Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

# FY2025 Q2
# Financial Results Presentation


## DAIICHI SANKYO CO., LTD.

**Hiroyuki Okuzawa**

**President and CEO**


**October 31, 2025**

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Management strategies and plans, financial forecasts, future projections and policies, and R&D information that Daiichi Sankyo discloses in this material are all classified as Daiichi Sankyo's future prospects. These forward-looking statements were determined by Daiichi Sankyo based on information obtained as of today with certain assumptions, premises and future forecasts, and thus, there are various inherent risks as well as uncertainties involved. As such, please note that actual results of Daiichi Sankyo may diverge materially from Daiichi Sankyo's outlook or the content of this material. Furthermore, there is no assurance that any forward-looking statements in this material will be realized. Regardless of the actual results or facts, Daiichi Sankyo is not obliged and does not have in its policy the duty to update the content of this material from the date of this material onward.

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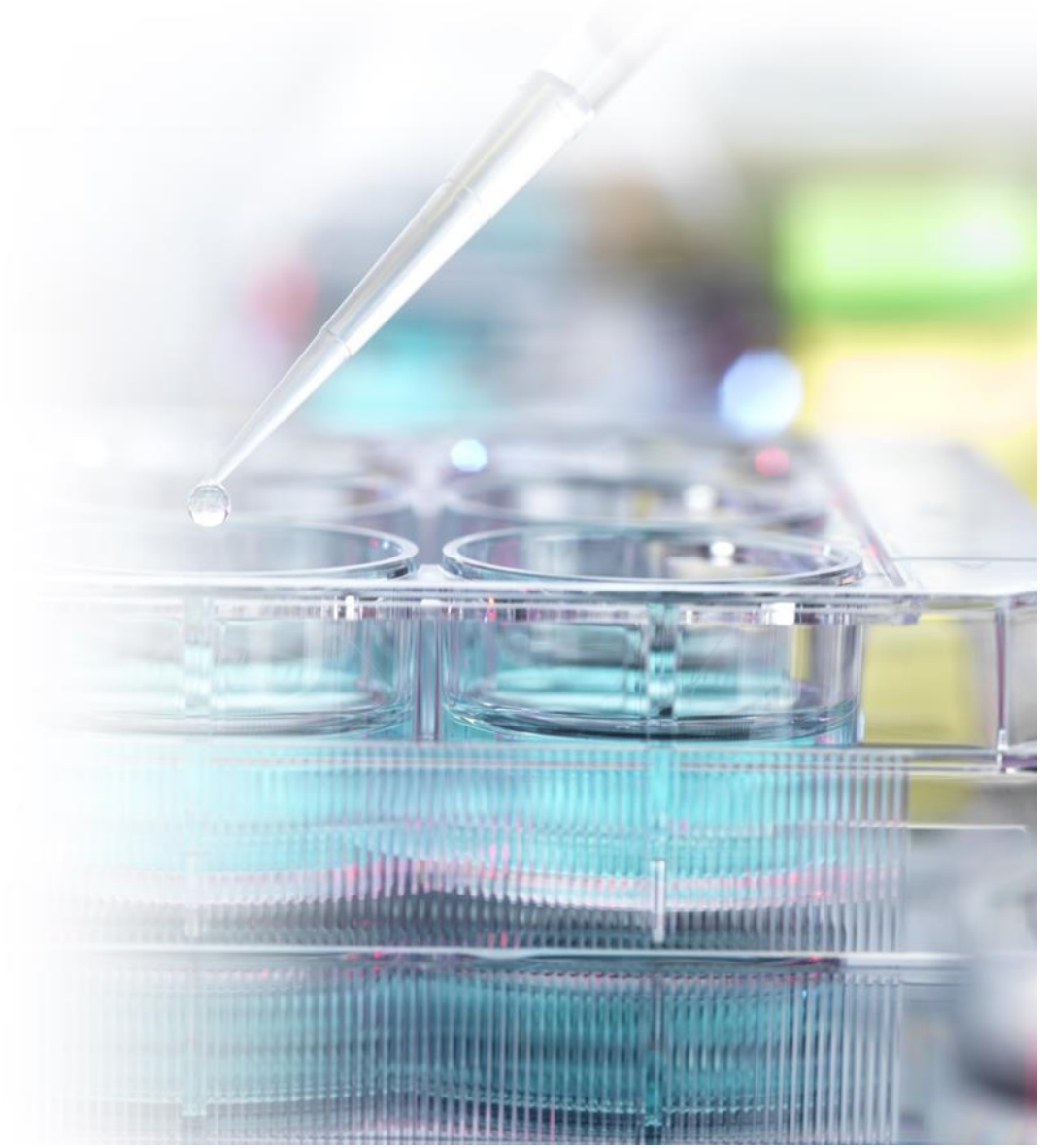
# Agenda

1. **FY2025 Q2 Financial Results**
2. FY2025 Forecast
3. Business Update
4. R&D Update
5. Appendix



# Overview of FY2025 Q2 Results

(Bn JPY)

| | FY2024 Q2 YTD Results | FY2025 Q2 YTD Results | YoY | |
|---|---|---|---|---|
| **Revenue** | **882.7** | **975.4** | **+10.5%** | **92.6** |
| Cost of sales*1 | 193.0 | 218.8 | | 25.8 |
| SG&A expenses*1 | 329.9 | 381.2 | | 51.3 |
| DXd ADC profit share *2 | 104.8 | 133.2 | | 28.4 |
| Other SG&A expenses | 225.1 | 248.0 | | 23.0 |
| R&D expenses*1 | 193.3 | 216.8 | | 23.5 |
| **Core operating profit*1** | **166.6** | **158.6** | **-4.8%** | **-8.0** |
| Temporary income*1 | 20.3 | 4.2 | | -16.1 |
| Temporary expenses*1 | 0.0 | 18.5 | | 18.5 |
| **Operating profit** | **186.9** | **144.2** | **-22.8%** | **-42.7** |
| **Profit before tax** | **192.6** | **163.2** | | **-29.4** |
| **Profit attributable to owners of the Company** | **146.7** | **130.8** | **-10.8%** | **-15.9** |

| | | | | |
|---|---|---|---|---|
| Currency Exchange Rate | USD/JPY | 152.62 | 146.04 | -6.58 |
| | EUR/JPY | 165.93 | 168.06 | +2.13 |

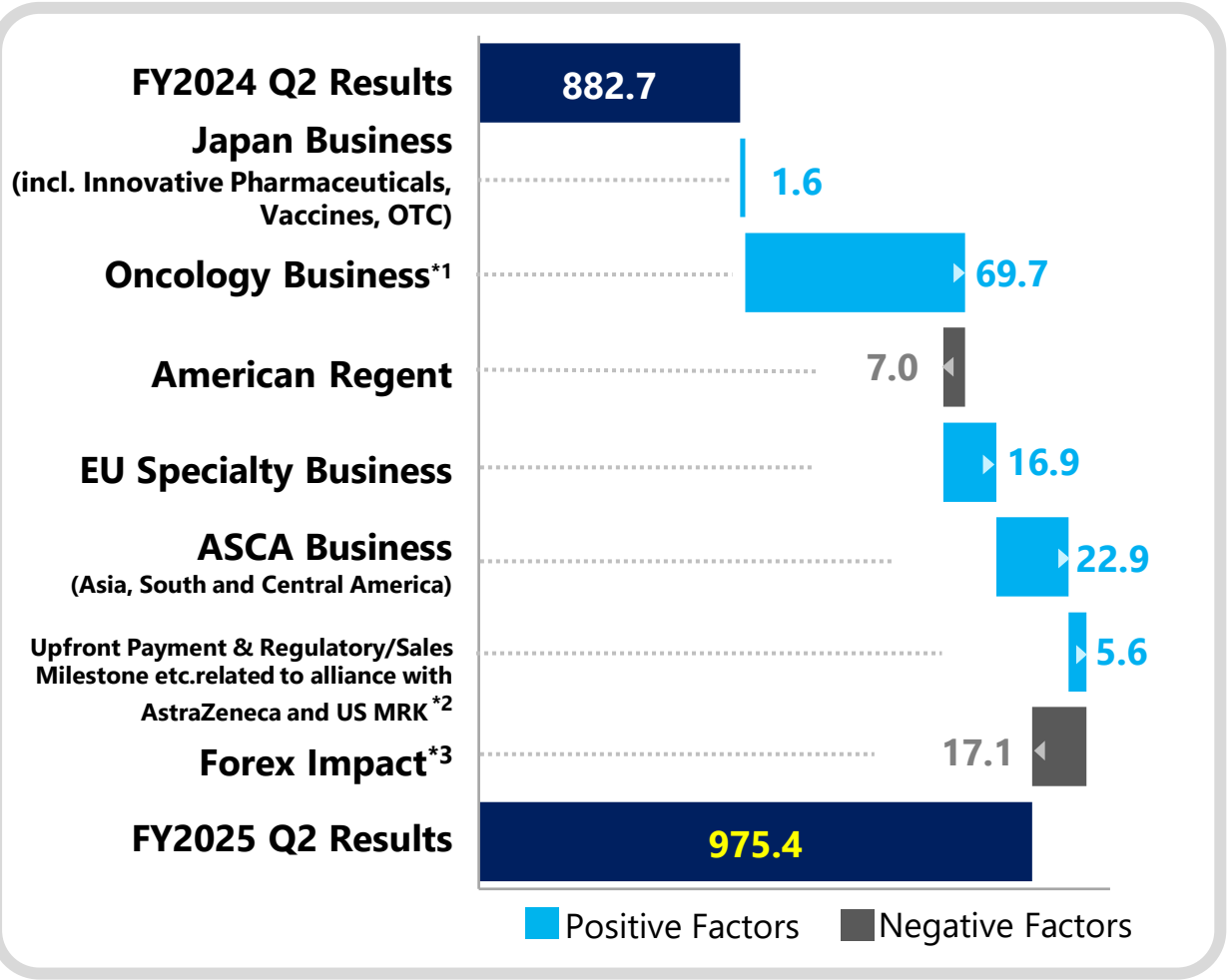
*1 As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed. Income and expenses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation, 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 92.6 Bn JPY (Increased by 109.7 Bn JPY excl. forex impact)

(Bn JPY)

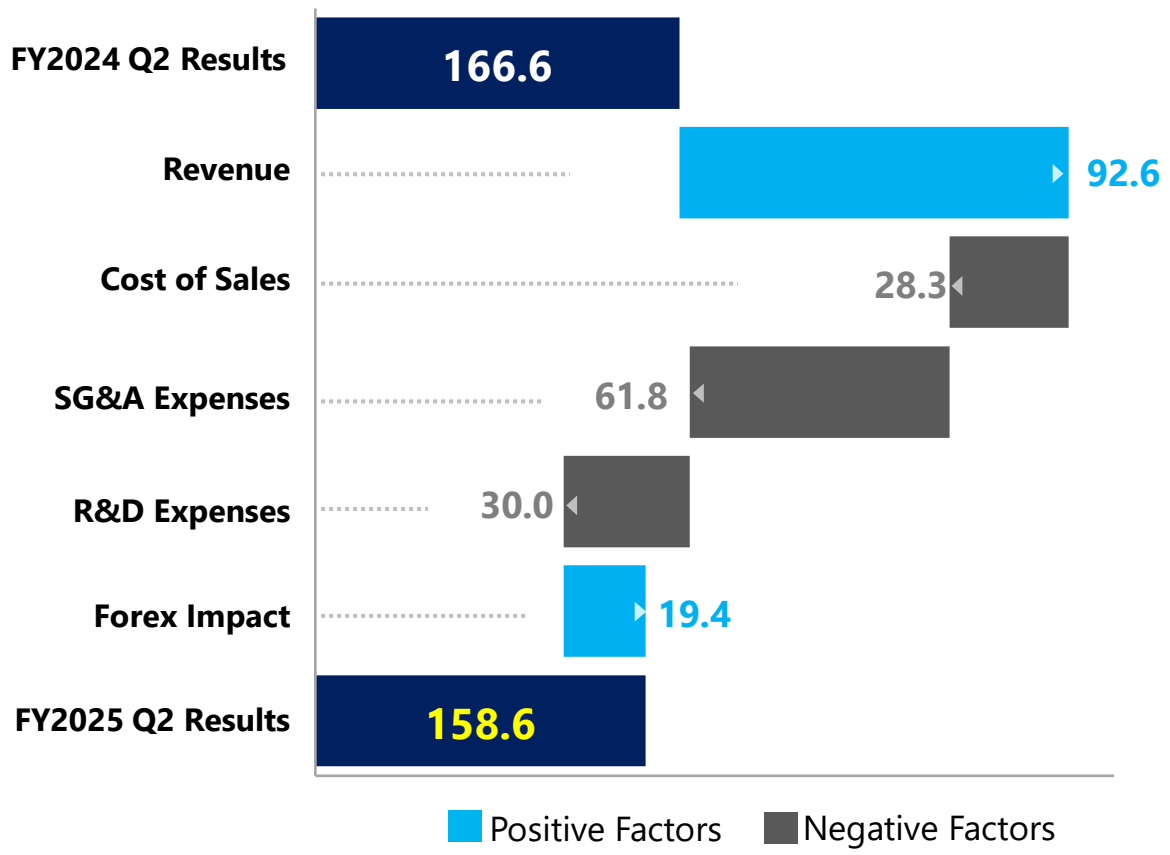



| Positive Factors | | Negative Factors | |
|---|---|---|---|
| **Japan Business Unit** | | | |
| Belsomra | +9.7 | Realized gains of unrealized gains of inventory for Daiichi Sankyo Espha | -11.2 |
| Datroway | +5.6 | | |
| Lixiana | +5.3 | | |
| Tarlige | +4.4 | Vaccine business | -6.1 |
| Enhertu | +2.4 | | |
| **Oncology Business Unit[1]** | | | |
| Enhertu | +57.0 | | |
| Datroway | +10.6 | | |
| **American Regent Unit** | | | |
| | | Injectafer | -4.8 |
| | | Venofer | -1.6 |
| **EU Specialty Business Unit** | | | |
| Nilemdo/Nustendi | +11.8 | | |
| Lixiana | +4.9 | | |
| **ASCA (Asia, South and Central America) Business Unit** | | | |
| Enhertu | +14.1 | | |
| **Upfront Payment & Regulatory/Sales Milestone etc. related to alliance with AstraZeneca and US MRK *2** | | | |
| AstraZeneca | +3.3 | | |
| 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: -15.2, EUR : +2.8, ASCA: -4.6

# Core Operating Profit

## Decreased by 8.0 Bn JPY (Decreased by 10.4 Bn JPY excl. forex impact)




(Bn JPY)

**Revenue** ..... **+92.6**
incl. forex impact of -17.1

**Cost of Sales** ..... **+28.3**
Increase in expenses related to sales expansion
Increase due to write-down of Inventories, etc

**SG&A Expenses** ..... **+61.8**
Increase in expenses related to Enhertu and Datroway
Due to an increase in profit share of gross profit with AstraZeneca

**R&D Expenses** ..... **+30.0**
Increase in 5DXd ADCs*1 R&D investments

**Forex Impact***2 ..... **-19.4 (Profit Increased)**
Cost of Sales ..... **-2.5**
SG&A Expenses ..... **-10.5**
R&D Expenses ..... **-6.4**

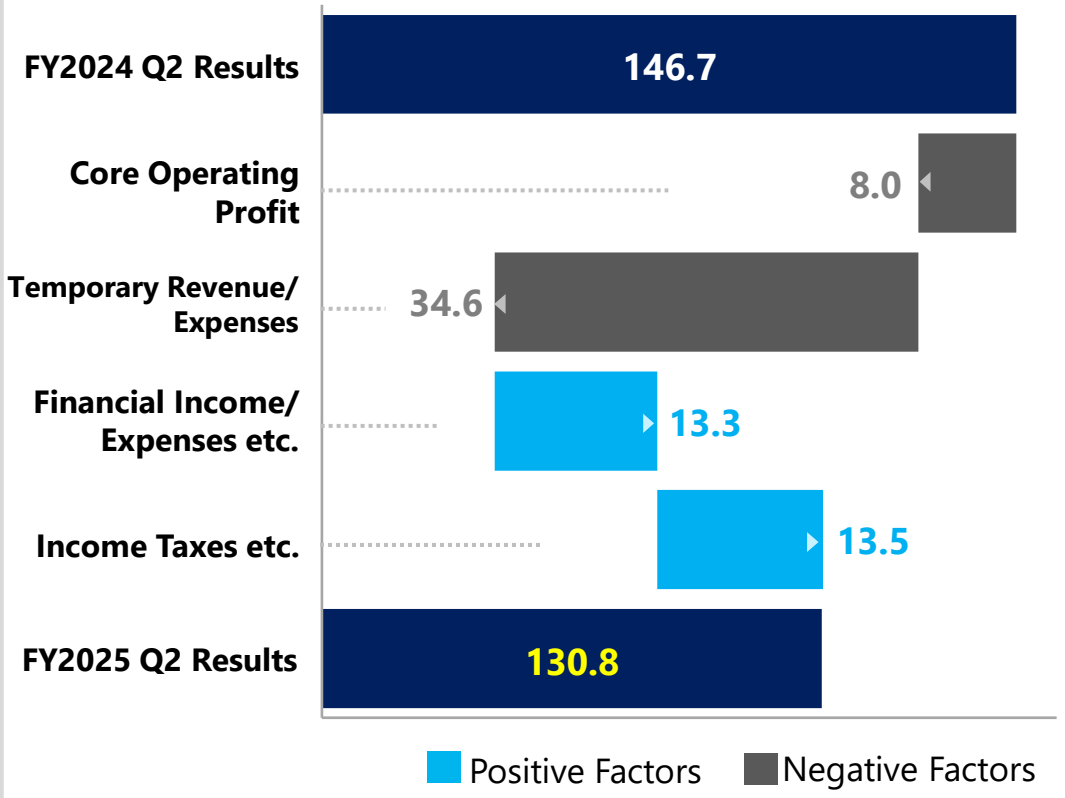
*2 Forex Impact related to revenue (-17.1) is not included

*1 **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

## Decreased by 15.9 Bn JPY

(Bn JPY)




**Temporary Income/Expenses** ····· -34.6 (Profit Decreased)

| | FY2024 Q2 Results | FY2025 Q2 Results | YoY |
|---|---|---|---|
| Temporary Income | 20.3*1 | 4.2*2 | -16.1 |
| Temporary Expenses | 0 | 18.5*3 | +18.5 |

*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（12.7）/ Write-down of Inventories of Datroway/HER3-DXd(4.6)

**Financial Income/Expenses etc.** ····· +13.3 (Profit Increased)

- Improvement in forex gains/losses ····· +13.4
- Improvement in investment securities valuation gains/losses ····· +2.2
- Decrease in interest income ····· -3.1

**Income Taxes etc.** ····· -13.5 (Profit Increased)

| | FY2024 Q2 Results | FY2025 Q2 Results | YoY |
|---|---|---|---|
| Profit before Tax | 192.6 | 163.2 | -29.4 |
| Income Taxes etc. | 45.9 | 32.4 | -13.5 |
| Tax rate | 23.8% | 19.9% | |

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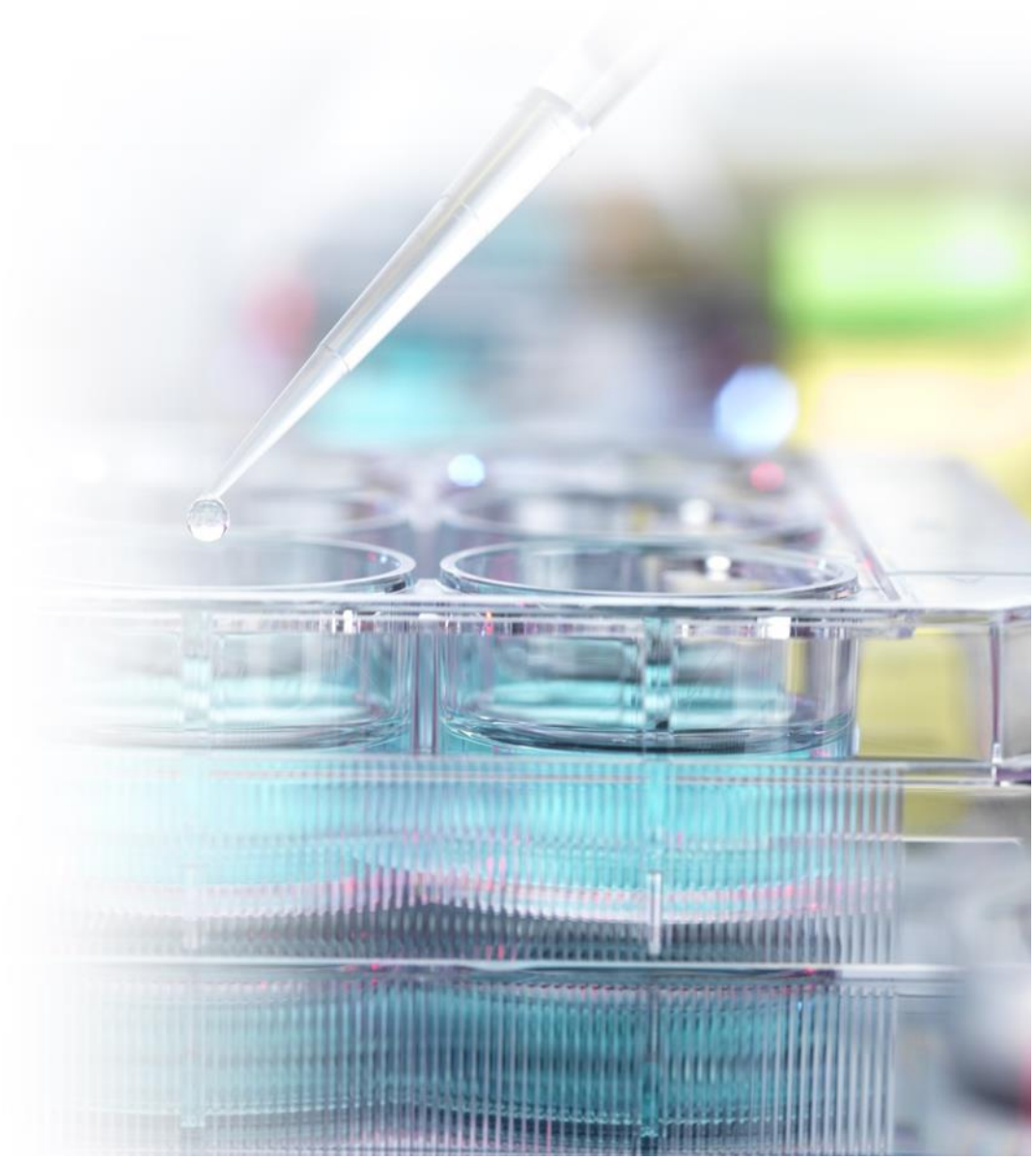

# Revision to the forecast

(Bn JPY)

| | FY2025 Forecast (As of Apr.) | FY2025 Forecast (As of Oct.) | vs. Forecast |
|---|---|---|---|
| **Revenue** | **2,000.0** | **2,100.0** | **+100.0** |
| Cost of sales *1 | 430.0 | 460.0 | +30.0 |
| SG&A expenses *1 | 765.0 | 830.0 | +65.0 |
| DXd ADC profit share *2 | 265.0 | 300.0 | +35.0 |
| Other SG&A expenses | 500.0 | 530.0 | +30.0 |
| R&D expenses *1 | 455.0 | 460.0 | 5.0 |
| **Core operating profit** *1 | **350.0** | **350.0** | **+0.0** |
| Temporary income *1 | - | 5.0 | +5.0 |
| Temporary expenses *1 | - | 20.0 | +20.0 |
| **Operating profit** | **350.0** | **335.0** | **-15.0** |
| **Profit before tax** | **370.0** | **355.0** | **-15.0** |
| **Profit attributable to owners of the Company** | **300.0** | **288.0** | **-12.0** |

| | | | | |
|---|---|---|---|---|
| Currency Exchange Rate | USD/JPY | 140.00 | 148.02 | +8.02 |
| | EUR/JPY | 160.00 | 169.03 | +9.03 |

Assumption of currency rate for Q3 and Q4 : USD/JPY 150, EUR/JPY 170

**Revenue**
: Increase by forex impact
: Sales expansion of Datroway in US and JPN, Enhertu in US, etc.
: Sales decrease of Injectafer and Venofer in ARU, etc.
: Decrease due to regulatory milestones payment for Enhertu

**Cost of Sales**
: Increase due to upward revision of revenue forecast and forex impact
: Increase due to write-down of Inventories, etc.

**SG&A Expenses**
: Increase by forex impact
: Increase due to an increase in profit share of gross profit with AstraZeneca, etc.

**R&D Expenses**
: Increase by forex impact, etc

**Forex Impact** vs. as of Apr.

**Revenue : +68.0 Bn JPY**
**Core operating profit : +6.0 Bn JPY**

*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.
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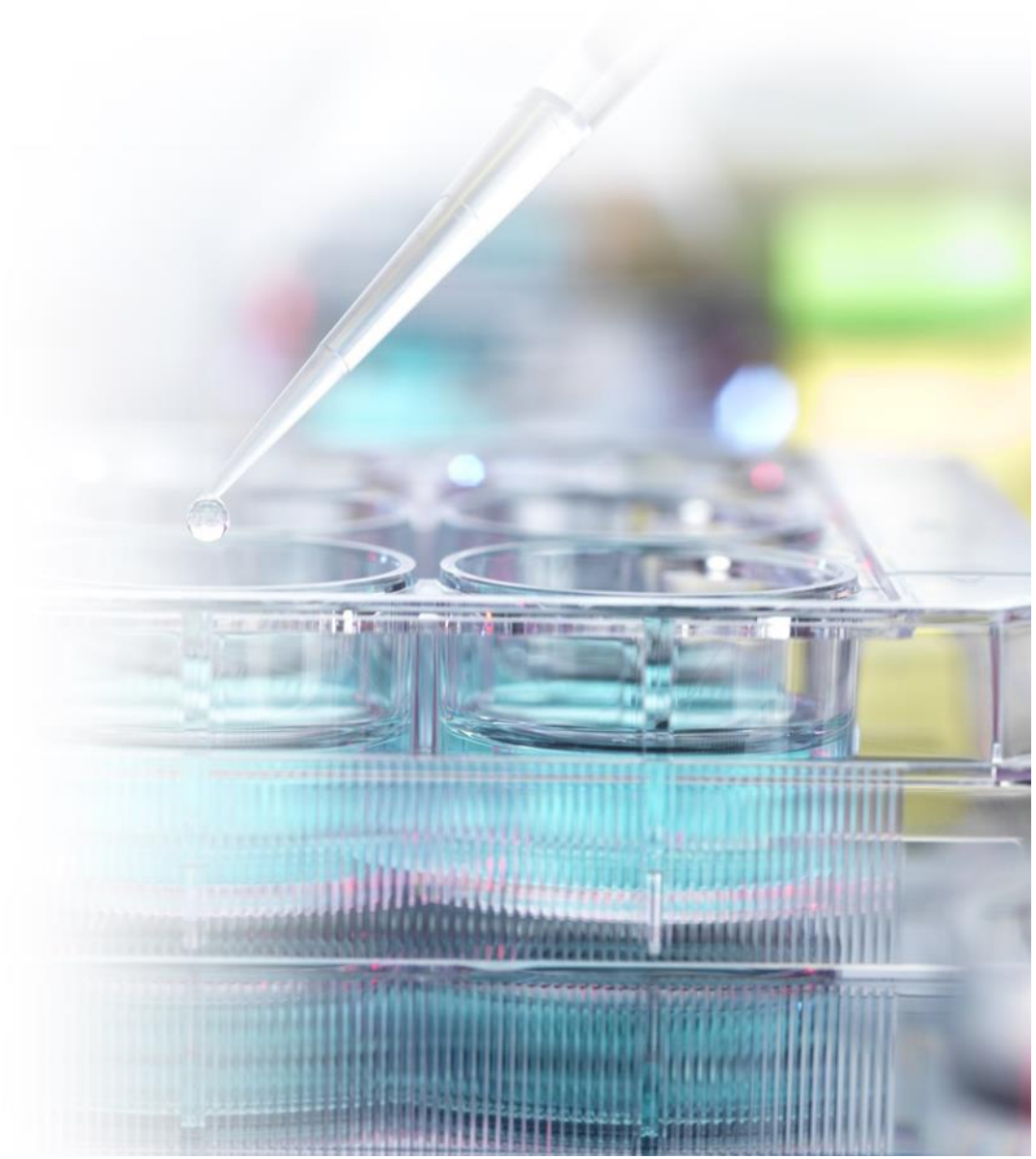
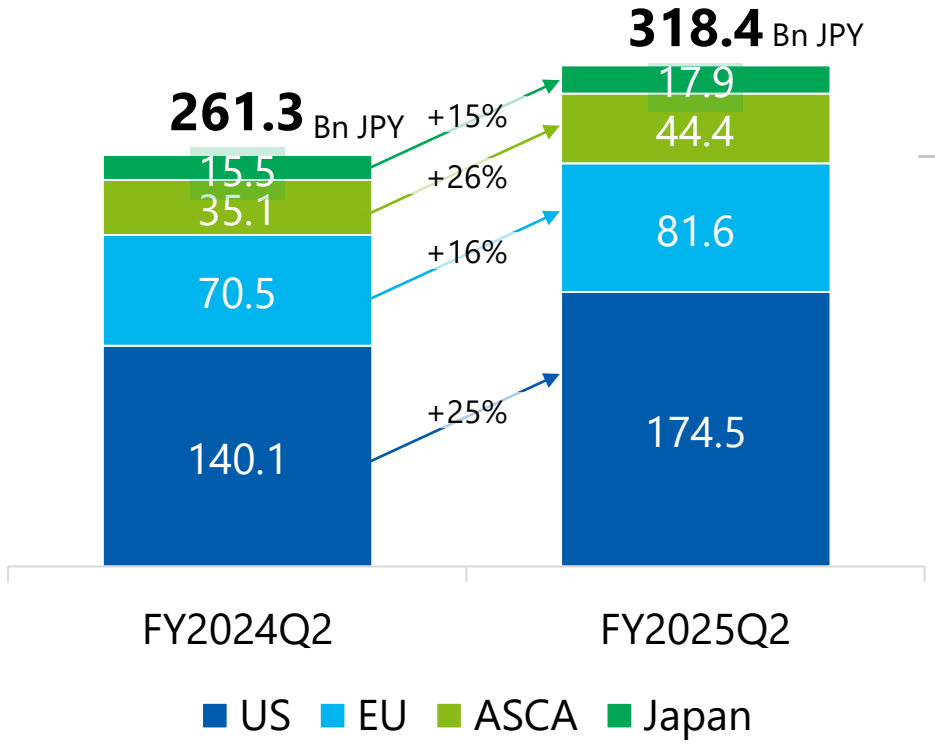


# ENHERTU® Performance

## Achieved First Billion-Dollar Quarter
## Maintained No.1 New Patient Share across Major Countries and Regions




Q2 YTD Global Product Sales Result **318.4 Bn JPY**
YoY **+57.1 Bn JPY (+21.9%)** Progress vs Apr. Forecast **48.1%**

- ◆ Updated annual forecast
  - ➢ Oct. forecast **694.2 Bn JPY** (vs Apr. forecast +32.1 Bn JPY)
- ◆ HR positive, HER2 low or ultralow BC (chemo naïve)
  - ➢ Solid progress in market penetration in US and Germany
    - Maintained No.1 new patient share in the US
    - Germany led the sales growth in EU as the only launched market
  - ➢ Indication launched in Japan in Aug.

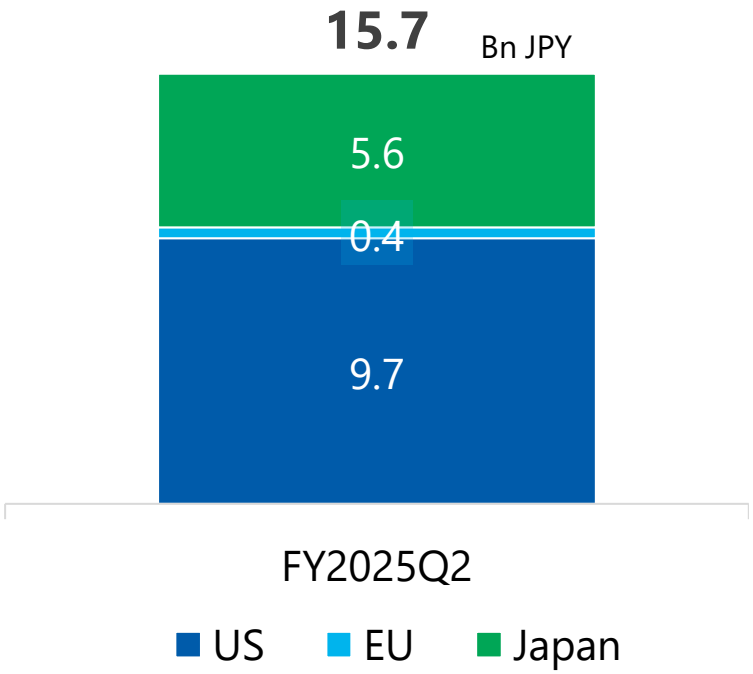
ENHERTU® trastuzumab deruxtecan

BC: breast cancer, Bn: billion, FY: fiscal year (Apr-Mar), HR: hormone receptor, JPY: Japanese yen, YoY: year on year, YTD: year to date

DATROWAY®

# Performance

## Robust Sales Growth over the Initial Forecast in US and Japan
## Treated Over 2,000 Patients Globally since Launch




Q2 YTD Global Product Sales Result **15.7 Bn JPY**
YoY **+15.7 Bn JPY (-%)** Progress vs Jul. Forecast **72.9%**

- Updated annual forecast: Oct. forecast **37.8 Bn JPY** (vs Jul. forecast +16.2 Bn JPY)
  - Larger number of eligible patients than expected due to high unmet needs
- HR positive and HER2 negative BC: Steady sales growth in US and Japan
  - Raised awareness of safety management such as stomatitis
  - 35+ countries and regions regulatory approved to date
- EGFR-mutated NSCLC: Strong sales uptake in the US as the only TROP2-directed ADC approved

DATROWAY® datopotamab deruxtecan

BC: breast cancer, Bn: billion, FY: fiscal year (Apr-Mar), HR: hormone receptor, JPY: Japanese yen, NSCLC: non-small cell lung cancer, YoY: year on year, YTD: year to date

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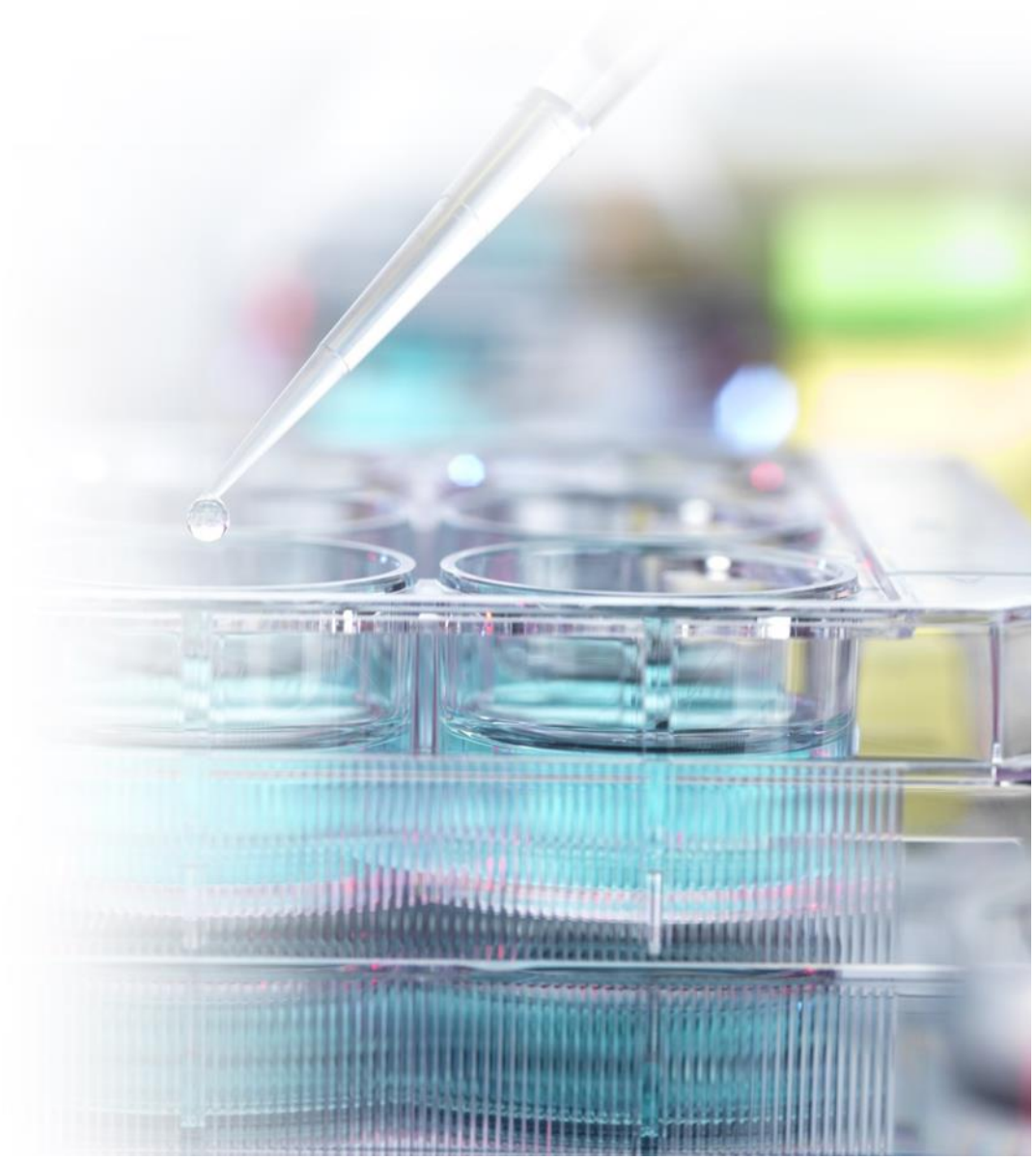


**5DXd ADCs Update**

Next Wave Update

News Flow

ENHERTU®

# Advancing ENHERTU® into Early HER2+ Breast Cancer

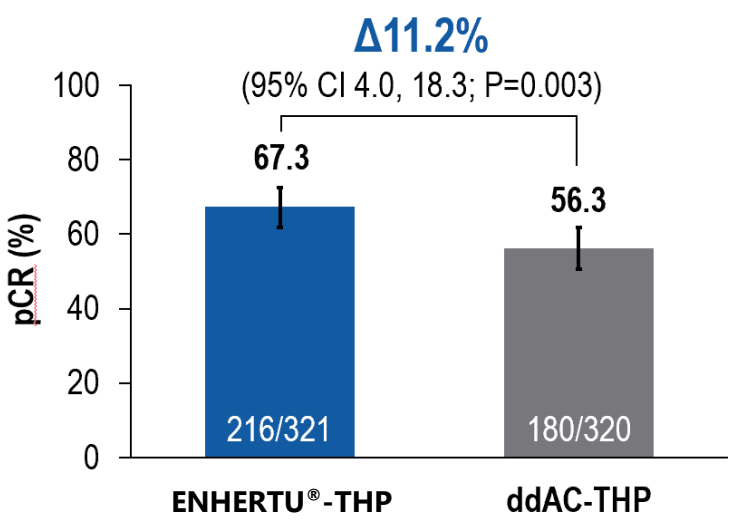
DESTINY-Breast11 Ph3 (ESMO 2025)

Daiichi-Sankyo

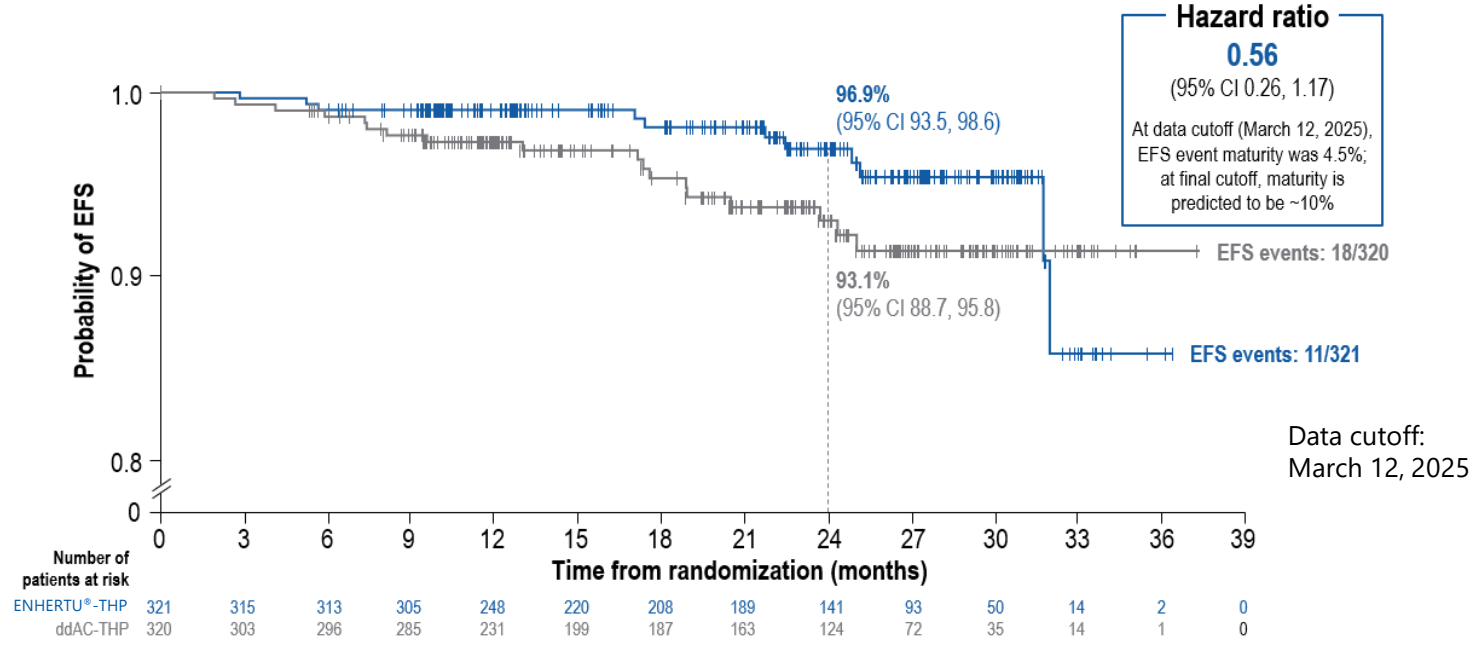
## ENHERTU® followed by THP showed statistically significant and clinically meaningful improvement in pCR rate in high-risk HER2 positive eBC neoadjuvant setting

### pCR

ITT population (primary endpoint)




### EFS




Data cutoff:
March 12, 2025

- ENHERTU®-THP arm showed 11.2% improvement in pCR rate compared to the ddAC-THP arm (95% CI 4.0-18.3)
- ENHERTU®-THP arm showed an early positive trend in EFS compared to the ddAC-THP arm (HR: 0.56; 95% CI 0.26-1.17)
- The safety profile of ENHERTU®-THP arm was favorable compared to the ddAC-THP arm, lower rates of Grade ≥3 AEs, serious AEs, and AEs leading to dose reductions/interruptions. ILD rates were low and similar between the two arms

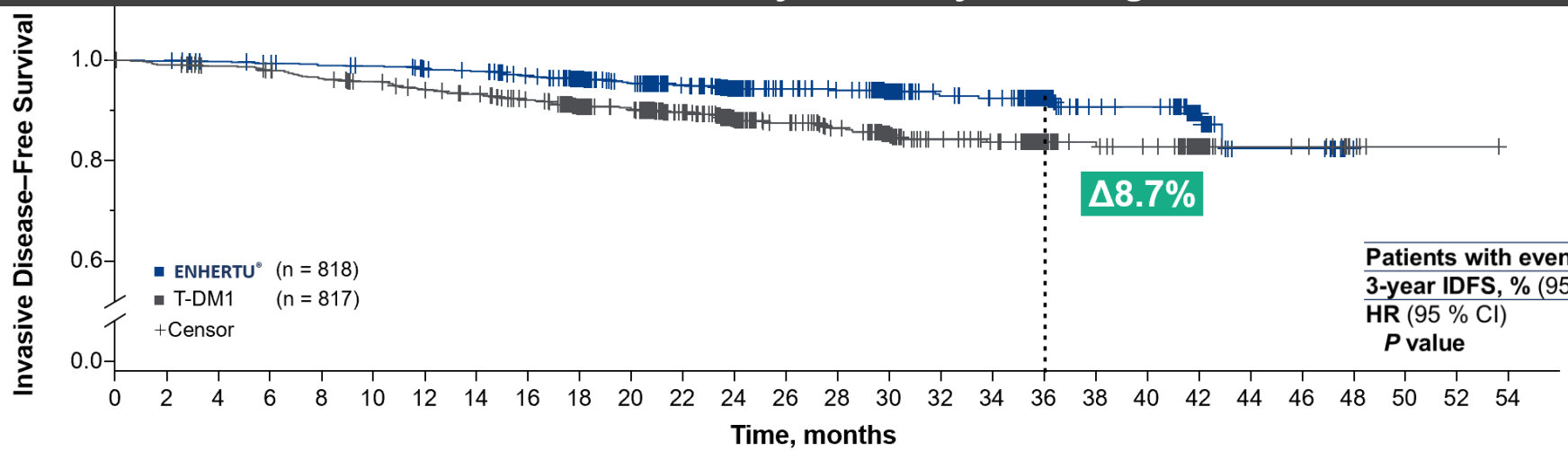
AE: adverse event, BC: breast cancer, CI: confidence interval, ddAC: doxorubicin + cyclophosphamide, eBC: early-stage breast cancer, EFS: event-free survival, ESMO: European Society for Medical Oncology, HR: hazard ratio, ILD: interstitial lung disease, ITT: intention-to-treat, pCR: pathological complete response, THP: paclitaxel + trastuzumab + pertuzumab

# Advancing ENHERTU® into Early HER2+ Breast Cancer

DESTINY-Breast05 Ph3 (ESMO 2025)

## ENHERTU® demonstrated a clinically meaningful and statistically significant benefit in patients with high-risk HER2 positive eBC following neoadjuvant therapy

### Efficacy: IDFS by investigator




| | T-DXd n = 818 | T-DM1 n = 817 |
|---|---|---|
| Patients with events, n (%) | **51** (6.2) | **102** (12.5) |
| 3-year IDFS, % (95% CI) | **92.4** (89.7-94.4) | **83.7** (80.2-86.7) |
| HR (95 % CI) | **0.47** (0.34-0.66) | |
| *P* value | **<0.0001**[b] | |

**Number at Risk:**

| | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ENHERTU® | 818 | 788 | 781 | 776 | 771 | 768 | 758 | 753 | 731 | 684 | 634 | 544 | 440 | 380 | 370 | 275 | 218 | 212 | 129 | 92 | 90 | 46 | 14 | 14 | 0 | 0 | 0 | 0 |
| T-DM1 | 817 | 781 | 769 | 760 | 745 | 734 | 719 | 708 | 687 | 632 | 599 | 527 | 417 | 355 | 337 | 233 | 186 | 177 | 120 | 84 | 79 | 38 | 14 | 13 | 4 | 1 | 1 | 0 |

Data cutoff: July 2, 2025

- ENHERTU® showed a three-year IDFS rate of 92.4%, reduced the risk of invasive disease recurrence or death by 53 % (95CI: 0.34-0.66; p<0.0001) compared to T-DM1
- Clinically meaningful benefit was observed in additional secondary endpoints of DRFI (HR, 0.49 [95% CI, 0.34-0.71]) and BMFI (HR, 0.64 [0.35-1.17])
- The overall safety profiles of ENHERTU® and T-DM1 were generally manageable with no new safety signals

BC: breast cancer , BMFI: brain metastasis-free interval, CI: confidence interval, DRFI: distant recurrence-free interval, eBC: early-stage breast cancer, ESMO: European Society for Medical Oncology, HR: hazard ratio, IDFS: invasive disease-free survival, INV: investigator, T-DM1: trastuzumab emtansine

ENHERTU®

# Regulatory Updates

DESTINY-Breast06, DESTINY-Breast09, DESTINY-Breast11 etc.

Daiichi-Sankyo

## Breast cancer-led indication expansion in each country and region

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

- Aug 2025: Approved in Japan

### HER2 positive BC 1L (DESTINY-Breast09)

- Sep 2025：Filing accepted in the US and Priority Review granted (PDUFA date: Jan 23, 2026)
- Oct 2025: Filing accepted in Japan

### HER2 positive BC neoadjuvant therapy (DESTINY-Breast11)

- Aug 2025: Filing accepted in China and Priority Review granted
- Oct 2025：Filing accepted in the US (PDUFA date: May 18, 2026)

### HER2 expressing solid tumors 2L+ (DESTINY-PanTumor02 etc.)

- Sep 2025：Filing accepted in the EU

### HER2 positive GC 2L (DESTINY-Gastric04)

- Jul 2025： Filing accepted in China and Priority Review granted

BC: breast cancer, GC: gastric cancer, HR: hormone receptor, PDUFA: prescription drug user fee act

# Paving the way for the new 1L SOC in mTNBC

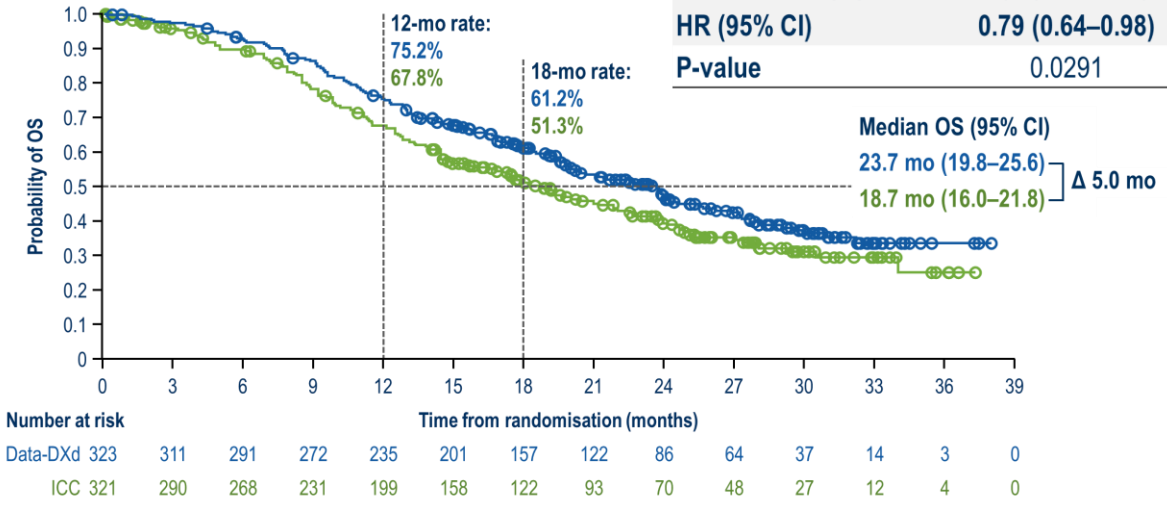
TROPION-Breast02 Ph3 (ESMO 2025)

Daiichi-Sankyo

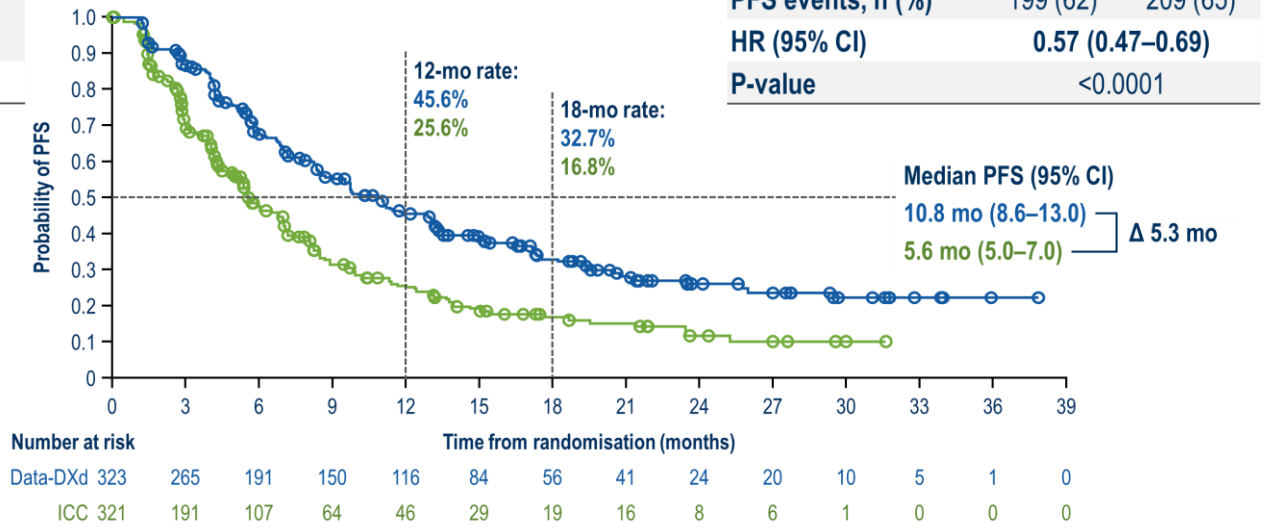
## TROPION-Breast02 met both dual primary endpoints OS and PFS in patients with mTNBC for whom immunotherapy is not an option

### Efficacy: OS (left) and PFS (right)

| | Dato-DXd | ICC |
|---|---|---|
| OS events, n (%) | 168 (52) | 181 (56) |
| HR (95% CI) | 0.79 (0.64–0.98) | |
| P-value | 0.0291 | |




| | Dato-DXd | ICC |
|---|---|---|
| PFS events, n (%) | 199 (62) | 209 (65) |
| HR (95% CI) | 0.57 (0.47–0.69) | |
| P-value | <0.0001 | |




Data cutoff: August 25, 2025

- DATROWAY® demonstrated a statistically significant and clinically meaningful improvement in OS and PFS with a 5.0-month improvement in median OS and 5.3-month improvement in median PFS
- ORR with DATROWAY® was more than double that with chemotherapy (62.5% vs. 29.3%)
- The safety profile of DATROWAY® was manageable and generally consistent with the known profile

CI: confidence interval, ESMO: European Society for Medical Oncology, HR: hazard ratio, ICC: investigator's choice of chemotherapy, mo: month, mTNBC: metastatic triple-negative breast cancer, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, SOC: standard of care

# Combination of DATROWAY® + Durvalumab in TNBC

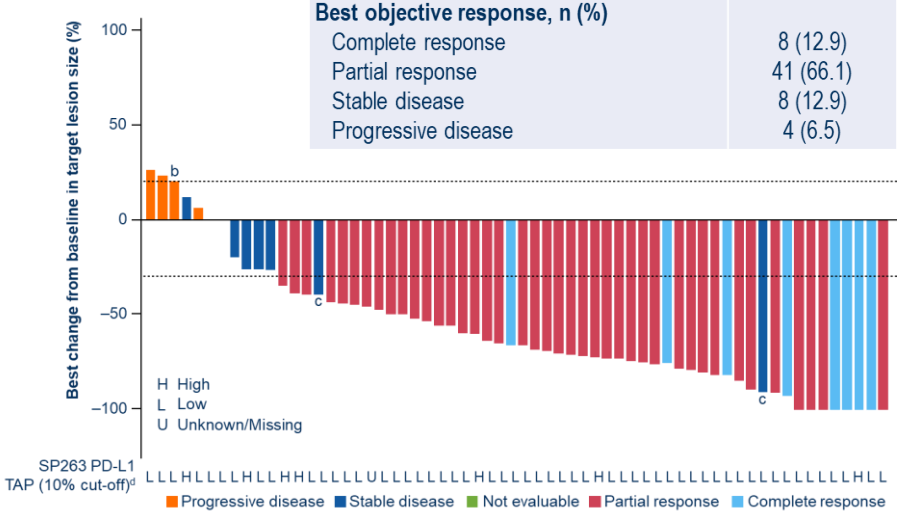
BEGONIA Ph1b/2 (ESMO 2025)

Daiichi-Sankyo

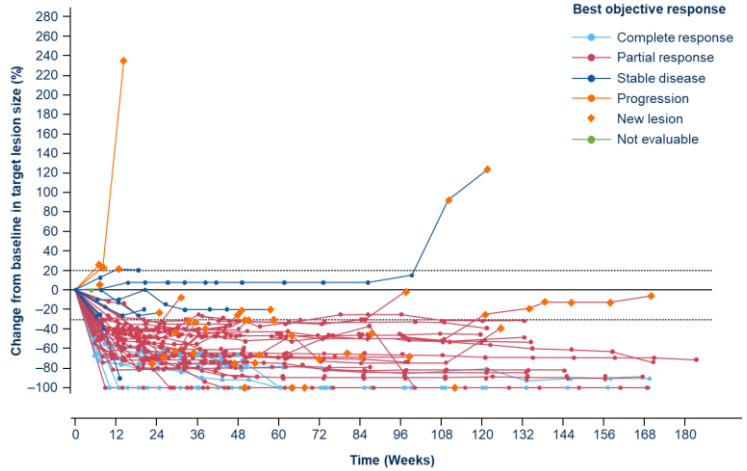
## Combination of DATROWAY® + durvalumab demonstrated robust antitumor activity in patients with TNBC regardless of PD-L1 expression

### Antitumor Activity in Arm 7: ORR (left), DOR (right)

| | Arm 7 (N=62) |
|---|---|
| Confirmed ORR,[a] % (95% CI) | 49 (79.0) (66.8–88.3) |
| **Best objective response, n (%)** | |
| Complete response | 8 (12.9) |
| Partial response | 41 (66.1) |
| Stable disease | 8 (12.9) |
| Progressive disease | 4 (6.5) |




| | Arm 7 (N=62) |
|---|---|
| Median duration of follow-up, months | 35.0 |
| **Median duration of treatment, months** | |
| Dato-DXd | 11.2 |
| Durvalumab | 11.5 |




Median **DOR** was 17.6 months (95% CI 10.5–27.3)
Median **PFS** was 14.0 months (95% CI 11.0–21.1)

Data cutoff: November 29, 2024

- Presented results from arm 7 with any PD-L1 expression and arm 8 with high PD-L1 expression at ESMO 2025
- cORR: 79.0% (66.8-88.3, 49/62) in arm 7 and 81.8% (64.5-93.0, 27/33) in arm 8
- The safety profile of the combination was manageable with no new safety signals
- Across both arms, rates of adjudicated drug-related ILD were low, with no Grade ≥3 events
- TROPION-Breast05, Ph3 study to evaluate the combination of DATROWAY® + durvalumab in PD-L1 positive TNBC is ongoing

cORR: confirmed objective response rate, DOR: duration of response, ESMO: European Society for Medical Oncology, ILD: interstitial lung disease, ORR: objective response rate, PFS: progression-free survival, TNBC: triple-negative breast cancer

DATROWAY®

# New Study to Address an Unmet Need in UC

TROPION-Urothelial03 Ph2/3

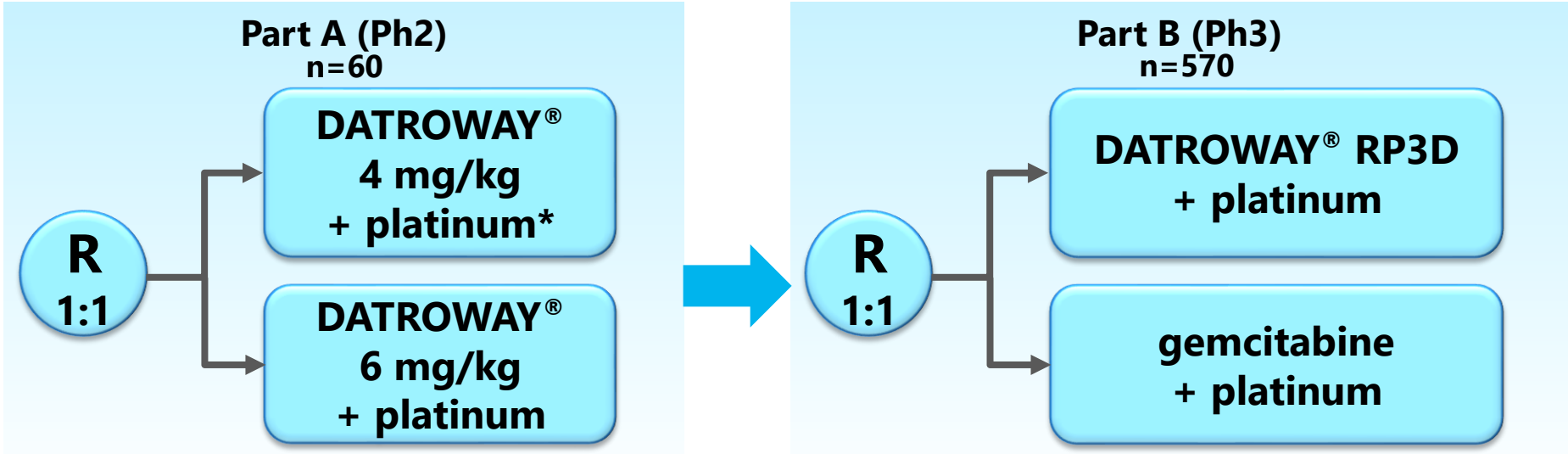
Daiichi-Sankyo

## TROPION-Urothelial03 expands DATROWAY® registration-potential studies beyond lung and breast cancers

### Study Design

**Eligible patient**

- Histologically or cytologically confirmed locally advanced or metastatic urothelial carcinoma
- Progressed during or after enfortumab vedotin plus pembrolizumab combination treatment




Primary endpoint: ORR
Secondary endpoint: DOR
*carboplatin or cisplatin

Primary endpoints: PFS by BICR, OS
Secondary endpoints: PFS by investigator, ORR

- Part A for dose optimization in combination with platinum in metastatic UC and part B for comparison with SOC
- The efficacy results from urothelial cohort of TROPION-PanTumor01 presented at ASCO GU 2025 (n=40, median number of prior lines of therapy: 3) were ORR 25.0% (95% CI 12.7-41.2), mDOR NE (95% CI 2.6-NE) and mPFS 6.9 mo (95% CI 2.9-NE)
- Study started in Oct 2025

ASCO GU: American Society of Clinical Oncology Genitourinary Cancers Symposium, BICR: blinded independent central review, CI: confidence interval, DOR: duration of response, mDOR: median duration of response, mo: month, mPFS: median progression-free survival, NE: not evaluable, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, RP3D: recommended Ph3 dose, SOC: standard of care, UC: urothelial carcinoma

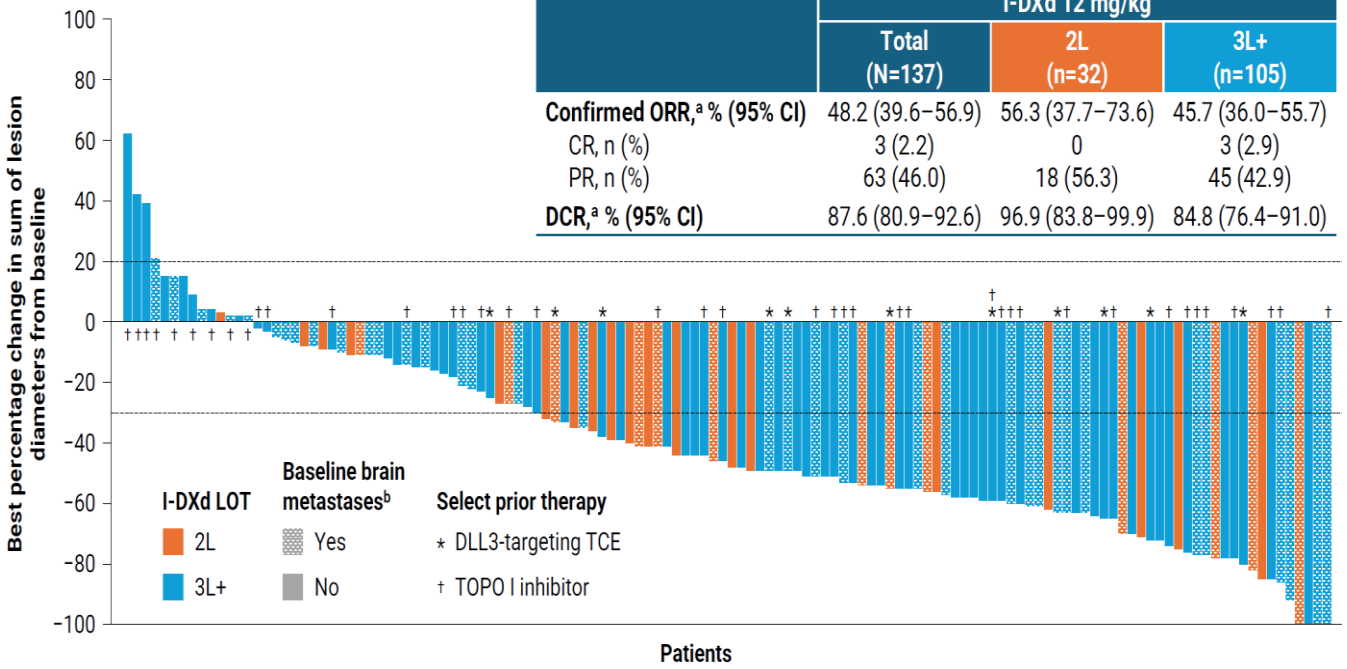
# Striving to Fill the Unmet Need in SCLC

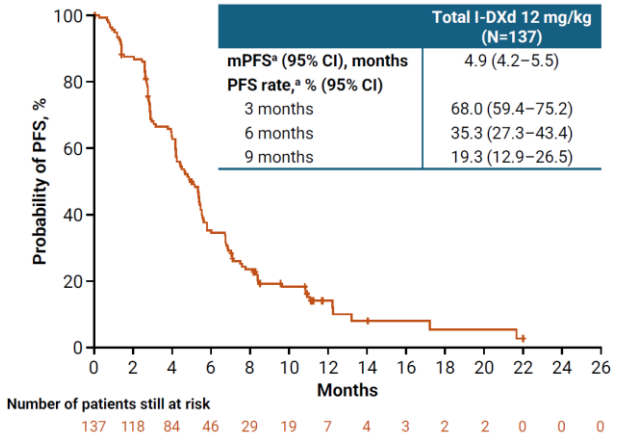
IDeate-Lung01 Ph2 (WCLC 2025)

## I-DXd demonstrated remarkable efficacy in previously treated ES-SCLC

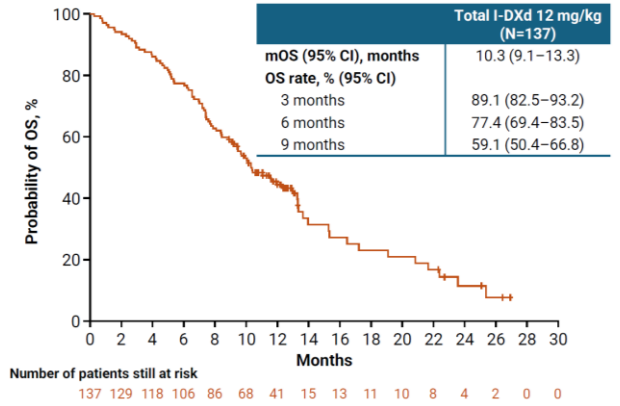
### Efficacy: ORR (left), PFS (upper right), OS (lower right)

| | I-DXd 12 mg/kg | | |
|---|---|---|---|
| | Total (N=137) | 2L (n=32) | 3L+ (n=105) |
| Confirmed ORR,[a] % (95% CI) | 48.2 (39.6–56.9) | 56.3 (37.7–73.6) | 45.7 (36.0–55.7) |
| CR, n (%) | 3 (2.2) | 0 | 3 (2.9) |
| PR, n (%) | 63 (46.0) | 18 (56.3) | 45 (42.9) |
| DCR,[a] % (95% CI) | 87.6 (80.9–92.6) | 96.9 (83.8–99.9) | 84.8 (76.4–91.0) |




| | Total I-DXd 12 mg/kg (N=137) |
|---|---|
| mPFS[a] (95% CI), months | 4.9 (4.2–5.5) |
| PFS rate,[a] % (95% CI) | |
| 3 months | 68.0 (59.4–75.2) |
| 6 months | 35.3 (27.3–43.4) |
| 9 months | 19.3 (12.9–26.5) |




| | Total I-DXd 12 mg/kg (N=137) |
|---|---|
| mOS (95% CI), months | 10.3 (9.1–13.3) |
| OS rate, % (95% CI) | |
| 3 months | 89.1 (82.5–93.2) |
| 6 months | 77.4 (69.4–83.5) |
| 9 months | 59.1 (50.4–66.8) |

- The overall confirmed ORR was 48.2%.
  - ✓ The ORR for 2L was 56.3%, and for 3L and beyond was 45.7%
- I-DXd 12 mg/kg showed mPFS 4.9 mo, and mOS 10.3 mo

**IDeate-Lung01**

- ✓ Evaluating the efficacy and safety of I-DXd monotherapy in ES-SCLC
- ✓ Comparing 8 mg/kg and 12 mg/kg in the dose-optimization phase
- ✓ 12 mg/kg selected for the expansion phase
- ✓ Primary endpoint: ORR

Data cutoff: March 3, 2025

CI: confidence interval, CR: complete response, DCR: disease control rate, ES-SCLC: extensive-stage small cell lung cancer, LOT: line of treatment, mo: month, mOS: median overall survival, mPFS: median progression-free survival, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, PR: partial response, SCLC: small cell lung cancer, TCE: T-call engager, WCLC: World Conference on Lung Cancer

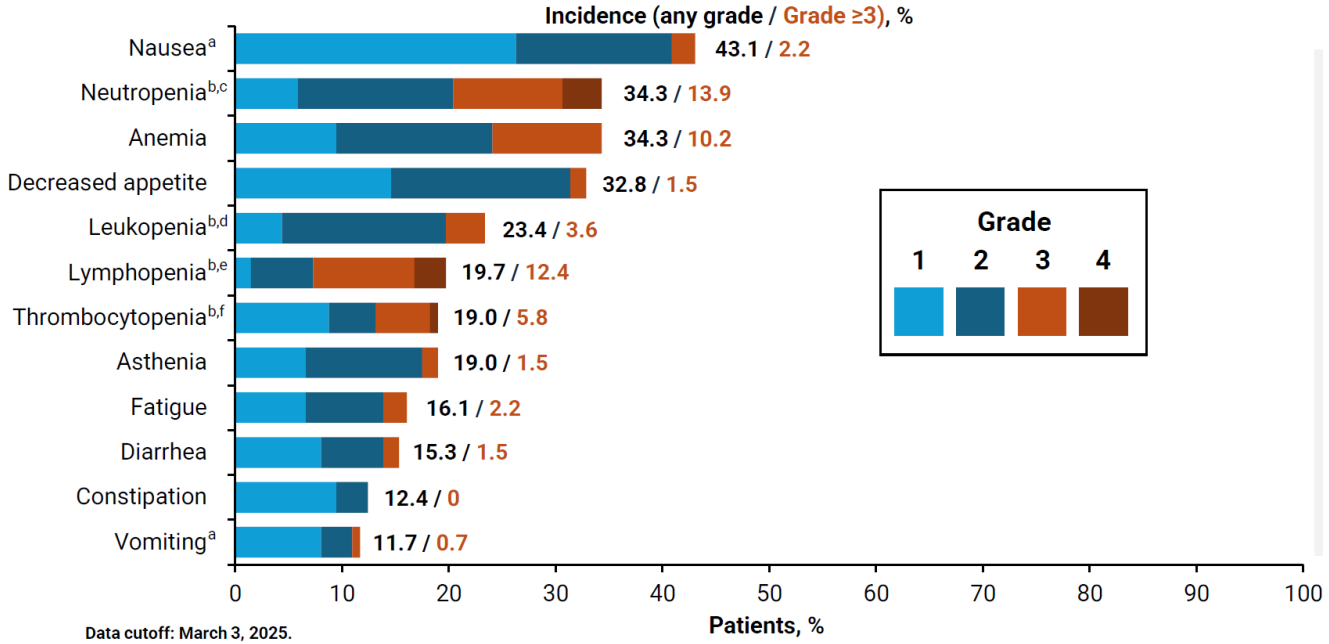
# Striving to Fill the Unmet Need in SCLC

IDeate-Lung01 Ph2 (WCLC 2025)

## Safety profile of I-DXd 12 mg/kg was manageable and consistent with previous studies

### Safety

**TRAEs reported in ≥10% of patients in the total I-DXd 12-mg/kg group (N=137)**




- Among the most common TRAEs, the majority were Grade 1 or 2
- Adjudicated treatment-related ILD reported in 17 patients (12.4%):
  - ✓ Grade 1 or 2, n=11 (8.0%)
  - ✓ Grade 3, n=4 (2.9%)
  - ✓ Grade 5, n=2 (1.5%)

Data cutoff: March 3, 2025

- The FDA granted Breakthrough Therapy Designation to I-DXd for ES-SCLC progressed after platinum-based chemotherapy in Aug 2025

ES-SCLC: extensive-stage small cell lung cancer, ILD: interstitial lung disease, SCLC: small cell lung cancer, TRAE: treatment-related adverse event, WCLC: World Conference on Lung Cancer

# Confirmed Clinical Meaningful Responses in Ph2 Part

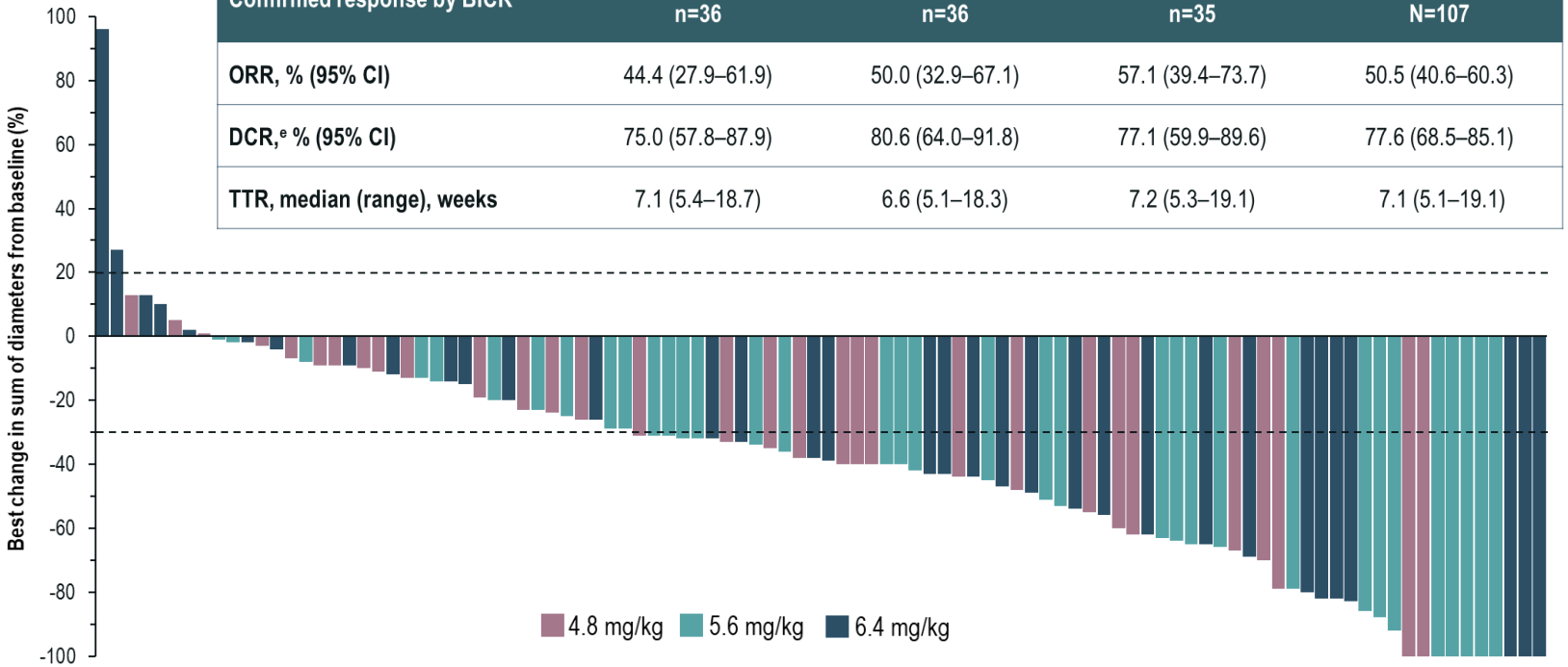
REJOICE-Ovarian01 Ph2/3 (ESMO 2025)

Daiichi-Sankyo

## R-DXd monotherapy demonstrated promising antitumor activity in platinum-resistant ovarian cancer in all doses evaluated

### Efficacy

| Confirmed response by BICR[a] | R-DXd 4.8 mg/kg n=36 | R-DXd 5.6 mg/kg n=36 | R-DXd 6.4 mg/kg n=35 | R-DXd 4.8–6.4 mg/kg N=107 |
|---|---|---|---|---|
| ORR, % (95% CI) | 44.4 (27.9–61.9) | 50.0 (32.9–67.1) | 57.1 (39.4–73.7) | 50.5 (40.6–60.3) |
| DCR,[e] % (95% CI) | 75.0 (57.8–87.9) | 80.6 (64.0–91.8) | 77.1 (59.9–89.6) | 77.6 (68.5–85.1) |
| TTR, median (range), weeks | 7.1 (5.4–18.7) | 6.6 (5.1–18.3) | 7.2 (5.3–19.1) | 7.1 (5.1–19.1) |




Data cutoff: February 26, 2025

- Doses 4.8-6.4 mg/kg (n=107) showed confirmed ORR of 50.5% (3 CRs, 51 PRs)
- Clinically meaningful antitumor activity observed across wide range of CDH6 expression levels
- Safety profile appears manageable and consistent with Ph1 study
- 5.6 mg/kg selected for Ph3 part to evaluate monotherapy vs. TPC (gemcitabine, PLD, topotecan, paclitaxel)
- FDA granted Breakthrough Therapy Designation for CDH6-expressing platinum-resistant OVC previously treated with bevacizumab in Sep 2025

BICR: blinded independent central review, CI: confidence interval, CR: complete response, DCR: disease control rate, ESMO: European Society for Medical Oncology, ORR: objective response rate, OVC: ovarian cancer, PLD: pegylated liposomal doxorubicin, PR: partial response, TPC: treatment of physician's choice, TTR: time to response

5DXd ADCs

# Other Clinical and Regulatory Approval Status Updates

Daiichi-Sankyo

## ENHERTU®

- Oct 2025: DESTINY-Lung06 (Ph3) started for 1L of HER2 overexpressing NSQ NSCLC

## DATROWAY®

- Aug 2025: Approved in China for chemo treated HR+/HER2- BC (TROPION-Breast01)

## HER3-DXd

- Aug 2025: HERTHENA-Breast04 (Ph3) started for HR+/HER2- BC (IHC 0 or 1+ or 2+/ISH-) who received one line of CDK4/6 inhibitor and ET

## I-DXd

- Aug 2025: IDeate-Prostate02 (Ph1/2) started for metastatic CRPC

BC: breast cancer, CRPC: castration-resistant prostate cancer, ET: endocrine therapy, HR: hormone receptor, NSCLC: non-small cell lung cancer, NSQ: nonsquamous

5DXd ADCs Update

**Next Wave Update**

News Flow

DS-3939

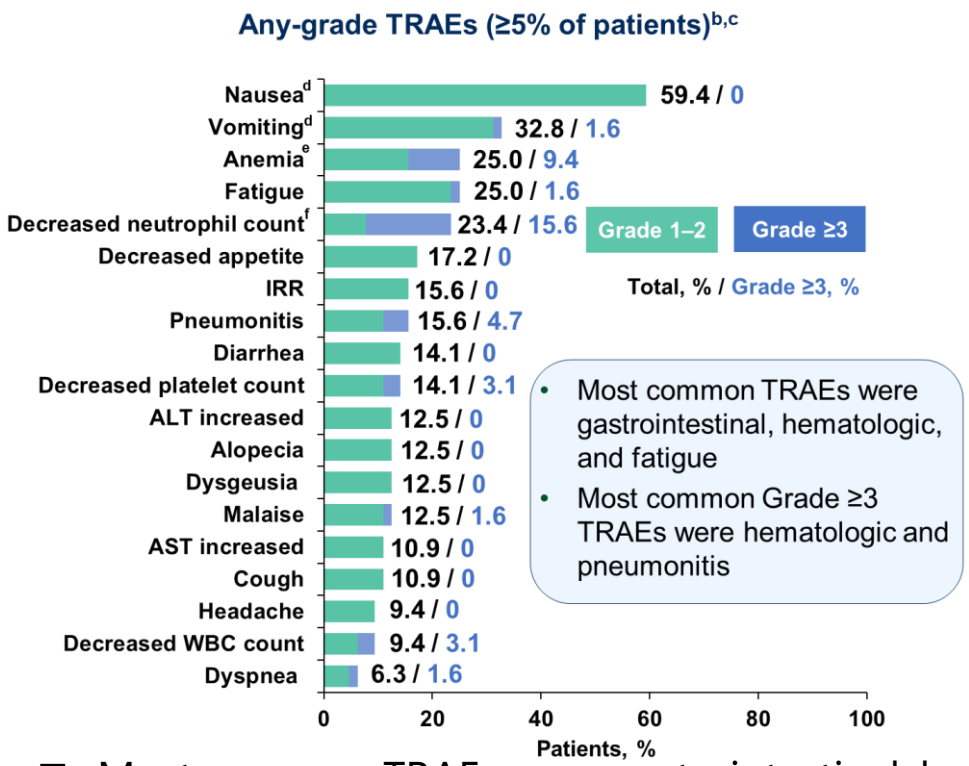
# Initial Results from a FIH Study Dose Escalation Part

Ph1/2 (ESMO 2025)

Daiichi-Sankyo

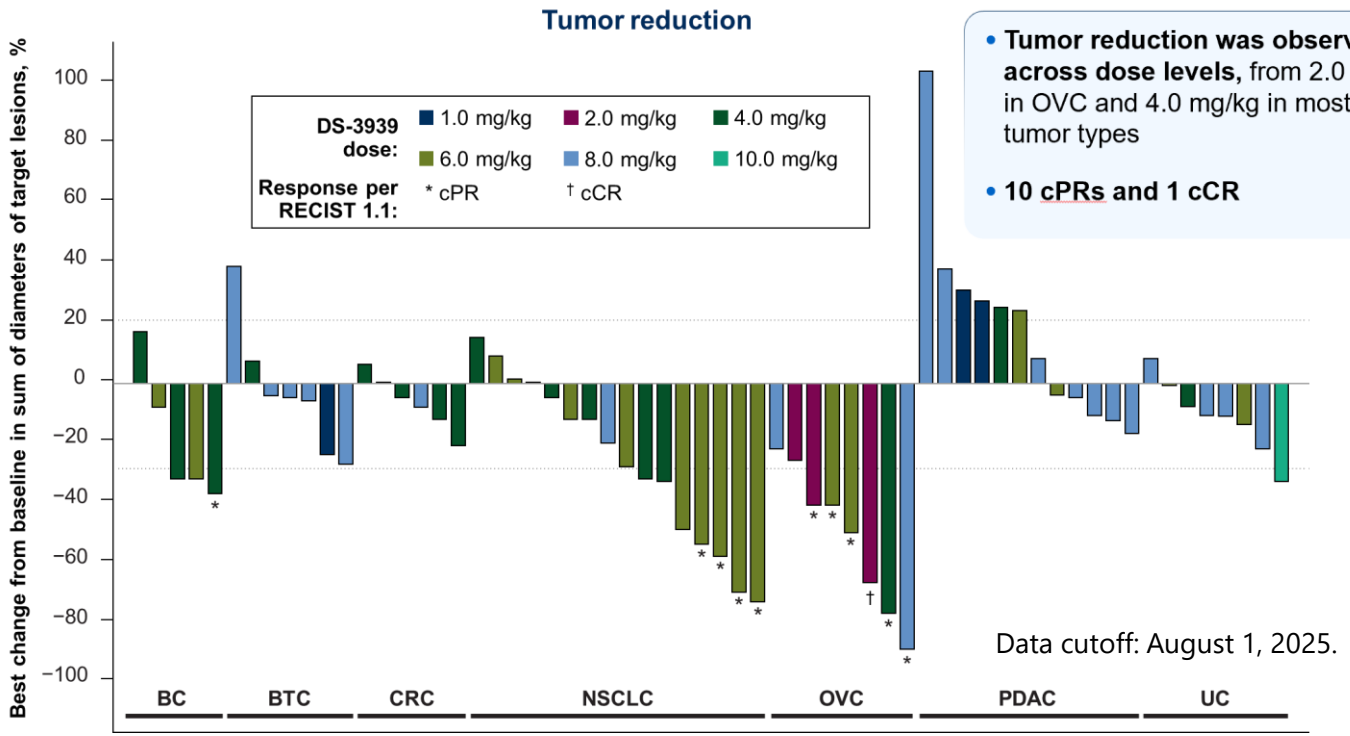
## DS-3939 demonstrated a manageable safety profile and promising preliminary antitumor activity against multiple solid tumors in previously treated patients

### Safety（n=64）




- Most common TRAEs were gastrointestinal, hematologic, and fatigue
- Most common Grade ≥3 TRAEs were hematologic and pneumonitis

### Antitumor Activity（n=64）




- **Tumor reduction was observed across dose levels,** from 2.0 mg/kg in OVC and 4.0 mg/kg in most other tumor types
- **10 cPRs and 1 cCR**

- Most common TRAEs were gastrointestinal, hematologic, and fatigue; most were Grade 1 or 2
- Adjudicated treatment-related ILD/pneumonitis was reported in 7/64 patients (10.9%); most were Grade 2
- Dose expansion and optimization are ongoing; multiple tumor types are being enrolled

ALT: alanine aminotransferase, AST: aspartate aminotransferase, BC: breast cancer, BTC: biliary tract cancer, cCR: confirmed complete response, cPR: confirmed partial response , CRC: colorectal cancer, ESMO: European Society for Medical Oncology, ILD: interstitial lung disease, IRR: infusion related reaction, NSCLC: non-small cell lung cancer, OVC: ovarian cancer, PDAC: pancreatic adenocarcinoma, TRAE: treatment-related adverse event , UC : urothelial carcinoma, WBC: white blood cell

DS3790

# CD37-directed ADC for Hematological Malignancies

Daiichi-Sankyo

## DS3790 is a DXd ADC, targeting CD37-expressing hematological malignancies

### Study design (n=420 in total)

**Eligible Patient**

- Histologically documented hematologic malignancies
- Adequate organ and bone marrow function
- ECOG PS of 0, 1 or 2

**Dose escalation**

DS3790 → RDE

Primary outcome measure: safety, PK

**Dose expansion & combination assessment**

- DS3790 monotherapy
- DS3790 + combination drug A
- DS3790 + combination drug B
- SOC

Primary outcome measure: CRR
Secondary outcome measure: ORR, BOR, DCR etc.

- CD37 is highly and widely expressed in B-cell malignancies
- Plan to start FIH Ph1/2 study in FY2025 H2

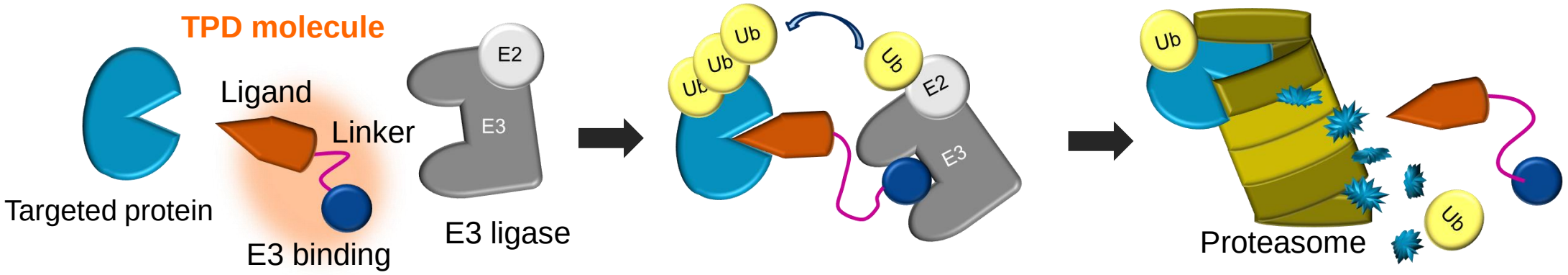
ADC: antibody-drug conjugate, BOR: best overall response, CRR: complete remission rate, DCR: disease control rate, ECOG: Eastern Cooperative Oncology Group, ORR: objective response rate, PK: pharmacokinetics, PS: performance status, RDE: recommended dose for expansion, SOC: standard of care

DS9051

# New Program for Solid Tumors including CRPC

## The first Daiichi Sankyo original targeted protein degradation (TPD) molecule

### Mechanism of Action of TPD Molecule




E3 ligase* is recruited to the targeted protein by the TPD molecule

Ubiquitin** is transferred to the targeted protein

Ubiquitinated target is degraded by proteasome

- The targeted protein is not disclosed
- Plan to start FIH study in solid tumors in FY2025 H2

*E3 ligase: enzyme which facilitates the transfer of ubiquitin from E2 ubiquitin-conjugating enzyme to targeted proteins
**Ubiquitin: protein which is bound to other proteins and functions in various ways such as a marker for degradation

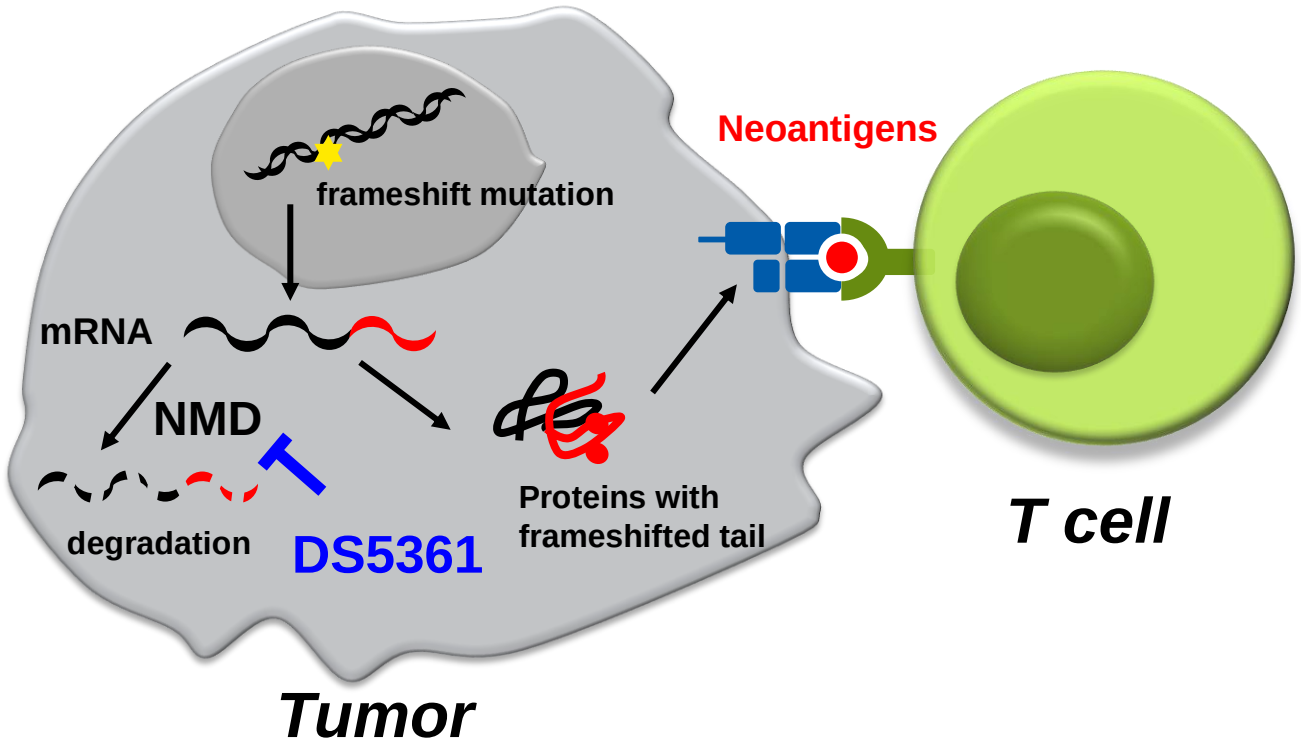
CRPC: castration-resistant prostate cancer, FIH: first-in-human

DS5361

# New Program for Solid Tumors

## DS5361 is a small molecule NMD inhibitor, expecting antitumor immunity by increasing neo-antigens derived from frameshift mutations

### Mechanism of Action




- Potential first-in-class orally available small molecule inhibitor targeting nonsense-mediated mRNA decay (NMD)
- Since NMD suppresses neoantigens derived from frameshift mutations, NMD inhibition is a potential strategy to increase neoantigen burden
- DS5361 enhanced antigen presentation and demonstrated immune-dependent anti-tumor efficacy, including T-cell activation, in preclinical studies
- Combination benefits with immune checkpoint inhibitors have been confirmed in mouse models
- FIH study started in Oct 2025

FIH: first-in-human

5DXd ADCs Update

Next Wave Update

**News Flow**

# FY2025 News Flow

As of Oct 2025

## Upcoming regulatory decisions

| | |
|---|---|
| ENHERTU® | **DESTINY-Breast09: HER2 positive BC, 1L, Ph3**<br>• **US: FY2025 H2** |
| | **DESTINY-Breast11: HER2 positive BC, neoadjuvant, Ph3**<br>• **US: FY2026 H1** |

## Upcoming key data readouts

| | |
|---|---|
| ENHERTU® | DESTINY-Lung04: HER2 mutation NSCLC, 1L<br>• FY2026 |
| DATROWAY® | TROPION-Lung07: non-squamous NSCLC, w/o AGA, PD-L1 TPS <50%, 1L, pembrolizumab ± PBC combo, Ph3,<br>• FY2026 |
| | TROPION-Lung08*: NSCLC, w/o AGA, PD-L1 TPS ≥50%, 1L, pembrolizumab combo, Ph3<br>• FY2026 |
| | TROPION-Lung15: EGFR mutated NSCLC progressed on prior osimertinib, 2L+, mono or osimertinib combo, Ph3<br>• FY2026 |
| | AVANZAR*: NSCLC, w/o AGA, 1L, durvalumab + carboplatin combo, Ph3<br>• CY2026 H1 |
| | TROPION-Breast05: TNBC, PD-L1 positive, 1L, durvalumab combo, Ph3<br>• FY2026 |

**Bold: update from FY2025 Q1**

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, PBC: platinum-based chemotherapy, TNBC: triple negative breast cancer, TPS: tumor proportion score, UC: urothelial cancer

# Upcoming IR Events

## Sustainability Meeting

### Date, time and format

Friday, November 28, 2025
3:30-5:00pm JST
On site + Virtual (Zoom)

### Speakers

- Hiroyuki Okuzawa
  President and CEO
- Shizuko Ueno
  Director, Executive Officer (Head of Japan Business Unit)
- Yasuhiro Komatsu
  Outside Director (Independent Director)
- Takaaki Nishii
  Outside Director (Independent Director)

## Science & Technology Day 2025

### Date, time and format

Monday, December 15, 2025
5:30-7:30pm EDT
Tuesday, December 16, 7:30-9:30am (JST)
Virtual (Zoom)

### Speakers

- Hiroyuki Okuzawa
  President and CEO
- Ken Keller
  Head of Global Oncology Business
- Hiroto Kashiwase
  Head of Global Technology
- Ken Takeshita
  Head of Global R&D
- Yuki Abe
  Head of R&D Division

# Q&A

**Hiroyuki Okuzawa**
President and CEO

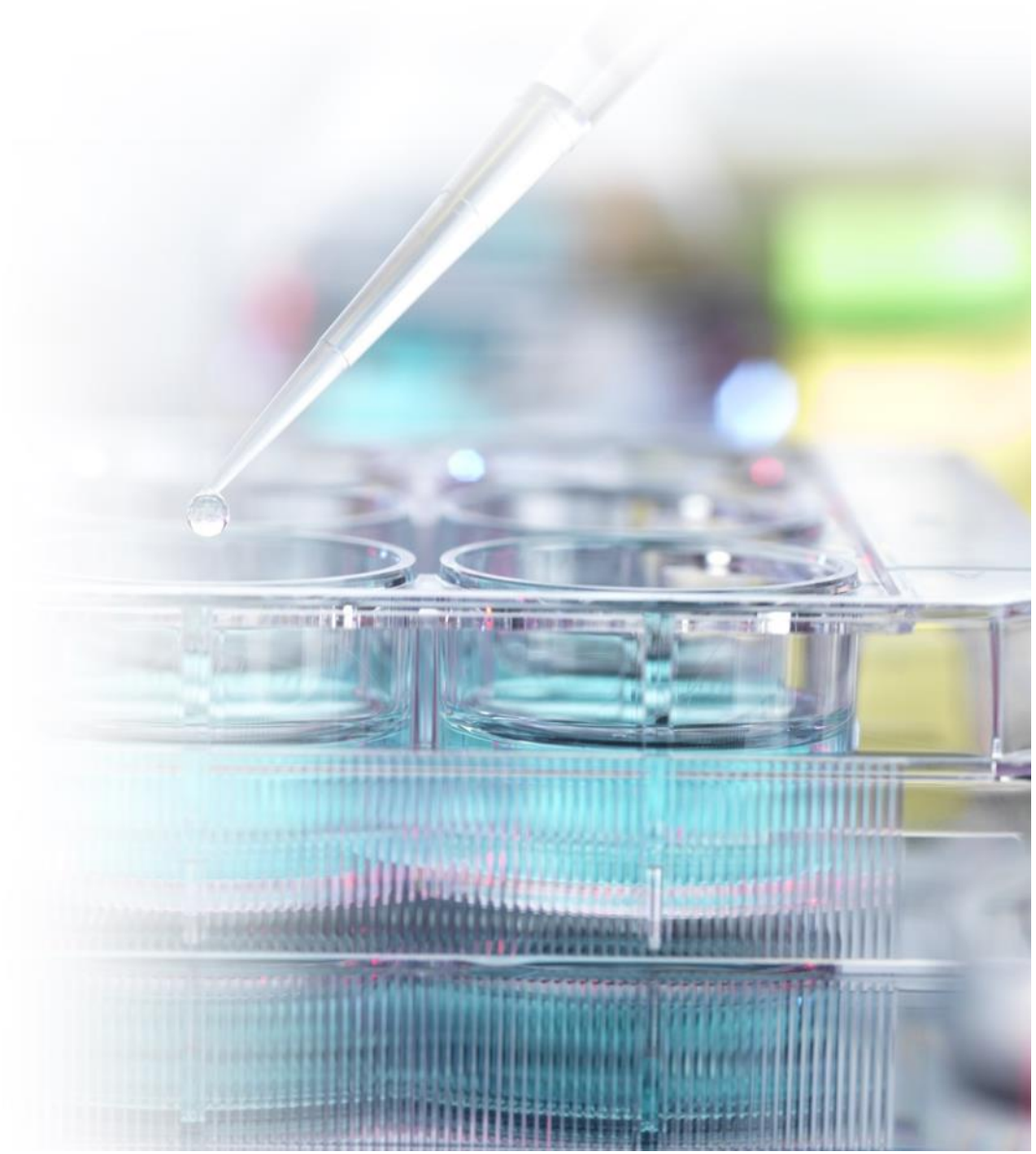
**Ken Takeshita**
Head of Global R&D

**Ken Keller**
Head of Global Oncology Business

**Koji Ogawa**
Senior Executive Officer, CFO

# Agenda

1. FY2025 Q2 Financial Results
2. FY2025 Forecast
3. Business Update
4. R&D Update
5. **Appendix**



# Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

| | FY2024 Q2 YTD Results | FY2025 Q2 YTD Results | YoY |
|---|---|---|---|
| Japan Business | 239.7 | 249.9 | +10.3 |
| Daiichi Sankyo Healthcare | 42.5 | 45.9 | +3.4 |
| Oncolgy Business | 215.5 | 273.0 | +57.4 |
| Enhertu | 210.7 | 256.1 | +45.5 |
| Datroway | - | 10.1 | +10.1 |
| Turalio | 3.2 | 3.0 | -0.2 |
| Vanflyta | 1.7 | 3.8 | +2.1 |
| American Regent | 108.1 | 96.8 | -11.3 |
| Injectafer | 28.5 | 22.6 | -5.8 |
| Venofer | 29.7 | 26.9 | -2.9 |
| GE injectables | 43.7 | 40.9 | -2.8 |
| EU Specialty Business | 118.2 | 136.8 | +18.6 |
| Lixiana | 90.6 | 96.8 | +6.2 |
| Nilemdo/Nustendi | 16.4 | 28.6 | +12.1 |
| Olmesartan | 9.5 | 10.3 | +0.8 |
| ASCA (Asia, South and Central America) Business | 99.6 | 117.9 | +18.3 |

| | | | | |
|---|---|---|---|---|
| Currency Exchange Rate | USD/JPY | 152.62 | 146.04 | -6.58 |
| | EUR/JPY | 165.93 | 168.06 | +2.13 |

# Revenue: Major Products in Japan

(Bn JPY)

| | | FY2024 Q2 YTD Results | FY2025 Q2 YTD Results | YoY |
|---|---|---|---|---|
| **Lixiana** | anticoagulant | **67.9** | **73.2** | **+5.3** |
| **Tarlige** | pain treatment | **27.8** | **32.2** | **+4.4** |
| **Pralia** | Treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis | **21.1** | **22.6** | **+1.5** |
| **Enhertu** | anti-cancer agent (HER2-directed antibody drug conjugate) | **15.5** | **17.9** | **+2.4** |
| **Efient** | antiplatelet agent | **15.7** | **18.0** | **+2.3** |
| **Vimpat** | anti-epileptic agent | **15.5** | **16.8** | **+1.4** |
| **Belsomra** | Anti-Insomnia Treatment | **-** | **9.7** | **+9.7** |
| **Ranmark** | treatment for bone complications caused by bone metastases from tumors | **10.4** | **10.0** | **-0.4** |
| **Canalia** | type 2 diabetes mellitus treatment | **8.1** | **7.7** | **-0.5** |
| **Minnebro** | antihypertensive agent | **4.8** | **5.3** | **+0.5** |
| **Loxonin** | anti-inflammatory analgesic | **6.8** | **5.9** | **-0.9** |
| **Emgality** | prophylaxis of migraine attacks | **5.1** | **6.3** | **+1.1** |
| **Inavir** | anti-influenza treatment | **0.2** | **0.0** | **-0.2** |

# 5DXd ADCs Revenue (incl. Forex Impact)

(Unit: Bn JPY)

| | FY2025 Q2 YTD Results | YoY | FY2025 Forecast (as of Oct.) | vs Apr Forecast |
|---|---|---|---|---|
| **ENHERTU®** | **330.3** | **+58.6** | **808.3** | **+47.0** |
| Product Sales | 318.4 | +57.1 | 694.2 | +32.1 |
| Upfront and Milestone Payments, etc. | 11.9 | +1.5 | 114.0 | +14.8 |
| **DATROWAY®** | **20.8** | **+17.6** | **46.2** | **+16.3*** |
| Product Sales | 15.7 | +15.7 | 37.8 | +16.2* |
| Upfront and Milestone Payments, etc. | 5.1 | +1.9 | 8.4 | +0.1 |
| **HER3-DXd** | **7.1** | **+2.7** | **13.1**** | **-3.2** |
| Upfront and Milestone Payments, etc. | 7.1 | +2.7 | 13.1 | -3.2 |
| **I-DXd** | **7.6** | **-0.2** | **15.1** | **-** |
| Upfront and Milestone Payments, etc. | 7.6 | -0.2 | 15.1 | - |
| **R-DXd** | **3.3** | **-0.2** | **21.5** | **+1.1** |
| Upfront and Milestone Payments, etc. | 3.3 | -0.2 | 21.5 | +1.1 |
| **5DXd ADCs Total** | **369.0** | **+78.5** | **904.2** | **+61.1** |

* DATROWAY product sales: vs July Forecast

** Extension of the exclusivity period for HER3-DXd

# 5DXd ADCs Upfront and Milestone Payments

(Unit: Bn JPY)

| Asset | Item | FY2025 Q2 YTD Results | YoY | FY2025 Forecast (as of Oct) | vs Apr Forecast | Total Consideration (as of Sep 2025) |
|---|---|---|---|---|---|---|
| ENHERTU® | Upfront Payment | 5.1 | - | 10.2 | - | 149.0 |
| | Regulatory Milestones | 6.2 | +1.5 | 23.1 | +10.5 | 185.9 |
| | Quid Related Payment | 0.6 | - | 1.2 | - | 17.2 |
| | Sales Milestone | - | - | 79.6 | +4.3 | 100.8 |
| DATROWAY® | Upfront Payment | 3.2 | - | 6.4 | - | 115.9 |
| | Regulatory Milestones | 1.9 | +1.9 | 2.1 | +0.1 | 6.6 |
| AZ Alliance Total | | **16.9** | **+3.3** | **122.4** | **+14.9** | **575.4** |
| HER3-DXd | Upfront Payment | 6.8 | +2.9 | 12.7 ** | -3.1 | 224.9 |
| | Satisfaction of Quid Rights * | 0.2 | -0.2 | 0.4 ** | -0.1 | 7.3 |
| I-DXd | Upfront Payment | 7.3 | - | 14.7 | - | 225.4 |
| | Satisfaction of Quid Rights * | 0.2 | -0.2 | 0.5 | - | 7.3 |
| R-DXd | Upfront Payment | 3.1 | - | 21.1 | +1.1 | 112.7 |
| | Satisfaction of Quid Rights * | 0.2 | -0.2 | 0.4 | +0.0 | 7.3 |
| US Merck Alliance Total | | **17.9** | **+2.3** | **49.7** | **-2.1** | **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
** Extension of the exclusivity period for HER3-DXd

# Major R&D Milestones (ENHERTU®)

As of Oct 2025

| Project | | Population/regimen [phase, study name] | FY2025 H1 | FY2025 H2 | FY2026 |
|---|---|---|---|---|---|
| ENHERTU® | BC | • HER2+, adjuvant*1 [Ph3, DESTINY-Breast05] | | **• TLR obtained** | |
| | | • HR+/HER2 low or HER2 ultralow, chemo naive [Ph3, DESTINY-Breast06] | **• Approved (JP)** • Filling accepted (CN) | | |
| | | • HER2+, 1L, pertuzumab combo*2 [Ph3, DESTINY-Breast09] | • TLR obtained **• Filling accepted (US)** | **• Filling accepted (JP)** **• Regulatory decision anticipated (US)** | |
| | | • HER2+, neoadjuvant, mono followed by THP [Ph3, DESTINY-Breast11] | • TLR obtained **• Filling accepted (US/CN)** | | |
| | GC | • HER2+, 2L [Ph3, DESTINY-Gastric04] | **• Filling accepted (CN)** | | |
| | NSCLC | • HER2 mutation, 1L [Ph3, DESTINY-Lung04] | | | • TLR anticipated |
| | | • HER2 overexpression, 1L, pembrolizumab combo [Ph3, DESTINY-Lung06] | | **• Study started** | |
| | 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 | |
| | Other tumors | • HER2 expressing tumors [Ph2, DESTINY-PanTumor02] | • Filling accepted (JP/**EU**) | | |

**Bold: update from FY2025 Q1**

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 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 Oct 2025

| Project | | Population/regimen [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 ± PBC 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)<br>**• Approved (CN)** | | |
| | | • TNBC, not an option for PD-1/PD-L1 inhibitor, 1L [Ph3, TROPION-Breast02] | | **• TLR obtained** | |
| | | • TNBC, PD-L1 positive, 1L, durvalumab combo [Ph3, TROPION-Breast05] | | | • TLR anticipated |
| | UC | **• Post EV + pembrolizumab combo treatment, PBC combo [Ph2/3, TROPION-Urothelial03]** | | **• Study started** | |

**Bold: update from FY2025 Q1**

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 Oct 2025

| Project | | Population/regimen [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, post ET and CDK4/6 inhibitor treatment [Ph3, HERTHENA-Breast04] | **• Study started** | | |
| I-DXd | SCLC | • 2L+ [Dose expansion, Ph2, IDeate-Lung01] | • TLR obtained | | |
| | ESCC | • 2L [Ph3, IDeate-Esophageal01] | • Study started | | |
| | CRPC | • Chemo naïve [Ph3, IDeate-Prostate01] | • Study started | | |
| R-DXd | OVC | • Platinum-resistant, 2L+ [Ph2/3, REJOICE-Ovarian01] | **• TLR obtained (Ph2 dose optimization)** | | |
| | GI cancers | • [Ph2, REJOICE-GI01] | • Study started | | |

**Bold: update from FY2025 Q1**

BC: breast cancer, CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, ET: endocrine therapy, GI: gastrointestinal, HR: hormone receptor, NSCLC: non-small cell lung cancer, OVC: ovarian 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 Milestones (Next Wave)

As of Oct 2025

| Project | Target indication [phase, study name] | FY2025 | | FY2026 |
|---|---|---|---|---|
| | | H1 | H2 | |
| **DS3610** | • **Solid tumors [Ph1]** | | • **Study start planned** | |
| **DS5361** | • **Solid tumors [Ph1]** | | • **Study started** | |
| **DS9051** | • **Solid tumors including CRPC [Ph1]** | | • **Study start planned** | |
| **DS3790** | • **CD37-expressing hematological malignancies [Ph1/2]** | | • **Study start planned** | |

**Bold: update from FY2025 Q1**

CRPC: castration-resistant prostate cancer
Timeline indicated is based on the current forecast and subject to change

# Major R&D Pipeline: 5DXd ADCs ①

As of Oct 2025

Daiichi-Sankyo

## Phase 1

- (US/EU/Asia) HER2 low BC chemo naïve/post chemo （combo) DESTINY-Breast08
- (US/EU/Asia) HER2 overexpressing non-squamous NSCLC 1L （ICI ± PBC combo) DESTINY-Lung03
- (US/EU) BC, NSCLC (pembrolizumab combo)
- (JP/US) in prep solid tumors (subcutaneous injection)
- (JP/US) solid tumors TROPION-PanTumor01
- (JP/US/EU/Asia) NSCLC (w/o AGA) (pembrolizumab ± PBC combo) TROPION-Lung02
- (JP/US/EU/Asia) NSCLC (w/o AGA) ((durvalumab, rilvegostomig or volrustomig) ± PBC or sabestomig combo) TROPION-Lung04
- (JP/US/EU/Asia) NSCLC
- (JP/US/Asia) EGFR mutated NSCLC 1L/2L (osimertinib combo)
- (JP/US) renal cell carcinoma, ovarian cancer

## Phase 1/2

- (US/EU/Asia) HER2+ BC 2L+/1L (chemo combo) DESTINY-Breast07
- (JP/US/EU/Asia) HER2 expressing GC 2L+/1L (combo) DESTINY-Gastric03
- (US/EU/Asia) TNBC (durvalumab combo) BEGONIA
- (JP/US/EU/Asia) solid tumors (saruparib combo) PETRA
- (US/EU/Asia) TNBC (durvalumab combo) BEGONIA
- (JP/US/EU/Asia) solid tumors (saruparib combo) PETRA
- (CN) NSCLC, TNBC TROPION-PanTumor02
- (US/EU/Asia) CRC, BTC, HCC, gastroesophageal cancer 2L+ HERTHENA-PanTumor02
- (US/EU/Asia) stageIV NSCLC 1L (pembrolizumab + PBC combo) KEYMAKER-U01 substudy 01A
- (JP/US/EU/Asia) HER2+ BC 2L+ (trastuzumab (± pertuzumab or tucatinib) combo) HERTHENA-Breast01
- (US/EU/Asia) r/r RMS, HBL (pediatric) LIGHTBEAM-U01
- (JP/US) ESCC, CRPC, squamous NSCLC, SCLC, etc. IDeate-PanTumor01
- (JP/US/EU/Asia) solid tumors 2L+ IDeate-PanTumor02
- (JP/US/EU) ES-SCLC 1L (atezolizumab combo) IDeate-Lung03
- (US/EU/Asia) chemo-naïve metastatic CRPC (mono or combo) IDeate-Prostate02
- (US/EU/Asia) in prep stageIV NSCLC 1L (pembrolizumab + PBC combo) KEYMAKER-U01 substudy 01A
- (JP/US/EU/Asia) ESCC 1L (pembrolizumab ± chemo combo) KEYMAKER-U06 substudy 06E
- (US/EU/Asia) ES-SCLC 2L KEYNOTE-B98
- (US/EU/Asia) ovarian cancer, relapsed after PBC (carboplatin, paclitaxel or bevacizumab combo) REJOICE-Ovarian02

## Phase 2

- (CN) HER2 expressing solid tumors DESTINY-PanTumor03
- (JP/US/EU/Asia) solid tumors TROPION-PanTumor03
- (JP/US/EU/Asia) EGFR mutated NSCLC 2L (osimertinib combo) ORCHARD
- (US/EU/Asia) resectable early-stage NSCLC neoadjuvant ((durvalumab or rilvegostomig) + PBC combo) NeoCOAST-2
- (JP/US/EU/Asia) solid tumors HERTHENA-PanTumor01
- (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 combo) KEYMAKER-U01 substudy 01G
- (JP/US/EU/Asia) ES-SCLC 2L+ IDeate-Lung01
- (US/EU/Asia) in prep non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
- (US/EU/Asia) in prep squamous NSCLC 2L KEYMAKER-U01 substudy 01I
- (US/EU/Asia) gastrointestinal cancers REJOICE-GI01
- (JP/US/EU/Asia) solid tumors REJOICE-PanTumor01
- (US/EU/Asia) non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
- (US/EU/Asia) squamous NSCLC 2L KEYMAKER-U01 substudy 01I

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, 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, TNBC: triple negative breast cancer

# Major R&D Pipeline: 5DXd ADCs ②

As of Oct 2025

Daiichi-Sankyo

| Phase 2/3 | Phase 3 | | | | Regulatory phase |
|---|---|---|---|---|---|
| (JP/US/EU/Asia) platinum-resistant ovarian cancer 2L+<br>REJOICE-Ovarian01 | (JP/US/EU/Asia) HER2+ BC adjuvant*1<br>DESTINY-Breast05 | (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)<br>AVANZAR | (JP/US/EU/Asia)<br>EGFR mutated NSCLC 2L<br>HERTHENA-Lung02 | (CN) HR+ and HER2 low or HER2 ultralow BC chemo naïve<br>DESTINY-Breast06 |
| (JP/US/EU/Asia) UC post enfortumab vedotin + pembrolizumab combo treatment (PCB combo)<br>TROPION-Urothelial03 | (JP/US/EU/Asia) HER2+ BC 1L (mono)<br>DESTINY-Breast09 | (JP/US/EU/Asia) in prep HER2 expressing EC adjuvant<br>DESTINY-Endometrial02 | (JP/US/EU/Asia) TNBC (not an option for PD-1/PD-L1 inhibitor) 1L<br>TROPION-Breast02 | (US/Asia) HR positive and HER2 negative BC post ET and CDK4/6 inhibitor treatment<br>HERTHENA-Breast04 | (JP/US) HER2+ BC 1L (pertuzumab combo)<br>DESTINY-Breast09 |
| | (JP/US/EU/Asia) HER2+ GC 1L (pembrolizumab + FP combo)<br>DESTINY-Gastric05 | (JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1 TPS <50%) 1L (pembrolizumab ± PBC combo)<br>TROPION-Lung07 | (JP/US/EU/Asia) TNBC adjuvant*1 (mono or durvalumab combo)<br>TROPION-Breast03 | (JP/US/EU/Asia) ES-SCLC 2L<br>IDeate-Lung02 | (US/CN) HER2+ BC neoadjuvant (mono followed by THP)<br>DESTINY-Breast11 |
| | (JP/US/EU/Asia) HER2+ and PD-L1 CPS≥1 GC 1L (rilvegostomig + FP combo)<br>ARTEMIDE-Gastric01 | (JP/US/EU/Asia) NSCLC (w/o AGA, PD-L1 TPS ≥50%) 1L (pembrolizumab combo)<br>TROPION-Lung08 | (JP/US/EU/Asia) TNBC, HR low and HER2 negative BC neoadjuvant and adjuvant (durvalumab combo)<br>TROPION-Breast04 | (JP/US/EU/Asia) ESCC 2L<br>IDeate-Esophageal01 | (CN) HER2+ GC 2L<br>DESTINY-Gastric04 |
| | (JP/US/EU/Asia) HER2 mutant NSCLC 1L<br>DESTINY-Lung04 | (JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1 TC ≥50%) 1L (rilvegostomig combo)<br>TROPION-Lung10 | (JP/US/EU/Asia) PD-L1 positive TNBC 1L (durvalumab combo)<br>TROPION-Breast05 | (JP/US/Asia) chemo-naïve metastatic CRPC<br>IDeate-Prostate01 | (JP*2/EU*3) HER2 expressing tumors<br>DESTINY-PanTumor02 etc |
| | (JP/US/Asia) HER2 overexpressing non-squamous NSCLC (w/o AGA, PD-L1 TPS < 50%) (pembrolizumab combo)<br>DESTINY-Lung06 | (JP/US/EU/Asia) Stage I adenocarcinoma NSCLC adjuvant (rilvegostomig combo)<br>TROPION-Lung12 | | | |
| | (JP/US/EU/Asia) HER2 expressing BTC 1L (rilvegostomig combo)<br>DESTINY-BTC01 | (JP/US/EU/Asia) EGFR mutated NSCLC 1L (osimertinib combo)<br>TROPION-Lung14 | | | |
| | (JP/US/Asia) HER2 expressing ovarian cancer 1L maintenance (bevacizumab combo)<br>DESTINY-Ovarian01 | (JP/US/EU/Asia) EGFR mutated NSCLC (progressed on prior osimertinib) 2L+ (mono or osimertinib combo)<br>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 Adjuvant therapy for patients with residual invasive disease following neoadjuvant therapy
*2 Filing based on this study and HERALD study (IIS), etc
*3 Filing based on this study, DESTINY-CRC02, DESTINY-Lung01

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

# Major R&D Pipeline: Next Wave

As of Oct 2025

| Phase 1 | Phase 1/2 | Phase 2 | Phase 3 | Regulatory phase |
|---|---|---|---|---|
| DS-9606 (US/EU)<br>CLDN6-directed ADC<br>Solid tumors | DS-3939 (JP/US/EU/Asia)<br>TA-MUC1-directed DXd ADC<br>Solid tumors | EZHARMIA® (EU)<br>EZH1/2 inhibitor<br>BCL | TURALIO® (Asia)<br>CSF-1/KIT/FLT3 inhibitor<br>Tenosynovial giant cell tumor | VANFLYTA® (CN)<br>FLT3 inhibitor<br>*FLT3* -ITD positive AML 1L<br>QuANTUM-First |
| DS-1103 (US/EU)<br>Anti-SIRPα antibody<br>HER2 expressing or mutant solid tumors, HER2 low BC (ENHERTU® combo) | MK-6070 (DS3280) (US)<br>DLL3 directed tri-specific T-cell engager<br>DLL3 expressing advanced cancer<br>(mono, I-DXd combo or atezolizumab combo)<br>MK-6070-001 | DS-1001 (JP)<br>Mutant IDH1 inhibitor<br>Glioma | VANFLYTA® (JP/US/EU/Asia)<br>FLT3 inhibitor<br>*FLT3* -ITD negative AML 1L<br>QuANTUM-Wild | VN-0102/JVC-001 (JP)<br>Mixed measles-mumps-rubella vaccine |
| EZHARMIA® (JP/US)<br>EZH1/2 inhibitor<br>HER2+ GC, HER2 low BC (ENHERTU® combo) and non-squamous NSCLC (DATROWAY® combo) | MK-6070 (DS3280) (US/EUAsia<br>DLL3 directed tri-specific T-cell engager<br>ES-SCLC 2L+ (I-DXd combo)<br>MK-6070-002 | TURALIO® (JP)<br>CSF-1/KIT/FLT3 inhibitor<br>Tenosynovial giant cell tumor | | |
| DS-2243（US/EU/Asia）<br>HLA-A*02/NY-ESO directed bispecific T-cell engager<br>Solid tumors | EZHARMIA® （JP/US/Asia）<br>EZH1/2 inhibitor<br>NSCLC (w/o AGA and PD-L1 TPS ≥50%) 1L<br>(pembrolizumab combo) | | | |
| DS3610 (TBA) in prep<br>STING agonist ADC<br>Solid tumors | DS3790 (TBA) in prep<br>CD37-directed DXd ADC<br>CD37-expressing hematological malignancies | | | |
| DS5361 (JP/US)<br>Small molecure NMD inhibitor<br>Solid tumors | DS-7011 (JP/US/EU/Asia)<br>Anti-TLR7 antibody<br>Systemic lupus erythematosus | | | |
| DS9051 (US/EU) in prep<br>Targeted protein degradation (TPD) molecule<br>Solid tumors including CRPC | | | | |

Oncology Specialty 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

## Contact address regarding this material

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