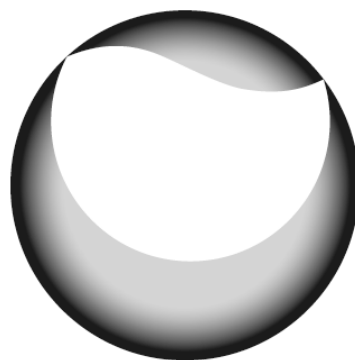


Reference Data

(Consolidated Financial Results for Q4 FY2019)



Daiichi-Sankyo

April 27, 2020

Daiichi Sankyo Co., Ltd.

<https://www.daiichisankyo.com>

Contents

1.	Consolidated Statement of Profit or Loss	P1
2.	Revenue of Global Products	P2
3.	Revenue by Business Units and Products	P3
4.	Consolidated Statement of Financial Position	P6
5.	Consolidated Statement of Cash Flows	P8
6.	Number of Employees	P9
7.	Capital Expenditure, Depreciation and Amortization	P9
8.	Other Financial Indicators	P9
9.	Summary of Product Outlines	P10
10.	Quarterly Data	P11
11.	Historical Data	P16
12.	Major R&D Pipeline (Innovative pharmaceuticals)	P20

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2018		FY2019					FY2020			
	to revenue	Results	to revenue	Results	(vs. Forecast (%))	YoY	YoY (%)	to revenue	Forecast	YoY	YoY (%)
Revenue	100.0%	929.7	100.0%	981.8	(101.2%)	52.1	+5.6%	100.0%	970.0	-11.8	-1.2%
Cost of sales	39.2%	364.6	35.0%	343.2	(102.4%)	-21.4	-5.9%	34.7%	337.0	-6.2	-1.8%
(excl. Special items)	37.6%	349.5	36.1%	354.4		4.9	+1.4%				
(Special items)	1.6%	15.1	-1.1%	-11.2		-26.3	-				
Gross Profit	60.8%	565.1	65.0%	638.6	(100.6%)	73.5	+13.0%	65.3%	633.0	-5.6	-0.9%
SG&A expenses	29.9%	277.7	30.8%	302.3	(104.2%)	24.6	+8.9%	33.5%	325.0	22.7	+7.5%
(excl. Special items)	30.2%	281.2	31.0%	304.8		23.6	+8.4%				
(Special items)	-0.4%	-3.5	-0.2%	-2.4		1.0	-				
R&D expenses	21.9%	203.7	20.1%	197.5	(94.0%)	-6.2	-3.1%	23.5%	228.0	30.5	+15.5%
(excl. Special items)	21.9%	203.7	20.1%	197.5		-6.2	-3.1%				
(Special items)	-	-	-	-		-	-				
Operating Profit	9.0%	83.7	14.1%	138.8	(102.8%)	55.1	+65.8%	8.2%	80.0	-58.8	-42.4%
(Operating Profit before Special items)	10.3%	95.3	12.7%	125.1		29.8	+31.3%				
Financial income/expenses		2.2		2.0		-0.2					
Share of profit or loss of investments accounted for using the equity method		-0.1		0.3		0.4					
Profit before tax	9.2%	85.8	14.4%	141.2	(104.6%)	55.3	+64.5%	8.2%	80.0	-61.2	-43.3%
Income taxes		-7.6		12.2		19.8	-				
Profit for the year	10.0%	93.4	13.1%	129.0	(117.2%)	35.5	+38.0%	5.8%	56.0	-73.0	-56.6%
Profit attributable to owners of the Company	10.0%	93.4	13.1%	129.1	(117.3%)	35.7	+38.2%	5.8%	56.0	-73.1	-56.6%
Tax rate		-8.8%		8.6%							
Overseas sales ratio		35.9%		38.1%							
Currency Rate (Average)											
USD/JPY		110.91		108.75					110.00		
EUR/JPY		128.40		120.83					120.00		

Forex impact: -15.1
(USD: -3.5, EUR: -6.0, ASCA: -5.6)

Forex impact: -3.3
(USD: -1.5, EUR: -0.7, ASCA: -1.2)

Forex impact: -5.9
(USD: -1.4, EUR: -2.5, ASCA: -2.0)

Forex impact: -2.5
(USD: -1.6, EUR: -0.8, ASCA: -0.2)

Forex impact: -3.4
(USD: +1.0, EUR: -2.1, ASCA: -2.3)

FY2018:
Increase in DTA due to trastuzumab deruxtecan strategic collaboration
FY2019:
Increase in DTA due to introduction of consolidated taxation system

Special items	FY2018		FY2019	
Cost of Sales	Impairment loss (Intangible)	15.1	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	-3.5	Gain on sales of fixed assets	-10.6
			Environmental expenditures	8.2
Total		11.6		-13.7

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		FY2018	FY2019				FY2020		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
	Trastuzumab Deruxtecan anti-cancer agent (anti-HER2 antibody drug conjugate)	0.1	14.0	(109.9%)	13.9	-	39.2	25.3	+181.0%
	Product sales	-	3.2	(161.6%)	3.2	-	28.5	25.3	+781.9%
	Enhertu (JPN)	-	-	-	-	-	1.5	1.5	-
	Enhertu (US)	-	3.2	(161.6%)	3.2	-	27.0	23.8	+735.5%
	Upfront payment	0.1	9.8	(100.0%)	9.7	-	9.8	-	-
	Regulatory milestone payment	-	0.9	(100.0%)	0.9	-	0.9	-	-
	Edoxaban anticoagulant	117.7	154.0	(102.0%)	36.3	+30.9%	163.0	9.0	+5.8%
	Lixiana (JPN)	64.9	83.0	(103.7%)	18.1	+27.8%	75.0	-8.0	-9.6%
	Savaysa (US)	2.3	2.6	(130.6%)	0.3	+13.8%	2.0	-0.6	-23.4%
	Lixiana (EU)	45.8	61.7	(99.5%)	15.9	+34.7%	76.0	14.3	+23.2%
	Other subsidiaries	4.7	6.8	(96.5%)	2.1	+44.2%	10.0	3.2	+48.0%
	Olmesartan antihypertensive agent	105.9	100.8	(101.8%)	-5.1	-4.8%	78.0	-22.8	-22.6%
	Olmetec (JPN)	14.9	11.7	(106.0%)	-3.2	-21.5%	8.0	-3.7	-31.4%
	Rezaltas (JPN)	15.5	14.6	(104.2%)	-0.9	-5.8%	12.0	-2.6	-17.8%
	Olmesartan (US)	10.7	9.8	(109.4%)	-0.9	-8.4%	7.0	-2.8	-28.9%
	Olmesartan (EU)	27.4	24.6	(107.0%)	-2.8	-10.2%	17.0	-7.6	-30.9%
	Other subsidiaries, export, etc	37.4	40.1	(95.5%)	2.7	+7.2%	34.0	-6.1	-15.3%
	Prasugrel antiplatelet agent	23.2	18.1	-	-5.1	-21.9%	not disclosed	-	-
	Effient alliance revenue (US)	2.4	0.5	-	-2.0	-81.4%	not disclosed	-	-
	Efient (EU)	5.7	2.5	(126.2%)	-3.2	-55.8%	1.0	-1.5	-60.4%
	Efient (JPN)	13.9	14.0	(100.0%)	0.1	+0.7%	14.0	0.0	+0.0%
	Other subsidiaries, export, etc	1.2	1.2	-	-0.0	-0.2%	not disclosed	-	-

3. Revenue by Business Units and Products (1)

JPY Bn		FY2018	FY2019				FY2020		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Japan		523.3	533.5	(101.0%)	10.2	+1.9%	483.0	-50.5	-9.5%
	Lixiana	64.9	83.0	(103.7%)	18.1	+27.8%	75.0	-8.0	-9.6%
	Nexium	78.3	79.8	(101.0%)	1.5	+1.9%	78.0	-1.8	-2.2%
	Memary	50.2	50.5	(101.0%)	0.3	+0.6%	24.0	-26.5	-52.5%
	Pralia	27.4	30.9	(99.8%)	3.6	+13.0%	33.0	2.1	+6.6%
	Tenelia	25.3	24.7	(98.9%)	-0.6	-2.4%	24.0	-0.7	-2.9%
	Loxonin	30.5	28.3	(104.6%)	-2.2	-7.3%	22.0	-6.3	-22.1%
	Inavir	18.2	19.3	(91.8%)	1.1	+5.9%	18.0	-1.3	-6.6%
	Ranmark	16.4	17.9	(99.4%)	1.5	+9.1%	18.0	0.1	+0.6%
	Efient	13.9	14.0	(100.0%)	0.1	+0.7%	14.0	0.0	+0.0%
	Rezaltas	15.5	14.6	(104.2%)	-0.9	-5.8%	12.0	-2.6	-17.8%
	Canalia	9.2	12.8	(98.6%)	3.6	+38.8%	15.0	2.2	+17.0%
	Vimpat	6.6	11.2	(101.5%)	4.6	+70.0%	14.0	2.8	+25.4%
	Omnipaque	12.0	10.3	(102.9%)	-1.7	-13.9%	7.0	-3.3	-32.0%
	Olmotec	14.9	11.7	(106.0%)	-3.2	-21.5%	8.0	-3.7	-31.4%
	Tarlige	-	8.0	-	8.0	-	16.0	8.0	+100.4%
	Enhertu	-	-	-	-	-	1.5	1.5	-
	Daiichi Sankyo Espha products	55.5	60.5	-	5.0	+8.9%	not disclosed	-	-
	Vaccines business	41.5	35.6	-	-5.9	-14.2%	not disclosed	-	-
Daiichi Sankyo Healthcare (OTC)		66.4	68.5	(97.8%)	2.1	+3.2%	74.0	5.5	+8.1%

3. Revenue by Business Units and Products (2)

JPY Bn		FY2018	FY2019				FY2020		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Daiichi Sankyo, Inc. (US)		36.3	32.1	(107.0%)	-4.2	-11.5%	48.0	15.9	+49.5%
	Enhertu anti-cancer agent (anti-HER2 antibody drug conjugate)	-	3.2	(161.6%)	3.2	-	27.0	23.8	+735.5%
	Olmesartan antihypertensive agent	10.7	9.8	(109.4%)	-0.9	-8.4%	7.0	-2.8	-28.9%
	Welchol hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	13.4	9.1	(101.2%)	-4.3	-31.9%	3.0	-6.1	-67.1%
	Effient antiplatelet agent	2.4	0.5	-	-2.0	-81.4%	not disclosed	-	-
	Savaysa anticoagulant	2.3	2.6	(130.6%)	0.3	+13.8%	2.0	-0.6	-23.4%
	Movantik opioid-induced constipation treatment	4.2	3.6	-	-0.6	-14.9%	not disclosed	-	-
American Regent, Inc. (US)		117.8	130.8	(102.2%)	13.0	+11.0%	135.0	4.2	+3.2%
	Injectafer treatment for iron deficiency anemia	44.2	51.8	(99.7%)	7.6	+17.2%	56.0	4.2	+8.1%
	Venofer treatment for iron deficiency anemia	28.9	31.0	(106.9%)	2.1	+7.1%	29.0	-2.0	-6.4%
Daiichi Sankyo Europe GmbH		88.6	95.5	(101.6%)	6.9	+7.8%	102.0	6.5	+6.8%
	Lixiana anticoagulant	45.8	61.7	(99.5%)	15.9	+34.7%	76.0	14.3	+23.2%
	Olmesartan antihypertensive agent	27.4	24.6	(107.0%)	-2.8	-10.2%	17.0	-7.6	-30.9%
	Efient antiplatelet agent	5.7	2.5	(126.2%)	-3.2	-55.8%	1.0	-1.5	-60.4%
Asia, South and Central America (ASCA)		87.7	98.3	(98.3%)	10.7	+12.2%	103.0	4.7	+4.8%
	Daiichi Sankyo China	38.5	46.0	-	7.6	+19.6%	not disclosed	-	-
	Daiichi Sankyo Taiwan	7.1	7.6	-	0.5	+6.7%	not disclosed	-	-
	Daiichi Sankyo Korea	15.7	17.2	-	1.5	+9.5%	not disclosed	-	-
	Daiichi Sankyo Thailand	3.3	3.3	-	0.1	+2.4%	not disclosed	-	-
	Daiichi Sankyo Brasil Farmacêutica	10.0	11.5	-	1.5	+14.6%	not disclosed	-	-

3. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

		FY2018	FY2019				FY2020		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
USD Mn									
Daiichi Sankyo, Inc. (US)		327	295	(107.3%)	-32	-9.7%	436	141	+47.7%
Enhertu	anti-cancer agent (anti-HER2 antibody drug conjugate)	-	30	(162.1%)	30	-	245	216	+725.4%
Olmesartan	antihypertensive agent	97	91	(109.8%)	-6	-6.5%	64	-27	-29.8%
Welchol	hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	121	84	(101.6%)	-37	-30.5%	27	-57	-67.5%
Effient	antiplatelet agent	22	4	-	-18	-81.1%	not disclosed	-	-
Savaysa	anticoagulant	21	24	(131.0%)	3	+16.1%	18	-6	-24.3%
Movantik	opioid-induced constipation treatment	38	33	-	-5	-13.2%	not disclosed	-	-
USD Mn									
American Regent, Inc. (US)		1,062	1,204	(102.5%)	142	+13.3%	1,227	24	+2.0%
Injectafer	treatment for iron deficiency anemia	399	477	(100.0%)	78	+19.7%	509	32	+6.7%
Venofer	treatment for iron deficiency anemia	261	285	(107.2%)	24	+9.3%	264	-22	-7.6%
EUR Mn									
Daiichi Sankyo Europe GmbH		690	789	(103.5%)	99	+14.4%	850	61	+7.7%
Lixiana	anticoagulant	357	509	(101.3%)	153	+42.9%	633	124	+24.3%
Olmesartan	antihypertensive agent	213	203	(109.0%)	-10	-4.7%	142	-62	-30.3%
Efient	antiplatelet agent	44	21	(128.5%)	-24	-53.1%	8	-13	-60.0%

4. Consolidated Statement of Financial Position

<Assets>		JPY Bn		
	Mar. 2019	Mar. 2020	vs. Mar. 2019	
Assets				
Current assets				
Cash and cash equivalents	243.2	424.2	181.0	
Trade and other receivables	419.6	309.4	-110.2	- Receivable for trastuzumab deruxtecan strategic collaboration upfront payment -75.9 - Insurance credit for olmesartan litigation settlement -39.2
Other financial assets	536.9	466.5	-70.4	
Inventories	176.1	173.4	-2.7	
Other current assets	15.5	10.5	-4.9	
Subtotal	1,391.2	1,384.0	-7.2	
Assets held for sale	2.0	0.1	-1.9	Mar. 2019: Nihonbashi building 2.0
Total current assets	1,393.2	1,384.1	-9.1	
Non-current assets				
Property, plant and equipment	229.1	247.1	18.0	- Acquisition +38.1, Depreciation -31.8 - Daiichi Sankyo Propharma Takatsuki Plant -12.3 - Increase in lease assets due to lease accounting standard change +30.1
Goodwill	77.9	76.8	-1.1	
Intangible assets	169.5	172.5	3.0	Acquisition +32.3, Amortization -20.6, Impairment loss -6.3, Forex impact -2.3
Investments accounted for using the equity method	2.2	0.4	-1.8	
Other financial assets	114.9	98.0	-16.9	
Deferred tax assets	94.8	114.7	19.9	Increase in deferred tax assets due to introduction of consolidated taxation system +13.1
Other non-current assets	6.6	12.1	5.5	
Total non-current assets	694.9	721.5	26.6	
Total assets	2,088.1	2,105.6	17.6	
* Liquidity on hand	779.5	891.2	111.7	
Debt with interest	261.9	266.3	4.4	
Net Cash	517.6	624.9	107.3	

<Liabilities and equity>

JPY Bn

	Mar. 2019	Mar. 2020	vs. Mar. 2019
Liabilities			
Current liabilities			
Trade and other payables	312.7	270.9	-41.8
Bonds and borrowings	40.0	40.4	0.4
Other financial liabilities	0.5	9.5	9.0
Income taxes payable	10.5	9.9	-0.5
Provisions	7.8	5.4	-2.5
Other current liabilities	12.7	15.0	2.3
Subtotal	384.2	351.1	-33.1
Liabilities directly associated with assets held for sale	0.3	-	-0.3
Total current liabilities	384.5	351.1	-33.5
Non-current liabilities			
Bonds and borrowings	220.6	183.8	-36.8
Other financial liabilities	5.7	37.1	31.4
Post employment benefit liabilities	10.4	5.3	-5.1
Provisions	5.0	10.6	5.6
Deferred tax liabilities	17.2	15.6	-1.5
Other non-current liabilities	195.0	195.8	0.8
Total non-current liabilities	453.8	448.3	-5.5
Total liabilities	838.3	799.3	-39.0
Equity			
Equity attributable to owners of the Company			
Share capital	50.0	50.0	-
Capital surplus	94.6	94.6	-
Treasury shares	-163.0	-162.5	0.4
Other components of equity	115.2	82.1	-33.1
Retained earnings	1,152.8	1,241.6	88.8
Total equity attributable to owners of the Company	1,249.6	1,305.8	56.2
Non-controlling interests			
Non-controlling interests	0.1	0.5	0.4
Total equity	1,249.7	1,306.3	56.6
Total liabilities and equity	2,088.1	2,105.6	17.6

Accounts payable for olmesartan litigation settlement -39.7

3rd Unsecured Corporate Bond +20.0, Syndicated loan +20.0
(Transfer from Non-current liabilities "Bonds and borrowings")
Redemption of 2nd Unsecured Corporate Bond -40.03rd Unsecured Corporate Bond -20.0, Syndicated loan -20.0
(Transfer to Current liabilities "Bonds and borrowings")

Lease liabilities +31.7

Deferred revenue for trastuzumab deruxtecan +2.1
(Regulatory milestone payment +11.9, Strategic collaboration upfront payment -9.8)

Profit for the period +129.1, Payment of dividends -45.4

5. Consolidated Statement of Cash Flows

JPY Bn

	FY2018	FY2019	YoY
Cash flows from operating activities			
Profit before tax	85.8	141.2	55.3
Depreciation and amortization	46.2	52.6	6.4
(Increase) decrease in receivables and payables	-127.4	65.4	192.8
Others, net	123.6	-36.4	-160.0
Income taxes paid	-36.1	-26.2	10.0
Net cash flows from operating activities	92.0	196.6	104.6
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	-103.1	67.7	170.9
(Acquisition of) proceeds from sales of fixed assets	-64.7	-52.4	12.3
Proceeds from sale of subsidiary	0.8	37.1	36.4
Net (increase) decrease in investment securities	16.4	14.7	-1.7
Others, net	8.1	14.5	6.3
Net cash flows from investing activities	-142.5	81.7	224.2
Cash flows from financing activities			
Net (increase) decrease in borrowings	-20.0	3.6	23.6
Repayments of bonds	-	-40.0	-40.0
Purchase of treasury shares	-0.0	-0.1	-0.0
Dividends paid	-45.3	-45.4	-0.0
Others, net	-0.8	-9.8	-9.0
Net cash flows from financing activities	-66.2	-91.6	-25.4
Net increase (decrease) in cash and cash equivalents	-116.7	186.6	303.3
Cash and cash equivalents at the beginning of the period	357.7	243.2	-114.5
Effect of exchange rate changes on cash and cash equivalents	2.1	-5.6	-7.8
Cash and cash equivalents at the end of the period	243.2	424.2	181.0
* Free cash flows (Cash flows from operating activities and investing activities)	-50.5	278.3	328.8

6. Number of Employees

	Mar. 2019	Mar. 2020
	Results	Results
Consolidated	14,887	15,348
Japan	8,865	8,754
North America	2,172	2,380
Europe	1,778	1,953
Others	2,072	2,261

7. Capital Expenditure, Depreciation and Amortization

		FY2018	FY2019	FY2020
	JPY Bn	Results	Results	Forecast
Capital expenditure		38.3	29.0	50.0
Depreciation and amortization		46.2	52.6	50.0
Property, plant and equipment		26.0	32.0	-
Intangible assets		20.2	20.6	-

8. Other Financial Indicators

		FY2018	FY2019
		Results	Results
Profit attributable to owners of the Company	93.4 JPY Bn	129.1 JPY Bn	
Dividends	45.3 JPY Bn	45.4 JPY Bn	
Purchase of treasury shares	- JPY Bn	- JPY Bn	
Total return ratio	48.5 %	35.1 %	
Average equity attributable to owners of the Company for the period	1,191.3 JPY Bn	1,277.7 JPY Bn	
Return on Equity	7.8 %	10.1 %	

9. Summary of Product Outlines

Brand Name	Generic Name	Therapeutic Category	Launched	Origin	Marketing Alliance	Type of Alliance
Japan						
Lixiana	edoxaban	anticoagulant	2011	Daiichi Sankyo		
Nexium	esomeprazole	ulcer treatment	2011	AstraZeneca	AstraZeneca	Co-promotion (DS: Sales)
Memary	memantine	Alzheimer's disease treatment	2011	Merz		
Pralia	denosumab	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	2013	Amgen		
Tenelia	teneligliptin	type 2 diabetes mellitus treatment	2012	Mitsubishi Tanabe	Mitsubishi Tanabe	Co-promotion (DS: Sales)
Loxonin			1986	Daiichi Sankyo		
Loxonin Poullice			2006	Lead Chemical		
Loxonin Tape	loxoprofen	anti-inflammatory analgesic	2008	Lead Chemical		
Loxonin Gel			2010	Daiichi Sankyo		
Inavir	laninamivir	anti-influenza agent	2010	Daiichi Sankyo		
Ranmark	denosumab	treatment for bone complications caused by bone metastases from tumors	2012	Amgen		
Efient	prasugrel	antiplatelet agent	2014	Daiichi Sankyo Ube Industries		
Rezaltas	olmesartan / azelnidipine	antihypertensive agent	2010	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)
Omnipaque	iohexol	contrast agent	1987	GE Healthcare		
Olmetec	olmesartan	antihypertensive agent	2004	Daiichi Sankyo		
Tarlige	mirogabalin	pain treatment	2019	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		2002			
Benicar HCT	olmesartan / hydrochlorothiazide		2003			
Azor	olmesartan / amlodipine	antihypertensive agent	2007	Daiichi Sankyo		
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		
Movantik	naloxegol	opioid-induced constipation treatment	2015	Nektar AstraZeneca	AstraZeneca	Co-promotion (DS: Co-pro revenue)
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		2002			
Olmetec Plus	olmesartan / hydrochlorothiazide		2005			
Sevikar	olmesartan / amlodipine	antihypertensive agent	2009	Daiichi Sankyo	Menarini Pfizer	Co-marketing
Sevikar HCT	olmesartan / amlodipine / hydrochlorothiazide		2010			
Efient	prasugrel	antiplatelet agent	2009	Daiichi Sankyo Ube Industries		

<10. Quarterly Data>

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2018	FY2018	FY2018	FY2018	FY2018		FY2019	FY2019	FY2019	FY2019	FY2019			
	Q1	Q2	Q3	Q4	to revenue	Results	Q1	Q2	Q3	Q4	to revenue	Results	YoY	YoY (%)
	Results	Results	Results	Results			Results	Results	Results	Results				
Revenue	225.7	221.1	256.2	226.6	100.0%	929.7	249.2	230.3	277.5	224.8	100.0%	981.8	52.1	+5.6%
Cost of sales	84.7	81.9	98.3	99.7	39.2%	364.6	87.9	89.2	79.2	86.9	35.0%	343.2	-21.4	-5.9%
(excl. Special items)	84.7	81.9	98.3	84.6	37.6%	349.5	86.6	85.4	98.0	84.5	36.1%	354.4	4.9	+1.4%
(Special items)	-	-	-	15.1	1.6%	15.1	1.3	3.8	-18.8	2.4	-1.1%	-11.2	-26.3	-
Gross Profit	141.0	139.2	158.0	126.9	60.8%	565.1	161.3	141.1	198.3	137.8	65.0%	638.6	73.5	+13.0%
SG&A expenses	65.6	63.0	70.0	79.2	29.9%	277.7	63.2	67.3	77.8	94.1	30.8%	302.3	24.6	+8.9%
(excl. Special items)	65.6	66.4	70.0	79.2	30.2%	281.2	73.8	67.3	77.8	85.9	31.0%	304.8	23.6	+8.4%
(Special items)	-	-3.5	-	-	-0.4%	-3.5	-10.6	-	-	8.2	-0.2%	-2.4	1.0	-
R&D expenses	45.5	48.2	48.9	61.1	21.9%	203.7	41.2	44.7	51.1	60.5	20.1%	197.5	-6.2	-3.1%
(excl. Special items)	45.5	48.2	48.9	61.1	21.9%	203.7	41.2	44.7	51.1	60.5	20.1%	197.5	-6.2	-3.1%
(Special items)	-	-	-	-	-	-	-	-	-	-	-	-	0.0	-
Operating Profit	29.9	28.1	39.1	-13.4	9.0%	83.7	57.0	29.2	69.4	-16.8	14.1%	138.8	55.1	+65.8%
(Operating Profit before Special items)	29.9	24.6	39.1	1.7	10.3%	95.3	47.7	33.0	50.6	-6.1	12.7%	125.1	29.8	+31.3%
Financial income/expenses	-0.2	1.0	-0.3	1.7		2.2	0.1	0.8	3.5	-2.3		2.0	-0.2	
Share of profit or loss of investments accounted for using the equity method	-0.1	-0.0	0.5	-0.5		-0.1	0.0	0.0	0.0	0.2		0.3	0.4	
Profit before tax	29.6	29.0	39.3	-12.1	9.2%	85.8	57.1	30.0	72.9	-18.8	14.4%	141.2	55.3	+64.5%
Income taxes	5.7	8.9	4.5	-26.7		-7.6	13.7	8.9	3.1	-13.6		12.2	19.8	-
Profit for the year	24.0	20.1	34.8	14.6	10.0%	93.4	43.3	21.1	69.8	-5.2	13.1%	129.0	35.5	+38.0%
Profit attributable to owners of the Company	24.0	20.1	34.8	14.6	10.0%	93.4	43.3	21.1	69.9	-5.2	13.1%	129.1	35.7	+38.2%
Tax rate	19.2%	30.8%	11.5%	220.5%		-8.8%	24.1%	29.8%	4.3%	72.2%		8.6%		
Overseas sales ratio	36.5%	37.5%	33.4%	36.6%		35.9%	37.5%	38.4%	34.9%	42.5%		38.1%		
Currency Rate (YTD Average)														
USD/JPY	109.07	110.27	111.15	110.91		110.91	109.90	108.63	108.67	108.75		108.75		
EUR/JPY	130.06	129.84	129.49	128.40		128.40	123.49	121.41	121.05	120.83		120.83		

<10. Quarterly Data>

2. Revenue of Global Products

JPY Bn	FY2018 Q1	FY2018 Q2	FY2018 Q3	FY2018 Q4	FY2018	FY2019 Q1	FY2019 Q2	FY2019 Q3	FY2019 Q4	FY2019		
	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results	YoY	YoY (%)
Trastuzumab deruxtecan	-	-	-	0.1	0.1	2.5	2.5	3.2	5.9	14.0	13.9	-
Product sales	-	-	-	-	-	-	-	0.0	3.2	3.2	3.2	-
Enhertu (US)	-	-	-	-	-	-	-	0.0	3.2	3.2	3.2	-
Upfront payment	-	-	-	0.1	0.1	2.5	2.5	2.5	2.5	9.8	9.7	-
Regulatory milestone payment	-	-	-	-	-	-	-	0.7	0.2	0.9	0.9	-
Edoxaban	25.8	28.3	33.3	30.3	117.7	37.2	36.5	42.6	37.6	154.0	36.3	+30.9%
Lixiana (JPN)	14.7	15.4	19.1	15.7	64.9	21.6	20.2	23.8	17.4	83.0	18.1	+27.8%
Savaysa (US)	0.4	0.7	0.5	0.7	2.3	0.6	0.6	0.8	0.7	2.6	0.3	+13.8%
Lixiana (EU)	9.7	11.1	12.5	12.4	45.8	13.5	14.0	16.4	17.8	61.7	15.9	+34.7%
Other subsidiaries	1.0	1.2	1.0	1.5	4.7	1.6	1.7	1.7	1.7	6.8	2.1	+44.2%
Olmesartan	28.5	25.0	27.4	25.1	105.9	27.5	23.2	26.3	23.9	100.8	-5.1	-4.8%
Olmotec (JPN)	4.2	3.7	4.1	2.9	14.9	3.5	2.7	3.2	2.2	11.7	-3.2	-21.5%
Rezaltas (JPN)	4.1	3.7	4.4	3.3	15.5	4.2	3.4	4.1	3.0	14.6	-0.9	-5.8%
Olmesartan (US)	3.2	2.7	2.1	2.8	10.7	3.1	2.4	2.2	2.1	9.8	-0.9	-8.4%
Olmesartan (EU)	8.2	6.2	6.6	6.4	27.4	6.4	4.8	5.8	7.7	24.6	-2.8	-10.2%
Other subsidiaries, export, etc	9.0	8.7	10.2	9.6	37.4	10.3	9.9	11.0	8.9	40.1	2.7	+7.2%
Prasugrel	6.4	7.1	5.3	4.4	23.2	5.0	4.4	4.9	3.8	18.1	-5.1	-21.9%
Effient alliance revenue (US)	0.6	2.1	-0.3	-0.0	2.4	0.1	0.3	0.0	0.1	0.5	-2.0	-81.4%
Efient (EU)	1.9	1.4	1.3	1.1	5.7	0.8	0.6	0.6	0.6	2.5	-3.2	-55.8%
Efient (JPN)	3.6	3.4	3.9	3.0	13.9	3.8	3.2	4.0	2.9	14.0	0.1	+0.7%
Other subsidiaries, export, etc	0.3	0.3	0.3	0.3	1.2	0.3	0.3	0.3	0.2	1.2	-0.0	-0.2%

3. Revenue by Business Units and Products (1)	FY2018 Q1	FY2018 Q2	FY2018 Q3	FY2018 Q4	FY2018	FY2019 Q1	FY2019 Q2	FY2019 Q3	FY2019 Q4	FY2019		
	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results	YoY	YoY (%)
JPY Bn												
Japan	123.9	119.8	152.0	127.6	523.3	139.0	122.0	161.3	111.2	533.5	10.2	+1.9%
Lixiana	14.7	15.4	19.1	15.7	64.9	21.6	20.2	23.8	17.4	83.0	18.1	+27.8%
Nexium	19.8	18.8	22.4	17.3	78.3	21.9	18.3	22.1	17.4	79.8	1.5	+1.9%
Memary	12.9	12.3	14.3	10.7	50.2	13.7	11.9	14.5	10.3	50.5	0.3	+0.6%
Pralia	6.6	6.4	8.0	6.4	27.4	8.2	7.3	8.8	6.7	30.9	3.6	+13.0%
Tenelia	6.4	6.2	7.3	5.4	25.3	6.9	5.9	6.9	5.0	24.7	-0.6	-2.4%
Loxonin	7.9	7.7	8.7	6.2	30.5	7.8	7.0	7.9	5.5	28.3	-2.2	-7.3%
Inavir	0.1	-0.0	4.4	13.7	18.2	0.0	1.0	10.5	7.7	19.3	1.1	+5.9%
Ranmark	3.9	4.2	4.6	3.7	16.4	4.7	4.5	4.8	3.9	17.9	1.5	+9.1%
Efient	3.6	3.4	3.9	3.0	13.9	3.8	3.2	4.0	2.9	14.0	0.1	+0.7%
Rezaltas	4.1	3.7	4.4	3.3	15.5	4.2	3.4	4.1	3.0	14.6	-0.9	-5.8%
Canalia	2.0	2.1	2.8	2.4	9.2	3.2	2.9	3.7	3.0	12.8	3.6	+38.8%
Vimpat	1.4	1.4	2.0	1.8	6.6	2.7	2.6	3.3	2.7	11.2	4.6	+70.0%
Omnipaque	3.3	3.0	3.3	2.4	12.0	3.0	2.5	2.8	1.9	10.3	-1.7	-13.9%
Olmotec	4.2	3.7	4.1	2.9	14.9	3.5	2.7	3.2	2.2	11.7	-3.2	-21.5%
Tarlige	-	-	-	-	-	2.0	1.3	2.1	2.6	8.0	8.0	-
Daiichi Sankyo Espha products	13.7	12.8	15.9	13.1	55.5	17.3	14.1	16.5	12.6	60.5	5.0	+8.9%
Vaccines business	8.2	8.6	17.8	6.9	41.5	7.5	8.4	16.9	2.8	35.6	-5.9	-14.2%
Daiichi Sankyo Healthcare (OTC)	18.4	16.4	18.1	13.4	66.4	15.4	18.7	18.8	15.6	68.5	2.1	+3.2%

3. Revenue by Business Units and Products (2)	FY2018 Q1	FY2018 Q2	FY2018 Q3	FY2018 Q4	FY2018	FY2019 Q1	FY2019 Q2	FY2019 Q3	FY2019 Q4	FY2019		
	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results	YoY	YoY (%)
JPY Bn												
Daiichi Sankyo, Inc. (US)	11.0	11.0	6.6	7.7	36.3	7.8	7.1	8.9	8.3	32.1	-4.2	-11.5%
Enhertu	-	-	-	-	-	-	-	0.0	3.2	3.2	3.2	-
Olmesartan	3.2	2.7	2.1	2.8	10.7	3.1	2.4	2.2	2.1	9.8	-0.9	-8.4%
Welchol	4.9	3.8	2.3	2.4	13.4	2.6	2.2	3.8	0.5	9.1	-4.3	-31.9%
Effient	0.6	2.1	-0.3	-0.0	2.4	0.1	0.3	0.0	0.1	0.5	-2.0	-81.4%
Savaysa	0.4	0.7	0.5	0.7	2.3	0.6	0.6	0.8	0.7	2.6	0.3	+13.8%
Movantik	0.9	1.2	1.1	0.9	4.2	0.8	1.0	1.0	0.8	3.6	-0.6	-14.9%
American Regent, Inc. (US)	28.6	29.8	31.7	27.6	117.8	36.0	32.4	31.4	31.0	130.8	13.0	+11.0%
Injectafer	11.2	10.8	11.6	10.5	44.2	13.7	12.3	13.3	12.5	51.8	7.6	+17.2%
Venofer	8.2	8.3	7.6	4.8	28.9	9.3	7.1	6.9	7.7	31.0	2.1	+7.1%
Daiichi Sankyo Europe GmbH	22.2	20.9	23.0	22.6	88.6	22.1	21.1	24.5	27.8	95.5	6.9	+7.8%
Lixiana	9.7	11.1	12.5	12.4	45.8	13.5	14.0	16.4	17.8	61.7	15.9	+34.7%
Olmesartan	8.2	6.2	6.6	6.4	27.4	6.4	4.8	5.8	7.7	24.6	-2.8	-10.2%
Efient	1.9	1.4	1.3	1.1	5.7	0.8	0.6	0.6	0.6	2.5	-3.2	-55.8%
Asia, South and Central America (ASCA)	19.7	20.4	23.0	24.5	87.7	24.3	24.6	24.6	24.8	98.3	10.7	+12.2%
Daiichi Sankyo China	8.4	8.2	10.3	11.5	38.5	12.0	12.0	10.9	11.1	46.0	7.6	+19.6%
Daiichi Sankyo Taiwan	1.8	1.7	1.8	1.8	7.1	1.9	1.8	1.9	2.1	7.6	0.5	+6.7%
Daiichi Sankyo Korea	3.0	4.2	4.0	4.5	15.7	4.0	4.3	4.2	4.7	17.2	1.5	+9.5%
Daiichi Sankyo Thailand	0.8	0.8	0.8	0.8	3.3	0.8	0.8	0.9	0.8	3.3	0.1	+2.4%
Daiichi Sankyo Brasil Farmacêutica	2.4	2.5	2.9	2.2	10.0	2.8	2.9	3.4	2.5	11.5	1.5	+14.6%

3. Revenue by Business Units and Products (3) [Reference] Revenue in Local Currency	FY2018 Q1	FY2018 Q2	FY2018 Q3	FY2018 Q4	FY2018	FY2019 Q1	FY2019 Q2	FY2019 Q3	FY2019 Q4	FY2019		
	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results	YoY	YoY (%)
USD Mn												
Daiichi Sankyo, Inc. (US)	101	99	58	70	327	71	66	82	76	295	-32	-9.7%
Enhertu	-	-	-	-	-	-	-	0	30	30	30	-
Olmesartan	29	24	18	26	97	28	23	21	19	91	-6	-6.5%
Welchol	45	34	20	22	121	23	21	35	5	84	-37	-30.5%
Effient	6	19	-3	0	22	1	2	0	1	4	-18	-81.1%
Savaysa	4	6	5	6	21	5	5	7	7	24	3	+16.1%
Movantik	9	11	10	8	38	7	9	10	7	33	-5	-13.2%
USD Mn												
American Regent, Inc. (US)	263	267	281	251	1,062	327	302	289	286	1,204	142	+13.3%
Injectafer	103	97	103	96	399	125	114	123	115	477	78	+19.7%
Venofer	75	75	67	44	261	85	66	64	70	285	24	+9.3%
EUR Mn												
Daiichi Sankyo Europe GmbH	170	161	178	180	690	179	177	203	230	789	99	+14.4%
Lixiana	75	86	97	99	357	109	117	136	147	509	153	+42.9%
Olmesartan	63	48	51	51	213	52	40	48	63	203	-10	-4.7%
Efient	15	10	10	9	44	6	5	5	5	21	-24	-53.1%

<11. Historical Data>

1. Revenue of Global Products

	FY2015	FY2016	FY2017	FY2018	FY2019
JPY Bn	Results	Results	Results	Results	Results
Trastuzumab deruxtecan	-	-	-	0.1	14.0
Product sales	-	-	-	-	3.2
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
Effient (EU)	5.4	7.9	8.0	5.7	2.5
Effient (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)

	FY2015	FY2016	FY2017	FY2018	FY2019
JPY Bn	Results	Results	Results	Results	Results
Japan	494.7	506.6	540.0	523.3	533.5
Lixiana	13.0	25.0	45.3	64.9	83.0
Nexium	82.4	84.0	86.5	78.3	79.8
Memary	42.4	46.9	48.6	50.2	50.5
Pralia	12.5	18.0	23.2	27.4	30.9
Tenelia	16.5	24.2	26.3	25.3	24.7
Loxonin	48.1	37.4	36.5	30.5	28.3
Inavir	14.0	19.6	25.3	18.2	19.3
Ranmark	12.4	13.9	15.4	16.4	17.9
Efient	4.9	10.4	12.8	13.9	14.0
Rezaltas	18.2	17.5	16.8	15.5	14.6
Canalia	-	-	2.7	9.2	12.8
Vimpat	-	0.4	2.6	6.6	11.2
Omnipaque	16.9	14.2	14.0	12.0	10.3
Olmetec	73.9	69.4	44.6	14.9	11.7
Tarlige	-	-	-	-	8.0
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)

	FY2015	FY2016	FY2017	FY2018	FY2019
JPY Bn	Results	Results	Results	Results	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
Movantik	2.0	4.2	4.7	4.2	3.6
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	FY2016	FY2017	FY2018	FY2019
	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
Movantik	17	38	42	38	33
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)

◆ 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
<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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)	<ul style="list-style-type: none"> • 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

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 antibody drug conjugate)

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.

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 Submission planned: FY2020 Q1 (EU) Dec 2019: approved (US) Mar 2020: approved (JP)
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 Q4
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 Q4
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: FY2022 Q4
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 Submission planned: FY2020 Q1 (JP) Mar 2018: SAKIGAKE Designation (JP)

Trastuzumab deruxtecan / DS-8201 (anti-HER2 antibody drug conjugate)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
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 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 Data anticipated: FY2020 Q1
Phase 2 DESTINY-Lung01 NCT03505710 JapicCTI-183916 AstraZeneca	HER2 overexpressing or mutated, unresectable/metastatic non-small-cell lung cancer	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 Q2
Phase 2 prep HUDSON NCT03334617 AstraZeneca	Non-small-cell lung cancer 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 planned
Phase 1b/2 prep 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 planned
Phase 1 NCT03523572 BMS	HER2 expressing, 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

Trastuzumab deruxtecan / DS-8201 (anti-HER2 antibody drug conjugate)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 prep NCT04042701 Merck	HER2 positive/low advanced metastatic breast cancer and HER2 expressing/mutated non-small cell lung cancer	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 planned

DS-1062 (anti-TROP2 antibody drug conjugate)

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	Unresectable advanced NSCLC	160	Non-randomized, 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:FY2018 Q3

U3-1402 (anti-HER3 antibody drug conjugate)

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	Non-small cell lung cancer	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.

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 1 st line indication
Phase 3 QuANTUM-First NCT02668653 JapicCTI-173667	Acute myeloid leukemia (1 st 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.

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 Mar 2019: submitted (EU) Aug 2019: obtained approval and launched (US)
Phase 1 NCT02734433	Solid tumors	11	Open Label • Pexidartinib	Primary endpoint: safety Secondary endpoint: PK, antitumor effect	Asia	FPD:FY2016 Q1 Data anticipated: FY2020 Q2

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: Q4 FY2018 Submission planned: FY2020 H1 Feb 2016: SAKIGAKE Designation Jul 2017:Orphan Drug Designation

Axi-Cel[®] / Axicabtagene ciloleucel (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 Data anticipated: FY2025 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
Phase 1/2 NCT03879798 Memorial Sloan Kettering Cancer Center	Small cell lung cancer	61	Non-randomized, open label, combination with irinotecan • DS-3201 + irinotecan	Primary endpoint: safety, ORR Secondary endpoint: N/A	US	FSD:FY2018 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	US	FSD:FY2013 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	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

DS-1205 (AXL inhibitor)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT03599518 JapicCTI-184026	Non-small cell lung cancer	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	Non-small cell lung cancer	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 antibody drug conjugate)

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 antibody drug conjugate)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 prep 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 planned

◆ 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.

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 Data anticipated: FY2020 Q1 Submission planned: FY2020 Q3

Prasugrel/CS-747 (ADP receptor inhibitor)

Oral antiplatelet agents. Inhibits arterial stenosis and occlusion by inhibiting platelet aggregation.

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 Data anticipated: FY2020 Q2 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.

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.

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

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

◆ 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

◆ Stage-up Projects (Major Changes from the FY2019 Q3 Financial Announcement in January 2020)

Generic Name/Project Code Number	Target indication	Current stage	Note
Mechanism of action			
Trastuzumab deruxtecan/DS-8201 Anti-HER2 antibody drug conjugate	Non-small-cell lung cancer progressed on PD-1/PD-L1 therapy	P2 prep	Umbrella study of durvalumab led by AstraZeneca
Trastuzumab deruxtecan/DS-8201 Anti-HER2 antibody drug conjugate	Triple negative breast neoplasms	P1b/2 prep	Umbrella study of durvalumab led by AstraZeneca
Axi-Cel [®] /axicabtagene ciloleucel Anti-CD19 CAR-T cells	Relapsed/refractory B-cell lymphoma	Submitted	
DS-6157 Anti-GPR20 antibody drug conjugate	Advanced gastrointestinal stromal tumors	P1 prep	

◆ Discontinued Project (Major Changes from the FY2019 Q3 Financial Announcement in January 2020)

Generic Name/Project Code Number	Target indication	Stage	Discontinued reasons
Mechanism of action			
DS-1040 TAF1a inhibitor	Acute ischemic stroke, acute pulmonary embolism	P1	Decided to discontinue the development after reviewing its study result