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Compassion for Patients.™



FY2025 Q3 Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Koji Ogawa
Senior Executive Officer, CFO
January 30, 2026

Forward-Looking Statements



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Agenda

① FY2025 Q3 Financial Results

② Business Update

③ R&D Update

④ Appendix



◆ FY2025 Q3 YTD Financial Results

➤ Revenue

Significant increase in consolidated revenue led by ENHERTU® and DATROWAY® product sales growth

➤ Core Operating Profit

COGs ratio improved compared to Q2 FY25. Core operating profit increased +8.8% YoY

➤ Others

No additional major temporary expenses were incurred in Q3 FY25

◆ Consolidated Annual Forecast Update

➤ No update from October forecast

Overview of FY2025 Q3 Results



(Bn JPY)

	FY2024 Q3 YTD Results	FY2025 Q3 YTD Results	YoY	
Revenue	1,367.6	1,533.5	+12.1%	165.9
Cost of sales*¹	321.4	335.2		13.8
SG&A expenses *¹	516.6	610.4		93.7
DXd ADC profit share * ²	168.5	223.1		54.7
Other SG&A expenses	348.2	387.2		39.1
R&D expenses*¹	300.6	338.7		38.1
Core operating profit*¹	229.0	249.2	+8.8%	20.2
Temporary income*¹	21.5	4.4		-17.1
Temporary expenses*¹	2.2	19.8		17.6
Operating profit	248.3	233.8	-5.9%	-14.5
Profit before tax	275.0	270.0		-5.1
Profit attributable to owners of the Company	208.6	217.4	+4.2%	8.8
Currency	USD/JPY	152.56		-3.81
Exchange Rate	EUR/JPY	164.82		+7.02

*¹ As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed. Income and expenses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation, settlement, and other non-temporary and material gains and losses are included in the "temporary income and expenses". Temporary income and expenses are excluded from results for cost of sales, SG&A expenses and R&D expenses shown in the list above. The adjustment table from operating profit to core operating profit is stated in the reference data.

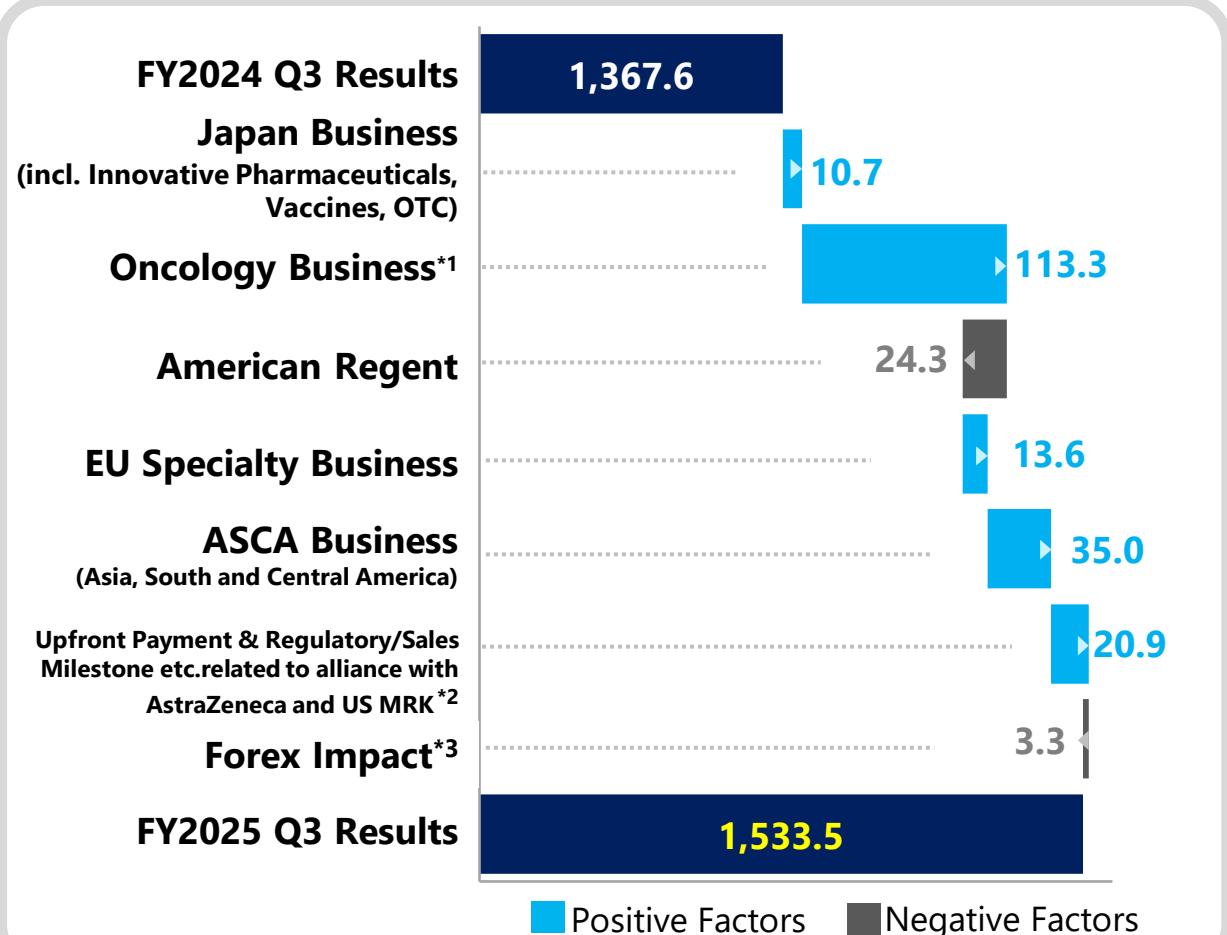
*² DS pays alliance partners 50% of gross profit for the product sales in countries/regions where DS book revenue (excluding Japan) to share profit with the partners.

Revenue



Increased by 165.9 Bn JPY (Increased by 169.2 Bn JPY excl. forex impact)

(Bn JPY)



Positive Factors		Negative Factors		
Japan Business Unit				
Datroway	+9.7	Inavir	-12.2	
Belsomra	+9.2	Realized gains of unrealized		
Lixiana	+8.9	gains of inventory for Daiichi		
Tarlige	+7.4	Sankyo Espha	-11.2	
<Ref> Net sales difference in vaccine biz after returns allowance	+0.3			
Oncology Business Unit¹				
Enhertu	+85.5	FY2024 Q3	FY2025 Q3	YoY
Datroway	+22.5	Revenue	27.7	11.3
		Returns allowance	-20.6	-4.0
		Net sales	7.1	7.4
				+0.3
American Regent Unit				
Venofer	-14.0			
Injectafer	-7.9			
EU Specialty Business Unit				
Nilemdo/Nustendi	+15.0			
ASCA (Asia, South and Central America) Business Unit				
Enhertu	+24.0			
Upfront Payment & Regulatory/Sales Milestone etc. related to alliance with AstraZeneca and US MRK *				
AstraZeneca	+13.5			
US MRK	+7.4			

*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products

*2 Merck & Co., Inc., Rahway, NJ, USA

*3 Forex impact USD: -13.6, EUR : +13.1, ASCA: -2.8

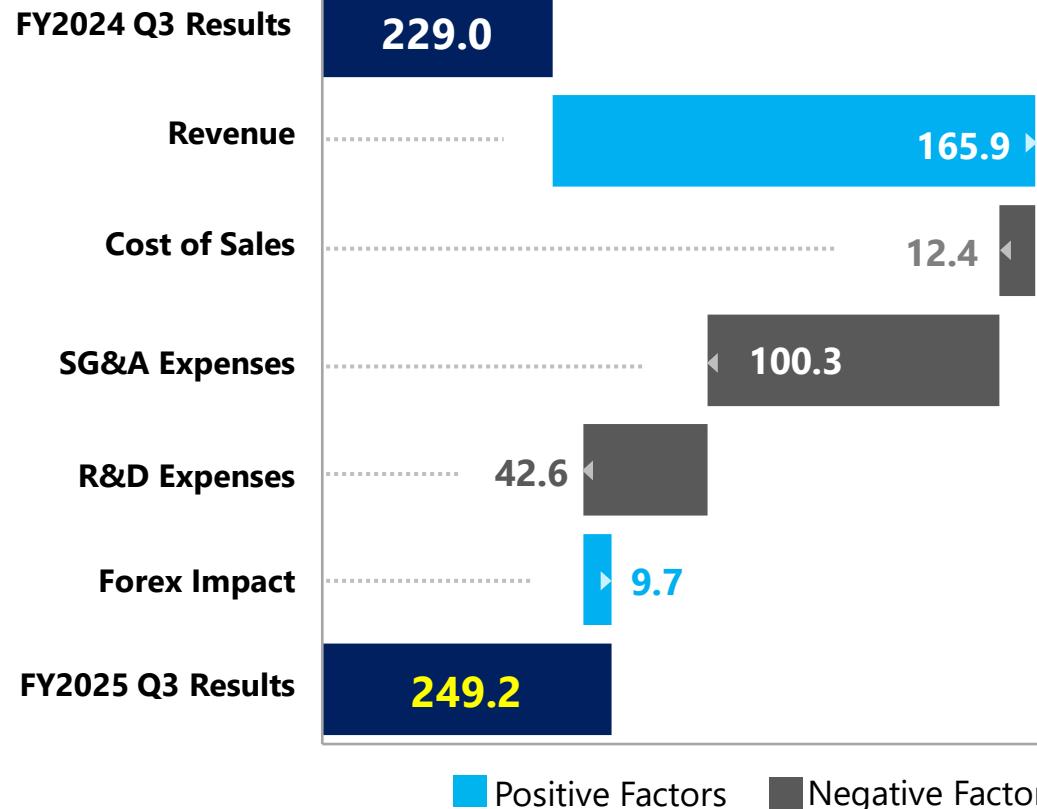
Core Operating Profit

Increased by 20.2 Bn JPY

(Increased by 13.8 Bn JPY excl. forex impact)

(Bn JPY)

FY2024 Q3 Results



Revenue +165.9

incl. forex impact of -3.3

Cost of Sales +12.4

Increase in expenses related to sales expansion

SG&A Expenses +100.3

Increase in expenses related to Enhertu and Datroway due to an increase in profit share of gross profit with AstraZeneca

R&D Expenses +42.6

Increase in 5DXd ADCs^{*1} R&D investments

Forex Impact^{*2} -9.7 (Profit Increased)

Cost of Sales +1.4 (Profit Decreased)

SG&A Expenses -6.6 (Profit Increased)

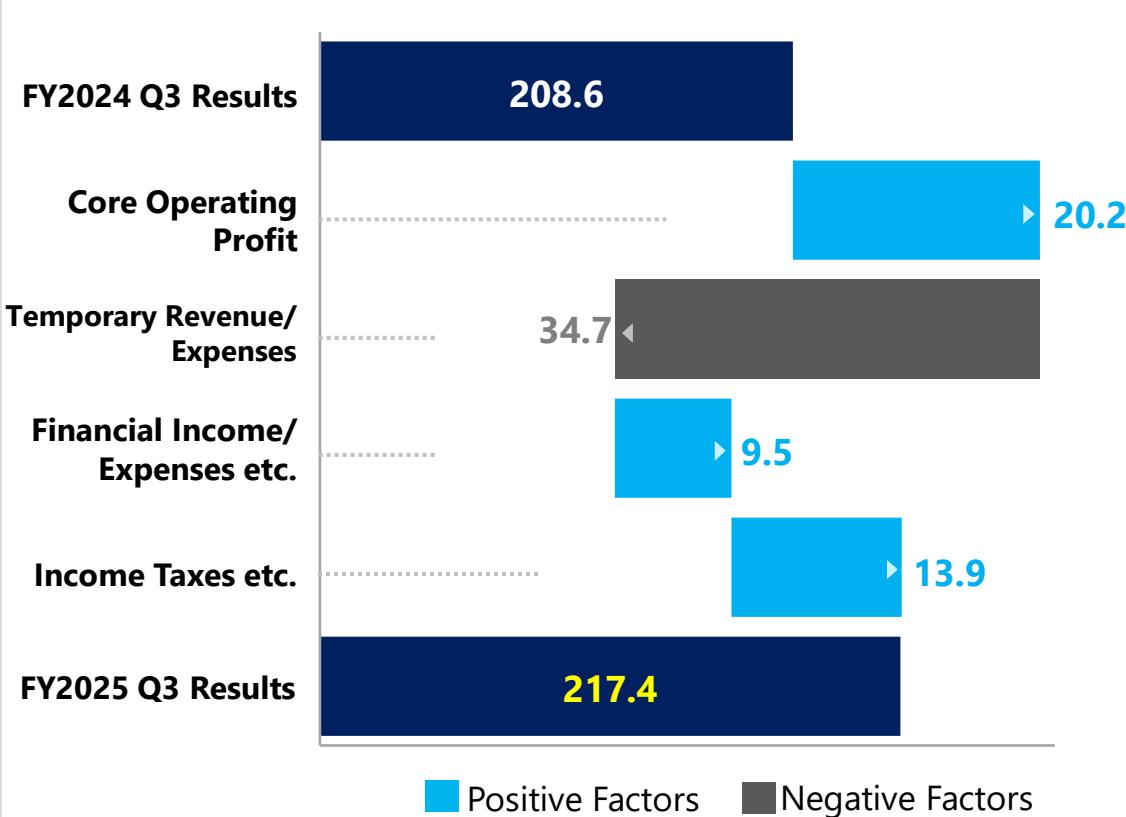
R&D Expenses -4.5 (Profit Increased)

*2 Forex Impact related to revenue (-3.3) is not included

Profit Attributable to Owners of the Company

Increased by 8.8 Bn JPY

(Bn JPY)



Temporary Income/Expenses -34.7 (Profit Decreased)

	FY2024 Q3 Results	FY2025 Q3 Results	YoY
Temporary Income	21.5* ¹	4.4* ²	-17.1
Temporary Expenses	2.2	19.8* ³	+17.6

*1 Gains on stock transfer of Daiichi Sankyo Espha (16.3)

*2 Incomes related to litigation with former shareholders of Ranbaxy(4.2)

*3 CMO Compensation Fee (12.6) / Write-down of Inventories of Datroway/HER3-DXd(4.7)

Financial Income/Expenses etc. +9.5 (Profit Increased)

- Improvement in forex gains/losses +11.3
- Improvement in investment securities valuation gains/losses +3.2
- Decrease in interest income -4.9

Income Taxes etc. -13.9 (Profit Increased)

	FY2024 Q3 Results	FY2025 Q3 Results	YoY
Profit before Tax	27.5	27.0	-5.1
Income Taxes etc.	66.4	52.5	-13.9
Tax rate	24.1%	19.4%	

Agenda

1 FY2025 Q3 Financial Results

2 Business Update

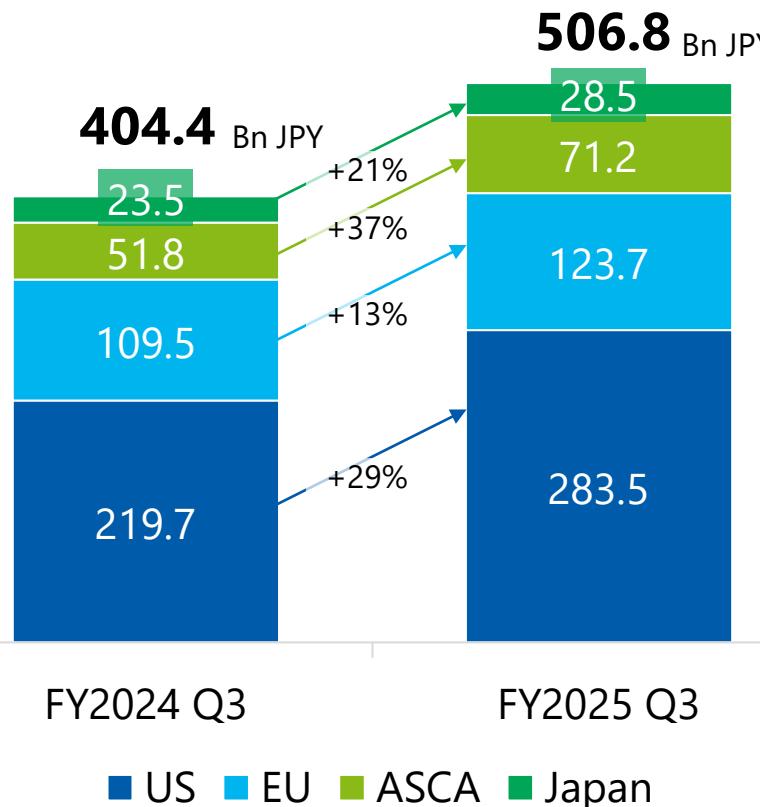
3 R&D Update

4 Appendix



Maintained No.1 new patient share across major countries and regions

New patient share continues to increase in HER2 positive BC 1L in US



Q3 YTD Global Product Sales Result **506.8 Bn JPY**
YoY +102.4 Bn JPY (+25.3%) Progress vs Oct. Forecast 73.0%

► New Indication Approvals

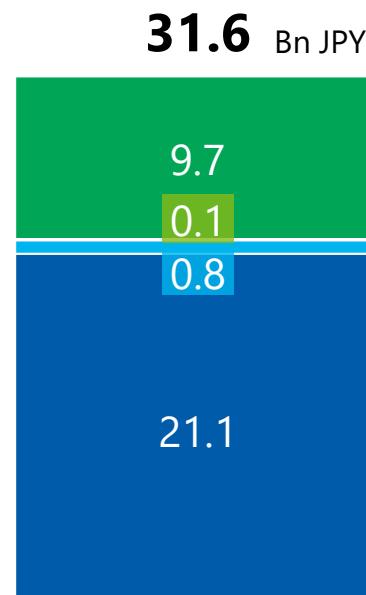
- HER2 positive BC 1L: Started to promote in US in Dec.
- HR positive, HER2 low or ultralow BC (chemo naïve): Started to promote in China in Dec.
- HER2 positive GC 2L: Started to promote in China in Jan.

► NCCN Guideline Updates

- Adjuvant therapy for HER2 positive BC with high risk of recurrence (category 1) **NEW!**
- HER2 positive BC 1L * (ENHERTU® + Pertuzumab) (category 2A) **NEW!**
- HER2 positive endometrial carcinosarcoma 2L+ (category 2A) **NEW!**
- HER2 positive esophageal cancer 2L (revised to category 1) **UPDATE**
- HER2 positive gastric cancer 2L (revised to category 1) **UPDATE**

* ENHERTU® monotherapy for HER2 positive BC 1L has already been included in NCCN guideline as category 2A recommendation based on DB-03 data

Treated more than 3,000 patients globally since launch, approx. 1.5 times the prior quarter
Robust sales growth over the initial forecast in US and Japan; US sales growth mainly driven by the lung cancer indication



FY2025 Q3

- US ■ EU ■ ASCA ■ Japan

Q3 YTD Global Product Sales Result **31.6 Bn JPY**
YoY +31.6 Bn JPY (-%)** Progress vs Oct. Forecast **83.8%****

► Annual Forecast Updated

- Jan. forecast **47.0 Bn JPY** (vs Oct. forecast +9.2 Bn JPY)
 - Larger number of eligible patients than expected due to high unmet needs and increased confidence in safety management

► Updates by Indication

- HR positive and HER2 negative BC: Steady sales growth in US and Japan
- EGFR-mutated NSCLC: Strong sales uptake in US as the only TROP2-directed ADC approved
 - New patient share primarily increased in 3L+

► NCCN Guideline Updates

- PD-L1 CPS<10 and non-BRCAm TNBC 1L (category 2A) **NEW!**
- Expansion of recommended EGFR mutation coverage in EGFRm NSCLC (category 2A) **UPDATE**

The U.S. Court of Appeals for the Federal Circuit (CAFC) Decisions

Dec. 2025:

- ◆ Patent Infringement Litigation: Reversed the decision that found Seagen (SGN)'s U.S. patent not invalid and vacated the order requiring DS to pay infringement damages
- ◆ Post Grant Review (PGR): Dismissed SGN's appeal as moot in view of invalidity finding in other appeal

Background and Key Developments

Patent Infringement Litigation

- ◆ Oct. 2023: The U.S. District Court for the Eastern District of Texas (the Texas District Court) issued a judgment ordering DS to pay SGN patent-infringement damages, including a royalty on U.S. sales of ENHERTU® from Apr. 1, 2022 through Nov. 4, 2024 (the expiry of SGN's U.S. patent)
- ◆ Nov. 2023: DS appealed to the U.S. Court of Appeals for the Federal Circuit seeking to reverse the Texas District Court

Post Grant Review (PGR)

- ◆ Jan. 2024: The U.S. Patent and Trademark Office rendered a Final Written Decision invalidating all challenged claims of SGN's U.S. patent in a PGR
- ◆ May 2024: SGN appealed to CAFC the Final Written Decision in a PGR

The 6th 5-year Business Plan Briefing



Date and Time	Tuesday, April 7, 2026, 6:30-8:30 pm EDT (Wednesday, April 8, 2026, 7:30-9:30 am JST)
Format	Virtual (Zoom) ☈Simultaneous interpretation will be provided

This content will be available on-demand at a later date

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③ R&D Update

④ Appendix



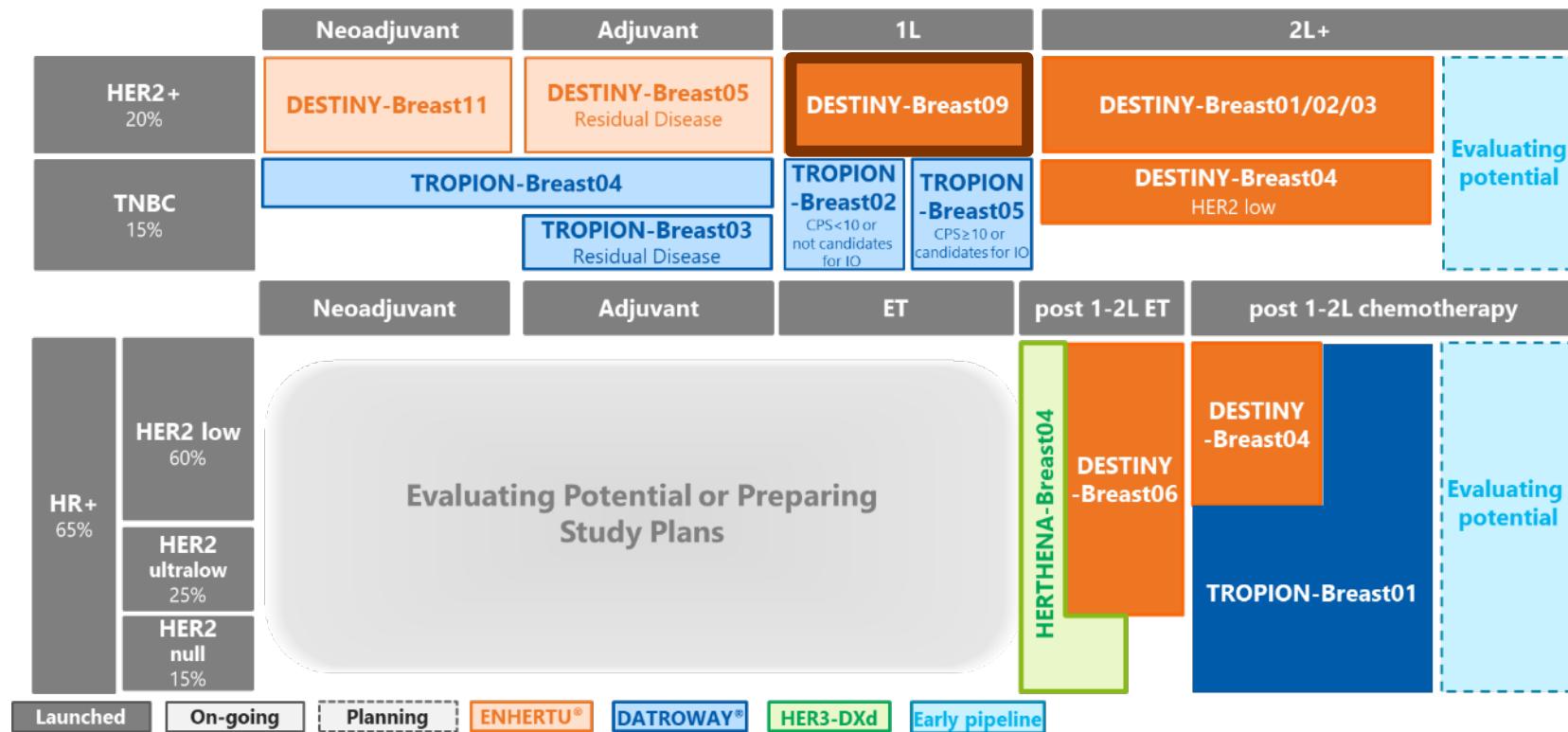
5DXd ADCs Update

Next Wave Update

News Flow

New indication approved based on DESTINY-Breast09*

Major Clinical Trials in the Breast Cancer



- Approved in US to combination with pertuzumab for the first-line treatment of patients with HER2 positive mBC in Dec 2025
- Approved under Real Time Oncology Review, following Priority Review and Breakthrough Therapy Designation

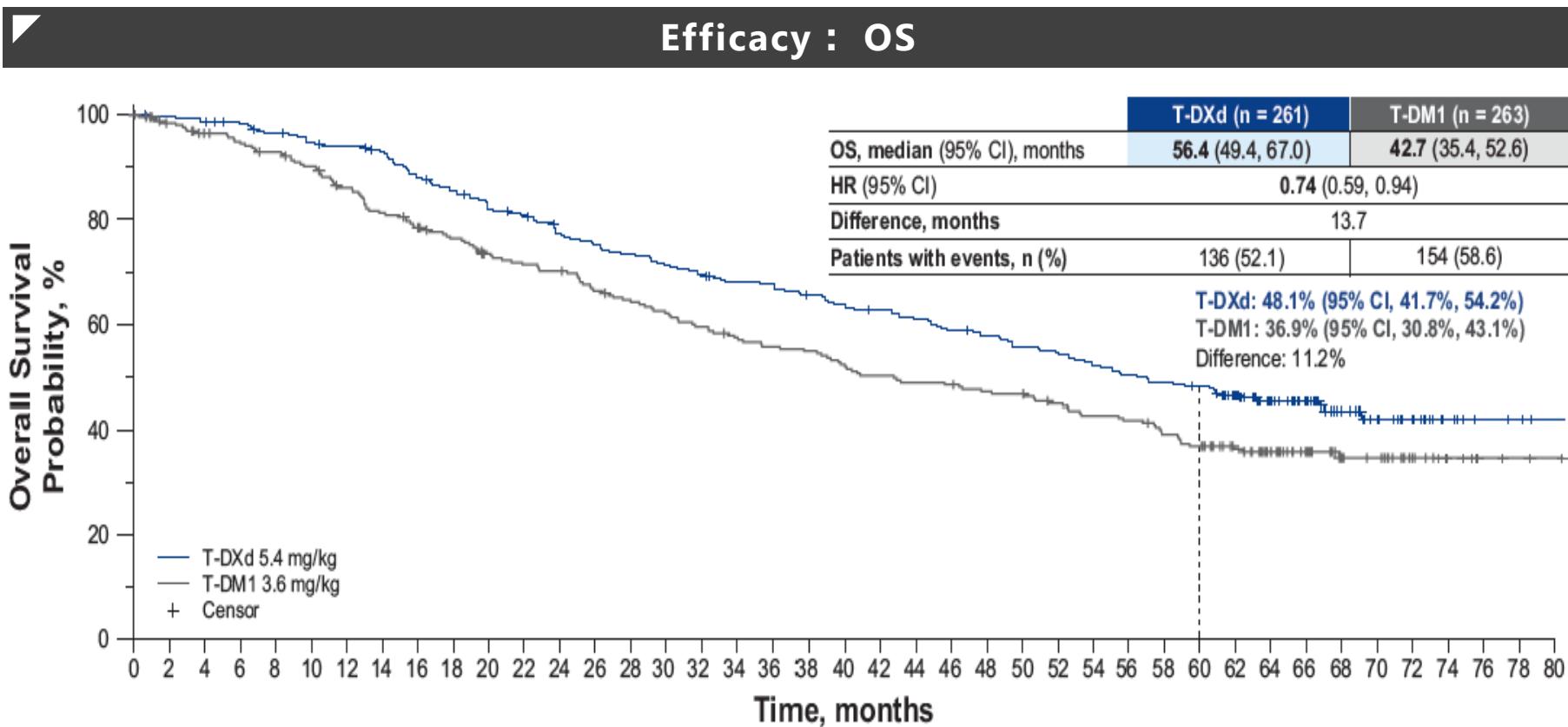
Regulatory status in other countries and regions

- Oct 2025: Filing accepted in Japan
- Nov 2025: Filing accepted in China
- Jan 2026: Filing accepted in EU
- As part of Project Orbis**, reviews are ongoing with multiple regulatory authorities

*Monotherapy arm remains until final analysis **Project Orbis provides a framework for concurrent submission and review of oncology medicines among participating international partners, may potentially allow patients to receive earlier access to products in other countries where there may be significant delays in regulatory submissions

CPS: combined positive score, ET: endocrine therapy, HR: hormone receptor, IO: immuno-oncology, mBC: metastatic breast cancer TNBC: triple-negative breast cancer

5-year OS results reinforce the durability and sustainability of the efficacy and long-term safety of ENHERTU® leading to improved survival outcomes



Data cutoff: June 27, 2025

- Median PFS was 29.0 months in ENHERTU® group compared with 7.8 months in T-DM1 group; estimated 5-year PFS rate was 37.6% and 10.0%, respectively
- Median OS was 56.4 months in ENHERTU® group and 42.7 months in T-DM1 group; estimated 5-year OS rate was 48.1% and 36.9%, respectively
- No new safety signals were observed with longer follow-up
- The rate of adjudicated drug-related ILD was 17.5% with ENHERTU®; no grade 4 or grade 5 events were reported during the trial

Indication expansion led by breast cancer are steadily progressing

HER2 positive BC post-neoadjuvant therapy (DESTINY-Breast05)

- Dec 2025: Granted Breakthrough Therapy Designation in US

HR positive and HER2 low or ultralow BC (chemo naïve) (DESTINY-Breast06)

- Dec 2025: Approved in China

HER2 positive GC, 2L (DESTINY-Gastric04)

- Jan 2026: Approved in China

Expanding benefits to broader HER2 expressing cancers

HER2 overexpressing NSQ NSCLC (w/o AGA and PD-L1 TPS <50%), 1L (DESTINY-Lung06)

- Oct 2025: Study started

HER2 expressing ovarian cancer, 1L maintenance therapy (DESTINY-Ovarian01)

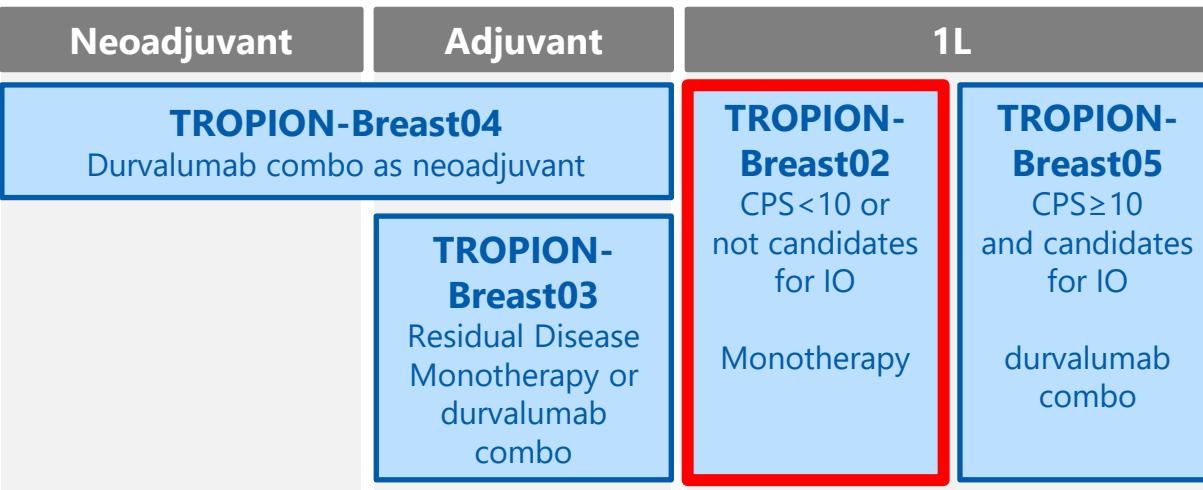
- Dec 2025: Study started (Randomization phase)

HER2 expressing endometrial cancer, adjuvant therapy (DESTINY-Endometrial02)

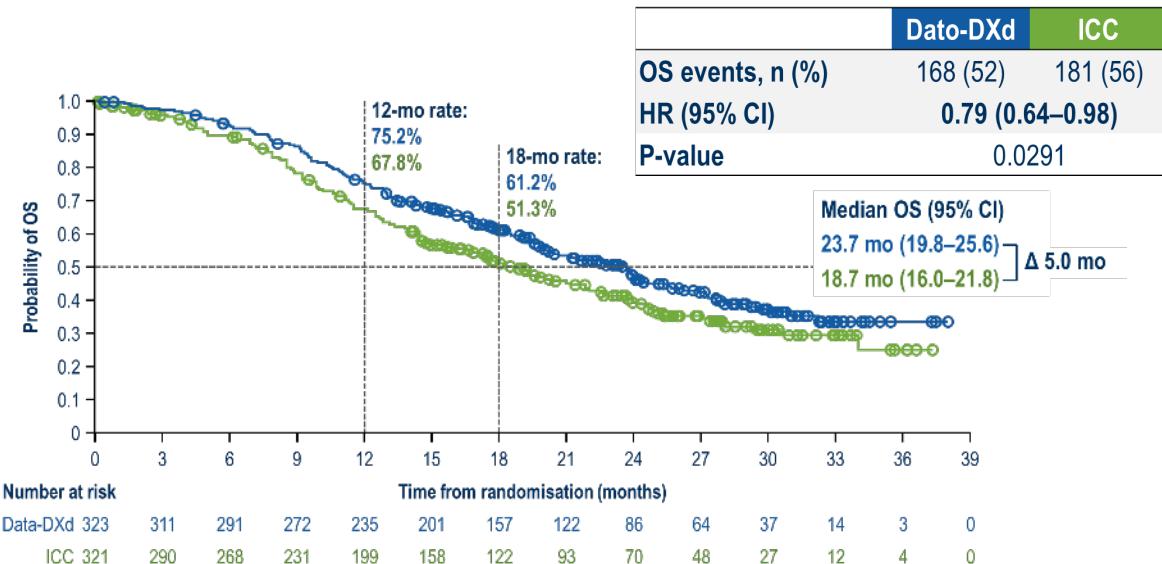
- Dec 2025: Study started

Regulatory submission accepted in the EU and China based on TROPION-Breast02 results

Ph3 studies of DATROWAY® in TNBC



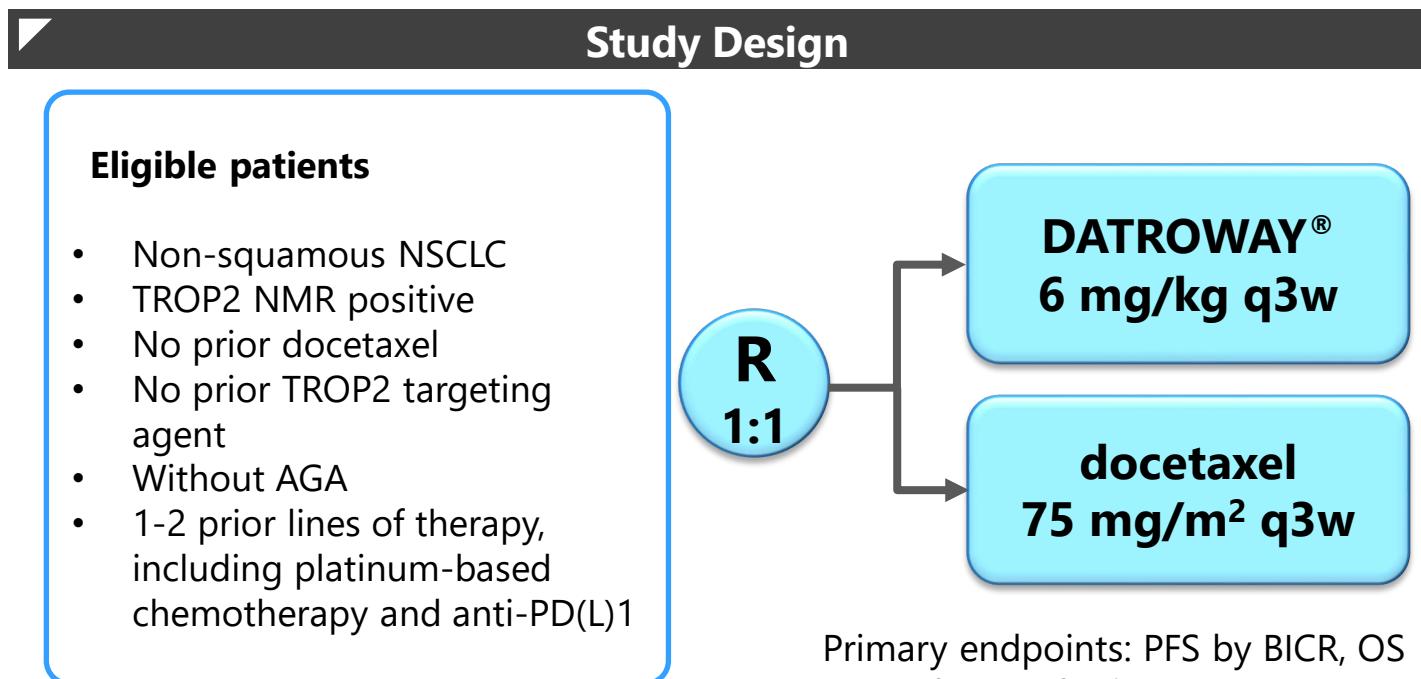
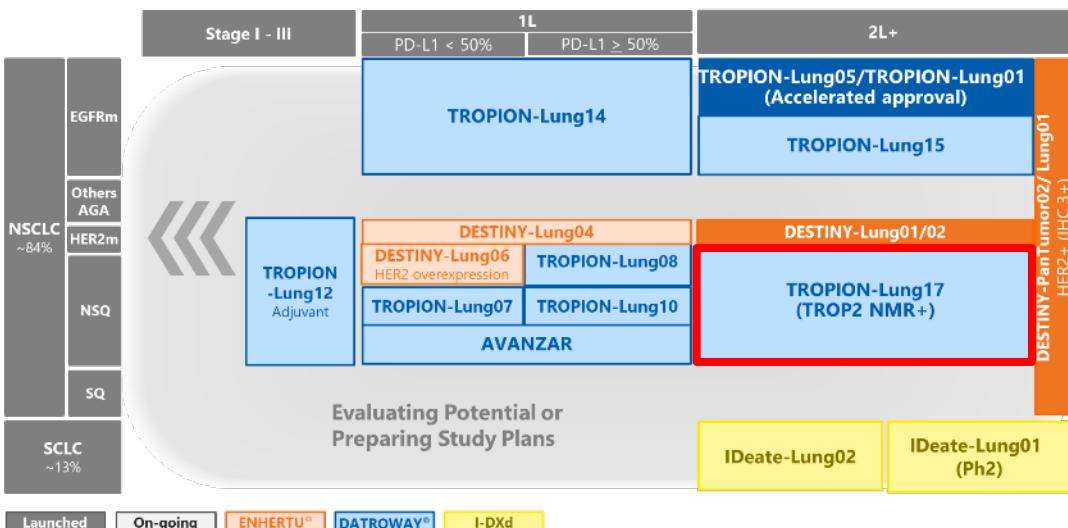
TROPION-Breast02 OS (ESMO 2025)



Data cutoff: August 25, 2025

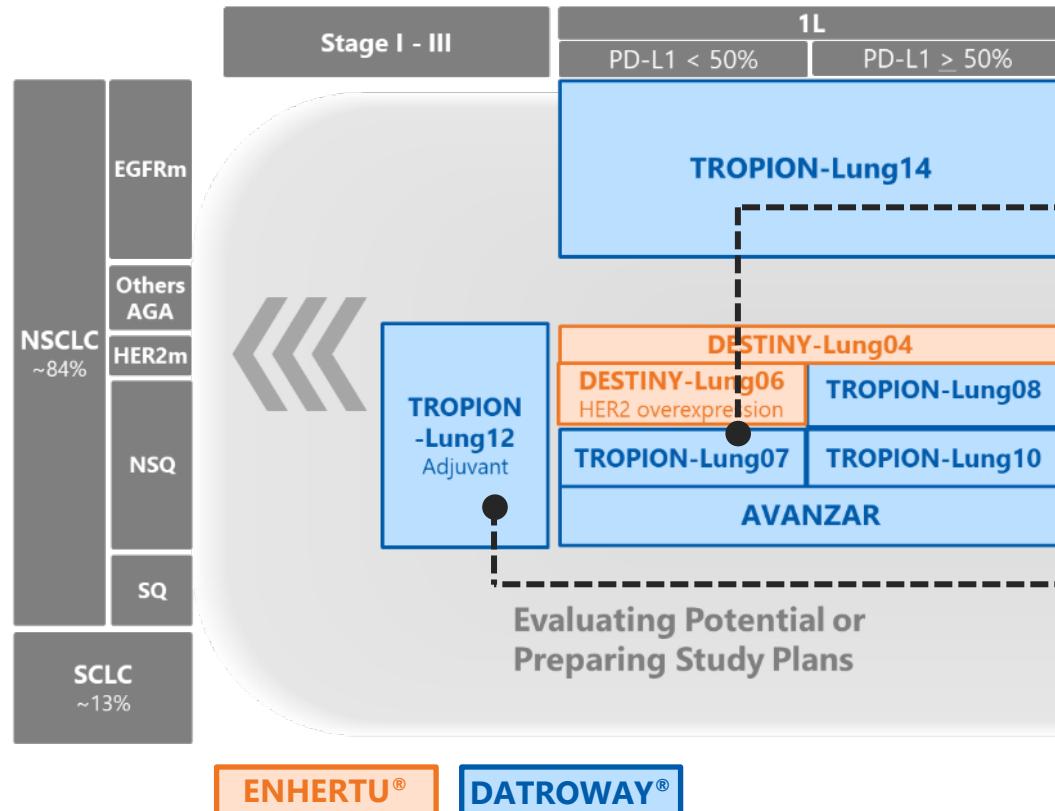
- Regulatory submission accepted in the EU and China for mTNBC who are not candidates for PD-1/PD-L1 inhibitor therapy in Dec 2025
- TROPION-Breast03, 04 and 05 are ongoing across early and mTNBC

TROP2 NMR biomarker explored in TROPION-Lung01 informed a new Ph3 study for NSCLC 2L+ treatment



- Develop DATROWAY® monotherapy as the new treatment opportunity for TROP2 NMR positive NSQ NSCLC 2L+
- Started in Jan 2026

TROPION-Lung07 leveraging TROP2 NMR biomarker to establish DATROWAY® as the preferred treatment option in 1L NSCLC



TROPION-Lung07

Non-AGA, PD-L1<50% NSQ NSCLC 1L, combination with pembrolizumab ± platinum chemo

- PFS and OS in TROP2 NMR positive population have been added as additional primary endpoints

TROPION-Lung12

Stage 1 NSCLC (ctDNA positive or have high-risk pathological feature), adjuvant, combination with rilvecostomig

- Recruitment into this study has been closed due to operational complexity

- ✓ There were no new safety signals

5DXd ADCs Update

Next Wave Update

News Flow

EZHARMIA®

- Plan to start Ph1 study combined with darolutamide for mCRPC

DS-9606 (CLDN6 directed mPBD ADC)

- Jan 2026: Internal development discontinued following a strategic portfolio review

DS3610 (STING agonist ADC/ target not disclosed)

- Nov 2025: Started FIH study for solid tumor

DS9051 (Targeted protein degradation molecule/ target not disclosed)

- Nov 2025: Started FIH study for solid tumors including CRPC

EZHARMIA® Award winning of the First Dual EZH1/2 Inhibitor



**Received "Prime Minister's Award"
for the 8th Japan Medical Research and Development Grand Prize***



- Obtained approval in Japan ahead of the rest of the world for relapsed or refractory adult T-cell leukemia lymphoma in 2022, and for relapsed or refractory peripheral T-cell lymphoma in 2024
- Recognized the healthcare contribution through establishing a new therapy targeting EZH1/2 epigenetic regulation

5DXd ADCs Update

Next Wave Update

News Flow

Upcoming regulatory decisions

ENHERTU®

DESTINY-Breast11: HER2 positive BC, neoadjuvant, Ph3
• US: FY2026 H1

Upcoming key data readouts

ENHERTU®

DESTINY-Lung04: HER2 mutation NSCLC, 1L, Ph3
• FY2026 H1

DATROWAY®

TROPION-Lung07: non-squamous NSCLC, w/o AGA, PD-L1 TPS <50%, pembrolizumab ± PBC combo, 1L, Ph3
• FY2026 H2

TROPION-Lung08*: NSCLC, w/o AGA, PD-L1 TPS ≥50%, pembrolizumab combo, 1L, Ph3
• FY2026 H2

TROPION-Lung15: EGFR mutated NSCLC progressed on prior osimertinib, mono or osimertinib combo, 2L+, Ph3
• FY2026 H2

AVANZAR*: NSCLC, w/o AGA, durvalumab + carboplatin combo, 1L, Ph3
• CY2026 H2

Bold: update from FY2025 Q2

Timeline indicated is based on the current forecast and subject to change

* Due to the protocol revision, the inclusion criteria are limited to non-squamous NSCLC

AGA: actionable genomic alteration, BC: breast cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, OVC: ovarian cancer, PBC: platinum-based chemotherapy, TNBC: triple negative breast cancer,

TPS: tumor proportion score, UC: urothelial cancer



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Agenda

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Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2024 Q3 YTD Results	FY2025 Q3 YTD Results	YoY
Japan Business	385.7	390.8	+5.2
Daiichi Sankyo Healthcare	67.4	70.6	+3.2
Oncology Business	337.2	439.2	+102.1
Enhertu	329.1	407.2	+78.1
Datroway	-	21.9	+21.9
Turalio	5.1	4.2	-0.9
Vanflyta	2.9	5.9	+3.0
American Regent	169.9	141.9	-28.0
Injectafer	41.6	32.8	-8.8
Venofer	51.0	36.1	-14.9
GE injectables	67.9	62.6	-5.3
EU Specialty Business	178.3	200.1	+21.8
Lixiana	135.6	141.1	+5.4
Nilemdo/Nustendi	26.5	43.3	+16.8
Olmesartan	13.9	14.1	+0.2
ASCA (Asia, South and Central America) Business	155.0	187.2	+32.2

Currency	USD/JPY	152.56	148.75	-3.81
Exchange Rate	EUR/JPY	164.82	171.84	+7.02

Revenue: Major Products in Japan



(Bn JPY)

		FY2024 Q3 YTD Results	FY2025 Q3 YTD Results	YoY
Lixiana	anticoagulant	103.2	112.1	+8.9
Tarlige	pain treatment	42.9	50.3	+7.4
Pralia	Treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	32.7	35.5	+2.9
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	23.5	28.5	+5.0
Efient	antiplatelet agent	24.2	30.1	+5.9
Vimpat	anti-epileptic agent	23.7	25.0	+1.4
Belsomra	Anti-Insomnia Treatment	5.6	14.8	+9.2
Ranmark	treatment for bone complications caused by bone metastases from tumors	15.7	15.2	-0.5
Canalia	type 2 diabetes mellitus treatment	12.3	11.5	-0.8
Minnebro	antihypertensive agent	7.4	8.4	+1.0
Loxonin	anti-inflammatory analgesic	10.1	9.3	-0.8
Emgality	prophylaxis of migraine attacks	8.1	9.8	+1.7
Datroway	anti-cancer agent (TROP2-directed antibody drug conjugate)	-	9.7	+9.7
Inavir	anti-influenza treatment	13.6	1.4	-12.2

5DXd ADCs Revenue (incl. Forex Impact)



(Unit: Bn JPY)

	FY2025 Q3 YTD Results	YoY	FY2025 Forecast(as of Jan.)	vs Oct Forecast
ENHERTU®	535.5	+113.9	805.6	-2.6
Product Sales	506.8	+102.4	689.9	-4.3
Upfront and Milestone Payments, etc.	28.6	+11.5	115.7	+1.7
DATROWAY®	38.4	+33.6	55.5	+9.2
Product Sales	31.6	+31.6	47.0	+9.2
Upfront and Milestone Payments, etc.	6.7	+2.0	8.4	-
HER3-DXd	10.1	-5.6	13.1	-
Upfront and Milestone Payments, etc.	10.1	-5.6	13.1	-
I-DXd	11.4	-0.2	15.1	-
Upfront and Milestone Payments, etc.	11.4	-0.2	15.1	-
R-DXd	18.3	+13.3	21.5	-
Upfront and Milestone Payments, etc.	18.3	+13.3	21.5	-
5DXd ADCs Total	613.6	+155.0	910.8	+6.6

5DXd ADCs Upfront and Milestone Payments



(Unit: Bn JPY)

Asset	Item	FY2025 Q3 YTD Results	YoY	FY2025 Forecast (as of Jan)	vs Oct Forecast	Total Consideration (as of Dec 2025)
ENHERTU®	Upfront Payment	7.7	-	10.2	-	149.0
	Regulatory Milestones	20.1	+11.5	23.7	+0.6	185.9
	Quid Related Payment	0.9	-	1.2	-	17.2
	Sales Milestone	-	-	80.6	+1.1	100.8
DATROWAY®	Upfront Payment	4.8	-	6.4	-	115.9
	Regulatory Milestones	2.0	+2.0	2.1	-	6.6
AZ Alliance Total		35.4	+13.5	124.1	+1.7	575.4
HER3-DXd	Upfront Payment	9.7	-5.4	12.7	-	224.9
	Satisfaction of Quid Rights	0.3	-0.3	0.4	-	7.3
I-DXd	Upfront Payment	11.0	-	14.7	-	225.4
	Satisfaction of Quid Rights	0.4	-0.2	0.5	-	7.3
R-DXd	Upfront Payment	18.0	+13.4	21.1	-	225.7
	Satisfaction of Quid Rights	0.3	-0.2	0.4	-	7.3
US Merck Alliance Total		39.8	+7.4	49.7	-	697.8

* "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

Temporary Expenses Itemized Breakdown



FY2025 Q3 YTD Results

(Unit: Bn JPY)

	Full base				Core base
	Cost of sales	SG&A expenses	R&D expenses	Total	Temporary expenses
CMO Compensation Fee	21.0	-8.6	0.2	12.6	12.6
Write-down of Datroway inventories	5.5	-2.8		2.7	2.7
Write-down of HER3-DXd inventories	3.5	-1.5		2.0	2.0
Others	1.4	0.2	0.9	2.5	2.5
Total	31.4	-12.7	1.1	19.8	19.8

Note: No additional major temporary expenses were incurred in Q3 FY25 (for reference: ¥18.5 billion on a Q2 FY25 YTD basis)

Major R&D Milestones : ENHERTU®



As of Jan 2026

Project	Population/regimen [phase, study name]	FY2025		FY2026
		H1	H2	
ENHERTU®	• HER2+ with high risk of recurrence, post neo-adjuvant [Ph3, DESTINY-Breast05]		• TLR obtained	
	• HR+/HER2 low or HER2 ultralow, chemo naive [Ph3, DESTINY-Breast06]	• Approved (JP) • Filing accepted (CN)	• Approved (CN)	
	• HER2+, 1L, pertuzumab combo* ¹ [Ph3, DESTINY-Breast09]	• TLR obtained • Filing accepted (US)	• Filing accepted (JP/EU/CN) • Approved (US)	
	• HER2+, neoadjuvant, mono followed by THP [Ph3, DESTINY-Breast11]	• TLR obtained • Filing accepted (US/CN)		• Regulatory decision anticipated (US)
	• HER2+, 2L [Ph3, DESTINY-Gastric04]	• Filing accepted (CN)	• Approved (CN)	
	• HER2 mutation, 1L [Ph3, DESTINY-Lung04]			• TLR anticipated
	• HER2 overexpression, w/o AGA, PD-L1 TPS <50%, 1L, pembrolizumab combo [Ph3, DESTINY-Lung06]		• Study started	
OVC	• HER2 expressing, bevacizumab combo [Ph3, DESTINY-Ovarian01]	• Study started (safety run-in phase)	• Study started (randomization phase)	
	• HER2 expressing, pMMR, 1L, rilvecostomig or pembrolizumab combo [Ph3, DESTINY-Endometrial01]	• Study started		
EC	• HER2 expressing, adjuvant [Ph3, DESTINY-Endometrial02]		• Study started	
	• HER2 expressing tumors [Ph2, DESTINY-PanTumor02]	• Filing accepted (JP/EU)		

Bold: update from FY2025 Q2

BC: breast cancer, EC: endometrial cancer, GC: gastric cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, OVC: ovarian cancer, pMMR: mismatch repair proficient,

THP: taxane (paclitaxel or docetaxel) + trastuzumab + pertuzumab, TLR: top line results

*¹ Monotherapy arm remains blinded until final PFS analysis Timeline indicated is based on the current forecast and subject to change

Major R&D Milestones : DATROWAY®



As of Jan 2026

Project	Population/regimen [phase, study name]	FY2025		FY2026
		H1	H2	
DATROWAY®	NSCLC	• EGFR mutated, previously treated EGFR-directed therapy and PBC [Ph2, TROPION-Lung05*1] • non-squamous, w/o AGA, PD-L1 TPS <50%, 1L, pembrolizumab ± PBC combo [Ph3, TROPION-Lung07] • w/o AGA, PD-L1 TPS ≥50%, 1L, pembrolizumab combo [Ph3, TROPION-Lung08*2] • EGFR mutated, progressed on prior osimertinib, 2L+, mono or osimertinib combo [Ph3, TROPION-Lung15] • non-squamous, TROP2 NMR+, w/o AGA, 2L+ [Ph3, TROPION-Lung17] • w/o AGA, 1L, durvalumab + carboplatin combo [Ph3, AVANZAR*2]	• Approved (US)	• TLR anticipated
				• TLR anticipated
				• TLR anticipated
				• TLR anticipated
			• Study started	
				• TLR anticipated (CY2026 H2)
BC		• HR+ and HER2 low or negative, 2/3L [Ph3, TROPION-Breast01] • TNBC, not candidates for PD-1/PD-L1 inhibitor therapy, 1L [Ph3, TROPION-Breast02]	• Approved (EU) • Approved (CN)	• TLR obtained • Filing accepted (EU/CN)
UC		• Post EV + pembrolizumab combo treatment, PBC combo [Ph2/3, TROPION-Urothelial03]		• Study started

Bold: update from FY2025 Q2

AGA: actionable genomic alterations, BC: breast cancer, EV: enfortumab vedotin, HR: hormone receptor, NSCLC: non-small cell lung cancer, PBC: platinum-based chemotherapy, TLR: top line results, TNBC: triple-negative breast cancer, TPS: tumor proportion score, UC: urothelial carcinoma

*1 Supported by data from TROPION-Lung01, TROPION-PanTumor01, *2 Due to the protocol amendment, the inclusion criteria are limited to non-squamous NSCLC

Timeline indicated is based on the current forecast and subject to change

Major R&D Milestones : HER3-DXd, I-DXd, R-DXd

As of Jan 2026

Project	Population/regimen [phase, study name]	FY2025		FY2026
		H1	H2	
HER3-DXd	NSCLC	<ul style="list-style-type: none"> EGFR mutated, 3L [Ph2, HERTHENA Lung01] 	<ul style="list-style-type: none"> Regulatory submission withdrawn (US) 	
	BC	<ul style="list-style-type: none"> TNBC, HR low and HER2 negative BC neoadjuvant [Ph2, HERTHENA-Breast03] HR+/HER2- BC, post ET and CDK4/6 inhibitor treatment [Ph3, HERTHENA-Breast04] 	<ul style="list-style-type: none"> Study started Study started 	
I-DXd	ES-SCLC	<ul style="list-style-type: none"> 2L+ [Dose expansion, Ph2, IDeate-Lung01] 	<ul style="list-style-type: none"> TLR obtained 	
I-DXd	ESCC	<ul style="list-style-type: none"> 2L [Ph3, IDeate-Esophageal01] 	<ul style="list-style-type: none"> Study started 	
	CRPC	<ul style="list-style-type: none"> Chemo naïve [Ph3, IDeate-Prostate01] 	<ul style="list-style-type: none"> Study started 	
R-DXd	OVC	<ul style="list-style-type: none"> Platinum-resistant, 2L+ [Ph2/3, REJOICE-Ovarian01] 	<ul style="list-style-type: none"> TLR obtained (Ph2 dose optimization) 	
	GI cancers	<ul style="list-style-type: none"> [Ph2, REJOICE-GI01] 	<ul style="list-style-type: none"> Study started 	

Bold: update from FY2025 Q2

BC: breast cancer, CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, ES-SCLC: extensive stage-small cell lung cancer, ET: endocrine therapy, GI: gastrointestinal, HR: hormone receptor,

NSCLC: non-small cell lung cancer, OVC: ovarian cancer, TNBC: triple-negative breast cancer, TLR: top line results

Timeline indicated is based on the current forecast and subject to change

Major R&D Milestones : Next Wave



As of Jan 2026

Project	Target indication [phase, study name]	FY2025		FY2026
		H1	H2	
EZHARMIA®	• CRPC, darolutamide combo [Ph1]		• Study start planned	
Gocatamig (MK-6070/DS3280)	• ES-SCLC, 1L, induction (I-DXd combo) and maintenance (I-DXd or atezolizumab combo) MK-6070-003 [Ph1b/2]		• Study start planned	
DS3610	• Solid tumors [Ph1]		• Study started	
DS5361	• Solid tumors [Ph1]		• Study started	
DS9051	• Solid tumors including CRPC [Ph1]		• Study started	
DS3790	• CD37-expressing hematological malignancies [Ph1/2]		• Study start planned	

Bold: update from FY2025 Q2

CRPC: castration-resistant prostate cancer, ES-SCLC: extensive stage-small cell lung cancer
Timeline indicated is based on the current forecast and subject to change

Major R&D Pipeline: 5DXd ADCs ①



As of Jan 2026

Phase 1	Phase 1/2	Phase 2
(US/EU/Asia) HER2 low BC chemo naïve/post chemo (combo) DESTINY-Breast08	(JP/US/EU/Asia) NSCLC	(US/EU/Asia) HER2+ BC 2L+/1L (chemo combo) DESTINY-Breast07
(US/EU/Asia) HER2 overexpressing non-squamous NSCLC 1L (ICI ± PBC combo) DESTINY-Lung03	(JP/US/EU/Asia) EGFR mutated NSCLC 1L/2L (osimertinib combo)	(JP/US/EU/Asia) HER2 expressing GC 2L+/1L (combo) DESTINY-Gastric03
(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US) renal cell carcinoma, ovarian cancer	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA
(JP/US/Asia) solid tumors (subcutaneous injection)		(JP/US/EU/Asia) solid tumors (saruparib combo) PETRA
(JP/US) solid tumors TROPION-PanTumor01		(US/EU/Asia) TNBC (durvalumab combo) BEGONIA
(JP/US/EU/Asia) NSCLC (w/o AGA) (pembrolizumab ± PBC combo) TROPION-Lung02		(JP/US/EU/Asia) solid tumors (saruparib combo) PETRA
(JP/US/EU/Asia) NSCLC (w/o AGA) ((durvalumab, rilvestomig or volrustomig) ± PBC or sabestomig combo) TROPION-Lung04		(CN) NSCLC, TNBC TROPION-PanTumor02
ENHERTU® (T-DXd)	DATROWAY® (Dato-DXd)	HER3-DXd
I-DXd	R-DXd	
★ Breakthrough Designation (US)		
★ Orphan drug designation (designated in at least one country/region among JP, US and EU)		

AGA: actionable genomic alterations, BTC: biliary tract cancer, BC: breast cancer, CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, ES-SCLC: extensive stage-small cell lung cancer, GC: gastric cancer, HBL: hepatoblastoma, HCC: hepatocellular carcinoma, ICI: immune checkpoint inhibitor, NSCLC: non-small cell lung cancer, PBC: platinum-based chemotherapy, r/r: relapse or refractory, RMS: rhabdomyosarcoma, SCLC: small cell lung cancer, TNBC: triple negative breast cancer

Major R&D Pipeline: 5DXd ADCs ②

As of Jan 2026

Phase 2/3		Phase 3		Regulatory phase
(JP/US/EU/Asia) UC post enfortumab vedotin + pembrolizumab combo treatment (PBC combo) TROPION-Urothelial03		(JP/US/EU/Asia) HER2+ BC (with high risk of recurrence) post neo-adjuvant DESTINY-Breast05	★	(EU/JP/CN) HER2+ BC 1L (pertuzumab combo) DESTINY-Breast09
(JP/US/EU/Asia) platinum-resistant ovarian cancer 2L+ REJOICE-Ovarian01	★ ★	(JP/US/EU/Asia) HER2+ BC 1L (mono) DESTINY-Breast09		(US/CN) HER2+ BC neoadjuvant (mono followed by THP) DESTINY-Breast11
		(JP/US/EU/Asia) HER2+ GC 1L (pembrolizumab + FP combo) DESTINY-Gastric05		(JP*¹/EU*²) HER2 expressing tumors DESTINY-PanTumor02 etc
		(JP/US/EU/Asia) HER2+ and PD-L1 CPS≥1 GC 1L (rilvegostomig + FP combo) ARTEMIDE-Gastric01		(EU/CN) TNBC (not candidates for PD-1/PD-L1 inhibitor therapy) 1L TROPION-Breast02
		(JP/US/EU/Asia) HER2 mutant NSCLC 1L DESTINY-Lung04		
		(JP/US/EU/Asia) HER2 overexpressing non-squamous NSCLC (w/o AGA, PD-L1 TPS < 50%) (pembrolizumab combo) DESTINY-Lung06		
		(JP/US/EU/Asia) HER2 expressing BTC 1L (rilvegostomig combo) DESTINY-BTC01		
		(JP/US/Asia) HER2 expressing ovarian cancer 1L maintenance (bevacizumab combo) DESTINY-Ovarian01		
		(JP/US/EU/Asia) HER2 expressing pMMR EC 1L (rilvegostomig or pembrolizumab combo) DESTINY-Endometrial01		(JP/US/EU/Asia) HR positive and HER2 negative BC post ET and CDK4/6 inhibitor treatment HERTHENA-Breast04
		(JP/US/EU/Asia) HER2 expressing EC adjuvant DESTINY-Endometrial02		(JP/US/EU/Asia) ES-SCLC 2L IDeate-Lung02
		(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1 TPS < 50%) 1L (pembrolizumab ± PBC combo) TROPION-Lung07		(JP/US/EU/Asia) ESCC 2L IDeate-Esophageal01
		(JP/US/EU/Asia) NSCLC (w/o AGA, PD-L1 TPS ≥ 50%) 1L (pembrolizumab combo) TROPION-Lung08		(JP/US/Asia) chemo-naïve CRPC IDeate-Prostate01
		(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1 TC ≥ 50%) 1L (rilvegostomig combo) TROPION-Lung10		
		(JP/US/EU/Asia) EGFR mutated NSCLC 1L (osimertinib combo) TROPION-Lung14		
		(JP/US/EU/Asia) EGFR mutated NSCLC (progressed on prior osimertinib) 2L+ (mono or osimertinib combo) TROPION-Lung15		

ENHERTU® (T-DXd) DATROWAY® (Dato-DXd)

HER3-DXd I-DXd R-DXd

*1 Filing based on this study and HERALD study (IIS), etc

*2 Filing based on this study, DESTINY-CRC02, DESTINY-Lung01

AGA: actionable genomic alterations, BC: breast cancer, BTC: biliary tract cancer, CPS: combined positive score, CRPC: castration-resistant prostate cancer, EC: endometrial cancer, ET: endocrine therapy, ES-SCLC: extensive stage-small cell lung cancer, FP: fluoropyrimidine, GC: gastric cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, PBC: platinum-based chemotherapy, pMMR: mismatch repair proficient, TC: tumor cells, TNBC: triple negative breast cancer, THP: taxane (paclitaxel or docetaxel) + trastuzumab + pertuzumab, TPS: tumor proportion score, UC: urothelial carcinoma

★ Breakthrough Designation (US)

★ Orphan drug designation (designated in at least one country/region among JP, US and EU)

Major R&D Pipeline: Next Wave

As of Jan 2026

Phase 1	Phase 1/2	Phase 2	Phase 3	Regulatory phase
DS-1103 (US/EU) Anti-SIRP α antibody HER2 expressing or mutant solid tumors, HER2 low BC (ENHERTU® combo)	DS-3939 (JP/US/EU/Asia) TA-MUC1-directed DXd ADC Solid tumors	EZHARMIA® (EU) EZH1/2 inhibitor BCL	TURALIO® (Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	VANFLYTA® (CN) FLT3 inhibitor FLT3 -ITD positive AML 1L QuANTUM-First
EZHARMIA® (JP/US) EZH1/2 inhibitor HER2+ GC, HER2 low BC (ENHERTU® combo) and non-squamous NSCLC (DATROWAY® combo)	Gocatamig (MK-6070/DS3280) (US) DLL3 directed trispecific T-cell engager DLL3 expressing advanced cancer (mono, I-DXd combo or atezolizumab combo) MK-6070-001	DS-1001 (JP) Mutant IDH1 inhibitor Glioma	VANFLYTA® (JP/US/EU/Asia) FLT3 inhibitor FLT3 -ITD negative AML 1L QuANTUM-Wild	VN-0102/JVC-001 (JP) Mixed measles-mumps-rubella vaccine
EZHARMIA® (TBA) in prep EZH1/2 inhibitor CRPC (darolutamide combo)	Gocatamig (MK-6070/DS3280) (US/EU/Asia) DLL3 directed trispecific T-cell engager ES-SCLC 2L+ (I-DXd combo) MK-6070-002	TURALIO® (JP) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor		
DS-2243 (US/EU/Asia) HLA-A*02/NY-ESO directed bispecific T-cell engager Solid tumors	Gocatamig (MK-6070/DS3280) (TBA) in prep DLL3 directed trispecific T-cell engager ES-SCLC 1L induction (I-DXd combo) and maintenance (I-DXd or atezolizumab combo) MK-6070-003			
DS3610 (JP) STING agonist ADC Solid tumors	EZHARMIA® (JP/US/Asia) EZH1/2 inhibitor NSCLC (w/o AGA and PD-L1 TPS $\geq 50\%$) 1L (pembrolizumab combo)			
DS5361 (JP/US) Small molecule NMD inhibitor Solid tumors	DS3790 (TBA) in prep CD37-directed DXd ADC CD37-expressing hematological malignancies			
DS9051 (US/EU) Targeted protein degradation (TPD) molecule Solid tumors including CRPC	DS-7011 (JP/US/EU/Asia) Anti-TLR7 antibody Systemic lupus erythematosus			

Oncology Specialty medicine Vaccine

 Orphan drug designation (designated in at least one country/region among JP, US and EU)

ADC: antibody-drug conjugate, AGA: actionable genomic alterations, AML: acute myeloid leukemia, BC: breast cancer, BCL: B cell lymphoma, CRPC: castration-resistant prostate cancer, ES-SCLC: extensive-stage small cell lung cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, TBA: to be announced, TPD: targeted protein degradation, TPS: tumor proportion score

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