

Passion for Innovation.
Compassion for Patients.™



FY2024 Financial Results Presentation

DAIICHI SANKYO CO., LTD.

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President and CEO

April 25, 2025

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Agenda

- 1 FY2024 Financial Results**
- 2 Business Update
- 3 R&D Update
- 4 5-Year Business Plan Update
- 5 FY2025 Forecast
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Overview of FY2024 Results

(Bn JPY)

	FY2023 Results	FY2024 Results	YoY	
Revenue	1,601.7	1,886.3	+17.8%	
Cost of sales *1	414.8	415.7	1.0	
SG&A expenses *1	627.3	724.8	97.5	
DXd ADC profit share*2	170.6	226.2	55.6	
Other SG&A expenses	456.8	498.6	41.9	
R&D expenses *1	364.3	432.9	68.5	
Core operating profit *1	195.3	312.8	+60.2%	
Temporary income *1	27.3	22.2	-5.1	
Temporary expenses *1	10.9	3.1	-7.9	
Operating profit	211.6	331.9	+56.9%	
Profit before tax	237.2	355.6	118.4	
Profit attributable to owners of the Company	200.7	295.8	+47.3%	
Currency	USD/JPY	144.62	152.57	+7.95
Exchange Rate	EUR/JPY	156.79	163.74	+6.95

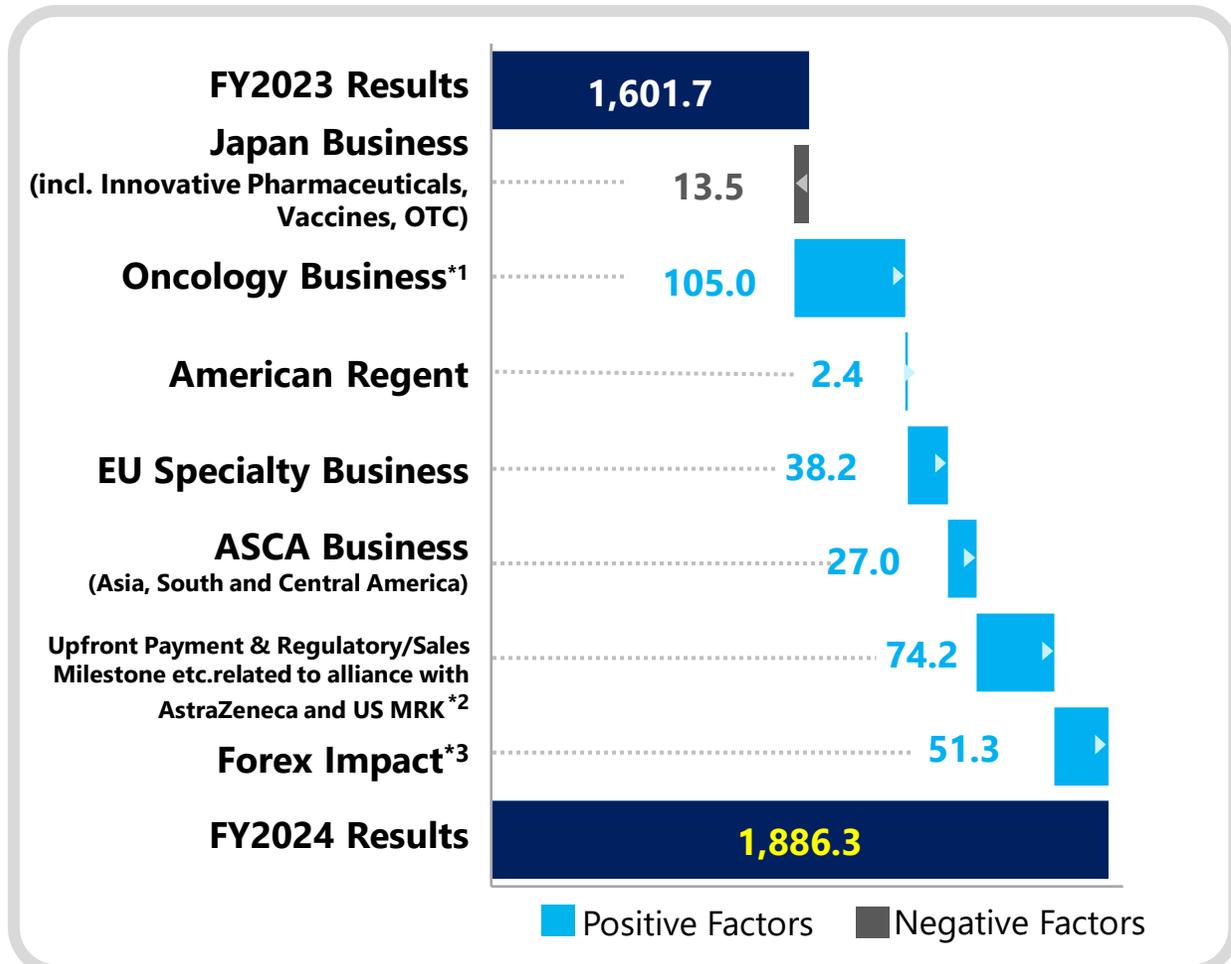
*1 As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed. Income and expenses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation, 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 284.6 Bn JPY (Increased by 233.3 Bn JPY excl. forex impact)

(Bn JPY)



Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+17.5	Vaccine business	-19.5
Tarlige	+10.0	Daiichi Sankyo	-83.0
Enhertu	+7.1	Espha	
Daiichi Sankyo Healthcare	+10.7		
Realized gains of unrealized gains of inventory for Daiichi Sankyo Espha	+9.4		
Oncology Business Unit*1			
Enhertu	+100.6		
American Regent Unit			
GE injectables	+3.4	Venofer	-2.2
EU Specialty Business Unit			
Lixiana	+25.2	olmesartan	-2.1
Nilemdo/Nustendi	+16.9		
ASCA (Asia, South and Central America) Business Unit			
Enhertu	+26.9		
Upfront Payment & Regulatory/Sales Milestone etc. related to alliance with AstraZeneca and US MRK*2			
AstraZeneca	+45.3		
MRK	+28.9		

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

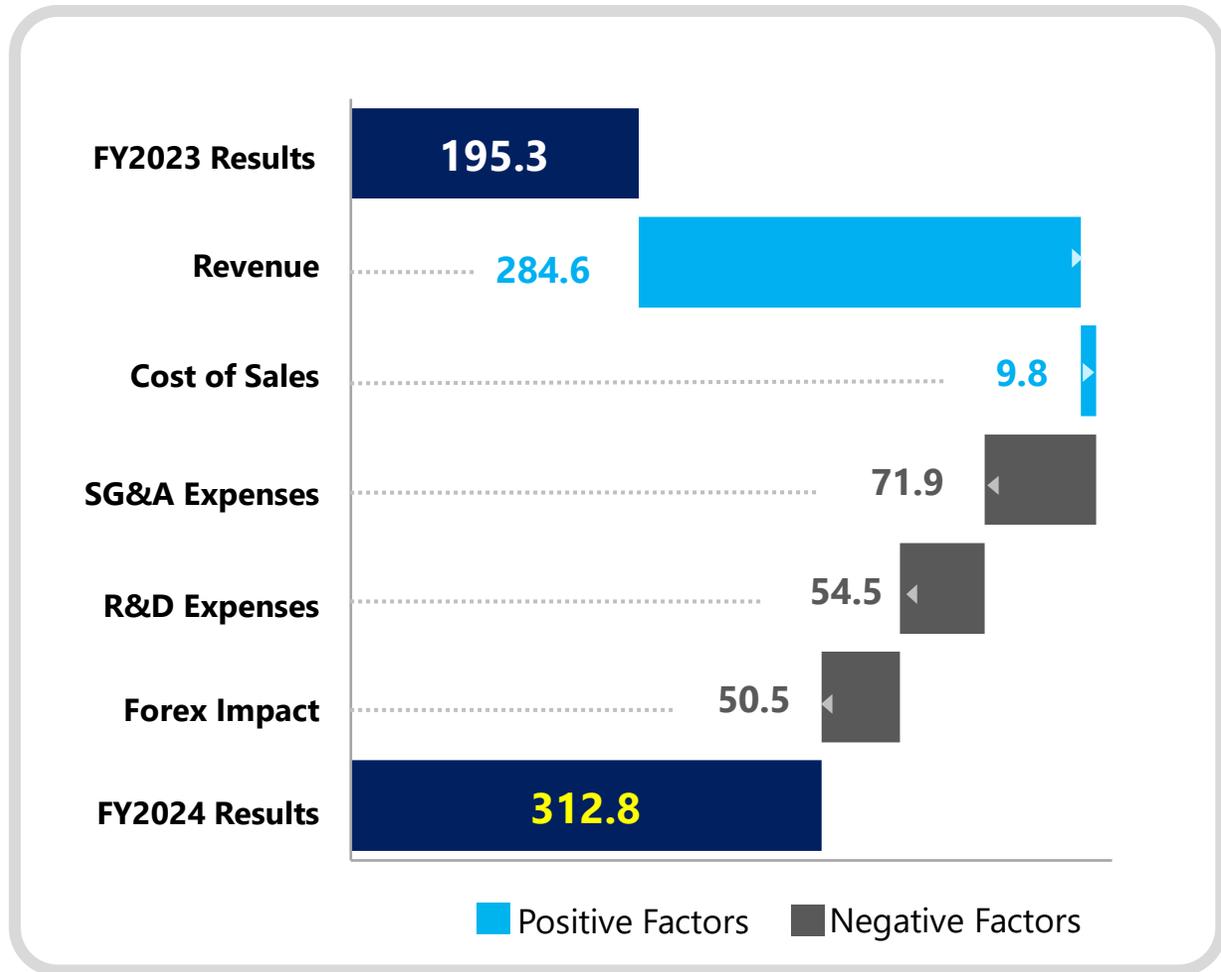
*2 Merck & Co., Inc., Rahway, NJ, USA

*3 Forex impact USD: +35.1, EUR: +16.0, ASCA: +0.2

Core Operating Profit

Increased by 117.6 Bn JPY (Increased by 116.8 Bn JPY excl. forex impact)

(Bn JPY)



Revenue **+284.6**

incl. forex impact of +51.3

Cost of Sales **-9.8**

Improvement in cost of sales ratio by change in product mix

SG&A Expenses **+71.9**

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

R&D Expenses **+54.5**

Increase in 5DXd ADCs* R&D investments

Forex Impact **+50.5 (Profit Decreased)**

Cost of Sales **+10.8**

SG&A Expenses **+25.6**

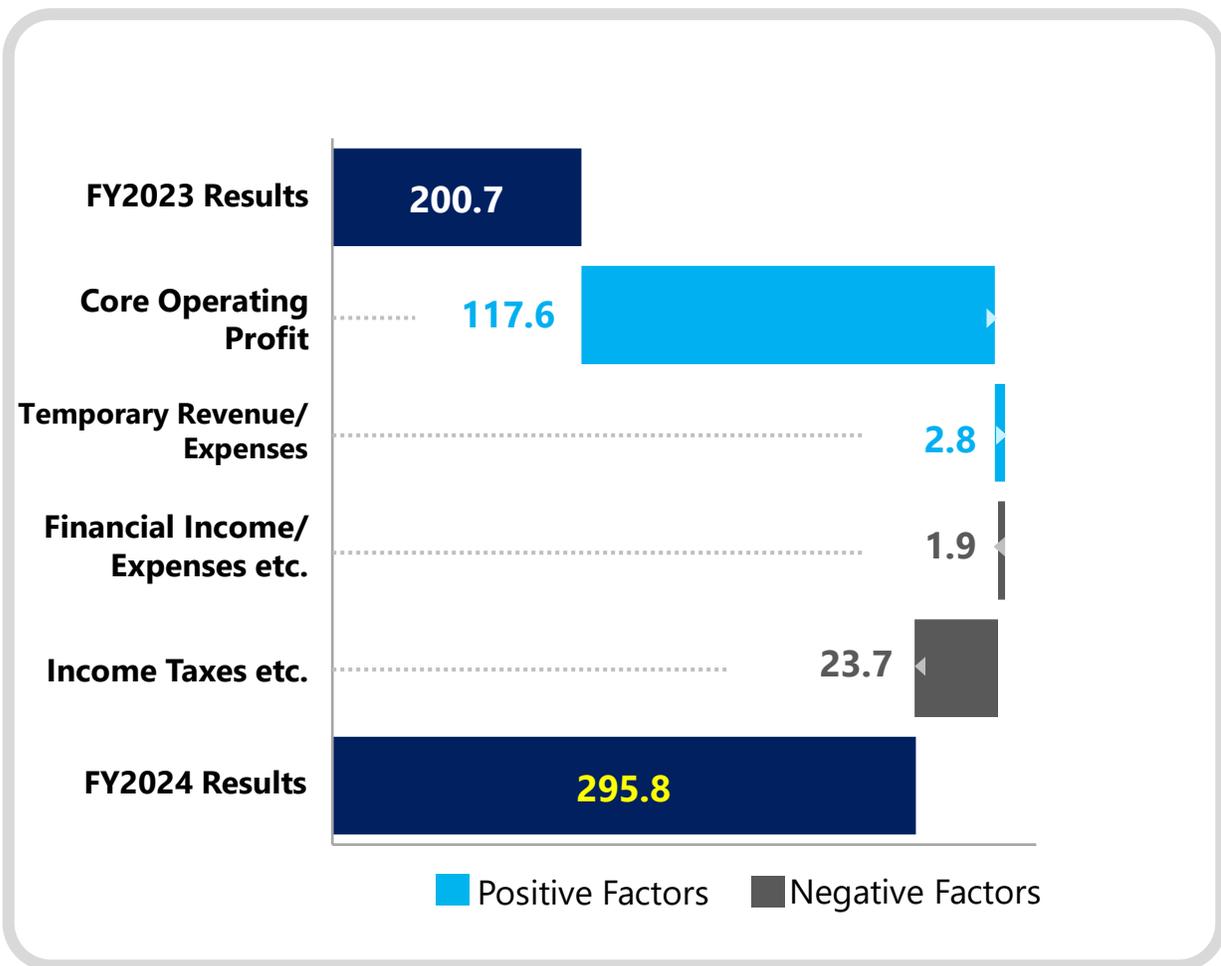
R&D Expenses **+14.1**

***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 (INN), DS-6000 (CDH6-directed ADC)

Profit Attributable to Owners of the Company

Increased by 95.0 Bn JPY

(Bn JPY)



Temporary Income/Expenses +2.8 (Profit Increased)

	FY2023 Results	FY2024 Results	YoY
Temporary Income	27.3 ^{*1}	22.2 ^{*2}	-5.1
Temporary Expenses	10.9 ^{*3}	3.1	-7.9

- *1 Lump sum payment received from Novartis following the settlement of Plexxikon's patent infringement lawsuit (26.4)
- *2 Gains on stock transfer of Daiichi Sankyo Espha (16.3)
- *3 Environmental expenditures related to former Yasugawa plant (4.1)

Financial Income/Expenses etc. -1.9 (Profit Decreased)

- Deterioration in forex gains/losses -4.5
- Increase in interest income +3.3

Income Taxes etc. +23.7 (Profit Decreased)

	FY2023 Results	FY2024 Results	YoY
Profit before Tax	237.2	355.6	+118.4
Income Taxes etc.	36.2	59.9	+23.7
Tax rate	15.3%	16.8%	

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Progress towards “Maximize 3ADCs”

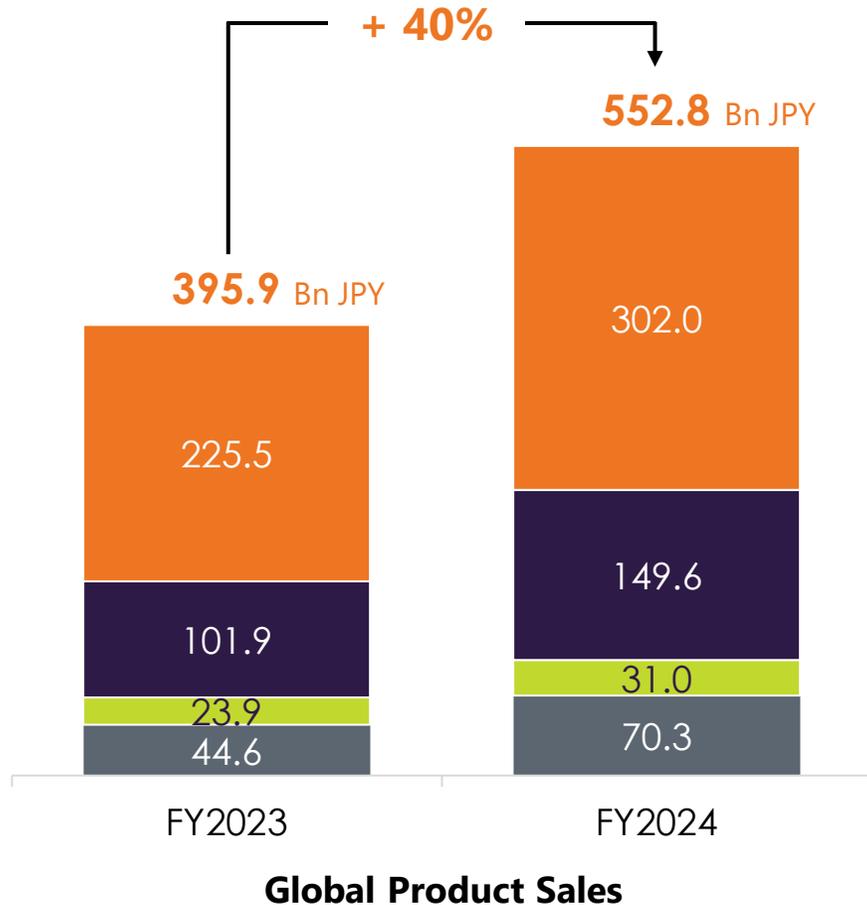
Progress towards “Profit growth for current business and products”

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Global Product Sales

FY2024 Product Sales Result **552.8 Bn JPY** (YoY **+156.9 Bn JPY**) FY2025 Forecast **662.1 Bn JPY** (YoY **+109.3 Bn 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 (+34%)	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 (+47%)	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 ➤ HR+, HER2 low* or HER2 ultralow** BC (chemo naïve) approved in Mar
Japan (+30%)	Maintained No.1 new patient share in all indications including early market adoption of HER2 low BC (post-chemo)
ASCA (+58%)	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[®] (anti-TROP2 ADC) approved in Japan, the US and EU

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

◆ Approval acquisition date

- Japan: December 2024
- US: January 2025
- EU: April 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 results for FY2024 (Japan, US)

- 1.4 Bn JPY
- Steady revenue uptake

◆ Included in NCCN guidelines (Jan)



Co-development and Co-commercialization for MK-6070

Added **MK-6070***, which is being developed by Merck & Co., Inc., Rahway, NJ, USA (MRK), to the existing global **co-development and co-commercialization agreement** for 3 DXd ADC products (HER3-DXd, I-DXd, R-DXd)

Development

- ◆ **Co-develop MK-6070 worldwide** (excluding Japan)
- ◆ Plan to evaluate MK-6070 in **combination with I-DXd** in certain patients with **SCLC**** as well as other potential products
- ◆ The companies will share **R&D expenses equally**
But **R&D expenses related to MK-6070 in combination with 3 DXd ADC products** will be shared in a manner consistent with the original agreement (MRK will be responsible for **75%** of the first 2 Bn USD of R&D expenses for each product, and the companies will share R&D expenses **equally** thereafter)

Commercialization

- ◆ **Global (excluding Japan):**
 - The companies will **co-promote** and **share gross profit** and **promotional expenses etc.**
- ◆ MRK will book product sales worldwide
- ◆ **Japan:** MRK will solely commercialize (DS will **receive royalty** from MRK)

Manufacturing

- ◆ MRK will **manufacture** and **supply** MK-6070

Financial Terms

- ◆ Consideration for collaboration : **320Mn USD**
 - DS's contingent quid rights*** from the original agreement (equivalent to 150Mn USD) is applied to the collaboration for MK-6070. In addition, 170Mn USD is paid in cash as an upfront payment
- ◆ Accounting treatment
 - Consideration of 320Mn USD (46.5Bn JPY) will be recorded as an expense over the expected loss of exclusivity (LOE) period starting from the regulatory approval of MK-6070
 - 150Mn USD (21.8Bn JPY) related to DS's contingent quid rights will be recorded as revenue over the expected LOE period of 3 DXd ADC products in collaboration with MRK under the original agreement

* DLL3 directed tri-specific T-cell engager (Formerly: HPN328, generic name: gocatamig) ** small cell lung cancer

***Rights to develop and/or commercialize MRK's developed products or products solely by DS or jointly with MRK. If the rights are not exercised within a certain period, DS receives 150Mn USD from MRK.

Progress towards “Maximize 3ADCs”

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Other Regional Initiatives

Japan

◆ **EZHARMIA[®] Anti-Cancer Agent / EZH1 and EZH2 Inhibitor**

- Jun. 2024 Approved for the treatment of adult patients with relapsed or refractory peripheral T-cell lymphoma (PTCL)

◆ **Belsomra[®] Anti-Insomnia Treatment / Dual Orexin Receptor Antagonist**

- Jul. 2024 Decision made to transfer of distribution rights from MSD to Daiichi Sankyo
 - Started sale and promotional activities from October 1, 2024 onwards

◆ **DAICHIRONA[®] INTRAMUSCULAR INJECTION COVID-19 Vaccine**

- Sep. 2024 Launched Omicron JN.1-adapted mRNA vaccine

◆ **FLUMIST[®] INTRANASAL SPRAY Influenza Vaccine**

- Oct. 2024 Launched Intranasal live attenuated influenza vaccine

◆ **LIXIANA[®] Anticoagulant / FXa inhibitor**

- Feb. 2025 Approved for the prevention of thromboembolism in patients with chronic thromboembolic pulmonary hypertension

EU

◆ **Nilemdo[®]/Nustendi[®] Cholesterol-lowering agent**

- May 2024 Approved for treatments to reduce the risk of adverse cardiovascular event
 - The first and only non-statin LDL-C-lowering treatments indicated for primary and secondary prevention of cardiovascular events

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

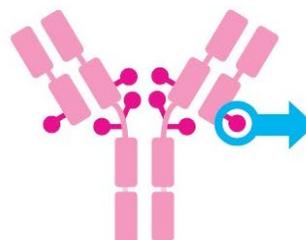
◆ Anti-TA-MUC1** antibody

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

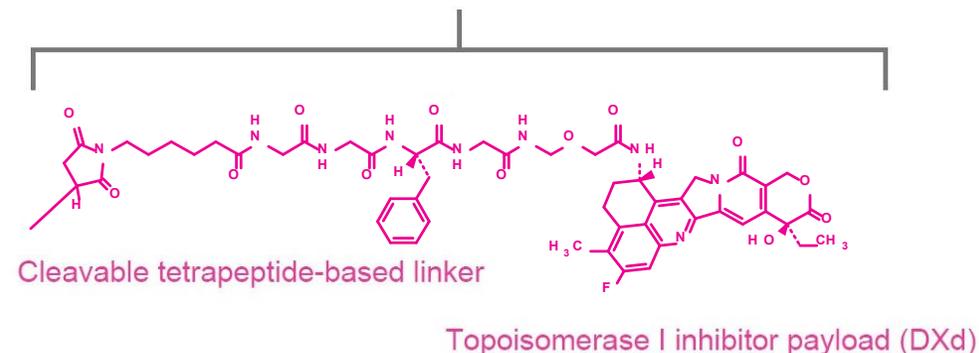
◆ Development status of DS-3939

- 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

Progress towards “Maximize 3ADCs”

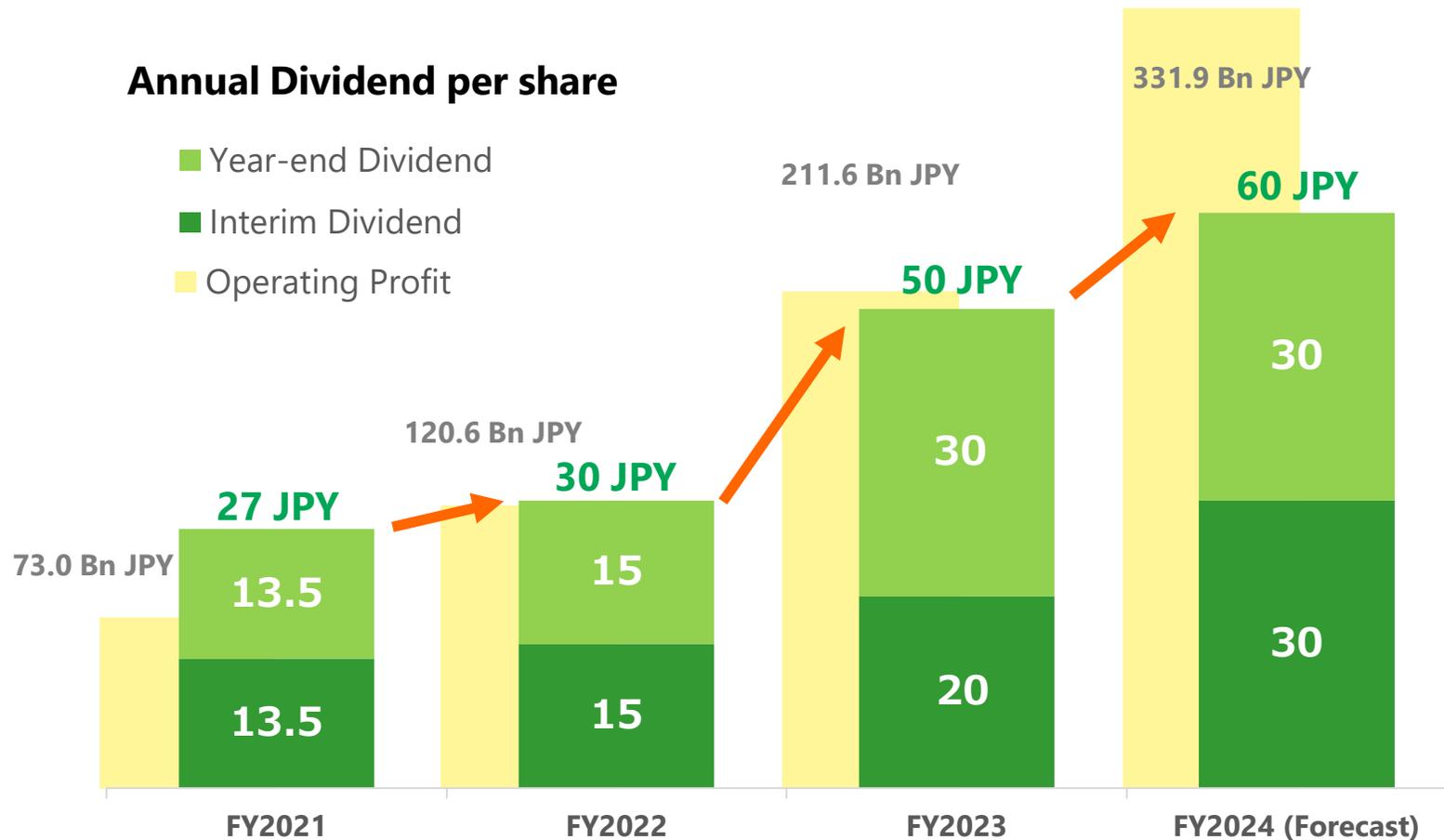
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FY2024 Annual Dividend Forecast

Increase annual dividend forecast per share from 50 JPY (FY2023) to 60 JPY (FY2024)
due to strong performance of ENHERTU® and others



Flexible Acquisition of Own Shares (Results)

- ◆ **Acquired own shares to strengthen and enhance shareholder returns**
- ◆ **FY2025 DOE is expected to be over 8.5%**

Apr. 2024 Resolution

- Acquisition period: **Apr. 26, 2024 – Jan. 9, 2025**
- Aggregate amount of acquisition cost: **200 billion JPY (maximum)**
- Total number of shares to be acquired: **38.71 million stocks (maximum)**
- Completed the cancellation of all of acquired own shares

Feb. 2025 Resolution

- Acquisition period: **Mar. 3, 2025 – Apr. 8, 2025**
- Aggregate amount of acquisition cost: **50 billion JPY (maximum)**
- Total number of shares to be acquired: **13.97 million stocks (maximum)**
- Scheduled to cancel all of acquired own shares on May 30, 2025.

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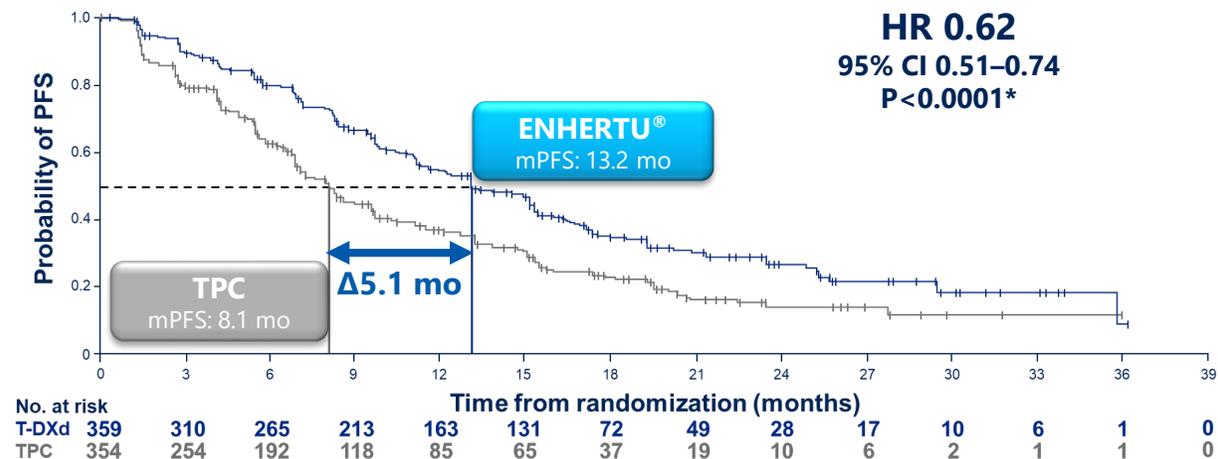
Progress towards “Profit growth for current business and products”

ASCO 2025

News Flow

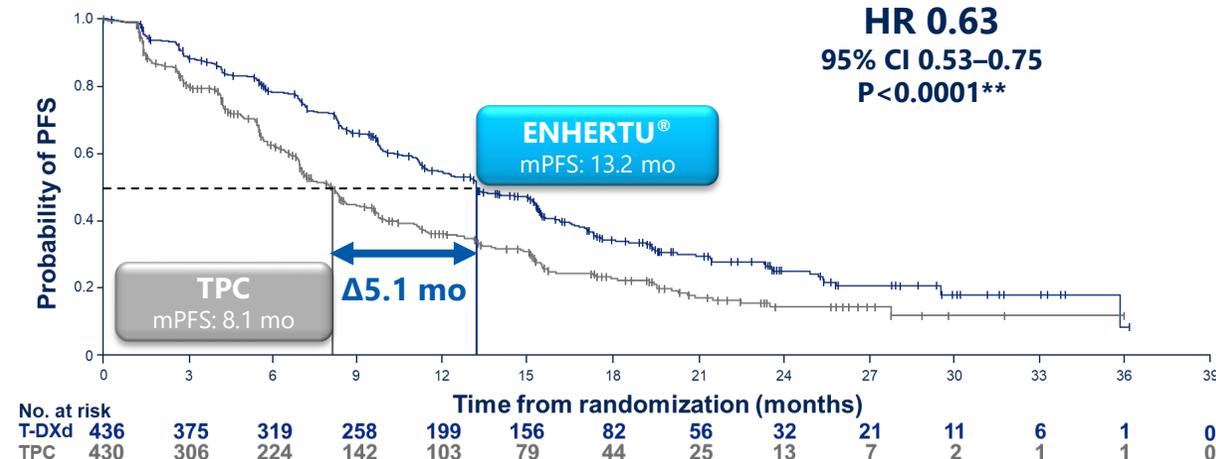
ENHERTU® demonstrated efficacy in HER2 ultralow as well as HER2 low chemo naïve BC, and is approved in the US and EU

PFS for HER2 low (BICR)



Data cutoff: March 18, 2024
*P-value of <0.05 required for statistical significance

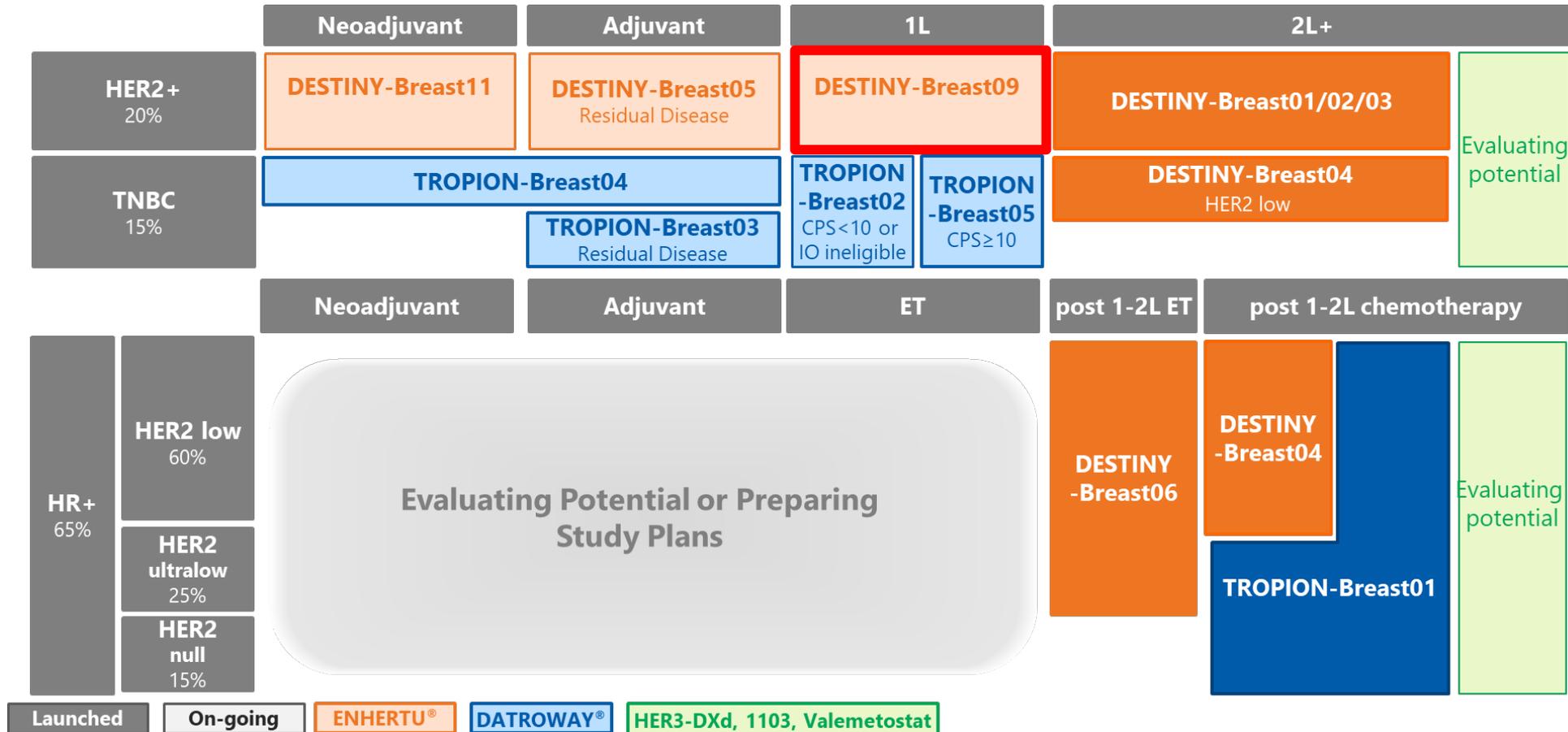
PFS for ITT (HER2 low and ultralow) (BICR)



Data cutoff: March 18, 2024
**P-value of <0.015 required for statistical significance

- ENHERTU® demonstrated a statistically significant and clinically meaningful improvement in PFS for chemo naïve HR positive, HER2 low and ultralow metastatic BC. No new safety concerns identified
- Approved for this indication in US in Jan 2025 and in EU in Mar 2025. Expected approval in Japan in FY2025 H1
- Filed in China in Apr 2025
- ENHERTU® is **approved to treat about 90 percent of people with mBC**

Ph3 study evaluating the efficacy and safety of ENHERTU® in mBC either alone or in combination with pertuzumab vs 1L SOC

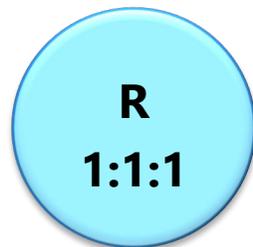


ENHERTU® + pertuzumab demonstrated highly statistically significant and clinically meaningful improvement in PFS as 1L therapy for patients with HER2+ mBC

DESTINY-Breast09 Study Design

Eligible patients

- Advanced and/or metastatic BC
- HER2 positive (IHC3+ or ISH+) by central confirmation
- No previous chemotherapy or HER2-targeted therapy for advanced or metastatic BC except for 1 previous line of endocrine therapy in the metastatic setting



Arm A: ENHERTU® + placebo

Arm B: ENHERTU® + pertuzumab

Arm C: THP*

Primary endpoint:
PFS by BICR

Secondary endpoint:
PFS by investigator,
OS, ORR, DOR, etc.

*THP: paclitaxel qw
+ trastuzumab q3w
+ pertuzumab q3w

- **The PFS improvement was seen across all pre-specified patient subgroups** with ENHERTU® in combination with pertuzumab
- OS was not mature at the time of this planned interim analysis; however, interim OS data showed an early trend favoring the ENHERTU® combination compared to THP
- The safety profile of ENHERTU® in combination with pertuzumab was consistent with the known profiles of each individual therapy
- ENHERTU® monotherapy arm versus THP remains blinded to patients and investigators and will continue to the final PFS analysis
- Data from the combination arm will be presented at an upcoming medical meeting and shared with regulatory authorities

Improving patient outcomes by expanding into earlier lines and building on the success of ENHERTU® in 2L+ HER2 positive GC

HER2 positive gastric cancer		
1L (PD-L1 CPS \geq 1)	2L	3L
DESTINY-Gastric05* (Ph3) pembrolizumab+ 5-FU or capecitabine combo	DESTINY-Gastric02 (Ph2) Completed	DESTINY-Gastric01 (Ph2) Completed
ARTEMIDE-Gastric01 (Ph3) rilvegostomig+ 5-FU or capecitabine combo	DESTINY-Gastric04 (Ph3) Monotherapy	DESTINY-Gastric06 (Ph2) China only

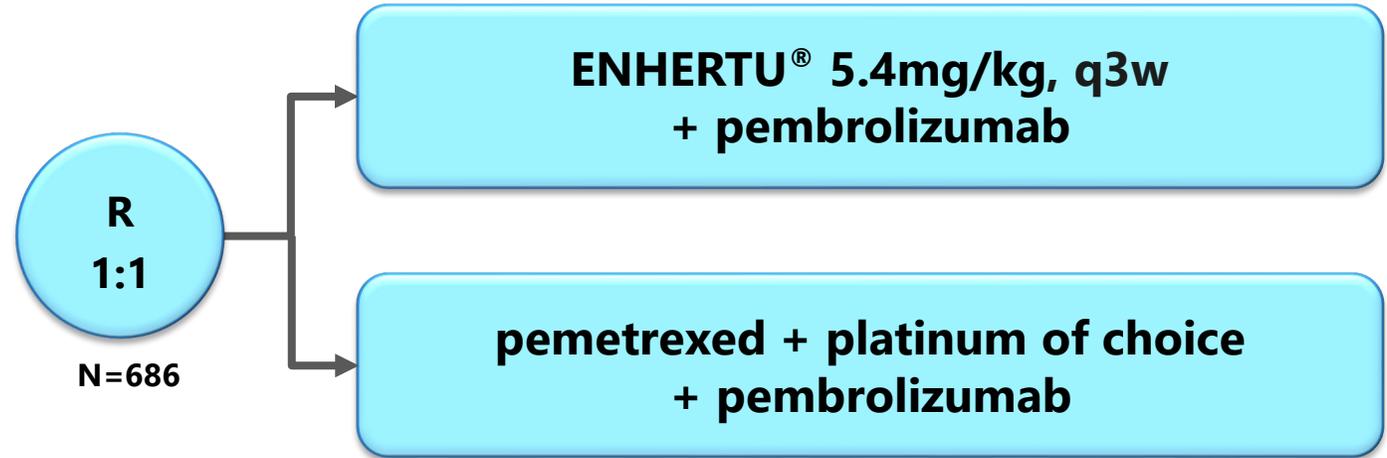
- In Mar 2025, **positive DESTINY-Gastric04 results demonstrated statistically significant and clinically meaningful improvement in OS** primary endpoint
 - Seeking approval in regions where ENHERTU® not currently indicated for 2L, i.e., Japan
 - Securing full approval in regions with conditional approval, i.e., EU and China
 - Data will be presented at ASCO 2025
- Both DESTINY-Gastric05 and ARTEMIDE-Gastric01 started in Mar 2025

Expand into earlier treatment lines by combining with current SOC to maximize patient outcomes for HER2 overexpressing NSCLC

DESTINY-Lung06 Study Design

Eligible Patients

- Locally advanced unresectable or metastatic non-squamous NSCLC
- No prior systemic anticancer therapy for advanced/metastatic NSCLC
- HER2 overexpression
- PD-L1 TPS <50%
- No known AGAs



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

- DESTINY-Lung06 aims to replace standard chemotherapy in 1L SOC with ENHERTU® for HER2 overexpressing and PD-L1 TPS <50% NSCLC
- Plan to start in FY2025 H1

Building on success of Tumor Agnostic indication, opportunities for ENHERTU® continue to expand

Expansion of approved countries

- Apr 2024: Approved in the US HER2 positive (IHC 3+) solid tumors with prior systemic treatment and without satisfactory alternative treatment options
- Apr 2025: **Filed in Japan for HER2 expressing recurrent or metastatic solid tumors** based on HERALD*, DESTINY-PanTumor02, DESTINY-CRC02 and DESTINY-Lung01

Expansion in HER2 Expressing tumors

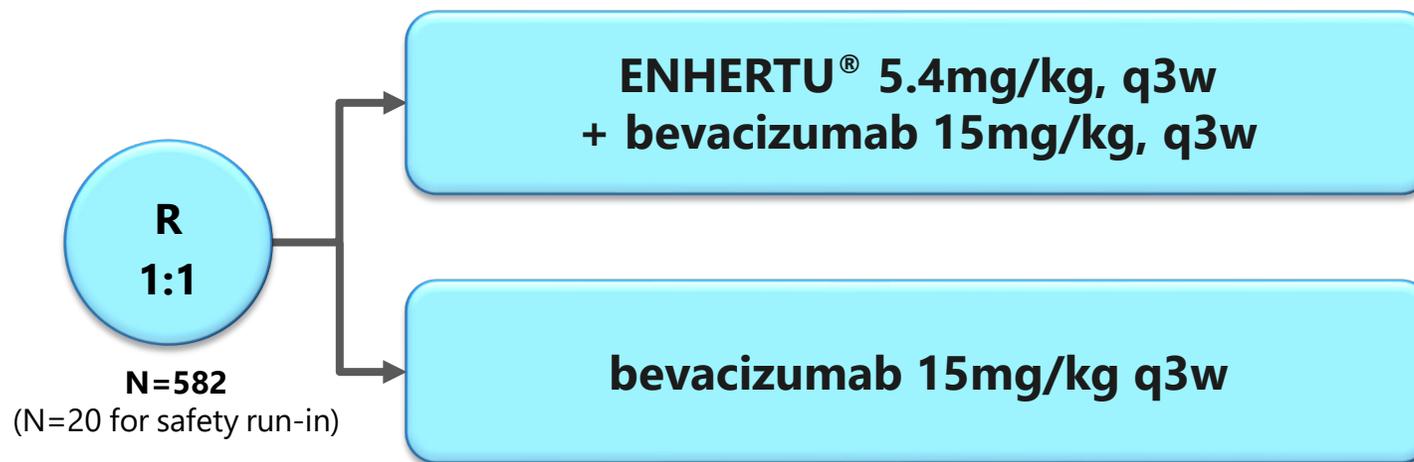
- Aug 2024: DESTINY-BTC01 Ph3 for HER2 expressing biliary tract cancer 1L started
- Plan to start **DESTINY-Ovarian01 Ph3** in HER2 IHC 3+/2+/1+ ovarian cancer 1L maintenance therapy

A new Ph3 study for HER2 expressing ovarian cancer 1L maintenance

DESTINY-Ovarian01 Study Design

Eligible Patients

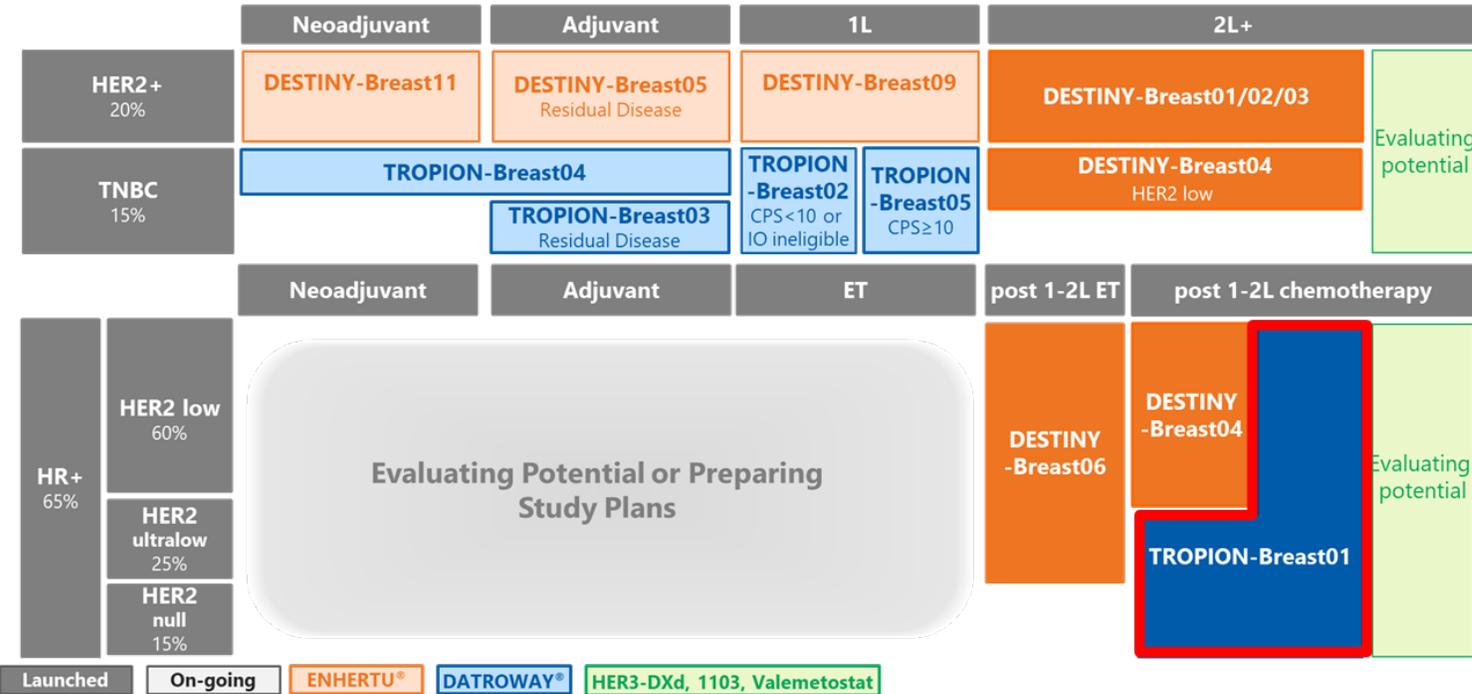
- Histologically confirmed diagnosis of epithelial high-grade ovarian, fallopian tube or primary peritoneal carcinoma
- Newly diagnosed FIGO Stage III or IV
- HER2 IHC3+, IHC2+ or IHC1+
- Have received standard of care bevacizumab in combination with front line platinum-based chemotherapy
- Without BRCA mutation
- Not eligible for PARPi maintenance



Primary endpoint: PFS by BICR in HER2 IHC 3+/2+ population
 Secondary endpoint: OS in HER2 IHC 3+/2+ population, PFS and OS in HER2 IHC 3+/2+/1+ population

- Observed encouraging signals in heavily pre-treated population in DESTINY-PanTumor02 study (ASCO 2023, ESMO 2023)
 - ✓ Data for ovarian cancer population: cORR: 45.0% (18/40), mDOR: 11.3 mo (95% CI: 4.1, 22), mPFS: 5.9 mo (95% CI: 4.0, 8.3)
- Plan to start in FY2025 H1

Providing new treatment options for HR positive, HER2 negative breast cancer patients



- DATROWAY® approved in Japan in Dec 2024 and in US in Jan 2025 for HR-positive, HER2 negative (IHC 0, IHC 1+ or IHC 2+/ISH-) post-chemo metastatic BC based on the results of TROPION-Breast01
- Positive CHMP opinion received January 2025 leading to **approval in EU in April 2025**
- TLR of TROPION-Breast02 (TNBC, PD-1/PD-L1 inhibitor ineligible, 1L) is anticipated for FY2025 H1

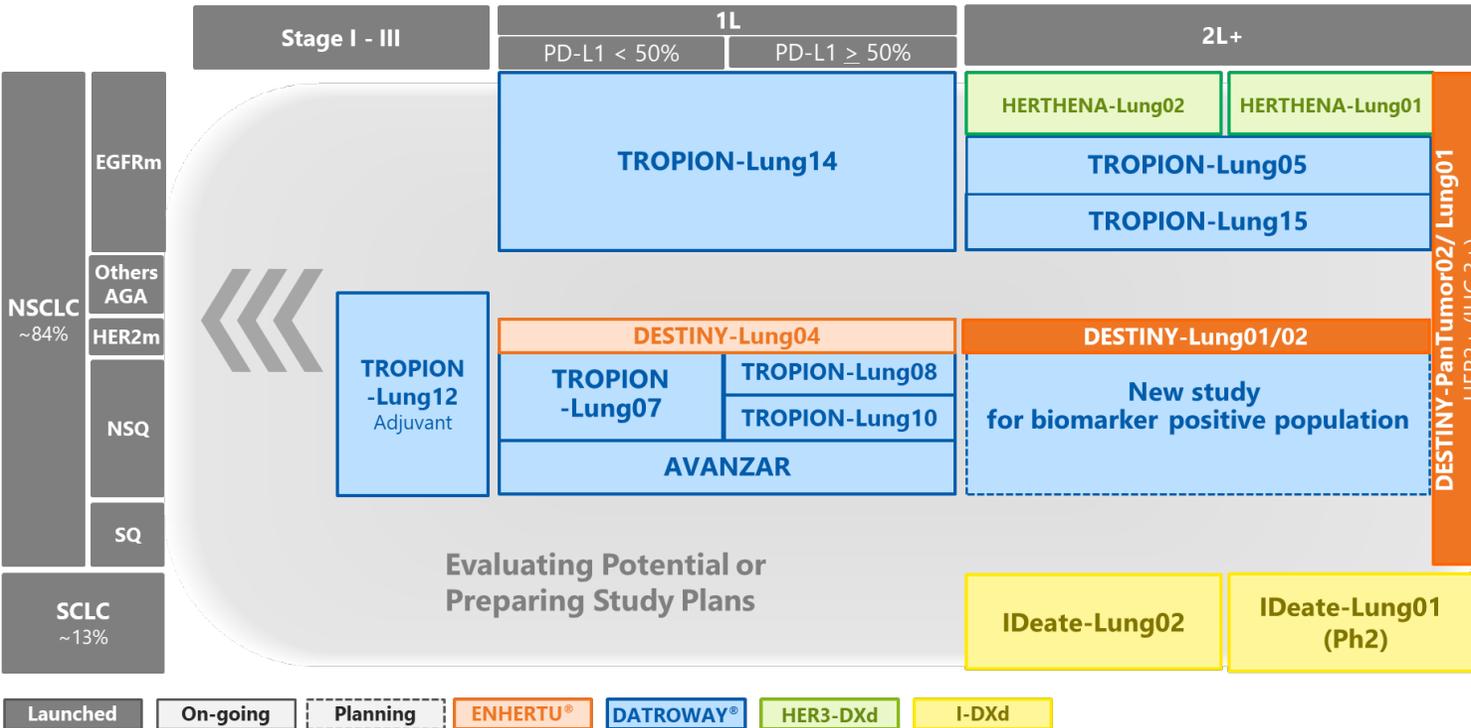
Progressing development for EGFR mutated NSCLC

EGFR mutated NSCLC

- FDA issued CRL for HER3-DXd HERTHENA-Lung01 in June 2024 following inspection of third-party manufacturing facility
- In Sep 2024, HERTHENA-Lung02 met its primary endpoint
- **FDA accepted DATROWAY® submission** with Priority Review for the treatment of patients with EGFR mutated NSCLC who have received prior systemic therapies, including an EGFR-directed therapy based on TROPION-Lung05* in Jan 2025 (PDUFA date: Jul 12, 2025)

Other NSCLC programs

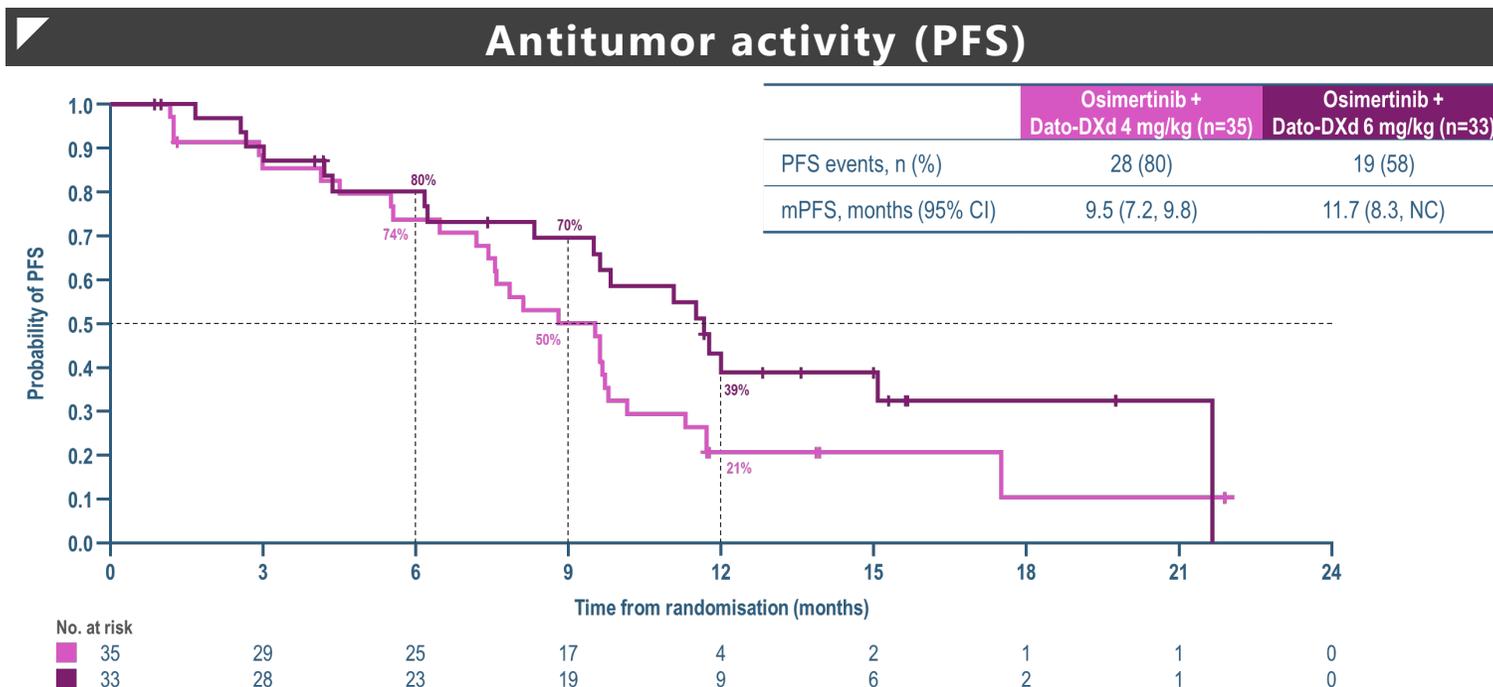
- Four new Ph3 studies of DATROWAY® started in FY2024
- TLR of AVANZAR Ph3 study for 1L treatment is anticipated in CY2025 H2



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

AGA: actionable genomic alteration, CRL: complete response letter, FDA: U.S. Food and Drug Administration, IHC: immunohistochemistry, PDUFA: prescription drug user fee act, NSQ: non-squamous, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, SQ: squamous, TLR: top line results

DATROWAY® in combination with osimertinib demonstrated promising efficacy in EGFR mutated NSCLC progressed after 1L osimertinib



ORCHARD (Ph2)

- ✓ EGFR mutated NSCLC progressing on 1L osimertinib monotherapy
- ✓ Evaluate safety and efficacy of combination therapy of osimertinib 80 mg and DATROWAY® (4 mg/kg or 6 mg/kg) in module10
- ✓ Primary endpoint: ORR

Data cut-off: Oct 12, 2024

- mPFS: 9.5 mo (95% CI: 7.2, 9.8), ORR: 43% (80% CI: 31, 55), mDOR: 6.3 mo (95% CI: 3.8, 8.2) in DATROWAY® 4 mg/kg cohort and mPFS: 11.7 mo (95% CI: 8.3, NC), ORR: 36% (80% CI: 25, 49), mDOR*: 20.5 (95% CI: 6.2, NC) in 6 mg/kg cohort
- No new safety signals were identified in either cohort
- Two Ph3 studies, TROPION-Lung14 and TROPION-Lung15 are ongoing to evaluate efficacy of DATROWAY® in combination with osimertinib in EGFR mutated NSCLC

*: mDOR not yet mature for 6 mg/kg cohort CI: confidence interval, Dato-DXd: datopotamab deruxtecan, DATROWAY®, ELCC: European Lung cancer Congress, NC: not calculable, NSCLC: non-small cell lung cancer, mDOR: median duration of response, mo: month(s), mPFS: median progression-free survival, ORR: objective response rate, PFS: progression-free survival

Ph2 signal seeking study for pCR improvement by determining optimal sequence of ADC and chemotherapy in neoadjuvant setting

HERTHENA-Breast03 Study Design (Part 2)

Eligible Patient

- Centrally confirmed TNBC or HR low/HER2 negative BC
- No metastases
- No previous systemic therapy
- No previous excision of primary tumor

R
1:1:1
N=342

Neoadjuvant Cycle 1-4

HER3-DXd
+ pembrolizumab

paclitaxel
+ carboplatin
+ pembrolizumab

paclitaxel
+ carboplatin
+ pembrolizumab

Neoadjuvant Cycle 5-8

paclitaxel
+ carboplatin
+ pembrolizumab

HER3-DXd
+ pembrolizumab

doxorubicin or
epirubicin
+ cyclophosphamide
+ pembrolizumab

Surgery ±
post surgery
radiotherapy

Adjuvant

Pts with pCR,
➤ pembrolizumab
400 mg q6w x 5

Pts with residual disease,
➤ pembrolizumab
400 mg q6w x 5
± additional
adjuvant TPC

Follow-up

- HER3-DXd Ph1 study demonstrated promising efficacy in heavily pretreated mTNBC
 - ✓ ORR: 22.6% (95% CI: 12.3, 36.2), mPFS: 5.5 mo (95% CI: 3.9, 6.8), mOS: 14.6 mo (95% CI: 11.2, 17.2) (ASCO 2022)
- Part 2 begins after DLT evaluation for HER3-DXd pembrolizumab combination as safety run-in (Part 1)
- Plan to start in FY2025 H1

Primary Endpoints: pCR, safety/tolerability
Secondary Endpoints: RCB, EFS, DPDRFS, OS

Progress towards “Maximize 3ADCs”

Progress towards “Profit growth for current business and products”

ASCO 2025

News Flow

I-DXd and R-DXd demonstrate their significance as 'further growth pillars' supported by the strategic collaboration with MRK*

I-DXd

- Steady progress for ES-SCLC
 - IDeate-Lung01 Ph2 study is proceeding
 - **IDeate-Lung02 Ph3 study in SCLC** started in Aug 2024
 - Combination study with MK-6070 (gocatumig) started
 - Granted Orphan Drug Designation for SCLC in Japan in Dec 2024
- Expand to tumor types beyond SCLC
 - Plan to start **IDeate-Esophageal01** Ph3 study for pretreated ESCC in FY2025 H1
 - Plan to start **two new studies for mCRPC**
 - Starting with IDeate-PanTumor02, conducting exploratory studies across a wide range of tumor types

R-DXd

- Steady progress for ovarian cancer
 - **First pivotal Ph2/3 study (REJOICE-Ovarian01)** started in Apr 2024
 - **REJOICE-Ovarian02 Ph1b/2 study** to evaluate combination of R-DXd with either carboplatin, paclitaxel, or bevacizumab is under preparation
 - Granted Orphan Drug Designation for ovarian cancer in EU in Feb 2025
 - Granted Orphan Drug Designation for platinum-resistant ovarian cancer in Japan in Mar 2025
- Exploratory studies across multiple tumor types underway
 - In Jan 2025, REJOICE-PanTumor01 for multiple solid tumors started
 - Studies for ES-SCLC, squamous NSCLC, non-squamous NSCLC, gastrointestinal cancers, etc are ongoing.

*MRK: Merck & Co., Inc., Rahway, NJ, USA

ESCC: esophageal squamous cell carcinoma, ES-SCLC: extensive-stage small cell lung cancer, mCRPC: metastatic castration-resistant prostate cancer, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, TLR: top line results

New Ph3 study of I-DXd in chemo naive metastatic castration-resistant prostate cancer (mCRPC)

IDeate-Prostate01 Study Design

Eligible Patients

- Metastatic CRPC with ≤ 2 ARPI treatment
- Prostate cancer progression while on androgen deprivation therapy (or post bilateral orchiectomy) within 6 months before screening
- No requirement on B7-H3 expression status (B7-H3 expression is to be confirmed during the study)



Primary endpoint: OS, rPFS

Secondary endpoint: TFST, OR, DOR etc.

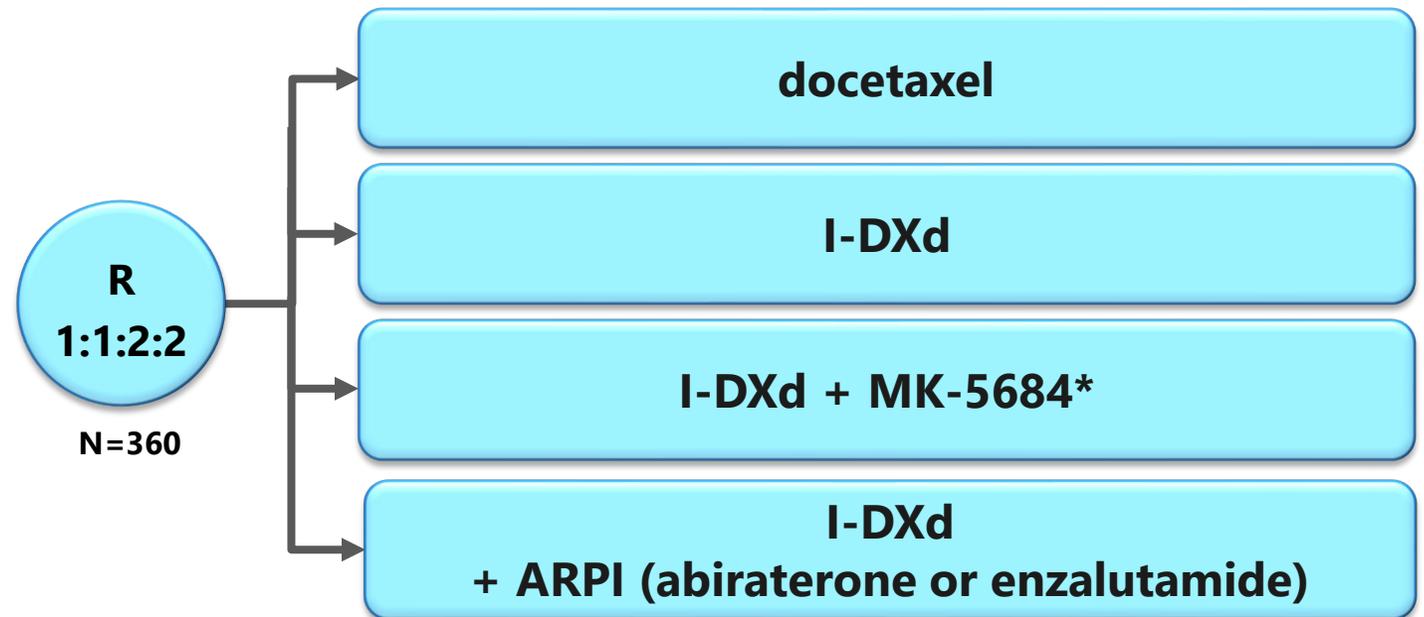
- B7-H3 is highly expressed in metastatic CRPC, and its overexpression is associated with a poor prognosis
- Observed encouraging signals in heavily pre-treated population in Ph1/2 study (ESMO 2023)
 - ✓ cORR: 25.4% (15/73, 95% CI: 15.0, 38.4), mPFS: 5.3 mo (95% CI: 4.1, 6.9), mOS: 13.0 mo (95% CI: 10.3, 16.0), Number of prior treatments, median: 6 (1-11)
- Plan to start in FY2025 H1

New Ph1/2 study of I-DXd in chemo naïve metastatic castration-resistant prostate cancer (mCRPC)

IDeate-Prostate02 Study Design

Eligible Patients

- Histologically- or cytologically-confirmed adenocarcinoma of the prostate without small cell histology
- Prostate cancer progression while on androgen deprivation therapy (or post bilateral orchiectomy) within 6 months before screening
- Received 1 or 2 prior ARPI treatment and progressed during or after treatment



Primary outcome measures: safety, PSA response rate
 Secondary outcome measures: ORR, rPFS, OS, DOR etc.

- Study will evaluate safety and tolerability of I-DXd, a safe dose level of I-DXd that can be used with other treatments and participant levels of prostate specific antigen (PSA) during treatment
- Plan to start FY2025 H1

Plan to start a **signal-seeking study in gastrointestinal cancers** in addition to REJOICE-PanTumor01 started in January 2025

REJOICE-GI01 Study Design

Eligible Patients

- One of the following cancers:
 - Pancreatic adenocarcinoma (PDAC)
 - Biliary tract cancer (BTC)
 - Colorectal cancer
 - Gastroesophageal adenocarcinoma
- Received prior therapy for the cancer

PDAC

BTC

Colorectal cancer

Gastroesophageal
adenocarcinoma

N=160

Outcome Measures

Primary:

ORR

Secondary:

safety, DOR, PFS, OS

- Assess safety and efficacy of R-DXd in gastrointestinal cancers
- Plan to start in FY2025 H1

Oncology

- ◆ **EZHARMIA[®]** (EZH1/2 inhibitor)
 - Approval for r/r PTCL in Japan (Jun 2024)
 - Started a Ph1b/2 study for NSCLC 1L in combination with pembrolizumab (Oct 2024)
- ◆ **VANFLYTA[®]** (FLT3 inhibitor)
 - Started QuANTUM-Wild Ph3 study for *FLT3*-ITD negative AML (Dec 2024)
- ◆ **DS-3939** (TA-MUC1 directed ADC)
 - **Acquired intellectual property rights for anti-TA-MUC1 antibody from Glycotope GmbH (Dec 2024)**
- ◆ **DS-2243** (HLA-A*02/NY-ESO directed bispecific T-cell engager)
 - **Started Ph1 study (Mar 2025)**

Specialty Medicine

- ◆ **LIXIANA[®]** (Factor Xa inhibitor)
 - **Approval for chronic thromboembolic pulmonary hypertension (CTEPH) in Japan (Feb 2025)**
- ◆ **TARLIGE[®]** ($\alpha_2\delta$ ligands)
 - Approval for diabetic peripheral neuropathic pain in China (Jun 2024)

Vaccine

- ◆ **DAICHIRONA^{®*}** (COVID-19 mRNA vaccine)
 - **Approval of vaccine for omicron strain for children aged 5 to 11 years in Japan (Mar 2025)**

Bold : update from FY2024 Q3

ADC: antibody-drug conjugate, AML: acute myeloid leukemia, NSCLC: non-small cell lung cancer, PTCL: peripheral T-cell lymphomas, r/r: relapsed/ refractory

* The research and development of DAICHIRONA[®] FOR INTRAMUSCULAR INJECTION is being conducted through the "Vaccine development project" promoted by the Japan Agency for Medical Research and Development (AMED) and the "Urgent improvement project for vaccine manufacturing systems" supported by the Japanese Ministry of Health, Labour and Welfare (MHLW).

Progress towards “Maximize 3ADCs”

Progress towards “Profit growth for current business and products”

ASCO 2025

News Flow

ASCO Highlights 2025: IR conference call



Hiroyuki Okuzawa
President and CEO



Ken Takeshita
Head of Global R&D



Mark Rutstein
Head of Therapeutic Area
Oncology Development

Date and Time

Jun 3, 2025 (Tue) 8:00-9:15am JST/
Jun 2, 2025 (Mon) 6:00-7:15pm CDT

Meeting style

Virtual (Zoom)

Content will be delivered on-demand after the meeting

Progress towards “Maximize 3ADCs”

Progress towards “Profit growth for current business and products”

ASCO 2025

News Flow

Planned major data disclosures

American Society of Clinical Oncology (ASCO, May 30-Jun 3, 2025)

ENHERTU®	DESTINY-Gastric04: HER2+ GC, 2L, Ph3 • Primary results
DATROWAY®	TROPION-Lung02: NSCLC (without AGA), 1L+, pembrolizumab combo, Ph1b • Data update
	TROPION-Lung04: NSCLC (without AGA), 1L/2L, ICI combo, Ph1b • First data of rilvegostomig combo cohort NeoCOAST-2: resectable, early-stage NSCLC, neoadjuvant • Final analysis of pCR and mPR rates in DATROWAY® combo cohort
HER3-DXd	HERTHENA-Lung02: EGFR mutated NSCLC, 2L • Primary data for PFS

Regulatory decisions

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

Key data readouts

ENHERTU®	DESTINY-Breast11: HER2+ BC, neoadjuvant, Ph3 • FY2025 H1
	DESTINY-Breast05*: HER2+ BC, Adjuvant, Ph3 • FY2025 H2
DATROWAY®	DESTINY-Lung04*: HER2 mutant NSCLC, 1L, Ph3 • FY2025 H1
	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, 2L+, Ph2 • FY2025 H1

Bold: update from FY2024 Q3

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

AGA: actionable genomic alteration, BC: breast cancer, ES-SCLC: extensive-stage small cell lung cancer, HR: hormone receptor, IHI: immune checkpoint inhibitor, mPR: major pathological response, NSCLC: non-small cell lung cancer, pCR: pathological complete response, PFS: progression-free survival, TNBC: triple negative breast cancer

Agenda

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- 2 Business Update
- 3 R&D Update
- 4 5-Year Business Plan Update**
- 5 FY2025 Forecast
- 6 Appendix



Strategic Pillars for the 5-Year Business Plan (FY2021-FY2025)

Realize 2025 Goal and Shift to Further Growth

FY2025

Financial Targets

- ◆ Revenue: 1.6 Tr JPY (Oncology > 600.0 Bn JPY)
- ◆ Core Operating Profit* Ratio before R&D Expense: 40%
- ◆ ROE > 16%
- ◆ DOE** > 8%

Maximize 3ADCs

- ◆ Maximize ENHERTU® and Dato-DXd through strategic alliance with AstraZeneca
- ◆ Maximize HER3-DXd without a partner
- ◆ Expand work force and supply capacity flexibly depending on changes around product potential

Profit growth for current business and products

- ◆ Maximize Lixiana® profit
- ◆ Grow Tarlige®, Nilemdo®, etc. quickly
- ◆ Transform to profit structure focused on patented drugs
- ◆ Profit growth for American Regent and Daiichi Sankyo Healthcare

Identify and build pillars for further growth

- ◆ Identify new growth drivers following 3ADCs
- ◆ Select and advance promising post DXd-ADC modalities

Create shared value with stakeholders

- ◆ Patients: Contributing to patients through "Patient Centric Mindset"
- ◆ Shareholders: Balanced investment for growth and shareholder returns
- ◆ Society: Environment load reduction across the value chain, and actions against pandemic risks
- ◆ Employees: Create one DS culture through fostering our core behaviors

- ◆ Data-driven management through DX, and company-wide transformation through advanced digital technology
- ◆ Agile decision making through new global management structure

*Excluding temporary income and expenses (gains/losses related to sales of fixed assets etc.) from operating income

**DOE: Dividend on Equity = Total dividend amount / Equity attributable to owners of the company

5-Year Business Plan: Progress in FY2021-FY2024

Maximize 3ADCs

- ◆ **Maximize product value of ENHERTU®**
 - **Approval of new indication**
 - HER2+ BC 2L, HER2 low BC post-chemo, HR+, HER2 low or HER2 ultralow BC chemo naïve
 - HER2 mutant NSCLC 2L+, HER2+ solid tumors 2L+, etc.
 - **Sales growth in each country/region**
 - **Progress of indication expansion**
- ◆ **Maximize product values of DATROWAY®**
 - **Approval and launch**
 - HR+, HER2- BC with prior endocrine-based therapy and chemotherapy
 - **Filing accepted**
 - EGFR mutated NSCLC with prior systemic therapies, including an EGFR-directed therapy
 - **Progress of indication expansion**
- ◆ **Strategic collaboration for HER3-DXd, I-DXd, and R-DXd, etc.**
 - **Co-development and co-commercialization with MRK*1**
 - **Co-development and co-commercialization for MK-6070**

Profit growth for current business and products

- ◆ **Growth of current products**
 - **Steady sales expansion of Lixiana®**
 - Increase product value with additional dosage and administration*2
 - **Sales increase of current products in each country/region**
 - Tarlige®, Venofer®, Nilemdo®/Nustendi® etc.
 - Increase product values of current products by additional indication/formulation
- ◆ **Transformation of business structure focused on patented drugs**
 - **Launch of new drug**
 - Emgality®, Ezharmia®, Vanflyta®, Daichirona®, FluMist® etc.
 - **Progress of product divestiture after loss of exclusivity in each country/region**
 - **Stock transfer of Daiichi Sankyo Espha Co., Ltd.**
 - Divestiture of generic business in Japan
- ◆ **Profit growth of American Regent and Daiichi Sankyo Healthcare**
 - **Contribution to consolidated performance through increased revenue and profit**

5-Year Business Plan: Progress in FY2021-FY2024

Identify and build pillars for further growth

- ◆ **Emerging growth drivers following 3ADCs**
 - **Progress of development for I-DXd (B7-H3-directed ADC)**
 - Started monotherapy Ph3 study for SCLC
 - Started combination therapy with MK-6070 for SCLC
 - Started exploratory studies for various tumor types
 - **Progress of development for R-DXd (CDH6-directed ADC)**
 - Accumulated promising data for OVC
 - Started Ph2/3 study for OVC
 - Started exploratory studies for several types of cancer
 - **Progress of development for DS-3939 (TA-MUC1-directed ADC)**
 - Started clinical study for solid tumor
- ◆ **Advancement to select post DXd-ADC modalities**
 - **Started clinical study for DS-9606, an ADC with mPBD payload**
 - **Approval and supply of mRNA COVID-19 vaccine, Daichirona® for intramuscular injection**
- ◆ **Established research institutes in the U.S. and EU, and smart research laboratory in the U.S**

Create shared value with stakeholders

- ◆ **Strengthening and enrichment of shareholder returns**
 - **Shareholder returns taking account of profit growth**
 - Increased annual dividend in three consecutive years due to profit growth of ENHERTU®, and received upfront payment related to strategic collaboration with MRK etc
 - Executed two rounds of own shares acquisition from April 2024
- ◆ **Actions against pandemic risks**
 - **Supply of Daichirona® for intramuscular injection**
- ◆ **Environment load reduction across the value chain**
 - **Progress initiative for environmental issues**
 - Joined RE100, a global initiative aiming to use 100% renewable energy for electricity consumed in business activities
 - Converted electricity consumed in bases in Japan to renewable energy
- ◆ **Penetration of Core Behavior for fostering one DS culture**
 - **Further understanding of three Core Behaviors through workshop by management and employees**

Expectation on achieving FY2025 KPIs

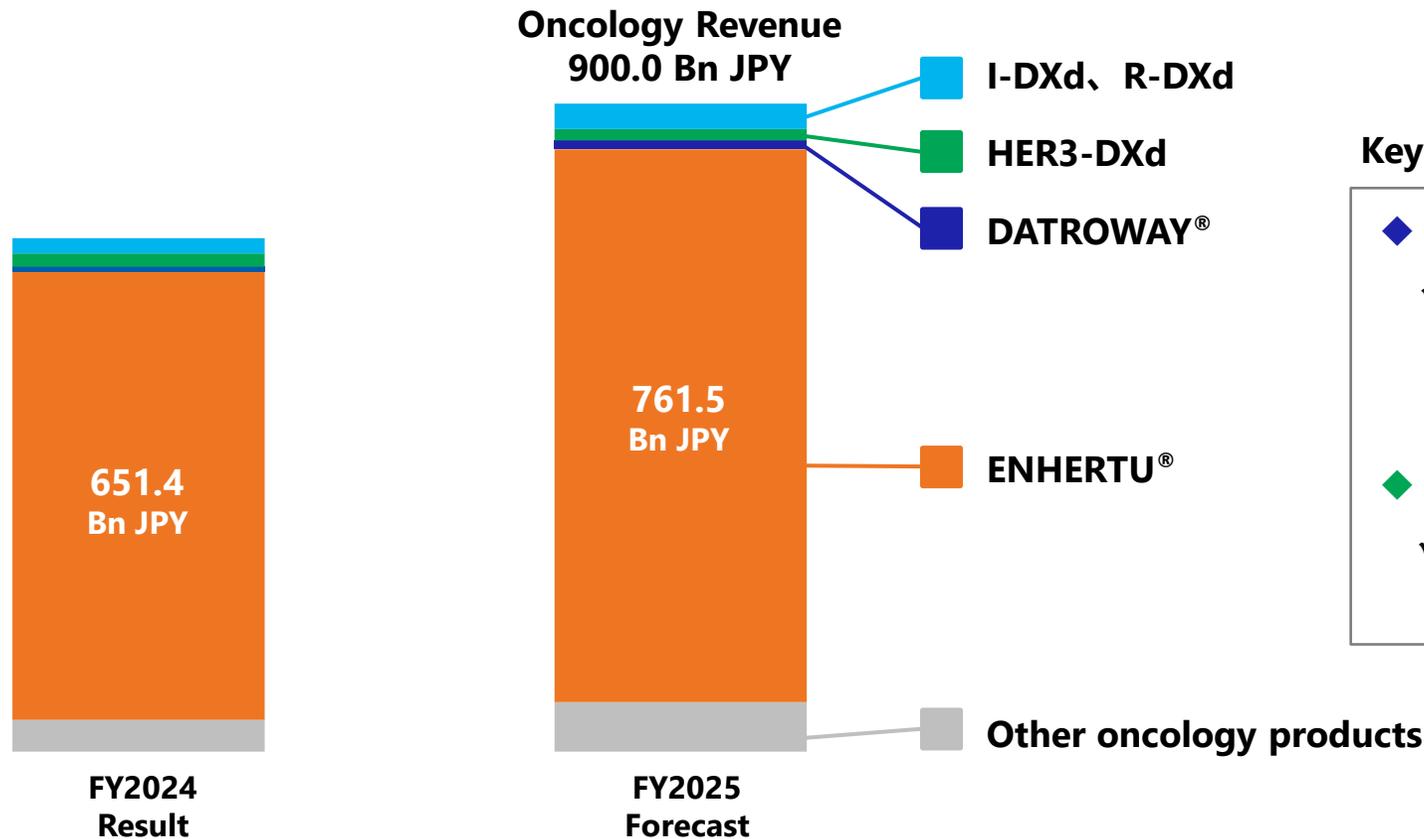
(as of Apr. 2025)

	At the time of planning 5YBP	As of Apr. 2024	As of Apr. 2025
Revenue	1.6 Tr JPY	2.1 Tr JPY	2.0 Tr JPY
Revenue in Oncology	> 600.0 Bn JPY	> 1.0 Tr JPY	900.0 Bn JPY
Core Operating Profit ratio before R&D expense	40%	40%	40%
ROE	> 16%	> 16%	> 16%
DOE	> 8%	> 8.5%	> 8.5%
Currency exchange rate assumptions	1 USD=105 JPY, 1 EUR=120 JPY	1 USD=145 JPY, 1 EUR=155 JPY	1 USD=140 JPY, 1 EUR=160 JPY

Oncology Revenue Forecast

(as of Apr. 2025)

FY2025 oncology revenue* is forecasted to be **900 Bn JPY**, driven by steady growth of ENHERTU[®], despite a decline from the April 2024 forecast due to changes in DATROWAY[®]'s development strategy



Key drivers of decline vs. Apr 2024 forecast

◆ DATROWAY[®]

- ✓ The number of eligible patients decreased and launch delayed due to development strategy update on NSCLC (TL01 → TL05 study)

◆ HER3-DXd

- ✓ Launch delayed due to complete response letter

* Revenue for 5DXd ADCs includes alliance revenue (50% of gross profit from product sales in countries/regions where AstraZeneca and US Merck book sales), upfront payments, development and sales milestones received from both collaborators based on strategic alliance agreements

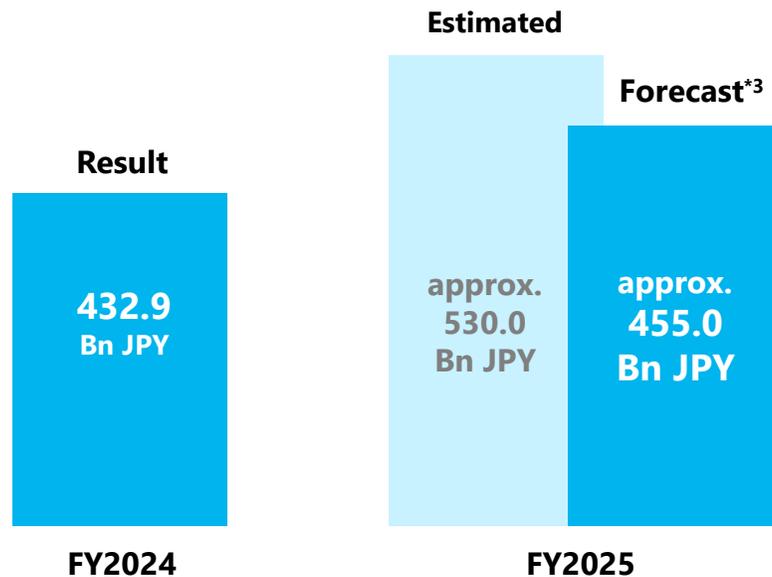
R&D Expense Forecast

(as of Apr. 2025)

FY2025 R&D expense is forecasted to be **455 Bn JPY** based on development plan updates

R&D Expense Trend

- as of Apr. 2024^{*1}
- as of Apr. 2025^{*2}



Currency exchange rate assumptions
*1: 1 USD=145 JPY, 1 EUR=155 JPY
*2: 1 USD=140 JPY, 1 EUR=160 JPY

Forecast
*3: as of Apr. 2025

Key drivers of decline vs. Apr 2024 forecast

- ◆ **Clinical development expense**
 - ✓ Development plan updated based on strategic collaboration with US Merck
- ◆ **Medical affairs expense**
 - ✓ NSCLC development strategy updated on DATROWAY[®]
 - ✓ Launch delayed on HER3-DXd

Forecast of FY2025 KPIs

(as of Apr. 2025)

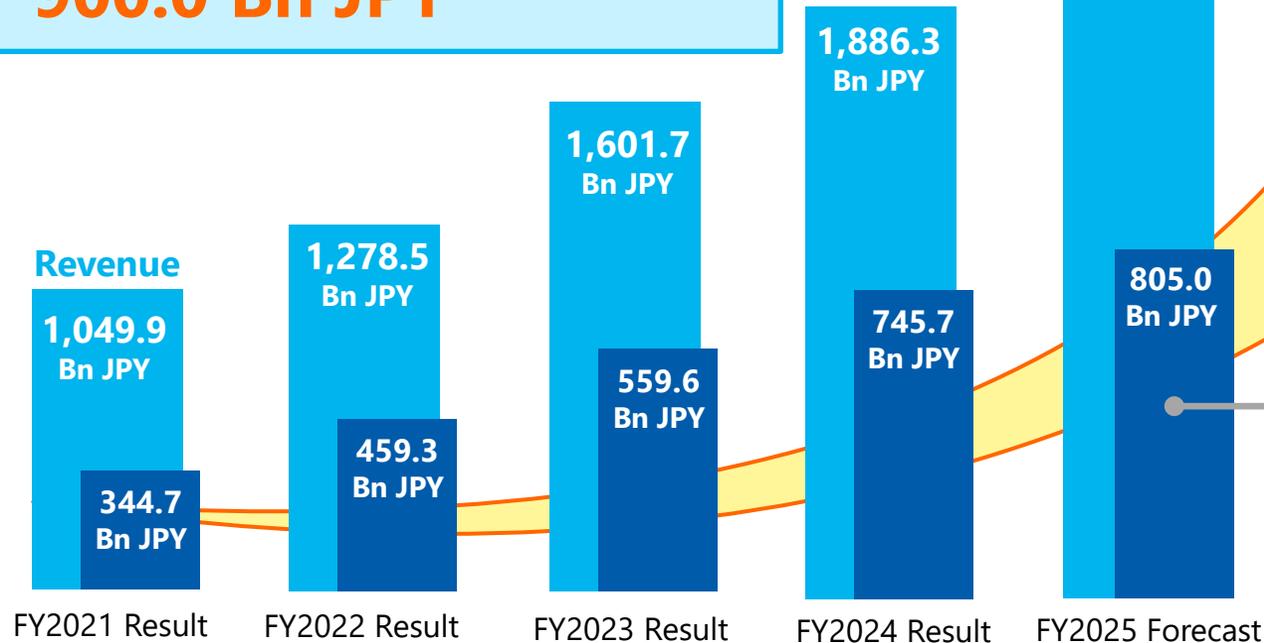
◆ Revenue

2.0 Tr JPY

➤ Revenue in Oncology

900.0 Bn JPY

Achieve significant revenue/profit growth after investment for DXd ADCs, and shift to a new stage for realizing 2030 vision



◆ Core Operating Profit* ratio before R&D expense: 40%

◆ ROE > 16%

◆ DOE > 8.5%

FY2025 currency exchange rate assumptions: 1 USD = 140 JPY, 1 EUR = 160 JPY

*Excluding temporary income and expenses (gains/losses related to sales of fixed assets etc.) from operating income



Daiichi Sankyo will contribute to the enrichment of quality of life around the world



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FY2025 Forecast

(Bn JPY)

	FY2024 Results	FY2025 Forecast	vs. Forecast
Revenue	1,886.3	2,000.0	+113.7
Cost of sales *1	415.7	430.0	+14.3
SG&A expenses *1	724.8	765.0	+40.2
DXd ADC profit share *2	226.2	265.0	+38.8
Other SG&A expenses	498.6	500.0	+1.4
R&D expenses *1	432.9	455.0	+22.1
Core operating profit *1	312.8	350.0	+37.2
Temporary income *1	22.2	-	-22.2
Temporary expenses *1	3.1	-	-3.1
Operating profit	331.9	350.0	+18.1
Profit before tax	355.6	370.0	+14.4
Profit attributable to owners of the Company	295.8	300.0	+4.2

Revenue

▲ : Sales expansion of ENHERTU; Increase in milestone income related to strategic alliance with AstraZeneca and US MRK*

▼ : Decrease due to forex impact

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

Cost of sales

▲ : Increase in cost of sales driven by sales growth

▼ : Decrease due to forex impact

SG&A expense

▲ : Increase due to profit share from ENHERTU's sales expansion, resource allocation to oncology business, strategic investments in DX / IT and human capital for mid- to long-term growth

▼ : Decrease due to forex impact

R&D expense

▲ : Increase due to R&D investment focused on 5DXd ADCs, expanded medical affairs activities, strengthened R&D structure (e.g. R&D headcount increase)

▼ : Decrease due to forex impact

Temporary income and expense

FY2024: Gain on stock transfer of DS Espha etc.

Currency	USD/JPY	152.57	140.00	-12.57
Exchange Rate	EUR/JPY	163.74	160.00	-3.74

Forex impact (vs FY2024)

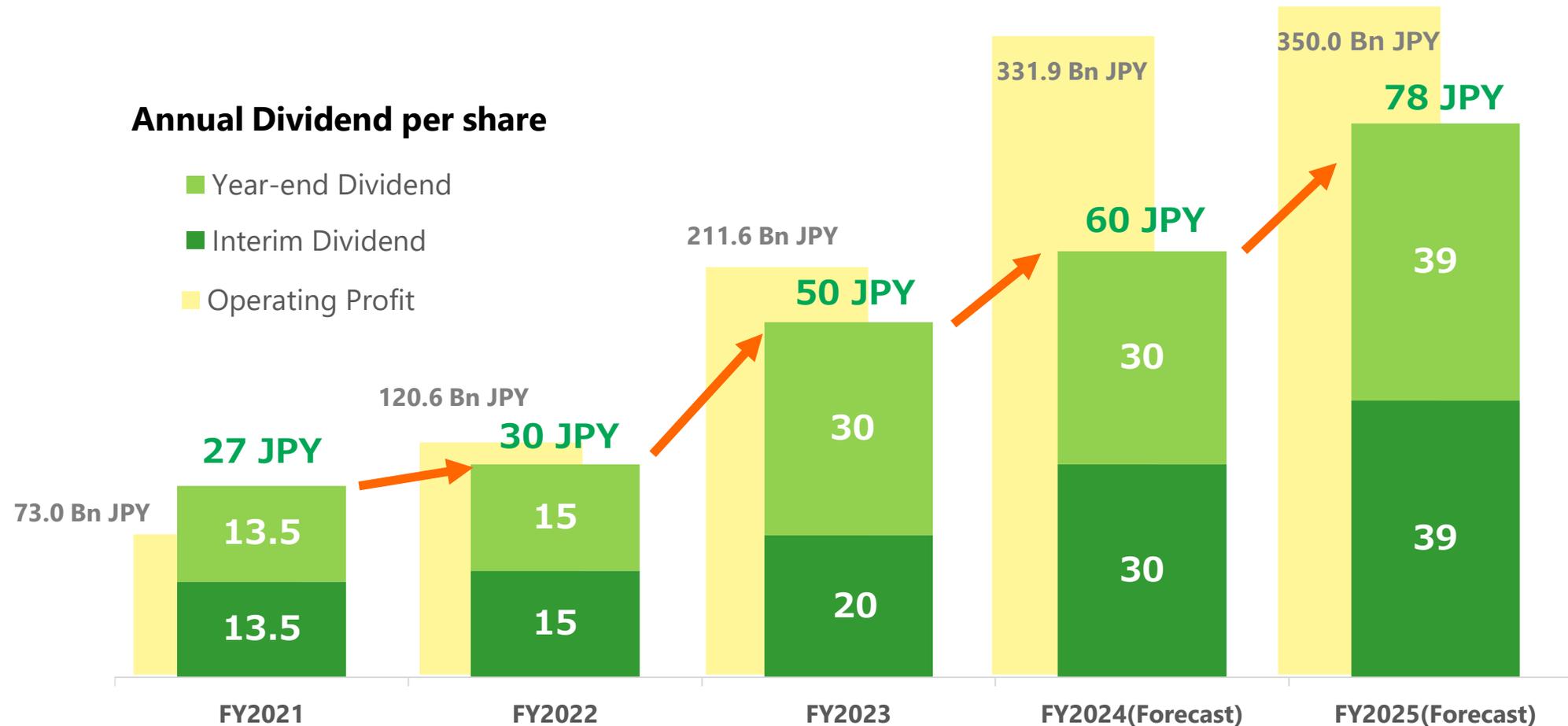
Revenue : Approx. -75.0 Bn JPY
Core operating profit: Approx. -3.5 Bn JPY

*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, 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.

FY2025 Annual Dividend Forecast

Plan to **increase annual dividend to 78 JPY per share for FY2025 (up 18 JPY)**
due to strong performance of ENHERTU® and others



Flexible Acquisition of Own Shares (Resolution)

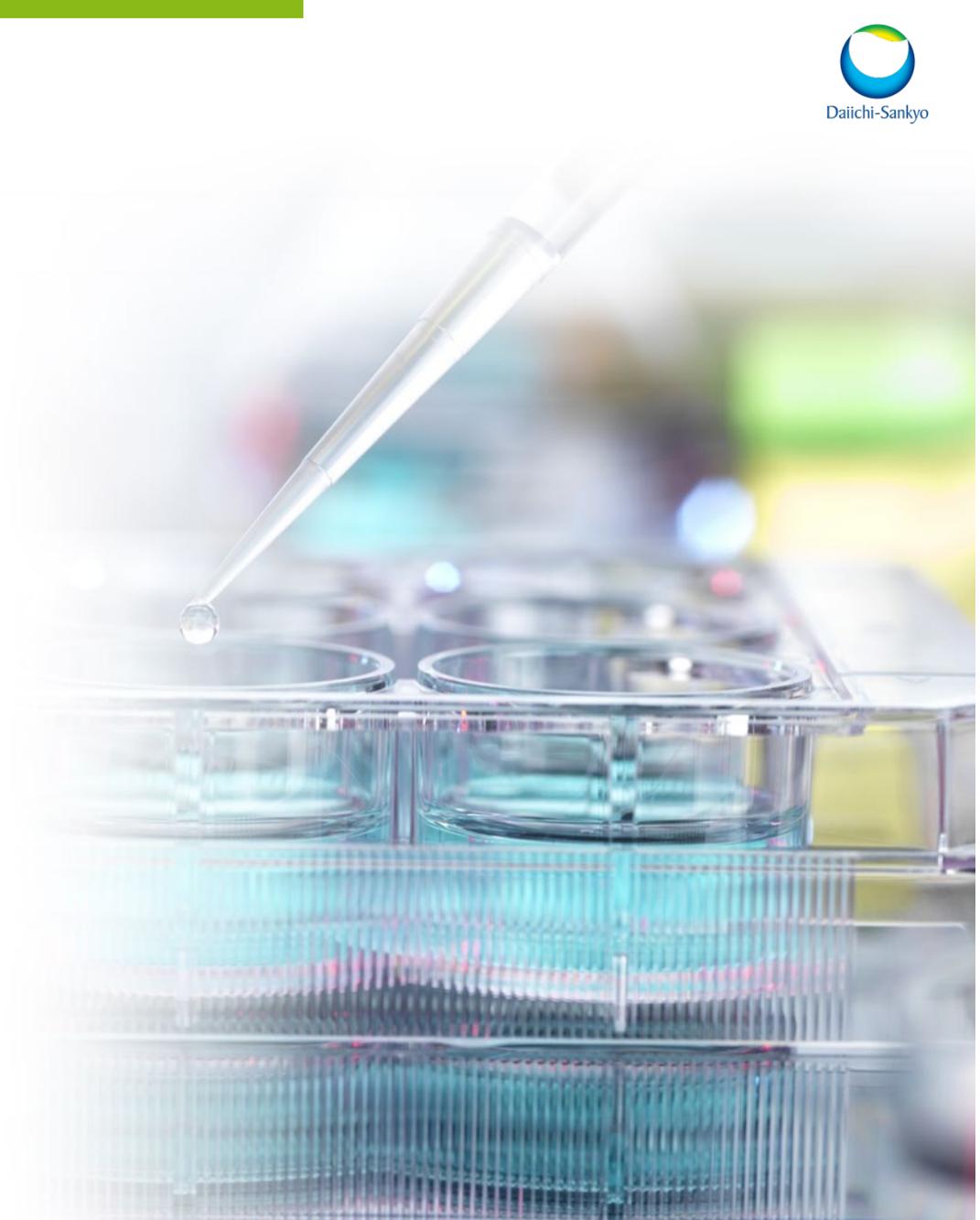
- ◆ **Established upper limits for acquiring own shares** to take flexible actions based on comprehensive consideration such as share price level and other factors
- ◆ **FY2025 DOE is expected to be over 8.5%**

Upper limits to acquire own shares

- Acquisition period: **May. 1, 2025 – Mar. 24, 2026**
- Aggregate amount of acquisition cost: **200 billion JPY (maximum)**
- Total number of shares to be acquired: **80.00 million stocks (maximum)**

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Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2023 Results	FY2024 Results	YoY	
Japan Business	518.9	476.9	-42.0	
Daiichi Sankyo Healthcare	76.0	86.7	+10.7	
Oncology Business	334.6	463.8	+129.2	
Enhertu	327.4	451.6	+124.2	
Turalio	5.3	6.6	+1.3	
Vanflyta	1.9	4.5	+2.7	
American Regent	203.4	217.2	+13.8	
Injectafer	50.1	53.4	+3.3	
Venofer	60.9	62.0	+1.1	
GE injectables	81.0	89.0	+8.0	
EU Specialty Business	189.2	237.4	+48.2	
Lixiana	146.2	179.0	+32.8	
Nilemdo/Nustendi	18.4	36.9	+18.5	
Olmesartan	19.6	18.3	-1.3	
ASCA (Asia, South and Central America) Business	184.1	211.2	+27.2	
Currency	USD/JPY	144.62	152.57	+7.95
Exchange Rate	EUR/JPY	156.79	163.74	+6.95

Revenue: Major Products in Japan

(Bn JPY)

		FY2023 Results	FY2024 Results	YoY
Lixiana	anticoagulant	115.6	133.0	+17.5
Tarlige	pain treatment	45.7	55.6	+10.0
Pralia	Treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	42.8	42.2	-0.6
Vimpat	anti-epileptic agent	25.7	30.4	+4.6
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	23.9	31.0	+7.1
Ranmark	treatment for bone complications caused by bone metastases from tumors	20.4	20.1	-0.3
Efient	antiplatelet agent	25.6	31.5	+5.9
Canalia	type 2 diabetes mellitus treatment	15.9	15.6	-0.3
Loxonin	anti-inflammatory analgesic	15.5	12.3	-3.2
Inavir	anti-influenza treatment	15.9	19.9	+4.0
Minnebro	antihypertensive agent	8.3	9.6	+1.4

5DXd ADCs Revenue (incl. Forex Impact)

(Unit: Bn JPY)

	FY2024 Results	YoY	FY2025 Forecast	YoY
ENHERTU®	651.4	+202.2	761.5	+110.1
Product Sales	552.8	+156.9	662.1	+109.3
Upfront and Milestone Payments, etc.	98.6	+45.3	99.4	+0.8
DATROWAY®	7.8	+1.4	13.0	+5.2
Product Sales	1.4	+1.4	4.7	+3.2
Upfront and Milestone Payments, etc.	6.4	-	8.3	+2.0
HER3-DXd	19.8	+16.2	16.3	-3.5
Product Sales	-	-	-	-
Upfront and Milestone Payments, etc.	19.8	+16.2	16.3	-3.5
I-DXd	15.3	+8.8	15.1	-0.2
Upfront and Milestone Payments, etc.	15.3	+8.8	15.1	-0.2
R-DXd	6.7	+4.0	20.5	+13.7
Upfront and Milestone Payments, etc.	6.7	+4.0	20.5	+13.7
5DXd ADCs Total	701.1	+232.6	826.4	+125.3

5DXd ADCs Upfront and Milestone Payments

(Unit: Bn JPY)

Asset	Item	FY2024 Results	YoY	FY2025 Forecast	YoY	Total Consideration (as of Mar 2025)
ENHERTU [®]	Upfront Payment	10.2	+0.1	10.2	+0.0	149.0
	Regulatory Milestones	29.2	+16.9	12.7	-16.5	167.7
	Quid Related Payment	1.2	+0.0	1.2	-	17.2
	Sales Milestone	57.9	+28.3	75.3	+17.3	100.8
DATROWAY [®]	Upfront Payment	6.4	-	6.4	-	115.9
	Regulatory Milestones	-	-	2.0	+2.0	-
AZ Alliance Total		104.9	+45.3	107.7	+2.8	550.5
HER3-DXd	Upfront Payment	19.0	+15.5	15.8	-3.3	224.9
	Satisfaction of Quid Rights	0.7	+0.7	0.5	-0.2	7.3
I-DXd	Upfront Payment	14.7	+8.1	14.7	-	225.4
	Satisfaction of Quid Rights	0.7	+0.7	0.5	-0.2	7.3
R-DXd	Upfront Payment	6.2	+3.4	20.1	+13.9	112.7
	Satisfaction of Quid Rights	0.6	+0.6	0.4	-0.2	7.3
US Merck Alliance Total		41.8	+28.9	51.9	+10.0	584.8

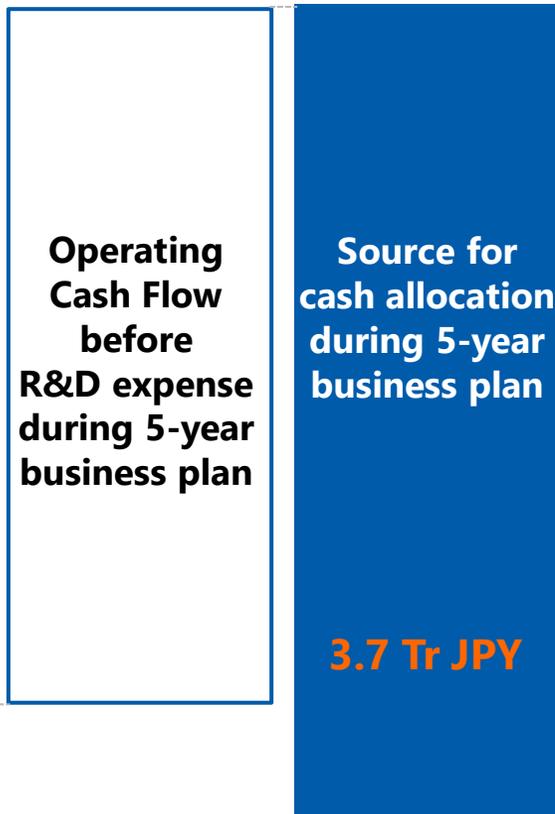
* "Quid rights" (worth \$150 mil.) that was held under the strategic alliance agreement with US Merck and was appropriated as part of consideration to obtain MK-6070 is booked as deferred revenue

Well-balanced Investment for Growth and Shareholder Returns

Cash Allocation

Increase **R&D expense** and **CAPEX** for further growth in future, and increase **shareholder returns**.

Image for cash allocation
(Comparison with as of April 2024)



R&D Expense

approx. 1.95 Tr JPY

Approx. → 1.85 Tr JPY

Prioritized investment for DXd-ADCs

CAPEX

approx. -800.0 Bn JPY

Investment focused on enhancing ADC supply capabilities

Flexible Allocation

Flexible allocation depending on pipeline progress for 1) investment to build pillars for further growth (in-house/external); and 2) acquisition of own shares

Dividends

Stable dividends and dividend increase that take account of profit growth

FY2020 cash in hands*
approx. 400.0 Bn JPY

Major R&D Milestones (ENHERTU®)

Project	Target indication [phase, study name]	FY2024	FY2025		
		H2	H1	H2	
ENHERTU®	• HER2+, adjuvant* [Ph3, DESTINY-Breast05]			• TLR anticipated	
	• HR+/HER2 low or HER2 ultralow, chemo naive [Ph3, DESTINY-Breast06]	• Filing accepted (JP/ CN) • Approved (US/ EU)	• Regulatory decision anticipated (JP)		
	• HER2+, 1L [Ph3, DESTINY-Breast09]		• TLR obtained		
	• HER2+, neoadjuvant [Ph3, DESTINY-Breast11]		• TLR anticipated		
	GC	• HER2+, 2L [Ph3, DESTINY-Gastric04]	• TLR obtained		
		• HER2+, 1L, pembrolizumab and chemo combo [Ph3, DESTINY-Gastric05]	• Study started		
		• HER2+ and PD-L1 CPS≥1, 1L, rivogostomig and chemo combo [Ph3, ARTEMIDE-Gastric01]	• Study started		
	NSCLC	• HER2 mutation, 1L [Ph3, DESTINY-Lung04]		• TLR anticipated	
		• HER2 overexpression, 1L, pembrolizumab combo [Ph3, DESTINY-Lung06]		• Study start planned	
	OVC	• HER2 expressing [Ph3, DESTINY-Ovarian01]		• Study start planned	

Bold: update from FY2024 Q3

BC: breast cancer, CPS: combined positive score, GC: gastric cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, OVC: ovarian cancer, TLR: Top Line Results

*: Adjuvant therapy for HER2 positive breast cancer patients with residual invasive disease following neoadjuvant therapy

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		
		H2	H1	H2	
DATROWAY®	NSCLC	• EGFR mutated, previously treated (incl. EGFR directed therapy) [Ph2, TROPION-Lung05*]	• Filing accepted (US)	• Regulatory decision anticipated (US)	
		• w/o AGA, durvalumab combo, 1L, [Ph3, AVANZAR]		• TLR anticipated (CY2025 H2)	
	BC	• HR+ and HER2 low or negative, 2/3L [Ph3, TROPION-Breast01]	• Approved (JP/US)	• Approved (EU)	
		• TNBC, PD-1/PD-L1 ineligible, 1L [Ph3, TROPION-Breast02]		• TLR anticipated	

Bold: update from FY2024 Q3

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	
			H2	H1	H2
HER3-DXd	BC	<ul style="list-style-type: none"> • TNBC, HR low and HER2 negative BC neoadjuvant [Ph2, HERTHENA-Breast03] 		<ul style="list-style-type: none"> • Study start planned 	
I-DXd	SCLC	<ul style="list-style-type: none"> • 2L+ [Dose optimization, Ph2, IDeate-Lung01] 		<ul style="list-style-type: none"> • TLR anticipated 	
	ESCC	<ul style="list-style-type: none"> • 2L [Ph3, IDeate-Esophageal01] 		<ul style="list-style-type: none"> • Study start planned 	
	CRPC	<ul style="list-style-type: none"> • Chemo naïve [Ph3, IDeate-Prostate01] 		<ul style="list-style-type: none"> • Study start planned 	
R-DXd	GI cancers	<ul style="list-style-type: none"> • [Ph2, REJOICE-GI01] 		<ul style="list-style-type: none"> • Study start planned 	

Bold: update from FY2024 Q3

BC: breast cancer, cRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, GI: gastrointestinal, HR: hormone receptor, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, TNBC: triple-negative breast cancer, TLR: top line results

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

Major R&D Milestones (Next Wave)

Project	Target indication [phase, study name]	FY2024	FY2025	
		H2	H1	H2
VANFLYTA®	• FLT3-ITD positive AML, 1L [Ph3, QuANTUM-First]	• Filing accepted (CN)		
MK-6070 (gocatumig)	• SCLC, I-DXd combo, 2L+ [Ph1b/2, MK-6070-002]	• Study started		
DS-2243	• Solid tumors [Ph1]	• Study started		
DAICHIRONA®	• COVID-19 mRNA vaccine (mutant strain), children aged 5 to 11 years [Ph2/3]	• Approved (JP)		

Bold: update from FY2024 Q3

AML: acute myeloid leukemia, SCLC: small cell lung cancer, TLR: top line results
Timeline indicated is based on the current forecast and subject to change

Major R&D Pipeline: 5DXd ADCs ①

Phase 1		Phase 1/2		Phase 2	
(US/EU/Asia) HER2 low BC chemo naïve/post chemo DESTINY-Breast08	(JP/US/EU/Asia) NSCLC	(US/EU/Asia) HER2+ BC 2L+/1L DESTINY-Breast07	(JP/US) ESCC, CRPC, squamous NSCLC, SCLC, etc. IDEate-PanTumor01	(JP/US/EU/Asia) HER2 expressing solid tumors DESTINY-PanTumor02	(JP/US/EU/Asia) ES-SCLC 2L+ IDEate-Lung01
(US/EU/Asia) HER2 overexpressing non-squamous 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) solid tumors 2L+ IDEate-PanTumor02	(CN) HER2 expressing solid tumors DESTINY-PanTumor03	(TBA) in prep non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US) renal cell carcinoma, ovarian cancer	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU) ES-SCLC 1L IDEate-Lung03	(JP/US/EU/Asia) solid tumors TROPION-PanTumor03	(TBA) in prep squamous NSCLC 2L KEYMAKER-U01 substudy 01I
(JP/US) solid tumors TROPION-PanTumor01		(JP/US/EU/Asia) solid tumors (saruparib combo) PETRA	(TBA) in prep chemo-naïve metastatic CRPC IDEate-Prostate02	(JP/US/EU/Asia) EGFR mutated NSCLC 2L (osimertinib combo) ORCHARD	(US/EU/Asia) in prep gastrointestinal cancers REJOICE-GI01
(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) TROPION-Lung02		(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(US/EU/Asia) in prep stageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01A	(US/EU/Asia) resectable early-stage NSCLC neoadjuvant (durvalumab combo) NeoCOAST-2	(JP/US/EU/Asia) solid tumors REJOICE-PanTumor01
(JP/US/EU/Asia) NSCLC (w/o AGA, durvalumab, rilvegostomig, volrustomig and sabestomig combo) TROPION-Lung04		(JP/US/EU/Asia) solid tumors (saruparib combo) PETRA	(TBA) in prep ESCC 1L (pembrolizumab combo) KEYMAKER-U06 substudy 06E	(JP/US/EU/Asia) solid tumors HERTHENA-PanTumor01	(TBA) in prep non-squamous NSCLC 2L KEYMAKER-U01 substudy 01H
		(US/EU/Asia) CRC, BTC, HCC 2L+ HERTHENA-PanTumor02	(US/EU/Asia) ES-SCLC 2L KEYNOTE-B98	(US/EU/Asia) in prep high-risk early stage TNBC, HR low and HER2 negative BC neoadjuvant (pembrolizumab combo) HERTHENA-Breast03	(TBA) in prep squamous NSCLC 2L KEYMAKER-U01 substudy 01I
		(US/EU/Asia) in prep stageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01A	(TBA) in prep ovarian cancer, relapsed after platinum-based chemo. (carboplatin, paclitaxel, bevacizumab combo) REJOICE-Ovarian02	(US/EU/Asia) in prep stageIV NSCLC 1L (pembrolizumab combo) KEYMAKER-U01 substudy 01G	
		(JP/US/EU/Asia) HER2+ BC 2L+ HERTHENA-Breast01			

■ 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 Apr 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) in prep HER2 expressing ovarian cancer 1L maintenance (bevacizumab combo) DESTINY-Ovarian01	(JP/US/EU/Asia) TNBC (PD-1/PD-L1 inhibitor ineligible) 1L TROPION-Breast02
	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1 TPS <50%) 1L (pembrolizumab combo) TROPION-Lung07	(JP/US/EU/Asia) TNBC adjuvant* ¹ (mono or durvalumab combo) TROPION-Breast03
	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11	(JP/US/EU/Asia) NSCLC (w/o AGA, PD-L1 TPS ≥50%) 1L (pembrolizumab combo) TROPION-Lung08	(JP/US/EU/Asia) TNBC, HR low and HER2 negative BC neoadjuvant and adjuvant (durvalumab combo) TROPION-Breast04
	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L TC 1 ≥50%) 1L (rilvegostomig combo) TROPION-Lung10	(JP/US/EU/Asia) PD-L1 positive TNBC 1L (mono or durvalumab combo) TROPION-Breast05
	(JP/US/EU/Asia) HER2+ GC 1L (pembrolizumab combo) DESTINY-Gastric05	(JP/US/EU/Asia) Stage I adenocarcinoma NSCLC adjuvant (rilvegostomig combo) TROPION-Lung12	(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 1L (osimertinib combo) TROPION-Lung14	(JP/US/EU/Asia) ES-SCLC 2L IDeate-Lung02
	(JP/US/EU/Asia) HER2 mutant NSCLC 1L DESTINY-Lung04	(JP/US/EU/Asia) EGFR mutated NSCLC (progressed on prior EGFR TKI) 2L+ (mono or osimertinib combo) TROPION-Lung15	(JP/US/EU/Asia) in prep ESCC 2L IDeate-Esophageal01
	(TBA) in prep HER2 overexpressing non- squamous NSCLC (w/o AGA, PD-L1 TPS < 50%) (pembrolizumab combo) DESTINY-Lung06	(JP/US/EU/Asia) NSCLC (w/o AGA) 1L (durvalumab combo) AVANZAR	(TBA) in prep chemo-naïve metastatic CRPC IDeate-Prostate01
	(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, BC: breast cancer, BTC: biliary tract 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

Phase 1	Phase 1/2	Phase 2	Phase 3	Regulatory phase
<p>DS-1055 (JP/US) Anti-GARP antibody Solid tumors</p>	<p>DS-3939 (JP/US/EU/Asia) TA-MUC1-directed ADC Solid tumors</p>	<p>EZHARMIA® (EU) EZH1/2 inhibitor BCL</p>	<p>TURALIO® (Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor</p>	<p>VANFLYTA® (CN) FLT3 inhibitor FLT3 -ITD positive AML 1L QuANTUM-First</p>
<p>DS-9606 (US/EU) CLDN6-directed ADC Solid tumors</p>	<p>MK-6070 (DS3280) (US) DLL3 directed tri-specific T-cell engager DLL3 expressing advanced cancer</p>	<p>DS-1001 (JP) Mutant IDH1 inhibitor Glioma</p>	<p>VANFLYTA® (JP/US/EU/Asia) FLT3 inhibitor FLT3 -ITD negative AML 1L QuANTUM-Wild</p>	<p>VN-0102/JVC-001 (JP) Mixed measles-mumps-rubella vaccine</p>
<p>DS-1103 (US/EU) Anti-SIRPα antibody HER2 expressing or mutant solid tumors, HER2 low BC (ENHERTU® combo)</p>	<p>MK-6070 (DS3280) (US/EU/Asia) DLL3 directed tri-specific T-cell engager ES-SCLC 2L+ (I-DXd combo) MK-6070-002</p>	<p>TURALIO® (JP) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor</p>		
<p>DS-1471 (JP) Anti-CD147 antibody Solid tumors</p>	<p>EZHARMIA® (JP/US/Asia) EZH1/2 inhibitor NSCLC (w/o AGA and PD-L1 TPS ≥50%) 1L (pembrolizumab combo)</p>	<p>DS-1211 (US/EU) TNAP inhibitor Pseudoxanthoma elasticum</p>		
<p>EZHARMIA® (JP/US) EZH1/2 inhibitor HER2+ GC, HER2 low BC (ENHERTU® combo) and non-squamous NSCLC (DATROWAY® combo)</p>	<p>DS-7011 (JP/US/EU/Asia) Anti-TLR7 antibody Systemic lupus erythematosus</p>			
<p>DS-2243 (US/EU/Asia) HLA-A*02/NY-ESO directed bispecific T-cell engager Solid tumors</p>	<p>DS-2325 (EU) KLK5 inhibitor Netherton syndrome</p>			

- Oncology
- Specialty medicine
- Vaccine

- ★ Orphan drug designation (designated in at least one country/region among JP, US and EU)
- ★ Fast Track Designation (US)
- ★ Rare Pediatric Disease Designation (US)

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

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