
Gross profit	354.4	378.5	24.0	(5.9)	6.8	376.5
SG&A expenses	190.0	211.8	21.8	(3.4)	11.5	212.5
R&D expenses	92.6	97.1	4.5	(1.7)	4.8	101.0
Core operating profit	72.0	69.6	(2.4)	(0.9)	(3.3)	63.0
Changes in fair value of contingent consideration (negative number indicates loss)	① 48.5	① 22.5	(26.0)			26.0
Other non-recurring items (negative number indicates loss)	② (37.2)	② (20.8)	16.4			(40.0)
Operating profit	83.2	71.2	(12.0)		(14.4)	49.0
Profit before taxes	83.9	77.9	(6.1)		(7.3)	43.0
Income tax expenses	48.0	41.0	(7.0)			34.0
Net profit	35.9	36.8	0.9		2.5	9.0
Net profit attributable to owners of the parent	40.8	56.2	15.5		38.0	27.0

① Cost reversal due to:
(FY19) Revised business plans for oncology pipelines and Lonhala® Magnair®
(FY20) Revised business plans for oncology pipelines

② Non-recurring items due to:
(FY19) Impairment losses on oncology pipelines, SB623, Lonhala® Magnair®
(FY20) Gain on sale of former Ibaraki plant of the Company
Impairment losses on oncology pipelines

(Ref.) Earnings related to Sumitovant

Billions of yen

	FY19	FY20
Revenue	-	7.8
SG&A expenses *	6.5	46.5
R&D expenses	9.0	24.6
Core operating profit	(15.6)	(63.6)
Operating profit	(15.5)	(63.6)
Net profit	(16.7)	(63.6)
Net profit attributable to owners of the parent	(11.9)	(44.3)

The figures are before intra-group elimination

* Include amortization of patent rights

FX rates:

FY19 Results : 1US\$ = ¥108.7, 1RMB = ¥15.6

FY20 Results : 1US\$ = ¥106.1, 1RMB = ¥15.7

FY20 forecasts : 1US\$ = ¥106.0, 1RMB = ¥15.5

Financial Results for FY2020

Segment Information (Core Basis)



Billions of yen

		Pharmaceuticals Business					Other Business	Total	
		Japan	North America	China	Other Regions	Subtotal			
FY2020 Results	Revenue (Sales to customers)	152.5	281.5	27.8	17.2	479.1	36.9	516.0	
	Cost of sales	77.5	20.8	5.4	5.7	109.4	28.1	137.5	
	Gross profit	75.1	260.7	22.5	11.5	369.8	8.7	378.5	
	SG&A expenses	50.8	143.8	9.2	2.8	206.7	5.1	211.8	
	Core segment profit	24.3	116.9	13.2	8.7	163.1	3.6	166.7	
	R&D expenses						96.2	0.9	97.1
	Core operating profit						66.9	2.7	69.6
FY2019 Results	Revenue (Sales to customers)	139.7	262.3	28.6	14.8	445.4	37.4	482.8	
	Cost of sales	65.0	24.0	5.4	5.0	99.5	28.9	128.3	
	Gross profit	74.7	238.3	23.2	9.8	346.0	8.4	354.4	
	SG&A expenses	51.8	120.8	8.8	3.4	184.8	5.2	190.0	
	Core segment profit	22.9	117.5	14.4	6.4	161.2	3.2	164.4	
	R&D expenses						91.7	0.9	92.6
	Core operating profit						69.7	2.3	72.0
Change	Revenue (Sales to customers)	12.8	19.2	(0.8)	2.4	33.7	(0.5)	33.2	
	SG&A expenses	(1.0)	23.0	0.5	(0.6)	21.9	(0.1)	21.8	
	Core segment profit	1.4	(0.6)	(1.2)	2.3	1.9	0.4	2.3	
	R&D expenses						4.5	(0.0)	4.5
	Core operating profit						(2.8)	0.4	(2.4)

- **Japan:** Higher profit due to increased margin from sales growth and reduced costs
- **North America:** Lower profit mainly due to incremental costs of Sumitovant in spite of higher revenue and reduced costs at Sunovion
- **China:** Profit decreased mainly due to lower revenue

Financial Forecasts for FY2021

Financial Forecasts for FY2021

Financial Forecasts for FY2021 (Core Basis)



Billions of yen

	FY2020 Results	FY2021 Forecasts	Change
Revenue	516.0	578.0	62.0
Cost of sales	137.5	156.0	18.5
Gross profit	378.5	422.0	43.5
SG&A expenses	211.8	263.0	51.2
R&D expenses	97.1	95.0	(2.1)
Core operating profit	69.6	64.0	(5.6)
Changes in fair value of contingent consideration (negative number indicates loss)	22.5	(1.0)	(23.5)
Other non-recurring item (negative number indicates loss)	(20.8)	(2.0)	18.8
Operating profit	71.2	61.0	(10.2)
Net profit attributable to owners of the parent	56.2	41.0	(15.2)
R O E (%)	10.1	6.9	
R O I C (%)	3.1	N/A	

Expect revenue up, profit down for FY2021

■ Revenue:

- Increase mainly in North America by ¥68.2B
- LATUDA® increase by ¥13.9B
- Includes net product revenues from ORGOVYX™, GEMTESA®, relugolix combination tablet (pending FDA approval) as well as collaboration and licensing/milestone revenues from Pfizer (Forecasts are not disclosed)
- Includes revenue from possible new alliance

- **SG&A and R&D expenses:** SG&A will increase mainly due to full sales activity of Sumitovant R&D includes cost reduction by possible new alliance

(Ref.) Expenses related to Sumitovant (¥B)

	2020	2021	Change
SG&A expenses *	46.5	96.0	49.5
R&D expenses	24.6	21.0	(3.6)

The figures are before intra-group elimination

* Include amortization of patent rights

FX rates:

FY20 Results : 1US\$ = ¥106.1, 1RMB = ¥15.7

FY21 Forecasts : 1US\$ = ¥110.0, 1RMB = ¥16.5

Financial Forecasts for FY2021

Segment Information (Core Basis)



Billions of yen

		Pharmaceuticals Business					Other Business	Total	
		Japan	North America	China	Other Regions	Subtotal			
FY2021 Forecasts	Revenue (Sales to customers)	150.0	349.7	29.8	10.3	539.8	38.2	578.0	
	Cost of sales	78.1	38.5	5.5	4.6	126.7	29.3	156.0	
	Gross profit	71.9	311.2	24.3	5.7	413.1	8.9	422.0	
	SG&A expenses	52.9	191.9	10.9	1.6	257.3	5.7	263.0	
	Core segment profit	19.0	119.3	13.4	4.1	155.8	3.2	159.0	
	R&D expenses						94.0	1.0	95.0
	Core operating profit						61.8	2.2	64.0
FY2020 Results	Revenue (Sales to customers)	152.5	281.5	27.8	17.2	479.1	36.9	516.0	
	Cost of sales	77.5	20.8	5.4	5.7	109.4	28.1	137.5	
	Gross profit	75.1	260.7	22.5	11.5	369.8	8.7	378.5	
	SG&A expenses	50.8	143.8	9.2	2.8	206.7	5.1	211.8	
	Core segment profit	24.3	116.9	13.2	8.7	163.1	3.6	166.7	
	R&D expenses						96.2	0.9	97.1
	Core operating profit						66.9	2.7	69.6
Change	Revenue (Sales to customers)	(2.5)	68.2	2.0	(6.9)	60.7	1.3	62.0	
	SG&A expenses	2.1	48.1	1.7	(1.2)	50.6	0.6	51.2	
	Core segment profit	(5.3)	2.4	0.2	(4.6)	(7.3)	(0.4)	(7.7)	
	R&D expenses						(2.2)	0.1	(2.1)
	Core operating profit						(5.1)	(0.5)	(5.6)

- **Japan segment:** Profit will decrease because revenue down mainly due to NHI price revision, and sales expenses up for imeglimin launch
- **North America segment:** LATUDA® will further increase
Sumitovant related profit will decline due to increase in sales costs and amortization despite revenue growth of ORGOVYX™ and GEMTESA®
Possible revenue from new alliance is included
In the segment both revenue and profit will increase
- **China segment:** Revenue will increase due to growth of ALMARL® and LATUDA® but MEROPEN® sales will not change

Financial Forecasts for FY2021

Revenue of Major Products in Japan



Billions of yen

	FY2020 Results	FY2021 Forecasts	Change	
			Value	%
Equa [®] /EquMet [®]	40.1	37.4	(2.7)	(6.8)
Trulicity [®] *	33.9	38.2	4.3	12.8
TRERIEF [®]	16.2	17.9	1.7	10.5
REPLAGAL [®]	13.8	13.8	(0.0)	(0.0)
METGLUCO [®]	9.1	6.9	(2.2)	(24.6)
LATUDA [®]	2.4	6.7	4.3	180.7
LONASEN [®] Tape	1.3	2.5	1.2	96.2
AMLODIN [®]	6.5	5.0	(1.5)	(23.5)
AG products	8.0	10.1	2.1	26.3
Others	21.1	11.5	(9.6)	(45.6)
Total	152.5	150.0	(2.5)	(1.6)

- LATUDA[®], Trulicity[®], TRERIEF[®] will increase
- Expect launch of imeglimin but sales for FY2021 are not large number
- Expect impact of NHI price revision : (¥7.0B)

Note: Sales of each product are shown by invoice price (* Trulicity[®] is shown by NHI price)

Financial Forecasts for FY2021

Revenue of Major Products in North America & China



	FY2020 Results	FY2021 Forecasts	Change	FY2020 Results	FY2021 Forecasts	Change	
						Value	%
North America	Million \$			Billions of yen			
LATUDA®	1,946	2,004	58	206.5	220.4	13.9	6.7
APTIOM®	242	249	7	25.7	27.4	1.7	6.5
BROVANA®	274	106	(168)	29.1	11.7	(17.4)	(59.8)
KYNMOBI™	2	28	26	0.2	3.1	2.9	—
Others	188	792	604	20.0	87.1	67.1	335.9
Total	2,653	3,179	526	281.5	349.7	68.2	24.2
China	Million RMB			Billions of yen			
MEROPEN®	1,435	1,364	(71)	22.5	22.5	0.0	0.0
Others	340	442	102	5.3	7.3	2.0	36.9
Total	1,775	1,806	31	27.8	29.8	2.0	7.1

■ North America: Revenue up

- LATUDA® will increase
- BROVANA® will decrease by GE erosion
- Focus on market penetration of KYNMOBI™
- Sumitovant sales are included in Others (forecast detail is not disclosed)
- Others include revenue from possible new alliance

■ China: Revenue up

- On RMB basis, sales will be in almost same level

FX rates:

FY20 Results : 1US\$ = ¥106.1, 1RMB = ¥15.7

FY21 Forecasts: 1US\$ = ¥110.0, 1RMB = ¥16.5

Research and Development

Research and Development

Development Pipeline (as of May 12, 2021)



 : Psychiatry & Neurology
 : Oncology
 : Regenerative medicine / Cell therapy
 : Others
 : Frontier business
 Revisions since the announcement of Jan. 2021 are shown in red

Area	Phase 1	Phase 2	Phase 3	NDA/BLA submitted
Japan	EPI-589 (ALS)	SEP-4199 (Bipolar I depression)	SEP-363856 (Schizophrenia)	imeglimin (Type 2 diabetes)
	DSP-1181 (Obsessive compulsive disorder)	DSP-7888 (Glioblastoma)	SMC-01 (Mobile App for management of type 2 diabetic patient)	
		Allo iPS cell-derived products (Parkinson's disease/ Investigator-initiated clinical study)		
U.S.	DSP-6745 (Parkinson's disease psychosis)	DSP-0509 (Solid tumors)	SEP-363856 (Schizophrenia)	RVT-802 (Pediatric congenital athymia) BLA resubmitted
	SEP-378608 (Bipolar disorder)	TP-0184 (Hematologic malignancies)	DSP-7888 (Glioblastoma)	
	DSP-3905 (Neuropathic pain)	TP-1287 (Solid tumors)	SEP-4199 (Bipolar I depression)	relugolix (Uterine fibroids)
	SEP-378614 (Treatment resistant depression)	TP-3654 (Hematologic malignancies)	TP-0903 (AML/Research group-initiated clinical study)	GEMTESA® (vibegron) (New indication: OAB in men with BPH)
	SEP-380135 (Alzheimer's disease agitation)	TP-1454 (Solid tumors)	rodatristat ethyl (Pulmonary arterial hypertension)	
	DSP-0038 (Alzheimer's disease psychosis)	TP-0390 (Solid tumors)	URO-902 (Overactive bladder)	
China			LATUDA® (New indication: Bipolar I depression)	
			SEP-363856 (Schizophrenia)	
Europe				relugolix (Prostate cancer/Uterine fibroids)

Clinical Development Status (Major Changes since January 28, 2021)

Submission and Resubmission

- relugolix Prostate cancer MAA submitted in March 2021 in Europe
- RVT-802 Pediatric congenital athymia BLA resubmitted in April 2021 in the U.S.

Advanced

- SEP-363856 Schizophrenia Started Phase 2/3 in Japan and China
- DSP-7888 Glioblastoma Changed from Phase 2 to Phase 3 in the U.S.

Newly added

- DSP-0038 Alzheimer's disease psychosis Started Phase 1 in the U.S.
- DSP-0390 Solid tumors Started Phase 1 in the U.S.
- TP-0903 (dubermatinib) * Acute myeloid leukemia (AML) Ongoing Phase 1/2 in the U.S.

*A study in AML is underway as a research group-initiated clinical study. Deleted due to completed Phase 1 study in the U.S. and Japan for solid tumors

Discontinuation

- BBI608 (napabucasin) Colorectal cancer Phase 3 (the U.S. and Japan) , other solid tumors
- EPI-743 (vatiquinone) Leigh syndrome Phase 2/3 (Japan)

Discontinuation in-house, under activity for out-license

- DSP-2033 (alvocidib) AML (Phase 2 in the U.S.), MDS (Phase 1/2 in the U.S.)
- DSP-0337 Solid tumors (Phase 1 in the U.S.)

Main Event / Target for FY2021

Psychiatry & Neurology

- ❑ SEP-363856 :
 - ❑ Start clinical program for the development (global study) of new indication
 - ❑ Advance Phase 3 study in the U.S. and Phase 2/3 study in Japan and China for schizophrenia
- ❑ SEP-4199 : Start Phase 3 study for Bipolar I depression

Oncology

- ❑ DSP-7888 : Advance global Phase 3 study for glioblastoma

Regenerative medicine / Cell therapy

- ❑ RVT-802 : Obtain approval for pediatric congenital athymia in the U.S.
- ❑ Allogeneic iPS cell-derived products (AMD: age-related macular degeneration) : Start clinical study
- ❑ Allogeneic iPS cell-derived products (Parkinson's disease) : Complete transplant in investigator-initiated clinical study

Infectious Diseases

- ❑ Antimicrobial resistance (AMR), universal influenza vaccine, malaria vaccines : Promote joint research and development projects

Others

- ❑ relugolix : (U.S.)
 - ❑ Obtain approval for uterine fibroids
 - ❑ Submit NDA for endometriosis
- ❑ relugolix : (Europe)
 - ❑ Obtain approval for uterine fibroids
 - ❑ Submit MAA for endometriosis
- ❑ imeglimin : Obtain approval for type 2 diabetes in Japan

Frontier

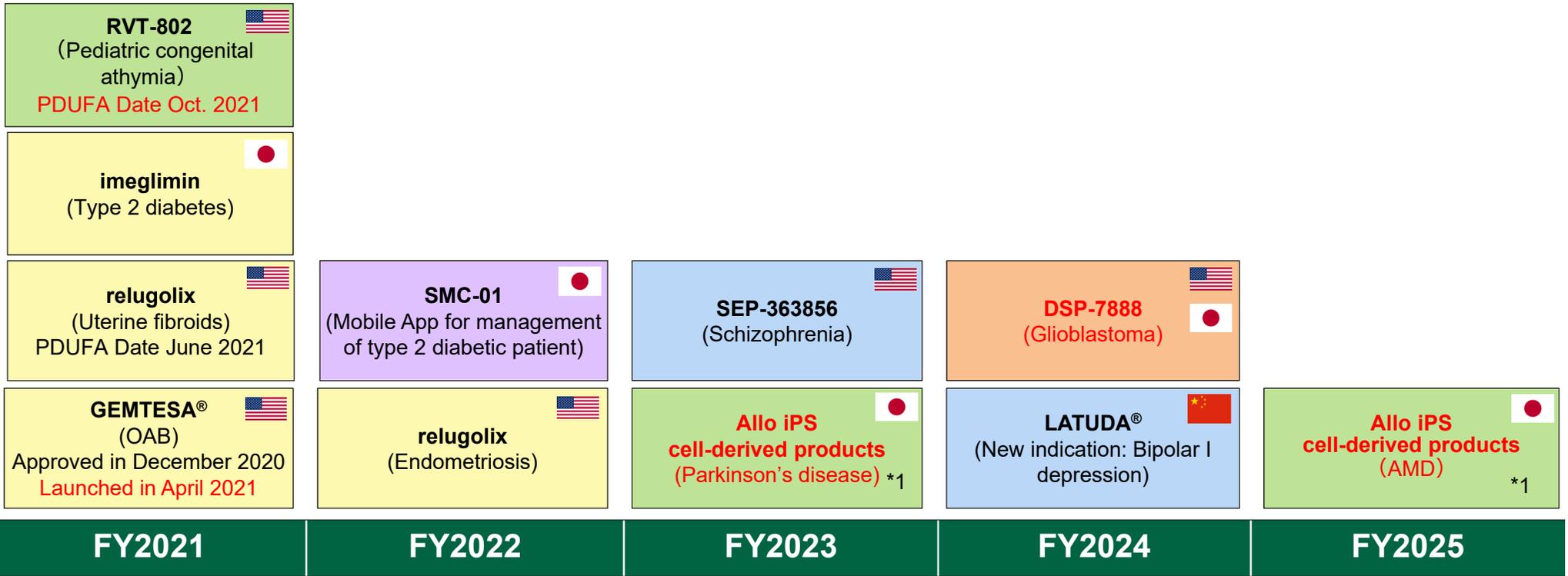
- ❑ Promote the current themes (MELTIN, Aikomi, Drawbridge, BehaVR, and internal themes), development of new themes

Research and Development

Product Launch Target (as of May 12, 2021)



Revisions since the announcement of Jan. 2021 are shown in red



Plan to launch multiple frontier business items from FY2023 to FY2025  

-  : Psychiatry & Neurology
-  : Oncology
-  : Regenerative medicine / cell therapy
-  : Others
-  : Frontier business

*1 Launch schedule is based on our goal pending agreement with partners

Revision of Mid-term Business Plan 2022

Background of Revision of Mid-term Business Plan 2022

- April 2019: Publication of Mid-term Business Plan 2022
 - ✓ Reshape business foundation through the “establishment of a growth engine” and the “building of a flexible and efficient organization,” preparing for the “Time for Change” and post-LATUDA revenue replacement
- ▼
- We decided to form the Strategic Alliance with Roivant due to a significant change in the medium- to long-term business outlook after the events such as discontinuation of development of napabucasin for pancreatic cancer which was expected as a revenue driver in post-LATUDA
 - ✓ Acquired relugolix and vibegron, which are expected to be the immediate revenues base
- ▼

Revision of Mid-term Business Plan 2022

- **Currently working on (1) maximizing the product value of relugolix and vibegron and products that are expected to contribute to latest revenues, (2) advancing R&D activities for medium- to long-term growth, (3) advancing the reinforcement of business infrastructure to strengthen the company**

Corporate Mission and CSR-Based Management

Corporate Mission

To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide

- ❑ Define implementation of corporate mission as “CSR-based management” and set material issues of CSR-based management (Materiality)
- ❑ Address material issues, aimed at solving social challenges and enhancing corporate value through our core competencies

Material issues linked to value creation

- solving issues is important for our sustained growth



Material issues that forms the foundation for business continuity

- solving issues is essential for our sustained growth

- Respecting human rights
- Corporate governance
- Compliance
- Risk management
- Fair and transparent corporate activities
- Corporate regulatory compliance, quality assurance and stable supply
- CSR procurement
- Health, safety, and welfare of employees
- Environmental initiatives



Contribute to improved quality of life (QOL) for patients and their families

Improve and sustain corporate value

- Returns to shareholders (stable dividends, increases in dividends linked to improvements in performance)
- Strategic investment aimed at sustained growth (includes research and development investment)

Also contributing to achieving the Sustainable Development Goals (SDGs)

3 GOOD HEALTH AND WELL-BEING

8 DECENT WORK AND ECONOMIC GROWTH

12 RESPONSIBLE CONSUMPTION AND PRODUCTION

17 PARTNERSHIPS FOR THE GOALS

Vision For Longer and Healthier Lives
We unlock the future with cutting-edge technology and ideas

Aspire to establish a position as a “Global Specialized Player” with ability to meet increasingly diversified needs for healthcare in 2033



Mid-Term Business Plan 2022: Rebuild Business Foundation

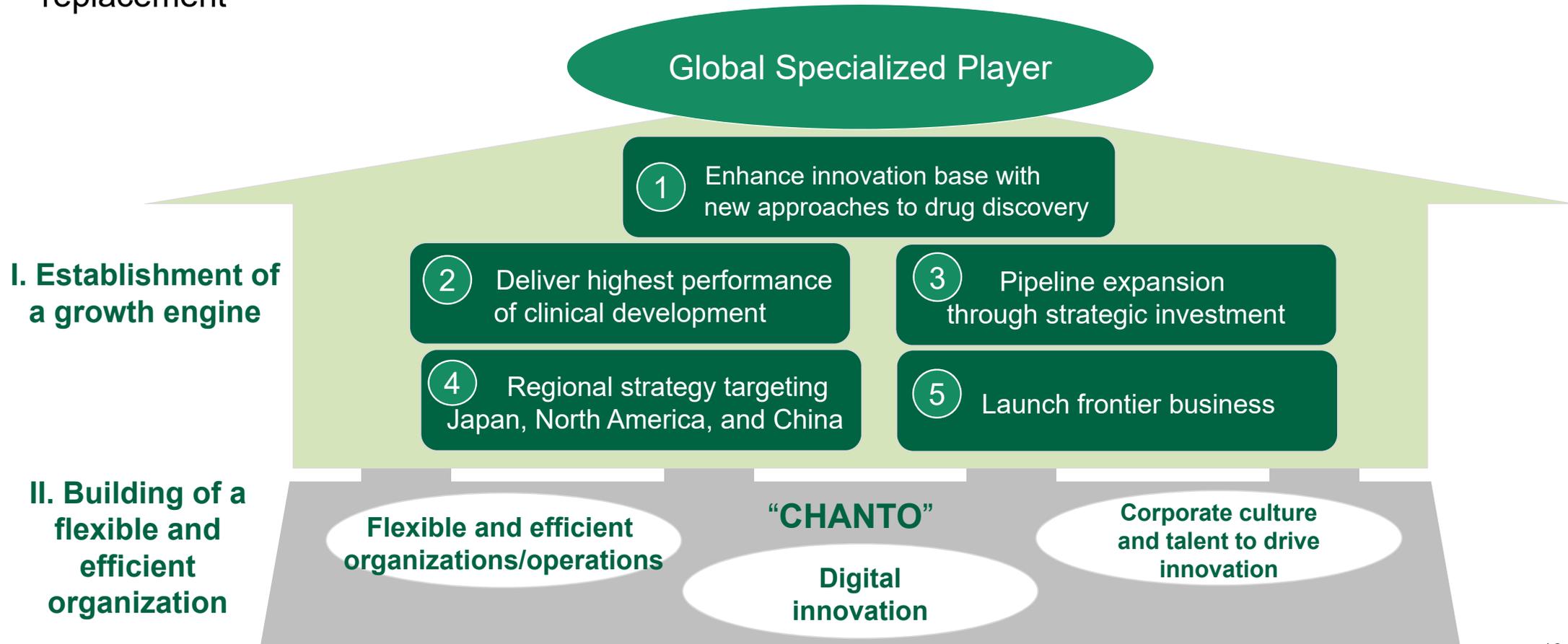
Establishment of growth engine + Building of flexible and efficient organization

Acceleration of our growth by strategic alliance with Roivant

Driver of sustained growth after LATUDA® LOE + Innovative change to new business model based on data technology of DrugOME and Digital Innovation

Mid-term Business Plan 2022: Basic Strategies

Reshape business foundation through the “establishment of a growth engine” and the “building of a flexible and efficient organization,” preparing for the “Time for Change” and post-LATUDA revenue replacement



Mid-term Business Plan 2022: Progresses and Updates

Significant changes in business outlook after LATUDA® LOE

	Positive events	Negative events
North America	<ul style="list-style-type: none"> ■ KYNMOBI™ (PD): Launched ■ ORGOVYX™ (Prostate cancer): Launched ■ GEMTESA® (Overactive bladder) : Launched ■ relugolix combination tablet (Uterine fibroids): NDA submitted ■ SEP-363856 (Schizophrenia): POC obtained (BTD), phase 3 started ■ SEP-4199 (Bipolar depression): Phase 3 in preparation ■ RVT-802 (Pediatric congenital athymia): BLA resubmitted 	<ul style="list-style-type: none"> ■ LONHALA® MAGNAIR® (COPD): Downward revision of marketing plan ■ KYNMOBI™ (PD): Delay of approval & downward revision of marketing plan ■ dasotraline (ADHD, BED): Withdrawal of application in U.S. / discontinuation of development ■ SB623 (Chronic stroke): Discontinuation of development / return of rights
North America, Japan	<ul style="list-style-type: none"> ■ DSP-7888 (Glioblastoma): Advanced to phase 3 (In process in Japan) 	<ul style="list-style-type: none"> ■ napabucasin (Pancreatic cancer/Colorectal cancer): Discontinuation of development ■ alvocidib (Hematologic malignancies): Discontinuation of in-house development / working on out-licensing ■ amcasertib (Solid tumors): Discontinuation of development
Japan	<ul style="list-style-type: none"> ■ Equa®/EquMet® (Diabetes): Marketing alliance ■ LONASEN® Tapes (Schizophrenia): Launched ■ LATUDA® (Schizophrenia / Bipolar depression): Launched ■ SEP-363856 (Schizophrenia): Phase 2/3 started ■ imeglimin (Diabetes): NDA submitted 	<ul style="list-style-type: none"> ■ LONASEN® Tapes (Schizophrenia): Downward revision of marketing plan ■ EPI-743 (Leigh syndrome): Discontinuation of development
China	<ul style="list-style-type: none"> ■ LATUDA® : Launched (Schizophrenia), Phase 3 started (Bipolar depression) ■ SEP-363856 (Schizophrenia): Phase 2/3 started 	

■ Psychiatry & Neurology ■ Oncology ■ Regenerative / Cell ■ Other

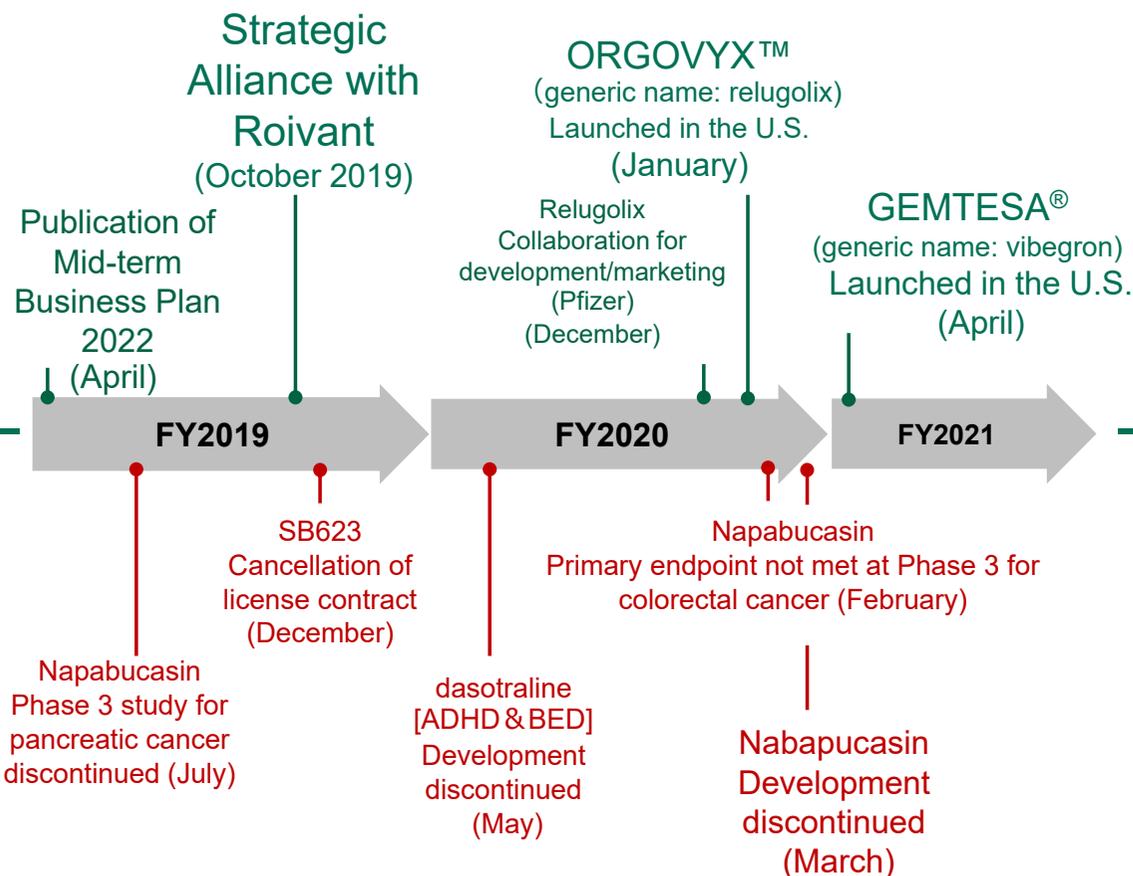
PD: Parkinson's disease; ADHD: attention-deficit hyperactivity disorder; BED: binge eating disorder; COPD: chronic obstructive pulmonary disease; POC: proof of concept; BTD: breakthrough therapy designation

Revision of Mid-term Business Plan 2022 (Positioning of the Revision)



Mid-term Business Plan 2022 : Major Changes in Business Conditions after Publication

A Decision on Strategic Alliance with Roivant



C Discontinued development of the pipelines

B Downward revision of marketing plans of the new products

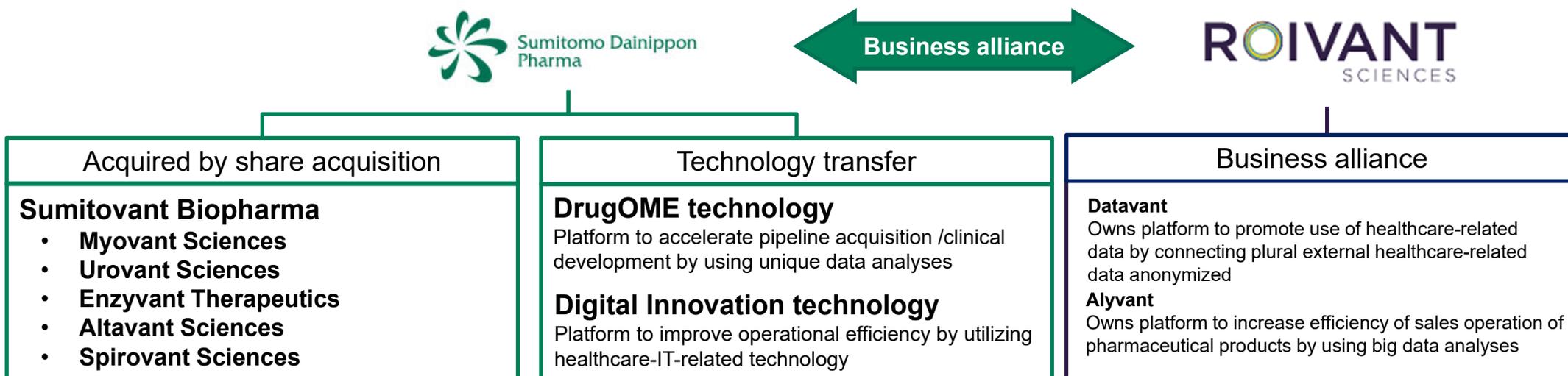
- LONHALA® MAGNAIR® [COPD]: Marketed in the U.S.
- KYNMOBI™ [PD]: Marketed in the U.S.
- LONASEN® Tape [Schizophrenia]: Marketed in Japan

D Acceleration of drug cost reduction measures

- Japan: Initiation of annual NHI drug price revision (FY2021)
- China: Expansion of centralized purchasing system or price bargaining system
- U.S.: Penetration of value-based pricing, possibility of introduction of international reference pricing

Effects of Strategic Alliance with Roivant

- ❑ Acquisition of revenue base in 2023 and beyond
 - ✓ relugolix (Myovant) and vibegron (Urovant)
- ❑ Expansion of pipelines
 - ✓ Acquisition of multiple assets with new modalities and unique characteristics
- ❑ Acquisition of digital technology platforms
 - ✓ DrugOME, Digital Innovation
- ❑ Expansion of global business alliances with acquisition of various talented human resources

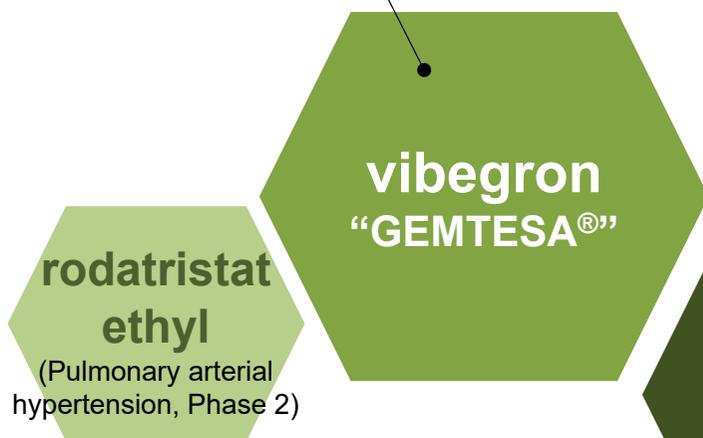


Revision of Mid-term Business Plan 2022 (Effects of Strategic Alliance with Roivant)

Acquisition of Pipelines that may Contribute to Early Revenue Generation and Development of Modalities



- Overactive bladder (marketed / U.S.)
- Overactive bladder with prostatic hyperplasia (Phase 3)



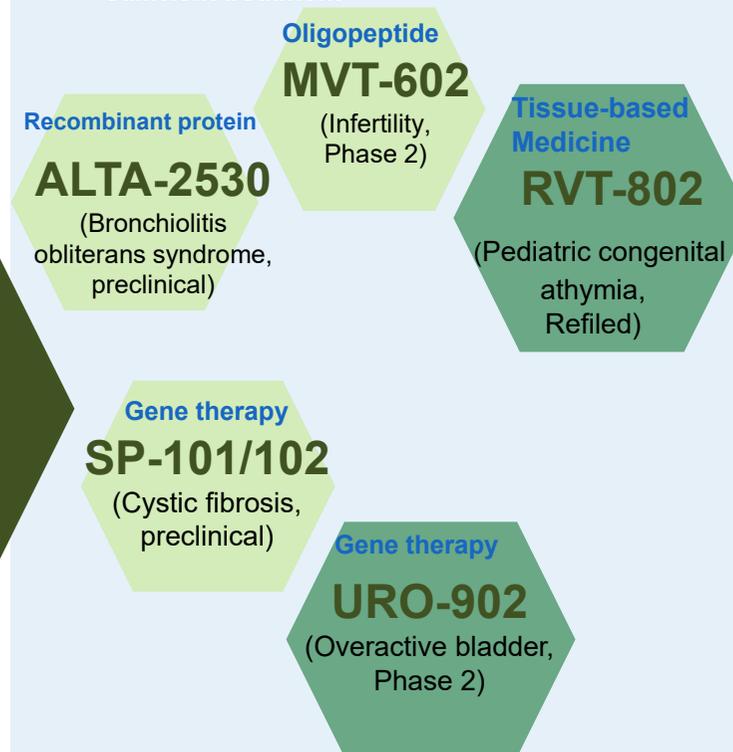
- Prostate cancer (marketed / U.S., submitted / Europe)
- Uterine fibroids (submitted / U.S. and Europe)
- Endometriosis (preparing for submission / U.S. and Europe)

(U.S.: Development / marketing alliance with Pfizer)
(Europe: Development / marketing alliance with Gedeon Richter (Gynecology area))



Non-low-molecular modalities

- Definitive therapy or continued duration of action can be expected
- For patients with any disease for which there is no sufficient treatment

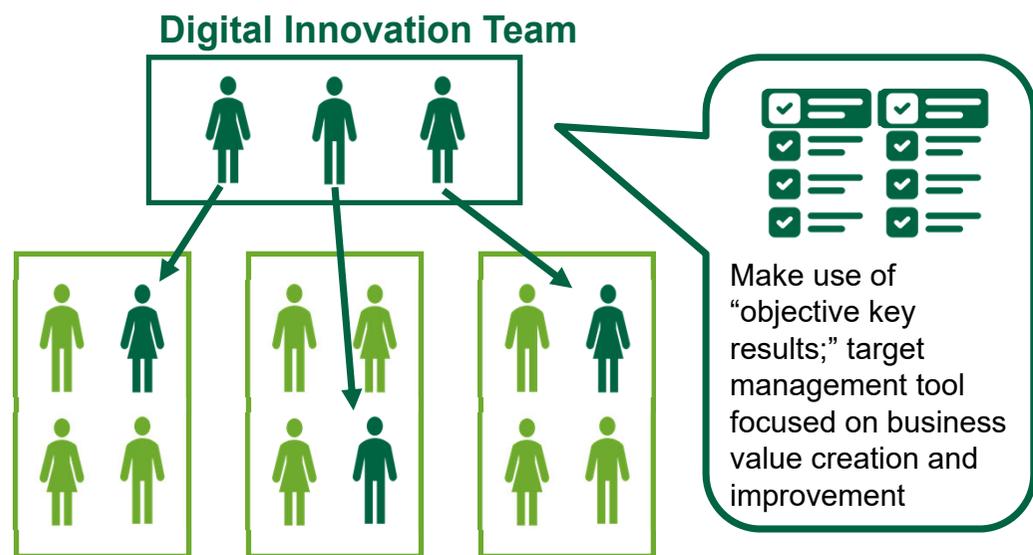


*Owned by Myovant, a publicly traded company in which Sumitovant is a majority shareholder

Development of “Digital Innovation” in Our Whole Company Group

- ❑ Expect improved probability of success in operations across whole group companies and R&D as well as impact on the return on investment goal

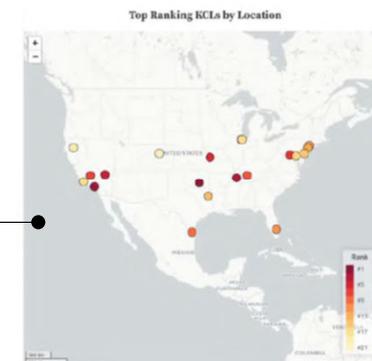
- Deploy digital innovators to each department/group
- Make efforts to solve problems on site and cooperate with each other cross-functionally



Each subsidiary/department

- Create a position of Chief Digital Officer responsible for our whole company group
- Foster citizen data scientists

- Research for drug discovery
 - Identifying targets of research for new drug discovery based on information analyses utilizing a unique AI algorithm (DrugOME)
- Non-clinical study
 - Automated data acquisition utilizing image recognition
- Clinical study
 - Optimization of development strategy based on real world data analyses (DrugOME)
- Marketing operation
 - Productivity enhancement by effective and timely KOL mapping



Initiatives for Medium-to-Long-Term Growth

Pursuit of efficiency in management

① Structural reform to enhance company strength

- a. Initiatives for business promotion
- b. Initiatives for business structure

Corporate culture/human resources

② Nurturing of corporate culture with professional talent that drives innovation

Establishment of revenue base

① Initiatives to maximize revenue from key products in the market

Stepping stone to medium-to-long-term growth

② Investment in pipelines expected to become major products in global market

Initiatives to utilize our competitive technology/know-how

③ Creation of products in Psychiatry & Neurology area on a consecutive basis

④ Initiatives and practical application of new therapies by developing modality

Challenge to start new businesses

⑤ Acceleration of frontier business development

Strengthening of management base

Establishment of growth engine

Corporate mission, CSR-based management

① Structural reform to enhance company strength

Launching initiatives to deal with environmental changes in the pharmaceutical industry and uncertainty after LATUDA® LOE

a. Initiatives for business promotion

- Consideration/promotion of partnering on global basis to maximize revenue and cost reduction
- Optimization of investment to R&D pipelines, sales and administrative costs suited to business scale
- Consideration/promotion of selling products that have reached loss of exclusivity (LOE) and R&D assets

b. Initiatives for business structure

North America

- ❑ Continued initiatives for optimization of infrastructure in North America
- ❑ Initiatives for creation of cost synergy by strengthening alliance among subsidiaries
 - Utilization of marketing platform of Sunovion (distribution or marketing functions, etc.)
 - Strengthening of shared service operations in North America by SDPA*

Europe

- ❑ Initiatives to optimize the structure to maintain sustainable revenue for business operations in Europe

Japan

- ❑ Initiatives to optimize the structure to maintain sustainable revenue for business operations in Japan
 - Business operation based on the assumption of shrinkage of the size of pharmaceutical market in Japan
 - Review global head office functions for optimization
 - Maximize sales/profits through partnerships with external parties and promotion of internal cost reduction

China / Asia

- ❑ Maximize sales/profits through partnerships with external parties and promotion of internal cost reduction
- ❑ Business expansion to geographical areas likely to contribute to our profits

② Nurturing of corporate culture with professional talent that drives innovation

- **Penetration/practice of “CHANTO”**
 - Deliver highest performance (“CHANTO”) to achieve the goals, while responding to environmental changes
 - The Conduct Guidelines are to be observed by each of our employees to establish our position as a global specialized player by 2033
 - Promote a company-wide project, aiming at understanding/penetration and practice/habituation of the Guidelines at each workplace, which was verbalized by our executive officers
- **Foster an organizational culture characterized by agility (quick and flexible) and unrelenting efforts instead of satisfaction with the status-quo**
- **Develop next-generation leaders by strategic personnel distribution and education/training program for selected employees**

“CHANTO” concept and key visual

CHANTO

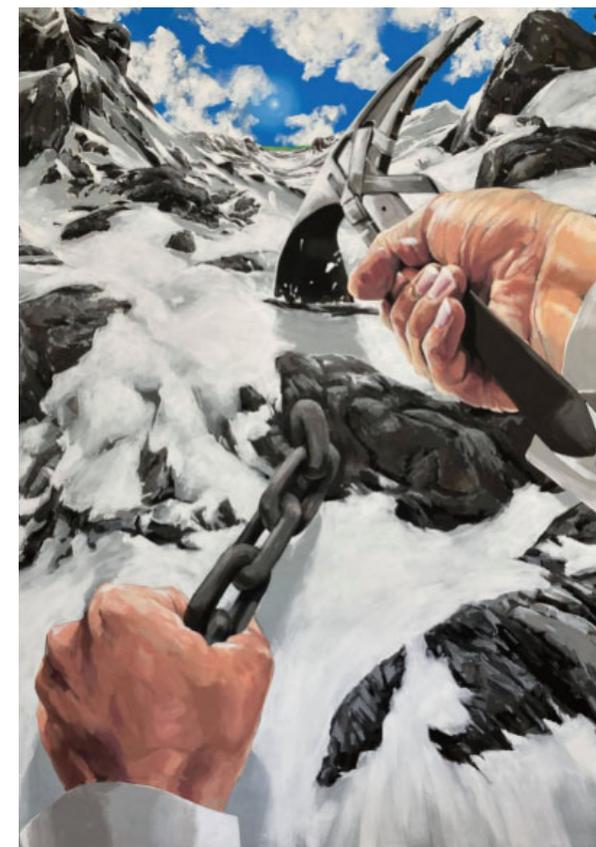
The era in which we cannot survive without each person's challenge

Drive in an anchor
Pave the way for ourselves

Supporting and encouraging each other,
Aim for the summit together

All leading roles, all supporting roles

Climb with our own strength
to realize the future we envision



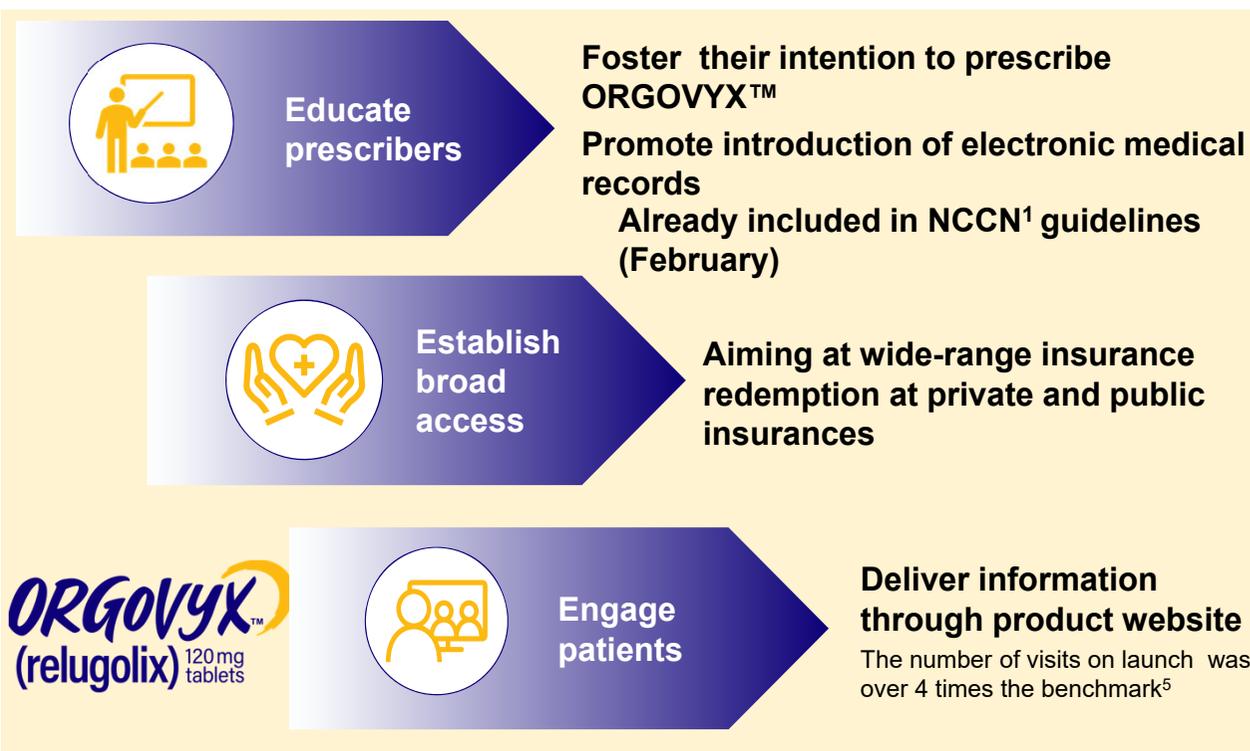
Establishment of Growth Engine: Establishment of Revenue Base

1 Initiatives to maximize revenue from key products in the market

- **ORGOVYX™*/**
relugolix* combination tablet (to be launched in 2021)
 - ▮ Maximize sales through alliance with Pfizer
 - ▮ Pursue synergies in costs by utilizing Sunovion's commercial capabilities (distribution)
- **GEMTESA®**
 - ▮ Pursue synergies in costs by utilizing Sunovion's commercial capabilities (marketing, distribution)
 - ▮ Maximize revenue outside of North America: partnership with external parties
- **LATUDA®**
 - ▮ North America: Leverage digital transformation for effective marketing operations that impact earnings
 - ▮ Maximize sales by expanding to Japan, China, and Asia
- **KYNMOBI™**
 - ▮ Concentrate on start-up in the U.S.
 - ▮ Maximize revenue outside of North America: partnership with external parties
- **Antidiabetics in Japan**
 - ▮ Maximize launched products and imeglimin by utilizing the infrastructure of the top sales company in the Japanese antidiabetic market

Realization of Product Value Maximization of Relugolix (North America)

❑ Achieve smooth market penetration and maximize product value by utilizing infrastructure and expertise of Pfizer under co-promotion agreement



Characteristics of ORGOVYX™ (Prostate cancer)

- Oral drug
- No occurrence of sharp increase of hormone transient
- Continuous and rapid decrease of PSA²
Rapid recovery of testosterone³

Characteristics of relugolix combination tablet (for gynecological diseases)

- Single dosage and administration
- Oral drug, one tablet once daily
- Favorable safety profile (incidence of hot flash: 5.6-13.6%⁴)

(1) NCCN, National Comprehensive Cancer Network

(2) PSA levels were monitored in the clinical study. The levels declined throughout the treatment period of 48 weeks: 65% decline in average after 2 weeks from initiation of ORGOVYX™, 83% after 4 weeks, and 92% after 3 months.

(3) On day 90 after termination of ORGOVYX™ administration, 55% of patients attained a testosterone level of the lower limit ($\geq 280\text{ng/dL}$) or over the baseline.

Source: Shore ND, Saad F, Cookson MS, et al. Oral relugolix for androgen-deprivation therapy in advanced prostate cancer. New England Journal of Medicine. 2020 June 4. DOI: 10.1056/NEJMoa2004325

(4) SPIRIT1 1 TLR: 2020/6/23 Webcast, SPIRIT 2 TLR: 2020/4/22 Webcast, LIBERTY 1/2: N Engl J Med 2021; 384:630-42

(5) DTC benchmark of cancer therapeutic drugs = The product website is visited 175 times/day

ORGOVYX™ prescribing information is available from www.myovant.com/orgovyx-prescribing-information.pdf.

Realization of Product Value Maximization of GEMTESA® (North America)

- ❑ Pursue group synergies between Urovant and Sunovion to optimize marketing structures for urology specialists, long-term care facilities, and primary care providers with high frequency of prescription to realize early maximization of the product value

Brand Vision

Establish GEMTESA® as the best in category treatment option for patients suffering from symptoms of overactive bladder (OAB)

1 Anchor launch performance through a focus in urology

2 Establish leadership for OAB in long-term care

3 Broaden uptake in primary care for OAB patients

4 Secure and maintain access and affordability for patients and healthcare professionals

5 Drive awareness, education and advocacy for OAB patients



Characteristics of GEMTESA®

- ✓ Single dose and administration, crushable tablets
- ✓ Dose adjustment not required¹
- ✓ Data on frequency of urge to urinate are stated in the package insert
- ✓ No warning for blood pressure increased
- ✓ No warning for drug interactions related to CYP2D6

(1) Treatment with Jemtesa for patients is started with prescription of 75 mg as initial and effective dose. Source: GEMTESA® U.S. FDA label for the treatment of overactive bladder. GEMTESA® prescribing information is available from www.gemtesa.com.

2 Investment in pipelines expected to become major products in global market

- **SEP-363856**
 - ▮ Advance Phase 3 study for schizophrenia
- **SEP-4199**
 - ▮ Initiate Phase 3 study for bipolar I disorder
- **rodatristat ethyl**
 - ▮ Advance Phase 2b study for pulmonary arterial hypertension

Utilization of external resources for maximization of revenue

- Collaboration with business partners to maximize operations is expected
- Out-licensing in geographies outside of North America, Japan and Asia

Advance of global study

- Advance of efficient clinical study and solution of time-lag

SEP-363856

【Indications】 Schizophrenia, symptoms of other psychiatric disorders

【Characteristics】 **Psychotropic drug with new mechanism of action, which does not act on dopamine receptors**

Designated as breakthrough therapy for schizophrenia

【Launch】 U.S.: Targeted for FY2023
Japan/Asia : Targeted for latter half of the 2020s

rodatristat ethyl

【Indications】 Pulmonary arterial hypertension

【Characteristics】 Due to new mechanism, this drug can be concurrently used for pulmonary arterial hypertension (tryptophan hydroxylase inhibitor)

Based on approach, expect to see **disease modifying effects** instead of symptomatic treatment

【Launch】 U.S./Japan/Asia: Targeted for latter half of the 2020s

Revision of Mid-term Business Plan 2022 (Initiatives for Medium-to-long-term Growth)

Establishment of Growth Engine: Initiatives to Utilize Our Competitive Technology/Know-how (1)



3 Creation of products in Psychiatry & Neurology area on a consecutive basis

- **Enhance probability of success in clinical settings**

Sumitomo Dainippon 15% (6-8% industry average*)

- ▣ Further improvement by utilization of biomarkers

- **Expand early pipeline**

12 candidates in the past 3 years

- ▣ Psychiatry (Phase 1; underlined)

SEP-380135, SEP-378614, DSP-1181,

DSP-0038, DSP-2342, DSP-3456

- ▣ Neurology

DSP-0187, DSP-0378, DSP-0551,

DSP-4240, DSP-7970

Extensive experience with clinical studies

- Launched 8 products since 1995

High-tech exploratory/development research aiming at improvement of efficacy in humans

- Utilization of AI
- Analysis of mechanism of action by optogenetics
- Utilization of high predictability biomarkers such as brain waves
- High-tech phenotype drug discovery
- Initiatives for new modalities

Organizational structure to support product creation on a consecutive basis

- Research project system integrated from idea generation to clinical levels
- Virtual one-team system to stimulate cross-sectional collaboration

4 Initiatives and practical application of new therapies by developing modality

- **Provide treatment options to patients with a disease that has no sufficient treatment, aiming at radical cure**
 - ▣ Cellular / tissue / transplanted organ drugs
 - ▣ Gene therapy
 - ▣ Protein drugs

Utilizing world-leading capability for regenerative / cellular drugs

- Application of world-leading iPS technology in clinical setting
- Utilization of infrastructure/know-how/human resources of the core technology for practical use (manufacturing)
- Efforts to deregulate regulatory affairs

Utilization of human resources who have knowledge about respective modalities; building of technological base

Allogenic iPS cell-derived drugs (Parkinson's disease)

【Indications】 Parkinson's disease

【Characteristics】 Co-development of **iPS cell-derived drug** with Center for iPS Cell Research and Application, Kyoto University. The drug is expected to recover nerve function.

Designated as Sakigake drug in Japan

【Launch】 Japan: Targeted for FY2023

(Clinical study is to be started in the U.S. in FY2022)

RVT-802

【Indications】 Pediatric congenital athymia

【Characteristics】 **The world's first drug of cultured thymus tissue** for fatal/congenital diseases

Designated as Regenerative Medicine

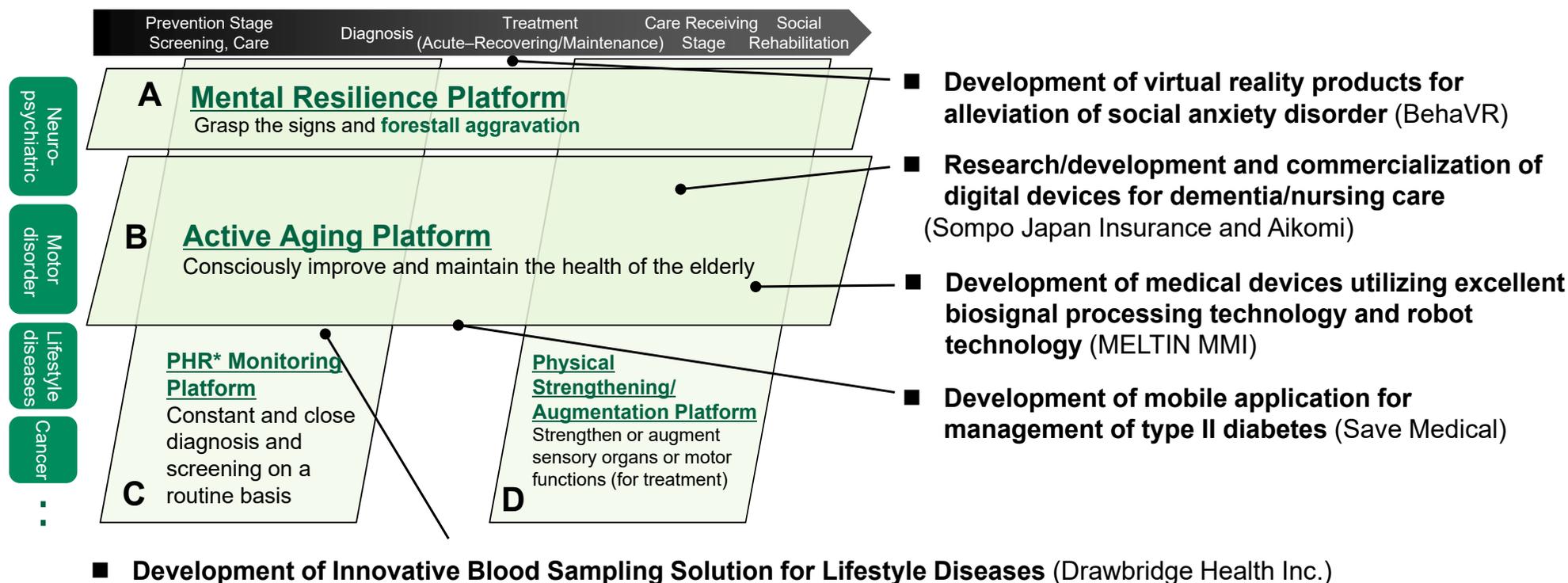
Advanced Therapy designation in the U.S., etc.

【Launch】 U.S.: Targeted for FY2021

Establishment of Growth Engine: Challenge to Start New Businesses

5 Acceleration of frontier business development

Continue investment in potential technologies and businesses in the areas aiming to contribute through all stages from prevention to social rehabilitation



*PHR: Personal Health Record

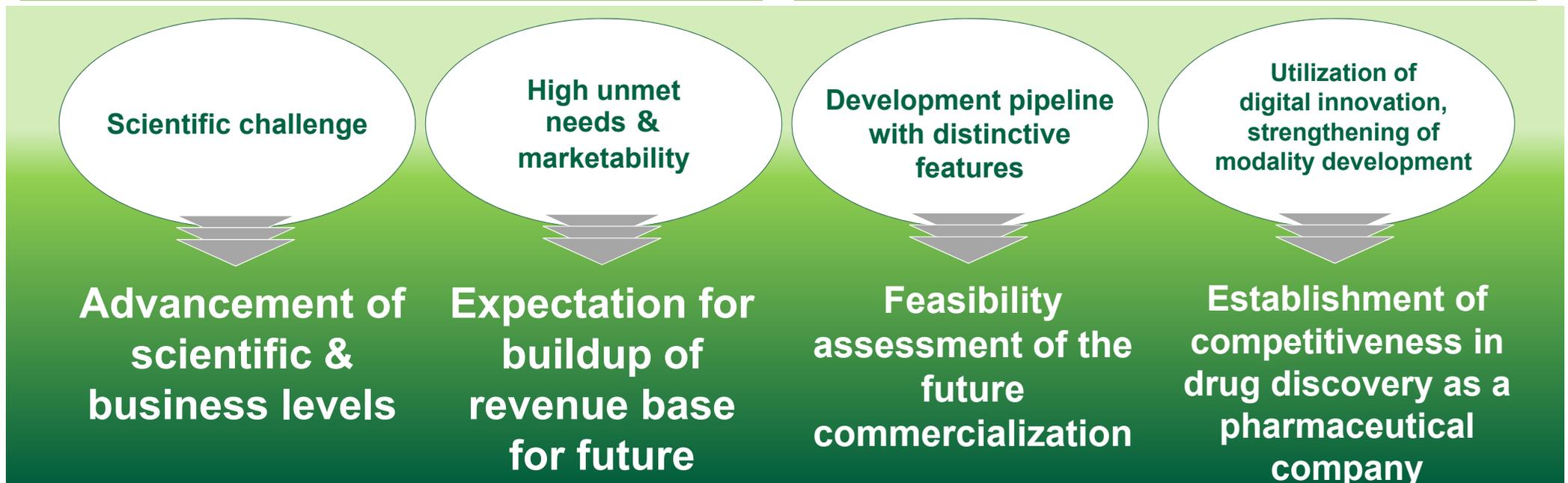
Policy of Approaching Oncology Area

❑ Revisit the R&D policy in oncology and undertake challenges on a continuous basis

- Development: Initiatives focused on assessment of value of existing pipelines
- Discovery research: Work continuously on drug discovery in pursuit of our competitive edge
- Promote business collaboration/out-licensing operation

Meaning of continuation

Our approach

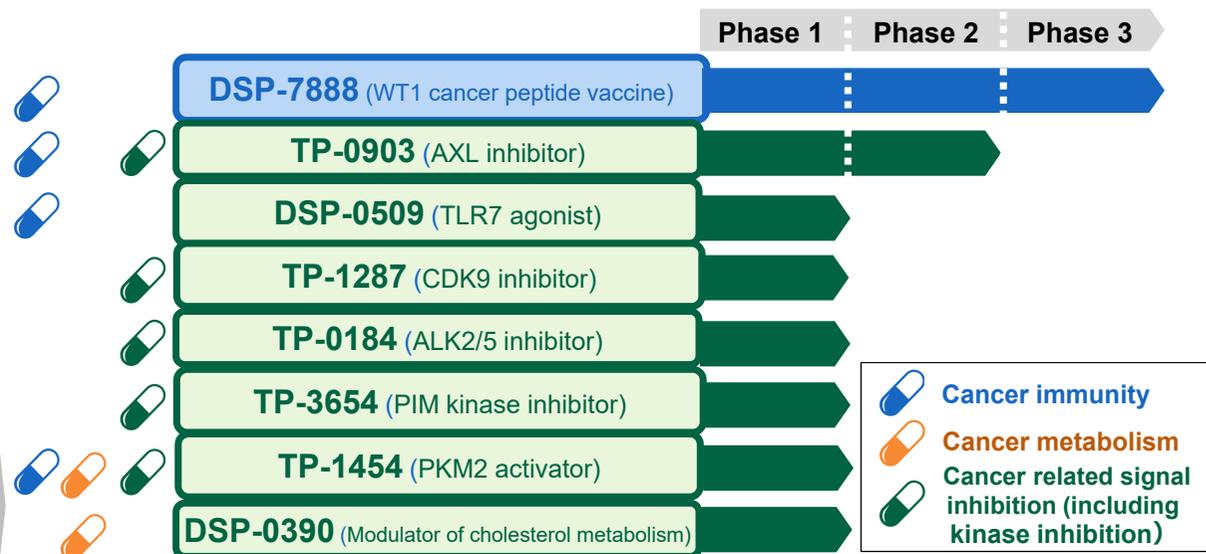


Initiatives for Existing Development Pipeline

□ Aim at early assessment of product value and commercialization

• **Strengthen initiatives to identify the types of cancer/patients optimally through brief and small-scale tests**

- ▣ Actively utilize adaptive design
- ▣ Strengthen connection between research and development
 - ✓ Translational research from research to clinical practice
 - ✓ Feedback between clinical data and research
- ▣ Analyze clinical and research data obtained by our own digital technology



Early assessment of product value

DSP-7888

【Indications】 Glioblastoma, other solid tumors (combined with immune checkpoint inhibitor)

【Characteristics】 The world's first WT1 cancer peptide vaccine for immunotherapy, which activates both helper T cells/cytotoxic T cells

【Launch】 U.S.: Targeted for FY2024 (indicated for glioblastoma)



Multiple new themes in progress specified by utilizing DrugOME

- ✓ Selection of target candidates for drug discovery based on literature with natural language processing technology used; exhaustive analyses of database information and trend forecasts



Utilization of our new technology

- ✓ Drug discovery based on distinctive pharmacological concept
 - DSP-7888 (peptide vaccine that enables to activate both helper T cells and cytotoxic T cells)
- ✓ Initiatives for technology aiming at higher levels of efficacy and safety:
 - New concept ADC: AiADC* (Antitumor activity is expected only within the target tumor cells)



Actively seeking of external input

- ✓ Participate in the planning of Beat AML Study led by LLS**: TP-0903 (indicated for AML)
- ✓ Searching for indicated type of cancer by joint research: TP-3654 (University of Virginia), TP-0184 (DFCI***)

Establishment of competitiveness
in drug discovery

Future Outlook

Review of Financial Goals

Throughout the Mid-term Business Plan 2022

- ❑ Focus on early expansion of new Sumitovant products
- ❑ Continue investment in research and development for medium-to-long-term growth (≥90 billion yen/year)
- ❑ Promote world-wide operational excellence by strengthening the management base and business structure
 - Optimize the business structure in North America, improve R&D productivity, active collaboration with external parties, etc.

	FY2022 Financial Goals (Published in April 2019)		FY2022 Financial Goals (Revised in May 2021)		Outlook for FY2025
Revenue	600 billion yen		600 billion yen		approx. 750 billion yen
Core operating profit	120 billion yen		60 billion yen		approx. 120 billion yen
ROIC	10 %		3 %		Long-term vision
ROE	12 %		3 %		ROE ≥10% in latter half of the 2020s
5-year average payout percentage	≥20 %		≥20 %		

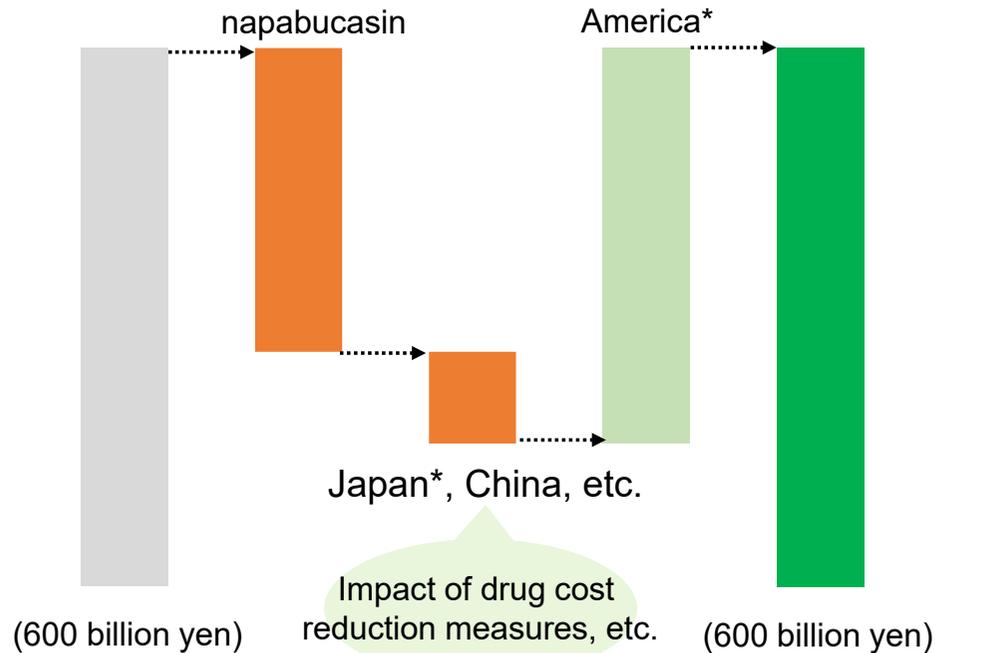
Exchange rate : 110 yen to the dollar 39

Factors to Be Reviewed for Financial Goals for FY2022

Revenue

Financial goals for FY2022

(Published in April 2019)



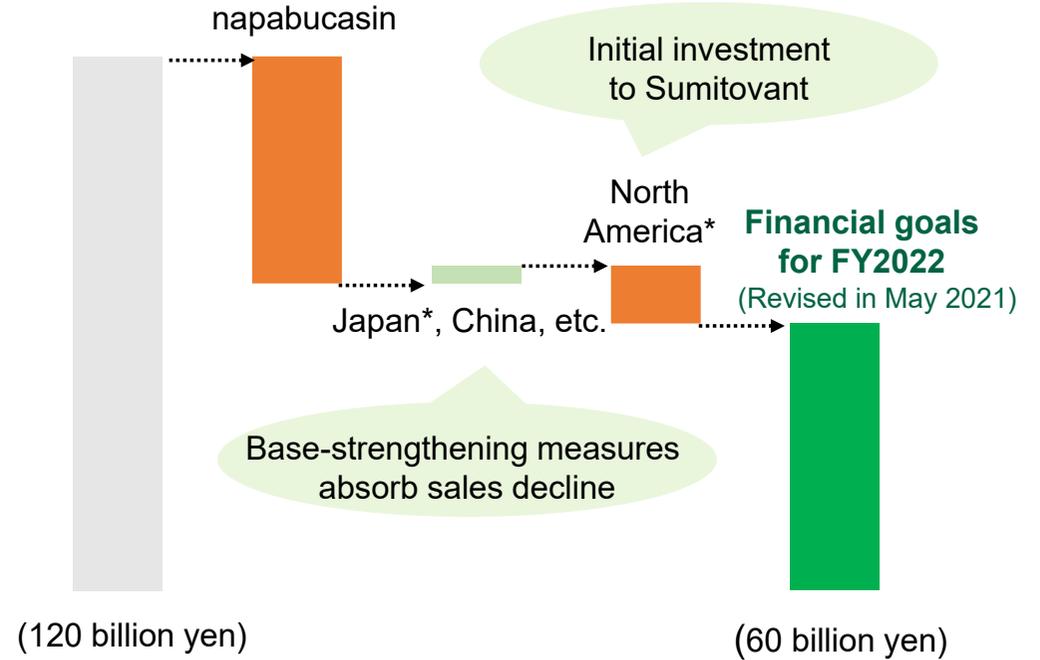
Financial goals for FY2022

(Revised in May 2021)

Core operating profit

Financial goals for FY2022

(Published in April 2019)

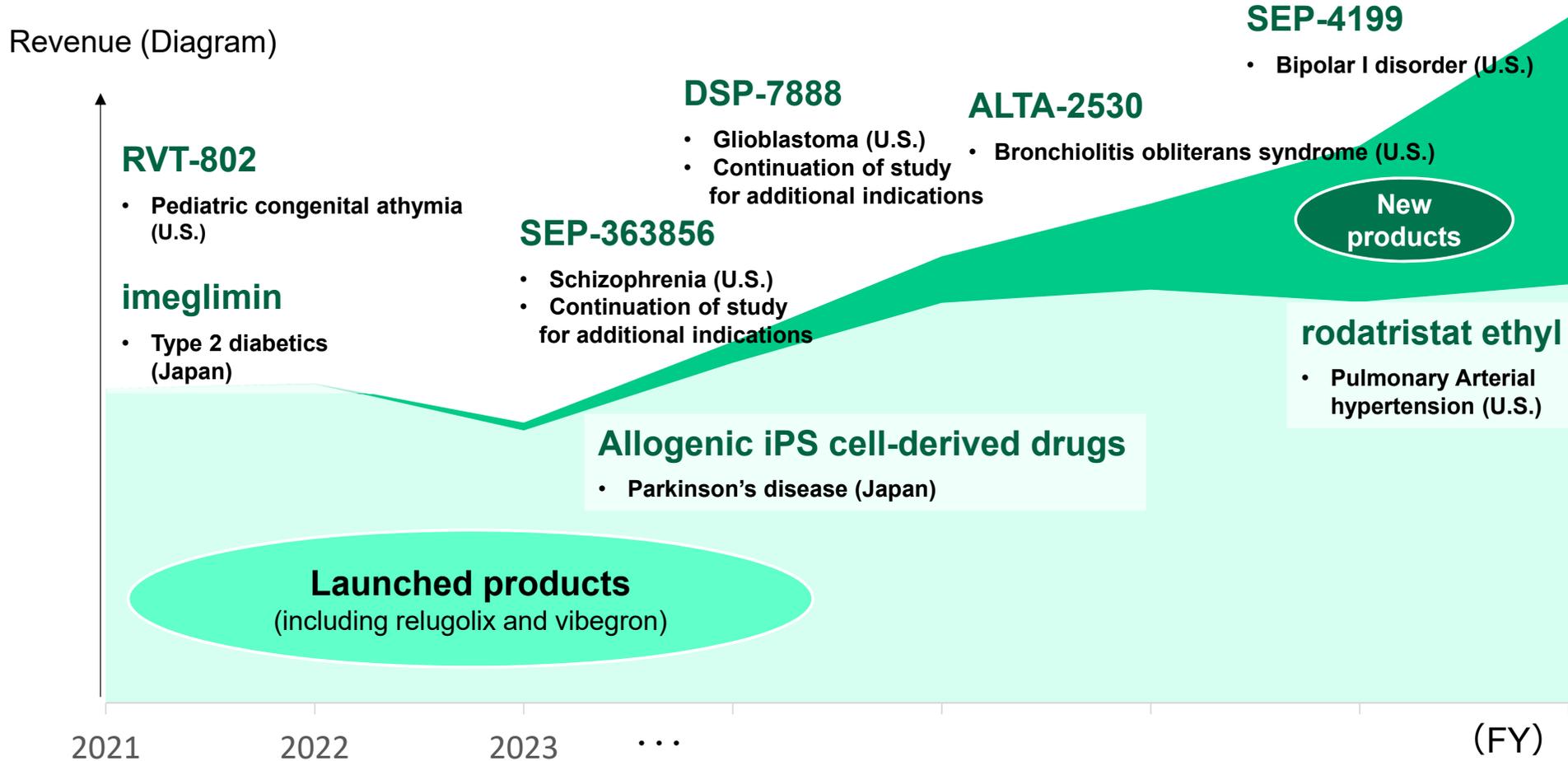


(Diagram)

*Exclude napabucasin

Future Outlook

Realization of Long-term Growth with Success of Promising Products



Change of Trade Name and Relocation of Tokyo Head Office

Change of Trade Name

Scheduled Date for Change : April 1, 2022

**New Trade
Name**

Sumitomo Pharma Co., Ltd.

- In order for the company to grow continuously, we have decided to change the name of the company from "Sumitomo Dainippon Pharma" to "Sumitomo Pharma" with the aim of maximizing the use of the simple and globally accepted "Sumitomo" brand and changing toward a new business stage
- To change trade names of consolidated subsidiaries (excluding Sunovion, Sumitovant group, and S-RACMO)

 住友ファーマ
 Sumitomo Pharma

Relocation of Tokyo Head Office

Scheduled Date of Relocation : the middle of 2022

New Address

**Tokyo Nihonbashi Tower (11F, 12F, 16F),
7-1 Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan**



- Nurturing of a sense of oneness and seamless interdepartmental alignment by consolidating different departments to a single floor
- Disaster response and security measures strengthened
- Strengthening of cooperation with Sumitomo Chemical Co., Ltd. (to be relocated to the same building)
- Better access due to excellent location directly connected to Nihonbashi Station

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Major Topics in FY2020

Increase in revenue y-o-y, core operating profit decrease due to incremental costs of newly consolidated Sumitovant and impairment loss

Japan

Year-round contribution of Equa[®]/EquMet[®] increased in revenue, outpacing the decrease in long-listed products
 Launched LATUDA[®] in June 2020
 Earning increased YoY due to a decrease in related expenses by activity restrictions

North America

LATUDA[®] and APTIOM[®] contributed to revenue increase
 Incremental full-year costs of consolidated Sumitovant was compensated for by the decrease costs of Sunovion, and profits decreased slightly
 Myovant collaborated with Pfizer on ORGOVYX[™], and started co-promotion in February

China/ Other

MEROPEN[®] was affected by COVID-19, and sales declined in many regions, including China

R&D

Obtained approvals and launch

- apomorphine (KYNMOBI[™]) U.S.: OFF episodes associated with Parkinson's disease, Launched in September 2020
- relugolix (ORGOVYX[™]) U.S.: Prostate cancer, Launched in January 2021
- vibegron (GEMTESA[®]) U.S.: Overactive bladder, Launched in April 2021

Submitted for approval:

- relugolix U.S.: Uterine fibroids
- imeglimin Japan: Type 2 diabetes

Discontinued

- napabucasin Colorectal cancer and other solid tumors
- alvocidib AML and MDS

· Changed development policy for TP-0903

Appendix (Financial Results for FY2020)



Revenue of Major Products in Japan

Billions of yen

	FY2019 Results	FY2020 Results	Change	
			Value	%
Equa [®] /EquMet [®]	17.1	40.1	23.0	134.1
Trulicity [®] *	30.0	33.9	3.9	13.0
TRERIEF [®]	16.2	16.2	0.0	0.0
REPLAGAL [®]	13.3	13.8	0.5	3.4
METGLUCO [®]	9.6	9.1	(0.5)	(5.0)
AmBisome [®]	4.2	3.5	(0.7)	(17.5)
LATUDA [®]	—	2.4	2.4	—
LONASEN [®] Tape	0.5	1.3	0.7	142.0
Promoted products Total	91.0	120.3	29.3	32.2
AMLODIN [®]	7.6	6.5	(1.1)	(14.4)
SUREPOST [®]	6.9	4.1	(2.8)	(40.6)
AG products	7.4	8.0	0.6	7.6
Others	26.8	13.6	(13.2)	(49.1)
Total	139.7	152.5	12.8	9.2

Note: Sales of each product are shown by invoice price (* Trulicity[®] is shown by NHI price)

- Year-round contribution of Equa[®]/EquMet[®] increased in revenue for FY2020
- LATUDA[®] was launched in June 2020, and achieved initial sales target despite limited activity
- LONASEN[®] Tape sales increased y-o-y, but short to initial target affected by COVID-19

Appendix (Financial Results for FY2020)



Revenue of Major Products in North America & China

	FY2019 Results	FY2020 Results	Change	FY2019 Results	FY2020 Results	Change		
						Value	FX impact	%
North America	Million \$			Billions of yen				
LATUDA®	1,743	1,946	203	189.5	206.5	17.0	(5.1)	9.0
BROVANA®	317	274	(43)	34.5	29.1	(5.4)	(0.7)	(15.5)
APTIOM®	215	242	27	23.4	25.7	2.3	(0.6)	9.9
LONHALA® MAGNAIR®	27	18	(9)	2.9	1.9	(1.0)	(0.0)	(34.3)
XOPENEX®	38	41	3	4.1	4.3	0.2	(0.1)	4.7
KYNMOBI™	—	2	2	—	0.2	0.2	(0.0)	—
Sunovion Others	72	68	(4)	7.9	7.2	(0.7)	(0.2)	(8.3)
Sumitovant	—	61	61	—	6.5	6.5	(0.2)	—
Total	2,413	2,653	240	262.3	281.5	19.2	(6.9)	7.3
China	Million RMB			Billions of yen				
MEROPEN®	1,542	1,435	(107)	24.1	22.5	(1.6)	0.1	(6.5)
Others	292	340	48	4.6	5.4	0.8	0.0	17.6
Total	1,834	1,775	(59)	28.6	27.8	(0.8)	0.1	(2.7)

■ North America segment

LATUDA® and APTIOM® showed growth y-o-y since impact of COVID-19 was not material

- KYNMOBI™ was launched at the end of September 2020, and affected by limitation in activity amid COVID-19

- Sumitovant revenue
ORGOVYX™ ¥0.4B
Alliance with Pfizer ¥2.4B
License to Europe ¥3.5B

■ China segment

Sales decreased y-o-y since MEROPEN® was affected by COVID-19

FX rates: FY19 Results : 1US\$ = ¥108.7, 1RMB = ¥15.6
FY20 Results : 1US\$ = ¥106.1, 1RMB = ¥15.7

Appendix (Financial Results for FY2020)



Financial Results for FY2020 (Full Basis)

Billions of yen

	FY2019 Results	FY2020 Results	Change	
			Value	%
Revenue	482.7	516.0	33.2	6.9
Cost of sales	129.7	137.8	8.1	6.2
Gross profit	353.1	378.2	25.1	7.1
SG&A expenses	154.3	190.4	36.0	23.3
R&D expenses	115.1	132.7	17.6	15.3
Other operating income and expenses	(0.4)	16.1	16.5	
Operating profit	83.2	71.2	(12.0)	(14.4)
Finance income and costs	0.7	6.6	5.9	
Profit before taxes	83.9	77.9	(6.1)	(7.3)
Income tax expenses	48.0	41.0	(7.0)	
Net profit	35.9	36.8	0.9	2.5
Net profit attributable to owners of the parent	40.8	56.2	15.5	38.0

Appendix (Financial Results for FY2020)



Adjustments to Core Operating Profit

FY2020 Results

Billions of yen

	IFRS Full Basis	Adjusted amount	IFRS Core Basis	Adjusted items
Revenue	516.0	-	516.0	
Cost of sales	137.8	(0.3)	137.5	
Gross profit	378.2	0.3	378.5	
SG&A expenses	190.4	21.4	211.8	Changes in fair value of contingent consideration 22.5 Business structure improvement expense (0.9)
R&D expenses	132.7	(35.6)	97.1	Impairment losses (35.4)
Other operating income and expenses	16.1	(16.1)	(0.0)	Gain on sale of former Ibaraki plant (16.7)
Operating profit	71.2	(1.6)	69.6	Core operating profit

IFRS Full Basis : Each item is shown by original financial value under IFRS

IFRS Core Basis : Each item is shown by value after adjustment for calculating core operating profit

Appendix (Financial Results for FY2020)

Financial Position

B / S	As of March 2020	As of March 2021	Change
Assets	1,256.5	1,308.1	51.6
Goodwill / Intangible assets	594.5	559.9	(34.6)
Other financial assets (Non-current)	200.9	193.0	(7.9)
Trade and other receivables	134.5	135.9	1.4
Cash and deposit / Short-term loan receivable	127.6	221.4	93.7
Liabilities	620.7	659.9	39.3
Bonds and borrowings	298.0	273.8	(24.2)
Fair value of contingent consideration (Other financial liabilities)	31.2	8.3	(22.9)
Provisions	84.6	99.9	15.2
Deferred revenue (Other liabilities)	4.4	55.3	50.9
Equity	635.9	648.2	12.3
Attributable to owners of the parent	532.7	580.6	47.9
Ratio of equity attributable to owners of the parent to total assets	42.4%	44.4%	
C / F	FY2019	FY2020	Change
Operating CF	46.1	135.6	89.5
Investment CF	(312.7)	8.9	321.6
Financial CF	231.1	(57.2)	(288.3)
Cash and cash equivalents	101.7	193.7	92.0
(Operating funds)	127.6	221.4	93.7

Billions of yen

Including decrease due to impairment of IPR&D related to developing pipeline

Decrease in fair value mainly due to review of development plan

Revenue from the alliance with Pfizer related to relugolix

FY2019
Acquired Roivant stocks and Sumitovant

FY2019
Financing ¥270 billion for the alliance with Roivant

Appendix (Research and Development)



Main Event / Target for FY2020 (as of May 12, 2021)

Revisions since the announcement of Jan. 2021 are shown in red ✓ Completed action / target

Psychiatry & Neurology	<ul style="list-style-type: none"> ✓ Apomorphine : Obtain approval for OFF episodes associated with Parkinson's disease in the U.S. □ SEP-363856 : □ Determine new indication for development (global study) ✓ Start Phase 2/3 study for schizophrenia in Asia including Japan and China ✓ SEP-4199 : Obtain results from Phase 2 study for Bipolar I depression
Oncology	<ul style="list-style-type: none"> ✓ Napabucasin : Obtain results from global Phase 3 study for colorectal cancer ✓ Relugolix : Submit NDA for prostate cancer in the U.S. → ✓ Obtain approval
Regenerative medicine / Cell therapy	<ul style="list-style-type: none"> ✓ RVT-802 : Resubmit BLA for pediatric congenital athymia in the U.S. (Resubmitted in April 2021) □ Allogeneic iPS cell-derived products (AMD: age-related macular degeneration) : Start clinical study □ Allogeneic iPS cell-derived products (Parkinson's disease) : Complete transplant in investigator-initiated clinical study
Infectious Diseases	<ul style="list-style-type: none"> ✓ Antimicrobial resistance (AMR), universal influenza vaccine, malaria vaccines (transmission-blocking/disease prevention) : Promote research and development projects
Others	<ul style="list-style-type: none"> ✓ Vibegron : Obtain approval for overactive bladder in the U.S. □ Relugolix : ✓ Obtain results from Phase 3 study for endometriosis (SPRIT 1, SPIRIT 2) ✓ Submit NDA for uterine fibroids in the U.S. □ Obtain approval for uterine fibroids in Europe ✓ Imeglimin : Submit NDA for type 2 diabetes in Japan
Frontier	<ul style="list-style-type: none"> ✓ Promotion of the current themes (MELTIN, Aikomi, Drawbridge and internal themes), development of new themes

Development Status of Relugolix and GEMTESA® (Vibegron)

■ Development status of relugolix

<p>Oncology area (monotherapy: ORGOVYX™)</p>	<p>Prostate cancer U.S. : Launched in January 2021 Europe : MAA submitted in March 2021</p> <ul style="list-style-type: none"> ➤ (North America) Entered into a collaborative development and commercialization agreement with Pfizer in December 2020 ➤ (Outside North America, excluding certain Asia) Granted an option to commercialize to Pfizer
<p>Women's health area (combination tablet)</p>	<p>Uterine fibroids U.S. : NDA submitted in May 2020, PDUFA date June 1st, 2021 Europe : MAA submitted in March 2020</p> <p>Endometriosis Phase 3 studies completed U.S. : Plan to submit in the first half of 2021 Europe : Plan to submit in 2021</p> <ul style="list-style-type: none"> ➤ (North America) Entered into a collaborative development and commercialization agreement with Pfizer in December 2020 ➤ (Europe, Russia etc.) Entered into a collaborative development and commercialization agreement with Gedeon Richter Plc. in March 2020

■ Development status of GEMTESA® (vibegron)

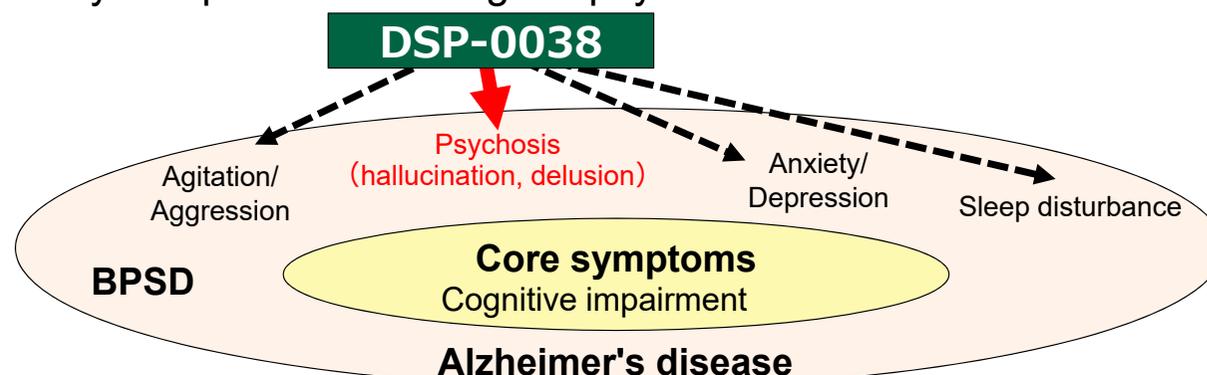
<p>Overactive bladder (OAB)</p>	<p>U.S. : Launched in April 2021</p>
<p>OAB in men with BPH</p>	<p>U.S. : Phase 3 study stage, Expect topline results in FY2022</p>

Appendix (Research and Development)

New Chemical Entity: DSP-0038



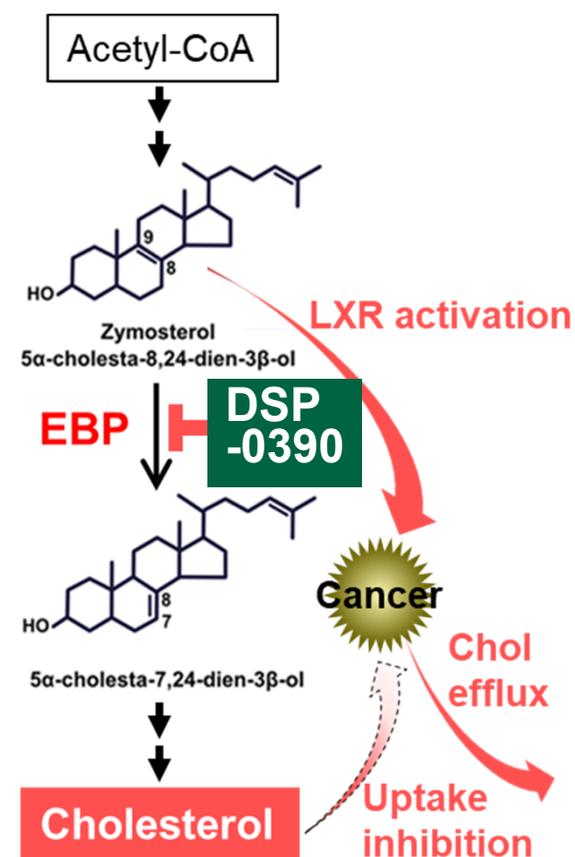
- ✓ Target indication : Alzheimer's disease psychosis
- ✓ Origin : In-house (Joint research with Exscientia)
- ✓ Mechanism of action : Serotonin 5-HT_{2A} receptor antagonist and serotonin 5-HT_{1A} receptor agonist
- ✓ Stage : Phase 1 (U.S.)
- ✓ Expected profile :
 - DSP-0038 is a novel compound discovered at Sumitomo Dainippon Pharma using Exscientia's AI technologies, and is expected to demonstrate a greater antipsychotic effect, based on the additive effect of 5-HT_{2A} receptor antagonist and 5-HT_{1A} receptor agonist. The compound could also have a broader efficacy in the treatment of behavioral and psychological symptoms of dementia (BPSD) which include agitation, aggression, anxiety, and depression
 - Furthermore, DSP-0038 has negligible affinity for dopamine D₂ receptors, and therefore it can be expected to show improved safety and tolerability compared to existing antipsychotics



Appendix (Research and Development)

New Chemical Entity: DSP-0390

- ✓ Target indication : Solid tumor
- ✓ Origin : In-house
- ✓ Mechanism of action : First in class Cholesterol metabolism modulator that exhibits a tumor cell growth inhibitory effect by inhibiting EBP (Emopamil Binding Protein), which is one of cholesterol biosynthetic enzymes
- ✓ Stage : Phase 1 (U.S.)
- ✓ Expected profile :
 - Cholesterol supply in brain depends on de novo synthesis and DSP-0390 has favorable BBB penetration property, so it is expected to show efficacy especially for GBM
 - Upregulation of cholesterol biosynthesis genes is observed in a wide variety of human cancers including prostate cancer, breast cancer and melanoma. And, additional indications for multiple cancer types as well as GBM are expected



- Essential for tumor proliferation as a component of cell membrane
- Important for cancer signaling

Appendix (Research and Development)

Regenerative Medicine/Cell Therapy Business Plan (as of May 12, 2021)



Revisions since the announcement of Jan. 2021 are shown in red

Proposed indication, etc.	Partnering	Region (planned)	Cell type	status
Pediatric congenital athymia (RVT-802)	Duke University	Global	Cultured thymus tissue	BLA resubmitted (April 2021)
AMD (age-related macular degeneration)	Healios RIKEN	Global	Allo iPS cell-derived retinal pigment epithelium	In progress: clinical research Preparing to start clinical study (Japan)
Parkinson's disease (Designated as a "SAKIGAKE")	Kyoto University CiRA	Global	Allo iPS cell-derived dopamine neural progenitor	In progress: investigator-initiated clinical study (Phase 1 / 2 study) (Japan)
Retinitis pigmentosa	RIKEN	Global	Allo iPS cell-derived photoreceptor (3D)	In progress: clinical research
Spinal cord injury	Keio University Osaka National Hospital	Global	Allo iPS cell-derived neural progenitor	In progress: clinical research
Kidney failure	Jikei University Bios PorMedTec	Japan, North America	Auto/ Allo iPS cell-based induced nephron progenitor cells (organ)	In progress: pre-clinical study

Aim to start clinical study in FY2021

Aim to launch in FY2023 *

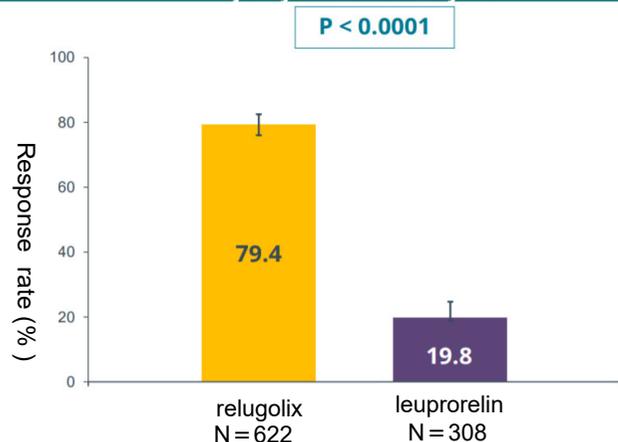
* Launch schedule is based on our goal pending agreement with partners

Appendix (Revision of Mid-term Business Plan 2022)

Clinical Characteristics of ORGOVYX™

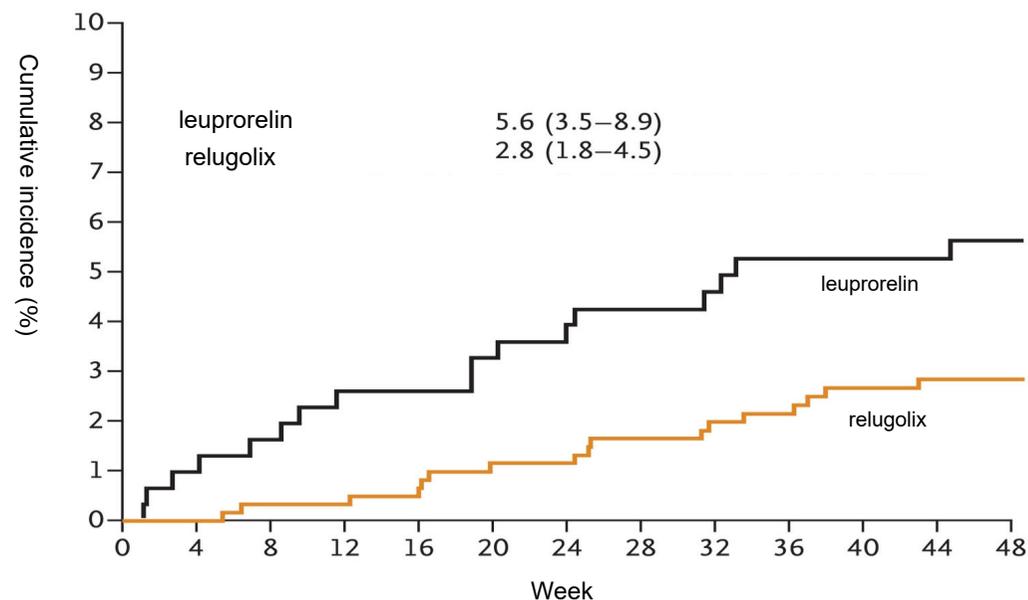
- Results of Phase 3 study (HERO study) indicated favorable efficacy and safety profile

ORGOVYX™ achieved a high PSA (cancer antigen) response rate¹ in the majority of men at Day 15



Tolerability	relugolix (N = 622)	leuprorelin (N = 308)
Hot flash	54.3%	51.6%
Fatigue	21.5%	18.5%
Constipation	12.2%	9.7%
Diarrhea ²	12.2%	6.8%
Arthralgia	12.1%	9.1%
Hypertension	7.9%	11.7%

Cumulative incidence of major adverse cardiovascular events (MACE) at week 48 of therapy



Number of patients evaluated

leuprorelin	308	305	303	298	298	293	292	288	281	279	278	269	259
relugolix	622	621	616	610	605	596	595	588	582	575	563	559	538

(1) The data of patients who achieved decrease of PSA by half on day 15 of this therapy and were still receiving the therapy on day 29. PSA: prostate-specific antigen

(2) Adverse events of grade 1 or 2 that did not trigger termination of the study.

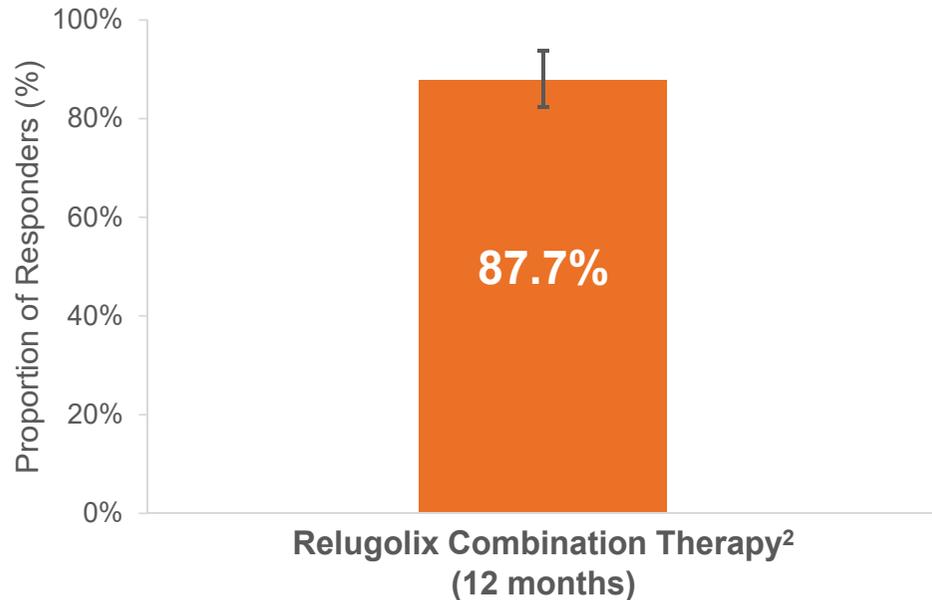
Source: Shore ND, Saad F, Cookson MS, et al. Oral relugolix for androgen-deprivation therapy in advanced prostate cancer. New England Journal of Medicine. 2020 June 4. DOI: 10.1056/NEJMoa2004325

Relugolix Combination Therapy: Clinical Profile (Uterine Fibroids)

At 52 weeks, both the efficacy and safety data for relugolix combination therapy were consistent with prior data demonstrating a clinically meaningful reduction in menstrual blood loss while maintaining bone health

Primary efficacy endpoint was met at one year, demonstrating durability of the response observed in LIBERTY 1 & 2¹

Proportion of responders with <80 mL menstrual blood loss/cycle and at least a 50% reduction in menstrual blood loss by alkaline hematin method



Changes in lumbar spine bone mineral density maintained through one year and were consistent with those in LIBERTY 1 & 2¹

Lumbar spine bone mineral density was also consistent with that of untreated women with uterine fibroids in a concurrent natural history study



(1) Al-Hendy A, et al. LIBERTY: Long-Term Extension Study Demonstrating One-Year Efficacy and Safety of Relugolix Combination Therapy in Women with Symptomatic Uterine Fibroids. Fertility and Sterility. 2020 September. DOI: <https://doi.org/10.1016/j.fertnstert.2020.08.027>

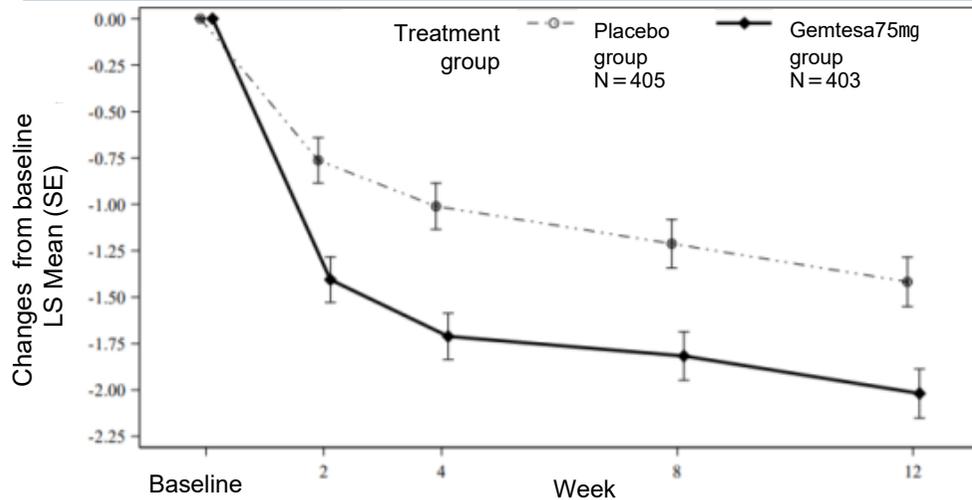
(2) Relugolix 40 mg + estradiol 1.0 mg + norethindrone acetate 0.5 mg
Relugolix combination tablet is an investigational drug that has not been approved for any use

Reference: Smitovant Meeting (March 23, 2021)

GEMTESA®: Product Clinical Highlights

The Phase 3 EMPOWUR study demonstrated GEMTESA®'s favorable clinical profile, highlighting its ability to sustain improved incontinence efficacy while maintaining a favorable safety profile

Mean change from baseline over time in average daily number of urge urinary incontinence episodes¹



	Baseline average	Change from baseline ²
GEMTESA® (75mg)	3.4 (403)	-2.0 (383)
Placebo	3.5 (405)	-1.4 (372)

GEMTESA® was generally well-tolerated with adverse event rates comparable to placebo, including hypertension³

Adverse events of special interest ^{2,3,4}	Placebo (n=540)	GEMTESA® (n=545)	Tolterodine (n=430)
Hypertension	9 (1.7)	9 (1.7)	11 (2.6)
Blood pressure increased	5 (0.9)	4 (0.7)	8 (1.9)
Tachycardia	0	0	1 (0.2)
Hypotension	1 (0.2)	1 (0.2)	1 (0.2)
Dizziness	6 (1.1)	5 (0.9)	4 (0.9)
Urinary tract infection	33 (6.1)	27 (5.0)	25 (5.8)
Urinary retention	2 (0.4)	3 (0.6)	3 (0.7)
Dry mouth	5 (0.9)	9 (1.7)	28 (6.5)
Constipation	7 (1.3)	9 (1.7)	6 (1.4)
Fatigue	5 (0.9)	2 (0.4)	6 (1.4)

(1) GEMTESA® U.S. FDA label for the treatment of overactive bladder
 (2) At Week 12
 (3) Staskin D, Frankel J, Varano S, et al. Phase 3 EMPOWUR results. The Journal of Urology. Volume 204. Issue 2. August 2020. Page: 316-324
 (4) List of adverse events is not exhaustive and is focused on potential cardiovascular and anti-cholinergic effects
 Full prescribing information for GEMTESA® is available at www.gemtesa.com



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