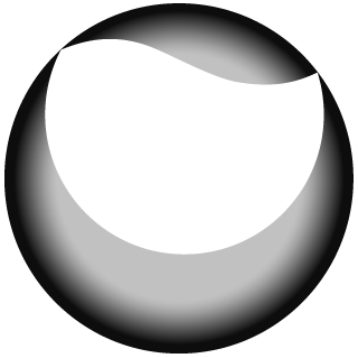
TSE:4568

Reference Data

(Consolidated Financial Results for Q1 FY2020)



Daiichi-Sankyo

July 31, 2020

Daiichi Sankyo Co., Ltd.

https://www.daiichisankyo.com

Contents

Daiichi-Sankyo

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2019 Q1 to revenue	FY2019 Q1 Results	FY2020 Q1 to revenue	FY2020 Q1 Results	(vs. Forecast (%))	YoY	YoY (%)		FY2020 to revenue	FY2020 Forecast	YoY	YoY (%)
Revenue	***100.0%***	**249.2**	***100.0%***	**236.9**	**(24.4%)**	**-12.3**	**-4.9%**	Forex impact: -4.0 (USD: -0.8, EUR: -1.2, ASCA: -2.0)	***100.0%***	**970.0**	**-11.8**	**-1.2%**
Cost of sales	*35.3%*	87.9	*34.7%*	82.2	(24.4%)	-5.7	-6.5%	Forex impact: -0.4 (USD: -0.1, EUR: -0.1, ASCA: -0.2)	*34.7%*	337.0	-6.2	-1.8%
(excl. Special items)	*34.7%*	86.6	*34.7%*	82.2		-4.4	-5.0%					
(Special items)	*0.5%*	1.3	-	-		-1.3	-					
Gross Profit	*64.7%*	161.3	*65.3%*	154.7	(24.4%)	-6.6	-4.1%		*65.3%*	633.0	-5.6	-0.9%
SG&A expenses	*25.3%*	63.2	*30.3%*	71.8	(22.1%)	8.6	+13.7%	Forex impact: -1.3 (USD: -0.4, EUR: -0.4, ASCA: -0.5)	*33.5%*	325.0	22.7	+7.5%
(excl. Special items)	*29.6%*	73.8	*30.3%*	71.8		-2.0	-2.7%					
(Special items)	*-4.3%*	-10.6	-	-		10.6	-					
R&D expenses	*16.5%*	41.2	*20.6%*	48.8	(21.4%)	7.6	+18.5%	Forex impact: -0.6 (USD: -0.5, EUR: -0.1)	*23.5%*	228.0	30.5	+15.5%
(excl. Special items)	*16.5%*	41.2	*20.6%*	48.8		7.6	+18.5%					
(Special items)	-	-	-	-		-	-					
Operating Profit	***22.9%***	**57.0**	***14.4%***	**34.1**	**(42.7%)**	**-22.9**	**-40.1%**	Forex impact: -1.6 (USD: +0.1, EUR: -0.6, ASCA: -1.2)	***8.2%***	**80.0**	**-58.8**	**-42.4%**
(Operating Profit before Special items)	*19.1%*	47.7	*14.4%*	34.1		-13.6	-28.4%					
Financial income/expenses		0.1		7.2		7.2		- Recognition of financial income due to decrease in contingent consideration of quizartinib acquisition +4.7 - Improvement in forex gains/losses +3.2				
Share of profit or loss of investments accounted for using the equity method		0.0		0.0		0.0						
Profit before tax	***22.9%***	**57.1**	***17.5%***	**41.4**	**(51.7%)**	**-15.7**	**-27.5%**		***8.2%***	**80.0**	**-61.2**	**-43.3%**
Income taxes		13.7		9.6		-4.2	-30.5%					
Profit for the year	***17.4%***	**43.3**	***13.4%***	**31.8**	**(56.8%)**	**-11.5**	**-26.5%**		***5.8%***	**56.0**	**-73.0**	**-56.6%**
Profit attributable to owners of the Company	***17.4%***	**43.3**	***13.4%***	**31.9**	**(56.9%)**	**-11.5**	**-26.5%**		***5.8%***	**56.0**	**-73.1**	**-56.6%**
Tax rate		24.1%		23.1%								
Overseas sales ratio		37.5%		38.6%								

Currency Rate (Average)

USD/JPY	109.90	107.62
EUR/JPY	123.49	118.47

Special items

	FY2019 Q1	FY2020 Q1
Cost of Sales	Restructuring costs in SC 1.3	
SG&A expenses	Gain on sales of fixed assets -10.6	
Total	-9.3	-

Currency Rate (Average)

	110.00
	120.00

Annual impact of one yen change

	Forecast	
	USD	EUR
Revenue	1.7 JPY Bn	0.9 JPY Bn
Operating Profit	-0.4 JPY Bn	0.1 JPY Bn

*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".

2. Revenue of Global Products

JPY Bn		FY2019 Q1	FY2020 Q1				FY2020		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Trastuzumab Deruxtecan	anti-cancer agent (anti-HER2 antibody drug conjugate)	**2.5**	**7.9**	**(20.1%)**	**5.4**	**+221.5%**	**39.2**	**25.3**	**+181.0%**
Product sales		-	5.2	(18.3%)	5.2	-	28.5	25.3	+781.9%
Enhertu (JPN)		-	0.2	(14.4%)	0.2	-	1.5	1.5	-
Enhertu (US)		-	5.0	(18.5%)	5.0	-	27.0	23.8	+735.5%
Upfront payment		2.5	2.5	(25.0%)	-	-	9.8	-	-
Regulatory milestone payment		-	0.2	(25.0%)	0.2	-	0.9	-	-
Edoxaban	anticoagulant	**37.2**	**38.7**	**(23.8%)**	**1.5**	**+4.0%**	**163.0**	**9.0**	**+5.8%**
Lixiana (JPN)		21.6	19.8	(26.4%)	-1.8	-8.2%	75.0	-8.0	-9.6%
Savaysa (US)		0.6	0.6	(28.4%)	-0.0	-0.7%	2.0	-0.6	-23.4%
Lixiana (EU)		13.5	16.4	(21.6%)	2.9	+21.8%	76.0	14.3	+23.2%
Other subsidiaries		1.6	1.9	(19.4%)	0.3	+19.6%	10.0	3.2	+48.0%
Olmesartan	antihypertensive agent	**27.5**	**25.7**	**(33.0%)**	**-1.8**	**-6.4%**	**78.0**	**-22.8**	**-22.6%**
Olmetec (JPN)		3.5	2.7	(33.9%)	-0.8	-23.4%	8.0	-3.7	-31.4%
Rezaltas (JPN)		4.2	3.6	(30.1%)	-0.5	-13.0%	12.0	-2.6	-17.8%
Olmesartan (US)		3.1	3.7	(53.1%)	0.6	+20.3%	7.0	-2.8	-28.9%
Olmesartan (EU)		6.4	5.2	(30.8%)	-1.1	-18.0%	17.0	-7.6	-30.9%
Other subsidiaries, export, etc		10.3	10.5	(30.7%)	0.1	+1.3%	34.0	-6.1	-15.3%
Prasugrel	antiplatelet agent	**5.0**	**4.4**	**-**	**-0.6**	**-11.5%**	**not disclosed**	**-**	**-**
Effient alliance revenue (US)		0.1	-0.0	-	-0.1	-	not disclosed	-	-
Efient (EU)		0.8	0.3	(31.6%)	-0.5	-60.0%	1.0	-1.5	-60.4%
Efient (JPN)		3.8	3.8	(27.3%)	-0.0	-0.5%	14.0	0.0	+0.0%
Other subsidiaries, export, etc		0.3	0.3	-	0.0	+2.2%	not disclosed	-	-

3. Revenue by Business Units and Products (1)

JPY Bn		FY2019 Q1	FY2020 Q1				FY2020		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Japan		**139.0**	**130.2**	**(27.0%)**	**-8.8**	**-6.3%**	**483.0**	**-50.5**	**-9.5%**
Nexium	ulcer treatment	21.9	19.9	(25.5%)	-2.0	-9.2%	78.0	-1.8	-2.2%
Lixiana	anticoagulant	21.6	19.8	(26.4%)	-1.8	-8.2%	75.0	-8.0	-9.6%
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	8.2	8.7	(26.2%)	0.5	+6.2%	33.0	2.1	+6.6%
Memary	Alzheimer's disease treatment	13.7	12.8	(53.3%)	-1.0	-6.9%	24.0	-26.5	-52.5%
Tenelia	type 2 diabetes mellitus treatment	6.9	6.6	(27.4%)	-0.3	-5.0%	24.0	-0.7	-2.9%
Loxonin	anti-inflammatory analgesic	7.8	6.2	(28.1%)	-1.6	-20.7%	22.0	-6.3	-22.1%
Ranmark	treatment for bone complications caused by bone metastases from tumors	4.7	5.0	(27.6%)	0.3	+6.2%	18.0	0.1	+0.6%
Inavir	anti-influenza agent	0.0	0.6	(3.6%)	0.6	-	18.0	-1.3	-6.6%
Tarlige	pain treatment	2.0	4.3	(26.7%)	2.3	+118.5%	16.0	8.0	+100.4%
Canalia	type 2 diabetes mellitus treatment	3.2	3.9	(26.3%)	0.8	+23.5%	15.0	2.2	+17.0%
Vimpat	anti-epileptic agent	2.7	3.8	(26.9%)	1.1	+41.8%	14.0	2.8	+25.4%
Efient	antiplatelet agent	3.8	3.8	(27.3%)	-0.0	-0.5%	14.0	0.0	+0.0%
Rezaltas	antihypertensive agent	4.2	3.6	(30.1%)	-0.5	-13.0%	12.0	-2.6	-17.8%
Olmetec	antihypertensive agent	3.5	2.7	(33.9%)	-0.8	-23.4%	8.0	-3.7	-31.4%
Enhertu	anti-cancer agent (anti-HER2 antibody drug conjugate)	-	0.2	(14.4%)	0.2	-	1.5	1.5	-
Daiichi Sankyo Espha products		17.3	17.6	-	0.3	+1.7%	not disclosed	-	-
Vaccines business		7.5	2.9	-	-4.6	-61.3%	not disclosed	-	-
Daiichi Sankyo Healthcare (OTC)		**15.4**	**14.3**	**(19.3%)**	**-1.1**	**-7.3%**	**74.0**	**5.5**	**+8.1%**

3. Revenue by Business Units and Products (2)

JPY Bn		FY2019 Q1	FY2020 Q1				FY2020		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Daiichi Sankyo, Inc. (US)		**7.8**	**11.6**	**(24.1%)**	**3.7**	**+47.6%**	**48.0**	**15.9**	**+49.5%**
Enhertu	anti-cancer agent (anti-HER2 antibody drug conjugate)	-	5.0	(18.5%)	5.0	-	27.0	23.8	+735.5%
Olmesartan	antihypertensive agent	3.1	3.7	(53.1%)	0.6	+20.3%	7.0	-2.8	-28.9%
Welchol	hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	2.6	0.6	(19.3%)	-2.0	-77.5%	3.0	-6.1	-67.1%
Effient	antiplatelet agent	0.1	-0.0	-	-0.1	-	not disclosed	-	-
Savaysa	anticoagulant	0.6	0.6	(28.4%)	-0.0	-0.7%	2.0	-0.6	-23.4%
American Regent, Inc. (US)		**36.0**	**26.5**	**(19.6%)**	**-9.5**	**-26.4%**	**135.0**	**4.2**	**+3.2%**
Injectafer	treatment for iron deficiency anemia	13.7	9.4	(16.8%)	-4.3	-31.4%	56.0	4.2	+8.1%
Venofer	treatment for iron deficiency anemia	9.3	6.9	(23.9%)	-2.4	-25.5%	29.0	-2.0	-6.4%
Daiichi Sankyo Europe GmbH		**22.1**	**27.7**	**(27.2%)**	**5.6**	**+25.3%**	**102.0**	**6.5**	**+6.8%**
Lixiana	anticoagulant	13.5	16.4	(21.6%)	2.9	+21.8%	76.0	14.3	+23.2%
Olmesartan	antihypertensive agent	6.4	5.2	(30.8%)	-1.1	-18.0%	17.0	-7.6	-30.9%
Efient	antiplatelet agent	0.8	0.3	(31.6%)	-0.5	-60.0%	1.0	-1.5	-60.4%
Asia, South and Central America (ASCA)		**24.3**	**22.5**	**(21.9%)**	**-1.8**	**-7.3%**	**103.0**	**4.7**	**+4.8%**
Daiichi Sankyo China		12.0	8.6	-	-3.4	-28.2%	not disclosed	-	-
Daiichi Sankyo Taiwan		1.9	2.1	-	0.2	+11.3%	not disclosed	-	-
Daiichi Sankyo Korea		4.0	4.4	-	0.4	+11.1%	not disclosed	-	-
Daiichi Sankyo Thailand		0.8	0.6	-	-0.2	-27.9%	not disclosed	-	-
Daiichi Sankyo Brasil Farmacêutica		2.8	2.9	-	0.1	+2.6%	not disclosed	-	-

3. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

		FY2019 Q1	FY2020 Q1				FY2020		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
USD Mn									
Daiichi Sankyo, Inc. (US)		**71**	**107**	**(24.6%)**	**36**	**+50.7%**	**436**	**141**	**+47.7%**
Enhertu	anti-cancer agent (anti-HER2 antibody drug conjugate)	-	46	(18.9%)	46	-	245	216	+725.4%
Olmesartan	antihypertensive agent	28	35	(54.3%)	6	+22.9%	64	-27	-29.8%
Welchol	hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	23	5	(19.7%)	-18	-77.0%	27	-57	-67.5%
Effient	antiplatelet agent	1	-0	-	-1	-	not disclosed	-	-
Savaysa	anticoagulant	5	5	(29.0%)	0	+1.4%	18	-6	-24.3%
USD Mn									
American Regent, Inc. (US)		**327**	**246**	**(20.0%)**	**-81**	**-24.8%**	**1,227**	**24**	**+2.0%**
Injectafer	treatment for iron deficiency anemia	125	88	(17.2%)	-37	-29.9%	509	32	+6.7%
Venofer	treatment for iron deficiency anemia	85	64	(24.4%)	-20	-23.9%	264	-22	-7.6%
EUR Mn									
Daiichi Sankyo Europe GmbH		**179**	**234**	**(27.5%)**	**55**	**+30.6%**	**850**	**61**	**+7.7%**
Lixiana	anticoagulant	109	139	(21.9%)	29	+26.9%	633	124	+24.3%
Olmesartan	antihypertensive agent	52	44	(31.2%)	-8	-14.5%	142	-62	-30.3%
Efient	antiplatelet agent	6	3	(32.0%)	-4	-58.3%	8	-13	-60.0%

4. Consolidated Statement of Financial Position

<Assets> JPY Bn

	Mar. 2020	Jun. 2020	vs. Mar. 2020
Assets			
Current assets			
Cash and cash equivalents	424.2	382.1	-42.1
Trade and other receivables	309.4	243.9	-65.5
Other financial assets	466.5	496.0	29.4
Inventories	173.4	183.7	10.3
Other current assets	10.5	12.0	1.5
Subtotal	1,384.0	1,317.7	-66.3
Assets held for sale	0.1	0.1	0.0
Total current assets	**1,384.1**	**1,317.8**	**-66.3**
Non-current assets			
Property,plant and equipment	247.1	247.9	0.8
Goodwill	76.8	76.2	-0.5
Intangible assets	172.5	182.8	10.3
Investments accounted for using the equity method	0.4	0.3	-0.1
Other financial assets	98.0	109.0	11.0
Deferred tax assets	114.7	116.8	2.1
Other non-current assets	12.1	12.3	0.3
Total non-current assets	**721.5**	**745.4**	**23.9**
Total assets	**2,105.6**	**2,063.2**	**-42.4**

*	Liquidity on hand	891.2	878.1	-13.1
	Debt with interest	266.3	268.1	1.8
	Net Cash	624.9	610.0	-14.9

Receivable for trastuzumab deruxtecan strategic collaboration upfront payment -74.5

- Acquisition +7.4, Depreciation -7.9
- Increase in lease assets +1.0

Acquisition +16.7, Amortization -6.2, Forex impact -0.2

<Liabilities and equity>

JPY Bn

	Mar. 2020	Jun. 2020	vs. Mar. 2020
Liabilities			
Current liabilities			
Trade and other payables	270.9	223.4	-47.4
Bonds and borrowings	40.4	40.4	0.0
Other financial liabilities	9.5	10.6	1.2
Income taxes payable	9.9	13.3	3.3
Provisions	5.4	4.6	-0.7
Other current liabilities	15.0	12.3	-2.7
Total current liabilities	**351.1**	**304.6**	**-46.4**
Non-current liabilities			
Bonds and borrowings	183.8	183.7	-0.1
Other financial liabilities	37.1	37.9	0.8
Post employment benefit liabilities	5.3	5.2	-0.1
Provisions	10.6	10.6	-0.0
Deferred tax liabilities	15.6	15.3	-0.4
Other non-current liabilities	195.8	189.7	-6.1
Total non-current liabilities	**448.3**	**442.4**	**-5.8**
Total liabilities	**799.3**	**747.1**	**-52.3**
Equity			
Equity attributable to owners of the Company			
Share capital	50.0	50.0	-
Capital surplus	94.6	94.6	-
Treasury shares	-162.5	-161.8	0.7
Other components of equity	82.1	82.1	0.0
Retained earnings	1,241.6	1,250.8	9.2
Total equity attributable to owners of the Company	1,305.8	1,315.7	9.9
Non-controlling interests			
Non-controlling interests	0.5	0.4	-0.0
Total equity	**1,306.3**	**1,316.1**	**9.8**
Total liabilities and equity	**2,105.6**	**2,063.2**	**-42.4**

Upfront payment for strategic partnership of gene therapy manufacturing technology with Ultragenyx -13.5

Decrease in contingent consideration of quizartinib introduction -4.7

Deferred revenue for trastuzumab deruxtecan -2.7
(Strategic collaboration upfront payment -2.5, Regulatory milestone payment -0.2)

Profit for the period +31.9, Payment of dividends -22.7

5. Consolidated Statement of Cash Flows

JPY Bn

	FY2019 Q1	FY2020 Q1	YoY
Cash flows from operating activities			
Profit before tax	57.1	41.4	-15.7
Depreciation and amortization	12.9	14.1	1.2
(Increase) decrease in receivables and payables	39.7	34.7	-5.0
Others, net	-21.9	-23.9	-2.0
Income taxes paid	-10.2	-10.4	-0.2
Net cash flows from operating activities	**77.6**	**55.9**	**-21.7**
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	3.2	-29.2	-32.4
(Acquisition of) proceeds from sales of fixed assets	-13.5	-39.0	-25.5
Net (increase) decrease in investment securities	1.0	-2.2	-3.2
Others, net	14.9	-0.5	-15.3
Net cash flows from investing activities	**5.6**	**-70.8**	**-76.4**
Cash flows from financing activities			
Net (increase) decrease in borrowings	3.9	-0.1	-4.0
Repayments of bonds	-40.0	-	40.0
Purchase of treasury shares	-0.0	-0.0	0.0
Dividends paid	-22.7	-22.8	-0.1
Others, net	-2.5	-3.2	-0.7
Net cash flows from financing activities	**-61.3**	**-26.1**	**35.2**
Net increase (decrease) in cash and cash equivalents	**21.9**	**-41.0**	**-62.9**
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	**-4.1**	**-1.0**	**3.1**
Cash and cash equivalents at the end of the period	**260.9**	**382.1**	**121.2**

*	**Free cash flows** (Cash flows from operating activities and investing activities)	**83.2**	**-15.0**	**-98.1**

6. Number of Employees

	Jun. 2019 Results	Mar. 2020 Results	Jun. 2020 Results
Consolidated	15,354	15,348	15,720
Japan	9,175	8,754	8,943
North America	2,225	2,380	2,488
Europe	1,818	1,953	1,977
Others	2,136	2,261	2,312

7. Capital Expenditure, Depreciation and Amortization

JPY Bn	FY2019 Q1 Results	FY2019 Results	FY2020 Q1 Results	FY2020 Forecast
Capital expenditure	5.6	29.0	6.3	50.0
Depreciation and amortization	12.9	52.6	14.1	56.0
Property, plant and equipment	8.1	32.0	7.9	-
Intangible assets	4.9	20.6	6.2	-

8. 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 (anti-HER2 antibody drug conjugate)	2020	Daiichi Sankyo		
Daiichi Sankyo, Inc. (US)						
Enhertu	trastuzumab deruxtecan	anti-cancer agent (anti-HER2 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						
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		

<9. 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**				***100.0%***	**236.9**
Cost of sales	87.9	89.2	79.2	86.9	*35.0%*	343.2	-21.4	-5.9%	82.2				*34.7%*	82.2
(excl. Special items)	86.6	85.4	98.0	84.5	*36.1%*	354.4	4.9	+1.4%	82.2				*34.7%*	82.2
(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				*65.3%*	154.7
SG&A expenses	63.2	67.3	77.8	94.1	*30.8%*	302.3	24.6	+8.9%	71.8				*30.3%*	71.8
(excl. Special items)	73.8	67.3	77.8	85.9	*31.0%*	304.8	23.6	+8.4%	71.8				*30.3%*	71.8
(Special items)	-10.6	-	-	8.2	*-0.2%*	-2.4	1.0	-	-				-	-
R&D expenses	41.2	44.7	51.1	60.5	*20.1%*	197.5	-6.2	-3.1%	48.8				*20.6%*	48.8
(excl. Special items)	41.2	44.7	51.1	60.5	*20.1%*	197.5	-6.2	-3.1%	48.8				*20.6%*	48.8
(Special items)	-	-	-	-	-	-	0.0	-	-				-	-
Operating Profit	**57.0**	**29.2**	**69.4**	**-16.8**	***14.1%***	**138.8**	**55.1**	**+65.8%**	**34.1**				***14.4%***	**34.1**
(Operating Profit before Special items)	47.7	33.0	50.6	-6.1	*12.7%*	125.1	29.8	+31.3%	34.1				*14.4%*	34.1
Financial income/expenses	0.1	0.8	3.5	-2.3		2.0	-0.2		7.2					7.2
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
Profit before tax	**57.1**	**30.0**	**72.9**	**-18.8**	***14.4%***	**141.2**	**55.3**	**+64.5%**	**41.4**				***17.5%***	**41.4**
Income taxes	13.7	8.9	3.1	-13.6		12.2	19.8	-	9.6					9.6
Profit for the year	**43.3**	**21.1**	**69.8**	**-5.2**	***13.1%***	**129.0**	**35.5**	**+38.0%**	**31.8**				***13.4%***	**31.8**
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**				***13.4%***	**31.9**
Tax rate	24.1%	29.8%	4.3%	72.2%		8.6%			23.1%					23.1%
Overseas sales ratio	37.5%	38.4%	34.9%	42.5%		38.1%			38.6%					38.6%
Currency Rate (YTD Average)														
USD/JPY	109.90	108.63	108.67	108.75		108.75			107.62					107.62
EUR/JPY	123.49	121.41	121.05	120.83		120.83			118.47					118.47

<9. Quarterly Data>

2. Revenue of Global Products

JPY Bn	FY2019 Q1 Results	FY2019 Q2 Results	FY2019 Q3 Results	FY2019 Q4 Results	FY2019 Results	FY2019 YoY	FY2019 YoY (%)	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 Results
Trastuzumab deruxtecan	**2.5**	**2.5**	**3.2**	**5.9**	**14.0**	**13.9**	**-**	**7.9**				**7.9**
Product sales	-	-	0.0	3.2	3.2	3.2	-	5.2				5.2
Enhertu(JPN)	-	-	-	-	-	-	-	0.2				0.2
Enhertu (US)	-	-	0.0	3.2	3.2	3.2	-	5.0				5.0
Upfront payment	2.5	2.5	2.5	2.5	9.8	9.7	-	2.5				2.5
Regulatory milestone payment	-	-	0.7	0.2	0.9	0.9	-	0.2				0.2
Edoxaban	**37.2**	**36.5**	**42.6**	**37.6**	**154.0**	**36.3**	**+30.9%**	**38.7**				**38.7**
Lixiana (JPN)	21.6	20.2	23.8	17.4	83.0	18.1	+27.8%	19.8				19.8
Savaysa (US)	0.6	0.6	0.8	0.7	2.6	0.3	+13.8%	0.6				0.6
Lixiana (EU)	13.5	14.0	16.4	17.8	61.7	15.9	+34.7%	16.4				16.4
Other subsidiaries	1.6	1.7	1.7	1.7	6.8	2.1	+44.2%	1.9				1.9
Olmesartan	**27.5**	**23.2**	**26.3**	**23.9**	**100.8**	**-5.1**	**-4.8%**	**25.7**				**25.7**
Olmetec (JPN)	3.5	2.7	3.2	2.2	11.7	-3.2	-21.5%	2.7				2.7
Rezaltas (JPN)	4.2	3.4	4.1	3.0	14.6	-0.9	-5.8%	3.6				3.6
Olmesartan (US)	3.1	2.4	2.2	2.1	9.8	-0.9	-8.4%	3.7				3.7
Olmesartan (EU)	6.4	4.8	5.8	7.7	24.6	-2.8	-10.2%	5.2				5.2
Other subsidiaries, export, etc	10.3	9.9	11.0	8.9	40.1	2.7	+7.2%	10.5				10.5
Prasugrel	**5.0**	**4.4**	**4.9**	**3.8**	**18.1**	**-5.1**	**-21.9%**	**4.4**				**4.4**
Effient alliance revenue (US)	0.1	0.3	0.0	0.1	0.5	-2.0	-81.4%	-0.0				-0.0
Efient (EU)	0.8	0.6	0.6	0.6	2.5	-3.2	-55.8%	0.3				0.3
Efient (JPN)	3.8	3.2	4.0	2.9	14.0	0.1	+0.7%	3.8				3.8
Other subsidiaries, export, etc	0.3	0.3	0.3	0.2	1.2	-0.0	-0.2%	0.3				0.3

3. Revenue by Business Units and Products (1)

JPY Bn	FY2019 Q1 Results	FY2019 Q2 Results	FY2019 Q3 Results	FY2019 Q4 Results	FY2019 Results	FY2019 YoY	FY2019 YoY (%)	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 Results
Japan	**139.0**	**122.0**	**161.3**	**111.2**	**533.5**	**10.2**	**+1.9%**	**130.2**				**130.2**
Nexium	21.9	18.3	22.1	17.4	79.8	1.5	+1.9%	19.9				19.9
Lixiana	21.6	20.2	23.8	17.4	83.0	18.1	+27.8%	19.8				19.8
Pralia	8.2	7.3	8.8	6.7	30.9	3.6	+13.0%	8.7				8.7
Memary	13.7	11.9	14.5	10.3	50.5	0.3	+0.6%	12.8				12.8
Tenelia	6.9	5.9	6.9	5.0	24.7	-0.6	-2.4%	6.6				6.6
Loxonin	7.8	7.0	7.9	5.5	28.3	-2.2	-7.3%	6.2				6.2
Ranmark	4.7	4.5	4.8	3.9	17.9	1.5	+9.1%	5.0				5.0
Inavir	0.0	1.0	10.5	7.7	19.3	1.1	+5.9%	0.6				0.6
Tarlige	2.0	1.3	2.1	2.6	8.0	8.0	-	4.3				4.3
Canalia	3.2	2.9	3.7	3.0	12.8	3.6	+38.8%	3.9				3.9
Vimpat	2.7	2.6	3.3	2.7	11.2	4.6	+70.0%	3.8				3.8
Efient	3.8	3.2	4.0	2.9	14.0	0.1	+0.7%	3.8				3.8
Rezaltas	4.2	3.4	4.1	3.0	14.6	-0.9	-5.8%	3.6				3.6
Olmetec	3.5	2.7	3.2	2.2	11.7	-3.2	-21.5%	2.7				2.7
Enhertu	-	-	-	-	-	-	-	0.2				0.2
Daiichi Sankyo Espha products	17.3	14.1	16.5	12.6	60.5	5.0	+8.9%	17.6				17.6
Vaccines business	7.5	8.4	16.9	2.8	35.6	-5.9	-14.2%	2.9				2.9
Daiichi Sankyo Healthcare (OTC)	**15.4**	**18.7**	**18.8**	**15.6**	**68.5**	**2.1**	**+3.2%**	**14.3**				**14.3**

3. Revenue by Business Units and Products (2)

JPY Bn	FY2019 Q1 Results	FY2019 Q2 Results	FY2019 Q3 Results	FY2019 Q4 Results	FY2019 Results	FY2019 YoY	FY2019 YoY (%)	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 Results
Daiichi Sankyo, Inc. (US)	**7.8**	**7.1**	**8.9**	**8.3**	**32.1**	**-4.2**	**-11.5%**	**11.6**				**11.6**
Enhertu	-	-	0.0	3.2	3.2	3.2	-	5.0				5.0
Olmesartan	3.1	2.4	2.2	2.1	9.8	-0.9	-8.4%	3.7				3.7
Welchol	2.6	2.2	3.8	0.5	9.1	-4.3	-31.9%	0.6				0.6
Effient	0.1	0.3	0.0	0.1	0.5	-2.0	-81.4%	-0.0				-0.0
Savaysa	0.6	0.6	0.8	0.7	2.6	0.3	+13.8%	0.6				0.6
American Regent, Inc. (US)	**36.0**	**32.4**	**31.4**	**31.0**	**130.8**	**13.0**	**+11.0%**	**26.5**				**26.5**
Injectafer	13.7	12.3	13.3	12.5	51.8	7.6	+17.2%	9.4				9.4
Venofer	9.3	7.1	6.9	7.7	31.0	2.1	+7.1%	6.9				6.9
Daiichi Sankyo Europe GmbH	**22.1**	**21.1**	**24.5**	**27.8**	**95.5**	**6.9**	**+7.8%**	**27.7**				**27.7**
Lixiana	13.5	14.0	16.4	17.8	61.7	15.9	+34.7%	16.4				16.4
Olmesartan	6.4	4.8	5.8	7.7	24.6	-2.8	-10.2%	5.2				5.2
Efient	0.8	0.6	0.6	0.6	2.5	-3.2	-55.8%	0.3				0.3
Asia, South and Central America (ASCA)	**24.3**	**24.6**	**24.6**	**24.8**	**98.3**	**10.7**	**+12.2%**	**22.5**				**22.5**
Daiichi Sankyo China	12.0	12.0	10.9	11.1	46.0	7.6	+19.6%	8.6				8.6
Daiichi Sankyo Taiwan	1.9	1.8	1.9	2.1	7.6	0.5	+6.7%	2.1				2.1
Daiichi Sankyo Korea	4.0	4.3	4.2	4.7	17.2	1.5	+9.5%	4.4				4.4
Daiichi Sankyo Thailand	0.8	0.8	0.9	0.8	3.3	0.1	+2.4%	0.6				0.6
Daiichi Sankyo Brasil Farmacêutica	2.8	2.9	3.4	2.5	11.5	1.5	+14.6%	2.9				2.9

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	YoY	YoY (%)	Results	Results	Results	Results	Results
USD Mn												
Daiichi Sankyo, Inc. (US)	**71**	**66**	**82**	**76**	**295**	**-32**	**-9.7%**	**107**				**107**
Enhertu	-	-	0	30	30	30	-	46				46
Olmesartan	28	23	21	19	91	-6	-6.5%	35				35
Welchol	23	21	35	5	84	-37	-30.5%	5				5
Effient	1	2	0	1	4	-18	-81.1%	-0				-0
Savaysa	5	5	7	7	24	3	+16.1%	5				5
USD Mn												
American Regent, Inc. (US)	**327**	**302**	**289**	**286**	**1,204**	**142**	**+13.3%**	**246**				**246**
Injectafer	125	114	123	115	477	78	+19.7%	88				88
Venofer	85	66	64	70	285	24	+9.3%	64				64
EUR Mn												
Daiichi Sankyo Europe GmbH	**179**	**177**	**203**	**230**	**789**	**99**	**+14.4%**	**234**				**234**
Lixiana	109	117	136	147	509	153	+42.9%	139				139
Olmesartan	52	40	48	63	203	-10	-4.7%	44				44
Efient	6	5	5	5	21	-24	-53.1%	3				3

<10. 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)	**FY2015**	**FY2016**	**FY2017**	**FY2018**	**FY2019**
[Reference] Revenue in Local Currency	Results	Results	Results	Results	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

11. Major R&D Pipeline (Innovative Pharmaceuticals）

As of July 2020

◆ Explanation of Description

Generic name/project Code Number (mechanism of action)

Detail on its mechanism

Study name	Population	ample siz	Study Design	Evaluation Items	Region	Status
・Phase of the study ・Study Name (if applicable) ・CTG registration number ・JapicCTI 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; CR: complete remission, CRL: complete response letter, DOR: duration of response, DCR: disease control rate, EVS: event-free survival, FPD: first patient dosed, 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 (anti-HER2 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)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 (pivotal) DESTINY-Breast01 NCT03248492 JapicCTI-173693 AstraZeneca	HER2 positive, unresectable/ metastatic breast cancer previously treated with T-DM1	253	Randomized, open label ・ DS-8201	Primary endpoint: ORR Secondary endpoint: ORR, DOR, PFS, OS, etc.	JP/US/EU/ Asia	FPD: FY2017 Q2 TLR: FY2019 Q1 Jan 2020: launched (US) May 2020: launched (JP) Jun 2020: submission validated (EU)
Phase 3 DESTINY-Breast02 NCT03523585 JapicCTI-184017 AstraZeneca	HER2 positive, unresectable/ metastatic breast cancer previously treated with T-DM1	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	JP/US/EU/ Asia	FPD: FY2018 Q2 Data anticipated: FY2021 H2
Phase 3 DESTINY-Breast03 NCT03529110 JapicCTI-183976 AstraZeneca	HER2 positive, unresectable/ metastatic breast cancer previously treated with trastuzumab and taxane	500	Randomized, open label, active control ・ DS-8201 ・ T-DM1	Primary endpoint: PFS Secondary endpoint: OS, ORR, DOR, PFS	JP/US/EU/ Asia	FPD: FY2018 Q2 Data anticipated: FY2021 H1
Phase 3 DESTINY-Breast04 NCT03734029 JapicCTI-184223 AstraZeneca	HER2-low, unresectable/metastatic breast cancer	540	Randomized, open label, active control ・DS-8201 ・Physician's choice (capecitabine, eribulin, gemcitabine, paclitaxel or nab-paclitaxel)	Primary endpoint: PFS Secondary endpoint: PFS, OS, ORR, DOR	JP/US/EU/ Asia	FPD: FY2018 Q3 Data anticipated: FY2021 H2

Trastuzumab deruxtecan / DS-8201 (anti-HER2 ADC)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 (pivotal) DESTINY-Gastric01 NCT03329690 JapicCTI-173727 AstraZeneca	HER2-overexpressing, advanced gastric or gastroesophageal junction adenocarcinoma	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: FY2017 Q3 TLR: FY2019 Q4 Mar 2018: SAKIGAKE Designation (JP) Apr 2020: submitted (JP) May 2020: Breakthrough Therapy Designation (US) May 2020: Orphan Drug Designation (US)
Phase 2 DESTINY-Gastric02 NCT04014075 AstraZeneca	HER2 positive, gastric cancer that cannot be surgically removed or has spread	72	Open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: PFS, ORR, OS, DOR	US/EU	FPD: FY2019 Q3
Phase 1b/2 DESTINY-Gastric03 NCT04379596 AstraZeneca	Part 1 HER2-overexpressing, previously treated gastric or gastro-esophageal junction (GEJ) cancer Part 2 HER2-overexpressing patients who have not received prior treatment for metastatic disease	220	Randomized, open label Part 1 ・DS-8201 + fluorouracil ・DS-8201 + capecitabine ・DS-8201 + durvalumab ・DS-8201 + oxaliplatin＋fluorouracil or capecitabine ・DS-8201 + durvalumab + fluorouracil or capecitabine 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: ORR Secondary endpoint: ORR, safety, DOR, DCR, PFS, OS, PK	US/EU/ Asia	FPD: FY2020 Q1

Trastuzumab deruxtecan / DS-8201 (anti-HER2 ADC)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 DESTINY-CRC01 NCT03384940 JapicCTI-173808 AstraZeneca	HER2 expressing, advanced colorectal cancer	90	Non-randomized, open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: PFS, OS, DOR, DCR, ORR, PK	JP/US/EU	FPD: FY2017 Q4 TLR: Presented at ASCO2020
Phase 2 DESTINY-Lung01 NCT03505710 JapicCTI-183916 AstraZeneca	HER2 overexpressing or mutated, unresectable/metastatic NSCLC	170	Non-randomized, open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: ORR, DOR, PFS, OS	JP/US/EU	FPD: FY2018 Q1 Data anticipated: FY2021 H1 May 2020: Breakthrough Therapy Designation (US)
Phase 2 HUDSON NCT03334617 AstraZeneca	NSCLC progressed on PD-1/PD-L1 therapy	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: FY2020 Q1
Phase 1b/2 BEGONIA NCT03742102 AstraZeneca	Triple negative breast neoplasms	110	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, etc.	US/EU/ Asia	FPD: FY2020 Q1
Phase 2 prep DESTINY-PanTumor02 NCT04482309 AstraZeneca	HER2 expressing tumors	280	Non-randomized ・DS-8201	Primary endpoint: ORR Secondary endpoint: DOR、DCR、PFS、OS	US/Asia	FPD：FY2020 Q2 planned
Phase 1 NCT03523572 BMS	HER2 positive, progressive breast cancer, urothelial (bladder) cancer	99	Non-randomized, open label, combination with nivolumab ・DS-8201+ nivolumab	Primary endpoint: ORR, safety Secondary endpoint: DOR, DCR, PFS, OS, ORR	US/EU	FPD: FY2018 Q1
Phase 1 NCT04042701 Merck	HER2 positive/low advanced metastatic breast cancer and 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: FY2020 Q1

DS-1062 (anti-TROP2 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 NCT03401385 JapicCTI-173812 AstraZeneca	Unresectable advanced NSCLC Advanced/unresectable or metastatic triple negative breast cancer	350	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: FY2017 Q4

Patritumab deruxtecan / U3-1402 (anti-HER3 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	Metastatic 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: FY2016 Q3
Phase 1 NCT03260491 JapicCTI-194868	EGFR mutant 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/ Asia	FPD: FY2017 Q3

◆ 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 control ・Quizartinib ・Chemotherapy	Primary endpoint: OS Secondary endpoint: EFS	JP/US/EU/ Asia	FPD: FY2014 Q1 TLR: FY2017 Q3 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 1st line indication
Phase 3 QuANTUM-First NCT02668653 JapicCTI-173667	Acute myeloid leukemia (1st line therapy)	539	Randomized, placebo-controlled, double-blind ・Quizartinib + chemotherapy ・Placebo + chemotherapy	Primary endpoint: EFS Secondary endpoint: OS, etc.	JP/US/EU/ Asia	FPD: FY2017 Q2 Data anticipated: FY2022 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, placebo-controlled, double-blind ・Pexidartinib ・Placebo	Primary endpoint: ORR Secondary endpoint: safety, DOR, etc.	US/EU/ Asia	FPD: FY2015 Q1 TLR: FY2017 Q3 Aug 2019: launched (US) Jun 2020: received negative CHMP opinion (EU)
Phase 1 NCT02734433	Solid tumors	11	Open Label ・Pexidartinib	Primary endpoint: safety Secondary endpoint: PK, antitumor effect	Asia	FPD: FY2016 Q1 Data anticipated: FY2021 Q1

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-randomised, open label ・ DS-1647/G47Δ	Primary endpoint: 1-year survival rate Secondary endpoint: OS, PFS, tumor response	JP	TLR: FY2018 Q4 Submission planned: FY2020 H1 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.

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 (pivotal) JapicCTI-183914 Kite/Gilead	Relapsed/refractory B-cell lymphoma	10	Non-randomized, open label ・ Axicabtagene ciloleucel	Primary endpoint: ORR Secondary endpoints: safety, ORR, DOR, PFS, OS, PK	JP	FSD: FY2018 Q3 March 2020: submitted 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, etc.	JP	FSD: FY2019 Q3
Phase 1 NCT02732275 JapicCTI-163173	Non-Hodgkin's lymphomas	70	Open Label ・ DS-3201	Primary endpoint: safety, PK, antitumor effect Secondary endpoint: ORR, DCR, DOR, PFS, etc.	JP/US	FSD: FY2015 Q4 Apr 2019: SAKIGAKE Designation for peripheral T-cell lymphoma (JP)
Phase 1 NCT03110354	Acute myeloid leukemia, acute lymphoblastic leukemia	48	Open Label ・ DS-3201	Primary endpoint: safety Secondary endpoint: PK, antitumor effect	US	FSD: FY2016 Q4

◆ Alpha (Oncology Early-Stage Pipeline Products)

Milademetan / DS-3032 (MDM2 inhibitor)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT01877382	Solid tumors	108	Non-randomized, open label ・DS-3032	Primary endpoint: safety, antitumor effect Secondary endpoint: PK, PD	JP/US	FSD: FY2013 Q2 Data anticipated: FY2020 Q2 Feb 2017: Orphan Drug Designation for liposarcoma (US) Mar 2017: Orphan Drug Designation for soft tissue sarcoma (EU) JP study for this indication completed (JapicCTI-142693)
Phase 1 NCT02319369	Acute myeloid leukemia, myelodysplastic syndrome	200	Non-randomized, open label, combination with azacitidine ・DS-3032 + azacitidine	Primary endpoint: safety, antitumor effect Secondary endpoint :PK	US	FSD: FY2014 Q3
Phase 1 NCT03552029	Acute myeloid leukemia	156	Non-randomized, open label, combination with quizartinib ・DS-3032 + quizartinib	Primary endpoint: safety Secondary endpoint: PK, antitumor effect	JP/US	FSD: FY2018 Q2 JP study for this indication completed (NCT03671564/JapicCTI-184054)

DS-1001 (Mutant IDH1 inhibitor)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT03030066 JapicCTI-163479	Glioma	60	Open label ・DS-1001	Primary endpoint: safety Secondary endpoint: safety, PK, antitumor effect	JP	FSD: FY2016 Q4
Phase 2 prep NCT04458272 JapicCTI-205339	Glioma	25	Open label ・DS-1001	Primary endpoint: ORR, safety Secondary endpoint: TTR, DOR, PFS, OS, PK	JP	FSD: FY2020 Q2 planned

DS-1205 (AXL inhibitor)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT03599518 JapicCTI-184026	EGFR mutant NSCLC	63	Open label, combination with gefitinib ・DS-1205 + gefitinib	Primary endpoint: safety Secondary endpoints: PK, ORR, DOR, DCR, PFS, OS, etc.	JP	FSD: FY2018 Q3
Phase 1 NCT03255083	EGFR mutant NSCLC	21	Open label, combination with osimertinib ・DS-1205 + osimertinib	Primary endpoint: safety Secondary endpoints: PK, ORR, DOR, DCR, PFS, OS	Asia	FSD: FY2019 Q1

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	FSD: FY2018 Q4
Phase 1 NCT03297424	Advanced malignancies	166	Open label ・PLX2853	Primary endpoint: safety, PK, antitumor effect Secondary endpoint: ORR, DOR, PFS, OS	US	FSD: FY2017 Q2

DS-7300 (anti-B7-H3 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, etc.	JP/US	FSD: FY2019 Q3

DS-6157 (anti-GPR20 ADC)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT04276415 JapicCTI-205184	Advanced 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, etc.	JP/US	FSD: FY2020 Q1

◆ 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, placebo-controlled, double-blind ・Edoxaban ・Placebo	Primary endpoint: annual incidence rate of stroke and systemic embolic events Secondary endpoint: annual incidence rate of bleeding events	JP	FSD: FY2016 Q1 TLR: FY2020 Q1 Submission planned: FY2020 Q3

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, active-controlled, double-blind ・Prasugrel ・Clopidogrel	Primary endpoint: incidence rate of cerebro-cardiovascular events Secondary endpoint: incidence rate of bleeding events	JP	FSD: FY2018 Q3 TLR: FY2020 Q1 Submission planned: FY2020 Q4

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, placebo-controlled, double-blind ・Mirogabalin ・Placebo	Primary endpoint: average daily pain score Secondary endpoint: visual analogue scale, average daily sleep interference score	JP/Asia	FSD: FY2018 Q4 Data anticipated: FY2021 Submission planned: FY2021
Phase 3 NCT04094662	Diabetic peripheral neuropathic pain	360	Randomized, placebo-controlled, double-blind ・Mirogabalin ・Placebo	Primary endpoint: average daily pain score Secondary endpoint: visual analogue scale, average daily sleep interference score	China	FSD: FY2019 Q2

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, placebo-controlled, double-blind ・Esaxerenone ・Placebo	Primary endpoint: UACR remission rate Secondary endpoint: change rate in UACR and eGFR, etc.	JP	FSD: FY2017 Q2 TLR: FY2019 Q2

◆ Alpha (Specialty Medicines Early-Stage Pipeline Products)

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	FSD: FY2015 Q3 Data anticipated: FY2020 3Q 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	Primary endpoint: safety, motor function, respiratory function, cardiac function, quantitative muscle strength evaluation Secondary endpoint: 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, placebo-controlled study, double-blind	Primary endpoint: safety Secondary endpoint: PK	JP	FSD: FY2019 Q4

DS-2319 (Nafamostat inhalation)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Clinical trial prep	COVID-19				JP	Scheduled to start clinical trial from March 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, placebo-controlled, double-blind ・VN0107 ・Placebo	Primary endpoint: onset of influenza, safety Secondary endpoint: onset of influenza	JP	FSD: FY2016 Q2 TLR: FY2017 Q1 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	FSD: FY2019 Q4 Data anticipated: FY2020 Q4

DS-5670 (COVID-19 mRNA vaccines)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Clinical trial prep	Prevention of COVID-19					Scheduled to start clinical trial from March 2021

◆ Stage-up Projects (Major Changes from the FY2019 Q4 Financial Announcement in April 2020)

Generic Name/Project Code Number Mechanism of action	Target indication	Current stage	Note
Trastuzumab deruxtecan/DS-8201 Anti-HER2 ADC	HER2 positive, unresectable/ metastatic breast cancer previously treated with T-DM1	Submitted (EU)	DESTINY-Breast01
Trastuzumab deruxtecan/DS-8201 Anti-HER2 ADC	HER2-overexpressing, advanced gastric or gastroesophageal junction adenocarcinoma	Submitted (JP)	DESTINY-Gastric01
Trastuzumab deruxtecan/DS-8201 Anti-HER2 ADC	NSCLC progressed on PD-1/PD-L1 therapy	P2	HUDSON Umbrella study of durvalumab led by AstraZeneca
Trastuzumab deruxtecan/DS-8201 Anti-HER2 ADC	Triple negative breast neoplasms	P1b/2	BEGONIA Umbrella study of durvalumab led by AstraZeneca
Trastuzumab deruxtecan/DS-8201 Anti-HER2 ADC	Part 1 HER2-overexpressing, previously treated gastric or gastro-esophageal junction (GEJ) cancer Part 2 HER2-overexpressing patients who have not received prior treatment for metastatic disease	P1b/2	DESTINY-Gastric03
Trastuzumab deruxtecan/DS-8201 Anti-HER2 ADC	HER2 positive/low advanced metastatic breast cancer and HER2 expressing/mutated NSCLC	P1b	Combination with pembrolizumab
DS-1001 Mutant IDH1 inhibitor	Glioma	P2 prep	
DS-6157 Anti-GPR20 ADC	Advanced gastrointestinal stromal tumors	P1	
DS-5141 ENA-oligonucleotides	Duchenne muscular dystrophy	P2	Long-term study of on-going phase 1/2 study