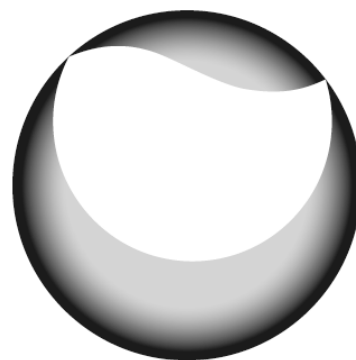


Reference Data

(Consolidated Financial Results for Q3 FY2020)



Daiichi-Sankyo

January 29, 2021

Daiichi Sankyo Co., Ltd.

<https://www.daiichisankyo.com>

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1. Consolidated Statement of Profit or Loss

JPY Bn	FY2019 Q3 YTD		FY2020 Q3 YTD					FY2020			
	to revenue	Results	to revenue	Results	(vs. Forecast (%))	YoY	YoY (%)	to revenue	Forecast	YoY	YoY (%)
Revenue	100.0%	757.0	100.0%	738.8	(77.0%)	-18.2	-2.4%	100.0%	960.0	-21.8	-2.2%
Cost of sales	33.9%	256.3	34.7%	256.4	(75.4%)	0.1	+0.1%	35.4%	340.0	-3.2	-0.9%
(excl. Special items)	35.7%	269.9	34.7%	256.4		-13.5	-5.0%				
(Special items)	-1.8%	-13.7	-	-		13.7	-				
Gross Profit	66.1%	500.8	65.3%	482.4	(77.8%)	-18.4	-3.7%	64.6%	620.0	-18.6	-2.9%
SG&A expenses	27.5%	208.2	31.0%	229.3	(72.3%)	21.0	+10.1%	33.0%	317.0	14.7	+4.9%
(excl. Special items)	28.9%	218.9	31.0%	229.3		10.4	+4.8%				
(Special items)	-1.4%	-10.6	-	-		10.6	-				
R&D expenses	18.1%	136.9	22.1%	163.6	(67.3%)	26.7	+19.5%	25.3%	243.0	45.5	+23.1%
(excl. Special items)	18.1%	136.9	22.1%	163.6		26.7	+19.5%				
(Special items)	-	-	-	-		-	-				
Operating Profit	20.6%	155.6	12.1%	89.5	(149.1%)	-66.1	-42.5%	6.3%	60.0	-78.8	-56.8%
(Operating Profit before Special items)	17.3%	131.3	12.1%	89.5		-41.8	-31.8%				
Financial income/expenses		4.3		10.0		5.7					
Share of profit or loss of investments accounted for using the equity method		0.1		0.1		-0.0					
Profit before tax	21.1%	160.0	13.5%	99.6	(144.3%)	-60.4	-37.8%	7.2%	69.0	-72.2	-51.1%
Income taxes		25.8		23.9		-1.9	-7.3%				
Profit for the year	17.7%	134.2	10.2%	75.7	(142.8%)	-58.5	-43.6%	5.5%	53.0	-76.0	-58.9%
Profit attributable to owners of the Company	17.7%	134.3	10.3%	75.8	(143.0%)	-58.5	-43.5%	5.5%	53.0	-76.1	-58.9%
Tax rate		16.1%		24.0%							
Overseas sales ratio		36.8%		40.3%							
Currency Rate (Average)											
USD/JPY		108.67		106.11					108.46		
EUR/JPY		121.05		122.37					120.65		

Forex impact: -5.9
(USD: -3.2, EUR: +0.9, ASCA: -3.6)

Forex impact: -0.7
(USD: -0.2, EUR: +0.1, ASCA: -0.5)

Forex impact: -2.1
(USD: -1.5, EUR: +0.3, ASCA: -1.0)

Forex impact: -1.8
(USD: -1.8, EUR: +0.1, ASCA: -0.1)

Forex impact: -1.3
(USD: +0.3, EUR: +0.4, ASCA: -2.1)

- Recognition of financial income due to decrease in contingent consideration of quizartinib acquisition +4.8
- Improvement in forex gains/losses +3.5

FY2019 Q3 YTD
Decrease in income taxes due to introduction of consolidated taxation system

	FY2019 Q3 YTD	FY2020 Q3 YTD
Cost of Sales	1.3	-
Restructuring costs in SC	3.8	-
Impairment loss (intangible)	-18.8	-
Gain on sales of subsidiary	-	-
SG&A expenses	-10.6	-
Gain on sales of fixed assets	-	-
Total	-24.3	-

	Forecast	
	USD	EUR
Revenue	1.5 JPY Bn	0.9 JPY Bn
Operating Profit	-0.5 JPY Bn	0.1 JPY Bn

Annual impact of one yen change

	Forecast	
	USD	EUR
Revenue	1.5 JPY Bn	0.9 JPY Bn
Operating Profit	-0.5 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 Q3 YTD	FY2020 Q3 YTD				FY2020				
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Oct.)	Forecast (as of Jan.)	vs. Forecast (as of Oct.)	YoY	YoY (%)
	Trastuzumab deruxtecan anti-cancer agent (HER2-directed antibody drug conjugate)	8.1	28.8	(59.5%)	20.7	+256.7%	47.1	48.3	1.2	34.4	+246.4%
	Product sales	0.0	20.7	(59.4%)	20.7	-	34.9	34.9	-	31.6	+978.8%
	Enhertu (JPN)	-	2.7	(47.6%)	2.7	-	5.6	5.6	-	5.6	-
	Enhertu (US)	0.0	18.0	(61.7%)	18.0	-	29.2	29.2	-	26.0	+804.3%
	Upfront payment	7.4	7.4	(75.0%)	-	-	9.8	9.8	-	-	-
	Regulatory milestone payment	0.7	0.7	(18.5%)	-	-	2.4	3.7	1.2	2.8	+304.7%
	Datopotamab deruxtecan anti-cancer agent (TROP2-directed antibody drug conjugate)	-	2.5	(63.2%)	2.5	-	3.9	3.9	-	3.9	-
	Upfront payment	-	2.5	(63.2%)	2.5	-	3.9	3.9	-	3.9	-
	Edoxaban anticoagulant	116.4	124.7	(76.6%)	8.3	+7.1%	160.9	162.9	1.9	8.8	+5.7%
	Lixiana (JPN)	65.6	59.8	(77.1%)	-5.8	-8.8%	75.6	77.5	1.9	-5.4	-6.6%
	Savaysa (US)	1.9	2.4	(85.2%)	0.5	+27.0%	2.8	2.8	-	0.2	+8.1%
	Lixiana (EU)	43.9	56.0	(76.1%)	12.2	+27.7%	73.7	73.7	-	12.0	+19.5%
	Other subsidiaries	5.1	6.5	(73.1%)	1.4	+27.3%	8.8	8.8	-	2.1	+30.7%
	Olmесartan antihypertensive agent	77.0	71.1	(80.1%)	-5.8	-7.6%	88.0	88.9	0.9	-12.0	-11.9%
	Olmесartan (JPN)	9.4	7.4	(80.8%)	-2.0	-21.4%	8.3	9.2	0.9	-2.5	-21.3%
	Rezaltas (JPN)	11.6	10.4	(77.7%)	-1.2	-10.7%	12.6	13.3	0.7	-1.3	-8.6%
	Olmесartan (US)	7.8	7.2	(80.2%)	-0.6	-7.7%	9.0	9.0	-	-0.9	-8.9%
	Olmесartan (EU)	16.9	16.2	(76.4%)	-0.7	-4.3%	21.2	21.2	-	-3.4	-13.7%
	Other subsidiaries, export, etc	31.2	29.9	(81.3%)	-1.2	-4.0%	36.8	36.8	-	-3.3	-8.2%
	Prasugrel antiplatelet agent	14.3	13.3	-	-1.0	-6.8%	not disclosed	not disclosed	-	-	-
	Effient alliance revenue (US)	0.4	0.2	-	-0.1	-35.8%	not disclosed	not disclosed	-	-	-
	Efient (EU)	1.9	1.2	(83.1%)	-0.8	-40.1%	1.4	1.4	-	-1.1	-44.8%
	Efient (JPN)	11.1	11.0	(76.5%)	-0.1	-0.8%	13.9	14.4	0.5	0.4	+2.8%
	Other subsidiaries, export, etc	0.9	0.9	-	0.0	+2.9%	not disclosed	not disclosed	-	-	-

3. Revenue by Business Units and Products (1)

JPY Bn	FY2019 Q3 YTD	FY2020 Q3 YTD				FY2020				
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Oct.)	Forecast (as of Jan.)	vs. Forecast (as of Oct.)	YoY
Japan	422.3	386.4	(79.6%)	-35.9	-8.5%	485.4	485.4	-	-48.1	-9.0%
Nexium	62.3	60.8	(79.3%)	-1.5	-2.4%	76.7	76.7	-	-3.0	-3.8%
Lixiana	65.6	59.8	(77.1%)	-5.8	-8.8%	75.6	77.5	1.9	-5.4	-6.6%
Pralia	24.3	26.4	(75.8%)	2.1	+8.8%	34.9	34.9	-	3.9	+12.6%
Memary	40.2	16.9	(87.7%)	-23.3	-57.9%	19.3	19.3	-	-31.2	-61.8%
Tenelia	19.7	19.2	(77.3%)	-0.5	-2.7%	24.0	24.8	0.8	0.1	+0.3%
Loxonin	22.7	19.1	(79.6%)	-3.6	-15.9%	23.4	24.0	0.6	-4.3	-15.0%
Ranmark	14.0	14.9	(76.1%)	0.9	+6.2%	19.6	19.6	-	1.7	+9.5%
Inavir	11.5	2.3	(50.0%)	-9.3	-80.4%	10.5	4.5	-6.0	-14.8	-76.5%
Tarlige	5.4	15.3	(74.5%)	9.9	+184.3%	20.0	20.6	0.6	12.6	+157.9%
Canalia	9.8	11.9	(77.1%)	2.1	+21.5%	15.5	15.5	-	2.7	+20.8%
Vimpat	8.5	11.2	(77.2%)	2.7	+32.1%	14.6	14.6	-	3.4	+30.5%
Efient	11.1	11.0	(76.5%)	-0.1	-0.8%	13.9	14.4	0.5	0.4	+2.8%
Rezaltas	11.6	10.4	(77.7%)	-1.2	-10.7%	12.6	13.3	0.7	-1.3	-8.6%
Olmotec	9.4	7.4	(80.8%)	-2.0	-21.4%	8.3	9.2	0.9	-2.5	-21.3%
Enhertu	-	2.7	(47.6%)	2.7	-	5.6	5.6	-	5.6	-
Daiichi Sankyo Espha products	47.9	55.1	-	7.3	+15.2%	not disclosed	not disclosed	-	-	-
Vaccines business	32.8	18.3	-	-14.5	-44.3%	not disclosed	not disclosed	-	-	-
Daiichi Sankyo Healthcare (OTC)	52.9	51.5	(75.2%)	-1.4	-2.6%	68.5	68.5	-	0.0	+0.0%

3. Revenue by Business Units and Products (2)

JPY Bn	FY2019 Q3 YTD		FY2020 Q3 YTD				FY2020				
	Results		Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Oct.)	Forecast (as of Jan.)	vs. Forecast (as of Oct.)	YoY	YoY (%)
Daiichi Sankyo, Inc. (US)	23.8		35.4	(71.2%)	11.6	+48.5%	49.7	49.7	-	17.6	+54.9%
Enhertu	0.0	anti-cancer agent (HER2-directed antibody drug conjugate)	18.0	(61.7%)	18.0	-	29.2	29.2	-	26.0	+804.3%
Olmesartan	7.8	antihypertensive agent	7.2	(80.2%)	-0.6	-7.7%	9.0	9.0	-	-0.9	-8.9%
Welchol	8.6	hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	3.9	(111.9%)	-4.7	-54.5%	3.5	3.5	-	-5.6	-61.7%
Effient	0.4	antiplatelet agent	0.2	-	-0.1	-35.8%	not disclosed	not disclosed	-	-	-
Savaysa	1.9	anticoagulant	2.4	(85.2%)	0.5	+27.0%	2.8	2.8	-	0.2	+8.1%
American Regent, Inc. (US)	99.7		91.0	(74.5%)	-8.7	-8.7%	122.1	122.1	-	-8.7	-6.6%
Injectafer	39.3	treatment for iron deficiency anemia	32.2	(69.1%)	-7.1	-18.1%	46.6	46.6	-	-5.2	-10.0%
Venofer	23.3	treatment for iron deficiency anemia	22.2	(78.8%)	-1.2	-5.1%	28.1	28.1	-	-2.9	-9.2%
Daiichi Sankyo Europe GmbH	67.7		82.9	(77.5%)	15.2	+22.5%	107.0	107.0	-	11.5	+12.0%
Lixiana	43.9	anticoagulant	56.0	(76.1%)	12.2	+27.7%	73.7	73.7	-	12.0	+19.5%
Olmesartan	16.9	antihypertensive agent	16.2	(76.4%)	-0.7	-4.3%	21.2	21.2	-	-3.4	-13.7%
Efient	1.9	antiplatelet agent	1.2	(83.1%)	-0.8	-40.1%	1.4	1.4	-	-1.1	-44.8%
Asia, South and Central America (ASCA)	73.5		74.5	(75.3%)	1.0	+1.3%	98.9	98.9	-	0.6	+0.6%
Daiichi Sankyo China	34.9		32.9	-	-2.0	-5.7%	not disclosed	not disclosed	-	-	-
Daiichi Sankyo Taiwan	5.5		6.2	-	0.7	+12.5%	not disclosed	not disclosed	-	-	-
Daiichi Sankyo Korea	12.5		14.4	-	1.9	+15.4%	not disclosed	not disclosed	-	-	-
Daiichi Sankyo Thailand	2.5		2.0	-	-0.6	-21.9%	not disclosed	not disclosed	-	-	-
Daiichi Sankyo Brasil Farmacêutica	9.1		8.2	-	-0.9	-9.8%	not disclosed	not disclosed	-	-	-

3. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

		FY2019 Q3 YTD	FY2020 Q3 YTD				FY2020				
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Oct.)	Forecast (as of Jan.)	vs. Forecast (as of Oct.)	YoY	YoY (%)
USD Mn											
Daiichi Sankyo, Inc. (US)		219	333	(72.7%)	114	+52.1%	459	459	-	163	+55.2%
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	0	170	(63.1%)	170	-	269	269	-	240	+806.0%
Olmesartan	antihypertensive agent	72	68	(81.9%)	-4	-5.4%	83	83	-	-8	-8.7%
Welchol	hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	79	37	(114.3%)	-42	-53.4%	32	32	-	-52	-61.6%
Effient	antiplatelet agent	3	2	-	-1	-34.3%	not disclosed	not disclosed	-	-	-
Savaysa	anticoagulant	17	23	(87.1%)	5	+30.1%	26	26	-	2	+8.3%
USD Mn											
American Regent, Inc. (US)		918	858	(76.2%)	-60	-6.5%	1,126	1,126	-	-78	-6.5%
Injectafer	treatment for iron deficiency anemia	362	304	(70.6%)	-58	-16.1%	430	430	-	-47	-9.9%
Venofer	treatment for iron deficiency anemia	215	209	(80.5%)	-6	-2.8%	259	259	-	-26	-9.1%
EUR Mn											
Daiichi Sankyo Europe GmbH		559	678	(76.4%)	118	+21.2%	887	887	-	98	+12.4%
Lixiana	anticoagulant	362	458	(75.0%)	96	+26.4%	611	611	-	101	+19.9%
Olmesartan	antihypertensive agent	140	132	(75.3%)	-8	-5.4%	176	176	-	-27	-13.5%
Efient	antiplatelet agent	16	9	(82.0%)	-7	-40.7%	12	12	-	-9	-44.6%

4. Consolidated Statement of Financial Position

<Assets>

JPY Bn

	Mar. 2020	Dec. 2020	vs. Mar. 2020
Assets			
Current assets			
Cash and cash equivalents	424.2	520.1	95.9
Trade and other receivables	309.4	263.4	-46.0
Other financial assets	466.5	303.6	-162.9
Inventories	173.4	183.9	10.5
Other current assets	10.5	11.0	0.4
Subtotal	1,384.0	1,282.0	-102.0
Assets held for sale	0.1	-	-0.1
Total current assets	1,384.1	1,282.0	-102.2
Non-current assets			
Property, plant and equipment	247.1	252.4	5.3
Goodwill	76.8	74.1	-2.7
Intangible assets	172.5	167.6	-4.9
Investments accounted for using the equity method	0.4	1.3	1.0
Other financial assets	98.0	137.1	39.1
Deferred tax assets	114.7	124.7	10.0
Other non-current assets	12.1	12.0	-0.1
Total non-current assets	721.5	769.2	47.7
Total assets	2,105.6	2,051.2	-54.4
* Liquidity on hand	891.2	823.0	-68.2
Debt with interest	266.3	223.7	-42.6
Net Cash	624.9	599.2	-25.6

Receivable for trastuzumab deruxtecan strategic collaboration
upfront payment -74.5

Acquisition +30.4, Depreciation -23.2

Acquisition +18.2, Amortization -19.5, Forex impact -1.7

<Liabilities and equity>

JPY Bn

	Mar. 2020	Dec. 2020	vs. Mar. 2020	
Liabilities				
Current liabilities				
Trade and other payables	270.9	241.5	-29.4	Upfront payment for strategic partnership of gene therapy manufacturing technology with Ultragenyx -13.5 Deferred revenue for datopotamab deruxtecan (Strategic collaboration upfront payment) +5.8
Bonds and borrowings	40.4	20.4	-20.0	Redemption of 3rd unsecured corporate bond -20.0 Repayment of syndicated loan -20.0 Transfer of syndicated loan +20.0 (Transfer from Non-current liabilities "Bonds and borrowings")
Other financial liabilities	9.5	9.8	0.3	
Income taxes payable	9.9	23.6	13.7	
Provisions	5.4	4.9	-0.5	
Other current liabilities	15.0	13.2	-1.8	Decrease in contingent consideration of quizartinib introduction -4.8
Total current liabilities	351.1	313.3	-37.8	
Non-current liabilities				
Bonds and borrowings	183.8	163.5	-20.3	Transfer of syndicated loan -20.0 (Transfer to current liabilities "Bonds and borrowings")
Other financial liabilities	37.1	34.3	-2.8	
Post employment benefit liabilities	5.3	5.6	0.3	
Provisions	10.6	10.3	-0.3	
Deferred tax liabilities	15.6	14.6	-1.0	
Other non-current liabilities	195.8	218.2	22.3	Deferred revenue for datopotamab deruxtecan (Strategic collaboration upfront payment) +28.6 Deferred revenue for trastuzumab deruxtecan -8.0 (Strategic collaboration upfront payment -7.4, Regulatory milestone payment -0.7)
Total non-current liabilities	448.3	446.6	-1.7	
Total liabilities	799.3	759.9	-39.5	
Equity				
Equity attributable to owners of the Company				
Share capital	50.0	50.0	-	
Capital surplus	94.6	94.6	-0.1	
Treasury shares	-162.5	-201.4	-38.9	Acquisition of treasury shares -40.0
Other components of equity	82.1	79.2	-2.9	
Retained earnings	1,241.6	1,268.9	27.3	Profit for the period +75.8, Payment of dividends -48.9
Total equity attributable to owners of the Company	1,305.8	1,291.3	-14.5	
Non-controlling interests				
Non-controlling interests	0.5	-	-0.5	
Total equity	1,306.3	1,291.3	-15.0	
Total liabilities and equity	2,105.6	2,051.2	-54.4	

5. Consolidated Statement of Cash Flows

JPY Bn

	FY2019 Q3 YTD	FY2020 Q3 YTD	YoY
Cash flows from operating activities			
Profit before tax	160.0	99.6	-60.4
Depreciation and amortization	39.2	42.9	3.7
(Increase) decrease in receivables and payables	-15.6	25.6	41.3
Others, net	-21.6	-13.1	8.5
Income taxes paid	-21.2	-22.7	-1.5
Net cash flows from operating activities	140.8	132.3	-8.5
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	8.5	161.0	152.5
(Acquisition of) proceeds from sales of fixed assets	-42.4	-54.2	-11.8
Proceeds from sale of subsidiary	37.1	-	-37.1
Net (increase) decrease in investment securities	15.4	-2.1	-17.5
Others, net	14.8	0.2	-14.6
Net cash flows from investing activities	33.4	104.9	71.5
Cash flows from financing activities			
Net (increase) decrease in borrowings	3.7	-20.3	-24.0
Repayments of bonds	-40.0	-20.0	20.0
Purchase of treasury shares	-0.1	-40.1	-40.0
Dividends paid	-45.4	-49.0	-3.6
Others, net	-7.3	-9.5	-2.3
Net cash flows from financing activities	-89.0	-138.9	-49.9
Net increase (decrease) in cash and cash equivalents	85.2	98.2	13.0
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	-1.9	-2.3	-0.4
Cash and cash equivalents at the end of the period	326.4	520.1	193.7
* Free cash flows (Cash flows from operating activities and investing activities)	174.2	237.1	62.9

6. Number of Employees

	Dec. 2019	Mar. 2020	Dec. 2020
	Results	Results	Results
Consolidated	15,297	15,348	16,010
Japan	8,806	8,754	8,979
North America	2,333	2,380	2,592
Europe	1,917	1,953	2,106
Others	2,241	2,261	2,333

7. Capital Expenditure, Depreciation and Amortization

	JPY Bn	FY2019 Q3 YTD	FY2019	FY2020 Q3 YTD	FY2020
		Results	Results	Results	Forecast
Capital expenditure		18.8	29.0	26.8	45.0
Depreciation and amortization		39.2	52.6	42.9	56.0
Property, plant and equipment		24.0	32.0	23.4	-
Intangible assets		15.2	20.6	19.5	-

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			1986	Daiichi Sankyo		
Loxonin Poulitice			2006	Lead Chemical		
Loxonin Tape	loxoprofen	anti-inflammatory analgesic	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		
Olmotec	olmesartan	antihypertensive agent	2004	Daiichi Sankyo		
Enhertu	trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	2020	Daiichi Sankyo		
Daiichi Sankyo, Inc. (US)						
Enhertu	trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	2020	Daiichi Sankyo	AstraZeneca	Co-promotion (DS: Sales)
Olmesartan						
Benicar	olmesartan		2002			
Benicar HCT	olmesartan / hydrochlorothiazide		2003	Daiichi Sankyo		
Azor	olmesartan / amlodipine	antihypertensive agent	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						
Olmotec	olmesartan		2002			
Olmotec Plus	olmesartan / hydrochlorothiazide		2005	Daiichi Sankyo	Menarini Pfizer	Co-marketing
Sevikar	olmesartan / amlodipine	antihypertensive agent	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	FY2019	FY2019	FY2019	FY2019				FY2020	FY2020	FY2020	FY2020	FY2020	
	Q1	Q2	Q3	Q4	to revenue	Results	YoY	YoY (%)	Q1	Q2	Q3	Q4	to revenue	Results
	Results	Results	Results	Results					Results	Results	Results	Results		
Revenue	249.2	230.3	277.5	224.8	100.0%	981.8	52.1	+5.6%	236.9	243.2	258.6		100.0%	738.8
Cost of sales	87.9	89.2	79.2	86.9	35.0%	343.2	-21.4	-5.9%	82.2	86.4	87.8		34.7%	256.4
(excl. Special items)	86.6	85.4	98.0	84.5	36.1%	354.4	4.9	+1.4%	82.2	86.4	87.8		34.7%	256.4
(Special items)	1.3	3.8	-18.8	2.4	-1.1%	-11.2	-26.3	-	-	-	-		-	-
Gross Profit	161.3	141.1	198.3	137.8	65.0%	638.6	73.5	+13.0%	154.7	156.9	170.8		65.3%	482.4
SG&A expenses	63.2	67.3	77.8	94.1	30.8%	302.3	24.6	+8.9%	71.8	76.8	80.7		31.0%	229.3
(excl. Special items)	73.8	67.3	77.8	85.9	31.0%	304.8	23.6	+8.4%	71.8	76.8	80.7		31.0%	229.3
(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	55.7	59.1		22.1%	163.6
(excl. Special items)	41.2	44.7	51.1	60.5	20.1%	197.5	-6.2	-3.1%	48.8	55.7	59.1		22.1%	163.6
(Special items)	-	-	-	-	-	-	0.0	-	-	-	-		-	-
Operating Profit	57.0	29.2	69.4	-16.8	14.1%	138.8	55.1	+65.8%	34.1	24.3	31.0		12.1%	89.5
(Operating Profit before Special items)	47.7	33.0	50.6	-6.1	12.7%	125.1	29.8	+31.3%	34.1	24.3	31.0		12.1%	89.5
Financial income/expenses	0.1	0.8	3.5	-2.3		2.0	-0.2		7.2	1.2	1.5			10.0
Share of profit or loss of investments accounted for using the equity method	0.0	0.0	0.0	0.2		0.3	0.4		0.0	0.0	0.0			0.1
Profit before tax	57.1	30.0	72.9	-18.8	14.4%	141.2	55.3	+64.5%	41.4	25.6	32.6		13.5%	99.6
Income taxes	13.7	8.9	3.1	-13.6		12.2	19.8	-	9.6	5.8	8.5			23.9
Profit for the year	43.3	21.1	69.8	-5.2	13.1%	129.0	35.5	+38.0%	31.8	19.8	24.1		10.2%	75.7
Profit attributable to owners of the Company	43.3	21.1	69.9	-5.2	13.1%	129.1	35.7	+38.2%	31.9	19.8	24.1		10.3%	75.8
Tax rate	24.1%	29.8%	4.3%	72.2%		8.6%			23.1%	22.8%	26.1%			24.0%
Overseas sales ratio	37.5%	38.4%	34.9%	42.5%		38.1%			38.6%	42.3%	40.1%			40.3%
Currency Rate (YTD Average)														
USD/JPY	109.90	108.63	108.67	108.75		108.75			107.62	106.92	106.11			106.11
EUR/JPY	123.49	121.41	121.05	120.83		120.83			118.47	121.29	122.37			122.37

<9. Quarterly Data>

2. Revenue of Global Products

JPY Bn	FY2019 Q1	FY2019 Q2	FY2019 Q3	FY2019 Q4	FY2019			FY2020 Q1	FY2020 Q2	FY2020 Q3	FY2020 Q4	FY2020
	Results	Results	Results	Results	Results	YoY	YoY (%)	Results	Results	Results	Results	Results
Trastuzumab deruxtecan	2.5	2.5	3.2	5.9	14.0	13.9	-	7.9	9.8	11.1		28.8
Product sales	-	-	0.0	3.2	3.2	3.2	-	5.2	7.1	8.4		20.7
Enhertu(JPN)	-	-	-	-	-	-	-	0.2	0.8	1.7		2.7
Enhertu (US)	-	-	0.0	3.2	3.2	3.2	-	5.0	6.3	6.7		18.0
Upfront payment	2.5	2.5	2.5	2.5	9.8	9.7	-	2.5	2.5	2.5		7.4
Regulatory milestone payment	-	-	0.7	0.2	0.9	0.9	-	0.2	0.2	0.2		0.7
Datopotamab deruxtecan	-	-	-	-	-	-	-	-	1.0	1.5		2.5
Upfront payment	-	-	-	-	-	-	-	-	1.0	1.5		2.5
Edoxaban	37.2	36.5	42.6	37.6	154.0	36.3	+30.9%	38.7	40.4	45.6		124.7
Lixiana (JPN)	21.6	20.2	23.8	17.4	83.0	18.1	+27.8%	19.8	18.5	21.5		59.8
Savaysa (US)	0.6	0.6	0.8	0.7	2.6	0.3	+13.8%	0.6	1.1	0.7		2.4
Lixiana (EU)	13.5	14.0	16.4	17.8	61.7	15.9	+34.7%	16.4	18.6	21.0		56.0
Other subsidiaries	1.6	1.7	1.7	1.7	6.8	2.1	+44.2%	1.9	2.2	2.3		6.5
Olmesartan	27.5	23.2	26.3	23.9	100.8	-5.1	-4.8%	25.7	22.4	23.0		71.1
Olmotec (JPN)	3.5	2.7	3.2	2.2	11.7	-3.2	-21.5%	2.7	2.2	2.5		7.4
Rezaltas (JPN)	4.2	3.4	4.1	3.0	14.6	-0.9	-5.8%	3.6	3.2	3.6		10.4
Olmesartan (US)	3.1	2.4	2.2	2.1	9.8	-0.9	-8.4%	3.7	1.8	1.7		7.2
Olmesartan (EU)	6.4	4.8	5.8	7.7	24.6	-2.8	-10.2%	5.2	5.8	5.2		16.2
Other subsidiaries, export, etc	10.3	9.9	11.0	8.9	40.1	2.7	+7.2%	10.5	9.5	10.0		29.9
Prasugrel	5.0	4.4	4.9	3.8	18.1	-5.1	-21.9%	4.4	4.2	4.7		13.3
Effient alliance revenue (US)	0.1	0.3	0.0	0.1	0.5	-2.0	-81.4%	-0.0	0.1	0.1		0.2
Efient (EU)	0.8	0.6	0.6	0.6	2.5	-3.2	-55.8%	0.3	0.4	0.4		1.2
Efient (JPN)	3.8	3.2	4.0	2.9	14.0	0.1	+0.7%	3.8	3.3	3.8		11.0
Other subsidiaries, export, etc	0.3	0.3	0.3	0.2	1.2	-0.0	-0.2%	0.3	0.3	0.3		0.9

3. Revenue by Business Units and Products (1)	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
JPY Bn												
Japan	139.0	122.0	161.3	111.2	533.5	10.2	+1.9%	130.2	119.9	136.3		386.4
Nexium	21.9	18.3	22.1	17.4	79.8	1.5	+1.9%	19.9	19.1	21.9		60.8
Lixiana	21.6	20.2	23.8	17.4	83.0	18.1	+27.8%	19.8	18.5	21.5		59.8
Pralia	8.2	7.3	8.8	6.7	30.9	3.6	+13.0%	8.7	8.3	9.4		26.4
Memary	13.7	11.9	14.5	10.3	50.5	0.3	+0.6%	12.8	2.1	2.0		16.9
Tenelia	6.9	5.9	6.9	5.0	24.7	-0.6	-2.4%	6.6	5.9	6.7		19.2
Loxonin	7.8	7.0	7.9	5.5	28.3	-2.2	-7.3%	6.2	6.1	6.8		19.1
Ranmark	4.7	4.5	4.8	3.9	17.9	1.5	+9.1%	5.0	4.7	5.2		14.9
Inavir	0.0	1.0	10.5	7.7	19.3	1.1	+5.9%	0.6	0.7	0.9		2.3
Tarlige	2.0	1.3	2.1	2.6	8.0	8.0	-	4.3	4.9	6.2		15.3
Canalia	3.2	2.9	3.7	3.0	12.8	3.6	+38.8%	3.9	3.7	4.3		11.9
Vimpat	2.7	2.6	3.3	2.7	11.2	4.6	+70.0%	3.8	3.4	4.1		11.2
Efient	3.8	3.2	4.0	2.9	14.0	0.1	+0.7%	3.8	3.3	3.8		11.0
Rezaltas	4.2	3.4	4.1	3.0	14.6	-0.9	-5.8%	3.6	3.2	3.6		10.4
Olmetec	3.5	2.7	3.2	2.2	11.7	-3.2	-21.5%	2.7	2.2	2.5		7.4
Enhertu	-	-	-	-	-	-	-	0.2	0.8	1.7		2.7
Daiichi Sankyo Espha products	17.3	14.1	16.5	12.6	60.5	5.0	+8.9%	17.6	16.7	20.9		55.1
Vaccines business	7.5	8.4	16.9	2.8	35.6	-5.9	-14.2%	2.9	7.8	7.6		18.3
Daiichi Sankyo Healthcare (OTC)	15.4	18.7	18.8	15.6	68.5	2.1	+3.2%	14.3	18.7	18.4		51.5

3. Revenue by Business Units and Products (2)	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
JPY Bn												
Daiichi Sankyo, Inc. (US)	7.8	7.1	8.9	8.3	32.1	-4.2	-11.5%	11.6	12.0	11.8		35.4
Enhertu	-	-	0.0	3.2	3.2	3.2	-	5.0	6.3	6.7		18.0
Olmesartan	3.1	2.4	2.2	2.1	9.8	-0.9	-8.4%	3.7	1.8	1.7		7.2
Welchol	2.6	2.2	3.8	0.5	9.1	-4.3	-31.9%	0.6	1.6	1.7		3.9
Effient	0.1	0.3	0.0	0.1	0.5	-2.0	-81.4%	-0.0	0.1	0.1		0.2
Savaysa	0.6	0.6	0.8	0.7	2.6	0.3	+13.8%	0.6	1.1	0.7		2.4
American Regent, Inc. (US)	36.0	32.4	31.4	31.0	130.8	13.0	+11.0%	26.5	32.5	32.1		91.0
Injectafer	13.7	12.3	13.3	12.5	51.8	7.6	+17.2%	9.4	11.5	11.3		32.2
Venofer	9.3	7.1	6.9	7.7	31.0	2.1	+7.1%	6.9	7.7	7.5		22.2
Daiichi Sankyo Europe GmbH	22.1	21.1	24.5	27.8	95.5	6.9	+7.8%	27.7	26.6	28.6		82.9
Lixiana	13.5	14.0	16.4	17.8	61.7	15.9	+34.7%	16.4	18.6	21.0		56.0
Olmesartan	6.4	4.8	5.8	7.7	24.6	-2.8	-10.2%	5.2	5.8	5.2		16.2
Efient	0.8	0.6	0.6	0.6	2.5	-3.2	-55.8%	0.3	0.4	0.4		1.2
Asia, South and Central America (ASCA)	24.3	24.6	24.6	24.8	98.3	10.7	+12.2%	22.5	25.8	26.1		74.5
Daiichi Sankyo China	12.0	12.0	10.9	11.1	46.0	7.6	+19.6%	8.6	11.4	12.9		32.9
Daiichi Sankyo Taiwan	1.9	1.8	1.9	2.1	7.6	0.5	+6.7%	2.1	2.0	2.1		6.2
Daiichi Sankyo Korea	4.0	4.3	4.2	4.7	17.2	1.5	+9.5%	4.4	5.0	4.9		14.4
Daiichi Sankyo Thailand	0.8	0.8	0.9	0.8	3.3	0.1	+2.4%	0.6	0.7	0.7		2.0
Daiichi Sankyo Brasil Farmacêutica	2.8	2.9	3.4	2.5	11.5	1.5	+14.6%	2.9	2.6	2.7		8.2

3. Revenue by Business Units and Products (3)	FY2019 Q1	FY2019 Q2	FY2019 Q3	FY2019 Q4	FY2019			FY2020 Q1	FY2020 Q2	FY2020 Q3	FY2020 Q4	FY2020
[Reference] Revenue in Local Currency	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	113	113		333
Enhertu	-	-	0	30	30	30	-	46	60	64		170
Olmesartan	28	23	21	19	91	-6	-6.5%	35	17	16		68
Welchol	23	21	35	5	84	-37	-30.5%	5	15	16		37
Effient	1	2	0	1	4	-18	-81.1%	-0	1	1		2
Savaysa	5	5	7	7	24	3	+16.1%	5	11	7		23
USD Mn												
American Regent, Inc. (US)	327	302	289	286	1,204	142	+13.3%	246	305	307		858
Injectafer	125	114	123	115	477	78	+19.7%	88	109	108		304
Venofer	85	66	64	70	285	24	+9.3%	64	72	72		209
EUR Mn												
Daiichi Sankyo Europe GmbH	179	177	203	230	789	99	+14.4%	234	214	230		678
Lixiana	109	117	136	147	509	153	+42.9%	139	150	169		458
Olmesartan	52	40	48	63	203	-10	-4.7%	44	47	42		132
Effient	6	5	5	5	21	-24	-53.1%	3	4	3		9

<10. 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 (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
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
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)

	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
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
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
Effient	41	67	62	44	21

11. Major R&D Pipeline (Innovative Pharmaceuticals)

As of January 2021

◆ 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/jRCT registration number • Partner, if any 	Patients and target indications for the study	Target sample size	Study design schematic (randomize or not, blinding or not, control group or not)	<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

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

◆ 3 ADCs

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

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

Brand name: ENHERTU (JP/US/EU)

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

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

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

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 (pivotal) DESTINY-Gastric01 NCT03329690 JapicCTI-173727 AstraZeneca	HER2 overexpressing, gastric or gastroesophageal junction adenocarcinoma, 3L	220	Randomized, open label, active control •DS-8201 •Physician's choice (irinotecan or paclitaxel)	Primary endpoint: ORR Secondary endpoint: PFS, OS, DOR, DCR, TTF, ORR, PK	JP/Asia	FPD: Nov 2017 TLR: Jan 2020 Sep 2020: Approved (JP) Jan 2021: Approved (US) Mar 2018: SAKIGAKE Designation (JP) May 2020: Breakthrough Therapy Designation (US) May 2020: Orphan Drug Designation (US)
Phase 2 DESTINY-Gastric02 NCT04014075 AstraZeneca	HER2 positive gastric cancer, 2L	72	Open label •DS-8201	Primary endpoint: ORR Secondary endpoint: PFS, ORR, OS, DOR	US/EU	FPD: Dec 2019
Phase 1b/2 DESTINY-Gastric03 NCT04379596 jRCT2031200203 AstraZeneca	Part 1 HER2 overexpressing gastric or gastro-esophageal junction cancer, 2L Part 2 HER2 overexpressing gastric or gastro-esophageal junction cancer, 1L	220	Randomized, open label Part 1 •DS-8201 + fluorouracil •DS-8201 + capecitabine •DS-8201 + durvalumab •DS-8201 + oxaliplatin + 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: Part 1: Safety, Part 2: ORR Secondary endpoint: ORR, safety, DOR, DCR, PFS, OS, PK	US/EU/ Asia	FPD: Jun 2020
Phase 3 DESTINY-Gastric04 NCT04704934 AstraZeneca	HER2 positive gastric cancer or, gastro-esophageal junction cancer, 2L	490	Randomized, open label •DS-8201 •Ramucirumab + paclitaxel	Primary endpoint: OS Secondary endpoint: PFS, ORR, DOR, DCR, safety, PK, ADA and etc.	JP/US/EU/ Asia	FPD: FY2021 Q1 planned

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 DESTINY-Lung01 NCT03505710 JapicCTI-183916 AstraZeneca	HER2 overexpressing or mutated NSCLC, 2L or later	170	Non-randomized, open label •DS-8201	Primary endpoint: ORR Secondary endpoint: ORR, DOR, PFS, OS	JP/US/EU	FPD: May 2018 Data anticipated: FY2021 H1 May 2020: Breakthrough Therapy Designation (US)
Phase 2 DESTINY-Lung02 NCT04644237 jRCT2061200038 AstraZeneca	HER2 mutated NSCLC, 2L or later	150	Randomized, double blind •DS-8201: 6.4mg/kg •DS-8201: 5.4mg/kg	Primary endpoint: ORR Secondary endpoint: ORR, DOR, DCR, PFS, OS, safety	TBD	FPD: FY2020 Q4 planned
Phase 1b DESTINY-Lung03 NCT04686305 AstraZeneca	HER2 positive NSCLC, 1L	120	Non-randomized, three-part (safety run-in, dose escalation, dose expansion) •DS-8201 + durvalumab + cisplatin •DS-8201 + durvalumab + carboplatin •DS-8201 + durvalumab + pemetrexed •DS-8201 + durvalumab	Primary endpoint: Safety Secondary endpoint: ORR, DOR, DCR, PFS, OS, PK and etc.	EU/Asia	FPD: FY2020 Q4 planned
Phase 2 HUDSON NCT03334617 AstraZeneca	NSCLC, 2L or later	320	Non-randomized, open label, combination with durvalumab •DS-8201 + durvalumab * Umbrella study of durvalumab led by AstraZeneca	Primary endpoint: ORR Secondary endpoint: DCR, ORR, DOR, PFS, OS	US/EU/Asia	FPD: Jun 2020
Phase 2 DESTINY-CRC01 NCT03384940 JapicCTI-173808 AstraZeneca	HER2 expressing colorectal cancer, 3L	90	Non-randomized, open label •DS-8201	Primary endpoint: ORR Secondary endpoint: PFS, OS, DOR, DCR, ORR, PK	JP/US/EU	FPD: Mar 2018 TLR: Oct 2019* *Results obtained for ASCO 2020

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 DESTINY-PanTumor01 NCT04639219 AstraZeneca	HER2 mutated tumor	100	Open label •DS-8201	Primary endpoint: ORR Secondary endpoint: DOR, DCR, PFS, ORR, OS, safety	US/EU/ Asia	FPD: Jan 2021
Phase 2 DESTINY-PanTumor02 NCT04482309 AstraZeneca	HER2 expressing tumors (bladder cancer, biliary tract cancer, cervical cancer, endometrial cancer, ovarian cancer, pancreatic cancer, rare tumors)	280	Non-randomized •DS-8201	Primary endpoint: ORR Secondary endpoint: DOR, DCR, PFS, OS	US/EU/ Asia	FPD: Oct 2020
Phase 1 NCT03523572 BMS	HER2 positive breast cancer HER2 positive 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: Aug 2018
Phase 1 NCT04042701 Merck	HER2 positive/low breast cancer HER2 expressing/mutated NSCLC	115	Non-randomized, open label, combination with pembrolizumab •DS-8201+ pembrolizumab	Primary endpoint: Safety, ORR Secondary endpoint: DOR, DCR, PFS, OS	US/EU	FPD: Apr 2020

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

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 TROPION- PanTumor01 NCT03401385 JapicCTI-173812 AstraZeneca	NSCLC Triple negative breast cancer	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: Feb 2018
Phase 3 TROPION-Lung01 NCT04656652 AstraZeneca	NSCLC (without actionable mutation), 2L/3L	590	Randomized, open label •DS-1062 •Docetaxel	Primary endpoint: PFS, OS Secondary endpoint: ORR, DOR, TTR, DCR, safety, PK, anti-drug antibodies (ADA)	JP/US/EU/ Asia	FPD: FY2020 Q4 planned
Phase 1 TROPION-Lung02 NCT04526691 jRCT2031200193 Merck AstraZeneca	NSCLC (without actionable mutation)	86	Open label, combination with pembrolizumab, two-part (dose escalation, dose expansion) •DS-1062 + pembrolizumab	Primary endpoint: Safety Secondary endpoint: ORR, DOR, PFS, OS, PK, anti-drug antibodies (ADA)	JP/US	FPD: Oct 2020
Phase 1 prep TROPION-Lung04 NCT04612751 AstraZeneca	NSCLC (without actionable mutation)	74	Open label, combination with durvalumab, two-part (dose escalation, dose expansion) •DS-1062 + durvalumab	Primary endpoint: Safety Secondary endpoint: ORR, DOR, DCR, PFS, TTR, OS, PK	JP/US	FPD: FY2020 Q4 planned
Phase 2 TROPION-Lung05 NCT04484142 AstraZeneca	NSCLC (with actionable mutation)	150	open label •DS-1062	Primary endpoint: ORR Secondary endpoint: DOR, PFS, OS, safety, PK, anti-drug antibodies (ADA)	JP/US/EU/ Asia	FPD: FY2020 Q4 planned

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

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1/2 NCT02980341 JapicCTI-163401	Breast cancer	180	Randomized, open label, two-part (dose escalation, dose expansion) •U3-1402	Primary endpoint: Safety, antitumor effect Secondary endpoint: PK	JP/US	FPD: Dec 2016 LPFD: May 2020
Phase 1 NCT03260491 JapicCTI-194868	NSCLC	198	Non-randomized, open label, two-part (dose escalation, dose expansion) •U3-1402	Primary endpoint: Safety, ORR Secondary endpoint: PK, ORR, DCR, DOR, PFS, OS, safety	JP/US/EU /Asia	FPD: Feb 2018
Phase 2 prep HERTHENA-Lung01 NCT04619004 jRCT2031200186	EGFR mutated NSCLC	420	Randomized, open label •U3-1402	Primary endpoint: ORR Secondary endpoint: DOR, PFS, ORR, DCR, TTR, OS, safety	JP/US	FPD: FY2020 Q4 planned
Phase 1 prep NCT04676477 jRCT2031200247 AstraZeneca	EGFR mutated NSCLC	252	Non-randomized, open label, two-part (dose escalation, dose expansion) •U3-1402 + Osimertinib	Primary endpoint: safety, ORR Secondary endpoint: ORR, DOR, DCR, TTR, PFS, OS, safety, PK, and etc.	JP/US	FPD: FY2020 Q4 planned
Phase 2 NCT04479436 jRCT2031200139	CRC, 3L or later	80	Non-randomized, open label •U3-1402	Primary endpoint: safety, ORR Secondary endpoint: DOR, ORR, DCR, TTR, PFS, OS, safety, PK	JP/US/EU	FPD: Sep 2020

◆ Alpha (Oncology Late-Stage Pipeline Products)

Quizartinib/AC220 (FLT3 inhibitor)

Kinase inhibitor against a receptor-type tyrosine kinase, FLT3. Therapeutic effect for patients with acute myeloid leukemia harboring FLT3-ITD mutation is expected.

Brand name: VANFLYTA (JP)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 QuANTUM-R NCT02039726	Acute myeloid leukemia, relapsed/refractory	367	Randomized, open label, active-controlled •Quizartinib •Chemotherapy	Primary endpoint: OS Secondary endpoint: EFS	JP/US/EU /Asia	FPD: May 2014 TLR: May 2018 Jun 2019: received CRL (US) Oct 2019: launched (JP) Oct 2019: received negative CHMP opinion (EU) Mar 2009: Orphan Drug Designation (US/EU) Submission strategy in US/EU/Asia is under discussion, together with 1L indication
Phase 3 QuANTUM-First NCT02668653 JapicCTI-173667	Acute myeloid leukemia, 1L	539	Randomized, double-blind, placebo-controlled •Quizartinib + chemotherapy •Placebo + chemotherapy	Primary endpoint: OS Secondary endpoint: EFS and etc.	JP/US/EU/ Asia	FPD: Sep 2016 Data anticipated: FY2021 H2 Mar 2009: Orphan Drug Designation (US/EU)

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

The molecular-targeted agent to inhibit CSF-1R, KIT and FLT3. This agent is expected to reduce tumor cell proliferation and expansion of metastases.

Brand name: TURALIO (US)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 ENLIVEN NCT02371369	Tenosynovial giant cell tumor	120	Randomized, double-blind, placebo-controlled •Pexidartinib •Placebo	Primary endpoint: ORR Secondary endpoint: Safety, DOR and etc.	US/EU/ Asia	FPD: May 2015 TLR: Oct 2017 Aug 2019: launched (US) Jun 2020: received negative CHMP opinion (EU)
Phase 3 NCT04488822	Tenosynovial giant cell tumor	35	Open label •Pexidartinib	Primary endpoint: PR, CR rate Secondary endpoint: TVS, ROM, PROMIS and etc.	Asia	FPD: Sep 2020
Phase 2 prep jRCT2041200074	Tenosynovial giant cell tumor	21	Open label •Pexidartinib	Primary endpoint: Safety, PR, CR rate Secondary endpoint: Safety, TVS, ROM, PROMIS, and etc.	JP	FPD: FY2020 Q4 planned
Phase 1 NCT02734433	Solid tumors	11	Open label •Pexidartinib	Primary endpoint: Safety Secondary endpoint: PK, antitumor effect	Asia	FPD: Sep 2016

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

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

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

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

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

Brand name: YESCARTA (JP)

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

Valemetostat/DS-3201 (EZH1/2 inhibitor)

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 (pivotal) NCT04102150 JapicCTI-194964	Adult T-cell leukemia/lymphoma	25	Open label •DS-3201	Primary endpoint: ORR Secondary endpoint: ORR, CR rate, DOR, PFS, OS and etc.	JP	FPD: Dec 2019 LPFD: Oct 2020
Phase 2 (pivotal) prep NCT04703192	Relapsed/ refractory peripheral T-cell lymphoma	176	Randomized, open label •DS-3201	Primary endpoint: ORR Secondary endpoint: DOR, CR rate, safety, and etc.	JP/US/EU/ Asia	FPD: FY2021 Q1 planned Apr 2019: SAKIGAKE Designation for peripheral T-cell lymphoma (JP)
Phase 1 NCT02732275 JapicCTI-163173	Non-Hodgkin's lymphomas	100	Open label •DS-3201	Primary endpoint: Safety, PK, antitumor effect Secondary endpoint: ORR, DCR, DOR, PFS and etc.	JP/US	FPD: Apr 2016
Phase 1 NCT03110354	Acute myeloid leukemia, acute lymphoblastic leukemia	48	Open label •DS-3201	Primary endpoint: Safety Secondary endpoint: PK, antitumor effect	US	FPD: Mar 2017

◆ Alpha (Oncology Early-Stage Pipeline Products)

DS-1001 (Mutant IDH1 inhibitor)

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

PLX2853 (BET inhibitor)

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

DS-7300 (B7-H3-directed ADC)

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

DS-6157 (GPR20-directed ADC)

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

DS-1055 (anti-GARP antibody)

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

DS-6000 (CDH6-directed ADC)

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 prep NCT04707248	Renal cell carcinoma, ovarian cancer	102	Non-randomized, open label, two-part (dose escalation, dose expansion) •DS-6000	Primary endpoint: Safety Secondary endpoint: PK, ORR, DOR, DCR and etc.	US	FPD: FY2020 Q4 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.
Brand name: LIXIANA (JP/EU/ Asia), SAVAYSA (US)

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

Prasugrel/CS-747 (ADP receptor inhibitor)

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

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

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

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

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

Esaxerenone/CS-3150 (MR blocker)

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

Brand name: MINNEBRO (JP)

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

◆ Alpha (Specialty Medicines Early-Stage Pipeline Products)

Renadirsen Sodium/DS-5141 (ENA-oligonucleotides)

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

DS-1211 (TNAP inhibitor)

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

DS-2741 (anti-Orai1 antibody)

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

DS-2319 (Nafamostat inhalation)

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

◆ Alpha (Vaccine)

VN-0107/MEDI3250 (live attenuated influenza vaccine)

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

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

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

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 JapicCTI-205118	Prevention of measles, mumps and rubella in healthy Japanese children aged 12 months or more and less than 24 months	840	Randomized, active-controlled •VN-0102/JVC-001 •Dry Live Attenuated Measles Rubella vaccine, Freeze-dried Live Attenuated Mumps vaccine	Primary endpoint: Seroprotection rates for measles, mumps and rubella Secondary endpoint: Seroconversion rates for measles, mumps, and rubella	JP	FPD: Feb 2020 LPD: Sep 2020 Data anticipated: 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 Mar 2021

◆ **Stage-up Projects (Major Changes from the FY2020 Q2 Financial Announcement in October 2020)**

Generic Name/Project Code Number Mechanism of action	Target indication	Current stage	Note
Trastuzumab deruxtecan/DS-8201/T-DXd HER2-directed ADC	HER2 positive breast cancer, 3L	Approved	EU DESTINY-Breast01
Trastuzumab deruxtecan/DS-8201/T-DXd HER2-directed ADC	HER2 positive, with residual invasive breast cancer following neoadjuvant therapy	P3	DESTINY-Breast05
Trastuzumab deruxtecan/DS-8201/T-DXd HER2-directed ADC	HER2 positive breast cancer Part 1: 2L or later Part 2: 1L	P1b/2	DESTINY-Breast07
Trastuzumab deruxtecan/DS-8201/T-DXd HER2-directed ADC	HER2 low breast cancer Chemotherapy naïve, post chemotherapy	P1b	DESTINY-Breast08
Trastuzumab deruxtecan/DS-8201/T-DXd HER2-directed ADC	HER2 positive gastric cancer, 2L	Approved	US DESTINY-Gastric01
Trastuzumab deruxtecan/DS-8201/T-DXd HER2-directed ADC	HER2 mutated NSCLC, 2L or later	P2 prep	DESTINY-Lung02
Trastuzumab deruxtecan/DS-8201/T-DXd HER2-directed ADC	HER2 positive NSCLC, 1L	P1b prep	DESTINY-Lung03 Combination with durvalumab
Trastuzumab deruxtecan/DS-8201/T-DXd HER2-directed ADC	HER2 mutated tumor	P2	DESTINY-PanTumor01

◆ **Stage-up Projects (Major Changes from the FY2020 Q2 Financial Announcement in October 2020)**

Generic Name/Project Code Number Mechanism of action	Target indication	Current stage	Note
Datopotamab deruxtecan/DS-1062/ Dato-DXd TROP2-directed ADC	NSCLC (without actionable mutation)	P1 prep	TROPION-Lung04 Combination with durvalumab
Patritumab deruxtecan/U3-1402/ HER3-DXd HER3-directed ADC	EGFR mutated NSCLC	P2 prep	HERTHENA-Lung01
Patritumab deruxtecan/U3-1402/ HER3-DXd HER3-directed ADC	EGFR mutated NSCLC	P1 prep	Combination with osimertinib
Pexidartinib/PLX3397 CSF-1/KIT/FLT3 inhibitor	Tenosynovial giant cell tumor	P2 prep	Japan
Teserpaturev/ DS-1647/G47Δ Oncolytic HSV-1	Malignant glioma	Submitted	Japan
Axicabtagene ciloleucel/ Axi-Cel™ Anti-CD19 CAR-T cell	Relapsed/refractory large B-cell lymphoma	Approved	Japan
PLX2853 BET inhibitor	Prostate cancer	P1	US
Prasugrel/CS-747 ADP receptor inhibitor	Ischemic stroke	Submitted	Japan