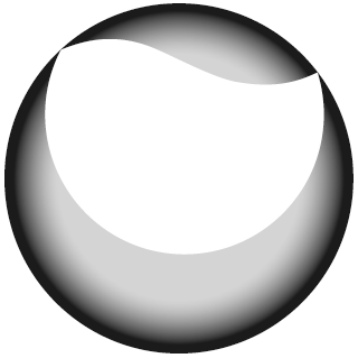
TSE:4568

Reference Data

(Consolidated Financial Results for Q3 FY2024)



Daiichi-Sankyo

January 31, 2025

Daiichi Sankyo Co., Ltd.

https://www.daiichisankyo.com

Contents

Daiichi-Sankyo

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2023 Q3 YTD to revenue	FY2023 Q3 YTD Results	FY2024 Q3 YTD to revenue	FY2024 Q3 YTD Results	(vs. Forecast (%))	YoY	YoY (%)	FY2024 to revenue	FY2024 Forecast (as of Apr.)	FY2024 to revenue	FY2024 Forecast	FY2024 to revenue	FY2024 Forecast (as of Jan.)	vs. Forecast (as of Oct.)
Revenue	*100.0%*	**1,173.3**	*100.0%*	**1,367.6**	**(74.7%)**	**194.3**	***+16.6%***	*100.0%*	**1,750.0**	*100.0%*	**1,830.0**	*100.0%*	**1,830.0**	**-**
Cost of sales*1	*26.4%*	310.3	*23.5%*	321.4	(78.4%)	11.1	*+3.6%*	*22.6%*	395.0	*22.4%*	410.0	*22.4%*	410.0	-
Gross Profit	*73.6%*	863.0	*76.5%*	1,046.2	(73.7%)	183.2	*+21.2%*	*77.4%*	1,355.0	*77.6%*	1,420.0	*77.6%*	1,420.0	-
SG&A expenses*1	*37.0%*	433.9	*37.8%*	516.6	(73.8%)	82.7	*+19.1%*	*38.6%*	675.0	*38.3%*	700.0	*38.3%*	700.0	-
DXd ADC profit share*2	*10.2%*	119.1	*12.3%*	168.5	(80.2%)	49.4	*+41.5%*	*12.0%*	210.8	*11.5%*	210.0	*11.5%*	210.0	-
Other SG&A expenses	*26.8%*	314.8	*25.5%*	348.2	(71.1%)	33.3	*+10.6%*	*26.5%*	464.2	*26.8%*	490.0	*26.8%*	490.0	-
R&D expenses*1	*21.9%*	256.8	*22.0%*	300.6	(65.3%)	43.8	*+17.0%*	*26.9%*	470.0	*25.1%*	460.0	*25.1%*	460.0	-
Core Operating Profit	*14.7%*	**172.2**	*16.7%*	**229.0**	**(88.1%)**	**56.8**	***+33.0%***	*12.0%*	**210.0**	*14.2%*	**260.0**	*14.2%*	**260.0**	**-**
Temporary income*3		26.9		21.5		-5.4			20.0		20.0		20.0	-
Temporary expenses*3		4.6		2.2		-2.4								
Operating Profit	*16.6%*	**194.6**	*18.2%*	**248.3**	**(88.7%)**	**53.8**	***+27.6%***	*13.1%*	**230.0**	*15.3%*	**280.0**	*15.3%*	**280.0**	**-**
Financial income/expenses		5.2		26.5		21.3								
Share of profit or loss of investments accounted for using the equity method		0.1		0.2		0.1								
Profit before tax	*17.0%*	**199.8**	*20.1%*	**275.0**	**(91.7%)**	**75.2**	***+37.6%***	*13.4%*	**235.0**	*15.6%*	**285.0**	*16.4%*	**300.0**	**15.0**
Income taxes		35.7		66.4		30.7								
Profit for the year	*14.0%*	**164.1**	*15.3%*	**208.6**	**(86.9%)**	**44.5**	***+27.1%***	*10.9%*	**190.0**	*12.3%*	**225.0**	*13.1%*	**240.0**	**15.0**
Profit attributable to owners of the Company	*13.9%*	**163.6**	*15.3%*	**208.6**	**(86.9%)**	**45.0**	***+27.5%***	*10.9%*	**190.0**	*12.3%*	**225.0**	*13.1%*	**240.0**	**15.0**

Forex impact: +45.7
(USD: +27.1, EUR: +16.3, ASCA: +2.3)

Forex impact: +11.1
(USD: +7.0, EUR: +3.6, ASCA: +0.6)

Forex impact: +22.4
(USD: +16.9, EUR: +4.1, ASCA: +1.3)

Forex impact: +13.1
(USD: +10.8, EUR: +2.0, ASCA: +0.3)

Forex impact: -0.9
(USD: -7.7, EUR: +6.6, ASCA: +0.1)

- Improvement in forex gains/losses +16.3
- Increase of interest income +4.5

Tax rate	17.9%	24.1%	
Overseas sales ratio	59.5%	66.8%	

(Assumption of currency rate for Q4)
USD/JPY 145, EUR/JPY 155

Currency Rate (Average)			Currency Rate	Currency Rate	Currency Rate
USD/JPY	143.29	152.56	145.00	148.81	150.67
EUR/JPY	155.28	164.82	155.00	160.47	162.37

Annual impact of JPY 1 change

	Forecast	
	USD	EUR
Revenue	JPY 4.5 Bn	JPY 2.3 Bn
Operating Profit	JPY -0.6 Bn	JPY 0.9 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 Q3 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	**1,173.3**						**1,173.3**
Cost of sales	310.8			-0.4		-0.1	310.3
SG&A expenses	437.9					-4.0	433.9
R&D expenses	257.1		-0.2			-0.0	256.8
Other income*	27.1	-0.1			-26.8	-0.2	-
Other expenses*	0.0	-0.0					-
Core Operating Profit**							**172.2**
Temporary income		0.1			26.8 *1		26.9
Temporary expenses		0.0	0.2	0.4		3.9	4.6
Operating Profit (full)	**194.6**						**194.6**

＜Major Temporary income and Temporary expenses＞

*1 Settlement payment for Plexxikon related to patent dispute with Novartis (26.1) etc.

FY2024 Q3 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	**1,367.6**						**1,367.6**
Cost of sales	321.5					-0.1	321.4
SG&A expenses	523.0		1.1		-7.5	-0.0	516.6
R&D expenses	302.6			-2.0		-0.1	300.6
Other income*	28.0	-3.8	-16.3		-7.7	-0.2	-
Other expenses*	0.1	-0.1					-
Core Operating Profit**							**229.0**
Temporary income		3.8 *2	17.4 *3		0.2		21.5
Temporary expenses		0.1		2.0			2.2
Operating Profit (full)	**248.3**						**248.3**

＜Major Temporary income and Temporary expenses＞

*2 Gains related to sale of Sapporo / Tokai Branch Building etc.

*3 Gains on stock transfer of Daiichi Sankyo Espha (16.3) etc.

* 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 Q3 YTD Results	FY2024 Q3 YTD Results	(vs. Forecast (%))	YoY	YoY (%)	FY2024 Forecast (as of Apr.)	Forecast (as of Oct.)	Forecast (as of Jan.)	vs. Forecast (as of Oct.)	YoY	YoY (%)
Trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	**294.4**	**421.6**	**(67.0%)**	**127.1**	**+43.2%**	**585.4**	**611.8**	**628.8**	**17.0**	**179.6**	**+40.0%**
Product sales	*Incl. Gross profit share in AstraZeneca territory	276.0	404.4	(74.9%)	128.4	+46.5%	508.4	523.0	539.9	16.9	144.0	+36.4%
Enhertu (JPN)		17.7	23.5	(76.0%)	5.8	+32.9%	25.7	30.5	31.0	0.5	7.1	+29.5%
Enhertu (US)		162.8	219.7	(74.8%)	56.9	+34.9%	266.6	277.4	293.8	16.4	68.3	+30.3%
Enhertu (EU)		64.7	109.5	(74.0%)	44.7	+69.2%	152.1	147.0	147.8	0.8	46.0	+45.1%
Enhertu (ASCA: Asia, South and Central America)		30.8	51.8	(77.0%)	21.0	+68.3%	64.0	68.1	67.3	-0.8	22.7	+50.8%
Brazil		16.8	22.7	(74.8%)	5.9	+35.3%	29.9	30.0	30.4	0.4	6.9	+29.3%
China (co-promotion revenue)		4.1	6.8	(71.1%)	2.8	+68.1%	10.8	9.6	9.6	-0.0	3.0	+46.7%
Others		9.9	22.2	(81.4%)	12.3	+124.4%	23.3	28.5	27.3	-1.2	12.7	+87.3%
Upfront payment		7.6	7.7	(75.0%)	0.1	+1.3%	10.2	10.2	10.2	-	0.1	+0.9%
Regulatory milestone payment		10.0	8.6	(40.2%)	-1.4	-14.3%	9.4	21.2	21.3	0.1	9.0	+72.6%
US HER2+ Breast Cancer 3L		0.7	0.7	(75.0%)	0.0	+1.3%	0.9	0.9	0.9	-	0.0	+1.0%
EU HER2+ Breast Cancer 3L		0.4	0.4	(75.0%)	0.0	+1.3%	0.5	0.5	0.5	-	0.0	+1.0%
US HER2+ Gastric Cancer 2L/3L		0.6	0.6	(75.0%)	0.0	+1.3%	0.8	0.8	0.8	-	0.0	+1.0%
US HER2+ Breast Cancer 2L		0.7	0.7	(75.0%)	0.0	+1.3%	0.9	0.9	0.9	-	0.0	+1.0%
EU HER2+ Breast Cancer 2L		0.5	0.5	(75.0%)	0.0	+1.3%	0.7	0.7	0.7	-	0.0	+1.0%
US HER2-low Breast Cancer (post chemo)		1.4	1.4	(75.0%)	0.0	+1.3%	1.9	1.9	1.9	-	0.0	+1.0%
EU HER2-low Breast Cancer (post chemo)		1.0	1.0	(75.0%)	0.0	+1.3%	1.4	1.4	1.4	-	0.0	+1.0%
EU HER2+ Gastric Cancer 2L		0.2	0.2	(75.0%)	0.0	+1.3%	0.3	0.3	0.3	-	0.0	+1.0%
US HER2 mutant NSCLC 2L		0.9	0.9	(75.0%)	0.0	+1.3%	1.2	1.2	1.2	-	0.0	+1.0%
EU HER2 mutant NSCLC 2L		3.6	0.6	(75.0%)	-3.0	-84.2%	0.8	0.8	0.8	-	-3.0	-80.0%
US HER2-low Breast Cancer (pre chemo)		-	-	-	-	-	-	10.3	10.3	-	10.3	-
US HER2+ Solid Tumors		-	1.5	(94.7%)	1.5	-	-	1.5	1.6	0.1	1.6	-
Quid related payment*		0.9	0.9	(75.0%)	0.0	+1.3%	1.2	1.2	1.2	-	0.0	+1.0%
Sales milestone payment		-	-	-	-	-	56.2	56.2	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 Q3 YTD	FY2024 Q3 YTD				FY2024					
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Apr.)	Forecast (as of Oct.)	Forecast (as of Jan.)	vs. Forecast	YoY	YoY (%)
Datopotamab deruxtecan	anti-cancer agent (TROP2-directed antibody drug conjugate)	**4.8**	**4.8**	**(70.4%)**	**-**	**-**	**17.6**	**17.8**	**6.8**	**-11.0**	**0.4**	**+6.5%**
Product sales	*Incl. Gross profit share in AstraZeneca territory	-	-	-	-	-	5.6	5.8	0.4	-5.4	0.4	-
Datroway (JPN)		-	-	-	-	-	-	-	0.0	0.0	0.0	-
Datroway (US)		-	-	-	-	-	5.6	5.8	0.4	-5.4	0.4	-
Upfront payment		4.8	4.8	(75.0%)	-	-	6.4	6.4	6.4	-	-	-
Regulatory milestone payment		-	-	-	-	-	5.6	5.6	-	-5.6	-	-
US NSCLC 2L/3L		-	-	-	-	-	5.6	5.6	-	-5.6	-	-
Patritumab deruxtecan	anti-cancer agent (HER3-directed antibody drug conjugate)	**1.6**	**15.7**	**(79.4%)**	**14.1**	**+900.4%**	**23.1**	**19.8**	**19.8**	**-**	**16.2**	**+458.2%**
Product sales	*Incl. Gross profit share in Merck territory	-	-	-	-	-	4.2	-	-	-	-	-
Patritumab deruxtecan (US)		-	-	-	-	-	4.2	-	-	-	-	-
Upfront payment		1.6	15.1	(79.3%)	13.5	+862.5%	18.9	19.0	19.0	-	15.5	+437.8%
Satisfaction of Quid Rights		-	0.6	(82.4%)	0.6	-	-	0.7	0.7	-	0.7	-
Ifinatamab deruxtecan	anti-cancer agent (B7-H3-directed antibody drug conjugate)	**2.9**	**11.6**	**(75.3%)**	**8.6**	**+296.0%**	**14.7**	**15.3**	**15.3**	**-**	**8.8**	**+133.0%**
Upfront payment		2.9	11.0	(75.0%)	8.1	+277.0%	14.7	14.7	14.7	-	8.1	+122.8%
Satisfaction of Quid Rights		-	0.6	(82.4%)	0.6	-	-	0.7	0.7	-	0.7	-
Raludotatug deruxtecan (DS-6000)	anti-cancer agent (CDH6-directed antibody drug conjugate)	**1.2**	**5.1**	**(75.6%)**	**3.9**	**+314.9%**	**6.2**	**6.7**	**6.7**	**-**	**4.0**	**+143.1%**
Upfront payment		1.2	4.6	(75.0%)	3.4	+277.0%	6.2	6.2	6.2	-	3.4	+122.8%
Satisfaction of Quid Rights		-	0.5	(82.4%)	0.5	-	-	0.6	0.6	-	0.6	-
Edoxaban	anticoagulant	**216.2**	**262.6**	**(78.0%)**	**46.4**	**+21.5%**	**293.6**	**330.5**	**336.6**	**6.1**	**48.9**	**+17.0%**
Lixiana (JPN)		89.5	103.2	(79.9%)	13.7	+15.3%	116.4	129.1	129.2	0.1	13.6	+11.8%
Savaysa (US)		2.0	2.8	(81.5%)	0.7	+36.3%	2.8	3.2	3.4	0.2	1.0	+40.8%
Lixiana (EU)		107.3	135.6	(76.7%)	28.3	+26.3%	149.5	171.5	176.9	5.4	30.7	+21.0%
Edoxaban (ASCA* etc.)		17.3	20.9	(77.2%)	3.6	+21.0%	24.9	26.8	27.1	0.3	3.6	+15.2%

* "Quid rights" (worth $150 mil.) that was held under the strategic alliance agreement with US Merck and was appropriated as part of consideration to obtain MK-6070 is booked as deferred revenue

*Asia, South and Central America

4. Revenue by Business Units and Products (1)

JPY Bn		FY2023 Q3 YTD	FY2024 Q3 YTD				FY2024					
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Apr.)	Forecast (as of Oct.)	Forecast (as of Jan.)	vs. Forecast (as of Oct.)	YoY	YoY (%)
Japan Business Unit		**412.3**	**385.7**	**(82.0%)**	**-26.6**	**-6.5%**	**434.9**	**468.8**	**470.6**	**1.8**	**-48.3**	**-9.3%**
Lixiana	anticoagulant	89.5	103.2	(79.9%)	13.7	+15.3%	116.4	129.1	129.2	0.1	13.6	+11.8%
Tarlige	pain treatment	35.4	42.9	(77.3%)	7.6	+21.5%	53.4	55.1	55.6	0.5	9.9	+21.6%
Pralia	Treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	33.3	32.7	(77.2%)	-0.6	-1.9%	39.3	41.5	42.3	0.8	-0.5	-1.2%
Vimpat	anti-epileptic agent	20.0	23.7	(78.3%)	3.7	+18.6%	29.2	30.2	30.2	-	4.5	+17.5%
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	17.7	23.5	(76.0%)	5.8	+32.9%	25.7	30.5	31.0	0.5	7.1	+29.5%
Ranmark	treatment for bone complications caused by bone metastases from tumors	15.8	15.7	(78.9%)	-0.1	-0.7%	20.7	20.0	19.9	-0.1	-0.4	-2.0%
Efient	antiplatelet agent	19.7	24.2	(77.4%)	4.5	+22.9%	16.2	30.9	31.2	0.4	5.6	+22.0%
Canalia	type 2 diabetes mellitus treatment	12.5	12.3	(79.3%)	-0.2	-1.4%	15.0	15.5	15.5	-0.1	-0.4	-2.6%
Loxonin	anti-inflammatory analgesic	12.5	10.1	(82.5%)	-2.3	-18.6%	12.7	12.4	12.3	-0.1	-3.2	-20.8%
Inavir	anti-influenza treatment	13.6	13.6	(63.1%)	0.1	+0.4%	11.3	11.3	21.6	10.3	5.7	+35.9%
Minnebro	antihypertensive agent	6.3	7.4	(75.9%)	1.1	+17.0%	10.8	9.7	9.7	0.0	1.5	+17.9%
Vaccines business		28.2	27.7	-	-0.5	-1.8%	not disclosed	not disclosed	not disclosed	-	-	-
Daiichi Sankyo Healthcare Unit		**59.9**	**67.4**	**(79.3%)**	**7.5**	**+12.4%**	**82.7**	**84.7**	**85.0**	**0.3**	**9.0**	**+11.9%**

4. Revenue by Business Units and Products (2)

JPY Bn		FY2023 Q3 YTD	FY2024 Q3 YTD				FY2024					
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Apr.)	Forecast (as of Oct.)	Forecast (as of Jan.)	vs. Forecast (as of Oct.)	YoY	YoY (%)
Oncology Business Unit		**233.0**	**337.2**	**(74.5%)**	**104.2**	**+44.7%**	**442.6**	**441.0**	**452.6**	**11.6**	**117.9**	**+35.2%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	227.5	329.1	(74.5%)	101.6	+44.7%	418.7	424.4	441.7	17.3	114.3	+34.9%
Enhertu (US)		162.8	219.7	(74.8%)	56.9	+34.9%	266.6	277.4	293.8	16.4	68.3	+30.3%
Enhertu (EU)		64.7	109.5	(74.0%)	44.7	+69.2%	152.1	147.0	147.8	0.8	46.0	+45.1%
Datroway (US)	anti-cancer agent (TROP2-directed antibody drug conjugate)	-	-	-	-	-	5.6	5.8	0.4	-5.4	0.4	-
Patritumab deruxtecan (US)	anti-cancer agent (HER3-directed antibody drug conjugate)	-	-	-	-	-	4.2	-	-	-	-	-
Turalio	anti-cancer agent	4.1	5.1	(79.5%)	1.0	+24.6%	5.8	6.2	6.4	0.2	1.1	+20.4%
Vanflyta	anti-cancer agent (FLT3 Inhibitor)	1.3	2.9	(71.9%)	1.6	+117.7%	8.3	4.6	4.1	-0.5	2.2	+118.4%
American Regent Unit		**152.0**	**169.9**	**(76.8%)**	**17.9**	**+11.8%**	**218.2**	**215.1**	**221.2**	**6.1**	**17.8**	**+8.7%**
Injectafer	treatment for iron deficiency anemia	38.0	41.6	(78.4%)	3.5	+9.3%	49.7	52.3	53.0	0.7	2.9	+5.9%
Venofer	treatment for iron deficiency anemia	45.2	51.0	(75.9%)	5.8	+12.9%	58.0	59.8	67.2	7.5	6.4	+10.4%
GE injectables		59.1	67.9	(76.9%)	8.7	+14.8%	95.7	89.4	88.3	-1.1	7.3	+9.0%
EU Specialty Business Unit		**137.6**	**178.3**	**(75.9%)**	**40.7**	**+29.6%**	**201.4**	**229.2**	**235.1**	**5.9**	**45.9**	**+24.3%**
Lixiana	anticoagulant	107.3	135.6	(76.7%)	28.3	+26.3%	149.5	171.5	176.9	5.4	30.7	+21.0%
Nilemdo/Nustendi	cholesterol-lowering agent	12.1	26.5	(70.6%)	14.4	+119.4%	33.6	37.4	37.5	0.1	19.1	+103.4%
Olmesartan	antihypertensive agent	14.5	13.9	(79.8%)	-0.6	-4.1%	15.6	17.4	17.4	0.1	-2.1	-10.9%
ASCA Business Unit		**131.8**	**155.0**	**(74.6%)**	**23.2**	**+17.6%**	**188.2**	**202.5**	**207.8**	**5.4**	**23.8**	**+12.9%**
Daiichi Sankyo China		49.8	53.7	(76.6%)	3.9	+7.9%	61.2	65.2	70.1	4.9	-0.4	-0.5%
Daiichi Sankyo Korea		21.9	24.9	(74.7%)	3.0	+13.8%	30.0	33.7	33.3	-0.4	4.1	+14.1%
Daiichi Sankyo Brasil Farmacêutica		30.1	36.4	(72.9%)	6.3	+20.8%	50.0	49.6	49.9	0.4	8.0	+19.0%
Daiichi Sankyo Taiwan		12.0	13.7	(78.5%)	1.8	+14.8%	16.4	17.2	17.5	0.3	1.5	+9.1%
Daiichi Sankyo Thailand		2.6	3.5	(72.3%)	0.9	+36.9%	3.4	4.6	4.9	0.3	1.4	+39.7%
Daiichi Sankyo Hong Kong		2.3	1.9	(74.0%)	-0.4	-17.5%	2.7	2.6	2.6	-0.1	-0.4	-12.1%

4. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

		FY2023 Q3 YTD	FY2024 Q3 YTD				FY2024					
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of Apr.)	Forecast (as of Oct.)	Forecast (as of Jan.)	vs. Forecast (as of Oct.)	YoY	YoY (%)
USD Mn												
Oncology Business Unit		**1,626**	**2,210**	**(73.6%)**	**584**	**+35.9%**	**3,052**	**2,964**	**3,004**	**40**	**690**	**+29.8%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	1,588	2,157	(73.6%)	570	+35.9%	2,887	2,852	2,931	79	667	+29.5%
Enhertu (US)		1,136	1,440	(73.8%)	304	+26.7%	1,839	1,864	1,950	86	391	+25.1%
Enhertu (EU)		452	717	(73.1%)	266	+58.9%	1,049	988	981	-7	277	+39.3%
Datroway (US)	anti-cancer agent (TROP2-directed antibody drug conjugate)	-	-	-	-	-	39	39	3	-36	3	-
Patritumab deruxtecan (US)	anti-cancer agent (HER3-directed antibody drug conjugate)	-	-	-	-	-	29	-	0	0	-	-
Turalio	anti-cancer agent	29	33	(78.5%)	5	+17.0%	40	42	42	1	6	+15.6%
Vanflyta	anti-cancer agent (FLT3 Inhibitor)	9	19	(71.0%)	10	+104.4%	57	31	27	-4	14	+109.6%
USD Mn												
American Regent Unit		**1,061**	**1,114**	**(75.9%)**	**53**	**+5.0%**	**1,505**	**1,445**	**1,468**	**23**	**61**	**+4.4%**
Injectafer	treatment for iron deficiency anemia	265	272	(77.4%)	7	+2.6%	343	351	352	1	6	+1.6%
Venofer	treatment for iron deficiency anemia	315	334	(74.9%)	19	+6.0%	400	402	446	45	25	+6.0%
GE injectables		413	445	(75.9%)	32	+7.8%	660	601	586	-15	26	+4.6%
EUR Mn												
EU Specialty Business Unit		**886**	**1,082**	**(74.7%)**	**196**	**+22.1%**	**1,300**	**1,428**	**1,448**	**20**	**241**	**+20.0%**
Lixiana	anticoagulant	691	823	(75.5%)	132	+19.0%	964	1,069	1,090	21	157	+16.8%
Nilemdo/Nustendi	cholesterol-lowering agent	78	161	(69.5%)	83	+106.7%	217	233	231	-2	113	+96.4%
Olmesartan	antihypertensive agent	94	84	(78.6%)	-9	-9.7%	101	108	107	-1	-18	-14.0%

5. Consolidated Statement of Financial Position

<Assets> JPY Bn

	Mar. 2024	Dec. 2024	vs. Mar. 2024	
Assets				
Current assets				
Cash and cash equivalents	647.2	682.1	35.0	
Trade and other receivables	454.2	624.2	170.0	
Other financial assets	577.0	108.6	-468.5	
Inventories	438.1	475.4	37.2	
Other current assets	33.0	73.2	40.2	
Subtotal	2,149.5	1,963.4	-186.1	
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
Total current assets	**2,174.0**	**1,975.6**	**-198.4**	
Non-current assets				
Property, plant and equipment	421.7	487.5	65.8	Acquisition +95.4, Depreciation -34.0, Forex +4.1
Goodwill	108.5	114.8	6.3	Forex +3.9
Intangible assets	168.3	241.7	73.4	Acquisition +85.0, Depreciation -16.5, Impairment loss -2.0, Forex +7.1
Investments accounted for using the equity method	0.6	0.7	0.1	
Other financial assets	147.9	144.1	-3.8	Investment securities -3.8
Deferred tax assets	249.4	238.3	-11.0	
Other non-current assets	190.7	240.8	50.1	Contribution for equipment +51.7
Total non-current assets	**1,287.1**	**1,468.0**	**180.9**	
Total assets	**3,461.1**	**3,443.6**	**-17.5**	

*	Liquidity on hand (Cash, Securities, Investment securities etc.)	1,223.6	789.2	-434.5
	Debt with interest	156.0	159.6	3.6
	Net Cash	1,067.6	629.6	-438.0

<Liabilities and equity> JPY Bn

	Mar. 2024	Dec. 2024	vs. Mar. 2024
Liabilities			
Current liabilities			
Trade and other payables	557.1	564.5	7.3
Bonds and borrowings	0.4	0.4	0.0
Other financial liabilities	12.8	14.3	1.5
Income taxes payable	46.4	34.0	-12.4
Provisions	15.4	4.2	-11.2
Contract liabilities	57.4	66.3	8.9
Other current liabilities	22.3	28.7	6.3
Subtotal	711.9	712.4	0.4
Liabilities directly associated with assets held for sale	11.5	-	-11.5
Total current liabilities	**723.4**	**712.4**	**-11.0**
Non-current liabilities			
Bonds and borrowings	101.3	101.0	-0.3
Other financial liabilities	46.2	48.3	2.1
Post employment benefit liabilities	1.3	1.6	0.3
Provisions	14.0	13.5	-0.4
Contract liabilities	680.2	754.1	73.9
Deferred tax liabilities	12.9	12.3	-0.5
Other non-current liabilities	193.3	176.0	-17.3
Total non-current liabilities	**1,049.1**	**1,106.9**	**57.7**
Total liabilities	**1,772.5**	**1,819.2**	**46.7**
Equity			
Equity attributable to owners of the Company			
Share capital	50.0	50.0	-
Capital surplus	2.0	5.0	3.0
Treasury shares	-36.6	-228.0	-191.3
Other components of equity	284.0	306.5	22.5
Retained earnings	1,388.8	1,490.8	102.0
Total equity attributable to owners of the Company	1,688.2	1,624.4	-63.8
Non-controlling interests	0.4	-	-0.4
Total equity	**1,688.6**	**1,624.4**	**-64.2**
Total liabilities and equity	**3,461.1**	**3,443.6**	**-17.5**

Exclusion of consolidation of DSEP -11.5

Deferred revenue for trastuzumab deruxtecan -13.5
(Strategic collaboration upfront payment -7.7, Regulatory milestone payment/Quid -5.6)
Deferred revenue for datopotamab deruxtecan -4.8
(Strategic collaboration upfront payment -4.8)
Deferred revenue for US MRK alliance +101.7
(Strategic collaboration upfront payment +81.5, Quid +20.2)

Currency translation difference +27.6, Valuation difference on financial assets -5.3

Profit for the period +208.6, Payment of dividends -114.4

6. Consolidated Statement of Cash Flows

JPY Bn

	FY2023Q3 YTD	FY2024Q3 YTD	YoY
Cash flows from operating activities			
Profit before tax	199.8	275.0	75.2
Depreciation and amortization	43.5	50.7	7.1
(Increase) decrease in receivables and payables	-9.4	-165.1	-155.6
Others, net	402.5	-86.7	-489.2
Income taxes paid	-67.1	-92.2	-25.1
Net cash flows from operating activities	**569.3**	**-18.3**	**-587.6**
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	-142.3	476.9	619.2
(Acquisition of) proceeds from sales of fixed assets	-75.4	-126.3	-51.0
Payments for acquisition of subsidiaries	-6.9	-	6.9
Proceeds from sale of subsidiaries	7.5	5.3	-2.3
Net (increase) decrease in investment securities	-1.7	11.5	13.2
Others, net	-0.5	-0.3	0.2
Net cash flows from investing activities	**-219.2**	**367.1**	**586.3**
Cash flows from financing activities			
Net (increase) decrease in borrowings	-21.3	-0.3	21.0
Repayments of bonds	-20.0	-	20.0
Purchase of treasury shares	-0.0	-191.8	-191.8
Dividends paid	-67.1	-114.4	-47.3
Others, net	-11.3	-12.8	-1.5
Net cash flows from financing activities	**-119.7**	**-319.3**	**-199.5**
Net increase (decrease) in cash and cash equivalents	**230.3**	**29.6**	**-200.8**
Cash and cash equivalents at the beginning of the period	**441.9**	**647.2**	**205.3**
Effect of exchange rate changes on cash and cash equivalents	**0.8**	**5.4**	**4.6**
Cash and cash equivalents at the end of the period	**673.1**	**682.1**	**9.1**
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)	**666.7**	**682.1**	**15.4**

*	**Free cash flows** (Cash flows from operating activities and investing activities)	**350.1**	**348.8**	**-1.2**

7. Number of Employees

	Dec. 2023	Mar. 2024	Dec. 2024
	Results	Results	Results
Consolidated	18,390	18,726	19,691
Japan	9,452	9,468	9,341
North America	3,443	3,573	3,951
Europe	2,800	2,901	3,259
Others	2,695	2,784	3,140

8. Capital Expenditure, Depreciation and Amortization

	FY2023 Q3 YTD	FY2023	FY2024 Q3 YTD	FY2024
JPY Bn	Results	Results	Results	Forecast
Capital expenditure	61.5	89.4	84.3	120.0
Depreciation and amortization	43.5	59.6	50.7	67.7
Property, plant and equipment	29.2	39.9	34.2	-
Intangible assets	14.3	19.8	16.5	-

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		
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	loxoprofen	anti-inflammatory analgesic	1986	Daiichi Sankyo		
Loxonin Poultice			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		
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		
Vanflyta	quizartinib	anti-cancer agent (FLT3 Inhibitor)	2023	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	FY2023 Q1 Results	FY2023 Q2 Results	FY2023 Q3 Results	FY2023 Q4 Results	FY2023 to revenue	FY2023 Results	FY2024 Q1 Results	FY2024 Q2 Results	FY2024 Q3 Results	FY2024 Q4 Results	FY2024 to revenue	FY2024 Results	FY2024 YoY	FY2024 YoY (%)
Revenue	**350.8**	**375.5**	**446.9**	**428.4**	***100.0%***	**1,601.7**	**436.2**	**446.6**	**484.8**	**-**	***100.0%***	**1,367.6**	**194.3**	**+16.6%**
Cost of sales	93.6	94.8	122.0	104.4	*25.9%*	414.8	95.0	98.0	128.4	-	*23.5%*	321.4	11.1	+3.6%
Gross Profit	257.2	280.8	325.0	324.0	*74.1%*	1,186.9	341.2	348.5	356.5	-	*76.5%*	1,046.2	183.2	+21.2%
SG&A expenses	135.6	141.0	157.3	193.4	*39.2%*	627.3	167.6	162.2	186.8	-	*37.8%*	516.6	82.7	+19.1%
DXd ADC profit share	34.8	44.0	40.3	51.5	*10.6%*	170.6	56.8	48.0	63.7	-	*12.3%*	168.5	49.4	+41.5%
Other SG&A expenses	100.8	97.1	117.0	141.9	*28.5%*	456.8	110.8	114.3	123.1	-	*25.5%*	348.2	33.3	+10.6%
R&D expenses	77.2	88.9	90.8	107.5	*22.7%*	364.3	100.7	92.6	107.3	-	*22.0%*	300.6	43.8	+17.0%
Core Operating Profit	**44.5**	**50.9**	**76.9**	**23.0**	***12.2%***	**195.3**	**72.9**	**93.7**	**62.4**	**-**	***16.7%***	**229.0**	**56.8**	**+33.0%**
Temporary income	0.5	0.2	26.2	0.4		27.3	20.1	0.2	1.1	-		21.5	-5.4	
Temporary expenses	0.9	0.0	3.6	6.4		10.9	0.0	-0.0	2.2	-		2.2	-2.4	
Operating Profit	**44.0**	**51.0**	**99.5**	**17.0**	***13.2%***	**211.6**	**93.0**	**93.9**	**61.4**	**-**	***18.2%***	**248.3**	**53.8**	**+27.6%**
Financial income/expenses	8.1	-1.1	-1.8	20.3		25.5	17.2	-11.6	20.9	-		26.5	21.3	
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	-		0.2	0.1	
Profit before tax	**52.1**	**50.0**	**97.7**	**37.4**	***14.8%***	**237.2**	**110.2**	**82.4**	**82.4**	**-**	***20.1%***	**275.0**	**75.2**	**+37.6%**
Income taxes	-4.9	10.0	30.7	0.5		36.2	24.8	21.1	20.5	-		66.4	30.7	
Profit for the year	**57.0**	**40.0**	**67.1**	**36.9**	***12.6%***	**201.0**	**85.4**	**61.3**	**61.9**	**-**	***15.3%***	**208.6**	**44.5**	**+27.1%**
Profit attributable to owners of the Company	**57.0**	**40.0**	**66.6**	**37.2**	***12.5%***	**200.7**	**85.4**	**61.3**	**61.9**	**-**	***15.3%***	**208.6**	**45.0**	**+27.5%**
Tax rate	-9.4%	20.0%	31.4%	1.3%		15.3%	22.5%	25.6%	24.9%			24.1%		
Overseas sales ratio	60.9%	60.0%	57.8%	71.0%		62.5%	66.7%	65.5%	68.2%			66.8%		
Currency Rate (YTD Average)														
USD/JPY	137.37	141.00	143.29	144.62		144.62	155.89	152.62	152.56			152.56		
EUR/JPY	149.46	153.38	155.28	156.79		156.79	167.88	165.93	164.82			164.82		

2. Revenue of Global Products (1)

JPY Bn	FY2023 Q1 Results	FY2023 Q2 Results	FY2023 Q3 Results	FY2023 Q4 Results	FY2023 Results	FY2024 Q1 Results	FY2024 Q2 Results	FY2024 Q3 Results	FY2024 Q4 Results	FY2024 Results
Trastuzumab deruxtecan	**86.6**	**96.5**	**111.4**	**154.8**	**449.2**	**134.8**	**136.9**	**149.9**	**-**	**421.6**
Product sales	81.7	91.6	102.6	119.9	395.9	129.6	131.7	143.1	-	404.4
Enhertu(JPN)	4.4	6.0	7.3	6.2	23.9	7.8	7.8	8.0	-	23.5
Enhertu (US)	51.6	54.3	57.0	62.7	225.5	68.9	71.3	79.5	-	219.7
Enhertu (EU)	17.8	21.4	25.5	37.2	101.9	35.2	35.3	39.0	-	109.5
Enhertu (ASCA: Asia, South and Central America)	8.0	9.9	12.8	13.8	44.6	17.8	17.3	16.7	-	51.8
Brazil	5.3	5.6	5.9	6.7	23.5	8.5	6.8	7.4	-	22.7
China (co-promotion revenue)	0.9	1.8	1.3	2.5	6.5	2.4	2.8	1.6	-	6.8
Others	1.8	2.5	5.7	4.7	14.6	6.8	7.7	7.7	-	22.2
Upfront payment	2.5	2.5	2.6	2.6	10.1	2.6	2.6	2.6	-	7.7
Regulatory milestone payment	2.1	2.1	5.8	2.4	12.4	2.4	2.4	3.9	-	8.6
US HER2+ Breast Cancer 3L	0.2	0.2	0.2	0.2	0.9	0.2	0.2	0.2	-	0.7
EU HER2+ Breast Cancer 3L	0.1	0.1	0.1	0.1	0.5	0.1	0.1	0.1	-	0.4
US HER2+ Gastric Cancer 2L/3L	0.2	0.2	0.2	0.2	0.8	0.2	0.2	0.2	-	0.6
US HER2+ Breast Cancer 2L	0.2	0.2	0.2	0.2	0.9	0.2	0.2	0.2	-	0.7
EU HER2+ Breast Cancer 2L	0.2	0.2	0.2	0.2	0.7	0.2	0.2	0.2	-	0.5
US HER2-low Breast Cancer (post chemo)	0.5	0.5	0.5	0.5	1.9	0.5	0.5	0.5	-	1.4
EU HER2-low Breast Cancer (post chemo)	0.3	0.3	0.4	0.3	1.3	0.3	0.3	0.3	-	1.0
EU HER2+ Gastric Cancer 2L	0.1	0.1	0.1	0.1	0.3	0.1	0.1	0.1	-	0.2
US HER2 Mutant NSCLC 2L	0.3	0.3	0.3	0.3	1.2	0.3	0.3	0.3	-	0.9
EU HER2 Mutant NSCLC 2L	-	-	3.6	0.2	3.8	0.2	0.2	0.2	-	0.6
US HER2-low Breast Cancer (pre chemo)	-	-	-	-	-	-	-	-	-	-
US HER2+ Solid Tumors	-	-	-	-	-	-	-	1.5	-	1.5
Quid related payment	0.3	0.3	0.3	0.3	1.2	0.3	0.3	0.3	-	0.9
Sales milestone payment	-	-	-	29.6	29.6	-	-	-	-	-

2. Revenue of Global Products (2)

JPY Bn	FY2023 Q1 Results	FY2023 Q2 Results	FY2023 Q3 Results	FY2023 Q4 Results	FY2023 Results	FY2024 Q1 Results	FY2024 Q2 Results	FY2024 Q3 Results	FY2024 Q4 Results	FY2024 Results
Datopotamab deruxtecan	**1.6**	**1.6**	**1.6**	**1.6**	**6.4**	**1.6**	**1.6**	**1.6**	**-**	**4.8**
Product sales	-	-	-	-	-	-	-	-	-	-
Datroway (JPN)	-	-	-	-	-	-	-	-	-	-
Datroway (US)	-	-	-	-	-	-	-	-	-	-
Upfront payment	1.6	1.6	1.6	1.6	6.4	1.6	1.6	1.6	-	4.8
Regulatory milestone payment	-	-	-	-	-	-	-	-	-	-
US NSCLC 2L/3L	-	-	-	-	-	-	-	-	-	-
Patritumab deruxtecan	**-**	**-**	**1.6**	**2.0**	**3.5**	**2.0**	**2.4**	**11.3**	**-**	**15.7**
Product sales	-	-	-	-	-	-	-	-	-	-
Patritumab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Upfront payment	-	-	1.6	2.0	3.5	2.0	2.0	11.2	-	15.1
Satisfaction of Quid Rights	-	-	-	-	-	-	0.5	0.1	-	0.6
Ifinatamab deruxtecan	**-**	**-**	**2.9**	**3.7**	**6.6**	**3.7**	**4.1**	**3.8**	**-**	**11.6**
Upfront payment	-	-	2.9	3.7	6.6	3.7	3.7	3.7	-	11.0
Satisfaction of Quid Rights	-	-	-	-	-	-	0.4	0.1	-	0.6
Raludotatug deruxtecan (DS-6000)	**-**	**-**	**1.2**	**1.5**	**2.8**	**1.5**	**1.9**	**1.6**	**-**	**5.1**
Upfront payment	-	-	1.2	1.5	2.8	1.5	1.5	1.5	-	4.6
Satisfaction of Quid Rights	-	-	-	-	-	-	0.4	0.1	-	0.5
Edoxaban	**66.0**	**71.7**	**78.5**	**71.6**	**287.7**	**88.3**	**85.9**	**88.4**	**-**	**262.6**
Lixiana (JPN)	27.9	29.3	32.4	26.1	115.6	34.9	33.1	35.3	-	103.2
Savaysa (US)	0.5	1.1	0.5	0.4	2.4	1.0	0.8	1.0	-	2.8
Lixiana (EU)	32.3	35.6	39.4	38.9	146.2	45.4	45.2	45.0	-	135.6
Edoxaban (ASCA* etc.)	5.3	5.8	6.2	6.2	23.5	7.0	6.8	7.2	-	20.9

*Asia, South and Central America

3. Revenue by Business Units and Products (1)

JPY Bn	FY2023 Q1 Results	FY2023 Q2 Results	FY2023 Q3 Results	FY2023 Q4 Results	FY2023 Results	FY2024 Q1 Results	FY2024 Q2 Results	FY2024 Q3 Results	FY2024 Q4 Results	FY2024 Results
Japan Business Unit	**119.0**	**127.8**	**165.5**	**106.6**	**518.9**	**117.7**	**122.0**	**146.0**	**-**	**385.7**
Lixiana	27.9	29.3	32.4	26.1	115.6	34.9	33.1	35.3	-	103.2
Tarlige	11.7	11.0	12.6	10.3	45.7	14.2	13.6	15.1	-	42.9
Pralia	10.7	10.4	12.2	9.5	42.8	11.1	10.0	11.6	-	32.7
Vimpat	6.4	6.3	7.2	5.8	25.7	8.1	7.4	8.2	-	23.7
Enhertu	4.4	6.0	7.3	6.2	23.9	7.8	7.8	8.0	-	23.5
Ranmark	5.0	5.3	5.6	4.5	20.4	5.4	5.0	5.4	-	15.7
Efient	6.1	6.3	7.3	5.9	25.6	8.1	7.6	8.5	-	24.2
Canalia	4.1	4.0	4.3	3.4	15.9	4.3	3.9	4.1	-	12.3
Loxonin	4.0	4.0	4.5	3.1	15.5	3.5	3.3	3.3	-	10.1
Inavir	0.1	1.7	11.7	2.3	15.9	0.2	0.0	13.5	-	13.6
Minnebro	2.1	1.9	2.3	1.9	8.3	2.6	2.2	2.6	-	7.4
Vaccines business	0.7	7.5	20.0	-0.5	27.7	0.7	12.0	15.0	-	27.7
Daiichi Sankyo Healthcare Unit	**17.1**	**20.3**	**22.5**	**16.0**	**76.0**	**20.0**	**22.5**	**24.9**	**-**	**67.4**

3. Revenue by Business Units and Products (2)

JPY Bn	FY2023 Q1 Results	FY2023 Q2 Results	FY2023 Q3 Results	FY2023 Q4 Results	FY2023 Results	FY2024 Q1 Results	FY2024 Q2 Results	FY2024 Q3 Results	FY2024 Q4 Results	FY2024 Results
Oncology Business Unit	**70.6**	**78.2**	**84.1**	**101.7**	**334.6**	**106.4**	**109.1**	**121.6**	**-**	**337.2**
Enhertu	69.4	75.7	82.4	99.9	327.4	104.1	106.6	118.5	-	329.1
Enhertu (US)	51.6	54.3	57.0	62.7	225.5	68.9	71.3	79.5	-	219.7
Enhertu (EU)	17.8	21.4	25.5	37.2	101.9	35.2	35.3	39.0	-	109.5
Datroway (US)	-	-	-	-	-	-	-	-	-	-
Patritumab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Turalio	1.2	1.4	1.5	1.2	5.3	1.5	1.7	1.9	-	5.1
Vanflyta	-	1.1	0.2	0.5	1.9	0.9	0.8	1.3	-	2.9
American Regent Unit	**50.7**	**48.0**	**53.3**	**51.4**	**203.4**	**55.9**	**52.2**	**61.8**	**-**	**169.9**
Injectafer	13.2	12.5	12.3	12.0	50.1	15.8	12.7	13.1	-	41.6
Venofer	15.8	13.3	16.1	15.7	60.9	16.3	13.4	21.3	-	51.0
GE injectables	18.3	19.0	21.8	21.9	81.0	20.6	23.1	24.2	-	67.9
EU Specialty Business Unit	**41.5**	**44.9**	**51.2**	**51.6**	**189.2**	**59.2**	**58.9**	**60.2**	**-**	**178.3**
Lixiana	32.3	35.6	39.4	38.9	146.2	45.4	45.2	45.0	-	135.6
Nilemdo/Nustendi	3.0	3.8	5.2	6.4	18.4	7.8	8.6	10.0	-	26.5
Olmesartan	4.7	4.5	5.3	5.1	19.6	5.3	4.2	4.4	-	13.9
ASCA Business Unit	**39.5**	**43.6**	**48.7**	**52.3**	**184.1**	**48.7**	**50.8**	**55.4**	**-**	**155.0**
Daiichi Sankyo China	15.5	15.2	19.0	20.7	70.5	15.7	18.4	19.6	-	53.7
Daiichi Sankyo Korea	6.3	8.3	7.3	7.3	29.2	8.2	8.2	8.4	-	24.9
Daiichi Sankyo Brasil Farmacêutica	8.9	10.0	11.3	11.8	42.0	12.3	11.2	12.9	-	36.4
Daiichi Sankyo Taiwan	4.0	3.9	4.1	4.1	16.0	4.6	4.4	4.7	-	13.7
Daiichi Sankyo Thailand	0.8	0.8	0.9	0.9	3.5	1.0	1.2	1.4	-	3.5
Daiichi Sankyo Hong Kong	1.1	0.5	0.6	0.6	2.9	0.7	0.6	0.7	-	1.9

3. Revenue by Business Units and Products (3) [Reference] Revenue in Local Currency	FY2023 Q1 Results	FY2023 Q2 Results	FY2023 Q3 Results	FY2023 Q4 Results	FY2023 Results	FY2024 Q1 Results	FY2024 Q2 Results	FY2024 Q3 Results	FY2024 Q4 Results	FY2024 Results
USD Mn										
Oncology Business Unit	**514**	**541**	**570**	**688**	**2,314**	**683**	**729**	**798**	**-**	**2,210**
Enhertu	505	524	559	676	2,264	668	713	777	-	2,157
Enhertu (US)	375	375	385	423	1,560	442	477	522	-	1,440
Enhertu (EU)	130	149	173	253	704	226	236	256	-	717
Datroway (US)	-	-	-	-	-	-	-	-	-	-
Patritumab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Turalio	9	9	10	8	37	10	11	12	-	33
Vanflyta	-	8	1	3	13	6	5	8	-	19
USD Mn										
American Regent Unit	**369**	**331**	**361**	**346**	**1,407**	**359**	**349**	**405**	**-**	**1,114**
Injectafer	96	86	83	81	346	101	85	86	-	272
Venofer	115	92	109	106	421	105	90	140	-	334
GE injectables	133	131	148	148	560	132	154	159	-	445
EUR Mn										
EU Specialty Business Unit	**278**	**286**	**323**	**320**	**1,207**	**353**	**359**	**370**	**-**	**1,082**
Lixiana	216	226	249	241	933	271	276	277	-	823
Nilemdo/Nustendi	20	24	33	40	118	47	53	61	-	161
Olmesartan	32	28	33	31	125	31	26	27	-	84

<11. Historical Data>

1. Revenue of Global Products

JPY Bn	FY2019 Results	FY2020 Results	FY2021 Results	FY2022 Results	FY2023 Results
Trastuzumab deruxtecan	**14.0**	**43.5**	**80.8**	**258.4**	**449.2**
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
US HER2-low Breast Cancer (pre chemo)	-	-	-	-	-
US HER2+ Solid Tumors	-	-	-	-	-
QUID related payment	-	-	3.4	1.1	1.2
Sales milestone payment	-	-	-	13.2	29.6
Datopotamab deruxtecan	**-**	**3.9**	**6.1**	**7.1**	**6.4**
Upfront payment	-	3.9	6.1	7.1	6.4
Patritumab deruxtecan	**-**	**-**	**-**	**-**	**3.5**
Upfront payment	-	-	-	-	3.5
Ifinatamab deruxtecan	**-**	**-**	**-**	**-**	**6.6**
Upfront payment	-	-	-	-	6.6
Raludotatug deruxtecan (DS-6000)	**-**	**-**	**-**	**-**	**2.8**
Upfront payment	-	-	-	-	2.8
Edoxaban	**154.0**	**165.9**	**205.6**	**244.0**	**287.7**
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)

JPY Bn	FY2019 Results	FY2020 Results	FY2021 Results	FY2022 Results	FY2023 Results
Japan Business Unit	**533.5**	**489.1**	**489.5**	**457.9**	**518.9**
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
Daiichi Sankyo Healthcare Unit	**68.5**	**67.2**	**64.7**	**70.3**	**76.0**

2. Revenue by Business Units and Products (2)	FY2019	FY2020	FY2021	FY2022	FY2023
JPY Bn	Results	Results	Results	Results	Results
Oncology Business Unit	**32.1**	**47.4**	**69.6**	**185.4**	**334.6**
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
American Regent Unit	**130.8**	**121.7**	**149.5**	**187.4**	**203.4**
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
EU Specialty Business Unit	**95.5**	**111.7**	**128.2**	**150.4**	**189.2**
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
ASCA Business Unit	**98.3**	**99.7**	**114.1**	**142.8**	**184.1**
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

2. Revenue by Business Units and Products (3) **[Reference] Revenue in Local Currency**	**FY2019** Results	**FY2020** Results	**FY2021** Results	**FY2022** Results	**FY2023** Results
USD Mn					
Oncology Business Unit	**295**	**447**	**619**	**1,369**	**2,314**
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					
American Regent Unit	**1,204**	**1,148**	**1,330**	**1,383**	**1,407**
Injectafer	477	416	472	398	346
Venofer	285	272	300	379	421
GE injectables	380	394	487	529	560
EUR Mn					
EU Specialty Business Unit	**789**	**903**	**982**	**1,067**	**1,207**
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
・Study phase ・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 (randomization or not, blinding or open label, control arm, etc)	・Primary and secondary endpoints are listed ・Safety measures are summarized as "safety" ・Pharmacokinetic indices are summarized as "PK"	Study locations	・Study initiation ・TLR ・Regulatory filing ・Status of application

◆ List of Abbreviations

ADA: anti-drug antibody, ADC: antibody drug conjugate, AGA: actionable genomic alterations, AML: acute myeloid leukemia, BICR: blinded independent central review, BMFI: brain metastases-free interval, BMS: Bristol Myers Squibb, BOR: best overall response, BTC: biliary tract cancer, CBR: clinical benefit rate, CPS: combined positive score, CR: complete remission, CRC: colorectal cancer, 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, ESSC: esophageal squamous cell carcinoma, ES-SCLC: extensive-stage small cell lung cancer, FAS: full analysis set, FPD: first patient dosed, FSD: first subject dosed, GMT: geometric mean titer, HCC: hepatocellular carcinoma, IA: interim analysis, ICR: independent central review, 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, RFS: relapse-free survival, TBA: to be announced, TKI: tyrosine kinase inhibitor, SCCHN: squamous cell carcinomas of the head and neck, SCLC: small cell lung cancer, TC: tumor cells, TLR: top line results, TNBC: triple negative breast cancer, TTD: time to deterioration, TTF: time to treatment failure, TEAE: treatment-emergent adverse events, 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 (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 H2
Phase3 DESTINY-Breast06 NCT04494425 jRCT2061200028 AstraZeneca	HR positive, HER2 low or ultralow 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 Aug 2024: Filing accepted (EU) Oct 2024: Filing accepted (JP) Jan 2025: Approved (US) Aug 2024: Breakthrough Therapy Designation (US) Oct 2024: Priority Review designation (US)
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	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 by BICR Secondary endpoint: OS, PFS by investigator, ORR, DOR, PK, safety, etc.	JP/US/EU /Asia	FPD: Jun 2021 TLR anticipated: FY2025 H1
Phase3 DESTINY-Breast11 NCT05113251 jRCT2041210097 AstraZeneca	HER2 positive breast cancer, neoadjuvant therapy	927	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: FY2025 H1
Phase 1b/2 BEGONIA NCT03742102 AstraZeneca	TNBC	243	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 expressing gastric, gastroesophageal junction and esophageal adenocarcinoma Part 1, Part 2: HER2 overexpressing (IHC3+ or IHC2+/ ISH+) Part3, Part4 : HER2 expressing Part 1: 2L or later Part 2: 1L Part 3: 1L Part 4: 1L	413	Randomized, open label, two-part (dose escalation, dose expansion) Part 1 (dose escalation) ・DS-8201 + 5-fluorouracil (5-FU) ・DS-8201 + capecitabine ・DS-8201 + durvalumab ・DS-8201 + oxaliplatin + 5-FU ・DS-8201 + capecitabine + oxaliplatin ・DS-8201 + durvalumab + 5-FU ・DS-8201 + capecitabine + durvalumab Part 2 (dose expansion) ・DS-8201 ・DS-8201 + oxaliplatin + 5-FU or capecitabine ・DS-8201 + pembrolizumab + 5-FU or capecitabine ・DS-8201 + pembrolizumab ・Trastuzumab + 5-FU or capecitabine + (cisplatin or oxaliplatin) Part 3 (dose expansion) ・DS-8201 + volrustomig (MEDI5752) + 5-FU or capecitabine Part 4 (dose expansion) ・DS-8201 + rilvegostomig (AZD2936) + 5-FU or capecitabine	Primary endpoint: ・Safety for part 1 ・ORR for part 2,3,4 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 H1
Phase 3 DESTINY-Gastric05 NCT06731478 jRCT2041240173 AstraZeneca	HER2 positive gastric or gastroesophageal junction adenocarcinoma, 1L	726	Randomized, open label, active controlled ・DS-8201 + pembrolizumab + 5-fluoro-uracil (5-FU) or capecitabine ・Trastuzumab + pembrolizumab + platinum-based chemotherapy (cisplatin + 5-FU or oxaliplatin + capecitabine) ・DS-8201 + 5FU or capecitabine ・Trastuzumab + platinum-based chemotherapy (cisplatin + 5-FU or oxaliplatin + capecitabine)	Primary endpoint: PFS Secondary endpoint: OS	JP/US/EU /Asia	FPD planned: FY2024 Q4
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 Aug 2024: Approved (CN) Nov 2023: Priority Review Designation (CN)
Phase 3 in prep ARTEMIDE-Gastric01 NCT06764875 AstraZeneca	HER2 positive and PD-L1 CPS≥1 gastric or gastroesophageal junction adenocarcinoma, 1L	840	Randomized, single blined, active controlied ・DS-8201 + rilvegostomig + capecitabine or 5-FU ・Pembrolizumab + trastuzumab + FP (5-FU + cisplatin) or CAPOX (capecitabine + oxaliplatin) ・Rilvegostomig + trastuzumab + FP (5-FU + cisplatin) or CAPOX (capecitabine + oxaliplatin)	Primary endpoint: PFS, OS Secondary endpoint: ORR, DOR, safety, PK, ADA, etc.	JP/US/EU /Asia	FPD: TBA

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 2 DESTINY-Lung01 NCT03505710 JapicCTI-183916 AstraZeneca	HER2 overexpressing or 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) Oct 2024: Approved (CN)

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 overexpressing non-squamous NSCLC, 1L	244	Randomized, open label, three-part (safety run-in, dose escalation, dose expansion) Part 1 (had one or two lines of systemic therapy) ・DS-8201 + durvalumab + cisplatin ・DS-8201 + durvalumab + carboplatin ・DS-8201 + durvalumab + pemetrexed ・DS-8201 Part 3 (treatment-naïve for advanced or metastatic NSCLC) ・DS-8201 + volrustomig (MEDI5752) ・DS-8201 + volrustomig (MEDI5752) + carboplatin Part 4(treatment-naïve for advanced or metastatic NSCLC) ・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 by BICR Secondary endpoint: OS, PFS by investigator, ORR, DOR, safety, PK, etc.	JP/US/EU /Asia	FPD: Dec 2021 TLR anticipated: FY2025 H1
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 Oct 2024: Approved based on the results of DESTINY-Lung02 and DESTINY-Lung05 (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 DESTINY-BTC01 NCT06467357 jRCT2031240225 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 (IHC3+) Secondary endpoint: ・OS (ITT) ・PFS, ORR, DOR (IHC3+ and ITT) safety and tolerability, TTD, PK, ADA, etc.	JP/US/EU /Asia	FPD: Aug 2024
Phase 2 DESTINY-PanTumor02 NCT04482309 jRCT2051240075 AstraZeneca	Part 1: bladder cancer, BTC, cervical cancer, endometrial cancer, ovarian cancer, pancreatic cancer, other rare tumors, any tumor type excluding breast cancer, gastric cancer, CRC Part 2: HER2 expressing/amplified solid tumors excluding breast cancer, gastric cancer, CRC	468	Non-randomized ・DS-8201	Primary endpoint: ORR Secondary endpoint: DOR, DCR, PFS, OS, safety, PK, ADA	JP/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 expressing solid tumors	175	Non-randomized, open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: 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	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.
Brand name: DATROWAY (JP/US)

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 2 TROPION-PanTumor03 NCT05489211 jRCT2031220404 AstraZeneca	Endometrial cancer Gastric cancer Castration-resistant prostate cancer Ovarian cancer Colorectal cancer Urothelial cancer BTC	582	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 controlled ・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) Nov 2024: Regulatory submission withdrawn (US) Dec 2024: Regulatory submission withdrawn (EU)
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, etc.	JP/US/EU /Asia	FPD: Oct 2020

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 TROPION-Lung04 NCT04612751 jRCT2031200449 AstraZeneca	NSCLC (without AGA), 1L/2L	371	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, DCR, PFS, TTR, OS, PK, ADA, etc.	JP/US/EU	FPD: Mar 2021
Phase 2 TROPION-Lung05 NCT04484142 jRCT2041200097 AstraZeneca	NSCLC with AGA and progressed on or after applicable targeted therapy and platinum based chemotherapy	137	Open label ・DS-1062	Primary endpoint: ORR Secondary endpoint: DOR, PFS, OS, safety, PK	JP/US/EU /Asia	FPD: Mar 2021 TLR: Mar 2023 Jan 2025: Filing* accepted (US) *supported by data from TROPION-Lung01, TROPION-PanTumor01 Dec 2024: Breakthrough Therapy Designation (US) Jan 2025: Priority Review Designation (US)
Phase 3 TROPION-Lung07 NCT05555732 jRCT2061220066 MRK AstraZeneca	non-squamous NSCLC (without AGA and PD-L1 TPS <50%), 1L	1,170	Randomized, open label, active controlled ・DS-1062 + pembrolizumab + cisplatin or carboplatin ・DS-1062 + pembrolizumab ・Pembrolizumab + pemetrexed + cisplatin or carboplatin	Primary endpoint: PFS by BICR, OS Secondary endpoint: ORR, PFS by investigator, DOR, TTR, DCR, TTD, safety, ADA, etc.	JP/US/EU /Asia	FPD: Jan 2023
Phase 3 TROPION-Lung08 NCT05215340 jRCT2061210074 MRK AstraZeneca	NSCLC (without AGA and PD-L1 TPS ≥ 50%), 1L Due to the protocol revision, the inclusion criteria are limited to non-squamous NSCLC	740	Randomized, open label, active controlled ・DS-1062 + pembrolizumab ・Pembrolizumab	Primary endpoint: PFS by BICR, OS (non-squamous) Secondary endpoint: ORR, PFS by investigator, DOR, TTR, DCR, TTD, safety, ADA, etc.	JP/US/EU /Asia	FPD: Mar 2022

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 TROPION-Lung10 NCT06357533 jRCT2031240095 AstraZeneca	non-squamous NSCLC (without AGA and PD-L1 TC ≥ 50%), 1L	675	Randomized, open label, active controlled ・DS-1062 + rilvegostomig (AZD2936) ・Rilvegostomig (AZD2936) ・Pembrolizumab	Primary endpoint: ・PFS, OS (TROP2 biomarker positive) Secondary endpoint: ・PFS, OS (FAS) ・ORR, DOR, PK, immunogenecity, etc.	JP/US/EU /Asia	FPD: May 2024
Phase 3 TROPION-Lung12 NCT06564844 jRCT2061240062 AstraZeneca	Stage I adenocarcinoma NSCLC (ctDNA-positive or have at least one high-risk pathological feature), adjuvant therapy	660	Randomized, open label, active controlled ・DS-1062 + rilvegostomig (AZD2936) ・Rilvegostomig (AZD2936) ・Observation or physician's choice (carboplatin, cisplatin, etoposide, pemetrexed, vinorelbine, UFT)	Primary endpoint: DFS by BICR Secondary endpoint: OS, participant-reported physical function, PK, immunogenecity, etc.	JP/US/EU /Asia	FPD: Jan 2025
Phase 3 TROPION-Lung14 NCT06350097 jRCT2031240580 AstraZeneca	EGFR mutated NSCLC, 1L	582	Randomized, open label, active controlled ・DS-1062 + osimertinib ・Osimertinib	Primary endpoint: PFS by BICR Secondary endpoint: OS, CNS PFS, PFS by investigator, ORR, DOR, PK, ADA, etc.	JP/US/EU /Asia	FPD: May 2024
Phase 3 TROPION-Lung15 NCT06417814 jRCT2061240051 AstraZeneca	EGFR mutated NSCLC, 2L or later (progressed on prior EGFR tyrosine kinase inhibitor)	630	Randomized, open label, active controlled ・DS-1062 + osimertinib ・DS-1062 ・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: Oct 2024
Phase 3 AVANZAR NCT05687266 jRCT2031220612 AstraZeneca	NSCLC (without AGA), 1L ・Due to the protocol revision, the inclusion criteria are limited to non-squamous NSCLC	1,350	Randomized, open label, active controlled ・DS-1062 + durvalumab + carboplatin ・Non-squamous NSCLC participants: pembrolizumab + pemetrexed + carboplatin or cisplatin ・Squamous NSCLC participants: pembrolizumab + paclitaxel + carboplatin	Primary endpoint: ・PFS by BICR, OS (TROP2 biomarker positive) Secondary endpoint: ・PFS, OS (ITT) ・PFS, OS (TROP2 biomarker negative) ・ORR, DOR, PFS (TROP2 biomarker positive and ITT) ・PK, ADA, 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	243	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 by BICR, OS Secondary endpoint: ORR, DOR, PFS by investigator, DCR, PK, ADA, etc.	JP/US/EU /Asia	FPD: Nov 2021 TLR: Sep 2023 Mar 2024: Filing accepted (EU, CN) Dec 2024: Approved (JP) Jan 2025: Approved (US)
Phase 3 TROPION-Breast02 NCT05374512 jRCT2061220029 AstraZeneca	TNBC, PD-1/PD-L1 inhibitor ineligible, 1L	637	Randomized, open label, active controlled ・DS-1062 ・Physician's choice (paclitaxel, nab-paclitaxel, carboplatin, capecitabine, eribulin)	Primary endpoint: PFS by BICR, OS Secondary endpoint: ORR, DOR, PFS by investigator, DCR, TTD, PK, ADA, safety, etc.	JP/US/EU /Asia	FPD: Jun 2022 TLR anticipated: FY2025 H1
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 (paclitaxel, nab-paclitaxel, or gemcitabine + carboplatin) + pembrolizumab	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	630	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 by BICR Secondary endpoint: DOR, PFS, ORR by investigator, DCR, TTR, OS, safety, etc.	JP/US/EU /Asia	FPD: Feb 2021 TLR: 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 by BICR Secondary endpoint: OS, PFS by local standard clinical practice, ORR, DOR, CBR, DCR, safety, etc.	JP/US/EU /Asia	FPD: Aug 2022 TLR: Sep 2024
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

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT04676477 jRCT2031200247 AstraZeneca MRK	EGFR mutated NSCLC, 1L/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
Phase 1b/2 in prep HERTHENA-Breast01 (MK-1022-009) NCT06686394 MRK	HER2 positive breast cancer, 2L or later	81	Non-randomized, open label ・U3-1402 + trastuzumab or trastuzumab biosimilar ・U3-1402 + pertuzumab + trastuzumab or trastuzumab biosimilar ・U3-1402 + tucatinib + trastuzumab or trastuzumab biosimilar	Primary endpoint: safety and tolerability Secondary endpoint: PK	JP/US/EU /Asia	FPD planned: FY2024 Q4
Phase 1/2 MK-1022-011 NCT06596694 MRK MRK	Colorectal cancer, BTC, hepatocellular carcinoma, 2L or later	130	Open label ・U3-1402	Primary endpoint: safety and tolerability, ORR Secondary endpoint: DOR, PFS, OS, PK	US/EU /Asia	FPD: Nov 2024
Phase 1/2 in prep KEYMAKER-U01 substudy 01A NCT04165070 MRK	Stage IV NSCLC, 1L	450	Non-randomized (part B), open label, combination with pembrolizumab, two-part (part A, part B) ・Part B: U3-1402 + pembrolizumab + carboplatin * Umbrella study of pembrolizumab led by MRK (part B: combination therapy with U3-1402 or DS-7300)	Primary endpoint (part B): safety and tolerability Secondary endpoint (part B): ORR, DOR, PK, etc.	JP/US/EU /Asia	FPD: TBA
Phase 2 in prep KEYMAKER-U01 substudy 01G NCT06731907 MRK	Stage IV NSCLC, 1L	90	Non-randomized, single-blined, active controlled ・U3-1402 + pembrolizumab ・Non-squamous NSCLC participants: pembrolizumab + pemetrexed + carboplatin Squamous NSCLC participants: pembrolizumab + paclitaxel or nab-paclitaxel + carboplatin * Umbrella study of pembrolizumab led by MRK	Primary endpoint: ORR, safety and tolerability Secondary endpoint: DOR, PFS, OS	US/EU /Asia	FPD: TBA

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-PanTumor01 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 1b/2 IDeate-PanTumor02 NCT06330064 jRCT2031240016 MRK	endometrial cancer, HNSCC, PDAC, CRC, HCC, adenocarcinoma of esophagus, gastroesophageal junction and stomach, urothelial carcinoma, ovarian cancer, cervical cancer, BTC, HER2 low breast cancer, HER2 IHC0 breast cancer, and cutaneous melanoma, 2L or later	520	Non-randomized, open label ・DS-7300	Primary endpoint: ORR, safety and tolerability Secondary endpoint: safety, DOR, PFS, DCR, OS, PK, ADA, etc.	JP/US/EU /Asia	FPD: May 2024
Phase 2 IDeate-Lung01 NCT05280470 jRCT2041220019 MRK	ES-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: FY2025 H1 Apr 2023: Orphan Drug Designation (US) Dec 2024: Orphan Drug Designation (JP)
Phase 3 IDeate-Lung02 NCT06203210 jRCT2031230631 MRK	ES-SCLC, 2L	540	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: Aug 2024 Apr 2023: Orphan Drug Designation (US) Dec 2024: Orphan Drug Designation (JP)

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1b/2 IDeate-Lung03 NCT06362252 jRCT2031240089 MRK	ES-SCLC, 1L	123	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: Aug 2024
Phase 3 in prep IDeate-Esophageal01 NCT06644781 jRCT2031240571 MRK	ESCC, 2L	510	Randomized, open label, active controlled ・DS-7300 ・Physician's choice (docetaxel, paclitaxel, irinotecan)	Primary endpoint: OS Secondary endpoint: PFS, ORR, DOR, DCR, safety, PK, ADA, etc.	JP/US/EU/Asia	FPD planned: FY2025 H1
Phase 1/2 in prep KEYMAKER-U01 substudy 01A NCT04165070 MRK	Stage IV NSCLC, 1L	450	Non-randomized (part B), open label, two-part (part A, part B) ・Part B: DS-7300 + pembrolizumab ・Part B: DS-7300 + pembrolizumab + carboplatin * Umbrella study of pembrolizumab led by MRK (part B: combination therapy with U3-1402 or DS-7300)	Primary endpoint (part B): safety and tolerability Secondary endpoint (part B): ORR, DOR, PK, etc.	JP/US/EU/Asia	FPD: TBA

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 2 in prep KEYMAKER-U06 substudy 06E NCT06780111 MRK	ESCC, 1L	209	Randomized, open label, active controlled ・DS-7300 + pembrolizumab ・DS-7300 + pembrolizumab + 5-FU + leucovorin or levoleucovorin DS-7300 + pembrolizumab + 5-FU + oxaliplatin ・Pembrolizumab + mFOLFOX6 chemotherapy * Umbrella study of pembrolizumab led by MRK	Primary endpoint: safety, ORR Secondary endpoint: DOR, PFS, OS, DCR, PK, ADA	TBA	FPD: TBA
Phase 2 in prep KEYMAKER-U01 substudy 01H NCT06780085 MRK	non-suquamous NSCLC, 2L	96	Randomized, single-blind, active controlled ・DS-7300；12mg/kg ・Docetaxel * Umbrella Study of investigational agents led by MRK	Primary endpoint: safety, ORR Secondary endpoint: DOR, PFS, OS	TBA	FPD: TBA
Phase 2 in prep KEYMAKER-U01 Substudy 01I NCT06780098 MRK	suquamous NSCLC, 2L	144	Randomized, single blind, active controlled ・DS-7300：12mg/kg ・DS-7300：8mg/kg ・Docetaxel * Umbrella Study of investigational agents led by MRK	Primary endpoint: ORR, safety Secondary endpoint: DOR, PFS, OS	TBA	FPD: TBA

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	179	Non-randomized, open label, two-part (dose escalation, dose expansion) ・DS-6000	Primary endpoint: safety and tolerability Secondary endpoint: PK, ORR, DOR, DCR, CBR, TTR, ADA	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: ・PFS for part A ・ORR by investigator, DOR, DCR, OS, safety, PK, etc.	JP/US/EU /Asia	FPD: Apr 2024
Phase 2 REJOICE-PanTumor01 NCT06660654 jRCT2031240486 MRK	Solid tumors (including endometrial cancer, cervical cancer, non-high-grade serous ovarian cancer, urothelial cancer, clear cell renal carcinoma (ccRCC))	200	Non-randomized, open label ・DS-6000	Primary endpoint: ORR (all cohorts except ccRCC), DCR (ccRCC cohort only), safety Secondary endpoint: PFS, DOR, TTR, ORR (ccRCC cohort only), DCR (all cohorts except ccRCC cohort), PK, ADA	JP/US/EU /Asia	FPD: Jan 2025
Phase 1b/2 in prep KEYNOTE-B98 NCT04938817 MRK	ES-SCLC, 2L	110	open label ・DS-6000 * Study of investigational agents as monotherapy or in combination with pembrolizumab led by MRK. Added DS-6000 monotherapy arm.	Primary endpoint: safety and tolerability, ORR Secondary endpoint: PFS, DOR	US/EU /Asia	FPD: TBA
Phase 2 in prep KEYMAKER-U01 substudy 01H NCT06780085 MRK	non-suquamous NSCLC, 2L	96	Randomized, single-blind, active controlled ・DS-6000 ・Docetaxel * Umbrella Study of investigational agents led by MRK	Primary endpoint: safety, ORR Secondary endpoint: DOR, PFS, OS	TBA	FPD: TBA
Phase 2 in prep KEYMAKER-U01 Substudy 01I NCT06780098 MRK	suquamous NSCLC, 2L	144	Randomized, single blind, active controlled ・DS-6000 ・Docetaxel * Umbrella Study of investigational agents led by MRK	Primary endpoint: ORR, safety Secondary endpoint: DOR, PFS, OS	TBA	FPD: TBA

◆ 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/EU)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
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: 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)
Phase 3 QuANTUM-Wild NCT06578247 jRCT2061240069	*FLT3*-ITD negative AML, 1L	700	Randomized, double-blind, placebo-controlled ・Arm A: quizartinib + chemotherapy followed by quizartinib maintenance ・Arm B: placebo + chemotherapy followed by placebo maintenance ・Arm C: quizartinib + chemotherapy followed by placebo maintenance	Primary endpoint: OS Secondary endpoint: EFS, duration of CR, RFS, etc.	JP/US/EU /Asia	FPD: Dec 2024 Mar 2009: Orphan Drug 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	155	Non-Randomized, open label ・DS-3201	Primay endpoint: ORR, safety Secondary endpoint: PK, 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	Primay endpoint: ORR Secondary endpoint: CRR, CR rate, PFS, DOR, TTR, safety, PK	EU	FPD: Jun 2021
Phase 1b NCT06244485 jRCT2031230614	HER2-positive gastric cancer or gastro-esophageal junction (GEJ) adenocarcinoma, HER2 low breast cancer (DS-8201 combination) non-squamous NSCLC (DS-1062 combination)	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 Secondary endpoint: BOR, ORR, DCR, DOR, PFS, etc.	JP/US	FPD: Apr 2016
Phase 1b/2 NCT06644768 jRCT2031240572	NSCLC (without AGA and PD-L1 TPS ≥ 50%), 1L	137	Randomized, open label, two-part (dose escalation, dose expansion) ・DS-3201 + pembrolizumab ・Pembrolizumab	Primary endpoint: ・safety and tolerability for phase 1b ・PFS by BICR for phase 2 Secondary endpoint: ・ ORR, DOR, DCR, OS, PFS by investigator for phase 2	JP/US./ Asia	FPD: Oct 2024

◆ 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（CLDN6-directed ADC）

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT05394675	Solid tumors	85	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 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	Solid tumors	430	Non-randomized, open label, two-part (dose escalation/part 1, dose expansion/part 2) ・DS-3939	Primary endpoint: safety and tolerability, ORR (part 1) Secondary endpoint: ORR (part 2), DCR, DOR, TTR, PFS, OS, PK, ADA, etc.	JP/US/EU Asia	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

MK-6070（DS3280）(DLL3 directed tri-specific T-cell engager)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1/2 NCT04471727 MRK	DLL3 expressing advanced cancer (SCLC, neuroendocrine carcinoma)	232	Non-randomized, open label ・MK-6070 ・MK-6070 + atezolizumab ・MK-6070 + DS-7300 (I-DXd)	Primary endpoint: safety and tolerability, PK Secondary endpoint: ORR, PFS, OS, DOR, ADA, etc.	US	FPD: Dec 2020 Mar 2022: Orphan Drug Designation for SCLC (US)
Phase 1b/2 in prep MK-6070-002 NCT06780137 MRK	ES-SCLC, 2L	138	Non-randomized, open label, two-part Part 1 ・MK-6070 (Q3W) + DS-7300 (Q3W) ・MK-6070 (Q2W) + DS-7300 (Q3W) ・MK-6070 (Q2W) + DS-7300 (Q2W) Part 2 ・MK-6070	Primary endpoint: safety and tolerability, ORR Secondary endpoint: DOR, PFS, PK, ADA	TBA	FPD: TBA

DS-2243 (HLA-A*02/NY-ESO directed bispecific T-cell engager)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 in prep NCT06644755	Solid tumors (HLA-A2 and/or NY-ESO positive synovial sarcoma, myxoid/round cell liposarcoma (MRCLS), squamous NSCLC, adenocarcinoma NSCLC, or urothelial carcinoma)	150	Open label, two-part (dose escalation/part 1, dose expansion/part 2) ・DS-2243	Primary endpoint: ・safety and tolerability ・ORR (part 2 only) Secondary endpoint: ・ORR (part 1) ・DCR, PFS, OS, etc. (part 1, 2)	US/EU/ Asia	FPD planned: FY2024 Q4

◆ 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)	26	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	9	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 TLR: Dec 2024

◆ 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 ・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 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 ・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 Mar 2024: Filing accepted (JP)

◆ Stage-up Projects (Major Changes from the FY2024 Q2 Financial Announcement in October 2024)

Generic Name/Project Code Number Mechanism of action	Target Indication	Current Stage	Note
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HR positive, HER2 low or ultralow breast cancer, chemotherapy naïve	Approved	US, DESTINY-Breast06
Datopotamab deruxtecan/DS-1062/ Dato-DXd TROP2-directed ADC	HR positive, HER2 low or negative breast cancer, 2L/3L	Approved	JP/US, TROPION-Breast01
Datopotamab deruxtecan/DS-1062/ Dato-DXd TROP2-directed ADC	NSCLC with prior systemic therapies, including an EGFR-directed therapy	Filed	US, TROPION-Lung05 (supported by data from TROPION-Lung05, TROPION-PanTumor01)
Datopotamab deruxtecan/DS-1062/ Dato-DXd TROP2-directed ADC	NSCLC, 2L or later	Regulatory submission withdrawn	US/EU, TROPION-Lung01
Datopotamab deruxtecan/DS-1062/ Dato-DXd TROP2-directed ADC	Stage I adenocarcinoma NSCLC (ctDNA-positive or have at least one high-risk pathological feature), adjuvant therapy	Ph3	JP/US/EU/Asia, TROPION-Lung12
Quizartinib/AC220 FLT3 inhibitor	*FLT3*-ITD negative AML, 1L	Ph3	JP/US/EU/Asia, QuANTUM-Wild
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 positive gastric or gastroesophageal junction adenocarcinoma, 1L	Ph3 prep	JP/US/EU/Asia, DESTINY-Gastric05

◆ Stage-up Projects (Major Changes from the FY2024 Q2 Financial Announcement in October 2024)

Generic Name/Project Code Number Mechanism of action	Target Indication	Current Stage	Note
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 positive and PD-L1 CPS≥1 gastric or gastroesophageal junction adenocarcinoma, 1L	Ph3 prep	JP/US/EU/Asia, ARTEMIDE-Gastric01
Ifinatamab deruxtecan/ DS-7300/I-DXd B7-H3-directed ADC	ESCC, 2L	Ph3 prep	JP/US/EU/Asia, IDeate-Esophageal01
Raludotatag deruxtecan/DS-6000/ R-DXd CDH6-directed ADC	Solid tumors	Ph2	JP/US/EU/Asia, REJOICE-PanTumor01
Patritumab deruxtecan/ U3-1402/HER3-DXd HER3-directed ADC	Stage IV NSCLC, 1L	Ph2 prep	US/EU/Asia, KEYMAKER-U01 substudy 01G
Ifinatamab deruxtecan/ DS-7300/I-DXd B7-H3-directed ADC	ESCC, 1L	Ph2 prep	KEYMAKER-U06 substudy 06E
Ifinatamab deruxtecan/ DS-7300/I-DXd B7-H3-directed ADC	non-suquamous NSCLC, 2L	Ph2 prep	KEYMAKER-U01 substudy 01H
Ifinatamab deruxtecan/ DS-7300/I-DXd B7-H3-directed ADC	suquamous NSCLC, 2L	Ph2 prep	KEYMAKER-U01 substudy 01I
Raludotatag deruxtecan/DS-6000/ R-DXd CDH6-directed ADC	non-suquamous NSCLC, 2L	Ph2 prep	KEYMAKER-U01 substudy 01H

◆ Stage-up Projects (Major Changes from the FY2024 Q2 Financial Announcement in October 2024)

Generic Name/Project Code Number Mechanism of action	Target Indication	Current Stage	Note
Raludotatag deruxtecan/DS-6000/ R-DXd CDH6-directed ADC	suquamous NSCLC, 2L	Ph2 prep	KEYMAKER-U01 substudy 01I
Valemetostat/DS-3201 EZH1/2 inhibitor	NSCLC (without AGA and PD-L1≥ 50%), 1L	Ph1b/2	JP/US/Asia
Patritumab deruxtecan/ U3-1402/HER3-DXd HER3-directed ADC	Colorectal cancer, BTC, hepatocellular carcinoma, 2L or later	Ph1b/2	US/EU/Asia, MK-1022-011
Patritumab deruxtecan/ U3-1402/HER3-DXd HER3-directed ADC	HER2 positive breast cancer, 2L or later	Ph1b/2 prep	JP/US/EU/Asia, HERTHENA-Breast01
Raludotatag deruxtecan/DS-6000/ R-DXd CDH6-directed ADC	ES-SCLC, 2L	Ph1b/2 prep	US/EU/Asia, KEYNOTE-B98
MK-6070（DS3280） DLL3 directed tri-specific T-cell engager	ES-SCLC, 2L	Ph1b/2 prep	MK-6070-002
DS-2243 HLA-A*02/NY-ESO directed bispecific T-cell engager	Solid tumors	Ph1 prep	US/EU/Asia