

Passion for Innovation.
Compassion for Patients.™



FY2023 Q1 Financial Results Presentation

DAIICHI SANKYO CO., LTD.

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Executive Officer, CFO

July 31, 2023

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Agenda

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③ R&D Update

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Overview of FY2023 Q1 Results

(Bn JPY)

	FY2022 Q1 Results	FY2023 Q1 Results	YoY	
Revenue	280.3	350.8	+25.2%	
Cost of sales*	74.7	93.6	18.9	
SG&A expenses*	96.3	135.6	39.3	
R&D expenses*	74.9	77.2	2.2	
Core operating profit*	34.4	44.5	+29.4%	
Temporary income*	0.0	0.5	0.5	
Temporary expenses*	-	0.9	0.9	
Operating profit	34.4	44.0	+28.1%	
Profit before tax	29.4	52.1	22.7	
Profit attributable to owners of the Company	18.9	57.0	+202.4%	
Currency Rate	USD/JPY	129.57	137.37	+7.80
	EUR/JPY	138.10	149.46	+11.36

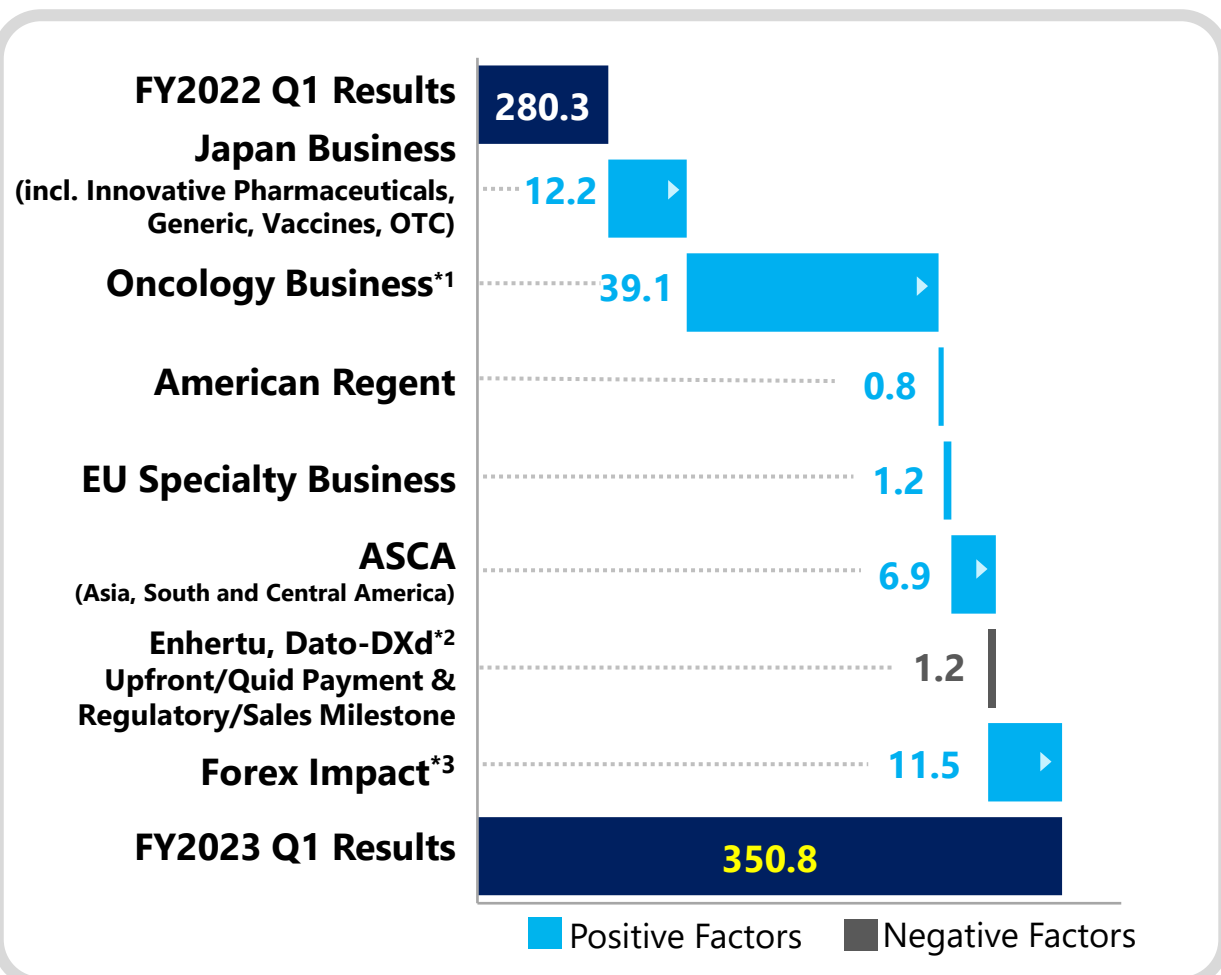
*As an indicator of ordinary profitability, "core operating profit" which excludes temporary income and expenses from operating income is disclosed. Income and expenses related to: sale of fixed assets, restructuring (excluding the sales of pipeline and launched products), impairment, loss compensation, 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

Increased by 70.5 Bn JPY (Increased by 59.0 Bn JPY excl. forex impact)

(Bn JPY)



Positive Factors		Negative Factors	
Japan Business Unit			
Lixiana	+2.8		
Tarlige	+2.8		
Enhertu	+1.9		
Efient	+1.3		
Daiichi Sankyo Healthcare	+1.9		
Oncology Business*1 Unit			
Enhertu	+38.7		
American Regent Unit			
Venofer	+2.5	Injectafer	-1.7
EU Specialty Business Unit			
Lixiana	+1.2	Olmesartan	-1.0
Nilemdo/ Nustendi	+1.5		
ASCA (Asia, South and Central America) Business Unit			
Enhertu	+5.5		

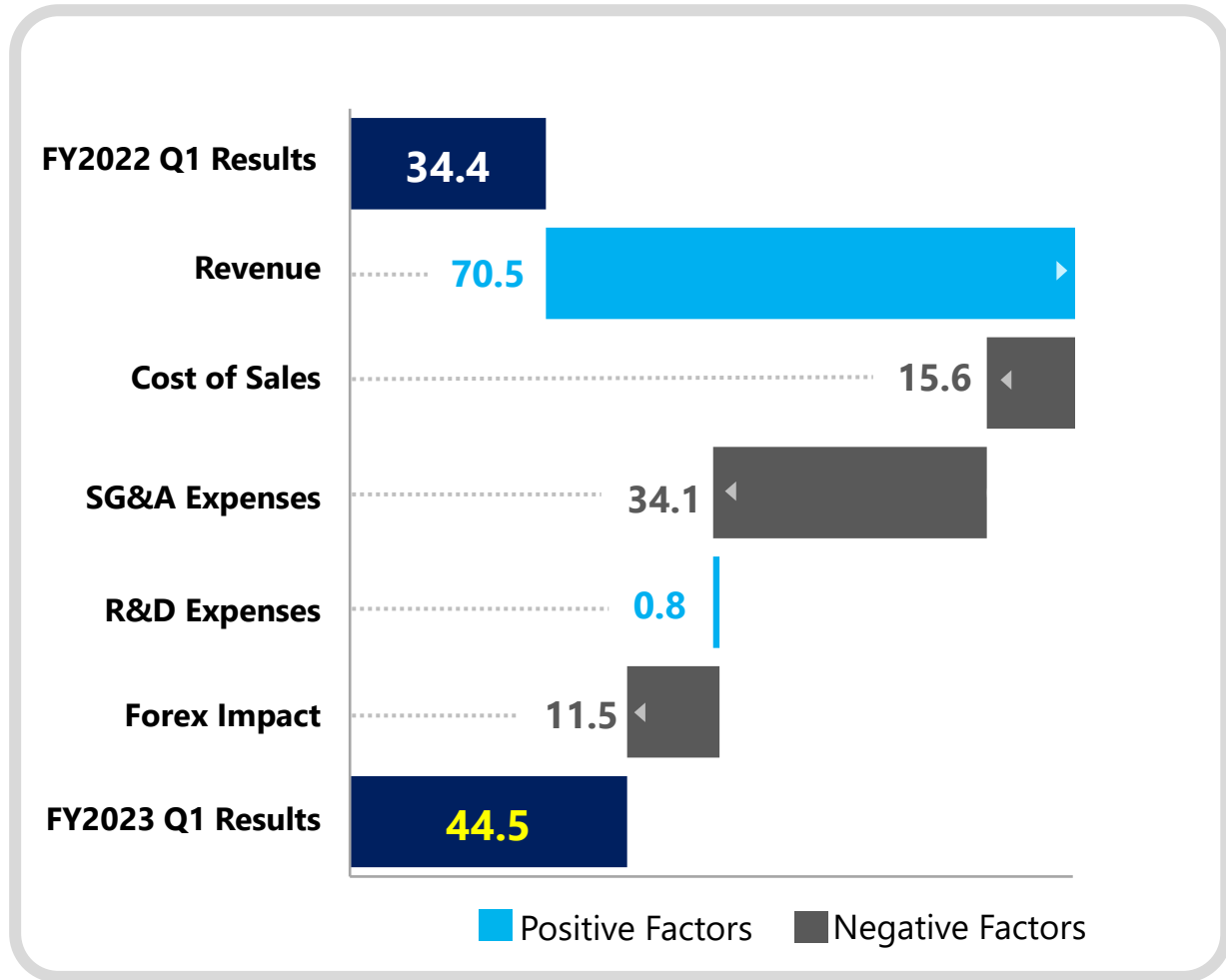
*1 Revenue for Daiichi Sankyo, Inc. and Daiichi Sankyo Europe's oncology products

*2 Dato-DXd: Datopotamab deruxtecan (DS-1062)

*3 Forex impact USD: +6.4, EUR: +4.5, ASCA: +0.7

Core Operating Profit

Increased by 10.1 Bn JPY (Increased by 10.0 Bn JPY excl. forex impact)

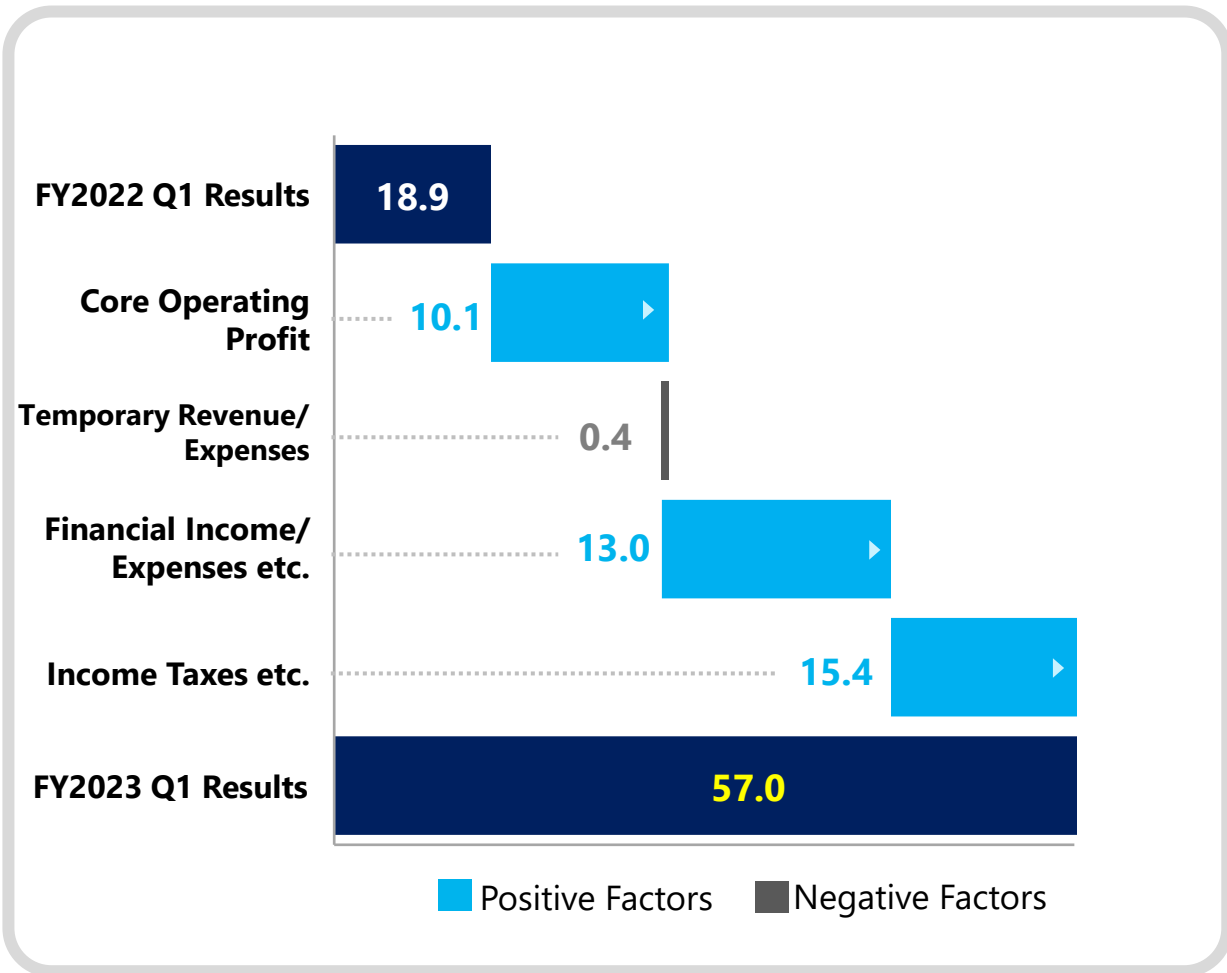


(Bn JPY)

Revenue	+70.5
incl. forex impact of +11.5	
Cost of Sales	+15.6
Increase in cost of sales due to the revenue increase	
SG&A Expenses	+34.1
Increase in expenses related to Enhertu due to an increase in profit share of gross profit with AstraZeneca	
Forex Impact	+11.5 (Profit Decreased)
Cost of Sales	+3.3
SG&A Expenses	+5.2
R&D Expenses	+3.0

Profit Attributable to Owners of the Company

Increased by 38.2 Bn JPY



(Bn JPY)

Financial Income/Expenses etc. +13.0 (Profit Increased)

- Improvement in forex gains/losses +4.9
- Improvement in investment securities valuation gains/losses +3.9
- Increase in interest income +2.9

Income Taxes etc. -15.4

	FY2022 Q1 Results	FY2023 Q1 Results	YoY
Profit before Tax	29.4	52.1	+22.7
Income Taxes etc.	10.6	-4.9	-15.4
Tax rate	35.9%	-9.4%	-45.3%

Revenue: Business Units (incl. Forex Impact)

(Bn JPY)

	FY2022 Q1 Results	FY2023 Q1 Results	YoY	
Japan Business	109.0	119.0	+10.0	
Daiichi Sankyo Healthcare	15.3	17.1	+1.9	
Oncology Business	27.5	70.6	+43.1	
Enhertu	26.7	69.4	+42.7	
Turalio	0.8	1.2	+0.4	
American Regent	47.0	50.7	+3.6	
Injectafer	14.1	13.2	-0.9	
Venofer	12.4	15.8	+3.4	
GE injectables	17.6	18.3	+0.8	
EU Specialty Business	37.1	41.5	+4.4	
Lixiana	28.6	32.3	+3.7	
Nilemdo/Nustendi	1.3	3.0	+1.7	
Olmesartan	5.4	4.7	-0.7	
ASCA (Asia, South and Central America) Business	31.9	39.5	+7.6	
Currency Rate	USD/JPY	129.57	137.37	+7.80
	EUR/JPY	138.10	149.46	+11.36

Revenue: Major Products in Japan

(Bn JPY)

		FY2022 Q1 Results	FY2023 Q1 Results	YoY
Lixiana	anticoagulant	25.1	27.9	+2.8
Pralia	treatment for osteoporosis/ inhibitor of the progression of bone erosion associated with rheumatoid arthritis	9.9	10.7	+0.8
Tarlige	pain treatment	8.9	11.7	+2.8
Vimpat	anti-epileptic agent	5.3	6.4	+1.1
Ranmark	treatment for bone complications caused by bone metastases from tumors	4.9	5.0	+0.0
Tenelia	type 2 diabetes mellitus treatment	5.6	5.3	-0.3
Enhertu	anti-cancer agent (HER2-directed antibody drug conjugate)	2.4	4.4	+1.9
Efient	antiplatelet agent	4.9	6.1	+1.3
Canalia	type 2 diabetes mellitus treatment	4.1	4.1	+0.1
Loxonin	anti-inflammatory analgesic	4.6	4.0	-0.6
Emgality	prophylaxis of migraine attacks	1.4	1.7	+0.3

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(Bn JPY)

	FY2023 Q1 Results		FY2023 Forecast		<Reference> Total Consideration
		YoY		YoY	
Product Sales	81.7	50.4	320.0	112.5	-
Japan	4.4	1.9	19.9	8.2	-
US	51.6	31.5	195.1	50.5	-
Europe	17.8	11.1	75.8	38.8	-
ASCA	8.0	5.8	29.2	15.1	-
Upfront payment	2.5 ^{*1}	-	9.8 ^{*1}	-	149.0
Regulatory milestone payment	2.1 ^{*1}	-1.3	11.6 ^{*1}	-15.1	136.3
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	0.2	-2.6	0.9	-2.6	13.1
EU HER2+ Breast Cancer 2L	0.2	0.2	0.7	-2.0	10.1
US HER2-low Breast Cancer (post-chemo)	0.5	0.5	1.8	-5.5	27.7
EU HER2-low Breast Cancer (post-chemo)	0.3	0.3	1.3	-3.9	19.8
EU HER2+ Gastric Cancer 2L	0.1	0.1	0.3	-0.9	4.8
US HER2 Mutant NSCLC 2L	0.3	0.3	1.1	-3.4	17.3
EU HER2 Mutant NSCLC 2L	-	-	3.2	3.2	9.8 ^{*2}
Quid related payment	0.3 ^{*1}	-	1.1 ^{*1}	-	17.2
Sales milestone payment	-	-	26.0 ^{*3}	12.8	39.2
Total	86.6	49.2	368.6	110.2	341.7

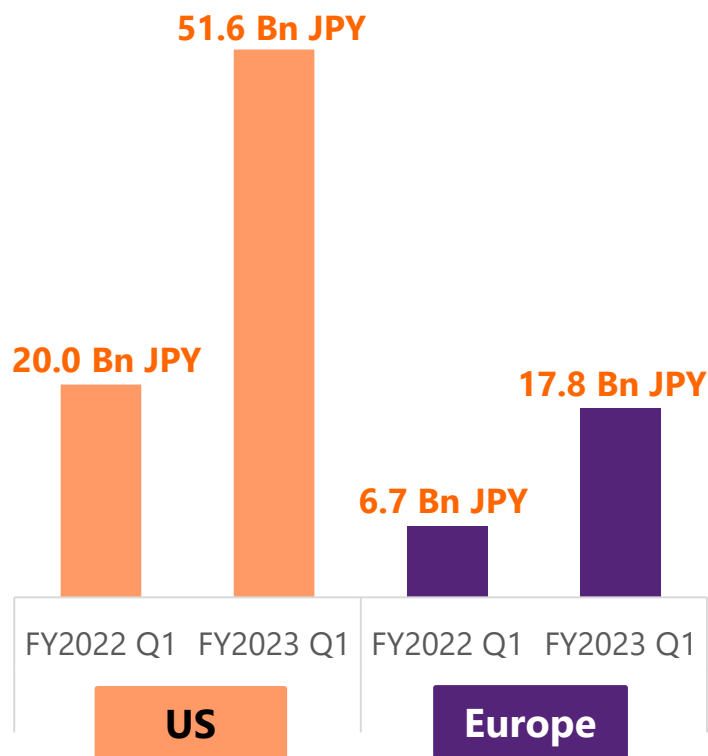
*1 Revenue recognized in each period

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

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

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

Global product sales: FY2023 Q1 results **81.7 Bn JPY** (YoY +50.4 Bn JPY) FY2023 forecast **320.0 Bn JPY** (YoY +112.5 Bn JPY)



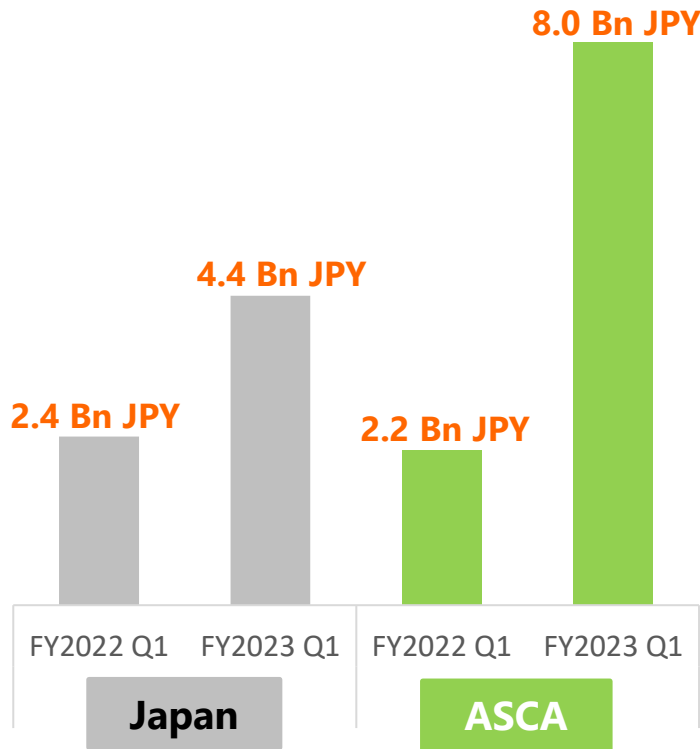
US

- ◆ **Product sales:** FY2023Q1 results **51.6 Bn JPY (375 Mn USD)** FY2023 forecast **195.1 Bn JPY (1.5 Bn USD)**
- ◆ **Indication:** HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 2L+, HER2 mutant mNSCLC 2L+
- ◆ **Market share status**
 - HER2+ mBC 2L: Maintaining No.1 new patient share
 - HER2 low mBC: Maintaining No.1 new patient share and growing further
 - HER2+ mGC 2L: Maintaining No.1 new patient share
 - HER2 mutant mNSCLC 2L: Maintaining No.1 new patient share

Europe

- ◆ **Product sales:** FY2023Q1 results **17.8 Bn JPY (130 Mn USD)** FY2023 forecast **75.8 Bn JPY (583 Mn USD)**
- ◆ **Indication:** HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 2L+
- ◆ **Market share status**
 - HER2+ mBC 2L: Maintaining No.1 new patient share in France, Germany and Spain
 - HER2 low mBC : Achieved No.1 new patient share in France and Germany
- ◆ **Other progress**
 - Launched in Italy (Jul. 2023)

Global product sales: FY2023 Q1 results **81.7 Bn JPY** (YoY +50.4 Bn JPY) FY2023 forecast **320.0 Bn JPY** (YoY +112.5 Bn JPY)



Japan

- ◆ **Product sales:** FY2023Q1 results **4.4 Bn JPY** FY2023 forecast **19.9 Bn JPY**
- ◆ **Indication:** HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 3L
- ◆ **Market share status**
 - HER2+ mBC 2L: Achieved No.1 new patient share
 - HER2 low mBC: Steady uptake in capturing new patient share
 - HER2+ mGC 3L: Maintaining No.1 new patient share

ASCA

- ◆ **Product sales:** FY2023Q1 results **8.0 Bn JPY** FY2023 forecast **29.2 Bn JPY**
- ◆ **Indication:** HER2+ mBC 2L+, HER2 low mBC (post-chemo), HER2+ mGC 3L
- ◆ **Market share status**
 - Sales growing in Brazil, Hong Kong and Taiwan
- ◆ **Other progress**
 - China: Launched for HER2+ mBC 2L (Jun. 2023), Approved for HER2 low mBC (post-chemo) and started promotion (Jul. 2023)

Initiatives Related to Profit Growth for Current Business and Products in Japan

Enhance product portfolio

◆ **VANFLYTA[®]** Anti-Cancer Agent /FLT3 Inhibitor

- **Obtained partial change approval for acute myeloid leukemia (AML) 1L therapy in May 2023**

Changed from "relapsed/refractory *FLT3*-ITD positive AML" to "*FLT3*-ITD positive AML"

◆ **TARLIGE[®]** Orally Disintegrating Tablet Pain Treatment

- **Launched** in May 2023



Enhance transformation into a profit structure focused on patented drugs

◆ **Stock Transfer of DAIICHI SANKYO ESPHA CO., LTD. (Concluded an agreement in May 2023)**

- Transferee: Qol Holdings Co., Ltd.
- Consideration for transfer: 25.0 Bn JPY
- Date of transfer (planned) :
October 1, 2023 (30% of the shares held by the Company), April 1, 2024 (21% of the shares held by the Company)
※ The date of execution of the transfer of the remaining 49% of the Company's shares will be determined by separate negotiation.

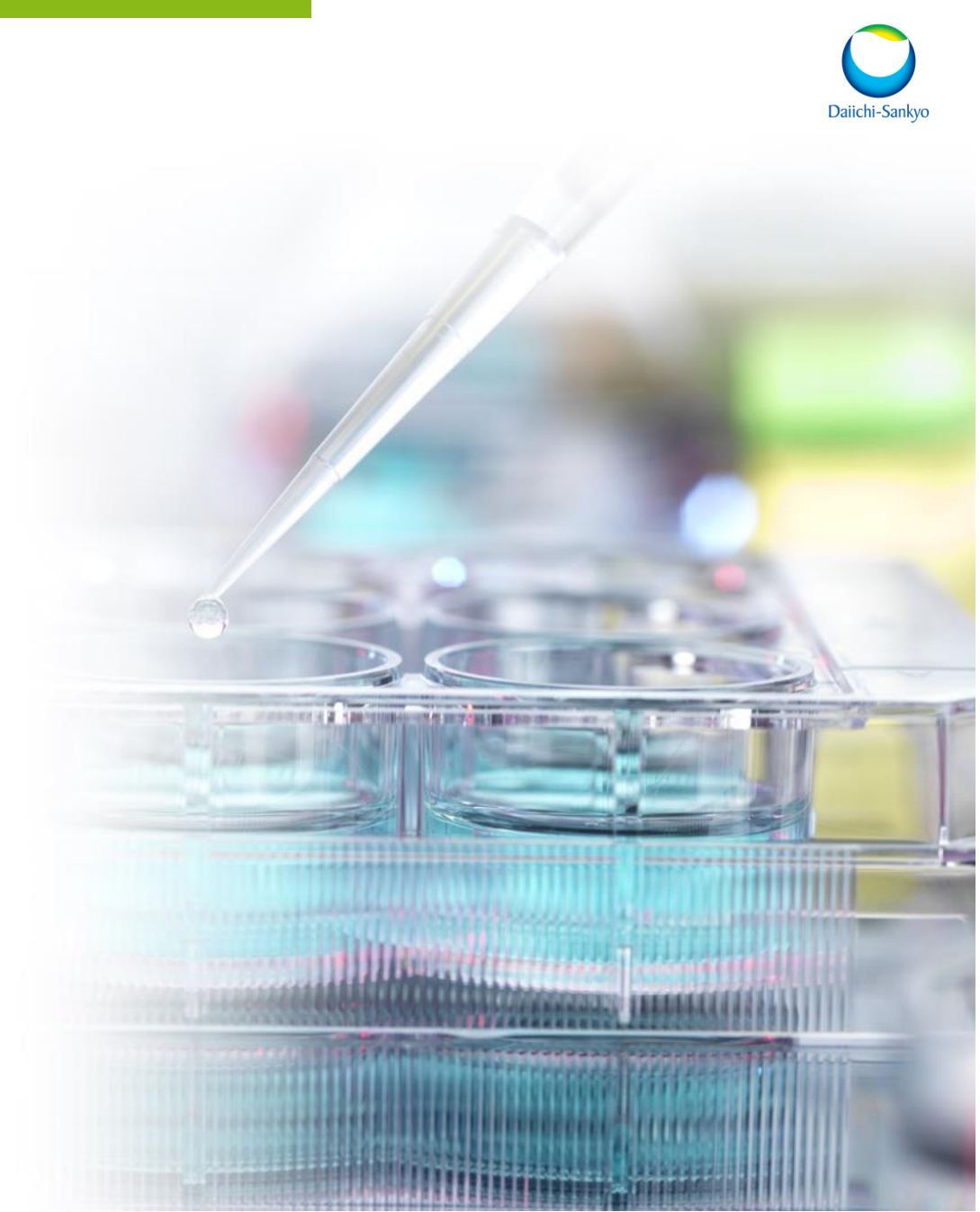
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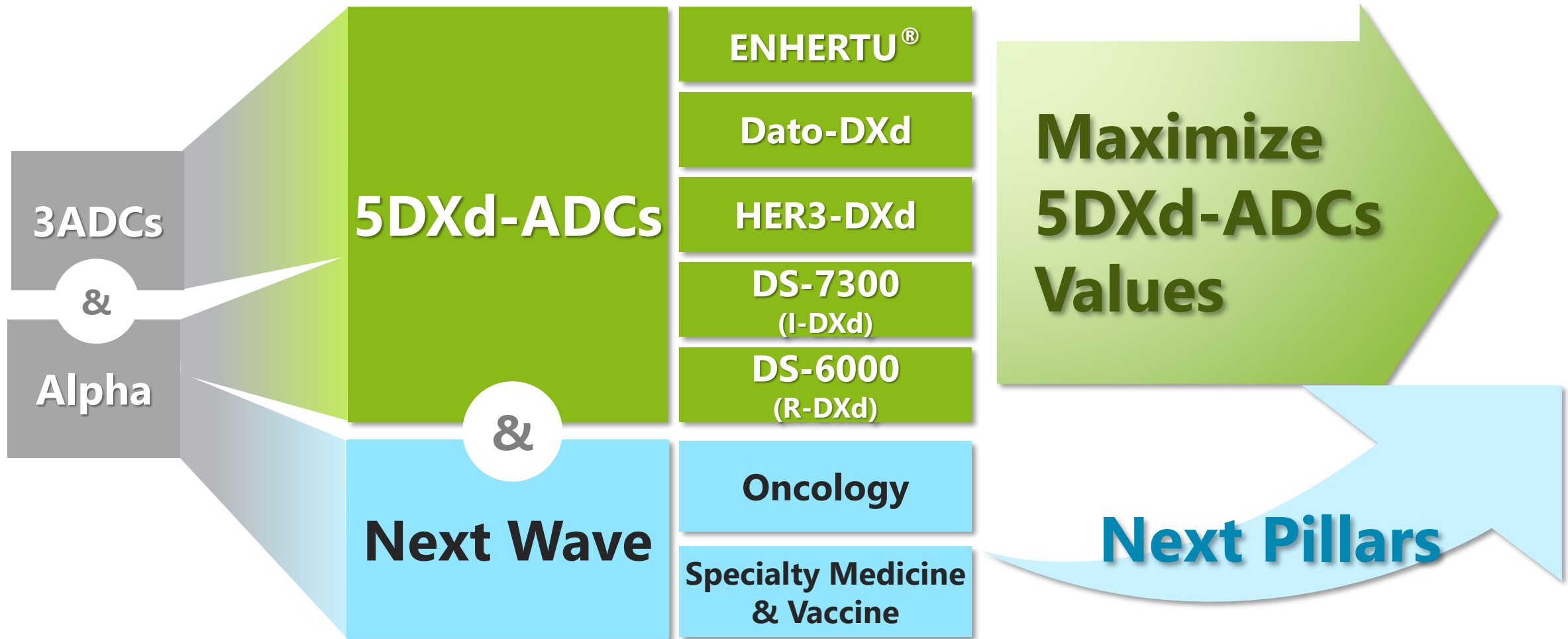


5DXd-ADCs Update

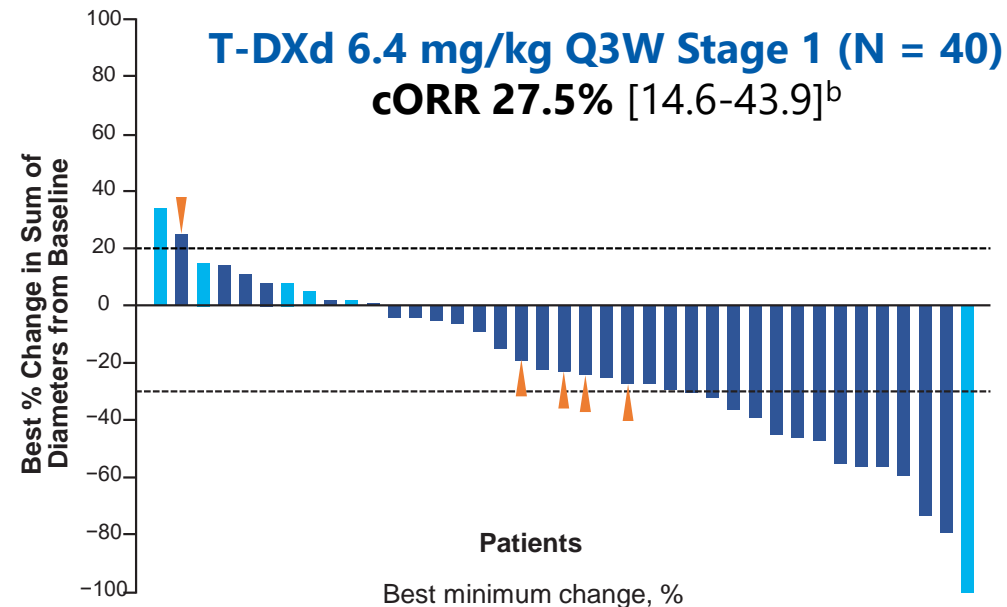
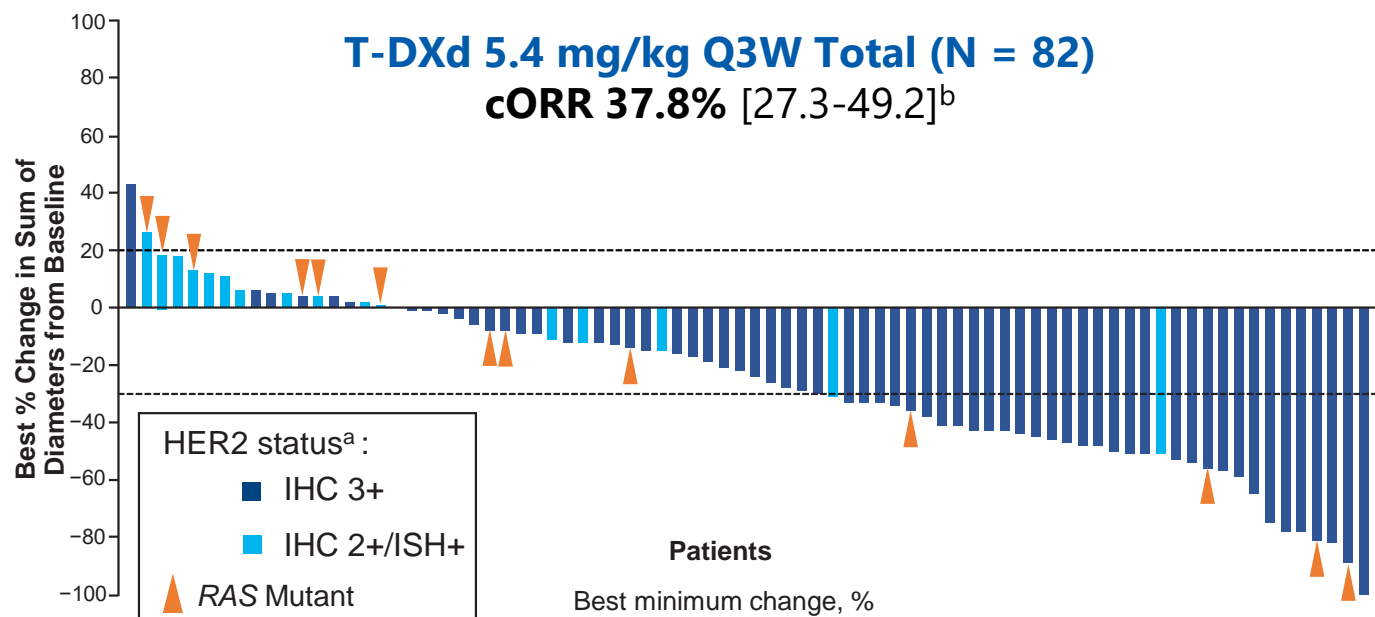
Next Wave Update

News Flow

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



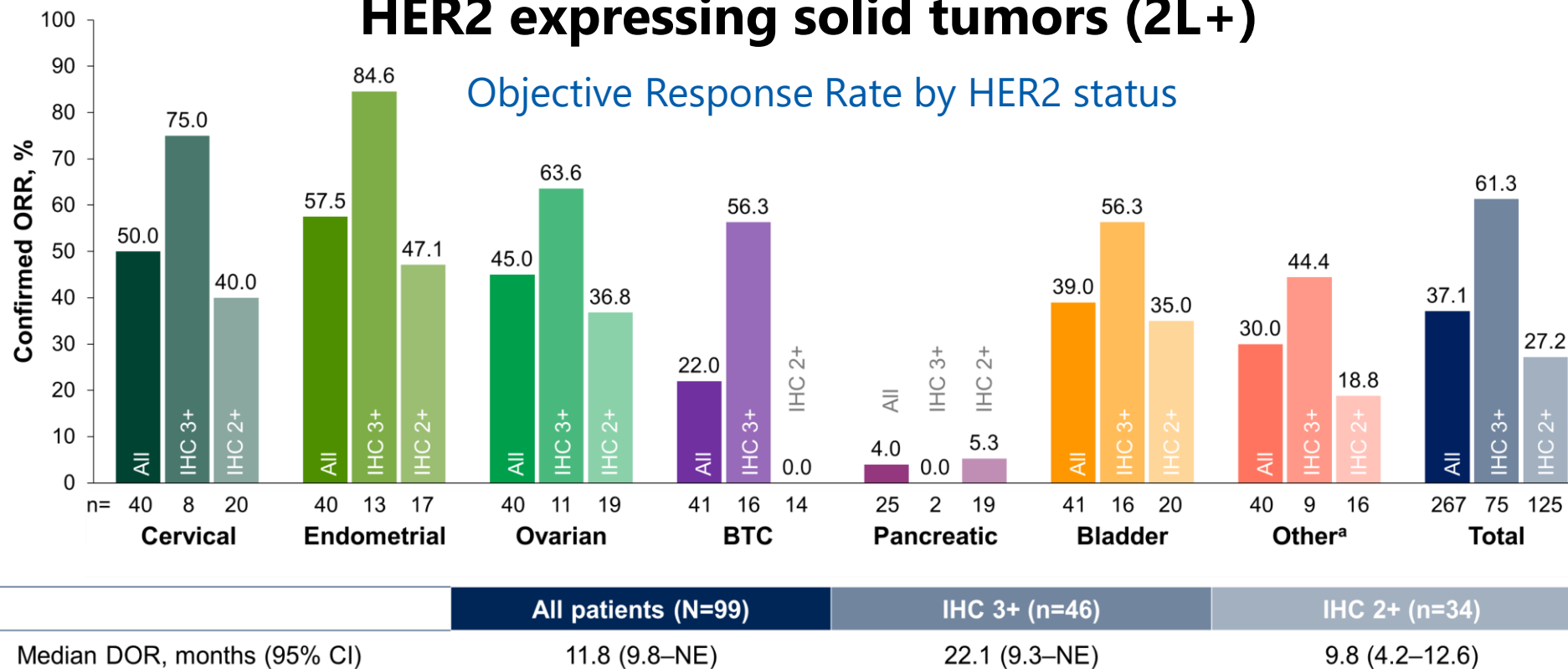
DESTINY-CRC02 study suggests 5.4 mg/kg is the optimal dose



- Both doses evaluated confirmed the promising antitumor activity
- Antitumor activity (ORR) in patients with and without RAS mutation at the 5.4 mg/kg dose
- The most common adverse events seen with ENHERTU® in this study were nausea, fatigue, neutropenia, anemia comparable to the known profile of T-DXd
- There was no grade ≥3 ILD/pneumonitis cases in the 5.4 mg/kg arm
- Efficacy and safety profile of both cohorts favors the 5.4 mg/kg dose

^a HER2 status was assessed by central laboratory. ^b 95% confidence interval. cORR: confirmed objective response rate, IHC: immunohistochemistry, ILD: interstitial lung disease, ISH: in situ hybridization, mCRC: metastatic colorectal cancer, Q3W: every 3 weeks, T-DXd: trastuzumab deruxtecan, TEAE: treatment emergent adverse events

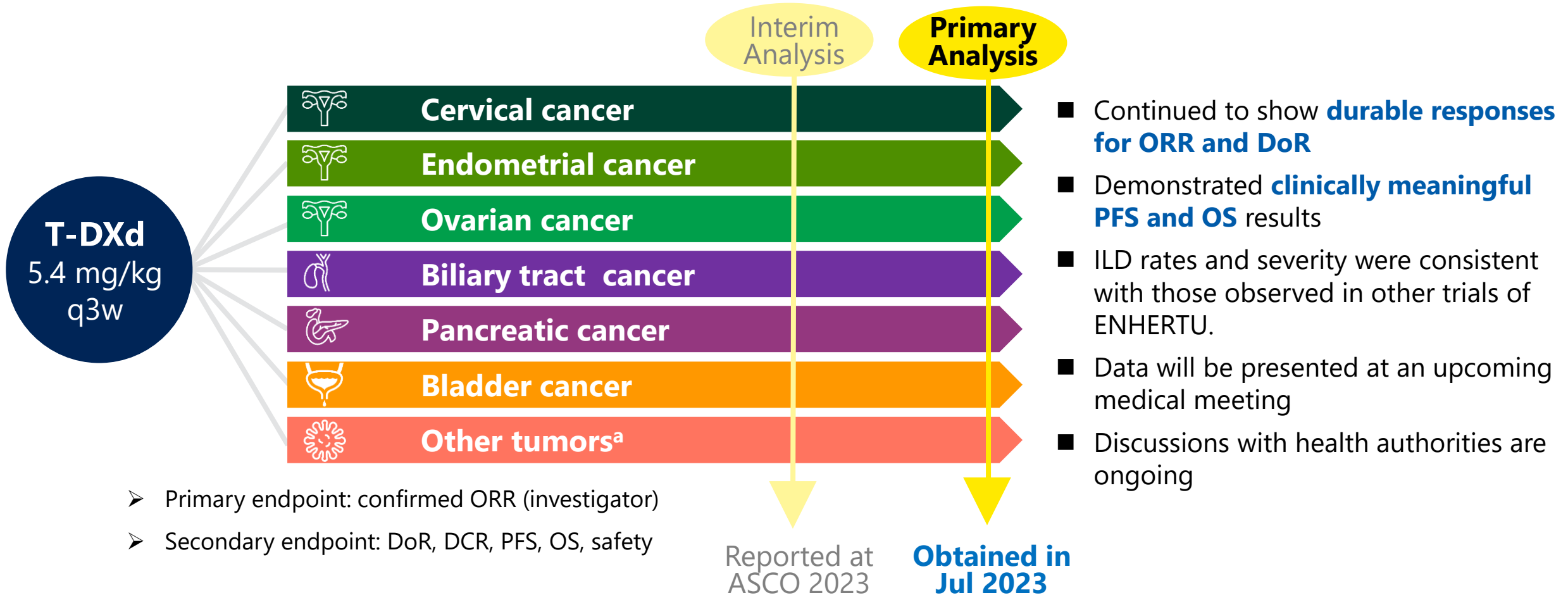
Demonstrated clinically meaningful activity across a broad range of HER2 expressing solid tumors (2L+)



- ORR: 37.1% in all patients (n=267) and 61.3% in patients with IHC 3+ (n=75)
- DoR: median DoR 11.8 months in all patients responded (n=99) and 22.1 months in patients with IHC 3+ (n=46)
- Most common adverse events of ENHERTU® in this study were neutropenia, anemia, fatigue, nausea, thrombocytopenia which were comparable to the known profile seen with T-DXd
- Majority of ILD/pneumonitis events were grade 1 or 2; one grade 3 event and one grade 5 event were observed

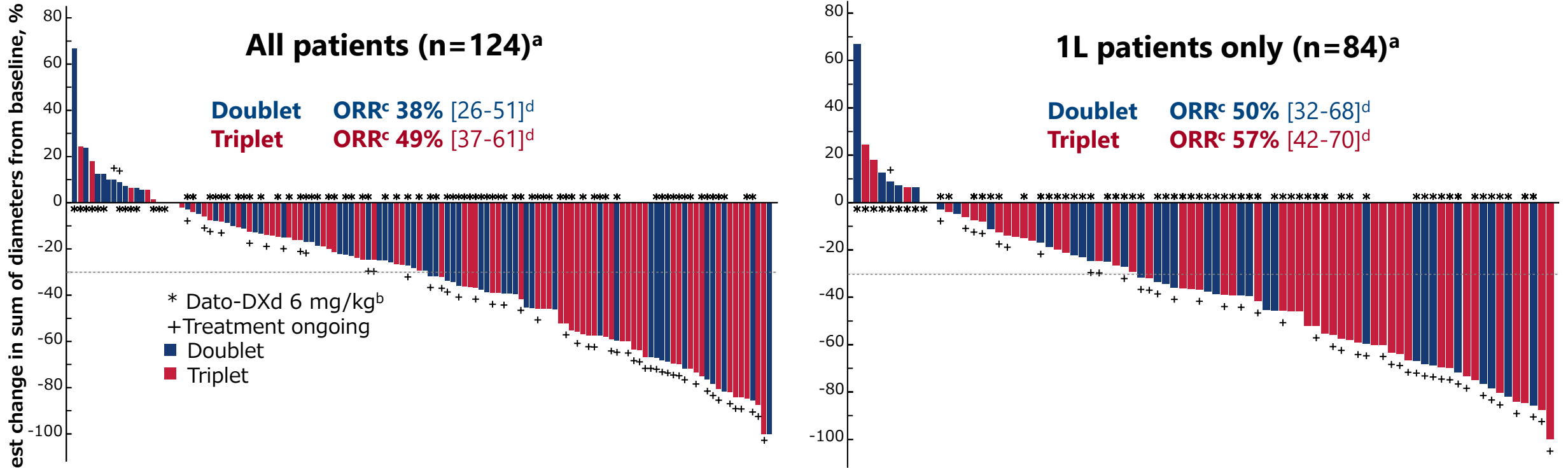
^a Analysis of DoR was performed in patients with objective response ^b Responses in extramammary Paget's disease, head and neck cancer, oropharyngeal neoplasm, and salivary gland cancer. BTC: biliary tract cancer, CI: confidence interval, DoR: duration of response, IHC: immunohistochemistry, ILD: interstitial lung disease, NE: non-estimable; ORR, objective response rate.

TLR from the primary analysis was acquired in Jul 2023



^a Patients with tumors that express HER2, excluding tumors in the tumor-specific cohorts, and breast cancer, non-small cell lung cancer, gastric cancer, and colorectal cancer.

Dato-DXd + Pembrolizumab (Doublet) and additional platinum chemotherapy (Triplet) demonstrated encouraging antitumor activity



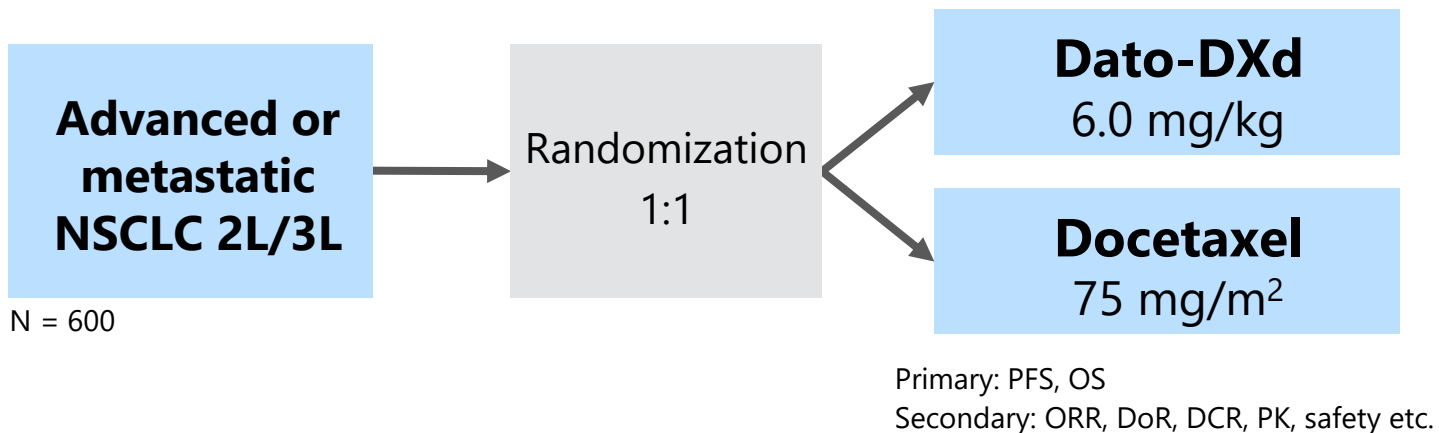
Data cutoff: April 7, 2023

- The left graph includes the patients with NSCLC in the 1L and 2L+ settings
- The most common adverse events of Dato-DXd in this study were stomatitis, nausea, anemia, fatigue which were comparable to the known profile of Dato-DXd
- Observed stomatitis and ILD/pneumonitis as AESI, predominantly grade 1 or 2 (no grade 4 or 5 ILD/pneumonitis observed)

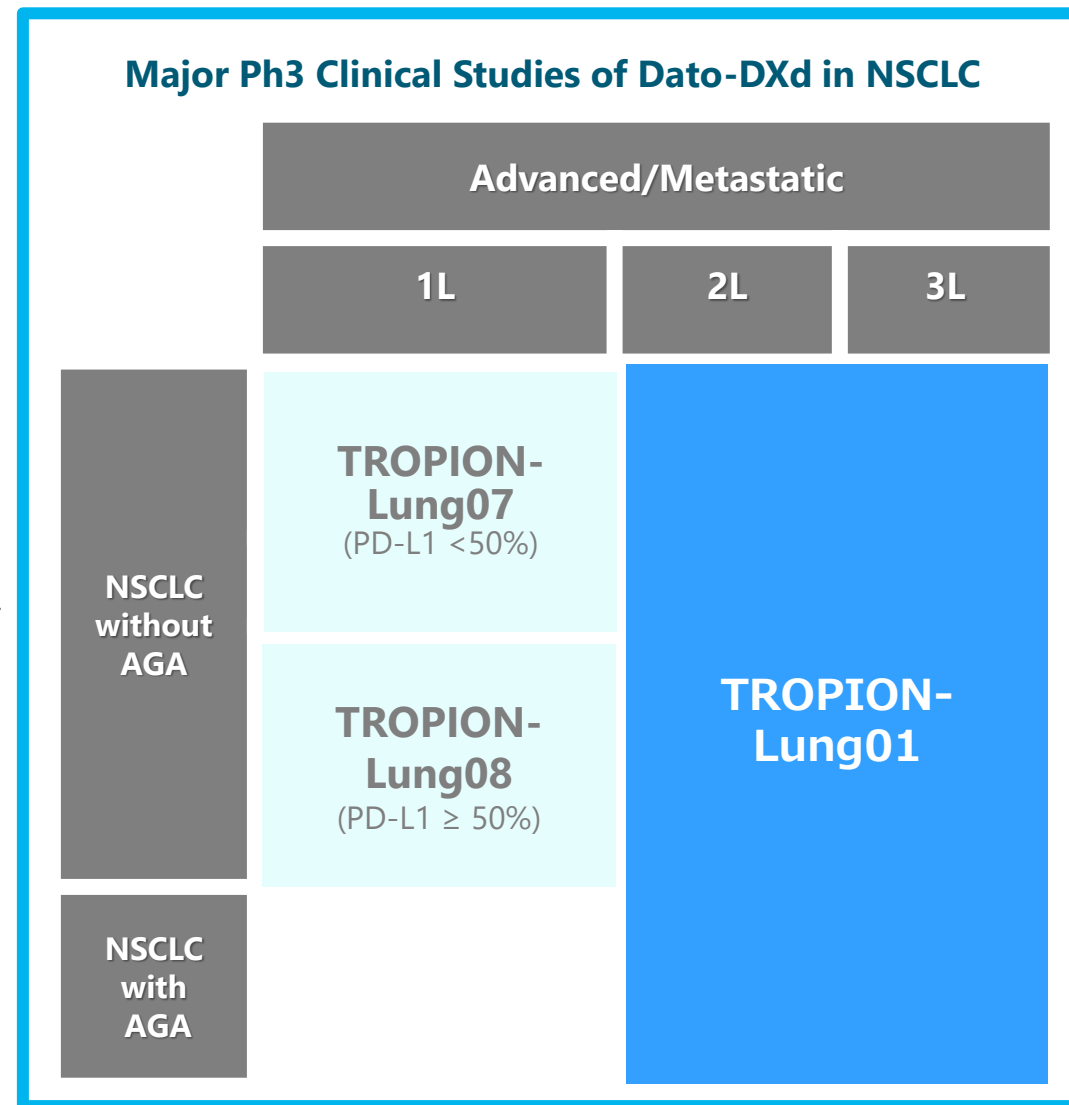
^a Patients with no baseline target lesions or no postbaseline tumor assessments were excluded from the waterfall plots. ^b Planned dose level. ^c Responses pending confirmation. ^d 95% confidence interval

1L: first line, AESI: adverse events of special interest, ASCO: American Society of Clinical Oncology, CI: confidence interval, ILD: interstitial lung disease, NSCLC: non small cell lung cancer, ORR: objective response rate, TEAE: treatment emergent adverse events

Disclosed TLR in July 2023



- Demonstrated statistically significant improvement in PFS
- No new safety signals identified, all grade ILD was generally consistent with prior clinical trials with the majority being grade 1 or 2. Grade 5 ILD events were observed
- **Proceeding to file the data with FDA**



Planned regulatory submission in US in FY2023 H2

Clinical studies of HER3-DXd in EGFR mutated NSCLC

Advanced/Metastatic

1L

2L

3L

**HERTHENA-
Lung02 Ph3**
(HER3-DXd mono vs
chemo)

**HERTHENA-
Lung01
registrational
Ph2**

Osimertinib combination Ph1b

- Announced the TLR outline in FY2022 Q4 earnings call
 - 5.6 mg/kg dose showed durable responses in patients with metastatic or locally advanced EGFR mutated NSCLC previously treated with an EGFR TKI and PBC
 - No new safety concerns identified
- Clinical data to be presented at **WCLC in Sep 2023**
- Other ongoing EGFR mutated NSCLC studies:
 - HERTHENA-Lung02 study (2L, Ph3)
 - Osimertinib combination Ph1b study

ENHERTU®

- Jun 2023: Combination study with DS-1103 (anti-SIRP α antibody) started
- Jul 2023: Approved in China for chemo treated HER2 low BC (DESTINY-Breast04)

DS-7300

- Apr 2023: Orphan drug designation granted by FDA for SCLC

5DXd-ADCs Update

Next Wave Update

News Flow

DXd-ADC directed **TA-MUC1** (DAR: 8)

Ph1/2 study in solid tumors is planned to start in **FY2023 Q2**

Ph1/2 Study Design

Dose Escalation Part

DS-3939 (IV, Q3W)

Locally advanced, metastatic, or unresectable NSCLC, BC, UC, OVC, BTC, or PDAC



Dose Expansion Part

DS-3939 (IV, Q3W)

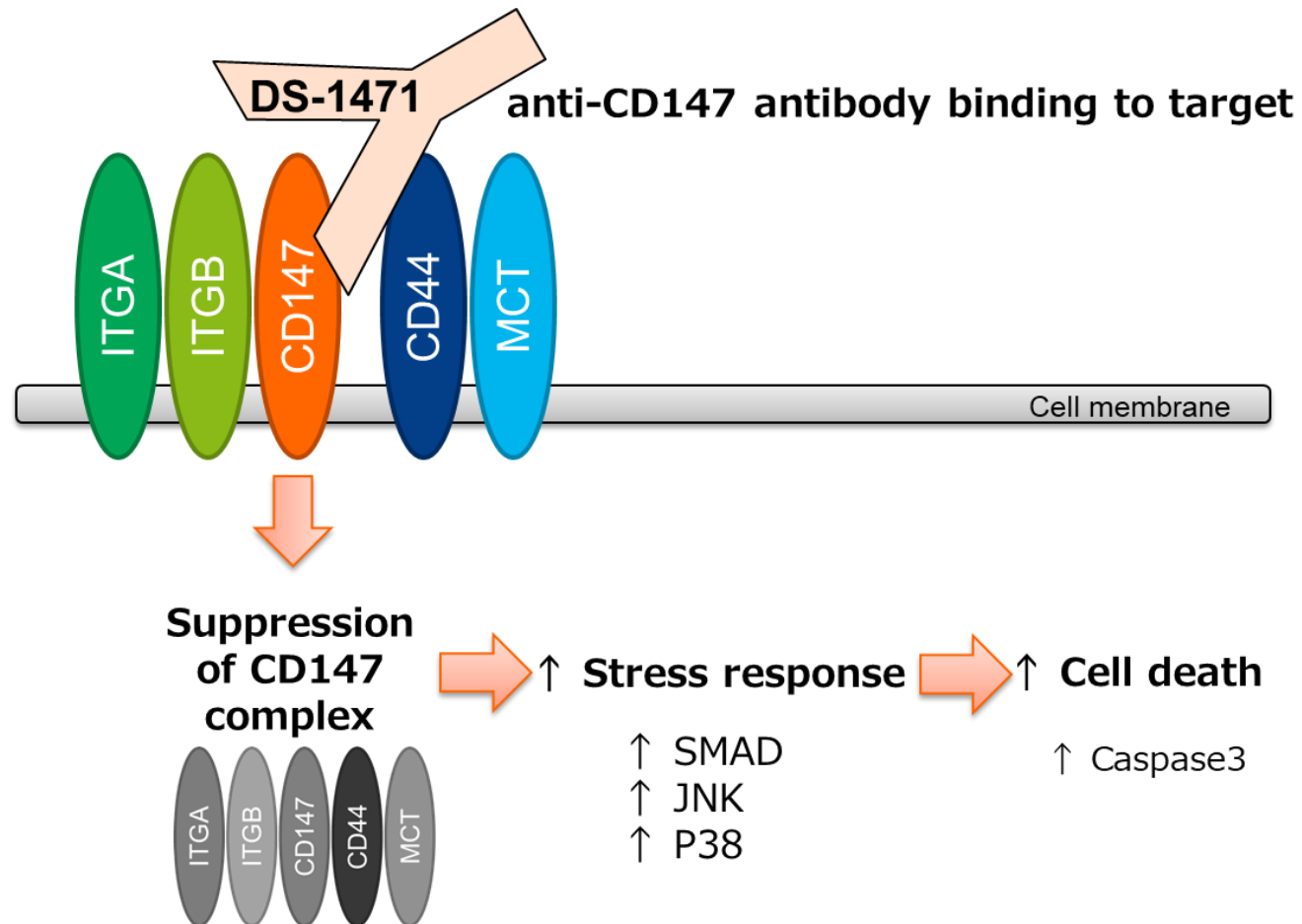
Multiple expansion cohorts targeting various advanced solid tumors

Evaluate safety and preliminary efficacy

- DS-3939 is an ADC developed by combining an anti-TA-MUC1 antibody in-licensed from Glycotope GmbH (Berlin, Germany) and Daiichi Sankyo's DXd-ADC technology
- Tumor-associated Mucin 1 (TA-MUC1) is a transmembrane glycoprotein overexpressed in LC, BC, OVC, and other tumor types
- FIH study in solid tumors composed of dose escalation and dose expansion part is planned to start in FY2023 Q2

DS-1471 is a monoclonal antibody targeting **CD147**

Ph1 study for solid tumors is planned to start in **FY2023 H2**



- CD147 complex is important in survival, such as invasion and metastasis, in cancer tissues; also involved in embryogenesis and wound healing etc., in normal tissue
- Unique MoA by downregulation of CD147 complex leading to cellular stress response and apoptotic cell death
- FIH study composed of dose escalation and dose expansion in solid tumors will start FY2023 H2

Vanflyta® (quizartinib) (*FLT3*-ITD positive acute myeloid leukemia [AML], 1L)

- May 2023: Approved in Japan
- Jul 2023: Approved in US

Ezharmia® (valemestostat) (relapsed/refractory peripheral T-cell lymphoma [PTCL])

- Jun 2023: TLR obtained

DS-5670 (COVID-19 mRNA vaccine)

- May 2023: Ph3 study for omicron strain booster vaccination in healthy volunteers 12 years and over
- May 2023: Ph2/3 study for omicron strain booster vaccination in children aged 5 to 11 years

DS-7011 (systemic lupus erythematosus [SLE])

- Jul 2023: Ph1b/2 study for SLE patients started

DS-2325 (Netherton syndrome)

- May 2023: Granted Rare Pediatric Disease Designation by FDA

5DXd-ADCs Update

Next Wave update

News Flow

Planned major publications

WCLC (Sep 9-12, 2023)

ENHERTU®	DESTINY-Lung02: HER2 mutant NSCLC, 2L+, Ph2 • Primary analysis data
Dato-DXd	TROPION-Lung04: NSCLC w/o AGA, 1L+, Ph1 • Interim data
HER3-DXd	HERTHENA-Lung01: EGFR mutant NSCLC, 3L, Ph2 • Primary analysis data
DS-7300 (I-DXd)	Ph1/2 • SCLC sub-analysis data

Regulatory decisions

ENHERTU®	DESTINY-Lung01, 02 : HER2 mutant NSCLC, 2L+, Ph2 • JP: FY2023 Q2 • EU: FY2023 H2
VANFLYTA®	QuANTUM-First: AML, 1L, Ph3 • EU: FY2023 H2
DS-5670	COVID-19 mRNA vaccine, original strain, booster vaccination, healthy adults, Ph1/2/3 • JP: FY2023 Q2

Key data readouts

ENHERTU®	DESTINY-Breast06*: HR+ and HER2 low BC, chemo naïve, Ph3 • FY2023 H2
Dato-DXd	TROPION-Breast01*: HR+ and HER2 low or negative BC, 2/3L, Ph3 • FY2023 H2

Bold: update from FY2022 Q4

AGA: actionable genomic alterations, AML: acute myeloid leukemia, BC: breast cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, WCLC: World Conference on Lung Cancer

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

*Event-driven study

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Major R&D Milestones (5DXd-ADCs ①)

Project	Target Indication [phase, study name]	FY2023		FY2024
		H1	H2	
ENHERTU®	• HER2 low, post chemo [Ph3, DESTINY-Breast04]	• Approved (China)		
	• HER2 low, chemo naïve [Ph3, DESTINY-Breast06]		• TLR anticipated	
	• HER2+, 1L [Ph3, DESTINY-Breast09]			• TLR anticipated
	• HER2+, Neoadjuvant [Ph3, DESTINY-Breast11]			• TLR anticipated
	• HER2 mutant, 2L [Ph2, DESTINY-Lung01, 02]	• Approval anticipated (JP)	• Approval anticipated (EU)	
	• HER2 mutant, 1L [Ph3, DESTINY-Lung04]			• TLR anticipated

Major R&D Milestones (5DXd-ADCs ②)

Project	Target Indication [phase, study name]	FY2023		FY2024
		H1	H2	
Dato-DXd	NSCLC • 2/3L [Ph3, TROPION-Lung01]	• TLR obtained		
	BC • HR+ and HER2 low or negative BC, 2/3L [Ph3, TROPION-Breast01]		• TLR anticipated	
	BC • TNBC, 1L [Ph3, TROPION-Breast02]			• TLR anticipated
HER3-DXd	NSCLC • EGFR mutated, 2L [Ph3, HERTHENA-Lung02]			• TLR anticipated
DS-7300 (I-DXd)	SCLC • 2L [Dose optimization, Ph2]			• TLR anticipated

Bold: update from FY2022 Q4 BC: breast cancer, HR: hormone receptor, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, TLR: top line results, TNBC: triple-negative breast cancer

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

Major R&D Milestones (Next Wave)

Project	Target Indication [phase, study name]	FY2023		FY2024
		H1	H2	
VANFLYTA®	• AML, 1L [Ph3, QuANTUM-First]	• Approved (JP/US)	• Approval anticipated (EU)	
EZHARMIA®	• r/r PTCL [Registrational Ph2, VALENTINE-PTCL01]	• TLR obtained		
DS-1103	• HER2 expressing or mutant solid tumors, HER2 low BC [Ph1]	• Study started		
DS-3939	• Solid tumors [Ph1/2]	• Study start planned		
DS-1471	• Solid tumors [Ph1]		• Study start planned	
DS-7011	• Systemic lupus erythematosus [Ph1b/2]	• Study started		
DS-5670	• COVID-19 mRNA vaccine (mutant strain), booster vaccination [Ph3]	• Study started		
	• COVID-19 mRNA vaccine (original strain), booster vaccination [Ph1/2/3]	• Approval anticipated (JP)		

Bold: update from FY2022 Q4 AML: acute myeloid leukemia, BC: breast cancer, PTCL: peripheral T cell lymphoma, r/r: relapsed/refractory, TLR: top line results

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

Major R&D Pipeline: 5DXd-ADCs

Phase 1		Phase 2		Phase 3		Filed	
(US/EU/Asia) HER2+ BC 2L+/1L DESTINY-Breast07	(JP/US) solid tumors TROPION-PanTumor01	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) solid tumors TROPION-PanTumor03	(JP/US/EU/Asia) HER2+ BC adjuvant* ¹ DESTINY-Breast05	(JP/EU) HER2 mutant NSCLC 2L+ DESTINY-Lung01/Lung02		
(US/EU/Asia) HER2 low BC Chemo naïve/ post chemo DESTINY-Breast08	(CN) NSCLC, TNBC TROPION-PanTumor02	(CN) HER2+ GC 3L DESTINY-Gastric06	(JP/US/EU/Asia) NSCLC (w/ AGA) TROPION-Lung05	(JP/US/EU/Asia) HER2 low BC chemo naïve DESTINY-Breast06			
(JP/US/EU/Asia) HER2+ GC combo, 2L+/1L DESTINY-Gastric03	(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) TROPION-Lung02	(CN) HER2 mutant NSCLC 2L+ DESTINY-Lung05	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09			
(US/EU/Asia) HER2+ NSCLC (durvalumab combo) 1L DESTINY-Lung03	(JP/US/EU) NSCLC (w/o AGA, durvalumab, AZD2936 and MEDI5752 combo) TROPION-Lung04	(US/EU/Asia) NSCLC (durvalumab combo) 2L+ HUDSON	(JP/US/EU/Asia) EGFR mutated NSCLC (osimertinib combo) 2L ORCHARD	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11			
(US/EU) BC, bladder (nivolumab combo)	(JP/US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(JP/US/EU) HER2+ CRC 3L DESTINY-CRC01	(US/EU/Asia) resectable early-stage NSCLC (durvalumab combo) neoadjuvant NeoCOAST-2	(US/EU/Asia) HER2 low BC, HER2 IHC 0 BC, 2/3L DESTINY-Breast15			
(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US/EU/Asia) NSCLC	(JP/US/EU/Asia) HER2+ CRC 3L DESTINY-CRC02	(JP/US/EU/Asia) EGFR mutated NSCLC 3L HERTHENA-Lung01	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04			
(US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(JP/US) EGFR mutated NSCLC (osimertinib combo)	(JP/US/EU/Asia) HER2 mutant tumor DESTINY-PanTumor01	DS-7300 (JP/US/EU/Asia) ES-SCLC	(JP/US/EU/Asia) NSCLC (w/ HER2 exon 19 or exon 20 mutation) 1L DESTINY-Lung04			
DS-7300 (JP/US) ESCC, CRPC, squamous NSCLC, SCLC, etc.	(JP/US) HER3+ BC	(US/EU/Asia) HER2 expressing tumor DESTINY-PanTumor02		(JP/US/EU/Asia) NSCLC 2/3L TROPION-Lung01			
DS-6000 (JP/US) Renal cell carcinoma, ovarian cancer				(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, pembrolizumab combo) 1L TROPION-Lung07			
				(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) 1L TROPION-Lung08			
				(JP/US/EU/Asia) BC* ² 2/3L TROPION-Breast01			
				(JP/US/EU/Asia) TNBC 1L TROPION-Breast02			
				(JP/US/EU/Asia) TNBC (mono or durvalumab combo) adjuvant* ³ TROPION-Breast03			
				(JP/US/EU/Asia) EGFR mutated NSCLC 2L HERTHENA-Lung02			

■ ENHERTU®
 ■ Dato-DXd
 ■ HER3-DXd
 ■ DS-7300
 ■ DS-6000










□ 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 (designated in at least one country/region among JP, US and EU)

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

AGA: actionable genomic alterations, BC: breast cancer, CRC: colorectal cancer, CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, ES-SCLC: extensive stage-small cell lung cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer, TNBC: triple negative breast cancer

Major R&D Pipeline: Next Wave

Phase 1		Phase 2	Phase 3	Filed
<p>DS-1055 (JP/US) Anti-GARP antibody Solid tumors</p>	<p>DS-7011 (US) Anti-TLR7 antibody Systemic lupus erythematosus</p>	<p>Valemetostat (DS-3201)(JP/US/EU/Asia)  </p> <p>EZH1/2 inhibitor PTCL</p>	<p>Pexidartinib (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor</p>	<p>Quizartinib (EU) FLT3 inhibitor AML 1L   </p>
<p>DS-1594 (US) Menin-MLL binding inhibitor AML, ALL</p>	<p>DS-2325 (US)    KLK5 inhibitor Netherton syndrome</p>	<p>Valemetostat (DS-3201) (EU) EZH1/2 inhibitor BCL</p>	<p>Esaxerenone (JP) MR blocker Diabetic nephropathy</p>	<p>Mirogabalin (CN) α2δ ligands Diabetic peripheral neuropathic pain</p>
<p>DS-9606 (US/EU) Target undisclosed ADC Solid tumors</p>		<p>DS-1001 (JP) Mutant IDH1 inhibitor Glioma</p>	<p>VN-0102/JVC-001 (JP) Measles mumps rubella combined vaccine</p>	<p>DS-5670 (JP) COVID-19 mRNA vaccine (original strain) COVID-19 (booster vaccination)</p>
<p>DS-1103 Anti-SIRPα antibody HER2 expressing or mutant advanced metastatic solid tumors, HER2 low BC (ENHERTU® combo)</p>		<p>DS-1211 (US/EU)  TNAP inhibitor Pseudoxanthoma elasticum</p>	<p>DS-5670 (JP) COVID-19 mRNA vaccine (original strain), COVID-19 (primary vaccination, 12 to 17 aged children)</p>	
<p>DS-3939 Anti-TA-MUC1 ADC Solid tumors (in prep.)</p>		<p>DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain), COVID-19 (primary vaccination, 5 to 11 aged children) (in prep.)</p>	<p>DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain) COVID-19 (booster vaccination, 12 years old and over)</p>	
<p>DS-1471 Anti-CD147 antibody Solid tumors (in prep.)</p>		<p>VN-0200 (JP) RS virus vaccine RS virus infection</p>	<p>DS-5670 (JP) COVID-19 mRNA vaccine (mutant strain), COVID-19 (booster vaccination, 5 to 11 aged children)</p>	

-  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)  Rare Pediatric Disease Designation (US)
-  Fast Track Designation (US)  Breakthrough Designation (US)

ALL: acute lymphoblastic leukemia, AML: acute myeloid leukemia, BCL: B cell lymphoma, LBCL: large B cell lymphoma, PTCL: peripheral T-cell lymphoma

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