



Securities Code: 4523

FY 2021 (Ended March 31, 2022)
Full Year Financial Results

Reference Data

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Forward-Looking Statements and Risk Factors

Materials and information provided in this announcement include current forecasts, targets, evaluations, estimates, assumptions that are accompanied by risks, and other matters that are based on uncertain factors. Accordingly, it is possible that actual results will deviate significantly from forecasts, etc., due to changes to a variety of factors. These risks and uncertainties include general industry and market conditions, fluctuation of interest rates and currency exchange rates, and other aspects of economic conditions in Japan and internationally.

Risks and uncertainties that could cause significant fluctuations in the results of the Group or have a material effect on investment decisions are as follows. However, these do not cover all of the risks and uncertainties faced by the Group, and it is possible that they will be affected in the future by other factors that cannot be foreseen, or are not deemed to be important, at this point in time.

These are judgments as of the time of the announcement, and statements in the text regarding the future are not guarantees that they will occur or be achieved.

Risks factors include risks related to management based on the Corporate Philosophy, risks related to maximizing the value of next-generation Alzheimer's Disease treatments, risks related to maximizing the value of Lenvima, risks related to partnership model, risks related to digital transformation, risks related to new drug development, risks related to side effects, risks related to product quality and stable supply, risks related to intellectual property, risks related to litigations, risks related to data reliability, risks related to trend to contain medical costs, risks related to succession, risks related to acquiring and developing human resources, risks related to information security, risks related to COVID-19, risks related to climate change, risks related to impairment of goodwill and intangible assets.

This English presentation was translated from the original Japanese version. In the event of any inconsistency between the statements in the two versions, the statements in the Japanese version shall prevail.

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Currency Exchange Rates

		US (USD/JPY)	EU (EUR/JPY)	UK (GBP/JPY)	China (RMB/JPY)
FY 2019	Yearly Average Rate	108.73	120.81	138.24	15.60
	Year End Rate	108.83	119.55	133.32	15.31
FY 2020	Yearly Average Rate	106.06	123.70	138.68	15.67
	Year End Rate	110.71	129.80	152.23	16.84
FY 2021	Yearly Average Rate	112.37	130.56	153.55	17.51
	Year End Rate	122.39	136.70	160.89	19.26
FY 2022	Forecast Rate	125.00	130.00	151.50	19.00

* Eisai Co., Ltd. ("the Company") discloses its consolidated financial statements in accordance with the International Financial Reporting Standards (IFRS).

* The Eisai Group's ("the Group") business is comprised of pharmaceutical business and other business. The pharmaceutical business is organized into the following six reporting segments in this report: Japan, Americas (North America), China, EMEA (Europe, the Middle East, Africa, Russia, and Oceania), Asia and Latin America (primarily South Korea, Taiwan, Hong Kong, India, ASEAN, Central and South America), and OTC and others (Japan).

* All amounts are rounded to the nearest specified unit.

* As described on pages 30 - 31 of Consolidated Financial, Supplemental Materials, the figures for FY2020 have been revised for retroactive application due to changes in accounting policies.

1. Consolidated Statement of Income

(billions of yen)

	FY 2020		FY 2021				FY 2022	
	Full year	Ratio (%)	Full year	Ratio (%)	YOY (%)	Diff.	Full year forecast	Ratio (%)
Revenue	645.9	100.0	756.2	100.0	117.1	110.3	700.0	100.0
Cost of sales	161.3	25.0	174.8	23.1	108.4	13.5	160.5	22.9
Gross profit	484.6	75.0	581.4	76.9	120.0	96.8	539.5	77.1
Selling, general and administrative expenses	281.6	43.6	366.4	48.5	130.1	84.8	339.0	48.4
Selling expenses	116.6	18.1	190.4	25.2	163.2	73.8	—	—
Personnel expenses	90.6	14.0	101.3	13.4	111.8	10.7	—	—
Administrative and other expenses	74.4	11.5	74.8	9.9	100.4	0.3	—	—
Research and development expenses	150.3	23.3	171.7	22.7	114.2	21.4	159.0	22.7
Other income	1.5	0.2	14.6	1.9	1009.8	13.2	13.5	1.9
Other expenses	2.6	0.4	4.1	0.5	157.3	1.5	—	—
Operating profit	51.5	8.0	53.7	7.1	104.3	2.2	55.0	7.9
Financial income	2.1	0.3	2.4	0.3	111.9	0.3	—	—
Financial costs	1.4	0.2	1.7	0.2	124.4	0.3	—	—
Profit before income taxes	52.3	8.1	54.5	7.2	104.1	2.2	55.5	7.9
Income taxes	10.0	1.5	8.7	1.2	87.5	(1.2)	—	—
Profit for the year	42.3	6.5	45.7	6.0	108.1	3.4	46.5	6.6
Profit for the year attributable to								
Owners of the parent	41.9	6.5	48.0	6.3	114.3	6.0	45.5	6.5
Non-controlling interests	0.4	0.1	(2.2)	(0.3)	—	(2.6)	—	—
Comprehensive income for the year	70.9	11.0	90.8	12.0	128.1	19.9		
Earnings per share (EPS, yen)	146.34		167.27				158.85	
Dividend per share (DPS, yen)	160.0		160.0				160.0	
Return on equity (ROE, %)	6.1		6.6				6.1	
Dividends on equity ratio (DOE, %)	6.6		6.3				6.1	
Overseas revenue ratio (%)	59.2		67.8					

* Full year forecast for other income has had other expenses deducted from it.

* EPS: Earnings Per Share attributable to owners of the parent (basic).

Notes

Revenue	Continuous growth of the anticancer agent Lenvima: 192.3 billion yen (previous fiscal year: 133.9 billion yen) Receipt of an upfront payment from Bristol Myers Squibb under strategic collaboration for antibody drug conjugate MORAb-202: 49.6 billion yen Recording of sales milestone payments from Merck & Co., Inc., Rahway, NJ, USA: 69.2 billion yen (achieved 1.4 billion U.S. dollars for CY2021: 34.5 billion yen, achieved 1.5 billion U.S. dollars for FY2021: 34.7 billion yen) (previous fiscal year: 20.7 billion yen)
Cost of Sales	Recording of impairment losses related to sales rights of Alzheimer's disease treatment ADUHELM (aducanumab): 8.0 billion yen
Selling, general and administrative expenses	Recording of expenses regarding shared profit of Lenvima paid to Merck & Co., Inc., Rahway, NJ, USA: 90.7 billion yen (previous fiscal year: 60.2 billion yen) Recording of cost related to ADUHELM: 57.4 billion yen (previous fiscal year: 20.4 billion yen) including the cost of 28.8 billion yen associated with the revision of the demand forecast
Research and development expenses	Increase due to aggressive resource investment in projects including anti amyloid-beta protofibril antibody lecanemab and Lenvima Control of the expenses through the partnership model (partner's burden: 68.6 billion yen (previous fiscal year: 58.1 billion yen)) including recording of reversal of 11.2 billion yen as regulatory milestone payments from Merck & Co., Inc., Rahway, NJ, USA due to approval of Lenvima for use in the treatment of renal cell carcinoma Recording of impairment losses and returning of subsidies received due to revaluation of the R&D pipeline of EA Pharma Co., Ltd., a consolidated subsidiary
Other income	Recording of profit from divestiture of rights for antiepileptic agent Zonagrán in Europe, the Middle East, Russia and Australia
Profit for the year attributable to Non-controlling interests	A yearly losses in EA Pharma Co., Ltd. in which the Company holds 60% of the voting rights
Exchange rate effects	Revenue: +34.81 billion yen, operating profit: +3.73 billion yen
Exchange rate sensitivity	Revenue (U.S. dollars: -2.61 billion yen, Euro: -0.30 billion yen, U.K. pounds: -0.06 billion yen, Chinese renminbi: -6.09 billion yen)
(annual effect of 1 yen appreciation in currency value)	Operating profit (U.S. dollars: +0.59 billion yen, Euro: -0.31 billion yen, U.K. pounds: +0.10 billion yen, Chinese renminbi: -4.05 billion yen)

2. Segment Information

1) Revenue by Reporting Segment

(billions of yen)

	FY 2020	Full year	FY 2021	CER YOY (%)
	Full year		YOY (%)	
Pharmaceutical Business Total	586.1	626.3	106.9	102.3
Japan pharmaceutical business	231.9	214.0	92.3	92.3
Americas pharmaceutical business	142.8	172.0	120.5	113.7
United States	140.9	169.5	120.3	113.6
China pharmaceutical business	85.1	106.4	125.1	112.1
EMEA pharmaceutical business	55.2	59.3	107.4	101.4
Asia and Latin America pharmaceutical business	45.9	50.6	110.3	104.6
OTC and others	25.2	23.8	94.7	94.7
Other business	59.9	129.9	217.0	203.6
Consolidated revenue	645.9	756.2	117.1	111.7

* Indicates revenue from external customers.

* CER=Constant Exchange Rates

2) Profit by Reporting Segment

(billions of yen)

	FY2020	Full year	FY 2021	CER YOY (%)
	Full year		YOY (%)	
Pharmaceutical Business Total	238.4	262.3	110.0	103.8
Japan pharmaceutical business	83.9	61.2	73.0	73.0
Americas pharmaceutical business	64.7	79.2	122.5	116.5
China pharmaceutical business	40.4	55.4	137.3	118.8
EMEA pharmaceutical business	25.7	40.9	159.3	151.2
Asia and Latin America pharmaceutical business	18.6	20.8	111.6	103.5
OTC and others	5.1	4.7	92.7	92.7
Other business	51.5	121.6	236.3	227.9
Research and development expenses	(150.3)	(171.7)	114.2	107.3
Group headquarters' management costs and other expenses [#]	(88.0)	(158.5)	180.1	174.3
Consolidated operating profit	51.5	53.7	104.3	97.1

* CER=Constant Exchange Rates

[#] Includes the amount of profits and expenses shared under strategic collaborations with partners.

3. Financial Result by Reporting Segment

1) Japan pharmaceutical business

(billions of yen)

	FY2020	FY 2021	
	Full year	Full year	YOY (%)
Revenue	231.9	214.0	92.3
Segment profit	83.9	61.2	73.0
Japan prescription medicines - revenue from major products			
Fully human anti-TNF- α monoclonal antibody Humira	52.0	50.6	97.5
Insomnia treatment Dayvigo	2.0	12.7	639.5
Peripheral neuropathy treatment Methycobal	12.4	10.8	86.9
Anticancer agent Lenvima	12.2	10.3	84.9
Anticancer agent Halaven	8.5	8.3	98.3
Antirheumatic agent Careram	7.8	7.8	100.2
Proton pump inhibitor Pariet [#]	7.9	7.1	90.2
Alzheimer's disease / Dementia with Lewy bodies treatment Aricept	9.3	6.9	74.1
Insomnia treatment Lunesta	13.9	6.9	49.2
Elemental diet Elental [#]	6.6	6.8	102.9
Chronic constipation treatment Goofice [#]	5.0	6.1	123.0
Pain treatment (neuropathic pain, fibromyalgia) Lyrica	21.5	5.7	26.6
Antiepileptic agent Fycompa	5.1	5.4	105.2

* The revenue for Pariet includes the revenue for triple formulation packs for *Helicobacter pylori* eradication, Rabecure Pack 400/800 and Rabefine Pack.

* Co-promotion revenue has been booked as revenue for Lyrica.

[#] EA Pharma product

2) Americas pharmaceutical business (North America)

(billions of yen)

	FY 2020	FY 2021	
	Full year	Full year	YOY (%)
Revenue	142.8	172.0	120.5 <113.7>
United States	140.9	169.5	120.3 <113.6>
Segment profit	64.7	79.2	122.5 <116.5>
Americas - revenue from major products			
Anticancer agent Lenvima	81.0	116.5	143.8 <135.7>
United States	80.1	115.5	144.1 <136.0>
	[Millions USD] [756]	[1,028]	
Antiepileptic agent Fycompa	12.2	14.6	119.4 <112.5>
United States	11.8	14.1	119.7 <113.0>
	[Millions USD] [111]	[125]	
Anticancer agent Halaven	12.6	14.3	113.5 <107.0>
United States	12.3	14.0	113.7 <107.4>
	[Millions USD] [116]	[125]	
Antiepileptic agent Banzel	18.9	7.0	36.9 <34.7>
United States	18.7	6.7	35.9 <33.8>
	[Millions USD] [176]	[60]	
Insomnia Treatment Dayvigo	1.1	3.7	321.0 <301.1>
United States	1.1	3.2	295.9 <279.3>
	[Millions USD] [10]	[29]	

* YOY percentage: figures shown in angle brackets "< >" exclude the effects of foreign exchange fluctuations.

3) China pharmaceutical business

(billions of yen)

	FY 2020	FY 2021	
	Full year	Full year	YOY (%)
Revenue	85.1	106.4	125.1 <112.1>
Segment profit	40.4	55.4	137.3 <118.8>
China - revenue from major products			
Anticancer agent Lenvima	[Millions RMB] 18.5 [1,178]	35.0 [1,998]	189.6 <169.7>
Peripheral neuropathy treatment Methycobal	[Millions RMB] 17.5 [1,116]	12.5 [713]	71.4 <63.9>
Liver disease / Allergic disease agents Stronger Neo-Minophagen C and Glycyron Tablets	[Millions RMB] 10.1 [643]	9.5 [541]	94.1 <84.2>
Proton pump inhibitor Pariet	[Millions RMB] 6.7 [430]	8.9 [509]	132.5 <118.5>
Alzheimer's disease treatment Aricept	[Millions RMB] 5.8 [367]	5.2 [295]	89.7 <80.3>
Anticancer agent Halaven	[Millions RMB] 1.6 [100]	1.5 [87]	96.8 <86.6>
Antiepileptic agent Fycompa	[Millions RMB] 0.5 [30]	1.1 [64]	238.8 <213.7>

* YOY percentage: figures shown in angle brackets "< >" exclude the effects of foreign exchange fluctuations.

4) EMEA pharmaceutical business (Europe, the Middle East, Africa, Russia and Oceania)

(billions of yen)

	FY 2020	FY 2021	
	Full year	Full year	YOY (%)
Revenue	55.2	59.3	107.4 <101.4>
Segment profit	25.7	40.9	159.3 <151.2>
EMEA - revenue from major products			
Anticancer agent Lenvima/Kispix	15.8	21.8	137.6 <129.6>
Anticancer agent Halaven	12.4	12.8	103.8 <97.9>
Antiepileptic agent Fycompa	7.6	9.2	121.1 <114.1>
Antiepileptic agent Inovelon	2.5	2.7	107.7 <100.8>

* YOY percentage: figures shown in angle brackets "< >" exclude the effects of foreign exchange fluctuations.

5) Asia and Latin America pharmaceutical business

(billions of yen)

	FY 2020	FY 2021	
	Full year	Full year	YOY (%)
Revenue	45.9	50.6	110.3 <104.6>
Segment profit	18.6	20.8	111.6 <103.5>
Asia and Latin America - revenue from major products			
Alzheimer's disease / Dementia with Lewy bodies treatment Aricept	10.9	11.9	110.1 <104.3>
Anticancer agent Lenvima	6.5	8.8	135.4 <126.6>
Fully human anti-TNF- α monoclonal antibody Humira	8.5	7.5	88.1 <83.7>
Proton pump inhibitor Pariet	4.0	4.2	103.2 <98.2>
Peripheral neuropathy treatment Methycobal	3.0	3.6	119.8 <114.0>
Anticancer agent Halaven	2.6	2.4	92.9 <86.4>
Antiepileptic agent Fycompa	1.3	1.5	117.0 <110.2>

* YOY percentage: figures shown in angle brackets "< >" exclude the effects of foreign exchange fluctuations.

* Indication of Aricept for the treatment of dementia with Lewy bodies is approved only in Japan, the Philippines and Thailand.

6) OTC and Others (Japan)

(billions of yen)

	FY 2020	FY 2021	
	Full year	Full year	YOY (%)
Revenue	25.2	23.8	94.7
Segment profit	5.1	4.7	92.7
OTC and others, revenue from major products			
Vitamin B2 preparation, "Chocola BB Plus," etc. Chocola BB Group	13.4	14.3	106.4

4. Revenue from Major Products

1) Neurology Products

(billions of yen)

	FY 2020	FY 2021	
	Full year	Full year	YOY (%)
Neurology Products Total	161.4	135.6	84.0 <80.6>
Fycompa (Antiepileptic agent)	26.7	31.9	119.2 <113.2>
Japan	5.1	5.4	105.2
Americas	12.2	14.6	119.4 <112.5>
China	0.5	1.1	238.8 <213.7>
EMEA	7.6	9.2	121.1 <114.1>
Asia and Latin America	1.3	1.5	117.0 <110.2>
Methycobal (Peripheral neuropathy treatment)	34.2	28.1	82.3 <78.0>
Japan	12.4	10.8	86.9
China	17.5	12.5	71.4 <63.9>
Asia and Latin America	3.0	3.6	119.8 <114.0>
Aricept (Alzheimer's disease / Dementia with Lewy bodies treatment)	26.3	24.4	92.8 <88.3>
Japan	9.3	6.9	74.1
China	5.8	5.2	89.7 <80.3>
Asia and Latin America	10.9	11.9	110.1 <104.3>
Dayvigo (Insomnia treatment)	3.1	16.4	525.2 <517.9>
Japan	2.0	12.7	639.5
Americas	1.1	3.7	321.0 <301.1>
Inovelon/Banzel (Antiepileptic agent)	22.0	10.3	46.8 <44.2>
Americas	18.9	7.0	36.9 <34.7>
EMEA	2.5	2.7	107.7 <100.8>
Lunesta (Insomnia treatment) - Japan	13.9	6.9	49.2
Lyrica (Pain treatment [neuropathic pain, fibromyalgia]) - Japan	21.5	5.7	26.6
Other	13.6	11.9	87.1 <84.2>

* YOY percentage: figures shown in angle brackets "< >" exclude the effects of foreign exchange fluctuations.

* Indication of Aricept for the treatment of dementia with Lewy bodies is approved only in Japan, the Philippines and Thailand.

* Co-promotion revenue has been booked as revenue for Lyrica.

2) Oncology Products

(billions of yen)

	FY 2020	FY 2021	
	Full year	Full year	YOY (%)
Oncology Products Total	183.3	238.5	130.1 <122.2>
Lenvima/Kispplx (Anticancer agent)	133.9	192.3	143.6 <134.6>
Japan	12.2	10.3	84.9
Americas	81.0	116.5	143.8 <135.7>
China	18.5	35.0	189.6 <169.7>
EMEA	15.8	21.8	137.6 <129.6>
Asia and Latin America	6.5	8.8	135.4 <126.6>
Halaven (Anticancer agent)	37.6	39.4	104.8 <99.8>
Japan	8.5	8.3	98.3
Americas	12.6	14.3	113.5 <107.0>
China	1.6	1.5	96.8 <86.6>
EMEA	12.4	12.8	103.8 <97.9>
Asia and Latin America	2.6	2.4	92.9 <86.4>
Other	11.8	6.8	57.8 <53.3>

* YOY percentage: figures shown in angle brackets "< >" exclude the effects of foreign exchange fluctuations.

5. Revenue Forecast by Reporting Segment (FY 2022)

(billions of yen)

	FY 2021	FY 2022	
	Full year	Full year forecast	YOY (%)
Japan (Prescription Medicines)	214.0	201.0	93.9
Fully human anti-TNF- α monoclonal antibody Humira	50.6	41.5	81.9
Insomnia treatment Dayvigo	12.7	18.0	141.4
Anticancer agent Lenvima	10.3	13.5	130.6
Peripheral neuropathy treatment Methycobal	10.8	9.0	83.7
Anticancer agent Halaven	8.3	8.5	102.1
Chronic constipation treatment Goofice [#]	6.1	7.0	114.7
Antiepilepsy agent Fycompa	5.4	6.5	120.9
Elemental diet Elental [#]	6.8	6.5	95.6
Proton pump inhibitor Pariet [#]	7.1	6.0	84.1
Chronic constipation treatment Movicol [#]	4.9	5.5	112.0
Americas	172.0	198.5	115.4
United States	169.5	195.5	115.3
China	108.4	97.5	89.9
EMEA	59.3	59.5	100.3
Asia and Latin America	48.6	45.5	93.6
OTC and others (Japan)	23.8	24.5	102.8
Vitamin B2 preparation, "Chocola BB Plus," etc. Chocola BB Group	14.3	14.5	101.6
Other	129.9	73.5	56.6
Consolidated revenue	756.2	700.0	92.6
Global revenue from major products			
Lenvima/Kispilyx	192.3	218.0	113.3
Japan	10.3	13.5	130.6
Americas	116.5	145.5	124.9
China	35.8	23.5	65.6
EMEA	21.8	26.5	121.8
Asia and Latin America	7.9	9.0	113.5
Halaven	39.4	38.0	96.5
Japan	8.3	8.5	102.1
Americas	14.3	11.5	80.3
China	1.6	2.0	125.3
EMEA	12.8	13.0	101.2
Asia and Latin America	2.3	3.0	129.0
Fycompa	31.9	37.5	117.7
Japan	5.4	6.5	120.9
Americas	14.6	17.5	119.7
China	1.2	2.0	168.7
EMEA	9.2	10.0	108.4
Asia and Latin America	1.5	1.5	103.2
Dayvigo	16.4	27.0	164.2
Japan	12.7	18.0	141.4
Americas	3.7	9.0	246.0

[#] EA Pharma product

* From April 1, 2022, Hong Kong was changed from Asia and Latin America pharmaceutical business to China pharmaceutical business. This change has been reflected in the segment information for FY 2021 in this page.

6. Consolidated Statement of Comprehensive Income

(billions of yen)

	FY 2020	FY 2021		
	Full year	Full year	YOY (%)	Diff.
Profit for the year	42.3	45.7	108.1	3.4
Other comprehensive income (loss)				
Items that will not be reclassified to profit or loss				
Financial assets measured at fair value through other comprehensive income (loss)	3.2	(0.8)	—	(4.1)
Remeasurements of defined benefit plans	3.2	(1.1)	—	(4.2)
Subtotal	6.4	(1.9)	—	(8.3)
Items that may be reclassified subsequently to profit or loss				
Exchange differences on translation of foreign operations	22.0	46.9	212.9	24.9
Cash flow hedges	0.1	0.1	55.7	(0.1)
Subtotal	22.1	47.0	212.1	24.8
Total other comprehensive income (loss), net of tax	28.5	45.1	157.8	16.5
Comprehensive income (loss) for the year	70.9	90.8	128.1	19.9
Comprehensive income (loss) for the year attributable to				
Owners of the parent	70.4	93.0	132.1	22.6
Non-controlling interests	0.4	(2.2)	—	(2.7)

7. Consolidated Statement of Cash Flows

(billions of yen)

	FY 2020	FY 2021	
	Full year	Full year	Diff.
Operating activities			
Profit before income taxes	52.3	54.5	2.2
Depreciation and amortization	35.8	38.4	2.6
Impairment losses	0.2	11.4	11.2
(Increase) decrease in working capital	0.3	34.1	33.9
Interest and dividends received	1.9	1.9	0.0
Interest paid	(1.0)	(1.3)	(0.3)
Income taxes paid	(17.9)	(10.6)	7.3
Income taxes refund	1.1	3.5	2.4
Other	0.5	(14.3)	(14.8)
Net cash from (used in) operating activities	73.1	117.6	44.5
Investing activities			
Purchases of property, plant and equipment	(19.1)	(29.0)	(9.9)
Purchases of intangible assets	(18.2)	(11.4)	6.8
Proceeds from sale of property, plant and equipment and intangible assets	0.0	13.4	13.4
Net cash outflow on acquisition of subsidiaries	—	(1.2)	(1.2)
Payments on investments in joint ventures	(0.2)	—	0.2
Purchases of financial assets	(2.6)	(3.1)	(0.5)
Proceeds from sale and redemption of financial assets	3.5	2.5	(1.1)
Subtotal <Capital expenditures (cash basis)>	(36.6)	(28.9)	7.8
Payments of time deposits exceeding three months	(0.0)	(0.0)	0.0
Proceeds from redemption of time deposits exceeding three months	0.2	0.0	(0.2)
Other	0.4	0.0	(0.3)
Net cash from (used in) investing activities	(36.1)	(28.8)	7.2
Financing activities			
Proceeds from long-term borrowings	34.9	44.9	10.0
Repayments of long-term borrowings	(35.0)	(40.0)	(5.0)
Repayments of lease liabilities	(10.0)	(10.3)	(0.3)
Dividends paid	(45.9)	(45.9)	(0.0)
Other	0.0	2.3	2.3
Net cash from (used in) financing activities	(55.9)	(49.0)	6.9
Effect of exchange rate change on cash and cash equivalents	13.4	21.1	7.7
Net increase (decrease) in cash and cash equivalents	(5.5)	60.9	66.4
Cash and cash equivalents at beginning of year	254.2	248.7	(5.5)
Cash and cash equivalents at end of year	248.7	309.6	60.9
Free cash flows	36.4	88.7	52.3

* "Free cash flows" = "Net cash from (used in) operating activities" - "Capital expenditures (cash basis)"

Notes

<p>■ Net cash from (used in) operating activities Receipt of an upfront payment as well as reimbursement for research and development payment from Bristol Myers Squibb under strategic collaboration.</p> <p>■ Net cash from (used in) investing activities While capital expenditures due to additional investment in research facilities and manufacturing facilities occurred, proceeds from divestiture of rights for Zonegran occurred</p> <p>■ Net cash from (used in) financing activities Refinancing of long-term borrowings and payment of dividends</p>

8. Capital Expenditures, Depreciation and Amortization

(billions of yen)

	FY 2020	FY 2021		FY 2022
	Full year	Full year	Diff.	Full year forecast
Capital expenditures (cash basis)	37.4	40.5	3.1	50.0
Property, plant and equipment	19.1	29.0	9.9	28.5
Intangible assets	18.2	11.4	(6.8)	21.5
Depreciation and amortization	35.8	38.4	2.6	39.5
Property, plant and equipment	19.3	21.8	2.4	22.0
Intangible assets	16.4	16.6	0.2	17.5

9. Consolidated Statement of Financial Position

<Assets>

(billions of yen)

	FY 2020		FY 2021			
	March 31, 2021	Ratio (%)	March 31, 2022	Ratio (%)	% change	Diff.
Assets						
Non-current assets						
Property, plant and equipment	160.9	14.8	169.9	13.7	105.6	9.0
Goodwill	171.8	15.8	191.8	15.5	111.6	20.0
Intangible assets	106.4	9.8	95.5	7.7	89.7	(11.0)
Other financial assets	43.8	4.0	44.0	3.6	100.5	0.2
Other assets	19.6	1.8	20.9	1.7	106.9	1.4
Deferred tax assets	67.6	6.2	76.6	6.2	113.4	9.1
Total non-current assets	570.1	52.4	598.7	48.3	105.0	28.6
Current assets						
Inventories	85.1	7.8	99.0	8.0	116.3	13.9
Trade and other receivables	160.3	14.7	207.9	16.8	129.7	47.6
Other financial assets	0.3	0.0	0.4	0.0	162.0	0.2
Other assets	23.9	2.2	23.6	1.9	98.6	(0.3)
Cash and cash equivalents	248.7	22.9	309.6	25.0	124.5	60.9
Total current assets	518.3	47.6	640.6	51.7	123.6	122.3
Total assets	1,088.4	100.0	1,239.3	100.0	113.9	150.9

Notes

■ Assets (Trade and other receivables)	Increase in trade receivables following the recording of a sales milestone payment from Merck & Co., Inc., Rahway, NJ, USA
(Cash and cash equivalents)	Increase due to receipt of an upfront payment as well as reimbursement for research and development payment from Bristol Myers Squibb and the sales milestone payments from Merck & Co., Inc., Rahway, NJ, USA

<Equity and Liabilities>

(billions of yen)

	FY 2020		FY 2021			
	March 31, 2021	Ratio (%)	March 31, 2022	Ratio (%)	% change	Diff.
Equity						
Equity attributable to owners of the parent						
Share capital	45.0	4.1	45.0	3.6	100.0	—
Capital surplus	77.6	7.1	77.6	6.3	100.0	(0.0)
Treasury shares	(34.0)	(3.1)	(33.9)	(2.7)	99.7	0.1
Retained earnings	506.4	46.5	506.6	40.9	100.0	0.2
Other components of equity	106.6	9.8	153.6	12.4	144.0	47.0
Total equity attributable to owners of the parent	701.6	64.5	748.8	60.4	106.7	47.2
Non-controlling interests	24.8	2.3	22.7	1.8	91.7	(2.0)
Total equity	726.4	66.7	771.5	62.3	106.2	45.2
Liabilities						
Non-current liabilities						
Borrowings	49.9	4.6	94.9	7.7	190.1	45.0
Other financial liabilities	39.8	3.7	39.2	3.2	98.5	(0.6)
Provisions	1.4	0.1	1.5	0.1	106.3	0.1
Other liabilities	14.4	1.3	18.4	1.5	127.5	4.0
Deferred tax liabilities	0.5	0.0	0.5	0.0	94.6	(0.0)
Total non-current liabilities	106.1	9.7	154.4	12.5	145.6	48.4
Current liabilities						
Borrowings	40.0	3.7	—	—	—	(40.0)
Trade and other payables	94.5	8.7	108.1	8.7	114.3	13.5
Other financial liabilities	17.0	1.6	40.9	3.3	240.5	23.9
Income taxes payable	2.5	0.2	6.9	0.6	272.6	4.4
Provisions	17.9	1.6	17.9	1.4	100.6	0.1
Other liabilities	84.1	7.7	139.6	11.3	165.9	55.5
Total current liabilities	256.0	23.5	313.3	25.3	122.4	57.3
Total liabilities	362.1	33.3	467.8	37.7	129.2	105.7
Total equity and liabilities	1,088.4	100.0	1,239.3	100.0	113.9	150.9

Notes

<p>■ Equity (Other components of equity)</p>	Increase in exchange differences on translation of foreign operations due to depreciation of yen
<p>■ Liabilities (Borrowings - current / non-current) (Other financial liabilities - current)</p>	Long-term borrowings have been refinanced Increase mainly in deposits received (reimbursement for research and development payment from Bristol Myers Squibb)
<p>(Other liabilities - current)</p>	Increase mainly in accrued expenses (cost related to ADUHELM paid to Biogen and shared profit of Lenvima paid to Merck & Co., Inc., Rahway, NJ, USA)

10. Changes in Quarterly Results

1) Income Statement

(billions of yen)

	FY 2020				FY 2021			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Revenue	165.6	151.5	181.3	147.6	198.9	163.5	203.0	190.9
Cost of sales	38.3	41.4	40.4	41.1	39.2	40.6	44.2	50.7
Gross profit	127.3	110.0	140.8	106.5	159.6	122.8	158.8	140.2
Selling, general and administrative expenses	64.9	69.0	77.5	70.2	74.8	79.9	101.5	110.3
Selling expenses	28.2	28.4	31.8	28.3	32.4	40.3	53.7	64.0
Personnel expenses	22.0	22.6	24.1	21.9	22.7	22.9	28.3	27.4
Administrative and other expenses	14.7	18.1	21.5	20.1	19.7	16.6	19.5	18.9
Research and development expenses	30.6	37.0	40.6	42.1	41.8	38.1	43.4	48.5
Other income	0.7	(0.1)	0.1	0.7	13.4	0.2	0.4	0.5
Other expenses	0.4	2.0	(0.7)	1.0	1.1	(0.3)	0.7	2.6
Operating profit	32.1	1.9	23.6	(6.1)	55.3	5.4	13.6	(20.6)
Financial income	0.7	0.3	0.6	0.6	0.7	0.5	0.6	0.5
Financial costs	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.5
Profit before income taxes	32.4	1.9	23.9	(6.0)	55.7	5.4	13.9	(20.6)
Income taxes	7.7	0.6	4.2	(2.5)	13.5	1.3	0.8	(6.9)
Profit for the period	24.7	1.3	19.7	(3.5)	42.3	4.1	13.0	(13.7)
Profit for the period attributable to								
Owners of the parent	24.4	1.3	19.4	(3.2)	42.1	3.9	14.2	(12.2)
Non-controlling interests	0.3	(0.0)	0.4	(0.3)	0.1	0.2	(1.1)	(1.5)
Comprehensive income for the period	23.7	(0.6)	17.3	30.5	42.4	7.9	26.2	14.3
Earnings per share (EPS, yen)	85.13	4.67	67.61	(11.06)	146.89	13.72	49.39	(42.72)

* EPS: Earnings Per Share attributable to owners of the parent (basic).

2) Cash Flows

(billions of yen)

	FY 2020				FY 2021			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Net cash from (used in) operating activities	9.9	8.4	3.3	51.4	(14.5)	82.4	4.6	45.1
Net cash from (used in) investing activities	(12.3)	(4.7)	(13.5)	(5.5)	0.3	(7.8)	(10.5)	(10.9)
Net cash from (used in) financing activities	(25.4)	(2.9)	(25.4)	(2.3)	(22.5)	(5.4)	(25.5)	4.5
Cash and cash equivalents at end of period	226.3	228.0	193.8	248.7	213.1	283.0	258.4	309.6
Free cash flow	(2.6)	3.7	(10.4)	45.7	(14.1)	74.6	(5.9)	34.1

* "Free cash flow" = "Net cash from (used in) operating activities" - "Capital expenditures (cash basis)"

3) Capital Expenditures, Depreciation and Amortization

(billions of yen)

	FY 2020				FY 2021			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Capital expenditures (cash basis)	11.9	4.4	14.1	7.0	14.7	6.8	10.4	8.6
Property, plant and equipment	8.8	4.0	1.6	4.7	12.1	6.1	3.8	7.0
Intangible assets	3.1	0.4	12.4	2.3	2.5	0.7	6.6	1.6
Depreciation and amortization	8.6	8.9	9.0	9.3	9.3	9.7	9.7	9.7
Property, plant and equipment	4.7	4.7	4.8	5.1	5.3	5.5	5.5	5.5
Intangible assets	3.9	4.1	4.2	4.2	4.0	4.2	4.2	4.2

4) Financial Positions

(billions of yen)

	Jun. 30,	Sept. 30,	Dec. 31,	Mar. 31,	Jun. 30,	Sept. 30,	Dec. 31,	Mar. 31,
	2020	2020	2020	2021	2021	2021	2021	2022
Total assets	1,038.9	1,045.2	1,027.1	1,088.4	1,127.7	1,138.4	1,165.6	1,239.3
Equity	701.9	701.4	695.8	726.4	745.7	753.6	756.9	771.5
Attributable to owners of the parent	677.2	676.8	670.8	701.6	720.9	728.6	733.0	748.8
Liabilities	337.0	343.8	331.4	362.1	382.0	384.8	408.7	467.8
Borrowings	89.9	89.9	89.9	89.9	92.7	89.9	89.9	94.9
Ratio of equity attributable to owners of the parent (%)	65.2	64.8	65.3	64.5	63.9	64.0	62.9	60.4
Net debt equity ratio (times)	(0.25)	(0.25)	(0.20)	(0.27)	(0.20)	(0.30)	(0.26)	(0.32)

* "Net debt equity ratio (Net DER)" = ("Interest-bearing debt" ("Borrowings") - "Cash and cash equivalents" -

"Time deposits exceeding three months, etc." - "Investment securities held by the parent") / "Equity attributable to owners of the parent"

5) Changes in Quarterly Revenue from Major Products

(1) Neurology Products

(billions of yen)

	FY 2020				FY 2021			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Neurology Total	43.8	43.1	40.4	34.0	34.1	33.3	36.1	32.2
Fycompa (Antiepileptic agent)	6.4	6.7	7.0	6.7	7.4	7.7	8.4	8.3
Japan	1.2	1.4	1.3	1.3	1.2	1.4	1.5	1.3
Americas	3.0	3.1	3.2	2.9	3.4	3.5	3.8	3.8
China	0.1	0.1	0.2	0.0	0.2	0.3	0.3	0.3
EMEA	1.7	1.8	2.0	2.1	2.2	2.2	2.4	2.5
Asia and Latin America	0.3	0.3	0.3	0.4	0.4	0.4	0.4	0.4
Methycobal (Peripheral neuropathy treatment)	10.9	9.4	6.3	7.6	6.8	7.3	7.7	6.4
Japan	3.3	3.0	3.0	3.1	2.4	2.8	2.9	2.5
China	6.9	5.1	2.1	3.4	3.3	3.3	3.3	2.6
Asia and Latin America	0.6	0.9	0.7	0.8	0.9	0.9	0.9	0.9
Aricept (Alzheimer's disease / Dementia with Lewy bodies treatment)	7.8	6.3	6.2	6.0	6.3	6.1	6.5	5.5
Japan	2.9	2.3	2.2	1.9	1.8	1.9	1.9	1.3
China	2.2	1.2	1.1	1.3	1.4	1.2	1.5	1.1
Asia and Latin America	2.6	2.7	2.8	2.7	3.0	2.9	3.0	3.0
Dayvigo (Insomnia treatment)	0.1	0.8	0.8	1.3	2.6	3.7	5.0	5.1
Japan	0.1	0.7	0.4	0.8	1.9	2.9	3.9	4.1
Americas	0.0	0.1	0.4	0.6	0.8	0.8	1.1	1.0
Inovelon/Banzel (Antiepileptic agent)	5.9	5.9	5.5	4.7	3.7	2.6	2.4	1.6
Americas	5.1	5.1	4.7	4.0	2.8	1.8	1.5	0.8
EMEA	0.6	0.6	0.7	0.6	0.7	0.7	0.7	0.7
Lunesta (Insomnia treatment) - Japan	3.6	3.3	3.5	3.5	2.9	1.5	1.4	1.1
Lyrica (Pain treatment [neuropathic pain, fibromyalgia]) - Japan	6.1	7.2	7.1	1.1	1.6	1.5	1.6	1.1
Other	3.0	3.4	4.0	3.2	2.8	2.8	3.2	3.1

* Indication of Aricept for the treatment of dementia with Lewy bodies is approved only in Japan, the Philippines and Thailand.

* Co-promotion revenue has been booked as revenue for Lyrica.

(2) Oncology Products

(billions of yen)

	FY 2020				FY 2021			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Oncology Total	47.7	46.4	48.2	40.9	56.1	59.1	60.8	62.5
Lenvima/Kispix (Anticancer agent)	34.7	33.8	35.3	30.2	44.2	47.6	49.3	51.2
Japan	3.7	3.3	2.8	2.4	2.5	2.6	2.6	2.6
Americas	21.5	20.4	20.2	18.8	24.4	26.9	31.3	33.8
China	4.2	4.9	6.0	3.3	10.5	10.3	6.9	7.2
EMEA	3.9	3.5	4.3	4.0	4.8	5.1	6.3	5.5
Asia and Latin America	1.4	1.7	1.9	1.5	2.0	2.6	2.2	2.0
Halaven (Anticancer agent)	9.4	9.2	9.5	9.5	10.2	9.8	9.8	9.7
Japan	2.2	2.1	2.0	2.2	2.0	2.1	2.2	2.0
Americas	3.2	3.1	3.2	3.1	3.3	3.6	3.6	3.9
China	0.1	0.5	0.6	0.4	0.9	0.3	0.0	0.3
EMEA	3.2	2.9	3.1	3.2	3.4	3.0	3.4	3.0
Asia and Latin America	0.7	0.6	0.7	0.6	0.6	0.6	0.5	0.6
Other	3.6	3.4	3.4	1.3	1.7	1.8	1.7	1.6

11. Trends in Financial Results

(billions of yen)

	FY 2014 Full year	FY 2015 Full year	FY 2016 Full year	FY 2017 Full year	FY 2018 Full year	FY 2019 Full year	FY 2020 Full year	FY 2021 Full year
<Income statement data>								
Revenue	548.5	547.9	539.1	600.1	642.8	695.6	645.9	756.2
Cost of sales	193.6	194.5	195.9	201.3	184.5	175.7	161.3	174.8
Selling, general and administrative expenses	194.5	192.8	174.9	183.9	228.2	256.3	281.6	366.4
Research and development expenses	131.9	122.3	117.2	139.6	144.8	140.1	150.3	171.7
Other income	1.0	17.7	13.6	3.0	2.6	6.4	1.5	14.6
Other expenses	1.1	4.1	5.6	1.1	1.7	4.4	2.6	4.1
Operating profit	28.3	51.9	59.1	77.2	86.2	125.5	51.5	53.7
Profit for the year	43.5	55.0	42.2	54.4	66.5	122.5	42.3	45.7
Comprehensive income for the year	114.2	16.5	36.8	53.8	79.5	96.2	70.9	90.8
<Cash flows>								
Net cash from (used in) operating activities	76.0	95.6	75.9	149.6	103.7	102.8	73.1	117.6
Net cash from (used in) investing activities	(18.8)	(6.7)	(28.6)	17.0	(7.9)	(27.6)	(36.1)	(28.8)
Net cash from (used in) financing activities	(59.7)	(72.9)	(35.4)	(81.9)	(79.2)	(103.5)	(55.9)	(49.0)
Free cash flows	61.3	81.2	81.7	136.7	85.1	68.2	36.4	88.7
<Financial positions>								
Assets	1,053.8	974.0	1,030.8	1,049.0	1,071.5	1,062.1	1,088.4	1,239.3
Equity	602.1	576.8	602.6	614.1	652.0	702.6	726.4	771.5
Share capital	45.0	45.0	45.0	45.0	45.0	45.0	45.0	45.0
Attributable to owners of the parent	598.7	573.7	584.6	593.6	628.1	678.1	701.6	748.8
<Capital expenditures, Depreciation and Amortization>								
Capital expenditures (cash basis)	18.4	40.1	20.0	24.7	27.6	50.2	37.4	40.5
Depreciation and amortization	38.9	34.1	26.5	26.2	26.8	33.7	35.8	38.4
<Managerial indices>								
Dividend payment (billions of yen)	42.8	42.9	42.9	42.9	43.0	45.9	45.9	45.9
Dividends on equity (DOE, %)	7.6	7.3	7.4	7.3	7.0	7.0	6.6	6.3
Dividend payout ratio (DPR, %)	99.0	78.0	109.0	82.8	67.8	37.6	109.3	95.7
Return on sales ratio (%)	7.9	10.0	7.8	9.1	10.3	17.6	6.5	6.0
Return on equity (ROE, %)	7.7	9.4	6.8	8.8	10.4	18.6	6.1	6.6
Return on assets (ROA, %)	4.3	5.4	4.2	5.2	6.3	11.3	3.9	3.9
Total capital turnover ratio (number of times)	0.5	0.5	0.5	0.6	0.6	0.6	0.6	0.6
Ratio of equity attributable to owners of the parent (%)	56.8	58.9	56.7	56.6	58.6	63.8	64.5	60.4
Net debt equity ratio (times)	0.00	(0.06)	(0.11)	(0.27)	(0.32)	(0.29)	(0.27)	(0.32)
Leverage (times)	1.8	1.7	1.8	1.8	1.7	1.6	1.6	1.7
Earnings per share (EPS, yen)	151.6	192.2	137.6	181.2	221.3	425.0	146.3	167.3
Diluted EPS (yen)	151.4	191.8	137.4	181.0	221.1	424.8	146.3	167.2
Dividend per share (DPS, yen)	150.0	150.0	150.0	150.0	150.0	160.0	160.0	160.0
Price-book value ratio (PBR, times)	4.1	3.4	2.8	3.3	2.8	3.4	3.0	2.2
Number of consolidated subsidiaries	48	46	45	44	44	45	46	48

* "Free cash flows" = "Net cash from (used in) operating activities" - "Capital expenditures (cash basis)"

* "Net debt equity ratio (Net DER)" = ("Interest-bearing debt" ("Borrowings") - "Cash and cash equivalents" -

"Time deposits exceeding three months, etc." - "Investment securities held by the parent") / "Equity attributable to owners of the parent"

* "Leverage" = "Total assets" / "Equity attributable to owners of the parent"

12. Stock Information

1) Number of Shares Issued and Shareholders

As of March 31, 2022

Total Number of Authorized Shares	Number of Shares Issued and Outstanding	Number of Shares Held as Treasury Stock	Number of Shareholders	Average Number of Shares per Shareholder
1,100,000,000	296,566,949	9,801,133	74,737	3,968

* Number of shares issued and outstanding includes treasury stock.

2) Principal Shareholders

As of March 31, 2022

Shareholders	Shares (1,000 shares)	Percentage of shares held (%)
The Master Trust Bank of Japan, Ltd. (Trust Account)	57,367	20.01
Custody Bank of Japan, Ltd. (Trust Account)	32,906	11.48
State Street Bank and Trust Company 505001	18,568	6.47
Nippon Life Insurance Company	9,781	3.41
Saitama Resona Bank, Limited	6,300	2.20
The Naito Foundation	4,212	1.47
State Street Bank West Client - Treaty 505234	3,965	1.38
JP Morgan Securities Japan Co., Ltd.	3,663	1.28
Government of Norway	3,429	1.20
JP Morgan Chase Bank 385781	3,429	1.20

* Number of shares has been rounded down to the nearest thousand.

* The percentage of shares held is calculated in proportion to the number of shares issued and outstanding (excluding treasury stock).

* Treasury stock (9,801 thousand shares, the percentage of treasury stock calculated in proportion to the number of shares issued and outstanding: 3.30%) has been excluded from the table as it has no voting rights.

* While the large shareholding reports (amendment reports) received up until March 31, 2022 are listed below, in cases where large shareholdings cannot be confirmed by the shareholder registry as of March 31, 2022 or where the number of shares held does not account among the top 10 shareholders, such shareholders are not listed in the above table. Furthermore, the percentage of shares held (rounded down) given inside the brackets is calculated in proportion to the number of shares issued and outstanding including treasury stock.

(1) As of July 13, 2015, four companies including Mitsubishi UFJ Financial Group jointly hold 16,113 thousand shares (5.43%).
(Amendment report dated July 21, 2015)

(2) As of August 15, 2017, eleven companies including BlackRock Japan Co., Ltd. jointly hold 18,308 thousand shares (6.17%).
(Amendment report dated August 21, 2017)

(3) As of July 15, 2020, three companies including Nomura Securities Co., Ltd. hold 18,380 thousand shares (6.20%).
(Amendment report dated July 21, 2020)

(4) As of September 15, 2020, Bank's Shareholdings Purchase Corporation holds 14,945 thousand shares (5.04%).
(Large shareholding report dated September 23, 2020)

(5) As of October 29, 2021, three companies including Sumitomo Mitsui Trust Bank, Ltd. jointly hold 19,442 thousand shares (6.56%).
(Amendment report dated November 5, 2021)

(6) As of March 15, 2022, the Wellington Management Company, LLP holds 23,761 thousand shares (8.01%).
(Amendment report dated March 22, 2022)

3) Number of Shares Held by Category

(1,000 shares)

	March 31, 2021	Ratio (%)	March 31, 2022	Ratio (%)	Diff.
Financial institutions	129,991	43.8	126,539	42.7	(3,452)
Financial instruments traders (securities companies)	8,872	3.0	10,987	3.7	2,115
Other companies	19,381	6.5	17,770	6.0	(1,610)
Foreign entities, etc.	89,495	30.2	89,937	30.3	442
Individuals, other	38,986	13.1	41,529	14.0	2,543
Treasury stock	9,839	3.3	9,801	3.3	(37)
Total	296,566	100.0	296,566	100.0	-

* Number of shares has been rounded down to the nearest thousand.

13. Number of Employees

1) Number of Employees on Consolidated Basis

(employees)

	March 31, 2019	March 31, 2020	March 31, 2021	March 31, 2022
Total employees	10,683	10,998	11,237	11,322
Japan	4,888	4,593	4,613	4,591
Americas (North America)	1,261	1,682	1,820	1,982
China	2,069	2,087	2,060	2,044
EMEA (Europe, the Middle East, Africa, Russia and Oceania)	1,046	1,113	1,166	1,200
Asia and Latin America	1,419	1,523	1,578	1,505

2) Number of Employees on Non-Consolidated Basis

(employees)

	March 31, 2019	March 31, 2020	March 31, 2021	March 31, 2022
Total employees (Eisai Co., Ltd.)	3,140	2,953	3,005	3,034
Production	408	367	375	389
Research and development	868	839	857	859
Sales, marketing and administration	1,864	1,747	1,773	1,786

* The number of total employees shown above includes staff dispatched to Eisai Co., Ltd. from other group companies, and excludes the employees of Eisai Co., Ltd. dispatched to other group companies.

14. Major R&D Pipeline

(1) Neurology

Development Code: E2007 Generic Name: perampanel Product Name: Fycompa					In-house
Indications / Drug class: Antiepileptic agent / AMPA receptor antagonist					Oral
Description: A selective antagonist against the AMPA receptor (a glutamate receptor subtype). Approved as an adjunctive therapy for partial-onset seizures in over 70 countries including Japan, the United States, China and countries in Europe and in Asia. Approved for monotherapy and adjunctive use in the treatment of partial onset seizures (with or without secondarily generalized seizures) in patients 4 years of age and older in Japan, the United States and China. Approved for adjunctive use in the treatment of partial onset seizures (with or without secondarily generalized seizures) in patients 4 years of age and older in Europe. Also approved as an adjunctive therapy for primary generalized tonic-clonic seizures in over 70 countries including Japan, the United States, and countries in Europe and in Asia. Approved for an adjunctive therapy for primary generalized tonic-clonic seizures in patients 7 years of age and older in Europe, and 12 years of age and older in Japan and United States. An oral suspension formulation has been approved in the United States and Europe. A fine granule formulation has been approved in Japan.					
	Pediatric epilepsy (Additional Dosage and Administration)	Study 311	CH	○	Approved (July, 2021)
	Monotherapy for partial-onset seizures (Additional Indication)	Study 335	CH	○	Approved (July, 2021)
	Lennox-Gastaut syndrome (Additional Indication)	Study 338	JP/US/EU		PIII

Development Code: E2006 Generic Name: lemborexant Product Name: Dayvigo					In-house
Indications / Drug class: Insomnia treatment / Orexin receptor antagonist					Oral
Description: An orexin receptor antagonist that blocks the receptors involved in the regulation of sleep and wakefulness. It is expected to alleviate wakefulness, thereby facilitating faster onset and maintenance of sleep. It has been approved for the treatment of insomnia in over 10 countries including Japan, the United States and countries in Asia. In addition, development for irregular sleep-wake rhythm disorder and Alzheimer's disease dementia is ongoing.					
○	Insomnia disorder	Study 311	CH		PIII
	Irregular sleep-wake rhythm disorder and Alzheimer's disease dementia (Additional Indication)	Study 202	JP/US		PII

Development Code: BAN2401 Generic Name: lecanemab					In-license (BioArctic AB)
Indications / Drug class: Disease modifying treatment for Alzheimer's disease / anti-A β protofibril antibody					Injection
Description: An IgG1 antibody that targets amyloid beta (A β) protofibrils. Expected to be effective in the treatment of Alzheimer's disease (AD) by halting disease progression through the elimination of neurotoxic A β protofibrils. The Phase III clinical study Clarity AD in patients with mild cognitive impairment due to AD or mild AD (collectively known as early AD) is underway. The Phase III clinical study AHEAD 3-45 for preclinical (asymptomatic) AD has been initiated and is underway in collaboration with the Alzheimer's Clinical Trials Consortium (ACTC). The United States Food and Drug Administration (FDA) granted Breakthrough Therapy designation in June 2021, and a rolling submission to the FDA for the Biological License Application for early AD has been initiated under the accelerated approval pathway in September 2021, and completed in May 2022. FDA granted Fast Track designation in December 2021. Submission to the Pharmaceuticals and Medical Devices Agency (PMDA) of application data under the prior assessment consultation system has been initiated in Japan in March 2022 with the aim of obtaining early approval. Joint development with Biogen Inc.					
	Early AD	Study 201	US	◎	Completion of rolling submission (May 2022)
		Study 301 (Clarity AD)	JP/US/EU/CH		PIII
	Preclinical AD	Study 303 (AHEAD 3-45)	JP/US/EU		PIII

JP: Japan, US: the United States, EU: Europe, CH: China, P: (Clinical trial) Phase

◎ : Development progress from January 2022 onwards ○ : Development progress from April 2021 onwards

Development Code: E2023 Generic Name: lorcaserin				In-license (Arena Pharmaceuticals)
Indications / Drug class: Treatment for Dravet syndrome / serotonin 2C receptor agonist				Oral
Description: By selectively activating serotonin 2C receptors in the brain, through the activation GABAergic inhibitory interneuron, expected to suppress seizure of Dravet syndrome by increasing synaptic suppression from GABAergic. Although approval for the obesity indication has been voluntarily withdrawn, due to the request from Dravet syndrome patient groups, the extended access program has been continued in the United States, and the Phase III clinical study is underway for this indication. FDA has designated it as an orphan drug for Dravet syndrome.				
Dravet syndrome	Study 304	US		PIII

Development Code: E2027				In-house
Indications / Drug class: Treatment for dementia with Lewy bodies, Parkinson's disease dementia / PDE9 inhibitor				Oral
Description: A selective phosphodiesterase (PDE) 9 inhibitor that reduces the degradation of cyclic GMP, which is critical to signal transduction among cells. Expected to be a new treatment for dementia with Lewy bodies and Parkinson's disease dementia by helping to maintain the concentration of cyclic GMP in the brain.				
Dementia with Lewy bodies, Parkinson's disease dementia	Study 203	US		PII

Development Code: E2730				In-house
Indications / Drug class: Antiepileptic agent, treatment for neurological diseases / synapse function modulator				Oral
Description: A compound with a novel mechanism of action that selectively regulates the function of activated synapses. Expected to be a new treatment for neurological diseases such as epilepsy, including orphan epilepsy, and epileptogenesis.				
Epilepsy	Study 201	US		PII

Development Code: E2814				Collaboration (University College London)
Indications / Drug class: anti-MTBR tau antibody				Injection
Description: E2814 is anti-microtubule binding region (MTBR) tau antibody that was discovered as part of the research collaboration between Eisai and University College London. Expected to prevent the spreading of tau seeds within the brain. Dominantly Inherited Alzheimer Network Trials Unit (DIAN-TU) has selected E2814 as the first investigational medicine among anti-tau drugs for their DIAN-TU tau study, and Phase Ib/II study and Phase II/III study Tau NexGen for dominantly inherited AD have been initiated.				
Alzheimer's disease	Tau NexGen study Study103	US US/EU	◎ ○	PII/III PI/II

Development Code: E2511				In-house
Indications / Drug class: Synapse regenerant				Oral
Description: E2511 is expected to promote recovery and synaptic remodeling of damaged cholinergic neurons, and to suppress cerebral atrophy caused by neurodegeneration.				
Alzheimer's disease	—	US		PI

Development Code: EA4017			In-house	Oral
Chemotherapy-induced peripheral neuropathy (Development conducted by EA Pharma)	—	JP		PI

◎ Aducanumab has been removed from this list due to amendment of collaboration agreement with Biogen Inc.

JP: Japan, US: the United States, EU: Europe, CH: China, P: (Clinical trial) Phase

◎ : Development progress from January 2022 onwards ○ : Development progress from April 2021 onwards

(2) Oncology

Development Code: E7080 Generic Name: lenvatinib Product Name: Lenvima					In-house
Indications / Drug class: Anticancer agent / kinase inhibitor					Oral
Description: An orally administered multiple receptor tyrosine kinase (RTK) inhibitor with a novel binding mode that selectively inhibits kinase activities of vascular endothelial growth factor receptors (VEGFR) and fibroblast growth factor receptors (FGFR) in addition to other proangiogenic and oncogenic pathway related RTKs (including the platelet-derived growth factor receptor (PDGFR), KIT and RET). Discovered and developed in-house. Approved for use in the treatment of thyroid cancer in over 80 countries including Japan, the United States, China and countries in Europe and in Asia. Approved for use in the treatment of hepatocellular carcinoma (first-line) in over 75 countries including in Japan, the United States, China and countries in Europe and in Asia. Also approved for use in the treatment of thymic carcinoma in Japan. Approved in combination with everolimus for use in the treatment of renal cell carcinoma (second-line) in over 60 countries including the United States and countries in Europe. Approved for use in the treatment of endometrial carcinoma (following prior systemic therapy) in combination with pembrolizumab in over 45 countries including in Japan, the United States, and countries in Europe and in Asia. In addition, approved for use in the treatment of renal cell carcinoma (first-line) in combination with pembrolizumab in over 35 countries including in Japan, the United States, and countries in Europe and in Asia. The agent is marketed under the product name Kisplyx only for this indication in Europe. Joint development with Merck & Co., Inc., Rahway, NJ, USA, through an affiliate.					
In combination with anti-PD-1 antibody pembrolizumab, joint development with Merck & Co., Inc., Rahway, NJ, USA, through an affiliate (Additional Indication)					
	Endometrial carcinoma, following prior systemic therapy	Study 309	US EU JP Asia (Taiwan)	○ ○ ○ ◎	Approved (July, 2021) Approved (November, 2021) Approved (December, 2021) Approved (February, 2022)
	Renal cell carcinoma / First-line	Study 307	US EU Asia (Taiwan) JP	○ ○ ◎ ◎	Approved (August, 2021) Approved (November, 2021) Approved (January, 2022) Approved (February, 2022)
	Endometrial carcinoma / First-line	LEAP-001	JP/US/EU/CH		PIII
	Hepatocellular carcinoma / First-line	LEAP-002	JP/US/EU/CH		PIII
	Melanoma / First-line	LEAP-003	US/EU/CH		PIII
	Non-small cell lung cancer (nonsquamous) (in combination with chemotherapy) / First-line	LEAP-006	JP/US/EU/CH		PIII
	Non-small cell lung cancer / Second-line	LEAP-008	JP/US/EU		PIII
	Head and neck cancer / First-line	LEAP-010	JP/US/EU/CH		PIII
	Hepatocellular carcinoma (in combination with transcatheter arterial chemoembolization) / First-line	LEAP-012	JP/US/EU/CH		PIII
○	Esophageal carcinoma (in combination with chemotherapy) / First-line	LEAP-014	JP/US/EU/CH		PIII
	Gastric cancer (in combination with chemotherapy) / First-line	LEAP-015	JP/US/EU/CH		PIII
	Colorectal cancer (non MSI-H / pMMR) / Third-line	LEAP-017	US/EU		PIII
	Melanoma / Second-line	LEAP-004	US/EU		PII
	Selected solid tumors (Gastric cancer, colorectal cancer, glioblastoma, biliary tract cancers and pancreatic cancer)	LEAP-005	US/EU		PII
	Head and neck cancer / Second-line	LEAP-009	US/EU		PII
	Selected solid tumors (Endometrial carcinoma, renal cell carcinoma, head and neck cancer, bladder cancer, non-small cell lung cancer and melanoma)	Study 111 —	US/EU JP		PI/II PI
In combination with anticancer agent everolimus, joint development with Merck & Co., Inc., Rahway, NJ, USA, through an affiliate (Additional Indication)					
	Renal cell carcinoma / First-line	Study 307	JP/US/EU		PIII
In combination with anti-PD-1 antibody nivolumab, joint development with Ono Pharmaceutical (Additional Indication)					
	Hepatocellular carcinoma	—	JP		PI

JP: Japan, US: the United States, EU: Europe, CH: China, P: (Clinical trial) Phase

◎ : Development progress from January 2022 onwards ○ : Development progress from April 2021 onwards

- Based on the external Data Monitoring Committee recommendation, Phase III clinical study of LEAP-007 for Non-small cell lung cancer, PD-L1 positive/First-line has been decided to be discontinued and therefore was removed from this list.
- Based on the external Data Monitoring Committee recommendation, Phase III clinical study of LEAP-011 for cisplatin-ineligible bladder cancer, First-line has been decided to be discontinued and therefore was removed from this list.

Development Code: E7389 Generic Name: eribulin Product Name: Halaven				In-house
Indications / Drug class: Anticancer agent / microtubule dynamics inhibitor				Injection
Description: A synthetic analog of halichondrin B derived from the marine sponge <i>Halichondria okadae</i> . Shows an antitumor effect by arresting the cell cycle through inhibition of the growth of microtubules. Approved in over 80 countries including Japan, the United States, China and countries in Europe and in Asia for use in the treatment of breast cancer. Approved in over 80 countries including Japan, the United States and countries in Europe and in Asia for use in the treatment of liposarcoma (soft tissue sarcoma in Japan).				
Monotherapy (Additional Formulation)				
Liposomal formulation	—	JP/EU		PI
In combination with anti-PD-1 antibody nivolumab, joint development with Ono Pharmaceutical (Additional Formulation)				
Liposomal formulation	Study 120	JP		PI/II

Development Code: E7438 Generic Name: tazemetostat Product Name: Tazverik				In-license (Epizyme, Inc.)
Indications / Drug class: Anticancer agent / EZH2 inhibitor				Oral
Description: Believed to have an important role in carcinogenesis, the epigenetic enzyme EZH2 is one of the proteins that constitute histone methyltransferases. Tazverik, a first-in-class, orally administered small molecule inhibitor, was discovered using Epizyme, Inc. proprietary product platform, and is expected to exhibit antitumor effects via inhibition of the epigenetic enzyme EZH2. Eisai holds development and commercialization rights in Japan.				
Non-Hodgkin B-cell lymphoma	Study 206	JP	○	Approved (June, 2021)

Development Code: H3B-6545				In-house
Indications / Drug class: Anticancer agent / ERα inhibitor				Oral
Description: An orally administered selective estrogen receptor (ER) α covalent antagonist that inhibits ERα wild type / ERα mutant. Expected to show an antitumor effect against ER positive / HER2 negative breast cancers.				
Breast cancer	Study 101	US/EU		PI/II
Breast cancer (in combination with CDK4/6 inhibitor palbociclib)	—	US/EU		PI

Development Code: E7090				In-house
Indications / Drug class: Anticancer agent / FGFR1, FGFR2, FGFR3 inhibitor				Oral
Description: An orally administered fibroblast growth factor receptors (FGFR1, FGFR2, FGFR3) selective tyrosine kinase inhibitor. Phase II clinical study for unresectable cholangiocarcinoma (one of biliary tract cancers) with <i>FGFR2</i> gene fusion is ongoing. It has received orphan drug designation with a prospective indication for unresectable biliary tract cancer with <i>FGFR2</i> gene fusion by the Ministry of Health, Labour and Welfare (MHLW) in Japan.				
Cholangiocarcinoma	Study 201	JP/CH		PII
Breast cancer	—	JP		PI

JP: Japan, US: the United States, EU: Europe, CH: China, P: (Clinical trial) Phase

◎ : Development progress from January 2022 onwards ○ : Development progress from April 2021 onwards

Development Code: MORAb-202				In-house
Indications / Drug class: Anticancer agent / farletuzumab- eribulin conjugate				Injection
Description: MORAb-202 is the antibody drug conjugate (ADC) with approved anticancer drug eribulin. Expected to show an antitumor effect against folate receptor α -positive tumors by concentrating eribulin on tumor; inclusive of endometrial, ovarian, lung and breast cancers. In June 2021, Eisai entered into an exclusive global strategic collaboration agreement for the co-development and co-commercialization with Bristol Myers Squibb.				
	Solid tumors	—	US	PI/II
	Solid tumors	—	JP	PI

Development Code: E7386			Collaboration (PRISM BioLab)	Oral
○	Solid tumors (in combination with pembrolizumab)	Study 201	JP/US	PI/II
	Solid tumors	—	JP/EU	PI
	Solid tumors (in combination with lenvatinib)	—	JP	PI

Development Code: H3B-6527			In-house	Oral
	Hepatocellular carcinoma	—	US/EU	PI

Development Code: E7130			Collaboration (Harvard University)	Injection
	Solid tumors	—	JP	PI

Development Code: E7766			In-house	Injection
	Solid tumors	—	US/EU	PI

○ Phase I/II study of MORAb-009 for mesothelioma in the United States and Europe has been finished and therefore was removed from this list.

○ H3B-8800 was licensed to a subsidiary of Roivant Sciences Ltd. and therefore has been removed from this list.

(3) Gastrointestinal Disorders

Development Code: AJM300 Generic Name: carotegrast methyl Product Name: Carogra				In-house
Indications / Drug class: Ulcerative colitis treatment / $\alpha 4$ integrin antagonist				Oral
Description: $\alpha 4$ integrin antagonist with a novel mechanism of action believed to suppress adhesion and infiltration of lymphocytes. In March 2022, EA Pharma obtained manufacturing and marketing approval in Japan as the first orally-available $\alpha 4$ integrin antagonist in the world to be effective in ulcerative colitis. Joint development by EA Pharma and Kissei Pharmaceutical.				
Ulcerative colitis	—	JP	◎	Approved (March, 2022)

Development Code: E3112		In-house	Injection
Liver disease (Development conducted by EA Pharma)	—	JP	PI

Development Code: AJM347		In-house	Oral
Inflammatory bowel disease (Development conducted by EA Pharma)	—	EU	PI

Development Code: EA1080		In-house	Oral
Inflammatory bowel disease (Development conducted by EA Pharma)	—	EU	PI

Development Code: EA3571		In-house	Oral
◎ Nonalcoholic steatohepatitis (Development conducted by EA Pharma)	—	JP	PI

- Due to business priorities, EA Pharma is no longer progressing the development at Phase I/II study in Japan of EA4000 as bowel cleansing agent and therefore EA4000 was removed from this list.
- Due to business priorities, EA Pharma is no longer progressing the development at Phase I study in Japan of EA3355 as an agent for liver disease and therefore EA3355 was removed from this list.
- ◎ Due to business priorities, EA Pharma is no longer progressing the development at Phase II study in Japan of E6007 as an agent for ulcerative colitis treatment and therefore E6007 was removed from this list.
- ◎ Due to business priorities, EA Pharma has decided to discontinue Phase II study in Japan and Europe of E6011 as an agent for Crohn's disease and therefore E6011 was removed from this list.

JP: Japan, US: the United States, EU: Europe, CH: China, P: (Clinical trial) Phase

◎ : Development progress from January 2022 onwards ○ : Development progress from April 2021 onwards

(4) Other

Development Code: D2E7 Generic Name: adalimumab Product Name: Humira				In-license (AbbVie GK)
Indications / Drug class: Fully human anti-TNF α monoclonal antibody				Injection
Description: A fully human anti-TNF α monoclonal antibody, which neutralizes tumor necrosis factor alpha (TNF α), a type of cytokine that plays a central role in inflammatory reactions in patients with autoimmune diseases. Approved in Japan for the treatment of rheumatoid arthritis (including inhibition of the progression of structural damage), psoriasis, Crohn's disease, ankylosing spondylitis, polyarticular juvenile idiopathic arthritis, intestinal Behçet's disease, ulcerative colitis, non-infectious uveitis, hidradenitis suppurativa, and pyoderma gangrenosum.				
<input type="radio"/>	Ulcerative Colitis (High-Dosage in Adult, and Pediatric)	—	JP	Approved (September, 2021)

Development Code: E5564 Generic Name: eritoran				In-house
Indications / Drug class: Suppression for increasing of severity of COVID-19/ TLR 4 antagonist				Injection
Description: Eritoran is a TLR (Toll-Like Receptor) 4 antagonist created with natural product organic synthesis technology. It is a structural analogue of Lipid A which is an activator of endotoxins of bacteria. It is expected to suppress inflammation and increasing in severity caused by COVID-19 by inhibiting the activation of TLR4, which is found in the most upstream position of various cytokine gene expression signaling that causes the cytokine-storm. Joint development with GCAR (Global Coalition for Adaptive Research).				
	Suppression for increasing of severity of COVID-19	REMAP-COVID	JP/US	PIII

Development Code: FYU-981 Generic Name: dotinurad				In-license (FUJI YAKUHIN)
Indications / Drug class: Treatment for Hyperuricemia and Gout / selective URAT1 inhibitor				Oral
Description: Dotinurad selectively inhibits URAT1, one of the uric acid transporters, thus preventing reabsorption of uric acid by kidneys and promoting uric acid excretion in urine. In addition, it has a small effect on other transporters affecting uric acid secretion, so it reduces serum uric acid levels at lower doses. Therefore, dotinurad is expected to have a low risk of side effects and drug interaction. In Japan, FUJI YAKUHIN obtained manufacturing and marketing approval for dotinurad in January 2020. Eisai entered into a license agreement concerning the development and distribution in China in February 2020, and in five ASEAN countries in August 2021 with FUJI YAKUHIN.				
<input type="radio"/>	Gout	Study 301	CH	PIII

Development Code: E6742				In-house
Indications / Drug class: Treatment for Systemic lupus erythematosus / TLR 7/8 inhibitor				Oral
Description: TLRs are receptors of the innate immune system, and activated TLRs initiate an inflammatory reaction or an antiviral response. E6742 is the inhibitor of oral and selective TLR7/8 which is associated with the pathogenesis of systemic lupus erythematosus. This project has been selected by the Japan Agency for Medical Research and Development (AMED) for its Cyclic Innovation for Clinical Empowerment (CiCLE) grand program.				
<input checked="" type="radio"/>	Systemic lupus erythematosus	Study 101	JP	PI/II

Development Code: E8001			In-house	Injection
	Rejection reaction associated with organ transplantation	—	JP	PI

JP: Japan, US: the United States, EU: Europe, CH: China, P: (Clinical trial) Phase

⊙ : Development progress from January 2022 onwards ○ : Development progress from April 2021 onwards