

FY2026 Q1 Financial Results Presentation

DAIICHI SANKYO CO., LTD.

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CFO

July 31, 2026

Forward-Looking Statements

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Agenda

① **FY2025 Correction of Financial Results**

② FY2026 Q1 Financial Results

③ FY2026 Forecast

④ Business Update

⑤ R&D Update

⑥ Appendix



Correction of the Consolidated Financial Results for FY2025, Submitted to the Tokyo Stock Exchange on July 31, 2026

Consolidated Statements of PL

(Bn JPY)

	FY2025 (Before Update)	Correction Amount	FY2025 (After Update)
Revenue	2,123.0	-	2,123.0
Cost of sales	441.3	-	441.3
SG&A expenses	859.6	-29.0	830.6
DXd ADC profit share	305.6	-	305.6
Other SG&A expenses	554.0	-29.0	525.1
R&D expenses	462.1	-	462.1
Core operating profit	360.0	29.0	388.9
Temporary income	22.1	-	22.1
Temporary expenses	153.0	-	153.0
Operating profit	229.1	29.0	258.0
Profit before tax	263.4	29.0	292.4
Profit attributable to owners of the Company	259.9	19.9	279.7

Consolidated Statements of Financial Position

(Bn JPY)

Consolidated Statements of Financial Position	FY2025 (Before Update)	Correction Amount	FY2025 (After Update)
Total assets	4,005.4	-9.1	3,996.3
Total current assets	2,142.5	-	2,142.5
Total non-current assets	1,862.9	-9.1	1,853.8
Deferred tax assets	465.3	-9.1	456.2
Total liabilities and equity	4,005.4	-9.1	3,996.3
Total liabilities	2,341.2	-29.0	2,312.3
Total current liabilities	885.0	-29.0	856.1
Trade and other payables	596.9	-29.0	567.9
Total non-current liabilities	1,456.2	-	1,456.2
Total equity	1,664.2	19.9	1,684.0
Equity attributable to owners of the Company	1,664.2	19.9	1,684.0
Retained earnings	1,550.6	19.9	1,570.4

*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, reconciliation, and other temporary and material gains and losses are included in the "temporary income and expenses". Temporary income and expenses are excluded from results and forecast 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.

Please refer to the following updated materials reflecting the corrections.
https://www.daiichisankyo.com/investors/library/quarterly_result/2025/

5-Year Business Plan (FY2021-FY2025) Recap: Financial Targets (Updated)

**At the time of
planning 5YBP**

FY2025

Revenue	1.6 Tn JPY
Revenue in Oncology	> 600.0 Bn JPY
Core Operating Profit ratio before R&D	40%
ROE	> 16%
DOE	> 8%

2.1 Tn JPY
954.0 Bn JPY
40.1%
16.9%
8.7%

Currency exchange
rate assumptions

1 USD=105 JPY, 1 EUR=120 JPY

1 USD=150.78 JPY, 1 EUR=174.79 JPY

Agenda

① FY2025 Correction of Financial Results

② **FY2026 Q1 Financial Results**

③ FY2026 Forecast

④ Business Update

⑤ R&D Update

⑥ Appendix



◆ FY2026 Q1 Financial Results

Revenue	Significant increase in consolidated revenue led by ENHERTU® and DATROWAY® product sales growth
Operating Profit	Operating profit decreased by 12.0% YoY due to increased expenses resulting from restructuring expenses related to EU Specialty Business Unit

◆ FY2026 Forecast Update

Revenue	Due to a revision of the assumed USD exchange rate for the second quarter and onward, in addition to stronger-than-expected sales of ENHERTU® in US markets, revenue is updated to 2.34 Tr JPY, 60 Bn JPY higher than the previous forecast
Operating Profit	Due to the reversal of provision for losses related to cancellation of Odawara site investment, operating profit is updated to 320 Bn JPY, 5 Bn JPY higher than the previous forecast

Overview of FY2026 Q1 Results

(Bn JPY)

	FY2025 Q1 Results	FY2026 Q1 Results	YoY		Forex Impact (YoY)
Revenue	474.6	574.7	+21.1%	100.1	+41.9
Cost of sales *1	87.6	126.0		38.5	+12.7
CMO Compensation Fee	-	1.0		1.0	
Other Cost os sales	87.6	125.0		37.5	
SG&A expenses *1	180.1	226.0		45.9	+10.9
DXd ADC profit share *2	60.6	96.9		36.3	
Other SG&A expenses	119.5	129.1		9.6	
R&D expenses *1	106.0	115.5		9.5	+8.6
Core operating profit *1	101.0	107.3	+6.2%	6.3	+9.7
Non-core income *1	0.8	0.1		-0.7	
Non-core expenses *1	5.1	22.2		17.2	
Operating profit	96.7	85.1	-12.0%	-11.6	+6.7
Profit before tax	105.4	91.3		-14.1	
Profit attributable to owners of the Company	85.5	68.6	-19.7%	-16.9	
Quarterly EPS (JPY)	46.03	37.72	-18.1%	-8.31	
Currency	USD/JPY	144.60	159.49	+14.89	
Exchange Rate	EUR/JPY	163.81	185.38	+21.57	

*1 DS has changed the definition of core operating profit starting from the fiscal year ending March 2027. Under the new definition, "core operating profit" is disclosed as an indicator of the fundamental profitability of the business, excluding the non-core incomes/expenses such as the 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 DS deems should be excluded to understand the fundamental profitability of the DS business. The non-core incomes/expenses are excluded from results and forecast 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.

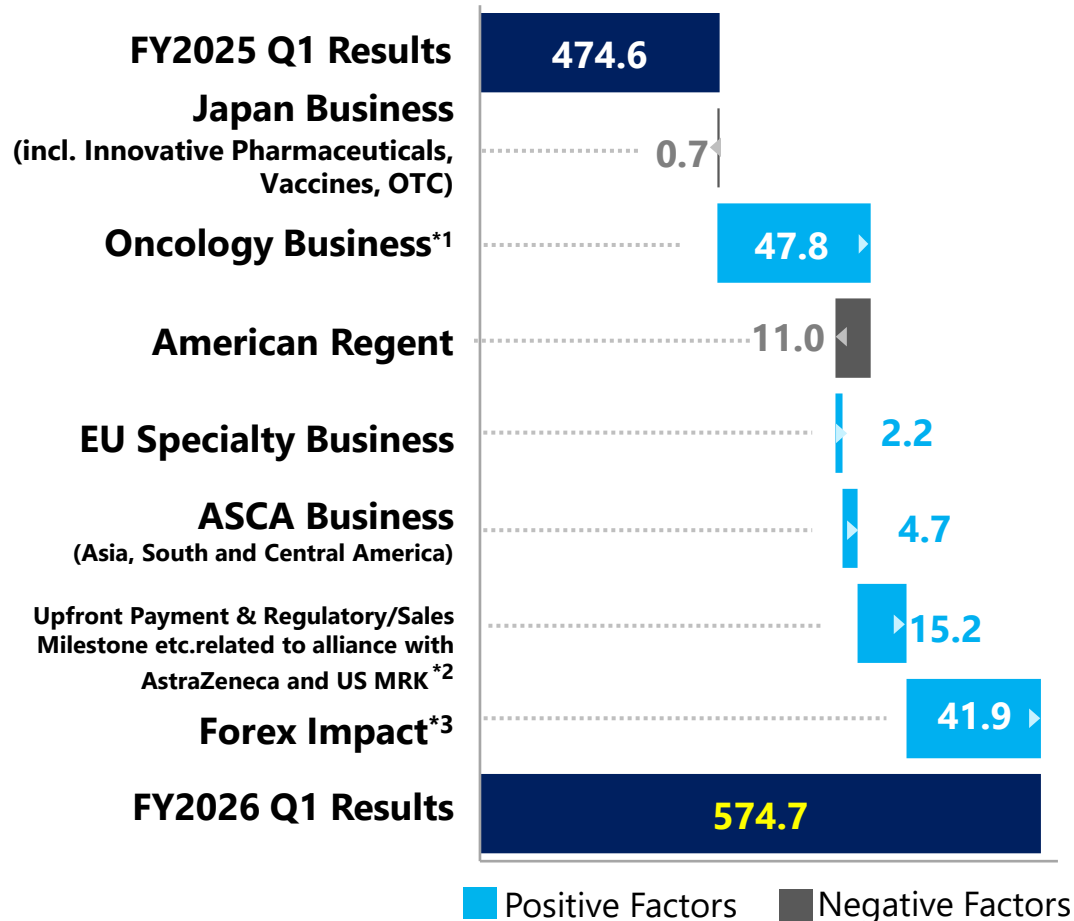
*2 DS pays alliance partners 50% of gross profit for the product sales in countries/regions where DS book revenue (excluding Japan) to share profit with the partners.

Revenue

Increased by 100.1 Bn JPY

(Increased by 58.2 Bn JPY excl. forex impact)

(Bn JPY)



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

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

*3 Forex impact USD: +20.9, EUR: +14.1, ASCA: +6.9

Positive Factors

Negative Factors

Japan Business

Enhertu	+3.5	Lixiana	-4.6
Tarlige	+3.0		
Datroway	+1.6		

Oncology Business Unit

Enhertu	+35.8 (US:+28.3, EU:+7.5)
Datroway	+11.9 (US:+11.5, EU:+0.4)

American Regent Unit

Venofor	-6.8
GE injectables	-4.1
Injectafer	-1.3

EU Specialty Business Unit

Nilemdo/Nustendi	+5.1	Lixiana	-2.2
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ASCA (Asia, South and Central America) Business Unit

Enhertu	+5.4
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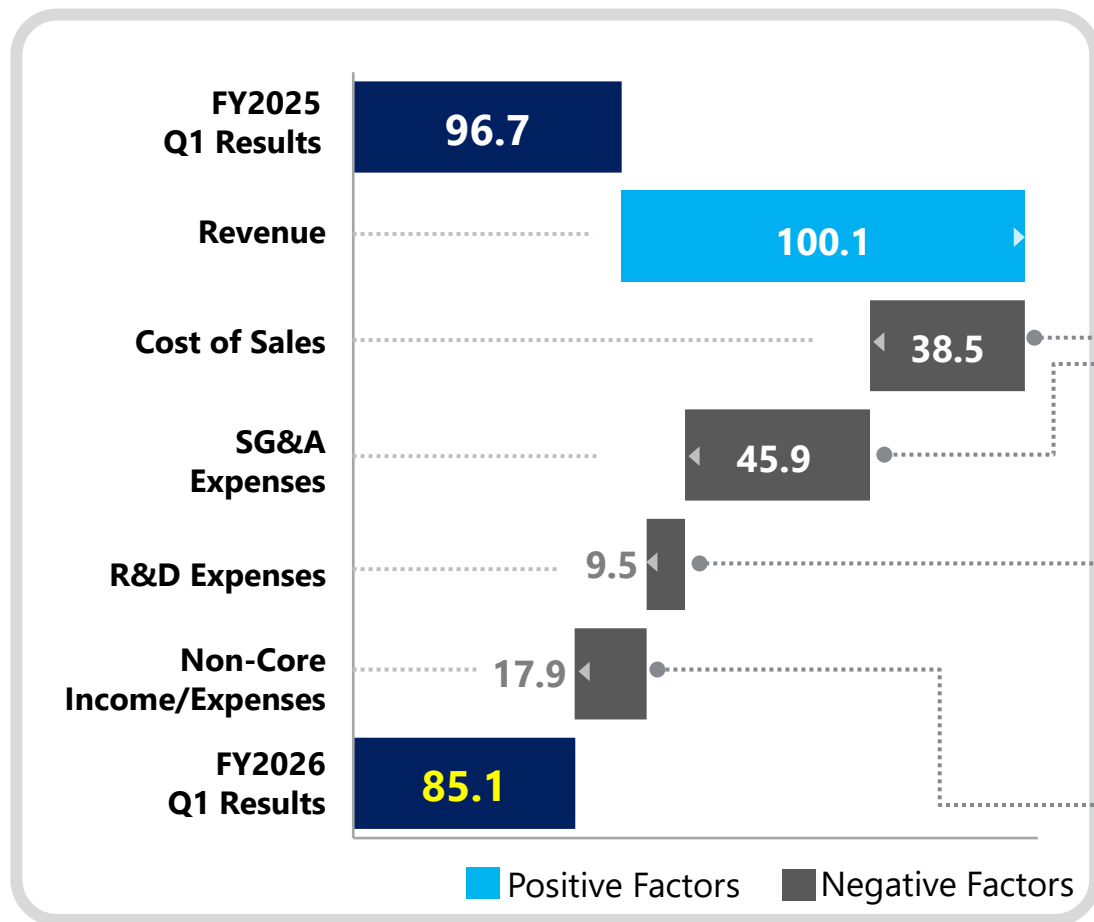
Upfront Payment & Regulatory/Sales Milestone etc. related to alliance with AstraZeneca and US MRK

AstraZeneca	+14.7
US MRK	+0.5

Operating Profit

Decreased by 11.6 Bn JPY

(Bn JPY)



Cost of Sales

CMO compensation Fee	+1.0	(Foreign Exchange Rate Fluctuations)
Other cost of sales	+37.5	(Increase in expenses related to sales expansion, Valuation Losses on related to inventories, etc.)

SG&A Expenses

DXd ADC Profit Share	+36.3
Other SG&A Expenses	+9.6

R&D Expenses

+9.5	Forex impact Increase in 5DXd ADCs* and DS3790 R&D investments
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Non-Core Income/Expenses

	FY2025 Q1 Results	FY2026 Q1 Results	YoY
Income	0.8	0.1	-0.7
Expenses	5.1 ^{*1}	22.2 ^{*2}	+17.2

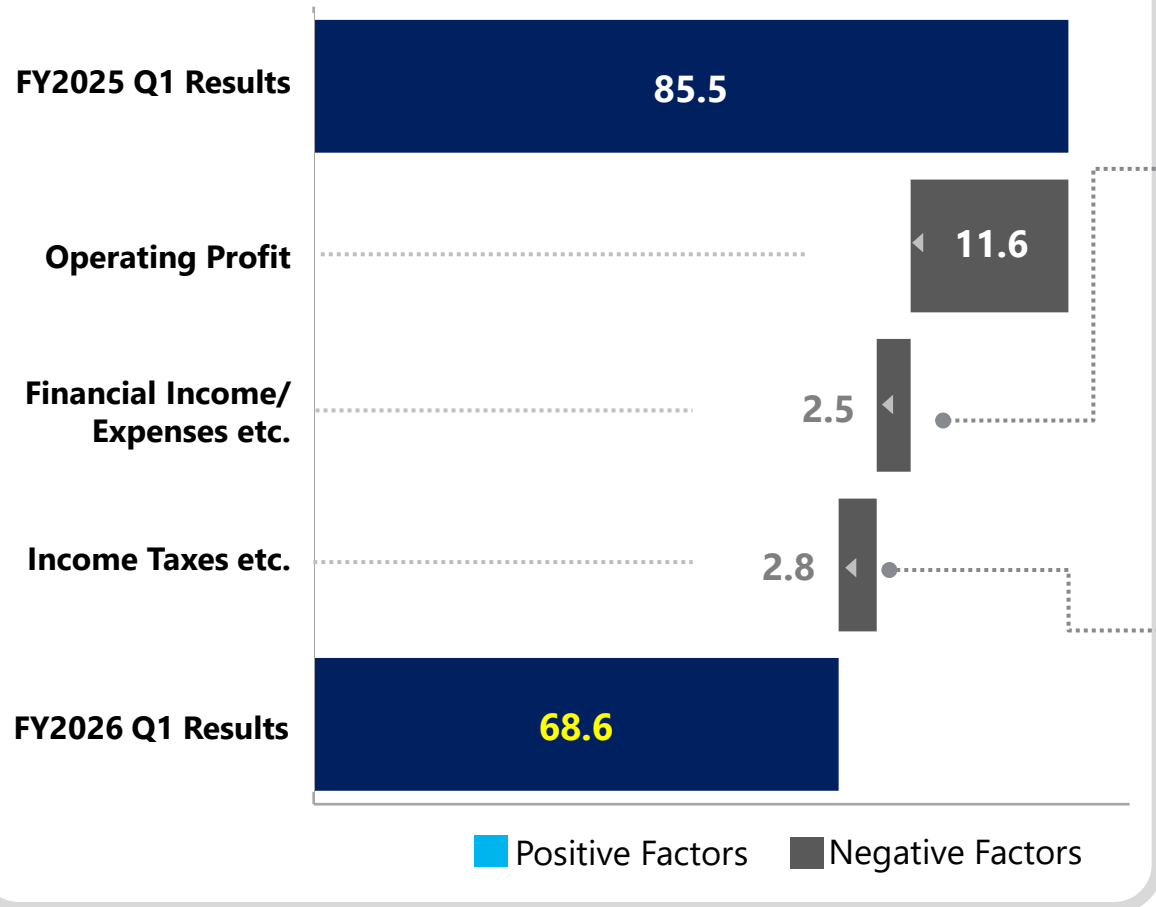
^{*1} Amortization of product-related intangible assets (4.8)

^{*2}: EU Specialty Business Unit restructuring expenses (24.0), Reversal of provision for compensation related to the cancellation of the Odawara Plant investment (-6.9), Amortization of product-related intangible assets (5.1)

Profit Attributable to Owners of the Company

Decreased by 16.9 Bn JPY

(Bn JPY)



Financial Income/Expenses etc. -2.5 (Profit decreased)

• Improvement in investment securities valuation gains/losses	+1.5
• Decrease in interest income	-0.7
• Decrease in dividend income	-1.2
• Increase in interest expense	-0.7
• Equity in earnings of affiliates	-0.6

Income Taxes etc. -2.8 (Profit decreased)

	FY2025 Q1 Results	FY2026 Q1 Results	YoY
Profit before Tax	105.4	91.3	-14.1
Income Taxes etc.	19.9	22.7	+2.8
Tax rate	18.9%	24.9%	

Agenda

① FY2025 Correction of Financial Results

② FY2026 Q1 Financial Results

③ **FY2026 Forecast**

④ Business Update

⑤ R&D Update

⑥ Appendix



Revision of FY2026 Forecast

		(Bn JPY)		
		FY2026 (As of May)	FY2026 (As of July)	vs. Forecast
Revenue		2,280.0	2,340.0	60.0
Cost of sales *1		530.0	550.0	20.0
CMO Compensation Fee		80.0	80.0	-
Other Cost of sales		450.0	470.0	20.0
SG&A expenses *1		890.0	930.0	40.0
DXd ADC profit share*2		370.0	395.0	25.0
Other SG&A expenses		520.0	535.0	15.0
R&D expenses *1		500.0	500.0	-
Core operating profit*1		360.0	360.0	-
Non-core income *1		-	-	-
Non-core expenses *1		45.0	40.0	-5.0
Operating profit		315.0	320.0	5.0
Profit before tax		329.0	334.0	5.0
Profit attributable to owners of the Company		260.0	251.0	-9.0
EPS (JPY)		142.88	137.94	-4.94
Currency	USD/JPY	150.00	156.12	+6.12
Exchange Rate	EUR/JPY	180.00	181.35	+1.35

Assumption of currency rate after Q2 : USD/JPY 155, EUR/JPY 180

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Revenue

⬆️ : Forex impact, Oncology Business Unit, EU Specialty Business Unit

⬇️ : ASCA Business Unit

Cost of Sales

⬆️ Forex impact, Increase due to expansion of revenue,
Valuation losses on related to inventories (Recorded in Q1), etc

SG&A expense

⬆️ Forex impact, Increase due to an increase in profit share of gross profit with AstraZeneca,
Strategic investments in DX / IT and human capital for mid- to long-term growth, etc

R&D expense

⬆️ : Forex impact

⬇️ : Refinement of Medical Affairs Expenses, etc

Non-core expenses

⬇️ Reversal of provision for compensation related to the cancellation of the Odawara Plant investment, etc

Income Taxes, etc

⬆️ Revision of the Tax Deduction for Research and Development Expenses, etc

Forex impact (vs May)

Revenue :	Approx.	+40.0 Bn JPY
Operating profit:	Approx.	+2.0 Bn JPY

Agenda

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② FY2026 Q1 Financial Results

③ FY2026 Forecast

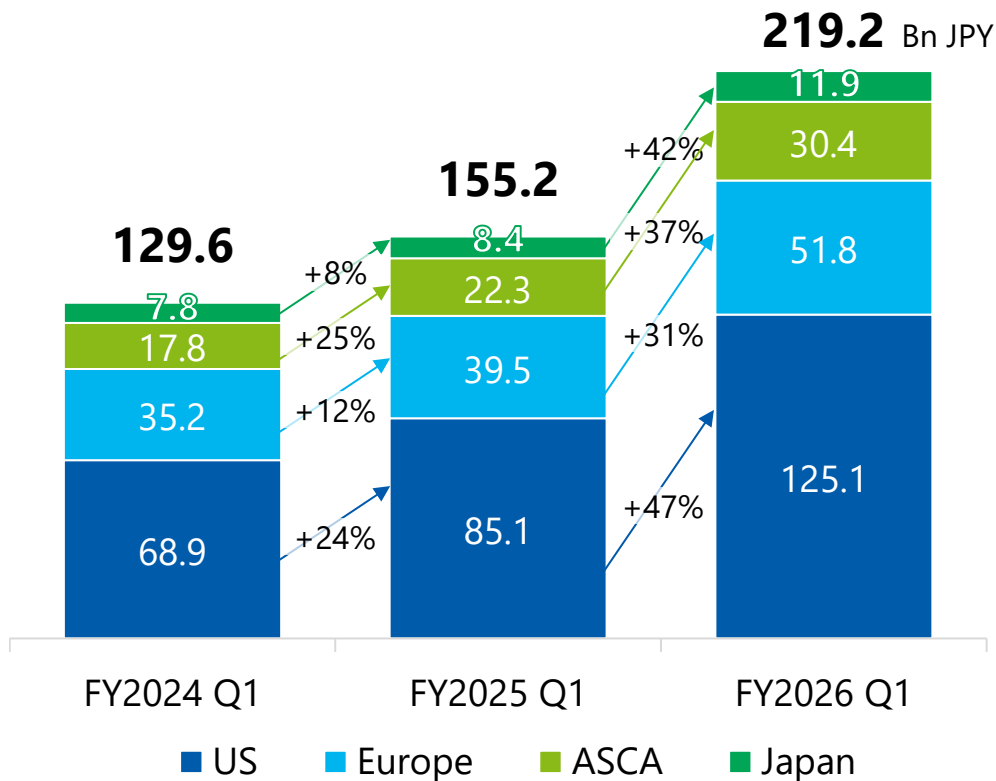
④ **Business Update**

⑤ R&D Update

⑥ Appendix



- ◆ **The simultaneous approvals of two indications for early-stage breast cancer enables coverage of a broad range of treatment lines, from early-stage to metastatic in the US**
- ◆ **Sales growth is driven not only by HER2+ BC 1L but also by HER2+ solid tumors in the US**
 - The solid tumor indication is steadily gaining market penetration in Japan and received approval in Europe



- Q1 Global Product Sales Result **219.2 Bn JPY**
YoY **+64.0 Bn JPY (+41.2%)** Progress vs May Forecast **25.4%**
- Updated annual forecast: Jul. forecast **894.9 Bn JPY** (vs May forecast +33.6 Bn JPY)

New Indication Approvals

- HER2 positive BC neoadjuvant: US in May
- HER2 positive BC post-neoadjuvant: US in May
- HER2 positive solid tumors: Europe in Jun.

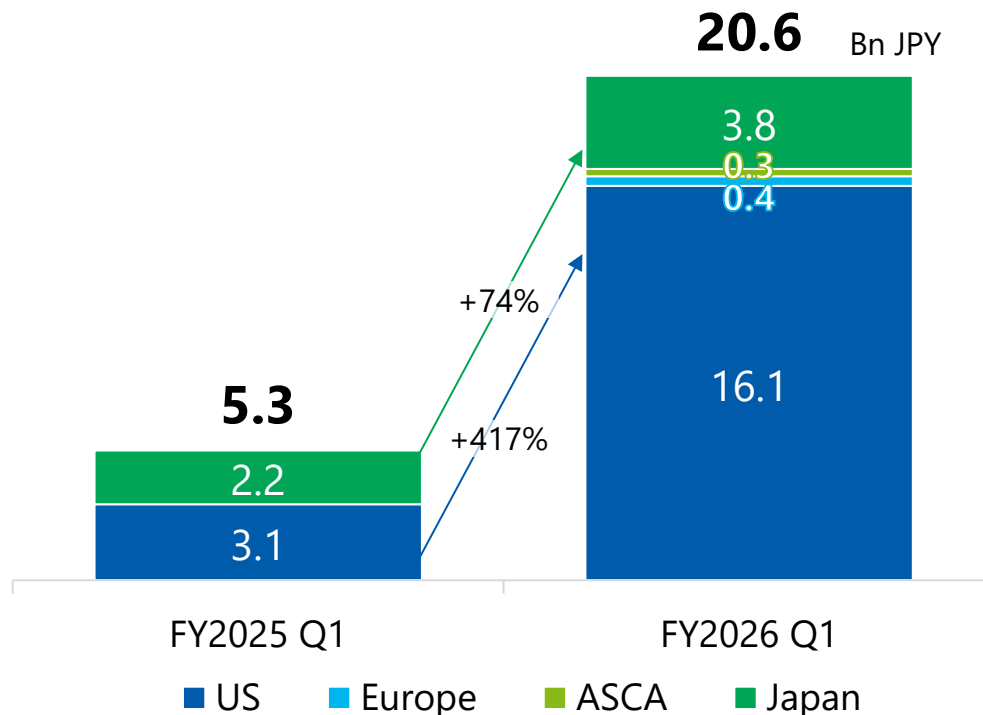
Updates by Indication

- Continue to observe growth in new patient starts in HR+ HER2 low/ultralow BC
- HER2+ BC 1L is expanding new patient share in the US
- In addition to HER2+ BC 1L, HER2+ solid tumors are leading sales growth in the US

NCCN Guideline Updates

- HER2 positive BC neoadjuvant (category 2A) **NEW**

- ◆ **Treated approx. 7,000 patients globally since launch, approx. 1.4 times the prior quarter**
- ◆ **Robust sales growth in the US and Japan**
 - The US sales mainly driven by lung cancer indication, and triple negative breast cancer (TNBC) is growing steadily post launch
 - With the approval of DATROWAY® in TNBC, ENHERTU® and DATROWAY® are now able to offer treatment options to over 90%* of metastatic breast cancer patients



- Q1 Global Product Sales Result **20.6 Bn JPY**
YoY **+15.3 Bn JPY (289.9%)** Progress vs May forecast **18.5%**
- Updated annual forecast: Jul. forecast **116.9 Bn JPY** (vs May forecast +5.5 Bn JPY)

New Indication Approvals

- HR positive HER2 negative BC: Brazil in Mar.
- TNBC 1L: US and Brazil in May
- EGFR-mutated NSCLC: Brazil in Jul.

Updates by Indication

- Maintained No1. patient share in 3L+ in EGFR-mutated NSCLC and increased in new patient in the US
- New patient starts are increasing in TNBC following approval in the US

* Based on molecular subtypes of breast cancer regardless of treatment line
1L: first line, BC: breast cancer, FY: fiscal year (Apr-Mar), HR: hormone receptor, JPY: Japanese Yen, NSCLC: non-small cell lung cancer, TNBC: triple negative breast cancer, Q1: the first quarter (Apr-Jun), YoY: year on year

Agenda

① FY2025 Correction of Financial Results

② FY2026 Q1 Financial Results

③ FY2026 Forecast

④ Business Update

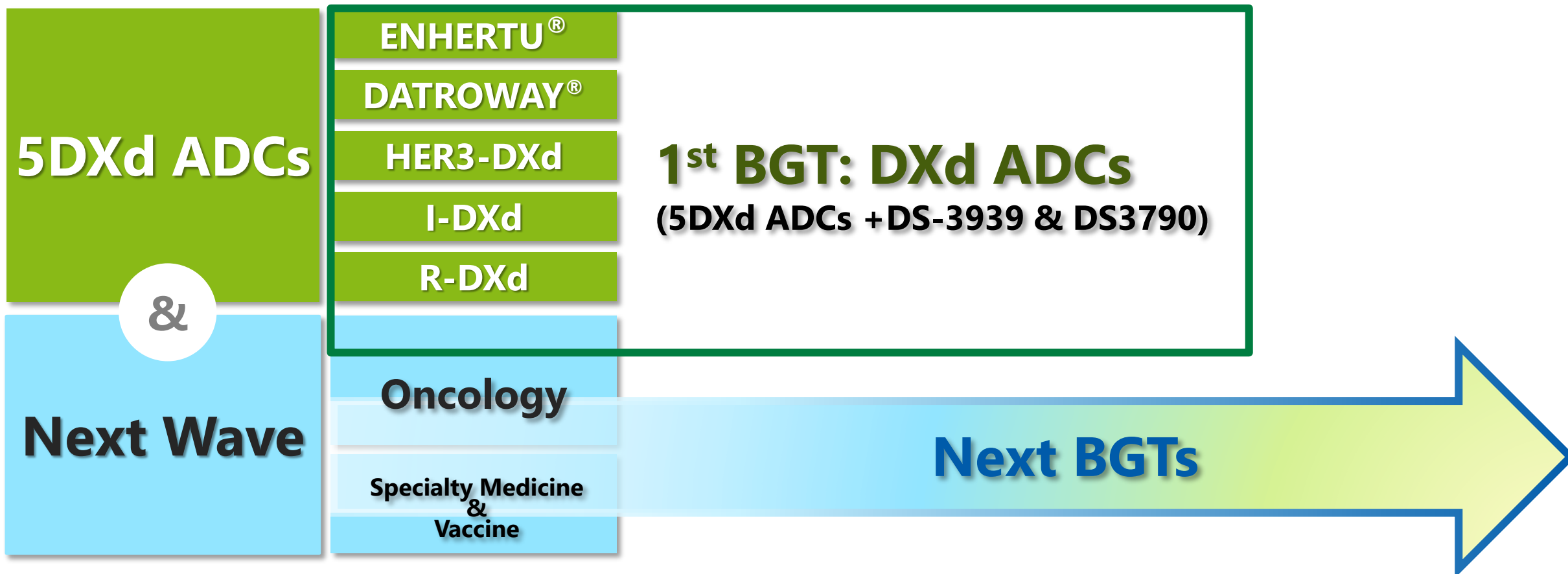
⑤ R&D Update

⑥ Appendix



Growth of DXd ADC during 5YBP (FY2026-FY2030) and Identification of Breakthrough Generating Technology (BGT)

Focus on DXd ADCs including DS-3939 and DS3790 as the 1st BGT and identify Next BGTs by FY2030



Neoadjuvant and adjuvant settings for HER2+ early breast cancer approved in US (May 2026)

DESTINY-Breast11 Study (Neoadjuvant Setting)

Enhertu® followed by a taxane, trastuzumab and pertuzumab (THP) approved for the treatment of patients with HER2 positive stage 2 or stage 3 breast cancer.

ENHERTU® 5.4mg/kg
q3w, 4 cycles



THP
4 cycles

Other than US, neoadjuvant setting for HER2+ early breast cancer approved in China (March 2026)

DESTINY-Breast05 Study (Adjuvant Setting)

Enhertu® approved for the treatment of patients with HER2 positive breast cancer who have residual invasive disease* following neoadjuvant chemotherapy including anti-HER2 therapy.

ENHERTU® 5.4mg/kg q3w, 14 cycles

Other than US, adjuvant setting for HER2+ breast cancer under review in Japan, EU, and China

Achieved approval for HER2 positive tumors across all three major regions (US, Japan, and EU)

HER2 positive solid tumors (DESTINY-PanTumor02 etc.)

May 2026:

- Received positive CHMP opinion

Jun 2026:

- Approved*1 in EU

- Approved in US (Apr 2024)*1 and Japan (Mar 2026)*2.
- In China, the application is currently under review based on the results of DESTINY-PanTumor03*3 and other studies*4 (Filing accepted in April 2026).

* 1 Unresectable or metastatic HER2 positive (IHC 3+) solid tumors with prior treatment history and no satisfactory treatment options

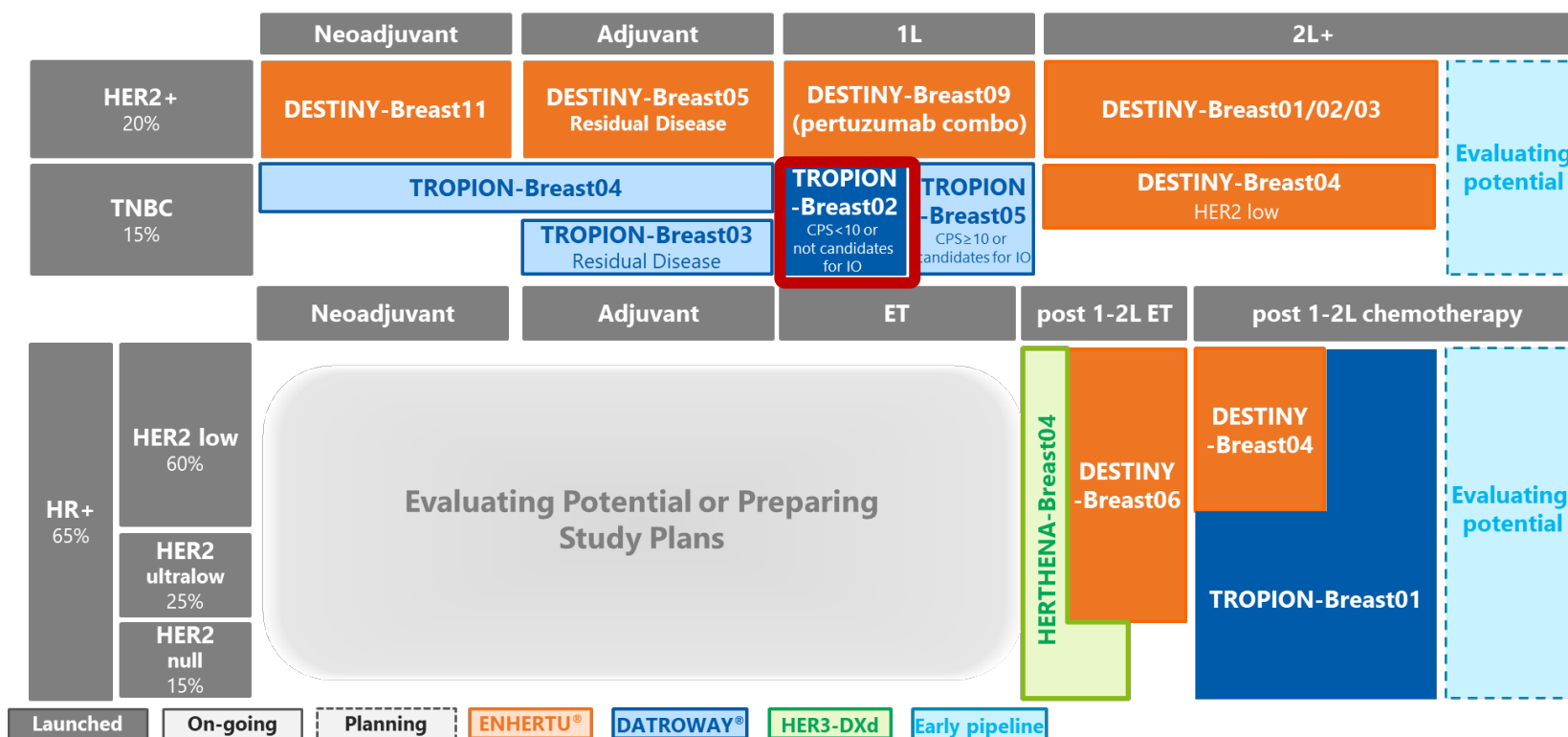
* 2 HER2 positive (HER2 gene amplification or IHC3+) advanced or recurrent solid tumors refractory or intolerant to standard treatments. A separate CDx submission to test tumor tissue for HER2 positive (IHC 3+) is planned.

* 3 Ph2 China bridging study in HER2 solid tumors

* 4 DESTINY-PanTumor02, DESTINY-CRC02, and DESTINY-Lung01

US approval granted for patients with metastatic or unresectable TNBC who are not candidates for PD-1/PD-L1 inhibitor therapy in May 2026

Main studies in Breast Cancer Field



- Datroway® improved mPFS by 5.3 months and mOS by 5.0 months vs. chemotherapy in this population, a statistically significant, clinically meaningful benefit in the TROPION-Breast02 study
- Confirmed ORR more than doubled vs. chemotherapy - 62.5% vs. 29.3%, with median duration of response of 12.3 months for Datroway®
- Regulatory submissions are under review in China, EU and Japan
- EU CHMP positive opinion granted in June 2026 for approval recommendation

Ph3 study to investigate Datroway® and rilvegostomig as adjuvant therapy in MIUC to be initiated in FY2026 H2

Study Design

Eligible Patients

- MIUC post radical surgery (with or without neoadjuvant systemic therapy)
- High risk, with residual disease at surgery

R
N=915

**DATROWAY®*1
+ rilvegostomig*2**

**DATROWAY®*1
monotherapy**

SOC
nivolumab or
durvalumab or
EV + pembrolizumab

Primary Endpoint

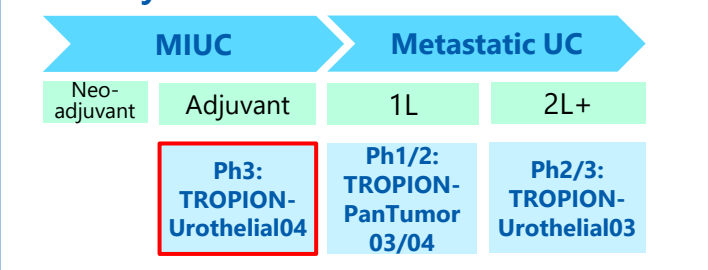
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Secondary Endpoints

OS, DSS, PK, safety, etc.

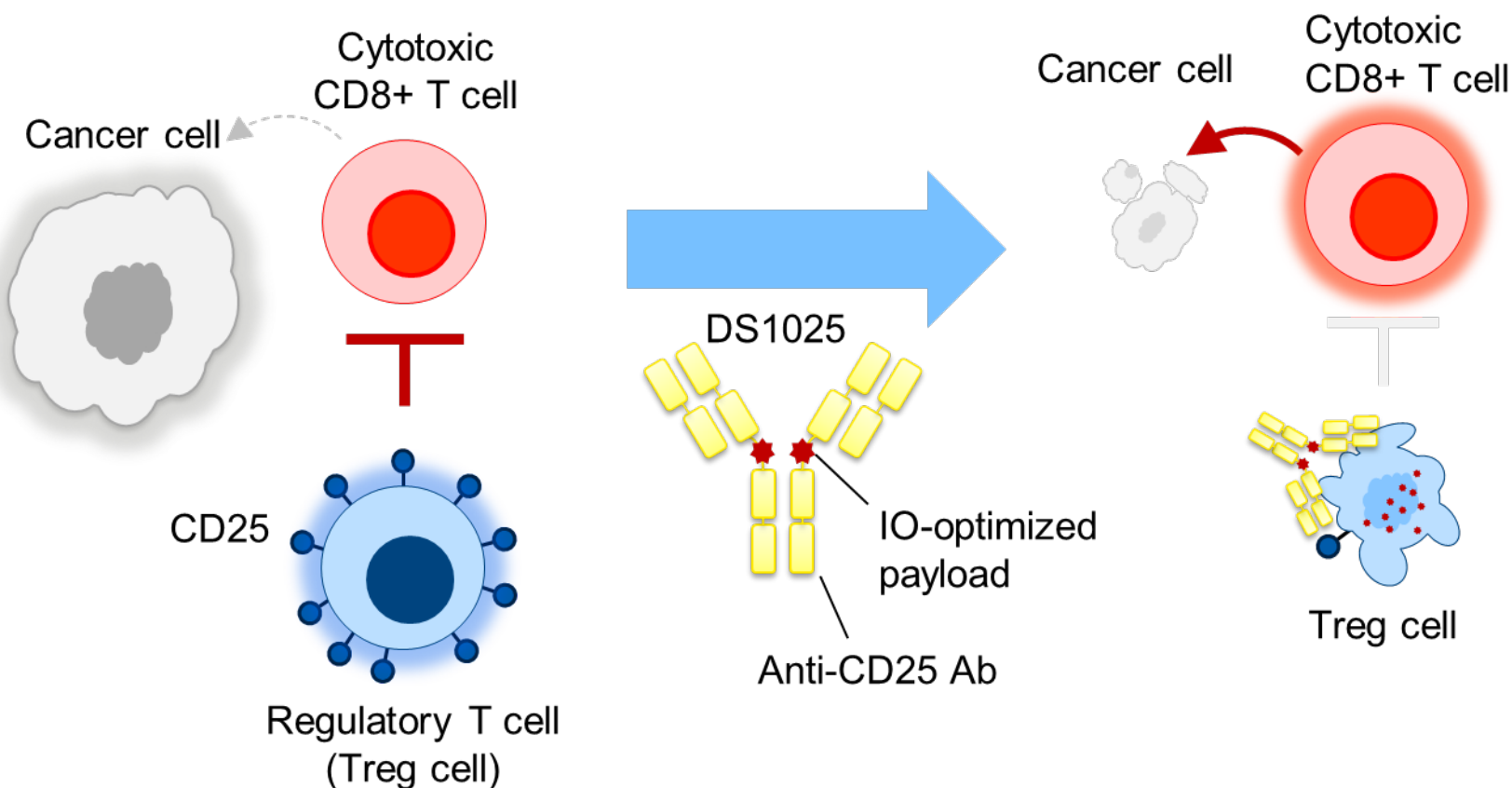
- Significant unmet medical need remains for patients who have invasive residual disease at surgery
- TROPION-Urothelial04 is a Ph3 study to investigate efficacy and safety of Datroway® and rilvegostomig as the adjuvant therapy for MIUC as compared with SOC
- Datroway® plus rilvegostomig delivered an ORR of 68.2% and 12m PFS rate of 73.5% in the 1L metastatic UC cohort of Ph2 TROPION-PanTumor03 (n=22; ESMO 2025)
— an early signal supporting the combination rationale

Datroway®'s Studies for Urothelial Carcinoma



DS1025 is an CD25-directed ADC designed to deplete immunosuppressive Treg cells in the tumor microenvironment and enhance anti-tumor immunity

Mechanism of Action



- Anti-CD25 ADC building on Daiichi Sankyo DXd ADC technology with an IO-optimized cytotoxic payload
- Preclinical studies demonstrated intratumoral Treg cell depletion, cytotoxic CD8+ cell activation, and anti-tumor activity
- FIH study for solid tumors planned for FY2026 H1

New assets approved in Japan and China

MIMRIT[®] (MMR vaccine)

Prevention of measles, mumps and rubella

May 2026:

— Approved in Japan

VANFLYTA[®] (quizartinib, FLT3 inhibitor)

FLT3-ITD positive AML, 1L

QuANTUM-First

Jun 2026:

— Approved in China

Upcoming regulatory decisions

ENHERTU®	DESTINY-Breast09: HER2 positive BC, 1L, Ph3 (pertuzumab combo) • EU: FY2026 H1
DATROWAY®	TROPION-Breast02: TNBC, not candidates for PD-1/PD-L1 inhibitor therapy, 1L, Ph3 • EU: FY2026 H1
I-DXd	Idete-Lung01: ES-SCLC, 2L+, Ph2 • US: FY2026 H2 (PDUFA date: Oct 10, 2026)

Upcoming key data readouts

ENHERTU®	DESTINY-Lung04: HER2 mutant NSCLC, 1L, Ph3 • FY2026 H1
DATROWAY®	TROPION-Lung15: EGFR mutated NSCLC progressed on prior osimertinib, mono or osimertinib combo, 2L+, Ph3 • FY2026 H2
	AVANZAR: non-squamous NSCLC, w/o AGA, durvalumab + carboplatin combo, 1L, Ph3 • CY2026 H2

Planned major data disclosures

European Society For Medical Oncology (ESMO, Oct 23-27, 2026)

HER3-DXd	HERTHENA-PanTumor01: solid tumors, Ph2 • melanoma, first data release
I-DXd	Idete-Lung01: ES-SCLC, 2L+, Ph2 • Data update
R-DXd	REJOICE-Ovarian01: platinum-resistant ovarian cancer, 2L+, Ph2 dose optimization part • Data update
	REJOICE-Ovarian02: platinum-resistant ovarian cancer, Ph1b/2 • Bevacizumab combo cohort in dose escalation part

Bold: update from FY2025 Q4

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

AGA: actionable genomic alteration, BC: breast cancer, ES-SCLC: extensive-stage small cell lung cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, PBC: platinum-based chemotherapy,

PDUFA: prescription drug user fee act, TPS: tumor proportion score



Tomohiro Kodama
CFO



Akihiro Inoguchi
Head of Development Function



Ken Keller
Head of Global Oncology
Business

Agenda

① FY2025 Correction of Financial Results

② FY2026 Q1 Financial Results

③ FY2026 Forecast

④ Business Update

⑤ R&D Update

⑥ **Appendix**



Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

		FY2025 Q1 Results	FY2026 Q1 Results	YoY
Japan Business		125.0	120.0	-4.9
Daiichi Sankyo Healthcare		20.9	22.6	+1.6
Oncolgy Business		131.2	197.4	+66.2
Enhertu		124.6	176.9	+52.3
Datroway		3.1	16.6	+13.4
Turalio		1.6	1.0	-0.6
Vanflyta		1.9	2.9	+1.1
American Regent		49.3	42.2	-7.1
Injectafer		11.8	11.7	-0.2
Venofer		13.1	6.9	-6.1
GE injectables		21.0	18.7	-2.3
EU Specialty Business		63.8	74.7	+10.9
Lixiana		45.7	49.2	+3.5
Nilemdo/Nustendi		12.6	20.0	+7.4
Olmesartan		5.0	5.0	-0.1
ASCA (Asia, South and Central America) Business		56.8	68.7	+11.9
Currency	USD/JPY	144.60	159.49	+14.89
Exchange Rate	EUR/JPY	163.81	185.38	+21.57

Revenue: Major Products in Japan

(Bn JPY)

		FY2025 Q1 Results	FY2026 Q1 Results	YoY
Lixiana	anticoagulant	37.7	33.0	-4.6
Tarlige	pain treatment	16.5	19.5	+3.0
Pralia	Treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	12.4	12.9	+0.5
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	8.4	11.9	+3.5
Belsomra	Anti-Insomnia Treatment	5.1	4.6	-0.5
Canalia	type 2 diabetes mellitus treatment	3.9	3.7	-0.2
Minnebro	antihypertensive agent	2.8	3.4	+0.7
Ranmark	treatment for bone complications caused by bone metastases from tumors	5.1	5.1	+0.1
Datroway	anti-cancer agent (TROP2-directed antibody drug conjugate)	2.2	3.8	+1.6
Loxonin	anti-inflammatory analgesic	2.9	3.3	+0.4
Emgality	prophylaxis of migraine attacks	3.0	3.5	+0.5
Inavir	anti-influenza treatment	-	0.0	+0.0

5DXd ADCs Revenue (incl. Forex Impact)

(Bn JPY)

	FY2026 Q1 Results	YoY	FY2026 Forecast(As of Jul.)	vs May. Forecast
ENHERTU®	239.8	+78.8	1,030.0	+36.6
Product Sales	219.2	+64.0	894.9	+33.6
Upfront and Milestone Payments, etc.	20.6	+14.8	135.1	+3.1
DATROWAY®	23.9	+15.3	127.2	+5.7
Product Sales	20.6	+15.3	116.9	+5.5
Upfront and Milestone Payments, etc.	3.3	-0.1	10.3	+0.2
HER3-DXd	3.0	-1.1	12.0	-
Upfront and Milestone Payments, etc.	3.0	-1.1	12.0	-
I-DXd	3.8	-	18.4	+0.1
Product Sales	-	-	3.3	+0.1
Upfront and Milestone Payments, etc.	3.8	-	15.1	-
R-DXd	3.2	+1.5	12.8	-
Upfront and Milestone Payments, etc.	3.2	+1.5	12.8	-
5DXd ADCs Total	273.7	+94.5	1,200.3	+42.4

5DXd ADCs Upfront and Milestone Payments

(Bn JPY)

Asset	Item	FY2026 Q1 Results	YoY	FY2026 Forecast (As of Jul)	vs May Forecast	Total Consideration (as of Jun 2026)
ENHERTU®	Upfront Payment	2.6	-	10.2	-	149.0
	Regulatory Milestones	17.8	+14.8	30.0	+3.1	238.6
	Quid Related Payment	0.3	-	1.2	-	17.2
	Sales Milestone	-	-	93.8	-	186.7
DATROWAY®	Upfront Payment	1.6	-	6.4	-	115.9
	Regulatory Milestones	1.7	-0.1	3.9	+0.2	11.5
AZ Alliance Total		23.9	+14.7	145.4	+3.3	718.8
HER3-DXd	Upfront Payment	2.9	-1.0	11.6	-	224.9
	Satisfaction of Quid Rights	0.1	-0.0	0.4	-	7.3
I-DXd	Upfront Payment	3.7	-	14.7	-	225.4
	Satisfaction of Quid Rights	0.1	-	0.5	-	7.3
R-DXd	Upfront Payment	3.1	+1.5	12.4	-	225.7
	Satisfaction of Quid Rights	0.1	-	0.4	-	7.3
US Merck Alliance Total		10.0	+0.5	39.9	-	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

Major R&D Milestones : ENHERTU®

As of Jul 2026

Project	Target indication [phase, study name]	FY2026		FY2027
		H1	H2	
ENHERTU®	BC	• Approved (US) • Filing accepted (CN)		
		• Regulatory decision anticipated (pertuzumab combo) (EU)	• TLR (mono) anticipated	
		• Approved (US)		
	NSCLC	• TLR anticipated		
	Other tumors	• Approved (EU)		
		• Filing accepted (CN)		

Bold: update from FY2025 Q3

BC: breast cancer, EC: endometrial cancer, NSCLC: non-small cell lung cancer, THP: taxane (paclitaxel or docetaxel) + trastuzumab + pertuzumab, TLR: top line results

*1 Unresectable or metastatic HER2 positive (IHC 3+) solid tumors who have received prior treatment and who have no satisfactory treatment options. Approval based on results from DESTINY-PanTumoro02,, DESTINY-CRC02, and DESTINY-Lung01

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

Major R&D Milestones : DATROWAY®

As of Jul 2026

Project	Target indication [phase, study name]	FY2026		FY2027
		H1	H2	
DATROWAY®	NSCLC	• Non-squamous, w/o AGA, PD-L1 TPS <50%, 1L, pembrolizumab ± PBC combo [Ph3, TROPION-Lung07]		• TLR anticipated
		• Non-squamous, w/o AGA, PD-L1 TPS ≥50%, 1L, pembrolizumab combo [Ph3, non-squamous, TROPION-Lung08*1]		• TLR anticipated
		• EGFR mutated, progressed on prior osimertinib, 2L+, mono or osimertinib combo [Ph3, TROPION-Lung15]	• TLR anticipated	
		• Non-squamous, w/o AGA, 1L, durvalumab + carboplatin combo [Ph3, AVANZAR]	• TLR anticipated (CY2026 H2)	
	BC	• TNBC, not candidates for PD-1/PD-L1 inhibitor therapy, 1L [Ph3, TROPION-Breast02]	• Approved (US) • Regulatory decision anticipated (EU)	
		• TNBC w/o pCR following neoadjuvant, adjuvant, mono or durvalumab combo [Ph3, TROPION-Breast03]		• TLR anticipated
		• PD-L1 positive TNBC, 1L, durvalumab combo [Ph3, TROPION-Breast05]		• TLR anticipated
	MIUC	• Post radical surgery, adjuvant, rilvegostomig combo [Ph3, TROPION-Urothelial04]	• Study start planned	

Bold: update from FY2025 Q4

AGA: actionable genomic alterations, BC: breast cancer, MIUC: muscle invasive urothelial carcinoma, NSCLC: non-small cell lung cancer, PBC: platinum-based chemotherapy, pCR: pathological complete response,

TLR: top line results, TNBC: triple-negative breast cancer, TPS: tumor proportion score, w/o: without

*1 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 : I-DXd and Next Wave

As of Jul 2026

Project	Target indication [phase, study name]	FY2026		FY2027
		H1	H2	
I-DXd	• ES-SCLC, 2L+ [Ph2, IDeate-Lung01]	• Filing accepted (US)	• Regulatory decision anticipated (US)	
	• ES-SCLC, 2L [Ph3, IDeate-Lung02]			• TLR anticipated
VANFLYTA®	• FLT3-ITD positive AML, 1L [Ph3, QuANTUM-First]	• Approved (CN)		
DS1025	• Solid tumors [Ph1]	• Study start planned		
DS2001	• Autoimmune diseases [healthy volunteers, Ph1]	• Study started		
MIMRIT®	• Measles-mumps-rubella combined vaccines	• Approved (JP)		

Oncology
 Specialty medicine
 Vaccine

Bold: update from FY2025 Q4

AML: acute myeloid leukemia, 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)

Phase 1		Phase 1/2		Phase 2	
(US/EU/Asia) HER2 low BC chemo naïve/post chemo (combo) DESTINY-Breast08		(US/EU/Asia) HER2+ BC 2L+/1L (combo) DESTINY-Breast07	(TBA) in prep HR+/HER2 low or HER2 ultralow BC chemo naïve (ENHERTU® combo) HERTHENA-Breast02	(JP/US/EU/Asia) solid tumors TROPION-PanTumor03	(US/EU/Asia) non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
(US/EU/Asia) HER2 overexpressing non-squamous NSCLC 1L (ICI ± PBC combo) DESTINY-Lung03		(JP/US/EU/Asia) HER2 expressing GC 2L+/1L (combo) DESTINY-Gastric03	(JP/US) ESCC, CRPC, squamous NSCLC, SCLC, etc. IDEate-PanTumor01	(JP/US/EU/Asia) EGFR-mutated NSCLC 2L (osimertinib combo) ORCHARD	(US/EU/Asia) squamous NSCLC 2L KEYMAKER-U01 substudy 01I
(US/EU) BC, NSCLC (pembrolizumab combo)		(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) solid tumors 2L+ IDEate-PanTumor02	(US/EU/Asia) resectable early-stage NSCLC neoadjuvant and adjuvant ((durvalumab or rilvegostomig) + PBC combo) NeoCOAST-2	(JP/Asia) ESCC 2L/3L KEYMAKER-U06 substudy 06F
(JP/US/EU/Asia) solid tumors (subcutaneous injection)		(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU) ES-SCLC 1L (atezolizumab combo) IDEate-Lung03	(JP/US/EU/Asia) solid tumors HERTHENA-PanTumor01	(US/EU/Asia) gastrointestinal cancers REJOICE-GI01
(JP/US) solid tumors TROPION-PanTumor01		(CN) NSCLC, TNBC TROPION-PanTumor02	(US/EU/Asia) chemo-naïve CRPC (mono or combo) IDEate-Prostate02	(US/EU/Asia) high-risk early stage TNBC, HR low and HER2 negative BC neoadjuvant and adjuvant (pembrolizumab combo) HERTHENA-Breast03	(JP/US/EU/Asia) solid tumors REJOICE-PanTumor01
(JP/US/EU/Asia) NSCLC (w/o AGA) (pembrolizumab ± PBC combo) TROPION-Lung02		(US/EU/Asia) BTC, HCC, gastroesophageal cancer 2L+ HERTHENA-PanTumor02	(US/EU/Asia) in prep r/r OST, NBL, RMS, WT (pediatric) LIGHTBEAM-U01 substudy 01D	(US/EU/Asia) stageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01G	(US/EU/Asia) non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
(JP/US/EU/Asia) NSCLC (w/o AGA) ((durvalumab, rilvegostomig or volrustomig) ± PBC or sabestomig combo) TROPION-Lung04		(JP/US/EU/Asia) HER2+ BC 2L+ (trastuzumab ± (pertuzumab or tucatinib) combo) HERTHENA-Breast01	(US/EU/Asia) stageIV NSCLC 1L (pembrolizumab + PBC combo) KEYMAKER-U01 substudy 01A		(US/EU/Asia) squamous NSCLC 2L KEYMAKER-U01 substudy 01I
		(US/EU/Asia) r/r HBL or RMS (pediatric) LIGHTBEAM-U01 substudy 01C	(JP/US/EU/Asia) ESCC 1L (pembrolizumab ± chemo combo) KEYMAKER-U06 substudy 06E		
		(US/EU/Asia) stageIV NSCLC 1L (pembrolizumab + PBC combo) KEYMAKER-U01 substudy 01A	(US/EU/Asia) ES-SCLC 2L KEYNOTE-B98		
		(US/EU/Asia) HER2 negative GC 1L (pembrolizumab + chemo combo) KEYMAKER-U06 substudy 06C	(US/EU/Asia) ovarian cancer, relapsed after PBC (bevacizumab, pembrolizumab, carboplatin, or paclitaxel combo) REJOICE-Ovarian02		
		(US/EU/Asia) HER2 negative GC 2L (ramucirumab combo) KEYMAKER-U06 substudy 06D			

 ENHERTU®
  DATROWAY®
  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, NBL: neuroblastoma, NSCLC: non-small cell lung cancer, OST: osteosarcoma, PBC: platinum-based chemotherapy, r/r: relapse or refractory, RMS: rhabdomyosarcoma, SCLC: small cell lung cancer, TBA: to be announced, TNBC: triple negative breast cancer, WT: Wilms tumor

Major R&D Pipeline: 5DXd ADCs (2)

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 1L (mono) DESTINY-Breast09	(JP/US/EU/Asia) HER2 expressing pMMR EC 1L (rilvegostomig or pembrolizumab combo) DESTINY-Endometrial01	(JP/US/EU/Asia) TROP2 NMR+ non-squamous NSCLC (w/o AGA) 2L+ TROPION-Lung17	(JP/US/EU/Asia) HR positive and HER2 negative BC post ET and CDK4/6 inhibitor treatment HERTHENA-Breast04	(JP/EU/CN) HER2+ BC with residual invasive disease following neoadjuvant, adjuvant DESTINY-Breast05
(JP/US/EU/Asia) platinum-resistant ovarian cancer 2L+ REJOICE-Ovarian01	(JP/US/EU/Asia) HER2+ GC 1L (pembrolizumab + FP combo) DESTINY-Gastric05	(JP/US/EU/Asia) HER2 expressing EC adjuvant DESTINY-Endometrial02	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA) 1L (durvalumab + carboplatin combo) AVANZAR	(JP/US/EU/Asia) ES-SCLC 2L IDeate-Lung02	(EU/JP/CN) HER2+ BC 1L (pertuzumab combo) DESTINY-Breast09
	(JP/US/EU/Asia) HER2+ and PD-L1 CPS≥1 GC 1L (rilvegostomig + FP combo) ARTEMIDE-Gastric01	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1 TPS <50%) 1L (pembrolizumab ± PBC combo) TROPION-Lung07	(JP/US/EU/Asia) TNBC (w/o pCR following neoadjuvant) adjuvant (mono or durvalumab combo) TROPION-Breast03	(JP/US/EU/Asia) ESCC 2L IDeate-Esophageal01	(CN) HER2 expressing solid tumors DESTINY-PanTumor03 etc ^{*1}
	(JP/US/EU/Asia) HER2 mutant NSCLC 1L DESTINY-Lung04	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1 TPS ≥50%) 1L (pembrolizumab combo) TROPION-Lung08	(JP/US/EU/Asia) TNBC, HR low and HER2 negative BC neoadjuvant and adjuvant (durvalumab combo) TROPION-Breast04	(JP/US/EU/Asia) chemo-naïve CRPC IDeate-Prostate01	(JP/EU/CN) TNBC (not candidates for PD-1/PD-L1 inhibitor therapy) 1L TROPION-Breast02
	(JP/US/Asia) HER2 overexpressing non-squamous NSCLC (w/o AGA, PD-L1 TPS < 50%) 1L (pembrolizumab combo) DESTINY-Lung06	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1 TC ≥50%) 1L (rilvegostomig combo) TROPION-Lung10	(JP/US/EU/Asia) PD-L1 positive TNBC 1L (durvalumab combo) TROPION-Breast05	4	(US) ES-SCLC 2L+ IDeate-Lung01
	(JP/US/EU/Asia) HER2 expressing BTC 1L (rilvegostomig combo) DESTINY-BTC01	(JP/US/EU/Asia) EGFR-mutated NSCLC 1L (osimertinib combo) TROPION-Lung14	(JP/US/EU/Asia) MIUC with high-risk residual disease at radical resection, adjuvant (rilvegostomig combo) TROPION-Urothelial04		
	(JP/US/EU/Asia) HER2 expressing ovarian cancer 1L maintenance (bevacizumab combo) DESTINY-Ovarian01	(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

Breakthrough Designation (US)

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

^{*1} Filing based on DESTINY-PanTumor03, DESTINY-PanTumor02, 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, MIUC: muscle invasive urothelial carcinoma NSCLC: non-small cell lung cancer, PBC: platinum-based chemotherapy, pCR: pathological complete response, pMMR: mismatch repair proficient, TC: tumor cells, TNBC: triple negative breast cancer, TPS: tumor proportion score, UC: urothelial carcinoma, w/o: without

Major R&D Pipeline: Next Wave

As of Jul 2026

Phase 1	Phase 1/2	Phase 2	Phase 3
DS-1103 (US/EU) Anti-SIRPα antibody HER2-altered solid tumors (ENHERTU® combo)	DS-3939 (JP/US/EU/Asia) TA-MUC1-directed DXd ADC Solid tumors	EZHARMIA® (EU) EZH1/2 inhibitor BCL	VANFLYTA® (JP/US/EU/Asia) FLT3 inhibitor FLT3 -ITD negative AML 1L QuANTUM-Wild
EZHARMIA® (JP/US) EZH1/2 inhibitor HER2+ GC, HER2 low BC (ENHERTU® combo) and non-squamous NSCLC (DATROWAY® combo)	Gocatumig (MK-6070/DS3280) (US) DLL3-directed trispecific T-cell engager DLL3 expressing advanced cancer (mono, I-DXd combo or atezolizumab combo) MK-6070-001		
EZHARMIA® (JP/US) EZH1/2 inhibitor CRPC (darolutamide combo)	Gocatumig (MK-6070/DS3280) (JP/US/EU/Asia) DLL3-directed trispecific T-cell engager ES-SCLC 2L+ (mono, I-DXd combo or durvalumab combo) MK-6070-002		
DS-2243 (US/EU/Asia) HLA-A*02:NY-ESO directed bispecific T-cell engager Solid tumors	Gocatumig (MK-6070/DS3280) (US/Asia) 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) EGFR-directed STING agonist ADC Solid tumors	EZHARMIA® (JP/US/Asia) EZH1/2 inhibitor NSCLC (w/o AGA and PD-L1 TPS ≥50%) 1L (pembrolizumab combo)		
DS5361 (JP/US) Small molecule NMD inhibitor Solid tumors	DS3790 (JP/US/EU) CD37-directed DXd ADC Relapsed or refractory B-cell non-Hodgkin lymphoma		
DS9051 (US/EU) Targeted protein degradation (TPD) molecule Solid tumors including CRPC	DS-7011 (JP/US/EU/Asia) Anti-TLR7 antibody Systemic lupus erythematosus		
DS1025 (JP) in prep CD25-directed ADC Solid tumors			
DS2001 (JP) Anti-ORAI1 antibody Autoimmune diseases			

 Oncology  Specialty medicine

 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, TPS: tumor proportion score

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