Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2022
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Hiroyuki Okuzawa

Representative Director, President & COO

April 27, 2023

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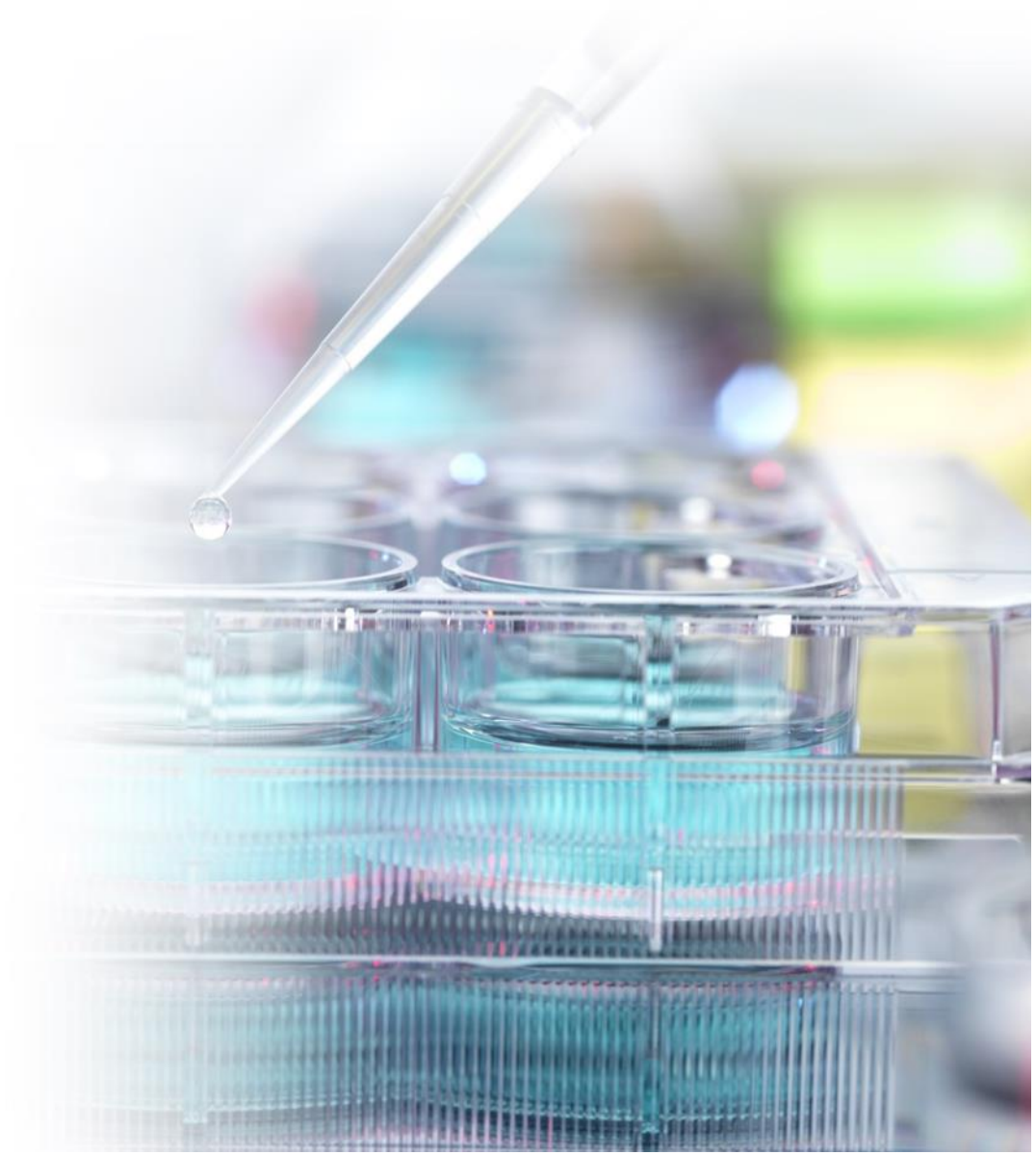
Agenda

1. **FY2022 Financial Results**
2. Business Update
3. R&D Update
4. 5-Year Business Plan Update
5. FY2023 Forecast
6. Appendix



Overview of FY2022 Results

(Bn JPY)

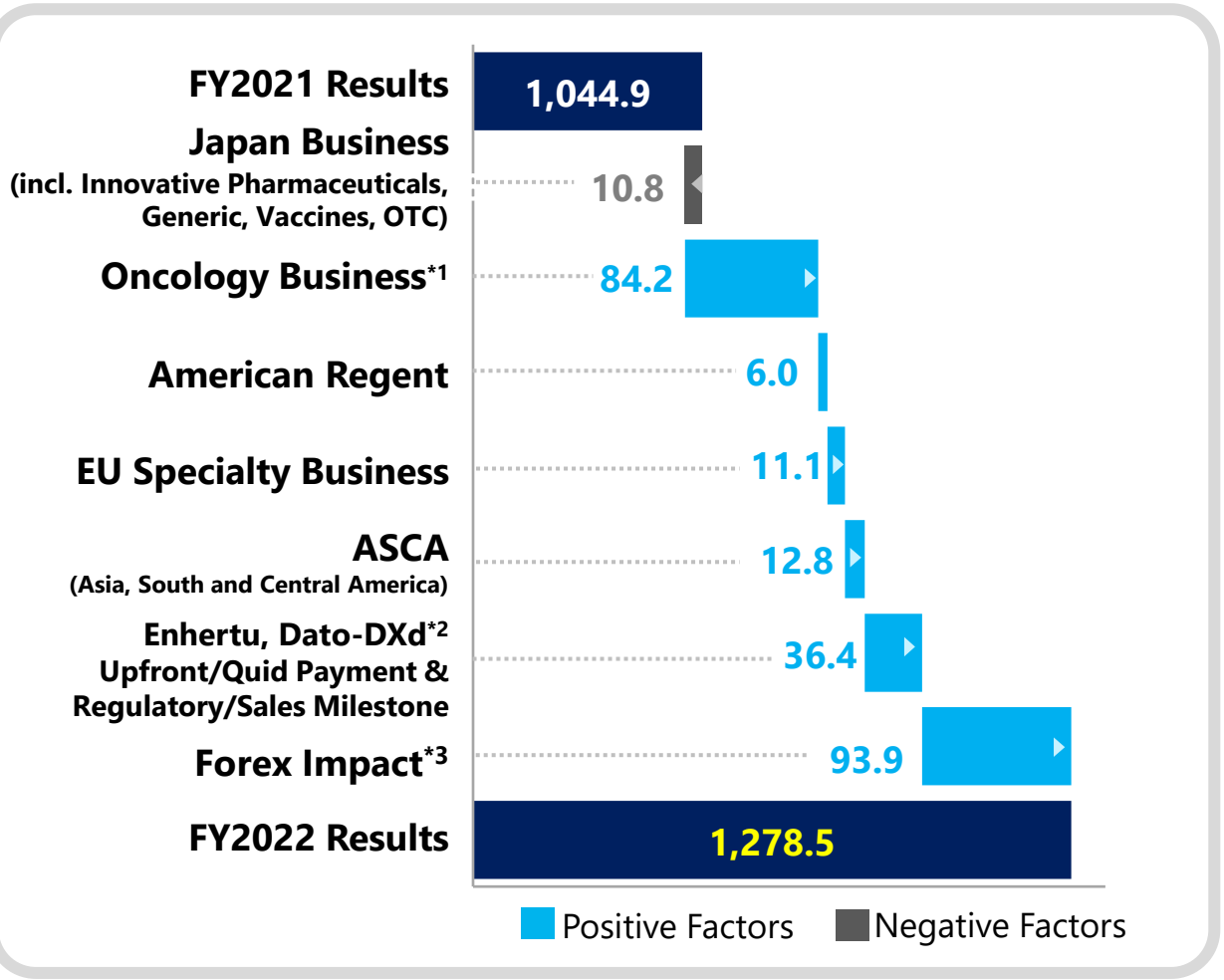
	FY2021 Results	FY2022 Results	YoY	
Revenue	**1,044.9**	**1,278.5**	**+22.4%**	**233.6**
Cost of sales *	348.0	349.1		1.0
SG&A expenses *	352.1	470.1		118.0
R&D expenses *	254.1	336.7		82.6
Core operating profit *	**90.6**	**122.6**	**+35.3%**	**32.0**
Temporary income *	3.9	21.9		18.0
Temporary expenses *	21.5	23.9		2.4
Operating profit	**73.0**	**120.6**	**+65.1%**	**47.6**
Profit before tax	**73.5**	**126.9**		**53.3**
Profit attributable to owners of the Company	**67.0**	**109.2**	**+63.0%**	**42.2**

Currency Rate	USD/JPY	112.38	135.48	+23.10
	EUR/JPY	130.56	140.97	+10.41

*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 233.6 Bn JPY (Increased by 139.7 Bn JPY excl. forex impact)



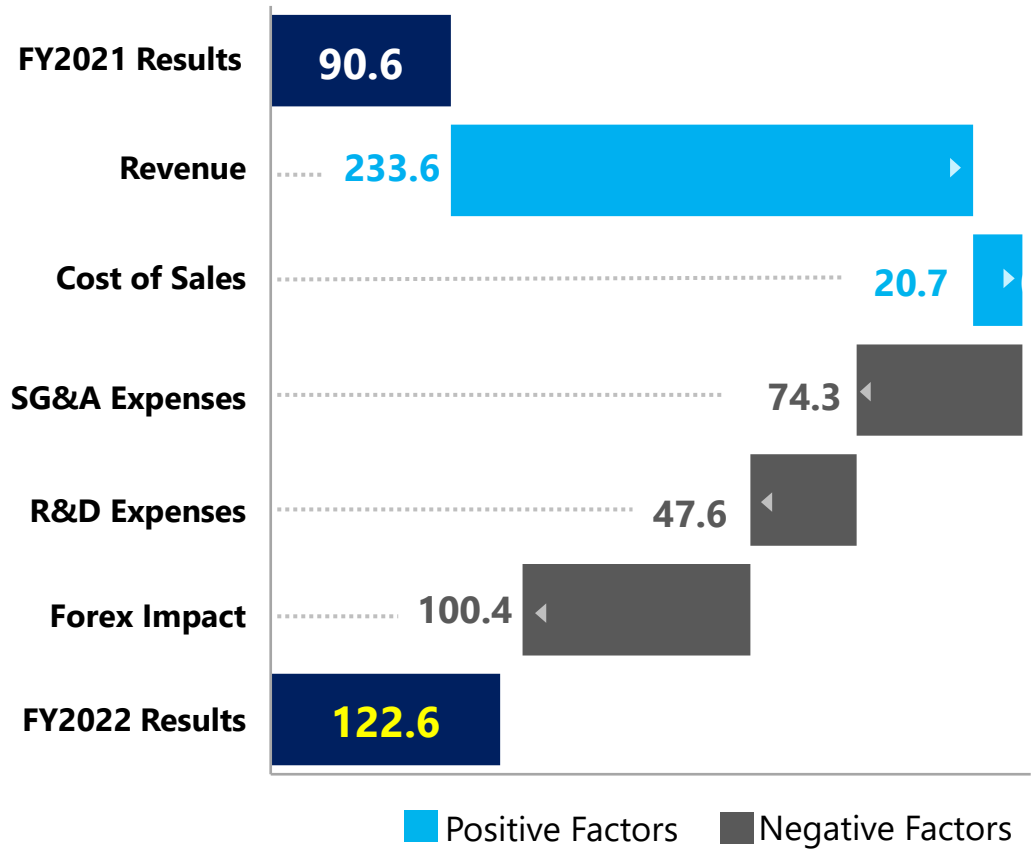
(Bn JPY)

Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+12.7	Nexium	-39.6
Tarlige	+8.4		
Gains on sales of products in US	+5.2		
Gains on sales of products in EU	+2.6		
Oncology Business*1 Unit			
Enhertu	+96.2	Transferred products	-8.3
American Regent Unit			
Venofer	+8.8	Injectafer	-8.3
Abraxane AG (HBT)	+5.7		
EU Specialty Business Unit			
Lixiana	+11.5		
Enhertu, Dato-DXd*2 Upfront/Quid Payment & Regulatory/Sales Milestone			
Enhertu Regulatory Milestone	+24.5		
Enhertu Sales Milestone	+13.2		

*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products
*2 Dato-DXd: Datopotamab deruxtecan (DS-1062)
*3 Forex impact USD: +64.1, EUR : +14.0, ASCA: +15.8

Core Operating Profit

Increased by 32.0 Bn JPY (Increased by 38.5 Bn JPY excl. forex impact)



(Bn JPY)

Revenue +233.6
incl. forex impact of +93.9

Cost of Sales -20.7
Improvement in cost of sales ratio by change in product mix

SG&A Expenses +74.3
Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca

R&D Expenses +47.6
Increase in 3ADCs* R&D investments

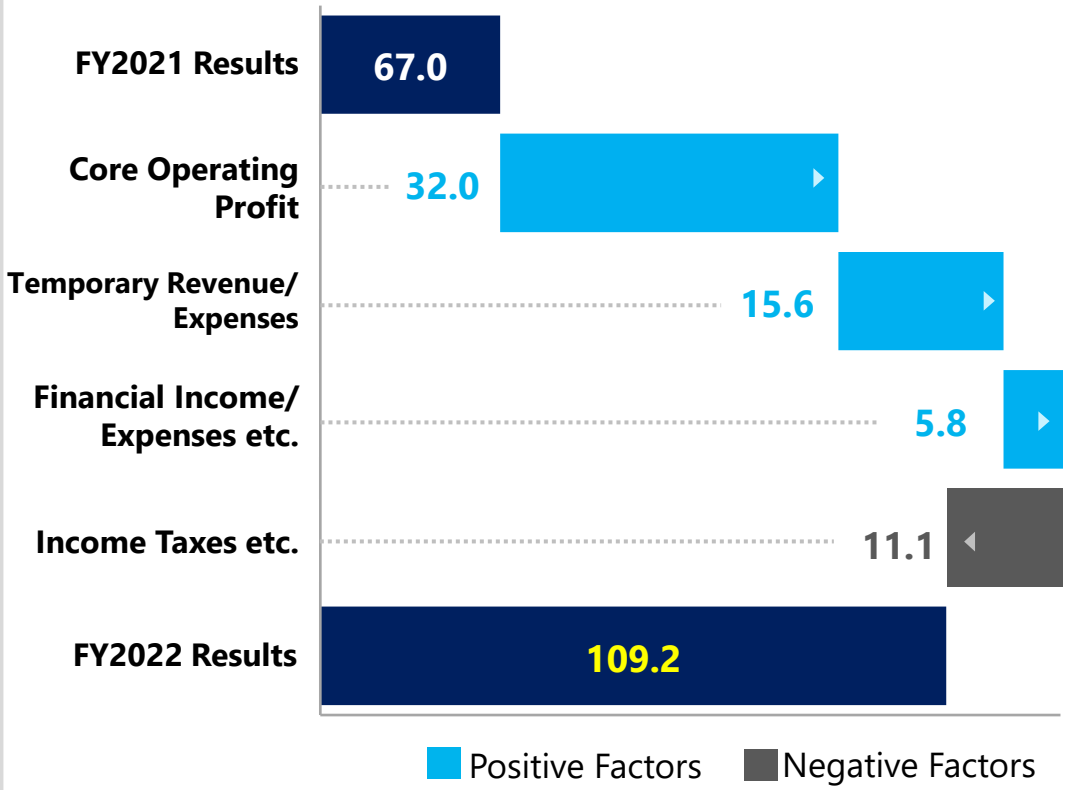
Forex Impact +100.4 (Profit Decreased)
Cost of Sales +21.7
SG&A Expenses +43.7
R&D Expenses +35.0

* 3ADCs: 1) Enhertu, Trastuzumab deruxtecan (T-DXd, DS-8201), 2) Datopotamab deruxtecan (Dato-DXd, DS-1062) and 3) Patritumab deruxtecan (HER3-DXd, U3-1402)

Profit Attributable to Owners of the Company

Increased by 42.2 Bn JPY

(Bn JPY)



Temporary Income/Expenses ····· +15.6 (Profit increased)

	FY2021 Results	FY2022 Results	YoY
Temporary Income	3.9*1	21.9*2	+18.0
Temporary Expenses	21.5*3	23.9*4	+2.4

*1 Gains related to sale of Osaka logistics center (2.1)
*2 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)
*3 Losses related to impairment of Intangible assets (Zelbolaf etc.) (10.4)
Environmental expenditures related to former Yasugawa plant (9.5)
*4 Losses related to impairment of Intangible assets of Turalio (14.2), DS-5141 (6.3) etc.

Financial Income/Expenses etc. ····· +5.8 (Profit Increased)

- Increase of interest income ····· +6.2

Income Taxes etc. ····· +11.1

	FY2021 Results	FY2022 Results	YoY
Profit before Tax	73.5	126.9	+53.3
Income Taxes etc.	6.5	17.7	+11.1
Tax rate	8.9%	13.9%	+5.0%

Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2021 Results	FY2022 Results	YoY
Japan Business	489.5	457.9	-31.6
Daiichi Sankyo Healthcare	64.7	70.3	+5.6
Oncolgy Business	69.6	185.4	+115.8
Enhertu	54.4	181.6	+127.2
Turalio	2.8	3.8	+1.0
American Regent	149.5	187.4	+37.9
Injectafer	53.1	54.0	+0.9
Venofer	33.8	51.3	+17.5
GE injectables	54.7	64.7	+10.0
EU Specialty Business	128.2	150.4	+22.2
Lixiana	96.9	117.1	+20.2
Nilemdo/Nustendi	3.1	7.1	+3.9
Olmesartan	20.3	20.0	-0.3
ASCA (Asia, South and Central America) Business	114.1	142.8	+28.6

Currency Rate	USD/JPY	112.38	135.48	+23.10
	EUR/JPY	130.56	140.97	+10.41

Revenue: Major Products in Japan

(Bn JPY)

		FY2021 Results	FY2022 Results	YoY
Lixiana	anticoagulant	**92.5**	**105.1**	**+12.7**
Tarlige	pain treatment	**30.1**	**38.5**	**+8.4**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**37.9**	**40.2**	**+2.3**
Efient	antiplatelet agent	**16.7**	**20.9**	**+4.2**
Tenelia	type 2 diabetes mellitus treatment	**23.7**	**21.9**	**-1.7**
Vimpat	anti-epileptic agent	**18.3**	**21.9**	**+3.7**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**20.4**	**20.4**	**-0.1**
Canalia	type 2 diabetes mellitus treatment	**16.8**	**16.3**	**-0.5**
Loxonin	anti-inflammatory analgesic	**22.2**	**18.5**	**-3.6**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**9.6**	**11.7**	**+2.2**
Emgality	prophylaxis of migraine attacks	**4.6**	**6.3**	**+1.6**

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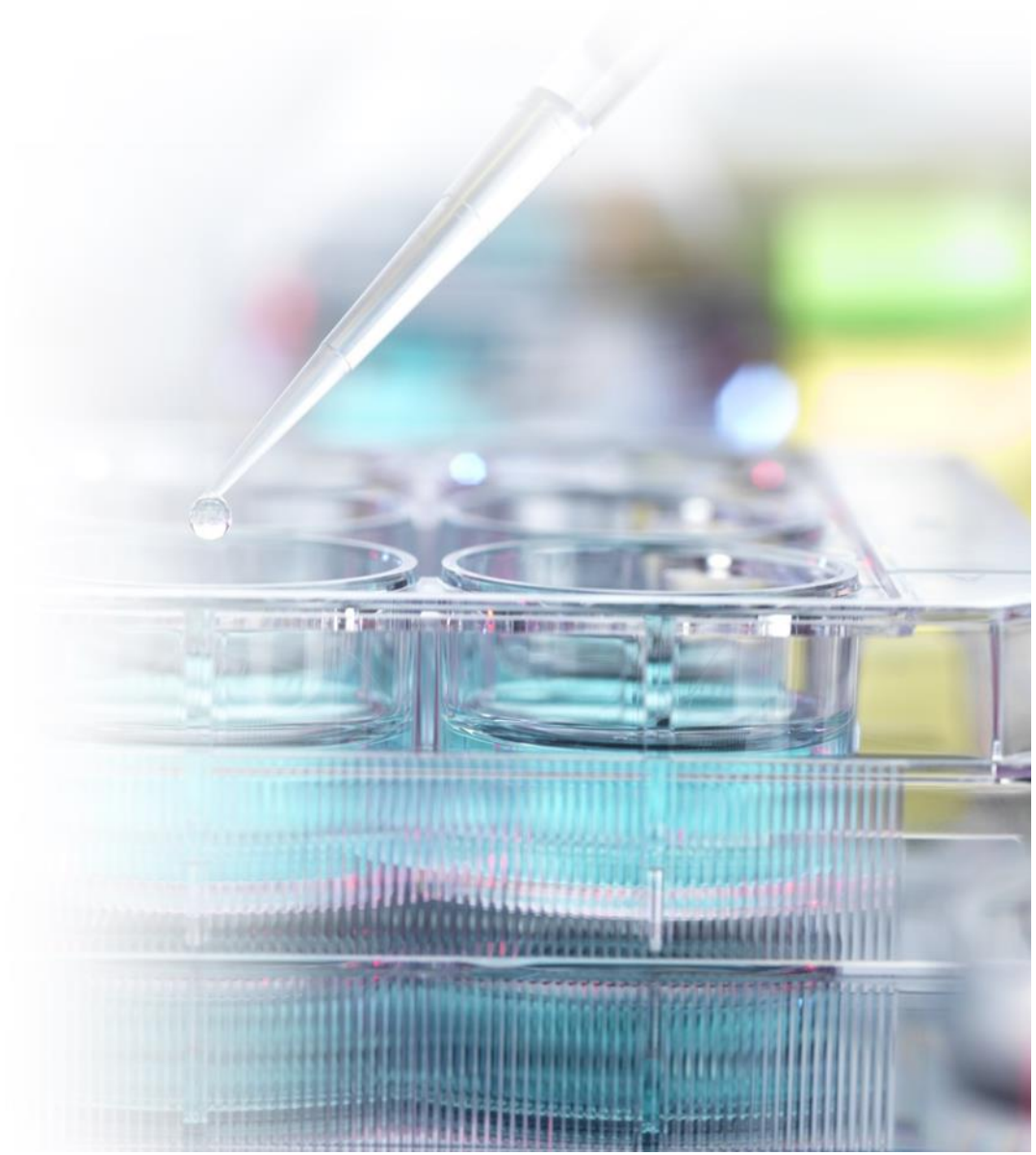


Progress towards “Maximize 3ADCs”

Progress towards “Profit growth for current business and products”

Progress towards “Create shared value with stakeholders”

ENHERTU®

Revenue

(Bn JPY)

	FY2022 Results	YoY	FY2023 Forecast	YoY	<Reference> Total Consideration
Product Sales	207.5	142.2	320.0	112.5	-
Japan	11.7	2.2	19.9	8.2	-
US	144.6	99.2	195.1	50.5	-
Europe	37.1	28.0	75.8	38.8	-
ASCA	14.2	12.8	29.2	15.1	-
Upfront payment	9.8 *1	-	9.8 *1	-	149.0
Regulatory milestone payment	26.7 *1	24.5	11.6 *1	-15.1	136.3
US HER2+ Breast Cancer 3L	0.9	-	0.9	-	13.7
EU HER2+ Breast Cancer 3L	0.5	-	0.5	-	7.9
US HER2+ Gastric Cancer 2L + 3L	0.8	-	0.8	-	12.1
US HER2+ Breast Cancer 2L	3.5	3.5	0.9	-2.6	13.1
EU HER2+ Breast Cancer 2L	2.7	2.7	0.7	-2.0	10.1
US HER2-low Breast Cancer (post-chemo)	7.3	7.3	1.8	-5.5	27.7
EU HER2-low Breast Cancer (post-chemo)	5.2	5.2	1.3	-3.9	19.8
EU HER2+ Gastric Cancer 2L	1.3	1.3	0.3	-0.9	4.8
US HER2 Mutant NSCLC 2L	4.6	4.6	1.1	-3.4	17.3
EU HER2 Mutant NSCLC 2L	-	-	3.2	3.2	9.8 *2
Quid related payment	1.1 *1	-2.3	1.1 *1	-	17.2
Sales milestone payment	13.2	13.2	26.0 *3	12.8	39.2
Total	258.4	177.6	368.6	110.2	341.8

*1 Revenue recognized in each period

*2 Converted with assumed forex rate for FY2023 of 130 JPY to 1 USD

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

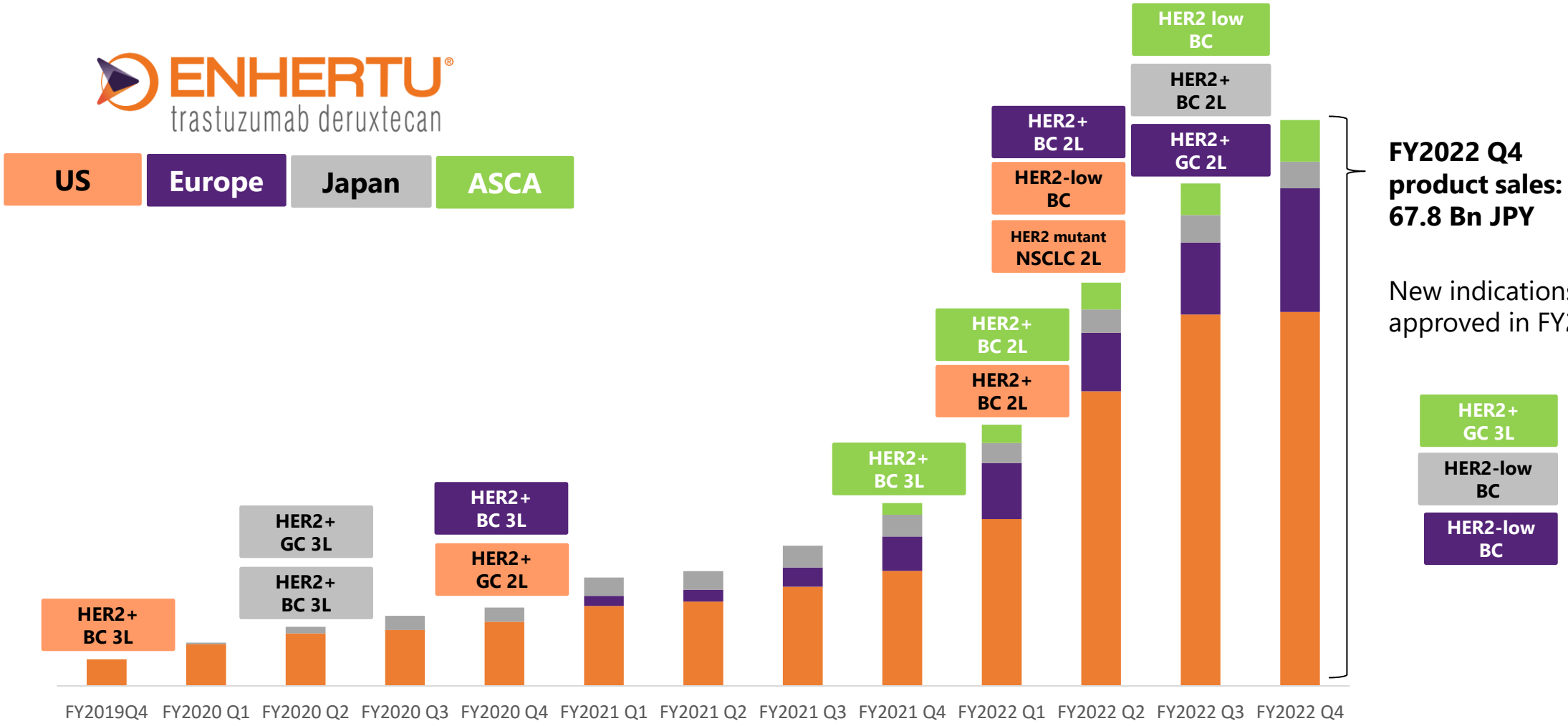
Ref. Total sales milestone payment:
1.75 Bn USD (Max)

ENHERTU®

Sales Increase since Launch

Daiichi-Sankyo

Steady increase in product sales due to market penetration and additional indications



FY2022 Q4 product sales: 67.8 Bn JPY

New indications approved in FY2022 Q4

ENHERTU®

Performance in Each Region (US, EU)

Daiichi-Sankyo

Large increase in product sales due to market penetration and additional indications

Global product sales: **FY2022 results** **207.5 Bn JPY** (YoY +142.2 Bn JPY)
FY2023 forecast **320.0 Bn JPY** (YoY +112.5 Bn JPY)

US

- **Product sales:** **FY2022 results** **144.6 Bn JPY** (**1,067 Mn USD**)
  FY2023 forecast **195.1 Bn JPY** (**1,500 Mn USD**)
- **Indication:** HER2+ BC 2L+, HER2 low BC (post-chemo), HER2+ GC 2L+, HER2 mutant NSCLC 2L+
- **Market share status**
  - HER2+ BC 2L/3L: Maintaining No.1 new patient share
  - HER2 low BC: Maintaining No.1 new patient share and growing further
  - HER2+ GC 2L: Maintaining No.1 new patient share
  - HER2 mutant NSCLC 2L: Good uptake in the population
- **Other progress**
  - Approved for HER2+ BC 2L and started promotion (May 2022)
  - Classified as a category 1 preferred regimen for patients with tumors that are HER2 IHC 1+ or 2+ and ISH negative in NCCN*1 guidelines (Jun. 2022)
  - Approved for HER2 low BC (post chemo) and HER2 mutant NSCLC 2L and started promotion (Aug. 2022)

*1 NCCN: National Comprehensive Cancer Network

Europe

- **Product sales:** **FY2022 results** **37.1 Bn JPY** (**274 Mn USD**)
  FY2023 forecast **75.8 Bn JPY** (**583 Mn USD**)
- **Indication**: HER2+ BC 2L+, HER2 low BC (post-chemo), HER2+ GC 2L+
- **Market share status**
  - HER2+ BC 2L: Increasing significantly in launched countries/regions (No.1 in France, Germany, Spain)
  - HER2 low BC : Increasing steadily in launched countries/regions (France, Germany)
- **Other progress**
  - Approved for HER2+ BC 2L and started promotion (Jul. 2022)
  - Approved for HER2+ GC 2L and started promotion (Dec. 2022)
  - Launched in Spain (Dec. 2022)
  - Approved for HER2 low BC (post-chemo) and started promotion (Jan. 2023)

Blue letters: updates from Q3

ENHERTU® trastuzumab deruxtecan

ENHERTU®

Performance in Each Region (Japan, ASCA)

Daiichi-Sankyo

Steady increase in product sales due to market penetration, additional indications and increasing launched countries/regions

Global product sales: FY2022 results 207.5 Bn JPY（YoY +142.2 Bn JPY）

FY2023 forecast 320.0 Bn JPY（YoY +112.5 Bn JPY）

Japan

- **Product sales: FY2022 results** 11.7 Bn JPY
  FY2023 forecast 19.9 Bn JPY
- **Indication:** HER2+ BC 2L+, HER2 low BC (post-chemo), HER2+ GC 3L
- **Market share status**
  - HER2+ BC 3L: Maintaining No.1 new patient share
  - HER2 low BC: Increasing new patient share steadily
  - HER2+ GC 3L: Maintaining No.1 new patient share
- **Other progress**
  - Classified as a preferred regimen for HER2+ BC 2L treatment in guidelines in Japan (Jun. 2022)
  - Approved for HER2+ BC 2L and started promotion (Nov. 2022)
  - Approved for HER2 low BC (post-chemo) and started promotion (Mar. 2023)

ASCA

- **Product sales: FY2022 results** 14.2 Bn JPY
  FY2023 forecast 29.2 Bn JPY
- **Indication:** HER2+ BC 2L+, HER2 low BC (post-chemo), HER2+ GC 3L
- **Market share status**
  - Sales growing in Brazil, Hong Kong and Taiwan
- **Other progress**
  - Launched in Taiwan (Apr. 2022)
  - Launched in Korea (Jan. 2023)
  - Approved for HER2+ BC 2L in China (Feb. 2022)
    * Plan to launch in FY2023

ENHERTU® trastuzumab deruxtecan

Blue letters: updates from Q3

Progress towards “Maximize 3ADCs”

Progress towards “Profit growth for current business and products”

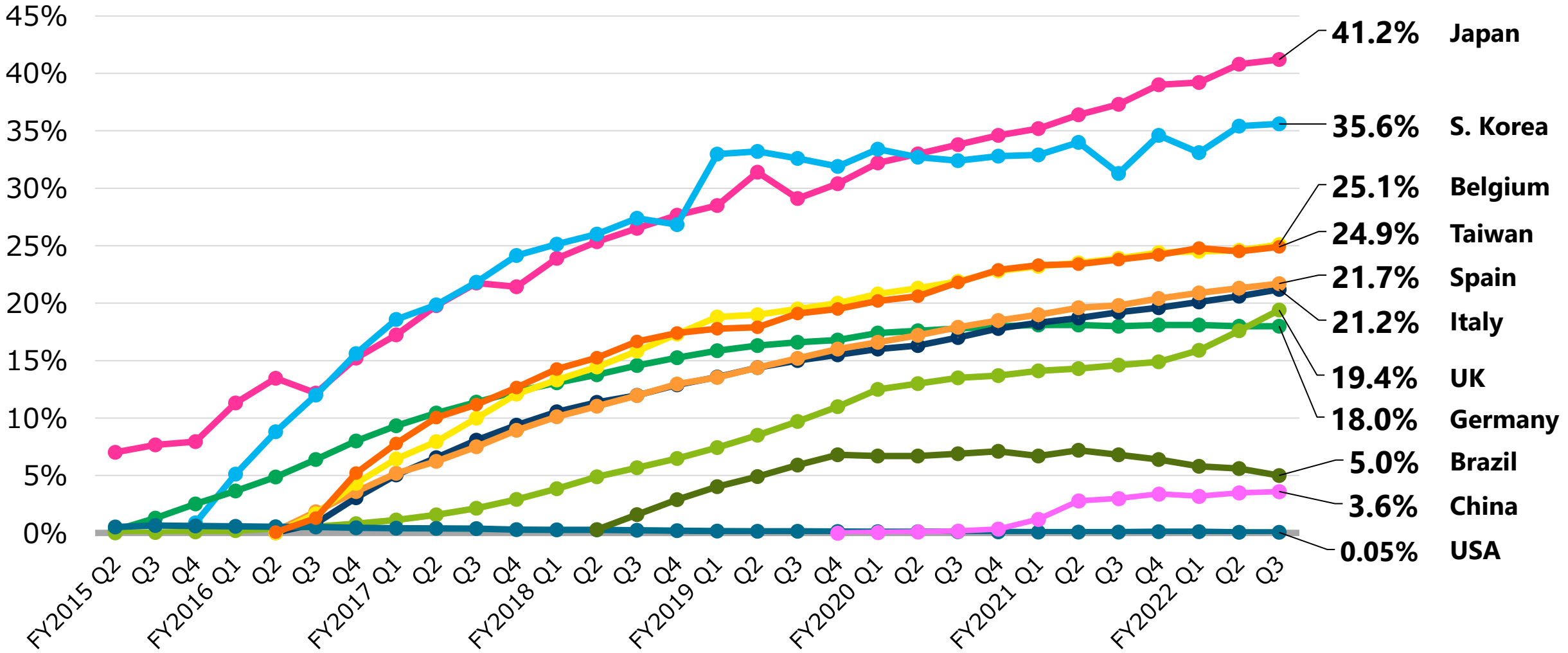
Progress towards “Create shared value with stakeholders”

LIXIANA®: Growth in Each Country/Region

Volume

Daiichi-Sankyo

Global revenue FY2022 results: 244.0 Bn JPY (YoY +38.3 Bn JPY)
FY2023 forecast: 259.4 Bn JPY (YoY +15.4 Bn JPY)

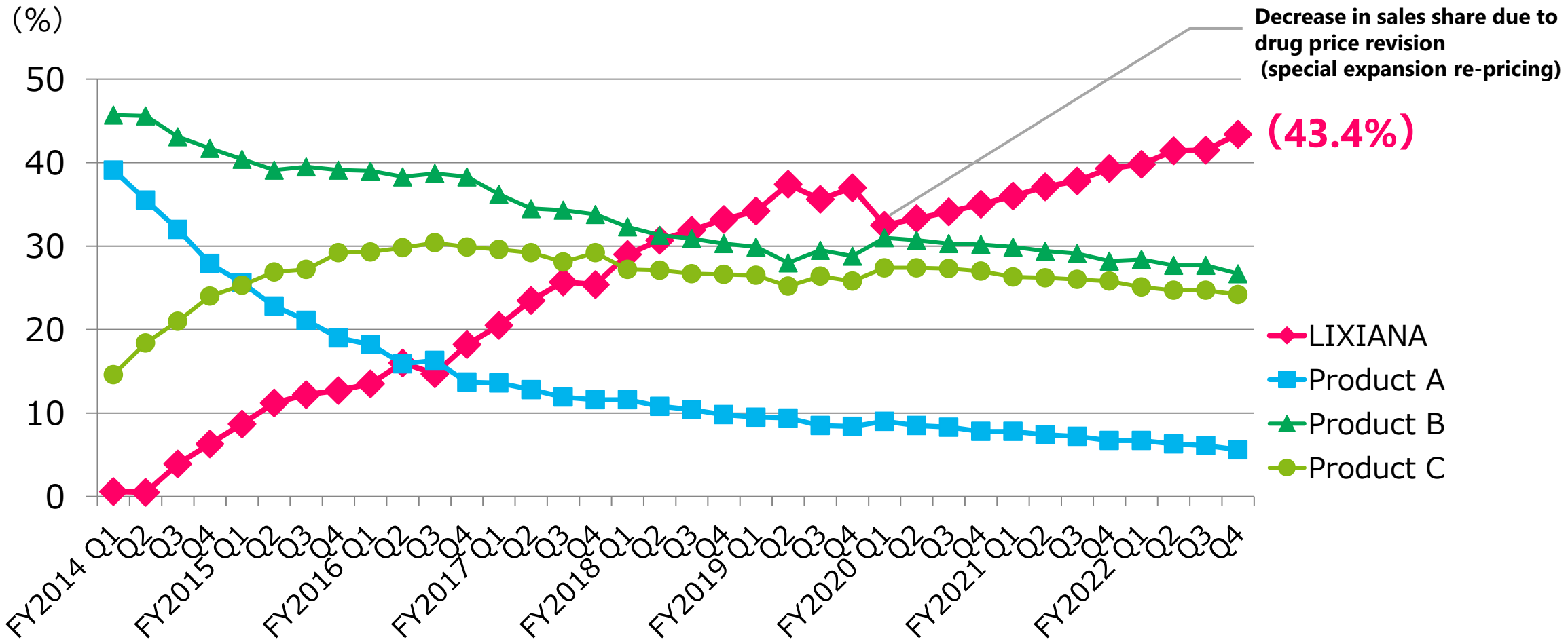


LIXIANA®: Growth in Japan

Sales

Daiichi-Sankyo

- No.1 sales share (FY2022 Q4: 43.4%)
- Revenue FY2022 results: 105.1 Bn JPY (YoY +12.7 Bn JPY)
  FY2023 forecast: 109.9 Bn JPY (YoY +4.8 Bn JPY)



Enhance Product Portfolio

Japan

- **MINEBRO ® Orally Disintegrating Tablet**
  Antihypertensive agent
  - **Launched** in May. 2022

- **REYVOW ® Migraine treatment**
  - **Launched** *1 in Jun. 2022

*1 Eli Lilly Japan and Daiichi Sankyo signed an agreement on reverse co-promotion in which Eli Lilly Japan is responsible for clinical development and manufacturing and Daiichi Sankyo is in charge of distribution and sales, and the companies will co-promote the product.

- **EZHARMIA® Anticancer agent**
  - **launched** in Dec. 2022

- **TARLIGE® Orally Disintegrating Tablet Pain treatment**
  - Obtained **marketing approval** in Sep. 2022
    - Planned launch date: FY2023 H1

- **FLUMIST® Intranasal live attenuated influenza viruses**
  - Obtained **marketing approval** *2 in Mar. 2023
    - Indication: the prevention of influenza disease
    - MOA: After intranasal administration, infect in cells lining the nasopharynx and induce immunity.
    - Administration: 1 dose, 0.2 mL for use in persons 2 through 19 years of age. (Administer as 0.1 mL per nostril)
    - Planned launch date: FY2024

*2 Flumist® is an in-licensed product from MedImmune, LLC, a subsidiary of AstraZeneca and concluded a licensing agreement with the company for the development and sales of this drug.

US (American Regent, Inc.)

- American Regent, Inc. **acquired** HBT Labs, Inc. August 2022
  - A healthcare company engaged in **research and development, manufacturing, sales, and sales of generic (GE) injections**
  - Aiming for further growth **by strengthening the product portfolio of GE injectables** through synergies with HBT Labs, Inc.

<HBT Labs, Inc.>

Other Initiatives in Each Region

Enhance transformation into a profit structure focused on patented drugs

US

◆ **Completed product transfer**

➢ **Date of Transfer: Aug. 2022**

➢ **Products: 8 products including antihypertensive agent BENICAR®**

FY2021 revenue of 8 products: 8.9 Bn JPY

➢ Gain on transfer: Total 57 Mn USD

- 37 Mn USD (5.2 Bn JPY) posted in FY2022
- FY2024 /20 Mn USD

Europe

◆ **Progress in product transfer in Europe**

➢ **Date of Transfer: Sep. 2022**

Each region except Turkey

➢ **Products: EFIENT® Antiplatelet agent**

FY2021 Revenue: 1.5 Bn JPY

➢ **Gain on transfer: Total 21 Mn EUR**

- 19 Mn EUR (2.6 Bn JPY) posted in FY2022
- After FY2023 (when transfer was completed in Turkey): 2 Mn EUR

ASCA

◆ **Completed products and subsidiary transfer in China**

➢ **Date of Transfer: Aug. 2022**

➢ **Product: Antibacterial agent Cravit®**

FY2021 Revenue: 8.9 Bn JPY

➢ **Subsidiary to be divested: Daiichi Sankyo Pharmaceutical (Beijing) Co., Ltd**

➢ **Gain on transfer: 5.9 Bn JPY**

(Full amount posted in FY2022)

Progress towards “Maximize 3ADCs”

Progress towards “Profit growth for current business and products”

Progress towards “Create shared value with stakeholders”

Shareholder Returns: Forecast of Annual Dividend in FY2022

Increase annual dividend per share from 27 JPY to 30 JPY
taking account of sales expansion of Enhertu® more than expected

Revised annual dividend per share: 30 JPY (interim dividend: 15 JPY, year-end dividend: 15 JPY)

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 by sales expansion of Enhertu®**
- **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

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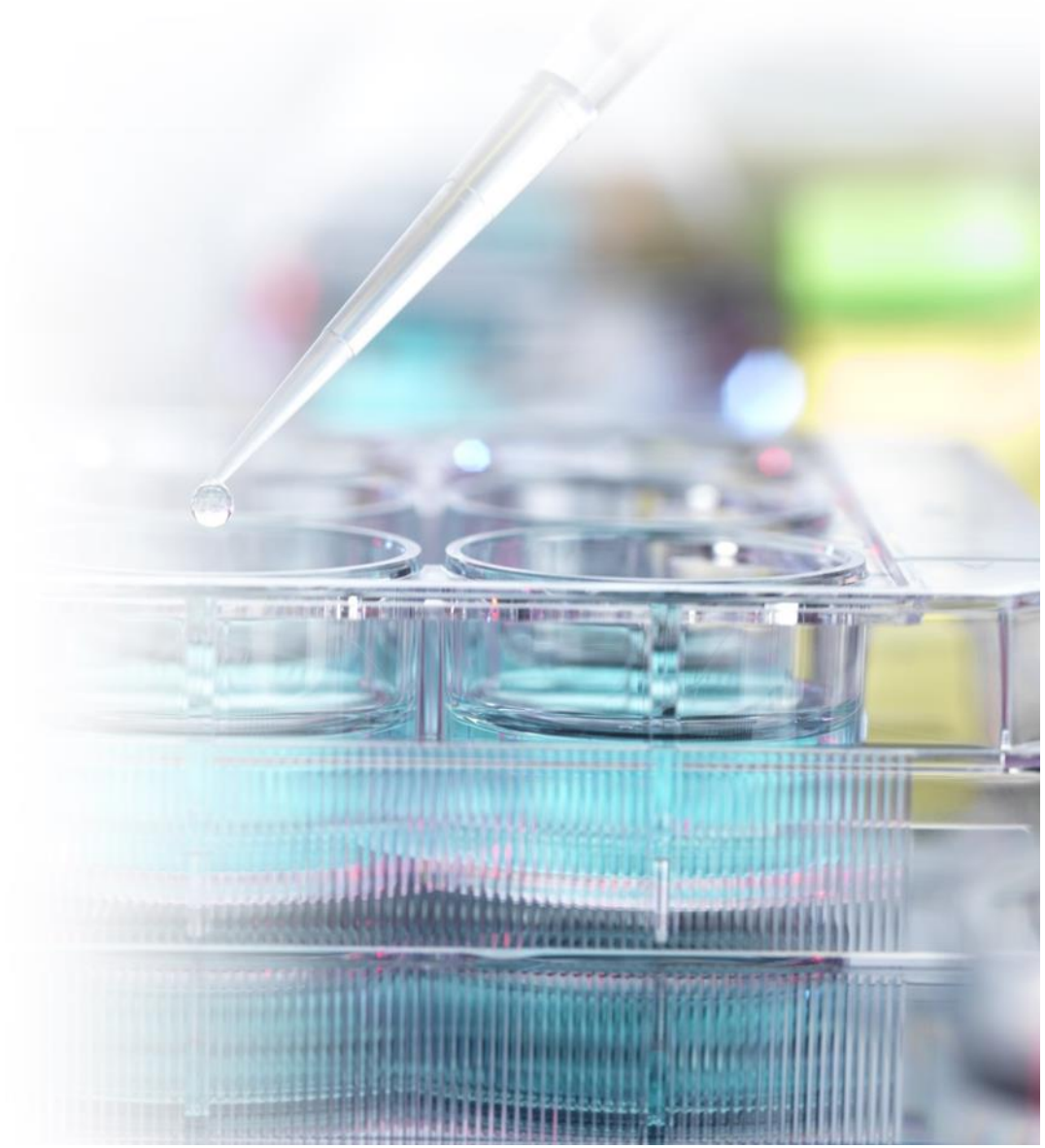


FY2022 R&D achievement

ENHERTU®

- **Transform** the course of HER2+ BC
- **Pioneer HER2 low BC as a new** clinically meaningful **patient segment**
- **Expand leadership across other** HER2 targetable **tumors**

Steady progress in maximizing product value of ENHERTU®

Dato-DXd / HER3-DXd / Alpha

- **Steady progress** to **accumulate and present study data** at conferences
- Established **new therapies for hematological cancers** with high UMN

BC: breast cancer, UMN: unmet medical needs

Progress towards “Maximize 3ADCs”

Progress towards “Identify and build pillars for further growth”

ASCO 2023

News Flow

ENHERTU®

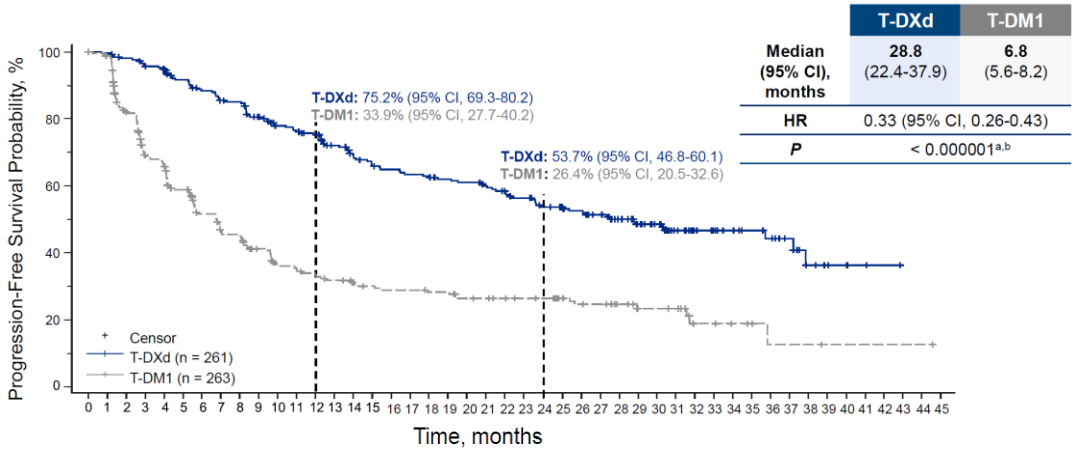
Transform the course of HER2+ BC

DESTINY-Breast03 （SABCS 2022）

Daiichi-Sankyo

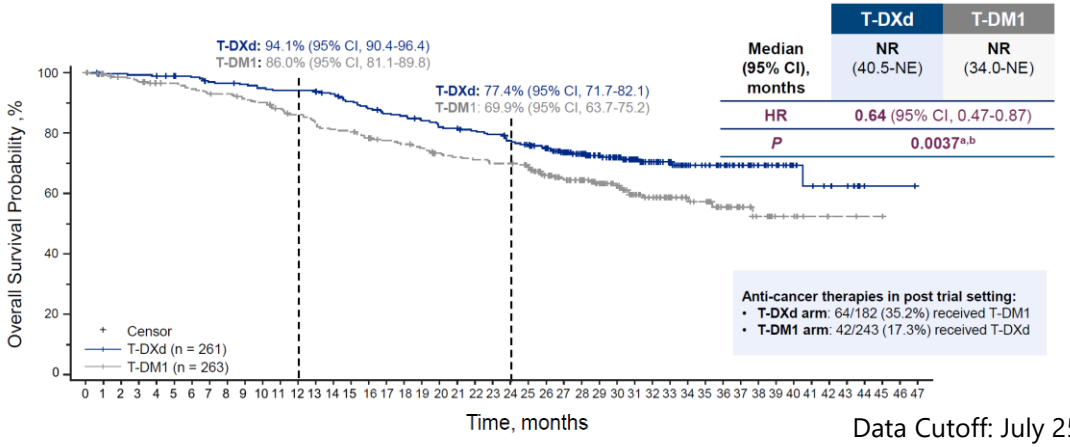
Established position as 2L SOC for HER2 positive BC

PFS in HER2+ BC



	T-DXd	T-DM1
Median (95% CI), months	28.8 (22.4-37.9)	6.8 (5.6-8.2)
HR	0.33 (95% CI, 0.26-0.43)	
P	< 0.000001[a,b]	

OS in HER2+ BC



	T-DXd	T-DM1
Median (95% CI), months	NR (40.5-NE)	NR (34.0-NE)
HR	0.64 (95% CI, 0.47-0.87)	
P	0.0037[a,b]	

Data Cutoff: July 25, 2022

- ENHERTU® **reduced the risk of death by 36%** (HR: 0.64)
- **mPFS** with ENHERTU® was **4 times longer** than with T-DM1 (28.8 months vs. 6.8 months)
- ORR was 78.5%; **1 in 5 (21%) patients experienced CR**
- **The incidence of TEAEs** was **almost the same** between ENHERTU® and T-DM1 (56.4% vs. 51.7%)
- The most common adverse events of ENHERTU® in this study were decreased neutrophil count, anemia, decreased platelet count, and nausea

Regulatory Progress: HER2+ BC, 2L

- **May 2022: Approval in US**
- **Jul 2022: Approval in EU**
- **Nov 2022: Approval in Japan**
- **Feb 2023: Approval in China**
  （First approval in China for ENHERTU®）

BC: breast cancer, CI: confidence interval, CR: complete response, HR: hazard ratio, PFS: progression-free survival, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, NE: not estimable, NR: not reached, SABCS: San Antonio Breast Cancer Symposium, SOC: standard of care, T-DM1: trastuzumab emtansine, T-DXd: trastuzumab deruxtecan, TEAEs: treatment emergent adverse events

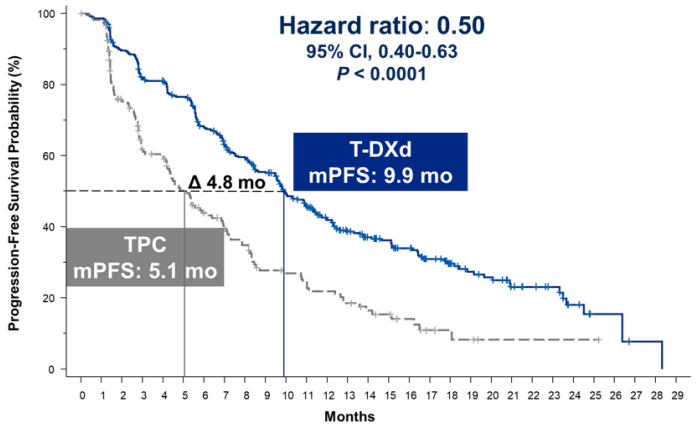
ENHERTU®

Pioneer HER2 low BC as a new clinically meaningful patient segment

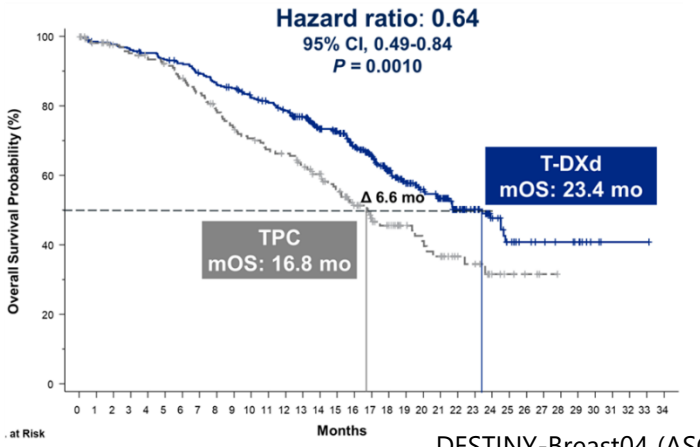
Daiichi-Sankyo

Provide patients with new treatment options based on clinical trial results

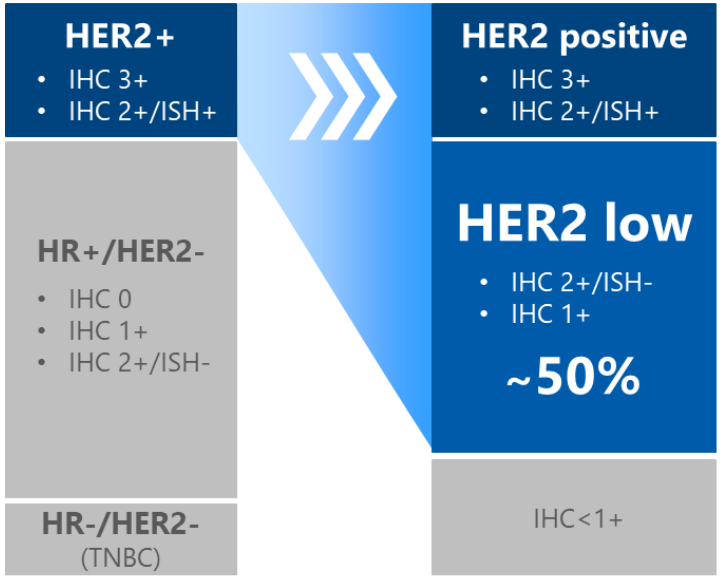
PFS in all patients with HR+ or HR- and HER2 low BC



OS in all patients with HR+ or HR- and HER2 low BC



DESTINY-Breast04 (ASCO2022)
Data Cutoff: Jan 11, 2022



- **50% reduction in the risk of disease progression or death** versus chemo, mPFS of **9.9 months** compared to 5.1 months with chemo
- **36% reduction in the risk of death** versus chemo, mOS of **23.4 months** compared to 16.8 months with chemo
- The most common TEAEs for ENHERTU® in this study were neutropenia, anemia, leukopenia, fatigue, thrombocytopenia, and the observed safety profile was comparable to the known profile of T-DXd

Regulatory Progress:

HER2 low breast cancer, post-chemo

- **Aug 2022: Approval in US**
- **Jan 2023: Approval in EU**
- **Mar 2023: Approval in JP**

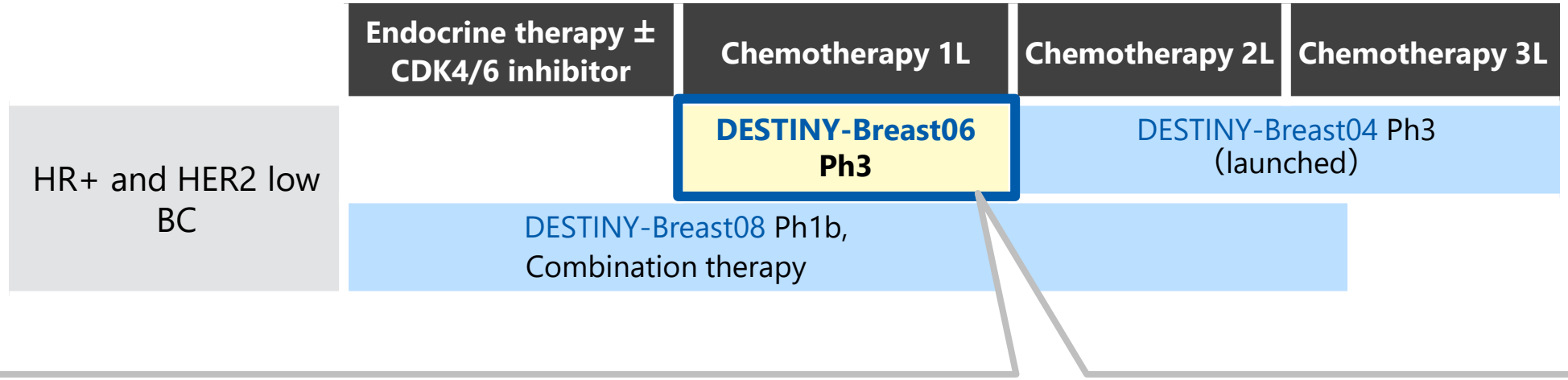
ASCO: American Society of Clinical Oncology, BC: breast cancer, CI: confidence interval, HR: hormone receptor, IHC: immunohistochemistry, OS: overall survival, PFS: progression-free survival, mOS: median overall survival, mPFS: median progression-free survival, SOC: standard of care, T-DXd: trastuzumab deruxtecan, TEAEs: treatment emergent adverse events, TPC: treatment of physician's choice, TNBC: triple-negative breast cancer

ENHERTU®

Pioneer HER2 low BC as a new clinically meaningful patient segment

Daiichi-Sankyo

Further development towards earlier lines of therapy for HER2 low BC



DESTINY-Breast06 Ph3 study design

Chemotherapy naïve
HR+ and HER2 low
Advanced/metastatic BC

→ **Randomization 1:1**

- **ENHERTU®**
- **Physician's choice chemotherapy**

N = 850

Primary endpoint: PFS, etc.
Secondary endpoint: OS, PFS, ORR, DoR, safety, etc.

Results of this study is anticipated in **FY2023 H1**

BC: breast cancer, DoR: duration of response, HR: hormone receptor, ORR: objective response rate, OS: overall survival, PFS: progression-free survival

ENHERTU®

Expand leadership across other HER2 targetable tumors

Daiichi-Sankyo

Challenges for diverse cancer types following breast cancer

Regulatory Progress: HER2+ GC (DESTINY-Gastric01/02 Ph2 study)

- Sep 2020: Approval in 3L in Japan
- Jan 2021: Approval in 2L in US
- **Dec 2022: Approval in 2L in EU**

Regulatory Progress: HER2 mutant NSCLC, 2L+ (DESTINY-Lung01/02 Ph2 study)

- **Aug 2022: Approval in US**
- JP and EU: Approval anticipated in FY2023

HER2+ CRC, 3L (DESTINY-CRC02 Ph2 study)

- Jan 2023: TLR obtained
  Publication at ASCO 2023

HER2 expressing solid tumors (DESTINY-PanTumor02 Ph2 study)

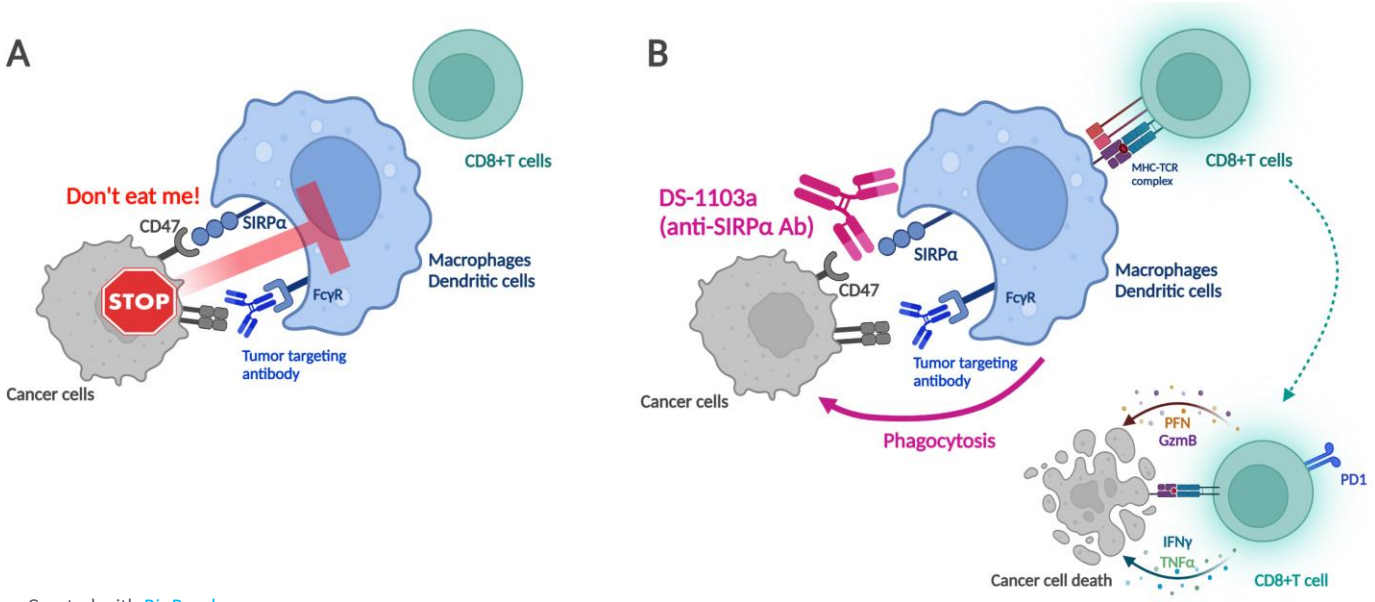
- **Mar 2023: Interim analysis results obtained**
  Publication at ASCO 2023

ASCO: American Society of Clinical Oncology, GC: gastric cancer, CRC: colorectal cancer, NSCLC: non small cell lung cancer, TLR: top line results

ENHERTU®

Accelerated combination development with Our Assets

Following the ENHERTU® combination with EZHARMIA®, a new combination study with anti-SIRPα antibody DS-1103 starts in FY2023 H1



Created with BioRender.com.

- DS-1103 is designed to block "Don't eat me" signal through SIRPα-CD47 axis by combining SIRPα on macropharges and dendric cells, leading to phagocytosis of tumor cells and subsequent activation of anti-tumor immunity
- Combination with anti-tumor antibodies with effector activity is necessary to maximize the efficacy of DS-1103a

Ph1 study design

Dose escalation part
DS-1103 + ENHERTU® (5.4 mg/kg Q3W)
HER2-expressing or HER2-mutant advanced metastatic solid tumors

→

Dose expansion part
DS-1103 + ENHERTU® (5.4 mg/kg Q3W)
HER2 low BC

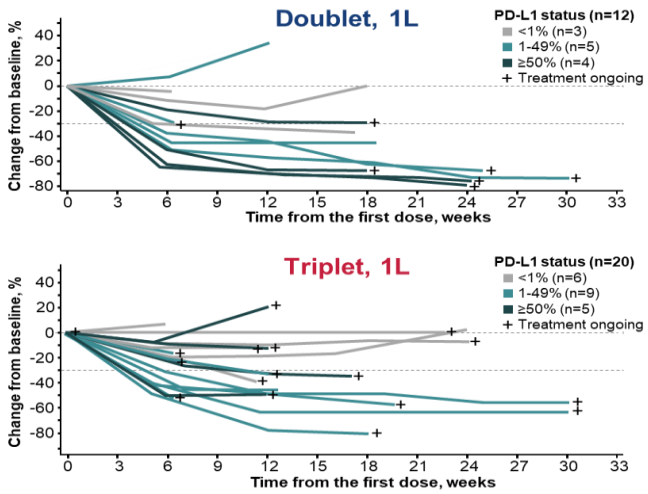
BC: breast cancer, FIH: first-in-human, Q3W: once every 3 weeks

Dato-DXd

Progress in FY2022: NSCLC

Initiated TROPION-Lung07 Ph3 study for PD-L1 <50% NSCLC 1L patients based on the data of TROPION-Lung02 study

TROPION-Lung02 study data（WCLC 2022）



TROPION-Lung02 study

Ph1b study to evaluate the safety and efficacy of **Dato-DXd + pembrolizumab (“doublet”)** and **Dato-DXd + pembrolizumab + platinum chemotherapy (“triplet”)** in metastatic NSCLC without actionable genomic alterations

Data Cutoff: May 2, 2022

- ORRs of 37% and 41% were seen with doublet and triplet therapy in the overall population. As 1L therapy, the doublet and triplet yielded ORRs of 62% and 50%, respectively
- Overall safety consistent with Dato-DXd monotherapy and no grade 4 or grade 5 ILD events were adjudicated as drug-related
- Stomatitis and nausea, mostly grade 1/2, were the most frequent TEAEs in patients receiving doublet and triplet therapy in this study, respectively

Ph3 Clinical Studies of Dato-DXd for NSCLC

	Advanced/Metastatic		
	1L	2L	3L
NSCLC without AGA	**TROPION-Lung07** (PD-L1 <50%) **Started in Jan 2023**		
	TROPION-Lung08 (PD-L1 ≥ 50%) Started Mar 2022		
	TROPION-Lung01 (includes NSCLC with AGA)		

AGA: actionable genomic alteration, ILD: interstitial lung disease, NSCLC: non-small cell lung cancer , ORR: objective response rate, TEAEs: treatment emergent adverse events, TLR: Top Line Results, WCLC: World Conference on Lung Cancer

Progress in FY2022: NSCLC

Studies for NSCLC 2L+ are also progressing as planned

TROPION-Lung01 Study

Ph3 randomized study of Dato-DXd versus docetaxel in patients with previously treated advanced or metastatic NSCLC with or without actionable genomic alterations

Primary endpoint: PFS, OS

Secondary endpoint: ORR, DoR, DCR, PK, safety, etc

TLR anticipated in FY2023 Q1

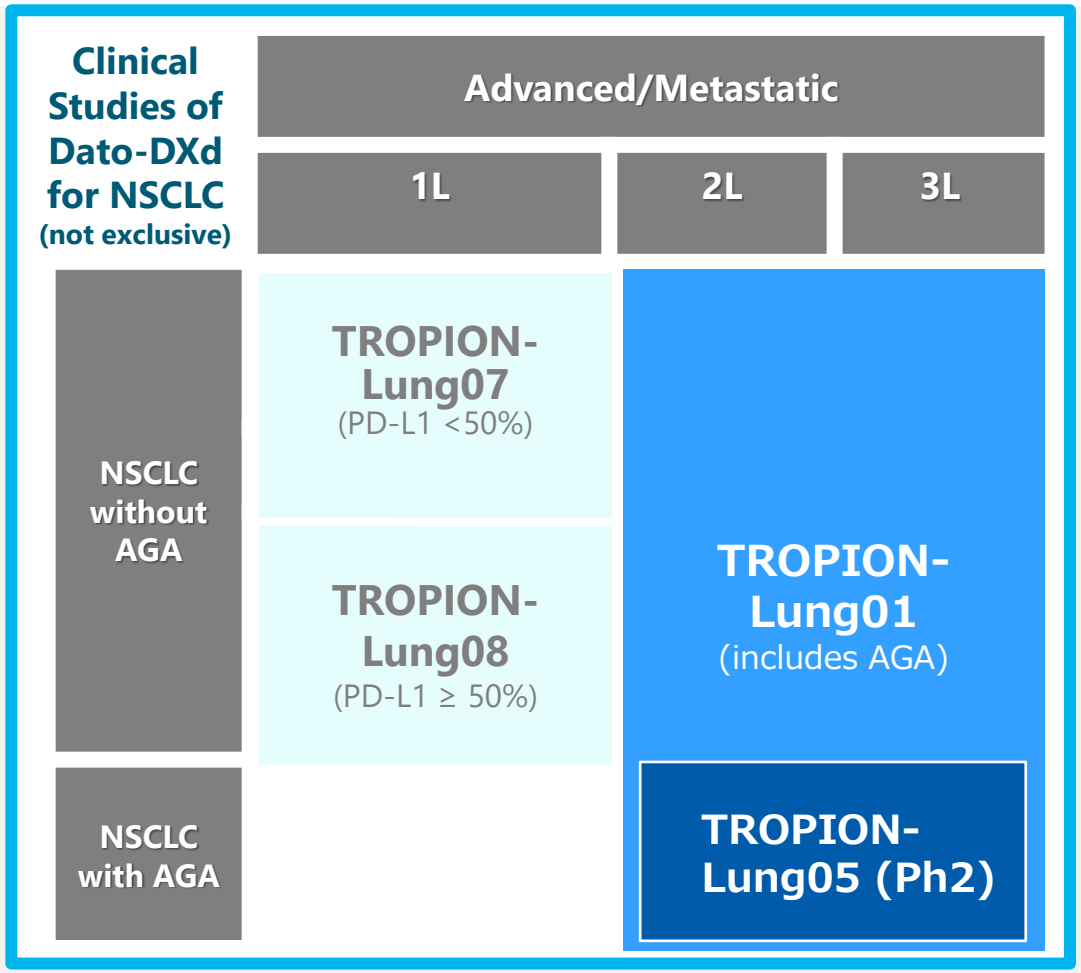
TROPION-Lung05 Study

Ph2, open-label, **single-arm study of Dato-DXd** in patients with advanced or metastatic NSCLC **with actionable genomic alteration** who have progressed on or after a target therapy and platinum-based chemotherapy containing regimen

Primary endpoint：ORR by BICR

Secondary ：DoR, DCR, PFS, OS, safety, PK, immunogenicity, etc

TLR obtained in Mar 2023, the data will be presented at future medical meeting

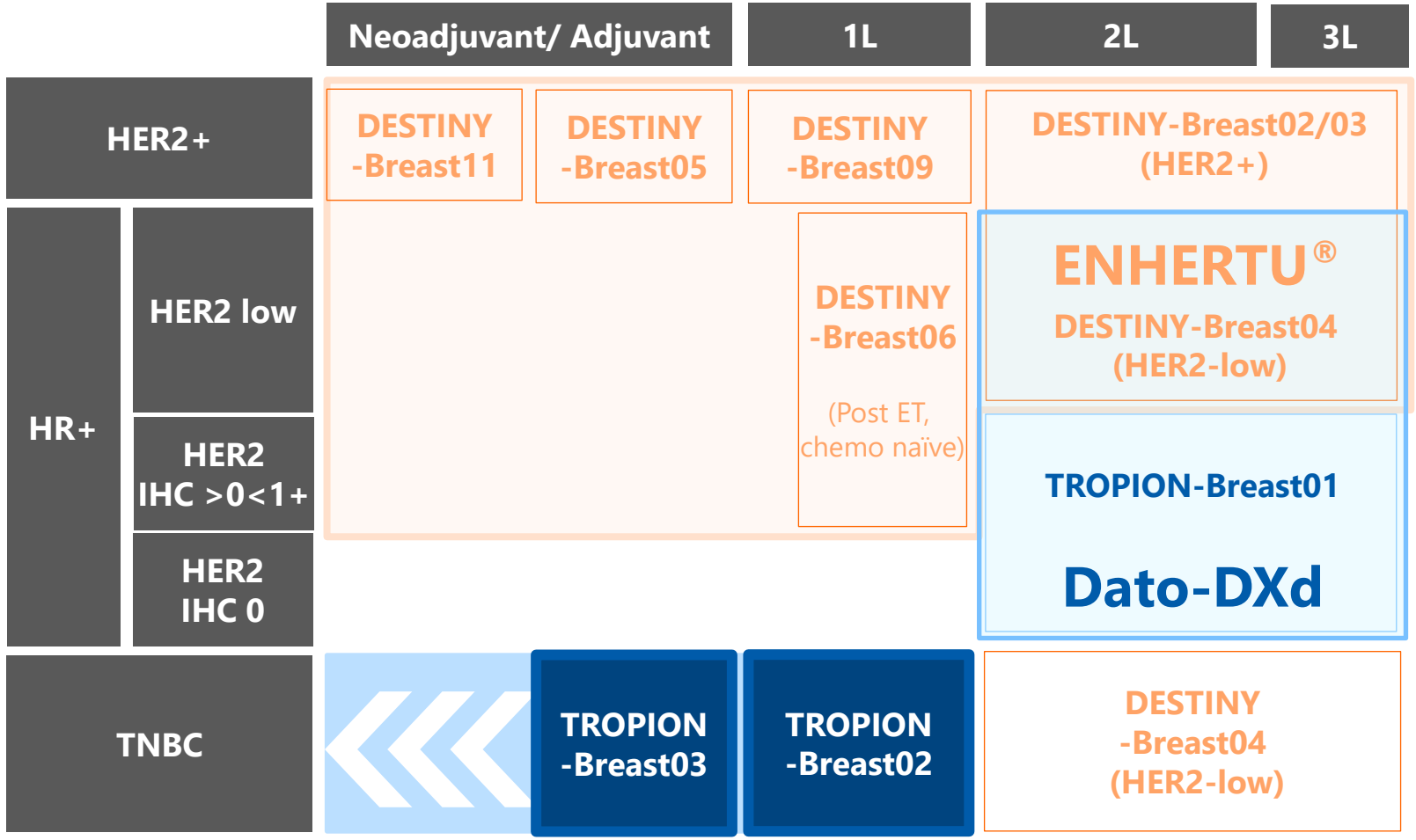


AGA: actionable genomic alteration, BICR: blinded independent central review, DCR: disease control rate, DoR: duration of response, NSCLC: non-small cell lung cancer, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, PK: pharmacokinetics, TLR: Top Line Results

Dato-DXd

Progress in FY2022: Breast Cancer

Durable efficacy and manageable safety profile in HR+ HER2 low or negative mBC and TNBC as shown in TROPION-PanTumor01 raises confidence in Ph3 studies



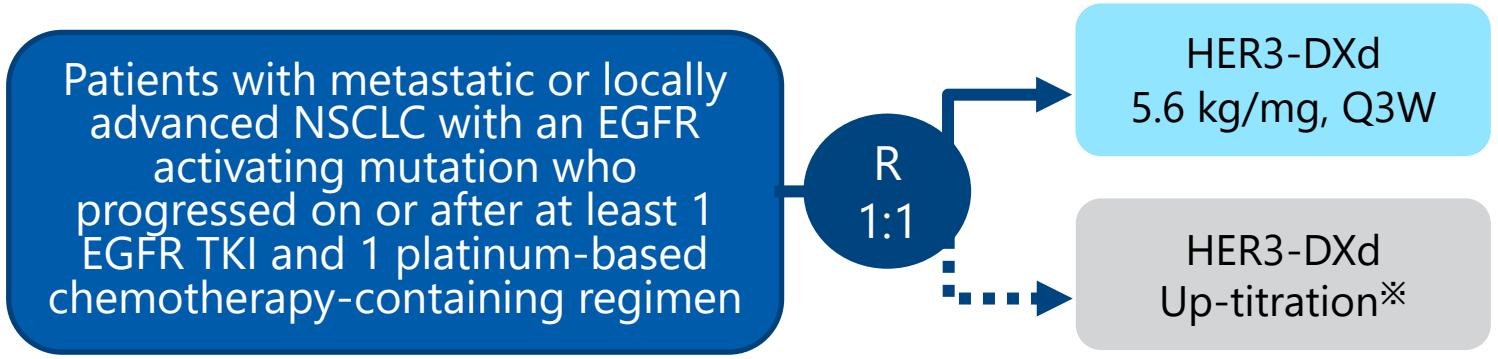
- **TROPION-Breast02 study** (PD-L1 ineligible, 1L TNBC) started in June 2022.
- **TROPION-Breast03 study** (TNBC with residual invasive disease following neoadjuvant therapy, adjuvant therapy) started in Dec 2022.

* Listed pivotal studies only
* Indicated treatment lines in HR+ breast cancer shows the number of chemotherapy-based regimens after an endocrine therapy

Chemo: chemotherapy, ET: endocrine therapy, HR: hormone receptor, IHC: immunohistochemistry, mBC: metastatic breast cancer, TNBC: triple-negative breast cancer

HERTHENA-Lung01 Study

HERTHENA-Lung01 Ph2 Study Design



※The 5.6 mg/kg dose selected for further development, and enrollment into up-titration cohort closed

Enrollment	277 patients
Primary endpoint	ORR
Secondary endpoint	DOR, DCR, PFS, OS, safety, etc.

Study outcome and next step

- Among 226 subjects who received the 5.6 mg/kg dose, HER3-DXd showed **evidence of efficacy with durable responses** in patients with metastatic or locally advanced EGFR-mutated NSCLC previously treated with an EGFR TKI and PBC
- The safety profile of HER3-DXd observed in HERTHENA-Lung01 was manageable, consistent with that seen in previous trials and **no new safety concerns were identified**
- **Plan to discuss and share results with health authorities**
- The data will be presented at a future medical meeting
- Ph3 study in 2L (HERTHENA-Lung02) is ongoing in patients with metastatic or locally advanced EGFR-mutated NSCLC after failure of EGFR TKI therapy

HER3-DXd demonstrated efficacy with durable responses in patient population with high unmet medical need

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, PFS: progression-free survival, TKI: tyrosine kinase inhibitor

Progress towards “Maximize 3ADCs”

Progress towards “Identify and build pillars for further growth”

ASCO 2023

News Flow

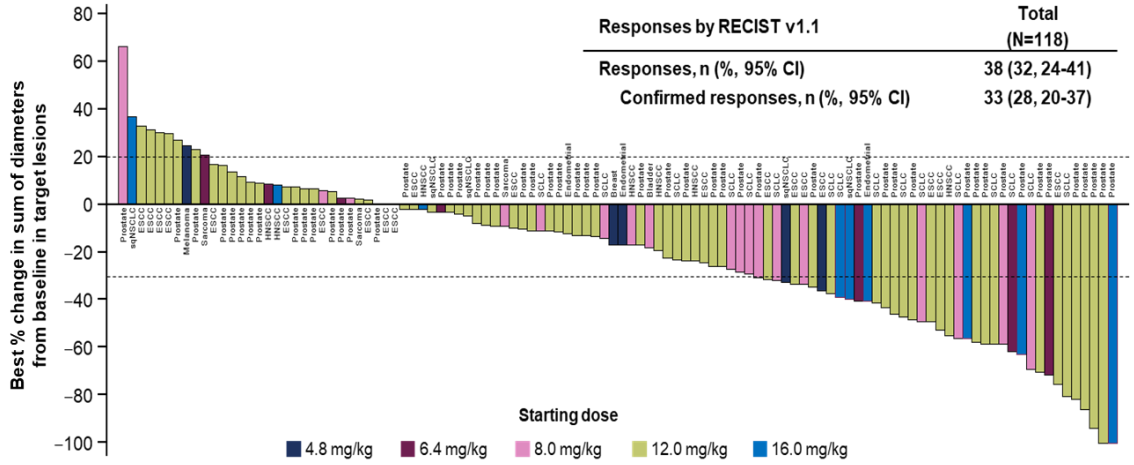
Progress in FY2022

Dose-optimization Ph2 study for patients with SCLC has started in June

Ph1/2 study data (ESMO 2022)

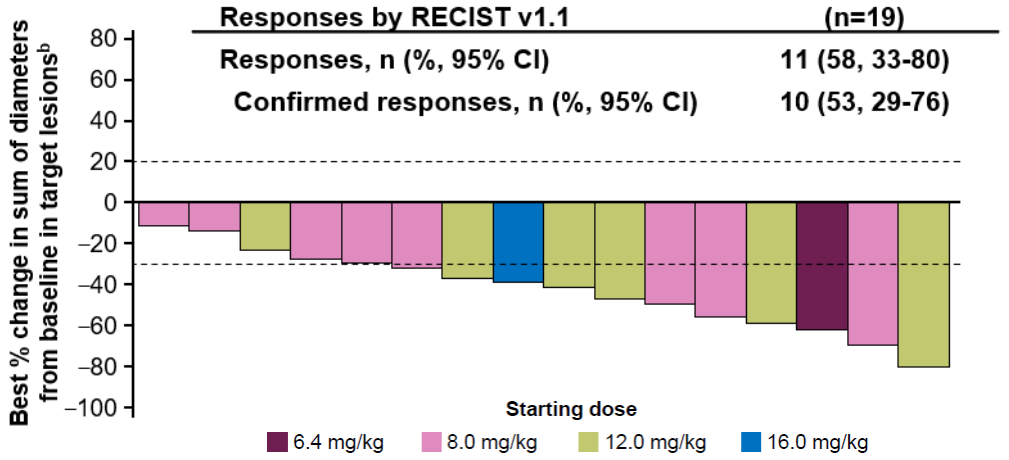
Efficacy across tumor types

Confirmed ORR: 28%



Efficacy in SCLC

Confirmed ORR: 53%



Data cutoff: Jun 30, 2022

- **Demonstrated promising efficacy for multiple cancer types in heavily pretreated patient**
- The most common adverse events were nausea, anemia, decreased appetite, fatigue, vomiting, and observed IRR in 47 patients (32%, all grade, no Gr. 3 or higher events reported)
- No new safety signals were observed, and the safety profile was consistent with previously reported results

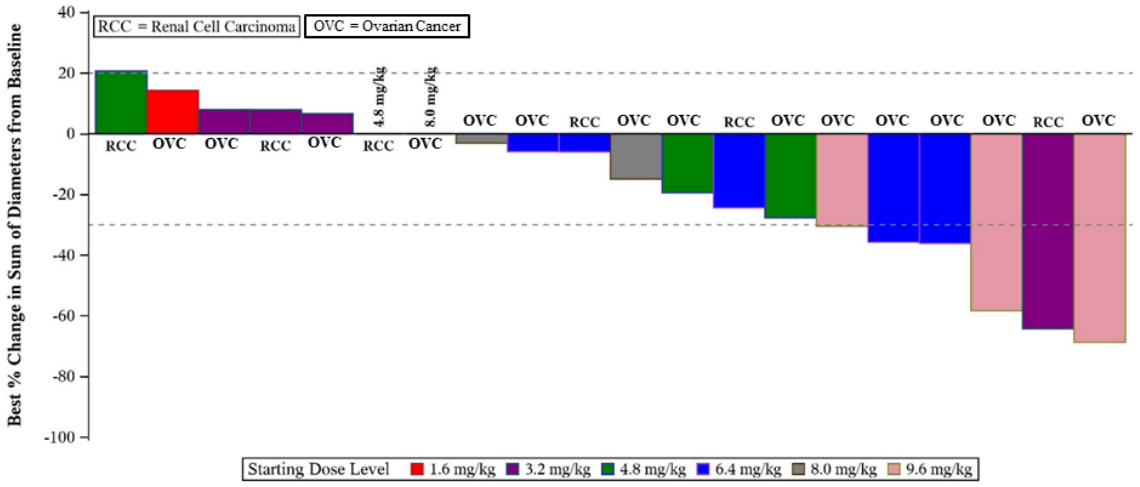
The data from the patients received DS-7300 at doses of 4.8 mg/kg to 16.0 mg/kg. CI: confidence interval, ESCC: esophageal squamous cell carcinoma, ESMO: European Society for Clinical Oncology, HNSCC: head and neck squamous cell carcinoma, NSCLC: non-small cell lung cancer, ORR: objective response rate, RECIST: Response Evaluation Criteria in Solid Tumors, SCLC: small cell lung cancer, sqNSCLC: squamous non-small cell lung cancer

Progress in FY2022

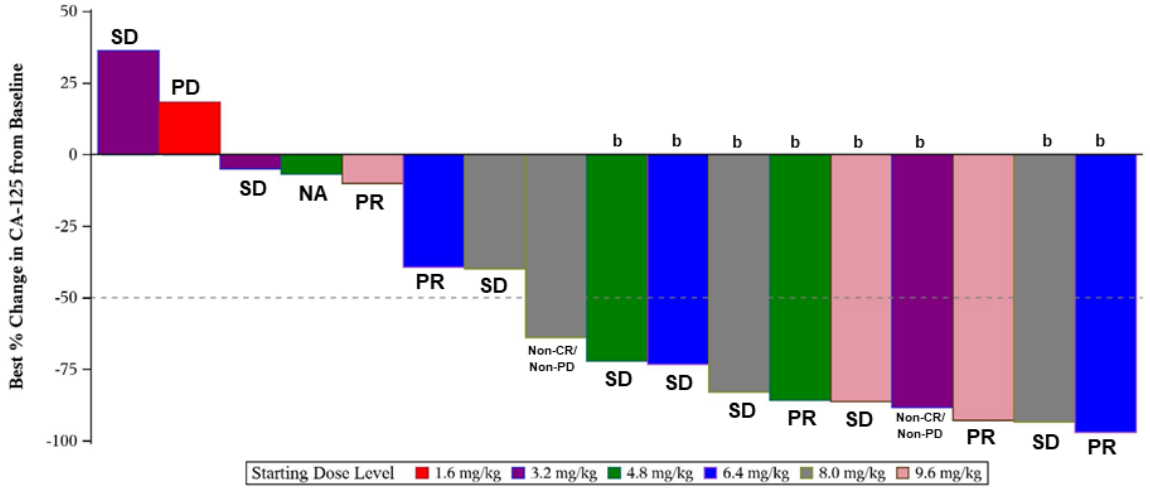
Demonstrated manageable safety and encouraging efficacy profile in heavily pre-treated patients with platinum-resistant OVC and RCC

Ph1 study dose-escalation part data (ASCO 2022)

Efficacy in OVC and RCC



Change from baseline in CA-125* levels (OVC)



Data cutoff: Feb 25, 2022

- Demonstrated early clinical signals in heavily pretreated patients with **advanced platinum-resistant OVC and RCC**
- The most common TEAEs were nausea, fatigue, vomiting, neutrophil count decrease, decreased appetite
- Recommended dose for expansion was declared 8.0 mg/kg

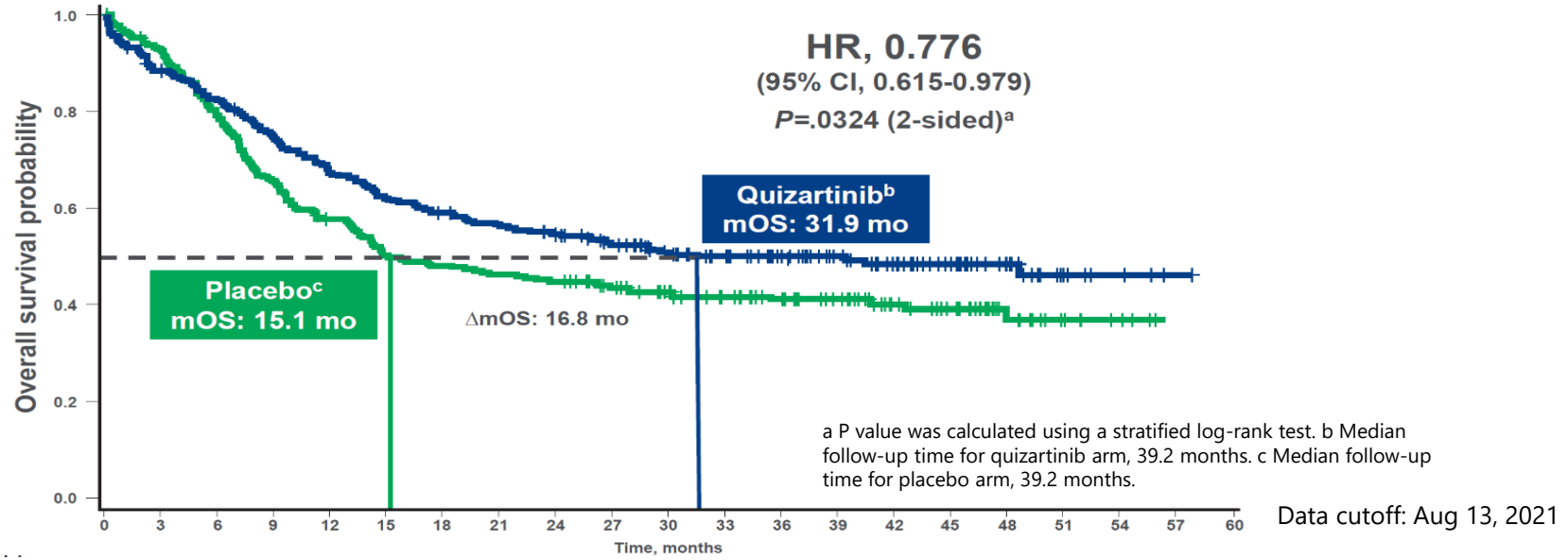
※ CA-125:): Protein which express on endometrium and peritoneum. CA-125 level in blood increases in patients with gynopathy such as ovarian cancer and uterine cancer

ASCO: American Society of Clinical Oncology, NA: not available, OVC: ovarian cancer, PD: progressive disease, PR: partial response, RCC: renal cell carcinoma, SD: stable disease, TEAEs: treatment emergent adverse events

New Therapies for Hematological Cancers: AML

Demonstrated statistically significant and clinically meaningful OS improvement in patients newly diagnosed FLT3-ITD(+) AML.

QuANTUM-First study primary end point: OS （ASH 2022）



a P value was calculated using a stratified log-rank test. b Median follow-up time for quizartinib arm, 39.2 months. c Median follow-up time for placebo arm, 39.2 months.

Data cutoff: Aug 13, 2021

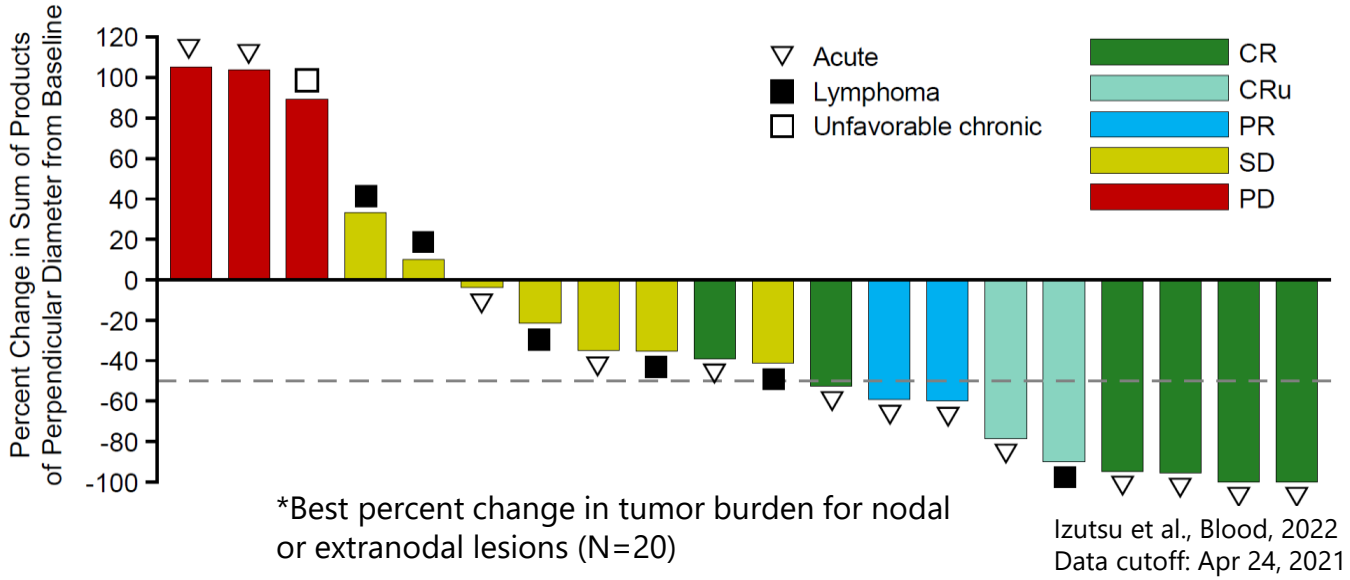
- **Demonstrated 31.9 months mOS** and **22.4% reduction in the risk of death**
- Observed low incidence of grade ≥3 QT prolongation which was manageable with dose modification or ECG monitoring
- The most common grade 3 or higher TEAEs occurring in ≥ 10% of patients were febrile neutropenia, neutropenia, hypokalemia and pneumonia. The incidence of TEAEs was almost the same between Quizartinib and placebo.
- Submitted NDAs/MAA in Japan, US and EU
- Discussion with FDA on REMS ongoing which **extended PDUFA date for 3 months** (new goal date: July 24th, 2023)

AML: acute myeloid leukemia, ASH: American Society of hematology, CI: confidence interval, HR: hazard ratio, MAA: market authorization application, mo: month, mOS: median overall survival, NDA: new drug application, OS: overall survival, PDUFA: Prescription Drug User Fee Act, REMS: risk evaluation and mitigation strategy, TEAEs: treatment emergent adverse events

New Therapies for Hematological Cancers: ATLL

Approved NDA for r/r ATLL treatment in Japan in Sep 2022

Efficacy in nodal and extranodal lesions in ATLL patients



*Best percent change in tumor burden for nodal or extranodal lesions (N=20)

Izutsu et al., Blood, 2022
Data cutoff: Apr 24, 2021

Development progress in major indications

Target indications	Therapy	Ph1	Ph2	Ph3	Filed	Launched
ATLL	Mono					
PTCL	Mono		*Pivotal Ph2*			
BCL	Mono					
Breast Cancer	Combo w/ ENHERTU®					

- Pivotal Ph2 study for r/r ATLL patient demonstrated **48% ORR** (CR: 20%, PR: 28%)
- The most common observed TEAEs were platelet count decrease, anemia, alopecia and dysgeusia. No new safety concerns were identified.
- **Global pivotal Ph2 study for r/r PTCL** patient is ongoing
- Ph1b study **combined with ENHERTU®** in patients with HER2 low or negative Metastatic BC is ongoing in collaboration with MDACC

ATL: adult T-cell leukemia-lymphoma, BC: breast cancer, BCL: B cell lymphoma, CR: complete response, CRu: unconfirmed complete response, MDACC: MD Anderson Cancer Center, NDA: new drug application, ORR: objective response rate, OS: overall survival, PD: progressive disease, PR: partial response, PTCL: peripheral T cell lymphoma, r/r: relapsed or refractory, SD: stable disease, TEAEs: treatment emergent adverse events

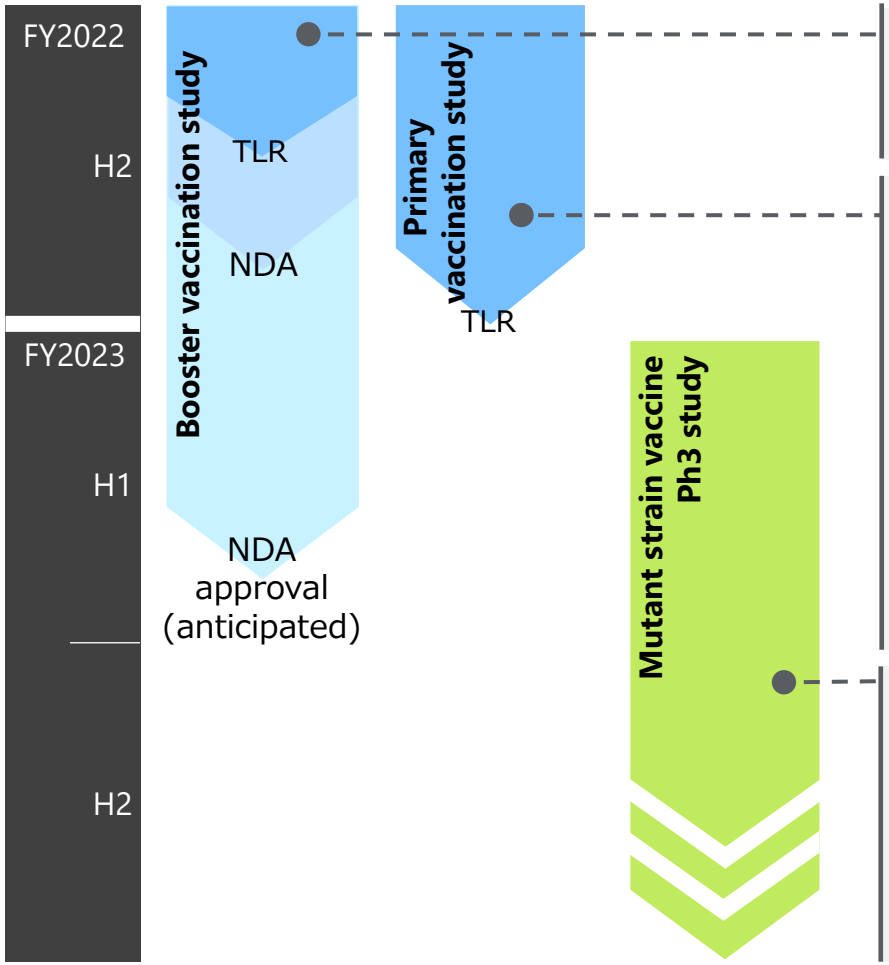
DS-5670

Current Development Status of COVID-19 mRNA vaccine

Daiichi-Sankyo

Regulatory submission for original strain booster vaccination in Japan was achieved in Jan 2023

Planning to develop mutant strain vaccine based on the incidence of Omicron variants



■ Development of booster vaccination (Original strain)

- Regulatory submission in Japan was achieved in Jan 2023

■ Development of primary vaccination (Original strain)

- **TLR obtained in Mar 2023**
  Confirmed an increase in neutralizing antibody titer in DS-5670a arm, but the data did not demonstrate non-inferiority of DS-5670a arm to control arm (Comirnaty®)
- **Planning to develop primary and booster vaccination with mutant strain vaccine**
- **Not submit regulatory filing for primary vaccination with original strain vaccine in adults**

■ Development of mutant strain vaccine

- Planning to start clinical studies one by one in FY2023 H1 for;
  - ✓ Ph3 booster vaccination study for 12 years old and elder
  - ✓ Ph2/3 booster vaccination study for 5-11 years old
  - ✓ Ph2/3 primary vaccination study for 5-11 years old

TLR: Top Line Results

Alpha

Other Progress in FY2022

Oncology

- **YESCARTA®** (axicabtagene ciloleucel)*1
  - Approved in Japan for relapsed/refractory large B-cell lymphoma (LBCL), 2L
- **DS-9606** (target undisclosed ADC)
  - Ph1 study for solid tumors started

Vaccines

- **FluMist®** (nasal splay influenza vaccine)
  - **Approved in Japan**
- **VN-0200** (RSV vaccine)
  - Ph2 study for healthy elderly started in Japan

Specialty Medicine

- **TARLIGE®** (mirogabalin, α2δ ligand)
  - Filing accepted in China for diabetic peripheral neuropathic pain (DPNP)
- **DS-1211** (TNAP inhibitor, Pseudoxanthoma elasticum (PXE))
  - Ph2 study for PXE patients started
- **DS-2325** (KLK5 inhibitor, Netherton syndrome)
  - Ph1 study started
  - Orphan Drug Designation and Fast Track Designation were granted by FDA
- **DS-5141** (Renadirsen Sodium, ENA-oligonucleotides, Duchenne muscular dystrophy(DMD))
  - Development discontinued*2

*1: In December 2022, Daiichi Sankyo, Kite Pharma, Inc. and Gilead Sciences K.K. agreed that manufacturing and marketing authorization rights in Japan for Yescarta held by Daiichi Sankyo shall be transferred to Gilead Sciences K.K. during 2023.
*2: Planning to continue the ongoing clinical trial for patients who are joining the trial and want to continue as DS-5141 showed certain level of efficacy

RSV: respiratory syncytial virus

Progress towards “Maximize 3ADCs”

Progress towards “Identify and build pillars for further growth”

ASCO 2023

News Flow

ASCO Highlights 2023: IR conference call

Sunao Manabe
Executive Chairperson
and CEO

Ken Takeshita
Head of Global R&D

Mark Rutstein
Head of Global
Oncology Development

Date and time	Jun 6, 2023 (Tue) 9:30-11:00am JST/ Jun 5, 2023 (Mon) 7:30-9:00pm CDT
Meeting style	Hybrid (Face to face meeting at the site and Zoom)

Content will be delivered on-demand after the meeting

Progress towards “Maximize 3ADCs”

Progress towards “Identify and build pillars for further growth”

ASCO 2023

News Flow

FY2023 News Flow

As of Apr 2023

Planned major publications

ASCO (Jun 2-6, 2023)

ENHERTU®	**DESTINY-CRC02: HER2+ CRC, Ph2, 3L** • **Primary analysis result**
	DESTINY-PanTumor02: HER2+ solid tumors, Ph2 • **Interim analysis results**
Dato-DXd	**TROPION-Lung02: NSCLC, 1L+, Ph1 dose expansion part** • **Data update**

Key data readouts

ENHERTU®	DESTINY-Breast06*: HR+ and HER2 low BC, chemo naïve, Ph3 • **FY2023 H1**
Dato-DXd	TROPION-Lung01*: NSCLC, 2/3L, Ph3 • FY2023 Q1
	TROPION-Breast01*: HR+ and HER2 low or negative BC, 2/3L, Ph3 • **FY2023 H1**
EZHARMIA®	**r/r PTCL, Registrational Ph2** • **FY2023 H1**

Regulatory decisions

ENHERTU®	**DESTINY-Breast04：HER2 low BC, post chemo, Ph3** • **China: FY2023 H1**
	DESTINY-Lung01, 02：HER2 mutant NSCLC, 2L+, Ph2 • JP: FY2023 H1 • EU: FY2023 H2
Quizartinib	QuANTUM-First: AML, 1L, Ph3 • JP, US: FY2023 H1 • EU: FY2023 H2

Planned pivotal study initiation

DS-5670	COVID-19 mRNA vaccines, mutant strain, booster vaccination, healthy adults, Ph3 • FY2023 H1

Bold: update from FY2022 Q3

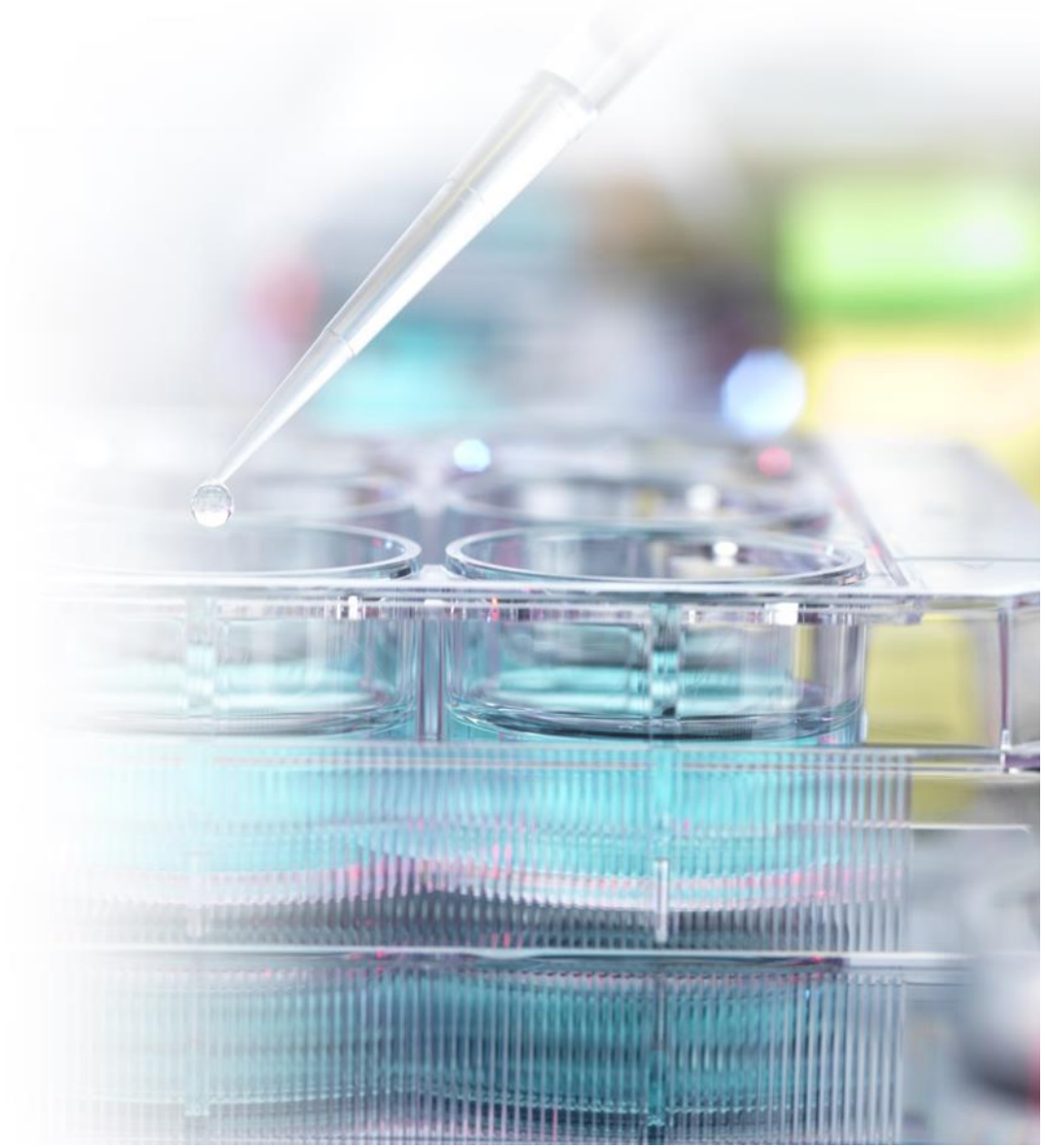
AML: acute myeloid leukemia, ASCO: American Society of Clinical Oncology, BC: breast cancer, CRC: colorectal cancer, NSCLC: non-small cell lung cancer, PTCL: peripheral T cell lymphoma, r/r: relapsed or refractory

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

*Event-driven study

Agenda

1. FY2022 Financial Results
2. Business Update
3. R&D Update
4. **5-Year Business Plan Update**
5. FY2023 Forecast
6. Appendix



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

Realize 2025 Vision 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-FY2022

Maximize 3ADCs

- **Maximize product value of ENHERTU®**
  - **Approval of new indication**
    - HER2+ BC 2L (DB-03)
      HER2 low BC post-chemo (DB-04)
      HER2 mutant NSCLC 2L+ (DL-01, DL-02)
  - **Sales growth in each country/ region**
    - Sales expansion exceeding initial plan based on the results of DB-03 and DB-04
  - **Progress of LCM**
    - 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**
  - **Progress of pivotal study for launch**
    - Dato-DXd：NSCLC 2L+ (TL-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)

Profit growth for current business and products

- **Growth of current products**
  - **Steady sales expansion of Lixiana®**
    - Increase product value with additional dosage and administration （Prevention for stroke and systemic embolism in elderly patients with non-valvular atrial fibrillation and high bleeding risk: ELDERCARE-AF study)
  - **Sales increase of current products in each countries/ regions**
    - Tarlige®, Injectafer®, 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®, Reyvow®, Ezharmia® etc.
  - **Progress of product divesture after loss of exclusivity in each country/region**

5-Year Business Plan: Progress in FY2021-FY2022

Identify and build pillars for further growth

- **Emerging candidates for new growth driver (Rising Stars) following 3ADCs**
  - **Progress of development for DS-7300 (B7-H3-direceted ADC)**
    - Obtained interim analysis data which showed early efficacy signals in multiple cancer types (SCLC, CRPC, ESCC, sqNSCLC)
    - Started new Ph2 study for ES-SCLC 2L+
  - **Progress of development for DS-6000 (CDH6-directed ADC)**
    - Obtained interim analysis data which showed early efficacy signals in multiple cancer types (OVC, RCC)
- **Advancement to select post DXd-ADC modalities**
  - **Started clinical study for the next generation ADC, DS-9606**

CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma,
ES-SCLC: extensive-stage small cell lung cancer, NSCLC: non-small cell lung cancer, OVC: ovarian cancer,
RCC: renal cell carcinoma, SCLC: small cell lung cancer, sqNSCLC: squamous non-small cell lung cancer,

Create shared value with stakeholders

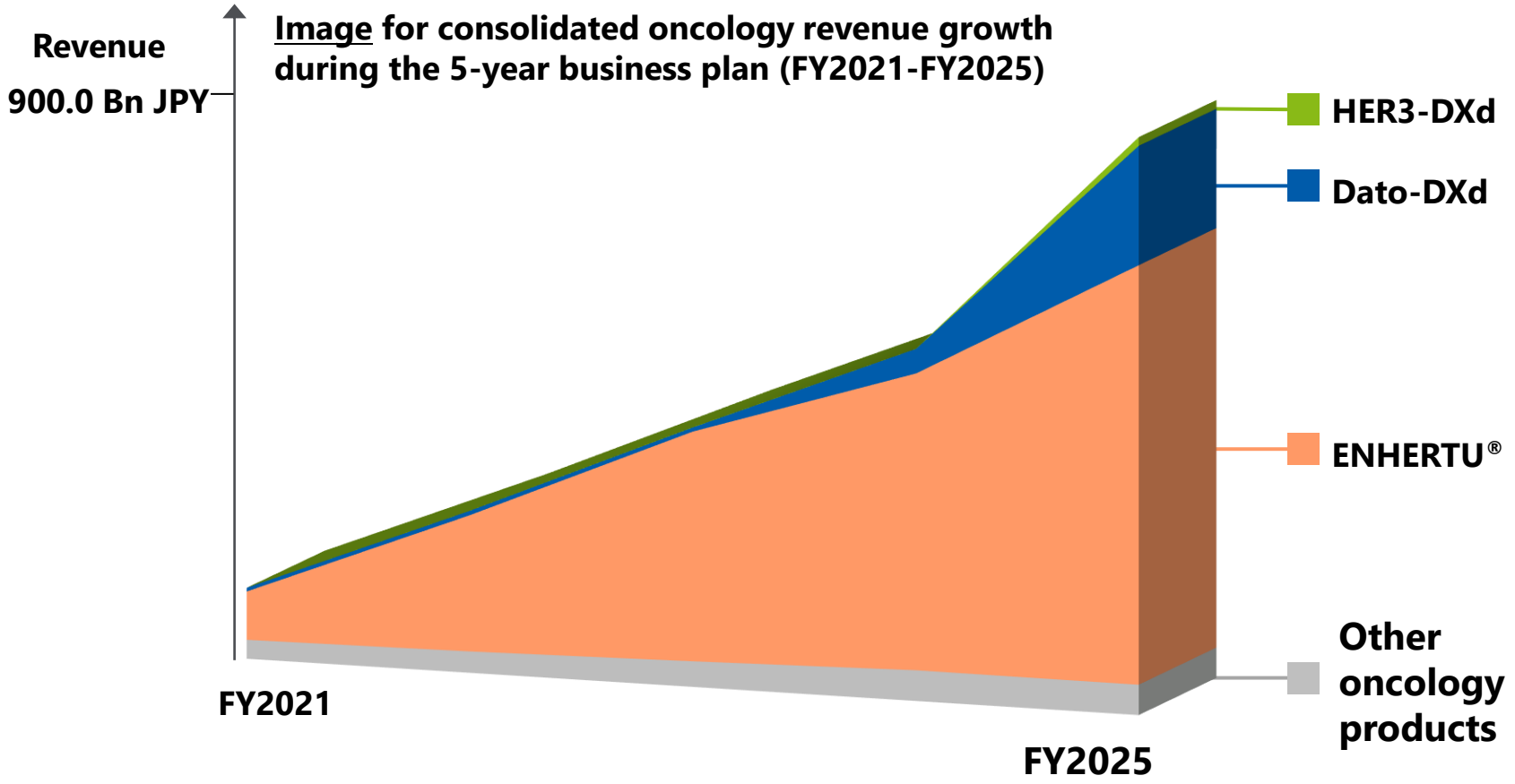
- **Strengthening shareholder returns**
  - **Increase dividend with profit growth**
    - Increase FY2022 annual dividend per share from 27 JPY to 30 JPY
- **Actions against pandemic risks**
  - **Regulatory submission for DS-5670 (COVID-19 mRNA vaccine)**
    - Regulatory submission for original strain 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**

Expectation on achieving FY2025 KPIs
(as of 2023 Apr.)

	At the time of planning 5YBP	As of 2023 Apr.
Revenue	1,600 Bn JPY	2.0 Tr JPY
Revenue in Oncology	> 600 Bn JPY	> 900 Bn JPY
Core Operating Profit ratio before R&D expense	40%	40%
ROE	> 16%	> 16%
DOE	> 8%	> 8%
Currency rate assumptions	1 USD=105 JPY, 1 EUR=120 JPY	1 USD=130 JPY, 1 EUR=140 JPY

Expectation on Oncology Revenue
（as of 2023 Apr.）

With the revenue growth of ENHERTU® and Dato-DXd, and progress of 3ADC development exceeding initial plan, oncology revenue* in FY2025 is estimated > 900.0 Bn JPY



Major factors increased from initial plan

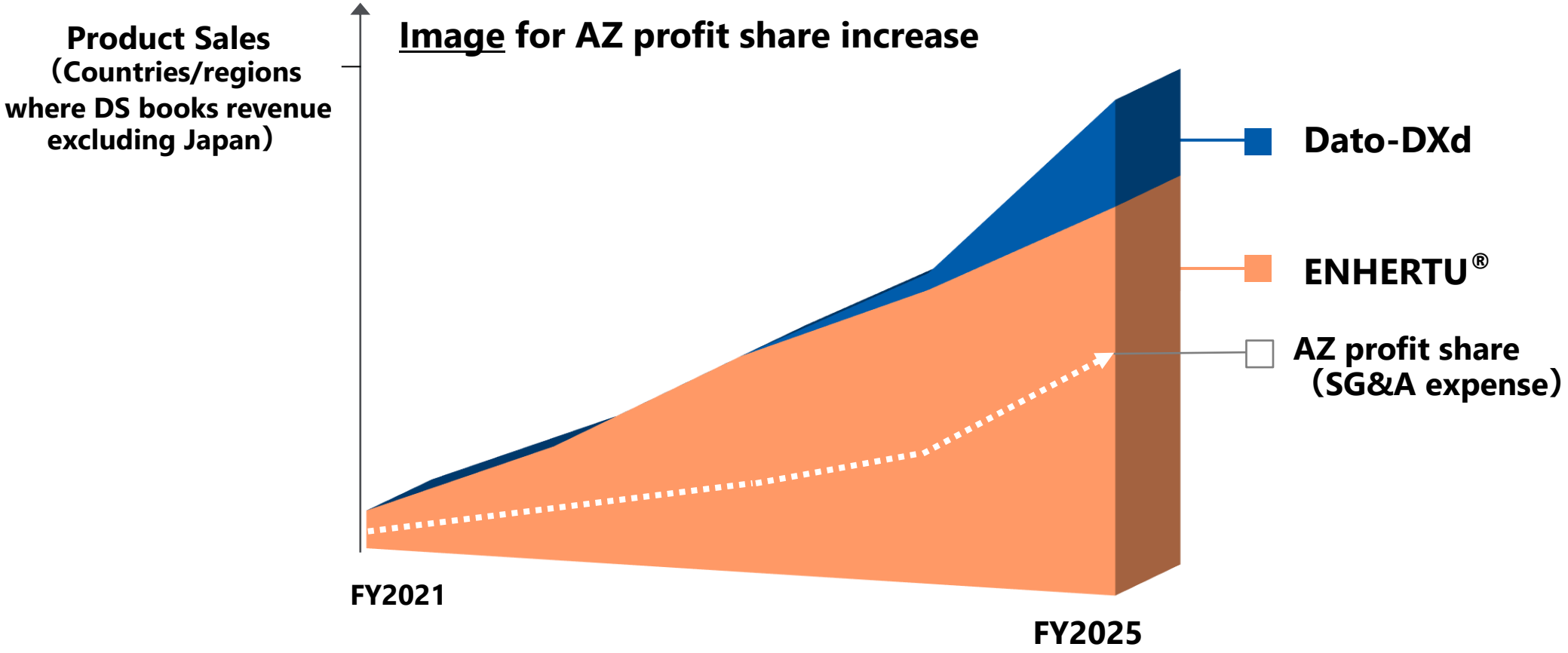
- ◆ **Sales expansion in NSCLC by expanding target patients at launch**
  - TL-01：NSCLC with/without actionable genomic alterations
- ◆ **Accelerated LCM driving sales expansion and increased development milestone revenue**
  - TL-08 etc.

- ◆ **Sales expansion in breast cancer based on the results of DB-03 and DB-04**
- ◆ **Accelerated LCM driving sales expansion and increased development milestone revenue**
  - DB-09 and DB-11 etc.
- ◆ **Sales milestone increase by product sales expansion exceeding initial plan**

*Revenue includes alliance revenue (50% of gross profit in countries/regions where AZ books revenue) upfront/Quid payment, development/sales milestones etc. for ENHERTU® and Dato-DXd

Profit Share Increase for ENHERTU® and Dato-DXd

Along with the growth of product sales of ENHERTU® and Dato-DXd, SG&A expenses increase with profit share* based on the strategic alliance with AZ



*For splitting profit of product sales, DS pays AZ 50% of gross profit in countries/regions where DS books revenue excluding Japan.

3ADC launch plan

Proactive investment in R&D, based on the exceeded progress in 3ADCs clinical development

~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-Gastric04
- DESTINY-Lung01/02
- DESTINY-Lung04
- DESTINY-CRC01/02

Dato-DXd

- TROPION-Lung01
- TROPION-Lung08
- TROPION-Breast01
- TROPION-Breast02

HER3-DXd

- HERTHENA-Lung01
- HERTHENA-Lung02

FY2026 & Beyond

ENHERTU®

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

Dato-DXd

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

HER3-DXd

- Combo with targeted therapy in NSCLC
- Other cancer types

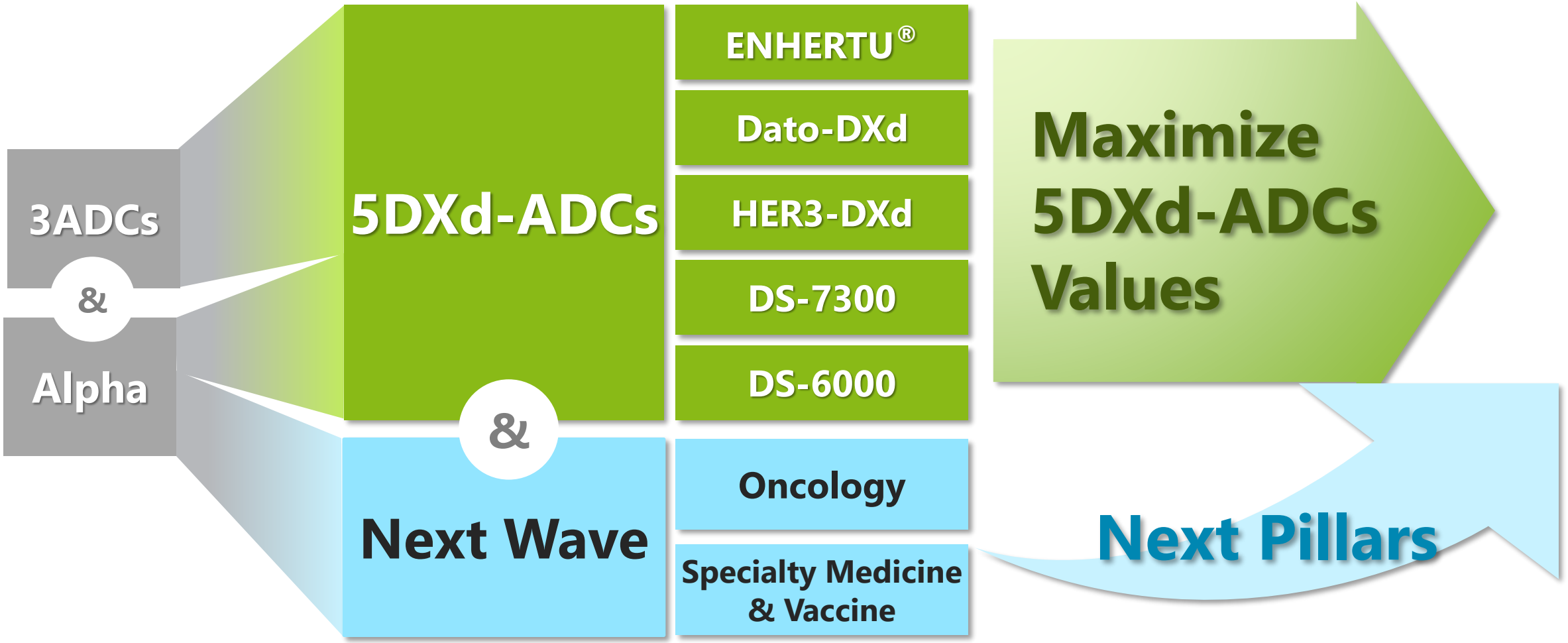
A study approved the indication during 5-Year Business Plan

A study accelerated to expect an approval during 5-Year Business Plan (including a new study)

Major study only (ref., appendices)

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

From “3 and Alpha” to “5DXd-ADCs and Next Wave”



Well-balanced Investment for Growth and Shareholder Returns
Cash Allocation

Increase R&D expense and CAPEX for further growth in future

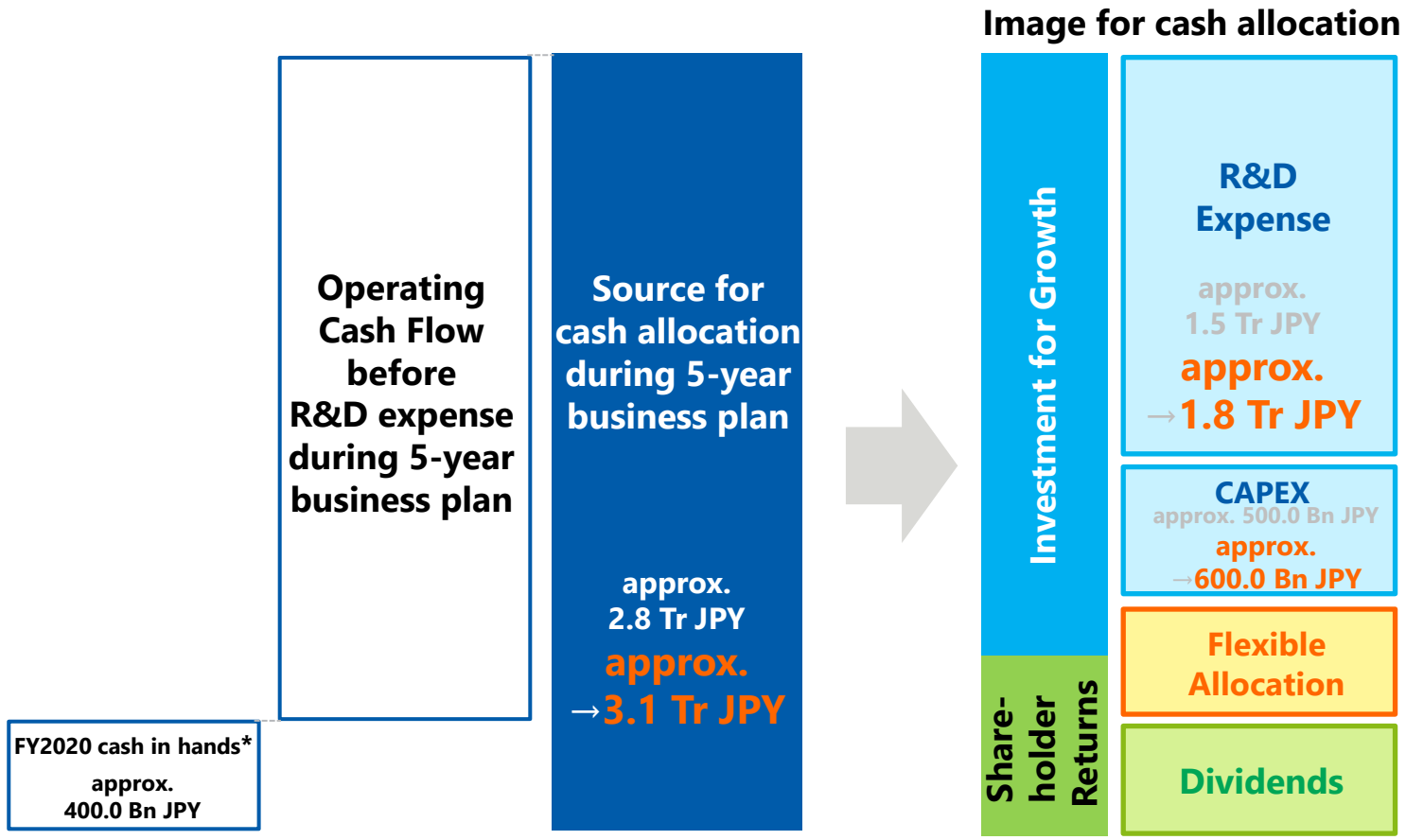


Image for cash allocation

Prioritized investment for DXd-ADC

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

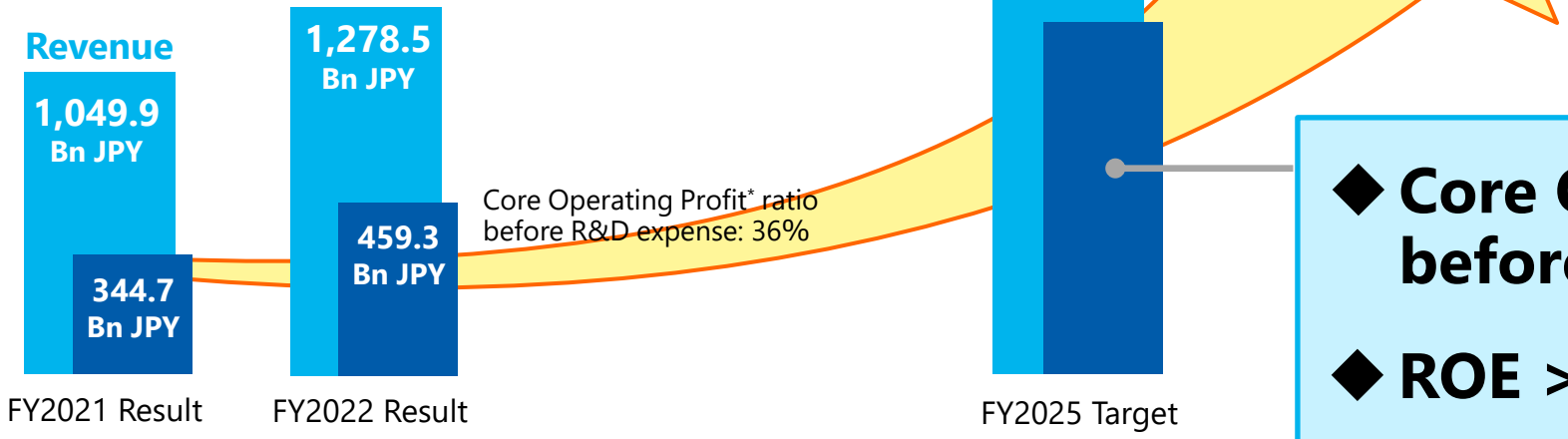
Stable dividends and dividend increase that take account of profit growth

*Cash in hands excluding working capital

Expectation on achieving FY2025 KPIs
(as of 2023 Apr.)

◆**Revenue**
2.0 Tr JPY
➢**Revenue in Oncology**
> 900.0 Bn JPY

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



Investment for DXd-ADC

Profit Growth

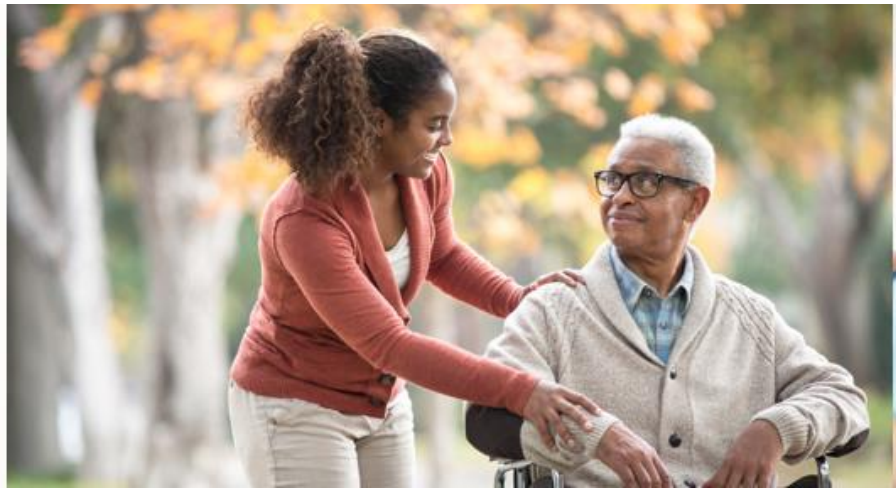
◆**Core Operating Profit* ratio before R&D expense: 40%**

◆**ROE > 16%**

◆**DOE > 8%**

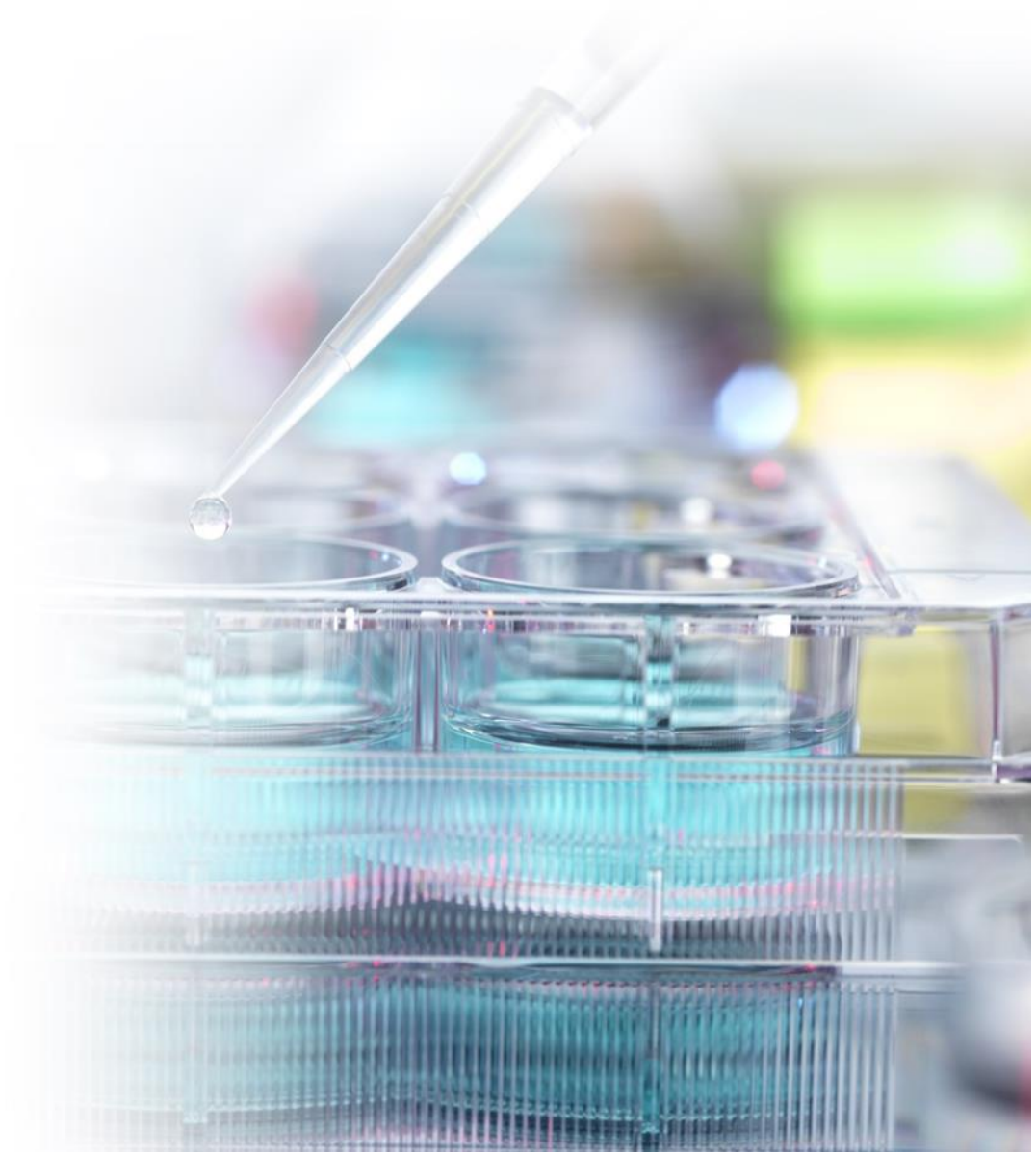
FY2025 Currency rate assumptions: 1 USD=**130 JPY**, 1 EUR=**140 JPY**
*Excluding temporary income and expenses (gains/losses related to sales of fixed assets etc.) from operating income

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



Agenda

1. FY2022 Financial Results
2. Business Update
3. R&D Update
4. 5-Year Business Plan Update
5. **FY2023 Forecast**
6. Appendix



FY2023 Forecast

(Bn JPY)

	FY2022 Results	FY2023 Forecast	vs. Forecast
Revenue	**1,278.5**	**1,450.0**	**+171.5**
Cost of sales *	349.1	400.0	+50.9
SG&A expenses *	470.1	550.0	+79.9
R&D expenses *	336.7	360.0	23.3
Core operating profit *	**122.6**	**140.0**	**+17.4**
Temporary income *	21.9	-	-21.9
Temporary expenses *	23.9	5.0	-18.9
Operating profit	**120.6**	**135.0**	**+14.4**
Profit before tax	**126.9**	**135.0**	**+8.1**
Profit attributable to owners of the Company	**109.2**	**115.0**	**+5.8**

Currency Rate	USD/JPY	135.48	130.00	-5.48
	EUR/JPY	140.97	140.00	-0.97

Revenue
Increase factor ↑ Sales expansion of main products (Enhertu, Lixiana, Tarlige, etc.)
Decrease Factor ↓ Drug price revision

Cost of sales
Increase in cost of sales due to revenue increase

SG&A expenses
Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca and others

R&D expenses
Increase in 5DXd-ADCs R&D investments and others

Temporary expenses
FY2022: Gains related to sales of fixed assets of Kyushu subsidiary
Losses rerated to impairment of Intangible assets of Turalio and others

Profit attributable to owners of the Company
FY2023 Tax Rate Forecast: 14.8% (Impact of Tax credit for R&D expenses and others)

* 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.

Increase Annual Dividend in FY2023

Increase annual dividend per share from 30 JPY (FY2022) to 34 JPY (FY2023)
taking account of increasing probability of achievement for FY2025 KPIs by sales expansion of Enhertu®

Annual dividend per share in FY2023: 34 JPY (interim dividend: 17 JPY, year-end dividend: 17 JPY)

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 by sales expansion of Enhertu®**
- **Flexible acquisition of own shares**

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

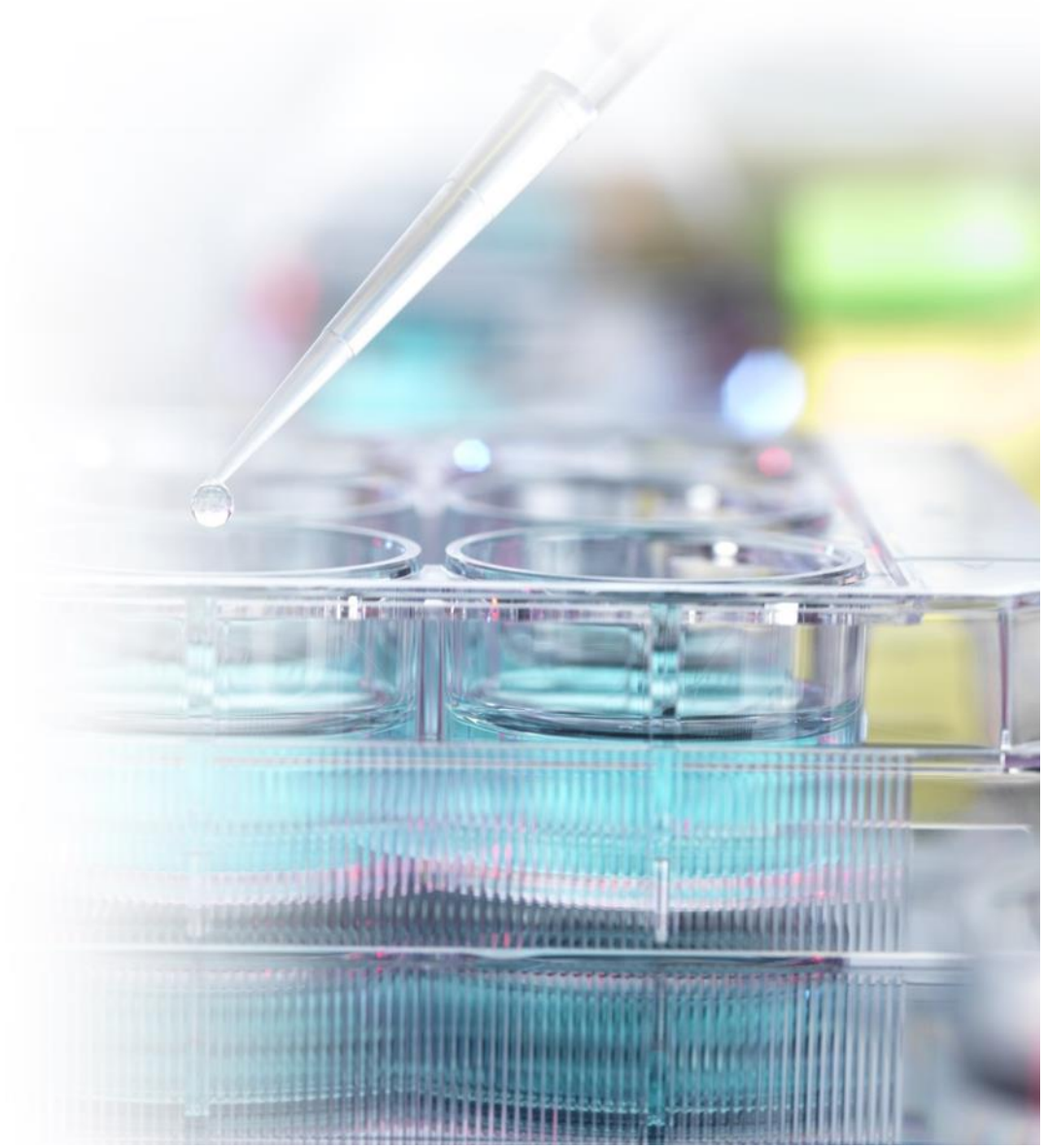
FY2025 Target: DOE > 8%

Maximize shareholder value

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

Agenda

1. FY2022 Financial Results
2. Business Update
3. R&D Update
4. 5-Year Business Plan Update
5. FY2023 Forecast
6. **Appendix**



Study list in 3ADC launch plan (slide #53)

ADC	Cancer type	Study name (ClinicalTrials.gov)	Brief note
ENHERTU®	Breast cancer	DESTINY-Breast01	HER2+ BC, previously treated w/ T-DM1
		DESTINY-Breast03	HER2+ BC, 2L, vs T-DM1
		DESTINY-Breast04	HER2 low BC, vs physician's choice
		DESTINY-Breast05	HER2+ BC, adjuvant following neoadjuvant therapy
		DESTINY-Breast06	HER2 low HR+ BC, chemo naïve, vs physician's choice chemotherapy
		DESTINY-Breast09	HER2+ 1L BC, vs T-DXd + Pertuzumab vs THP
		DESTINY-Breast11	HER2+ early-stage BC, neoadjuvant, vs T-DXd + THP vs AC+THP
	Gastric cancer	DESTINY-Gastric01	HER2 expressing GC, 3L+, vs physician's choice
		DESTINY-Gastric02	HER2+ GC, 2L
		DESTINY-Gastric04	HER2+ GC, 2L, vs SOC
	NSCLC	DESTINY-Lung01/02	HER2 over-expressing or mutant NSCLC, and HER2 mutant metastatic NSCLC 2L+, 2 doses (5.4, 6.4mg/kg)
		DESTINY-Lung04	HER2 mutant (Exon 19 or 20) NSCLC, 1L vs SOC
	Colorectal cancer	DESTINY-CRC01/02	HER2 expressing colorectal cancer, 3L, 2 doses (5.4, 6.4mg/kg)

Study list in 3ADC launch plan (slide #53)

ADC	Cancer type	Study name (ClinicalTrials.gov)	Brief note
Dato-DXd	NSCLC	TROPION-Lung01	NSCLC, 2L/3L, with/ without actionable gene alterations
		TROPION-Lung07	PD-L1 <50% non-squamous NSCLC w/o actionable genomic alterations, 1L, pembrolizumab combo vs ±pemetrexed/±platinum-based chemotherapy
		TROPION-Lung08	PD-L1 ≥50% NSCLC w/o actionable gene alterations,1L, Dato-DXd + pembrolizumab vs pembrolizumab alone
	Breast cancer	TROPION-Breast01	HR+, HER2 low or negative BC, 2/3L+, vs investigator's choice of chemotherapy
		TROPION-Breast02	Locally recurrent inoperable or metastatic TNBC 1L, vs investigator's choice of chemotherapy
		TROPION-Breast03	Residual invasive disease in the breast and/or axillary lymph nodes at surgical resection stage I-III TNBC following neoadjuvant, vs Dato-DXd + durvalumab vs investigator's choice of therapy
HER3-DXd	NSCLC	HERTHENA-Lung01	EGFR-mutated NSCLC, 3L
		HERTHENA-Lung02	EGFR-mutated NSCLC, 2L, vs platinum-based chemotherapy

Major R&D Milestones (3ADCs)

As of Apr 2023

Project		Target Indication [phase, study name]	FY2022 H2	FY2023 H1	FY2023 H2
ENHERTU®	BC	• HER2+, 2L [Ph3, DESTINY-Breast03]	**• Approved（China）**		
		• HER2 low, post chemo [Ph3, DESTINY-Breast04]	• Approval (EU) **• Approval（JP）**	**• Approval anticipated (China)**	
		• HER2 low, chemo naïve [Ph3, DESTINY-Breast06]		**• TLR anticipated**	
	NSCLC	• HER2 mutant, 2L [Ph2, DESTINY-Lung01, 02]	• Filing accepted (JP/EU)	• Approval anticipated (JP)	• Approval anticipated (EU)
Dato-DXd	NSCLC	• 2/3L [Ph3, TROPION-Lung01]		• TLR anticipated	
	BC	**• HR+ and HER2 low or negative BC, 2/3L [Ph3, TROPION-Breast01]**		**• TLR anticipated**	
HER3-DXd	NSCLC	• EGFR mutant, 3L [Registrational Ph2, HERTHENA-Lung01]	**• TLR obtained**		

Bold: update from FY2022 Q3 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 (Alpha)

As of Apr 2023

Project	Target Indication [phase, study name]	FY2022 H2	FY2023 H1	FY2023 H2
Quizartinib	• AML, 1L [Ph3, JP/US/EU/Asia]	• Filing accepted (US)	• Approval anticipated (JP, US)	• Approval anticipated (EU)
EZHARMIA®	**• r/r PTCL [Registrational Ph2, JP/US/EU/Asia]**		**• TLR anticipated**	
DS-1103	**• HER2+ solid tumors, HER2 low BC [Ph1, US]**		**• Study start anticipated**	
DS-5670	• COVID-19 mRNA vaccine (original strain), primary vaccination [Ph3, JP]	**• TLR obtained**		
	• COVID-19 mRNA vaccine (mutant strain), booster vaccination [Ph3, JP]		• Study start anticipated	
FluMist® (VN-0107)	• nasal spray live attenuated influenza vaccine [JP]	**• Approval (JP)**		

Bold: update from FY2022 Q3 PTCL: peripheral T cell lymphoma, PXE: pseudoxanthoma elasticum, r/r: relapsed/refractory, TLR: top line results

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

Major R&D Pipeline: 3ADCs

As of Apr 2023

Daiichi-Sankyo

Phase 1	Phase 2	Phase 3	Filed
(US/EU/Asia) HER2+ BC 2L+/1L DESTINY-Breast07	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) HER2+ BC adjuvant*2 DESTINY-Breast05	(CN) HER2 low BC post chemo DESTINY-Breast04
(US/EU/Asia) HER2 low BC Chemo naïve/ post chemo DESTINY-Breast08	(CN) HER2+ GC 3L DESTINY-Gastric06	(JP/US/EU/Asia) HER2 low BC chemo naïve DESTINY-Breast06	(JP/EU) HER2 mutant NSCLC 2L+ DESTINY-Lung01/Lung02
(JP/US/EU/Asia) HER2+ GC combo, 2L+/1L DESTINY-Gastric03	(CN) HER2 mutant NSCLC 2L+ DESTINY-Lung05	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09	
(EU/Asia) HER2+ NSCLC (durvalumab combo) 1L DESTINY-Lung03	(US/EU/Asia) NSCLC (durvalumab combo) 2L+ HUDSON	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11	
(US/EU) BC, bladder (nivolumab combo)	(JP/US/EU) HER2+ CRC 3L DESTINY-CRC01	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	
(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US/EU/Asia) HER2+ CRC 3L DESTINY-CRC02	(JP/US/EU/Asia) NSCLC (w/ HER2 exon 19 or exon 20 mutation) 1L DESTINY-Lung04	
(US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(JP/US/EU/Asia) HER2 mutant tumor DESTINY-PanTumor01	(JP/US/EU/Asia) NSCLC 2/3L TROPION-Lung01	
	(US/EU/Asia) HER2 expressing tumor DESTINY-PanTumor02	(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*1 2/3L TROPION-Breast01	
		(JP/US/EU/Asia) TNBC 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	

Phase 1	Phase 2	Phase 3	Filed
(JP/US) solid tumors TROPION-PanTumor01	(JP/US/EU/Asia) solid tumors TROPION-PanTumor03		
(CN) NSCLC, TNBC TROPION-PanTumor02	(JP/US/EU/Asia) NSCLC (w/ AGA) TROPION-Lung05		
(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) TROPION-Lung02	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA		
(JP/US/EU) NSCLC (w/o AGA, durvalumab combo) TROPION-Lung04	(JP/US/EU/Asia) EGFR mutated NSCLC (osimertinib combo) 2L ORCHARD		
(JP/US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(US/EU/Asia) recectable early-stage NSCLC (durvalumab combo) neoadjuvant NeoCOAST-2		
(JP/US/EU/Asia) NSCLC	(JP/US/EU/Asia) EGFR mutated NSCLC 3L HERTHENA-Lung01		
(JP/US) EGFR mutated NSCLC (osimertinib combo)			
(JP/US) HER3+ BC			

ENHERTU®

Dato-DXd

HER3-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 (JP)

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

AGA: actionable genomic alterations, BC: breast cancer, CRC: colorectal cancer,
GC: gastric cancer, NSCLC: non-small cell lung cancer, TNBC: triple negative breast cancer

Major R&D Pipeline: Alpha

As of Apr 2023

Daiichi-Sankyo

Phase 1	Phase 2	Phase 3	Filed
DS-7300 (JP/US) B7-H3-directed ADC ESCC, CRPC, squamous NSCLC, SCLC, etc.	Valemetostat (DS-3201)(JP/US/EU/Asia) EZH1/2 inhibitor PTCL	Pexidartinib (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	Quizartinib (JP/US/EU) FLT3 inhibitor AML 1L
DS-6000 (JP/US) CDH6-directed ADC Renal cell carcinoma, ovarian cancer	Valemetostat (DS-3201) (EU) EZH1/2 inhibitor BCL	Esaxerenone (JP) MR blocker Diabetic nephropathy	Mirogabalin (CN) α2δ ligands Diabetic peripheral neuropathic pain
DS-1055 (JP/US) Anti-GARP antibody 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 (original strain) COVID-19 (booster vaccination)
DS-1594 (US) Menin-MLL binding inhibitor AML, ALL	DS-7300 (JP/US/EU/Asia) B7-H3-directed ADC ES-SCLC	DS-5670 (JP) COVID-19 mRNA vaccine (original strain), COVID-19 (primary vaccination, 12 to 17 aged children)	
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, adults) (in prep.)	
DS-1103 Anti-SIRPα antibody HER2 expressing or mutant advanced metastatic solid tumors, HER2 low BC (in prep.)	DS-5670 (JP) COVID-19 mRNA vaccine, COVID-19 (primary vaccination, 5 to 11 aged children) (in prep.)		
DS-7011 (US) Anti-TLR7 antibody Systemic lupus erythematosus	VN-0200 (JP) RS virus vaccine RS virus infection		
DS-2325 (US) 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)

Fast Track Designation (US)

Breakthrough Designation (US)

ALL: acute lymphoblastic leukemia, AML: acute myeloid leukemia, BCL: B cell lymphoma, CRPC: castration-resistant prostate cancer, DMD: Duchenne muscular dystrophy, ESCC: esophageal squamous cell carcinoma, FOP: Fibrodysplasia ossificans progressiva, LBCL: large B cell lymphoma, NSCLC: non small cell lung cancer, ES-SCLC: extensive stage-small cell lung cancer, PTCL: peripheral T-cell lymphoma

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