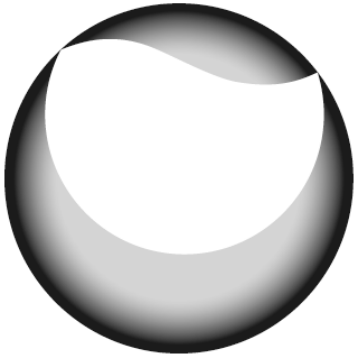
TSE:4568

Reference Data

(Consolidated Financial Results for Q2 FY2020)



Daiichi-Sankyo

October 30, 2020

Daiichi Sankyo Co., Ltd.

https://www.daiichisankyo.com

Contents

Daiichi-Sankyo

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2019 Q2 YTD to revenue	FY2019 Q2 YTD Results	FY2020 Q2 YTD to revenue	FY2020 Q2 YTD Results	(vs. Forecast (%))	YoY	YoY (%)	FY2020 to revenue	FY2020 Forecast (as of Apr.)	FY2020 to revenue	FY2020 Forecast (as of Oct.)	vs. Forecast (as of Apr.)	YoY	YoY (%)
Revenue	*100.0%*	**479.6**	*100.0%*	**480.2**	**(50.0%)**	**0.6**	**+0.1%**	*100.0%*	**970.0**	*100.0%*	**960.0**	**-10.0**	**-21.8**	**-2.2%**
Cost of sales	*36.9%*	177.1	*35.1%*	168.6	(49.6%)	-8.5	-4.8%	*34.7%*	337.0	*35.4%*	340.0	3.0	-3.2	-0.9%
(excl. Special items)	*35.9%*	172.0	*35.1%*	168.6		-3.4	-2.0%							
(Special items)	*1.1%*	5.1	-	-		-5.1	-							
Gross Profit	*63.1%*	302.5	*64.9%*	311.6	(50.3%)	9.1	+3.0%	*65.3%*	633.0	*64.6%*	620.0	-13.0	-18.6	-2.9%
SG&A expenses	*27.2%*	130.5	*31.0%*	148.6	(46.9%)	18.2	+13.9%	*33.5%*	325.0	*33.0%*	317.0	-8.0	14.7	+4.9%
(excl. Special items)	*29.4%*	141.1	*31.0%*	148.6		7.5	+5.3%							
(Special items)	*-2.2%*	-10.6	-	-		10.6	-							
R&D expenses	*17.9%*	85.9	*21.8%*	104.5	(43.0%)	18.7	+21.7%	*23.5%*	228.0	*25.3%*	243.0	15.0	45.5	+23.1%
(excl. Special items)	*17.9%*	85.9	*21.8%*	104.5		18.7	+21.7%							
(Special items)	-	-	-	-		-	-							
Operating Profit	*18.0%*	**86.2**	*12.2%*	**58.5**	**(97.4%)**	**-27.7**	**-32.1%**	*8.2%*	**80.0**	*6.3%*	**60.0**	**-20.0**	**-78.8**	**-56.8%**
(Operating Profit before Special items)	*16.8%*	80.7	*12.2%*	58.5		-22.2	-27.5%							
Financial income/expenses		0.8		8.5		7.7								
Share of profit or loss of investments accounted for using the equity method		0.1		0.0		-0.0								
Profit before tax	*18.1%*	**87.0**	*14.0%*	**67.0**	**(97.1%)**	**-20.1**	**-23.0%**	*8.2%*	**80.0**	*7.2%*	**69.0**	**-11.0**	**-72.2**	**-51.1%**
Income taxes		22.7		15.4		-7.3	-32.1%							
Profit for the year	*13.4%*	**64.4**	*10.7%*	**51.6**	**(97.3%)**	**-12.8**	**-19.9%**	*5.8%*	**56.0**	*5.5%*	**53.0**	**-3.0**	**-76.0**	**-58.9%**
Profit attributable to owners of the Company	*13.4%*	**64.4**	*10.8%*	**51.7**	**(97.5%)**	**-12.8**	**-19.8%**	*5.8%*	**56.0**	*5.5%*	**53.0**	**-3.0**	**-76.1**	**-58.9%**

Forex impact: -4.4 (USD: -1.4, EUR: -0.1, ASCA: -2.9)

Forex impact: -0.5 (USD: -0.1, ASCA: -0.4)

Forex impact: -1.5 (USD: -0.7, ASCA: -0.8)

Forex impact: -0.8 (USD: -0.7, ASCA: -0.1)

Forex impact: -1.6 (USD: +0.1, ASCA: -1.7)

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

	FY2019 Q2 YTD	FY2020 Q2 YTD
Tax rate	26.0%	23.0%
Overseas sales ratio	37.9%	40.5%

Currency Rate (Average)

	FY2019 Q2 YTD	FY2020 Q2 YTD	FY2020	FY2020
USD/JPY	108.63	106.92	110.00	108.46
EUR/JPY	121.41	121.29	120.00	120.65

Special items

		FY2019 Q2 YTD	FY2020 Q2 YTD
Cost of Sales	Restructuring costs in SC	1.3	-
	Impairment loss (intangible)	3.8	
SG&A expenses	Gain on sales of fixed assets	-10.6	-
Total		-5.5	-

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 Q2 YTD	FY2020 Q2 YTD				FY2020				
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Apr.)	Forecast (as of Oct.)	vs. Forecast (as of Apr.)	YoY	YoY (%)
Trastuzumab Deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	**4.9**	**17.7**	**(37.5%)**	**12.8**	**+260.0%**	**39.2**	**47.1**	**7.9**	**33.1**	**+237.5%**
Product sales		-	12.3	(35.3%)	12.3	-	28.5	34.9	6.4	31.6	+978.8%
Enhertu (JPN)		-	1.0	(17.3%)	1.0	-	1.5	5.6	4.1	5.6	-
Enhertu (US)		-	11.3	(38.8%)	11.3	-	27.0	29.2	2.2	26.0	+804.3%
Upfront payment		4.9	4.9	(50.0%)	-	-	9.8	9.8	-	-	-
Regulatory milestone payment		-	0.5	(18.7%)	0.5	-	0.9	2.4	1.5	1.5	+167.6%
DS-1062	anti-cancer agent (TROP2-directed antibody drug conjugate)	**-**	**1.0**	**(26.5%)**	**1.0**	**-**	**-**	**3.9**	**3.9**	**3.9**	**-**
Upfront payment		-	1.0	(26.5%)	1.0	-	-	3.9	3.9	3.9	-
Edoxaban	anticoagulant	**73.8**	**79.1**	**(49.2%)**	**5.4**	**+7.3%**	**163.0**	**160.9**	**-2.1**	**6.9**	**+4.5%**
Lixiana (JPN)		41.8	38.3	(50.6%)	-3.5	-8.4%	75.0	75.6	0.6	-7.4	-8.9%
Savaysa (US)		1.1	1.7	(59.9%)	0.6	+48.4%	2.0	2.8	0.8	0.2	+8.1%
Lixiana (EU)		27.5	35.0	(47.5%)	7.5	+27.4%	76.0	73.7	-2.3	12.0	+19.5%
Other subsidiaries		3.4	4.2	(47.2%)	0.8	+23.8%	10.0	8.8	-1.2	2.1	+30.7%
Olmesartan	antihypertensive agent	**50.7**	**48.1**	**(54.7%)**	**-2.6**	**-5.1%**	**78.0**	**88.0**	**10.0**	**-12.9**	**-12.8%**
Olmetec (JPN)		6.2	4.9	(59.6%)	-1.3	-21.1%	8.0	8.3	0.3	-3.4	-29.0%
Rezaltas (JPN)		7.5	6.8	(53.6%)	-0.8	-10.1%	12.0	12.6	0.6	-2.0	-13.4%
Olmesartan (US)		5.5	5.5	(61.1%)	-0.1	-1.1%	7.0	9.0	2.0	-0.9	-8.9%
Olmesartan (EU)		11.2	11.0	(51.8%)	-0.2	-1.5%	17.0	21.2	4.2	-3.4	-13.7%
Other subsidiaries, export, etc		20.2	19.9	(54.1%)	-0.3	-1.5%	34.0	36.8	2.8	-3.3	-8.2%
Prasugrel	antiplatelet agent	**9.4**	**8.6**	**-**	**-0.8**	**-8.2%**	**not disclosed**	**not disclosed**	**-**	**-**	**-**
Effient alliance revenue (US)		0.4	0.1	-	-0.3	-71.7%	not disclosed	not disclosed	-	-	-
Efient (EU)		1.4	0.8	(54.5%)	-0.6	-44.7%	1.0	1.4	0.4	-1.1	-44.8%
Efient (JPN)		7.1	7.2	(51.7%)	0.1	+1.2%	14.0	13.9	-0.1	-0.1	-0.9%
Other subsidiaries, export, etc		0.6	0.6	-	0.0	+1.6%	not disclosed	not disclosed	-	-	-

3. Revenue by Business Units and Products (1)

JPY Bn		FY2019 Q2 YTD	FY2020 Q2 YTD				FY2020				
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Apr.)	Forecast (as of Oct.)	vs. Forecast (as of Apr.)	YoY	YoY (%)
Japan		**261.0**	**250.1**	**(51.5%)**	**-10.9**	**-4.2%**	**483.0**	**485.4**	**2.4**	**-48.1**	**-9.0%**
Nexium	ulcer treatment	40.2	39.0	(50.8%)	-1.3	-3.1%	78.0	76.7	-1.3	-3.0	-3.8%
Lixiana	anticoagulant	41.8	38.3	(50.6%)	-3.5	-8.4%	75.0	75.6	0.6	-7.4	-8.9%
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	15.4	17.0	(48.7%)	1.5	+9.9%	33.0	34.9	1.9	3.9	+12.6%
Memary	Alzheimer's disease treatment	25.7	14.9	(77.1%)	-10.8	-42.2%	24.0	19.3	-4.7	-31.2	-61.8%
Tenelia	type 2 diabetes mellitus treatment	12.8	12.4	(51.8%)	-0.3	-2.6%	24.0	24.0	0.0	-0.7	-2.8%
Loxonin	anti-inflammatory analgesic	14.8	12.3	(52.5%)	-2.5	-16.9%	22.0	23.4	1.4	-4.8	-17.1%
Ranmark	treatment for bone complications caused by bone metastases from tumors	9.2	9.7	(49.4%)	0.5	+5.3%	18.0	19.6	1.6	1.7	+9.5%
Inavir	anti-influenza agent	1.0	1.3	(12.8%)	0.3	+34.8%	18.0	10.5	-7.5	-8.8	-45.4%
Tarlige	pain treatment	3.3	9.1	(45.8%)	5.8	+177.3%	16.0	20.0	4.0	12.0	+150.4%
Canalia	type 2 diabetes mellitus treatment	6.1	7.7	(49.4%)	1.5	+24.9%	15.0	15.5	0.5	2.7	+20.8%
Vimpat	anti-epileptic agent	5.2	7.1	(48.9%)	1.9	+36.6%	14.0	14.6	0.6	3.4	+30.5%
Efient	antiplatelet agent	7.1	7.2	(51.7%)	0.1	+1.2%	14.0	13.9	-0.1	-0.1	-0.9%
Rezaltas	antihypertensive agent	7.5	6.8	(53.6%)	-0.8	-10.1%	12.0	12.6	0.6	-2.0	-13.4%
Olmetec	antihypertensive agent	6.2	4.9	(59.6%)	-1.3	-21.1%	8.0	8.3	0.3	-3.4	-29.0%
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	-	1.0	(17.3%)	1.0	-	1.5	5.6	4.1	5.6	-
Daiichi Sankyo Espha products		31.4	34.2	-	2.9	+9.1%	not disclosed	not disclosed	-	-	-
Vaccines business		15.8	10.7	-	-5.1	-32.4%	not disclosed	not disclosed	-	-	-
Daiichi Sankyo Healthcare (OTC)		**34.1**	**33.0**	**(48.2%)**	**-1.0**	**-3.0%**	**74.0**	**68.5**	**-5.5**	**0.0**	**+0.0%**

3. Revenue by Business Units and Products (2)

JPY Bn		FY2019 Q2 YTD	FY2020 Q2 YTD				FY2020				
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Apr.)	Forecast (as of Oct.)	vs. Forecast (as of Apr.)	YoY	YoY (%)
Daiichi Sankyo, Inc. (US)		**14.9**	**23.5**	**(47.4%)**	**8.6**	**+57.9%**	**48.0**	**49.7**	**1.7**	**17.6**	**+54.9%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	-	11.3	(38.8%)	11.3	-	27.0	29.2	2.2	26.0	+804.3%
Olmesartan	antihypertensive agent	5.5	5.5	(61.1%)	-0.1	-1.1%	7.0	9.0	2.0	-0.9	-8.9%
Welchol	hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	4.8	2.2	(62.5%)	-2.6	-54.6%	3.0	3.5	0.5	-5.6	-61.7%
Effient	antiplatelet agent	0.4	0.1	-	-0.3	-71.7%	not disclosed	not disclosed	-	-	-
Savaysa	anticoagulant	1.1	1.7	(59.9%)	0.6	+48.4%	2.0	2.8	0.8	0.2	+8.1%
American Regent, Inc. (US)		**68.3**	**58.9**	**(48.3%)**	**-9.4**	**-13.7%**	**135.0**	**122.1**	**-12.9**	**-8.7**	**-6.6%**
Injectafer	treatment for iron deficiency anemia	26.0	21.0	(45.0%)	-5.0	-19.4%	56.0	46.6	-9.4	-5.2	-10.0%
Venofer	treatment for iron deficiency anemia	16.4	14.6	(52.0%)	-1.8	-10.8%	29.0	28.1	-0.9	-2.9	-9.2%
Daiichi Sankyo Europe GmbH		**43.2**	**54.3**	**(50.8%)**	**11.1**	**+25.7%**	**102.0**	**107.0**	**5.0**	**11.5**	**+12.0%**
Lixiana	anticoagulant	27.5	35.0	(47.5%)	7.5	+27.4%	76.0	73.7	-2.3	12.0	+19.5%
Olmesartan	antihypertensive agent	11.2	11.0	(51.8%)	-0.2	-1.5%	17.0	21.2	4.2	-3.4	-13.7%
Efient	antiplatelet agent	1.4	0.8	(54.5%)	-0.6	-44.7%	1.0	1.4	0.4	-1.1	-44.8%
Asia, South and Central America (ASCA)		**49.0**	**48.4**	**(48.9%)**	**-0.6**	**-1.2%**	**103.0**	**98.9**	**-4.1**	**0.6**	**+0.6%**
Daiichi Sankyo China		24.0	20.0	-	-4.0	-16.7%	not disclosed	not disclosed	-	-	-
Daiichi Sankyo Taiwan		3.6	4.1	-	0.4	+11.7%	not disclosed	not disclosed	-	-	-
Daiichi Sankyo Korea		8.3	9.5	-	1.2	+14.9%	not disclosed	not disclosed	-	-	-
Daiichi Sankyo Thailand		1.7	1.3	-	-0.4	-23.4%	not disclosed	not disclosed	-	-	-
Daiichi Sankyo Brasil Farmacêutica		5.7	5.4	-	-0.2	-4.1%	not disclosed	not disclosed	-	-	-

3. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

		FY2019 Q2 YTD	FY2020 Q2 YTD				FY2020				
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Apr.)	Forecast (as of Oct.)	vs. Forecast (as of Apr.)	YoY	YoY (%)
USD Mn											
Daiichi Sankyo, Inc. (US)		**137**	**220**	**(48.0%)**	**83**	**+60.5%**	**436**	**459**	**22**	**163**	**+55.2%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	-	106	(39.4%)	106	-	245	269	24	240	+806.0%
Olmesartan	antihypertensive agent	51	51	(62.0%)	0	+0.5%	64	83	19	-8	-8.7%
Welchol	hypercholesterolemia treatment/ type 2 diabetes mellitus treatment	44	20	(63.4%)	-24	-53.9%	27	32	5	-52	-61.6%
Effient	antiplatelet agent	3	1	-	-2	-71.3%	not disclosed	not disclosed	-	-	-
Savaysa	anticoagulant	10	16	(60.7%)	5	+50.8%	18	26	8	2	+8.3%
USD Mn											
American Regent, Inc. (US)		**629**	**551**	**(49.0%)**	**-78**	**-12.3%**	**1,227**	**1,126**	**-101**	**-78**	**-6.5%**
Injectafer	treatment for iron deficiency anemia	239	196	(45.6%)	-43	-18.1%	509	430	-79	-47	-9.9%
Venofer	treatment for iron deficiency anemia	151	137	(52.8%)	-14	-9.4%	264	259	-4	-26	-9.1%
EUR Mn											
Daiichi Sankyo Europe GmbH		**356**	**448**	**(50.5%)**	**92**	**+25.8%**	**850**	**887**	**37**	**98**	**+12.4%**
Lixiana	anticoagulant	226	289	(47.3%)	62	+27.5%	633	611	-23	101	+19.9%
Olmesartan	antihypertensive agent	92	91	(51.6%)	-1	-1.4%	142	176	34	-27	-13.5%
Efient	antiplatelet agent	11	6	(54.2%)	-5	-44.6%	8	12	3	-9	-44.6%

4. Consolidated Statement of Financial Position

<Assets> JPY Bn

	Mar. 2020	Sep. 2020	vs. Mar. 2020
Assets			
Current assets			
Cash and cash equivalents	424.2	451.3	27.1
Trade and other receivables	309.4	252.8	-56.6
Other financial assets	466.5	430.5	-36.0
Inventories	173.4	183.3	9.9
Other current assets	10.5	10.2	-0.4
Subtotal	1,384.0	1,328.0	-56.0
Assets held for sale	0.1	-	-0.1
Total current assets	**1,384.1**	**1,328.0**	**-56.1**
Non-current assets			
Property,plant and equipment	247.1	246.8	-0.2
Goodwill	76.8	75.2	-1.5
Intangible assets	172.5	174.4	1.9
Investments accounted for using the equity method	0.4	0.3	-0.1
Other financial assets	98.0	119.5	21.6
Deferred tax assets	114.7	123.2	8.5
Other non-current assets	12.1	12.2	0.2
Total non-current assets	**721.5**	**751.8**	**30.3**
Total assets	**2,105.6**	**2,079.8**	**-25.9**

Receivable for trastuzumab deruxtecan strategic collaboration upfront payment -74.5

Acquisition +16.2, Depreciation -15.8

Acquisition +17.5, Amortization -12.8, Forex impact -0.8

*	Liquidity on hand	891.2	882.9	-8.3
	Debt with interest	266.3	225.4	-40.9
	Net Cash	624.9	657.5	32.6

<Liabilities and equity>

JPY Bn

	Mar. 2020	Sep. 2020	vs. Mar. 2020
Liabilities			
Current liabilities			
Trade and other payables	270.9	232.4	-38.5
Bonds and borrowings	40.4	20.4	-20.0
Other financial liabilities	9.5	10.2	0.7
Income taxes payable	9.9	20.8	10.8
Provisions	5.4	4.7	-0.7
Other current liabilities	15.0	8.3	-6.7
Total current liabilities	**351.1**	**296.6**	**-54.4**
Non-current liabilities			
Bonds and borrowings	183.8	163.6	-20.2
Other financial liabilities	37.1	35.6	-1.5
Post employment benefit liabilities	5.3	5.4	0.1
Provisions	10.6	10.3	-0.3
Deferred tax liabilities	15.6	15.0	-0.6
Other non-current liabilities	195.8	219.5	23.6
Total non-current liabilities	**448.3**	**449.4**	**1.1**
Total liabilities	**799.3**	**746.0**	**-53.3**
Equity			
Equity attributable to owners of the Company			
Share capital	50.0	50.0	-
Capital surplus	94.6	94.6	-
Treasury shares	-162.5	-161.4	1.1
Other components of equity	82.1	79.4	-2.7
Retained earnings	1,241.6	1,270.7	29.1
Total equity attributable to owners of the Company	1,305.8	1,333.3	27.5
Non-controlling interests			
Non-controlling interests	0.5	0.4	-0.1
Total equity	**1,306.3**	**1,333.7**	**27.5**
Total liabilities and equity	**2,105.6**	**2,079.8**	**-25.9**

Upfront payment for strategic partnership of gene therapy manufacturing technology with Ultragenyx -13.5
Deferred revenue for DS-1062 (Strategic collaboration upfront payment) +5.8

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

Decrease in contingent consideration of quizartinib introduction -4.8

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

Deferred revenue for DS-1062 (Strategic collaboration upfront payment) +30.1
Deferred revenue for trastuzumab deruxtecan -5.4
(Strategic collaboration upfront payment -4.9, Regulatory milestone payment -0.5)

Profit for the period +51.7, Payment of dividends -22.7

5. Consolidated Statement of Cash Flows

JPY Bn

	FY2019 Q2 YTD	FY2020 Q2 YTD	YoY
Cash flows from operating activities			
Profit before tax	87.0	67.0	-20.1
Depreciation and amortization	26.4	28.5	2.1
(Increase) decrease in receivables and payables	18.0	33.9	15.8
Others, net	-18.8	-3.3	15.5
Income taxes paid	-10.3	-14.2	-3.8
Net cash flows from operating activities	**102.3**	**111.8**	**9.5**
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	22.5	34.9	12.4
(Acquisition of) proceeds from sales of fixed assets	-25.0	-46.6	-21.6
Net (increase) decrease in investment securities	9.1	-1.5	-10.6
Others, net	14.7	-0.4	-15.1
Net cash flows from investing activities	**21.3**	**-13.6**	**-34.9**
Cash flows from financing activities			
Net (increase) decrease in borrowings	3.8	-20.2	-24.0
Repayments of bonds	-40.0	-20.0	20.0
Purchase of treasury shares	-0.0	-0.0	0.0
Dividends paid	-22.7	-22.7	-0.0
Others, net	-4.9	-6.4	-1.4
Net cash flows from financing activities	**-63.9**	**-69.3**	**-5.4**
Net increase (decrease) in cash and cash equivalents	**59.7**	**29.0**	**-30.8**
Cash and cash equivalents at the beginning of the period	**243.2**	**424.2**	**181.0**
Effect of exchange rate changes on cash and cash equivalents	**-5.3**	**-1.9**	**3.4**
Cash and cash equivalents at the end of the period	**297.6**	**451.3**	**153.7**

*	**Free cash flows** (Cash flows from operating activities and investing activities)	**123.6**	**98.2**	**-25.4**

6. Number of Employees

	Sep. 2019 Results	Mar. 2020 Results	Sep. 2020 Results
Consolidated	15,494	15,348	15,878
Japan	9,163	8,754	8,952
North America	2,292	2,380	2,541
Europe	1,880	1,953	2,062
Others	2,159	2,261	2,323

7. Capital Expenditure, Depreciation and Amortization

JPY Bn	FY2019 Q2 YTD Results	FY2019 Results	FY2020 Q2 YTD Results	FY2020 Forecast
Capital expenditure	13.3	29.0	13.2	50.0
Depreciation and amortization	26.4	52.6	28.5	56.0
Property, plant and equipment	16.3	32.0	15.6	-
Intangible assets	10.1	20.6	12.9	-

8. Summary of Product Outlines

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

<9. Quarterly Data>

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2019 Q1 Results	FY2019 Q2 Results	FY2019 Q3 Results	FY2019 Q4 Results	FY2019 to revenue	FY2019 Results	FY2019 YoY	FY2019 YoY (%)	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 to revenue	FY2020 Results
Revenue	**249.2**	**230.3**	**277.5**	**224.8**	***100.0%***	**981.8**	**52.1**	**+5.6%**	**236.9**	**243.2**			***100.0%***	**480.2**
Cost of sales	87.9	89.2	79.2	86.9	*35.0%*	343.2	-21.4	-5.9%	82.2	86.4			*35.1%*	168.6
(excl. Special items)	86.6	85.4	98.0	84.5	*36.1%*	354.4	4.9	+1.4%	82.2	86.4			*35.1%*	168.6
(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			*64.9%*	311.6
SG&A expenses	63.2	67.3	77.8	94.1	*30.8%*	302.3	24.6	+8.9%	71.8	76.8			*31.0%*	148.6
(excl. Special items)	73.8	67.3	77.8	85.9	*31.0%*	304.8	23.6	+8.4%	71.8	76.8			*31.0%*	148.6
(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			*21.8%*	104.5
(excl. Special items)	41.2	44.7	51.1	60.5	*20.1%*	197.5	-6.2	-3.1%	48.8	55.7			*21.8%*	104.5
(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**			***12.2%***	**58.5**
(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			*12.2%*	58.5
Financial income/expenses	0.1	0.8	3.5	-2.3		2.0	-0.2		7.2	1.2				8.5
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
Profit before tax	**57.1**	**30.0**	**72.9**	**-18.8**	***14.4%***	**141.2**	**55.3**	**+64.5%**	**41.4**	**25.6**			***14.0%***	**67.0**
Income taxes	13.7	8.9	3.1	-13.6		12.2	19.8	-	9.6	5.8				15.4
Profit for the year	**43.3**	**21.1**	**69.8**	**-5.2**	***13.1%***	**129.0**	**35.5**	**+38.0%**	**31.8**	**19.8**			***10.7%***	**51.6**
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**			***10.8%***	**51.7**
Tax rate	24.1%	29.8%	4.3%	72.2%		8.6%			23.1%	22.8%				23.0%
Overseas sales ratio	37.5%	38.4%	34.9%	42.5%		38.1%			38.6%	42.3%				40.5%
Currency Rate (YTD Average)														
USD/JPY	109.90	108.63	108.67	108.75		108.75			107.62	106.92				106.92
EUR/JPY	123.49	121.41	121.05	120.83		120.83			118.47	121.29				121.29

<9. Quarterly Data>

2. Revenue of Global Products

JPY Bn	FY2019 Q1 Results	FY2019 Q2 Results	FY2019 Q3 Results	FY2019 Q4 Results	FY2019 Results	FY2019 YoY	FY2019 YoY (%)	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 Results
Trastuzumab deruxtecan	**2.5**	**2.5**	**3.2**	**5.9**	**14.0**	**13.9**	**-**	**7.9**	**9.8**			**17.7**
Product sales	-	-	0.0	3.2	3.2	3.2	-	5.2	7.1			12.3
Enhertu(JPN)	-	-	-	-	-	-	-	0.2	0.8			1.0
Enhertu (US)	-	-	0.0	3.2	3.2	3.2	-	5.0	6.3			11.3
Upfront payment	2.5	2.5	2.5	2.5	9.8	9.7	-	2.5	2.5			4.9
Regulatory milestone payment	-	-	0.7	0.2	0.9	0.9	-	0.2	0.2			0.5
DS-1062	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**1.0**			**1.0**
Upfront payment	-	-	-	-	-	-	-	-	1.0			1.0
Edoxaban	**37.2**	**36.5**	**42.6**	**37.6**	**154.0**	**36.3**	**+30.9%**	**38.7**	**40.4**			**79.1**
Lixiana (JPN)	21.6	20.2	23.8	17.4	83.0	18.1	+27.8%	19.8	18.5			38.3
Savaysa (US)	0.6	0.6	0.8	0.7	2.6	0.3	+13.8%	0.6	1.1			1.7
Lixiana (EU)	13.5	14.0	16.4	17.8	61.7	15.9	+34.7%	16.4	18.6			35.0
Other subsidiaries	1.6	1.7	1.7	1.7	6.8	2.1	+44.2%	1.9	2.2			4.2
Olmesartan	**27.5**	**23.2**	**26.3**	**23.9**	**100.8**	**-5.1**	**-4.8%**	**25.7**	**22.4**			**48.1**
Olmetec (JPN)	3.5	2.7	3.2	2.2	11.7	-3.2	-21.5%	2.7	2.2			4.9
Rezaltas (JPN)	4.2	3.4	4.1	3.0	14.6	-0.9	-5.8%	3.6	3.2			6.8
Olmesartan (US)	3.1	2.4	2.2	2.1	9.8	-0.9	-8.4%	3.7	1.8			5.5
Olmesartan (EU)	6.4	4.8	5.8	7.7	24.6	-2.8	-10.2%	5.2	5.8			11.0
Other subsidiaries, export, etc	10.3	9.9	11.0	8.9	40.1	2.7	+7.2%	10.5	9.5			19.9
Prasugrel	**5.0**	**4.4**	**4.9**	**3.8**	**18.1**	**-5.1**	**-21.9%**	**4.4**	**4.2**			**8.6**
Effient alliance revenue (US)	0.1	0.3	0.0	0.1	0.5	-2.0	-81.4%	-0.0	0.1			0.1
Efient (EU)	0.8	0.6	0.6	0.6	2.5	-3.2	-55.8%	0.3	0.4			0.8
Efient (JPN)	3.8	3.2	4.0	2.9	14.0	0.1	+0.7%	3.8	3.3			7.2
Other subsidiaries, export, etc	0.3	0.3	0.3	0.2	1.2	-0.0	-0.2%	0.3	0.3			0.6

3. Revenue by Business Units and Products (1)

JPY Bn	FY2019 Q1 Results	FY2019 Q2 Results	FY2019 Q3 Results	FY2019 Q4 Results	FY2019 Results	FY2019 YoY	FY2019 YoY (%)	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 Results
Japan	**139.0**	**122.0**	**161.3**	**111.2**	**533.5**	**10.2**	**+1.9%**	**130.2**	**119.9**			**250.1**
Nexium	21.9	18.3	22.1	17.4	79.8	1.5	+1.9%	19.9	19.1			39.0
Lixiana	21.6	20.2	23.8	17.4	83.0	18.1	+27.8%	19.8	18.5			38.3
Pralia	8.2	7.3	8.8	6.7	30.9	3.6	+13.0%	8.7	8.3			17.0
Memary	13.7	11.9	14.5	10.3	50.5	0.3	+0.6%	12.8	2.1			14.9
Tenelia	6.9	5.9	6.9	5.0	24.7	-0.6	-2.4%	6.6	5.9			12.4
Loxonin	7.8	7.0	7.9	5.5	28.3	-2.2	-7.3%	6.2	6.1			12.3
Ranmark	4.7	4.5	4.8	3.9	17.9	1.5	+9.1%	5.0	4.7			9.7
Inavir	0.0	1.0	10.5	7.7	19.3	1.1	+5.9%	0.6	0.7			1.3
Tarlige	2.0	1.3	2.1	2.6	8.0	8.0	-	4.3	4.9			9.1
Canalia	3.2	2.9	3.7	3.0	12.8	3.6	+38.8%	3.9	3.7			7.7
Vimpat	2.7	2.6	3.3	2.7	11.2	4.6	+70.0%	3.8	3.4			7.1
Efient	3.8	3.2	4.0	2.9	14.0	0.1	+0.7%	3.8	3.3			7.2
Rezaltas	4.2	3.4	4.1	3.0	14.6	-0.9	-5.8%	3.6	3.2			6.8
Olmetec	3.5	2.7	3.2	2.2	11.7	-3.2	-21.5%	2.7	2.2			4.9
Enhertu	-	-	-	-	-	-	-	0.2	0.8			1.0
Daiichi Sankyo Espha products	17.3	14.1	16.5	12.6	60.5	5.0	+8.9%	17.6	16.7			34.2
Vaccines business	7.5	8.4	16.9	2.8	35.6	-5.9	-14.2%	2.9	7.8			10.7
Daiichi Sankyo Healthcare (OTC)	**15.4**	**18.7**	**18.8**	**15.6**	**68.5**	**2.1**	**+3.2%**	**14.3**	**18.7**			**33.0**

3. Revenue by Business Units and Products (2)

JPY Bn	FY2019 Q1 Results	FY2019 Q2 Results	FY2019 Q3 Results	FY2019 Q4 Results	FY2019 Results	FY2019 YoY	FY2019 YoY (%)	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 Results
Daiichi Sankyo, Inc. (US)	**7.8**	**7.1**	**8.9**	**8.3**	**32.1**	**-4.2**	**-11.5%**	**11.6**	**12.0**			**23.5**
Enhertu	-	-	0.0	3.2	3.2	3.2	-	5.0	6.3			11.3
Olmesartan	3.1	2.4	2.2	2.1	9.8	-0.9	-8.4%	3.7	1.8			5.5
Welchol	2.6	2.2	3.8	0.5	9.1	-4.3	-31.9%	0.6	1.6			2.2
Effient	0.1	0.3	0.0	0.1	0.5	-2.0	-81.4%	-0.0	0.1			0.1
Savaysa	0.6	0.6	0.8	0.7	2.6	0.3	+13.8%	0.6	1.1			1.7
American Regent, Inc. (US)	**36.0**	**32.4**	**31.4**	**31.0**	**130.8**	**13.0**	**+11.0%**	**26.5**	**32.5**			**58.9**
Injectafer	13.7	12.3	13.3	12.5	51.8	7.6	+17.2%	9.4	11.5			21.0
Venofer	9.3	7.1	6.9	7.7	31.0	2.1	+7.1%	6.9	7.7			14.6
Daiichi Sankyo Europe GmbH	**22.1**	**21.1**	**24.5**	**27.8**	**95.5**	**6.9**	**+7.8%**	**27.7**	**26.6**			**54.3**
Lixiana	13.5	14.0	16.4	17.8	61.7	15.9	+34.7%	16.4	18.6			35.0
Olmesartan	6.4	4.8	5.8	7.7	24.6	-2.8	-10.2%	5.2	5.8			11.0
Efient	0.8	0.6	0.6	0.6	2.5	-3.2	-55.8%	0.3	0.4			0.8
Asia, South and Central America (ASCA)	**24.3**	**24.6**	**24.6**	**24.8**	**98.3**	**10.7**	**+12.2%**	**22.5**	**25.8**			**48.4**
Daiichi Sankyo China	12.0	12.0	10.9	11.1	46.0	7.6	+19.6%	8.6	11.4			20.0
Daiichi Sankyo Taiwan	1.9	1.8	1.9	2.1	7.6	0.5	+6.7%	2.1	2.0			4.1
Daiichi Sankyo Korea	4.0	4.3	4.2	4.7	17.2	1.5	+9.5%	4.4	5.0			9.5
Daiichi Sankyo Thailand	0.8	0.8	0.9	0.8	3.3	0.1	+2.4%	0.6	0.7			1.3
Daiichi Sankyo Brasil Farmacêutica	2.8	2.9	3.4	2.5	11.5	1.5	+14.6%	2.9	2.6			5.4

3. Revenue by Business Units and Products (3) [Reference] Revenue in Local Currency	FY2019 Q1	FY2019 Q2	FY2019 Q3	FY2019 Q4	FY2019			FY2020 Q1	FY2020 Q2	FY2020 Q3	FY2020 Q4	FY2020
	Results	Results	Results	Results	Results	YoY	YoY (%)	Results	Results	Results	Results	Results
USD Mn												
Daiichi Sankyo, Inc. (US)	**71**	**66**	**82**	**76**	**295**	**-32**	**-9.7%**	**107**	**11**			**220**
Enhertu	-	-	0	30	30	30	-	46	6			106
Olmesartan	28	23	21	19	91	-6	-6.5%	35	2			51
Welchol	23	21	35	5	84	-37	-30.5%	5	2			20
Effient	1	2	0	1	4	-18	-81.1%	-0	0			1
Savaysa	5	5	7	7	24	3	+16.1%	5	1			16
USD Mn												
American Regent, Inc. (US)	**327**	**302**	**289**	**286**	**1,204**	**142**	**+13.3%**	**246**	**31**			**551**
Injectafer	125	114	123	115	477	78	+19.7%	88	11			196
Venofer	85	66	64	70	285	24	+9.3%	64	7			137
EUR Mn												
Daiichi Sankyo Europe GmbH	**179**	**177**	**203**	**230**	**789**	**99**	**+14.4%**	**234**	**21**			**448**
Lixiana	109	117	136	147	509	153	+42.9%	139	15			289
Olmesartan	52	40	48	63	203	-10	-4.7%	44	5			91
Efient	6	5	5	5	21	-24	-53.1%	3	0			6

<10. Historical Data>

1. Revenue of Global Products

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

2. Revenue by Business Units and Products (1)

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

2. Revenue by Business Units and Products (2)

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

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

11. Major R&D Pipeline (Innovative Pharmaceuticals)

As of October 2020

◆ Explanation of Description

Generic name/project Code Number (mechanism of action)

Detail on its mechanism

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

◆ List of Abbreviations

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

◆ 3 ADCs

Trastuzumab deruxtecan / DS-8201 (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)

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) Jun 2020: submission validated (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 H2
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 H1
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 H2
Phase 3 prep DESTINY-Breast05 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: FY2020 H2 planned

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase3 DESTINY-Breast06 NCT04494425 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 prep 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.	TBD	FPD: FY2020 H2 planned
Phase1b prep 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.	TBD	FPD: FY2020 H2 planned
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 Mar 2018: SAKIGAKE Designation (JP) May 2020: Breakthrough Therapy Designation (US) May 2020: Orphan Drug Designation (US) Sep 2020: approved (JP) Oct 2020: submission accepted (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

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1b/2 DESTINY-Gastric03 NCT04379596 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 ・DS-8201 + durvalumab + fluorouracil or capecitabine Part 2 ・DS-8201 ・DS-8201 + oxaliplatin + fluorouracil or capecitabine ・DS-8201 + durvalumab + fluorouracil or capecitabine ・Trastuzumab + fluorouracil or capecitabine + cisplatin or oxaliplatin	Primary endpoint: Part 1: safety, Part 2: ORR Secondary endpoint: ORR, safety, DOR, DCR, PFS, OS, PK	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
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 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

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
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
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

DS-1062 (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 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	JP/US	FPD: Feb 2018
Phase 1 TROPION-Lung02 NCT04526691 AstraZeneca Merck	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 2 prep TROPION-Lung05 NCT04484142 AstraZeneca	NSCLC (with actionable mutation)	150	Randomized, open label ・DS-1062	Primary endpoint: ORR Secondary endpoint: DOR, PFS, OS, safety	JP/US/EU/ Asia	FPD：FY2020 Q3 planned

Patritumab deruxtecan / U3-1402 (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
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 NCT04479436 jRCT2031200139	Colorectal cancer, 3L	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 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 1 NCT02734433	Solid tumors	11	Open label ・Pexidartinib	Primary endpoint: safety Secondary endpoint: PK, antitumor effect	Asia	FPD: Sep 2016

DS-1647 / G47Δ (oncolytic HSV-1)

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2/IIS (pivotal) ActiVec Inc.	Malignant glioma	30	Non-randomised, open label ・DS-1647/G47Δ	Primary endpoint: 1-year survival rate Secondary endpoint: OS, PFS, tumor response	JP	TLR: FY2018 Q4 Submission planned: FY2020 H2 Feb 2016: SAKIGAKE Designation Jul 2017: Orphan Drug Designation

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

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 (pivotal) JapicCTI-183914 Kite/Gilead	Relapsed/refractory B-cell lymphoma	10	Non-randomized, open label ・Axicabtagene ciloleucel	Primary endpoint: ORR Secondary endpoints: safety, ORR, DOR, PFS, OS, PK	JP	FPD: Nov 2018 Mar 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 and etc.	JP	FPD: Dec 2019
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 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	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

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

◆ 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 (JP)

Prasugrel / CS-747 (ADP receptor inhibitor)

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 JapicCTI-184141	Ischemic stroke	250	Randomized, double-blind, active-controlled ・Prasugrel ・Clopidogrel	Primary endpoint: incidence rate of cerebro-cardiovascular events Secondary endpoint: incidence rate of bleeding events	JP	FPD: Oct 2018 TLR: Jun 2020 Submission planned: FY2020 Q4

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

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

Study name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 NCT03901352 JapicCTI-194653	Central neuropathic pain	274	Randomized, 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 Data anticipated: FY2020 Q4 Submission planned: FY2021
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)

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 Data anticipated: FY2020 3Q Apr 2017: SAKIGAKE Designation Apr 2018: announced TLR of 12-week treatment study
Phase 2 NCT04433234 JapicCTI-205321	Duchenne muscular dystrophy	8	Long-term study of above phase 1/2 study ・DS-5141	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 Q1 Financial Announcement in July 2020)

Generic Name/Project Code Number Mechanism of action	Target indication	Current stage	Note
Trastuzumab deruxtecan/DS-8201 HER2-directed ADC	HER2 overexpressing gastric or gastroesophageal junction adenocarcinoma	Approved (JP)	DESTINY-Gastric01
Trastuzumab deruxtecan/DS-8201 HER2-directed ADC	HER2 positive, with residual invasive breast cancer following neoadjuvant therapy	P3 prep	DESTINY-Breast05
Trastuzumab deruxtecan/DS-8201 HER2-directed ADC	HER2 low/HR positive breast cancer, chemotehrapy naïve	P3	DESTINY-Breast06
Trastuzumab deruxtecan/DS-8201 HER2-directed ADC	HER2 positive breast cancer Part 1: 2L or later Part 2: 1L	P1b/2 prep	DESTINY-Breast07
Trastuzumab deruxtecan/DS-8201 HER2-directed ADC	HER2 low breast cancer Chemotherapy naïve, post chemotherapy	P1b prep	DESTINY-Breast08
Trastuzumab deruxtecan/DS-8201 HER2-directed ADC	HER2 expressing tumors (bladder cancer, biliary tract cancer, cervical cancer, endometrial cancer, ovarian cancer, pancreatic cancer, rare tumors)	P2	DESTINY-PanTumor02
DS-1062 TROP2-directed ADC	NSCLC (without actionable mutation)	P1	TROPION-Lung02 Combination with pembrolizumab
DS-1062 TROP2-directed ADC	NSCLC (with actionable mutation)	P2 prep	TROPION-Lung05
Patritumab deruxtecan/U3-1402 HER3-directed ADC	Colorectal cancer, 3L	P2	
DS-1001 Mutant IDH1 inhibitor	Glioma	P2	
DS-1055 Anti-GARP antibody	Solid tumors	P1	

◆ Licensed Out Project (Major Changes from the FY2020 Q1 Financial Announcement in July 2020)

Generic Name/Project Code Number Mechanism of action	Target indication	Stage	Note
Milademetan/DS-3032 MDM2 inhibitor	Solid tumors, acute myeloid leukemia and etc.	P1	Licensed out to Rain Therapeutics
DS-1205 AXL inhibitor	EGFR mutant NSCLC	P1	Licensed out to AnHeart Therapeutics