Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2024 Q2
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Hiroyuki Okuzawa

Representative Director, President & COO

October 31, 2024

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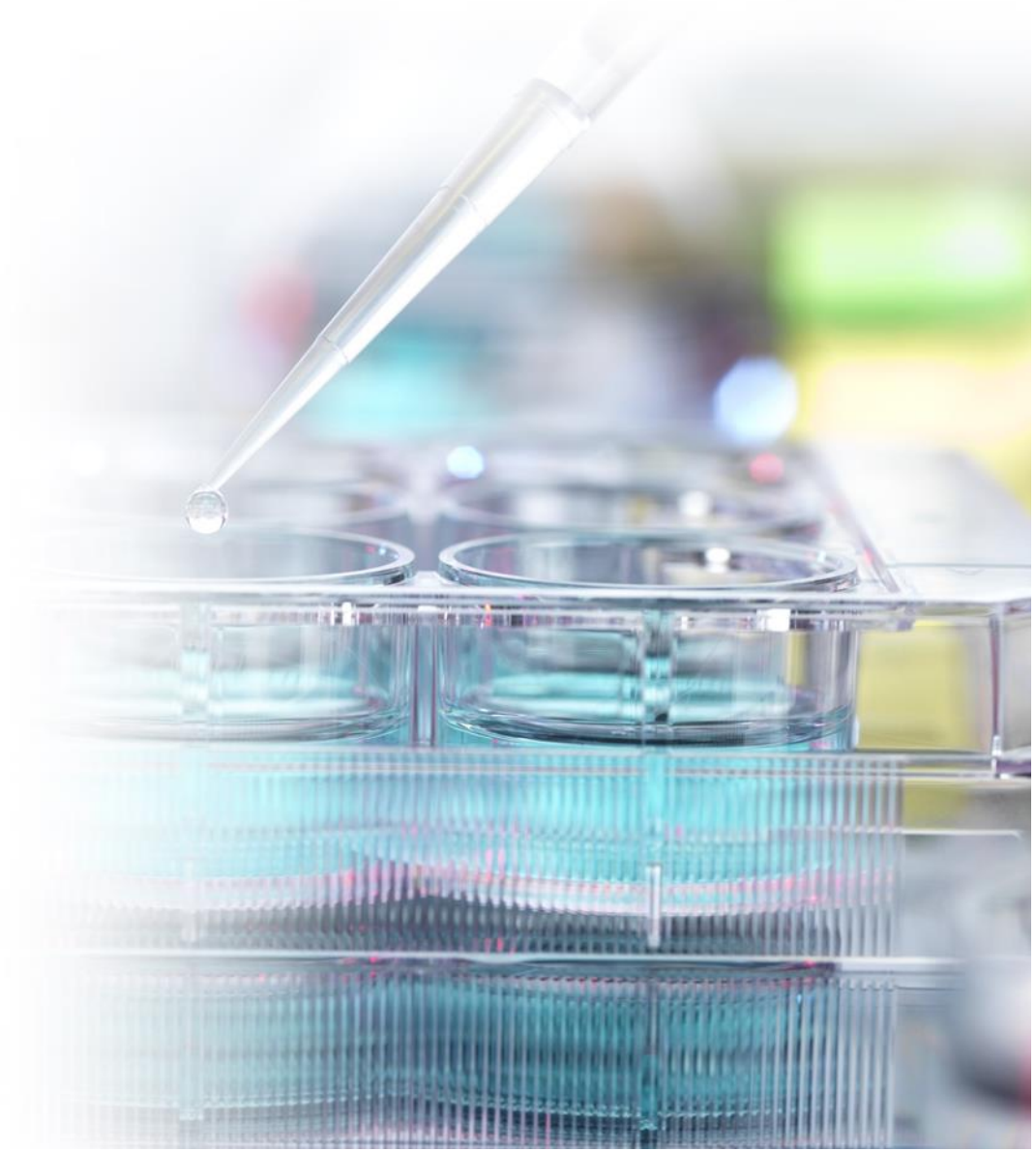
1. **FY2024 Q2 Financial Results**
2. FY2024 Forecast
3. Business Update
4. R&D Update
5. Appendix



Overview of FY2024 Q2 Results

(Bn JPY)

	FY2023 Q2 YTD Results	FY2024 Q2 YTD Results	YoY	
Revenue	**726.3**	**882.7**	+21.5%	**156.4**
Cost of sales*1	188.4	193.0		4.6
SG&A expenses*1	276.6	329.9		53.2
DXd ADC profit share *2	78.8	104.8		26.0
Other SG&A expenses	197.8	225.1		27.3
R&D expenses*1	166.0	193.3		27.3
Core operating profit*1	**95.3**	**166.6**	+74.8%	**71.3**
Temporary income*1	0.7	20.3		19.6
Temporary expenses*1	1.0	0.0		-1.0
Operating profit	**95.1**	**186.9**	+96.6%	**91.8**
Profit before tax	**102.1**	**192.6**		**90.5**
Profit attributable to owners of the Company	**97.0**	**146.7**	+51.2%	**49.7**

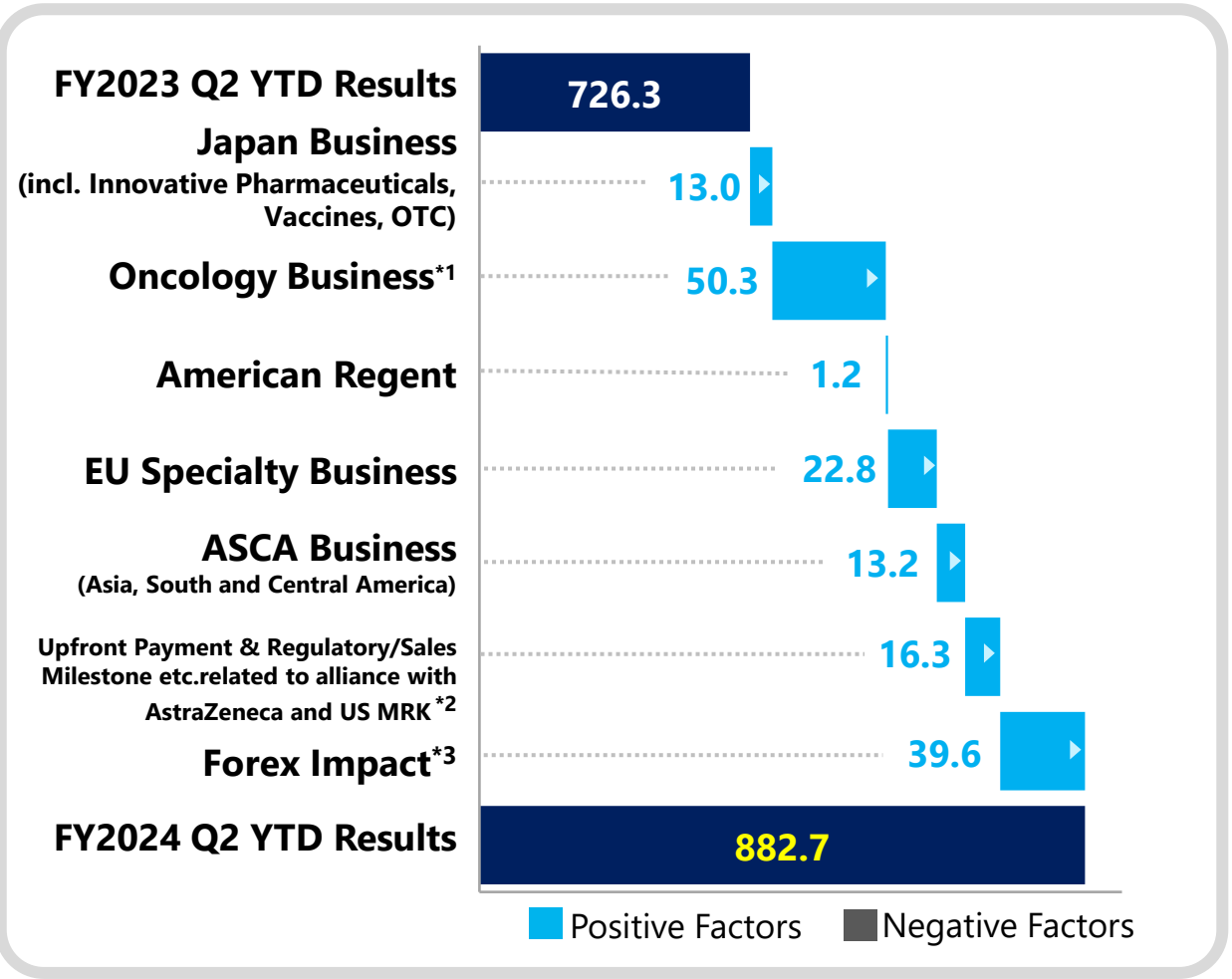
Currency Rate	USD/JPY	141.00	152.62	+11.62
	EUR/JPY	153.38	165.93	+12.55

*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 156.4 Bn JPY (Increased by 116.7 Bn JPY excl. forex impact)



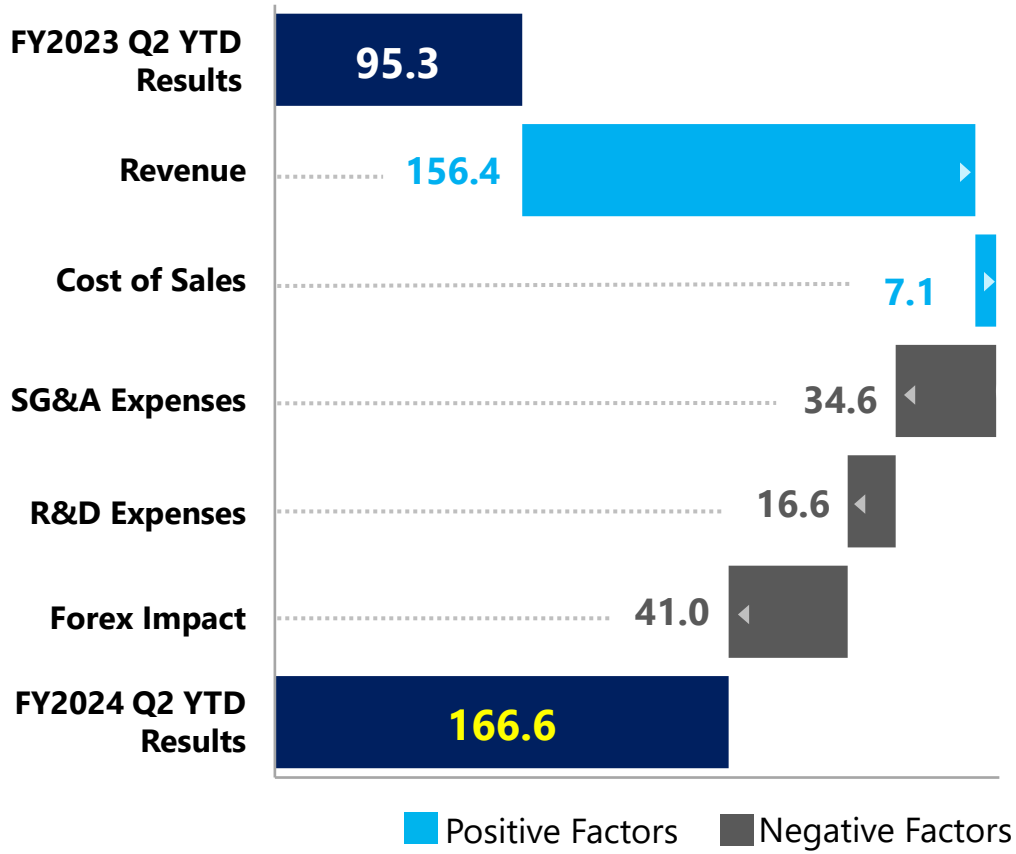
(Bn JPY)

Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+10.8	Daiichi Sankyo Espha	-41.1
Enhertu	+5.1		
Tarlige	+5.1		
Vaccines	+4.5		
Daiichi Sankyo Healthcare	+5.1		
Realized gains of unrealized gains of inventory for Daiichi Sankyo Espha	+11.2		
Oncology Business Unit*1			
Enhertu	+49.5		
American Regent Unit			
GE injectables	+3.0	Venofer	-1.7
EU Specialty Business Unit			
Lixiana	+15.9		
Nilemdo/Nustendi	+8.4		
ASCA (Asia, South and Central America) Business Unit			
Enhertu	+13.1		
Upfront Payment & Regulatory/Sales Milestone etc. related to alliance with AstraZeneca and US MRK *2			
Upfront Payment related to alliance with US MRK	+14.3		

*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products
*2 Merck & Co., Inc., Rahway, NJ, USA
*3 Forex impact USD: +22.0, EUR : +14.4, ASCA: +3.3

Core Operating Profit

Increased by 71.3 Bn JPY (Increased by 72.6 Bn JPY excl. forex impact)



(Bn JPY)

Revenue +156.4
incl. forex impact of +39.6

Cost of Sales -7.1
Improvement in cost of sales ratio by change in product mix

SG&A Expenses +34.6
Increase in expenses related to Enhertu
due to an increase in profit share of gross profit with AstraZeneca

R&D Expenses +16.6
Increase in 5DXd ADCs* R&D investments

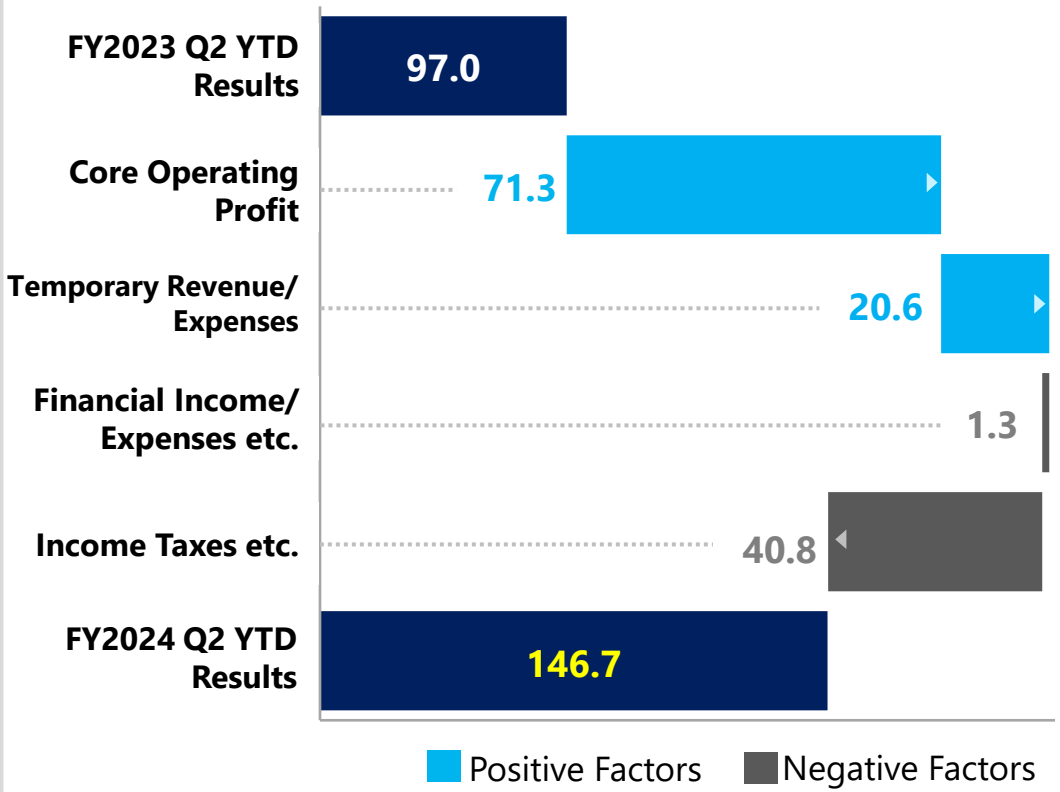
Forex Impact +41.0 (Profit Decreased)
Cost of Sales +11.7
SG&A Expenses +18.6
R&D Expenses +10.7

***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 49.7 Bn JPY

(Bn JPY)



Temporary Income/Expenses ····· **+20.6 (Profit Increased)**

	FY2023 Q2 YTD Results	FY2024 Q2 YTD Results	YoY
Temporary Income	0.7	20.3*1	+19.6
Temporary Expenses	1.0	0.0	-1.0

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

Financial Income/Expenses etc. ····· **-1.3（Profit Decreased）**

- Deterioration in forex gains/losses ····· -8.5
- Increase in interest income ····· +4.6
- Improvement in investment securities valuation gains/losses ····· +0.9

Income Taxes etc. ····· **+40.8 (Profit Decreased)**

	FY2023 Q2 YTD Results	FY2024 Q2 YTD Results	YoY
Profit before Tax	102.1	192.6	+90.5
Income Taxes etc.	5.1	45.9	+40.8
Tax rate	5.0%	23.8%	

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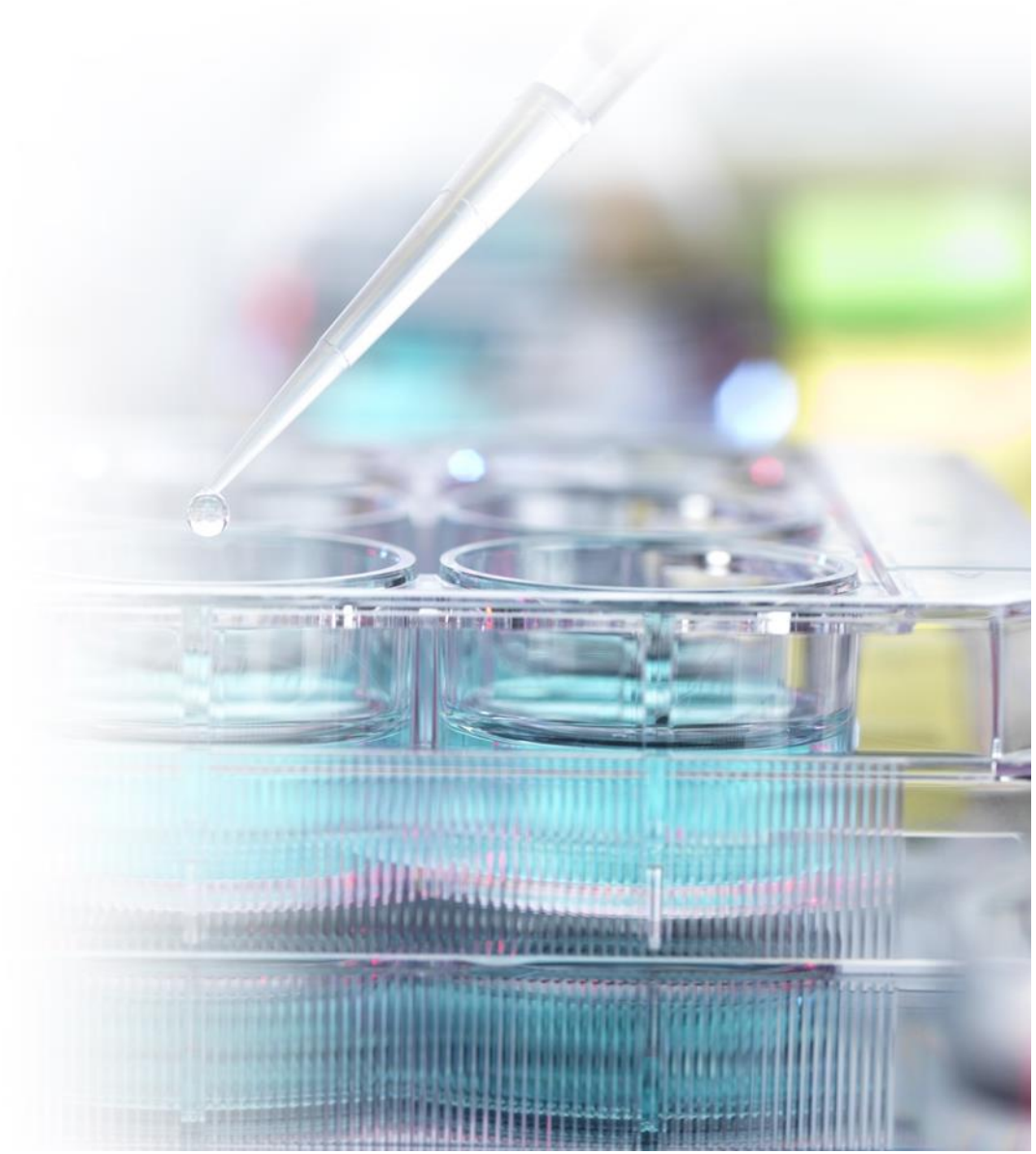

Revision to the forecast

(Bn JPY)

	FY2024 Forecast (As of Apr.)	FY2024 Forecast (As of Oct.)	vs. Forecast
Revenue	**1,750.0**	**1,830.0**	**+80.0**
Cost of sales *1	395.0	410.0	+15.0
SG&A expenses *1	675.0	700.0	+25.0
DXd ADC profit share *2	210.8	210.0	-0.8
Other SG&A expenses	464.2	490.0	+25.8
R&D expenses *1	470.0	460.0	-10.0
Core operating profit*1	**210.0**	**260.0**	**+50.0**
Temporary income*1	20.0	20.0	-
Temporary expenses*1	-	-	-
Operating profit	**230.0**	**280.0**	**+50.0**
Profit before tax	**235.0**	**285.0**	**+50.0**
Profit attributable to owners of the Company	**190.0**	**225.0**	**+35.0**

Currency Rate	USD/JPY	145.00	148.81	+3.81
	EUR/JPY	155.00	160.47	+5.47

Assumption of currency rate for Q3 and Q4 : USD/JPY 145, EUR/JPY 155

Revenue
↑ : Increase by forex impact, sales expansion of Lixiana and Enhertu, etc.
↓ : Sales decrease of GE injectables in ARU, delay in the launch of HER3-DXd in US

Cost of sales
↑ : Increase due to upward revision of revenue forecast and forex impact

SG&A Expenses
↑ : Increase by forex impact, increase due to strategic investments in DX/IT expenses and human capital
↓ : Decrease in expenses due to the receipt of arbitration costs, etc. from Seagen following the confirmation of the arbitration

R&D Expenses
↑ : Increase by forex impact
↓ : Decrease due to a partial revisit of the timing of expense execution

Forex Impact vs. as of Apr.

Revenue +37.0 Bn JPY
Core operating profit +8.0 Bn JPY

*1 As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed. Income and expenses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation, reconciliation, and other non-temporary and material gains and losses are included in the "temporary income and expenses". Temporary income and expenses are excluded from results and forecast for cost of sales, SG&A expenses and R&D expenses shown in the list above. The adjustment table from operating profit to core operating profit is stated in the reference data.
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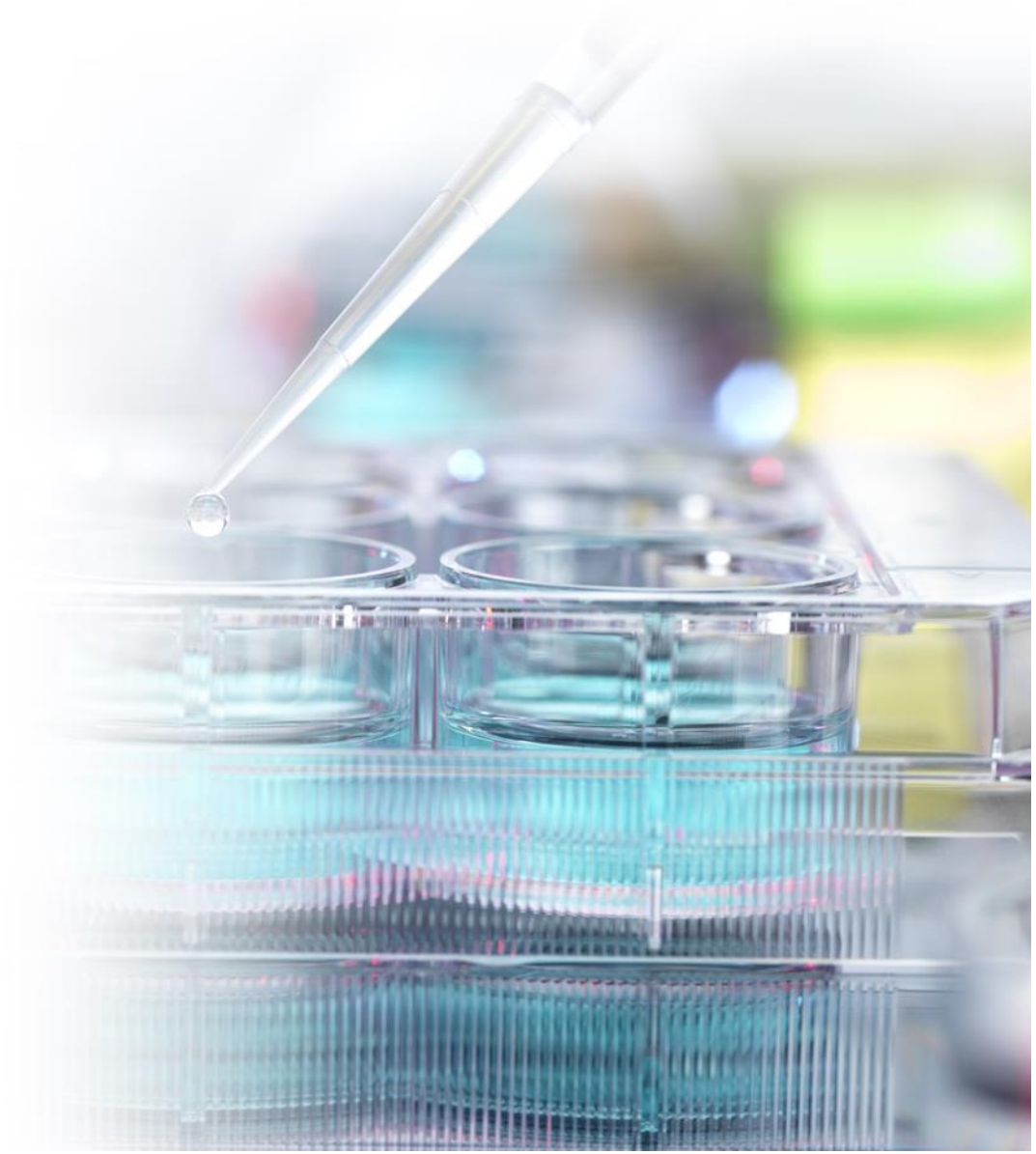
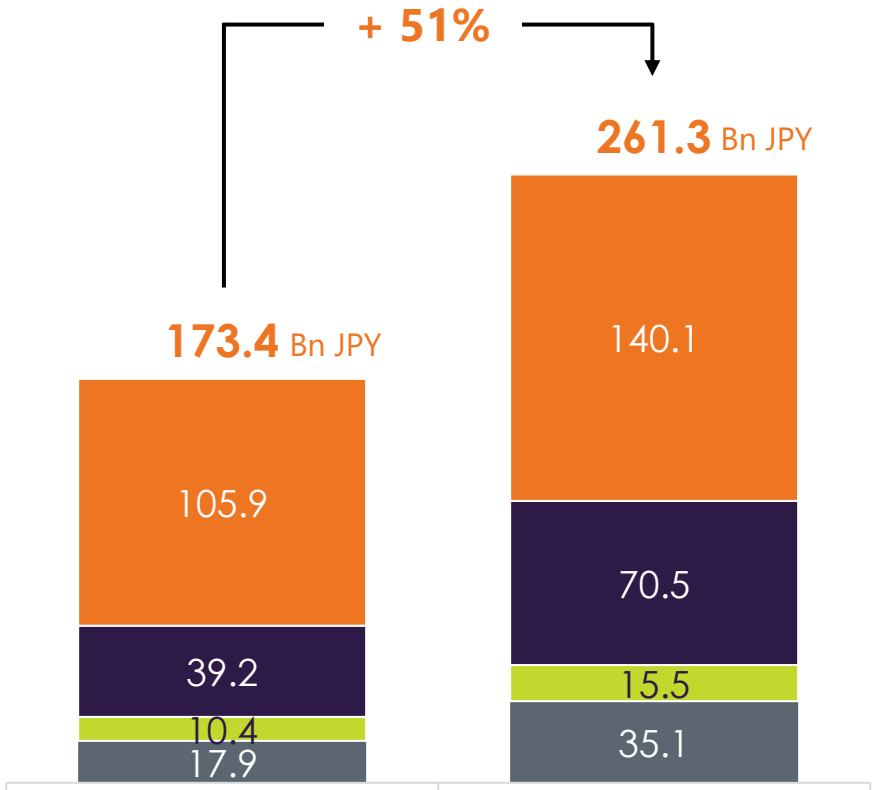


ENHERTU® Performance

Global Product Sales

Q2 YTD Product Sales Result **261.3Bn JPY** (YoY **+87.9Bn JPY**) FY2024 Forecast **523.0Bn JPY** (vs Apr Forecast **+14.7Bn JPY**)



Global Product Sales

◆ Key Growth Factors (YoY YTD Results)

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

US (+32%)	Maintained No.1 new patient share in BC, GC, NSCLC indications; Expanded new patient uses in various tumor types in HER2+ solid tumors
EU (+80%)	Expanded sales leading by DE, FR, IT, ES; Achieved further growth in new patient share in BC indications while maintaining No.1 position
Japan (+50%)	Maintained No.1 new patient share in all indications including early market adoption of HER2 low BC (post-chemo)
ASCA (+96%)	Expanded sales mainly in Brazil and China; Achieved and maintained No.1 new patient share in HER2+ BC 2L in Brazil

◆ 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, DE: Germany, FR: France, IT: Italy, ES: Spain, NCCN: National Comprehensive Cancer Network

Co-development and Co-commercialization for MK-6070

Added MK-6070*, which is being developed by Merck & Co., Inc., Rahway, NJ, USA (MRK), to the existing global co-development and co-commercialization agreement for 3 DXd ADC products (HER3-DXd, I-DXd, R-DXd (DS-6000))

Development

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

Commercialization

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

Manufacturing

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

Financial Terms

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

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

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

Other Regional Initiatives

Japan

◆ DAICHIRONA® INTRAMUSCULAR INJECTION COVID-19 Vaccine

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

◆ FLUMIST® INTRANASAL SPRAY Influenza Vaccine

- ➢ Oct. 2024 **Launched** Intranasal live attenuated influenza vaccine
  - Trivalent vaccine (2 types of type A, 1 type of type B)
  - Started to supply the first intranasally administered seasonal influenza vaccine in Japan from this season

DAICHIRONA®

FLUMIST®

Meeting Information

- **Meeting title: Discussion meeting on sustainability (Value Report 2024)**
- **Date and time: Monday, December 23, 2024 10:00-11:30am (JST)**
- **Speaker: Okuzawa COO, Matsumoto CHRO*, Nishii Outside Director, Nohara Outside Director and others**

* Chief Human Resources Officer

- **Meeting style: on site+virtual (Zoom)**

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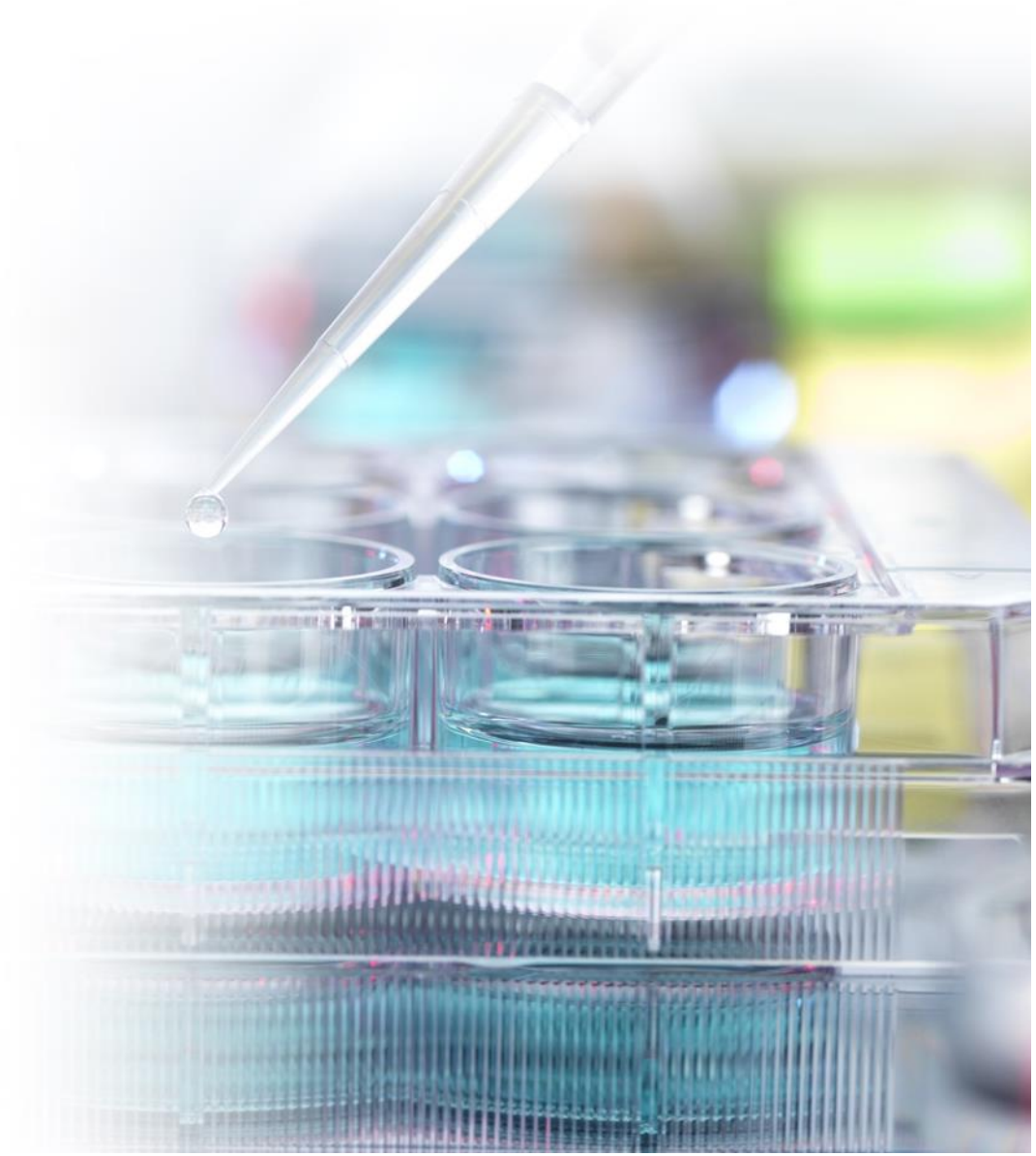


5DXd ADCs Update

Next Wave Update

Science and Technology Day 2024

News Flow

Regulatory updates

DESTINY-Breast06, DESTINY-Gastric06, DESTINY-Lung05

Indication expansion in each country and region

HR positive and HER2 low or ultralow BC (chemo naïve) (DESTINY-Breast06)

- Aug 2024：Filing accepted in EU
- Aug 2024：Breakthrough Designation granted by FDA in the US
- Oct 2024：Filing accepted in the US and Priority Review granted (PDUFA date: Feb 1st, 2025)
- Oct 2024：Filing accepted in Japan

HER2 positive GC 3L+ (DESTINY-Gastric06)

- Aug 2024：Approved in China

HER2 mutant NSCLC 2L+ (DESTINY-Lung05)

- Oct 2024：Approved in China

BC: breast cancer, GC: gastric cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, PDUFA: prescription drug user fee act

ENHERTU®

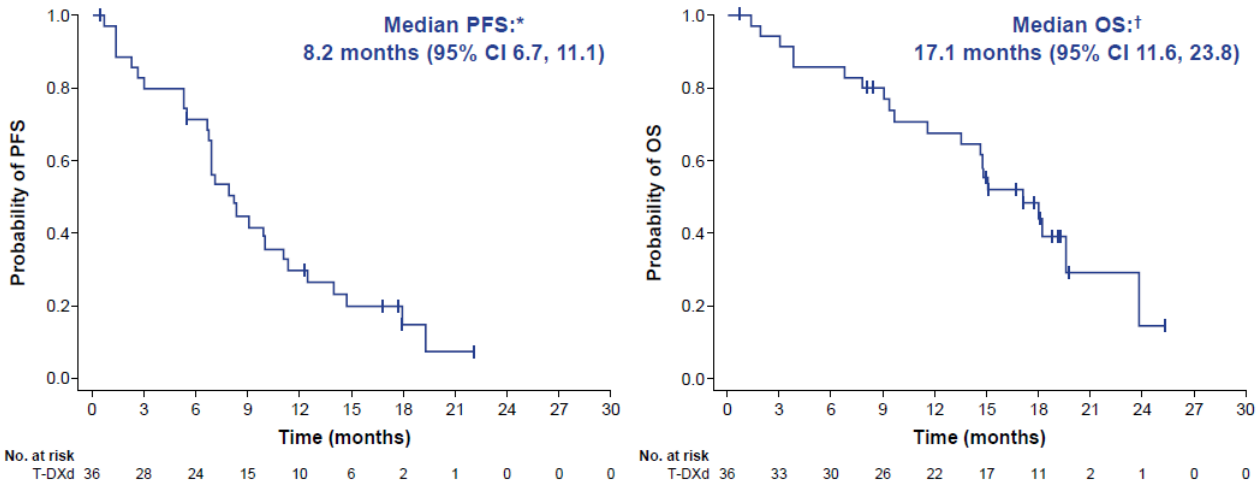
HER2 expressing NSCLC update

DESTINY-Lung03 Ph1b (WCLC 2024)

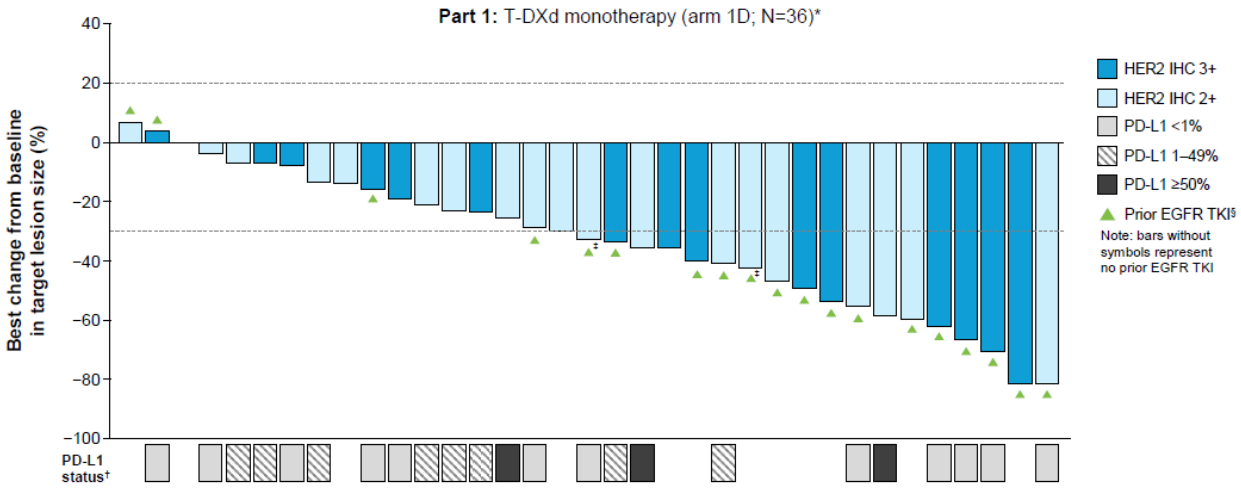
Daiichi-Sankyo

ENHERTU® monotherapy cohort showed clinical benefit in pretreated HER2 overexpressing NSCLC

PFS and OS of ENHERTU® monotherapy



ORR



Data cutoff: April 1st, 2024

- Exploratory analyses showed promising activity in HER2-OE NSCLC w and w/o prior EGFR TKI
  - ✓ HER2 IHC 3+ (ORR: 56.3%, mPFS: 6.9mo, mOS: 16.4 mo), HER2 IHC 2+ (ORR: 35.0%, mPFS: 8.2 mo, mOS: 17.1 mo)
  - ✓ Prior EGFR TKI (ORR: 68.4%, mPFS: 8.2 mo, mOS: 19.6 mo), no prior EGFR TKI (ORR: 17.6%, mPFS: 7.1 mo, mOS: 14.7 mo)
- No new safety signals were identified. The safety profile was consistent with the known profile of ENHERTU®
- DESTINY-Lung03 is ongoing to assess ENHERTU® combo therapies for treatment-naïve HER2-OE NSCLC

CI: confidence interval, IHC: immunohistochemistry, mo: month, mOS: median overall survival, mPFS: median progression-free survival, NSCLC: non-small cell lung cancer, OE: over-expressing, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, T-DXd: trastuzumab deruxtecan, TKI: tyrosine kinase inhibitor, WCLC: World Conference on Lung Cancer

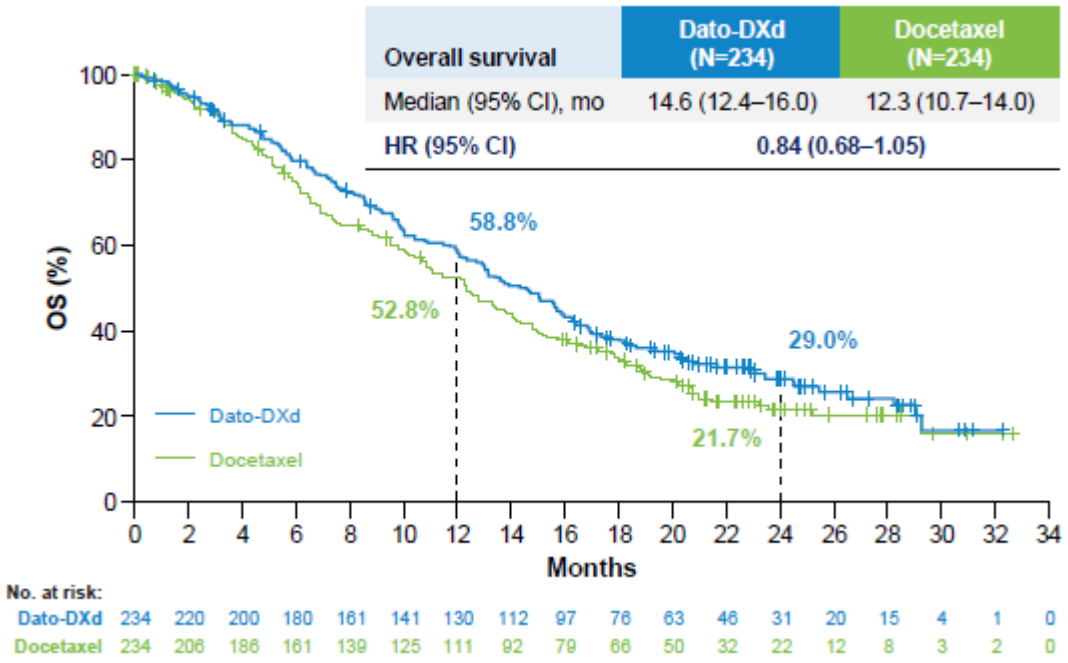
TROPION-Lung01

Topline OS results (WCLC 2024)

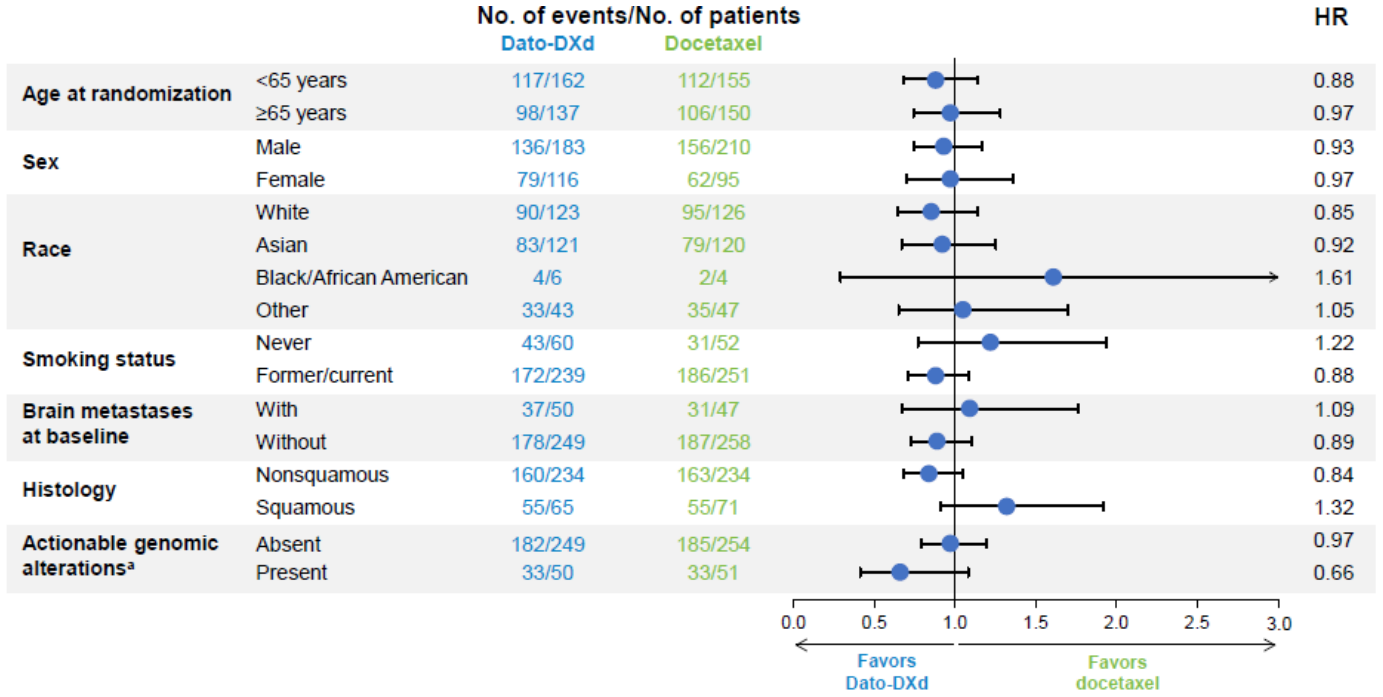
Daiichi-Sankyo

Clinically meaningful trend continued in NSQ NSCLC (2L+)

Overall Survival in NSQ NSCLC



Overall Survival: subgroup analysis



Data cutoff: Mar 1st, 2024

- **In ITT population, OS results numerically favored Dato-DXd** compared to docetaxel (mOS 12.9mo versus 11.8mo) but **did not reach statistical significance** (HR=0.94, 95% CI: 0.78-1.14, p-value=0.530)
- **In NSQ NSCLC, demonstrated 14.6 month of mOS** (mOS 12.3mo (docetaxel), HR=0.84, 95% CI: 0.68-1.05)
- The tolerability profile remains manageable and **no new safety signals** were identified. **No late-onset toxicities** were observed.
- The OS data have been shared with health authorities currently reviewing applications for this indication (PDUFA date in US: Dec 20th, 2024)

CI: confidence interval, HR: hazard ratio, ITT: intention to treat, mo: month, mOS: median overall survival, NSQ: non squamous, NSCLC: non-small cell lung cancer, OS: overall survival, PDUFA: prescription drug user fee act, WCLC: World Conference on Lung Cancer

Computational pathology platform for TROP2 biomarker

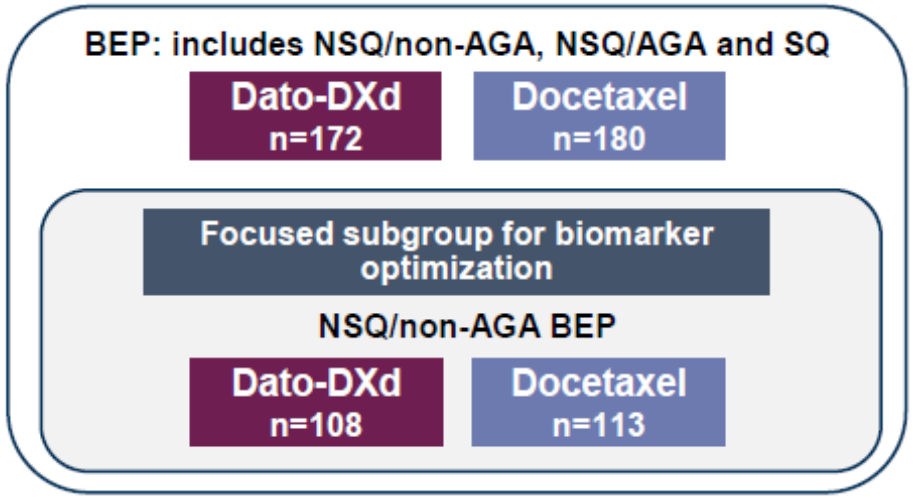
QCS analysis on TROPION-Lung01 PFS (WCLC 2024)

Daiichi-Sankyo

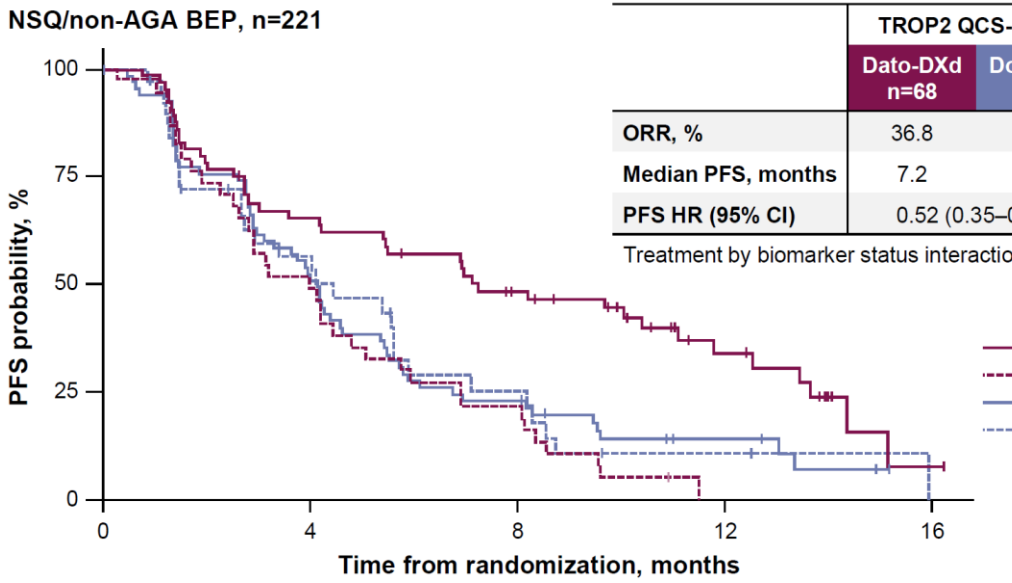
TROP2 QCS-NMR is a promising biomarker for Dato-DXd in NSQ/non-AGA NSCLC

Population and Methods

- QCS is a computational pathology approach that precisely quantifies and locates target proteins
- QCS-NMR cut-points were optimized for PFS in NSQ/non-AGA patients from the study



Efficacy by TROP2 QCS-NMR status in NSQ/non-AGA BEP



	TROP2 QCS-NMR+		TROP2 QCS-NMR–	
	Dato-DXd n=68	Docetaxel n=72	Dato-DXd n=40	Docetaxel n=41
ORR, %	36.8	15.3	22.5	12.2
Median PFS, months	7.2	4.1	4.0	4.4
PFS HR (95% CI)	0.52 (0.35–0.78)		1.22 (0.74–2.00)	

Treatment by biomarker status interaction: p=0.0098

- **Exploratory, retrospective QCS analysis** in TROPION-Lung01 demonstrated **meaningfully greater magnitude of PFS benefit** in NSQ NSCLC
- In TROP2 QCS-NMR+ NSQ NSCLC w/o AGA, Dato-DXd reduced the risk of disease progression or death by 48% versus docetaxel
  - ✓ **mPFS of 7.2mo** vs. 4.1 mo (docetaxel); **HR=0.52**, 95% CI: 0.35-0.78
- TROP2 QCS-NMR has been applied to AVANZAR and TROPION-Lung10 studies for further investigation

AGA: actionable genomic alteration, BEP: biomarker evaluable population, CI: confidence interval, HR: hazard ratio, mo: month, mPFS: median progression-free survival, NMR: normalized membrane ratio, NSQ: non squamous, NSCLC: non-small cell lung cancer, ORR: objective response rate, PFS: progression-free survival, QCS: quantitative continuous scoring, SQ: squamous, WCLC: World Conference on Lung Cancer

Dato-DXd

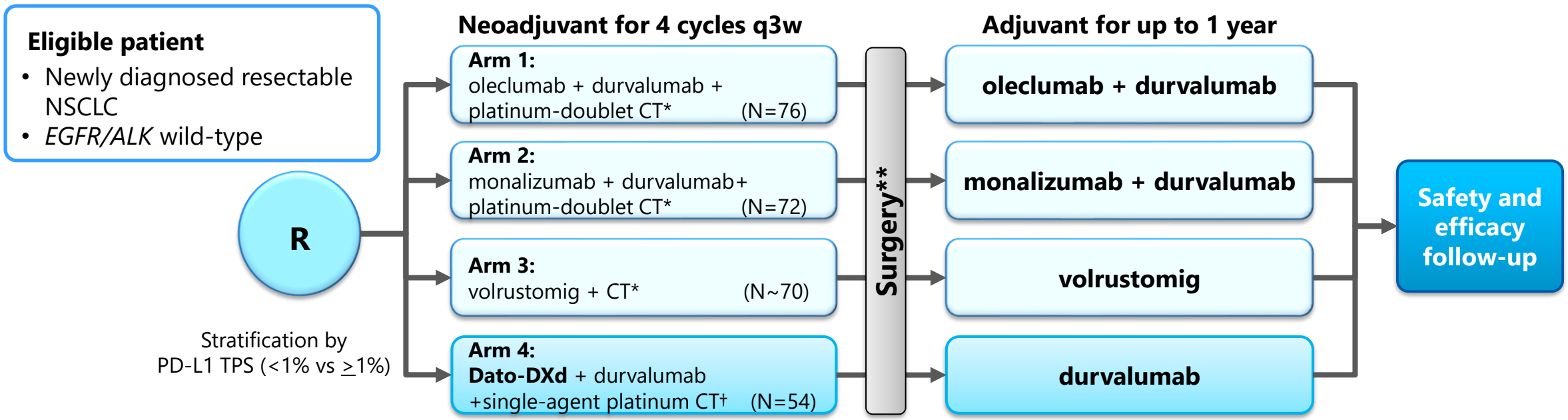
Combination therapy for early-stage NSCLC

NeoCOAST-2 Ph2 (WCLC 2024)

Daiichi-Sankyo

Interim result showed encouraging efficacy and manageable safety profile in neoadjuvant setting for resectable NSCLC

NeoCOAST-2 study design



- Numerically higher pCR and/or mPR rates compared to historical benchmarks
  - ✓ Arm 4 **efficacy: pCR rate 34.1%, mPR rate 65.9%**
- All arms demonstrated a manageable safety profile and surgical rates comparable to currently approved regimens
  - ✓ Arm 4 **Grade ≥3 TRAE: neoadjuvant (10/54), post-surgery(0/46), adjuvant (0/25)**

Primary endpoint: pCR rate***, safety and tolerability
Key secondary endpoint: mPR rate***, EFS, Feasibility of surgery

*Carboplatin + paclitaxel for squamous tumour histology, pemetrexed + cisplatin or carboplatin for non-squamous tumour histology. †Physician's choice of carboplatin or cisplatin. **Within 40 days of the last dose of neoadjuvant treatment. ***Proportion of patients with no viable tumour cells and ≤10% residual viable tumour cells, respectively, in resected tumour specimen and sampled nodes at surgery.

CT: chemotherapy, EFS: event free survival, mPR: major pathological response, NSCLC: non-small cell lung cancer, pCR: pathological complete response, q3w: once every 3 weeks, TPS: tumor proportion score, TRAE: treatment-related adverse events, WCLC: World Conference on Lung Cancer

Dato-DXd

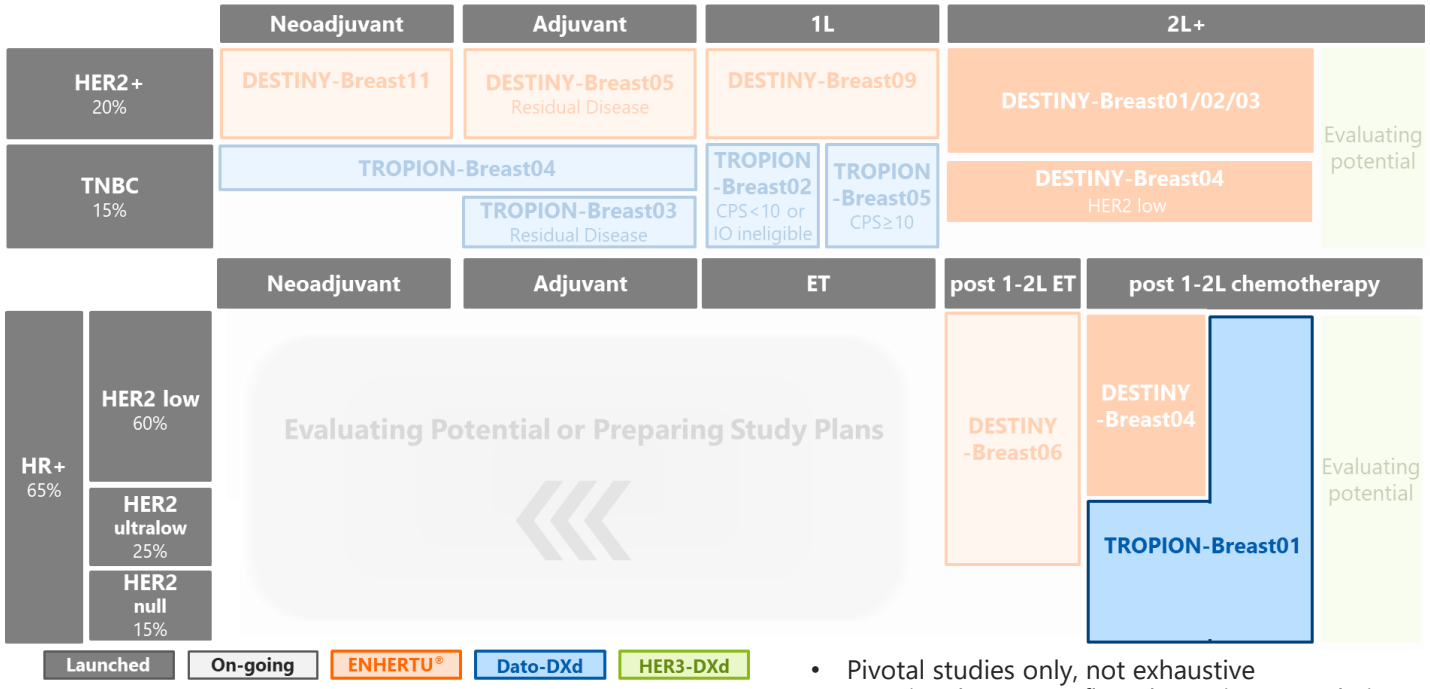
Expand Dato-DXd treatment to HR positive BC

TROPION-Breast01 Ph3

Daiichi-Sankyo

Topline overall survival results were announced in Sep 2024

TROPION-Breast01 in BC map



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

TROPION-Breast01

- ✓ BC with inoperable or metastatic HR positive, HER2 low or negative (IHC 0, IHC 1+ or IHC 2+/ISH-) previously treated with ET and at least one systemic therapy
- ✓ The dual primary endpoints are PFS and OS

- **Did not achieve statistical significance in the final OS analysis**. This analysis follows the positive PFS results presented at ESMO 2023, which showed Dato-DXd demonstrated a **statistically significant and clinically meaningful improvement in PFS**.
- The data will be presented at a forthcoming medical meeting and shared with regulatory authorities currently reviewing applications for this indication
- PDUFA date in US: Jan 29th, 2025

BC: breast cancer, CPS: combined positive score, ESMO: European Society for Medical Oncology, ET: endocrine therapy, HR: hormone receptor, IHC: immunohistochemistry, IO: immune oncology, ISH: *in situ* hybridization, pCR: pathological complete response, PFS: progression-free survival, OS: overall survival, PDUFA: prescription drug user fee act, TNBC: triple-negative breast cancer

Further evaluation in early stage NSCLC

TROPION-Lung12 Ph3

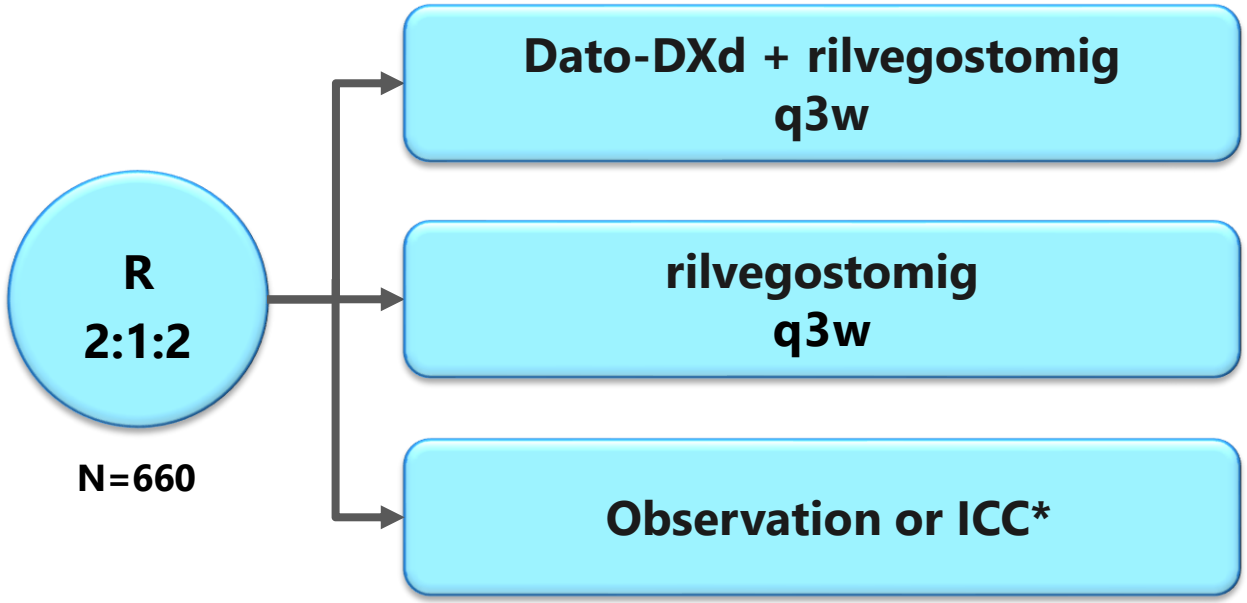
Daiichi-Sankyo

New Ph3 combination study w/ rilvegostomig in NSCLC with ctDNA-positive or at least one high-risk pathological feature starts

TROPION-Lung12 study design

Eligible patient

- Stage I, treatment-naive adenocarcinoma NSCLC
- Complete surgical resection of the primary NSCLC
- Pre-surgical ctDNA-positive result, or presence of at least one high-risk pathological feature



- Dato-DXd is assessed in an **adjuvant setting**
- Study starts in **FY2024 H2**

Primary endpoint: DFS (BICR)
Key secondary endpoint: OS, PRO

ICC*: carboplatin, cisplatin, etoposide, pemetrexed, vinorelbine, UFT

BICR: blinded independent central review, ctDNA: circulating tumor DNA, DFS: disease-free survival, ICC: investigator's choice of chemotherapy, NSCLC: non-small cell lung cancer, OS: overall survival, PRO: patient reported outcome, q3w: once every 3 weeks, UFT: tegafur-uracil

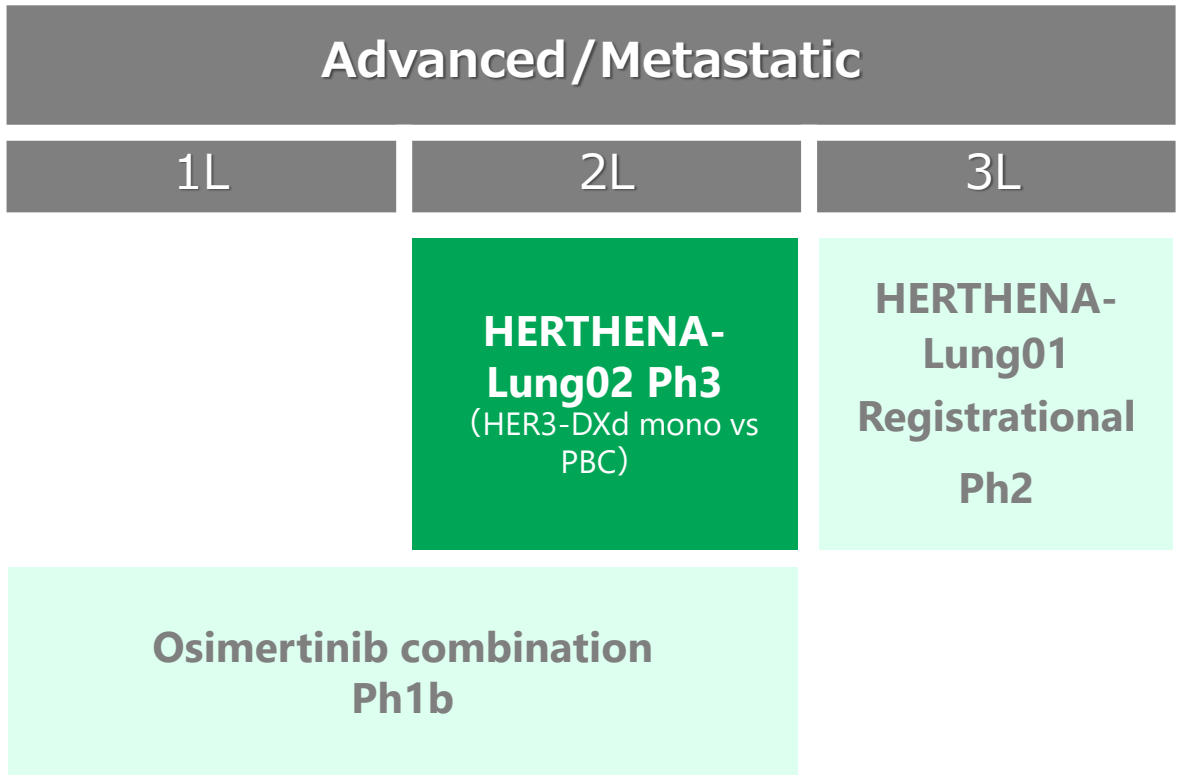
HER3-DXd

EGFR mutated NSCLC update

HERTHENA-Lung01, HERTHENA-Lung02

HERTHENA-Lung02 met its primary endpoint of PFS

Clinical studies of HER3-DXd in EGFR mutated NSCLC



- **In Sep 2024, TLR of HERTHENA-Lung02 were disclosed**
  - ✓ HER3-DXd demonstrated **statistically significant improvement in PFS**, the primary endpoint, versus PBC in patients with EGFR mutated NSCLC who received prior EGFR TKI treatment.
  - ✓ OS data, an important secondary endpoint, were immature at the time of the analysis and the trial will continue to further assess OS
  - ✓ No new safety signals identified
  - ✓ The majority of ILD events were low grade (grade1 and 2). There were two grade 5 ILD events observed
- HERTHENA-Lung01 progress: Working closely with the FDA and the manufacturer to address the feedback in CRL regarding findings in the third-party manufacturing facility

CRL: complete response letter, ILD: interstitial lung disease, NSCLC: non-small cell lung cancer, OS: overall survival, PBC: platinum-based chemotherapy, PFS: progression-free survival, TKI: tyrosine kinase inhibitor

HER3-DXd in breast cancer

ICARUS-Breast01 Ph2 (ESMO 2024)

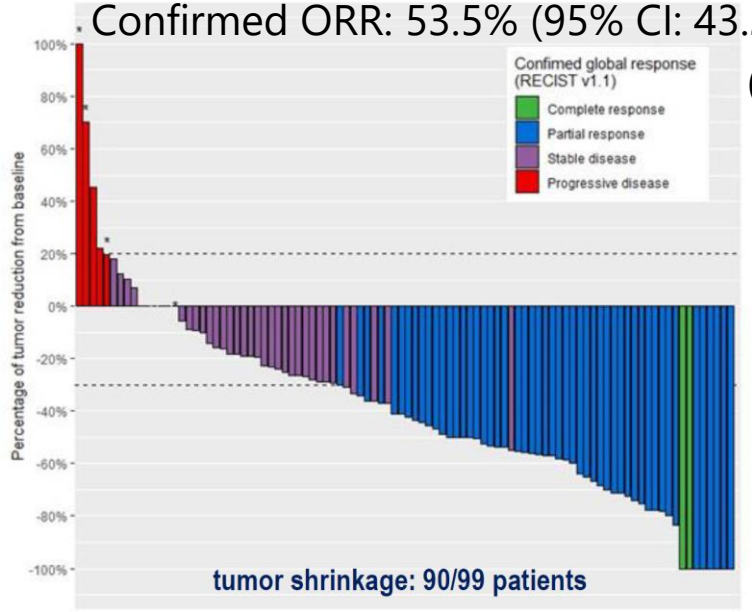
HER3-DXd showed clinically meaningful activity and manageable safety profile in patients with HR+/HER2- BC progressing after 2L+ of therapy including CDK4/6i

Key Eligibility

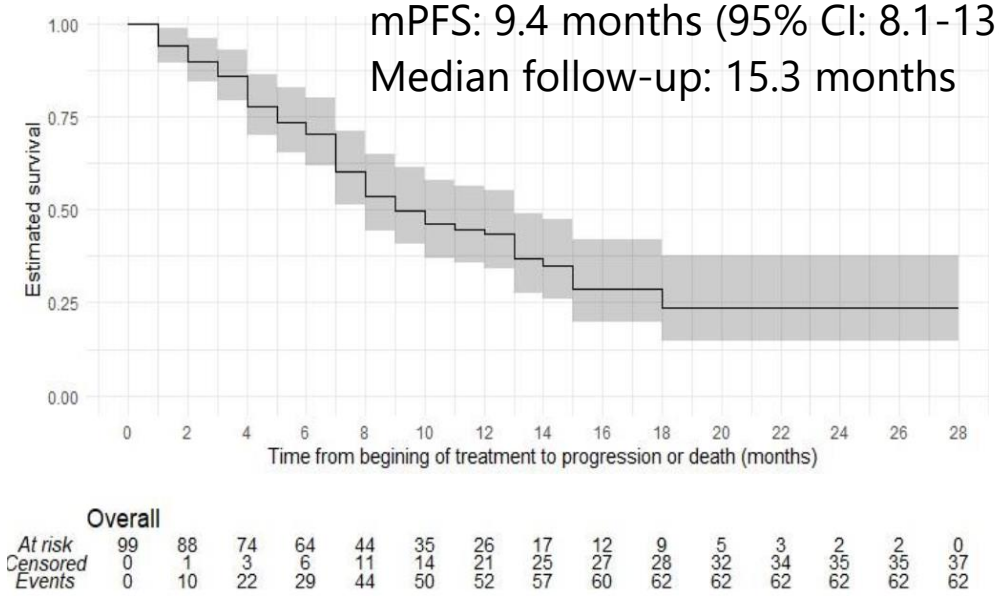
- Unresectable locally advanced/metastatic HR+/HER2- BC
- Progression on CDK4/6 inhibitor +ET
- Progression on 1 prior chemotherapy for advanced BC
- No prior ENHERTU®

Antitumor activity

Confirmed ORR: 53.5% (95% CI: 43.2-63.6)
(53/99)



mPFS: 9.4 months (95% CI: 8.1-13.4)
Median follow-up: 15.3 months



Data cutoff: Apr 16th, 2024

- Clinically meaningful activity and manageable safety profile were observed in ICARUS-Breast01 IIS for HR+/HER2- BC with confirmed ORR 53.5% and mPFS 9.4mo. No significant association between HER2 expression and either ORR or PFS
- Efficacy and safety profile of HER3-DXd make it an optimal candidate for further larger trials in this setting

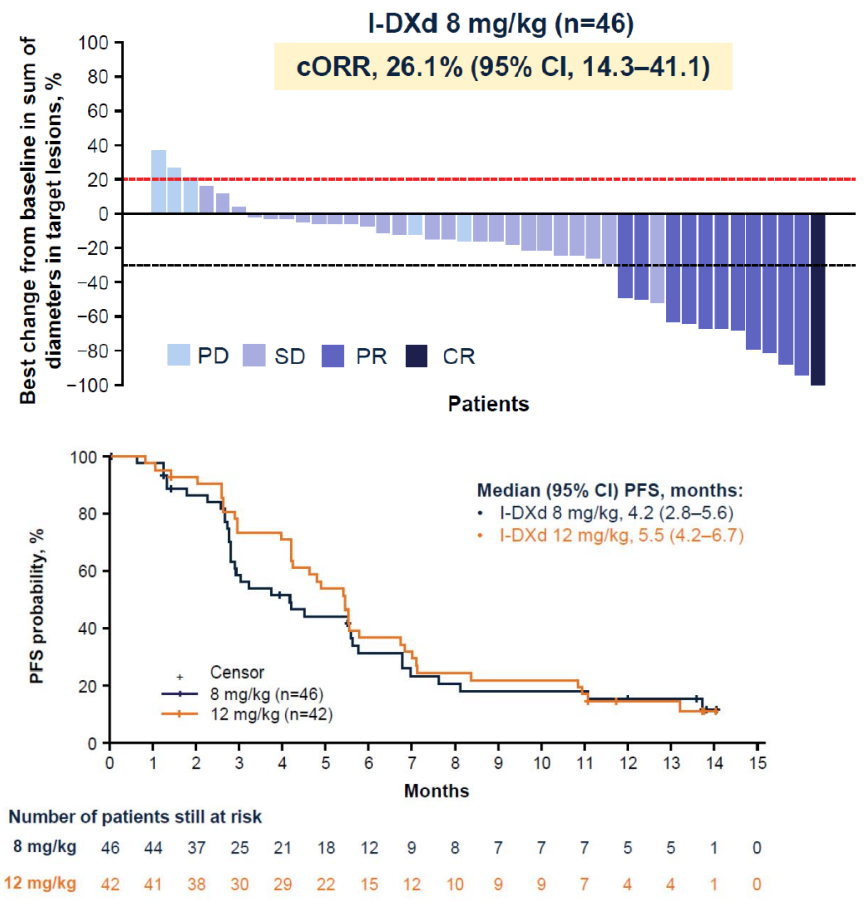
CI: confidence interval, BC: breast cancer, ESMO: European Society for Medical Oncology, ET: endocrine therapy, HR: hormone receptor, IIS: investigator initiated study, mPFS: median progression-free survival, ORR: objective response rate, PFS: progression-free survival

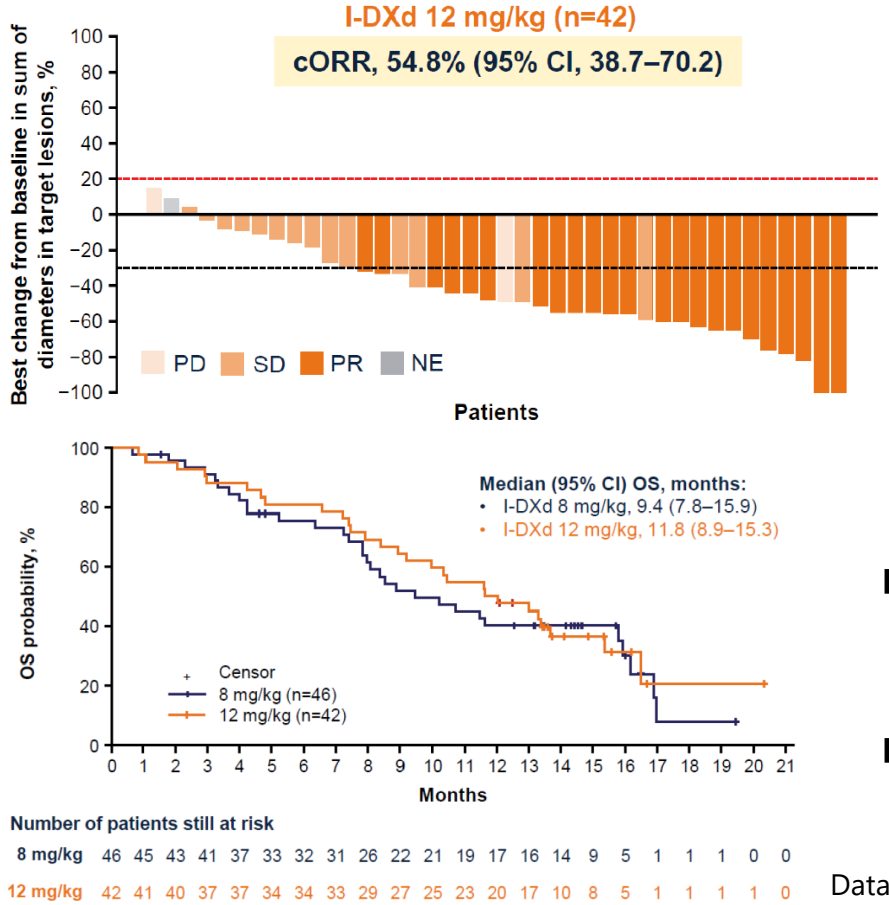
ES-SCLC update

IDeate-Lung01 Ph2 (WCLC 2024)

I-DXd demonstrated promising efficacy and tolerability in pretreated ES-SCLC and 12mg/kg was selected for Ph3 study

cORR (upper), PFS and OS (lower)





IDeate-Lung01

Ph2 study comparing 2 doses in patients with ES-SCLC who received ≥ 1 prior line of PBC and ≤ 3 prior lines of therapy

- I-DXd 12mg/kg had improved efficacy compared with the 8mg/kg dose
- There tended to be higher AE rates at 12mg/kg but still a manageable safety profile
- The most common treatment-related TEAEs were gastrointestinal and hematologic
- The majority of cases of adjudicated drug-related ILD were grade 1or 2

Data cutoff: April 25th, 2024

AE: adverse event, CI: confidence interval, cORR: confirmed objective response rate, CR: complete response, , ES-SCLC: extensive-stage small cell lung cancer, ILD: interstitial lung disease, NE: not evaluable, OS: overall survival, PBC: platinum-based chemotherapy, PD: progressive disease, PFS: progression-free survival, PR: partial response, SD: stable disease, TEAE: treatment emergent adverse events, WCLC: World Conference on Lung Cancer

5DXd ADCs

Other clinical updates

ENHERTU®

- Aug 2024: DESTINY-BTC01 Ph3 combination study with rilvegostomig for BTC 1L started

Dato-DXd

- Oct 2024: TROPION-Lung15 Ph3 study for mono and combination with osimertinib for EGFR mutated NSCLC 2L+ started

HER3-DXd

- MK-1022-011 Ph1b/2 study for CRC, BTC and HCC 2L+ under preparation
- Added a new arm of HER3-DXd in combination with pembrolizumab and carboplatin to KEYMAKER-U01 substudy 01A for stage IV NSCLC 1L

I-DXd

- Aug 2024: IDeate-Lung02 Ph3 study for SCLC 2L started
- Aug 2024: IDeate-Lung03 Ph1b/2 study for SCLC 1L started
- Added new arms of I-DXd in combination with pembrolizumab ± carboplatin to KEYMAKER-U01 substudy 01A for stage IV NSCLC 1L

BTC: biliary tract cancer, CRC: colorectal cancer, HCC: hepatocellular carcinoma, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer

5DXd ADCs Update

Next Wave Update

Science and Technology Day 2024

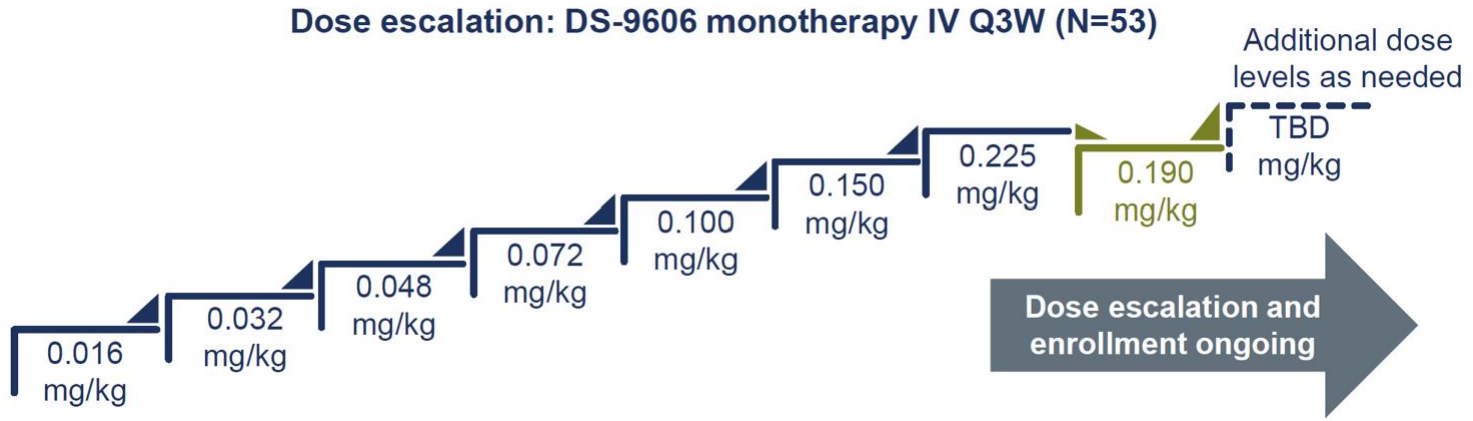
News Flow

Ph1 study dose escalation part

ESMO 2024

Daiichi-Sankyo

Reported preliminary safety and efficacy data at ESMO 2024



DS-9606 dose, mg/kg	0.016 (n=3)	0.032 (n=7)	0.048 (n=7)	0.072 (n=6)	0.100 (n=7)	0.150 (n=14)	0.190 (n=3)	0.225 (n=6)	Total (N=53)
TEAEs, n with event (%)									
Any grade	3 (100.0)	6 (85.7)	7 (100)	6 (100)	5 (71.4)	13 (92.9)	1 (33.3)	4 (66.7)	45 (84.9)
Related	0	5 (71.4)	5 (71.4)	4 (66.7)	2 (28.6)	8 (57.1)	0	4 (66.7)	28 (52.8)
Grade ≥3	1 (33.3)	2 (28.6)	3 (42.9)	2 (33.3)	2 (28.6)	4 (28.6)	0	2 (33.3)	16 (30.2)
Related	0	1 (14.3)	1 (14.3)	0	0	0	0	1 (16.7)	3 (5.7)
Serious	1 (33.3)	1 (14.3)	3 (42.9)	2 (33.3)	2 (28.6)	4 (28.6)	0	3 (50.0)	16 (30.2)
Related	0	0	0	0	0	0	0	2 (33.3)	2 (3.8)
Associated with:									
Treatment interruption	0	2 (28.6)	2 (28.6)	2 (33.3)	0	2 (14.3)	0	1 (16.7)	9 (17.0)
Related	0	0	0	0	0	0	0	1 (16.7)	1 (1.9)
Dose reduction	0	0	1 (14.3)	0	0	1 (7.1)	0	1 (16.7)	3 (5.7)
Related	0	0	1 (14.3)	0	0	1 (7.1)	0	1 (16.7)	3 (5.7)
Treatment withdrawal	0	0	0	0	0	1 (7.1)	0	0	1 (1.9)
Related	0	0	0	0	0	0	0	0	0
Death	0	0	0	0	0	0	0	0	0

Data cutoff: Jun 14th, 2024

- DS-9606 is a CLDN6 directed, modified PBD ADC **from Daiichi Sankyo's second ADC platform**
- CLDN6 is an important component of cell-to-cell tight junctions and nearly absent in normal adult tissue but expressed in several tumor types including ovarian, endometrial, and gastric cancers, GCTs and NSCLC

- DS-9606 showed **manageable and tolerable safety profile and promising preliminary efficacy** in Ph1 study in patients with locally advanced or metastatic solid tumors
  - ✓ 4 PRs are observed in GCT (n=2), G/GEJ/E-AC (n=1), and NSCLC (n=1)
  - ✓ No DLTs to date
  - ✓ MTD and RDE for the next part not yet determined
  - ✓ No cases of CLS or ILD

CLDN6: claudin-6, CLS: capillary leak syndrome, DLT: dose limiting toxicity, ESMO: European Society for Medical Oncology, GCT: germ cell tumor, G/GEJ/E-AC: gastric/gastroesophageal junction/esophageal adenocarcinoma, ILD: interstitial lung disease, IV: intravenous, MTD: maximum tolerated dose, NSCLC: non-small cell lung cancer, PBD: pyrrolobenzodiazepine, Q3W: every 3 weeks, RDE: recommended dose for expansion, TBD: to be determined, TEAEs: treatment emergent adverse events

Expanding collaboration with MRK

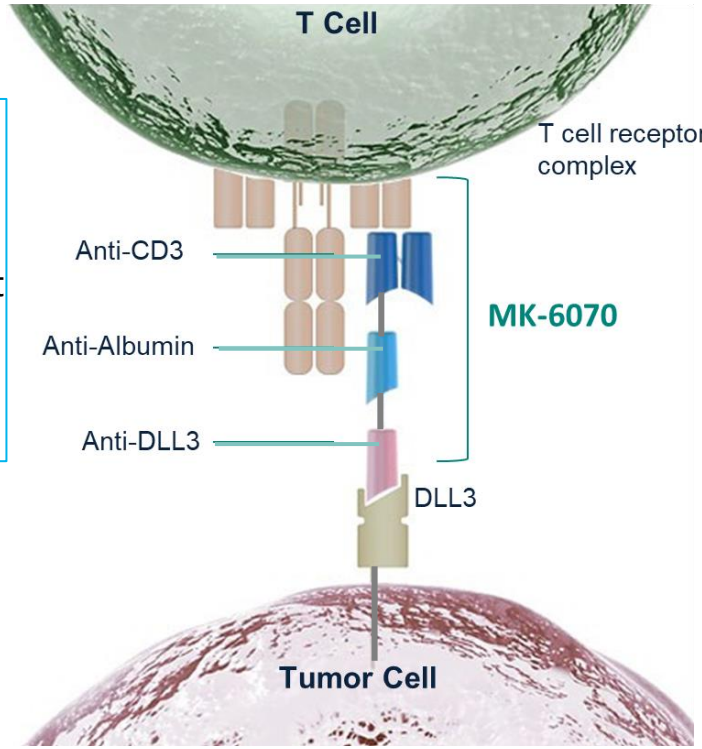
Daiichi-Sankyo

Plan to evaluate combination with I-DXd in dose escalation study for MK-6070

MoA and profile

MK-6070 (DS3280)

- T-cell engager targeting delta-like ligand 3 (DLL3), that is highly expressed in SCLC and neuroendocrine tumors



Ph1/2 study design

Dose escalation: N=232

Eligible patients
- histologically or cytologically confirmed malignancy associated with expression of DLL3

→ **MK-6070 q1w**
→ **MK-6070 q2w**
→ **MK-6070 q3w**

Eligible patients
- ES-SCLC

→ **MK-6070 q2w + atezolizumab q4w**
→ **MK-6070 q2w + I-DXd q3w** **New**

Primary outcome measure: Safety, PK
Secondary outcome measure: ORR, BOR, PFS, OS, etc

- Ph1/2 study in patients with advanced cancers associated with expression of DLL3 is ongoing
- New cohort for MK-6070 in combination with I-DXd has been added in Ph1/2 dose escalation study
- Safety profiles of MK-6070 and I-DXd reported in their clinical studies are largely non-overlapping

BOR: best overall response, ES-SCLC: extensive-stage small cell lung cancer, MoA: mechanism of action, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, PK: pharmacokinetics, qxw: every x weeks, SCLC: small cell lung cancer

5DXd ADCs Update

Next Wave Update

Science and Technology Day 2024

News Flow

Science and Technology Day 2024

Date & Time

Format

Monday, December 16th, 2024

5:30pm-7:30pm (EST)

Tuesday, December 17th

7:30am-9:30am (JST)

Virtual (Zoom)

Content will be delivered on-demand after the event

Major topics

- Latest publications at medical conferences
- R&D strategy
- R&D updates
- Manufacturing and supply

5DXd ADCs Update

Next Wave Update

Science and Technology Day 2024

News Flow

FY2024 News Flow

As of Oct 2024

Planned major data disclosures

San Antonio Breast Cancer Symposium (SABCS, Dec 10-13, 2024)

ENHERTU®	**DESTINY-Breast06:** **HR+/HER2 low BC, chemo naïve, Ph3** • **Follow-up from ASCO 2024 presentation**
	DESTINY-Breast08: **HER2 low BC, chemo naïve/post chemo, Ph1b** • **Partial cohort data (combo with capecitabine or capivasertib)**

Regulatory decisions

Dato-DXd	TROPION-Lung01: non-squamous 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

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

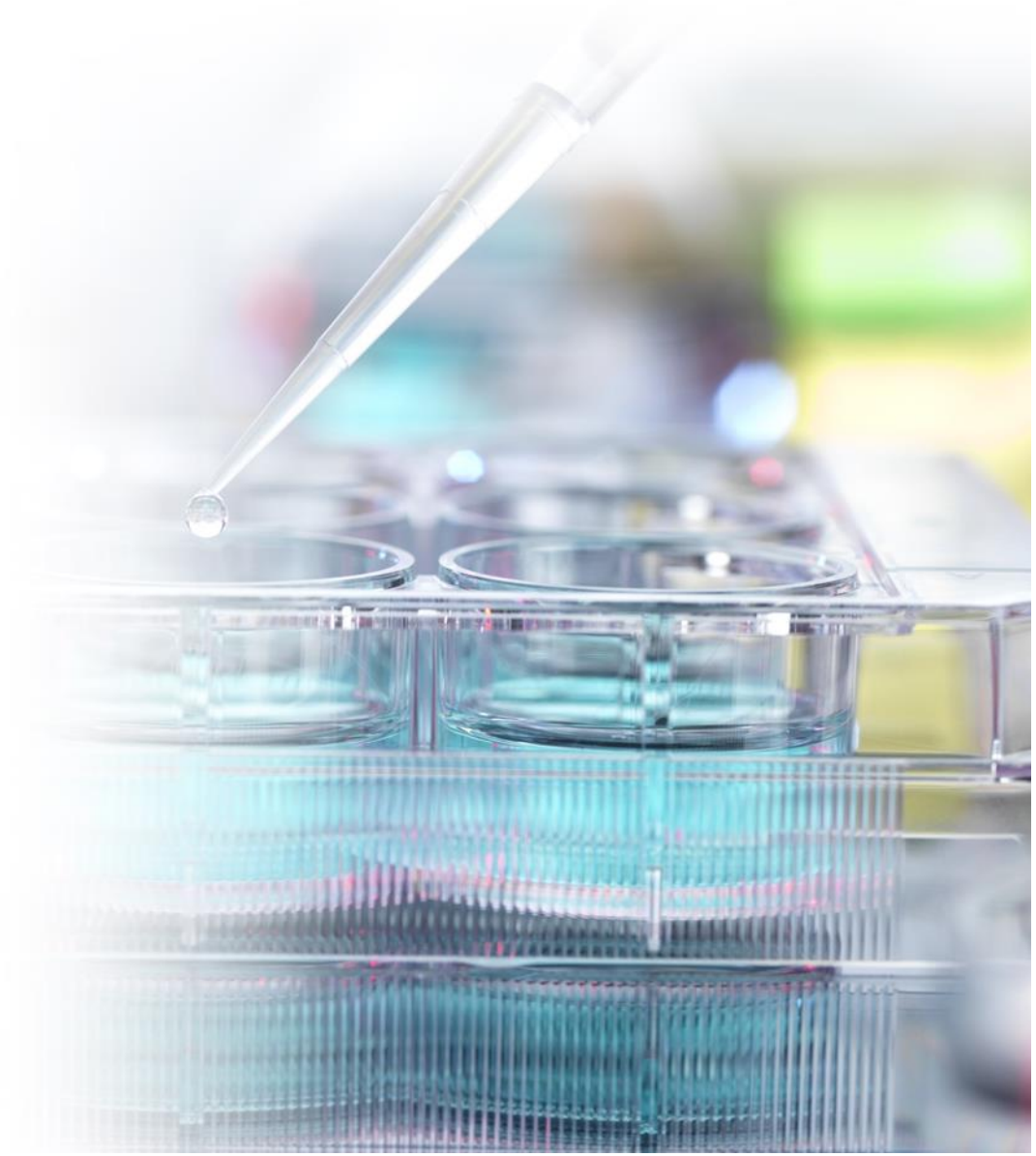
Bold: update from FY2024 Q1

ASCO: American Society of Clinical Oncology, BC: breast cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, TNBC: triple negative breast cancer

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

Agenda

1. FY2024 Q2 Financial Results
2. FY2024 Forecast
3. Business Update
4. R&D Update
5. **Appendix**



Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2023 Q2 YTD Results	FY2024 Q2 YTD Results	YoY
Japan Business	246.8	239.7	-7.2
Daiichi Sankyo Healthcare	37.4	42.5	+5.1
Oncolgy Business	148.8	215.5	+66.7
Enhertu	145.1	210.7	+65.6
Turalio	2.6	3.2	+0.6
Vanflyta	1.1	1.7	+0.5
American Regent	98.7	108.1	+9.4
Injectafer	25.7	28.5	+2.8
Venofer	29.1	29.7	+0.6
GE injectables	37.3	43.7	+6.4
EU Specialty Business	86.4	118.2	+31.7
Lixiana	67.9	90.6	+22.7
Nilemdo/Nustendi	6.8	16.4	+9.6
Olmesartan	9.2	9.5	+0.3
ASCA (Asia, South and Central America) Business	83.0	99.6	+16.5

Currency Rate	USD/JPY	141.00	152.62	+11.62
	EUR/JPY	153.38	165.93	+12.55

Revenue: Major Products in Japan

(Bn JPY)

		FY2023 Q2 YTD Results	FY2024 Q2 YTD Results	YoY
Lixiana	anticoagulant	**57.1**	**67.9**	**+10.8**
Tarlige	pain treatment	**22.7**	**27.8**	**+5.1**
Pralia	Treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**21.1**	**21.1**	**+0.0**
Vimpat	anti-epileptic agent	**12.7**	**15.5**	**+2.7**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**10.4**	**15.5**	**+5.1**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**10.3**	**10.4**	**+0.1**
Efient	antiplatelet agent	**12.4**	**15.7**	**+3.3**
Canalia	type 2 diabetes mellitus treatment	**8.1**	**8.1**	**+0.0**
Loxonin	anti-inflammatory analgesic	**8.0**	**6.8**	**-1.2**
Inavir	anti-influenza treatment	**1.9**	**0.2**	**-1.7**
Minnebro	antihypertensive agent	**4.0**	**4.8**	**+0.8**

5DXd ADCs Revenue (incl. Forex Impact)

(Unit: Bn JPY)

	FY2024 Q2 YTD Results	YoY	FY2024 Forecast (as of Oct)	vs Apr Forecast
ENHERTU	**271.7**	**+88.7**	**611.8**	**+26.5**
Product Sales	261.3	+87.9	523.0	+14.7
Upfront and Milestone Payments, etc.	10.4	+0.8	88.8	+11.8
Dato-DXd	**3.2**	**-**	**17.8**	**+0.2**
Product Sales	-	-	5.8	+0.2
Upfront and Milestone Payments, etc.	3.2	-	12.0	-
HER3-DXd	**4.4**	**+4.4**	**19.8**	**-3.4**
Product Sales	-	-	-	-4.2
Upfront and Milestone Payments, etc.	4.4	+4.4	19.8	+0.8
I-DXd	**7.8**	**+7.8**	**15.3**	**+0.7**
Upfront and Milestone Payments, etc.	7.8	+7.8	15.3	+0.7
DS-6000 (R-DXd)	**3.4**	**+3.4**	**6.7**	**+0.6**
Upfront and Milestone Payments, etc.	3.4	+3.4	6.7	+0.6
5DXd ADCs Total	**290.5**	**+104.3**	**671.5**	**+24.5**

5DXd ADCs Upfront and Milestone Payments

(Unit: Bn JPY)

Asset	Item	FY2024 Q2 YTD Results	YoY	FY2024 Forecast (as of Oct)	vs Apr Forecast	Total Consideration (as of Sep 2024)
ENHERTU	Upfront Payment	5.1	+0.2	10.2	-	149.0
	Regulatory Milestones	4.7	+0.5	21.2	+11.8 *	137.7
	Quid Related Payment	0.6	+0.0	1.2	-	17.2
	Sales Milestones	-	-	56.2	-	42.8
Dato-DXd	Upfront Payment	3.2	-	6.4	-	115.9
	Regulatory Milestones	-	-	5.6	-	-
AZ Alliance Total		**13.6**	+0.8	**100.8**	+11.8	**462.6**
HER3-DXd	Upfront Payment	3.9	+3.9	19.0	+0.1	112.7
	Satisfaction of Quid Rights **	0.5	+0.5	0.7	+0.7	7.3
I-DXd	Upfront Payment	7.3	+7.3	14.7	-	225.4
	Satisfaction of Quid Rights	0.4	+0.4	0.7	+0.7	7.3
DS-6000 (R-DXd)	Upfront Payment	3.1	+3.1	6.2	-	112.7
	Satisfaction of Quid Rights	0.4	+0.4	0.6	+0.6	7.3
US Merck Alliance Total		**15.6**	+15.6	**41.8**	+2.1	**472.6**

* Added US HER2 low BC (pre chemo) (¥10.3 Bn) and US HER2+ solid tumors (¥1.5 Bn) to the Oct forecast as regulatory milestones.

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

Major R&D Milestones (ENHERTU®)

As of Oct 2024

Project		Target indication [phase, study name]	FY2024 H1	FY2024 H2	FY2025
ENHERTU®	BC	• HER2+, adjuvant* [Ph3, DESTINY-Breast05]			• TLR anticipated
		• HR+/HER2 low or HER2 ultralow, chemo naive [Ph3, DESTINY-Breast06]	**• Filing accepted（EU）**	**• Filing accepted（JP/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]	**• Approved (CN)**		
	NSCLC	• HER2 mutation, 2L+ [Ph2, DESTINY-Lung05]		**• Approved (CN) ****	
		• HER2 mutation, 1L [Ph3, DESTINY-Lung04]			• TLR anticipated
	BTC	• HER2 expressing, 1L [Ph3, DESTINY-BTC01]	**• Study started**		
	Other tumors	• HER2 expressing tumors [Ph2, DESTINY-PanTumor02]	• Approved (US)		

Bold: update from FY2024 Q1

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

*: Adjuvant therapy for HER2 positive breast cancer patients with residual invasive disease following neoadjuvant therapy **: Approved based on the results of DESTINY-Lung02 and DESTINY-Lung05

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

Major R&D Milestones (Dato-DXd)

As of Oct 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		
		• Stage I adenocarcinoma NSCLC, EGFR mutated, mono or rilvegostomig combo [Ph3, TROPION-Lung12]		**• Study start planned**	
		• 1L, EGFR mutated, osimertinib combo [Ph3, TROPION-Lung14]	• Study started		
		• 2L+, EGFR mutated, osimertinib combo [Ph3, TROPION-Lung15]		**• Study started**	
		• 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 FY2024 Q1

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 Oct 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 obtained**		
	CRC, BTC, HCC	**• 2L+ [Ph1/2, MK-1022-011]**		**• Study start planned**	
I-DXd	SCLC	• 2L+ [Dose optimization, Ph2, IDeate-Lung01]			**• TLR anticipated**
		• 2L [Ph3, IDeate-Lung02]	**• Study started**		
		• 1L [Ph1b/2, IDeate-Lung03]	**• Study started**		
	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 FY2024 Q1

BTC; biliary tract cancer, CRC: colorectal cancer, CRL: complete response letter, HCC: hepatocellular carcinoma, NSCLC: non-small cell lung cancer, OVC: ovarian cancer, SCLC: small cell lung cancer, TLR: top line results

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

Major R&D Milestones (Next Wave)

As of Oct 2024

Project	Target indication [phase, study name]	FY2024		FY2025
		H1	H2	
valemetostat	• r/r PTCL [Registrational Ph2, VALENTINE-PTCL01]	• Approved (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)	
MMR vaccine (VN-0102)	• Mixed measles-mumps-rubella vaccine [Ph3]	• Filing accepted (JP)		

Bold: update from FY2024 Q1

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

*: Timeline for "Planned regulatory filing" indicates expected filing acceptance date
Timeline indicated is based on the current forecast and subject to change

Major R&D Pipeline: 5DXd ADCs ①

As of Oct 2024

Daiichi-Sankyo

Phase 1	Phase 1/2	Phase 2
(US/EU/Asia) HER2 low BC Chemo naïve/post chemo DESTINY-Breast08	(US/EU/Asia) HER2+ BC 2L+/1L DESTINY-Breast07	(JP/US/EU/Asia) HER2 expressing solid tumors DESTINY-PanTumor02
(US/EU/Asia) HER2+ NSCLC (durvalumab, volrustomig and rilvegostomig combo) 1L DESTINY-Lung03	(JP/US/EU/Asia) HER2 expressing GC combo, 2L+/1L DESTINY-Gastric03	(CN) HER2 expressing solid tumors DESTINY-PanTumor03
(US/EU) BC, NSCLC (pembrolizumab combo)	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) solid tumors TROPION-PanTumor03
(JP/US) solid tumors TROPION-PanTumor01	(US/EU/Asia) solid tumors (saruparib combo) PETRA	(JP/US/EU/Asia) EGFR mutated NSCLC 2L (osimertinib combo) ORCHARD
(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) TROPION-Lung02	(CN) NSCLC, TNBC TROPION-PanTumor02	(US/EU/Asia) resectable early-stage NSCLC neoadjuvant (durvalumab combo) NeoCOAST-2
(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	

Phase 1	Phase 1/2	Phase 2
(JP/US/EU/Asia) NSCLC	(US/EU/Asia) in prep CRC, BTC, HCC 2L+ MK-1022-011	(JP/US/EU/Asia) solid tumors HERTHENA-PanTumor01
(JP/US/Asia) EGFR mutated NSCLC, 1/2L (osimertinib combo)	(JP/US/EU/Asia) in prep StageIV NSCLC 1L (pembrolizumab + carboplatin combo) KEYMAKER-U01 Substudy 01A	(JP/US/EU/Asia) ES-SCLC 2L+ IDeate-Lung01
(JP/US) renal cell carcinoma, ovarian cancer	(JP/US) ESCC, CRPC, squamous NSCLC, SCLC, etc. IDeate-PanTumor01	(JP/US/EU/Asia) solid tumors 2L+ IDeate-PanTumor02
	(JP/US/EU/Asia) ES-SCLC, 1L IDeate-Lung03	
	(JP/US/EU/Asia) in prep StageIV NSCLC 1L (pembrolizumab ± carboplatin combo) KEYMAKER-U01 Substudy 01A	

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

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

AGA: actionable genomic alterations, BTC: biliary tract cancer, BC: breast cancer, CRC: colorectal cancer, CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, ES-SCLC: extensive stage-small cell lung cancer, GC: gastric cancer, HCC: hepatocellular carcinoma, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, TNBC: triple negative breast cancer

Major R&D Pipeline: 5DXd ADCs ②

As of Oct 2024

Phase 2/3	Phase 3			Regulatory phase
(JP/US/EU/Asia) platinum-resistant ovarian cancer 2L+ REJOICE-Ovarian01	(JP/US/EU/Asia) HER2+ BC adjuvant*1 DESTINY-Breast05	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1<50%) 1L (pembrolizumab combo) TROPION-Lung07	(JP/US/EU/Asia) TNBC (PD-1/PD-L1 inhibitor ineligible) 1L TROPION-Breast02	(JP/US/EU) HR+ and HER2 low or HER2 ultralow BC chemo naïve DESTINY-Breast06
	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09	(JP/US/EU/Asia) NSCLC (w/o AGA, PD-L1≥ 50%) 1L (pembrolizumab combo) TROPION-Lung08	(JP/US/EU/Asia) TNBC adjuvant*1 (mono or durvalumab combo) TROPION-Breast03	(US/EU) non-squamous NSCLC 2L+ TROPION-Lung01
	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11	(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, PD-L1≥ 50%) 1L (rilvegostomig combo) TROPION-Lung10	(JP/US/EU/Asia) TNBC neoadjuvant and adjuvant (durvalumab combo) TROPION-Breast04	(JP/US/EU/CN) HR+ and HER2 low or HER2 negative BC 2/3L TROPION-Breast01
	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	(JP/US/EU/Asia) Stage I adenocarcinoma NSCLC adjuvant (rilvegostomig combo) TROPION-Lung12	(JP/US/EU/Asia) PD-L1 positive TNBC 1L (mono or durvalumab combo) TROPION-Breast05	(US) EGFR mutated NSCLC 3L HERTHENA-Lung01
	(JP/US/EU/Asia) HER2 mutant NSCLC 1L DESTINY-Lung04	(JP/US/EU/Asia) EGFR mutated NSCLC 1L (osimertinib combo) TROPION-Lung14	(JP/US/EU/Asia) EGFR mutated NSCLC 2L HERTHENA-Lung02	
	(JP/US/EU/Asia) in prep HER2 expressing BTC 1L (mono or rilvegostomig combo) DESTINY-BTC01	(JP/US/EU/Asia) EGFR mutated NSCLC 2L+ (mono or osimertinib combo) TROPION-Lung15	(JP/US/EU/Asia) ES-SCLC 2L IDeate-Lung02	
		(JP/US/EU/Asia) NSCLC (w/o AGA) 1L (durvalumab combo) AVANZAR		

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

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

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

AGA: actionable genomic alterations, BTC: biliary tract cancer, BC: breast cancer, ES-SCLC: extensive stage-small cell lung cancer, GC: gastric cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, TNBC: triple negative breast cancer

Major R&D Pipeline: Next Wave

As of Oct 2024

Phase 1	Phase 1/2	Phase 2	Phase 3	Regulatory phase
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	DS-3939 TA-MUC1-directed ADC 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) CLDN6-directed ADC Solid tumors	MK-6070 (DS3280) (US) DLL3 directed tri-specific T-cell engager DLL3 expressing advanced cancer	DS-1001 (JP) Mutant IDH1 inhibitor Glioma	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-7011 (JP/US/EU/Asia) Anti-TLR7 antibody Systemic lupus erythematosus	DS-1211 (US/EU) TNAP inhibitor Pseudoxanthoma elasticum		
DS-1471 Anti-CD147 antibody Solid tumors	DS-2325 (EU) KLK5 inhibitor Netherton syndrome			
Valemetostat EZH1/2 inhibitor, HER2+ GC, HER2 low BC (ENHERTU® combo) and non-squamous NSCLC (Dato-DXd combo)				

Oncology

Specialty medicine

Vaccine

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

Rare Pediatric Disease Designation (US)

Fast Track Designation (US)

BC: breast cancer, BCL: B cell lymphoma, GC: gastric cancer, NSCLC: non-small cell lung cancer

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