

Passion for Innovation.  
Compassion for Patients.™



# FY2024 Q3 Financial Results Presentation

**DAIICHI SANKYO CO., LTD.**

**Koji Ogawa**

**Executive Officer, CFO**

**January 31, 2025**

# Forward-Looking Statements

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# Agenda

① **FY2024 Q3 Financial Results**

② FY2024 Forecast

③ Business Update

④ R&D Update

⑤ Appendix



# Overview of FY2024 Q3 Results

(Bn JPY)

	FY2023 Q3 YTD Results	FY2024 Q3 YTD Results	YoY	
<b>Revenue</b>	<b>1,173.3</b>	<b>1,367.6</b>	<b>+16.6%</b>	
<b>Cost of sales</b> *1	<b>310.3</b>	<b>321.4</b>	<b>11.1</b>	
<b>SG&amp;A expenses</b> *1	<b>433.9</b>	<b>516.6</b>	<b>82.7</b>	
DXd ADC profit share*2	<b>119.1</b>	<b>168.5</b>	<b>49.4</b>	
Other SG&A expenses	<b>314.8</b>	<b>348.2</b>	<b>33.3</b>	
<b>R&amp;D expenses</b> *1	<b>256.8</b>	<b>300.6</b>	<b>43.8</b>	
<b>Core operating profit</b> *1	<b>172.2</b>	<b>229.0</b>	<b>+33.0%</b>	
Temporary income*1	<b>26.9</b>	<b>21.5</b>	<b>-5.4</b>	
Temporary expenses*1	<b>4.6</b>	<b>2.2</b>	<b>-2.4</b>	
<b>Operating profit</b>	<b>194.6</b>	<b>248.3</b>	<b>+27.6%</b>	
<b>Profit before tax</b>	<b>199.8</b>	<b>275.0</b>	<b>75.2</b>	
<b>Profit attributable to owners of the Company</b>	<b>163.6</b>	<b>208.6</b>	<b>+27.5%</b>	
<b>Currency Rate</b>	<b>USD/JPY</b>	<b>143.29</b>	<b>152.56</b>	<b>+9.27</b>
	<b>EUR/JPY</b>	<b>155.28</b>	<b>164.82</b>	<b>+9.54</b>

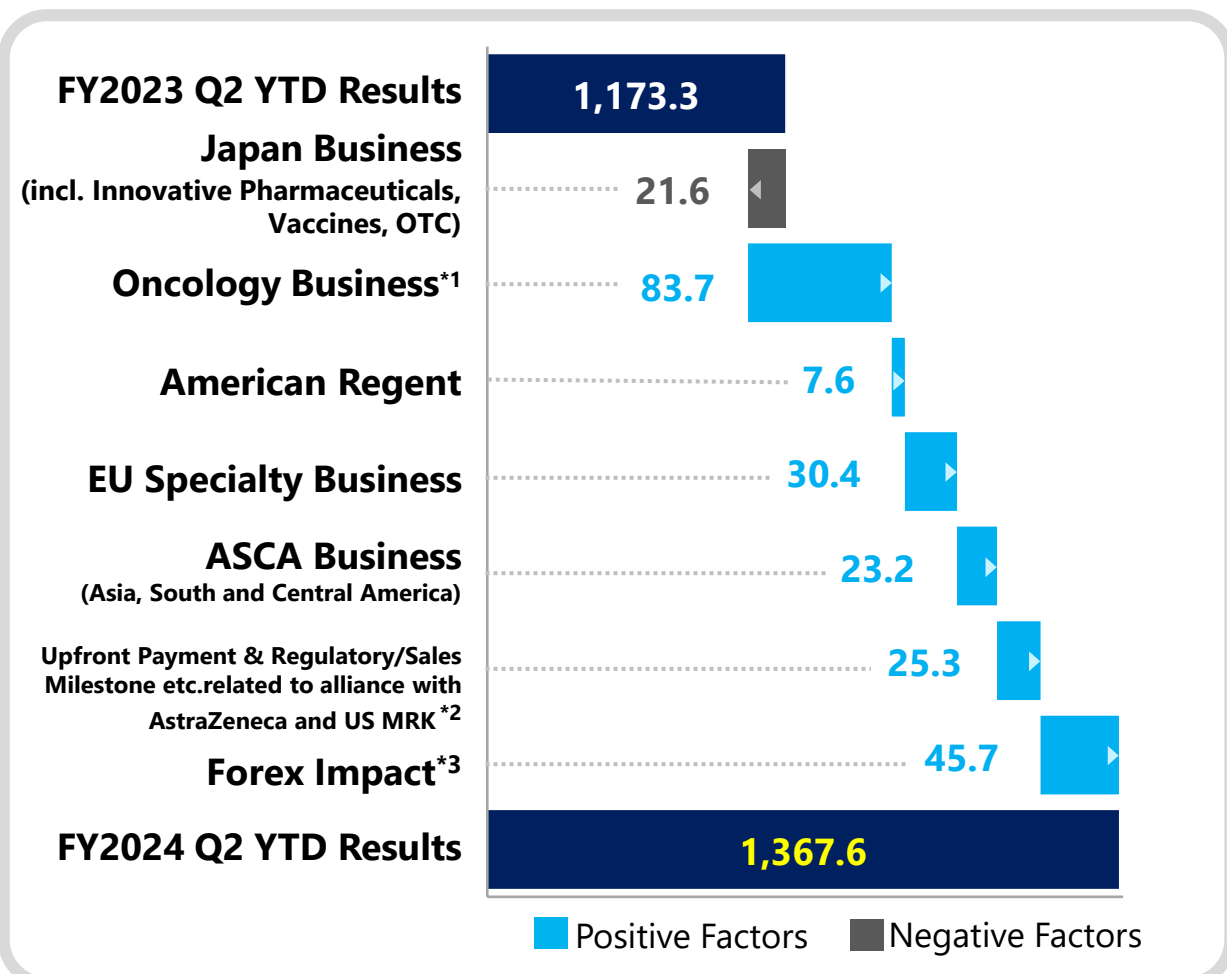
\*1 As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed. Income and expenses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation, 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 194.3 Bn JPY** (Increased by 148.6 Bn JPY excl. forex impact)

(Bn JPY)



Positive Factors		Negative Factors	
<b>Japan Business Unit</b>			
Lixiana	+13.7	Daiichi Sankyo	-64.9
Tarlige	+7.6	Espha	
Enhertu	+5.8		
Daiichi Sankyo Healthcare	+7.5		
Realized gains of unrealized gains of inventory for Daiichi Sankyo Espha	+11.2		
<b>Oncology Business Unit*1</b>			
Enhertu	+81.6		
<b>American Regent Unit</b>			
GE injectables	+4.6		
Venofer	+2.7		
<b>EU Specialty Business Unit</b>			
Lixiana	+20.4	olmesartan	-1.4
Nilemdo/Nustendi	+12.9		
<b>ASCA (Asia, South and Central America) Business Unit</b>			
Enhertu	+19.1		
<b>Upfront Payment &amp; Regulatory/Sales Milestone etc. related to alliance with AstraZeneca and US MRK *2</b>			
Upfront Payment related to alliance with US MRK	+26.6		

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

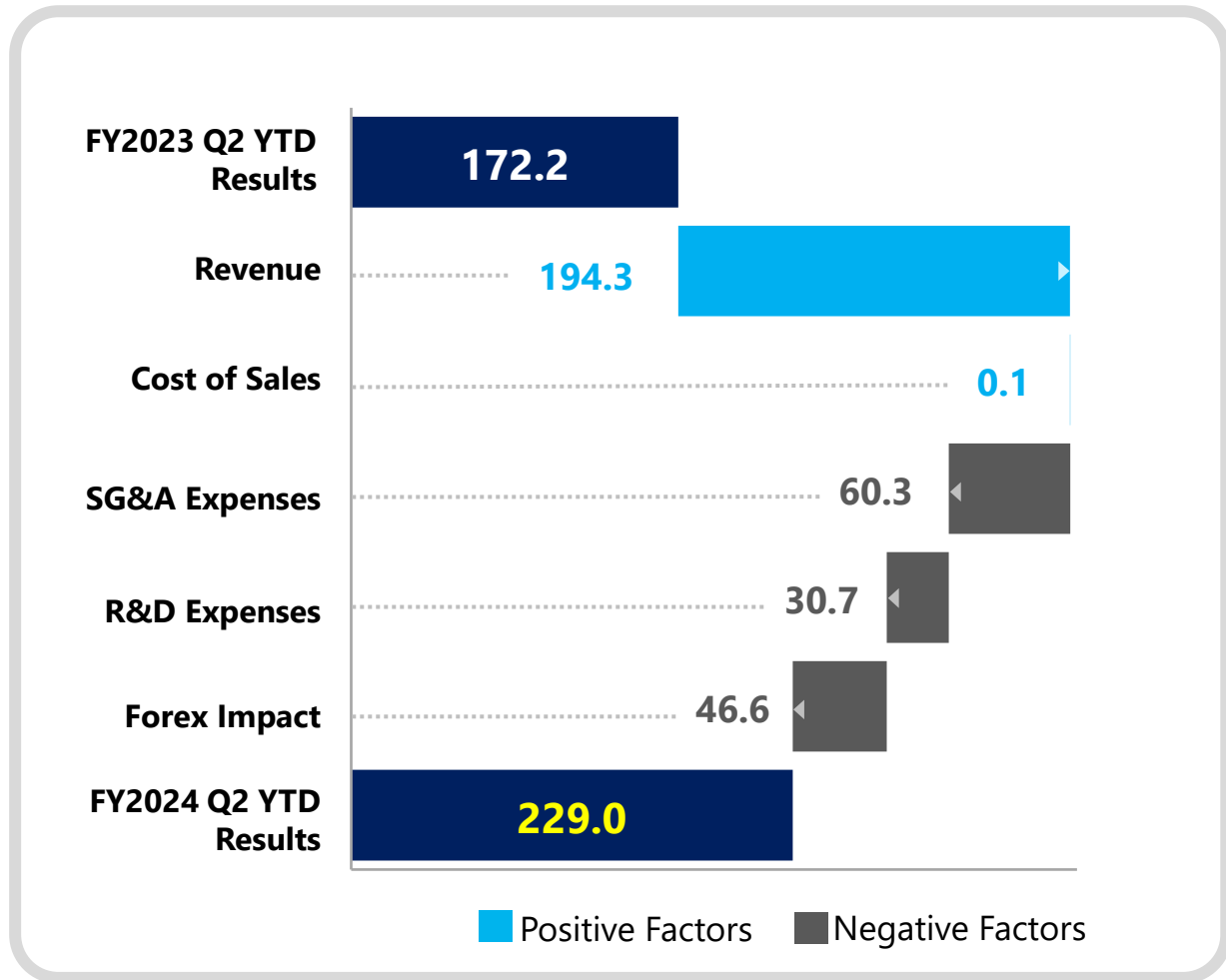
\*2 Merck & Co., Inc., Rahway, NJ, USA

\*3 Forex impact USD: +27.1, EUR: +16.3, ASCA: +2.3

# Core Operating Profit

**Increased by 56.8 Bn JPY** (Increased by 57.7 Bn JPY excl. forex impact)

(Bn JPY)



**Revenue** ..... +194.3

incl. forex impact of +39.6

**Cost of Sales** ..... -0.1

Improvement in cost of sales ratio by change in product mix

**SG&A Expenses** ..... +60.3

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

**R&D Expenses** ..... +30.7

Increase in 5DXd ADCs\* R&D investments

**Forex Impact** ..... +46.6 (Profit Decreased)

Cost of Sales ..... +11.1

SG&A Expenses ..... +22.4

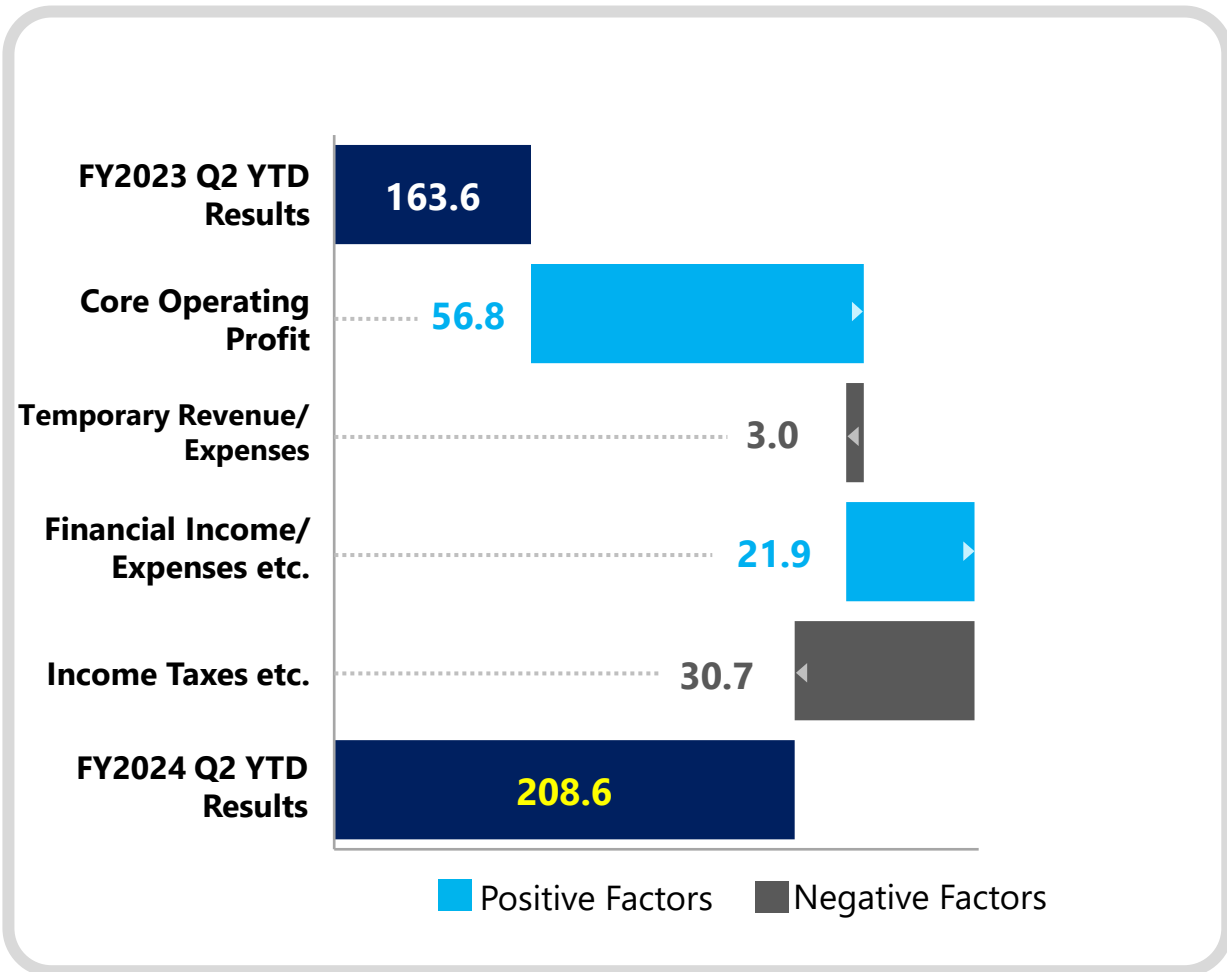
R&D Expenses ..... +13.1

\***ENHERTU®**: trastuzumab deruxtecan (International Nonproprietary Name: INN), T-DXd, DS-8201 (HER2-directed ADC), **DATROWAY®**: datopotamab deruxtecan (INN), Dato-DXd, 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 45.0 Bn JPY**

(Bn JPY)



Temporary Income/Expenses ..... -3.0 (Profit Decreased)

	FY2023 Q3 YTD Results	FY2024 Q3 YTD Results	YoY
Temporary Income	26.9 <sup>*1</sup>	21.5 <sup>*2</sup>	-5.4
Temporary Expenses	4.6	2.2	-2.4

\*1 Lump sum payment received from Novartis following the settlement of Plexxikon's patent infringement lawsuit (26.1)

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

Financial Income/Expenses etc. .... +21.9 (Profit Increased)

- Improvement in forex gains/losses ..... +16.3
- Increase in interest income ..... +4.5

Income Taxes etc. .... +30.7 (Profit Decreased)

	FY2023 Q3 YTD Results	FY2024 Q3 YTD Results	YoY
Profit before Tax	199.8	275.0	+75.2
Income Taxes etc.	35.7	66.4	+30.7
Tax rate	17.9%	24.1%	

# Agenda

① FY2024 Q3 Financial Results

② **FY2024 Forecast**

③ Business Update

④ R&D Update

⑤ Appendix





# Revision to the forecast


(Bn JPY)

	FY2024 Forecast (As of Oct.)	FY2024 Forecast (As of Jan.)	vs. Forecast
<b>Revenue</b>	<b>1,830.0</b>	<b>1,830.0</b>	-
<b>Cost of sales</b> *1	<b>410.0</b>	<b>410.0</b>	-
<b>SG&amp;A expenses</b> *1	<b>700.0</b>	<b>700.0</b>	-
DXd ADC profit share *2	<b>210.0</b>	<b>210.0</b>	-
Other SG&A expenses	<b>490.0</b>	<b>490.0</b>	-
<b>R&amp;D expenses</b> *1	<b>460.0</b>	<b>460.0</b>	-
<b>Core operating profit</b> *1	<b>260.0</b>	<b>260.0</b>	-
<b>Temporary income</b> *1	<b>20.0</b>	<b>20.0</b>	-
<b>Temporary expenses</b> *1	-	-	-
<b>Operating profit</b>	<b>280.0</b>	<b>280.0</b>	-
<b>Profit before tax</b>	<b>285.0</b>	<b>300.0</b>	<b>+15.0</b>
<b>Profit attributable to owners of the Company</b>	<b>225.0</b>	<b>240.0</b>	<b>+15.0</b>

## Revenue

 : Sales expansion of mainstay products including Enhertu, etc.  
 : Delays in approval and launch of Datroway for lung cancer, etc.

## Profit before tax, Profit attributable to owners of the Company

 : Expansion of financial income due to improvement in forex gains and losses, etc.

<b>Currency</b>	<b>USD/JPY</b>	<b>148.81</b>	<b>150.67</b>	<b>+1.86</b>
<b>Rate</b>	<b>EUR/JPY</b>	<b>160.47</b>	<b>162.37</b>	<b>+1.90</b>

Assumption of currency rate for Q4 : USD/JPY 145, EUR/JPY 155

\*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.

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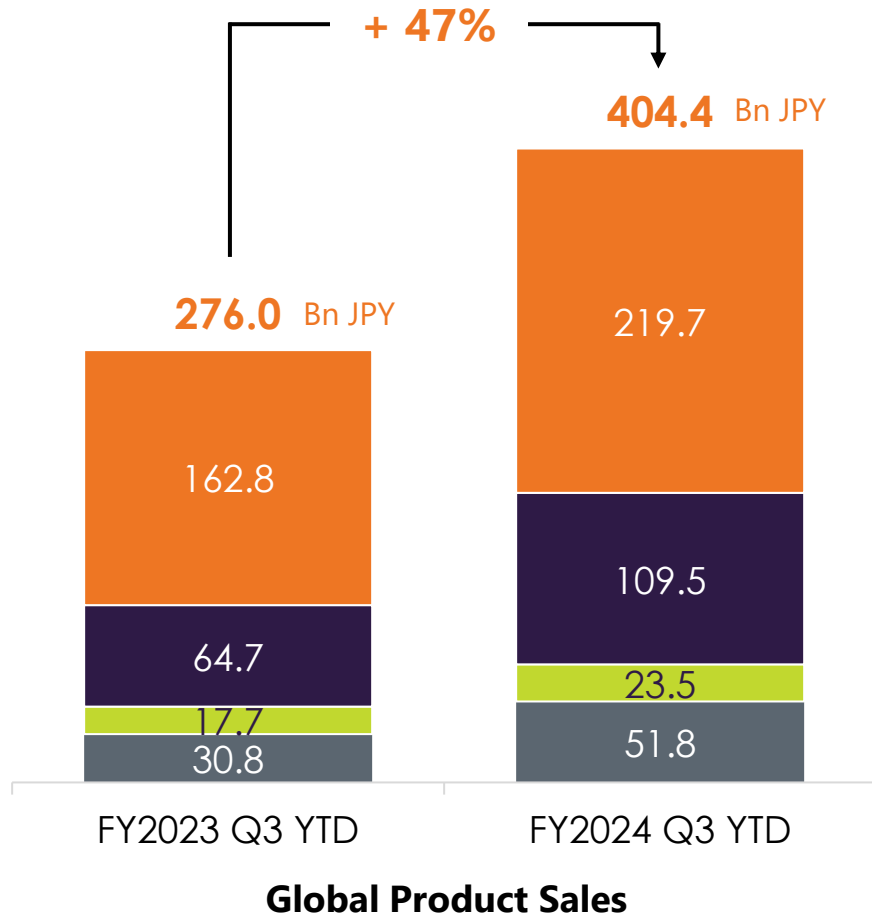
④ R&D Update

⑤ Appendix



## Global Product Sales

Q3 YTD Product Sales Result **404.4Bn JPY** (YoY **+128.4Bn JPY**) FY2024 Forecast **539.9Bn JPY** (vs Oct Forecast **+16.9Bn JPY**)



### ◆ Key Growth Factors (YoY YTD Results) and Key Updates

Achieved double-digit growth rate in all regions leading by HER2+ BC 2L and HER2 low BC (post-chemo)

- US (+35%)** Maintained No.1 new patient share in BC, GC, NSCLC indications; Expanded new patient uses in various tumor types in HER2+ solid tumors
  - HR+, HER2 low\* or HER2 ultralow\*\* BC (chemo naïve) approved in Jan
- EU (+69%)** Expanded sales leading by DE, FR, IT, ES; Achieved high new patient share in BC indications while maintaining No.1 position
  - Spain: **Began to be reimbursed for HER2 low BC (post-chemo) in Nov**
- Japan (+33%)** Maintained No.1 new patient share in all indications including early market adoption of HER2 low BC (post-chemo)
- ASCA (+68%)** Expanded sales mainly in Brazil and China; Achieved and maintained No.1 new patient share in HER2+ BC 2L in Brazil
  - China: HER2+ GC approved in Aug, **HER2m NSCLC approved in Oct, NRDL listed for HER2+ BC and HER2 low BC (post-chemo) in Jan**
  - Brazil: **HER2+solid tumors approved in Nov**

### ◆ NCCN Guideline Updates

Biliary Tract Cancers, NSCLC, Occult Primary, Pancreatic Adenocarcinoma, Colon Cancer, Rectal Cancer, Small Bowel Adenocarcinoma (April); Head and Neck Cancers, Vulvar Cancer, Bladder Cancer (May); **Ampullary Adenocarcinoma (Dec)**

## DATROWAY<sup>®</sup> (anti-TROP2 ADC) approved in Japan and the US

- Second product approved on our DXd ADC platform after ENHERTU<sup>®</sup>

### ◆ Approval acquisition date

- Japan : December 2024
- US : January 2025

### ◆ Indication

Unresectable or metastatic, hormone receptor (HR) positive, HER2 negative (IHC 0, IHC 1+, or IHC 2+/*ISH*-) breast cancer with prior endocrine-based therapy and chemotherapy

### ◆ Dosage and Administration

6 mg/kg per dose intravenously at 3-weeks intervals

### ◆ Product sales forecast for FY2024

400 Mn JPY



## In Dec. 2024, acquired the intellectual property rights for gatipotuzumab (anti-TA-MUC1 antibody) from Glycotope\*

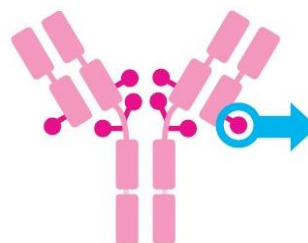
### ◆ Anti-TA-MUC1\*\* antibody

- Antibody of our sixth DXd ADC, DS-3939, currently under development by Daiichi Sankyo

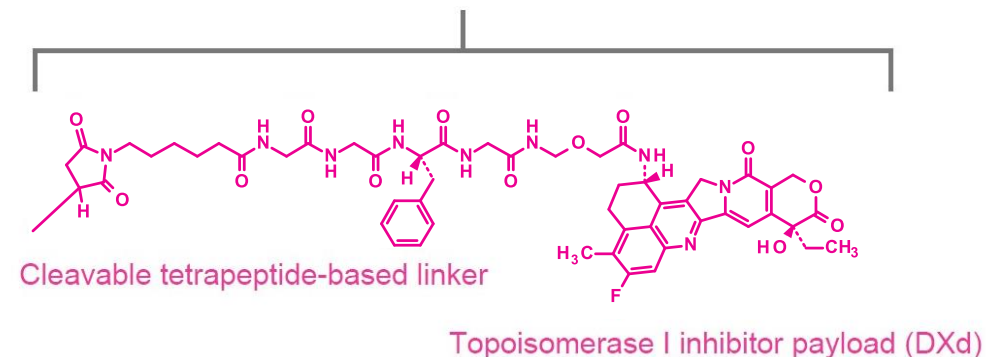
### ◆ Development status of DS-3939

- Being evaluated in a phase 1/2 clinical trial in patients with several types of solid tumors including non-small cell lung, breast, urothelial, ovarian, biliary tract and pancreatic ductal adenocarcinoma, etc.

Humanized anti-TA-MUC1  
IgG1 mAb



Deruxtecan



### ◆ Background and overview of the acquisition of intellectual property rights

- In 2018, in-licensed exclusive rights to develop and commercialize gatipotuzumab (anti-TA-MUC1 antibody) as an ADC from Glycotope.
- in Dec. 2024, acquired the intellectual property rights of gatipotuzumab considering the product potential of DS-3939.
- Consideration : 132.5 Mn USD (22.0 Bn JPY)
  - This consideration satisfies all potential milestone payments, as well as royalties as part of a 2018 licensing agreement.
  - After the sales approval of DS-3939, this consideration will be recorded as an expense over the anticipated exclusive sales period.

\* Glycotope GmbH (Berlin, Germany)

\*\*TA-MUC1 : A transmembrane glycoprotein overexpressed in broad range of tumors including non-small cell lung, breast, urothelial, ovarian, biliary tract and pancreatic ductal adenocarcinoma

# Information: Oncology Business Briefing

## Oncology Business Briefing

- ◆ **Time & Date :** **Wednesday, February 26, 2025, 7:30 - 9:00 AM (JST)**  
(Tuesday, February 25, 5:30 - 7:00 PM (EST))
- ◆ **Speakers:**
  - Sunao Manabe** Executive Chairperson & CEO
  - Ken Keller** Head of Oncology Business Unit
  - Dan Switzer** Head of US Oncology Business Division
  - Markus Kosch** Head of EU Oncology Business Division
- ◆ **Contents:** **Marketing strategy for ENHERTU® and DATROWAY®**
- ◆ **Format:** **Virtual (ZOOM)**



**Sunao Manabe**

*Executive Chairperson,  
CEO*



**Ken Keller**

*President and CEO,  
Daiichi Sankyo, Inc.  
Global Head of  
Oncology Business*



**Dan Switzer**

*Head of US Oncology  
Business Division*



**Markus Kosch**

*Head of EU Oncology  
Business Division*

# Agenda

① FY2024 Q3 Financial Results

② FY2024 Forecast

③ Business Update

**④ R&D Update**

⑤ Appendix



**5DXd ADCs Update**

Next Wave Update

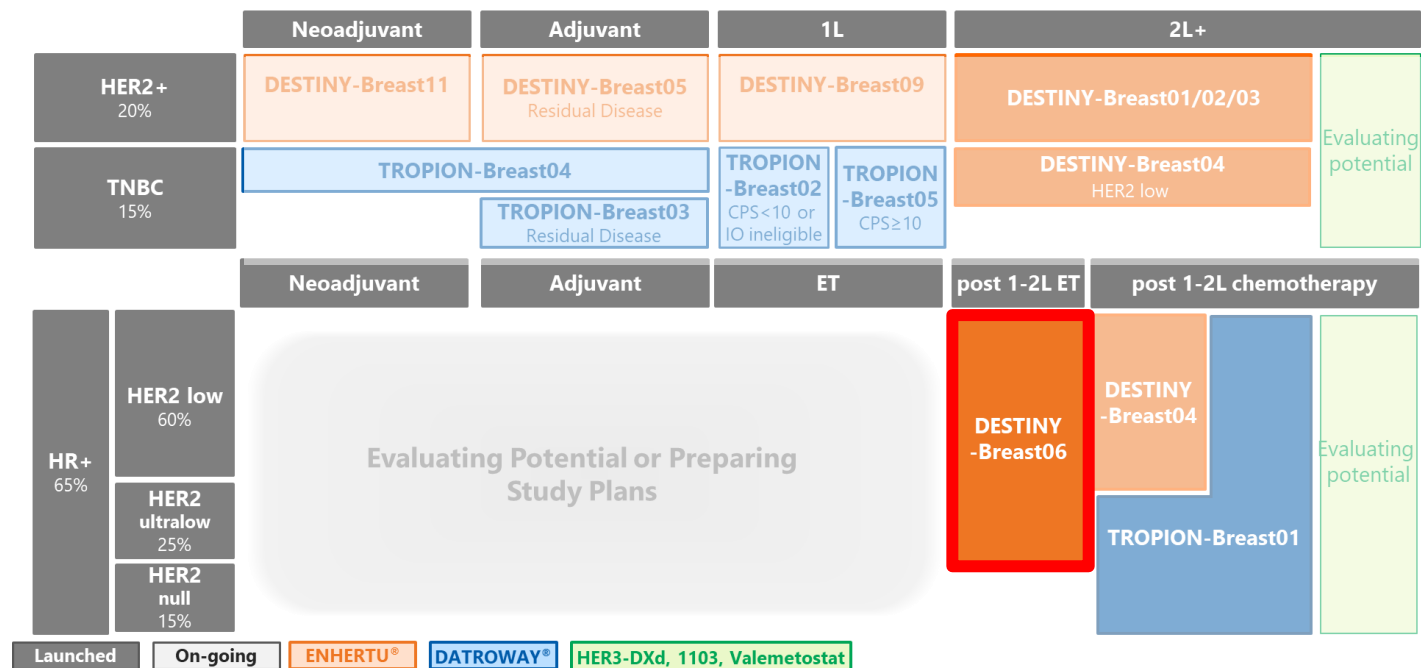
News Flow

## DESTINY-Breast06 brings ENHERTU® benefit earlier and broader

- Approved in the US for the treatment of patients with HER2 low (IHC 1+ or IHC 2+/ISH-) or HER2 ultralow (IHC 0 with membrane staining) BC, who progressed on one or more ET in metastatic setting on Jan 27, 2025
- Granted Breakthrough Therapy Designation and Priority Review

### Regulatory status in other countries and regions

- Aug 2024: Filing accepted in EU
  - Oct 2024: Filing accepted in Japan
- Regulatory review is ongoing and approval is anticipated in FY2025 H1 in Japan and EU



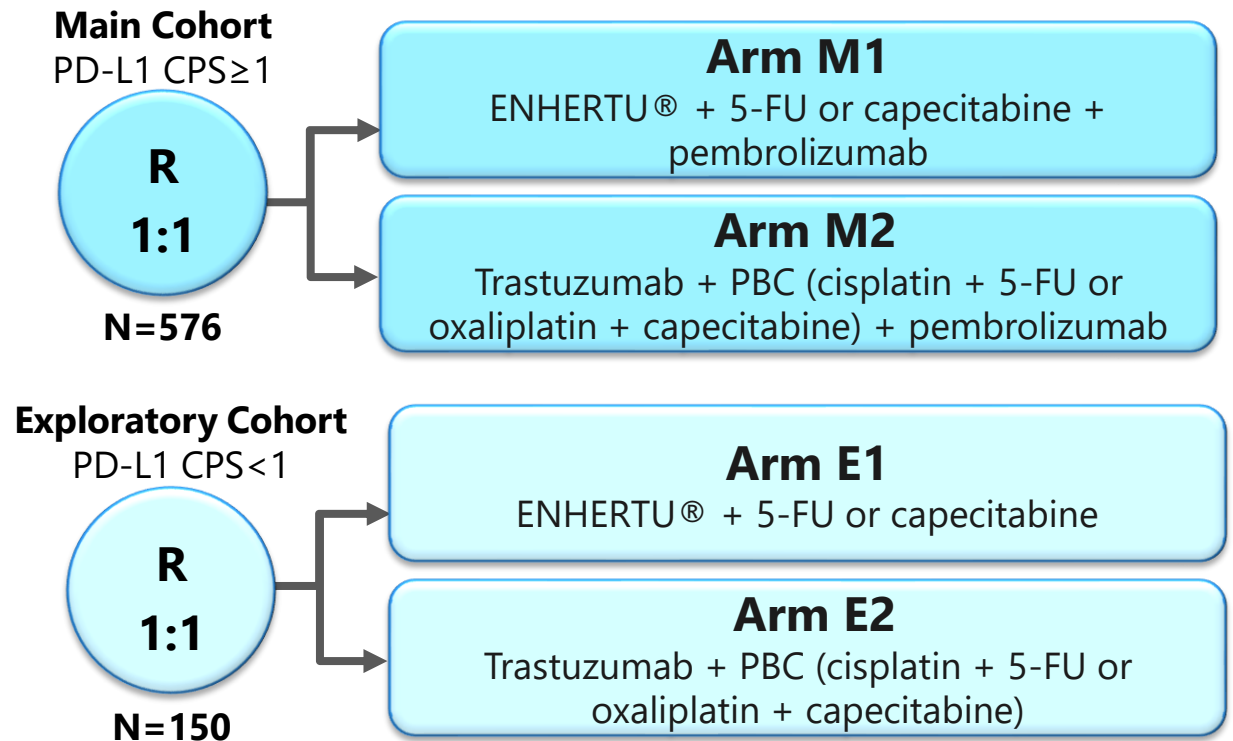
## Expand into earlier treatment lines by combining with current SOC to maximize patient outcomes

### DESTINY-Gastric05 Study Design

#### Eligible patient

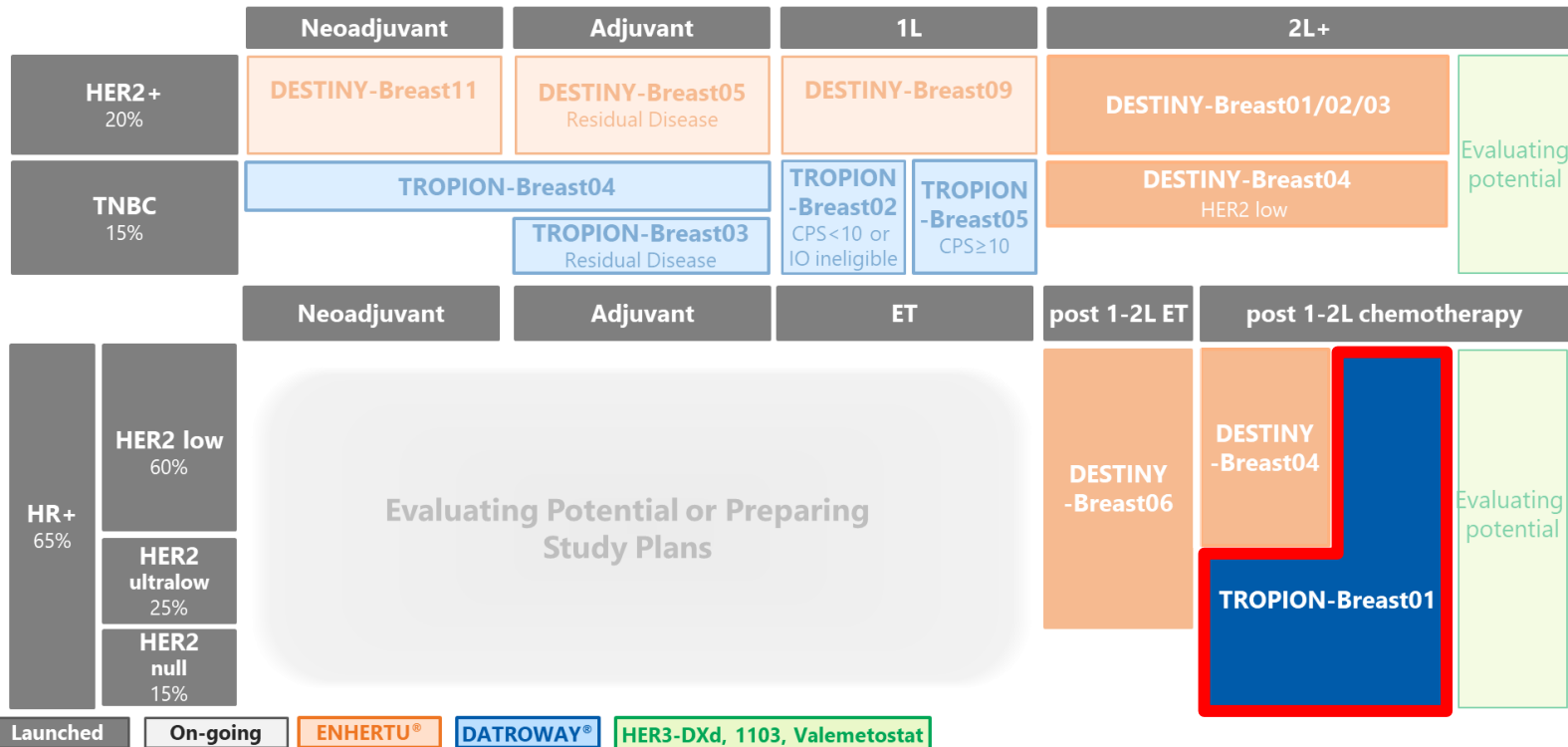
- Locally advanced or metastatic GC or GEJ adenocarcinoma
- No systemic therapy or relapse more than 6 months after the last dose of perioperative or neoadjuvant therapy
- HER2 IHC3+ or IHC2+/ISH+

- Aim to provide best in class care for patients with 1L HER2+ GC
- Plan to start in **FY2024 Q4**
- Plan to start ARTEMIDE-Gastric01 study (NCT06764875) which evaluates the combination of ENHERTU® and rilvegostomig in 1L GC



Primary endpoint: PFS (BICR)  
Key secondary endpoint: OS

## Approved for HR+/HER2- metastatic BC as the first indication in the US and Japan



### TROPION-Breast01 Study

- ✓ Inoperable or metastatic HR positive, HER2 low or negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer previously treated with ET and at least one systemic therapy
- ✓ Primary endpoint: PFS and/or OS

- Approved on Dec 27, 2024 in Japan
- Approved on Jan 17, 2025 in the US

## Target indication changed from NSQ NSCLC to **EGFR mutated NSCLC** in the US

### US

- Nov 2024: Application for 2/3L NSQ NSCLC based on TROPION-Lung01 withdrawn
- Nov 2024: New application\* submitted for accelerated approval for the treatment of patients with EGFR mutated NSCLC who have received prior systemic therapies, including an EGFR-directed therapy based on TROPION-Lung05
- Dec 2024: Breakthrough Therapy Designation granted for the treatment of patients with EGFR mutated NSCLC with disease progression on or after treatment with an EGFR TKI and PBD
- Jan 2025: Filing accepted and Priority Review granted (PDUFA date: Jul 12, 2025)

### EU

- Dec 2024: Application for 2/3L NSQ NSCLC based on TROPION-Lung01 withdrawn

\* This application was supported by data from TROPION-Lung01 and TROPION-PanTumor01

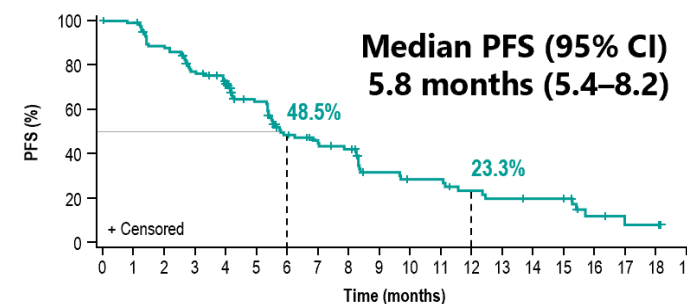
NSQ: non squamous, NSCLC: non-small cell lung cancer, OS: overall survival, PBC: platinum-based chemotherapy, PDUFA: prescription drug user fee act, TKI: tyrosine kinase inhibitor

## DATROWAY<sup>®</sup> is a potential treatment option for patients with EGFRm NSCLC in the 2L and later settings

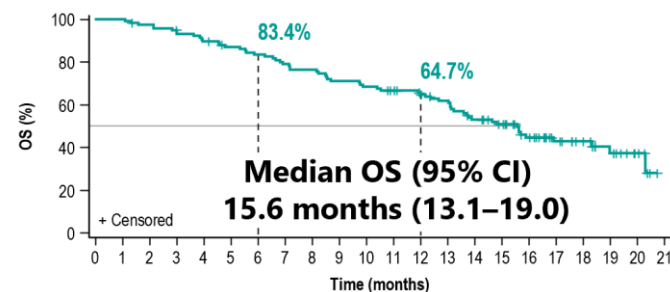
### Efficacy

Response	EGFRm Pool (N=117)	Prior Osimertinib (N=96)
<b>Confirmed ORR<sup>a</sup>, n (%)</b> [95% CI]	50 (42.7) [33.6–52.2]	43 (44.8) [34.6–55.3]
<b>BOR, n (%)</b>		
CR	5 (4.3)	4 (4.2)
PR	45 (38.5)	39 (40.6)
SD	48 (41.0)	37 (38.5)
Non-CR/Non-PD	3 (2.6)	2 (2.1)
PD	12 (10.3)	10 (10.4)
NE	4 (3.4)	4 (4.2)
<b>Median DOR, months (95% CI)</b>	<b>7.0 (4.2–9.8)</b>	<b>6.9 (4.2–9.8)</b>
<b>DCR<sup>b</sup>, n (%)</b> [95% CI]	101 (86.3) [78.7–92.0]	82 (85.4) [76.7–91.8]
<b>Median PFS, months (95% CI)</b>	<b>5.8 (5.4–8.2)</b>	<b>5.7 (5.4–7.9)</b>
<b>Median OS, months (95% CI)</b>	<b>15.6 (13.1–19.0)</b>	<b>14.7 (13.0–18.3)</b>

### PFS and OS in the EGFRm Pool (N=117)



No. at risk: 117 115 101 86 77 61 42 34 31 20 17 17 13 11 10 10 4 2 2 0



No. at risk: 117 117 113 109 103 98 94 89 86 80 77 73 68 63 53 47 35 24 19 12 6 0

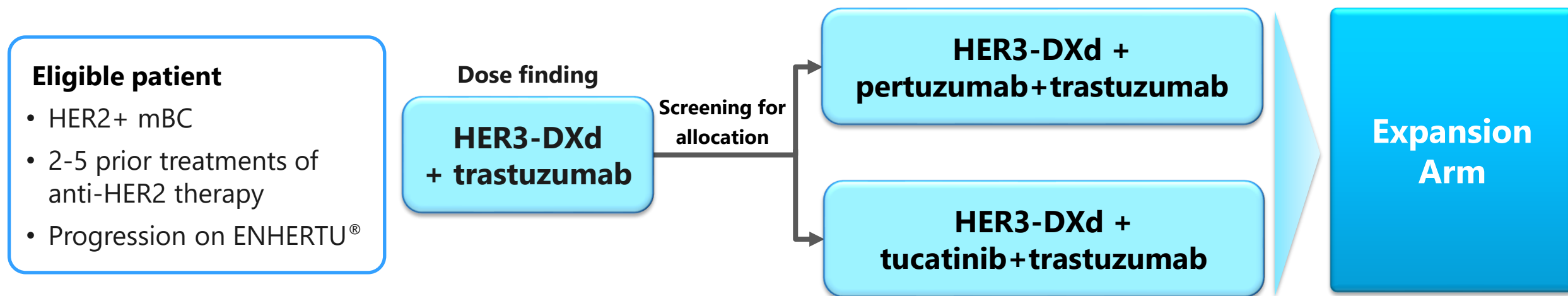
- DATROWAY<sup>®</sup> demonstrated robust clinical activity in patients with EGFRm NSCLC with ORR 42.7%, mDOR 7.0 months, mPFS 5.8 months and mOS 15.6 months
- Outcomes for patients with prior osimertinib treatment were similar to the overall pooled population
- Low rates of serious TRAEs or TRAEs leading to treatment discontinuations
- Grade ≥2 stomatitis/oral mucositis seen in ~1/3 patients was effectively managed with dose reductions/delay
- No grade 4 or 5 ILD events

<sup>a</sup>CR+PR; <sup>b</sup>CR+PR+SD or non-CR/non-PD.

BICR: blinded independent central review, BOR: best overall response, CI: confidence interval, CR: complete response, DCR: disease control rate, DOR: duration of response, ESMO: European Society for Medical Oncology, ILD: interstitial lung disease, mDOR: median duration of response, mOS: median overall survival, mPFS: median progression-free survival, NE: not evaluable, NSCLC: non-small cell lung cancer, ORR: overall response rate, OS: overall survival, PFS: progression-free survival, PD: progressive disease, PR: partial response, SD: stable disease, TRAE: treatment-related adverse event

## Ph1b/2 dose-finding combination study for post ENHERTU<sup>®</sup> progression in HER2+ unresectable locally advanced BC or mBC

### HERTHENA-Breast01 Study Design



Primary objectives: safety

Secondary objectives: preliminary efficacy, PK, biomarkers

Exploratory objectives: ORR, DOR, PFS, CBR, OS, ADA, Biomarker (HER3 expression)

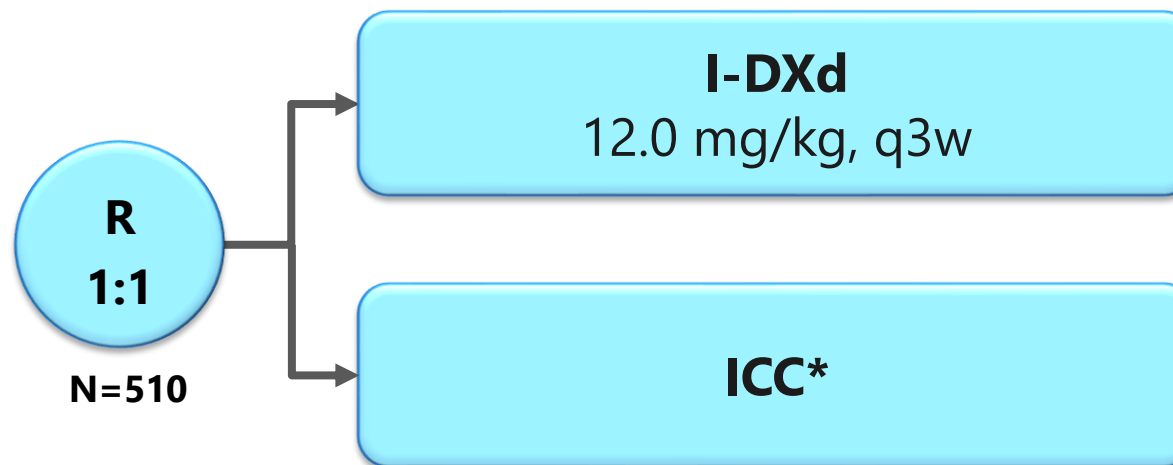
- Ph1 study has shown efficacy of monotherapy HER3-DXd in patients (n=14) with HER3+/HER2+ mBC without prior ENHERTU<sup>®</sup> treatment (ASCO 2022)
  - ✓ ORR 42.9%, mPFS 11.0 mo
- Preliminary data confirmed the safety of HER3-DXd monotherapy after ENHERTU<sup>®</sup> treatment
- Plan to start in **FY2024 Q4**

## New Ph3 study of I-DXd in pretreated advanced or metastatic esophageal squamous cell carcinoma (ESCC)

### IDeate-Esophageal01 Study Design

#### Eligible patient

- Unresectable advanced or metastatic ESCC
- Progression after a platinum-containing and an ICI treatment
- No more than 1 prior line of systemic therapy for unresectable advanced or metastatic ESCC



Primary endpoint: OS

Key secondary endpoint: PFS, ORR

ICC\*: paclitaxel, docetaxel, irinotecan

- B7-H3 is highly expressed in ESCC, and overexpression is associated with a poor prognosis
- Observed encouraging signals in heavily pre-treated population in Ph1/2 study (ESMO 2023)
  - ✓ cORR: 21.4% (6/28 95% CI 8.3-41.0), mPFS: 2.8 mo (2.1-5.5), mOS: 7.0 mo (4.8-12.2), No. of prior treatments, median: 4 (1-7)
- Plan to start in FY2025 H1

## Initiated a signal-seeking study in solid tumors with various CDH6 expression levels

### REJOICE-PanTumor01 Study Design

#### Eligible patient

- Locally advanced or metastatic solid tumors
- Have at least 1 lesion, not previously irradiated
- Disease progression after having received  $\geq 1$  line of therapy (For ccRCC, previously treated more than 3 prior systemic regimens)

Endometrial cancer

Cervical cancer

Non-high-grade serous ovarian cancer

Urothelial cancer

Clear cell renal cell carcinoma (ccRCC)

#### Endpoints

##### Primary (except ccRCC):

ORR, safety

##### Primary (ccRCC only):

DCR, safety

##### Secondary:

PFS, DOR, TTR, ORR, DCR, PK, ADA

N= 200

- Study started in Jan 2025
- Preliminary efficacy and safety of R-DXd monotherapy in ES-SCLC will be evaluated in KEYNOTE-B98 study separately

## ENHERTU®

- Plan to develop ENHERTU® **subcutaneous injection** in collaboration with Alteogen Inc., Korea

## DATROWAY®

- Jan 2025: **TROPION-Lung12** Ph3 combination study with rilvegostomig for adjuvant therapy in NSCLC with ctDNA-positive or at least one high-risk pathological feature started

## HER3-DXd

- Nov 2024: **MK-1022-011** Ph1b/2 study for CRC, BTC and HCC 2L+ started

## I-DXd

- Plan to start **KEYMAKER-U06 substudy 06E** (Ph1/2) for ESCC 1L with pembrolizumab
- Plan to start **MK-6070-002** Ph1b/2 combination study with MK-6070 for relapsed/refractory ES-SCLC

## I-DXd/R-DXd

- Plan to start **KEYMAKER-U01 Ph2 01H and 01I substudies for NSQ and SQ NSCLC** 2L respectively to evaluate efficacy and safety of I-DXd and R-DXd monotherapy comparing to docetaxel

5DXd ADCs Update

**Next Wave Update**

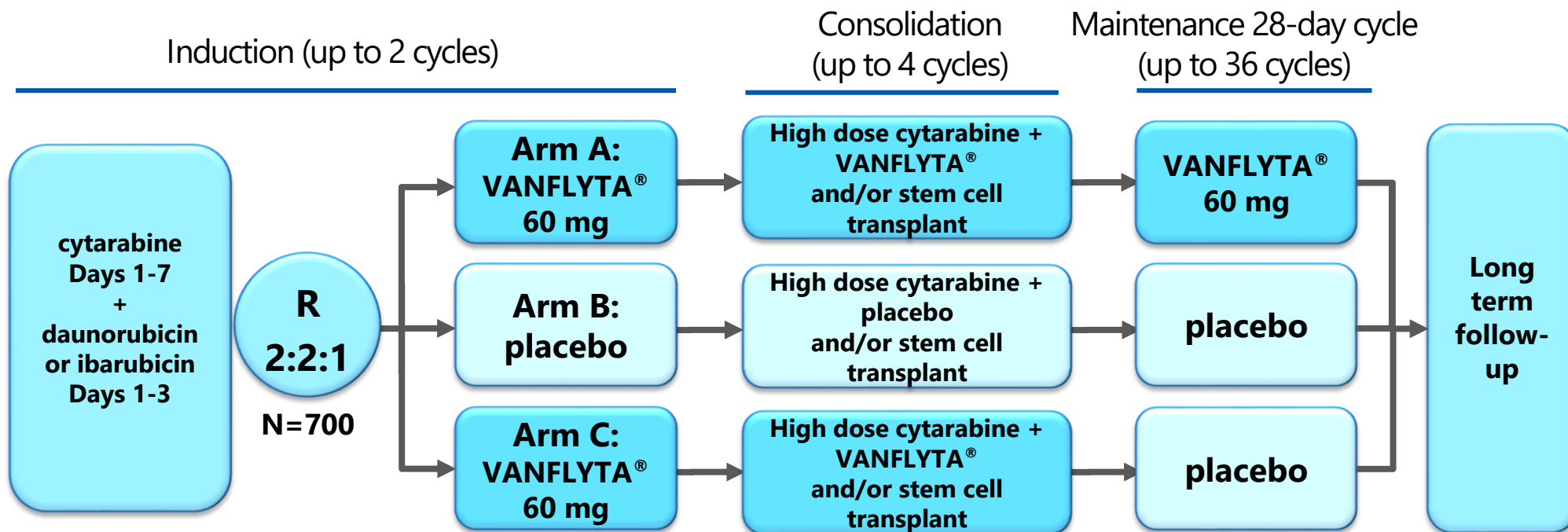
News Flow

## Started QuANTUM-Wild Ph3 study for *FLT3*-ITD negative AML based on data from QUIWI study

### QuANTUM-Wild Study Design

#### Eligible patients

- Newly diagnosed AML
- Without *FLT3*-ITD mutations



- VANFLYTA® + chemotherapy demonstrated preliminary efficacy in patients with newly diagnosed *FLT3*-ITD negative AML compared to placebo+ chemotherapy in the interim analysis of QUIWI study (EHA 2023)
- Started the study in Dec 2024 to expand indication for *FLT3*-ITD negative AML based on QUIWI study results

- Primary endpoint
  - OS
- Secondary endpoint
  - EFS, DCR, RFS, CR rate etc.

## Ph1b/2 signal seeking combination study with pembrolizumab in NSCLC 1L

### Ph1b/2 Study Design

#### Eligible patients

- PD-L1 TPS  $\geq$  50% IHC
- Non-AGA
- Unresectable or metastatic NSCLC
- Anti-PD-1/PD-L1 checkpoint naïve
- Sample size: 137

#### Ph1b dose escalation

**EZHARMIA<sup>®</sup>  
+ pembrolizumab**

**Ph1b**  
Primary objectives: RP2D, safety

#### Ph2

**EZHARMIA<sup>®</sup>  
+ pembrolizumab**

**pembrolizumab**

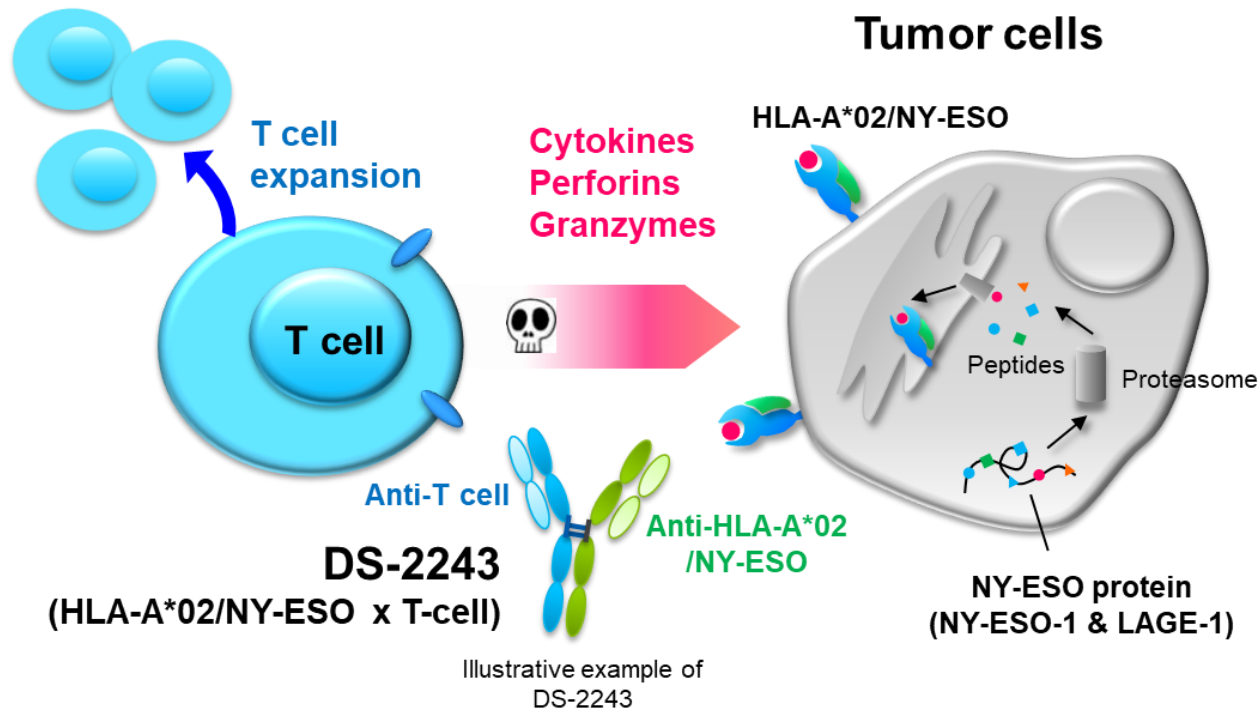
**R  
1:1**

**Ph2**  
Primary objectives: PFS  
Secondary objectives: ORR, DOR, DCR, OS, Safety

- Preclinical rationale supports EZHARMIA<sup>®</sup>-IO combination across various tumor types, including NSCLC
  - ✓ EZH2 inhibition or knock down increase responses *in-vivo* to PD-1/PD-L1 inhibitors in murine models of NSCLC (DuCote T, et al. CRC 2024; Qiu F, et al. J Cancer 2022)
- Started in Oct 2024

## A Potential First-in-Class Bispecific T-cell Engager (Bi-TCE) Targeting HLA-A\*02/NY-ESO Tumors

### Mode of Action



- **Cutting-Edge Bi-TCE:** Engineered to selectively engage both tumor antigens and T-cells, driving a targeted and potent immune response
- **Tumor-Specific Targeting:** Precise targeting through the HLA-A\*02/NY-ESO complex mediated by NY-ESO, a highly tumor-specific antigen. NY-ESO is only expressed in the testis in normal tissue, where it is present without HLA-A molecules
- **Broad Applicability:** High/moderate frequency of NY-ESO expression observed in Synovial Sarcoma, Myxoid/Round Cell Liposarcoma, NSCLC, UC etc.
- **Promising Efficacy:** Exhibits robust anti-tumor activity and significant combination therapy potential in preclinical studies

5DXd ADCs Update

Next Wave Update

**News Flow**

## Planned major data disclosures

### ESMO Virtual (Feb 12, 2025 at 18:30 CET)

**DATROWAY®**      **TROPION-Breast01:**  
**HR+ /HER2 low BC, 2/3L, Ph3**  
 • Final OS

## Regulatory decisions

**ENHERTU®**      **DESTINY-Breast06:**  
**HR+ /HER2 low or HER2 ultralow, chemo naïve, Ph3**  
 • JP/EU: FY2025 H1

**DATROWAY®**      **TROPION-Lung05\*<sup>#</sup>: EGFR mutated NSCLC with prior systemic therapies, including an EGFR-directed therapy**  
 • US: FY2025 H1  
<sup>#</sup>supported by data from TROPION-Lung01, TROPION-PanTumor01  
**TROPION-Breast01: HR+ and HER2 low or negative BC, 2/3L**  
 • EU: FY2024 Q4

**DAICHIRONA®**      COVID-19 mRNA vaccine (mutant strain),  
 Children aged 5 to 11 years  
 • JP: FY2024 Q4

## Key data readouts

**ENHERTU®**      DESTINY-Breast11\*: HER2+ BC, neoadjuvant, Ph3  
 • FY2025 H1

DESTINY-Breast05\*: HER2+ BC, Adjuvant, Ph3  
 • FY2025 H2

DESTINY-Breast09\*: HER2+ BC, 1L, Ph3  
 • FY2025 H1

DESTINY-Gastric04\*: HER2+ GC, 2L, Ph3  
 • FY2025 H1

DESTINY-Lung04\*: HER2 mutant NSCLC, 1L, Ph3  
 • FY2025 H1

**DATROWAY®**      TROPION-Breast02\*:  
 PD-1/PD-L1 ineligible TNBC, 1L, Ph3  
 • FY2025 H1  
 AVANZAR\*:  
 TROP2+ NSCLC, 1L, Ph3  
 • CY2025 H2

**I-DXd**      IDeate-Lung01:  
 ES-SCLC, 3L, Ph2  
 • FY2025 H1

BC: breast cancer, HR: hormone receptor, ESMO: European Society for Medical Oncology, ES-SCLC: extensive-stage small cell lung cancer, NSCLC: non-small cell lung cancer, OS: overall survival, TNBC: triple negative breast cancer

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

※ Timeline for “Planned regulatory filing” indicates expected filing acceptance date

\*: event-driven study

# Agenda

① FY2024 Q3 Financial Results

② FY2024 Forecast

③ Business Update

④ R&D Update

⑤ **Appendix**



# Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2023 Q3 YTD Results	FY2024 Q3 YTD Results	YoY	
Japan Business	412.3	385.7	-26.6	
Daiichi Sankyo Healthcare	59.9	67.4	+7.5	
Oncolgy Business	233.0	337.2	+104.2	
Enhertu	227.5	329.1	+101.6	
Turalio	4.1	5.1	+1.0	
Vanflyta	1.3	2.9	+1.6	
American Regent	152.0	169.9	+17.9	
Injectafer	38.0	41.6	+3.5	
Venofer	45.2	51.0	+5.8	
GE injectables	59.1	67.9	+8.7	
EU Specialty Business	137.6	178.3	+40.7	
Lixiana	107.3	135.6	+28.3	
Nilemdo/Nustendi	12.1	26.5	+14.4	
Olmesartan	14.5	13.9	-0.6	
ASCA (Asia, South and Central America) Business	131.8	155.0	+23.2	
Currency Rate	USD/JPY	143.29	152.56	+9.27
	EUR/JPY	155.28	164.82	+9.54

# Revenue: Major Products in Japan

(Bn JPY)

		FY2023 Q3 YTD Results	FY2024 Q3 YTD Results	YoY
<b>Lixiana</b>	anticoagulant	<b>89.5</b>	<b>103.2</b>	<b>+13.7</b>
<b>Tarlige</b>	pain treatment	<b>35.4</b>	<b>42.9</b>	<b>+7.6</b>
<b>Pralia</b>	Treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	<b>33.3</b>	<b>32.7</b>	<b>-0.6</b>
<b>Vimpat</b>	anti-epileptic agent	<b>20.0</b>	<b>23.7</b>	<b>+3.7</b>
<b>Enhertu</b>	anti-cancer agent (HER2-directed antibody drug conjugate)	<b>17.7</b>	<b>23.5</b>	<b>+5.8</b>
<b>Ranmark</b>	treatment for bone complications caused by bone metastases from tumors	<b>15.8</b>	<b>15.7</b>	<b>-0.1</b>
<b>Efient</b>	antiplatelet agent	<b>19.7</b>	<b>24.2</b>	<b>+4.5</b>
<b>Canalia</b>	type 2 diabetes mellitus treatment	<b>12.5</b>	<b>12.3</b>	<b>-0.2</b>
<b>Loxonin</b>	anti-inflammatory analgesic	<b>12.5</b>	<b>10.1</b>	<b>-2.3</b>
<b>Inavir</b>	anti-influenza treatment	<b>13.6</b>	<b>13.6</b>	<b>+0.1</b>
<b>Minnebro</b>	antihypertensive agent	<b>6.3</b>	<b>7.4</b>	<b>+1.1</b>

# 5DXd ADCs Revenue (incl. Forex Impact)

(Unit: Bn JPY)

	FY2024 Q3 YTD Results	YoY	FY2024 Forecast (as of Jan)	vs Oct Forecast
<b>ENHERTU</b>	<b>421.6</b>	<b>+127.1</b>	<b>628.8</b>	<b>+17.0</b>
Product Sales	404.4	+128.4	539.9	+16.9
Upfront and Milestone Payments, etc.	17.1	-1.3	88.9	+0.1
<b>DATROWAY</b>	<b>4.8</b>	<b>-</b>	<b>6.8</b>	<b>-11.0</b>
Product Sales	-	-	0.4	-5.4
Upfront and Milestone Payments, etc.	4.8	-	6.4	-5.6
<b>HER3-DXd</b>	<b>15.7</b>	<b>+14.1</b>	<b>19.8</b>	<b>-</b>
Product Sales	-	-	-	-
Upfront and Milestone Payments, etc.	15.7	+14.1	19.8	-
<b>I-DXd</b>	<b>11.6</b>	<b>+8.6</b>	<b>15.3</b>	<b>-</b>
Upfront and Milestone Payments, etc.	11.6	+8.6	15.3	-
<b>DS-6000 (R-DXd)</b>	<b>5.1</b>	<b>+3.9</b>	<b>6.7</b>	<b>-</b>
Upfront and Milestone Payments, etc.	5.1	+3.9	6.7	-
<b>5DXd ADCs Total</b>	<b>458.7</b>	<b>+153.8</b>	<b>677.4</b>	<b>+6.0</b>

# 5DXd ADCs Upfront and Milestone Payments

(Unit: Bn JPY)

Asset	Item	FY2024 Q3 Results	YoY	FY2024 Forecast (As of Jan)	vs Oct Forecast	Total Consideration (as of Dec 2024)
ENHERTU®	Upfront Payment	7.7	+0.1	10.2	-	149.0
	Regulatory Milestones	8.6	-1.4	21.3	+0.1	141.6
	Quid Related Payment	0.9	+0.0	1.2	-	17.2
	Sales Milestone	-	-	56.2	-	42.8
DATROWAY®	Upfront Payment	4.8	-	6.4	-	115.9
	Regulatory Milestones	-	-	-	-5.6	-
AZ Alliance Total		<b>21.9</b>	<b>-1.3</b>	<b>95.3</b>	<b>-5.5</b>	<b>466.5</b>
HER3-DXd	Upfront Payment	15.1	+13.5	19.0	-	224.9
	Satisfaction of Quid Rights *	0.6	+0.6	0.7	-	7.3
I-DXd	Upfront Payment	11.0	+8.1	14.7	-	225.4
	Satisfaction of Quid Rights	0.6	+0.6	0.7	-	7.3
R-DXd	Upfront Payment	4.6	+3.4	6.2	-	112.7
	Satisfaction of Quid Rights	0.5	+0.5	0.6	-	7.3
US Merck Alliance Total		<b>32.3</b>	<b>+26.6</b>	<b>41.8</b>	-	<b>584.8</b>

\* "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®)

Project	Target indication [phase, study name]	FY2024		FY2025
		H1	H2	
ENHERTU®	• HER2+, adjuvant* [Ph3, DESTINY-Breast05]			• TLR anticipated
	• HR+/HER2 low or HER2 ultralow, chemo naive [Ph3, DESTINY-Breast06]	• Filing accepted (EU)	• Filing accepted (JP) • <b>Approved (US)</b>	• <b>Regulatory decision anticipated (JP/EU)</b>
	• HER2+, 1L [Ph3, DESTINY-Breast09]			• TLR anticipated
	• HER2+, neoadjuvant [Ph3, DESTINY-Breast11]			• <b>TLR anticipated</b>
	• HER2+, 2L [Ph3, DESTINY-Gastric04]			• TLR anticipated
	• <b>HER2+, 1L, pembrolizumab and chemo combo [Ph3, DESTINY-Gastric05]</b>		• <b>Study start planned</b>	
	• <b>HER2+and PD-L1 CPS≥1, 1L, rilvegostomig and chemo combo [Ph3, ARTEMIDE-Gastric01]</b>		• <b>Study start planned</b>	
	• HER2+, 3L+ [Ph2, DESTINY-Gastric06]	• Approved (CN)		
	• HER2 mutation, 2L+ [Ph2, DESTINY-Lung05]		• Approved (CN) **	
	• HER2 mutation, 1L [Ph3, DESTINY-Lung04]			• TLR anticipated
BTC	• HER2 expressing, 1L, mono or rilvegostomig combo [Ph3, DESTINY-BTC01]	• Study started		
Other tumors	• HER2 expressing tumors [Ph2, DESTINY-PanTumor02]	• Approved (US)		

**Bold: update from FY2024 Q2**

BC: breast cancer, BTC: biliary tract cancer, GC: gastric cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, TLR: Top Line Results

\*: Adjuvant therapy for HER2 positive breast cancer patients with residual invasive disease following neoadjuvant therapy \*\*: Approved based on the results of DESTINY-Lung02 and DESTINY-Lung05

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

# Major R&D Milestones (DATROWAY®)

Project	Target indication [phase, study name]	FY2024		FY2025
		H1	H2	
DATROWAY®	<ul style="list-style-type: none"> <li>• non-squamous, 2L+ [Ph3, TROPION-Lung01]</li> </ul>		<ul style="list-style-type: none"> <li>• <b>Regulatory submission withdrawn (US/EU)</b></li> </ul>	
	<ul style="list-style-type: none"> <li>• <b>EGFR mutated, previously treated (incl. EGFR directed therapy) [Ph2, TROPION-Lung05*]</b></li> </ul>		<ul style="list-style-type: none"> <li>• <b>Filing accepted (US)</b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Regulatory decision anticipated (US)</b></li> </ul>
	<ul style="list-style-type: none"> <li>• non-squamous, PD-L1 high, rilvegostomig combo, 1L, [Ph3, TROPION-Lung10]</li> </ul>	<ul style="list-style-type: none"> <li>• Study started</li> </ul>		
	<ul style="list-style-type: none"> <li>• Stage I adenocarcinoma NSCLC, mono or rilvegostomig combo [Ph3, TROPION-Lung12]</li> </ul>		<ul style="list-style-type: none"> <li>• <b>Study started</b></li> </ul>	
	<ul style="list-style-type: none"> <li>• EGFR mutated, osimertinib combo, 1L, [Ph3, TROPION-Lung14]</li> </ul>	<ul style="list-style-type: none"> <li>• Study started</li> </ul>		
	<ul style="list-style-type: none"> <li>• EGFR mutated, osimertinib combo, 2L+ [Ph3, TROPION-Lung15]</li> </ul>		<ul style="list-style-type: none"> <li>• Study started</li> </ul>	
	<ul style="list-style-type: none"> <li>• w/o AGA, durvalumab combo, 1L, [Ph3, AVANZAR]</li> </ul>			<ul style="list-style-type: none"> <li>• TLR anticipated</li> </ul>
	<ul style="list-style-type: none"> <li>• HR+ and HER2 low or negative, 2/3L [Ph3, TROPION-Breast01]</li> </ul>		<ul style="list-style-type: none"> <li>• <b>Approved (JP/US)</b></li> <li>• <b>Regulatory decision anticipated (EU)</b></li> </ul>	
<ul style="list-style-type: none"> <li>• TNBC, PD-1/PD-L1 ineligible, 1L [Ph3, TROPION-Breast02]</li> </ul>			<ul style="list-style-type: none"> <li>• <b>TLR anticipated</b></li> </ul>	

**Bold: update from FY2024 Q2**

AGA: actionable genomic alterations, BC: breast cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, TLR: top line results, TNBC: triple-negative breast cancer

\* Supported by data from TROPION-Lung01, TROPION-PanTumor01

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

# Major R&D Milestones (HER3-DXd, I-DXd, R-DXd)

Project	Target indication [phase, study name]	FY2024		FY2025
		H1	H2	
HER3-DXd	NSCLC	• EGFR mutated, 3L [Ph2, HERTHENA-Lung01]	• CRL received (US)	
		• EGFR mutated, 2L [Ph3, HERTHENA-Lung02]	• TLR obtained	
	<b>BC</b>	• <b>HER2+, 2L+</b> <b>[Ph1b/2, HERTHENA-Breast01]</b>		• <b>Study start planned</b>
	CRC, BTC, HCC	• 2L+ [Ph1/2, MK-1022-011]		• <b>Study started</b>
I-DXd		• 2L+ [Dose optimization, Ph2, IDeate-Lung01]		• TLR anticipated
	SCLC	• 2L [Ph3, IDeate-Lung02]	• Study started	
		• 1L [Ph1b/2, IDeate-Lung03]	• Study started	
	<b>ESCC</b>	• <b>2L [Ph3, IDeate-Esophageal01]</b>		• <b>Study start planned</b>
	Other tumors	• Endometrial cancer, SCCHN, etc., 2L+ [Ph1b/2, IDeate-PanTumor02]	• Study started	
R-DXd	OVC	• Platinum resistant, 2L+ [Ph2/3, REJOICE-Ovarian01]	• Study started	
	<b>Solid tumors</b>	• <b>locally advanced or metastatic</b> <b>[Ph2, REJOICE-PanTumor01]</b>		• <b>Study started</b>

**Bold: update from FY2024 Q2**

# Major R&D Milestones (Next Wave)

Project	Target indication [phase, study name]	FY2024		FY2025
		H1	H2	
VANFLYTA®	<ul style="list-style-type: none"> <li>• <b>FLT3-ITD negative AML, 1L [Ph3, QuANTUM-Wild]</b></li> </ul>		<ul style="list-style-type: none"> <li>• <b>Study started</b></li> </ul>	
EZHARMIA®	<ul style="list-style-type: none"> <li>• r/r PTCL [Registrational Ph2, VALENTINE-PTCL01]</li> </ul>	<ul style="list-style-type: none"> <li>• Approved (JP)</li> </ul>		
	<ul style="list-style-type: none"> <li>• <b>NSCLC (without AGA and PD-L1 ≥50%), pembrolizumab combo, 1L [Ph1b/2]</b></li> </ul>		<ul style="list-style-type: none"> <li>• <b>Study started</b></li> </ul>	
MK-6070	<ul style="list-style-type: none"> <li>• <b>SCLC, I-DXd combo, 2L [Ph1b/2, MK-6070-002]</b></li> </ul>		<ul style="list-style-type: none"> <li>• <b>Study start planned</b></li> </ul>	
DS-2243	<ul style="list-style-type: none"> <li>• <b>Solid tumors [Ph1b]</b></li> </ul>		<ul style="list-style-type: none"> <li>• <b>Study start planned</b></li> </ul>	
TARLIGE®	<ul style="list-style-type: none"> <li>• DPNP [Ph3]</li> </ul>	<ul style="list-style-type: none"> <li>• Approved (CN)</li> </ul>		
DAICHIRONA®	<ul style="list-style-type: none"> <li>• COVID-19 mRNA vaccine (mutant strain), children aged 5 to 11 years [Ph2/3]</li> </ul>	<ul style="list-style-type: none"> <li>• Filing accepted (JP)</li> </ul>	<ul style="list-style-type: none"> <li>• Regulatory decision anticipated (JP)</li> </ul>	
MMR vaccine (VN-0102)	<ul style="list-style-type: none"> <li>• Mixed measles-mumps-rubella vaccine [Ph3]</li> </ul>	<ul style="list-style-type: none"> <li>• Filing accepted (JP)</li> </ul>		

**Bold: update from FY2024 Q2**

DPNP: diabetic peripheral neuropathic pain, PTCL: peripheral T cell lymphoma, r/r: relapsed/refractory, TLR: top line results

\*: Timeline for "Planned regulatory filing" indicates expected filing acceptance date

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

# Major R&D Pipeline: 5DXd ADCs ①

As of Jan 2025

Phase 1		Phase 1/2		Phase 2	
(US/EU/Asia) HER2 low BC chemo naive/post chemo DESTINY-Breast08	(JP/US/EU/Asia) NSCLC	(US/EU/Asia) HER2+ BC 2L+/1L DESTINY-Breast07	(US/EU/Asia) CRC, BTC, HCC 2L+ MK-1022-011	(JP/US/EU/Asia) HER2 expressing solid tumors DESTINY-PanTumor02	(JP/US/EU/Asia) ES-SCLC 2L+ IDEate-Lung01
(US/EU/Asia) HER2+ NSCLC (durvalumab, volrustomig and rilvegostomig combo) 1L DESTINY-Lung03	(JP/US/Asia) EGFR mutated NSCLC, 1L/2L (osimertinib combo)	(JP/US/EU/Asia) HER2 expressing GC combo, 2L+/1L DESTINY-Gastric03	(JP/US/EU/Asia) in prep StageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01A	(CN) HER2 expressing solid tumors DESTINY-PanTumor03	(TBA) in prep ESCC, 1L (pembrolizumab combo) KEYMAKER-U06 substudy 06E
(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US) renal cell carcinoma, ovarian cancer	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) in prep HER2+ BC HERTHENA-Breast01	(JP/US/EU/Asia) solid tumors TROPION-PanTumor03	(TBA) in prep non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
(JP/US) solid tumors TROPION-PanTumor01		(US/EU/Asia) solid tumors (saruparib combo) PETRA	(JP/US) ESCC, CRPC, squamous NSCLC, SCLC, etc. IDEate-PanTumor01	(JP/US/EU/Asia) EGFR mutated NSCLC 2L (osimertinib combo) ORCHARD	(TBA) in prep squamous NSCLC 2L KEYMAKER-U01 substudy 01I
(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) TROPION-Lung02		(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) ES-SCLC, 1L IDEate-Lung03	(US/EU/Asia) resectable early-stage NSCLC neoadjuvant (durvalumab combo) NeoCOAST-2	(JP/US/EU/Asia) solid tumors REJOICE-PanTumor01
(JP/US/EU) NSCLC (w/o AGA, durvalumab, rilvegostomig, volrustomig and sabestomig combo) TROPION-Lung04		(JP/US/EU/Asia) solid tumors (saruparib combo) PETRA	(JP/US/EU/Asia) solid tumors 2L+ IDEate-PanTumor02	(JP/US/EU/Asia) solid tumors HERTHENA-PanTumor01	(TBA) in prep non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
			(JP/US/EU/Asia) in prep StageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01A	(US/EU/Asia) in prep StageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01G	(TBA) in prep squamous NSCLC 2L KEYMAKER-U01 substudy 01I
			(US/EU/Asia) in prep ES-SCLC 2L KEYNOTE-B98		

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, HCC: hepatocellular carcinoma, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, TBA: to be announced, TNBC: triple negative breast cancer

# Major R&D Pipeline: 5DXd ADCs ②

As of Jan 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* <sup>1</sup> DESTINY-Breast05	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1 TPS <50%) 1L (pembrolizumab combo) TROPION-Lung07	(JP/US/EU/Asia) TNBC (PD-1/PD-L1 inhibitor ineligible) 1L TROPION-Breast02	(JP/EU) HR+ and HER2 low or HER2 ultralow BC chemo naïve DESTINY-Breast06
	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09	(JP/US/EU/Asia) NSCLC (w/o AGA, PD-L1 TPS ≥50%) 1L (pembrolizumab combo) TROPION-Lung08	(JP/US/EU/Asia) TNBC adjuvant* <sup>1</sup> (mono or durvalumab combo) TROPION-Breast03	(US) EGFR mutated NSCLC (after systemic therapies, incl. EGFR-directed therapy) TROPION-Lung05* <sup>2</sup>
	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1 TC 1≥50%) 1L (rilvegostomig combo) TROPION-Lung10	(JP/US/EU/Asia) TNBC neoadjuvant and adjuvant (durvalumab combo) TROPION-Breast04	(EU/CN) HR+ and HER2 low or HER2 negative BC 2/3L TROPION-Breast01
	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	(JP/US/EU/Asia) Stage I adenocarcinoma NSCLC adjuvant (rilvegostomig combo) TROPION-Lung12	(JP/US/EU/Asia) PD-L1 positive TNBC 1L (mono or durvalumab combo) TROPION-Breast05	(US) EGFR mutated NSCLC 3L HERTHENA-Lung01
	(JP/US/EU/Asia) HER2+ GC 1L (pembrolizumab combo) DESTINY-Gastric05	(JP/US/EU/Asia) EGFR mutated NSCLC 1L (osimertinib combo) TROPION-Lung14	(JP/US/EU/Asia) EGFR mutated NSCLC 2L HERTHENA-Lung02	
	(JP/US/EU/Asia) HER2+ and PD-L1 CPS≥1 GC 1L (rilvegostomig combo) ARTEMIDE-Gastric01	(JP/US/EU/Asia) EGFR mutated NSCLC (progressed on prior EGFR TKI) 2L+ (mono or osimertinib combo) TROPION-Lung15	(JP/US/EU/Asia) -ES-SCLC 2L IDeate-Lung02	
	(JP/US/EU/Asia) HER2 mutant NSCLC 1L DESTINY-Lung04	(JP/US/EU/Asia) NSCLC (w/o AGA) 1L (durvalumab combo) AVANZAR	(JP/US/EU/Asia) in prep ESCC 2L IDeate-Esophageal01	
	(JP/US/EU/Asia) HER2 expressing BTC 1L (mono or rilvegostomig combo) DESTINY-BTC01			

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 Adjuvant therapy for patients with residual invasive disease following neoadjuvant therapy

\*2 Supported by data from TROPION-Lung01, TROPION-PanTumor01

AGA: actionable genomic alterations, BTC: biliary tract cancer, BC: breast cancer, CPS: combined positive score  
 ES-SCLC: extensive stage-small cell lung cancer, GC: gastric cancer, HR: hormone receptor, NSCLC: non-small cell lung  
 cancer, TKI: tyrosine kinase inhibitor, TC: tumor cells, TNBC: triple negative breast cancer, TPS: tumor proportion score

# Major R&D Pipeline: Next Wave

As of Jan 2025

Phase 1	Phase 1/2	Phase 2	Phase 3	Regulatory phase
DS-1055 (JP/US) Anti-GARP antibody 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	DAICHIRONA® (JP) COVID-19 mRNA vaccine (mutant strain), COVID-19 (booster vaccination, 5 to 11 aged children)
DS-9606 (US/EU) CLDN6-directed ADC Solid tumors	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-1103 (US/EU) Anti-SIRPα antibody HER2 expressing or mutant solid tumors, HER2 low BC (ENHERTU® combo)	MK-6070 (DS3280) (TBA) in prep 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	MINNEBRO® (JP) MR blocker Diabetic nephropathy	
DS-1471 (JP) Anti-CD147 antibody Solid tumors	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		
EZHARMIA® (JP/US) EZH1/2 inhibitor HER2+ GC, HER2 low BC (ENHERTU® combo) and non-squamous NSCLC (DATROWAY® combo)	DS-7011 (JP/US/EU/Asia) Anti-TLR7 antibody Systemic lupus erythematosus			
DS-2243 (US/EU/Asia) in prep HLA-A*02/NY-ESO directed bispecific T-cell engager Solid tumors	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)

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, TBA: to be announced, TPS: tumor proportion score

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