Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2023 Q2
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Hiroyuki Okuzawa

Representative Director, President & COO

October 31, 2023

Forward-Looking Statements

Management strategies and plans, financial forecasts, future projections and policies, and R&D information that Daiichi Sankyo discloses in this material are all classified as Daiichi Sankyo's future prospects. These forward-looking statements were determined by Daiichi Sankyo based on information obtained as of today with certain assumptions, premises and future forecasts, and thus, there are various inherent risks as well as uncertainties involved. As such, please note that actual results of Daiichi Sankyo may diverge materially from Daiichi Sankyo's outlook or the content of this material. Furthermore, there is no assurance that any forward-looking statements in this material will be realized. Regardless of the actual results or facts, Daiichi Sankyo is not obliged and does not have in its policy the duty to update the content of this material from the date of this material onward.

Some of the compounds under discussion are investigational agents and are not approved by the FDA or any other regulatory agency worldwide as a treatment for indications under investigation. Efficacy and safety have not been established in areas under investigation. There are no guarantee that these compounds will become commercially available in indications under investigation.

Daiichi Sankyo takes reasonable care to ensure the accuracy of the content of this material, but shall not be obliged to guarantee the absolute accuracy, appropriateness, completeness and feasibility, etc. of the information described in this material. Furthermore, any information regarding companies, organizations or any other matters outside the Daiichi Sankyo Group that is described within this material has been compiled or cited using publicly available information or other information, and Daiichi Sankyo has not performed in-house inspection of the accuracy, appropriateness, completeness and feasibility, etc. of such information, and does not guarantee the accuracy thereof.

The information described in this material may be changed hereafter without notice. Accordingly, this material or the information described herein should be used at your own judgment, together with any other information you may otherwise obtain.

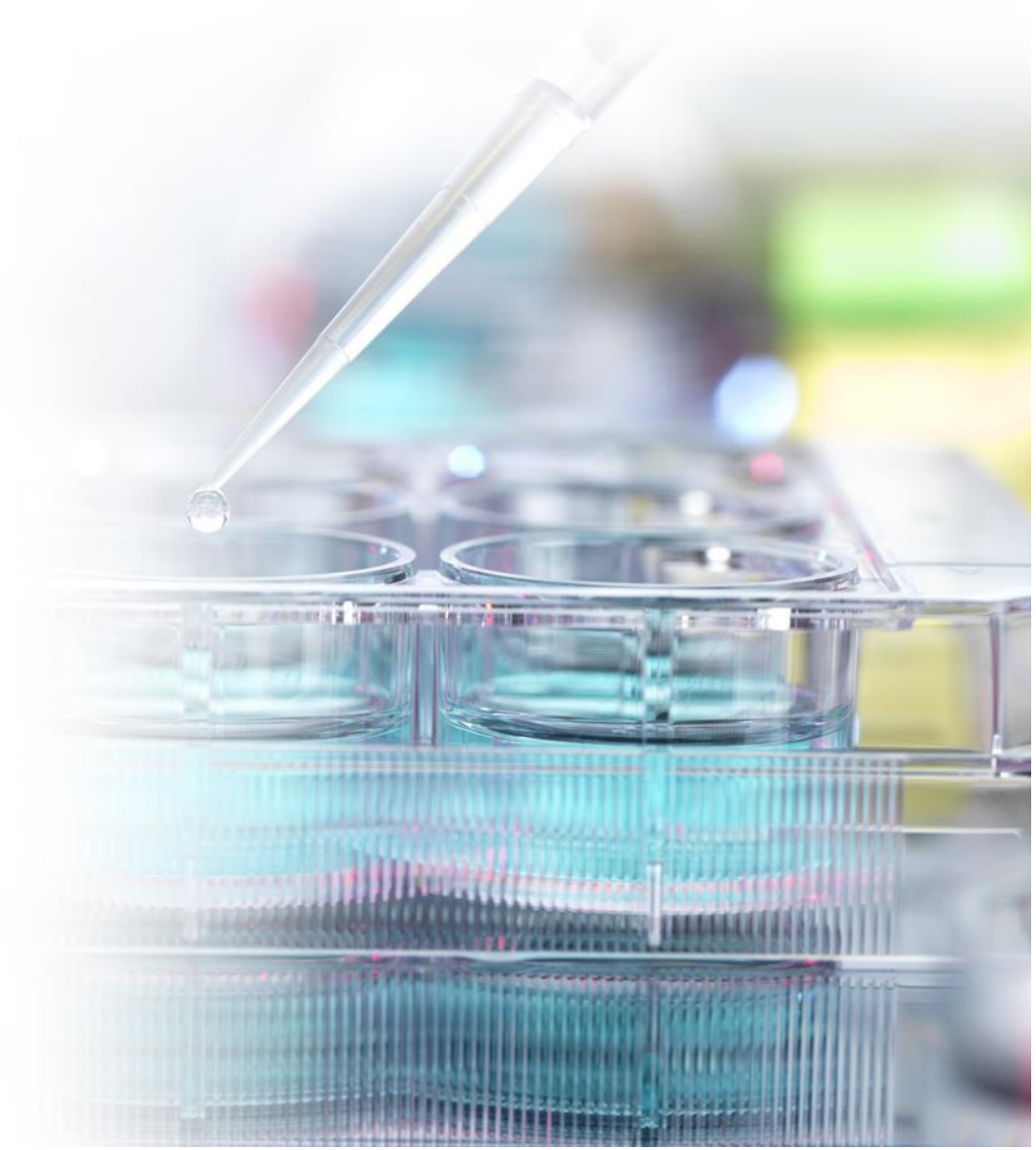
This material does not constitute a solicitation of application to acquire or an offer to sell any security in the United States, Japan or elsewhere.

This material disclosed here is for reference purposes only. Final investment decisions should be made at your own discretion.

Daiichi Sankyo assumes no responsibility for any damages resulting from the use of this material or its content, including without limitation damages related to the use of erroneous information.

Agenda

1. **FY2023 Q2 Financial Results**
2. Strategic Collaboration
3. FY2023 Forecast/ Annual Dividend
4. Business Update
5. R&D Update
6. Appendix



Overview of FY2023 Q2 Results

(Bn JPY)

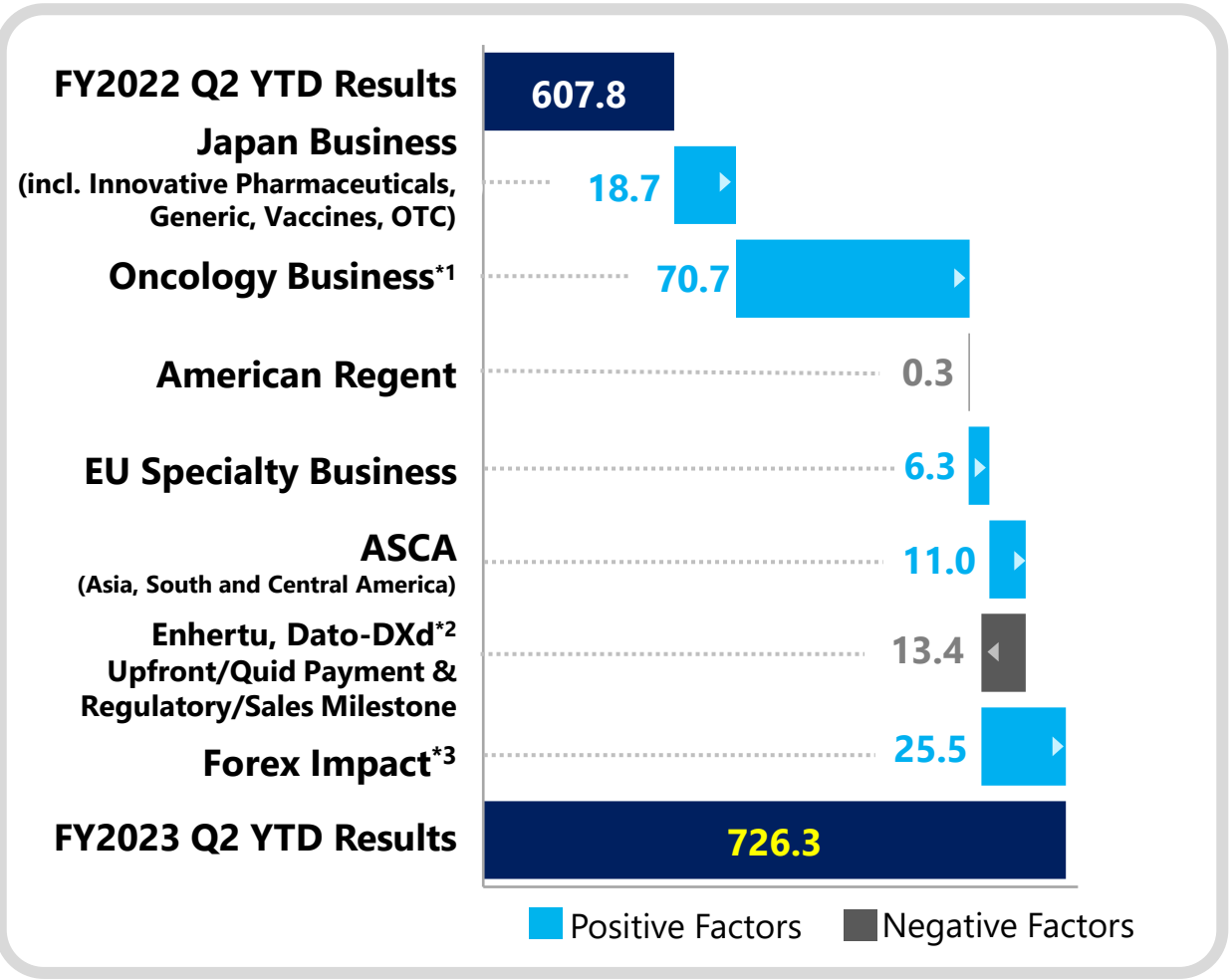
	FY2022 Q2 YTD Results	FY2023 Q2 YTD Results	YoY	
Revenue	**607.8**	**726.3**	**+19.5%**	**118.5**
Cost of sales*	159.4	188.4		29.0
SG&A expenses*	209.8	276.6		66.9
R&D expenses*	153.9	166.0		12.2
Core operating profit*	**84.8**	**95.3**	**+12.4%**	**10.5**
Temporary income*	10.8	0.7		-10.1
Temporary expenses*	0.0	1.0		0.9
Operating profit	**95.6**	**95.1**	**-0.5%**	**-0.5**
Profit before tax	**91.3**	**102.1**		**10.8**
Profit attributable to owners of the Company	**58.3**	**97.0**	**+66.4%**	**38.7**

Currency Rate	USD/JPY	133.98	141.00	+7.02
	EUR/JPY	138.72	153.38	+14.66

*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 118.5 Bn JPY (Increased by 93.0 Bn JPY excl. forex impact)



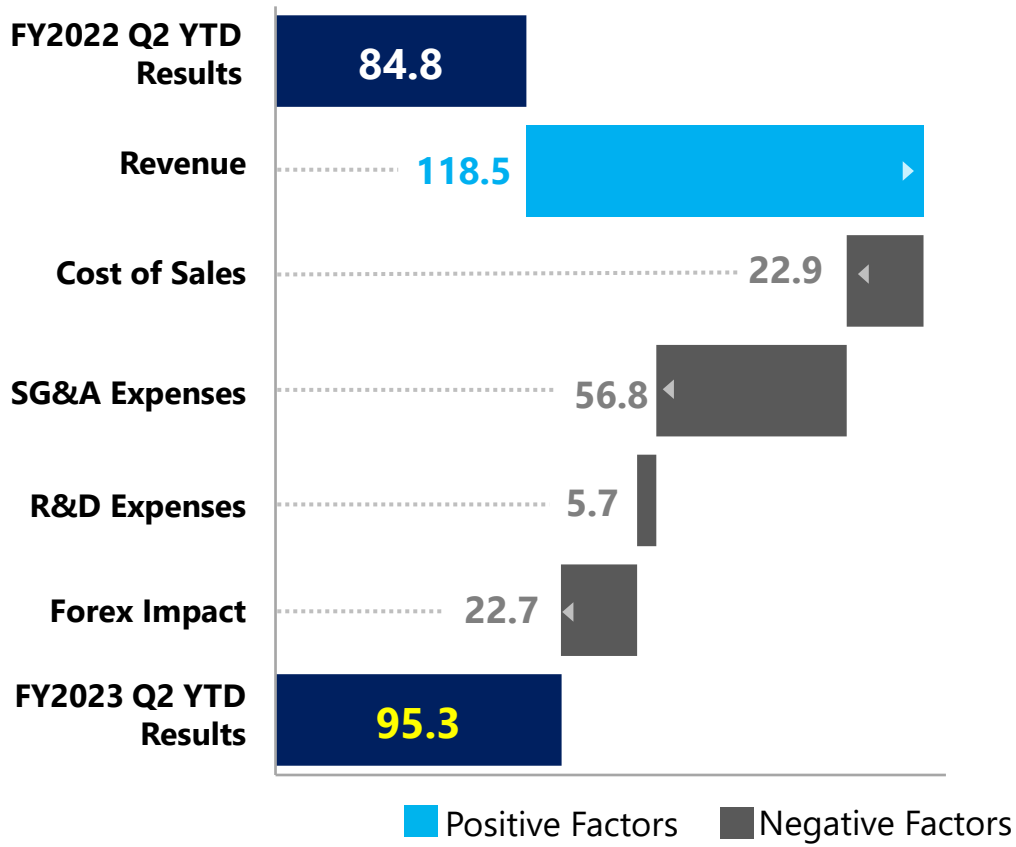
(Bn JPY)

Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+6.4		
Enhertu	+5.2		
Tarlige	+4.4		
Daiichi Sankyo Healthcare	+3.8		
Oncology Business*1 Unit			
Enhertu	+68.9		
Vanflyta	+1.1		
American Regent Unit			
Venofer	+2.6	Injectafer	-3.0
EU Specialty Business Unit			
Lixiana	+5.6	Olmesartan	-1.5
Nilemdo/ Nustendi	+3.4		
ASCA (Asia, South and Central America) Business Unit			
Enhertu	+11.2		
Enhertu, Dato-DXd*2 Upfront/ Quid Payment & Regulatory Milestone			
		Enhertu Regulatory Milestone	-12.7

*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products
*2 Dato-DXd: Datopotamab deruxtecan (DS-1062)
*3 Forex impact USD: +11.4, EUR : +11.9, ASCA: +2.2

Core Operating Profit

Increased by 10.5 Bn JPY (Increased by 7.7 Bn JPY excl. forex impact)



(Bn JPY)

Revenue +118.5
incl. forex impact of +25.5

Cost of Sales +22.9
Increase in cost of sales due to the revenue increase

SG&A Expenses +56.8
Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca

R&D Expenses +5.7
Increase in 5DXd-ADCs* R&D investments

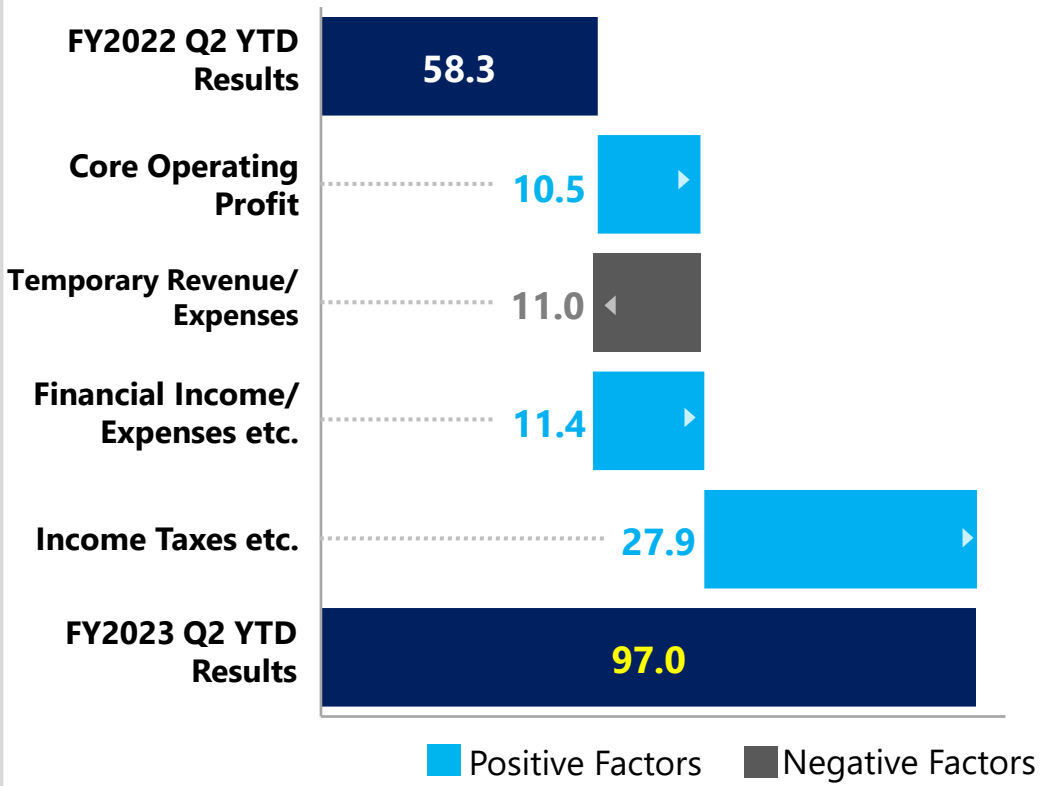
Forex Impact +22.7 (Profit Decreased)
Cost of Sales +6.1
SG&A Expenses +10.1
R&D Expenses +6.5

***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, DS-7300 (B7-H3-directed ADC), **R-DXd**: raludotatug deruxtecan, DS-6000 (CDH6-directed ADC)

Profit Attributable to Owners of the Company

Increased by 38.7 Bn JPY

(Bn JPY)



Temporary Income/Expenses ····· -11.0 (Profit decreased)

	FY2022 Q2 YTD	FY2023 Q2 YTD	YoY
Temporary Income	10.8*1	0.7	-10.1
Temporary Expenses	0	1.0	+0.9

*1 Gains related to sales of subsidiary of Daiichi Sankyo (China) (6.0)
Gains on reversal related to closure of Plexxikon (3.2)

Financial Income/Expenses etc. ····· +11.4 (Profit Increased)

- Increase in interest income ····· +5.8
- Improvement in investment securities valuation gains/losses ····· +4.2
- Improvement in forex gains/losses ····· +2.7

Income Taxes etc. ····· -27.9

	FY2022 Q2 YTD Results	FY2023 Q2 YTD Results	YoY
Profit before Tax	91.3	102.1	+10.8
Income Taxes etc.	33.0	5.1	-27.9
Tax rate	36.1%	5.0%	-31.1%

Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2022 Q2 YTD Results	FY2023 Q2 YTD Results	YoY
Japan Business	225.1	246.8	+21.8
Daiichi Sankyo Healthcare	33.6	37.4	+3.8
Oncolgy Business	70.7	148.8	+78.1
Enhertu	69.0	145.1	+76.1
Turalio	1.7	2.6	+0.9
American Regent	94.1	98.7	+4.6
Injectafer	27.4	25.7	-1.7
Venofer	25.0	29.1	+4.1
GE injectables	36.4	37.3	+0.9
EU Specialty Business	71.8	86.4	+14.6
Lixiana	55.8	67.9	+12.1
Nilemdo/Nustendi	2.8	6.8	+4.0
Olmesartan	9.8	9.2	-0.6
ASCA (Asia, South and Central America) Business	69.8	83.0	+13.2

Currency Rate	USD/JPY	133.98	141.00	+7.02
	EUR/JPY	138.72	153.38	+14.66

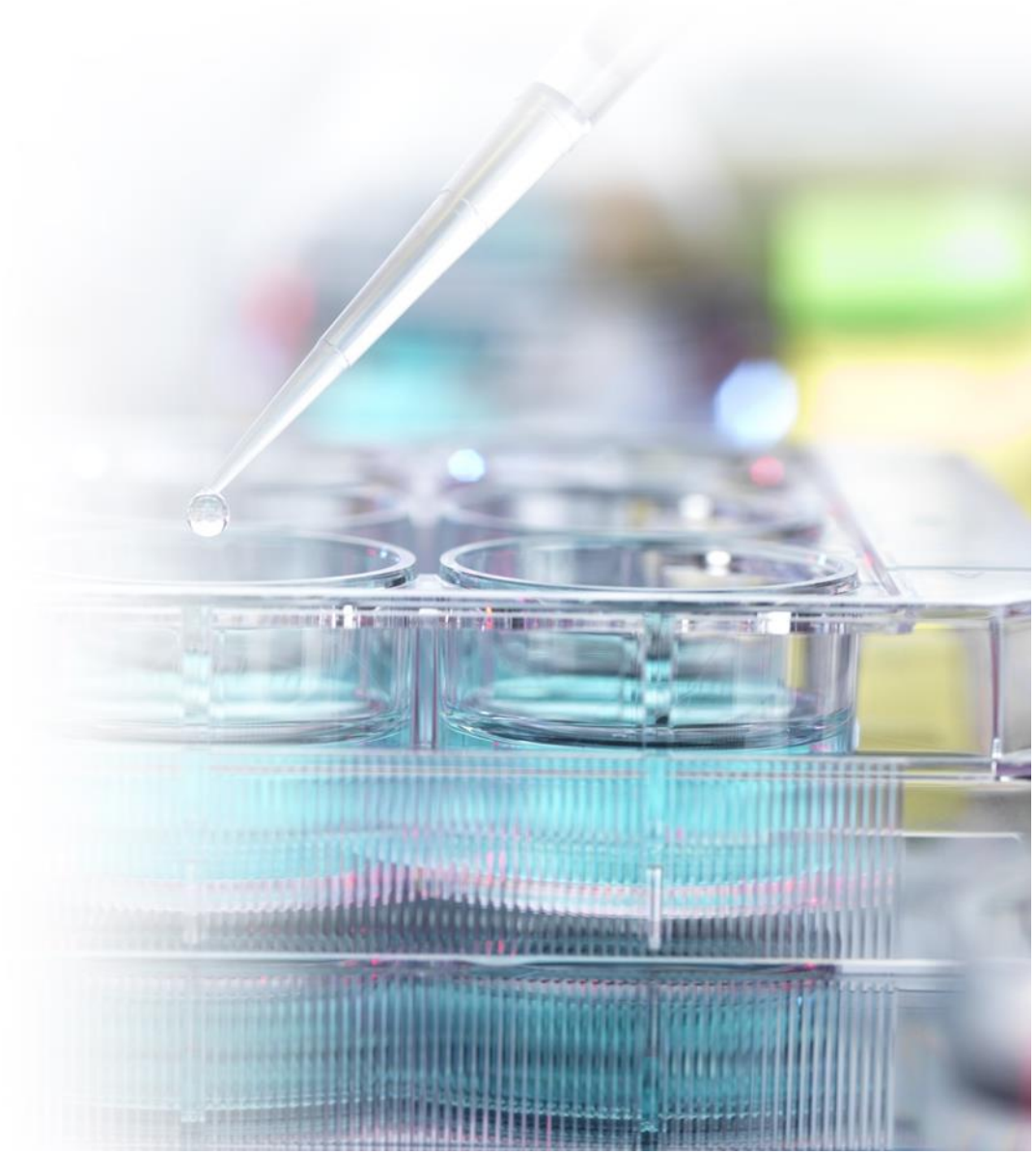
Revenue: Major Products in Japan

(Bn JPY)

		FY2022 Q2 YTD Results	FY2023 Q2 YTD Results	YoY
Lixiana	anticoagulant	**50.7**	**57.1**	**+6.4**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**19.3**	**21.1**	**+1.7**
Tarlige	pain treatment	**18.3**	**22.7**	**+4.4**
Vimpat	anti-epileptic agent	**10.6**	**12.7**	**+2.1**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**10.1**	**10.3**	**+0.2**
Tenelia	type 2 diabetes mellitus treatment	**11.0**	**10.5**	**-0.5**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**5.2**	**10.4**	**+5.2**
Efient	antiplatelet agent	**9.9**	**12.4**	**+2.5**
Canalia	type 2 diabetes mellitus treatment	**8.1**	**8.1**	**+0.0**
Loxonin	anti-inflammatory analgesic	**9.4**	**8.0**	**-1.4**
Emgality	prophylaxis of migraine attacks	**3.0**	**3.6**	**+0.5**

Agenda

1. FY2023 Q2 Financial Results
2. **Strategic Collaboration**
3. FY2023 Forecast/ Annual Dividend
4. Business Update
5. R&D Update
6. Appendix



Overview of Strategic Collaboration

- **Co-development and co-commercialization of HER3-DXd, I-DXd (DS-7300), R-DXd (DS-6000) with Merck & Co., Inc., Rahway, NJ, USA (MRK)**
  - **Maximize the value of 3 products by accelerating and expanding development**
  - **Allocate resource rapidly with flexibility** to new growth drivers following 5DXd-ADCs, post DXd-ADC modalities, etc.

Development

- **Co-development** as monotherapy and combination therapy for **HER3-DXd, I-DXd (DS-7300), R-DXd (DS-6000)**

- **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**

Manufacturing

- **Daiichi Sankyo** will **manufacture** and **supply** all 3 products

Commercial

- **Global (excluding Japan):**
  The companies will **co-promote** and **share gross profit** and **promotional expenses etc.**
- **Japan:**
  Daiichi Sankyo will **solely commercialize** and **pay royalty** to MRK
- **Sales booking**
  Daiichi Sankyo will book product sales in **all countries/regions where Daiichi Sankyo has local operations (including Japan)**

Financial Terms for Strategic Collaboration

Daiichi-Sankyo

Up to 22.0 Bn USD (3,300.0 Bn JPY) in total (1USD=150JPY)

Upfront payments 4.5 Bn USD (675.0 Bn JPY) : 1.5 Bn USD×3 products

	HER3-DXd	I-DXd (DS-7300)	R-DXd (DS-6000)	**Total**
Upon contract execution	0.75 Bn USD	1.5 Bn USD	0.75 Bn USD	**3.0 Bn USD**
12 months after execution	0.75 Bn USD	-	-	**0.75 Bn USD**
24 months after execution	-	-	0.75 Bn USD	**0.75 Bn USD**
Total	**1.5 Bn USD**	**1.5 Bn USD**	**1.5 Bn USD**	**4.5 Bn USD**

MRK may elect not to pay the two upfront payments of 0.75 Bn USD each that are due after 12 months and after 24 months, respectively. If MRK opts out of HER3-DXd and/or R-DXd, the upfront payments already paid will be retained by DS and rights related to such products will be returned to DS

- Received upfront payments **will be deferred and booked as revenue** considering the estimated exclusivity period

R&D expenses related refundable upfront payments 1.0 Bn USD (150.0 Bn JPY) : 0.5 Bn USD×2 products (HER3-DXd,I-DXd)

- MRK will be responsible for 75% of the first 2 Bn USD of R&D expenses for each product (MRK to bear 0.5 Bn USD more than DS compared to equal share)
  - ✓ 0.5 Bn USD for HER3-DXd and I-DXd, respectively to be paid upon contract execution as R&D expenses related refundable upfront payments (Pro-rated portion may be refundable in the event of early termination of development for both products).
    As for R-DXd, 75% of R&D expenses will be paid by MRK as they are incurred
  - ✓ **Accounting treatment is not yet determined**

Sales milestones Up to 16.5 Bn USD (2,475.0 Bn JPY) : Up to 5.5 Bn USD×3 products

- Received sales milestones **will be booked as revenue in the year of achievement**

How R&D Expenses will be Shared, and How Cash will be Paid

◆ **How R&D expenses for 3 products will be shared between the companies**

① **MRK will be responsible for 75% of the first 2 Bn USD of R&D expenses for each product** (MRK will bear 0.5 Bn USD (25% of 2 Bn USD) more than DS compared to 50% : 50% share)

② **MRK and DS will share R&D expenses equally thereafter for each product**

◆ **How cash for R&D expenses of 0.5 Bn USD (25% of the first 2 Bn USD) , which MRK will bear more than DS compared to 50% : 50% share, will be paid**

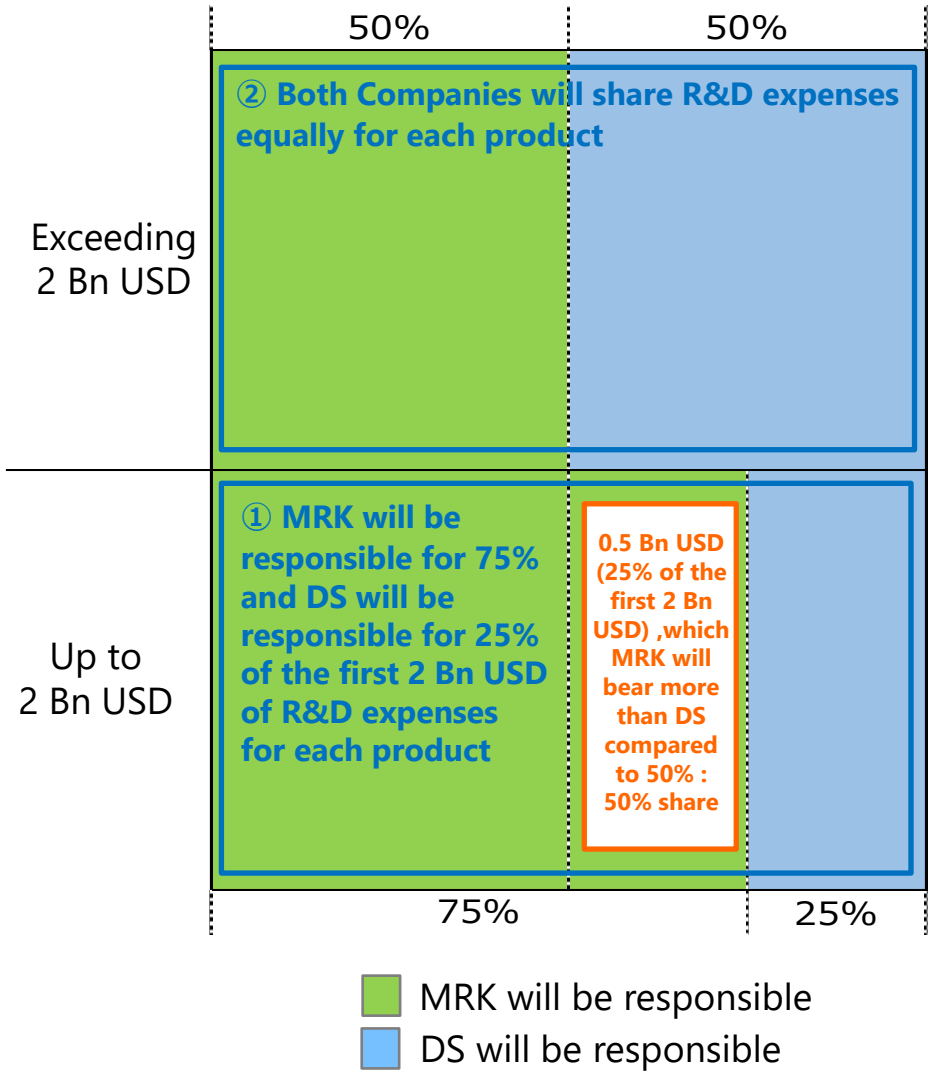
✓ **HER3-DXd, I-DXd (DS-7300)**

- **Will be paid upon contract execution** as "R&D expenses related refundable upfront payments" (Pro-rated portion may be refundable in the event of early termination of development for both products)
- Amount equivalent to 25% of R&D expenses will be appropriated from "R&D expenses related refundable upfront payments" as they are incurred

✓ **R-DXd (DS-6000)**

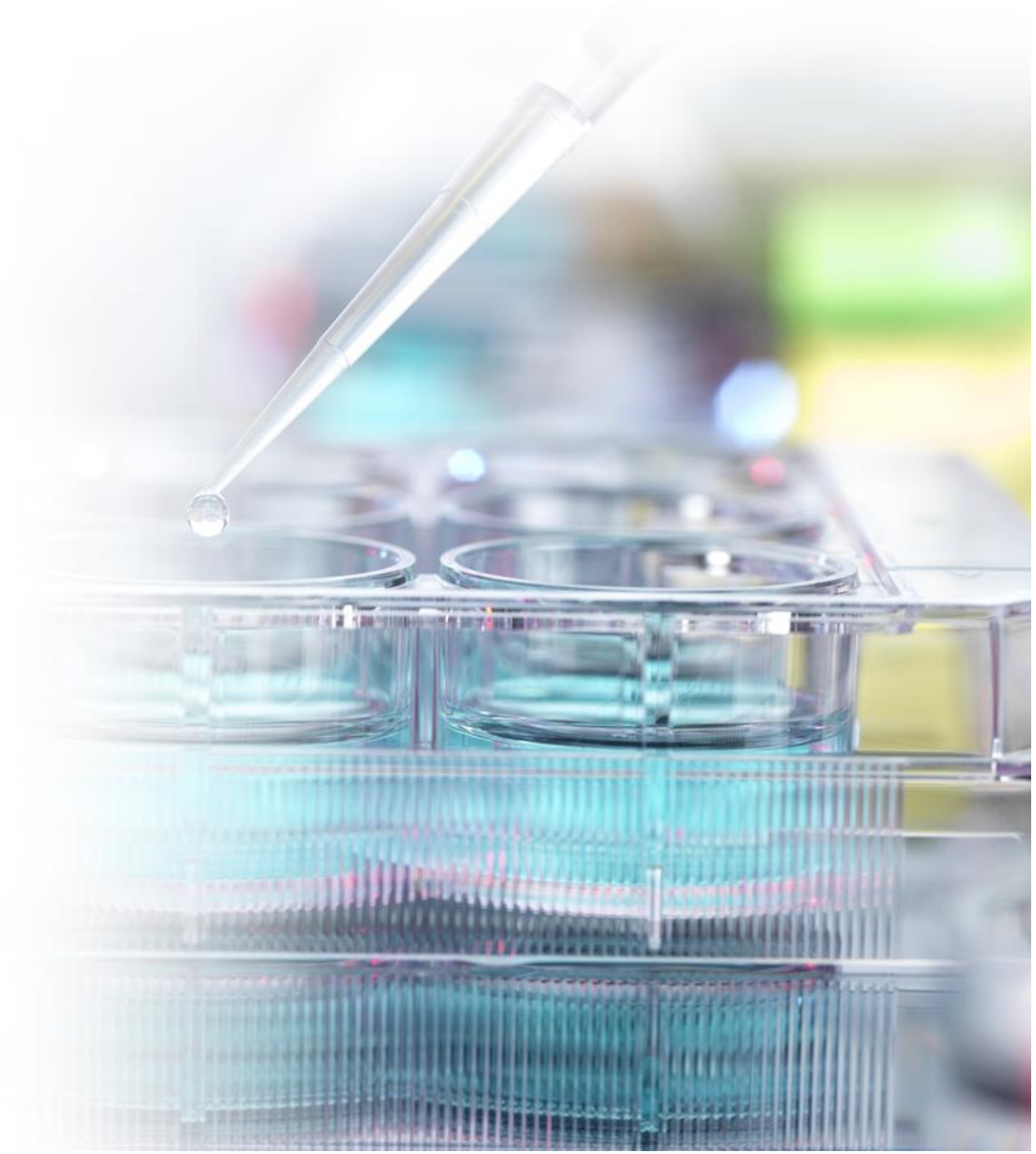
- **Will not be paid upon contract execution** as "R&D expenses related refundable upfront payments"
- To be paid as R&D expenses are incurred

R&D expenses for each product



Agenda

1. FY2023 Q2 Financial Results
2. Strategic Collaboration
3. **FY2023 Forecast/ Annual Dividend**
4. Business Update
5. R&D Update
6. Appendix



Revision to the forecast

(Bn JPY)

	FY2023 Forecast (as of Apr.)	FY2023 Forecast (as of Oct.)	vs. Forecast as of Apr.
Revenue	**1,450.0**	**1,550.0**	**+100.0**
Cost of sales *	400.0	410.0	+10.0
SG&A expenses *	550.0	610.0	+60.0
R&D expenses *	360.0	375.0	15.0
Core operating profit*	**140.0**	**155.0**	**+15.0**
Temporary income*	-	-	-
Temporary expenses*	5.0	5.0	-
Operating profit	**135.0**	**150.0**	**+15.0**
Profit before tax	**135.0**	**160.0**	**+25.0**
Profit attributable to owners of the Company	**115.0**	**135.0**	**+20.0**

Currency Rate	USD/JPY	130.00	143.00	+13.00
	EUR/JPY	140.00	154.19	+14.19

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

Revenue
↑ : Increase by forex, sales increase mainly driven by Enhertu growth, increase by deferred revenue of upfront payment associated with strategic collaboration with Merck & Co., Inc., Rahway, NJ, USA for 3 DXd-ADC products
↓ : Sales decrease of GE injectables in ARU

Cost of sales
↑ : Increase by forex impact,
↓ : Improvement in cost of sales ratio by change in product mix

SG&A Expenses
↑ : Increase by forex impact Increase in profit share of gross profit with AstraZeneca due to sales expansion of Enhertu,

R&D Expenses
↑ : Increase by forex impact, increase due to acceleration of the development of DXd-ADC products
↓ : Commencement of cost sharing for 3 DXd-ADC products with Merck & Co., Inc., Rahway, NJ, USA

Profit before tax
↑ : Increase in financial income due to rising interest rates in the U.S.

Forex Impact vs. as of Apr.

Revenue +80.0 Bn JPY
Core operating profit -6.0 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 from 34 JPY to 40 JPY

Revised annual dividend per share: 40 JPY (interim dividend: 20 JPY, year-end dividend: 20 JPY)

- **FY2023 annual dividend forecast announced on Apr. 27, 2023**
  Planned to be **increased by 4 yen** compared to FY2022 results resulting in **annual dividend of 34 yen per share** based on the increased likelihood of achieving the KPIs for FY2025 by the expansion of sales of Enherts® and others.

- **FY2023 annual dividend forecast announced on Oct. 31, 2023**
  Planned to be **increased by 6 yen compared to the announcement in April**, and, planned to be **increased by 10 yen compared to the fiscal year 2022 results** resulting in **annual dividend of 40 yen per share** based on upfront payment received by the strategic collaboration with Merck & Co., Inc., Rahway, NJ, USA for three DXd-ADC products, and upward revision of the FY2023 forecast due to the strong performance of Enherts® and others.

Capital efficiency improvement
- **Profit growth driven by 3ADCs**
- **Flexible acquisition of own shares**

FY2025 Target: ROE > 16%

Shareholder returns enhancement
- **Dividend increase taking account of profit growth**
- **Flexible acquisition of own shares**

- **Stable shareholder returns by adopting DOE based on shareholder's equity**
- **DOE exceeding shareholder's equity cost**

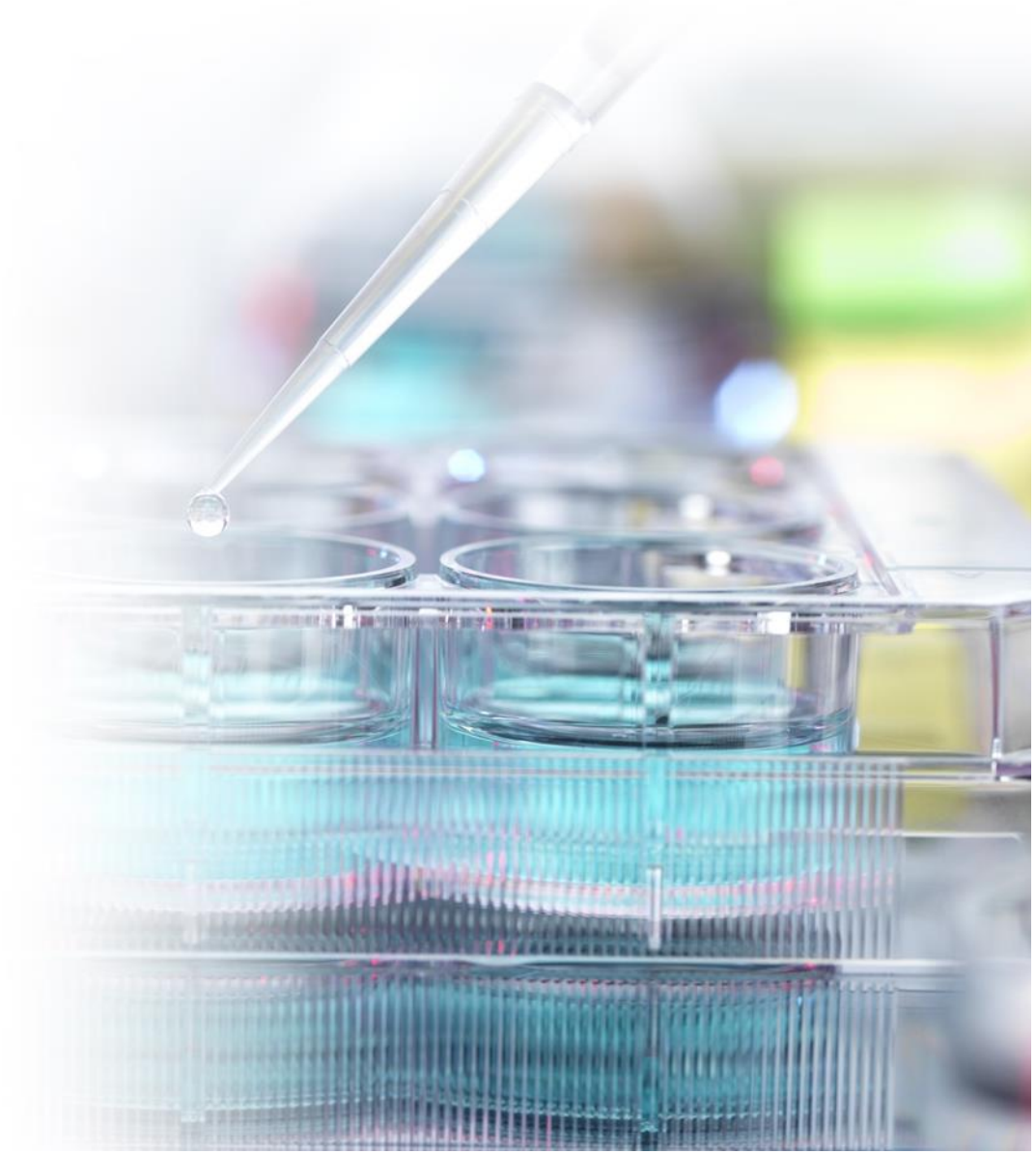
FY2025 Target: DOE > 8%

Maximize shareholder value

*DOE: Dividend on Equity = Total dividend amount / Equity attributable to owners of the company

Agenda

1. FY2023 Q2 Financial Results
2. Strategic Collaboration
3. FY2023 Forecast/ Annual Dividend
4. **Business Update**
5. R&D Update
6. Appendix



ENHERTU®

Revenue

(Bn JPY)

	FY2023 Q2 Results	YoY	FY2023 Forecast	vs. Forecast as of Apr.	<Reference> Total Consideration
Product Sales	173.4	93.9	381.7	61.7	-
Japan	10.4	5.2	21.5	1.6	-
US	105.9	50.5	229.5	34.4	-
Europe	39.2	25.6	92.8	17.0	-
ASCA	17.9	12.6	37.8	8.6	-
Upfront payment	4.9 *1	-	9.8 *1	-	149.0
Regulatory milestone payment	4.2 *1	-12.7	11.9 *1	0.4	137.4
US HER2+ Breast Cancer 3L	0.5	-	0.9	-	13.7
EU HER2+ Breast Cancer 3L	0.3	-	0.5	-	7.9
US HER2+ Gastric Cancer 2L + 3L	0.4	-	0.8	-	12.1
US HER2+ Breast Cancer 2L	0.4	-2.6	0.9	-	13.1
EU HER2+ Breast Cancer 2L	0.3	-2.0	0.7	-	10.1
US HER2-low Breast Cancer (post-chemo)	0.9	-5.5	1.8	-	27.7
EU HER2-low Breast Cancer (post-chemo)	0.7	0.7	1.3	-	19.8
EU HER2+ Gastric Cancer 2L	0.2	0.2	0.3	-	4.8
US HER2 Mutant NSCLC 2L	0.6	-3.4	1.1	-	17.3
EU HER2 Mutant NSCLC 2L	-	-	3.6 *2	0.4	10.9 *2
Quid related payment	0.6 *1	-	1.1 *1	-	17.2
Sales milestone payment	-	-	29.0 *2 *3	3.0	42.2
Total	183.0	81.2	433.6	65.0	345.8

*1 Revenue recognized in each period

*2 Converted with assumed forex rate for FY2023 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 AstraZenceca. (Total amount to be recognized in FY2023)

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

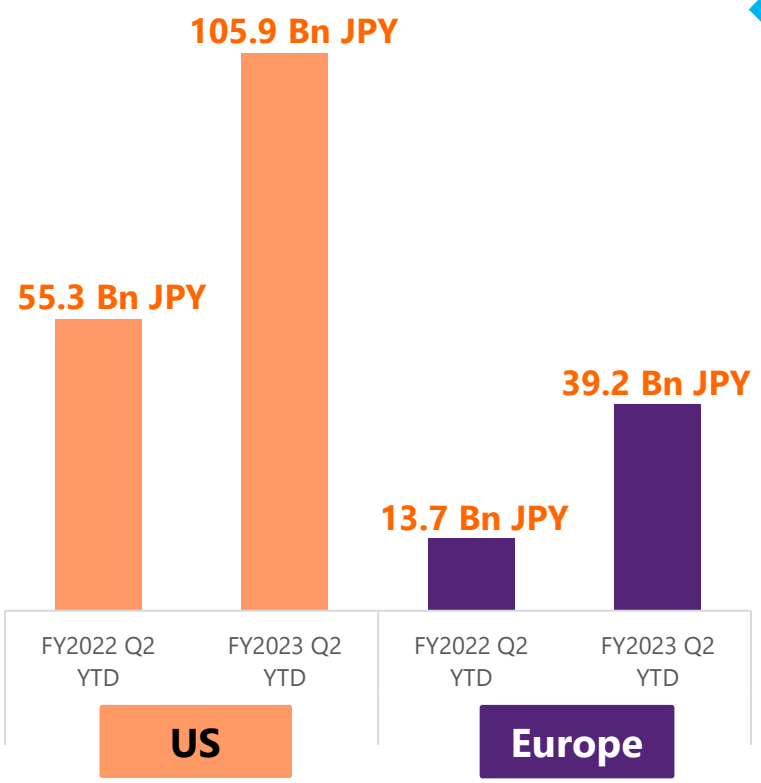
ENHERTU®

Performance in Each Region (US, EU)

Daiichi-Sankyo

Global product sales: FY2023Q2 YTD results 173.4 Bn JPY（YoY +93.9 Bn JPY）FY2023 forecast 381.7 Bn JPY（vs. Forecast as of Apr. +61.7 Bn JPY）

ENHERTU®
trastuzumab deruxtecan



US

- **Product sales: FY2023Q2 YTD results 105.9 Bn JPY (751 Mn USD) FY2023 forecast 229.5 Bn JPY (1,605 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
  - 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

Europe

- **Product sales: FY2023Q2 YTD results 39.2 Bn JPY (278 Mn USD) FY2023 forecast 92.8 Bn JPY (649 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 and Spain, achieved No.1 new patient share in UK
  - 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)

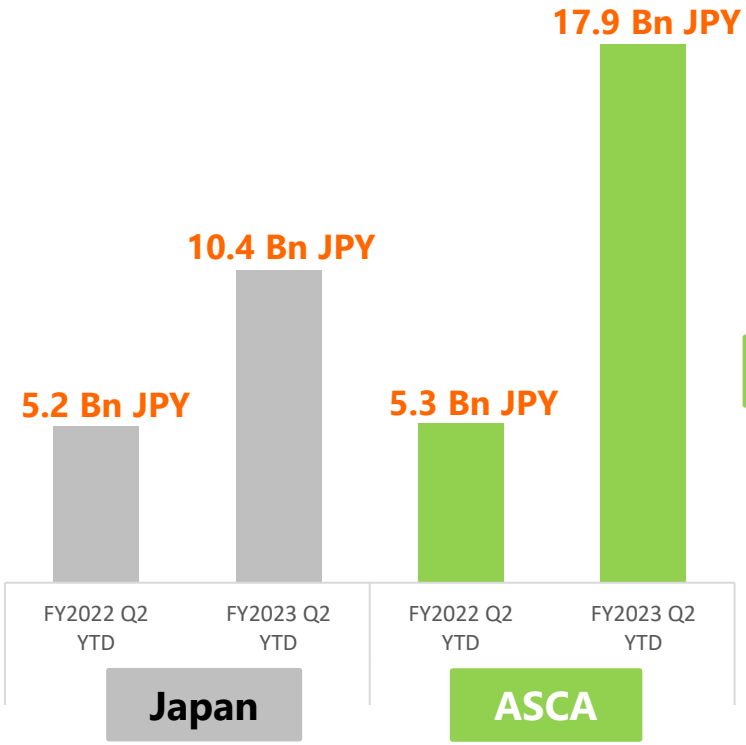
Blue letters: updates from Q1

ENHERTU®

Performance in Each Region (Japan, ASCA)

Global product sales: FY2023Q2 YTD results 173.4 Bn JPY（YoY +93.9 Bn JPY）FY2023 forecast 381.7 Bn JPY（vs. Forecast as of Apr. +61.7 Bn JPY）

ENHERTU® trastuzumab deruxtecan



Japan

- **Product sales: FY2023Q2 YTD results 10.4 Bn JPY FY2023 forecast 21.5 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: Achieved 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)

ASCA

- **Product sales: FY2023Q2 YTD results 17.9 Bn JPY FY2023 forecast 37.8 Bn JPY**
- **Indication:** HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 3L
- **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)

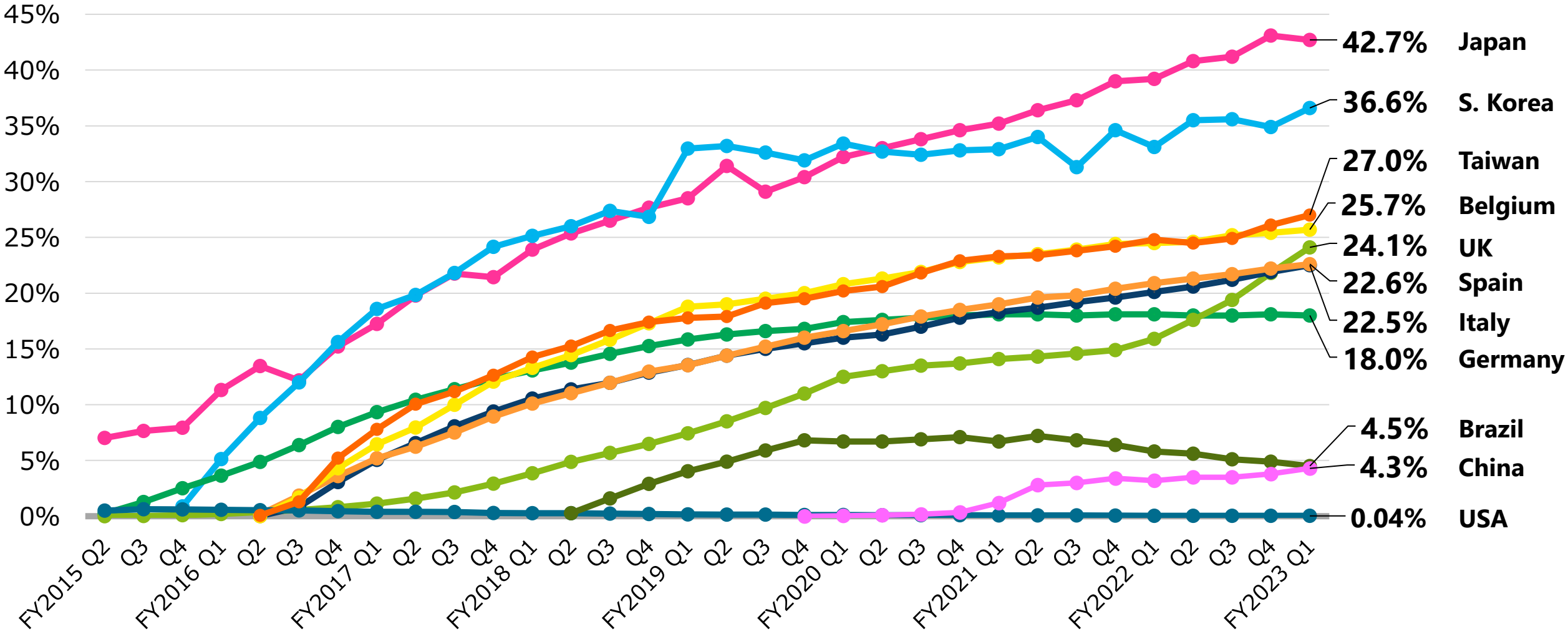
Blue letters: updates from Q1

LIXIANA®: Growth in Each Country/Region

Volume

Daiichi-Sankyo

Global revenue FY2023 Q2 YTD results: 137.7 Bn JPY (YoY +20.4 Bn JPY)
FY2023 forecast: 277.3 Bn JPY (YoY +33.4 Bn JPY)

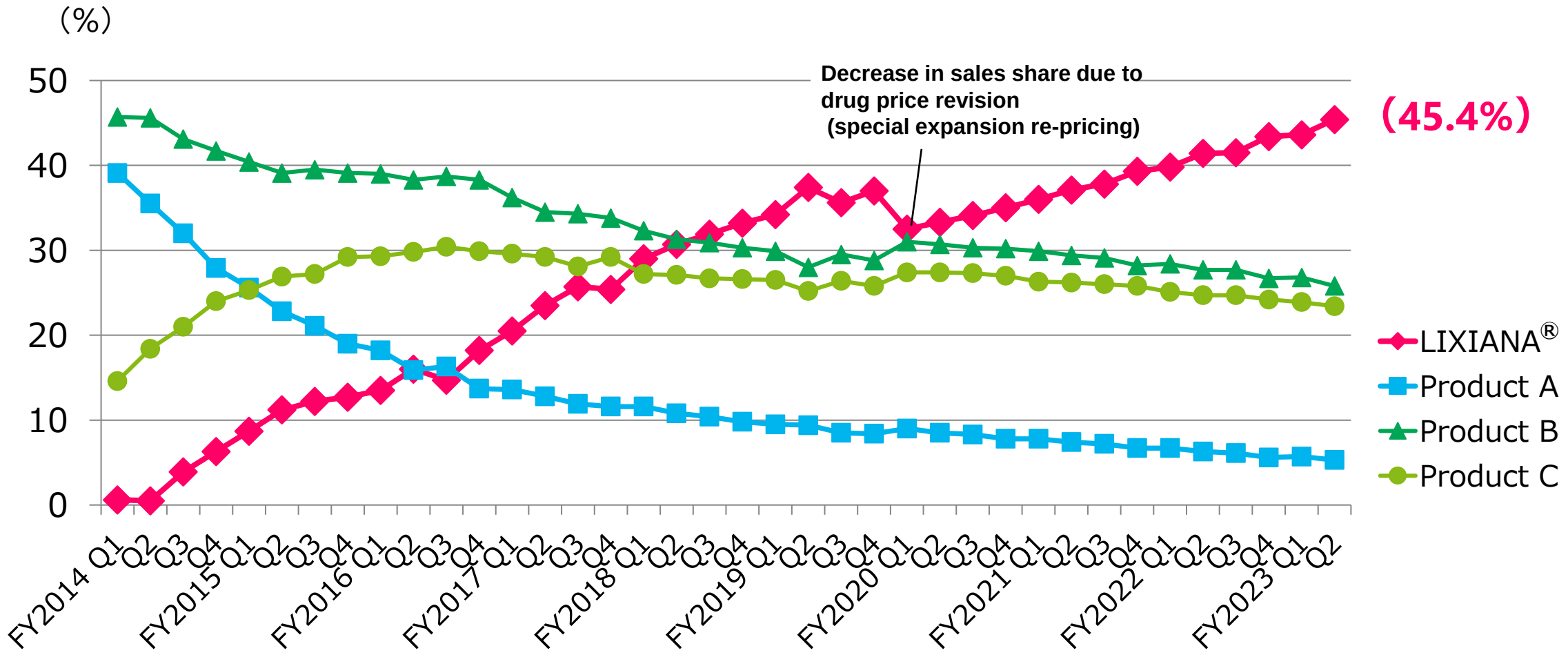


LIXIANA®: Growth in Japan

Sales

Daiichi-Sankyo

- No.1 sales share (FY2023 Q2: 45.4%)
- Revenue FY2023 Q2 YTD results: 57.1 Bn JPY (YoY +6.4 Bn JPY)
  FY2023 forecast: 112.9 Bn JPY (YoY +7.7 Bn JPY)



Major Update on Patent Disputes

Dispute with Seagen(SGN) regarding Daiichi Sankyo antibody drug conjugates

- **In October 2023, the U.S. District Court for the Eastern District of Texas issued an amended final judgment**
  - 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

- **DS intends to appeal to U.S. Court of Appeals for the Federal Circuit**

Course of events for patent infringement lawsuit

- 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

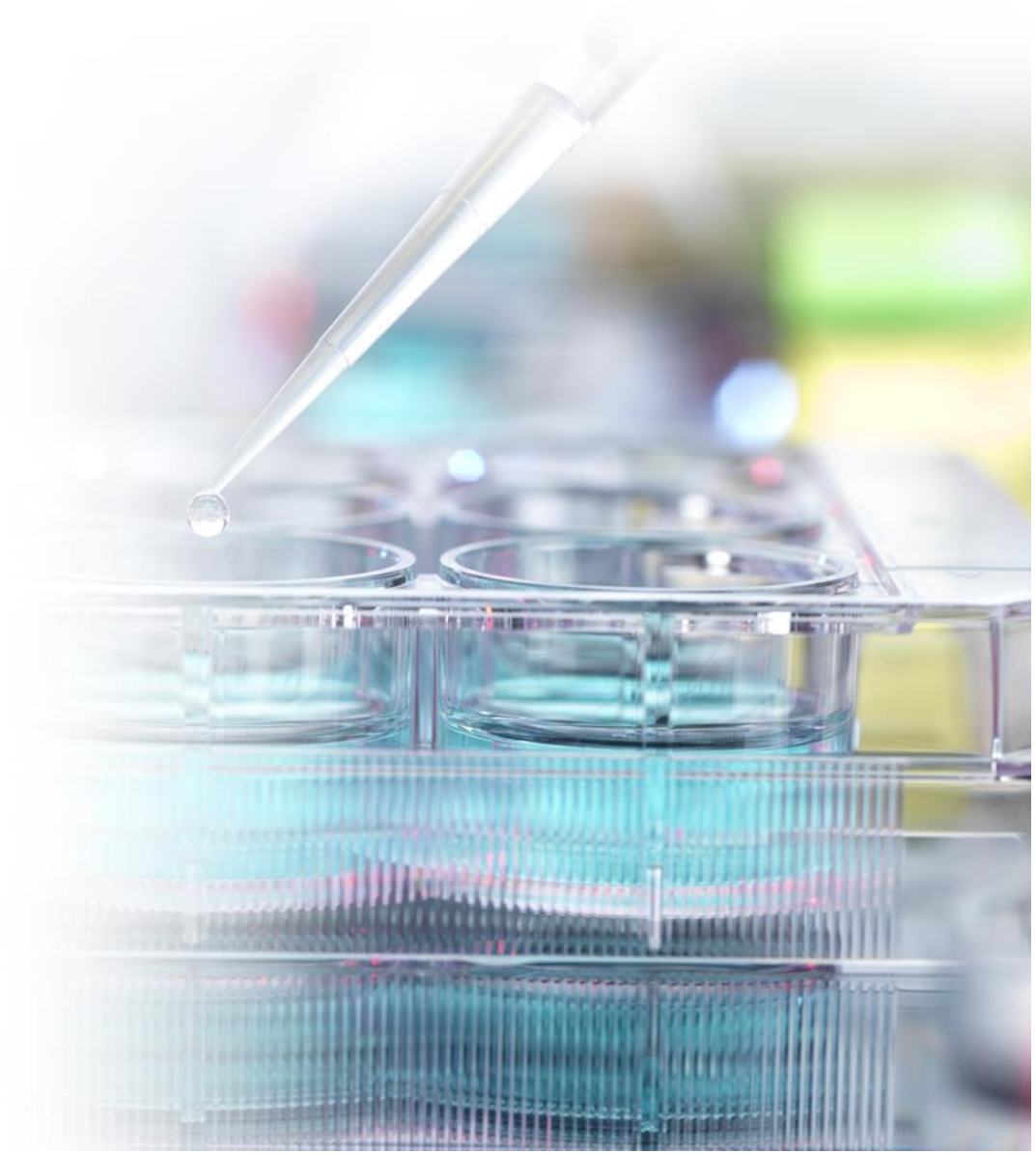
- **We will receive a decision within the next few months in the PGR (Post Grant Review) of SGN's patent**

Course of events for PGR

- Dec. 2020: DS filed a petition with the USPTO (U.S. Patent and Trademark Office) 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"

Agenda

1. FY2023 Q2 Financial Results
2. Strategic Collaboration
3. FY2023 Forecast/ Annual Dividend
4. Business Update
5. **R&D Update**
6. Appendix



5DXd-ADCs Update

Next Wave Update

R&D day

News Flow

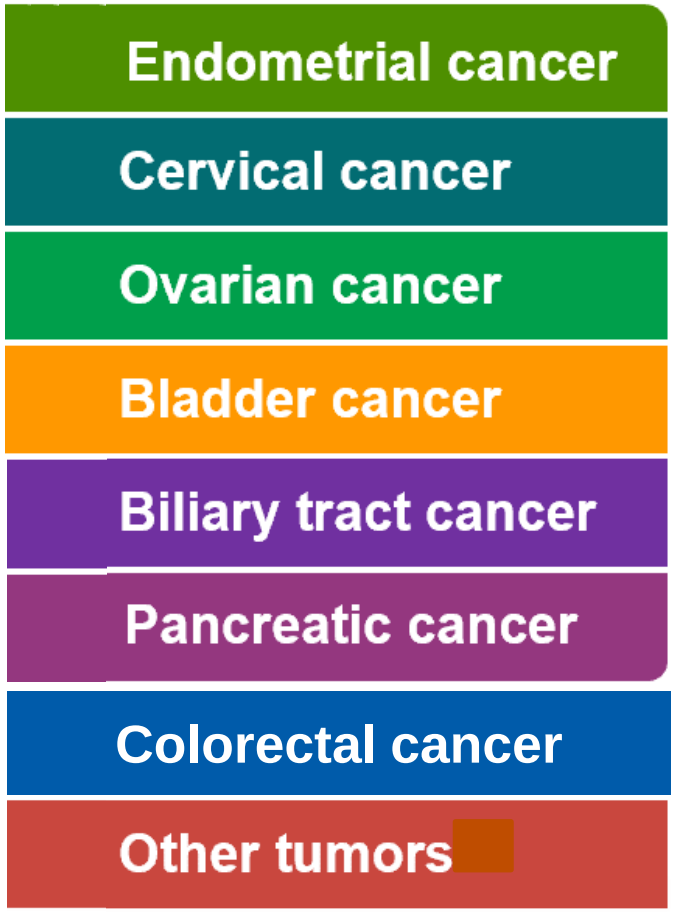
ENHERTU®

Two Breakthrough Therapy Designations

DESTINY-PanTumor02 & DESTINY-CRC01/02

Daiichi-Sankyo

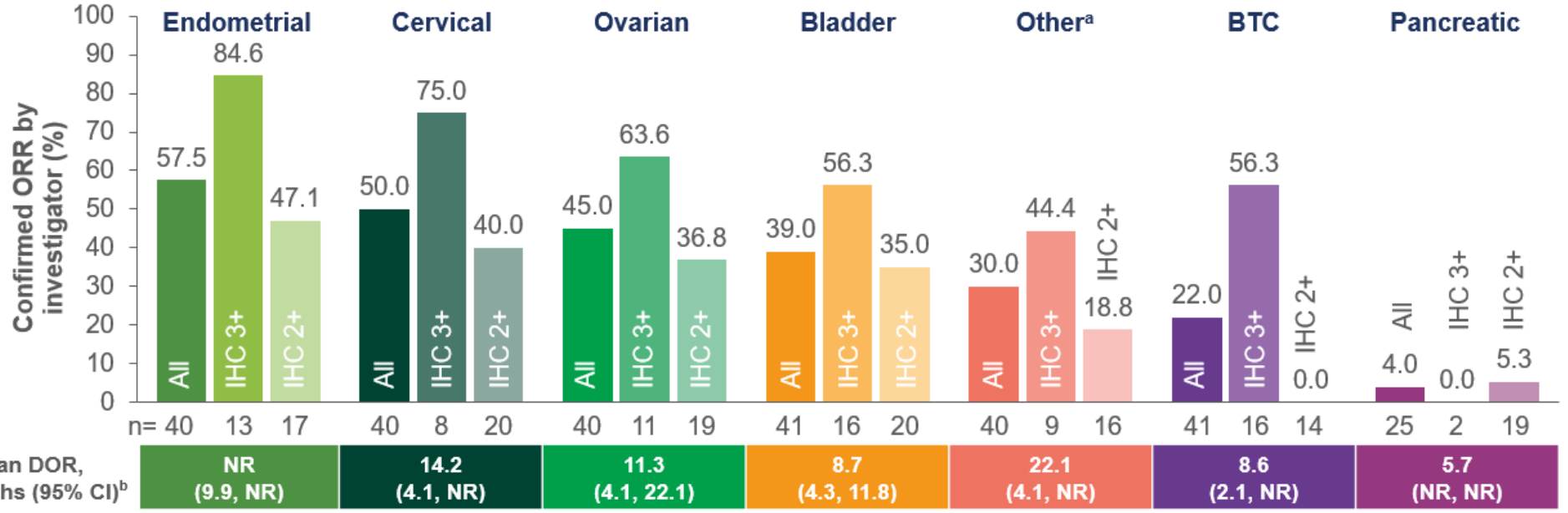
Expand leadership across HER2-targetable tumors



- ENHERTU ® is the **first HER2 directed therapy** to demonstrate a potential benefit across a series of difficult-to-treat cancers.
- ENHERTU ® has been granted additional two Breakthrough Therapy Designations in the US for the following indications:
  - Treatment of adult patients with unresectable or metastatic **HER2+ (IHC 3+) solid tumors** that have progressed following prior treatment and who have no satisfactory alternative treatment options **(DESTINY-PanTumor02)**
  - Treatment of patients with **HER2+ (IHC 3+) metastatic CRC** who have received two or more prior regimens **(DESTINY-CRC01/02)**
- Results reaffirm potential role of ENHERTU as **a tumor agnostic therapy**
- Discussions with regulatory authorities are ongoing **towards filing**

CRC: colorectal cancer, IHC: immunohistochemistry

DESTINY-PanTumor02 demonstrated clinically meaningful and durable responses across a broad range of HER2 expressing advanced solid tumors



	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)

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

- All patients: ORR 37.1% and median DOR 11.3months
- Patients with IHC 3+: ORR 61.3% and median DOR 22.1months
- Durable responses led to clinically meaningful PFS and OS
- The safety profile was consistent with the known profile with grade 5 ILD 1.1%

Data cutoff: Jun 2023

BTC: biliary tract cancer, CI: confidence interval, DOR: duration of response, IHC: immunohistochemistry, ILD: interstitial lung disease, NR: not reached, ORR: objective response rate, OS: overall survival, PFS: progression-free survival

ENHERTU®

Additional updates in clinical studies and regulatory communications

Daiichi-Sankyo

HER2 mutant NSCLC, 2L+

- Aug 2023: Approval in Japan
- Sep 2023: Recommended for approval in EU by CHMP
- Oct 2023: Approval in EU

DESTINY-PanTumor01 study (HER2 mutant solid tumors)

- Oct 2023: Data presentation at ESMO 2023

CHMP: Committee for Medicinal Products for Human Use, ESMO: European Society for Medical Oncology, NSCLC: non-small cell lung cancer

Dato-DXd

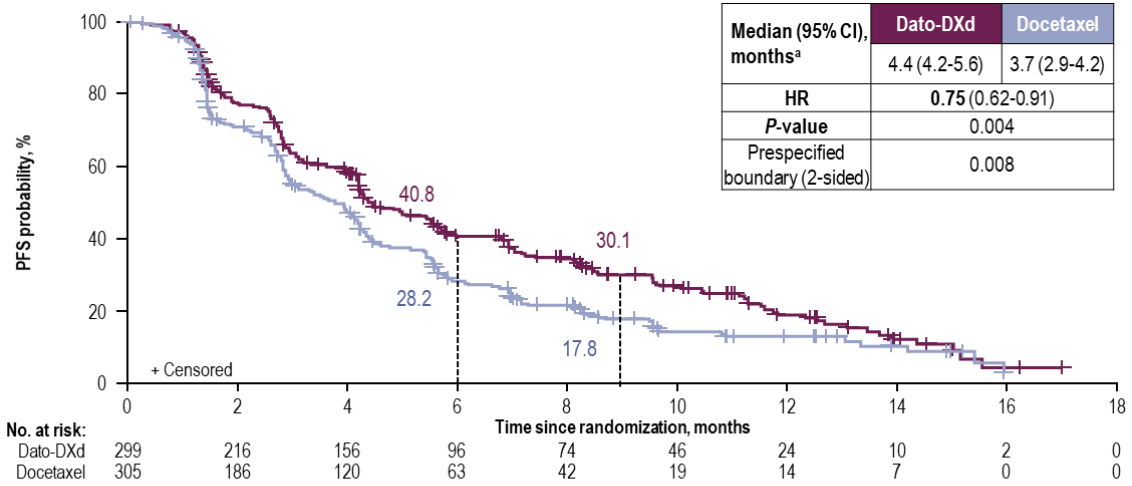
TROPION-Lung01 overall efficacy in NSCLC 2/3L

ESMO 2023

Daiichi-Sankyo

Dato-DXd is the first ADC to demonstrate a statistically significant improvement in PFS over docetaxel in NSCLC

PFS for ITT

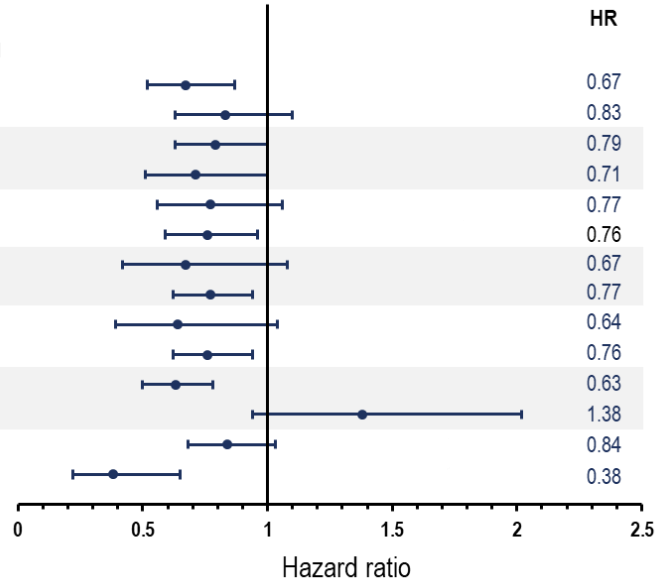


Median (95% CI), months[a]	Dato-DXd	Docetaxel
	4.4 (4.2-5.6)	3.7 (2.9-4.2)
HR	**0.75** (0.62-0.91)	
P-value	0.004	
Prespecified boundary (2-sided)	0.008	

	Dato-DXd	Docetaxel
ORR (95% CI), %[b]	**26.4** (21.5-31.8)	**12.8** (9.3-17.1)
DOR (95% CI), mo	**7.1** (5.6-10.9)	**5.6** (5.4-8.1)

PFS in Key Subgroups

		Events/n Dato-DXd	Events/n Docetaxel	HR
Age at randomization	<65 years	118/162	115/155	0.67
	≥65 years	95/137	103/150	0.83
Sex	Male	136/183	158/210	0.79
	Female	77/116	60/95	0.71
Race	Asian	76/119	82/120	0.77
	Non-Asian	131/172	129/177	0.76
Smoking status	Never	36/61	33/52	0.67
	Former/current	177/238	184/251	0.77
Brain metastasis at baseline	With	33/50	31/47	0.64
	Without	180/249	187/258	0.76
Histology	Non-squamous	156/229	168/232	0.63
	Squamous	57/70	50/73	1.38
Actionable genomic alterations[c]	Absent	189/252	184/255	0.84
	Present	24/47	34/50	0.38



Data cutoff: Mar 2023

- **Met dual primary endpoint of PFS**
- Hazard Ratio: 0.75 (95% CI, 0.62-0.91)
- ORR: Dato-DXd; 26.4%, DTX; 12.8%
- Median PFS: Dato-DXd; 4.4 m, DTX; 3.7 m
- The interim OS favor Dato-DXd, and the trial is continuing to final analysis

- Hazard ratio for non-squamous: 0.63, and for squamous:1.38
- Hazard ratio for patients without AGA: 0.84, and for patients with AGA: 0.38

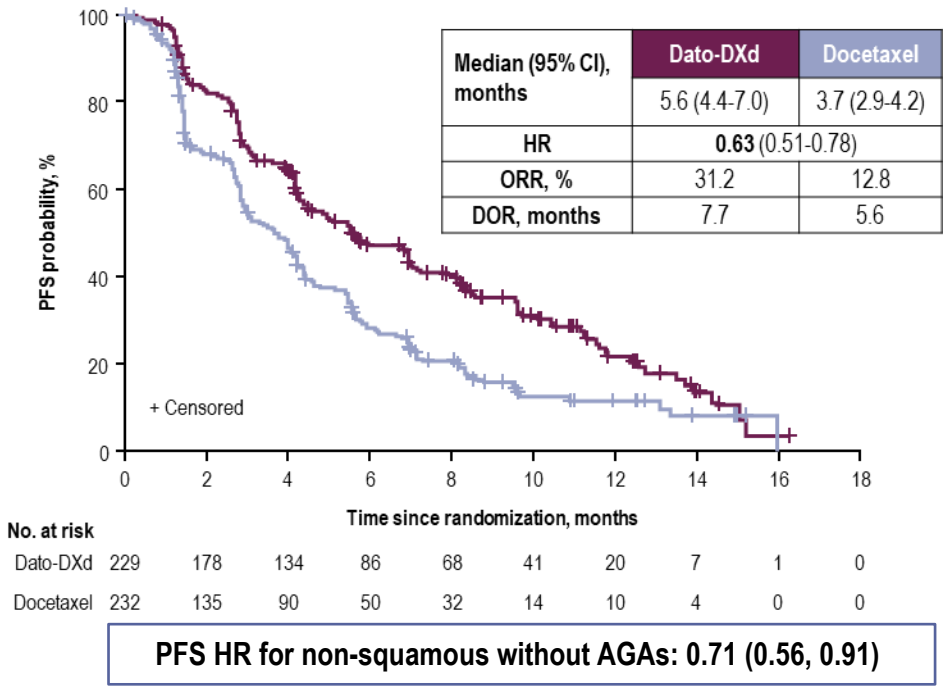
[a]Median PFS follow-up time was 10.9 (95% CI, 9.8-12.5) and 9.6 (95% CI, 8.2-11.9) months for Dato-DXd and docetaxel, respectively. [b]Included four CRs and 75 PRs for Dato-DXd and 39 PRs for docetaxel. [c]Regardless of histology.
AGA: actionable genomic alteration, CI: confidence interval, CR: complete response, DOR: duration of response, DTX: docetaxel, HR: hazard ratio, ITT: intention-to-treat, NSCLC: non-small cell lung cancer, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, PR: partial response

TROPION-Lung01 efficacy in non-sq and sq NSCLC

ESMO 2023

Dato-DXd is potentially practice-changing in non-squamous 2L+ NSCLC

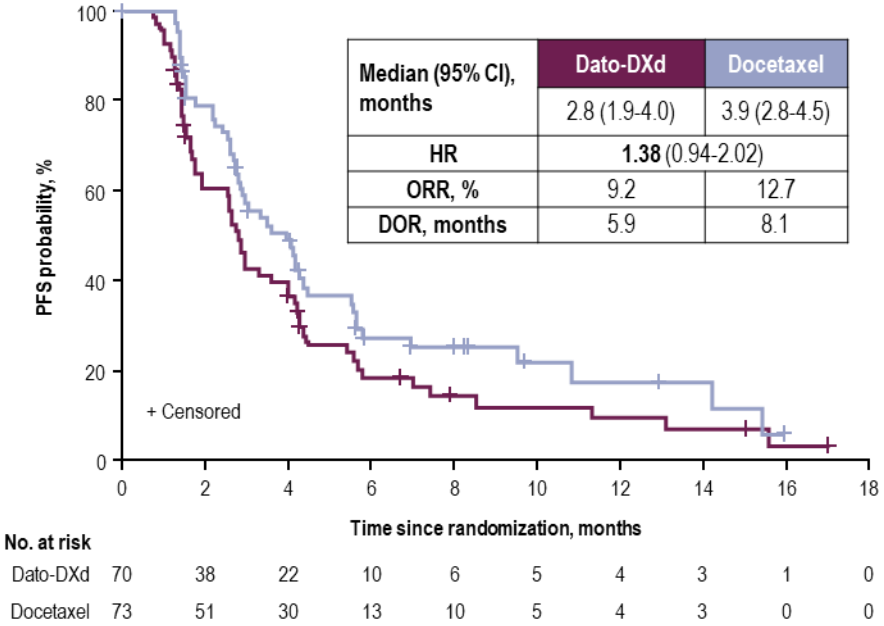
PFS in Non-squamous (with and without AGAs)



Median (95% CI), months	Dato-DXd	Docetaxel
	5.6 (4.4-7.0)	3.7 (2.9-4.2)
HR	**0.63** (0.51-0.78)	
ORR, %	31.2	12.8
DOR, months	7.7	5.6

PFS HR for non-squamous without AGAs: 0.71 (0.56, 0.91)

PFS in Squamous (with and without AGAs)



Median (95% CI), months	Dato-DXd	Docetaxel
	2.8 (1.9-4.0)	3.9 (2.8-4.5)
HR	**1.38** (0.94-2.02)	
ORR, %	9.2	12.7
DOR, months	5.9	8.1

- Longer median PFS was observed in prespecified subgroups including non-squamous histology (Nsq; 5.6 vs 3.7 months).
- Plan to amend TROPION-Lung08 study protocol to cap the squamous population
- Data have been shared with FDA and **discussion ongoing toward filing**

Squamous subset included 3 patients with AGAs

AGA: actionable genomic alterations, CI: confidence interval, DOR: duration of response, HR: hazard ratio, NSCLC: non-small cell lung cancer, Nsq: non-squamous, ORR: objective response rate, PFS: progression-free survival, sq: squamous

TROPION-Lung01 Safety

ESMO 2023

Favorable tolerability against chemotherapy, careful monitoring is required for ILD management

TRAEs, n (%)	Dato-DXd N=297	Docetaxel N=290
All grades	257 (87)	252 (87)
Grade ≥3	73 (25)	120 (41)
Associated with dose reduction	58 (20)	85 (29)
Associated with dose delay	49 (17)	31 (11)
Associated with discontinuation	23 (8)	34 (12)
Associated with death[a]	3 (1)	2 (1)
Serious TRAEs	30 (10)	36 (12)
Grade ≥3	25 (8)	33 (11)

[a]Investigator assessed. Dato-DXd: 2 cases of ILD/pneumonitis and 1 case of sepsis; docetaxel: 1 case of ILD/pneumonitis and 1 case of septic shock.
The safety analysis set included all randomized patients who received ≥1 dose of the study drug.

- Fewer grade ≥3 TRAEs were observed with Dato-DXd compared with docetaxel
- Fewer TRAEs leading to dose reductions or discontinuations were seen with Dato-DXd compared with docetaxel

AESI, n (%)	Dato-DXd N=297	Docetaxel N=290
Stomatitis/oral mucositis[a]		
All grades	160 (54)	59 (20)
Grade ≥3	19 (6)	4 (1)
Ocular events[b]		
All grades	57 (19)	27 (9)
Grade ≥3	5 (2)[c]	0
Adjudicated drug-related ILD[d]		
All grades	25 (8)	12 (4)
Grade ≥3	10 (3)	4 (1)
Grade 5	7 (2)	1 (0.3)

[a]Events included the selected PTs oral mucositis/stomatitis, oropharyngeal pain, mouth ulceration, odynophagia, dysphagia, oral pain, glossitis, pharyngeal inflammation, aphthous ulcer, and oral mucosa erosion. [b]Ocular events included selected PTs from the corneal disorder SMQ and selected relevant PTs from the eye disorder SOC. [c]Included 4 cases of keratitis and 1 case of ulcerative keratitis. [d]ILD includes events that were adjudicated as ILD and related to use of Dato-DXd or docetaxel (includes cases of potential ILD/pneumonitis based on MedDRA v26.0 for the narrow ILD SMQ, selected terms from the broad ILD SMQ, and PTs of respiratory failure and acute respiratory failure). [e]Among treated patients, histology information per the case report form.

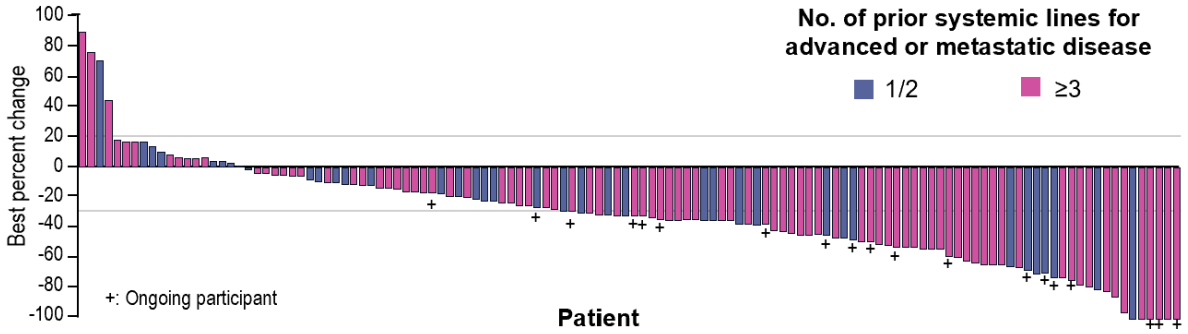
- Seven adjudicated drug-related grade 5 ILD events
  - Primary cause of death in 4 out of 7 was attributed to disease progression by investigator
  - Non-squamous: 4 of 232 patients (1.7%); Squamous: 3 of 65 patients (4.6%)[e]

AESI: adverse event of special interest, ILD: interstitial lung disease, MedDRA: Medical Dictionary for Regulatory Activities, PT: preferred term, SMQ: standard MedDRA queries, TRAE: treatment-related adverse events

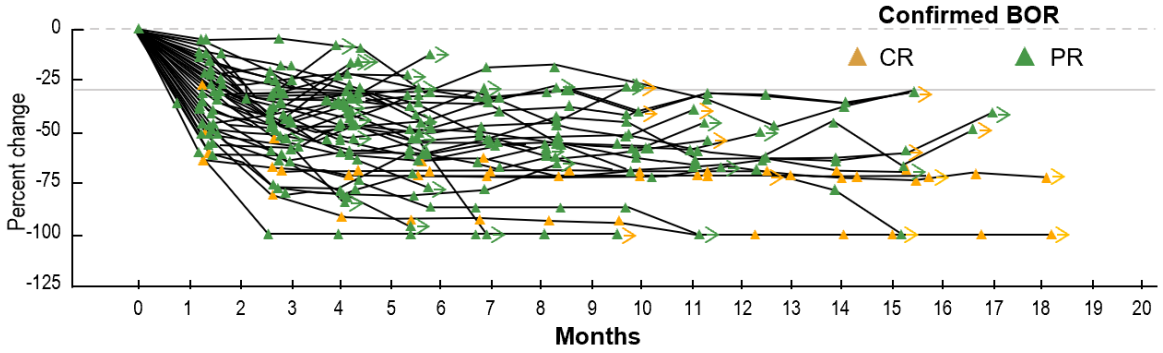
Encouraging antitumor activity was observed with Dato-DXd treatment in a heavily pretreated NSCLC population with AGAs

Efficacy

Best Percent Change From Baseline in Sum of Diameters of Target Lesions



Percent Change From Baseline in Sum of Diameters of Target Lesions in Patients With Confirmed CR/PR[c]



TROPION-Lung05 Study

- Phase 2, single-arm study evaluating Dato-DXd in patients with advanced or metastatic NSCLC with AGAs that progressed on or after targeted therapy and platinum-based chemotherapy

Response per BICR	All treated patients (N=137)	Patients with *EGFR* mutations (N=78)	Patients with *ALK* rearrangement (N=34)
ORR confirmed, n (%) [95% CI][a]	49 (35.8) [27.8-44.4]	34 (43.6) [32.4-55.3]	8 (23.5) [10.7-41.2]
Median DOR (95% CI), months	7.0 (4.2-9.8)	7.0 (4.2-10.2)	7.0 (2.8-8.4)
DCR confirmed, n (%) [95% CI][a]	108 (78.8) [71.0-85.3]	64 (82.1) [71.7-89.8]	25 (73.5) [55.6-87.1]
Median PFS, (95% CI), months[b]	5.4 (4.7-7.0)	5.8 (5.4-8.3)	4.3 (2.6-6.9)

Data cutoff: Dec 2022

- Confirmed ORR and median PFS in all treated patients were **35.8% and 5.4 months**, respectively
- Dato-DXd had a manageable safety profile, characterized by a low incidence of hematologic or drug-related grade ≥3 toxicities
- Adjudicated drug related ILD was 5 (4%) in total and 1 (1%) for grade ≥3

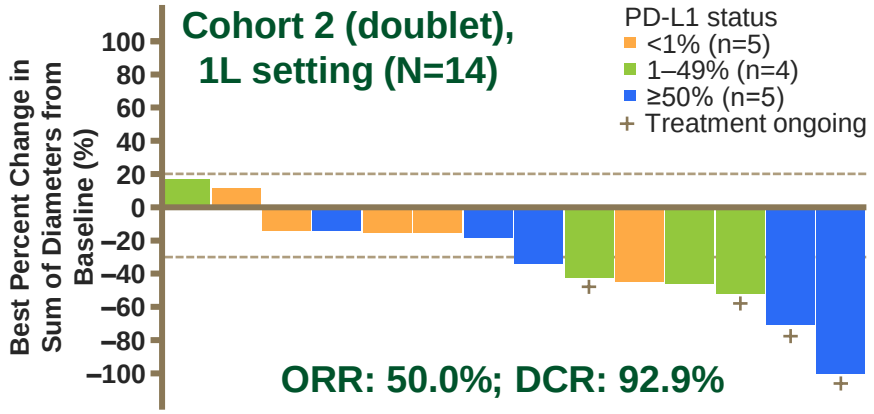
AGA: actionable genomic alterations, BOR: best overall response, CI: confidence interval, CR: complete response, DCR: disease control rate, DOR: duration of response, ILD: interstitial lung disease, NSCLC: non-small cell lung cancer, ORR: objective response rate, PFS: progression-free survival, PR: partial response

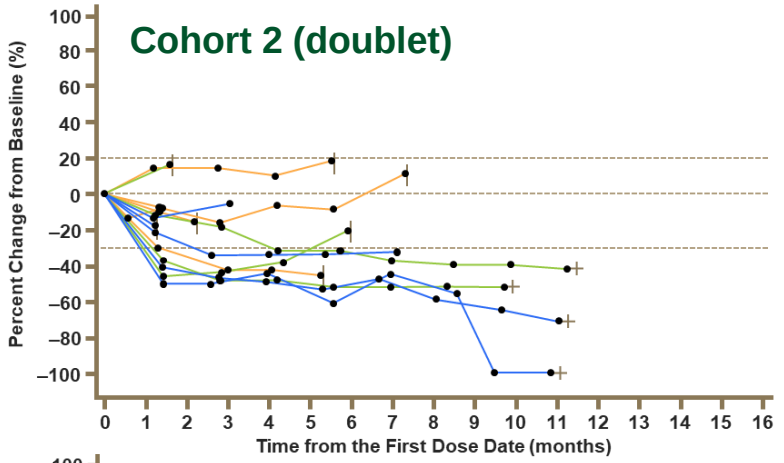
TROPION-Lung04

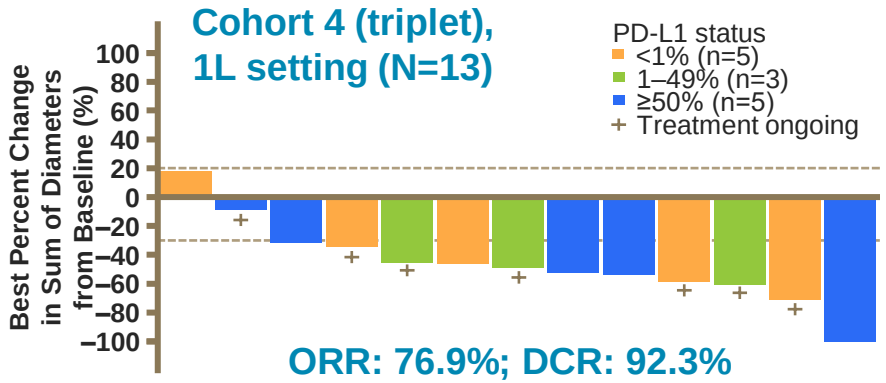
WCLC 2023

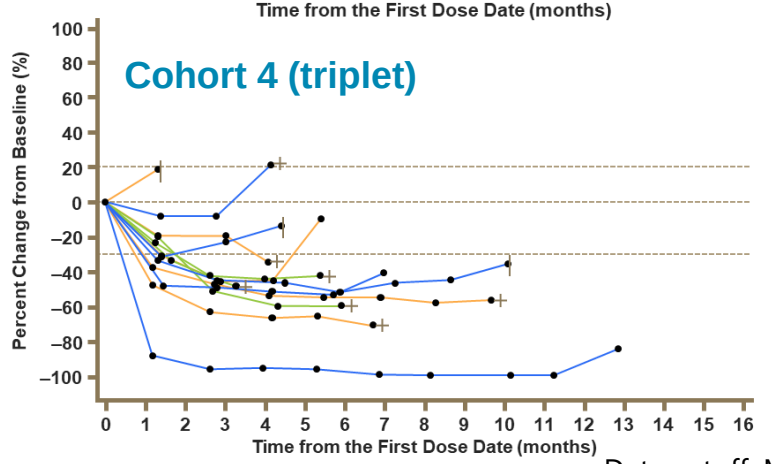
The interim analysis data demonstrated promising ORRs with durable responses in NSCLC for both the doublet and triplet combination

Efficacy









TROPION-Lung04 Study

Ph1b study in NSCLC to investigate Dato-DXd in combination with immunotherapy agents ± carboplatin

- Interim analysis data of combination with durvalumab (cohort 2) and durvalumab + carboplatin (cohort 4) were reported in WCLC 2023

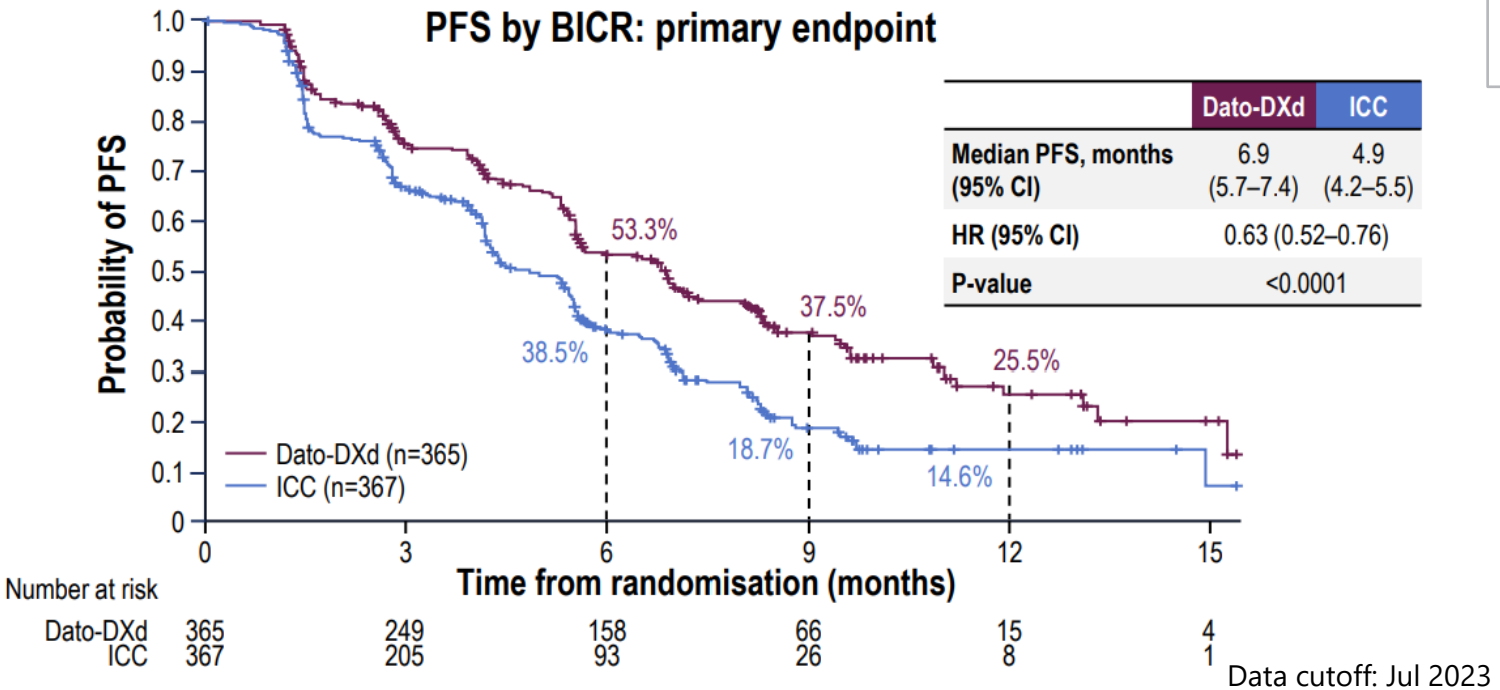
- In the overall population, confirmed ORR were 47.4% for cohort 2 (n=19) and 71.4% for cohort 4 (n=14). **In the 1st line setting, cORR were 50.0% for cohort 2 (n=14) and 76.9% for cohort 4 (n=13)**
- No new safety signals were observed. There were four cases of ILD; 3 cases were grade 1 or 2 and one grade 4 in cohort 2. None were grade 5.

Data cutoff: Mar 2023

DCR: disease control rate, ILD: interstitial lung disease, NSCLC: non-small cell lung cancer, ORR: objective response rate, WCLC: World Conference on Lung Cancer

TROPION-Breast01 enables Dato-DXd to aim to set a new standard for TROP2 ADCs in HR+/HER2 low or negative BC

Efficacy



Data cutoff: Jul 2023

PFS by investigator assessment: Median 6.9 vs 4.5 months; HR 0.64 (95% CI 0.53–0.76)

TROPION-Breast01 Study

- The dual primary endpoints are PFS and OS
- TLR was obtained in Sep 2023

- 63% of the patients received 1L and 37% received 2L chemotherapy prior to Dato-DXd
- **Median PFS by BICR: 6.9 months** for Dato-DXd (n=365) and 4.9 months for ICC (n=367). OS data was not mature at the point of analysis
- **Confirmed ORR: 36.4%** for Dato-DXd and 22.9% for ICC.
- Rate of grade≥3 TRAEs in the Dato-DXd group was **less than half** that in the ICC group
- **ILD rate was low; mainly grade 1/2 events**. There were one grade 3 and one grade 5 adjudicated ILD event
- Communication with regulatory authorities is ongoing **toward filing**

BC: breast cancer, BICR: blinded independent central review, CI: confidence interval, HR: hazard ratio, HR+: hormone receptor positive, ICC: investigator's choice of chemotherapy, ILD: interstitial lung disease, ORR: objective response rate, PFS: progression-free survival, OS: overall survival, TLR: top line results, TRAE: treatment related adverse events

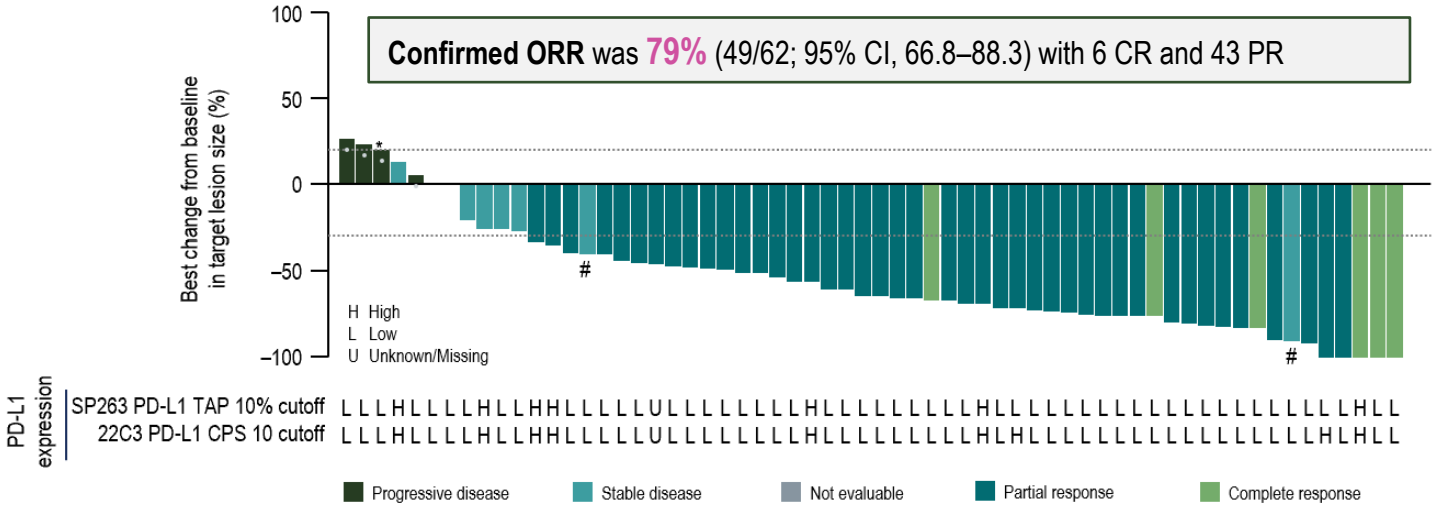
BEGONIA Data Update

ESMO 2023

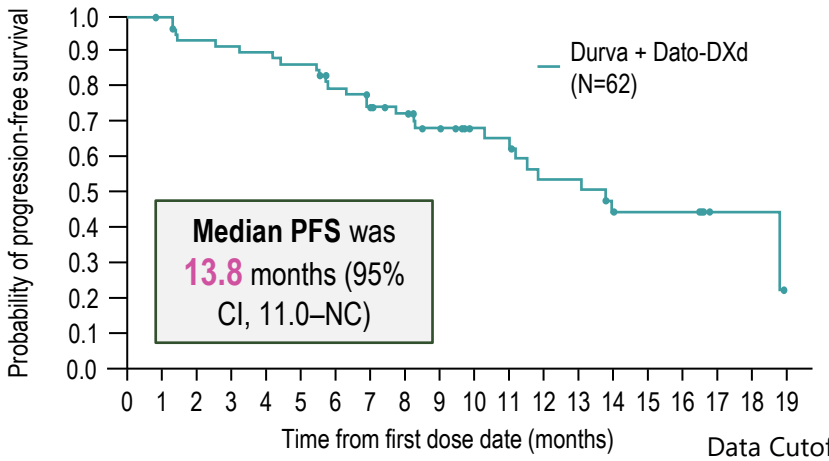
Daiichi-Sankyo

Dato-DXd + durvalumab continues to demonstrate robust, durable responses in 1L TNBC in a biomarker-unselected population

Efficacy (ORR)



Efficacy (PFS)



Data Cutoff: Feb 2022

BEGONIA（Arm7）

BEGONIA is open-label platform study to evaluate safety and efficacy of durvalumab combined with other novel therapies in 1L advanced/ metastatic TNBC. Combination of durvalumab and Dato-DXd is evaluated in Arm7 and Arm8 (PD-L1 high)

- Confirmed ORR: 79%, median DOR: 15.5 months and median PFS: 13.8 months
- **Antitumor responses were observed regardless of PD-L1 expression level**
- The most common AEs were gastrointestinal and generally of low grade
- There were 3 (5%) adjudicated treatment-related ILD/pneumonitis events (2 grade 2 events, 1 grade 1 event)

AE: adverse events, CI: confidence interval, CPS: combined positive score, CR: complete response, DOR: duration of response, ILD: interstitial lung disease, NC: not calculable, ORR: objective response rate, PFS: progression-free survival, PR: partial response, TAP: tumor area positivity, TNBC: triple-negative breast cancer

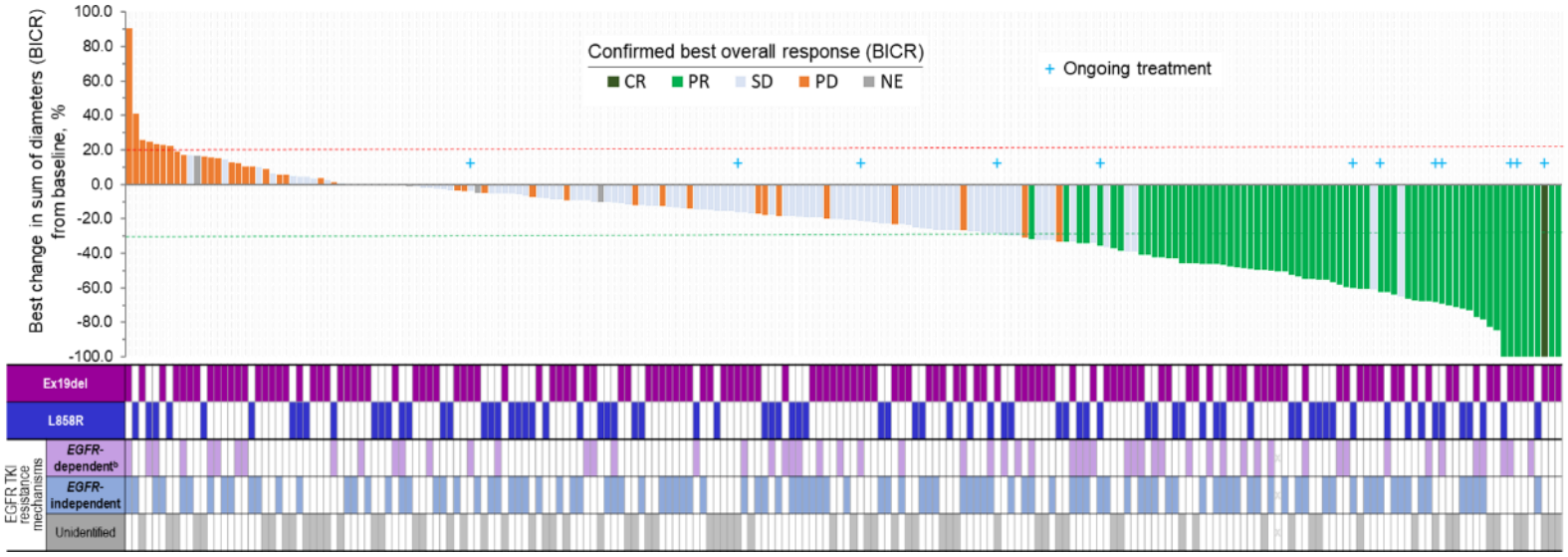
HERTHENA-Lung01 study

WCLC 2023

Daiichi-Sankyo

HER3-DXd demonstrated clinically meaningful and durable efficacy in patients with EFGR-mutated NSCLC whose disease progressed after EGFR TKI and PBC

Efficacy



Snapshot data cutoff: May 2023

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
- Regulatory submission in US is planned for FY2023
- The confirmatory Ph3 study HERTHENA-Lung02 study is ongoing

- Overall population: confirmed ORR 29.8%, median DOR 6.4 months, median PFS 5.5 months, median OS 11.9 months. **Efficacy was observed across diverse mechanisms of EGFR TKI resistance** and **across a broad range of pretreatment tumor HER3 membrane expression**.
- The most common TEAEs were nausea, thrombocytopenia and decreased-appetite. Incidence of ILD was 5.3% and one patient experienced grade 5 ILD. Overall safety profile was manageable and consistent with previous reports.

BICR: blinded independent central review, BTD: breakthrough therapy designation, CR: complete response, DOR: duration of response, ILD: interstitial lung disease, NE: not evaluable, NSCLC: non-small cell lung cancer, ORR: objective response rate, OS: overall survival, PBC: platinum-based chemotherapy, PFS: progression-free survival, PR: partial response, SD: stable disease, PD: progressive disease, TEAE: treatment emergent adverse event, TKI: tyrosine kinase inhibitor

DS-7300 (I-DXd)

Ph1/2 Study Data Update

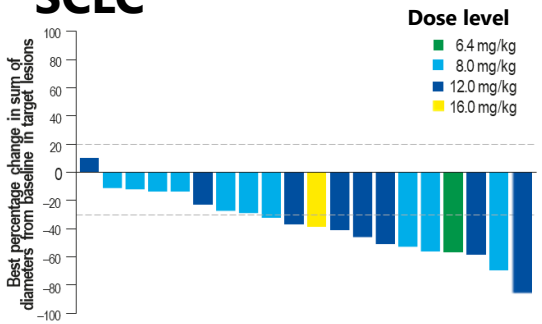
WCLC 2023/ESMO 2023

Daiichi-Sankyo

DS-7300 continued to show durable efficacy in patients with heavily pretreated solid tumors, including SCLC, ESCC, mCRPC, and sqNSCLC

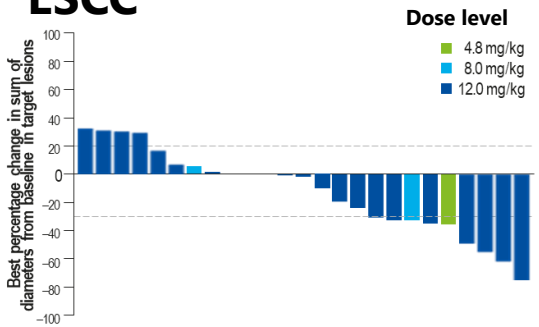
Efficacy analysis in selected tumor types

SCLC



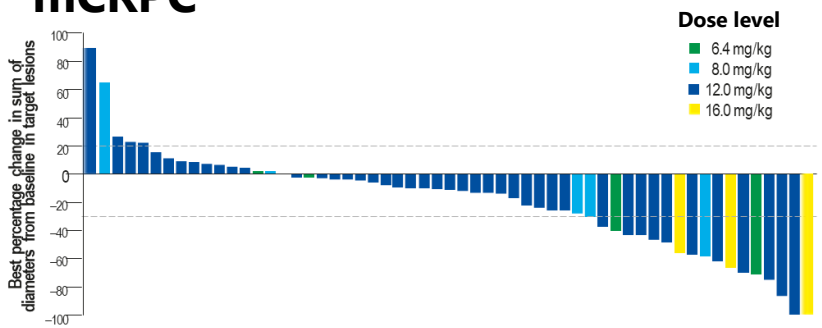
- cORR: 52.4% (11/21)
  (95% CI 29.8–74.3)
- mPFS: 5.6 m (3.9-8.1)
- mOS: 12.2 m (6.4-NE)
- No. of treatments, median: 2 (1-7)

ESCC



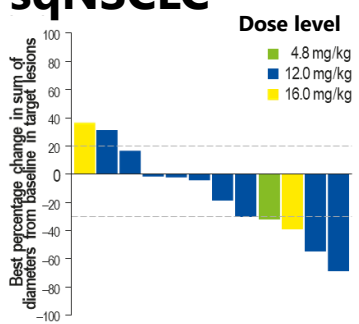
- cORR: 21.4% (6/28)
  (95% CI 8.3–41.0)
- mPFS: 2.8 m (2.1-5.5)
- mOS: 7.0 m (4.8-12.2)
- No. of treatments, median: 4 (1-7)

mCRPC*



- cORR: 25.4% (15/73)
  (95% CI 15.0–38.4)
- mPFS: 5.3 m (4.1-6.9)
- mOS: 13.0 m (10.3-16.0)
- No. of treatments, median: 6 (1-11)

sqNSCLC



- cORR: 30.8% (4/13)
  (95% CI 9.1–61.4)
- Since enrollment in this cohort is ongoing, analyses of PFS and OS are not yet mature.
- No. of treatments, median: 3 (1-12)

- Observed safety profile was manageable and tolerable
  - No new safety signals were observed, and the safety profile was consistent with previous data
  - Incidence of ILD was consistent with the previously observed data.
  - 10 (5.7%) confirmed cases of adjudicated ILD were observed, of which two cases were Grade ≥3 (one grade 4 in 12 mg/kg cohort and one grade 5 in 16 mg/kg cohort)

Data cutoff: Jan 2023

* n=73, including patients with bone metastases who were not evaluable for ORR. The ORR is calculated based on 59 patients who received ≥1 dose ≥4.8 mg/kg, had measurable disease at baseline, ≥2 postbaseline scans, and/or discontinued treatment for any reason at data cutoff.

CI: confidence interval, ESCC: esophageal squamous cell carcinoma, ILD: interstitial lung disease, mCRPC: metastatic castration-resistant prostate cancer, mOS: median overall survival, mPFS: median progression-free survival, NE: not estimable, cORR: confirmed objective response rate, OS: overall survival, PFS: progression-free survival, SCLC: small cell lung cancer, sqNSCLC: squamous non-small cell lung cancer

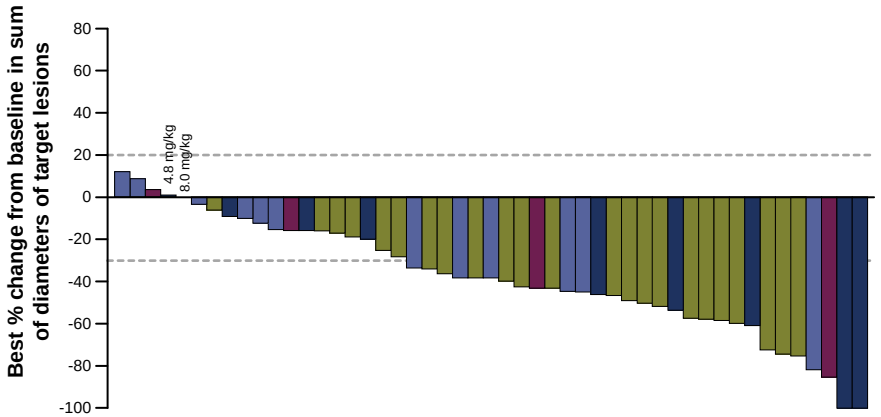
Ph1 Study OVC Cohort Data Update

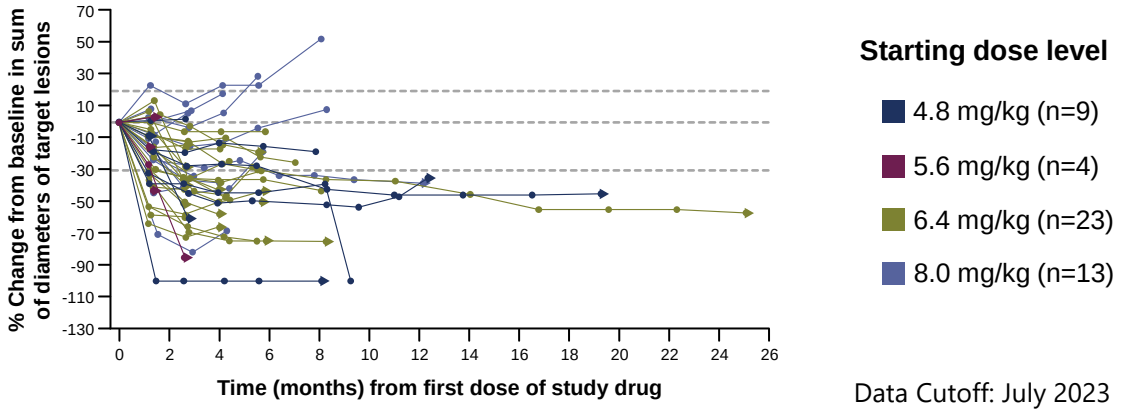
ESMO 2023

DS-6000 (CDH6 directed DXd-ADC) continues to demonstrate strong clinical activity in patients with platinum resistant ovarian cancer

Efficacy*

- **Confirmed ORR: 46%** in the 4.8–8.0 mg/kg OVC cohort (23/50; 95% CI: 32–61)
- **DCR**: **98%**
- **Number of prior systemic regimens, median (range):** 4 (1-13)
- Median time to response: 6 weeks (95% CI: 5–11)
- Median **DOR**: **11.2 months** (95% CI: 3.0–NE)
- Median **PFS**: **7.9 months** (95% CI: 4.4–12.4)





Data Cutoff: July 2023

- Confirmed ORR: 46%, median DOR: 11.2 months and median PFS: 7.9 months
- Safety profile is manageable and toxicities are consistent with those observed with other DXd-ADCs
- 8.9% (4/45) of patients in 4.8-6.4 mg/kg cohort experienced ILD (all grade 2), of which 2 were adjudicated as treatment-related. 3.3% (2/60) of patients in 8.0 mg/kg cohort experienced grade 5 ILD
- Based on the accumulated overall safety, tolerability, PK and efficacy profile, the 8.0 mg/kg cohort was closed and further assessment is ongoing at three dose levels: 4.8, 5.6 and 6.4 mg/kg

*: one patient who discontinued and did not have a post-baseline tumor assessment was not included in the waterfall or spider plots.
CI: confidence interval, DCR: disease control rate, DOR: duration of response, ILD: interstitial lung disease, NE: not estimable, ORR: objective response rate, OVC: ovarian cancer, PFS: progression-free survival, PK: pharmacokinetics

External reputations to DXd-ADC technology

Daiichi-Sankyo

Received the "Prime Minister's Award" at the 6th Japan Medical Research and Development Grand Prize.

- **Developed the unique DXd-ADC technology to generate ENHERTU®**
- **The clinical development of multiple drug candidates applying this technology is underway, which expects further contributions to cancer treatment.**

The Japan Medical Research and Development Grand Prize, established 2017, honors achievements that have made significant contributions to the progress of research and development in the medical field, with its aim of advancing medical care not only in Japan but around the world. The Prime Minister's Award is given to one which showed extremely outstanding achievements.

5DXd-ADCs Update

Next Wave Update

R&D day

News Flow

DAICHIRONA® (DS-5670)

Development status of COVID-19 vaccine

DAICHIRONA® for intramuscular injection*

- **Aug 2023: Approval obtained in Japan for booster vaccination of the original strain monovalent mRNA vaccine against COVID-19**
- **Sep 2023: Regulatory submission in Japan for booster vaccination of monovalent mRNA vaccine for Omicron XBB.1.5 strain against COVID-19**

- **The first mRNA vaccine made in Japan** using cationic lipids originally optimized by Daiichi Sankyo
- Distribution and storage possible under refrigeration (2-8℃)
- **Plan to start the supply within this year** of Omicron XBB.1.5 strain monovalent vaccine

* The research and development of DAICHIRONA® 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).

Next Wave

Clinical and Regulatory Progress

VANFLYTA® (quizartinib) (*FLT3*-ITD positive acute myeloid leukemia [AML], 1L)

- Sep 2023: Recommended for approval in EU by CHMP

DS-3939 (TA-MUC1 directed ADC, Solid tumors)

- Sep 2023: Ph1/2 started

DS-1471 (Anti-CD147 antibody, Solid tumors)

- Sep 2023: Ph1 started

AML: acute myeloid leukemia, CHMP: Committee for Medicinal Products for Human Use

5DXd-ADCs Update

Next Wave Update

R&D day

News Flow

R&D Day 2023

Sunao Manabe
Executive Chairperson and CEO

Ken Takeshita
Head of Global R&D

Mark Rutstein
Head of Global Oncology Clinical Development

Date and time

Monday, December 11th, 2023
17:30-19:00 (EST)
(Tue, Dec 12th 7:30-9:00 (JST))

Meeting style

Virtual (Zoom)

5DXd-ADCs Update

Next Wave Update

R&D day

News Flow

FY2023 News Flow

As of Oct 2023

Planned major publications

San Antonio Breast Cancer Symposium (SABCS, Dec 5-9, 2023)

ENHERTU®	**DESTINY-Breast08: HER2 low BC, chemo naïve/post chemo, Ph1b** • **Partial cohort data**

American Society of Hematology (ASH, Dec 9-12, 2023)

EZHARMIA®	**VALENTINE-PTCL-01: relapsed/refractory PTCL, Ph2** • **Primary analysis data**

Planned regulatory submissions

ENHERTU®	**DESTINY-Lung05: HER2 mutant NSCLC, 2L+** • **CN: FY2023 H2** **DESTINY-Gastric06: HER2 positive GC, 3L** • **CN: FY2023 H2**
HER3-DXd	**HERTHENA-Lung01: EGFR mutant NSCLC, 3L** • **US: FY2023 H2**

Regulatory decisions

VANFLYTA®	QuANTUM-First: AML, 1L • EU: FY2023 H2
DAICHIRONA® (DS-5670)	**COVID-19 mRNA vaccine, mutant strain, booster vaccination** • **JP: FY2023 Q3**

Key data readouts

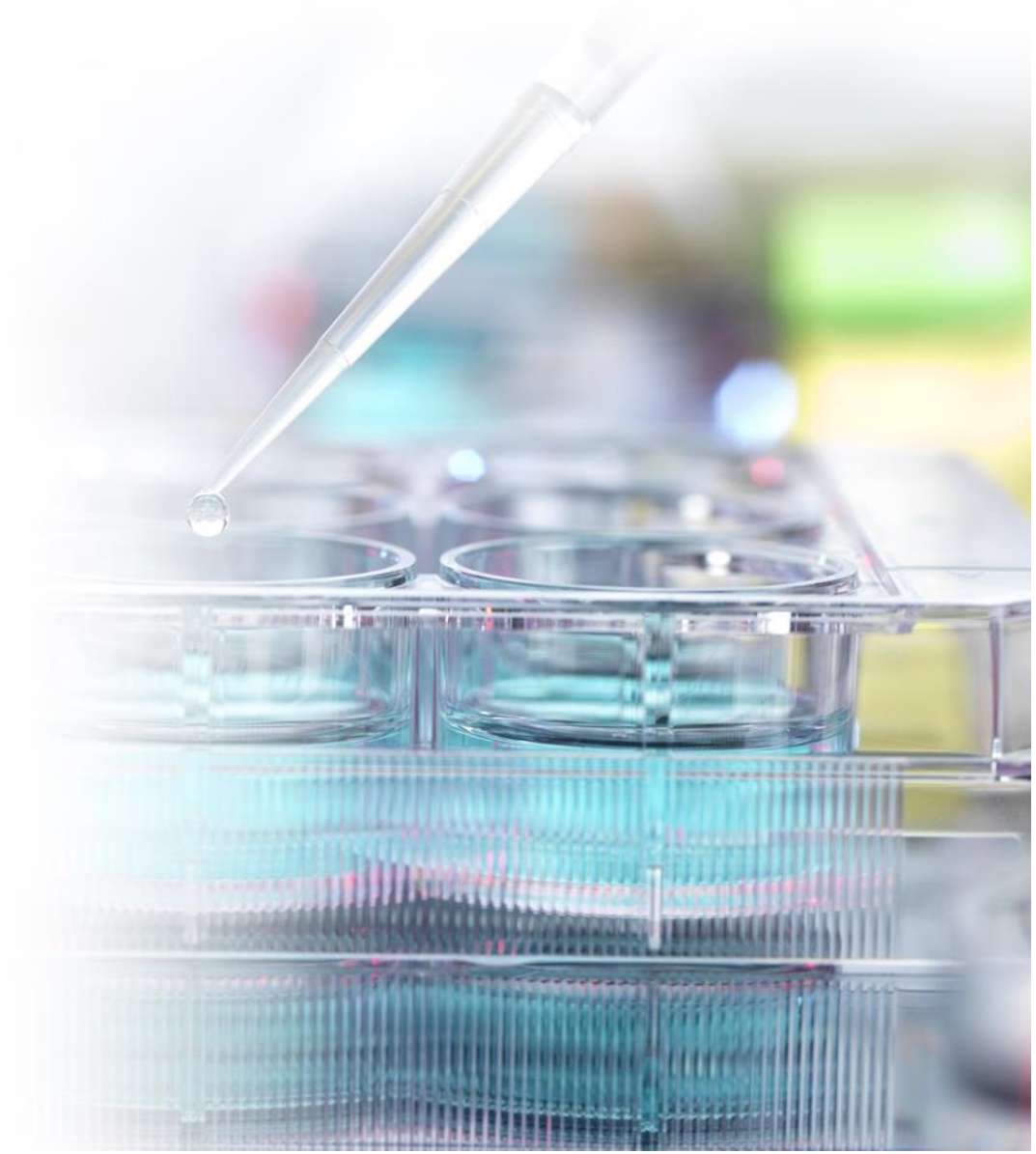
ENHERTU®	DESTINY-Breast06*: HR+ and HER2 low BC, chemo naïve, Ph3 • FY2023 H2

Bold: update from FY2023 Q1
Timeline indicated is based on the current forecast and subject to change.
*Event-driven study

AML: acute myeloid leukemia, BC: breast cancer, GC: gastric cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, PTCL: peripheral T cell lymphoma

Agenda

1. FY2023 Q2 Financial Results
2. Strategic Collaboration
3. FY2023 Forecast/ Annual Dividend
4. Business Update
5. R&D Update
6. **Appendix**



Major R&D Milestones (5DXd-ADCs ①)

Project		Target Indication [phase, study name]	FY2023 H1	FY2023 H2	FY2024
ENHERTU®	BC	• HER2 low, post chemo [Ph3, DESTINY-Breast04]	• Approved (China)		
		• HER2 low, chemo naïve [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**	**• Filing anticipated (CN)**	
	NSCLC	• HER2 mutant, 2L [Ph2, DESTINY-Lung01, 02]	**• Approved (JP)**	**• Approved (EU)**	
		• HER2 mutant, 1L [Ph3, DESTINY-Lung04]			• TLR anticipated
		• HER2 mutant, 2L [Ph2, DESTINY-Lung05]		**• TLR anticipated** **• Filing anticipated (CN)**	
	Other tumors	• HER2 expressing tumors [Ph2, DESTINY-PanTumor02]	**• TLR obtained**		

Bold: update from FY2023 Q1 BC: breast cancer, GC: gastric cancer, NSCLC: non small cell lung cancer, TLR: top line results

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

Major R&D Milestones (5DXd-ADCs ②)

As of Oct 2023

Project		Target Indication [phase, study name]	FY2023 H1	FY2023 H2	FY2024
Dato-DXd	NSCLC	• 2/3L [Ph3, TROPION-Lung01]	• TLR obtained		
	BC	• HR+ and HER2 low or negative BC, 2/3L [Ph3, TROPION-Breast01]	**• TLR obtained**		
		• TNBC, PD-1/PD-L1 inhibitor ineligible, 1L [Ph3, TROPION-Breast02]			• TLR anticipated
HER3-DXd	NSCLC	• EGFR mutant, 3L [Ph2, HERTHENA-Lung01]		**• Filing anticipated (US)**	
		• EGFR mutant, 2L [Ph3, HERTHENA-Lung02]			• TLR anticipated
DS-7300 (I-DXd)	SCLC	• 2L [Dose optimization, Ph2]			• TLR anticipated

Bold: update from FY2023 Q1 BC: breast cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, SCLC: 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 (Next Wave)

As of Oct 2023

Project	Target Indication [phase, study name]	FY2023 H1	FY2023 H2	FY2024
VANFLYTA® (Quizartinib)	• AML, 1L [Ph3, QuANTUM-First]	• Approved (JP/US)	• Approval anticipated (EU)	
EZHARMIA®	• r/r PTCL [Registrational Ph2, VALENTINE-PTCL01]	• TLR obtained		
DS-3939	• Solid tumors [Ph1/2]	**• Study started**		
DS-1471	• Solid tumors [Ph1]	**• Study started**		
DS-2325	**• Netherton syndrome [Ph1b/2]**		**• Study start planned**	
DS-5670	• COVID-19 mRNA vaccine (mutant strain), booster vaccination [Ph3]	**• Filing accepted (JP)**		
	• COVID-19 mRNA vaccine (original strain), booster vaccination [Ph1/2/3]	**• Approved (JP)**		

Bold: update from FY2023 Q1 AML: acute myeloid leukemia, BC: breast cancer, 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

Major R&D Pipeline: 5DXd-ADCs

As of Oct, 2023

Daiichi-Sankyo

Phase 1	Phase 2	Phase 3
(US/EU/Asia) HER2+ BC 2L+/1L DESTINY-Breast07	(JP/US) solid tumors TROPION-PanTumor01	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) solid tumors TROPION-PanTumor03	(JP/US/EU/Asia) HER2+ BC adjuvant*1 DESTINY-Breast05
(US/EU/Asia) HER2 low BC Chemo naïve/ post chemo DESTINY-Breast08	(CN) NSCLC, TNBC TROPION-PanTumor02	(CN) HER2+ GC 3L DESTINY-Gastric06	(JP/US/EU/Asia) NSCLC (w/ AGA) TROPION-Lung05	(JP/US/EU/Asia) HER2 low BC chemo naïve DESTINY-Breast06
(JP/US/EU/Asia) HER2+ GC combo, 2L+/1L DESTINY-Gastric03	(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) TROPION-Lung02	(CN) HER2 mutant NSCLC 2L+ DESTINY-Lung05	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09
(US/EU/Asia) HER2+ NSCLC (durvalumab, MEDI5752 combo) 1L DESTINY-Lung03	(JP/US/EU) NSCLC (w/o AGA, durvalumab, AZD2936 and MEDI5752 combo) TROPION-Lung04	(US/EU/Asia) NSCLC (durvalumab combo) 2L+ HUDSON	(JP/US/EU/Asia) EGFR mutated NSCLC (osimertinib combo) 2L ORCHARD	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11
(US/EU) BC, bladder (nivolumab combo)	(JP/US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(JP/US/EU/Asia) HER2+ CRC 3L DESTINY-CRC02	(US/EU/Asia) resectable early-stage NSCLC (durvalumab combo) neoadjuvant NeoCOAST-2	(US/EU/Asia) HER2 low BC, HER2 IHC 0 BC, 2/3L DESTINY-Breast15
(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US/EU/Asia) NSCLC	(JP/US/EU/Asia) HER2 mutant tumor DESTINY-PanTumor01	(JP/US/EU/Asia) EGFR mutated NSCLC 3L HERTHENA-Lung01 ★	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04
(US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(JP/US) EGFR mutated NSCLC (osimertinib combo)	(US/EU/Asia) HER2 expressing tumor DESTINY-PanTumor02	DS-7300 (JP/US/EU/Asia) ES-SCLC ★	(JP/US/EU/Asia) NSCLC (w/ HER2 exon 19 or exon 20 mutation) 1L DESTINY-Lung04
DS-7300 (JP/US) ESCC, CRPC, squamous NSCLC, SCLC, etc.	(JP/US/Asia) HER3+ BC			(JP/US/EU/Asia) NSCLC 2/3L TROPION-Lung01
DS-6000 (JP/US) Renal cell carcinoma, ovarian cancer				(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) BC*2 2/3L TROPION-Breast01
				(JP/US/EU/Asia) TNBC (PD-1/PD-L1 inhibitor ineligible) 1L TROPION-Breast02
				(JP/US/EU/Asia) TNBC (mono or durvalumab combo) adjuvant*3 TROPION-Breast03
				(JP/US/EU/Asia) EGFR mutated NSCLC 2L HERTHENA-Lung02

ENHERTU® (T-DXd) / Dato-DXd / HER3-DXd / DS-7300 (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 HR+, HER2 low or negative BC
*3 Adjuvant therapy for TNBC patients with residual invasive disease following neoadjuvant therapy

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 Oct 2023

Phase 1	Phase 2	Phase 3	Filed
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	Valemetostat (DS-3201)(JP/US/EU/Asia) EZH1/2 inhibitor PTCL	Pexidartinib (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	Quizartinib (EU) FLT3 inhibitor AML 1L
DS-1594 (US) Menin-MLL binding inhibitor AML, ALL	Valemetostat (DS-3201) (EU) EZH1/2 inhibitor BCL	Esaxerenone (JP) MR blocker Diabetic nephropathy	Mirogabalin (CN) α2δ ligands Diabetic peripheral neuropathic pain
DS-9606 (US/EU) Target undisclosed ADC Solid tumors	DS-1001 (JP) Mutant IDH1 inhibitor Glioma	VN-0102/JVC-001 (JP) Measles mumps rubella combined vaccine	DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain) COVID-19 (booster vaccination, 12 years old and over)
DS-1103 Anti-SIRPα antibody HER2 expressing or mutant advanced metastatic solid tumors, HER2 low BC (ENHERTU® combo)	DS-1211 (US/EU) TNAP inhibitor Pseudoxanthoma elasticum	DS-5670 (JP) COVID-19 mRNA vaccine (original strain), COVID-19 (primary vaccination, 12 to 17 aged children)	
DS-3939 Anti-TA-MUC1 ADC Solid tumors	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-1471 Anti-CD147 antibody Solid tumors			
DS-7011 (US) Anti-TLR7 antibody Systemic lupus erythematosus			
DS-2325 (EU) in prep 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, AML: acute myeloid leukemia, BCL: B cell lymphoma, LBCL: large B cell lymphoma, PTCL: peripheral T-cell lymphoma

Contact address regarding this material

Daiichi Sankyo Co., Ltd.
Corporate Communications Department

TEL: +81-3-6225-1125
Email: DaiichiSankyoIR@daiichisankyo.co.jp