

Passion for Innovation.
Compassion for Patients.™



FY2022 Financial Results Presentation

DAIICHI SANKYO CO., LTD.

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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	USD/JPY	112.38	135.48	+23.10
Rate	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".

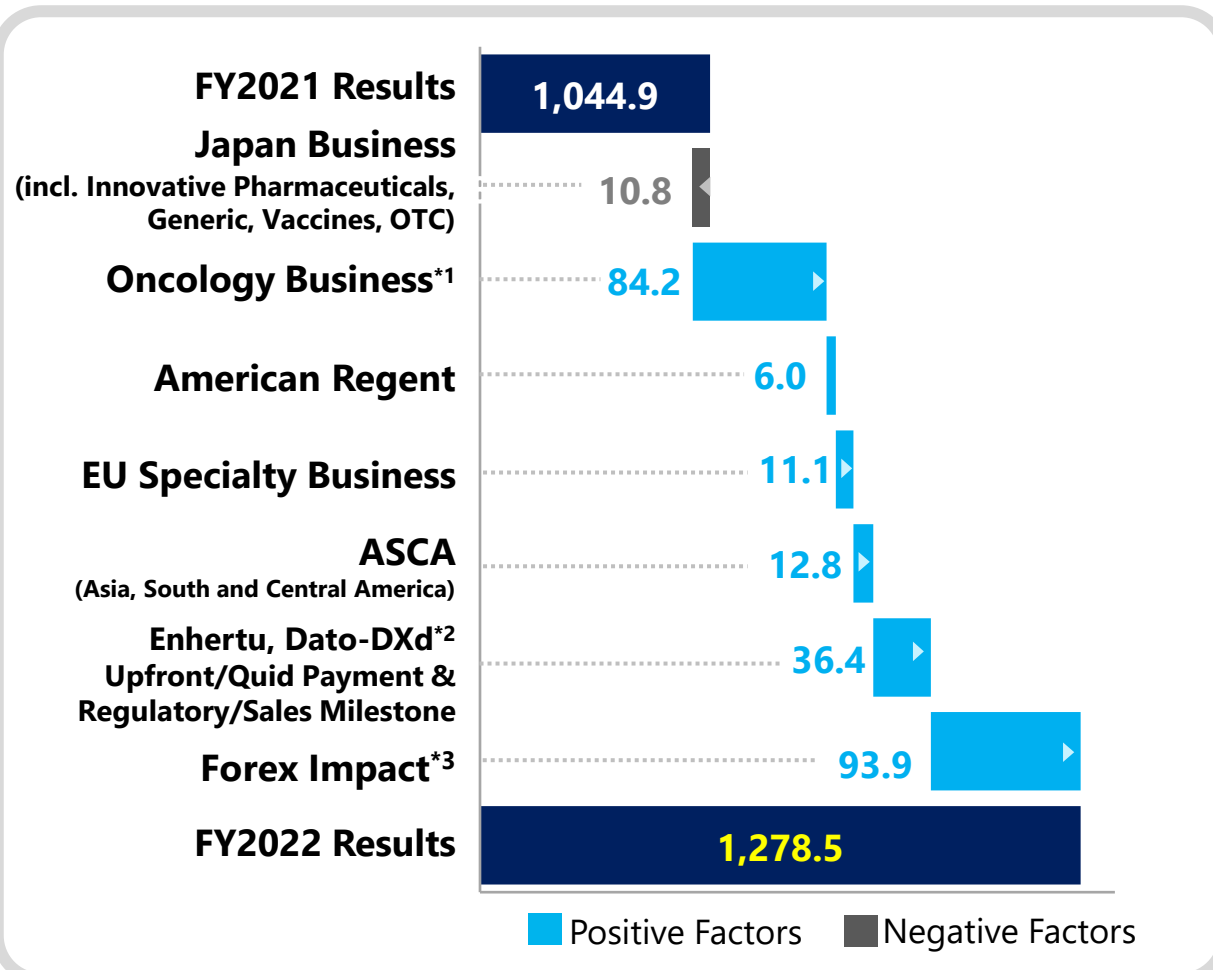
Temporary income and expenses are excluded from results and forecast for cost of sales, SG&A expenses and R&D expenses shown in the list above.

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		

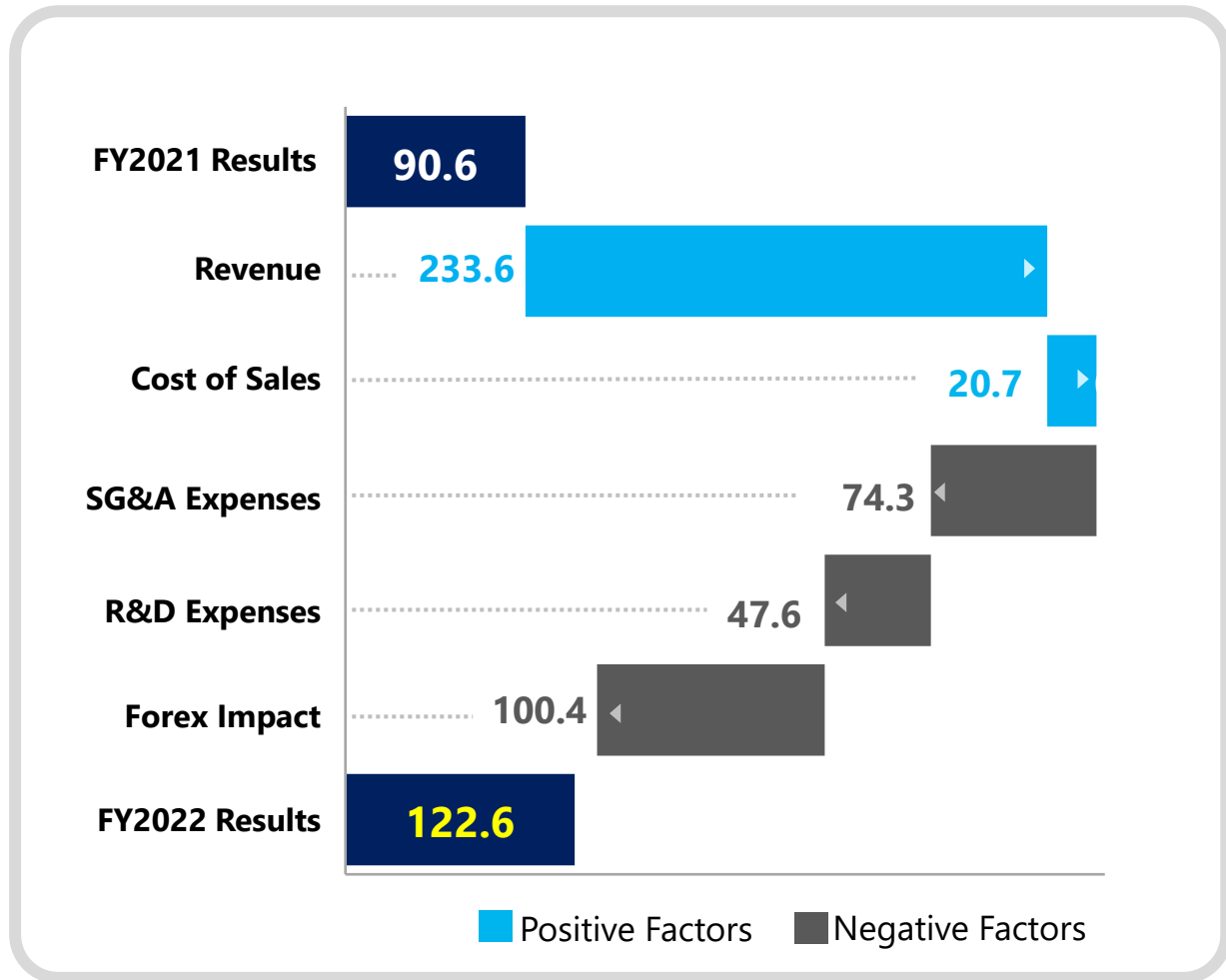
*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products

*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

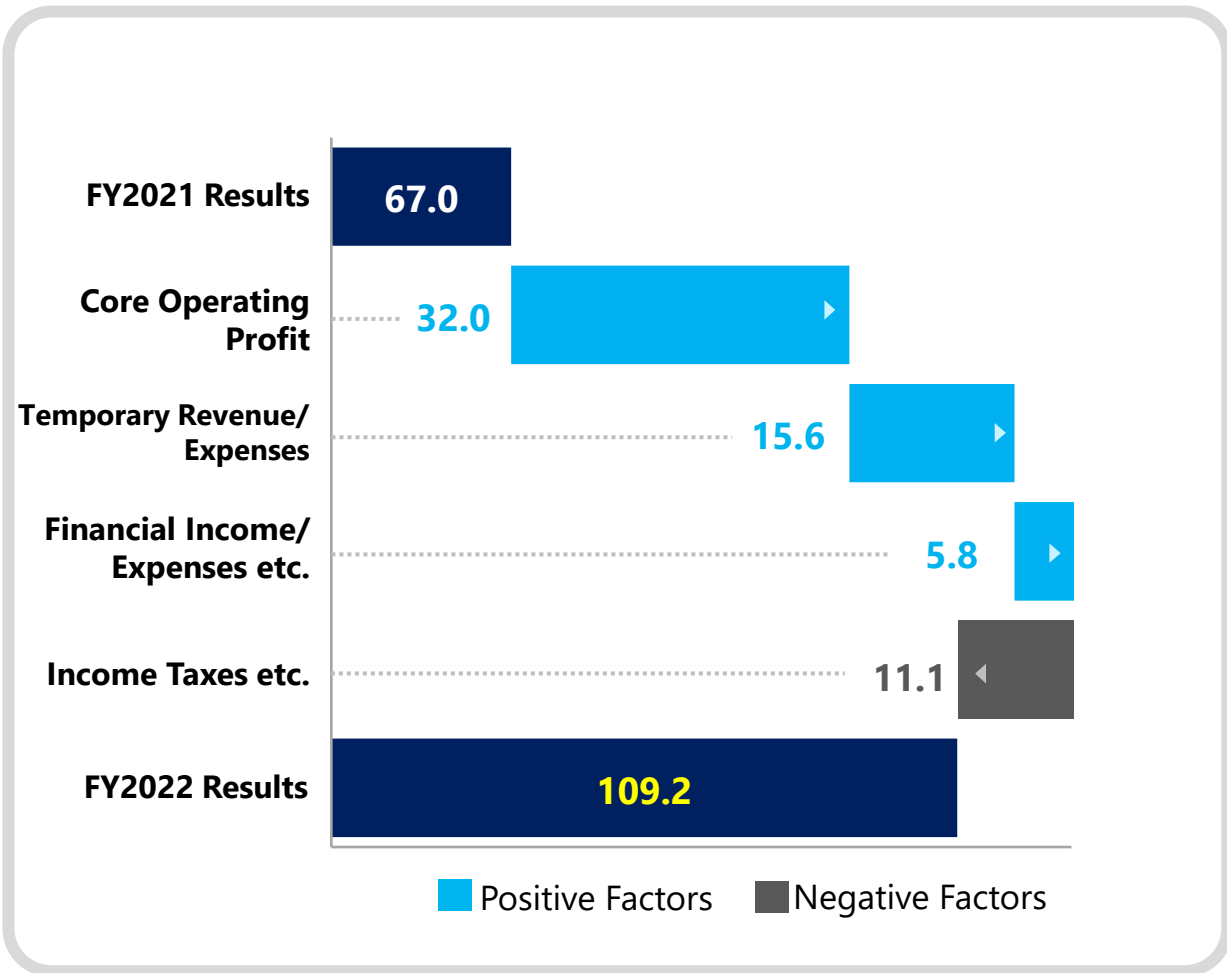
R&D Expenses +35.0

* 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	
Oncology 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	USD/JPY	112.38	135.48	+23.10
Rate	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”

(Bn JPY)

	FY2022 Results		FY2023 Forecast		<Reference> Total Consideration
		YoY		YoY	
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	8.3 ^{*1}	-18.4	126.6
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	365.3	107.0	332.0

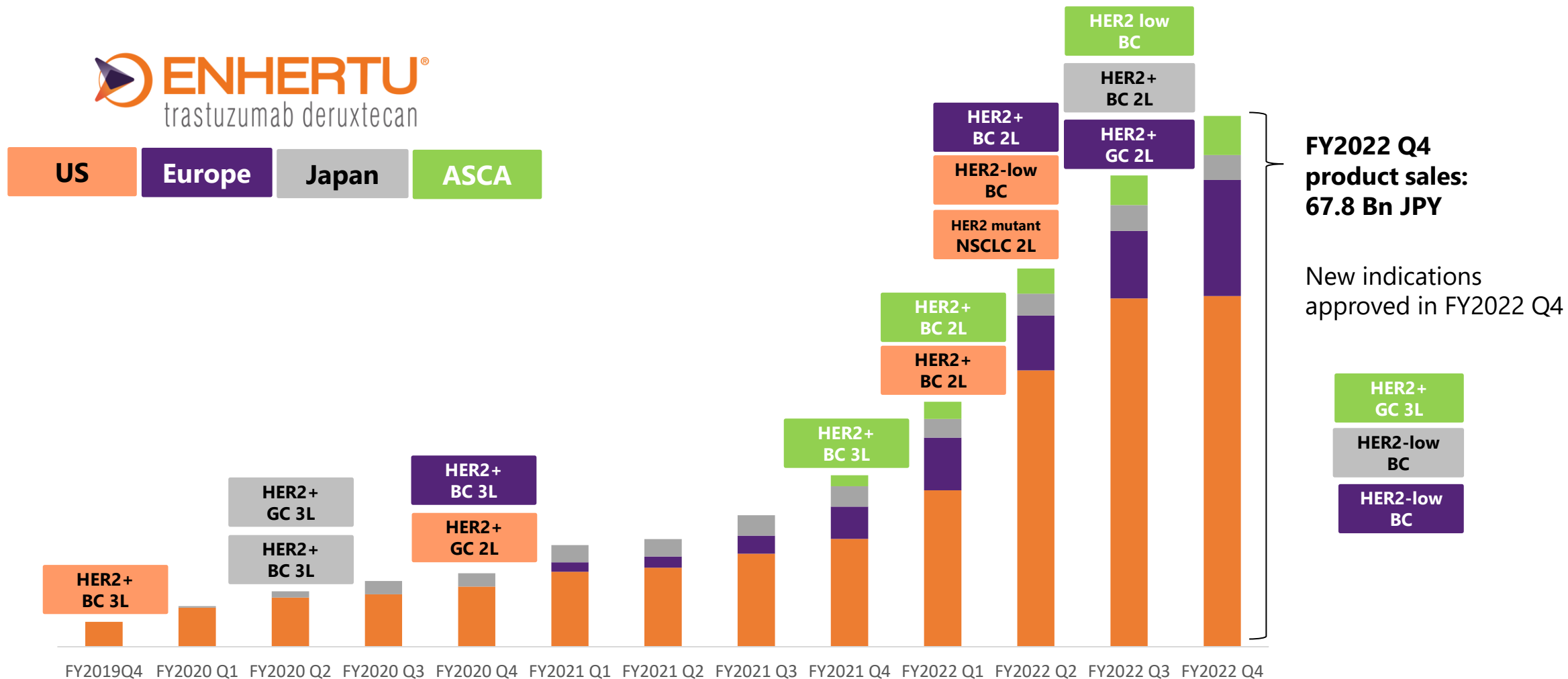
*1 Revenue recognized in each period

*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 AstraZeneca. (Total revenue expected to be recognized in FY2023)

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

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



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

Blue letters: updates from Q3

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)

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



Progress towards “Maximize 3ADCs”

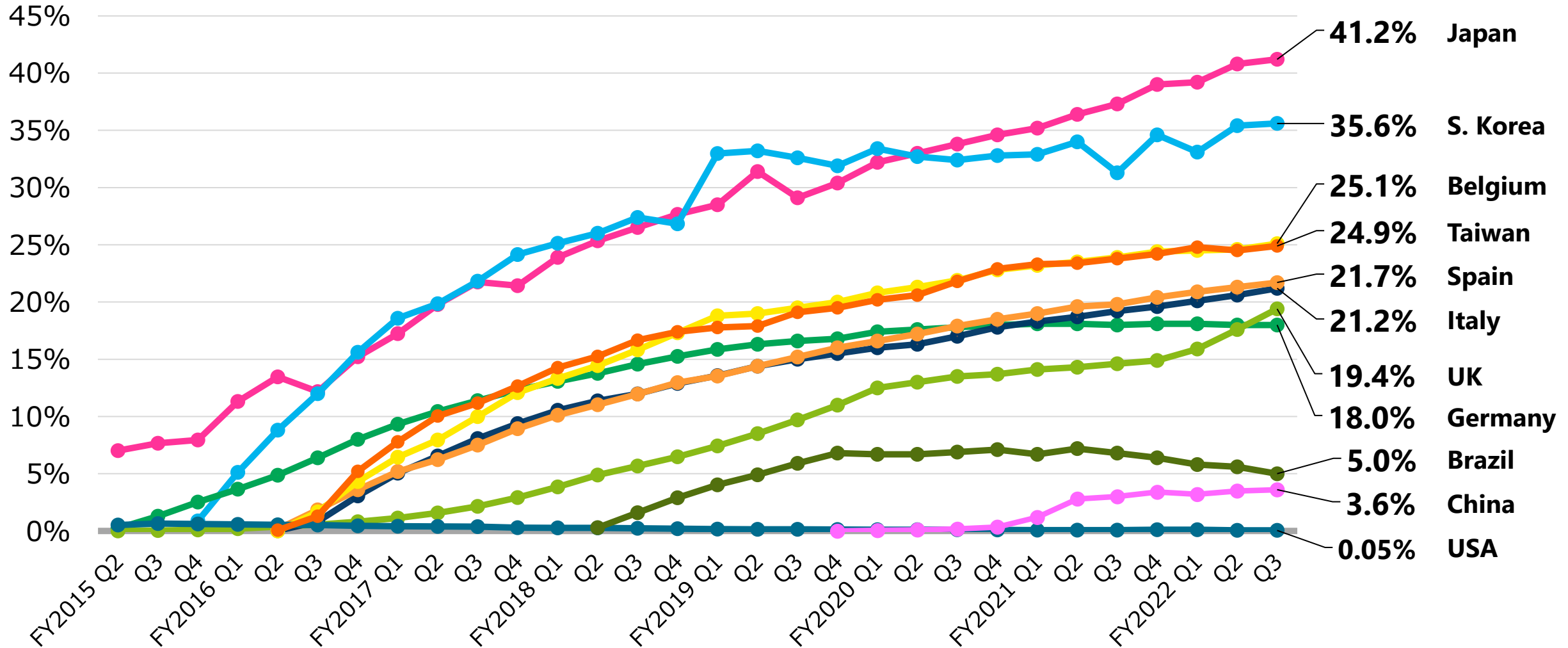
Progress towards “Profit growth for current business and products”

Progress towards “Create shared value with stakeholders”

LIXIANA[®]: Growth in Each Country/Region



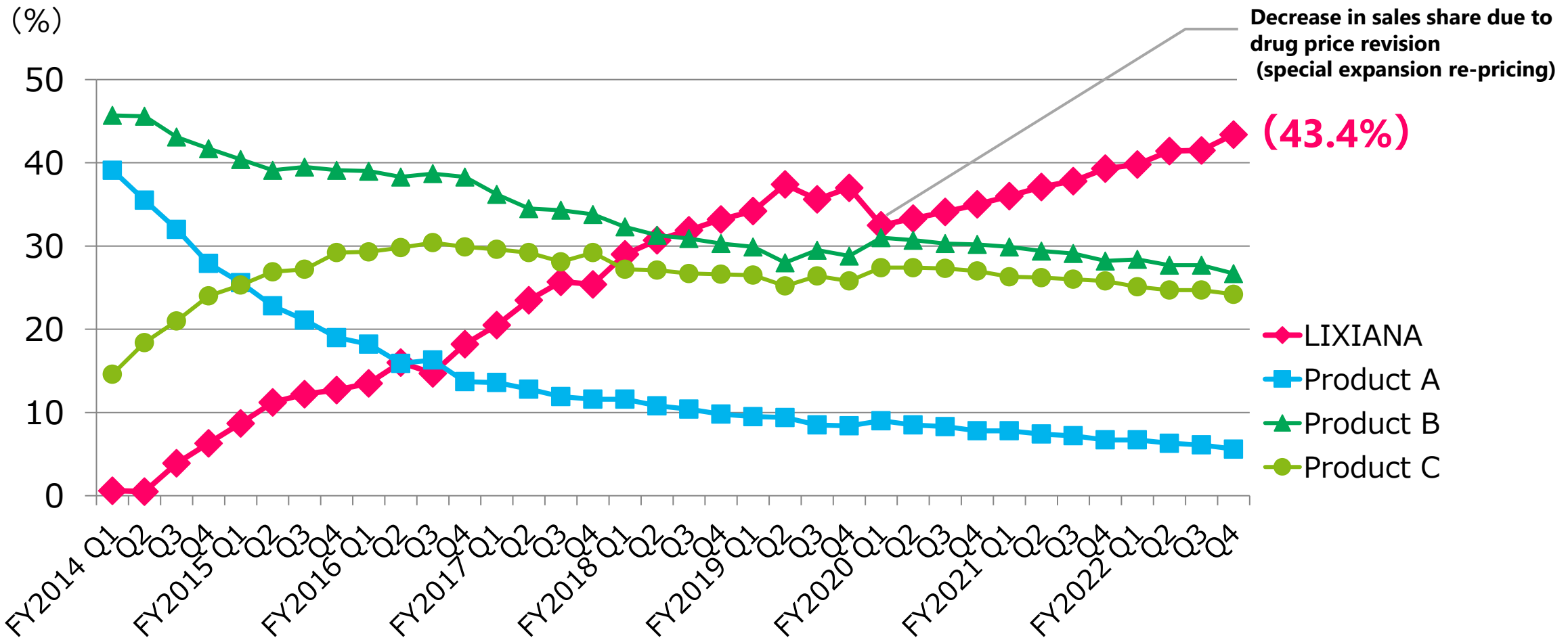
Global revenue FY2022 results: **244.0 Bn JPY (YoY +38.3 Bn JPY)**
 FY2023 forecast: **259.4 Bn JPY (YoY +15.4 Bn JPY)**



LIXIANA®: Growth in Japan



◆ 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.>

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”

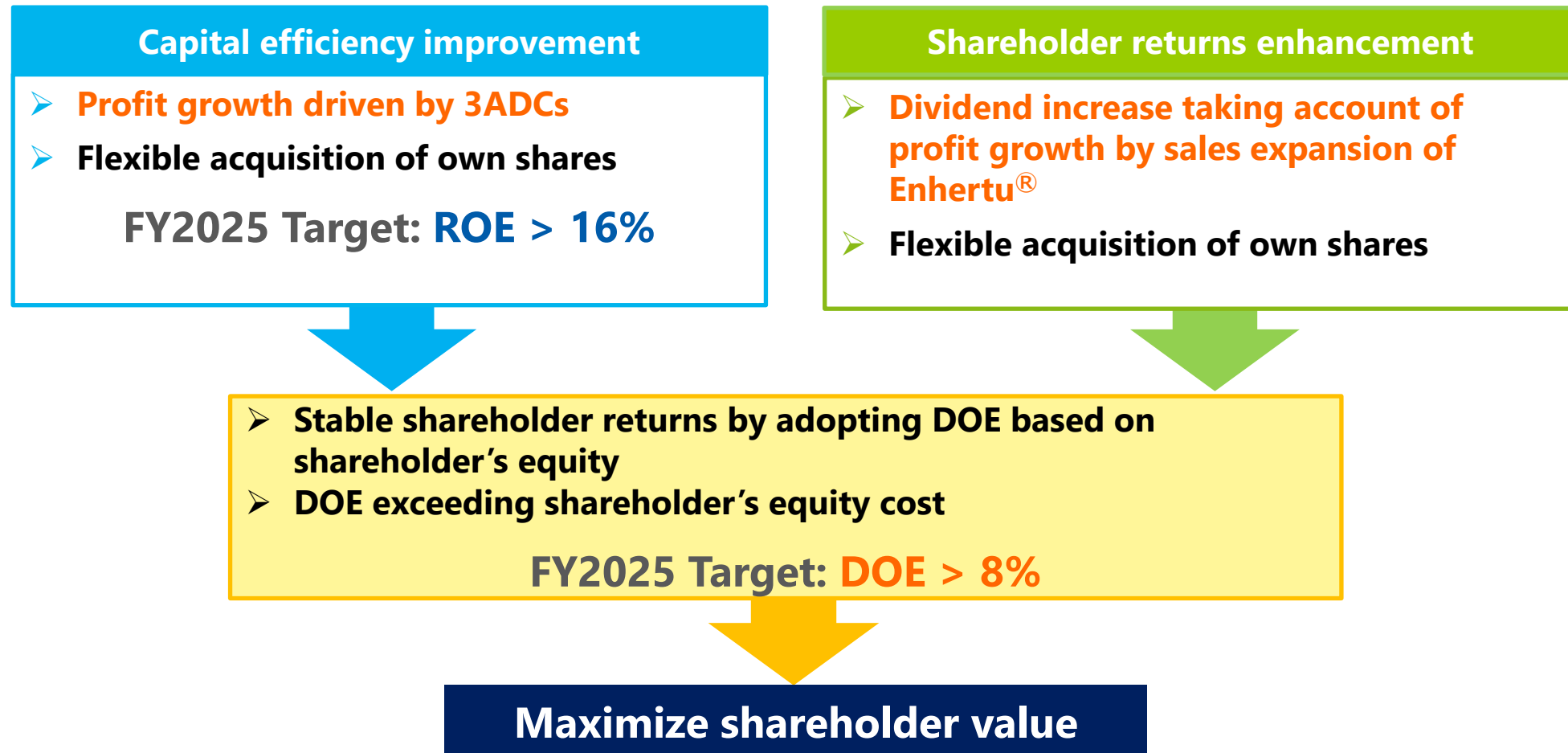
Progress towards “Profit growth for current business and products”

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)



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

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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

Progress towards “Maximize 3ADCs”

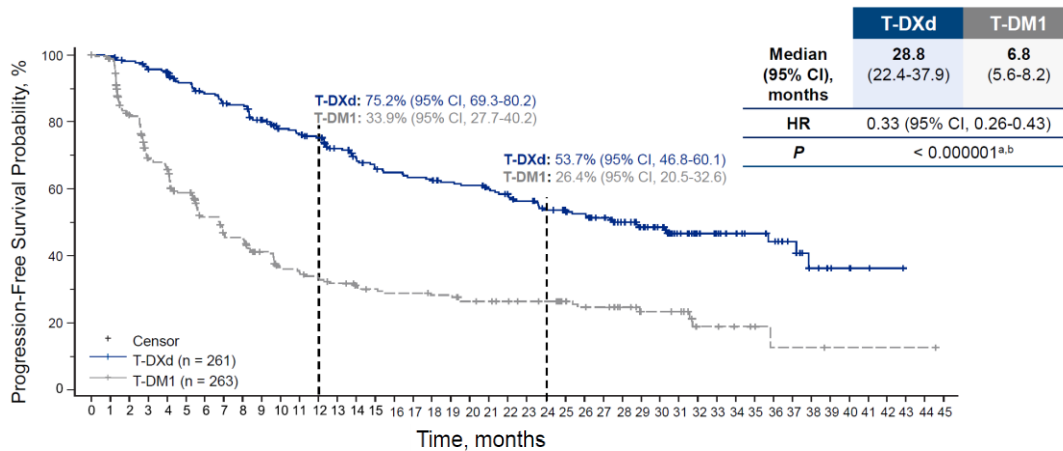
Progress towards “Identify and build pillars for further growth”

ASCO 2023

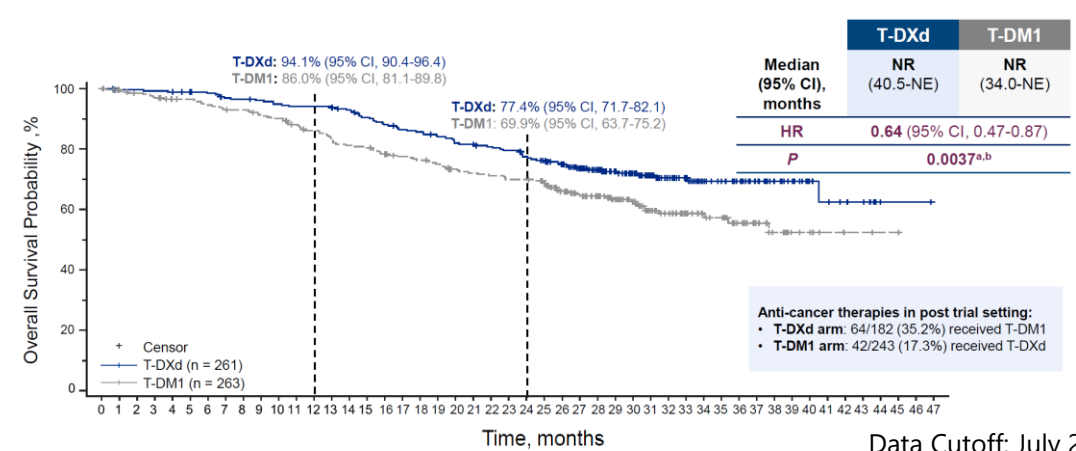
News Flow

Established position as 2L SOC for HER2 positive BC

PFS in HER2+ BC



OS in HER2+ BC



Data Cutoff: July 25, 2022

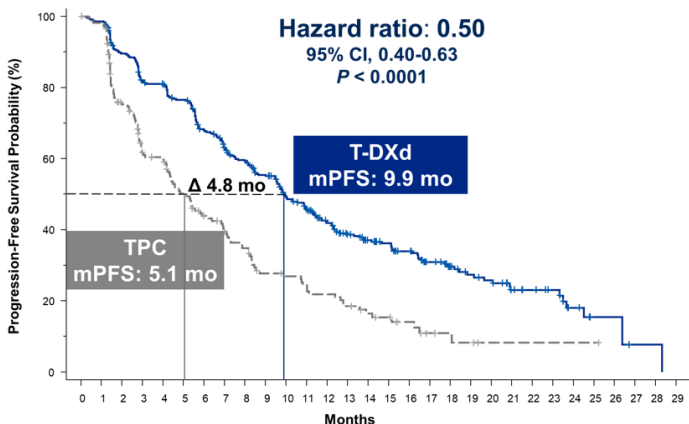
- ENHERTU® reduced the risk of death by 36% (HR: 0.64)
- mPFS with ENHERTU® was 4 times longer than with T-DM1 (28.8 months vs. 6.8 months)
- ORR was 78.5%; 1 in 5 (21%) patients experienced CR
- The incidence of TEAEs was almost the same between ENHERTU® and T-DM1 (56.4% vs. 51.7%)
- The most common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

Regulatory Progress: HER2+ BC, 2L

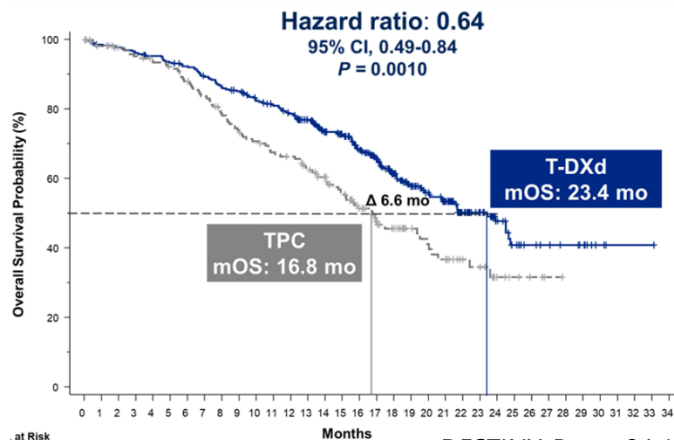
- May 2022: Approval in US
- Jul 2022: Approval in EU
- Nov 2022: Approval in Japan
- Feb 2023: Approval in China (First approval in China for ENHERTU®)

Provide patients with new treatment options based on clinical trial results

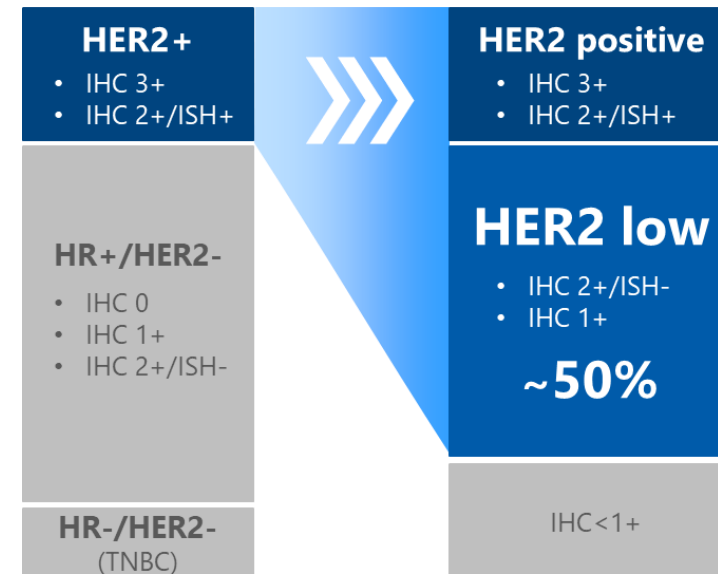
PFS in all patients with HR+ or HR- and HER2 low BC



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



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



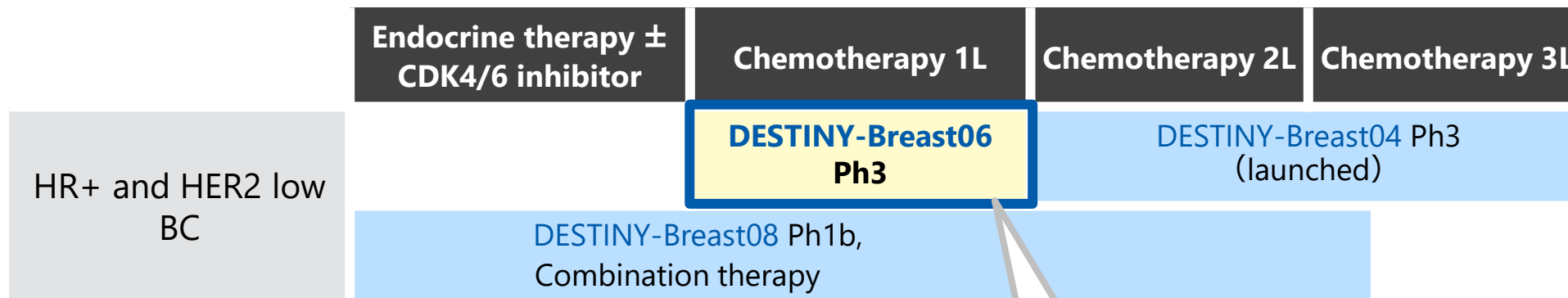
- **50% reduction in the risk of disease progression or death** versus chemo, mPFS of **9.9 months** compared to 5.1 months with chemo
- **36% reduction in the risk of death** versus chemo, mOS of **23.4 months** compared to 16.8 months with chemo
- The most common TEAEs for ENHERTU® in this study were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

Regulatory Progress:

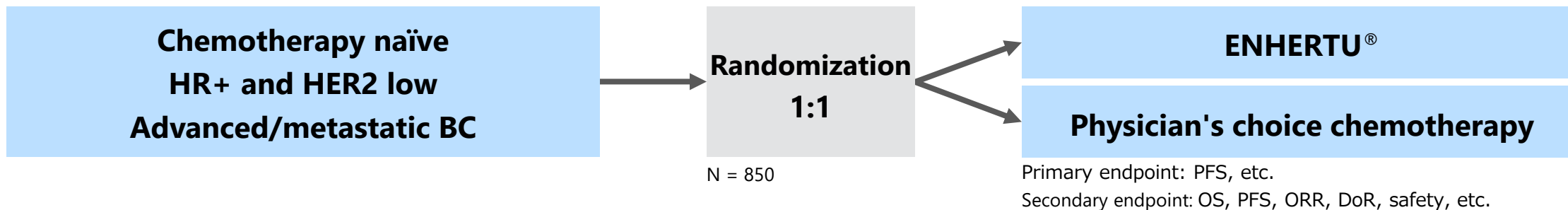
HER2 low breast cancer, post-chemo

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

Further development towards earlier lines of therapy for HER2 low BC



DESTINY-Breast06 Ph3 study design



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

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)

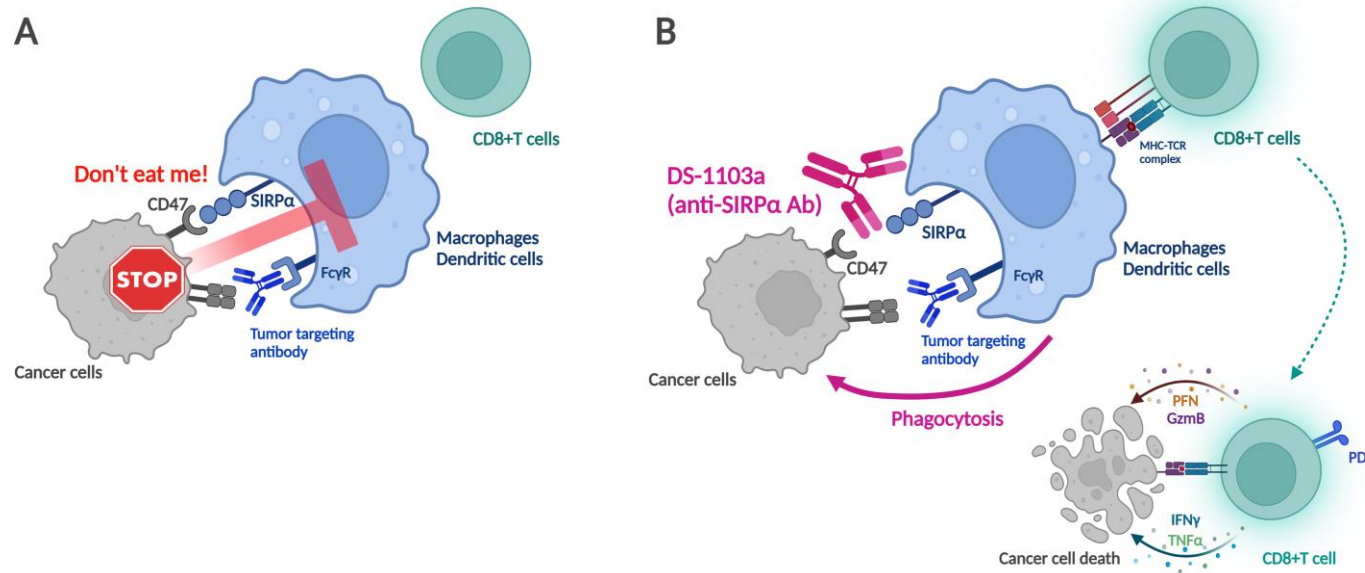


- Jan 2023: TLR obtained
- **Publication at ASCO 2023**

HER2 expressing **solid tumors** (DESTINY-PanTumor02 Ph2 study)

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

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



- DS-1103 is designed to block “Don’t eat me” signal through SIRPα-CD47 axis by combining SIRPα on macrophages and dendritic 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

Created with BioRender.com.

Ph1 study design

Dose escalation part

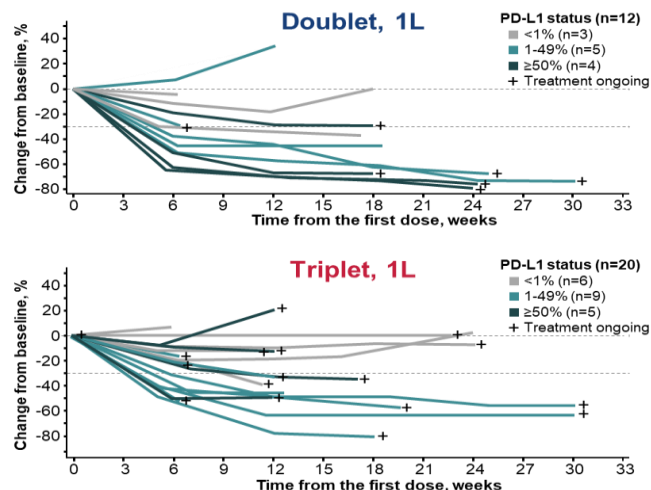
DS-1103 + ENHERTU® (5.4 mg/kg Q3W)
HER2-expressing or HER2-mutant advanced metastatic solid tumors

Dose expansion part

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

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

Ph3 Clinical Studies of Dato-DXd for NSCLC

Advanced/Metastatic

1L

2L

3L

TROPION-Lung07
(PD-L1 <50%)
Started in Jan 2023

TROPION-Lung01
(includes NSCLC with AGA)

NSCLC without AGA

TROPION-Lung08
(PD-L1 ≥ 50%)
Started Mar 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

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

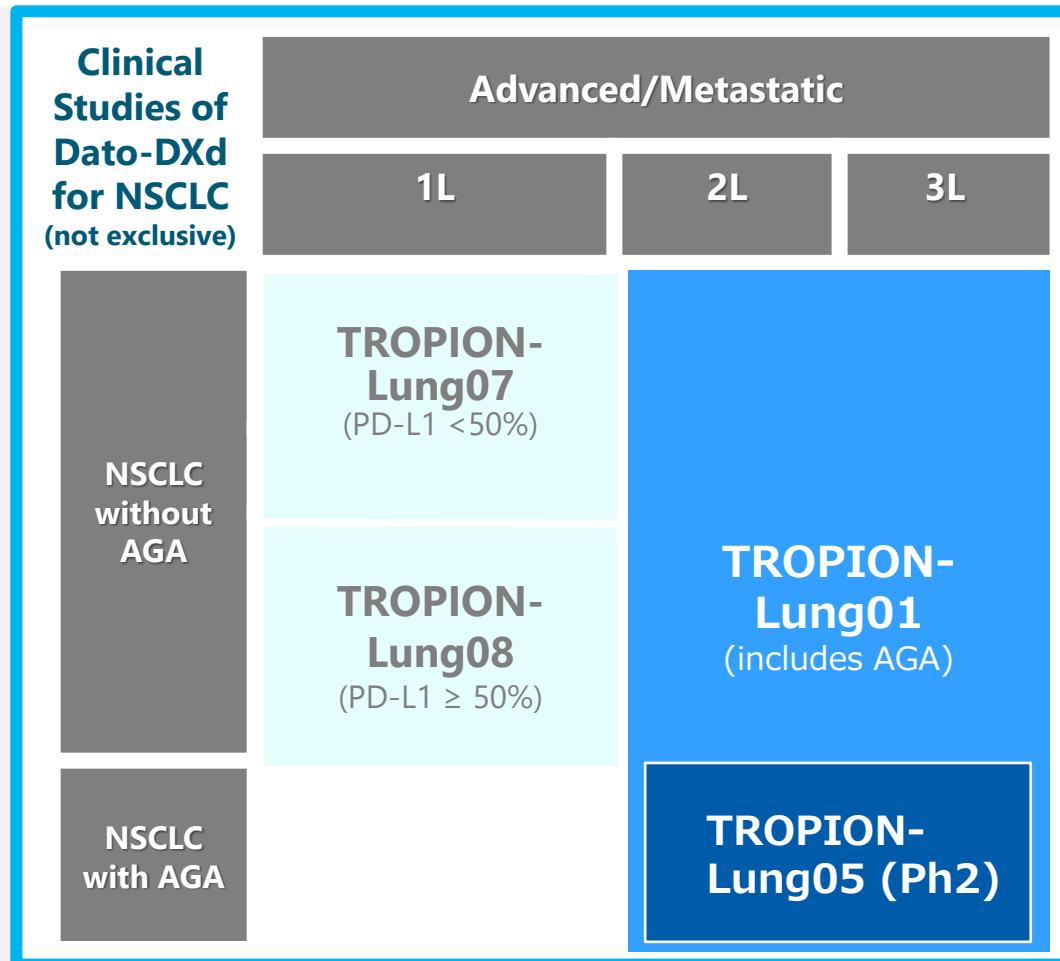
TROPION-Lung05 Study

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



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

		Neoadjuvant/ Adjuvant		1L	2L	3L
HER2+		DESTINY -Breast11	DESTINY -Breast05	DESTINY -Breast09	DESTINY-Breast02/03 (HER2+)	
HR+	HER2 low	DESTINY -Breast06 (Post ET, chemo naïve)			ENHERTU® DESTINY-Breast04 (HER2-low)	
	HER2 IHC >0<1+				TROPION-Breast01	
	HER2 IHC 0				Dato-DXd	
TNBC		TROPION -Breast03		TROPION -Breast02	DESTINY -Breast04 (HER2-low)	

- **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

HERTHENA-Lung01 Ph2 Study Design

Patients with metastatic or locally advanced NSCLC with an EGFR activating mutation who progressed on or after at least 1 EGFR TKI and 1 platinum-based chemotherapy-containing regimen

R
1:1

HER3-DXd
5.6 mg/kg, Q3W

HER3-DXd
Up-titration[※]

※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**

Progress towards “Maximize 3ADCs”

Progress towards “Identify and build pillars for further growth”

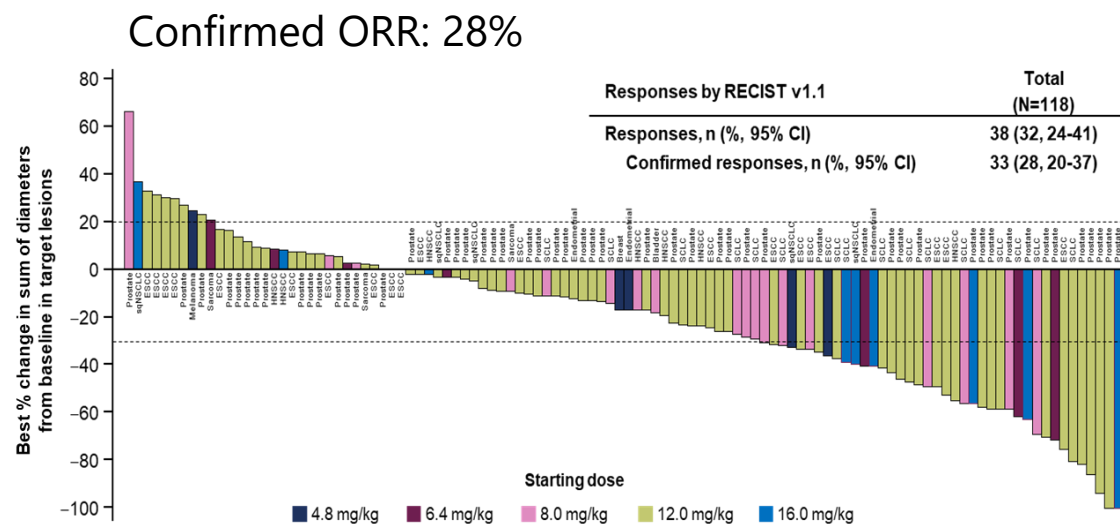
ASCO 2023

News Flow

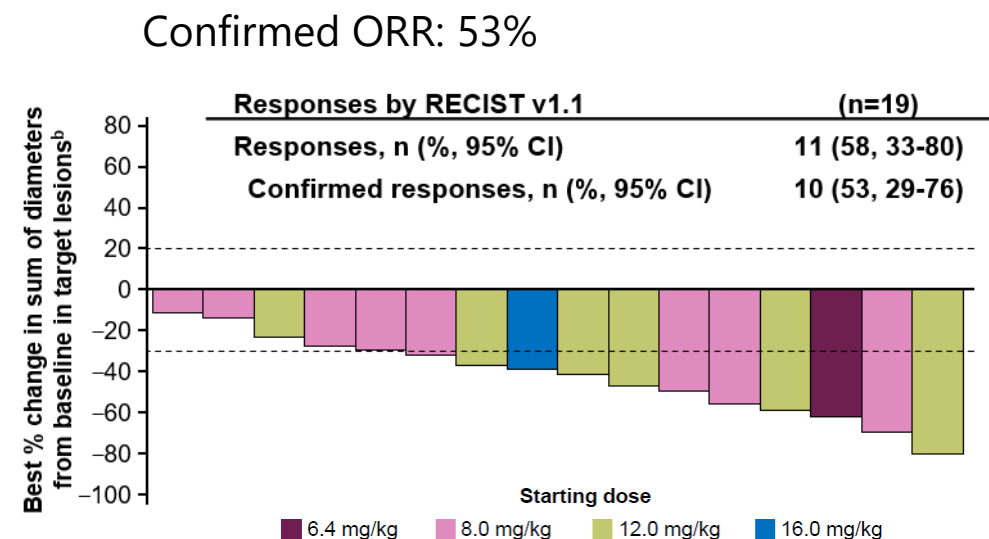
Dose-optimization Ph2 study for patients with SCLC has started in June

Ph1/2 study data (ESMO 2022)

Efficacy across tumor types



Efficacy in SCLC



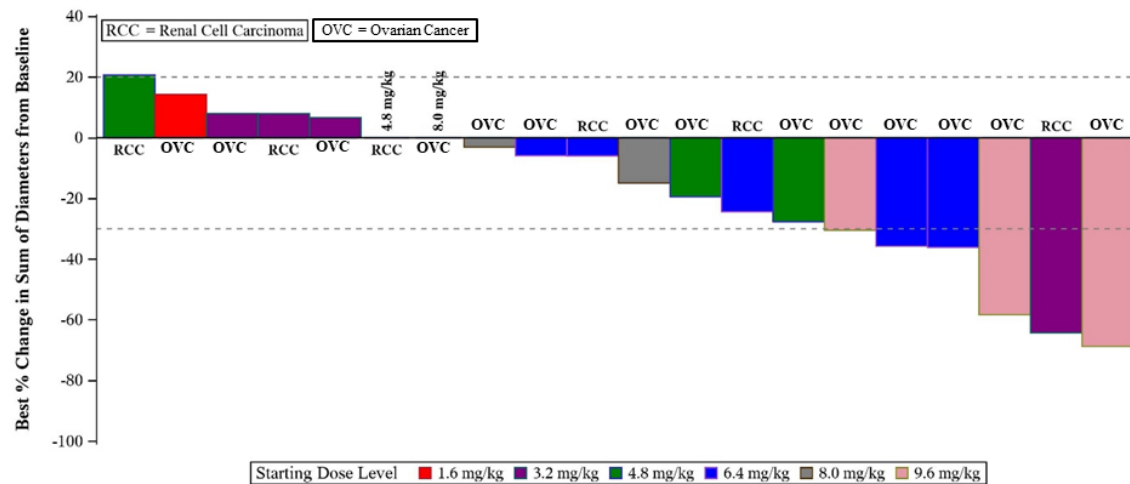
Data cutoff: Jun 30, 2022

- 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

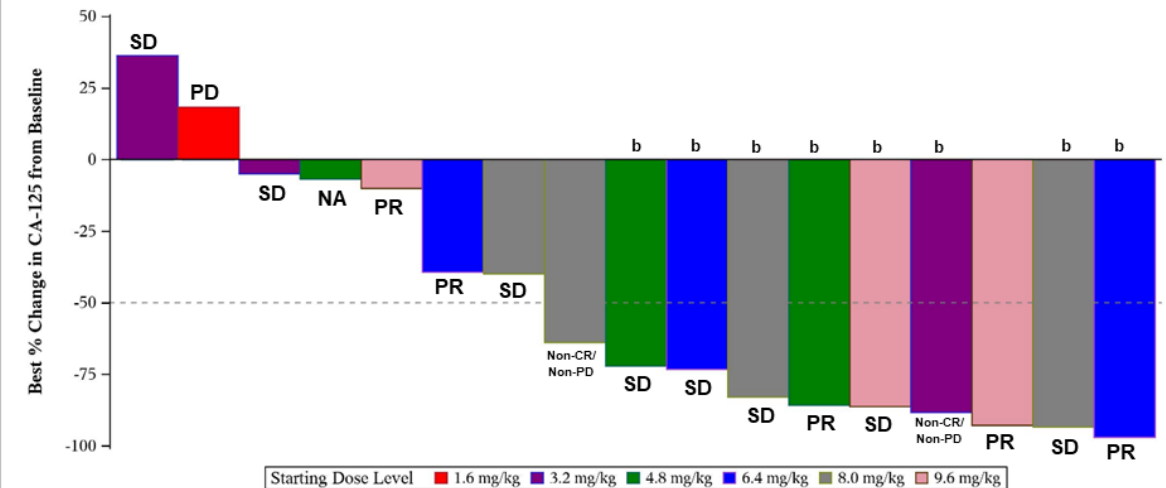
Demonstrated manageable safety and encouraging efficacy profile in heavily pre-treated patients with platinum-resistant OVC and RCC

Ph1 study dose-escalation part data (ASCO 2022)

Efficacy in OVC and RCC



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

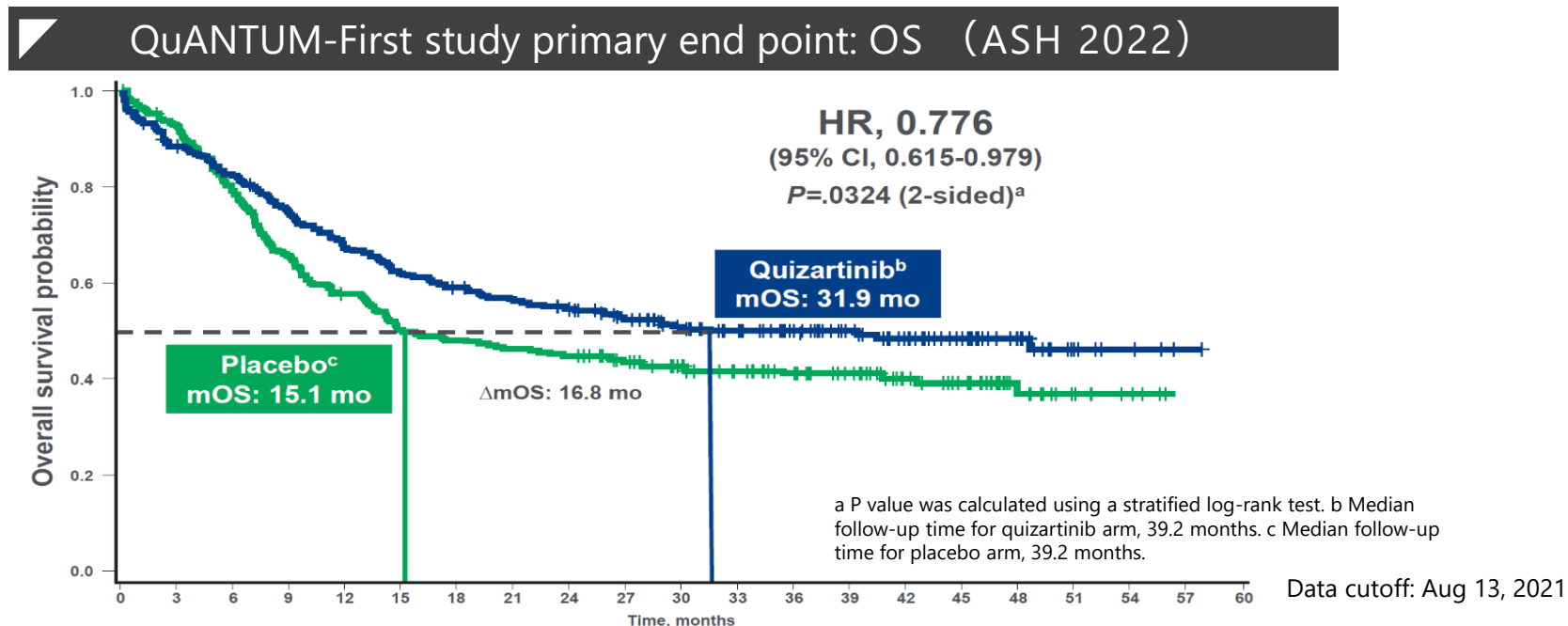


Data cutoff: Feb 25, 2022

- 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 gynecopathy 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

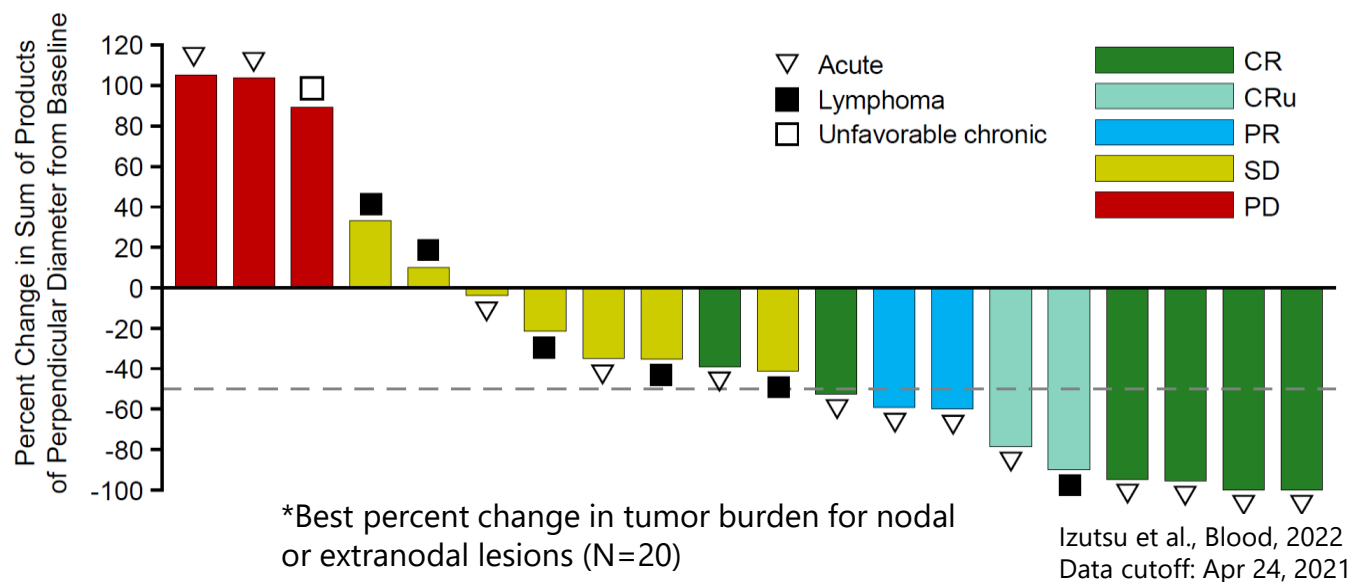
Demonstrated statistically significant and clinically meaningful OS improvement in patients newly diagnosed FLT3-ITD(+) AML.



- 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 $\geq 10\%$ 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)

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

Efficacy in nodal and extranodal lesions in ATLL patients

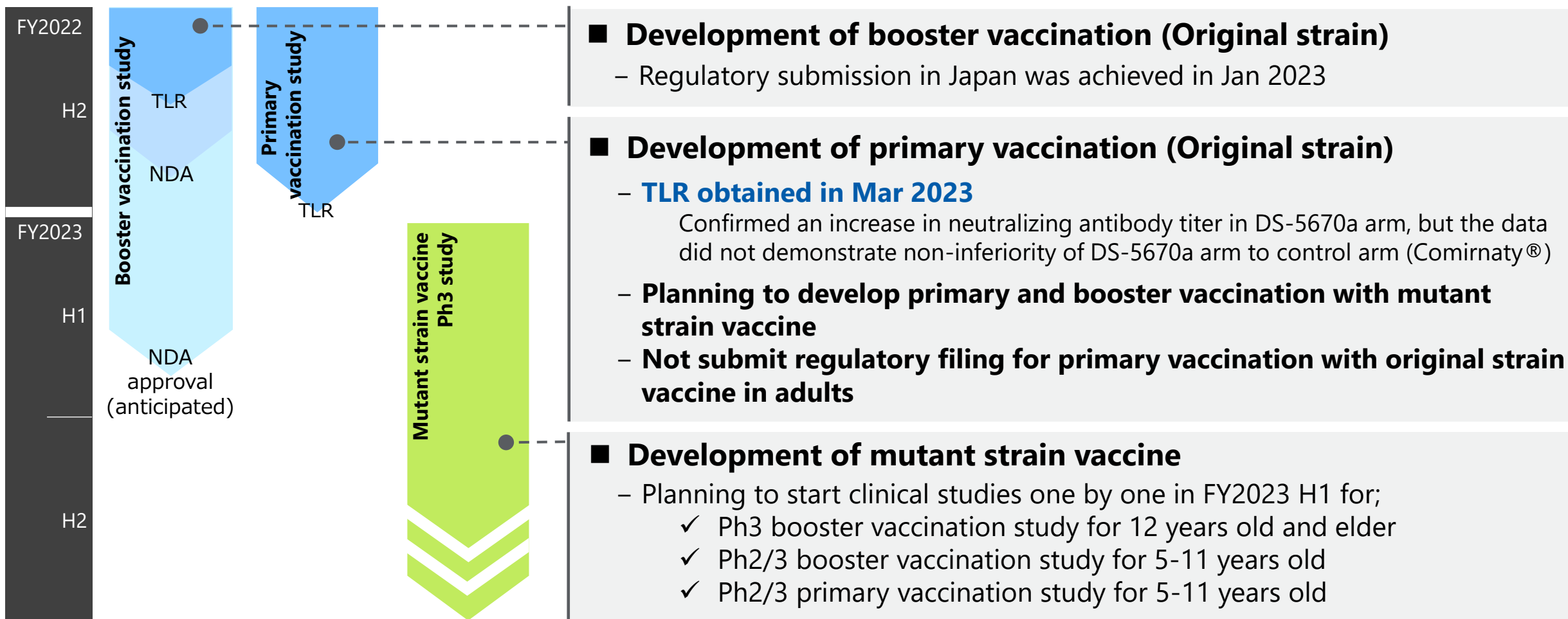


Development progress in major indications

Target indications	Therapy	Ph1	Ph2	Ph3	Filed	Launched
ATLL	Mono	[Progression from Ph1 to Launched]				
PTCL	Mono	Pivotal Ph2				
BCL	Mono	[Progression from Ph1 to Ph3]				
Breast Cancer	Combo w/ ENHERTU®	[Progression from Ph1 to Ph2]				

- 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

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

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, $\alpha 2\delta$ 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

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

Planned major publications

ASCO (Jun 16-18, 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

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

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

Planned pivotal study initiation

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

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 divestiture 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-directed 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

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

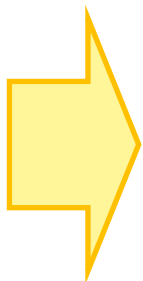
- Joined RE100, a global initiative aiming to use 100% renewable energy for electricity consumed in business activities
- Converted electricity consumed in bases in Japan to renewable energy

◆ 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.)

	<u>At the time of planning 5YBP</u>		<u>As of 2023 Apr.</u>
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

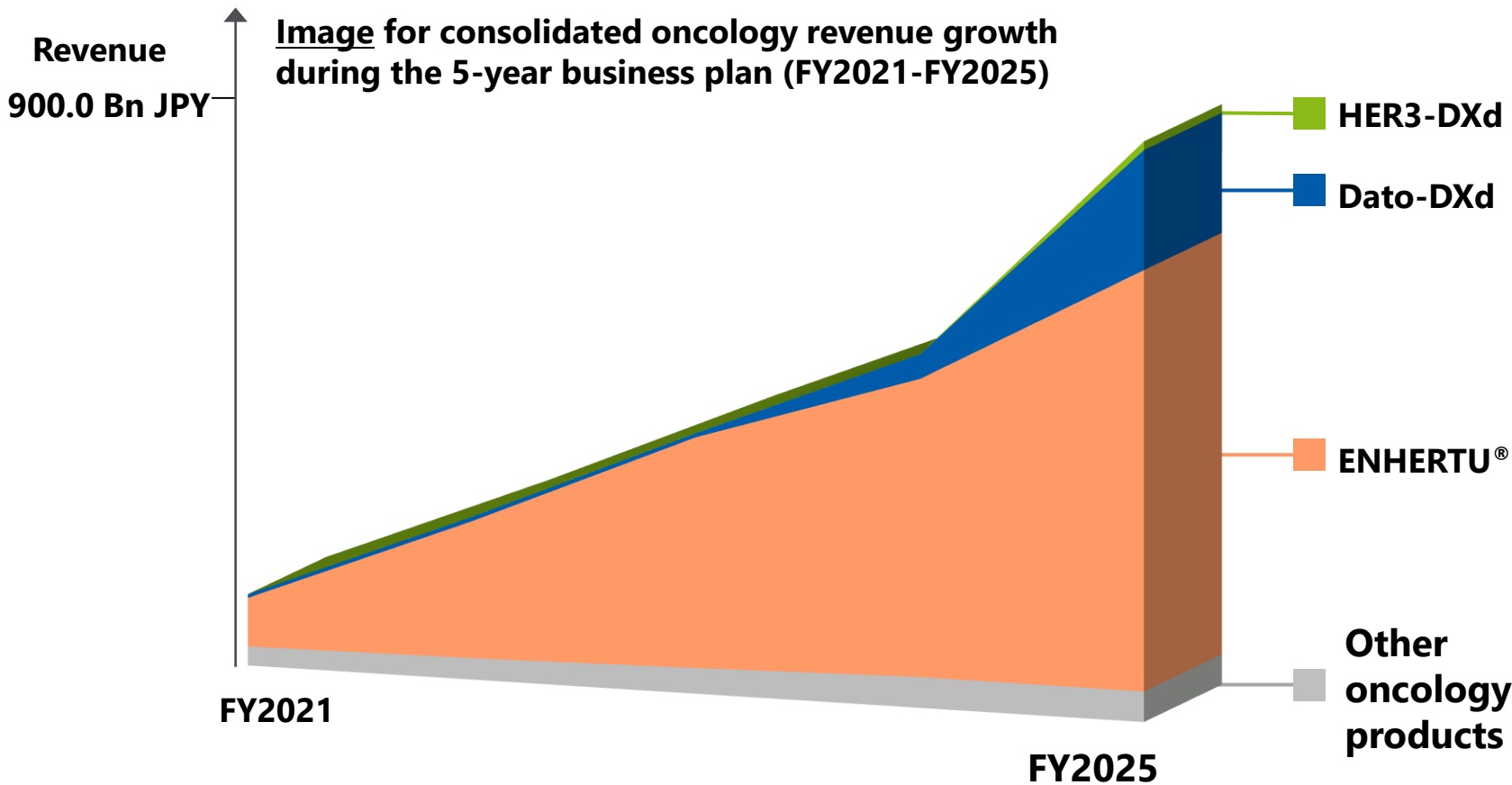
1 USD=105 JPY, 1 EUR=120 JPY

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



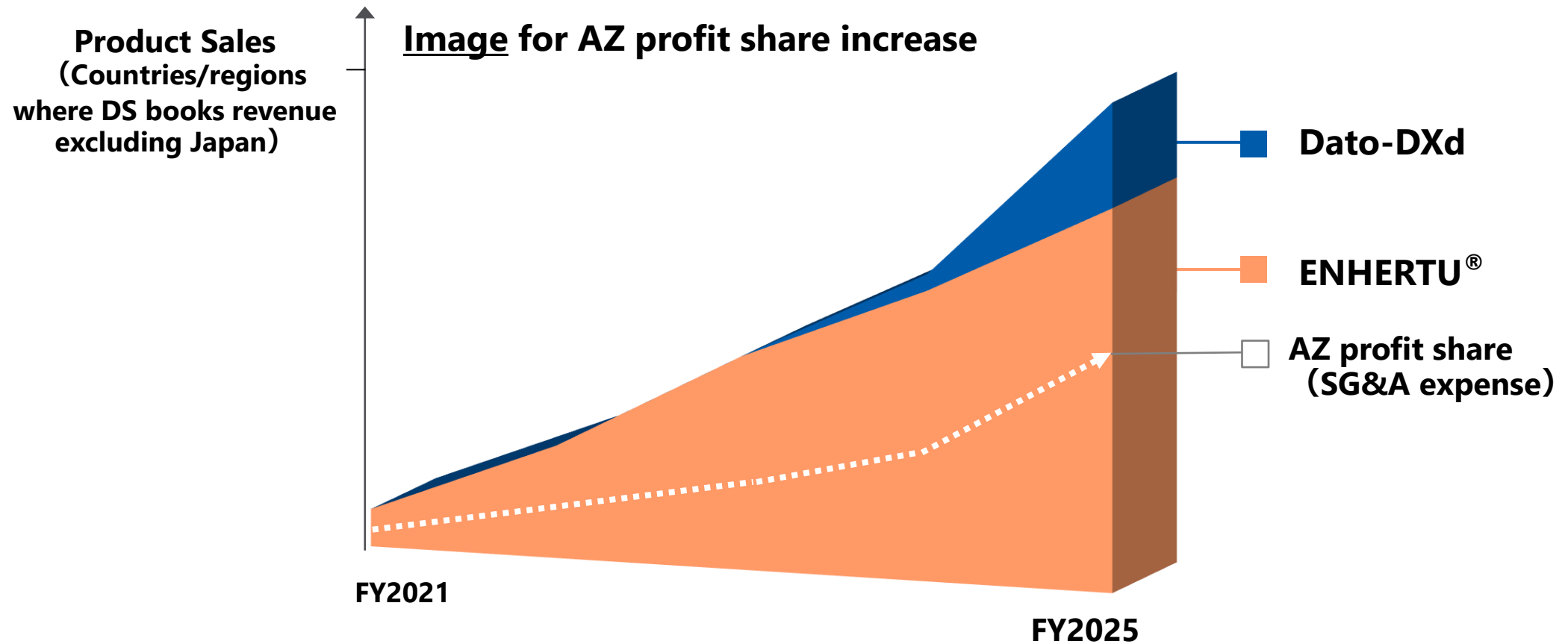
Major factors increased from initial plan

- ◆ 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.

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

5-Year Business Plan (FY2021-FY2025)

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

Dato-DXd

TROPION-Lung01

TROPION-Lung08

TROPION-Breast01

TROPION-Breast02

HER3-DXd

HERTHENA-Lung01

HERTHENA-Lung02

ENHERTU®

DESTINY-Breast03

DESTINY-Breast04

DESTINY-Breast06

DESTINY-Breast09

DESTINY-Breast11

DESTINY-Gastric02

DESTINY-Gastric04

DESTINY-Lung01/02

DESTINY-Lung04

DESTINY-CRC01/02

~FY2020

ENHERTU®

DESTINY-Breast01

DESTINY-Gastric01



A study approved the indication during 5-Year Business Plan

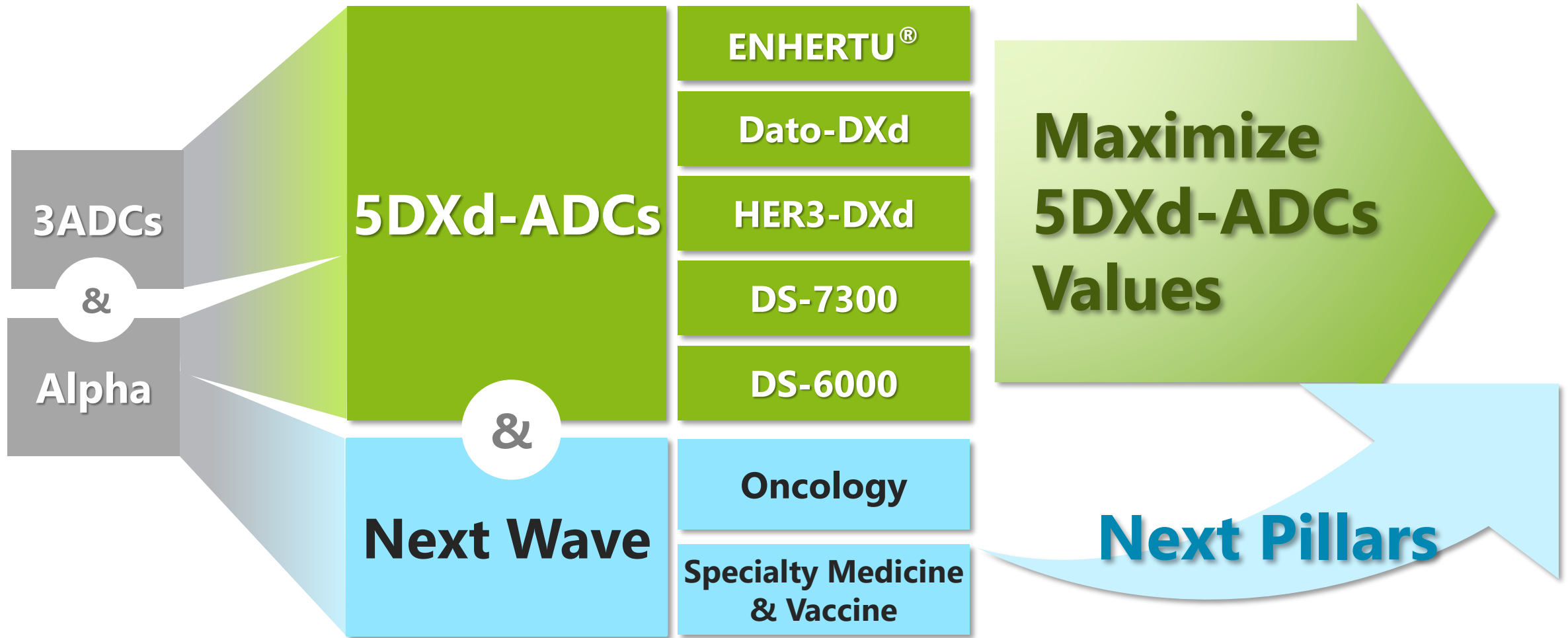


A study accelerated to expect an approval during 5-Year Business Plan (including a new study)

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"

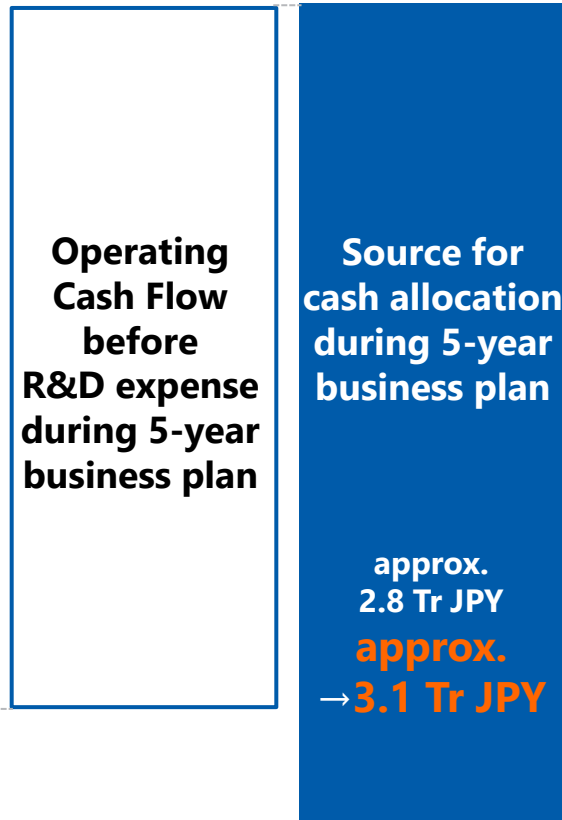


Well-balanced Investment for Growth and Shareholder Returns

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

FY2020 cash in hands*
approx. 400.0 Bn JPY

*Cash in hands excluding working capital

Expectation on achieving FY2025 KPIs

(as of 2023 Apr.)

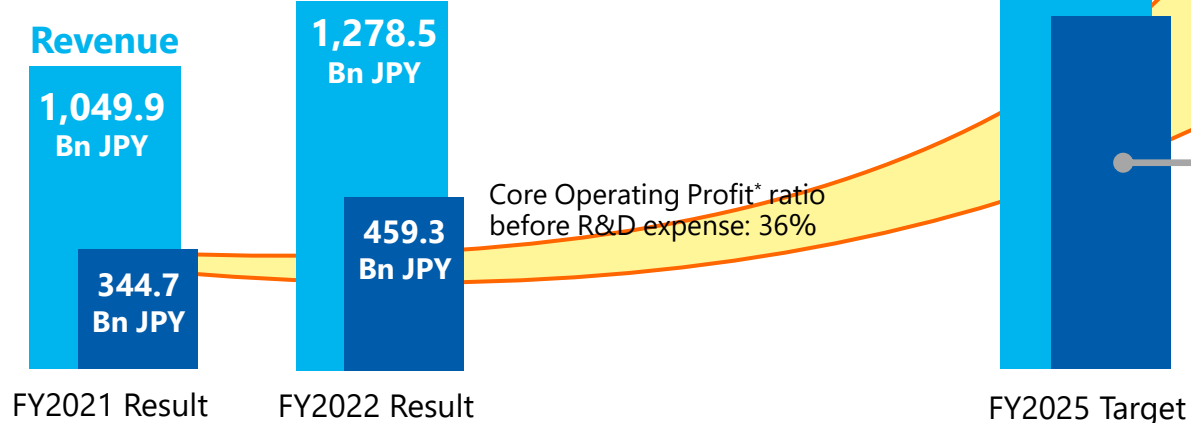
◆ Revenue

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



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

◆ ROE > **16%**

◆ DOE > **8%**

Investment for DXd-ADC

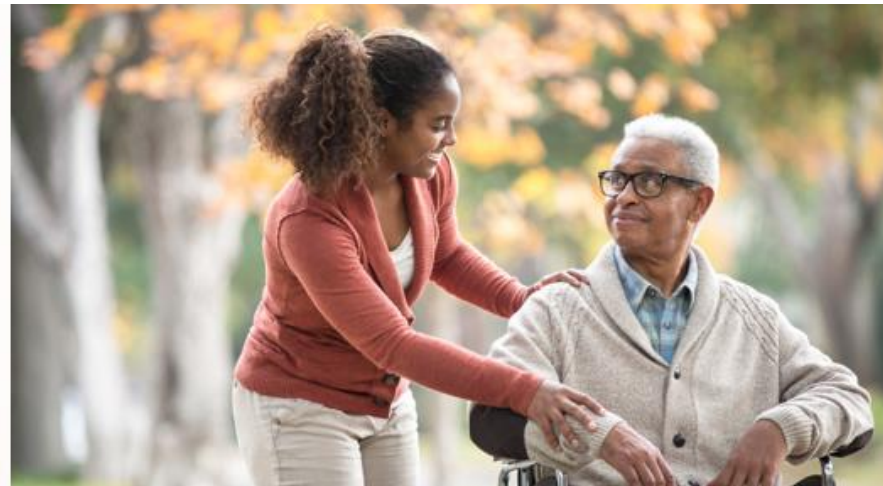
Profit Growth

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	USD/JPY	135.48	130.00	-5.48
Rate	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 related to impairment of Intangible assets of Turalio and others

Profit attributable to owners of the Company

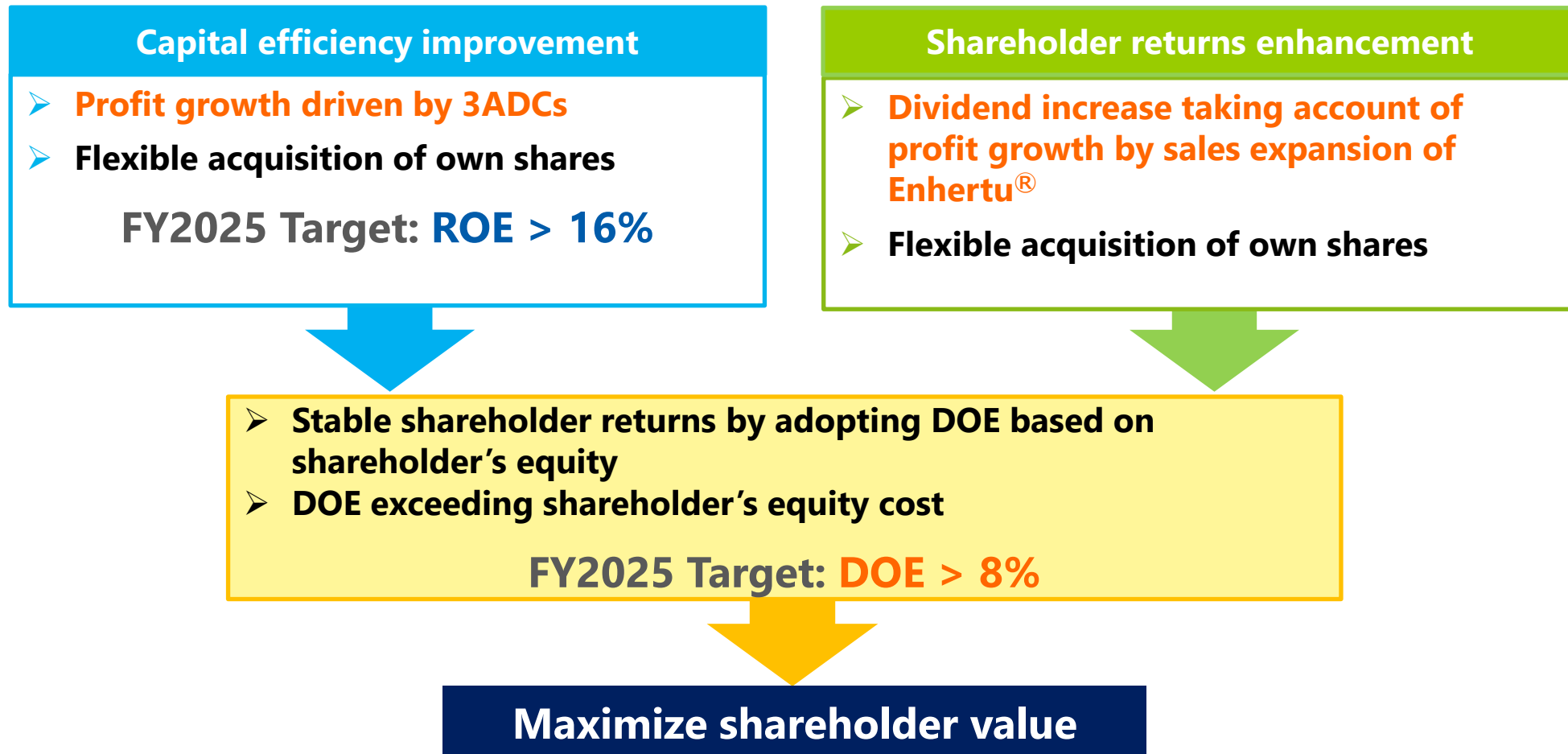
FY2023 Tax Rate Forecast: 14.8% (Impact of Tax credit for R&D expenses and others)

* 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)



*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	<u>DESTINY-Breast01</u>	HER2+ BC, previously treated w/ T-DM1
		<u>DESTINY-Breast03</u>	HER2+ BC, 2L, vs T-DM1
		<u>DESTINY-Breast04</u>	HER2 low BC, vs physician's choice
		<u>DESTINY-Breast05</u>	HER2+ BC, adjuvant following neoadjuvant therapy
		<u>DESTINY-Breast06</u>	HER2 low HR+ BC, chemo naïve, vs physician's choice chemotherapy
		<u>DESTINY-Breast09</u>	HER2+ 1L BC, vs T-DXd + Pertuzumab vs THP
	Gastric cancer	<u>DESTINY-Breast11</u>	HER2+ early-stage BC, neoadjuvant, vs T-DXd + THP vs AC+THP
		<u>DESTINY-Gastric01</u>	HER2 expressing GC, 3L+, vs physician's choice
		<u>DESTINY-Gastric02</u>	HER2+ GC, 2L
	NSCLC	<u>DESTINY-Gastric04</u>	HER2+ GC, 2L, vs SOC
		<u>DESTINY-Lung01/02</u>	HER2 over-expressing or mutant NSCLC, and HER2 mutant metastatic NSCLC 2L+, 2 doses (5.4, 6.4mg/kg)
	Colorectal cancer	<u>DESTINY-Lung04</u>	HER2 mutant (Exon 19 or 20) NSCLC, 1L vs SOC
		<u>DESTINY-CRC01/02</u>	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	<u>TROPION-Lung01</u>	NSCLC, 2L/3L, with/ without actionable gene alterations
		<u>TROPION-Lung07</u>	PD-L1 <50% non-squamous NSCLC w/o actionable genomic alterations, 1L, pembrolizumab combo vs ±pemetrexed/±platinum-based chemotherapy
		<u>TROPION-Lung08</u>	PD-L1 ≥50% NSCLC w/o actionable gene alterations, 1L, Dato-DXd + pembrolizumab vs pembrolizumab alone
	Breast cancer	<u>TROPION-Breast01</u>	HR+, HER2 low or negative BC, 2/3L+, vs investigator's choice of chemotherapy
		<u>TROPION-Breast02</u>	Locally recurrent inoperable or metastatic TNBC 1L, vs investigator's choice of chemotherapy
		<u>TROPION-Breast03</u>	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	<u>HERTHENA-Lung01</u>	EGFR-mutated NSCLC, 3L
		<u>HERTHENA-Lung02</u>	EGFR-mutated NSCLC, 2L, vs platinum-based chemotherapy

Major R&D Milestones (3ADCs)

Project	Target Indication [phase, study name]	FY2022	FY2023	
		H2	H1	H2
ENHERTU®	• 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)

Project	Target Indication [phase, study name]	FY2022 H2	FY2023	
			H1	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)		

Major R&D Pipeline: 3ADCs

Phase 1		Phase 2		Phase 3		Filed	
(US/EU/Asia) HER2+ BC 2L+/1L DESTINY-Breast07	(JP/US) solid tumors TROPION-PanTumor01	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) solid tumors TROPION-PanTumor03	(JP/US/EU/Asia) HER2+ BC adjuvant* ² DESTINY-Breast05	(CN) HER2 low BC post chemo DESTINY-Breast04		
(US/EU/Asia) HER2 low BC Chemo naïve/ post chemo DESTINY-Breast08	(CN) NSCLC, TNBC TROPION-PanTumor02	(CN) HER2+ GC 3L DESTINY-Gastric06	(JP/US/EU/Asia) NSCLC (w/ AGA) TROPION-Lung05	(JP/US/EU/Asia) HER2 low BC chemo naïve DESTINY-Breast06	(JP/EU) HER2 mutant NSCLC 2L+ DESTINY-Lung01/Lung02		
(JP/US/EU/Asia) HER2+ GC combo, 2L+/1L DESTINY-Gastric03	(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) TROPION-Lung02	(CN) HER2 mutant NSCLC 2L+ DESTINY-Lung05	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09			
(EU/Asia) HER2+ NSCLC (durvalumab combo) 1L DESTINY-Lung03	(JP/US/EU) NSCLC (w/o AGA, durvalumab combo) TROPION-Lung04	(US/EU/Asia) NSCLC (durvalumab combo) 2L+ HUDSON	(JP/US/EU/Asia) EGFR mutated NSCLC (osimertinib combo) 2L ORCHARD	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11			
(US/EU) BC, bladder (nivolumab combo)	(JP/US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(JP/US/EU) HER2+ CRC 3L DESTINY-CRC01	(US/EU/Asia) resectable early-stage NSCLC (durvalumab combo) neoadjuvant NeoCOAST-2	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04			
(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US/EU/Asia) NSCLC	(JP/US/EU/Asia) HER2+ CRC 3L DESTINY-CRC02	(JP/US/EU/Asia) EGFR mutated NSCLC 3L HERTHENA-Lung01	(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) EGFR mutated NSCLC (osimertinib combo)	(JP/US/EU/Asia) HER2 mutant tumor DESTINY-PanTumor01		(JP/US/EU/Asia) NSCLC 2/3L TROPION-Lung01			
	(JP/US) HER3+ BC	(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			

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

Phase 1		Phase 2		Phase 3		Filed	
DS-7300 (JP/US) B7-H3-directed ADC ESCC, CRPC, squamous NSCLC, SCLC, etc.	DS-7011 (US) Anti-TLR7 antibody Systemic lupus erythematosus	Valemetostat (DS-3201)(JP/US/EU/Asia) EZH1/2 inhibitor PTCL  	Valemetostat (DS-3201) (EU) EZH1/2 inhibitor BCL	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	DS-2325 (US)   KLK5 inhibitor Netherton syndrome	DS-1001 (JP) Mutant IDH1 inhibitor Glioma	DS-7300 (JP/US/EU/Asia) B7-H3-directed ADC ES-SCLC	Esaxerenone (JP) MR blocker Diabetic nephropathy	Mirogabalin (CN) α2δ ligands Diabetic peripheral neuropathic pain		
DS-1055 (JP/US) Anti-GARP antibody Solid tumors		DS-1211 (US/EU)  TNAP inhibitor Pseudoxanthoma elasticum	DS-5670 (JP) COVID-19 mRNA vaccine, COVID-19 (primary vaccination, 12 to 17 aged children)	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-5670 (JP) COVID-19 mRNA vaccine, COVID-19 (primary vaccination, 5 to 11 aged children) (in prep.)	DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain) COVID-19 (booster vaccination, adults) (in prep.)				
DS-9606 (US/EU) Target undisclosed ADC Solid tumors		VN-0200 (JP) RS virus vaccine RS virus infection					
DS-1103 Anti-SIRPα antibody HER2 expressing or mutant advanced metastatic solid tumors, HER2 low BC (in prep.)							

-  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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