Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2023
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Hiroyuki Okuzawa

Representative Director, President & COO

April 25, 2024

Forward-Looking Statements

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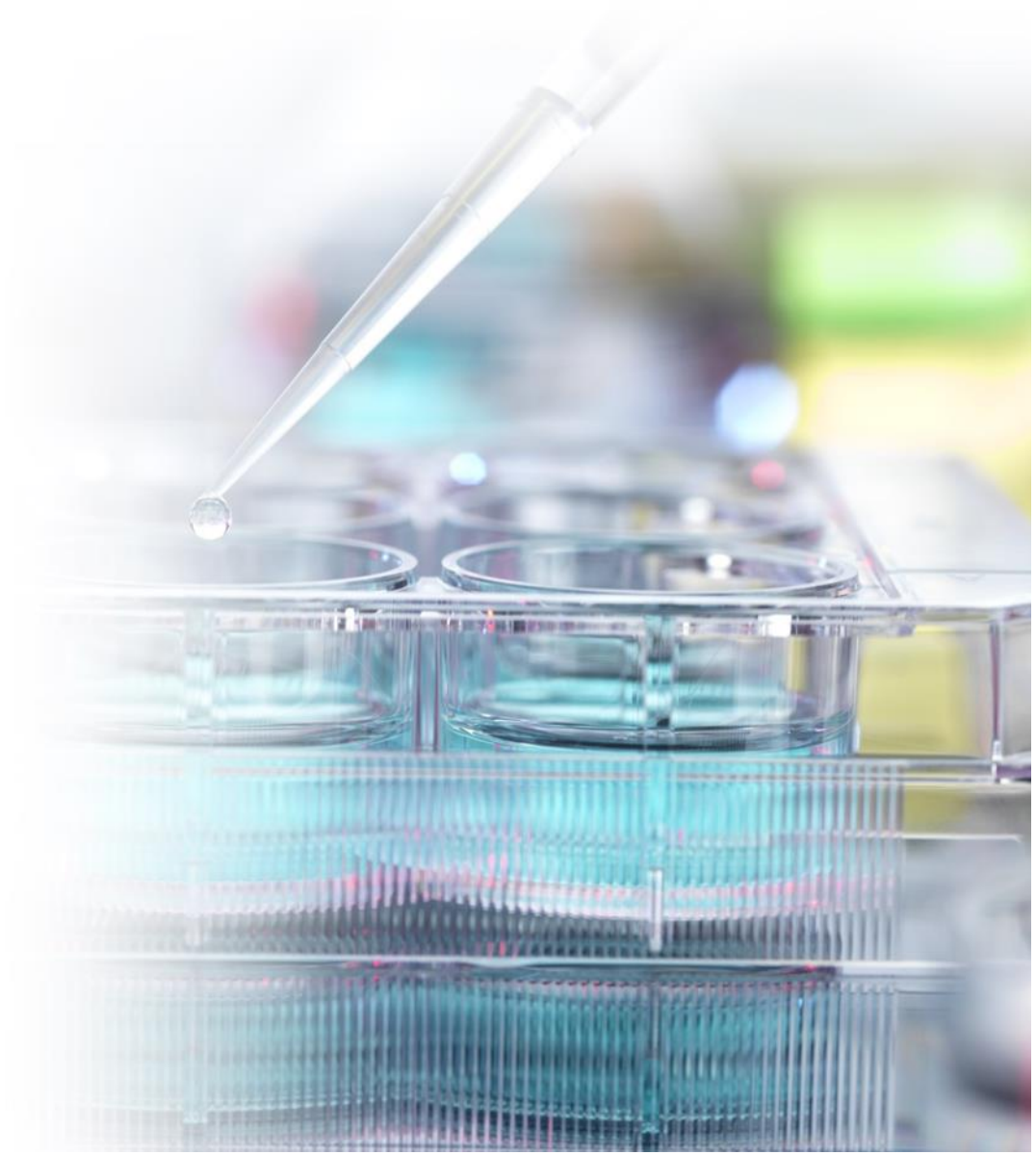
Agenda

1. **FY2023 Financial Results**
2. Business Update
3. R&D Update
4. 5-Year Business Plan Update
5. FY2024 Forecast
6. Appendix



Overview of FY2023 Results

(Bn JPY)

	FY2022 Results	FY2023 Results	YoY	
Revenue	**1,278.5**	**1,601.7**	**+25.3%**	**323.2**
Cost of sales*1	349.1	414.8		65.7
SG&A expenses*1	470.1	627.3		157.2
DXd ADC profit share *2	90.8	170.6		79.8
Other SG&A expenses	379.3	456.8		77.5
R&D expenses*1	336.7	364.3		27.6
Core operating profit *1	**122.6**	**195.3**	**+59.3%**	**72.7**
Temporary income*1	21.9	27.3		5.4
Temporary expenses*1	23.9	10.9		-13.0
Operating profit	**120.6**	**211.6**	**+75.5%**	**91.0**
Profit before tax	**126.9**	**237.2**		**110.4**
Profit attributable to owners of the Company	**109.2**	**200.7**	**+83.8%**	**91.5**

Currency Rate	USD/JPY	135.48	144.62	+9.14
	EUR/JPY	140.97	156.79	+15.82

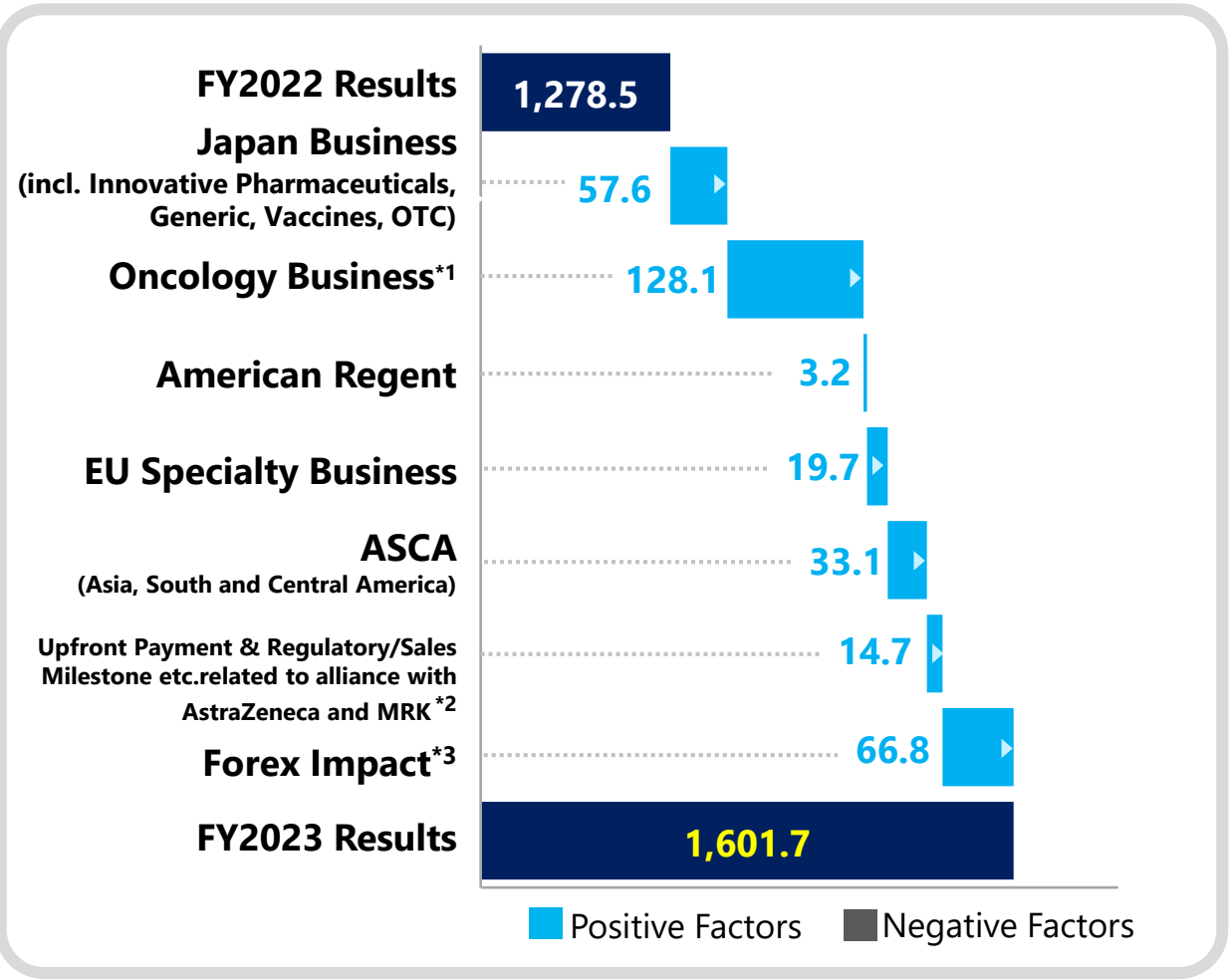
*1 As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed. Income and expenses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation,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

*2 DS pays alliance partners 50% of gross profit for the product sales in countries/regions where DS book revenue (excluding Japan) to share profit with the partners.

Revenue

Increased by 323.2 Bn JPY (Increased by 256.4 Bn JPY excl. forex impact)

(Bn JPY)

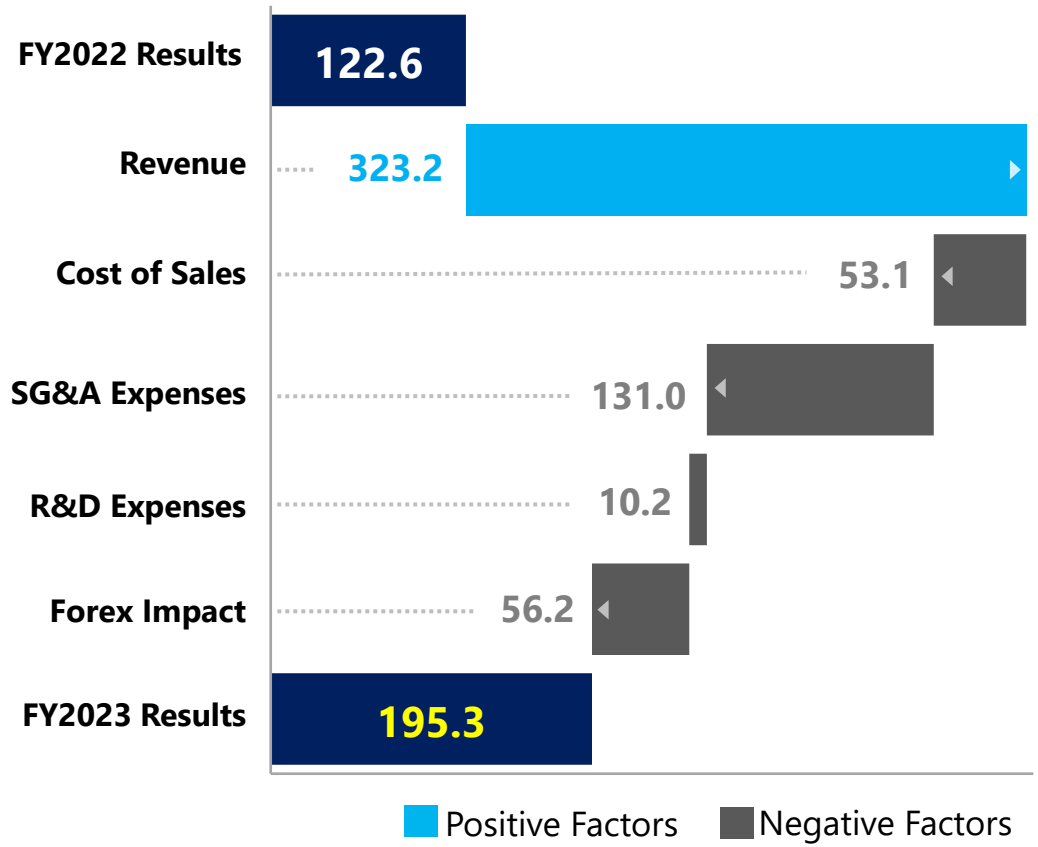


	Positive Factors	Negative Factors
Japan Business Unit		
Inavir	+15.0	
Enhertu	+12.2	
Lixiana	+10.4	
Tarlige	+7.2	
Vacciness Business	+14.3	
Oncology Business Unit*1		
Enhertu	+125.1	
Vanflyta	+1.7	
American Regent Unit		
Venofer	+5.7	
GE injectables	+4.3	
Injectafer		-7.1
EU Specialty Business Unit		
Lixiana	+14.3	
Nilemdo/Nustendi	+9.5	
Olmesartan		-2.4
ASCA (Asia, South and Central America) Business Unit		
Enhertu	+25.4	
Lixiana	+3.8	
Upfront Payment & Regulatory/Sales Milestone etc. related to alliance with AstraZeneca and MRK *2		
Enhertu Sales Milestone	+16.5	
Upfront Payment from MRK	+12.9	
Enhertu Regulatory Milestone		-14.3

*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products
*2 Merck & Co., Inc., Rahway, NJ, USA
*3 Forex impact USD: +29.6, EUR : +29.0, ASCA: +8.2

Core Operating Profit

Increased by 72.7 Bn JPY (Increased by 62.1 Bn JPY excl. forex impact)



(Bn JPY)

Revenue +323.2
incl. forex impact of +66.8

Cost of Sales +53.1
Increase in cost of sales due to the revenue increase

SG&A Expenses +131.0
Increase in profit share due to the Enhertu revenue expansion
Increase in expenses due to new indications for Enharts, and the launch preparation for Dato-DXd and HER3-DXd, etc.

R&D Expenses +10.2
Increase in 5DXd ADCs* R&D investments

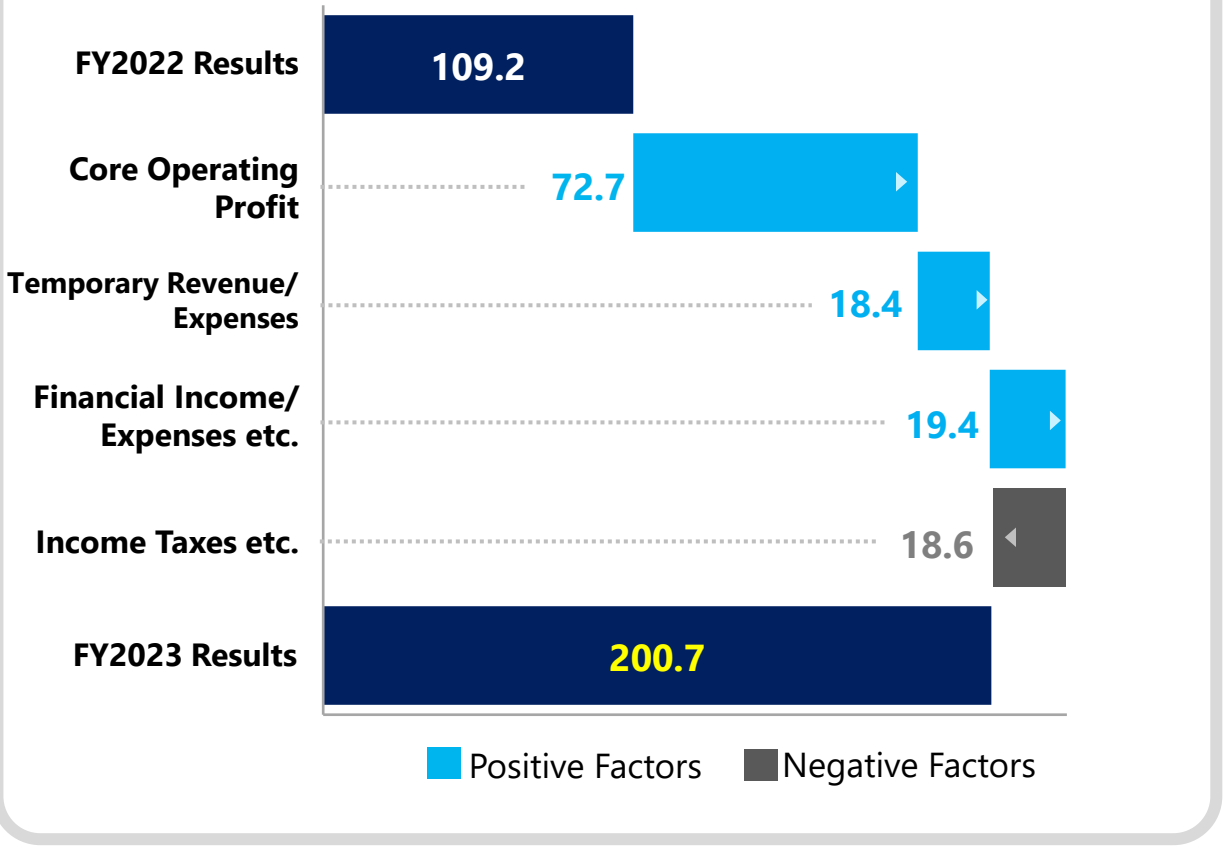
Forex Impact +56.2 **(Profit Decreased)**
Cost of Sales +12.6
SG&A Expenses +26.2
R&D Expenses +17.4

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

Profit Attributable to Owners of the Company

Increased by 91.5 Bn JPY

(Bn JPY)



Temporary Income/Expenses ····· **+18.4 (Profit Increased)**

	FY2022 Results	FY2023 Results	YoY
Temporary Income	**21.9**[*1]	**27.3**[*2]	**+5.4**
Temporary Expenses	**23.9**[*3]	**10.9**[*4]	**-13.0**

*1 Gains related to sales of fixed assets of Kyushu Branch Building (8.1)
Gains related to sales of subsidiary of Daiichi Sankyo (China) (5.9)
Gains on reversal related to closure of Plexxikon (3.2)
*2 Lump sum payment received from Novartis following the settlement of Plexxikon's patent infringement lawsuit (26.4)
*3 Losses related to impairment of Intangible assets of Turalio (14.2), DS-5141 (6.3) etc.
*4 Environmental expenditures related to former Yasugawa plant (4.1)

Financial Income/Expenses etc. ····· **+19.4 (Profit Increased)**

- Increase in interest income ····· **+13.6**
- Improvement in investment securities valuation gains/losses ····· **+6.2**

Income Taxes etc. ····· **+18.6 (Profit Decreased)**

	FY2022 Results	FY2023 Results	YoY
Profit before Tax	**126.9**	**237.2**	**+110.4**
Income Taxes etc.	**17.7**	**36.2**	**+18.6**
Tax rate	**13.9%**	**15.3%**	**+1.4%**

Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2022 Results	FY2023 Results	YoY
Japan Business	457.9	518.9	+61.0
Daiichi Sankyo Healthcare	70.3	76.0	+5.6
Oncolgy Business	185.4	334.6	+149.2
Enhertu	181.6	327.4	+145.8
Turalio	3.8	5.3	+1.5
American Regent	187.4	203.4	+16.1
Injectafer	54.0	50.1	-3.9
Venofer	51.3	60.9	+9.6
GE injectables	71.6	81.0	+9.4
EU Specialty Business	150.4	189.2	+38.8
Lixiana	117.1	146.2	+29.1
Nilemdo/Nustendi	7.1	18.4	+11.4
Olmesartan	20.0	19.6	-0.4
ASCA (Asia, South and Central America) Business	142.8	184.1	+41.3

Currency Rate	USD/JPY	135.48	144.62	+9.14
	EUR/JPY	140.97	156.79	+15.82

Revenue: Major Products in Japan

(Bn JPY)

		FY2022 Results	FY2023 Results	YoY
Lixiana	anticoagulant	**105.1**	**115.6**	**+10.4**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**40.2**	**42.8**	**+2.6**
Tarlige	pain treatment	**38.5**	**45.7**	**+7.2**
Vimpat	anti-epileptic agent	**21.9**	**25.7**	**+3.8**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**20.4**	**20.4**	**-0.0**
Tenelia	type 2 diabetes mellitus treatment	**21.9**	**20.5**	**-1.5**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**11.7**	**23.9**	**+12.2**
Efient	antiplatelet agent	**20.9**	**25.6**	**+4.7**
Canalia	type 2 diabetes mellitus treatment	**16.3**	**15.9**	**-0.4**
Loxonin	anti-inflammatory analgesic	**18.5**	**15.5**	**-3.0**
Emgality	prophylaxis of migraine attacks	**6.3**	**7.6**	**+1.3**
Inavir	anti-influenza treatment	**0.9**	**15.9**	**+15.0**

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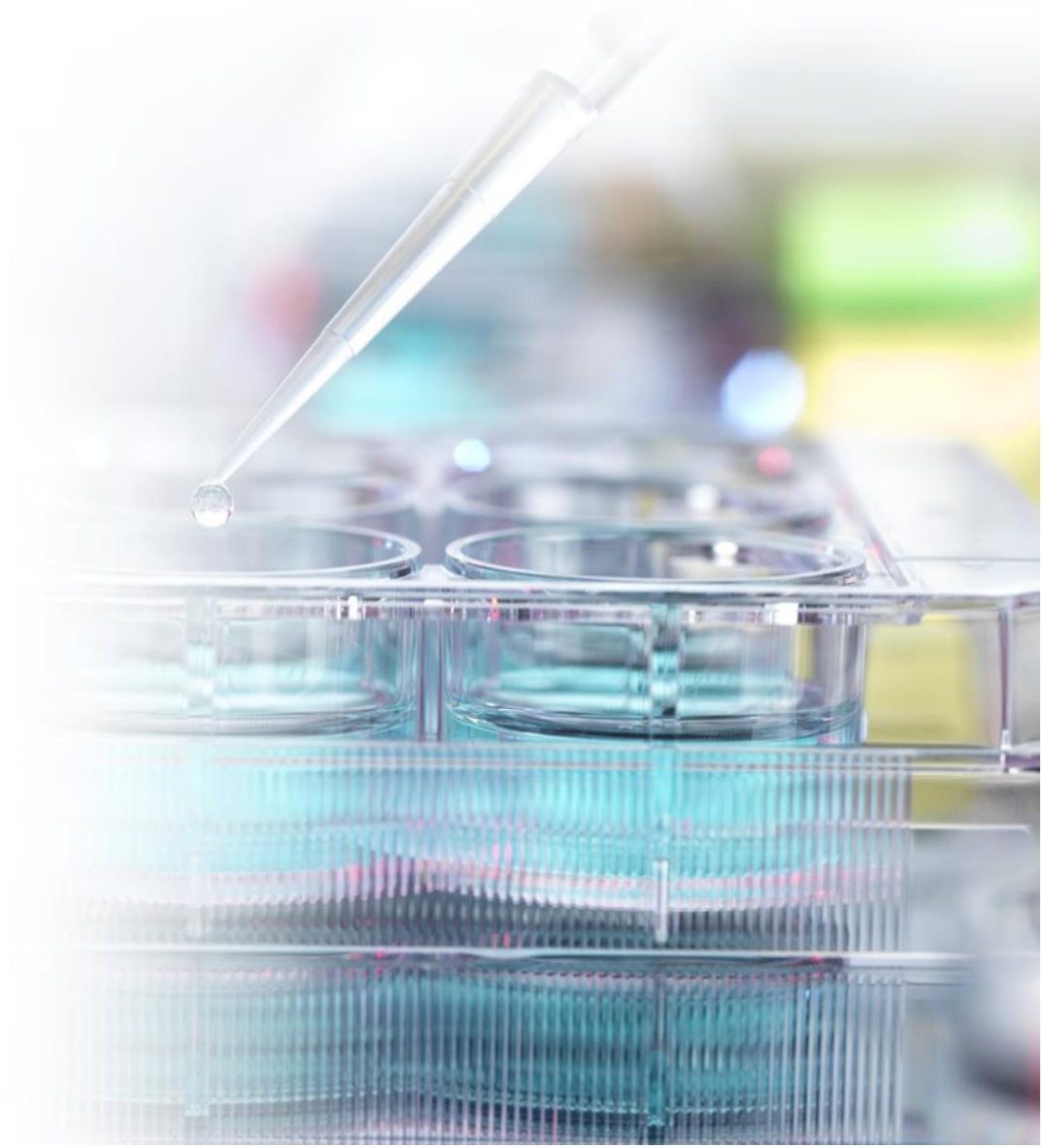


Progress towards “Maximize 3ADCs”

Progress towards “Profit growth for current business and products”

Progress towards “Create shared value with stakeholders”

ENHERTU®

Revenue

(Bn JPY)

	FY2023 Results	YoY	FY2024 Forecast	YoY	<Reference> Total Consideration
Product Sales	395.9	188.4	508.4	112.4	-
Japan	23.9	12.2	25.7	1.8	-
US	225.5	81.0	266.6	41.1	-
Europe	101.9	64.8	152.1	50.2	-
ASCA	44.6	30.4	64.0	19.4	-
Upfront payment	10.1 *1	0.3	10.2 *1	0.1	149.0
Regulatory milestone payment	12.4 *1	-14.3	9.4 *1	-2.9	137.7
US HER2+ Breast Cancer 3L	0.9	0.0	0.9	0.0	13.7
EU HER2+ Breast Cancer 3L	0.5	0.0	0.5	0.0	7.9
US HER2+ Gastric Cancer 2L + 3L	0.8	0.0	0.8	0.0	12.1
US HER2+ Breast Cancer 2L	0.9	-2.6	0.9	0.0	13.1
EU HER2+ Breast Cancer 2L	0.7	-2.0	0.7	0.0	10.1
US HER2-low Breast Cancer (post-chemo)	1.9	-5.4	1.9	0.0	27.7
EU HER2-low Breast Cancer (post-chemo)	1.3	-3.9	1.4	0.0	19.8
EU HER2+ Gastric Cancer 2L	0.3	-0.9	0.3	0.0	4.8
US HER2 Mutant NSCLC 2L	1.2	-3.4	1.2	0.0	17.3
EU HER2 Mutant NSCLC 2L	3.8	3.8	0.8	-3.0	11.1
Quid related payment	1.2 *1	0.0	1.2 *1	0.0	17.2
Sales milestone payment	29.6 *3	16.5	56.2 *2 *4	26.6	42.8
Total	449.2	190.8	585.4	136.2	346.7

*1 Revenue recognized in each period

*2 Converted with assumed forex rate for FY2024 of 145 JPY to 1 USD

*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)

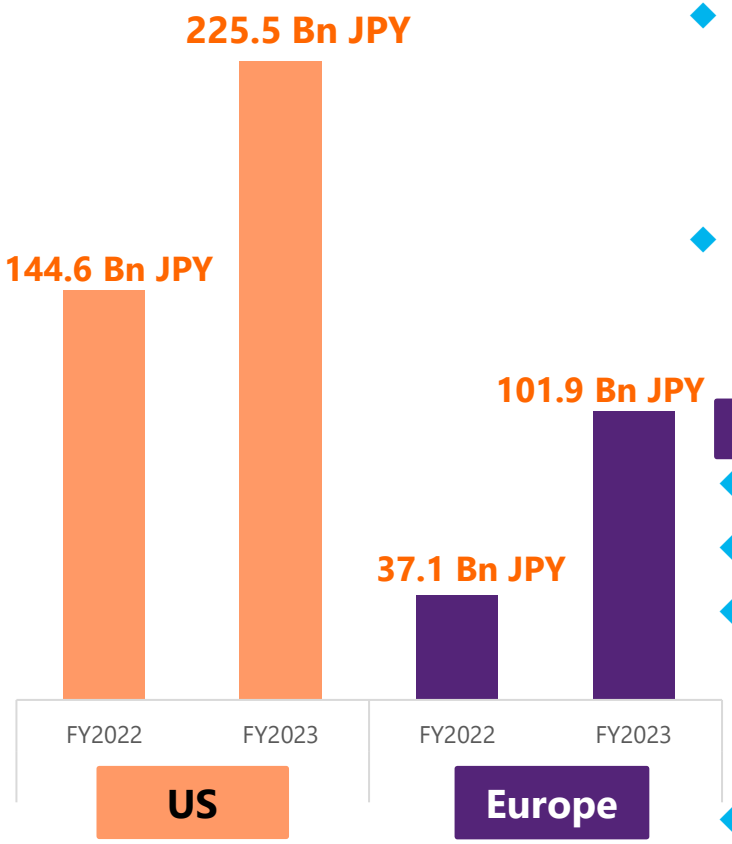
*4 Milestone of 387.5Mn USD for achieving annual product sales of 3.5 Bn USD in co-commercialization territory with AstraZeneca.
(Total amount to be recognized as revenue in FY2024)

ENHERTU®

Performance in Each Region (US, EU)

Global product sales: FY2023 results 395.9 Bn JPY（YoY +188.4 Bn JPY）FY2024 forecast 508.4 Bn JPY（YoY +112.4 Bn JPY）

ENHERTU® trastuzumab deruxtecan



US

- **Product sales: FY2023 results 225.5 Bn JPY (1,560 Mn USD) FY2024 forecast 266.6 Bn JPY (1,839 Mn USD)**
- **Indication:** HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 2L+, HER2 mutant mNSCLC 2L+, HER2+ (IHC3+) Metastatic Solid Tumors 2L+
- **Market share status**
  - HER2+ mBC 2L: Increasing 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
- **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), vaginal cancer (Mar. 2024), biliary tract cancer (Apr. 2024)
  - Approved for HER2+ (IHC3+) Metastatic Solid Tumors 2L+ and started promotion (Apr. 2024)

Europe

- **Product sales: FY2023 results 101.9 Bn JPY (704 Mn USD) FY2024 forecast 152.1 Bn JPY (1,049 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, Spain and Italy, and increasing new patient share
  - HER2 low mBC : Maintaining No.1 new patient share in France and Germany, and achieving No.1 new patient share in Spain and Italy
- **Other progress**
  - Launched in Italy (Jul. 2023)
  - Approved for HER2 mutant mNSCLC 2L+ and started promotion (Oct. 2023)

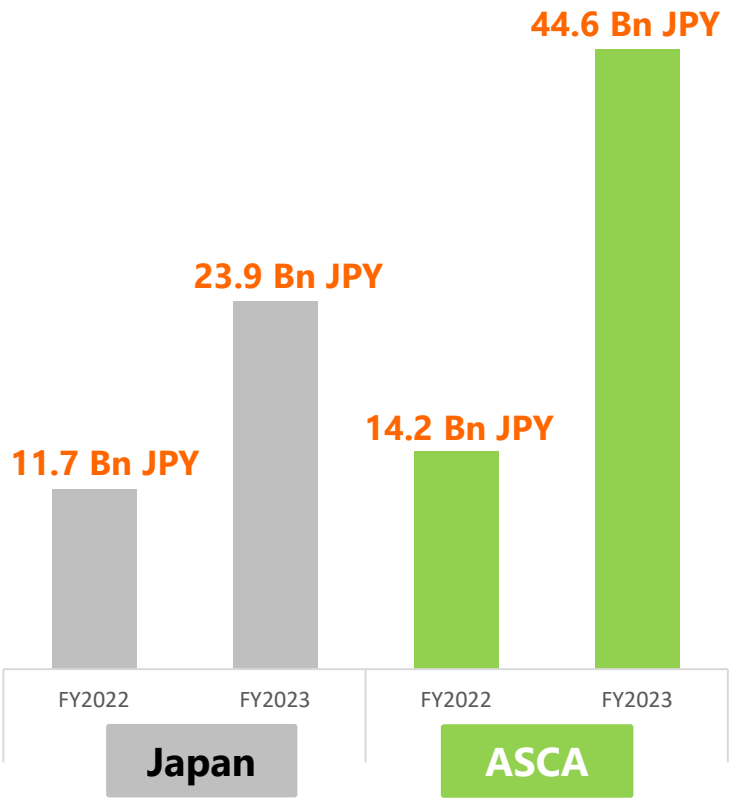
*1 NCCN: National Comprehensive Cancer Network

Blue letters: updates from Q3

ENHERTU®

Performance in Each Region (Japan, ASCA)

Global product sales: FY2023 results 395.9 Bn JPY（YoY +188.4 Bn JPY）FY2024 forecast 508.4 Bn JPY（YoY +112.4 Bn JPY）



Japan

- **Product sales: FY2023 results 23.9 Bn JPY FY2024 forecast 25.7 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: Achieving No.1 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: FY2023 results 44.6 Bn JPY FY2023 forecast 64.0 Bn JPY**
- **Indication:** HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 2L+, HER2 mutant mNSCLC 2L+
- **Sales status**
  - Sales growing in Brazil and China
- **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 Q3

Strategic Collaboration with Merck & Co., Inc., Rahway, NJ, USA

- **October 2023: Decide co-development and co-commercialization of HER3-DXd, I-DXd, DS-6000**
  - **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-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)**

* Merck & Co., Inc., Rahway, NJ, USA

Progress towards “Maximize 3ADCs”

Progress towards “Profit growth for current business and products”

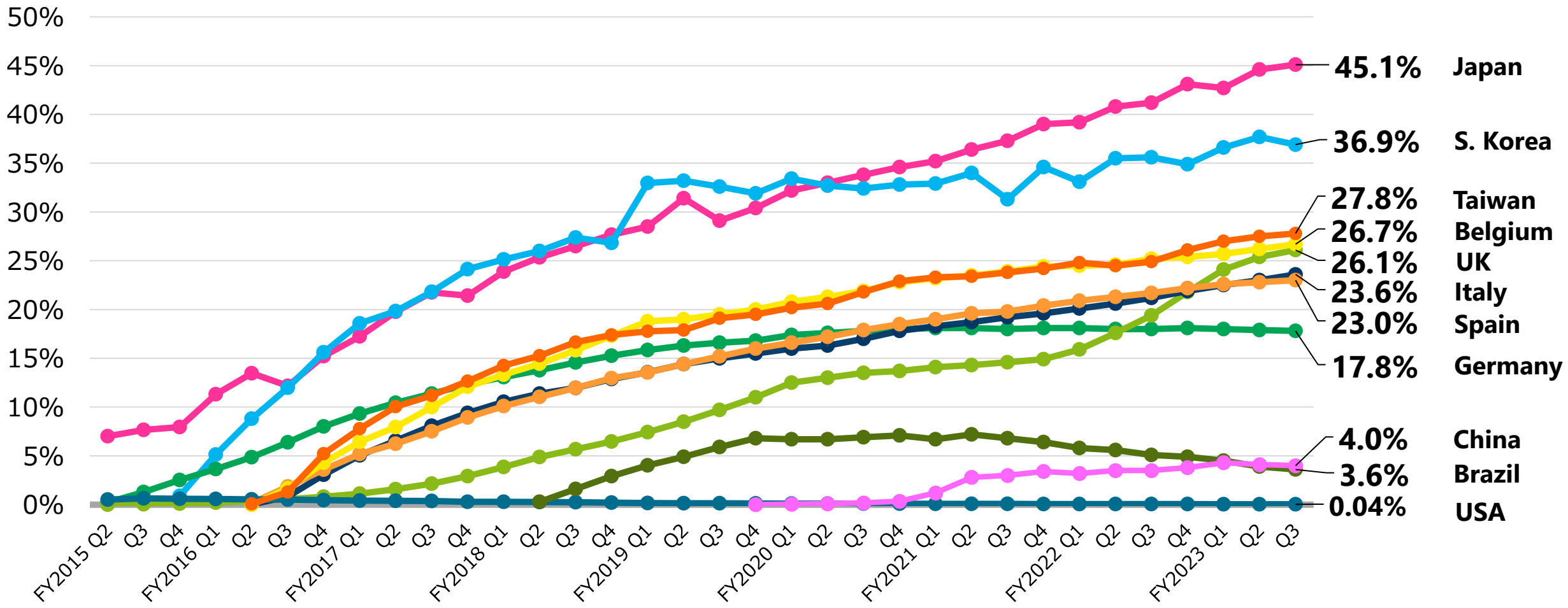
Progress towards “Create shared value with stakeholders”

LIXIANA®: Growth in Each Country/Region

Volume

Daiichi-Sankyo

Global revenue FY2023 results: 287.7 Bn JPY (YoY +43.8 Bn JPY)

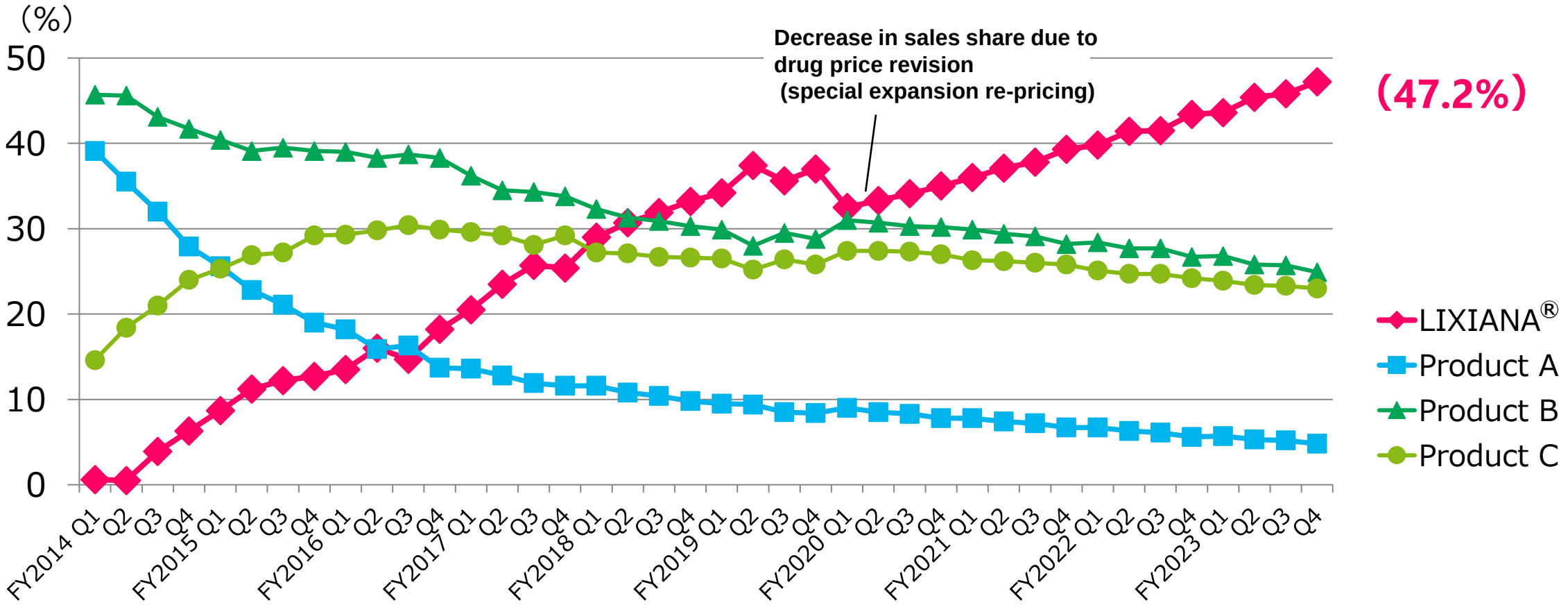


LIXIANA®: Growth in Japan

Sales

Daiichi-Sankyo

- No.1 sales share (FY2023 Q4: 47.2%)
- Revenue FY2023 results: 115.6 Bn JPY (YoY +10.4 Bn JPY)



Other Initiatives in Japan

Enhance product portfolio

◆ **VANFLYTA® Anti-Cancer Agent / FLT3 Inhibitor**

➢ **Approved for acute myeloid leukemia (AML) 1L therapy in May 2023**

Label updated from "relapsed/refractory FLT-ITD positive AML" to "FLT3-ITD positive AML"

◆ **TARLIGE® Orally Disintegrating Tablet**

Pain Treatment

➢ **Launched** in May 2023

◆ **DAICHIRONA®FOR INTRAMUSCULAR INJECTION**

COVID-19 vaccine

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

Enhance transformation into a profit structure focused on patented drugs

◆ **Stock Transfer of DAIICHI SANKYO ESPHA CO., LTD. (Concluded an agreement in May 2023)**

➢ Transferee: Qol Holdings Co., Ltd.

➢ Date of transfer: October 1, 2023 (30% of the shares held by the Company), April 1, 2024 (21% of the shares held by the Company)

※ The date of execution of the transfer of the remaining 49% of the Company's shares will be determined by separate negotiation.

➢ Consideration for transfer: 25.0 Bn JPY

➢ Gain on transfer: Approximately 16 Bn JPY will be booked as "Temporary income" in the first quarter of FY2024

➢ Impacts beyond FY2024:

- Daiichi Sankyo will be responsible for distribution operations for a certain period
- Only distribution operations related revenues will be booked as consolidated P&L but not the product sales

Other Regional Initiatives

US・EU

- **Abraxane® (paclitaxel) generic Anti-Cancer Agent**

  Launched (US: May 2023)

- **VANFLYTA® Anti-Cancer Agent / FLT3 inhibitor for acute myeloid leukemia (AML) 1L therapy**

  Launched (US: Aug. 2023, EU: Feb. 2024)

- **Nilemdo® / Nustendi® Updates**

  - Jan. 2024 DSE and Esperion Therapeutics, Inc. **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

  - Mar. 2024 **CHMP issued positive opinions** and recommended an update the label as treatments for hypercholesterolemia and significantly reducing cardiovascular events

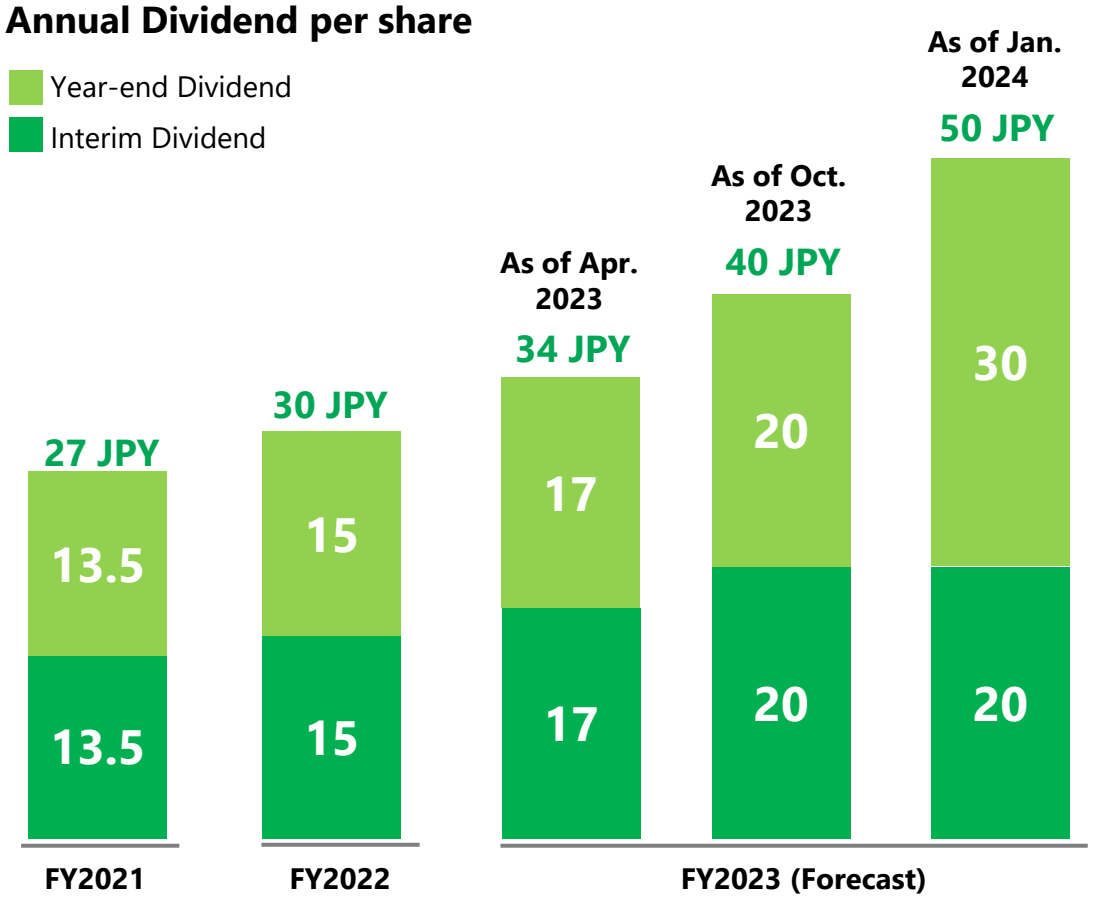
Progress towards “Maximize 3ADCs”

Progress towards “Profit growth for current business and products”

Progress towards “Create shared value with stakeholders”

FY2023 Annual Dividend Forecast

Increase FY2023 annual dividend forecast per share to 50 JPY due to strong performance of ENHERTU® and others, and upfront payment related to strategic collaboration with MRK*1 (by 20 JPY compared to FY2022)



- **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 upfront payment related to strategic collaboration with MRK 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 lump sum payment from Novartis following the settlement of Plexxikon's patent infringement lawsuit

*1 Merck & Co., Inc., Rahway, NJ, USA

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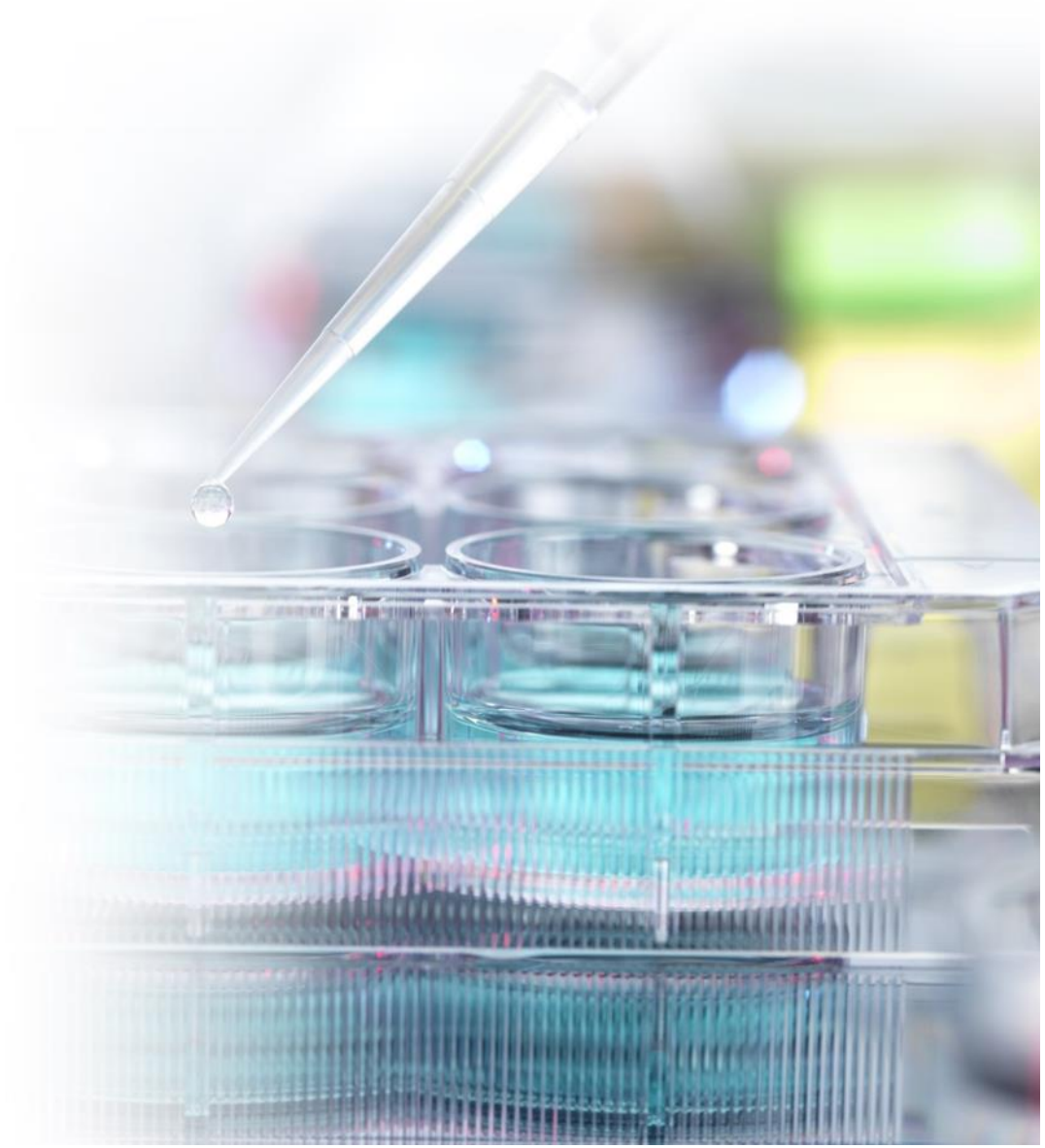
5. FY2024 Forecast
6. Appendix



FY2023 R&D major achievements

Realizing the strategic pillars of 5-Year Business Plan
“Maximize 3ADC” and “Identify and build pillars for further growth”

5DXd ADCs

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

- Expanded ENHERTU® eligible target patients with tumor agnostic indication for HER2 positive solid tumors
- BLA filings were accepted for Dato-DXd and HER3-DXd which demonstrated the wide applicability of DXd ADCs technology platform
- Collaboration with Merck & Co., Inc., Rahway, NJ, USA accelerates and expands the clinical development in HER3-DXd, I-DXd, and DS-6000
- Progress in I-DXd and DS-6000 evolved R&D strategy from “3ADCs and Alpha” to “**5DXd ADCs and Next Wave**”

&

Next Wave

- **Oncology**
- **Specialty Medicine & Vaccine**

- Started combination studies of DXd ADCs and internal assets, i.e., valemetostat and DS-1103
- Progress of quizartinib and valemetostat to potentially address the high unmet needs in hematologic malignancy
- COVID-19 vaccine for Omicron XBB.1.5 strain was approved in Japan

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), **DS-6000**: raludotatug deruxtecan (INN), R-DXd（CDH6-directed ADC）

Progress towards “Maximize 3ADCs”

Progress towards “Profit growth for current business and products”

ASCO 2024

News Flow

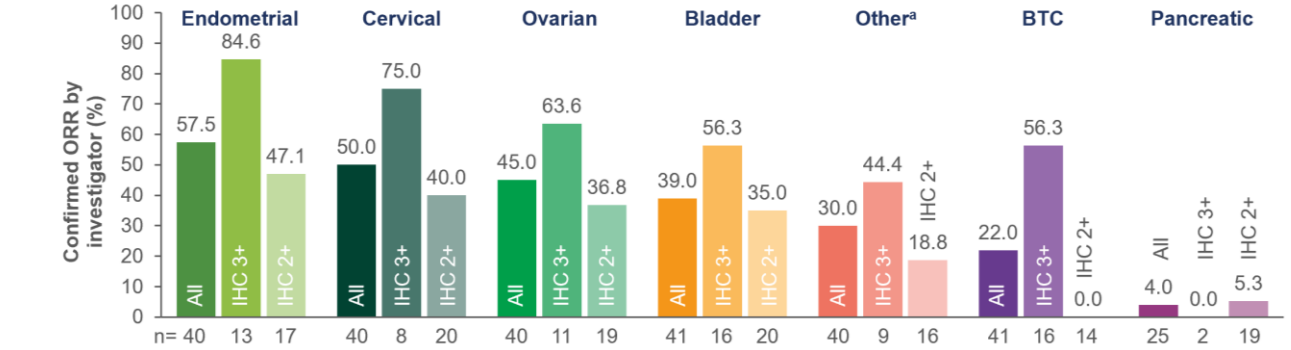
ENHERTU®

DESTINY-PanTumor02 study

Daiichi-Sankyo

FDA approved ENHERTU® as the first tumor agnostic HER2 directed therapy in unresectable or metastatic HER2 positive (IHC 3+) solid tumors in Apr 2024*

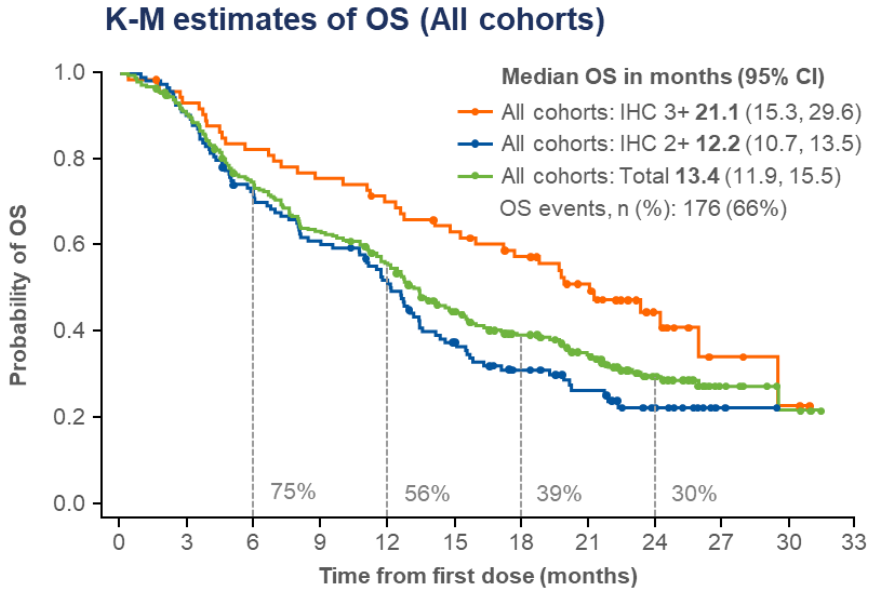
Objective response and duration of response (ESMO 2023)



	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)

Data cut off: Jun 8th, 2023

OS by HER2 status (ESMO 2023)



Data cut off: Jun 8th, 2023

Number at risk, month												
All cohorts: IHC 3+	75	69	61	56	51	45	39	29	13	4	2	0
All cohorts: IHC 2+	125	113	88	75	62	43	31	22	12	2	0	
All cohorts: Total	267	239	194	165	143	108	86	65	34	10	4	0

- **ENHERTU® is the first ADC approved for tumor agnostic therapy**
- Demonstrated clinically meaningful and durable responses across a broad range of HER2 expressing advanced solid tumors with consistent safety profile
- **NCCN guidelines have listed ENHERTU® to treat 2L HER2 positive endometrial carcinoma, cervical and ovarian cancers etc.**, based on DESTINY-PanTumor02 study

[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
* Submission data package includes DESTINY-CRC02 and DESTINY-Lung01 study, priority review was granted in US under the RTOR program
BTC: biliary tract cancer, CI: confidence interval, DOR: duration of response, IHC: immunohistochemistry, K-M: Kaplan-Meier, NCCN: National Comprehensive Cancer Network, NR: not reached, ORR: objective response rate, OS: overall survival

ENHERTU®

Expanding treatment opportunities beyond Japan, US and EU

Daiichi-Sankyo

Indication expansion in China has been progressing

HER2 low BC* (post chemo)

- Approved in China in Jul 2023, based on DESTINY-Breast04 study data

HER2 positive GC 3L+

- **Filing accepted in China in Dec 2023**, based on DESTINY-Gastric06 study data

HER2 mutant NSCLC 2L+

- **Filing accepted in China in Mar 2024**, based on DESTINY-Lung05 study data

*Note; NDA was approved in China for HER2 positive BC 2L+ in Feb 2023

Bold: update from FY2023 Q3

BC: breast cancer, NSCLC: non-small cell lung cancer

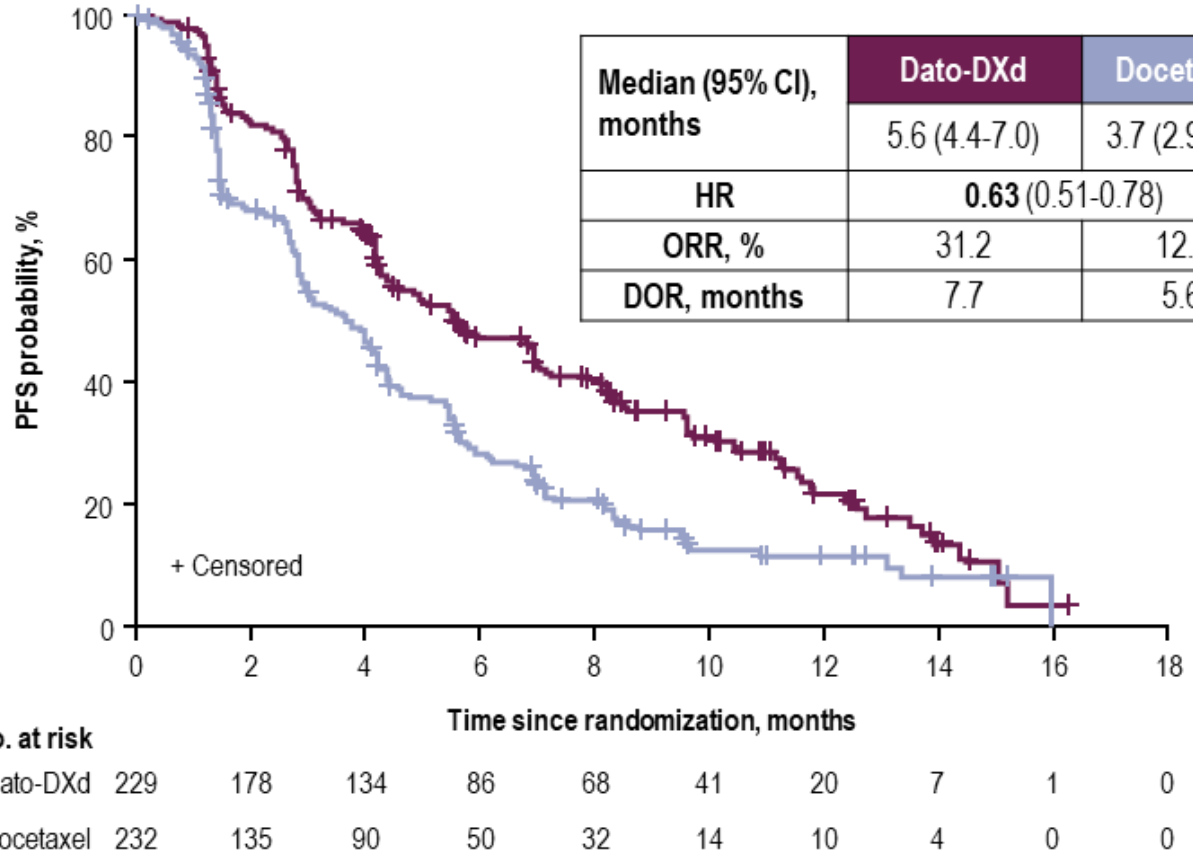
Dato-DXd

Progress in FY2023: NSCLC

TROPION-Lung01

Filing accepted for nonsquamous NSCLC 2L+ in US (Feb 2024) and EU (Mar 2024), based on the data from TROPION-Lung01 study

PFS in nonsquamous NSCLC (ESMO 2023)



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

Data cutoff: Mar 2023

- Dato-DXd median PFS: 5.6 months
- Docetaxel median PFS: 3.7 months
- PFS HR for nonsquamous NSCLC without AGAs: 0.71 (0.56, 0.91)
- Manageable safety profile in nonsquamous NSCLC, consistent with the overall population in TROPION-Lung01 study
  - ✓ Low rate of AEs leading to discontinuation of treatment (9%)
  - ✓ Low rate of ILD grade 3+ (2%)
- **PDUFA date: Dec 20th, 2024**

AGA: actionable genomic alteration, DOR: duration of response, HR: hazard ratio, NSCLC: non-small cell lung cancer, ORR: objective response rate, PDUFA: Prescription Drug User Fee Act, PFS: progression-free survival

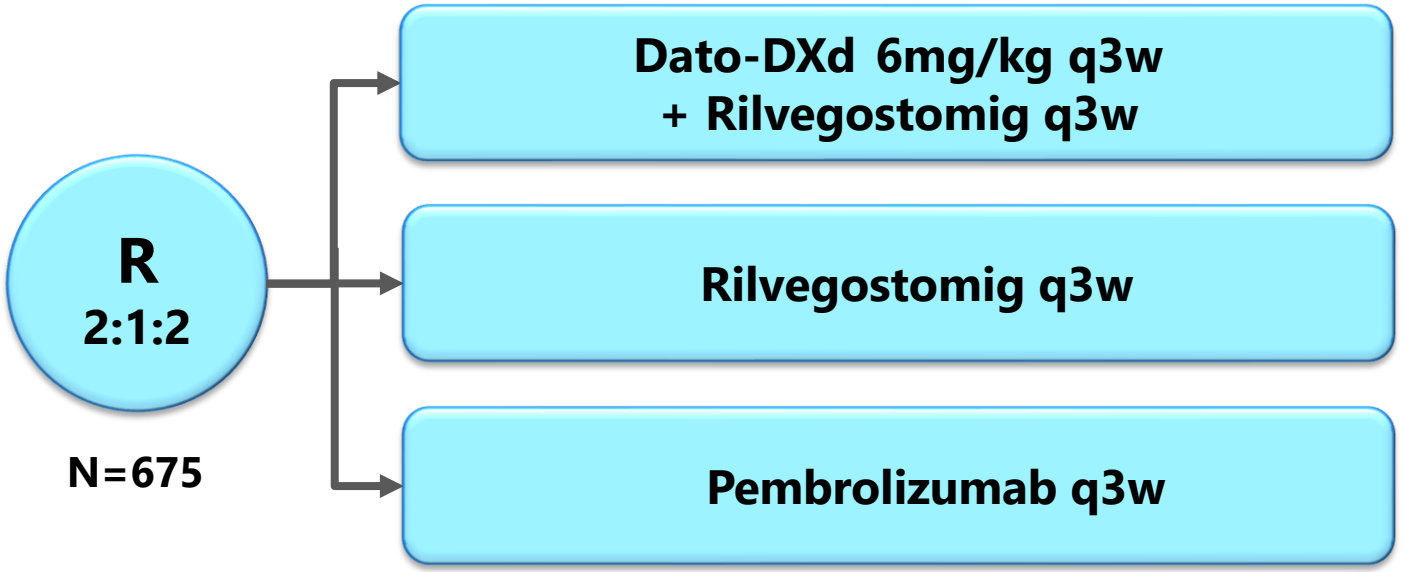
TROPION-Lung10 study

New Ph3 combination study of Dato-DXd and Rilvegostomig* for 1L locally-advanced or metastatic nonsquamous NSCLC

TROPION-Lung10 study design

Key Eligibility

- Stage IIIB-IV nonsquamous NSCLC
- No prior treatment for advanced/ metastatic disease
- No AGA
- High PD-L1 expression (TC ≥ 50%)



- Compare Dato-DXd in combination with Rilvegostomig or Rilvegostomig monotherapy with Pembrolizumab monotherapy
- **Plan to start in 2024 H1**

Primary endpoint: PFS and OS in TROP2 BM+
Secondary endpoint: PFS and OS in ITT, ORR, DOR etc.

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

AGA: actionable genetic alterations, BM: biomarker, DOR: duration of response, ITT: intention-to-treat, NSCLC: non small cell lung cancer, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, q3w: every 3 weeks, TC: tumor cells

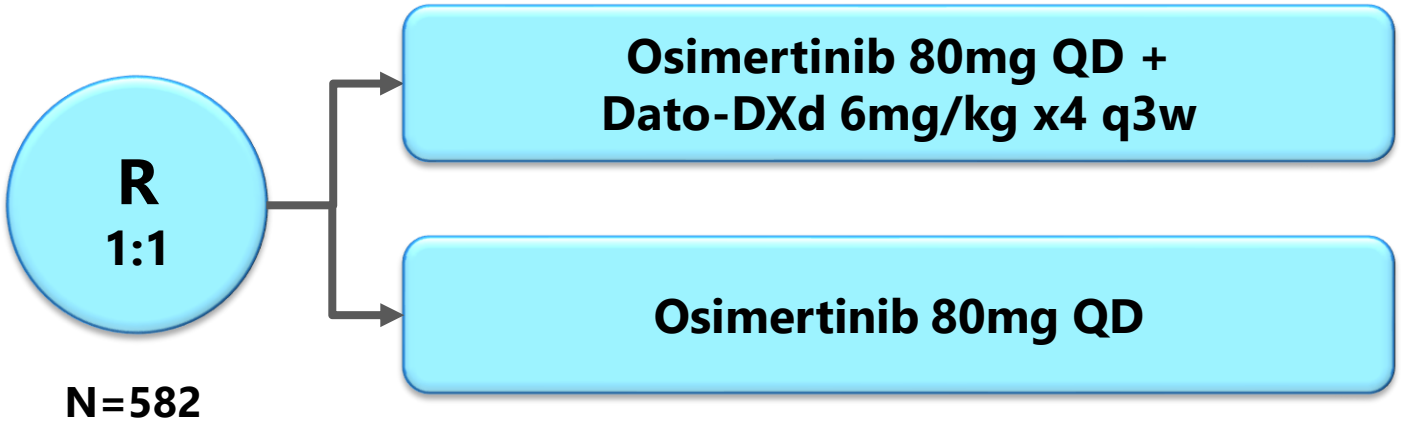
TROPION-Lung14 study

Started a new Ph3 study for 1L EGFR mutated, locally advanced or metastatic nonsquamous NSCLC in Apr 2024

TROPION-Lung14 study design

Key Eligibility

- EGFR mutation (Ex19Del or L858R)
- Locally advanced/metastatic nonsquamous NSCLC
- No prior therapy for advanced disease



N=582

Primary endpoint: PFS by BICR
Secondary endpoint: OS, ORR, DOR, DCR, Safety, PK and Immunogenicity etc.

- Ph3 study comparing the efficacy and safety of Osimertinib mono therapy and combination of Osimertinib and Dato-DXd for 1L of **nonsquamous NSCLC with at least one EGFR mutation, Ex19Del or L858R**.

BICR: blinded independent central review, DCR: disease control ratio, DOR: duration of response, NSCLC: small cell lung cancer, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, PK: pharmacokinetics , q3w: quaque 3 weeks, QD: quaque die,

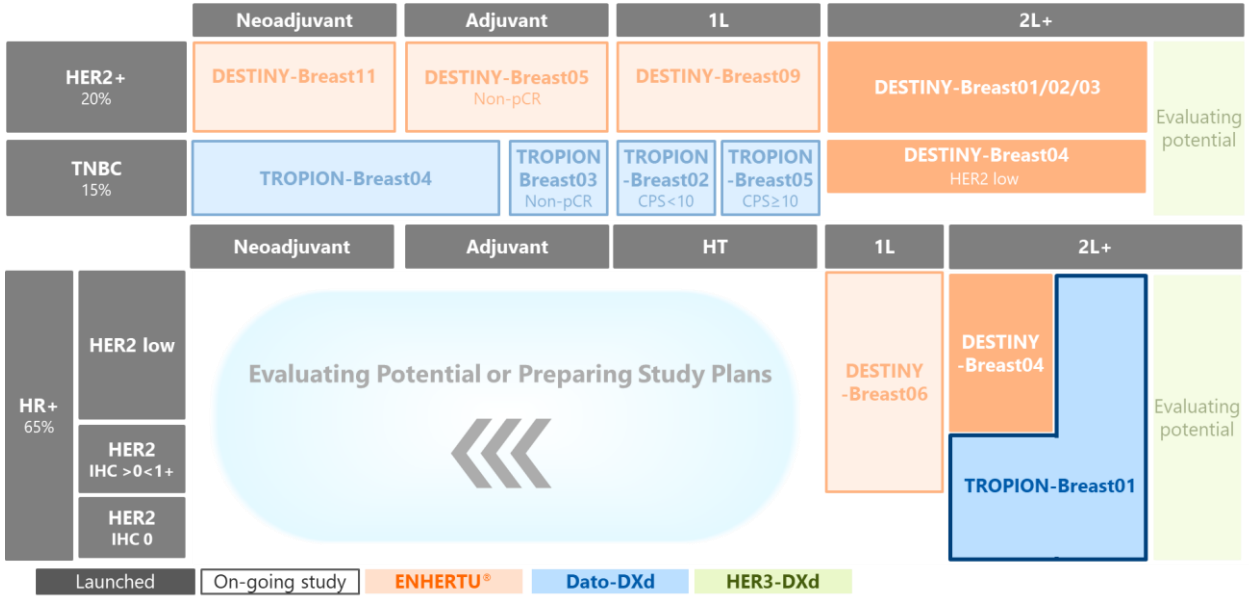
Dato-DXd

Progress in FY2023: breast cancer

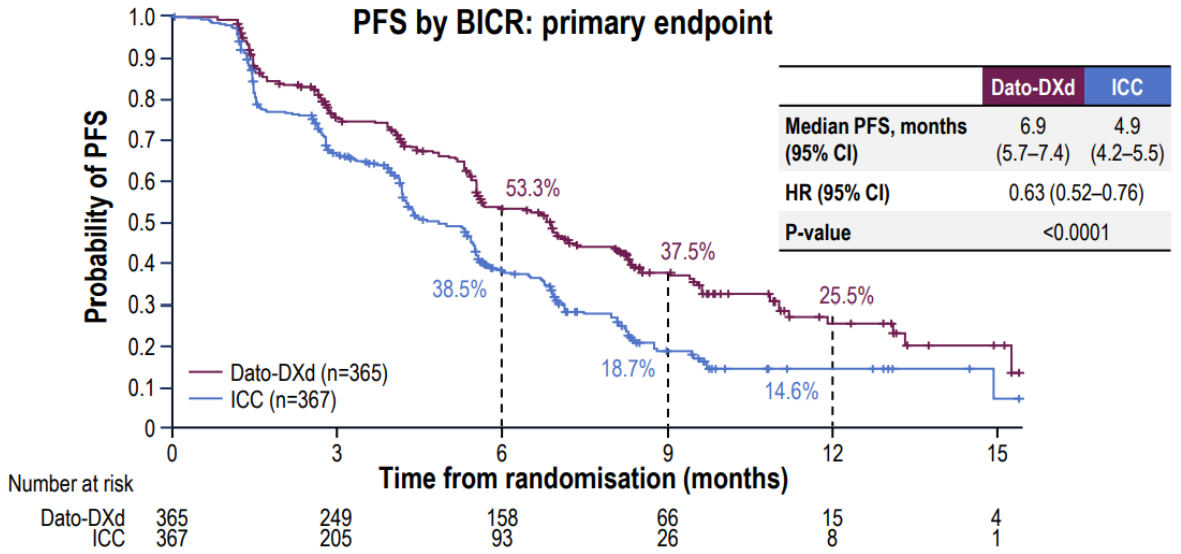
TROPION-Breast01

Filing accepted in US, EU, China and Japan for the treatment of HR+/HER2 low or negative BC, based on the data from TROPION-Breast01 study

TROPION-Breast01 in BC development map



TROPION-Breast01 PFS (ESMO 2023)



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

Data cutoff: Jul 2023

- Median PFS by BICR: 6.9 months for Dato-DXd (n=365) and 4.9 months for ICC (n=367).
- **Final OS data will be analyzed once the target number of events accumulate**
- ILD rate was low; mainly grade 1/2 events. There were one grade 3 and one grade 5 adjudicated ILD event
- **Filing accepted in Mar 2024 in Japan, EU and China, followed by in US in Apr 2024 (PDUFA date: Jan 29th, 2025)**

BC: breast cancer, BICR: blinded independent central review, CI: confidence interval, HR (in the left figure): hormone receptor, HR (in the right figure): hazard ratio, ICC: investigator's choice of chemotherapy, ILD: interstitial lung disease, IHC: immunohistochemistry, OS: overall survival, PDUFA: Prescription Drug User Fee Act, PFS: progression-free survival, TNBC: triple negative breast cancer

HER3-DXd

Progress in FY2023

To be the first HER3-targeted drug

Daiichi-Sankyo

Based on HERTHENA-Lung01 study data, filing accepted with priority review in US for *EGFR*-mutated NSCLC after TKI and platinum-based chemotherapy Started a new study for expanding indications (HERTHENA-PanTumor01 study)

HER3-DXd development in NSCLC

	Advanced/ metastatic 1L	Advanced/ metastatic 2L	Advanced/ metastatic 3L
EGFR mutated NSCLC		HERTHENA-Lung02 Ph3 TLR anticipated in FY24 H2	HERTHENA-Lung01 Registrational Ph2 Filing accepted
	Ph1b Combination with osimertinib Ongoing		

HERTHENA-PanTumor01 study design

Ph2 study in patients with locally advanced or metastatic solid tumors

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

HER3-DXd 5.6mg/kg Q3W

N=120

- Melanoma (N=40)
- SCCHN (N=40)
- HER2 negative gastric cancer (N=40)

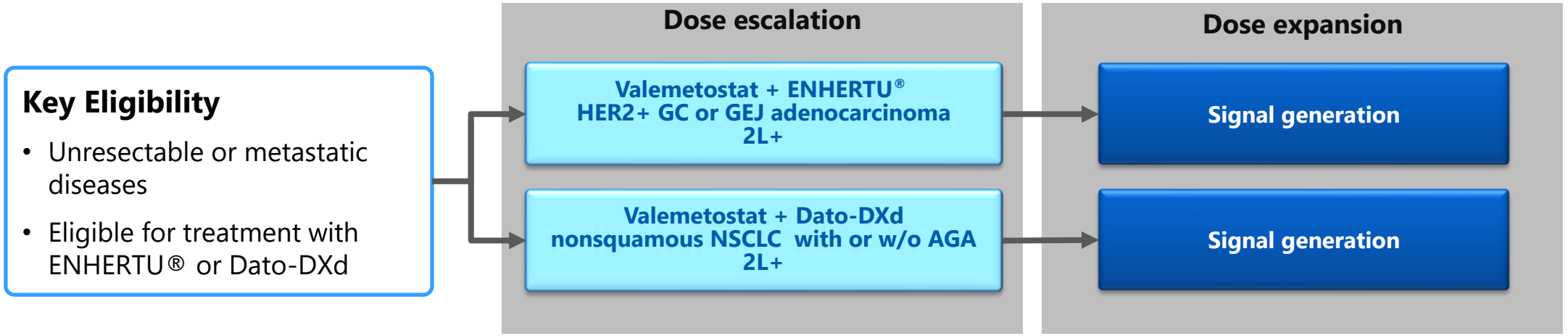
Primary endpoint: ORR
Secondary endpoint: DOR、DCR, PFS, OS, safety, etc.

- HERTHENA-Lung01 study demonstrated HER3-DXd efficacy across diverse mechanisms of EGFR TKI resistance and across a broad range of pretreatment tumor HER3 membrane expression.
- Safety profile observed in HERTHENA-Lung01 study was consistent with other HER3-DXd studies
- In Dec 2023 filing accepted and priority review granted in US under the RTOR program. **PDUFA date: Jun 26th, 2024**
- HERTHENA-Lung02 study (Ph3) is in progress to obtain **TLR in FY2024 H2**
- **HERTHENA-PanTumor01 study started in Mar 2024**

DCR: disease control rate, 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, q3w: every 3 weeks, RTOR: Real time oncology review, SCCHN: squamous cell carcinoma of the head and neck, TKI: tyrosine kinase inhibitor, TLR: top line results

Combination studies with internal asset

Valemetostat combination with DXd ADCs



- Data from this study may form the basis for registrational study (ies)
- Potential new cohorts could be added in the future
- **Started in Feb 2024**

Primary endpoint: Safety, ORR
Secondary endpoint: PFS, OS, DOR,

DS-1103 (anti- SIRPα antibody) combination with DXd ADCs

- **Combination study with ENHERTU®,** targeting HER2-expressing or HER2-mutated solid tumors is **on-going**

AGA: actionable genomic alteration, DOR: duration of response, GC: gastric cancer, GEJ: gastroesophageal junction, NSCLC: non-small cell lung cancer, ORR: overall response rate, OS: overall survival, PFS: progression-free survival

Progress towards “Maximize 3ADCs”

Progress towards “Profit growth for current business and products”

ASCO 2024

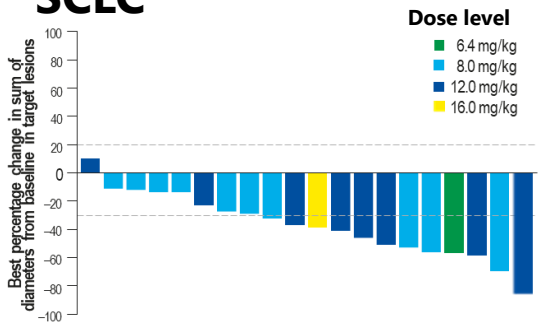
News Flow

Progress in FY2023

Durable efficacy and manageable safety profile were observed in multiple tumor types and a new Ph3 study in SCLC will start

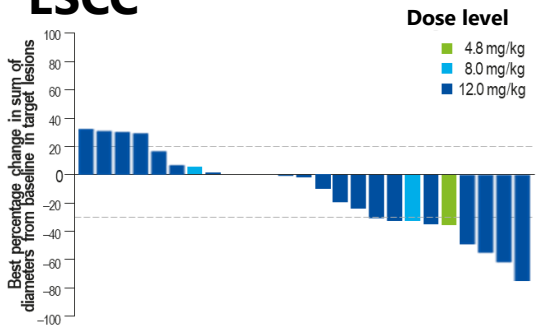
Efficacy analysis in selected tumor types (ESMO 2023)

SCLC



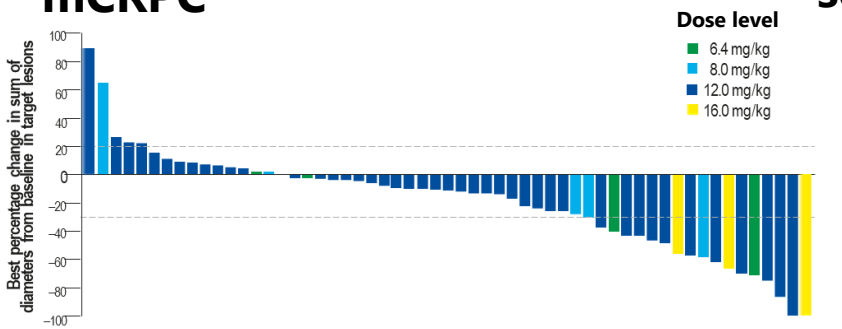
- cORR: 52.4% (11/21) (95% CI 29.8–74.3)
- mPFS: 5.6 m (3.9-8.1)
- mOS: 12.2 m (6.4-NE)
- No. of prior treatments, median: 2 (1-7)

ESCC



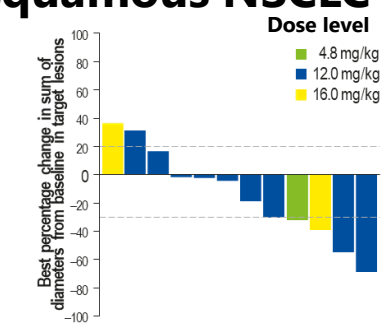
- cORR: 21.4% (6/28) (95% CI 8.3–41.0)
- mPFS: 2.8 m (2.1-5.5)
- mOS: 7.0 m (4.8-12.2)
- No. of prior treatments, median: 4 (1-7)

mCRPC



- cORR: 25.4% (15/59)[a] (95% CI 15.0–38.4)
- mPFS: 5.3 m (4.1-6.9)[b]
- mOS: 13.0 m (10.3-16.0)[b]
- No. of prior treatments, median: 6 (1-11)

squamous NSCLC



- 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 prior treatments, median: 3 (1-12)

Data cutoff: Jan 2023

- Ph1/2 study data in SCLC, ESCC, mCRPC, squamous NSCLC were presented at WCLC 2023 and ESMO 2023
- **IDeate-Lung02 study** (Ph3) for relapsed SCLC comparing I-DXd and TPC will start FY2024 H1

a: 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. b: n=73, including patients with bone metastases who were not evaluable for ORR.

CI: confidence interval, cORR: confirmed objective response rate, ESCC: esophageal squamous cell carcinoma, ESMO: European Society for Medical Oncology, mCRPC: metastatic castration-resistant prostate cancer, mOS: median overall survival, mPFS: median progression-free survival, NE: not estimable, NSCLC: non-small cell lung cancer, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, SCLC: small cell lung cancer, TPC: treatment of physician's choice, WCLC: World Conference on Lung Cancer

I-DXd

IDeate-Lung03 study

Plan to start combination study in 1L in FY2024 H1 to maximize the value of I-DXd in SCLC

IDeate-Lung03 study design (N=149)

Cohort 1

Part A: Maintenance Only
Patients who completed 1L induction with 4 cycles of SOC without PD

Part B: SOC induction + Maintenance
Treatment naïve ES-SCLC patients

Part A: Safety Run-in

Maintenance

I-DXd 12 mg/kg + Atezolizumab q3w

Part B:Dose Optimization

Induction

Etoposide + Atezolizumab + Carboplatin

R 1:1

Patients with CR, PR or SD

Maintenance
Arm 1: I-DXd 8 mg/kg
Arm 2: I-DXd 12 mg/kg

I-DXd + Atezolizumab q3w

Cohort 2

Induction + Maintenance
Treatment naïve ES-SCLC patients

Part A: Safety Run-in

Induction

I-DXd 8 mg/kg or 12 mg/kg + Atezolizumab + Carboplatin q3w

Maintenance

I-DXd 8 mg/kg or 12 mg/kg + Atezolizumab q3w

Part B: Dose Optimization

Induction
Arm 3: I-DXd 8 mg/kg
Arm 4: I-DXd 12 mg/kg

I-DXd + Atezolizumab + Carboplatin q3w

Maintenance
Arm 3: I-DXd 8 mg/kg
Arm 4: I-DXd 12 mg/kg

I-DXd + Atezolizumab q3w

Primary endpoint
- Safety

Secondary endpoint
- PFS, ORR, DOR, etc

CR: complete response, DOR: duration of response, ES-SCLC: extensive stage small cell lung cancer, ORR: objective response rate, PD: progressive disease, PFS: progression-free survival, PR: partial response, q3w: every 3 weeks, SCLC: small cell lung cancer, SD: stable disease, SOC: standard of care

I-DXd

Ph2 study targeting multiple solid tumors

Daiichi-Sankyo

Plan to start a new signal seeking Ph2 study in multiple cancers to investigate further possibility of I-DXd

Study Design

Population
- Recurrent or Metastatic solid tumors
- Previously treated with one or more systemic therapy for the selected tumor indication

N=260
I-DXd 12 mg/kg

- Endometrial cancer
- SCCHN
- PDAC
- CRC
- HCC
- Ad-Eso/GEJ/GC
- Nonsquamous NSCLC
- Urothelial carcinoma

Endpoints

Primary:
ORR

Secondary:
safety, DOR, PFS, DCR, OS, PK, immunogenicity

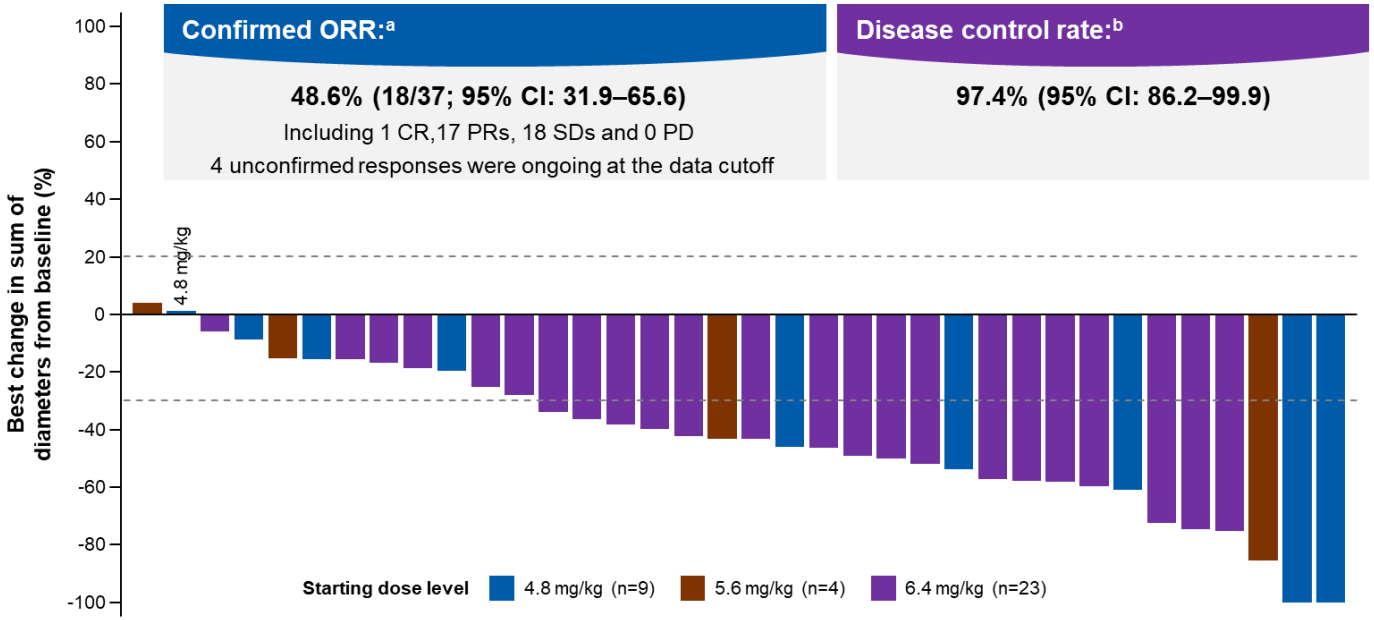
Ad-Eso: esophageal adenocarcinoma, CRC: colorectal cancer, DCR: disease control rate, DOR: duration of response, GC: gastric cancer, GEJ: gastroesophageal junction, HCC: hepatocellular carcinoma, NSCLC: non-small cell lung cancer, ORR: objective response rate, OS: overall survival, PDAC: pancreatic ducatal adenocarcinoma, PFS: progression-free survival, PK: pharmacokinetics, SCCHN: squamous cell carcinoma of head and neck

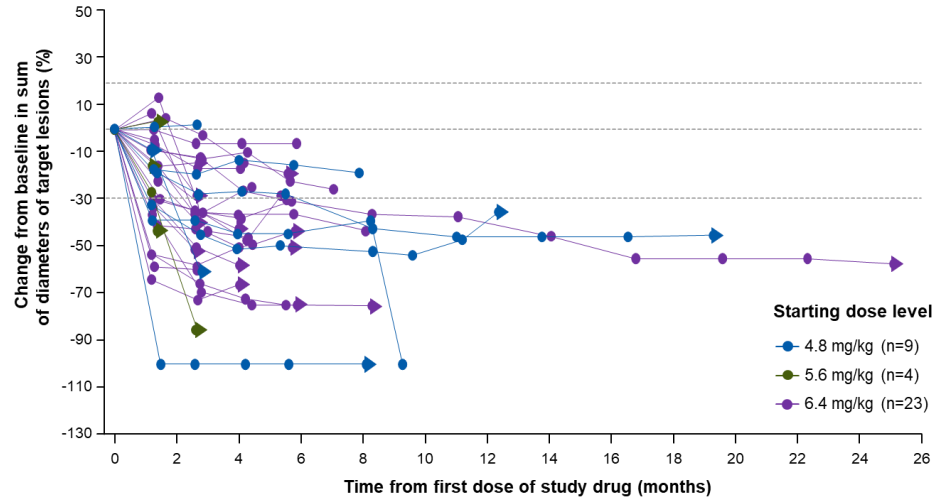
DS-6000 (R-DXd)

Progress in FY2023

Promising data were obtained in platinum resistant ovarian cancer and new Ph2/3 study started

Efficacy in Ph1 study (SGO 2024)





Median DOR:
11.2 months (95% CI: 3.1–NE)
Median (range) FU: 6.7 months (1.4–16.8)

Median TTR:
5.7 weeks (95% CI: 5.3–11.4)

Median PFS:
8.1 months (95% CI: 5.3–NE)
Median (range) FU: 4.0 months (0–25.1)

Data Cutoff: July 2023

- DS-6000 demonstrated strong clinical activity and manageable safety profile in Ph1 study platinum resistant ovarian cancer cohort
- **REJOICE-Ovarian01 study (Ph2/3)** for platinum resistant ovarian, primary peritoneal or fallopian tube cancer **started in Apr 2024** based on the data from Ph1 study

CI: confidence interval, CR: complete response, DOR: duration of response, FU: follow up, NE: not estimable, ORR: objective response rate, PD: progressive disease, PFS: progression-free survival, PR: partial response, SD: stable disease, SGO: Society of Gynecologic Annual Meeting on Women's Cancer, TTR: time to response

Hematological malignancy

Progress in FY2023

Providing new treatment options addressing high unmet medical needs

VANFLYTA®

- **Approved in countries and regions** shown below based on QuANTUM-First study (Ph3) for *FLT3*-ITD positive AML 1L
  - May 2023: Japan
  - Jul 2023: US
  - Nov 2023: EU

Valemetostat (Brand name in Japan: EZHARMIA®)

- VALENTINE-PTCL01 study (Ph2) data were presented at ASH2023. monotherapy of valemetostat demonstrated high ORR (43.7%) and manageable safety profile in patients with relapsed/ refractory PTCL
- **Filing accepted in Japan** in Jan 2024 based on the VALENTINE-PTCL01 **and regulatory decision is anticipated in FY2024 H1**

AML: acute myeloid leukemia, ASH: American Society of hematology, ORR: objective response rate, PTCL: peripheral T-cell lymphomas

Next Wave

Other Progress in FY2023

Oncology

- **DS-3939** (TA-MUC1 directed ADC)
  - Ph1/2 study for solid tumors started in Sep 2023
- **DS-1471** (anti-CD147 antibody)
  - Ph1 study for solid tumors started in Sep 2023
- **DS-1594** (Menin-MLL binding inhibitor, AML and ALL)
  - **Development discontinued**

Vaccine

- **DAICHIRONA® FOR INTRAMUSCULAR INJECTION*** (COVID-19 vaccine)
  - Vaccine for original strain was approved in Japan in Aug 2023
  - Vaccine for Omicron XBB.1.5 strain was approved in Japan in Nov 2023
- **VN-0102/JVC-001** (mixed measles-mumps-rubella vaccine)
  - **Filing accepted in Japan in Mar 2024**

Specialty Medicine

- **DS-1211** (TNAP inhibitor, PXE)
  - **Positive TLR from Ph2 study in Apr 2024**
- **DS-7011** (anti-TLR7 antibody, SLE)
  - Ph1b/2 study for SLE patients started in Jul 2023
- **DS-2325** (KLK5 inhibitor, Netherton syndrome)
  - Rare pediatric disease designation was granted in US in May 2023
  - Ph1b/2 study in Netherton syndrome patients started in Dec 2023

Bold: update from FY2023 Q3

ALL: acute lymphoblastic leukemia, AML: acute myeloid leukemia, PXE: pseudoxanthoma elasticum , SLE: systemic lupus erythematous, TLR: Top Line Results

* 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).

Progress towards “Maximize 3ADCs”

Progress towards “Profit growth for current business and products”

ASCO 2024

News Flow

ASCO Highlight 2024: IR conference call

Hiroyuki Okuzawa
President and COO

Ken Takeshita
Head of Global R&D

Mark Rutstein
Head of Global Oncology Development

Date and Time	Jun 4, 2024 (Tue) 8:00-9:00am JST/ Jun 3, 2024 (Mon) 6:00-7:00pm CDT
Meeting style	Virtual (Zoom)

Content will be delivered on-demand after the meeting

Progress towards “Maximize 3ADCs”

Progress towards “Profit growth for current business and products”

ASCO 2024

News Flow

FY2024 News Flow

As of Apr 2024

Planned major publications

American Society of Clinical Oncology（ASCO, May 31-Jun 4, 2024）

ENHERTU®	**DESTINY-Breast03: HER2+ BC, 2L, Ph3** • **Updated OS data**
	DESTINY-Breast07: HER2+ BC, 1L, Ph1b/2 • **ENHERTU®±pertuzumab dose expansion phase interim analysis results**
	DESTINY-Lung02: HER2 mutant NSCLC, 2L+, Ph2 • **Final analysis results**
	DESTINY-PanTumor02: HER2+ solid tumors, 2L+, Ph2 • **BTC and pancreatic cancer** • **Bladder cancer** • **Head and neck tumors**
Dato-DXd	**TROPION-Lung02: NSCLC, pembrolizumab combo, Ph1** • **Data update**

Regulatory decisions

ENHERTU®	**DESTINY-Gastric06: HER2+ GC, 3L+** • **CN: FY2024 H1**
	DESTINY-Lung05: HER2 mutant NSCLC, 2L+ • **CN: FY2024 H2**
Dato-DXd	**TROPION-Lung01: NSCLC, 2/3L** • **US：FY2024 H2**
	TROPION-Breast01: HR+ and HER2 low or negative BC, 2/3L • **JP/US: FY2024 H2**

Regulatory decisions

HER3-DXd	**HERTHENA-Lung01: EGFR mutated NSCLC, 3L** • **US: FY2024 H1**
Valemetostat	**VALENTINE-PTCL01：r/r PTCL** • **JP: FY2024 H1**

Key data readouts

ENHERTU®	DESTINY-Breast06*： HR+/HER2 low BC, chemo naïve, Ph3 • **FY2024 H1**
	DESTINY-Breast11：HER2+ BC, neoadjuvant, Ph3 • **FY2024 H2**
Dato-DXd	TROPION-Breast02*： PD-1/PD-L1 ineligible TNBC, 1L, Ph3 • **FY2024 H2**
HER3-DXd	HERTHENA-Lung02*： EGFR mutated NSCLC, 2L, Ph3 • **FY2024 H2**

BC: breast cancer, BTC: biliary tract cancer, CN: China, GC: gastric cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, OS: overall survival, PTCL: peripheral T cell lymphoma, r/r: relapsed/refractory, TNBC: triple-negative breast cancer

Bold: update from FY2023 Q3

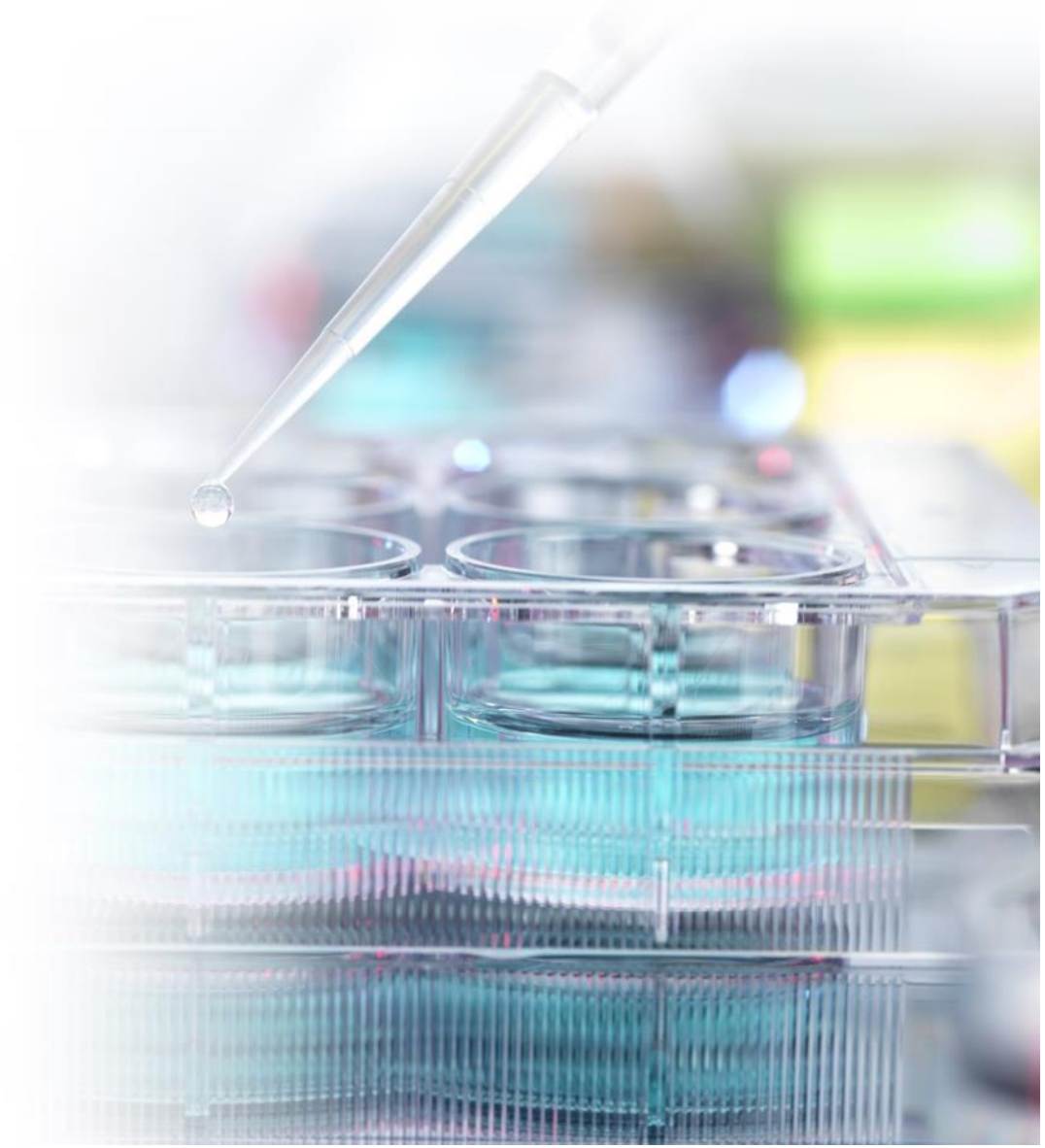
Timeline indicated is based on the current forecast and subject to change

※ Timeline for “Planned regulatory filing” indicates expected filing acceptance date

*: event-driven study

Agenda

1. FY2023 Financial Results
2. Business Update
3. R&D Update
4. **5-Year Business Plan Update**
5. FY2024 Forecast
6. Appendix



Strategic Pillars for the 5-Year Business Plan (FY2021-FY2025)

Realize 2025 Goal and Shift to Further Growth

FY2025 Financial Targets

- Revenue: 1.6 Tr JPY (Oncology > 600.0 Bn JPY)
- Core Operating Profit* Ratio before R&D Expense: 40%
- ROE > 16%
- DOE** > 8%

Maximize 3ADCs

- Maximize ENHERTU® and Dato-DXd through strategic alliance with AstraZeneca
- Maximize HER3-DXd without a partner
- Expand work force and supply capacity flexibly depending on changes around product potential

Profit growth for current business and products

- Maximize Lixiana® profit
- Grow Tarlige®, Nilemdo®, etc. quickly
- Transform to profit structure focused on patented drugs
- Profit growth for American Regent and Daiichi Sankyo Healthcare

Identify and build pillars for further growth

- Identify new growth drivers following 3ADCs
- Select and advance promising post DXd-ADC modalities

Create shared value with stakeholders

- Patients: Contributing to patients through "Patient Centric Mindset"
- Shareholders: Balanced investment for growth and shareholder returns
- Society: Environment load reduction across the value chain, and actions against pandemic risks
- Employees: Create one DS culture through fostering our core behaviors

- Data-driven management through DX, and company-wide transformation through advanced digital technology
- Agile decision making through new global management structure

*Excluding temporary income and expenses (gains/losses related to sales of fixed assets etc.) from operating income

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

5-Year Business Plan: Progress in FY2021-FY2023

Maximize 3ADCs

- **Maximize product value of ENHERTU®**
  - **Approval of new indication**
    - HER2+ BC 2L, HER2 low BC post-chemo, HER2 mutant NSCLC 2L+, HER2+ Solid Tumors 2L+ etc.
  - **Sales growth in each country/region**
  - **Progress of indication expansion**
    - HER2+ BC 1L (DB-09), HER2+ BC neoadjuvant (DB-11), HER2 low BC chemo naïve (DB-06) etc.
- **Maximize product values of Dato-DXd and HER3-DXd**
  - **Filing accepted**
    - Dato-DXd：Non SQ NSCLC 2L+ (TL-01)
      HR+/HER2 low or negative BC 2L (TB-01)
    - HER3-DXd：EGFR mutated NSCLC 3L (HL-01)
  - **Initiation of new Ph3 studies**
    - Dato-DXd：NSCLC（without actionable genomic alteration）1L (TL-07 and TL-08) etc.
    - HER3-DXd：EGFR mutated NSCLC 2L (HL-02) etc.
- **Strategic collaboration for HER3-DXd, I-DXd and DS-6000**
  - **Co-development and co-commercialization with MRK[*1]**

Profit growth for current business and products

- **Growth of current products**
  - **Steady sales expansion of Lixiana®**
    - Increase product value with additional dosage and administration[*2]
  - **Sales increase of current products in each country/region**
    - Tarlige®, Venofer®, Nilemdo®/Nustendi® etc.
    - Increase product values of current products by additional indication/ formulation
- **Transformation of business structure focused on patented drugs**
  - **Launch of new drug**
    - Emgality®, Ezharmia®, Vanflyta®, Daichirona® etc.
  - **Progress of product divesture after loss of exclusivity in each country/region**
  - **Stock transfer of Daiichi Sankyo Espha Co., Ltd.**
    - Divesture of generic business in Japan
- **Profit growth for American Regent and Daiichi Sankyo Healthcare**
  - **Contribution to consolidated performance through increased revenue and profit.**

[*1] Merck & Co., Inc., Rahway, NJ, USA

[*2] Prevention for stroke and systemic embolism in elderly patients with non-valvular atrial fibrillation and high bleeding risk: ELDERCARE-AF study

5-Year Business Plan: Progress in FY2021-FY2023

Identify and build pillars for further growth

- **Emerging growth drivers following 3ADCs**
  - **Progress of development for I-DXd (B7-H3-direceted ADC)**
    - Accumulated promising data in Ph1/2 study for multiple cancer types
    - Plan to start Ph3 study for SCLC
    - Accelerate development through strategic collaboration with MRK
  - **Progress of development for DS-6000 (CDH6-directed ADC)**
    - Accumulated promising data for OVC
    - Accelerate development through strategic collaboration with MRK
- **Advancement to select post DXd-ADC modalities**
  - **Started clinical study for 2nd generation ADC, DS-9606**
  - **Approval and supply of mRNA COVID-19 vaccine, Daichirona® for intramuscular injection**

OVC: ovarian cancer, SCLC: small cell lung cancer,,

Create shared value with stakeholders

- **Strengthening shareholder returns**
  - **Increase dividend taking account of profit growth**
    - Increase annual dividend in two consecutive years due to profit growth of ENHERTU®, and received upfront payment related to strategic collaboration with MRK etc
- **Actions against pandemic risks**
  - **Supply of Daichirona® for intramuscular injection (Omicron XBB.1.5-adapted monovalent vaccine)**
    - Submitted approval application for original strain booster vaccination
- **Environment load reduction across the value chain**
  - **Progress initiative for environmental issues**
    - Joined RE100, a global initiative aiming to use 100% renewable energy for electricity consumed in business activities
    - Converted electricity consumed in bases in Japan to renewable energy
- **Penetration of Core Behavior for fostering one DS culture**
  - **Further understanding of three Core Behaviors through workshop by management and employees**

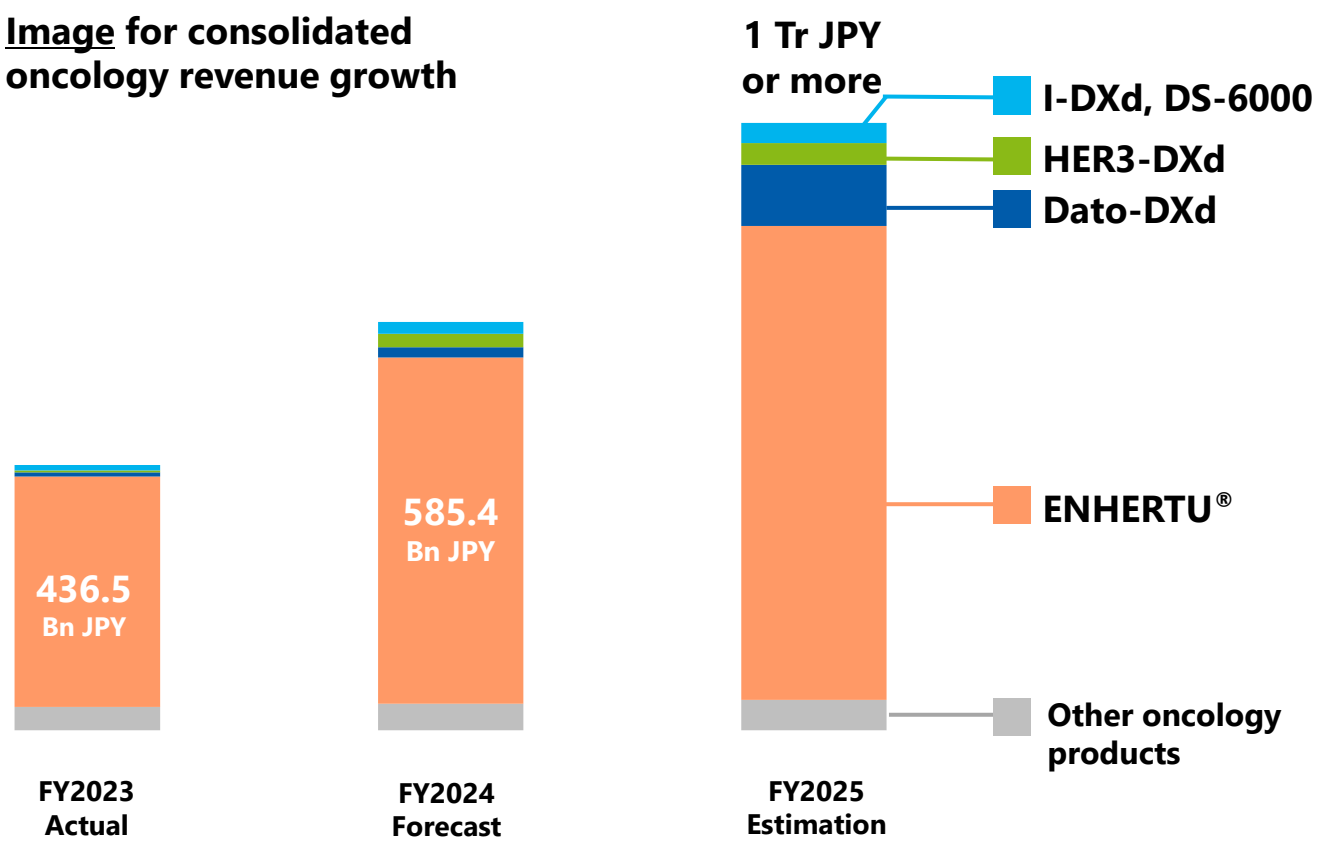
Estimate for FY2025 KPIs
(as of Apr. 2024)

	5YBP Target (Apr. 2021)	Estimate as of Apr. 2023	Estimate as of Apr. 2024
Revenue	1,600 Bn JPY	2.0 Tr JPY	2.1 Tr JPY
Revenue in Oncology	> 600 Bn JPY	> 900 Bn JPY	> 1.0 Tr JPY
Core Operating Profit ratio before R&D expense	40%	40%	40%
ROE	> 16%	> 16%	> 16%
DOE	> 8%	> 8%	> 8.5%
Currency rate assumptions	1 USD=105 JPY, 1 EUR=120 JPY	1 USD=130 JPY, 1 EUR=140 JPY	1 USD=145 JPY, 1 EUR=155 JPY

Estimated Oncology Revenue
(as of Apr. 2024)

Estimate oncology revenue of 1 Tr JPY or more in FY2025 driven by further revenue growth of ENHERTU® and upfront payments related to strategic collaboration with MRK*1 for HER3-DXd, I-DXd, and DS-6000

Image for consolidated oncology revenue growth



Increase/decrease from Apr. 2023 estimation

Major Increase

◆ **ENHERTU®**

- ✓ **Further revenue growth in breast cancer driven by DB-03/04 indications**

◆◆ **HER3-DXd, I-DXd, DS-6000**

- ✓ **Revenue increase from upfront payments related to strategic collaboration with Merck**

Major decrease

◆ **Dato-DXd**

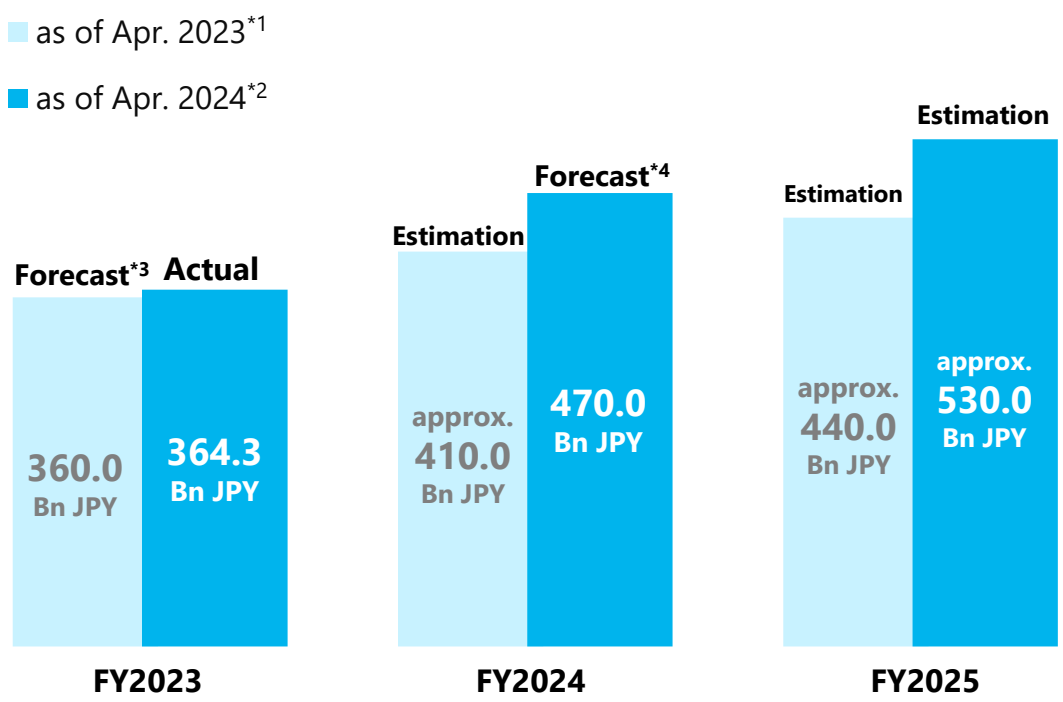
- ✓ **Revised target patient population based on TL-01 results**
- ✓ **Revised timeline for TL-08**

*1 Merck & Co., Inc., Rahway, NJ, USA
*2 Revenue for ENHERTU®, Dato-DXd, HER3-DXd, I-DXd and DS-6000 includes alliance revenue (50% of gross profit from product sales in countries/regions where AstraZeneca and Merck book sales), upfront payments, development and sales milestones received from both collaborators based on strategic alliance agreements

Estimated R&D Expenses
(as of Apr. 2024)

Estimate R&D expenses of approx. 1 Tr JPY for FY2024 and FY2025 in total driven by new study initiation for ENHERTU® and other expenses

R&D expenses trend



Currency rate assumptions
*1: 1USD=130 JPY、1EUR=140 JPY
*2: 1USD=145 JPY、1EUR=155 JPY

Forecast
*3: as of Apr. 2023
*4: as of Apr. 2024

Increase/decrease from Apr. 2023 estimation

Major Increase

- ◆ **Initiation of new studies for ENHERTU®**
  - ✓ New studies considering DPT-02 results
- ◆ **Acceleration of indication expansion studies and initiation of new studies for Next Wave products** (DS-3939, etc.)
- ◆ **Expanded medical affairs activities** (Create and deliver new evidence for ENHERTU®, Dato-DXd and HER3-DXd)
- ◆ **Strengthen R&D infrastructure** (Increased R&D headcount)

Major decrease

- ◆ **HER3-DXd, I-DXd, DS-6000**
  - ✓ Acceleration of indication expansion studies and initiation of new studies through the strategic collaboration with Merck*1 (IDeate-Lung02, REJOICE-Ovarian01, etc.)
  - ✓ Meanwhile, Daiichi Sankyo's R&D expenses for these three ADCs will decrease from the cost share with Merck
    (Merck 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

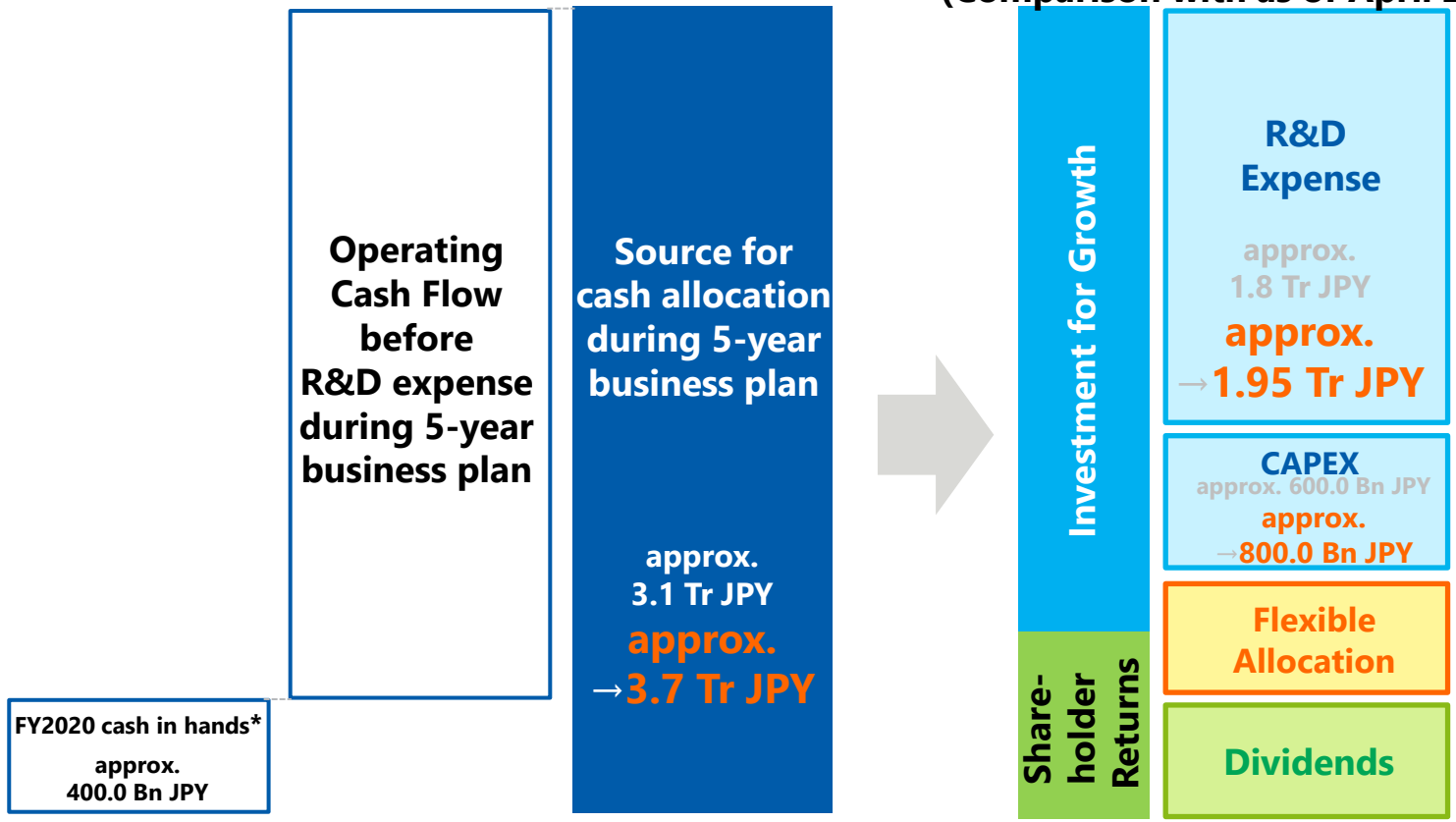
*1 Merck & Co., Inc., Rahway, NJ, USA

Well-balanced Investment for Growth and Shareholder Returns

Cash Allocation

Increase R&D expense and CAPEX for further growth in future, and increase shareholder returns with cash flow of approx. 600.0 Bn JPY increased due to the received upfront payment related to strategic collaboration with MRK etc.

Image for cash allocation
(Comparison with as of April 2023)



Prioritized investment for DXd-ADCs

Investment focused on enhancing ADC supply capabilities

Flexible allocation depending on pipeline progress for 1) investment to build pillars for further growth (in-house/external); and 2) acquisition of own shares

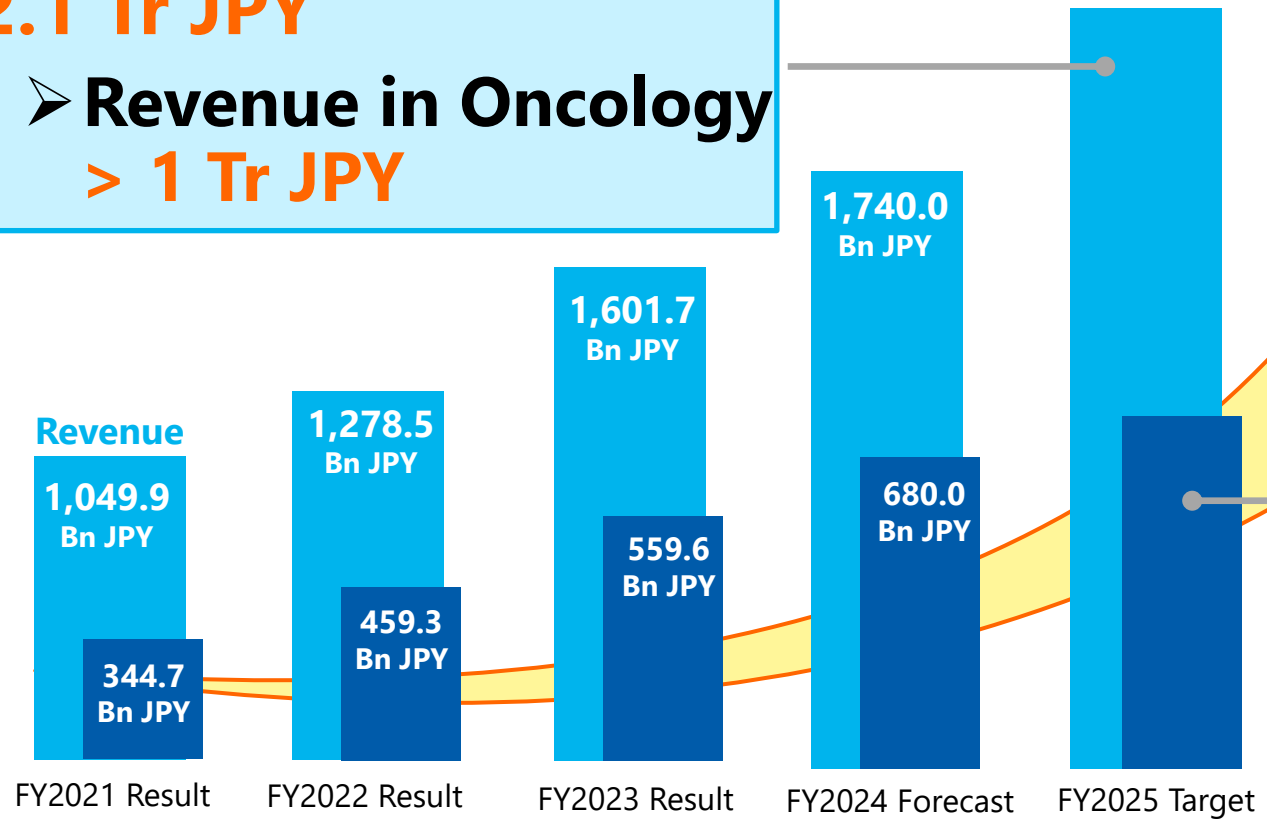
Stable dividends and dividend increase that take account of profit growth

*Cash in hands excluding working capital

Forecast of FY2025 KPIs
(as of Apr. 2024)

◆**Revenue**
2.1 Tr JPY
➢**Revenue in Oncology**
> 1 Tr JPY

Achieve significant revenue/profit growth after investment for DXd ADCs, and shift to a new stage for realizing 2030 vision



Forecast of Core Operating Profit* ratio before R&D expense: 39%

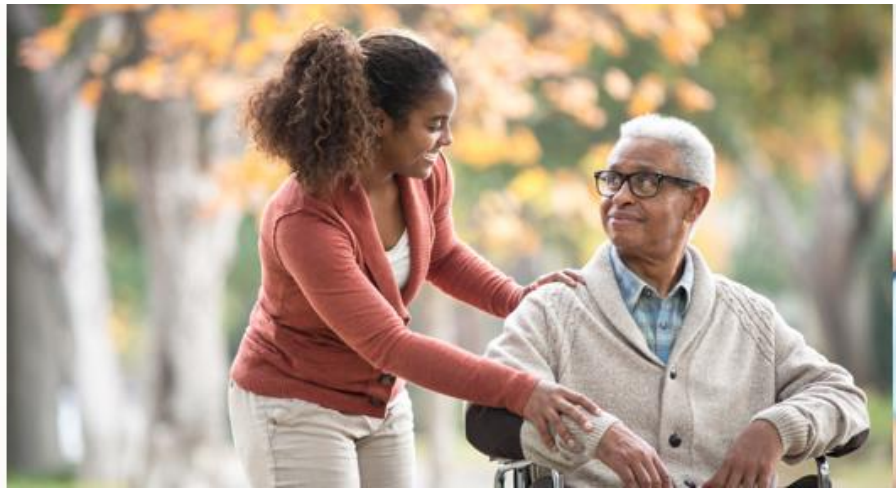
◆**Core Operating Profit* ratio before R&D expense: 40%**

◆**ROE > 16%**

◆**DOE > 8.5%**

FY2025 Currency rate assumptions: 1 USD=**145 JPY**, 1 EUR=**155 JPY**
*Excluding temporary income and expenses (gains/losses related to sales of fixed assets etc.) from operating income

Daiichi Sankyo will contribute to the enrichment of quality of life around the world



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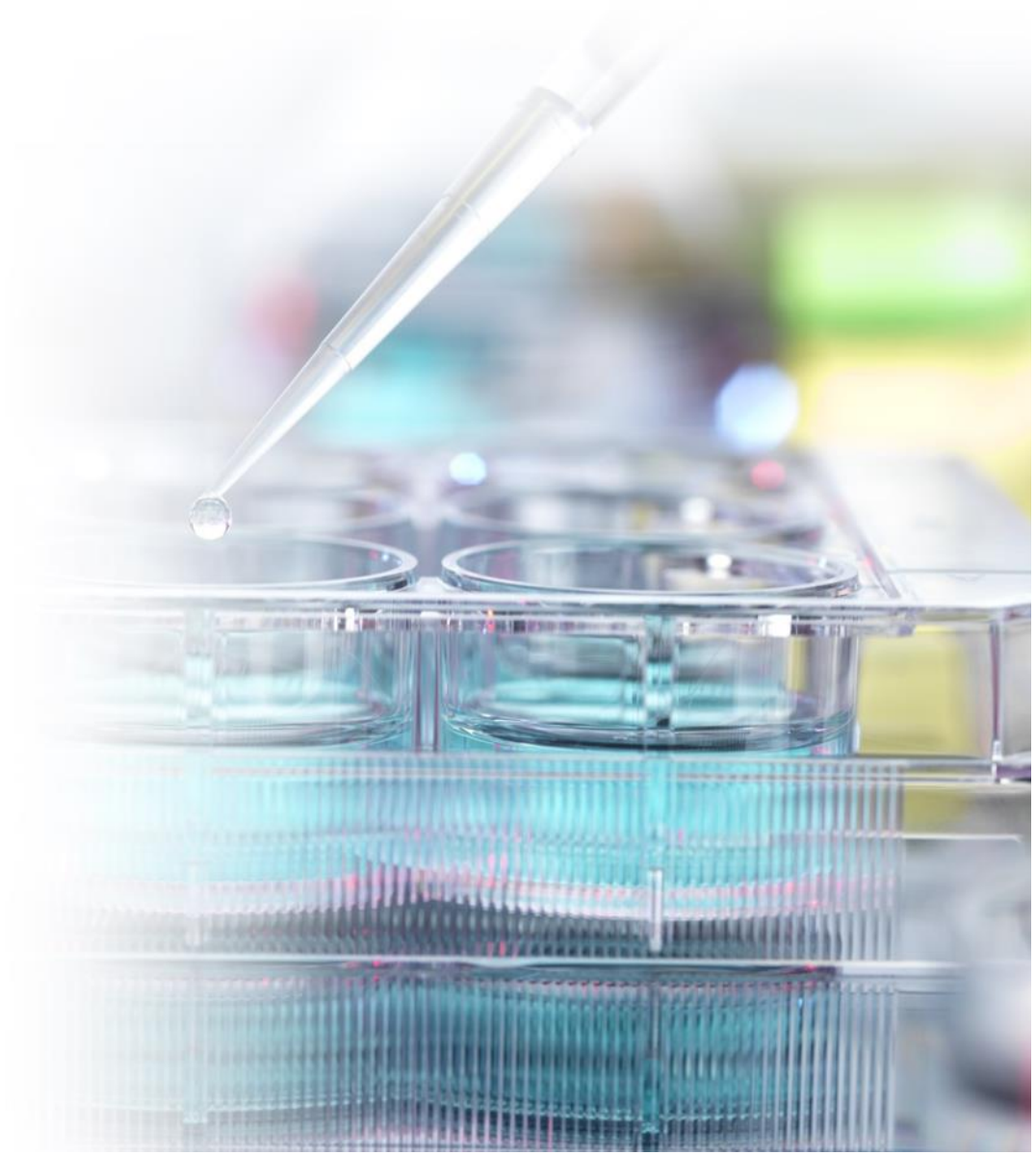


FY2024 Forecast

(Bn JPY)

	FY2023 Results	FY2024 Forecast	vs. Forecast
Revenue	**1,601.7**	**1,750.0**	**+148.3**
Cost of sales *1	414.8	395.0	-19.8
SG&A expenses *1	627.3	675.0	+47.7
DXd ADC profit share *2	170.6	193.6	+23.0
Other SG&A expenses	456.8	481.4	+24.6
R&D expenses *1	364.3	470.0	105.7
Core operating profit *1	**195.3**	**210.0**	**+14.7**
Temporary income *1	27.3	20.0	-7.3
Temporary expenses *1	10.9	-	-10.9
Operating profit	**211.6**	**230.0**	**+18.4**
Profit before tax	**237.2**	**235.0**	**-2.2**
Profit attributable to owners of the Company	**200.7**	**190.0**	**-10.7**

Currency Rate	USD/JPY	144.62	145.00	+0.38
	EUR/JPY	156.79	155.00	-1.79

Revenue
Increase factor ↑ Sales expansion of main products (Enhertu, Lixiana, Tarlige, etc.)
Deferred revenue increase from upfront payments related to strategic collaboration with Merck
Decrease Factor ↓ DS Espha product (Impact of stock transfer), Drug price revision

Cost of sales
Decrease due to improvement in cost of sales ratio through changing in product mix

SG&A expenses
- Increase in profit share due to sales expansion of Enhertu
- Increase due to intensive resource allocation to the oncology business, strategic investments in DX/IT and human capital for long-term growth

R&D expenses
Increase due to increased R&D investment focused on 5DXd ADCs, expanded medical affairs activities and strengthen R&D infrastructure (Increased R&D headcount)

Temporary expenses
FY2023: Lump sum payment for the settlement of patent infringement lawsuit in US etc.
FY2024: Gain on stock transfer of DS Espha etc.

Profit before tax
Decrease in interest income and others due to the decrease financial assets in US dollar

Profit attributable to owners of the Company
FY2023 Tax Rate: 15.3% (Impact of Tax credit for R&D expenses and stock transfer of DS Espha etc.)
FY2024 Tax Rate: approx. 19% (Impact of Tax credit for R&D expenses etc.)

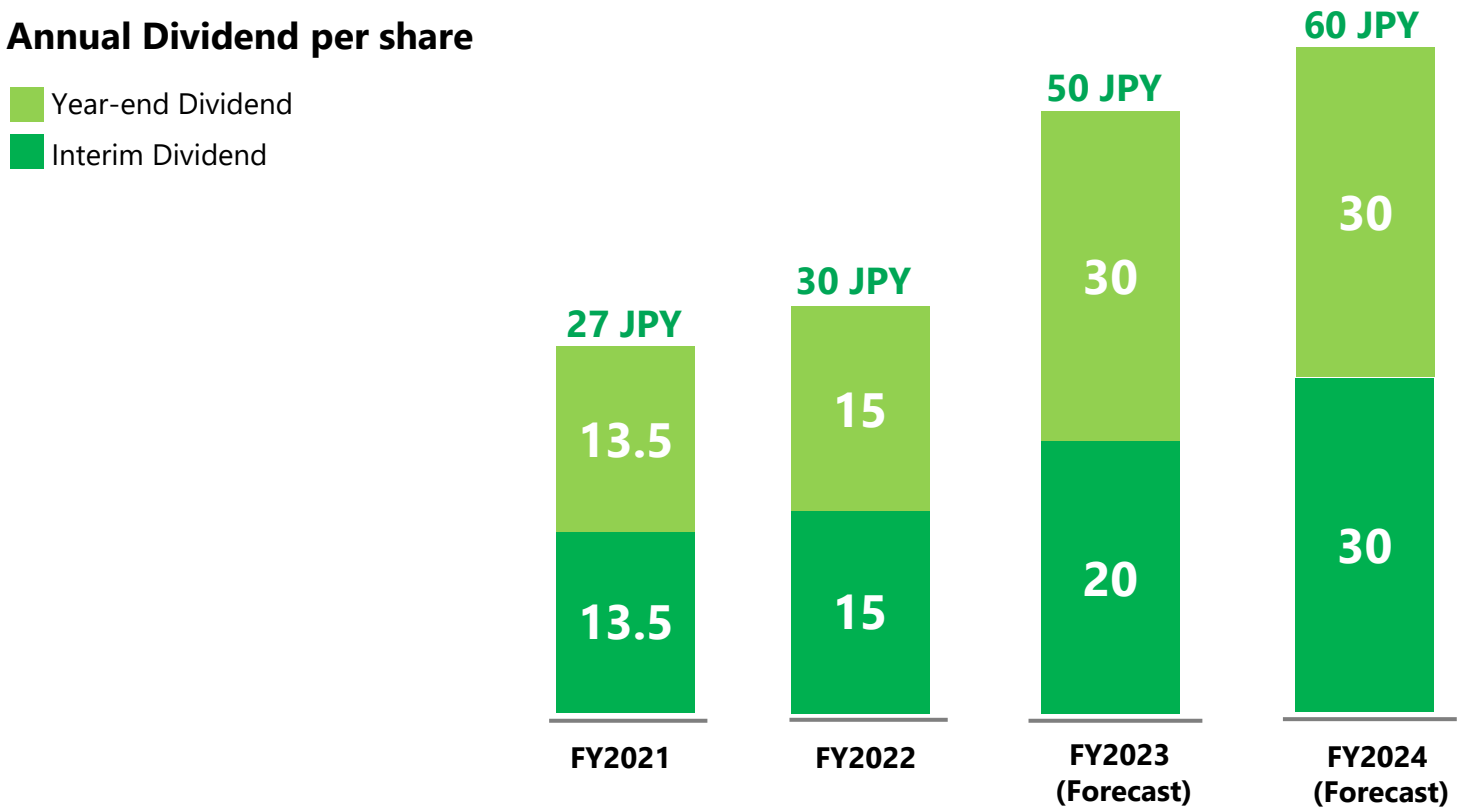
*1 As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed. Income and expenses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation, reconciliation, and other non-temporary and material gains and losses are included in the "temporary income and expenses". Temporary income and expenses are excluded from results and forecast for cost of sales, SG&A expenses and R&D expenses shown in the list above. The adjustment table from operating profit to core operating profit is stated in the reference data.
*2 DS pays alliance partners 50% of gross profit for the product sales in countries/regions where DS book revenue (excluding Japan) to share profit with the partners.

FY2024 Annual Dividend Forecast

Increase annual dividend per share from 50 JPY (FY2023) to 60 JPY (FY2024)

taking account of increasing probability of achieving FY2025 KPIs following further sales expansion of Enhertu®

Annual dividend per share in FY2024: 60 JPY (interim dividend: 30 JPY, year-end dividend: 30 JPY)



Flexible Acquisition of Own Shares

- **Decided acquisition and cancellation of own shares for shareholder returns enhancement and capital efficiency improvement**
- **FY2025 DOE is expected over 8.5% which exceeds the original target**

Acquisition

- Acquisition period: **Apr. 26, 2024 – Jan. 15, 2025**
- Aggregate amount of acquisition cost: **200 billion JPY** (maximum)
- Total number of shares to be acquired: **55 million stocks** (maximum)

Cancellation

- Cancellation date: **Jan. 31, 2025**
- Number of shares to be cancelled: **All of acquired own shares**

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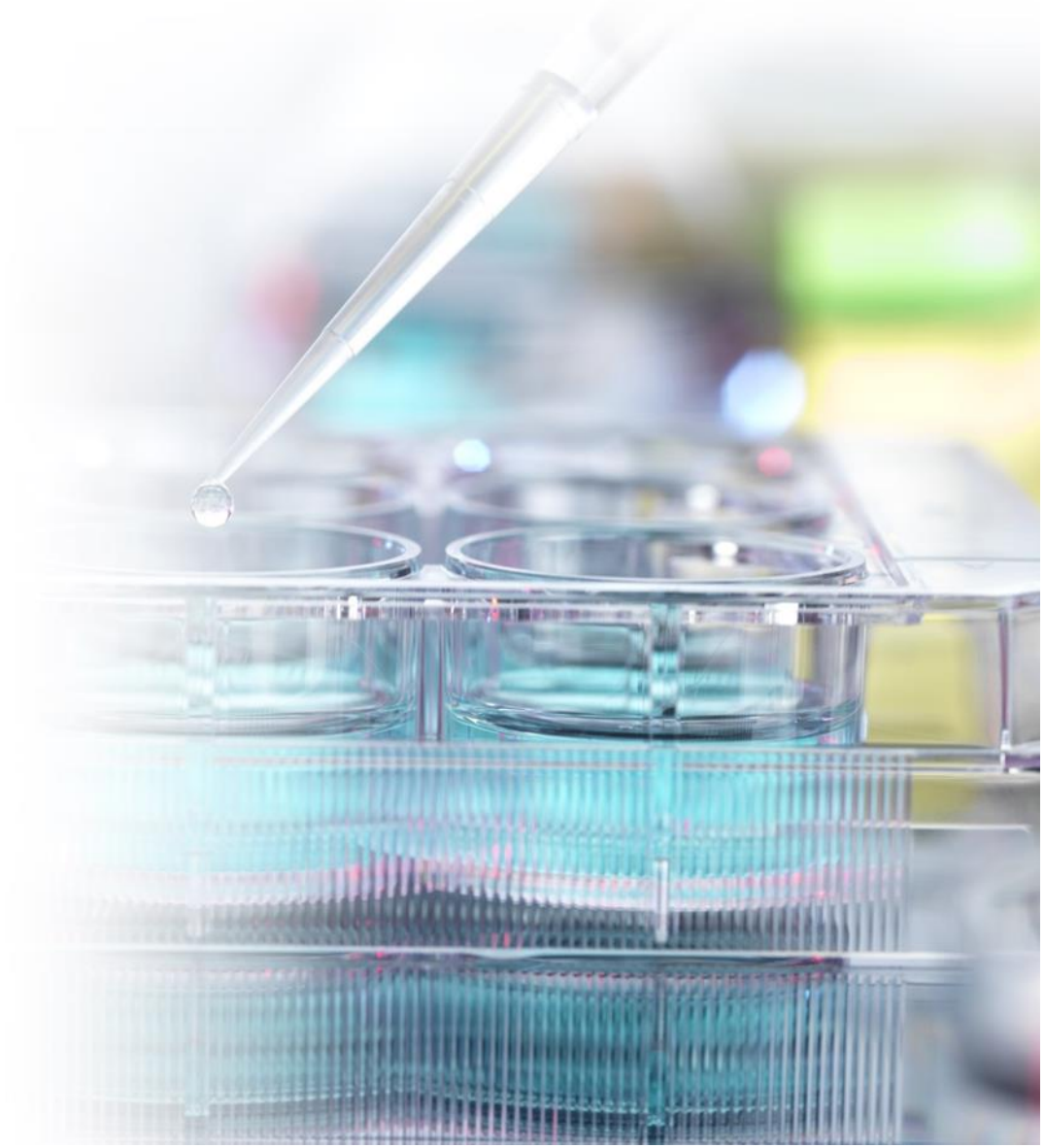

3ADCs launch plan

Realize maximizing the product values of 3ADCs through expanding the indications

~FY2020

ENHERTU®

- DESTINY-Breast01
- DESTINY-Gastric01

5-Year Business Plan (FY2021-FY2025)

ENHERTU®

- DESTINY-Breast03
- DESTINY-Breast04
- DESTINY-Breast06
- DESTINY-Breast09
- DESTINY-Breast11
- DESTINY-Gastric02
- DESTINY-Lung01/02
- DESTINY-Lung04
- DESTINY-PanTumor02*

Dato-DXd

- TROPION-Lung01
- TROPION-Breast01
- TROPION-Breast02

HER3-DXd

- HERTHENA-Lung01
- HERTHENA-Lung02

FY2026 & Beyond

ENHERTU®

- DESTINY-Breast05
- DESTINY-Gastric04
- Combo with DS internal asset, I/O or targeted therapy in BC and NSCLC
- Other cancer types

Dato-DXd

- TROPION-Lung07
- TROPION-Lung08
- TROPION-Breast03
- Combo with I/O in BC and NSCLC etc.
- Other cancer types

HER3-DXd

- Combo with targeted therapy in NSCLC
- Other cancer types

Major study only (ref., appendices)

Already approved indications

Studies with updated timeline from the estimation in Apr 2023

* Submission data package includes DESTINY-CRC02 and DESTINY-Lung01 study

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

ADC: antibody-drug conjugate, BC: breast cancer, I/O: immuno-oncology, NSCLC: non-small cell lung cancer

Major R&D Milestones (ENHERTU®)

As of Apr 2024

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

Bold: update from FY2023 Q3

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

Major R&D Milestones (Dato-DXd)

As of Apr 2024

Project		Target indication [phase, study name]	FY2023 H2	FY2024 H1	FY2024 H2
Dato-DXd	NSCLC	• 2/3L [Ph3, TROPION-Lung01]	• **Filing accepted (US, EU)**		• **Regulatory decision anticipated (US)**
		• 1L, nonsquamous, PD-L1 high, rilvegostomig combo [TROPION-Lung10]		• **Study start planned**	
		• 1L, nonsquamous, EGFR mutated, osimertinib combo [Ph3, TROPION-Lung14]		• **Study start planned**	
	BC	• HR+ and HER2 low or negative, 2/3L [Ph3, TROPION-Breast01]	• **Filing accepted (JP, EU, CN)**	• **Filing accepted (US)**	• **Regulatory decision anticipated (JP, 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 Q3

BC: breast cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, TLR: top line results, TNBC: triple-negative breast cancer

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

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

As of Apr 2024

Project		Target indication [phase, study name]	FY2023 H2	FY2024 H1	FY2024 H2
HER3-DXd	NSCLC	• EGFR mutant, 3L [Ph2, HERTHENA-Lung01]	• Filing accepted (US)	• Regulatory decision anticipated (US)	
		• EGFR mutant, 2L [Ph3, HERTHENA-Lung02]			• TLR anticipated
	Other tumors	• Melanoma, SCCHN, HER2 negative GC [Ph2, HERTHENA-PanTumor01]	**• Study started**		
I-DXd	SCLC	• 2L+ [Dose optimization, Ph2, IDeate-Lung01]			• TLR anticipated
		• 2L+ [Ph3, IDeate-Lung02]		• Study start planned	
		• 1L [Ph1b/2, IDeate-Lung03]		**• Study start planned**	
	Other tumors	**• Endometrial cancer, SCCHN, etc [Ph2, IDeate-PanTumor02]**		**• Study start planned**	
DS-6000 (R-DXd)	OVC	• 2L+ [Ph2/3, REJOICE-Ovarian01]		**• Study started**	

Bold: update from FY2023 Q2

GC: gastric cancer, NSCLC: non-small cell lung cancer, OVC: ovarian cancer, SCCHN: squamous cell carcinoma of the head and neck, SCLC: small cell lung cancer, TLR: top line results

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

Major R&D Milestones (Next Wave)

As of Apr 2024

Project	Target indication [phase, study name]	FY2023 H2	FY2024 H1	FY2024 H2
valemetostat	• r/r PTCL [Registrational Ph2, VALENTINE-PTCL01]	**• Filing accepted (JP)**	**• Regulatory decision anticipated (JP)**	
	• HER2+ GC, non-squamous NSCLC [Ph1b、ENHERTU®, Dato-DXd combo]	**• Study started**		
DAICHIRONA®	• COVID-19 mRNA vaccine (mutant strain), Children aged 5 to 11 years [Ph2/3]	**• TLR obtained**	**• Planned regulatory filing※ (JP)**	
MMR vaccine (VN-0102)	• mixed measles-mumps-rubella vaccine [JP]	**• Filing accepted (JP)**		

Bold: update from FY2023 Q3

GC: gastric cancer, NSCLC: non-small cell lung 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
※ Timeline for "Planned regulatory filing" indicates expected filing acceptance date

Major R&D Pipeline: 5DXd ADCs

As of Apr 2024

Daiichi-Sankyo

Phase 1		Phase 2	Phase 3		Regulatory phase
(US/EU/Asia) HER2+ BC 2L+/1L DESTINY-Breast07	(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) TROPION-Lung02	(CN) HER2 expressing solid tumors DESTINY-PanTumor03	(JP/US/EU/Asia) HER2+ BC adjuvant*1 DESTINY-Breast05	(JP/US/EU/Asia) in prep PD-L1 high nonsquamous NSCLC (w/o AGA, rilvegostomig combo) 1L TROPION-Lung10	(CN) HER2+ GC 3L DESTINY-Gastric06
(US/EU/Asia) HER2 low BC Chemo naïve/post chemo DESTINY-Breast08	(JP/US/EU) NSCLC (w/o AGA, durvalumab, rilvegostomig, volrustomig and sabestomig combo) TROPION-Lung04	(JP/US/EU/Asia) solid tumors TROPION-PanTumor03	(JP/US/EU/Asia) HER2 low BC chemo naïve DESTINY-Breast06	(JP/US/EU/Asia) in prep EGFR mutated NSCLC (osimertinib combo) 1L TROPION-Lung14	(CN) HER2 mutant NSCLC 2L+ DESTINY-Lung05
(JP/US/EU/Asia) HER2+ GC combo, 2L+/1L DESTINY-Gastric03	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) EGFR mutated NSCLC (osimertinib combo) 2L ORCHARD	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09	(JP/US/EU/Asia) TNBC (PD-1/PD-L1 inhibitor ineligible) 1L TROPION-Breast02	(US/EU) NSCLC 2/3L TROPION-Lung01
(US/EU/Asia) HER2+ NSCLC (durvalumab, volrustomig combo) 1L DESTINY-Lung03	(JP/US/EU/Asia) solid tumors (saruparib combo) PETRA	(US/EU/Asia) resectable early-stage NSCLC (durvalumab combo) neoadjuvant NeoCOAST-2	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11	(JP/US/EU/Asia) TNBC adjuvant*2 (mono or durvalumab combo) TROPION-Breast03	(JP/US/EU/CN) BC*3 2/3L TROPION-Breast01
(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US/EU/Asia) NSCLC	(JP/US/EU/Asia) melanoma, SCCHN, HER2 negative GC, 2L+ HERTHENA-PanTumor01	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	(JP/US/EU/Asia) TNBC neoadjuvant and adjuvant (durvalumab combo) TROPION-Breast04	(US) EGFR mutated NSCLC 3L HERTHENA-Lung01
(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/Asia) EGFR mutated NSCLC, 1/2L (osimertinib combo)	(JP/US/EU/Asia) ES-SCLC, 2L+ IDeate-Lung01	(JP/US/EU/Asia) NSCLC (w/ HER2 exon 19 or exon 20 mutation) 1L DESTINY-Lung04	(JP/US/EU/Asia) PD-L1 positive TNBC 1L (mono or durvalumab combo) TROPION-Breast05	
(US/EU/Asia) solid tumors (saruparib combo) PETRA	(JP/US) ESCC, CRPC, squamous NSCLC, SCLC, etc. IDeate-PanTumor01	(JP/US/EU/Asia) solid tumors, 2L+	(JP/US/EU/Asia) nonsquamous NSCLC (w/o AGA, pembrolizumab combo) 1L TROPION-Lung07	(JP/US/EU/Asia) EGFR mutated NSCLC 2L HERTHENA-Lung02	
(JP/US) solid tumors TROPION-PanTumor01	(JP/US/EU/Asia) in prep ES-SCLC, 1L IDeate-Lung03	(JP/US/EU/Asia) ovarian cancer REJOICE-Ovarian01	(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) 1L TROPION-Lung08	(JP/US/EU/Asia) in prep ES-SCLC, 2L+ IDeate-Lung02	
(CN) NSCLC, TNBC TROPION-PanTumor02	(JP/US) renal cell carcinoma, ovarian cancer				

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

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

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

* 1 Adjuvant therapy for 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, SCCHN: squamous cell carcinoma of head and neck, SCLC: small cell lung cancer, TNBC: triple negative breast cancer

Major R&D Pipeline: Next Wave

As of Apr 2024

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

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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