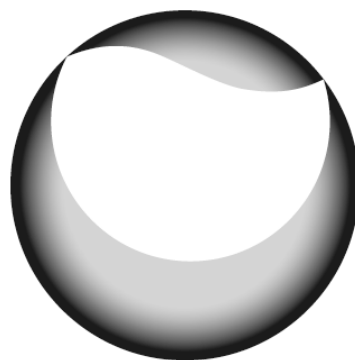


# Reference Data

(Consolidated Financial Results for Q1 FY2024)



Daiichi-Sankyo

July 31, 2024

Daiichi Sankyo Co., Ltd.

<https://www.daiichisankyo.com>

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# 1. Consolidated Statement of Profit or Loss

JPY Bn	FY2023 Q1 YTD		FY2024 Q1 YTD					FY2024			
	to revenue	Results	to revenue	Results	(vs. Forecast (%))	YoY	YoY (%)	to revenue	Forecast (as of Apr.)	YoY	YoY (%)
<b>Revenue</b>	<b>100.0%</b>	<b>350.8</b>	<b>100.0%</b>	<b>436.2</b>	<b>24.9%</b>	<b>85.3</b>	<b>+24.3%</b>	<b>100.0%</b>	<b>1,750.0</b>	<b>148.3</b>	<b>+9.3%</b>
Cost of sales*1	26.7%	93.6	21.8%	95.0	24.0%	1.4	+1.5%	22.6%	395.0	-19.8	-4.8%
<b>Gross Profit</b>	<b>73.3%</b>	<b>257.2</b>	<b>78.2%</b>	<b>341.2</b>	<b>25.2%</b>	<b>84.0</b>	<b>+32.6%</b>	<b>77.4%</b>	<b>1,355.0</b>	<b>168.1</b>	<b>+14.2%</b>
SG&A expenses*1	38.7%	135.6	38.4%	167.6	24.8%	32.0	+23.6%	38.6%	675.0	47.7	+7.6%
DXd ADC profit share*2	9.9%	34.8	13.0%	56.8	27.0%	22.0	+63.0%	12.0%	210.8	40.2	+23.6%
Other SG&A expenses	28.7%	100.8	25.4%	110.8	23.9%	10.0	+10.0%	26.5%	464.2	7.4	+1.6%
R&D expenses*1	22.0%	77.2	23.1%	100.7	21.4%	23.5	+30.5%	26.9%	470.0	105.7	+29.0%
<b>Core Operating Profit</b>	<b>12.7%</b>	<b>44.5</b>	<b>16.7%</b>	<b>72.9</b>	<b>34.7%</b>	<b>28.4</b>	<b>+63.9%</b>	<b>12.0%</b>	<b>210.0</b>	<b>14.7</b>	<b>+7.5%</b>
Temporary income*3		0.5		20.1		19.6			20.0	-7.3	
Temporary expenses*3		0.9		0.0		-0.9			-	-10.9	
<b>Operating Profit</b>	<b>12.6%</b>	<b>44.0</b>	<b>21.3%</b>	<b>93.0</b>	<b>40.4%</b>	<b>48.9</b>	<b>+111.2%</b>	<b>13.1%</b>	<b>230.0</b>	<b>18.4</b>	<b>+8.7%</b>
Financial income/expenses		8.1		17.2		9.1					
Share of profit or loss of investments accounted for using the equity method		0.0		0.1		0.1					
<b>Profit before tax</b>	<b>14.9%</b>	<b>52.1</b>	<b>25.3%</b>	<b>110.2</b>	<b>46.9%</b>	<b>58.1</b>	<b>+111.4%</b>	<b>13.4%</b>	<b>235.0</b>	<b>-2.2</b>	<b>-0.9%</b>
Income taxes		-4.9		24.8		29.7					
<b>Profit for the year</b>	<b>16.3%</b>	<b>57.0</b>	<b>19.6%</b>	<b>85.4</b>	<b>44.9%</b>	<b>28.4</b>	<b>+49.8%</b>	<b>10.9%</b>	<b>190.0</b>	<b>-11.0</b>	<b>-5.5%</b>
<b>Profit attributable to owners of the Company</b>	<b>16.3%</b>	<b>57.0</b>	<b>19.6%</b>	<b>85.4</b>	<b>44.9%</b>	<b>28.4</b>	<b>+49.8%</b>	<b>10.9%</b>	<b>190.0</b>	<b>-10.7</b>	<b>-5.3%</b>
Tax rate		-9.4%		22.5%							
Overseas sales ratio		60.9%		66.7%							
<u>Currency Rate (Average)</u>								<u>Currency Rate</u>			
USD/JPY		137.37		155.89				145.00			
EUR/JPY		149.46		167.88				155.00			

Forex impact: +30.4  
(USD: +16.9, EUR: +10.1, ASCA: +3.4)

Forex impact: +9.4  
(USD: +6.1, EUR: +2.8, ASCA: +0.5)

Forex impact: +14.6  
(USD: +10.9, EUR: +2.8, ASCA: +1.0)

Forex impact: +8.4  
(USD: +7.5, EUR: +0.6, ASCA: +0.2)

Forex impact: -2.0  
(USD: -7.5, EUR: +3.9, ASCA: +1.6)

- Improvement in forex gains/losses +7.8  
- Increase of interest income +2.8

## Annual impact of JPY 1 change

	Forecast	
	USD	EUR
Revenue	JPY 4.3 Bn	JPY 2.3 Bn
Operating Profit	JPY -0.2 Bn	JPY 0.3 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 DS pays alliance partners 50% of gross profit for the product sales in countries/regions where DS book revenue (excluding Japan) to share profit with the partners

\*3 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

### 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	
<b>Revenue</b>	<b>350.8</b>						<b>350.8</b>
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					-
<b>Core Operating Profit**</b>							<b>44.5</b>
Temporary income		0.0			0.5		0.5
Temporary expenses		0.0				0.9	0.9
<b>Operating Profit (full)</b>	<b>44.0</b>						<b>44.0</b>

<Major Temporary income and Temporary expenses>

### FY2024 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	
<b>Revenue</b>	<b>436.2</b>						<b>436.2</b>
Cost of sales	95.0					-0.1	95.0
SG&A expenses	175.1				-7.5	-0.0	167.6
R&D expenses	100.7					-0.0	100.7
Other income*	27.7	-3.8	-16.3		-7.5	-0.1	-
Other expenses*	0.0	-0.0					-
<b>Core Operating Profit**</b>							<b>72.9</b>
Temporary income		3.8 <sup>*1</sup>	16.3 <sup>*2</sup>				20.1
Temporary expenses		0.0					0.0
<b>Operating Profit (full)</b>	<b>93.0</b>						<b>93.0</b>

<Major Temporary income and Temporary expenses>

<sup>\*1</sup> Gains related to sale of Sapporo / Tokai Branch Building etc.

<sup>\*2</sup> Gains on stock transfer of Daiichi Sankyo Espha

\* 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	FY2023 Q1 YTD		FY2024 Q1 YTD				FY2024		
	Results		Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
<b>Trastuzumab deruxtecan</b> <small>anti-cancer agent (HER2-directed antibody drug conjugate)</small>	<b>86.6</b>		<b>134.8</b>	<b>(23.0%)</b>	<b>48.2</b>	<b>+55.7%</b>	<b>585.4</b>	<b>136.2</b>	<b>+30.3%</b>
Product sales <small>*Incl. Gross profit share in AstraZeneca territory</small>	81.7		129.6	(25.5%)	47.9	+58.6%	508.4	112.4	+28.4%
Enhertu (JPN)	4.4		7.8	(30.2%)	3.4	+78.1%	25.7	1.8	+7.5%
Enhertu (US)	51.6		68.9	(25.8%)	17.3	+33.5%	266.6	41.1	+18.2%
Enhertu (EU)	17.8		35.2	(23.2%)	17.4	+97.7%	152.1	50.2	+49.2%
Enhertu (ASCA: Asia, South and Central America)	8.0		17.8	(27.8%)	9.8	+121.9%	64.0	19.4	+43.5%
Brazil	5.3		8.5	(28.5%)	3.2	+61.1%	29.9	6.4	+27.2%
China (co-promotion revenue)	0.9		2.4	(22.3%)	1.5	+159.5%	10.8	4.3	+65.2%
Others	1.8		6.8	(29.3%)	5.0	+282.5%	23.3	8.7	+60.0%
Upfront payment	2.5		2.6	(25.0%)	0.1	+3.9%	10.2	0.1	+0.9%
Regulatory milestone payment	2.1		2.4	(25.0%)	0.3	+13.0%	9.4	-2.9	-23.7%
US HER2+ Breast Cancer 3L	0.2		0.2	(25.0%)	0.0	+4.0%	0.9	0.0	+1.0%
EU HER2+ Breast Cancer 3L	0.1		0.1	(25.0%)	0.0	+4.0%	0.5	0.0	+1.0%
US HER2+ Gastric Cancer 2L/3L	0.2		0.2	(25.0%)	0.0	+4.0%	0.8	0.0	+1.0%
US HER2+ Breast Cancer 2L	0.2		0.2	(25.0%)	0.0	+4.0%	0.9	0.0	+1.0%
EU HER2+ Breast Cancer 2L	0.2		0.2	(25.0%)	0.0	+4.0%	0.7	0.0	+1.0%
US HER2-low Breast Cancer (post chemo)	0.5		0.5	(25.0%)	0.0	+4.0%	1.9	0.0	+1.0%
EU HER2-low Breast Cancer (post chemo)	0.3		0.3	(25.0%)	0.0	+4.0%	1.4	0.0	+1.0%
EU HER2+ Gastric Cancer 2L	0.1		0.1	(25.0%)	0.0	+4.0%	0.3	0.0	+1.0%
US HER2 mutant NSCLC 2L	0.3		0.3	(25.0%)	0.0	+4.0%	1.2	0.0	+1.0%
EU HER2 mutant NSCLC 2L	-		0.2	(25.0%)	0.2	-	0.8	-3.0	-80.0%
Quid related payment*	0.3		0.3	(25.0%)	0.0	+4.0%	1.2	0.0	+1.0%
Sales milestone payment	-		-	-	-	-	56.2	26.6	+89.6%

\*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		FY2023 Q1 YTD	FY2024 Q1 YTD				FY2024		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
	<b>Datopotamab deruxtecan</b> anti-cancer agent (TROP2-directed antibody drug conjugate)	<b>1.6</b>	<b>1.6</b>	<b>(9.1%)</b>	-	-	<b>17.6</b>	<b>11.2</b>	<b>+175.8%</b>
	Product sales *Incl. Gross profit share in AstraZeneca territory	-	-	-	-	-	5.6	5.6	-
	Datopotamab deruxtecan (US)	-	-	-	-	-	5.6	5.6	-
	Upfront payment	1.6	1.6	(25.0%)	-	-	6.4	-	-
	Regulatory milestone payment	-	-	-	-	-	5.6	5.6	-
	US NSCLC 2L/3L	-	-	-	-	-	5.6	5.6	-
	<b>Patritumab deruxtecan</b> anti-cancer agent (HER3-directed antibody drug conjugate)	<b>-</b>	<b>2.0</b>	<b>(8.5%)</b>	<b>2.0</b>	-	<b>23.1</b>	<b>19.6</b>	<b>+553.1%</b>
	Product sales *Incl. Gross profit share in Merck territory	-	-	-	-	-	4.2	4.2	-
	Patritumab deruxtecan (US)	-	-	-	-	-	4.2	4.2	-
	Upfront payment	-	2.0	(10.4%)	2.0	-	18.9	15.4	+434.2%
	<b>Ifinatamab deruxtecan</b> anti-cancer agent (B7-H3-directed antibody drug conjugate)	<b>-</b>	<b>3.7</b>	<b>(25.0%)</b>	<b>3.7</b>	-	<b>14.7</b>	<b>8.1</b>	<b>+122.8%</b>
	Upfront payment	-	3.7	(25.0%)	3.7	-	14.7	8.1	+122.8%
	<b>Raludotatug deruxtecan</b> anti-cancer agent (DS-6000) (CDH6-directed antibody drug conjugate)	<b>-</b>	<b>1.5</b>	<b>(25.0%)</b>	<b>1.5</b>	-	<b>6.2</b>	<b>3.4</b>	<b>+122.8%</b>
	Upfront payment	-	1.5	(25.0%)	1.5	-	6.2	3.4	+122.8%
	<b>Edoxaban</b> anticoagulant	<b>66.0</b>	<b>88.3</b>	<b>(30.1%)</b>	<b>22.3</b>	<b>+33.8%</b>	<b>293.6</b>	<b>5.9</b>	<b>+2.1%</b>
	Lixiana (JPN)	27.9	34.9	(30.0%)	7.0	+25.1%	116.4	0.8	+0.7%
	Savaysa (US)	0.5	1.0	(35.6%)	0.5	+99.7%	2.8	0.4	+16.6%
	Lixiana (EU)	32.3	45.4	(30.4%)	13.1	+40.6%	149.5	3.3	+2.2%
	Edoxaban (ASCA* etc.)	5.3	7.0	(28.0%)	1.7	+31.7%	24.9	1.4	+6.0%
	*Asia, South and Central America								

#### 4. Revenue by Business Units and Products (1)

JPY Bn

		FY2023 Q1 YTD		FY2024 Q1 YTD				FY2024		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)	
<b>Japan Business Unit</b>		<b>119.0</b>	<b>117.7</b>	<b>(27.1%)</b>	<b>-1.3</b>	<b>-1.1%</b>	<b>434.9</b>	<b>-84.0</b>	<b>-16.2%</b>	
Lixiana	anticoagulant	27.9	34.9	(30.0%)	7.0	+25.1%	116.4	0.8	+0.7%	
Tarlige	pain treatment	11.7	14.2	(26.5%)	2.5	+20.9%	53.4	7.7	+16.9%	
Pralia	Treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	10.7	11.1	(28.3%)	0.4	+4.0%	39.3	-3.5	-8.3%	
Vimpat	anti-epileptic agent	6.4	8.1	(27.6%)	1.6	+25.6%	29.2	3.5	+13.5%	
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	4.4	7.8	(30.2%)	3.4	+78.1%	25.7	1.8	+7.5%	
Ranmark	treatment for bone complications caused by bone metastases from tumors	5.0	5.4	(25.9%)	0.4	+7.8%	20.7	0.3	+1.6%	
Efient	antiplatelet agent	6.1	8.1	(49.7%)	1.9	+31.1%	16.2	-9.4	-36.7%	
Canalia	type 2 diabetes mellitus treatment	4.1	4.3	(28.5%)	0.2	+3.7%	15.0	-0.9	-5.8%	
Loxonin	anti-inflammatory analgesic	4.0	3.5	(27.8%)	-0.5	-12.0%	12.7	-2.8	-17.9%	
Inavir	anti-influenza treatment	0.1	0.2	(1.4%)	0.0	+45.8%	11.3	-4.6	-28.9%	
Minnebro	antihypertensive agent	2.1	2.6	(23.8%)	0.5	+24.3%	10.8	2.5	+30.3%	
Vaccines business		0.7	0.7	-	-0.0	-5.0%	not disclosed	-	-	
<b>Daiichi Sankyo Healthcare Unit</b>		<b>17.1</b>	<b>20.0</b>	<b>(24.2%)</b>	<b>2.9</b>	<b>+17.0%</b>	<b>82.7</b>	<b>6.7</b>	<b>+8.9%</b>	

#### 4. Revenue by Business Units and Products (2)

JPY Bn			FY2023 Q1 YTD				FY2024 Q1 YTD				FY2024		
			Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)			
<b>Oncology Business Unit</b>			<b>70.6</b>	<b>106.4</b>	<b>(24.0%)</b>	<b>35.8</b>	<b>+50.7%</b>	<b>442.6</b>	<b>108.0</b>	<b>+32.3%</b>			
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)		69.4	104.1	(24.9%)	34.7	+50.0%	418.7	91.2	+27.9%			
	Enhertu (US)		51.6	68.9	(25.8%)	17.3	+33.5%	266.6	41.1	+18.2%			
	Enhertu (EU)		17.8	35.2	(23.2%)	17.4	+97.7%	152.1	50.2	+49.2%			
Datopotamab deruxtecan (US)	anti-cancer agent (TROP2-directed antibody drug conjugate)		-	-	-	-	-	5.6	5.6	-			
Patritumab deruxtecan (US)	anti-cancer agent (HER3-directed antibody drug conjugate)		-	-	-	-	-	4.2	4.2	-			
Turalio	anti-cancer agent		1.2	1.5	(25.8%)	0.3	+22.0%	5.8	0.5	+8.7%			
Vanflyta	anti-cancer agent (FLT3 Inhibitor)		-	0.9	(10.3%)	0.9	-	8.3	6.5	+347.4%			
<b>American Regent Unit</b>			<b>50.7</b>	<b>55.9</b>	<b>(25.6%)</b>	<b>5.3</b>	<b>+10.4%</b>	<b>218.2</b>	<b>14.8</b>	<b>+7.3%</b>			
Injectafer	treatment for iron deficiency anemia		13.2	15.8	(31.7%)	2.6	+19.5%	49.7	-0.3	-0.7%			
Venofer	treatment for iron deficiency anemia		15.8	16.3	(28.1%)	0.6	+3.5%	58.0	-2.9	-4.7%			
	GE injectables		18.3	20.6	(21.5%)	2.3	+12.5%	95.7	14.7	+18.1%			
<b>EU Specialty Business Unit</b>			<b>41.5</b>	<b>59.2</b>	<b>(29.4%)</b>	<b>17.7</b>	<b>+42.7%</b>	<b>201.4</b>	<b>12.3</b>	<b>+6.5%</b>			
Lixiana	anticoagulant		32.3	45.4	(30.4%)	13.1	+40.6%	149.5	3.3	+2.2%			
Nilemdo/Nustendi	cholesterol-lowering agent		3.0	7.8	(23.3%)	4.8	+158.6%	33.6	15.2	+82.4%			
Olmesartan	antihypertensive agent		4.7	5.3	(33.8%)	0.5	+11.5%	15.6	-4.0	-20.4%			
<b>ASCA Business Unit</b>			<b>39.5</b>	<b>48.7</b>	<b>(25.9%)</b>	<b>9.2</b>	<b>+23.4%</b>	<b>188.2</b>	<b>4.1</b>	<b>+2.2%</b>			
	Daiichi Sankyo China		15.5	15.7	(25.6%)	0.1	+0.8%	61.2	-9.3	-13.1%			
	Daiichi Sankyo Korea		6.3	8.2	(27.4%)	1.9	+30.2%	30.0	0.8	+2.7%			
	Daiichi Sankyo Brasil Farmacêutica		8.9	12.3	(24.6%)	3.4	+37.8%	50.0	8.0	+19.1%			
	Daiichi Sankyo Taiwan		4.0	4.6	(28.0%)	0.6	+15.6%	16.4	0.4	+2.3%			
	Daiichi Sankyo Thailand		0.8	1.0	(28.3%)	0.2	+19.4%	3.4	-0.1	-2.8%			
	Daiichi Sankyo Hong Kong		1.1	0.7	(24.0%)	-0.5	-41.0%	2.7	-0.2	-6.0%			

#### 4. Revenue by Business Units and Products (3)

##### [Reference] Revenue in Local Currency

		FY2023 Q1 YTD	FY2024 Q1 YTD				FY2024		
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast	YoY	YoY (%)
USD Mn									
<b>Oncology Business Unit</b>		<b>514</b>	<b>683</b>	<b>(22.4%)</b>	<b>169</b>	<b>+32.8%</b>	<b>3,052</b>	<b>738</b>	<b>+31.9%</b>
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	505	668	(23.1%)	163	+32.2%	2,887	623	+27.5%
Enhertu (US)		375	442	(24.0%)	66	+17.7%	1,839	279	+17.9%
Enhertu (EU)		130	226	(21.6%)	96	+74.2%	1,049	344	+48.9%
Datopotamab deruxtecan (US)	anti-cancer agent (TROP2-directed antibody drug conjugate)	-	-	-	-	-	39	39	-
Patritumab deruxtecan (US)	anti-cancer agent (HER3-directed antibody drug conjugate)	-	-	-	-	-	29	29	-
Turalio	anti-cancer agent	9	10	(24.0%)	1	+7.5%	40	3	+8.4%
Vanflyta	anti-cancer agent (FLT3 Inhibitor)	-	6	(9.6%)	6	-	57	45	+346.3%
USD Mn									
<b>American Regent Unit</b>		<b>369</b>	<b>359</b>	<b>(23.8%)</b>	<b>-10</b>	<b>-2.7%</b>	<b>1,505</b>	<b>98</b>	<b>+7.0%</b>
Injectafer	treatment for iron deficiency anemia	96	101	(29.5%)	5	+5.3%	343	-3	-0.9%
Venofer	treatment for iron deficiency anemia	115	105	(26.2%)	-10	-8.8%	400	-21	-5.0%
GE injectables		133	132	(20.0%)	-1	-0.9%	660	100	+17.8%
EUR Mn									
<b>EU Specialty Business Unit</b>		<b>278</b>	<b>353</b>	<b>(27.2%)</b>	<b>75</b>	<b>+27.0%</b>	<b>1,300</b>	<b>93</b>	<b>+7.7%</b>
Lixiana	anticoagulant	216	271	(28.1%)	54	+25.2%	964	32	+3.4%
Nilemdo/Nustendi	cholesterol-lowering agent	20	47	(21.5%)	26	+130.2%	217	99	+84.5%
Olmesartan	antihypertensive agent	32	31	(31.2%)	-0	-0.7%	101	-24	-19.5%

## 5. Consolidated Statement of Financial Position

<Assets>

JPY Bn

	Mar. 2024	Jun. 2024	vs. Mar. 2024	
Assets				
Current assets				
Cash and cash equivalents	647.2	805.3	158.1	
Trade and other receivables	454.2	544.5	90.3	
Other financial assets	577.0	204.1	-372.9	
Inventories	438.1	444.7	6.6	
Other current assets	33.0	51.1	18.1	
Subtotal	2,149.5	2,049.6	-99.9	
Assets held for sale	24.5	12.3	-12.3	Exclusion of consolidation of DSEP -23.5, Transfer of DSEP assets held for sale +12.3
<b>Total current assets</b>	<b>2,174.0</b>	<b>2,061.8</b>	<b>-112.2</b>	
Non-current assets				
Property, plant and equipment	421.7	448.3	26.7	Acquisition +28.3, Depreciation -11.1, Forex +10.0
Goodwill	108.5	114.0	5.5	Forex +5.5
Intangible assets	168.3	174.9	6.6	Acquisition +4.9, Depreciation -5.5, Forex +7.1
Investments accounted for using the equity method	0.6	0.6	0.0	
Other financial assets	147.9	159.4	11.5	Investment securities +11.4
Deferred tax assets	249.4	242.2	-7.1	
Other non-current assets	190.7	235.8	45.0	Contribution for equipment +43.7
<b>Total non-current assets</b>	<b>1,287.1</b>	<b>1,375.3</b>	<b>88.2</b>	
<b>Total assets</b>	<b>3,461.1</b>	<b>3,437.1</b>	<b>-24.0</b>	
* Liquidity on hand (Cash, Securities, Investment securities etc.)	1,223.6	1,009.1	-214.6	
Debt with interest	156.0	160.6	4.6	
Net Cash	1,067.6	848.5	-219.2	

## &lt;Liabilities and equity&gt;

JPY Bn

	Mar. 2024	Jun. 2024	vs. Mar. 2024
<b>Liabilities</b>			
Current liabilities			
Trade and other payables	557.1	531.2	-26.0
Bonds and borrowings	0.4	0.4	0.0
Other financial liabilities	12.8	13.8	1.0
Income taxes payable	46.4	21.3	-25.1
Provisions	15.4	11.4	-4.0
Contract liabilities	57.4	57.0	-0.5
Other current liabilities	22.3	27.6	5.3
Subtotal	711.9	662.7	-49.2
Liabilities directly associated with assets held for sale	11.5	-	-11.5
<b>Total current liabilities</b>	<b>723.4</b>	<b>662.7</b>	<b>-60.7</b>
Non-current liabilities			
Bonds and borrowings	101.3	101.2	-0.1
Other financial liabilities	46.2	49.6	3.3
Post employment benefit liabilities	1.3	1.5	0.2
Provisions	14.0	14.1	0.1
Contract liabilities	680.2	666.1	-14.1
Deferred tax liabilities	12.9	13.3	0.4
Other non-current liabilities	193.3	207.9	14.6
<b>Total non-current liabilities</b>	<b>1,049.1</b>	<b>1,053.6</b>	<b>4.5</b>
<b>Total liabilities</b>	<b>1,772.5</b>	<b>1,716.3</b>	<b>-56.2</b>
<b>Equity</b>			
Equity attributable to owners of the Company			
Share capital	50.0	50.0	-
Capital surplus	2.0	2.7	0.8
Treasury shares	-36.6	-82.3	-45.7
Other components of equity	284.0	333.6	49.6
Retained earnings	1,388.8	1,416.9	28.0
Total equity attributable to owners of the Company	1,688.2	1,720.8	32.7
Non-controlling interests	0.4	-	-0.4
<b>Total equity</b>	<b>1,688.6</b>	<b>1,720.8</b>	<b>32.2</b>
<b>Total liabilities and equity</b>	<b>3,461.1</b>	<b>3,437.1</b>	<b>-24.0</b>

Exclusion of consolidation of DSEP -11.5

Deferred revenue for trastuzumab deruxtecan -5.2  
 (Strategic collaboration upfront payment -2.6, Regulatory milestone payment/Quid -2.7)  
 Deferred revenue for datopotamab deruxtecan -1.6  
 (Strategic collaboration upfront payment -1.6)  
 Deferred revenue for US MRK alliance -7.2  
 (Strategic collaboration upfront payment -7.2)

Currency translation difference +44.9, Valuation difference on financial assets +4.5

Profit for the period +85.4, Payment of dividends -57.5

## 6. Consolidated Statement of Cash Flows

JPY Bn

	FY2023Q1	FY2024Q1	YoY
Cash flows from operating activities			
Profit before tax	52.1	110.2	58.1
Depreciation and amortization	14.2	16.6	2.4
(Increase) decrease in receivables and payables	-25.4	-112.8	-87.5
Others, net	-79.3	-82.3	-3.0
Income taxes paid	-7.9	-41.7	-33.9
<b>Net cash flows from operating activities</b>	<b>-46.2</b>	<b>-110.0</b>	<b>-63.8</b>
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	169.0	381.8	212.8
(Acquisition of) proceeds from sales of fixed assets	-26.5	-31.5	-5.0
Proceeds from sale of subsidiaries	-	5.3	5.3
Net (increase) decrease in investment securities	-1.5	-2.3	-0.9
Others, net	-0.7	4.1	4.7
<b>Net cash flows from investing activities</b>	<b>140.4</b>	<b>357.3</b>	<b>216.9</b>
Cash flows from financing activities			
Net (increase) decrease in borrowings	-0.1	-0.1	-0.0
Purchase of treasury shares	-0.0	-45.7	-45.7
Dividends paid	-28.8	-57.6	-28.8
Others, net	-3.6	-4.2	-0.5
<b>Net cash flows from financing activities</b>	<b>-32.5</b>	<b>-107.6</b>	<b>-75.0</b>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>61.6</b>	<b>139.7</b>	<b>78.1</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>441.9</b>	<b>647.2</b>	<b>205.3</b>
<b>Effect of exchange rate changes on cash and cash equivalents</b>	<b>22.4</b>	<b>18.4</b>	<b>-4.0</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>526.0</b>	<b>805.3</b>	<b>279.3</b>
<b>Transfer to Assets held for sale</b>	<b>-6.3</b>	<b>-</b>	<b>6.3</b>
<b>Cash and cash equivalents at the end of the period (Amount on Consolidated Statement of Financial Position)</b>	<b>519.7</b>	<b>805.3</b>	<b>285.6</b>
<b>* Free cash flows (Cash flows from operating activities and investing activities)</b>	<b>94.2</b>	<b>247.3</b>	<b>153.1</b>

## 7. Number of Employees

	Jun. 2023	Mar. 2024	Jun. 2024
	Results	Results	Results
Consolidated	17,907	18,726	18,907
Japan	9,414	9,468	9,309
North America	3,187	3,573	3,741
Europe	2,638	2,901	3,023
Others	2,668	2,784	2,834

## 8. Capital Expenditure, Depreciation and Amortization

	JPY Bn	FY2023 Q1 YTD	FY2023	FY2024 Q1 YTD	FY2024
		Results	Results	Results	Forecast
Capital expenditure		23.0	89.4	27.9	79.0
Depreciation and amortization		14.2	59.6	16.6	67.7
Property, plant and equipment		9.3	39.9	11.1	-
Intangible assets		4.8	19.8	5.5	-

## 9. Summary of Product Outlines

Brand Name	Generic Name	Therapeutic Category	Launched	Origin	Marketing Alliance	Type of Alliance
<b>Japan Business Unit</b>						
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		
Vimpat	lacosamide	anti-epileptic agent	2016	UCB	UCB	Co-promotion (DS: Sales)
Enhertu	trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	2020	Daiichi Sankyo		
Ranmark	denosumab	treatment for bone complications caused by bone metastases from tumors	2012	Amgen		
Efient	prasugrel	antiplatelet agent	2014	Daiichi Sankyo Ube Industries		
Canalia	teneligliptin / canagliflozin	type 2 diabetes mellitus treatment	2017	Mitsubishi Tanabe	Mitsubishi Tanabe	Co-promotion (DS: Sales)
Loxonin			1986	Daiichi Sankyo		
Loxonin Poultrice			2006	Lead Chemical		
Loxonin Tape			2008	Lead Chemical		
Loxonin Gel			2010	Daiichi Sankyo		
Inavir	laninamivir octanoate	anti-influenza treatment	2010	Daiichi Sankyo		
Minnebro	esaxerenone	antihypertensive agent	2019	Daiichi Sankyo		
<b>Oncology Business Unit</b>						
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		
Vanflyta	quizartinib	anti-cancer agent (FLT3 Inhibitor)	2023	Daiichi Sankyo		
<b>American Regent Unit</b>						
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
<b>EU Specialty Business Unit</b>						
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		2002			
Olmetec Plus	olmesartan / hydrochlorothiazide		2005			
Sevikar	olmesartan / amlodipine	antihypertensive agent	2009	Daiichi Sankyo	Menarini Pfizer	Co-marketing
Sevikar HCT	olmesartan / amlodipine / hydrochlorothiazide		2010			

<10. Quarterly Data>

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2023	FY2023	FY2023	FY2023	FY2023		FY2024	FY2024	FY2024	FY2024	FY2024			
	Q1	Q2	Q3	Q4	to revenue	Results	Q1	Q2	Q3	Q4	to revenue	Results	YoY	YoY (%)
	Results	Results	Results	Results			Results	Results	Results	Results				
<b>Revenue</b>	<b>350.8</b>	<b>375.5</b>	<b>446.9</b>	<b>428.4</b>	<b>100.0%</b>	<b>1,601.7</b>	<b>436.2</b>	-	-	-	<b>100.0%</b>	<b>436.2</b>	<b>85.3</b>	<b>+24.3%</b>
Cost of sales	93.6	94.8	122.0	104.4	25.9%	414.8	95.0	-	-	-	21.8%	95.0	1.4	+1.5%
<b>Gross Profit</b>	<b>257.2</b>	<b>280.8</b>	<b>325.0</b>	<b>324.0</b>	<b>74.1%</b>	<b>1,186.9</b>	<b>341.2</b>	-	-	-	<b>78.2%</b>	<b>341.2</b>	<b>84.0</b>	<b>+32.6%</b>
SG&A expenses	135.6	141.0	157.3	193.4	39.2%	627.3	167.6	-	-	-	38.4%	167.6	32.0	+23.6%
DXd ADC profit share	34.8	44.0	40.3	51.5	10.6%	170.6	56.8	-	-	-	13.0%	56.8	22.0	+63.0%
Other SG&A expenses	100.8	97.1	117.0	141.9	28.5%	456.8	110.8	-	-	-	25.4%	110.8	10.0	+10.0%
R&D expenses	77.2	88.9	90.8	107.5	22.7%	364.3	100.7	-	-	-	23.1%	100.7	23.5	+30.5%
<b>Core Operating Profit</b>	<b>44.5</b>	<b>50.9</b>	<b>76.9</b>	<b>23.0</b>	<b>12.2%</b>	<b>195.3</b>	<b>72.9</b>	-	-	-	<b>16.7%</b>	<b>72.9</b>	<b>28.4</b>	<b>+63.9%</b>
Temporary income	0.5	0.2	26.2	0.4		27.3	20.1	-	-	-		20.1	19.6	
Temporary expenses	0.9	0.0	3.6	6.4		10.9	0.0	-	-	-		0.0	-0.9	
<b>Operating Profit</b>	<b>44.0</b>	<b>51.0</b>	<b>99.5</b>	<b>17.0</b>	<b>13.2%</b>	<b>211.6</b>	<b>93.0</b>	-	-	-	<b>21.3%</b>	<b>93.0</b>	<b>48.9</b>	<b>+111.2%</b>
Financial income/expenses	8.1	-1.1	-1.8	20.3		25.5	17.2	-	-	-		17.2	9.1	
Share of profit or loss of investments accounted for using the equity method	0.0	0.0	0.0	0.1		0.2	0.1	-	-	-		0.1	0.1	
<b>Profit before tax</b>	<b>52.1</b>	<b>50.0</b>	<b>97.7</b>	<b>37.4</b>	<b>14.8%</b>	<b>237.2</b>	<b>110.2</b>	-	-	-	<b>25.3%</b>	<b>110.2</b>	<b>58.1</b>	<b>+111.4%</b>
Income taxes	-4.9	10.0	30.7	0.5		36.2	24.8	-	-	-		24.8	29.7	
<b>Profit for the year</b>	<b>57.0</b>	<b>40.0</b>	<b>67.1</b>	<b>36.9</b>	<b>12.6%</b>	<b>201.0</b>	<b>85.4</b>	-	-	-	<b>19.6%</b>	<b>85.4</b>	<b>28.4</b>	<b>+49.8%</b>
<b>Profit attributable to owners of the Company</b>	<b>57.0</b>	<b>40.0</b>	<b>66.6</b>	<b>37.2</b>	<b>12.5%</b>	<b>200.7</b>	<b>85.4</b>	-	-	-	<b>19.6%</b>	<b>85.4</b>	<b>28.4</b>	<b>+49.8%</b>
Tax rate	-9.4%	20.0%	31.4%	1.3%		15.3%	22.5%					22.5%		
Overseas sales ratio	60.9%	60.0%	57.8%	71.0%		62.5%	66.7%					66.7%		
Currency Rate (YTD Average)														
USD/JPY	137.37	141.00	143.29	144.62		144.62	155.89					155.89		
EUR/JPY	149.46	153.38	155.28	156.79		156.79	167.88					167.88		

<b>2. Revenue of Global Products (1)</b>	<b>FY2023 Q1</b>	<b>FY2023 Q2</b>	<b>FY2023 Q3</b>	<b>FY2023 Q4</b>	<b>FY2023</b>	<b>FY2024 Q1</b>	<b>FY2024 Q2</b>	<b>FY2024 Q3</b>	<b>FY2024 Q4</b>	<b>FY2024</b>
JPY Bn	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results
<b>Trastuzumab deruxtecan</b>	<b>86.6</b>	<b>96.5</b>	<b>111.4</b>	<b>154.8</b>	<b>449.2</b>	<b>134.8</b>	-	-	-	<b>134.8</b>
Product sales	81.7	91.6	102.6	119.9	395.9	129.6	-	-	-	129.6
Enhertu(JPN)	4.4	6.0	7.3	6.2	23.9	7.8	-	-	-	7.8
Enhertu (US)	51.6	54.3	57.0	62.7	225.5	68.9	-	-	-	68.9
Enhertu (EU)	17.8	21.4	25.5	37.2	101.9	35.2	-	-	-	35.2
Enhertu (ASCA: Asia, South and Central America)	8.0	9.9	12.8	13.8	44.6	17.8	-	-	-	17.8
Brazil	5.3	5.6	5.9	6.7	23.5	8.5	-	-	-	8.5
China (co-promotion revenue)	0.9	1.8	1.3	2.5	6.5	2.4	-	-	-	2.4
Others	1.8	2.5	5.7	4.7	14.6	6.8	-	-	-	6.8
Upfront payment	2.5	2.5	2.6	2.6	10.1	2.6	-	-	-	2.6
Regulatory milestone payment	2.1	2.1	5.8	2.4	12.4	2.4	-	-	-	2.4
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	0.2	0.2	0.2	0.2	0.9	0.2	-	-	-	0.2
EU HER2+ Breast Cancer 2L	0.2	0.2	0.2	0.2	0.7	0.2	-	-	-	0.2
US HER2-low Breast Cancer (post chemo)	0.5	0.5	0.5	0.5	1.9	0.5	-	-	-	0.5
EU HER2-low Breast Cancer (post chemo)	0.3	0.3	0.4	0.3	1.3	0.3	-	-	-	0.3
EU HER2+ Gastric Cancer 2L	0.1	0.1	0.1	0.1	0.3	0.1	-	-	-	0.1
US HER2 Mutant NSCLC 2L	0.3	0.3	0.3	0.3	1.2	0.3	-	-	-	0.3
EU HER2 Mutant NSCLC 2L	-	-	3.6	0.2	3.8	0.2	-	-	-	0.2
QUID related payment	0.3	0.3	0.3	0.3	1.2	0.3	-	-	-	0.3
Sales milestone payment	-	-	-	29.6	29.6	-	-	-	-	-

<b>2. Revenue of Global Products (2)</b>	<b>FY2023 Q1</b>	<b>FY2023 Q2</b>	<b>FY2023 Q3</b>	<b>FY2023 Q4</b>	<b>FY2023</b>	<b>FY2024 Q1</b>	<b>FY2024 Q2</b>	<b>FY2024 Q3</b>	<b>FY2024 Q4</b>	<b>FY2024</b>
JPY Bn	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results
<b>Datopotamab deruxtecan</b>	<b>1.6</b>	<b>1.6</b>	<b>1.6</b>	<b>1.6</b>	<b>6.4</b>	<b>1.6</b>	-	-	-	<b>1.6</b>
Product sales	-	-	-	-	-	-	-	-	-	-
Datopotamab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Upfront payment	1.6	1.6	1.6	1.6	6.4	1.6	-	-	-	1.6
Regulatory milestone payment	-	-	-	-	-	-	-	-	-	-
US NSCLC 2L/3L	-	-	-	-	-	-	-	-	-	-
<b>Patritumab deruxtecan</b>	-	-	<b>1.6</b>	<b>2.0</b>	<b>3.5</b>	<b>2.0</b>	-	-	-	<b>2.0</b>
Product sales	-	-	-	-	-	-	-	-	-	-
Patritumab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Upfront payment	-	-	1.6	2.0	3.5	2.0	-	-	-	2.0
<b>Ifinatamab deruxtecan</b>	-	-	<b>2.9</b>	<b>3.7</b>	<b>6.6</b>	<b>3.7</b>	-	-	-	<b>3.7</b>
Upfront payment	-	-	2.9	3.7	6.6	3.7	-	-	-	3.7
<b>Raludotatug deruxtecan (DS-6000)</b>	-	-	<b>1.2</b>	<b>1.5</b>	<b>2.8</b>	<b>1.5</b>	-	-	-	<b>1.5</b>
Upfront payment	-	-	1.2	1.5	2.8	1.5	-	-	-	1.5
<b>Edoxaban</b>	<b>66.0</b>	<b>71.7</b>	<b>78.5</b>	<b>71.6</b>	<b>287.7</b>	<b>88.3</b>	-	-	-	<b>88.3</b>
Lixiana (JPN)	27.9	29.3	32.4	26.1	115.6	34.9	-	-	-	34.9
Savaysa (US)	0.5	1.1	0.5	0.4	2.4	1.0	-	-	-	1.0
Lixiana (EU)	32.3	35.6	39.4	38.9	146.2	45.4	-	-	-	45.4
Edoxaban (ASCA* etc.)	5.3	5.8	6.2	6.2	23.5	7.0	-	-	-	7.0
*Asia, South and Central America										

<b>3. Revenue by Business Units and Products (1)</b>	<b>FY2023 Q1</b>	<b>FY2023 Q2</b>	<b>FY2023 Q3</b>	<b>FY2023 Q4</b>	<b>FY2023</b>	<b>FY2024 Q1</b>	<b>FY2024 Q2</b>	<b>FY2024 Q3</b>	<b>FY2024 Q4</b>	<b>FY2024</b>
JPY Bn	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results
<b>Japan Business Unit</b>	<b>119.0</b>	<b>127.8</b>	<b>165.5</b>	<b>106.6</b>	<b>518.9</b>	<b>117.7</b>	-	-	-	<b>117.7</b>
Lixiana	27.9	29.3	32.4	26.1	115.6	34.9	-	-	-	34.9
Tarlige	11.7	11.0	12.6	10.3	45.7	14.2	-	-	-	14.2
Pralia	10.7	10.4	12.2	9.5	42.8	11.1	-	-	-	11.1
Vimpat	6.4	6.3	7.2	5.8	25.7	8.1	-	-	-	8.1
Enhertu	4.4	6.0	7.3	6.2	23.9	7.8	-	-	-	7.8
Ranmark	5.0	5.3	5.6	4.5	20.4	5.4	-	-	-	5.4
Efient	6.1	6.3	7.3	5.9	25.6	8.1	-	-	-	8.1
Canalia	4.1	4.0	4.3	3.4	15.9	4.3	-	-	-	4.3
Loxonin	4.0	4.0	4.5	3.1	15.5	3.5	-	-	-	3.5
Inavir	0.1	1.7	11.7	2.3	15.9	0.2	-	-	-	0.2
Minnebro	2.1	1.9	2.3	1.9	8.3	2.6	-	-	-	2.6
Vaccines business	0.7	7.5	20.0	-0.5	27.7	0.7	-	-	-	0.7
<b>Daiichi Sankyo Healthcare Unit</b>	<b>17.1</b>	<b>20.3</b>	<b>22.5</b>	<b>16.0</b>	<b>76.0</b>	<b>20.0</b>	-	-	-	<b>20.0</b>

<b>3. Revenue by Business Units and Products (2)</b>	<b>FY2023 Q1</b>	<b>FY2023 Q2</b>	<b>FY2023 Q3</b>	<b>FY2023 Q4</b>	<b>FY2023</b>	<b>FY2024 Q1</b>	<b>FY2024 Q2</b>	<b>FY2024 Q3</b>	<b>FY2024 Q4</b>	<b>FY2024</b>
JPY Bn	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results
<b>Oncology Business Unit</b>	<b>70.6</b>	<b>78.2</b>	<b>84.1</b>	<b>101.7</b>	<b>334.6</b>	<b>106.4</b>	-	-	-	<b>106.4</b>
Enhertu	69.4	75.7	82.4	99.9	327.4	104.1	-	-	-	104.1
Enhertu (US)	51.6	54.3	57.0	62.7	225.5	68.9	-	-	-	68.9
Enhertu (EU)	17.8	21.4	25.5	37.2	101.9	35.2	-	-	-	35.2
Datopotamab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Patritumab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Turalio	1.2	1.4	1.5	1.2	5.3	1.5	-	-	-	1.5
Vanflyta	-	1.1	0.2	0.5	1.9	0.9	-	-	-	0.9
<b>American Regent Unit</b>	<b>50.7</b>	<b>48.0</b>	<b>53.3</b>	<b>51.4</b>	<b>203.4</b>	<b>55.9</b>	-	-	-	<b>55.9</b>
Injectafer	13.2	12.5	12.3	12.0	50.1	15.8	-	-	-	15.8
Venofer	15.8	13.3	16.1	15.7	60.9	16.3	-	-	-	16.3
GE injectables	18.3	19.0	21.8	21.9	81.0	20.6	-	-	-	20.6
<b>EU Specialty Business Unit</b>	<b>41.5</b>	<b>44.9</b>	<b>51.2</b>	<b>51.6</b>	<b>189.2</b>	<b>59.2</b>	-	-	-	<b>59.2</b>
Lixiana	32.3	35.6	39.4	38.9	146.2	45.4	-	-	-	45.4
Nilemdo/Nustendi	3.0	3.8	5.2	6.4	18.4	7.8	-	-	-	7.8
Olmesartan	4.7	4.5	5.3	5.1	19.6	5.3	-	-	-	5.3
<b>ASCA Business Unit</b>	<b>39.5</b>	<b>43.6</b>	<b>48.7</b>	<b>52.3</b>	<b>184.1</b>	<b>48.7</b>	-	-	-	<b>48.7</b>
Daiichi Sankyo China	15.5	15.2	19.0	20.7	70.5	15.7	-	-	-	15.7
Daiichi Sankyo Korea	6.3	8.3	7.3	7.3	29.2	8.2	-	-	-	8.2
Daiichi Sankyo Brasil Farmacêutica	8.9	10.0	11.3	11.8	42.0	12.3	-	-	-	12.3
Daiichi Sankyo Taiwan	4.0	3.9	4.1	4.1	16.0	4.6	-	-	-	4.6
Daiichi Sankyo Thailand	0.8	0.8	0.9	0.9	3.5	1.0	-	-	-	1.0
Daiichi Sankyo Hong Kong	1.1	0.5	0.6	0.6	2.9	0.7	-	-	-	0.7

<b>3. Revenue by Business Units and Products (3)</b>	<b>FY2023 Q1</b>	<b>FY2023 Q2</b>	<b>FY2023 Q3</b>	<b>FY2023 Q4</b>	<b>FY2023</b>	<b>FY2024 Q1</b>	<b>FY2024 Q2</b>	<b>FY2024 Q3</b>	<b>FY2024 Q4</b>	<b>FY2024</b>
<b>[Reference] Revenue in Local Currency</b>	Results	Results	Results	Results	Results	Results	Results	Results	Results	Results
USD Mn										
<b>Oncology Business Unit</b>	<b>514</b>	<b>541</b>	<b>570</b>	<b>688</b>	<b>2,314</b>	<b>683</b>	-	-	-	<b>683</b>
Enhertu	505	524	559	676	2,264	668	-	-	-	668
Enhertu (US)	375	375	385	423	1,560	442	-	-	-	442
Enhertu (EU)	130	149	173	253	704	226	-	-	-	226
Datopotamab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Patritumab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Turalio	9	9	10	8	37	10	-	-	-	10
Vanflyta	-	8	1	3	13	6	-	-	-	6
USD Mn										
<b>American Regent Unit</b>	<b>369</b>	<b>331</b>	<b>361</b>	<b>346</b>	<b>1,407</b>	<b>359</b>	-	-	-	<b>359</b>
Injectafer	96	86	83	81	346	101	-	-	-	101
Venofer	115	92	109	106	421	105	-	-	-	105
GE injectables	133	131	148	148	560	132	-	-	-	132
EUR Mn										
<b>EU Specialty Business Unit</b>	<b>278</b>	<b>286</b>	<b>323</b>	<b>320</b>	<b>1,207</b>	<b>353</b>	-	-	-	<b>353</b>
Lixiana	216	226	249	241	933	271	-	-	-	271
Nilemdo/Nustendi	20	24	33	40	118	47	-	-	-	47
Olmesartan	32	28	33	31	125	31	-	-	-	31

<11. Historical Data>

**1. Revenue of Global Products**

	FY2019	FY2020	FY2021	FY2022	FY2023
JPY Bn	Results	Results	Results	Results	Results
<b>Trastuzumab deruxtecan</b>	<b>14.0</b>	<b>43.5</b>	<b>80.8</b>	<b>258.4</b>	<b>449.2</b>
Product sales	3.2	30.1	65.4	207.5	395.9
Enhertu (JPN)	-	4.4	9.6	11.7	23.9
Enhertu (US)	3.2	25.7	45.4	144.6	225.5
Enhertu (EU)	-	0.0	9.0	37.1	101.9
Enhertu (ASCA: Asia, South and Central America)	-	-	1.4	14.2	44.6
Upfront payment	9.8	9.8	9.8	9.8	10.1
Regulatory milestone payment	0.9	3.5	2.2	26.7	12.4
US HER2+ Breast Cancer 3L	0.9	0.9	0.9	0.9	0.9
EU HER2+ Breast Cancer 3L	-	1.0	0.5	0.5	0.5
US HER2+ Gastric Cancer 2L/3L	-	1.6	0.8	0.8	0.8
US HER2+ Breast Cancer 2L	-	-	-	3.5	0.9
EU HER2+ Breast Cancer 2L	-	-	-	2.7	0.7
US HER2-low Breast Cancer (post chemo)	-	-	-	7.3	1.9
EU HER2-low Breast Cancer (post chemo)	-	-	-	5.2	1.3
EU HER2+ Gastric Cancer 2L	-	-	-	1.3	0.3
US HER2 Mutant NSCLC 2L	-	-	-	4.6	1.2
EU HER2 Mutant NSCLC 2L	-	-	-	-	3.8
QUID related payment	-	-	3.4	1.1	1.2
Sales milestone payment	-	-	-	13.2	29.6
<b>Datopotamab deruxtecan</b>	<b>-</b>	<b>3.9</b>	<b>6.1</b>	<b>7.1</b>	<b>6.4</b>
Upfront payment	-	3.9	6.1	7.1	6.4
<b>Patritumab deruxtecan</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>3.5</b>
Upfront payment	-	-	-	-	3.5
<b>Ifinatamab deruxtecan</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>6.6</b>
Upfront payment	-	-	-	-	6.6
<b>Raludotatug deruxtecan (DS-6000)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>2.8</b>
Upfront payment	-	-	-	-	2.8
<b>Edoxaban</b>	<b>154.0</b>	<b>165.9</b>	<b>205.6</b>	<b>244.0</b>	<b>287.7</b>
Lixiana (JPN)	83.0	77.4	92.5	105.1	115.6
Savaysa (US)	2.6	3.0	1.9	3.0	2.4
Lixiana (EU)	61.7	76.7	96.9	117.1	146.2
Edoxaban (ASCA etc.)	6.8	8.9	14.3	18.7	23.5

**2. Revenue by Business Units and Products (1)**

	FY2019	FY2020	FY2021	FY2022	FY2023
JPY Bn	Results	Results	Results	Results	Results
<b>Japan Business Unit</b>	<b>533.5</b>	<b>489.1</b>	<b>489.5</b>	<b>457.9</b>	<b>518.9</b>
Lixiana	83.0	77.4	92.5	105.1	115.6
Tarlige	8.0	20.6	30.1	38.5	45.7
Pralia	30.9	34.6	37.9	40.2	42.8
Vimpat	11.2	14.5	18.3	21.9	25.7
Enhertu	-	4.4	9.6	11.7	23.9
Ranmark	17.9	19.3	20.4	20.4	20.4
Efient	14.0	14.1	16.7	20.9	25.6
Canalia	12.8	15.4	16.8	16.3	15.9
Loxonin	28.3	24.2	22.2	18.5	15.5
Inavir	19.3	3.6	1.3	0.9	15.9
Minnebro	0.4	2.5	5.0	6.9	8.3
Vaccines business	35.6	18.5	14.8	13.4	27.7
<b>Daiichi Sankyo Healthcare Unit</b>	<b>68.5</b>	<b>67.2</b>	<b>64.7</b>	<b>70.3</b>	<b>76.0</b>

<b>2. Revenue by Business Units and Products (2)</b>	<b>FY2019</b>	<b>FY2020</b>	<b>FY2021</b>	<b>FY2022</b>	<b>FY2023</b>
JPY Bn	Results	Results	Results	Results	Results
<b>Oncology Business Unit</b>	<b>32.1</b>	<b>47.4</b>	<b>69.6</b>	<b>185.4</b>	<b>334.6</b>
Enhertu	3.2	25.7	54.4	181.6	327.4
Enhertu (US)	3.2	25.7	45.4	144.6	225.5
Enhertu (EU)	-	0.0	9.0	37.1	101.9
Turalio	-	1.8	2.8	3.8	5.3
Vanflyta	-	-	-	-	1.9
<b>American Regent Unit</b>	<b>130.8</b>	<b>121.7</b>	<b>149.5</b>	<b>187.4</b>	<b>203.4</b>
Injectafer	51.8	44.1	53.1	54.0	50.1
Venofer	31.0	28.8	33.8	51.3	60.9
GE injectables	41.2	41.8	54.7	71.6	81.0
<b>EU Specialty Business Unit</b>	<b>95.5</b>	<b>111.7</b>	<b>128.2</b>	<b>150.4</b>	<b>189.2</b>
Lixiana	61.7	76.7	96.9	117.1	146.2
Nilemdo/Nustendi	-	0.6	3.1	7.1	18.4
Olmesartan	24.6	21.5	20.3	20.0	19.6
<b>ASCA Business Unit</b>	<b>98.3</b>	<b>99.7</b>	<b>114.1</b>	<b>142.8</b>	<b>184.1</b>
Daiichi Sankyo China	46.0	45.6	53.3	58.3	70.5
Daiichi Sankyo Korea	17.2	19.6	23.2	25.6	29.2
Daiichi Sankyo Brasil Farmacêutica	11.5	10.5	13.7	27.8	42.0
Daiichi Sankyo Taiwan	7.6	8.3	10.0	13.3	16.0
Daiichi Sankyo Thailand	3.3	2.3	2.2	2.9	3.5
Daiichi Sankyo Hong Kong	-	0.7	1.7	3.5	2.9

<b>2. Revenue by Business Units and Products (3)</b>	<b>FY2019</b>	<b>FY2020</b>	<b>FY2021</b>	<b>FY2022</b>	<b>FY2023</b>
<b>[Reference] Revenue in Local Currency</b>	Results	Results	Results	Results	Results
USD Mn					
<b>Oncology Business Unit</b>	<b>295</b>	<b>447</b>	<b>619</b>	<b>1,369</b>	<b>2,314</b>
Enhertu	30	243	484	1,341	2,264
Enhertu (US)	30	243	404	1,067	1,560
Enhertu (EU)	-	0	80	274	704
Turalio	-	17	25	28	37
Vanflyta	-	-	-	-	13
USD Mn					
<b>American Regent Unit</b>	<b>1,204</b>	<b>1,148</b>	<b>1,330</b>	<b>1,383</b>	<b>1,407</b>
Injectafer	477	416	472	398	346
Venofer	285	272	300	379	421
GE injectables	380	394	487	529	560
EUR Mn					
<b>EU Specialty Business Unit</b>	<b>789</b>	<b>903</b>	<b>982</b>	<b>1,067</b>	<b>1,207</b>
Lixiana	509	620	742	831	933
Nilemdo/Nustendi	-	5	24	50	118
Olmesartan	203	174	155	142	125

◆ Explanation of Description

**Generic name/Project Code Number (mechanism of action)**

Detail on its mechanism

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
<ul style="list-style-type: none"> <li>• Study phase</li> <li>• Study name (if applicable)</li> <li>• CTG registration number</li> <li>• JapicCTI/jRCT registration number</li> <li>• Partner (if applicable)</li> </ul>	Patients and target indications for the study	Target sample size	Study design schematic (randomization or not, blinding or open label, control arm, etc)	<ul style="list-style-type: none"> <li>• Primary and secondary endpoints are listed</li> <li>• Safety measures are summarized as "safety"</li> <li>• Pharmacokinetic indices are summarized as "PK"</li> </ul>	Study locations	<ul style="list-style-type: none"> <li>• Study initiation</li> <li>• TLR</li> <li>• Regulatory filing</li> <li>• Status of application</li> </ul>

◆ List of Abbreviations

ADA: anti-drug antibody, ADC: antibody drug conjugate, AGA: actionable genomic alterations, AML: acute myeloid leukemia, BMFI: brain metastases-free interval, BMS: Bristol Myers Squibb, BOR: best overall response, BTC: biliary tract cancer, 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, GMT: geometric mean titer, HCC: hepatocellular carcinoma, IA: interim analysis, IDFS: invasive disease-free survival, MLFS: morphologic leukemia-free state, MRK: Merck & Co., Inc., Rahway, NJ, USA, NSCLC: non small cell lung cancer, ORR: overall response rate/objective response rate, OS: overall survival, PA: primary analysis, pCR: pathological complete response, PDAC: Pancreatic Ductal Adenocarcinoma, PFS: progression-free survival, PK: pharmacokinetics, PLD: pegylated liposomal doxorubicin, PR: partial remission, PRO: patient reported outcome, SCCHN: squamous cell carcinomas of the head and neck, SCLC: small cell lung cancer, TLR: top line results, TNBC: triple negative breast cancer, TTD: Time to deterioration, TTNT: Time to next treatment, 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 (registrational) 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: Launched (US) May 2020: Launched (JP) Feb 2021: Launched (EU)
Phase 3 DESTINY-Breast02  NCT03523585 JapicCTI-184017  AstraZeneca	HER2 positive breast cancer, 3L	608	Randomized, open label, active controlled •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 controlled •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: Approved (US) Jul 2022: Approved (EU) Nov 2022: Approved (JP) Feb 2023: Approved (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 controlled •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: Approved (US) Jan 2023: Approved (EU) Mar 2023: Approved (JP) Jul 2023: Approved (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 controlled •DS-8201 •T-DM1	Primary endpoint: IDFS Secondary endpoint: DFS, OS, DRFI, BMFI, safety, PK, etc.	JP/US/EU /Asia	FPD: Dec 2020 TLR anticipated: FY2025
Phase3 DESTINY-Breast06  NCT04494425 jRCT2061200028  AstraZeneca	HER2 low/HR positive breast cancer, chemotherapy naïve	866	Randomized, open label, active controlled •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: Apr 2024
Phase1b/2 DESTINY-Breast07  NCT04538742  AstraZeneca	HER2 positive breast cancer Part 1: 2L or later Part 2: 1L	244	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	138	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	1,157	Randomized, open label, active controlled •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 TLR anticipated: FY2025
Phase3 DESTINY-Breast11  NCT05113251 jRCT2041210097  AstraZeneca	HER2 positive breast cancer, neoadjuvant	912	Randomized, open label, active controlled •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 TLR anticipated: FY2024 H2
Phase 1b/2 BEGONIA  NCT03742102  AstraZeneca	TNBC	240	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 (registrational) DESTINY-Gastric01  NCT03329690 JapicCTI-173727  AstraZeneca	HER2 positive, gastric or gastroesophageal junction adenocarcinoma, 3L	233	Randomized, open label, active controlled •DS-8201 •Physician's choice (irinotecan or paclitaxel)	Primary endpoint: ORR Secondary endpoint: PFS, OS, DOR, DCR, TTF, ORR, PK	JP/Asia	FPD: Nov 2017 TLR: Jan 2020 Sep 2020: Approved (JP) Jan 2021: Approved (US) Dec 2022: Approved (EU)  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	79	Open label •DS-8201	Primary endpoint: ORR Secondary endpoint: PFS, ORR, OS, DOR	US/EU	FPD: Dec 2019 TLR: Jun 2021 Dec 2022: Approved (EU)
Phase 1b/2 DESTINY-Gastric03  NCT04379596 jRCT2031200203  AstraZeneca	HER2 positive gastric, gastroesophageal junction and esophageal adenocarcinoma Part 1: 2L Part 2: 1L Part 3: 1L Part 4: 1L	413	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  Part 3 •DS-8201 + volrustomig (MEDI5752) + fluorouracil or capecitabine  Part 4 •DS-8201 + rilvegostomig (AZD2936) + fluorouracil or capecitabine	Primary endpoint: Part 1: safety Part 2,3,4: 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 TLR anticipated: FY2025
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 TLR: Jul 2023  Dec 2023: Filing accepted (CN)  Nov 2023: Priority Review Designation (CN)
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 /Asia	FPD: May 2018 TLR: Jun 2021  HER2 mutant NSCLC Aug 2022: Approved (US) (with consideration of the interim analysis data of DESTINY-Lung02) May 2020: Breakthrough Therapy Designation (US) Sep 2022: Orphan Drug Designation (JP)  HER2 overexpressing NSCLC Apr 2024: Approved as part of HER2 positive tumor-agnostic (US) Jan 2024: Priority Review Designation (US)
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 TLR (IA): May 2022 TLR (PA): Feb 2023  Aug 2022: Approved (US) Aug 2023: Approved (JP) Oct 2023: Approved (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 non-squamous NSCLC, 1L	248	Randomized, open label, three-part (safety run-in, dose escalation, dose expansion) •DS-8201 + durvalumab + cisplatin •DS-8201 + durvalumab + carboplatin •DS-8201 + durvalumab + pemetrexed •DS-8201 •DS-8201 + volrustomig (MEDI5752) •DS-8201 + volrustomig (MEDI5752) + carboplatin •DS-8201 + rilvegostomig (AZD2936) •DS-8201 + rilvegostomig (AZD2936) + carboplatin	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	450	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 TLR anticipated: FY2025
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 TLR: Nov 2023  Mar 2024: Filing accepted (CN) Mar 2024: Priority Review Designation (CN)
Phase 2 HUDSON  NCT03334617  AstraZeneca	NSCLC, 2L or later	531	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 TLR: Aug 2022

## 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 Apr 2024: Approved as part of HER2 positive tumor-agnostic (US)  Breakthrough Therapy Designation (US) Jan 2024: Priority Review Designation (US)
Phase 3 in prep DESTINY-BTC01  NCT06467357  AstraZeneca	HER2 expressing BTC, 1L	620	Randomized, open label, active controlled •DS-8201 + rilvegostomig (AZD2936) •DS-8201 •Gemcitabine + cisplatin + durvalumab	Primary endpoint: safety and tolerability, OS Secondary endpoint: OS, PFS, ORR, DOR, safety and tolerability, TTD, PK, ADA	JP/US/EU /Asia	FPD planned: FY2024 H1
Phase 2 DESTINY-PanTumor02  NCT04482309  AstraZeneca	HER2 expressing tumors (bladder cancer, BTC, cervical cancer, endometrial cancer, ovarian cancer, pancreatic cancer, other rare tumors)	468	Non-randomized •DS-8201	Primary endpoint: ORR Secondary endpoint: DOR, DCR, PFS, OS, safety, PK, ADA	US/EU /Asia	FPD: Oct 2020 TLR: Jul 2023 Apr 2024: Approved (US)  Sep 2023: Breakthrough Therapy Designation (US) Jan 2024: Priority Review Designation (US)
Phase 2 DESTINY-PanTumor03  NCT06271837  AstraZeneca	HER2 overexpressing tumors	50	Non-randomized, open label •DS-8201	Primary endpoint: ORR Secondary endpoint: ORR by investigator, DOR, DCR, BOR, PFS, OS, safety, PK, ADA	China	FPD: Feb 2024
Phase 1  NCT04042701  MRK	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 jRCT2031210609  AstraZeneca	Solid tumors	804	Non-randomized, open label, combination with AZD5305 •DS-8201 + saruparib (AZD5305)	Primary endpoint: safety Secondary endpoint: tumor size change, ORR, DOR, PFS, TTR, PK, ADA, etc	JP/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.	890	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	119	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 Urothelial cancer BTC	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
Phase 3 TROPION-Lung01  NCT04656652 jRCT2071200104  AstraZeneca	NSCLC, 2L or later	590	Randomized, open label, active controled •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: Jul 2023  Feb 2024: Filing accepted (US) Mar 2024: Filing accepted (EU)

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 TROPION-Lung02  NCT04526691 jRCT2031200193  MRK 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	321	Open label, combination with immunotherapy, two-part (dose escalation, dose expansion) •DS-1062 + durvalumab ± carboplatin •DS-1062 + rilvegostomig (AZD2936) ± carboplatin •DS-1062 + volrustomig (MEDI5752) ± carboplatin •DS-1062 + sabestomig (AZD7789)	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
Phase 3 TROPION-Lung07  NCT05555732 jRCT2061220066  MRK AstraZeneca	non-squamous NSCLC (without AGA and PD-L1 <50%), 1L	975	Randomized, open label, active controled •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

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 TROPION-Lung08  NCT05215340 jRCT2061210074  MRK AstraZeneca	NSCLC (without AGA and PD-L1 $\geq$ 50%), 1L	740	Randomized, open label, active controled •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 3 TROPION-Lung10  NCT06357533  AstraZeneca	non-squamous NSCLC (without AGA and PD-L1 $\geq$ 50%), 1L	675	Randomized, open label, active controled •Rilvegostomig (AZD2936) •DS-1062+ rilvegostomig (AZD2936) •Pembrolizumab	Primary endpoint: PFS (TROP2 biomarker positive), OS (TROP2 biomarker positive) Secondary endpoint: PFS (ITT), OS (ITT), ORR, DOR, PK, immunogenecity, etc.	JP/US/EU /Asia	FPD: May 2024
Phase 3 TROPION-Lung14  NCT06350097  AstraZeneca	EGFR mutated NSCLC, 1L	582	Randomized, open label, active controled •DS-1062 + osimertinib •Osimertinib	Primary endpoint: PFS Secondary endpoint: OS, CNS PFS, PFS by investigator, ORR, DOR, ADA, etc.	JP/US/EU /Asia	FPD: May 2024
Phase 3 in prep TROPION-Lung15  NCT06417814  AstraZeneca	EGFR mutated NSCLC, 2L or later	630	Randomized, open label, active controled •DS-1062 + osimertinib •Osimertinib •Pemetrexed + carboplatin or cisplatin, followed by pemetrexed	Primary endpoint: PFS Secondary endpoint: OS, CNS PFS, ORR, DOR, PK, ADA, etc.	JP/US/EU /Asia	FPD planned: FY2024 H1
Phase 3 AVANZAR  NCT05687266  AstraZeneca	NSCLC (without AGA), 1L	1,280	Randomized, open label, active controled •DS-1062 + durvalumab + carboplatin •Non-squamous NSCLC participants: pembrolizumab + pemetrexed + carboplatin or cisplatin •squamous NSCLC participants: pembrolizumab + paclitaxel + carboplatin	Primary endpoint: •PFS, OS (TROP2 biomarker positive) Secondary endpoint: •PFS, OS (ITT) •PFS, OS (TROP2 biomarker negative) •ORR, DOR (TROP2 biomarker positive and ITT) •PK, AGA, etc.	JP/US/EU /Asia	FPD: FY2022 Q4  TLR anticipated: CY2025 H2

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1b/2 BEGONIA  NCT03742102  AstraZeneca	TNBC, 1L	240	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	732	Randomized, open label, active controlled •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: Sep 2023  Mar 2024: Filing accepted (JP, EU, CN) Apr 2024: Filing accepted (US)
Phase 3 TROPION-Breast02  NCT05374512 jRCT2061220029  AstraZeneca	TNBC, PD-1/PD-L1 inhibitor ineligible, 1L	600	Randomized, open label, active controlled •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 TLR anticipated: FY2024 H2
Phase 3 TROPION-Breast03  NCT05629585 jRCT2061220087  AstraZeneca	TNBC with residual invasive disease following neoadjuvant therapy, adjuvant therapy	1,075	Randomized, open label, active controlled •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 3 TROPION-Breast04  NCT06112379 jRCT2031230723  AstraZeneca	TNBC, HR low and HER2 negative BC, neoadjuvant with durvalumab and ajuvant with durvalumab ± chemotherapy	1,728	Randomized, open label, active controlled •DS-1062 + durvalumab as neoadjuvant, durvalumab ± chemotherapy as adjuvant •pembrolizumab + chemotherapy as neoadjuvant, pembrolizumab ± chemotherapy as adjuvant	Primary endpoint: pCR, EFS Secondary endpoint: OS, DDFS, PRO, PK, ADA, safety, etc	JP/US/EU /Asia	FPD: Nov 2023

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 TROPION-Breast05  NCT06103864 jRCT2061230102  AstraZeneca	PD-L1 positive TNBC, with or without durvalumab, 1L	625	Randomized, open label, active controlled •DS-1062 + durvalumab •DS-1062 •Physician's choice of chemotherapy in combination with pembrolizumab (paclitaxel, nab-paclitaxel, or gemcitabine + carboplatin)	Primary endpoint: PFS Secondary endpoint: OS, ORR, DOR, PFS by investigator assesment, CBR, TTD, etc.	JP/US/EU /Asia	FPD: Nov 2023
Phase 1/2a PETRA  NCT04644068 jRCT2031210609  AstraZeneca	Solid tumors	804	Non-randomized, open label, combination with AZD5305 •DS-1062 + saruparib (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 jRCT2080224686  AstraZeneca	EGFR mutated NSCLC, 2L	248	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 NeoCOAST-2  NCT05061550  AstraZeneca	Resectable, early-stage NSCLC, neoadjuvant	490	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	FPD: Aug 2023

## 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 NCT03260491 JapicCTI-194868 MRK	NSCLC	309	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 (registrational) HERTHENA-Lung01 NCT04619004 jRCT2031200186 MRK	EGFR mutated NSCLC, 3L	277	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 2023: Filing accepted (US) Jun 2024: CRL received (US)  Dec 2021: Breakthrough Therapy Designation (US) Real Time Oncology Review Designation (US) Dec 2023: Priority Review Designation (US)
Phase 3 HERTHENA-Lung02 NCT05338970 jRCT2021220002 MRK	EGFR mutated NSCLC, 2L	586	Randomized, open label, active controlled •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 TLR anticipated: FY2024 H1
Phase 1 NCT04676477 jRCT2031200247 AstraZeneca MRK	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, CBR, DCR, TTR, PFS, OS, safety, PK, etc.	JP/US /Asia	FPD: Jun 2021

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 2 HERTHENA- PanTumor01  NCT06172478 jRCT2031230575  MRK	Melanoma, SCCHN, HER2-negative gastric cancer, ovarian carcinoma, cervical cancer, endometrial cancer, bladder cancer, esophageal carcinoma, pancreatic carcinoma, and prostate cancer	400	Non-randomized, open label •U3-1402	Primary endpoint: ORR Secondary endpoint: safety, DOR, CBR, DCR, TTR, PFS, OS, PK, etc.	JP/US/EU /Asia	FPD: Mar 2024

## 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 IDeate-Pantum01  NCT04145622 JapicCTI-194992  MRK	Esophageal squamous cell carcinoma, castration-resistant prostate cancer, sq-NSCLC, SCLC, etc.	250	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 IDeate-Lung01  NCT05280470 jRCT2041220019  MRK	Extensive-stage SCLC, 2L or later	187	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 TLR anticipated: FY2024 H2  Apr 2023: Orphan Drug Designation (US)
Phase 3 in prep IDeate-Lung02  NCT06203210 jRCT2031230631  MRK	Extensive-stage SCLC, 2L	468	Randomized, open label, active controlled •DS-7300 : 12mg/kg •Physician's choice (topotecan, amrubicin, lurbinectedin)	Primary endpoint: ORR by BICR, OS Secondary endpoint: ORR by investigator, PFS, DOR, DCR, TTR, safety, PK, ADA, etc.	JP/US/EU /Asia	FPD planned: FY2024 H1

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1b/2 in prep IDeate-Lung03  NCT06362252  MRK	Extensive-stage SCLC, 1L	149	Randomized, open label, two-cohort, two-part (safety run-in and dose optimization) Part A Cohort 1: maintenance •DS-7300 12mg/kg + atezolizumab Cohort 2: induction and maintenance •DS-7300 8mg/kg or 12mg/kg + atezolizumab, carboplatin for induction + atezolizumab for maintenance Part B Cohort 1: randomization after induction by etoposide + atezolizumab + carboplatin •DS-7300 8mg/kg or 12mg/kg + atezolizumab Cohort 2: induction and maintenance •DS-7300 8mg/kg or 12mg/kg + atezolizumab, carboplatin for induction + atezolizumab for maintenance	Primary endpoint: safety Secondary endpoint: PFS, ORR, DOR, DCR, CBR, TTR, OS, PK, etc.	JP/US/EU /Asia	FPD planned: FY2024 H1
Phase 2 IDeate-Pantum02  NCT06330064 jRCT2031240016  MRK	endometrial cancer, SCCHN, PDAC, CRC, HCC, adenocarcinoma of esophagus, gastroesophageal junction and stomach, non-squamous NSCLC, urothelial carcinoma, 2L or later	260	Non-randomized, open label •DS-7300	Primary endpoint: ORR Secondary endpoint: safety, DOR, PFS, DCR, OS, PK, ADA, etc.	JP/US/EU /Asia	FPD: May 2024

## 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  MRK	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
Phase 2/3 REJOICE-Ovarian01  NCT06161025 jRCT2031230556  MRK	Platinum-resistant ovarian cancer, primary peritoneal cancer, fallopian tube cancer, 2L or later	650	Randomized, open label, two-part (Part A (Phase 2): dose optimization, Part B (Phase 3): comparing efficacy with investigator's choice of chemotherapy) •DS-6000 •Physician's choice (gemcitabine, paclitaxel, topotecan, PLD)	Primary endpoint: ORR by BICR for Part A. PFS, ORR by BICR for Part B Secondary endpoint: ORR by investigator, DOR, PFS (for Part A), DCR, OS, safety, PK, etc.	JP/USEU/ Asia	FPD: Apr 2024

## ◆ 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/US)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 QuANTUM-First  NCT02668653 JapicCTI-173667	<i>FLT3</i> -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: Approved (JP) Jul 2023: Approved (US) Nov 2023: Approved (EU)  Mar 2009: Orphan Drug Designation (US/EU) Sep 2018: Orphan Drug Designation (JP)  Fast Track Designation (US) Priority Review Designation (US)

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

The molecular-targeted agent to inhibit CSF-1R, KIT and FLT3 specifically. 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	40	Open label •Pexidartinib	Primary endpoint: ORR Secondary endpoint: TVS, ROM, PROMIS, DOR, etc.	Asia	FPD: Sep 2020 TLR: May 2023
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 (registrational) 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: Approved (JP)  Nov 2021: Orphan Drug Designation
Phase 2 (registrational) VALENTINE-PTCL01 NCT04703192 jRCT2071200095	Relapsed/refractory peripheral T-cell lymphoma	148	Non-Randomized, open label •DS-3201	Primary endpoint: ORR Secondary endpoint: DOR, CR rate, safety, etc.	JP/US/EU /Asia	FPD: Jun 2021 TLR: Jun 2023  Jun 2024: Approved (JP)  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	Primary endpoint: ORR Secondary endpoint: CR rate, PFS, DOR, TTR, safety, PK	EU	FPD: Jun 2021

## Valemetostat/DS-3201 (EZH1/2 inhibitor)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1b NCT06244485 jRCT2031230614	HER2-positive gastric cancer or gastro-esophageal junction (GEJ) adenocarcinoma, non-squamous NSCLC, HER2 low breast cancer	210	Non-Randomized, open-label, two-part Part 1: Dose escalation and Part 2: Dose expansion •DS-3201+DS-8201 •DS-3201+DS-1062	Primary endpoint: Part 1: safety Part 2: ORR Secondary endpoint: OS, PFS, DOR, ORR, PK, safety, etc	JP/US	FPD: Feb 2024
Phase 1 NCT02732275 JapicCTI-163173	Non-Hodgkin's lymphoma	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: Sep 2023

### 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-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-SIRP $\alpha$ antibody)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT05765851	HER2 expressing or mutant 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 (TA-MUC1-directed ADC)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1/2 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: Sep 2023

### DS-1471 (anti-CD147 antibody)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT06074705 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: Sep 2023

## ◆ 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, etc.	China	FPD: Sep 2019 Jun 2024: Approved (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.

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

## ◆ 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	65	Randomized, double-blind, placebo-controlled •DS-1211	Primary endpoint: safety, pharmacodynamic (PD) dose response Secondary endpoint: PK	US/EU	FPD: Nov 2022 TLR: Apr 2024

### DS-7011 (anti-TLR7 antibody)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1b/2 NCT05638802 jRCT2031230588	Adult subjects with SLE including cutaneous lupus erythematosus (CLE)	24	Randomized, double-blind, placebo-controlled •DS-7011	Primary endpoint: safety and tolerability Secondary endpoint: PK, efficacy, immunogenicity	JP/US/EU /Asia	FPD: Jul 2023

### DS-2325 (KLK5 inhibitor)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1b/2 NCT05979831	Netherton syndrome	12	Randomized, double-Blind, placebo-controlled •DS-2325 •Placebo	Primary endpoint: safety Secondary endpoint: PK, efficacy, mean Ichthyosis Area Severity Index (IASI) Scores, mean Investigator Global Assessment (IGA) Scores, etc.	EU	Dec 2022: Orphan Drug Designation (US) Feb 2023: Fast Track Designation (US) May 2023: Rare Pediatric Disease Designation (US)  FPD: Dec 2023

◆ Next Wave (Vaccine)

DS-5670 (mutant strain) (COVID-19 mRNA vaccine)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 jRCT2071220111	Healthy volunteers 12 years and older who have completed primary vaccination of approved COVID-19 vaccine, prevention of COVID-19	1,400	Randomized,-double-blind, active-controlled, Main Study and Sub study 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 BA.5) 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 TLR: Sep 2023 Sep 2023: Filing accepted for monovalent omicron XBB.1.5 (JP) Nov 2023: Approved for monovalent omicron XBB.1.5 (JP)
Phase 3 jRCT2031230424	Healthy volunteers 12 years and older, prevention of COVID-19, single dose	690	Randomized, double-blind, active-controlled ·DS-5670 (XBB.1.5 strain variant-adapted monovalent vaccine) ·Comirnaty® RTU	Primary endpoint: GMT and seroresponse rate of blood neutralising activity against SARS-CoV-2 (Omicron XBB.1.5) at 4 weeks after the administration in adults and children aged 12 years and older with at least one of SARS-CoV-2 infection history and SARS-CoV-2 vaccination history Secondary endpoint: GMT and seroresponse rate of blood neutralising activity against SARS-CoV-2 (Omicron XBB.1.5) at 4 weeks after the administration in adults and children aged 12 years and older regardless of SARS-CoV-2 infection history and SARS-CoV-2 vaccination history	JP	FSD: Jan 2024 TLR: May 2024

## DS-5670 (mutant strain) (COVID-19 mRNA vaccine)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
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 <ul style="list-style-type: none"> <li>DS-5670 (omicron variant-adapted bivalent vaccine (original/ BA.4-5))</li> <li>Comirnaty® for 5 to 11 years old</li> </ul>	<p>Primary endpoint: GMT of blood neutralizing activity against SARS-CoV-2 (Omicron strain) and seroresponse rate at 4 weeks after study drug administration.</p> <p>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</p>	JP	FSD: May 2023 TLR: Feb 2024 Apr 2024: Filing accepted (JP)

## 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, single-blind, active-controlled <ul style="list-style-type: none"> <li>VN-0102/ JVC-001</li> <li>Dry Live Attenuated Measles Rubella vaccine, Freeze-dried Live Attenuated Mumps vaccine</li> </ul>	<p>Primary endpoint: Seroprotection rates for measles, mumps and rubella</p> <p>Secondary endpoint: Seroconversion rates for measles, mumps, and rubella</p>	JP	FSD: Feb 2020 Mar 2024: Filing accepted (JP)

## VN-0200 (RS virus vaccine)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 2 NCT05547087 jRCT2071220051	Healthy elderly, prevention of respiratory syncytial (RS) virus infection	342	Randomized, double-blind, dose-comparison <ul style="list-style-type: none"> <li>VN-0200</li> </ul>	<p>Primary endpoint: immunogenicity</p> <p>Secondary endpoint: safety</p>	JP	FSD: Oct 2022 TLR: Dec 2023

◆ Stage-up Projects (Major Changes from the FY2023 Q4 Financial Announcement in April 2024)

Generic Name/Project Code Number Mechanism of action	Target Indication	Current Note Stage	
Valemetostat/DS-3201  EZH1/2 inhibitor	Relapsed/refractory peripheral T-cell lymphoma	Approved	Japan, VALENTINE-PTCL01
Mirogabalin/DS-5565  $\alpha 2\delta$ ligands	Diabetic peripheral neuropathic pain	Approved	China
DS-5670 (mutant strain)  COVID-19 mRNA vaccine	Prevention of COVID-19 (booster vaccination, omicron variant-adapted bivalent vaccine (original/BA.4-5), children aged 5 to 11 years ))	Filed	Japan
Datopotamab deruxtecan/DS-1062/ Dato-DXd  TROP2-directed ADC	non-squamous NSCLC (without AGA and PD-L1 $\geq$ 50%), 1L	Ph3	JP/US/EU/Asia, TROPION-Lung10
Datopotamab deruxtecan/DS-1062/ Dato-DXd  TROP2-directed ADC	EGFR mutated NSCLC, 1L	Ph3	JP/US/EU/Asia, TROPION-Lung14
Trastuzumab deruxtecan/DS-8201/T-DXd  HER2-directed ADC	HER2 expressing BTC, 1L	Ph3 prep	JP/US/EU/Asia, DESTINY-BTC01

◆ **Stage-up Projects (Major Changes from the FY2023 Q4 Financial Announcement in April 2024)**

Generic Name/Project Code Number Mechanism of action	Target Indication	Current Stage	Note
Datopotamab deruxtecan/DS-1062/ Dato-DXd  TROP2-directed ADC	EGFR mutated NSCLC, 2L	Ph3 prep	JP/US/EU/Asia, TROPION-Lung15
Ifinatamab deruxtecan/ DS-7300/ I-DXd  B7-H3-directed ADC	endometrial cancer, SCCHN, PDAC, CRC, HCC, adenocarcinoma of esophagus, gastroesophageal junction and stomach, non-squamous NSCLC, urothelial carcinoma, 2L or later	Ph2	JP/US/EU/Asia, IDEATE-Pantumor02