Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

FY2022 Q3
Financial Results Presentation

DAIICHI SANKYO CO., LTD.

Hiroyuki Okuzawa

Director, Senior Executive Officer, CFO

January 31, 2023

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Agenda

1. **FY2022 Q3 Financial Results**
2. Business Update
3. R&D Update
4. Appendix

Overview of FY2022 Q3 Results

(Bn JPY)

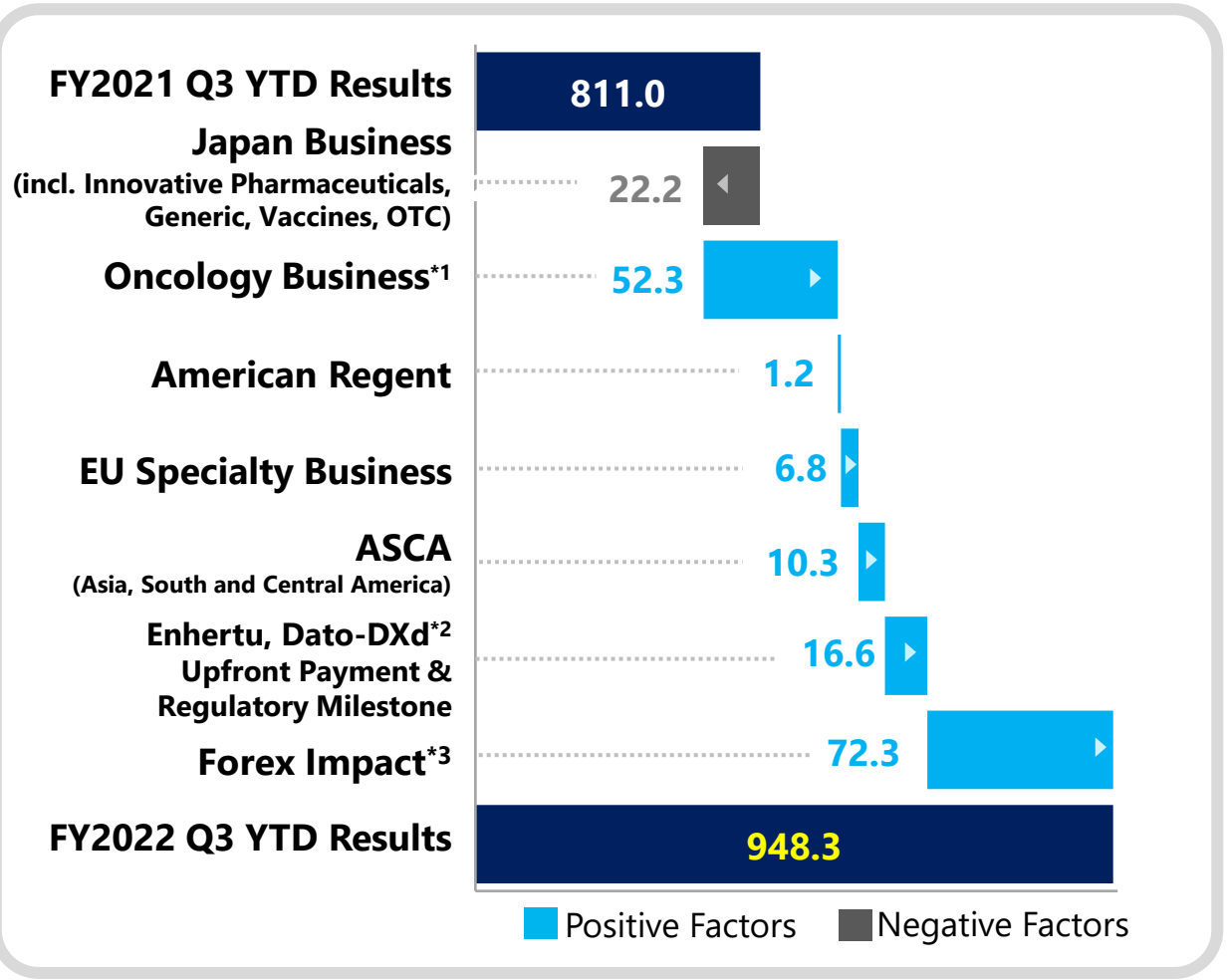
	FY2021 Q3 YTD Results	FY2022 Q3 YTD Results	YoY	
Revenue	**811.0**	**948.3**	**+16.9%**	**137.3**
Cost of sales *	263.2	257.4		-5.8
SG&A expenses *	255.7	330.8		75.1
R&D expenses *	169.1	241.7		72.6
Core operating profit *	**123.0**	**118.3**	**-3.8%**	**-4.7**
Temporary income*	2.1	11.0		8.9
Temporary expenses*	1.3	2.2		0.9
Operating profit	**123.8**	**127.1**	**+2.7%**	**3.4**
Profit before tax	**125.9**	**127.5**		**1.6**
Profit attributable to owners of the Company	**94.3**	**86.7**	**-8.1%**	**-7.6**

Currency Rate	USD/JPY	111.10	136.53	+25.43
	EUR/JPY	130.62	140.60	+9.98

*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 137.3 Bn JPY (Increased by 65.0 Bn JPY excl. forex impact)



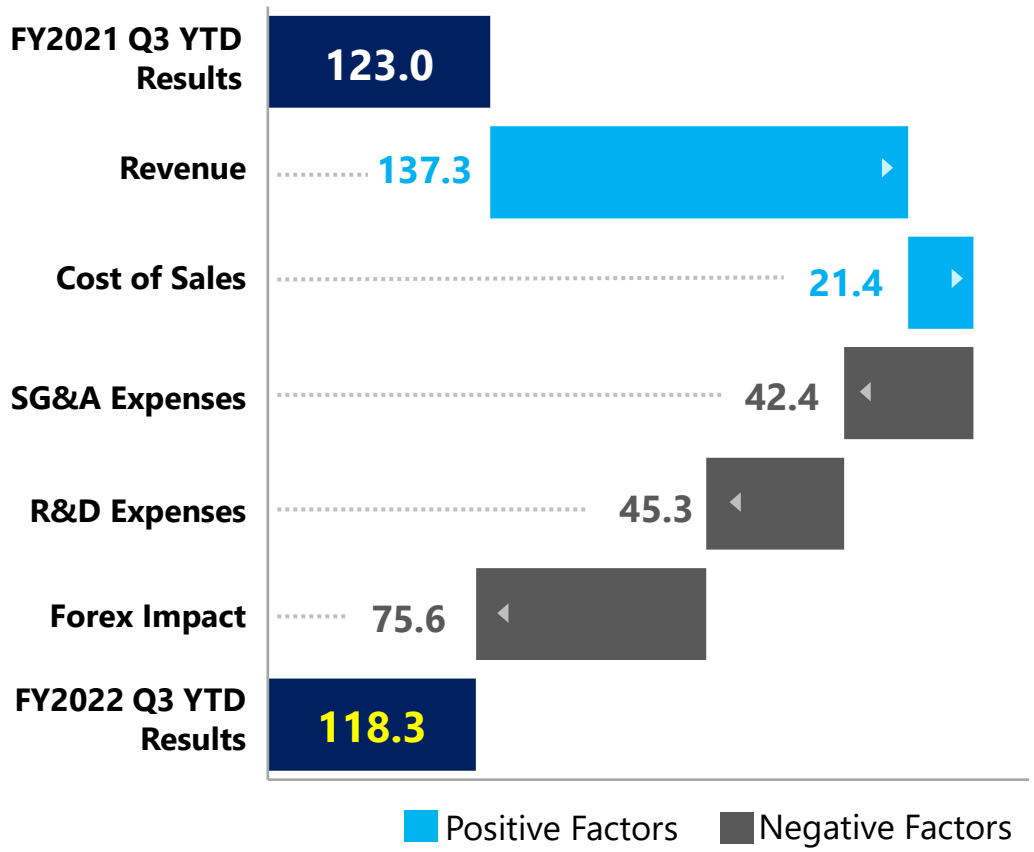
(Bn JPY)

Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+9.1	Nexium	-39.6
Tarlige	+6.3	Loxonin	-2.8
Gains on sales of products in US	+3.5		
Gains on sales of products in EU	+2.6		
Oncology Business*1 Unit			
Enhertu	+62.8	Transferred products	-7.1
American Regent Unit			
Venofer	+5.8	Injectafer	-8.3
HBT products	+3.3		
EU Specialty Business Unit			
Lixiana	+7.2	Gain on sales of transferring long-listed products	-1.4
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: +49.4, EUR : +9.7, ASCA: +13.2

Core Operating Profit

Decreased by 4.7 Bn JPY (Decreased by 1.5 Bn JPY excl. forex impact)



(Bn JPY)

Revenue +137.3
incl. forex impact of +72.3

Cost of Sales -21.4
Improvement in cost of sales ratio by change in product mix

SG&A Expenses +42.4
Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca

R&D Expenses +45.3
Increase in 3ADCs* R&D investments

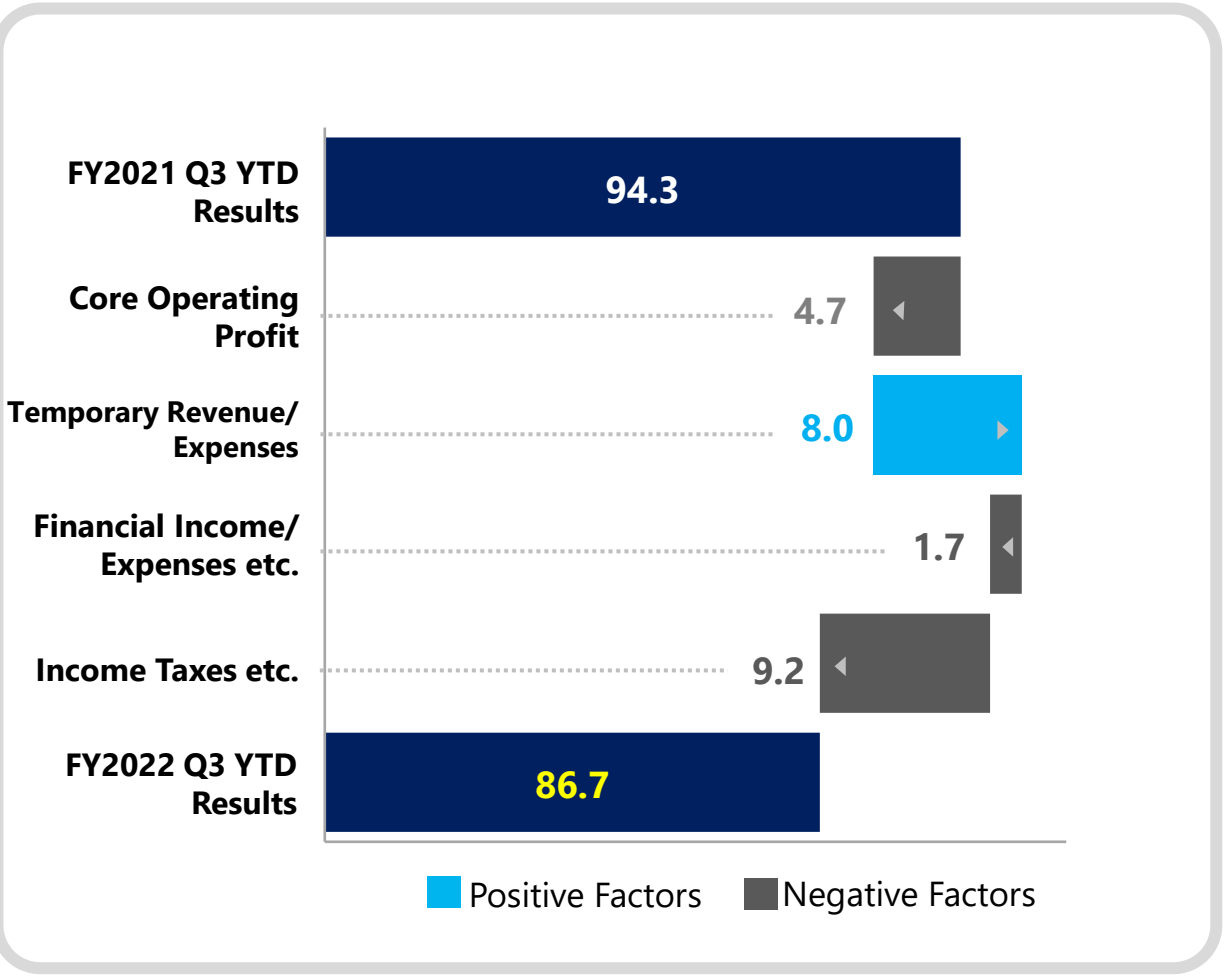
Forex Impact +75.6 (Profit Decreased)
Cost of Sales +15.6
SG&A Expenses +32.7
R&D Expenses +27.3

* 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 7.6 Bn JPY

(Bn JPY)



Temporary Income/Expenses ····· **+8.0 (Profit increased)**

	FY2021 Q3 YTD	FY2022 Q3 YTD	YoY
Temporary Income	2.1*1	11.0*2	+8.9
Temporary Expenses	1.3	2.2	+0.9

*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 (3.3)

Financial Income/Expenses etc. ····· **+1.7（Profit Decreased）**

- Deterioration in forex gains/losses ····· +1.4

Income Taxes etc. ····· **+9.2**

	FY2021 Q3 YTD	FY2022 Q3 YTD	YoY
Profit before Tax	125.9	127.5	+1.6
Income Taxes etc.	31.6	40.8	+9.2
Tax rate	25.1%	32.0%	+6.9%

Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2021 Q3 YTD Results	FY2022 Q3 YTD Results	YoY
Japan Business	393.7	356.4	-37.3
Daiichi Sankyo Healthcare	49.7	54.8	+5.1
Oncolgy Business	49.2	124.7	+75.6
Enhertu	36.6	122.1	+85.5
Turalio	2.0	2.7	+0.6
American Regent	115.6	143.5	+27.9
Injectafer	42.3	41.8	-0.5
Venofer	25.2	38.2	+12.9
GE injectables	41.7	51.6	+9.9
EU Specialty Business	97.9	112.5	+14.6
Lixiana	74.3	87.8	+13.5
Nilemdo/Nustendi	2.2	4.9	+2.6
Olmesartan	14.9	14.8	-0.1
ASCA (Asia, South and Central America) Business	82.9	106.4	+23.5

Currency Rate	USD/JPY	111.10	136.53	+25.43
	EUR/JPY	130.62	140.60	+9.98

Revenue: Major Products in Japan

(Bn JPY)

		FY2021 Q3 YTD Results	FY2022 Q3 YTD Results	YoY
Lixiana	anticoagulant	**70.5**	**79.5**	**+9.1**
Tarlige	pain treatment	**22.8**	**29.1**	**+6.3**
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	**28.7**	**30.4**	**+1.7**
Efient	antiplatelet agent	**12.7**	**15.7**	**+3.0**
Tenelia	type 2 diabetes mellitus treatment	**18.6**	**17.0**	**-1.6**
Vimpat	anti-epileptic agent	**13.9**	**16.7**	**+2.8**
Ranmark	treatment for bone complications caused by bone metastases from tumors	**15.6**	**15.6**	**-0.0**
Canalia	type 2 diabetes mellitus treatment	**13.0**	**12.5**	**-0.5**
Loxonin	anti-inflammatory analgesic	**17.6**	**14.7**	**-2.8**
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	**6.9**	**8.5**	**+1.5**
Emgality	prophylaxis of migraine attacks	**3.4**	**4.7**	**+1.3**

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ENHERTU®

Revenue

(Bn JPY)

	FY2022 Q3 YTD Results	YoY	FY2022 Forecast	vs. Forecast as of Oct.	<Reference> Total Consideration
Product Sales	139.7	96.2	200.4	5.1	-
Japan	8.5	1.5	12.4	-3.6	-
US	99.8	68.2	141.6	4.6	-
Europe	22.3	17.4	32.8	2.6	-
ASCA	9.2	9.2	13.6	1.5	-
Upfront payment	7.4 *1	-	9.8 *1	-	149.0
Regulatory milestone payment	19.7 *1	18.0	26.6 *1	5.1	126.2
US HER2+ Breast Cancer 3L	0.7	-	0.9	-	13.7
EU HER2+ Breast Cancer 3L	0.4	-	0.5	-	7.9
US HER2+ Gastric Cancer 2L + 3L	0.6	-	0.8	-	12.1
US HER2+ Breast Cancer 2L	3.2	3.2	3.5	-	13.1
EU HER2+ Breast Cancer 2L	2.5	2.5	2.7	-	10.1
US HER2-low Breast Cancer (post-chemo)	6.8	6.8	7.3	-	27.7
EU HER2-low Breast Cancer (post-chemo)	-	-	5.1	5.1	19.5 *2
EU HER2+ Gastric Cancer 2L	1.2	1.2	1.3	-0.0	4.8
US HER2 Mutant NSCLC 2L	4.3	4.3	4.6	-	17.3
Quid related payment	0.9 *1	-2.3	1.1 *1	-	17.2
Sales milestone payment	-	-	13.0	-1.0	13.0 *2 *3
Total	167.6	112.0	250.9	9.2	305.5

*1 Revenue recognized in each period

*2 Converted with assumed forex rate for Q4 (Jan. - Mar. 2023) of 130 JPY to 1 USD (Forecast as of October was converted with assumed 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)

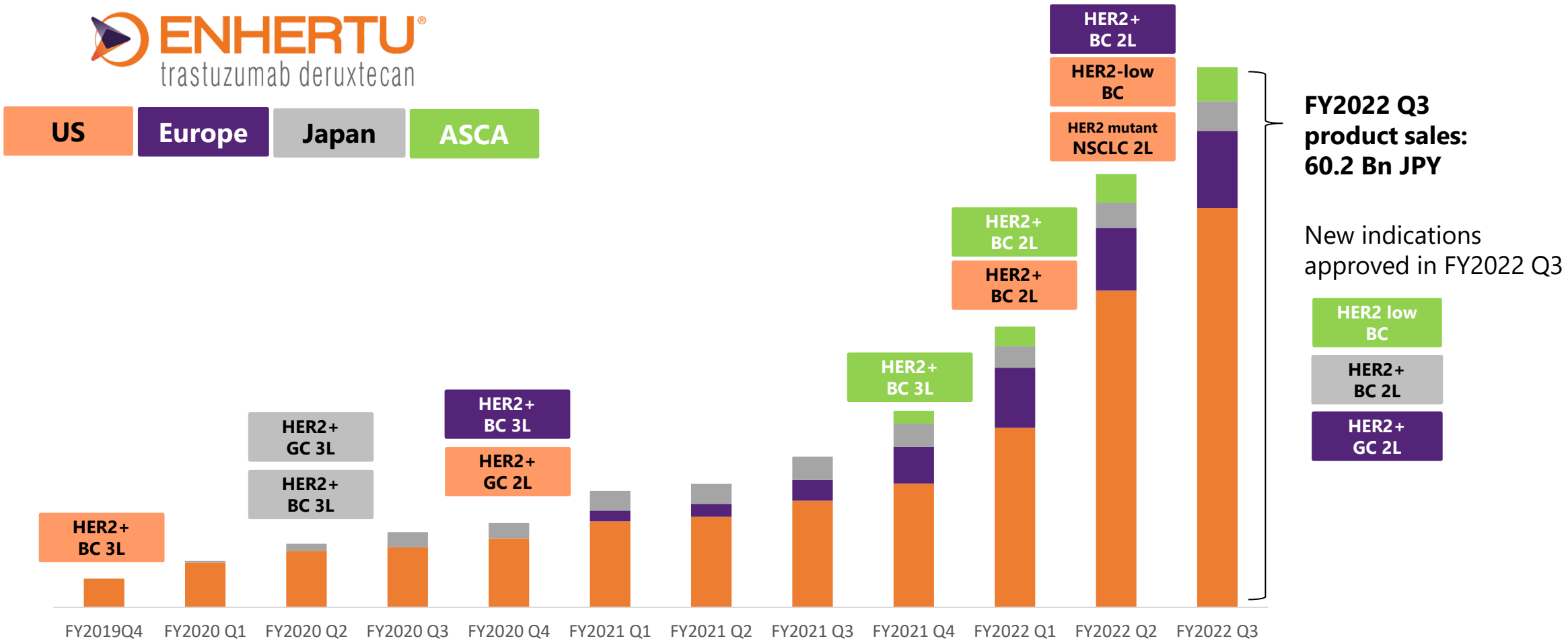
Ref. Total sales milestone payment:
1.75 Bn USD (Max)

ENHERTU®

Sales Increase since Launch

Daiichi-Sankyo

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



ENHERTU®

Performance in Each Region (US, EU)

Daiichi-Sankyo

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

Global product sales: **FY2022 Q3 YTD results** **139.7 Bn JPY**（**YoY** **+96.2 Bn JPY**）
FY2022 forecast **200.4 Bn JPY**（**YoY** **+135.0 Bn JPY**）

US

- **Product sales:** **FY2022 Q3 YTD results** **99.8 Bn JPY** **(731 Mn USD)**
  FY2022 forecast **141.6 Bn JPY** **(1,050 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/3L: Maintaining No.1 new patient share
  - HER2 low BC: Achieved No.1 new patient share
  - HER2+ GC 2L: Maintaining No.1 new patient share
  - HER2 mutant NSCLC 2L: Good uptake in the population
- **Other progress**
  - Approved for HER2+ BC 2L and started promotion (May 2022)
  - Classified as a category 1 preferred regimen for patients with tumors that are HER2 IHC 1+ or 2+ and ISH negative in NCCN*1 guidelines (Jun. 2022)
  - Approved for HER2 low BC (post chemo) and HER2 mutant NSCLC 2L and started promotion (Aug. 2022)

*1 NCCN: National Comprehensive Cancer Network

Europe

- **Product sales:** **FY2022 Q3 YTD results** **22.3 Bn JPY** **(163 Mn USD)**
  FY2022 forecast **32.8 Bn JPY** **(243 Mn USD)**
- **Indication**: HER2+ BC 2L/3L, HER2 low BC (post-chemo), HER2+ GC 2L
- **Market share status**
  - HER2+ BC 2L: Increasing significantly in launched countries/regions (No.1 in France)
  - HER2+ BC 3L: Maintaining No.1 new patient share (UK, France, Germany)
- **Other progress**
  - Approved for HER2+ BC 2L and started promotion (Jul. 2022)
  - Approved for HER2+ GC 2L and started promotion (Dec. 2022)
  - Launched in Spain (Dec. 2022)
  - Approved for HER2 low BC (post-chemo) and started promotion (Jan. 2023)

Blue letters: updates from Q2

ENHERTU® trastuzumab deruxtecan

ENHERTU®

Performance in Each Region (Japan, ASCA)

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

Global product sales: **FY2022 Q3 YTD results** **139.7 Bn JPY** (YoY **+96.2 Bn JPY**)
FY2022 forecast **200.4 Bn JPY** (YoY **+135.0 Bn JPY**)

Japan

- **Product sales:** **FY2022 Q3 YTD results** **8.5 Bn JPY**
  FY2022 forecast **12.4 Bn JPY**
- **Indication:** HER2+ BC 2L/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)
  - Approved for HER2+ BC 2L and started promotion (Nov. 2022)

ASCA

- **Product sales:** **FY2022 Q3 YTD results** **9.2 Bn JPY**
  FY2022 forecast **13.6 Bn JPY**
- **Indication:** HER2+ BC 2L/3L, 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)

ENHERTU® trastuzumab deruxtecan

Blue letters: updates from Q2

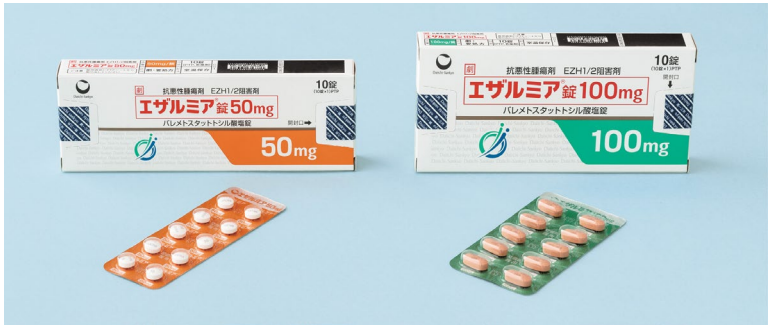
Other Initiatives in Each Region

Daiichi-Sankyo

JPN

- **Anticancer agent EZHARMIA® launched in Dec. 2022**
  - Indication: Relapsed or refractory adult T-cell leukemia-lymphoma (ATLL)
  - MOA: Dual EZH1 and EZH2* inhibitor
  - Administration: Usually, dosage for adult is 200 mg of valemetostat orally administered once daily on an empty stomach. The dose should be reduced as appropriate according to the patient's condition

  *Histone methyltransferase involved in hematological cancer progression



EZHARMIA® Tablet 50mg, 100mg

- **Agreement with Kite Pharma, Inc.: MA Transfer of Human Cell Therapy Product YESCARTA®**
  - Objective: Expansion of access to YESCARTA® therapy
  - Transfer to: Gilead Sciences, K.K. (an affiliate of Kite Pharma, Inc.)
  - Timing: In CY 2023
  - Financials: DS to receive a royalty on product sales and a sales milestone payment

Europe/ ASCA

- **CLEAR Outcomes trial of lipid-lowering treatment NILEMDO® met the primary study endpoint. The trial has been designed to evaluate if bempedoic acid reduces CV events in high- and very high-risk patients who tolerate no or very low doses of statin (Jan. 2023)**

  CLEAR Outcomes study
  - event-driven, randomized, multicenter, double-blind, placebo-controlled Ph3 study led by Esperion Therapeutics, Inc.
  - The primary endpoint was relative risk reduction in major adverse cardiovascular events (MACE-4*)
  - Comprehensive data will be presented at a key medical congress

  * Composite of the time to first cardiovascular death, nonfatal myocardial infarction, non-fatal stroke, or coronary revascularization

ENHERTU® Business Briefing

Sunao Manabe
President and CEO

Ken Keller
Global Head,
Oncology Business Unit

Date and time	**2023 March (TBD)**
Meeting style	Virtual (Zoom)

Agenda

1. FY2022 Q3 Financial Results
2. Business Update
3. **R&D Update**
4. Appendix

3ADCs Update

Alpha Update

News Flow

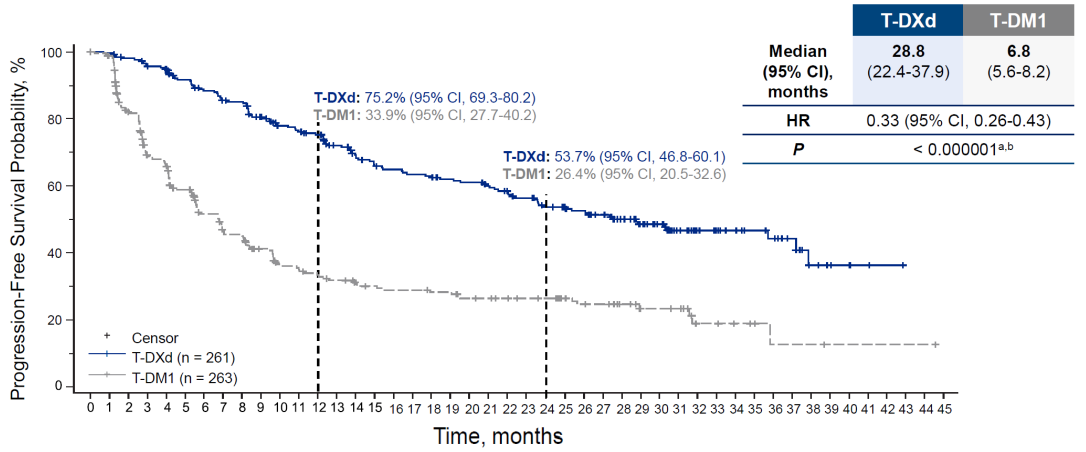
ENHERTU®

DESTINY-Breast03 Study

SABCS 2022

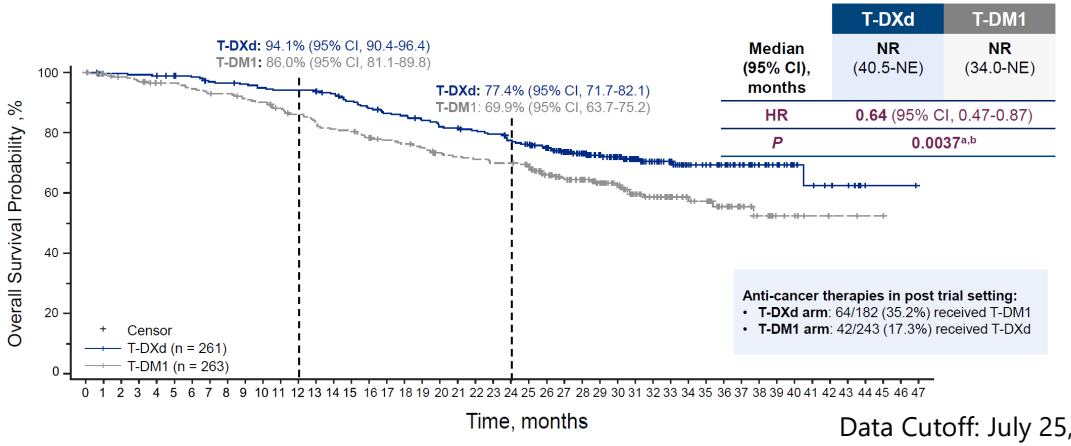
Daiichi-Sankyo

Efficacy (PFS)



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

Efficacy (OS)



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

Data Cutoff: July 25, 2022

DESTINY-Breast03 Study

Comparative study of ENHERTU® and T-DM1 as a 2nd line treatment in patients with HER2 positive recurrent metastatic BC

- 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 safety profile observed with ENHERTU® in DESTINY-Breast03 was consistent with previous clinical trials with no new safety concerns identified

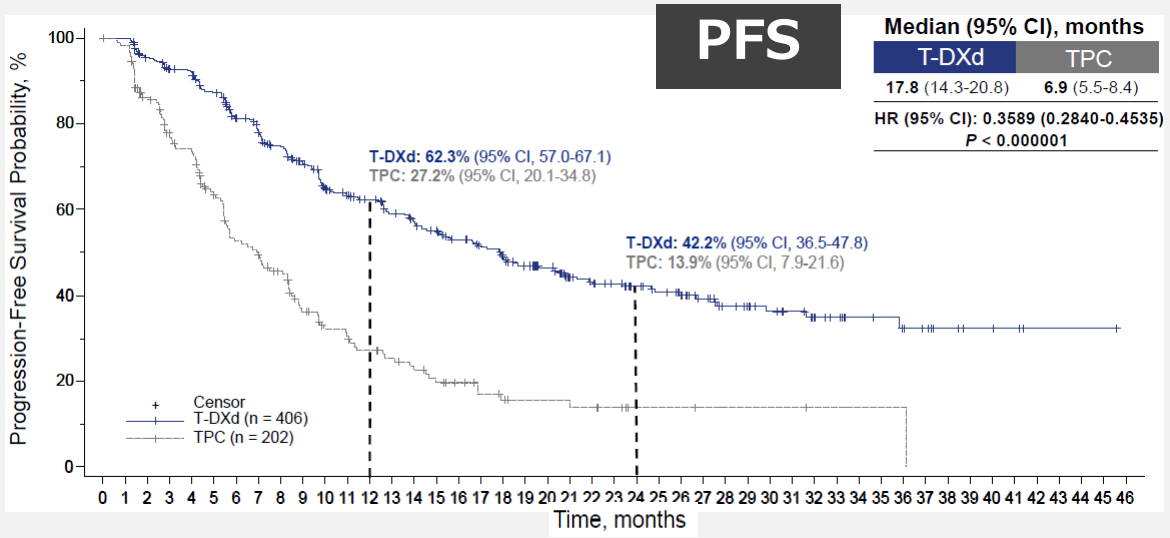
Groundbreaking survival supports ENHERTU® as the 2L SOC in HER2+ BC

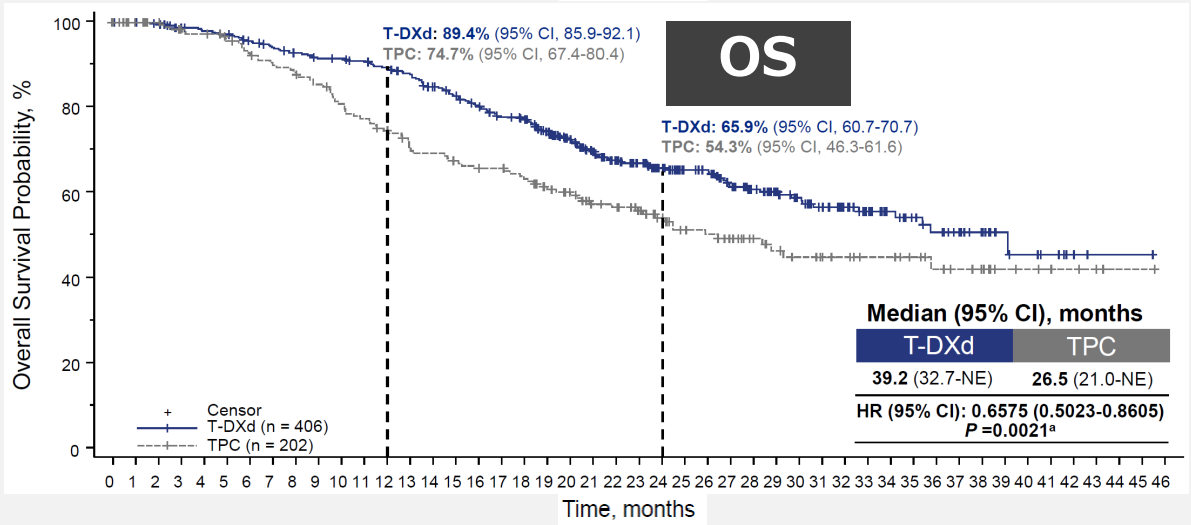
BC: breast cancer, CI: confidence interval, CR: complete response, HR: hazard ratio, ILD: interstitial lung disease, mPFS: median progression-free survival, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, NE: not estimable, NR: not reached, SABCS: San Antonio Breast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

DESTINY-Breast02 Study

SABCS 2022

Reconfirm favorable benefit-risk profile as a 3L treatment of HER2 positive BC





DESTINY-Breast02 Study

Comparative study of ENHERTU® and TPC as a 3rd line treatment in patients with HER2 positive recurrent metastatic BC

- ENHERTU® demonstrated **statistically significant and clinically meaningful improvement in PFS and OS vs. TPC** for patients with HER2+ BC previously treated with T-DM1
  - mPFS: T-DXd (17.8 months) vs. TPC (6.9 months)
  - mOS: T-DXd (39.2 months) vs. TPC (26.5 monthes)
- Overall safety profile was consistent with the established safety of ENHERTU®, with no new safety signals observed

Data cutoff: June 30, 2022

BC: breast cancer, CI: confidence interval, HR: hazard ratio, NE: not estimable, mOS: median overall survival, mPFS: median progression-free survival, OS: overall survival, PFS: progression-free survival, SABCS: San Antonio Breast Cancer Symposium, T-DM1: trastuzumab emtansine, T-DXd: trastuzumab deruxtecan, TPC: treatment of physician's choice

ENHERTU®

Gastric Cancer Update

ENHERTU® was approved in the EU for patients with HER2+ unresectable advanced/recurrent gastric cancer in Dec 2022

- Approval was based on the results from Ph2 study for 2nd line treatment in unresectable advanced/recurrent gastric cancer (**DESTINY-Gastric02** in North America and Europe) and Ph2 study for 3rd line treatment (**DESTINY-Gastric01** in Japan and Korea)

DESTINY-Gastric02 data presented at ESMO 2022

- **ORR (Primary endpoint): 41.8%** (95% CI: 30.8-53.4)
- **DoR: 8.1 months** (95% CI: 5.9-NE)
- Safety profile was generally consistent with the established safety profile of ENHERTU®

- Approval for the 2nd cancer type following breast cancer by EMA

CI: confidence interval, DoR: duration of response, EMA: European Medicines Agency, ESMO: European Society for Medical Oncology, NE: not estimable, ORR: objective response rate

ENHERTU®

Clinical and Regulatory Progress

HER2+ breast cancer, 2L

- Nov 2022: Approval in Japan

HER2 low breast cancer, post-chemo

- Dec 2022: Recommended for approval in EU by CHMP
- Jan 2023: Approval in EU

HER2 mutant NSCLC, 2L+

- Dec 2022: Filing accepted in Japan
- Jan 2023: Filing accepted in EU

CHMP: Committee for Medicinal Products for Human Use, NSCLC: non-small cell lung cancer

Dato-DXd

TROPION-PanTumor01 Study

SABCS 2022, HR positive and HER2 low or negative BC Cohort

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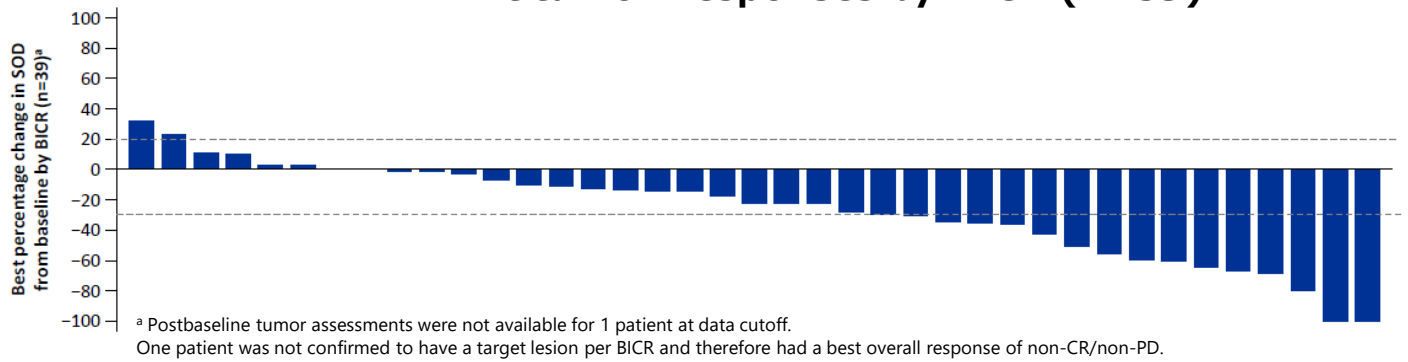
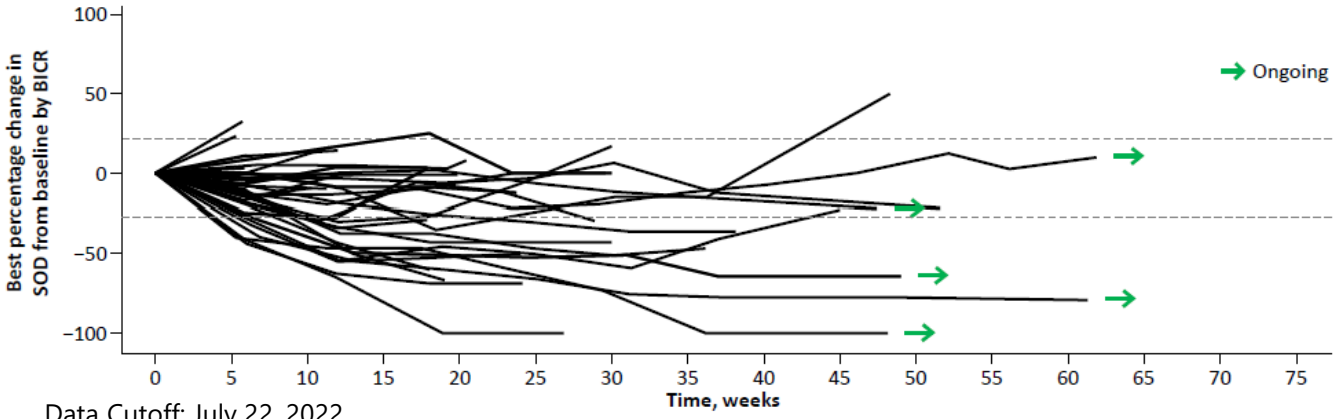
Efficacy

Antitumor Responses by BICR (n=39)



[a] Postbaseline tumor assessments were not available for 1 patient at data cutoff.
One patient was not confirmed to have a target lesion per BICR and therefore had a best overall response of non-CR/non-PD.



Data Cutoff: July 22, 2022

TROPION-PanTumor01
HR positive and HER2 low or negative BC Cohort

Cohort of patients with HR positive and HER2 low or negative unresectable or metastatic BC in Ph1 trial to evaluate safety and efficacy of Dato-DXd

- Dato-DXd showed **encouraging and durable efficacy** in patients with HR positive and HER2 low or negative BC who previously received median of 5 lines of treatment for metastatic disease
  - Confirmed ORR and DCR were 27% and 85%, respectively
  - mPFS was 8.3 months
  - 95% patients were pretreated with CDK4/6 inhibitors
- Dato-DXd demonstrated a manageable safety profile with no new safety signals. The most common TEAEs were stomatitis, nausea, and fatigue

Durable efficacy and manageable safety shown in TROPION-PanTumor01 raises confidence in TROPION-Breast01 study

BC: breast cancer, BICR: blinded independent central review, DCR: disease control rate, HR: hormone receptor, mPFS: median progression-free survival, ORR: objective response rate, SABCS: San Antonio Breast Cancer Symposium, TEAEs: treatment emergent adverse events

Dato-DXd

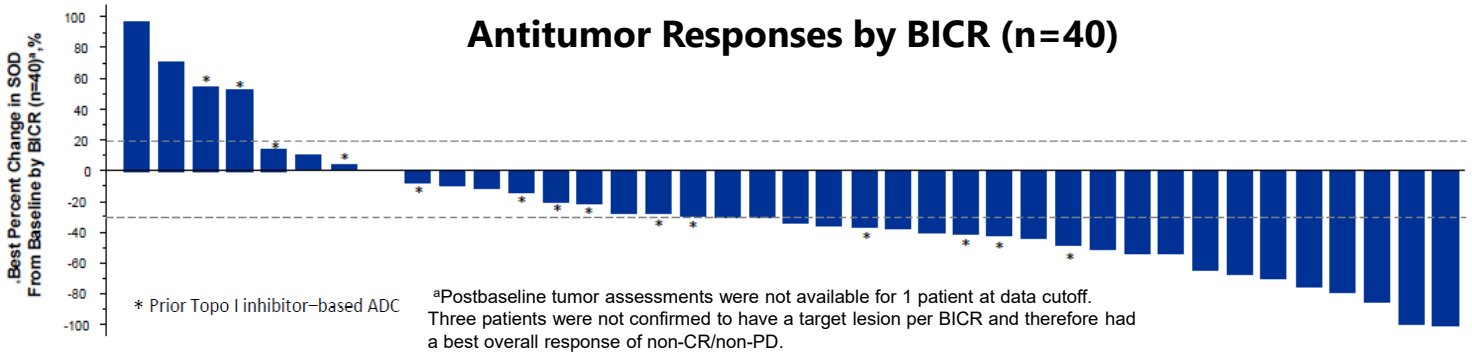
TROPION-PanTumor01 Study

SABCS 2022, TNBC Cohort

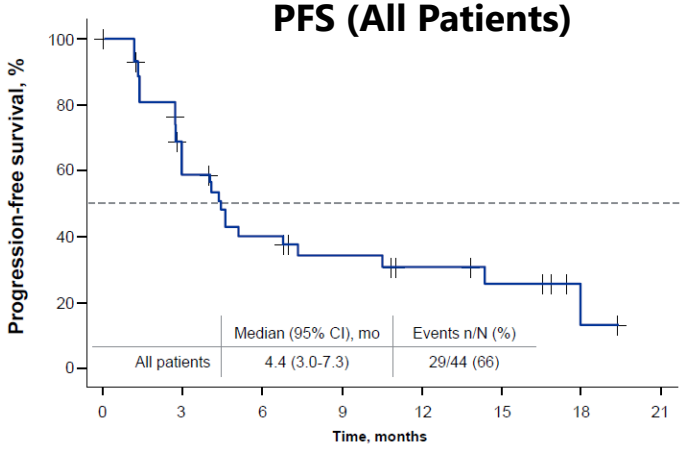
Daiichi-Sankyo

Efficacy

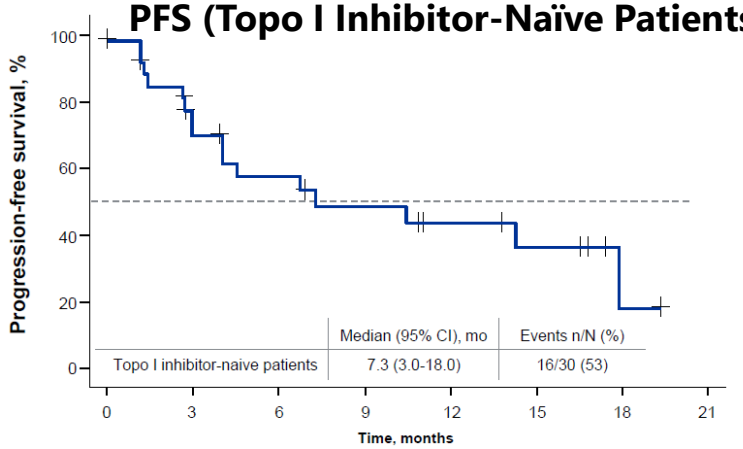
Antitumor Responses by BICR (n=40)



PFS (All Patients)



PFS (Topo I Inhibitor-Naïve Patients)



Data cutoff: July 22, 2022

TROPION-PanTumor01 TNBC Cohort

Cohort of patients with unresectable or metastatic TNBC (including HER2 low) in Ph1 trial to evaluate safety and efficacy of Dato-DXd. Patients in this cohort received a median of three lines of treatment for metastatic disease previously.

- ORR was 32% in all patients (n=44) and 44% in Topo I inhibitor-naïve patients (n=27) with measurable disease; mDOR was 16.8 months in both groups
- mPFS was 4.4 months in all patients and 7.3 months in Topo I inhibitor-naïve patients
- mOS was 13.5 months in all patients and 14.3 months in Topo I inhibitor-naïve patients
- No cases of ILD, febrile neutropenia, or grade ≥3 diarrhea were reported

Results demonstrate encouraging efficacy and manageable safety profile in TNBC and support ongoing TROPION-Breast02 study

BICR: blinded independent central review, CI: confidence interval, ILD: interstitial lung disease, mDOR: median duration of response, mOS: median overall survival, mPFS: median progression-free survival, ORR: objective response rate, PFS: progression-free survival, SABCS: San Antonio Breast Cancer Symposium, TNBC: triple-negative breast cancer

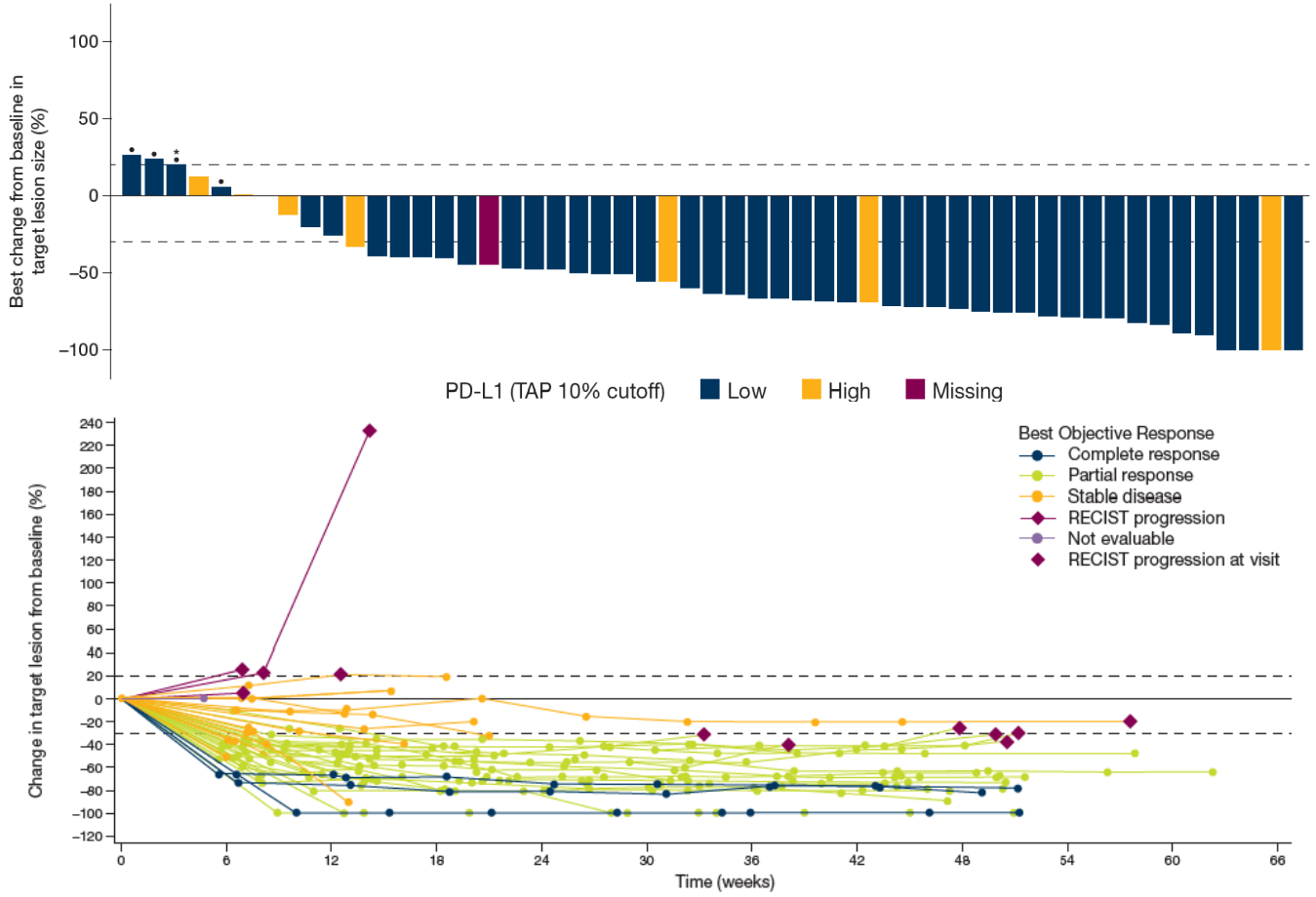
Dato-DXd

BEGONIA Study

SABCS 2022

Daiichi-Sankyo

Efficacy



BEGONIA（Arm7）

BEGONIA is open-label platform study to evaluate safety and efficacy of durvalumab combined with other novel therapies in 1L advanced/ metastatic TNBC. Combination of durvalumab and Dato-DXd is evaluated in Arm7

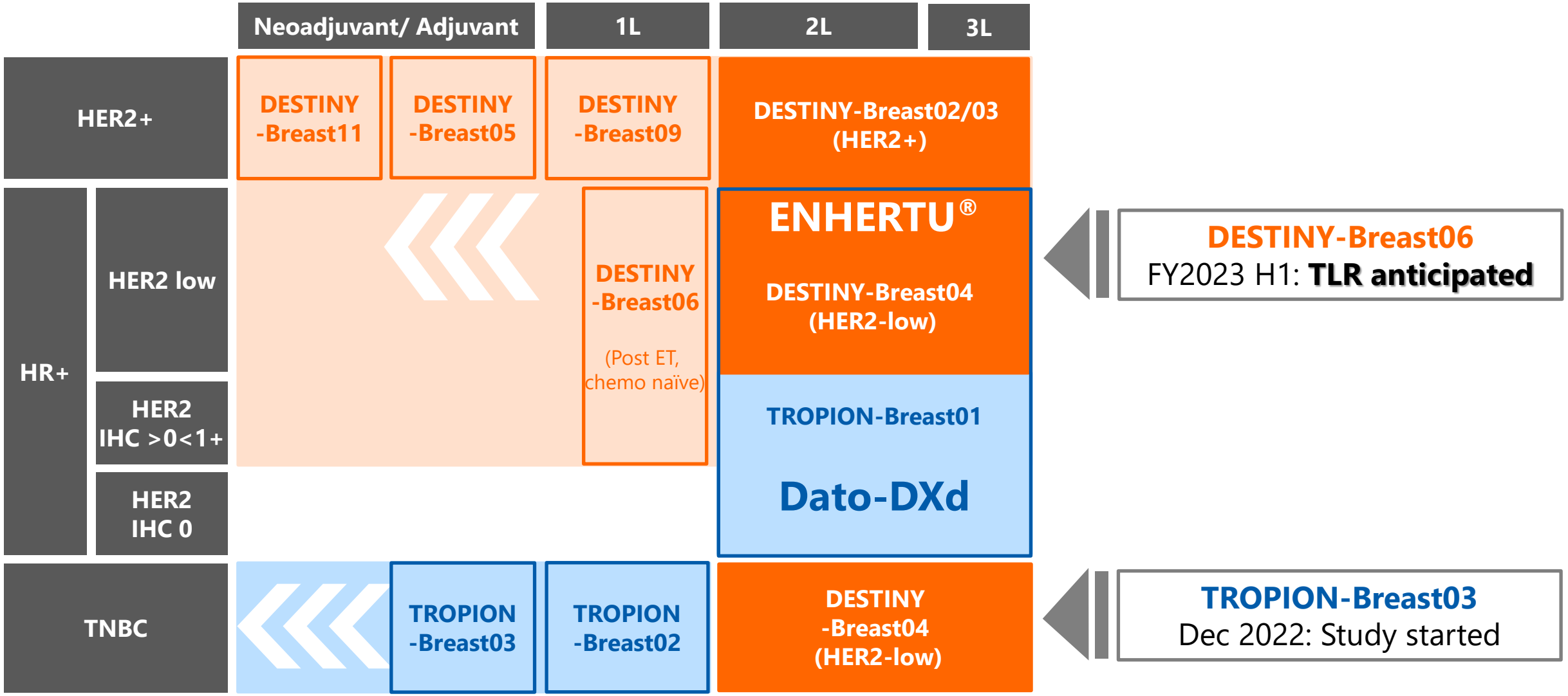
- **Confirmed ORR was 73.6%** in 53 evaluable patients, including 4 (7.5%) CR
- **Durable responses** with 82% patients remaining in response at the data cut off
- The most common AEs were nausea, stomatitis, and alopecia
- Dato-DXd + durvalumab demonstrated a tolerable and manageable safety profile

Data Cutoff: July 22, 2022

AEs: adverse events, CR: complete response, ORR: objective response rate, RECIST: Response Evaluation Criteria in Solid Tumours, SABCS: San Antonio Breast Cancer Symposium, TNBC: triple-negative breast cancer

Results demonstrate a compelling response and support further investigation of combination therapies in 1L advanced/ metastatic TNBC and early stage disease

Status of Clinical Studies in Breast Cancer

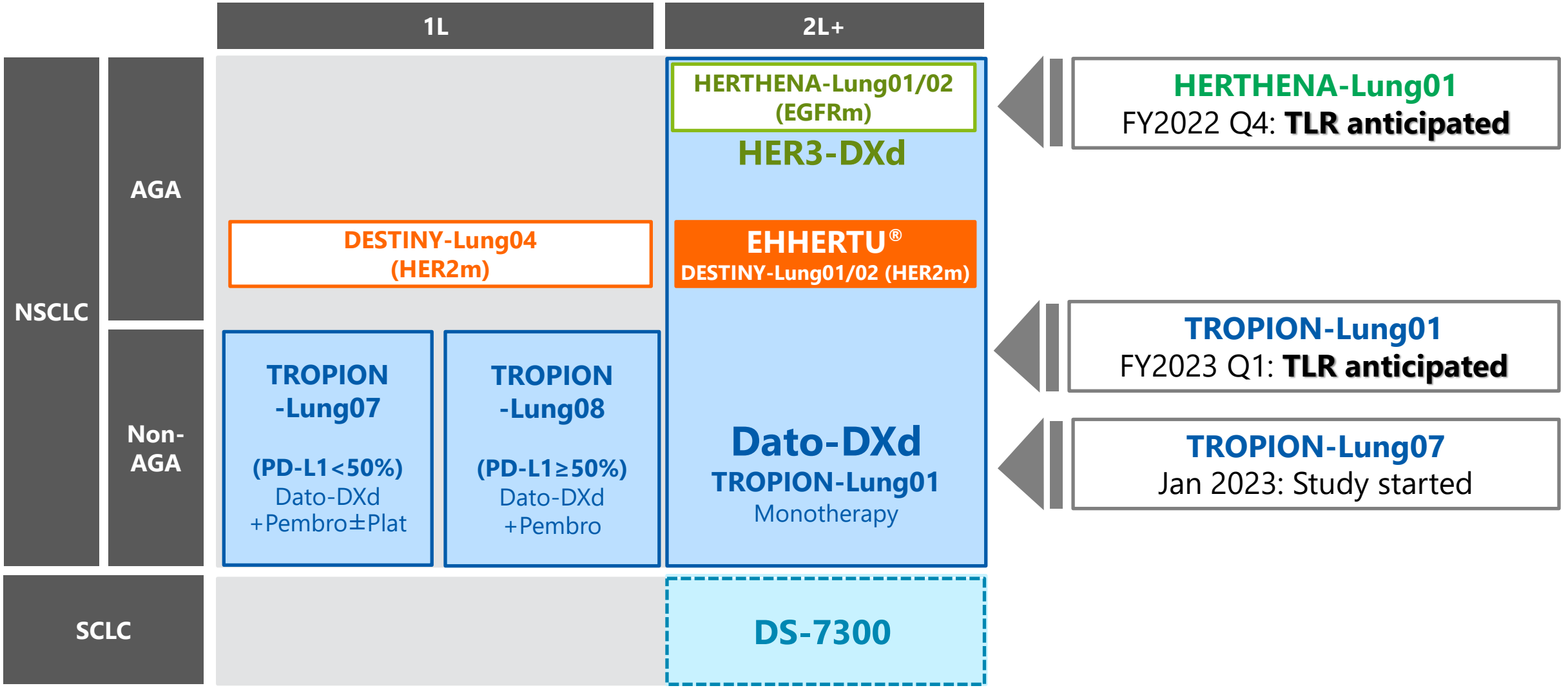


Pivotal studies only, not exhaustive

* In HR+ BC, the line of therapy indicates post-ET setting

chemo: chemotherapy, ET: endocrine therapy, HR: hormone receptor, IHC: immunohistochemistry, TLR: top line results, TNBC: triple-negative breast cancer

Status of Clinical Studies in Lung Cancer



Pivotal studies only, not exhaustive

Planning study

AGA: actionable genomic alteration, EGFRm: EGFR mutated, HER2m: HER2 mutant, NSCLC: non-small cell lung cancer, Pembro: pembrolizumab, Plat: platinum-based chemotherapy, SCLC: small cell lung cancer, TLR: top line results

3ADCs Update

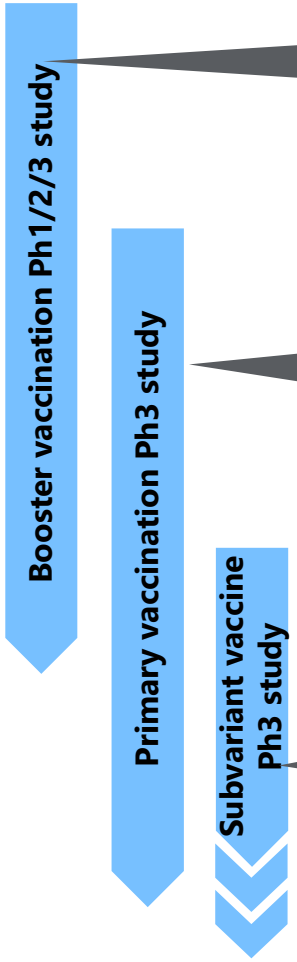
Alpha Update

News Flow

DS-5670

Current development status

TLR of Ph1/2/3 booster vaccination study obtained in Nov 2022, regulatory submission in Japan achieved in Jan 2023



■ Development of booster vaccination (Original strain)

- TLR of Ph1/2/3 study part 2 was obtained in Nov 2022 and **primary endpoint was achieved**
- Regulatory submission in Japan was achieved in Jan 2023

■ Development of primary vaccination (Original strain)

- Sep 2022: Ph3 study started in Japan

Primary vaccination Ph3 study

- Subjects: 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®

■ Development of BA.4-5 subvariant vaccine

- Planning to start clinical study in FY2023 H1

The clinical development of DS-5670 is being conducted through "Vaccine development project" promoted by the Japan Agency for Medical Research and Development (AMED) and "Urgent improvement project for vaccine manufacturing systems" supported by the Ministry of Health, Labour and Welfare (MHLW)

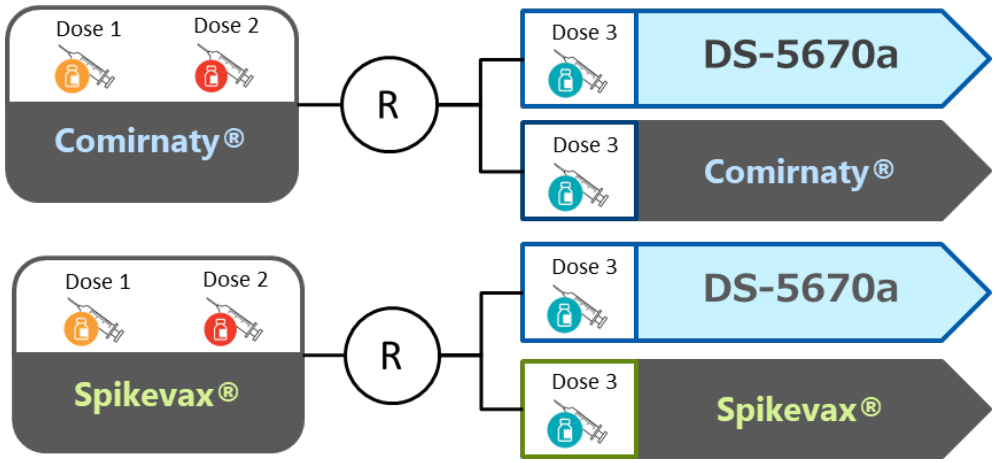
TLR: top line results

DS-5670

Booster vaccination Ph1/2/3 Study Part 2
(non-inferiority verification part)

The 26th Annual Meeting of the Japanese Society of vaccinology

Daiichi-Sankyo

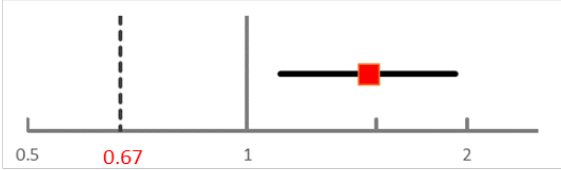


Booster vaccination Ph1/2/3 Study Part 2 (non-inferiority verification part)

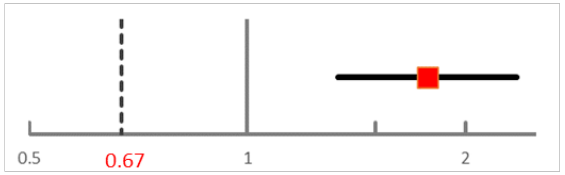
- Subjects: Healthy adults and the elderly subjects who received the primary vaccination (the first and second dose) of approved COVID-19 mRNA vaccine (Comirnaty® or Spikevax®) in Japan
- Primary endpoint: Geometric mean fold rise (GMFR) of serum neutralizing antibody titer against SARS-CoV-2 (original strain) after four weeks (Day 29) from the administration of study drug
  Secondary endpoints: Geometric mean titer (GMT) and seroconversion rate of serum neutralizing against SARS-CoV-2 (original strain) after four weeks (Day 29) from the vaccination, etc

Non-inferiority verification of DS-5670a against approved mRNA vaccines

GMFR ratio (DS-5670a/ Comirnaty®)



GMFR ratio (DS-5670a/ Spikevax®)



- GMFR ratio (DS-5670a/Comrnaty® or Spikevax®) of serum neutralizing antibody titer against SARS-CoV-2 on Day 29 was calculated. The result demonstrated non-inferiority of DS-5670a arm to control arms with the two-sided 97.5% lower confidence interval exceeding the non-inferiority margin 0.67.
- Rates of TEAE and severity of DS-5670a arm were comparable to those of control arms

- **Confirmed efficacy and safety of DS-5670a booster vaccination in subjects who received approved mRNA vaccine as the primary vaccination**
- **Verified non-inferiority of DS-5670a booster vaccination in statistical comparison with Comirnaty® and Spikevax® booster vaccination**

Alpha

Clinical and Regulatory Progress

YESCARTA® (axicabtagene ciloleucel) (relapsed/refractory large B-cell lymphoma (LBCL), 2L)

- Dec 2022 : Approved in Japan

TARLIGE® (mirogabalin) (diabetic peripheral neuropathic pain (DPNP))

- Jan 2023：Filing accepted in China

DS-1211（Pseudoxanthoma Elasticum（PXE））

- Nov 2022 : Ph2 study in PXE patients started

DS-2325 (Netherton syndrome)

- Dec 2022 : Granted Orphan Drug Designation by FDA

3ADCs Update

Alpha update

News Flow

FY2022, 2023 News Flow

As of Jan 2023

Planned major publications

JSMO (Mar 16-18, 2023)

HER3-DXd	**Ph1 study: EGFR mutated NSCLC** • **Data update of dose escalation cohort and dose expansion cohort**

Regulatory decisions

ENHERTU®	**DESTINY-Breast04：HER2 low BC, post chemo, Ph3** • **JP: FY2022 Q4**
	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**
FLUMIST® (VN-0107)	**Nasal seasonal influenza vaccine** • **JP: FY2022 Q4**

Key data readouts

EHHERTU®	**DESTINY-Breast06*： HR positive and HER2 low BC, chemo naïve, Ph3** • **FY2023 H1**
Dato-DXd	TROPION-Lung01*： NSCLC, 2/3L, Ph3 • **FY2023 Q1**
HER3-DXd	**HERTHENA-Lung01: EGFR mutated NSCLC, 3L, registrational Ph2** • **FY2022 Q4**
DS-5670	**Primary vaccination, original strain, Ph3** • **FY2023 H1**

Planned pivotal study initiation

DS-5670	**COVID-19 mRNA subvariant vaccine, booster study, healthy volunteers, Ph3** • **FY2023 H1**

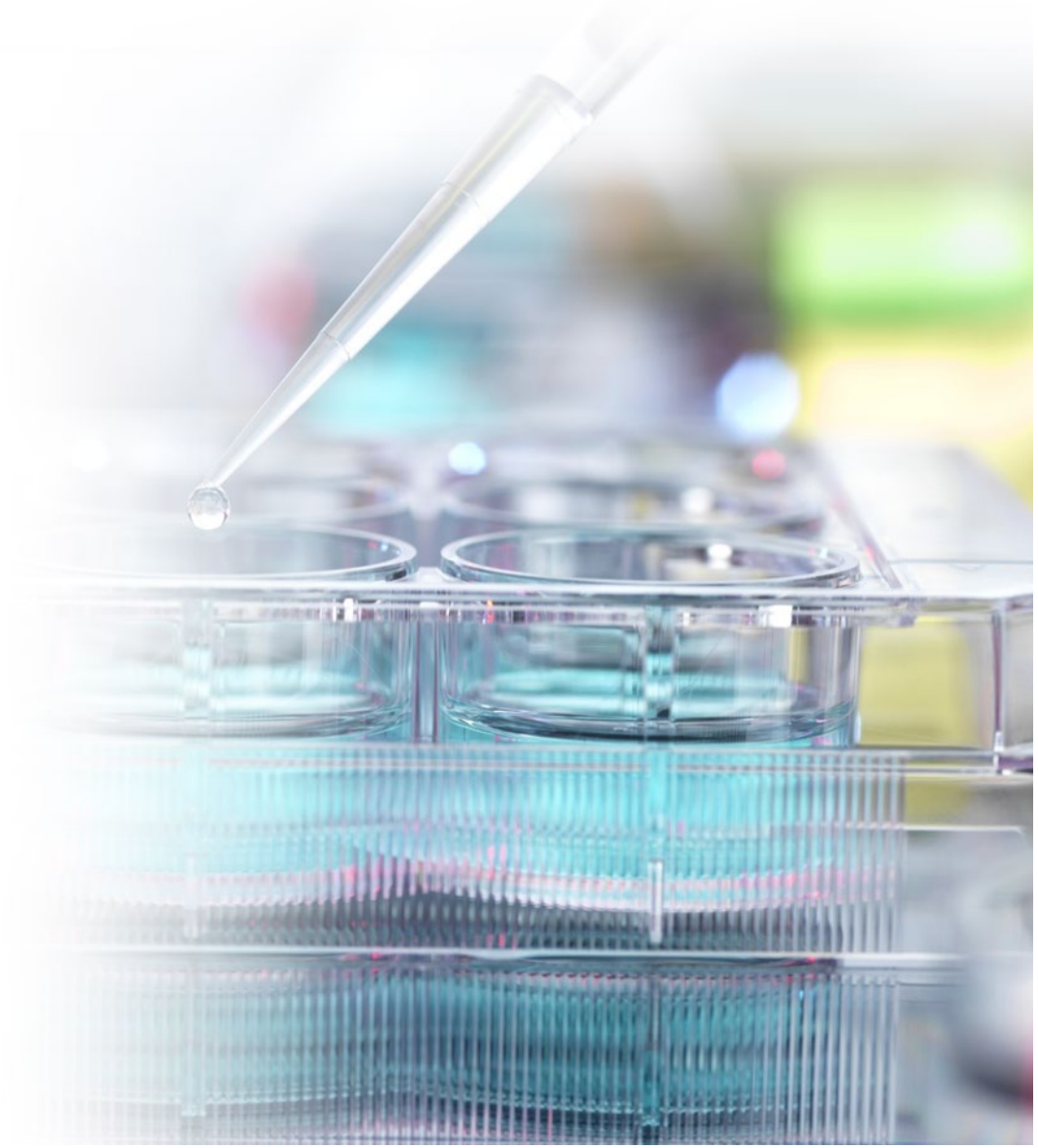
Bold: update from FY2022 Q2

AML: acute myeloid leukemia, BC: breast cancer, JSMO: Japanese Society of Medical Oncology, NSCLC: non-small cell lung cancer

Timeline indicated is based on the current forecast and subject to change.
*Event-driven study

Agenda

1. FY2022 Q3 Financial Results
2. Business Update
3. R&D Update
4. **Appendix**



Major R&D Milestones (3ADCs)

As of Jan 2023

Project		Target Indication [phase, study name]	FY2022 H2	FY2023 H1	FY2023 H2
ENHERTU®	BC	• HER2+, 2L [Ph3, DESTINY-Breast03]	**• Approved (JP)**		
		• HER2 low, post chemo [Ph3, DESTINY-Breast04]	**• Approved (EU)** **• Approval anticipated (JP)**		
		• HER2 low, chemo naïve [Ph3, DESTINY-Breast06]		**• TLR anticipated**	
	GC	• HER2+, 2L [Ph2, DESTINY-Gastric02, EU]	**• Approved (EU)**		
	NSCLC	• HER2 mutant, 2L [Ph2, DESTINY-Lung01, 02]	**• Filing accepted (JP/EU)**	**• Approval anticipated (JP)**	**• Approval anticipated (EU)**
	CRC	• HER2+, 3L [Ph2, DESTINY-CRC02]	**• TLR obtained**		
Dato-DXd	NSCLC	• 2/3L [Ph3, TROPION-Lung01]		**• TLR anticipated**	
		• 1L [Ph3, TROPION-Lung07]	**• Study started**		
	BC	• TNBC, adjuvant* [Ph3, TROPION-Breast03]	**• Study started**		
HER3-DXd	NSCLC	• EGFR mutated, 3L [Registrational Ph2, HERTHENA-Lung01]	**• TLR anticipated**		

Bold: update from FY2022 Q2 BC: breast cancer, CRC: colorectal cancer, GC: gastric cancer, 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.

* Adjuvant therapy for patients with TNBC who have residual disease after neoadjuvant therapy

Major R&D Milestones (Alpha)

As of Jan 2023

Project	Target Indication [phase, study name]	FY2022 H2	FY2023 H1	FY2023 H2
Quizartinib	• AML, 1L [Ph3, JP/US/EU/Asia]	**• Filing accepted (US)**	**• Approval anticipated (JP/US)**	**Approval anticipated (EU)**
TARLIGE® (mirogabalin)	• DPNP	**• Filing accepted (China)**		
DS-1211	• PXE [Ph2, US/EU]	**• Study Started**		
DS-5670	• COVID-19 mRNA vaccine (original strain), booster vaccination [Ph1/2/3, JP]	**• TLR obtained** **• Filing accepted (JP)**		
	• COVID-19 mRNA vaccine (original strain), primary vaccination [Ph3, JP]		**• TLR anticipated**	
	• COVID-19 mRNA vaccine (BA.4-5), vaccination [Ph3, JP]		**• Study start anticipated**	
FLUMIST® (VN-0107)	• Nasal seasonal influenza vaccine [JP]	**• Approval anticipated (JP)**		

Bold: update from FY2022 Q2 AML: acute myeloid leukemia, DPNP: diabetic peripheral neuropathic pain, PXE: pseudoxanthoma elasticum, TLR: Top Line Results

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

Major R&D Pipeline: 3ADCs

As of Jan 2023

Daiichi-Sankyo

Phase 1	Phase 2	Phase 3	Filed
(US/EU/Asia) HER2+ BC 2L+/1L DESTINY-Breast07	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) HER2+ BC 3L DESTINY-Breast02	(CN) 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*2 DESTINY-Breast05	(JP/CN) HER2 low BC post chemo DESTINY-Breast04
(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) HER2 mutant NSCLC 2L+ DESTINY-Lung01/Lung02
(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) non-squamous NSCLC (w/o AGA, pembrolizumab combo) 1L TROPION-Lung07	
	(US/EU/Asia) HER2 expressing tumor DESTINY-PanTumor02	(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	

Phase 1	Phase 2	Phase 3
(JP/US) NSCLC, TNBC, BC*1, SCLC, GC, urothelial, esophageal, prostate, etc. TROPION-PanTumor01	(JP/US/EU/Asia) endometrial, ovarian, CRPC, GC, CRC combo TROPION-PanTumor03	
(CN) NSCLC, TNBC TROPION-PanTumor02	(JP/US/EU/Asia) NSCLC (w/ AGA) TROPION-Lung05	
(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) TROPION-Lung02	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	
(JP/US/EU) NSCLC (w/o AGA, durvalumab combo) TROPION-Lung04	(JP/US/EU/Asia) EGFR mutated NSCLC (osimertinib combo) 2L ORCHARD	
(JP/US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(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		
		(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, CRPC: castration-resistant prostate 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 Jan 2023

Phase 1	Phase 2	Phase 3	Filed
DS-7300 (JP/US) B7-H3-directed ADC ESCC, CRPC, squamous NSCLC, SCLC, etc.	Valemetostat (DS-3201)(JP/US/EU/Asia) EZH1/2 inhibitor PTCL	Pexidartinib (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	Quizartinib (JP/US/EU) FLT3 inhibitor AML 1L
DS-6000 (JP/US) CDH6-directed ADC Renal cell carcinoma, ovarian cancer	Valemetostat (DS-3201) (EU) EZH1/2 inhibitor BCL	Esaxerenone (JP) MR blocker Diabetic nephropathy	Mirogabalin (CN) α2δ ligands Diabetic peripheral neuropathic pain
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	DS-1001 (JP) Mutant IDH1 inhibitor Glioma	VN-0102/JVC-001 (JP) Measles mumps rubella combined vaccine	VN-0107/MEDI3250 (JP) Live attenuated influenza vaccine nasal spray
DS-1594 (US) Menin-MLL binding inhibitor AML, ALL	DS-7300 (JP/US/EU/Asia) B7-H3-directed ADC ES-SCLC	DS-5670 (JP) COVID-19 mRNA vaccine (original strain) COVID-19 (primary vaccination, adults)	DS-5670 (JP) COVID-19 mRNA vaccine (original strain) COVID-19 (booster vaccination)
DS-9606 (US/EU) Target undisclosed ADC Solid tumors	DS-5141 (JP) ENA oligonucleotides DMD	DS-5670 (JP) COVID-19 mRNA vaccine (original strain), COVID-19 (primary vaccination, 12 to 17 aged children)	
DS-6016 (JP) Anti-ALK2 antibody FOP	DS-1211 (US/EU) TNAP inhibitor Pseudoxanthoma elasticum		
DS-7011 (US) Anti-TLR7 antibody Systemic lupus erythematosus	DS-5670 (JP) COVID-19 mRNA vaccine, COVID-19 (primary vaccination, 5 to 11 aged children) (in prep.)		
DS-2325 (US) KLK5 inhibitor Netherton syndrome	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 (designated in at least one country/region among JP, US and 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 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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