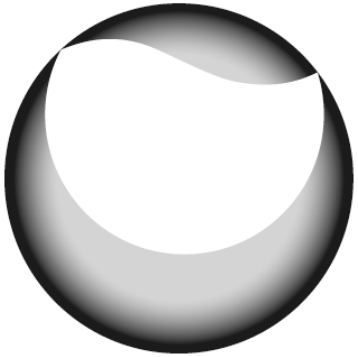
TSE:4568

Reference Data

(Consolidated Financial Results for Q1 FY2023)



Daiichi-Sankyo

July 31, 2023

Daiichi Sankyo Co., Ltd.

https://www.daiichisankyo.com

Contents

Daiichi-Sankyo

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2022 Q1 YTD to revenue	FY2022 Q1 YTD Results	FY2023 Q1 YTD to revenue	FY2023 Q1 YTD Results	(vs. Forecast (%))	FY2023 Q1 YTD YoY	FY2023 Q1 YTD YoY (%)	FY2023 to revenue	FY2023 Forecast	FY2023 YoY	FY2023 YoY (%)
Revenue	*100.0%*	**280.3**	*100.0%*	**350.8**	*24.2%*	**70.5**	*+25.2%*	*100.0%*	**1,450.0**	**171.5**	**+13.4%**
Cost of sales※1	*26.6%*	74.7	*26.7%*	93.6	*23.4%*	18.9	*+25.3%*	*27.6%*	400.0	50.9	+14.6%
Gross Profit	*73.4%*	205.6	*73.3%*	257.2	*24.5%*	51.6	*+25.1%*	*72.4%*	1,050.0	120.6	+13.0%
SG&A expenses※1	*34.4%*	96.3	*38.7%*	135.6	*24.7%*	39.3	*+40.8%*	*37.9%*	550.0	79.9	+17.0%
R&D expenses※1	*26.7%*	74.9	*22.0%*	77.2	*21.4%*	2.2	*+3.0%*	*24.8%*	360.0	23.3	+6.9%
Core Operating Profit	*12.3%*	**34.4**	*12.7%*	**44.5**	*31.8%*	**10.1**	*+29.4%*	*9.7%*	**140.0**	**17.4**	**+14.2%**
Temporary income※2		0.0		0.5	-	0.5			-	-21.9	
Temporary expenses※2		-		0.9	*18.9%*	0.9			5.0	-18.9	
Operating Profit	*12.3%*	**34.4**	*12.6%*	**44.0**	*32.6%*	**9.7**	*+28.1%*	*9.3%*	**135.0**	**14.4**	**+12.0%**
Financial income/expenses		-4.9		8.1		13.0					
Share of profit or loss of investments accounted for using the equity method		-0.0		0.0		0.0					
Profit before tax	*10.5%*	**29.4**	*14.9%*	**52.1**	*38.6%*	**22.7**	*+77.2%*	*9.3%*	**135.0**	**8.1**	**+6.4%**
Income taxes		10.6		-4.9		-15.4					
Profit for the year	*6.7%*	**18.9**	*16.3%*	**57.0**	*49.6%*	**38.2**	*+202.4%*	*7.9%*	**115.0**	**5.8**	**+5.3%**
Profit attributable to owners of the Company	*6.7%*	**18.9**	*16.3%*	**57.0**	*49.6%*	**38.2**	*+202.4%*	*7.9%*	**115.0**	**5.8**	**+5.3%**

Forex impact: +11.5
(USD: +6.4, EUR: +4.5, ASCA: +0.7)

Forex impact: +3.3
(USD: +2.0, EUR: +1.3, ASCA: +0.0)

Forex impact: +5.2
(USD: +3.8, EUR: +1.2, ASCA: +0.2)

Forex impact: +3.0
(USD: +2.4, EUR: +0.6, ASCA: +0.0)

Forex impact: +0.1
(USD: -1.8, EUR: +1.4, ASCA: +0.5)

- Improvement in forex gains/losses +4.9
- Improvement in investment securities valuation gains/losses +3.9
- Increase of interest income +2.9

	FY2022 Q1 YTD	FY2023 Q1 YTD	FY2023
Tax rate	35.9%	-9.4%	
Overseas sales ratio	55.4%	60.9%	

Currency Rate (Average)

	FY2022 Q1 YTD	FY2023 Q1 YTD	FY2023 Currency Rate
USD/JPY	129.57	137.37	130.00
EUR/JPY	138.10	149.46	140.00

Annual impact of JPY 1 change

	Forecast	
	USD	EUR
Revenue	JPY 3.5 Bn	JPY 1.7 Bn
Operating Profit	JPY -0.7 Bn	JPY 0.5 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

FY2022 Q1 YTD Results

JPY Bn	Full base	Adjustment					Core base
		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	**280.3**						**280.3**
Cost of sales	74.8					-0.1	74.7
SG&A expenses	96.4					-0.0	96.3
R&D expenses	74.9					-0.0	74.9
Other income*	0.2	-0.0				-0.2	-
Other expenses*	-						-
Core Operating Profit**							**34.4**
Temporary income		0.0					0.0
Temporary expenses							-
Operating Profit (full)	**34.4**						**34.4**

＜Major Temporary income and Temporary expenses＞

FY2023 Q1 YTD Results

JPY Bn	Full base	Adjustment					Core base
		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	**350.8**						**350.8**
Cost of sales	93.7					-0.1	93.6
SG&A expenses	136.6					-1.0	135.6
R&D expenses	77.2					-0.0	77.2
Other income*	0.6	-0.0			-0.5	-0.1	-
Other expenses*	0.0	-0.0					-
Core Operating Profit**							**44.5**
Temporary income		0.0			0.5		0.5
Temporary expenses		0.0				0.9	0.9
Operating Profit (full)	**44.0**						**44.0**

＜Major Temporary income and Temporary expenses＞

* The Company discloses profit and loss for which the offsetting of income and expenses is not permitted as Other income and Other expenses in the consolidated statement of income on a full basis (IFRS standards). Profit and loss from the sale of assets, etc. are included in this Other income and Other expenses.

** 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		FY2022 Q1 YTD Results	FY2023 Q1 YTD Results	(vs. Forecast (%))	YoY	YoY (%)	FY2023 Forecast	YoY	YoY (%)
Trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	**37.4**	**86.6**	**(23.5%)**	**49.2**	**+131.5%**	**368.6**	**110.2**	**+42.6%**
Product sales	*Incl. Gross profit share in AstraZeneca territory	31.3	81.7	(25.5%)	50.4	+161.1%	320.0	112.5	+54.2%
Enhertu (JPN)		2.4	4.4	(21.9%)	1.9	+80.1%	19.9	8.2	+69.9%
Enhertu (US)		20.0	51.6	(26.4%)	31.5	+157.3%	195.1	50.5	+34.9%
Enhertu (EU)		6.7	17.8	(23.5%)	11.1	+166.8%	75.8	38.8	+104.6%
Enhertu (ASCA: Asia, South and Central America)		2.2	8.0	(27.4%)	5.8	+269.1%	29.2	15.1	+106.1%
Upfront payment		2.5	2.5	(25.0%)	-	-	9.8	-	-
Regulatory milestone payment		3.4	2.1	(18.0%)	-1.3	-37.9%	11.6	-15.1	-56.7%
US HER2+ Breast Cancer 3L		0.2	0.2	(25.0%)	-	-	0.9	-	-
EU HER2+ Breast Cancer 3L		0.1	0.1	(25.0%)	-	-	0.5	-	-
US HER2+ Gastric Cancer 2L/3L		0.2	0.2	(25.0%)	-	-	0.8	-	-
US HER2+ Breast Cancer 2L		2.8	0.2	(25.0%)	-2.6	-92.3%	0.9	-2.6	-75.0%
EU HER2+ Breast Cancer 2L		-	0.2	(25.0%)	0.2	-	0.7	-2.0	-75.0%
US HER2-low Breast Cancer (post chemo)		-	0.5	(25.0%)	0.5	-	1.8	-5.5	-75.0%
EU HER2-low Breast Cancer (post chemo)		-	0.3	(25.0%)	0.3	-	1.3	-3.9	-75.0%
EU HER2+ Gastric Cancer 2L		-	0.1	(25.0%)	0.1	-	0.3	-0.9	-75.0%
US HER2 mutant NSCLC 2L		-	0.3	(25.0%)	0.3	-	1.1	-3.4	-75.0%
EU HER2 mutant NSCLC 2L		-	-	-	-	-	3.2	3.2	-
Quid related payment*		0.3	0.3	(25.0%)	-	-	1.1	-	-
Sales milestone payment		-	-	-	-	-	26.0	12.8	+97.3%
Datopotamab deruxtecan	anti-cancer agent (TROP2-directed antibody drug conjugate)	**1.5**	**1.6**	**(25.0%)**	**0.1**	**+6.9%**	**6.4**	**-0.7**	**-9.8%**
Upfront payment		1.5	1.6	(25.0%)	0.1	+6.9%	6.4	-0.7	-9.8%

*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		FY2022 Q1 YTD	FY2023 Q1 YTD				FY2023		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Edoxaban	anticoagulant	**58.9**	**66.0**	**(25.4%)**	**7.1**	**+12.1%**	**259.4**	**15.4**	**+6.3%**
Lixiana (JPN)		25.1	27.9	(25.4%)	2.8	+11.1%	109.9	4.8	+4.5%
Savaysa (US)		0.6	0.5	(16.0%)	-0.1	-14.9%	3.2	0.2	+5.1%
Lixiana (EU)		28.6	32.3	(25.8%)	3.7	+12.9%	125.1	8.0	+6.8%
Edoxaban (ASCA* etc.)		4.6	5.3	(25.0%)	0.7	+15.7%	21.2	2.5	+13.3%

*Asia, South and Central America

4. Revenue by Business Units and Products (1)

JPY Bn		FY2022 Q1 YTD	FY2023 Q1 YTD				FY2023		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Japan Business Unit		**109.0**	**119.0**	**(23.8%)**	**10.0**	**+9.1%**	**499.4**	**41.5**	**+9.1%**
Lixiana	anticoagulant	25.1	27.9	(25.4%)	2.8	+11.1%	109.9	4.8	+4.5%
Pralia	Treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	9.9	10.7	(24.6%)	0.8	+7.9%	43.5	3.3	+8.3%
Tarlige	pain treatment	8.9	11.7	(28.3%)	2.8	+31.9%	41.4	2.9	+7.5%
Vimpat	anti-epileptic agent	5.3	6.4	(25.9%)	1.1	+21.3%	24.8	2.8	+12.9%
Ranmark	treatment for bone complications caused by bone metastases from tumors	4.9	5.0	(23.3%)	0.0	+0.7%	21.3	0.9	+4.6%
Tenelia	type 2 diabetes mellitus treatment	5.6	5.3	(25.4%)	-0.3	-4.5%	20.9	-1.0	-4.7%
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	2.4	4.4	(21.9%)	1.9	+80.1%	19.9	8.2	+69.9%
Efient	antiplatelet agent	4.9	6.1	(32.7%)	1.3	+26.5%	18.8	-2.1	-10.1%
Canalia	type 2 diabetes mellitus treatment	4.1	4.1	(24.0%)	0.1	+1.4%	17.1	0.8	+5.2%
Loxonin	anti-inflammatory analgesic	4.6	4.0	(24.0%)	-0.6	-12.7%	16.7	-1.8	-9.7%
Emgality	prophylaxis of migraine attacks	1.4	1.7	(16.2%)	0.3	+17.7%	10.5	4.3	+67.9%
Daiichi Sankyo Espha products		21.0	20.6	-	-0.4	-2.1%	not disclosed	-	-
Vaccines business		0.5	0.7	-	0.2	+34.3%	not disclosed	-	-
Daiichi Sankyo Healthcare Unit		**15.3**	**17.1**	**(23.0%)**	**1.9**	**+12.3%**	**74.4**	**4.1**	**+5.8%**

4. Revenue by Business Units and Products (2)

JPY Bn		FY2022 Q1 YTD	FY2023 Q1 YTD				FY2023		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
Oncology Business Unit		**27.5**	**70.6**	**(25.6%)**	**43.1**	**+156.6%**	**276.2**	**90.7**	**+48.9%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	26.7	69.4	(25.6%)	42.7	+159.7%	270.9	89.3	+49.1%
Enhertu (US)		20.0	51.6	(26.4%)	31.5	+157.3%	195.1	50.5	+34.9%
Enhertu (EU)		6.7	17.8	(23.5%)	11.1	+166.8%	75.8	38.8	+104.6%
TURALIO	anti-cancer agent	0.8	1.2	(34.5%)	0.4	+53.3%	3.5	-0.3	-6.7%
American Regent Unit		**47.0**	**50.7**	**(25.5%)**	**3.6**	**+7.7%**	**198.7**	**11.4**	**+6.1%**
Injectafer	treatment for iron deficiency anemia	14.1	13.2	(25.3%)	-0.9	-6.5%	52.0	-1.9	-3.6%
Venofer	treatment for iron deficiency anemia	12.4	15.8	(35.8%)	3.4	+27.3%	44.1	-7.2	-14.1%
GE injectables		17.6	18.3	(21.0%)	0.8	+4.3%	87.5	15.9	+22.2%
EU Specialty Business Unit		**37.1**	**41.5**	**(25.8%)**	**4.4**	**+11.8%**	**161.0**	**10.6**	**+7.0%**
Lixiana	anticoagulant	28.6	32.3	(25.8%)	3.7	+12.9%	125.1	8.0	+6.8%
Nilemdo/Nustendi	cholesterol-lowering agent	1.3	3.0	(19.0%)	1.7	+126.8%	15.9	8.9	+125.4%
Olmesartan	antihypertensive agent	5.4	4.7	(29.0%)	-0.7	-12.6%	16.3	-3.7	-18.6%
ASCA Business Unit		**31.9**	**39.5**	**(25.3%)**	**7.6**	**+23.8%**	**156.3**	**13.5**	**+9.5%**
Daiichi Sankyo China		13.3	15.5	(23.7%)	2.2	+16.5%	65.5	7.3	+12.4%
Daiichi Sankyo Korea		6.1	6.3	(24.4%)	0.2	+2.7%	25.8	0.2	+1.0%
Daiichi Sankyo Brasil Farmacêutica		4.8	8.9	(26.2%)	4.1	+86.3%	34.0	6.2	+22.5%
Daiichi Sankyo Taiwan		3.1	4.0	(30.2%)	0.9	+27.8%	13.2	-0.2	-1.2%
Daiichi Sankyo Thailand		0.6	0.8	(27.7%)	0.2	+25.7%	2.9	0.0	+0.2%
Daiichi Sankyo Hong Kong		0.6	1.1	(54.9%)	0.5	+75.9%	2.0	-1.5	-42.6%

4. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

		FY2022 Q1 YTD	FY2023 Q1 YTD				FY2023		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
USD Mn									
Oncology Business Unit		**212**	**514**	**(24.2%)**	**302**	**+142.1%**	**2,124**	**755**	**+55.2%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	206	505	(24.2%)	299	+145.0%	2,084	743	+55.4%
Enhertu (US)		155	375	(25.0%)	221	+142.7%	1,500	433	+40.6%
Enhertu (EU)		52	130	(22.2%)	78	+151.7%	583	310	+113.3%
TURALIO	anti-cancer agent	6	9	(32.7%)	3	+44.6%	27	-1	-2.8%
USD Mn									
American Regent Unit		**363**	**369**	**(24.1%)**	**6**	**+1.6%**	**1,529**	**146**	**+10.5%**
Injectafer	treatment for iron deficiency anemia	109	96	(24.0%)	-13	-11.8%	400	2	+0.5%
Venofer	treatment for iron deficiency anemia	96	115	(33.9%)	19	+20.1%	339	-39	-10.4%
GE injectables		136	133	(19.8%)	-2	-1.6%	673	144	+27.3%
EUR Mn									
EU Specialty Business Unit		**269**	**278**	**(24.2%)**	**9**	**+3.3%**	**1,150**	**83**	**+7.8%**
Lixiana	anticoagulant	207	216	(24.2%)	9	+4.3%	894	63	+7.6%
Nilemdo/Nustendi	cholesterol-lowering agent	10	20	(17.8%)	11	+109.6%	114	64	+127.0%
Olmesartan	antihypertensive agent	39	32	(27.1%)	-8	-19.3%	116	-26	-18.0%

5. Consolidated Statement of Financial Position

<Assets> JPY Bn

	Mar. 2023	Jun. 2023	vs. Mar. 2023	
Assets				
Current assets				
Cash and cash equivalents	441.9	519.7	77.7	
Trade and other receivables	349.1	390.5	41.4	
Other financial assets	383.2	221.2	-162.0	
Inventories	301.6	339.3	37.7	
Other current assets	19.2	20.0	0.8	
Subtotal	1,495.1	1,490.7	-4.4	
Assets held for sale	-	17.9	17.9	Transfer of DSEP assets held for sale +17.9
Total current assets	**1,495.1**	**1,508.6**	**13.5**	
Non-current assets				
Property,plant and equipment	348.9	374.2	25.2	Acquisition +24.3, Depreciation -9.4, Forex +10.4
Goodwill	98.3	104.8	6.5	Forex +6.5
Intangible assets	159.6	155.7	-3.9	Acquisition +0.9, Depreciation -4.8, Forex +8.4, Transfer to Assets held for sale (DSEP) -8.4
Investments accounted for using the equity method	1.3	0.5	-0.8	
Other financial assets	130.4	148.2	17.8	Investment securities +17.4
Deferred tax assets	180.1	195.4	15.3	
Other non-current assets	95.2	128.8	33.6	Contribution for equipment +34.0
Total non-current assets	**1,013.8**	**1,107.5**	**93.7**	
Total assets	**2,508.9**	**2,616.1**	**107.2**	

*	Liquidity on hand (Cash, Securities, Investment securities etc.)	824.4	740.3	-84.1
	Debt with interest	192.9	196.0	3.2
	Net Cash	631.5	544.2	-87.3

<Liabilities and equity>

JPY Bn

	Mar. 2023	Jun. 2023	vs. Mar. 2023
Liabilities			
Current liabilities			
Trade and other payables	424.0	431.4	7.3
Bonds and borrowings	41.4	41.4	0.0
Other financial liabilities	11.1	11.9	0.9
Income taxes payable	21.5	20.4	-1.0
Provisions	7.6	3.4	-4.2
Other current liabilities	24.7	28.7	4.1
Subtotal	530.3	537.3	7.1
Liabilities directly associated with assets held for sale	-	14.1	14.1
Total current liabilities	**530.3**	**551.4**	**21.1**
Non-current liabilities			
Bonds and borrowings	101.7	101.6	-0.1
Other financial liabilities	41.6	44.0	2.3
Post employment benefit liabilities	1.3	1.5	0.1
Provisions	16.4	16.4	0.0
Deferred tax liabilities	12.6	13.8	1.2
Other non-current liabilities	359.1	357.5	-1.6
Total non-current liabilities	**532.8**	**534.8**	**2.0**
Total liabilities	**1,063.0**	**1,086.2**	**23.2**
Equity			
Equity attributable to owners of the Company			
Share capital	50.0	50.0	-
Treasury shares	-36.8	-36.8	0.0
Other components of equity	200.9	256.4	55.5
Retained earnings	1,231.8	1,260.3	28.5
Total equity attributable to owners of the Company	1,445.9	1,529.9	84.0
Total equity	**1,445.9**	**1,529.9**	**84.0**
Total liabilities and equity	**2,508.9**	**2,616.1**	**107.2**

Transfer of liabilities associated with DSEP assets held for sale +14.1

Deferred revenue for trastuzumab deruxtecan -4.8
(Strategic collaboration upfront payment -2.5, Regulatory milestone payment/Quid -2.4)
Deferred revenue for datopotamab deruxtecan -1.6
(Strategic collaboration upfront payment -1.6)

Currency translation difference +48.2, Valuation difference on financial assets +7.7

Profit for the period +57.0, Payment of dividends -28.8

6. Consolidated Statement of Cash Flows

JPY Bn

	FY2022Q1	FY2023Q1	YoY
Cash flows from operating activities			
Profit before tax	29.4	52.1	22.7
Depreciation and amortization	14.9	14.2	-0.7
(Increase) decrease in receivables and payables	-21.3	-25.4	-4.1
Others, net	-34.2	-79.3	-45.1
Income taxes paid	-9.6	-7.9	1.8
Net cash flows from operating activities	**-20.8**	**-46.2**	**-25.5**
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	48.2	169.0	120.8
(Acquisition of) proceeds from sales of fixed assets	-20.0	-26.5	-6.5
Net (increase) decrease in investment securities	-1.8	-1.5	0.3
Others, net	-0.1	-0.7	-0.6
Net cash flows from investing activities	**26.3**	**140.4**	**114.1**
Cash flows from financing activities			
Net (increase) decrease in borrowings	-0.1	-0.1	-0.0
Purchase of treasury shares	-0.0	-0.0	0.0
Dividends paid	-25.9	-28.8	-2.9
Others, net	-3.6	-3.6	0.0
Net cash flows from financing activities	**-29.7**	**-32.5**	**-2.9**
Net increase (decrease) in cash and cash equivalents	**-24.1**	**61.6**	**85.7**
Cash and cash equivalents at the beginning of the period	**662.5**	**441.9**	**-220.6**
Effect of exchange rate changes on cash and cash equivalents	**19.7**	**22.4**	**2.7**
Cash and cash equivalents at the end of the period	**658.1**	**526.0**	**-132.1**
Transfer to Assets held for sale	**-**	**-6.3**	**-6.3**
Cash and cash equivalents at the end of the period (Amount on Consolidated Statement of Financial Position)	**658.1**	**519.7**	**-138.4**

*	**Free cash flows** (Cash flows from operating activities and investing activities)	**5.5**	**94.2**	**88.6**

7. Number of Employees

	Jun. 2022	Mar. 2023	Jun. 2023
	Results	Results	Results
Consolidated	16,739	17,435	17,907
Japan	9,265	9,263	9,414
North America	2,743	3,062	3,187
Europe	2,337	2,554	2,638
Others	2,394	2,556	2,668

8. Capital Expenditure, Depreciation and Amortization

	FY2022 Q1 YTD	FY2022	FY2023 Q1 YTD	FY2023
JPY Bn	Results	Results	Results	Forecast
Capital expenditure	13.7	71.5	23.0	48.5
Depreciation and amortization	14.9	67.8	14.2	57.0
Property, plant and equipment	8.7	36.3	9.3	-
Intangible assets	6.2	31.4	4.8	-

9. 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		
Tarlige	mirogabalin	pain treatment	2019	Daiichi Sankyo		
Pralia	denosumab	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	2013	Amgen		
Efient	prasugrel	antiplatelet agent	2014	Daiichi Sankyo Ube Industries		
Tenelia	teneligliptin	type 2 diabetes mellitus treatment	2012	Mitsubishi Tanabe	Mitsubishi Tanabe	Co-promotion (DS: Sales)
Vimpat	lacosamide	anti-epileptic agent	2016	UCB	UCB	Co-promotion (DS: Sales)
Ranmark	denosumab	treatment for bone complications caused by bone metastases from tumors	2012	Amgen		
Canalia	teneligliptin / canagliflozin	type 2 diabetes mellitus treatment	2017	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		
Enhertu	trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	2020	Daiichi Sankyo		
Emgality	galcanezumab-gnlm	Prophylaxis of migraine attacks	2021	Eli Lilly Japan	Eli Lilly Japan	Co-promotion (DS: Sales)
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	CSL Vifor	Daiichi Sankyo, Inc.	Promotion (Daiichi Sankyo, Inc.)
Venofer	iron sucrose injection	treatment for iron deficiency anemia	2000	CSL Vifor	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	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			

<10. Quarterly Data>

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2022 Q1 Results	FY2022 Q2 Results	FY2022 Q3 Results	FY2022 Q4 Results	FY2022 to revenue	FY2022 Results	FY2023 Q1 Results	FY2023 Q2 Results	FY2023 Q3 Results	FY2023 Q4 Results	FY2023 to revenue	FY2023 Results	FY2023 YoY	FY2023 YoY (%)
Revenue	**280.3**	**327.5**	**340.5**	**330.2**	***100.0%***	**1,278.5**	**350.8**	**-**	**-**	**-**	***100.0%***	**350.8**	**70.5**	**+25.2%**
Cost of sales	74.7	84.7	98.0	91.7	*27.3%*	349.1	93.6	-	-	-	*26.7%*	93.6	18.9	+25.3%
Gross Profit	205.6	242.8	242.5	238.5	*72.7%*	929.4	257.2	-	-	-	*73.3%*	257.2	51.6	+25.1%
SG&A expenses	96.3	113.4	121.1	139.3	*36.8%*	470.1	135.6	-	-	-	*38.7%*	135.6	39.3	+40.8%
R&D expenses	74.9	78.9	87.9	95.0	*26.3%*	336.7	77.2	-	-	-	*22.0%*	77.2	2.2	+3.0%
Core Operating Profit	**34.4**	**50.4**	**33.6**	**4.3**	***9.6%***	**122.6**	**44.5**	**-**	**-**	**-**	***12.7%***	**44.5**	**10.1**	**+29.4%**
Temporary income	0.0	10.8	0.2	10.9		21.9	0.5	-	-	-		0.5	0.5	
Temporary expenses	-	0.0	2.2	21.7		23.9	0.9	-	-	-		0.9	0.9	
Operating Profit	**34.4**	**61.2**	**31.6**	**-6.6**	***9.4%***	**120.6**	**44.0**	**-**	**-**	**-**	***12.6%***	**44.0**	**9.7**	**+28.1%**
Financial income/expenses	-4.9	0.7	4.7	5.9		6.3	8.1	-	-	-		8.1	13.0	
Share of profit or loss of investments accounted for using the equity method	-0.0	-0.0	-0.0	0.1		-0.0	0.0	-	-	-		0.0	0.0	
Profit before tax	**29.4**	**61.8**	**36.2**	**-0.6**	***9.9%***	**126.9**	**52.1**	**-**	**-**	**-**	***14.9%***	**52.1**	**22.7**	**+77.2%**
Income taxes	10.6	22.4	7.8	-23.1		17.7	-4.9	-	-	-		-4.9	-15.4	
Profit for the year	**18.9**	**39.5**	**28.4**	**22.5**	***8.5%***	**109.2**	**57.0**	**-**	**-**	**-**	***16.3%***	**57.0**	**38.2**	**+202.4%**
Profit attributable to owners of the Company	**18.9**	**39.5**	**28.4**	**22.5**	***8.5%***	**109.2**	**57.0**	**-**	**-**	**-**	***16.3%***	**57.0**	**38.2**	**+202.4%**
Tax rate	35.9%	36.2%	21.5%	-		13.9%	-9.4%					-9.4%		
Overseas sales ratio	55.4%	58.1%	55.8%	63.4%		58.3%	60.9%					60.9%		
Currency Rate (YTD Average)														
USD/JPY	129.57	138.38	141.64	132.32		135.48	137.37					137.37		
EUR/JPY	138.10	139.34	144.35	142.07		140.97	149.46					149.46		

2. Revenue of Global Products

JPY Bn	FY2022 Q1 Results	FY2022 Q2 Results	FY2022 Q3 Results	FY2022 Q4 Results	FY2022 Results	FY2023 Q1 Results	FY2023 Q2 Results	FY2023 Q3 Results	FY2023 Q4 Results	FY2023 Results
Trastuzumab deruxtecan	**37.4**	**64.4**	**65.8**	**90.7**	**258.4**	**86.6**	**-**	**-**	**-**	**86.6**
Product sales	31.3	48.2	60.2	67.8	207.5	81.7	-	-	-	81.7
Enhertu(JPN)	2.4	2.8	3.3	3.2	11.7	4.4	-	-	-	4.4
Enhertu (US)	20.0	35.3	44.5	44.8	144.6	51.6	-	-	-	51.6
Enhertu (EU)	6.7	7.0	8.6	14.8	37.1	17.8	-	-	-	17.8
Enhertu (ASCA: Asia, South and Central America)	2.2	3.2	3.8	5.0	14.2	8.0	-	-	-	8.0
Upfront payment	2.5	2.5	2.5	2.5	9.8	2.5	-	-	-	2.5
Regulatory milestone payment	3.4	13.5	2.9	7.0	26.7	2.1	-	-	-	2.1
US HER2+ Breast Cancer 3L	0.2	0.2	0.2	0.2	0.9	0.2	-	-	-	0.2
EU HER2+ Breast Cancer 3L	0.1	0.1	0.1	0.1	0.5	0.1	-	-	-	0.1
US HER2+ Gastric Cancer 2L/3L	0.2	0.2	0.2	0.2	0.8	0.2	-	-	-	0.2
US HER2+ Breast Cancer 2L	2.8	0.2	0.2	0.2	3.5	0.2	-	-	-	0.2
EU HER2+ Breast Cancer 2L	-	2.3	0.2	0.2	2.7	0.2	-	-	-	0.2
US HER2-low Breast Cancer (post chemo)	-	6.4	0.5	0.5	7.3	0.5	-	-	-	0.5
EU HER2-low Breast Cancer (post chemo)	-	-	-	5.2	5.2	0.3	-	-	-	0.3
EU HER2+ Gastric Cancer 2L	-	-	1.2	0.1	1.3	0.1	-	-	-	0.1
US HER2 Mutant NSCLC 2L	-	4.0	0.3	0.3	4.6	0.3	-	-	-	0.3
EU HER2 Mutant NSCLC 2L	-	-	-	-	-	-	-	-	-	-
QUID related payment	0.3	0.3	0.3	0.3	1.1	0.3	-	-	-	0.3
Sales milestone payment	-	-	-	13.2	13.2	-	-	-	-	-
Datopotamab deruxtecan	**1.5**	**2.4**	**1.6**	**1.6**	**7.1**	**1.6**	**-**	**-**	**-**	**1.6**
Upfront payment	1.5	2.4	1.6	1.6	7.1	1.6	-	-	-	1.6
Edoxaban	**58.9**	**58.4**	**65.9**	**60.8**	**244.0**	**66.0**	**-**	**-**	**-**	**66.0**
Lixiana (JPN)	25.1	25.6	28.8	25.6	105.1	27.9	-	-	-	27.9
Savaysa (US)	0.6	0.9	0.5	1.1	3.0	0.5	-	-	-	0.5
Lixiana (EU)	28.6	27.2	32.0	29.3	117.1	32.3	-	-	-	32.3
Edoxaban (ASCA* etc.)	4.6	4.7	4.7	4.7	18.7	5.3	-	-	-	5.3

*Asia, South and Central America

3. Revenue by Business Units and Products (1) JPY Bn	FY2022 Q1 Results	FY2022 Q2 Results	FY2022 Q3 Results	FY2022 Q4 Results	FY2022 Results	FY2023 Q1 Results	FY2023 Q2 Results	FY2023 Q3 Results	FY2023 Q4 Results	FY2023 Results
Japan Business Unit	**109.0**	**116.0**	**131.3**	**101.5**	**457.9**	**119.0**	**-**	**-**	**-**	**119.0**
Lixiana	25.1	25.6	28.8	25.6	105.1	27.9	-	-	-	27.9
Pralia	9.9	9.4	11.1	9.8	40.2	10.7	-	-	-	10.7
Tarlige	8.9	9.4	10.8	9.4	38.5	11.7	-	-	-	11.7
Vimpat	5.3	5.3	6.1	5.2	21.9	6.4	-	-	-	6.4
Ranmark	4.9	5.1	5.5	4.8	20.4	5.0	-	-	-	5.0
Tenelia	5.6	5.4	6.0	4.9	21.9	5.3	-	-	-	5.3
Enhertu	2.4	2.8	3.3	3.2	11.7	4.4	-	-	-	4.4
Efient	4.9	5.0	5.8	5.2	20.9	6.1	-	-	-	6.1
Canalia	4.1	4.0	4.4	3.8	16.3	4.1	-	-	-	4.1
Loxonin	4.6	4.8	5.3	3.8	18.5	4.0	-	-	-	4.0
Emgality	1.4	1.6	1.7	1.5	6.3	1.7	-	-	-	1.7
Daiichi Sankyo Espha products	21.0	20.9	24.3	19.9	86.0	20.6	-	-	-	20.6
Vaccines business	0.5	8.1	7.5	-2.7	13.4	0.7	-	-	-	0.7
Daiichi Sankyo Healthcare Unit	**15.3**	**19.7**	**19.8**	**15.6**	**70.3**	**17.1**	**-**	**-**	**-**	**17.1**

3. Revenue by Business Units and Products (2)

JPY Bn

	FY2022 Q1 Results	FY2022 Q2 Results	FY2022 Q3 Results	FY2022 Q4 Results	FY2022 Results	FY2023 Q1 Results	FY2023 Q2 Results	FY2023 Q3 Results	FY2023 Q4 Results	FY2023 Results
Oncology Business Unit	**27.5**	**43.2**	**54.0**	**60.7**	**185.4**	**70.6**	**-**	**-**	**-**	**70.6**
Enhertu	26.7	42.3	53.1	59.6	181.6	69.4	-	-	-	69.4
Enhertu (US)	20.0	35.3	44.5	44.8	144.6	51.6	-	-	-	51.6
Enhertu (EU)	6.7	7.0	8.6	14.8	37.1	17.8	-	-	-	17.8
Turalio	0.8	0.9	0.9	1.1	3.8	1.2	-	-	-	1.2
American Regent Unit	**47.0**	**47.1**	**49.4**	**43.8**	**187.4**	**50.7**	**-**	**-**	**-**	**50.7**
Injectafer	14.1	13.3	14.4	12.1	54.0	13.2	-	-	-	13.2
Venofer	12.4	12.6	13.1	13.1	51.3	15.8	-	-	-	15.8
GE injectables	17.6	18.8	19.2	16.0	71.6	18.3	-	-	-	18.3
EU Specialty Business Unit	**37.1**	**34.7**	**40.7**	**37.9**	**150.4**	**41.5**	**-**	**-**	**-**	**41.5**
Lixiana	28.6	27.2	32.0	29.3	117.1	32.3	-	-	-	32.3
Nilemdo/Nustendi	1.3	1.5	2.1	2.2	7.1	3.0	-	-	-	3.0
Olmesartan	5.4	4.4	5.0	5.2	20.0	4.7	-	-	-	4.7
ASCA Business Unit	**31.9**	**37.9**	**36.6**	**36.3**	**142.8**	**39.5**	**-**	**-**	**-**	**39.5**
Daiichi Sankyo China	13.3	16.9	14.4	13.6	58.3	15.5	-	-	-	15.5
Daiichi Sankyo Korea	6.1	6.2	6.3	6.8	25.6	6.3	-	-	-	6.3
Daiichi Sankyo Brasil Farmacêutica	4.8	7.4	7.8	7.8	27.8	8.9	-	-	-	8.9
Daiichi Sankyo Taiwan	3.1	3.3	3.5	3.4	13.3	4.0	-	-	-	4.0
Daiichi Sankyo Thailand	0.6	0.7	0.8	0.8	2.9	0.8	-	-	-	0.8
Daiichi Sankyo Hong Kong	0.6	0.9	0.9	1.0	3.5	1.1	-	-	-	1.1

3. Revenue by Business Units and Products (3) [Reference] Revenue in Local Currency	FY2022 Q1 Results	FY2022 Q2 Results	FY2022 Q3 Results	FY2022 Q4 Results	FY2022 Results	FY2023 Q1 Results	FY2023 Q2 Results	FY2023 Q3 Results	FY2023 Q4 Results	FY2023 Results
USD Mn										
Oncology Business Unit	**212**	**315**	**386**	**455**	**1,369**	**514**	**-**	**-**	**-**	**514**
Enhertu	206	309	379	447	1,341	505	-	-	-	505
Enhertu (US)	155	258	318	336	1,067	375	-	-	-	375
Enhertu (EU)	52	50	61	110	274	130	-	-	-	130
Turalio	6	7	7	9	28	9	-	-	-	9
USD Mn										
American Regent Unit	**363**	**340**	**349**	**332**	**1,383**	**369**	**-**	**-**	**-**	**369**
Injectafer	109	96	102	92	398	96	-	-	-	96
Venofer	96	91	93	99	379	115	-	-	-	115
GE injectables	136	136	136	121	529	133	-	-	-	133
EUR Mn										
EU Specialty Business Unit	**269**	**249**	**282**	**267**	**1,067**	**278**	**-**	**-**	**-**	**278**
Lixiana	207	195	222	207	831	216	-	-	-	216
Nilemdo/Nustendi	10	11	14	15	50	20	-	-	-	20
Olmesartan	39	32	35	37	142	32	-	-	-	32

<11. Historical Data>

1. Revenue of Global Products

JPY Bn	FY2018 Results	FY2019 Results	FY2020 Results	FY2021 Results	FY2022 Results
Trastuzumab deruxtecan	**0.1**	**14.0**	**43.5**	**80.8**	**258.4**
Product sales	-	3.2	30.1	65.4	207.5
Enhertu (JPN)	-	-	4.4	9.6	11.7
Enhertu (US)	-	3.2	25.7	45.4	144.6
Enhertu (EU)	-	-	0.0	9.0	37.1
Enhertu (ASCA: Asia, South and Central America)	-	-	-	1.4	14.2
Upfront payment	0.1	9.8	9.8	9.8	9.8
Regulatory milestone payment	-	0.9	3.5	2.2	26.7
US HER2+ Breast Cancer 3L	-	0.9	0.9	0.9	0.9
EU HER2+ Breast Cancer 3L	-	-	1.0	0.5	0.5
US HER2+ Gastric Cancer 2L/3L	-	-	1.6	0.8	0.8
US HER2+ Breast Cancer 2L	-	-	-	-	3.5
EU HER2+ Breast Cancer 2L	-	-	-	-	2.7
US HER2-low Breast Cancer (post chemo)	-	-	-	-	7.3
EU HER2-low Breast Cancer (post chemo)	-	-	-	-	5.2
EU HER2+ Gastric Cancer 2L	-	-	-	-	1.3
US HER2 Mutant NSCLC 2L	-	-	-	-	4.6
EU HER2 Mutant NSCLC 2L	-	-	-	-	-
QUID related payment	-	-	-	3.4	1.1
Sales milestone payment	-	-	-	-	13.2
Datopotamab deruxtecan	**-**	**-**	**3.9**	**6.1**	**7.1**
Upfront payment	-	-	3.9	6.1	7.1
Edoxaban	**117.7**	**154.0**	**165.9**	**205.6**	**244.0**
Lixiana (JPN)	64.9	83.0	77.4	92.5	105.1
Savaysa (US)	2.3	2.6	3.0	1.9	3.0
Lixiana (EU)	45.8	61.7	76.7	96.9	117.1
Other subsidiaries	4.7	6.8	8.9	14.3	18.7

2. Revenue by Business Units and Products (1)

JPY Bn	FY2018 Results	FY2019 Results	FY2020 Results	FY2021 Results	FY2022 Results
Japan Business Unit	**523.3**	**533.5**	**489.1**	**489.5**	**457.9**
Lixiana	64.9	83.0	77.4	92.5	105.1
Pralia	27.4	30.9	34.6	37.9	40.2
Tarlige	-	8.0	20.6	30.1	38.5
Vimpat	6.6	11.2	14.5	18.3	21.9
Ranmark	16.4	17.9	19.3	20.4	20.4
Tenelia	25.3	24.7	24.2	23.7	21.9
Enhertu	-	-	4.4	9.6	11.7
Efient	13.9	14.0	14.1	16.7	20.9
Canalia	9.2	12.8	15.4	16.8	16.3
Loxonin	30.5	28.3	24.2	22.2	18.5
Emgality	-	-	-	4.6	6.3
Inavir	18.2	19.3	3.6	1.3	1.1
Daiichi Sankyo Espha products	55.5	60.5	71.4	82.8	86.0
Vaccines business	41.5	35.6	18.5	14.8	13.4
Daiichi Sankyo Healthcare Unit	**66.4**	**68.5**	**67.2**	**64.7**	**70.3**

2. Revenue by Business Units and Products (2)

JPY Bn	FY2018 Results	FY2019 Results	FY2020 Results	FY2021 Results	FY2022 Results
Oncology Business Unit	**36.3**	**32.1**	**47.4**	**69.6**	**185.4**
Enhertu	-	3.2	25.7	54.4	181.6
Enhertu (US)	-	3.2	25.7	45.4	144.6
Enhertu (EU)	-	-	0.0	9.0	37.1
Turalio	-	-	1.8	2.8	3.8
American Regent Unit	**117.8**	**130.8**	**121.7**	**149.5**	**187.4**
Injectafer	44.2	51.8	44.1	53.1	54.0
Venofer	28.9	31.0	28.8	33.8	51.3
EU Specialty Business Unit	**88.6**	**95.5**	**111.7**	**128.2**	**150.4**
Lixiana	45.8	61.7	76.7	96.9	117.1
Nilemdo/Nustendi	-	-	0.6	3.1	7.1
Olmesartan	27.4	24.6	21.5	20.3	20.0
ASCA Business Unit	**87.7**	**98.3**	**99.7**	**114.1**	**142.8**
Daiichi Sankyo China	38.5	46.0	45.6	53.3	58.3
Daiichi Sankyo Korea	15.7	17.2	19.6	23.2	25.6
Daiichi Sankyo Brasil Farmacêutica	10.0	11.5	10.5	13.7	27.8
Daiichi Sankyo Taiwan	7.1	7.6	8.3	10.0	13.3
Daiichi Sankyo Thailand	3.3	3.3	2.3	2.2	2.9
Daiichi Sankyo Hong Kong	-	-	0.7	1.7	3.5

2. Revenue by Business Units and Products (3) **[Reference] Revenue in Local Currency**	**FY2018** Results	**FY2019** Results	**FY2020** Results	**FY2021** Results	**FY2022** Results
USD Mn					
Oncology Business Unit	**327**	**295**	**447**	**619**	**1,369**
Enhertu	-	30	243	484	1,341
Enhertu (US)	-	30	243	404	1,067
Enhertu (EU)	-	-	0	80	274
Turalio	-	-	17	25	28
USD Mn					
American Regent Unit	**1,062**	**1,204**	**1,148**	**1,330**	**1,383**
Injectafer	399	477	416	472	398
Venofer	261	285	272	300	379
EUR Mn					
EU Specialty Business Unit	**690**	**789**	**903**	**982**	**1,067**
Lixiana	357	509	620	742	831
Nilemdo/Nustendi	-	-	5	24	50
Olmesartan	213	203	174	155	142

◆ 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, etc)	・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 develop-ment)	・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: anti-drug antibody, ADC: antibody drug conjugate, AGA: actionable genomic alterations, AML: acute myeloid leukemia, BMFI: brain metastases-free interval, BOR: best overall response, CBR: clinical benefit rate, CR: complete remission, CRL: complete response letter, DCR: disease control rate, DDFS: distant disease-free survival, DFS: disease-free survival, DOR: duration of response, DRFI: distant recurrence-free interval, EFS: event-free survival, eGFR: estimated glomerular filtration rate, FPD: first patient dosed, FSD: first subject dosed, GMFR: geometric mean fold rise, GMT: geometric mean titer, IDFS: invasive disease-free survival, LPD: last patient dosed, MLFS: morphologic leukemia-free state, 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, PR: partial remission, PRO: patient reported outcome, SCLC: small cell lung cancer, SCR: seroconversion rate, TLR: top line results, TNBC: triple negative breast cancer, TTD: Time to deterioration, TTNT: Time to next teatment, TTR: time to response, UACR: urine albumin-creatinine ratio

◆ 5DXd-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/China)

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: Aug 2022
Phase 3 DESTINY-Breast03 NCT03529110 JapicCTI-183976 AstraZeneca	HER2 positive breast cancer, 2L	524	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 May 2022: Approval (US) Jul 2022: Approval (EU) Nov 2022: Approval (JP) Feb 2023: Approval (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	557	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 Aug 2022: Approval (US) Jan 2023: Approval (EU) Mar 2023: Approval (JP) Jul 2023: Approval (CN) Feb 2022: Real Time Oncology Review Designation (US) Apr 2022: Breakthrough Therapy Designation (US) Aug 2022: Priority Review Designation (JP)
Phase 3 DESTINY-Breast05 NCT04622319 jRCT2061200033 AstraZeneca	HER2 positive breast cancer with residual invasive disease following neoadjuvant therapy, adjuvant 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	866	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 TLR anticipated: FY2023 H2
Phase1b/2 DESTINY-Breast07 NCT04538742 AstraZeneca	HER2 positive breast cancer Part 1: 2L or later Part 2: 1L	245	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	139	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	644	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	TNBC	210	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

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

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 2 (pivotal) DESTINY-Gastric01 NCT03329690 JapicCTI-173727 AstraZeneca	HER2 expressing, gastric or gastroesophageal junction adenocarcinoma, 3L	233	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) Dec 2022: Approval (EU) Mar 2018: SAKIGAKE Designation (JP) May 2020: Breakthrough Therapy Designation (US) May 2020: Orphan Drug Designation (US)
Phase 2 DESTINY-Gastric02 NCT04014075 AstraZeneca	HER2 positive gastric or gastroesophageal junction adenocarcinoma, 2L	79	Open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: PFS, ORR, OS, DOR	US/EU	FPD: Dec 2019 TLR: Jun 2021 Dec 2022: Approval (EU)
Phase 1b/2 DESTINY-Gastric03 NCT04379596 jRCT2031200203 AstraZeneca	HER2 positive gastric/gastroesophageal junction and esophageal adenocarcinoma Part 1: 2L Part 2: 1L	357	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, ADA	JP/US/EU /Asia	FPD: Jun 2020

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
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
Phase 2 DESTINY-Gastric06 NCT04989816 AstraZeneca	HER2 positive gastric or gastroesophageal junction adenocarcinoma, 3L	95	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 HER2 mutant NSCLC, 2L or later	181	Non-randomized, open label HER2 overexpressing NSCLC ・DS-8201 6.4mg/kg ・DS-8201 5.4mg/kg HER2 mutant NSCLC ・DS-8201 6.4mg/kg	Primary endpoint: ORR Secondary endpoint: ORR, DOR, PFS, OS, DCR	JP/US/EU	FPD: May 2018 TLR: Jun 2021 HER2 mutant NSCLC Aug 2022: Approval (US) (with consideration of the interim analysis data of DESTINY-Lung02) Dec 2022: Filing accepted (JP) Jan 2023: Filing accepted (EU) May 2020: Breakthrough Therapy Designation (US) Sep 2022: Orphan Drug Designation (JP)
Phase 2 DESTINY-Lung02 NCT04644237 jRCT2061200038 AstraZeneca	HER2 mutant NSCLC, 2L or later	152	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 Aug 2022: Approval (US) Dec 2022: Filing accepted (JP) Jan 2023: Filing accepted (EU)

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1b DESTINY-Lung03 NCT04686305 AstraZeneca	HER2 positive NSCLC, 1L	168	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.	US/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
Phase 2 DESTINY-Lung05 NCT05246514 AstraZeneca	NSCLC with HER2 exon 19 or exon 20 mutation, 2L or later	72	Open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: ORR, DOR, DCR, PFS, OS, PK, ADA, safety	China	FPD: Aug 2022
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	86	Non-randomized, open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: PFS, OS, DOR, DCR, ORR, PK	JP/US/EU	FPD: Mar 2018 Study completed: Nov 2020

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 2 DESTINY-CRC02 NCT04744831 jRCT2051200124 AstraZeneca	HER2 overexpressing colorectal cancer, 3L	122	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, etc.	JP/US/EU /Asia	FPD: Mar 2021 TLR: Jan 2023
Phase 2 DESTINY-PanTumor01 NCT04639219 jRCT2031210132 AstraZeneca	HER2 mutant 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)	102	Open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: DOR, DCR, PFS, ORR, OS, safety, PK, ADA	JP/US/EU /Asia	FPD: Jan 2021 TLR: Apr 2023
Phase 2 DESTINY-PanTumor02 NCT04482309 AstraZeneca	HER2 expressing tumors (bladder cancer, biliary tract cancer, cervical cancer, endometrial cancer, ovarian cancer, pancreatic cancer, rare tumors)	268	Non-randomized ・DS-8201	Primary endpoint: ORR Secondary endpoint: DOR, DCR, PFS, OS, safety, PK, ADA	US/EU /Asia	FPD: Oct 2020 IA TLR: Mar 2023
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 TLR: Sep 2021
Phase 1 NCT04042701 Merck	HER2 positive/low breast cancer HER2 expressing/HER2 mutant 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	FPD: Sep 2022

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 TNBC HR positive, HER2 low or negative breast cancer SCLC Transitional cell carcinoma of the urothelium HER2 negative gastroesophageal cancer Esophageal cancer Prostate cancer, etc.	770	Open label, two-part (dose escalation, dose expansion) ・DS-1062	Primary endpoint: Safety Secondary endpoint: PK, ADA	JP/US	FPD: Feb 2018
Phase 1/2 TROPION-PanTumor02 NCT05460273 AstraZeneca	NSCLC TNBC	118	Open label ・DS-1062	Primary endpoint: ORR Secondary endpoint: ORR, DOR, DCR, BOR, TTR, PFS, OS, safety, PK, etc.	China	FPD: Jul 2022
Phase 2 TROPION-PanTumor03 NCT05489211 jRCT2031220404 AstraZeneca	Endometrial cancer Gastric cancer Castration-resistant prostate cancer Ovarian cancer Colorectal cancer	531	Open label ・DS-1062 ・DS-1062 in combination with approved or novel anticancer agents	Primary endpoint: ORR, safety Secondary endpoint: PFS, DOR, DCR, best percentage change in tumor size, ADA, PK, etc.	JP/US/EU /Asia	FPD: Sep 2022

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 TROPION-Lung01 NCT04656652 jRCT2071200104 AstraZeneca	NSCLC, 2L/3L	590	Randomized, open label, active control ・DS-1062 ・Docetaxel	Primary endpoint: PFS, OS Secondary endpoint: PFS, ORR, DOR, TTR, DCR, safety, PK, ADA	JP/US/EU /Asia	FPD: Feb 2021 TLR: disclosed in Jul 2023
Phase 1 TROPION-Lung02 NCT04526691 jRCT2031200193 Merck AstraZeneca	NSCLC (without AGA) Part 1: 3L or later Part 2: 1L/2L	145	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
Phase 1 TROPION-Lung04 NCT04612751 jRCT2031200449 AstraZeneca	NSCLC (without AGA), 1L/2L	232	Open label, combination with immunotherapy, two-part (dose escalation, dose expansion) ・DS-1062 + durvalumab ± carboplatin ・DS-1062 + AZD2936 ± carboplatin ・DS-1062 + MEDI5752 ± carboplatin	Primary endpoint: Safety and tolerability Secondary endpoint: ORR, DOR, PFS, TTR, OS, PK, ADA, etc.	JP/US/EU	FPD: Mar 2021
Phase 2 TROPION-Lung05 NCT04484142 jRCT2041200097 AstraZeneca	NSCLC (with AGA)	137	Open label ・DS-1062	Primary endpoint: ORR Secondary endpoint: DOR, PFS, OS, safety, PK, ADA	JP/US/EU /Asia	FPD: Mar 2021 TLR: Mar 2023

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 TROPION-Lung07 NCT05555732 jRCT2061220066 Merck AstraZeneca	non-squamous NSCLC (without AGA and PD-L1 <50%), 1L	975	Randomized, open label, active control ・DS-1062 + pembrolizumab + cisplatin or carboplatin ・DS-1062 + pembrolizumab ・Pembrolizumab + pemetrexed + cisplatin or carboplatin	Primary endpoint: PFS, OS Secondary endpoint: ORR, PFS, DOR, TTR, DCR, TTD, safety, ADA, etc.	JP/US/EU /Asia	FPD: Jan 2023
Phase 3 TROPION-Lung08 NCT05215340 jRCT2061210074 Merck AstraZeneca	NSCLC (without AGA and PD-L1 ≥ 50%), 1L	740	Randomized, open label, active control ・DS-1062 + pembrolizumab ・Pembrolizumab	Primary endpoint: PFS, OS Secondary endpoint: ORR, PFS, DOR, TTR, DCR, TTD, safety, ADA, etc.	JP/US/EU /Asia	FPD: Mar 2022
Phase 1b/2 BEGONIA NCT03742102 AstraZeneca	TNBC, 1L	210	Non-randomized, open label, combination with durvalumab ・DS-1062 + durvalumab ・DS-1062 + durvalumab (patients with PD-L1 positive status) * 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 low or negative breast cancer, 2L/3L	733	Randomized, open label, active control ・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 TLR anticipated: FY2023 H2

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 TROPION-Breast02 NCT05374512 jRCT2061220029 AstraZeneca	TNBC, 1L	600	Randomized, open label, active control ・DS-1062 * Physician's choice (paclitaxel, nab-paclitaxel, carboplatin, capecitabine, eribulin)	Primary endpoint: PFS, OS Secondary endpoint: ORR, DOR, PFS, TTD, PK, ADA, safety, etc	JP/US/EU /Asia	FPD: Jun 2022
Phase 3 TROPION-Breast03 NCT05629585 AstraZeneca	TNBC with residual invasive disease following neoadjuvant therapy, adjuvant therapy	1,075	Randomized, open label, active control ・DS-1062 + durvalumab ・DS-1062 ・Physician's choice (capecitabine, pembrolizumab, capecitabine + pembrolizumab)	Primary endpoint: IDFS Secondary endpoint: DDFS, OS, IDFS, TTD, fatigue, PK, ADA, safety and tolerability	JP/US/EU /Asia	FPD: Dec 2022
Phase 1/2a PETRA NCT04644068 AstraZeneca AstraZeneca	Solid tumors	559	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
Phase 2 ORCHARD NCT03944772 AstraZeneca	EGFR mutated NSCLC, 2L	250	Non-randomized, open label ・DS-1062 + osimertinib * Platform study of osimertinib led by AstraZeneca	Primary endpoint: ORR Secondary endpoint: PFS, DOR, OS, PK, safety, etc.	JP/US/EU /Asia	FPD: Jul 2022
Phase 2 prep NeoCOAST-2 NCT05061550 AstraZeneca	Resectable, early-stage NSCLC, neoadjuvant	350	Non-randomized, open label ・DS-1062 + durvalumab + single agent platinum chemotherapy as neoadjuvant treatment and durvalumab as adjuvant treatment * Platform study of durvalumab led by AstraZeneca	Primary endpoint: pCR, safety Secondary endpoint: EFS, DFS, ORR, OS, etc.	US/EU /Asia	

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, ADA	JP/US	FPD: Dec 2016
Phase 1 NCT03260491 JapicCTI-194868	NSCLC	264	Non-randomized, open label, two-part (dose escalation, dose expansion) ・U3-1402	Primary endpoint: Safety and tolerability, ORR, PK Secondary endpoint: PK, ADA, ORR, DCR, DOR, TTR, PFS, OS, safety	JP/US/EU /Asia	FPD: Feb 2018
Phase 2 (pivotal) 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, etc.	JP/US/EU /Asia	FPD: Feb 2021 TLR: disclosed in Apr 2023 Dec 2021: Breakthrough Therapy Designation (US)
Phase 3 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: Aug 2022
Phase 1 NCT04676477 jRCT2031200247 AstraZeneca	EGFR mutated NSCLC, 1/2L	280	Non-randomized, open label, two-part (dose escalation, dose expansion) ・U3-1402 + Osimertinib	Primary endpoint: Safety and tolerability, ORR Secondary endpoint: ORR, DOR, DCR, TTR, PFS, OS, safety, PK, etc.	JP/US	FPD: Jun 2021

Ifinatamab deruxtecan/ DS-7300/ I-DXd (B7-H3-directed ADC)

Antibody-drug conjugate which is composed of fully human monoclonal antibody specifically targeting B7-H3, one of the immunomodulatory molecules belonging to B7 family, 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 1/2 NCT04145622 JapicCTI-194992	Esophageal squamous cell carcinoma, castration-resistant prostate cancer, sq-NSCLC, SCLC, etc.	195	Non-randomized, open label, two-part (dose escalation, dose expansion) ・DS-7300	Primary endpoint: Safety and tolerability, antitumor effect Secondary endpoint: PK, etc.	JP/US	FPD: Oct 2019
Phase 2 NCT05280470 jRCT2041220019	Extensive-stage SCLC, 2L or later	91	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: Jun 2022 Apr 2023: Orphan Drug Designation (US)

Raludotatug deruxtecan/ DS-6000/ R-DXd（CDH6-directed ADC）

Antibody-drug conjugate which is composed of fully human monoclonal antibody specifically targeting CDH6, one of the cadherin proteins relating to tumor growth and poor prognosis, 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 NCT04707248 jRCT2031220075	Renal cell carcinoma, ovarian cancer	140	Non-randomized, open label, two-part (dose escalation, dose expansion) ・DS-6000	Primary endpoint: Safety and tolerability Secondary endpoint: PK, ORR, DOR, DCR, etc.	JP/US	FPD: Jan 2021

◆ Next Wave (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	FLT3-ITD positive AML, 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)
Phase 3 QuANTUM-First NCT02668653 JapicCTI-173667	FLT3-ITD positive AML, 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 May 2023: Approval (JP) Jul 2023: Approval (US) Aug 2022: Filing accepted (EU) Mar 2009: Orphan Drug Designation (US/EU) Fast Track designation (US) Priority review was granted (US)

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 and tolerability, PK, ORR Secondary endpoint: Safety, ORR, ROM, PROMIS, DOR, etc.	JP	FPD: Apr 2021

Valemetostat/DS-3201 (EZH1/2 inhibitor)

Inhibitor of histone methylases, EZH1 and EZH2. Some cancer cells grow dependently on these enzymes.
Brand name: EZHARMIA (JP)

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 Sep 2022: Approval (JP) 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 TLR: Jun 2023 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

◆ Next Wave (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: Tolerability 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 TLR anticipated: FY2023 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 and tolerability Secondary endpoint: PK, ADA, etc.	JP/US	FPD: Oct 2020

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 and tolerability, CR rate Secondary endpoint: composite CR rate, MLFS rate, PR rate, ORR, DOR, EFS, OS, mortality rate, etc.	US	FPD: Apr 2021

DS-9606（Target undisclosed ADC）

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT05394675	Solid tumors	125	Non-randomized, open label ・DS-9606	Primary endpoint: Safety and tolerability, ORR Secondary endpoint: PK, DOR, DCR, TTR, PFS, ADA, etc.	US/EU	FPD: Jun 2022

DS-1103（anti-SIRPα antibody）

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT05765851	HER2 expressing or mutant advanced metastatic solid tumors (dose escalation part), HER2-low BC (dose expansion part)	78	Non-randomized, open label, two-part (dose escalation, dose expansion) ・DS-1103 + DS-8201	Primary endpoint: Safety and tolerability, ORR Secondary endpoint: ORR, DCR, CBR, DOR, PK. ADA, etc.	US/EU	FPD: Jun 2023

DS-3939（anti-TA-MUC1 ADC）

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1/2 prep NCT05875168 jRCT2031230233 Glycotope GmbH	Solid tumors	430	Non-randomized, open label, two-part (dose escalation, dose expansion) ・DS-3939	Primary endpoint: Safety and tolerability, ORR Secondary endpoint: ORR, DCR, DOR, TTR, PFS, OS, PK. ADA, etc.	JP/US	FPD planned: FY2023 Q2

DS-1471（anti-CD147 antibody）

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 prep jRCT2031230234	Solid tumors	80	Non-randomized, open label, two-part (dose escalation, dose expansion) ・DS-1471	Primary endpoint: Safety and tolerability Secondary endpoint: BOR, ORR, DCR, DOR, TTR, PFS, OS, PK, ADA etc.	JP	FPD planned: FY2023 H2

◆ Next Wave (Specialty Medicines Late-Stage Pipeline Products)

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 NCT04094662	Diabetic peripheral neuropathic pain	393	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 Jan 2023: Filing accepted (CN)

Esaxerenone/CS-3150 (MR blocker)

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 JapicCTI-173695 Exelixis, Inc.	Diabetic nephropathy	400	Randomized, 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

◆ Next Wave (Specialty Medicines Early-Stage Pipeline Products)

DS-1211 (TNAP inhibitor)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 2 NCT05569252	Pseudoxanthoma elasticum	64	Randomized, double-blind, placebo-controlled ・DS-1211	Primary endpoint: Safety, pharmacodynamic (PD) dose response Secondary endpoint: PK	US/EU	FPD: Nov 2022

DS-7011 (anti-TLR7 antibody)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT05203692	Healthy volunteers, systemic lupus erythematosus	80	Randomized, double-blind, placebo-controlled ・DS-7011	Primary endpoint: Safety Secondary endpoint: PK, PD, Immunogenicity	US	FSD: Feb 2022 TLR: Jun 2023
Phase 1b/2 NCT05638802	Systemic lupus erythematosus	24	Randomized, double-blind, placebo-controlled ・DS-7011	Primary endpoint: Safety Secondary endpoint: PK, PD, change of autoantibodies snd complement factors	US	FPD: Jul 2023

DS-2325 (KLK5 inhibitor)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT05388903	Healthy volunteers, Netherton syndrome	64	Randomized, double-blind, placebo-controlled ・DS-2325 (single ascending dose)	Primary endpoint: Safety Secondary endpoint: PK, ADA, etc.	US	FSD: Jun 2022 Dec 2022: Orphan Drug Designation (US)
Phase 1 NCT05583669	Healthy volunteers, Netherton syndrome	24	Randomized, double-blind, placebo-controlled ・DS-2325 (multiple ascending dose)	Primary endpoint: Safety Secondary endpoint: PK, ADA, etc.	US	FSD: Nov 2022 Dec 2022: Orphan Drug Designation (US) Feb 2023: Fast Track Designation (US) May 2023: Rare Pediatric Disease Designation (US)

◆ Next Wave (Vaccine)

VN-0107 (nasal spray 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	Approval: Mar 2023

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

DS-5670 (COVID-19 mRNA vaccine)

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 (original strain) ·Placebo	Primary endpoint: Safety, immunogenicity (neutralizing 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 ·DS-5670 (original strain)	Primary endpoint: Safety Secondary endopoint: Immunogenicity	JP	FSD: Nov 2021 TLR: Apr 2022
Phase 3 jRCT2031220264	Healthy adults with no history of vaccination against COVID-19, prevention of COVID-19	420	Randomized, single-blind, active-controlled, non-inferiority ·DS-5670 (original strain) ·Comirnaty®	Primary endpoint: Immunogenicity (GMT and SCR of neutralizing activity) Secondary endopoint:	JP	FSD: Sep 2022 TLR: Mar 2023
Phase 3 jRCT2031220400	Children aged 12 to 17 years with no history of vaccination against COVID-19, prevention of COVID-19	450	Randomized, single-blind, active-controlled, non-inferiority ·DS-5670 (original strain) ·Comirnaty®	Primary endpoint: Immunogenicity (GMT and SCR of neutralizing activity) Secondary endopoint: Immunogenicity (GMFR of neutralizing activity), incidence of COVID-19 infection, safety	JP	FSD: Nov 2022
Phase 2/3 prep jRCT2031220399	Children aged 5 to 11 years with no history of vaccination against COVID-19, prevention of COVID-19	640	Randomized, single-blind, active-controlled, non-inferiority ·DS-5670 (mutant strain) ·Comirnaty® for 5 to 11 years old	Primary endpoint: Immunogenicity (GMT and SCR of neutralizing activity) Secondary endopoint: Immunogenicity (GMFR of neutralizing activity), incidence of COVID-19 infection, safety	JP	
Phase 1/2/3 jRCT2071210106	Healthy adults who have completed primary vaccination of approved COVID-19 vaccine, prevention of COVID-19	5,028	Randomized, single-blind, active-controlled, two-part (dose confirmation and non-inferiority) ·DS-5670 (original strain) ·Comirnaty® ·Spikevax®	Primary endpoint: Immunogenicity (GMFR of neutralizing activity), safety Secondary endopoint: Immunogenicity, safety	JP	FSD: Jan 2022 TLR: Nov 2022 Jan 2023: Filing accepted (JP)

DS-5670 (COVID-19 mRNA vaccine)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 jRCT2071220111	Healthy volunteers 12 years and over who have completed primary vaccination of approved COVID-19 vaccine, prevention of COVID-19	1,400	Randomized, single-blind, active-controlled, Main Study and Substudy A (dose validity examination), Sub study B (examination for immunogenicity and safety) ・DS-5670 (omicron variant-adapted bivalent vaccine (original/ omicron BA.4-5)) ・Comirnaty® RTU (original/ omicron BA.4-5)	Primary endpoint: Main Study: GMT of blood neutralizing activity against SARS-CoV-2 (Omicron strain) and seroresponse rate at 4 weeks after study drug administration Sub Study A, Sub Study B: Not applicable. Secondary endpoint: Main Study: GMT of blood neutralizing activity against SARS-CoV-2 (original strain) and seroresponse rate at 4 weeks after study drug administration, Incidence of COVID-19 for 52 weeks after study drug administration, safety Sub Study A, Sub Study B: safety	JP	FSD: May 2023
Phase 2/3 jRCT2031220665	Children aged 5 to 11 years who have completed primary vaccination of approved COVID-19 vaccine, prevention of COVID-19	210	Randomized, double-blind, active-controlled, non-inferiority ・DS-5670 (omicron variant-adapted bivalent vaccine (original/ BA.4-5)) ・Comirnaty® for 5 to 11 years old	Primary endpoint: GMT of blood neutralizing activity against SARS-CoV-2 (Omicron strain) and seroresponse rate at 4 weeks after study drug administration. Secondary endpoint: GMT of blood neutralizing activity against SARS-CoV-2 (original strain) and seroresponse rate at 4 weeks after study drug administration, Incidence of COVID-19 for 52 weeks after study drug administration, safety	JP	FSD: May 2023

VN-0200 (RS virus vaccine)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT04914520 jRCT2031210069	Healthy adults and elderly, prevention of respiratory syncytial (RS) virus infection	48	Randomized, double-blind, placebo-controlled ·VN-0200 ·Placebo	Primary endpoint: Safety Secondary endpoint: immunogenicity	JP	FSD: Jun 2021 TLR: Apr 2022
Phase 2 NCT05547087 jRCT2071220051	Healthy elderly, prevention of respiratory syncytial (RS) virus infection	340	Randomized, double-blind, dose-comparison ·VN-0200	Primary endpoint: Immunogenicity Secondary endpoint: Safety	JP	FSD: Oct 2022

◆ Stage-up Projects (Major Changes from the FY2022 Q4 Financial Announcement in April 2023)

Generic Name/Project Code Number Mechanism of action	Target Indication	Current Stage	Note
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 low breast cancer, post chemotherapy	Approved	China, DESTINY-Breast04
Quizartinib FLT3 inhibitor	FLT3-ITD positive AML, 1L	Approved	JP/US, QuANTUM-First
DS-1103 anti-SIRPα antibody	Solid tumors	Ph1	US/EU
DS-3939 TA-MUC1 directed ADC Glycotope	Solid tumors	Ph1/2 prep	JP/US
DS-1471 anti-CD147 antibody	Solid tumors	Ph1 prep	Japan
DS-7011 anti-TLR7 antibody	Systemic lupus erythematosus	Ph1b/2	US
DS-5670 COVID-19 mRNA vaccine (mutant strain)	Prevention of COVID-19 (booster vaccination, omicron variant-adapted bivalent vaccine (original/ BA.4-5), healthey volunteers of 12 years and over)	Ph3	Japan
DS-5670 COVID-19 mRNA vaccine (mutant strain)	Prevention of COVID-19 (booster vaccination, omicron variant-adapted bivalent vaccine (original/ BA.4-5), children aged 5 to 11 years)	Ph2/3	Japan