Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2022 Q2
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Sunao Manabe

President and CEO

October 31, 2022

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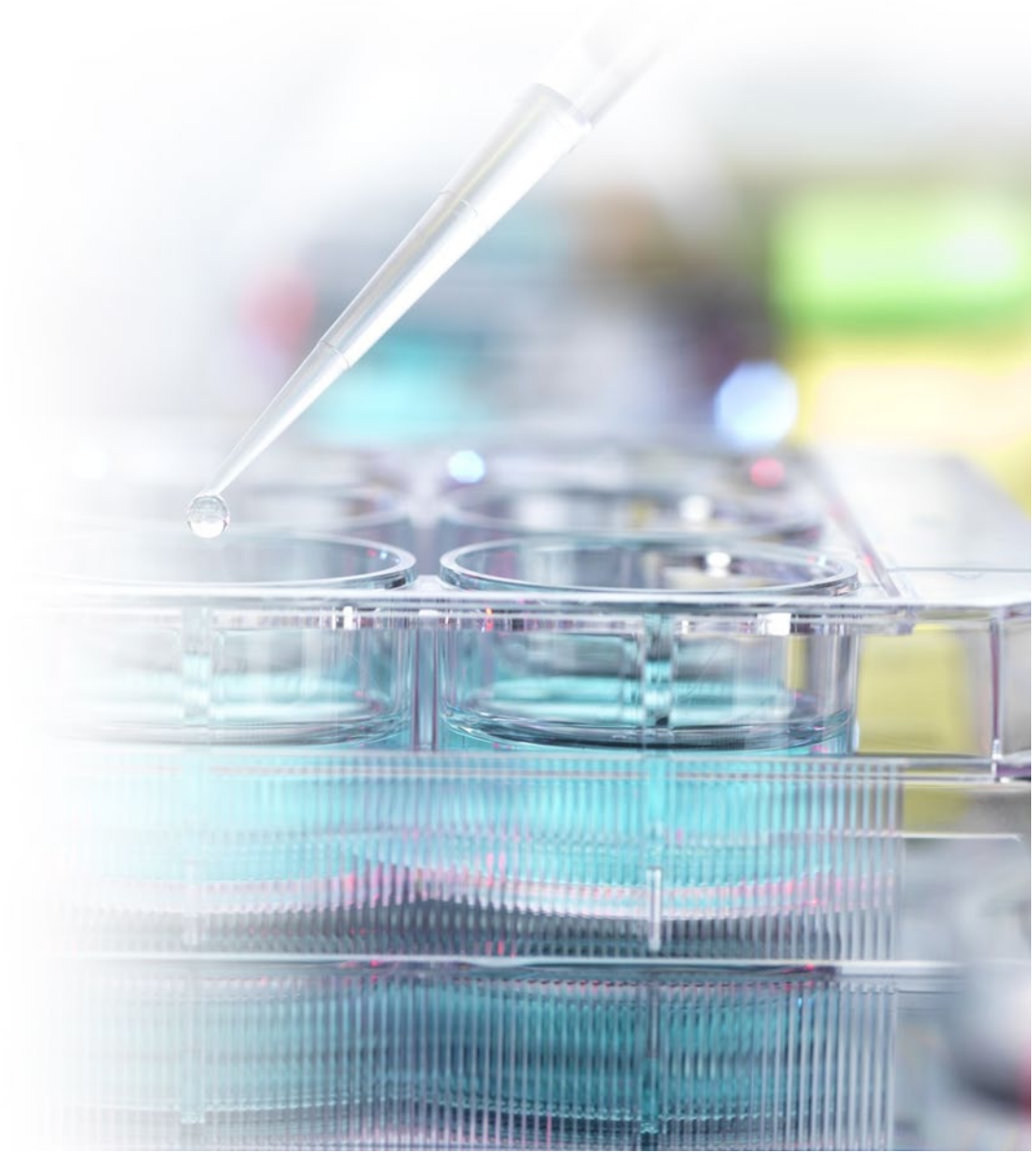
Agenda

1. **FY2022 Q2 Financial Results**
2. FY2022 Forecast
3. Business Update
4. R&D Update
5. Appendix



Overview of FY2022 Q2 Results

(Bn JPY)

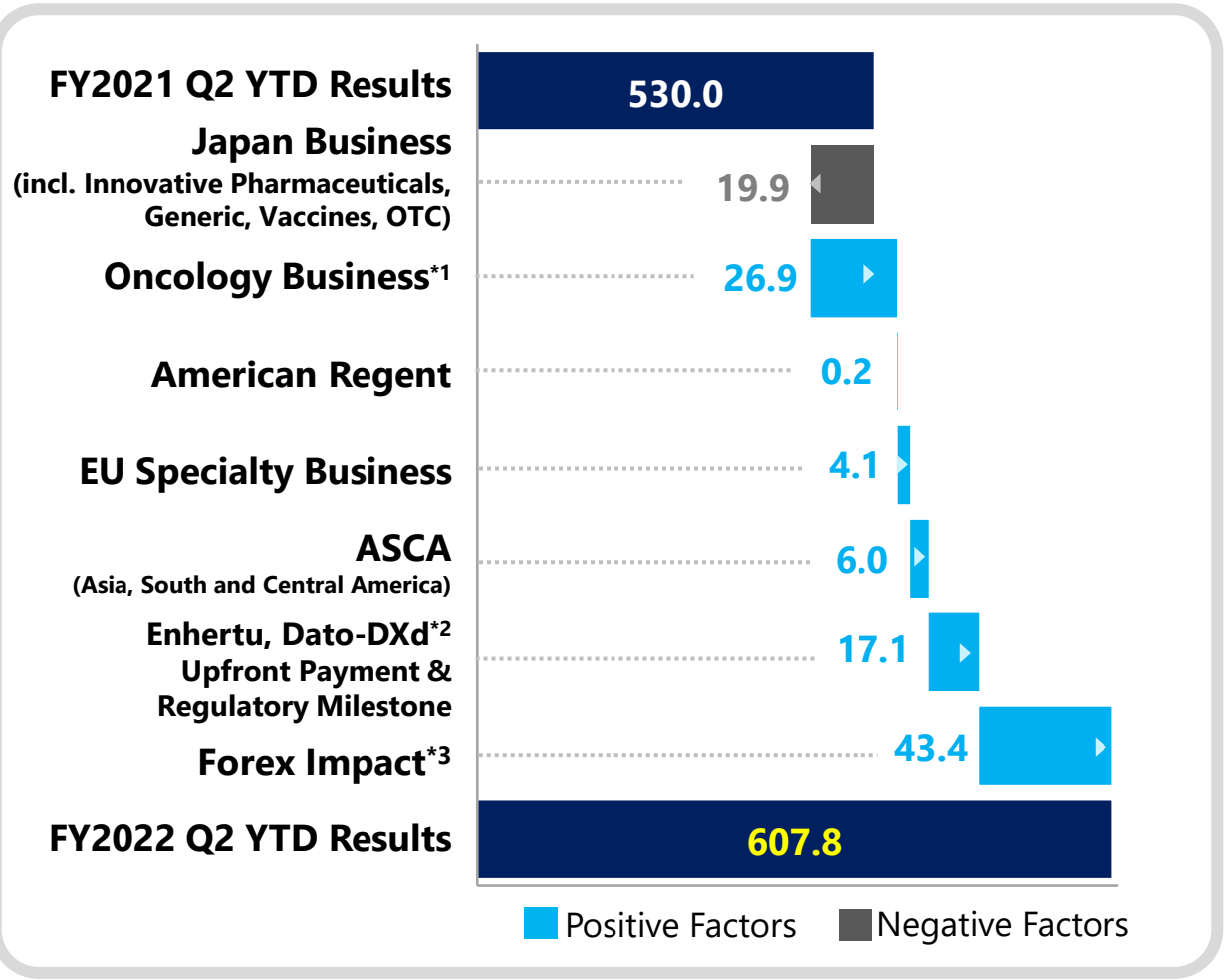
	FY2021 Q2 YTD Results	FY2022 Q2 YTD Results	YoY	
Revenue	**530.0**	**607.8**	**+14.7%**	**77.8**
Cost of sales *	172.6	159.4		-13.2
SG&A expenses *	165.7	209.8		44.0
R&D expenses *	109.0	153.9		44.8
Core operating profit *	**82.7**	**84.8**	**+2.5%**	**2.1**
Temporary income *	2.1	10.8		8.7
Temporary expenses *	0.1	0.0		-0.0
Operating profit	**84.7**	**95.6**	**+12.8%**	**10.8**
Profit before tax	**86.0**	**91.3**		**5.3**
Profit attributable to owners of the Company	**62.5**	**58.3**	**-6.7%**	**-4.2**

Currency Rate	USD/JPY	109.80	133.98	+24.18
	EUR/JPY	130.89	138.72	+7.83

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 77.8 Bn JPY (Increased by 34.4 Bn JPY excl. forex impact)



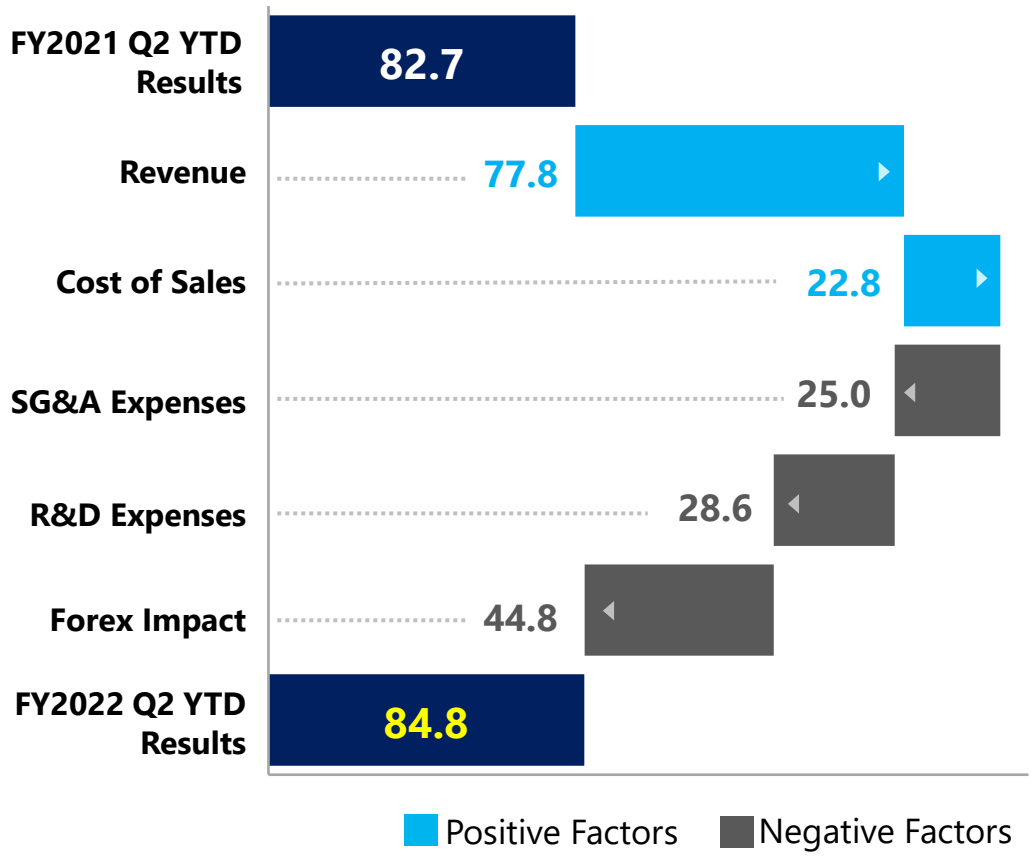
(Bn JPY)

Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+5.9	Nexium	-39.6
Tarlige	+4.2		
Vaccines business	+3.2		
Gains on sales of products in US	+3.2		
Gains on sales of product in EU	+2.7		
Oncology Business*1 Unit			
Enhertu	+34.2	Transferred products	-3.3
American Regent Unit			
Venofer	+4.0	Injectafer	-6.5
HBT products	+1.9		
GE injectables	+1.4		
EU Specialty Business Unit			
Lixiana	+5.6	Gain on sales of transferring long-listed products	-1.1
Enhertu, Dato-DXd*2 Upfront Payment & Regulatory Milestone			
Enhertu Regulatory Milestone	+15.7		

*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products
*2 Dato-DXd: Datopotamab deruxtecan (DS-1062)
*3 Forex impact USD: +29.6, EUR : +5.0, ASCA: +8.8

Core Operating Profit

Increased by 2.1 Bn JPY (Increased by 3.5 Bn JPY excl. forex impact)



(Bn JPY)

Revenue +77.8
incl. forex impact of +43.4

Cost of Sales -22.8
Improvement in cost of sales ratio by change in product mix

SG&A Expenses +25.0
Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca

R&D Expenses +28.6
Increase in 3ADCs* R&D investments

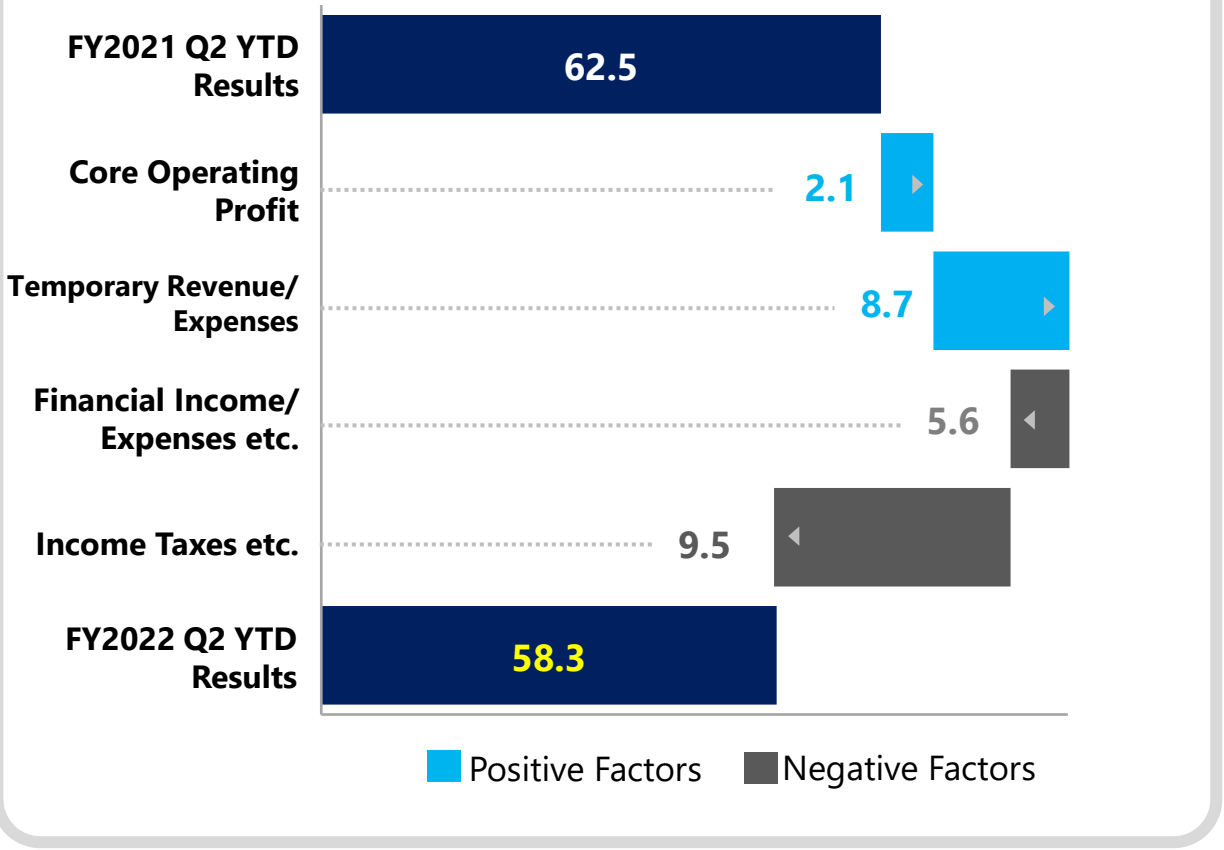
Forex Impact +44.8 (Profit Decreased)
Cost of Sales +9.6
SG&A Expenses +19.0
R&D Expenses +16.2

* 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

Decreased by 4.2 Bn JPY

(Bn JPY)



Temporary Income/Expenses ····· **+8.7 (Profit increased)**

	FY2021 Q2 YTD	FY2022 Q2 YTD	YoY
Temporary Income	2.1*1	10.8*2	+8.7
Temporary Expenses	1	0	-0.0

*1 Gains related to sale of Osaka logistics center (2.1)
*2 Gains related to sales of subsidiary of Daiichi Sankyo (China) (6.0)
Gains on reversal related to closure of Plexxikon (3.2)

Financial Income/Expenses etc. ····· **+5.6（Profit Decreased）**

- Deterioration in forex gains/losses ····· +3.8

Income Taxes etc. ····· **+9.5**

	FY2021 Q2 YTD	FY2022 Q2 YTD	YoY
Profit before Tax	86.0	91.3	+5.3
Income Taxes etc.	23.5	33.0	+9.5
Tax rate	27.3%	36.1%	+8.8%

Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2021 Q2 YTD Results	FY2022 Q2 YTD Results	YoY
Japan Business	255.6	225.1	-30.5
Daiichi Sankyo Healthcare	33.8	33.6	-0.2
Oncolgy Business	31.0	70.7	+39.7
Enhertu	22.4	69.0	+46.6
Turalio	1.3	1.7	+0.4
American Regent	77.0	94.1	+17.2
Injectafer	28.9	27.4	-1.5
Venofer	16.5	25.0	+8.5
GE injectables	26.5	34.1	+7.6
EU Speciality Business	63.7	71.8	+8.2
Lixiana	47.1	55.8	+8.7
Nilemdo/Nustendi	1.6	2.8	+1.2
Olmesartan	10.3	9.8	-0.5
ASCA (Asia, South and Central America) Business	55.1	69.8	+14.8

Currency Rate	USD/JPY	109.80	133.98	+24.18
	EUR/JPY	130.89	138.72	+7.83

Revenue: Major Products in Japan

(Bn JPY)

		FY2021 Q2 YTD Results	FY2022 Q2 YTD Results	YoY
Lixiana	anticoagulant	**44.8**	**50.7**	**+5.9**
Tarlige	pain treatment	**14.2**	**18.3**	**+4.2**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**18.4**	**19.3**	**+0.9**
Efient	antiplatelet agent	**8.0**	**9.9**	**+1.9**
Tenelia	type 2 diabetes mellitus treatment	**12.1**	**11.0**	**-1.1**
Vimpat	anti-epileptic agent	**8.9**	**10.6**	**+1.7**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**10.1**	**10.1**	**-0.1**
Canalia	type 2 diabetes mellitus treatment	**8.4**	**8.1**	**-0.3**
Loxonin	anti-inflammatory analgesic	**11.3**	**9.4**	**-1.9**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**4.4**	**5.2**	**+0.8**
Emgality	prophylaxis of migraine attacks	**2.1**	**3.0**	**+1.0**

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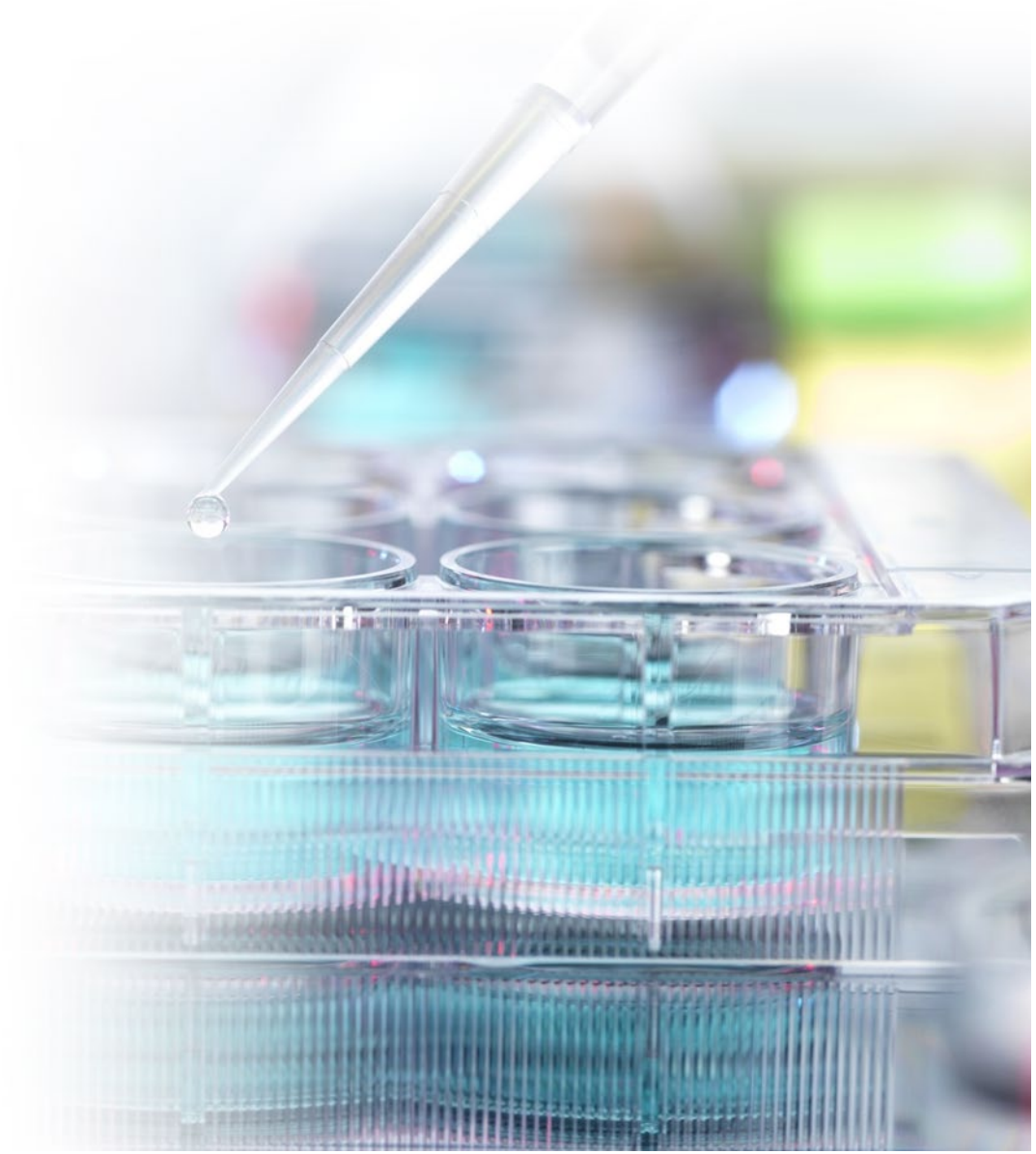

Revision to the forecast

(Bn JPY)

	FY2022 Forecast (as of Apr.)	FY2022 Forecast (as of Oct.)	vs. Forecast as of Apr.
Revenue	**1,150.0**	**1,250.0**	**+100.0**
Cost of sales *	328.0	338.0	+10.0
SG&A expenses *	410.0	468.0	+58.0
R&D expenses *	307.0	324.0	17.0
Core operating profit *	**105.0**	**120.0**	**+15.0**
Temporary income *	-	10.0	+10.0
Temporary expenses *	-	-	-
Operating profit	**105.0**	**130.0**	**+25.0**
Profit before tax	**105.0**	**130.0**	**+25.0**
Profit attributable to owners of the Company	**83.0**	**100.0**	**+17.0**

Currency Rate	USD/JPY	130.00	136.99	+6.99
	EUR/JPY	140.00	139.36	-0.64

Assumption of currency rate for Q3 and Q4 : USD/JPY 140, EUR/JPY 140

Revenue
- Sales increase mainly driven by Enhertu growth, increase by forex impact

Cost of sales
- Increase by revenue increase, increase by forex impact, Improvement in cost of sales ratio by change in product mix

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

R&D Expenses
- Increase in cost share of R&D investments with AstraZeneca due to acceleration of the development of Enhertu, increase by forex impact

Temporary expenses
- Gains related to sales of subsidiary of Daiichi Sankyo (China) , Gains on reversal related to closure of Plexxikon etc.

Forex Impact

Revenue +30.0 Bn JPY
Core operating profit -17.0 Bn JPY

* As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed.
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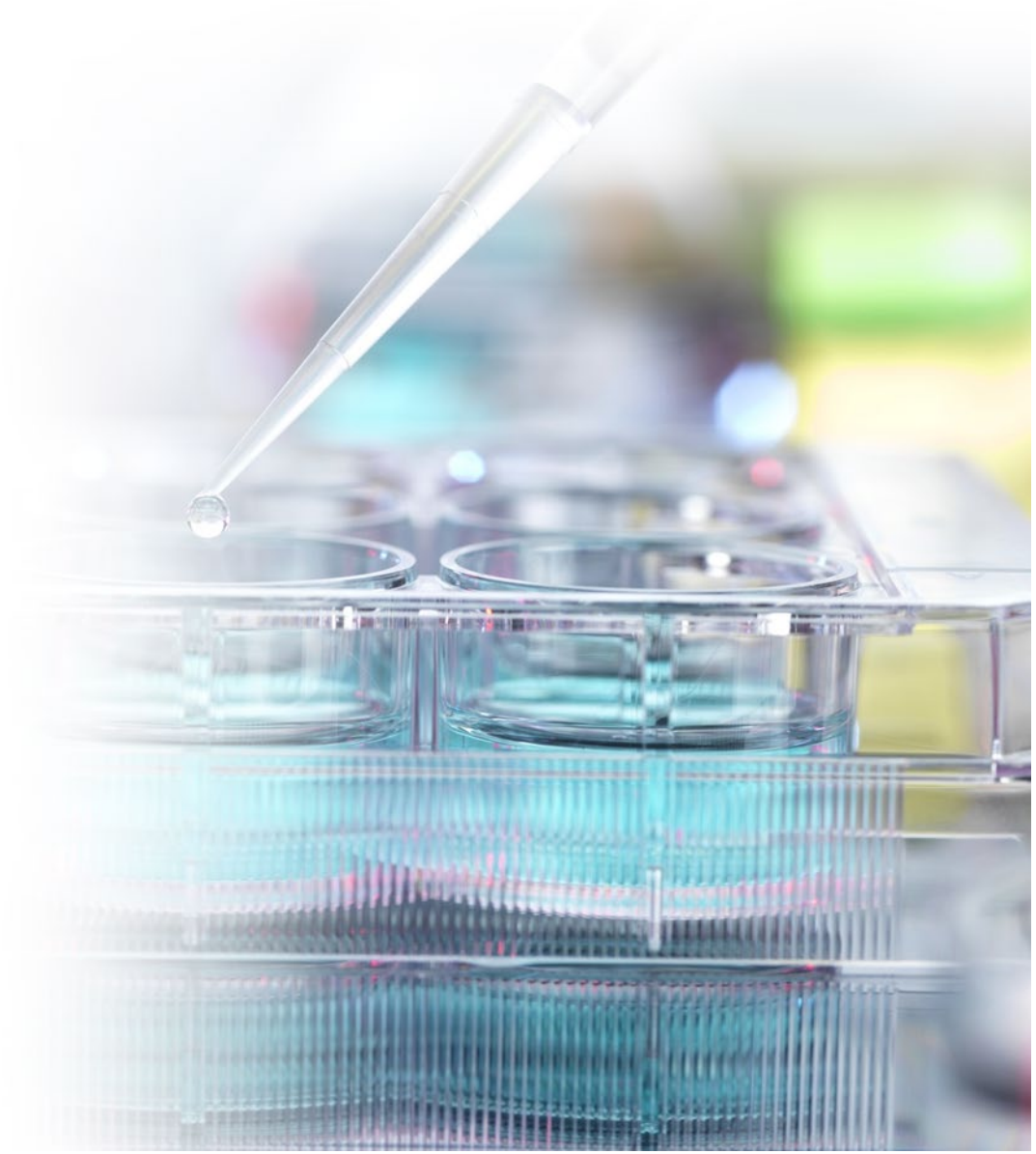


ENHERTU®

Revenue

(Bn JPY)

	FY2022 Q2 YTD Results	YoY	FY2022 Forecast	vs. Forecast as of Apr.	<Reference> Total Consideration
Product Sales	79.5	52.8	195.2	66.9	-
Japan	5.2	0.8	16.0	-	-
US	55.3	35.6	137.0	53.9	-
Europe	13.7	11.0	30.1	7.1	-
ASCA	5.3	5.3	12.1	5.8	-
Upfront payment	4.9 *1	-	9.8 *1	-	149.0
Regulatory milestone payment	16.8 *1	15.7	21.5 *1	0.9	106.8
US HER2+ Breast Cancer 3L	0.5	-	0.9	-	13.7
EU HER2+ Breast Cancer 3L	0.3	-	0.5	-	7.9
US HER2+ Gastric Cancer 2L + 3L	0.4	-	0.8	-	12.1
US HER2+ Breast Cancer 2L	3.0	3.0	3.5	0.0	13.1
EU HER2+ Breast Cancer 2L	2.3	2.3	2.7	0.1	10.1
US HER2-low Breast Cancer (post-chemo)	6.4	6.4	7.3	0.4	27.7
EU HER2+ Gastric Cancer 2L	-	-	1.3	0.1	4.9 *2
US HER2 Mutant NSCLC 2L	4.0	4.0	4.6	0.3	17.3
Quid related payment	0.6 *1	0.6	1.1 *1	-	17.2
Sales milestone payment	-	-	14.0	14.0	14.0 *2 *3
Total	101.9	69.1	241.7	81.8	287.1

*1 Revenue recognized in each period

*2 Revenue based on the assumption that milestone will be achieved in FY2022; Expected consideration converted with forex rate of 140 JPY to 1 USD

*3 Milestone of 100Mn USD for achieving annual product sales of 1 Bn USD in co-commercialization territory with AstraZenceca.
(Total revenue expected to be recognized in FY2022)

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

ENHERTU®

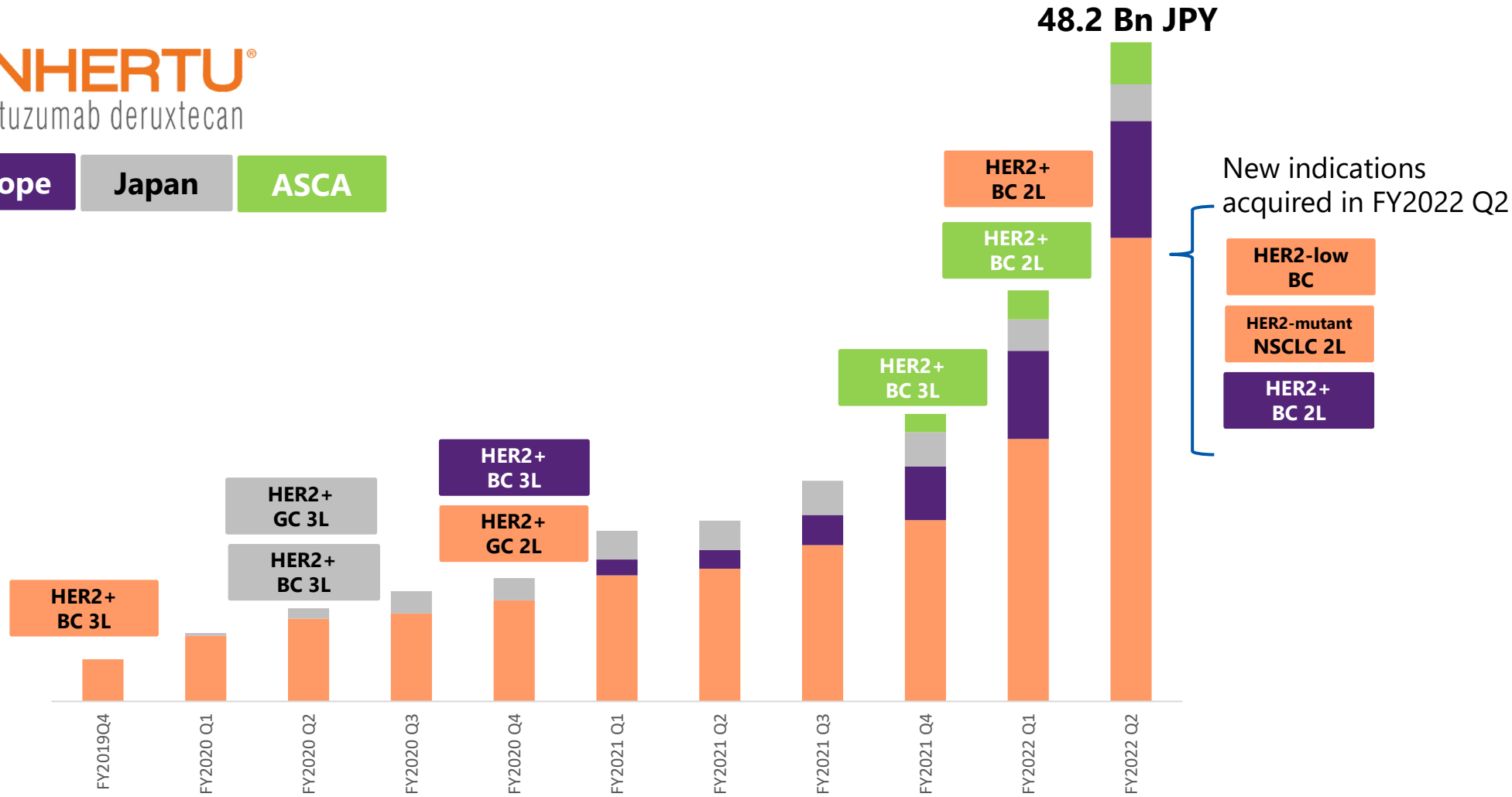
Sales Increase since Launch

Daiichi-Sankyo

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

ENHERTU® trastuzumab deruxtecan

US | Europe | Japan | ASCA



ENHERTU®

Performance in Each Region (US, EU)

Daiichi-Sankyo

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

Global product sales: FY2022 Q2 YTD results 79.5 Bn JPY（YoY +52.8 Bn JPY）
FY2022 forecast 195.2 Bn JPY（YoY +129.9 Bn JPY, vs. forecast as of Apr. +66.9 Bn JPY）

US

- **Product sales: FY2022 Q2 YTD results 55.3 Bn JPY (413 Mn USD)**
  FY2022 forecast 137.0 Bn JPY (1,000 Mn USD)
- **Indication:** HER2+ BC 2L/3L, HER2-low BC (post-chemo), HER2+ GC 2L, HER2-mutant NSCLC 2L
- **Market share status**
  - HER2+ BC 2L: Maintaining No.1 new patient share
  - HER2+ BC 3L: Maintaining No.1 new patient share
  - HER2-low BC: Rapid uptake in the population
  - HER2+ GC 2L: Maintaining No.1 new patient share
- **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)

Europe

- **Product sales: FY2022 Q2 YTD results 13.7 Bn JPY (102 Mn USD)**
  FY2022 forecast 30.1 Bn JPY (220 Mn USD)
- **Indication**: HER2+ BC 2L/3L
- **Market share status**
  - HER2+ BC 3L: Maintaining No.1 new patient share (UK, France, Germany)
- **Other progress**
  - Approved for HER2+ BC 2L and started promotion (Jul. 2022)

ENHERTU®
trastuzumab deruxtecan

*1 NCCN: National Comprehensive Cancer Network

Blue letters: updates from Q1

ENHERTU®

Performance in Each Region (Japan, ASCA)

Daiichi-Sankyo

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

Global product sales: FY2022 Q2 YTD results 79.5 Bn JPY（YoY +52.8 Bn JPY）
FY2022 forecast 195.2 Bn JPY（YoY +129.9 Bn JPY, vs. forecast as of Apr. +66.9 Bn JPY）

Japan

- **Product sales: FY2022 Q2 YTD results 5.2 Bn JPY**
  FY2022 forecast 16.0 Bn JPY
- **Indication:** HER2+ BC 3L, HER2+ GC 3L
- **Market share status**
  - HER2+ BC 3L: Maintaining No.1 new patient share
  - 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)

ASCA

- **Product sales: FY2022 Q2 YTD results 5.3 Bn JPY**
  FY2022 forecast 12.1 Bn JPY
- **Indication:** HER2+ BC 2L/3L
- **Market share status**
  - Sales growing in Brazil, Hong Kong and Taiwan
- **Other progress**
  - Launched in Taiwan (Apr. 2022)

ENHERTU®
trastuzumab deruxtecan

Received “Pharma Company of The Year” award

Received **“Pharma Company of The Year”** award in “Pharma Intelligence Award 2022” held in Japan for the first time as the Japan version of “Scrip Awards” .

The award is to **celebrate prominent achievement of pharmaceutical company** in CY2021 evaluating various indexes such as sales, profit and expansion of pipeline.

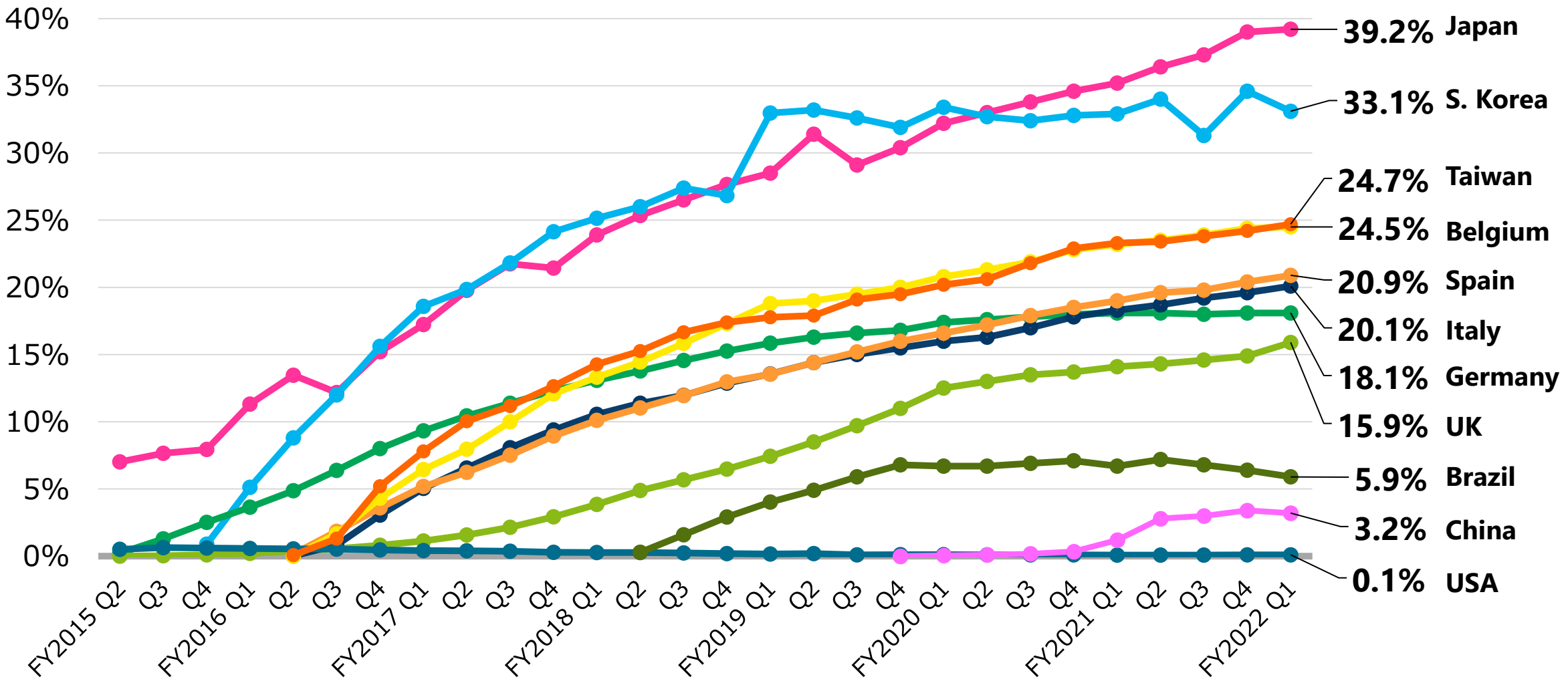
Efforts on oncology area, **strength of the unique antibody drug conjugate (ADC) platform**, the efficacy and its broad range of possibilities of ENHERTU® for breast cancer were cited.

LIXIANA®: Growth in Each Country/Region

Volume

Daiichi-Sankyo

Global revenue FY2022 Q2 YTD results: 117.3 Bn JPY (YoY +18.1 Bn JPY)
FY2022 forecast: 242.1 Bn JPY (YoY +36.4 Bn JPY)

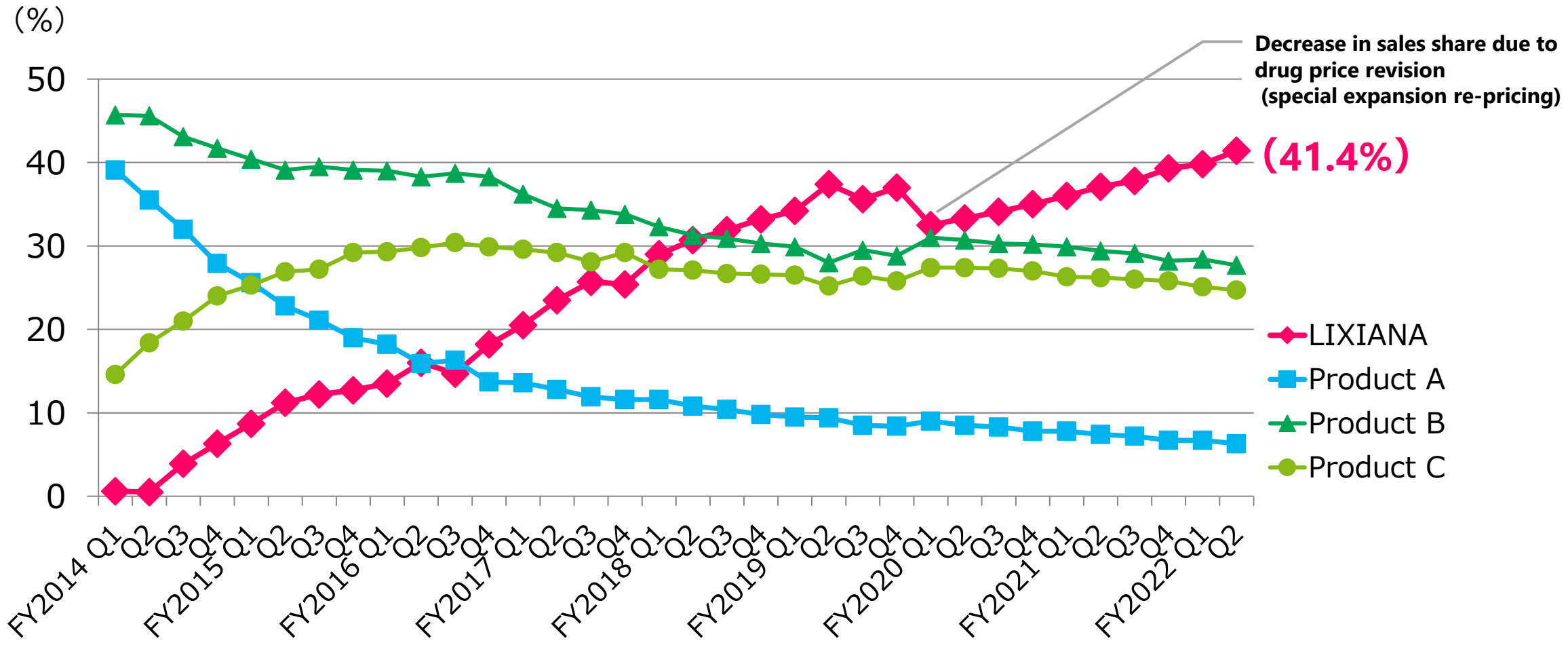


LIXIANA®: Growth in Japan

Sales

Daiichi-Sankyo

- No.1 sales share (FY2022 Q2: 41.4%)
- Revenue FY2022 Q2 YTD results: 50.7 Bn JPY (YoY +5.9 Bn JPY)
  FY2022 forecast: 106.6 Bn JPY (YoY +14.1 Bn JPY)



Investment in the US Business

American Regent, Inc. acquired HBT Labs, Inc. (August 2022)

Overview of HBT Labs, Inc.

- Business
  - **Research and development, manufacturing, sales and marketing** etc. of **generic (GE) injectables**
- Launched product
  - Mitotic inhibitor **Abraxane®** (generic name: paclitaxel) **authorized generic**
    - The company sells Abraxane AG supplied by Bristol Myers Squibb (Celgene)
- Major pipeline
  - Mitotic inhibitor **paclitaxel**
    - **Abraxane GE** originally developed by HBT
    - Approved by FDA (July 2022)
    - Planned to be launched in FY2022 4Q
  - Atypical antipsychotic **aripiprazole (GE)**
  - Local anesthetic **bupivacaine (GE)**
- Headquarter and plant California, USA
- Number of employees 83

Background, Purpose, Terms of Contract

- Background
  - For mid-to-long-term growth of ARI, it is necessary to **strengthen the product portfolio of GE injectables**
- Purpose
  - Contribution to sales revenue and profit by **paclitaxel**
  - HBT's advanced manufacturing technology will enable ARI to expand its **GE injectable pipeline**, including oncology
- Terms of contract
  - Upfront payment **225 Mn USD (30.0 Bn JPY)**
  - Milestone payment **20 Mn USD** (maximum)
    - 10 Mn USD to each launch for aripiprazole and bupivacaine
  - Royalty payment
    - Payment of 10% and 6%, respectively, for 3 years after the launch of aripiprazole and bupivacaine

Aiming for further growth by strengthening the product portfolio through synergies with HBT Labs, Inc.

Other initiatives in Each Region

Enhance transformation into a profit structure focused on patented drugs

US

◆ Transferred products in US

- Products : 8 products including antihypertensive agent BENICAR® (FY2021 revenue of 8 products: 8.9 Bn JPY)
- **Gain on transfer : 【Total 57 Mn USD】**
  - **・Aug. 2022: 22 Mn USD (3.2 Bn JPY) posted**
  - ・2022H2: 15 Mn USD, FY2024 /20 Mn USD

Europe

◆ Transferred products in EU

- Products : EFIENT ® Antiplatelet agent (FY2021 Revenue：1.5 Bn JPY)
- **Gain on transfer : 【Total 20.5 Mn EUR】**
  - **・Sep. 2022: 18.7 Mn EUR (2.7 Bn JPY) posted**
  - ・After FY2023 (when transfer was completed in Turkey): 1.8 Mn EUR

ASCA

◆ Transferred products and subsidiary in China

- Product : Antibacterial agent Cravit® (FY2021 Revenue ：8.9 Bn JPY)
- Subsidiary to be divested：Daiichi Sankyo Pharmaceutical (Beijing) Co., Ltd
- **Gain on transfer : 【Total 6 Bn JPY】**
  - **・Aug. 2022: Full amount posted**

Major Updates on Patent Disputes

Dispute with Seagen regarding Daiichi Sankyo antibody drug conjugates

- **2022 Aug. An arbitrator issued a decision denying all claims made by Seagen.**
  - With the decision denying claims by Seagen, **Daiichi Sankyo retains all patent rights to its antibody drug conjugate (ADC) technology** and will continue to develop and commercialize these medicines as planned.
- 2022 Jul. The U.S. District Court for the Eastern District of Texas has entered judgment that ENHERTU® infringes Seagen's U.S. Patent 10,808,039 (the '039 patent). The Court has not yet addressed whether to award a running royalty on future sales of ENHERTU® until the expiry of the '039 patent in 2024.

Dispute with Novartis regarding Plexxikon's U.S. Patents

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

Revision of Annual Dividend

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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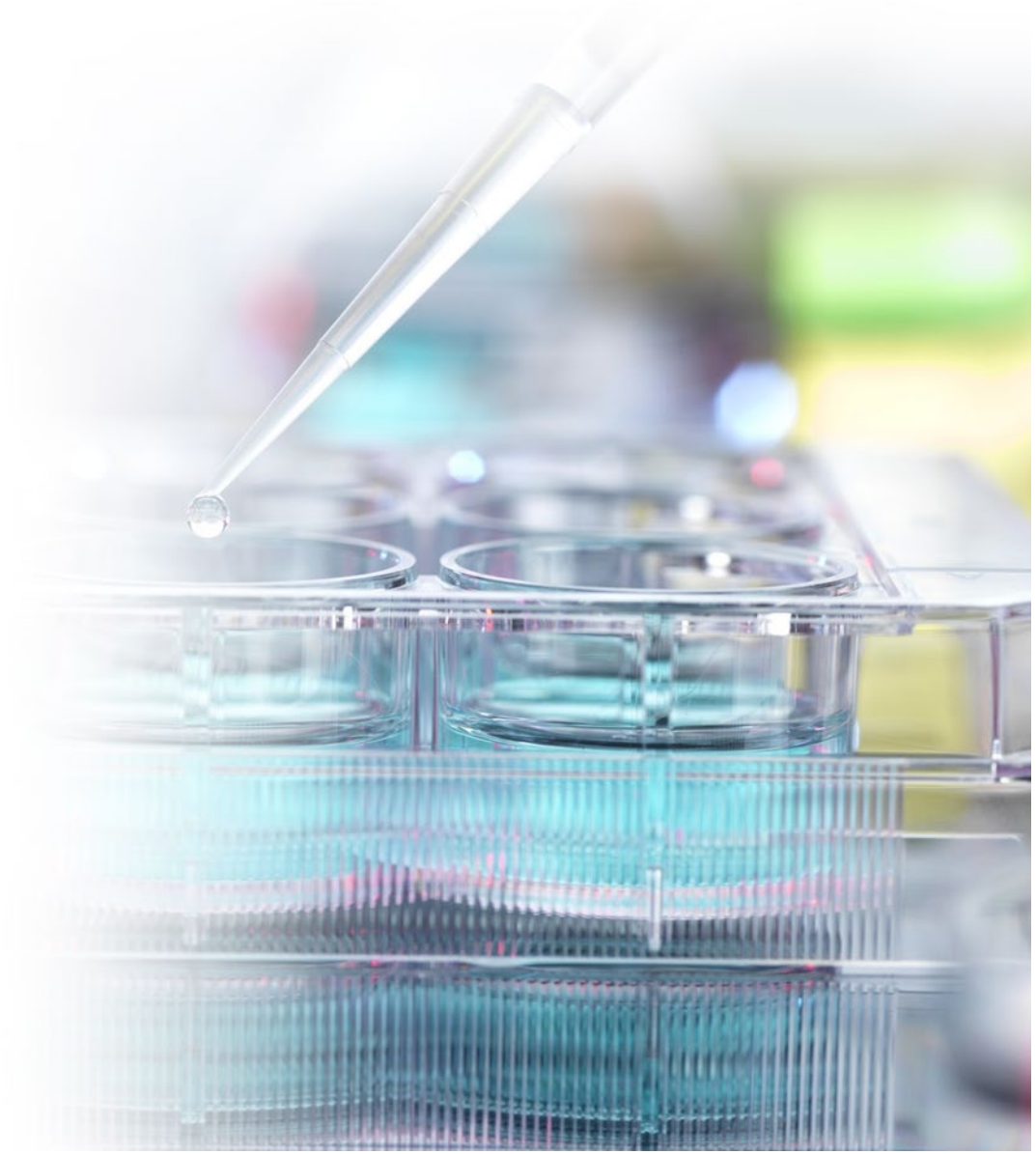


3ADCs Update

Alpha Update

R&D day

News Flow

Breast cancer update

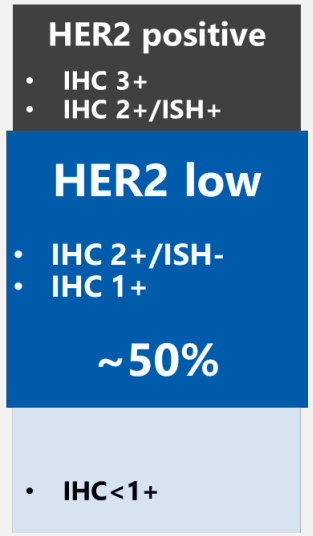
Pioneer HER2 low BC as a new clinically meaningful patient segment

In Aug 2022, ENHERTU® was approved in US for HER2 low BC previously treated with chemotherapy

- **Approved after 11 days from filing acceptance under the FDA's RTOR program, priority review and BTD**
- FDA approved CDx in Oct

Regulatory submission status in other countries and regions

- Jun 2022: Filing accepted in JP & EU
- Aug 2022: **Filing accepted in China**



Major development status of breast cancer

- HER2 low BC: DESTINY-Breast06 study (HR+ mBC, chemotherapy naïve, monotherapy) and DESTINY-Breast08 study (chemotherapy naïve/post chemotherapy, combination therapy) are ongoing
- HER2 positive BC: DESTINY-Breast09 study (1L) , DESTINY-Breast05 study (adjuvant therapy *) and DESTINY-Breast11 study (neoadjuvant therapy) are ongoing

*adjuvant therapy for patients with HER2 positive early breast cancer with high risk of disease recurrence who have residual invasive disease after receiving neo-adjuvant therapy
BC: breast cancer, BTD: Breakthrough Therapy Designation, CDx: companion diagnostics, mBC: metastatic breast cancer, RTOR: real-time oncology review program

ENHERTU®

Lung cancer update

Expand leadership across other HER2 targetable tumors

In Aug 2022, ENHERTU® was approved in US for HER2 mutant NSCLC 2L+

- This indication was **approved under BTD, priority review and accelerated approval process based on the results of DESTINY-Lung02** as well as DESTINY-Lung01
- Approved dose is **5.4mg/kg**

- FDA approved two types of CDx to detect HER2 mutation along with approval of ENHERTU® for NSCLC

Regulatory submission status in other countries and regions

– Sep 2022: **Granted orphan drug designation for unresectable, advanced or recurrent NSCLC in JP**

– FY2022 H2: Filing planned in JP & EU

Major development status of lung cancer

– DESTINY-Lung04 study (HER2 mutant NSCLC, 1L) is ongoing

– Aug 2022: Initiated **DESTINY-Lung05 study** (HER2 mutant NSCLC, 2L+) in China

BTD: Breakthrough Therapy Designation, CDx: companion diagnostics, NSCLC: non small cell lung cancer

ENHERTU®

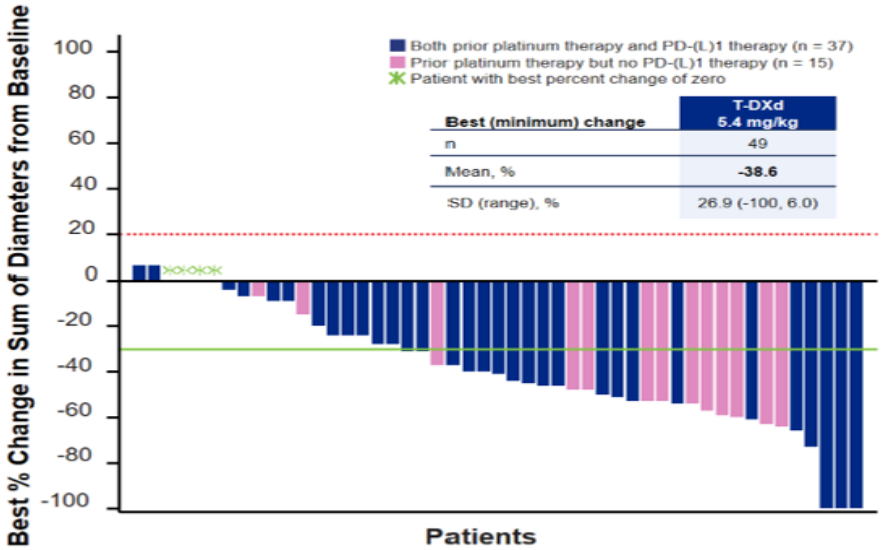
DESTINY-Lung02 study interim analysis data

ESMO 2022

Daiichi-Sankyo

Data supported FDA approval of ENHERTU® 5.4 mg/kg as the first HER2 directed therapy for treatment of previously treated patients with HER2 mutant NSCLC

Anti-tumor activity
(ENHERTU® 5.4 mg/kg, n=52)



Response Assessment by BICR (March 24, 2022 DCO)	T-DXd 5.4 mg/kg n=52	T-DXd 6.4 mg/kg n=28
Confirmed ORR, n (%) [95% CI]	28(53.8) [39.5, 67.8]	12 (42.9) [24.5, 62.8]
Best overall response, n (%)		
CR	1 (1.9)	1 (3.6)
PR	27 (51.9)	27 (39.3)
SD	19 (36.5)	14 (50.0)
PD	2 (3.8)	1 (3.6)
Not evaluable	3 (5.8)	1 (3.6)
DCR, n (%) [95% CI]	47 (90.4) [79.0,96.8]	26 (92.9) [76.5, 99.1]
Median DoR, months [95% CI]	NE [4.2, NE]	5.9 [2.8, NE]
Median follow-up, months [range]	5.6 [1.1-11.7]	5.4 [0.6-12.1]

Response Assessment by BICR – 90-Day Follow Up (June 22, 2022 DCO)	T-DXd 5.4 mg/kg n=52
Confirmed ORR, % [95% CI]	57.7 [43.2, 71.3]
CR, %	1.9
PR, %	55.8
Median DoR, months [95% CI]	8.7 [7.1, NE]

DESTINY-Lung02 study

Comparative study of 5.4 mg/kg and 6.4 mg/kg ENHERTU® in patients with previously treated HER2 mutant NSCLC

- ORR were 53.8% (5.4 mg/kg) and 42.9% (6.4 mg/kg) at the time of the interim analysis, and **ORR was 57.7% (5.4mg/kg)** after additional 90-day follow-up response analysis
- No new safety concerns were identified

BICR: blinded independent central review, CI: confidence interval, CR: complete response, DCO: data cutoff, DCR: disease control rate, ESMO: European Society for Medical Oncology, NE: not evaluable, NSCLC: non-small cell lung cancer, ORR: objective response rate, PD: progressive disease, PR: partial response, SD: stable disease

TROPION-Lung02 study interim analysis data

WCLC 2022

Interim analysis data of TROPION-Lung02 presented at WCLC 2022 for the first time

Study design

	Dato-DXd IV Q3W	+	pembro IV Q3W	+	platinum CT IV Q3W	
Cohort 1 (n=20)[a]:	4 mg/kg	+	200 mg			"Doublet"
Cohort 2 (n=20)[a]:	6 mg/kg	+	200 mg			
Cohort 3 (n=17)[a]:	4 mg/kg	+	200 mg	+	carboplatin AUC 5	"Triplet"
Cohort 4 (n=20)[a]:	6 mg/kg	+	200 mg	+	carboplatin AUC 5	
Cohort 5 (n=7)[a]:	4 mg/kg	+	200 mg	+	cisplatin 75 mg/m^2	
Cohort 6 (n=4)[a]:	6 mg/kg	+	200 mg	+	cisplatin 75 mg/m^2	

a: As of the May 2, 2022 data cutoff.

TROPION-Lung02 study

Ph1b study evaluating the safety and efficacy of **Dato-DXd + pembrolizumab (Doublet)**, or **Dato-DXd + pembrolizumab + platinum chemotherapy (Triplet)** for relapsed and progressive NSCLC without actionable genomic alterations regardless of PD-L1 expression level

- Dose confirmatory study (for patients with 2 or fewer lines of prior treatment) and dose expansion studies (for patients with 1 or fewer lines of platinum-based chemotherapy as prior therapy in cohorts 1 and 2, and patients with no prior therapy in all other cohorts.)
- Primary endpoint: safety and tolerability
- Secondary endpoint: ORR, DoR, PFS, OS, PK, ADA

ADA: anti-drug antibody, DoR: duration of response, IV: intravenous, NSCLC: non-small cell lung cancer, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, PK: pharmacokinetics

Dato-DXd

TROPION-Lung02 study interim analysis data

WCLC 2022

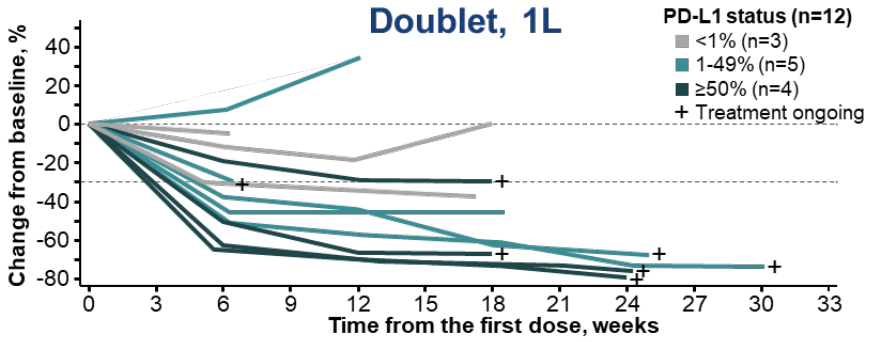
Daiichi-Sankyo

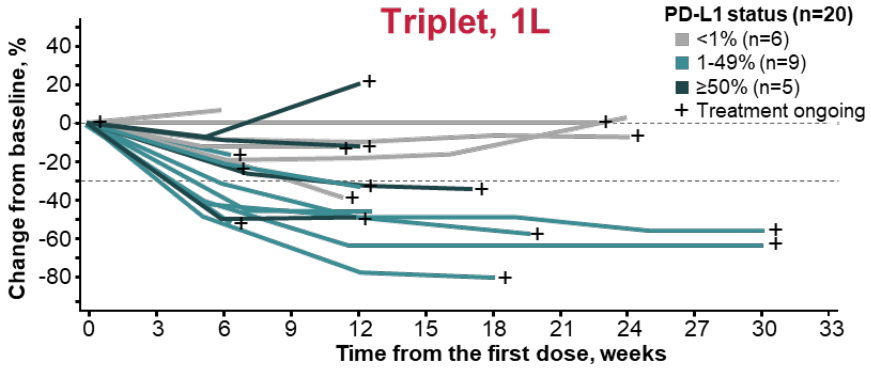
Encouraging interim analysis data was obtained overall and for 1L patients which supports further development in NSCLC

Response Rate (1L)

Response, n (%)	Doublet (n=13)	Triplet (n=20)
ORR confirmed + pending	**8 (62%)**	**10 (50%)**
CR	0	0
PR confirmed	8 (62%)	7 (35%)
PR pending	0	3 (15%)
SD	5 (39%)	8 (40%)
DCR	13 (100%)	18 (90%)

Anti-tumor activities (Change in sum of tumor diameters, 1L)





- ORR was **62% (doublet) and 50% (triplet) for 1L patients and responses were observed across all levels of PD-L1 expression**
- Overall safety consistent with Dato-DXd monotherapy and no grade 4 or grade 5 ILD events were adjudicated as drug-related.
- Conducting Ph3, TROPION-Lung08 study to evaluate the efficacy and safety of Dato-DXd + pembro combination therary for 1L NSCLC without actionable genomic alterations, PD-L1 ≥50%
- These data also support a new study in PD-L1 <50% (next slide)

ILD: interstitial lung disease, NSCLC: non-small cell lung cancer, ORR: objective response rate

Dato-DXd

New clinical study: TROPION-Lung07

Planning to initiate new Ph3 study for PD-L1 <50% non-squamous NSCLC

Patient Population (N≈975)

- Advanced or metastatic non-squamous NSCLC without actionable genomic alterations
- No prior systemic therapy for advanced non-squamous NSCLC
- PD-L1 <50%

R 1:1:1

Randomization

Arm A: Dato-DXd (6 mg/kg) + pembrolizumab+ platinum chemotherapy

Arm B: Dato-DXd (6 mg/kg) + pembrolizumab

Arm C: pembrolizumab + pemetrexed + platinum chemotherapy

Dato-DXd NSCLC (Ph3)	Advanced 1L	Advanced 2L	Advanced 3L
NSCLC without actionable genomic alterations	**TROPION-Lung07** (PD-L1 <50%) To be initiated in FY2022 H2	**TROPION-Lung01** (includes actionable genomic alterations)	
	TROPION-Lung08 (PD-L1 ≥50%)		

TROPION-Lung07 study

- Global study, open label
- Primary endpoint: PFS, OS
  Secondary endpoint: ORR, DoR, TTR, DCR, ADA, etc.

ADA: anti-drug antibody, 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, TTR: time to response

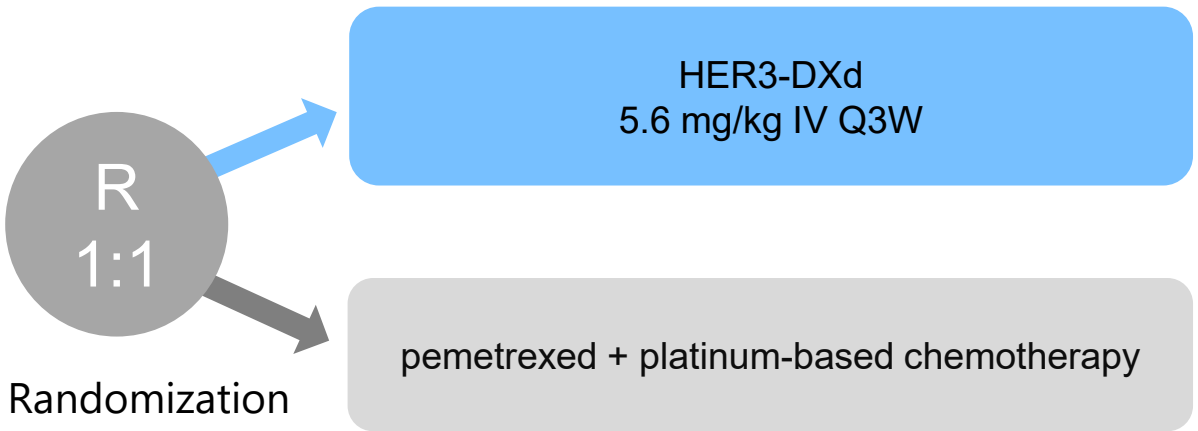
HER3-DXd

New clinical study: HERTHENA-Lung02

Initiated Ph3 study for post TKI EGFR mutated NSCLC patients in Aug 2022

Patient Population (N≈560)

- Metastatic or locally advanced non-squamous NSCLC with an EGFR-activating mutation (exon 19 deletion or L858R)
- Received 1 or 2 lines of EGFR TKI treatment including a third-generation EGFR TKI



HER3-DXd

NSCLC Dev. status	Advanced/metastatic 1L	Advanced/metastatic 2L	Advanced/metastatic 3L
EGFR mutated NSCLC		**HERTHENA-Lung02** Ph3 Started in Aug 2022	**HERTHENA-Lung01** Registrational Ph2 Started in Feb 2021
	Ph1b Combination with osimertinib Started in Jun 2021		

HERTHENA-Lung02 study

- Global study, open label
- Primary endpoint: PFS
  Secondary endpoint: OS. ORR, DoR, CBR, DCR, safety, etc.

CBR: clinical benefit rate, 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, TKI: tyrosine kinase inhibitor

3ADCs Update

Alpha Update

R&D day

News Flow

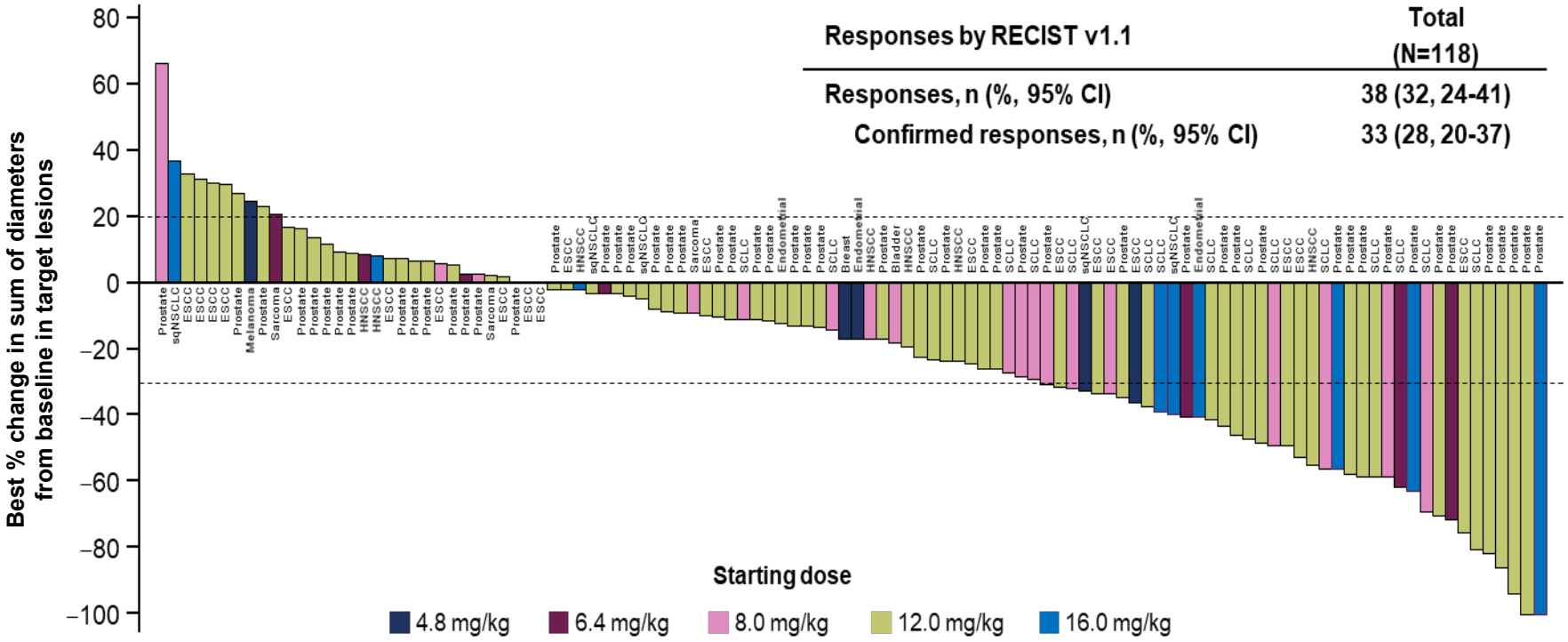
Ph1/2 study interim analysis data

ESMO 2022

Daiichi-Sankyo

DS-7300 showed promising efficacy for multiple cancer types in heavily pretreated patients

Antitumor activity (across tumor types)



Data cutoff: June 30, 2022

DS-7300 Ph1/2 study

Ph1/2 study to evaluate the safety and efficacy of DS-7300

- Targeted cancer type: SCLC, mCRPC, ESCC, sqNSCLC, etc.
- Primary endpoint: safety, antitumor effect
- Secondary endpoint: PK, etc.

- As a preliminary efficacy, **confirmed ORR was 28% for the entire study population**
- Safety profile was consistent with previously reported results

CI: confidence interval, ESCC: esophageal squamous cell carcinoma, mCRPC: metastatic castration-resistant prostate cancer, NSCLC: non-small cell kung cancer, ORR: objective response rate, PK: pharmacokinetics, RECIST: Response Evaluation Criteria in Solid Tumours, SCLC: small cell lung cancer, sqNSCLC: squamous non-small cell lung cancer

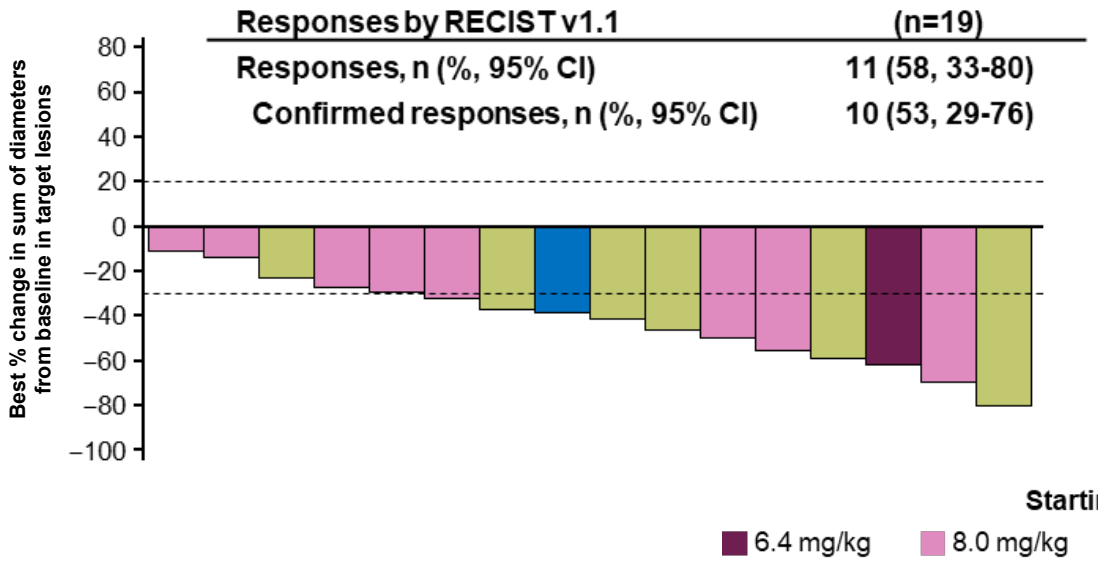
DS-7300

Ph1/2 study interim analysis data

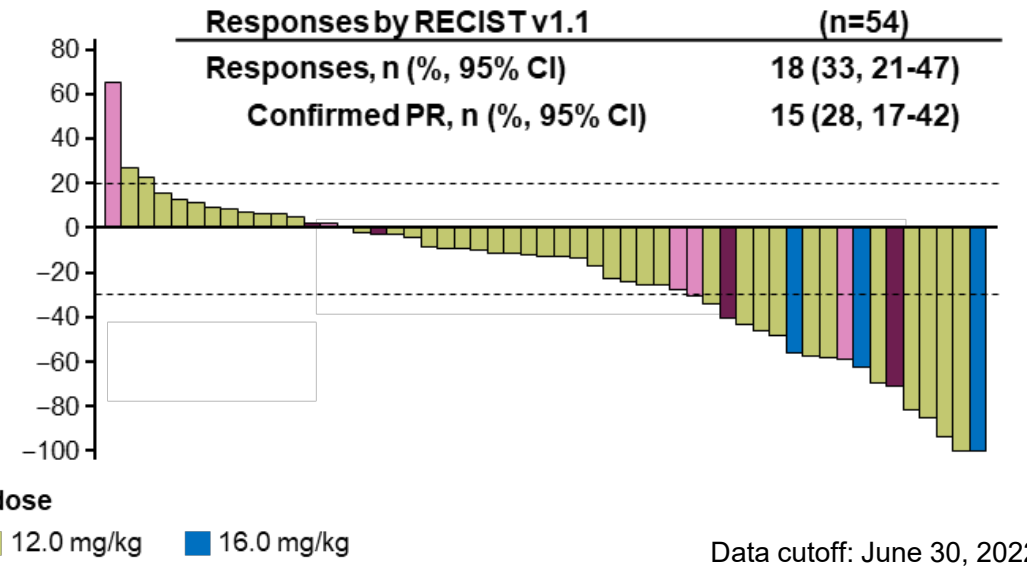
ESMO 2022

Daiichi-Sankyo

Antitumor activity (SCLC)



Antitumor activity (mCRPC)



Starting dose

6.4 mg/kg　8.0 mg/kg　12.0 mg/kg　16.0 mg/kg

Data cutoff: June 30, 2022

■ Confirmed ORR by cancer type were **53% for SCLC (n=19)**, **28% for mCRPC (n=54)**, 40% for sqNSCLC (n=5), and 18% for ESCC (n=22)

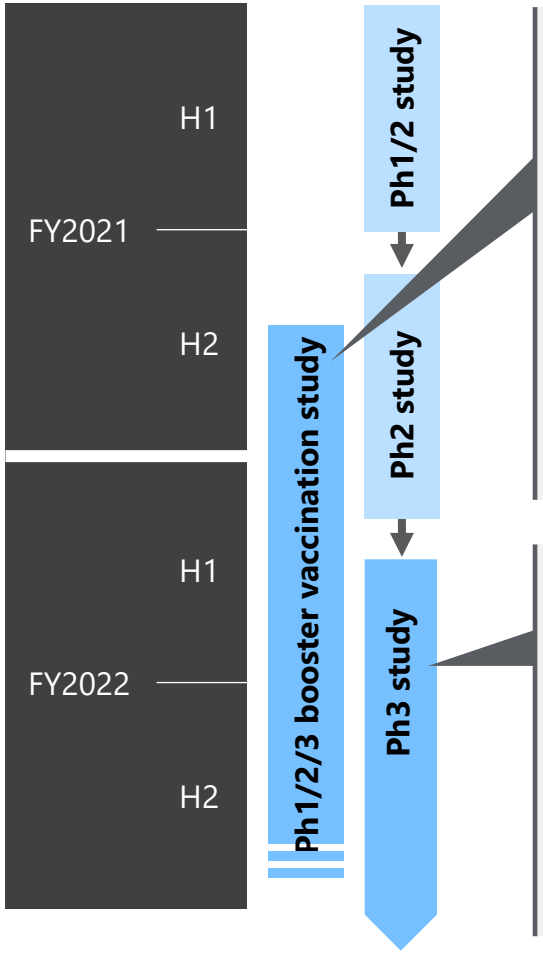
Based on findings of this study, Development of DS-7300 will be accelerated in SCLC and other cancer types

CI: confidence interval, ESCC: esophageal squamous cell carcinoma, mCRPC: metastatic castration-resistant prostate cancer, NSCLC: non-small cell kung cancer, ORR: objective response rate, PR: partial response, RECIST: Response Evaluation Criteria in Solid Tumours, SCLC: small cell lung cancer, sqNSCLC: squamous non-small cell lung cancer

DS-5670

Current development status

Each clinical study is progressing as planned
Prior assessment consultation with PMDA began in September 2022 and planning regulatory submission for booster vaccination within FY2022



■ Development of booster vaccination

– TLR of Ph1/2/3 study part 2 anticipated in FY2022 Q3.

– Planning to regulatory submission within FY2022

Booster vaccination Ph1/2/3 study Part 2

- Subjects: 4500 healthy adults and the elderly subjects who received the primary vaccination (the first and second administration) of approved COVID-19 mRNA vaccine (Comirnaty® or Spikevax®) in Japan
- Confirm non-inferiority of neutralizing antibodies against SARS-CoV-2 (original strain) levels in blood for DS-5670 to approved mRNA vaccine

■ Development of primary vaccination

– Sep 2022: **Ph3 study** started in Japan

Primary vaccination Ph3 study

- Subjects: 322 healthy adults with no history of COVID-19 vaccination
- Confirm non-inferiority of neutralizing antibodies against SARS-CoV-2 (original strain) levels in blood for DS-5670 to Comirnaty®

Alpha

Study progress and regulatory decisions/submissions

Ezharmia ® (Valemetostat) (relapsed or refractory adult T-cell leukemia-lymphoma (ATLL))

- Sep 2022：Approved in JP for ATLL

Quizartinib（FLT3-ITD positive acute myeloid leukemia (AML), 1L）

- Aug 2022: Filing accepted in EU
- Aug 2022: Filing accepted in JP
- Oct 2022: Filing accepted in US (Priority Review granted, PDUFA date: April 24, 2023)

VN-0200（RSV vaccine）

- Oct 2022: Started Ph2 study for healthy elderly in JP

PDUFA date: Prescription Drug User Fee Act date (the FDA action date for their regulatory decision), RSV: respiratory syncytial virus

3ADCs Update

Alpha Update

R&D day

News Flow

R&D Day 2022

Sunao Manabe
President and CEO

Ken Takeshita
Global R&D Head

Date and time	**Dec 12 (Mon) 17:30-19:00 EST** (Dec 13 (Tue) 7:30-9:00 JST)
Meeting style	Virtual (Zoom)

3ADCs Update

Alpha update

R&D day

News Flow

FY2022 News Flow

As of Oct 2022

Planned major publications

SABCS (Dec 6-10, 2022)

ENHERTU®	**DESTINY-Breast03: HER2+ BC, 2L, Ph3** • **Efficacy including OS and safety updates**
	DESTINY-Breast02: HER2+ BC, 3L, Ph3 • **Primary data**
	DESTINY-Breast07: HER2+ BC, 1/2L, Ph1b • **Initial data for dose expansion part**
Dato-DXd	**TROPION-PanTumor01: HR+/HER2- BC, Ph1** • **First data release**
	TROPION-PanTumor01: TNBC, Ph1 • **Data update**
	BEGONIA：TNBC, 1L (durvalumab combo), Ph1b/2 • **Data update**

Regulatory decisions

ENHERTU®	DESTINY-Breast03: HER2+ BC, 2L, Ph3 • JP: FY2022 H2 DESTINY-Gastric02: HER2+ BC, 2L, Ph2 • EU: FY2022 H2
Quizartinib	**QuANTUM-First: AML, 1L, Ph3** • **JP/US/EU: FY2023**

Planned regulatory submissions

DS-5670	Ph1/2/3: COVID-19 mRNA vaccines, booster vaccination • JP: FY2022 H2

Key data readouts

Dato-DXd	TROPION-Lung01*: NSCLC, 2/3L, Ph3 • FY2022 H2
DS-5670	Ph1/2/3：COVID-19 mRNA vaccines, booster vaccination • FY2022 H2

Planned pivotal study initiation

Dato-DXd	**TROPION-Lung07: non-squamous NSCLC w/o actionable genomic alterations, PD-L1 <50% 1L (pembrolizumab combo), Ph3** • **FY2022 H2**

Bold: update from FY2022 Q1

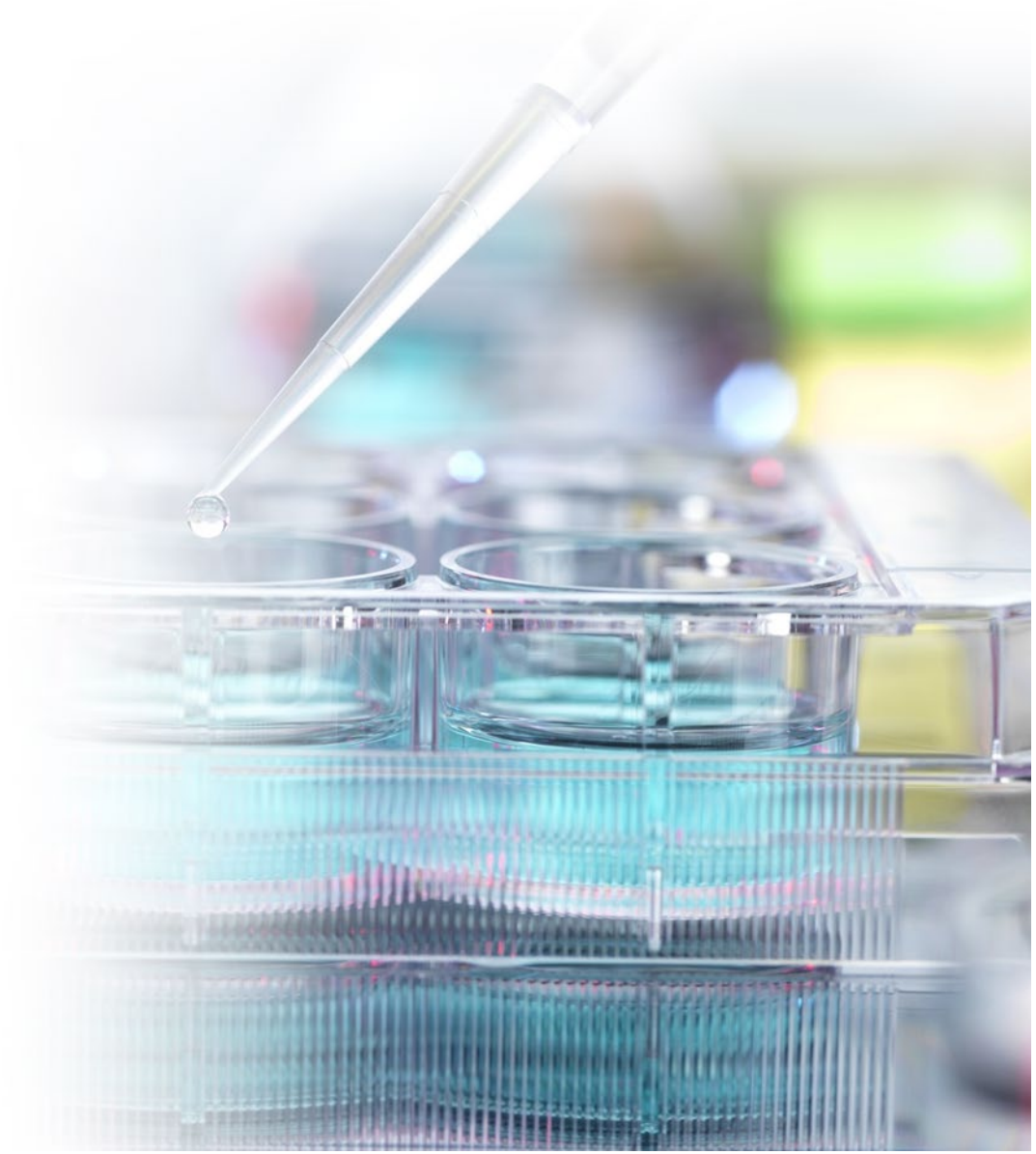
AML: acute myeloid leukemia, NSCLC: non-small cell lung cancer, TNBC: triple negative breast cancer

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

*Event-driven study

Agenda

1. FY2022 Q2 Financial Results
2. FY2022 Forecast
3. Business Update
4. R&D Update
5. **Appendix**



Major R&D Milestones (3ADCs)

As of Oct 2022

Project	Target Indication	[phase, study name]	FY2022 H1	FY2022 H2	FY2023
ENHERTU®	BC	• HER2+, 3L [P3, DESTINY-Breast02]	**• TLR obtained**		
		• HER2+, 2L [P3, DESTINY-Breast03]	• Approved (US/EU)	• Approval anticipated (JP)	
		• HER2 low, post chemo [P3, DESTINY-Breast04]	• Filing accepted (JP/EU/**China**) **• Approved (US)**		• Approval anticipated (JP/EU)
		• HER2 low, chemo naïve [P3, DESTINY-Breast06]			• TLR anticipated
	GC	• HER2+, 2L [P2, DESTINY-Gastric02, EU]		• Approval anticipated (EU)	
	NSCLC	• HER2 mutant, 2L [P2, DESTINY-Lung01, 02]	**• Approved (US)**	**• Filing anticipated (JP/EU)**	
		• HER2 mutant, 2L [P2, DESTINY-Lung05, China]	**• Study started**		
Dato-DXd	NSCLC	• 2/3L [P3, TROPION-Lung01]		• TLR anticipated	
	NSCLC	• 1L [P3, TROPION-Lung07]		**• Study start planned**	
	BC	• 1L TNBC IO-ineligible [P3, TROPION-Breast02]	**• Study started**		
	Solid tumors	• [P2, TROPION-PanTumor03]	**• Study started**		
HER3-DXd	NSCLC	• EGFR mutated, 3L [Registrational P2, HERTHENA-Lung01]			• TLR anticipated
		• EGFR mutated, 2L [P3, HERTHENA-Lung02]	**• Study started**		

Bold: update from FY2022 Q1

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

NSCLC: non-small cell lung cancer, TLR: Top Line Results, TNBC: triple negative breast cancer

Major R&D Milestones (Alpha)

As of Oct 2022

Project	Target Indication [phase, study name]	FY2022 H1	FY2022 H2	FY2023
Quizartinib	• AML, 1L [P3, JP/US/EU/Asia]	**• Filing accepted (JP/EU)**	**Filing accepted (US)**	• Approval anticipated (JP/US/EU)
Valemetostat (DS-3201)	• ATLL [Registrational P2, JP]	**• Approved (JP)**		
DS-1211	• PXE [P2, US/EU]		**• Study start planned**	
DS-5670	• COVID-19 mRNA vaccines, booster vaccination [P1/2/3, JP]		• TLR anticipated • Filing anticipated (JP)	
DS-5670	• COVID-19 mRNA vaccines, primary vaccination [P3, JP]	**• Study started**		
VN-0200	• RSV vaccine [P2, JP]		**• Study started**	

Bald: update from FY2022 Q1 AML: acute myeloid leukemia, ATLL: adult T-cell leukemia-lymphoma, PXE: pseudoxanthoma elasticum, RSV: respiratory syncytial virus, SCLC: small cell lung cancer、TLR: Top Line Results
Timeline indicated is based on the current forecast and subject to change.

Major R&D Pipeline: 3ADCs

As of Oct 2022

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 3L DESTINY-Breast02	(JP/China) HER2+ BC 2L DESTINY-Breast03
(US/EU/Asia) HER2 low BC Chemo naïve/ post chemo DESTINY-Breast08	(CN) HER2+ GC 3L DESTINY-Gastric06	(JP/US/EU/Asia) HER2+ BC adjuvant* DESTINY-Breast05	(EU) HER2+ GC 2L DESTINY-Gastric02
(JP/US/EU/Asia) HER2+ GC combo, 2L~/1L DESTINY-Gastric03	(JP/US/EU) HER2+ or HER2 mutant NSCLC 2L~ DESTINY-Lung01	(JP/US/EU/Asia) HER2 low BC chemo naïve DESTINY-Breast06	(JP/EU/China) HER2 low BC post chemo DESTINY-Breast04
(EU/Asia) HER2+ NSCLC (durvalumab combo) 1L DESTINY-Lung03	(JP/US/EU/Asia) HER2 mutant NSCLC 2L~ DESTINY-Lung02	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09	
(US/EU) BC, bladder (nivolumab combo)	(CN) HER2 mutant NSCLC 2L~ DESTINY-Lung05	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11	
(US/EU) BC, NSCLC (pembrolizumab combo)	(US/EU/Asia) NSCLC (durvalumab combo) 2L~ HUDSON	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	
(US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(JP/US/EU) HER2+ CRC 3L DESTINY-CRC01	(JP/US/EU/Asia) NSCLC (w/ HER2 exon 19 or exon 20 mutation) 1L DESTINY-Lung04	
	(JP/US/EU/Asia) HER2+ CRC 3L DESTINY-CRC02	(JP/US/EU/Asia) NSCLC 2/3L TROPION-Lung01	
	(JP/US/EU/Asia) HER2 mutant tumor DESTINY-PanTumor01	(JP/US/EU/Asia) NSCLC (w/o actionable mutation, pembro combo) 1L TROPION-Lung07 (in prep.)	
	(US/EU/Asia) HER2 expressing tumor DESTINY-PanTumor02	(JP/US/EU/Asia) NSCLC (w/o actionable mutation, pembro combo) 1L TROPION-Lung08	
		(JP/US/EU/Asia) HR+ BC 2/3L TROPION-Breast01	
		(JP/US/EU/Asia) TNBC 1L TROPION-Breast02	
		(JP/US/EU/Asia) EGFR mutated NSCLC 2L HERTHENA-Lung02	

Phase 1	Phase 2	Phase 3
(JP/US) NSCLC, TNBC, HR+ BC, SCLC, GC, urothelial, esophageal, prostate, etc. TROPION-PanTumor01	(JP/US/EU/Asia) endometrial, ovarian, prostate cancer, GC, CRC combo TROPION-PanTumor03	
(CN) NSCLC, TNBC TROPION-PanTumor02	(JP/US/EU/Asia) NSCLC (w/ actionable mutation) TROPION-Lung05	
(JP/US/EU/Asia) NSCLC (pembrolizumab combo) TROPION-Lung02	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	
(JP/US/EU) NSCLC (durvalumab combo) TROPION-Lung04	(JP/US/EU/Asia) EGFR mutated NSCLC 2L (osimertinib combo) ORCHARD	
(JP/US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(JP/US/EU/Asia) EGFR mutated NSCLC 3L HERTHENA-Lung01	
(JP/US/EU/Asia) NSCLC		
(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)

*DESTINY-Breast05: adjuvant therapy for patients with HER2 positive early breast cancer with high risk of disease recurrence who have residual invasive disease after receiving neo-adjuvant therapy

BC: breast cancer, CRC: colorectal cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, TNBC: triple negative breast cancer

Major R&D Pipeline: Alpha

As of Oct 2022

Phase 1	Phase 2	Phase 3	Filed
DS-7300 (JP/US) B7-H3-directed ADC ESCC, CRPC, squamous NSCLC, 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	VN-0107/MEDI3250 (JP) Live attenuated influenza vaccine nasal spray
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-6016 (JP) Anti-ALK2 antibody FOP	DS-7300 (JP/US/EU/Asia) B7-H3-directed ADC ES-SCLC	DS-5670 (JP) COVID-19 mRNA vaccine COVID-19 (booster vaccination)	
DS-7011 (US) Anti-TLR7 antibody Systemic lupus erythematosus	DS-5141 (JP) ENA oligonucleotide DMD	DS-5670 (JP) COVID-19 mRNA vaccine COVID-19 (primary vaccination, adults)	
DS-2325 (US) KLK5 inhibitor Netherton syndrome	DS-1211 (US/EU) TNAP inhibitor Pseudoxanthoma elasticum (in prep.)	DS-5670 (JP) COVID-19 mRNA vaccine, COVID-19 (primary vaccination, 12 to 17 aged children) (in prep.)	
PLX2853 (US) BET inhibitor AML	DS-5670 (JP) COVID-19 mRNA vaccine, COVID-19 (primary vaccination, 5 to 11 aged children) (in prep.)		
PLX2853 (US) BET inhibitor Solid tumor	VN-0200 (JP) RS virus vaccine RS virus infection		
PLX2853 (US) BET inhibitor Gynecologic neoplasms, ovarian cancer			
PLX2853 (US) BET inhibitor Prostate cancer			
DS-1594 (US) Menin-MLL binding inhibitor AML, ALL			
DS-9606 (US/EU) Target undisclosed ADC Solid tumors			

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 (JP/US/EU)

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 progressive, 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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