Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2024 Q1
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Koji Ogawa

Executive Officer, CFO

July 31, 2024

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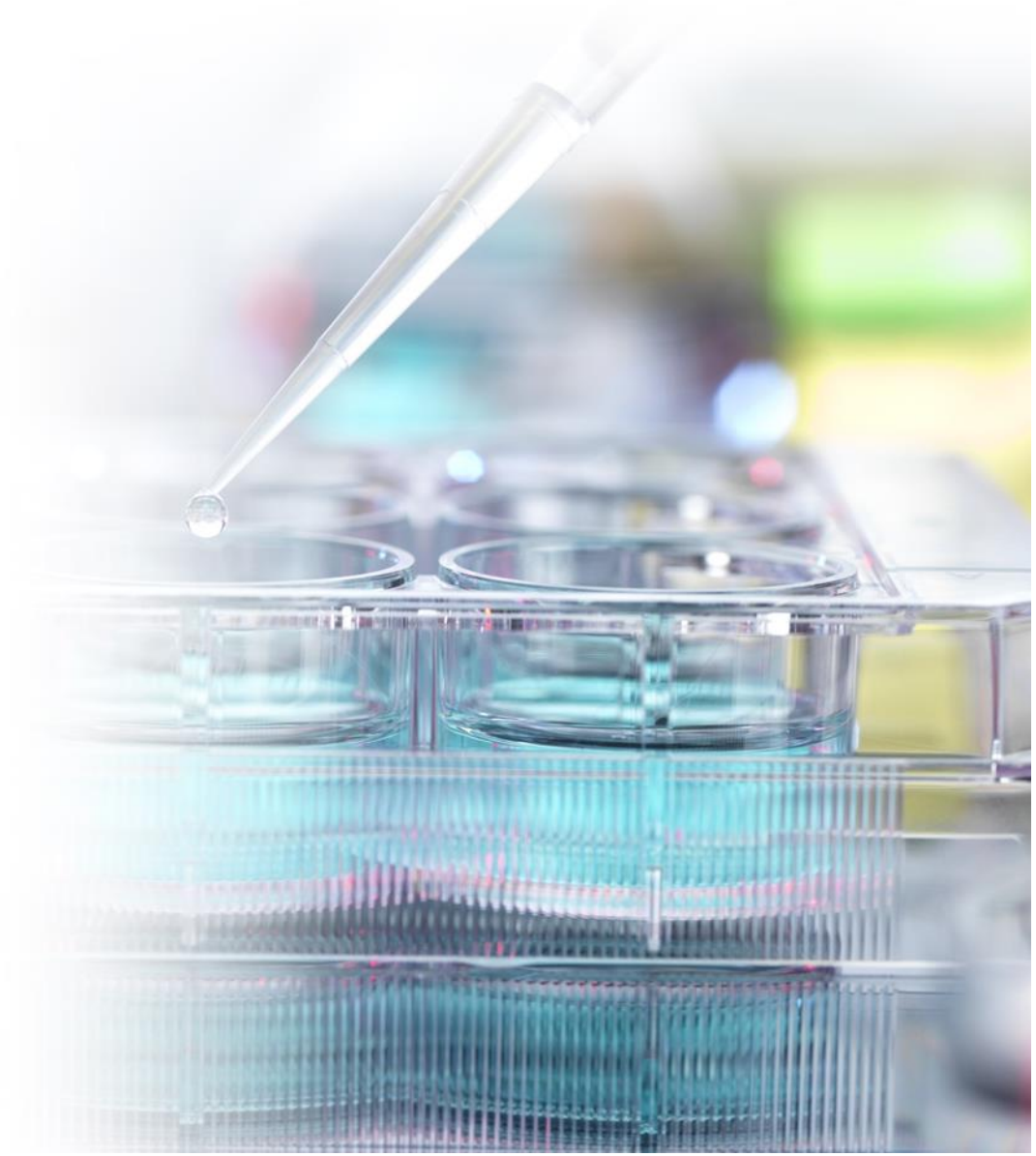
Agenda

1. **FY2024 Q1 Financial Results**
2. Business Update
3. R&D Update
4. Appendix



Overview of FY2024 Q1 Results

(Bn JPY)

	FY2023 Q1 Results	FY2024 Q1 Results	YoY	
Revenue	**350.8**	**436.2**	+24.3%	**85.3**
Cost of sales*1	93.6	95.0		1.4
SG&A expenses*1	135.6	167.6		32.0
DXd ADC profit share *2	34.8	56.8		22.0
Other SG&A expenses	100.8	110.8		10.0
R&D expenses*1	77.2	100.7		23.5
Core operating profit*1	**44.5**	**72.9**	+63.9%	**28.4**
Temporary income*1	0.5	20.1		19.6
Temporary expenses*1	0.9	0.0		-0.9
Operating profit	**44.0**	**93.0**	+111.2%	**48.9**
Profit before tax	**52.1**	**110.2**		**58.1**
Profit attributable to owners of the Company	**57.0**	**85.4**	+49.8%	**28.4**

Currency Rate	USD/JPY	137.37	155.89	+18.52
	EUR/JPY	149.46	167.88	+18.42

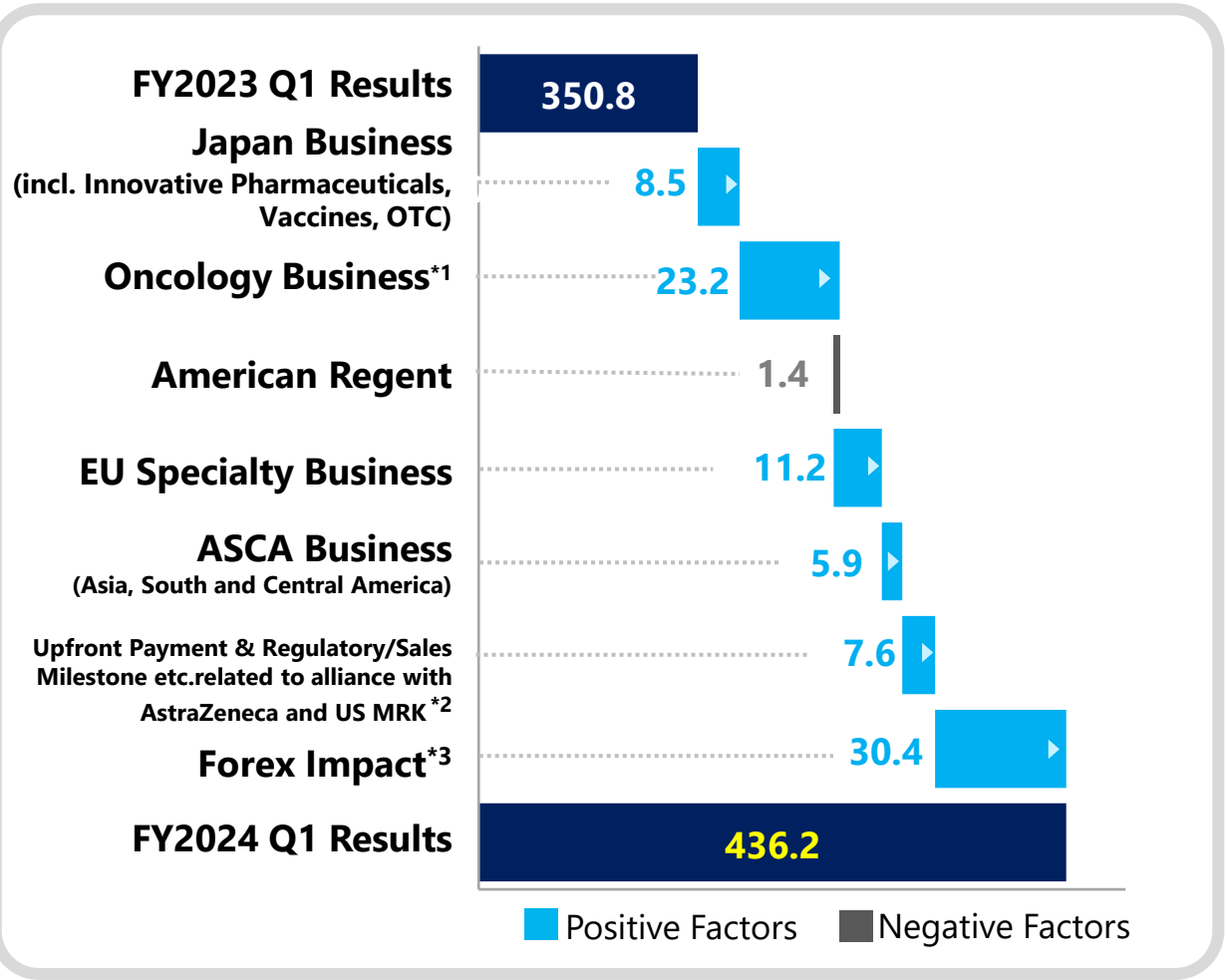
*1 As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed. Income and expenses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation, 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 85.3 Bn JPY (Increased by 55.0 Bn JPY excl. forex impact)

(Bn JPY)

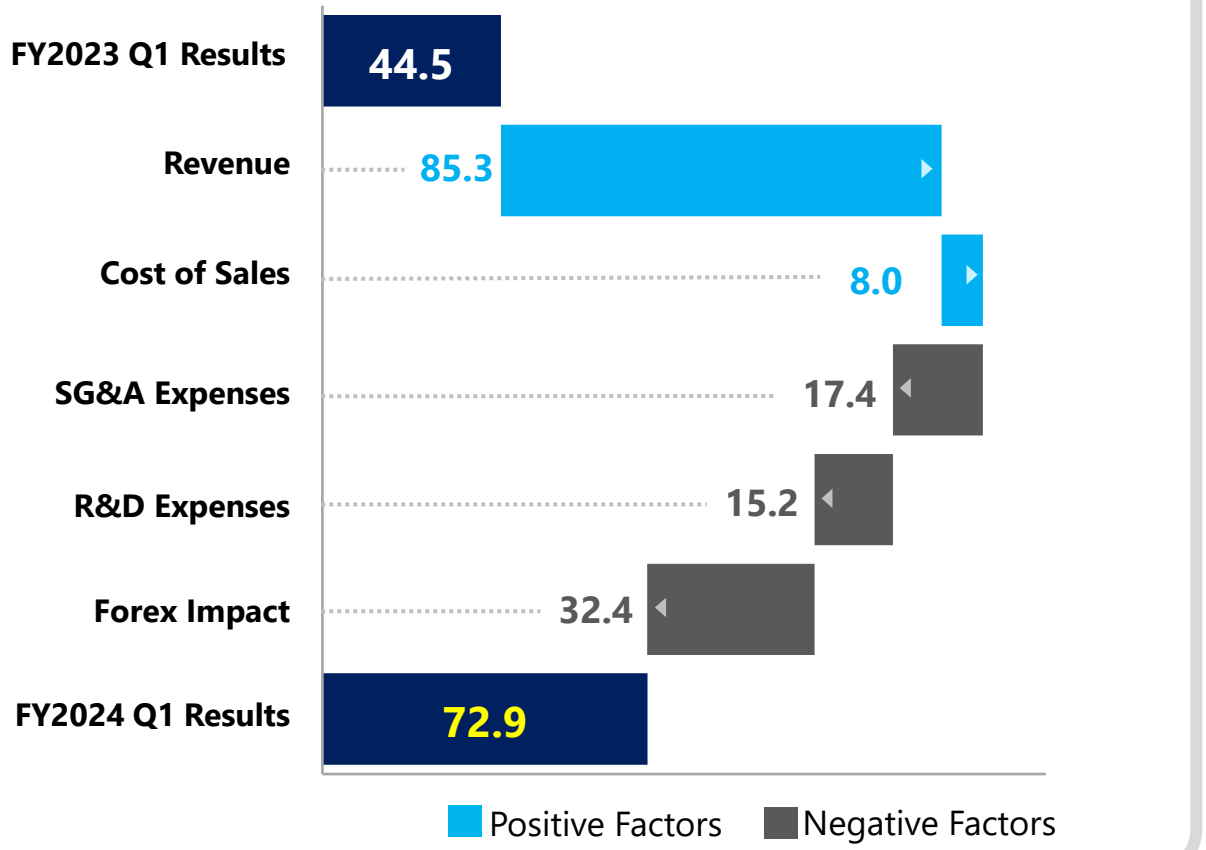


Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+7.0	Daiichi Sankyo Espha	-20.6
Enhertu	+3.4		
Tarlige	+2.5		
Daiichi Sankyo Healthcare	+2.9		
Realized gains of unrealized gains of inventory for Daiichi Sankyo Espha	+5.6		
Oncology Business Unit*1			
Enhertu	+22.3		
American Regent Unit			
		Venofer	-1.4
EU Specialty Business Unit			
Lixiana	+8.1		
Nilemdo/Nustendi	+3.9		
ASCA (Asia, South and Central America) Business Unit			
Enhertu	+6.6		
Upfront Payment & Regulatory/Sales Milestone etc. related to alliance with AstraZeneca and US MRK *2			
Upfront Payment related to alliance with US MRK	+7.2		

*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products
*2 Merck & Co., Inc., Rahway, NJ, USA
*3 Forex impact USD: +16.9, EUR : +10.1, ASCA: +3.4

Core Operating Profit

Increased by 28.4 Bn JPY (Increased by 30.4 Bn JPY excl. forex impact)



(Bn JPY)

Revenue +85.3
incl. forex impact of +30.4

Cost of Sales -8.0
Improvement in cost of sales ratio by change in product mix

SG&A Expenses +17.4
Increase in expenses related to Enhertu
due to an increase in profit share of gross profit with AstraZeneca

R&D Expenses +15.2
Increase in 5DXd ADCs* R&D investments

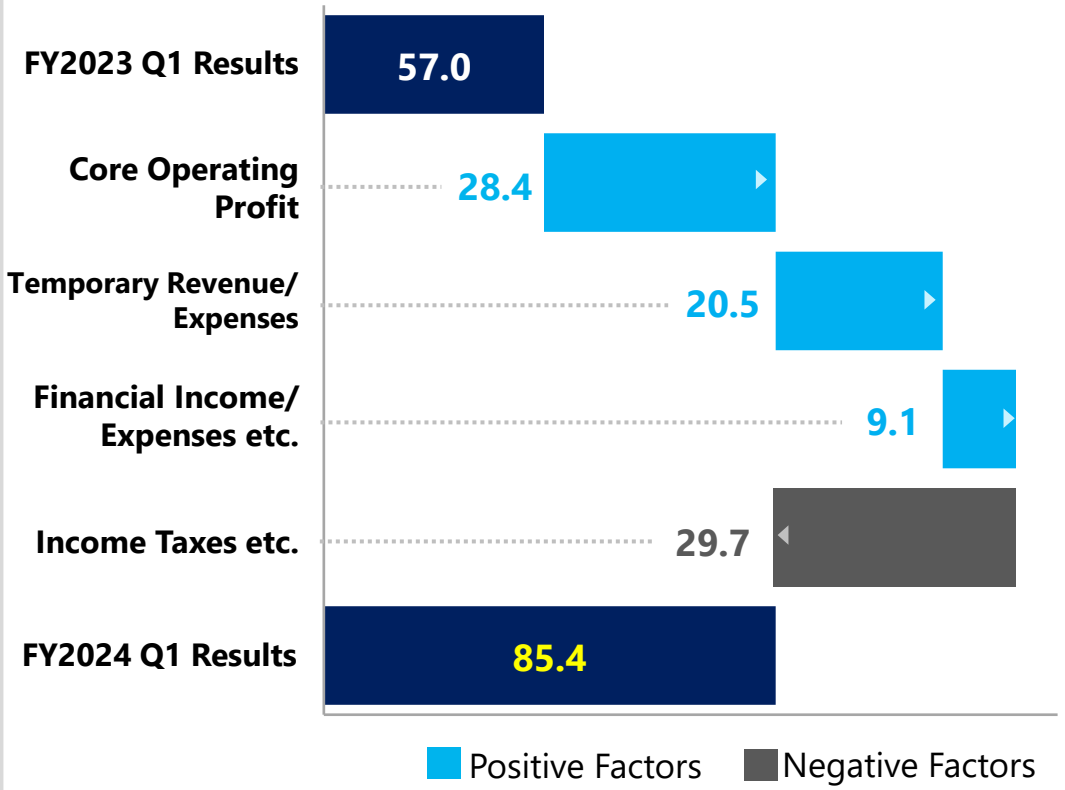
Forex Impact +32.4 (Profit Decreased)
Cost of Sales +9.4
SG&A Expenses +14.6
R&D Expenses +8.4

***ENHERTU®**: trastuzumab deruxtecan (International Nonproprietary Name: INN), T-DXd, DS-8201 (HER2-directed ADC), **Dato-DXd**: datopotamab deruxtecan (INN), DS-1062 (TROP2-directed ADC), **HER3-DXd**: patritumab deruxtecan (INN), U3-1402 (HER3-directed ADC), **I-DXd**: ifinatamab deruxtecan (INN), DS-7300 (B7-H3-directed ADC), **R-DXd**: raludotatug deruxtecan, DS-6000 (CDH6-directed ADC)

Profit Attributable to Owners of the Company

Increased by 28.4 Bn JPY

(Bn JPY)



Temporary Income/Expenses ····· **+20.5 (Profit Increased)**

	FY2023 Q1 Results	FY2024 Q1 Results	YoY
Temporary Income	0.5	20.1*1	+19.6
Temporary Expenses	0.9	0.0	-0.9

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

Financial Income/Expenses etc. ····· **+9.1（Profit Increased）**

- Improvement in forex gains/losses ····· +7.8
- Increase in interest income ····· +2.8
- Deterioration in investment securities valuation gains/losses ····· -1.2

Income Taxes etc. ····· **+29.7 (Profit Decreased)**

	FY2023 Q1 Results	FY2024 Q1 Results	YoY
Profit before Tax	52.1	110.2	+58.1
Income Taxes etc.	-4.9	24.8	+29.7
Tax rate	-9.4%	22.5%	

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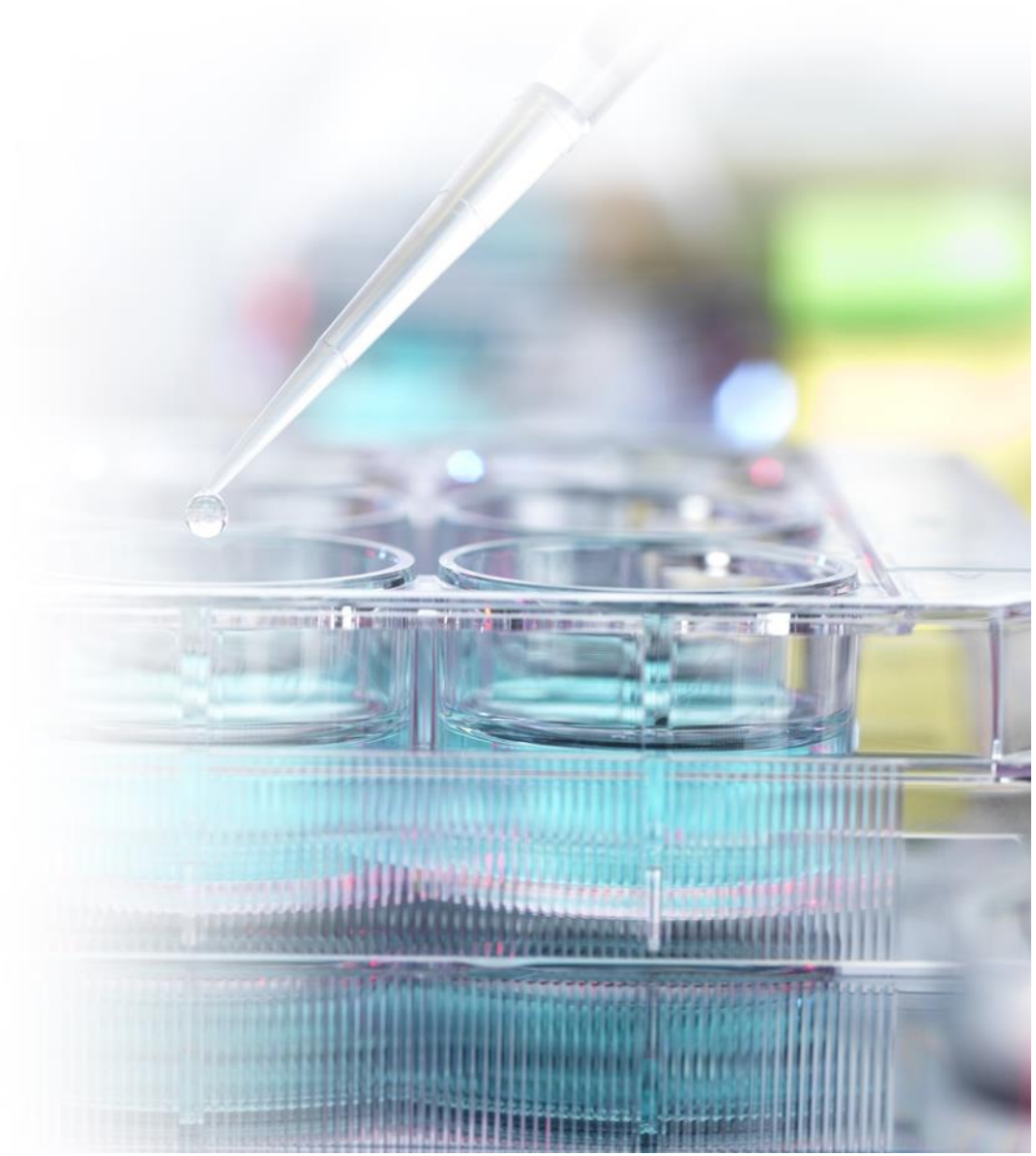
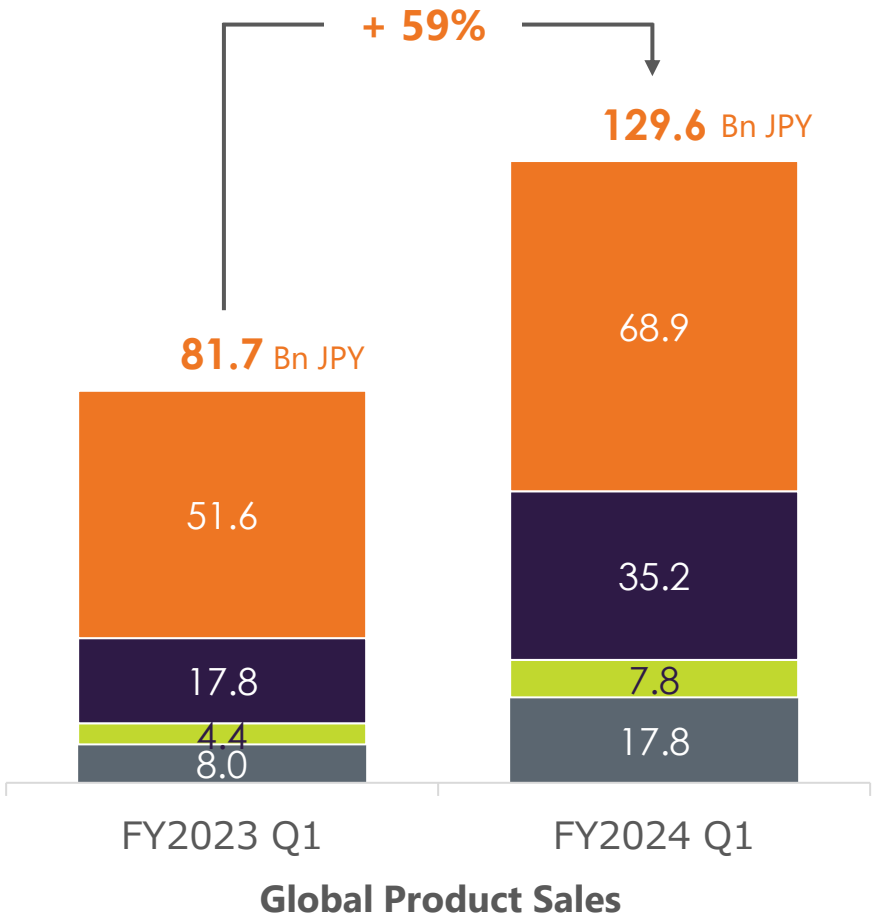


ENHERTU® Performance

Global Product Sales

Q1 Product Sales Result **¥129.6Bn** (YoY **+¥47.9Bn**) FY2024 Forecast **¥508.4Bn** (YoY **+¥112.4Bn**)



Global Product Sales

◆ Key Growth Factors (YoY Quarterly Results)

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

US (+34%)	Maintained the No.1 new patient share in BC, GC, NSCLC; Steadily increased sales uptake in HER2+ tumor-agnostic
EU (+98%)	Expanded sales mainly in Germany, France, Italy; Maintained the No. 1 new patient share in HER2+ BC 2L and HER2 low BC (post-chemo)
Japan (+78%)	Maintained the No.1 new patient share in all indications
ASCA (+122%)	Expanded sales mainly in Brazil and China

◆ Other Progresses: 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)

BC: breast cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, NCCN: National Comprehensive Cancer Network

Other Regional Initiatives

Japan

- **Ezharmia® Anti-Cancer Agent / EZH1 and EZH2 Inhibitor**
  - **Approved for the treatment of adult patients with relapsed or refractory peripheral T-cell lymphoma (PTCL)** in June 2024
- **Belsomra® Anti-Insomnia Treatment / Dual Orexin Receptor Antagonist**
  - Decision made to transfer of distribution rights from MSD to Daiichi Sankyo in July 2024
    - Daiichi Sankyo will be responsible for sales and promotional activities from October 1, 2024 onwards

EU

- **Nilemdo®/Nustendi® Cholesterol-lowering agent**
  - 2024 May **Approved for treatments to reduce the risk of adverse cardiovascular events**
    - The first and only non-statin LDL-C-lowering treatments indicated for primary and secondary prevention of cardiovascular events

Major Updates on Patent Disputes

Dispute with Seagen (SGN) regarding Daiichi Sankyo ADC ① (Arbitration on ADC Technology)

- **May 2024 Final award issued by an arbitrator has been finalized**
- **Jun. 2024 SGN has paid DS based on the Final award**
  - SGN has paid DS **approx. U.S. $47 million** (approx. 7.5 bn JPY) in connection with **attorneys' fees and costs** plus interest awarded by the arbitrator of the party's dispute.
  - The payment has been booked as **reversal of SG&A** in the FY2024 Q1 financial results.

Dispute with SGN regarding Daiichi Sankyo ADC ② (Disputes regarding SGN's U.S. patent)

- **Nov. 2023 DS appealed to the U.S. Court of Appeals for the Federal Circuit (CAFC) the amended final judgment* by the U.S. District Court for the Eastern District of Texas**

  *The Court's amended final judgment requires DS to pay SGN a royalty of 8% on sales of ENHERTU® from Apr. 1, 2022 through Nov. 4, 2024 (the expiry of SGN's U.S. patent) in addition to the 41.8 Mn USD in damages previously awarded by the Court in July 2022 (Oct. 2023)

- **May 2024 SGN appealed to CAFC the Final Written Decision* in a Post Grant Review (PGR)**

  *The U.S. Patent and Trademark Office (USPTO) rendered a Final Written Decision invalidating all challenged claims of SGN's U.S. patent in a Post Grant Review (PGR) (Jan. 2024)

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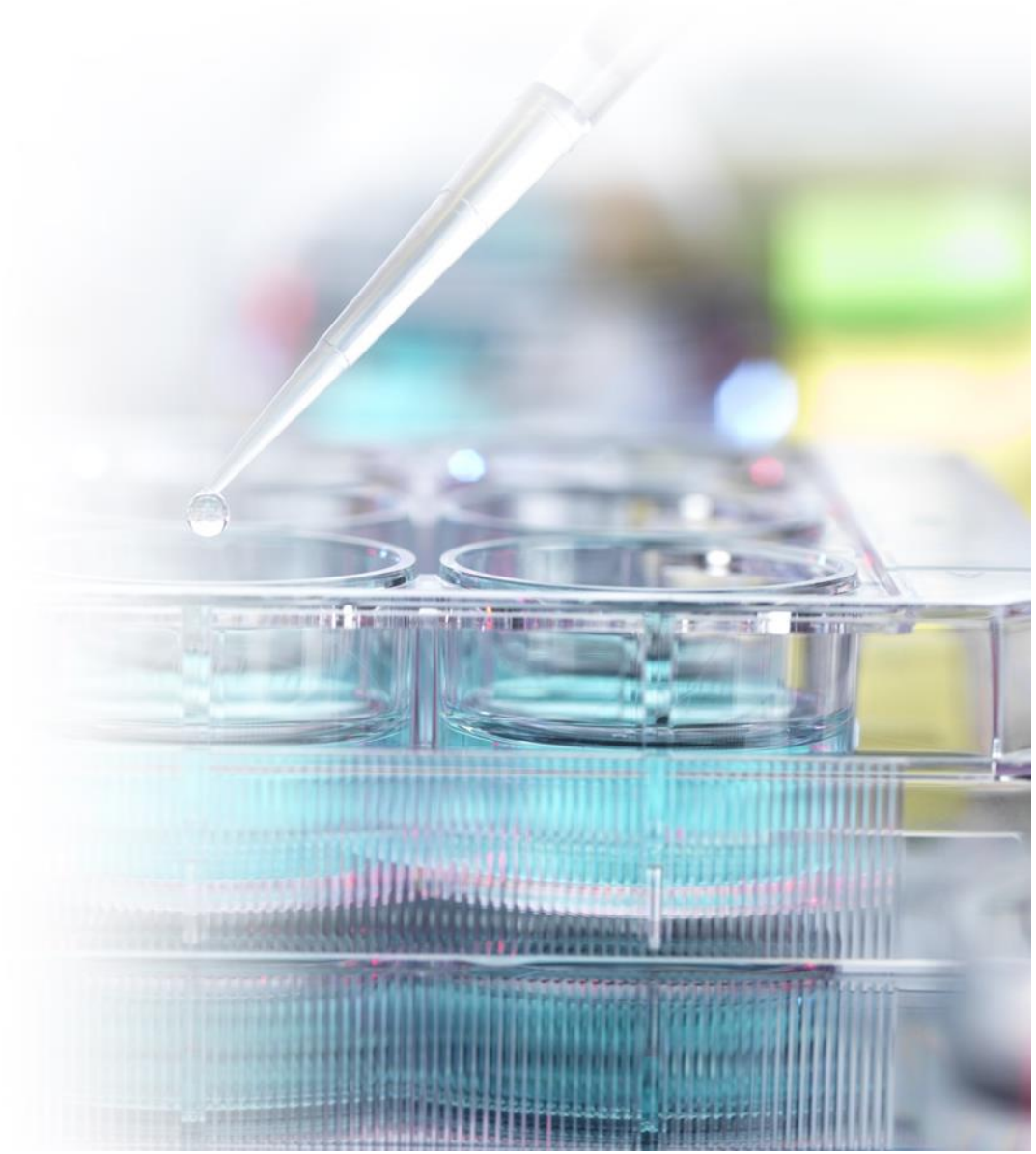


5DXd ADCs Update

Next Wave Update

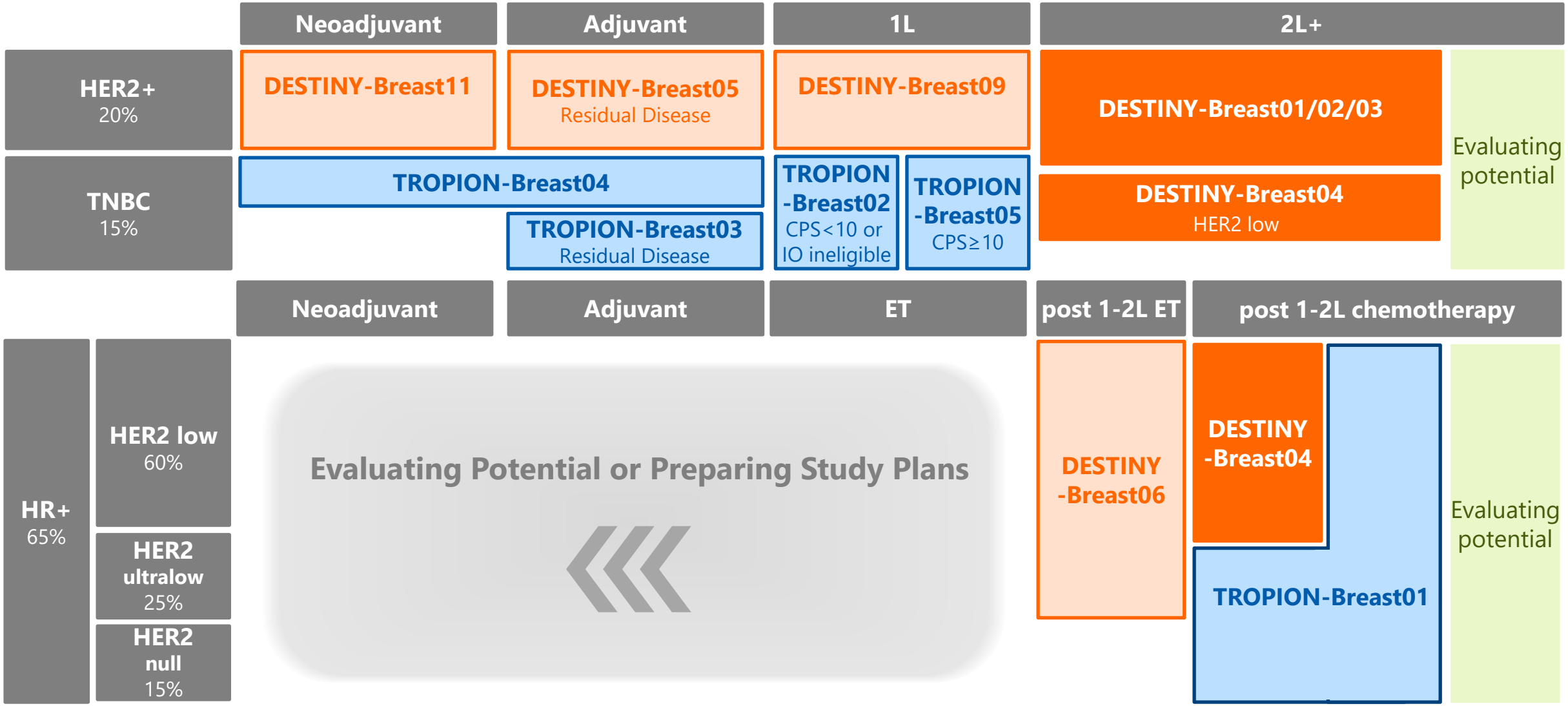
WCLC/ESMO 2024

News Flow

5DXd ADCs

Establish and expand DXd ADCs to address the broader spectrum of Breast Cancer

Daiichi-Sankyo



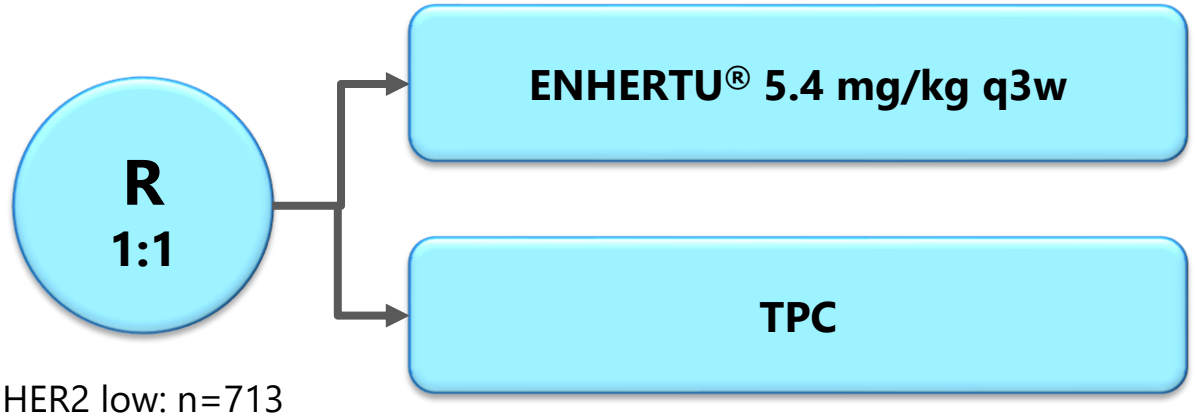
- Pivotal studies only, not exhaustive
- Box size does not reflect the patient population
- Box indicates current potential target segment

ASCO: American Society of Clinical Oncology, CPS: combined positive score; ET: endocrine therapy; HR: hormone receptor; IHC: immunohistochemistry, pCR: pathological complete response, TNBC: triple-negative breast cancer

DESTINY-Breast06 primary analysis data presented at ASCO 2024

DESTINY-Breast06 study design

Key Eligibility
- HR positive mBC
- HER2 low (IHC 1+ or IHC 2+/ISH−) or HER2 ultralow (IHC 0 with membrane staining)*
- Chemotherapy naïve in the mBC setting



HER2 low: n=713
HER2 ultralow: n=153

Primary endpoint
- PFS (BICR) in HER2 low

Secondary endpoint
- PFS (BICR) in ITT (HER2 low + ultralow)
- OS in HER2 low
- OS in ITT (HER2 low + ultralow)
- Safety and tolerability

- HER2 low and HER2 ultralow mBC after one or more treatments of endocrine therapy
- The study covers ~85% of HR positive and HER2 negative mBC by previous definition, which consists of 60-65% of HER2 low and 20-25% of HER2 ultralow

*Study enrollment was based on central HER2 testing. HER2 status was determined based on the most recent evaluable HER2 IHC sample prior to randomization. HER2 ultralow was defined as faint, partial membrane staining in ≤10% of tumor cells (also known as IHC >0<1+)

ASCO: American Society of Clinical Oncology, BC: breast cancer, BICR: blinded independent central review, HR: hormone receptor, IHC: immunohistochemistry, ISH: in situ hybridization, ITT: intent-to-treat, mBC: metastatic breast cancer, PFS: progression free survival, OS: overall survival, q3w: every 3 weeks, TPC: treatment of physician's choice, i.e., capecitabine, nab-paclitaxel, paclitaxel

ENHERTU®

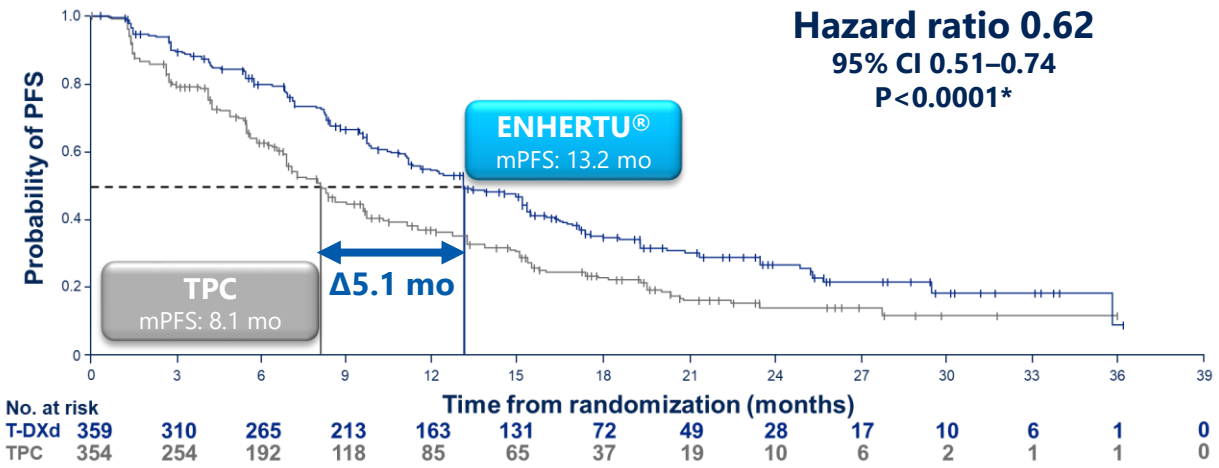
For earlier and broader treatment of HER2 low BC

DESTINY-Breast06 study (ASCO 2024)

Daiichi-Sankyo

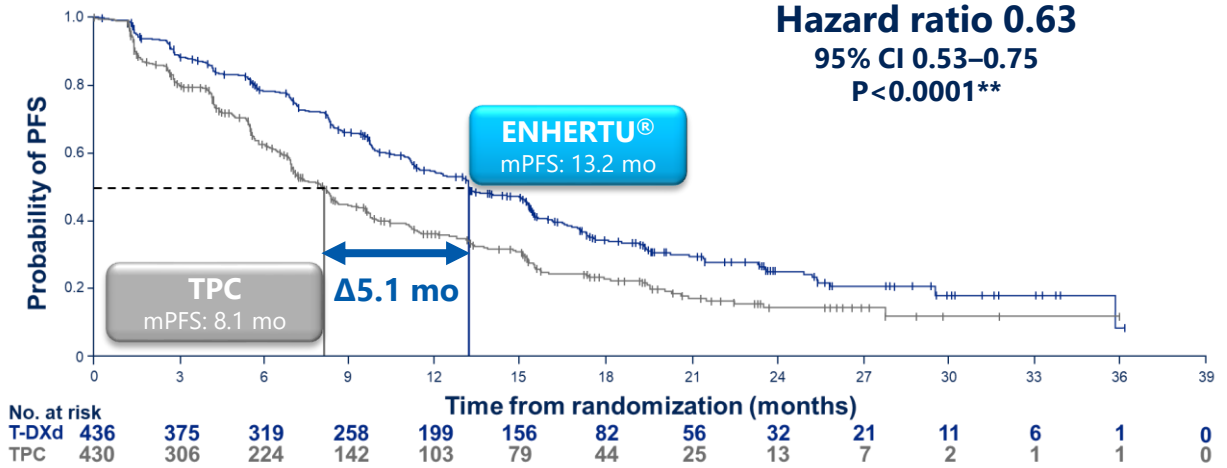
ENHERTU® demonstrated a statistically significant and clinically meaningful PFS benefit in HR positive, HER2 low and HER2 ultralow mBC

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

- Demonstrated mPFS of 13.2 months in ITT population (HR positive HER2 low and HER2 ultralow).
- Efficacy in the HER2 ultralow population was consistent with that in the HER2 low population.
- No new safety signals were identified. Adjudicated as drug-related ILD grade ≥3 occurred in 1.4% of patients treated with ENHERTU® (three for grade 3 and grade 5, respectively)
- Plan to file in US, EU and Japan

ASCO: American Society of Clinical Oncology, BC: breast cancer, BICR: Blinded independent central review, CI: confidence interval, HR: hormone receptor, ILD: interstitial lung disease, ITT: intent-to-treat, mBC: metastatic breast cancer, mPFS: median progression free survival. PFS: progression free survival, T-DXd: trastuzumab deruxtecan, ENHERTU®, TPC: treatment of physician's choice

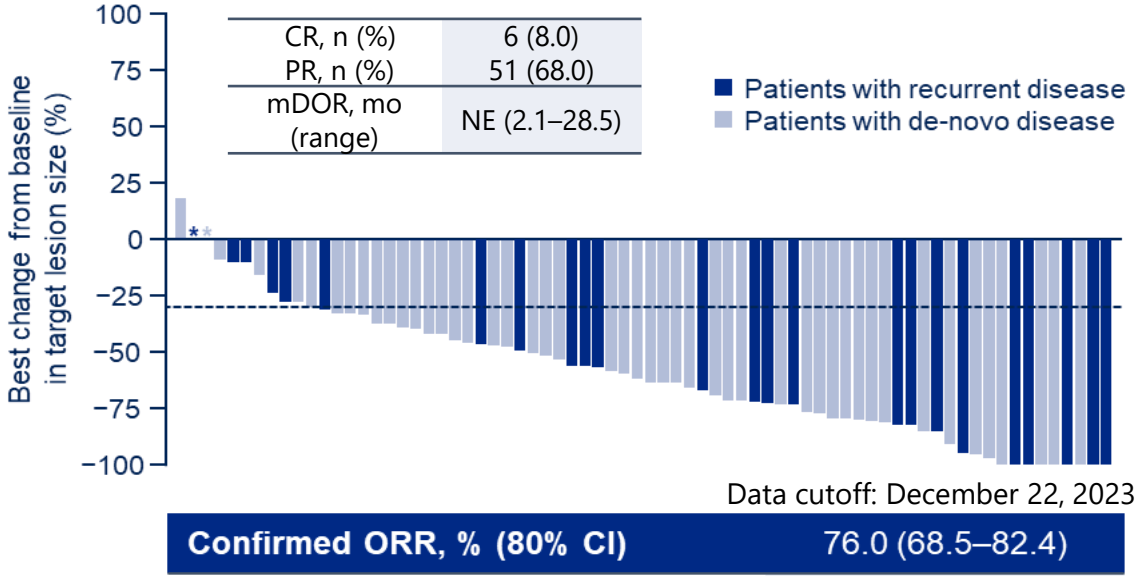
Approach to 1L treatment in HER2 positive BC

DESTINY-Breast07 study (ASCO 2024)

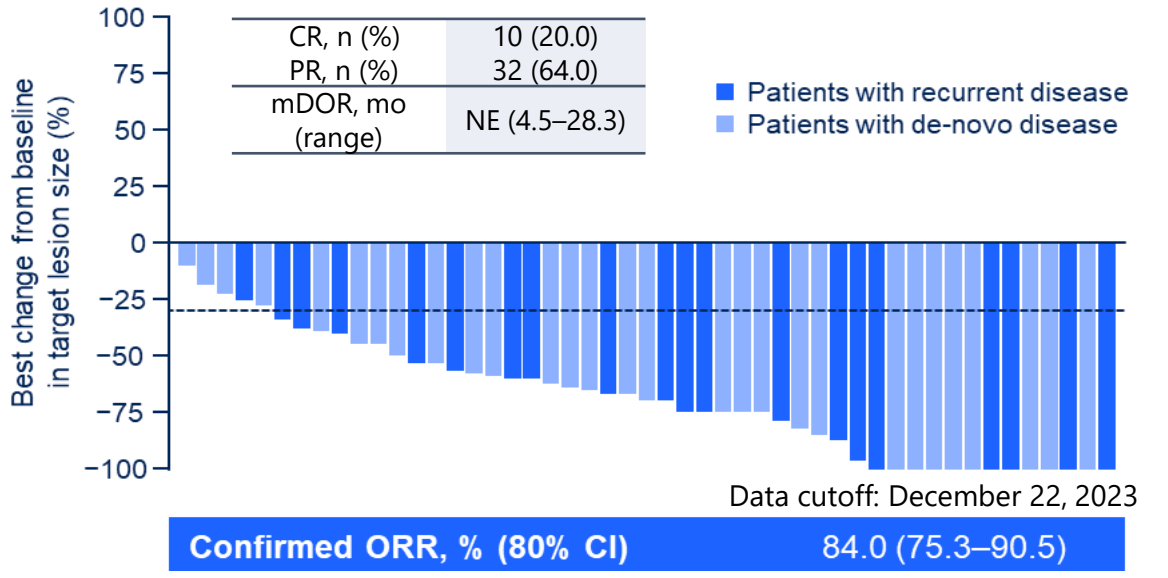
Daiichi-Sankyo

Interim analysis of the Ph1b/2 study to evaluate ENHERTU® combination w/ or w/o pertuzumab in 1L HER2 positive BC shows robust efficacy and durability

ENHERTU® monotherapy (n=75)



ENHERTU® + pertuzumab (n=50)



- ENHERTU® monotherapy and combo with pertuzumab showed robust efficacy
  - ✓ Confirmed ORR: mono 76.0%, combo 84.0%
  - ✓ PFS rate at 12 months: mono 80.8%, combo 89.4%
- The safety profiles of ENHERTU® and pertuzumab combination were consistent with their individual known profiles
  - ✓ The incidence of adjudicated ILD events: mono 9.3%, combo 14.0%, all ILD incidences were Gr3 or lower
- This dataset of ENHERTU® for 1L treatment of HER2 positive mBC may provide a preliminary insight for DESTINY-Breast09 study

ASCO: American Society of Clinical Oncology, BC: breast cancer, CI: confidence interval, CR: complete response, ILD: interstitial lung disease, mBC: metastatic breast cancer, mDOR: median duration of response, NE: not evaluable, ORR: objective response rate, PFS: progression free survival, PR: partial response

ENHERTU®

Addressing additional HER2 expressing solid tumors

DESTINY-BTC01 study

Daiichi-Sankyo

Based on the outcome from DESTINY-PanTumor02 study*, a new Ph3 study for 1L BTC in combination with rilvegostomig has been planned

DESTINY-BTC01 study design

Key Eligibility
- Advanced or metastatic BTC or GBC
- No prior treatment in advanced or metastatic setting.
- HER2 expressing (IHC 3+/2+)

Safety Run-in

ENHERTU® 5.4 mg/kg + rilvegostomig** 750 mg q3w until PD (n=20)

R 1:1:1

N=600

Arm A
ENHERTU®+rilvegostomig

Arm B
ENHERTU® monotherapy

Arm C
gemcitabine + cisplatin or carboplatin + durvalumab

- DESTINY-PanTumor02 BTC cohort ORR: IHC 3+: 56.3% (n=16)
- Plan to start in FY2024 H1

Primary endpoint: OS in IHC 3+
Secondary endpoint: OS (ITT), PFS, ORR, DOR, Safety etc.

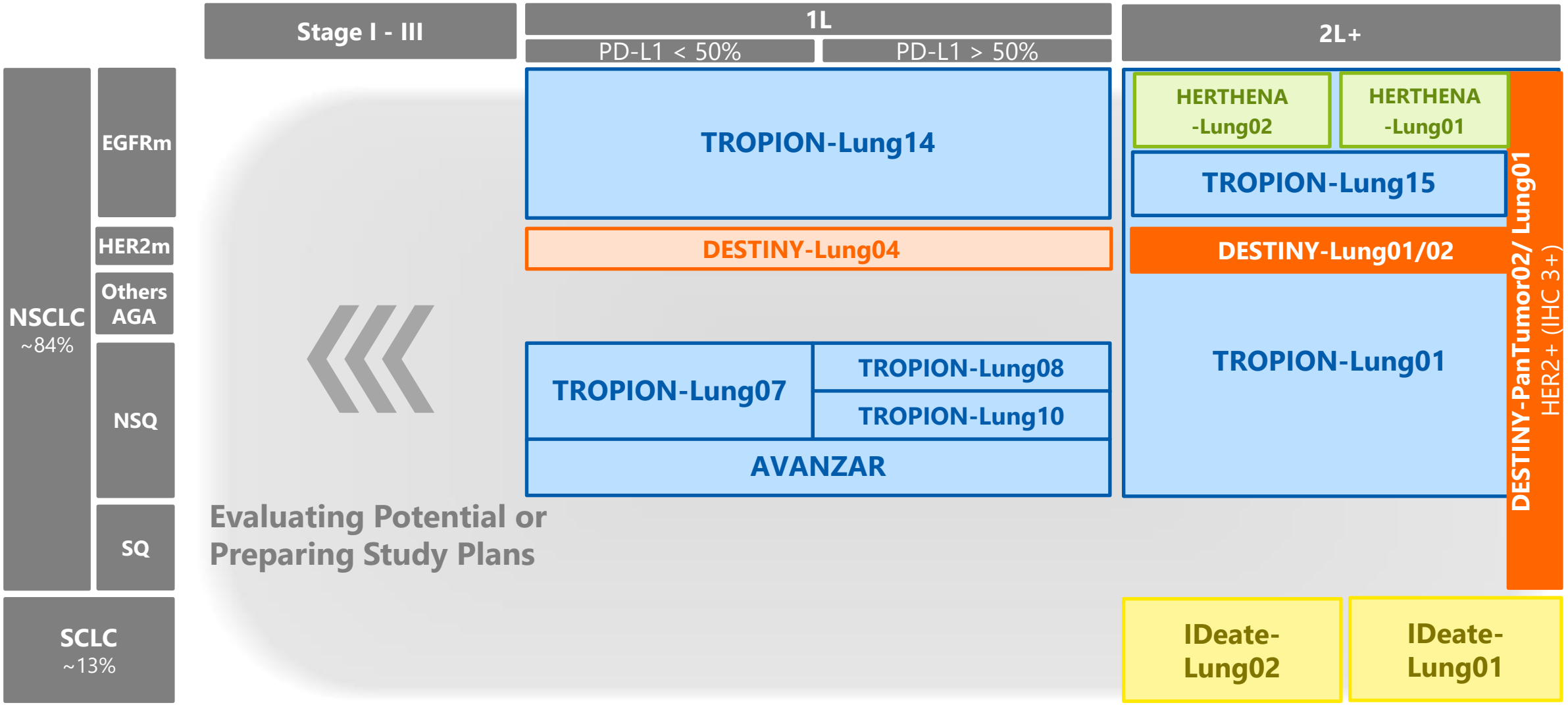
* Based on the three Ph2 studies including DESTINY-PanTumor02, ENHERTU® was approved in US for tumor agnostic HER2 directed therapy for metastatic HER2 positive solid tumors in Apr 2024

** Rilvegostomig is a PD-1/TIGIT bispecific antibody in a clinical development by AstraZeneca

BTC: biliary tact cancer, DOR: duration of response, GBD: gallbladder cancer, IHC: immunohistochemistry, ITT: intent-to-treat, mBTC: metastatic biliary tact cancer, ORR: objective response rate, OS: overall survival, PD: progressive disease, PFS: progression free survival, q3w: every 3 weeks

5DXd ADCs

Establish and expand DXd ADCs to address the broader 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

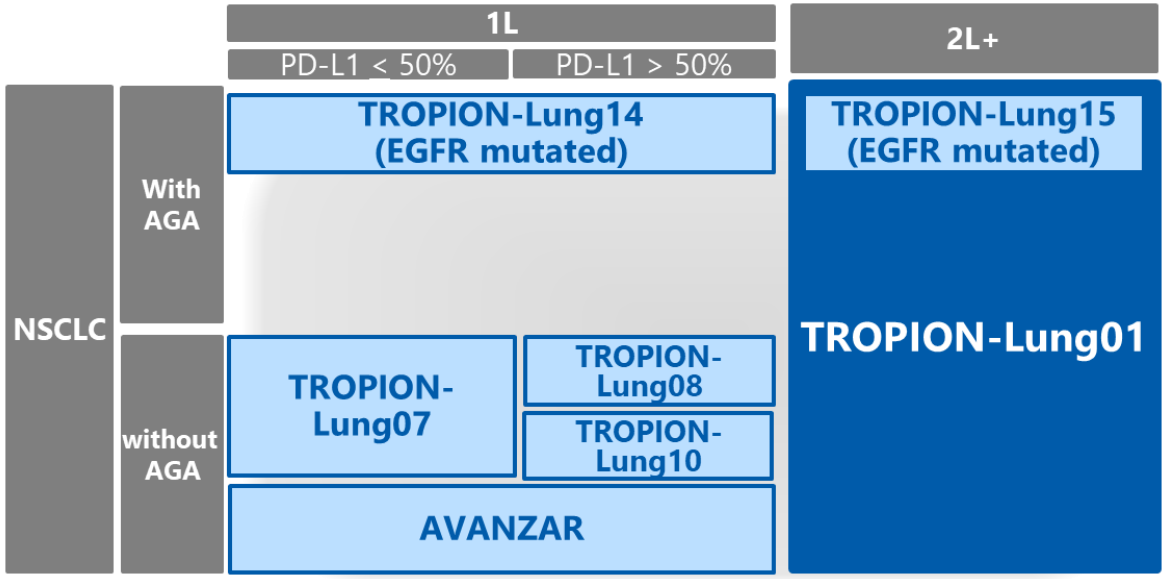
AGA: actionable genomic alteration, IHC: immunohistochemistry, NSQ: non- squamous, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, SQ: squamous

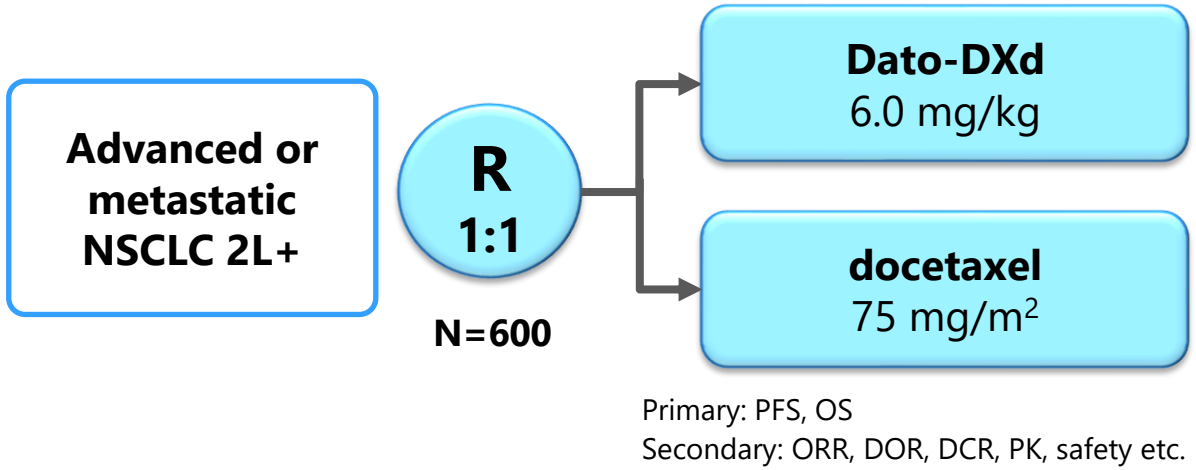
Dato-DXd

Progress in 2L+ NSCLC treatment

TROPION-Lung01 study

Topline overall survival (OS) results were announced in May 2024





Primary: PFS, OS
Secondary: ORR, DOR, DCR, PK, safety etc.

- Dual primary endpoint PFS BICR statistically significant improvement driven by NSQ NSCLC population (ESMO 2023)
- Clinically meaningful OS improvement in NSQ NSCLC compared to docetaxel
- No new safety concerns identified. No new ILD of any grades were adjudicated as drug related
- In process of sharing the OS data package with regulatory agencies
- PDUFA date in US: Dec 20th, 2024

AGA: actionable genomic alteration, BICR: blinded independent central review, DCR: disease control rate, DOR: duration of response, ESMO: European Society for Medical Oncology, ILD: interstitial lung disease, NSCLC: non-small cell lung cancer, NSQ: non-squamous, OS: overall survival, ORR: objective response rate, PDUFA: Prescription Drug User Fee Act, PFS: progression free survival, PK: pharmacokinetics,

Insight on Dato-DXd combination for 1L NSCLC

TROPION-Lung02 study (ASCO 2024)

Daiichi-Sankyo

A subgroup analysis of Ph1 Dato-DXd combination study with pembrolizumab w/ or w/o PBC presented at ASCO 2024

TROPION-Lung02 study

- 1L advanced or metastatic NSCLC without AGA
- Combination
  - ✓ Doublet: Dato-DXd + pembrolizumab
  - ✓ Triplet: Dato-DXd + pembrolizumab + PBC
- Study objectives
  - ✓ Primary: safety and tolerability
  - ✓ Secondary: efficacy, PK, and antidrug antibodies

Efficacy outcomes in 1L patients, overall and by PD-L1 status[a,b]

	All 1L (n=96)		1L PD-L1 <1% (n=34)		1L PD-L1 1–49% (n=42)		1L PD-L1 ≥50% (n=20)	
	Doublet (n=42)	Triplet (n=54)	Doublet (n=18)	Triplet (n=16)	Doublet (n=19)	Triplet (n=23)	Doublet (n=5)	Triplet (n=15)
ORR, n (%)	**22 (52)**	**30 (56)**	**8 (44)**	**5 (31)**	**9 (47)**	**17 (74)**	**5 (100)**	**8 (53)**
[95% CI]	[36–68]	[41–69]	[22–69]	[11–59]	[24–71]	[52–90]	[48–100]	[27–79]
DCR, n (%)	**37 (88)**	**48 (89)**	**16 (89)**	**15 (94)**	**16 (84)**	**20 (87)**	**5 (100)**	**13 (87)**
[95% CI]	[74–96]	[77–96]	[65–99]	[70–100]	[60–97]	[66–97]	[48–100]	[60–98]
mDOR, mo	NE	12.9	NE	12.9	12.0	14.6	NE	18.1
[95% CI]	[9.7–NE]	[5.7–NE]	NE	[4.1–NE]	[4.2–NE]	[4.2–NE]	[5.5–NE]	[4.1–NE]
Patient segment			TROPION-Lung07				TROPION-Lung08	

[a] Evaluated locally by tumor proportion score using immunohistochemistry (22C3 assay).
[b] Responses with confirmed CR/PR.

Data cutoff: October 31, 2023

- Both doublet and triplet regimens showed durable antitumor activity across all levels of PD-L1 expression
- Tolerability of the combinations were consistent with their individual known profiles. No new safety signals observed.
- The data support continuous evaluation of Dato-DXd combinations in TROPION-Lung07 and TROPION-Lung08

AGA: actionable genomic alteration, ASCO: American Society of Clinical Oncology, CI: confidence interval, CR: complete response, DCR: disease control rate, mDOR: median duration of response, NE: not evaluable, NSCLC: non-small cell lung cancer, ORR: objective response rate, PBC: platinum-based chemotherapy, PK, pharmacokinetics, PR: partial response

New treatment approach for 2L+ EGFR mutated NSCLC

TROPION-Lung15 study

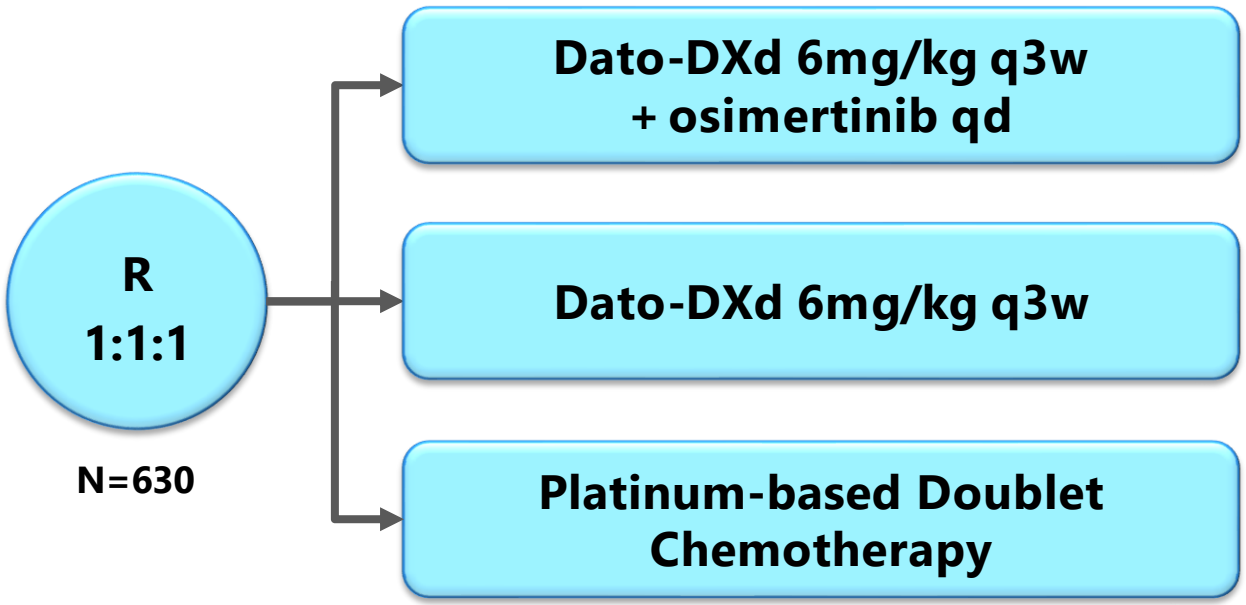
Daiichi-Sankyo

New Ph3 study in 2L+ EGFR mutated NSCLC to evaluate Dato-DXd combination w/ or w/o osimertinib starts in FY2024 H1

TROPION-Lung15 study design

Key Eligibility

- Advanced or metastatic NSQ NSCLC who have progressed on prior osimertinib
- Less than or equal to 2 prior lines of EGFR TKI treatments
- Sensitizing EGFR mutations



Primary endpoint
- PFS

Secondary endpoint
- OS, ORR, DOR, Safety etc.

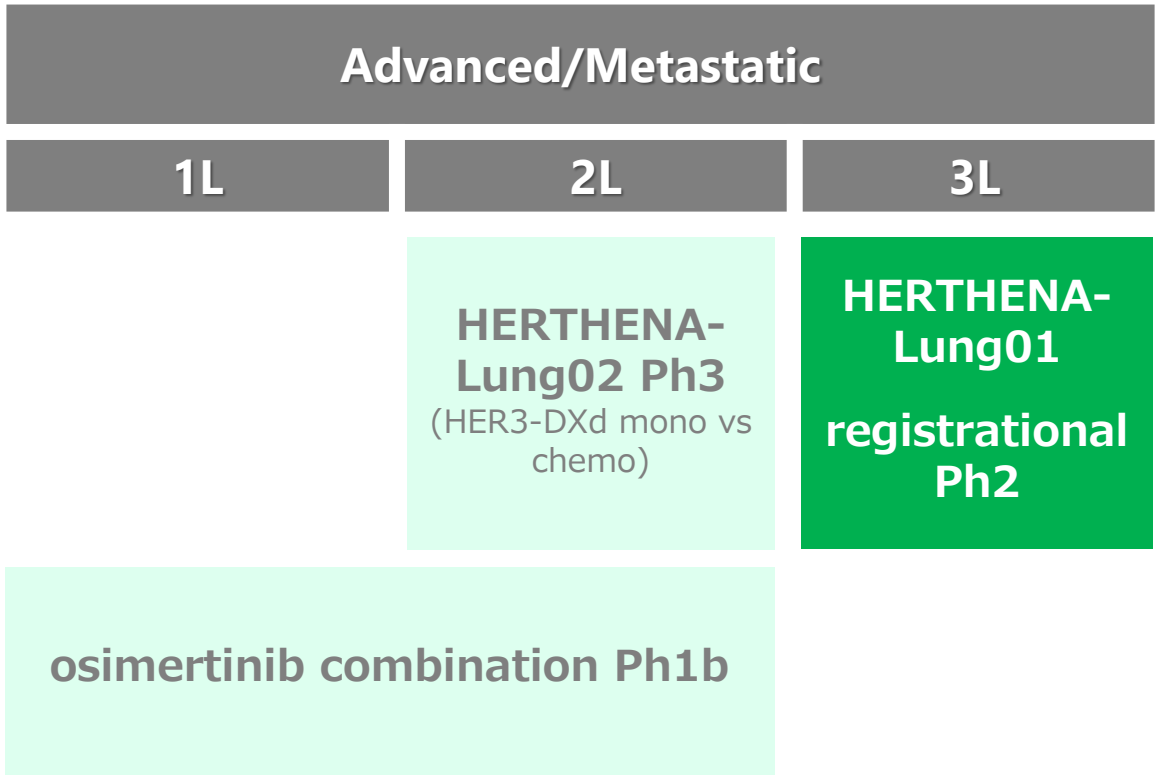
DOR: duration of response, NSCLC: non small cell lung cancer, NSQ: non squamous, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, qd: quaque die, q3w: every 3 weeks, TKI: tyrosine kinase inhibitor

EGFR mutated NSCLC 3L

HERTHENA-Lung01

FDA issued Complete Response Letter for BLA based on HERTHENA-Lung01 in June 2024

Clinical studies of HER3-DXd in EGFR mutated NSCLC



- Filing was accepted based on HERTHENA-Lung01 study data by the FDA in Dec 2023
- In June 2024, due to findings pertaining to an inspection of a third-party manufacturing facility, the FDA notified that they did not approve HER3-DXd by the PDUFA date, Jun 26th 2024
  - The CRL did not identify any issues with the efficacy or safety data submitted
  - Withdrawal and resubmission of the BLA is not required
- DS will work closely with the FDA and the manufacturer to address the feedback as quickly as possible
- Majority of regulatory submissions in countries and regions outside the US will be done with upcoming HERTHENA-Lung02 study data as originally planned (TLR: FY2024 H1)

BLA: Biologics license application, CRL: Complete response letter, NSCLC: non-small cell lung cancer, PDUFA: Prescription Drug User Fee Act, TLR: Top Line Results

5DXd ADCs

Clinical and Regulatory Progress

Dato-DXd

- May 2024 : TROPION-Lung10 Ph3 combination study with rilvegostomig for PD-L1≥50% NSCLC 1L started
- May 2024 : TROPION-Lung14 Ph3 combination study with osimertinib for EGFR mutated NSCLC 1L started

I-DXd

- May 2024 : IDeate-Pantumor02 Ph2 study for solid tumors 2L+ started

NSCLC: non-small cell lung cancer , SCLC: small cell lung cancer

5DXd ADCs Update

Next Wave Update

WCLC/ESMO 2024

News Flow

Next Wave

Clinical and Regulatory Progress

Valemetostat (relapsed/refractory peripheral T-cell lymphoma [PTCL])

- Jun 2024: Approval in Japan

TARLIGE® (mirogabalin) (diabetic peripheral neuropathic pain [DPNP])

- Jun 2024: Approval in China

DAICHIRONA® (COVID-19 mRNA vaccine)

- Apr 2024: Filing accepted in Japan for omicron strain booster vaccination in children aged 5 to 11 years
- May 2024: Revision of the package insert allowing for a single administration to patients aged 12 years or older.*
- Jun 2024: Filing accepted in Japan as a vaccine against the strain selected by the Ministry of Health, Labour and Welfare for this fiscal year

* Minor changes based on the notification issued by the Ministry of Health, Labour and Welfare.

5DXd ADCs Update

Next Wave Update

WCLC/ESMO 2024

News Flow

WCLC/ESMO 2024 Highlight

Speakers

Ken Takeshita
Head of Global R&D

Mark Rutstein
Head of Global Oncology
Clinical Development

Date & time
Format

Tuesday, September 17th, 2024
8:00-9:30am (EDT)
9:00-10:30pm (JST)

Virtual (Zoom)

Content will be delivered
on-demand after the meeting

5DXd ADCs Update

Next Wave Update

WCLC/ESMO 2024

News Flow

FY2024 News Flow

As of Jul 2024

Planned major data disclosures

WCLC (Sep 7 -10, 2024)

ENHERTU®	**DESTINY-Lung03: HER2+ NSCLC, 1L, Ph1b** • **First data release**
I-DXd	**IDeate-Lung01: SCLC, 2L+, Ph2** • **Interim data**

ESMO (Sep 13-17, 2024)

ENHERTU®	**DESTINY-Gastric03: HER2+ GC, GEJC and esophageal cancer, 2L+/1L, Ph1b/2** • **Dose expansion part first data release**
Dato-DXd	**TROPION-PanTumor03: solid tumors, 2L+, Ph2** • **Endometrial cancer and ovarian cancer, first data release**
DS-9606	**Solid tumors, Ph1** • **First data release**

Regulatory decisions

ENHERTU®	DESTINY-Gastric06: HER2+ GC, 3L+ • CN: FY2024 H1
	DESTINY-Lung05: HER2 mutant NSCLC, 2L+ • CN: FY2024 H2
Dato-DXd	TROPION-Lung01: NSCLC, 2L+ • US：FY2024 H2
	TROPION-Breast01: HR+ and HER2 low or negative BC, 2/3L • JP/US: FY2024 H2
DAICHIRONA®	**COVID-19 mRNA vaccine (mutant strain), Children aged 5 to 11 years** • **JP: FY2024 H2**

Planned regulatory filing※

ENHERTU®	**DESTINY-Breast06:** HR+/HER2 low BC, chemo naïve • **JP/EU: FY2024 H1** • **US: FY2024 H2**

Key data readouts

ENHERTU®	DESTINY-Breast11*：HER2+ BC, neoadjuvant, Ph3 • FY2024 H2
Dato-DXd	TROPION-Breast02*： PD-1/PD-L1 ineligible TNBC, 1L, Ph3 • FY2024 H2
HER3-DXd	HERTHENA-Lung02*： EGFR mutated NSCLC, 2L, Ph3 • **FY2024 H1**

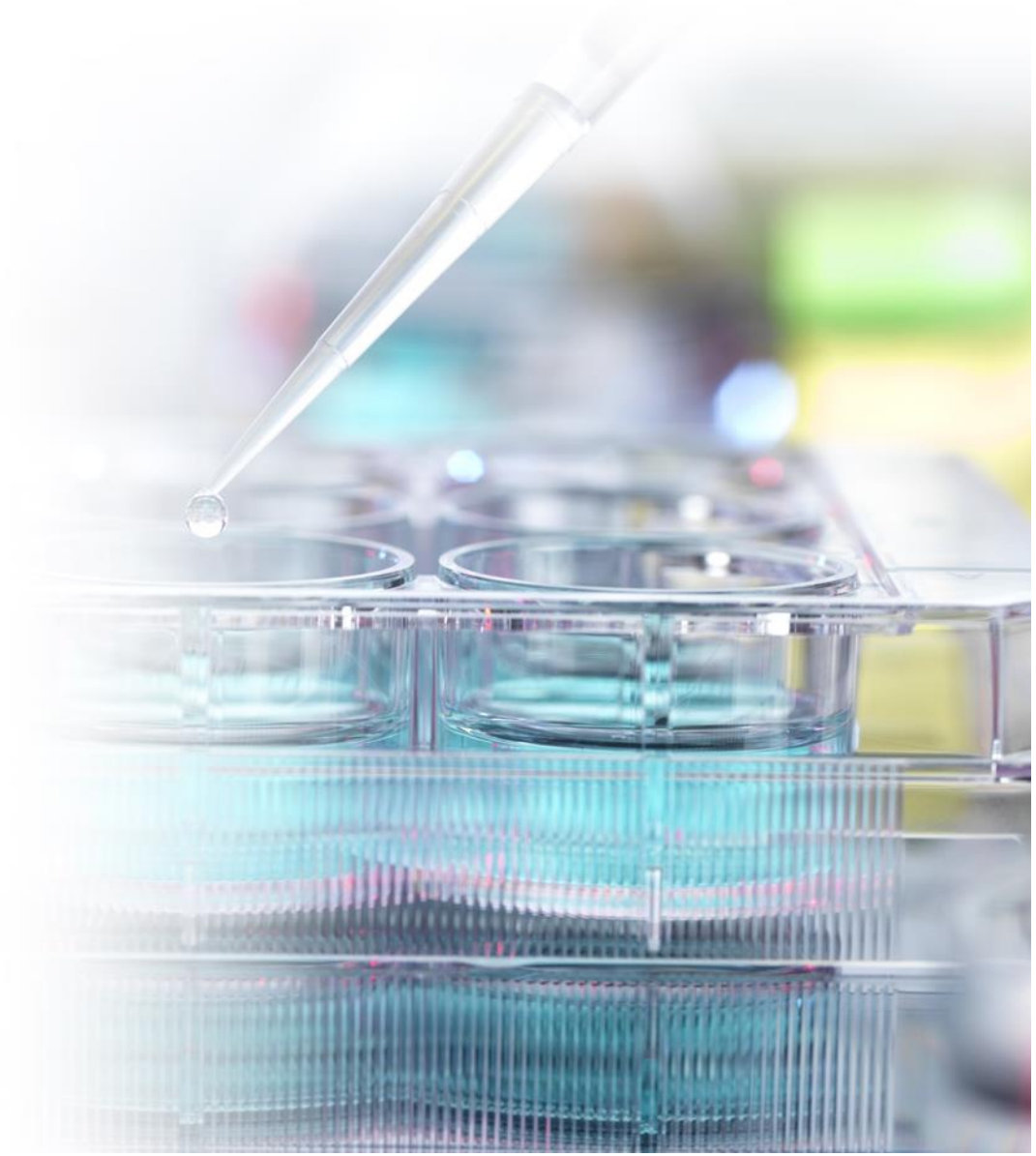
Bold: update from FY2023 Q4

BC: breast cancer, ESMO: European Society for Medical Oncology, GC: gastric cancer, GEJC: gastroesophageal junction cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, TNBC: triple negative breast cancer, WCLC: World Conference on Lung Cancer

Timeline indicated is based on the current forecast and subject to change
※ Timeline for “Planned regulatory filing” indicates expected filing acceptance date
*: event-driven study

Agenda

1. FY2024 Q1 Financial Results
2. Business Update
3. R&D Update
4. **Appendix**



Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2023 Q1 Results	FY2024 Q1 Results	YoY
Japan Business	119.0	117.7	-1.3
Daiichi Sankyo Healthcare	17.1	20.0	+2.9
Oncolgy Business	70.6	106.4	+35.8
Enhertu	69.4	104.1	+34.7
Turalio	1.2	1.5	+0.3
Vanflyta	-	0.9	+0.9
American Regent	50.7	55.9	+5.3
Injectafer	13.2	15.8	+2.6
Venofer	15.8	16.3	+0.6
GE injectables	18.3	20.6	+2.3
EU Specialty Business	41.5	59.2	+17.7
Lixiana	32.3	45.4	+13.1
Nilemdo/Nustendi	3.0	7.8	+4.8
Olmesartan	4.7	5.3	+0.5
ASCA (Asia, South and Central America) Business	39.5	48.7	+9.2

Currency Rate	USD/JPY	137.37	155.89	+18.52
	EUR/JPY	149.46	167.88	+18.42

Revenue: Major Products in Japan

(Bn JPY)

		FY2023 Q1 Results	FY2024 Q1 Results	YoY
Lixiana	anticoagulant	**27.9**	**34.9**	**+7.0**
Tarlige	pain treatment	**11.7**	**14.2**	**+2.5**
Pralia	Treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**10.7**	**11.1**	**+0.4**
Vimpat	anti-epileptic agent	**6.4**	**8.1**	**+1.6**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**4.4**	**7.8**	**+3.4**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**5.0**	**5.4**	**+0.4**
Efient	antiplatelet agent	**6.1**	**8.1**	**+1.9**
Canalia	type 2 diabetes mellitus treatment	**4.1**	**4.3**	**+0.2**
Loxonin	anti-inflammatory analgesic	**4.0**	**3.5**	**-0.5**
Inavir	anti-influenza treatment	**0.1**	**0.2**	**+0.0**
Minnebro	antihypertensive agent	**2.1**	**2.6**	**+0.5**

5DXd ADCs Revenue (incl. Forex Impact)

(Unit: Bn JPY)

	FY2024 Q1 Results	YoY	FY2024 Forecast	YoY
ENHERTU	**134.8**	**+48.2**	**585.4**	**+136.2**
Product Sales	129.6	+47.9	508.4	+112.4
Upfront and Milestone Payments	5.2	+0.4	77.0	+23.7
Dato-DXd	**1.6**	**-**	**17.6**	**+11.2**
Product Sales	-	-	5.6	+5.6
Upfront and Milestone Payments	1.6	-	12.0	+5.6
HER3-DXd	**2.0**	**+2.0**	**23.1**	**+19.6**
Product Sales	-	-	4.2	+4.2
Upfront and Milestone Payments	2.0	+2.0	18.9	+15.4
I-DXd	**3.7**	**+3.7**	**14.7**	**+8.1**
Upfront and Milestone Payments	3.7	+3.7	14.7	+8.1
DS-6000 (R-DXd)	**1.5**	**+1.5**	**6.2**	**+3.4**
Upfront and Milestone Payments	1.5	+1.5	6.2	+3.4
5DXd ADCs Total	**143.6**	**+55.4**	**646.9**	**+178.5**

5DXd ADCs Upfront and Milestone Payments

(Unit: Bn JPY)

Asset	Item	FY2024 Q1 Results	YoY	FY2024 Forecast	YoY	Total Consideration
ENHERTU	Upfront Payment	2.6	+0.1	10.2	+0.1	149.0
	Regulatory Milestones	2.4	+0.3	9.4	-2.9	137.7
	Quid Related Payment	0.3	0	1.2	0	17.2
	Sales Milestone	-	-	56.2	+26.6	42.8
Dato-DXd	Upfront Payment	1.6	-	6.4	-	115.9
	Regulatory Milestones	-	-	5.6	+5.6	-
AZ Alliance Total		**6.8**	+0.4	**89.0**	+29.3	**462.6**
HER3-DXd	Upfront Payment	2.0	+2.0	18.9	+15.4	112.7
I-DXd	Upfront Payment	3.7	+3.7	14.7	+8.1	225.4
DS-6000 (R-DXd)	Upfront Payment	1.5	+1.5	6.2	+3.4	112.7
US Merck Alliance Total		**7.2**	+7.2	**39.8**	+26.9	**450.8**

Major R&D Milestones (ENHERTU®)

As of Jul 2024

Project		Target indication [phase, study name]	FY2024 H1	FY2024 H2	FY2025
ENHERTU®	BC	**• HER2+, adjuvant* [Ph3, DESTINY-Breast05]**			**• TLR anticipated**
		• HR+/HER2 low, chemo naive [Ph3, DESTINY-Breast06]	**• Planned regulatory filing** (JP/EU)**	**• Planned regulatory filing** (US)**	
		• HER2+, 1L [Ph3, DESTINY-Breast09]			**• TLR anticipated**
		• HER2+, neoadjuvant [Ph3, DESTINY-Breast11]		• TLR anticipated	
	GC	**• HER2+, 2L [Ph3, DESTINY-Gastric04]**			**• TLR anticipated**
		• HER2+, 3L+ [Ph2, DESTINY-Gastric06]	• Regulatory decision anticipated (CN)		
	NSCLC	• HER2 exon 19 or exon 20 mutation, 2L+ [Ph2, DESTINY-Lung05]		• Regulatory decision anticipated (CN)	
		• HER2 exon 19 or exon 20 mutation, 1L [Ph3, DESTINY-Lung04]			**• TLR anticipated**
	BTC	**• HER2 expressing, 1L [Ph3, DESTINY-BTC01]**	**• Study start planned**		
	Other tumors	• HER2 expressing tumors [Ph2, DESTINY-PanTumor02]	• Approved (US)		

Bold: update from FY2023 Q4

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

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

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

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

Major R&D Milestones (Dato-DXd)

As of Jul 2024

Project		Target indication [phase, study name]	FY2024 H1	FY2024 H2	FY2025
Dato-DXd	NSCLC	• 2L+, **non-squamous**, [Ph3, TROPION-Lung01]		• Regulatory decision anticipated (US)	
		• 1L, non-squamous, PD-L1 high, rilvegostomig combo [Ph3, TROPION-Lung10]	**• Study started**		
		• 1L, EGFR mutated, osimertinib combo [Ph3, TROPION-Lung14]	**• Study started**		
		• 2L+, EGFR mutated, osimertinib combo [Ph3, TROPION-Lung15]	**• Study start planned**		
		• 1L, w/o AGA, durvalumab combo [Ph3, AVANZAR]			**• TLR anticipated (CY2025 H2)**
	BC	• HR+ and HER2 low or negative, 2/3L [Ph3, TROPION-Breast01]		• Regulatory decision anticipated (JP/US)	**• Regulatory decision anticipated (EU)**
		• TNBC, PD-1/PD-L1 ineligible, 1L [Ph3, TROPION-Breast02]		• TLR anticipated	

Bold: update from FY2023 Q4

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

Major R&D Milestones (HER3-DXd, I-DXd, DS-6000)

As of Jul 2024

Project		Target indication [phase, study name]	FY2024 H1	FY2024 H2	FY2025
HER3-DXd	NSCLC	• EGFR mutated, 3L [Ph2, HERTHENA-Lung01]	**• CRL received (US)**		
		• EGFR mutated, 2L [Ph3, HERTHENA-Lung02]	**• TLR anticipated**		
I-DXd	SCLC	• 2L+ [Dose optimization, Ph2, IDeate-Lung01]		• TLR anticipated	
		• 2L [Ph3, IDeate-Lung02]	• Study start planned		
		• 1L [Ph1b/2, IDeate-Lung03]	• Study start planned		
	Other tumors	• Endometrial cancer, SCCHN, etc., 2L+ [Ph2, IDeate-Pantumor02]	**• Study started**		
DS-6000 (R-DXd)	OVC	• Platinum resistant, 2L+ [Ph2/3, REJOICE-Ovarian01]	• Study started		

Bold: update from FY2023 Q4

CRL: complete response letter, NSCLC: non-small cell lung cancer, OVC: ovarian cancer, SCCHN: squamous cell carcinoma of the head and neck, SCLC: small cell lung cancer, TLR: top line results
Timeline indicated is based on the current forecast and subject to change

Major R&D Milestones (Next Wave)

As of Jul 2024

Project	Target indication [phase, study name]	FY2024 H1	FY2024 H2	FY2025
valemetostat	• r/r PTCL [Registrational Ph2, VALENTINE-PTCL01]	**• Approval (JP)**		
mirogabalin	• DPNP	**• Approved (CN)**		
DAICHIRONA®	• COVID-19 mRNA vaccine (mutant strain), Children aged 5 to 11 years [Ph2/3]	**• Filing accepted (JP)**	**• Regulatory decision anticipated (JP)**	
	• COVID-19 mRNA vaccine (mutant strain), single dose, aged 12 years and over [Ph3]	**• TLR obtained※**		
MMR vaccine (VN-0102)	• mixed measles-mumps-rubella vaccine [Ph3]	• Filing accepted (JP)		

Bold: update from FY2023 Q4

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

※ The package insert has been revised based on the TLR and a notification issued by the Ministry of Health, Labour and Welfare.
Timeline indicated is based on the current forecast and subject to change

Major R&D Pipeline: 5DXd ADCs

As of Jul 2024

Daiichi-Sankyo

Phase 1

- (US/EU/Asia) HER2+ BC 2L+/1L
  DESTINY-Breast07
- (US/EU/Asia) HER2 low BC
  Chemo naïve/post chemo
  DESTINY-Breast08
- (JP/US/EU/Asia) HER2+ GC combo, 2L+/1L
  DESTINY-Gastric03
- (US/EU/Asia) HER2+ NSCLC
  (durvalumab, volrustomig and rilvegostomig combo) 1L
  DESTINY-Lung03
- (US/EU) BC, NSCLC
  (pembrolizumab combo)
- (US/EU/Asia) TNBC
  (durvalumab combo)
  BEGONIA
- (US/EU/Asia) solid tumors
  (saruparib combo)
  PETRA
- (JP/US) solid tumors
  TROPION-PanTumor01
- (CN) NSCLC, TNBC
  TROPION-PanTumor02
- (JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo)
  TROPION-Lung02
- (JP/US/EU) NSCLC (w/o AGA, durvalumab, rilvegostomig, volrustomig and sabestomig combo) TROPION-Lung04
- (US/EU/Asia) TNBC
  (durvalumab combo)
  BEGONIA
- (JP/US/EU/Asia) solid tumors
  (saruparib combo)
  PETRA
- (JP/US/EU/Asia) NSCLC
- (JP/US/Asia) EGFR mutated NSCLC, 1/2L
  (osimertinib combo)
- (JP/US)
  ESCC, CRPC, squamous NSCLC, SCLC, etc.
  IDeate-Pantumor01
- (JP/US/EU/Asia) in prep
  ES-SCLC, 1L
  IDeate-Lung03
- (JP/US)
  renal cell carcinoma, ovarian cancer

Phase 2

- (CN) HER2 expressing solid tumors
  DESTINY-PanTumor03
- (JP/US/EU/Asia) solid tumors
  TROPION-PanTumor03
- (JP/US/EU/Asia) EGFR mutated NSCLC (osimertinib combo) 2L
  ORCHARD
- (US/EU/Asia) resectable early-stage NSCLC (durvalumab combo) neoadjuvant
  NeoCOAST-2
- (JP/US/EU/Asia) solid tumors
  HERTHENA-PanTumor01
- (JP/US/EU/Asia)
  ES-SCLC 2L+
  IDeate-Lung01
- (JP/US/EU/Asia)
  solid tumors 2L+
  IDeate-Pantumor02
- (JP/US/EU/Asia)
  platinum-resistant ovarian cancer 2L+
  REJOICE-Ovarian01

Phase 3

- (JP/US/EU/Asia) HER2+ BC adjuvant*1
  DESTINY-Breast05
- (JP/US/EU/Asia) HER2 low BC
  chemo naïve
  DESTINY-Breast06
- (JP/US/EU/Asia) HER2+ BC 1L
  DESTINY-Breast09
- (JP/US/EU/Asia) HER2+ BC
  neoadjuvant
  DESTINY-Breast11
- (JP/EU/Asia) HER2+ GC 2L
  DESTINY-Gastric04
- (JP/US/EU/Asia) NSCLC (w/ HER2 exon 19 or exon 20 mutation) 1L
  DESTINY-Lung04
- (JP/US/EU/Asia) in prep HER2 expressing BTC 1L
  DESTINY-BTC01
- (JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, pembrolizumab combo) 1L
  TROPION-Lung07
- (JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) 1L
  TROPION-Lung08
- (JP/US/EU/Asia) PD-L1 high non-squamous NSCLC (w/o AGA, rilvegostomig combo) 1L
  TROPION-Lung10
- (JP/US/EU/Asia) EGFR mutated NSCLC (osimertinib combo) 1L
  TROPION-Lung14
- (JP/US/EU/Asia) in prep EGFR mutated NSCLC (osimertinib combo) 2L
  TROPION-Lung15
- (JP/US/EU/Asia) NSCLC (w/o AGA, durvalumab combo) 1L
  AVANZAR
- (JP/US/EU/Asia) TNBC (PD-1/PD-L1 inhibitor ineligible) 1L
  TROPION-Breast02
- (JP/US/EU/Asia) TNBC adjuvant*1
  (mono or durvalumab combo)
  TROPION-Breast03
- (JP/US/EU/Asia) TNBC neoadjuvant and adjuvant (durvalumab combo)
  TROPION-Breast04
- (JP/US/EU/Asia) PD-L1 positive TNBC 1L
  (mono or durvalumab combo)
  TROPION-Breast05
- (JP/US/EU/Asia) EGFR mutated NSCLC 2L
  HERTHENA-Lung02
- (JP/US/EU/Asia) in prep
  ES-SCLC 2L
  IDeate-Lung02

Regulatory phase

- (CN) HER2+ GC 3L
  DESTINY-Gastric06
- (CN) HER2 mutant NSCLC 2L+
  DESTINY-Lung05
- (US/EU) NSCLC 2L+
  TROPION-Lung01
- (JP/US/EU/CN) BC*2 2/3L
  TROPION-Breast01
- (US) EGFR mutated NSCLC 3L
  HERTHENA-Lung01

ENHERTU® (T-DXd) / Dato-DXd / HER3-DXd / I-DXd / DS-6000 (R-DXd)

Project in oncology that is planned to be submitted for approval in some countries/regions based on the results of phase 2 trials

Breakthrough Designation (US) / Orphan drug designation (designated in at least one country/region among JP, US and EU)

* 1 Adjuvant therapy for patients with residual invasive disease following neoadjuvant therapy
* 2 HR+, HER2 low or negative BC

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, NSCLC: non-small cell lung cancer, SCCHN: squamous cell carcinoma of head and neck, SCLC: small cell lung cancer, TNBC: triple negative breast cancer

Major R&D Pipeline: Next Wave

As of Jul 2024

Phase 1	Phase 2	Phase 3	Regulatory phase
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	Valemetostat (EU) EZH1/2 inhibitor BCL	Pexidartinib (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain), COVID-19 (booster vaccination, 5 to 11 aged children)
DS-9606 (US/EU) Target undisclosed ADC Solid tumors	DS-1001 (JP) Mutant IDH1 inhibitor Glioma	Esaxerenone (JP) MR blocker Diabetic nephropathy	VN-0102/JVC-001 (JP) Mixed measles-mumps-rubella vaccine
DS-1103 Anti-SIRPα antibody HER2 expressing or mutant solid tumors, HER2 low BC (ENHERTU® combo)	DS-1211 (US/EU) TNAP inhibitor Pseudoxanthoma elasticum	DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain), COVID-19 (single dose,12 years old and over)	
DS-3939 Anti-TA-MUC1 ADC Solid tumors	VN-0200 (JP) RS virus vaccine RS virus infection		
DS-1471 Anti-CD147 antibody Solid tumors			
Valemetostat EZH1/2 inhibitor, HER2+ GC, HER2 low BC (ENHERTU® combo) and non-squamous NSCLC (Dato-DXd combo)			
DS-7011 (JP/US/EU/Asia) Anti-TLR7 antibody Systemic lupus erythematosus			
DS-2325 (EU) KLK5 inhibitor Netherton syndrome			

Oncology

Specialty medicine

Vaccine

Project in oncology that is planned to be submitted for approval in some countries/regions based on the results of phase 2 trials

SAKIGAKE Designation (JP)

Orphan drug designation (designated in at least one country/region among JP, US and EU)

Rare Pediatric Disease Designation (US)

Fast Track Designation (US)

BC: breast cancer, BCL: B cell lymphoma, GC: gastric cancer

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