Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2025 Q1
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Koji Ogawa

Senior Executive Officer, CFO

July 31, 2025

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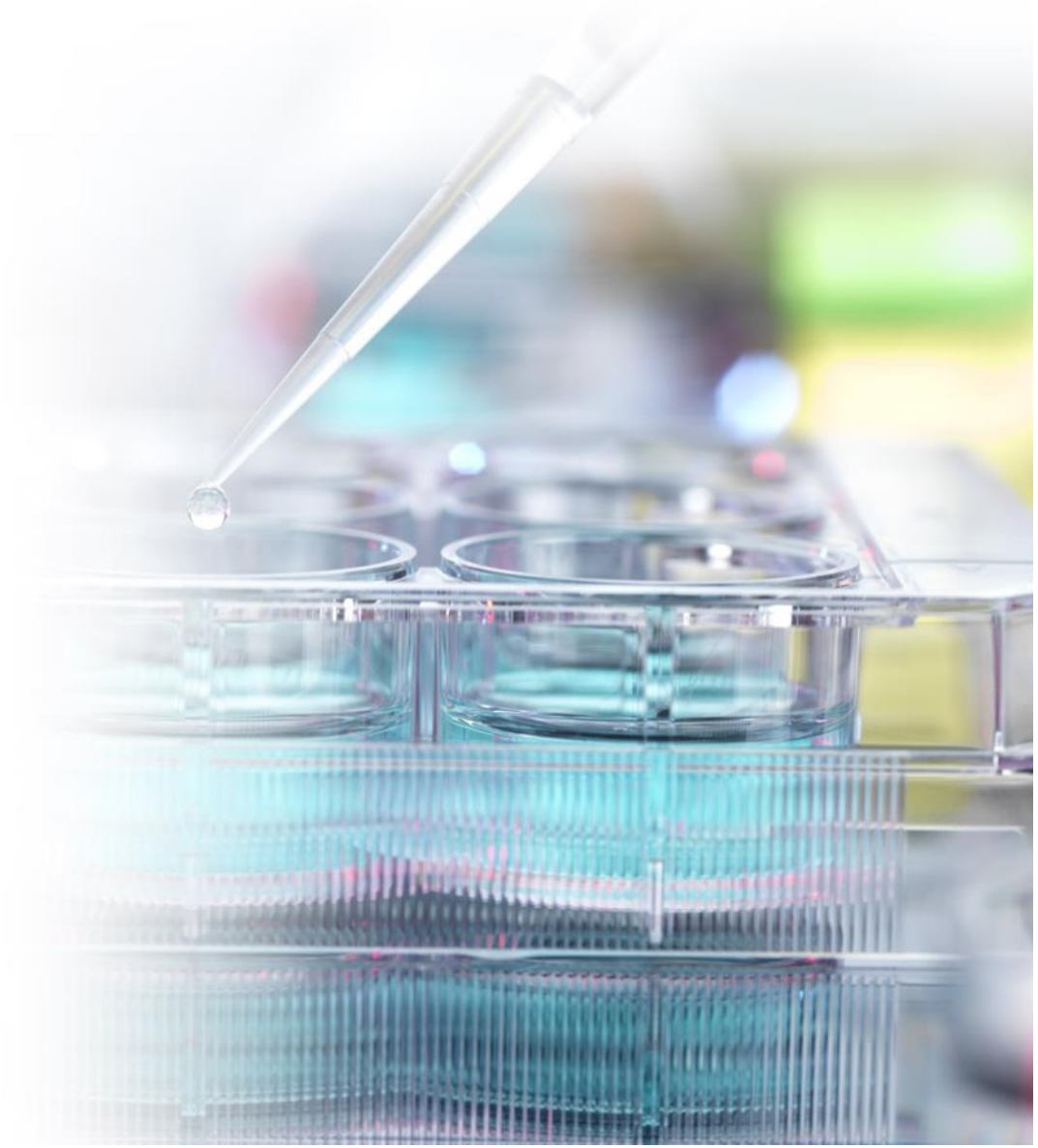
Agenda

1. **FY2025 Q1 Financial Results**
2. Business Update
3. R&D Update
4. Appendix



Overview of FY2025 Q1 Results

(Bn JPY)

	FY2024 Q1 Results	FY2025 Q1 Results	YoY	
Revenue	**436.2**	**474.6**	**+8.8%**	**38.4**
Cost of sales *1	95.0	92.3		-2.6
SG&A expenses *1	167.6	180.0		12.4
DXd ADC profit share *2	56.8	60.6		3.8
Other SG&A expenses	110.8	119.4		8.6
R&D expenses *1	100.7	105.9		5.3
Core operating profit *1	**72.9**	**96.3**	**+32.1%**	**23.4**
Temporary income *1	20.1	0.7		-19.4
Temporary expenses *1	0.0	0.3		0.3
Operating profit	**93.0**	**96.7**	**+4.0%**	**3.7**
Profit before tax	**110.2**	**105.4**		**-4.8**
Profit attributable to owners of the Company	**85.4**	**85.5**	**+0.1%**	**0.1**

Currency Exchange Rate	USD/JPY	155.89	144.60	-11.29
	EUR/JPY	167.88	163.81	-4.07

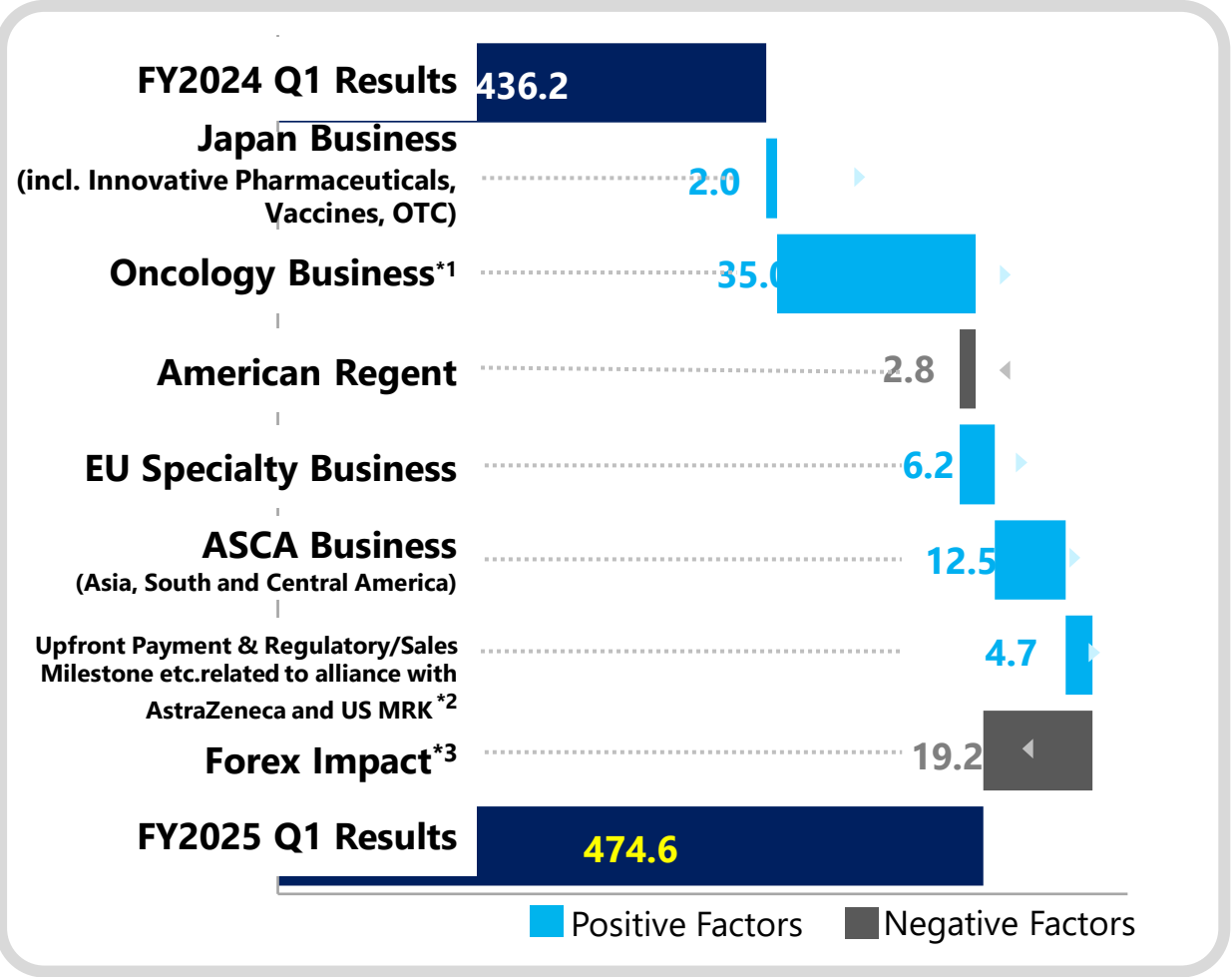
*1 As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed. Income and expenses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation, reconciliation, and other non-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.

Revenue

Increased by 38.4 Bn JPY (Increased by 57.6 Bn JPY excl. forex impact)

(Bn JPY)

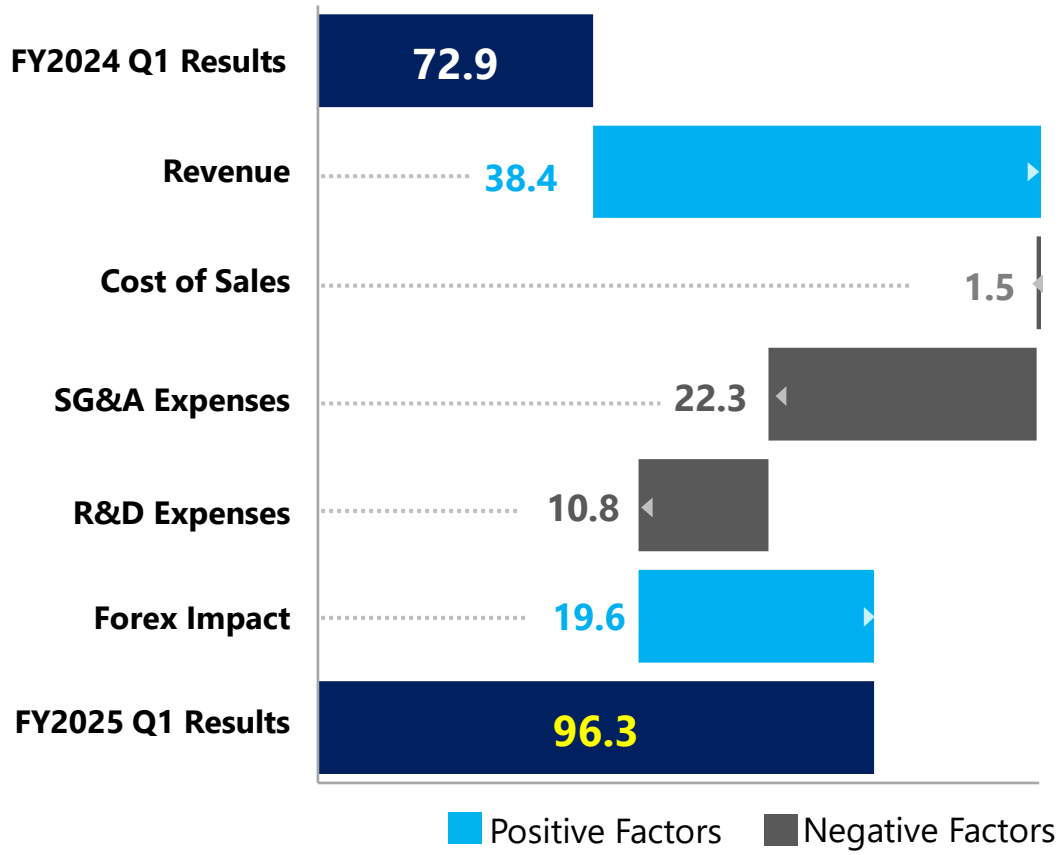


	Positive Factors	Negative Factors
Japan Business Unit		
Belsomra	+5.1	
Lixiana	+2.8	
Tarlige	+2.4	
Datroway	+2.2	
Realized gains of unrealized gains of inventory for Daiichi Sankyo Espha		-5.6
Tenelia		-5.4
Oncology Business Unit[1]		
Enhertu	+30.2	
Datroway	+3.4	
American Regent Unit		
Injectafer		-3.0
Venofer		-2.2
EU Specialty Business Unit		
Nilemdo/Nustendi	+5.1	
Lixiana	+1.4	
ASCA (Asia, South and Central America) Business Unit		
Enhertu	+6.8	
Upfront Payment & Regulatory/Sales Milestone etc. related to alliance with AstraZeneca and US MRK *2		
AstraZeneca	+2.4	
US MRK	+2.3	

*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products
*2 Merck & Co., Inc., Rahway, NJ, USA
*3 Forex impact USD: -12.3, EUR : -2.5, ASCA: -4.4

Core Operating Profit

Increased by 23.4 Bn JPY (Increased by 23.0 Bn JPY excl. forex impact)



(Bn JPY)

Revenue +38.4
incl. forex impact of -19.2

Cost of Sales +1.5
Improvement in cost of sales ratio by change in product mix

SG&A Expenses +22.3
Increase in expenses
due to an increase in profit share of gross profit with AstraZeneca

R&D Expenses +10.8
Increase in 5DXd ADCs* R&D investments

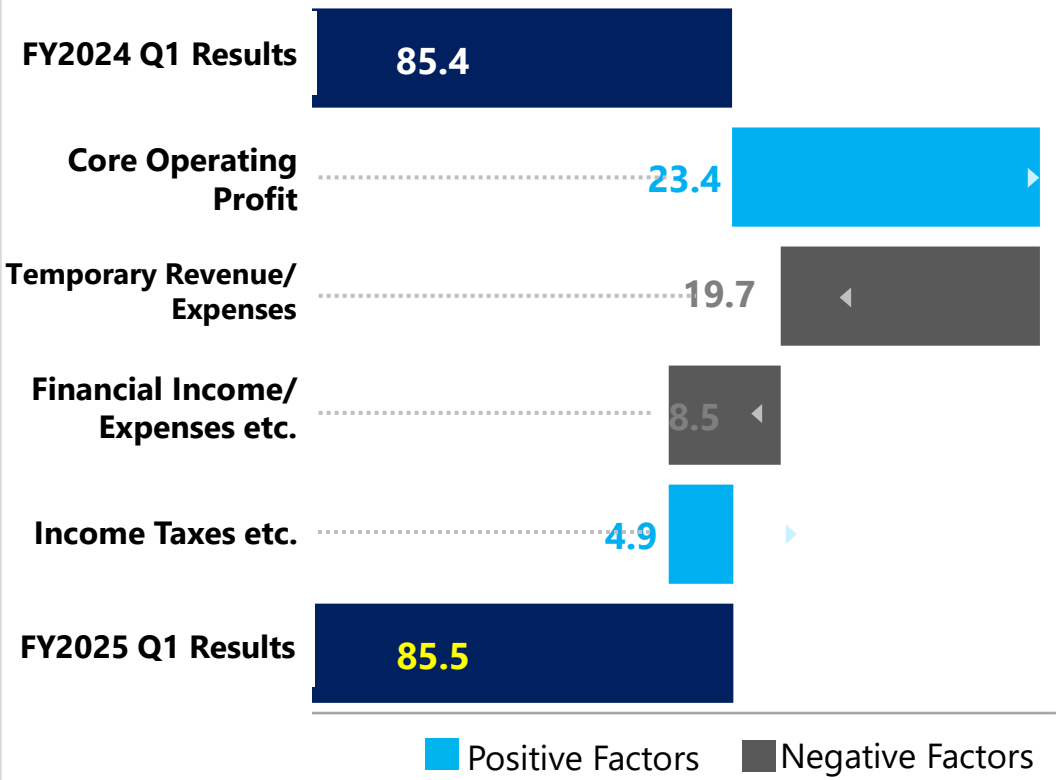
Forex Impact -19.6 **(Profit Increased)**
Cost of Sales -4.1
SG&A Expenses -9.9
R&D Expenses -5.6

***ENHERTU®**: trastuzumab deruxtecan (International Nonproprietary Name: INN), T-DXd, DS-8201 (HER2-directed ADC), **DATROWAY®**: : datopotamab deruxtecan (INN), DS-1062 (TROP2-directed ADC), **HER3-DXd**: patritumab deruxtecan (INN), U3-1402 (HER3-directed ADC), **I-DXd**: ifinatamab deruxtecan (INN), DS-7300 (B7-H3-directed ADC), **R-DXd**: raludotatug deruxtecan, DS-6000 (CDH6-directed ADC)

Profit Attributable to Owners of the Company

Increased by 0.1 Bn JPY

(Bn JPY)



Temporary Income/Expenses ····· **-19.7 (Profit Decreased)**

	FY2024 Q1 Results	FY2025 Q1 Results	YoY
Temporary Income	20.1*1	0.7	-19.4
Temporary Expenses	0.0	0.3	+0.3

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

Financial Income/Expenses etc. ····· **-8.5 (Profit Decreased)**

- Deterioration in forex gains/losses ····· -9.9
- Decrease in interest income ····· -1.3
- Improvement in investment securities valuation gains/losses ····· +1.8

Income Taxes etc. ····· **-4.9 (Profit Increased)**

	FY2024 Q1 Results	FY2025 Q1 Results	YoY
Profit before Tax	110.2	105.4	-4.8
Income Taxes etc.	24.8	19.9	-4.9
Tax rate	22.5%	18.9%	

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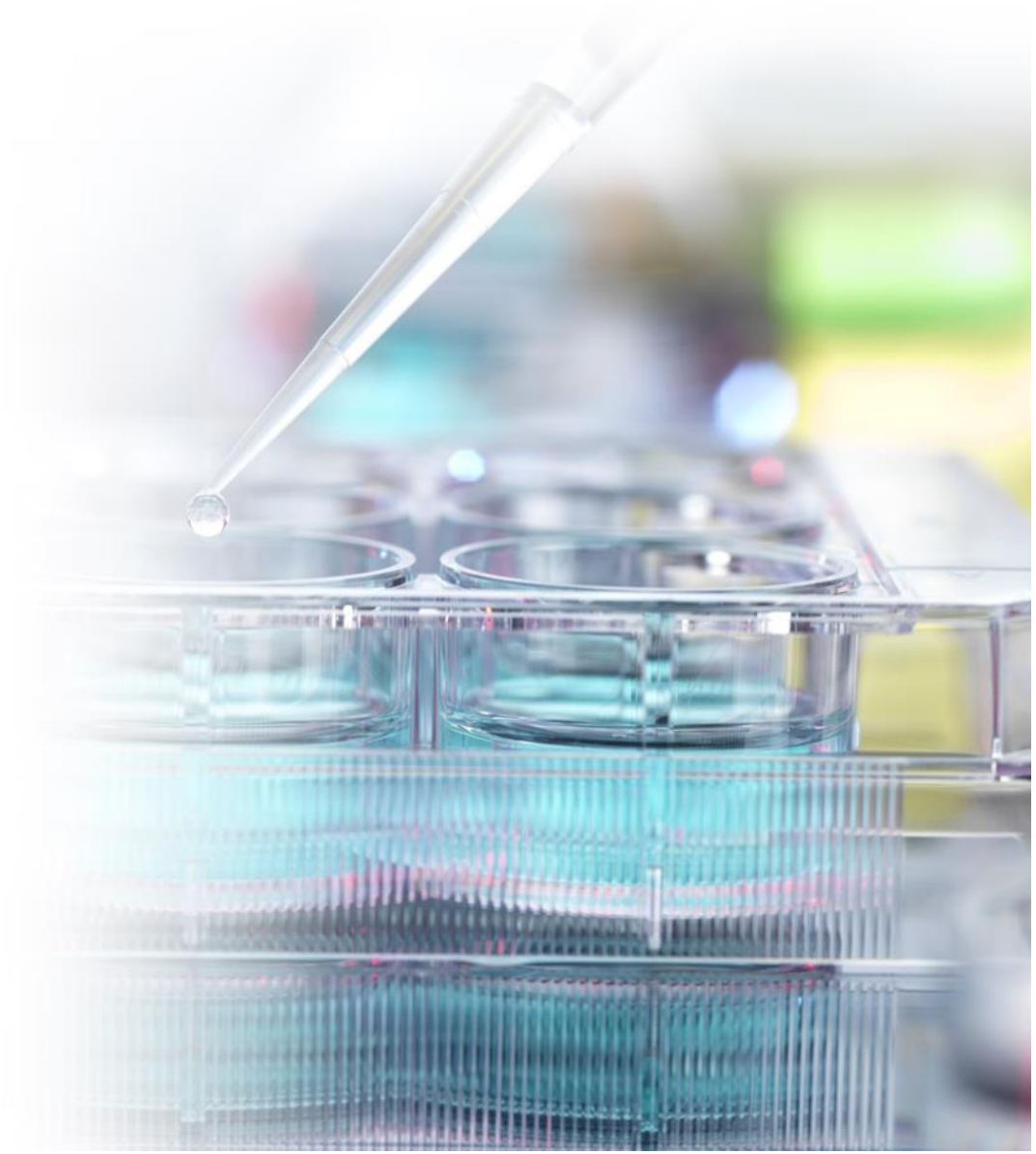
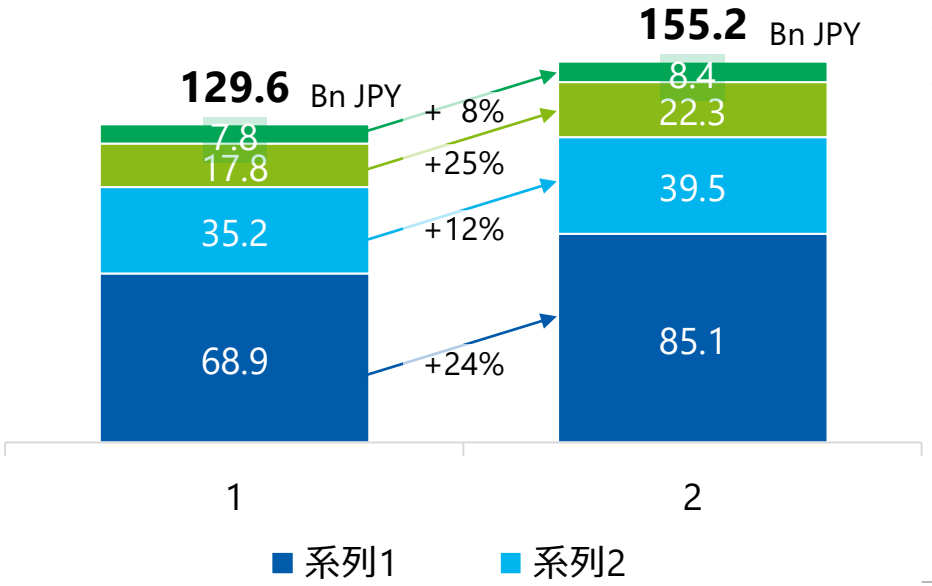


Performance

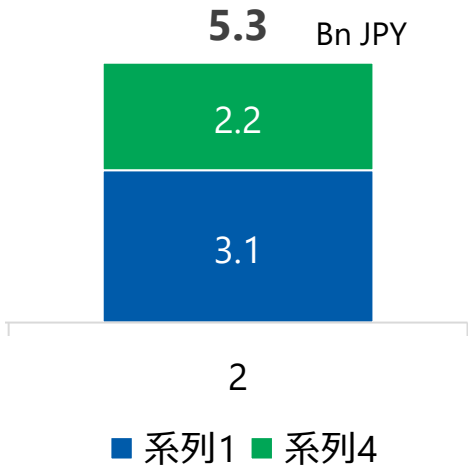


ENHERTU® trastuzumab deruxtecan

Q1 Global Product Sales Result **155.2 Bn JPY**
YoY **+25.6 Bn JPY (+19.7%)** Progress vs Apr. Forecast **23.4%**

Maintained the No.1 New Patient Share across Major Countries and Regions

- HR positive, HER2 low or ultralow BC (chemo naïve)
  - Solid progress in market penetration in US; Maintained the No.1 New Patient Share
  - Indication launched in EU in Apr.
- HER2 low BC (post-chemo): Reimbursement started in public sector in France from Apr.
- Robust sales growth in China following NRDL enlistment* in Jan.
  *HER2+ BC 2L, HER2 low BC (post-chemo)



DATROWAY® datopotamab deruxtecan

Q1 Global Product Sales Result **5.3 Bn JPY**
YoY **+5.3 Bn JPY (-%)** Progress vs Apr. Forecast **113.6%**

- HR positive and HER2 negative BC
  - Strong initial uptake in US and Japan
    - Updated annual forecast: Jul. forecast **21.6 Bn JPY** (vs Apr. forecast +16.9 Bn JPY)
    - Raised awareness of safety management such as stomatitis
  - Product launched in EU in Jun.
- EGFR-mutated NSCLC: Indication launched in US in Jun.
- NCCN guideline inclusion: NSCLC

AE: Adverse Event, BC: Breast Cancer, HR: Hormone Receptor, NCCN: National Comprehensive Cancer Network, NRDL: National Reimbursement Drug List, NSCLC: Non-Small Cell Lung Cancer

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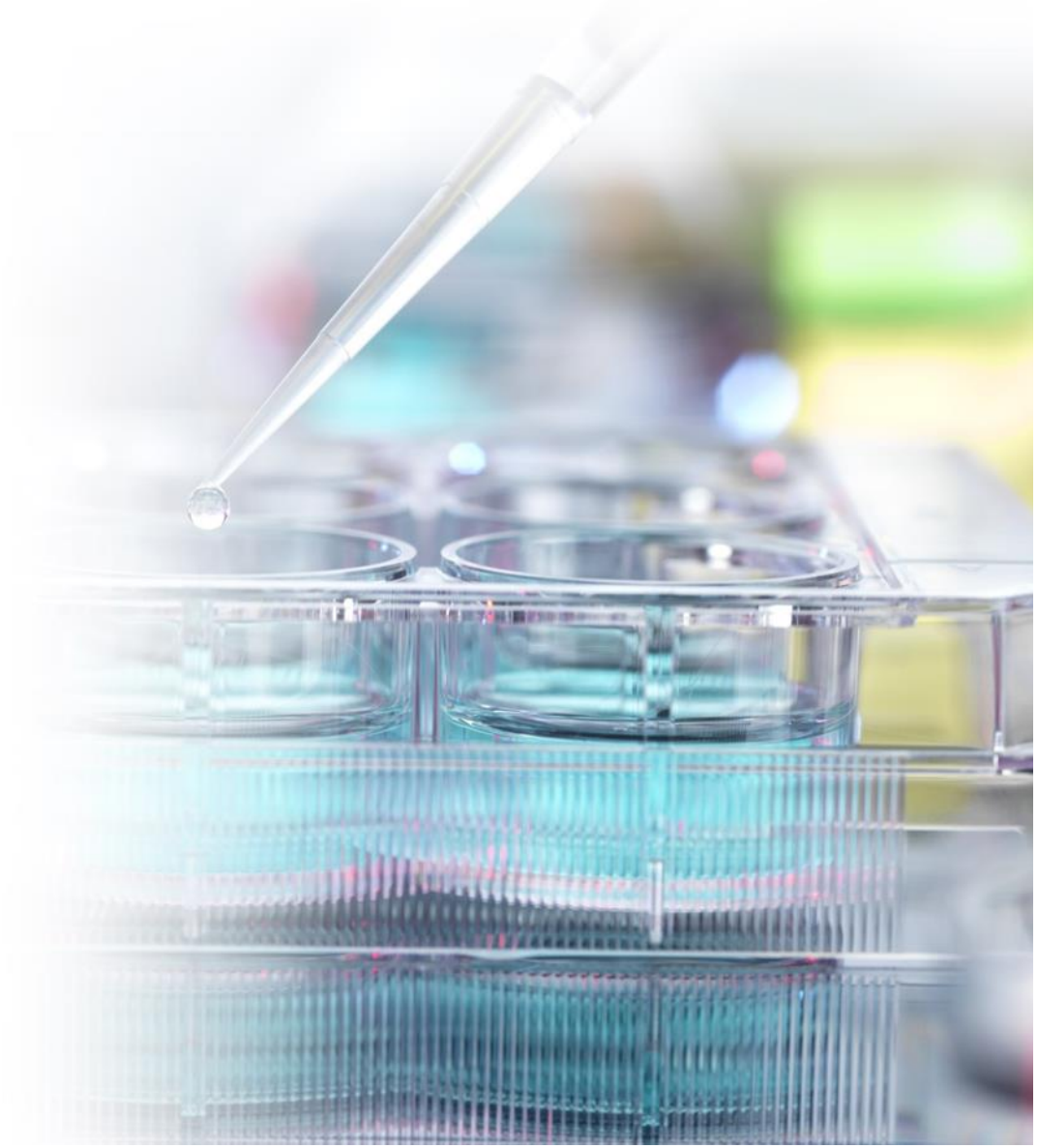


5DXd ADCs Update

Next Wave Update

Out Licensed Products Update

IR Event Information

News Flow

More Advancements in HER2 Positive Breast Cancer

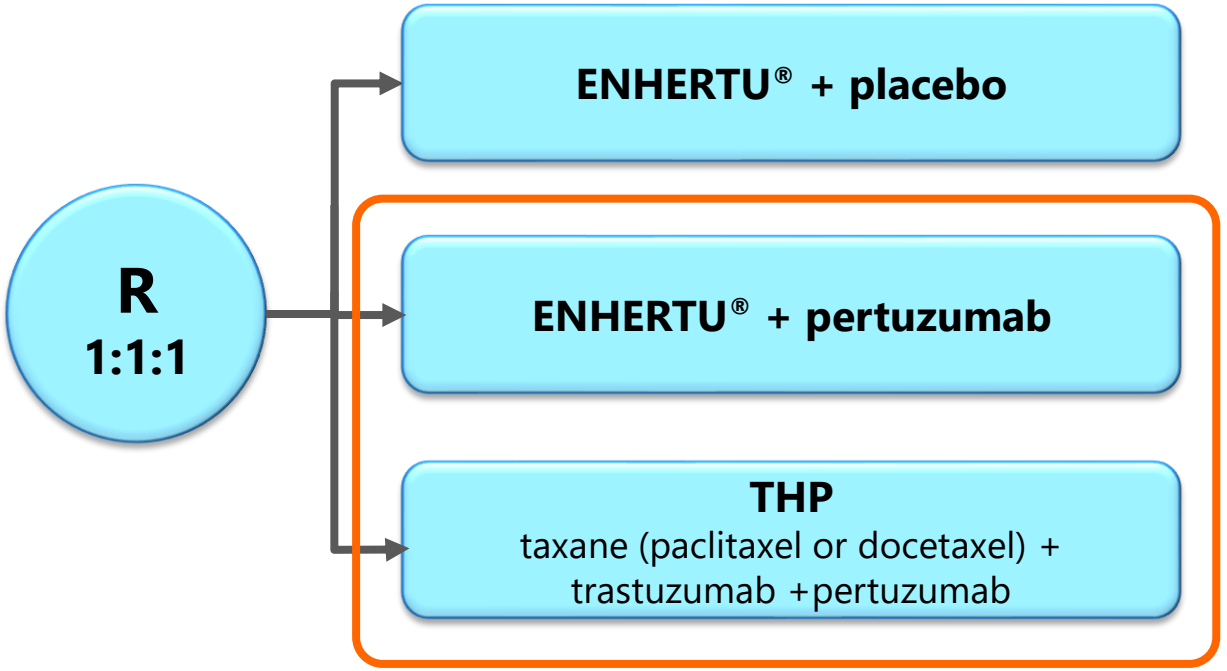
DESTINY-Breast09 Ph3 (ASCO 2025)

DESTINY-Breast09 evaluates the efficacy and safety of ENHERTU® ± pertuzumab vs SOC in 1L HER2 positive mBC

DESTINY-Breast09 Study Design

Eligible Patient

- HER2 positive advanced or metastatic breast cancer
- One prior line of ET for metastatic breast cancer permitted
- No other prior systemic treatment for metastatic breast cancer



Primary endpoint

- PFS (BICR)

Secondary endpoints

- OS
- PFS (investigator)
- ORR
- DOR
- PFS2
- Safety and tolerability

- At ASCO 2025, interim analysis results for the combination arm, ENHERTU® + pertuzumab, comparing to THP arm were presented (data cut-off: Feb 26, 2025)
- The arm assessing ENHERTU® monotherapy versus THP remains blinded to patients and investigators and will continue to the final PFS analysis

ASCO: American Society of Clinical Oncology, BC: breast cancer, BICR: blinded independent central review, DOR: duration of response, ORR: objective response rate, OS: overall survival, PFS: progression-free survival

ENHERTU®

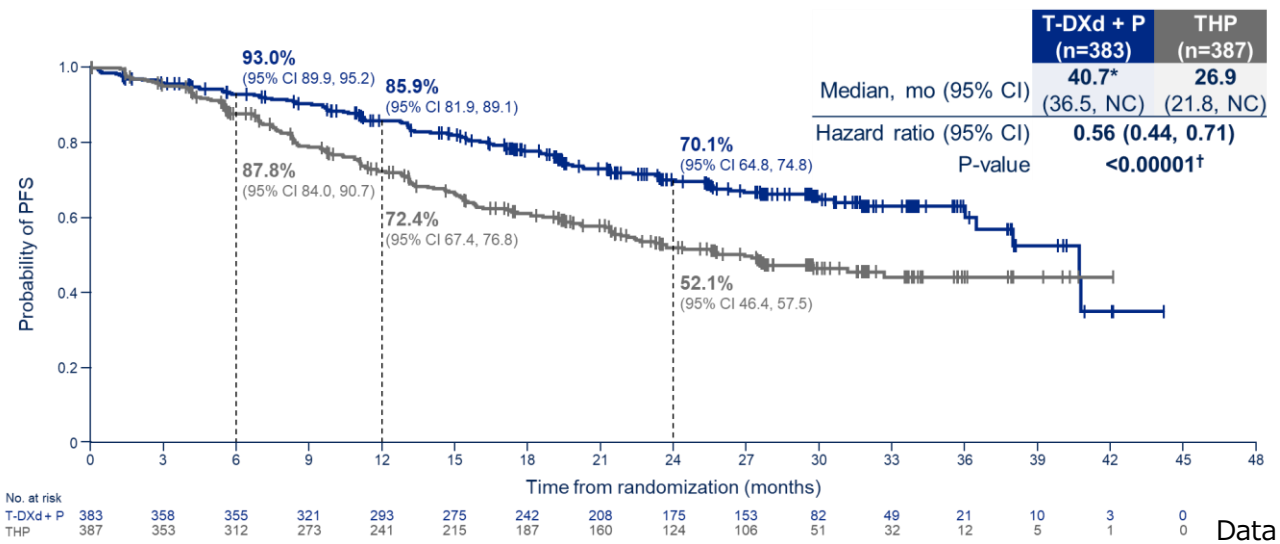
Establish a New 1L Treatment for HER2 Positive BC

DESTINY-Breast09 Ph3 (ASCO 2025)

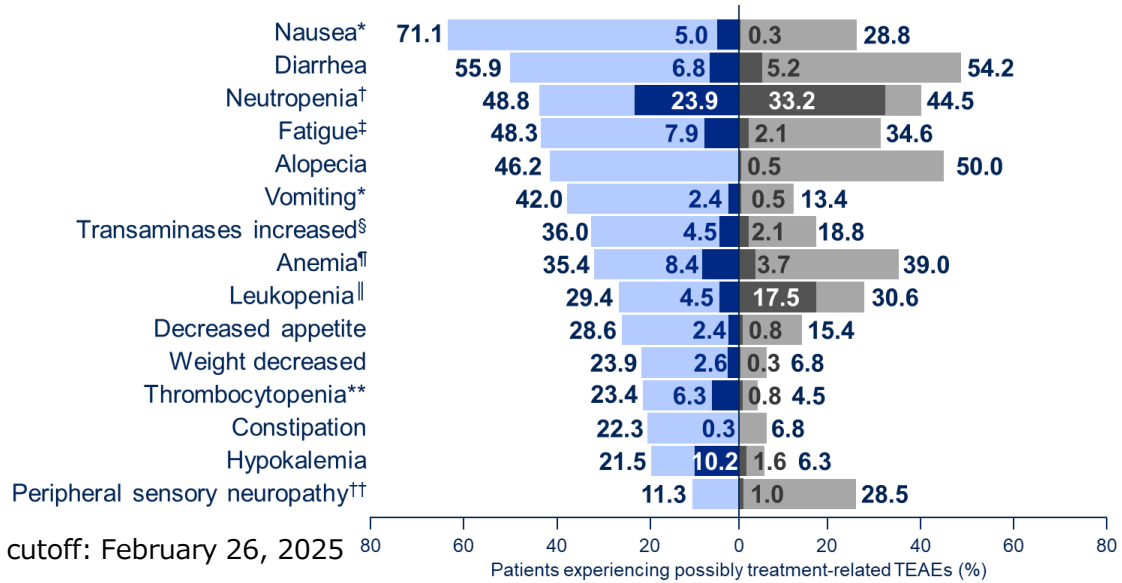
Daiichi-Sankyo

ENHERTU® in combination with pertuzumab (T-DXd+P) showed statistically significant and clinically meaningful PFS in the 1L treatment of HER2+ mBC

Antitumor Activity (PFS (BICR))



Safety



Data cutoff: February 26, 2025

- mPFS in T-DXd+P arm was 40.7 mo versus 26.9 mo in THP arm with 44% reduction in the risk of disease progression or death
- Interim OS data showed an early trend favoring T-DXd+P compared to THP with HR 0.84 (95% CI 0.59-1.19) with 16% maturity
- T-DXd+P safety data were consistent with known profiles of individual treatments. The majority of ILD were low grade. There were two grade 5 ILD events (0.5%) in T-DXd+P
- Breakthrough Therapy Designation was granted by FDA in July 2025
- Data will be shared with regulatory authorities toward regulatory submission

ASCO: American Society of Clinical Oncology, BC: breast cancer, BICR: blinded independent central review, CI: confidence interval, FDA: U.S. Food and Drug Administration, ILD: interstitial lung disease, mBC: metastatic breast cancer, mo: month, mPFS: median progression-free survival, NC: not calculated, OS: overall survival, PFS: progression-free survival, T-DXd: trastuzumab deruxtecan, ENHERTU® , THP: taxane + trastuzumab +pertuzumab

ENHERTU®

First Ph3 Study Demonstrated Benefit of ENHERTU® in Early Breast Cancer

DESTINY-Breast11 Ph3

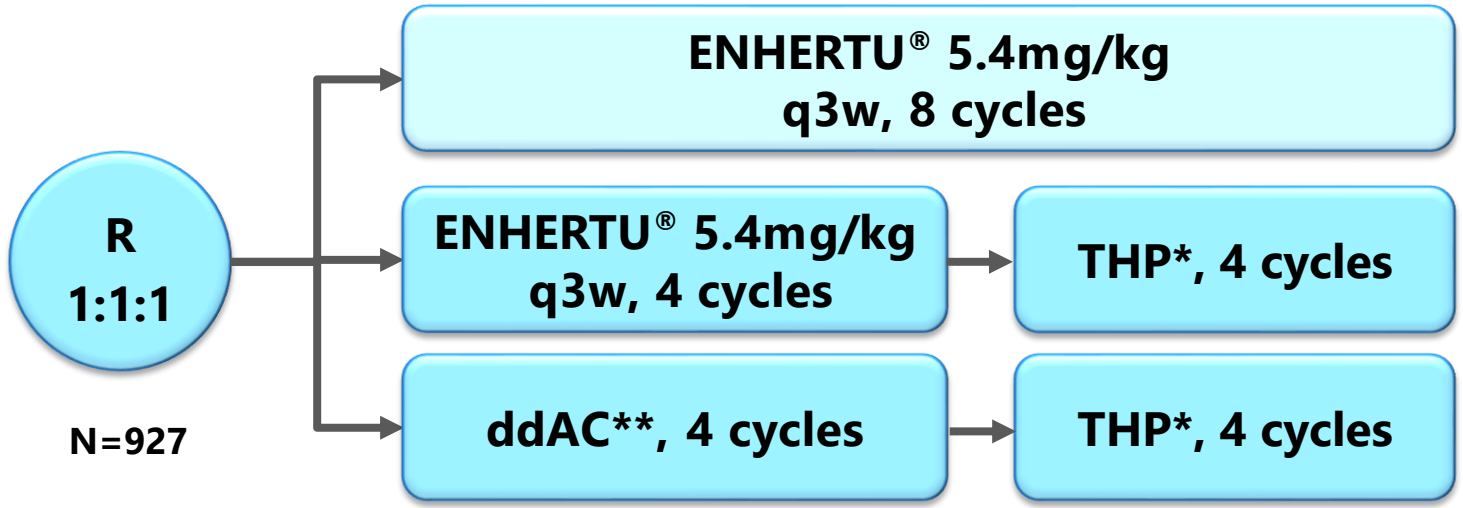
Daiichi-Sankyo

ENHERTU® followed by THP demonstrated statistically significant and clinically meaningful improvement in pCR in high-risk HER2 positive eBC neoadjuvant setting

DESTINY-Breast11 Study Design

Eligible Patient

- Histologically documented HER2 positive early BC
- Eligible for following clinical stage (based on mammogram or breast MRI assessment)
  - ✓ >T3 or N+ or inflammatory BC as determined by the AJCC staging system



* THP: paclitaxel qw + trastuzumab q3w + pertuzumab q3w
** ddAC: doxorubicin + cyclophosphamide q2w

Primary endpoint: pCR
Secondary endpoint: EFS, OS

- EFS was not mature at the time of this analysis, however, preliminary EFS data showed an early trend favoring ENHERTU®-THP therapy compared to ddAC-THP therapy
- Safety profile of ENHERTU®-THP therapy was consistent with the known profiles for each individual therapy, and showed an improvement compared to SOC
- Enrollment for ENHERTU® monotherapy arm was halted based on interim evaluation by IDMC
- Data will be presented at ESMO 2025

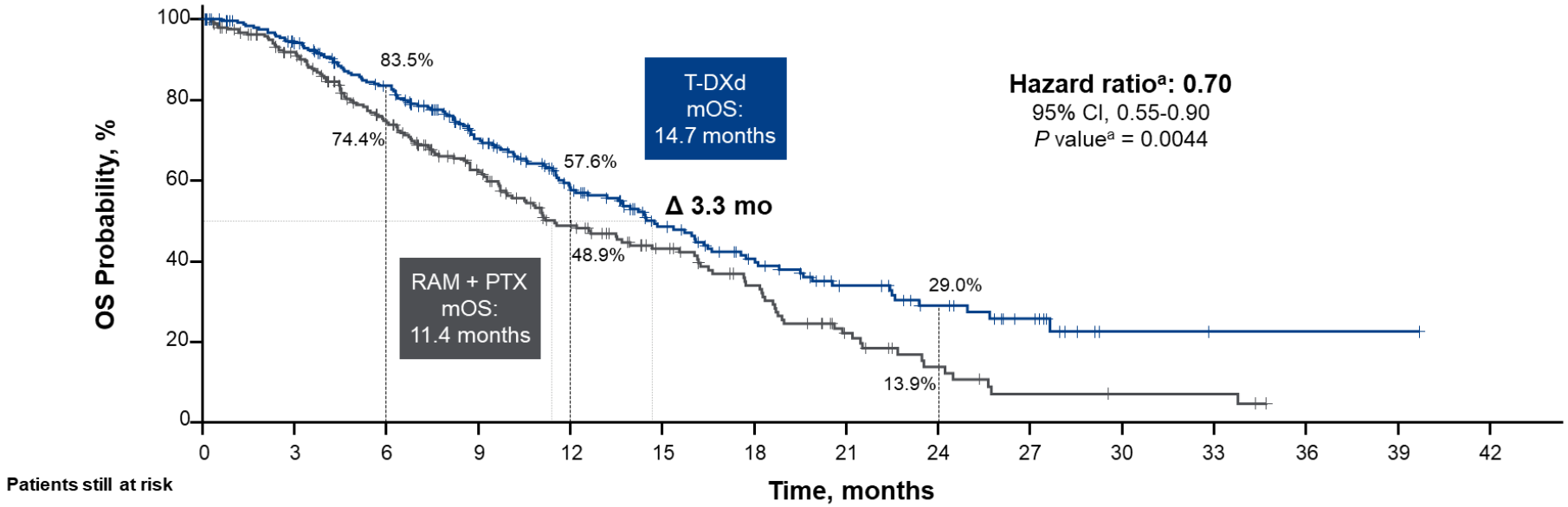
AJCC: American Joint Committee on Cancer, BC: breast cancer, eBC: early-stage breast cancer, EFS: event-free survival, HR: hormone receptor, IDMC: independent data monitoring committee, MRI: Magnetic Resonance Imaging, OS: overall survival, pCR: pathological complete response, qw: once weekly, q2w: every 2 weeks, q3w: every 3 weeks, TLR: top line results

For Earlier Treatment of HER2 Positive GC

DESTINY-Gastric04 Ph3 (ASCO 2025)

Daiichi-Sankyo

DESTINY-Gastric04 establishes ENHERTU® as global 2L HER2+ SOC for patients with HER2+ mGC/GEJA



Data cutoff: October 24, 2024

- ENHERTU® demonstrated mOS 14.7 mo with 30% reduction in risk of death compared with ramucirumab plus paclitaxel combination therapy
- Improvement in mPFS (6.7 mo vs 5.6 mo), cORR (44.3% vs 29.1%), DCR (91.9% vs 75.9%), and mDOR (7.4 mo vs 5.3 mo) was also observed
- No new safety signals were identified. ILD/pneumonitis events in ENHERTU® arm were mainly low-grade, with no grade 4 or 5 events. Adjudicated as drug-related ILD occurred in 13.9 % (grade 3: 0.4%) of patients treated with ENHERTU®

ASCO: American Society of Clinical Oncology, CI: confidence interval, cORR: confirmed objective response rate, DCR: disease control rate, GC: gastric cancer, GEJA: gastroesophageal junction adenocarcinoma, ILD: interstitial lung disease, mDOR: median duration of response, mGC: metastatic gastric cancer, mo: month(s), mOS: median overall survival, mPFS: median progression free survival, OS: overall survival

[a]Two-sided *P* value from stratified log-rank test and stratified Cox proportional hazards model adjusted for stratification factor: HER2 status (IHC 3+ or IHC 2+/ISH+).

ENHERTU®

New Challenge in Gynecological Cancers

DESTINY-Endometrial01 Ph3

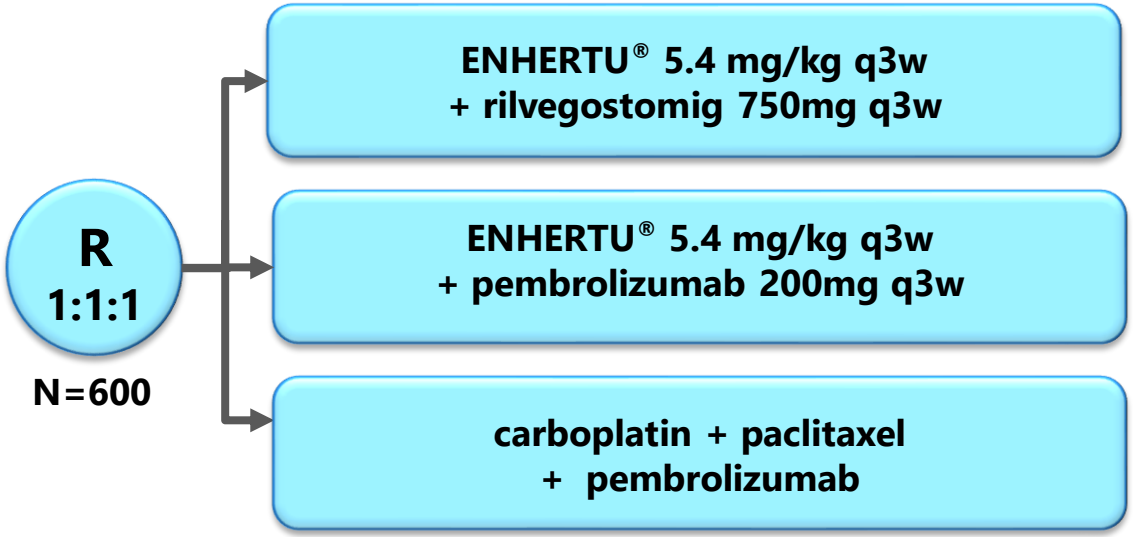
Daiichi-Sankyo

Expand development for 1L therapy in HER2 expressing mismatch repair proficient (pMMR) endometrial cancer

DESTINY-Endometrial01 Study Design

Eligible Patient

- Primary Stage III, Stage IV or recurrent histologically-confirmed endometrial cancer
- pMMR endometrial cancer
- HER2 IHC 3+/2+
- Received 1 prior line of adjuvant/ neoadjuvant chemotherapy if recurrence ≥6 months after last dose of chemo



Primary endpoint：PFS (BICR) in ITT
Secondary endpoint：OS, PFS (investigator), ORR, etc.

- Observed encouraging signals in heavily pre-treated population in DESTINY-PanTumor02 study (ESMO 2023)
  - ✓ Data for endometrial cancer population (median prior therapy lines: 2 (range 0-7)): cORR: 57.5% (23/40), mDOR: NR (95% CI: 9.9, NE), mPFS: 11.1 mo (95% CI: 7.1, NR)
- Study started in June 2025

ASCO: American Society of Clinical Oncology, BICR: blinded independent central review, CI: confidence interval, cORR: confirmed objective response rate, DOR: duration of response, ESMO: European Society for Medical Oncology, IHC: immunohistochemistry, ITT: intention-to-treat, mDOR: median duration of response, mo: month(s), mPFS: median progression-free survival, NR: not reached, NE: not estimated, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, q3w: every 3 weeks

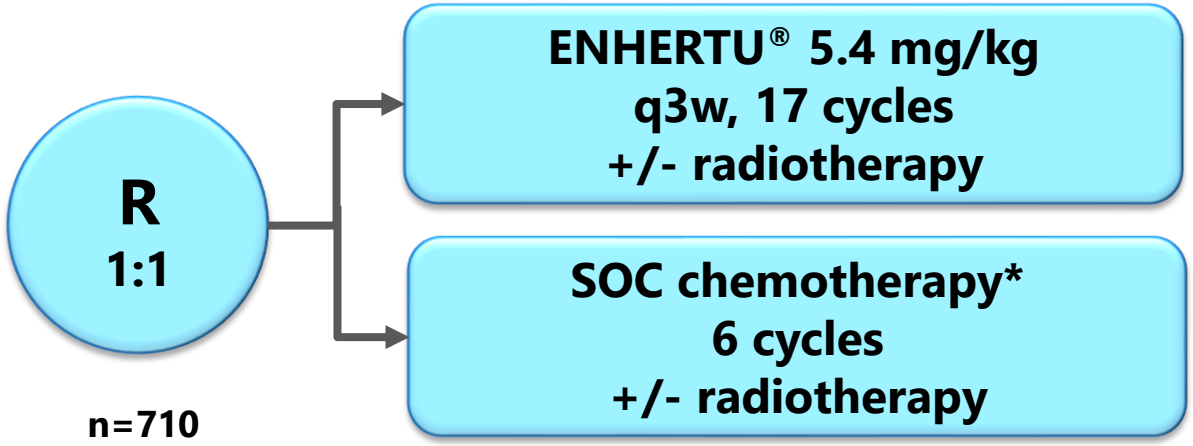
New Challenge in Gynecological Cancers

DESTINY-Endometrial02 Ph3

New Ph3 Study of ENHERTU® for adjuvant therapy in HER2 expressing high risk Endometrial cancer

DESTINY-Endometrial02 Study Design

Eligible Patient
- Stage IIC or III (FIGO 2023)
- HER2 IHC 2+/3+
- No evidence of disease post-surgery confirmed by BICR.
- Endometrial cancer systemic therapy naïve



Primary endpoint：DFS ITT (BICR or pathology)
Secondary endpoint：OS ITT

* carboplatin/ paclitaxel

- DESTINY-Endometrial02 aims to cultivate early identification of HER2 expressing endometrial cancer, and establish a curative treatment for a patient segment with high unmet need
- Plan to start in FY2025 H2

BICR: blinded independent central review, DFS: Disease-Free Survival, IHC: immunohistochemistry, ITT: intention-to-treat, OS: overall survival, SOC: standard of care

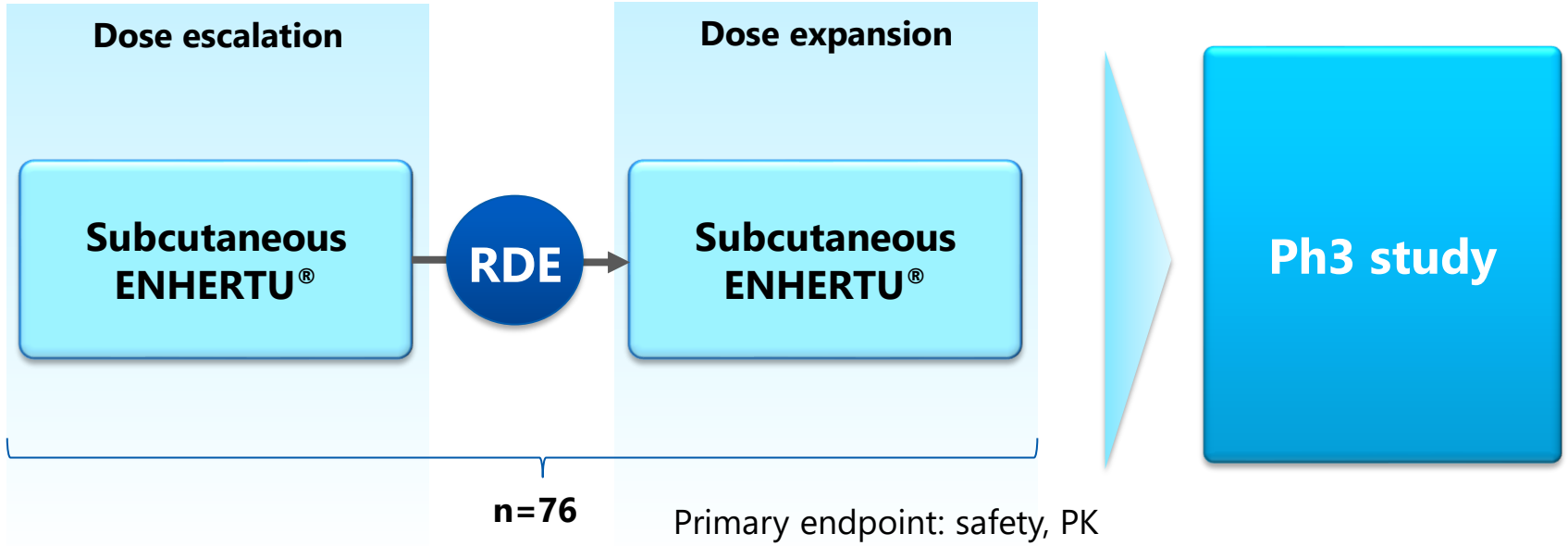
New Formulation to Provide Better Treatment Option

Ph1 study will inform subcutaneous formulation dose selection

Subcutaneous Formulation Study

Eligible Patient

- Recurrent and metastatic solid tumors



- The subcutaneous formulation can contribute to better patients' QOL
- Registrational study is to follow based on this study outcome
- Plan to start in FY2025 H1

PK: pharmacokinetics, RDE: recommended dose for expansion

DATROWAY®

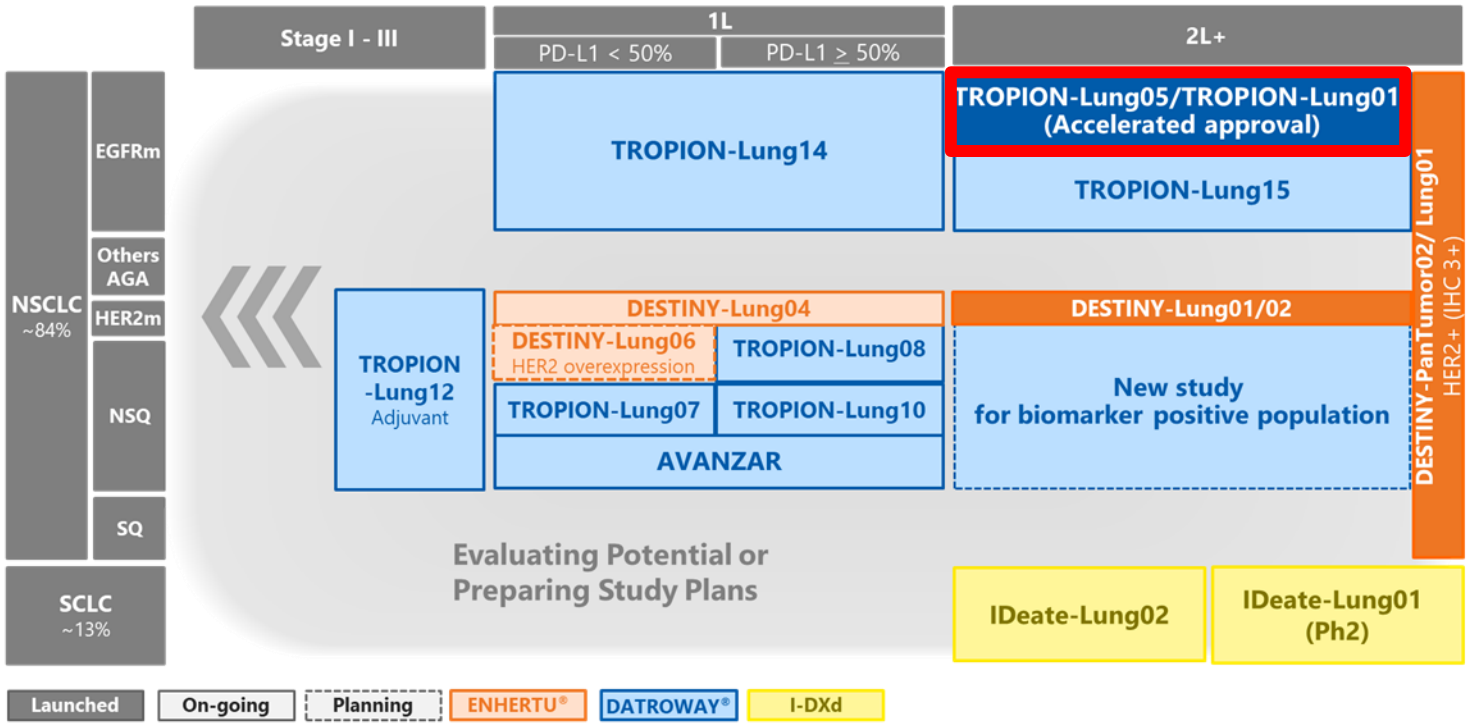
First Step into Lung Cancer

TROPION-Lung05 Ph2, TROPION-Lung01 Ph3

Daiichi-Sankyo

DATROWAY® first approval for lung cancer in the US

Major Studies for Lung Cancer



- **Approved in the US for the treatment of patients with locally advanced or metastatic EGFR mutated NSCLC** in June 2025
- The approval is based on the results of TROPION-Lung05 (Ph2) and TROPION-Lung01 (Ph3)
- Approved under accelerated approval following Priority Review and Breakthrough Therapy Designation
- Further validation of clinical benefit is required for full approval and **TROPION-Lung15 (Ph3) is ongoing as a confirmatory study**

AGA: actionable genomic alteration, IHC: immunohistochemistry, NSQ: non-squamous, NSCLC: non-small cell lung cancer , SCLC: small cell lung cancer , SQ: squamous

TROP2 NMR as a Potential Biomarker in NSCLC

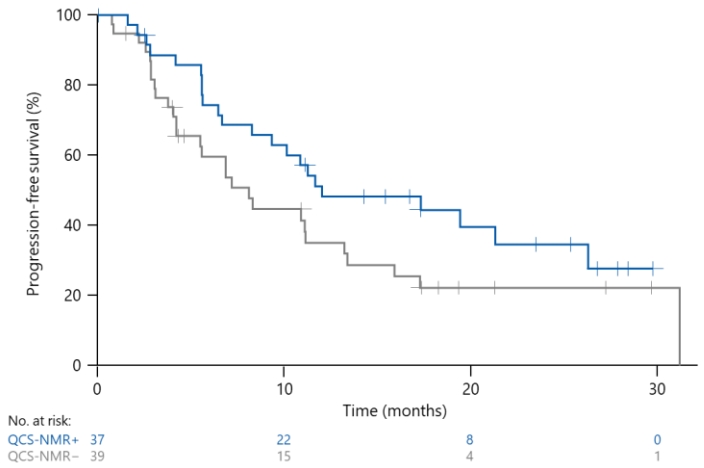
TROPION-Lung02 Ph1b (ASCO 2025)

Daiichi-Sankyo

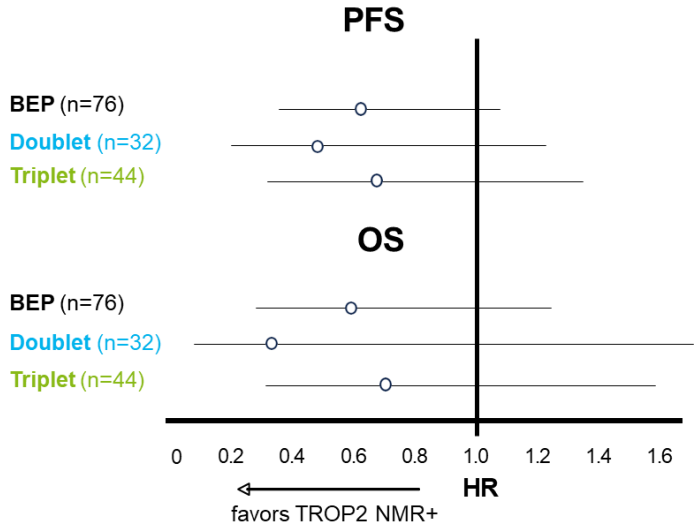
Retrospective analysis in 1L NSCLC showed a trend towards improved response to DATROWAY® in TROP2 NMR* positive patients, measured by QCS**

Antitumor Activity

	Median PFS (95% CI)
TROP2 NMR+ (n=37)	12.0 mo (8.2–26.2)
TROP2 NMR− (n=39)	8.1 mo (4.2–13.2)
HR = 0.62 (0.35–1.10)	



Pooled analysis of doublet and triplet



Data cut-off: April 29, 2024

TROPION-Lung02 (Ph1b)

✓ Evaluate efficacy and safety of DATROWAY® + pembrolizumab ± platinum chemotherapy in patients with advanced or metastatic non-AGA NSCLC

- In the 1L treatment group both doublet and triplet showed durable antitumor activity and tolerability of the combinations was as expected based on known profiles of the individual agents
- TROP2 NMR positive subgroup showed a prolonged PFS. Improvement of both PFS and OS was observed in doublet and triplet cohorts
- TROP2 NMR by QCS will be utilized in AVANZAR (Ph3) and TROPION-Lung10 (Ph3) as a biomarker

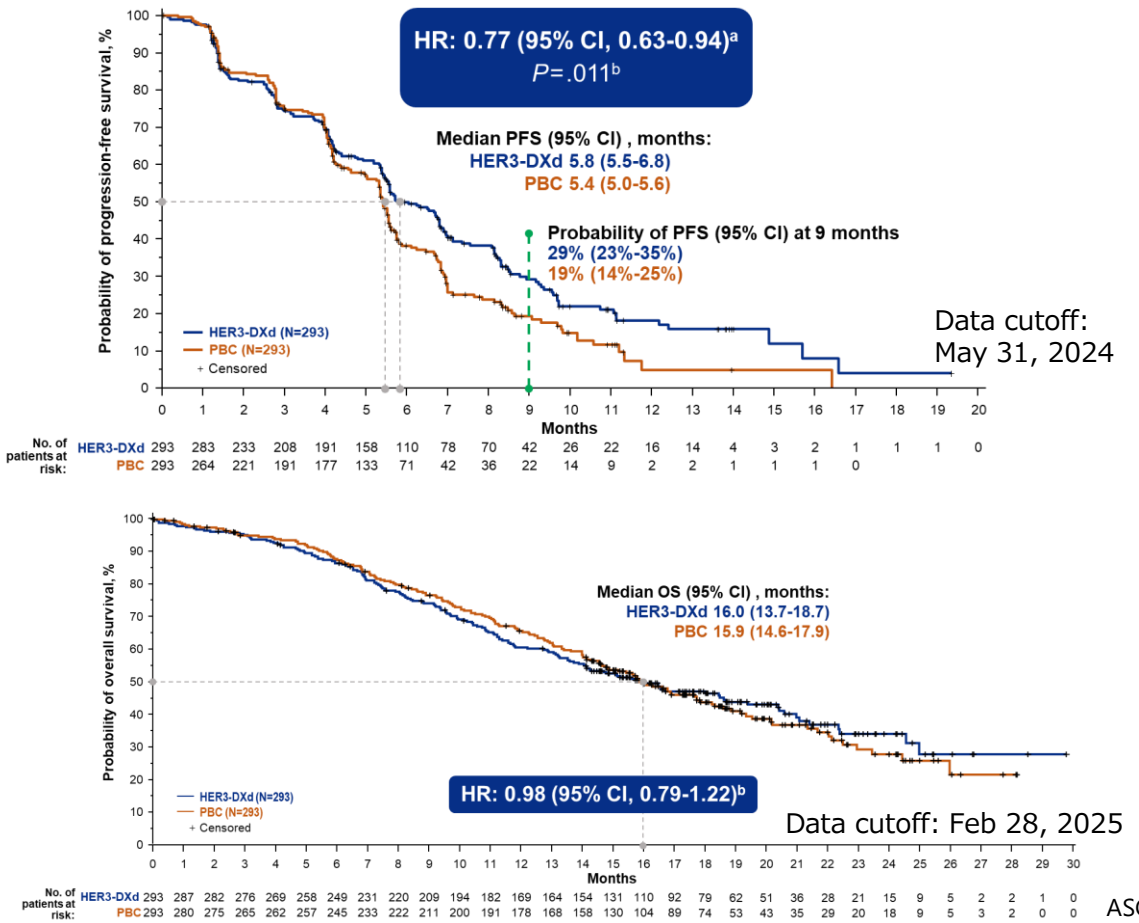
** QCS (quantitative continuous scoring) is a novel computational pathology approach that precisely quantifies and locates targets
* TROP2 NMR (normalized membrane ratio) by QCS potentially predicts the efficacy of DATROWAY® through analyzing the TROP2 expression in the cell membrane relative to total TROP2
AGA: actionable genomic alteration, ASCO: American Society of Clinical Oncology, CI: confidence interval, HR: hazard ratio, mo: month, PFS: progression-free survival

EGFR mutated NSCLC 3L Treatment

HERTHENA-Lung01 (Ph2) and HERTHENA-Lung02 (Ph3)

Regulatory submission in the US based on HERTHENA-Lung01 was voluntarily withdrawn in May 2025

HERTHENA-Lung02 PFS (upper) and OS (lower)



Data cutoff: May 31, 2024

- This application was accepted by the FDA based on the results from HERTHENA-Lung01 (Ph2) in EGFR mutated NSCLC 3L treatment in December 2023
- HERTHENA-Lung02 met its primary endpoint of PFS; safety profile consistent with that observed in previous HER3-DXd lung cancer clinical trials; no new safety signals identified
- **Based on OS results from HERTHENA-Lung02 confirmatory Ph3 study**, which included for patients with EGFR mutated locally advanced or metastatic NSCLC for 2L treatment, and **on discussions with the FDA**, **the application was withdrawn**
- HERTHENA-Lung02 results were presented at ASCO 2025
- **Broad development across multiple solid tumors underway; position of HER3-DXd in our pipeline has not been changed**

ASCO: American Society of Clinical Oncology, CI: confidence interval, HR: hazard ratio, FDA: U.S. Food& Drug Administration, NSCLC: non-small cell lung cancer, OS: overall survival, PBC: platinum-based chemotherapy, PFS: progression-free survival

Expand HR+/HER2- mBC Treatment Options

HERTHENA-Breast04 Ph3

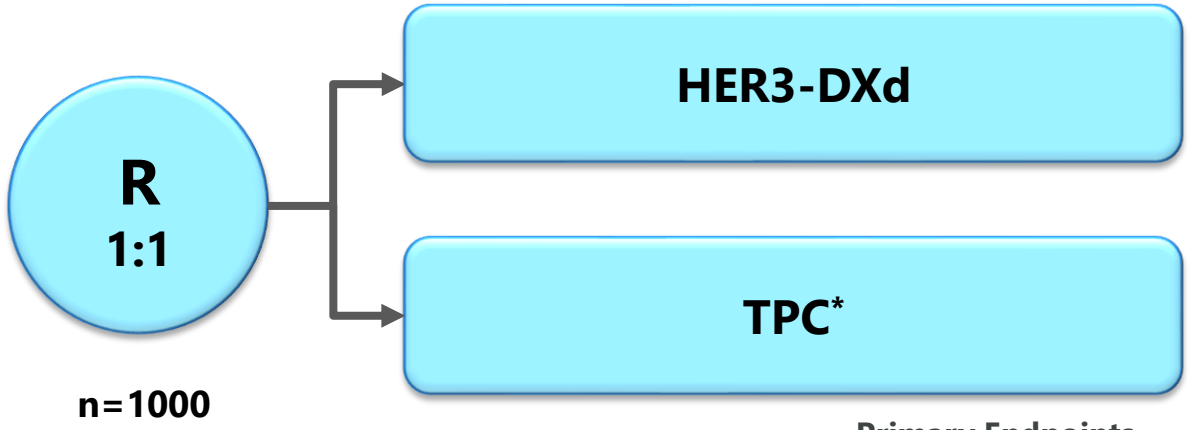
Daiichi-Sankyo

New Ph3 study of HER3-DXd for HR+/HER2- mBC post CDK4/6 inhibitor treatment in 1L

HERTHENA-Breast04 Study Design

Eligible Patient

- HR+/HER2- mBC (HER2 IHC 0 or 1+ or 2+/ISH-)
- Chemotherapy and ADC naive
- Eligible for one of TPC options
- Not eligible for further ET-based therapy
- Meets criteria for one the following:
  - ✓ PD while on 1L ET+ CDK4/6 inhibitor, or
  - ✓ Relapse while on or within 24 mo of last dose of adjuvant CDK 4/6i + ET



Primary Endpoints

- PFS by BICR
- OS

Secondary endpoint

- ORR, DOR, HRQoL, safety

- ICARUS-Breast01 showed positive efficacy in HR+/HER2- mBC of post CDK4/6 inhibitors and one line of chemotherapy
  - ✓ ORR: 53.5% (95% CI: 43.2, 63.6), mPFS: 9.4 mo (95% CI: 8.1, 13.4) (ESMO 2024)
- Plan to start in FY2025 H1

*TPC may be any of the following options: paclitaxel, nab-paclitaxel, capecitabine, liposomal doxorubicin or ENHERTU®

BICR: blinded independent central review, CI: confidence interval, ESMO: European Society for Medical Oncology, ET: endocrine therapy, HR: hormone receptor, HRQoL: health-related quality of life, IHC: immunohistochemistry, ISH: *in situ* hybridization, mBC: metastatic breast cancer, mPFS: median progression-free survival, OS: overall survival, ORR: objective response rate, PD: progressive disease, PFS: progression-free survival, TPC: treatment of physician's choice,

Addressing Unmet Needs in ES-SCLC

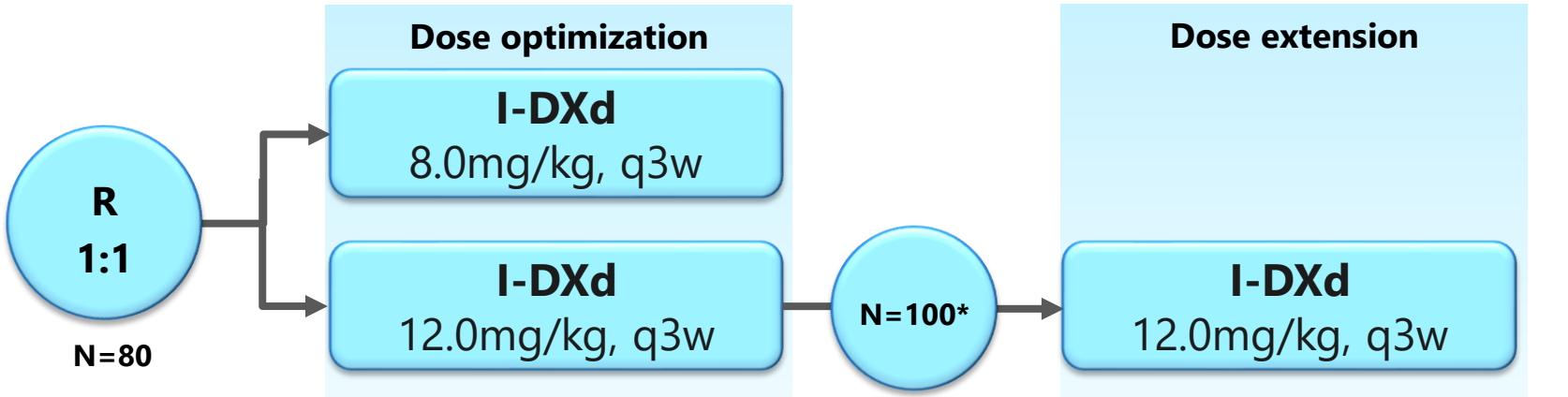
IDeate-Lung01 Ph2

Promising data from dose extension part in ES-SCLC in Apr 2025

IDeate-Lung01 Study Design

Eligible Patients

- ES-SCLC
- Prior therapy with at least one platinum-based line
- Minimum of two previous lines of systemic therapy (current protocol)



Primary endpoint: ORR
Secondary endpoint: PFS, DOR, OS etc.

- IDeate-Lung01 compared 8.0mg/kg and 12mg/kg and choose 12mg/kg as an optimal dose in dose optimization part
- The data will be presented at a future medical conference
- As for ES-SCLC, IDeate-Lung02 (Ph3) for 2L treatment and combination study with MK-6070 (gocatamig) are ongoing

* Extended enrollment at the selected dose

DOR: duration of response, ES-SCLC: extensive-stage small cell lung cancer, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, q3w: every 3 weeks

5DXd ADCs

Other Clinical and Regulatory Approval Status Updates

HER3-DXd

- June 2025: LIGHTBEAM-U01 Ph1/2 study for relapsed or refractory pediatric cancers, hepatoblastoma or rhabdomyosarcoma started

I-DXd

- May 2025: IDeate-Esophageal01 Ph3 study for ESCC 2L started
- June 2025: IDeate-Prostate01 Ph3 study for chemo naive mCRPC started

R-DXd

- April 2025: REJOICE-GI01 signal-seeking Ph2 study for GI cancers and REJOICE-Ovarian02 Ph1b/2 study to evaluate combination therapy for ovarian cancer relapsed after PBC started

ESCC: esophageal squamous cell carcinoma, ES-SCLC: extensive-stage small cell lung cancer, mCRPC: metastatic castration-resistant prostate cancer, GI: gastrointestinal, PBC: platinum-based chemotherapy

5DXd ADCs Update

Next Wave Update

Out Licensed Products Update

IR Event Information

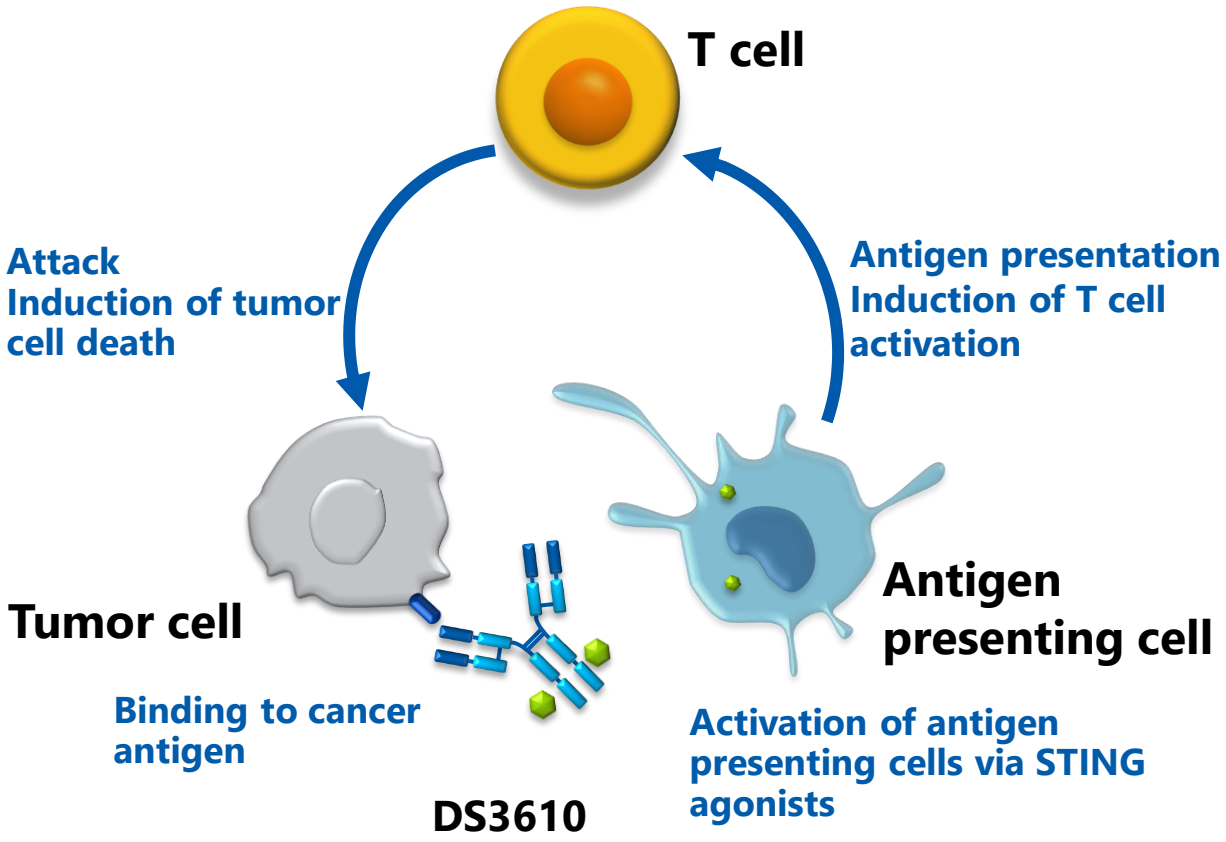
News Flow

DS3610

New STING Agonist ADC

DS3610 delivers STING* agonists to cancer cells via an antibody targeting a cancer antigen and activates antitumor immunity within the tumor microenvironment

Mechanism of Action



- ADC that combines Daiichi Sankyo original STING agonists with an antibody
- The novel Fc modification technology reduces the risk of systemic cytokine release
- Activation of immune cells including antigen presenting cells and T cells, and durable antitumor activity by immune memory formation have been confirmed in preclinical studies
- Combination effect with various therapeutic agents has been observed
- The FIH study will start in FY2025 H2

ADC: antibody-drug conjugate, FIH: first-in human

*A key molecule in the activation of innate immunity and attracting attention in the field of cancer immunity

5DXd ADCs Update

Next Wave Update

Out Licensed Products Update

IR Event Information

News Flow

Out Licensed Products

Status Updates

Taletrectinib (IBTROZI®, DS-6051)

- Taletrectinib is **an oral ROS1/NTRK inhibitor** generated by Daiichi Sankyo as DS-6051
- Daiichi Sankyo entered into a license agreement (product licensing) with AnHeart Therapeutics Inc.* in December 2018 and granted AnHeart Therapeutics Inc. exclusive rights to develop, manufacture and commercialize DS-6051 worldwide

  *AhHeart Therapeutics Inc. was acquired by Nuvation Bio Inc. in March 2024 and Nuvation Bio Inc. has exclusive rights of Taletrectinib/DS-6051 now

- **Approved for patients with locally advanced or metastatic ROS1-positive NSCLC** in China in January and in the US in June, 2025

NSCLC: non-small cell lung cancer

5DXd ADCs Update

Next Wave Update

Out Licensed Products Update

IR Event Information

News Flow

Upcoming IR Events

WCLC 2025 Highlights

Date, time and format

Wednesday, September 17, 2025
7:00-8:15pm EDT
Thursday, September 18, 2025
8:00-9:15am JST
Virtual (Zoom)

The content will be available on demand at a later date

Speakers

Ken Takeshita, Global R&D Head
Mark Rutstein, Head of Global Therapeutic Area Oncology
Abder Laadem, Head of Late-Stage Oncology Clinical Development

ESMO 2025 Highlights

Date, time and format

Tuesday, October 21, 2025
8:00-9:30am EDT
9:00-10:30pm JST
Virtual (Zoom)

The content will be available on demand at a later date

Speakers

Ken Takeshita, Global R&D Head
Mark Rutstein, Head of Global Therapeutic Area Oncology

5DXd ADCs Update

Next Wave Update

Out Licensed Products Update

IR Event Information

News Flow

FY2025 News Flow

As of Jul 2025

Planned major data disclosures

World Conference on Lung Cancer（WCLC, Sep 6-9, 2025）

DATROWAY®	**TROPION-Lung01: NSCLC, 2L+, Ph3** • **Retrospective analysis （intracranial efficacy）**

European Society For Medical Oncology（ESMO, Oct 17-21, 2025）

ENHERTU®	**DESTINY-Breast11: HER2+ BC, neoadjuvant, Ph3** • **Primary analysis**
DATROWAY®	**TROPION-PanTumor03: Ph2** • **First data release for UC**
DS-3939	**Advanced or metastatic solid tumors, Ph1/2** • **Dose escalation part first data release**

Regulatory decisions

ENHERTU®	DESTINY-Breast06: HR+/HER2 low or HER2 ultralow, chemo naïve, Ph3 • JP: FY2025 H1
DATROWAY®	**TROPION-Breast01: HR+ and HER2 low or negative BC, 2/3L** • **CN: FY2025 H1**

Key data readouts

ENHERTU®	DESTINY-Breast05*: HER2+ BC, adjuvant*[1], Ph3 • FY2025 H2
DATROWAY®	TROPION-Breast02: PD-1/PD-L1 ineligible TNBC, 1L, Ph3 • **FY2025 H2**

Bold: update from FY2024 Q4

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

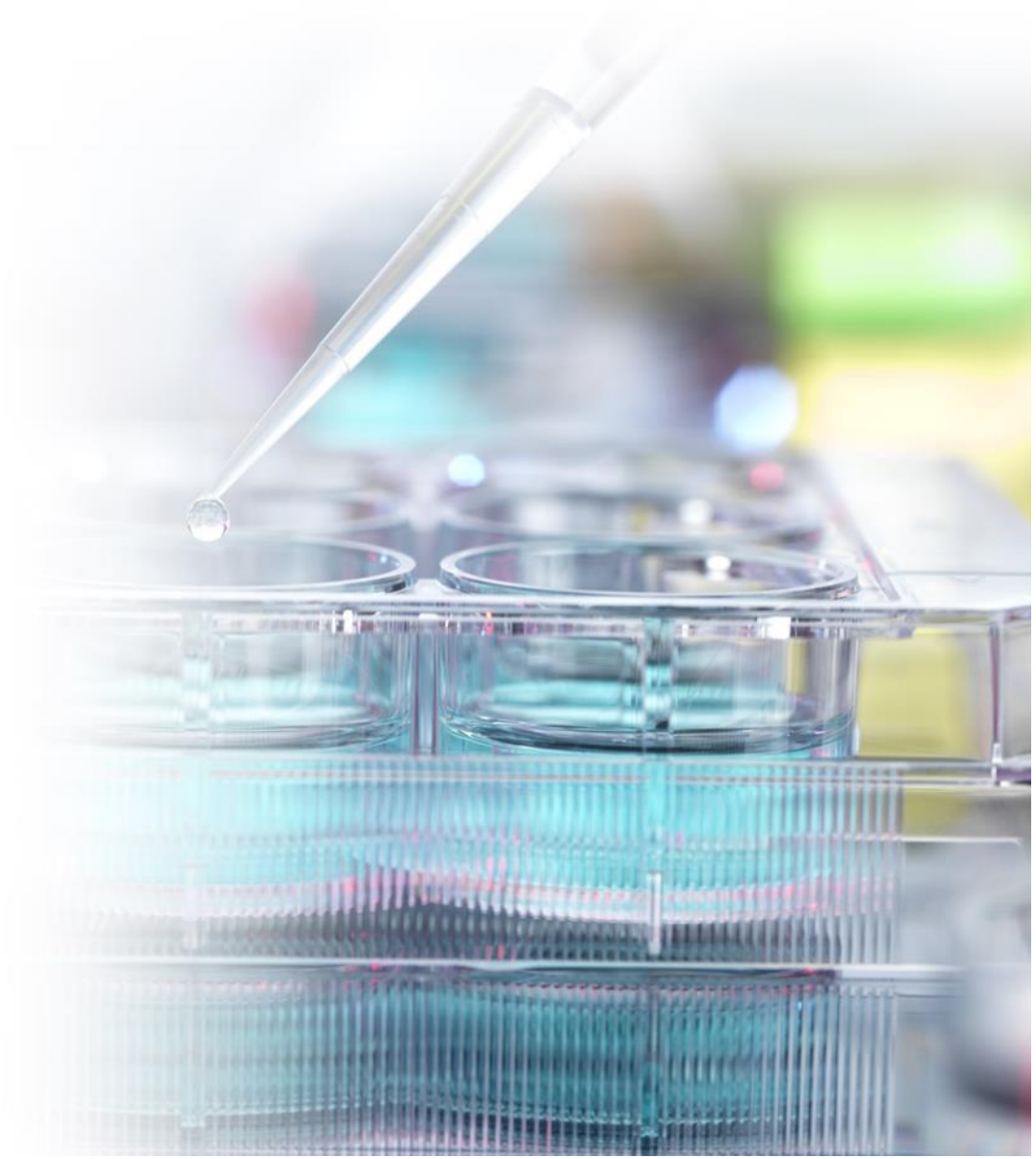
*[1] Adjuvant therapy for patients with residual invasive disease following neoadjuvant therapy

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

BC: breast cancer, HR: hormone receptor, IHI: immune checkpoint inhibitor, NSCLC: non-small cell lung cancer, TNBC: triple negative breast cancer, UC: urothelial cancer

Agenda

1. FY2025 Q1 Financial Results
2. Business Update
3. R&D Update
4. **Appendix**



Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2024 Q1 Results	FY2025 Q1 Results	YoY
Japan Business	117.7	125.0	+7.3
Daiichi Sankyo Healthcare	20.0	20.9	+0.9
Oncolgy Business	106.4	131.2	+24.8
Enhertu	104.1	124.6	+20.5
Datroway	-	3.1	+3.1
Turalio	1.5	1.6	+0.1
Vanflyta	0.9	1.9	+1.0
American Regent	55.9	49.3	-6.7
Injectafer	15.8	11.8	-3.9
Venofer	16.3	13.1	-3.3
GE injectables	20.6	21.0	+0.4
EU Specialty Business	59.2	63.8	+4.6
Lixiana	45.4	45.7	+0.3
Nilemdo/Nustendi	7.8	12.6	+4.8
Olmesartan	5.3	5.0	-0.2
ASCA (Asia, South and Central America) Business	48.7	56.8	+8.0

Currency Exchange Rate	USD/JPY	155.89	144.60	-11.29
	EUR/JPY	167.88	163.81	-4.07

Revenue: Major Products in Japan

(Bn JPY)

		FY2024 Q1 Results	FY2025 Q1 Results	YoY
Lixiana	anticoagulant	**34.9**	**37.7**	**+2.8**
Tarlige	pain treatment	**14.2**	**16.5**	**+2.4**
Pralia	Treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**11.1**	**12.4**	**+1.3**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**7.8**	**8.4**	**+0.6**
Efient	antiplatelet agent	**8.1**	**9.2**	**+1.2**
Vimpat	anti-epileptic agent	**8.1**	**8.7**	**+0.6**
Belsomra	Anti-Insomnia Treatment	**-**	**5.1**	**+5.1**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**5.4**	**5.1**	**-0.3**
Canalia	type 2 diabetes mellitus treatment	**4.3**	**3.9**	**-0.3**
Minnebro	antihypertensive agent	**2.6**	**2.8**	**+0.2**
Loxonin	anti-inflammatory analgesic	**3.5**	**2.9**	**-0.6**
Emgality	prophylaxis of migraine attacks	**2.5**	**3.0**	**+0.5**
Inavir	anti-influenza treatment	**0.2**	**-**	**-0.2**

5DXd ADCs Revenue (incl. Forex Impact)

(Unit: Bn JPY)

	FY2025 Q1 Results	YoY	FY2025 Forecast	YoY
ENHERTU®	**161.0**	**+26.2**	**761.3**	**+109.9**
Product Sales	155.2	+25.6	662.1	+109.3
Upfront and Milestone Payments, etc.	5.8	+0.6	99.2	+0.6
DATROWAY®	**8.7**	**+7.1**	**29.9**	**+22.1**
Product Sales	5.3	+5.3	21.6	+20.1
Upfront and Milestone Payments, etc.	3.4	+1.8	8.3	+2.0
HER3-DXd	**4.1**	**+2.1**	**16.3**	**-3.5**
Upfront and Milestone Payments, etc.	4.1	+2.1	16.3	-3.5
I-DXd	**3.8**	**+0.1**	**15.1**	**-0.2**
Upfront and Milestone Payments, etc.	3.8	+0.1	15.1	-0.2
R-DXd	**1.6**	**+0.1**	**20.5**	**+13.7**
Upfront and Milestone Payments, etc.	1.6	+0.1	20.5	+13.7
5DXd ADCs Total	**179.2**	**+35.6**	**843.1**	**+142.0**

5DXd ADCs Upfront and Milestone Payments

(Unit: Bn JPY)

Asset	Item	FY2025 Q1 Results	YoY	FY2025 Forecast	YoY	Total Consideration (as of Jun 2025)
ENHERTU®	Upfront Payment	2.6	-	10.2	+0.0	149.0
	Regulatory Milestones	3.0	+0.6	12.5	-16.7	185.9
	Quid Related Payment	0.3	-	1.2	-	17.2
	Sales Milestone	-	-	75.3	+17.3	100.8
DATROWAY®	Upfront Payment	1.6	-	6.4	-	115.9
	Regulatory Milestones	1.8	+1.8	2.0	+2.0	-
AZ Alliance Total		**9.2**	**+2.4**	**107.5**	**+2.6**	**568.8**
HER3-DXd	Upfront Payment	3.9	+2.0	15.8	-3.3	224.9
	Satisfaction of Quid Rights	0.1	+0.1	0.5	-0.2	7.3
I-DXd	Upfront Payment	3.7	-	14.7	-	225.4
	Satisfaction of Quid Rights	0.1	+0.1	0.5	-0.2	7.3
R-DXd	Upfront Payment	1.5	-	20.1	+13.9	112.7
	Satisfaction of Quid Rights	0.1	+0.1	0.4	-0.2	7.3
US Merck Alliance Total		**9.5**	**+2.3**	**51.9**	**+10.0**	**584.8**

* "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 2025

Project		Target indication [phase, study name]	FY2025 H1	FY2025 H2	FY2026
ENHERTU®	BC	• HER2+, adjuvant*1 [Ph3, DESTINY-Breast05]		• TLR anticipated	
		• HR+/HER2 low or HER2 ultralow, chemo naive [Ph3, DESTINY-Breast06]	• Regulatory decision anticipated (JP) • Filling accepted (CN)		
		• HER2+, 1L, mono or pertuzumab combo [Ph3, DESTINY-Breast09]	• TLR obtained*2		
		• HER2+, neoadjuvant, mono followed by THP [Ph3, DESTINY-Breast11]	**• TLR obtained**		
	NSCLC	• HER2 mutation, 1L [Ph3, DESTINY-Lung04]			**• TLR anticipated**
		• HER2 overexpression, 1L, pembrolizumab combo [Ph3, DESTINY-Lung06]	• Study start planned		
	OVC	• HER2 expressing, bevacizumab combo [Ph3, DESTINY-Ovarian01]	**• Study started**		
	EC	**• HER2 expressing, pMMR,1L, rilvegostomig or pembrolizumab combo [Ph3, DESTINY-Endometrial01]**	**• Study started**		
		• HER2 expressing, adjuvant [Ph3, DESTINY-Endometrial02]		**• Study start planned**	

Bold: update from FY2024 Q4

EC: endometrial cancer, BC: breast 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 Adjuvant therapy for HER2 positive breast cancer patients with residual invasive disease following neoadjuvant therapy, *2 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 Jul 2025

Project		Target indication [phase, study name]	FY2025 H1	FY2025 H2	FY2026
DATROWAY®	NSCLC	• EGFR mutated, previously treated EGFR-directed therapy and PBC [Ph2, TROPION-Lung05*1]	**• Approved (US)**		
		• non-squamous, w/o AGA, PD-L1 TPS <50%, 1L, pembrolizumab combo [Ph3, TROPION-Lung07]			**• TLR anticipated**
		• w/o AGA, PD-L1 TPS ≥50%, 1L, pembrolizumab combo [Ph3, TROPION-Lung08*2]			**• TLR anticipated**
		• EGFR mutated, progressed on prior osimertinib） 2L+ mono or osimertinib combo [Ph3, TROPION-Lung15]			**• TLR anticipated**
		• w/o AGA, 1L, durvalumab + carboplatin combo [Ph3, AVANZAR*2]		**• TLR anticipated (CY2026 H1)**	
	BC	• HR+ and HER2 low or negative, 2/3L [Ph3, TROPION-Breast01]	• Approved (EU) **• Regulatory decision anticipated (CN)**		
		• TNBC, PD-1/PD-L1 ineligible, 1L [Ph3, TROPION-Breast02]		**• TLR anticipated**	
		• TNBC, PD-L1 positive, 1L (durvalumab combo) [Ph3, TROPION-Breast05]			**• TLR anticipated**

Bold: update from FY2024 Q4

AGA: actionable genomic alterations, BC: breast cancer, 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

*1 Supported by data from TROPION-Lung01, TROPION-PanTumor01, *2 Due to the protocol revision, 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 Jul 2025

Project		Target indication [phase, study name]	FY2025 H1	FY2025 H2	FY2026
HER3-DXd	NSCLC	• EGFR mutated, 3L [Ph2, HERTHENA Lung01]	• **Regulatory submission withdrawn (US)**		
	BC	• TNBC, HR low and HER2 negative BC neoadjuvant [Ph2, HERTHENA-Breast03]	• **Study started**		
		• HR+/HER2- BC, chemo naïve [Ph3, HERTHENA-Breast04]	• **Study start planned**		
I-DXd	SCLC	• 2L+ [Dose expansion, Ph2, IDeate-Lung01]	• **TLR obtained**		
	ESCTLC	• 2L [Ph3, IDeate-Esophageal01]	• **Study started**		
	CRPC	• Chemo naïve [Ph3, IDeate-Prostate01]	• **Study started**		
R-DXd	GI cancers	• [Ph2, REJOICE-GI01]	• **Study started**		

Bold: update from FY2024 Q4

BC: breast cancer, CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, GI: gastrointestinal, HR: hormone receptor, NSCLC: non-small cell lung cancer, SCLC: small cell lung 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 Pipeline: 5DXd ADCs ①

As of Jul 2025

Daiichi-Sankyo

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 (chemo combo) DESTINY-Breast07	(JP/US/EU/Asia) HER2 expressing solid tumors DESTINY-PanTumor02
(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	(CN) HER2 expressing solid tumors DESTINY-PanTumor03
(US/EU) BC, NSCLC (pembrolizumab combo)	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) solid tumors TROPION-PanTumor03
(TBA) in prep solid tumors (subcutaneous injection)	(JP/US/EU/Asia) solid tumors (saruparib combo) PETRA	(JP/US/EU/Asia) EGFR mutated NSCLC 2L (osimertinib combo) ORCHARD
(JP/US) solid tumors TROPION-PanTumor01	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(US/EU/Asia) resectable early-stage NSCLC neoadjuvant ((durvalumab or rilvegostomig) + PBC combo) NeoCOAST-2
(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) solid tumors HERTHENA-PanTumor01
(JP/US/EU/Asia) NSCLC (w/o AGA) ((durvalumab, rilvegostomig or volrustomig) ± PBC or sabestomig combo) TROPION-Lung04	(US/EU/Asia) CRC, BTC, HCC 2L+ HERTHENA-PanTumor02	(US/EU/Asia) high-risk early stage TNBC, HR low and HER2 negative BC neoadjuvant (pembrolizumab combo) HERTHENA-Breast03
	(US/EU/Asia) stageIV NSCLC 1L (pembrolizumab + PBC combo) KEYMAKER-U01 substudy 01A	(US/EU/Asia) stageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01G
	(JP/US/EU/Asia) HER2+ BC 2L+ (trastuzumab (± pertuzumab or tucatinib) combo) HERTHENA-Breast01	

Phase 1	Phase 1/2	Phase 2
(JP/US/EU/Asia) NSCLC	(US/Asia) r/r RMS, HBL pediatric LIGHTBEAM-U01	(JP/US/EU/Asia) ES-SCLC 2L+ IDeate-Lung01
(JP/US/Asia) EGFR mutated NSCLC 1L/2L (osimertinib combo)	(JP/US) ESCC, CRPC, squamous NSCLC, SCLC, etc. IDeate-PanTumor01	(US/Asia) in prep non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
(JP/US) renal cell carcinoma, ovarian cancer	(JP/US/EU/Asia) solid tumors 2L+ IDeate-PanTumor02	(TBA) in prep squamous NSCLC 2L KEYMAKER-U01 substudy 01I
	(JP/US/EU) ES-SCLC 1L (atezolizumab combo) IDeate-Lung03	(US/EU/Asia) gastrointestinal cancers REJOICE-GI01
	(TBA) in prep chemo-naïve metastatic CRPC (mono or combo) IDeate-Prostate02	(JP/US/EU/Asia) solid tumors REJOICE-PanTumor01
	(US/EU/Asia) in prep stageIV NSCLC 1L (pembrolizumab + PBC combo) KEYMAKER-U01 substudy 01A	(US/Asia) in prep non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
	(TBA) in prep ESCC 1L (pembrolizumab ± chemo combo) KEYMAKER-U06 substudy 06E	(US) in prep squamous NSCLC 2L KEYMAKER-U01 substudy 01I
	(US/EU/Asia) ES-SCLC 2L KEYNOTE-B98	
	(US/EU/Asia) ovarian cancer, relapsed after PBC (carboplatin, paclitaxel or bevacizumab combo) REJOICE-Ovarian02	

ENHERTU® (T-DXd)　DATROWAY® (Dato-DXd)　HER3-DXd　I-DXd　R-DXd (DS-6000)

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, CRC: colorectal 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, TBA: to be announced, TNBC: triple negative breast cancer

Major R&D Pipeline: 5DXd ADCs ②

As of Jul 2025

Phase 2/3	Phase 3				Regulatory phase
(JP/US/EU/Asia) platinum-resistant ovarian cancer 2L+ REJOICE-Ovarian01	(JP/US/EU/Asia) HER2+ BC adjuvant*1 DESTINY-Breast05	(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) EGFR mutated NSCLC 2L HERTHENA-Lung02	(JP/CN) HR+ and HER2 low or HER2 ultralow BC chemo naïve DESTINY-Breast06
	(JP/US/EU/Asia) HER2+ BC 1L (mono or pertuzumab combo) DESTINY-Breast09*1	(JP/US/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	(TBA) in prep HR positive and HER2 negative BC, post CDK4/6 inhibitor treatment in 1L HERTHENA-Breast04	(CN) HR+ and HER2 low or negative BC 2/3L TROPION-Breast01
	(JP/US/EU/Asia) HER2+ BC neoadjuvant (mono or mono followed by THP) DESTINY-Breast11	(JP/US/EU/Asia) HER2 expressing pMMR EC 1L (rilvegostomig or pembrolizumab combo) DESTINY-Endometrial01	(JP/US/EU/Asia) NSCLC (w/o AGA) 1L (durvalumab + carboplatin combo) AVANZAR	(JP/US/EU/Asia) ES-SCLC 2L IDeate-Lung02	
	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	(JP/US/EU/Asia) in prep HER2 expressing EC adjuvant DESTINY-Endometrial02	(JP/US/EU/Asia) TNBC (PD-1/PD-L1 inhibitor ineligible) 1L TROPION-Breast02	(JP/US/EU/Asia) ESCC 2L IDeate-Esophageal01	
	(JP/US/EU/Asia) HER2+ GC 1L (pembrolizumab + FP combo) DESTINY-Gastric05	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1 TPS <50%) 1L (pembrolizumab ± PBC combo) TROPION-Lung07	(JP/US/Asia) TNBC adjuvant*2 (mono or durvalumab combo) TROPION-Breast03	(JP/US/Asia) chemo-naïve metastatic CRPC IDeate-Prostate01	
	(JP/US/EU/Asia) HER2+ and PD-L1 CPS≥1 GC 1L (rilvegostomig + FP combo) ARTEMIDE-Gastric01	(JP/US/EU/Asia) 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) HER2 mutant NSCLC 1L DESTINY-Lung04	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L TC 1≥50%) 1L (rilvegostomig combo) TROPION-Lung10	(JP/US/EU/Asia) PD-L1 positive TNBC 1L (durvalumab combo) TROPION-Breast05		
	(TBA) in prep HER2 overexpressing non-squamous NSCLC (w/o AGA, PD-L1 TPS < 50%) (pembrolizumab combo) DESTINY-Lung06	(JP/US/EU/Asia) Stage I adenocarcinoma NSCLC adjuvant (rilvegostomig combo) TROPION-Lung12			

ENHERTU® (T-DXd) / DATROWAY® (Dato-DXd) / HER3-DXd / I-DXd / R-DXd (DS-6000)

Project in oncology that is planned to be submitted for approval in some countries/regions based on the results of

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

*1 Breakthrough Designation (US) for ENHERTU® and pertuzumab combo

*2 Adjuvant therapy for patients with residual invasive disease following neoadjuvant therapy

AGA: actionable genomic alterations, BC: breast cancer, BTC: biliary tract cancer, CPS: combined positive score, EC: endometrial cancer, 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

Major R&D Pipeline: Next Wave

As of Jul 2025

Phase 1	Phase 1/2	Phase 2	Phase 3	Regulatory phase
DS-9606 (US/EU) CLDN6-directed ADC Solid tumors	DS-3939 (JP/US/EU/Asia) TA-MUC1-directed 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
DS-1103 (US/EU) Anti-SIRPα antibody HER2 expressing or mutant solid tumors, HER2 low BC (ENHERTU® combo)	MK-6070 (DS3280) (US) DLL3 directed tri-specific T-cell engager DLL3 expressing advanced cancer	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
DS-1471 (JP) Anti-CD147 antibody Solid tumors	MK-6070 (DS3280) (US/EUAsia) DLL3 directed tri-specific T-cell engager ES-SCLC 2L+ (I-DXd combo) MK-6070-002	TURALIO® (JP) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor		
EZHARMIA® (JP/US) EZH1/2 inhibitor HER2+ GC, HER2 low BC (ENHERTU® combo) and non-squamous NSCLC (DATROWAY® combo)	EZHARMIA® (JP/US/Asia) EZH1/2 inhibitor NSCLC (w/o AGA and PD-L1 TPS ≥50%) 1L (pembrolizumab combo)	DS-1211 (US/EU) TNAP inhibitor Pseudoxanthoma elasticum		
DS-2243（US/EU/Asia） HLA-A*02/NY-ESO directed bispecific T-cell engager Solid tumors	DS-7011 (JP/US/EU/Asia) Anti-TLR7 antibody Systemic lupus erythematosus			
	DS-2325 (EU) KLK5 inhibitor Netherton syndrome			

Oncology

Specialty medicine

Vaccine

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

Rare Pediatric Disease Designation (US)

Fast Track Designation (US)

AGA: actionable genomic alterations, AML: acute myeloid leukemia, BC: breast cancer, BCL: B cell lymphoma, ES-SCLC: extensive-stage small cell lung cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, TPS: tumor proportion score

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