Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

ASCO Highlights 2023

DAIICHI SANKYO CO., LTD.

June 5th (US)/ 6th (JP), 2023

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ASCO Highlights 2023: IR conference call

Sunao Manabe
Executive Chairperson
and CEO

Ken Takeshita
Head of Global R&D

Mark Rutstein
Head of Global
Oncology Clinical Development

Date and time	Jun 6, 2023 (Tue) 9:30-11:00am JST/ Jun 5, 2023 (Mon) 7:30-9:00pm CDT
Meeting style	Hybrid (Face to face and Zoom)

Content will be delivered on-demand after the meeting

Agenda

1. **Introduction**
2. R&D strategy
3. Highlights from ASCO & ESMO Breast
4. Closing
5. Q&A

5-Year Business Plan (FY2021-FY2025) for Sustainable Growth

We will achieve our 2025 Goal, **Global Pharma Innovator with Competitive Advantage in Oncology**, and will shift to further growth towards our 2030 Vision

As of FY2020

- Oncology business launched
- Edoxaban growing
- Regional value being enhanced
- AZ strategic alliance
- Increased RD investment

2030 Vision

Innovative Global Healthcare Company Contributing to the Sustainable Development of Society

- Global top 10 in Oncology
- Additional growth pillars being source of revenue and profit
- New products being source of profit in each business unit
- Contributing to sustainable development of society through our business

Strategic Pillars for the 5-Year Business Plan (FY2021-FY2025)

Achieve 2025 Goal and Shift to Further Growth

FY2025 Financial Targets

- Revenue: 1.6 Tn JPY (Oncology > 600.0 Bn JPY)
- Core Operating Profit* Ratio before R&D Expense: 40%
- ROE > 16%
- DOE** > 8%

Maximize 3ADCs

- Maximize ENHERTU® and Dato-DXd through strategic alliance with AstraZeneca
- Maximize HER3-DXd without a partner
- Expand work force and supply capacity flexibly depending on changes around product potential

Profit growth for current business and products

- Maximize Lixiana® profit
- Grow Tarlige®, Nilemdo®, etc. quickly
- Transform to profit structure focused on patented drugs
- Profit growth for American Regent and Daiichi Sankyo Healthcare

Identify and build pillars for further growth

- Identify new growth drivers following 3ADCs
- Select and advance promising post DXd-ADC modalities

Create shared value with stakeholders

- Patients: Contributing to patients through "Patient Centric Mindset"
- Shareholders: Balanced investment for growth and shareholder returns
- Society: Environment load reduction across the value chain, and actions against pandemic risks
- Employees: Create one DS culture through fostering our core behaviors

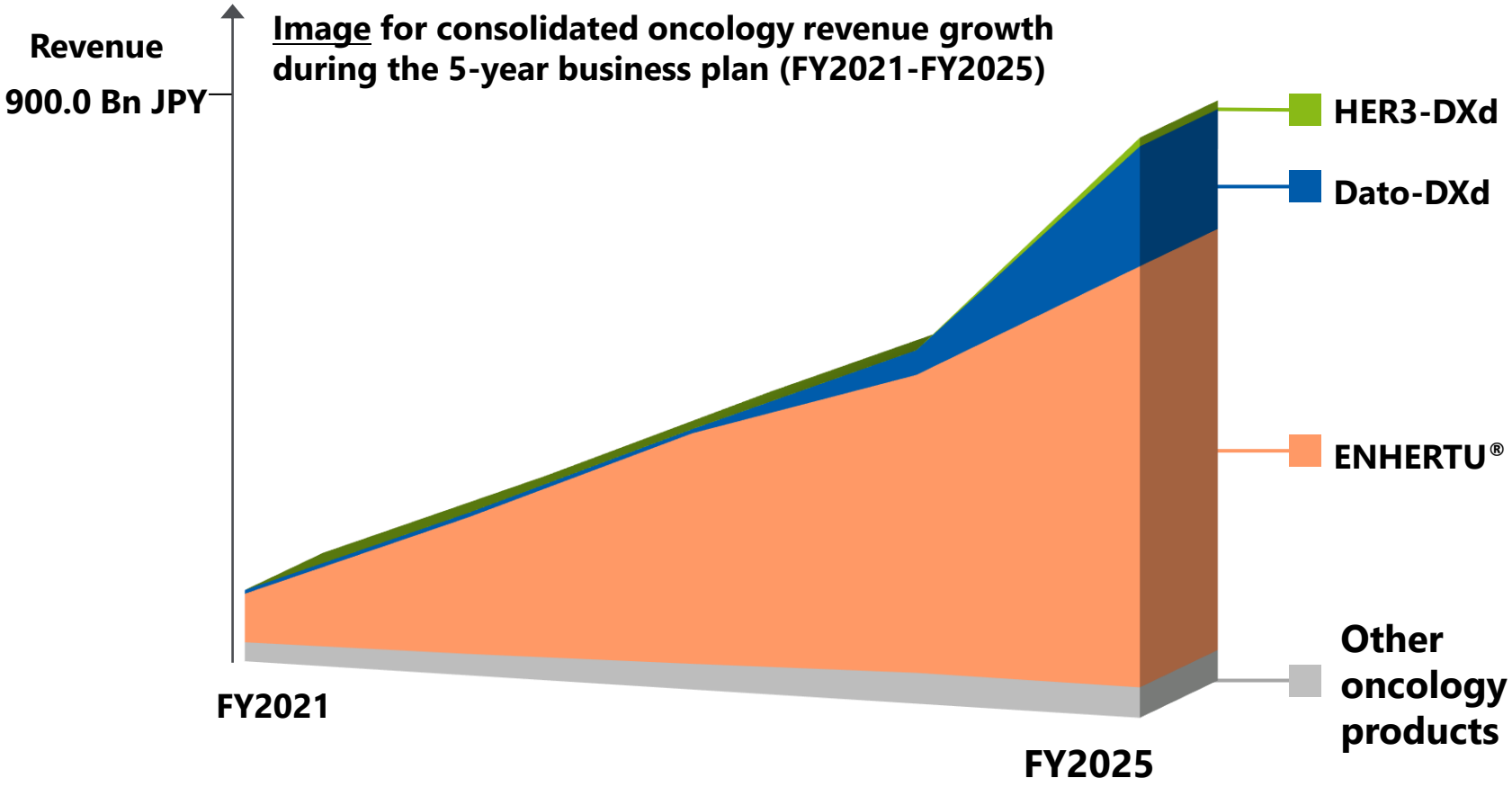
- Data-driven management through DX, and company-wide transformation through advanced digital technology
- Agile decision making through new global management structure

*Excluding temporary income and expenses (gains/losses related to sales of fixed assets etc.) from operating income

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

Expectation on Oncology Revenue
(as of Apr. 2023)

Oncology revenue* in FY2025 is estimated > 900.0 Bn JPY due to revenue growth of ENHERTU® and Dato-DXd, and progress of 3ADCs development exceeding the initial plan



Major factors increased from initial plan

- **Sales expansion in NSCLC by expanding target patients at launch**
  - TL-01：NSCLC with/without actionable genomic alterations
- **Increase in product sales and development milestone revenue due to accelerated indication expansion**
  - TL-08 etc.

- **Sales expansion in breast cancer based on the results of DB-03 and DB-04**
- **Increase in product sales and development milestone revenue due to accelerated indication expansion**
  - DB-09 and DB-11 etc.
- **Increase in sales milestone due to sales growth exceeding initial plan**

*Revenue includes alliance revenue (50% of gross profit in countries/regions where AZ books revenue) upfront/Quid payment, development/sales milestones etc. for ENHERTU® and Dato-DXd

Well-balanced Investment for Growth and Shareholder Returns
Cash Allocation

Increase R&D expense and CAPEX for further growth in future

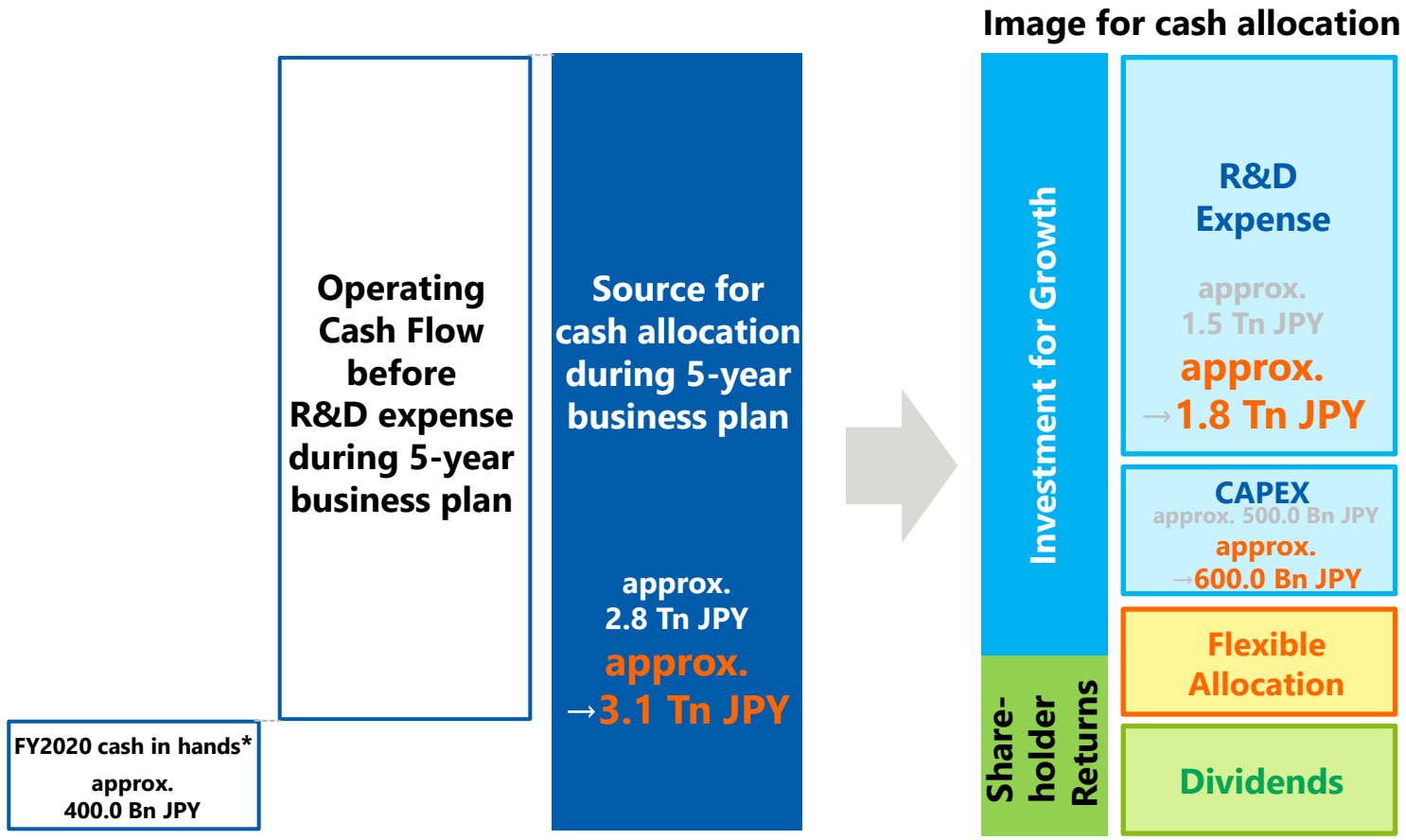


Image for cash allocation

Prioritized investment for DXd-ADCs

Investment focused on enhancing ADC supply capabilities

Flexible allocation depending on pipeline progress for 1) investment to build pillars for further growth (in-house/external); and 2) acquisition of own shares

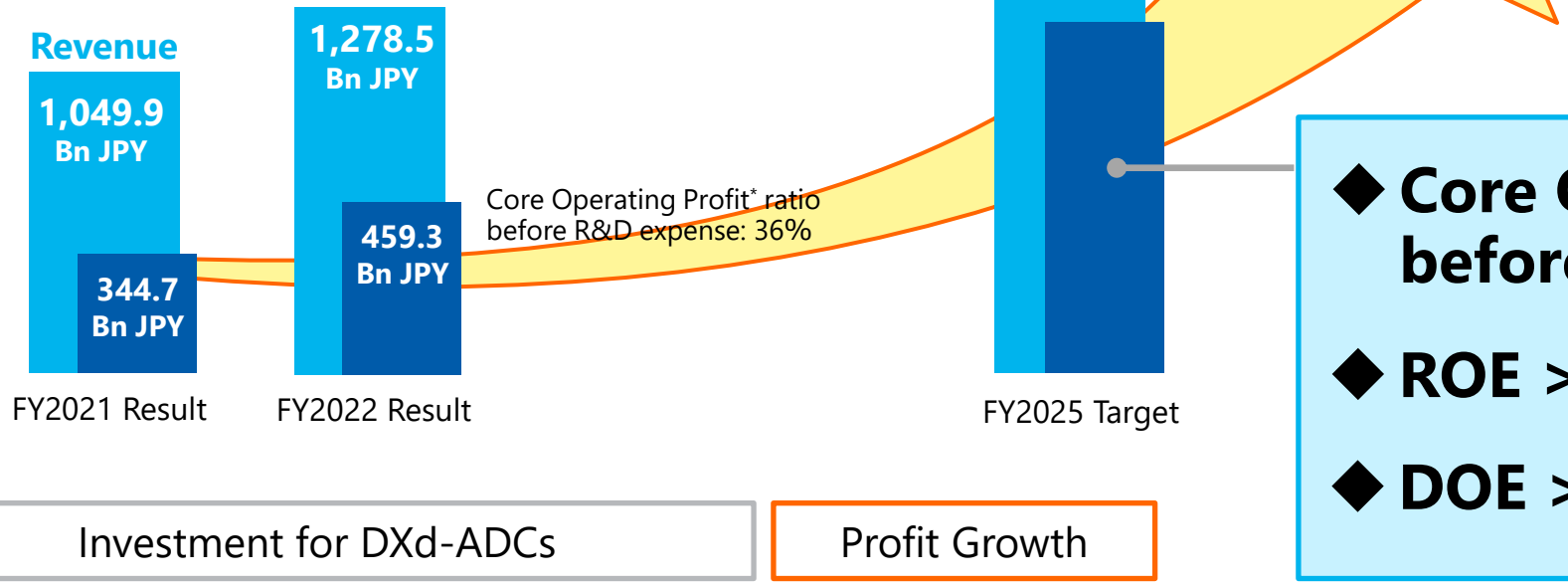
Stable dividends and dividend increase that take account of profit growth

*Cash in hands excluding working capital

Expectation on achieving FY2025 KPIs
(as of Apr. 2023)

◆**Revenue**
2.0 Tn JPY
➢**Revenue in Oncology**
> 900.0 Bn JPY

Achieve significant revenue/profit growth after investment for DXd-ADCs, and shift to a new stage for realizing 2030 vision



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

◆**ROE > 16%**

◆**DOE > 8%**

FY2025 Currency rate assumptions: 1 USD=**130 JPY**, 1 EUR=**140 JPY**
*Excluding temporary income and expenses (gains/losses related to sales of fixed assets etc.) from operating income

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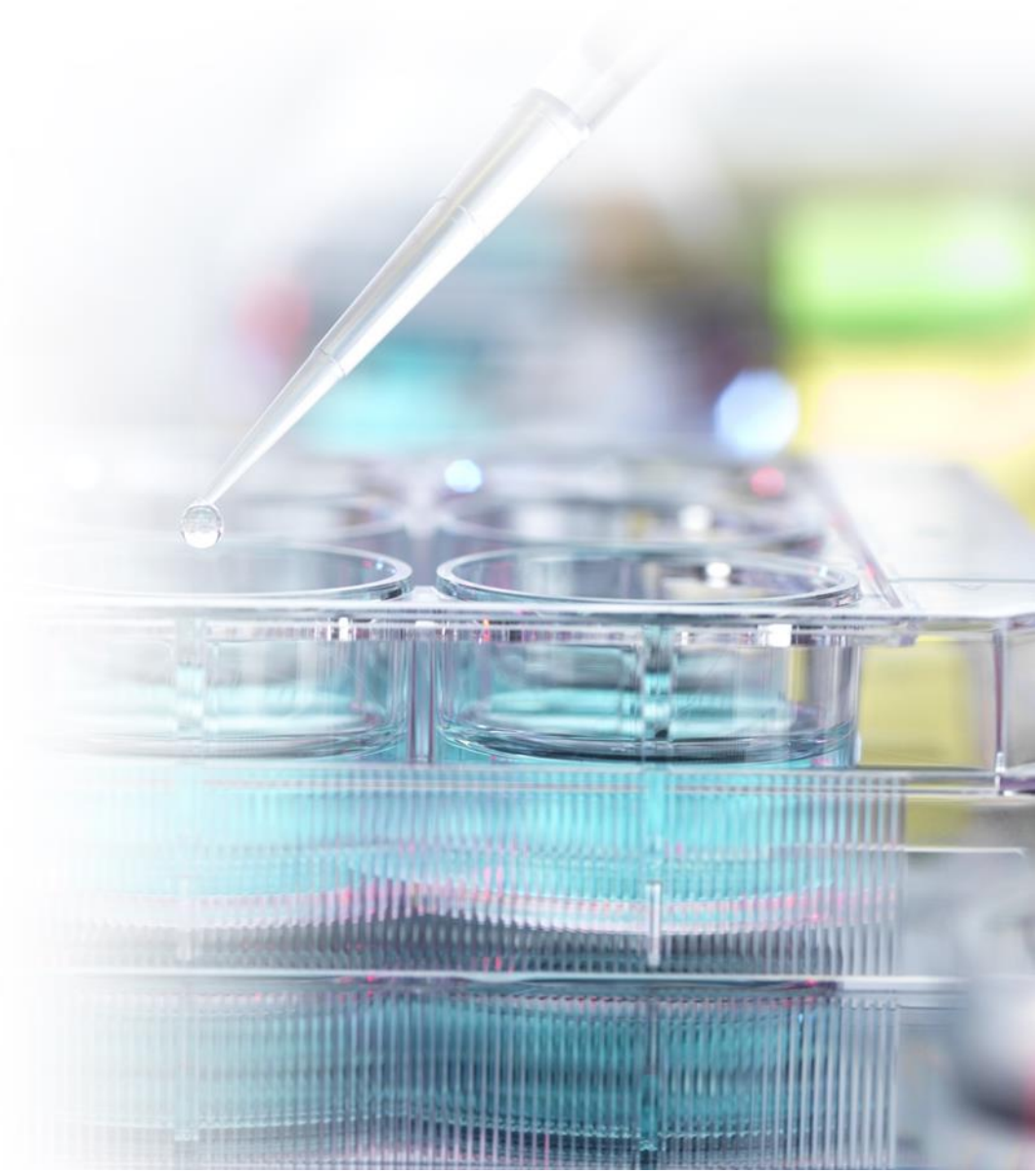


3ADCs launch plan

Active R&D investment following 3ADCs development progress exceeding the initial plan

~FY2020

ENHERTU®

- DESTINY-Breast01
- DESTINY-Gastric01

5-Year Business Plan (FY2021-FY2025)

ENHERTU®

- DESTINY-Breast03
- DESTINY-Breast04
- DESTINY-Breast06
- DESTINY-Breast09
- DESTINY-Breast11
- DESTINY-Gastric02
- DESTINY-Gastric04
- DESTINY-Lung01/02
- DESTINY-Lung04
- DESTINY-CRC01/02

Dato-DXd

- TROPION-Lung01
- TROPION-Lung08
- TROPION-Breast01
- TROPION-Breast02

HER3-DXd

- HERTHENA-Lung01
- HERTHENA-Lung02

FY2026 & Beyond

ENHERTU®

- DESTINY-Breast05
  - Combo with DS internal asset, I/O or targeted therapy in BC and NSCLC
  - Other cancer types

Dato-DXd

- TROPION-Lung07
- TROPION-Breast03
  - Combo with I/O in BC and NSCLC
  - Other cancer types

HER3-DXd

- Combo with targeted therapy in NSCLC
- Other cancer types

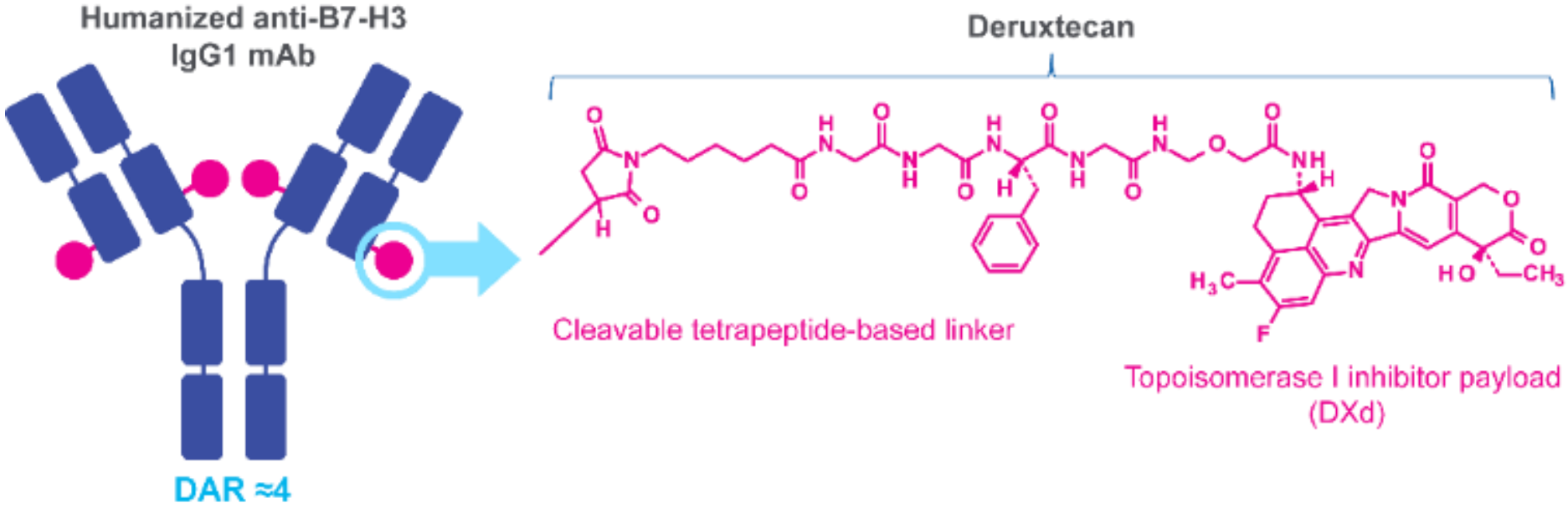
Already approved indications

Studies that were not expected to be approved during 5YBP period (including new study)

Major study only (ref., appendices)

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

DS-7300 targeting B7-H3

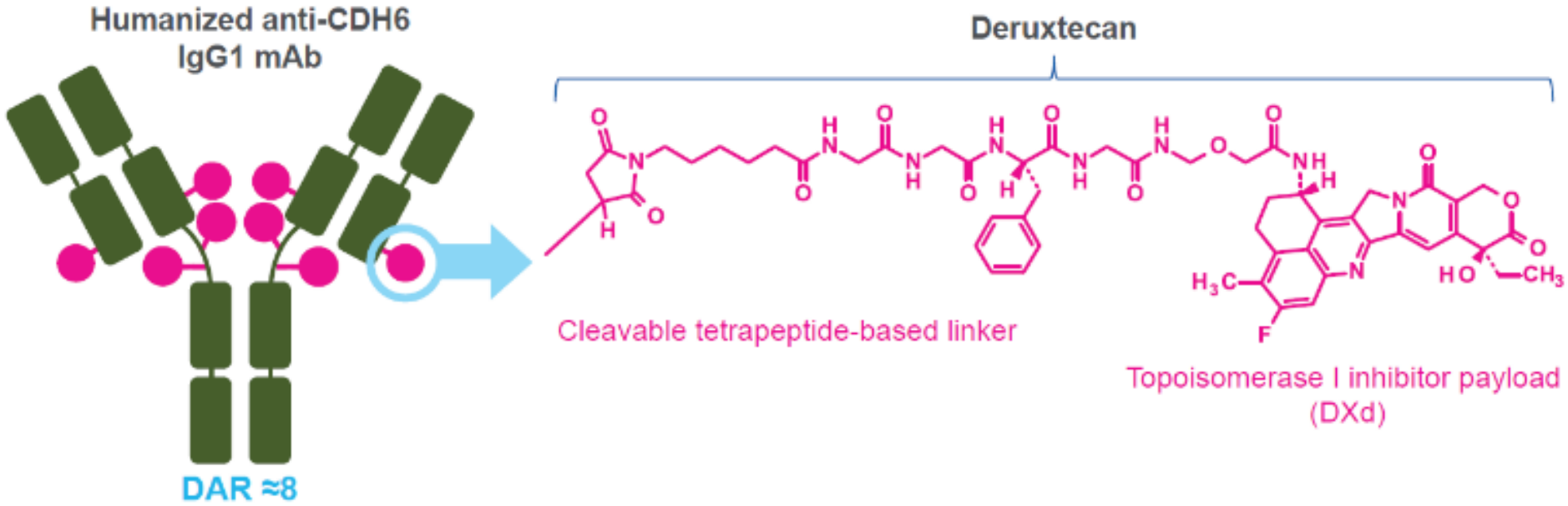


Recent progress

- Ph1/2 interim analysis data presented at ESMO 2022 demonstrated durable efficacy, manageable safety and tolerability in patients with **several types of heavily pretreated cancers** including lung, prostate or esophageal cancer
- **Dose-optimization Ph2 study for patients with SCLC** has started in June 2022
- Complete Interim Analysis of the Ph2 study in H2 2023

DAR: drug-antibody ratio, ESMO: European Society for Medical Oncology, mAb: monoclonal antibody, SCLC: small cell lung cancer

DS-6000 targeting CDH6

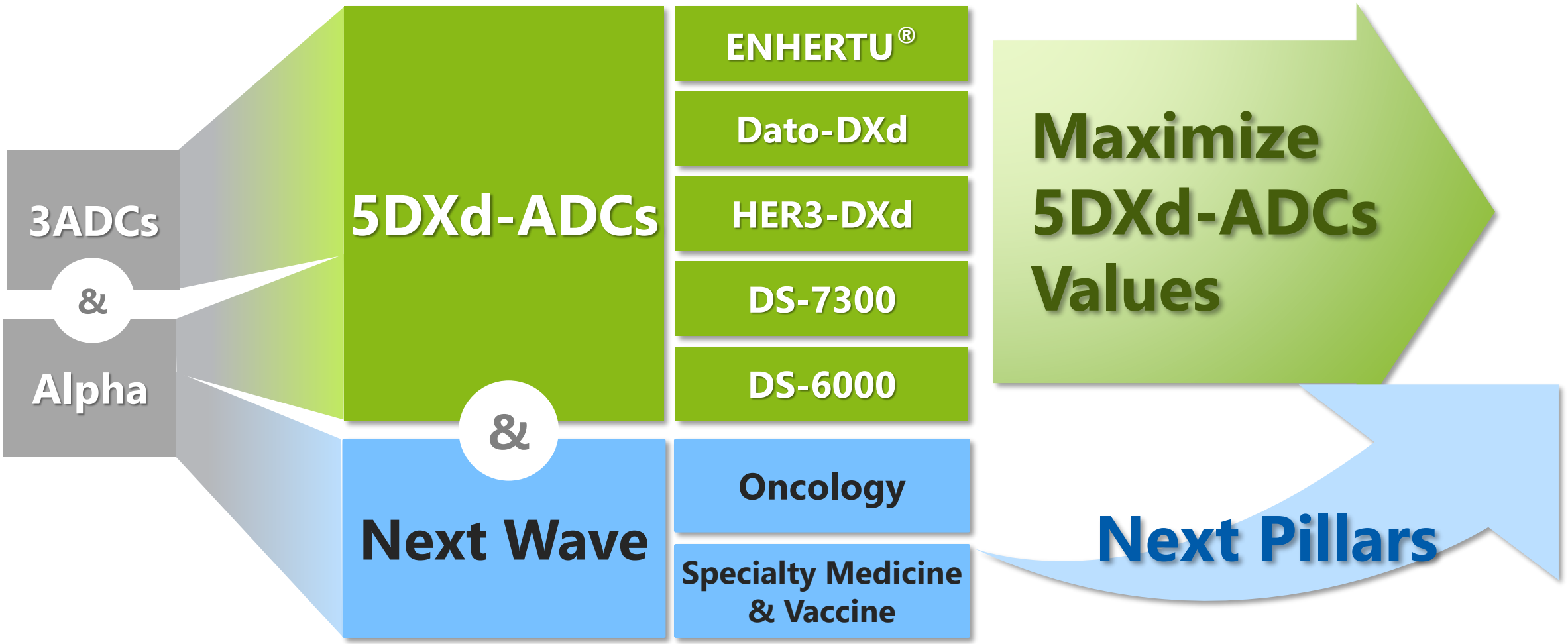


Recent progress

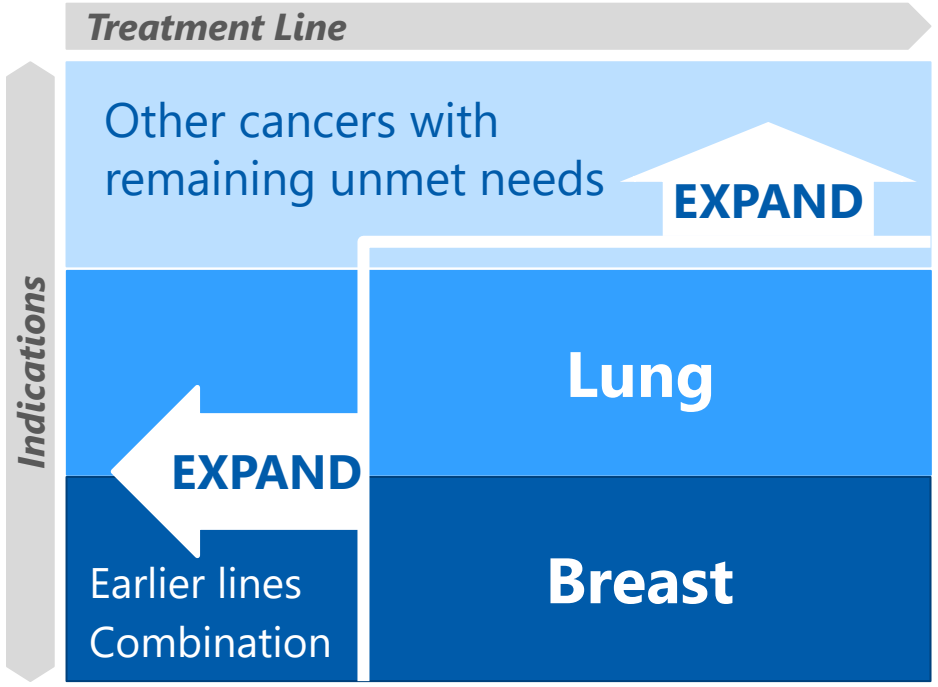
- Ph1 interim analysis data for dose-escalation part (ASCO 2022) demonstrated **manageable safety** and **encouraging efficacy** profile in heavily pre-treated patients with **advanced platinum-resistant OVC and RCC**
- Dose-expansion part is on-going
- Updated data will be presented at future scientific conference

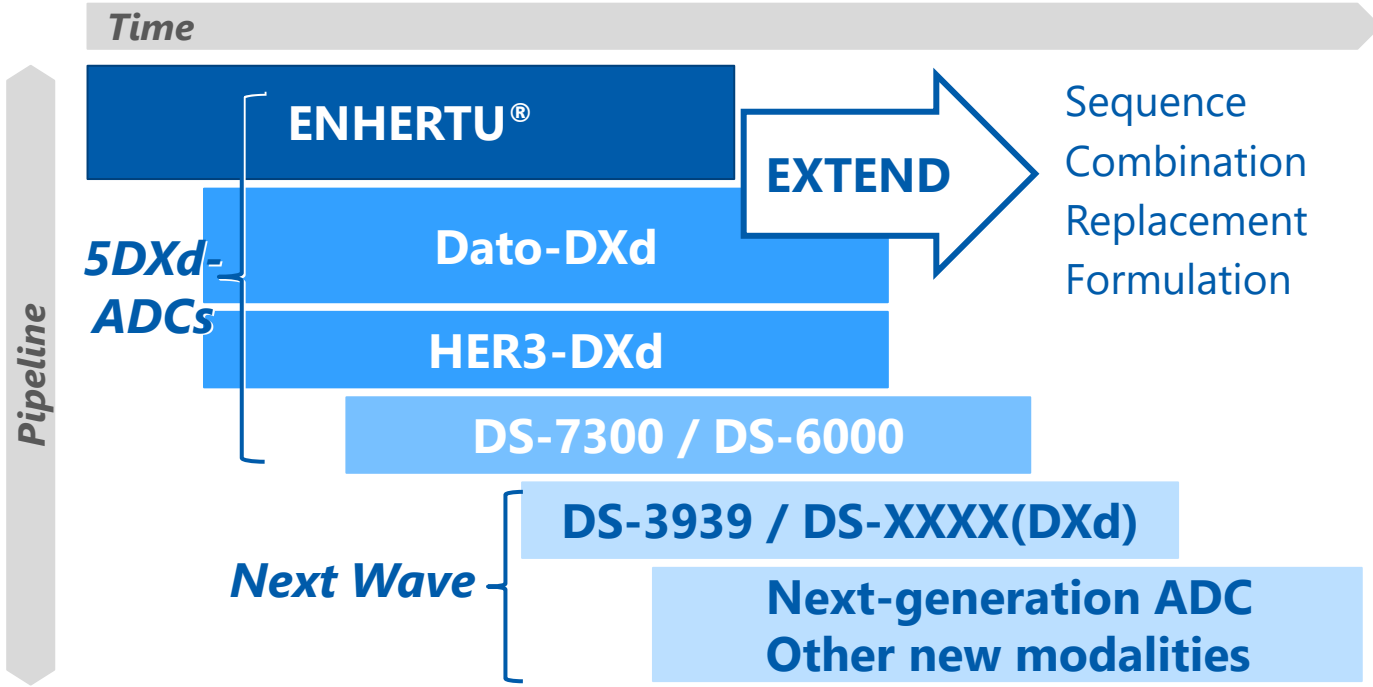
ASCO: American Society of Clinical Oncology, DAR: drug-antibody ratio, mAb: monoclonal antibody, OVC, ovarian cancer; RCC, renal cell carcinoma; SCLC: small cell lung cancer

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



EXPAND & EXTEND to deliver our technology to more patients





- **Establish DXd-ADC therapies** in Breast and Lung cancers
- Expand to **earlier and wider** patient segments with or without combinations
- Expand into **other cancer types** with high unmet medical needs

- Address unmet needs **after ENHERTU®** treatment
- Seek effective **treatment sequencing** between DXd-ADCs or novel assets including next-generation/new-concept ADCs
- Propose **novel combinations** to enhance efficacy

Our Pipeline Continues to support our Expand and Extend strategy

- **3DXd-ADCs** continue to **EXPAND** to early treatment lines and additional tumor types
- **+2DXd-ADCs** **EXPAND** advantage of DXd-ADC to new tumor types
- **Next Wave** will contribute to **EXTEND** our growth to address remaining unmet needs

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Data Highlights from ASCO & ESMO Breast

ESMO Breast 2023
10 Abstracts

2 Mini Oral Presentations
4 Poster Presentations
4 Proffered Paper Presentations

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5 on ENHERTU®
1 on Dato-DXd
4 on HER3-DXd

ASCO 2023
19 Abstracts

5 Oral Presentations
8 Poster Presentations
6 E-publications

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12 on ENHERTU®
3 on Dato-DXd
2 on HER3-DXd

ENHERTU®
Breast Cancer Updates

ENHERTU®

ENHERTU® remains as an effective treatment option in elderly patients with HER2+ metastatic breast cancer

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ASCO 2023

- An age-specific (<65 vs. ≥65 years) pooled analysis from DESTINY-Breast01/02/03
- Efficacy in patients <65 and ≥65 years treated with ENHERTU® was generally similar

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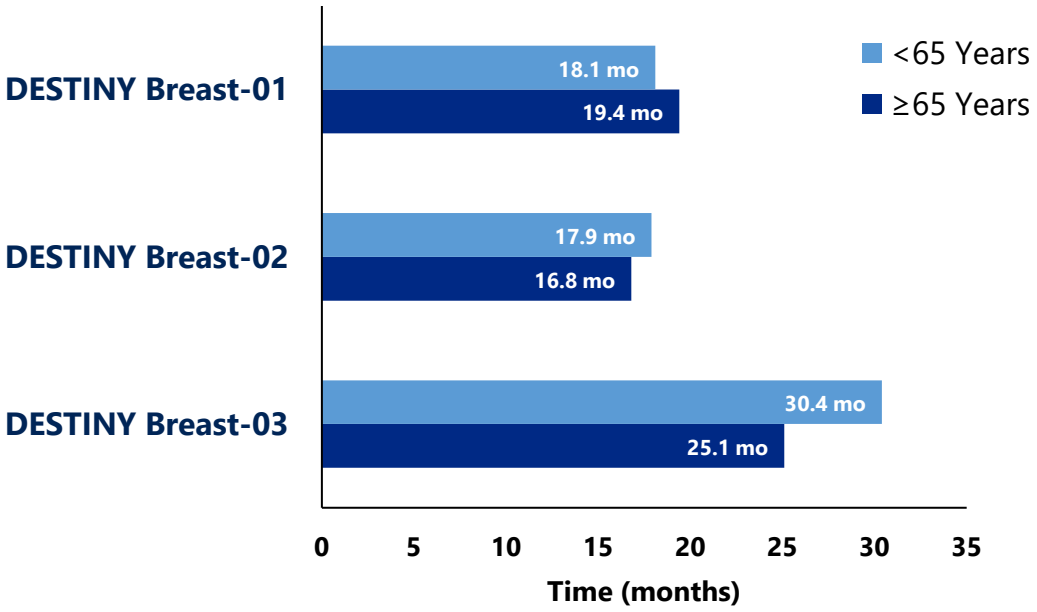
Efficacy Summary for ENHERTU®

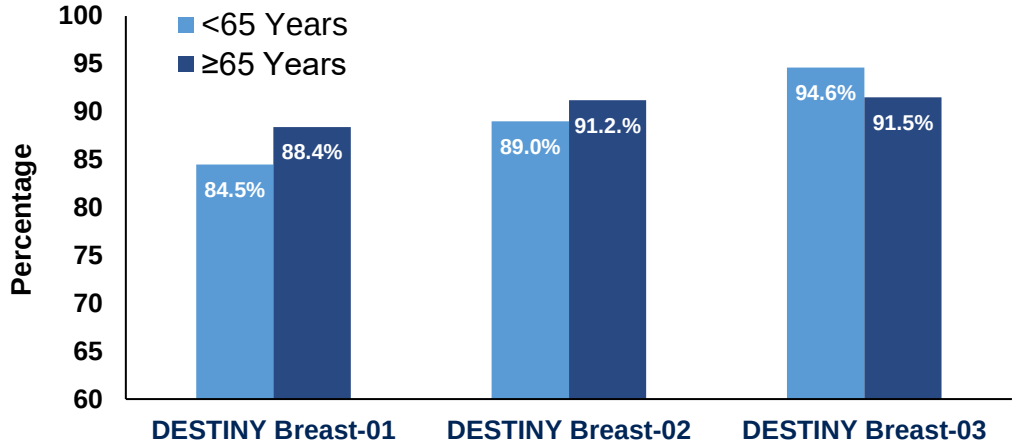
Median Progression Free Survival



Median Overall Survival

	DESTINY-Breast01		DESTINY-Breast02		DESTINY-Breast03	
	<65 (n = 140)	≥65 (n = 44)	<65 (n = 321)	≥65 (n = 85)	<65 (n = 212)	≥65 (n = 49)
mOS, months (95% CI)	28.1 (23.3-36.1)	30.9 (21.9-NE)	NR (35.5-NE)	30.2 (22.3-39.2)	NR (40.5-NE)	NR (26.3-NE)

12-month Landmark Overall Survival



Source: Krop et al., ASCO 2023, Oral Presentation #1006

DESTINY-Breast01 data cutoff: March 26, 2021; DESTINY-Breast02 data cutoff: June 30, 2022; DESTINY-Breast03 data cutoff: July 25, 2022. mOS, median overall survival; NE, not estimable; NR, not reached; T-DXd, trastuzumab deruxtecan

ENHERTU®

ENHERTU® remains as an effective and tolerable treatment option in elderly patients with HER2+ mBC

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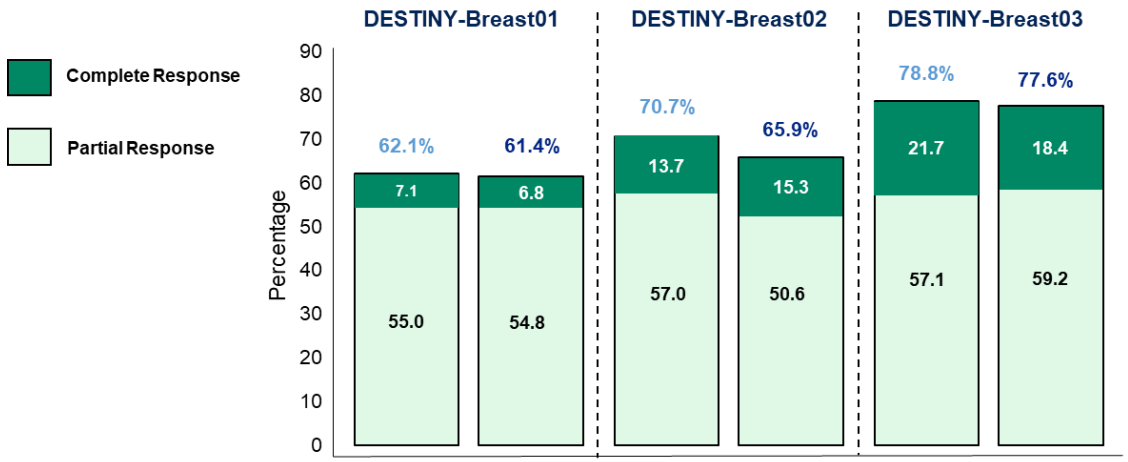
(Continued)

- Patients ≥65 years of age experienced more TEAE across all trials

Confirmed ORR in ENHERTU®



	DESTINY-Breast01		DESTINY-Breast02		DESTINY-Breast03	
	<65 (n = 140)	≥65 (n = 44)	<65 (n = 321)	≥65 (n = 85)	<65 (n = 212)	≥65 (n = 49)
Stable disease	49 (35.0)	16 (36.4)	69 (21.5)	26 (30.6)	38 (17.9)	9 (18.4)
Progressive disease	3 (2.1)	0	17 (5.3)	2 (2.4)	3 (1.4)	0
Not estimable	1 (0.7)	1 (2.3)	8 (2.5)	1 (1.2)	4 (1.9)	2 (4.1)
Duration of response, months (95% CI)	20.8 (14.8- NE)	15.5 (9.7-NE)	19.6 (15.6- NE)	19.4 (12.2-NE)	36.6 (26.3-NE)	20.3 (12.5-NE)
Disease control rate, n (%)	136 (97.1)	43 (97.7)	296 (92.2)	82 (96.5)	205 (96.7)	47 (95.9)

Overall Safety Summary

	T-DXd Pool	
	<65 (n = 668)	≥65 (n = 177)
TEAE, n (%)	**665 (99.6)**	**177 (100.0)**
Drug-related	653 (97.8)	176 (99.4)
TEAEs grade ≥3, n (%)	**358 (53.6)**	**116 (65.5)**
Drug-related	291 (43.6)	96 (54.2)
Serious TEAEs, n (%)	**162 (24.3)**	**57 (32.2)**
Drug-related	77 (11.5)	29 (16.4)
TEAEs associated with drug discontinuation, n (%)	**125 (18.7)**	**45 (25.4)**
Drug-related	100 (15.0)	42 (23.7)
TEAEs associated with dose reduction, n (%)	**163 (24.4)**	**51 (28.8)**
Drug-related	156 (23.4)	47 (26.6)
TEAEs associated with dose interruption, n (%)	**302 (45.2)**	**94 (53.1)**
Drug-related	226 (33.8)	74 (41.8)
TEAEs associated with death, n (%)	**17 (2.5)**	**10 (5.6)**
Drug-related	4 (0.6)	3 (1.7)

ASCO presentation included an exploratory safety data of T-DXd in patients aged ≥75 years.

Source: Krop et al., ASCO 2023, Oral Presentation #1006

CI, confidence interval; ORR, objective response rate; mBC, metastatic breast cancer; NE, not estimable; T-DXd, trastuzumab deruxtecan; TEAE, treatment emergent adverse event

DESTINY-Breast01 data cutoff: March 26, 2021; DESTINY-Breast02 data cutoff: June 30, 2022; DESTINY-Breast03 data cutoff: July 25, 2022.

ENHERTU®

Patient-Reported Outcome results from DESTINY-Breast02 are consistent with those of DESTINY-Breast03

ESMO Breast 2023

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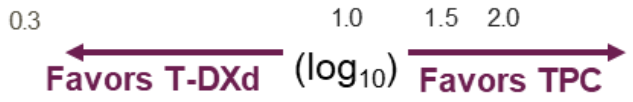
- In DESTINY-Breast02, overall HRQoL was maintained longer with ENHERTU® than with TPC and the definitive deterioration was delayed for patients in the ENHERTU® arm
- These results are consistent with those reported in DESTINY-Breast03 [1,2]

Time to definitive deterioration in PRO measures

		Median (95% CI) TDD, months		HR (95% CI)	Nominal *P* value[a]
		T-DXd (n = 406)	TPC (n = 202)		
EORTC QLQ-C30	GHS/QoL[b]	14.1 (10.4-18.7)	5.9 (4.3-7.9)	0.56 (0.44-0.71)	<0.0001
	Physical functioning[c]	18.7 (15.5-22.9)	6.8 (5.7-8.8)	0.46 (0.36-0.60)	<0.0001
	Emotional functioning[c]	21.4 (16.9-NE)	10.7 (6.9-15.4)	0.67 (0.51-0.88)	0.0041
	Social functioning[c]	18.7 (13.9-28.8)	6.3 (4.9-8.8)	0.54 (0.42-0.70)	<0.0001
	Pain[c]	18.7 (14.1-23.8)	5.8 (5.0-7.0)	0.38 (0.29-0.49)	<0.0001
EORTC QLQ-BR45[d]	Arm symptoms[c]	18.3 (13.9-21.2)	8.8 (6.1-11.6)	0.57 (0.44-0.75)	<0.0001
	Breast symptoms[c]	NE (30.3-NE)	18.1 (12.5-NE)	0.42 (0.29-0.59)	<0.0001
EQ-5D-5L	VAS[c]	16.6 (13.6-20.2)	7.3 (5.8-10.6)	0.59 (0.46-0.76)	<0.0001



Source: Fehm et al., ESMO Breast 2023, Proffered Paper Presentation #186O

CI, confidence interval; EORTC, European Organisation for Research and Treatment of Cancer; EQ-5D-5L, EuroQol 5-dimension, 5-level questionnaire; GHS, global health status; HR, hazard ratio; PRO, patient-reported outcome; QLQ-BR45, Quality of Life Breast cancer questionnaire; QLQ-C30, Quality of Life Core 30 questionnaire; QoL, quality of life; TDD, time to definitive deterioration; T-DXd, trastuzumab deruxtecan; TPC, treatment of physician's choice; VAS, visual analogue scale; [1] Curigliano et al. ESMO Breast 2022 163O; [2] Cortes et al. N Eng J Med 2022;386:12

ENHERTU®

Benefit of ENHERTU® is consistent in HER2 low mBC with ER-negative and ER-low expression

ESMO Breast 2023

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- In the sub-analysis of DESTINY-Breast04, ENHERTU® showed better efficacy compared to TPC both in patients with HER2 low/ER-negative (IHC 0%) and HER2 low/ER-low (IHC 1-10%) metastatic breast cancer

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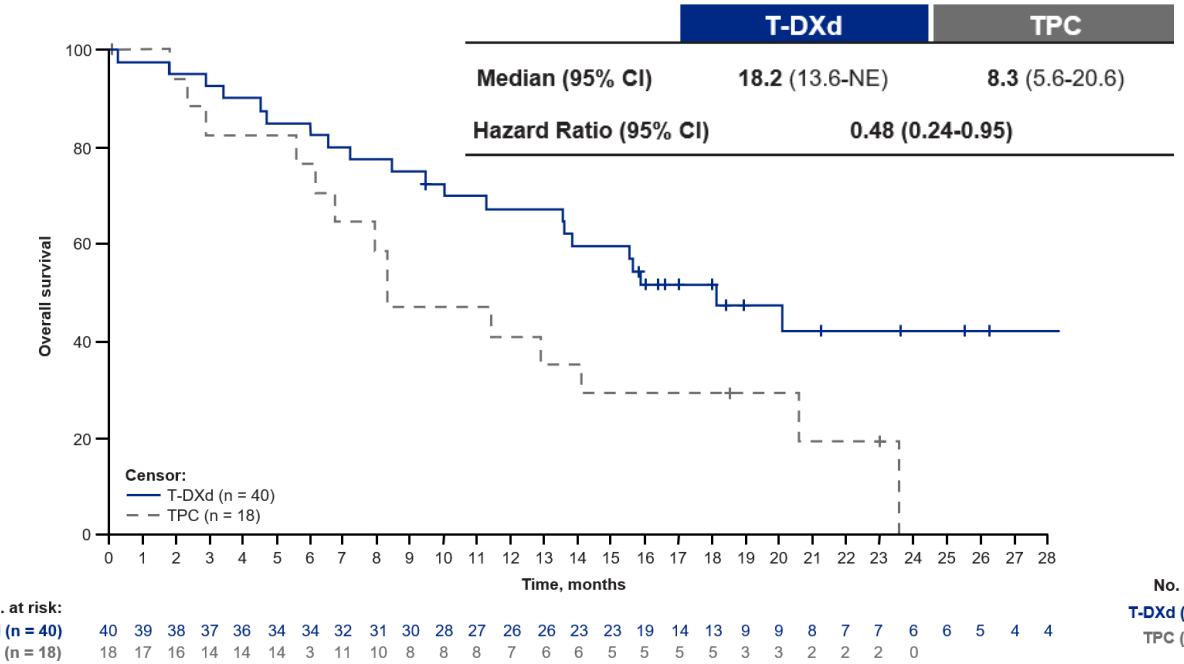
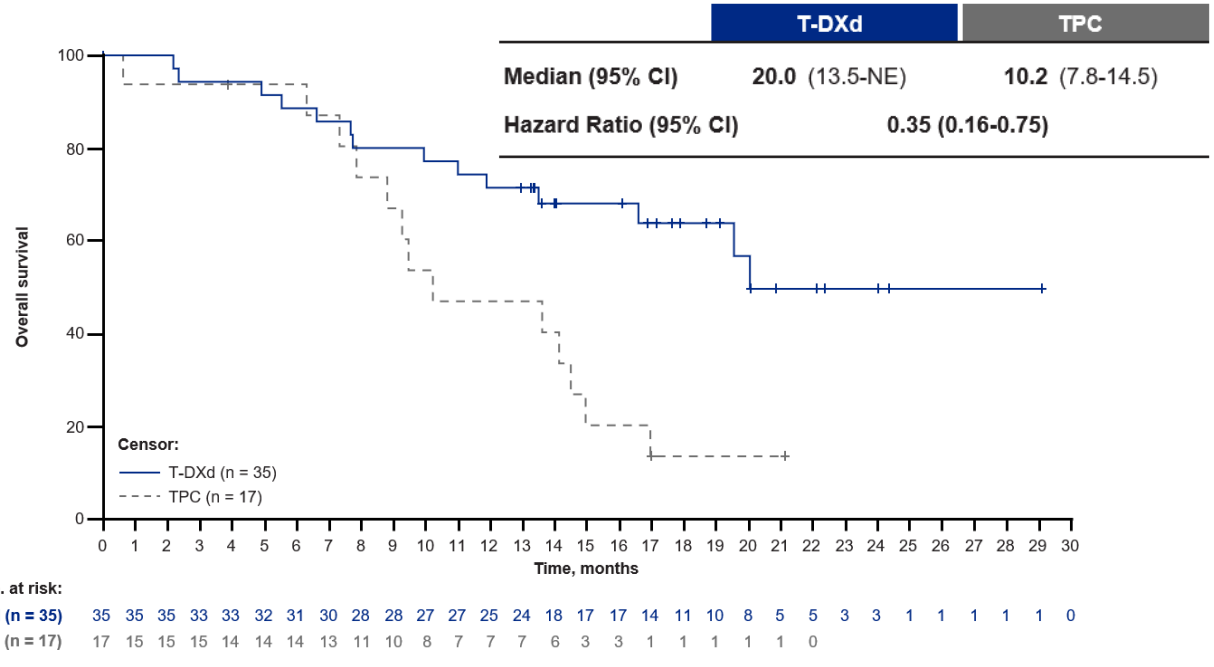
Overall Survival in Patients by ER Expression

Patients with ER-negative (IHC 0%)



Patients with ER-low (IHC 1-10%)



Source: Cameron et al., ESMO Breast 2023, Mini Oral Presentation #192MO

CI, confidence interval; ER, estrogen receptor; IHC, immunohistochemistry; mBC, metastatic breast cancer; NE, not estimable; OS, overall survival; T-DXd, trastuzumab deruxtecan; TPC, treatment of physician's choice; Cutoff date: January 11, 2022

ENHERTU®

ENHERTU® also demonstrated a manageable safety profile in patients with ER IHC 0-10%

ESMO Breast 2023

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(continued)

- Safety profile in ER IHC 0-10% patients were consistent with results observed in the primary analysis of DESTINY-Breast04

Most common TEAEs in ≥20% Patients with ER IHC 0-10%

Preferred Term, %	T-DXd (N = 75)		TPC (N = 32)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Any		53.3		75.0
Nausea	77.3	4.0	34.4	0
Vomiting	40.0	1.3	21.9	0
Fatigue	37.3	8.0	40.6	9.4
Decreased appetite	34.7	1.3	25.0	3.1
Alopecia	33.3	0	31.3	0
Constipation	33.3	0	21.9	0
Anemia	30.7	10.7	34.4	3.1
Diarrhea	29.3	2.7	21.9	3.1
Aspartate aminotransferase increased	26.7	5.3	28.1	0
Alanine aminotransferase increased	18.7	4.0	21.9	0
White blood cell count decreased	18.7	5.3	31.3	25.0
Neutrophil count decreased	14.7	2.7	31.3	25.0
Median duration of treatment, months (range)	**8.2 (0.2 to 33.3)**		**3.5 (0.3 to 17.6)**	

Source: Modi S et al. N Engl J Med. 2022;387(1):9-20 and Cameron et al., ESMO Breast 2023, Mini Oral Presentation #192MO

ER, estrogen receptor; IHC, immunohistochemistry; T-DXd, trastuzumab deruxtecan; TEAEs, treatment-emergent adverse events; TPC, treatment of physician's choice.

ENHERTU®

Benefit of ENHERTU® is consistent across molecular subtypes in HER2 low metastatic breast cancer

ASCO 2023

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- Exploratory biomarker analysis in baseline samples of DESTINY-Breast04, ENHERTU® vs. TPC in patients with HER2 low breast cancer
- Improved ORR for ENHERTU® over TPC was observed regardless of intrinsic molecular subtype, *ESR1* or *PIK3CA* mutation status, and CDK4/6i resistant markers

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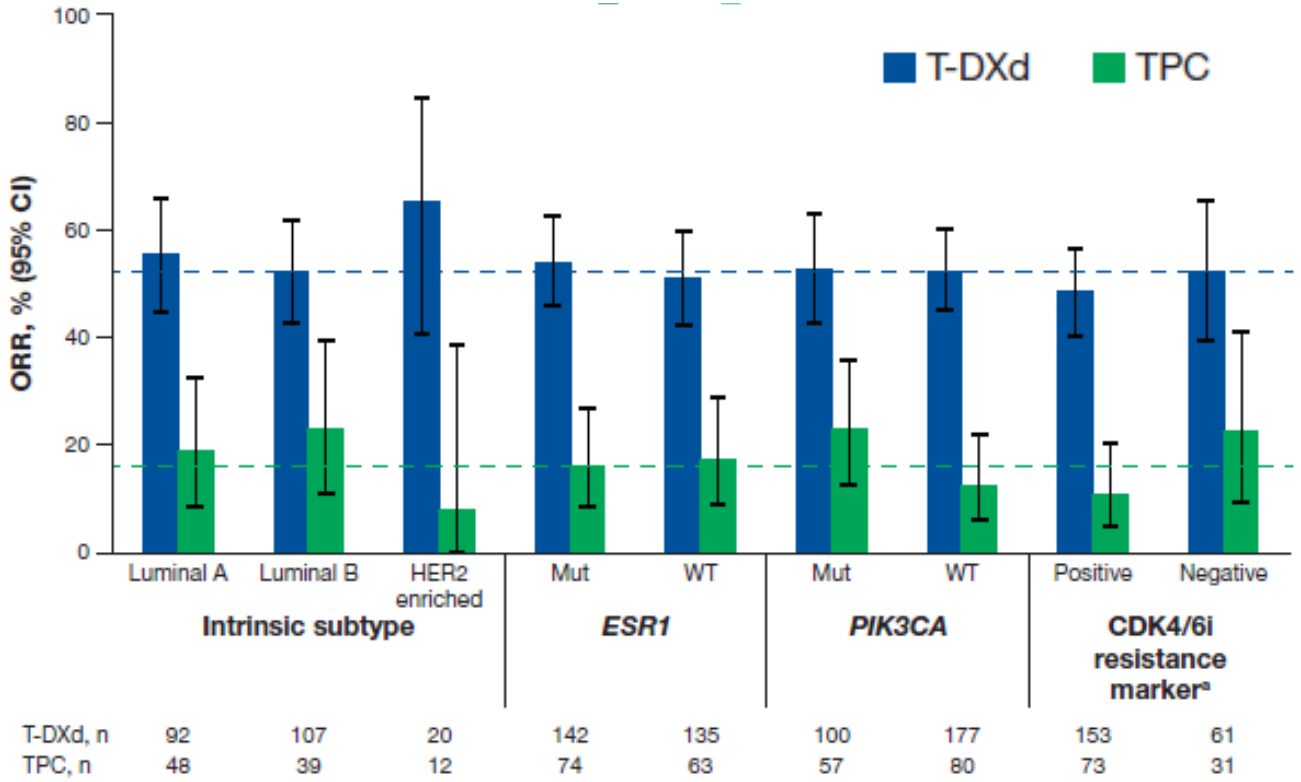


Source: Modi et al., ASCO 2023, Poster Discussion #1020

CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; *ESR1*, estrogen receptor 1 gene; *PIK3CA*, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha gene; T-DXd, trastuzumab deruxtecan; TPC: treatment of physician's choice. [a] *CCND1, CCNE1, CDK6, FGFR1/2* amplification; *RB1, PTEN, RAS, AKT1, ERBB2*, and *FAT1* mutations. Dashed horizontal lines show ORR in the overall HR+ cohort (Modi S et al. *N Engl J Med*. 2022;387:9-20).

ENHERTU®

Benefit of ENHERTU® is consistent across molecular subtypes in HER2 low metastatic breast cancer

Daiichi-Sankyo

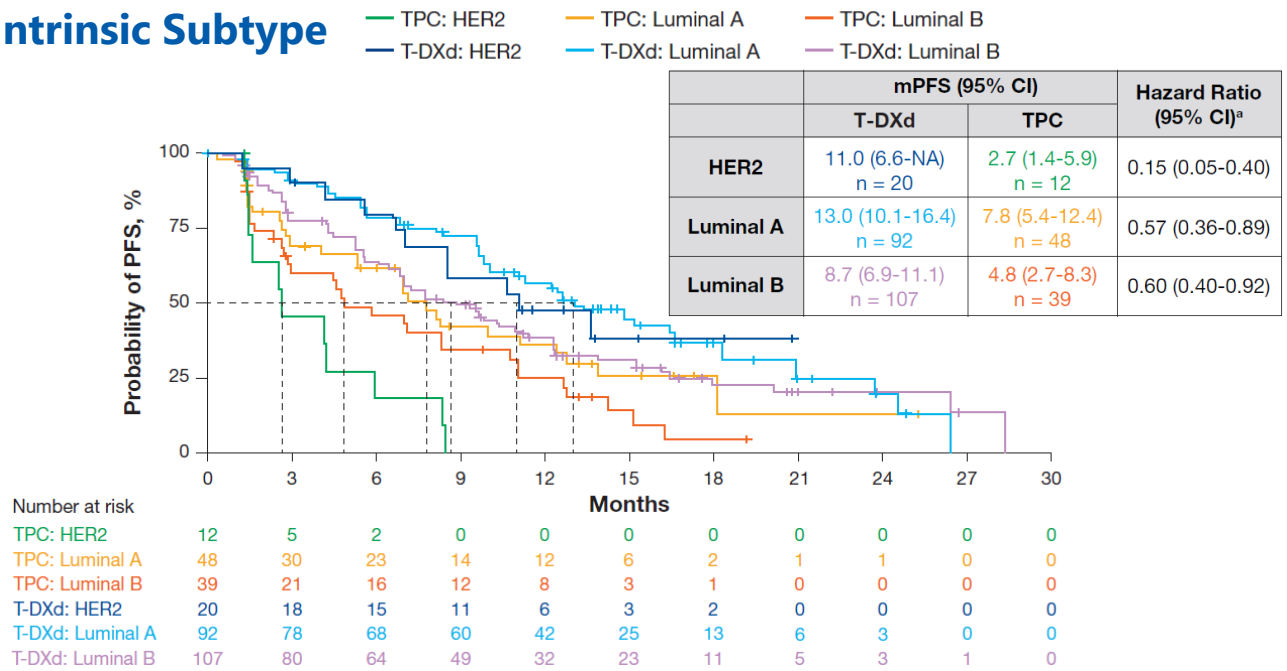
ASCO 2023

(Continued)

- Longer mPFS was observed in ENHERTU® compared to TPC regardless of intrinsic molecular subtypes, *ESR1* or *PIK3CA* mutation status

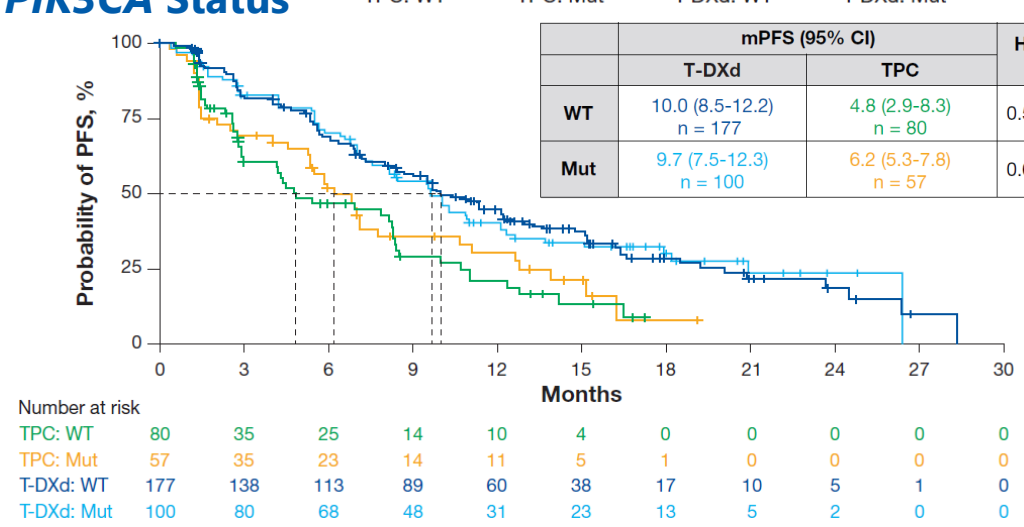
(DESTINY-Breast 04 sub-analysis, continues to the next slide)

Intrinsic Subtype



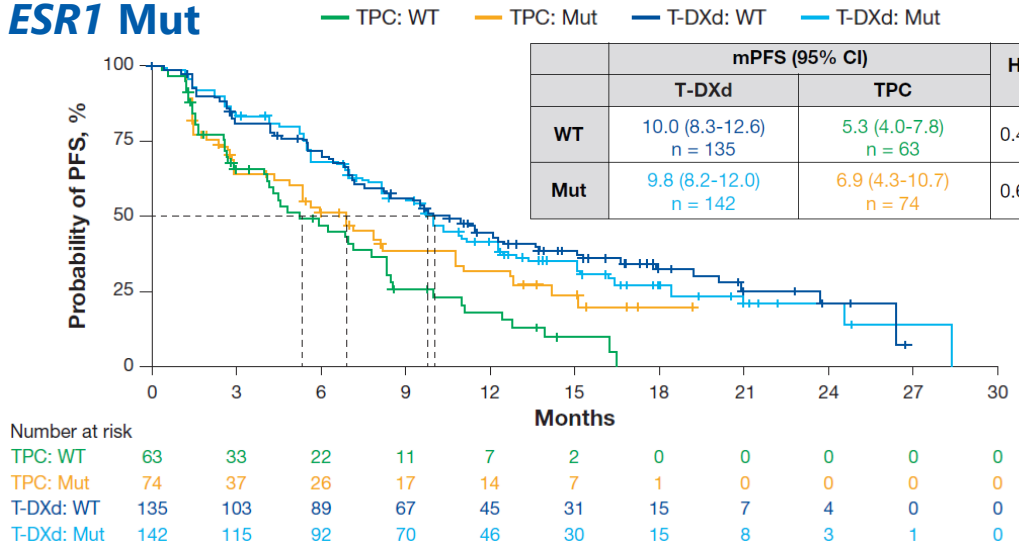
	mPFS (95% CI)		Hazard Ratio (95% CI)[a]
	T-DXd	TPC	
HER2	11.0 (6.6-NA) n = 20	2.7 (1.4-5.9) n = 12	0.15 (0.05-0.40)
Luminal A	13.0 (10.1-16.4) n = 92	7.8 (5.4-12.4) n = 48	0.57 (0.36-0.89)
Luminal B	8.7 (6.9-11.1) n = 107	4.8 (2.7-8.3) n = 39	0.60 (0.40-0.92)

PIK3CA Status



	mPFS (95% CI)		Hazard Ratio (95% CI)[a]
	T-DXd	TPC	
WT	10.0 (8.5-12.2) n = 177	4.8 (2.9-8.3) n = 80	0.50 (0.35-0.70)
Mut	9.7 (7.5-12.3) n = 100	6.2 (5.3-7.8) n = 57	0.60 (0.40-0.91)

ESR1 Mut



	mPFS (95% CI)		Hazard Ratio (95% CI)[a]
	T-DXd	TPC	
WT	10.0 (8.3-12.6) n = 135	5.3 (4.0-7.8) n = 63	0.43 (0.29-0.62)
Mut	9.8 (8.2-12.0) n = 142	6.9 (4.3-10.7) n = 74	0.67 (0.47-0.97)

Source: Modi et al., ASCO 2023, Poster Discussion #1020

CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; ESR1, estrogen receptor 1 gene; PIK3CA, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha gene; T-DXd, trastuzumab deruxtecan; TPC: treatment of physician's choice. [a] Median PFS was estimated by the Kaplan-Meier method and the hazard ratio was calculated comparing the T-DXd and TPC arm in each biomarker-derived subgroup.

ENHERTU®

Benefit of ENHERTU® is consistent across molecular subtypes in HER2 low metastatic breast cancer

ASCO 2023

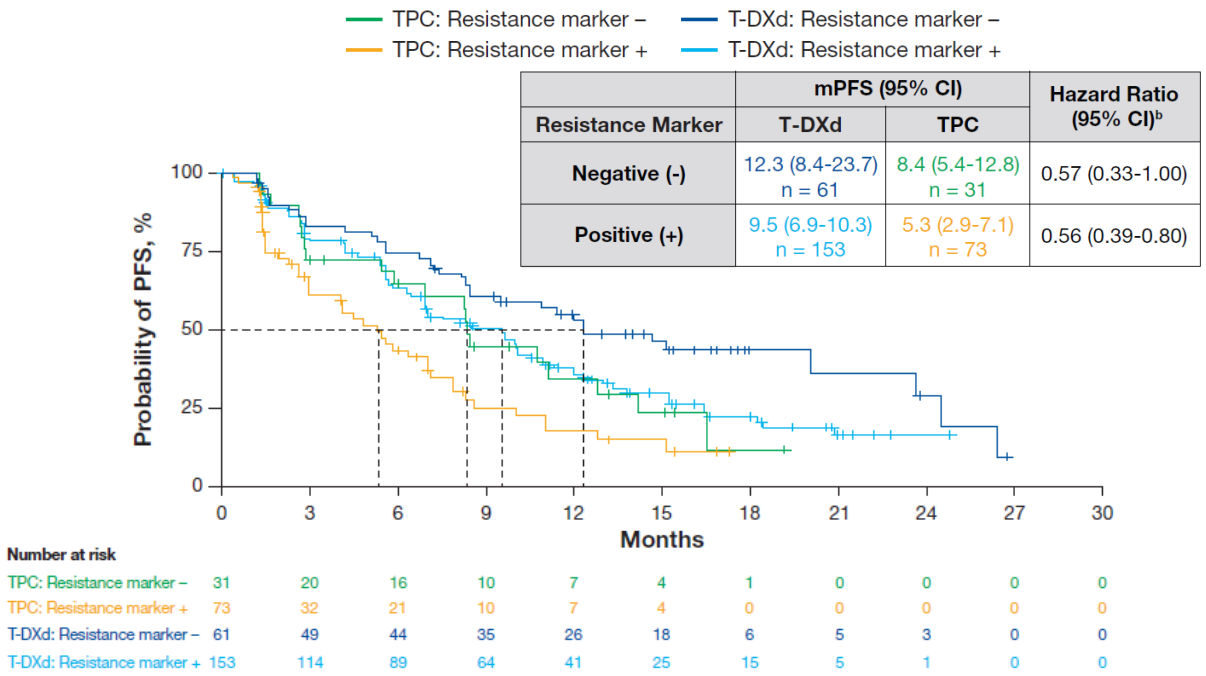
Daiichi-Sankyo

(Continued)

- Longer mPFS was observed in ENHERTU® compared to TPC regardless of presence of CDK4/6i resistance markers both in patients with and without prior CDK4/6i treatment

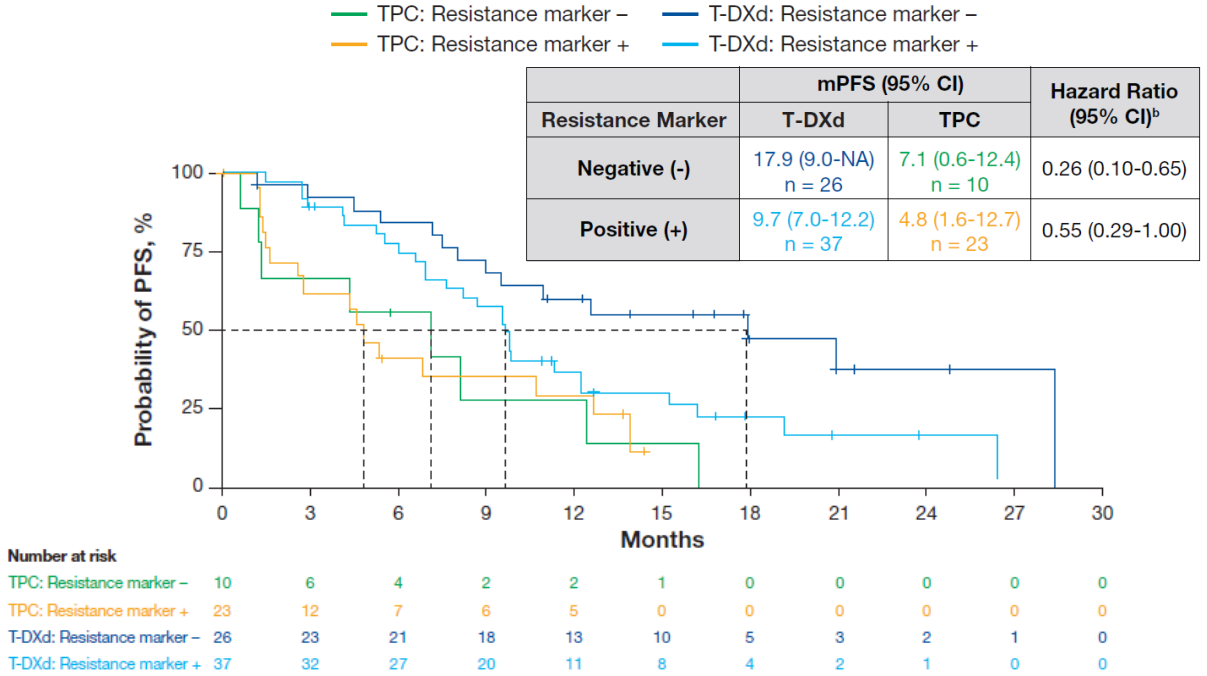
(DESTINY-Breast04 sub-analysis)

Patients With Prior CDK4/6i Treatment



Resistance Marker	mPFS (95% CI) T-DXd	mPFS (95% CI) TPC	Hazard Ratio (95% CI)[b]
Negative (-)	12.3 (8.4-23.7) n = 61	8.4 (5.4-12.8) n = 31	0.57 (0.33-1.00)
Positive (+)	9.5 (6.9-10.3) n = 153	5.3 (2.9-7.1) n = 73	0.56 (0.39-0.80)

Patients Without Prior CDK4/6i Treatment



Resistance Marker	mPFS (95% CI) T-DXd	mPFS (95% CI) TPC	Hazard Ratio (95% CI)[b]
Negative (-)	17.9 (9.0-NA) n = 26	7.1 (0.6-12.4) n = 10	0.26 (0.10-0.65)
Positive (+)	9.7 (7.0-12.2) n = 37	4.8 (1.6-12.7) n = 23	0.55 (0.29-1.00)

Source: Modi et al., ASCO 2023, Poster Discussion #1020

CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; ESR1, estrogen receptor 1 gene; PIK3CA, phosphatidylinositol-4,5-bisphosphate 3-kinase catalytic subunit alpha gene; T-DXd, trastuzumab deruxtecan; TPC: treatment of physician's choice. [a] *CCND1, CCNE1, CDK6, FGFR1/2* amplification; *RB1, PTEN, RAS, AKT1, ERBB2*, and *FAT1* mutations., [b] Median PFS was estimated by the Kaplan-Meier method and the hazard ratio was calculated comparing the T-DXd and TPC arm in each biomarker-derived subgroup.

ENHERTU®

A detailed safety analysis of DESTINY-Breast04 continues to support use of ENHERTU® as the new SOC in HER2 low mBC

Daiichi-Sankyo

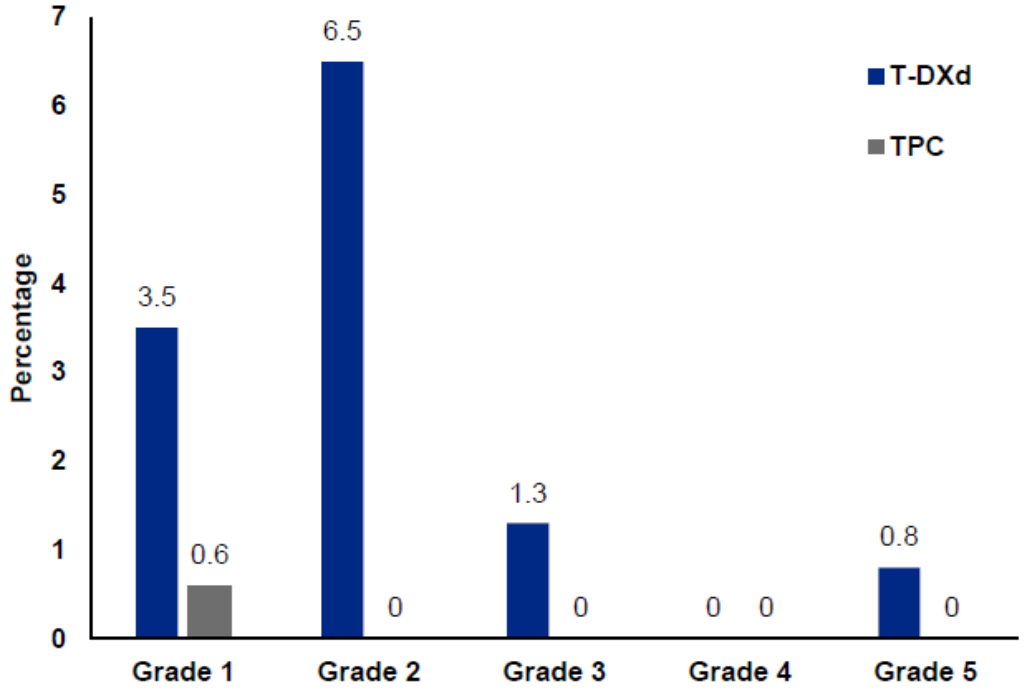
ESMO Breast 2023

- Exposure-adjusted incidence rates of anemia, neutropenia, alopecia and fatigue were lower in ENHERTU®, whereas nausea, vomiting, thrombocytopenia and ILD were higher, compared to TPC
- Most ILD/pneumonitis events associated with ENHERTU® were low in grade and resolved over time

EAIRs for selected TEAEs in ≥10% of patients

	T-DXd n = 371		TPC n = 172	
n (%)	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Total patient-years of exposure	**283.5**		**63.6**	
Nausea EAIR per patient-year	282 (76.0) 0.99	17 (4.6) 0.06	52 (30.2) 0.82	0 0
Vomiting EAIR per patient-year	150 (40.4) 0.53	6 (1.6) 0.02	23 (13.4) 0.36	0 0
Anemia EAIR per patient-year	143 (38.5) 0.50	38 (10.2) 0.13	47 (27.3) 0.74	9 (5.2) 0.14
Neutropenia EAIR per patient-year	126 (34.0) 0.44	52 (14.0) 0.18	90 (52.3) 1.42	71 (41.3) 1.12
Thrombocytopenia EAIR per patient-year	95 (25.6) 0.34	22 (5.9) 0.08	16 (9.3) 0.25	1 (0.6) 0.02
Alopecia EAIR per patient-year	147 (39.6) 0.52	0 0	57 (33.1) 0.90	0 0
Fatigue EAIR per patient-year	199 (53.6) 0.70	32 (8.6) 0.11	83 (48.3) 1.31	8 (4.7) 0.13
ILD EAIR per patient-year	45 (12.1) 0.16	8 (2.2) 0.03	1 (0.6) 0.02	0 0

Treatment-related ILD per grade



Source: Rugo et al., ESMO Breast 2023, Proffered Paper Presentation #185O

EAIR, exposure-adjusted incidence rate; ILD, interstitial lung disease; T-DXd, trastuzumab deruxtecan; TPC, treatment of physician's choice

ENHERTU® in Breast Cancer

Accumulating data continue to support benefit of ENHERTU® in patients with HER2+ and HER2 low metastatic Breast Cancer

HER2+ mBC

- ENHERTU® remains as an effective treatment option in elderly patients with a manageable safety profile
- Data continue to support improved quality of life of patients with ENHERTU® treatment

HER2 low mBC

- Benefit of ENHERTU® is consistent across baseline subtypes of HER2 low mBC
- Detailed safety analysis continues to support ENHERTU® as the new SOC in HER2 low mBC

ENHERTU® Potential in Multiple Tumor Types

ENHERTU® showed promising efficacy in HER2+ mCRC - Primary analysis of Ph2 DESTINY-CRC02

- DESTINY-CRC02 is a randomized, 2-stage, 2-arm, multicenter, global, Ph2 study in patients with mCRC

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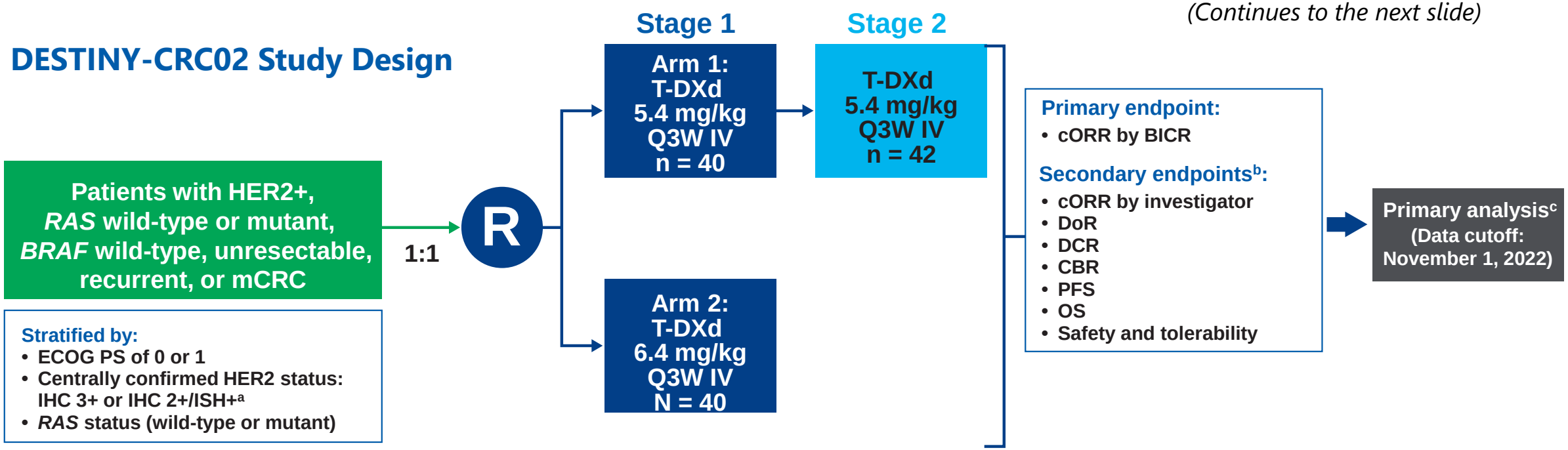
DESTINY-CRC02 Study Design



This study was not powered to statistically compare the two arms.

Source: Raghav et al., ASCO 2023, Oral Presentation #3501

BICR, blinded independent central review; BRAF, v-raf murine sarcoma viral oncogene homolog B1; CBR, clinical benefit rate; cORR, confirmed objective response rate; DCR, disease control rate; DoR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in situ hybridization; IV, intravenously; mCRC, metastatic colorectal cancer; OS, overall survival; PFS, progression-free survival; Q3W, every 3 weeks; R, randomization; RAS, rat sarcoma; T-DXd, trastuzumab deruxtecan. Both investigators and patients were blind to treatments.

[a]HER2 status was assessed with the Roche VENTANA HER2 Dual ISH DNA probe cocktail assay (IUO). [b]Exploratory endpoints included best percent change in the sum of diameters of measurable tumors based on BICR and investigator. [c]Primary analysis occurred ≥6 months after the last patient had been enrolled or when all patients discontinued from the study, whichever was earlier.

ENHERTU®

ENHERTU® showed promising efficacy in HER2+ mCRC - Primary analysis of Ph2 DESTINY-CRC02

ASCO 2023

Daiichi-Sankyo

(Continued)

- Promising antitumor activity was observed at both 5.4 mg/kg and 6.4 mg/kg doses

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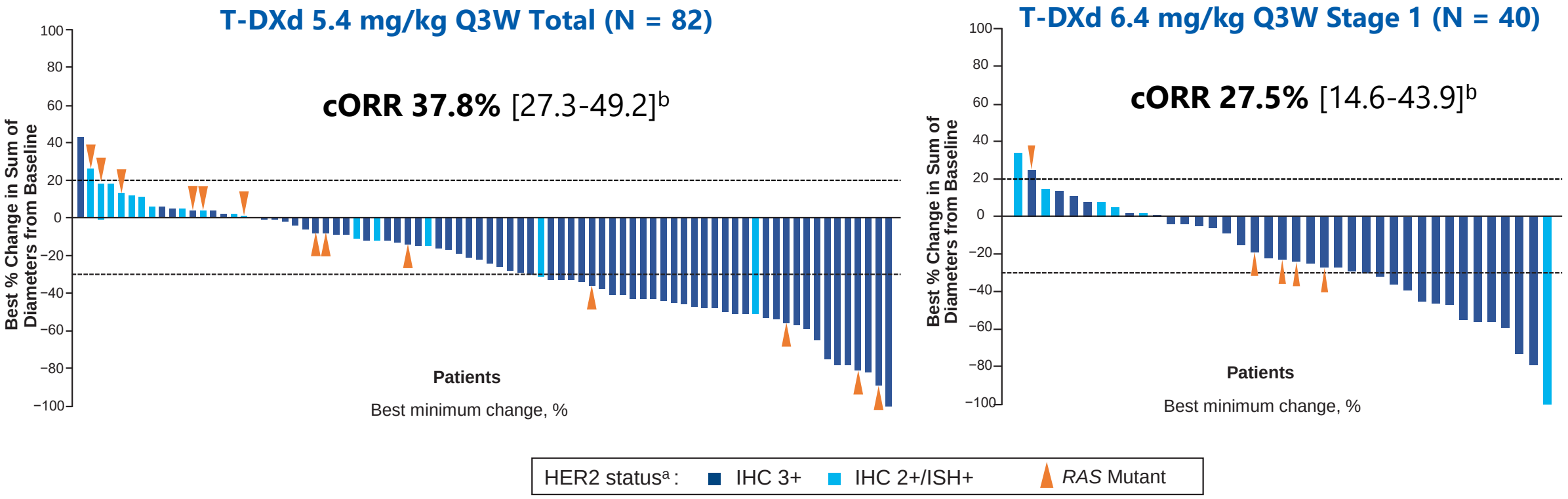

Source: Raghav et al., ASCO 2023, Oral Presentation #3501

cORR, confirmed objective response rate; IHC, immunohistochemistry; ISH, in situ hybridization; mCRC, metastatic colorectal cancer; Q3W, every 3 weeks; RAS, rat sarcoma; T-DXd, trastuzumab deruxtecan. Only patients with measurable disease at baseline and at least one postbaseline tumor assessment were included in the waterfall graphs.

[A] HER2 status was assessed by central laboratory. [b] 95% confidence interval.

ENHERTU® showed promising efficacy in HER2+ mCRC - Primary analysis of Ph2 DESTINY-CRC02

(Continued)

- Antitumor efficacy was observed irrespective of *RAS* mutation status at 5.4 mg/kg dose

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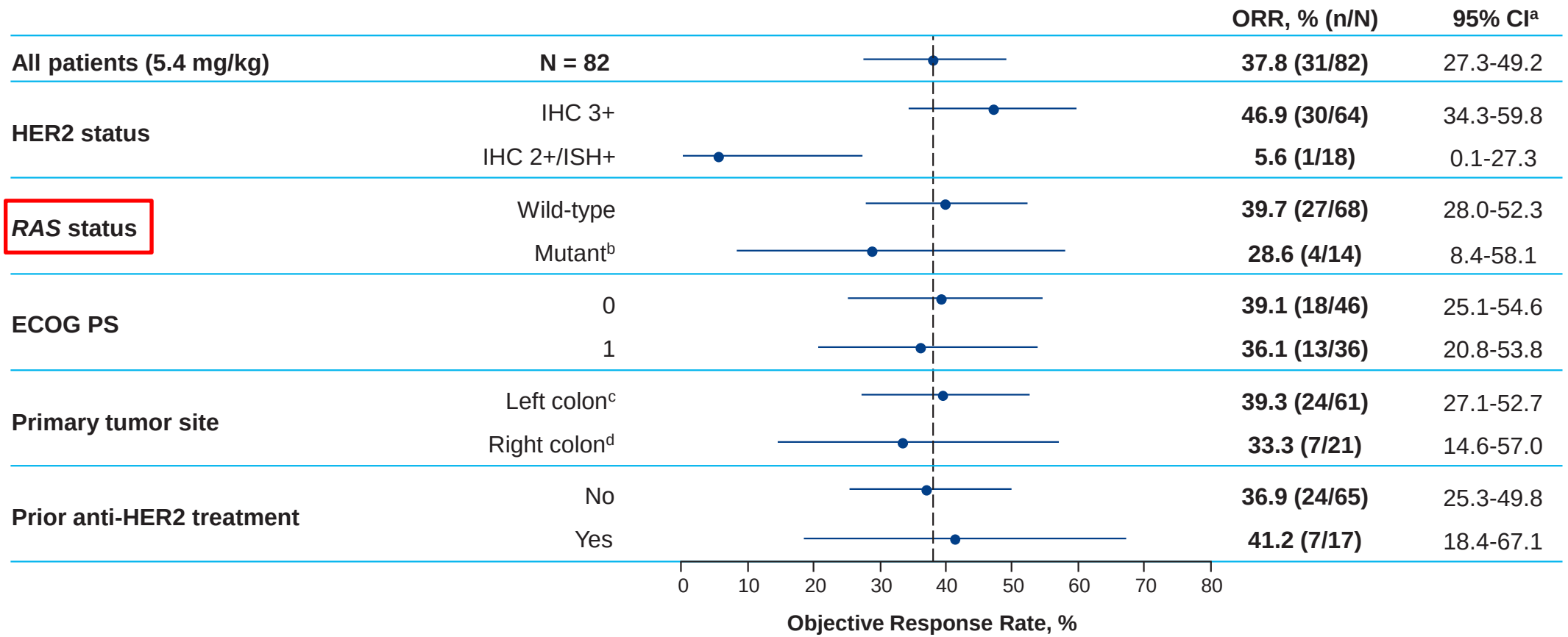

Source: Raghav et al., ASCO 2023, Oral Presentation #3501

BICR, blinded independent central review; ECOG PS, Eastern Cooperative Oncology Group Performance Status; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ISH, in situ hybridization; mCRC, metastatic colorectal cancer; ORR, objective response rate; RAS, rat sarcoma; T-DXd, trastuzumab deruxtecan.

[a]Based on the exact Clopper-Pearson method for binomial distribution. [b]All RASm responders were IHC 3+. [c]Includes rectum, sigmoid, and descending. [d]Includes cecum, ascending, and transverse.

ENHERTU®

ENHERTU® showed manageable safety in HER2+ mCRC - Primary analysis of Ph2 DESTINY-CRC02

ASCO 2023

Daiichi-Sankyo

(Continued)

- Safety profile was consistent with the known profile of ENHERTU® and favored the 5.4 mg/kg
- These results support ENHERTU® 5.4 mg/kg as the optimal dose with positive benefit-risk profile

	T-DXd 5.4 mg/kg Q3W			T-DXd 6.4 mg/kg Q3W
n (%)	Stage 1, n = 41[a]	Stage 2, n = 42	Total, N = 83	Stage 1, N = 39
TEAEs	**40 (97.6)**	**42 (100)**	**82 (98.8)**	**39 (100)**
Drug-related	38 (92.7)	38 (90.5)	76 (91.6)	37 (94.9)
TEAEs grade ≥3	**20 (48.8)**	**21 (50.0)**	**41 (49.4)**	**23 (59.0)**
Drug-related	16 (39.0)	18 (42.9)	34 (41.0)	19 (48.7)
Serious TEAEs	**8 (19.5)**	**12 (28.6)**	**20 (24.1)**	**12 (30.8)**
Drug-related	4 (9.8)	7 (16.7)	11 (13.3)	6 (15.4)
TEAEs associated with drug discontinuation	**3 (7.3)**	**5 (11.9)**	**8 (9.6)**	**3 (7.7)**
Drug-related	3 (7.3)	3 (7.1)	6 (7.2)	2 (5.1)
TEAEs associated with dose reduction	**9 (22.0)**	**6 (14.3)**	**15 (18.1)**	**10 (25.6)**
Drug-related	9 (22.0)	6 (14.3)	15 (18.1)	9 (23.1)
TEAEs associated with drug interruption	**19 (46.3)**	**20 (47.6)**	**39 (47.0)**	**19 (48.7)**
Drug-related	13 (31.7)	9 (21.4)	22 (26.5)	10 (25.6)
TEAEs associated with death	**1 (2.4)**	**3 (7.1)**	**4 (4.8)**	**3 (7.7)**
Drug-related	1 (2.4)[b]	0	1 (1.2)[b]	0[c]

Source: Raghav et al., ASCO 2023, Oral Presentation #3501

Q3W, every 3 weeks; T-DXd, trastuzumab deruxtecan; TEAEs, treatment-emergent adverse events.

[a]1 patient randomized to receive T-DXd 6.4 mg/kg was mistakenly given T-DXd 5.4 mg/kg and counted in the 5.4 mg/kg arm safety analysis set. [b]Patient experienced grade 5 hepatic failure. [c]There was 1 adjudicated, drug-related, grade 5 ILD/pneumonitis event, which was reported as respiratory failure, which was considered unrelated to study drug by investigator.

ENHERTU®

DESTINY-PanTumor02 interim results showed potential of ENHERTU® as a new treatment option in HER2-exp tumors

Daiichi-Sankyo

ASCO 2023

- DESTINY-PanTumor02 is an open-label, multicenter study, in HER2-expressing advanced solid tumors not eligible for curative therapy

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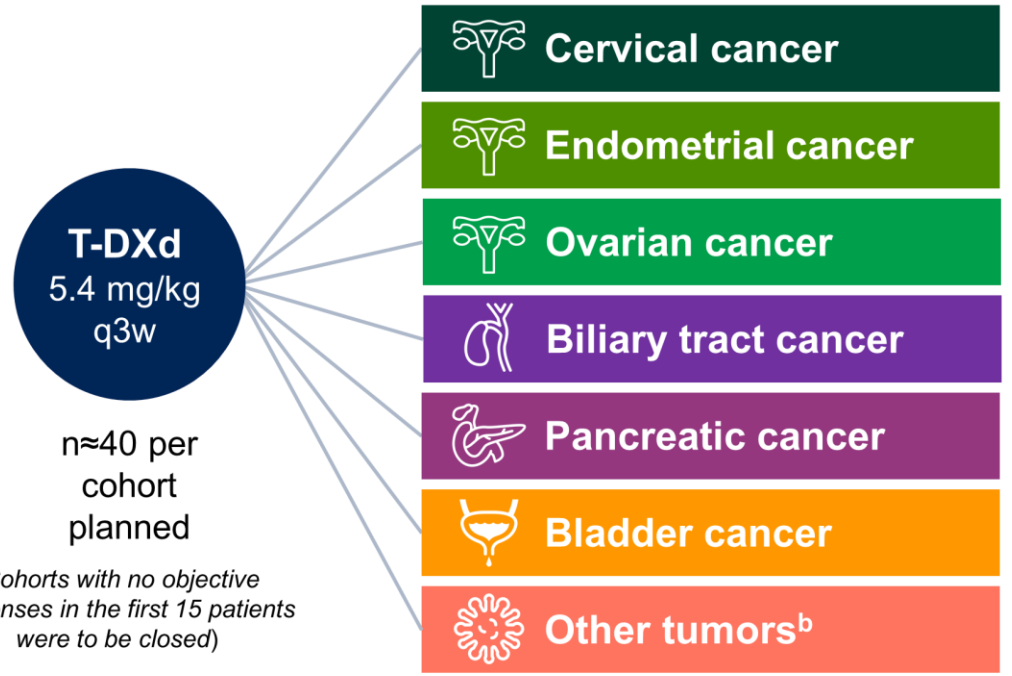
- Advanced solid tumors not eligible for curative therapy
- 2L+ patient population
- HER2 expression (IHC 3+ or 2+)
  - Local test or central test by Herceptest if local test not feasible (ASCO/CAP gastric cancer guidelines[1])[a]
- Prior HER2-targeting therapy allowed
- ECOG/WHO PS 0–1



Primary endpoint

- Confirmed ORR (investigator)[c]

Secondary endpoints

- DOR[c]
- DCR[c]
- PFS[c]
- OS
- Safety

Data cut-off for analysis:

- Nov 16, 2022

Source: Meric-Bernstam et al., ASCO 2023, Oral Presentation #3000

[a]Patients were eligible for either test. All patients were centrally confirmed. [b]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. [c]Investigator-assessed per Response Evaluation Criteria In Solid Tumors version 1.1. 2L, second-line; ASCO, American Society of Clinical Oncology; DCR, disease control rate; CAP, College of American Pathologists; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; HER2, human epidermal growth factor receptor 2; IHC, immunohistochemistry; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PS, performance status; q3w, every 3 weeks; T-DXd, trastuzumab deruxtecan; WHO, World Health Organization. 1. Hofmann M, et al. Histopathology 2008;52(7):797–805.

ENHERTU®

DESTINY-PanTumor02 interim results showed potential of ENHERTU® as a new treatment option in HER2-exp tumors

Daiichi-Sankyo

ASCO 2023

(Continued)

- ENHERTU® demonstrated clinically meaningful activity across a broad range of HER2-expressing solid tumors - encouraging ORR: 37.1% in all patients and 61.3% in patients with IHC 3+

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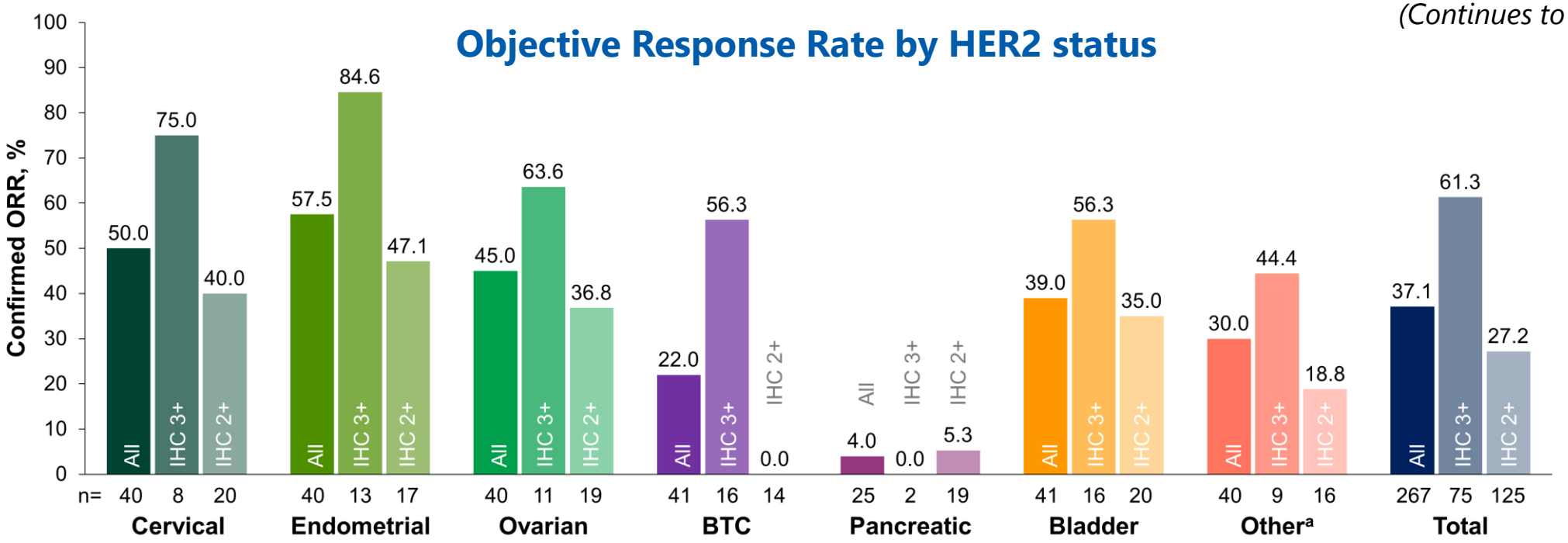

	All patients (N=99)	IHC 3+ (n=46)	IHC 2+ (n=34)
Median DOR, months (95% CI)	11.8 (9.8–NE)	22.1 (9.3–NE)	9.8 (4.2–12.6)

Source: Meric-Bernstam et al., ASCO 2023, Oral Presentation #3000

Analysis of ORR was performed in patients who received ≥1 dose of T-DXd; all patients (n=267; including 67 patients with IHC 1+ [n=25], IHC 0 [n=30], or unknown IHC status [n=12] by central testing) and patients with centrally confirmed HER2 IHC 3+ (n=75) or IHC 2+ (n=125) status. Analysis of DOR was performed in patients with objective response who received ≥1 dose of T-DXd; all patients (n=99; including 19 patients with IHC 1+ [n=6], IHC 0 [n=9], or unknown IHC status [n=4] by central testing) and patients with centrally confirmed HER2 IHC 3+ (n=46) or IHC 2+ (n=34) status. [a]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; NE, non-estimable; ORR, objective response rate.

ENHERTU®

DESTINY-PanTumor02 interim results showed potential of ENHERTU® as a new treatment option in HER2-exp tumors

Daiichi-Sankyo

ASCO 2023

(Continued)

- Durable responses: median DOR 11.8 months in all patients and 22.1 months in patients with IHC 3+

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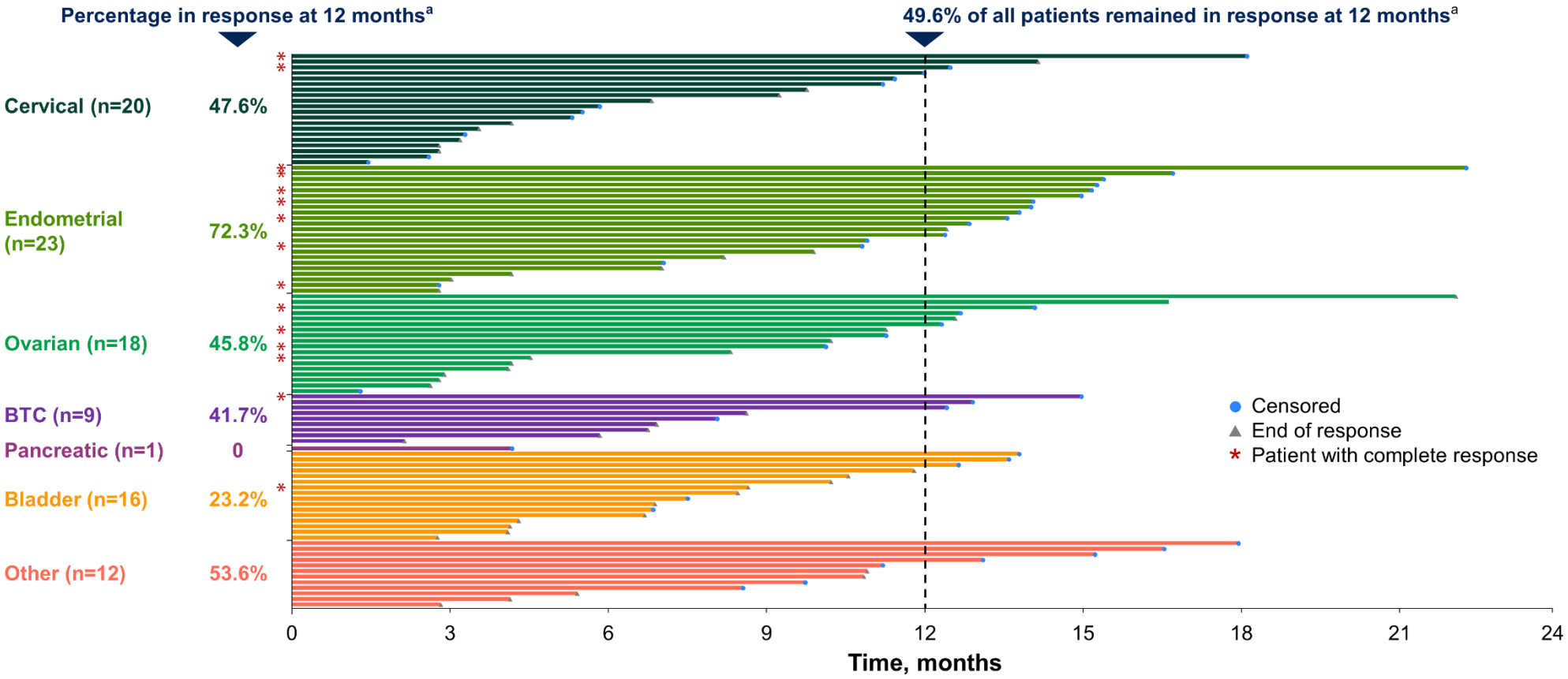
Duration of Objective Response



Source: Meric-Bernstam et al., ASCO 2023, Oral Presentation #3000

Analyses were performed in patients with objective response who received ≥1 dose of T-DXd (n=99).

[a]Determined by the Kaplan-Meier technique. At data cut-off, 44 patients (16.5%) are still ongoing treatment, and 128 patients (47.9%) remain in the study. BTC, biliary tract cancer; IHC, immunohistochemistry.

ENHERTU®

DESTINY-PanTumor02 interim results showed potential of ENHERTU® as a new treatment option in HER2-exp tumors

ASCO 2023

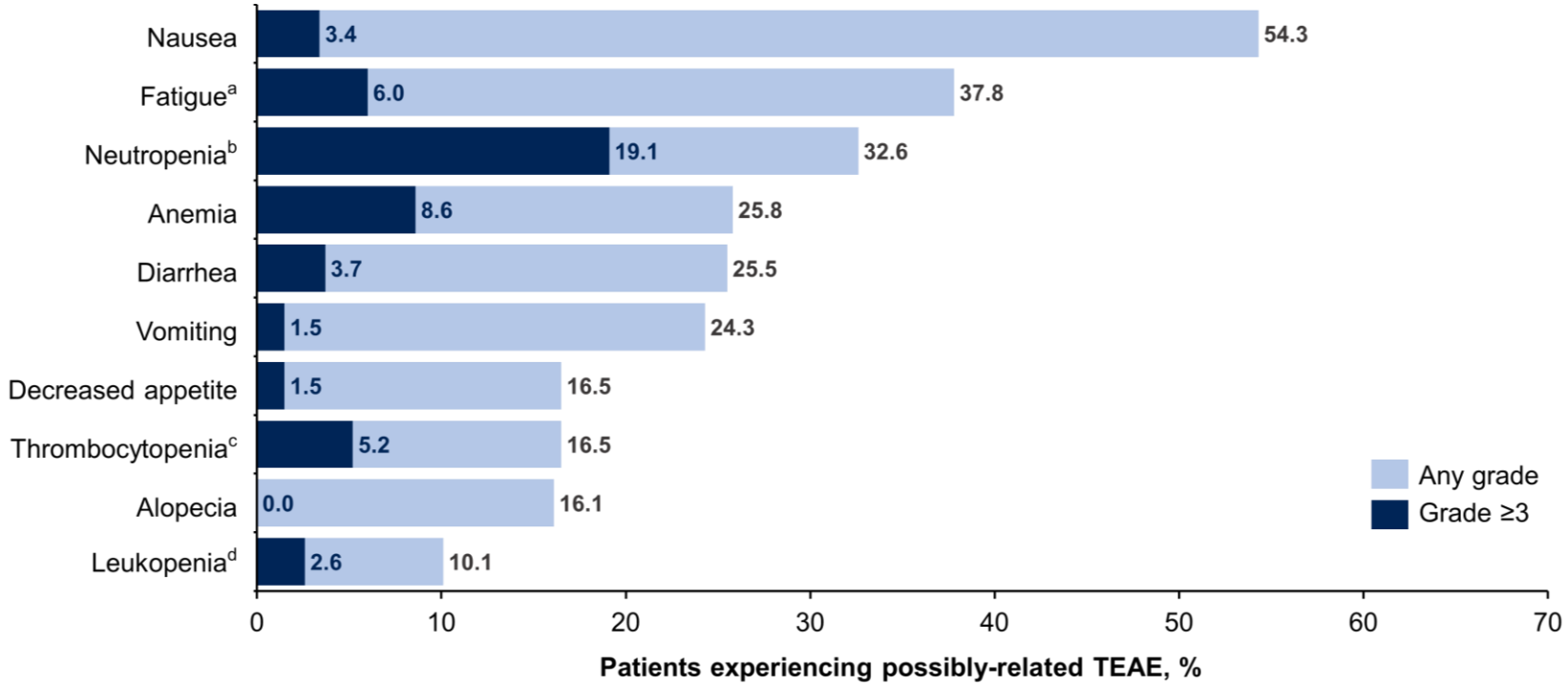
(Continued)

- Safety profile was consistent with the known profile of ENHERTU®

Overall Safety Summary

n (%)	All patients (N=267)
Any drug-related TEAEs	225 (84.3)
Drug-related TEAEs Grade ≥3	103 (38.6)
Serious drug-related TEAEs	32 (12.0)
Drug-related TEAEs associated with dose discontinuations	22 (8.2)
Drug-related TEAEs associated with dose interruptions	49 (18.4)
Drug-related TEAEs associated with dose reductions	50 (18.7)
Drug-related TEAEs associated with deaths	2 (0.7)[$]

Drug-Related TEAE in ≥10% of Patients



Source: Meric-Bernstam et al., ASCO 2023, Oral Presentation #3000

Analyses were performed in patients who received ≥1 dose of T-DXd (n=267). [$]Included neutropenic sepsis (n=1) and pneumonia (n=1). [a]This category includes the preferred terms fatigue, asthenia, and malaise. [b]This category includes the preferred terms neutrophil count decreased and neutropenia. [c]This category includes the preferred terms platelet count decreased and thrombocytopenia. [d]This category includes the preferred terms white blood cell count decreased and leukopenia. TEAE, treatment-emergent adverse event; T-DXd, trastuzumab deruxtecan.

ENHERTU®

ENHERTU® demonstrated promising efficacy and manageable safety in HER2-amplified solid tumors identified by cfDNA

Daiichi-Sankyo

ASCO 2023

- HERALD/EPOC1806 study was a multicenter, investigator-initiated Ph2 trial in *HER2*-amplified advanced solid tumors identified by plasma cell-free DNA (cfDNA) as a part of the Nationwide Cancer Genome Screening Project (GOZILA study) in Japan

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1) Patients with unresectable solid tumors* refractory or intolerant to standard of care (SoC) or no SoC available
2) *HER2* amplification by G360 within 8 weeks
3) Age ≥ 20 years
4) ECOG PS 0-1
5) Measurable lesion per RECIST version 1.1

- Esophagus
- Pancreas
- Urothelium
- Cervix
- Endometrium
- Ovary
- Salivary gland
- Head and neck
- Others

Trastuzumab deruxtecan (T-DXd)
5.4 mg/kg Q3W

Funding:
Japan AMED
Daiichi Sankyo Co., Ltd.

Study identifier:
JapicCTI-194707

*Excluding gastric cancer, breast cancer, colorectal cancer, lung cancer, biliary tract cancer or uterine carcinosarcoma, which have already been confirmed to have HER2 overexpression in tumor tissue. For gastric cancer and breast cancer, tissue HER2 testing is mandatory.

- Primary endpoint : ORR by Investigator's assessment
- Secondary endpoints : PFS, DoR, DCR, OS, ORR by ICR and TEAEs

Source: Taniguchi et al., ASCO 2023, Poster Discussion #3014

ORR, objective response rate; PFS, progression free survival; DoR, duration of response; DCR, disease control rate; OS, overall survival; ICR, independent central review; TEAE, treatment emergent adverse event

ENHERTU®

ENHERTU® demonstrated promising efficacy and manageable safety in HER2-amplified solid tumors identified by cfDNA

Daiichi-Sankyo

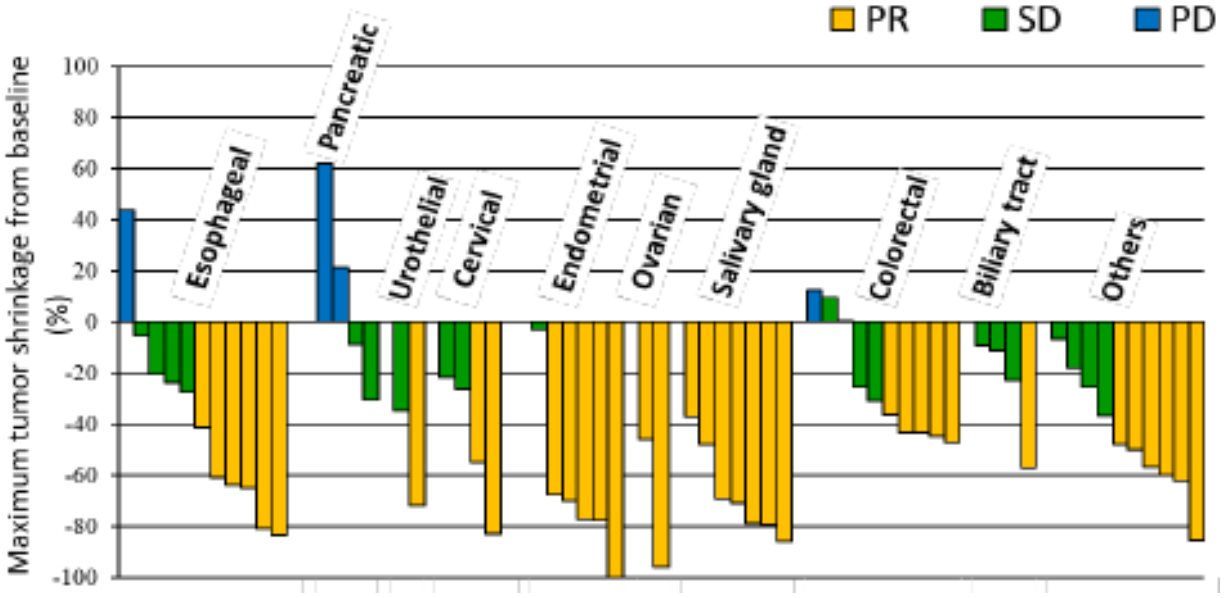
ASCO 2023

(Continued)

- ENHERTU® demonstrated a high ORR, durable response with manageable safety profile in multiple solid tumors

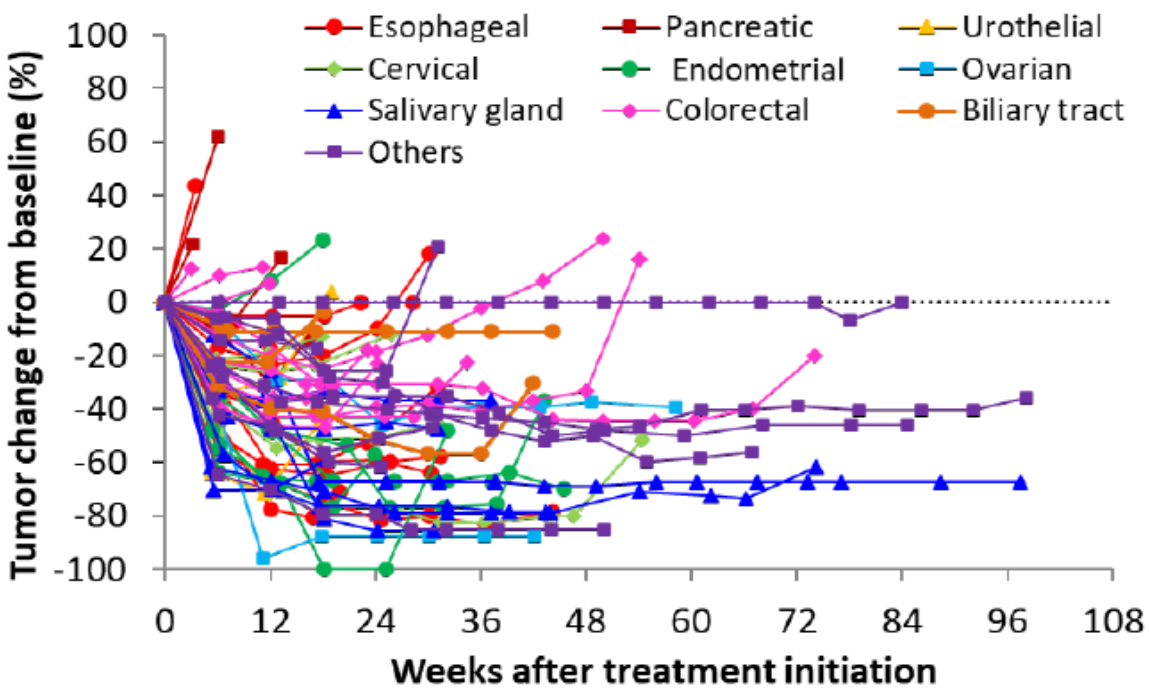
Best Tumor Response

ORR 56.5% [43.3-69.0][a]



Tumor Response Over Time

mDoR 8.8 months [5.8-11.2][a]
mPFS 7.0 months [4.9-9.7][a]
mOS 14.6 months [10.8-22.3] [a]



Source: Taniguchi et al., ASCO 2023, Poster Discussion #3014

mDoR, median duration of response; mOS, median overall survival; mPFS, median progression free survival; ORR, objective response rate. [a] 95% confidence interval.

ENHERTU®

ENHERTU® demonstrated promising efficacy and manageable safety in HER2-amplified solid tumors identified by cfDNA

Daiichi-Sankyo

ASCO 2023

(Continued)

- ENHERTU® demonstrated a high ORR, durable response with manageable safety profile in multiple solid tumors

Summary of TEAEs

	n=62
Treatment duration median, [range]	181.5 days [6–700]
TEAEs	62 (100.0)
TEAEs with ≥Grade 3	39 (62.9)
drug withdrawn	12 (19.4)
dose reduced	23 (37.1)
drug interrupted	37 (59.7)
TEAE-related death	1 (1.6)*

*Cause of death was DIC and sepsis.

Common TEAEs (≥20% in all patients)

Adverse event, n (%)	Any Grade	≥Grade 3
Nausea	37 (59.7)	1 (1.6)
Decreased appetite	34 (54.8)	4 (6.5)
Malaise	26 (41.9)	0
Anemia	25 (40.3)	14 (22.6)
Neutrophil count decreased	20 (32.3)	12 (19.4)
WBC count decreased	20 (32.3)	8 (12.9)
Constipation	17 (27.4)	0
ILD/pneumonitis*	16 (25.8)	1 (1.6)
Pyrexia	15 (24.2)	1 (1.6)
Platelet count decreased	15 (24.2)	5 (8.1)
Stomatitis	14 (22.6)	0
Diarrhea	13 (21.0)	1 (1.6)

Source: Taniguchi et al., ASCO 2023, Poster Discussion #3014

ILD, intestinal lung disease; TEAE, treatment emergent adverse event; * Investigator assessment without ILD adjudication committee.

ENHERTU® in Multiple Tumor Types

ENHERTU® has a potential to expand to HER2-expressing or amplified solid tumors beyond Breast, Gastric, and Lung

- ENHERTU® showed promising efficacy and manageable safety in HER2+ mCRC
- ENHERTU® showed its potential to be a new treatment option for patients with multiple HER2-expressing tumors
- ENHERTU® demonstrated promising efficacy and manageable safety profile in patients with HER2-amplified solid tumors identified by cfDNA

Dato-DXd
NSCLC Updates

Dato-DXd

TROPION-Lung02 updated data continue to support potential of Dato-DXd in 1L NSCLC with combinations

Daiichi-Sankyo

ASCO 2023

- TROPION-Lung02 is the first study evaluating Dato-DXd + pembrolizumab ± platinum CT[a] in advanced NSCLC without known actionable genomic alterations[b]
  - The safety of the Dato-DXd + pembrolizumab doublet was established prior to evaluation of the platinum-containing triplet
  - The safety of Dato-DXd 4-mg/kg combinations was established prior to evaluation of 6-mg/kg combinations

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Key eligibility criteria

- **Advanced/metastatic NSCLC**
- **Dose escalation**[c]: ≤2 lines of prior therapy[d]
- **Dose expansion**
  - ≤1 line of platinum-based CT (cohorts 1 and 2)[d]
  - Treatment naive (cohort 2; enrollment after Jun 30, 2022)[d]
  - Treatment naive (cohorts 3-6)[d]

	Dato-DXd IV Q3W	+	pembro IV Q3W	+	platinum CT IV Q3W	
Cohort 1 (n=20):	4 mg/kg	+	200 mg			Doublet
Cohort 2 (n=44):	6 mg/kg	+	200 mg			Doublet
Cohort 3 (n=20):	4 mg/kg	+	200 mg	+	carboplatin AUC 5	Triplet
Cohort 4 (n=30):	6 mg/kg	+	200 mg	+	carboplatin AUC 5	Triplet
Cohort 5 (n=12):	4 mg/kg	+	200 mg	+	cisplatin 75 mg/m^2	Triplet
Cohort 6 (n=10):	6 mg/kg	+	200 mg	+	cisplatin 75 mg/m^2	Triplet

- **Primary objectives:** safety and tolerability
- **Secondary objectives:** efficacy, pharmacokinetics, and antidrug antibodies

Above data will be presented at ASCO 2023, Tuesday June 6, Lung Cancer—Non-Small Cell Metastatic

Source: Goto et al., ASCO 2023 Oral Abstract Session #9004

Data cutoff: April 7, 2023. AUC, area under the curve; CT, chemotherapy; Dato-DXd, datopotamab deruxtecan; DLT, dose-limiting toxicity; IV, intravenous; NSCLC, non-small cell lung cancer; pembro, pembrolizumab; Q3W, every 3 weeks. [a] Administered sequentially at the same visit. [b] Patients with known actionable EGFR, ALK, ROS1, NTRK, BRAF, RET, or MET mutations or alterations in other actionable oncogenic driver kinases were not eligible for this study. Testing for EGFR and ALK alterations was not required for patients with squamous histology who were smokers or ≥40 years of age. [c] The first 3 to 6 patients in each cohort were enrolled to confirm acceptable safety/DLT rate; the remaining patients are considered part of dose expansion (for which enrollment was ongoing at the time of data cutoff). [d] Prior therapy requirements are for treatment in the advanced/metastatic setting.

Dato-DXd

TROPION-Lung02 updated data continue to support potential of Dato-DXd in 1L NSCLC with combinations

Daiichi-Sankyo

ASCO 2023

(Continued)

- Dato-DXd + pembrolizumab ± platinum chemotherapy demonstrated encouraging antitumor activity in patients with NSCLC in the 1L and 2L+ settings

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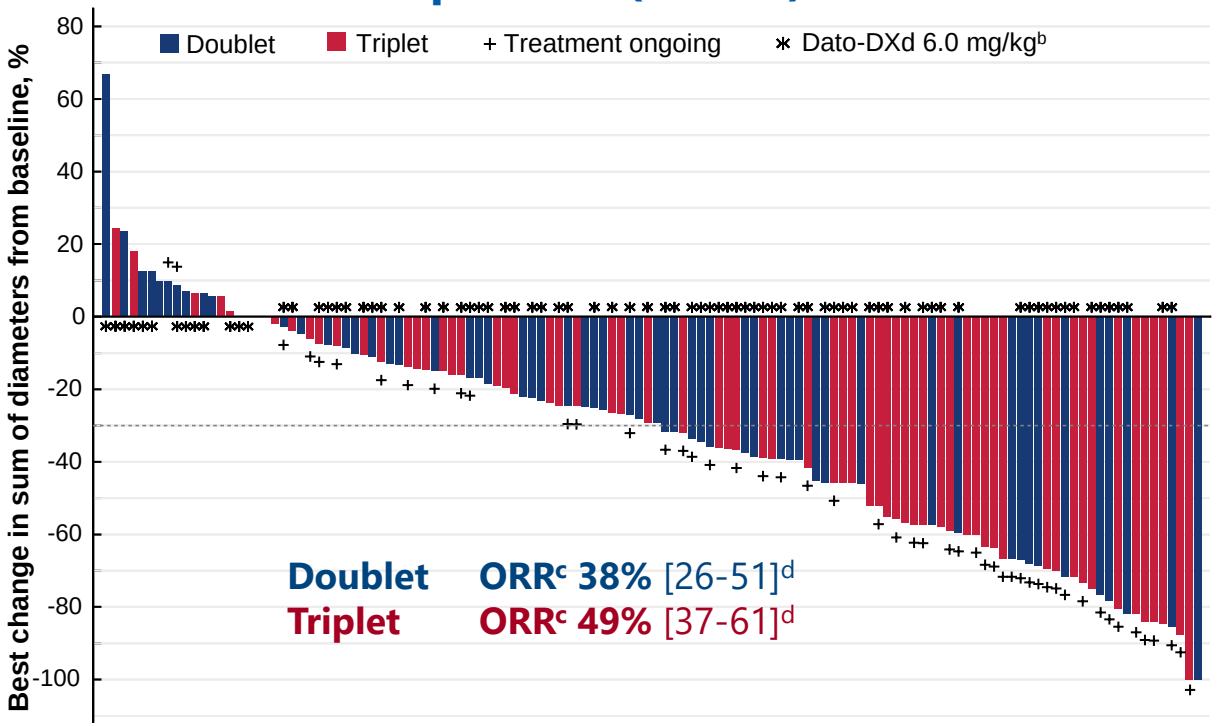
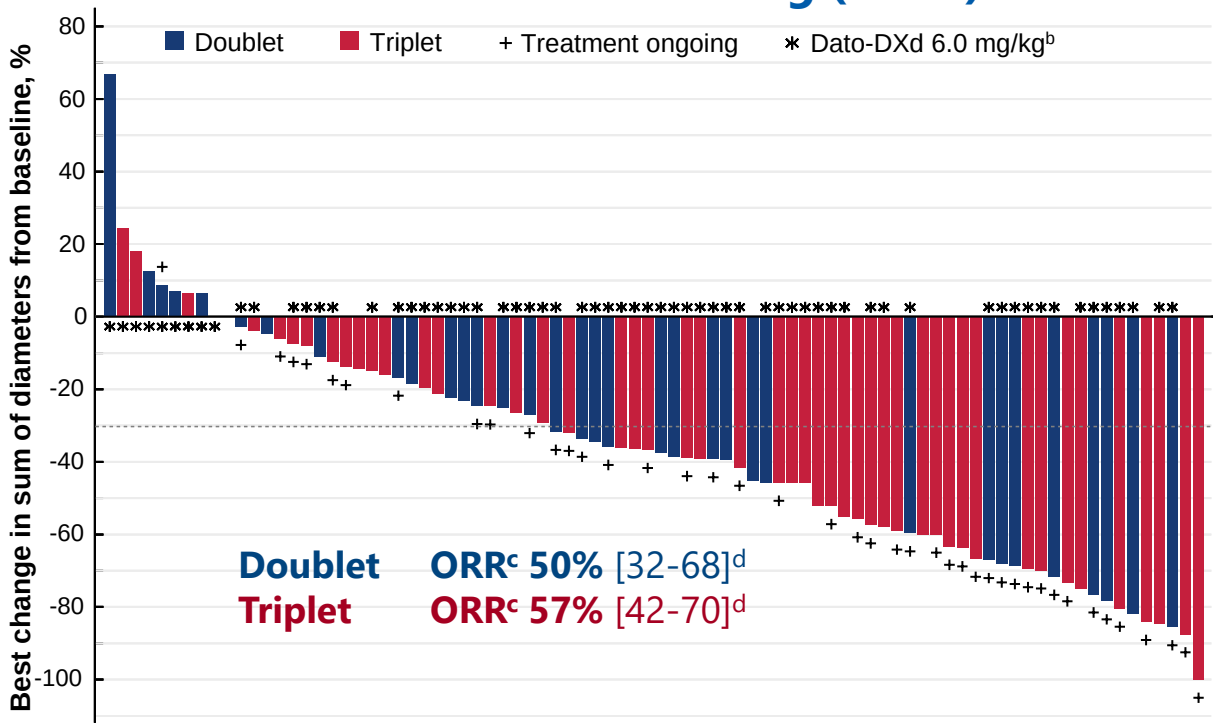
All patients (n=124)[a]



Patients in the 1L setting (n=84)[a]



Above data will be presented at ASCO 2023, Tuesday June 6, Lung Cancer—Non-Small Cell Metastatic

Source: Goto et al., ASCO 2023 Oral Abstract Session #9004

Data cutoff: April 7, 2023. 1L, first line. CI, confidence interval; ORR, objective response rate; [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

Dato-DXd

TROPION-Lung02 updated data continue to support potential of Dato-DXd in 1L NSCLC with combinations

ASCO 2023

(Continued)

- No new safety signals were observed
  - The most frequent TEAEs of any grade were stomatitis, nausea, anemia, and fatigue
- In general, hematologic TEAEs, particularly those of grade ≥3, were more frequently observed with triplet therapy than with doublet therapy

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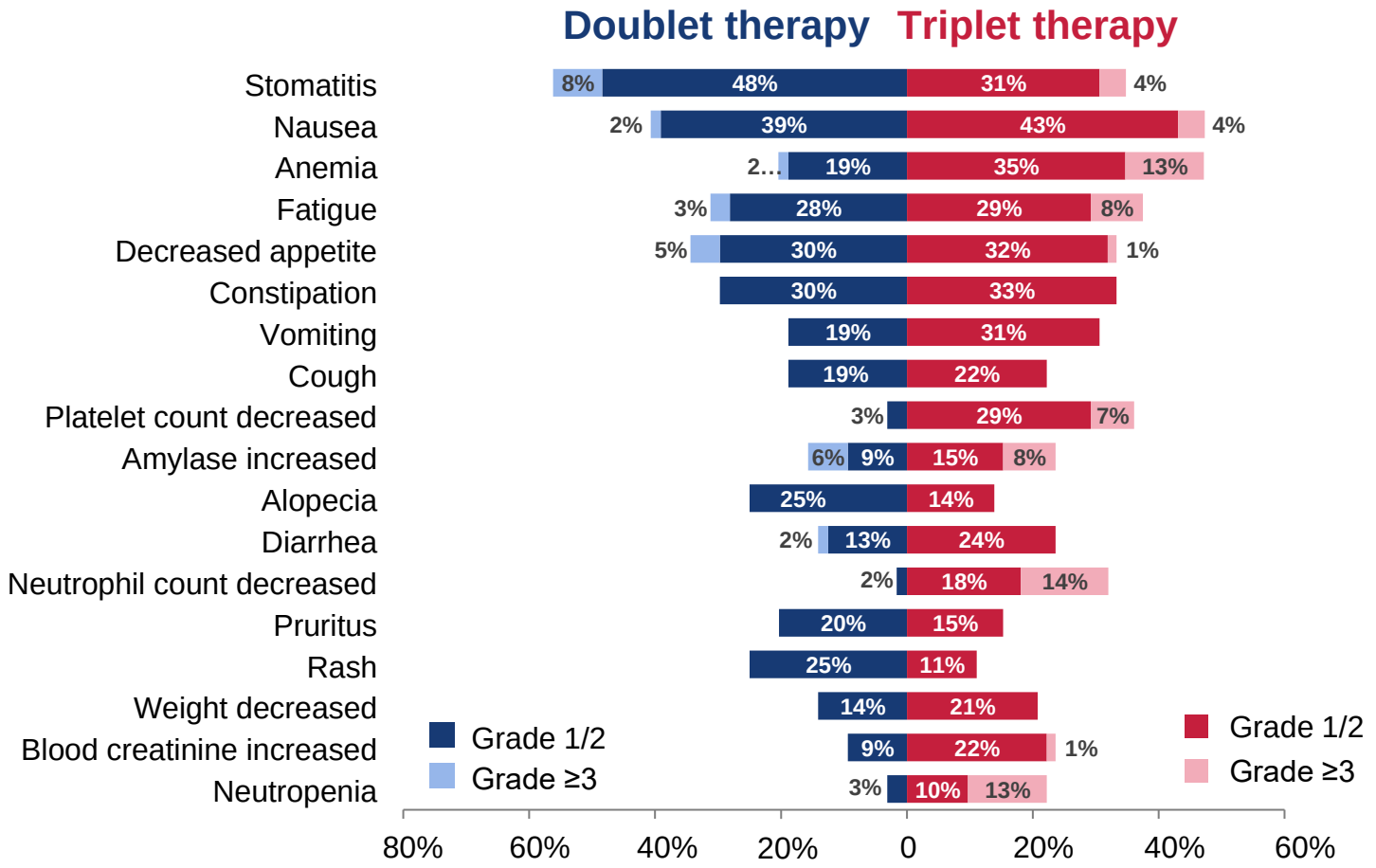
TEAEs Occurring in ≥20% of Patients



Above data will be presented at ASCO 2023, Tuesday June 6, Lung Cancer—Non-Small Cell Metastatic

Source: Goto et al., ASCO 2023 Oral Abstract Session #9004

Data cutoff: April 7, 2023. TEAE, treatment-emergent adverse event

TROPION-Lung02 updated data continue to support potential of Dato-DXd in 1L NSCLC with combinations

(Continued)

- Oral mucositis/stomatitis was the most common AESI and was predominantly grade 1/2
- No grade 5 AESIs have occurred
- There were no grade 4 or 5 adjudicated ILD/pneumonitis events[f]

Adverse Events of Special Interest

AESI, n (%)[a,b]	Doublet (n=64)		Triplet (n=72)	
	All grades	Grade ≥3	All grades	Grade ≥3
Oral mucositis/stomatitis	37 (58)	5 (8)	31 (43)	4 (6)
ILD/pneumonitis adjudicated as drug related[c]	11 (17)	2 (3)	16 (22)	2 (3)
Ocular surface toxicity[d]	10 (16)	1 (2)	17 (24)	2 (3)
IRR[e]	15 (23)	0	10 (14)	0

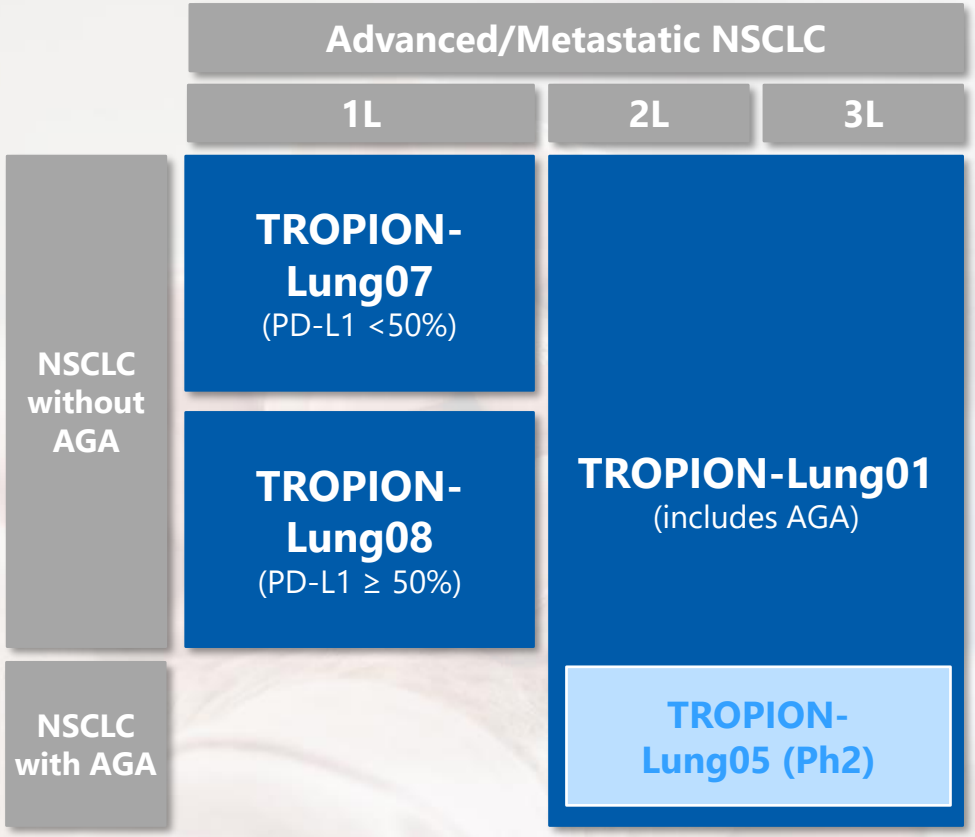
Above data will be presented at ASCO 2023, Tuesday June 6, Lung Cancer—Non-Small Cell Metastatic

Source: Goto et al., ASCO 2023 Oral Abstract Session #9004

Data cutoff: April 7, 2023. AESI, adverse event of special interest; ILD, interstitial lung disease; IRR, infusion-related reaction. [a] AESIs listed in this slide include all preferred terms that define the medical concept. [b] No cases of mucosal inflammation occurred in patients receiving doublet or triplet therapy. [c] Five ILD cases are pending adjudication. [d] The majority of these events were cases of dry eye (n=12 patients) and lacrimation increased (n=8 patients); grade ≥3 events were keratitis (n=2 patients) and dry eye (n=1 patient). [e] IRR refers to all IRR events that occurred in a patient who experienced any of the preselected preferred terms within the same day of Dato-DXd infusion. [f] There was 1 grade 5 event initially adjudicated as drug-related ILD in a patient receiving triplet therapy; this event was ultimately readjudicated to be grade 2.

Dato-DXd in NSCLC

Dato-DXd ongoing studies in NSCLC



Data continue to support our increasing confidence in expanding Dato-DXd into earlier lines of NSCLC

- TROPION-Lung01 Ph3 in NSCLC 2/3L expects readout in Q1 FY2023 as the potential first-to-market indication
- Two Ph3 studies in NSCLC 1L are progressing:
  - **TROPION-Lung07** (NSCLC 1L PD-L1<50%, + pembro ± Pt-CT)
  - **TROPION-Lung08** (NSCLC 1L PD-L1≥50%, +pembro)
- TROPION-Lung02 updated results continue to support TROPION-Lung07 and TROPION-Lung08

HER3-DXd
Breast Cancer Updates

HER3-DXd

Emerging data continue to support potential in metastatic breast cancer – BRE354 interim results

ASCO 2023

- A Ph2 BRE354 study of HER3-DXd in patients with mBC in collaboration with SCRI
- Part A data in HER2-negative mBC was presented at ASCO 2023
- Part Z is ongoing to evaluate potential in mBC patients with prior ENHERTU® treatment

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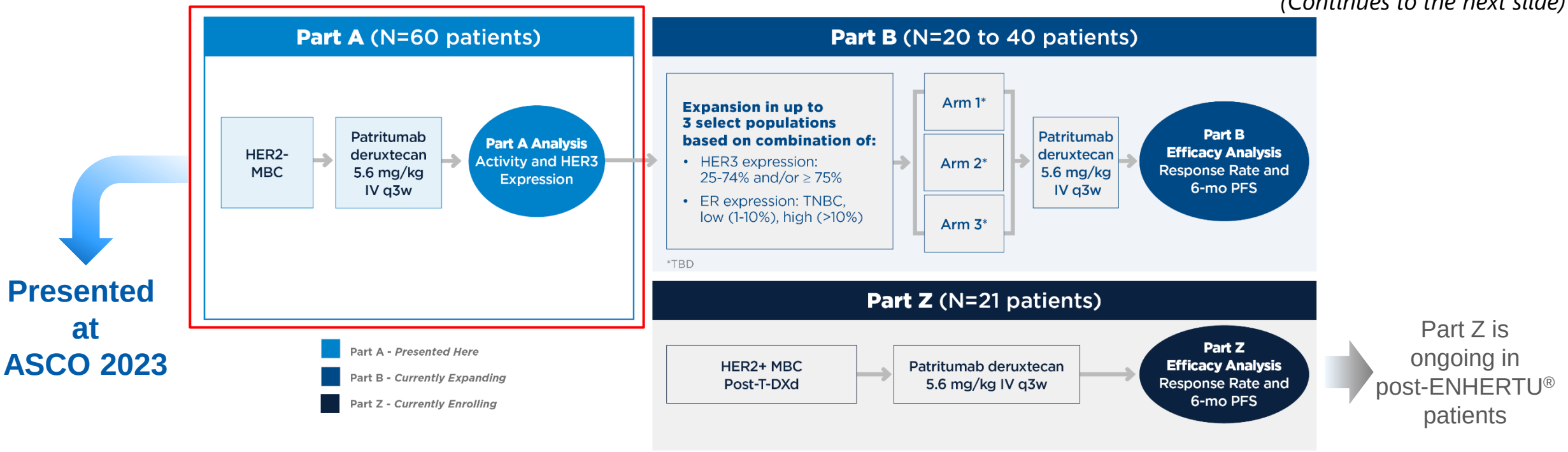


HER3 expression was not an enrollment criterion for Part A; HER3 expression was retrospectively assessed using immunohistochemistry.

Source: Hamilton et al., ASCO 2023, Oral Presentation #1004

mBC, metastatic breast cancer; SCRI, Sarah Cannon Research Institute

HER3-DXd

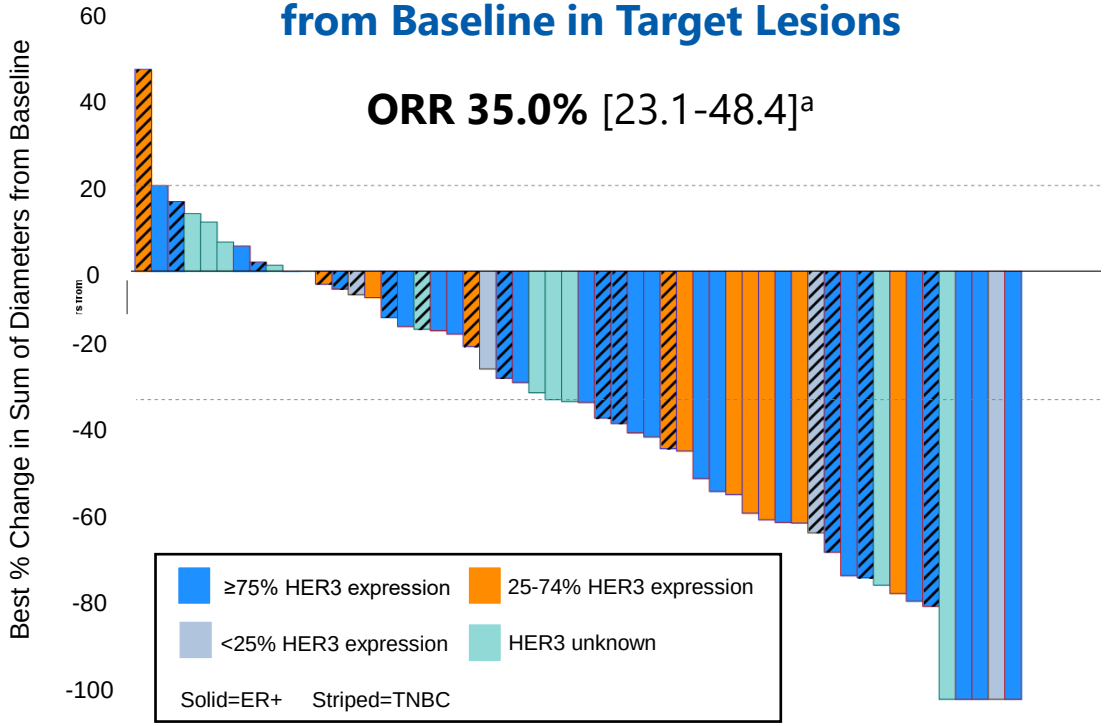
Emerging data continue to support potential in metastatic breast cancer – BRE354 interim results

ASCO 2023

(Continued)

- Interim results from Part A showed an acceptable safety and encouraging efficacy in heavily pre-treated mBC across the broad range of HER3 expression

Best Percent Change in Sum of Diameters from Baseline in Target Lesions



Treatment-Related Adverse Events Occurring in ≥10% of Patients by Highest Reported Grade*

	Any grade (N=60) n (%)	Grade ¾ (N=60) n (%)
Any Adverse Event (AE)	56 (93.3)	19 (31.7)
Nausea	30 (50.0)	2 (3.3)
Fatigue	27 (45.0)	4 (6.7)
Diarrhea	22 (36.7)	3 (5.0)
Vomiting	19 (31.7)	1 (1.7)
Anemia	18 (30.0)	0
Alopecia	17 (28.3)	N/A
Hypokalemia	9 (15.0)	1 (1.7)
Decreased Appetite	8 (13.3)	0
Neutrophil Count Decreased**	7 (11.7)	3 (5.0)
White Blood Cell Count Decreased**	7 (11.7)	1 (1.7)

Treatment-Emergent Serious Adverse Events

Treatment-related SAEs	(N=60), n (%)
Interstitial Lung Disease†	1 (1.7)
Nausea/Vomiting	1 (1.7)
Pneumonitis	1 (1.7)
Thrombocytopenia	1 (1.7)

Source: Hamilton et al., ASCO 2023, Oral Presentation #1004

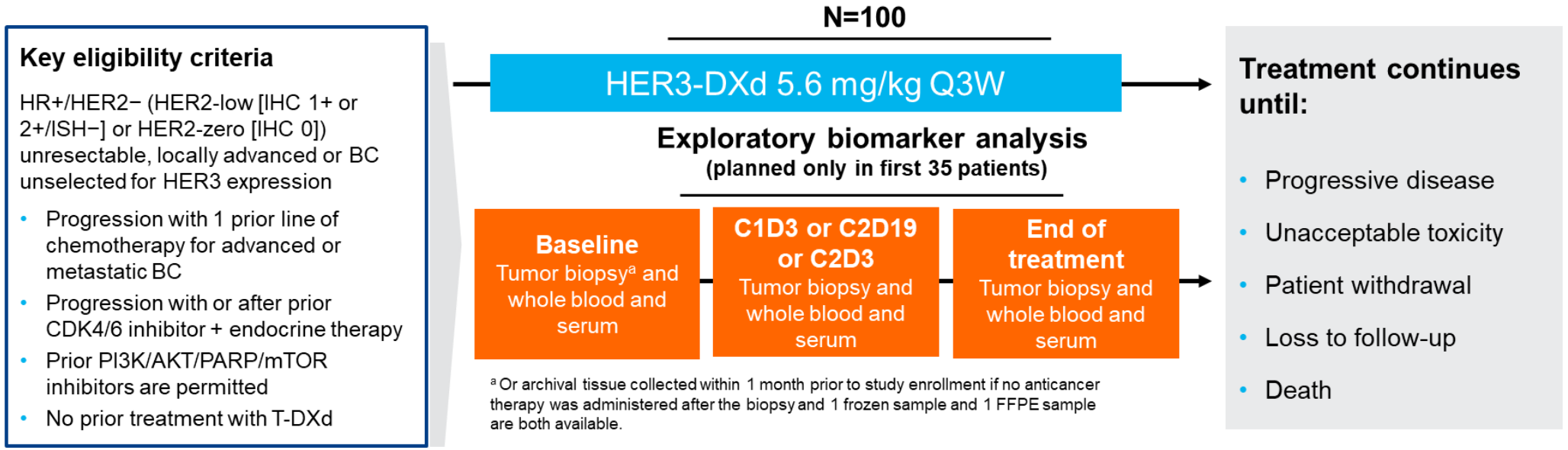
mBC, metastatic breast cancer; SCRI, Sarah Cannon Research Institute; SAE, serious adverse event; TNBC, triple negative breast cancer. *No Grade 5 treatment-related adverse events had occurred prior to data cutoff. **More than 1 adverse event could be reported per patient. [a] 95% confidence interval.

HER3-DXd

Emerging data continue to support potential in metastatic breast cancer – ICARUS-Breast01 interim results

ESMO Breast 2023

- A Ph2 clinical study in HR+/HER2- mBC, with translational aim in collaboration with GRCC
- Encouraging preliminary efficacy, with an ORR of 28.6% at 3 months
- A manageable safety profile ws observed at 5.6 mg/kg, with a low rate of adjudicated treatment-related ILD (1.8%, grade 1)
- Total and HER3+ circulating tumor cell count decreased after the first cycle of HER3-DXd, although not statistically significant



Source: Pistilli et al., ESMO Breast 2023, Proffered Paper Presentation #189O

mBC, metastatic breast cancer; GRCC, Gustave Roussy Cancer Center; ILD, interstitial lung disease inter; ORR, objective response rate

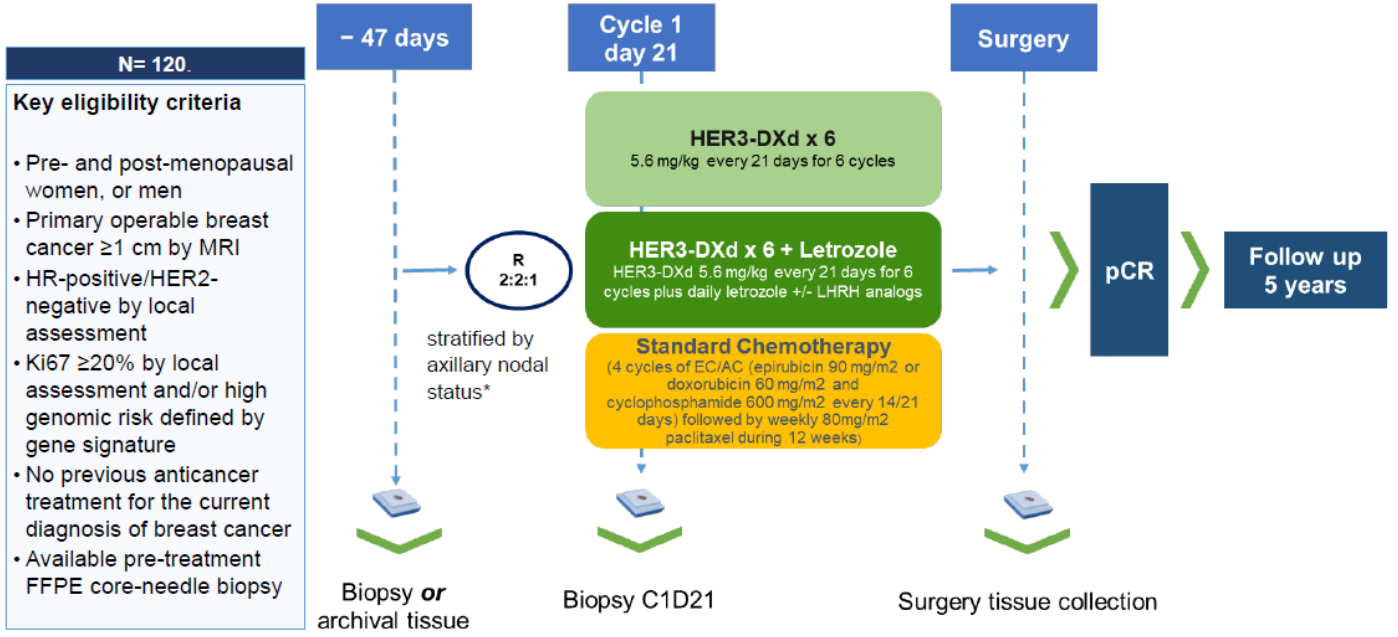
HER3-DXd

Early breast cancer is also a potential opportunity for HER3-DXd – SOLTI TOT-HER3 updated results

ESMO Breast 2023

- Updated results of SOLTI TOT-HER3 window of opportunity trial continue to support potential of HER3-DXd in early breast cancer[1-3]
  - A significant increase in CelTIL score was observed after 1 dose of HER3-DXd at 5.6 mg/kg[1]
  - A single dose of HER3-DXd induced a 30% ORR measured by US[1]
  - A lower incidence of toxicity with 5.6 mg/kg compared with 6.4 mg/kg[1]
  - A correlative analysis from Part A showed that low HER2 expression and copy-number signal are associated with early response to HER3-DXd[3]
- Further validation is ongoing in SOLTI-2103 VALENTINE trial[4] in neoadjuvant setting

SOLTI-2103 VALENTINE trial[4]



Source: [1] Oliveira et al. ESMO Breast 2023 Proffered Paper Presentation #124O; [2] Prat A et al. ESMO Breast 2022, [3] Brasó-Maristany et al. ESMO Breast 2023 Mini Oral Presentation #3MO; [4] Oliveira et al. ESMO Breast 2023 Poster Presentation #155TiP

CelTIL score= -0.8 x tumor cellularity (%) + 1.3 x TILs (%); FFPE, formalin-fixed paraffin-embetted; FNA, fine needle aspiration; iDFS, invasive disease-free survival; MRI, magnetic resonance imaging; ORR, overall response rate; pCR, pathological complete response; TILs, tumor infiltrating lymphocytes; US, ultrosound

HER3-DXd in Breast Cancer

We continue to evaluate potential of HER3-DXd in opportunities including post-ENHERTU® and early breast cancers

- New data continue to support potential of HER3-DXd in mBC – waiting for further data including patients with prior ENHERTU® treatment and translational analysis
- Ealy breast cancer is also a potential opportunity for HER3-DXd – waiting further validation in the ongoing SOLTI-2103 VALENTINE trial

Combinations with DXd-ADCs

Combinations to expand DXd-ADCs' opportunity

Combinations in on-going clinical trials (examples, not exhaustive)

Ph1 or Ph2 | Ph3

DXd ADC +

Checkpoint Inhibitor

pembrolizumab	DS8201-A-U106	TROPION-Lung02	
	TROPION-Lung08	TROPION-Lung07	
durvalumab	DESTINY-Breast07	DESTINY-Breast08	BEGONIA
	TROPION-Breast03		
	DESTINY-Lung03	TROPION-Lung04	HUDSON
AZD2936 or MEDI5752	TROPION-Lung04		

Targeted Therapy

pertuzumab	DESTINY-Breast09		
tucatinib	DESTINY-Breast07		
capivasertib	DESTINY-Breast08		
osimertinib	ORCHARD	U31402-A-U103	

Internal Assets

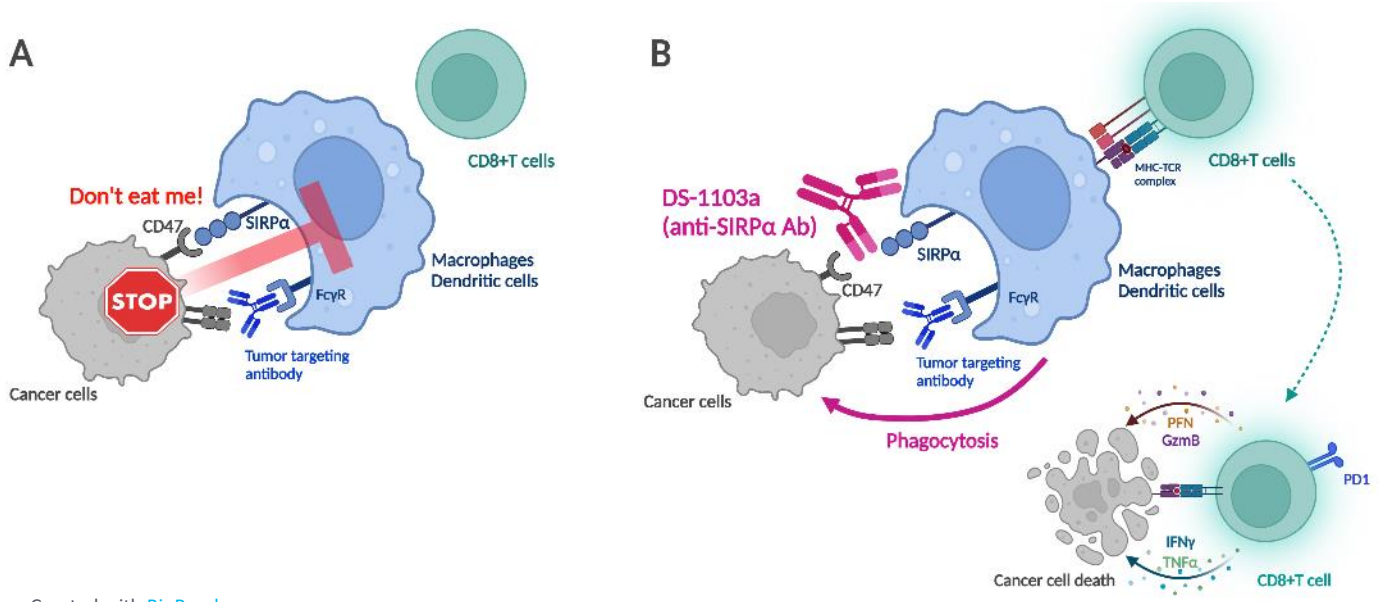
- **ENHERTU® + EZHARMIA® (EZH1/2 inhibitor) in HER2 low mBC** (Ongoing in collaboration with MDACC)
- **ENHERTU® + DS-1103 (anti-SIRPα antibody)** (FSD in H1 FY2023)
- More potential combo partners in preclinical pipeline

FSD, first subject dosed; mBC, metastatic breast cancer; MDACC, MD Anderson Cancer Center

DS-1103

DS-1103 anti-SIRPα antibody initiates combination study with ENHERTU®

- A new combination study of ENHERTU® with anti-SIRPα antibody DS-1103 starts in FY2023 H1



Created with BioRender.com.

- DS-1103 is designed to block the "Don't eat me" signal of the SIRPα-CD47 axis in macrophages and dendric cells, leading to phagocytosis of tumor cells and subsequent activation of anti-tumor immunity
- DS-1103 could potentiate efficacy of anti-tumor antibody drugs, including DXd-ADCs
- A related E-publication at ASCO 2023 (Abstract# e14509) on a QSP model informing DS-1103 dosing

Ph1 study design

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

→

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

BC: breast cancer, FIH: first-in-human, Q3W: once every 3 weeks, QSP: quantitative systems pharmacology, SIRPα, signal-regulatory protein alpha

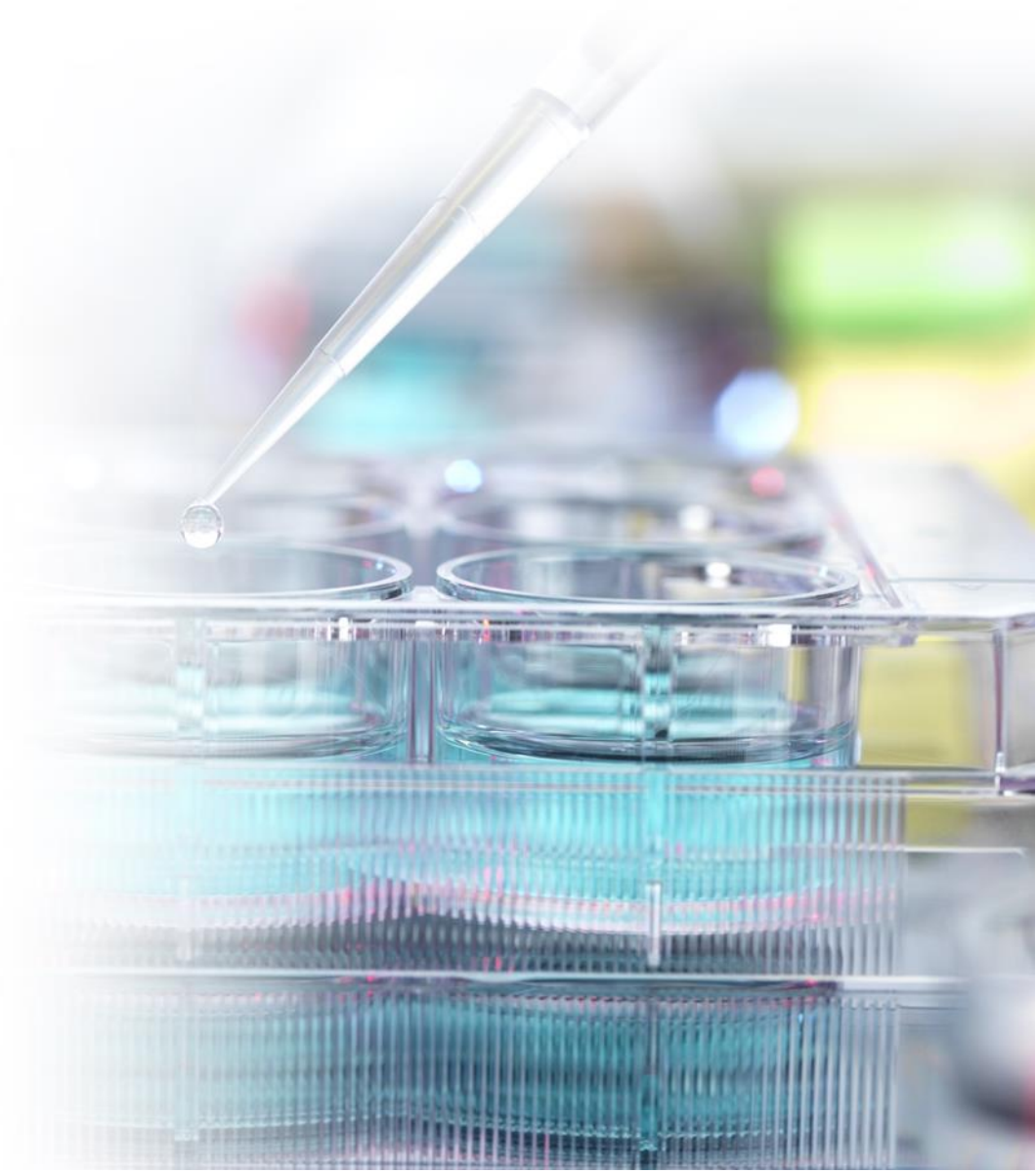
Combinations with DXd-ADCs

Combinations of DXd-ADCs with our internal assets is one of the key strategies to expand and extend our oncology portfolio

- Combination study of ENHERTU® with EZHARMIA® is ongoing
- A new combination study of ENHERTU® with anti-SIRPα antibody DS-1103 will start soon
- Further combinations including other DXd-ADCs are under planning

Agenda

1. Introduction
2. R&D strategy
3. Highlights from ASCO & ESMO Breast
4. **Closing**
5. Q&A



Daiichi Sankyo's Purpose and R&D Vision

Purpose	**Contribute to the enrichment of quality of life around the world**
R&D Vision	**Source of innovation for improving patient's lives**

Serve Patients Globally

by delivering our strength,

Science & Technology

worldwide

Agenda

1. Introduction
2. R&D strategy
3. Highlights from ASCO & ESMO Breast
4. Closing
5. **Q&A**

Appendix

FY2023 News Flow

As of Apr 2023

Regulatory decisions

ENHERTU®	DESTINY-Breast04：HER2 low BC, post chemo, Ph3 • China: FY2023 H1
	DESTINY-Lung01, 02：HER2 mutant NSCLC, 2L+, Ph2 • JP: FY2023 H1 • EU: FY2023 H2
Quizartinib	QuANTUM-First: AML, 1L, Ph3 • US: FY2023 H1 • EU: FY2023 H2

Key data readouts

ENHERTU®	DESTINY-Breast06*: HR+ and HER2 low BC, chemo naïve, Ph3 • FY2023 H1
Dato-DXd	TROPION-Lung01*: NSCLC, 2/3L, Ph3 • FY2023 Q1
	TROPION-Breast01*: HR+ and HER2 low or negative BC, 2/3L, Ph3 • FY2023 H1
EZHARMIA®	r/r PTCL, Registrational Ph2 • FY2023 H1

Bold: update from FY2022 Q3

AML: acute myeloid leukemia, BC: breast cancer, HR: hormone receptor,
NSCLC: non-small cell lung cancer, PTCL: peripheral T cell lymphoma, r/r: relapsed or refractory

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

Major R&D Milestones (5DXd-ADCs)

As of Jun 2023

Project	Target Indication [phase, study name]	FY2023 H1	FY2023 H2	FY2024
ENHERTU®	BC: • HER2 low, post chemo [Ph3, DESTINY-Breast04]	• Approval anticipated (China)		
	BC: • HER2 low, chemo naïve [Ph3, DESTINY-Breast06]	• TLR anticipated		
	BC: **• HER2+, 1L [Ph3, DESTINY-Breast09]**			**• TLR anticipated**
	BC: **• HER2+, Neoadjuvant [Ph3, DESTINY-Breast11]**			**• TLR anticipated**
	NSCLC: • HER2 mutant, 2L [Ph2, DESTINY-Lung01, 02]	• Approval anticipated (JP)	• Approval anticipated (EU)	
	NSCLC: **• HER2 mutant, 1L [Ph3, DESTINY-Lung04]**			**• TLR anticipated**
Dato-DXd	NSCLC: • 2/3L [Ph3, TROPION-Lung01]	• TLR anticipated		
	BC: • HR+ and HER2 low or negative BC, 2/3L [Ph3, TROPION-Breast01]	• TLR anticipated		
	BC: **• TNBC, 1L [Ph3, TROPION-Breast02]**			**• TLR anticipated**
HER3-DXd	NSCLC: **• EGFR mutant, 2L [Ph3, HERTHENA-Lung02]**			**• TLR anticipated**
DS-7300	SCLC: **• 2L [Dose optimization, Ph2]**			**• TLR anticipated**

Bold: update from FY2022 Q4 BC: breast cancer, GC: gastric cancer, 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)

As of Jun 2023

Project	Target Indication [phase, study name]	FY2023 H1	FY2023 H2	FY2024
Quizartinib	• AML, 1L [Ph3, JP/US/EU/Asia]	**• Approved (JP)** • Approval anticipated (US)	• Approval anticipated (EU)	
EZHARMIA®	• r/r PTCL [Registrational Ph2, JP/US/EU/Asia]	• TLR anticipated		
DS-1103	• HER2+ solid tumors, HER2 low BC [Ph1, US]	• Study start anticipated		
DS-5670	• COVID-19 mRNA vaccine (mutant strain), booster vaccination [Ph3, JP]	**• Study started**		

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

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

ENHERTU®: Clinical Development Plan | Breast cancer

As of Jun 2023			FY2023	FY2024	FY2025
HER2 Positive		Metastatic 3L+	Monotherapy: approved in JP/US/EU based on DESTINY-Breast01		
		Metastatic 2L	Monotherapy: approved in JP/US/EU based on DESTINY-Breast03		
			DESTINY-Breast07 combination (1L/2L) Ph1b/2		
		Metastatic 1L			
			DESTINY-Breast09 T-DXd ± pertuzumab vs THP		
		Adjuvant*	DESTINY-Breast05 monotherapy vs T-DM1		
		Neoadjuvant	DESTINY-Breast11 T-DXd vs T-DXd / THP vs AC / THP		
HER2 low	HR+ HR-	Metastatic Post Chemo	Monotherapy: approved in JP/US/EU based on DESTINY-Breast04		
			DESTINY-Breast08 combination		
		Adjuvant			
	HR+	Metastatic Chemo Naive	DESTINY-Breast06 monotherapy vs PC		
	HR-	Metastatic 1L	BEGONIA durvalumab combination Ph1b/2 (Arm 6)		
		Neoadjuvant			

*Adjuvant therapy for patients with HER2+ early BC with high risk of disease recurrence who have residual invasive disease after receiving neoadjuvant therapy

Ph 1 ongoing | Ph 2 ongoing | Ph 3 ongoing | New

Study initiation & end points are all shown as either beginning of H1 or H2

AC: adriamycin + cyclophosphamide, HR: hormone receptor, PC: physician's choice, T-DM1: trastuzumab emtansine,
T-DXd: trastuzumab deruxtecan, THP: taxane + Herceptin + pertuzumab,

ENHERTU®: Clinical Development Plan | GC & NSCLC

As of Jun 2023			FY2023	FY2024	FY2025
Gastric	HER2 Positive	Metastatic 3L+	Monotherapy: approved in JP based on DESTINY-Gastric01		
		Metastatic 2L	Monotherapy: approved in US/EU based on DESTINY-Gastric01 and 02		
			DESTINY-Gastric06 monotherapy China		
			DESTINY-Gastric04 mono vs ramucirumab+paclitaxel		
			DESTINY-Gastric03 combination (1L/2L) Ph1b/2		
		Metastatic 1L			
NSCLC	HER2 Expressing	Metastatic 2L+	DESTINY-Lung01 (Ph2) completed in FY2021 H1		
			HUDSON durvalumab combination		
		Metastatic 1L	DESTINY-Lung03 combination		
	HER2 Mutant	Metastatic 2L+	Monotherapy: approved in US based on DESTINY-Lung01 and 02		
			DESTINY-Lung05 China		
		Metastatic 1L	DESTINY-Lung04 mono vs SOC		

Ph 1 ongoing | Ph 2 ongoing | Ph 3 ongoing | New

Study initiation & end points are all shown as either beginning of H1 or H2

NSCLC: non-small cell lung cancer, SOC: standard of care

ENHERTU®: Clinical Development Plan | CRC & other tumors

As of Jun 2023			FY2023	FY2024	FY2025
CRC	HER2 Expressing	Metastatic 3L	TLR of DESTINY-CRC02 (Ph2) obtained in FY2022 H2		
Other Tumors/ multiple tumors	HER2 Expressing	Metastatic 2L	Pembrolizumab combination (breast, NSCLC)		
			DESTINY-PanTumor02		
	HER2 Mutant	Metastatic 2L	DESTINY-PanTumor01 (Ph2) completed in FY2023 H1		
			PETRA AZD5305 combination Ph1/2a		

Ph 1 ongoing | Ph 2 ongoing | Ph 3 ongoing | New

Study initiation & end points are all shown as either beginning of H1 or H2

CRC: colorectal cancer, NSCLC: non small cell lung cancer

Dato-DXd: Clinical Development Plan | NSCLC

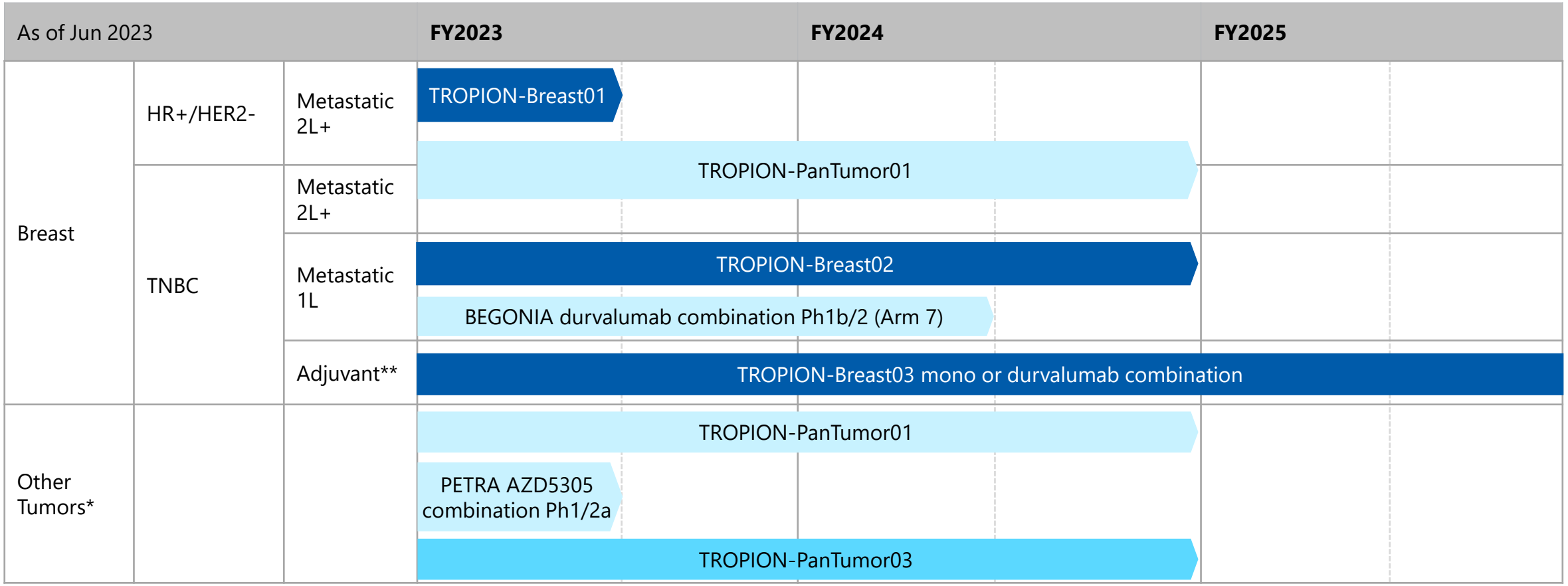
As of Jun 2023			FY2023	FY2024	FY2025
NSCLC	All comers	Metastatic 2L/3L	TROPION-Lung01 monotherapy		
	ICI combination Without actionable genomic alterations	Metastatic 1L/2L	TROPION-Lung02 pembrolizumab combination		
			TROPION-Lung04 durvalumab, AZD2936 and MEDI5752 combination		
		Metastatic 1L	TROPION-Lung07 pembrolizumab ± platinum combination (PD-L1<50%)		
			TROPION-Lung08 pembrolizumab combination (PD-L1≥50%)		
	With actionable genomic alterations	Metastatic 2L+	TLR of TROPION-Lung05 obtained in FY2022 H2		
		Metastatic 2L with EGFR mutation	ORCHARD osimertinib combination		

Ph 1 ongoing | Ph 2 ongoing | Ph 3 ongoing | New

Study initiation & end points are all shown as either beginning of H1 or H2

ICI: immune checkpoint inhibitor, NSCLC: non small cell lung cancer

Dato-DXd: Clinical Development Plan | Breast & other tumors



*Other tumors are gastric, esophageal, urothelial, SCLC, endometrial, CRPC, etc. Inclusion of these tumors is based upon TROP2 expression as well as preclinical and other evidence that Dato-DXd may be effective.
**Adjuvant therapy for patients with TNBC with residual disease after neoadjuvant therapy

Ph 1 ongoing | Ph 2 ongoing | Ph 3 ongoing | New

Study initiation & end points are all shown as either beginning of H1 or H2

CRPC: Castration-resistant prostate cancer, HR: hormone receptor, SCLC: small cell lung cancer, TNBC: triple-negative breast cancer

HER3-DXd: Clinical Development Plan | NSCLC & other tumors

As of Jun 2023			FY2023	FY2024	FY2025
NSCLC	EGFR mutated	Advanced/ Metastatic 3L+	Ph1 dose expansion		
			TLR of HERTHENA-Lung01 obtained in FY2022 H2		
		Advanced/ Metastatic 2L	HERTHENA-Lung02 monotherapy vs chemotherapy		
		Advanced/ Metastatic 1L	Osimertinib combination Ph1b		
Breast		Metastatic BC	Several ARO studies ongoing		

Ph 1 ongoing | Ph 2 ongoing | Ph 3 ongoing | New

Study initiation & end points are all shown as either beginning of H1 or H2

ARO: Academic Research Organization, BC: breast cancer, NSCLC: non small cell lung cancer

DS-7300: Clinical Development Plan

As of Jun 2023			FY2023	FY2024	FY2025
ES-SCLC		Advanced/ Metastatic 2L+	Ph2 dose optimization		
Solid tumor	mCRPC, ESCC, sqNSCLC	Metastatic	Ph1 dose expansion		

Ph 1 ongoing | Ph 2 ongoing | Ph 3 ongoing | New

Study initiation & end points are all shown as either beginning of H1 or H2

ESCC: esophageal squamous cell carcinoma, ES-SCLC: extensive-stage small cell lung cancer, mCRPC: metastatic castration-resistant prostate cancer, sqNSCLC: squamous non-small cell lung cancer

DS-6000: Clinical Development Plan

As of Jun 2023			FY2023	FY2024	FY2025
Solid tumor	OVC	Advanced/ Metastatic	Ph1 dose expansion		
	RCC	Advanced/ Metastatic			

Ph 1 ongoing | Ph 2 ongoing | Ph 3 ongoing | New

Study initiation & end points are all shown as either beginning of H1 or H2

OVC: ovarian cancer, RCC: renal cell carcinoma

Major R&D Pipeline: 5DXd-ADCs

As of Jun 2023

Phase 1	Phase 2	Phase 3	Filed
(US/EU/Asia) HER2+ BC 2L+/1L DESTINY-Breast07	(JP/US) solid tumors TROPION-PanTumor01	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) solid tumors TROPION-PanTumor03	(JP/US/EU/Asia) HER2+ BC adjuvant*2 DESTINY-Breast05	(CN) HER2 low BC post chemo DESTINY-Breast04
(US/EU/Asia) HER2 low BC Chemo naïve/ post chemo DESTINY-Breast08	(CN) NSCLC, TNBC TROPION-PanTumor02	(CN) HER2+ GC 3L DESTINY-Gastric06	(JP/US/EU/Asia) NSCLC (w/ AGA) TROPION-Lung05	(JP/US/EU/Asia) HER2 low BC chemo naïve DESTINY-Breast06	(JP/EU) HER2 mutant NSCLC 2L+ DESTINY-Lung01/Lung02
(JP/US/EU/Asia) HER2+ GC combo, 2L+/1L DESTINY-Gastric03	(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) TROPION-Lung02	(CN) HER2 mutant NSCLC 2L+ DESTINY-Lung05	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09	
(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	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	
(US/EU) BC, NSCLC (pembrolizumab combo)	(JP/US/EU/Asia) NSCLC	(JP/US/EU/Asia) HER2+ CRC 3L DESTINY-CRC02	(JP/US/EU/Asia) EGFR mutated NSCLC 3L HERTHENA-Lung01	(JP/US/EU/Asia) NSCLC (w/ HER2 exon 19 or exon 20 mutation) 1L DESTINY-Lung04	
(US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(JP/US) EGFR mutated NSCLC (osimertinib combo)	(JP/US/EU/Asia) HER2 mutant tumor DESTINY-PanTumor01	DS-7300 (JP/US/EU/Asia) B7-H3-directed ADC ES-SCLC	(JP/US/EU/Asia) NSCLC 2/3L TROPION-Lung01	
DS-7300 (JP/US) B7-H3-directed ADC ESCC, CRPC, squamous NSCLC, SCLC, etc.	(JP/US) HER3+ BC	(US/EU/Asia) HER2 expressing tumor DESTINY-PanTumor02		(JP/US/EU/Asia) non-squamous NSCLC (w/o AGA, pembrolizumab combo) 1L TROPION-Lung07	
DS-6000 (JP/US) CDH6-directed ADC Renal cell carcinoma, ovarian cancer				(JP/US/EU/Asia) NSCLC (w/o AGA, pembrolizumab combo) 1L TROPION-Lung08	
				(JP/US/EU/Asia) BC*1 2/3L TROPION-Breast01	
				(JP/US/EU/Asia) TNBC 1L TROPION-Breast02	
				(JP/US/EU/Asia) TNBC (mono or durvalumab combo) adjuvant*3 TROPION-Breast03	
				(JP/US/EU/Asia) EGFR mutated NSCLC 2L HERTHENA-Lung02	

ENHERTU® / DS-7300
Dato-DXd / DS-6000
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 (designated in at least one country/region among JP, US and EU)

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

AGA: actionable genomic alterations, BC: breast cancer, CRC: colorectal cancer,
GC: gastric cancer, NSCLC: non-small cell lung cancer, TNBC: triple negative breast cancer

Major R&D Pipeline: Next Wave

As of Jun 2023

Phase 1	Phase 2	Phase 3	Filed
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	Valemetostat (DS-3201)(JP/US/EU/Asia) EZH1/2 inhibitor PTCL	Pexidartinib (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	Quizartinib (US/EU) FLT3 inhibitor AML 1L
DS-1594 (US) Menin-MLL binding inhibitor AML, ALL	Valemetostat (DS-3201) (EU) EZH1/2 inhibitor BCL	Esaxerenone (JP) MR blocker Diabetic nephropathy	Mirogabalin (CN) α2δ ligands Diabetic peripheral neuropathic pain
DS-9606 (US/EU) Target undisclosed ADC Solid tumors	DS-1001 (JP) Mutant IDH1 inhibitor Glioma	VN-0102/JVC-001 (JP) Measles mumps rubella combined vaccine	DS-5670 (JP) COVID-19 mRNA vaccine (original strain) COVID-19 (booster vaccination)
DS-1103 Anti-SIRPα antibody HER2 expressing or mutant advanced metastatic solid tumors, HER2 low BC (in prep.)	DS-1211 (US/EU) TNAP inhibitor Pseudoxanthoma elasticum	DS-5670 (JP) COVID-19 mRNA vaccine (original strain), COVID-19 (primary vaccination, 12 to 17 aged children)	
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-5670 (JP) COVID-19 mRNA vaccine (mutant strain) COVID-19 (booster vaccination, adults)	
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)

Rare Pediatric Disease Designation (US)

Fast Track Designation (US)

Breakthrough Designation (US)

ALL: acute lymphoblastic leukemia, AML: acute myeloid leukemia, BCL: B cell lymphoma, CRPC: castration-resistant prostate cancer, DMD: Duchenne muscular dystrophy, ESCC: esophageal squamous cell carcinoma, FOP: Fibrodysplasia ossificans progressiva, LBCL: large B cell lymphoma, NSCLC: non small cell lung cancer, ES-SCLC: extensive stage-small cell lung cancer, PTCL: peripheral T-cell lymphoma

Contact address regarding this material

Daiichi Sankyo Co., Ltd.
Corporate Communications Department

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