Securities Code: 4523

FY 2021 (Ending March 31, 2022)
Third Quarter Financial Results

Reference Data

February 3, 2022

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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 establishment of AD franchise, risks related to maximization of the value of Lenvima, risks related to partnership model, risks related to digital transformation, risks related to uncertainties in new drug development, risks related to occurrences of 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 medical cost containment measures, risks related to succession, 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.

Contents

Currency Exchange Rates

		US (USD/JPY)	EU (EUR/JPY)	UK (GBP/JPY)	China (RMB/JPY)
FY 2020 Q3	Quarterly Average Rate	106.11	122.37	136.24	15.44
	Quarter End Rate	103.50	126.95	139.82	15.88
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 Q3	Quarterly Average Rate	111.10	130.62	152.76	17.25
	Quarter End Rate	115.02	130.51	155.24	18.06
FY 2021	Q4 Forecast Rate	110.00	130.00	151.50	17.10

* 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.

1. Consolidated Statement of Income

(billions of yen)

	FY 2020				FY 2021				FY 2021	
	Q3	Ratio (%)	Full year	Ratio (%)	Q3	Ratio (%)	YOY (%)	Diff.	Full year forecast	Ratio (%)
Revenue	498.3	100.0	645.9	100.0	565.3	100.0	113.4	67.0	730.0	100.0
Cost of sales	120.2	24.1	161.3	25.0	124.1	22.0	103.3	3.9	163.5	22.4
Gross profit	378.2	75.9	484.6	75.0	441.2	78.0	116.7	63.1	566.5	77.6
Selling, general and administrative expenses	211.4	42.4	281.4	43.6	255.9	45.3	121.1	44.6	325.5	44.6
Selling expenses	88.4	17.7	116.6	18.1	126.4	22.4	143.0	38.0	—	—
Personnel expenses	68.7	13.8	90.6	14.0	73.9	13.1	107.6	5.2	—	—
Administrative and other expenses	54.3	10.9	74.2	11.5	55.6	9.8	102.5	1.3	—	—
Research and development expenses	108.2	21.7	150.3	23.3	123.3	21.8	114.0	15.1	174.5	23.9
Other income	0.7	0.1	1.5	0.2	14.1	2.5	1956.6	13.4	11.5	1.6
Other expenses	1.7	0.3	2.6	0.4	1.6	0.3	93.2	(0.1)	—	—
Operating profit	57.7	11.6	51.8	8.0	74.6	13.2	129.2	16.9	78.0	10.7
Financial income	1.6	0.3	2.1	0.3	1.9	0.3	117.2	0.3	—	—
Financial costs	0.9	0.2	1.4	0.2	1.2	0.2	127.5	0.3	—	—
Profit before income taxes	58.4	11.7	52.6	8.1	75.2	13.3	128.9	16.9	78.5	10.8
Income taxes	12.5	2.5	10.1	1.6	15.6	2.8	125.2	3.1	—	—
Profit for the period	45.9	9.2	42.5	6.6	59.6	10.5	130.0	13.7	61.0	8.4
Profit for the period attributable to										
Owners of the parent	45.2	9.1	42.1	6.5	60.4	10.7	133.6	15.2	60.5	8.3
Non-controlling interests	0.7	0.1	0.4	0.1	(0.8)	(0.1)	—	(1.5)	—	—
Comprehensive income for the period	40.4	8.1	71.0	11.0	76.6	13.6	189.5	36.2		

Earnings per share (EPS, yen)	157.59	146.95	210.54	211.00
Dividend per share (DPS, yen)	—	160.0	—	160.0
Return on equity (ROE, %)	—	6.1	—	8.4
Dividends on equity ratio (DOE, %)	—	6.6	—	6.3

* 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: 141.1 billion yen (the same period in previous fiscal year: 103.8 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., Kenilworth, N.J., U.S.A.: 34.5 billion yen (achieved 1.4 billion U.S. dollars for CY2021) (the same period in previous fiscal year: 20.7 billion yen)
Selling, general and administrative expenses	Recording of expenses regarding shared profit of Lenvima paid to Merck & Co., Inc., Kenilworth, N.J., U.S.A.: 65.6 billion yen (the same period in previous fiscal year: 47.0 billion yen)
	Recording of cost related to Alzheimer's disease treatment ADUHELM (aducanumab): 32.1 billion yen (the same period in previous fiscal year: 15.4 billion yen) including the cost of 8.2 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, ADUHELM and Lenvima
	Control of the expenses through the partnership model (partner's burden: 52.6 billion yen (the same period in previous fiscal year: 46.8 billion yen)) including recording of 8.3 billion yen as a regulatory milestone payment from Merck & Co., Inc., Kenilworth, N.J., U.S.A. due to approval of Lenvima for use in the treatment of renal cell carcinoma in the U.S.
Other income	Recording of profit from divestiture of rights for antiepileptic agent Zonegran in Europe, the Middle East, Russia and Australia
Profit for the period attributable to Non-controlling interests	A quarterly loss due to recording of termination benefits following an implementation of a special second career program as well as impairment losses resulting from a revaluation of the R&D pipeline, in EA Pharma Co., Ltd., a consolidated subsidiary in which the Company holds 60% of the voting rights
Exchange rate effects	Revenue: +24.59 billion yen, operating profit: +7.03 billion yen
Exchange rate sensitivity (annual effect of 1 yen appreciation in currency value)	Revenue (U.S. dollars: -2.53 billion yen, Euro: -0.30 billion yen, U.K. pounds: -0.06 billion yen, Chinese renminbi: -6.43 billion yen) Operating profit (U.S. dollars: +0.53 billion yen, Euro: -0.31 billion yen, U.K. pounds: +0.09 billion yen, Chinese renminbi: -4.73 billion yen)

2. Segment Information

1) Revenue by Reporting Segment

(billions of yen)

	FY 2020		FY 2021		
	Q3	Full year	Q3	YOY (%)	CER YOY (%)
Pharmaceutical Business Total	454.5	586.1	472.8	104.0	99.7
Japan pharmaceutical business	180.9	231.9	163.4	90.3	90.3
Americas pharmaceutical business	110.9	142.8	125.2	112.9	107.7
United States	109.5	140.9	123.3	112.6	107.6
China pharmaceutical business	66.4	85.1	83.1	125.1	112.1
EMEA pharmaceutical business	41.6	55.2	44.3	106.7	99.3
Asia and Latin America pharmaceutical business	34.7	45.9	38.0	109.5	103.5
OTC and others	19.9	25.2	18.7	94.0	94.0
Other business	43.8	59.9	92.5	211.1	199.5
Consolidated revenue	498.3	645.9	565.3	113.4	108.5

* Indicates revenue from external customers.

* CER=Constant Exchange Rates

2) Profit by Reporting Segment

(billions of yen)

	FY 2020		FY 2021		
	Q3	Full year	Q3	YOY (%)	CER YOY (%)
Pharmaceutical Business Total	196.2	238.4	207.6	105.8	99.8
Japan pharmaceutical business	70.3	83.9	47.4	67.4	67.4
Americas pharmaceutical business	52.5	64.7	58.1	110.8	106.7
China pharmaceutical business	33.9	40.4	46.8	138.0	119.1
EMEA pharmaceutical business	20.0	25.7	34.9	174.9	164.9
Asia and Latin America pharmaceutical business	14.8	18.6	16.0	108.0	100.1
OTC and others	4.7	5.1	4.3	92.2	92.2
Other business	37.9	51.5	86.7	228.8	216.8
Research and development expenses	(108.2)	(150.3)	(123.3)	114.0	108.1
Group headquarters' management costs and other expenses[#]	(68.3)	(87.8)	(96.5)	141.3	137.1
Consolidated operating profit	57.7	51.8	74.6	129.2	117.0

* 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)

	FY 2020		FY 2021	
	Q3	Full year	Q3	YOY (%)
Revenue	180.9	231.9	163.4	90.3
Segment profit	70.3	83.9	47.4	67.4
Japan prescription medicines - revenue from major products				
Fully human anti-TNF-α monoclonal antibody Humira	38.5	52.0	38.7	100.6
Insomnia treatment Dayvigo	1.2	2.0	8.6	699.4
Peripheral neuropathy treatment Methycobal	9.3	12.4	8.2	88.2
Anticancer agent Lenvima	9.7	12.2	7.7	79.5
Anticancer agent Halaven	6.2	8.5	6.3	101.5
Antirheumatic agent Careram	5.7	7.8	6.2	109.8
Insomnia treatment Lunesta	10.4	13.9	5.8	55.3
Alzheimer's disease / Dementia with Lewy bodies treatment Aricept	7.4	9.3	5.6	75.3
Proton pump inhibitor Pariet[#]	6.3	7.9	5.5	86.6
Elemental diet Elental[#]	5.1	6.6	5.2	102.1
Chronic constipation treatment Goofice[#]	3.7	5.0	4.6	123.5
Pain treatment (neuropathic pain, fibromyalgia) Lyrica	20.5	21.5	4.6	22.6
Antiepileptic agent Fycompa	3.8	5.1	4.1	105.6

* 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	
	Q3	Full year	Q3	YOY (%)
Revenue	110.9	142.8	125.2	112.9 <107.7>
United States	109.5	140.9	123.3	112.6 <107.6>
Segment profit	52.5	64.7	58.1	110.8 <106.7>
Americas - revenue from major products				
Anticancer agent Lenvima	62.2	81.0	82.6	132.9 <126.8>
United States [Millions USD]	61.6 [580]	80.1 [756]	81.9 [737]	133.1 <127.1>
Antiepileptic agent Fycompa	9.3	12.2	10.8	115.9 <110.4>
United States [Millions USD]	9.0 [84]	11.8 [111]	10.4 [94]	116.1 <110.9>
Anticancer agent Halaven	9.5	12.6	10.4	110.2 <105.1>
United States [Millions USD]	9.3 [87]	12.3 [116]	10.2 [92]	110.4 <105.4>
Antiepileptic agent Banzel	15.0	18.9	6.2	41.2 <39.3>
United States [Millions USD]	14.8 [139]	18.7 [176]	6.0 [54]	40.3 <38.5>
Insomnia Treatment Dayvigo	0.6	1.1	2.7	478.7 <453.8>
United States [Millions USD]	0.6 [5]	1.1 [10]	2.4 [21]	427.4 <408.2>

* 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	
	Q3	Full year	Q3	YOY (%)
Revenue	66.4	85.1	83.1	125.1 <112.1>
Segment profit	33.9	40.4	46.8	138.0 <119.1>
China - revenue from major products				
Anticancer agent Lenvima [Millions RMB]	15.1 [979]	18.5 [1,178]	27.8 [1,609]	183.7 <164.4>
Peripheral neuropathy treatment Methycobal [Millions RMB]	14.1 [915]	17.5 [1,116]	9.8 [571]	69.7 <62.4>
Liver disease / Allergic disease agents Stronger Neo-Minophagen C and Glycyron Tablets [Millions RMB]	7.9 [515]	10.1 [643]	7.3 [422]	91.7 <82.1>
Proton pump inhibitor Pariet [Millions RMB]	4.7 [308]	6.7 [430]	6.7 [387]	140.4 <125.7>
Alzheimer's disease treatment Aricept [Millions RMB]	4.5 [291]	5.8 [367]	4.1 [237]	90.8 <81.3>
Anticancer agent Halaven [Millions RMB]	1.2 [78]	1.6 [100]	1.3 [73]	103.7 <92.8>
Antiepileptic agent Fycompa [Millions RMB]	0.4 [28]	0.5 [30]	0.8 [46]	183.4 <164.2>

* 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	
	Q3	Full year	Q3	YOY (%)
Revenue	41.6	55.2	44.3	106.7 <99.3>
Segment profit	20.0	25.7	34.9	174.9 <164.9>
EMEA - revenue from major products				
Anticancer agent Lenvima/Kisplyx	11.8	15.8	16.3	137.9 <128.1>
Anticancer agent Halaven	9.2	12.4	9.9	107.2 <99.6>
Antiepileptic agent Fycompa	5.5	7.6	6.8	122.3 <113.8>
Antiepileptic agent Inovelon	1.9	2.5	2.0	108.3 <100.0>

* 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	
	Q3	Full year	Q3	YOY (%)
Revenue	34.7	45.9	38.0	109.5 <103.5>
Segment profit	14.8	18.6	16.0	108.0 <100.1>
Asia and Latin America - revenue from major products				
Alzheimer's disease / Dementia with Lewy bodies treatment Aricept	8.2	10.9	9.0	110.2 <103.7>
Anticancer agent Lenvima	4.9	6.5	6.8	136.7 <127.9>
Fully human anti-TNF-α monoclonal antibody Humira	6.3	8.5	5.7	90.3 <84.7>
Proton pump inhibitor Pariet	3.2	4.0	3.0	93.9 <89.1>
Peripheral neuropathy treatment Methycobal	2.3	3.0	2.7	121.5 <116.0>
Anticancer agent Halaven	2.0	2.6	1.8	89.3 <83.1>
Antiepileptic agent Fycompa	0.9	1.3	1.1	118.9 <111.8>

* 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	
	Q3	Full year	Q3	YOY (%)
Revenue	19.9	25.2	18.7	94.0
Segment profit	4.7	5.1	4.3	92.2
OTC and others, revenue from major products				
Vitamin B2 preparation, "Chocola BB Plus," etc. Chocola BB Group	10.4	13.4	11.3	107.8

4. Revenue from Major Products

1) Neurology Products

(billions of yen)

	FY 2020		FY 2021	
	Q3	Full year	Q3	YOY (%)
Neurology Products Total	127.4	161.4	103.5	81.2 <77.9>
Fycompa (Antiepileptic agent)	20.1	26.7	23.5	117.3 <111.6>
Japan	3.8	5.1	4.1	105.6
Americas	9.3	12.2	10.8	115.9 <110.4>
China	0.4	0.5	0.8	183.4 <164.2>
EMEA	5.5	7.6	6.8	122.3 <113.8>
Asia and Latin America	0.9	1.3	1.1	118.9 <111.8>
Methycobal (Peripheral neuropathy treatment)	26.6	34.2	21.7	81.8 <77.4>
Japan	9.3	12.4	8.2	88.2
China	14.1	17.5	9.8	69.7 <62.4>
Asia and Latin America	2.3	3.0	2.7	121.5 <116.0>
Aricept (Alzheimer's disease / Dementia with Lewy bodies treatment)	20.4	26.3	19.0	93.3 <88.4>
Japan	7.4	9.3	5.6	75.3
China	4.5	5.8	4.1	90.8 <81.3>
Asia and Latin America	8.2	10.9	9.0	110.2 <103.7>
Dayvigo (Insomnia treatment)	1.8	3.1	11.3	633.0 <625.2>
Japan	1.2	2.0	8.6	699.4
Americas	0.6	1.1	2.7	478.7 <453.8>
Inovelon/Banzel (Antiepileptic agent)	17.3	22.0	8.7	50.3 <47.6>
Americas	15.0	18.9	6.2	41.2 <39.3>
EMEA	1.9	2.5	2.0	108.3 <100.0>
Lunesta (Insomnia treatment) - Japan	10.4	13.9	5.8	55.3
Lyrica (Pain treatment [neuropathic pain, fibromyalgia]) - Japan	20.5	21.5	4.6	22.6
Other	10.4	13.6	8.8	84.6 <81.4>

* 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	
	Q3	Full year	Q3	YOY (%)
Oncology Products Total	142.4	183.3	176.0	123.6 <116.6>
Lenvima/Kisplyx (Anticancer agent)	103.8	133.9	141.1	136.0 <128.1>
Japan	9.7	12.2	7.7	79.5
Americas	62.2	81.0	82.6	132.9 <126.8>
China	15.1	18.5	27.8	183.7 <164.4>
EMEA	11.8	15.8	16.3	137.9 <128.1>
Asia and Latin America	4.9	6.5	6.8	136.7 <127.9>
Halaven (Anticancer agent)	28.1	37.6	29.7	105.5 <100.4>
Japan	6.2	8.5	6.3	101.5
Americas	9.5	12.6	10.4	110.2 <105.1>
China	1.2	1.6	1.3	103.7 <92.8>
EMEA	9.2	12.4	9.9	107.2 <99.6>
Asia and Latin America	2.0	2.6	1.8	89.3 <83.1>
Other	10.5	11.8	5.2	49.6 <45.7>

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

5. Revenue Forecast by Reporting Segment (FY 2021)

(billions of yen)

	FY 2020		FY 2021	
	Q3	Full year	Q3	Full year forecast
Japan (Prescription Medicines)	180.9	231.9	163.4	207.0
Fully human anti-TNF-α monoclonal antibody Humira	38.5	52.0	38.7	46.0
Anticancer agent Lenvima	9.7	12.2	7.7	12.5
Peripheral neuropathy treatment Methycobal	9.3	12.4	8.2	10.5
Anticancer agent Halaven	6.2	8.5	6.3	7.5
Antirheumatic agent Careram	5.7	7.8	6.2	7.5
Chronic constipation treatment Goofice[#]	3.7	5.0	4.6	7.0
Antiepilepsy agent Fycompa	3.8	5.1	4.1	6.5
Alzheimer's disease / Dementia with Lewy bodies treatment Aricept	7.4	9.3	5.6	6.5
Elemental diet Elental[#]	5.1	6.6	5.2	6.5
Insomnia treatment Lunesta	10.4	13.9	5.8	6.0
Americas	110.9	142.8	125.2	165.0
United States	109.5	140.9	123.3	162.0
China	66.4	85.1	83.1	102.0
EMEA	41.6	55.2	44.3	58.0
Asia and Latin America	34.7	45.9	38.0	49.0
OTC and others (Japan)	19.9	25.2	18.7	26.0
Vitamin B2 preparation, "Chocola BB Plus," etc. Chocola BB Group	10.4	13.4	11.3	13.0
Other	43.8	59.9	92.5	123.0
Consolidated revenue	**498.3**	**645.9**	**565.3**	**730.0**
Global revenue from major products				
Lenvima/Kisplyx	103.8	133.9	141.1	181.5
Japan	9.7	12.2	7.7	12.5
Americas	62.2	81.0	82.6	110.0
China	15.1	18.5	27.8	29.0
EMEA	11.8	15.8	16.3	21.5
Asia and Latin America	4.9	6.5	6.8	8.5
Halaven	28.1	37.6	29.7	39.5
Japan	6.2	8.5	6.3	7.5
Americas	9.5	12.6	10.4	13.0
China	1.2	1.6	1.3	2.5
EMEA	9.2	12.4	9.9	13.5
Asia and Latin America	2.0	2.6	1.8	3.0
Fycompa	20.1	26.7	23.5	33.0
Japan	3.8	5.1	4.1	6.5
Americas	9.3	12.2	10.8	15.0
China	0.4	0.5	0.8	1.0
EMEA	5.5	7.6	6.8	9.0
Asia and Latin America	0.9	1.3	1.1	1.5

[#] EA Pharma product

6. Consolidated Statement of Comprehensive Income

(billions of yen)

	FY 2020		FY 2021		
	Q3	Full year	Q3	YOY (%)	Diff.
Profit for the period	45.9	42.5	59.6	130.0	13.7
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)	1.0	3.2	(1.4)	–	(2.4)
Remeasurements of defined benefit plans	–	3.2	–	–	–
Subtotal	1.0	6.4	(1.4)	–	(2.4)
Items that may be reclassified subsequently to profit or loss					
Exchange differences on translation of foreign operations	(6.5)	22.0	18.4	–	24.8
Cash flow hedges	0.1	0.1	0.1	79.0	(0.0)
Subtotal	(6.4)	22.2	18.4	–	24.8
Total other comprehensive income (loss), net of tax	(5.4)	28.6	17.0	–	22.5
Comprehensive income (loss) for the period	40.4	71.0	76.6	189.5	36.2
Comprehensive income (loss) for the period attributable to					
Owners of the parent	39.7	70.6	77.4	194.9	37.7
Non-controlling interests	0.7	0.4	(0.8)	–	(1.5)

7. Consolidated Statement of Cash Flows

(billions of yen)

	FY 2020	FY 2021	
	Q3	Q3	Diff.
Operating activities			
Profit before income taxes	58.4	75.2	16.9
Depreciation and amortization	26.8	29.2	2.4
Impairment losses	0.2	1.9	1.7
(Increase) decrease in working capital	(48.3)	(13.2)	35.1
Interest and dividends received	1.6	1.5	(0.1)
Interest paid	(0.7)	(0.9)	(0.2)
Income taxes paid	(16.6)	(8.5)	8.2
Income taxes refund	1.1	3.5	2.4
Other	(0.3)	(15.6)	(15.3)
Net cash from (used in) operating activities	22.1	73.2	51.1
Investing activities			
Purchases of property, plant and equipment	(14.5)	(22.0)	(7.6)
Purchases of intangible assets	(16.4)	(10.5)	5.9
Proceeds from sale of property, plant and equipment and intangible assets	0.0	13.3	13.3
Payments on investments in joint ventures	(0.2)	―	0.2
Purchases of financial assets	(1.4)	(1.8)	(0.4)
Proceeds from sale and redemption of financial assets	1.2	2.4	1.3
Subtotal <Capital expenditures (cash basis)>	(31.4)	(18.6)	12.8
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	0.1	(0.1)	(0.2)
Net cash from (used in) investing activities	(31.1)	(18.7)	12.4
Financing activities			
Proceeds from long-term borrowings	34.9	―	(34.9)
Repayments of long-term borrowings	(35.0)	―	35.0
Repayments of lease liabilities	(7.6)	(7.8)	(0.1)
Dividends paid	(45.9)	(45.9)	(0.0)
Other	(0.1)	0.2	0.3
Net cash from (used in) financing activities	(53.6)	(53.4)	0.2
Effect of exchange rate change on cash and cash equivalents	2.1	8.6	6.5
Net increase (decrease) in cash and cash equivalents	(60.5)	9.7	70.1
Cash and cash equivalents at beginning of period	254.2	248.7	(5.5)
Cash and cash equivalents at end of period	193.8	258.4	64.6

Free cash flows	(9.3)	54.6	63.8

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

Notes

■Net cash from (used in) operating activities
In addition to increase in profit before income taxes, reimbursement for research and development payment was received from Bristol Myers Squibb.

■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

■Net cash from (used in) financing activities
Dividends have been paid

8. Capital Expenditures, Depreciation and Amortization

(billions of yen)

	FY 2020		FY 2021		FY 2021
	Q3	Full year	Q3	Diff.	Full year forecast
Capital expenditures (cash basis)	30.9	38.1	32.5	1.7	56.0
Property, plant and equipment	14.5	19.1	22.0	7.6	23.5
Intangible assets	16.4	19.0	10.5	(5.9)	32.5
Depreciation and amortization	26.8	36.3	29.2	2.4	36.5
Property, plant and equipment	14.2	19.3	16.3	2.1	20.5
Intangible assets	12.6	17.0	12.9	0.3	16.0

9. Consolidated Statement of Financial Position

<Assets>

(billions of yen)

	FY 2020		FY 2021			
	March 31, 2021	Ratio (%)	December 31, 2021	Ratio (%)	% change	Diff.
Assets						
Non-current assets						
Property, plant and equipment	160.9	14.8	162.4	13.9	100.9	1.5
Goodwill	171.8	15.8	178.6	15.3	103.9	6.8
Intangible assets	108.6	10.0	105.3	9.0	96.9	(3.3)
Other financial assets	43.8	4.0	42.0	3.6	95.8	(1.8)
Other assets	19.6	1.8	19.2	1.6	98.3	(0.3)
Deferred tax assets	66.9	6.1	72.8	6.2	108.8	5.9
Total non-current assets	571.7	52.4	580.3	49.7	101.5	8.6
Current assets						
Inventories	85.1	7.8	92.5	7.9	108.7	7.4
Trade and other receivables	160.3	14.7	214.6	18.4	133.9	54.3
Other financial assets	0.3	0.0	0.9	0.1	345.3	0.7
Other assets	23.9	2.2	20.6	1.8	86.2	(3.3)
Cash and cash equivalents	248.7	22.8	258.4	22.1	103.9	9.7
Total current assets	518.3	47.6	587.1	50.3	113.3	68.7
Total assets	1,090.0	100.0	1,167.4	100.0	107.1	77.3

Notes

■ Assets	
(Trade and other receivables)	Increase in trade receivables following the recording of sales milestone payments from Merck & Co., Inc., Kenilworth, N.J., U.S.A.
(Cash and cash equivalents)	Increase due to receipt of an upfront payment and reimbursement for research and development payment from Bristol Myers Squibb

<Equity and Liabilities>

(billions of yen)

	FY 2020		FY 2021			
	March 31, 2021	Ratio (%)	December 31, 2021	Ratio (%)	% change	Diff.
Equity						
Equity attributable to owners of the parent						
Share capital	45.0	4.1	45.0	3.9	100.0	—
Capital surplus	77.6	7.1	77.6	6.6	100.0	(0.0)
Treasury shares	(34.0)	(3.1)	(34.0)	(2.9)	99.8	0.1
Retained earnings	508.0	46.6	521.1	44.6	102.6	13.1
Other components of equity	106.6	9.8	125.1	10.7	117.3	18.5
Total equity attributable to owners of the parent	703.2	64.5	734.8	62.9	104.5	31.6
Non-controlling interests	24.8	2.3	23.9	2.0	96.5	(0.9)
Total equity	727.9	66.8	758.7	65.0	104.2	30.7
Liabilities						
Non-current liabilities						
Borrowings	49.9	4.6	49.9	4.3	100.0	0.0
Other financial liabilities	39.8	3.7	36.6	3.1	92.0	(3.2)
Provisions	1.4	0.1	1.5	0.1	105.5	0.1
Other liabilities	14.4	1.3	15.3	1.3	106.4	0.9
Deferred tax liabilities	0.5	0.0	0.3	0.0	61.9	(0.2)
Total non-current liabilities	106.1	9.7	103.7	8.9	97.8	(2.4)
Current liabilities						
Borrowings	40.0	3.7	40.0	3.4	100.0	0.0
Trade and other payables	94.5	8.7	90.6	7.8	95.9	(3.9)
Other financial liabilities	17.0	1.6	39.9	3.4	234.7	22.9
Income taxes payable	2.5	0.2	14.4	1.2	569.6	11.8
Provisions	17.9	1.6	16.4	1.4	91.8	(1.5)
Other liabilities	84.1	7.7	103.7	8.9	123.3	19.6
Total current liabilities	256.0	23.5	305.0	26.1	119.1	49.0
Total liabilities	362.1	33.2	408.7	35.0	112.9	46.6
Total equity and liabilities	1,090.0	100.0	1,167.4	100.0	107.1	77.3

Notes

■ Equity	
(Retained earnings)	Increase due to recording of profit for the period exceeding dividends paid
(Other components of equity)	Increase in exchange differences on translation of foreign operations due to depreciation of yen
■ Liabilities	
(Other financial liabilities - current)	Increase mainly in deposits received (reimbursement for research and development payment from Bristol Myers Squibb)
(Other liabilities - current)	Increase mainly in accrued expenses (shared profit paid to Merck & Co., Inc., Kenilworth, N.J., U.S.A.)

10. Changes in Quarterly Results

1) Income Statement

(billions of yen)

	FY 2020				FY 2021		
	Q1	Q2	Q3	Q4	Q1	Q2	Q3
Revenue	165.6	151.5	181.3	147.6	198.9	163.5	203.0
Cost of sales	38.3	41.4	40.4	41.1	39.2	40.6	44.2
Gross profit	127.3	110.0	140.8	106.5	159.6	122.8	158.8
Selling, general and administrative expenses	64.9	69.0	77.5	70.0	74.7	79.8	101.5
Selling expenses	28.2	28.4	31.8	28.3	32.4	40.3	53.7
Personnel expenses	22.0	22.6	24.1	21.9	22.7	22.9	28.3
Administrative and other expenses	14.7	18.0	21.5	19.9	19.7	16.5	19.4
Research and development expenses	30.5	37.0	40.6	42.1	41.8	38.1	43.4
Other income	0.7	(0.1)	0.1	0.7	13.4	0.2	0.4
Other expenses	0.4	2.0	(0.7)	1.0	1.1	(0.3)	0.7
Operating profit	32.1	2.0	23.6	(5.9)	55.4	5.5	13.6
Financial income	0.7	0.3	0.6	0.6	0.7	0.5	0.6
Financial costs	0.3	0.3	0.3	0.4	0.4	0.4	0.4
Profit before income taxes	32.4	2.0	23.9	(5.8)	55.8	5.6	13.9
Income taxes	7.7	0.6	4.2	(2.4)	13.5	1.3	0.8
Profit for the period	24.8	1.4	19.7	(3.4)	42.3	4.2	13.0
Profit for the period attributable to							
Owners of the parent	24.4	1.4	19.4	(3.0)	42.2	4.0	14.2
Non-controlling interests	0.3	(0.0)	0.4	(0.3)	0.1	0.2	(1.1)
Comprehensive income for the period	23.7	(0.6)	17.3	30.6	42.4	8.0	26.2
Earnings per share (EPS, yen)	85.23	4.79	67.58	(10.63)	147.07	14.04	49.43

* 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
Net cash from (used in) operating activities	10.0	8.6	3.5	51.7	(14.3)	82.7	4.8
Net cash from (used in) investing activities	(12.5)	(4.9)	(13.7)	(5.8)	0.1	(8.1)	(10.7)
Net cash from (used in) financing activities	(25.4)	(2.9)	(25.4)	(2.3)	(22.5)	(5.4)	(25.5)
Cash and cash equivalents at end of period	226.3	228.0	193.8	248.7	213.1	283.0	258.4
Free cash flow	(2.6)	3.7	(10.4)	45.7	(14.1)	74.6	(5.9)

* "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
Capital expenditures (cash basis)	12.1	4.6	14.2	7.3	14.9	7.1	10.6
Property, plant and equipment	8.8	4.0	1.6	4.7	12.1	6.1	3.8
Intangible assets	3.2	0.6	12.6	2.6	2.8	0.9	6.8
Depreciation and amortization	8.7	9.0	9.2	9.5	9.5	9.8	9.9
Property, plant and equipment	4.7	4.7	4.8	5.1	5.3	5.5	5.5
Intangible assets	4.0	4.3	4.4	4.3	4.2	4.4	4.4

4) Financial Positions

(billions of yen)

	Jun. 30, 2020	Sept. 30, 2020	Dec. 31, 2020	Mar. 31, 2021	Jun. 30, 2021	Sept. 30, 2021	Dec. 31, 2021
Total assets	1,040.3	1,046.6	1,028.6	1,090.0	1,129.3	1,140.1	1,167.4
Equity	703.3	702.8	697.2	727.9	747.4	755.3	758.7
Attributable to owners of the parent	678.6	678.2	672.2	703.2	722.6	730.3	734.8
Liabilities	337.0	343.8	331.4	362.1	382.0	384.8	408.7
Borrowings	89.9	89.9	89.9	89.9	92.7	89.9	89.9
Ratio of equity attributable to owners of the parent (%)	65.2	64.8	65.4	64.5	64.0	64.1	62.9
Net debt equity ratio (times)	(0.25)	(0.25)	(0.20)	(0.27)	(0.20)	(0.30)	(0.26)

* "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
Neurology Total	43.8	43.1	40.4	34.0	34.1	33.3	36.1
Fycompa (Antiepileptic agent)	6.4	6.7	7.0	6.7	7.4	7.7	8.4
Japan	1.2	1.4	1.3	1.3	1.2	1.4	1.5
Americas	3.0	3.1	3.2	2.9	3.4	3.5	3.8
China	0.1	0.1	0.2	0.0	0.2	0.3	0.3
EMEA	1.7	1.8	2.0	2.1	2.2	2.2	2.4
Asia and Latin America	0.3	0.3	0.3	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
Japan	3.3	3.0	3.0	3.1	2.4	2.8	2.9
China	6.9	5.1	2.1	3.4	3.3	3.3	3.3
Asia and Latin America	0.6	0.9	0.7	0.8	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
Japan	2.9	2.3	2.2	1.9	1.8	1.9	1.9
China	2.2	1.2	1.1	1.3	1.4	1.2	1.5
Asia and Latin America	2.6	2.7	2.8	2.7	3.0	2.9	3.0
Dayvigo (Insomnia treatment)	0.1	0.8	0.8	1.3	2.6	3.7	5.0
Japan	0.1	0.7	0.4	0.8	1.9	2.9	3.9
Americas	0.0	0.1	0.4	0.6	0.8	0.8	1.1
Inovelon/Banzel (Antiepileptic agent)	5.9	5.9	5.5	4.7	3.7	2.6	2.4
Americas	5.1	5.1	4.7	4.0	2.8	1.8	1.5
EMEA	0.6	0.6	0.7	0.6	0.7	0.7	0.7
Lunesta (Insomnia treatment) - Japan	3.6	3.3	3.5	3.5	2.9	1.5	1.4
Lyrica (Pain treatment [neuropathic pain, fibromyalgia]) - Japan	6.1	7.2	7.1	1.1	1.6	1.5	1.6
Other	3.0	3.4	4.0	3.2	2.8	2.8	3.2

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

11. 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 5 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: **BIIB037** Generic Name: **aducanumab** Product Name: **ADUHELM**	Co-development (Biogen Inc.)
Indications / Drug class: Treatment for Alzheimer's disease / anti-Aβ monoclonal antibody	Injection

Description: A human recombinant monoclonal antibody (mAb) that is derived from a de-identified library of B cells collected from healthy elderly subjects with no signs of cognitive impairment or cognitively impaired elderly subjects with unusually slow cognitive decline using Neurimmune's technology platform, Reverse Translational Medicine (RTM). Biogen Inc. licensed aducanumab from Neurimmune. Aducanumab is thought to target aggregated forms of amyloid beta (Aβ) including soluble oligomers and insoluble fibrils, which can form into amyloid plaque in Alzheimer's disease (AD) patients. The United States Food and Drug Administration (FDA) granted accelerated approval as the first and only AD treatment to address a defining pathology of the disease in June 2021. Continued approval for ADUHELM's indication as a treatment for AD may be contingent upon verification of clinical benefit in confirmatory trial(s). The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a negative opinion on the Marketing Authorization Application (MAA) for aducanumab in December 2021. Process for seeking a re-examination of the opinion by the CHMP is underway. In December 2021, in Japan, additional data were requested on the application for the manufacturing and marketing approval and the application needed to be deliberated continuously. Joint development with Biogen Inc.

	Alzheimer's disease	ENGAGE/ EMERGE Studies	US EU JP	○	Approved (June, 2021) Submitted (accepted: October, 2020) Submitted (December, 2020)

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

◎：Development progress from October 2021 onwards ○：Development progress from April 2021 onwards

Development Code: **BAN2401** Generic Name: **lecanemab**					In-license (BioArctic AB)
Indications / Drug class: Disease modifying treatment for Alzheimer's disease / anti-Aβ protofibril antibody					Injection
Description: An IgG1 antibody that targets Aβ protofibrils. Expected to be effective in the treatment of AD by halting disease progression through the elimination of neurotoxic Aβ 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). 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. FDA granted Fast Track designation in December 2021. Joint development with Biogen Inc.					
	Early AD	Study 201 Study 301 (Clarity AD)	US JP/US/EU/CH	○	Rolling submission (initiated: September 2021) PIII
	Preclinical AD	Study 303 (AHEAD 3-45)	JP/US/EU		PIII

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

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

◎：Development progress from October 2021 onwards ○：Development progress from April 2021 onwards

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	

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

◎：Development progress from October 2021 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 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 75 countries including Japan, the United States, China and countries in Europe and in Asia. Approved for use in the treatment of thymic carcinoma in Japan. Also 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. The agent is marketed under the product name Kisplyx only for this indication in Europe. Approved for use in the treatment of hepatocellular carcinoma (first-line) in over 70 countries including in Japan, the United States, China and countries in Europe and in Asia. Approved for use in the treatment of endometrial carcinoma (following prior systemic therapy) in combination with pembrolizumab in the United States in July 2021, in Europe in November 2021, and approved for the similar indication (including conditional approval) in over 10 countries such as Canada and Australia. In addition, approved for use in the treatment of endometrial carcinoma in Japan in December 2021. Approved for use in the treatment of renal cell carcinoma (first-line) in combination with pembrolizumab in the United States in August 2021, in Europe in November 2021 and in Taiwan in January 2022. Joint development with Merck & Co., Inc., Kenilworth, N.J., U.S.A., through an affiliate.					
In combination with anti-PD-1 antibody pembrolizumab, joint development with Merck & Co., Inc., Kenilworth, N.J., U.S.A., through an affiliate (Additional Indication)					
	Endometrial carcinoma, following prior systemic therapy	Study 309	US EU JP	○ ◎ ◎	Approved (July, 2021) Approved (November, 2021) Approved (December, 2021)
	Renal cell carcinoma / First-line	Study 307	US EU Asia (Taiwan) JP	○ ◎ ◎	Approved (August, 2021) Approved (November, 2021) Approved (January, 2022) Submitted (March, 2021)
	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., Kenilworth, N.J., U.S.A., 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 October 2021 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 *Halichondria okadai*. Shows an antitumor effect by arresting the cell cycle through inhibition of the growth of microtubules. Approved in over 75 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 75 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. In June 2021, approved for *EZH2* gene mutation-positive follicular lymphoma 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 / FGFR1,2,3 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 *FGFR2* gene fusion is ongoing. It has received orphan drug designation with a prospective indication for unresectable biliary tract cancer with *FGFR2* gene fusion by the Ministry of Health, Labour and Welfare (MHLW).					
	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 October 2021 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.

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

◎：Development progress from October 2021 onwards ○：Development progress from April 2021 onwards

(3) Gastrointestinal Disorders

Development Code: **AJM300** Generic Name: **carotegrast methyl**					In-house
Indications / Drug class: Ulcerative colitis treatment / α4 integrin antagonist					Oral
Description: α4 integrin antagonist with a novel mechanism of action believed to suppress adhesion and infiltration of lymphocytes. Aiming to be marketed as the first orally-available α4 integrin antagonist in the world to be effective in ulcerative colitis. In May 2021, EA Pharma filed the New Drug Application in Japan. Joint development by EA Pharma and Kissei Pharmaceutical.					
	Ulcerative colitis	—	JP	○	Submitted (May, 2021)

Development Code: **E6007** Generic Name: **milategrast**					In-house
Indications / Drug class: Ulcerative colitis treatment / integrin activation inhibitor					Oral
Description: A compound with a novel mechanism of action that is believed to suppress the adhesion and infiltration of multiple leukocyte types by inhibiting integrin activation. EA Pharma aims for commercialization jointly with the University of Tsukuba as an industry-academia practical application project under the Japan Science and Technology Agency. Development conducted by EA Pharma.					
	Ulcerative colitis	Study 201	JP		PII

Development Code: **E6011** Generic Name: **quetmolimab**					In-house
Indications / Drug class: Crohn's disease / humanized anti-fractalkine monoclonal antibody					Injection
Description: The world's first humanized anti-fractalkine monoclonal antibody discovered by the Eisai Group subsidiary KAN Research Institute. Expected to exert an anti-inflammatory effect by neutralizing fractalkine. Fractalkine is found in vascular endothelial cells and induces an inflammatory response associated with diseases such as inflammatory bowel disease. Development conducted by EA Pharma.					
	Crohn's disease	Study ET2	JP/EU		PII

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

○ 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 EA3335 was removed from this list.

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

◎：Development progress from October 2021 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-TNFα monoclonal antibody					Injection
Description: A fully human anti-TNFα monoclonal antibody, which neutralizes tumor necrosis factor alpha (TNFα), 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.					
○	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/ TLR4 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.					
◎	Gout	Study 301	CH		PIII

Development Code: **E6742**			In-house		Oral
	Autoimmune disease	—	JP/US		PI

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 October 2021 onwards ○：Development progress from April 2021 onwards