

Passion for Innovation.  
Compassion for Patients.™



# Striving to Become a Leader in ADCs

**DAIICHI SANKYO CO., LTD.**

**Sunao Manabe**  
Executive Chairperson and CEO

January 13, 2025

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# Agenda

**1 Overview of Daiichi Sankyo**

**2 Our ADCs**

**3 Our Science and Technology**

**4 Shareholder Returns**

**5 Closing**

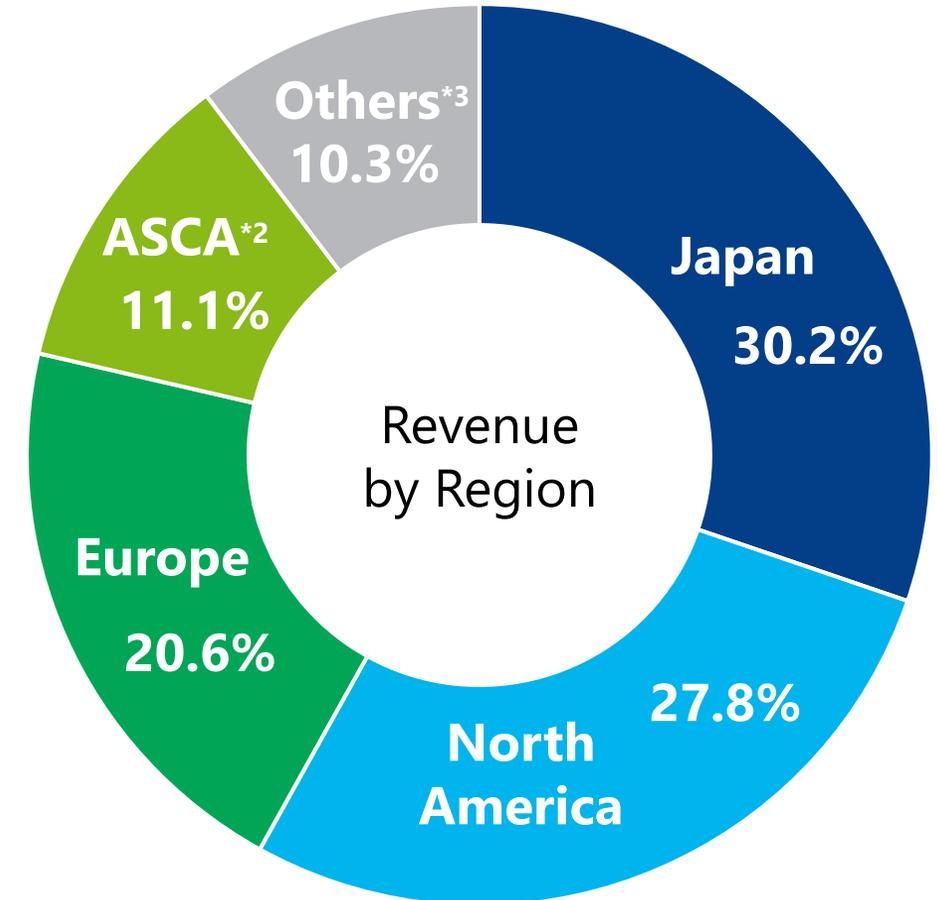


# Overview of Daiichi Sankyo

## Overview of FY2024 consolidated P&L

(Bn JPY)

	FY2024 Forecast as of Oct. 2024		
		to revenue	vs FY2023
<b>Revenue</b>	<b>1,830.0</b>	<b>100.0%</b>	<b>+14.3%</b> <b>+228.3</b>
<b>Cost of sales <sup>*1</sup></b>	<b>410.0</b>	<b>22.4%</b>	<b>-4.8</b>
<b>SG&amp;A expenses <sup>*1</sup></b>	<b>700.0</b>	<b>38.3%</b>	<b>+72.7</b>
<b>R&amp;D expenses <sup>*1</sup></b>	<b>460.0</b>	<b>25.1%</b>	<b>+95.7</b>
<b>Core operating profit <sup>*1</sup></b>	<b>260.0</b>	<b>14.2%</b>	<b>+33.2%</b> <b>+64.7</b>
<b>Operating profit</b>	<b>280.0</b>	<b>15.3%</b>	<b>+32.3%</b> <b>+68.4</b>
<b>Profit attributable to owners of the Company</b>	<b>225.0</b>	<b>12.3%</b>	<b>+12.1%</b> <b>+24.3</b>



<sup>\*1</sup> 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.

<sup>\*2</sup> Asia, South & Central America

<sup>\*3</sup> Revenue related to upfront and milestone payments based on ENHERTU<sup>®</sup> and DATROWAY<sup>®</sup> strategic alliance agreements with AstraZeneca, and HER3-DXd, I-DXd and R-DXd strategic alliance agreement with Merck & Co., Inc., Rahway, NJ, USA.

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2 **Our ADCs**

3 Our Science and Technology

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5 Closing



# Daiichi Sankyo Original ADC Platforms

- ◆ Our ADC platforms are growing, and we now have 7 DXd ADCs from the DXd platform
- ◆ DS-9606 data presented at ESMO 2024 as the first asset from Daiichi Sankyo's 2<sup>nd</sup> ADC platform

	Asset (Target Antigen)	Target Indications	Pre-Clinical	Ph1	Ph2	Ph3	Filed	Launched
DXd ADCs	<b>ENHERTU<sup>®</sup></b> (HER2)	Breast, Gastric, NSCLC, Solid Tumors, etc.	[Progress bar: Pre-Clinical to Launched]					
	<b>DATROWAY<sup>®</sup></b> (TROP2)	Breast, NSCLC, etc.	[Progress bar: Pre-Clinical to Ph3]					
	<b>HER3-DXd</b> (HER3)	NSCLC, CRC, BTC, HCC, etc.	[Progress bar: Pre-Clinical to Ph3]					
	<b>I-DXd</b> (B7-H3)	SCLC, ESCC, etc.	[Progress bar: Pre-Clinical to Ph2]					
	<b>R-DXd</b> (CDH6)	Ovarian, Renal, etc.	[Progress bar: Pre-Clinical to Ph2]					
	<b>DS-3939</b> (TA-MUC1)	Solid Tumors	[Progress bar: Pre-Clinical to Ph2]					
	<b>7<sup>th</sup> DXd ADC</b> (undisclosed)	Undisclosed	[Progress bar: Pre-Clinical to Ph1]					
PBD ADC	<b>DS-9606</b> (CLDN6)	Solid Tumors	[Progress bar: Pre-Clinical to Ph1]					

Timeline indicates the most advanced stage of each asset, and that status may not apply to all categories listed in the "target indications" column

BTC: biliary tract cancer, CRC: colorectal cancer, CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, HCC: hepatocellular carcinoma, NSCLC: non small cell lung cancer, PBD: pyrrolbenzodiazepine, SCLC: small cell lung cancer

# 2024 Prix Galien USA Award



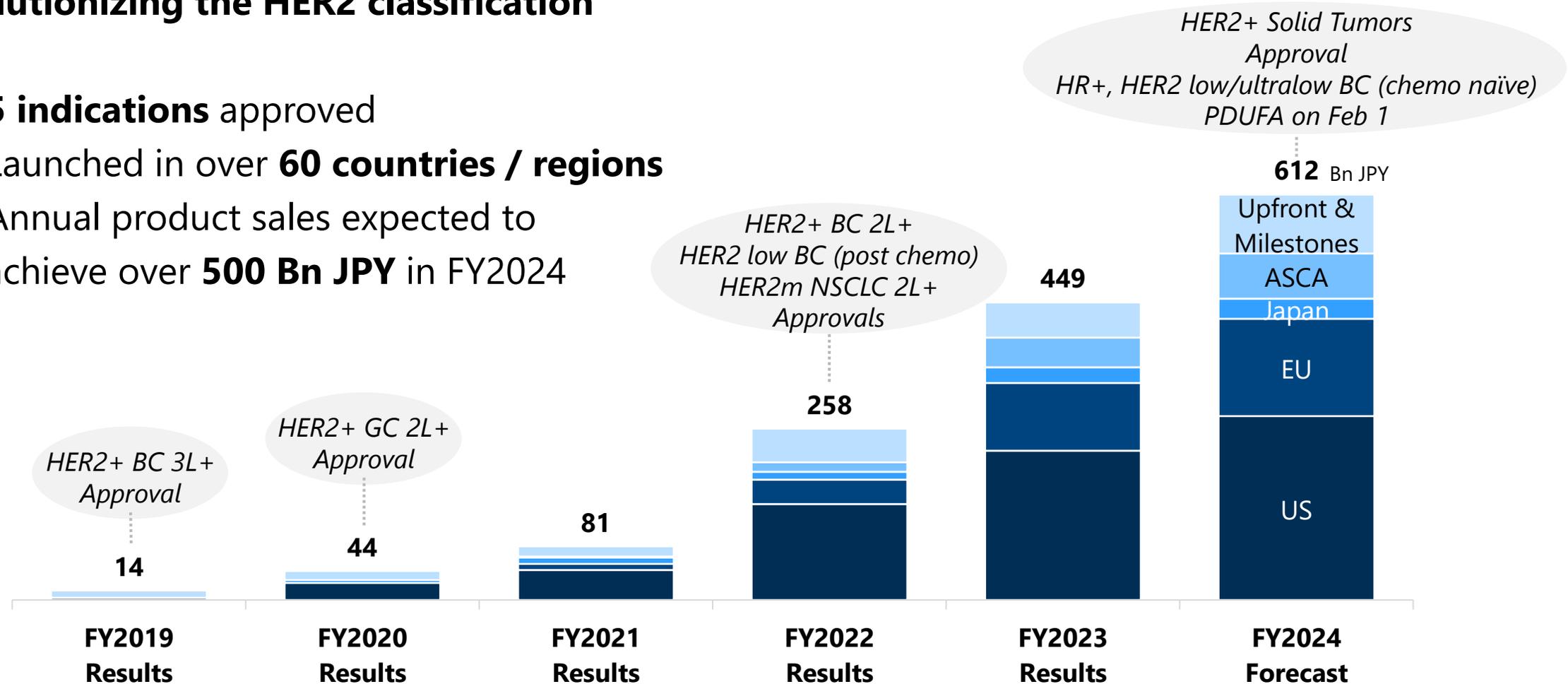
**ENHERTU<sup>®</sup>**  
Daiichi Sankyo  
& AstraZeneca

Daiichi Sankyo and AstraZeneca have been awarded The Galien Foundation 2024 Prix Galien USA Award for Best Biotechnology Product for **ENHERTU<sup>®</sup>**

# AstraZeneca Collaboration – 5-Year Achievement

## ENHERTU<sup>®</sup> is transforming the treatment landscape by redefining SoCs and revolutionizing the HER2 classification

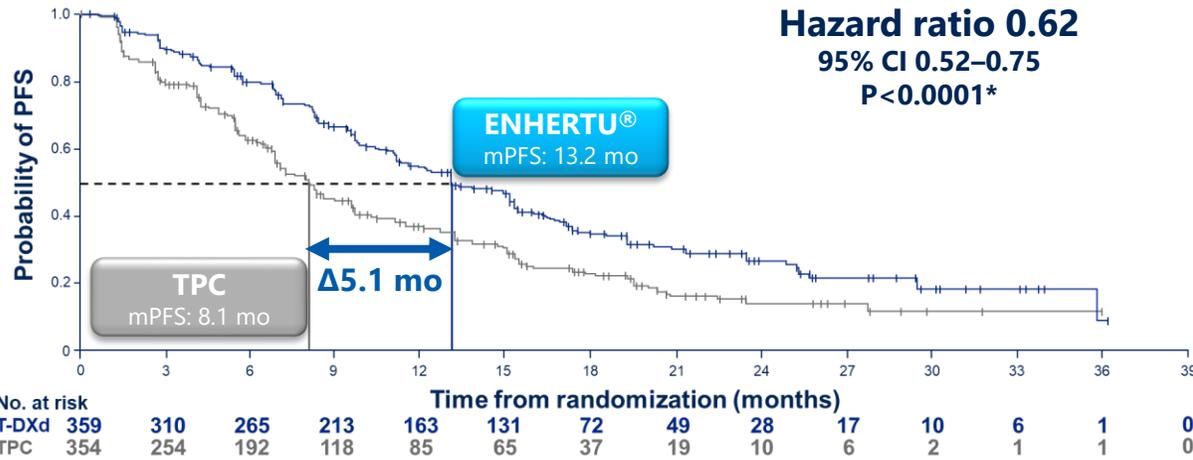
- ◆ **5 indications** approved
- ◆ Launched in over **60 countries / regions**
- ◆ Annual product sales expected to achieve over **500 Bn JPY** in FY2024



# Maximize Product Value

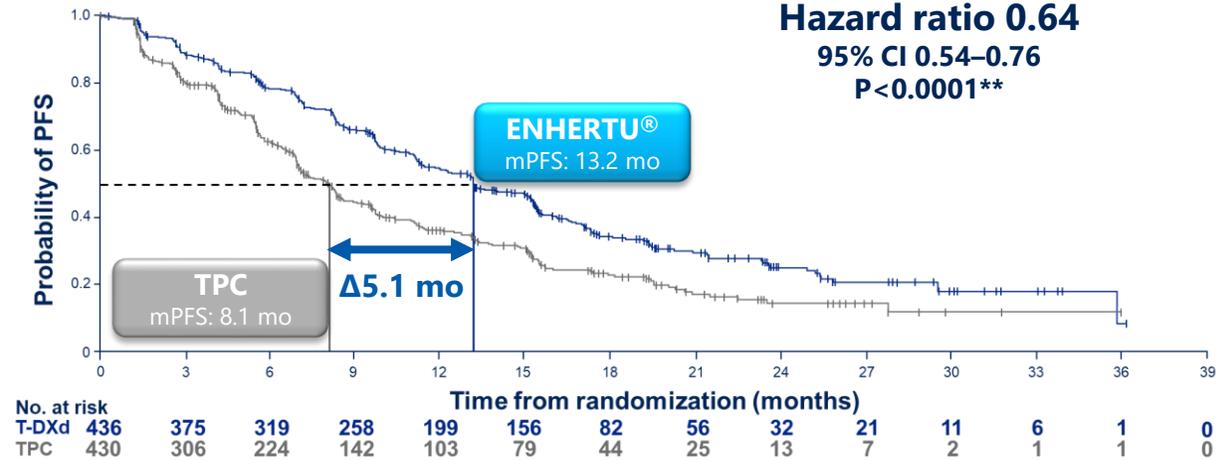
## Further indication expansion and formulation development

**PFS (BICR) in HER2 low**



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

**PFS (BICR) in ITT (HER2 low and HER2 ultralow)**



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

- ◆ DESTINY-Breast06 demonstrated a statistically significant and clinically meaningful PFS benefit in HR positive, HER2 low and HER2 ultralow mBC
- ◆ If approved, ENHERTU<sup>®</sup> will be the first HER2 directed therapy and ADC for patients prior to receiving chemotherapy for HER2 low and HER2 ultralow mBC
- ◆ Regulatory submissions based on DESTINY-Breast06 outcome are under review in Japan, US and EU (US PDUFA date: Feb 1<sup>st</sup>, 2025)
- ◆ Planning to develop a subcutaneous injection of ENHERTU<sup>®</sup>, which we anticipate will benefit patients by reducing treatment burden

## Establish a primary indication in breast cancer

- ◆ Approved in Japan for HR+/HER2- BC 2L+ based on TROPION-Breast01 outcome
- ◆ The regulatory submissions are under review in US, EU and China

## Be the first TROP2-directed ADC in NSCLC

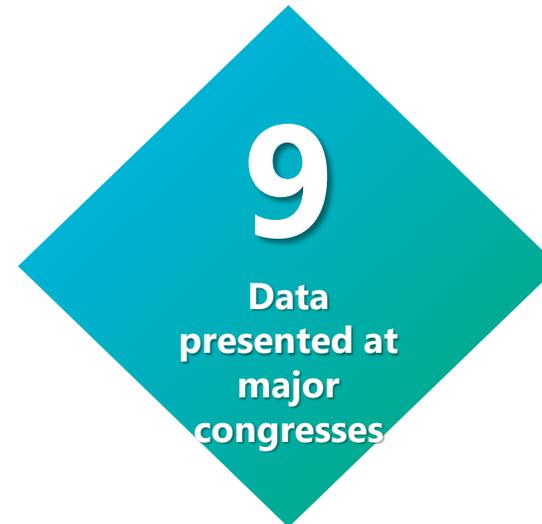
- ◆ Withdrawal of the application in US and EU for NSQ NSCLC 2/3L based on TROPION-Lung01
- ◆ New BLA submission for accelerated approval was submitted in US for EGFRm NSCLC based on pooled data from TROPION-Lung05, TROPION-Lung01 and TROPION-PanTumor01 in Nov 2024
- ◆ Granted Breakthrough Therapy Designation in US in Dec 2024

## Biomarker driven clinical development

- ◆ An additional clinical study in patients with biomarker-positive tumors in the NSQ NSCLC 2L setting is planned
- ◆ AVANZAR and TROPION-Lung10 have the potential to clinically validate the TROP2 QCS biomarker for DATROWAY®

# US Merck Collaboration – the First-Year Achievement

- ◆ Strategic collaboration started in Oct 2023 for **HER3-DXd, I-DXd, R-DXd** to co-develop and co-commercialize globally
- ◆ **MK-6070** (DLL3 targeting T-cell engager) added to the strategic collaboration in Aug 2024 as the 4<sup>th</sup> asset to initially evaluate the combination with I-DXd in ES-SCLC



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3 **Our Science and Technology**

4 Shareholder Returns

5 Closing



# Establish and Expand DXd ADCs to Address the Broader Spectrum of Breast Cancer

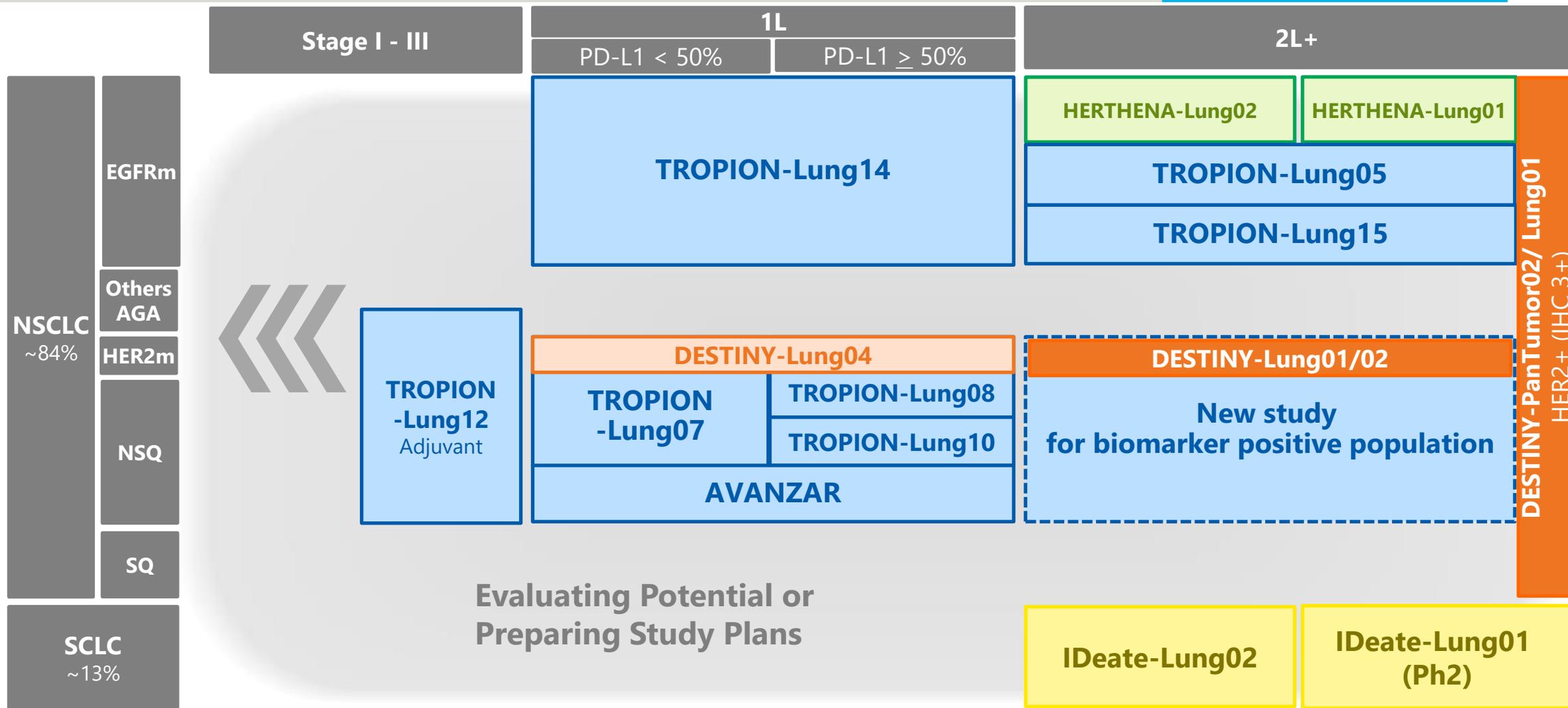
	Neoadjuvant	Adjuvant	1L	2L+	
HER2+ 20%	DESTINY-Breast11	DESTINY-Breast05 Residual Disease	DESTINY-Breast09	DESTINY-Breast01/02/03	Evaluating potential
TNBC 15%	TROPION-Breast04		TROPION-Breast02 CPS < 10 or IO ineligible	TROPION-Breast05 CPS ≥ 10	

	Neoadjuvant	Adjuvant	ET	post 1-2L ET	post 1-2L chemotherapy	
HR+ 65%	Evaluating Potential or Preparing Study Plans			DESTINY-Breast06	DESTINY-Breast04	Evaluating potential
				TROPION-Breast01		

Launched
On-going
ENHERTU®
DATROWAY®
HER3-DXd

- Pivotal studies only, not exhaustive
- Box size does not reflect the patient population
- Box indicates current potential target segment

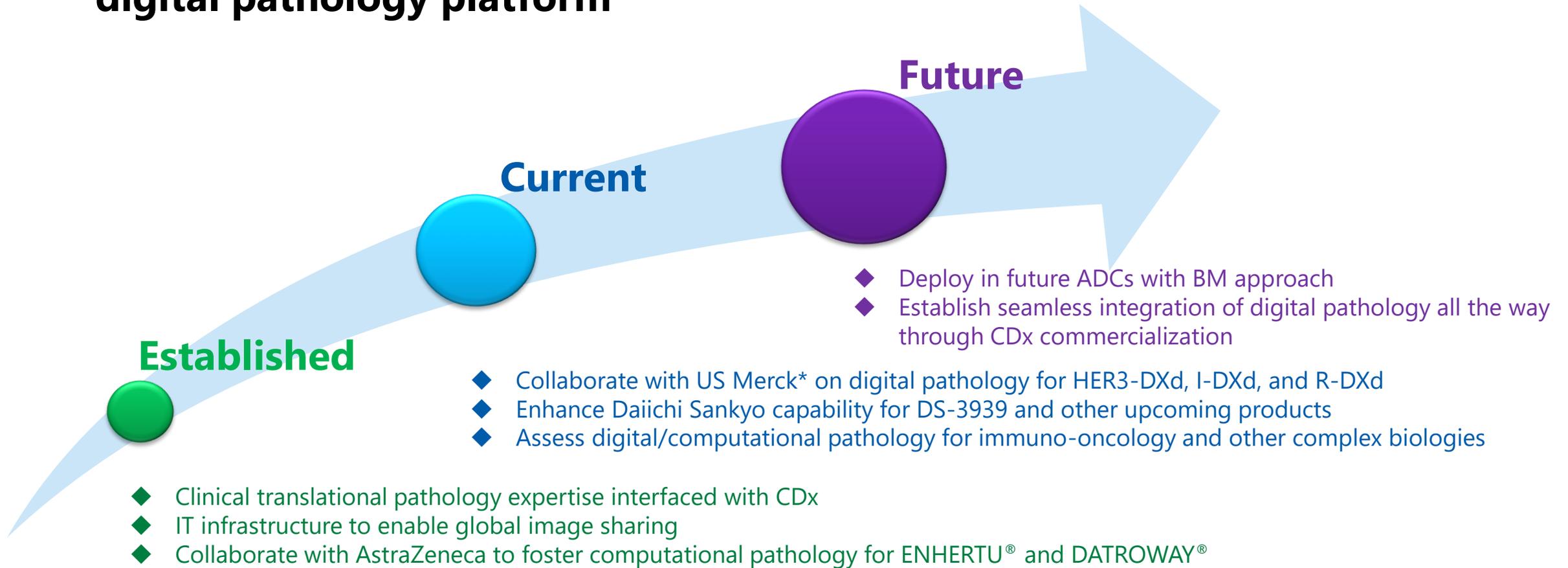
# Establish and Expand DXd ADCs to Address the Broad Spectrum of Lung Cancer



- Pivotal studies and major Ph2 only, not exhaustive
- Box size does not reflect the patient population
- Box indicates current potential target segment

# Steps to Build Digital Pathology Platform

Through the collaborations with partners DS deploys our own digital pathology platform

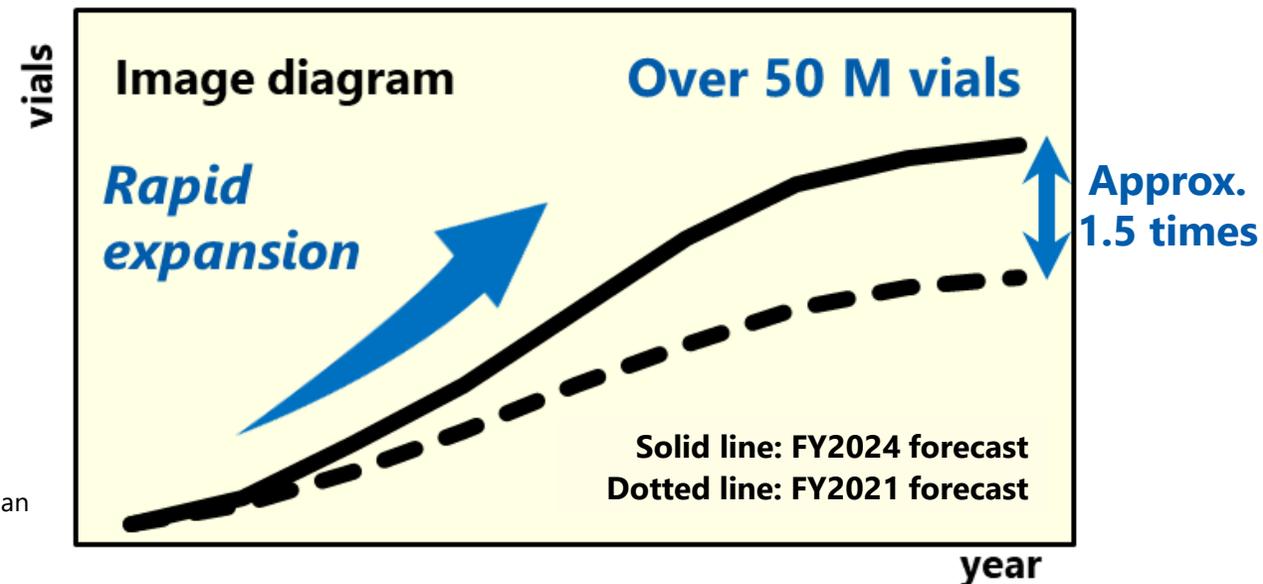


# Rapidly Expand Demand for 5 major DXd ADCs

**With strong progress of clinical development, the overall demand forecast for 5DXd ADCs\*<sup>1</sup> has significantly increased**

- ◆ Collaboration with AstraZeneca enhancing the product value of ENHERTU<sup>®</sup> and DATROWAY<sup>®</sup>
- ◆ ENHERTU<sup>®</sup> product sales forecast for FY2024 increased to 523.0 Bn JPY
- ◆ Collaboration with US Merck\*<sup>2</sup> realized the broader clinical development opportunity in HER3-DXd, I-DXd and R-DXd
- ◆ The number of clinical studies has been increasing in 5DXd ADCs

- ◆ Over 50 M vials\*<sup>3</sup> expected for 5DXd ADCs demand
- ◆ Demand increased 1.5 times\*<sup>4</sup> over the original forecast in the 5-Year Business Plan (FY2021-FY2025)



\*<sup>1</sup> **ENHERTU<sup>®</sup>**: trastuzumab deruxtecan (International Nonproprietary Name: INN), T-DXd, DS-8201 (HER2-directed ADC), **DATROWAY<sup>®</sup>**: 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)

\*<sup>2</sup> Merck & Co., Inc., Rahway, NJ, USA

\*<sup>3</sup> Number of vials required per year at peak time (Total of 5DXd ADCs)

\*<sup>4</sup> Comparison with number of vials required per year at peak time calculated in the 5-Year Business Plan

# Enhancement of Supply Capacity



# Agenda

1 Overview of Daiichi Sankyo

2 Our ADCs

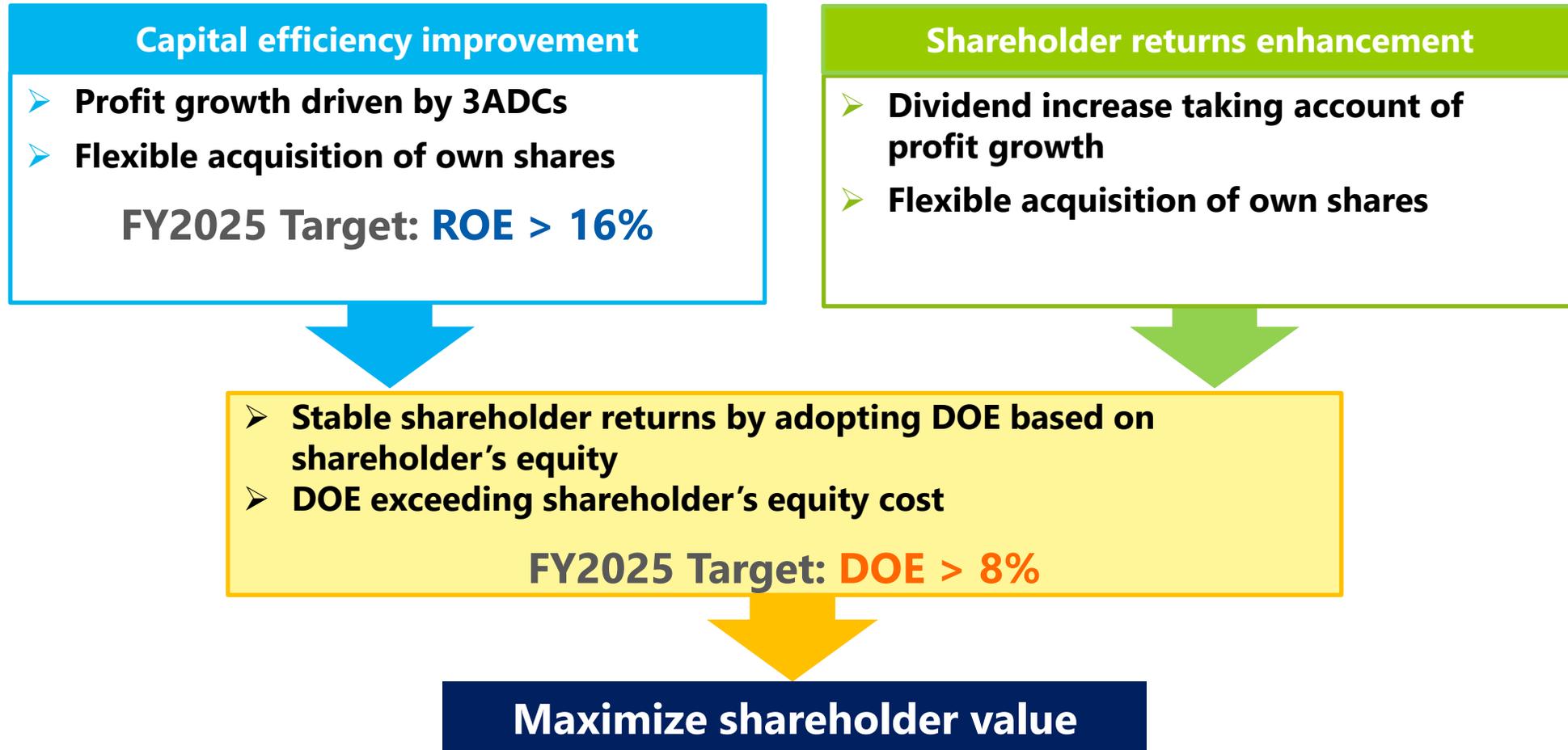
3 Our Science and Technology

4 Shareholder Returns

5 Closing

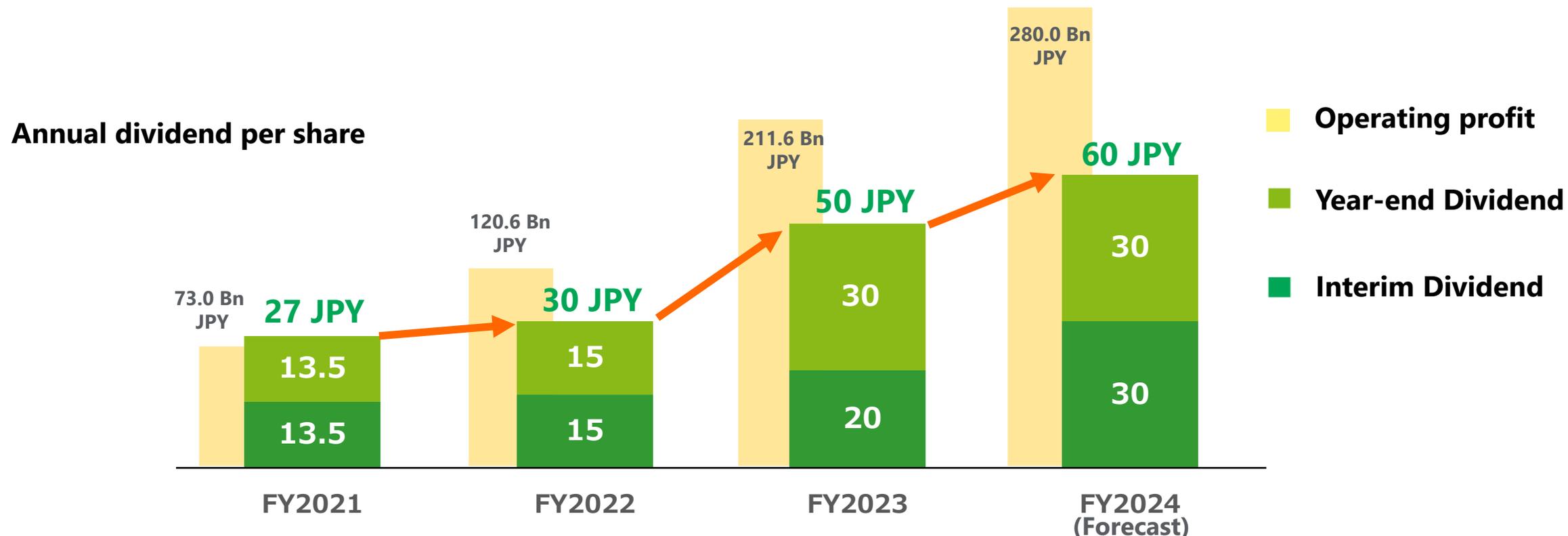


# Shareholder Return Policy (FY2021-FY2025)



# Dividend Increase & Acquisition of Own Shares

- ◆ Plan to **increase dividend** for three consecutive years taking account of **profit growth**



- ◆ Implemented **acquisition of own shares** to enhance shareholder returns and to improve **capital efficiency** (from Apr. 2024 to Jan. 2025 / total acquisition cost: 200 Bn JPY)
- ◆ Expect **DOE of 8.5% or more in FY2025** which exceeds the original target

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3 Our Science and Technology

4 Shareholder Returns

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# 5-Year Business Plan (FY2021-FY2025) for Sustainable Growth

We will achieve our 2025 Goal, **Global Pharma Innovator with Competitive Advantage in Oncology**, and will shift to further growth toward our 2030 Vision

## 2030 Vision

**Innovative Global Healthcare Company Contributing to the Sustainable Development of Society**

### 5-Year Business Plan (FY2021-FY2025)

Achieve FY2025 Goal "Global Pharma Innovator with Competitive Advantage in Oncology" and shift to further growth

#### As of FY2020

- ◆ Oncology business launched
- ◆ Edoxaban growing
- ◆ Regional value being enhanced
- ◆ AZ strategic alliance
- ◆ Increased RD investment

- ◆ Global top 10 in Oncology
- ◆ Additional growth pillars being source of revenue and profit
- ◆ New products being source of profit in each business unit
- ◆ Contributing to sustainable development of society through our business



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



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