Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2023 Q3
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Koji Ogawa

Executive Officer, CFO

January 31, 2024

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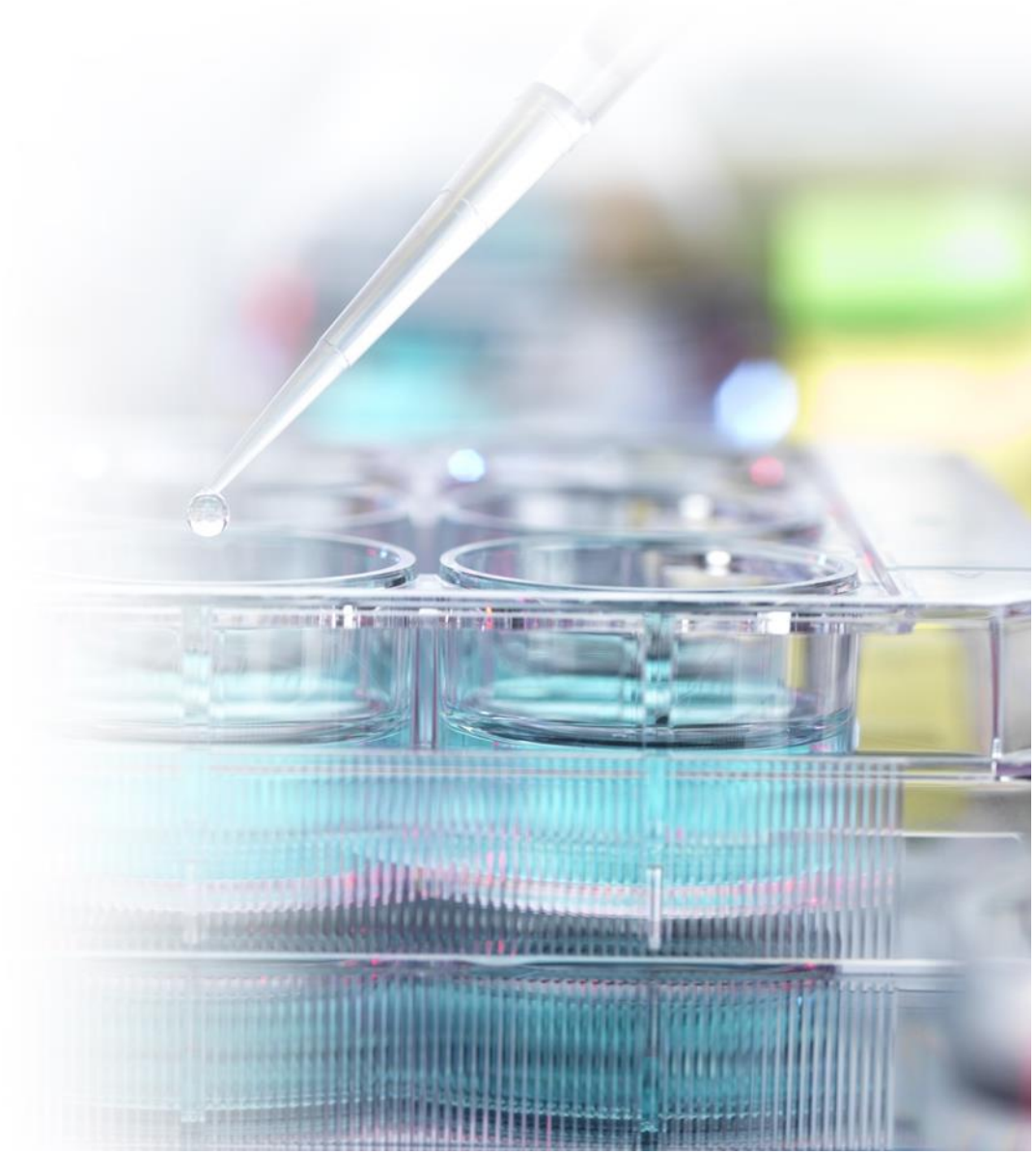
1. **FY2023 Q3 Financial Results**
2. FY2023 Forecast/ Annual Dividend
3. Business Update
4. R&D Update
5. Appendix



Overview of FY2023 Q3 Results

(Bn JPY)

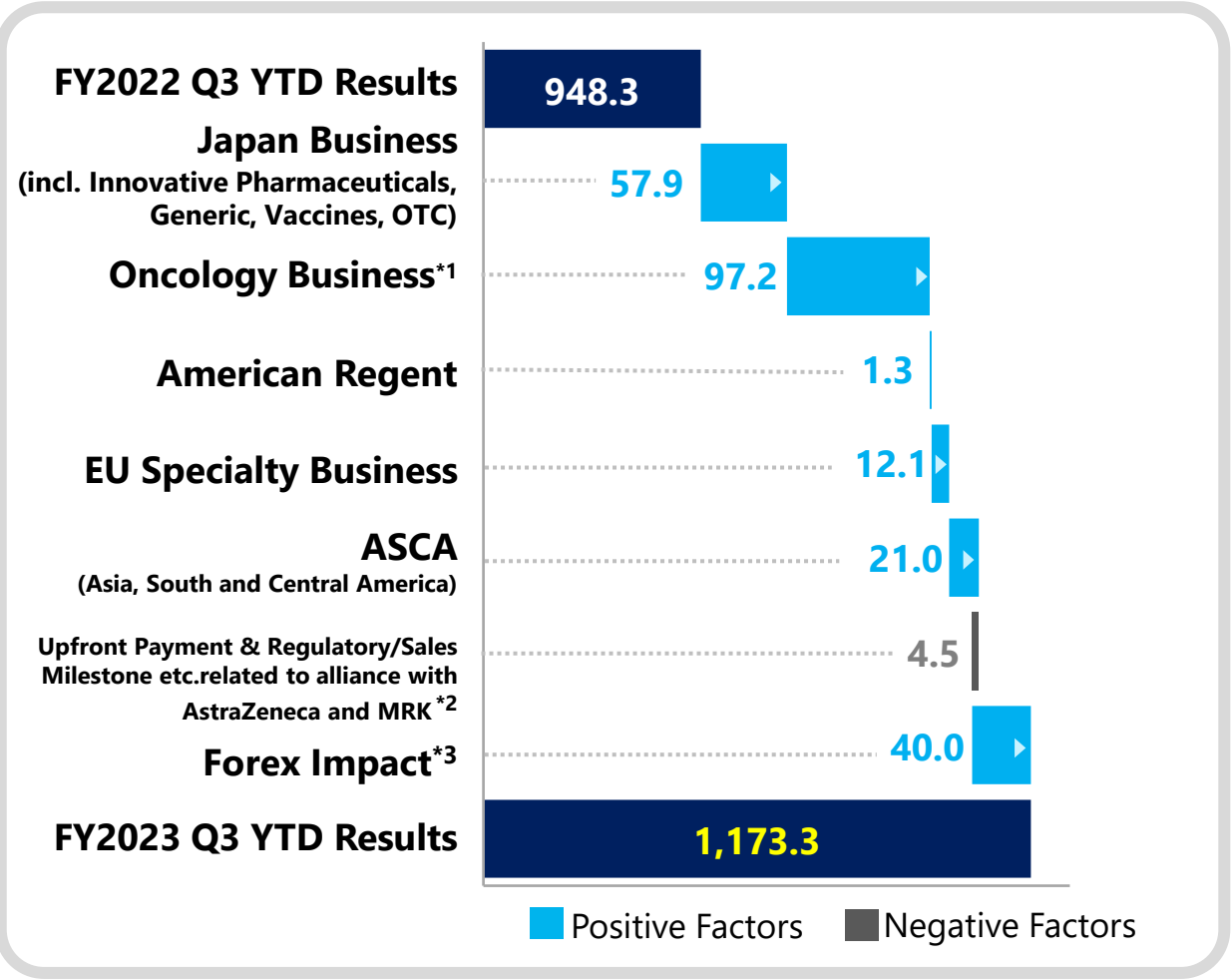
	FY2022 Q3 YTD Results	FY2023 Q3 YTD Results	YoY	
Revenue	**948.3**	**1,173.3**	**+23.7%**	**225.0**
Cost of sales*	257.4	310.3		52.9
SG&A expenses*	330.8	433.9		103.1
R&D expenses*	241.7	256.8		15.1
Core operating profit *	**118.3**	**172.2**	**+45.5%**	**53.9**
Temporary income*	11.0	26.9		15.8
Temporary expenses*	2.2	4.6		2.3
Operating profit	**127.1**	**194.6**	**+53.0%**	**67.4**
Profit before tax	**127.5**	**199.8**		**72.4**
Profit attributable to owners of the Company	**86.7**	**163.6**	**+88.7%**	**76.9**

Currency Rate	USD/JPY	136.53	143.29	+6.76
	EUR/JPY	140.60	155.28	+14.68

*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

Revenue

Increased by 225.0 Bn JPY (Increased by 185.0 Bn JPY excl. forex impact)



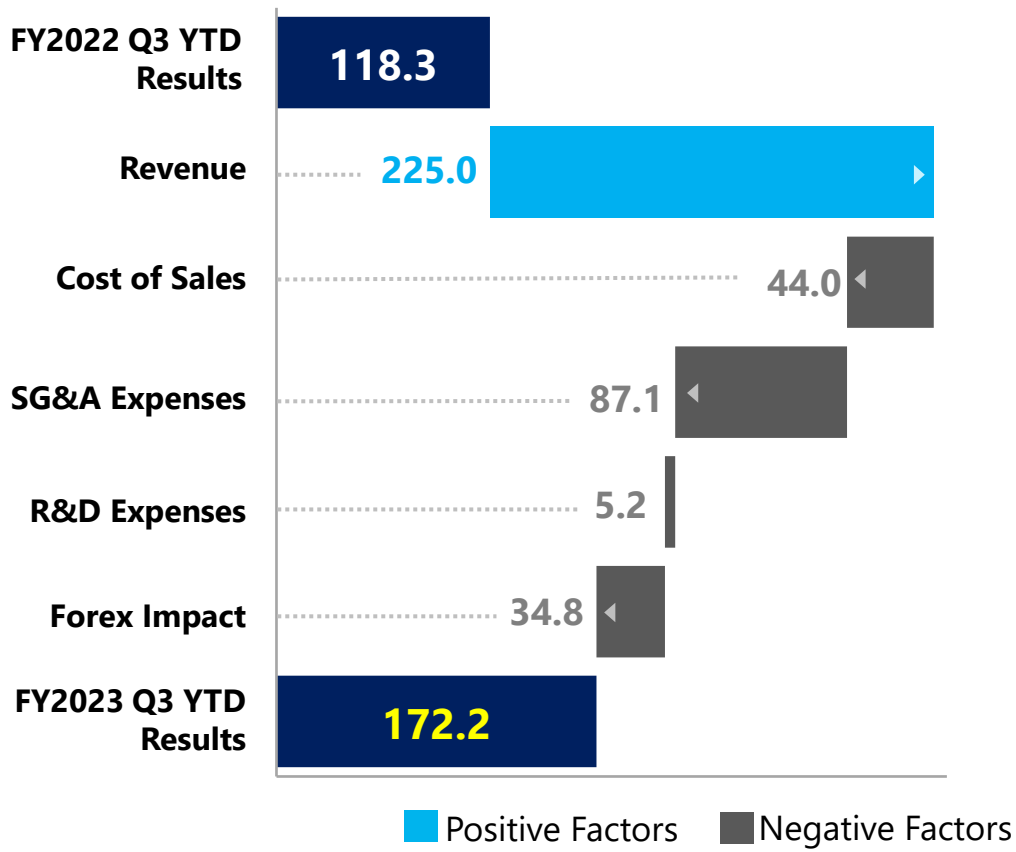
(Bn JPY)

Positive Factors		Negative Factors	
Japan Business Unit			
Inavir	+13.8		
Lixiana	+10.0		
Enhertu	+9.2		
Tarlige	+6.3		
Vacciness Business	+12.1		
Daiichi Sankyo Healthcare	+5.1		
Oncology Business Unit*1			
Enhertu	+94.7		
Vanflyta	+1.3		
American Regent Unit			
Venofer	+4.9	Injectafer	-5.6
GE injectables	+0.7		
EU Specialty Business Unit			
Lixiana	+9.4	Olmesartan	-1.7
Nilemdo/Nustendi	+6.0		
ASCA (Asia, South and Central America) Business Unit			
Enhertu	+18.3		
Upfront Payment & Regulatory/Sales Milestone etc. related to alliance with AstraZeneca and MRK *2			
Upfront Payment related to alliance with MRK	+5.7	Enhertu Regulatory Milestone	-9.7

*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products
*2 Merck & Co., Inc., Rahway, NJ, USA
*3 Forex impact USD: +16.5, EUR : +19.1, ASCA: +4.4

Core Operating Profit

Increased by 53.9 Bn JPY (Increased by 48.6 Bn JPY excl. forex impact)



(Bn JPY)

Revenue +225.0
incl. forex impact of +40.0

Cost of Sales +44.0
Increase in cost of sales due to the revenue increase

SG&A Expenses +87.1
Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca

R&D Expenses +5.2
Increase in 5DXd ADCs* R&D investments

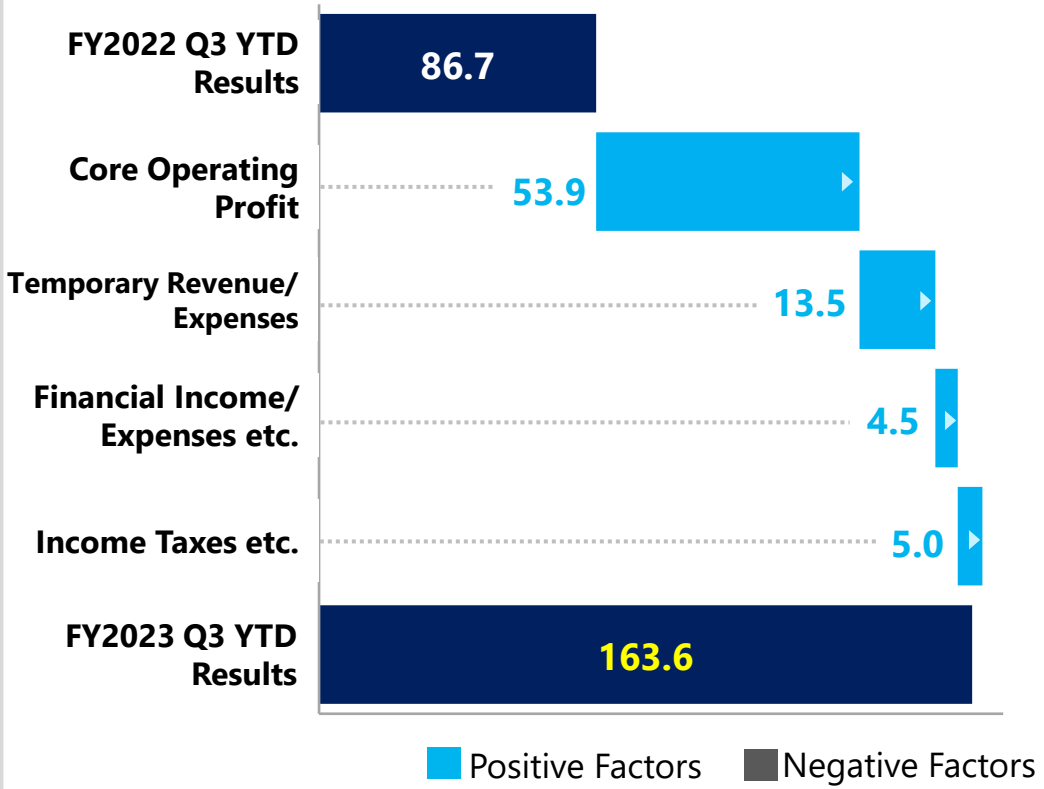
Forex Impact +34.8 **(Profit Decreased)**
Cost of Sales +8.9
SG&A Expenses +16.0
R&D Expenses +9.9

***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 76.9 Bn JPY

(Bn JPY)



Temporary Income/Expenses ····· **+13.5 (Profit Increased)**

	FY2022 Q3 YTD Results	FY2023 Q3 YTD Results	YoY
Temporary Income	11.0*1	26.9*2	+15.8
Temporary Expenses	2.2	4.6	+2.3

*1 Gains related to sales of subsidiary of Daiichi Sankyo (China) (6.0)
Gains on reversal related to closure of Plexxikon (3.3)
*2 Lump sum payment received from Novartis following the settlement of Plexxikon's patent infringement lawsuit (26.1)

Financial Income/Expenses etc. ····· **+4.5 (Profit Increased)**

- Increase in interest income ····· +9.6
- Improvement in investment securities valuation gains/losses ····· +5.3
- Deterioration in forex gains/losses ····· -9.3

Income Taxes etc. ····· **-5.0 (Profit Increased)**

	FY2022 Q3 YTD Results	FY2023 Q3 YTD Results	YoY
Profit before Tax	127.5	199.8	+72.4
Income Taxes etc.	40.8	35.7	-5.0
Tax rate	32.0%	17.9%	-14.1%

Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2022 Q3 YTD Results	FY2023 Q3 YTD Results	YoY
Japan Business	356.4	412.3	+55.9
Daiichi Sankyo Healthcare	54.8	59.9	+5.1
Oncolgy Business	124.7	233.0	+108.2
Enhertu	122.1	227.5	+105.4
Turalio	2.7	4.1	+1.4
American Regent	143.5	152.0	+8.5
Injectafer	41.8	38.0	-3.8
Venofer	38.2	45.2	+7.0
GE injectables	55.6	59.1	+3.5
EU Specialty Business	112.5	137.6	+25.1
Lixiana	87.8	107.3	+19.6
Nilemdo/Nustendi	4.9	12.1	+7.2
Olmesartan	14.8	14.5	-0.3
ASCA (Asia, South and Central America) Business	106.4	131.8	+25.4

Currency Rate	USD/JPY	136.53	143.29	+6.76
	EUR/JPY	140.60	155.28	+14.68

Revenue: Major Products in Japan

(Bn JPY)

		FY2022 Q3 YTD Results	FY2023 Q3 YTD Results	YoY
Lixiana	anticoagulant	**79.5**	**89.5**	**+10.0**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**30.4**	**33.3**	**+2.9**
Tarlige	pain treatment	**29.1**	**35.4**	**+6.3**
Vimpat	anti-epileptic agent	**16.7**	**20.0**	**+3.2**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**15.6**	**15.8**	**+0.3**
Tenelia	type 2 diabetes mellitus treatment	**17.0**	**16.1**	**-0.9**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**8.5**	**17.7**	**+9.2**
Efient	antiplatelet agent	**15.7**	**19.7**	**+3.9**
Canalia	type 2 diabetes mellitus treatment	**12.5**	**12.5**	**-0.1**
Loxonin	anti-inflammatory analgesic	**14.7**	**12.5**	**-2.3**
Emgality	prophylaxis of migraine attacks	**4.7**	**5.7**	**+1.0**

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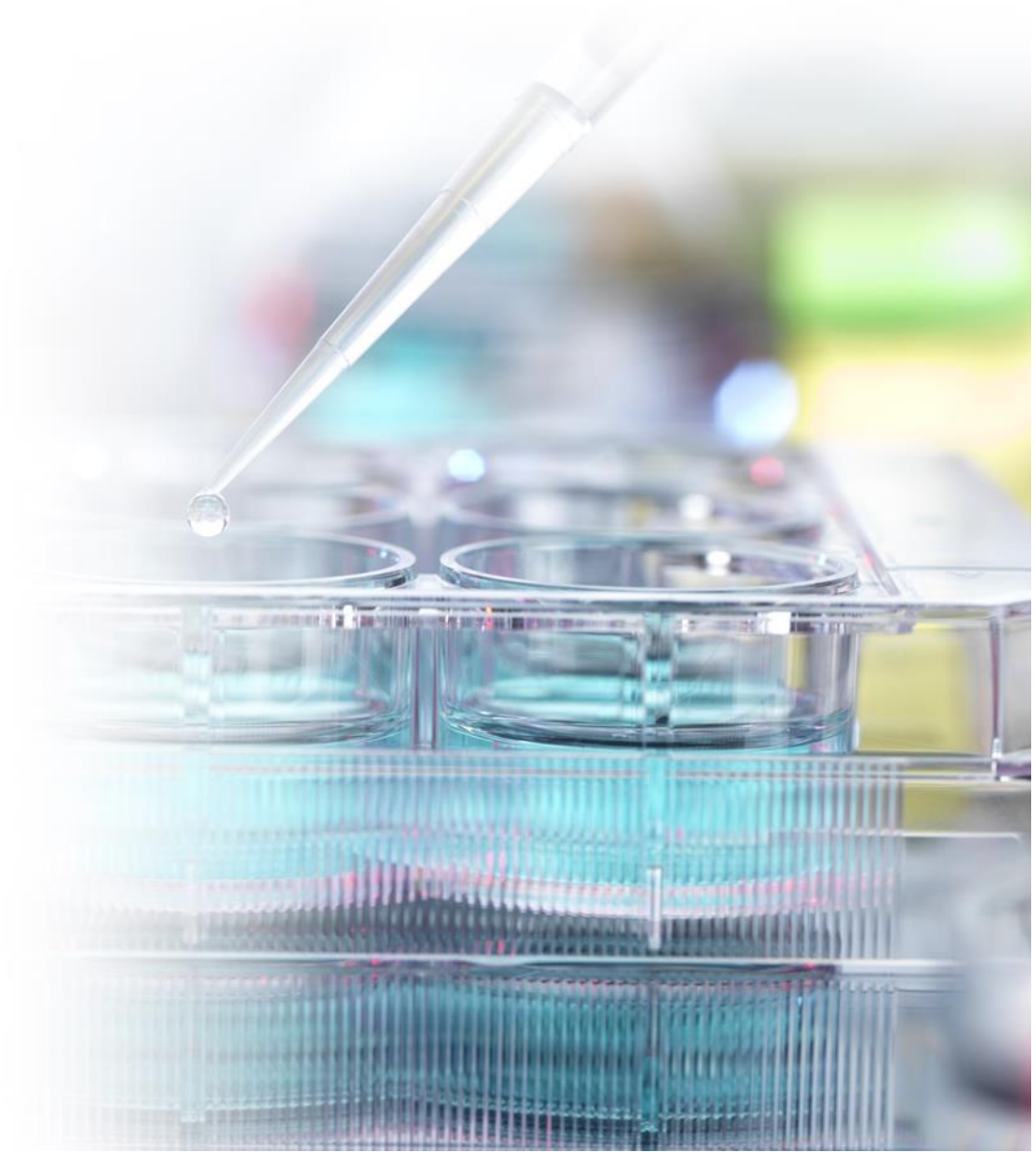


Revision to the forecast

(Bn JPY)

	FY2023 Forecast (As of Oct.)	FY2023 Forecast (As of Jan.)	vs. Forecast as of Oct.
Revenue	**1,550.0**	**1,580.0**	**+30.0**
Cost of sales *	410.0	413.0	+3.0
SG&A expenses *	610.0	619.0	+9.0
R&D expenses *	375.0	368.0	-7.0
Core operating profit*	**155.0**	**180.0**	**+25.0**
Temporary income*	-	27.0	+27.0
Temporary expenses*	5.0	7.0	+2.0
Operating profit	**150.0**	**200.0**	**+50.0**
Profit before tax	**160.0**	**205.0**	**+45.0**
Profit attributable to owners of the Company	**135.0**	**175.0**	**+40.0**

Currency Rate	USD/JPY	143.00	143.72	+0.72
	EUR/JPY	154.19	155.21	+1.02

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

Revenue
↑ : Increase by forex impact, sales increase of Inavir® due to outbreak of influenza, sales increase due to supply of Daichirona®, etc.

Cost of sales
↑ : Increase due to the revenue increase, increase by forex impact
↓ : Improvement in cost of sales ratio by change in product mix

SG&A Expenses
↑ : Increase due to ADC production expansion

R&D Expenses
↓ : Decrease by increase of cost sharing for 3 DXd ADC products with Merck & Co., Inc., Rahway, NJ, USA

Temporary income
↑ : Increase by lump sum payment received from Novartis following the settlement of Plexxikon's patent infringement lawsuit

Profit before tax
↓ : Increase in financial expenses due to deterioration in forex gains/losses etc.

Forex Impact vs. as of Oct.

Revenue +8.5 Bn JPY
Core operating profit +5.5 Bn JPY

* 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.

Revision of Annual Dividend

Increase FY2023 annual dividend forecast per share to 50 JPY

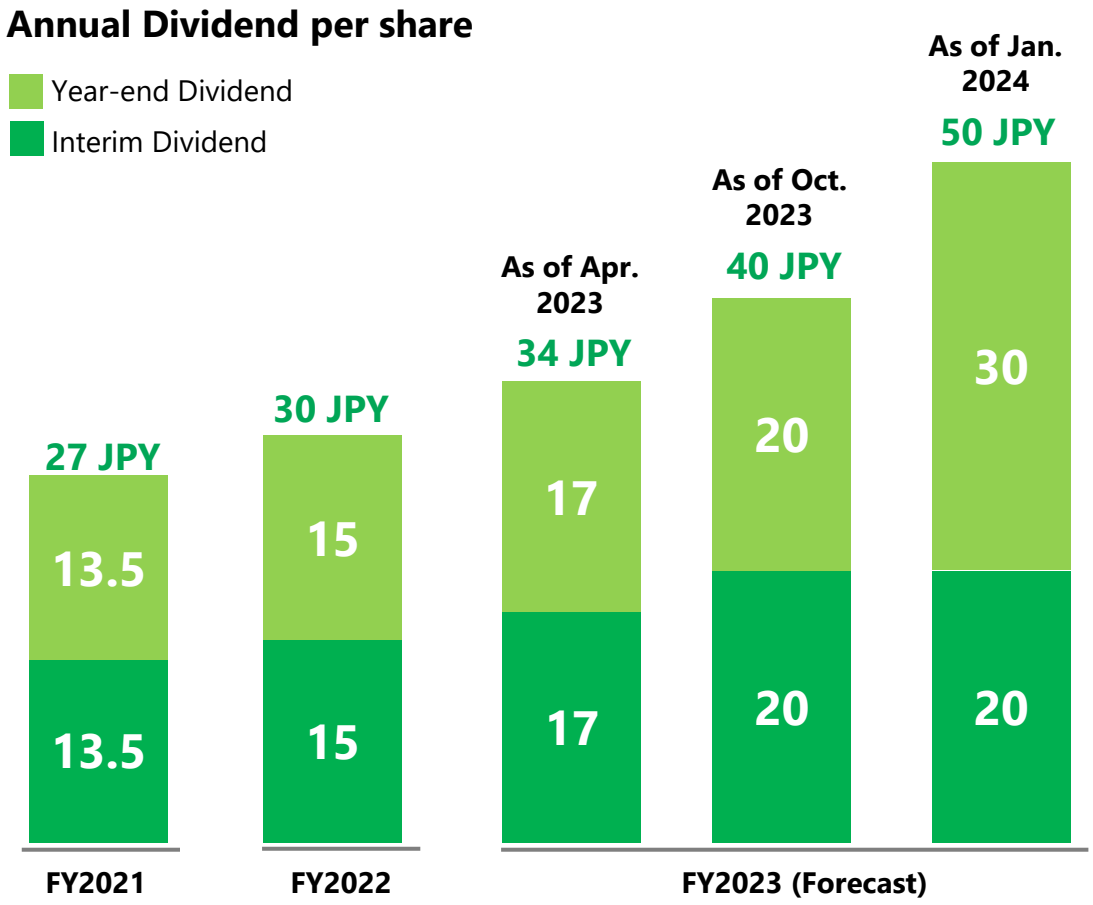
(Increase by 10 JPY compared to forecast as of October 2023; by 20 JPY compared to FY2022)

◆ FY2023 Annual Dividend Forecast

- **Forecast as of April 2023**
  Increase by 4 JPY to 34 JPY compared to FY2022 due to increased likelihood of achieving KPIs for FY2025 driven by sales growth of ENHERTU® and others

- **Forecast as of October 2023**
  Increase by 6 JPY to 40 JPY compared to forecast as of April 2023 due to received upfront payment related to strategic collaboration with Merck & Co., Inc., Rahway, NJ, USA for 3 DXd ADC products, and strong performance of ENHERTU® and others

- **Forecast as of January 2024**
  Increase by 10 JPY compared to forecast as of October 2023 to 50 JPY upon **FY2023 consolidated forecast revision** based on **continuous strong business performance** and **received lump sum payment from Novartis following the settlement of Plexxikon's patent infringement lawsuit**



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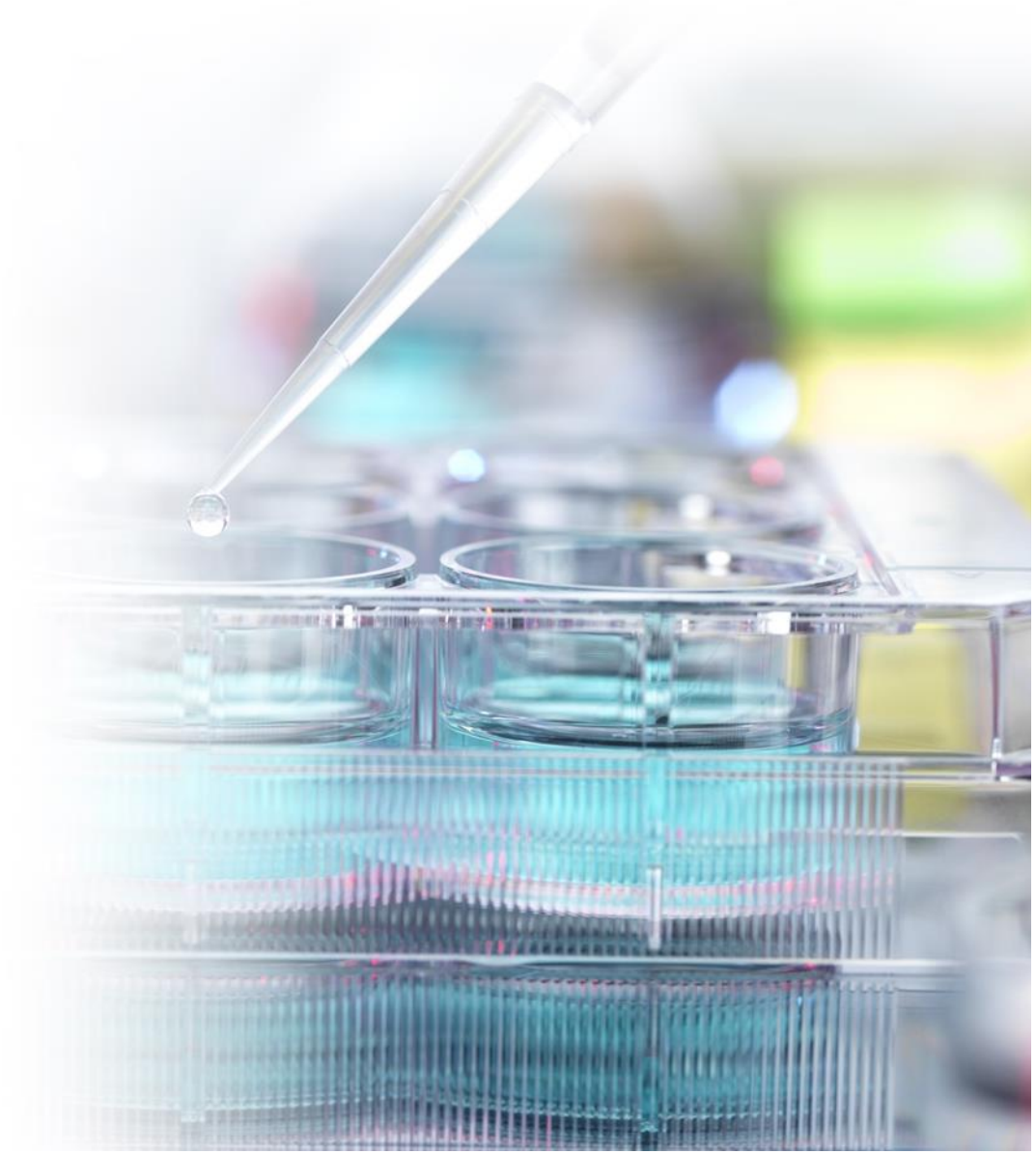


ENHERTU®

Revenue

(Bn JPY)

	FY2023 Q3 YTD Results	YoY	FY2023 Forecast	vs. Forecast as of Oct.	<Reference> Total Consideration
Product Sales	276.0	136.3	383.9	2.2	-
Japan	17.7	9.2	22.8	1.3	-
US	162.8	63.0	226.3	-3.2	-
Europe	64.7	42.4	94.5	1.7	-
ASCA	30.8	21.6	40.3	2.4	-
Upfront payment	7.6 *1	0.2	10.1 *1	0.3	149.0
Regulatory milestone payment	10.0 *1	-9.7	12.4 *1	0.4	137.7
US HER2+ Breast Cancer 3L	0.7	0.0	0.9	0.0	13.7
EU HER2+ Breast Cancer 3L	0.4	0.0	0.5	0.0	7.9
US HER2+ Gastric Cancer 2L + 3L	0.6	0.0	0.8	0.0	12.1
US HER2+ Breast Cancer 2L	0.7	-2.6	0.9	0.0	13.1
EU HER2+ Breast Cancer 2L	0.5	-2.0	0.7	0.0	10.1
US HER2-low Breast Cancer (post-chemo)	1.4	-5.4	1.9	0.1	27.7
EU HER2-low Breast Cancer (post-chemo)	1.0	1.0	1.3	0.0	19.8
EU HER2+ Gastric Cancer 2L	0.2	-0.9	0.3	0.0	4.8
US HER2 Mutant NSCLC 2L	0.9	-3.4	1.2	0.0	17.3
EU HER2 Mutant NSCLC 2L	3.6	3.6	3.8	0.2	11.1
Quid related payment	0.9 *1	0.0	1.2 *1	0.0	17.2
Sales milestone payment	-	-	29.0 *2 *3	-	42.2
Total	294.4	126.8	436.5	2.9	346.0

*1 Revenue recognized in each period

*2 Converted with assumed forex rate for FY2023 Q4 of 145 JPY to 1 USD (130 JPY to 1 USD as of Apr.)

*3 Milestone of 200Mn USD for achieving annual product sales of 2 Bn USD in co-commercialization territory with AstraZeneca.
(Total amount to be recognized as revenue in FY2023)

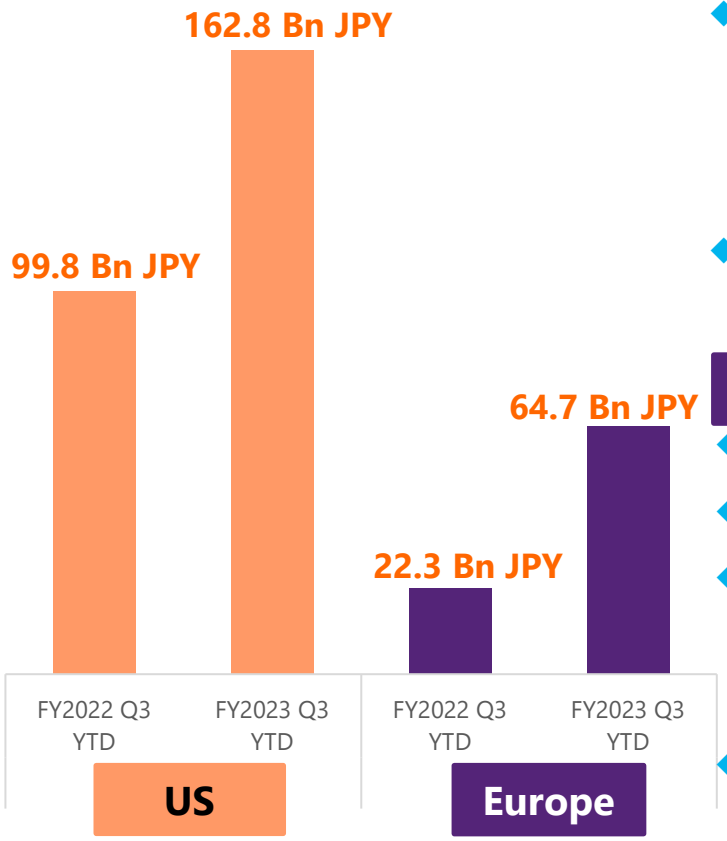
Ref. Total sales milestone payment:
1.75 Bn USD (Max)

ENHERTU®

Performance in Each Region (US, EU)

Global product sales: FY2023Q3 YTD results 276.0 Bn JPY（YoY +136.3 Bn JPY）FY2023 forecast 383.9 Bn JPY（vs. Forecast as of Oct. +2.2 Bn JPY）

ENHERTU®
trastuzumab deruxtecan



US

- **Product sales: FY2023Q3 YTD results 162.8 Bn JPY（1,136 Mn USD） FY2023 forecast 226.3 Bn JPY（1,575 Mn USD）**
- **Indication:** HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 2L+, HER2 mutant mNSCLC 2L+
- **Market share status**
  - HER2+ mBC 2L: Maintaining No.1 and increasing new patient share
  - HER2 low mBC: Maintaining No.1 new patient share
  - HER2+ mGC 2L: Maintaining No.1 new patient share
  - HER2 mutant mNSCLC 2L: Maintaining No.1 new patient share
- **Other progress**
  - Classified in NCCN*1 guidelines: endometrial cancer (Sep. 2023), cervical cancer (Sep. 2023) head and neck cancer (Dec. 2023), ovarian cancer (Jan. 2024)

Europe

- **Product sales: FY2023Q3 YTD results 64.7 Bn JPY (452 Mn USD) FY2023 forecast 94.5 Bn JPY (658 Mn USD)**
- **Indication**: HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 2L+, HER2 mutant mNSCLC 2L+
- **Market share status**
  - HER2+ mBC 2L: Maintaining No.1 new patient share in France, Germany and Spain, achieved No.1 new patient share in Italy
  - HER2 low mBC : Maintaining No.1 new patient share in France and Germany
- **Other progress**
  - Launched in Italy (Jul. 2023)
  - Approved for HER2 mutant mNSCLC 2L+ and started promotion (Oct. 2023)

Blue letters: updates from Q2

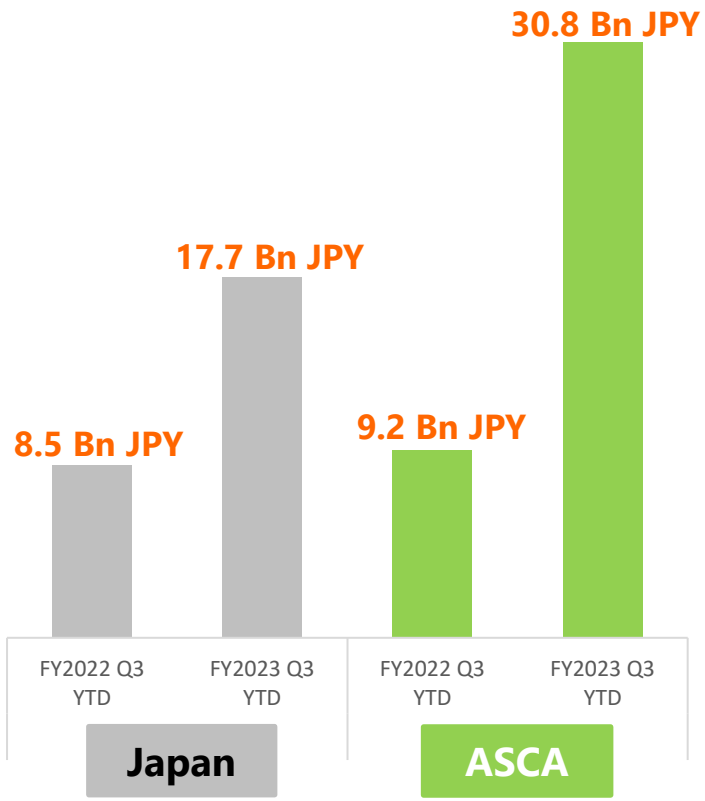
*1 NCCN: National Comprehensive Cancer Network

ENHERTU®

Performance in Each Region (Japan, ASCA)

Global product sales: FY2023Q3 YTD results 276.0 Bn JPY（YoY +136.3 Bn JPY）FY2023 forecast 383.9 Bn JPY（vs. Forecast as of Oct. +2.2 Bn JPY）

ENHERTU®
trastuzumab deruxtecan



Japan

- **Product sales: FY2023Q3 YTD results 17.7 Bn JPY FY2023 forecast 22.8 Bn JPY**
- **Indication:** HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 3L, HER2 mutant mNSCLC 2L+
- **Market share status**
  - HER2+ mBC 2L: Maintaining No.1 new patient share
  - HER2 low mBC: Maintaining No.1 new patient share
  - HER2+ mGC 3L: Maintaining No.1 new patient share
  - HER2 mutant mNSCLC 2L: Steady uptake in capturing new patient share
- **Other progress**
  - Approved for HER2 mutant mNSCLC 2L+ and started promotion (Aug. 2023)
  - Classified as a preferred regimen for HER2 mutant mNSCLC 2L+ treatment in guidelines in Japan (Nov. 2023)

ASCA

- **Product sales: FY2023Q3 YTD results 30.8 Bn JPY FY2023 forecast 40.3 Bn JPY**
- **Indication:** HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 2L+, HER2 mutant mNSCLC 2L+
- **Market share status**
  - Sales growing in Brazil, China and Taiwan
- **Other progress**
  - China: Launched for HER2+ mBC 2L (Jun. 2023), Approved for HER2 low mBC (post-chemo) and started promotion (Jul. 2023)
  - Brazil: Approved for HER2+ mGC 2L+ and HER2 mutant mNSCLC 2L+ and started promotion (Nov. 2023)

Blue letters: updates from Q2

Major Updates on Patent Disputes

Dispute with Novartis regarding Plexxikon's Patents

Dec. 2023 Our U.S. subsidiary Plexxikon settled with Novartis

- Plexxikon **received** a lump sum payment of **182 Mn USD (26.1 Bn JPY)** and the settlement resulted in the dismissal of Novartis's appeal
- The payment is **recorded as "Temporary income"** in Q3 financial results

Course of events

- Aug. 2017: Plexxikon filed a claim that Novartis' BRAF inhibitor Tafinlar® infringes Plexxikon's U.S. Patents to the U.S. District Court for the Northern District of California.
- Sep. 2022: the U.S. District Court ordered in favor of Plexxikon
- Oct. 2022: Novartis filed an appeal to the U.S. Court of Appeals for the Federal Circuit.

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

Nov. 2023 Final award issued by an arbitrator

- The final award followed and incorporated the Aug. 2022 decision* by the arbitrator, and **required SGN to pay 46 Mn USD** in **attorneys' fees and arbitration costs** to Daiichi Sankyo.

  * Aug. 2022 decision by arbitrator denied all claims by SGN that it has ownership interest in certain intellectual property rights related to Daiichi Sankyo's ADC technology

- The final award confirmed that the arbitrator **once again denied all claims made by SGN**, and with this award, **the arbitration proceedings were concluded**.

Major Updates on Patent Disputes

Dispute with Seagen (SGN) regarding Daiichi Sankyo ADC ② (Disputes regarding SGN's patent)

◆ **Nov. 2023 DS filed a notice of appeal to the U.S. Court of Appeals for the Federal Circuit seeking review of the amended final judgment by the U.S. District Court for the Eastern District of Texas**

Course of events for patent infringement litigation in Texas

- Oct. 2020: SGN filed a patent infringement lawsuit in the U.S. District Court for the Eastern District of Texas
- Apr. 2022: A trial was conducted in the court and the jury awarded SGN 41.8 Mn USD in damages
- Jul. 2022: The Court entered a judgment confirming the aforementioned jury verdict
- Oct. 2023: The Court's amended final judgment requires DS to pay SGN a royalty of 8% on sales of ENHERTU® from April 1, 2022 through November 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

◆ **Jan. 2024 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)**

➢ **The patent was the sole patent-in-suit in the infringement litigation in the U.S. District Court for the Eastern District of Texas between the parties, an appeal of which is now pending.**

Course of events for PGR

- Dec. 2020: DS filed a petition with the USPTO for the PGR contesting the patentability
- April 2022: The USPTO initiated the PGR
- July 2022: The USPTO deinstituted the PGR
- Feb. 2023: The USPTO reinitiated the PGR on the ground that DS's petition "presents compelling evidence of unpatentability"

Other Regional Initiatives

Japan

◆ **DAICHIRONA®FOR INTRAMUSCULAR INJECTION COVID-19 vaccine**

➢ Dec. 2023 **Supply** Omicron XBB.1.5-adapted monovalent vaccine

Europe

◆ **Update on Collaboration with Esperion Therapeutics, Inc**

➢ Jan. 2024 DSE and Esperion amended their collaboration as below

- for Esperion to transition to DSE manufacturing and supply responsibilities (tech transfer)
- to expand their collaboration in Europe and other territories, with DSE receiving the full right to the potential development and commercialization of a triple formulation product *1
- for DSE to now lead regulatory communications with the European Medicines Agency (EMA) regarding the pending "Cardiovascular outcome trial" label update for Nilemdo/Nustendi
- for DSE to pay Esperion 100Mn USD after execution of amended agreement, and 25Mn USD after EMA's decision on pending CLEAR Outcomes study *2 (125Mn USD in total)
- for Esperion to dismiss the pending litigation against DSE

*1 bempedoic acid, ezetimibe and a statin

*2 The trial has been designed to evaluate if bempedoic acid reduces CV events in high- and very high-risk patients who tolerate no or very low doses of statin

Meeting Information

ESG Meeting

- **Date and time: Thursday, February 29, 2024 16:00-17:30 (JST)**
- **Speaker: Kama Chairperson of the Board, Manabe CEO, Okuzawa COO, Fukuoka CStO[*1], Ogawa CFO, Matsumoto CHRO[*2] and others**
- **Meeting style: on site+virtual (Zoom)**

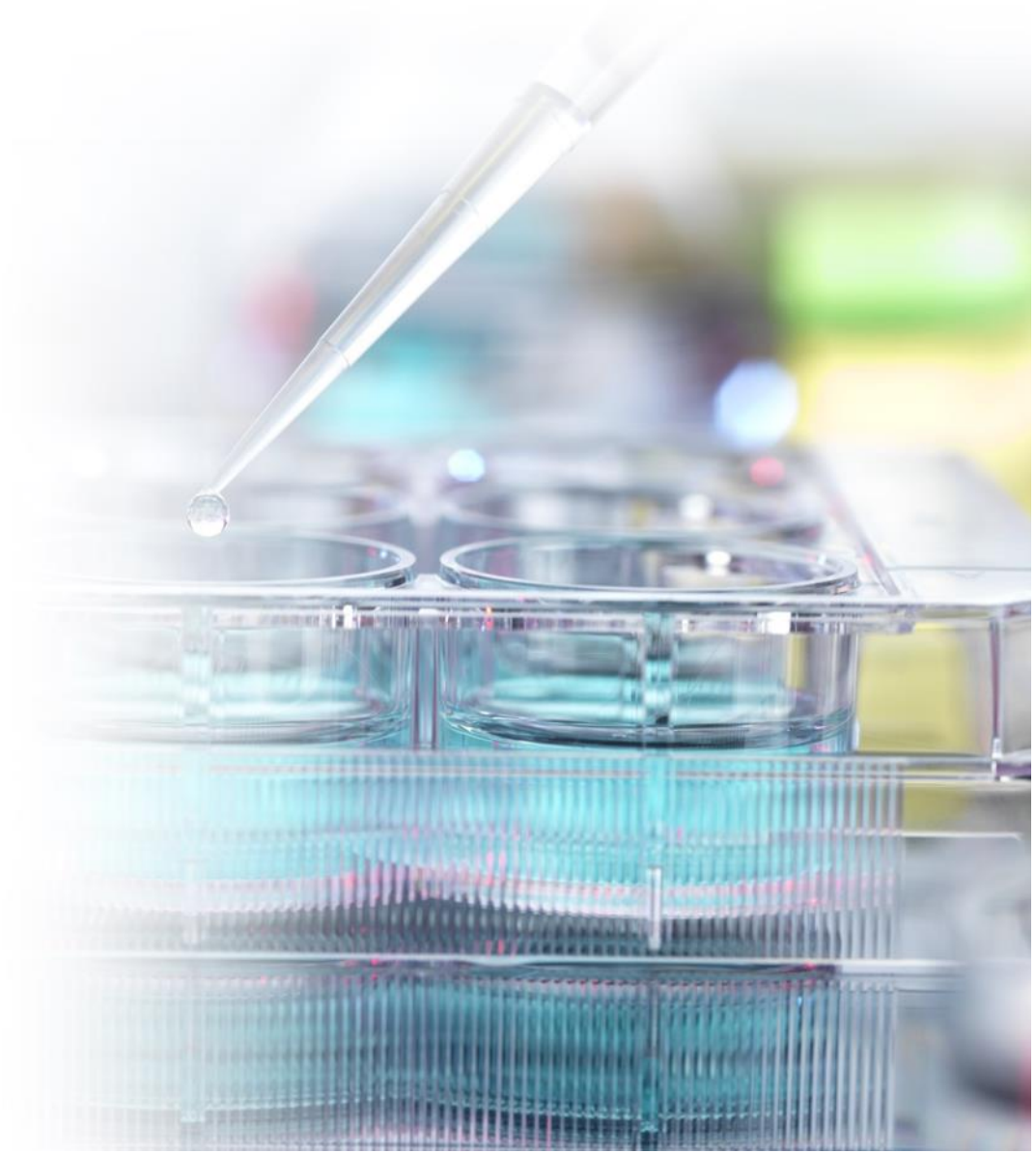
[*1] Chief Strategy Officer、[*2] Chief Human Resources Officer

ENHERTU® Business Briefing

- **Date and time: Friday, March 22, 2024 7:30-9:00 (JST)** (Thursday, March 21, 2024 18:30-20:00 (EDT))
- **Speaker: Manabe CEO, Ken Keller Global Head, Oncology Business Unit**
- **Meeting style: virtual (Zoom)**

Agenda

1. FY2023 Q3 Financial Results
2. Business Update
3. **R&D Update**
4. Appendix



5DXd ADCs Update

Next Wave Update

News Flow

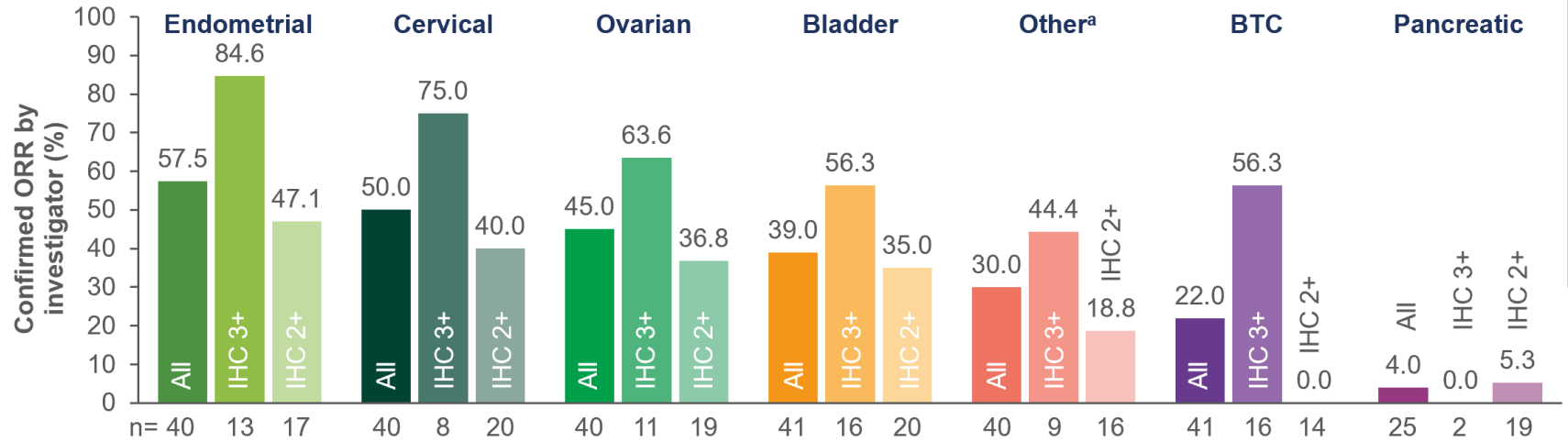
ENHERTU®

DESTINY-PanTumor02 study

Daiichi-Sankyo

Filing accepted with priority review in US in Jan 2024 for a tumor agnostic therapy in previously treated patients with HER2 expressing solid tumors

ORR



Median DOR, months (95% CI)[b]	Endometrial	Cervical	Ovarian	Bladder	Other[a]	BTC	Pancreatic
	NR (9.9, NR)	14.2 (4.1, NR)	11.3 (4.1, 22.1)	8.7 (4.3, 11.8)	22.1 (4.1, NR)	8.6 (2.1, NR)	5.7 (NR, NR)

	All patients (N=267)	IHC 3+ (n=75)	IHC 2+ (n=125)
ORR, % (95% CI)	37.1 (31.3, 43.2)	61.3 (49.4, 72.4)	27.2 (19.6, 35.9)
Median DOR, months (95% CI)[b]	11.3 (9.6, 17.8)	22.1 (9.6, NR)	9.8 (4.3, 12.6)

DESTINY-PanTumor02 study

An open-label, multicenter study, in HER2-expressing advanced solid tumors not eligible for curative therapy

- Primary endpoint: confirmed ORR
- Secondary endpoint: DOR, DCR, PFS, OS etc.

- Demonstrated clinically meaningful and durable responses and the safety profile was consistent with the known profile
- Submission data package includes DESTINY-CRC02 study and others*
- PDUFA date: May 30th, 2024

Analysis of ORR by investigator was performed in patients who received ≥1 dose of T-DXd; all patients (n=267; including 67 patients with IHC 1+ [n=25], IHC 0 [n=30], or unknown IHC status [n=12] by central testing) and patients with centrally confirmed HER2 IHC 3+ (n=75) or IHC 2+ (n=125) status. Analysis of DOR was performed in patients with objective response who received ≥1 dose of T-DXd; all patients (n=99; including 19 patients with IHC 1+ [n=6], IHC 0 [n=9], or unknown IHC status [n=4] by central testing) and patients with centrally confirmed HER2 IHC 3+ (n=46) or IHC 2+ (n=34) status. [a] Responses in extramammary Paget's disease, head and neck cancer, oropharyngeal neoplasm, and salivary gland cancer; [b] includes patients with a confirmed objective response only,

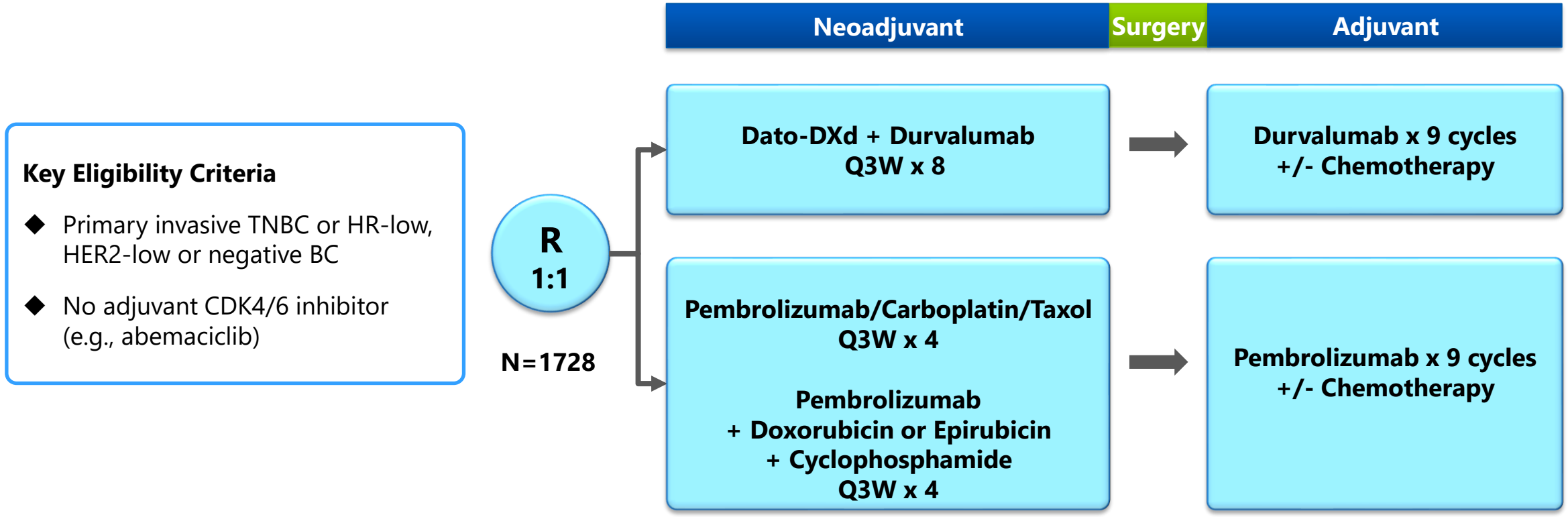
BTC: biliary tract cancer, CI: confidence interval, CRC: colorectal cancer, DCR: disease control rate, DOR: duration of response, IHC: immunohistochemistry, NR: not reached, ORR: objective response rate, OS: overall survival, PDUFA: Prescription Drug User Fee Act, PFS: progression-free survival

*Include DESTINY-Breast01, DESTINY-Gastric02 and DESTINY-Lung01 data

Dato-DXd TROPION-Breast04 study

Started new Ph3 study for neoadjuvant and adjuvant therapy of TNBC or HR-low, HER2-low or negative BC in Nov 2023

TROPION-Breast04 study design



Primary endpoint: pCR and EFS

Secondary endpoint: OS, DDFS, safety, PROs, etc.

BC; Breast cancer, DDFS: distant disease-free survival, EFS: event-free survival, ER: estrogen receptor, OS: overall survival, pCR: pathological complete response, PR: progesterone receptor, PRO: patient reported outcome, Q3W: every 3 weeks, TNBC: triple negative breast cancer

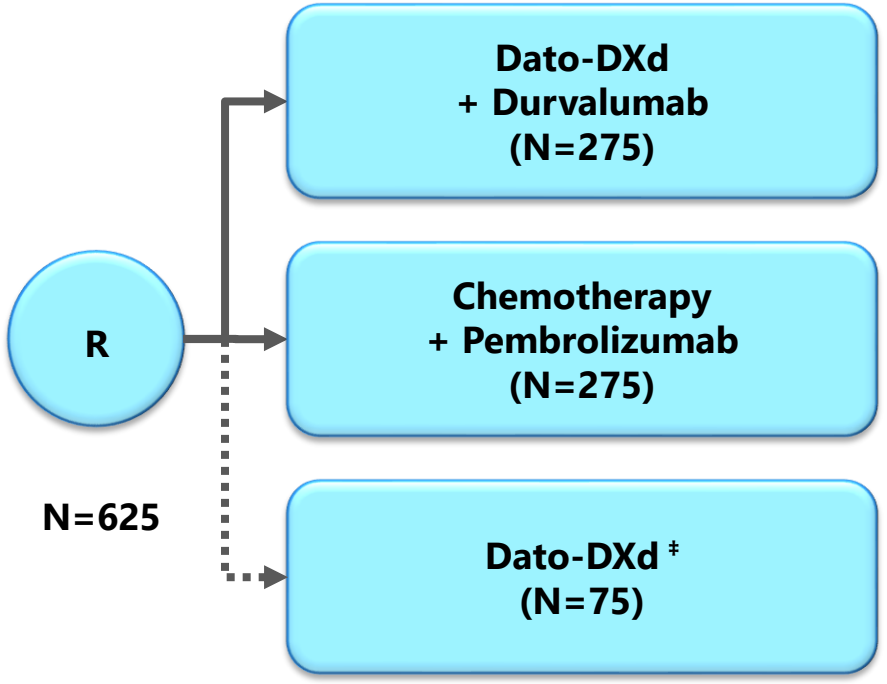
TROPION-Breast05 study

Started Ph3 combination study with durvalumab for PD-L1 positive metastatic TNBC 1L in Nov 2023

TROPION-Breast05 study design

Key Eligibility Criteria

- Previously untreated metastatic or locally advanced inoperable TNBC
- PD-L1+ (CPS ≥ 10 IHC 22C3) by central testing



Primary endpoint: PFS (BICR)

Secondary endpoint: OS, PFS (inv), ORR, DOR, etc.

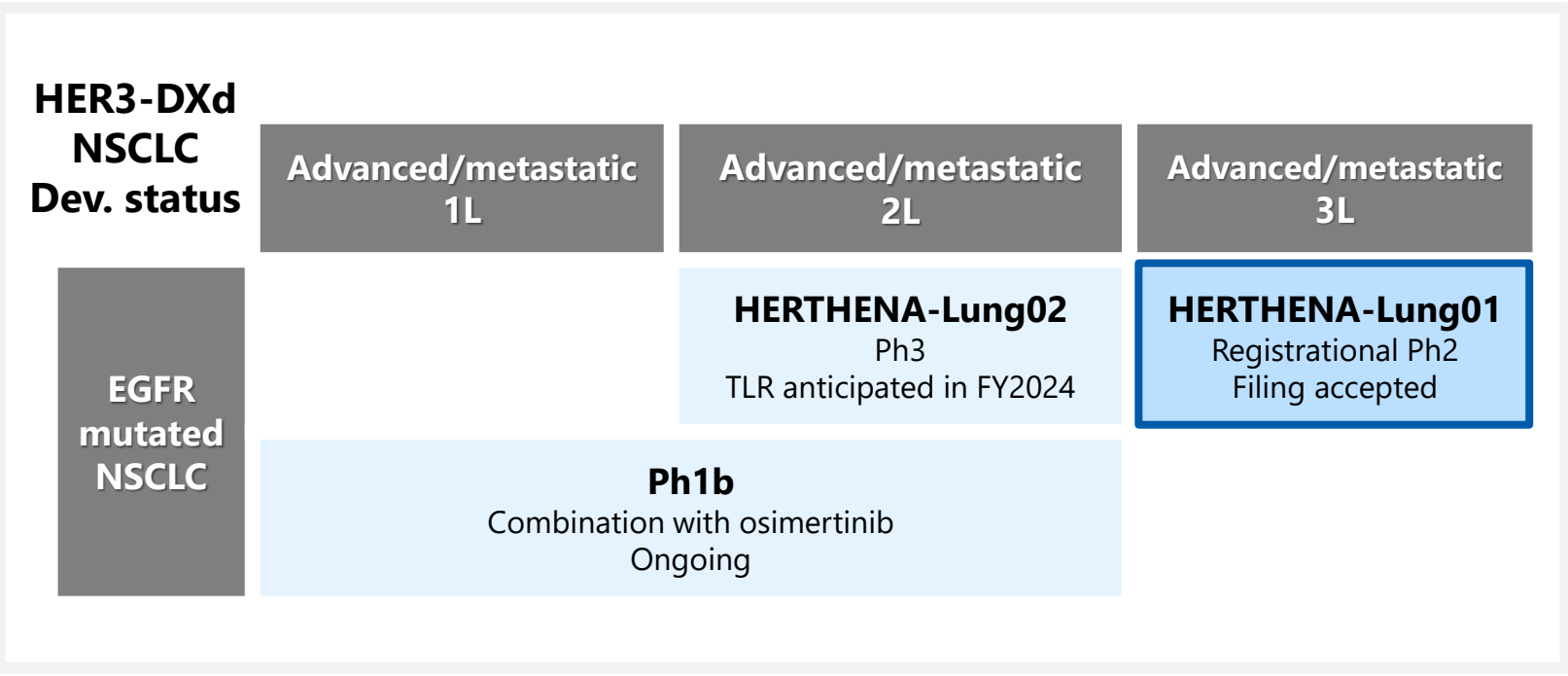
‡ This arm will be applied only to selected countries and regions with 1:1:1 randomization strategy, otherwise 1:1 in other arms.

BICR: blinded independent central review, CPS: combined positive score, DOR: duration of response, ER: estrogen receptor, IHC: immunohistochemistry, inv: investigator, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, PR: progesterone receptor, TNBC: triple negative breast cancer

HER3-DXd

HERTHENA-Lung01 study

Filing accepted with priority review in US for the treatment of patients with EGFR mutated NSCLC 3L, as a potential first HER3-targeted drug



HERTHENA-Lung01 study

Registrational Ph2 study to evaluate antitumor activities of HER3-DXd in patients with EGFR mutated NSCLC previously treated with at least one EGFR TKI and PBC

- Primary endpoint is ORR, and secondary endpoints are DOR, PFS, OS etc
- FDA granted BTD in Dec 2021
- HERTHENA-Lung02 study (Ph3) is ongoing as a confirmatory study

- **Sep 2023:** Data presented at WCLC. Efficacy was observed **across diverse mechanisms of EGFR TKI resistance** and **across a broad range of pretreatment tumor HER3 membrane expression**
- **Dec 2023:** Under the RTOR program, filing accepted and priority review granted in US. PDUFA date: Jun 26th, 2024

BTD: breakthrough therapy designation, DOR: duration of response, NSCLC: non-small cell lung cancer, ORR: objective response rate, OS: overall survival, PBC: platinum-based chemotherapy, PDUFA: Prescription Drug User Fee Act, PFS: progression-free survival, RTOR: Real time oncology review, TKI: tyrosine kinase inhibitor, TLR: top line results, WCLC: World Conference on Lung Cancer

HERTHENA-PanTumor01 study

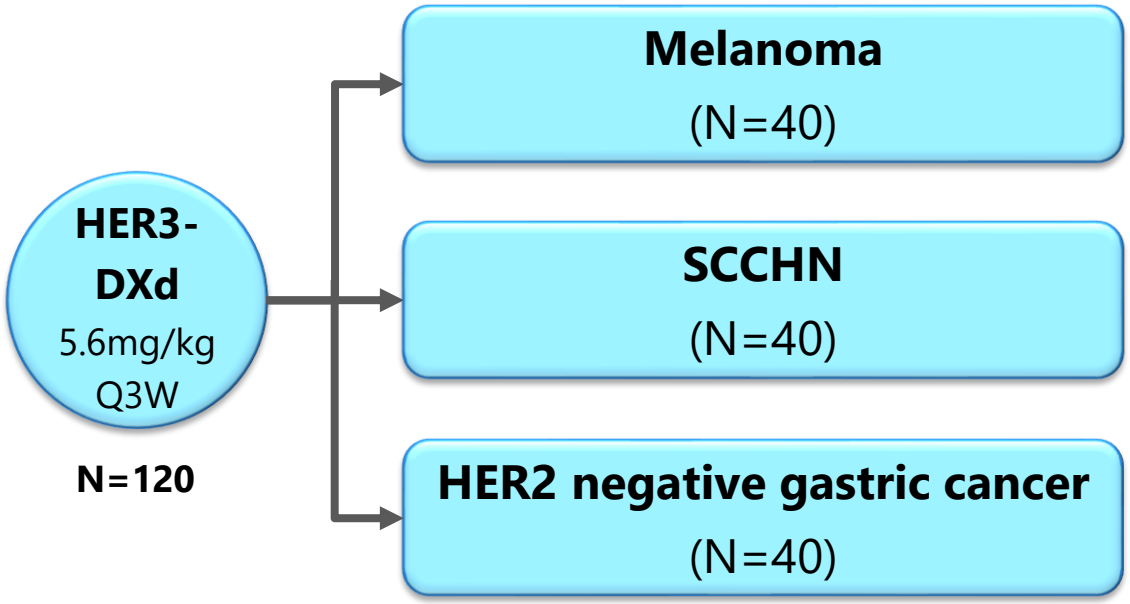
Seeking to expand to new tumor types

HERTHENA-PanTumor01 study design

HERTHENA-PanTumor01 study

Ph2 study in patients with locally advanced or metastatic solid tumors

- Patients who have received 1 or more prior lines of therapy



Primary endpoint: ORR

Secondary endpoint: DOR、DCR, PFS, OS, safety, etc.

- Selected new tumor targets based on in-house preclinical data
- Potential new cohorts to be added in the future
- Study start planned in FY2023

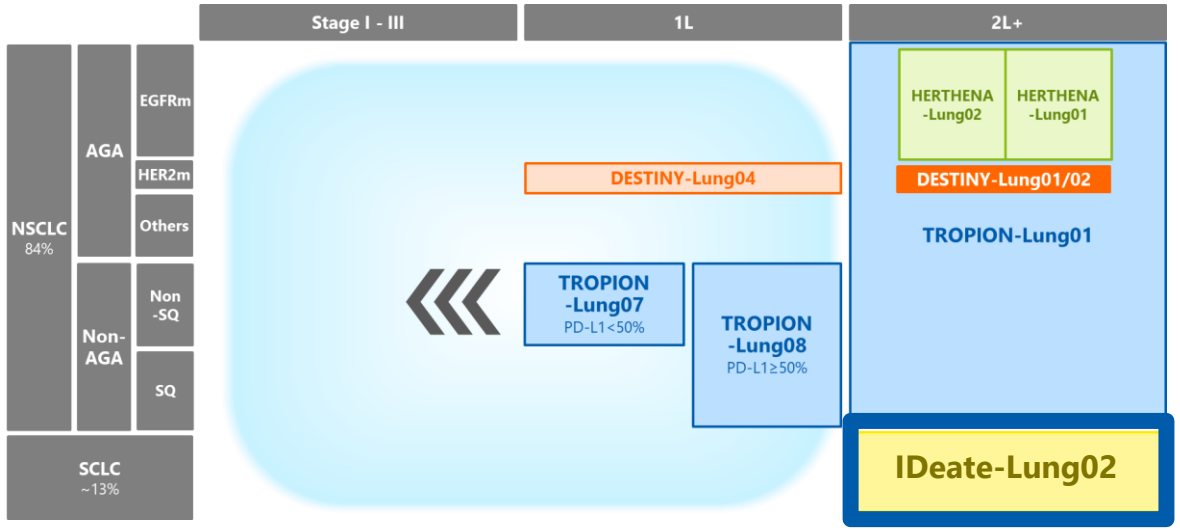
DCR: disease control rate, DOR: duration of response, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, Q3W: every 3 weeks, SCCHN: squamous cell carcinoma of head and neck

I-DXd*

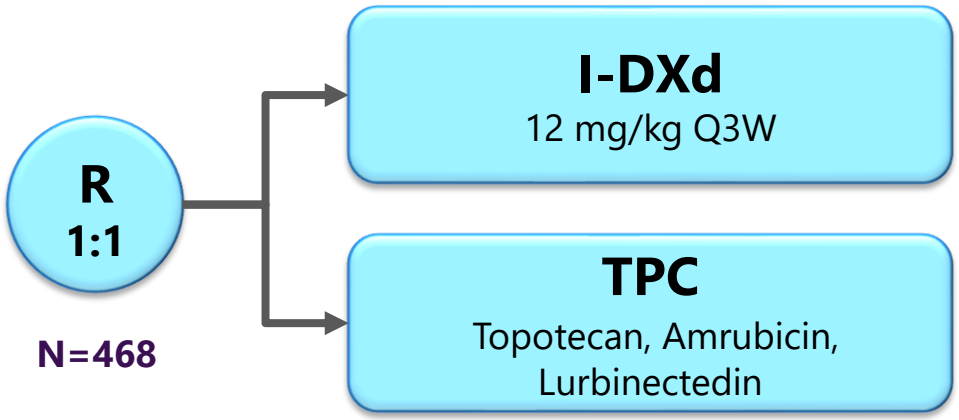
IDeate-Lung02 study**

SCLC 2L+ Ph3 study

Plan to start a pivotal study based on the promising data in SCLC patients in FY2024 H1



IDeate-Lung02 Study Design



Primary Endpoint: ORR by BICR, OS
Secondary Endpoint: ORR by investigator, PFS, DOR, DCR, TTR, safety, etc.

IDeate-Lung02 Study

Ph3 study for relapsed SCLC

- Patient has received prior therapy with at least one prior platinum-based line

* I-DXd: Ifinatamab deruxtecan, DS-7300
** Clinical Trials.gov indicates IDeate-2 for this study which will be renamed to IDeate-Lung02
AGA: actionable genomic alterations, BICR: blinded independent central review, DCR: disease control rate, DOR: duration of response, Non-SQ: non-squamous, NSCLC: non small cell lung cancer, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, Q3W: every 3 weeks, SCLC: small cell lung cancer, SQ: squamous, TPC: treatment of physician's choice, TTR: time to response

DS-6000 (R-DXd)

REJOICE-Ovarian01 study

Based on promising Ph1 data, planning to initiate Ph2/3 for platinum-resistant ovarian cancer in FY2023 Q4

REJOICE-Ovarian01 study design (N=650)

Population

- Platinum-resistant ovarian, primary peritoneal or fallopian tube cancer
- 1 to 3 prior lines of therapy

Ph2 part

R 1:1:1

- DS-6000 4.8mg/kg, Q3W
- DS-6000 5.6mg/kg, Q3W
- DS-6000 6.4mg/kg, Q3W

■ Primary endpoint: ORR
■ Secondary endpoint: Safety, DOR, DCR, PFS, etc.

Recommended Ph3 dose

Ph3 part

R 1:1

- DS-6000 RP3D, Q3W
- **Investigator's choice** (Paclitaxel, PLD, Gemcitabine, Topotecan)

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

DCR: disease control rate, DOR: duration of response, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, PLD: pegylated liposomal doxorubicin, Q3W: every 3 weeks, R-DXd: Raludotatug deruxtecan, RP3D: recommended Ph3 dose

5DXd ADCs

Other clinical progresses and regulatory updates

ENHERTU®

- Dec 2023: **Filing accepted in China** for HER2 positive locally advanced or metastatic gastric or GEJ adenocarcinoma 3L based on **DESTINY-Gastric06** study data

Dato-DXd

- FY2023 Q4: **Expected to obtain a filing acceptance in US** based on **TROPION-Lung01** study data
- FY2023 Q4: **Expected to obtain a filing acceptance in US** based on **TROPION-Breast01** study data

GEJ: gastroesophageal junction

5DXd ADCs Update

Next Wave Update

News Flow

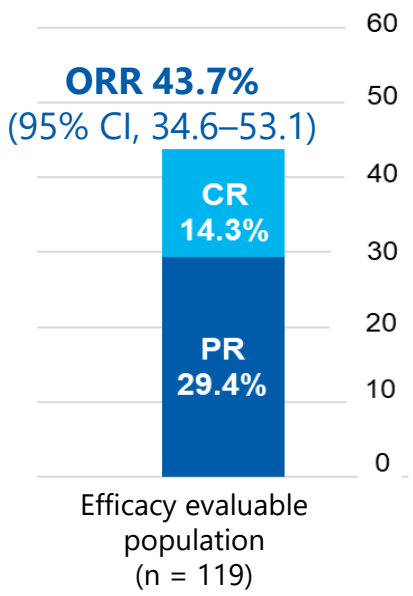
VALENTINE-PTCL01 Primary Results

ASH 2023

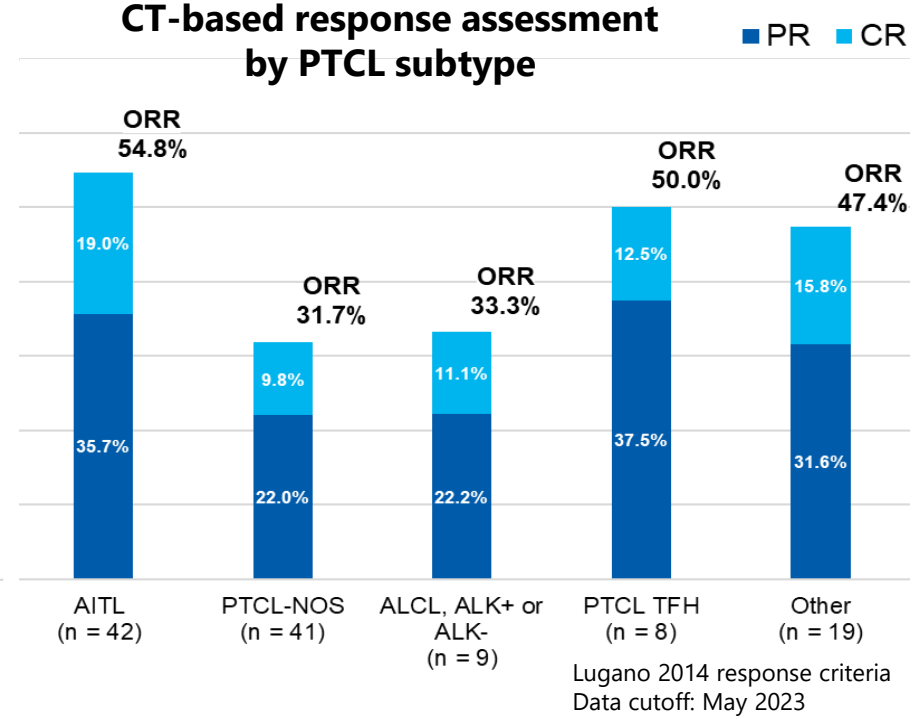
Valemetostat monotherapy provided a clinically meaningful benefit for patients with R/R PTCL

Efficacy

CT-based BICR assessment (primary endpoint)



CT-based response assessment by PTCL subtype



Lugano 2014 response criteria
Data cutoff: May 2023

VALENTINE-PTCL01

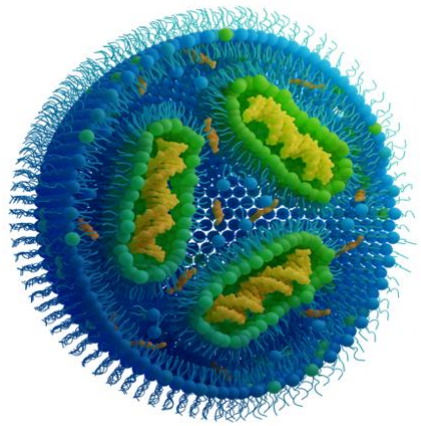
A Ph2 single-arm study in R/R PTCL (N=133) treated with 200 mg/day valemetostat

- Valemetostat monotherapy demonstrated a high ORR of 43.7% with CR rate 14.3%
- Responses were durable (mDOR 11.9 months)
- The safety profile was acceptable and AEs were generally manageable; 57.9% patients experienced grade ≥3 TEAEs (cytopenias were the most common)
- **Planning regulatory submission in Japan in FY2023**

AITL: angioimmunoblastic T-cell lymphoma, ALCL: anaplastic large cell lymphoma, ALK: anaplastic lymphoma kinase, ASH: American Society of Hematology, BICR: blinded independent central review, CI: confidence interval, CT: computed tomography, CR: complete response, mDOR: median duration of response, ORR: objective response rate, PR: partial response, PTCL-NOS: PTCL-not otherwise specified, R/R-PTCL: relapsed or refractory peripheral T-cell lymphomas, TEAEs: treatment emergent adverse events, TFH: T follicular helper

DAICHIRONA® (DS-5670) Approval of COVID-19 vaccine

DAICHIRONA® FOR INTRAMUSCULAR INJECTION*



Lipid nanoparticle(LNP)-mRNA

- **DS original cationic lipid** is applied
  - Best lipid and lipid composition ratio are selected based on efficacy & safety perspectives
- **The first mRNA vaccine made in Japan**
- COVID-19 vaccine for Omicron XBB.1.5 strain was **approved in Japan** in Nov 2023

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

DS-2325
(KLK5 inhibitor)

Ph1b/2 study start

Target Disease

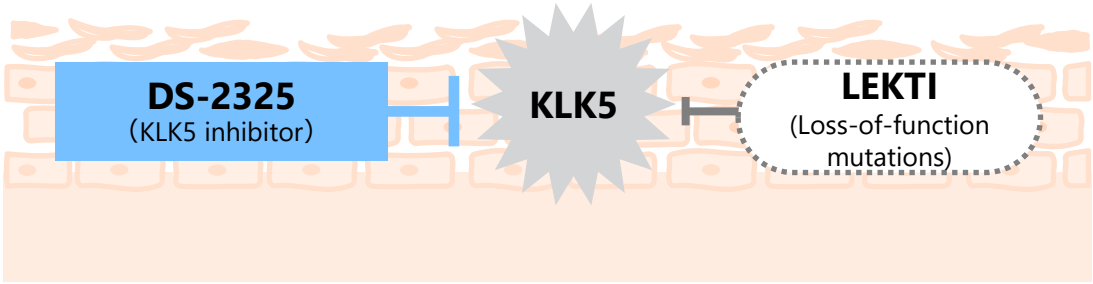
- **Netherton syndrome**
  - An autosomal recessive genetic disease affecting skin, hair and immune system
  - Caused by mutations in the SPINK5 gene, which encodes LEKTI, a serine protease inhibitor
  - Incidence is estimated at 1/200,000 births

Current status of development

- **Ph1b/2 study started in Dec 2023**
  - Randomized, placebo-controlled, double-blind study in patients with Netherton syndrome
  - Primary objective: safety
  - Secondary objective: pharmacokinetics, pharmacodynamics, early clinical signal
- **Following designations granted in US**
  - Orphan drug designation (Dec 2022)
  - Fast track designation (Feb 2023)
  - Rare pediatric disease designation (May 2023)

Mode of Action

- **Skin of Netherton syndrome patient**
  - Desquamation
  - Inflammation



5DXd ADCs Update

Next Wave Update

News Flow

FY2023, FY2024 News Flow

As of Jan 2024

Regulatory decisions

ENHERTU®	**DESTINY-PanTumor02, DESTINY-CRC02, etc.: HER2 IHC3+ solid tumors** **• US: FY2024 H1**
	DESTINY-Gastric06: HER2+ GC, 3L+ **• CN: FY2024 H1**
HER3-DXd	**HERTHENA-Lung01: EGFR mutated NSCLC, 3L** **• US: FY2024 H1**

Planned regulatory filing※

Dato-DXd	**TROPION-Lung01: NSCLC, 2/3L** **• US: FY2023 Q4**
	TROPION-Breast01: HR positive and HER2 low or negative BC, 2/3L **• US: FY2023 Q4**
ENHERTU®	DESTINY-Lung05: HER2 mutant NSCLC, 2L • CN: FY2023 Q4
EZHERMIA®	**VALENTINE-PTCL01: r/r PTCL** **• JP: FY2023 Q4**

Key data readouts

ENHERTU®	DESTINY-Breast06*: HR+ and HER2 low BC, chemo naïve, Ph3 **• FY2024 H1**

BC: breast cancer, CN: China, CRC: colorectal cancer, GC: gastric cancer, HR: hormone receptor, IHC: immunohistochemistry, NSCLC: non-small cell lung cancer, PTCL: peripheral T cell lymphoma, r/r: relapsed/refractory

Bold: update from FY2023 Q2

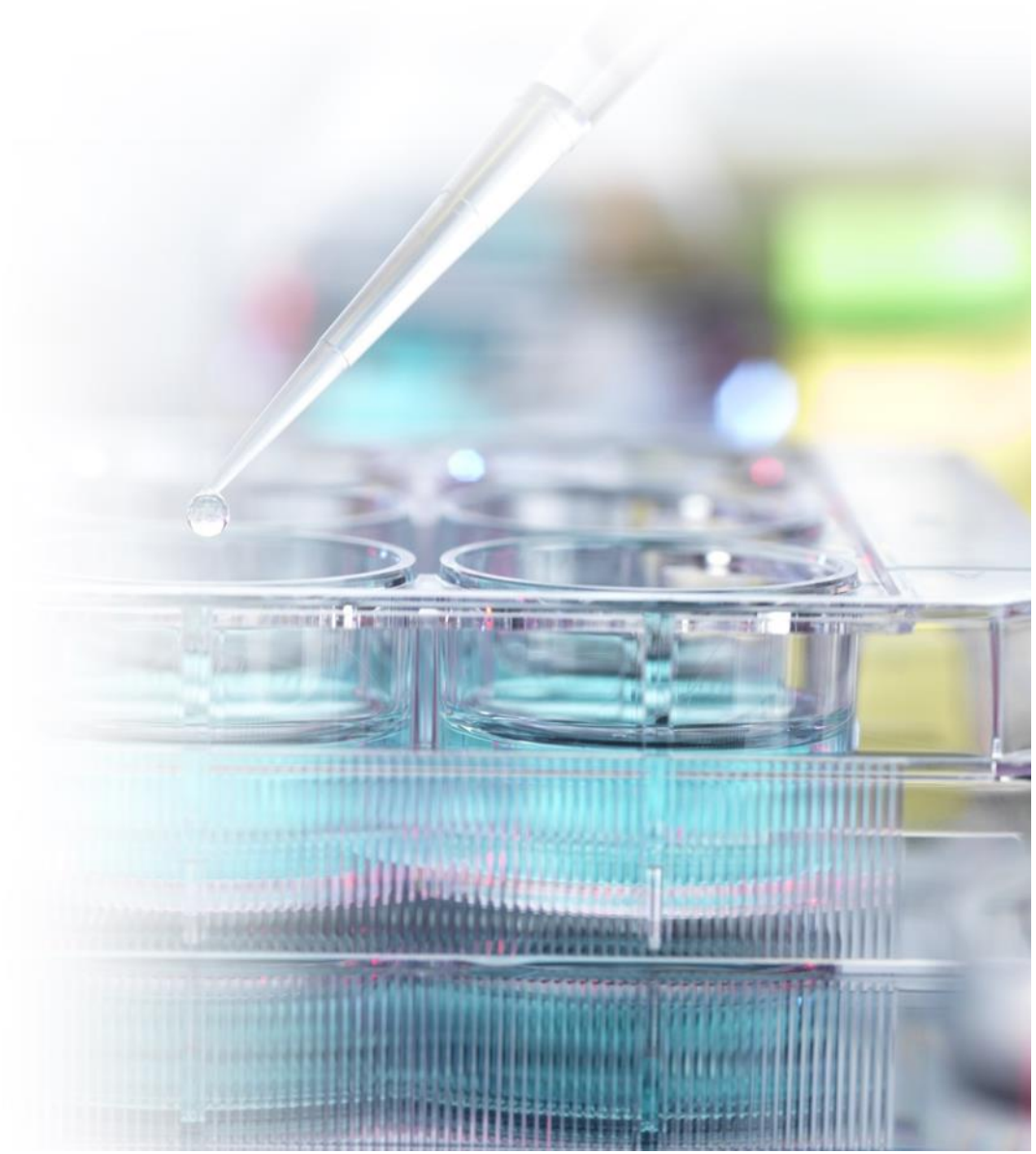
Timeline indicated is based on the current forecast and subject to change

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

*: event-driven study

Agenda

1. FY2023 Q3 Financial Results
2. Business Update
3. R&D Update
4. **Appendix**



Major R&D Milestones (ENHERTU®)

As of Jan 2024

Project		Target Indication [phase, study name]	FY2023 H1	FY2023 H2	FY2024
ENHERTU®	BC	• HR+/HER2 low, chemo naive [Ph3, DESTINY-Breast06]			• **TLR anticipated**
		• HER2+, 1L [Ph3, DESTINY-Breast09]			• TLR anticipated
		• HER2+, neoadjuvant [Ph3, DESTINY-Breast11]			• TLR anticipated
	GC	• HER2+, 3L+ [Ph2, DESTINY-Gastric06]	• TLR obtained	• **Filed (CN)**	• **Regulatory decision anticipated (CN)**
	NSCLC	• HER2 mutant, 2L [Ph2, DESTINY-Lung05]		• **TLR obtained** • Planned regulatory filing※ (CN)	
	Other tumors	• HER2 expressing tumors [Ph2, DESTINY-PanTumor02]	• TLR obtained	• **Filed (US)**	• **Regulatory decision anticipated (US)**

Bold: update from FY2023 Q2 BC: breast cancer, GC: gastric cancer, HR: hormone receptor, NSCLC: non small cell lung cancer, TLR: top line results

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

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

Major R&D Milestones (Dato-DXd)

As of Jan 2024

Project		Target Indication [phase, study name]	FY2023 H1	FY2023 H2	FY2024
Dato-DXd	NSCLC	• 2/3L [Ph3, TROPION-Lung01]	• TLR obtained	• **Planned regulatory filing※ (US)**	
	BC	• HR+ and HER2 low or negative, 2/3L [Ph3, TROPION-Breast01]	• **TLR obtained**	• **Planned regulatory filing※ (US)**	
		• TNBC, PD-1/PD-L1 ineligible,1L [Ph3, TROPION-Breast02]			• TLR anticipated
		• **TNBC or HR low, HER2 low or negative BC, neoadjuvant/adjuvant [Ph3, TROPION-Breast04]**		• **Study started**	
		• **TNBC, PD-L1 positive, 1L [Ph3, TROPION-Breast05]**		• **Study started**	

Bold: update from FY2023 Q2 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

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

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

As of Jan 2024

Project		Target Indication [phase, study name]	FY2023 H1	FY2023 H2	FY2024
HER3-DXd	NSCLC	• EGFR mutated, 3L [Ph2, HERTHENA-Lung01]		**• Filed (US)**	**• Regulatory decision anticipated (US)**
		• EGFR mutated, 2L [Ph3, HERTHENA-Lung02]			• TLR anticipated
	Other tumors	**• Melanoma, SCCHN, HER2 negative GC [Ph2, HERTHENA-PanTumor01]**		**• Study start planned**	
I-DXd	SCLC	• 2L+ [Dose optimization, Ph2, IDeate-Lung01 (IDeate-1)※]			• TLR anticipated
		• 2L+ [Ph3, IDeate-Lung02 (IDeate-2) ※]			**• Study start planned**
DS-6000 (R-DXd)	OVC	**• 2L+ [Ph2/3, REJOICE-Ovarian01]**		**• Study start planned**	

Bold: update from FY2023 Q2 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
※ Study names i.e. IDeate-x will be renamed to IDeate-Lung0x

Major R&D Milestones (Next Wave)

As of Jan 2024

Project	Target Indication [phase, study name]	FY2023 H1	FY2023 H2	FY2024
EZHARMIA®	• r/r PTCL [Registrational Ph2, VALENTINE-PTCL01]	• TLR obtained	• **Planned regulatory filing※ (JP)**	• **Regulatory decision anticipated (JP)**
DS-2325	• Netherton syndrome [Ph1b/2]		• **Study started**	
DAICHIRONA® (DS-5670)	• COVID-19 mRNA vaccine (mutant strain), booster vaccination [Ph3]	• Filing accepted (JP)	• **Approved (JP)**	

Bold: update from FY2023 Q2 PTCL: peripheral T cell lymphoma, r/r: relapsed/refractory, TLR: top line results

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

Major R&D Pipeline: 5DXd ADCs

As of Jan 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, MEDI5752 combo) 1L
  DESTINY-Lung03
- (US/EU) BC, bladder
  (nivolumab combo)
- (US/EU) BC, NSCLC
  (pembrolizumab combo)
- (US/EU/Asia) solid tumors
  (AZD5305 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, AZD2936 and MEDI5752
  combo) TROPION-Lung04
- (JP/US/EU/Asia) solid tumors
  (AZD5305 combo)
  PETRA
- (JP/US/EU/Asia) NSCLC
- (JP/US/Asia) EGFR mutated NSCLC
  (osimertinib combo)
- (JP/US)
  ESCC, CRPC, squamous NSCLC, SCLC, etc.
  IDeate-PanTumor01
- (JP/US)
  renal cell carcinoma, ovarian cancer

Phase 2

- (US/EU/Asia) TNBC
  (durvalumab combo)
  BEGONIA
- (CN) HER2 mutant NSCLC 2L+
  DESTINY-Lung05
- (US/EU/Asia) NSCLC
  (durvalumab combo) 2L+
  HUDSON
- (JP/US/EU/Asia) solid tumors
  TROPION-PanTumor03
- (US/EU/Asia) TNBC
  (durvalumab combo)
  BEGONIA
- (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) in prep, melanoma, SCCHN,
  HER2 negative GC, 2L+
  HERTHENA-PanTumor01
- (JP/US/EU/Asia)
  ES-SCLC, 2L+
  IDeate-Lung01 (IDeate-1)
- (JP/US/EU/Asia) in prep
  ovarian cancer
  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) 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) TNBC (PD-1/PD-L1 inhibitor
  ineligible) 1L
  TROPION-Breast02
- (JP/US/EU/Asia) TNBC adjuvant*2
  (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 (IDeate-2)

Regulatory phase

- (US) HER2 expressing tumors
  DESTINY-PanTumor02,
  DESTINY-CRC02 etc
- (CN) HER2+ GC 3L
  DESTINY-Gastric06
- (JP/US/EU/Asia) NSCLC 2/3L
  TROPION-Lung01
- (JP/US/EU/Asia) BC*3 2/3L
  TROPION-Breast01
- (US) EGFR mutated
  NSCLC 3L
  HERTHENA-Lung01

ENHERTU® 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 HER2 positive breast cancer patients with residual invasive disease following neoadjuvant therapy
*2 Adjuvant therapy for TNBC patients with residual invasive disease following neoadjuvant therapy
*3 HR+, HER2 low or negative BC

AGA: actionable genomic alterations, 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, SCLC: small cell lung cancer, TNBC: triple negative breast cancer

Major R&D Pipeline: Next Wave

As of Jan 2024

Phase 1	Phase 2	Phase 3	Regulatory phase
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	Valemetostat (DS-3201) (EU) EZH1/2 inhibitor BCL	Pexidartinib (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	Valemetostat (DS-3201) (JP/US/EU/Asia) EZH1/2 inhibitor PTCL
DS-1594 (US) Menin-MLL binding inhibitor AML, ALL	DS-1001 (JP) Mutant IDH1 inhibitor Glioma	Esaxerenone (JP) MR blocker Diabetic nephropathy	Mirogabalin (CN) α2δ ligands Diabetic peripheral neuropathic pain
DS-9606 (US/EU) Target undisclosed ADC Solid tumors	DS-1211 (US/EU) TNAP inhibitor Pseudoxanthoma elasticum	VN-0102/JVC-001 (JP) Measles mumps rubella combined vaccine	
DS-1103 Anti-SIRPα antibody HER2 expressing or mutant solid tumors, HER2 low BC (ENHERTU® combo)	VN-0200 (JP) RS virus vaccine RS virus infection	DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain), COVID-19 (booster vaccination, 5 to 11 aged children)	
DS-3939 Anti-TA-MUC1 ADC Solid tumors		DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain), COVID-19 (single dose,12 years old and over)	
DS-1471 Anti-CD147 antibody Solid tumors			
DS-7011 (US) 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)

ALL: acute lymphoblastic leukemia, BCL: B cell lymphoma, LBCL: large B cell lymphoma, PTCL: peripheral T-cell lymphoma

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