Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2022 Q1
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Hiroyuki Okuzawa

Director, Senior Executive Officer, CFO

July 29, 2022

Forward-Looking Statements

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

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

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

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

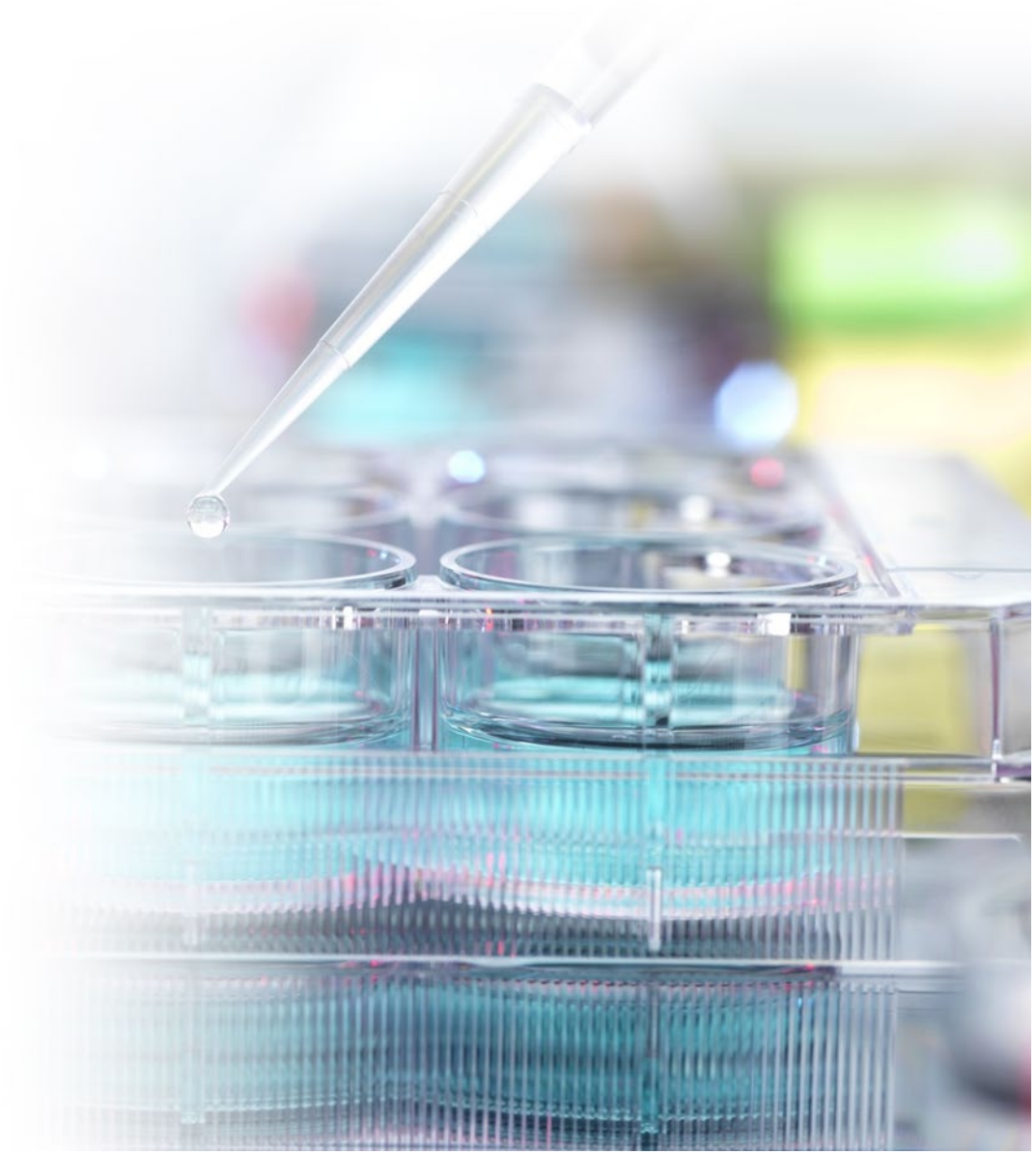
This material does not constitute a solicitation of application to acquire or an offer to sell any security in the United States, Japan or elsewhere.

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

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

Agenda

1. **FY2022 Q1 Financial Results**
2. Business Update
3. R&D Update
4. Appendix



Overview of FY2022 Q1 Results

(Bn JPY)

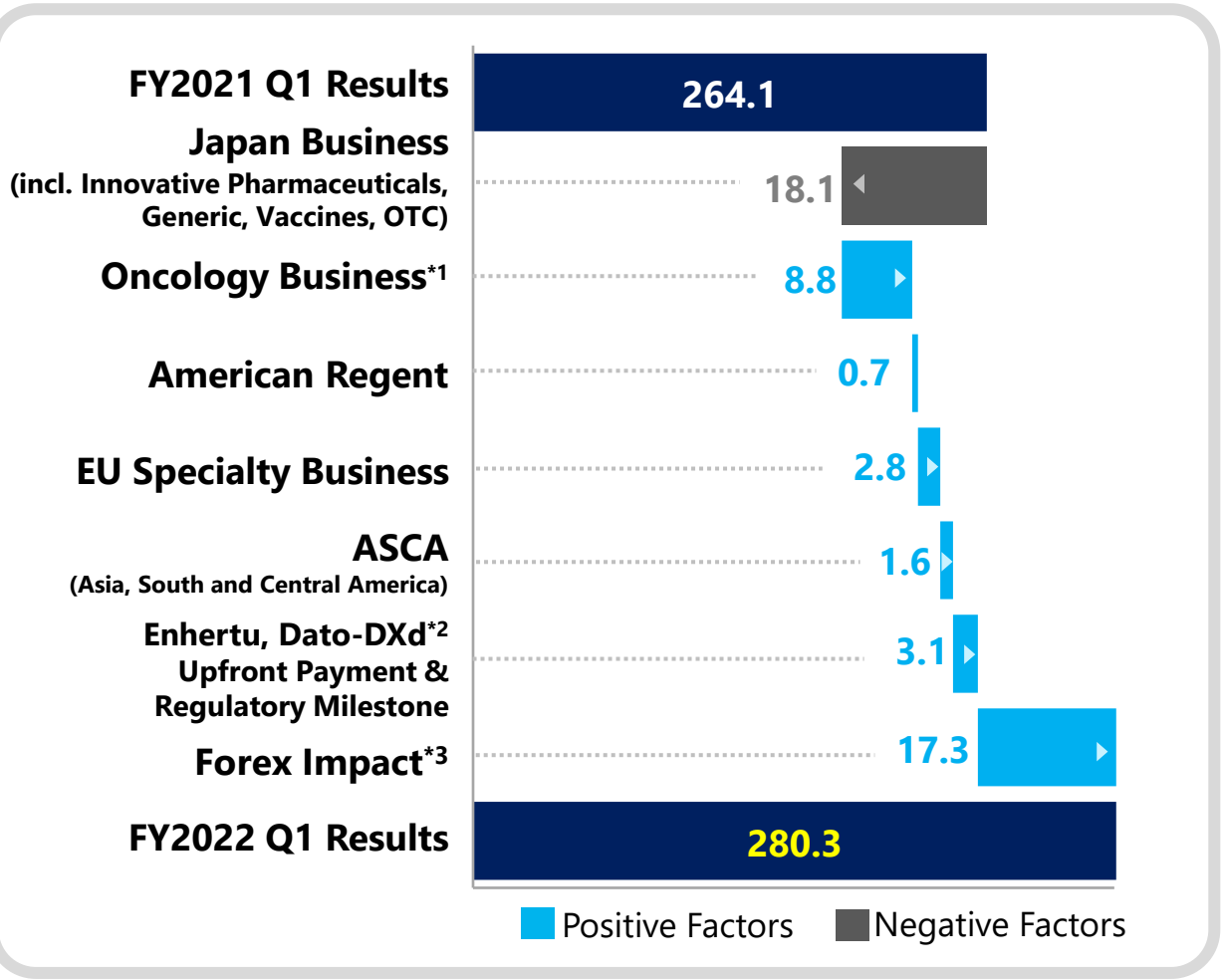
	FY2021 Q1 Results	FY2022 Q1 Results	YoY	
Revenue	**264.1**	**280.3**	+6.2%	**16.2**
Cost of sales *	85.2	74.7		-10.5
SG&A expenses *	81.2	96.3		15.1
R&D expenses *	54.0	74.9		20.9
Core operating profit *	**43.7**	**34.4**	-21.3%	**-9.3**
Temporary income *	2.1	0.0		-2.1
Temporary expenses *	0.0	-		-0.0
Operating profit	**45.8**	**34.4**	-24.9%	**-11.4**
Profit before tax	**47.1**	**29.4**		**-17.6**
Profit attributable to owners of the Company	**35.2**	**18.9**	-46.5%	**-16.4**

Currency Rate	USD/JPY	109.49	129.57	+20.08
	EUR/JPY	131.95	138.10	+6.15

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 16.2 Bn JPY (Decreased by 1.1 Bn JPY excl. forex impact)



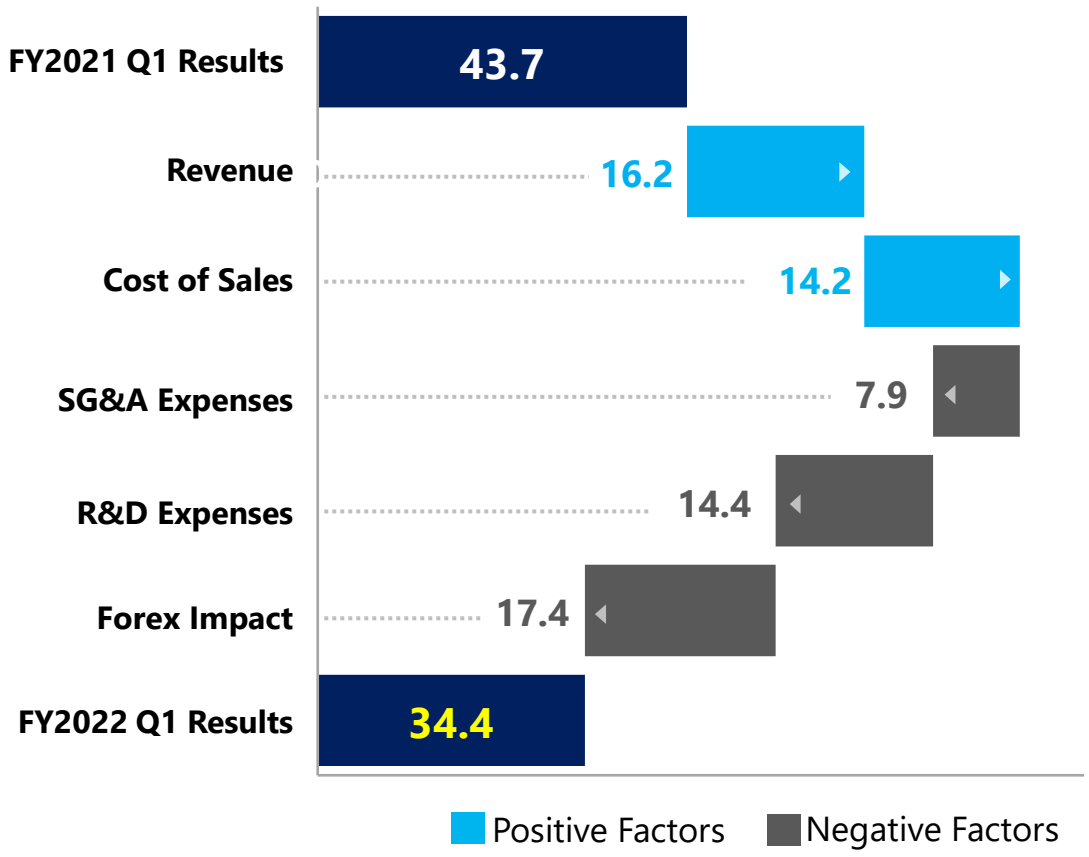
(Bn JPY)

Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+2.2	Nexium	-19.7
Tarlige	+1.8		
Daiichi Sankyo Espha	+1.0	Vaccines business	-0.9
Oncology Business*1 Unit			
Enhertu	+11.8	Olmesartan	-1.5
American Regent Unit			
Venofer	+2.5	Injectafer	-2.9
GE injectables	+1.0		
EU Specialty Business Unit			
Lixiana	+3.9	Gain on sales of transferring long-listed products	-1.1
Enhertu, Dato-DXd*2 Upfront Payment & Regulatory Milestone			
Enhertu Regulatory Milestone	+2.8		

*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products
*2 Dato-DXd: Datopotamab deruxtecan (DS-1062)
*3 Forex impact USD: +11.5, EUR : +1.9, ASCA: +3.8

Core Operating Profit

Decreased by 9.3 Bn JPY (Decreased by 9.1 Bn JPY excl. forex impact)



(Bn JPY)

Revenue +16.2
incl. forex impact of +17.3

Cost of Sales -14.2
Improvement in cost of sales ratio by change in product mix

SG&A Expenses +7.9
Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca

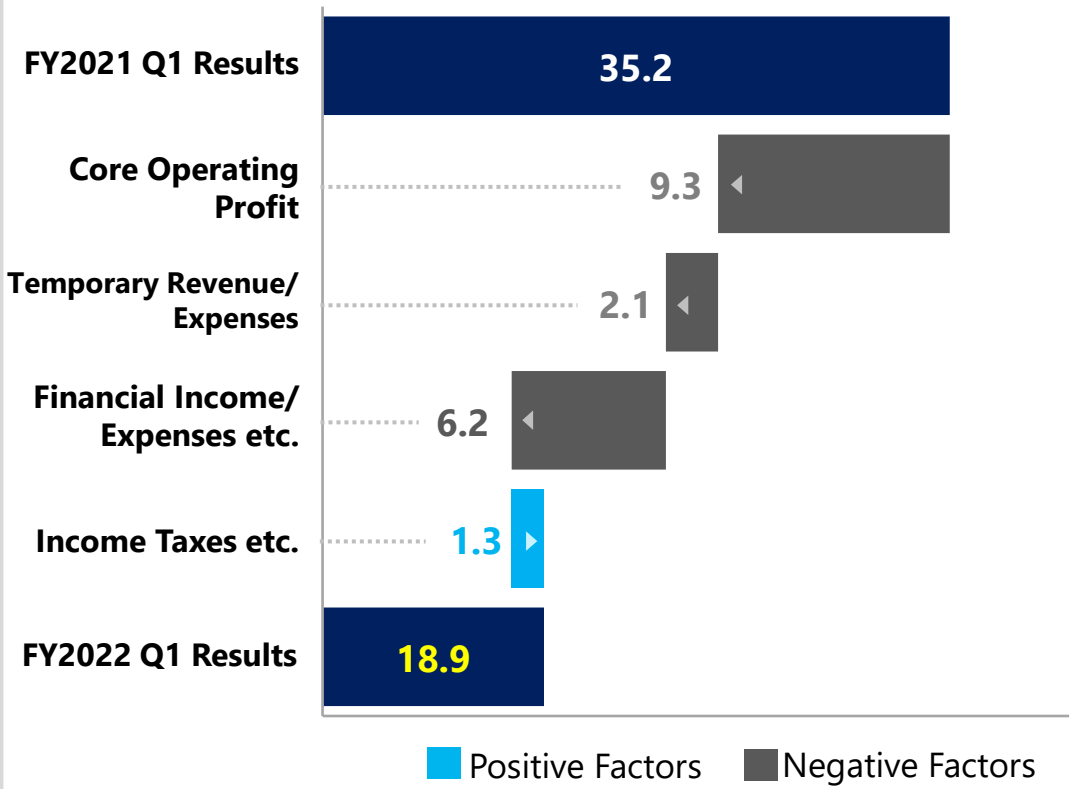
R&D Expenses +14.4
Increase in 3ADCs* R&D investments

Forex Impact +17.4 (Profit Decreased)
Cost of Sales +3.7
SG&A Expenses +7.2
R&D Expenses +6.5

* 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 16.4 Bn JPY



(Bn JPY)

Temporary Revenue/Expenses ····· **+2.1 (Profit Decreased)**

FY2021: Gains related to sale of Osaka logistics center (2.1)

Financial Income/Expenses etc. ····· **+6.2 (Profit Decreased)**

- Deterioration in forex gains/losses ····· **+3.2**
- Deterioration in investment securities valuation gains / losses ····· **+2.8**

Income Taxes etc. ····· **+1.3**

	FY2021 Q1	FY2022 Q1	YoY
Profit before Tax	47.1	29.4	-17.6
Income Taxes etc.	11.8	10.6	-1.3
Tax rate	25.2%	35.9%	+10.7%

Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2021 Q1 Results	FY2022 Q1 Results	YoY
Japan Business	129.1	109.0	-20.1
Daiichi Sankyo Healthcare	15.4	15.3	-0.1
Oncolgy Business	14.5	27.5	+13.1
Enhertu	10.8	26.7	+15.9
Turalio	0.6	0.8	+0.2
American Regent	39.1	47.0	+7.9
Injectafer	14.9	14.1	-0.8
Venofer	7.9	12.4	+4.5
GE injectables	13.8	17.6	+3.8
EU Speciality Business	32.7	37.1	+4.4
Lixiana	23.4	28.6	+5.2
Nilemdo/Nustendi	0.7	1.3	+0.6
Olmesartan	5.6	5.4	-0.2
ASCA (Asia, South and Central America) Business	26.5	31.9	+5.4

Currency Rate	USD/JPY	109.49	129.57	+20.08
	EUR/JPY	131.95	138.10	+6.15

Revenue: Major Products in Japan

(Bn JPY)

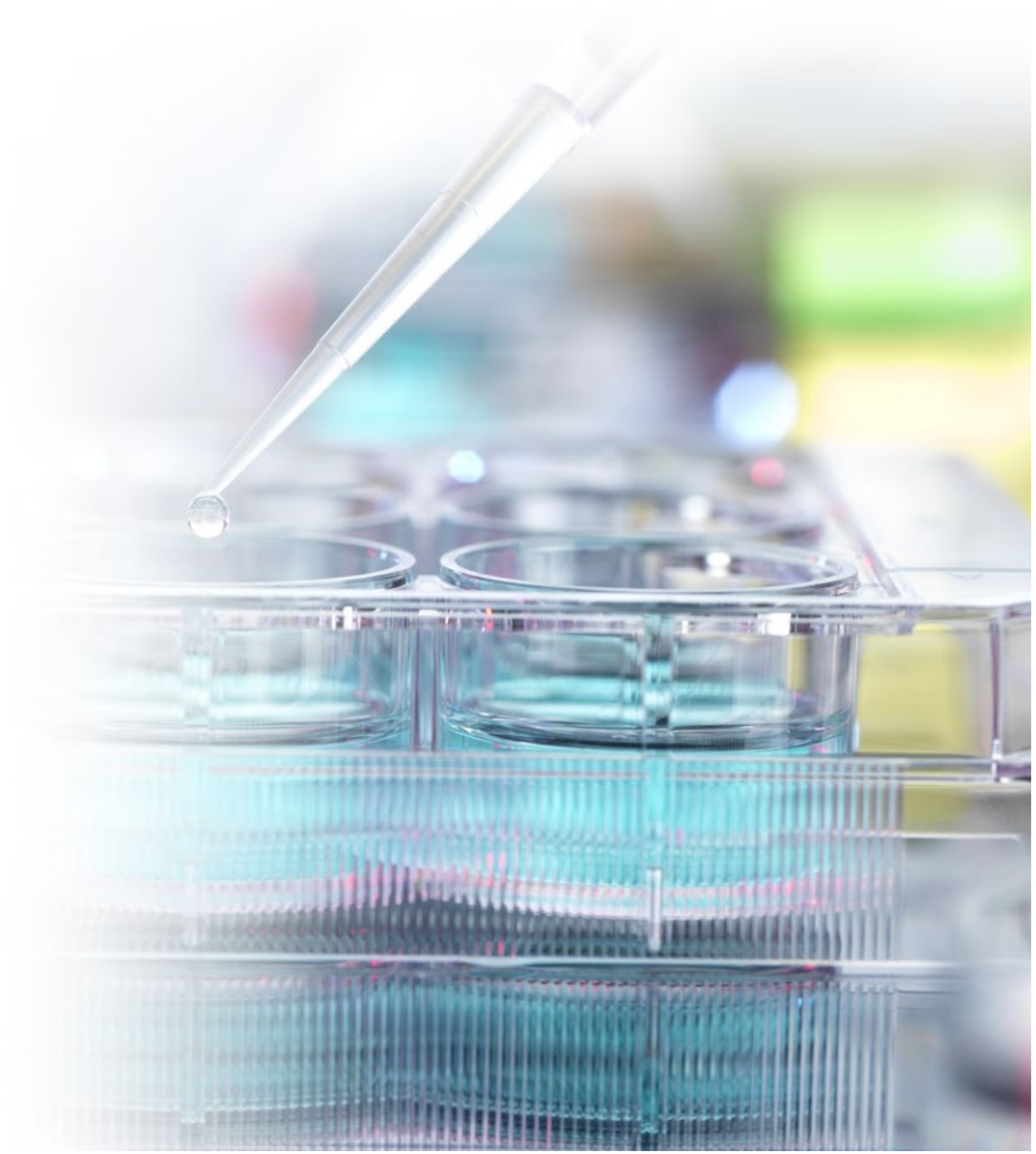
		FY2021 Q1 Results	FY2022 Q1 Results	YoY
Lixiana	anticoagulant	**22.9**	**25.1**	**+2.2**
Tarlige	pain treatment	**7.1**	**8.9**	**+1.8**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**9.2**	**9.9**	**+0.7**
Efient	antiplatelet agent	**4.1**	**4.9**	**+0.7**
Tenelia	type 2 diabetes mellitus treatment	**6.4**	**5.6**	**-0.8**
Vimpat	anti-epileptic agent	**4.5**	**5.3**	**+0.8**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**5.1**	**4.9**	**-0.2**
Canalia	type 2 diabetes mellitus treatment	**4.3**	**4.1**	**-0.3**
Loxonin	anti-inflammatory analgesic	**5.8**	**4.6**	**-1.2**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**2.2**	**2.4**	**+0.3**
Emgality	prophylaxis of migraine attacks	**0.9**	**1.4**	**+0.6**

1 FY2021 Q1 Financial Results

2 **Business Update**

3 R&D Update

4 Appendix



ENHERTU®

Revenue

(Bn JPY)

	FY2022 Q1 Results	YoY	FY2022 Forecast	YoY	<Reference> Total Consideration
Product Sales	31.3	18.4	128.4	63.0	-
Japan	2.4	0.3	16.0	6.4	-
US	20.0	10.5	83.1	37.7	-
Europe	6.7	5.5	23.0	14.0	-
ASCA	2.2	2.2	6.3	4.9	-
Upfront payment	2.5 *1	-	9.8 *1	-	149.0
Regulatory milestone payment	3.4 *1	2.8	20.6 *1	18.3	100.3
US HER2+ Breast Cancer 3L	0.2	-	0.9	-	13.7
EU HER2+ Breast Cancer 3L	0.1	-	0.5	-	7.9
US HER2+ Gastric Cancer 2L + 3L	0.2	-	0.8	-	12.1
US HER2+ Breast Cancer 2L	2.8	2.8	3.4	3.4	13.1
EU HER2+ Breast Cancer 2L	-	-	2.6	2.6	9.8 *2
US HER2-low Breast Cancer (post-chemo)	-	-	6.9	6.9	26.0 *2
EU HER2+ Gastric Cancer 2L	-	-	1.2	1.2	4.6 *2
US HER2+ or HER2 Mutant NSCLC 2L	-	-	4.3	4.3	13.1 *2
Quid related payment	0.3 *1	0.3	1.1 *1	-2.3	17.2
Total	37.4	21.4	159.9	79.1	266.5

*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 130 JPY to 1 USD

ENHERTU®

Performance in Each Region (US, EU)

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

Global product sales: FY2022 Q1 results 31.3 Bn JPY（YoY +18.4 Bn JPY）FY2022 forecast 128.4 Bn JPY（YoY +63.0 Bn JPY）

US

- **Product sales:** **FY2022 Q1 results 20.0 Bn JPY (155 Mn USD)**
  FY2022 forecast 83.1 Bn JPY (639 Mn USD)
- **Indication:** HER2+ BC 2L/3L, HER2+ GC 2L
- **Market share status**
  - HER2+ BC 3L: Maintaining No.1 new patient share
  - HER2+ BC 2L: Achieving No.1 new patient share already
  - HER2+ GC 2L: Achieving 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)

Europe

- **Product sales:** **FY2022 Q1 results 6.7 Bn JPY (52 Mn USD)**
  FY2022 forecast 23.0 Bn JPY (177 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

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 Q1 results 31.3 Bn JPY（YoY +18.4 Bn JPY）FY2022 forecast 128.4 Bn JPY（YoY +63.0 Bn JPY）

Japan

- **Product sales:** **FY2022 Q1 results 2.4 Bn JPY (19 Mn USD)**
  FY2022 forecast 16.0 Bn JPY (123 Mn USD)
- **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 (Jun. 2022)

ASCA

- **Product sales:** **FY2022 Q1 results 2.2 Bn JPY (17 Mn USD)**
  FY2022 forecast 6.3 Bn JPY (48 Mn USD)
- **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

Initiatives Related to Profit Growth for Current Business and Products

Enhance product portfolio in Japan Business

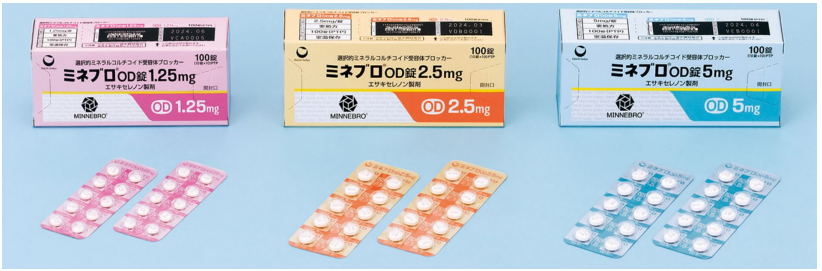
◆ **REYVOW® Migraine treatment**

➢ **Launched**[*1] in June 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.

◆ **MINEBRO® Orally Disintegrating Tablet Antihypertensive agent**

➢ **Launched** in May 2022



Enhance transformation into a profit structure focused on patented drugs

◆ **Concluded an asset sale agreement in Europe**

➢ Divested Products：**EFIENT® Antiplatelet agent** (FY2021 Revenue：1.5 Bn JPY)

➢ Date of Agreement：**June 2022**

➢ New Owner：**Substipharm**

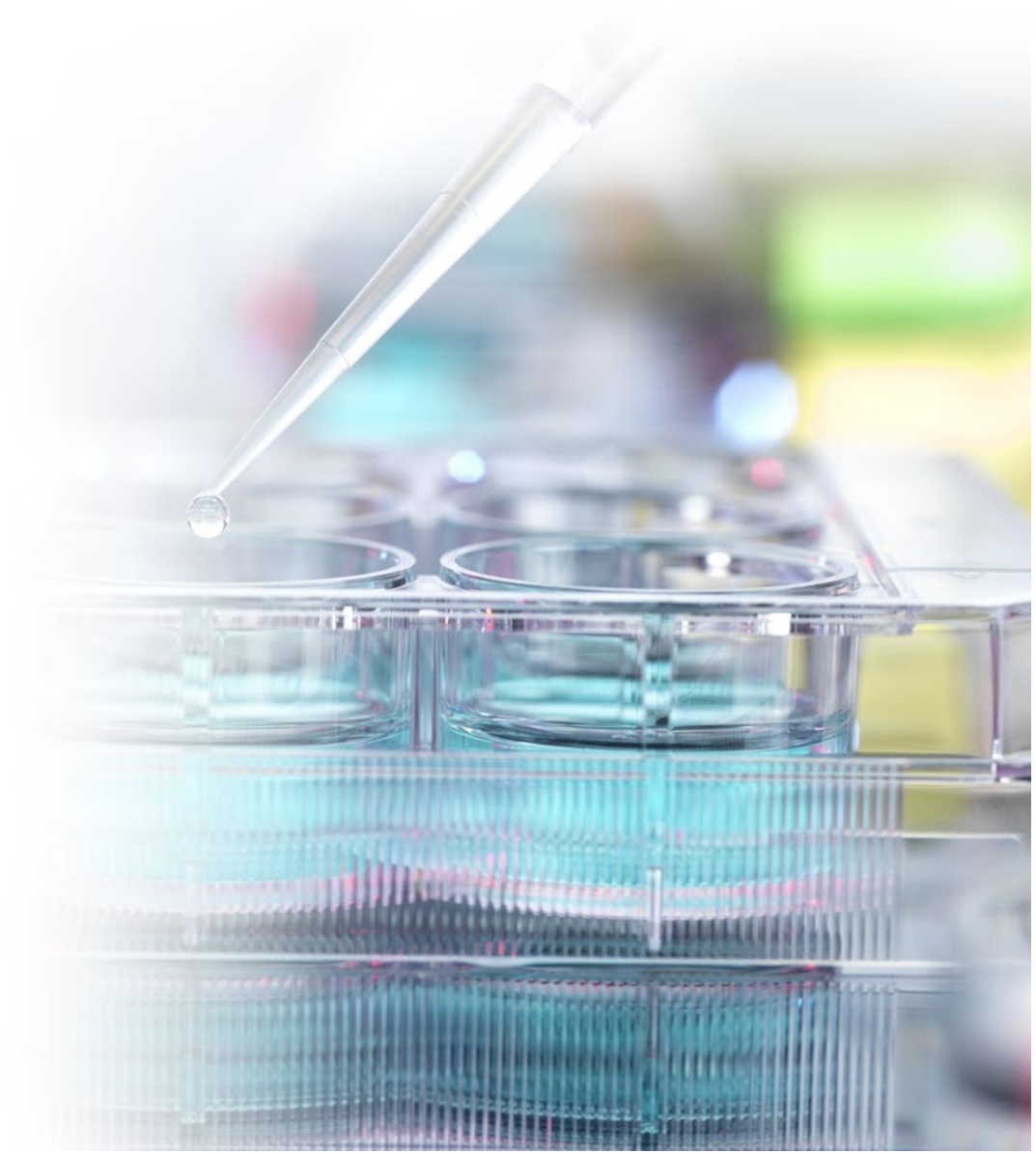
14

1 FY2021 Q1 Financial Results

2 Business Update

3 **R&D Update**

4 Appendix



3ADC Update

Alpha Update

News Flow

ENHERTU®

DESTINY-Breast04 study

Pioneer HER2 low BC as a new clinically meaningful patient segment

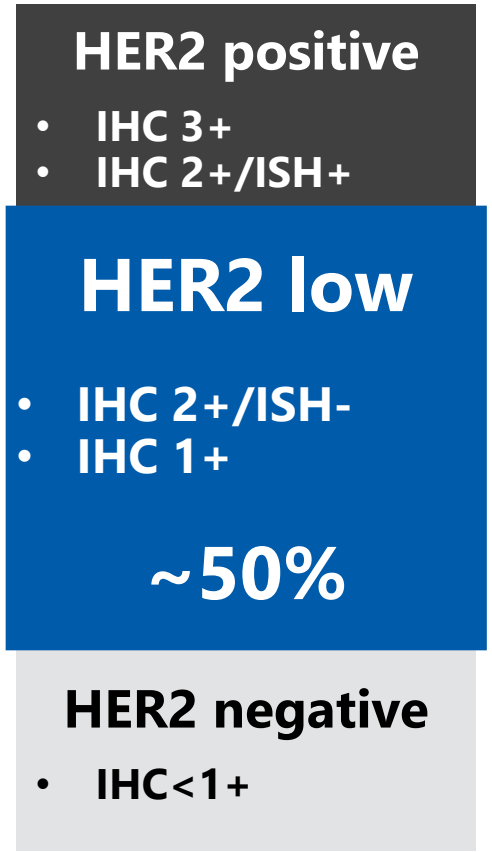
- ENHERTU® **met the primary endpoint and all key secondary endpoints** in the global Ph3 study for **patients with HER2 low breast cancer** previously treated with chemotherapy

- ENHERTU® is the **first and only HER2-directed therapy** to demonstrate a survival benefit for patients with HER2 low breast cancer. In Jun 2022, ENHERTU® was listed in US NCCN guidelines as preferred regimen (category 1) for HER2 low breast cancer previously treated with chemotherapy

- **About 50% of all breast cancer patients** are reclassified as HER2 low, a new targetable patient segment

Regulatory submission status in each countries

- Jun 2022: Filing accepted in JP & EU
- Jul 2022: Filing accepted and granted priority review in US (PDUFA date Nov 26)
- FY2022 Q2: Filing planned in China



BC: breast cancer, NCCN: National Comprehensive Cancer Network

ENHERTU®

DESTINY-Breast04 data

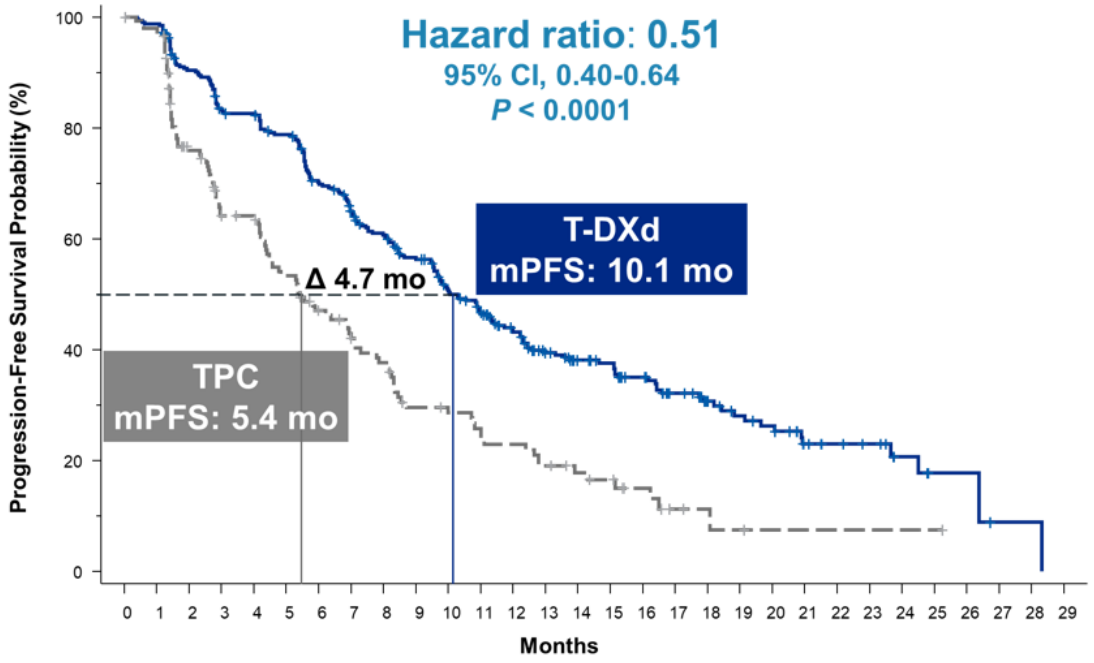
ASCO 2022 Highlights (Plenary Session)

Daiichi-Sankyo

PFS in patients with HR+/HER2 low BC

- **49% reduction in the risk of disease progression or death** versus chemo, mPFS of **10.1m** compared to 5.4m with chemo

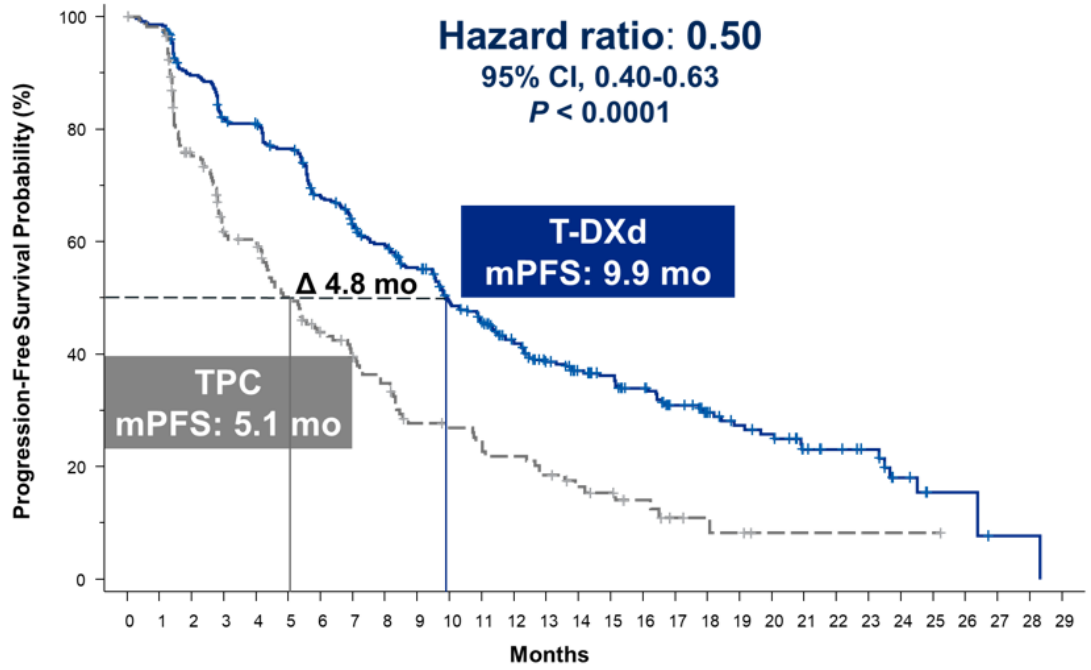
PFS（HR+）



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

- **50% reduction in the risk of disease progression or death** versus chemo, mPFS of **9.9m** compared to 5.1m with chemo

PFS (All patients)



BC: breast cancer, HR: hormone receptor, mPFS: median progression-free survival, PFS: progression-free survival, T-DXd: trastuzumab deruxtecan, TPC: treatment of physician's choice

ENHERTU®

DESTINY-Breast04 data

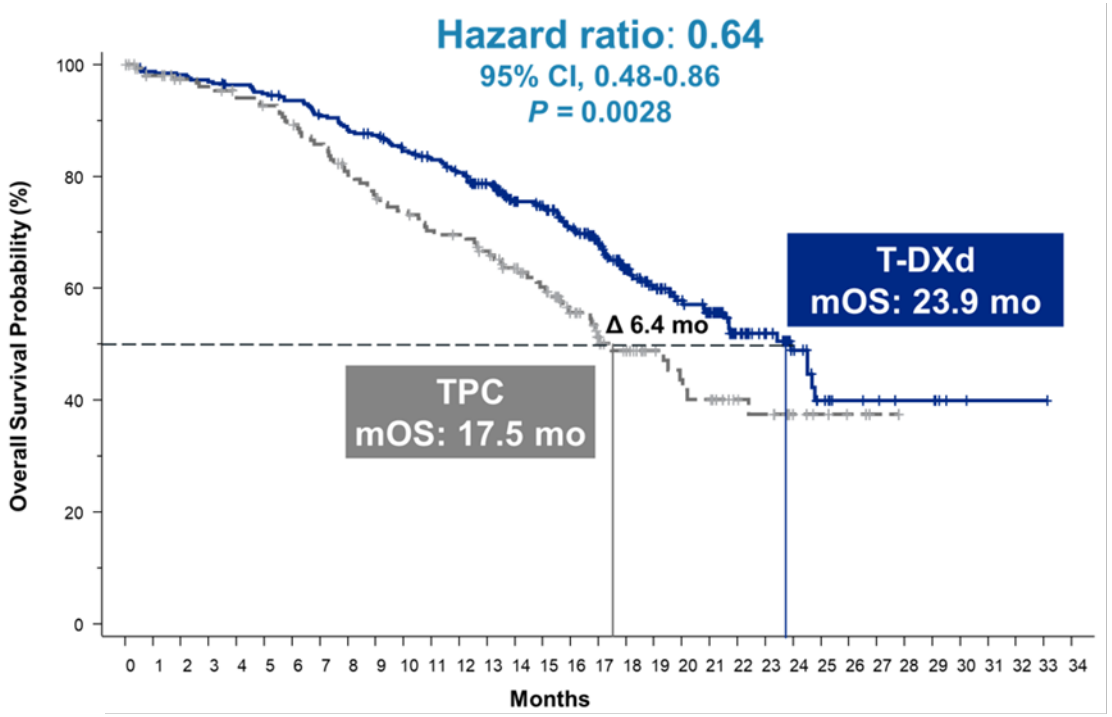
ASCO 2022 Highlights (Plenary Session)

Daiichi-Sankyo

OS in patients with HR+/HER2 low BC

- **36% reduction in the risk of death** versus chemo, mOS of **23.9m** compared to 17.5m with chemo

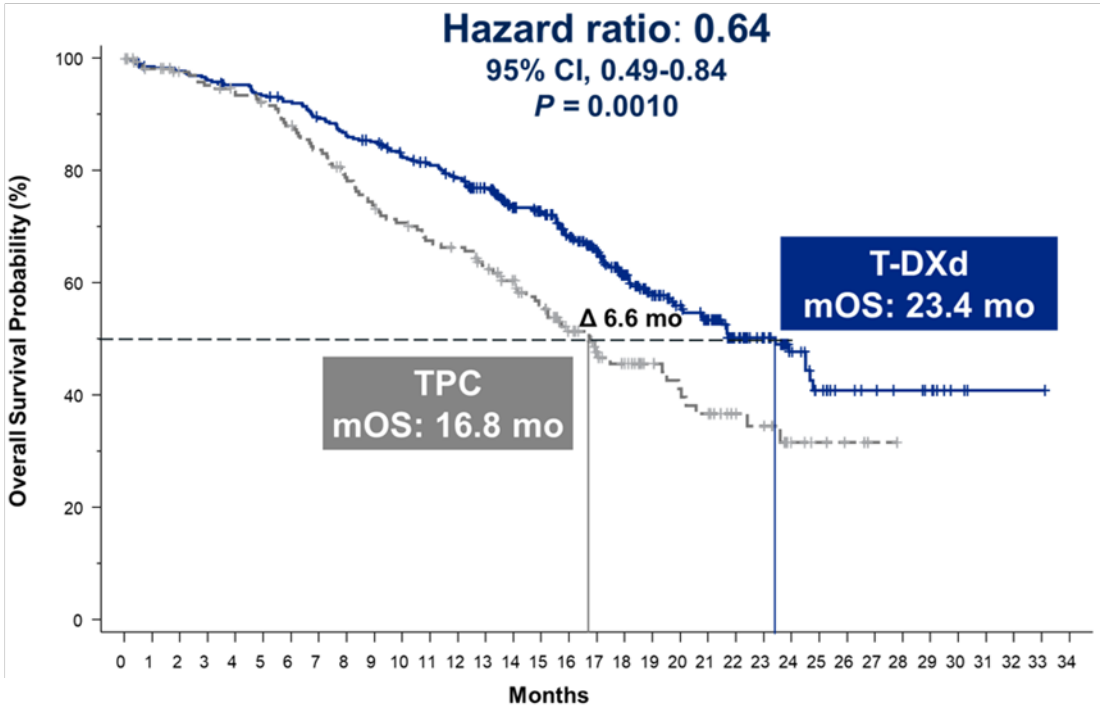
OS（HR+）



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

- **36% reduction in the risk of death** versus chemo, mOS of **23.4m** compared to 16.8m with chemo

OS (All patients)



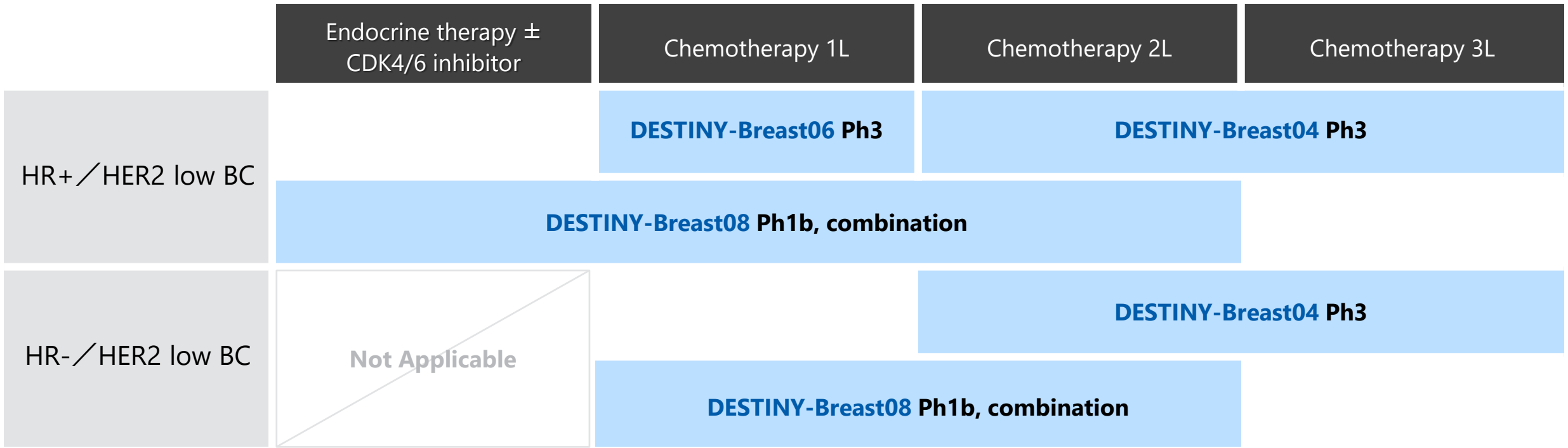
BC: breast cancer, HR: hormone receptor, mOS: median overall survival, OS: overall survival, T-DXd: trastuzumab deruxtecan, TPC: treatment of physician's choice

ENHERTU®

Development of HER2 low breast cancer

Daiichi-Sankyo

Now conducting DESTINY-Breast06/08 studies in earlier lines of HER2 low breast cancer and further development is under discussion

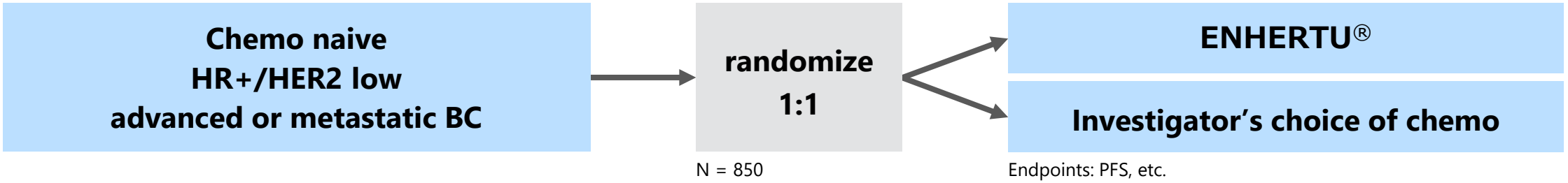


BC: breast cancer, HR: hormone receptor

ENHERTU®

DESTINY-Breast06/08 studies

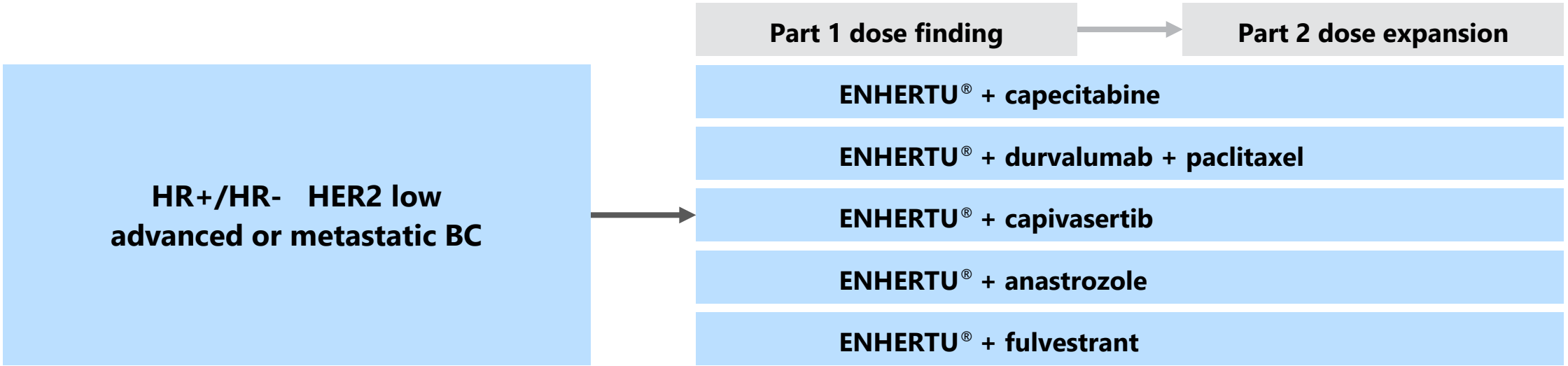
■ DESTINY-Breast06 Ph3 study design



N = 850

Endpoints: PFS, etc.

■ DESTINY-Breast08 Ph1b study design



N = 182 Endpoints: safety, efficacy, etc.

BC: breast cancer、PFS: progression free survival

DESTINY-Breast03 safety data update

ASCO 2022 Highlights

Daiichi-Sankyo

The data reinforce the established favorable benefit/risk profile over T-DM1 in HER2+ BC

Safety update overview (Sep 7, 2021)

- No new safety signals were observed for T-DXd
- Incidence rates of AEs were similar between the T-DXd and T-DM1 arms

n (%)	T-DXd n = 257	T-DM1 n = 261
Patients discontinued from study treatment	141 (54.9)	222 (85.1)
Any grade TEAE	256 (99.6)	249 (95.4)
Grade ≥3 TEAE	137 (53.3)	130 (49.8)
Any grade serious TEAE	54 (21.0)	50 (19.2)
Grade ≥3 serious TEAE	39 (15.2)	38 (14.6)
TEAE associated with drug discontinuation	38 (14.8)	19 (7.3)
TEAE associated with dose reduction	59 (23.0)	36 (13.8)

AE: adverse events, BC: breast cancer, TEAE, treatment-emergent adverse event.

Adjudicated drug-related ILD/pneumonitis

- No Gr4/5 ILD/pneumonitis occurred in the T-DXd arm

	T-DXd n = 257	T-DM1 n = 261
Any grade, n (%)	28 (10.9)	5 (1.9)
Grade 1	7 (2.7)	4 (1.5)
Grade 2	19 (7.4)	1 (0.4)
Grade 3	2 (0.8)	0
Grade 4	0	0
Grade 5	0	0
Time to first onset, median (range), days	181 (33-507)	289 (80-499)
Outcome of worst event, n (%)		
Fatal	0	1 (20.0)[a]
Not recovered/not resolved	8 (28.6)	0
Ongoing	0	0
Recovering/resolving	2 (7.1)	0
Recovered/resolved with sequelae	2 (7.1)	0
Recovered/resolved	16 (57.1)	4 (80.0)

[a]Patient had an event of pulmonary embolism that the investigator considered to be grade 5. This was initially reported as respiratory failure but subsequently updated to pulmonary embolism. The ILD adjudication committee adjudicated this event as drug-related grade 1 ILD／pneumonitis. The death was not evaluable for adjudication. The investigator recorded disease progression as the primary cause of death.[1]

1. Cortés J et al. *N Engl J Med.* 2022;386:1143-1154 （supplementary appendix）.

ENHERTU®

FY2022 approval status

HER2+ BC 2L

- May 2022: FDA approval based on Priority Review, Breakthrough Therapy Designation and Real Time Oncology Review program
- Jul 2022: EMA approval

* Approval also obtained in the countries joining Project Orbis (Brazil, Australia, Israel, Canada, Switzerland) in FY2022 H1

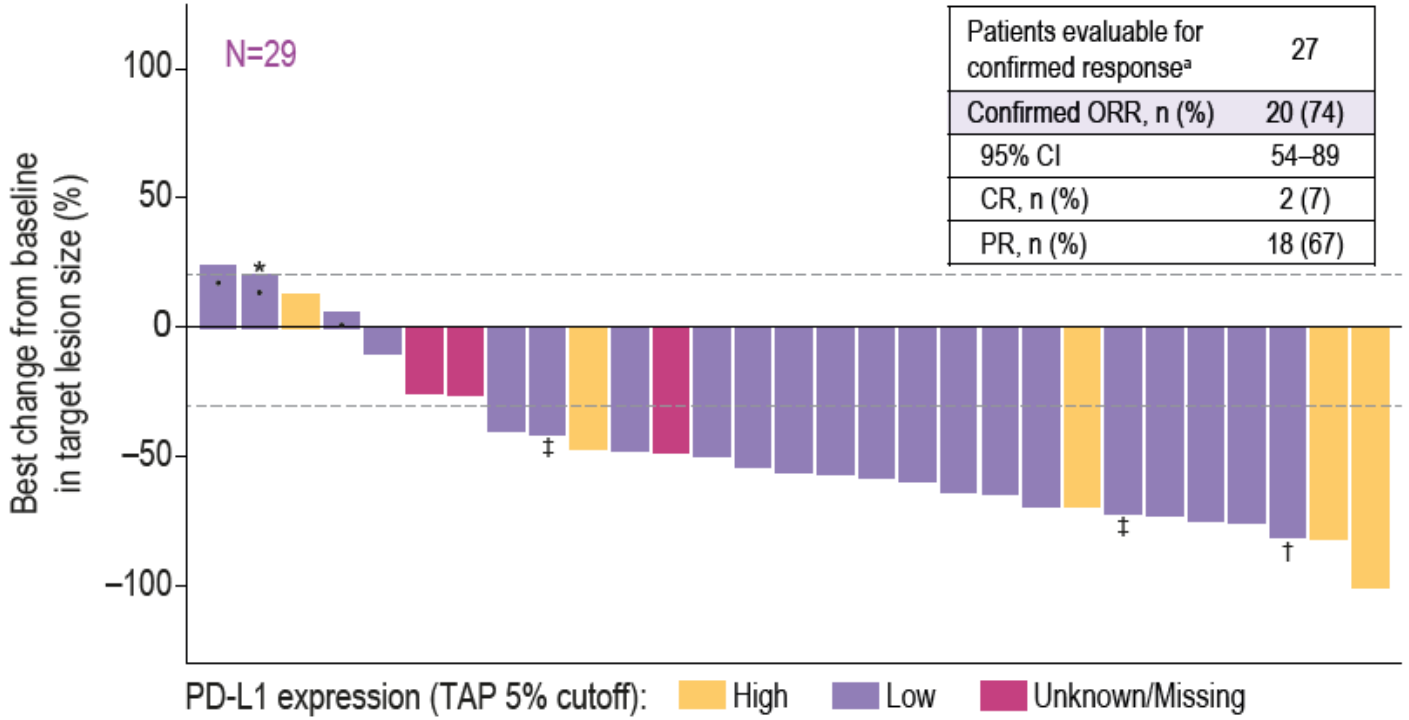
BC: breast cancer

BEGONIA study interim data

ESMO BC 2022 Highlights

Evidence of strong synergy between Dato-DXd and immune checkpoint inhibitor supports further development in TNBC

Anti-tumor activity



Patients evaluable for confirmed response[a]	27
Confirmed ORR, n (%)	20 (74)
95% CI	54–89
CR, n (%)	2 (7)
PR, n (%)	18 (67)

aHad the opportunity to have 2 postbaseline scans. Dotted lines indicate thresholds for partial response (−30%) and progressive disease (20%).
*If the best percentage change from baseline of target lesions cannot be calculated due to progression, withdrawal, or death, the value is imputed at +20%.
"•" Patients with PD as best overall response. †CR with lymph node disease (CR per RECIST in lymph nodes, is <10mm). ‡ Unconfirmed response.
CR, complete response; ORR, objective response rate; PR, partial response, TNBC, triple negative breast cancer.

BEGONIA study

Ph1b/2 study for TNBC 1L sponsored by AstraZeneca. Several drugs are tested for combination with durvalumab.

- Responses were observed regardless of PD-L1 expression, and **confirmed ORR was 74%**
- Combination of Dato-DXd + durvalumab demonstrated a safety profile which was consistent with known profile of the individual agents
- Part 1 is completed and enrollment of part 2 (expansion) is ongoing

New clinical study

TROPION-Breast02 study (TNBC 1L, Ph3) started in Jun 2022,
TROPION-PanTumor02 study (NSCLC/TNBC, Ph1/2, China only) started in Jul 2022

■ TROPION-Breast02 Ph3 study design

*Patients who are not candidates for PD-1/PD-L1 inhibitor therapy

N = 600

Endpoints: PFS, OS, etc.

■ TROPION-PanTumor02 Ph1/2 study design

Possibility to add new cohorts for other tumors in the future

NSCLC: non small cell lung cancer, ORR: overall response rate, OS: overall survival, PFS: progression free survival, TNBC: triple negative breast cancer

Breast cancer Ph1/2 study data

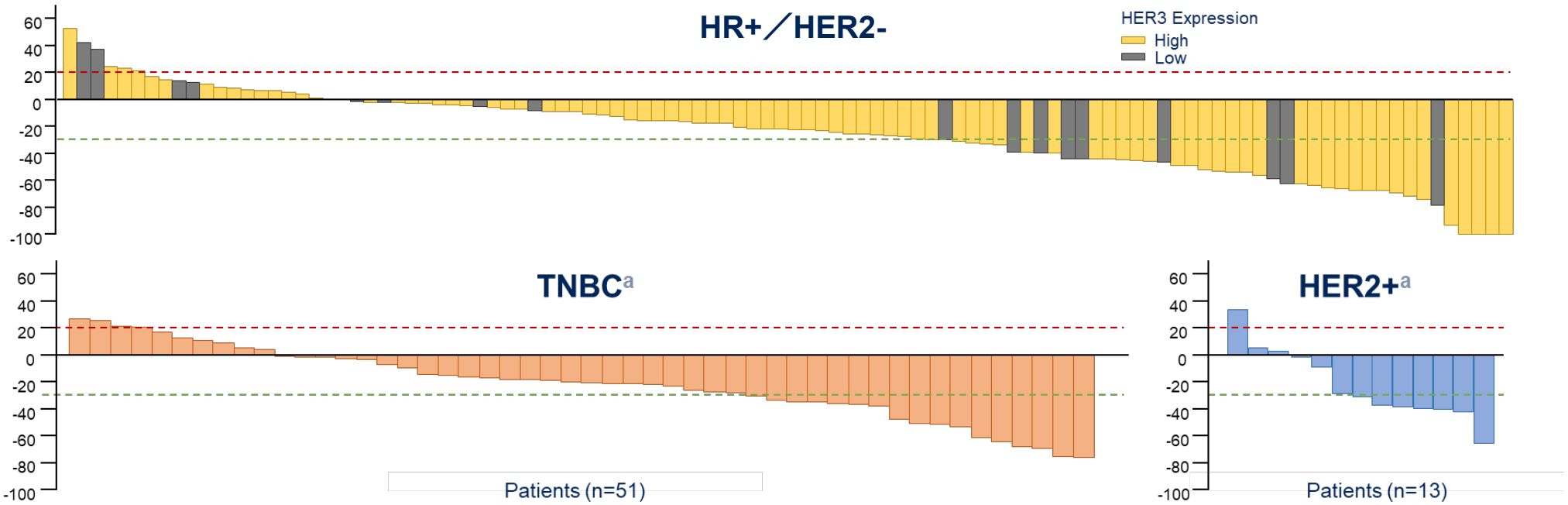
ASCO 2022 Highlights

Daiichi-Sankyo

Clinically meaningful and durable responses were observed across breast cancer subtypes, responses were seen across a broad range of HER3 expression

Anti-tumor activities (HR+/HER2-, TNBC, HER2+ cohorts)

- HR+/HER2- （ORR 30%, mDOR 7.2m）, TNBC （ORR 23%, mDOR 5.9m）, HER2+ （ORR 43%, mDOR 8.3m）



a Patients with TNBC and HER2+ were all HER3-high.
b Best percentage change from baseline in sum of diameters based on BICR for all target lesions identified is represented by patient. If any lesion measurement is missing at a post-baseline tumor assessment visit, that visit is not taken into consideration for best percent change from baseline in sum of diameters.

DOR: duration of response, HR: hormone receptor, ORR: objective response rate, TNBC: triple negative breast cancer

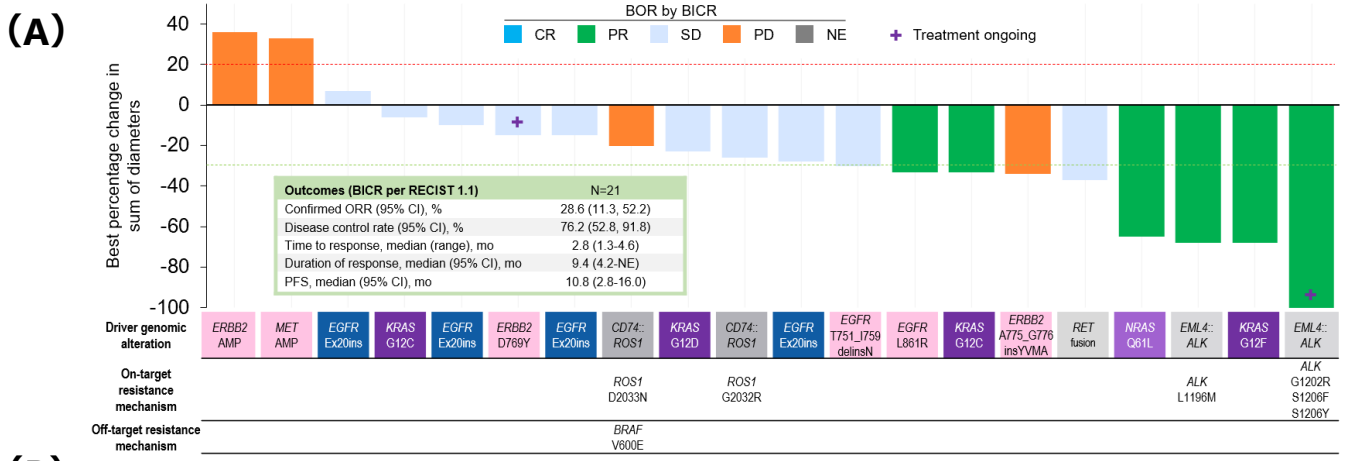
NSCLC Ph1 study cohort 2 data

ASCO 2022 Highlights

Daiichi-Sankyo

The promising clinical activity of HER3-DXd in patients with NSCLC harboring a broad range of genomic alterations or without genomic alterations

Anti-tumor activity (With (A) or Without (B) genomic alterations)



Data cutoff: January 28, 2022. Twenty of 21 patients with identified driver mutations, and 24 of 26 patients without, had best percentage change in sum of diameters data available.

Cohort 2

Patients with advanced NSCLC without common EGFR mutations

- HER3-DXd showed promising clinical activity and manageable safety profile in patients with or without genomic alterations
- Presented cohort 1 data with EGFR mutations at last year's ASCO

BICR: blinded independent central review, BOR: best objective response, NSCLC: non small cell lung cancer

3ADC Update

Alpha Update

News Flow

DS-7300

ES-SCLC Ph2 study

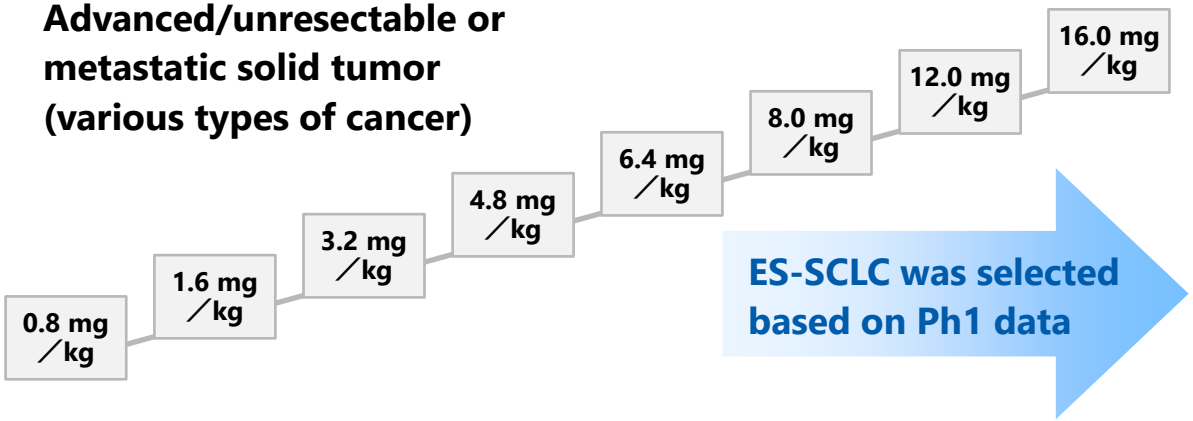
Development update

Ph2 dose-finding study for ES-SCLC was initiated in June

Ph1/2 study design

Dose escalation (Part 1)

Advanced/unresectable or metastatic solid tumor (various types of cancer)



Dose expansion (Part 2)

［Cohort 1］ESCC
［Cohort 2］CRPC
［Cohort 3］Squamous NSCLC

ES-SCLC Ph2 study design

ES-SCLC 2L or later → **randomize 1:1** → **DS-7300 8mg/kg** / **DS-7300 12mg/kg**

N = 80

Primary endpoint: ORR

Secondary endpoint: PFS, DOR, OS, etc

- Extensive stage (ES) means cancer spreads across a wide area and surgical operation and radiation therapy are not applicable
- No effective treatment and high unmet need for ES-SCLC 2L or later
- Efficacy and safety of two doses will be evaluated in Ph2 study in patients with ES-SCLC who received at least one prior line of platinum-based chemotherapy
- Option for addition of 60 patient expansion at RP2D

CRPC: castration-resistant prostate cancer, DOR: duration of response , ESCC: esophageal squamous cell carcinoma, NSCLC: non small cell lung cancer, ORR: objective response rate, OS: overall survival, PFS: progression free survival, RP2D: recommended Ph2 dose, SCLC: small cell lung cancer

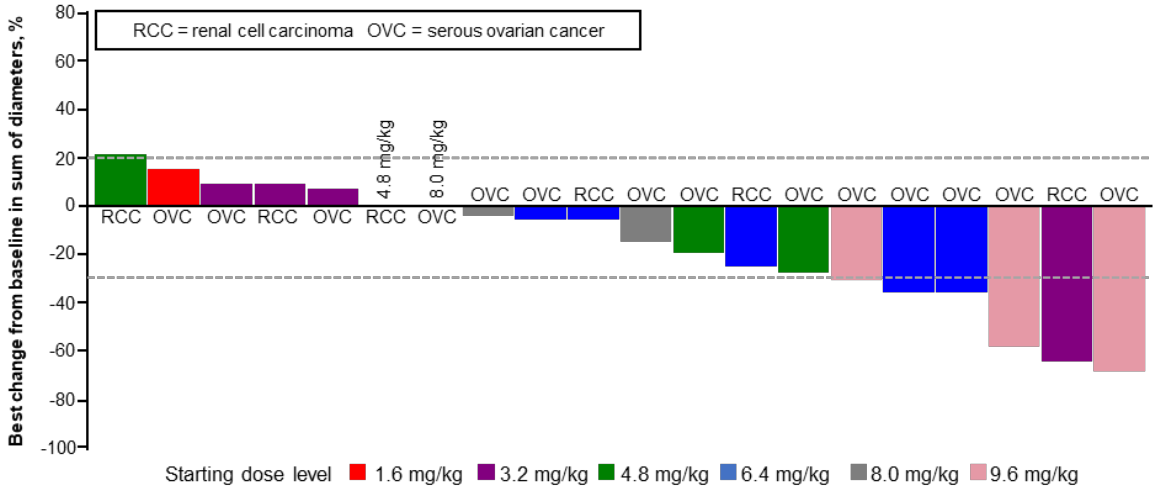
Ovarian cancer/renal cell carcinoma Ph1 data

ASCO 2022 Highlights

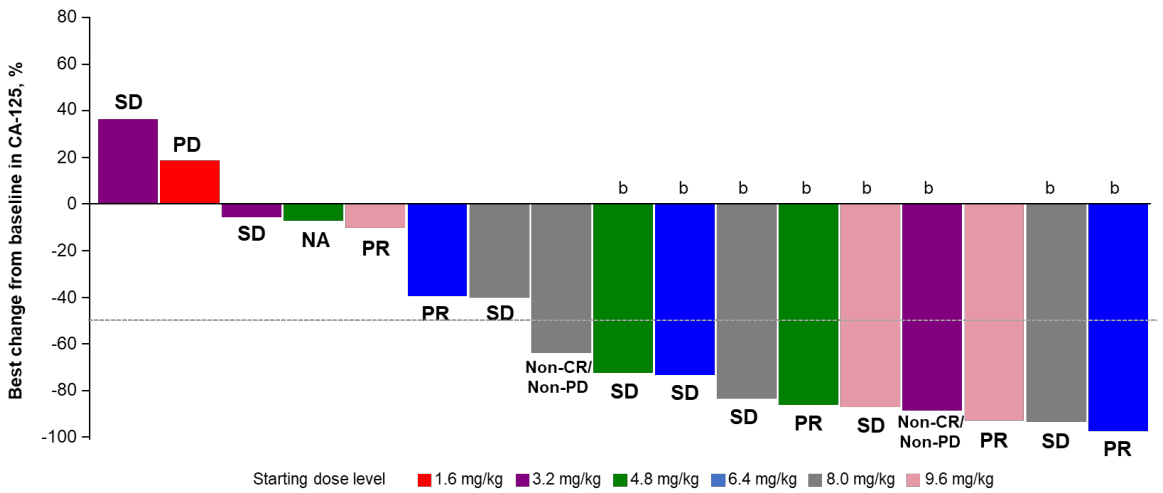
Tolerability and preliminary efficacy were observed in the interim Ph1 data

- DS-6000 was generally well tolerated
- DS-6000 demonstrated early clinical signals (RECIST and CA-125 responses) in heavily pretreated patients with advanced platinum-resistant OVC and RCC
- Expansion cohorts (part B) opened at 8.0 mg/kg are enrolling patients with OVC and RCC

Anti-tumor activity (OVC, RCC)



Change from baseline in CA-125* levels in patients with OVC[a]



Data cutoff: February 25, 2022.
CA-125, cancer antigen 125; CR, complete response; GCIG, Gynecologic Cancer InterGroup; NA, not available; OVC, ovarian cancer; PD, progressive disease; PR, partial response; SD, stable disease.
[a] Patients with baseline CA-125 value and ≥1 postbaseline CA-125 value were included.
[b] According to the GCIG criteria, patients can be evaluated for response only if they have a baseline sample that is ≥2 × the upper limit of normal obtained within 2 weeks prior to starting treatment. CA-125 response is defined as a ≥50% reduction in CA-125 levels from a pretreatment sample. The response must be confirmed and maintained for ≥28 days.

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

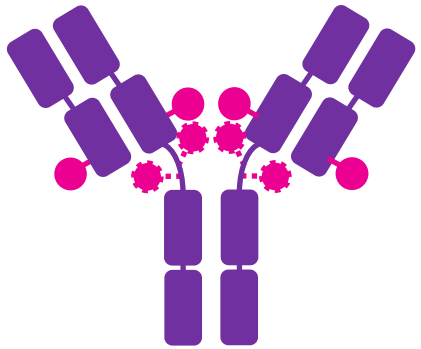
DXd-ADC Technology

Grand prize for 6th Bioindustry awards

Significant efficacy of ENHERTU® and future potential of DXd-ADC technology are recognized as breakthrough

Japan Bioindustry Award
バイオインダストリー大賞

DXd-ADC Technology



- **5 researchers at Daiichi Sankyo received the grand prize for Bioindustry for "Innovation of New Generation Antibody Drug Conjugate Technology, DXd-ADC"**
  - This prize is to award an achievement which is expected to have a strong impact on the development of the fields of bioscience, biotechnology and bioindustry
  - It is the first time that a company alone receive the prize
  - General Incorporated Association Japan Bioindustry Association announced award on July 15, 2022
  - Award recipients:
    - Toshinori Agatsuma (Head of Oncology Research Laboratories I, Corporate Officer)
    - Yuki Abe (Head of Oncology Research Laboratories II)
    - Hiroyuki Naito (Medicinal Chemistry Research Laboratories)
    - Takashi Nakada (Oncology Research Laboratories I)
    - Yusuke Ogitani (Oncology Research Laboratories II)

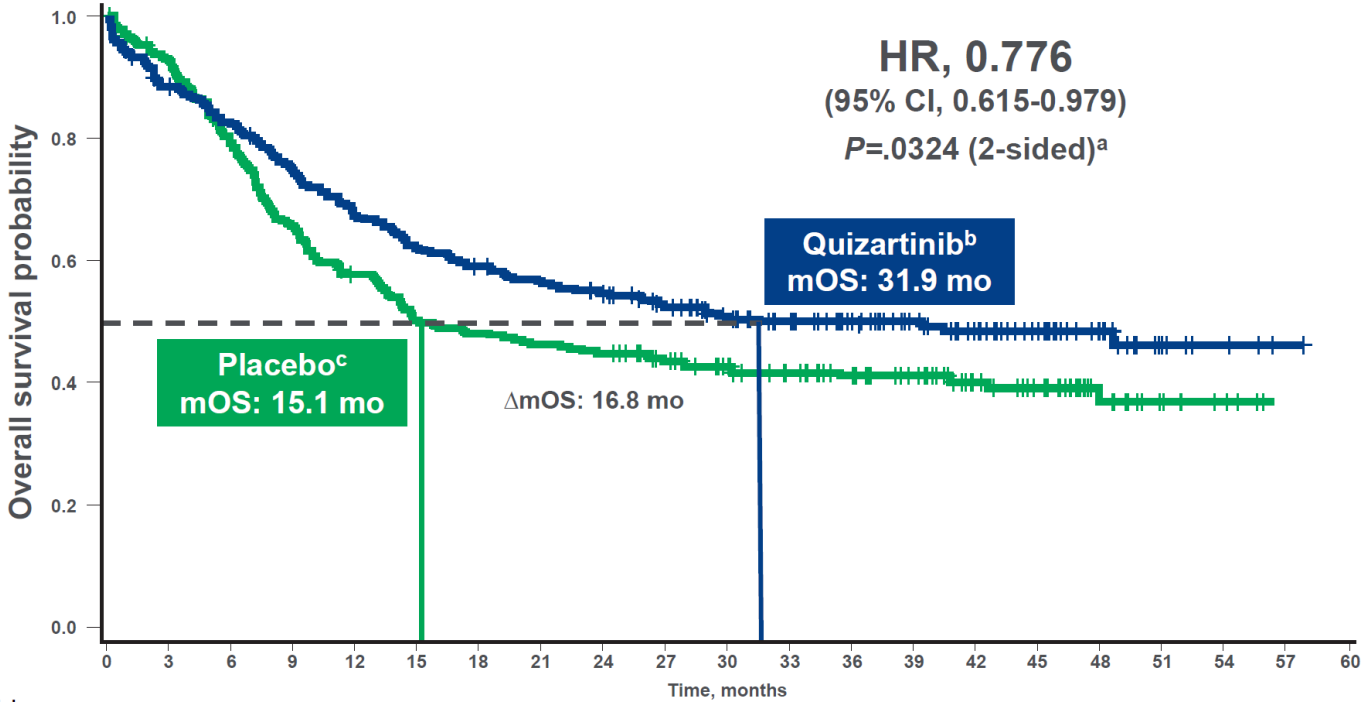
Image is for illustrative purposes only; actual drug to antibody ratio and drug positions may vary.

QuANTUM-First study data

EHA 2022 Highlights (Presidential Symposium)

Quizartinib + SOC doubled OS in patients with AML 1L with FLT3-ITD mutation vs SOC, regulatory submission planned in FY2022 H1 in JP/US/EU

Primary Endpoint: OS



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

AML: acute myeloid leukemia, OS: overall survival, SOC: standard of care

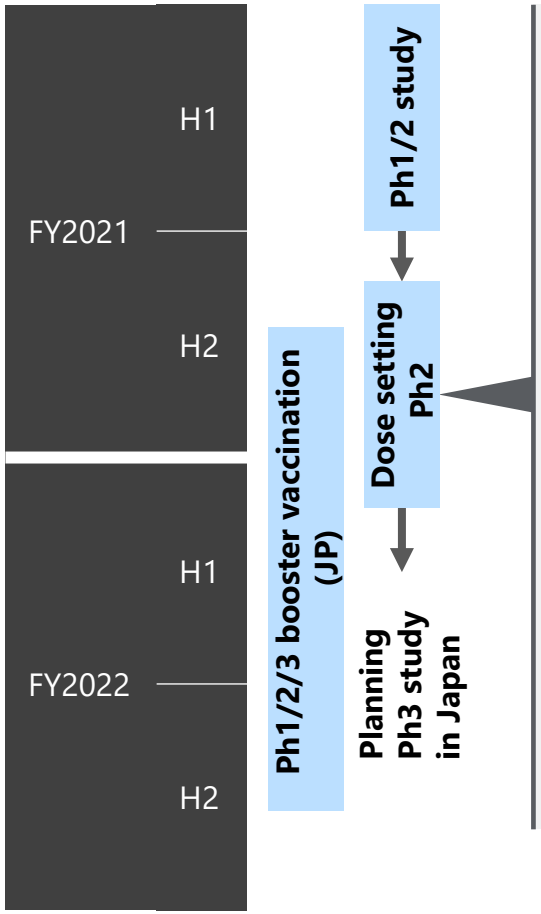
QuANTUM-First study

Ph3 study for patients with newly diagnosed AML with FLT3-ITD mutation

- Efficacy and safety were evaluated in quizartinib + standard chemotherapy arm and placebo + standard chemotherapy arm
- Quizartinib demonstrated a **22.4% reduction in the risk of death** compared to standard chemotherapy alone
- **Median OS of 31.9m** compared to 15.1m with chemotherapy
- No new safety signals were observed

Current development status

Development of COVID-19 vaccine progressed



■ Development of initial vaccination

– **Dose setting Ph2 study**
  - Results presented no significant safety concerns.
  - The neutralizing antibody titers 14 days after the 2nd shot of DS-5670 have demonstrated adequate immunity.

– Planning to start **Ph3 study** in Japan in FY2022 H1

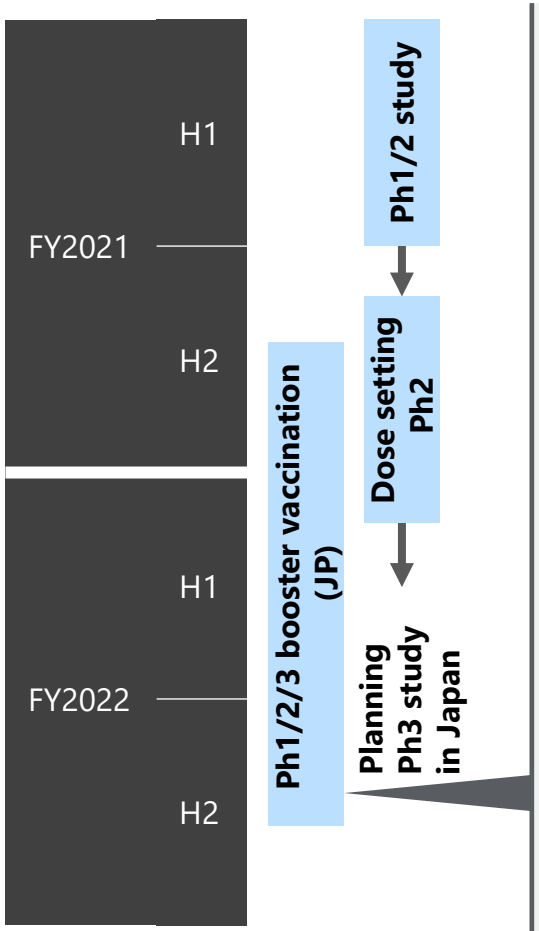
Study design

- Subjects: COVID-19 unvaccinated Japanese healthy adults
- Randomized, non-controlled, parallel-group comparison study (30μg and 60μg)
- Investigate safety, immunogenicity (anti-SARS-CoV-2 neutralizing activity of RBD IgG in blood, antibody titer) and PK

Current development status

Daiichi-Sankyo

Development of COVID-19 vaccine progressed



■ Development of booster vaccination

- **Ph1/2/3 study** Part 1 was completed
  - Efficacy: Data on neutralizing activities four weeks after receiving the vaccination show that the efficacy of DS-5670 is comparable to or higher than an approved mRNA vaccine in both healthy adult and elderly subjects
  - Safety: no serious adverse reactions at the injection site or systemic ones were observed.
- **Part 2** was initiated in May 2022
- Commercialization in Japan is expected within CY2022

Part 1 Dose confirmation study (528 subjects) ▶ **Part 2 Active-controlled, non-inferiority study (4500 subjects)**

Confirmatory study of booster effect comparing to approved COVID-19 mRNA vaccine in subjects who completed the initial vaccination (1st &2nd shots) of approved COVID-19 mRNA vaccine

DS-2325
(KLK5 inhibitor)

New clinical study

Target Disease

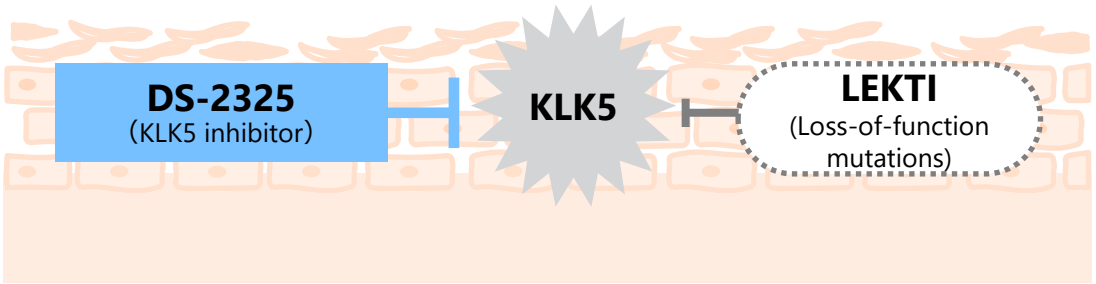
- **Netherton syndrome**
  - An autosomal recessive genetic disease affecting skin, hair and immune system
  - Caused by mutations in the SPINK5 gene, which encodes LEKTI, a serine protease inhibitor
  - Incidence is estimated at 1/200,000-1/300,000 births

Development Stage

- **Ph1 study started in June 2022**
  - Randomized, placebo-controlled, double-blind study in healthy adults
  - Evaluate the safety, tolerability, and PK

Mode of Action

- **Skin of NS patient**
  - Desquamation
  - Inflammation



3ADC Update

Alpha Update

News Flow

FY2022 Future News Flow

As of Jul 2022

Planned major publications

World Conference on Lung Cancer (WCLC, Aug 6-9, 2022)

Dato-DXd	**TROPION-Lung02: NSCLC without actionable gene mutation, Ph1b, pembrolizumab combo** • **Initial interim data**

European Society for Medical Oncology (ESMO, Sep 9-13, 2022)

DS-7300	**Solid tumors Ph1/2** • **Data update**

Regulatory decisions

ENHERTU®	DESTINY-Breast03: HER2+ BC, 2L, Ph3 • JP: FY2022 H2 DESTINY-Breast04: HER2 low BC, post chemo, Ph3 • US: FY2022 H2 DESTINY-Gastric02: HER2+ GC, 2L, Ph2 • EU: FY2022 H2 DESTINY-Lung01: HER2 mutated NSCLC, 2L, Ph2 • US: FY2022 H1
Valemetostat	Registrational Ph2: R/R ATL/L • JP: FY2022 H1

Planned regulatory submissions

ENHERTU®	DESTINY-Breast04: HER2 low BC, post chemo, Ph3 • CN: FY2022 H1
Quizartinib	QuANTUM-First： AML, 1L, Ph3 • JP/US/EU: FY2022 H1
DS-5670	Ph1/2/3: COVID-19 mRNA vaccine, booster shot • JP: FY2022 H2

Key data readouts

ENHERTU®	DESTINY-Breast02: HER2+ BC, 3L, Ph3 • FY2022 H1
Dato-DXd	TROPION-Lung01*: NSCLC, 2/3L, Ph3 • FY2022 H2
DS-5670	Ph1/2/3: COVID-19 mRNA vaccine, booster vaccination • FY2022 H2

Planned pivotal study initiation

HER3-DXd	HERTHENA-Lung02: EGFR mutated NSCLC, 2L, Ph3 • FY2022 H1

Bold: update from FY2021 Q4

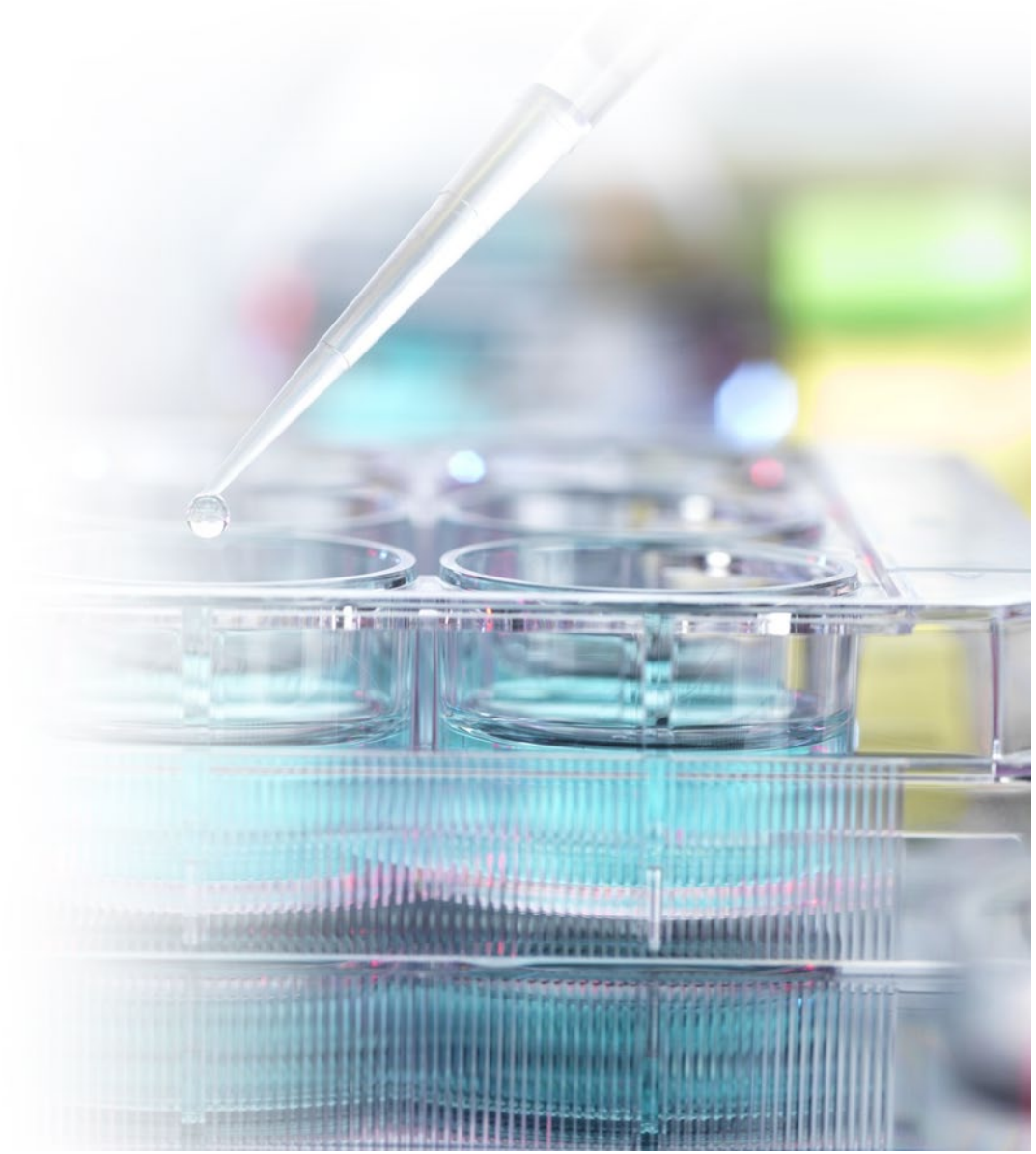
AML: acute myeloid leukemia, ATL/L: adult T-cell leukemia/lymphoma, BC: breast cancer, GC: gastric cancer, NSCLC: non small cell lung cancer, R/R: relapsed/refractory

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

*Event-driven study

Agenda

1. FY2022 Q1 Financial Results
2. Business Update
3. R&D Update
4. **Appendix**



Major R&D Milestones (3ADCs)

As of Jul 2022

Project		Target Indication [phase, study name]	FY2022 H1	FY2022 H2	FY2023
ENHERTU®	BC	• HER2+, 3L [P3, DESTINY-Breast02]	• TLR anticipated		
		• HER2+, 2L [P3, DESTINY-Breast03]	**• Approved (US/EU)**	• Approval anticipated (JP)	
		• HER2 low, Post chemo [P3, DESTINY-Breast04]	**• Filing accepted (JP/US/EU)** • Filing planned (CN)	• Approval anticipated (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 mutated, 2L [P2, DESTINY-Lung01]	• Filing accepted (US) • Approval anticipated (US)		
		• HER2 mutated, 2L [P2, DESTINY-Lung05, CN]	• Study start planned		
Dato-DXd	NSCLC	• 2/3L [P3, TROPION-Lung01]		• TLR anticipated	
	BC	• TNBC, 1L, [P3, TROPION-Breast02]	**• Study started**		
	Solid tumors	• NSCLC, TNBC [P1/2, TROPION-PanTumor02, CN]	**• Study started**		
HER3-DXd	NSCLC	• EGFR mutated, 3L [Registrational P2, HERTHENA-Lung01]			• TLR anticipated
		• EGFR mutated, 2L [P3, HERTHENA-Lung02]	• Study start planned		

Bold: update from FY2021 Q4 BC: breast cancer, GC: gastric cancer, NSCLC: non small cell lung cancer, TLR: top line results
The timeline indicated is based on the current forecast and subject to change.

Major R&D Milestones (Alpha)

As of Jul 2022

Project	Target Indication [phase, study name]	FY2022 H1	FY2022 H2	FY2023
DS-7300	• ES-SCLC, 2L [P2, JP/US/EU/Asia]	**• Study started**		
Quizartinib	• AML, 1L [P3, JP/US/EU/Asia]	• Filing anticipated (JP/US/EU)		**• Approval anticipated (JP/US/EU)**
Valemetostat (DS-3201)	• ATL/L [Registrational P2, JP]	• Approval anticipated (JP)		
DS-9606	• Solid tumors [P1, US/EU]	**• Study started**		
DS-2325	• Netherton syndrome [P1, US]	**• Study started**		
DS-5670	• COVID-19 mRNA vaccine, booster [P1/2/3, JP]		• TLR anticipated • Filing anticipated (JP)	

Bold: update from FY2021 Q4 AML: acute myeloid leukemia, ATL/L: adult T-cell leukemia/lymphoma, ES-SCLC: extensive stage-small cell lung cancer, TLR: top line results

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

Major R&D Pipeline: 3ADCs

As of Jul 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/US/EU/Asia) 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 post neoadjuvant DESTINY-Breast05	(EU) HER2+ GC 2L DESTINY-Gastric02
(JP/US/EU/Asia) HER2+ GC combo, 2L~/1L DESTINY-Gastric03	(JP/US/EU) HER2+ NSCLC 2L~ DESTINY-Lung01	(JP/US/EU/Asia) HER2 low BC chemo naive DESTINY-Breast06	(US) HER2 mutated NSCLC 2L~ DESTINY-Lung01 ★
(EU/Asia) HER2+ NSCLC (durvalumab combo) 1L DESTINY-Lung03	(JP/US/EU/Asia) HER2 mutated NSCLC 2L~ DESTINY-Lung02	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09	(JP/US/EU/Asia) HER2 low BC post chemo DESTINY-Breast04 ★
(US/EU) BC, bladder (nivolumab combo)	(CN) HER2 mutated 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/US/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 1L (w/ HER2 exon 19 or exon 20 mutation) DESTINY-Lung04	
(JP/US) NSCLC, TNBC, HR+ BC, SCLC, urothelial, GC, esophageal, etc. TROPION-PanTumor01	(JP/US/EU/Asia) HER2+ CRC 3L DESTINY-CRC02	(JP/US/EU/Asia) NSCLC 2/3L TROPION-Lung01	
(CN) NSCLC, TNBC TROPION-PanTumor02	(JP/US/EU/Asia) HER2 mutated tumor DESTINY-PanTumor01	(JP/US/EU/Asia) NSCLC (w/o actionable mutation, pembro combo) 1L TROPION-Lung08	
(JP/US/EU/Asia) NSCLC (w/o actionable mutation, pembrolizumab combo) TROPION-Lung02	(US/EU/Asia) HER2 expressing tumor DESTINY-PanTumor02	(JP/US/EU/Asia) HR+ BC 2/3L TROPION-Breast01	
(JP/US/EU) NSCLC (w/o actionable mutation, durvalumab combo) TROPION-Lung04	(JP/US/EU/Asia) NSCLC (w/ actionable mutation) TROPION-Lung05	(JP/US/EU/Asia) TNBC 1L TROPION-Breast02	
(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) EGFR mutated NSCLC 2L (osimertinib combo) ORCHARD	(JP/US/EU/Asia) EGFR mutated NSCLC 2L HERTHENA-Lung02	
(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)

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 Jul 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	Valemetostat (DS-3201) (JP) EZH1/2 inhibitor ATL/L
DS-6000 (US) CDH6-directed ADC Renal cell carcinoma, ovarian cancer	Valemetostat (DS-3201) (EU) EZH1/2 inhibitor BCL	Quizartinib (JP/US/EU/Asia) FLT3 inhibitor AML 1L	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	Esaxerenone (JP) MR blocker Diabetic nephropathy	
DS-1211 (US) TNAP inhibitor Pseudoxanthoma elasticum	DS-7300 (JP/US/EU/Asia) B7-H3-directed ADC ES-SCLC	VN-0102/JVC-001 (JP) Measles mumps rubella combined vaccine	
DS-6016 (JP) Anti-ALK2 antibody FOP	DS-5141 (JP) ENA oligonucleotide DMD	DS-5670 (JP) COVID-19 mRNA vaccine COVID-19 (booster vaccination)	
DS-7011 (US) Anti-TLR7 antibody Systemic lupus erythematosus	DS-5670 (JP) COVID-19 mRNA vaccine COVID-19 (initial vaccination)		
DS-2325 (US) KLK5 inhibitor Netherton syndrome			
PLX2853 (US) BET inhibitor AML			
PLX2853 (US) BET inhibitor Solid tumor			
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			
VN-0200 (JP) RS virus vaccine RS virus infection			

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, ATL/L: adult T-cell leukemia/lymphoma, 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

Contact address regarding this material

Daiichi Sankyo Co., Ltd.
Corporate Communications Department

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