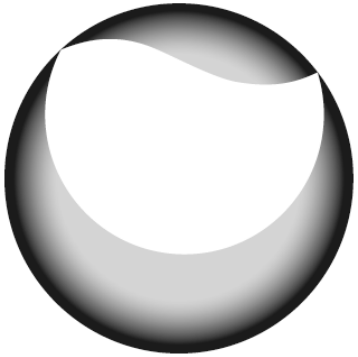
TSE:4568

Reference Data

(Consolidated Financial Results for Q1 FY2026)



Daiichi-Sankyo

July 31, 2026

Daiichi Sankyo Co., Ltd.

https://www.daiichisankyo.com

Contents

Daiichi-Sankyo

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2025 Q1 YTD to revenue	FY2025 Q1 YTD Results	FY2026 Q1 YTD to revenue	FY2026 Q1 YTD Results	(vs. Forecast (%)*)	YoY	YoY (%)	FY2026 to revenue	FY2026 Forecast (as of May.)	FY2026 to revenue	FY2026 Forecast (as of Jul.)	vs. Forecast (as of May.)
Revenue	*100.0%*	**474.6**	*100.0%*	**574.7**	**(24.6%)**	**100.1**	***+21.1%***	*100.0%*	**2,280.0**	*100.0%*	**2,340.0**	**60.0**
Cost of sales*1	*18.5%*	87.6	*21.9%*	126.0	(22.9%)	38.5	*+43.9%*	*23.2%*	530.0	*23.5%*	550.0	20.0
CMO compensation fee	-	-	*0.2%*	1.0	(1.3%)	1.0	-	*3.5%*	80.0	*3.4%*	80.0	-
Other Cost of sales	*18.5%*	87.6	*21.8%*	125.0	(26.6%)	37.5	*+42.8%*	*19.7%*	450.0	*20.1%*	470.0	20.0
Gross Profit	*81.5%*	387.0	*78.1%*	448.7	(25.1%)	61.7	*+15.9%*	*76.8%*	1,750.0	*76.5%*	1,790.0	40.0
SG&A expenses*1	*37.9%*	180.1	*39.3%*	226.0	(24.3%)	45.9	*+25.5%*	*39.0%*	890.0	*39.7%*	930.0	40.0
DXd ADC profit share*2	*12.8%*	60.6	*16.9%*	96.9	(24.5%)	36.3	*+60.0%*	*16.2%*	370.0	*16.9%*	395.0	25.0
Other SG&A expenses	*25.2%*	119.5	*22.5%*	129.1	(24.1%)	9.6	*+8.0%*	*22.8%*	520.0	*22.9%*	535.0	15.0
R&D expenses*1	*22.3%*	106.0	*20.1%*	115.5	(23.1%)	9.5	*+9.0%*	*21.9%*	500.0	*21.4%*	500.0	-
Core Operating Profit	*21.3%*	**101.0**	*18.7%*	**107.3**	**(29.8%)**	**6.3**	***+6.2%***	*15.8%*	**360.0**	*15.4%*	**360.0**	**-**
Non-core income*3		0.8		0.1		-0.7			-		-	-
Non-core expenses*3		5.1		22.2		17.2			45.0		40.0	-5.0
Operating Profit	*20.4%*	**96.7**	*14.8%*	**85.1**	**(26.6%)**	**-11.6**	***-12.0%***	*13.8%*	**315.0**	*13.7%*	**320.0**	**5.0**
Financial income/expenses		8.4		6.5		-1.9			12.5		12.5	-
Share of profit or loss of investments accounted for using the equity method		0.4		-0.3		-0.6			1.5		1.5	-
Profit before tax	*22.2%*	**105.4**	*15.9%*	**91.3**	**(27.3%)**	**-14.1**	***-13.4%***	*14.4%*	**329.0**	*14.3%*	**334.0**	**5.0**
Income taxes		19.9		22.7		2.8			66.0		80.0	14.0
Profit for the year	*18.0%*	**85.5**	*11.9%*	**68.6**	**(27.0%)**	**-16.9**	***-19.7%***	*11.5%*	**263.0**	*10.9%*	**254.0**	**-9.0**
Profit attributable to owners of the Company	*18.0%*	**85.5**	*11.9%*	**68.6**	**(27.3%)**	**-16.9**	***-19.7%***	*11.4%*	**260.0**	*10.7%*	**251.0**	**-9.0**

Forex impact: +41.9
(USD: +20.9, EUR: +14.1, ASCA: +6.9)

Forex impact: +12.7
(USD: +2.8, EUR: +9.3, ASCA: +0.6)

Forex impact: +10.9
(USD: +7.2, EUR: +2.4, ASCA: +1.3)

Forex impact: +8.6
(USD: +7.7, EUR: +0.6, ASCA: +0.3)

Forex impact: +9.7
(USD: +3.3, EUR: +1.8, ASCA: +4.6)

Forex impact: +6.7
(USD: +3.2, EUR: -1.1, ASCA: +4.6)

- Improvement in investment securities valuation gains/losses +1.5
- Decrease of interest income -0.7
- Decrease of dividend income -1.2
- Increase of interest expenses -0.7

Tax rate	18.9%	24.9%		
Overseas sales ratio	69.2%	74.6%		
Currency Rate (Average)				
USD/JPY	144.60	159.49		
EUR/JPY	163.81	185.38		

(Assumed ratess rate for Q2 and onward)
USD/JPY 155, EUR/JPY 180

Currency Rate	Currency Rate **
150.00	156.12
180.00	181.35

* vs. Jul. Forecast
** Weighted average of actual rates through Q1 and assumed rates for Q2 and onward

Annual impact of JPY 1 change

	Forecast	
	USD	EUR
Revenue	JPY 6.6 Bn	JPY 2.6 Bn
Operating Profit	JPY -0.05 Bn	JPY 0.5 Bn

This report is not subject to audit procedures.
*1 Non-core 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 Non-core income and expenses and the adjustment of operating profit and core operating profit

2. Sheet to adjust Operating Profit to Core Operating Profit

FY2025 Q1 YTD Results

JPY Bn	Full base	Adjustment						Core base
		Amortization expenses of intangible assets related to	Gains/losses associated with restructuring	Impairment losses on property, plant and equipment, intangible assets, and goodwill	Gains/losses related to damages and settlements	Acquisition-related costs	Others	
Revenue	**474.6**							**474.6**
Cost of sales	92.3	-4.8						87.6
SG&A expenses	180.3			-0.3				180.1
R&D expenses	106.0							106.0
Other income*	0.8				-0.7		-0.1	-
Other expenses*	0.0						-0.0	-
Core Operating Profit**								**101.0**
Non-core income					0.7		0.1	0.8
Non-core expenses		4.8		0.3			0.0	5.1
Operating Profit (full)	**96.7**							**96.7**

FY2026 Q1 YTD Results

JPY Bn	Full base	Adjustment						Core base
		Amortization expenses of intangible assets related to	Gains/losses associated with restructuring	Impairment losses on property, plant and equipment, intangible assets, and goodwill	Gains/losses related to damages and settlements	Acquisition-related costs	Others	
Revenue	**574.7**							**574.7**
Cost of sales	124.3	-5.1	6.9 *1					126.0
SG&A expenses	250.0		-24.0 *2					226.0
R&D expenses	115.5							115.5
Other income*	0.1						-0.1	-
Other expenses*	0.0						-0.0	-
Core Operating Profit**								**107.3**
Non-core income							0.1	0.1
Non-core expenses		5.1	17.1				0.0	22.2
Operating Profit (full)	**85.1**							**85.1**

＜Major Non-core income and Non-core expenses＞

*1 Reversal of provision for losses related to cancellation of Odawara site investment

*2 EUSBU restructuring expenses

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

** Core operating profit is disclosed as an indicator of the fundamental profitability of the business, excluding the following items from operating profit.
- Amortization expenses of intangible assets related to products
- Gains/losses associated with restructuring
- Impairment losses on property, plant and equipment, intangible assets, and goodwill
- Gains/losses related to damages and settlements
- Acquisition-related costs
- Loss (gain) on exchange differences (applicable from the fiscal year ending March 2028)
- Other gains/losses that the Company deems should be excluded to understand the fundamental profitability of the Group’s business

3. Revenue of Global Products (1)

JPY Bn		FY2025 Q1 YTD Results	FY2026 Q1 YTD Results	(vs. Forecast (%))	YoY	YoY (%)	FY2026 Forecast (as of May.)	Forecast (as of Jul.)	vs. Forecast (as of May.)	YoY	YoY (%)
Trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	**161.0**	**239.8**	**(23.3%)**	**78.8**	**+48.9%**	**993.3**	**1,030.0**	**36.6**	**210.4**	**+25.7%**
Product sales	*Incl. Gross profit share in AstraZeneca territory	155.2	219.2	(24.5%)	64.0	+41.2%	861.3	894.9	33.6	196.5	+28.1%
Enhertu (JPN)		8.4	11.9	(25.5%)	3.5	+41.9%	45.0	46.4	1.4	8.8	+23.3%
Enhertu (US)		85.1	125.1	(24.7%)	40.0	+47.0%	466.3	505.6	39.4	119.4	+30.9%
Enhertu (EU)		39.5	51.8	(24.7%)	12.3	+31.2%	204.2	209.9	5.8	35.1	+20.1%
Enhertu (ASCA: Asia, South and Central America)		22.3	30.4	(22.9%)	8.2	+36.7%	145.9	132.9	-13.0	33.2	+33.3%
Brazil		8.1	10.5	(24.4%)	2.4	+29.7%	46.9	42.9	-4.0	4.9	+13.0%
China (co-promotion revenue)		4.5	5.8	(19.4%)	1.4	+31.2%	35.3	30.1	-5.2	10.1	+50.5%
Others		9.7	14.1	(23.6%)	4.4	+45.0%	63.7	59.8	-3.8	18.1	+43.5%
Upfront payment		2.6	2.6	(25.0%)	-	-	10.2	10.2	-	-	-
Regulatory milestone payment		3.0	17.8	(59.3%)	14.8	+493.6%	26.9	30.0	3.1	6.2	+26.0%
US HER2+ Breast Cancer 3L		0.2	0.2	(25.0%)	-	-	0.9	0.9	-	-	-
EU HER2+ Breast Cancer 3L		0.1	0.1	(25.0%)	-	-	0.5	0.5	-	-	-
US HER2+ Gastric Cancer 2L/3L		0.2	0.2	(25.0%)	-	-	0.8	0.8	-	-	-
US HER2+ Breast Cancer 2L		0.2	0.2	(25.0%)	-	-	0.9	0.9	-	-	-
EU HER2+ Breast Cancer 2L		0.2	0.2	(25.0%)	-	-	0.7	0.7	-	-	-
US HER2-low Breast Cancer (post chemo)		0.5	0.5	(25.0%)	-	-	1.9	1.9	-	-	-
EU HER2-low Breast Cancer (post chemo)		0.3	0.3	(25.0%)	-	-	1.4	1.4	-	-	-
EU HER2+ Gastric Cancer 2L		0.1	0.1	(25.0%)	-	-	0.3	0.3	-	-	-
US HER2 mutant NSCLC 2L		0.3	0.3	(25.0%)	-	-	1.2	1.2	-	-	-
EU HER2 mutant NSCLC 2L		0.2	0.2	(25.0%)	-	-	0.8	0.8	-	-	-
US HER2-low Breast Cancer (pre chemo)		0.4	0.4	(25.0%)	-	-	1.8	1.8	-	-	-
EU HER2-low Breast Cancer (pre chemo)		0.1	0.3	(25.0%)	0.2	+138.3%	1.2	1.2	-	0.2	+17.0%
US HER2+ Solid Tumors		0.1	0.1	(25.0%)	-	-	0.3	0.3	-	-	-
US HER2+ Breast Cancer 1L		-	0.4	(25.0%)	0.4	-	1.6	1.6	-	-9.7	-85.7%
US HER2+ Breast Cancer Neoaduvant		-	2.4	(90.6%)	2.4	-	2.4	2.6	0.2	2.6	-
US HER2+ Breast Cancer Adjuvant		-	9.8	(90.6%)	9.8	-	10.2	10.9	0.7	10.9	-
EU HER2+ Solid Tumors		-	2.0	(90.6%)	2.0	-	-	2.2	2.2	2.2	-
Quid related payment*		0.3	0.3	(25.0%)	-	-	1.2	1.2	-	-	-
Sales milestone payment		-	-	-	-	-	93.8	93.8	-	7.8	+9.1%

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

3. Revenue of Global Products (2)

JPY Bn		FY2025 Q1 YTD Results	FY2026 Q1 YTD Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of May.)	Forecast (as of Jul.)	vs. Forecast (as of May.)	FY2026 YoY	FY2026 YoY (%)
Datopotamab deruxtecan	anti-cancer agent (TROP2-directed antibody drug conjugate)	**8.7**	**23.9**	**(18.8%)**	**15.3**	**+176.4%**	**121.5**	**127.2**	**5.7**	**71.1**	**+126.9%**
Product sales	*Incl. Gross profit share in AstraZeneca territory	5.3	20.6	(17.7%)	15.3	+289.9%	111.4	116.9	5.5	69.2	+145.4%
Datroway (JPN)		2.2	3.8	(28.6%)	1.6	+74.2%	13.1	13.1	-	0.0	+0.1%
Datroway (US)		3.1	16.1	(16.6%)	13.0	+417.4%	92.2	97.1	4.9	63.9	+192.1%
Datroway (EU)		0.0	0.4	(23.3%)	0.4	-	2.3	1.8	-0.5	0.6	+51.6%
Datroway (ASCA: Asia, South and Central America)		-	0.3	(6.6%)	0.3	-	3.8	4.9	1.0	4.8	-
Upfront payment		1.6	1.6	(25.0%)	-	-	6.4	6.4	-	-	-
Regulatory milestone payment		1.8	1.7	(42.5%)	-0.1	-4.9%	3.8	3.9	0.2	1.9	+91.9%
US EGFR mutated NSCLC 3L		1.8	0.1	(25.0%)	-1.7	-94.9%	0.4	0.4	-	-1.7	-82.4%
US TNBC		-	1.6	(44.3%)	1.6	-	3.4	3.6	0.2	3.6	-
Patritumab deruxtecan	anti-cancer agent (HER3-directed antibody drug conjugate)	**4.1**	**3.0**	**(25.0%)**	**-1.1**	**-26.3%**	**12.0**	**12.0**	**-**	**-1.1**	**-8.2%**
Upfront payment		3.9	2.9	(25.0%)	-1.0	-26.3%	11.6	11.6	-	-1.0	-8.2%
Satisfaction of Quid Rights *		0.1	0.1	(25.0%)	-0.0	-26.3%	0.4	0.4	-	-0.0	-8.2%
Ifinatamab deruxtecan	anti-cancer agent (B7-H3-directed antibody drug conjugate)	**3.8**	**3.8**	**(20.6%)**	**-**	**-**	**18.3**	**18.4**	**0.1**	**3.3**	**+21.5%**
Product sales		-	-	-	-	-	3.1	3.3	0.1	3.3	-
Ifinatamab deruxtecan (US)		-	-	-	-	-	3.1	3.3	0.1	3.3	-
Upfront payment		3.7	3.7	(25.0%)	-	-	14.7	14.7	-	-	-
Satisfaction of Quid Rights *		0.1	0.1	(25.0%)	-	-	0.5	0.5	-	-	-
Raludotatug deruxtecan	anti-cancer agent (CDH6-directed antibody drug conjugate)	**1.6**	**3.2**	**(25.0%)**	**1.5**	**+94.4%**	**12.8**	**12.8**	**-**	**-8.8**	**-40.8%**
Upfront payment		1.5	3.1	(25.0%)	1.5	+100.5%	12.4	12.4	-	-8.8	-41.5%
Satisfaction of Quid Rights *		0.1	0.1	(25.0%)	-	-	0.4	0.4	-	-	-
Edoxaban	anticoagulant	**91.1**	**90.7**	**(27.4%)**	**-0.4**	**-0.4%**	**325.4**	**330.6**	**5.2**	**-37.1**	**-10.1%**
Lixiana (JPN)		37.7	33.0	(28.4%)	-4.6	-12.2%	114.0	116.3	2.2	-25.5	-18.0%
Savaysa (US)		0.4	0.3	(22.3%)	-0.0	-7.0%	1.5	1.5	0.0	0.0	+3.4%
Lixiana (EU)		45.7	49.2	(26.8%)	3.5	+7.7%	175.5	183.4	7.9	-9.6	-5.0%
Edoxaban (ASCA etc.)		7.3	8.1	(27.5%)	0.8	+10.3%	34.4	29.4	-4.9	-2.1	-6.5%

* "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

4. Revenue by Business Units and Products (1)

JPY Bn		FY2025 Q1 YTD	FY2026 Q1 YTD				FY2026				
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of May.)	Forecast (as of Jul.)	vs. Forecast (as of May.)	YoY	YoY (%)
Japan Business Unit		**125.0**	**120.0**	**(27.9%)**	**-4.9**	**-3.9%**	**425.0**	**430.4**	**5.5**	**-55.4**	**-11.4%**
Lixiana	anticoagulant	37.7	33.0	(28.4%)	-4.6	-12.2%	114.0	116.3	2.2	-25.5	-18.0%
Tarlige	pain treatment	16.5	19.5	(26.0%)	3.0	+18.1%	73.8	75.0	1.2	9.6	+14.7%
Pralia	Treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	12.4	12.9	(27.5%)	0.5	+4.1%	46.0	46.9	0.9	1.2	+2.5%
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	8.4	11.9	(25.5%)	3.5	+41.9%	45.0	46.4	1.4	8.8	+23.3%
Belsomra	Anti-Insomnia Treatment	5.1	4.6	(29.1%)	-0.5	-10.3%	17.8	15.8	-2.0	-2.8	-15.1%
Canalia	type 2 diabetes mellitus treatment	3.9	3.7	(26.7%)	-0.2	-5.4%	13.9	13.9	-	-0.6	-4.4%
Minnebro	antihypertensive agent	2.8	3.4	(25.0%)	0.7	+24.6%	13.8	13.8	0.1	2.7	+24.7%
Ranmark	treatment for bone complications caused by bone metastases from tumors	5.1	5.1	(37.1%)	0.1	+1.3%	13.3	13.9	0.5	-5.6	-28.8%
Datroway	anti-cancer agent (TROP2-directed antibody drug conjugate)	2.2	3.8	(28.6%)	1.6	+74.2%	13.1	13.1	-	0.0	+0.1%
Loxonin	anti-inflammatory analgesic	2.9	3.3	(25.7%)	0.4	+13.2%	12.8	12.8	-	1.0	+8.1%
Emgality	prophylaxis of migraine attacks	3.0	3.5	(27.2%)	0.5	+15.0%	12.4	12.8	0.4	0.0	+0.3%
Inavir	anti-influenza treatment	-	0.0	(0.1%)	0.0	-	6.0	6.0	-	4.5	+279.6%
Vaccines business		0.3	0.4	(3.4%)	0.1	+48.1%	11.8	11.8	-	5.0	+73.4%
Daiichi Sankyo Healthcare Unit		**20.9**	**22.6**	**(23.1%)**	**1.6**	**+7.9%**	**98.1**	**97.8**	**-0.3**	**7.0**	**+7.8%**

4. Revenue by Business Units and Products (2)

JPY Bn		FY2025 Q1 YTD Results	FY2026 Q1 YTD Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of May.)	Forecast (as of Jul.)	vs. Forecast (as of May.)	FY2026 YoY	YoY (%)
Oncology Business Unit		**131.2**	**197.4**	**(23.7%)**	**66.2**	**+50.5%**	**783.5**	**833.8**	**50.3**	**225.0**	**+36.9%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	124.6	176.9	(24.7%)	52.3	+42.0%	670.4	715.6	45.1	154.5	+27.5%
Enhertu (US)		85.1	125.1	(24.7%)	40.0	+47.0%	466.3	505.6	39.4	119.4	+30.9%
Enhertu (EU)		39.5	51.8	(24.7%)	12.3	+31.2%	204.2	209.9	5.8	35.1	+20.1%
Datroway	anti-cancer agent (TROP2-directed antibody drug conjugate)	3.1	16.6	(16.8%)	13.4	+427.6%	94.5	98.9	4.4	64.5	+187.3%
Datroway (US)		3.1	16.1	(16.6%)	13.0	+417.4%	92.2	97.1	4.9	63.9	+192.1%
Datroway (EU)		0.0	0.4	(23.3%)	0.4	-	2.3	1.8	-0.5	0.6	+51.6%
Ifinatamab deruxtecan (US)	anti-cancer agent (B7-H3-directed antibody drug conjugate)	-	-	-	-	-	3.1	3.3	0.1	3.3	-
Turalio	anti-cancer agent	1.6	1.0	(43.2%)	-0.6	-36.2%	2.3	2.4	0.1	-2.8	-53.5%
Vanflyta	anti-cancer agent (FLT3 Inhibitor)	1.9	2.9	(21.6%)	1.1	+58.2%	13.1	13.6	0.5	5.5	+67.2%
American Regent Unit		**49.3**	**42.2**	**(29.5%)**	**-7.1**	**-14.3%**	**139.1**	**142.9**	**3.8**	**-39.3**	**-21.6%**
Injectafer	treatment for iron deficiency anemia	11.8	11.7	(35.5%)	-0.2	-1.6%	33.3	32.8	-0.5	-11.1	-25.3%
Venofer	treatment for iron deficiency anemia	13.1	6.9	(26.3%)	-6.1	-46.9%	25.1	26.4	1.4	-17.4	-39.7%
GE injectables		21.0	18.7	(28.0%)	-2.3	-11.0%	64.5	66.7	2.3	-13.7	-17.0%
EU Specialty Business Unit		**63.8**	**74.7**	**(26.0%)**	**10.9**	**+17.1%**	**276.4**	**287.4**	**11.0**	**10.9**	**+3.9%**
Lixiana	anticoagulant	45.7	49.2	(26.8%)	3.5	+7.7%	175.5	183.4	7.9	-9.6	-5.0%
Nilemdo/Nustendi	cholesterol-lowering agent	12.6	20.0	(22.7%)	7.4	+58.8%	86.5	88.0	1.6	25.4	+40.5%
Olmesartan	antihypertensive agent	5.0	5.0	(35.9%)	-0.1	-1.3%	12.3	13.8	1.6	-4.5	-24.6%
ASCA Business Unit		**56.8**	**68.7**	**(24.6%)**	**11.9**	**+21.0%**	**292.8**	**279.0**	**-13.9**	**28.0**	**+11.1%**
Daiichi Sankyo China		21.8	23.1	(24.9%)	1.3	+5.8%	99.8	92.7	-7.1	5.2	+6.0%
Daiichi Sankyo Korea		8.4	7.7	(24.5%)	-0.7	-8.9%	33.1	31.3	-1.8	-3.4	-9.9%
Daiichi Sankyo Brasil Farmacêutica		11.6	16.8	(24.9%)	5.2	+45.0%	70.2	67.4	-2.8	7.4	+12.4%
Daiichi Sankyo Taiwan		5.2	5.3	(25.7%)	0.0	+0.9%	21.3	20.5	-0.8	-0.8	-4.0%

4. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

		FY2025 Q1 YTD	FY2026 Q1 YTD				FY2026				
		Results	Results	(vs. Forecast (%))	YoY	YoY (%)	Forecast (as of May.)	Forecast (as of Jul.)	vs. Forecast (as of May.)	YoY	YoY (%)
USD Mn											
Oncology Business Unit		**907**	**1,238**	**(23.2%)**	**330**	**+36.4%**	**5,223**	**5,341**	**118**	**1,303**	**+32.3%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	862	1,109	(24.2%)	248	+28.7%	4,470	4,583	114	862	+23.2%
Enhertu (US)		588	784	(24.2%)	196	+33.3%	3,108	3,239	130	677	+26.4%
Enhertu (EU)		273	325	(24.2%)	52	+18.9%	1,361	1,345	-16	185	+16.0%
Datroway	anti-cancer agent (TROP2-directed antibody drug conjugate)	22	104	(16.4%)	82	+378.3%	630	634	4	405	+177.4%
Datroway (US)		22	101	(16.3%)	80	+369.1%	615	622	7	402	+182.1%
Datroway (EU)		0	3	(22.9%)	3	-	15	12	-4	4	+46.4%
Ifinatamab deruxtecan (US)	anti-cancer agent (B7-H3-directed antibody drug conjugate)	-	-	-	-	-	21	21	-	21	-
Turalio	anti-cancer agent	11	7	(42.3%)	-5	-42.2%	15	15	0	-19	-55.1%
Vanflyta	anti-cancer agent (FLT3 Inhibitor)	13	18	(21.1%)	6	+43.5%	87	87	0	33	+61.5%
USD Mn											
American Regent Unit		**341**	**265**	**(28.9%)**	**-76**	**-22.3%**	**927**	**915**	**-12**	**-293**	**-24.3%**
Injectafer	treatment for iron deficiency anemia	82	73	(34.8%)	-9	-10.8%	222	210	-12	-81	-27.9%
Venofer	treatment for iron deficiency anemia	90	44	(25.7%)	-47	-51.8%	167	169	2	-121	-41.8%
GE injectables		145	117	(27.4%)	-28	-19.3%	430	428	-2	-106	-19.9%
EUR Mn											
EU Specialty Business Unit		**390**	**403**	**(25.4%)**	**13**	**+3.4%**	**1,535**	**1,585**	**49**	**3**	**+0.2%**
Lixiana	anticoagulant	279	266	(26.3%)	-13	-4.8%	975	1,011	36	-93	-8.4%
Nilemdo/Nustendi	cholesterol-lowering agent	77	108	(22.2%)	31	+40.3%	480	485	5	127	+35.4%
Olmesartan	antihypertensive agent	31	27	(35.1%)	-4	-12.8%	68	76	8	-29	-27.4%

5. Consolidated Statement of Financial Position

<Assets> JPY Bn

	Mar. 2026	Jun. 2026	vs. Mar. 2026
Assets			
Current assets			
Cash and cash equivalents	449.8	637.9	188.0
Trade and other receivables	741.1	676.9	-64.2
Other financial assets	104.7	32.5	-72.2
Inventories	692.4	733.1	40.7
Other current assets	32.3	35.5	3.2
Subtotal	2,020.3	2,115.9	95.5
Assets held for sale	122.2	118.6	-3.6
Total current assets	**2,142.5**	**2,234.4**	**91.9**
Non-current assets			
Property, plant and equipment	596.6	626.1	29.6
Goodwill	97.4	98.4	1.0
Intangible assets	241.1	242.1	1.0
Investments accounted for using the equity method	4.9	4.6	-0.3
Other financial assets	194.4	204.3	9.9
Long-term advance payments	192.9	189.3	-3.6
Deferred tax assets	456.2	449.7	-6.5
Other non-current assets	70.3	65.6	-4.7
Total non-current assets	**1,853.8**	**1,880.1**	**26.3**
Total assets	**3,996.3**	**4,114.5**	**118.3**

*	Liquidity on hand (Cash, Securities, Investment securities etc.)	551.3	666.1	114.8
	Debt with interest	350.1	550.2	200.1
	Net Cash	201.2	115.9	-85.3

Acquisition +36.9, Depreciation -14.5, Forex +4.4

Forex +1.0

Acquisition +5.5, Depreciation -6.9, Forex +1.7

<Liabilities and equity> JPY Bn

	Mar. 2026	Jun. 2026	vs. Mar. 2026
Liabilities			
Current liabilities			
Trade and other payables	567.9	539.1	-28.8
Bonds and borrowings	0.4	0.5	0.1
Other financial liabilities	13.6	13.9	0.2
Income taxes payable	88.3	16.9	-71.4
Provisions	49.8	65.9	16.1
Contract liabilities	74.4	76.2	1.8
Other current liabilities	30.1	28.1	-2.0
Subtotal	824.5	740.5	-84.0
Liabilities directly associated with assets held for sale	31.6	25.2	-6.3
Total current liabilities	**856.1**	**765.7**	**-90.4**
Non-current liabilities			
Bonds and borrowings	300.1	500.0	199.9
Other financial liabilities	39.2	39.2	-0.0
Post employment benefit liabilities	1.5	1.6	0.2
Provisions	164.6	164.4	-0.2
Contract liabilities	806.8	799.7	-7.1
Deferred tax liabilities	3.2	3.2	-0.0
Other non-current liabilities	140.8	138.0	-2.8
Total non-current liabilities	**1,456.2**	**1,646.1**	**189.9**
Total liabilities	**2,312.3**	**2,411.8**	**99.6**
Equity			
Equity attributable to owners of the Company			
Share capital	50.0	50.0	-
Own shares	-248.0	-144.3	103.7
Other components of equity	311.6	330.6	19.0
Retained earnings	1,570.4	1,466.4	-104.0
Total equity attributable to owners of the Company	1,684.0	1,702.7	18.7
Total equity	**1,684.0**	**1,702.7**	**18.7**
Total liabilities and equity	**3,996.3**	**4,114.5**	**118.3**

Provision for EUSBU restructuring expenses +24.0,
Provision for losses related to cancellation of Odawara site investment -7.3

Syndicated loan +200.0

Deferred revenue for Enhertu +6.2
(Strategic collaboration upfront payment -2.5, Regulatory milestone payment/Quid +8.7)
Deferred revenue for Datroway -1.7
(Strategic collaboration upfront payment -1.6, Regulatory milestone payment -0.1)
Deferred revenue for US MRK alliance -10.0

Cancellation of own shares +100.7

Currency translation difference +17.1, Valuation difference on financial assets +1.9

Profit for the period +68.6, Payment of dividends -71.2, Cancellation of own shares -100.7

6. Consolidated Statement of Cash Flows

JPY Bn

	FY2025Q1	FY2026Q1	YoY
Cash flows from operating activities			
Profit before tax	105.4	91.3	-14.1
Depreciation and amortization	17.8	21.5	3.7
(Increase) decrease in receivables and payables	-51.0	32.8	83.8
Others, net	-54.1	-32.8	21.4
Income taxes paid	-54.6	-92.5	-37.9
Net cash flows from operating activities	**-36.6**	**20.3**	**56.9**
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	28.6	73.3	44.7
(Acquisition of) proceeds from sales of fixed assets	-36.1	-42.9	-6.7
Proceeds from sale of subsidiaries and affiliates	7.3	-	-7.3
Net (increase) decrease in investment securities	0.0	-1.7	-1.7
Others, net	-0.6	-0.3	0.3
Net cash flows from investing activities	**-0.8**	**28.4**	**29.2**
Cash flows from financing activities			
Net (increase) decrease in borrowings	99.9	199.9	100.0
Purchase of treasury shares	-58.5	-0.0	58.5
Dividends paid	-56.1	-71.2	-15.1
Others, net	-4.4	-6.2	-1.8
Net cash flows from financing activities	**-19.2**	**122.5**	**141.6**
Net increase (decrease) in cash and cash equivalents	**-56.5**	**-168.5**	**-111.9**
Cash and cash equivalents at the beginning of the period (Amount on Consolidated Statement of Financial Position)	**639.8**	**449.8**	**-190.0**
Transfer from Assets held for sale	**-**	**39.2**	**39.2**
Cash and cash equivalents at the beginning of the period	**639.8**	**489.0**	**-150.9**
Effect of exchange rate changes on cash and cash equivalents	**-9.0**	**9.6**	**18.6**
Cash and cash equivalents at the end of the period	**574.3**	**669.8**	**95.5**
Transfer to Assets held for sale	**-**	**-31.9**	**-31.9**
Cash and cash equivalents at the end of the period (Amount on Consolidated Statement of Financial Position)	**574.3**	**637.9**	**63.6**

*	**Free cash flows** (Cash flows from operating activities and investing activities)	**-37.4**	**48.8**	**86.1**

7. Number of Employees

	Jun. 2025 Results	Mar. 2026 Results	Jun. 2026 Results
Consolidated	20,102	20,171	20,468
Japan	9,530	9,531	9,805
North America	4,118	4,098	4,118
Europe	3,413	3,468	3,449
Others	3,041	3,074	3,096

8. Capital Expenditure, Depreciation and Amortization

JPY Bn	FY2025 Q1 YTD Results	FY2025 Results	FY2026 Q1 YTD Results	FY2026 Forecast
Capital expenditure	27.8	135.4	33.8	200.0
Depreciation and amortization	17.8	77.5	21.5	83.3
Property, plant and equipment	12.5	54.1	14.6	60.1
Intangible assets	5.3	23.3	6.9	23.2

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		
Enhertu	trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	2020	Daiichi Sankyo		
Belsomra	suvorexant	Anti-Insomnia treatment	2014	MSD		
Canalia	teneligliptin / canagliflozin	type 2 diabetes mellitus treatment	2017	Tanabe Pharma	Tanabe Pharma	Co-promotion
Minnebro	esaxerenone	antihypertensive agent	2019	Daiichi Sankyo		
Ranmark	denosumab	treatment for bone complications caused by bone metastases from tumors	2012	Amgen		
Datroway	datopotamab deruxtecan	anti-cancer agent (TROP2-directed antibody drug conjugate)	2025	Daiichi Sankyo		
Loxonin	loxoprofen	anti-inflammatory analgesic	1986	Daiichi Sankyo		
Loxonin Poultice			2006	Lead Chemical		
Loxonin Tape			2008	Lead Chemical		
Loxonin Gel			2010	Daiichi Sankyo		
Emgality	galcanezumab-gnlm	Prophylaxis of migraine attacks	2021	Eli Lilly Japan	Eli Lilly Japan	Co-promotion
Inavir	laninamivir octanoate	anti-influenza treatment	2010	Daiichi Sankyo		
Oncology Business Unit						
Enhertu	trastuzumab deruxtecan	anti-cancer agent (HER2-directed antibody drug conjugate)	2020	Daiichi Sankyo	AstraZeneca	Co-promotion
Datroway	datopotamab deruxtecan	anti-cancer agent (TROP2-directed antibody drug conjugate)	2025	Daiichi Sankyo	AstraZeneca	Co-promotion
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		
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	FY2025 Q1 Results	FY2025 Q2 Results	FY2025 Q3 Results	FY2025 Q4 Results	FY2025 to revenue	FY2025 Results	FY2026 Q1 Results	FY2026 Q2 Results	FY2026 Q3 Results	FY2026 Q4 Results	FY2026 to revenue	FY2026 Results	FY2026 YoY	FY2026 YoY (%)
Revenue	**474.6**	**500.8**	**558.1**	**589.6**	***100.0%***	**2,123.0**	**574.7**	**-**	**-**	**-**	***100.0%***	**574.7**	**100.1**	**+21.1%**
Cost of sales	87.6	151.1	111.9	259.8	*28.7%*	610.3	126.0	-	-	-	*21.9%*	126.0	38.5	+43.9%
CMO compensation fee	-	21.0	-	148.5	*8.0%*	169.5	1.0	-	-	-	*0.2%*	1.0	1.0	-
Other Cost of sales	87.6	130.1	111.9	111.3	*20.8%*	440.8	125.0	-	-	-	*21.8%*	125.0	37.5	+42.8%
Gross Profit	387.0	349.6	446.2	329.8	*71.3%*	1,512.7	448.7	-	-	-	*78.1%*	448.7	61.7	+15.9%
SG&A expenses	180.1	189.1	228.2	142.4	*34.8%*	739.7	226.0	-	-	-	*39.3%*	226.0	45.9	+25.5%
DXd ADC profit share	60.6	72.6	90.0	82.4	*14.4%*	305.6	96.9	-	-	-	*16.9%*	96.9	36.3	+60.0%
Other SG&A expenses	119.5	116.5	138.2	60.0	*20.5%*	434.2	129.1	-	-	-	*22.5%*	129.1	9.6	+8.0%
R&D expenses	106.0	110.9	122.1	122.7	*21.7%*	461.6	115.5	-	-	-	*20.1%*	115.5	9.5	+9.0%
Core Operating Profit	**101.0**	**49.7**	**96.0**	**64.7**	***14.7%***	**311.3**	**107.3**	**-**	**-**	**-**	***18.7%***	**107.3**	**6.3**	**+6.2%**
Non-core income	0.8	3.6	0.0	17.7		22.1	0.1	-	-	-		0.1	-0.7	
Non-core expenses	5.1	5.7	6.5	58.1		75.4	22.2	-	-	-		22.2	17.2	
Operating Profit	**96.7**	**47.5**	**89.5**	**24.3**	***12.2%***	**258.0**	**85.1**	**-**	**-**	**-**	***14.8%***	**85.1**	**-11.6**	**-12.0%**
Financial income/expenses	8.4	9.8	16.9	-2.3		32.8	6.5	-	-	-		6.5	-1.9	
Share of profit or loss of investments accounted for using the equity method	0.4	0.4	0.3	0.5		1.5	-0.3	-	-	-		-0.3	-0.6	
Profit before tax	**105.4**	**57.8**	**106.7**	**22.4**	***13.8%***	**292.4**	**91.3**	**-**	**-**	**-**	***15.9%***	**91.3**	**-14.1**	**-13.4%**
Income taxes	19.9	12.5	20.1	-39.8		12.7	22.7	-	-	-		22.7	2.8	
Profit for the year	**85.5**	**45.3**	**86.6**	**62.3**	***13.2%***	**279.7**	**68.6**	**-**	**-**	**-**	***11.9%***	**68.6**	**-16.9**	**-19.7%**
Profit attributable to owners of the Company	**85.5**	**45.3**	**86.6**	**62.3**	***13.2%***	**279.7**	**68.6**	**-**	**-**	**-**	***11.9%***	**68.6**	**-16.9**	**-19.7%**
Tax rate	18.9%	21.6%	18.8%	-177.5%		4.3%	24.9%					24.9%		
Overseas sales ratio	69.2%	70.7%	70.6%	79.1%		72.7%	74.6%					74.6%		
Currency Rate (YTD Average)														
USD/JPY	144.60	146.04	148.75	150.78		150.78	159.49					159.49		
EUR/JPY	163.81	168.06	171.84	174.79		174.79	185.38					185.38		

2. Revenue of Global Products (1)

JPY Bn	FY2025 Q1 Results	FY2025 Q2 Results	FY2025 Q3 Results	FY2025 Q4 Results	FY2025 Results	FY2026 Q1 Results	FY2026 Q2 Results	FY2026 Q3 Results	FY2026 Q4 Results	FY2026 Results
Trastuzumab deruxtecan	**161.0**	**169.2**	**205.2**	**284.1**	**819.5**	**239.8**	**-**	**-**	**-**	**239.8**
Product sales	155.2	163.2	188.4	191.6	698.4	219.2	-	-	-	219.2
Enhertu(JPN)	8.4	9.6	10.6	9.2	37.7	11.9	-	-	-	11.9
Enhertu (US)	85.1	89.4	109.0	102.7	386.3	125.1	-	-	-	125.1
Enhertu (EU)	39.5	42.1	42.0	51.1	174.8	51.8	-	-	-	51.8
Enhertu (ASCA: Asia, South and Central America)	22.3	22.1	26.8	28.5	99.7	30.4	-	-	-	30.4
Brazil	8.1	8.6	10.9	10.4	38.0	10.5	-	-	-	10.5
China (co-promotion revenue)	4.5	4.8	4.9	5.9	20.0	5.8	-	-	-	5.8
Others	9.7	8.7	11.0	12.2	41.7	14.1	-	-	-	14.1
Upfront payment	2.6	2.6	2.6	2.6	10.2	2.6	-	-	-	2.6
Regulatory milestone payment	3.0	3.2	13.9	3.7	23.8	17.8	-	-	-	17.8
US HER2+ Breast Cancer 3L	0.2	0.2	0.2	0.2	0.9	0.2	-	-	-	0.2
EU HER2+ Breast Cancer 3L	0.1	0.1	0.1	0.1	0.5	0.1	-	-	-	0.1
US HER2+ Gastric Cancer 2L/3L	0.2	0.2	0.2	0.2	0.8	0.2	-	-	-	0.2
US HER2+ Breast Cancer 2L	0.2	0.2	0.2	0.2	0.9	0.2	-	-	-	0.2
EU HER2+ Breast Cancer 2L	0.2	0.2	0.2	0.2	0.7	0.2	-	-	-	0.2
US HER2-low Breast Cancer (post chemo)	0.5	0.5	0.5	0.5	1.9	0.5	-	-	-	0.5
EU HER2-low Breast Cancer (post chemo)	0.3	0.3	0.3	0.3	1.4	0.3	-	-	-	0.3
EU HER2+ Gastric Cancer 2L	0.1	0.1	0.1	0.1	0.3	0.1	-	-	-	0.1
US HER2 Mutant NSCLC 2L	0.3	0.3	0.3	0.3	1.2	0.3	-	-	-	0.3
EU HER2 Mutant NSCLC 2L	0.2	0.2	0.2	0.2	0.8	0.2	-	-	-	0.2
US HER2-low Breast Cancer (pre chemo)	0.4	0.4	0.4	0.4	1.8	0.4	-	-	-	0.4
EU HER2-low Breast Cancer (pre chemo)	0.1	0.3	0.3	0.3	1.1	0.3	-	-	-	0.3
US HER2+ Solid Tumors	0.1	0.1	0.1	0.1	0.3	0.1	-	-	-	0.1
US HER2+ Breast Cancer 1L	-	-	10.7	0.5	11.3	0.4	-	-	-	0.4
US HER2+ Breast Cancer Neoaduvant	-	-	-	-	-	2.4	-	-	-	2.4
US HER2+ Breast Cancer Adjuvant	-	-	-	-	-	9.8	-	-	-	9.8
EU HER2+ Solid Tumors	-	-	-	-	-	2.0	-	-	-	2.0
Quid related payment	0.3	0.3	0.3	0.3	1.2	0.3	-	-	-	0.3
Sales milestone payment	-	-	-	86.0	86.0	-	-	-	-	-

2. Revenue of Global Products (2)

JPY Bn	FY2025 Q1 Results	FY2025 Q2 Results	FY2025 Q3 Results	FY2025 Q4 Results	FY2025 Results	FY2026 Q1 Results	FY2026 Q2 Results	FY2026 Q3 Results	FY2026 Q4 Results	FY2026 Results
Datopotamab deruxtecan	**8.7**	**12.1**	**17.6**	**17.7**	**56.1**	**23.9**	**-**	**-**	**-**	**23.9**
Product sales	5.3	10.4	15.9	16.0	47.6	20.6	-	-	-	20.6
Datroway (JPN)	2.2	3.5	4.1	3.4	13.1	3.8	-	-	-	3.8
Datroway (US)	3.1	6.6	11.4	12.1	33.2	16.1	-	-	-	16.1
Datroway (EU)	0.0	0.4	0.4	0.4	1.2	0.4	-	-	-	0.4
Datroway (ASCA: Asia, South and Central America)	-	0.0	0.0	0.0	0.1	0.3	-	-	-	0.3
Upfront payment	1.6	1.6	1.6	1.6	6.4	1.6	-	-	-	1.6
Regulatory milestone payment	1.8	0.1	0.1	0.1	2.1	1.7	-	-	-	1.7
US EGFR mutatad NSCLC 3L	1.8	0.1	0.1	0.1	2.1	0.1	-	-	-	0.1
US TNBC	-	-	-	-	-	1.6	-	-	-	1.6
Patritumab deruxtecan	**4.1**	**3.0**	**3.0**	**3.0**	**13.1**	**3.0**	**-**	**-**	**-**	**3.0**
Upfront payment	3.9	2.9	2.9	2.9	12.7	2.9	-	-	-	2.9
Satisfaction of Quid Rights	0.1	0.1	0.1	0.1	0.4	0.1	-	-	-	0.1
Ifinatamab deruxtecan	**3.8**	**3.8**	**3.8**	**3.8**	**15.1**	**3.8**	**-**	**-**	**-**	**3.8**
Product sales	-	-	-	-	-	-	-	-	-	-
Ifinatamab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Upfront payment	3.7	3.7	3.7	3.7	14.7	3.7	-	-	-	3.7
Satisfaction of Quid Rights	0.1	0.1	0.1	0.1	0.5	0.1	-	-	-	0.1
Raludotatug deruxtecan	**1.6**	**1.6**	**15.1**	**3.2**	**21.5**	**3.2**	**-**	**-**	**-**	**3.2**
Upfront payment	1.5	1.5	15.0	3.1	21.1	3.1	-	-	-	3.1
Satisfaction of Quid Rights	0.1	0.1	0.1	0.1	0.4	0.1	-	-	-	0.1
Edoxaban	**91.1**	**94.9**	**92.2**	**89.5**	**367.7**	**90.7**	**-**	**-**	**-**	**90.7**
Lixiana (JPN)	37.7	35.6	38.9	29.6	141.8	33.0	-	-	-	33.0
Savaysa (US)	0.4	0.3	0.4	0.3	1.4	0.3	-	-	-	0.3
Lixiana (EU)	45.7	51.1	44.3	51.9	193.0	49.2	-	-	-	49.2
Edoxaban (ASCA etc.)	7.3	7.9	8.6	7.6	31.5	8.1	-	-	-	8.1

3. Revenue by Business Units and Products (1)

JPY Bn	FY2025 Q1 Results	FY2025 Q2 Results	FY2025 Q3 Results	FY2025 Q4 Results	FY2025 Results	FY2026 Q1 Results	FY2026 Q2 Results	FY2026 Q3 Results	FY2026 Q4 Results	FY2026 Results
Japan Business Unit	**125.0**	**124.9**	**140.9**	**95.0**	**485.8**	**120.0**	**-**	**-**	**-**	**120.0**
Lixiana	37.7	35.6	38.9	29.6	141.8	33.0	-	-	-	33.0
Tarlige	16.5	15.6	18.1	15.1	65.4	19.5	-	-	-	19.5
Pralia	12.4	10.2	12.9	10.2	45.8	12.9	-	-	-	12.9
Enhertu	8.4	9.6	10.6	9.2	37.7	11.9	-	-	-	11.9
Belsomra	5.1	4.6	5.1	3.8	18.6	4.6	-	-	-	4.6
Canalia	3.9	3.8	3.8	3.0	14.5	3.7	-	-	-	3.7
Minnebro	2.8	2.5	3.1	2.7	11.1	3.4	-	-	-	3.4
Ranmark	5.1	4.9	5.2	4.3	19.5	5.1	-	-	-	5.1
Datroway	2.2	3.5	4.1	3.4	13.1	3.8	-	-	-	3.8
Loxonin	2.9	3.0	3.5	2.5	11.9	3.3	-	-	-	3.3
Emgality	3.0	3.3	3.5	3.0	12.8	3.5	-	-	-	3.5
Inavir	-	0.0	1.4	0.2	1.6	0.0	-	-	-	0.0
Vaccines business	0.3	6.3	4.7	-4.5	6.8	0.4	-	-	-	0.4
Daiichi Sankyo Healthcare Unit	**20.9**	**25.0**	**24.6**	**20.2**	**90.7**	**22.6**	**-**	**-**	**-**	**22.6**

3. Revenue by Business Units and Products (2)

JPY Bn	FY2025 Q1 Results	FY2025 Q2 Results	FY2025 Q3 Results	FY2025 Q4 Results	FY2025 Results	FY2026 Q1 Results	FY2026 Q2 Results	FY2026 Q3 Results	FY2026 Q4 Results	FY2026 Results
Oncology Business Unit	**131.2**	**141.8**	**166.2**	**169.6**	**608.8**	**197.4**	**-**	**-**	**-**	**197.4**
Enhertu	124.6	131.5	151.1	153.9	561.1	176.9	-	-	-	176.9
Enhertu (US)	85.1	89.4	109.0	102.7	386.3	125.1	-	-	-	125.1
Enhertu (EU)	39.5	42.1	42.0	51.1	174.8	51.8	-	-	-	51.8
Datroway	3.1	7.0	11.8	12.5	34.4	16.6	-	-	-	16.6
Datroway (US)	3.1	6.6	11.4	12.1	33.2	16.1	-	-	-	16.1
Datroway (EU)	0.0	0.4	0.4	0.4	1.2	0.4	-	-	-	0.4
Ifinatamab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Turalio	1.6	1.3	1.2	1.0	5.2	1.0	-	-	-	1.0
Vanflyta	1.9	1.9	2.2	2.2	8.2	2.9	-	-	-	2.9
American Regent Unit	**49.3**	**47.5**	**45.2**	**40.3**	**182.2**	**42.2**	**-**	**-**	**-**	**42.2**
Injectafer	11.8	10.8	10.2	11.1	43.9	11.7	-	-	-	11.7
Venofer	13.1	13.8	9.2	7.8	43.8	6.9	-	-	-	6.9
GE injectables	21.0	19.9	21.7	17.9	80.4	18.7	-	-	-	18.7
EU Specialty Business Unit	**63.8**	**73.0**	**63.3**	**76.4**	**276.6**	**74.7**	**-**	**-**	**-**	**74.7**
Lixiana	45.7	51.1	44.3	51.9	193.0	49.2	-	-	-	49.2
Nilemdo/Nustendi	12.6	16.0	14.7	19.4	62.7	20.0	-	-	-	20.0
Olmesartan	5.0	5.3	3.8	4.2	18.3	5.0	-	-	-	5.0
ASCA Business Unit	**56.8**	**61.1**	**69.3**	**63.8**	**251.0**	**68.7**	**-**	**-**	**-**	**68.7**
Daiichi Sankyo China	21.8	21.2	24.5	19.9	87.5	23.1	-	-	-	23.1
Daiichi Sankyo Korea	8.4	9.4	8.9	8.0	34.7	7.7	-	-	-	7.7
Daiichi Sankyo Brasil Farmacêutica	11.6	13.9	18.2	16.3	60.0	16.8	-	-	-	16.8
Daiichi Sankyo Taiwan	5.2	5.6	5.6	4.9	21.3	5.3	-	-	-	5.3

3. Revenue by Business Units and Products (3) [Reference] Revenue in Local Currency	FY2025 Q1 Results	FY2025 Q2 Results	FY2025 Q3 Results	FY2025 Q4 Results	FY2025 Results	FY2026 Q1 Results	FY2026 Q2 Results	FY2026 Q3 Results	FY2026 Q4 Results	FY2026 Results
USD Mn										
Oncology Business Unit	**907**	**962**	**1,084**	**1,085**	**4,038**	**1,238**	**-**	**-**	**-**	**1,238**
Enhertu	862	892	984	984	3,721	1,109	-	-	-	1,109
Enhertu (US)	588	606	711	656	2,562	784	-	-	-	784
Enhertu (EU)	273	286	272	328	1,159	325	-	-	-	325
Datroway	22	48	78	81	228	104	-	-	-	104
Datroway (US)	22	45	75	78	220	101	-	-	-	101
Datroway (EU)	0	2	3	3	8	3	-	-	-	3
Ifinatamab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Turalio	11	9	8	6	34	7	-	-	-	7
Vanflyta	13	13	14	14	54	18	-	-	-	18
USD Mn										
American Regent Unit	**341**	**322**	**292**	**254**	**1,208**	**265**	**-**	**-**	**-**	**265**
Injectafer	82	73	66	71	291	73	-	-	-	73
Venofer	90	93	59	48	291	44	-	-	-	44
GE injectables	145	135	141	113	533	117	-	-	-	117
EUR Mn										
EU Specialty Business Unit	**390**	**424**	**351**	**418**	**1,582**	**403**	**-**	**-**	**-**	**403**
Lixiana	279	297	245	283	1,104	266	-	-	-	266
Nilemdo/Nustendi	77	93	82	107	358	108	-	-	-	108
Olmesartan	31	30	21	23	105	27	-	-	-	27

<11. Historical Data>

1. Revenue of Global Products (1)

JPY Bn	FY2021 Results	FY2022 Results	FY2023 Results	FY2024 Results	FY2025 Results
Trastuzumab deruxtecan	**80.8**	**258.4**	**449.2**	**651.4**	**819.5**
Product sales	65.4	207.5	395.9	552.8	698.4
Enhertu (JPN)	9.6	11.7	23.9	31.0	37.7
Enhertu (US)	45.4	144.6	225.5	302.0	386.3
Enhertu (EU)	9.0	37.1	101.9	149.6	174.8
Enhertu (ASCA: Asia, South and Central America)	1.4	14.2	44.6	70.3	99.7
Brazil	0.4	9.7	23.5	31.3	38.0
China (co-promotion revenue)	-	-	6.5	10.3	20.0
Others	0.9	4.5	14.6	28.7	41.7
Upfront payment	9.8	9.8	10.1	10.2	10.2
Regulatory milestone payment	2.2	26.7	12.4	29.2	23.8
US HER2+ Breast Cancer 3L	0.9	0.9	0.9	0.9	0.9
EU HER2+ Breast Cancer 3L	0.5	0.5	0.5	0.5	0.5
US HER2+ Gastric Cancer 2L/3L	0.8	0.8	0.8	0.8	0.8
US HER2+ Breast Cancer 2L	-	3.5	0.9	0.9	0.9
EU HER2+ Breast Cancer 2L	-	2.7	0.7	0.7	0.7
US HER2-low Breast Cancer (post chemo)	-	7.3	1.9	1.9	1.9
EU HER2-low Breast Cancer (post chemo)	-	5.2	1.3	1.4	1.4
EU HER2+ Gastric Cancer 2L	-	1.3	0.3	0.3	0.3
US HER2 Mutant NSCLC 2L	-	4.6	1.2	1.2	1.2
EU HER2 Mutant NSCLC 2L	-	-	3.8	0.8	0.8
US HER2-low Breast Cancer (pre chemo)	-	-	-	10.6	1.8
EU HER2-low Breast Cancer (pre chemo)	-	-	-	7.6	1.1
US HER2+ Solid Tumors	-	-	-	1.6	0.3
US HER2+ Breast Cancer 1L	-	-	-	-	11.3
QUID related payment	3.4	1.1	1.2	1.2	1.2
Sales milestone payment	-	13.2	29.6	57.9	86.0

1. Revenue of Global Products (2)

JPY Bn	FY2020 Results	FY2021 Results	FY2022 Results	FY2023 Results	FY2024 Results
Datopotamab deruxtecan	**6.1**	**7.1**	**6.4**	**7.8**	**56.1**
Product sales	-	-	-	1.4	47.6
Datroway (JPN)	-	-	-	0.3	13.1
Datroway (US)	-	-	-	1.1	33.2
Datroway (EU)	-	-	-	-	1.2
Datroway (ASCA: Asia, South and Central America)	-	-	-	-	0.1
Upfront payment	6.1	7.1	6.4	6.4	6.4
Regulatory milestone payment	-	-	-	-	2.1
US EGFR mutatad NSCLC 3L	-	-	-	-	2.1
Patritumab deruxtecan	**-**	**-**	**3.5**	**19.8**	**13.1**
Upfront payment	-	-	3.5	19.0	12.7
Satisfaction of Quid Rights	-	-	-	0.7	0.4
Ifinatamab deruxtecan	**-**	**-**	**6.6**	**15.3**	**15.1**
Upfront payment	-	-	6.6	14.7	14.7
Satisfaction of Quid Rights	-	-	-	0.7	0.5
Raludotatug deruxtecan	**-**	**-**	**2.8**	**6.7**	**21.5**
Upfront payment	-	-	2.8	6.2	21.1
Satisfaction of Quid Rights	-	-	-	0.6	0.4
Edoxaban	**205.6**	**244.0**	**287.7**	**344.0**	**367.7**
Lixiana (JPN)	92.5	105.1	115.6	133.0	141.8
Savaysa (US)	1.9	3.0	2.4	3.6	1.4
Lixiana (EU)	96.9	117.1	146.2	179.0	193.0
Edoxaban (ASCA etc.)	14.3	18.7	23.5	28.3	31.5

2. Revenue by Business Units and Products (1)

JPY Bn	FY2021 Results	FY2022 Results	FY2023 Results	FY2024 Results	FY2025 Results
Japan Business Unit	**489.5**	**457.9**	**518.9**	**476.9**	**485.8**
Lixiana	92.5	105.1	115.6	133.0	141.8
Tarlige	30.1	38.5	45.7	55.6	65.4
Pralia	37.9	40.2	42.8	42.2	45.8
Enhertu	9.6	11.7	23.9	31.0	37.7
Belsomra	-	-	-	9.9	18.6
Canalia	16.8	16.3	15.9	15.6	14.5
Minnebro	5.0	6.9	8.3	9.6	11.1
Ranmark	20.4	20.4	20.4	20.1	19.5
Datroway	-	-	-	0.3	13.1
Loxonin	22.2	18.5	15.5	12.3	11.9
Emgality	4.6	6.3	7.6	10.7	12.8
Inavir	1.3	0.9	15.9	19.9	1.6
Vaccines business	14.8	13.4	27.7	8.2	6.8
Daiichi Sankyo Healthcare Unit	**64.7**	**70.3**	**76.0**	**86.7**	**90.7**

2. Revenue by Business Units and Products (2)

JPY Bn	FY2021 Results	FY2022 Results	FY2023 Results	FY2024 Results	FY2025 Results
Oncology Business Unit	**69.6**	**185.4**	**334.6**	**463.8**	**608.8**
Enhertu	54.4	181.6	327.4	451.6	561.1
Enhertu (US)	45.4	144.6	225.5	302.0	386.3
Enhertu (EU)	9.0	37.1	101.9	149.6	174.8
Datroway	-	-	-	1.1	34.4
Datroway (US)	-	-	-	1.1	33.2
Datroway (EU)	-	-	-	-	1.2
Turalio	2.8	3.8	5.3	6.6	5.2
Vanflyta	-	-	1.9	4.5	8.2
American Regent Unit	**149.5**	**187.4**	**203.4**	**217.2**	**182.2**
Injectafer	53.1	54.0	50.1	53.4	43.9
Venofer	33.8	51.3	60.9	62.0	43.8
GE injectables	54.7	71.6	81.0	89.0	80.4
EU Specialty Business Unit	**128.2**	**150.4**	**189.2**	**237.4**	**276.6**
Lixiana	96.9	117.1	146.2	179.0	193.0
Nilemdo/Nustendi	3.1	7.1	18.4	36.9	62.7
Olmesartan	20.3	20.0	19.6	18.3	18.3
ASCA Business Unit	**114.1**	**142.8**	**184.1**	**211.2**	**251.0**
Daiichi Sankyo China	53.3	58.3	70.5	72.4	87.5
Daiichi Sankyo Korea	23.2	25.6	29.2	33.0	34.7
Daiichi Sankyo Brasil Farmacêutica	13.7	27.8	42.0	50.6	60.0
Daiichi Sankyo Taiwan	10.0	13.3	16.0	18.0	21.3

2. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

	FY2021 Results	FY2022 Results	FY2023 Results	FY2024 Results	FY2025 Results
USD Mn					
Oncology Business Unit	**619**	**1,369**	**2,314**	**3,040**	**4,038**
Enhertu	484	1,341	2,264	2,960	3,721
Enhertu (US)	404	1,067	1,560	1,980	2,562
Enhertu (EU)	80	274	704	980	1,159
Datroway	-	-	-	7	228
Datroway (US)	-	-	-	7	220
Datroway (EU)	-	-	-	-	8
Turalio	25	28	37	43	34
Vanflyta	-	-	13	30	54
USD Mn					
American Regent Unit	**1,330**	**1,383**	**1,407**	**1,424**	**1,208**
Injectafer	472	398	346	350	291
Venofer	300	379	421	406	291
GE injectables	487	529	560	584	533
EUR Mn					
EU Specialty Business Unit	**982**	**1,067**	**1,207**	**1,450**	**1,582**
Lixiana	742	831	933	1,093	1,104
Nilemdo/Nustendi	24	50	118	225	358
Olmesartan	155	142	125	112	105

12. Major R&D Pipeline (Innovative Pharmaceuticals)

As of Jul 2026

◆ 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, AUC: area under the curve, 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, CNS: central nervous system, CPS: combined positive score, CR: complete response, CRC: colorectal cancer, CRR: complete response rate, CRL: complete response letter, CRPC: castration-resistant prostate cancer, ctDNA: circulating tumor DNA, DCIS: ductal carcinoma in situ, DCR: disease control rate, DDFS: distant disease-free survival, DFS: disease-free survival, DOCR: duration of complete response, DOR: duration of response, DPDRFS: distant progression or distant recurrence-free survival, DRFI: distant recurrence-free interval, EFS: event-free survival, eGFR: estimated glomerular filtration rate, ESCC: esophageal squamous cell carcinoma, ET: endocrine therapy, ES-SCLC: extensive-stage small cell lung cancer, FAS: full analysis set, FPD: first patient dosed, FPE: first patient enrolled, FSD: first subject dosed, GMT: geometric mean titer, HCC: hepatocellular carcinoma, HNSCC: head and neck squamous cell 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, OR: objective response, ORR: 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, pMMR: mismatch repair proficient, PRO: patient reported outcome, PSA: prostate specific antigen, RCB: residual clinical burden, RFS: relapse-free survival, rPFS: radiographic progression-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, TFST: time to first subsequent therapy, TLR: top line results, TNBC: triple negative breast cancer, TPD: targeted protein degradation, TTD: time to deterioration, TTF: time to treatment failure, TEAE: treatment-emergent adverse events, TTNT: time to next treatment, TTR: time to response, UACR: urine albumin-creatinine ratio

◆ 5DXd ADCs

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

Antibody-drug conjugate which is composed of a humanized monoclonal antibody specifically targeting HER2, one of the Epidermal Growth Factor Receptor (EGFR) family proteins, and a covalently linked drug (payload) via a cleavable linker. Payload is a potent and membrane permeable DNA topoisomerase I inhibitor which enables elimination of both target tumor cells and the surrounding tumor cells. Drug-to-antibody ratio is approximately 8.
Brand name: ENHERTU (JP/US/EU/CN)

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) 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: Sep 2025 Feb 2026: Filing accepted (JP/EU) Apr 2026: Filing accepted (CN) May 2026: Approved (US) Dec 2025: Breakthrough Therapy Designation (US) Mar 2026: Priority Review designation (US/CN)
Phase 3 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 Jan 2025: Approved (US) Apr 2025: Approved (EU) Aug 2025: Approved (JP) Dec 2025: Approved (CN) Aug 2024: Breakthrough Therapy Designation (US) Oct 2024: Priority Review designation (US)

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1b/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
Phase 1b 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
Phase 3 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: Apr 2025 (pertuzumab combo) TLR anticipated: FY2026 H2 (DS-8201 mono) Oct 2025: Filing* accepted (JP) Nov 2025: Filing* accepted (CN) Jan 2026: Filing* accepted (EU) Dec 2025: Approved* (US) Jul 2025: Breakthrough Therapy Designation* (US) Sep 2025: Priority Review designation* (US) *combination with pertuzumab

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

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
Phase 3 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 (THP) ・Doxorubicin + cyclophosphamide, followed by THP	Primary endpoint: pCR Secondary endpoint: EFS, IDFS, OS	JP/US/EU /Asia	FPD: Nov 2021 TLR: May 2025 Mar 2026: Approved* (CN) May 2026: Approved* (US) Aug 2025: Priority Review designation (CN) * Neoadjuvant therapy consisting of DS-8201 followed by THP regimen
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)
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)

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

Study Name	Population	Sample size	Study Design	Evaluation Items	Region	Status
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	450	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 + (5-FU or capecitabine) + (cisplatin or oxaliplatin) ・DS-8201 + (5-FU or capecitabine) ・DS-8201 + pembrolizumab + (5-FU or capecitabine) ・DS-8201 + pembrolizumab ・Trastuzumab + (5-FU or capecitabine) + (cisplatin or oxaliplatin) Part 3, Part 5 (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 for part 1 ・Safety for part 2,3,4 ・DOR, DCR, PFS, OS, PK, ADA	JP/US/EU/Asia	FPD: Jun 2020
Phase 3 DESTINY-Gastric04 NCT04704934 jRCT2031200369 AstraZeneca	HER2 positive gastric or gastroesophageal junction adenocarcinoma, 2L	490	Randomized, open label, active controlled ・DS-8201 ・Ramucirumab + paclitaxel	Primary endpoint: OS Secondary endpoint: PFS, ORR, DOR, DCR, safety, PK, ADA, etc.	JP/EU/Asia	FPD: Jun 2021 TLR: Mar 2025 Jan 2026: Approved (CN) Mar 2026: Indication expansion to include 2L GC based on prescribing information update (JP) Jul 2025: Priority Review Designation (CN)

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 DESTINY-Gastric05 NCT06731478 jRCT2041240173	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: Mar 2025
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	CN	FPD: Sep 2021 TLR: Jul 2023 Aug 2024: Approved (CN) Nov 2023: Priority Review Designation (CN)
Phase 3 ARTEMIDE-Gastric01 NCT06764875 jRCT2031250011 AstraZeneca unilateral study	HER2 positive and PD-L1 CPS≥1 gastric or gastroesophageal junction adenocarcinoma, 1L	840	Randomized, single blind, active controlled ・DS-8201 + rilvegostomig + (capecitabine or 5-FU) ・Pembrolizumab + trastuzumab + FP (5-FU + cisplatin) or CAPOX (capecitabine + oxaliplatin) ・Rilvegostomig + trastuzumab + FP or CAPOX	Primary endpoint: PFS, OS Secondary endpoint: ORR, DOR, safety, PK, ADA, etc.	JP/US/EU /Asia	FPD: Mar 2025

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, Part 5 (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	454	Randomized, open label, active controlled ・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: FY2026 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	CN	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 3 DESTINY-Lung06 NCT06899126	HER2 overexpressing non-squamous NSCLC (without AGA, PD-L1 TPS < 50%), 1L	686	Randomized, open label, active controlled ・DS-8201 + pembrolizumab ・Pemetrexed + pembrolizumab + (cisplatin or carboplatin)	Primary endpoint: PFS by BICR Secondary endpoint: OS	JP/US/ Asia	FPD: Oct 2025

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 2 HUDSON NCT03334617 AstraZeneca	NSCLC, 2L or later	528	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
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) Sep 2023: Breakthrough Therapy Designation (US) Jan 2024: Priority Review Designation (US)
Phase 3 DESTINY-BTC01 NCT06467357 jRCT2031240225 AstraZeneca unilateral study	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+, combo arm) Secondary endpoint: ・OS (ITT, combo arm) ・OS (IHC3+, DS-8201 mono arm) ・PFS, ORR, DOR (IHC3+ and ITT) safety and tolerability, TTD, PK, ADA, etc.	JP/US/EU /Asia	FPD: Aug 2024
Phase 3 DESTINY-Ovarian01 NCT06819007 jRCT2051240289	HER2 expressing ovarian cancer, 1L maintenance therapy	582	Randomized, open label, active controlled ・DS-8201 + bevacizumab ・Bevacizumab	Primary endpoint:PFS (IHC 3+/2+) by BICR Secondary endpoint: ・PFS by BICR, OS, PFS by investigator (IHC 3+/2+/1+) ・OS, PFS by investigator (IHC 3+/2+)	JP/US/EU /Asia	FPD: May 2025 (safety run-in phase), Dec 2025 (randomization phase)
Phase 3 DESTINY-Endometrial01 NCT06989112 AstraZeneca	HER2 expressing (IHC 3+/2+), pMMR endometrial cancer, 1L	600	Randomized, single blind, active controlled ・DS-8201 + rilvegostomig (AZD2936) ・DS-8201 + pembrolizumab ・Pembrolizumab + carboplatin + (paclitaxel or docetaxel) followed by pembrolizumab as maintenance	Primary endpoint: PFS by BICR Secondary endpoint: OS, PFS by investigator, ORR, DOR, safety, PK, ADA, etc.	JP/US/EU /Asia	FPD: Jun 2025

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 DESTINY-Endometrial02 NCT07022483 jRCT2031250423 AstraZeneca	HER2 expressing (IHC 3+/2+) endometrial cancer, adjuvant therapy	710	Randomized, open label, active controlled ・DS-8201 ・Carboplatin + paclitaxel or carboplatin + paclitaxel followed by chemoradiotherapy.	Primary endpoint: PFS by BICR Secondary endpoint: OS	JP/US/EU /Asia	FPD: Dec 2025
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 Part2: HER2 IHC 3+ or HER2 IHC 2+/ISH+ tumors (excluding breast, gastric, and colorectal cancer), or HER2 IHC 2+ or 1+ endometrial, ovarian, or cervical cancer	477	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) Mar 2026: Approved* (JP) *Approval based on results from this study and HERALD study (IIS), etc. Jun 2026: Approved** (EU) **Approval based on results from this study, DESTINY-CRC02, and DESTINY-Lung01 Sep 2023: Breakthrough Therapy Designation (US) Jan 2024: Priority Review Designation (US)
Phase 2 DESTINY-PanTumor03 NCT06271837 AstraZeneca	HER2 expressing solid tumors	127	Non-randomized, open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: DOR, DCR, BOR, PFS, OS, safety, PK, ADA	CN	FPD: Feb 2024 Apr 2026: Filing* accepted (CN) *Filing based on results from this study, DESTINY-PanTumor02, DESTINY-CRC02, and DESTINY-Lung01
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 NCT07015697 jRCT2031250307 AstraZeneca	Solid tumors	76	Non-randomized, open label, two-part (dose escalation, dose expansion) ・DS-8201 (subcutaneous injection)	Primary endpoint: safety and tolerability, AUC Secondary endpoint: ADA, ORR, DCR	JP/US/EU /Asia	FPD: Nov 2025

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/EU)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 TROPION-PanTumor01 NCT03401385 JapicCTI-173812 AstraZeneca	NSCLC TNBC HR positive, HER2 low or negative breast cancer SCLC Transitional cell carcinoma of the urothelium HER2 negative gastroesophageal cancer Esophageal cancer Prostate cancer, etc.	890	Open label, two-part (dose escalation, dose expansion) ・DS-1062	Primary endpoint: safety Secondary endpoint: PK, ADA	JP/US	FPD: Feb 2018
Phase 1/2 TROPION-PanTumor02 NCT05460273 AstraZeneca	NSCLC TNBC	119	Open label ・DS-1062	Primary endpoint: ORR by ICR Secondary endpoint: ORR by investigator, DOR, DCR, BOR, TTR, PFS, OS, safety, PK, etc.	CN	FPD: Jul 2022
Phase 2 TROPION-PanTumor03 NCT05489211 jRCT2031220404 AstraZeneca	Endometrial cancer Gastric cancer CRPC Ovarian cancer CRC Urothelial cancer BTC	454	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	605	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)

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1b TROPION-Lung02 NCT04526691 jRCT2031200193 MRK AstraZeneca	NSCLC (without AGA) Part 1: 3L or later Part 2: 1L/2L	145	Open label, combination with pembrolizumab, two-part (dose escalation, dose expansion) ・DS-1062 + pembrolizumab ± platinum chemotherapy	Primary endpoint: safety and tolerability Secondary endpoint: ORR, DOR, PFS, OS, PK, ADA	JP/US/EU /Asia	FPD: Oct 2020
Phase 1b TROPION-Lung04 NCT04612751 jRCT2031200449 AstraZeneca	NSCLC (without AGA), 1L/2L	155	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 /Asia	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 Jun 2025: Approved** (US) **EGFR-mutated NSCLC previously treated targeted therapy and platinum based chemotherapy Dec 2024: Breakthrough Therapy Designation (US) Jan 2025: Priority Review Designation (US)

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 TROPION-Lung07 NCT05555732 jRCT2061220066 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, DOR, TTR, DCR by BICR ・PFS, ORR, TTR, DCR by investigator ・TTD, safety, ADA, etc *both all randomized participants and TROP2 NMR+ randomized participants	JP/US/EU /Asia	FPD: Jan 2023 TLR anticipated: FY2027
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 TLR anticipated: FY2027
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, immunogenicity, etc.	JP/US/EU /Asia	FPD: May 2024
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 osimertinib treatment)	744	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 TLR anticipated: FY2026 H2

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 TROPION-Lung17 NCT07291037 jRCT2031250462 AstraZeneca	TROP2 NMR positive non-squamous NSCLC (without AGA), 2L or later	400	Randomized, open label, active controlled ・DS-1062 ・Docetaxel	Primary endpoint: PFS by BICR, OS Secondary endpoint: ORR by BICR, DOR by BICR, relationship between TROP2 NMR expression and efficacy endpoints, PK, ADA, etc.	JP/US/EU /Asia	FPD: Jan 2026
Phase 3 AVANZAR NCT05687266 jRCT2031220612 AstraZeneca unilateral study	NSCLC (without AGA), 1L	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 (non-squamous TROP2 biomarker positive) ・PFS by BICR, OS (non-squamous) Secondary endpoint: ・PFS by BICR, OS (ITT and TROP2 biomarker defined) ・ORR, DOR, PFS (ITT, non-squamous and TROP2 biomarker defined) ・PK, ADA, etc.	JP/US/EU /Asia	FPD: FY2022 Q4 TLR anticipated: CY2026 H2
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 Dec 2024: Approved (JP) Jan 2025: Approved (US) Apr 2025: Approved (EU) Aug 2025: Approved (CN)

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 TROPION-Breast02 NCT05374512 jRCT2061220029 AstraZeneca	TNBC, not candidates for PD-1/PD-L1 inhibitor, 1L	644	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: Oct 2025 Dec 2025: Filing accepted (EU/CN) Feb 2026: Filing accepted (JP) May 2026: Approved (US) Feb 2026: Priority Review Designation (US)
Phase 3 TROPION-Breast03 NCT05629585 jRCT2061220087 AstraZeneca	TNBC without pCR following neoadjuvant therapy, adjuvant therapy	1,174	Randomized, open label, active controlled ・DS-1062 + durvalumab（combo） ・DS-1062 ・Physician's choice (capecitabine, pembrolizumab, capecitabine + pembrolizumab)	Primary endpoint: IDFS (combo vs physician's choice) Secondary endpoint: DDFS, OS, IDFS, TTD, fatigue, PK, ADA, safety and tolerability	JP/US/EU /Asia	FPD: Dec 2022 TLR anticipated: FY2027
Phase 3 TROPION-Breast04 NCT06112379 jRCT2031230723 AstraZeneca	TNBC, HR low and HER2 negative BC, neoadjuvant therapy and adjuvant therapy	1,902	Randomized, open label, active controlled ・DS-1062 + durvalumab as neoadjuvant therapy, durvalumab ± chemotherapy as adjuvant therapy ・Pembrolizumab + chemotherapy as neoadjuvant therapy, pembrolizumab ± chemotherapy as adjuvant therapy	Primary endpoint: pCR, EFS Secondary endpoint: OS, DDFS, PRO, PK, ADA, safety, etc	JP/US/EU /Asia	FPD: Nov 2023
Phase 3 TROPION-Breast05 NCT06103864 jRCT2061230102 AstraZeneca	PD-L1 positive TNBC, 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, CBR, TTD, etc.	JP/US/EU /Asia	FPD: Nov 2023 TLR anticipated: FY2027

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 2/3 TROPION-Urothelial03 NCT07129993 jRCT2061250062 AstraZeneca	Urothelial carcinoma, 2L or later	630	Randomized, open label Part A (Ph2) ・DS-1062 (4mg/kg or 6mg/kg) + carboplatin or cisplatin Part B (Ph3) ・DS-1062 + (carboplatin or cisplatin) ・Gemcitabine + (carboplatin or cisplatin)	Primary endpoint: ・ORR (part A) ・PFS by BICR, OS (part B) Secondary endpoint: ・DOR (part A) ・PFS by investigator, ORR (part B)	JP/US/EU/Asia	FPD: Oct 2025
Phase 3 in prep TROPION-Urothelial04 NCT07720284 AstraZeneca	Muscle-invasive urothelial carcinoma (MIUC) after radical resection, adjuvant therapy	915	Randomized, single blind, active controlled ・DS-1062 + rilvegostomig (arm 1) ・DS-1062 (arm 2) ・Nivolumab, durvalumab, or (enfortumab vedotin + pembrolizumab) (arm 3)	Primary endpoint: ・DFS by investigator (arm 1 vs arm 3) Secondary endpoint： ・OS, DFS by BICR, etc (arm 1 vs arm 3) ・OS, DFS by investigator, DFS by BICR (arm 2 vs arm 3) and (arm 1 vs arm 2) Other endpoint：PK, immunogenicity	JP/US/EU/Asia	FPD planned: FY2026 H2
Phase 2 ORCHARD NCT03944772 jRCT2080224686 AstraZeneca	EGFR-mutated NSCLC, 2L	247	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 therapy and adjuvant therapy	630	Non-randomized, open label ・DS-1062 + durvalumab + single agent platinum as neoadjuvant therapy and durvalumab as adjuvant therapy ・DS-1062 + rilvegostomig + single agent platinum as neoadjuvant therapy and rilvegostomig as adjuvant therapy ∗ 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 jRCT2080224788 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 HERTHENA-PanTumor01 NCT06172478 jRCT2031230575 MRK	Melanoma, SCCHN, HER2-negative gastric cancer, ovarian carcinoma, cervical cancer, endometrial cancer, bladder cancer, esophageal carcinoma, pancreatic carcinoma, prostate cancer, HR positive and HER2 negative breast cancer, and NSCLC (without AGA)	740	Non-randomized, open label ・U3-1402	(Except prostate cancer) Primary endpoint: ORR Secondary endpoint: safety, DOR, CBR, DCR, TTR, PFS, OS, PK, etc. (Prostate Cancer) Primary endpoint: PSA50 response rate Secondary endpoint: safety, rPFS, OS, TFST, PK, etc.	JP/US/EU /Asia	FPD: Mar 2024
Phase 1/2 HERTHENA-PanTumor02 NCT06596694 MRK	BTC, hepatocellular carcinoma, gastroesophageal cancer, 2L or later	180	Open label ・U3-1402	Primary endpoint: safety and tolerability, ORR Secondary endpoint: DOR, PFS, OS, PK	US/EU/ Asia	FPD: Nov 2024
Phase 1 NCT04676477 jRCT2031200247 AstraZeneca MRK	EGFR-mutated NSCLC, 1L/2L	246	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 HERTHENA-Breast01 NCT06686394 jRCT2041250022 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, ADA	JP/US/EU /Asia	FPD: Apr 2025

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1/2 in prep HERTHENA-Breast02 NCT07701941 jRCT2031260321 MRK	HR positive, HER2 low or ultralow breast cancer, chemotherapy naïve	220	Randomized, open label, active controlled, two-part (dose regimen determination/part 1, dose expansion/part 2) ・U3-1402 + DS-8201 ・DS-8201	Primary endpoint: ・safety (part 1) ・ORR by investigator (part 2) Secondary endpoint: ・ORR by investigator, PK (part 1) ・safety, etc(part 2) ・DCR, DOR, CBR, PFS, TTR, OS (part 1 and part 2)	TBA	FPD planned: FY2026 H2
Phase 2 HERTHENA-Breast03 NCT06797635 MRK	High-risk early stage TNBC, HR low and HER2 negative BC, neoadjuvant therapy and adjuvant therapy	372	non-randomized (part 1), randomized (part 2), open label, active controlled Neoadjuvant therapy ・Pembrolizumab + U3-1402 followed by pembrolizumab + paclitaxel + carboplatin (part 1, part 2A) ・Pembrolizumab + paclitaxel + carboplatin followed by pembrolizumab + U3-1402 (part 2B) ・Pembrolizumab + paclitaxel + carboplatin followed by pembrolizumab + doxorubicin (or epirubicin) + cyclophosphamide (part 2C) Adjuvant therapy (part 2) ・Pembrolizumab ± chemotherapy	Primary endpoint: ・safety and tolerability (part 1 and part 2) ・pCR (part 2) Secondary endpoint: ・pCR-no DCIS, EFS, OS, DPDRFS, RCB (part 2)	US/EU/Asia	FPD: May 2025
Phase 3 HERTHENA-Breast04 NCT07060807 jRCT2031250297 MRK	HR positive and HER2 negative breast cancer, post one line of ET and CDK4/6 inhibitor	1,000	Randomized, open label, active controlled ・U3-1402 ・Physician's choice (paclitaxel, nab-paclitaxel, capecitabine, liposomal doxorubicin or DS-8201)	Primary endpoint: PFS by BICR, OS Secondary endpoint: ORR, DOR, TTD, safety, etc.	JP/US/EU/Asia	FPD: Aug 2025
Phase 1/2 LIGHTBEAM-U01 substudy 01C NCT06941272 MRK	Relapsed or refractory hepatoblastoma or rhabdomyosarcoma (pediatric)	50	open label, two-part (determine the recommended dose for expansion, dose expansion) ・U3-1402	Primary endpoint: ・safety and tolerability, PK (part 1) ・ORR (part 1 and part 2) Secondary endpoint: ・safety, PK (part 2) ・DCR, TTR, DOR, PFS, OS (part 1 and part 2)	US/EU/Asia	FPD: Jun 2025

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1/2 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.	US/EU/ Asia	FPD: Jun 2025
Phase 2 KEYMAKER-U01 substudy 01G NCT06731907 MRK	Stage IV NSCLC, 1L	90	Randomized, single-blind, 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: May 2025
Phase 1/2 KEYMAKER-U06 substudy 06C NCT06469944 MRK	HER2 negative gastric adenocarcinoma, gastroesophageal junction adenocarcinoma, or esophageal adenocarcinoma, 1L	160	Randomized, open label, active controlled ・U3-1402 + pembrolizumab + chemotherapy ・Pembrolizumab + chemotherapy ＊ Umbrella study of pembrolizumab led by MRK	Primary endpoint: safety and tolerability, ORR by BICR Secondary endpoint: PFS, DOR, OS, ADA, etc.	US/EU/ Asia	FPE：Apr 2026
Phase 1/2 KEYMAKER-U06 substudy 06D NCT06445972 MRK	HER2 negative gastric adenocarcinoma, gastroesophageal junction adenocarcinoma, or esophageal adenocarcinoma, 2L	210	Randomized, single-blind , active controlled ・U3-1402 + ramucirumab ・Paclitaxel + ramucirumab ＊ Umbrella study led by Merck that evaluates combination therapies with SOC.	Primary endpoint: safety, ORR by BICR Secondary endpoint: PFS, DOR, OS, ADA, etc.	US/EU/ Asia	FPE：Apr 2026

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

Antibody-drug conjugate which is composed of humanized 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 jRCT2080224907 MRK	Esophageal squamous cell carcinoma, CRPC, squamous-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, Ad-eso/GEJ/ gastric cancer, 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、two-part (dose optimization and extension) ・DS-7300	Primary endpoint: ORR by BICR Secondary endpoint: safety, PFS, DOR, OS, TTR, ORR, by investigator, DCR, PK, ADA	JP/US/EU /Asia	FPD: Jun 2022 TLR: Apr 2025 Apr 2026: Filing accepted (US) Apr 2023: Orphan Drug Designation (US) Dec 2024: Orphan Drug Designation (JP) Aug 2025: Breakthrough Therapy Designation (US) Apr 2026: Priority Review Designation (US)
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) Aug 2025: Breakthrough Therapy Designation (US)

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	FPD: Aug 2024 Apr 2023: Orphan Drug Designation (US) Dec 2024: Orphan Drug Designation (JP)
Phase 3 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: May 2025 Jan 2026: Orphan Drug Designation (US)
Phase 3 IDeate-Prostate01 NCT06925737 jRCT2071250013 MRK	Chemo naïve CRPC	1,440	Randomized, open label, active controlled ・DS-7300 ・Docetaxel + prednisone	Primary endpoint: OS, rPFS Secondary endpoint: TFST, OR, DOR, etc.	JP/US/EU /Asia	FPD: Jun 2025
Phase 1/2 IDeate-Prostate02 NCT06863272 MRK	Chemo naïve CRPC	360	Randomized, open label, active controlled ・DS-7300 ・DS-7300 + MK-5684 (ODM-208) ・DS-7300 + abiraterone or enzalutamide ・Docetaxel	Primary endpoint: ・safety and tolerability ・PSA response rate (efficacy phase) Secondary endpoint: ORR, rPFS, OS, DOR, etc.	US/EU/ Asia	FPD: Aug 2025

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase1b/2 in prep LIGHTBEAM-U01 substudy 01D NCT07630974 MRK	Relapsed or refractory solid tumors (pediatric) Part 1: solid tumors (excluding primary CNS) Part 2: osteosarcoma (OST), neuroblastoma (NBL), rhabdomyosarcoma (RMS), Wilms tumor (WT).	134	open label, two-part (determine the recommended dose for expansion, dose expansion) ・DS-7300	Primary endpoint: ・safety and tolerability ・ORR (NBL, RMS, WT) ・DCS-4 (OST) Secondary endpoint: ・DOR, DCR,TTR, PFS, PK, ADA (NBL, RMS, WT, OST) ・ORR (OST) ・OS	US/EU/ Asia	FPE: TBA
Phase 1/2 KEYMAKER-U06 substudy 06E NCT06780111 jRCT2041240166 MRK	ESCC, 1L	298	Randomized, open label, active controlled ・DS-7300 + pembrolizumab ・DS-7300 + pembrolizumab + 5-FU + (leucovorin or levoleucovorin) ・DS-7300 + pembrolizumab + 5-FU + (leucovorin or levoleucovorin) + oxaliplatin ・Pembrolizumab + mFOLFOX6 chemotherapy * Umbrella study of pembrolizumab led by MRK	Primary endpoint: safety, ORR Secondary endpoint: DOR, PFS, OS, DCR, PK, ADA	JP/US/EU /Asia	FPD: Aug 2025
Phase 2 KEYMAKER-U06 substudy 06F NCT07405151 jRCT2041250179 MRK	ESCC, 2L/3L	60	Non-randomized, open label ・DS-7300	Primary endpoint: ORR Secondary endpoint: DOR, PFS, OS, safety	JP/Asia	FPE: Mar 2026
Phase 1/2 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.	US/EU/ Asia	FPD: Jun 2025

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 2 KEYMAKER-U01 substudy 01H NCT06780085 MRK	Non-squamous 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	US/EU/ Asia	FPE: Jul 2025
Phase 2 KEYMAKER-U01 Substudy 01I NCT06780098 MRK	Squamous 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	US/EU/ Asia	FPD: Sep 2025

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

Antibody-drug conjugate which is composed of humanized 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	182	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	860	Randomized, open label, two-part (part A /phase 2: dose optimization and dose extension, part B/phase 3: comparing efficacy with investigator's choice of chemotherapy) ・DS-6000 ・Investigator's choice (gemcitabine, paclitaxel, topotecan, PLD)	Primary endpoint: ・ORR by BICR (part A) ・PFS, ORR by BICR (part B) Secondary endpoint: ・ORR by investigator, OS, DOR, PFS by BICR and investigator, DCR, safety, PK, etc.	JP/US/EU /Asia	FPD: Apr 2024 TLR (Phase 2 dose optimization): Apr 2025 Feb 2025: Orphan Drug Designation (EU) Mar 2025: Orphan Drug Designation (JP) Sep 2025: Breakthrough Therapy Designation (US)
Phase 1b/2 REJOICE-Ovarian02 NCT06843447 MRK	High-grade serous epithelial ovarian, primary peritoneal, or fallopian tube cancer, relapsed after prior platinum-based chemotherapy	280	Non-randomized, open label ・DS-6000 + carboplatin ・DS-6000 + paclitaxel ・DS-6000 + bevacizumab ・DS-6000 + pembrolizumab	Primary endpoint: safety and tolerability Secondary endpoint: ORR	US/EU/ Asia	FPD: Apr 2025
Phase 2 REJOICE-GI01 NCT06864169 MRK	Gastrointestinal cancers (PDAC, BTC, CRC, gastroesophageal adenocarcinoma)	160	Open label ・DS-6000	Primary endpoint: ORR Secondary endpoint: safety, DOR, PFS, OS	US/EU/ Asia	FPD: Apr 2025
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

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1b/2 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: Mar 2025
Phase 2 KEYMAKER-U01 substudy 01H NCT06780085 MRK	non-squamous 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	US/EU/ Asia	FPD: July 2025
Phase 2 KEYMAKER-U01 Substudy 01I NCT06780098 MRK	squamous 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	US/EU/ Asia	FPD: Aug 2025

◆ 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/CN)

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) Jun 2026: Approved (CN) 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 (arm A vs arm B): OS Secondary endpoint (arm A vs arm B): EFS, duration of CR, RFS, safety, etc.	JP/US/EU/Asia	FPD: Dec 2024 Mar 2009: Orphan Drug Designation (US)

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 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 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	Primary 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	Primary endpoint: ORR Secondary endpoint: CRR, CR rate, PFS, DOR, TTR, safety, PK	EU	FPD: Jun 2021 TLR: Jun 2025

Valemetostat/DS-3201 (EZH1/2 inhibitor)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1b NCT06244485 jRCT2031230614	HER2-positive gastric cancer or gastro-esophageal junction (GEJ) adenocarcinoma, HER2 low breast cancer (DS-8201 combination) Non-squamous NSCLC (DS-1062 combination)	210	Non-Randomized, open-label, two-part (dose escalation/part 1 and dose expansion/part 2) ・DS-3201 + DS-8201 ・DS-3201 + DS-1062	Primary endpoint: ・safety (part 1) ・ORR (part 2) Secondary endpoint: OS, PFS, DOR, ORR, PK, safety, etc	JP/US	FPD: Feb 2024
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
Phase 1 NCT07244341 jRCT2031250584	CRPC	60	Non-Randomized, open label, two-part (dose escalation, dose expansion) ・DS-3201 + darolutamide	Primary endpoint: safety and tolerability Secondary endpoint: PSA response rate, rPFS, OS, ORR, PK, etc	JP/US/EU /Asia	FPD: Feb 2026

◆ Next Wave (Oncology Early-Stage Pipeline Products)

DS-1103（anti-SIRPα antibody）

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT05765851 jRCT2031260255	HER2-expressing or HER2-mutated solid tumors (dose escalation part), HER2-altered solid tumors (dose expansion part)	108	Non-randomized, open label, two-part (dose escalation/part 1, dose expansion/part 2) ・DS-1103 + DS-8201	Primary endpoint: ・Safety and tolerability ・ORR by BICR (part 2) Secondary endpoint: ・ORR by investigator (part 2) ・DCR, CBR, DOR by BICR (part 2) ・DCR, CBR, DOR by investigator ・PK, ADA, etc.	JP/US/EU	FPD: Jun 2023

DS-3939（TA-MUC1-directed DXd ADC）

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1/2 NCT05875168 jRCT2031230233	Solid tumors	590	Non-randomized, open label, two-part (dose escalation/part 1, dose expansion/part 2) ・DS-3939	Primary endpoint: ・ORR (part 2) ・PSA50 response rate (part 2 CRPC cohort only) ・safety and tolerability Secondary endpoint: ・ORR (part 1) ・DCR, DOR, TTR, PFS, OS, PK, ADA, etc.	JP/US/EU /Asia	FPD: Sep 2023

Gocatamig (MK-6070/DS3280）(DLL3-directed trispecific T-cell engager)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1/2 MK-6070-001 NCT04471727 MRK	DLL3 expressing advanced cancer (SCLC, neuroendocrine carcinoma)	232	Non-randomized, open label ・MK-6070 ・MK-6070 + atezolizumab ・MK-6070 + DS-7300	Primary endpoint: safety and tolerability, PK Secondary endpoint: ORR, BOR, PFS, OS, DOR, ADA, etc.	US	FPD: Dec 2020 Mar 2022: Orphan Drug Designation for SCLC (US)
Phase 1b/2 MK-6070-002 NCT06780137 jRCT2031250039 MRK	ES-SCLC, 2L or later	242	Randomized, open label, three-part ・MK-6070 + DS-7300 (part 1) ・MK-6070 (part 1 and part 2) ・MK-6070 + durvalumab (part 3)	Primary endpoint: ・safety and tolerability ・ORR (part 1) Secondary endpoint: ・DOR, PFS, PK, ADA ・ORR (part 2 and part 3)	JP/US/EU /Asia	FPD: Mar 2025
Phase 1b/2 MK-6070-003 NCT07227597 MRK	ES-SCLC, 1L（induction and maintenance therapy)	170	Two-part (Part A: Arm 1-2, Part B: Arm 1-4), non-randomized (Part A, Part B/Arm1), randomized (Part B/Arm2-4), open label, active controlled ■induction therapy → maintenance therapy: ・Arm 1: SOC induction chemotherapy (carboplatin + etoposide + atezolizumab) + PD-1/PD-L1 inhibitor → MK-6070 + I-DXd ・Arm 2: MK-6070 + I-DXd → MK-6070 + I-DXd ・Arm 3: MK-6070 + I-DXd → MK-6070 + atezolizumab ・Arm 4: SOC induction chemotherapy → atezolizumab	Primary endpoint: safety, ORR by BICR Secondary endpoint: ・DCR, DOR, PFS (by BICR) ・OS, PK, ADA	US/Asia	FPE: Jan 2026

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 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 for part 2 Secondary endpoint: ・ORR for part 1 ・DCR, PFS, OS, etc.	US/EU/ Asia	FPD: Mar 2025

DS3610 (EGFR-directed STING agonist ADC)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT07159126 jRCT2031250388	Solid tumors	70	Non-randomized, open label ・DS3610	Primary endpoint: safety and tolerability Secondary endpoint: PK, ADA	JP	FPD: Nov 2025

DS5361 (Small molecule NMD inhibitor)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT07182591 jRCT2031250489	Solid tumors	192	Non-randomized, open label, three-part (dose escalation/part 1 and part 2, dose expansion/part 3) ・DS5361 (part 1) ・DS5361 + pembrolizumab (part 2 and part 3)	Primary endpoint: ・tolerability (part 1 and part 2) ・safety ・ORR (part3) Secondary endpoint: ・ORR (part 1 and part 2) ・PK, DCR, DOR	JP/US	FPD: Oct 2025

DS9051 (Targeted protein degradation (TPD) molecule)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT07189403	Solid tumors including CRPC	40	Non-randomized, open label ・DS9051	Primary endpoint: safety and tolerability Secondary endpoint: ・rPFS for mCRPC ・PK, etc.	US/EU	FPD: Nov 2025

DS3790 (CD37-directed DXd ADC)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1/2 NCT07220616 jRCT2031250487	Relapsed or refractory B-cell non-Hodgkin lymphoma	420	open label, dose escalation/part 1, dose expansion/part 2, randomization, optimization/part 3, mono and combination regimen evaluation/phase 2 ・DS3790 ・DS3790 + selected agent ・SOC	Primary endpoint: ・safety and tolerability ・CRR by investigator (part 2) ・CRR by BICR (part 3 and Ph2) Secondary endpoint: ・ORR (part 1) ・DCR, DOCR, DOR, TTR, PFS, OS	JP/US/EU	FPD: Feb 2026

DS1025 (CD25-directed ADC)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 in prep NCT07681882 jRCT2031260320	Solid tumors	45	open label ・DS1025	Primary endpoint: safety and tolerability Secondary endpoint: ・PK, ADA	JP	FPD planned: FY2026 H1

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

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 TLR: May 2025

DS2001 (anti-ORAI1 antibody)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 jRCT2031250859	Healthy volunteers, autoimmune diseases	64	Randomized, double-blind, placebo-controlled ・DS2001	Primary endpoint: safety and tolerability Secondary endpoint: ・PK, ADA	JP	FSD: Apr 2026

◆ Next Wave (Vaccine)

VN-0102/JVC-001 (Measles-mumps-rubella combined vaccine)

Combined vaccine (MMR vaccine) containing three attenuated viruses of measles, mumps and rubella.
Brand name: MIMRIT (JP)

Study Name	Target indication	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 May 2026: Approved (JP)

◆ Stage-up Projects (Major Changes from the FY2025 Q4 Financial Announcement in May 2026)

Generic Name/Project Code Number Mechanism of action	Population or indication	Current Stage	Note
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 positive breast cancer with residual invasive disease following neoadjuvant therapy, adjuvant therapy	Approved	US, DESTINY-Breast05
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 positive breast cancer, neoadjuvant therapy	Approved	US, DESTINY-Breast11 (Neoadjuvant therapy consisting of DS-8201 followed by THP regimen)
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 positive solid tumors	Approved	EU, Approval based on results from DESTINY-PanTumor02, DESTINY-CRC02, and DESTINY-Lung01
Datopotamab deruxtecan/DS-1062/ Dato-DXd TROP2-directed ADC	TNBC, not candidates for PD-1/PD-L1 inhibitor, 1L	Approved	US, TROPION-Breast02
Quizartinib/AC220 FLT3 inhibitor	*FLT3*-ITD positive AML, 1L	Approved	China, QuANTUM-First
VN-0102/JVC-001 Measles-mumps-rubella combined vaccine	Indication: Prevention of measles, mumps and rubella in persons aged 12 months or older	Approved	JP
Datopotamab deruxtecan/DS-1062/ Dato-DXd TROP2-directed ADC	Muscle-invasive urothelial carcinoma (MIUC) after radical resection, adjuvant therapy	Ph3 in prep	JP/US/EU/Asia, TROPION-Urothelial04
Patritumab deruxtecan/ U3-1402/HER3-DXd HER3-directed ADC	HER2 negative gastric, gastroesophageal junction, or esophageal adenocarcinoma, 1L	Ph1/2	US/EU/Asia, KEYMAKER-U06 substudy 06C

◆ Stage-up Projects (Major Changes from the FY2025 Q4 Financial Announcement in May 2026)

Generic Name/Project Code Number Mechanism of action	Population or indication	Current Stage	Note
Patritumab deruxtecan/ U3-1402/HER3-DXd HER3-directed ADC	HER2 negative gastric, gastroesophageal junction, or esophageal adenocarcinoma, 2L	Ph1/2	US/EU/Asia, KEYMAKER-U06 substudy 06D
Patritumab deruxtecan/ U3-1402/HER3-DXd HER3-directed ADC	HR positive, HER2 low or ultralow breast cancer, chemotherapy naïve	Ph1/2 in prep	TBA, HERTHENA-Breast02
Ifinatamab deruxtecan/ DS-7300/I-DXd B7-H3-directed ADC	Relapsed or refractory solid tumors (pediatric) Part 1: solid tumors (excluding primary CNS) Part 2: osteosarcoma (OST), neuroblastoma (NBL), rhabdomyosarcoma (RMS), Wilms tumor (WT).	Ph1b/2 in prep	US/EU/Asia, LIGHTBEAM-U01 substudy 01D
DS2001 anti-ORAI1 antibody	Healthy volunteers, autoimmune diseases	Ph1	JP
DS1025 CD25-directed ADC	Solid tumors	Ph1 in prep	JP