Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2024 Q3
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Koji Ogawa

Executive Officer, CFO

January 31, 2025

Forward-Looking Statements

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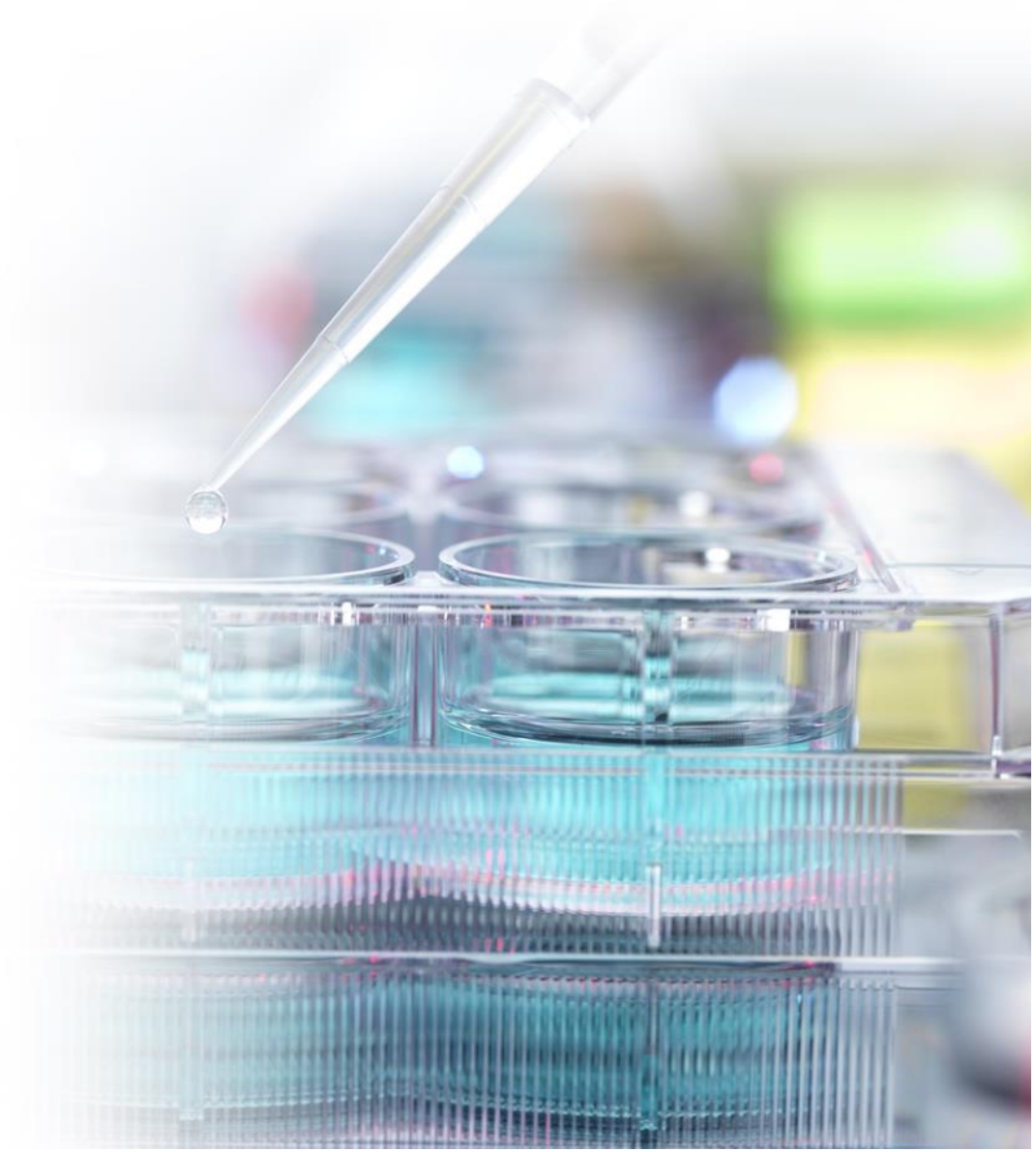
Agenda

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	
Revenue	**1,173.3**	**1,367.6**	+16.6%	**194.3**
Cost of sales*1	310.3	321.4		11.1
SG&A expenses*1	433.9	516.6		82.7
DXd ADC profit share *2	119.1	168.5		49.4
Other SG&A expenses	314.8	348.2		33.3
R&D expenses*1	256.8	300.6		43.8
Core operating profit*1	**172.2**	**229.0**	+33.0%	**56.8**
Temporary income*1	26.9	21.5		-5.4
Temporary expenses*1	4.6	2.2		-2.4
Operating profit	**194.6**	**248.3**	+27.6%	**53.8**
Profit before tax	**199.8**	**275.0**		**75.2**
Profit attributable to owners of the Company	**163.6**	**208.6**	+27.5%	**45.0**

Currency Rate	USD/JPY	143.29	152.56	+9.27
	EUR/JPY	155.28	164.82	+9.54

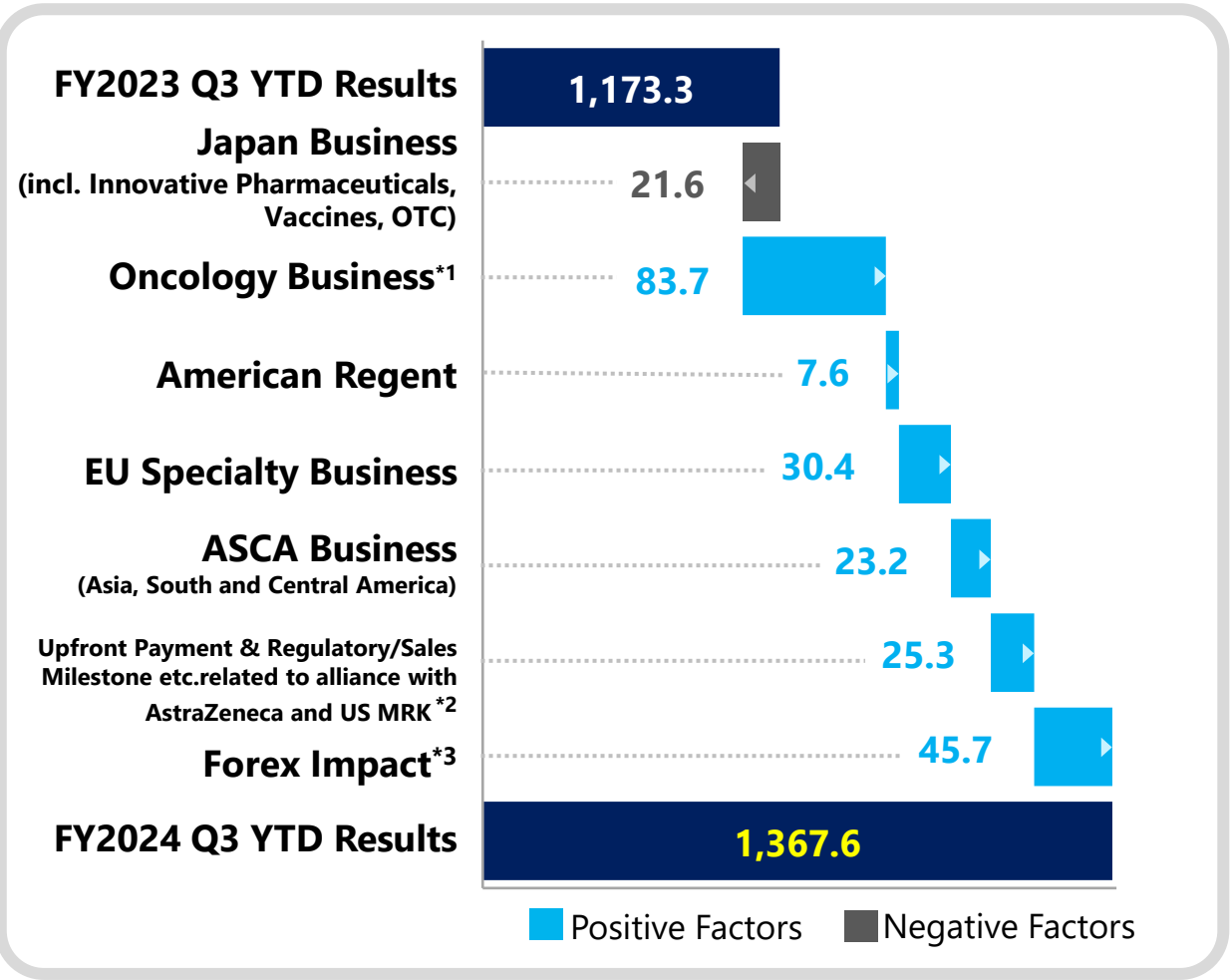
*1 As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed. Income and expenses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation,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

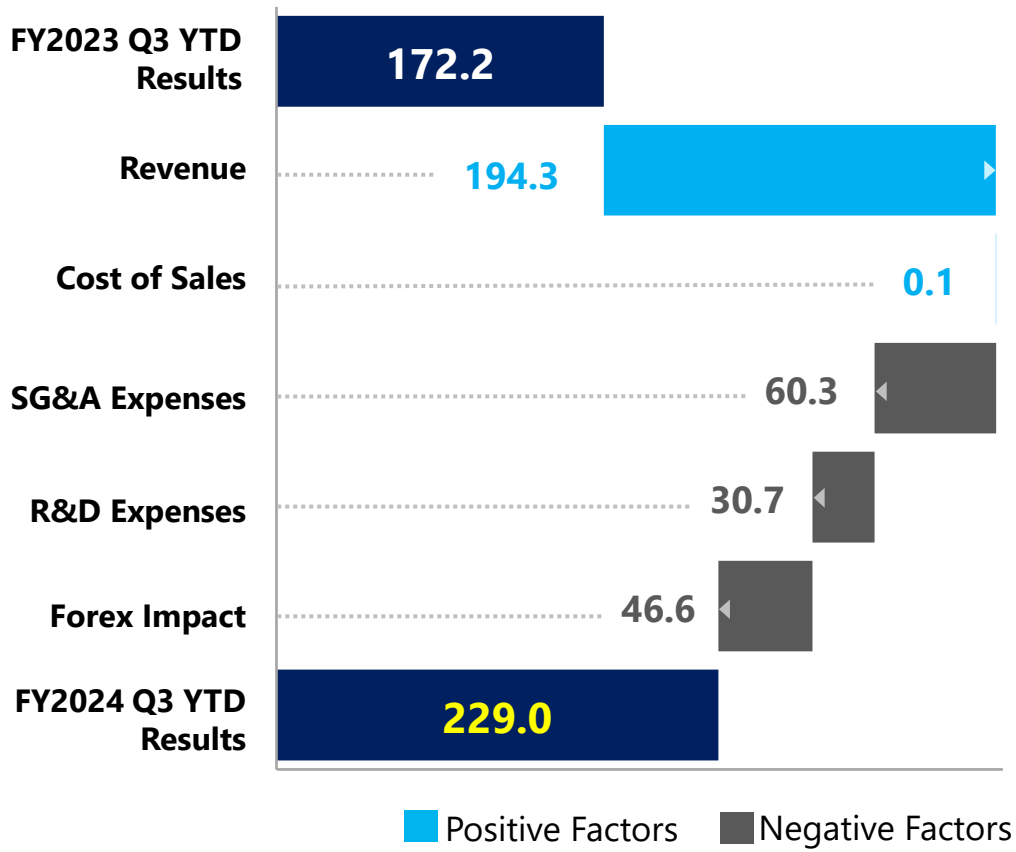


Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+13.7	Daiichi Sankyo Espha	-64.9
Tarlige	+7.6		
Enhertu	+5.8		
Daiichi Sankyo Healthcare	+7.5		
Realized gains of unrealized gains of inventory for Daiichi Sankyo Espha	+11.2		
Oncology Business Unit*1			
Enhertu	+81.6		
American Regent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

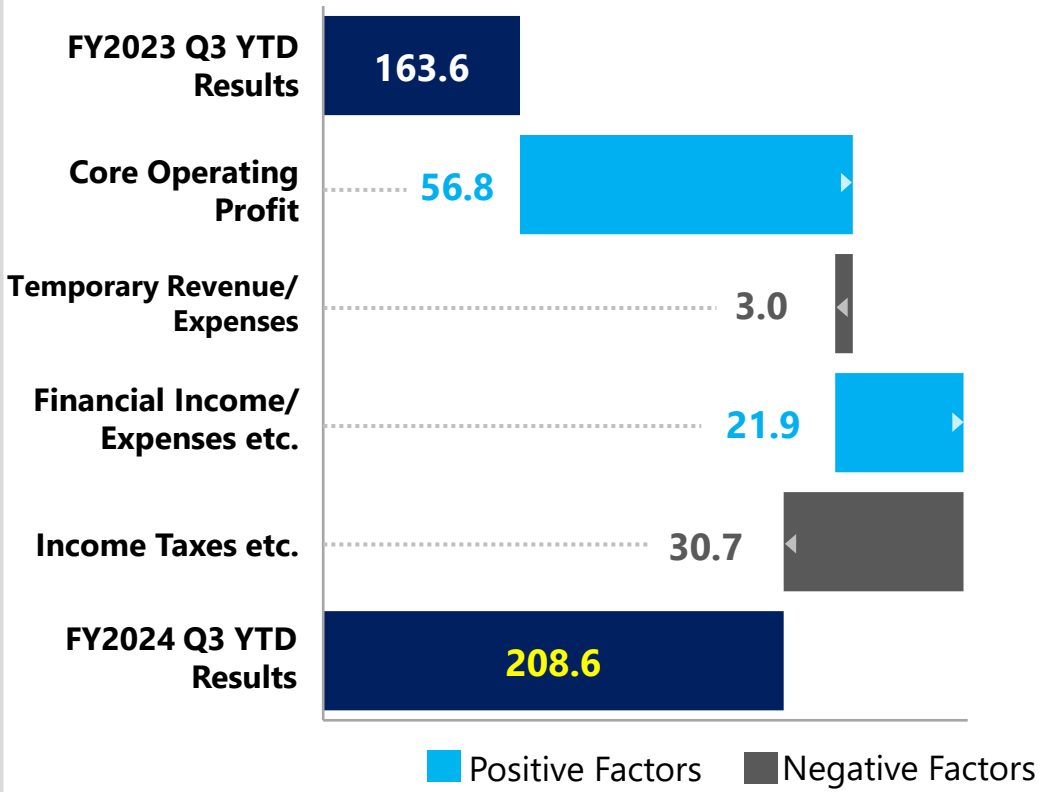
Forex Impact +46.6 (Profit Decreased)
Cost of Sales +11.1
SG&A Expenses +22.4
R&D Expenses +13.1

*__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*1	21.5*2	-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%	

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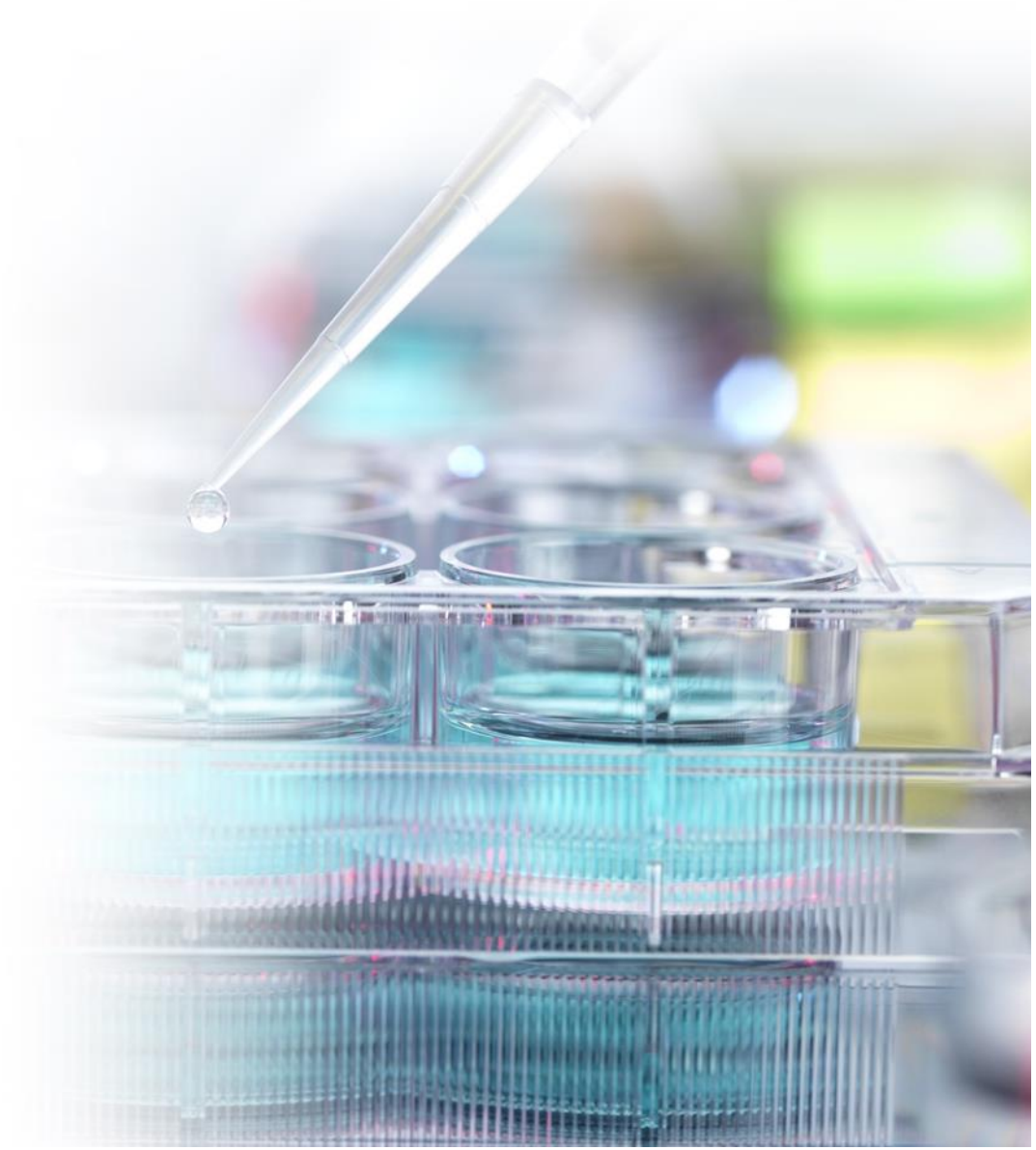

Revision to the forecast

(Bn JPY)

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

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.

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

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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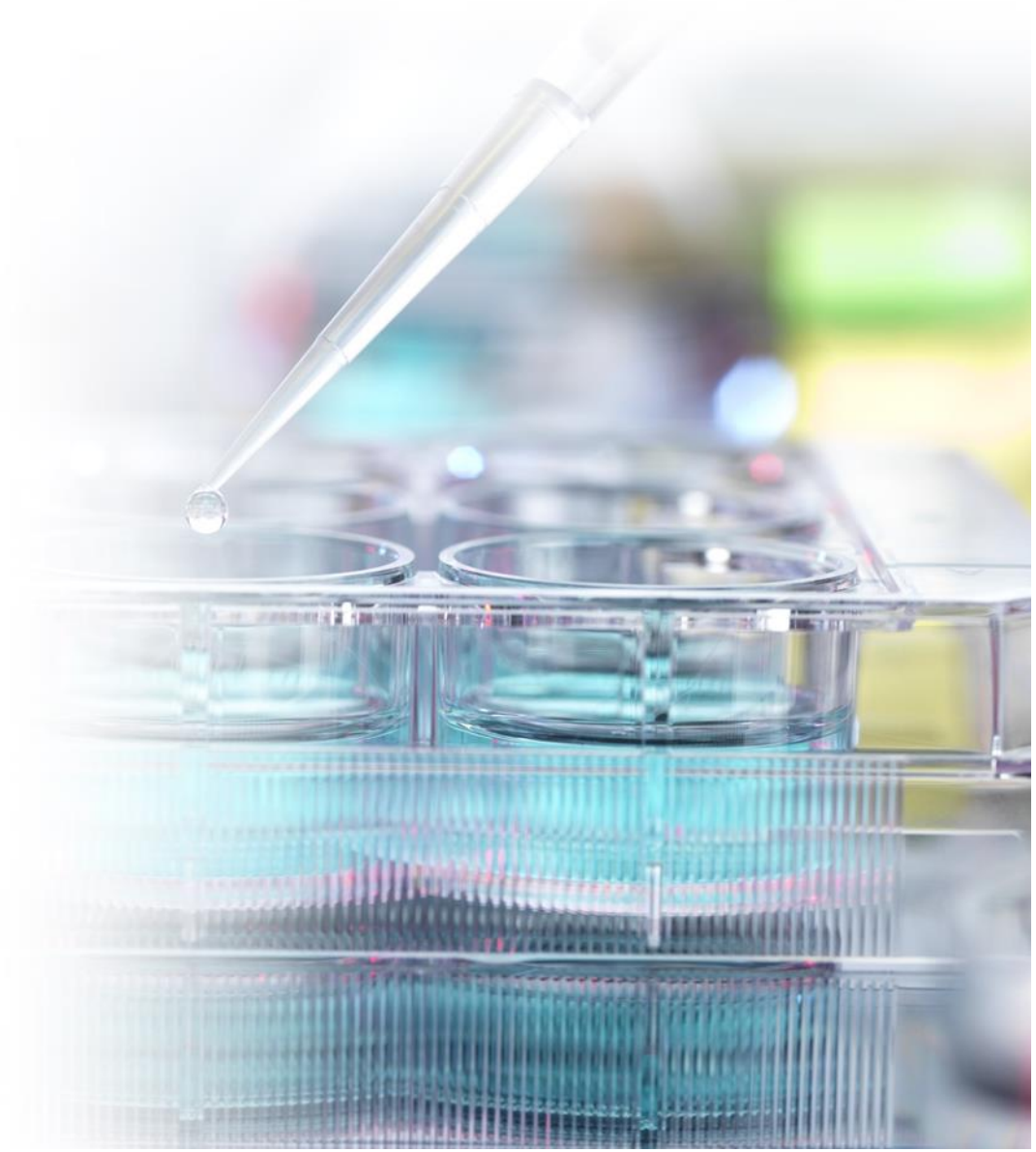


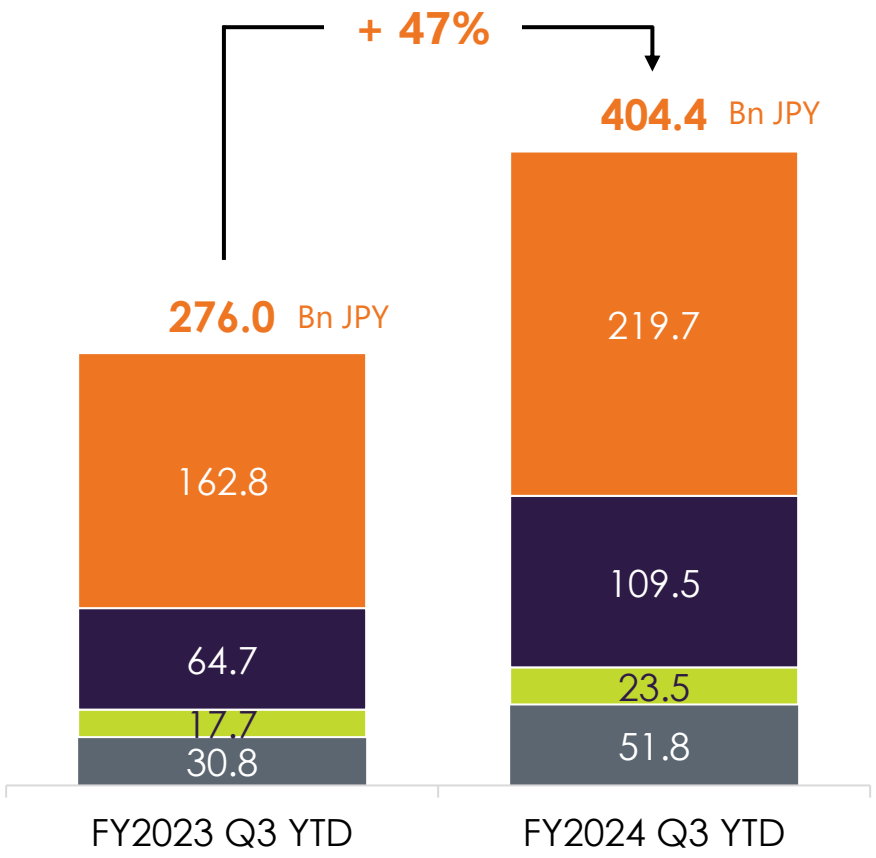
ENHERTU® Performance

ENHERTU® trastuzumab deruxtecan

Daiichi-Sankyo

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**)



Global Product Sales

◆ 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)

* IHC 1+ or IHC 2+/ISH-, **IHC 0 with membrane staining

BC: breast cancer, DE: Germany, ES: Spain, FR: France, GC: gastric cancer, HR: hormone receptor, IT: Italy, NCCN: National Comprehensive Cancer Network, NSCLC: non-small cell lung cancer, NRDL: National Reimbursement Drug List

Approved in Japan and the US

DATROWAY® (anti-TROP2 ADC) approved in Japan and the US

- Second product approved on our DXd ADC platform after ENHERTU®

- **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

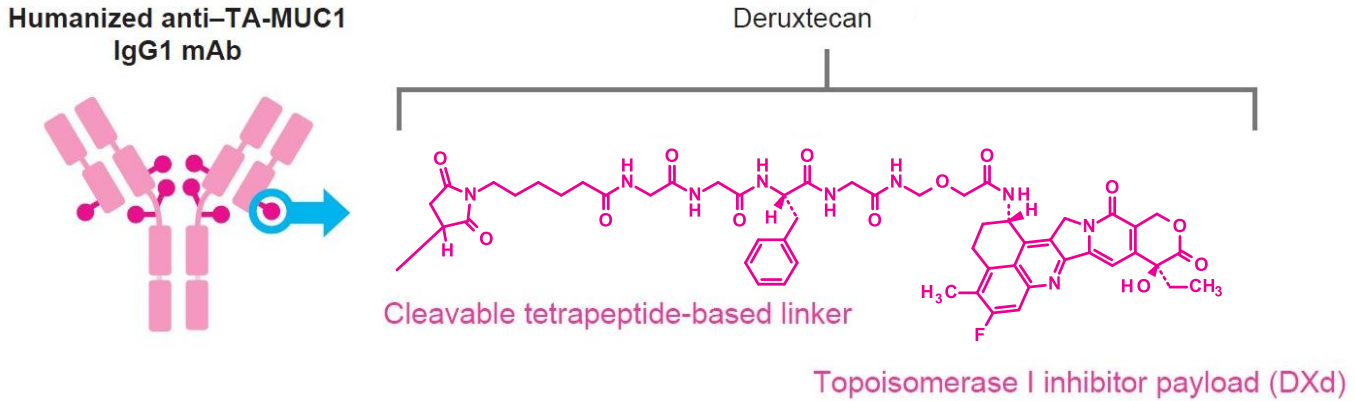
- **Dosage and Administration**
  6 mg/kg per dose intravenously at 3-weeks intervals

- **Product sales forecast for FY2024**
  400 Mn JPY

DS-3939 Acquisition of Intellectual Property Rights for Anti-TA-MUC1 Antibody

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.

- **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

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5DXd ADCs Update

Next Wave Update

News Flow

ENHERTU®

Approval of New Indication for Breast Cancer

DESTINY-Breast06

Daiichi-Sankyo

DESTINY-Breast06 brings ENHERTU® benefit earlier and broader

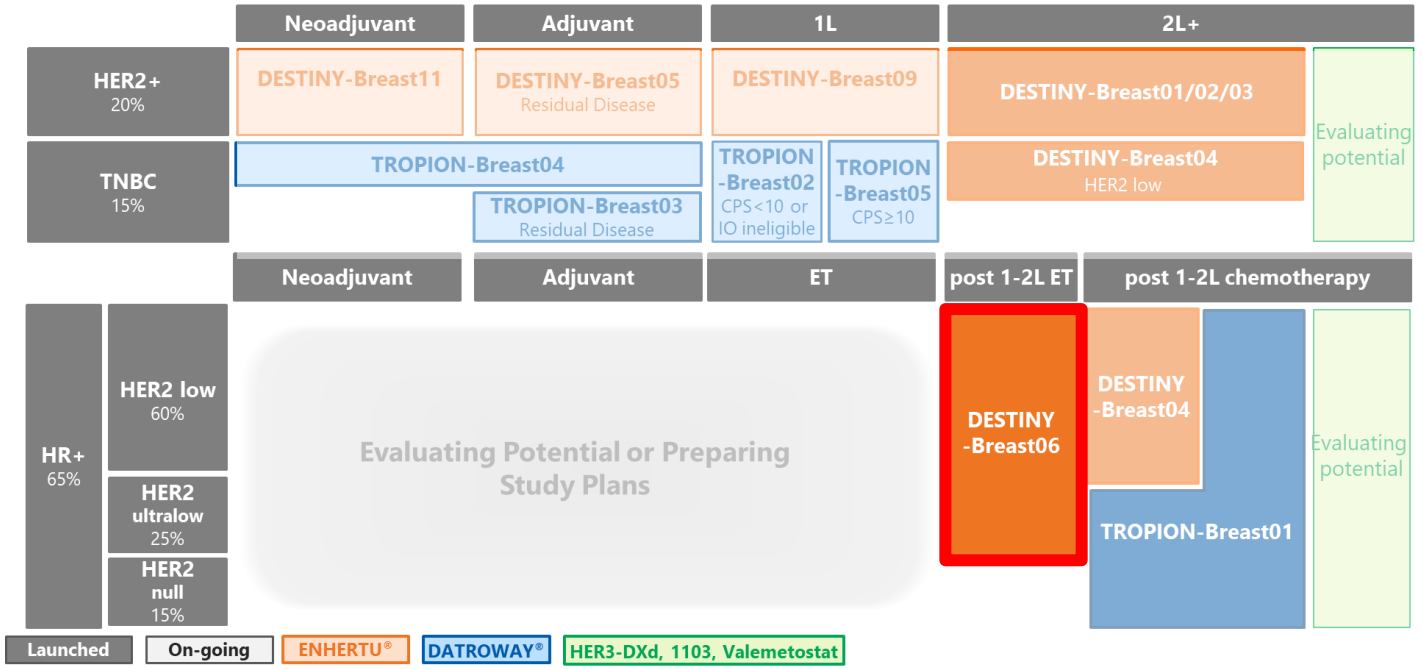
- Approved in the US for the treatment of patients with HER2 low (IHC 1+ or IHC 2+/ISH-) or HER2 ultralow (IHC 0 with membrane staining) BC, who progressed on one or more ET in metastatic setting on Jan 27, 2025
- Granted Breakthrough Therapy Designation and Priority Review

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



BC: breast cancer, ET: endocrine therapy, HR: hormone receptor, IHC: immunohistochemistry, IST: *in situ* hybridization, TNBC: triple-negative breast cancer,

ENHERTU®

1L Treatment for HER2+ Gastric Cancer

DESTINY-Gastric05 Ph3

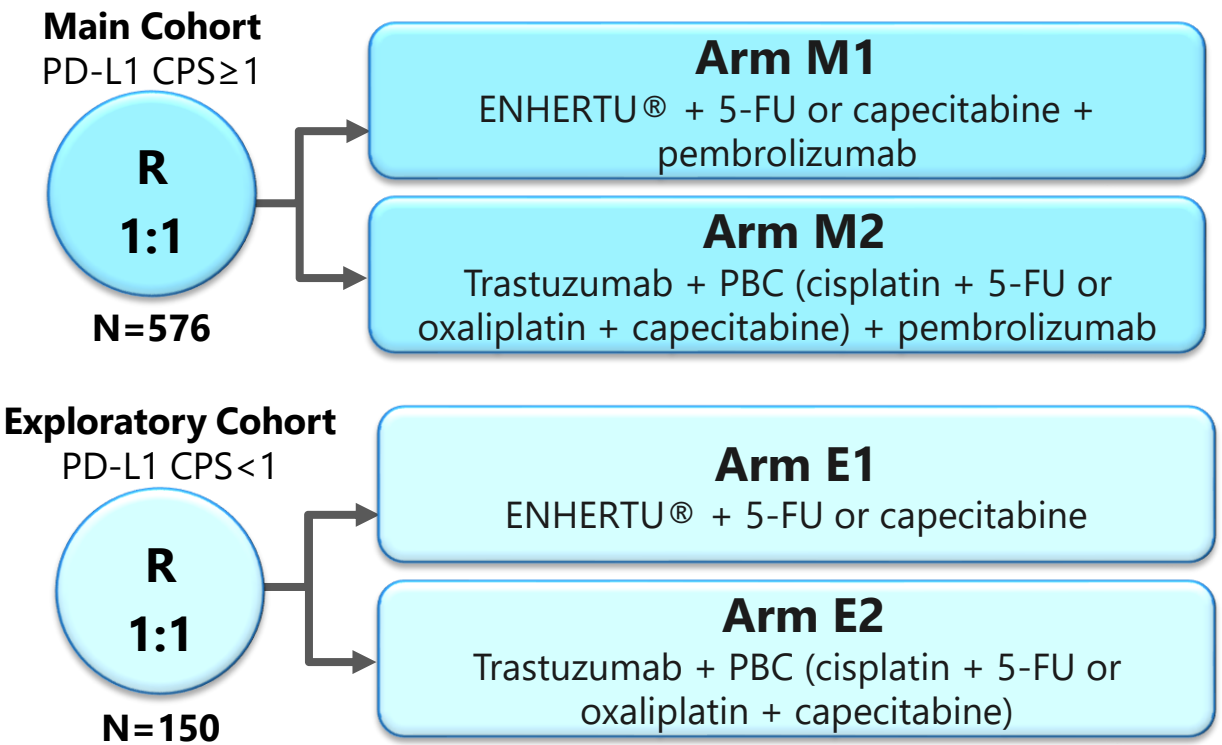
Daiichi-Sankyo

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

BICR: blinded independent central review, CPS: combined positive score, GC: gastric cancer, GEJ: gastroesophageal junction , IHC: immunohistochemistry, ISH: *in situ* hybridization, OS: overall survival, PBC: platinum-based chemotherapy, PFS: progression-free survival, SOC: standard of care

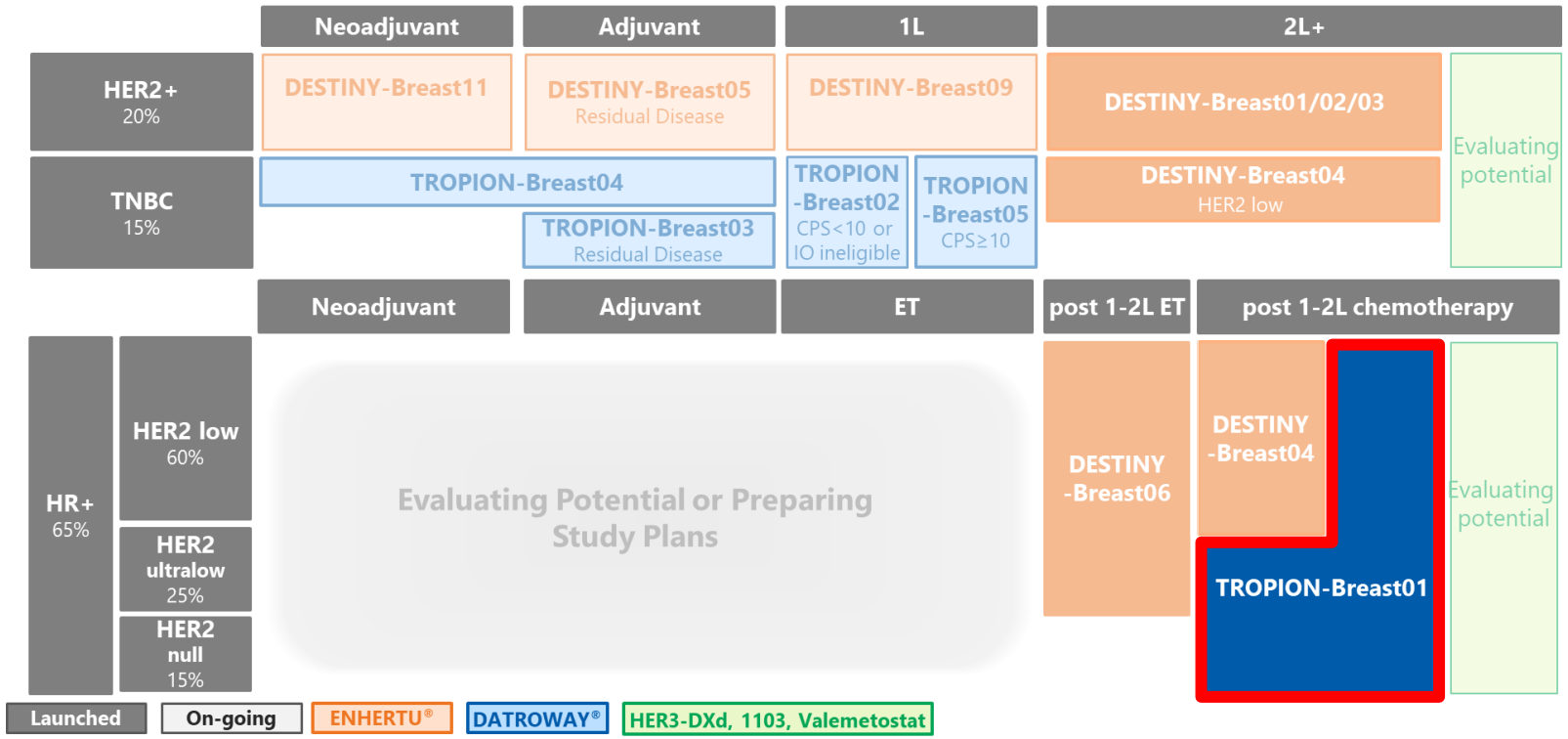
DATROWAY®
(Dato-DXd)

Breast Update: First approval of DATROWAY®

TROPION-Breast01 Ph3

Daiichi-Sankyo

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

BC: breast cancer, CPS: combined positive score, ET: endocrine therapy, HR: hormone receptor, IHC: immunohistochemistry, IO: immuno-oncology, ISH: *in situ* hybridization, OS: overall survival, pCR: pathological complete response, PFS: progression-free survival, TNBC: triple-negative breast cancer

DATROWAY®
(Dato-DXd)

Lung Update

Regulatory Status in the US and EU

Daiichi-Sankyo

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

Pooled Analysis of TROPION-Lung05 and TROPION-Lung01

ESMO Asia 2024

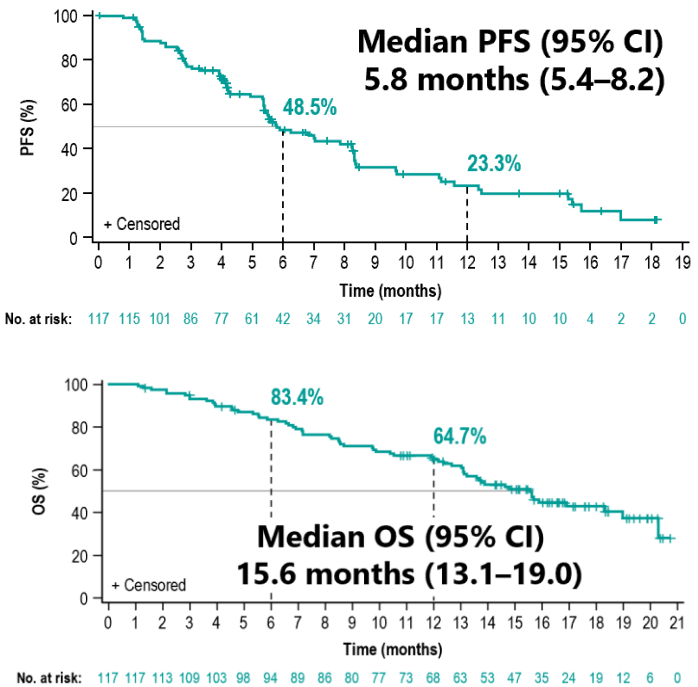
Daiichi-Sankyo

DATROWAY® is a potential treatment option for patients with EGFRm NSCLC in the 2L and later settings

Efficacy

Response	*EGFR*m Pool (N=117)	Prior Osimertinib (N=96)
Confirmed ORR,[a] n (%) [95% CI]	50 (**42.7**) [33.6–52.2]	43 (**44.8**) [34.6–55.3]
BOR, n (%)		
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)
Median DOR, months (95% CI)	**7.0** (4.2–9.8)	**6.9** (4.2–9.8)
DCR,[b] n (%) [95% CI]	101 (**86.3**) [78.7–92.0]	82 (**85.4**) [76.7–91.8]
Median PFS, months (95% CI)	**5.8** (5.4–8.2)	**5.7** (5.4–7.9)
Median OS, months (95% CI)	**15.6** (13.1–19.0)	**14.7** (13.0–18.3)

PFS and OS in the *EGFR*m Pool (N=117)



- DATROWAY® 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

[a]CR+PR; [b]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

HER3-DXd

Investigating Optimal Treatment Sequence of DXd ADCs

HERTHENA-Breast01 Ph1b/2

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

HERTHENA-Breast01 Study Design

Eligible patient

- HER2+ mBC
- 2-5 prior treatments of anti-HER2 therapy
- Progression on ENHERTU®

Dose finding

HER3-DXd + trastuzumab

Screening for allocation

HER3-DXd + pertuzumab+trastuzumab

HER3-DXd + tucatinib+trastuzumab

Expansion Arm

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® treatment (ASCO 2022)
  - ✓ ORR 42.9%, mPFS 11.0 mo
- Preliminary data confirmed the safety of HER3-DXd monotherapy after ENHERTU® treatment
- Plan to start in **FY2024 Q4**

ADA: anti-drug antibody, ASCO: American Society of Clinical Oncology, BC: breast cancer, CBR: clinical benefit rate, DOR: duration of response, mBC: metastatic breast cancer, mPFS: median progression-free survival, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, PK: pharmacokinetics

I-DXd

Expand Target Indications to ESCC

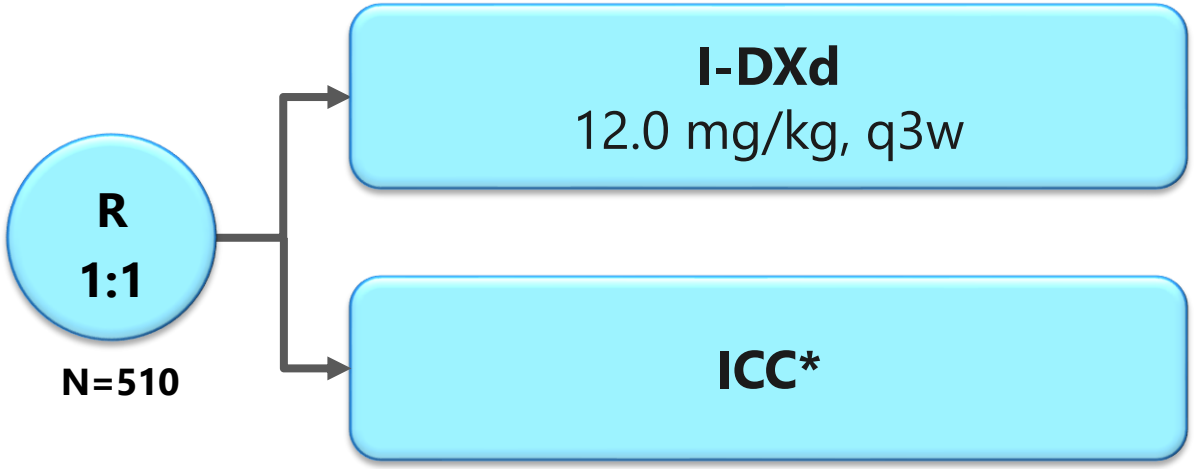
IDeate-Esophageal01 Ph3

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

CI: confidence interval, cORR: confirmed objective response rate, ESMO: European Society of Medical Oncology, ICC: investigator choice of chemotherapy, ICI: immune checkpoint inhibitor, mOS: medial overall survival, mPFS: median progression-free survival, ORR: objective response rate, OS: overall survival, q3w: every 3 week,

R-DXd

Investigate Possibilities beyond Platinum-Resistant Ovarian Cancer

REJOICE-PanTumor01 Ph2

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 ≥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 call carcinoma (ccRCC)

N= 200

Endpoints

Primary (except ccRCC):
ORR, safety
Primary (ccRCC only):
DCR, safety
Secondary:
PFS, DOR, TTR, ORR, DCR, PK, ADA

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

ADA: anti-drug antibody, DCR: disease control rate, DOR: duration of response, ES-SCLC: extensive-stage small cell lung cancer, ORR: objective response rate, PFS: progression-free survival, PK: pharmacokinetics, TTR: time to response

5DXd ADCs

Other Clinical Updates

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

BTC: biliary tact cancer, CRC: colorectal cancer, ctDNA: circulating tumor DNA, HCC: hepatocellular carcinoma, ESCC: esophageal squamous cell carcinoma, ES-SCLC: extensive-stage small cell lung cancer, NSCLC: non-small cell lung cancer, NSQ: non-squamous

5DXd ADCs Update

Next Wave Update

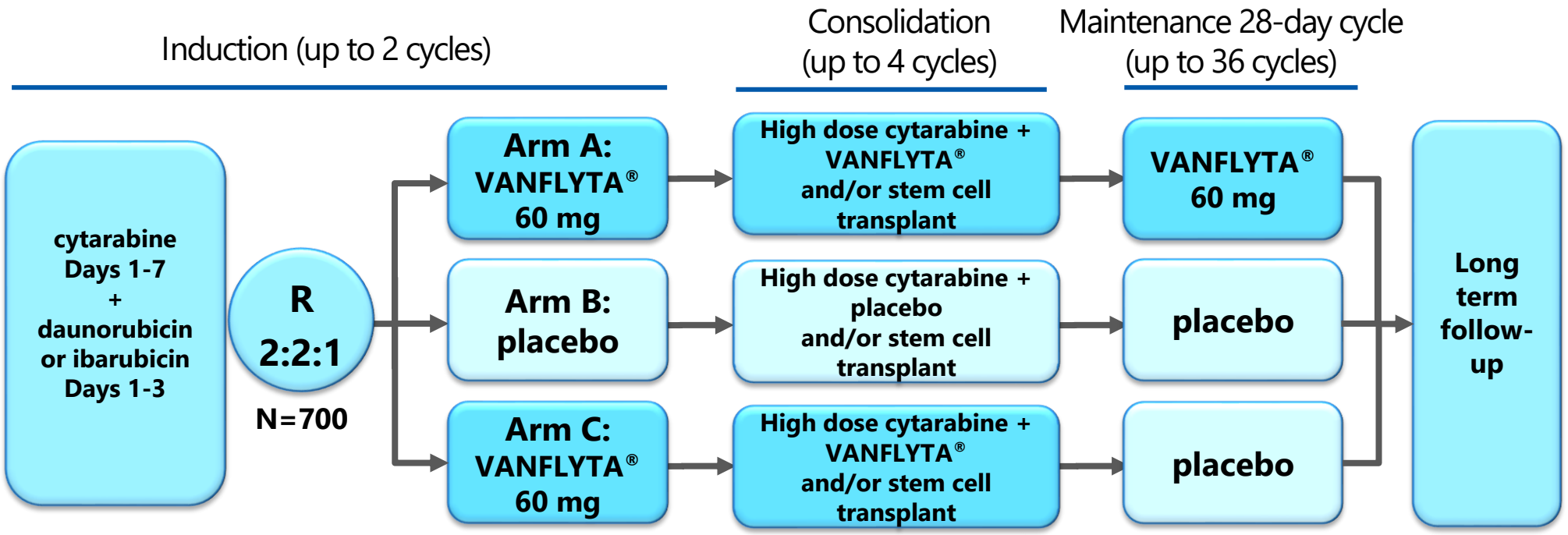
News Flow

QuANTUM-Wild Study Design

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.

AML: acute myeloid leukemia, CR: complete response, DCR: disease control rate:, EFS: event-free survival, EHA: European Hematology Association, OS: overall survival, RFS: relapse-free survival

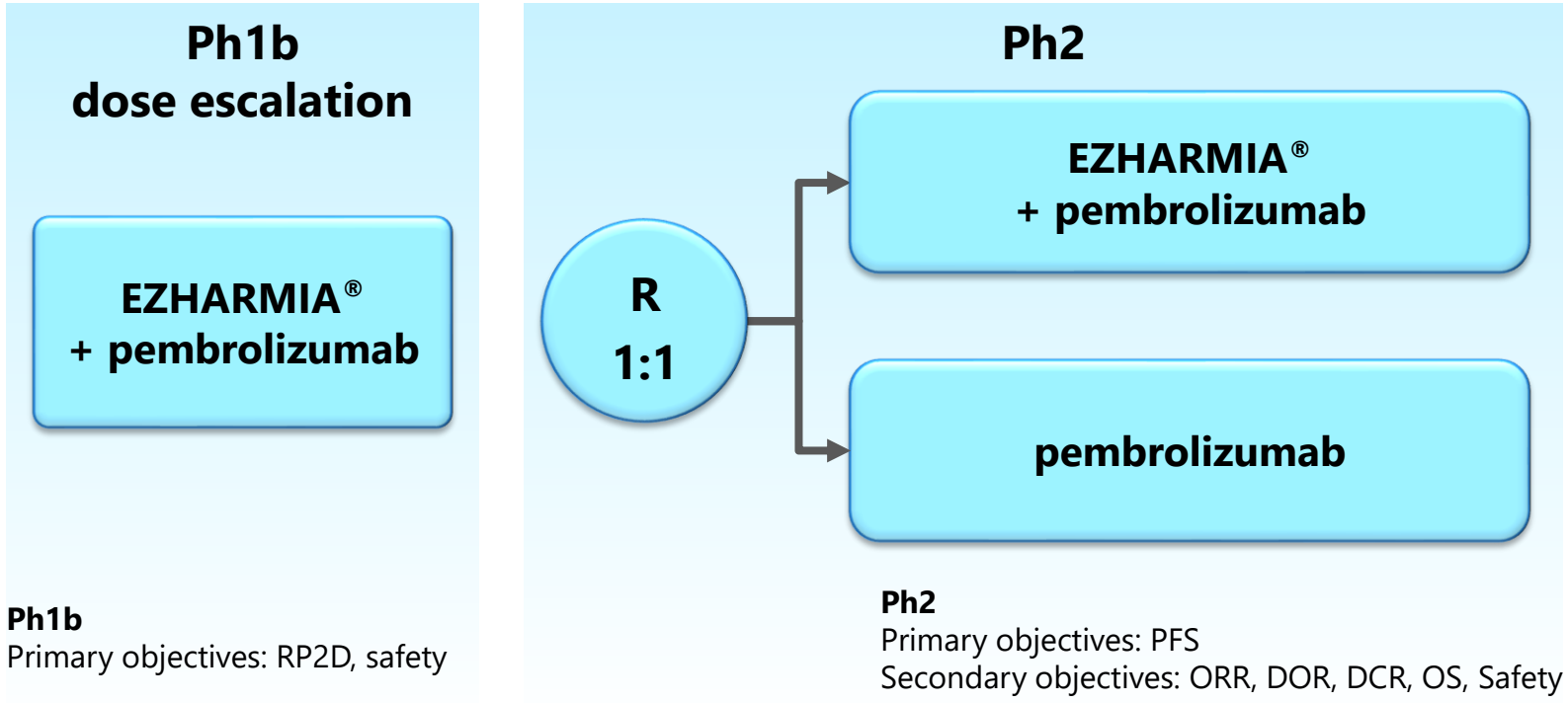
EZHARMIA® IO Combination for NSCLC

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

Ph1b/2 Study Design

Eligible patients

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



Ph1b
Primary objectives: RP2D, safety

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

- Preclinical rationale supports EZHARMIA®-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

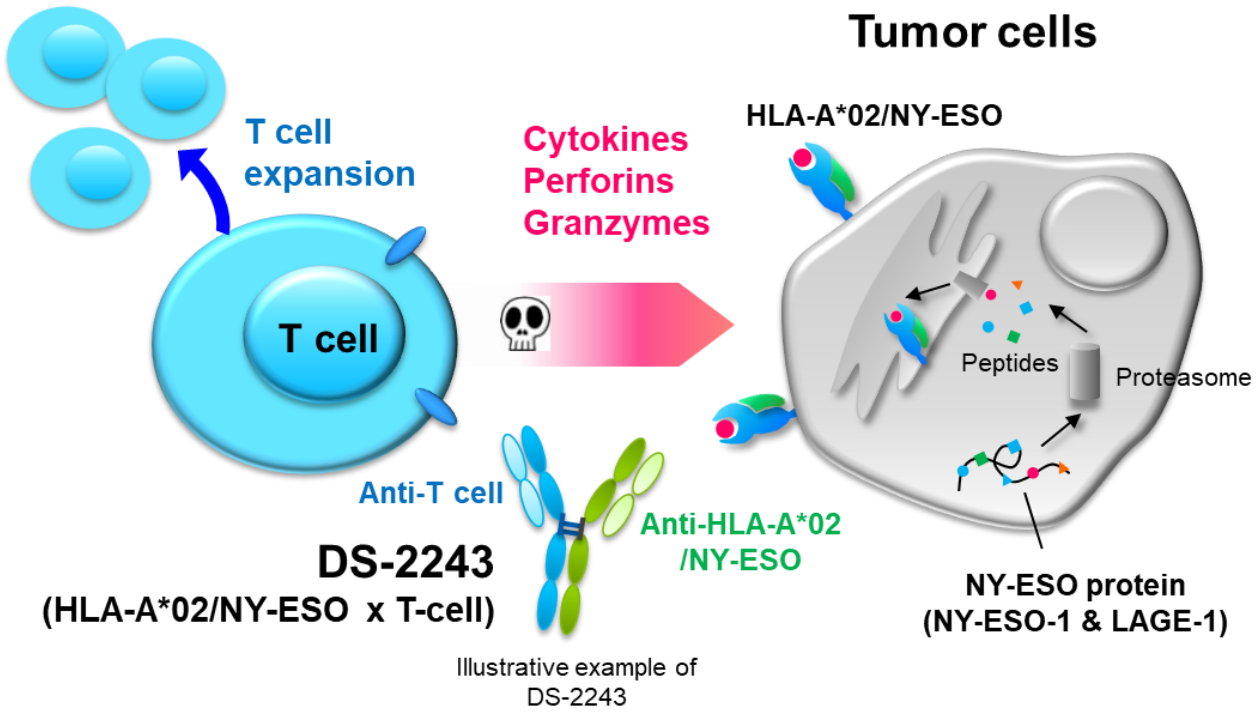
AGA: actionable genomic alteration, CRC: colorectal cancer, DCR: disease control rate, DOR: duration of response, IHC: immunohistochemistry, IO: immune oncology, NSCLC: non-small cell lung cancer, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, q3w: every 3 week, RP2D: recommended phase 2 dose, TPS: tumor proportion score

DS-2243

Plan to Start a Clinical Study for New T-cell Engager

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

Mode of Action



Illustrative example of DS-2243

- **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

NSCLC: non-small cell lung cancer, UC: urothelial cancer

5DXd ADCs Update

Next Wave Update

News Flow

FY2024 and FY2025 News Flow

As of Jan 2025

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[#]: EGFR mutated NSCLC with prior systemic therapies, including an EGFR-directed therapy** • **US: FY2025 H1** [#]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

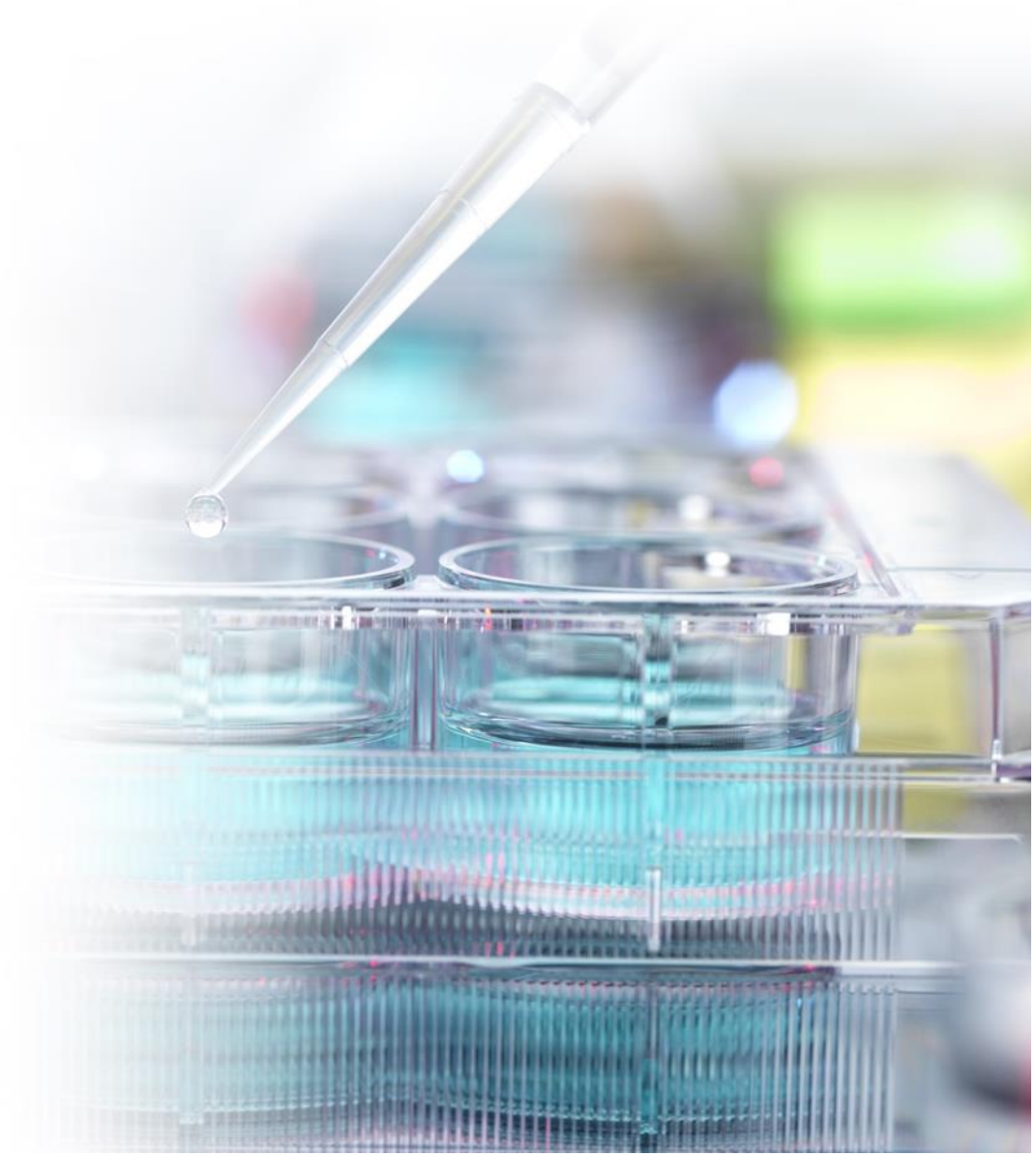
Timeline indicated is based on the current forecast and subject to change

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

5DXd ADCs Revenue (incl. Forex Impact)

(Unit: Bn JPY)

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

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		**21.9**	-1.3	**95.3**	-5.5	**466.5**
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		**32.3**	+26.6	**41.8**	-	**584.8**

* "Quid rights" (worth $150 mil.) that was held under the strategic alliance agreement with US Merck and was appropriated as part of consideration to obtain MK-6070 is booked as deferred revenue

Major R&D Milestones (ENHERTU®)

As of Jan 2025

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

As of Jan 2025

Project		Target indication [phase, study name]	FY2024 H1	FY2024 H2	FY2025
DATROWAY®	NSCLC	• non-squamous, 2L+ [Ph3, TROPION-Lung01]		**• Regulatory submission withdrawn (US/EU)**	
		• EGFR mutated, previously treated (incl. EGFR directed therapy) [Ph2, TROPION-Lung05*]		**• Filing accepted (US)**	**• Regulatory decision anticipated (US)**
		• non-squamous, PD-L1 high, rilvegostomig combo, 1L, [Ph3, TROPION-Lung10]	• Study started		
		• Stage I adenocarcinoma NSCLC, mono or rilvegostomig combo [Ph3, TROPION-Lung12]		**• Study started**	
		• EGFR mutated, osimertinib combo, 1L, [Ph3, TROPION-Lung14]	• Study started		
		• EGFR mutated, osimertinib combo, 2L+ [Ph3, TROPION-Lung15]		• Study started	
		• w/o AGA, durvalumab combo, 1L, [Ph3, AVANZAR]			• TLR anticipated
	BC	• HR+ and HER2 low or negative, 2/3L [Ph3, TROPION-Breast01]		**• Approved (JP/US)** **• Regulatory decision anticipated (EU)**	
		• TNBC, PD-1/PD-L1 ineligible, 1L [Ph3, TROPION-Breast02]			**• TLR anticipated**

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)

As of Jan 2025

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

Bold: update from FY2024 Q2

BC: breast cancer, BTC; biliary tract cancer, CRC: colorectal cancer, CRL: complete response letter, ESCC: esophageal squamous cell carcinoma, IHI: immune checkpoint inhibito, HCC: hepatocellular carcinoma, NSCLC: non-small cell lung cancer, OVC: ovarian cancer, SCLC: small cell lung cancer, TLR: top line results

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

Major R&D Milestones (Next Wave)

As of Jan 2025

Project	Target indication [phase, study name]	FY2024 H1	FY2024 H2	FY2025
VANFLYTA®	• ***FLT3*-ITD negative AML, 1L [Ph3, QuANTUM-Wild]**		• **Study started**	
EZHARMIA®	• r/r PTCL [Registrational Ph2, VALENTINE-PTCL01]	• Approved (JP)		
	• **NSCLC (without AGA and PD-L1≥50%), pembrolizumab combo, 1L [Ph1b/2]**		• **Study started**	
MK-6070	• **SCLC, I-DXd combo, 2L [Ph1b/2, MK-6070-002]**		• **Study start planned**	
DS-2243	• **Solid tumors [Ph1b]**		• **Study start planned**	
TARLIGE®	• DPNP [Ph3]	• Approved (CN)		
DAICHIRONA®	• COVID-19 mRNA vaccine (mutant strain), children aged 5 to 11 years [Ph2/3]	• Filing accepted (JP)	• Regulatory decision anticipated (JP)	
MMR vaccine (VN-0102)	• Mixed measles-mumps-rubella vaccine [Ph3]	• Filing accepted (JP)		

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

Daiichi-Sankyo

Phase 1

- (US/EU/Asia) HER2 low BC chemo naïve/post chemo DESTINY-Breast08
- (US/EU/Asia) HER2+ NSCLC (durvalumab, volrustomig and rilvegostomig combo) 1L DESTINY-Lung03
- (US/EU) BC, NSCLC (pembrolizumab combo)
- (JP/US) solid tumors TROPION-PanTumor01
- (JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) TROPION-Lung02
- (JP/US/EU) NSCLC (w/o AGA, durvalumab, rilvegostomig, volrustomig and 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 DESTINY-Breast07
- (JP/US/EU/Asia) HER2 expressing GC combo, 2L+/1L DESTINY-Gastric03
- (US/EU/Asia) TNBC (durvalumab combo) BEGONIA
- (US/EU/Asia) solid tumors (saruparib combo) PETRA
- (US/EU/Asia) TNBC (durvalumab combo) BEGONIA
- (JP/US/EU/Asia) solid tumors (saruparib combo) PETRA
- (US/EU/Asia) CRC, BTC, HCC 2L+ MK-1022-011
- (JP/US/EU/Asia) in prep StageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01A
- (JP/US/EU/Asia) in prep HER2+ BC HERTHENA-Breast01
- (JP/US) ESCC, CRPC, squamous NSCLC, SCLC, etc. IDeate-PanTumor01
- (JP/US/EU/Asia) ES-SCLC, 1L IDeate-Lung03
- (JP/US/EU/Asia) solid tumors 2L+ IDeate-PanTumor02
- (JP/US/EU/Asia) in prep StageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01A
- (US/EU/Asia) in prep ES-SCLC 2L KEYNOTE-B98

Phase 2

- (JP/US/EU/Asia) HER2 expressing solid tumors DESTINY-PanTumor02
- (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 combo) NeoCOAST-2
- (JP/US/EU/Asia) solid tumors HERTHENA-PanTumor01
- (US/EU/Asia) in prep StageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01G
- (JP/US/EU/Asia) ES-SCLC 2L+ IDeate-Lung01
- (TBA) in prep ESCC, 1L (pembrolizumab combo) KEYMAKER-U06 substudy 06E
- (TBA) in prep non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
- (TBA) in prep squamous NSCLC 2L KEYMAKER-U01 substudy 01I
- (JP/US/EU/Asia) solid tumors REJOICE-PanTumor01
- (TBA) in prep non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
- (TBA) in prep squamous NSCLC 2L KEYMAKER-U01 substudy 01I

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*1 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*1 (mono or durvalumab combo) TROPION-Breast03	(US) EGFR mutated NSCLC (after systemic therapies, incl. EGFR-directed therapy) TROPION-Lung05*2
	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L 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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