TSE:4568

Reference Data

(Consolidated Financial Results for Q4 FY2020)

Daiichi-Sankyo

April 27, 2021

Daiichi Sankyo Co., Ltd.

https://www.daiichisankyo.com

Contents

Daiichi-Sankyo

1. Consolidated Statement of Profit or Loss (FY2020 Results)

JPY Bn	FY2019 to revenue	FY2019 Results	FY2020 to revenue	FY2020 Results	(vs. Forecast (%))	YoY	YoY (%)
Revenue	*100.0%*	**981.8**	*100.0%*	**962.5**	**(100.3%)**	**-19.3**	**-2.0%**
Cost of sales	*35.0%*	343.2	*35.1%*	338.3	(99.5%)	-4.9	-1.4%
(excl. Special items)	*36.1%*	354.4	*35.1%*	338.3		-16.1	-4.6%
(Special items)	*-1.1%*	-11.2	-	-		11.2	-
Gross Profit	*65.0%*	638.6	*64.9%*	624.2	(100.7%)	-14.4	-2.2%
SG&A expenses	*30.8%*	302.3	*34.6%*	333.1	(105.1%)	30.8	+10.2%
(excl. Special items)	*31.0%*	304.8	*33.0%*	318.1		13.3	+4.4%
(Special items)	*-0.2%*	-2.4	*1.6%*	15.0		17.4	-
R&D expenses	*20.1%*	197.5	*23.6%*	227.4	(93.6%)	29.9	+15.1%
(excl. Special items)	*20.1%*	197.5	*23.6%*	227.4		29.9	+15.1%
(Special items)	-	-	-	-		-	-
Operating Profit	*14.1%*	**138.8**	*6.6%*	**63.8**	**(106.3%)**	**-75.0**	**-54.0%**
(Operating Profit before Special items)	*12.7%*	125.1	*8.2%*	78.8		-46.3	-37.0%
Financial income/expenses		2.0		10.2		8.1	
Share of profit or loss of investments accounted for using the equity method		0.3		0.2		-0.2	
Profit before tax	*14.4%*	**141.2**	*7.7%*	**74.1**	**(107.4%)**	**-67.0**	**-47.5%**
Income taxes		12.2		-1.7		-13.9	-
Profit for the year	*13.1%*	**129.0**	*7.9%*	**75.8**	**(143.1%)**	**-53.1**	**-41.2%**
Profit attributable to owners of the Company	*13.1%*	**129.1**	*7.9%*	**76.0**	**(143.3%)**	**-53.1**	**-41.2%**
Tax rate		8.6%		-2.3%			
Overseas sales ratio		38.1%		41.7%			
Currency Rate (Average)							
USD/JPY		108.75		106.06			
EUR/JPY		120.83		123.70			

Forex impact: -5.3
(USD: -4.5, EUR: +2.6, ASCA: -3.4)

Forex impact: -0.8
(USD: -0.6, EUR: +0.2, ASCA: -0.4)

Forex impact: -2.1
(USD: -2.2, EUR: +1.0, ASCA: -1.0)

Forex impact: -2.3
(USD: -2.6, EUR: +0.4, ASCA: -0.1)

Forex impact: -0.0
(USD: +0.8, EUR: +1.0, ASCA: -1.9)

- Recognition of financial income due to decrease in contingent consideration of quizartinib acquisition +4.7
- Improvement in forex gains/losses +3.6

FY2019
Impact of introduction of consolidated taxation system

FY2020
Increase in DTA attributable to future expected taxable income increase of ENHERTU and Dato-DXd etc.

Special items

	FY2019		FY2020	
Cost of Sales	Restructuring costs in SC	1.3		
	Impairment loss (intangible)	6.3		-
	Gain on sales of subsidiary	-18.8		
SG&A expenses	Gain on sales of fixed assets	-10.6	Vaccine business loss compensation	15.0
	Environmental expenditures	8.2		
Total		-13.7		15.0

*This report is not subject to audit procedures.

*Special items : Items having a transitory and material impact on operating profit are defined as "Special items".
Specifically, gains and losses related to: sale of fixed assets, restructuring, impairment, litigation, etc. amounting to 1 billion JPY or more are defined as "Special items".

1. Consolidated Statement of Profit or Loss (FY2021 Forecast)

JPY Bn	FY2020 to revenue	FY2020 Results	FY2020 YoY	FY2020 YoY (%)	FY2021 to revenue	FY2021 Forecast	FY2021 YoY	FY2021 YoY (%)
Revenue	*100.0%*	**962.5**	**-19.3**	*-2.0%*	*100.0%*	**990.0**	**27.5**	*2.9%*
Cost of sales※1	*35.1%*	337.8	-16.6	*-4.7%*	*32.3%*	320.0	-17.8	*-5.3%*
Gross Profit	*64.9%*	624.8	-2.6	*-0.4%*	*67.7%*	670.0	45.2	*7.2%*
SG&A expenses※1	*33.1%*	318.5	13.7	*4.5%*	*33.7%*	334.0	15.5	*4.9%*
R&D expenses※1	*23.6%*	227.4	29.9	*15.2%*	*26.9%*	266.0	38.6	*17.0%*
Core Operating Profit	*8.2%*	**78.9**	**-46.2**	*-37.0%*	*7.1%*	**70.0**	**-8.9**	*-11.2%*
Other income※2		0.6				-	-0.6	
Other expenses※2		15.6				-	-15.6	
Operating Profit	*6.6%*	**63.8**	**-75.0**	*-54.0%*	*7.1%*	**70.0**	**6.2**	*9.7%*
Financial income/expenses		10.2	8.2					
Share of profit or loss of investments accounted for using the equity method		0.2	-0.1					
Profit before tax	*7.7%*	**74.1**	**-67.1**	*-47.5%*	*7.1%*	**70.0**	**-4.1**	*-5.6%*
Income taxes		-1.7	-13.9					
Profit for the year	*7.9%*	**75.8**	**-53.2**	*-41.2%*	*5.1%*	**50.0**	**-25.8**	*-34.1%*
Profit attributable to owners of the Company	*7.9%*	**76.0**	**-53.1**	*-41.2%*	*5.1%*	**50.0**	**-26.0**	*-34.2%*
Tax rate		-2.3%						
Overseas sales ratio		41.7%						

Forex impact: -5.3
(USD: -4.5, EUR: +2.6, ASCA: -3.4)

Forex impact: -0.8
(USD: -0.6, EUR: +0.2, ASCA: -0.4)

Forex impact: -2.1
(USD: -2.2, EUR: +1.0, ASCA: -1.0)

Forex impact: -2.3
(USD: -2.6, EUR: +0.4, ASCA: -0.1)

Forex impact: -0.0
(USD: +0.8, EUR: +1.0, ASCA: -1.9)

- Recognition of financial income due to decrease in contingent consideration of quizartinib acquisition +4.7
- Improvement in forex gains/losses +3.6

FY2020
Increase in DTA attributable to future expected taxable income increase of ENHERTU and Dato-DXd etc.

Currency Rate (Average)

	FY2020	FY2021
USD/JPY	106.06	105.00
EUR/JPY	123.70	120.00

Annual impact of one yen change

	Forecast	
	USD	EUR
Revenue	1.8 JPY Bn	0.9 JPY Bn
Operating Profit	-0.6 JPY Bn	0.3 JPY Bn

*This report is not subject to audit procedures.

※1 Temporary gains and losses are excluded for cost of sales, SG&A expenses and R&D expenses
※2 See page 3 for the definition of temporary gains and losses and the adjustment of operating profit and core operating profit

2. Sheet to adjust Operating Profit to Core Operating Profit

FY2020 Results

JPY Bn	Operating Profit (full)	Adjustment					Operating Profit (Core)
		gains and losses related to sale of fixed assets	gains and losses related to restructuring	gains and losses related to impairment,	gains and losses related to loss compensation, reconciliation	Others	
Revenue	**962.5**						**962.5**
Cost of sales	338.3	-0.0	-	0.5	-	-	337.8
SG&A expenses	333.1	0.0	-	0.0	15.0	-0.4	318.5
R&D expenses	227.4	-0.1	-	0.0	-	-	227.4
Core Operating Profit	**63.8**	-0.1	-	0.6	15.0	-0.4	**78.9**
Other income		0.1	-	-	-	0.4	0.6
(Cost of sales)		0.0					0.0
(SG&A expenses)		0.0				0.4	0.4
(R&D expenses)		0.1					0.1
Other expenses		0.0	-	0.6	15.0	-	15.6
(Cost of sales)				0.5			0.5
(SG&A expenses)		0.0		0.0	15.0 *1		15.0
(R&D expenses)				0.0			0.0
Operating Profit (full)	**63.8**	-	-	-	-	-	**63.8**

＜Major Other income and Other expenses＞

*1 Vaccine business loss compensation

FY2021 Forecast

JPY Bn	Operating Profit (full)	Adjustment					Operating Profit (Core)
		gains and losses related to sale of fixed assets	gains and losses related to restructuring	gains and losses related to impairment,	gains and losses related to loss compensation, reconciliation	Others	
Revenue	**990.0**						**990.0**
Cost of sales	320.0	-	-	-	-	-	320.0
SG&A expenses	334.0	-	-	-	-	-	334.0
R&D expenses	266.0	-	-	-	-	-	266.0
Core Operating Profit	**70.0**	-	-	-	-	-	**70.0**
Other income		-	-	-	-	-	-
(Cost of sales)							-
(SG&A expenses)							-
(R&D expenses)							-
Other expenses		-	-	-	-	-	-
(Cost of sales)							-
(SG&A expenses)							-
(R&D expenses)							-
Operating Profit (full)	**70.0**	-	-	-	-	-	**70.0**

＜Major Other income and Other expenses＞

As an indicator of ordinary profitability, “core operating profit” which excludes temporary gains and losses (other revenue and other expenses) from operating income is disclosed. Gains and losses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation, reconciliation, and other non-temporary and material gains and losses are included in the “temporary gains and losses”.

3. Revenue of Global Products

JPY Bn		FY2019	FY2020				FY2021		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	**14.0**	**43.5**	**(89.9%)**	**29.5**	**+211.4%**	**84.0**	**40.6**	**+93.3%**
Product sales		3.2	30.1	(86.3%)	26.9	+831.5%	69.4	39.3	+130.6%
Enhertu (JPN)		-	4.4	(77.2%)	4.4	-	13.4	9.0	+206.9%
Enhertu (US)		3.2	25.7	(88.0%)	22.5	+696.2%	50.4	24.7	+96.0%
Enhertu (EU)		-	0.0	-	0.0	-	5.4	5.4	-
Enhertu (ASCA: Asia, South and Central America)		-	-	-	-	-	0.2	0.2	-
Upfront payment		9.8	9.8	(100.0%)	-	-	9.8	-	-
Regulatory milestone payment		0.9	3.5	(96.9%)	2.6	+292.1%	4.8	1.3	+36.0%
US HER2+ Breast Cancer 3L		0.9	0.9	(100.0%)	-	-	0.9	-	-
EU HER2+ Breast Cancer 3L		-	1.0	(95.8%)	1.0	-	0.5	-0.5	-50.0%
US HER2+ Gastric Cancer 2L+3L		-	1.6	(95.9%)	1.6	-	0.8	-0.8	-50.0%
US HER2+ or HER2 Mutant NSCLC 2L		-	-	-	-	-	2.6	2.6	-
Datopotamab deruxtecan	anti-cancer agent (TROP2-directed antibody drug conjugate)	**-**	**3.9**	**(100.0%)**	**3.9**	**-**	**5.8**	**1.8**	**+46.2%**
Upfront payment		-	3.9	(100.0%)	3.9	-	5.8	1.8	+46.2%

3. Revenue of Global Products

JPY Bn		FY2019 Results	FY2020 Results	FY2020 (vs. Forecast (%))	FY2020 YoY	FY2020 YoY (%)	FY2021 Forecast	FY2021 YoY	FY2021 YoY (%)
Edoxaban	anticoagulant	**154.0**	**165.9**	**(101.9%)**	**11.9**	**+7.7%**	**188.4**	**22.4**	**+13.5%**
Lixiana (JPN)		83.0	77.4	(99.8%)	-5.6	-6.8%	90.4	13.0	+16.8%
Savaysa (US)		2.6	3.0	(106.2%)	0.4	+14.8%	2.2	-0.8	-26.4%
Lixiana (EU)		61.7	76.7	(104.1%)	15.0	+24.4%	84.6	7.9	+10.3%
Edoxaban (ASCA: Asia, South and Central America)		6.8	8.9	(100.4%)	2.1	+31.1%	11.1	2.3	+25.8%
Olmesartan	antihypertensive agent	**100.8**	**91.8**	**(103.3%)**	**-9.0**	**-8.9%**	**77.6**	**-14.2**	**-15.4%**
Olmetec (JPN)		11.7	9.2	(100.6%)	-2.4	-20.8%	6.7	-2.6	-28.0%
Rezaltas (JPN)		14.6	13.1	(98.4%)	-1.5	-10.1%	11.8	-1.3	-10.1%
Olmesartan (US)		9.8	8.6	(95.5%)	-1.3	-13.0%	6.4	-2.2	-25.6%
Olmesartan (EU)		24.6	21.5	(101.4%)	-3.1	-12.6%	16.9	-4.7	-21.6%
Other subsidiaries, export, etc		40.1	39.4	(106.9%)	-0.7	-1.8%	36.0	-3.4	-8.7%
Prasugrel	antiplatelet agent	**18.1**	**17.3**	**-**	**-0.8**	**-4.5%**	**not disclosed**	**-**	**-**
Effient alliance revenue (US)		0.5	0.3	-	-0.1	-26.8%	not disclosed	-	-
Efient (EU)		2.5	1.6	(114.7%)	-0.9	-36.7%	1.2	-0.4	-22.0%
Efient (JPN)		14.0	14.1	(97.9%)	0.1	+0.6%	15.6	1.6	+11.1%
Other subsidiaries, export, etc		1.2	1.3	-	0.2	+13.6%	not disclosed	-	-

4. Revenue by Business Units and Products (1)

JPY Bn		FY2019	FY2020				FY2021		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Japan+Vaccines		**533.5**	**489.1**	**(100.8%)**	**-44.4**	**-8.3%**	**482.3**	**-6.8**	**-1.4%**
Nexium	ulcer treatment	79.8	77.8	(101.4%)	-1.9	-2.4%	37.2	-40.7	-52.3%
Lixiana	anticoagulant	83.0	77.4	(99.8%)	-5.6	-6.8%	90.4	13.0	+16.8%
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	30.9	34.6	(99.3%)	3.7	+11.9%	35.6	1.0	+2.9%
Memary	Alzheimer's disease treatment	50.5	18.4	(95.6%)	-32.1	-63.5%	9.9	-8.5	-46.2%
Tenelia	type 2 diabetes mellitus treatment	24.7	24.2	(97.8%)	-0.5	-1.9%	23.2	-1.1	-4.5%
Loxonin	anti-inflammatory analgesic	28.3	24.2	(100.7%)	-4.1	-14.5%	19.8	-4.4	-18.1%
Ranmark	treatment for bone complications caused by bone metastases from tumors	17.9	19.3	(98.7%)	1.4	+8.1%	20.4	1.1	+5.6%
Inavir	anti-influenza agent	19.3	3.6	(80.3%)	-15.6	-81.2%	9.8	6.2	+170.4%
Tarlige	pain treatment	8.0	20.6	(99.9%)	12.6	+157.6%	29.5	9.0	+43.6%
Canalia	type 2 diabetes mellitus treatment	12.8	15.4	(99.6%)	2.6	+20.3%	15.7	0.2	+1.5%
Vimpat	anti-epileptic agent	11.2	14.5	(99.8%)	3.4	+30.3%	19.1	4.6	+31.4%
Efient	antiplatelet agent	14.0	14.1	(97.9%)	0.1	+0.6%	15.6	1.6	+11.1%
Rezaltas	antihypertensive agent	14.6	13.1	(98.4%)	-1.5	-10.1%	11.8	-1.3	-10.1%
Olmetec	antihypertensive agent	11.7	9.2	(100.6%)	-2.4	-20.8%	6.7	-2.6	-28.0%
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	-	4.4	(77.2%)	4.4	-	13.4	9.0	+206.9%
Daiichi Sankyo Espha products		60.5	71.4	-	10.9	+18.1%	not disclosed	-	-
Vaccines business		35.6	18.5	-	-17.1	-48.1%	not disclosed	-	-
Daiichi Sankyo Healthcare (OTC)		**68.5**	**67.2**	**(98.1%)**	**-1.3**	**-1.8%**	**69.4**	**2.2**	**+3.3%**

4. Revenue by Business Units and Products (2)

JPY Bn		FY2019	FY2020				FY2021		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Daiichi Sankyo, Inc. (US)*1		**32.1**	**47.4**	**(95.2%)**	**15.3**	**+47.6%**	**71.8**	**24.4**	**+51.6%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	3.2	25.7	(88.0%)	22.5	+696.2%	55.9	30.1	+117.1%
Enhertu (US)		3.2	25.7	0.9	22.5	7.0	50.4	24.7	1.0
Enhertu (EU)		-	-	-	-	-	5.4	5.4	-
Olmesartan	antihypertensive agent	9.8	8.6	(95.5%)	-1.3	-13.0%	6.4	-2.2	-25.6%
Welchol	hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	9.1	5.0	(143.2%)	-4.1	-45.2%	1.4	-3.6	-71.7%
Effient	antiplatelet agent	0.5	0.3	-	-0.1	-26.8%	not disclosed	-	-
Savaysa	anticoagulant	2.6	3.0	(106.2%)	0.4	+14.8%	2.2	-0.8	-26.4%
*1 Oncology products revenue in EU will be booked in Oncology business unit (OBU) from FY2021.									
American Regent, Inc. (US)		**130.8**	**121.7**	**(99.7%)**	**-9.1**	**-6.9%**	**125.8**	**4.1**	**+3.4%**
Injectafer	treatment for iron deficiency anemia	51.8	44.1	(94.7%)	-7.7	-14.8%	47.2	3.1	+7.1%
Venofer	treatment for iron deficiency anemia	31.0	28.8	(102.5%)	-2.2	-7.0%	26.8	-2.1	-7.2%
Daiichi Sankyo Europe GmbH*2		**95.5**	**111.7**	**(104.3%)**	**16.1**	**+16.9%**	**110.8**	**-0.9**	**-0.8%**
Enhertu	anti-cancer agent (HER2 directed antibody drug conjugate)	-	0.0	-	0.0	-	-	-	-
Lixiana	anticoagulant	61.7	76.7	(104.1%)	15.0	+24.4%	84.6	7.9	+10.3%
Olmesartan	antihypertensive agent	24.6	21.5	(101.4%)	-3.1	-12.6%	16.9	-4.7	-21.6%
Efient	antiplatelet agent	2.5	1.6	(114.7%)	-0.9	-36.7%	1.2	-0.4	-22.0%
*2 EU speciality business unit (EUSBU) from FY2021. Oncology product revenue will be booked in OBU.									
Asia, South and Central America (ASCA)		**98.3**	**99.7**	**(100.8%)**	**1.3**	**+1.4%**	**95.7**	**-3.9**	**-3.9%**
Daiichi Sankyo China		46.0	45.6	-	-0.4	-0.9%	41.2	-4.4	-9.7%
Daiichi Sankyo Taiwan		7.6	8.3	-	0.7	+9.6%	8.4	0.1	+1.4%
Daiichi Sankyo Korea		17.2	19.6	-	2.4	+14.0%	21.9	2.3	+12.0%
Daiichi Sankyo Thailand		3.3	2.3	-	-1.1	-32.5%	2.1	-0.2	-6.8%
Daiichi Sankyo Brasil Farmacêutica		11.5	10.5	-	-1.0	-8.9%	10.8	0.3	+2.5%

4. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

		FY2019	FY2020				FY2021		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
USD Mn									
Daiichi Sankyo, Inc. (US)*1		**295**	**447**	**(97.4%)**	**151**	**+51.2%**	**684**	**237**	**+53.1%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	30	243	(90.0%)	213	+715.8%	532	289	+119.3%
Enhertu (US)		30	243	(90.0%)	213	+715.8%	480	238	+98.0%
Enhertu (EU)		-	-	-	-	-	5.2	5.2	-
Olmesartan	antihypertensive agent	91	81	(97.6%)	-10	-10.9%	61	-20	-24.9%
Welchol	hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	84	47	(146.5%)	-37	-43.8%	13	-34	-71.4%
Effient	antiplatelet agent	4	3	-	-1	-24.9%	not disclosed	-	-
Savaysa	anticoagulant	24	28	(108.6%)	4	+17.7%	21	-7	-25.6%

*1 Oncology products revenue in EU will be booked in Oncology business unit (OBU) from FY2021.

USD Mn									
American Regent, Inc. (US)		**1,204**	**1,148**	**(101.9%)**	**-56**	**-4.6%**	**1,198**	**51**	**+4.4%**
Injectafer	treatment for iron deficiency anemia	477	416	(96.8%)	-61	-12.7%	450	34	+8.1%
Venofer	treatment for iron deficiency anemia	285	272	(104.8%)	-13	-4.7%	255	-17	-6.2%
EUR Mn									
Daiichi Sankyo Europe GmbH		**789**	**903**	**(101.8%)**	**114**	**+14.4%**	**923**	**20**	**+2.3%**
Enhertu	anti-cancer agent (HER2 directed antibody drug conjugate)	-	0	-	0	-	-	-	-
Lixiana	anticoagulant	509	620	(101.5%)	111	+21.7%	705	85	+13.7%
Olmesartan	antihypertensive agent	203	174	(98.9%)	-29	-14.4%	140	-33	-19.2%
Efient	antiplatelet agent	21	13	(111.8%)	-8	-38.0%	10	-3	-19.6%

*2 EU speciality business unit (EUSBU) from FY2021. Oncology product revenue will be booked in OBU.

5. Consolidated Statement of Financial Position

<Assets> JPY Bn

	Mar. 2020	Mar. 2021	vs. Mar. 2020
Assets			
Current assets			
Cash and cash equivalents	424.2	380.5	-43.6
Trade and other receivables	309.4	232.0	-77.3
Other financial assets	466.5	444.4	-22.2
Inventories	173.4	200.9	27.5
Other current assets	10.5	10.6	0.1
Subtotal	1,384.0	1,268.4	-115.6
Assets held for sale	0.1	-	-0.1
Total current assets	**1,384.1**	**1,268.4**	**-115.7**
Non-current assets			
Property,plant and equipment	247.1	265.3	18.2
Goodwill	76.8	77.7	0.9
Intangible assets	172.5	172.8	0.3
Investments accounted for using the equity method	0.4	1.4	1.1
Other financial assets	98.0	140.0	42.0
Deferred tax assets	114.7	128.5	13.8
Other non-current assets	12.1	31.0	18.9
Total non-current assets	**721.5**	**816.8**	**95.3**
Total assets	**2,105.6**	**2,085.2**	**-20.4**

*	Liquidity on hand	891.2	827.2	-64.0
	Debt with interest	266.3	226.2	-40.2
	Net Cash	624.9	601.0	-23.8

Receivable for trastuzumab deruxtecan strategic collaboration upfront payment -74.5

Acquisition +49.3, Depreciation -31.1

Acquisition +18.7, Amortization -26.1, Forex impact +3.0

<Liabilities and equity>

JPY Bn

	Mar. 2020	Mar. 2021	vs. Mar. 2020
Liabilities			
Current liabilities			
Trade and other payables	270.9	297.5	26.6
Bonds and borrowings	40.4	20.4	-20.0
Other financial liabilities	9.5	9.4	-0.1
Income taxes payable	9.9	6.1	-3.8
Provisions	5.4	6.1	0.7
Other current liabilities	15.0	14.2	-0.8
Total current liabilities	**351.1**	**353.6**	**2.5**
Non-current liabilities			
Bonds and borrowings	183.8	163.4	-20.4
Other financial liabilities	37.1	37.0	-0.1
Post employment benefit liabilities	5.3	3.9	-1.3
Provisions	10.6	8.7	-1.9
Deferred tax liabilities	15.6	17.5	1.9
Other non-current liabilities	195.8	228.9	33.1
Total non-current liabilities	**448.3**	**459.6**	**11.3**
Total liabilities	**799.3**	**813.1**	**13.8**
Equity			
Equity attributable to owners of the Company			
Share capital	50.0	50.0	-
Capital surplus	94.6	94.5	-0.1
Treasury shares	-162.5	-261.3	-98.7
Other components of equity	82.1	111.5	29.4
Retained earnings	1,241.6	1,277.3	35.7
Total equity attributable to owners of the Company	1,305.8	1,272.1	-33.8
Non-controlling interests			
Non-controlling interests	0.5	-	-0.5
Total equity	**1,306.3**	**1,272.1**	**-34.2**
Total liabilities and equity	**2,105.6**	**2,085.2**	**-20.4**

Upfront payment for strategic partnership of gene therapy manufacturing technology with Ultragenyx -13.5
Vaccine business loss compensation +15.0
Deferred revenue for datopotamab deruxtecan (Strategic collaboration upfront payment) +5.8

Redemption of 3rd unsecured corporate bond -20.0
Repayment of syndicated loan -20.0
Transfer of syndicated loan +20.0
(Transfer from Non-current liabilities "Bonds and borrowings")

Decrease in contingent consideration of quizartinib introduction -4.8

Transfer of syndicated loan -20.0
(Transfer to current liabilities "Bonds and borrowings")

Deferred revenue for datopotamab deruxtecan (Strategic collaboration upfront payment) +27.2
Deferred revenue for trastuzumab deruxtecan +5.3
(Strategic collaboration upfront payment -9.8, Regulatory milestone payment +15.2)

Acquisition of treasury shares -100.0

Profit for the period +76.0, Payment of dividends -48.9

6. Consolidated Statement of Cash Flows

JPY Bn

	FY2019	FY2020	YoY
Cash flows from operating activities			
Profit before tax	141.2	74.1	-67.0
Depreciation and amortization	52.6	57.4	4.8
(Increase) decrease in receivables and payables	65.4	107.0	41.5
Others, net	-36.4	-21.7	14.7
Income taxes paid	-26.2	-24.5	1.7
Net cash flows from operating activities	**196.6**	**192.2**	**-4.4**
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	67.7	29.2	-38.5
(Acquisition of) proceeds from sales of fixed assets	-52.4	-64.1	-11.6
Proceeds from sale of subsidiary	37.1	-	-37.1
Net (increase) decrease in investment securities	14.7	-0.2	-15.0
Others, net	14.5	-4.2	-18.6
Net cash flows from investing activities	**81.7**	**-39.2**	**-120.9**
Cash flows from financing activities			
Net (increase) decrease in borrowings	3.6	-20.4	-24.0
Repayments of bonds	-40.0	-20.0	20.0
Purchase of treasury shares	-0.1	-100.2	-100.1
Dividends paid	-45.4	-48.9	-3.6
Others, net	-9.8	-12.9	-3.1
Net cash flows from financing activities	**-91.6**	**-202.4**	**-110.8**
Net increase (decrease) in cash and cash equivalents	**186.6**	**-49.5**	**-236.1**
Cash and cash equivalents at the beginning of the period	**243.2**	**424.2**	**181.0**
Effect of exchange rate changes on cash and cash equivalents	**-5.6**	**5.8**	**11.4**
Cash and cash equivalents at the end of the period	**424.2**	**380.5**	**-43.6**

*	**Free cash flows** (Cash flows from operating activities and investing activities)	**278.3**	**153.0**	**-125.3**

7. Number of Employees

	Mar. 2020 Results	Mar. 2021 Results
Consolidated	15,348	16,033
Japan	8,754	8,979
North America	2,380	2,602
Europe	1,953	2,137
Others	2,261	2,315

8. Capital Expenditure, Depreciation and Amortization

JPY Bn	Mar. 2020 Results	Mar. 2021 Results	FY2021 Forecast
Capital expenditure	29.0	40.1	48.0
Depreciation and amortization	52.6	57.4	56.0
Property, plant and equipment	32.0	31.3	-
Intangible assets	20.6	26.1	-

9. Other Financial Indicators

	FY2019 Results		FY2020 Results	
Profit attributable to owners of the Company	129.1	JPY Bn	76.0	JPY Bn
Dividends	45.4	JPY Bn	52.1	JPY Bn
Purchase of treasury shares	-	JPY Bn	100.0	JPY Bn
Total return ratio	35.1	%	200.3	%
Average equity attributable to owners of the Company for the period	1,277.7	JPY Bn	1,288.9	JPY Bn
Return on Equity	10.1	%	5.9	%

10. Summary of Product Outlines

Brand Name	Generic Name	Therapeutic Category	Launched	Origin	Marketing Alliance	Type of Alliance
Japan						
Nexium	esomeprazole	ulcer treatment	2011	AstraZeneca	AstraZeneca	Co-promotion (DS: Sales)
Lixiana	edoxaban	anticoagulant	2011	Daiichi Sankyo		
Pralia	denosumab	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	2013	Amgen		
Memary	memantine	Alzheimer's disease treatment	2011	Merz		
Tenelia	teneligliptin	type 2 diabetes mellitus treatment	2012	Mitsubishi Tanabe	Mitsubishi Tanabe	Co-promotion (DS: Sales)
Loxonin	loxoprofen	anti-inflammatory analgesic	1986	Daiichi Sankyo		
Loxonin Poultice			2006	Lead Chemical		
Loxonin Tape			2008	Lead Chemical		
Loxonin Gel			2010	Daiichi Sankyo		
Ranmark	denosumab	treatment for bone complications caused by bone metastases from tumors	2012	Amgen		
Inavir	laninamivir	anti-influenza agent	2010	Daiichi Sankyo		
Tarlige	mirogabalin	pain treatment	2019	Daiichi Sankyo		
Canalia	teneligliptin / canagliflozin	type 2 diabetes mellitus treatment	2017	Mitsubishi Tanabe	Mitsubishi Tanabe	Co-promotion (DS: Sales)
Vimpat	lacosamide	anti-epileptic agent	2016	UCB	UCB	Co-promotion (DS: Sales)
Efient	prasugrel	antiplatelet agent	2014	Daiichi Sankyo Ube Industries		
Rezaltas	olmesartan / azelnidipine	antihypertensive agent	2010	Daiichi Sankyo		
Olmetec	olmesartan	antihypertensive agent	2004	Daiichi Sankyo		
Enhertu	trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	2020	Daiichi Sankyo		
Daiichi Sankyo, Inc. (US)						
Enhertu	trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	2020	Daiichi Sankyo	AstraZeneca	Co-promotion (DS: Sales)
Olmesartan						
Benicar	olmesartan	antihypertensive agent	2002	Daiichi Sankyo		
Benicar HCT	olmesartan / hydrochlorothiazide		2003			
Azor	olmesartan / amlodipine		2007			
Tribenzor	olmesartan / amlodipine / hydrochlorothiazide		2010			
Welchol	colesevelam	hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	2000	Genzyme		
Effient	prasugrel	antiplatelet agent	2009	Daiichi Sankyo Ube Industries	Lilly	Co-promotion (DS: Co-pro revenue)
Savaysa	edoxaban	anticoagulant	2015	Daiichi Sankyo		
American Regent, Inc. (US)						
Injectafer	ferric carboxymaltose injection	treatment for iron deficiency anemia	2013	Vifor Pharma	Daiichi Sankyo, Inc.	Promotion (Daiichi Sankyo, Inc.)
Venofer	iron sucrose injection	treatment for iron deficiency anemia	2000	Vifor Pharma	Fresenius	Co-marketing
Daiichi Sankyo Europe GmbH						
Enhertu	trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	2021	Daiichi Sankyo	AstraZeneca	Co-promotion (DS: Sales)
Lixiana	edoxaban	anticoagulant	2015	Daiichi Sankyo	Merck (MSD)	Co-marketing
Olmesartan						
Olmetec	olmesartan	antihypertensive agent	2002	Daiichi Sankyo	Menarini Pfizer	Co-marketing
Olmetec Plus	olmesartan / hydrochlorothiazide		2005			
Sevikar	olmesartan / amlodipine		2009			
Sevikar HCT	olmesartan / amlodipine / hydrochlorothiazide		2010			
Efient	prasugrel	antiplatelet agent	2009	Daiichi Sankyo Ube Industries		

<11. Quarterly Data>

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2019 Q1 Results	FY2019 Q2 Results	FY2019 Q3 Results	FY2019 Q4 Results	FY2019 to revenue	FY2019 Results	FY2019 YoY	FY2019 YoY (%)	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 to revenue	FY2020 Results
Revenue	**249.2**	**230.3**	**277.5**	**224.8**	***100.0%***	**981.8**	**52.1**	**+5.6%**	**236.9**	**243.2**	**258.6**	**223.7**	***100.0%***	**962.5**
Cost of sales	87.9	89.2	79.2	86.9	*35.0%*	343.2	-21.4	-5.9%	82.2	86.4	87.8	81.9	*35.1%*	338.3
(excl. Special items)	86.6	85.4	98.0	84.5	*36.1%*	354.4	4.9	+1.4%	82.2	86.4	87.8	81.9	*35.1%*	338.3
(Special items)	1.3	3.8	-18.8	2.4	*-1.1%*	-11.2	-26.3	-	-	-	-	-	-	-
Gross Profit	161.3	141.1	198.3	137.8	*65.0%*	638.6	73.5	+13.0%	154.7	156.9	170.8	141.8	*64.9%*	624.2
SG&A expenses	63.2	67.3	77.8	94.1	*30.8%*	302.3	24.6	+8.9%	71.8	76.8	80.7	103.8	*34.6%*	333.1
(excl. Special items)	73.8	67.3	77.8	85.9	*31.0%*	304.8	23.6	+8.4%	71.8	76.8	80.7	88.8	*33.0%*	318.1
(Special items)	-10.6	-	-	8.2	*-0.2%*	-2.4	1.0	-	-	-	-	15.0	*1.6%*	15.0
R&D expenses	41.2	44.7	51.1	60.5	*20.1%*	197.5	-6.2	-3.1%	48.8	55.7	59.1	63.7	*23.6%*	227.4
(excl. Special items)	41.2	44.7	51.1	60.5	*20.1%*	197.5	-6.2	-3.1%	48.8	55.7	59.1	63.7	*23.6%*	227.4
(Special items)	-	-	-	-	-	-	0.0	-	-	-	-	-	-	-
Operating Profit	**57.0**	**29.2**	**69.4**	**-16.8**	***14.1%***	**138.8**	**55.1**	**+65.8%**	**34.1**	**24.3**	**31.0**	**-25.7**	***6.6%***	**63.8**
(Operating Profit before Special items)	47.7	33.0	50.6	-6.1	*12.7%*	125.1	29.8	+31.3%	34.1	24.3	31.0	-10.7	*8.2%*	78.8
Financial income/expenses	0.1	0.8	3.5	-2.3		2.0	-0.2		7.2	1.2	1.5	0.1		10.2
Share of profit or loss of investments accounted for using the equity method	0.0	0.0	0.0	0.2		0.3	0.4		0.0	0.0	0.0	0.1		0.2
Profit before tax	**57.1**	**30.0**	**72.9**	**-18.8**	***14.4%***	**141.2**	**55.3**	**+64.5%**	**41.4**	**25.6**	**32.6**	**-25.4**	***7.7%***	**74.1**
Income taxes	13.7	8.9	3.1	-13.6		12.2	19.8	-	9.6	5.8	8.5	-25.6		-1.7
Profit for the year	**43.3**	**21.1**	**69.8**	**-5.2**	***13.1%***	**129.0**	**35.5**	**+38.0%**	**31.8**	**19.8**	**24.1**	**0.2**	***7.9%***	**75.8**
Profit attributable to owners of the Company	**43.3**	**21.1**	**69.9**	**-5.2**	***13.1%***	**129.1**	**35.7**	**+38.2%**	**31.9**	**19.8**	**24.1**	**0.2**	***7.9%***	**76.0**
Tax rate	24.1%	29.8%	4.3%	72.2%		8.6%			23.1%	22.8%	26.1%	100.6%		-2.3%
Overseas sales ratio	37.5%	38.4%	34.9%	42.5%		38.1%			38.6%	42.3%	40.1%	46.4%		41.7%
Currency Rate (YTD Average)														
USD/JPY	109.90	108.63	108.67	108.75		108.75			107.62	106.92	106.11	106.06		106.06
EUR/JPY	123.49	121.41	121.05	120.83		120.83			118.47	121.29	122.37	123.70		123.70

<11. Quarterly Data>

2. Revenue of Global Products

JPY Bn	FY2019 Q1 Results	FY2019 Q2 Results	FY2019 Q3 Results	FY2019 Q4 Results	FY2019 Results	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 Results	FY2020 YoY	FY2020 YoY (%)
Trastuzumab deruxtecan	**2.5**	**2.5**	**3.2**	**5.9**	**14.0**	**7.9**	**9.8**	**11.1**	**14.7**	**43.5**	**29.5**	**-**
Product sales	-	-	0.0	3.2	3.2	5.2	7.1	8.4	9.4	30.1	26.9	+831.5%
Enhertu(JPN)	-	-	-	-	-	0.2	0.8	1.7	1.7	4.4	4.4	-
Enhertu (US)	-	-	0.0	3.2	3.2	5.0	6.3	6.7	7.7	25.7	22.5	+696.2%
Enhertu (EU)	-	-	-	-	-	-	-	-	0.0	0.0	-	-
Enhertu (ASCA: Asia, South and Central America)	-	-	-	-	-	-	-	-	-	-	-	-
Upfront payment	2.5	2.5	2.5	2.5	9.8	2.5	2.5	2.5	2.5	9.8	-	-
Regulatory milestone payment	-	-	0.7	0.2	0.9	0.2	0.2	0.2	2.9	3.5	2.6	+292.1%
US HER2+ Breast Cancer 3L	-	-	0.7	0.2	0.9	0.2	0.2	0.2	0.2	0.9	-	-
EU HER2+ Breast Cancer 3L	-	-	-	-	-	-	-	-	1.0	1.0	1.0	-
US HER2+ Gastric Cancer 2L+3L	-	-	-	-	-	-	-	-	1.6	1.6	1.6	-
US HER2+ or HER2 Mutant NSCLC 2L	-	-	-	-	-	-	-	-	1.6	1.6	1.6	-
Datopotamab deruxtecan	**-**	**-**	**-**	**-**	**-**	**-**	**1.0**	**1.5**	**1.5**	**3.9**	**3.9**	**-**
Upfront payment	-	-	-	-	-	-	1.0	1.5	1.5	3.9	3.9	-
Edoxaban	**37.2**	**36.5**	**42.6**	**37.6**	**154.0**	**38.7**	**40.4**	**45.6**	**41.2**	**165.9**	**11.9**	**+7.7%**
Lixiana (JPN)	21.6	20.2	23.8	17.4	83.0	19.8	18.5	21.5	17.6	77.4	-5.6	-6.8%
Savaysa (US)	0.6	0.6	0.8	0.7	2.6	0.6	1.1	0.7	0.6	3.0	0.4	+14.8%
Lixiana (EU)	13.5	14.0	16.4	17.8	61.7	16.4	18.6	21.0	20.7	76.7	15.0	+24.4%
Edoxaban (ASCA: Asia, South and Central America)	1.6	1.7	1.7	1.7	6.8	1.9	2.2	2.3	2.4	8.9	2.1	+31.1%
Olmesartan	**27.5**	**23.2**	**26.3**	**23.9**	**100.8**	**25.7**	**22.4**	**23.0**	**20.7**	**91.8**	**-9.0**	**-8.9%**
Olmetec (JPN)	3.5	2.7	3.2	2.2	11.7	2.7	2.2	2.5	1.8	9.2	-2.4	-20.8%
Rezaltas (JPN)	4.2	3.4	4.1	3.0	14.6	3.6	3.2	3.6	2.8	13.1	-1.5	-10.1%
Olmesartan (US)	3.1	2.4	2.2	2.1	9.8	3.7	1.8	1.7	1.4	8.6	-1.3	-13.0%
Olmesartan (EU)	6.4	4.8	5.8	7.7	24.6	5.2	5.8	5.2	5.3	21.5	-3.1	-12.6%
Other subsidiaries, export, etc	10.3	9.9	11.0	8.9	40.1	10.5	9.5	10.0	9.4	39.4	-0.7	-1.8%
Prasugrel	**5.0**	**4.4**	**4.9**	**3.8**	**18.1**	**4.4**	**4.2**	**4.7**	**4.0**	**17.3**	**-0.8**	**-4.5%**
Effient alliance revenue (US)	0.1	0.3	0.0	0.1	0.5	-0.0	0.1	0.1	0.1	0.3	-0.1	-26.8%
Efient (EU)	0.8	0.6	0.6	0.6	2.5	0.3	0.4	0.4	0.4	1.6	-0.9	-36.7%
Efient (JPN)	3.8	3.2	4.0	2.9	14.0	3.8	3.3	3.8	3.1	14.1	0.1	+0.6%
Other subsidiaries, export, etc	0.3	0.3	0.3	0.2	1.2	0.3	0.3	0.3	0.4	1.3	0.2	+13.6%

3. Revenue by Business Units and Products (1)

JPY Bn

	FY2019 Q1	FY2019 Q2	FY2019 Q3	FY2019 Q4	FY2019	FY2020 Q1	FY2020 Q2	FY2020 Q3	FY2020 Q4	FY2020		
	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results	YoY	YoY (%)
Japan+Vaccines	**139.0**	**122.0**	**161.3**	**111.2**	**533.5**	**130.2**	**119.9**	**136.3**	**102.7**	**489.1**	**-44.4**	**-8.3%**
Nexium	21.9	18.3	22.1	17.4	79.8	19.9	19.1	21.9	17.0	77.8	-1.9	-2.4%
Lixiana	21.6	20.2	23.8	17.4	83.0	19.8	18.5	21.5	17.6	77.4	-5.6	-6.8%
Pralia	8.2	7.3	8.8	6.7	30.9	8.7	8.3	9.4	8.2	34.6	3.7	+11.9%
Memary	13.7	11.9	14.5	10.3	50.5	12.8	2.1	2.0	1.5	18.4	-32.1	-63.5%
Tenelia	6.9	5.9	6.9	5.0	24.7	6.6	5.9	6.7	5.1	24.2	-0.5	-1.9%
Loxonin	7.8	7.0	7.9	5.5	28.3	6.2	6.1	6.8	5.1	24.2	-4.1	-14.5%
Ranmark	4.7	4.5	4.8	3.9	17.9	5.0	4.7	5.2	4.4	19.3	1.4	+8.1%
Inavir	0.0	1.0	10.5	7.7	19.3	0.6	0.7	0.9	1.4	3.6	-15.6	-81.2%
Tarlige	2.0	1.3	2.1	2.6	8.0	4.3	4.9	6.2	5.2	20.6	12.6	+157.6%
Canalia	3.2	2.9	3.7	3.0	12.8	3.9	3.7	4.3	3.5	15.4	2.6	+20.3%
Vimpat	2.7	2.6	3.3	2.7	11.2	3.8	3.4	4.1	3.3	14.5	3.4	+30.3%
Efient	3.8	3.2	4.0	2.9	14.0	3.8	3.3	3.8	3.1	14.1	0.1	+0.6%
Rezaltas	4.2	3.4	4.1	3.0	14.6	3.6	3.2	3.6	2.8	13.1	-1.5	-10.1%
Olmetec	3.5	2.7	3.2	2.2	11.7	2.7	2.2	2.5	1.8	9.2	-2.4	-20.8%
Enhertu	-	-	-	-	-	0.2	0.8	1.7	1.7	4.4	4.4	-
Daiichi Sankyo Espha products	17.3	14.1	16.5	12.6	60.5	17.6	16.7	20.9	16.3	71.4	10.9	+18.1%
Vaccines business	7.5	8.4	16.9	2.8	35.6	2.9	7.8	7.6	0.2	18.5	-17.1	-48.1%
Daiichi Sankyo Healthcare (OTC)	**15.4**	**18.7**	**18.8**	**15.6**	**68.5**	**14.3**	**18.7**	**18.4**	**15.7**	**67.2**	**-1.3**	**-1.8%**

3. Revenue by Business Units and Products (2)

JPY Bn	FY2019 Q1 Results	FY2019 Q2 Results	FY2019 Q3 Results	FY2019 Q4 Results	FY2019 Results	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 Results	FY2020 YoY	FY2020 YoY (%)
Daiichi Sankyo, Inc. (US)[*1]	**7.8**	**7.1**	**8.9**	**8.3**	**32.1**	**11.6**	**12.0**	**11.8**	**12.0**	**47.4**	**15.3**	**+47.6%**
Enhertu	-	-	0.0	3.2	3.2	5.0	6.3	6.7	7.7	25.7	22.5	+696.2%
Enhertu (US)		-	0.0	3.2	3.2	5.0	6.3	6.7	7.7	25.7	22.5	+696.2%
Enhertu (EU)		-	-	-	-	-	-	-	-	-	-	-
Olmesartan	3.1	2.4	2.2	2.1	9.8	3.7	1.8	1.7	1.4	8.6	-1.3	-13.0%
Welchol	2.6	2.2	3.8	0.5	9.1	0.6	1.6	1.7	1.1	5.0	-4.1	-45.2%
Effient	0.1	0.3	0.0	0.1	0.5	-0.0	0.1	0.1	0.1	0.3	-0.1	-26.8%
Savaysa	0.6	0.6	0.8	0.7	2.6	0.6	1.1	0.7	0.6	3.0	0.4	+14.8%
American Regent, Inc. (US)	**36.0**	**32.4**	**31.4**	**31.0**	**130.8**	**26.5**	**32.5**	**32.1**	**30.7**	**121.7**	**-9.1**	**-6.9%**
Injectafer	13.7	12.3	13.3	12.5	51.8	9.4	11.5	11.3	11.9	44.1	-7.7	-14.8%
Venofer	9.3	7.1	6.9	7.7	31.0	6.9	7.7	7.5	6.7	28.8	-2.2	-7.0%
Daiichi Sankyo Europe GmbH[*2]	**22.1**	**21.1**	**24.5**	**27.8**	**95.5**	**27.7**	**26.6**	**28.6**	**28.7**	**111.7**	**16.1**	**+16.9%**
Enhertu	-	-	-	-	-	-	-	-	0.0	0.0	-	-
Lixiana	13.5	14.0	16.4	17.8	61.7	16.4	18.6	21.0	20.7	76.7	15.0	+24.4%
Olmesartan	6.4	4.8	5.8	7.7	24.6	5.2	5.8	5.2	5.3	21.5	-3.1	-12.6%
Efient	0.8	0.6	0.6	0.6	2.5	0.3	0.4	0.4	0.4	1.6	-0.9	-36.7%
Asia, South and Central America (ASCA)	**24.3**	**24.6**	**24.6**	**24.8**	**98.3**	**22.5**	**25.8**	**26.1**	**25.2**	**99.7**	**1.3**	**+1.4%**
Daiichi Sankyo China	12.0	12.0	10.9	11.1	46.0	8.6	11.4	12.9	12.7	45.6	-0.4	-0.9%
Daiichi Sankyo Taiwan	1.9	1.8	1.9	2.1	7.6	2.1	2.0	2.1	2.1	8.3	0.7	+9.6%
Daiichi Sankyo Korea	4.0	4.3	4.2	4.7	17.2	4.4	5.0	4.9	5.2	19.6	2.4	+14.0%
Daiichi Sankyo Thailand	0.8	0.8	0.9	0.8	3.3	0.6	0.7	0.7	0.3	2.3	-1.1	-32.5%
Daiichi Sankyo Brasil Farmacêutica	2.8	2.9	3.4	2.5	11.5	2.9	2.6	2.7	2.3	10.5	-1.0	-8.9%

*1 Oncology products revenue in EU will be booked in Oncology business unit (OBU) from FY2021.

*2 EU speciality business unit (EUSBU) from FY2021. Oncology product revenue will be booked in OBU.

3. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

	FY2019 Q1	FY2019 Q2	FY2019 Q3	FY2019 Q4	FY2019	FY2020 Q1	FY2020 Q2	FY2020 Q3	FY2020 Q4	FY2020		
	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results	YoY	YoY (%)
USD Mn												
Daiichi Sankyo, Inc. (US)[*1]	**71**	**66**	**82**	**76**	**295**	**107**	**113**	**113**	**113**	**447**	**151**	**+51.2%**
Enhertu	-	-	0	30	30	46	60	64	73	243	213	+715.8%
Enhertu (US)	-	-	0	30	30	46	60	64	73	243	213	+715.8%
Enhertu (EU)	-	-	-	-	-	-	-	-	-	-	-	-
Olmesartan	28	23	21	19	91	35	17	16	13	81	-10	-10.9%
Welchol	23	21	35	5	84	5	15	16	10	47	-37	-43.8%
Effient	1	2	0	1	4	-0	1	1	1	3	-1	-24.9%
Savaysa	5	5	7	7	24	5	11	7	6	28	4	+17.7%
USD Mn												
American Regent, Inc. (US)	**327**	**302**	**289**	**286**	**1,204**	**246**	**305**	**307**	**290**	**1,148**	**-56**	**-4.6%**
Injectafer	125	114	123	115	477	88	109	108	113	416	-61	-12.7%
Venofer	85	66	64	70	285	64	72	72	63	272	-13	-4.7%
EUR Mn												
Daiichi Sankyo Europe GmbH[*2]	**179**	**177**	**203**	**230**	**789**	**234**	**214**	**230**	**225**	**903**	**114**	**+14.4%**
Enhertu	-	-	-	-	-	-	-	-	0	0	-	-
Lixiana	109	117	136	147	509	139	150	169	162	620	111	+21.7%
Olmesartan	52	40	48	63	203	44	47	42	41	174	-29	-14.4%
Efient	6	5	5	5	21	3	4	3	3	13	-8	-38.0%

*1 Oncology products revenue in EU will be booked in Oncology business unit (OBU) from FY2021.

<12. Historical Data>

1. Revenue of Global Products

JPY Bn	FY2015 Results	FY2016 Results	FY2017 Results	FY2018 Results	FY2019 Results
Trastuzumab deruxtecan	**-**	**-**	**-**	**0.1**	**14.0**
Product sales	-	-	-	-	3.2
Enhertu (JPN)	-	-	-	-	-
Enhertu (US)	-	-	-	-	3.2
Upfront payment	-	-	-	0.1	9.8
Regulatory milestone payment	-	-	-	-	0.9
Edoxaban	**15.0**	**37.3**	**77.1**	**117.7**	**154.0**
Lixiana (JPN)	13.0	25.0	45.3	64.9	83.0
Savaysa (US)	0.4	1.9	2.2	2.3	2.6
Lixiana (EU)	1.5	9.7	27.0	45.8	61.7
Other subsidiaries	0.0	0.8	2.6	4.7	6.8
Olmesartan	**284.1**	**218.0**	**149.7**	**105.9**	**100.8**
Olmetec (JPN)	73.9	69.4	44.6	14.9	11.7
Rezaltas (JPN)	18.2	17.5	16.8	15.5	14.6
Olmesartan (US)	111.6	66.4	21.3	10.7	9.8
Olmesartan (EU)	58.9	43.2	33.5	27.4	24.6
Other subsidiaries, export, etc	21.6	21.5	33.5	37.4	40.1
Prasugrel	**32.2**	**41.6**	**32.8**	**23.2**	**18.1**
Effient alliance revenue (US)	20.7	22.2	10.7	2.4	0.5
Efient (EU)	5.4	7.9	8.0	5.7	2.5
Efient (JPN)	4.9	10.4	12.8	13.9	14.0
Other subsidiaries, export, etc	1.2	1.0	1.3	1.2	1.2

2. Revenue by Business Units and Products (1)

JPY Bn	FY2015 Results	FY2016 Results	FY2017 Results	FY2018 Results	FY2019 Results
Japan	**494.7**	**506.6**	**540.0**	**523.3**	**533.5**
Nexium	82.4	84.0	86.5	78.3	79.8
Lixiana	13.0	25.0	45.3	64.9	83.0
Pralia	12.5	18.0	23.2	27.4	30.9
Memary	42.4	46.9	48.6	50.2	50.5
Tenelia	16.5	24.2	26.3	25.3	24.7
Loxonin	48.1	37.4	36.5	30.5	28.3
Ranmark	12.4	13.9	15.4	16.4	17.9
Inavir	14.0	19.6	25.3	18.2	19.3
Tarlige	-	-	-	-	8.0
Canalia	-	-	2.7	9.2	12.8
Vimpat	-	0.4	2.6	6.6	11.2
Efient	4.9	10.4	12.8	13.9	14.0
Rezaltas	18.2	17.5	16.8	15.5	14.6
Olmetec	73.9	69.4	44.6	14.9	11.7
Enhertu	-	-	-	-	-
Daiichi Sankyo Espha products	18.5	20.2	46.7	55.5	60.5
Vaccines business	36.8	38.5	41.9	41.5	35.6
Daiichi Sankyo Healthcare (OTC)	**53.4**	**66.7**	**72.9**	**66.4**	**68.5**

2. Revenue by Business Units and Products (2)

JPY Bn	FY2015 Results	FY2016 Results	FY2017 Results	FY2018 Results	FY2019 Results
Daiichi Sankyo, Inc. (US)	**185.1**	**142.3**	**74.8**	**36.3**	**32.1**
Enhertu	-	-	-	-	32
Olmesartan	111.6	66.4	21.3	10.7	9.8
Welchol	48.4	45.5	33.9	13.4	9.1
Effient	20.7	22.2	10.7	2.4	0.5
Savaysa	0.4	1.9	2.2	2.3	2.6
American Regent, Inc. (US)	**91.0**	**88.1**	**105.4**	**117.8**	**130.8**
Injectafer	18.6	24.0	34.3	44.2	51.8
Venofer	31.2	28.5	31.0	28.9	31.0
Daiichi Sankyo Europe GmbH	**77.8**	**71.0**	**79.4**	**88.6**	**95.5**
Lixiana	1.5	9.7	27.0	45.8	61.7
Olmesartan	58.9	43.2	33.5	27.4	24.6
Efient	5.4	7.9	8.0	5.7	2.5
Asia, South and Central America (ASCA)	**75.3**	**72.1**	**80.4**	**87.7**	**98.3**
Daiichi Sankyo China	34.2	33.8	35.3	38.5	46.0
Daiichi Sankyo Taiwan	5.4	5.2	6.6	7.1	7.6
Daiichi Sankyo Korea	9.3	8.8	11.8	15.7	17.2
Daiichi Sankyo Thailand	4.1	2.5	2.9	3.3	3.3
Daiichi Sankyo Brasil Farmacêutica	8.1	8.8	10.1	10.0	11.5

2. Revenue by Business Units and Products (3) [Reference] Revenue in Local Currency	FY2015 Results	FY2016 Results	FY2017 Results	FY2018 Results	FY2019 Results
USD Mn					
Daiichi Sankyo, Inc. (US)	**1,540**	**1,312**	**674**	**327**	**295**
Enhertu	-	-	-	-	30
Olmesartan	929	612	192	97	91
Welchol	403	420	306	121	84
Effient	173	205	96	22	4
Savaysa	4	17	20	21	24
USD Mn					
American Regent, Inc. (US)	**758**	**812**	**951**	**1,062**	**1,204**
Injectafer	155	221	310	399	477
Venofer	260	263	279	261	285
EUR Mn					
Daiichi Sankyo Europe GmbH	**587**	**597**	**613**	**690**	**789**
Lixiana	12	81	208	357	509
Olmesartan	444	363	258	213	203
Efient	41	67	62	44	21

◆ Explanation of Description

Generic name/project Code Number (mechanism of action)

Detail on its mechanism

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
・Phase of the study ・Study Name (if applicable) ・CTG registration number ・JapicCTI/jRCT registration number ・Partner, if any	Patients and target indications for the study	Target sample size	Study design schematic (randomize or not, blinding or not, control group or not)	・Primary and secondary endpoints are listed ・Safety measures are summarized as "safety" ・Pharmacokinetic indices are summarized as "PK"	Region under study (not consistent with region under development)	・Announcements as these trials open ・Scheduled time to achieve TLR (LPD if achieved) ・Schedule timing of submission for late-phase projects ・Application status, status of obtaining various review preference systems, etc.

◆ List of Abbreviations

ADC: antibody drug conjugate; MFI: brain metastases-free interval, CR: complete remission, CRL: complete response letter, DCR: disease control rate, DFS: disease-free survival, DOR: duration of response, DRFI: distant recurrence-free interval, EVS: event-free survival, FPD: first patient dosed, IDFS: invasive disease-free survival, LPD: last patient dosed, ORR: overall response rate/objective response rate, OS: overall survival, PFS: progression-free survival, PK: pharmacokinetics, TLR: top line results

◆ 3 ADCs

Trastuzumab deruxtecan/DS-8201/T-DXd (HER2-directed ADC)

Antibody-drug conjugate which is composed of a humanized monoclonal antibody specifically targeting HER2, one of the Epidermal Growth Factor Receptor (EGFR) family proteins, and a covalently linked drug (payload) via a cleavable linker. Payload is a potent and membrane permeable DNA topoisomerase I inhibitor which enables elimination of both target tumor cells and the surrounding tumor cells. Drug-to-antibody ratio is approximately 8.
Brand name: ENHERTU (JP/US/EU)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 (pivotal) DESTINY-Breast01 NCT03248492 JapicCTI-173693 AstraZeneca	HER2 positive breast cancer, 3L	253	Randomized, open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: ORR, DOR, PFS, OS and etc.	JP/US/EU/ Asia	FPD: Oct 2017 TLR: May 2019 Jan 2020: Launched (US) May 2020: Launched (JP) Jan 2021: Approved (EU)
Phase 3 DESTINY-Breast02 NCT03523585 JapicCTI-184017 AstraZeneca	HER2 positive breast cancer, 3L	600	Randomized, open label, active control ・DS-8201 ・Physician's choice (trastuzumab + capecitabine or lapatinib + capecitabine)	Primary endpoint: PFS Secondary endpoint: OS, ORR, DOR, PFS and etc.	JP/US/EU/ Asia	FPD: Sep 2018 Data anticipated: FY2022 Q2
Phase 3 DESTINY-Breast03 NCT03529110 JapicCTI-183976 AstraZeneca	HER2 positive breast cancer, 2L	500	Randomized, open label, active control ・DS-8201 ・T-DM1	Primary endpoint: PFS Secondary endpoint: OS, ORR, DOR, PFS and etc.	JP/US/EU/ Asia	FPD: Aug 2018 Data anticipated: FY2021 Q2
Phase 3 DESTINY-Breast04 NCT03734029 JapicCTI-184223 AstraZeneca	HER2-low breast cancer, post chemotherapy	540	Randomized, open label, active control ・DS-8201 ・Physician's choice (capecitabine, eribulin, gemcitabine, paclitaxel or nab-paclitaxel)	Primary endpoint: PFS Secondary endpoint: OS, ORR, DOR and etc.	JP/US/EU/ Asia	FPD: Dec 2018 Data anticipated: FY2021 Q4

Trastuzumab deruxtecan/DS-8201/T-DXd (HER2-directed ADC)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 DESTINY-Breast05 NCT04622319 jRCT2061200033 AstraZeneca	HER2 positive, with residual invasive breast cancer following neoadjuvant therapy	1600	Randomized, open label, active control ・DS-8201 ・T-DM1	Primary endpoint: IDFS Secondary endpoint: DFS, OS, DRFI, BMFI, safety, PK and etc.	JP/US/EU/ Asia	FPD: Dec 2020
Phase3 DESTINY-Breast06 NCT04494425 jRCT2061200028 AstraZeneca	HER2 low/HR positive breast cancer, chemotherapy naïve	850	Randomized, open label, active control ・DS-8201 ・Physician's choice (capecitabine, paclitaxel or nab-paclitaxel)	Primary endpoint: PFS Secondary endpoint: OS, PFS, ORR, DOR, safety and etc.	JP/US/EU/ Asia	FPD: Aug 2020
Phase1b/2 DESTINY-Breast07 NCT04538742 AstraZeneca	HER2 positive breast cancer Part 1: 2L or later Part 2: 1L	350	Open label, two-part (dose escalation, dose expansion) ・DS-8201+ durvalumab ・DS-8201+ pertuzumab ・DS-8201+ paclitaxel ・DS-8201+ durvalumab + paclitaxel ・DS-8201+ tucatinib ・DS-8201	Primary endpoint: Safety Secondary endpoint: ORR, PFS, DOR, OS, PK and etc.	US/EU/ Asia	FPD: Jan 2021
Phase1b DESTINY-Breast08 NCT04556773 AstraZeneca	HER2 low breast cancer Chemotherapy naïve, post chemotherapy	185	Open label, two-part (dose escalation, dose expansion) ・DS-8201+ capecitabine ・DS-8201+ durvalumab + paclitaxel ・DS-8201+ capivasertib (AZD5363) ・DS-8201+ anastrozole ・DS-8201+ fulvestrant	Primary endpoint: Safety Secondary endpoint: ORR, PFS, DOR, OS, PK and etc.	US/EU/ Asia	FPD: Jan 2021
Phase3 DESTINY-Breast09 NCT04784715 AstraZeneca	HER2 positive breast cancer, 1L	1134	Randomized, open label, active control ・DS-8201 ・DS-8201 + pertuzumab ・Taxane + trastuzumab + pertuzumab	Primary endpoint: PFS Secondary endpoint: OS, FPS, ORR, DOR, PK, safety, etc.	US	FPD: FY2021 Q1 planned
Phase 1b/2 BEGONIA NCT03742102 AstraZeneca	Triple negative breast cancer	140	Non-randomized, open label, combination with durvalumab ・DS-8201 + durvalumab * Umbrella study of durvalumab led by AstraZeneca	Primary endpoint: Safety Secondary endpoint: ORR, PFS, DOR, OS, PK and etc.	US/EU/ Asia	FPD: May 2020

Trastuzumab deruxtecan/DS-8201/T-DXd (HER2-directed ADC)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 (pivotal) DESTINY-Gastric01 NCT03329690 JapicCTI-173727 AstraZeneca	HER2 overexpressing, gastric or gastroesophageal junction adenocarcinoma, 3L	220	Randomized, open label, active control ・DS-8201 ・Physician's choice (irinotecan or paclitaxel)	Primary endpoint: ORR Secondary endpoint: PFS, OS, DOR, DCR, TTF, ORR, PK	JP/Asia	FPD: Nov 2017 TLR: Jan 2020 Sep 2020: Approved (JP) Jan 2021: Approved (US) Mar 2018: SAKIGAKE Designation (JP) May 2020: Breakthrough Therapy Designation (US) May 2020: Orphan Drug Designation (US)
Phase 2 DESTINY-Gastric02 NCT04014075 AstraZeneca	HER2 positive gastric cancer, 2L	72	Open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: PFS, ORR, OS, DOR	US/EU	FPD: Dec 2019
Phase 1b/2 DESTINY-Gastric03 NCT04379596 jRCT2031200203 AstraZeneca	Part 1 HER2 overexpressing gastric or gastro-esophageal junction cancer, 2L Part 2 HER2 overexpressing gastric or gastro-esophageal junction cancer, 1L	250	Randomized, open label Part 1 ・DS-8201 + fluorouracil ・DS-8201 + capecitabine ・DS-8201 + durvalumab ・DS-8201 + oxaliplatin + fluorouracil ・DS-8201 + durvalumab + capecitabine + oxaliplatin ・DS-8201 + durvalumab + fluorouracil ・DS-8201 + capecitabine + durvalumab Part 2 ・DS-8201 ・DS-8201 + oxaliplatin + fluorouracil or capecitabine ・DS-8201 + durvalumab + fluorouracil or capecitabine ・Trastuzumab + fluorouracil or capecitabine + cisplatin or oxaliplatin	Primary endpoint: Part 1: Safety, Part 2: ORR Secondary endpoint: ORR, safety, DOR, DCR, PFS, OS, PK	US/EU/ Asia	FPD: Jun 2020

Trastuzumab deruxtecan/DS-8201/T-DXd (HER2-directed ADC)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 DESTINY-Gastric04 NCT04704934 AstraZeneca	HER2 positive gastric cancer or, gastro-esophageal junction cancer, 2L	490	Randomized, open label ・DS-8201 ・Ramucirumab + paclitaxel	Primary endpoint: OS Secondary endpoint: PFS, ORR, DOR, DCR, safety, PK, ADA and etc.	JP/US/EU/ Asia	FPD: FY2021 Q1 planned
Phase 2 DESTINY-Lung01 NCT03505710 JapicCTI-183916 AstraZeneca	HER2 overexpressing or mutated NSCLC, 2L or later	170	Non-randomized, open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: ORR, DOR, PFS, OS	JP/US/EU	FPD: May 2018 Data anticipated: FY2021 Q2 May 2020: Breakthrough Therapy Designation (US)
Phase 2 DESTINY-Lung02 NCT04644237 jRCT2061200038 AstraZeneca	HER2 mutated NSCLC, 2L or later	150	Randomized, double blind ・DS-8201: 6.4mg/kg ・DS-8201: 5.4mg/kg	Primary endpoint: ORR Secondary endpoint: ORR, DOR, DCR, PFS, OS, safety	JP/US/EU/ Asia	FPD: Mar 2021
Phase 1b DESTINY-Lung03 NCT04686305 AstraZeneca	HER2 positive NSCLC, 1L	120	Non-randomized, three-part (safety run-in, dose escalation, dose expansion) ・DS-8201 + durvalumab + cisplatin ・DS-8201 + durvalumab + carboplatin ・DS-8201 + durvalumab + pemetrexed ・DS-8201 + durvalumab	Primary endpoint: Safety Secondary endpoint: ORR, DOR, DCR, PFS, OS, PK and etc.	EU/Asia	FPD: FY2021 Q2 planned
Phase 2 HUDSON NCT03334617 AstraZeneca	NSCLC, 2L or later	320	Non-randomized, open label, combination with durvalumab ・DS-8201 + durvalumab * Umbrella study of durvalumab led by AstraZeneca	Primary endpoint: ORR Secondary endpoint: DCR, ORR, DOR, PFS, OS	US/EU/ Asia	FPD: Jun 2020
Phase 2 DESTINY-CRC01 NCT03384940 JapicCTI-173808 AstraZeneca	HER2 expressing colorectal cancer, 3L	90	Non-randomized, open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: PFS, OS, DOR, DCR, ORR, PK	JP/US/EU	FPD: Mar 2018 TLR: Oct 2019* *Results obtained for ASCO 2020

Trastuzumab deruxtecan/DS-8201/T-DXd (HER2-directed ADC)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 DESTINY-CRC02 NCT04744831 jRCT2051200124 AstraZeneca	HER2 expressing colorectal cancer, 3L	120	Randomized, double blind ・DS-8201 : 6.4mg/kg ・DS-8201 : 5.4mg/kg	Primary endpoint: ORR Secondary endpoint: DOR, DCR, PFS, OS, PK, PRO, safety	JP/US/EU/ Asia	FPD: Mar 2021
Phase 2 DESTINY-PanTumor01 NCT04639219 AstraZeneca	HER2 mutated tumors (e.g. colorectal cancer, urothelial cancer, gastric cancer, hepatobiliary cancer, endometrial cancer, melanoma, ovarian cancer, cervical cancer, salivary gland cancer, pancreatic cancer, breast cancer)	100	Open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: DOR, DCR, PFS, ORR, OS, safety	JP/US/EU/ Asia	FPD: Jan 2021
Phase 2 DESTINY-PanTumor02 NCT04482309 AstraZeneca	HER2 expressing tumors (bladder cancer, biliary tract cancer, cervical cancer, endometrial cancer, ovarian cancer, pancreatic cancer, rare tumors)	280	Non-randomized ・DS-8201	Primary endpoint: ORR Secondary endpoint: DOR, DCR, PFS, OS	US/EU/ Asia	FPD: Oct 2020
Phase 1 NCT03523572 BMS	HER2 positive/low breast cancer HER2 positive/low urothelial (bladder) cancer	99	Non-randomized, open label, combination with nivolumab, two-part (dose escalation, dose expansion) ・DS-8201+ nivolumab	Primary endpoint: ORR, safety Secondary endpoint: DOR, DCR, PFS, OS, ORR	US/EU	FPD: Aug 2018
Phase 1 NCT04042701 Merck	HER2 positive/low breast cancer HER2 expressing/mutated NSCLC	115	Non-randomized, open label, combination with pembrolizumab ・DS-8201+ pembrolizumab	Primary endpoint: Safety, ORR Secondary endpoint: DOR, DCR, PFS, OS	US/EU	FPD: Apr 2020

Datopotamab deruxtecan/DS-1062/Dato-DXd (TROP2-directed ADC)

Antibody-drug conjugate which is composed of a humanized monoclonal antibody specifically targeting TROP2, antigen highly expressed on the cell membrane of cancer cells, and a covalently linked drug (payload) via a cleavable linker. Payload is a potent and membrane permeable DNA topoisomerase I inhibitor which enables elimination of both target tumor cells and the surrounding tumor cells. Drug-to-antibody ratio is approximately 4.

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 TROPION-PanTumor01 NCT03401385 JapicCTI-173812 AstraZeneca	NSCLC Triple negative breast cancer HR positive breast cancer The following may be evaluated in dose expansion: SCLC, endometrial cancer, pancreatic adenocarcinoma, HER2-negative gastric/gastroesophageal junction cancer, esophageal cancer, HNSCC, transitional cell carcinoma of the urothelium, CRC, ovarian cancer, cervical cancer, and prostate cancer	770	Open label, two-part (dose escalation, dose expansion) ・DS-1062	Primary endpoint: Safety Secondary endpoint: PK, antitumor activity, anti-drug antibodies (ADA)	JP/US	FPD: Feb 2018
Phase 3 TROPION-Lung01 NCT04656652 jRCT2071200104 AstraZeneca	NSCLC (without actionable mutation), 2L/3L	590	Randomized, open label ・DS-1062 ・Docetaxel	Primary endpoint: PFS, OS Secondary endpoint: ORR, DOR, TTR, DCR, safety, PK, anti-drug antibodies (ADA)	JP/US/EU/ Asia	FPD: Feb 2021
Phase 1 TROPION-Lung02 NCT04526691 jRCT2031200193 Merck AstraZeneca	NSCLC (without actionable mutation), 2L/1L	120	Open label, combination with pembrolizumab, two-part (dose escalation, dose expansion) ・DS-1062 + pembrolizumab ± platinum chemotherapy	Primary endpoint: Safety and tolerability Secondary endpoint: ORR, DoR, DCR, CBR, PFS, TTR, Best percentage change in SoD of measurable tumors, OS, PK, Immunogenicity (ADA)	JP/US/EU/ Asia	FPD: Oct 2020
Phase 1 TROPION-Lung04 NCT04612751 jRCT2031200449 AstraZeneca	NSCLC (without actionable mutation), 2L/1L	120	Open label, combination with durvalumab, two-part (dose escalation, dose expansion) ・DS-1062 + durvalumab± platinum chemotherapy	Primary endpoint: Safety and tolerability Secondary endpoint: ORR, DoR, DCR, CBR, PFS, TTR, Best percentage change in SoD of measurable tumors, OS, PK, Immunogenicity (ADA)	JP/US/EU/ Asia	FPD: Mar 2021

Datopotamab deruxtecan/DS-1062/Dato-DXd (TROP2-directed ADC)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 TROPION-Lung05 NCT04484142 AstraZeneca	NSCLC (with actionable mutation)	150	open label ・DS-1062	Primary endpoint: ORR Secondary endpoint: DOR, PFS, OS, safety, PK, anti-drug antibodies (ADA)	JP/US/EU/ Asia	FPD: Mar 2021
Phase 1b/2 BEGONIA NCT03742102 AstraZeneca	Triple negative breast cancer	140	Non-randomized, open label, combination with durvalumab ・DS-1062+ durvalumab * Umbrella study of durvalumab led by AstraZeneca	Primary endpoint: Safety Secondary endpoint: ORR, PFS, DOR, OS, PK, etc.	US/EU/ Asia	FPD: FY2021 Q1 planned

Patritumab deruxtecan/U3-1402/HER3-DXd (HER3-directed ADC)

Antibody-drug conjugate which is composed of fully human monoclonal antibody specifically targeting HER3, one of the Epidermal Growth Factor Receptor (EGFR) family proteins, and a covalently linked drug (payload) via a cleavable linker. Payload is a potent and membrane permeable DNA topoisomerase I inhibitor which enables elimination of both target tumor cells and the surrounding tumor cells. Drug-to-antibody ratio is approximately 8.

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1/2 NCT02980341 JapicCTI-163401	Breast cancer	180	Randomized, open label, two-part (dose escalation, dose expansion) ・U3-1402	Primary endpoint: Safety, antitumor effect Secondary endpoint: PK	JP/US	FPD: Dec 2016 LPFD: May 2020
Phase 1 NCT03260491 JapicCTI-194868	NSCLC	198	Non-randomized, open label, two-part (dose escalation, dose expansion) ・U3-1402	Primary endpoint: Safety, ORR Secondary endpoint: PK, ORR, DCR, DOR, PFS, OS, safety	JP/US/EU /Asia	FPD: Feb 2018
Phase 2 prep HERTHENA-Lung01 NCT04619004 jRCT2031200186	EGFR mutated NSCLC	420	Randomized, open label ・U3-1402	Primary endpoint: ORR Secondary endpoint: DOR, PFS, ORR, DCR, TTR, OS, safety	JP/US/EU /Asia	FPD: Feb 2021
Phase 1 prep NCT04676477 jRCT2031200247 AstraZeneca	EGFR mutated NSCLC	252	Non-randomized, open label, two-part (dose escalation, dose expansion) ・U3-1402 + Osimertinib	Primary endpoint: safety, ORR Secondary endpoint: ORR, DOR, DCR, TTR, PFS, OS, safety, PK, and etc.	JP/US	FPD: FY2021 Q1 planned
Phase 2 NCT04479436 jRCT2031200139	CRC, 3L or later	80	Non-randomized, open label ・U3-1402	Primary endpoint: safety, ORR Secondary endpoint: DOR, ORR, DCR, TTR, PFS, OS, safety, PK	JP/US/EU	FPD: Sep 2020

◆ Alpha (Oncology Late-Stage Pipeline Products)

Quizartinib/AC220 (FLT3 inhibitor)

Kinase inhibitor against a receptor-type tyrosine kinase, FLT3. Therapeutic effect for patients with acute myeloid leukemia harboring FLT3-ITD mutation is expected.
Brand name: VANFLYTA (JP)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 QuANTUM-R NCT02039726	Acute myeloid leukemia, relapsed/refractory	367	Randomized, open label, active-controlled ・Quizartinib ・Chemotherapy	Primary endpoint: OS Secondary endpoint: EFS	JP/US/EU /Asia	FPD: May 2014 TLR: May 2018 Jun 2019: received CRL (US) Oct 2019: launched (JP) Oct 2019: received negative CHMP opinion (EU) Mar 2009: Orphan Drug Designation (US/EU) Submission strategy in US/EU/Asia is under discussion, together with 1L indication
Phase 3 QuANTUM-First NCT02668653 JapicCTI-173667	Acute myeloid leukemia, 1L	539	Randomized, double-blind, placebo-controlled ・Quizartinib + chemotherapy ・Placebo + chemotherapy	Primary endpoint: OS Secondary endpoint: EFS and etc.	JP/US/EU/ Asia	FPD: Sep 2016 Data anticipated: FY2021 3Q Mar 2009: Orphan Drug Designation (US/EU)

Pexidartinib/PLX3397 (CSF-1/KIT/FLT3 inhibitor)

The molecular-targeted agent to inhibit CSF-1R, KIT and FLT3. This agent is expected to reduce tumor cell proliferation and expansion of metastases.
Brand name: TURALIO (US)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 ENLIVEN NCT02371369	Tenosynovial giant cell tumor	120	Randomized, double-blind, placebo-controlled ・Pexidartinib ・Placebo	Primary endpoint: ORR Secondary endpoint: Safety, DOR and etc.	US/EU/ Asia	FPD: May 2015 TLR: Oct 2017 Aug 2019: launched (US) Jun 2020: received negative CHMP opinion (EU)
Phase 3 NCT04488822	Tenosynovial giant cell tumor	35	Open label ・Pexidartinib	Primary endpoint: PR, CR rate Secondary endpoint: TVS, ROM, PROMIS and etc.	Asia	FPD: Sep 2020
Phase 2 jRCT2041200074	Tenosynovial giant cell tumor	21	Open label ・Pexidartinib	Primary endpoint: Safety, PR, CR rate Secondary endpoint: Safety, TVS, ROM, PROMIS, and etc.	JP	FPD: Apr 2021

Teserpaturev/DS-1647/G47Δ (oncolytic HSV-1)

The third generation oncolytic herpes simplex virus type 1(HSV-1), genetically-engineered to restrict virus replication to tumor cells. This oncolytic virus therapy is expected equal or better safety and better efficacy profile compare to existing oncolytic virus.

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2/IIS (pivotal) ActiVec Inc.	Malignant glioma	30	Non-randomized, open label ・DS-1647/G47Δ	Primary endpoint: 1-year survival rate Secondary endpoint: OS, PFS, tumor response	JP	TLR: FY2018 Q4 Dec 2020: Submitted Approval anticipated: FY2021 Q1 Feb 2016: SAKIGAKE Designation Jul 2017: Orphan Drug Designation

Axicabtagene ciloleucel/Axi-Cel™ (anti-CD19 CAR-T cells)

Chimeric antigen receptor T (CAR-T), which is a cell therapy directed against CD19, an antigen expressed on the surface of B-cell malignant lymphoma cells.
Brand name: YESCARTA (JP)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 (pivotal) JapicCTI-183914 Kite/Gilead	Relapsed/refractory large B-cell lymphoma	10	Non-randomized, open label ・Axicabtagene ciloleucel	Primary endpoint: ORR Secondary endpoints: Safety, ORR, DOR, PFS, OS, PK	JP	FPD: Nov 2018 Jan 2021: Approved Oct 2018: Orphan Drug Designation

Valemetostat/DS-3201 (EZH1/2 inhibitor)

Inhibitor of histone methylases, EZH1 and EZH2. Some cancer cells grow dependently on these enzymes.

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 (pivotal) NCT04102150 JapicCTI-194964	Adult T-cell leukemia/lymphoma	25	Open label ・DS-3201	Primary endpoint: ORR Secondary endpoint: ORR, CR rate, DOR, PFS, OS and etc.	JP	FPD: Dec 2019 Data anticipated: FY2021 Q2
Phase 2 (pivotal) prep NCT04703192	Relapsed/ refractory peripheral T-cell lymphoma	176	Randomized, open label ・DS-3201	Primay endpoint: ORR Secondary endpoint: DOR, CR rate, safety, and etc.	JP/US/EU/ Asia	FPD: FY2021 Q1 planned Apr 2019: SAKIGAKE Designation for peripheral T-cell lymphoma (JP)
Phase 1 NCT02732275 JapicCTI-163173	Non-Hodgkin's lymphomas	100	Open label ・DS-3201	Primary endpoint: Safety, PK, antitumor effect Secondary endpoint: ORR, DCR, DOR, PFS and etc.	JP/US	FPD: Apr 2016
Phase 1 NCT03110354	Acute myeloid leukemia, acute lymphoblastic leukemia	48	Open label ・DS-3201	Primary endpoint: Safety Secondary endpoint: PK, antitumor effect	US	FPD: Mar 2017

◆ Alpha (Oncology Early-Stage Pipeline Products)

DS-1001 (Mutant IDH1 inhibitor)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT03030066 JapicCTI-163479	Glioma	47	Open label ・DS-1001	Primary endpoint: Safety Secondary endpoint: Safety, PK, antitumor effect	JP	FPD: Jan 2017
Phase 2 NCT04458272 JapicCTI-205339	Glioma	25	Open label ・DS-1001	Primary endpoint: ORR, safety Secondary endpoint: TTR, DOR, PFS, OS, PK	JP	FPD: Jul 2020

PLX2853 (BET inhibitor)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT03787498	Relapsed/refractory acute myeloid leukemia, myelodysplastic syndrome	36	Open label ・PLX2853	Primary endpoint: Safety, PK Secondary endpoint: ORR, DOR, EFS, PFS, OS	US	FPD: Mar 2019
Phase 1 NCT03297424	Advanced malignancies	166	Open label ・PLX2853	Primary endpoint: Safety, PK, antitumor effect Secondary endpoint: ORR, DOR, PFS, OS	US	FPD: Sep 2017
Phase 1b/2a NCT04493619	Gynecologic neoplasms Epithelial ovarian cancer	67	Non-randomized, open label ・PLX2853 + carboplatin	Primary endpoint: ORR, MTD, RP2D Secondary endpoint: Safety, DOR, DCR, PFS, OS, PK	US	FPD: Aug 2020
Phase 1/2 NCT04556617	Prostate cancer	110	Non-randomized, open label ・PLX2853 + abiraterone + prednisone ・PLX2853 + abiraterone + olaparib	Primary endpoint: ORR, safety Secondary endpoint: PFS, OS, PK and etc.	US	FPD: Sep 2020

DS-7300 (B7-H3-directed ADC)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1/2 NCT04145622 JapicCTI-194992	Solid tumors	160	Non-randomized, open label, two-part (dose escalation, dose expansion) ・DS-7300	Primary endpoint: Safety, antitumor effect Secondary endpoint: PK and etc.	JP/US	FPD: Oct 2019

DS-6157 (GPR20-directed ADC)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT04276415 JapicCTI-205184	Gastrointestinal stromal tumors	100	Non-randomized, open label, two-part (dose escalation, dose expansion) ・DS-6157	Primary endpoint: Safety, ORR, DOR, DCR, PFS Secondary endpoint: PK, ORR, DOR, DCR, PFS and etc.	JP/US	FPD: May 2020

DS-1055（anti-GARP antibody)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT04419532 JapicCTI-205292	Solid tumors	40	Non-randomized, open label ・DS-1055	Primary endpoint: Safety Secondary endpoint: PK, anti-drug antibodies and etc.	JP/US	FPD: Oct 2020

DS-6000（CDH6-directed ADC）

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT04707248	Renal cell carcinoma, ovarian cancer	102	Non-randomized, open label, two-part (dose escalation, dose expansion) ・DS-6000	Primary endpoint: Safety Secondary endpoint: PK, ORR, DOR, DCR and etc.	US	FPD: Jan 2021

DS-1594（Menin inhibitor）

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1/2 NCT04752163	Acute myeloid leukemia, acute lymphoblastic leukemia	122	Non-randomized, open label ・DS-1594 ・DS-1594 + venetoclax + azacitidine ・DS-1594 + mini HCVD	Primary endpoint: Safety, CR rate Secondary endpoint: CR rate, MLFS rate, PR rate, ORR, EFS, OS, mortality rate, etc.	US	FPD: Apr 2021

◆ Alpha (Specialty Medicines Late-Stage Pipeline Products)

Edoxaban/DU-176b (Factor Xa inhibitor)

The once daily oral anti coagulant (Factor Xa inhibitor) discovered by Daiichi Sankyo. Edoxaban specifically, reversibly and directly inhibits the enzyme, Factor Xa, a clotting factor in the blood.
Brand name: LIXIANA (JP/EU/ Asia), SAVAYSA (US)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 NCT02801669 JapicCTI-163266	Very elderly patients with non-valvular atrial fibrillation	984	Randomized, double-blind, placebo-controlled ・Edoxaban ・Placebo	Primary endpoint: annual incidence rate of stroke and systemic embolic events Secondary endpoint: annual incidence rate of bleeding events	JP	FPD: Aug 2016 TLR: Apr 2020 Submission: Sep 2020 Approval anticipated: FY2021 Q2

Prasugrel/CS-747 (ADP receptor inhibitor)

Oral antiplatelet agents. Inhibits arterial stenosis and occlusion by inhibiting platelet aggregation.
Brand name: EFIENT (JP/EU), EFFIENT (US/Asia)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 JapicCTI-184141	Ischemic stroke	250	Randomized, double-blind, active-controlled ・Prasugrel ・Clopidogrel	Primary endpoint: incidence rate of cerebro-cardiovascular events Secondary endpoint: incidence rate of bleeding events	JP	FPD: Oct 2018 TLR: Jun 2020 Submission: Dec 2020 Approval anticipated: FY2021 Q3

Mirogabalin/DS-5565 ($\alpha_2\delta$ ligands)

The pain therapy agent to reduce the neurotransmitter release from nerve terminals. This agent is expected to show the good balanced efficacy and safety profile.
Brand name: TARLIGE (JP)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 NCT03901352 JapicCTI-194653	Central neuropathic pain	274	Randomized, double-blind, placebo-controlled ・Mirogabalin ・Placebo	Primary endpoint: average daily pain score Secondary endpoint: visual analogue scale, average daily sleep interference score	JP/Asia	FPD: Mar 2019 TLR: Dec 2020 Submission planned: FY2021 Q1
Phase 3 NCT04094662	Diabetic peripheral neuropathic pain	360	Randomized, double-blind, placebo-controlled ・Mirogabalin ・Placebo	Primary endpoint: average daily pain score Secondary endpoint: visual analogue scale, average daily sleep interference score	China	FPD: Sep 2019

Esaxerenone/CS-3150 (MR blocker)

The agent inhibits aldosterone binding to Mineralocorticoid Receptor (MR) which stimulate the sodium absorption into kidney. This agent is expected to exhibit antihypertensive and organ-protective effect.
Brand name: MINNEBRO (JP)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 JapicCTI-173695 Exelixis, Inc.	Diabetic nephropathy	400	Randomized, double-blind, placebo-controlled ・Esaxerenone ・Placebo	Primary endpoint: UACR remission rate Secondary endpoint: change rate in UACR and eGFR and etc.	JP	FPD: Sep 2017 TLR: Jul 2019

◆ Alpha (Specialty Medicines Early-Stage Pipeline Products)

Renadirsen Sodium/DS-5141 (ENA-oligonucleotides)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1/2 NCT02667483 JapicCTI-153072 ODTI	Duchenne muscular dystrophy	8	Open label ・DS-5141	Primary endpoint: Safety, PK, dystrophin protein expression in muscle tissue Secondary endpoint: production of exon 45-skipped dystrophin mRNA in muscle tissue	JP	FPD: Oct 2015 TLR: Dec 2020 Apr 2017: SAKIGAKE Designation Apr 2018: announced TLR of 12-week treatment study
Phase 2 NCT04433234 JapicCTI-205321	Duchenne muscular dystrophy	8	Long-term study of above phase 1/2 study ・DS-5141	Endpoint: Safety, motor function, respiratory function, cardiac function, quantitative muscle strength evaluation, PK	JP	

DS-1211 (TNAP inhibitor)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 prep	Pseudoxanthoma elasticum				US	SAD and MAD studies completed

DS-2741 (anti-Orai1 antibody)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT04211415 JapicCTI-195071	Healthy volunteers, atopic dermatitis	75	Randomized, double-blind, placebo-controlled	Primary endpoint: Safety Secondary endpoint: PK	JP	FPD: Jan 2020

DS-2319 (Nafamostat inhalation)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 jRCT2051200153	Healthy volunteers, COVID-19	76	Randomized, double-blind, placebo-controlled	Primary endpoint: Safety Secondary endpoint: PK	JP	FPD: Mar 2021

DS-6016 (anti-ALK2 antibody)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 prep jRCT2051200155	Healthy volunteers, progressive ossifying fibrodysplasia		Randomized, double-blind, placebo-controlled	Primary endpoint: Safety Secondary endpoint: PK	JP	FPD: Apr 2021

◆ Alpha (Vaccine)

VN-0107/MEDI3250 (live attenuated influenza vaccine)

The US brand name of this vaccine is FluMist Quadrivalent that is a live attenuated influenza vaccine which is administered as a nasal spray and contains four protective strains.

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 JapicCTI-163400 AstraZeneca/ MedImmune	Prevention of seasonal influenza	782	Randomized, double-blind, placebo-controlled ・VN0107 ・Placebo	Primary endpoint: onset of influenza, safety Secondary endpoint: onset of influenza	JP	Jun 2016: Submitted by Daiichi Sankyo

VN-0102/JVC-001 (mixed measles-mumps-rubella vaccines)

Trivalent mixed vaccine (MMR vaccine) containing three attenuated viruses of measles (Measles), mumps (Mumps) and rubella (Rubella), which has not been approved in Japan.

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 JapicCTI-205118	Prevention of measles, mumps and rubella in healthy Japanese children aged 12 months or more and less than 24 months	840	Randomized, active-controlled ・VN-0102/JVC-001 ・Dry Live Attenuated Measles Rubella vaccine, Freeze-dried Live Attenuated Mumps vaccine	Primary endpoint: Seroprotection rates for measles, mumps and rubella Secondary endpoint: Seroconversion rates for measles, mumps, and rubella	JP	FPD: Feb 2020 LPD: Sep 2020 Data anticipated: FY2022 Q1

DS-5670 (COVID-19 mRNA vaccines)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1/2	Health adults and elderly, prevention of COVID-19	152	Randomized, placebo-controlled ・DS-5670 ・Placebo	Primary endpoint: safety, immunogenicity Secondary endpoint: immunogenicity, PK	JP	FPD: Mar 2021

◆ Stage-up Projects (Major Changes from the FY2020 Q3 Financial Announcement in January 2021)

Generic Name/Project Code Number Mechanism of action	Target indication	Current stage	Note
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 positive breast cancer, 1L	P3 prep	DESTINY-Breast09
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 mutated NSCLC, 2L	P2	DESTINY-Lung02
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 positive CRC, 3L	P2 prep	DESTINY-CRC02
Datopotamab deruxtecan/DS-1062/ Dato-DXd TROP2-directed ADC	NSCLC (without actionable mutation), 2/3L	P3	TROPION-Lung01
Datopotamab deruxtecan/DS-1062/ Dato-DXd TROP2-directed ADC	NSCLC (without actionable mutation)	P1b	TROPION-Lung04 Combination with durvalumab
Datopotamab deruxtecan/DS-1062/ Dato-DXd TROP2-directed ADC	NSCLC (with actionable mutation)	P2	TROPION-Lung05
Datopotamab deruxtecan/DS-1062/ Dato-DXd TROP2-directed ADC	Triple negative breast cancer	P1b/2 prep	Addition of cohort to BEGONIA study

◆ Stage-up Projects (Major Changes from the FY2020 Q3 Financial Announcement in January 2021)

Generic Name/Project Code Number Mechanism of action	Target indication	Current stage	Note
Patritumab deruxtecan/U3-1402/ HER3-DXd HER3-directed ADC	EGFR mutated NSCLC	P2	HERTHENA-Lung01
Pexidartinib/PLX3397 CSF-1/KIT/FLT3 inhibitor	Tenosynovial giant cell tumor	P2	Japan
DS-6000 CDH6-directed ADC	Renal cell carcinoma, ovarian cancer	P1	US
DS-1594 Menin inhibitor	Acute myeloid leukemia, acute lymphoblastic leukemia	P1/2	US
DS-2319 Nafamostat inhalation	COVID-19	P1	JP
DS-5670 COVID-19 mRNA vaccine	Prevention of COVID-19	P1	JP
DS-6016 anti-ALK2 antibody	Progressive ossifying fibrodysplasia	P1/2	JP