

Passion for Innovation.  
Compassion for Patients.™



# Science & Technology Day 2025

**DAIICHI SANKYO CO., LTD.**

**December 16<sup>th</sup>, 2025**

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# Science & Technology Day 2025 Presenters

**Hiroyuki Okuzawa**  
President and CEO



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



**Ken Keller**  
Head of Global Oncology  
Business



**Hiroto Kashiwase**  
Head of Global Technology



**Yuki Abe**  
Head of Global Research



# Agenda

- ① **Welcome**
- ② **Clinical Development**
- ③ **Oncology Business**
- ④ **Technology**
- ⑤ **Research**
- ⑥ **Q&A**








# Agenda

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# Daiichi Sankyo Won Three World ADC Awards in 2025



-  **TROP2 Directed ADC** recognized for  
“Best ADC Clinical Impact”
-  **HER2 Directed ADC** recognized for  
“Best ADC Clinical Publication”
-  **Daiichi Sankyo’s DXd ADC  
Technology** recognized for  
“Best ADC Platform Technology”



# Agenda

- ① Welcome
- ② **Clinical Development**
- ③ Oncology Business
- ④ Technology
- ⑤ Research
- ⑥ Q&A



# Looking Towards the Horizon ...

## Future of Daiichi Sankyo's ADC Technology

- **DXd ADCs ... More than ENHERTU<sup>®</sup>**  
Updates from DXd ADC portfolio
- **New Concept ADCs**  
mPBD, STING agonist payloads & others
- **New Non-ADC Oncology Pipeline**  
Targeted Protein Degraders, Novel Immune-Oncology Targets
- **Scientifically Rational Combinations**  
Unlocking the potential of DXd ADCs





# Multiple Accomplishments & Recognitions Continue to Demonstrate the Value of DXd ADCs



As of CY2025 ...

**ENHERTU®**

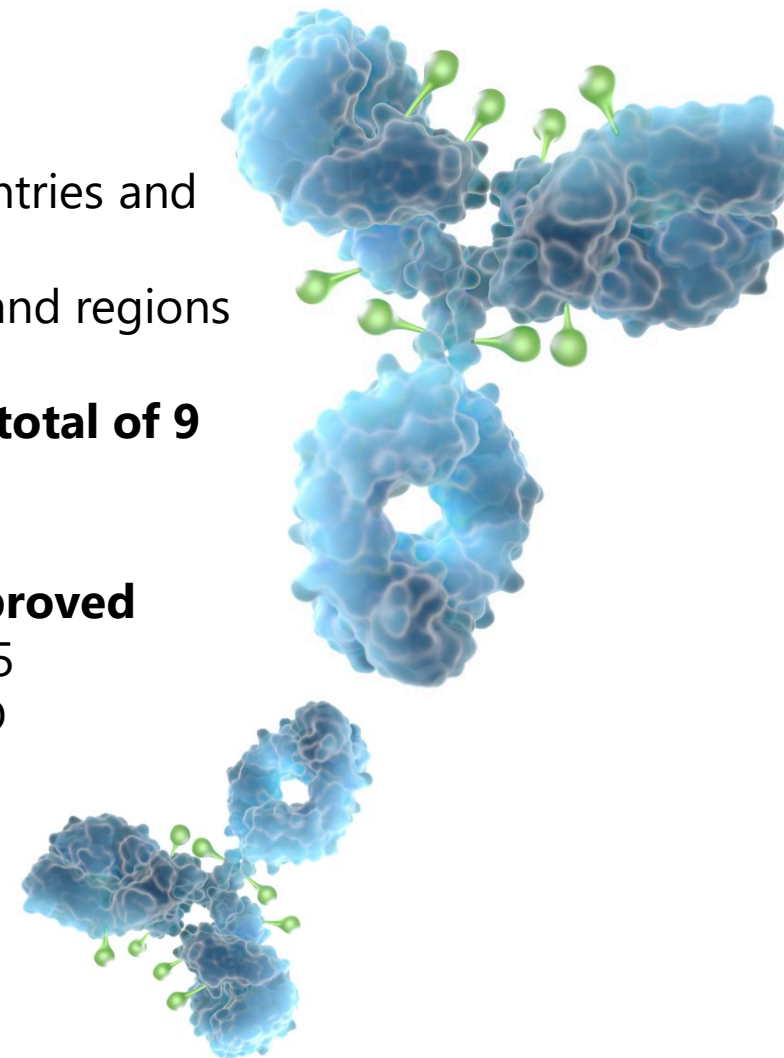
- **15 new Regulatory Approvals** across 15 countries and regions
- **94 extension Approvals** across 45 countries and regions
- **85 Regulatory Submissions**
- **Recent BTM in 1L HER2 positive mBC, for a total of 9 BTMs for ENHERTU®**

**DATROWAY®**

- **35+ Countries and Regions Regulatory Approved**
- **1 Accelerated Approval** for TROPION-Lung05 supported by TROPION-Lung01 based on BTM

**I-DXd & R-DXd**

- **BTMs for I-DXd in SCLC, and R-DXd in PROC, resulting in a total of 13 BTMs for DXd ADC portfolio**



# Multiple Accomplishments & Recognitions Continue to Demonstrate the Value of DXd ADCs

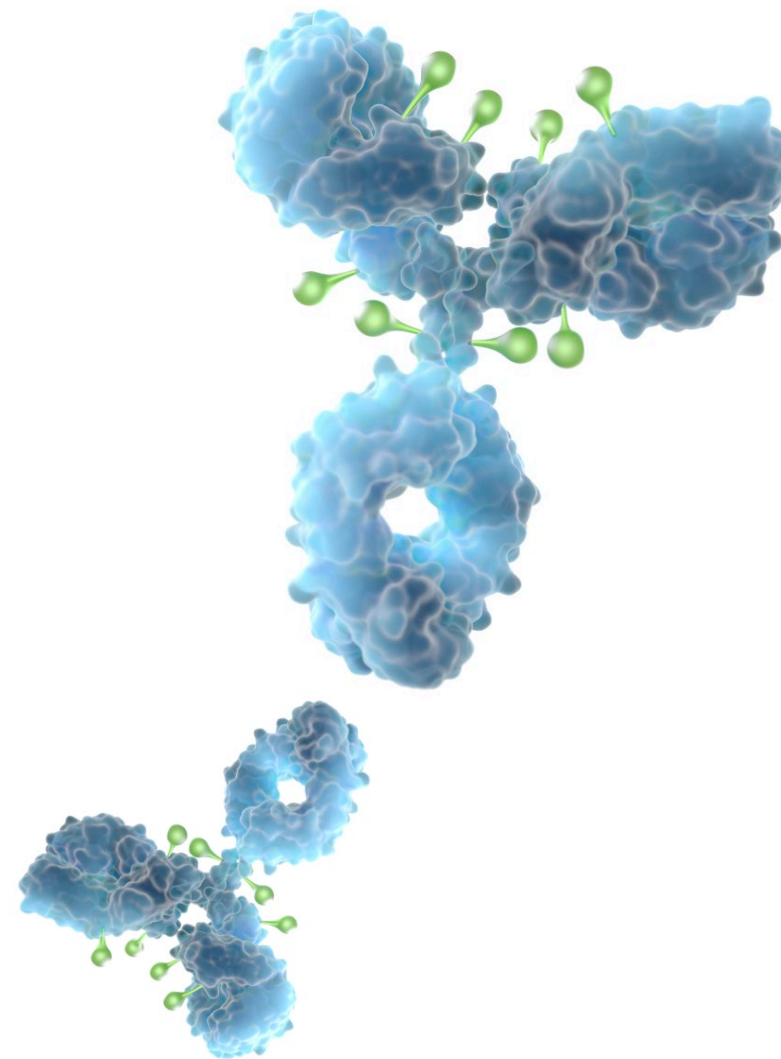


In the past two years, **22 articles** about our DXd ADC technology have been featured in prestigious journals\* including The New England Journal of Medicine & Nature Medicine



Since 2019, Daiichi Sankyo has received **15 awards & recognitions for our world-class science.**

Most recently, Daiichi Sankyo was honored to receive 3 World ADC Awards for ENHERTU<sup>®\*\*</sup> and DATROWAY<sup>®\*\*\*</sup> as well as for “Best ADC Platform Technology”.



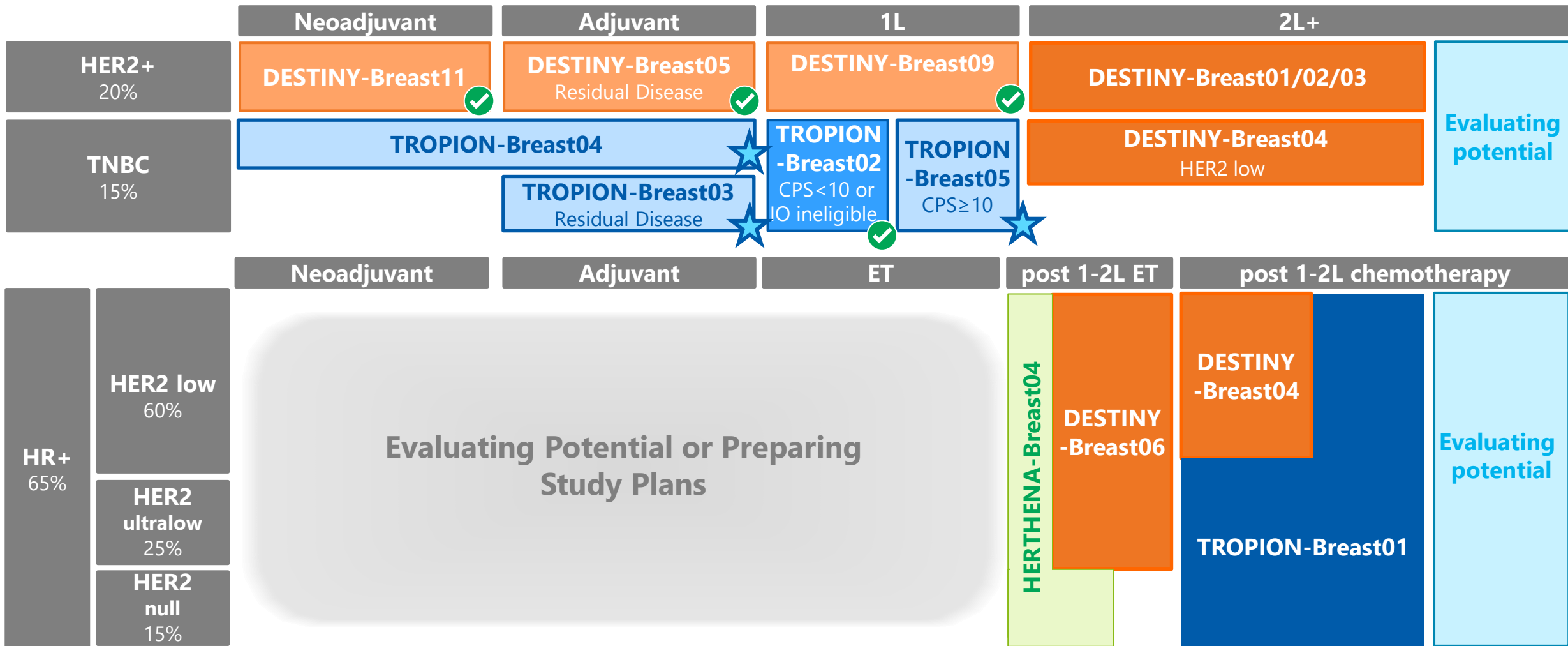
\* Journal of Clinical Oncology, Nature Medicine, The New England Journal of Medicine, The Lancet Oncology

\*\* Best ADC Clinical Publication Award for DESTINY-PanTumor02 publication in 2024

\*\*\* Best ADC Clinical Impact Award for studies including TROPION-Breast01, TROPION-Breast02, TROPION-Lung05



# Advancing ENHERTU® into Early Breast Cancer and DATROWAY® as the New 1L SOC in TNBC



**ENHERTU®** **DATROWAY®** : Launched **ENHERTU®** ✓ **DATROWAY®** ✓ : Completed Data Readout

**DATROWAY®** ★ : BEGONIA data supports TROPION-Breast03, TROPION-Breast04, TROPION-Breast05

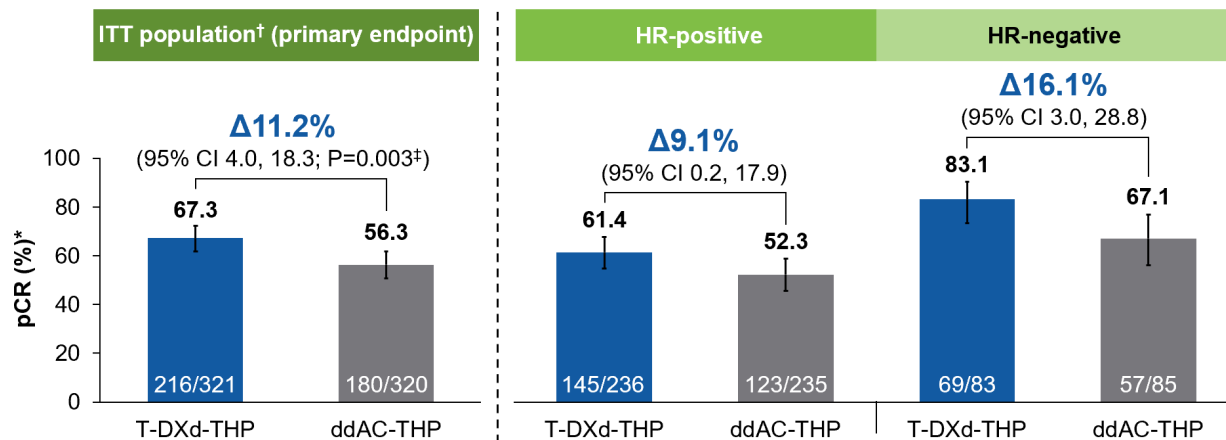
**DATROWAY®** **HER3-DXd** **Early Pipeline** : On-going

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

# Go Earlier in HER2+ eBC: Positive Trials, with Potential Cure of eBC at a High Risk of Recurrence

## DESTINY-Breast11 (Neoadjuvant)

Primary endpoint: pCR (ypT0/is ypN0)



Neoadjuvant T-DXd-THP demonstrated a **statistically significant and clinically meaningful improvement** in pCR vs ddAC-THP in patients with high-risk HER2+ eBC.

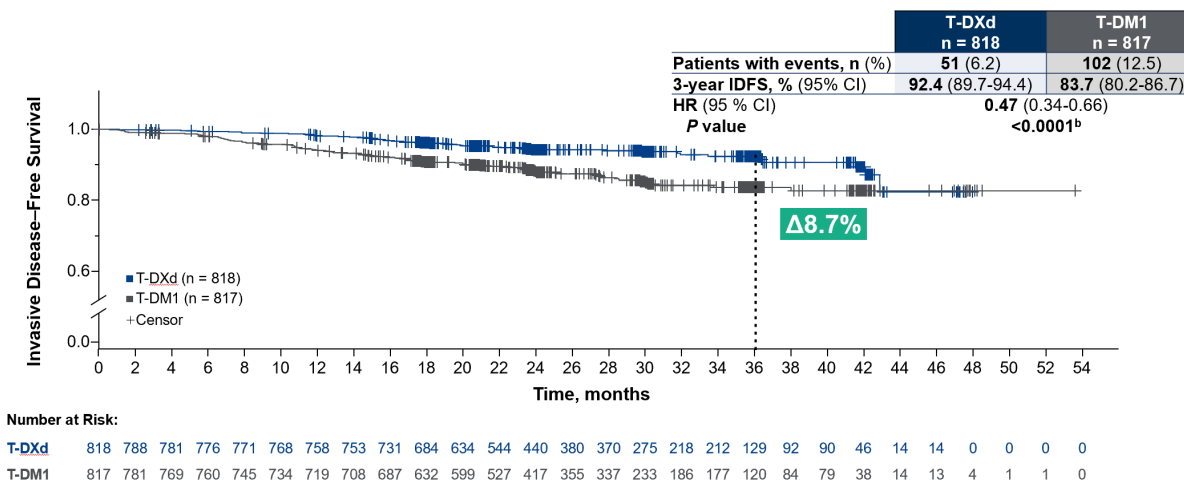
Improvement was observed **in both the HR-positive and HR-negative subgroups**

**For the ITT population, treatment effects were estimated by the difference in pCR with 95% CIs and P-values based on the stratified Miettinen and Nurminen's method, with strata weighting by sample size (ie Mantel-Haenszel weights)**

\*By blinded central review; †pCR responders were defined as patients who only received randomized study treatment (at least one dose) and had pCR; ‡two-sided P-value crossed the 0.03 prespecified boundary.

## DESTINY-Breast05 (Post Neoadjuvant)

Primary endpoint: IDFS<sup>a</sup>



**53% reduction** in the risk of invasive disease recurrence or death for T-DXd compared with T-DM1 in patients with HER2+ eBC

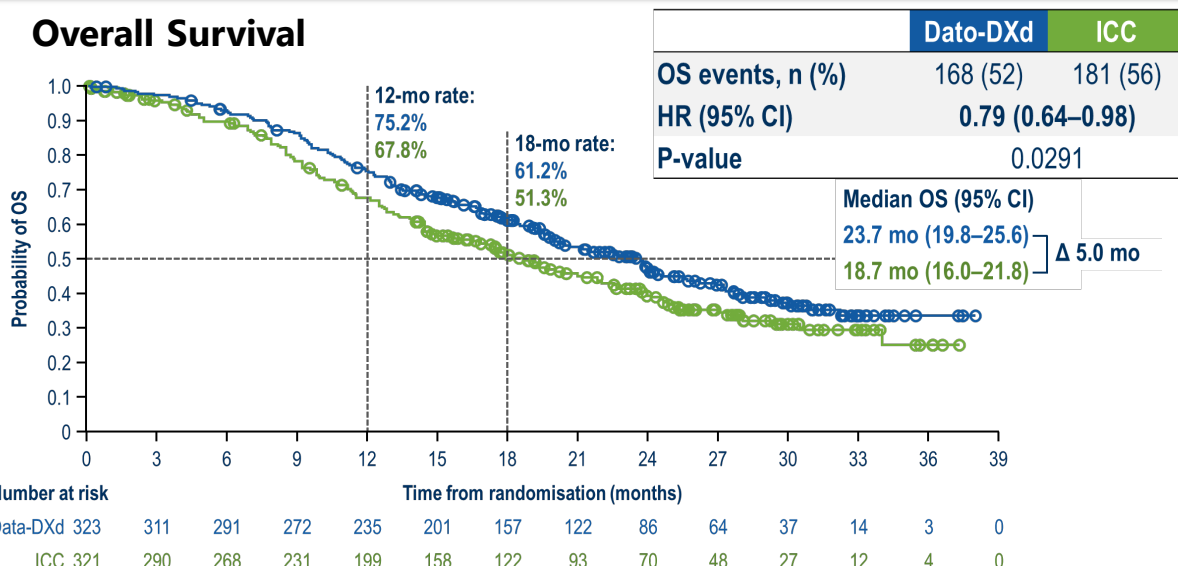
**Efficacy stopping boundary, P = 0.0183**

<sup>a</sup>IDFS is defined as the time from randomization until the date of first occurrence of one of the following events: recurrence of ipsilateral invasive breast tumor, recurrence of ipsilateral locoregional invasive breast cancer, contralateral invasive breast cancer, a distant disease recurrence, or death from any cause. <sup>b</sup>Two-sided P value from stratified log-rank test. Hazard ratio and 95% CI from stratified Cox proportional hazards model with stratification factor of operative status at disease presentation.

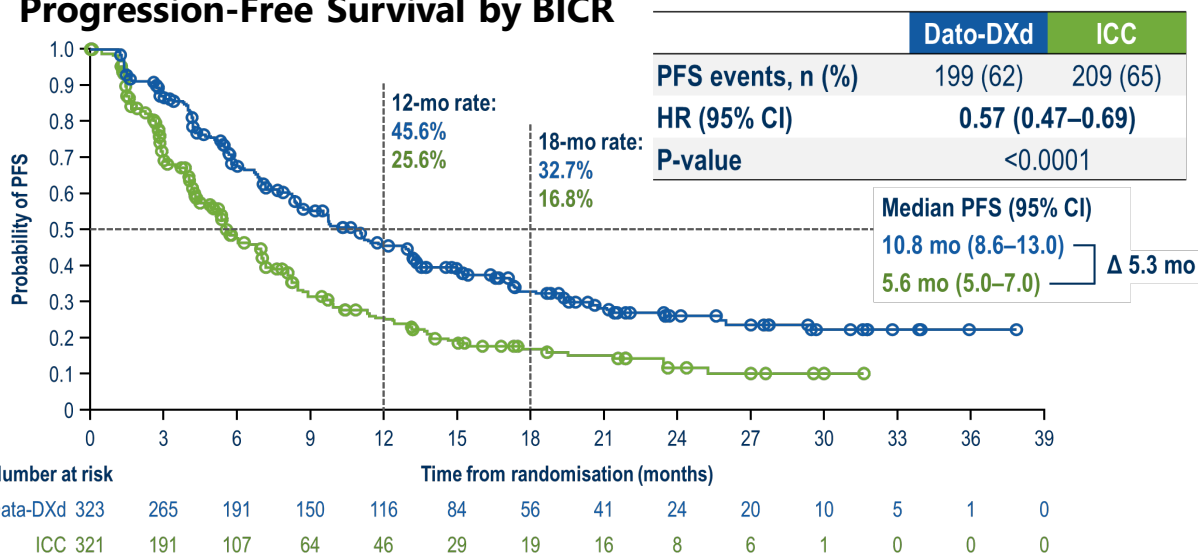
# DATROWAY<sup>®</sup> is the First and Only TROP2 directed ADC Showing Statistically Significant & Clinically Meaningful OS Results in 1L mTNBC

## TROPION-Breast02 (1L mTNBC)

### Overall Survival



### Progression-Free Survival by BICR



- In TROPION-Breast02, **DATROWAY<sup>®</sup>** demonstrated a statistically significant and clinically meaningful improvement of ~5 months in both mOS and mPFS vs chemotherapy (OS HR: 0.79, mOS: 23.7 vs. 18.7 mo)
  - **Statistically significant OS despite use of subsequent ADCs in the control arm**
  - DATROWAY<sup>®</sup> achieved ORR two-fold higher than chemotherapy (62% vs. 29.3% for chemotherapy), with durable responses lasting >1 year. Durable responses are important in TNBC where responses with chemotherapy are short-lived
- TROPION-Breast02 enrolled a population representing ~70% of patients with 1L mTNBC, and included those often excluded from clinical trials with the poorest prognosis (e.g. DFI < 6 months)
- Despite more than double the duration of treatment (8.5 vs 4.1 mo), rates of Grade ≥3 and serious TRAEs were similar, and discontinuations were lower, with DATROWAY<sup>®</sup> vs chemotherapy. AEs (e.g. stomatitis, ILD) were primarily Grade 1–2 and manageable
- DATROWAY<sup>®</sup> has **more convenient administration schedule (Q3W)**
- DATROWAY<sup>®</sup> leverages the clinically-validated DXd technology with a tumor-selective cleavable linker that is specifically designed to reduce systemic exposure to the payload
- TROPION-Breast02 results support DATROWAY<sup>®</sup> as a potential new 1L standard of care for patients with metastatic TNBC for whom immunotherapy is not an option
- Three additional studies of DATROWAY<sup>®</sup> are ongoing with PD-L1 agents in the TNBC setting including neoadjuvant, adjuvant and metastatic 1L

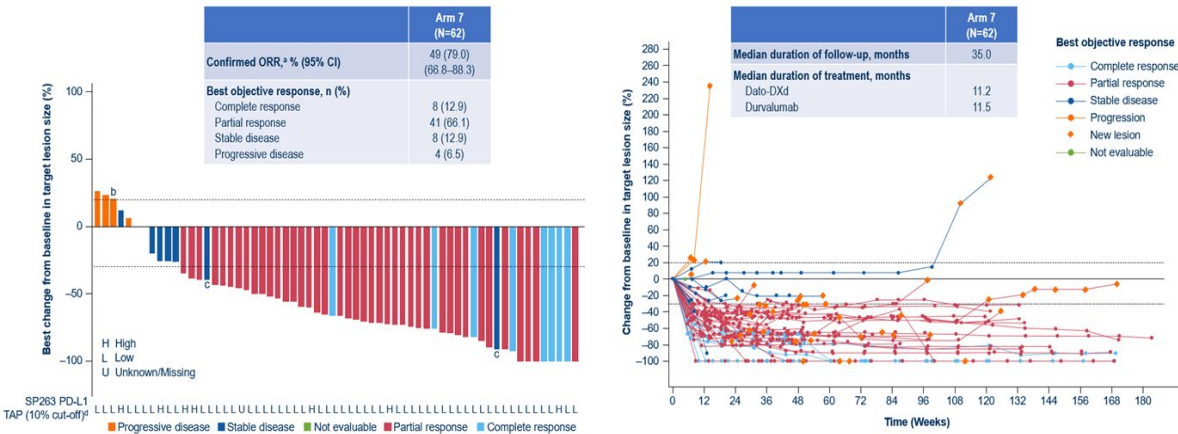
AESi: adverse event of special interest, BICR: blinded independent central review, CI: confidence interval, DFI: disease-free interval, ESMO: European Society for Medical Oncology, HR: hazard ratio, ICC: Investigator's choice of chemotherapy, ILD: interstitial lung disease, IO: immune oncology, mo: months, mOS: median overall survival, mPFS: median progression-free survival, OS: overall survival, ORR: Objective Response Rate, PFS: progression-free survival, Q3W: once every 3 weeks, mTNBC: metastatic triple-negative breast cancer, TRAE: treatment-related adverse event

# DATROWAY® + durvalumab demonstrated promising efficacy in BEGONIA, supporting the combination in TNBC

Three Ph3 studies (TROPION-Breast03, TROPION-Breast04, TROPION-Breast05) are underway with DATROWAY® + durvalumab across TNBC settings

## Arm 7 (87.1% had PD-L1 low tumors)

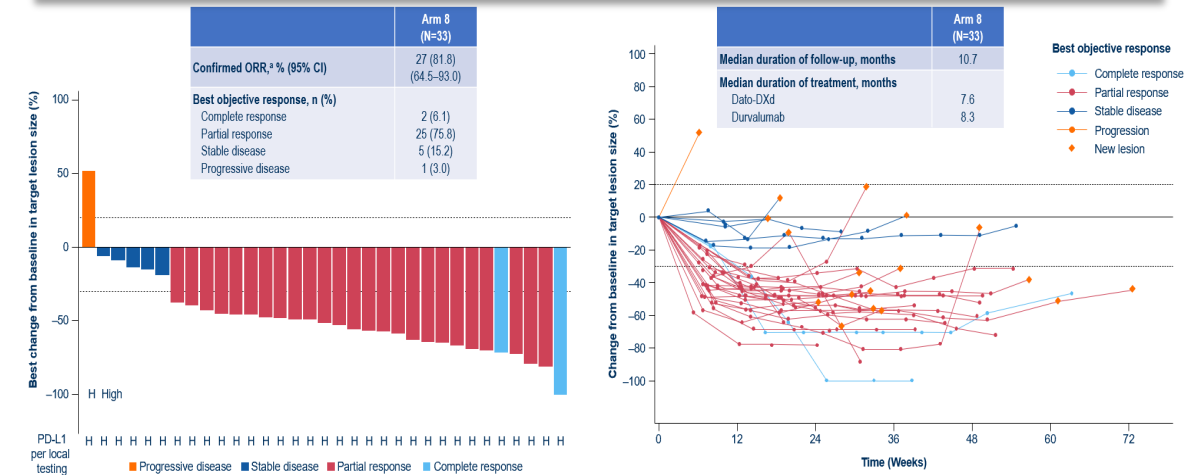
Confirmed ORR was **79.0%** (49/62; 95% CI, 66.8–88.3) with 8 CR and 41 PR



median DOR: 17.6 months and median PFS: 14 months

## Arm 8 (PD-L1 high)

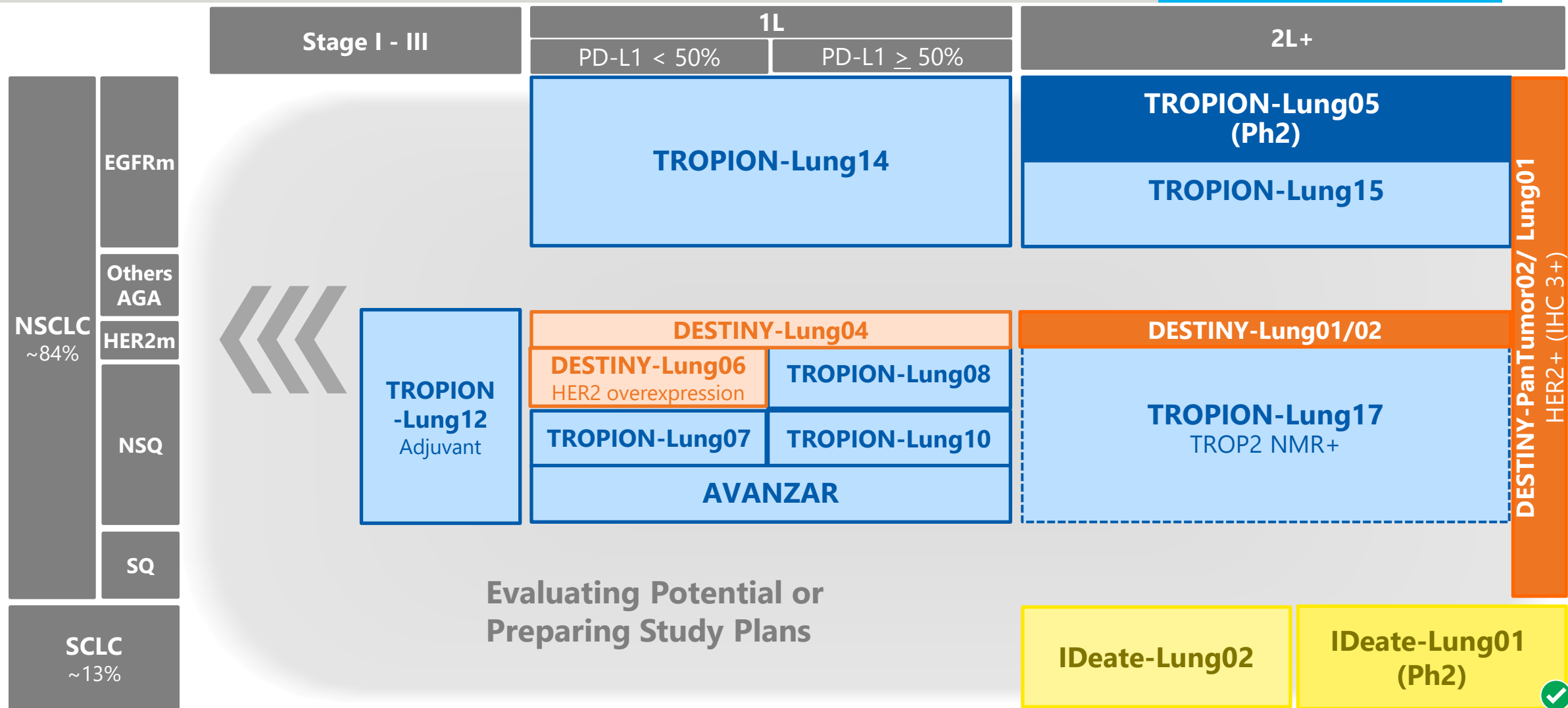
Confirmed ORR was **81.8%** (27/33; 95% CI, 64.5–93.0) with 2 CR and 25 PR



median DOR: median PFS were immature

- AEs were primarily low grade (Grade 1-2); and the most common AEs were stomatitis, nausea, and alopecia
- ✓ Across both arms, rates of adjudicated drug-related ILD were low, with no grade ≥3 events

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



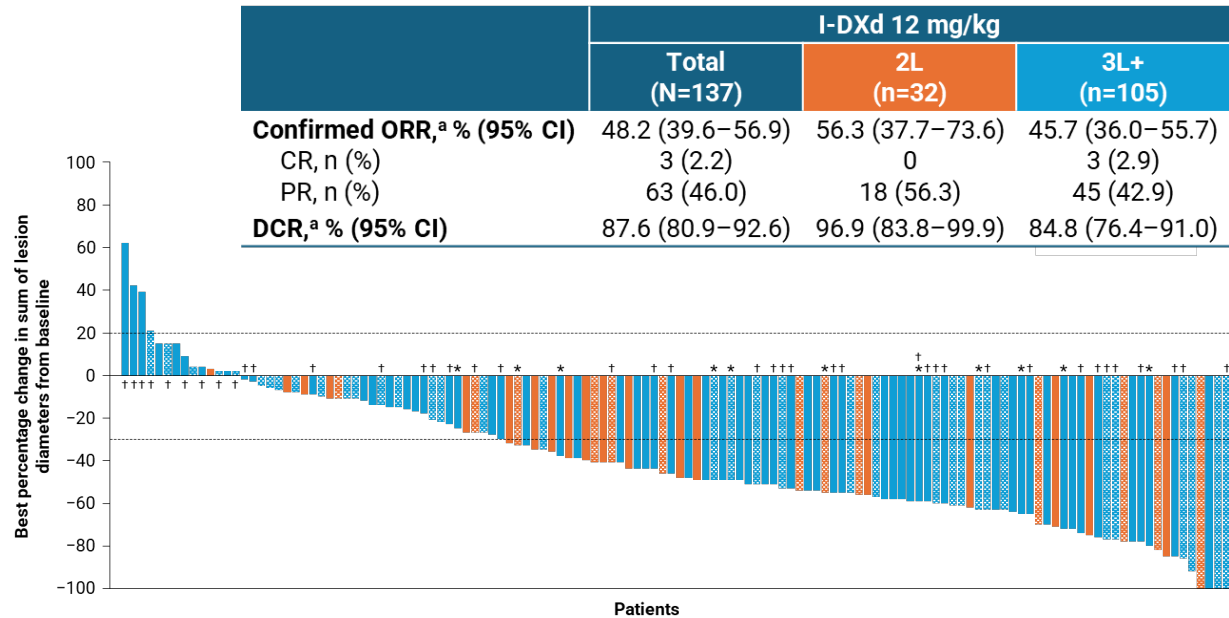
**ENHERTU®** **DATROWAY®** : Launched, **I-DXd** : Completed Data Readout,

**ENHERTU®** **DATROWAY®** **I-DXd** : On-going, **DATROWAY®** : Planning

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

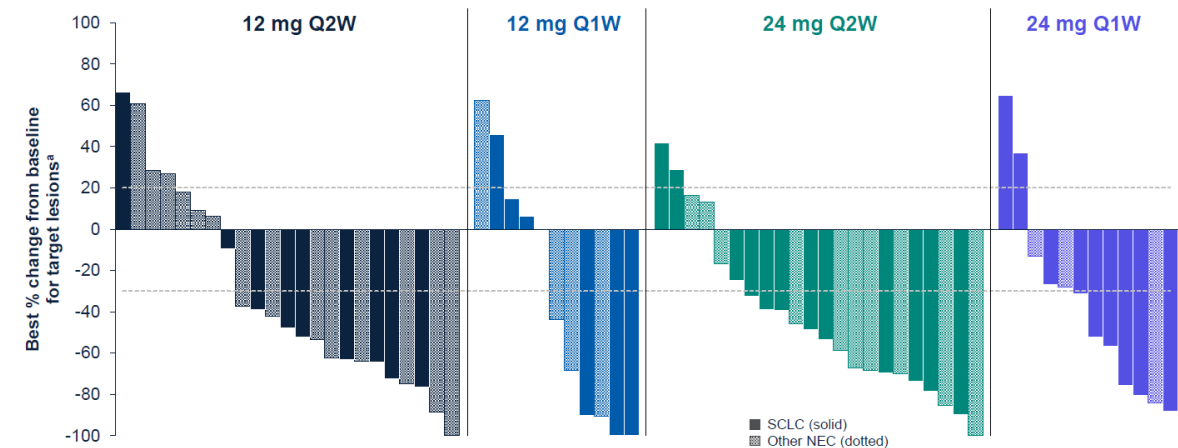
# Daiichi Sankyo/US Merck\* Partnership Includes Two Complementary Assets with Activity in SCLC, and Combination Data are Eagerly Waited

## I-DXd 12 mg/kg demonstrated promising antitumor activity in ES-SCLC



Data cutoff: March 3, 2025

## Gocatumig DLL3-targeting T-cell engager cORR, 44% (95% CI, 32-56) in all cohorts (N=73)



Data cutoff: February 28, 2025.

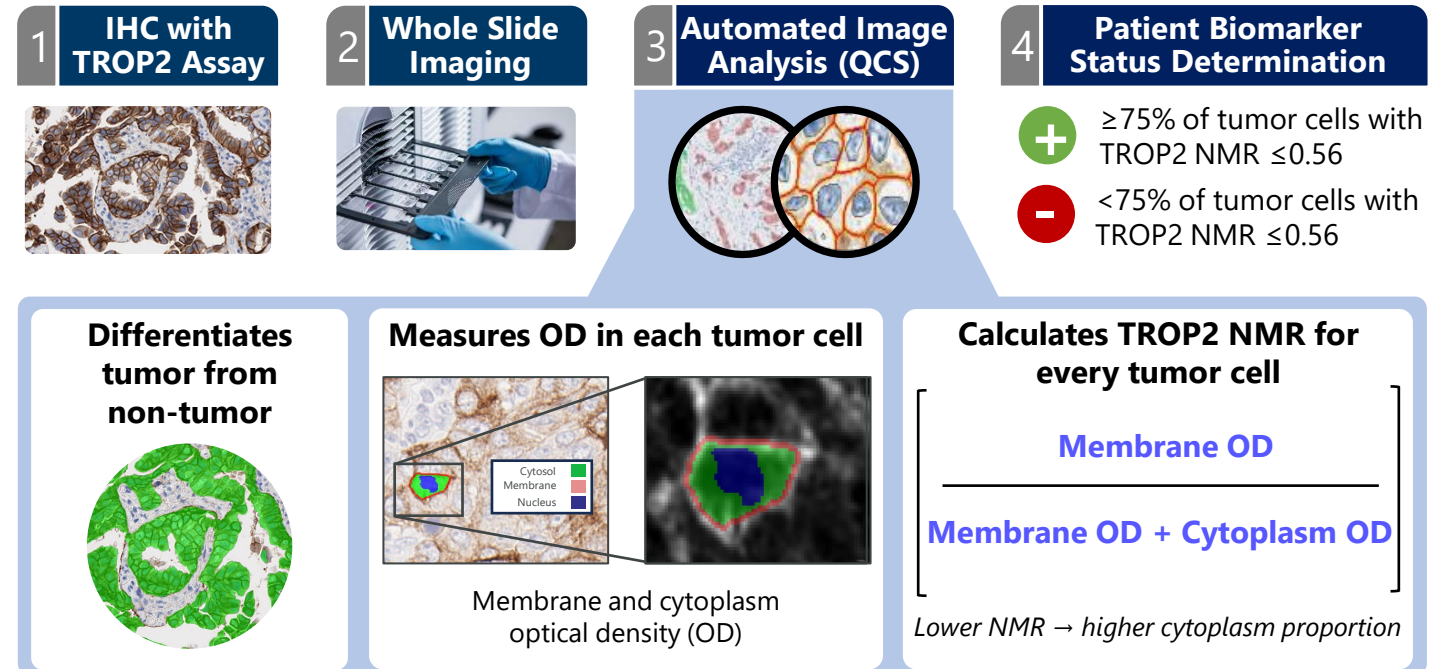
<sup>a</sup>Among 68 participants who received any amount of study treatment and had at least one postbaseline scan.

\* Merck & Co., Inc., Rahway, NJ, USA  
<sup>a</sup>Assessed by BICR per RECIST 1.1. <sup>b</sup>By BICR.



# How a Novel Computational Predictive Biomarker Gives DATROWAY<sup>®</sup> an Advantage in 1L NSCLC: TROP2 NMR by Novel Pathology Approach, QCS

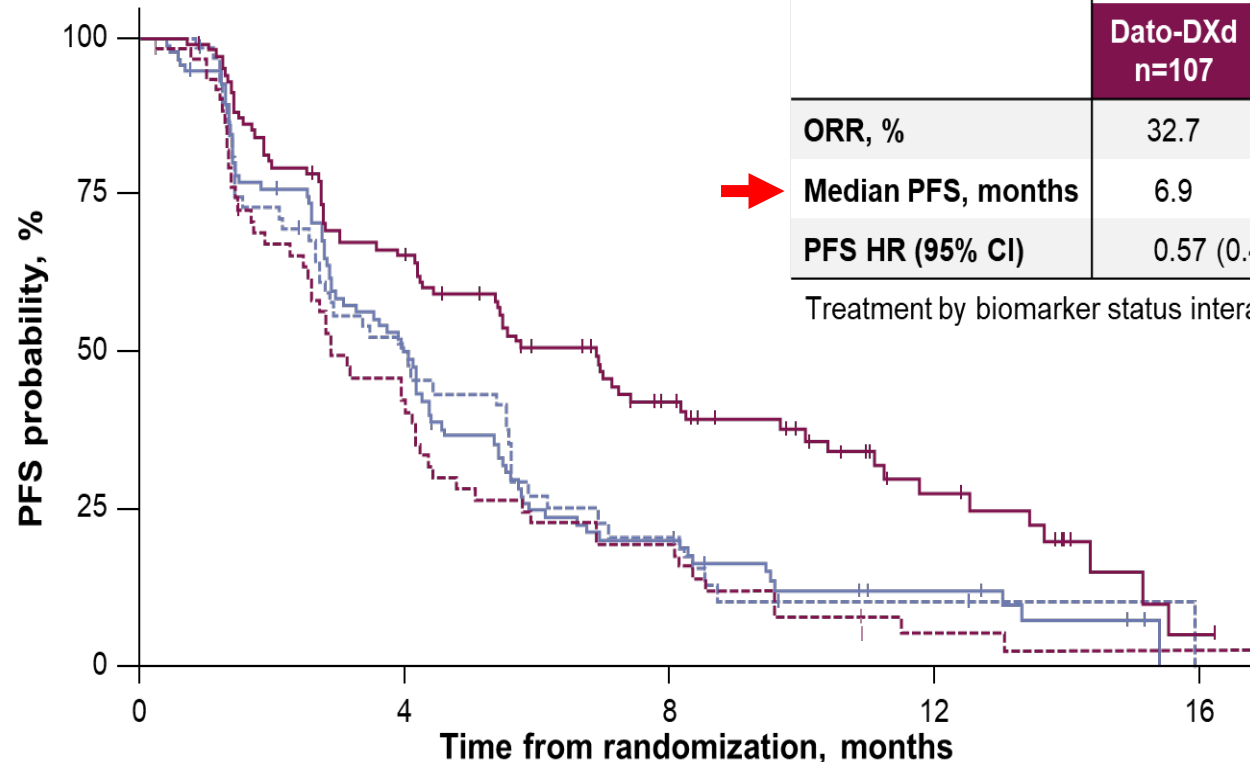
- TROP2 Tumor membrane expression using conventional IHC and pathology visual scoring does not enrich for response in NSCLC
- TROP2 NMR as measured by QCS reflects the expression of TROP2 in the membrane relative to total TROP2 (membrane and cytoplasm)



# TROP2 NMR Positivity was Predictive for Longer PFS with DATROWAY<sup>®</sup> in TROPION-Lung01

TROP2 NMR measured by QCS predicted outcomes in an exploratory analysis in the TROPION-Lung01 trial evaluating DATROWAY<sup>®</sup> as monotherapy in the 2L+ setting<sup>1</sup>

Biomarker-evaluable population, n=352

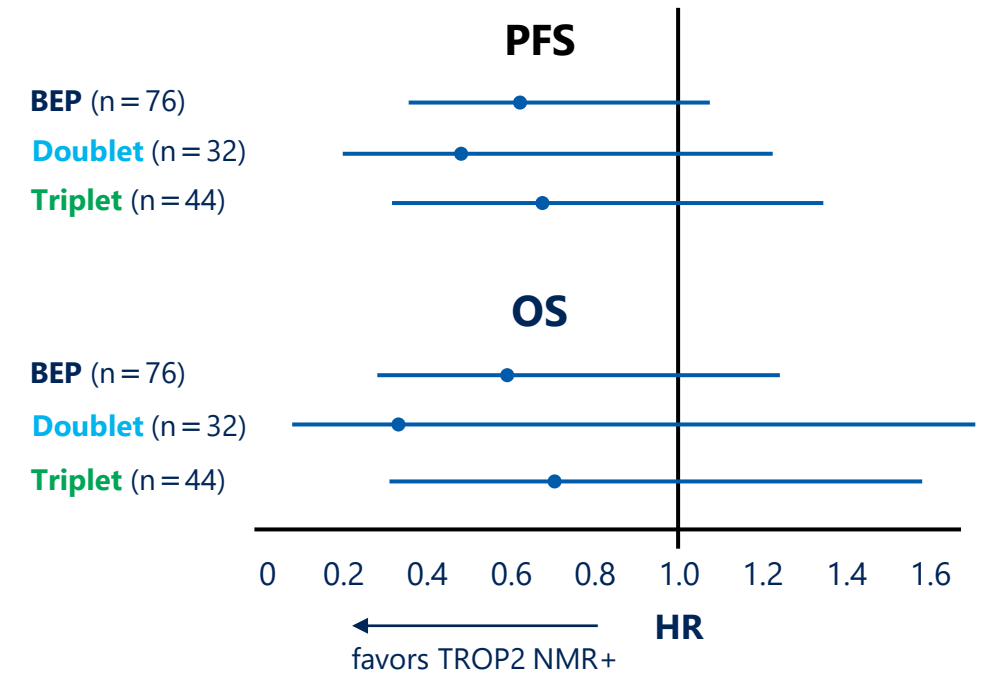
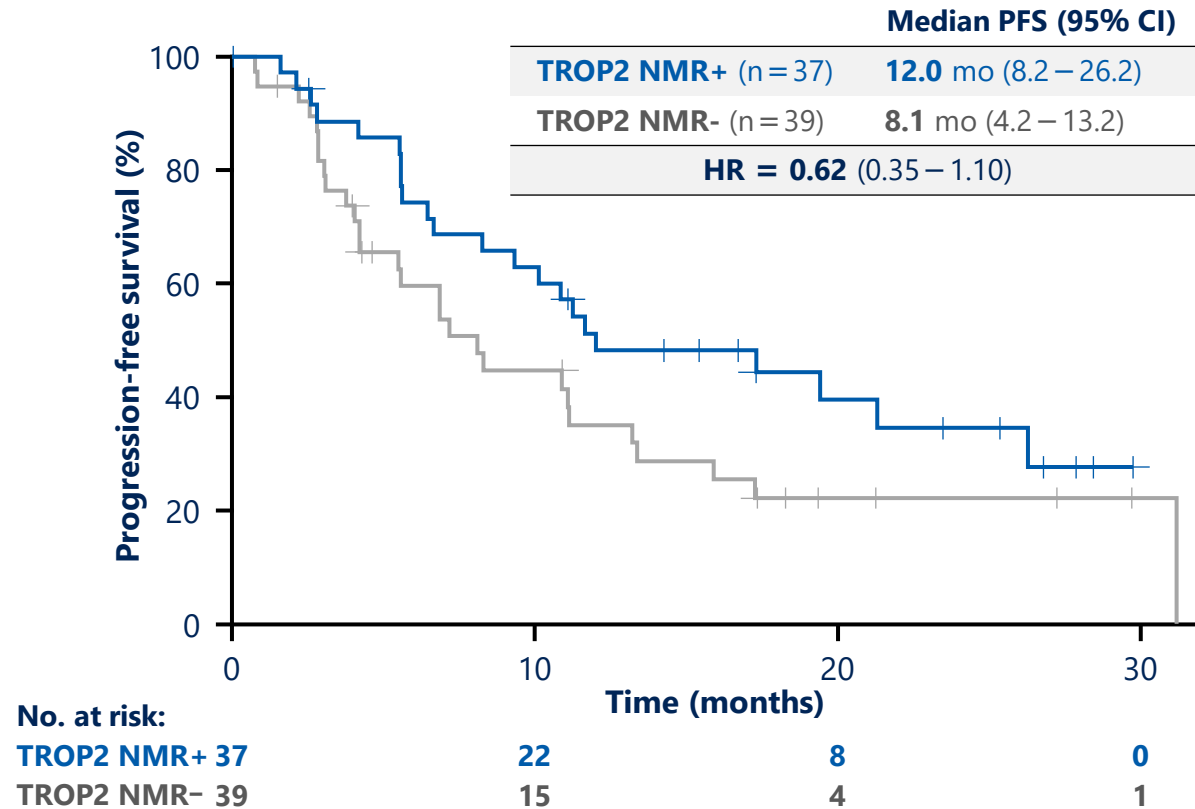


	TROP2 NMR+		TROP2 NMR-	
	Dato-DXd n=107	Docetaxel n=107	Dato-DXd n=65	Docetaxel n=73
ORR, %	32.7	10.3	16.9	15.1
Median PFS, months	6.9	4.1	2.9	4.0
PFS HR (95% CI)	0.57 (0.41–0.79)		1.16 (0.79–1.70)	

Treatment by biomarker status interaction: p=0.0063

# Exploratory Analysis per TROP2 NMR in 1L NSCLC

## TROPION-Lung02 : PFS by TROP2 QCS-NMR, 1L Biomarker Evaluable Population



Exploratory TROP2 NMR testing showed a trend towards prolonged PFS and OS in biomarker positive patients treated with DATROWAY<sup>®</sup> in combination with PD-1 agents (doublet) or with CT+ PD-1 agents (triplet)

Data cutoff: April 29, 2024.

ASCO: American Society of Clinical Oncology, BEP: biomarker evaluable population, CI: confidence interval, HR: hazard ratio, CT: chemotherapy, mo: months, NMR: normalized membrane ratio, ORR: objective response rate, OS: overall survival, PFS: progression-free survival

# DATROWAY®: 5 Combination Studies with IO in the 1L NSCLC Ongoing, Some applied TROP2 NMR Biomaker e.g., AVANZAR

## DATROWAY® + Immune checkpoint inhibitors

pembrolizumab	TROPION-Lung02 w/o AGA		Ph3
	TROPION-Lung08* w/o AGA PD-L1 ≥50%. 1L	TROPION-Lung07 NSQ w/o AGA PD-L1 <50%, 1L	Ph2
durvalumab	NeoCOAST-2 early stage, neoadjuvant	AVANZAR* w/o AGA, 1L	Ph1
	TROPION-Lung04 w/o AGA		TROP2 NMR applied prospectively
rilvegostomig	TROPION-Lung12 stage1 high risk, adjuvant	TROPION-Lung10 NSQ w/o AGA PD-L1 ≥50%, 1L	

## DATROWAY® + tyrosine kinase inhibitors

osimertinib	ORCHARD EGFRm, 2L	
	TROPION-Lung14 EGFRm, 1L	TROPION-Lung15 EGFRm, 2L+

\* Due to the protocol revision, the inclusion criteria are limited to NSQ NSCLC

AGA: actionable genomic alteration, EGFRm: EGFR mutated, IO: immuno oncology, NMR: normalized membrane ratio, NSQ: non-squamous, NSCLC: non-small cell lung cancer

# Expanding Daiichi Sankyo ADCs within Women's Cancers to Address Broad Spectrum of **Gynecologic Cancers**

## Daiichi Sankyo Registrational Studies Across Gynecological Cancers

### Ovarian Cancer

Early (I-II)		Advanced (III-IV)		Recurrent Disease	
		1L induction	1L Maintenance	Platinum-sensitive	Platinum-resistant
BRCAm 15%	HRD 50%	<b>DESTINY-Ovarian01</b> HER2+ (IHC 3+/2+/1+)		<b>DESTINY-PanTumor02</b> HER2+ (IHC 3+)*	<b>REJOICE-Ovarian 01</b>
BRCA wt 85%	HRP 50%				







### Endometrial Cancer

Endometrial Cancer		Early stage		Advanced / Recurrent		
		Adjuvant		1L	2L+	
dMMR 25%		DESTINY-Endometrial02 HER2+ (IHC 3+/2+)		DESTINY-PanTumor02 HER2+ (IHC 3+)*		
pMMR R 75%						
p53 WT 60%						
p53m ~40%						

\*ENHERTU® tumor agnostic approval (HER2 IHC 3+) in 2L+ setting. NCCN Ovarian Cancer Guidelines (Jan 2025) update Category 2B recommendation of ENHERTU® in HER2+ (IHC 3+) PSOC. NCCN Endometrial Cancer Guidelines (2025) includes a Category 2B recommendation for ENHERTU® in HER2+ (IHC 2+/3+) endometrial cancer in the 2L+ setting.

**ENHERTU®** : Launched, **ENHERTU®** **R-DXd** : On-going

## Exploring 7 Clinical Stage Assets in GYN

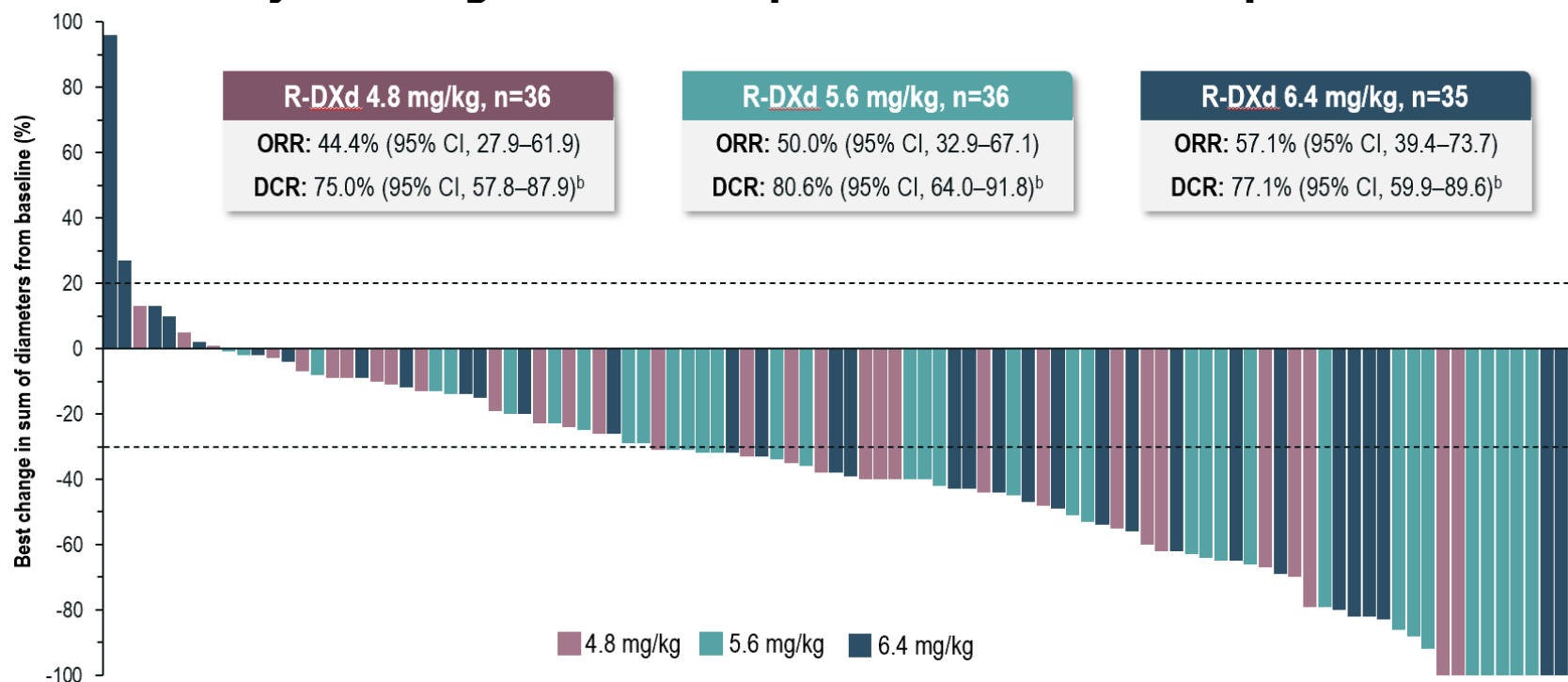
Compound	Target	Payload	
ENHERTU®	HER2	TOPO1	
DATROWAY®	TROP2	TOPO1	
HER3-DXd	HER3	TOPO1	
I-DXd	B7-H3	TOPO1	
R-DXd	CDH6	TOPO1	
DS-3939	TA-MUC1	TOPO1	
DS-9606	CLDN6	mPBD	

 Indicates DXd ADC technology

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

# R-DXd Confirmed Clinical Meaningful Responses in Ph2 Part REJOICE-Ovarian01 Ph2/3

Clinically meaningful tumor responses were seen irrespective of dose<sup>a</sup>



**R-DXd Granted Breakthrough Therapy Designation** by U.S. FDA for Patients with CDH6 Expressing Platinum-Resistant Ovarian, Primary Peritoneal or Fallopian Tube Cancers Previously Treated with Bevacizumab – September 2025

**Data cutoff: February 26, 2025. The median follow-up for 4.8-mg/kg, 5.6-mg/kg, and 6.4-mg/kg cohorts was 5.6 months (95% CI, 4.7–6.3), 5.6 months (95% CI, 4.6–5.8), and 5.2 months (95% CI, 4.9–5.8), respectively.**

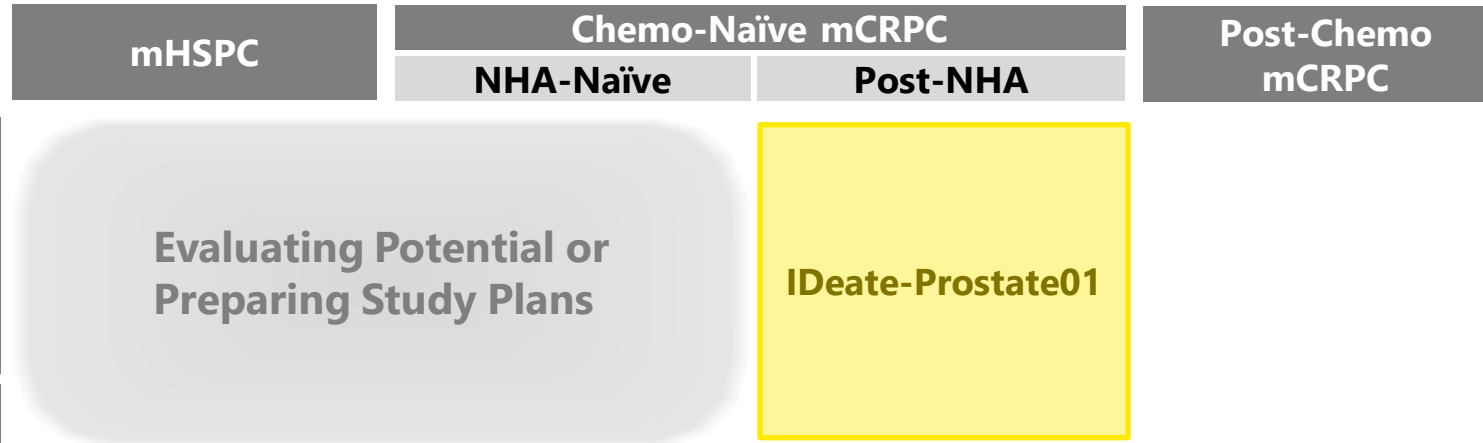
<sup>a</sup>Antitumor response assessed by BICR per RECIST 1.1. Only patients with measurable disease at baseline and  $\geq 1$  post-baseline tumor scan, both by BICR, were included in the waterfall plot (n=100). Six patients (R-DXd 4.8 mg/kg [n=5]; 6.4 mg/kg [n=1]) did not have measurable disease at baseline and one patient (R-DXd 5.6 mg/kg) had no adequate post-baseline tumor assessment. <sup>b</sup>DCR was defined as percentage of patients with BOR of CR, PR, or SD (per RECIST 1.1).



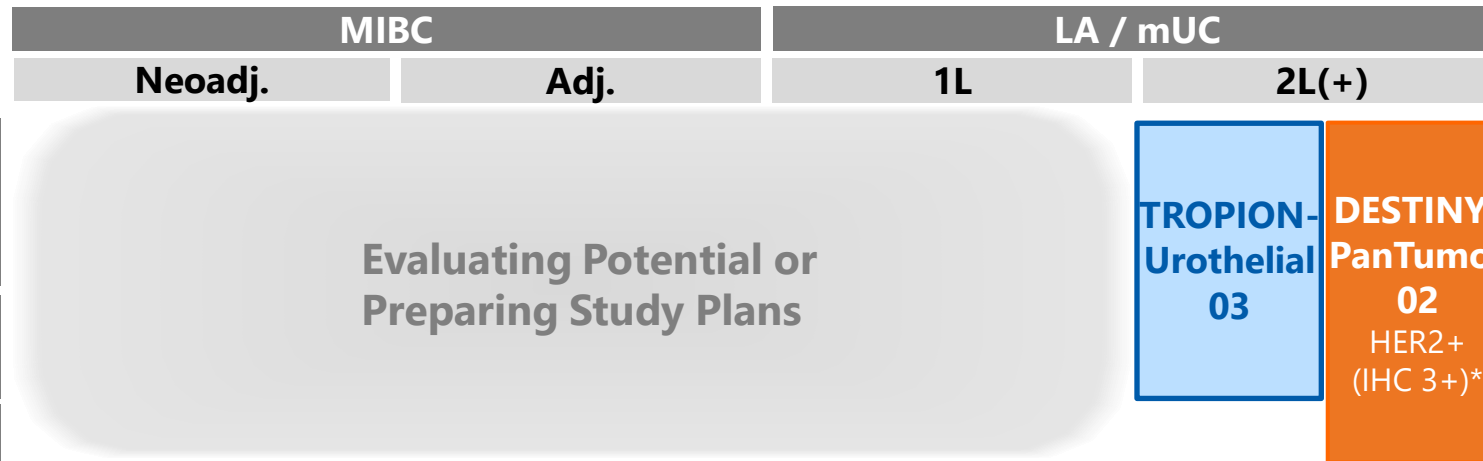
# Expanding Daiichi Sankyo Assets within Genitourinary Cancers to Address a Broad Spectrum of Unmet Needs

## Daiichi Sankyo Registrational Studies Across Genitourinary Cancers

### Prostate Cancer



### Bladder Cancer



## Exploring 8 Clinical Stage Assets in GU Tumors

Compound	Target
ENHERTU®	HER2 DXd ADC
DATROWAY®	TROP2 DXd ADC
HER3-DXd	HER3 HER2 DXd ADC
I-DXd	B7-H3 DXd ADC
DS-3939	TA-MUC1 DXd ADC
EZHARMIA®	EZH1/2 inhibitor
DS-2243	HLA-A*02 / NY-ESO Bispecific TCE
DS9051	Targeted Protein Degradation Molecule

\*ENHERTU® tumor agnostic approval (HER2 IHC 3+) in 2L+ setting. NCCN Bladder Cancer Guidelines (Oct 2025) Category 2A recommendation

**ENHERTU®** : Launched, **DATROWAY®** **I-DXd** : On-going

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# Looking Towards the Horizon ...

## Future of Daiichi Sankyo's ADC Technology

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Updates from DXd ADC portfolio
- **New Concept ADCs**  
mPBD, STING agonist payloads & others
- **New Non-ADC Oncology Pipeline**  
Targeted Protein Degraders, Novel Immune-Oncology Targets
- **Scientifically Rational Combinations**  
Unlocking the potential of DXd ADCs



# The Evolution of our ADC Technologies Will Continue

**ADCs are modular, and interchanging the modules can create new drugs**

## Our Proprietary Technologies

### Payload Module

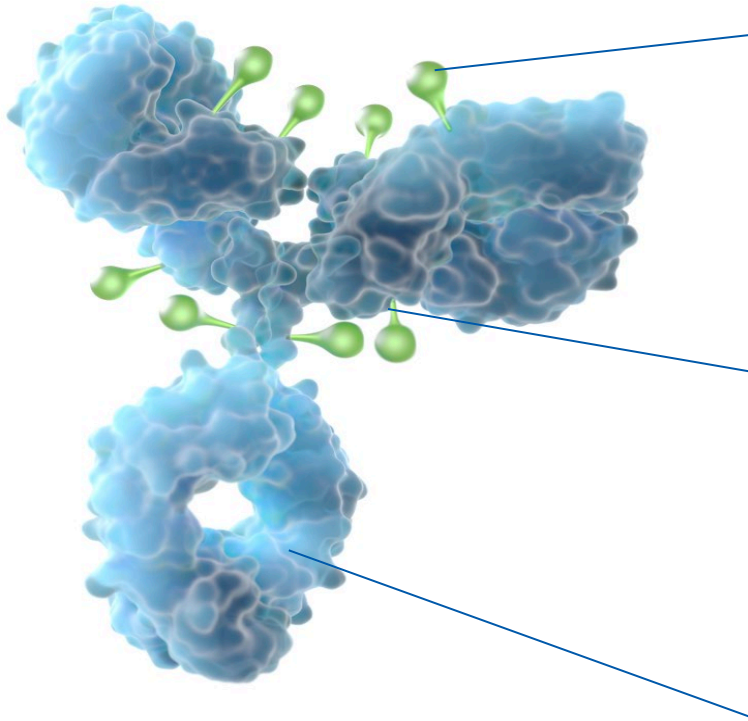
- ✓ Cytotoxic payloads
  - DXd, mPBD
- ✓ Other new payloads to combat refractory/resistant tumors
  - IO payloads
  - Novel payloads

### Linker Module

- ✓ DAR control
- ✓ Site specificity
- ✓ Novel conjugation

### Antibody Module

- ✓ Unique binders targeting disease specific proteins and glycans
- ✓ Fc engineering
- ✓ Novel technologies to increase specificity



## DXd ADCs with New mAb Targets

**DS-3939**  
(TA-MUC1)

- Tumor specific glycoprotein with high expression in tumors

**DS3790**  
(CD37)

- The First DXd ADC targeting hematopoietic tumors

## New DXd ADCs with engineered mAb or Payload-Linker

**New ADC1**

- Featuring tissue selectivity

**New ADC2**

- Featuring optimized retention within cells to increase efficacy

## Different Payload from DXd ADC

**DS-9606**  
(mPBD ADC)

- Featuring stability and selectivity

**DS3610**  
(STING agonist ADC)

- Optimized STING agonist payload and Fc technology to reduce irrelevant immune activation

**New ADC3**

- Novel payload with distinct mechanism of action






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Unlocking the potential of DXd ADCs



# Advancing New Non-ADC Oncology Pipeline in Global Clinical Development

Modality	Generic Name/Code Name	Target	Representative Target Indications	Pre-Clinical	Ph1	Ph1/2	Ph2	Status
T-cell engager	<b>Gocatamig</b>	DLL3	SCLC					FPD in Dec 2020
	<b>DS-2243</b>	NY-ESO/HLA-A*02	NSCLC, UC, Sarcoma					FPD in Mar 2025
Antibody	<b>DS-1103</b>	anti-SIRPα	Solid tumors					FPD in Jun 2023
Small or mid-size molecules	<b>DS5361</b>	Not Disclosed	Solid tumors					FPD in Oct 2025
	<b>DS9051</b>	Not Disclosed	CRPC					FPD in Nov 2025

 Timeline indicates the most advanced stage of each asset, and that status may not apply to all tumors listed in the “target tumor” column

# Unique Immune-Oncology Drugs

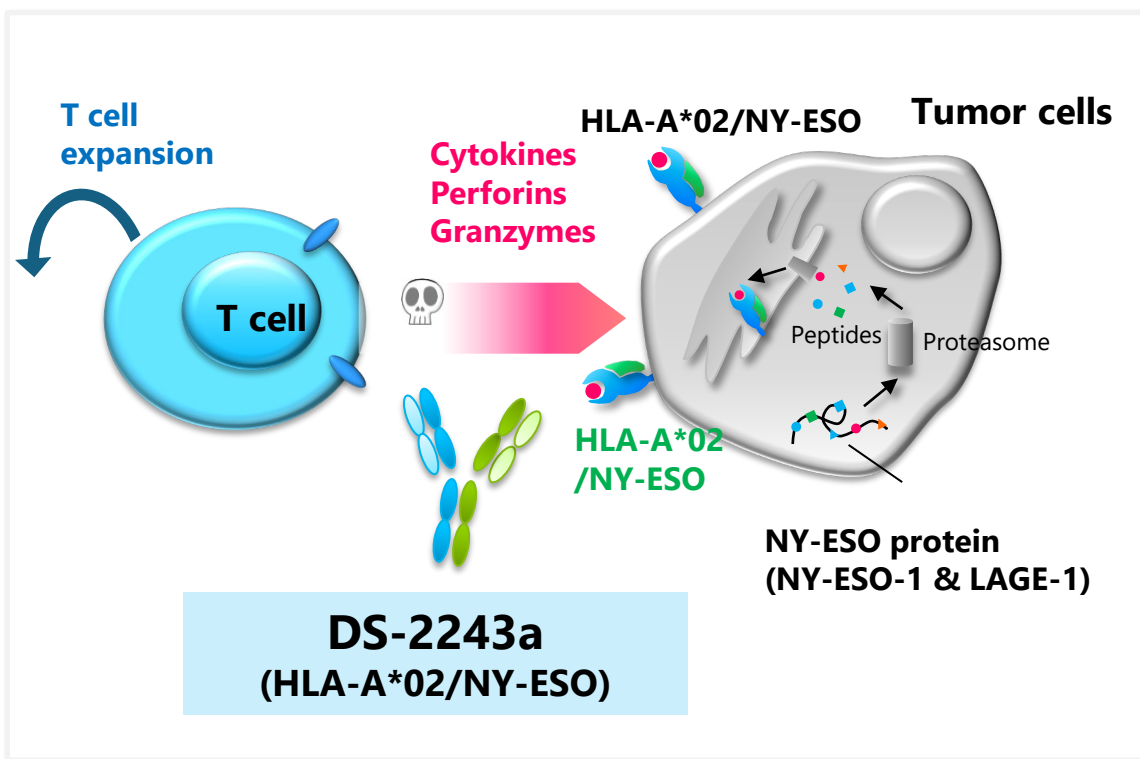
**DS-2243**

**T cell engager targeting  
HLA-A\*02/NY-ESO**

Modality: Bispecific  
Antibody



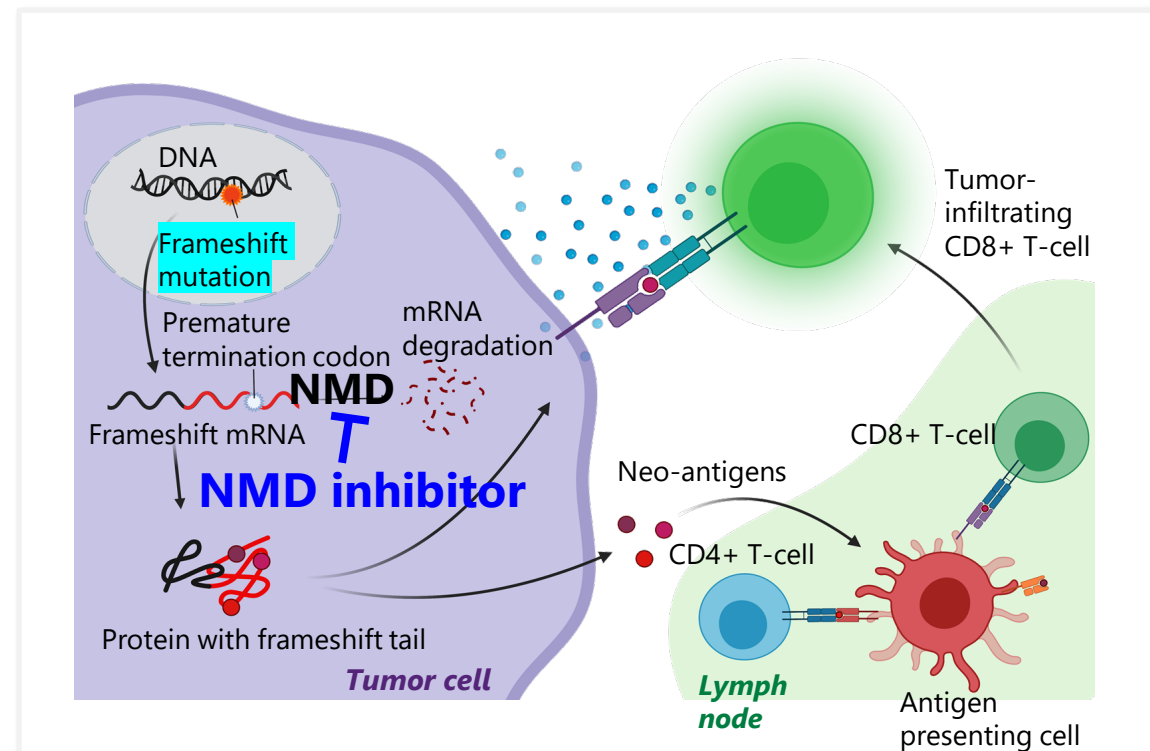
**T cell receptor  
like antibody**



**DS5361**

**Novel IO agent which enhance tumor immuno-  
genicity**

Modality: small molecule



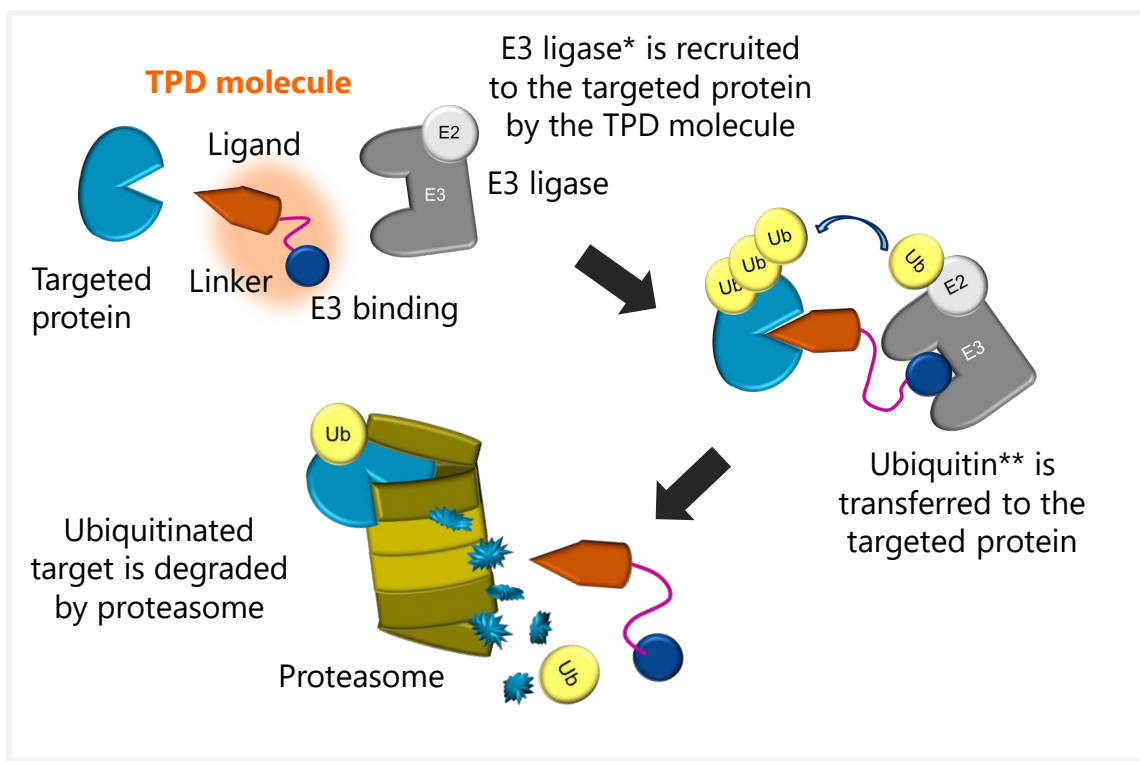


# The New Modality to Fight against Cancer-Targeted Protein Degraders

**DS9051**

## Targeted Protein Degraders

Modality: Mid-size Molecule



- Targeted protein degradation is an approach to eliminate disease-causing proteins by the endogenous ubiquitin-proteasome system
- DS9051 is the first Daiichi Sankyo original targeted protein degrader
- FIH study started on Nov 2025 in solid tumors including CRPC

\*E3 ligase: enzyme which facilitates the transfer of ubiquitin from E2 ubiquitin-conjugating enzyme to targeted proteins

\*\*Ubiquitin: protein which is bound to other proteins and functions in various ways such as a marker for degradation

CRPC: castration-resistant prostate cancer, FIH: first-in-human, TPD: targeted protein degradation

# Looking Towards the Horizon ...

## Future of Daiichi Sankyo's ADC Technology

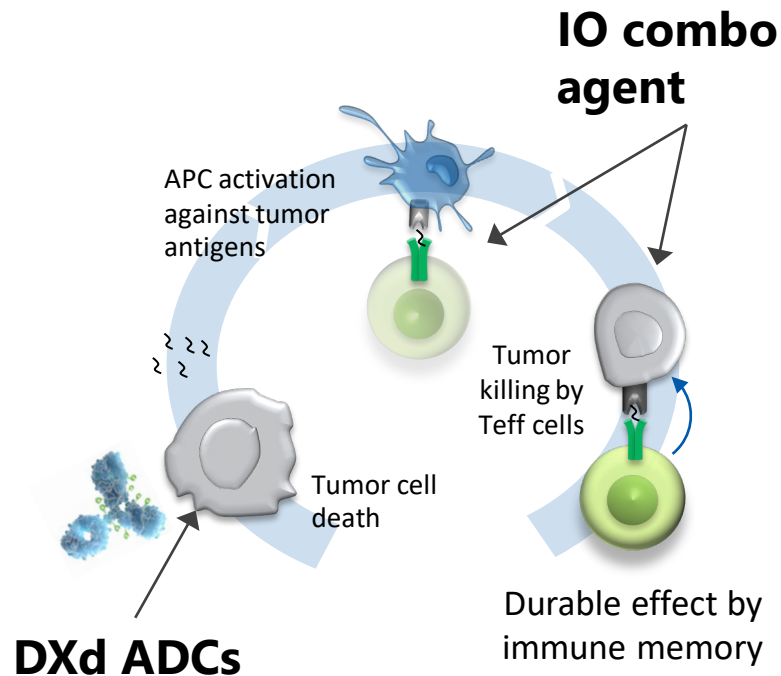
- **DXd ADCs ... More than ENHERTU®**  
Updates from DXd ADC portfolio
- **New Concept ADCs**  
mPBD, STING agonist payloads & others
- **New Non-ADC Oncology Pipeline**  
Targeted Protein Degraders, Novel Immune-Oncology Targets
- **Scientifically Rational Combinations**  
Unlocking the potential of DXd ADCs



# Combination Therapy - Unlocking the Potential of DXd ADCs

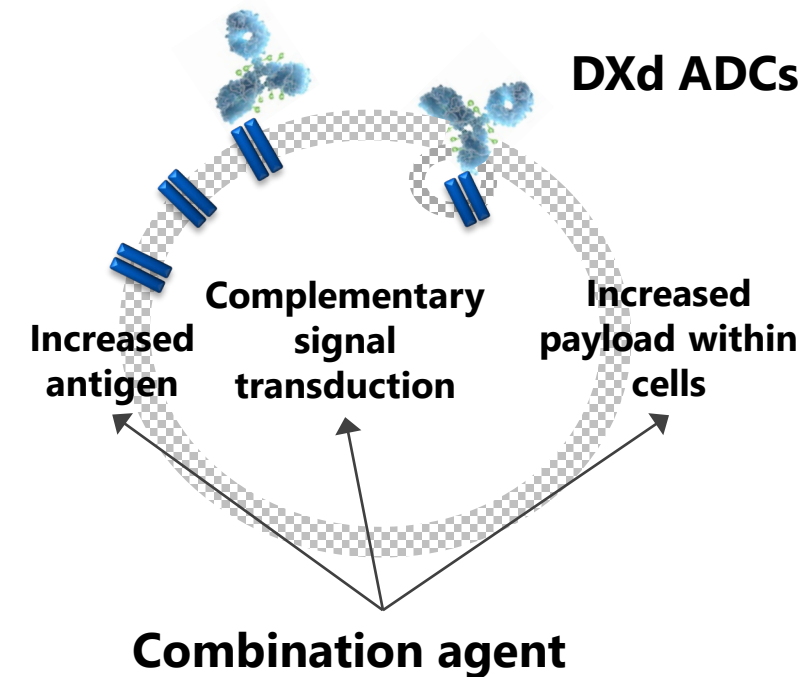
## 1 Addition of durable effect

Combination agents that have IO mechanism to add the durable effect induced by the immune system



## 2 Enhancement of ADC effect

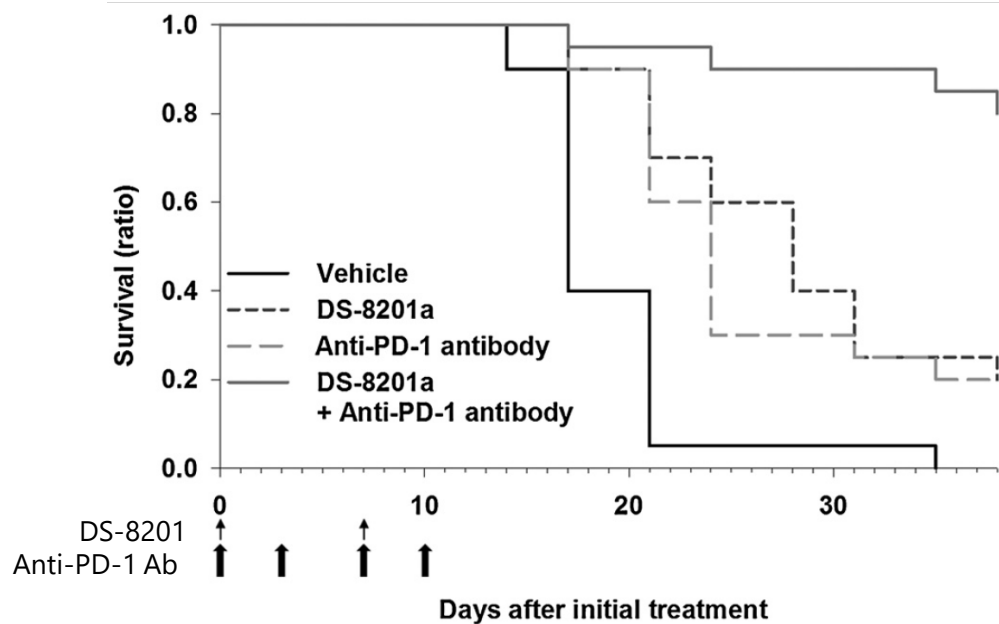
The potential to promote ADC engagement and/or potentiate synthetic lethality



# IO Combinations Would Provide Additional Value

## DXd ADC + IO

**DXd ADC efficacy is enhanced by anti-PD-1/L1 antibody in preclinical models**



hHER2 expressing CT26WT mouse tumor model  
DS-8201: ENHERTU®

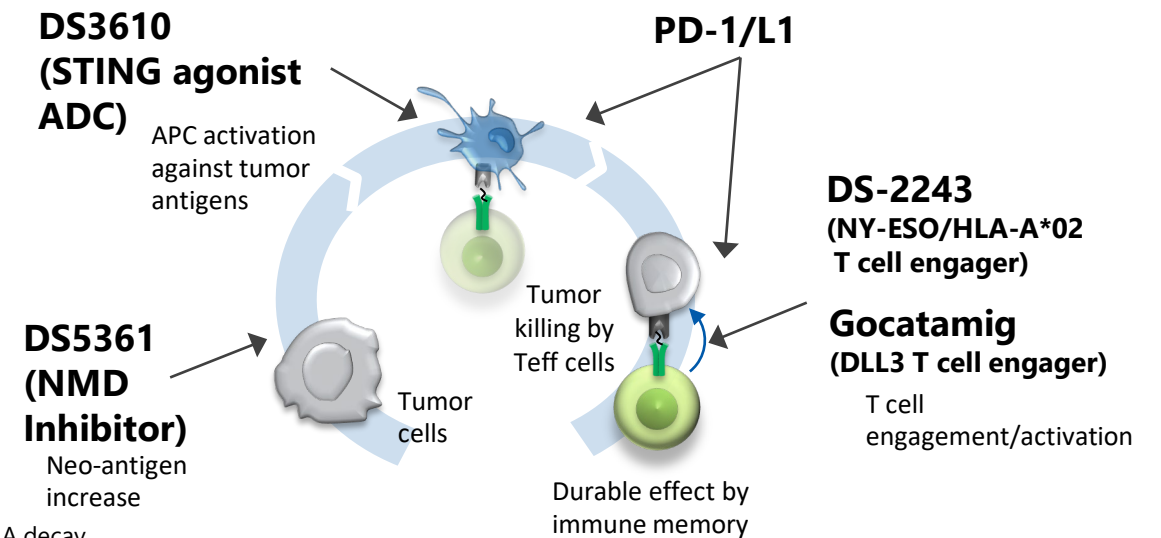
*Mol Cancer Ther* 2018, 17(7):1494-1503

## IO + IO

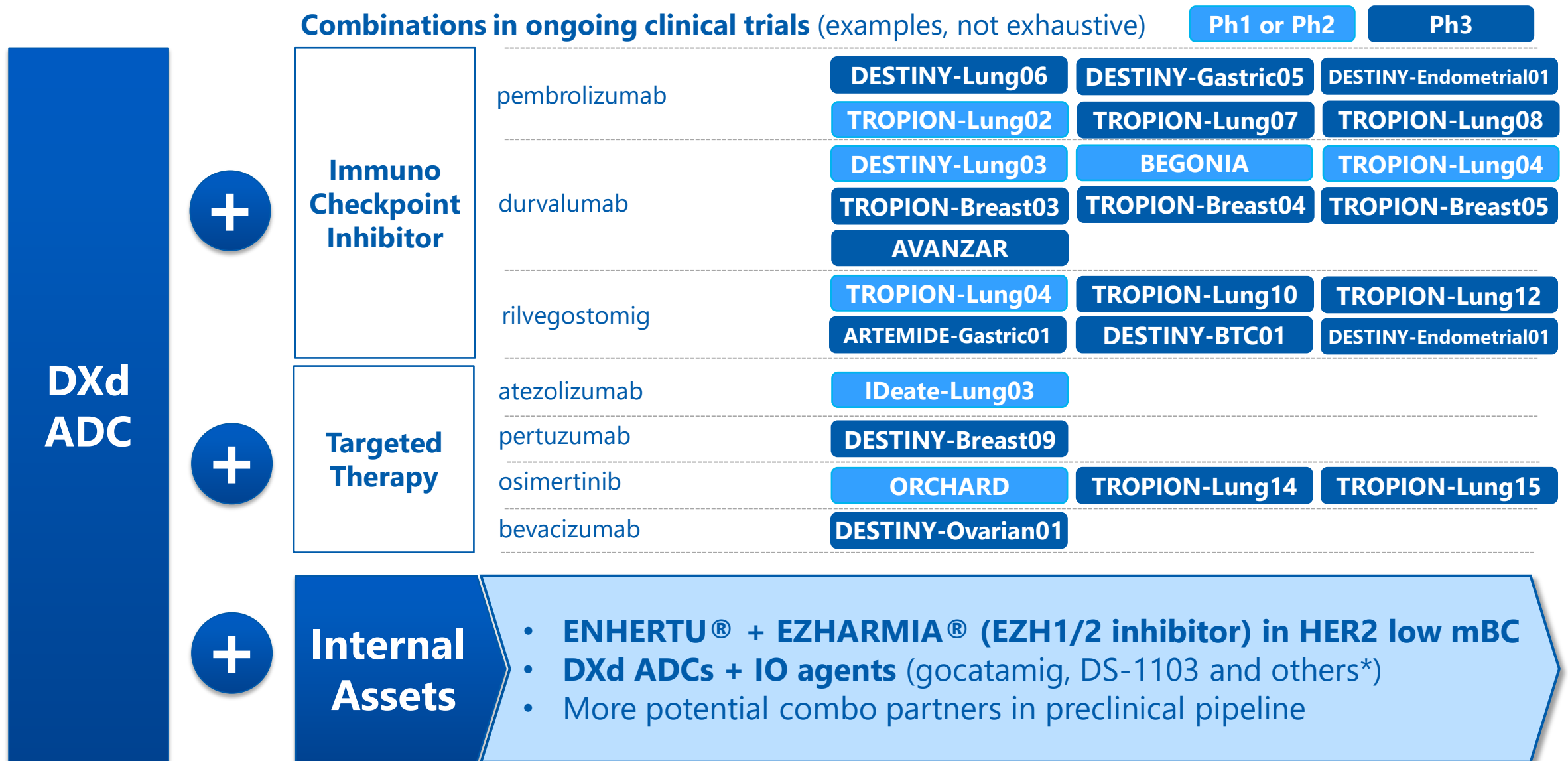
**Daiichi Sankyo IO drugs + anti-PD-1/L1 antibodies**

Potential combinations with anti-PD-1/L1 antibodies

- **DS-2243** (NY-ESO/HLA-A\*02 T cell engager)
- **Gocatamig** (DLL3 T-cell engager)
- **DS5361** (NMD Inhibitor)
- **DS3610** (STING agonist ADC)
- Others



# Combinations to Expand DXd ADCs Opportunities



\* Plan

ADC: antibody-drug conjugate, mBC: metastatic breast cancer

# Overall R&D Strategy



**Research will continue to focus on oncology & non-oncology indications**



**In the clinical pipeline, we are prioritizing the strength of our clinical oncology pipeline**



**Leverage our extensive research capabilities in ADC technology to create new ADCs**



**Emerging clinical stage non-ADC pipeline can be leveraged to create novel combinations with existing ADCs**



# Agenda

- ① Welcome
- ② Clinical Development
- ③ **Oncology Business**
- ④ Technology
- ⑤ Research
- ⑥ Q&A



# Oncology Business Unit Update



**5 Year  
Performance  
Recap**

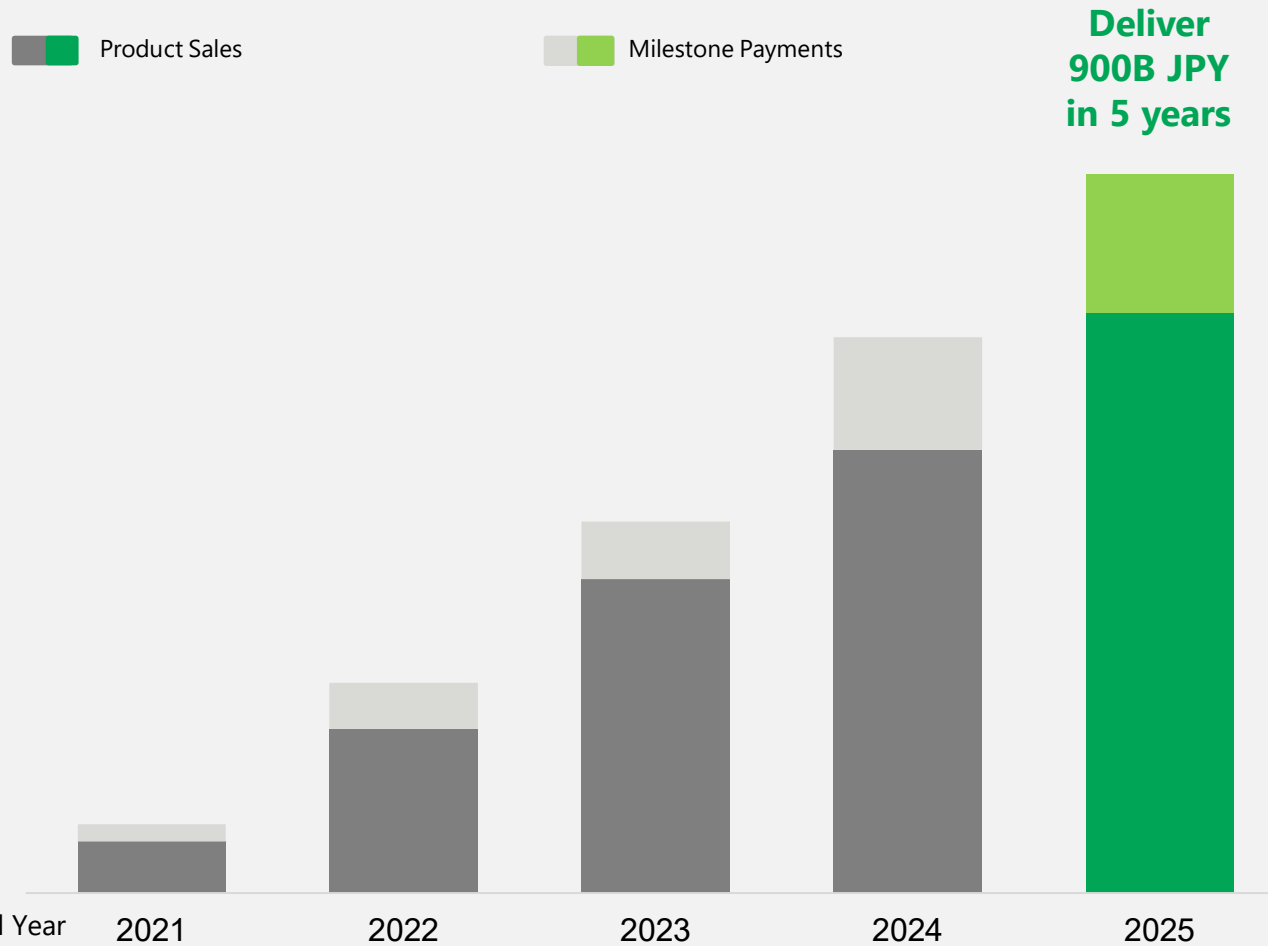


**Ongoing Growth  
Opportunities for  
ENHERTU<sup>®</sup> and  
DATROWAY<sup>®</sup>**



**2030 Ambition**

# Daiichi Sankyo Oncology Revenue Growth: FY 2021 to 2025



## Daiichi Sankyo will start from a Position of Strength with a Growth Catalyst-Rich Year in FY2026

- Developed ENHERTU<sup>®</sup> to become the most successful ADC ever\* with additional growth expected
- ENHERTU<sup>®</sup> has treated 194k patients globally
- Launched 2<sup>nd</sup> DXd ADC DATROWAY<sup>®</sup>
- Potential for 4 standard of care changing launches in FY 2026 for ENHERTU and DATROWAY.
- 3<sup>rd</sup> DXd ADC, I-DXd, received the FDA's Breakthrough Therapy Designation in SCLC
- 4<sup>th</sup> DXd ADC, R-DXd, received the FDA's Breakthrough Therapy Designation in PROC
- Two major alliances with top oncology companies
- Built an organization that is focused on meeting customer needs and executes with precision and urgency

5YBP: 5 year Business Plan, ADC: antibody drug conjugate, FY: Fiscal Year, MTP: Mid-Term Plan, JPY: Japanese Yen, PROC: platinum resistant ovarian cancer, SCLC: small cell lung cancer  
\*Based on product sales  
Source: Daiichi Sankyo Financial Results Reference Data

# ENHERTU®: strong global performance

>85

countries/  
regions

Commercial  
Footprint

>40%

YOY

Accelerating  
momentum  
throughout the globe  
and major catalysts in  
place for 2026-27

¥552.8B\*

in revenue

delivered in FY 2024  
with US and EU leading  
the way

More than

194K\*\*

patients

across breast, lung,  
gastric cancer and  
tumor agnostic



Achieved #1 Market share\*\*\*  
in 100% of fully launched countries/regions

**ENHERTU®**  
trastuzumab deruxtecan

\*FY2024 Daiichi Sankyo Financial Results Reference Data, including gross profit share in AstraZeneca territory, does not include milestone payments

\*\*Estimated through end of fiscal Q2 2025

\*\*\*Internal market research results

\*\*\*\*3L HER2+ metastatic gastric cancer is approved in Japan. There is no current 2L approval in Japan for metastatic gastric cancer

2L: second-line, B: billion, HR: hormone receptor, HER2: human epidermal growth factor receptor 2 IHC: immunohistochemistry, K: thousand, YOY: year over year

US APPROVAL: MAY 2022 | EU Approval: JULY 2022



2L HER2+ Metastatic  
Breast Cancer



JP APPROVAL: NOV 2022

US APPROVAL: AUG 2022 | EU Approval: JAN 2023



Post-chemo HER2 low  
Metastatic Breast Cancer



JP APPROVAL: MAR 2023

US APPROVAL: JAN 2025 | EU Approval: APR 2025



Chemo naive HR+/HER2 low  
or ultralow Metastatic  
Breast Cancer

JP APPROVAL: AUG 2025

US APPROVAL: AUG 2022 | EU Approval: OCT 2023



2L+ HER2 Mutant  
Metastatic  
Lung Cancer



JP APPROVAL: AUG 2023

US APPROVAL: JAN 2021 | EU Approval: DEC 2022



2L+ HER2+ Metastatic  
Gastric Cancer\*\*\*\*



JP APPROVAL: SEP 2020

US APPROVAL: APR 2024 |



2L+ HER2+ (IHC3+)  
Metastatic  
Tumor Agnostic

# Daiichi Sankyo has delivered by maximizing ENHERTU® since our launch in FY2019 and created the most successful launch in oncology over the last 5 years

## Global net sales in FY2025

**Q2 totaled 163.2 Bn JPY;**

**+107% CAGR FY2020 to FY2024;**

**+24% vs FY2024 Q2**

**In the US, FY2025 Q2: 89.4Bn JPY**

+85% CAGR FY2020 to FY2024

+25% vs FY2024 Q2

US

**In Europe, FY2025 Q2: 42.1 Bn JPY**

+155% CAGR FY2021 to FY2024

+19% vs FY2024 Q2

EU

**In Japan, FY2025 Q2: 9.6 Bn JPY**

+63% CAGR FY2020 to FY2024

+23% vs FY2024 Q2

Japan

**In ASCA, FY2025 Q2: 22.1 Bn JPY**

+123% CAGR FY2022 to FY2024

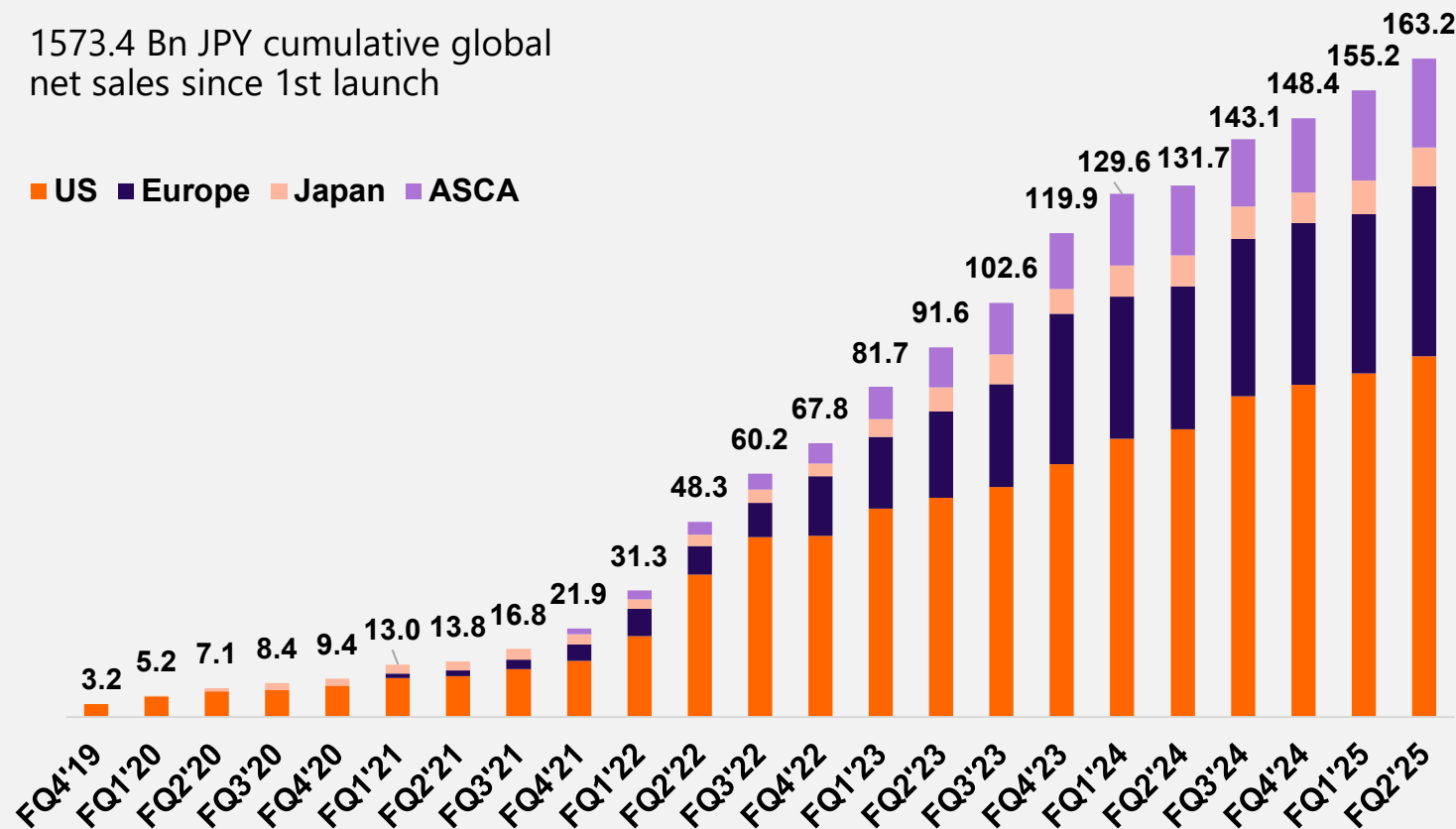
+28% vs FY2024 Q2

ASCA

## ENHERTU® GLOBAL NET SALES BY REGION (Bn JPY)

1573.4 Bn JPY cumulative global net sales since 1st launch

■ US ■ Europe ■ Japan ■ ASCA



\*Incl. Gross profit share in AstraZeneca territory

**ENHERTU®**  
trastuzumab deruxtecan

# The next two years are pivotal for ENHERTU® in breast cancer with multiple data catalyst and new launches



~ 125K ENHERTU® G7  
ELIGIBLE PATIENTS IN  
BREAST CANCER BY 2030

\*pending approvals

## ENHERTU® BC Priorities\*

HER2+  
BC

- **Establish** new 1L standard of care based on DB-09
- **Move** to the eBC curative setting based on DB-11 and DB-05

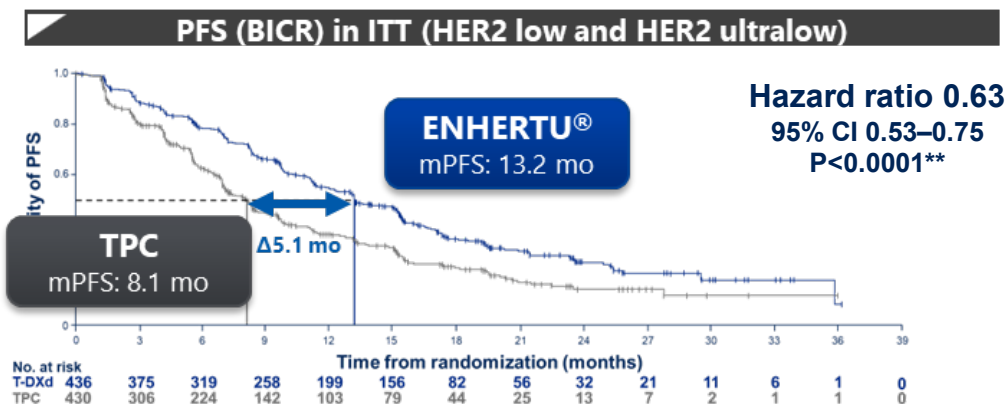
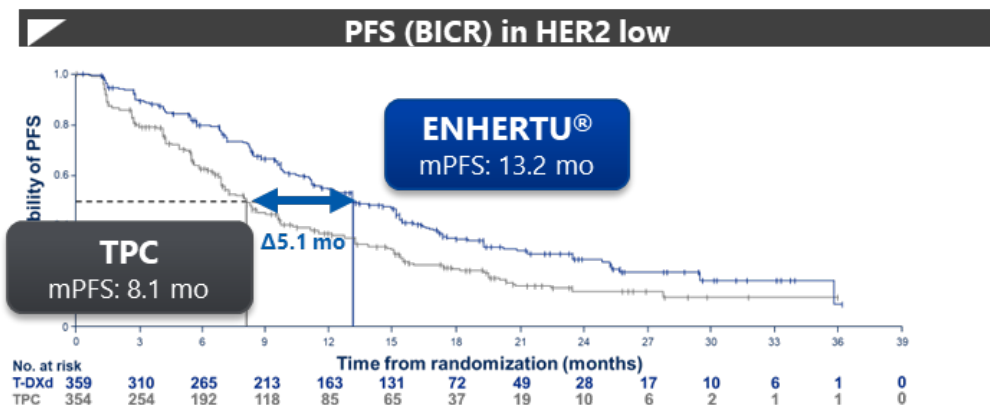
HER2-low  
BC

- **Move earlier**, creating urgency to treat with ENHERTU® post 2L ET in most eligible patients based on DB-06
- **Expand to a broader population**: quickly identify ultralow patients



# DESTINY-Breast06: ENHERTU® adoption in HR+ HER2 low BC continues to expand

## DESTINY-Breast06 Clinical trial data: PFS (BICR) in HER2 low and ultralow

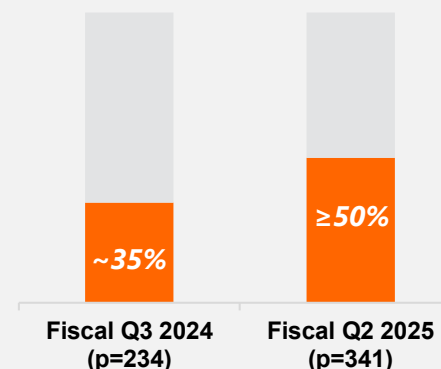


\*Based on internal market research. DESTINY-Breast06 has launched in Germany, but additional European markets are awaiting reimbursement

\*\*P-value of <0.015 required for statistical significance; Data according to ASCO 2024 presentation  
2L: second line, BICR: blinded independent central review, BC: breast cancer, CI: confidence interval, HR: hormone receptor, HER2: human epidermal growth factor receptor 2, PFS: progression free survival, Q: quarter, TPC: treatment of physician's choice

## Market share trend\*

HR+ HER2 low 2L+ Chemo naïve patients (US)



ENHERTU® US market share has seen robust expansion following DB-06 approval in the chemo-naïve setting.

## Launch status by countries and regions



US Approval  
**2025.Jan**



EMA  
Approval  
**2025.Apr**



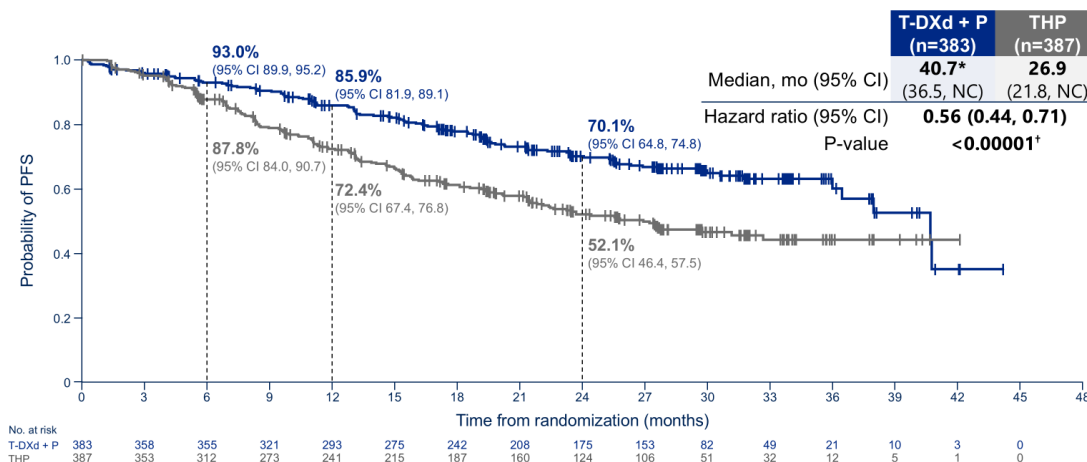
JP Approval  
**2025.Aug**



**2026+**

# DESTINY-Breast09: Launch of ENHERTU® in 1<sup>st</sup> Line HER2+ mBC will be a near-term growth catalyst with potential to benefit 24k eligible patients

## DESTINY-Breast09 Clinical trial data: PFS (BICR)



**Statistically significant and clinically meaningful PFS benefit with T-DXd + P (median Δ 13.8 mo)**

\*Median PFS estimate for T-DXd + P is likely to change at updated analysis; †stratified log-rank test. A P-value of <0.00043 was required for interim analysis superiority  
BICR, blinded independent central review; CI, confidence interval; mo, months; (m)PFS, (median) progression-free survival; NC, not calculable; P, pertuzumab; T-DXd, trastuzumab deruxtecan, ENHERTU®; THP, taxane + trastuzumab + pertuzumab

HER2: human epidermal growth factor receptor 2, mBC: metastatic breast cancer, K: thousand  
G7 consists of the US, Japan, France, Germany, Italy, Spain and United Kingdom

## Market Opportunity (Eligible patient numbers)

**~24,000\***

Market opportunity in G7

\*Incremental to 2L Eligible patients: ~7,000

- Currently, ~30% of patients do not receive treatment beyond first line.

## External Excitement for 1L HER2+ mBC

**STAT**

"This is a pivotal advancement for the treatment of HER2-positive metastatic breast cancer"

**Bloomberg**

The strong results in delaying progression "make it a clear front-runner" as an initial treatment for HER2 patients

# Daiichi Sankyo @ ESMO 2025: Three Landmark Trials Showcase Potential Practice-Changing Results in Breast Cancer

Moving **ENHERTU®** into early  
HER2+ breast cancer

## DESTINY-Breast11

Neoadjuvant **ENHERTU®** → THP  
*High-risk HER2+ eBC*

- **67% pCR** with early trend to EFS benefit
- **Highest reported pCR** rate seen in a Phase III registrational trial in this setting

## DESTINY-Breast05

Post-neoadjuvant **ENHERTU®**  
*High-risk HER2+ eBC*

- **53% reduction** in risk of disease recurrence or death vs T-DM1
- **>92% patients free of invasive disease** at 3 years

Together, demonstrate the potential of **ENHERTU®** as a  
**foundational treatment in curative-intent eBC**



Broadening potential  
of **DATROWAY®**

## TROPION-Breast02

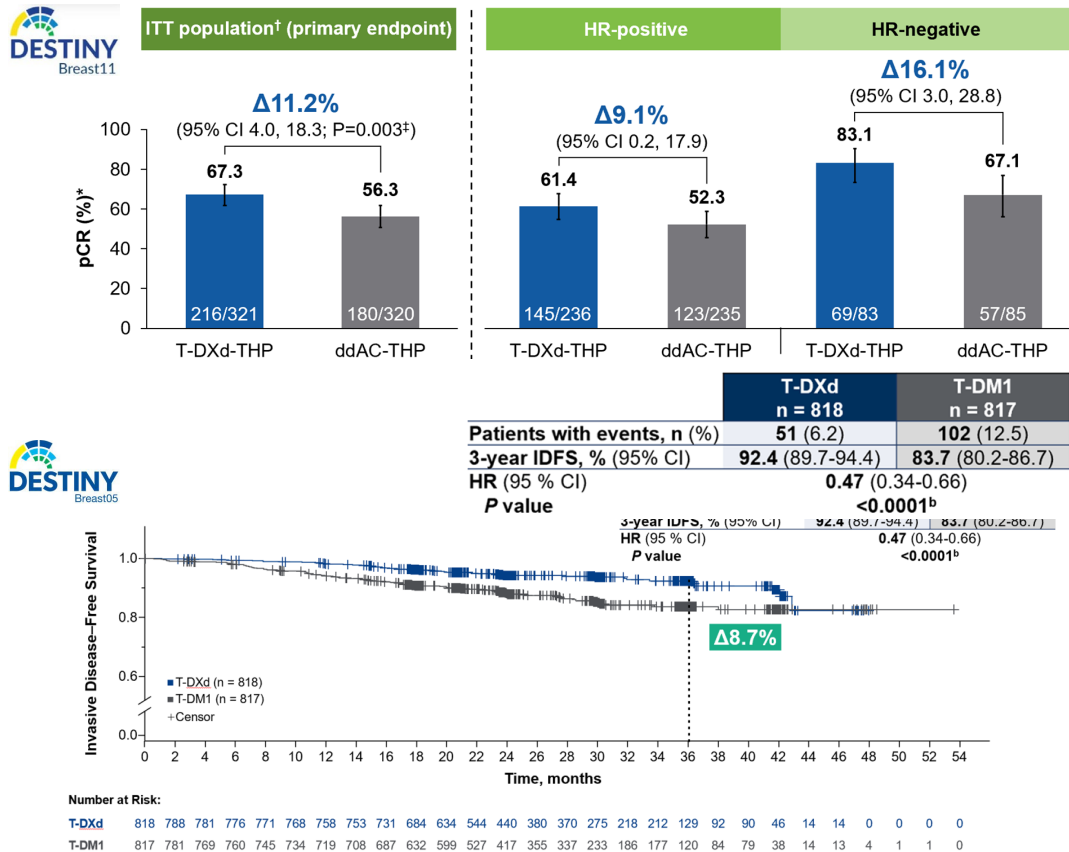
**DATROWAY®**  
*1L TNBC not suitable for PDx*

- **Unprecedented mOS improvement** of 5 mo vs CTx
- **Robust anti-tumor activity with 63% ORR**
- **First ever trial** to show a **mOS benefit** in 1L TNBC in patients where immunotherapy was not an option



# DESTINY-Breast11, DESTINY-Breast05: Launches of ENHERTU® in early-stage BC will present significant growth catalysts

## DESTINY-Breast11/05 Clinical trial data



## Market Opportunity (Eligible patient numbers)

**DB-11: ~29,000**

**DB-05: ~11,000**

Market opportunity in G7

## External Excitement for DESTINY-Breast11 / 05\*

**Question:** Which single statement best captures your initial takeaway from the DB-11 and DB-05 studies? (% of US and EU oncologists)

Enhertu looks practice-changing in both neo- and post-neoadjuvant settings

More compelling in post-neoadjuvant than neoadjuvant

Signals are promising but I need longer follow-up/safety

Data are insufficient to change practice now

**72%**

BC: breast cancer, CI: confidence interval, DB: DESTINY-Breast, IDFS: invasive disease-free survival, ITT: intention to treat, HR: hormone receptor, HR: hazard ratio, G7: US, Japan, France, Italy, Germany, Spain, and United Kingdom  
ddAC-THP: doxorubicin + cyclophosphamide followed by taxane + trastuzumab + pertuzumab  
\*FirstWord Pharma physician survey results (n=140 US and EU oncologists), published November 19<sup>th</sup>

# ENHERTU<sup>®</sup> is DESTINED for more as key clinical trial results and new indications seek to go earlier and broader

Potential new indications could benefit ~100k additional eligible patients by 2030

**BREAST INDICATIONS: ~50k eligible patients**

**FY 2025-2026 Potential New Indications**

- Destiny-Breast09  
HER2 positive metastatic breast cancer (1L) ✓
- DESTINY-Breast11  
HER2 positive early breast cancer (neoadjuvant) ✓
- DESTINY-Breast05  
HER2 positive early breast cancer (adjuvant\*) ✓

**LUNG AND GASTRIC INDICATIONS: ~5k eligible patients**

- DESTINY-Gastric04  
HER2 positive gastric cancer (2L) ✓
- DESTINY-Lung04  
HER2 mutant metastatic NSCLC (1L)

✓ = Positive TLR achieved

**PAN TUMOR INDICATIONS: ~45k eligible patients**

**Potential New Indications 2027+**

- DESTINY-Gastric05  
HER2 positive gastric cancer (1L)
- DESTINY-BTC01  
HER2 positive biliary tract cancer (1L)
- DESTINY-Ovarian01  
HER2 positive ovarian cancer (1L)
- DESTINY-Lung06  
HER2 positive, PD-L1 <50% NSCLC (1L)
- DESTINY-Endometrial01  
HER2 positive pMMR endometrial cancer (1L)
- DESTINY-Endometrial02  
HER2 positive early endometrial cancer (adjuvant)

\*Adjuvant therapy for patients with residual invasive disease following neoadjuvant therapy  
1L: first-line, 2L: second-line, HER2: human epidermal growth factor receptor 2, HR: hormone receptor, NSCLC: non-small cell lung cancer, PD-L1: programmed cell death ligand 1, pMMR: mismatch repair proficient

# Global DATROWAY® net sales have now exceeded 10 Bn JPY in Q2 FY '25

Overall, global net sales in  
FY2025 Q2 was 10.4 Bn JPY;  
**+95.9% sequential QtQ growth**  
driven by US and Japan

**In the US, FY2025 Q2: 6.6 Bn JPY**  
+112.9% vs. prior quarter

Sales driven by HR+ HER2- mBC and  
EGFRm NSCLC

US

**DATROWAY® was approved by the  
EMA in April 2025**

Launches expected throughout 2026

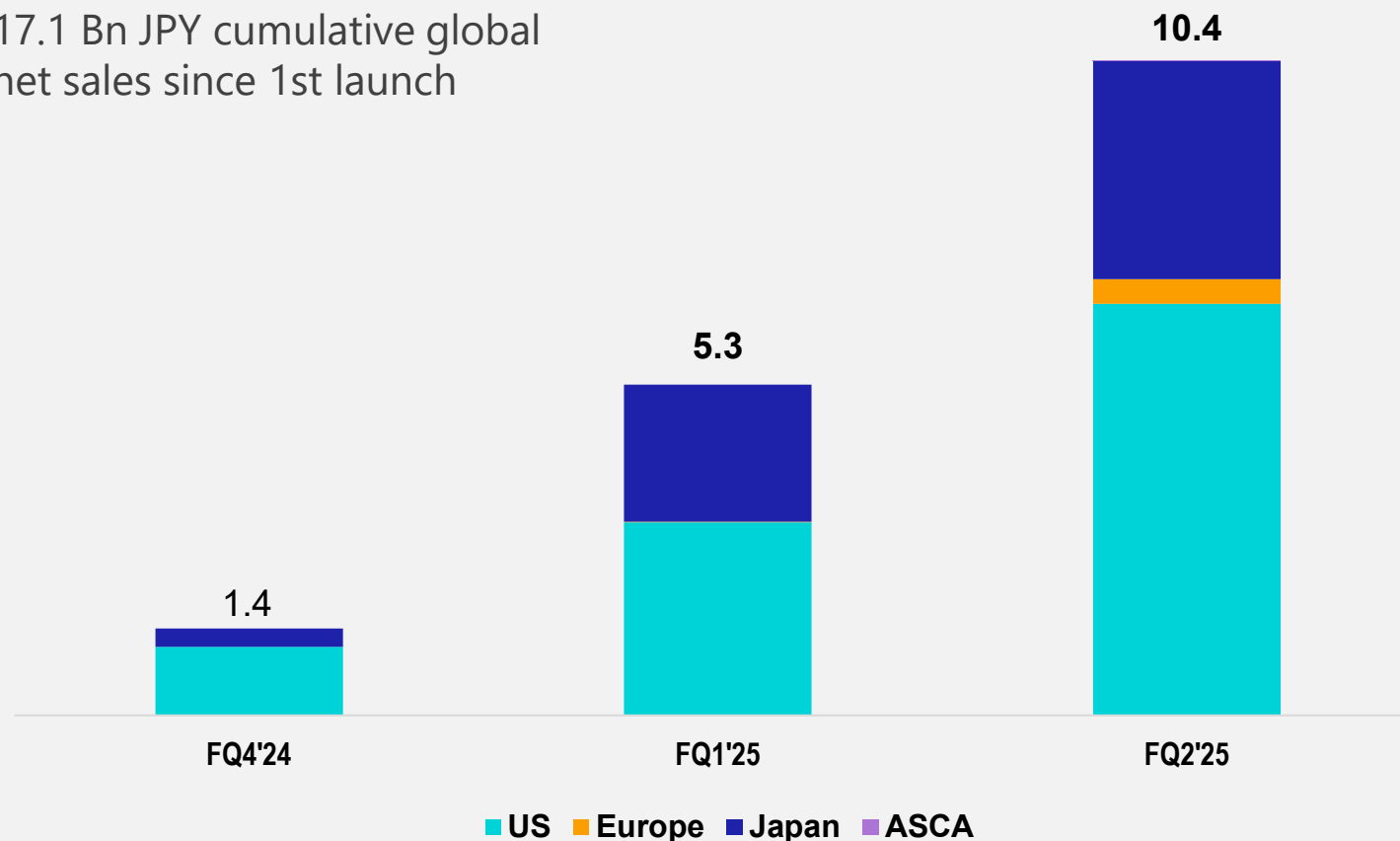
EU

**In Japan, FY2025 Q2: 3.5 Bn JPY**  
+59.1% vs. prior quarter

JP

## DATROWAY® GLOBAL NET SALES BY REGION (Bn JPY)

17.1 Bn JPY cumulative global  
net sales since 1st launch



Daiichi Sankyo Financial Results Reference Data, including gross profit share in AstraZeneca territory, does not include milestone payments

\*Datroway® has launched in Germany, but reimbursement negotiations are ongoing

ASCA: Asia, South and Central America, Bn: billion, EGFRm: epidermal growth factor receptor mutant, FQ: fiscal quarter, FY: fiscal year,  
mBC: metastatic Breast Cancer, NSCLC: non-small cell lung cancer, JPY: Japanese Yen, Q: quarter, QtQ: quarter to quarter



# Early adoption and experience is building confidence amongst prescribers and we expect accelerating performance in FY2026

## DATROWAY<sup>®</sup> indication expansion expected in 2026

### HR+/HER2- mBC



**Build the foundation** as the preferred TROP2 ADC with positive first experiences in efficacy and tolerability

### EGFRm NSCLC



**Drive rapid adoption** as first TROP2 ADC approved in NSCLC for a range of EGFR mutations

### IO ineligible mTNBC



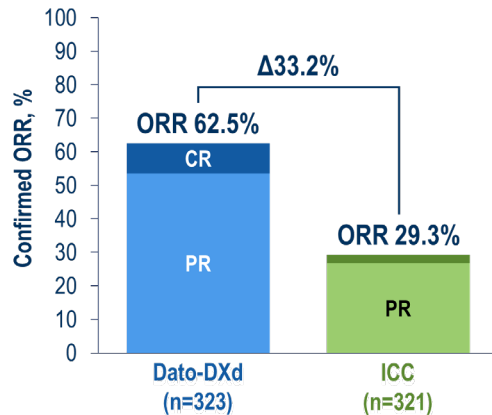
ENTRENCH as new SOC and the **only TROP2 ADC** to **demonstrate overall survival**

ADC: antibody drug conjugate, EGFR: epidermal growth factor receptor, FY: fiscal year, HR: hormone receptor, HER2: human epidermal growth factor receptor 2, mBC: metastatic breast cancer, NSCLC: non-small cell lung cancer, SOC: standard of care, TNBC: triple negative breast cancer, TROP2: Trophoblast cell-surface antigen 2

# TROPION-Breast02 study showed a statistically significant & clinically meaningful improvement in PFS and OS compared with ICC

## TROPION-Breast02 Clinical trial data

	Dato-DXd	ICC	Δ
Median PFS	10.8 mo	5.6 mo	Δ 5.3 mo
Median OS	23.7 mo	18.8 mo	Δ 5.0 mo
Median DOR	12.3 mo	7.1 mo	Δ 5.2 mo



Despite more than double the duration of treatment, rates of grade ≥3 and serious TRAEs were similar, and discontinuations were lower, with Dato-DXd vs ICC

## Market Opportunity (Eligible patient numbers)

# TB02: ~16,000

Market opportunity in G7

## Market Insights (Triple Negative Breast Cancer)

- **For nearly 15 years, there have been no new treatment advancements** in 1L mTNBC for patients who are PD-L1-negative, non-BRCA mutated, or not candidates for immunotherapy.<sup>2,3,4</sup>
- **Advanced/metastatic TNBC is the most aggressive cancer subtype** with the fewest treatment options; **Metastatic TNBC 5-year OS: 14.9%**<sup>5</sup>



~70% not candidates for 1L immunotherapy<sup>6</sup>



~50% do not receive treatment beyond 1L<sup>6,7</sup>

1. Dent R et al. Presented at: ESMO 2025; October 17-21, 2025; Berlin, Germany. Presentation LBA21  
2. <https://pubmed.ncbi.nlm.nih.gov/38601487/>  
3. <https://pubmed.ncbi.nlm.nih.gov/37229447/>  
4. <https://ascopost.com/issues/august-25-2023/new-challenge-in-triple-negative-breast-cancer-optimizing-the-sequencing-of-treatments/>  
5. National Cancer Institute SEER Program. Available at: <https://seer.cancer.gov/statfacts/html/breast-subtypes.html>  
6. Punie K, et al. Oncologist 2025;30:oyaf034;  
7. Traina T, et al. Clin Cancer Res 2025;31:P3-08-10; 8. Li CH, et al. Breast Cancer Res 2019;21:143  
1L: first line, BRCA: Breast cancer gene, DOR: Duration of response, ICC: investigators choice chemo, G7: US, Japan, France, Germany, Italy, Spain, United Kingdom, mo: months, ORR: overall response rate, OS: overall survival, PD-L1: programmed cell death ligand, PFS: progression free survival, TRAE: treatment related adverse events, TNBC: triple negative breast cancer

# Media and KEEs Highlight ‘Unprecedented’ DATROWAY<sup>®</sup> Data in TNBC

## The Pharma Letter

ESMO 2025: Daiichi Sankyo and AstraZeneca’s DATROWAY Results  
**‘Unprecedented’**

## OncLive

TROPION-Breast02 Data Support  
Dato-DXd as **New First-Line Standard of Care** in TNBC

## ApexOnco

“Both agents impressed, but the results (of TROPION-Breast02) suggest that **DATROWAY could have an edge**”

## BioPharma Dive

AstraZeneca, Daiichi’s DATROWAY **Excels in Hard-to-Treat Breast Cancer**

## BioPharma Dive

**Dato-DXd Doubles Response Rates and Extends Survival** in First-Line Metastatic TNBC

## Fierce Pharma

ESMO: AZ, Daiichi’s **DATROWAY Outshines Gilead’s Trodelvy** in First Global TROP2 Showdown

## Endpoints News

“DATROWAY appears to offer **numerically better progression-free survival** data”

“I was amazed when I saw the more than **doubling of response and tripling of CR** with Dato-DXd”

**- Asia-Pacific KEE**

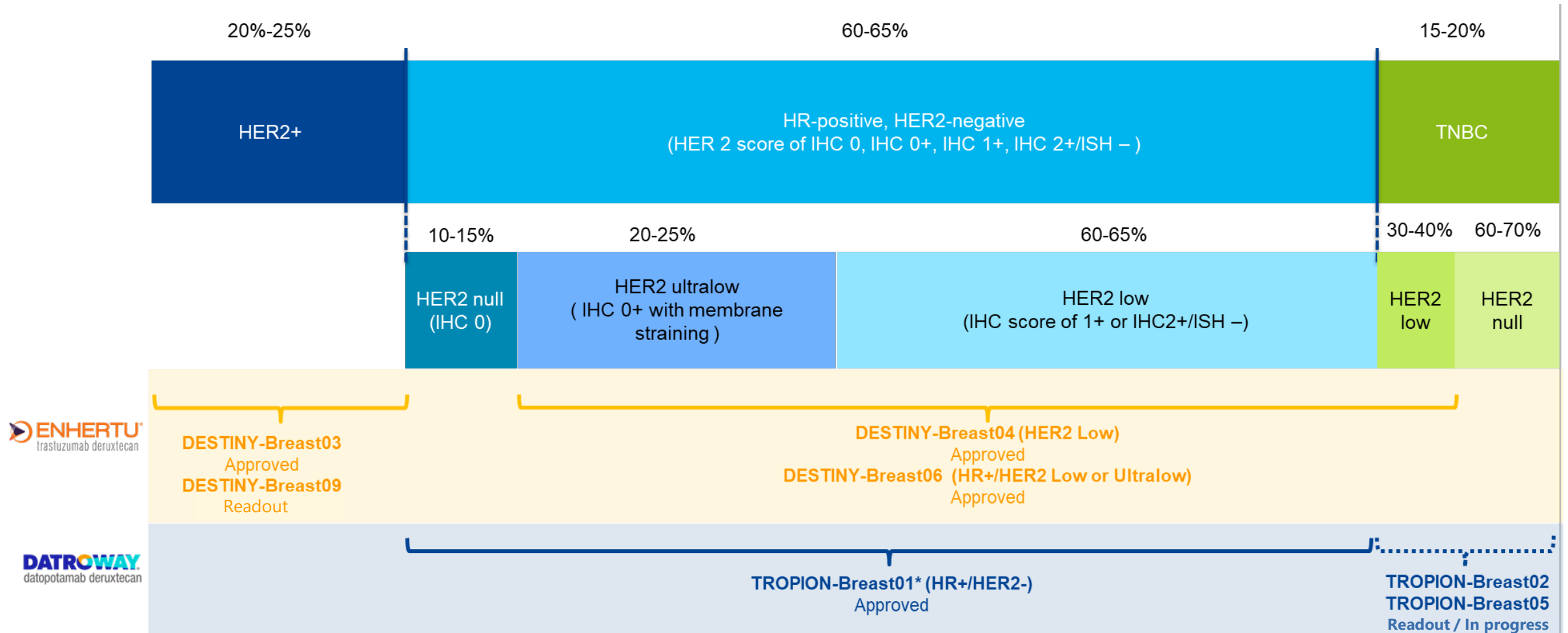
“The **low ILD rate** with Dato-DXd is amazing”

**- Asia-Pacific KEE**

“Patients with short DFI have poor prognosis, so it is **great to have an option other than ChT**”

**- Europe KEE**

# With DATROWAY®'s potential indications in TNBC, Daiichi Sankyo's oncology portfolio has the potential to benefit 100% of mBC patients



\*TROPION-Breast01 indication: HR+/HER2- (IHC0, 1+ or 2+/ISH-) mBC

mBC: metastatic breast cancer, HER2: human epidermal growth factor receptor 2, HR: hormone receptor, IHC: immunohistochemistry,

ISH: in situ hybridization, TNBC: triple negative breast cancer

Source: npj Breast Cancer volume 7, Article number: 1 (2021)

# Potential future indications can significantly expand the patients DATROWAY<sup>®</sup> can benefit

✓ = Positive TLR achieved

Expected TLRs in  
FY2025 - 2026

## BREAST INDICATIONS: ~24k eligible patients

TROPION-Breast02

TNBC, not an option for PD-1/PD-L1 (1L) ✓

TROPION-Breast05

TNBC, PD-L1 positive (1L)

## LUNG INDICATIONS: ~160k eligible patients

AVANZAR

NSQ non-AGA NSCLC (1L)

TROPION-Lung15

EGFRm NSCLC, DATROWAY<sup>®</sup> +/- osimertinib (2L+)

TROPION-Lung07

NSQ non-AGA NSCLC, PD-L1 TPS < 50% (1L)

TROPION-Lung08

NSQ non-AGA NSCLC, PD-L1 TPS ≥ 50% (1L)

Expected TLRs in  
FY 2027 +

## BREAST INDICATIONS: ~46k eligible patients

TROPION-Breast03

Early TNBC (Adjuvant\*)

TROPION-Breast04

Early TNBC (Neoadjuvant)

## LUNG INDICATIONS: ~70k eligible patients

TROPION-Lung10

NSQ non-AGA NSCLC, PD-L1 TPS ≥ 50% (1L)

TROPION-Lung14

EGFRm NSCLC, , DATROWAY<sup>®</sup> + osimertinib (1L)

TROPION-Lung17

NSQ non-AGA TROP2 NMR+ NSCLC (2L+)

## OTHER INDICATIONS: ~15k eligible patients

TROPION-Urothelial03

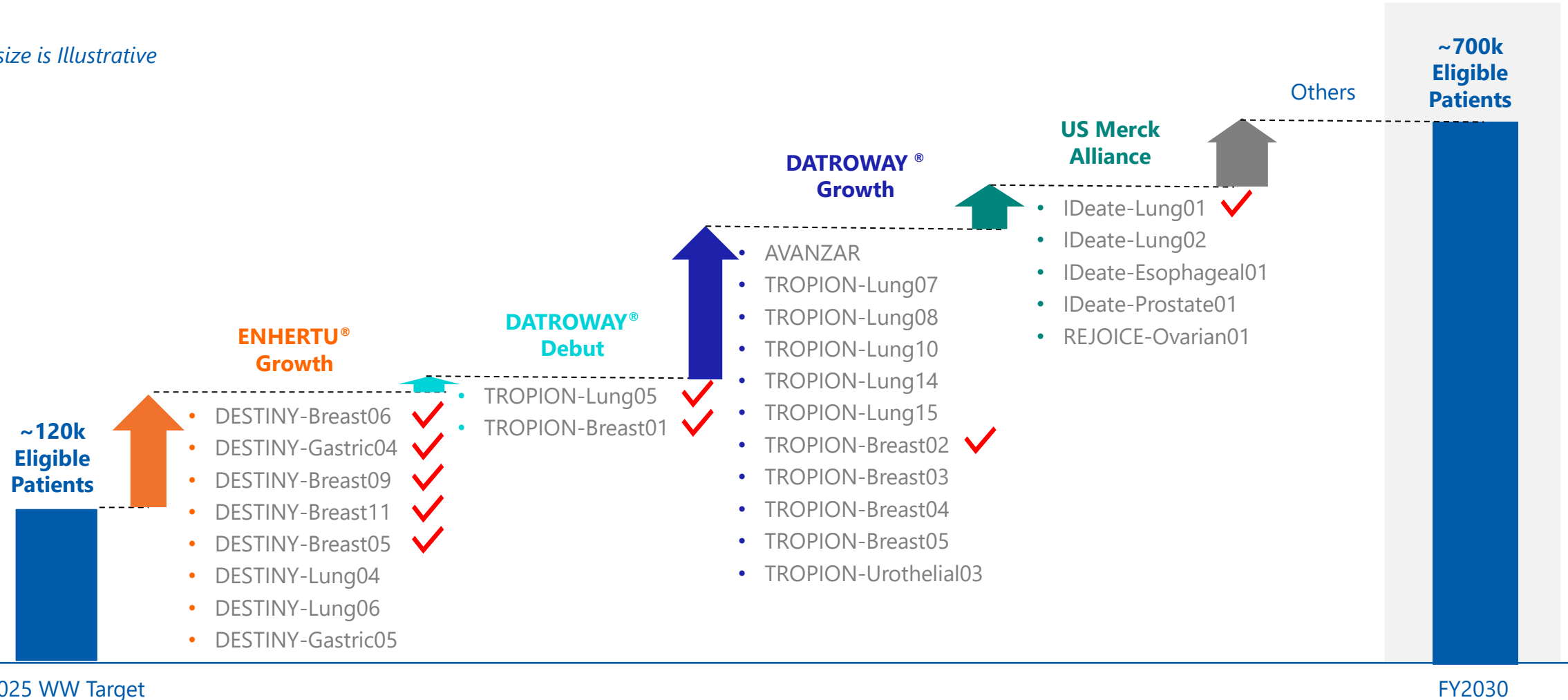
Metastatic Urothelial Carcinoma (2L+)

1L: first line, 2L: second line, AGA: actionable genomic alteration, EGFRm: epidermal growth factor receptor mutant, NMR: normalized membrane ratio, NSCLC: non-small cell lung cancer, NSQ: non-squamous, PD-L1: programmed cell death ligand, TNBC: triple negative breast cancer, TPS: tumor proportion score, TROP2: trophoblast cell surface antigen 2

\*Adjuvant therapy for patients with residual invasive disease following neoadjuvant therapy

# Daiichi Sankyo plans to launch numerous indications across at least 4 ADCs by 2030, contributing nearly six times as many patients

\*Arrow size is Illustrative



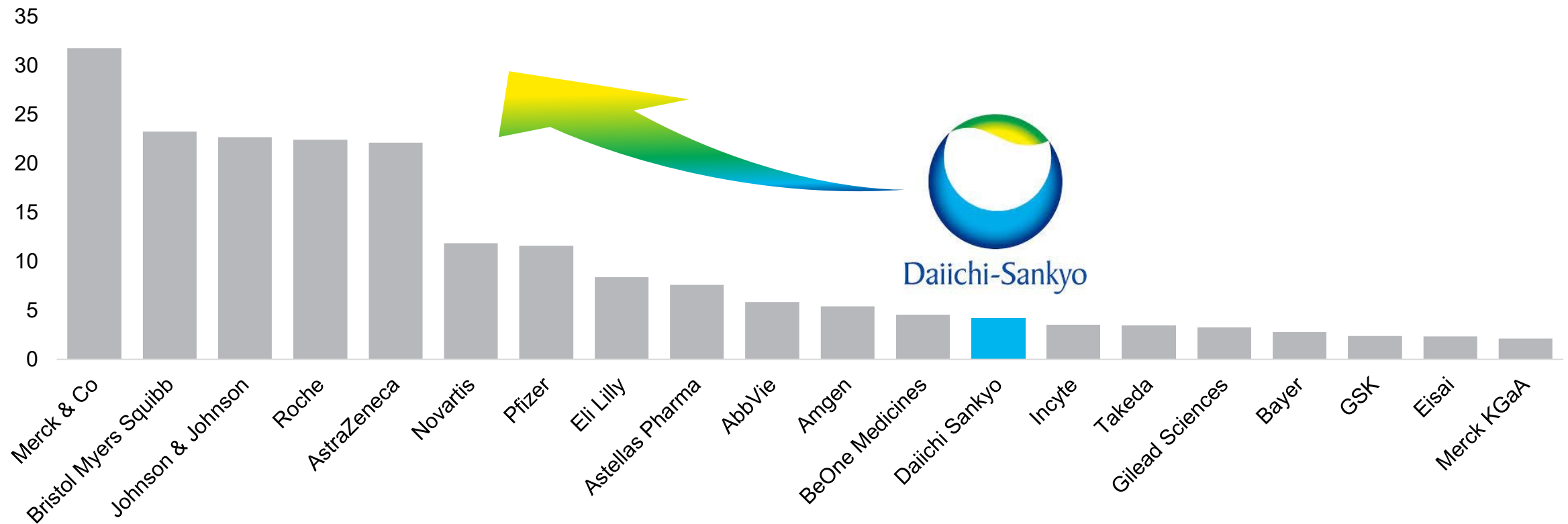
ADC: antibody drug conjugate, k: thousand, CRPC: castration resistant prostate cancer DB: DESTINY-Breast, DL: DESTINY-Lung, DG: DESTINY-Gastric, EGFRm: epidermal growth factor receptor mutant, ESCC: esophageal squamous cell carcinoma, FY: fiscal year, PROC: platinum resistant ovarian cancer, SCLC: small cell lung cancer TL: TROPION-Lung, TB: TROPION-Breast, TLR: top line results WW: worldwide

✓ = Positive TLR achieved



# Daiichi Sankyo remains highly confident we will reach and exceed our goal to be a top 10 oncology company

GLOBAL ONCOLOGY PRODUCT SALES (\$B)



Source: Evaluate Pharma, accessed November 19, 2025

\*MAT = Moving Annual Total (MAT Sept 2025 refers to Oct 2024 – Sept 2025 period)

B: billion, Co: company, GSK: GlaxoSmithKline, KGaA: Kommanditgesellschaft auf Aktien

# Agenda

- ① Welcome
- ② Clinical Development
- ③ Oncology Business
- ④ **Technology**
- ⑤ Research
- ⑥ Q&A



# Development Status and Stable Supply System for 5DXd ADCs

## Development Status

### ENHERTU®

- **Steady market penetration and expansion of approved countries and regions** through the strategic partnership with AstraZeneca (more than 85 countries and regions)
- **Further growth** driven mainly by the U.S. and Europe (Global product sales: ¥261.3 billion in H1 FY2024 and ¥318.4 billion in H1 FY2025)

### DATROWAY®

- **Approved in more than 35 countries and regions**, including Japan, the U.S., and Europe
- **Strong sales ramp-up** in Japan and the US

### HER3-DXd

### I-DXd

### R-DXd

- **Maximizing product potential** through a strategic partnership with US Merck\*
- **Positive clinical trial data accumulating** for I-DXd and R-DXd

## Stable Supply System

- **Ensuring stable supply across countries and regions while responding to rapidly increasing demand since the launch of ENHERTU®**
- **Establishing a global supply system capable of meeting peak demand for all 5DXd ADCs**

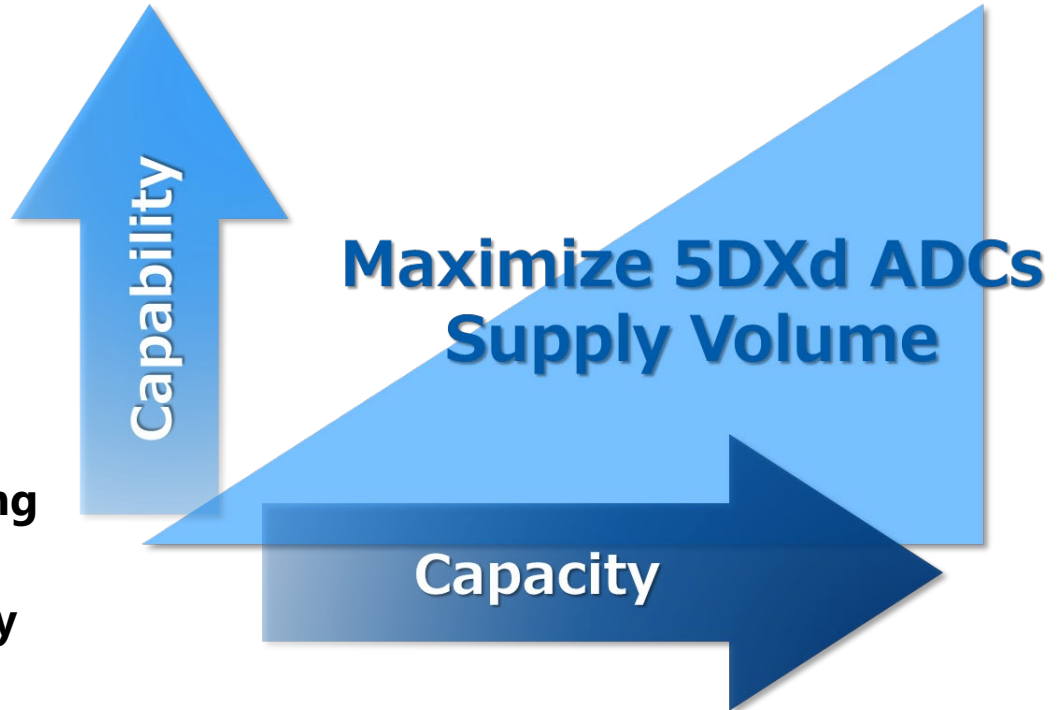
# Supply Strategy for 5DXd ADCs

- **Production Capacity: Expansion of Capacity**

- Enhancement of production capacity through capital investment
- Establishment and expansion of a global supply system

- **Productivity: Enhancement of Capability**

- Further improvement of productivity by leveraging technology
- Development and strengthening of biotechnology specialist
- Transformation into a high-productivity organization



**Expansion of  
Capacity**

**×**

**Enhancement of  
Capability**

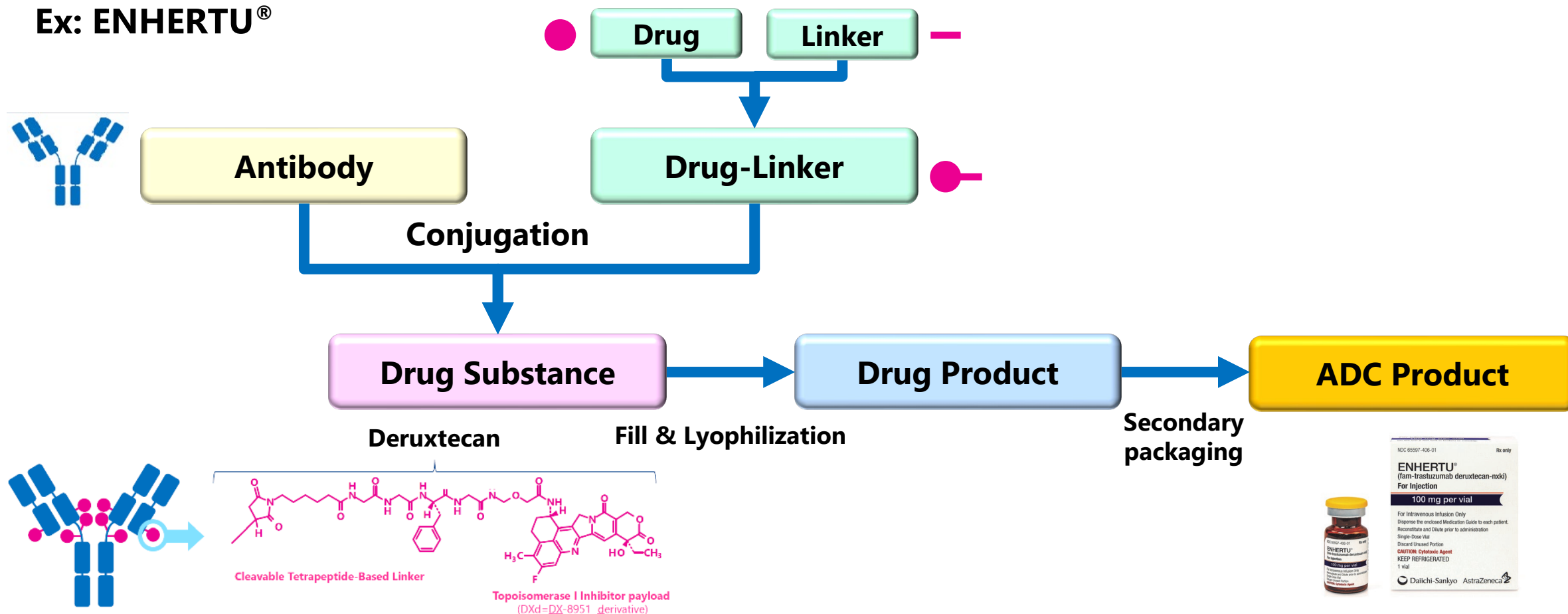
**=**

**Maximization of  
supply volume**

# ADC Manufacturing Process

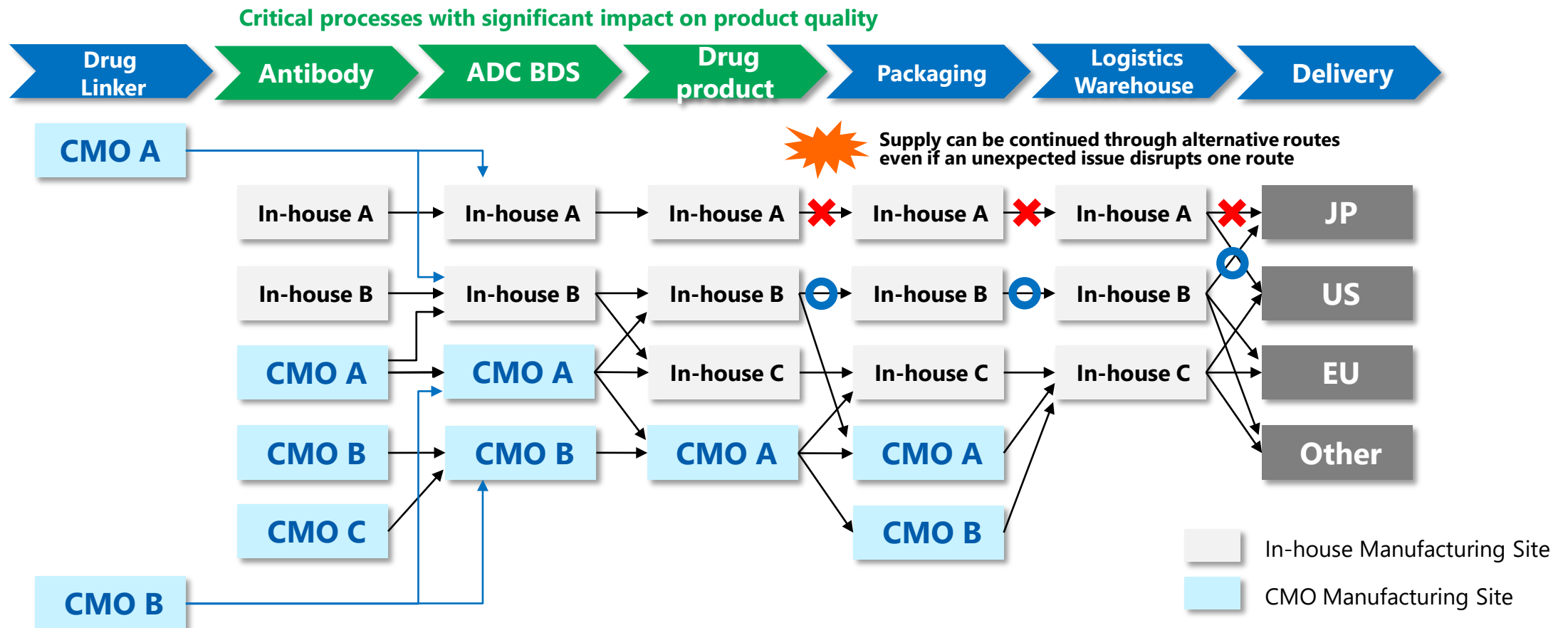
- ADCs are composed of multiple components, which are manufactured and managed separately
- The manufacturing process involves many steps, resulting in a lead time significantly longer than that of small-molecule drugs (typically over one year)

Ex: ENHERTU<sup>®</sup>



# Global Supply Overview

- Utilizing both in-house manufacturing and multiple CMO(Contract Manufacturing Organizations) to establish **diversified manufacturing and supply routes** for each product
- Securing sufficient **capacity** to meet rapid demand growth and **reducing supply risks from unexpected issues**





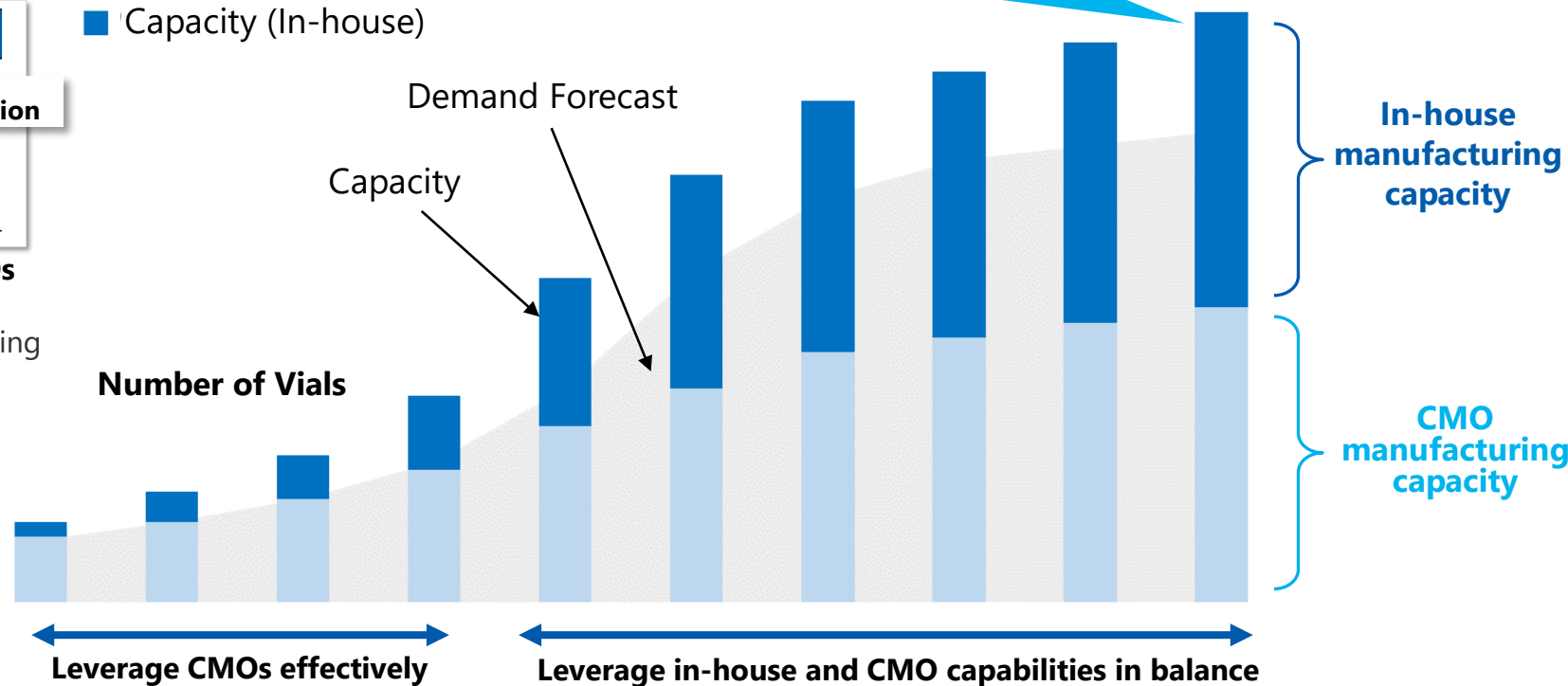
# Approach to In-House Facilities and CMO Utilization

- Adjusting manufacturing and supply volumes based on the latest demand forecasts, while **enhancing overall capacity** through capital investments and CMO partnerships
- In the short term, **effectively leverage existing CMO capabilities to prioritize speed**; in the long term, **promote in-house capital investments to optimize cost and ensure a stable supply**

## Illustration

Demand  
 Capacity (CMO)  
 Capacity (In-house)

**Ensure supply capacity exceeds demand**



## Illustration

	Bldg.	Equip.	Product Launch Lead Time		
CMO	✓	✓	Tech Transfer		
	✓	—	Equip. Installation	Tech Transfer	
In-house	—	—	Bldg. Construction	Equip. Installation	Tech Transfer

## ■ Difference in Product Launch Lead Time Between CMOs and In-House Manufacturing

In contrast to CMOs that already have existing manufacturing equipment or facilities, expanding in-house manufacturing capacity requires a longer lead time

# Global In-House Manufacturing Sites



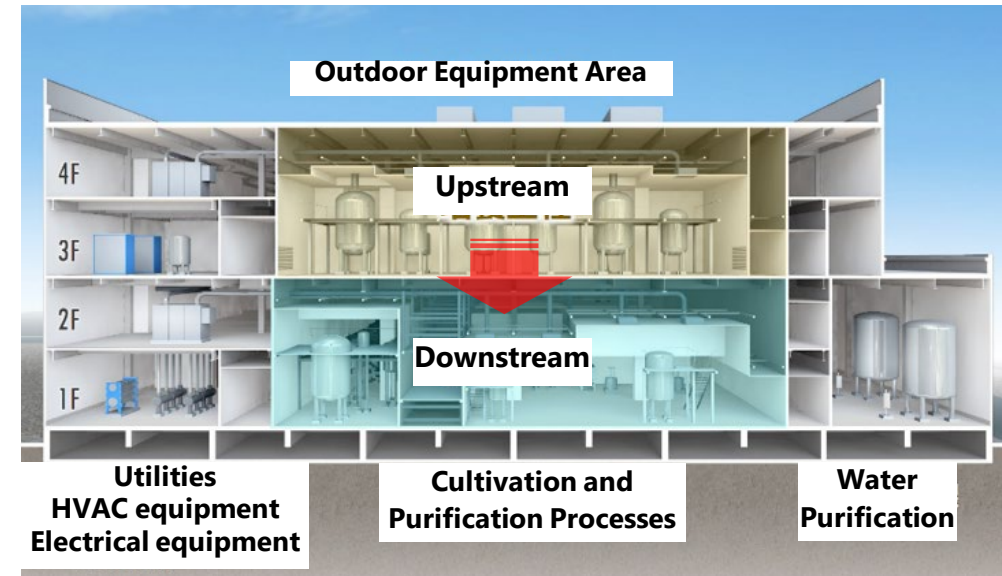
# Antibody Supply System

- Effectively leveraging CMO speed and technical capabilities at present
- Strengthening in-house supply capabilities over the mid- to long-term to build a low-cost, stable supply system



## ● Onahama Site - Antibody Building

- Completion: FY2024
- Antibody manufacturing equipment (multi-use)
- Cultivation: 15 kL × 3 bioreactors,  
Purification: 1 line



- All processes located on the same floor to shorten workflow paths
- Upstream cultivation on the upper floor and downstream purification on the lower floor to minimize loss during process transfer



# ADC Drug Substance Supply System

- **Requiring dedicated facilities and advanced technical capabilities** for ADC drug substance manufacturing, a stable supply system is being built through **in-house facilities and selected CMOs**
- **Completing new ADC drug substance facilities at the Hiratsuka Site** in Feb 2026, with comparable capacity under construction at the **Pfaffenhofen Site** in Germany



- **Hiratsuka Site – ADC Drug Substance Building**
  - Completion: FY2025 (planned)
  - Drug substance manufacturing equipment (multi-use)
  - Drug substance: 1,200 L × 2 lines

- **Pfaffenhofen Site - ADC Building F5**
  - Completion: FY2028 (planned)
  - Drug substance & Drug Product manufacturing equipment (multi-use)
  - Drug substance: 1,200 L × 2 lines

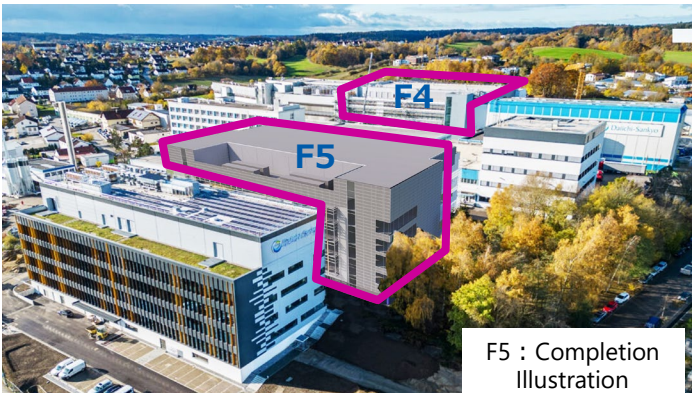
# ADC Drug Product Supply System

- Building regional supply system worldwide based on a “**LOCAL PRODUCTION FOR LOCAL CONSUMPTION**” approach
- A new drug product line is scheduled for completion in FY2026 at **American Regent’s New Albany site in the US**



## ● New Albany (US)

- One drug product line scheduled for completion in FY2026



## ● Pfaffenhofen (Germany)

- F4 : One drug product line completed in FY2024
- F5 : Two drug product lines scheduled for completion in FY2028



## ● Hiratsuka (Japan)

- One drug product line completed in FY2019
- Two drug product lines completed in FY2023



## ● Shanghai (China)

- Two drug product lines scheduled for completion in FY2027



# Advantage of One-Stop Manufacturing Approach

- ADCs require multiple manufacturing steps, **resulting in longer lead times than small-molecule drugs** (over one year from start of production to finished product)
- Consolidating key manufacturing processes at a single site **reduces inter-site transportation time and enhances production flexibility**

## Onahama Site (Antibody~Drug substance)



3F : ADC Drug substance line



transportation



1F : Antibody line

Established an efficient production system by integrating antibody and drug substance manufacturing within a single building

## Hiratsuka Site (Drug substance~Drug product)



Sterile Formulation Building No.2

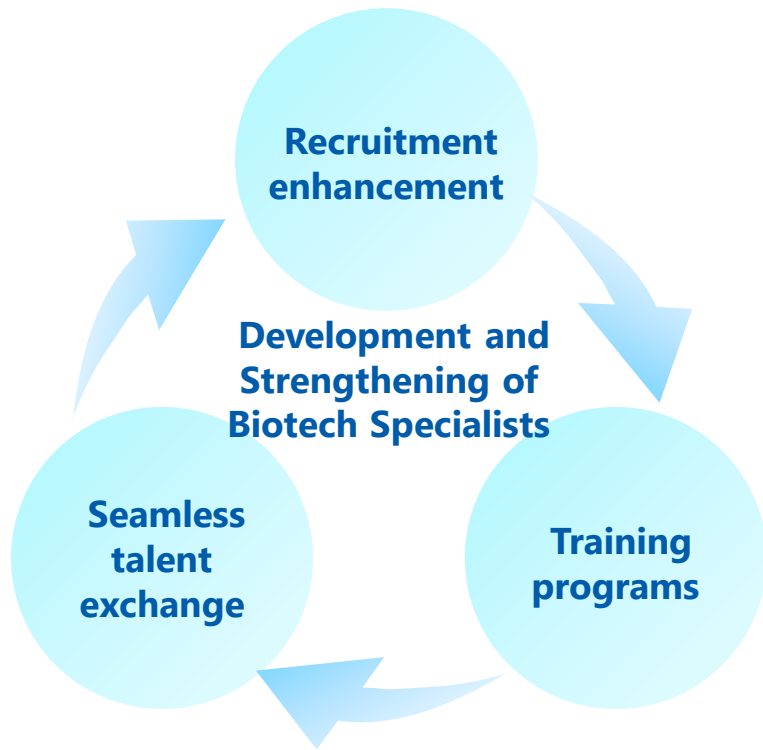
ADC Drug Substance Building

Established an integrated manufacturing system manufacturing from Drug substance to Drug product & packaging



# Initiatives to Develop and Strengthen Biotech Specialist

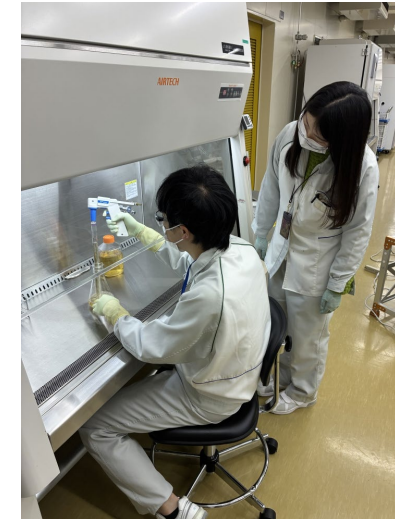
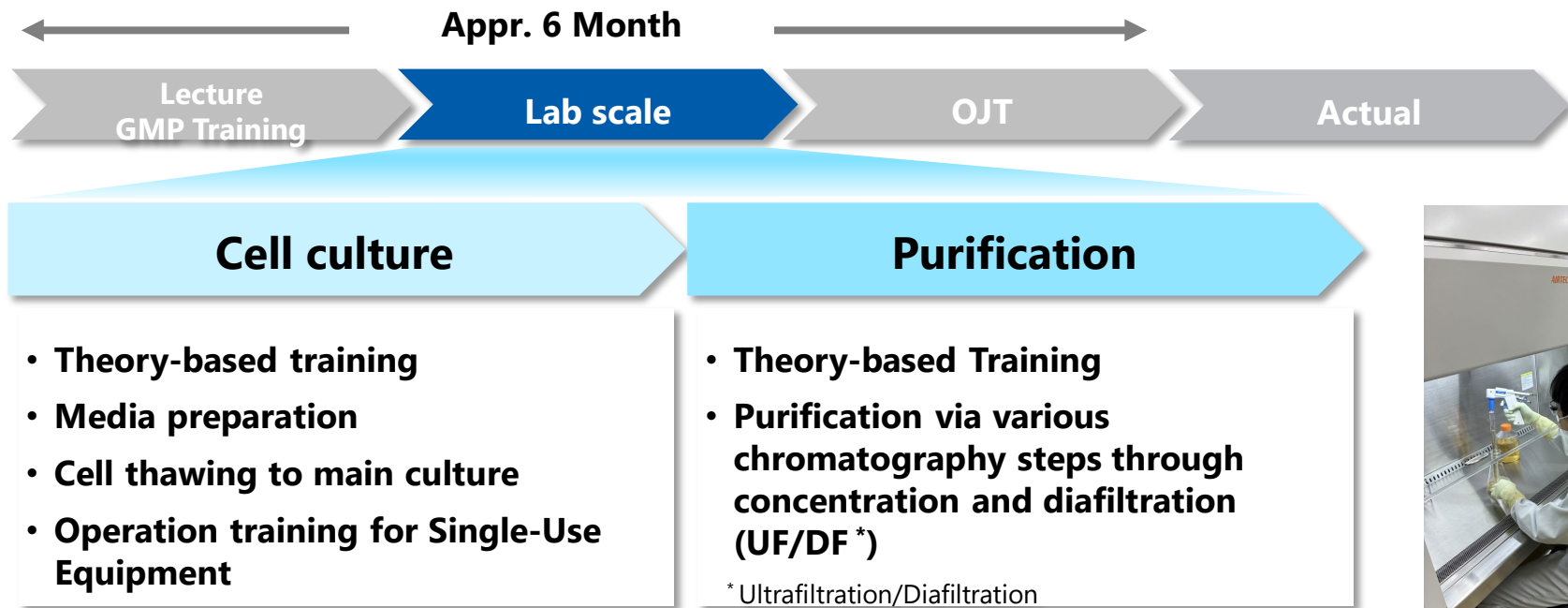
- Develop and strengthen biotech specialists (process development, manufacturing, quality assurance, regulatory affairs, etc.) to ensure ADC product development and stable supply
- In the manufacturing function, **securing more production staff and accelerating operator training** is essential to meet increasing production demands.



- **Strengthening Recruitment Activities**
  - Internship programs targeting students
  - Proactive mid-career hiring to secure experienced talent
- **Accelerate the Early Development and Strengthening of Manufacturing Operators through Training Programs**
  - Establish dedicated training environments for manufacturing engineers
  - Develop and implement the “Manufacturing Operator Training Program”
- **Seamless talent exchange across organizational and functional boundaries**
  - Engineer training coordinated across global manufacturing sites
  - Cross-regional talent exchange on a global scale

# Accelerate the Early Development and Strengthening of Manufacturing Operators through Training Programs

- Establish **training environments** for antibody manufacturing operators
- Develop **training programs** for antibody manufacturing operators and achieve **efficient development** of biotech specialists



- **Small-group**, practice-oriented program
- Skill development using lab-scale, **training-dedicated equipment**
- Enhanced **process comprehension** through integrated theoretical and practical trainings
- OJT and GMP training at each manufacturing sites

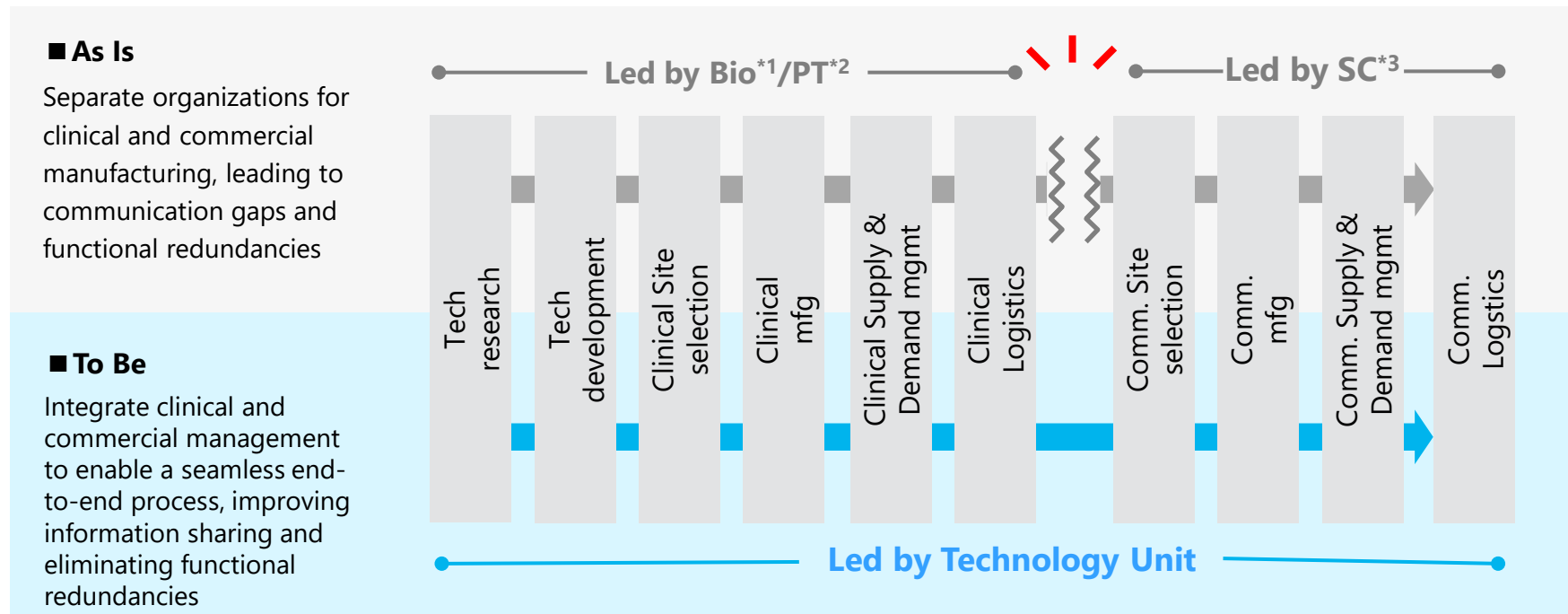
# Organizational Optimization to Meet Environmental Changes

## ■ Transition to an integrated organization covering clinical to commercial manufacturing

### Environmental Changes

Shift in major production items from small molecules to oncology and new modalities

Shorter lead times from development to commercial manufacturing due to accelerated approval processes

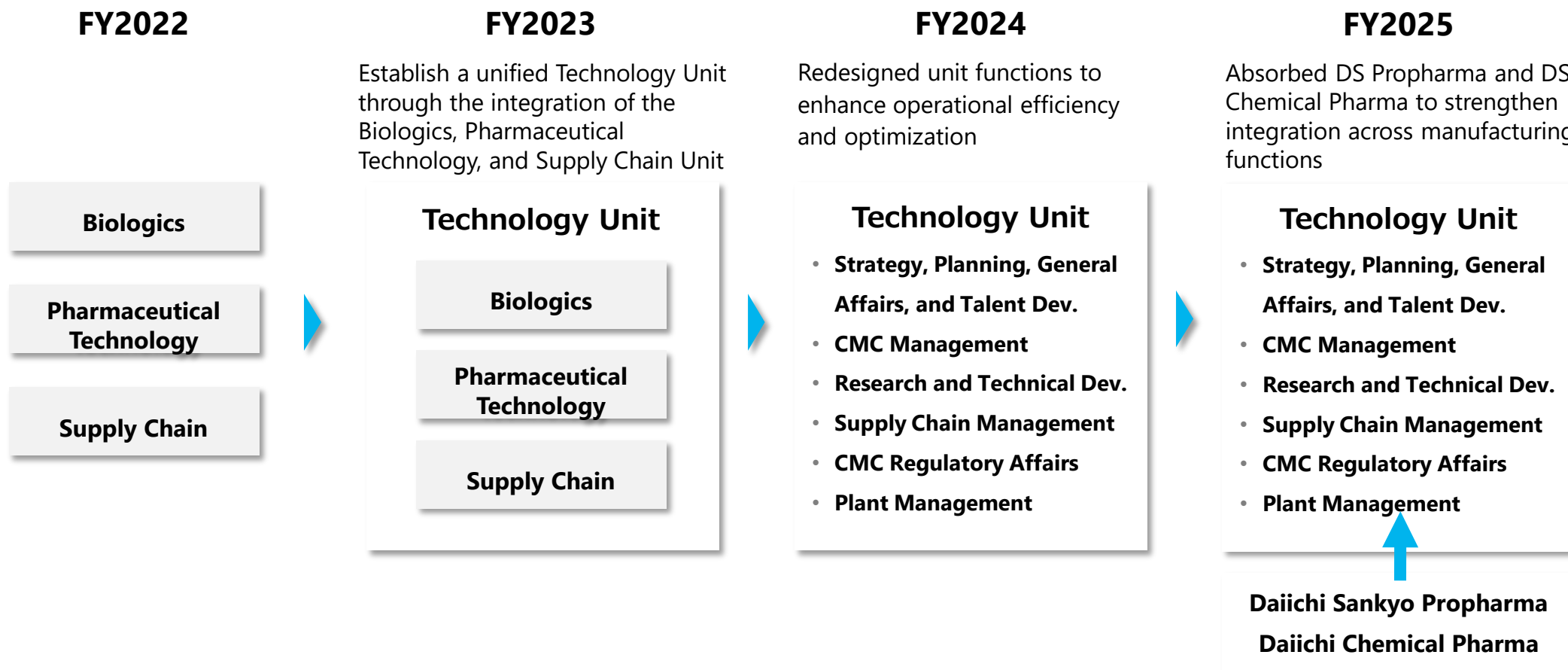


**Shift from a separated clinical/commercial manufacturing structure to a unified organization that leads both areas together**

# Organizational Optimization to Meet Environmental Changes

## ■ Evolution of the Technology

Establish an integrated structure that works seamlessly from early development through commercial manufacturing and supply, **enabling more efficient support for ADC and oncology businesses**



# Agenda

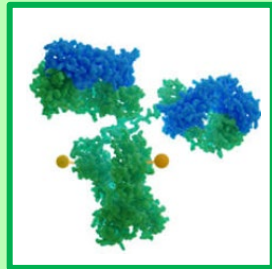
- ① Opening
- ② Clinical development
- ③ Oncology business
- ④ Technology
- ⑤ Research
- ⑥ Q&A



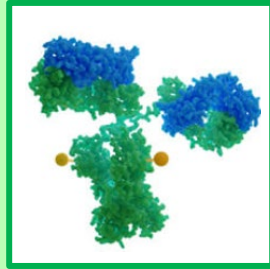
# Daiichi Sankyo Takes Multi-Modality Strategy

Establishing proprietary technologies unique to Daiichi Sankyo and building a robust and competitive drug discovery platform across diverse modalities.

## ADC Platform



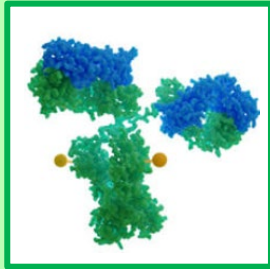
DXd ADC



mPBD ADC



STING agonist  
ADC

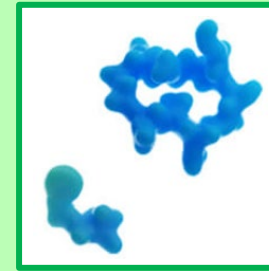


New Concept  
ADCs

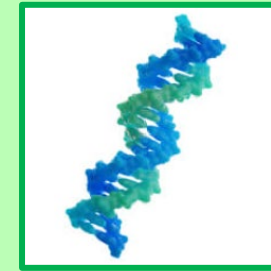
## New Modalities (beyond ADC)



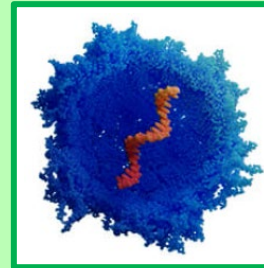
Multispecific  
Antibody



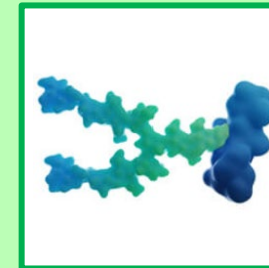
Mid-size Molecule  
(incl. TPD molecule)



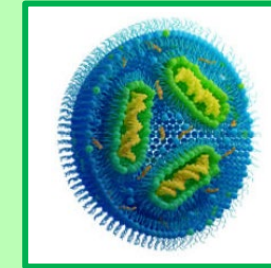
Nucleotide



Gene Therapy



Glycan



LNP-mRNA

etc.

**Continuous Generation of Innovative Medicines that Transform the SOC**



# Today's Topics for Our Future Innovation

## Deliver Durable Patient Benefit and Maximize Portfolio Value

### ADCs

#### DXd and New-concept

- Leverage deep DXd ADC experience
- Expanding value across tumor types
- High clinical success probability

### Immuno-Oncology (IO)

- Long-term remission via immune memory
- DXd ADC and IO combinations with complementary mechanisms
- Innovative approaches for cancers with high unmet needs

### Combination Strategy

- Building the next standard of care
- Enhancing portfolio leverage
- Combining DXd ADCs and new MoA

### New Modalities

- Establishing the technological advantages in multi-modality
- Long-term growth options
- Accelerating the innovation through partnership/collaboration

### Smart Lab / Open Innovation

- Accelerating research productivity and scientific innovation through digital technology / external expertise

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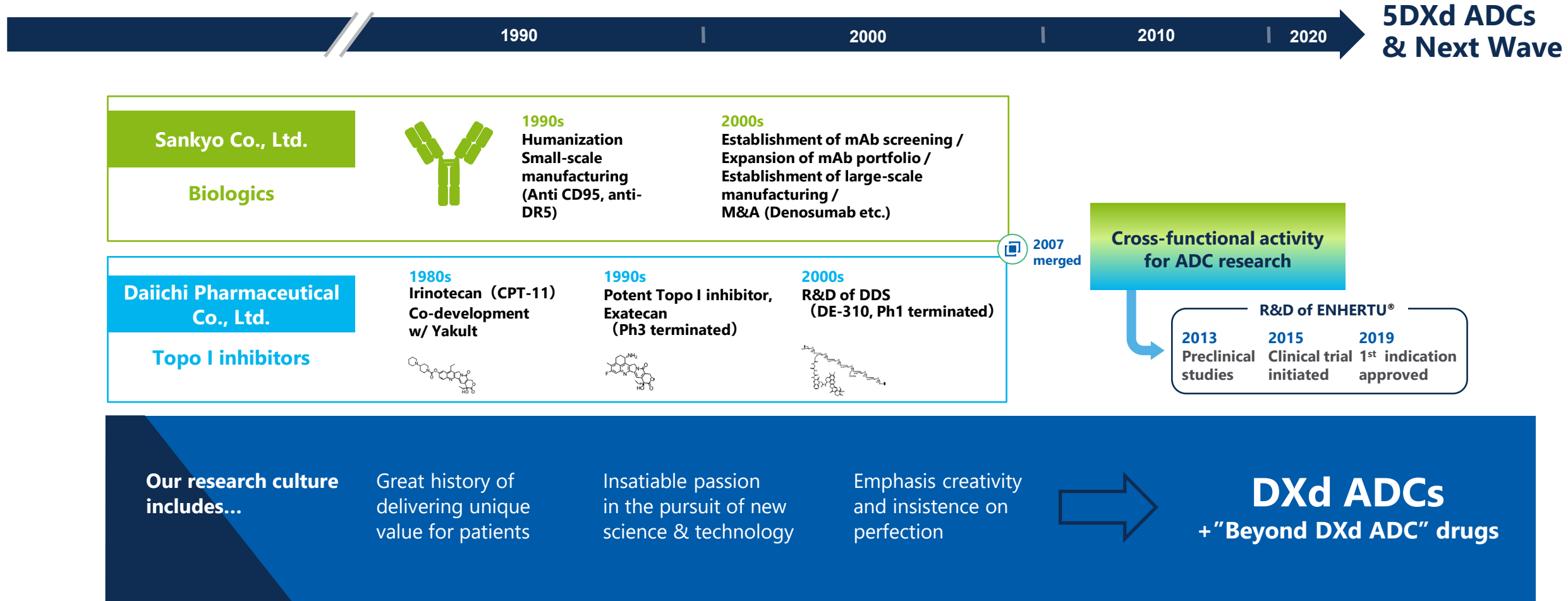
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# Long history behind the birth of DXd ADC




**Several inventors of ENHERTU® have been involved in other launched products**

- ◆ They have long tenure at DS, leveraged their expertise and are now research leaders growing our future talent

# DXd ADC is Daiichi Sankyo Original ADC Technology Platform

Our ADC technology platform is growing, and we have generated 7DXd ADCs from the technology

	Asset (Target Antigen)	Target tumor	Pre-Clinical	Ph1	Ph2	Ph3	Filed	Launched
DXd ADCs	<b>ENHERTU<sup>®</sup></b> (HER2)	BC, GC, NSCLC, Solid Tumors						
	<b>DATROWAY<sup>®</sup></b> (TROP2)	BC, NSCLC, etc.						
	<b>I-DXd</b> (B7-H3)	SCLC, ESCC, CRPC, etc.						
	<b>R-DXd</b> (CDH6)	OVC, RCC, etc.						
	<b>HER3-DXd</b> (HER3)	BC, GC, Melanoma etc.						
	<b>DS-3939</b> (TA-MUC1)	Solid Tumors						
	<b>DS3790</b> (CD37)	Hematological malignancies						

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

# External Evaluation of DXd ADC Technology

Since 2017, a total of 13 **Breakthrough Therapy designations\*** have been granted in the United States



Timing	Indications
August 2017	Third-line treatment for HER2-positive breast cancer
May 2020	Second-line treatment for HER2 gene mutation-positive non-small cell lung cancer
May 2020	Third-line treatment for HER2-positive gastric cancer
September 2021	Second-line treatment for HER2-positive breast cancer
April 2022	Low HER2 expression breast cancer (previously treated with chemotherapy)
September 2023	HER2-positive colorectal cancer (third-line treatment and beyond)
September 2023	Second-line or later treatment for HER2-positive solid tumors
August 2024	HR-positive and HER2-low/ultra-low breast cancer (chemotherapy-naïve)
July 2025	HER2-positive breast cancer first-line treatment



Timing	Indication
December 2024	EGFR-mutated non-small cell lung cancer with prior treatment history, including EGFR-targeted therapy

## I-DXd

Timing	Indication
August 2025	Extensive-stage small cell lung cancer

## R-DXd

Timing	Indication
September 2025	CDH6 expressing platinum-resistant ovarian cancer

## HER3-DXd

Timing	Indication
December 2021	Third-line treatment for EGFR-mutated non-small cell lung cancer

\*Breakthrough Therapy Designation: A program established to expedite the development and review of drugs that may demonstrate a greater therapeutic effect than existing treatments for serious conditions, enabling faster delivery of new drugs to patients in the US. 75

# The Evolution of Our ADC Technologies Will Continue

15 years of ADC platform advancement - expanding Innovation

## Antibody

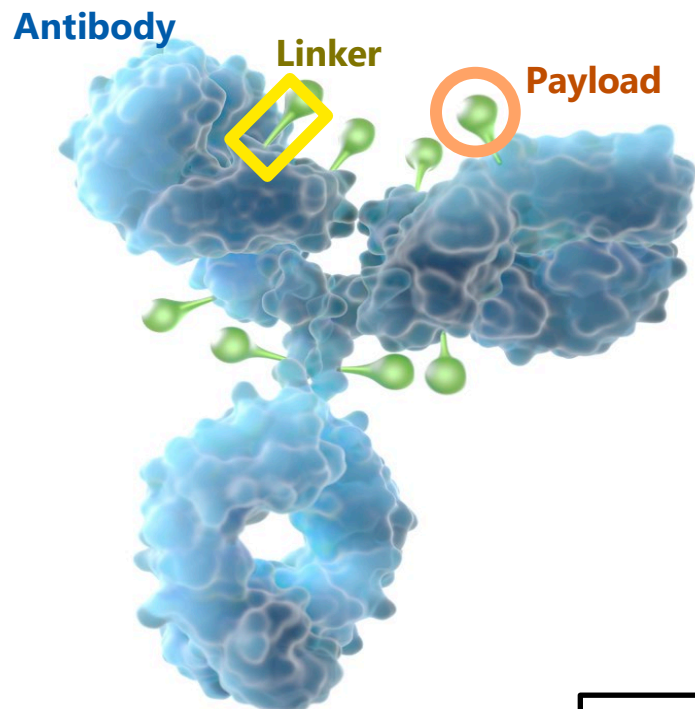
- ✓ Unique binders targeting disease specific proteins and glycans
- ✓ Fc engineering
- ✓ Novel technologies to increase specificity

## Linker

- ✓ DAR control
- ✓ Site specificity
- ✓ Novel conjugation

## Payload

- ✓ FIC/BIC Cytotoxic payloads
  - DXd, mPBD, etc.
- ✓ Other new payloads for refractory/resistant tumors
  - IO payloads, etc.



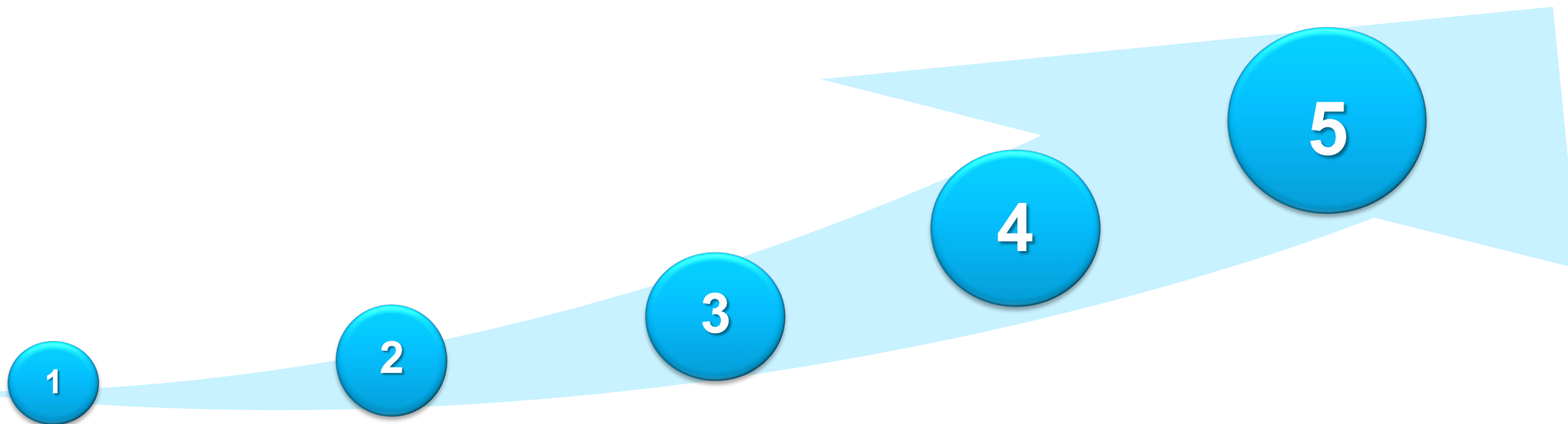
## Our Proprietary Technologies X ADC-leading Expertise

- ✓ **15+ years** of continuous ADC platform innovation
- ✓ Exploration of **diverse MoA - based payloads**
- ✓ Extensive validation of **dozens of tumor antigens**
- ✓ Deep expertise from **broad linker-payload conjugation**

**Unique ADC Research Experience Enabling Ongoing Breakthroughs**



# Sustainable ADC Platform Development



## DXd ADC

**ENHERTU<sup>®</sup>**  
**DATROWAY<sup>®</sup>**  
**I-DXd**  
**R-DXd**  
**HER3-DXd**  
**DS-3939**  
**DS3790**

## mPBD ADC

**DS-9606**  
Expanding into  
new technology in  
discovery stage

## STING agonist ADC

**DS3610**  
Multiple projects  
in preclinical stage

## New Concept ADC 1

Multiple projects  
in discovery stage

## New Concept ADC 2

Multiple projects  
in discovery stage

## New Concept ADC 3

Multiple projects  
in discovery stage

## New Concept ADC 4

Multiple projects  
in discovery stage

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### New Modalities

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### Smart Lab / Open Innovation

- Accelerating research productivity and scientific innovation through digital technology / external expertise

# Why We Invest in IO?

Immuno-Oncology (IO) Franchise

**Unlocking durable benefit, expanding treatment options, and maximizing internal asset value.**



## Durable Effect

IO therapies can deliver **long-lasting remission** beyond the treatment period.



## Immune Memory

Activated immune cells '**remember**' **tumor antigens** and suppress recurrence over time.



## New Treatment Opportunities

IO mechanisms create **new treatment options** for cancers less responsive to cytotoxic agents.

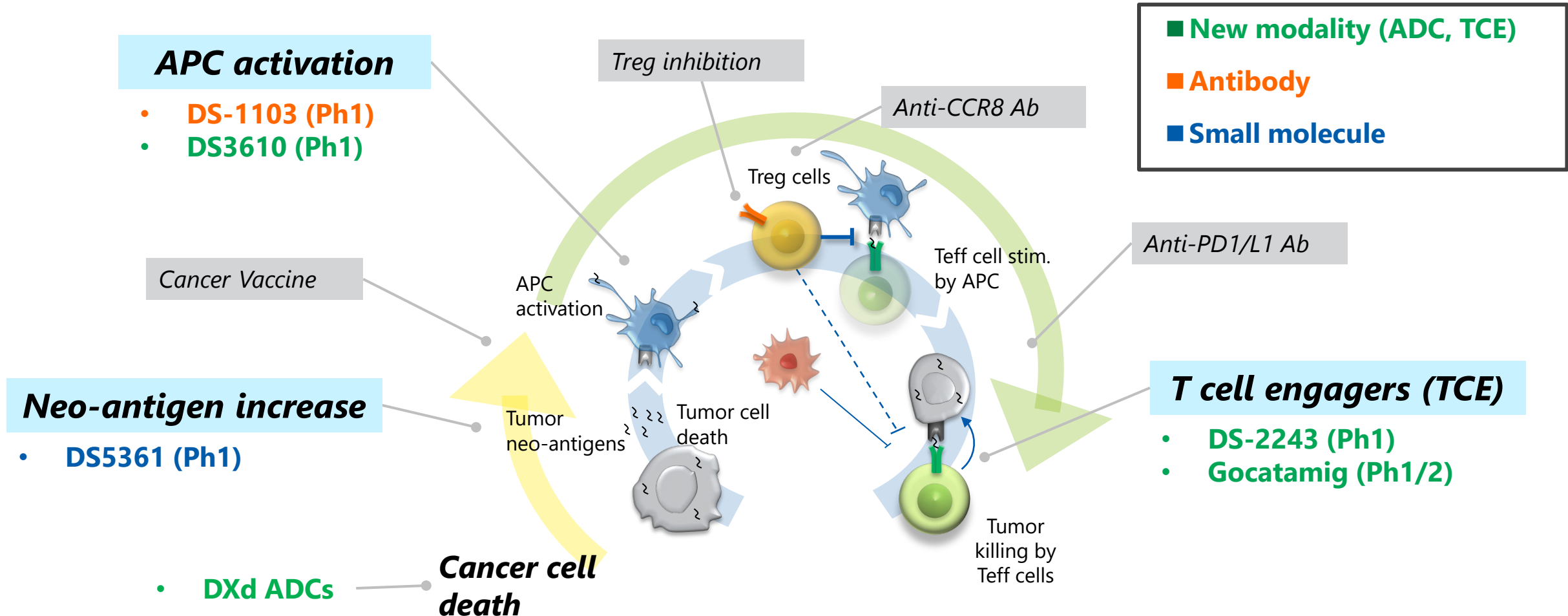


## Combinations therapy with complementary mechanisms

**IO × DXd ADC combinations** maximize the value of our internal assets and possibly provide new SOC.

# Our 10 Years Research History Has Built the IO Franchise

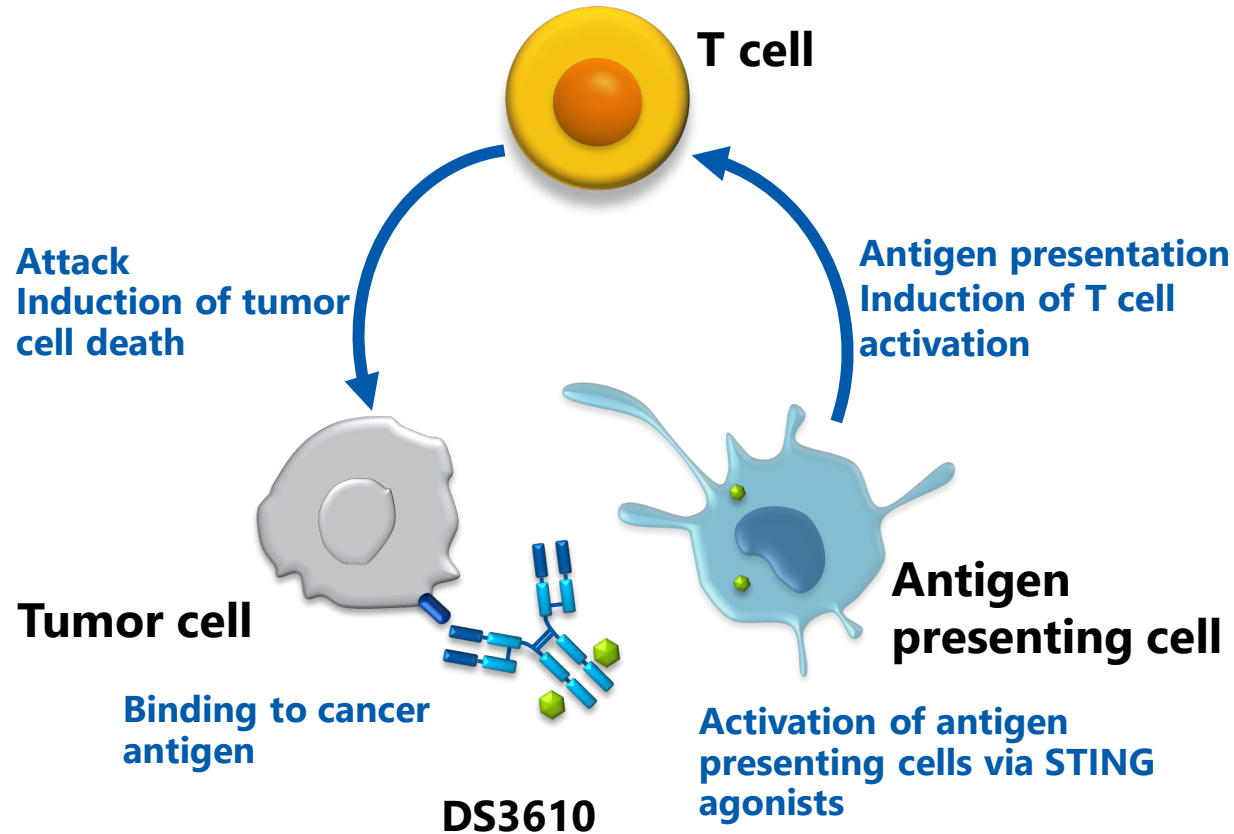
Leveraging a multi-modality strategy, we are establishing a portfolio that targets and activates key mechanisms in IO signaling



# DS3610: New STING Agonist ADC

DS3610 delivers STING\* agonists to cancer cells via an antibody targeting a cancer antigen and **activates antitumor immunity within the tumor microenvironment**

## Mechanism of Action



- ADC that combines Daiichi Sankyo original STING agonists with an antibody
- The novel Fc modification technology reduces the risk of systemic cytokine release
- Activation of immune cells including antigen presenting cells and T cells, and durable antitumor activity by immune memory formation have been confirmed in preclinical studies
- Combination effect with various therapeutic agents has been observed
- The FIH study started in Nov 2025

\*A key molecule in the activation of innate immunity and attracting attention in the field of cancer immunity

ADC: antibody-drug conjugate, FIH: first-in human

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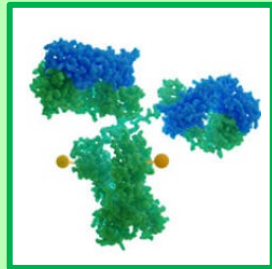
### Smart Lab / Open Innovation

- Accelerating research productivity and scientific innovation through digital technology / external expertise

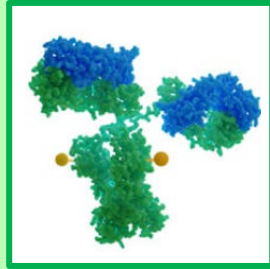
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## ADC Platform



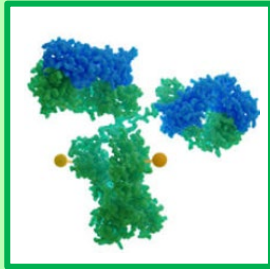
DXd ADC



mPBD ADC



STING agonist  
ADC

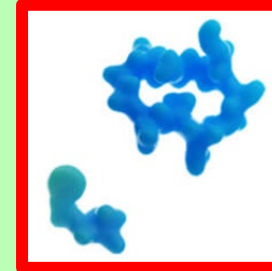


New Concept  
ADCs

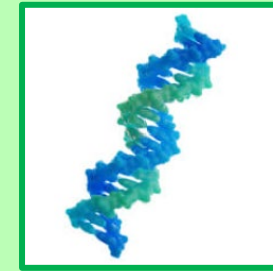
## New Modalities (beyond ADC)



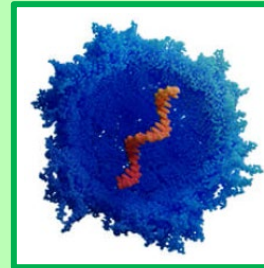
Multispecific  
Antibody



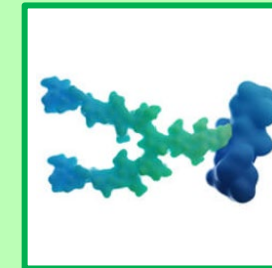
Mid-size Molecule  
(incl. **TPD** molecule)



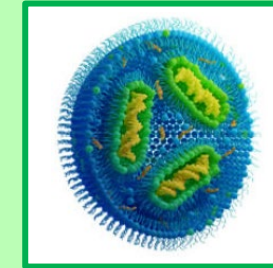
Nucleotide



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**Continuous Generation of Innovative Medicines that Transform the SOC**



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### Smart Lab / Open Innovation

- Accelerating research productivity and scientific innovation through digital technology / external expertise

# Smart Lab: Enabling Competitive AI-driven Drug Discovery

## What Smart Lab Delivers:

### 1. High-quality, Large-scale Data

- Automation, Robotics & Integrated Data Platform

### 2. Smarter and Faster AI-learning Loop

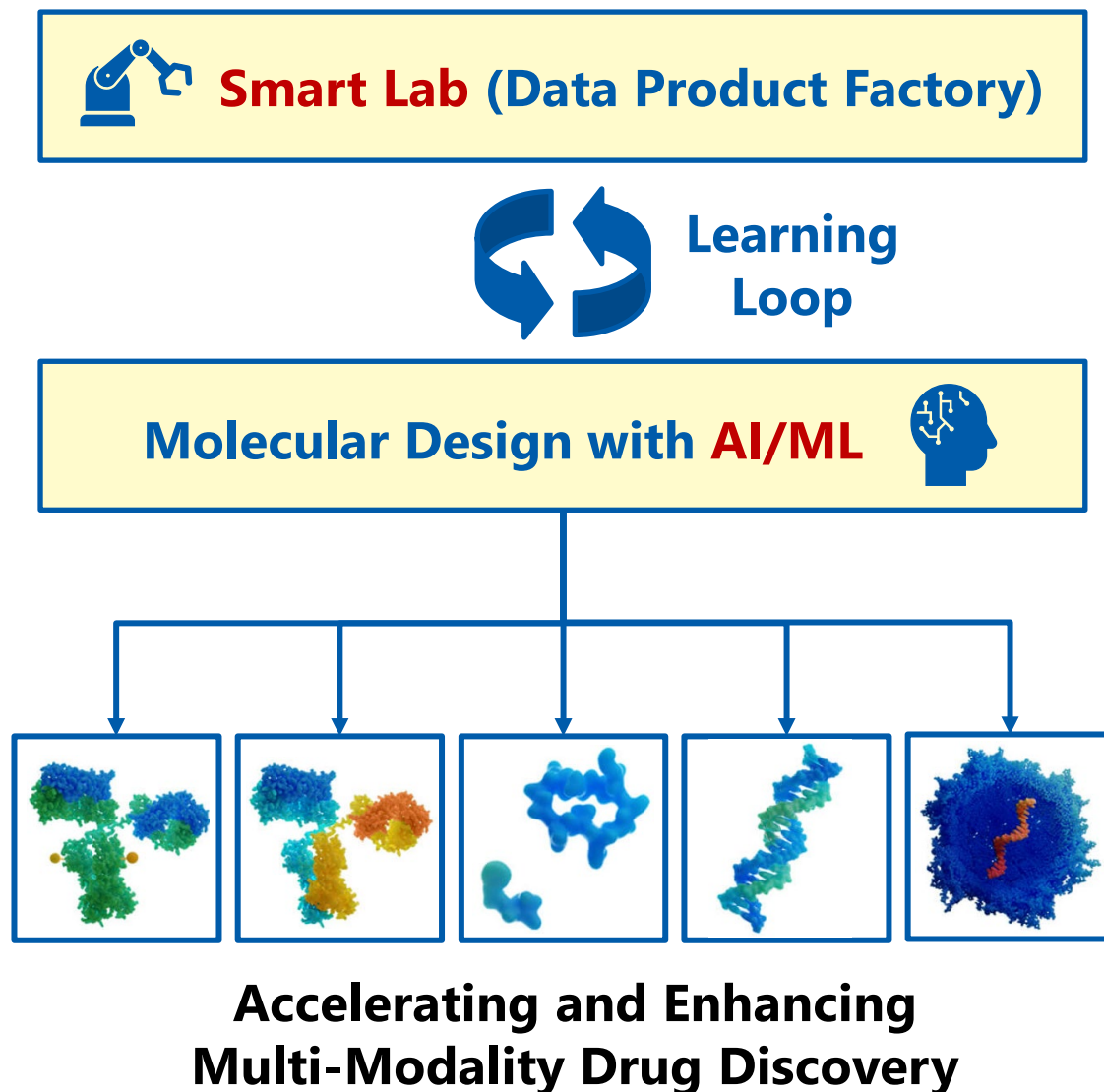
- Seamless data feedback to molecular design AI

### 3. Sustainable Competitive Advantage

- Data & learning accumulate over time
- Barriers to entry for competitors



**Smart Lab is the cornerstone of  
AI-driven drug design success.**



# Launched Smart Research Lab in San Diego to Accelerate Innovation

## Capabilities & Benefits

- **Automate data generation** to power AI-driven drug discovery
- Accelerate drug-candidate selection with **24/7 operations**
- Unlock new insights through **harmonized, high-quality data**
- Enable researchers to focus on high-value science

## Facility & Team Development

- Integrated **robotic automation** for end-to-end workflows
- Foster close collaboration between **researchers and engineers**
- **DS's first dedicated drug discovery base in the U.S.**

Data Generation  
(San Diego)



Molecular Design  
with AI/ML  
(Tokyo)

**Building a scalable foundation for sustained innovation and long-term growth.**



# Daiichi Sankyo Research Institutes for External Collaboration

**Daiichi Sankyo research activities are mainly based in Tokyo, where we have 10+ Research Laboratories**

**In 2024 and 2025, we opened Daiichi Sankyo Research Institutes for external collaboration**

- to build a global network with academia/startup for innovative research
- to drive 'sponsored research' supporting DS research strategy

**RESEARCH INSTITUTE MUNICH (RIM)**



**DS TRCE\*\*  
MUNICH, GERMANY**

\*\* Translational Research Center Europe

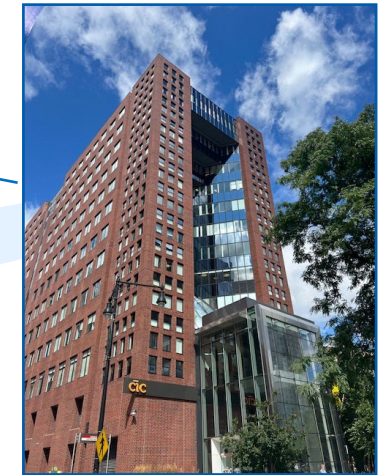
**DS RESEARCH LABORATORIES\***

**TOKYO, JAPAN**  
(SHINAGAWA, KASAI)



\* Wet laboratories

**RESEARCH INSTITUTE BOSTON (RIB)**



**RESEARCH INSTITUTE SAN DIEGO (RISD)**

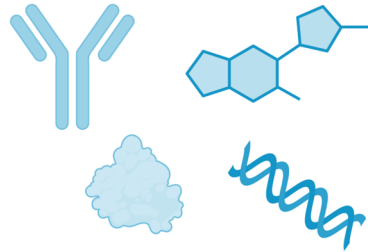




# Research Institute Scouting Strategy

Incubate either *Novel Modality* or *New Biology* through scientific discussion

MODALITY



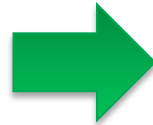
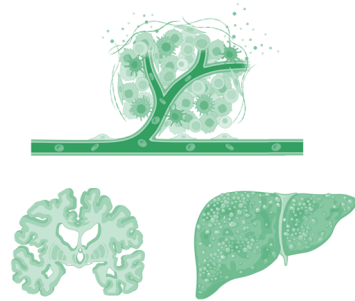
## NOVEL MODALITY

*for established biology/target*  
(e.g., drug delivery, brandnew technology)

×

INCUBATE BLOOMING/  
EMERGING CONCEPTS

BIOLOGY



## NEW BIOLOGY RESEARCH

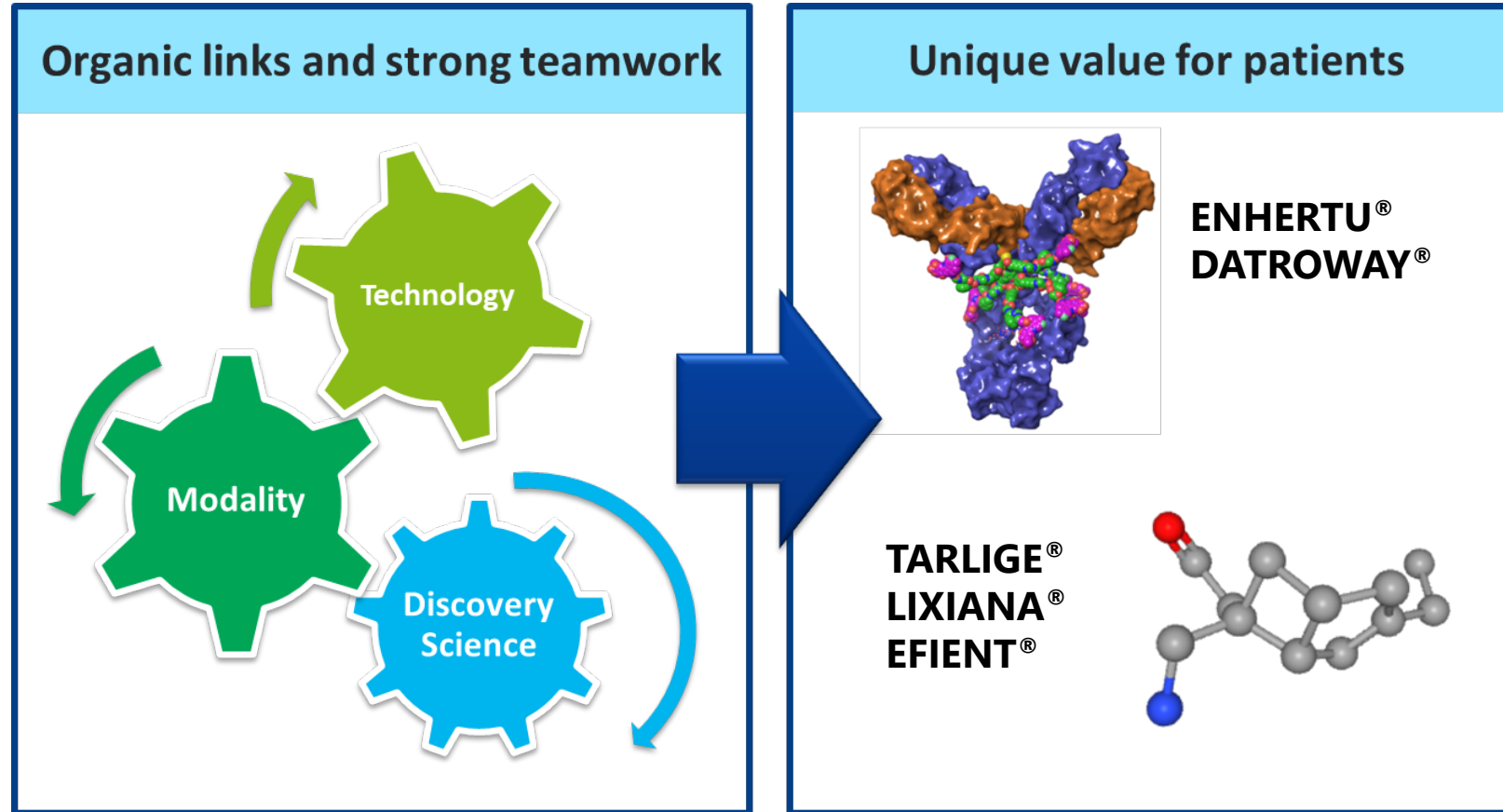
*for DS's modality*  
(e.g., target identification, novel concept)



Created with BioRender.com

***We focus on early-stage Modality Development and Biology Research via Sponsored Research Programs***

# Science & Technology through Craftspersonship

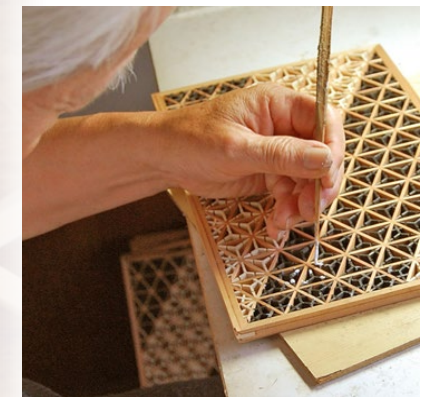
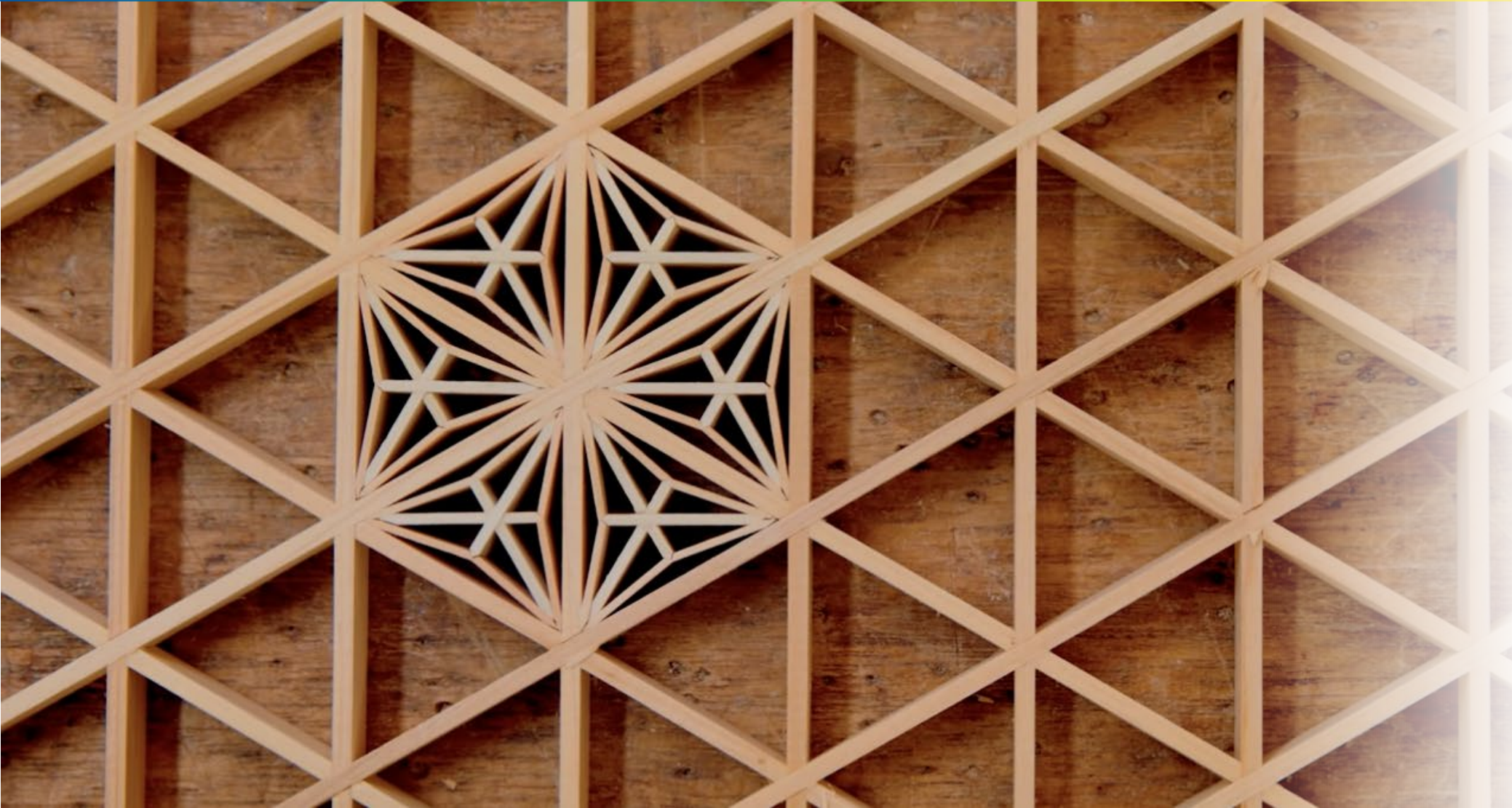


**At DS, we**

- Have an insatiable passion to pursue new **science & technology**
- Apply exceptional **craftspersonship** aiming for Innovation
- Deliver unique **value for patients**



# *Crafting New Standards of Care*



# Agenda

- ① Welcome
- ② Clinical Development
- ③ Oncology Business
- ④ Technology
- ⑤ Research
- ⑥ Q&A



**Contact address regarding this material**

**Daiichi Sankyo Co., Ltd.**

Corporate Communications Department

TEL: +81-3-6225-1125

Email: [DaiichiSankyoIR\\_jp@daiichisankyo.com](mailto:DaiichiSankyoIR_jp@daiichisankyo.com)