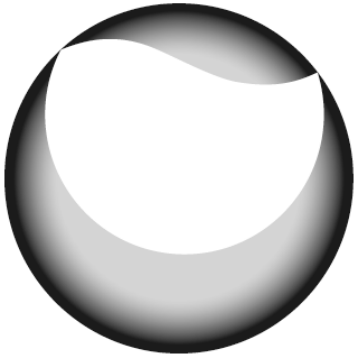
TSE:4568

Reference Data

(Consolidated Financial Results for FY2025)



Daiichi-Sankyo

May 11, 2026

Daiichi Sankyo Co., Ltd.

https://www.daiichisankyo.com

Contents

Daiichi-Sankyo

1. Consolidated Statement of Profit or Loss（FY2025 Results）

JPY Bn	FY2024 to revenue	FY2024 Results	FY2025 to revenue	FY2025 Results	(vs. Forecast (%))*	FY2025 YoY	FY2025 YoY (%)
Revenue	***100.0%***	**1,886.3**	***100.0%***	**2,123.0**	**(101.1%)**	**236.8**	***+12.6%***
Cost of sales*1	*22.0%*	415.7	*20.8%*	441.3	(95.9%)	25.6	*+6.2%*
Gross Profit	*78.0%*	1,470.5	*79.2%*	1,681.7	(102.5%)	211.2	*+14.4%*
SG&A expenses*1	*38.4%*	724.8	*40.5%*	859.6	(103.6%)	134.8	*+18.6%*
DXd ADC profit share*2	*12.0%*	226.2	*14.4%*	305.6	(101.9%)	79.4	*+35.1%*
Other SG&A expenses	*26.4%*	498.6	*26.1%*	554.0	(104.5%)	55.4	*+11.1%*
R&D expenses*1	*22.9%*	432.9	*21.8%*	462.1	(100.5%)	29.3	*+6.8%*
Core Operating Profit	***16.6%***	**312.8**	***17.0%***	**360.0**	**(102.8%)**	**47.1**	***+15.1%***
Temporary income*3		22.2		22.1		-0.1	
Temporary expenses*3		3.1		153.0		149.9	
Operating Profit	***17.6%***	**331.9**	***10.8%***	**229.1**	**(68.4%)**	**-102.8**	***-31.0%***
Financial income/expenses		22.2		32.8		10.6	
Share of profit or loss of investments accounted for using the equity method		1.5		1.5		0.1	
Profit before tax	***18.9%***	**355.6**	***12.4%***	**263.4**	**(74.2%)**	**-92.2**	***-25.9%***
Income taxes		59.9		3.6		-56.3	
Profit for the year	***15.7%***	**295.8**	***12.2%***	**259.9**	**(90.2%)**	**-35.9**	***-12.1%***
Profit attributable to owners of the Company	***15.7%***	**295.8**	***12.2%***	**259.9**	**(90.2%)**	**-35.9**	***-12.1%***
Tax rate		16.8%		1.4%			
Overseas sales ratio		69.0%		72.7%			
Currency Rate (Average)							
USD/JPY		152.57		150.78			
EUR/JPY		163.74		174.79			

Forex impact: +21.8
(USD: -8.2, EUR: +28.3, ASCA: +1.7)

Forex impact: +3.8
(USD: -1.3, EUR: +5.3, ASCA: -0.1)

Forex impact: +1.5
(USD: -5.9, EUR: +6.8, ASCA: +0.6)

Forex impact: -0.1
(USD: -3.7, EUR: +3.4, ASCA: +0.1)

Forex impact: +16.6
(USD: +2.7, EUR: +12.8, ASCA: +1.1)

- Improvement in forex gains/losses +16.0
- Improvement in investment securities valuation gains/losses +3.3
- Decrease of interest income -6.7
- Increase of interest expenses -1.9

* vs. Oct. Forecast

This report is not subject to audit procedures.
*1 Temporary income and expenses are excluded for cost of sales, SG&A expenses and R&D expenses
*2 DS pays alliance partners 50% of gross profit for the product sales in countries/regions where DS book revenue (excluding Japan) to share profit with the
*3 See page 3 for the definition of temporary income and expenses and the adjustment of operating profit and core operating profit

1. Consolidated Statement of Profit or Loss（FY2026 Forecast）

JPY Bn	FY2025 to revenue	FY2025 Results	FY2026 to revenue	FY2026 Forecast	YoY	YoY (%)
Revenue	***100.0%***	**2,123.0**	***100.0%***	**2,280.0**	**157.0**	***+7.4%***
Cost of sales*1	*28.7%*	610.3	*23.2%*	530.0	-80.3	*-13.2%*
CMO compensation fee	*8.0%*	169.5	*3.5%*	80.0	-89.5	*-52.8%*
Other Cost of sales	*20.8%*	440.8	*19.7%*	450.0	9.2	*+2.1%*
Gross Profit	*71.3%*	1,512.7	*76.8%*	1,750.0	237.3	*+15.7%*
SG&A expenses*1	*36.2%*	768.7	*39.0%*	890.0	121.3	*+15.8%*
DXd ADC profit share*2	*14.4%*	305.6	*16.2%*	370.0	64.4	+21.1%
Other SG&A expenses	*21.8%*	463.1	*22.8%*	520.0	56.9	+12.3%
R&D expenses*1	*21.7%*	461.6	*21.9%*	500.0	38.4	*+8.3%*
Core Operating Profit	***13.3%***	**282.4**	***15.8%***	**360.0**	**77.6**	***+27.5%***
Non-core income*3		22.1		-	-22.1	
Non-core expenses*3		75.4		45.0	-30.4	
Operating Profit	***10.8%***	**229.1**	***13.8%***	**315.0**	**85.9**	***+37.5%***
Financial income/expenses		32.8		12.5		
Share of profit or loss of investments accounted for using the equity method		1.5		1.5		
Profit before tax	***12.4%***	**263.4**	***14.4%***	**329.0**	**65.6**	***+24.9%***
Income taxes		3.6		66.0		
Profit for the year	***12.2%***	**259.9**	***11.5%***	**263.0**	**3.1**	***+1.2%***
Profit attributable to owners of the Company	***12.2%***	**259.9**	***11.4%***	**260.0**	**0.1**	***+0.0%***

Tax rate	1.4%	
Overseas sales ratio	72.7%	
Currency Rate (Average)		Currency Rate (Average)
USD/JPY	150.78	150.00
EUR/JPY	174.79	180.00

Annual impact of JPY 1 change

	Forecast	
	USD	EUR
Revenue	JPY 6.5 Bn	JPY 2.6 Bn
Operating Profit	JPY -0.2 Bn	JPY 0.7 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 4 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（Previous Definition）

FY2024 Results

JPY Bn	Full base	Adjustment					Core base
		Gains and losses related to sale of fixed assets	Gains and losses related to restructuring	Gains and losses related to impairment,	Gains and losses related to loss compensation, reconciliation	Others	
Revenue	**1,886.3**						**1,886.3**
Cost of sales	415.8					-0.1	415.7
SG&A expenses	731.2		1.1		-7.5	-0.0	724.8
R&D expenses	436.0			-3.0		-0.1	432.9
Other income*	28.7	-3.8	-17.0		-7.7	-0.2	-
Other expenses*	0.1	-0.1					-
Core Operating Profit**							**312.8**
Temporary income		3.8 *1	18.1 *2		0.2		22.2
Temporary expenses		0.1		3.0			3.1
Operating Profit (full)	**331.9**						**331.9**

＜Major Temporary income and Temporary expenses＞

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

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

FY2025 Results

JPY Bn	Full base	Adjustment					Core base
		Gains and losses related to sale of fixed assets	Gains and losses related to restructuring	Gains and losses related to impairment,	Gains and losses related to loss compensation, reconciliation	Others	
Revenue	**2,123.0**						**2,123.0**
Cost of sales	669.0			-4.8	-14	-208.4	441.3
SG&A expenses	780.7			-0.3		79.2	859.6
R&D expenses	466.0			-0.9		-3.0	462.1
Other income*	22.1	-0.0			-5.1	-17.0	-
Other expenses*	0.3	-0.3					-
Core Operating Profit**							**360.0**
Temporary income		0.0			5.1 *3	17.0 *4	22.1
Temporary expenses		0.3		6.0 *5	14.4 *5	132.2 *6	153.0
Operating Profit (full)	**229.1**						**229.1**

＜Major Temporary income and Temporary expenses＞

*3 Income related to litigation with former shareholders of Ranbaxy (5.1)

*4 Gains on liquidation of a subsidiary (16.8)

*5 Losses related to cancellation of Odawara site investment (19.3)

*6 CMO Compensation Fee (88.3)

*6 Environmental measures costs in Yasu (16.0)

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

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

2. Sheet to adjust Operating Profit to Core Operating Profit（New Definition）

FY2025 Results

JPY Bn	Full base	Adjustment						Core base
		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	Others	
Revenue	**2,123.0**							**2,123.0**
Cost of sales	669.0	-20.0	-14.4	-4.8			-19.4	610.3
SG&A expenses	780.7		-5.6	-0.3			-6.1	768.7
R&D expenses	466.0	-0.8	-2.7	-0.9			0.0	461.6
Other income*	22.1		-16.8		-5.1		-0.2	-
Other expenses*	0.3						-0.3	-
Core Operating Profit**								**282.4**
Non-core income			16.8 *2		5.1 *1		0.2	22.1
Non-core expenses		20.8	22.7 *3	6.0 *3			25.9 *4	75.4
Operating Profit (full)	**229.1**							**229.1**

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

*1 Income related to litigation with former shareholders of Ranbaxy (5.1)

*2 Gains on liquidation of a subsidiary (16.8)

*3 Losses related to cancellation of Odawara site investment (19.3)

*4 Environmental measures costs in Yasu (16.0)

FY2026 Forecast

JPY Bn	Full base	Adjustment						Core base
		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	Others	
Revenue	**2,280.0**							**2,280.0**
Cost of sales	549.2	-19.2						530.0
SG&A expenses	912.2		-22.2					890.0
R&D expenses	503.6		-3.6					500.0
Other income*								-
Other expenses*								-
Core Operating Profit**								**360.0**
Non-core income								-
Non-core expenses		19.2	25.8 *5					45.0
Operating Profit (full)	**315.0**							**315.0**

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

*5 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	FY2024 Results	FY2025 Results	(vs. Forecast (%))*	YoY	YoY (%)	FY2026 Forecast	YoY	YoY (%)
Trastuzumab deruxtecan anti-cancer agent (HER2-directed antibody drug conjugate)	**651.4**	**819.5**	**(101.7%)**	**168.1**	**+25.8%**	**993.3**	**173.8**	**+21.2%**
Product sales *Incl. Gross profit share in AstraZeneca territory	552.8	698.4	(101.2%)	145.5	+26.3%	861.3	162.9	+23.3%
Enhertu (JPN)	31.0	37.7	(101.4%)	6.6	+21.4%	45.0	7.3	+19.5%
Enhertu (US)	302.0	386.3	(99.7%)	84.2	+27.9%	466.3	80.0	+20.7%
Enhertu (EU)	149.6	174.8	(103.8%)	25.2	+16.9%	204.2	29.4	+16.8%
Enhertu (ASCA: Asia, South and Central America)	70.3	99.7	(103.0%)	29.4	+41.9%	145.9	46.2	+46.4%
Brazil	31.3	38.0	(105.9%)	6.7	+21.4%	46.9	9.0	+23.6%
China (co-promotion revenue)	10.3	20.0	(104.6%)	9.8	+95.1%	35.3	15.3	+76.3%
Others	28.7	41.7	(99.9%)	13.0	+45.2%	63.7	22.0	+52.7%
Upfront payment	10.2	10.2	(99.9%)	-	-	10.2	-	-
Regulatory milestone payment	29.2	23.8	(100.5%)	-5.5	-18.7%	26.9	3.1	+13.1%
US HER2+ Breast Cancer 3L	0.9	0.9	(100.0%)	-	-	0.9	-	-
EU HER2+ Breast Cancer 3L	0.5	0.5	(100.0%)	-	-	0.5	-	-
US HER2+ Gastric Cancer 2L/3L	0.8	0.8	(100.0%)	-	-	0.8	-	-
US HER2+ Breast Cancer 2L	0.9	0.9	(100.0%)	-	-	0.9	-	-
EU HER2+ Breast Cancer 2L	0.7	0.7	(100.0%)	-	-	0.7	-	-
US HER2-low Breast Cancer (post chemo)	1.9	1.9	(100.0%)	-	-	1.9	-	-
EU HER2-low Breast Cancer (post chemo)	1.4	1.4	(100.0%)	-	-	1.4	-	-
EU HER2+ Gastric Cancer 2L	0.3	0.3	(100.0%)	-	-	0.3	-	-
US HER2 mutant NSCLC 2L	1.2	1.2	(100.0%)	-	-	1.2	-	-
EU HER2 mutant NSCLC 2L	0.8	0.8	(100.0%)	-	-	0.8	-	-
US HER2-low Breast Cancer (pre chemo)	10.6	1.8	(100.0%)	-8.9	-83.3%	1.8	-	-
EU HER2-low Breast Cancer (pre chemo)	7.6	1.1	(100.0%)	-6.5	-86.1%	1.2	0.2	+17.0%
US HER2+ Solid Tumors	1.6	0.3	(100.0%)	-1.3	-83.3%	0.3	-	-
US HER2+ Breast Cancer 1L	-	11.3	(101.1%)	11.3	-	1.6	-9.7	-85.7%
US HER2+ Breast Cancer Neoaduvant	-	-	-	-	-	2.4	2.4	-
US HER2+ Breast Cancer Post Neoadjuvant	-	-	-	-	-	10.2	10.2	-
Quid related payment**	1.2	1.2	(100.0%)	-	-	1.2	-	-
Sales milestone payment	57.9	86.0	(106.6%)	28.0	+48.4%	93.8	7.8	+9.1%

* vs. Jan. Forecast

**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		FY2024 Results	FY2025 Results	(vs. Forecast (%))*	YoY	YoY (%)	FY2026 Forecast	YoY	YoY (%)
Datopotamab deruxtecan	anti-cancer agent (TROP2-directed antibody drug conjugate)	**7.8**	**56.1**	**(101.1%)**	**48.2**	**+618.0%**	**121.5**	**65.5**	**+116.8%**
Product sales	*Incl. Gross profit share in AstraZeneca territory	1.4	47.6	(101.3%)	46.2	-	111.4	63.8	+133.9%
Datroway (JPN)		0.3	13.1	(101.5%)	12.8	-	13.1	0.0	+0.1%
Datroway (US)		1.1	33.2	(101.2%)	32.1	-	92.2	59.0	+177.4%
Datroway (EU)		-	1.2	(104.6%)	1.2	-	2.3	1.1	+90.3%
Datroway (ASCA: Asia, South and Central America)		-	0.1	(70.3%)	0.1	-	3.8	3.7	-
Upfront payment		6.4	6.4	(100.0%)	-	-	6.4	-	-
Regulatory milestone payment		-	2.1	(99.8%)	2.1	-	3.8	1.7	+83.0%
US EGFR mutated NSCLC 3L		-	2.1	(99.8%)	2.1	-	0.4	-1.7	-82.4%
US TNBC		-	-	-	-	-	3.4	3.4	-
Patritumab deruxtecan	anti-cancer agent (HER3-directed antibody drug conjugate)	**19.8**	**13.1**	**(100.0%)**	**-6.7**	**-33.9%**	**12.0**	**-1.1**	**-8.2%**
Upfront payment		19.0	12.7	(100.0%)	-6.4	-33.6%	11.6	-1.0	-8.2%
Satisfaction of Quid Rights **		0.7	0.4	(100.0%)	-0.3	-43.4%	0.4	-0.0	-8.2%
Ifinatamab deruxtecan	anti-cancer agent (B7-H3-directed antibody drug conjugate)	**15.3**	**15.1**	**(100.0%)**	**-0.2**	**-1.3%**	**18.3**	**3.1**	**+20.5%**
Product sales		-	-	-	-	-	3.1	3.1	-
Ifinatamab deruxtecan (US)		-	-	-	-	-	3.1	3.1	-
Upfront payment		14.7	14.7	(100.0%)	-	-	14.7	-	-
Satisfaction of Quid Rights **		0.7	0.5	(100.0%)	-0.2	-29.4%	0.5	-	-
Raludotatug deruxtecan	anti-cancer agent (CDH6-directed antibody drug conjugate)	**6.7**	**21.5**	**(100.0%)**	**14.8**	**+220.0%**	**12.8**	**-8.8**	**-40.8%**
Upfront payment		6.2	21.1	(100.0%)	15.0	+242.9%	12.4	-8.8	-41.5%
Satisfaction of Quid Rights **		0.6	0.4	(100.0%)	-0.2	-29.4%	0.4	-	-
Edoxaban	anticoagulant	**344.0**	**367.7**	**(101.2%)**	**23.7**	**+6.9%**	**325.4**	**-42.3**	**-11.5%**
Lixiana (JPN)		133.0	141.8	(101.4%)	8.7	+6.6%	114.0	-27.7	-19.6%
Savaysa (US)		3.6	1.4	(98.5%)	-2.2	-60.6%	1.5	0.0	+2.4%
Lixiana (EU)		179.0	193.0	(101.5%)	14.0	+7.8%	175.5	-17.5	-9.1%
Edoxaban (ASCA etc.)		28.3	31.5	(99.2%)	3.1	+11.0%	34.4	2.9	+9.2%

* vs. Jan. Forecast

** "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		FY2024	FY2025				FY2026		
		Results	Results	(vs. Forecast (%))*	YoY	YoY (%)	Forecast	YoY	YoY (%)
Japan Business Unit		**476.9**	**485.8**	**(101.4%)**	**8.9**	**+1.9%**	**425.0**	**-60.8**	**-12.5%**
Lixiana	anticoagulant	133.0	141.8	(101.4%)	8.7	+6.6%	114.0	-27.7	-19.6%
Tarlige	pain treatment	55.6	65.4	(100.0%)	9.7	+17.5%	73.8	8.4	+12.9%
Pralia	Treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	42.2	45.8	(100.4%)	3.5	+8.3%	46.0	0.2	+0.5%
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	31.0	37.7	(101.4%)	6.6	+21.4%	45.0	7.3	+19.5%
Efient	antiplatelet agent	31.5	35.2	(103.9%)	3.7	+11.7%	7.9	-27.2	-77.4%
Vimpat	anti-epileptic agent	30.4	28.5	(103.8%)	-1.9	-6.2%	5.3	-23.2	-81.4%
Belsomra	Anti-Insomnia Treatment	9.9	18.6	(98.3%)	8.7	+87.9%	17.8	-0.8	-4.1%
Ranmark	treatment for bone complications caused by bone metastases from tumors	20.1	19.5	(101.5%)	-0.6	-3.1%	13.3	-6.1	-31.5%
Canalia	type 2 diabetes mellitus treatment	15.6	14.5	(100.9%)	-1.0	-6.6%	13.9	-0.6	-4.4%
Minnebro	antihypertensive agent	9.6	11.1	(99.2%)	1.4	+14.9%	13.8	2.7	+24.2%
Loxonin	anti-inflammatory analgesic	12.3	11.9	(106.5%)	-0.5	-3.7%	12.8	1.0	+8.1%
Emgality	prophylaxis of migraine attacks	10.7	12.8	(98.4%)	2.1	+19.4%	12.4	-0.3	-2.6%
Datroway	anti-cancer agent (TROP2-directed antibody drug conjugate)	0.3	13.1	(101.5%)	12.8	-	13.1	0.0	+0.1%
Inavir	anti-influenza treatment	19.9	1.6	(109.2%)	-18.3	-92.0%	6.0	4.5	+279.6%
Vaccines business		8.2	6.8	(96.0%)	-1.4	-17.2%	11.8	5.0	+73.4%
Daiichi Sankyo Healthcare Unit		**86.7**	**90.7**	**(99.2%)**	**4.1**	**+4.7%**	**98.1**	**7.4**	**+8.1%**

* vs. Jan. Forecast

4. Revenue by Business Units and Products (2)

JPY Bn		FY2024 Results	FY2025 Results	FY2025 (vs. Forecast (%))*	FY2025 YoY	FY2025 YoY (%)	FY2026 Forecast	FY2026 YoY	FY2026 YoY (%)
Oncology Business Unit		**463.8**	**608.8**	**(100.9%)**	**145.0**	**+31.3%**	**783.5**	**174.6**	**+28.7%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	451.6	561.1	(100.9%)	109.5	+24.2%	670.4	109.4	+19.5%
Enhertu (US)		302.0	386.3	(99.7%)	84.2	+27.9%	466.3	80.0	+20.7%
Enhertu (EU)		149.6	174.8	(103.8%)	25.2	+16.9%	204.2	29.4	+16.8%
Datroway	anti-cancer agent (TROP2-directed antibody drug conjugate)	1.1	34.4	(101.3%)	33.3	-	94.5	60.1	+174.4%
Datroway (US)		1.1	33.2	(101.2%)	32.1	-	92.2	59.0	+177.4%
Datroway (EU)		-	1.2	(104.6%)	1.2	-	2.3	1.1	+90.3%
Ifinatamab deruxtecan (US)	anti-cancer agent (B7-H3-directed antibody drug conjugate)	-	-	-	-	-	3.2	3.2	-
Turalio	anti-cancer agent	6.6	5.2	(107.8%)	-1.4	-21.3%	2.3	-2.9	-55.6%
Vanflyta	anti-cancer agent (FLT3 Inhibitor)	4.5	8.2	(93.7%)	3.6	+79.8%	13.0	4.8	+59.4%
American Regent Unit		**217.2**	**182.2**	**(101.3%)**	**-35.0**	**-16.1%**	**139.1**	**-43.2**	**-23.7%**
Injectafer	treatment for iron deficiency anemia	53.4	43.9	(103.8%)	-9.5	-17.8%	33.3	-10.6	-24.1%
Venofer	treatment for iron deficiency anemia	62.0	43.8	(100.6%)	-18.1	-29.2%	25.1	-18.8	-42.8%
GE injectables		89.0	80.4	(100.2%)	-8.6	-9.7%	64.5	-16.0	-19.8%
EU Specialty Business Unit		**237.4**	**276.6**	**(102.0%)**	**39.1**	**+16.5%**	**276.4**	**-0.2**	**-0.1%**
Lixiana	anticoagulant	179.0	193.0	(101.5%)	14.0	+7.8%	175.5	-17.5	-9.1%
Nilemdo/Nustendi	cholesterol-lowering agent	36.9	62.7	(101.8%)	25.8	+69.8%	86.5	23.8	+38.0%
Olmesartan	antihypertensive agent	18.3	18.3	(105.4%)	0.0	+0.2%	12.3	-6.1	-33.1%
ASCA Business Unit		**211.2**	**251.0**	**(101.6%)**	**39.8**	**+18.8%**	**292.8**	**41.8**	**+16.7%**
Daiichi Sankyo China		72.4	87.5	(100.8%)	15.1	+20.8%	99.8	12.3	+14.1%
Daiichi Sankyo Korea		33.0	34.7	(102.4%)	1.7	+5.1%	33.1	-1.6	-4.6%
Daiichi Sankyo Brasil Farmacêutica		50.6	60.0	(104.8%)	9.4	+18.6%	70.2	10.3	+17.1%
Daiichi Sankyo Taiwan		18.0	21.3	(101.6%)	3.3	+18.5%	21.3	-0.0	-0.1%

* vs. Jan. Forecast

4. Revenue by Business Units and Products (3)

[Reference] Revenue in Local Currency

		FY2024	FY2025				FY2026		
		Results	Results	(vs. Forecast (%))*	YoY	YoY (%)	Forecast	YoY	YoY (%)
USD Mn									
Oncology Business Unit		**3,040**	**4,038**	**(99.7%)**	**998**	**+32.8%**	**5,223**	**1,185**	**+29.3%**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	2,960	3,721	(99.7%)	761	+25.7%	4,470	748	+20.1%
Enhertu (US)		1,980	2,562	(98.5%)	582	+29.4%	3,108	547	+21.3%
Enhertu (EU)		980	1,159	(102.6%)	179	+18.3%	1,361	202	+17.4%
Datroway	anti-cancer agent (TROP2-directed antibody drug conjugate)	7	228	(100.2%)	221	-	630	402	+175.8%
Datroway (US)		7	220	(100.1%)	213	-	615	394	+178.9%
Datroway (EU)		-	8	(103.4%)	8	-	15	7	+91.3%
Ifinatamab deruxtecan (US)	anti-cancer agent (B7-H3-directed antibody drug conjugate)	-	-	-	-	-	21	21	-
Turalio	anti-cancer agent	43	34	(106.6%)	-9	-20.3%	15	-19	-55.1%
Vanflyta	anti-cancer agent (FLT3 Inhibitor)	30	54	(92.6%)	24	+81.9%	87	33	+61.3%
USD Mn									
American Regent Unit		**1,424**	**1,208**	**(100.2%)**	**-215**	**-15.1%**	**927**	**-281**	**-23.3%**
Injectafer	treatment for iron deficiency anemia	350	291	(102.6%)	-59	-16.8%	222	-69	-23.8%
Venofer	treatment for iron deficiency anemia	406	291	(99.4%)	-115	-28.4%	167	-124	-42.5%
GE injectables		584	533	(99.1%)	-50	-8.6%	430	-104	-19.4%
EUR Mn									
EU Specialty Business Unit		**1,450**	**1,582**	**(101.4%)**	**132**	**+9.1%**	**1,535**	**-47**	**-3.0%**
Lixiana	anticoagulant	1,093	1,104	(100.9%)	11	+1.0%	975	-129	-11.7%
Nilemdo/Nustendi	cholesterol-lowering agent	225	358	(101.3%)	133	+59.1%	480	122	+34.0%
Olmesartan	antihypertensive agent	112	105	(104.8%)	-7	-6.1%	68	-37	-35.0%

* vs. Jan. Forecast

5. Consolidated Statement of Financial Position

<Assets> JPY Bn

	Mar. 2025	Mar. 2026	vs. Mar. 2025
Assets			
Current assets			
Cash and cash equivalents	639.8	449.8	-190.0
Trade and other receivables	619.1	741.1	122.0
Other financial assets	80.9	104.7	23.8
Inventories	514.9	692.4	177.5
Other current assets	47.4	32.3	-15.2
Subtotal	1,902.2	2,020.3	118.2
Assets held for sale	7.3	122.2	114.9
Total current assets	**1,909.4**	**2,142.5**	**233.1**
Non-current assets			
Property, plant and equipment	498.5	596.6	98.0
Goodwill	108.4	97.4	-11.1
Intangible assets	235.8	241.1	5.2
Investments accounted for using the equity method	5.6	4.9	-0.7
Other financial assets	139.2	194.4	55.3
Long-term advance payments	167.4	192.9	25.5
Deferred tax assets	305.0	465.3	160.3
Other non-current assets	86.7	70.3	-16.3
Total non-current assets	**1,546.7**	**1,862.9**	**316.2**
Total assets	**3,456.1**	**4,005.4**	**549.3**

*	Liquidity on hand (Cash, Securities, Investment securities etc.)	676.0	551.3	-124.7
	Debt with interest	155.9	350.1	194.2
	Net Cash	520.1	201.2	-318.9

Partial sale of DSEP shares -7.3, DSHC assets' reclassification to assets held for sale +122.2

Acquisition +141.0, Depreciation -54.0, Impairment -4.8, Forex +25.8

Forex +5.9, Reclassification to assets held for sale -17.0

Acquisition +19.7, Depreciation -23.7, Impairment -1.1, Forex +12.7

Contribution for equipment -4.0

<Liabilities and equity>

JPY Bn

	Mar. 2025	Mar. 2026	vs. Mar. 2025
Liabilities			
Current liabilities			
Trade and other payables	580.0	596.9	16.9
Bonds and borrowings	0.4	0.4	0.0
Other financial liabilities	14.7	13.6	-1.1
Income taxes payable	60.4	88.3	27.9
Provisions	5.8	49.8	44.0
Contract liabilities	68.0	74.4	6.4
Other current liabilities	24.8	30.1	5.2
Subtotal	754.0	853.5	99.4
Liabilities directly associated with assets held for sale	-	31.6	31.6
Total current liabilities	**754.0**	**885.0**	**131.0**
Non-current liabilities			
Bonds and borrowings	100.9	300.1	199.1
Other financial liabilities	43.7	39.2	-4.5
Post employment benefit liabilities	1.6	1.5	-0.1
Provisions	13.0	164.6	151.5
Contract liabilities	751.0	806.8	55.8
Deferred tax liabilities	11.1	3.2	-7.8
Other non-current liabilities	157.4	140.8	-16.5
Total non-current liabilities	**1,078.7**	**1,456.2**	**377.5**
Total liabilities	**1,832.7**	**2,341.2**	**508.5**
Equity			
Equity attributable to owners of the Company			
Share capital	50.0	50.0	-
Own shares	-147.3	-248.0	-100.7
Other components of equity	263.7	311.6	47.9
Retained earnings	1,457.0	1,550.6	93.5
Total equity attributable to owners of the Company	1,623.4	1,664.2	40.8
Total equity	**1,623.4**	**1,664.2**	**40.8**
Total liabilities and equity	**3,456.1**	**4,005.4**	**549.3**

Corporate bonds +200.0

Deferred revenue for trastuzumab deruxtecan -8.0
(Strategic collaboration upfront payment -10.2, Regulatory milestone payment/Quid +9.4)
Deferred revenue for datopotamab deruxtecan -1.8
(Strategic collaboration upfront payment -6.4, Regulatory milestone payment +4.5)
Deferred revenue for US MRK alliance +63.3

Acquisition of own shares (DS) -106.5, Acquisition of own shares (share delivery trust) -43.9,
Cancellation of own shares +49.0

Currency translation difference +50.4, Valuation difference on financial assets -2.4

Profit for the period +259.8, Payment of dividends -128.5, Cancellation of own shares -40.3

6. Consolidated Statement of Cash Flows

JPY Bn

	FY2024	FY2025	YoY
Cash flows from operating activities			
Profit before tax	355.6	263.4	-92.2
Depreciation and amortization	68.6	77.5	8.8
(Increase) decrease in receivables and payables	-117.1	-108.8	8.3
Others, net	-145.0	-25.9	119.1
Income taxes paid	-108.3	-128.5	-20.2
Net cash flows from operating activities	**53.8**	**77.7**	**23.8**
Cash flows from investing activities			
Net (increase) decrease in time deposits and securities	499.7	-17.4	-517.1
(Acquisition of) proceeds from sales of fixed assets	-187.4	-149.0	38.4
Proceeds from sale of subsidiaries and affiliates	5.3	8.4	3.1
Net (increase) decrease in investment securities	16.1	12.1	-4.0
Others, net	0.5	-2.3	-2.8
Net cash flows from investing activities	**334.2**	**-148.2**	**-482.4**
Cash flows from financing activities			
Net (increase) decrease in borrowings	-0.4	-0.4	0.0
Proceeds from bonds and borrowings	-	200.0	200.0
Purchase of treasury shares	-246.1	-150.5	95.6
Dividends paid	-114.3	-128.4	-14.1
Others, net	-17.0	-18.6	-1.6
Net cash flows from financing activities	**-377.8**	**-97.9**	**279.9**
Net increase (decrease) in cash and cash equivalents	**10.2**	**-168.5**	**-178.7**
Cash and cash equivalents at the beginning of the period	**647.2**	**639.8**	**-7.3**
Effect of exchange rate changes on cash and cash equivalents	**-17.6**	**17.6**	**35.2**
Cash and cash equivalents at the end of the period	**639.8**	**489.0**	**-150.9**
Transfer to Assets held for sale	**-**	**-39.2**	**-39.2**
Cash and cash equivalents at the end of the period (Amount on Consolidated Statement of Financial Position)	**639.8**	**449.8**	**-190.0**

*	**Free cash flows** (Cash flows from operating activities and investing activities)	**388.0**	**-70.6**	**-458.6**

7. Number of Employees

	Mar. 2025 Results	Mar. 2026 Results
Consolidated	19,765	20,171
Japan	9,362	9,531
North America	4,025	4,098
Europe	3,367	3,468
Others	3,011	3,074

8. Capital Expenditure, Depreciation and Amortization

JPY Bn	FY2024 Results	FY2025 Results	FY2026 Forecast
Capital expenditure	113.8	135.4	200.0
Depreciation and amortization	68.6	77.5	83.3
Property, plant and equipment	46.7	54.1	60.1
Intangible assets	21.9	23.3	23.2

9. Other Financial Indicators

	FY2024 Results		FY2025 Results	
Profit attributable to owners of the Company	295.8	JPY Bn	259.9	JPY Bn
Dividends	112.9	JPY Bn	144.3	JPY Bn
Average equity attributable to owners of the Company for the period	1,655.8	JPY Bn	1,643.8	JPY Bn
Return on Equity (ROE)	17.9	%	15.8	%
Dividend on Equity (DOE)	6.9	%	8.7	%

10. Summary of Product Outlines

Brand Name	Generic Name	Therapeutic Category	Launched	Origin	Marketing Alliance	Type of Alliance
Japan Business Unit						
Lixiana	edoxaban	anticoagulant	2011	Daiichi Sankyo		
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		
Vimpat	lacosamide	anti-epileptic agent	2016	UCB	UCB	Co-promotion
Ranmark	denosumab	treatment for bone complications caused by bone metastases from tumors	2012	Amgen		
Efient	prasugrel	antiplatelet agent	2014	Daiichi Sankyo Ube Industries		
Canalia	teneligliptin / canagliflozin	type 2 diabetes mellitus treatment	2017	Mitsubishi Tanabe	Mitsubishi Tanabe	Co-promotion
Loxonin	loxoprofen	anti-inflammatory analgesic	1986	Daiichi Sankyo		
Loxonin Poultice			2006	Lead Chemical		
Loxonin Tape			2008	Lead Chemical		
Loxonin Gel			2010	Daiichi Sankyo		
Inavir	laninamivir octanoate	anti-influenza treatment	2010	Daiichi Sankyo		
Minnebro	esaxerenone	antihypertensive agent	2019	Daiichi Sankyo		
Emgality	galcanezumab-gnlm	Prophylaxis of migraine attacks	2021	Eli Lilly Japan	Eli Lilly Japan	Co-promotion
Datroway	datopotamab deruxtecan	anti-cancer agent (TROP2-directed antibody drug conjugate)	2025	Daiichi Sankyo		
Belsomra	suvorexant	Anti-Insomnia treatment	2014*	MSD		

* Distribution rights were transferred from MSD to Daiichi Sankyo on October 1, 2024

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	Daiichi Sankyo, Inc.	Promotion (Daiichi Sankyo, Inc.)
Venofer	iron sucrose injection	treatment for iron deficiency anemia	2000	CSL Vifor	Fresenius	Co-marketing
EU Specialty Business Unit						
Lixiana	edoxaban	anticoagulant	2015	Daiichi Sankyo	Merck (MSD)	Co-marketing
Nilemdo/Nustendi	bempedoic acid, bempedoic acid / ezetimibe	cholesterol-lowering agent	2020	Esperion		
Olmesartan						
Olmetec	olmesartan	antihypertensive agent	2002	Daiichi Sankyo	Menarini Pfizer	Co-marketing
Olmetec Plus	olmesartan / hydrochlorothiazide		2005			
Sevikar	olmesartan / amlodipine		2009			
Sevikar HCT	olmesartan / amlodipine / hydrochlorothiazide		2010			

<11. Quarterly Data>

1. Consolidated Statement of Profit or Loss

JPY Bn	FY2024 Q1 Results	FY2024 Q2 Results	FY2024 Q3 Results	FY2024 Q4 Results	FY2024 to revenue	FY2024 Results	FY2025 Q1 Results	FY2025 Q2 Results	FY2025 Q3 Results	FY2025 Q4 Results	FY2025 to revenue	FY2025 Results	FY2025 YoY	FY2025 YoY (%)
Revenue	**436.2**	**446.6**	**484.8**	**518.7**	***100.0%***	**1,886.3**	**474.6**	**500.8**	**558.1**	**589.6**	***100.0%***	**2,123.0**	**236.8**	**+12.6%**
Cost of sales	95.0	98.0	128.4	94.3	*22.0%*	415.7	92.3	126.4	116.4	106.1	*20.8%*	441.3	25.6	+6.2%
Gross Profit	341.2	348.5	356.5	424.4	*78.0%*	1,470.5	382.3	374.3	441.7	483.5	*79.2%*	1,681.7	211.2	+14.4%
SG&A expenses	167.6	162.2	186.8	208.2	*38.4%*	724.8	180.0	201.2	229.2	249.2	*40.5%*	859.6	134.8	+18.6%
DXd ADC profit share	56.8	48.0	63.7	57.7	*12.0%*	226.2	60.6	72.6	90.0	82.4	*14.4%*	305.6	79.4	+35.1%
Other SG&A expenses	110.8	114.3	123.1	150.5	*26.4%*	498.6	119.4	128.6	139.2	166.8	*26.1%*	554.0	55.4	+11.1%
R&D expenses	100.7	92.6	107.3	132.3	*22.9%*	432.9	105.9	110.9	121.9	123.5	*21.8%*	462.1	29.3	+6.8%
Core Operating Profit	**72.9**	**93.7**	**62.4**	**83.8**	***16.6%***	**312.8**	**96.3**	**62.3**	**90.6**	**110.8**	***17.0%***	**360.0**	**47.1**	**+15.1%**
Temporary income	20.1	0.2	1.1	0.7		22.2	0.7	3.5	0.2	17.7		22.1	-0.1	
Temporary expenses	0.0	-0.0	2.2	0.9		3.1	0.3	18.2	1.3	133.2		153.0	149.9	
Operating Profit	**93.0**	**93.9**	**61.4**	**83.6**	***17.6%***	**331.9**	**96.7**	**47.5**	**89.5**	**-4.7**	***10.8%***	**229.1**	**-102.8**	**-31.0%**
Financial income/expenses	17.2	-11.6	20.9	-4.2		22.2	8.4	9.8	16.9	-2.3		32.8	10.6	
Share of profit or loss of investments accounted for using the equity method	0.1	0.1	0.1	1.2		1.5	0.4	0.4	0.3	0.5		1.5	0.1	
Profit before tax	**110.2**	**82.4**	**82.4**	**80.6**	***18.9%***	**355.6**	**105.4**	**57.8**	**106.7**	**-6.5**	***12.4%***	**263.4**	**-92.2**	**-25.9%**
Income taxes	24.8	21.1	20.5	-6.5		59.9	19.9	12.5	20.1	-48.9		3.6	-56.3	
Profit for the year	**85.4**	**61.3**	**61.9**	**87.2**	***15.7%***	**295.8**	**85.5**	**45.3**	**86.6**	**42.4**	***12.2%***	**259.9**	**-35.9**	**-12.1%**
Profit attributable to owners of the Company	**85.4**	**61.3**	**61.9**	**87.2**	***15.7%***	**295.8**	**85.5**	**45.3**	**86.6**	**42.4**	***12.2%***	**259.9**	**-35.9**	**-12.1%**
Tax rate	22.5%	25.6%	24.9%	-8.1%		16.8%	18.9%	21.6%	18.8%	751.0%		1.4%		
Overseas sales ratio	66.7%	65.5%	68.2%	71.0%		69.0%	69.2%	70.7%	70.6%	79.1%		72.7%		
Currency Rate (YTD Average)														
USD/JPY	155.89	152.62	152.56	152.57		152.57	144.60	146.04	148.75	150.78		150.78		
EUR/JPY	167.88	165.93	164.82	163.74		163.74	163.81	168.06	171.84	174.79		174.79		

2. Revenue of Global Products (1)

JPY Bn	FY2024 Q1 Results	FY2024 Q2 Results	FY2024 Q3 Results	FY2024 Q4 Results	FY2024 Results	FY2025 Q1 Results	FY2025 Q2 Results	FY2025 Q3 Results	FY2025 Q4 Results	FY2025 Results
Trastuzumab deruxtecan	**134.8**	**136.9**	**149.9**	**229.9**	**651.4**	**161.0**	**169.2**	**205.2**	**284.1**	**819.5**
Product sales	129.6	131.7	143.1	148.4	552.8	155.2	163.2	188.4	191.6	698.4
Enhertu(JPN)	7.8	7.8	8.0	7.5	31.0	8.4	9.6	10.6	9.2	37.7
Enhertu (US)	68.9	71.3	79.5	82.3	302.0	85.1	89.4	109.0	102.7	386.3
Enhertu (EU)	35.2	35.3	39.0	40.1	149.6	39.5	42.1	42.0	51.1	174.8
Enhertu (ASCA: Asia, South and Central America)	17.8	17.3	16.7	18.5	70.3	22.3	22.1	26.8	28.5	99.7
Brazil	8.5	6.8	7.4	8.5	31.3	8.1	8.6	10.9	10.4	38.0
China (co-promotion revenue)	2.4	2.8	1.6	3.4	10.3	4.5	4.8	4.9	5.9	20.0
Others	6.8	7.7	7.7	6.5	28.7	9.7	8.7	11.0	12.2	41.7
Upfront payment	2.6	2.6	2.6	2.6	10.2	2.6	2.6	2.6	2.6	10.2
Regulatory milestone payment	2.4	2.4	3.9	20.7	29.2	3.0	3.2	13.9	3.7	23.8
US HER2+ Breast Cancer 3L	0.2	0.2	0.2	0.2	0.9	0.2	0.2	0.2	0.2	0.9
EU HER2+ Breast Cancer 3L	0.1	0.1	0.1	0.1	0.5	0.1	0.1	0.1	0.1	0.5
US HER2+ Gastric Cancer 2L/3L	0.2	0.2	0.2	0.2	0.8	0.2	0.2	0.2	0.2	0.8
US HER2+ Breast Cancer 2L	0.2	0.2	0.2	0.2	0.9	0.2	0.2	0.2	0.2	0.9
EU HER2+ Breast Cancer 2L	0.2	0.2	0.2	0.2	0.7	0.2	0.2	0.2	0.2	0.7
US HER2-low Breast Cancer (post chemo)	0.5	0.5	0.5	0.5	1.9	0.5	0.5	0.5	0.5	1.9
EU HER2-low Breast Cancer (post chemo)	0.3	0.3	0.3	0.3	1.4	0.3	0.3	0.3	0.3	1.4
EU HER2+ Gastric Cancer 2L	0.1	0.1	0.1	0.1	0.3	0.1	0.1	0.1	0.1	0.3
US HER2 Mutant NSCLC 2L	0.3	0.3	0.3	0.3	1.2	0.3	0.3	0.3	0.3	1.2
EU HER2 Mutant NSCLC 2L	0.2	0.2	0.2	0.2	0.8	0.2	0.2	0.2	0.2	0.8
US HER2-low Breast Cancer (pre chemo)	-	-	-	10.6	10.6	0.4	0.4	0.4	0.4	1.8
EU HER2-low Breast Cancer (pre chemo)	-	-	-	7.6	7.6	0.1	0.3	0.3	0.3	1.1
US HER2+ Solid Tumors	-	-	1.5	0.1	1.6	0.1	0.1	0.1	0.1	0.3
US HER2+ Breast Cancer 1L	-	-	-	-	-	-	-	10.7	0.5	11.3
US HER2+ Breast Cancer Neoaduvant	-	-	-	-	-	-	-	-	-	-
US HER2+ Breast Cancer Post Neoadjuvant	-	-	-	-	-	-	-	-	-	-
Quid related payment	0.3	0.3	0.3	0.3	1.2	0.3	0.3	0.3	0.3	1.2
Sales milestone payment	-	-	-	57.9	57.9	-	-	-	86.0	86.0

2. Revenue of Global Products (2)

JPY Bn	FY2024 Q1 Results	FY2024 Q2 Results	FY2024 Q3 Results	FY2024 Q4 Results	FY2024 Results	FY2025 Q1 Results	FY2025 Q2 Results	FY2025 Q3 Results	FY2025 Q4 Results	FY2025 Results
Datopotamab deruxtecan	**1.6**	**1.6**	**1.6**	**3.0**	**7.8**	**8.7**	**12.1**	**17.6**	**17.7**	**56.1**
Product sales	-	-	-	1.4	1.4	5.3	10.4	15.9	16.0	47.6
Datroway (JPN)	-	-	-	0.3	0.3	2.2	3.5	4.1	3.4	13.1
Datroway (US)	-	-	-	1.1	1.1	3.1	6.6	11.4	12.1	33.2
Datroway (EU)	-	-	-	-	-	0.0	0.4	0.4	0.4	1.2
Datroway (ASCA: Asia, South and Central America)	-	-	-	-	-	-	0.0	0.0	0.0	0.1
Upfront payment	1.6	1.6	1.6	1.6	6.4	1.6	1.6	1.6	1.6	6.4
Regulatory milestone payment	-	-	-	-	-	1.8	0.1	0.1	0.1	2.1
US EGFR mutatad NSCLC 3L	-	-	-	-	-	1.8	0.1	0.1	0.1	2.1
US TNBC	-	-	-	-	-	-	-	-	-	-
Patritumab deruxtecan	**2.0**	**2.4**	**11.3**	**4.1**	**19.8**	**4.1**	**3.0**	**3.0**	**3.0**	**13.1**
Upfront payment	2.0	2.0	11.2	3.9	19.0	3.9	2.9	2.9	2.9	12.7
Satisfaction of Quid Rights	-	0.5	0.1	0.1	0.7	0.1	0.1	0.1	0.1	0.4
Ifinatamab deruxtecan	**3.7**	**4.1**	**3.8**	**3.8**	**15.3**	**3.8**	**3.8**	**3.8**	**3.8**	**15.1**
Product sales	-	-	-	-	-	-	-	-	-	-
Ifinatamab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Upfront payment	3.7	3.7	3.7	3.7	14.7	3.7	3.7	3.7	3.7	14.7
Satisfaction of Quid Rights	-	0.4	0.1	0.1	0.7	0.1	0.1	0.1	0.1	0.5
Raludotatug deruxtecan	**1.5**	**1.9**	**1.6**	**1.6**	**6.7**	**1.6**	**1.6**	**15.1**	**3.2**	**21.5**
Upfront payment	1.5	1.5	1.5	1.5	6.2	1.5	1.5	15.0	3.1	21.1
Satisfaction of Quid Rights	-	0.4	0.1	0.1	0.6	0.1	0.1	0.1	0.1	0.4
Edoxaban	**88.3**	**85.9**	**88.4**	**81.4**	**344.0**	**91.1**	**94.9**	**92.2**	**89.5**	**367.7**
Lixiana (JPN)	34.9	33.1	35.3	29.8	133.0	37.7	35.6	38.9	29.6	141.8
Savaysa (US)	1.0	0.8	1.0	0.8	3.6	0.4	0.3	0.4	0.3	1.4
Lixiana (EU)	45.4	45.2	45.0	43.3	179.0	45.7	51.1	44.3	51.9	193.0
Edoxaban (ASCA etc.)	7.0	6.8	7.2	7.4	28.3	7.3	7.9	8.6	7.6	31.5

3. Revenue by Business Units and Products (1)

JPY Bn	FY2024 Q1 Results	FY2024 Q2 Results	FY2024 Q3 Results	FY2024 Q4 Results	FY2024 Results	FY2025 Q1 Results	FY2025 Q2 Results	FY2025 Q3 Results	FY2025 Q4 Results	FY2025 Results
Japan Business Unit	**117.7**	**122.0**	**146.0**	**91.2**	**476.9**	**125.0**	**124.9**	**140.9**	**95.0**	**485.8**
Lixiana	34.9	33.1	35.3	29.8	133.0	37.7	35.6	38.9	29.6	141.8
Tarlige	14.2	13.6	15.1	12.7	55.6	16.5	15.6	18.1	15.1	65.4
Pralia	11.1	10.0	11.6	9.6	42.2	12.4	10.2	12.9	10.2	45.8
Enhertu	7.8	7.8	8.0	7.5	31.0	8.4	9.6	10.6	9.2	37.7
Efient	8.1	7.6	8.5	7.3	31.5	9.2	8.8	12.1	5.1	35.2
Vimpat	8.1	7.4	8.2	6.7	30.4	8.7	8.1	8.2	3.5	28.5
Belsomra	-	-	5.6	4.3	9.9	5.1	4.6	5.1	3.8	18.6
Ranmark	5.4	5.0	5.4	4.3	20.1	5.1	4.9	5.2	4.3	19.5
Canalia	4.3	3.9	4.1	3.3	15.6	3.9	3.8	3.8	3.0	14.5
Minnebro	2.6	2.2	2.6	2.2	9.6	2.8	2.5	3.1	2.7	11.1
Loxonin	3.5	3.3	3.3	2.2	12.3	2.9	3.0	3.5	2.5	11.9
Emgality	2.5	2.7	3.0	2.6	10.7	3.0	3.3	3.5	3.0	12.8
Datroway	-	-	-	0.3	0.3	2.2	3.5	4.1	3.4	13.1
Inavir	0.2	0.0	13.5	6.3	19.9	-	0.0	1.4	0.2	1.6
Vaccines business	0.7	12.0	15.0	-19.5	8.2	0.3	6.3	4.7	-4.5	6.8
Daiichi Sankyo Healthcare Unit	**20.0**	**22.5**	**24.9**	**19.3**	**86.7**	**20.9**	**25.0**	**24.6**	**20.2**	**90.7**

3. Revenue by Business Units and Products (2)

JPY Bn	FY2024 Q1 Results	FY2024 Q2 Results	FY2024 Q3 Results	FY2024 Q4 Results	FY2024 Results	FY2025 Q1 Results	FY2025 Q2 Results	FY2025 Q3 Results	FY2025 Q4 Results	FY2025 Results
Oncology Business Unit	**106.4**	**109.1**	**121.6**	**126.7**	**463.8**	**131.2**	**141.8**	**166.2**	**169.6**	**608.8**
Enhertu	104.1	106.6	118.5	122.4	451.6	124.6	131.5	151.1	153.9	561.1
Enhertu (US)	68.9	71.3	79.5	82.3	302.0	85.1	89.4	109.0	102.7	386.3
Enhertu (EU)	35.2	35.3	39.0	40.1	149.6	39.5	42.1	42.0	51.1	174.8
Datroway	-	-	-	1.1	1.1	3.1	7.0	11.8	12.5	34.4
Datroway (US)	-	-	-	1.1	1.1	3.1	6.6	11.4	12.1	33.2
Datroway (EU)	-	-	-	-	-	0.0	0.4	0.4	0.4	1.2
Ifinatamab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Turalio	1.5	1.7	1.9	1.5	6.6	1.6	1.3	1.2	1.0	5.2
Vanflyta	0.9	0.8	1.3	1.6	4.5	1.9	1.9	2.2	2.2	8.2
American Regent Unit	**55.9**	**52.2**	**61.8**	**47.3**	**217.2**	**49.3**	**47.5**	**45.2**	**40.3**	**182.2**
Injectafer	15.8	12.7	13.1	11.8	53.4	11.8	10.8	10.2	11.1	43.9
Venofer	16.3	13.4	21.3	10.9	62.0	13.1	13.8	9.2	7.8	43.8
GE injectables	20.6	23.1	24.2	21.1	89.0	21.0	19.9	21.7	17.9	80.4
EU Specialty Business Unit	**59.2**	**58.9**	**60.2**	**59.1**	**237.4**	**63.8**	**73.0**	**63.3**	**76.4**	**276.6**
Lixiana	45.4	45.2	45.0	43.3	179.0	45.7	51.1	44.3	51.9	193.0
Nilemdo/Nustendi	7.8	8.6	10.0	10.4	36.9	12.6	16.0	14.7	19.4	62.7
Olmesartan	5.3	4.2	4.4	4.4	18.3	5.0	5.3	3.8	4.2	18.3
ASCA Business Unit	**48.7**	**50.8**	**55.4**	**56.3**	**211.2**	**56.8**	**61.1**	**69.3**	**63.8**	**251.0**
Daiichi Sankyo China	15.7	18.4	19.6	18.7	72.4	21.8	21.2	24.5	19.9	87.5
Daiichi Sankyo Korea	8.2	8.2	8.4	8.1	33.0	8.4	9.4	8.9	8.0	34.7
Daiichi Sankyo Brasil Farmacêutica	12.3	11.2	12.9	14.2	50.6	11.6	13.9	18.2	16.3	60.0
Daiichi Sankyo Taiwan	4.6	4.4	4.7	4.2	18.0	5.2	5.6	5.6	4.9	21.3

3. Revenue by Business Units and Products (3) [Reference] Revenue in Local Currency	FY2024 Q1 Results	FY2024 Q2 Results	FY2024 Q3 Results	FY2024 Q4 Results	FY2024 Results	FY2025 Q1 Results	FY2025 Q2 Results	FY2025 Q3 Results	FY2025 Q4 Results	FY2025 Results
USD Mn										
Oncology Business Unit	**683**	**729**	**798**	**830**	**3,040**	**907**	**962**	**1,084**	**1,085**	**4,038**
Enhertu	668	713	777	802	2,960	862	892	984	984	3,721
Enhertu (US)	442	477	522	540	1,980	588	606	711	656	2,562
Enhertu (EU)	226	236	256	263	980	273	286	272	328	1,159
Datroway	-	-	-	7	7	22	48	78	81	228
Datroway (US)	-	-	-	7	7	22	45	75	78	220
Datroway (EU)	-	-	-	-	-	0	2	3	3	8
Ifinatamab deruxtecan (US)	-	-	-	-	-	-	-	-	-	-
Turalio	10	11	12	10	43	11	9	8	6	34
Vanflyta	6	5	8	11	30	13	13	14	14	54
USD Mn										
American Regent Unit	**359**	**349**	**405**	**310**	**1,424**	**341**	**322**	**292**	**254**	**1,208**
Injectafer	101	85	86	78	350	82	73	66	71	291
Venofer	105	90	140	72	406	90	93	59	48	291
GE injectables	132	154	159	139	584	145	135	141	113	533
EUR Mn										
EU Specialty Business Unit	**353**	**359**	**370**	**368**	**1,450**	**390**	**424**	**351**	**418**	**1,582**
Lixiana	271	276	277	270	1,093	279	297	245	283	1,104
Nilemdo/Nustendi	47	53	61	65	225	77	93	82	107	358
Olmesartan	31	26	27	27	112	31	30	21	23	105

<12. Historical Data>

1. Revenue of Global Products (1)

JPY Bn	FY2020 Results	FY2021 Results	FY2022 Results	FY2023 Results	FY2024 Results
Trastuzumab deruxtecan	**43.5**	**80.8**	**258.4**	**449.2**	**651.4**
Product sales	30.1	65.4	207.5	395.9	552.8
Enhertu (JPN)	4.4	9.6	11.7	23.9	31.0
Enhertu (US)	25.7	45.4	144.6	225.5	302.0
Enhertu (EU)	0.0	9.0	37.1	101.9	149.6
Enhertu (ASCA: Asia, South and Central America)	-	1.4	14.2	44.6	70.3
Brazil	-	0.4	9.7	23.5	31.3
China (co-promotion revenue)	-	-	-	6.5	10.3
Others	-	0.9	4.5	14.6	28.7
Upfront payment	9.8	9.8	9.8	10.1	10.2
Regulatory milestone payment	3.5	2.2	26.7	12.4	29.2
US HER2+ Breast Cancer 3L	0.9	0.9	0.9	0.9	0.9
EU HER2+ Breast Cancer 3L	1.0	0.5	0.5	0.5	0.5
US HER2+ Gastric Cancer 2L/3L	1.6	0.8	0.8	0.8	0.8
US HER2+ Breast Cancer 2L	-	-	3.5	0.9	0.9
EU HER2+ Breast Cancer 2L	-	-	2.7	0.7	0.7
US HER2-low Breast Cancer (post chemo)	-	-	7.3	1.9	1.9
EU HER2-low Breast Cancer (post chemo)	-	-	5.2	1.3	1.4
EU HER2+ Gastric Cancer 2L	-	-	1.3	0.3	0.3
US HER2 Mutant NSCLC 2L	-	-	4.6	1.2	1.2
EU HER2 Mutant NSCLC 2L	-	-	-	3.8	0.8
US HER2-low Breast Cancer (pre chemo)	-	-	-	-	10.6
EU HER2-low Breast Cancer (pre chemo)	-	-	-	-	7.6
US HER2+ Solid Tumors	-	-	-	-	1.6
QUID related payment	-	3.4	1.1	1.2	1.2
Sales milestone payment	-	-	13.2	29.6	57.9

1. Revenue of Global Products (2)

JPY Bn	FY2020 Results	FY2021 Results	FY2022 Results	FY2023 Results	FY2024 Results
Datopotamab deruxtecan	**3.9**	**6.1**	**7.1**	**6.4**	**7.8**
Product sales	-	-	-	-	1.4
Datroway (JPN)	-	-	-	-	0.3
Datroway (US)	-	-	-	-	1.1
Datroway (EU)	-	-	-	-	-
Datroway (ASCA: Asia, South and Central America)	-	-	-	-	-
Upfront payment	3.9	6.1	7.1	6.4	6.4
Regulatory milestone payment	-	-	-	-	-
US EGFR mutatad NSCLC 3L	-	-	-	-	-
Patritumab deruxtecan	**-**	**-**	**-**	**3.5**	**19.8**
Upfront payment	-	-	-	3.5	19.0
Satisfaction of Quid Rights	-	-	-	-	0.7
Ifinatamab deruxtecan	**-**	**-**	**-**	**6.6**	**15.3**
Upfront payment	-	-	-	6.6	14.7
Satisfaction of Quid Rights	-	-	-	-	0.7
Raludotatug deruxtecan	**-**	**-**	**-**	**2.8**	**6.7**
Upfront payment	-	-	-	2.8	6.2
Satisfaction of Quid Rights	-	-	-	-	0.6
Edoxaban	**165.9**	**205.6**	**244.0**	**287.7**	**344.0**
Lixiana (JPN)	77.4	92.5	105.1	115.6	133.0
Savaysa (US)	3.0	1.9	3.0	2.4	3.6
Lixiana (EU)	76.7	96.9	117.1	146.2	179.0
Edoxaban (ASCA etc.)	8.9	14.3	18.7	23.5	28.3

2. Revenue by Business Units and Products (1)

JPY Bn	FY2020 Results	FY2021 Results	FY2022 Results	FY2023 Results	FY2024 Results
Japan Business Unit	**489.1**	**489.5**	**457.9**	**518.9**	**476.9**
Lixiana	77.4	92.5	105.1	115.6	133.0
Tarlige	20.6	30.1	38.5	45.7	55.6
Pralia	34.6	37.9	40.2	42.8	42.2
Enhertu	4.4	9.6	11.7	23.9	31.0
Efient	14.1	16.7	20.9	25.6	31.5
Vimpat	14.5	18.3	21.9	25.7	30.4
Belsomra	-	-	-	-	9.9
Ranmark	19.3	20.4	20.4	20.4	20.1
Canalia	15.4	16.8	16.3	15.9	15.6
Minnebro	2.5	5.0	6.9	8.3	9.6
Loxonin	24.2	22.2	18.5	15.5	12.3
Emgality	-	4.6	6.3	7.6	10.7
Inavir	3.6	1.3	0.9	15.9	19.9
Vaccines business	18.5	14.8	13.4	27.7	8.2
Daiichi Sankyo Healthcare Unit	**67.2**	**64.7**	**70.3**	**76.0**	**86.7**

2. Revenue by Business Units and Products (2)	FY2020	FY2021	FY2022	FY2023	FY2024
JPY Bn	Results	Results	Results	Results	Results
Oncology Business Unit	**47.4**	**69.6**	**185.4**	**334.6**	**463.8**
Enhertu	25.7	54.4	181.6	327.4	451.6
Enhertu (US)	25.7	45.4	144.6	225.5	302.0
Enhertu (EU)	0.0	9.0	37.1	101.9	149.6
Datroway	-	-	-	-	1.1
Datroway (US)	-	-	-	-	1.1
Datroway (EU)	-	-	-	-	-
Turalio	1.8	2.8	3.8	5.3	6.6
Vanflyta	-	-	-	1.9	4.5
American Regent Unit	**121.7**	**149.5**	**187.4**	**203.4**	**217.2**
Injectafer	44.1	53.1	54.0	50.1	53.4
Venofer	28.8	33.8	51.3	60.9	62.0
GE injectables	41.8	54.7	71.6	81.0	89.0
EU Specialty Business Unit	**111.7**	**128.2**	**150.4**	**189.2**	**237.4**
Lixiana	76.7	96.9	117.1	146.2	179.0
Nilemdo/Nustendi	0.6	3.1	7.1	18.4	36.9
Olmesartan	21.5	20.3	20.0	19.6	18.3
ASCA Business Unit	**99.7**	**114.1**	**142.8**	**184.1**	**211.2**
Daiichi Sankyo China	45.6	53.3	58.3	70.5	72.4
Daiichi Sankyo Korea	19.6	23.2	25.6	29.2	33.0
Daiichi Sankyo Brasil Farmacêutica	10.5	13.7	27.8	42.0	50.6
Daiichi Sankyo Taiwan	8.3	10.0	13.3	16.0	18.0

2. Revenue by Business Units and Products (3) **[Reference] Revenue in Local Currency**	**FY2020** Results	**FY2021** Results	**FY2022** Results	**FY2023** Results	**FY2024** Results
USD Mn					
Oncology Business Unit	**447**	**619**	**1,369**	**2,314**	**3,040**
Enhertu	243	484	1,341	2,264	2,960
Enhertu (US)	243	404	1,067	1,560	1,980
Enhertu (EU)	0	80	274	704	980
Datroway	-	-	-	-	7
Datroway (US)	-	-	-	-	7
Datroway (EU)	-	-	-	-	-
Turalio	17	25	28	37	43
Vanflyta	-	-	-	13	30
USD Mn					
American Regent Unit	**1,148**	**1,330**	**1,383**	**1,407**	**1,424**
Injectafer	416	472	398	346	350
Venofer	272	300	379	421	406
GE injectables	394	487	529	560	584
EUR Mn					
EU Specialty Business Unit	**903**	**982**	**1,067**	**1,207**	**1,450**
Lixiana	620	742	831	933	1,093
Nilemdo/Nustendi	5	24	50	118	225
Olmesartan	174	155	142	125	112

◆ 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, CPS: combined positive score, CR: complete response, CRC: colorectal cancer, 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, ESSC: 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 teatment, TTR: time to response, UACR: urine albumin-creatinine ratio

◆ 5DXd ADCs

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

Antibody-drug conjugate which is composed of a humanized monoclonal antibody specifically targeting HER2, one of the Epidermal Growth Factor Receptor (EGFR) family proteins, and a covalently linked drug (payload) via a cleavable linker. Payload is a potent and membrane permeable DNA topoisomerase I inhibitor which enables elimination of both target tumor cells and the surrounding tumor cells. Drug-to-antibody ratio is approximately 8.
Brand name: ENHERTU (JP/US/EU/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 high risk of disease recurrence, post neo-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) Mar 2026: Filing accepted (US) Apr 2026: Filing accepted (CN) Dec 2025: Breakthrough Therapy Designation (US Mar 2026: Priority Review designation (US/CN)
Phase3 DESTINY-Breast06 NCT04494425 jRCT2061200028 AstraZeneca	HR positive, HER2 low or ultralow breast cancer, chemotherapy naïve	866	Randomized, open label, active controlled ・DS-8201 ・Physician's choice (capecitabine, paclitaxel or nab-paclitaxel)	Primary endpoint: PFS Secondary endpoint: OS, PFS, ORR, DOR, safety, etc.	JP/US/EU /Asia	FPD: Aug 2020 TLR：Apr 2024 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
Phase1b/2 DESTINY-Breast07 NCT04538742 AstraZeneca	HER2 positive breast cancer Part 1: 2L or later Part 2: 1L	245	Open label, two-part (dose escalation, dose expansion) ・DS-8201 + durvalumab ・DS-8201 + pertuzumab ・DS-8201 + paclitaxel ・DS-8201 + durvalumab + paclitaxel ・DS-8201 + tucatinib ・DS-8201	Primary endpoint: safety Secondary endpoint: ORR, PFS, DOR, OS, PK, etc.	US/EU/ Asia	FPD: Jan 2021
Phase1b DESTINY-Breast08 NCT04556773 AstraZeneca	HER2 low breast cancer chemotherapy naïve, post chemotherapy	138	Open label, two-part (dose escalation, dose expansion) ・DS-8201 + capecitabine ・DS-8201 + durvalumab + paclitaxel ・DS-8201 + capivasertib (AZD5363) ・DS-8201 + anastrozole ・DS-8201 + fulvestrant	Primary endpoint: safety Secondary endpoint: ORR, PFS, DOR, OS, PK, etc.	US/EU/ Asia	FPD: Jan 2021
Phase3 DESTINY-Breast09 NCT04784715 jRCT2031210130 AstraZeneca	HER2 positive breast cancer, 1L	1,157	Randomized, open label, active controlled ・DS-8201 ・DS-8201 + pertuzumab ・Taxane + trastuzumab + pertuzumab	Primary endpoint: PFS by BICR Secondary endpoint: OS, PFS by investigator, ORR, DOR, PK, safety, etc.	JP/US/EU /Asia	FPD: Jun 2021 TLR: Apr 2025 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
Phase3 DESTINY-Breast11 NCT05113251 jRCT2041210097 AstraZeneca	HER2 positive breast cancer, neoadjuvant therapy	927	Randomized, open label, active controlled ・DS-8201 ・DS-8201, followed by paclitaxel + trastuzumab + pertuzumab ・Doxorubicin + cyclophosphamide, followed by paclitaxel + trastuzumab + pertuzumab	Primary endpoint: pCR Secondary endpoint: EFS, IDFS, OS	JP/US/EU /Asia	FPD: Nov 2021 TLR: May 2025 Mar 2026: Approved (CN) Oct 2025: Filing accepted (US) Aug 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 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-820 + (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 blined, active controlled ・DS-8201 + rilvegostomig + (capecitabine or 5-FU) ・Pembrolizumab + trastuzumab + FP (5-FU + cisplatin) or CAPOX (capecitabine + oxaliplatin) ・Rilvegostomig + trastuzumab + FP (5-FU + cisplatin) or CAPOX (capecitabine + oxaliplatin)	Primary endpoint: PFS, OS Secondary endpoint: ORR, DOR, safety, PK, ADA, etc.	JP/US/EU /Asia	FPD: Mar 2025
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)

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
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)
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

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 2 DESTINY-Lung05 NCT05246514 AstraZeneca	NSCLC with HER2 exon 19 or exon 20 mutation, 2L or later	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
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) \S (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

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase3 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)
Phase3 DESTINY-Endometrial01 NCT06989112 AstraZeneca	HER2 expressing (IHC 3+/2+), pMMR endometrial cancer, 1L	600	Randomized, single blind, active controled ・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
Phase3 DESTINY-Endometrial02 NCT07022483 jRCT2031250423 AstraZeneca	HER2 expressing (IHC 3+/2+) endometrial cancer, adjuvant therapy	710	Randomized, open label, active controled ・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. Sep 2025: Filing** accepted (EU) **Filing based on results from this study, DESTINY-CRC02, DESTINY-Lung01 Sep 2023: Breakthrough Therapy Designation (US) Jan 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 2 DESTINY-PanTumor03 NCT06271837 AstraZeneca	HER2 expressing solid tumors	175	Non-randomized, open label ・DS-8201	Primary endpoint: ORR Secondary endpoint: DOR, DCR, BOR, PFS, OS, safety, PK, ADA	CN	FPD: Feb 2024 Apr 2026: Filing accepted (CN) Mar 2026: Priority Review Designation (CN)
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
Phase1 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	582	Open label ・DS-1062 ・DS-1062 in combination with approved or novel anticancer agents	Primary endpoint: ORR, safety Secondary endpoint: PFS, DOR, DCR, best percentage change in tumor size, ADA, PK, etc.	JP/US/EU/Asia	FPD: Sep 2022
Phase 3 TROPION-Lung01 NCT04656652 jRCT2071200104 AstraZeneca	NSCLC, 2L or later	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	165	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: FY2026 H2
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
Phase 3 TROPION-Lung10 NCT06357533 jRCT2031240095 AstraZeneca	Non-squamous NSCLC (without AGA and PD-L1 TC ≥ 50%), 1L	675	Randomized, open label, active controlled ・DS-1062 + rilvegostomig (AZD2936) ・Rilvegostomig (AZD2936) ・Pembrolizumab	Primary endpoint: ・PFS, OS (TROP2 biomarker positive) Secondary endpoint: ・PFS, OS (FAS) ・ORR, DOR, PK, immunogenecity, etc.	JP/US/EU /Asia	FPD: May 2024
Phase 3 TROPION-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/US) Feb 2026: Priority Review Designation (US)
Phase 3 TROPION-Breast03 NCT05629585 jRCT2061220087 AstraZeneca	TNBC with high risk of disease recurrence, post neo-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
Phase 3 TROPION-Breast04 NCT06112379 jRCT2031230723 AstraZeneca	TNBC, HR low and HER2 negative BC, neoadjuvant therapy and ajuvant 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
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

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
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 ajuvant therapy	630	Non-randomized, open label ・DS-1062 + durvalumab + single agent platinum as neoadjuvant therapy and durvalumab as adjuvant therapy ・DS-1062 + rilvegostpmig + single agent platinum as neoadjuvant therapy and rilvegostpmig 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	(Exceptp 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
Phase2 HERTHENA-Breast03 NCT06797635 MRK	High-risk early stage TNBC, HR low and HER2 negative BC, neoadjuvant therapy	372	non-randomized (part 1), randomized (part 2), open label, active controlled ・Pembrolizimab + 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)	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
Phase3 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
Phase1/2 LIGHTBEAM-U01 NCT06941272 MRK	Relapsed or refractory hepatoblastoma or rhabdomyosarcoma (pediatric)	50	open label ・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
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

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

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 2 KEYMAKER-U01 substudy 01G NCT06731907 MRK	Stage IV NSCLC, 1L	90	Randomized, single-blined, active controlled ・U3-1402 + pembrolizumab ・Non-squamous NSCLC participants: pembrolizumab + pemetrexed + carboplatin ・Squamous NSCLC participants: pembrolizumab + (paclitaxel or nab-paclitaxel) + carboplatin * Umbrella study of pembrolizumab led by MRK	Primary endpoint: ORR, safety and tolerability Secondary endpoint: DOR, PFS, OS	US/EU/ Asia	FPD: May 2025
Phase1/2 in prep 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	FPD: TBA
Phase1/2 in prep 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	FPD: TBA

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

Antibody-drug conjugate which is composed of fully human monoclonal antibody specifically targeting B7-H3, one of the immunomodulatory molecules belonging to B7 family, and a covalently linked drug (payload) via a cleavable linker. Payload is a potent and membrane permeable DNA topoisomerase I inhibitor which enables elimination of both target tumor cells and the surrounding tumor cells. Drug-to-antibody ratio is approximately 4.

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1/2 IDeate-PanTumor01 NCT04145622 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 optomization 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	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)
Phase3 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/ 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
Phase 1/2 KEYMAKER-U06 substudy 06E NCT06780111 jRCT2041240166 MRK	ESCC, 1L	228	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
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/ Asis	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 fully human monoclonal antibody specifically targeting CDH6, one of the cadherin proteins relating to tumor growth and poor prognosis, and a covalently linked drug (payload) via a cleavable linker. Payload is a potent and membrane permeable DNA topoisomerase I inhibitor which enables elimination of both target tumor cells and the surrounding tumor cells. Drug-to-antibody ratio is approximately 8.

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT04707248 jRCT2031220075 MRK	Renal cell carcinoma, ovarian cancer	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 extention, 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: ・PFS (part A) ・ORR by investigator, DOR, DCR, OS, 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/ Asis	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)

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) Jan 2025: Filing accepted (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)

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

The molecular-targeted agent to inhibit CSF-1R, KIT and FLT3 specifically. This agent is expected to reduce tumor cell proliferation and expansion of metastases.
Brand name: TURALIO (US)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 NCT04488822	Tenosynovial giant cell tumor	40	Open label ・Pexidartinib	Primary endpoint: ORR Secondary endpoint: TVS, ROM, PROMIS, DOR, etc.	Asia	FPD: Sep 2020 TLR: May 2023 Development discontinued: Apr 2026
Phase 2 NCT04703322 jRCT2041200074	Tenosynovial giant cell tumor	9	Open label ・Pexidartinib	Primary endpoint: safety and tolerability, PK, ORR Secondary endpoint: safety, ORR, ROM, PROMIS, DOR, etc.	JP	FPD: Apr 2021 Development discontinued: Apr 2026

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	Primay endpoint: ORR, safety Secondary endpoint: PK, DOR, CR rate, safety, etc.	JP/US/EU /Asia	FPD: Jun 2021 TLR: Jun 2023 Jun 2024: Approved (JP) Apr 2019: SAKIGAKE Designation (JP) Dec 2021: Orphan Drug Designation (US)
Phase 2 NCT04842877 LYSA	Relapsed/refractory B-cell lymphoma	141	Non-Randomized, open label ・DS-3201	Primay endpoint: ORR Secondary endpoint: CRR, CR rate, PFS, DOR, TTR, safety, PK	EU	FPD: Jun 2021 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	FPD: Feb 2026

◆ Next Wave (Oncology Early-Stage Pipeline Products)

DS-1001 (Mutant IDH1 inhibitor)

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT03030066 JapicCTI-163479	Glioma	47	Open label ・DS-1001	Primary endpoint: tolerability Secondary endpoint: safety, PK, antitumor effect	JP	FPD: Jan 2017 Out-licensed development and commercialization rights in Japan to Nuvation Bio Inc.: Apr 2026
Phase 2 NCT04458272 JapicCTI-205339	Glioma	25	Open label ・DS-1001	Primary endpoint: ORR, safety Secondary endpoint: antitumor effect, TTR, DOR, PFS, OS, PK, etc.	JP	FPD: Jul 2020 TLR: Sep 2023 Out-licensed development and commercialization rights in Japan to Nuvation Bio Inc.: Apr 2026

DS-1103（anti-SIRPα antibody）

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 1 NCT05765851	HER2 expressing or mutant solid tumors (dose escalation part), HER2-low BC (dose expansion part)	78	Non-randomized, open label, two-part (dose escalation, dose expansion) ・DS-1103 + DS-8201	Primary endpoint: safety and tolerability, ORR by BICR Secondary endpoint: ORR by investigator, DCR, CBR, DOR, PK, ADA, etc.	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	540	Non-randomized, open label, two-part (dose escalation/part 1, dose expansion/part 2) ・DS-3939	Primary endpoint: ・ORR (part 2) ・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, two-part Part 1 ・MK-6070 + DS-7300 Part 2 ・MK-6070	Primary endpoint: safety and tolerability, ORR Secondary endpoint: DOR, PFS, PK, ADA	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-60700 + 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 (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 molecure 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
Phase1 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
Phase1/2 NCT07220616 jRCT2031250487	Relapsed or refractory B-cell non-Hodgkin lymphoma	420	open labell, 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 phase 2) Secondary endpoint: ・CRR (part 1) ・DCR, DOCR, DOR, TTR, PFS, OS	JP/US/EU /Asia	FPD: Feb 2026

◆ 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

◆ Next Wave (Vaccine)

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

In Japan, there is no approved trivalent mixed vaccine (MMR vaccine) containing three attenuated viruses of measles, mumps and rubella.

Study Name	Population	Sample Size	Study Design	Evaluation Items	Region	Status
Phase 3 JapicCTI-205118	Prevention of measles, mumps and rubella in healthy Japanese children aged 12 months or more and less than 24 months	840	Randomized, single-blind, active-controlled ・VN-0102/ JVC-001 ・Dry Live Attenuated Measles Rubella vaccine, Freeze-dried Live Attenuated Mumps vaccine	Primary endpoint: Seroprotection rates for measles, mumps and rubella Secondary endpoint: Seroconversion rates for measles, mumps, and rubella	JP	FSD: Feb 2020 Mar 2024: Filing accepted (JP)

◆ Stage-up Projects (Major Changes from the FY2025 Q3 Financial Announcement in January 2026)

Generic Name/Project Code Number Mechanism of action	Population	Current Stage	Note
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	High recurrence risk HER2 positive (IHC 3+ or ISH+) breast cancer, neoadjuvant therapy	Approved	CN, DESTINY-Breast11
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 positive solid tumors (intolerant to standard treatments)	Approved	JP, Approval based on results from HERALD study (IIS) and DESTINY-PanTumor02, etc.
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 positive gastric cancer, 2L	Indication expansion	JP, Indication expansion to include 2L gastric cancer based on prescribing information update following the results of the DESTINY-Gastric04 study
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 positive breast cancer with high risk of disease recurrence, post neo-adjuvant therapy	Filing accepted	JP/US/EU/CN, DESTINY-Breast05
Trastuzumab deruxtecan/DS-8201/ T-DXd HER2-directed ADC	HER2 positive (IHC 3+) solid tumors	Filing accepted	CN, DESTINY-PanTumor03* *China bridging study of DESTINY-PanTumor02
Datopotamab deruxtecan/DS-1062/ Dato-DXd TROP2-directed ADC	TNBC, not candidates for PD-1/PD-L1 inhibitor, 1L	Filing accepted	JP/US, TROPION-Breast02
Ifinatamab deruxtecan/ DS-7300/I-DXd B7-H3-directed ADC	ES-SCLC, 2L or later	Filing accepted	US, IDeate-Lung01
Ifinatamab deruxtecan/ DS-7300/I-DXd B7-H3-directed ADC	ESCC, 2L/3L	Ph2	JP/Asia, KEYMAKER-U06 substudy 06F

◆ Stage-up Projects (Major Changes from the FY2025 Q3 Financial Announcement in January 2026)

Generic Name/Project Code Number Mechanism of action	Population	Current Stage	Note
Gocatamig/MK-6070 (DS3280) DLL3 directed trispecific T-cell engager	ES-SCLC, 1L (induction and maintenance therapy)	Ph1b/2	US/Asia, MK-6070-003
DS3790 CD37-directed DXd ADC	Relapsed or refractory B-cell non-Hodgkin lymphoma	Ph1/2	JP/US/EU/Asia
Valemetostat/DS-3201 EZH1/2 inhibitor	CRPC	Ph1	JP/US

◆ Discontinued Project (Major Changes from the FY2025 Q3 Financial Announcement in January 2026)

Generic Name/Project Code Number Mechanism of action	Population	Study phase (region)	Reason
Pexidartinib/PLX3397 CSF-1/KIT/FLT3 inhibitor	Tenosynovial giant cell tumor	Ph3 (Asia)	Discontinuation based on strategic decision
Pexidartinib/PLX3397 CSF-1/KIT/FLT3 inhibitor	Tenosynovial giant cell tumor	Ph2 (JP)	Discontinuation based on strategic decision

◆ Out-licensing (Major Changes from the FY2025 Q3 Financial Announcement in January 2026)

Generic Name/Project Code Number Mechanism of action	Status
DS-1001 Mutant IDH1 inhibitor	Amended the existing exclusive license agreement for DS-1001 with Nuvation Bio Inc. to expand the licensed territory to include Japan, thereby granting Nuvation Bio Inc. worldwide exclusive development and commercialization rights for DS-1001