TSE:4568

Reference Data

(Consolidated Financial Results for Q4 FY2021)

Daiichi-Sankyo

April 27, 2022

Daiichi Sankyo Co., Ltd.

https://www.daiichisankyo.com

Contents

Daiichi-Sankyo

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2020 to revenue	FY2020 Results	FY2021 to revenue	FY2021 Results	(vs. Forecast (%))	FY2021 YoY	FY2021 YoY (%)	FY2022 to revenue	FY2022 Forecast	FY2022 YoY	FY2022 YoY (%)
Revenue	*100.0%*	**962.5**	*100.0%*	**1,044.9**	*101.4%*	**82.4**	*+8.6%*	*100.0%*	**1,150.0**	**105.1**	*+10.1%*
Cost of sales※1	*35.1%*	337.8	*33.3%*	348.0	*105.5%*	10.3	*+3.0%*	*28.5%*	328.0	-20.0	*-5.8%*
Gross Profit	*64.9%*	624.8	*66.7%*	696.9	*99.6%*	72.1	*+11.5%*	*71.5%*	822.0	125.1	*+18.0%*
SG&A expenses※1	*33.1%*	318.5	*33.7%*	352.1	*99.2%*	33.7	*+10.6%*	*35.7%*	410.0	57.9	*+16.4%*
R&D expenses※1	*23.6%*	227.4	*24.3%*	254.1	*99.7%*	26.7	*+11.7%*	*26.7%*	307.0	52.9	*+20.8%*
Core Operating Profit	*8.2%*	**78.9**	*8.7%*	**90.6**	*100.7%*	**11.8**	*+14.9%*	*9.1%*	**105.0**	**14.4**	*+15.9%*
Temporary income※2		0.6		3.9		3.4			-	-3.9	
Temporary expenses※2		15.6		21.5		5.9			-	-21.5	
Operating Profit	*6.6%*	**63.8**	*7.0%*	**73.0**	*79.4%*	**9.2**	*+14.5%*	*9.1%*	**105.0**	**32.0**	*+43.8%*
Financial income/expenses		10.2		0.4		-9.8					
Share of profit or loss of investments accounted for using the equity method		0.2		0.1		-0.0					
Profit before tax	*7.7%*	**74.1**	*7.0%*	**73.5**	*79.9%*	**-0.6**	*-0.8%*	*9.1%*	**105.0**	**31.5**	*+42.8%*
Income taxes		-1.7		6.5		8.2					
Profit for the year	*7.9%*	**75.8**	*6.4%*	**67.0**	*104.6%*	**-8.9**	*-11.7%*	*7.2%*	**83.0**	**16.0**	*+23.9%*
Profit attributable to owners of the Company	*7.9%*	**76.0**	*6.4%*	**67.0**	*104.6%*	**-9.0**	*-11.8%*	*7.2%*	**83.0**	**16.0**	*+23.9%*
Tax rate		-2.3%		8.9%							
Overseas sales ratio		41.7%		46.6%							

Forex impact: +28.7
(USD: +12.7, EUR: +7.2, ASCA: +8.7)

Forex impact: +3.8
(USD: +4.0, EUR: -1.5, ASCA: +1.3)

Forex impact: +11.7
(USD: +5.9, EUR: +2.4, ASCA: +3.3)

Forex impact: +9.2
(USD: +6.9, EUR: +2.0, ASCA: +0.3)

Forex impact: +3.9
(USD: -4.2, EUR: +4.4, ASCA: +3.7)

- Recognition of financial income due to decrease in contingent consideration of quizartinib acquisition -4.7 (FY2020)
- Deterioration in forex gains/losses -1.1

Currency Rate (Average)

	FY2020	FY2021	FY2022
USD/JPY	106.06	112.38	130.00
EUR/JPY	123.70	130.56	140.00

Annual impact of one yen change

	Forecast	
	USD	EUR
Revenue	2.5 JPY Bn	1.2 JPY Bn
Operating Profit	-0.5 JPY Bn	0.3 JPY Bn

*This report is not subject to audit procedures.

※1 Temporary income and expenses are excluded for cost of sales, SG&A expenses and R&D expenses

※2 See page 2 for the definition of temporary income and expenses and the adjustment of operating profit and core operating profit

2. Sheet to adjust Operating Profit to Core Operating Profit

FY2020 Results

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

<Major Temporary income and Temporary expenses>

*1 Vaccine business loss compensation (15.0)

FY2021 Results

JPY Bn	Operating Profit (full)	Adjustment					Operating Profit (Core)
		gains and losses related to sale of fixed assets	gains and losses related to restructuring	gains and losses related to impairment,	gains and losses related to loss compensation, reconciliation	Others	
Revenue	**1,044.9**						**1,044.9**
Cost of sales	353.3	0.0	-	5.3	-	-	348.0
SG&A expenses	358.3	-3.8	0.5	0.0	-	9.5	352.1
R&D expenses	260.2	-0.1	1.0	5.2	-	-	254.1
Core Operating Profit	**73.0**	-3.9	1.6	10.4	-	9.5	**90.6**
Temporary income		3.9	-	-	-	0.0	3.9
(Cost of sales)		0.0					0.0
(SG&A expenses)		3.8 *1				0.0	3.8
(R&D expenses)		0.1					0.1
Temporary expenses		0.0	1.6	10.4	-	9.5	21.5
(Cost of sales)		0.0		5.3 *2			5.3
(SG&A expenses)		0.0	0.5 *3	0.0		9.5 *4	10.0
(R&D expenses)		0.0	1.0 *3	5.2 *3			6.2
Operating Profit (full)	**73.0**	-	-	-	-	-	**73.0**

<Major Temporary income and Temporary expenses>

*1 Gains related to sale of fixed assets of Osaka logistics center (2.1)

*2 Losses rerated to impairment of Intangible assets of Zelboraf (2.8)

Losses rerated to impairment of Intangible assets of Turalio (2.2)

*3 Losses related to closure of PLX (5.8)

*4 Environmental expenditures related to former Yasugawa plant (9.5)

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

3. Revenue of Global Products (1)

JPY Bn		FY2020 Results	FY2021 Results	(vs. Forecast (%))	YoY	YoY (%)	FY2022 Forecast	YoY	YoY (%)
Trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	**43.5**	**80.8**	**(105.5%)**	**37.4**	**+85.9%**	**159.9**	**79.1**	**+97.8%**
Product sales	*Incl. Gross profit share in AstraZeneca territory	30.1	65.4	(106.9%)	35.3	+117.1%	128.4	63.0	+96.4%
Enhertu (JPN)		4.4	9.6	(95.6%)	5.2	+119.5%	16.0	6.4	+67.4%
Enhertu (US)		25.7	45.4	(103.5%)	19.7	+76.4%	83.1	37.7	+83.0%
Enhertu (EU)		0.0	9.0	(126.8%)	9.0	-	23.0	14.0	+154.7%
Enhertu (ASCA: Asia, South and Central America)		-	1.4	-	1.4	-	6.3	4.9	+355.8%
Upfront payment		9.8	9.8	(100.0%)	-	-	9.8	-	-
Regulatory milestone payment		3.5	2.2	(100.0%)	-1.3	-37.2%	20.6	18.3	+824.4%
US HER2+ Breast Cancer 3L		0.9	0.9	(100.0%)	-	-	0.9	-	-
EU HER2+ Breast Cancer 3L		1.0	0.5	(100.0%)	-0.5	-50.0%	0.5	-	-
US HER2+ Gastric Cancer 2L/3L		1.6	0.8	(100.0%)	-0.8	-50.0%	0.8	-	-
US HER2+ Breast Cancer 2L		-	-	-	-	-	3.4	3.4	-
EU HER2+ Breast Cancer 2L		-	-	-	-	-	2.6	2.6	-
US HER2-low Breast Cancer (post chemo)		-	-	-	-	-	6.9	6.9	-
EU HER2+ Gastric Cancer 2L		-	-	-	-	-	1.2	1.2	-
US HER2+ or HER2 Mutant NSCLC 2L		-	-	-	-	-	4.3	4.3	-
Quid related payment*		-	3.4	(100.0%)	3.4	-	1.1	-2.3	-66.7%
Datopotamab deruxtecan	anti-cancer agent (TROP2-directed antibody drug conjugate)	**3.9**	**6.1**	**(100.0%)**	**2.1**	**+53.7%**	**6.9**	**0.9**	**+14.1%**
Upfront payment		3.9	6.1	(100.0%)	2.1	+53.7%	6.9	0.9	+14.1%

*Payment which shall be paid by AstraZeneca to Daiichi Sankyo if both parties do not enter into potential licensing opportunity (Granting Daiichi Sankyo rights to develop or commercialize AstraZeneca's proprietary products, programs or technologies)

3. Revenue of Global Products (2)

JPY Bn		FY2020	FY2021				FY2022		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Edoxaban	anticoagulant	**165.9**	**205.6**	**(101.4%)**	**39.7**	**+23.9%**	**237.7**	**32.1**	**+15.6%**
Lixiana (JPN)		77.4	92.5	(100.6%)	15.1	+19.5%	104.3	11.8	+12.8%
Savaysa (US)		3.0	1.9	(100.8%)	-1.1	-35.4%	2.4	0.5	+26.4%
Lixiana (EU)		76.7	96.9	(101.4%)	20.2	+26.4%	112.1	15.2	+15.7%
Edoxaban (ASCA: Asia, South and Central America)		8.9	14.3	(106.5%)	5.4	+61.2%	18.8	4.5	+31.8%

4. Revenue by Business Units and Products (1)

JPY Bn		FY2020	FY2021				FY2022		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Japan Business Unit		**489.1**	**489.5**	**(100.1%)**	**0.4**	**+0.1%**	**483.8**	**-5.7**	**-1.2%**
Lixiana	anticoagulant	77.4	92.5	(100.6%)	15.1	+19.5%	104.3	11.8	+12.8%
Nexium	ulcer treatment	77.8	39.6	(100.0%)	-38.2	-49.1%	-	-39.6	-
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	34.6	37.9	(102.7%)	3.3	+9.4%	36.0	-1.9	-5.0%
Tarlige	pain treatment	20.6	30.1	(100.2%)	9.6	+46.6%	38.2	8.1	+26.8%
Tenelia	type 2 diabetes mellitus treatment	24.2	23.7	(99.4%)	-0.6	-2.4%	23.0	-0.6	-2.6%
Ranmark	treatment for bone complications caused by bone metastases from tumors	19.3	20.4	(102.5%)	1.1	+5.6%	21.0	0.6	+2.9%
Loxonin	anti-inflammatory analgesic	24.2	22.2	(97.7%)	-2.0	-8.2%	17.5	-4.7	-21.0%
Vimpat	anti-epileptic agent	14.5	18.3	(100.1%)	3.7	+25.6%	21.9	3.6	+19.5%
Canalia	type 2 diabetes mellitus treatment	15.4	16.8	(99.6%)	1.4	+8.8%	18.8	2.0	+11.9%
Efient	antiplatelet agent	14.1	16.7	(100.4%)	2.7	+18.9%	23.5	6.8	+40.7%
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	4.4	9.6	(95.6%)	5.2	+119.5%	16.0	6.4	+67.4%
Rezaltas	antihypertensive agent	13.1	12.0	(97.6%)	-1.1	-8.6%	8.4	-3.6	-30.2%
Inavir	anti-influenza agent	3.6	1.3	(100.0%)	-2.3	-63.1%	8.7	7.3	+547.5%
Emgality	prophylaxis of migraine attacks	-	4.6	-	4.6	-	13.1	8.5	+182.8%
Daiichi Sankyo Espha products		71.4	82.8	-	11.4	+15.9%	not disclosed	-	-
Vaccines business		18.5	14.8	-	-3.7	-20.2%	not disclosed	-	-
Daiichi Sankyo Healthcare Unit		**67.2**	**64.7**	**(93.2%)**	**-2.5**	**-3.7%**	**69.4**	**4.7**	**+7.3%**

4. Revenue by Business Units and Products (2)

JPY Bn		FY2020 Results	FY2021 Results	(vs. Forecast (%))	YoY	YoY (%)	FY2022 Forecast	YoY	YoY (%)
Oncology Business Unit*1		**47.4**	**69.6**	**(103.2%)**	**22.2**	**+46.9%**	**110.0**	**40.4**	**+58.1%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	25.7	54.4	(106.8%)	28.7	+111.5%	106.1	51.7	+94.9%
Enhertu (US)		25.7	45.4	(103.5%)	19.7	+76.4%	83.1	37.7	+83.0%
Enhertu (EU)		0.0	9.0	(126.8%)	9.0	-	23.0	14.0	+154.7%
TURALIO	anti-cancer agent	1.8	2.8	(104.0%)	1.0	+53.7%	3.9	1.1	+40.7%
American Regent Unit		**121.7**	**149.5**	**(101.5%)**	**27.7**	**+22.8%**	**175.8**	**26.3**	**+17.6%**
Injectafer	treatment for iron deficiency anemia	44.1	53.1	(99.8%)	8.9	+20.2%	63.1	10.0	+18.8%
Venofer	treatment for iron deficiency anemia	28.8	33.8	(105.0%)	4.9	+17.1%	37.4	3.6	+10.8%
EU Specialty Business Unit*2		**111.7**	**128.2**	**(101.8%)**	**16.6**	**+14.9%**	**139.5**	**11.2**	**+8.7%**
Lixiana	anticoagulant	76.7	96.9	(101.4%)	20.2	+26.4%	112.1	15.2	+15.7%
Nilemdo/Nustendi	cholesterol-lowering agent	0.6	3.1	(109.5%)	2.6	+448.2%	7.1	4.0	+127.0%
Olmesartan	antihypertensive agent	21.5	20.3	(101.6%)	-1.2	-5.6%	16.1	-4.2	-20.8%
ASCA Business Unit		**99.7**	**114.1**	**(104.4%)**	**14.5**	**+14.5%**	**126.3**	**12.1**	**+10.6%**
Daiichi Sankyo China		45.6	53.3	(105.6%)	7.7	+16.9%	61.0	7.7	+14.4%
Daiichi Sankyo Korea		19.6	23.2	(98.5%)	3.6	+18.4%	23.0	-0.1	-0.5%
Daiichi Sankyo Brasil Farmacêutica		10.5	13.7	(107.1%)	3.2	+30.5%	17.2	3.6	+26.0%
Daiichi Sankyo Taiwan		8.3	10.0	(114.6%)	1.7	+20.4%	9.9	-0.1	-1.1%
Daiichi Sankyo Thailand		2.3	2.2	(102.2%)	-0.1	-4.2%	2.3	0.1	+4.9%
Daiichi Sankyo Hong Kong		0.7	1.7	-	1.0	+151.6%	4.4	2.7	+165.8%

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

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

4. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

		FY2020	FY2021				FY2022		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
USD Mn									
Oncology Business Unit*1		**447**	**619**	**(100.6%)**	**173**	**+38.7%**	**846**	**227**	**+36.6%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	243	484	(104.1%)	242	+99.7%	816	332	+68.5%
Enhertu (US)		243	404	(100.9%)	161	+66.5%	639	235	+58.2%
Enhertu (EU)		0.1	80	(123.6%)	80	-	177	97	+120.2%
TURALIO	anti-cancer agent	17	25	(101.4%)	8	+45.0%	30	5	+21.6%

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

USD Mn									
American Regent Unit		**1,148**	**1,330**	**(98.9%)**	**182**	**+15.9%**	**1,352**	**22**	**+1.7%**
Injectafer	treatment for iron deficiency anemia	416	472	(97.3%)	56	+13.5%	485	13	+2.7%
Venofer	treatment for iron deficiency anemia	272	300	(102.4%)	29	+10.5%	288	-13	-4.3%
EUR Mn									
EU Specialty Business Unit*2		**903**	**982**	**(99.8%)**	**80**	**+8.8%**	**996**	**14**	**+1.4%**
Lixiana	anticoagulant	620	742	(99.4%)	122	+19.7%	801	58	+7.9%
Nilemdo/Nustendi	cholesterol-lowering agent	5	24	(107.3%)	19	+419.4%	51	27	+111.7%
Olmesartan	antihypertensive agent	174	155	(99.6%)	-18	-10.6%	115	-41	-26.1%

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

5. Consolidated Statement of Financial Position

<Assets> JPY Bn

	Mar. 2021	Mar. 2022	vs. Mar. 2021
Assets			
Current assets			
Cash and cash equivalents	380.5	662.5	281.9
Trade and other receivables	232.0	266.7	34.6
Other financial assets	444.4	181.4	-263.0
Inventories	200.9	217.9	17.0
Other current assets	10.6	16.8	6.2
Total current assets	**1,268.4**	**1,345.3**	**76.9**
Non-current assets			
Property,plant and equipment	265.3	304.1	38.8
Goodwill	77.7	83.6	5.8
Intangible assets	172.8	163.9	-8.9
Investments accounted for using the equity method	1.4	1.4	-0.0
Other financial assets	140.0	131.5	-8.5
Deferred tax assets	128.5	138.2	9.6
Other non-current assets	31.0	53.5	22.5
Total non-current assets	**816.8**	**876.1**	**59.4**
Total assets	**2,085.2**	**2,221.4**	**136.2**

*	Liquidity on hand	827.2	842.9	15.7
	Debt with interest	226.2	213.6	-12.6
	Net Cash	601.0	629.3	28.3

Acquisition +75.1, Depreciation -33.0, Impairment Loss -4.7

Acquisition +13.9, Amortization -25.0, Impairment Loss -5.8

Investment securities -7.7

Contribution for equipment +11.1

<Liabilities and equity>

JPY Bn

	Mar. 2021	Mar. 2022	vs. Mar. 2021
Liabilities			
Current liabilities			
Trade and other payables	297.5	324.8	27.3
Bonds and borrowings	20.4	20.4	0.0
Other financial liabilities	9.4	10.8	1.4
Income taxes payable	6.1	6.9	0.8
Provisions	6.1	6.8	0.7
Other current liabilities	14.2	25.6	11.4
Total current liabilities	**353.6**	**395.3**	**41.7**
Non-current liabilities			
Bonds and borrowings	163.4	143.1	-20.4
Other financial liabilities	37.0	42.6	5.6
Post employment benefit liabilities	3.9	2.6	-1.3
Provisions	8.7	18.3	9.5
Deferred tax liabilities	17.5	12.4	-5.1
Other non-current liabilities	228.9	256.2	27.3
Total non-current liabilities	**459.6**	**475.3**	**15.7**
Total liabilities	**813.1**	**870.5**	**57.4**
Equity			
Equity attributable to owners of the Company			
Share capital	50.0	50.0	-
Capital surplus	94.5	-	-94.5
Treasury shares	-261.3	-37.5	223.8
Other components of equity	111.5	168.1	56.7
Retained earnings	1,277.3	1,170.2	-107.1
Total equity attributable to owners of the Company	1,272.1	1,350.9	78.8
Total equity	**1,272.1**	**1,350.9**	**78.8**
Total liabilities and equity	**2,085.2**	**2,221.4**	**136.2**

Vaccine business loss compensation -15.0

Repayment of syndicated loan -20.0
Transfer of syndicated loan +20.0
(Transfer from Non-current liabilities "Bonds and borrowings")

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

Deferred revenue for datopotamab deruxtecan +29.5 (Strategic collaboration upfront payment +35.6, Profit recording -6.1)
Deferred revenue for trastuzumab deruxtecan +0.6
(Strategic collaboration upfront payment -9.8, Regulatory milestone payment +10.5)

Acquisition of treasury shares -94.5

Acquisition of treasury shares +223.0

Profit for the period +67.0, Payment of dividends -51.7,
Acquisition of treasury shares -128.5

6. Consolidated Statement of Cash Flows

JPY Bn

	FY2020	FY2021	YoY
Cash flows from operating activities			
Profit before tax	74.1	73.5	-0.6
Depreciation and amortization	57.4	58.2	0.9
(Increase) decrease in receivables and payables	107.0	-5.8	-112.7
Others, net	-21.7	35.8	57.6
Income taxes paid	-24.5	-22.6	1.9
Net cash flows from operating activities	**192.2**	**139.2**	**-53.0**
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	29.2	283.3	254.1
(Acquisition of) proceeds from sales of fixed assets	-64.1	-70.8	-6.8
Net (increase) decrease in investment securities	-0.2	0.1	0.3
Others, net	-4.2	-0.2	4.0
Net cash flows from investing activities	**-39.2**	**212.3**	**251.6**
Cash flows from financing activities			
Net (increase) decrease in borrowings	-20.4	-20.4	-0.0
Repayments of bonds	-20.0	-	20.0
Purchase of treasury shares	-100.2	-0.0	100.2
Dividends paid	-48.9	-51.7	-2.8
Others, net	-12.9	-14.1	-1.2
Net cash flows from financing activities	**-202.4**	**-86.2**	**116.2**
Net increase (decrease) in cash and cash equivalents	**-49.5**	**265.3**	**314.8**
Cash and cash equivalents at the beginning of the period	**424.2**	**380.5**	**-43.6**
Effect of exchange rate changes on cash and cash equivalents	**5.8**	**16.6**	**10.8**
Cash and cash equivalents at the end of the period	**380.5**	**662.5**	**281.9**

*	**Free cash flows** (Cash flows from operating activities and investing activities)	**153.0**	**351.6**	**198.6**

7. Number of Employees

	Dec. 2020 Results	Dec. 2021 Results
Consolidated	16,033	16,458
Japan	8,979	9,135
North America	2,602	2,706
Europe	2,137	2,279
Others	2,315	2,338

8. Capital Expenditure, Depreciation and Amortization

JPY Bn	FY2020 Results	FY2021 Results	FY2022 Forecast
Capital expenditure	40.1	56.2	52.0
Depreciation and amortization	57.4	58.2	58.0
Property, plant and equipment	31.3	33.2	-
Intangible assets	26.1	25.1	-

9. Other Financial Indicators

	FY2020 Results		FY2021 Results	
Profit attributable to owners of the Company	76.0	JPY Bn	67.0	JPY Bn
Dividends	52.1	JPY Bn	51.8	JPY Bn
Average equity attributable to owners of the Company for the period	1,288.9	JPY Bn	1,311.5	JPY Bn
Return on Equity (ROE)	5.9	%	5.1	%
Dividend on Equity (DOE)	4.0	%	3.9	%

10. Summary of Product Outlines

Brand Name	Generic Name	Therapeutic Category	Launched	Origin	Marketing Alliance	Type of Alliance
Japan Business Unit						
Lixiana	edoxaban	anticoagulant	2011	Daiichi Sankyo		
Nexium	esomeprazole	ulcer treatment	2011	AstraZeneca	AstraZeneca	Co-promotion (DS: Sales)
Pralia	denosumab	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	2013	Amgen		
Tarlige	mirogabalin	pain treatment	2019	Daiichi Sankyo		
Tenelia	teneligliptin	type 2 diabetes mellitus treatment	2012	Mitsubishi Tanabe	Mitsubishi Tanabe	Co-promotion (DS: Sales)
Ranmark	denosumab	treatment for bone complications caused by bone metastases from tumors	2012	Amgen		
Loxonin	loxoprofen	anti-inflammatory analgesic	1986	Daiichi Sankyo		
Loxonin Poultice			2006	Lead Chemical		
Loxonin Tape			2008	Lead Chemical		
Loxonin Gel			2010	Daiichi Sankyo		
Vimpat	lacosamide	anti-epileptic agent	2016	UCB	UCB	Co-promotion (DS: Sales)
Canalia	teneligliptin / canagliflozin	type 2 diabetes mellitus treatment	2017	Mitsubishi Tanabe	Mitsubishi Tanabe	Co-promotion (DS: Sales)
Efient	prasugrel	antiplatelet agent	2014	Daiichi Sankyo Ube Industries		
Enhertu	trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	2020	Daiichi Sankyo		
Rezaltas	olmesartan / azelnidipine	antihypertensive agent	2010	Daiichi Sankyo		
Inavir	laninamivir	anti-influenza agent	2010	Daiichi Sankyo		
Oncology Business Unit						
Enhertu	trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	2020	Daiichi Sankyo	AstraZeneca	Co-promotion (DS: Sales)
Turalio	pexidartinib	anti-cancer agent	2019	Daiichi Sankyo		
American Regent Unit						
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
EU Specialty Business Unit						
Lixiana	edoxaban	anticoagulant	2015	Daiichi Sankyo	Merck (MSD)	Co-marketing
Nilemdo/Nustendi	bempedoic acid, bempedoic acid / ezetimibe	cholesterol-lowering agent	2020	Daiichi Sankyo	Esperion	
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			

<11. Quarterly Data>

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 to revenue	FY2020 Results	FY2021 Q1 Results	FY2021 Q2 Results	FY2021 Q3 Results	FY2021 Q4 Results	FY2021 to revenue	FY2021 Results	FY2021 YoY	FY2021 YoY (%)
Revenue	**236.9**	**243.2**	**258.6**	**223.7**	***100.0%***	**962.5**	**264.1**	**265.9**	**281.0**	**233.9**	***100.0%***	**1,044.9**	**82.4**	**+8.6%**
Cost of sales	82.2	86.4	87.8	81.3	*35.1%*	337.8	85.2	87.4	90.6	84.8	*33.3%*	348.0	10.3	+3.0%
Gross Profit	154.7	156.9	170.8	142.4	*64.9%*	624.8	178.9	178.5	190.4	149.1	*66.7%*	696.9	72.1	+11.5%
SG&A expenses	71.8	76.8	80.7	89.2	*33.1%*	318.5	81.2	84.5	90.0	96.4	*33.7%*	352.1	33.7	+10.6%
R&D expenses	48.9	55.7	59.1	63.7	*23.6%*	227.4	54.0	55.0	60.1	85.0	*24.3%*	254.1	26.7	+11.7%
Core Operating Profit	**34.1**	**24.3**	**31.0**	**-10.5**	***8.2%***	**78.9**	**43.7**	**39.0**	**40.3**	**-32.4**	***8.7%***	**90.6**	**11.8**	**+14.9%**
Temporary income	0.1	0.0	0.0	0.4		0.6	2.1	0.0	0.0	1.8		3.9	3.4	
Temporary expenses	0.0	0.0	0.0	15.6		15.6	0.0	0.1	1.3	20.1		21.5	5.9	
Operating Profit	**34.1**	**24.3**	**31.0**	**-25.7**	***6.6%***	**63.8**	**45.8**	**39.0**	**39.0**	**-50.7**	***7.0%***	**73.0**	**9.2**	**+14.5%**
Financial income/expenses	7.2	1.2	1.5	0.1		10.2	1.3	-0.1	0.9	-1.7		0.4	-9.8	
Share of profit or loss of investments accounted for using the equity method	0.0	0.0	0.0	0.1		0.2	-0.0	0.0	0.0	0.1		0.1	-0.0	
Profit before tax	**41.4**	**25.6**	**32.6**	**-25.4**	***7.7%***	**74.1**	**47.1**	**38.9**	**39.9**	**-52.4**	***7.0%***	**73.5**	**-0.6**	**-0.8%**
Income taxes	9.6	5.8	8.5	-25.6		-1.7	11.8	11.6	8.1	-25.0		6.5	8.2	-483.6%
Profit for the year	**31.8**	**19.8**	**24.1**	**0.2**	***7.9%***	**75.8**	**35.2**	**27.2**	**31.9**	**-27.3**	***6.4%***	**67.0**	**-8.9**	**-11.7%**
Profit attributable to owners of the Company	**31.9**	**19.8**	**24.1**	**0.2**	***7.9%***	**76.0**	**35.2**	**27.2**	**31.9**	**-27.3**	***6.4%***	**67.0**	**-9.0**	**-11.8%**
Tax rate	23.1%	22.8%	26.1%	-		-2.3%	25.2%	29.9%	20.2%	-		8.9%		
Overseas sales ratio	38.6%	42.3%	40.1%	46.4%		41.7%	44.7%	45.1%	45.7%	51.3%		46.6%		
Currency Rate (YTD Average)														
USD/JPY	107.62	106.92	106.11	106.06		106.06	109.49	110.11	113.71	11.62		112.38		
EUR/JPY	118.47	121.29	122.37	123.70		123.70	131.95	129.83	130.07	13.04		130.56		

<11. Quarterly Data>

2. Revenue of Global Products

JPY Bn	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 Results	FY2021 Q1 Results	FY2021 Q2 Results	FY2021 Q3 Results	FY2021 Q4 Results	FY2021 Results
Trastuzumab deruxtecan	**7.9**	**9.8**	**11.1**	**14.7**	**43.5**	**16.0**	**16.8**	**22.9**	**25.1**	**80.8**
Product sales	5.2	7.1	8.4	9.4	30.1	13.0	13.8	16.8	21.9	65.4
Enhertu(JPN)	0.2	0.8	1.7	1.7	4.4	2.2	2.2	2.6	2.6	9.6
Enhertu (US)	5.0	6.3	6.7	7.7	25.7	9.6	10.1	11.9	13.8	45.4
Enhertu (EU)	-	-	-	0.0	0.0	1.2	1.4	2.3	4.1	9.0
Enhertu (ASCA: Asia, South and Central America)	-	-	-	-	-	-	-	-	1.4	1.4
Upfront payment	2.5	2.5	2.5	2.5	9.8	2.5	2.5	2.5	2.5	9.8
Regulatory milestone payment	0.2	0.2	0.2	2.9	3.5	0.6	0.6	0.6	0.6	2.2
US HER2+ Breast Cancer 3L	0.2	0.2	0.2	0.2	0.9	0.2	0.2	0.2	0.2	0.9
EU HER2+ Breast Cancer 3L	-	-	-	1.0	1.0	0.1	0.1	0.1	0.1	0.5
US HER2+ Gastric Cancer 2L/3L	-	-	-	1.6	1.6	0.2	0.2	0.2	0.2	0.8
US HER2+ Breast Cancer 2L	-	-	-	-	-	-	-	-	-	-
EU HER2+ Breast Cancer 2L	-	-	-	-	-	-	-	-	-	-
US HER2-low Breast Cancer (post chemo)	-	-	-	-	-	-	-	-	-	-
EU HER2+ Gastric Cancer 2L	-	-	-	-	-	-	-	-	-	-
US HER2+ or HER2 Mutant NSCLC 2L	-	-	-	-	-	-	-	-	-	-
QUID related payment	-	-	-	-	-	-	-	3.1	0.3	3.4
Datopotamab deruxtecan	**-**	**1.0**	**1.5**	**1.5**	**3.9**	**1.5**	**1.6**	**1.5**	**1.5**	**6.1**
Upfront payment	-	1.0	1.5	1.5	3.9	1.5	1.6	1.5	1.5	6.1
Edoxaban	**38.7**	**40.4**	**45.6**	**41.2**	**165.9**	**49.5**	**49.7**	**57.0**	**49.4**	**205.6**
Lixiana (JPN)	19.8	18.5	21.5	17.6	77.4	22.9	21.9	25.6	22.0	92.5
Savaysa (US)	0.6	1.1	0.7	0.6	3.0	0.5	0.5	0.4	0.5	1.9
Lixiana (EU)	16.4	18.6	21.0	20.7	76.7	23.4	23.7	27.2	22.6	96.9
Edoxaban (ASCA: Asia, South and Central America)	1.9	2.2	2.3	2.4	8.9	2.7	3.6	3.8	4.2	14.3

3. Revenue by Business Units and Products (1)

JPY Bn	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 Results	FY2021 Q1 Results	FY2021 Q2 Results	FY2021 Q3 Results	FY2021 Q4 Results	FY2021 Results
Japan Business Unit	**130.2**	**119.9**	**136.3**	**102.7**	**489.1**	**129.1**	**126.5**	**138.1**	**95.8**	**489.5**
Lixiana	19.8	18.5	21.5	17.6	77.4	22.9	21.9	25.6	22.0	92.5
Nexium	19.9	19.1	21.9	17.0	77.8	19.7	19.9	-0.0	-0.0	39.6
Pralia	8.7	8.3	9.4	8.2	34.6	9.2	9.3	10.3	9.2	37.9
Tarlige	4.3	4.9	6.2	5.2	20.6	7.1	7.1	8.7	7.3	30.1
Tenelia	6.6	5.9	6.7	5.1	24.2	6.4	5.7	6.5	5.1	23.7
Ranmark	5.0	4.7	5.2	4.4	19.3	5.1	5.0	5.5	4.8	20.4
Loxonin	6.2	6.1	6.8	5.1	24.2	5.8	5.5	6.3	4.6	22.2
Vimpat	3.8	3.4	4.1	3.3	14.5	4.5	4.4	5.1	4.3	18.3
Canalia	3.9	3.7	4.3	3.5	15.4	4.3	4.0	4.7	3.8	16.8
Efient	3.8	3.3	3.8	3.1	14.1	4.1	3.9	4.7	4.0	16.7
Enhertu	0.2	0.8	1.7	1.7	4.4	2.2	2.2	2.6	2.6	9.6
Rezaltas	3.6	3.2	3.6	2.8	13.1	3.3	2.9	3.3	2.4	12.0
Inavir	0.6	0.7	0.9	1.4	3.6	0.3	0.5	0.2	0.3	1.3
Emgality	-	-	-	-	-	0.9	1.2	1.3	1.2	
Daiichi Sankyo Espha products	17.6	16.7	20.9	16.3	71.4	20.0	19.8	24.2	18.8	82.8
Vaccines business	2.9	7.8	7.6	0.2	18.5	1.4	4.0	12.3	-2.9	14.8
Daiichi Sankyo Healthcare Unit	**14.3**	**18.7**	**18.4**	**15.7**	**67.2**	**15.4**	**18.4**	**15.9**	**15.0**	**64.7**

3. Revenue by Business Units and Products (2)

JPY Bn	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 Results	FY2021 Q1 Results	FY2021 Q2 Results	FY2021 Q3 Results	FY2021 Q4 Results	FY2021 Results
Oncology Business Unit[*1]	**11.6**	**12.0**	**11.8**	**12.0**	**47.4**	**14.5**	**16.6**	**18.1**	**20.4**	**69.6**
Enhertu	5.0	6.3	6.7	7.7	25.7	10.8	11.6	14.2	17.9	54.4
Enhertu (US)	5.0	6.3	6.7	7.7	25.7	9.6	10.1	11.9	13.8	45.4
Enhertu (EU)	-	-	-	0.0	0.0	1.2	1.4	2.3	4.1	9.0
Turalio	0.3	0.5	0.5	0.5	1.8	0.6	0.7	0.7	0.8	2.8
American Regent Unit	**26.5**	**32.5**	**32.1**	**30.7**	**121.7**	**39.1**	**37.9**	**38.7**	**33.8**	**149.5**
Injectafer	9.4	11.5	11.3	11.9	44.1	14.9	14.1	13.4	10.7	53.1
Venofer	6.9	7.7	7.5	6.7	28.8	7.9	8.6	8.8	8.5	33.8
EU Specialty Business Unit[*2]	**27.7**	**26.6**	**28.6**	**28.7**	**111.7**	**32.7**	**30.9**	**34.3**	**30.3**	**128.2**
Lixiana	16.4	18.6	21.0	20.7	76.7	23.4	23.7	27.2	22.6	96.9
Nilemdo/Nustendi	-	-	0.1	0.4	0.6	0.7	0.9	0.6	0.9	3.1
Olmesartan	5.2	5.8	5.2	5.3	21.5	5.6	4.7	4.6	5.4	20.3
ASCA Business Unit	**22.5**	**25.8**	**26.1**	**25.2**	**99.7**	**26.5**	**28.6**	**27.9**	**31.2**	**114.1**
Daiichi Sankyo China	8.6	11.4	12.9	12.7	45.6	11.8	13.7	13.0	14.8	53.3
Daiichi Sankyo Korea	4.4	5.0	4.9	5.2	19.6	5.8	6.1	5.9	5.3	23.2
Daiichi Sankyo Brasil Farmacêutica	2.9	2.6	2.7	2.3	10.5	3.3	3.2	3.6	3.6	13.7
Daiichi Sankyo Taiwan	2.1	2.0	2.1	2.1	8.3	2.3	2.3	2.2	3.3	10.0
Daiichi Sankyo Thailand	0.6	0.7	0.7	0.3	2.3	0.5	0.5	0.5	0.6	2.2
Daiichi Sankyo Hong Kong	0.2	0.1	0.1	0.2	0.7	0.3	0.1	0.4	0.9	1.7

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

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

3. Revenue by Business Units and Products (3) [Reference] Revenue in Local Currency	FY2020 Q1 Results	FY2020 Q2 Results	FY2020 Q3 Results	FY2020 Q4 Results	FY2020 Results	FY2021 Q1 Results	FY2021 Q2 Results	FY2021 Q3 Results	FY2021 Q4 Results	FY2021 Results
USD Mn										
Oncology Business Unit*1	**107**	**113**	**113**	**113**	**447**	**132**	**150**	**160**	**177**	**619**
Enhertu	46	60	64	73	243	99	105	125	155	484
Enhertu (US)	46	60	64	73	243	88	92	105	119	404
Enhertu (EU)	-	-	-	0	0	11	13	20	36	80
Turalio	3	5	4	5	17	6	6	6	7	25
*1 Oncology products revenue in EU will be booked in Oncology business unit (OBU) from FY2021.										
USD Mn										
American Regent Unit	**246**	**305**	**307**	**290**	**1,148**	**357**	**344**	**340**	**289**	**1,330**
Injectafer	88	109	108	113	416	136	128	118	91	472
Venofer	64	72	72	63	272	72	78	77	73	300
EUR Mn										
EU Specialty Business Unit*2	**234**	**214**	**230**	**225**	**903**	**248**	**238**	**263**	**232**	**982**
Lixiana	139	150	169	162	620	177	182	209	174	742
Nilemdo/Nustendi	-	-	1	3	5	6	7	5	7	24
Olmesartan	44	47	42	41	174	43	36	36	41	155

<12. Historical Data>

1. Revenue of Global Products

JPY Bn	FY2016 Results	FY2017 Results	FY2018 Results	FY2019 Results	FY2020 Results
Trastuzumab deruxtecan	**-**	**-**	**0.1**	**14.0**	**43.5**
Product sales	-	-	-	3.2	30.1
Enhertu (JPN)	-	-	-	-	4.4
Enhertu (US)	-	-	-	3.2	25.7
Enhertu (EU)	-	-	-	-	0.0
Enhertu (ASCA: Asia, South and Central America)	-	-	-	-	-
Upfront payment	-	-	0.1	9.8	9.8
Regulatory milestone payment	-	-	-	0.9	3.5
US HER2+ Breast Cancer 3L	-	-	-	0.9	0.9
EU HER2+ Breast Cancer 3L	-	-	-	-	1.0
US HER2+ Gastric Cancer 2L+3L	-	-	-	-	1.6
Datopotamab deruxtecan	**-**	**-**	**-**	**-**	**3.9**
Upfront payment	-	-	-	-	3.9
Edoxaban	**37.3**	**77.1**	**117.7**	**154.0**	**165.9**
Lixiana (JPN)	25.0	45.3	64.9	83.0	77.4
Savaysa (US)	1.9	2.2	2.3	2.6	3.0
Lixiana (EU)	9.7	27.0	45.8	61.7	76.7
Other subsidiaries	0.8	2.6	4.7	6.8	8.9
Olmesartan	**218.0**	**149.7**	**105.9**	**100.8**	**91.8**
Olmetec (JPN)	69.4	44.6	14.9	11.7	9.2
Rezaltas (JPN)	17.5	16.8	15.5	14.6	13.1
Olmesartan (US)	66.4	21.3	10.7	9.8	8.6
Olmesartan (EU)	43.2	33.5	27.4	24.6	21.5
Other subsidiaries, export, etc	21.5	33.5	37.4	40.1	39.4
Prasugrel	**41.6**	**32.8**	**23.2**	**18.1**	**17.3**
Effient alliance revenue (US)	22.2	10.7	2.4	0.5	0.3
Efient (EU)	7.9	8.0	5.7	2.5	1.6
Efient (JPN)	10.4	12.8	13.9	14.0	14.1
Other subsidiaries, export, etc	1.0	1.3	1.2	1.2	1.3

2. Revenue by Business Units and Products (1)

JPY Bn	FY2016 Results	FY2017 Results	FY2018 Results	FY2019 Results	FY2020 Results
Japan Business Unit	**506.6**	**540.0**	**523.3**	**533.5**	**489.1**
Lixiana	25.0	45.3	64.9	83.0	77.4
Nexium	84.0	86.5	78.3	79.8	77.8
Pralia	18.0	23.2	27.4	30.9	34.6
Tarlige	-	-	-	8.0	20.6
Tenelia	24.2	26.3	25.3	24.7	24.2
Ranmark	13.9	15.4	16.4	17.9	19.3
Loxonin	37.4	36.5	30.5	28.3	24.2
Vimpat	0.4	2.6	6.6	11.2	14.5
Canalia	-	2.7	9.2	12.8	15.4
Efient	10.4	12.8	13.9	14.0	14.1
Enhertu	-	-	-	-	4.4
Rezaltas	17.5	16.8	15.5	14.6	13.1
Inavir	19.6	25.3	18.2	19.3	3.6
Daiichi Sankyo Espha products	20.2	46.7	55.5	60.5	71.4
Vaccines business	38.5	41.9	41.5	35.6	18.5
Daiichi Sankyo Healthcare Unit	**66.7**	**72.9**	**66.4**	**68.5**	**67.2**

2. Revenue by Business Units and Products (2)

JPY Bn	FY2016 Results	FY2017 Results	FY2018 Results	FY2019 Results	FY2020 Results
Oncology Business Unit	**142.3**	**74.8**	**36.3**	**32.1**	**47.4**
Enhertu	-	-	-	3.2	25.7
Enhertu (US)	-	-	-	3.2	25.7
Enhertu (EU)	-	-	-	-	0.0
Turalio	-	-	-	-	1.8
Olmesartan	66.4	21.3	10.7	9.8	8.6
Welchol	45.5	33.9	13.4	9.1	5.0
Effient	22.2	10.7	2.4	0.5	0.3
Savaysa	1.9	2.2	2.3	2.6	3.0
American Regent Unit	**88.1**	**105.4**	**117.8**	**130.8**	**121.7**
Injectafer	24.0	34.3	44.2	51.8	44.1
Venofer	28.5	31.0	28.9	31.0	28.8
EU Specialty Business Unit	**71.0**	**79.4**	**88.6**	**95.5**	**111.7**
Lixiana	9.7	27.0	45.8	61.7	76.7
Nilemdo/Nustendi	-	-	-	-	0.6
Olmesartan	43.2	33.5	27.4	24.6	21.5
Efient	7.9	8.0	5.7	2.5	1.6
ASCA Business Unit	**72.1**	**80.4**	**87.7**	**98.3**	**99.7**
Daiichi Sankyo China	33.8	35.3	38.5	46.0	45.6
Daiichi Sankyo Korea	8.8	11.8	15.7	17.2	19.6
Daiichi Sankyo Brasil Farmacêutica	8.8	10.1	10.0	11.5	10.5
Daiichi Sankyo Taiwan	5.2	6.6	7.1	7.6	8.3
Daiichi Sankyo Thailand	2.5	2.9	3.3	3.3	2.3

2. Revenue by Business Units and Products (3) [Reference] Revenue in Local Currency	FY2016 Results	FY2017 Results	FY2018 Results	FY2019 Results	FY2020 Results
USD Mn					
Oncology Business Unit	**1,312**	**674**	**327**	**295**	**447**
Enhertu	-	-	-	30	243
Enhertu (US)	-	-	-	30	243
Enhertu (EU)	-	-	-	-	0
Turalio	-	-	-	-	17
Olmesartan	612	192	97	91	81
Welchol	420	306	121	84	47
Effient	205	96	22	4	3
Savaysa	17	20	21	24	28
USD Mn					
American Regent Unit	**812**	**951**	**1,062**	**1,204**	**1,148**
Injectafer	221	310	399	477	416
Venofer	263	279	261	285	272
EUR Mn					
EU Specialty Business Unit	**597**	**613**	**690**	**789**	**903**
Lixiana	81	208	357	509	620
Nilemdo/Nustendi	-	-	-	-	5
Olmesartan	363	258	213	203	174
Efient	67	62	44	21	13

12. Major R&D Pipeline (Innovative Pharmaceuticals)

As of Apr 2022

◆ 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 applicable	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

ADA: ant-drug antibody; ADC: antibody drug conjugate; BMFI: 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, EFS: event-free survival, FPD: first patient dosed, FSD: first subject dosed, IDFS: invasive disease-free survival, LPD: last patient dosed, NSCLC: non small cell lung cancer, ORR: overall response rate/objective response rate, OS: overall survival, pCR: pathological complete response, PFS: progression-free survival, PK: pharmacokinetics, SCLC: small cell lung cancer, TLR: top line results, TTR: time to response

◆ 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, etc.	JP/US/EU /Asia	FPD: Oct 2017 TLR: May 2019 Jan 2020: Launch (US) May 2020: Launch (JP) Feb 2021: Launch (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, etc.	JP/US/EU /Asia	FPD: Sep 2018 TLR anticipated: FY2022 H1
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, etc.	JP/US/EU /Asia	FPD: Aug 2018 TLR: Aug 2021 Dec 2021: Filing accepted (JP/EU) Jan 2022: Filing accepted (US) Mar 2022: Filing accepted (CN) Aug 2021: Real Time Oncology Review Designation (US) Sep 2021: Breakthrough Therapy Designation (US)

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

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
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, etc.	JP/US/EU /Asia	FPD: Dec 2018 TLR: Feb 2022 Filing anticipated: FY2022 H1 Feb 2022: Real Time Oncology Review Designation (US) Apr 2022: Breakthrough Therapy Designation (US)
Phase 3 DESTINY-Breast05 NCT04622319 jRCT2061200033 AstraZeneca	HER2 positive, with residual invasive breast cancer following neoadjuvant therapy	1,600	Randomized, open label, active control ・DS-8201 ・T-DM1	Primary endpoint: IDFS Secondary endpoint: DFS, OS, DRFI, BMFI, safety, PK, 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, 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	450	Open label, two-part (dose escalation, dose expansion) ・DS-8201 + durvalumab ・DS-8201 + pertuzumab ・DS-8201 + paclitaxel ・DS-8201 + durvalumab + paclitaxel ・DS-8201 + tucatinib ・DS-8201	Primary endpoint: Safety Secondary endpoint: ORR, PFS, DOR, OS, PK, etc.	US/EU /Asia	FPD: Jan 2021

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

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
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, etc.	US/EU /Asia	FPD: Jan 2021
Phase3 DESTINY-Breast09 NCT04784715 jRCT2031210130 AstraZeneca	HER2 positive breast cancer, 1L	1,134	Randomized, open label, active control ・DS-8201 ・DS-8201 + pertuzumab ・Taxane + trastuzumab + pertuzumab	Primary endpoint: PFS Secondary endpoint: OS, PFS, ORR, DOR, PK, safety, etc.	JP/US/EU /Asia	FPD: Jun 2021
Phase3 DESTINY-Breast11 NCT05113251 jRCT2041210097 AstraZeneca	HER2 positive breast cancer, neoadjuvant	624	Randomized, open label, active control ・DS-8201 ・DS-8201, followed by paclitaxel + trastuzumab + pertuzumab ・doxorubicin + cyclophosphamide, followed by paclitaxel + trastuzumab + pertuzumab	Primary endpoint: pCR Secondary endpoint: EFS, IDFS, OS	JP/US/EU /Asia	FPD: Nov 2021
Phase 1b/2 BEGONIA NCT03742102 AstraZeneca	Triple negative breast cancer	200	Non-randomized, open label, combination with durvalumab ・DS-8201 + durvalumab * Umbrella study of durvalumab led by AstraZeneca	Primary endpoint: Safety Secondary endpoint: ORR, PFS, DOR, OS, PK, etc.	US/EU /Asia	FPD: May 2020
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: Approval (JP) Jan 2021: Approval (US) Mar 2018: SAKIGAKE Designation (JP) May 2020: Breakthrough Therapy Designation (US) May 2020: Orphan Drug Designation (US)

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

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 DESTINY-Gastric02 NCT04014075 AstraZeneca	HER2 positive gastric or gastroesophageal junction adenocarcinoma 2L	72	Open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: PFS, ORR, OS, DOR	US/EU	FPD: Dec 2019 TLR: Jun 2021 Nov 2021: Filing accepted (EU)
Phase 1b/2 DESTINY-Gastric03 NCT04379596 jRCT2031200203 AstraZeneca	Part 1 HER2 positive gastric/gastroesophageal junction and esophageal adenocarcinoma Part1: 2L Part 2: 1L	255	Randomized, open label Part 1 ・DS-8201 + fluorouracil ・DS-8201 + capecitabine ・DS-8201 + durvalumab ・DS-8201 + oxaliplatin + fluorouracil ・DS-8201 + capecitabine + oxaliplatin ・DS-8201 + durvalumab + fluorouracil ・DS-8201 + capecitabine + durvalumab Part 2 ・DS-8201 ・DS-8201 + oxaliplatin + fluorouracil or capecitabine ・DS-8201 + pembrolizumab + fluorouracil or capecitabine ・DS-8201 + pembrolizumab ・Trastuzumab + fluorouracil or capecitabine + cisplatin or oxaliplatin	Primary endpoint: Part 1: Safety, Part 2: ORR Secondary endpoint: ORR, safety, DOR, DCR, PFS, OS, PK	JP/US/EU /Asia	FPD: Jun 2020
Phase 3 DESTINY-Gastric04 NCT04704934 jRCT2031200369 AstraZeneca	HER2 positive gastric or gastroesophageal junction adenocarcinoma, 2L	490	Randomized, open label ・DS-8201 ・Ramucirumab + paclitaxel	Primary endpoint: OS Secondary endpoint: PFS, ORR, DOR, DCR, safety, PK, ADA, etc.	JP/EU /Asia	FPD: Jun 2021

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

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 DESTINY-Gastric06 NCT04989816 AstraZeneca	HER2 positive gastric or gastroesophageal junction adenocarcinoma, 3L	100	Open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: ORR, PFS, DCR, DOR, OS, Tumor size change, PK, ADA	China	FPD: Sep 2021
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 TLR: Jun 2021 Apr 2022: Filing accepted (US) May 2020: Breakthrough Therapy Designation (US)
Phase 2 DESTINY-Lung02 NCT04644237 jRCT2061200038 AstraZeneca	HER2 mutated NSCLC, 2L or later	150	Randomized, double blind ・DS-8201: 6.4mg/kg ・DS-8201: 5.4mg/kg	Primary endpoint: ORR Secondary endpoint: ORR, DOR, DCR, PFS, OS, safety	JP/US/EU /Asia	FPD: Mar 2021
Phase 1b DESTINY-Lung03 NCT04686305 AstraZeneca	HER2 positive NSCLC, 1L	120	Non-randomized, three-part (safety run-in, dose escalation, dose expansion) ・DS-8201 + durvalumab + cisplatin ・DS-8201 + durvalumab + carboplatin ・DS-8201 + durvalumab + pemetrexed ・DS-8201 + durvalumab	Primary endpoint: Safety Secondary endpoint: ORR, DOR, DCR, PFS, OS, PK, etc.	EU/Asia	FPD: Nov 2021
Phase 3 DESTINY-Lung04 NCT05048797 jRCT2011210058 AstraZeneca	NSCLC with HER2 exon 19 or exon 20 mutation, 1L	264	Randomized, open label ・DS-8201 ・pemetrexed + pembrolizumab + cisplatin or carboplatin	Primary endpoint: PFS Secondary endpoint: OS, PFS, ORR, DOR, safety, PK, etc.	JP/US/EU /Asia	FPD: Dec 2021

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

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 DESTINY-Lung05 NCT05246514 AstraZeneca	NSCLC with HER2 exon 19 or exon 20 mutation, 2L or later	66	Open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: ORR, DOR, DCR, PFS, OS, PK, ADA, safety	China	FPD: FY2022 H1
Phase 2 HUDSON NCT03334617 AstraZeneca	NSCLC, 2L or later	420	Non-randomized, open label, combination with durvalumab ・DS-8201 + durvalumab * Umbrella study of durvalumab led by AstraZeneca	Primary endpoint: ORR Secondary endpoint: DCR, best percentage change in tumor size, 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
Phase 2 DESTINY-CRC02 NCT04744831 jRCT2051200124 AstraZeneca	HER2 overexpressing colorectal cancer, 3L	120	Randomized, double blind ・DS-8201 : 6.4mg/kg ・DS-8201 : 5.4mg/kg	Primary endpoint: ORR Secondary endpoint: DOR, DCR, PFS, OS, PK, PRO, safety	JP/US/EU /Asia	FPD: Mar 2021
Phase 2 DESTINY-PanTumor01 NCT04639219 jRCT2031210132 AstraZeneca	HER2 mutated tumors (e.g. colorectal cancer, urothelial cancer, gastric cancer, hepatobiliary cancer, endometrial cancer, melanoma, ovarian cancer, cervical cancer, salivary gland cancer, pancreatic cancer, breast cancer)	100	Open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: DOR, DCR, PFS, ORR, OS, safety, PK	JP/US/EU /Asia	FPD: Jan 2021

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

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
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, safety, PK, ADA	US/EU /Asia	FPD: Oct 2020
Phase 1 NCT03523572 BMS	HER2 positive/low breast cancer HER2 positive/low urothelial carcinoma	99	Non-randomized, open label, combination with nivolumab, two-part (dose escalation, dose expansion) ・DS-8201 + nivolumab	Primary endpoint: ORR, safety Secondary endpoint: DOR, DCR, PFS, OS, ORR	US/EU	FPD: Aug 2018
Phase 1 NCT04042701 Merck	HER2 positive/low breast cancer HER2 expressing/mutated NSCLC	115	Non-randomized, open label, combination with pembrolizumab ・DS-8201 + pembrolizumab	Primary endpoint: Safety, ORR Secondary endpoint: DOR, DCR, PFS, TTR, OS	US/EU	FPD: Apr 2020
Phase 1/2a PETRA NCT04644068 AstraZeneca	Solid tumors	715	Non-randomized, open label, combination with AZD5305 ・DS-8201 + AZD5305	Primary endpoint: Safety Secondary endpoint: Tumor size change, ORR, DOR, PFS, TTR, PK, ADA, etc	US/EU /Asia	

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

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

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 TROPION-PanTumor01 NCT03401385 JapicCTI-173812 AstraZeneca	NSCLC Triple negative breast cancer HR positive breast cancer SCLC Transitional cell carcinoma of the urothelium HER2 negative gastroesophageal cancer Esophageal cancer	770	Open label, two-part (dose escalation, dose expansion) ・DS-1062	Primary endpoint: Safety Secondary endpoint: PK, ADA	JP/US	FPD: Feb 2018
Phase 3 TROPION-Lung01 NCT04656652 jRCT2071200104 AstraZeneca	NSCLC, 2L/3L	590	Randomized, open label ・DS-1062 ・Docetaxel	Primary endpoint: PFS, OS Secondary endpoint: ORR, DOR, TTR, DCR, safety, PK, ADA	JP/US/EU /Asia	FPD: Feb 2021
Phase 1 TROPION-Lung02 NCT04526691 jRCT2031200193 Merck AstraZeneca	NSCLC (without actionable mutation) Part1: 3L or later Part2: 1L/2L	120	Open label, combination with pembrolizumab, two-part (dose escalation, dose expansion) ・DS-1062 + pembrolizumab ± platinum chemotherapy	Primary endpoint: Safety and tolerability Secondary endpoint: ORR, DOR, PFS, OS, PK, ADA	JP/US/EU /Asia	FPD: Oct 2020

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

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 TROPION-Lung04 NCT04612751 jRCT2031200449 AstraZeneca	NSCLC (without actionable mutation), 1L/2L	68	Open label, combination with durvalumab, two-part (dose escalation, dose expansion) ・DS-1062 + durvalumab ± carboplatin	Primary endpoint: Safety and tolerability Secondary endpoint: ORR, DOR, PFS, OS, PK, ADA	JP/US/EU	FPD: Mar 2021
Phase 2 TROPION-Lung05 NCT04484142 jRCT2041200097 AstraZeneca	NSCLC (with actionable mutation)	150	Open label ・DS-1062	Primary endpoint: ORR Secondary endpoint: DOR, PFS, OS, safety, PK	JP/US/EU /Asia	FPD: Mar 2021
Phase 3 TROPION-Lung08 NCT05215340 jRCT2061210074 Merck AstraZeneca	NSCLC (without actionable mutation and PD-L1 ≥50%), 1L	740	Randomized, open label ・DS-1062 + pembrolizumab ・Pembrolizumab	Primary endpoint: PFS, OS Secondary endpoint: ORR, PFS, DOR, TTR, DCR, Time to deterioration (TTD), safety, ADA, etc.	JP/US/EU /Asia	FPD: Mar 2022
Phase 1b/2 BEGONIA NCT03742102 AstraZeneca	Triple negative breast cancer	200	Non-randomized, open label, combination with durvalumab ・DS-1062 + durvalumab * Umbrella study of durvalumab led by AstraZeneca	Primary endpoint: Safety Secondary endpoint: ORR, PFS, DOR, OS, PK	US/EU /Asia	FPD: May 2021
Phase 3 TROPION-Breast01 NCT05104866 jRCT2031210440 AstraZeneca	HR positive/HER2 negative breast cancer, 2L/3L	700	Randomized, open label ・DS-1062 * Physician's choice (capecitabine, gemcitabine, eribulin or vinorelbine)	Primary endpoint: PFS, OS Secondary endpoint: ORR, DOR, PFS, DCR, PK, ADA, etc	JP/US/EU /Asia	FPD: Nov 2021
Phase 1/2a PETRA NCT04644068 AstraZeneca	Solid tumors	715	Non-randomized, open label, combination with AZD5305 ・DS-1062 + AZD5305	Primary endpoint: Safety Secondary endpoint: Tumor size change, ORR, DOR, PFS, TTR, PK, ADA, etc	JP/US/EU /Asia	FPD: Mar 2022

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	184	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	216	Non-randomized, open label, two-part (dose escalation, dose expansion) ・U3-1402	Primary endpoint: Safety, ORR Secondary endpoint: PK, ORR, DCR, DOR, TTR, PFS, OS, safety	JP/US/EU /Asia	FPD: Feb 2018
Phase 2 HERTHENA-Lung01 NCT04619004 jRCT2031200186	EGFR mutated NSCLC, 3L	420	Randomized, open label ・U3-1402	Primary endpoint: ORR Secondary endpoint: DOR, PFS, ORR, DCR, TTR, OS, safety	JP/US/EU /Asia	FPD: Feb 2021 Dec 2021: Breakthrough Therapy Designation (US)
Phase 1 NCT04676477 jRCT2031200247 AstraZeneca	EGFR mutated NSCLC, 1/2L	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, etc.	JP/US	FPD: Jun 2021
Phase 3 prep HERTHENA-Lung02 NCT05338970 jRCT2021220002	EGFR mutated NSCLC, 2L	560	Randomized, open label, active control ・U3-1402 ・Platinum-based chemotherapy	Primary endpoint: PFS Secondary endpoint: OS, PFS, ORR, DOR, CBR, DCR, safety, etc.	JP/US/EU /Asia	FPD planned: FY2022 H1

◆ 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: Launch (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, etc.	JP/US/EU /Asia	FPD: Sep 2016 TLR: Nov 2021 Filing anticipated: FY2022 H1 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 NCT04488822	Tenosynovial giant cell tumor	35	Open label ・Pexidartinib	Primary endpoint: ORR Secondary endpoint: TVS, ROM, PROMIS, DOR, etc.	Asia	FPD: Sep 2020
Phase 2 NCT04703322 jRCT2041200074	Tenosynovial giant cell tumor	21	Open label ・Pexidartinib	Primary endpoint: Safety, PK, ORR Secondary endpoint: Safety, TVS, ROM, PROMIS, DOR, etc.	JP	FPD: Apr 2021

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

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

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: Submission Jun 2021: Approval Nov 2021: Launch 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 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: Approval 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, TTR, DOR, PFS, OS, etc.	JP	FPD: Dec 2019 TLR: Jul 2021 Submission: Dec 2021 Nov 2021: Orphan Drug Designation
Phase 2 (pivotal) VALENTINE-PTCL01 NCT04703192 jRCT2071200095	Relapsed/refractory peripheral T-cell lymphoma	176	Non-Randomized, open label ・DS-3201	Primay endpoint: ORR Secondary endpoint: DOR, CR rate, safety, etc.	JP/US/EU /Asia	FPD: Jun 2021 Apr 2019: SAKIGAKE Designation (JP) Dec 2021: Orphan Drug Designation (US)
Phase 2 NCT04842877 LYSA	Relapsed/refractory B-cell lymphoma	141	Non-Randomized, open label ・DS-3201	Primay endpoint: ORR Secondary endpoint: CR rate, PFS, DOR, TTR, safety, PK	EU	FPD: Jun 2021
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, etc.	JP/US	FPD: Apr 2016

◆ 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: antitumor effect, TTR, DOR, PFS, OS, PK, etc	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	22	Open label ・PLX2853	Primary endpoint: Safety, PK Secondary endpoint: OCR, 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 acetate + prednisone ・PLX2853 + olaparib	Primary endpoint: ORR, safety Secondary endpoint: PFS, OS, PK, 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	Esophageal squamous cell carcinoma, castration-resistant prostate cancer, SCLC, etc.	160	Non-randomized, open label, two-part (dose escalation, dose expansion) ・DS-7300	Primary endpoint: Safety, antitumor effect Secondary endpoint: PK, etc.	JP/US	FPD: Oct 2019
Phase 2 prep NCT05280470	SCLC	80	Randomized, open label ・DS-7300 : 8mg/kg ・DS-7300 : 12mg/kg	Primary endpoint: ORR Secondary endpoint: Safety, PFS, DOR, OS, TTR, ORR, DCR, PK, ADA	JP/US/EU /Asia	FPD planned: FY2022 H1

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, ADA, etc.	JP/US	FPD: Oct 2020

DS-6000（CDH6-directed ADC）

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

DS-1594（Menin-MLL binding inhibitor）

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

◆ Alpha (Specialty Medicines Late-Stage Pipeline Products)

Edoxaban/DU-176b (Factor Xa inhibitor)

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

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 NCT02801669 JapicCTI-163266	Very elderly patients with non-valvular atrial fibrillation	984	Randomized, double-blind, placebo-controlled ・Edoxaban ・Placebo	Primary endpoint: annual incidence rate of stroke and systemic embolic events Secondary endpoint: annual incidence rate of bleeding events	JP	FPD: Aug 2016 TLR: Apr 2020 Submission: Sep 2020 Approval : Aug 2021

Prasugrel/CS-747 (ADP receptor inhibitor)

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

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 JapicCTI-184141	Ischemic stroke	250	Randomized, double-blind, active-controlled ・Prasugrel ・Clopidogrel	Primary endpoint: incidence rate of cerebro-cardiovascular events Secondary endpoint: incidence rate of bleeding events	JP	FPD: Oct 2018 TLR: Jun 2020 Submission: Dec 2020 Approval : Dec 2021

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	300	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: May 2021 Approval: Mar 2022
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, 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 Jun 2021: announced TLR of 48-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-6016 (anti-ALK2 antibody)

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT04818398 jRCT2051200155	Healthy volunteers, fibrodysplasia ossificans progressiva	48	Randomized, double-blind, placebo-controlled	Primary endpoint: Safety Secondary endpoint: PK	JP	FSD: Apr 2021 TLR：Mar 2022

DS-7011 (anti-TLR7 antibody)

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT05203692	Systemic lupus erythematosus	80	Randomized, double-blind, placebo-controlled	Primary endpoint: Safety Secondary endpoint: PK, PD, Immunogenicity	US	FSD: Feb 2022

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 ・VN-0107 ・Placebo	Primary endpoint: onset of influenza, safety Secondary endpoint: onset of influenza	JP	Jun 2016: Submission by Daiichi Sankyo

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

Trivalent mixed vaccine (MMR vaccine) containing three attenuated viruses of measles, mumps and 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, double-blind, active-controlled ・VN-0102/JVC-001 ・Dry Live Attenuated Measles Rubella vaccine, Freeze-dried Live Attenuated Mumps vaccine	Primary endpoint: Seroprotection rates for measles, mumps and rubella Secondary endpoint: Seroconversion rates for measles, mumps, and rubella	JP	FSD: Feb 2020 LSD: Sep 2020 Data anticipated: FY2022 Q1

DS-5670 (COVID-19 mRNA vaccines)

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1/2 NCT04821674 jRCT2071200110	Healthy adults and elderly, prevention of COVID-19	152	Randomized, double-blind, placebo-controlled ・DS-5670 ・Placebo	Primary endpoint: Safety, immunogenicity (neurralizing activity) Secondary endpoint: immunogenicity, PK	JP	FSD: Mar 2021 TLR: Oct 2021
Phase 2 jRCT2071210086	Healthy adults, prevention of COVID-19	~~80~~	Randomized, double-blind, uncontrolled	Primary endpoint: Safety Secondary endopoint: Immunogenicity	JP	FSD: Nov 2021
Phase 1/2/3 jRCT2071210106	Healthy adults who have completed initial vaccination of approved COVID-19 vaccine, prevention of COVID-19	5,028	Randomized, single-blind, active-controlled ・DS-5670 ・Comirnaty ・Spikevax	Primary endpoint: Immunogenicity (Geometric mean fold rise of neutralizing activity), safety Secondary endopoint: Immunogenicity, safety	JP	FSD: Jan 2022 TLR planned: FY2022 H2

VN-0200 (RS virus vaccines)

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT04914520 jRCT2031210069	Health adults and elderly, prevention of respiratory syncytial (RS) virus infection	48	Randomized, double-blind, placebo-controlled ・VN-0200 ・Placebo	Primary endpoint: Safety, tolerability Secondary endpoint: immunogenicity	JP	FSD: Jun 2021 TLR: Apr 2022

◆ Stage-up Projects (Major Changes from the FY2021 Q3 Financial Announcement in January 2022)

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, 2L	Filed	China, DESTINY-Breast03
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 mutated NSCLC, 2L or later	Filed	US, DESTINY-Lung01
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	NSCLC with HER2 exon 19 or exon 20 mutation, 2L or later	Ph2 prep	China, DESTINY-Lung05
Datopotamab deruxtecan/DS-1062/ Dato-DXd TROP2-directed ADC	NSCLC (without actionable mutation and PD-L1 ≥50%), 1L	Ph3	TROPION-Lung08, pembrolizumab combo
Patritumab deruxtecan/U3-1402/ HER3-DXd HER3-directed ADC	EGFR mutated NSCLC, 2L	Ph3 prep	HERTHENA-Lung02
DS-7300 B7-H3-directed ADC	SCLC	Ph2 prep	
Mirogabalin/ DS-5565 α2δ ligands	Central neuropathic pain	Approved	Japan
DS-7011 Anti-TLR7 antibody	Systemic lupus erythematosus	Ph1	