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Daiichi Sankyo's "R&D Day 2022"

Tokyo, Japan (December 12, 2022) - Daiichi Sankyo Company, Limited (hereafter, Daiichi Sankyo) will hold its "R&D Day 2022" at 7:30am JST on Tuesday, December 13, 2022 for institutional investors, security analysts and media.

In addition to the Zoom webinar, on-demand recorded video will be available at a later date.
URL: https://www.daiichisankyo.com/investors/library/materials/2022.html

Attachment: presentation material

Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

R&D Day

DAIICHI SANKYO CO., LTD.

December 12th, 13th 2022

Forward-Looking Statements

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

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

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

Participants

Presenters

Sunao Manabe
President and CEO

Ken Takeshita
Head of Global R&D

Joining for Q&A session

Wataru Takasaki
Head of Japan R&D

Mark Rutstein
Head of Global
Oncology Development

Agenda

1. **Opening**
2. Clinical Progress
3. R&D Strategy
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 FY2025 Goal and Shift to Further Growth

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

*3ADCs: 1) ENHERTU®, Trastuzumab deruxtecan (T-DXd, DS-8201), 2) Datopotamab deruxtecan (Dato-DXd, DS-1062) and 3) Patritumab deruxtecan (HER3-DXd, U3-1402)

Progress since R&D Day 2021

ENHERTU® trastuzumab deruxtecan

Daiichi-Sankyo

Steady progress in maximizing product value of ENHERTU® based on approval of new indications and strong market penetration

Transform the course of HER2+ BC

- Approved for **HER2+ BC 2L** in US based on DESTINY-Breast03 study which showed unparalleled improvement in PFS compared to T-DM1; started promotion in May 2022
- Established **leadership in HER2+ BC 2L** in US market
- **Expanding market to other countries and regions**

Pioneer HER2 low BC as a new clinically meaningful patient segment

- Approved for **HER2 low BC previously treated with chemotherapy** in US based on DESTINY-Breast04 study which showed potential to transform treatment for HER2 low patients; started promotion in August 2022
- **Rapid uptake** for HER2-low BC in US
- **Accelerating market expansion to other countries and regions**

Expand leadership across other HER2 targetable tumors

- Approved for **HER2 mutant NSCLC 2L+** based on DESTINY-Lung01 and 02 study; started promotion in August 2022
- **Approval for the third cancer type following BC and GC**
- **Accelerating market expansion to other countries and regions**

Provide new treatment option for previously "un-targetable" HER2 low BC patients; approximately half of all BC patients

BC: breast cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, T-DM1: trastuzumab emtansine

Progress since R&D Day 2021 Dato-DXd, HER3-DXd and Alpha

Steady progress in development of growth drivers after ENHERTU®
Increased options for post DXd-ADC modalities

Dato-DXd & HER3-DXd

■ **Pivotal studies are on track**

- Dato-DXd: **NSCLC 2L/3L** (TROPION-Lung01 study)
- HER3-DXd: **EGFR mutated NSCLC 3L** (HERTHENA-Lung01 study)

■ **Started new Ph3 studies**

- Dato-DXd: **NSCLC w/o actionable genomic alterations, PD-L1 ≥50%, 1L** (TROPION-Lung08 study)
- Dato-DXd: **TNBC 1L, not candidate for PD-1/PD-L1** (TROPION-Breast02 study)
- HER3-DXd: **EGFR mutated NSCLC 2L** (HERTHENA-Lung02 study)

Rising Stars DS-7300 & DS-6000

■ **Obtained interim analysis data which showed early efficacy signals in multiple cancer types**

- DS-7300：**SCLC, CRPC, ESCC, sqNSCLC** (Ph1/2 study ongoing)
- DS-6000：**OVC, RCC** (Ph1 study ongoing)

■ **Started new Ph2 study**

- DS-7300：**ES-SCLC, 2L+** (Ph2 study ongoing)

Post DXd-ADC modalities

■ **Clinical studies for DS-5670 (COVID-19 mRNA vaccine) are progressing steadily**

- **Booster vaccination trial**
  Primary endpoint was achieved in Ph1/2/3 study
- **Primary vaccination trial**
  Started Ph3 study

■ **Started clinical study for the next generation ADC, DS-9606**
DS-9606：target undisclosed (Ph1 study ongoing)

ADC: antibody-drug conjugate, BC: breast cancer, CRPC: castration-resistant prostate cancer, ESCC: esophageal squamous cell carcinoma, ES-SCLC: extensive-stage small cell lung cancer, NSCLC: non-small cell lung cancer, OVC: ovarian cancer, RCC: renal cell carcinoma, SCLC: small cell lung cancer, sqNSCLC: squamous non-small cell lung cancer, TNBC: triple-negative breast cancer, w/o: without

DS Strategy to Enrich Delivery to Patients

3 and Alpha strategy is evolving

3ADCs

- ENHERTU®
- Dato-DXd
- HER3-DXd

&

Alpha

- Oncology
- Specialty Medicine
- Vaccine

3ADCs Value Maximization

Rising Stars

Next Pillars

Agenda

1. Opening
2. **Clinical Progress**
3. R&D Strategy
4. Closing
5. Q&A

Progress in Breast Cancer

ENHERTU®

Practice-changing achievement in HER2 low BC

DESTINY-Breast04 data presented at ASCO 2022 Plenary Session

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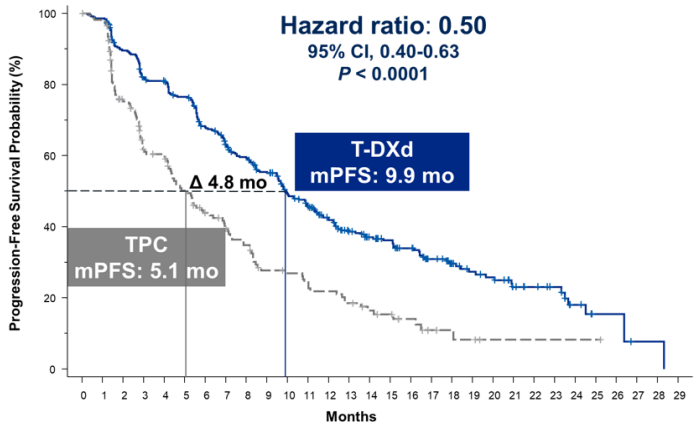
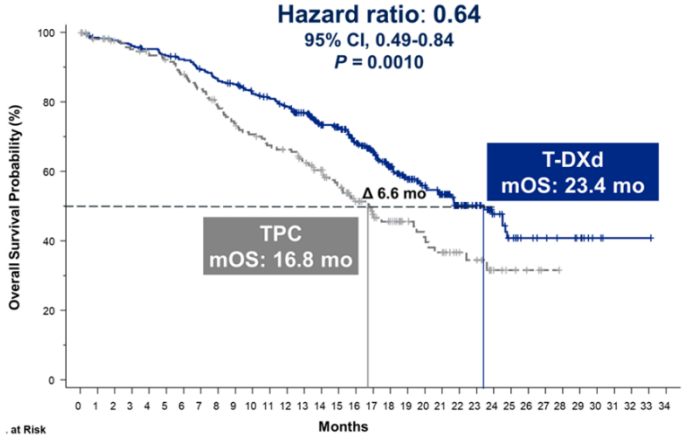
PFS in all patients with HR+ or HR-/HER2 low BC

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



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

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



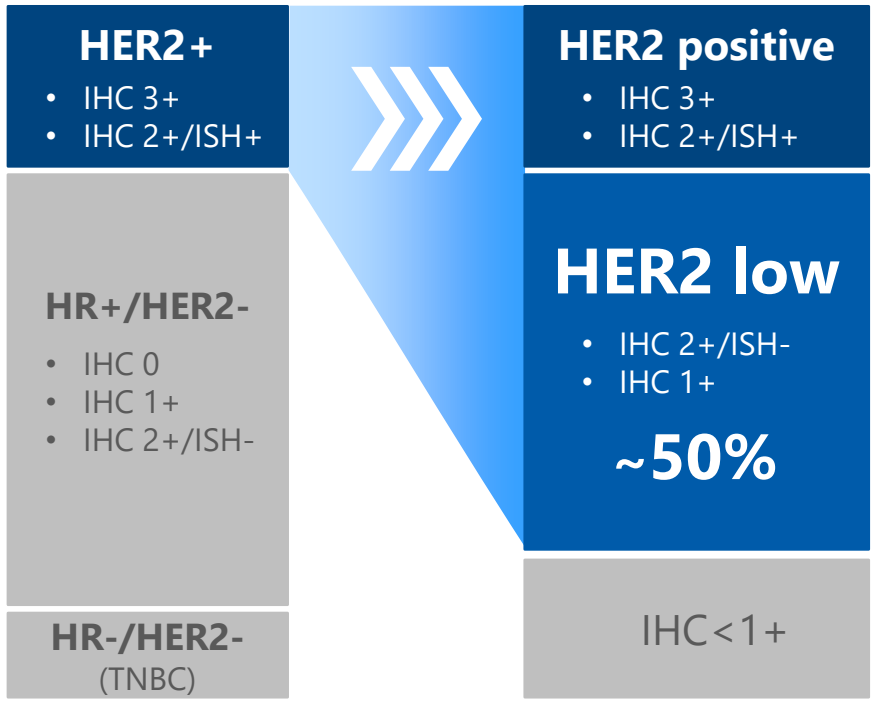
Safety Summary

- Median treatment duration
  T-DXd: 8.2 months vs. TPC: 3.5 months
- Observed safety profile is consistent with the known safety profile of T-DXd

ASCO: American Society of Clinical Oncology, BC: breast cancer, CI: confidence interval, HR: hormone receptor, mPFS: median progression-free survival, mo: month, mOS: median overall survival, OS: overall survival, PFS: progression-free survival, T-DXd: trastuzumab deruxtecan, TEAE: treatment emerged adverse event, TPC: treatment of physician's choice

ENHERTU®

Pioneer HER2 low BC as a new clinically meaningful patient segment



ENHERTU® was approved in US for HER2 low BC previously treated with chemotherapy in August

- Approved within 11 days of filing acceptance under the FDA's RTOR program
- First-ever FDA approval for **HER2 Low** Companion Diagnostic in Oct 2022

Regulatory submission status in other countries and regions

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

BC: breast cancer, BTD: Breakthrough Therapy Designation, HR: hormone receptor, IHC: immuno-histochemistry, ISH: in situ hybridization, RTOR: real-time oncology review program, TNBC: triple-negative breast cancer

SABCS 2022 Highlights

SABCS 2022
30 Abstracts

3 Oral Presentations

2 Spotlight Poster

25 Poster Presentations

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24 on ENHERTU®

5 on Dato-DXd

1 on HER3-DXd

Key Highlights

ENHERTU®

- Significantly improved survival in **DESTINY-Breast03** and **DESTINY-Breast02**, two Ph3 trials in patients with previously treated HER2 positive metastatic breast cancer

Dato-DXd

- First reported results in patients with **HR+/HER2- metastatic breast cancer** from the **TROPION-PanTumor01** Ph1 trial
- Updated results from TROPION-PanTumor01 Ph1 in patients with **metastatic TNBC**
- Updated data from **BEGONIA** Ph1b/2 durvalumab combo

HR: hormone receptor, SABCS: San Antonio Breast Cancer Symposium, TNBC: triple-negative breast cancer

ENHERTU®

Data further supports the 2L SOC in HER2+ BC

Updated data from DESTINY-Breast03 presented at SABCS 2022 (1/2)

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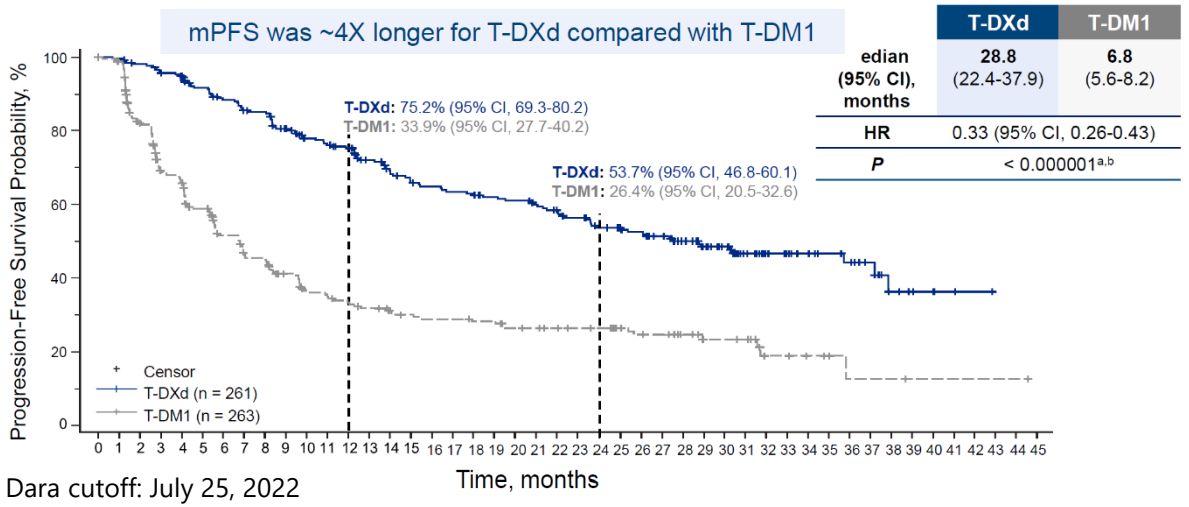
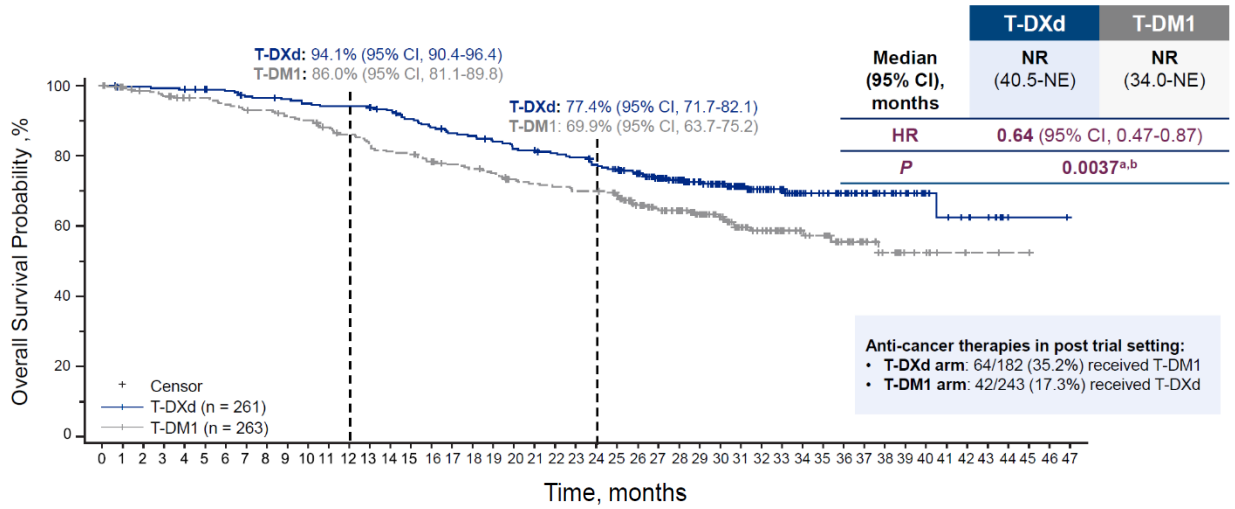
Updated PFS in HER2+ BC, 2L



Dara cutoff: July 25, 2022

Updated OS in HER2+ BC, 2L



- T-DXd demonstrated **clinically meaningful** and **statistically significant improvement of OS** over T-DM1, as well as **continued PFS benefit**
  - T-DXd significantly reduced the risk of death by 36% (HR, 0.64)
  - mPFS with T-DXd was 4 times longer than with T-DM1 (28.8 months vs. 6.8 months)
  - Confirmed ORR was 78.5%; 1 in 5 (21%) patients experienced CR
- **Consistent OS benefit** across key subgroups, such as hormone receptor status, prior pertuzumab, baseline visceral disease, or prior lines of systemic therapy

(Continues to the next slide)

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

ENHERTU®

Data further supports the 2L SOC in HER2+ BC

Updated data from DESTINY-Breast03 presented at SABCS 2022 (2/2)

Daiichi-Sankyo

(Continued from the previous slide)

Safety

- Median treatment duration:

  T-DXd: 18.2 months vs. T-DM1: 6.9 months

- Rates of grade ≥3 TEAEs were similar between the T-DXd (56.4%) and T-DM1 (51.7%) treatment arms
- The most common drug-related TEAEs associated with discontinuation were:
  - T-DXd: pneumonitis (5.8%), ILD (5.1%), and pneumonia (1.9%)
  - T-DM1: platelet count decreased (1.5%), pneumonitis (1.1%), and thrombocytopenia (1.1%)

Dara cutoff: July 25, 2022

- Rates of drug-related ILD/pneumonitis adjudicated by the external ILD adjudication committee **were similar to other BC trials** with T-DXd
  - With longer treatment exposure and follow-up, the ILD/pneumonitis rate increased from 10.5% in the PFS interim analysis[1] to 15.2%
  - The overall incidence of grade 3 events (0.8%) was the same as the PFS interim analysis[1]
  - No adjudicated drug-related grade 4 or 5 events

Adjudicated Drug-Related ILD/Pneumonitis

	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Any grade
T-DXd (n=257)	11 (4.3%)	26 (10.1%)	2 (0.8%)	0	0	39 (15.2%)
T-DM1 (n=261)	4 (1.5%)	3 (1.1%)	1 (0.4%)	0	0	8 (3.1%)

Updated results from DESTINY-Breast03 further support ENHERTU® as the 2nd-line standard of care in HER2+ BC

The result of DESTINY-Breast03 study was published in THE LANCET on the same day as the presentation at SABCS.

1:Cortes K et al. N Engl J Med. 2022;386:1143-1154

BC: breast cancer, ILD: interstitial lung disease, PFS: progression-free survival, SABCS: San Antonio Breast Cancer Symposium, SOC: standard of care, T-DM1: trastuzumab emtansine, T-DXd: trastuzumab deruxtecan, TEAE: treatment-emergent adverse even

ENHERTU®

Phase 3 results confirm the favorable profile

DESTINY-Breast02 data presented at SABCS 2022

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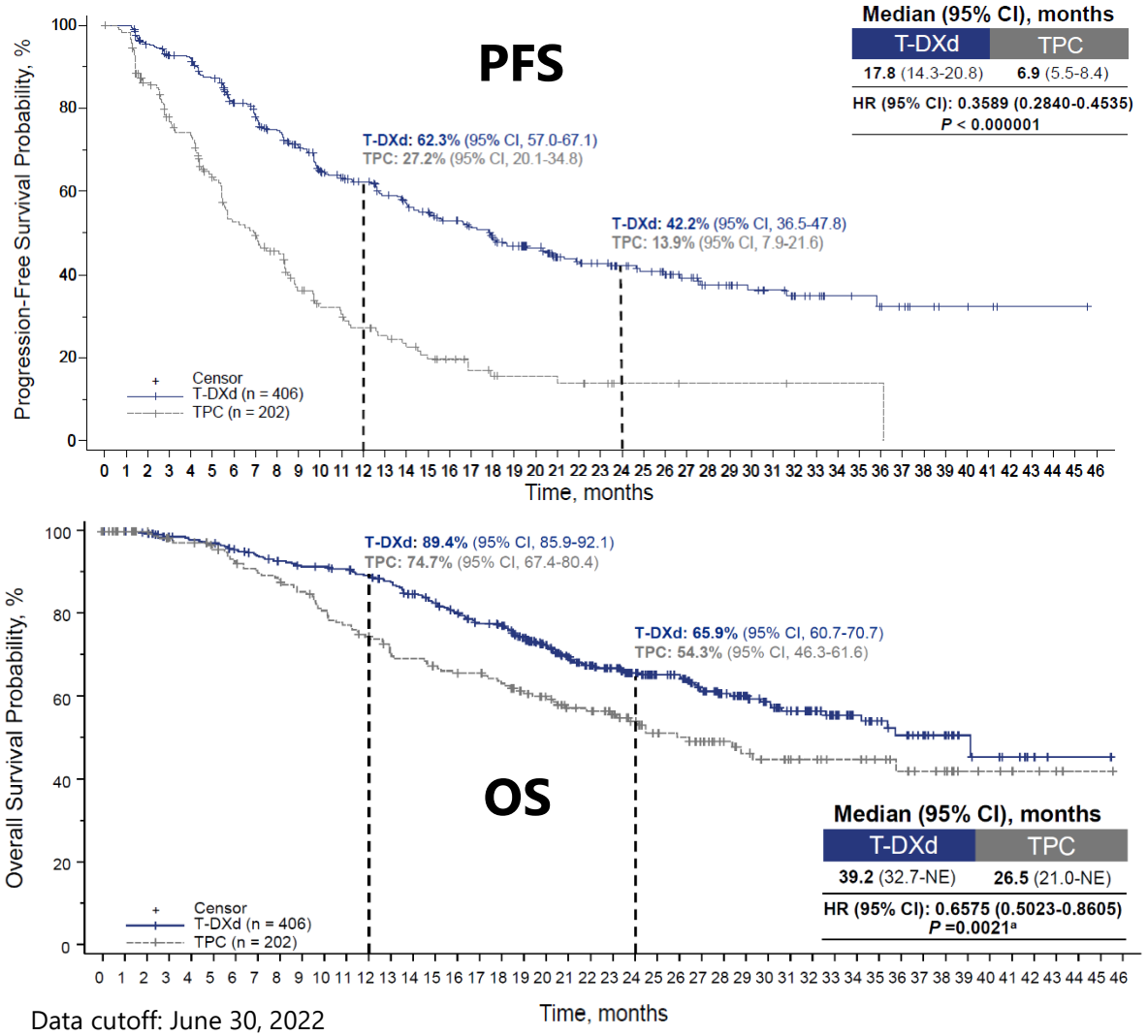
PFS and OS in HER2+ BC 3L+



Data cutoff: June 30, 2022

- T-DXd demonstrated statistically significant and clinically meaningful improvement in PFS and OS vs. TPC for patients with HER2+ BC previously treated with T-DM1
  - mPFS: T-DXd (17.8 months) vs. TPC (6.0 months)
  - mOS: T-DXd (39.2 months) vs. TPC (26.5 monthes)

Safety

- Overall safety profile was consistent with the established safety of T-DXd, with no new safety signals observed
  - Incidence of ILD was 10.4% (grade 1/2 , 9.2%)
  - Fewer grade 5 ILD events (0.5%) compared with DESTINY-Breast01 (2.7%)

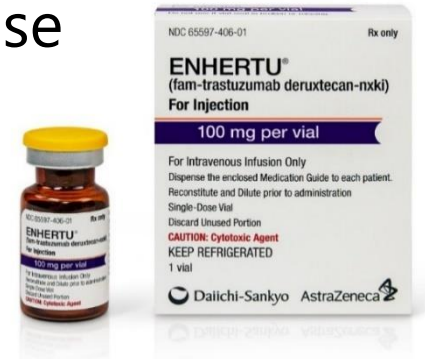
The results confirms the favorable benefit/risk profile of T-DXd in HER2+ BC as previously demonstrated by DESTINY-Breast01

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

ENHERTU® Breast Cancer Summary

- **A new standard of care in HER2+ metastatic breast cancer** was firmly supported by efficacy and safety data from DESTINY-Breast03 and DESTINY-Breast02 follow up
- **A new treatment paradigm for patients with HER2 low metastatic beast cancer** was pioneered by DESTINY-Breast04
- Accumulating data continues to support opportunities for ENHERTU® to benefit patients on early disease and treatment line

ENHERTU®
trastuzumab deruxtecan



Dato-DXd

Reported the first data in HR+/HER2- BC

TROPION-PanTumor01 HR+/HER2- cohort data presented at SABCS 2022

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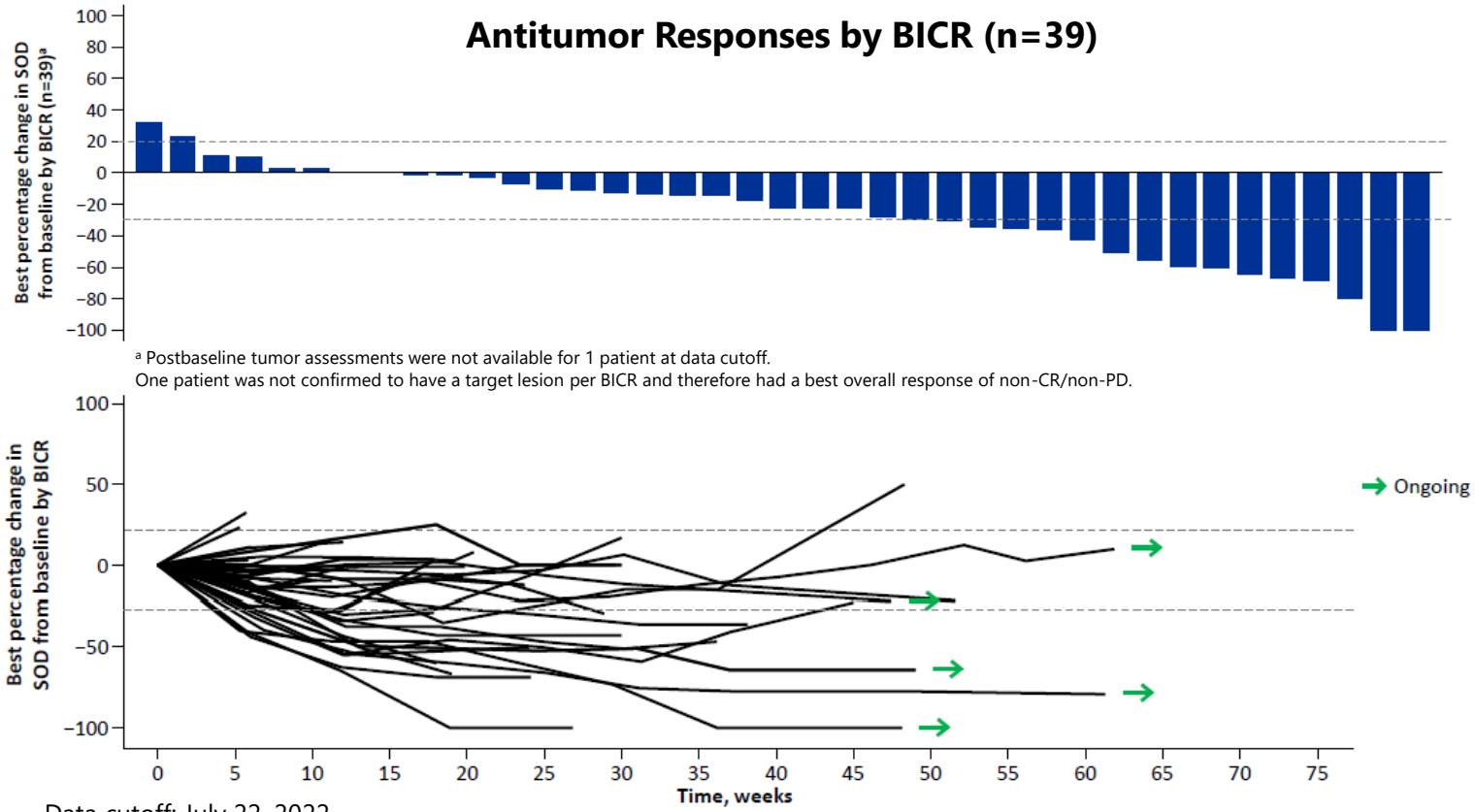
Efficacy



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

Data cutoff: July 22, 2022

*Patients with HER2 low BC (IHC 2+/ ISH -, IHC 1+) is included in this study as a part of HER2-

- Dato-DXd showed **encouraging and durable efficacy** in patients with HR+/HER2- BC who previously received median of 5 lines of treatment for metastatic disease.
  - Confirmed ORR and DCR were 27% and 85%, respectively
  - mPFS was 8.3 months
  - 95% patients were pretreated with CDK4/6 inhibitors

Safety

- Among 41 patients, grade ≥3 TEAEs were observed in 41% patients
- The most common TEAEs (any grade, grade ≥3) were stomatitis (83%, 10%), nausea (56%, 0%), and fatigue (46%, 2%)
- Two patients had pneumonitis (grade 2 and 3), and 1 was adjudicated as having grade 3 drug-related interstitial lung disease

Dato-DXd demonstrated encouraging efficacy and manageable safety profile, that support further studies including on-going Ph3 study TROPION-Breast01 in 2L HR+/HER2- BC

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

Dato-DXd

Continues to demonstrate encouraging data in TNBC

TROPION-PanTumor01 TNBC cohort update presented at SABCS 2022

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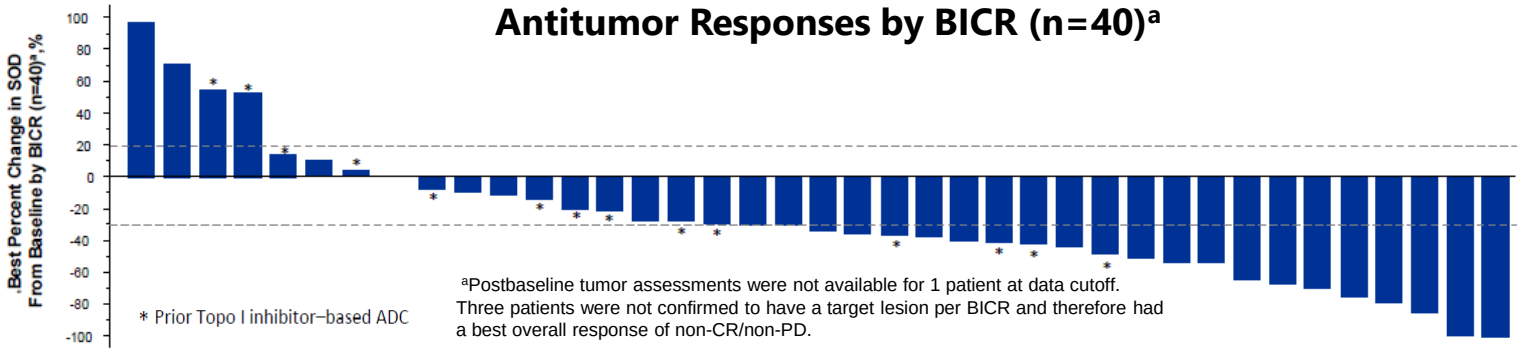
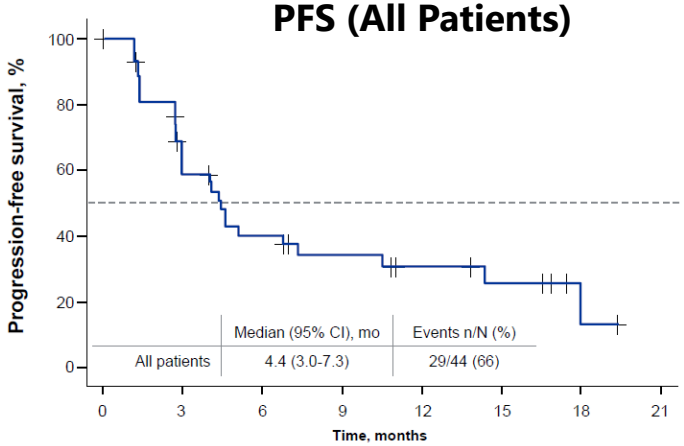
Efficacy

Antitumor Responses by BICR (n=40)[a]

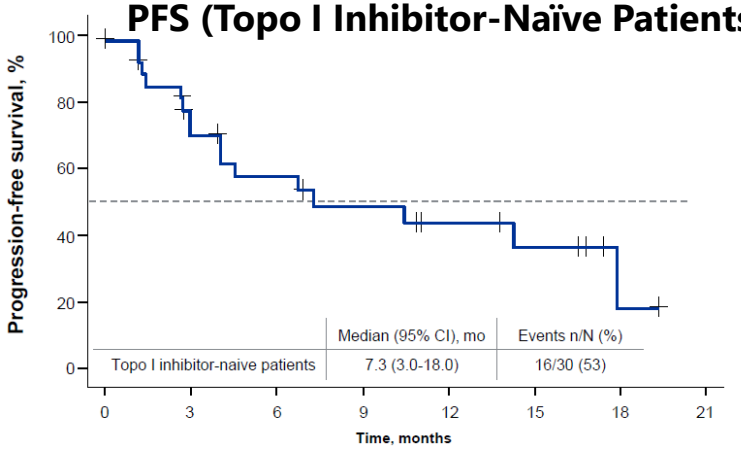


[a]Postbaseline tumor assessments were not available for 1 patient at data cutoff. Three patients were not confirmed to have a target lesion per BICR and therefore had a best overall response of non-CR/non-PD.

PFS (All Patients)



PFS (Topo I Inhibitor-Naïve Patients)



Dato-DXd continues to demonstrate manageable safety profile and encouraging efficacy, that support on-going Ph3 study TROPION-Breast02 in 1L TNBC

- ORR was 32% in all patients (n=44) and 44% in Topo I inhibitor-naïve patients (n=27) with measurable disease; mDOR was 16.8 months in both groups
- mPFS was 4.4 months in all patients and 7.3 months in Topo I inhibitor-naïve patients
- mOS was 13.5 months in all patients and 14.3 months in Topo I inhibitor-naïve patients

Safety

- Among 44 patients, grade ≥3 TEAEs were observed in 52% of patients
- The most common TEAEs (any grade, grade ≥3) were stomatitis (73%, 11%), nausea (66%, 2%), and vomiting (39%, 5%)
- One patient experienced grade 3 decreased neutrophil count
- No cases of ILD, febrile neutropenia, or grade ≥3 diarrhea were reported
- No treatment-related deaths were observed

Data cutoff: July 22, 2022

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

Dato-DXd

Dato-DXd+durvalumab shows a high ORR in TNBC

BEGONIA update presented at SABCS 2022

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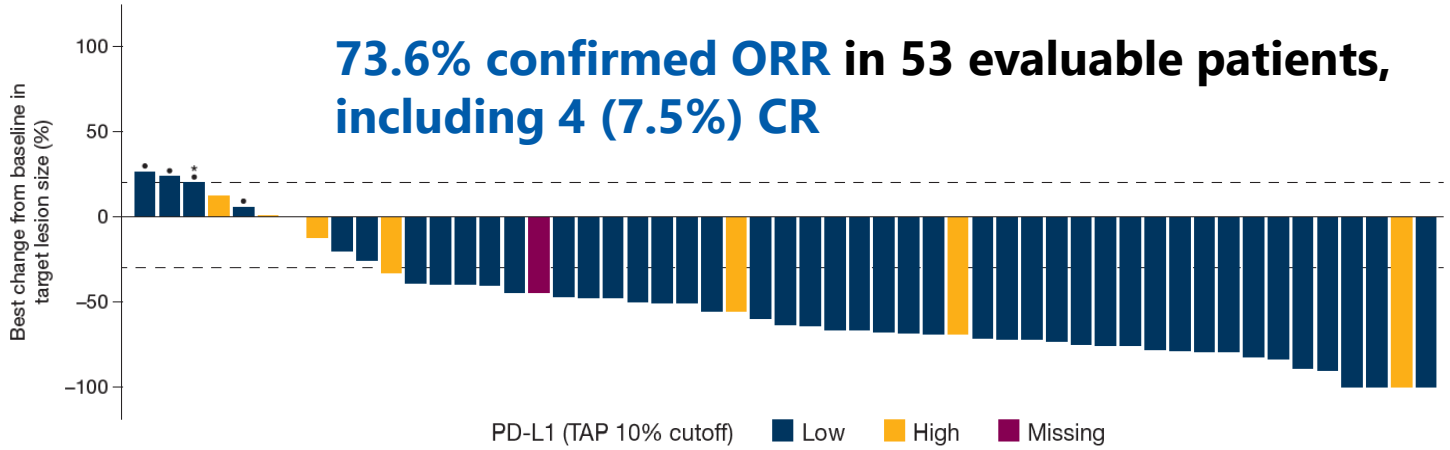
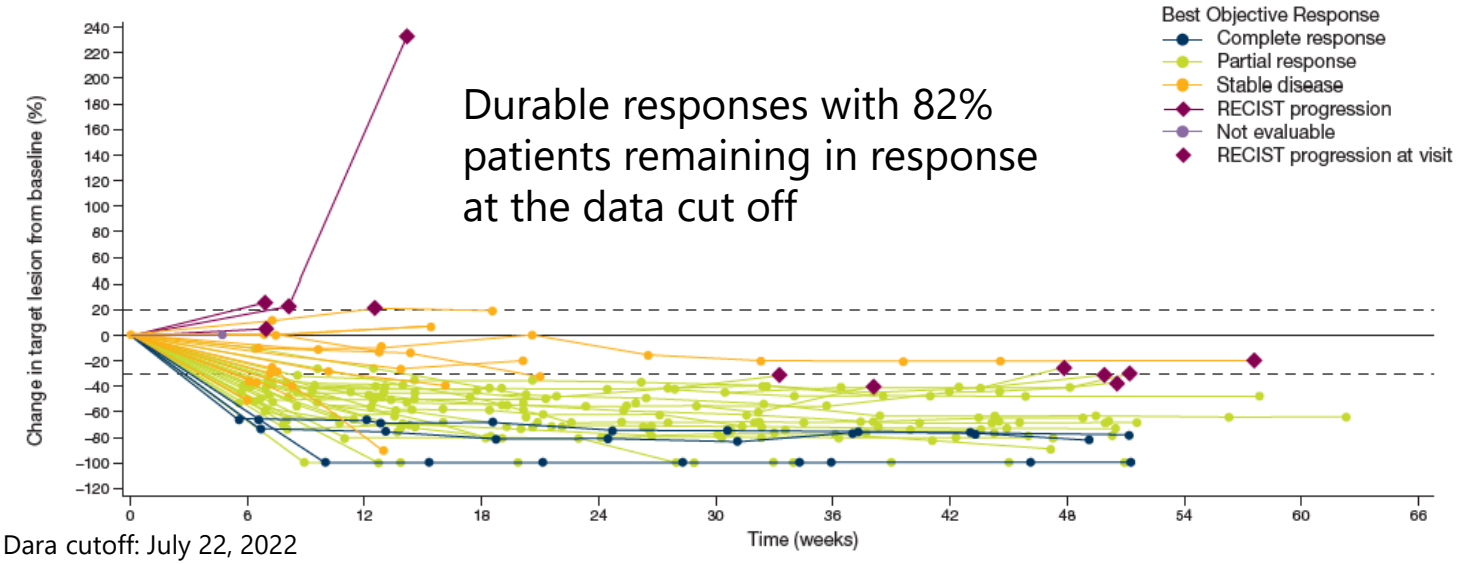
Efficacy

73.6% confirmed ORR in 53 evaluable patients, including 4 (7.5%) CR



Durable responses with 82% patients remaining in response at the data cut off



Dara cutoff: July 22, 2022

Safety

- 61 patients received Dato-DXd + durvalumab
- The most common AEs were nausea (57.4%), stomatitis (55.7%), and alopecia (45.9%)
- Any grade ≥3 treatment-related AEs were observed in 34.4% patients
- Dato-DXd + durvalumab discontinued by due to AEs in 6.6% patients.
- Adjudicated ILD/pneumonitis of grade 1 in 2 (3.3%) patients

Dato-DXd + durvalumab combination showed a compelling high response rate and manageable safety profile in 1L TNBC, that support further investigation of this combination in this patient population

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

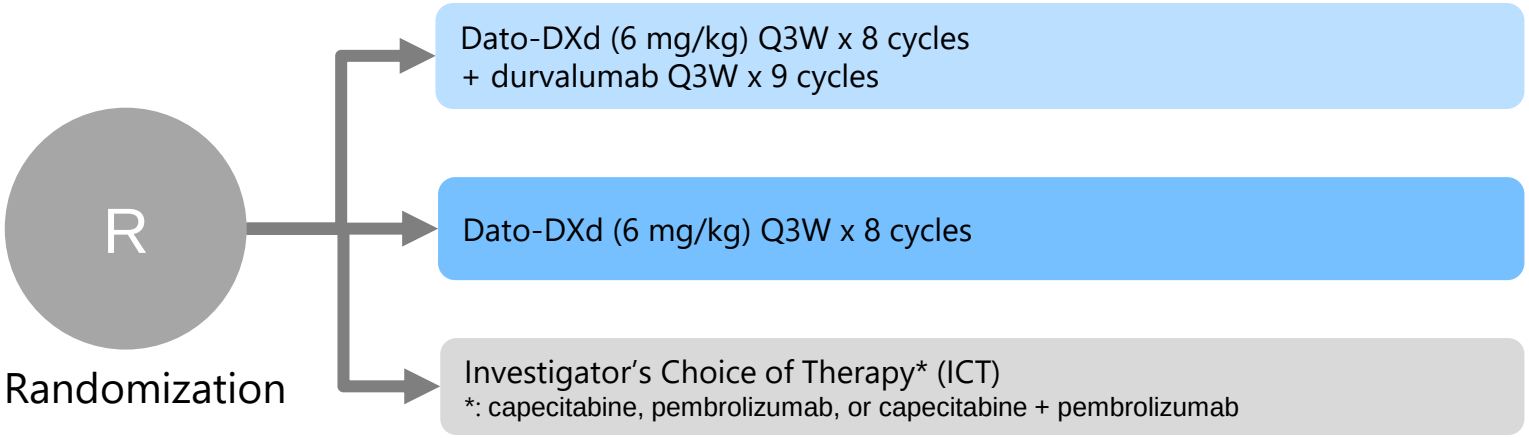
Dato-DXd

New clinical study: TROPION-Breast03

Planning to initiate new Ph3 study for residual disease TNBC in December

Patient Population (N≈1075)

- Histologically confirmed invasive TNBC (ER<1%, PR<1%, HER2-negative)
- Completed at least 6 cycles of neoadjuvant therapy containing an anthracycline and/or a taxane with or without carboplatin. Prior PD-1/PD-L1 inhibitor in the neoadjuvant setting is allowed.
- Residual invasive disease in the breast and/or axillary lymph node(s) after neoadjuvant therapy
- No adjuvant systemic therapy



TROPION-Breast03 study

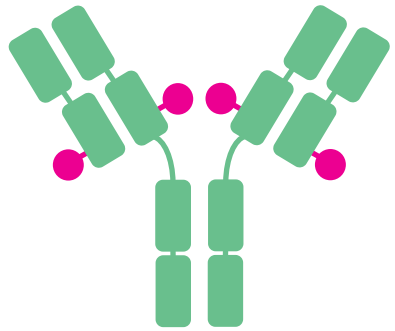
■ Primary endpoint:	Dato + durva vs ICT: iDFS
■ Secondary endpoint:	Dato + durva vs ICT: DDFS, OS
	Dato vs ICT: iDFS, DDFS, OS
	Dato + durva vs Dato: iDFS, DDFS
	Dato + durva vs ICT (subset*): iDFS, DDFS, PROs, PK, immunogenicity, safety

* Subset of participants with prior adjuvant PD-1/PD-L1 therapy

ER: estrogen receptor, DDFS: distant disease-free survival, iDFS: invasive Disease-free survival, OS: overall survival, PR: progesterone receptor, PROs: patient reported outcomes, PK: pharmacokinetics, TNBC: triple-negative breast cancer

Dato-DXd Breast Cancer Summary

- Dato-DXd demonstrated encouraging antitumor activity and a consistent safety profile in heavily pretreated patients with **HR+/HER2- metastatic breast cancer**, giving us further confidence for Ph3 **TROPION-Breast01**
- **Durable antitumor activity** in heavily pretreated patients with metastatic **TNBC** continues to raise our expectations for Ph3 **TROPION-Breast02**
- Updated data from BEGONIA opens opportunity for early **TNBC** by combination with durvalumab; for a new Ph3 **TROPION-Breast03**



datopotamab deruxtecan

TNBC: triple-negative breast cancer

Progress in Lung Cancer

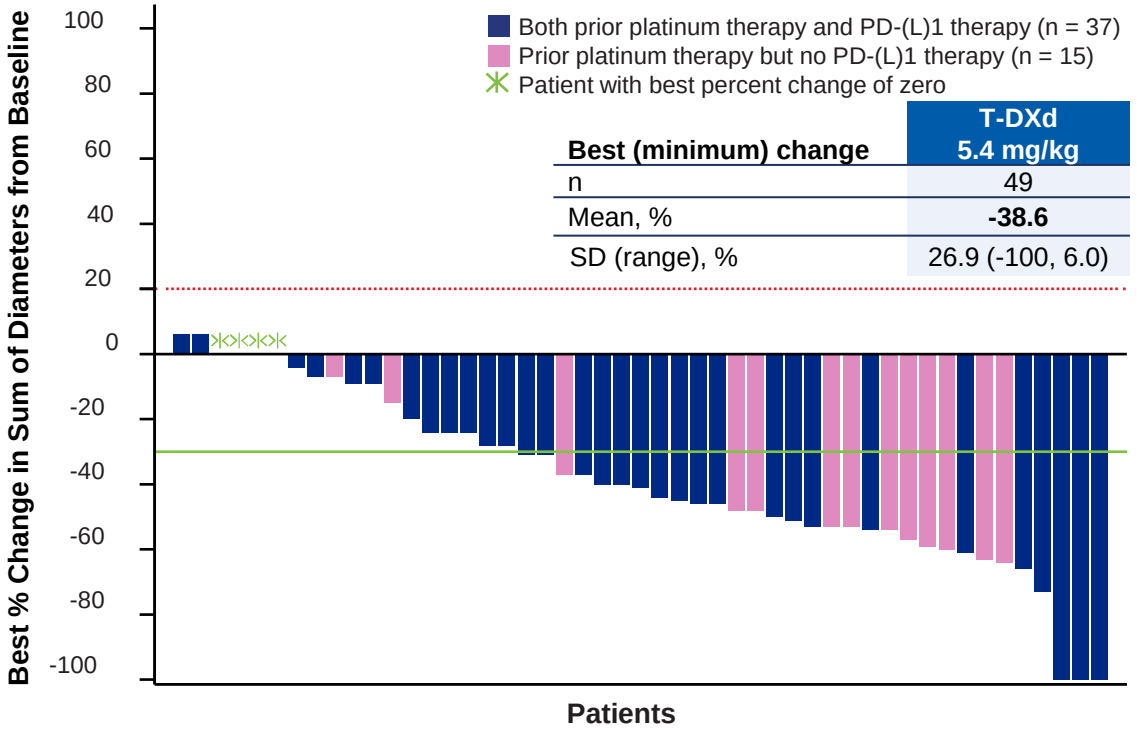
ENHERTU®

Clinically meaningful responses in HER2 mut NSCLC

DESTINY-Lung02 interim analysis data presented at ESMO 2022

Daiichi-Sankyo

Efficacy (ENHERTU®5.4 mg/kg, n=52)



Best (minimum) change	T-DXd 5.4 mg/kg
n	49
Mean, %	**-38.6**
SD (range), %	26.9 (-100, 6.0)

Data cutoff: Mar 24, 2022.

- Comparative study for 5.4 mg/kg and 6.4 mg/kg ENHERTU® in patients with previously treated HER2 mutant NSCLC
- ORR were 53.8% (5.4 mg/kg) and 42.9% (6.4 mg/kg) at the time of the interim analysis. Confirmed ORR was 57.7% (5.4mg/kg) and median DoR was 8.7 months after additional 90-day follow-up response analysis

Safety

- The safety profile at both doses was consistent with the established safety profile of ENHERTU®
- A favorable safety profile and a lower incidence of ILD were observed in the 5.4 mg/kg arm compared to 6.4 mg/kg arm

  Drug-related TEAE: 5.4 mg/kg vs. 6.4 mg/kg, %
  - Grade≥3: 31.7% vs. 58.0%
  - Associated with drug discontinuation: 7.9% vs. 16.0%
  - Adjudicated drug-related ILD: 5.9% vs. 14%, most cases were low grade (grade 1 or 2)

ENHERTU® at the 5.4 mg/kg dose demonstrated clinically meaningful responses in 2L+ HER2 mutant NSCLC

DoR: duration of response, ESMO: European Society for Medical Oncology, ILD: interstitial lung disease, NSCLC: non-small cell lung cancer, ORR: objective response rate, SD: standard deviation, T-DXd: trastuzumab deruxtecan

ENHERTU® for HER2 mutant NSCLC

Expand leadership across other HER2 targetable tumors

Approved in US for HER2 mutant NSCLC 2L+ in August

- Under BTD, priority review and accelerated approval process based on the results of **DESTINY-Lung02** and **DESTINY-Lung01**
- Approved dose is **5.4 mg/kg**
- First-ever FDA approval of HER2 mutant Companion Diagnostics – both **Tissue and Liquid tests approved** on the same day as drug

Regulatory submission status in other countries and regions

- Sep 2022: Granted orphan drug designation for unresectable, advanced or recurrent NSCLC in JP
- FY2022 H2: Filing planned in JP & EU

Major development status of lung cancer

- DESTINY-Lung04 study (HER2 mutant NSCLC, 1L) is ongoing
- DESTINY-Lung05 study (HER2 mutant NSCLC, 2L+) is on-going in China

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

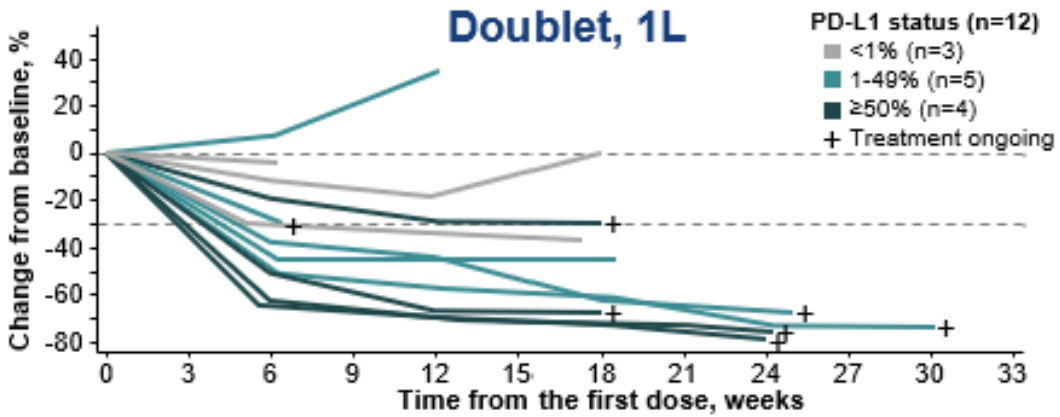
Dato-DXd

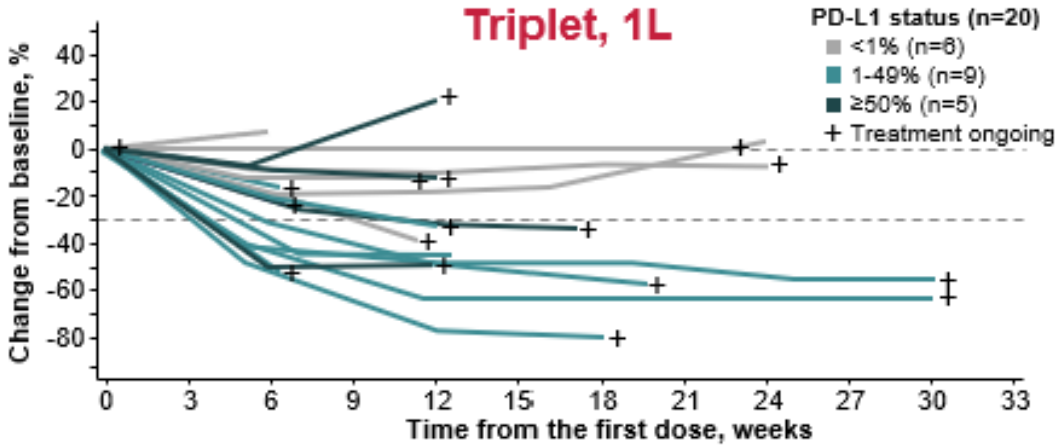
Data supports further development in 1L NSCLC

TROPION-Lung02 study interim analysis data presented at WCLC 2022

Daiichi-Sankyo

Efficacy





- First reported data of Dato-DXd + pembrolizumab ("doublet") and Dato-DXd + pembrolizumab + platinum chemotherapy ("triplet") in metastatic NSCLC
- ORR was 62% (doublet) and 50% (triplet) for 1L patients and responses were observed across all levels of PD-L1 expression

Safety

- Study treatment-related TEAEs at grade ≥3 observed in patients of 35% (doublet) and 54% (triplet)
- The most frequent TEAE in doublet and triplet was stomatitis (56%) and nausea (48%), respectively, mostly grade 1 or 2

The interim data demonstrated tolerable safety profile and encouraging efficacy responses that supports further evaluation of 6 mg/kg Dato-DXd in the immunotherapy combination regimens

Data cut off: May 2, 2022

ILD: interstitial lung disease, NSCLC: non-small cell lung cancer, ORR: objective response rate, TEAEs: treatment emergent adverse events, WCLC: World Conference on Lung Cancer

Dato-DXd

Two Ph3 studies addressing 1L NSCLC without AGA

Daiichi-Sankyo

TROPION-Lung07

(PD-L1 <50%)

To be initiated in FY2022 H2

Patient Population (N≈975)

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

R 1:1:1

Randomization

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

Primary Endpoints

PFS, OS

Secondary Endpoints

ORR, DoR, TTR, DCR, ADA, etc.

TROPION-Lung08

(PD-L1 ≥50%)

On-going

Patient Population (N=740)

- Stage IIIb, IIIc, or IV NSCLC without AGA
- No prior systemic therapy for advanced or metastatic NSCLC
- PD-L1 ≥50%

R 1:1

Randomization

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

Primary Endpoints

PFS, OS

Secondary Endpoints

ORR, DoR, TTR, DCR, ADA, etc.

ADA: anti-drug antibody, AGA: actionable genomic alterations, DCR: disease control rate, DoR: duration of response, NSCLC: non-small cell lung cancer, ORR: objective response rate, OS: overall survival, PFS: progression-free survival, TTR: time to response

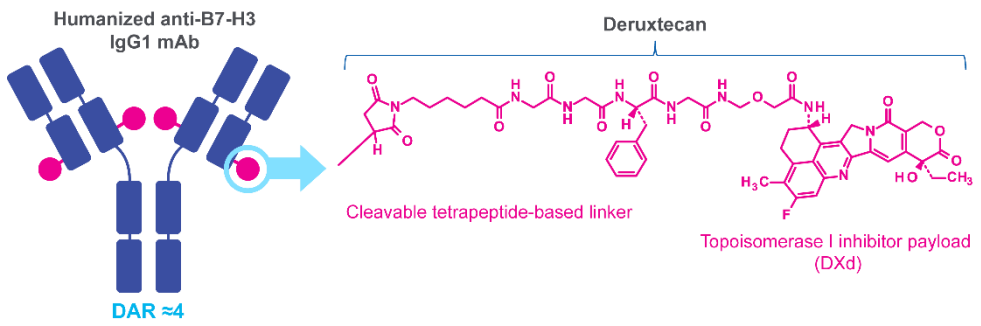
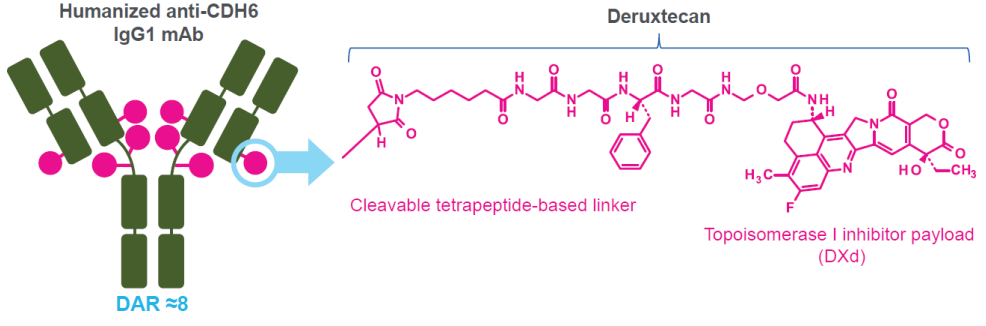
Lung Cancer Summary

- **ENHERTU® was approved for HER2 mutant NSCLC 2L+** in US in August
  - Supporting data was presented in ESMO 2022
  - **DESTINY-Lung04** Ph3 in HER2 mutant NSCLC 1L is on-going
- Dato-DXd **TROPION-Lung02** interim analysis data was presented at WCLC 2022
  - High expectations and confidence in two Ph3 studies in 1L, **TROPION-Lung08** and **TROPION-Lung07**
  - **TROPION-Lung01** Ph3 in 2L/3L NSCLC is on-going
- HER3-DXd is progressing in 2L+ EGFR mutated NSCLC
  - Initiated Ph3 **HERTHENA-Lung02** in Aug

ESMO: European Society for Clinical Oncology, NSCLC: non-small cell lung cancer, WCLC: World Conference on Lung Cancer

Rising Stars and Hematology

Rising Stars follow 3ADCs as potential new growth drivers

	DS-7300	DS-6000
Target	B7-H3	CDH6
Structure		
Progress in 2022	■ Updated Ph1/2 interim analysis data at ESMO 2022, which continues to demonstrate promising efficacy for **multiple cancer types** ■ Ph2 in **SCLC** initiated for dose optimization	■ Reported first interim data from Ph1 dose escalation at ASCO 2022, demonstrating favorable tolerability and early clinical signals in **ovarian cancer** and **renal cell carcinoma** ■ Continues to dose expansion

ASCO: : American Society of Clinical Oncology, DAR: drug-antibody ratio, ESMO: European Society for Clinical Oncology, mAb: monoclonal antibody, SCLC: small cell lung cancer

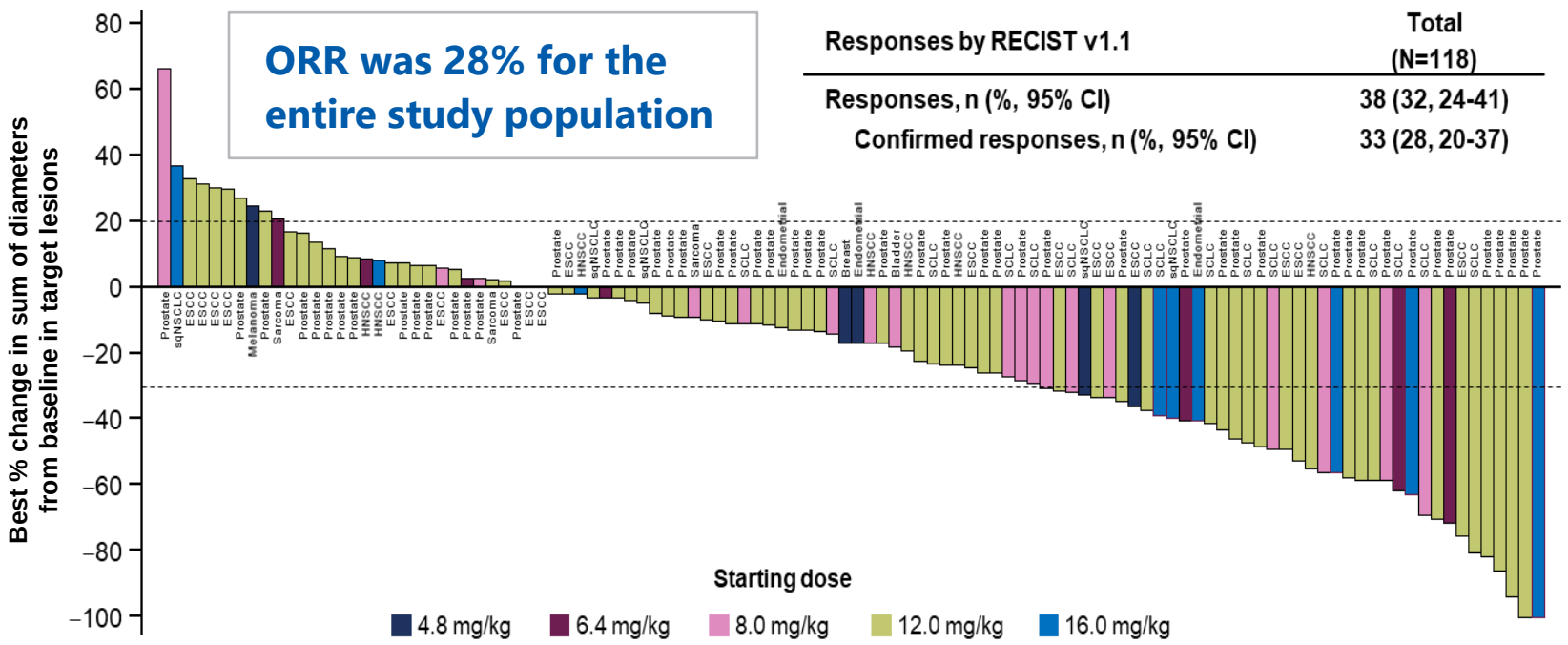
DS-7300

Promising efficacy in multiple cancer types

Ph1/2 interim analysis data presented at ESMO 2022 (1/2)

Daiichi-Sankyo

Efficacy (across tumor types)



Data cutoff: June 30, 2022

Safety

- The most common (≥3%) grade ≥3 TEAEs were anemia (19%), neutropenia (4%), nausea (3%), pneumonia (3%), and decreased neutrophil count (3%)
- Drug-related ILD/pneumonitis were reported in 9 patients including one grade 5 by the data cutoff date (including 2 pending adjudication)
- The 16 mg/kg cohort was closed due to higher rates of serious and grade ≥3 TEAE within a shorter treatment duration than other cohorts

DS-7300 was well tolerated and demonstrated promising efficacy for multiple cancer types in heavily pretreated patients

CI: confidence interval, ESCC: esophageal squamous cell carcinoma, ESMO: European Society for Clinical Oncology, HNSCC: head and neck squamous cell carcinoa, ILD: interstitial lung disease, mCRPC: metastatic castration-resistant prostate cancer, NSCLC: non-small cell kung cancer, ORR: objective response rate, RECIST: Response Evaluation Criteria in Solid Tumours, SCLC: small cell lung cancer, sqNSCLC: squamous non-small cell lung cancer, TEAE: treatment emergent adverse event

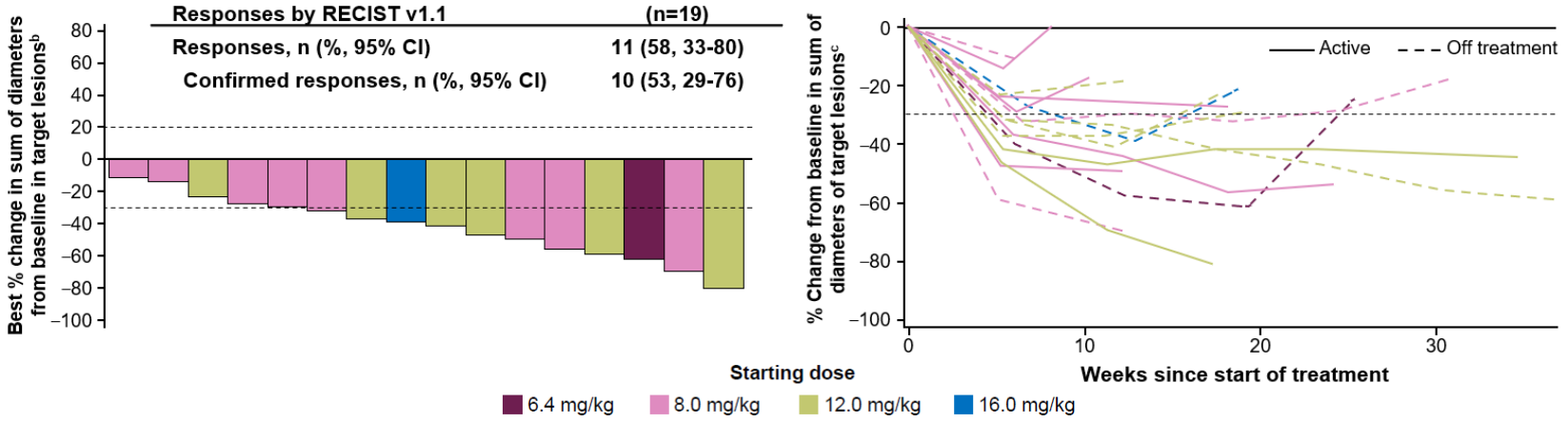
DS-7300

Promising efficacy in multiple cancer types

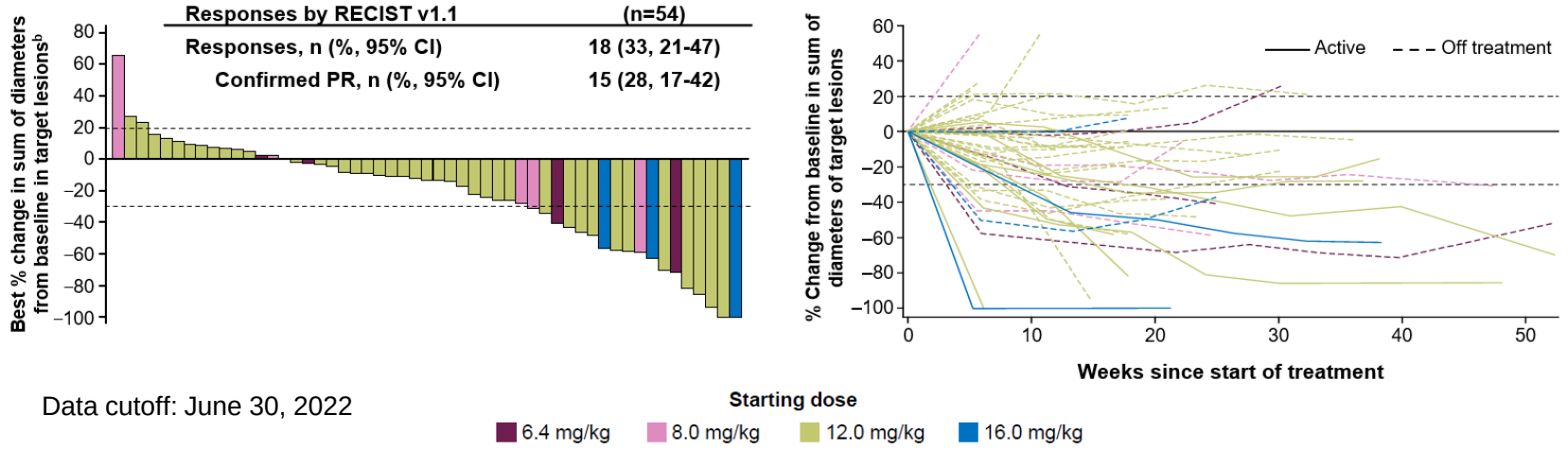
Ph1/2 interim analysis data presented at ESMO 2022 (2/2)

Daiichi-Sankyo

Efficacy (SCLC)



Efficacy (mCRPC)



Data cutoff: June 30, 2022

- DS-7300 continues to demonstrate promising efficacy in heavily pretreated patients with SCLC, mCRPC, ESCC, and sqNSCLC
- SCLC: Confirmed ORR was 53%, with a median duration of response of 5.5 months
- mCRPC: Confirmed ORR was 28%, 46% of patients had baseline liver metastasis
- Confirmed ORR was 18% (4/22) and 40% (2/5) in ESCC and sqNSCLC, respectively

Based on these data, we are accelerating development of DS-7300 in SCLC and other cancer types

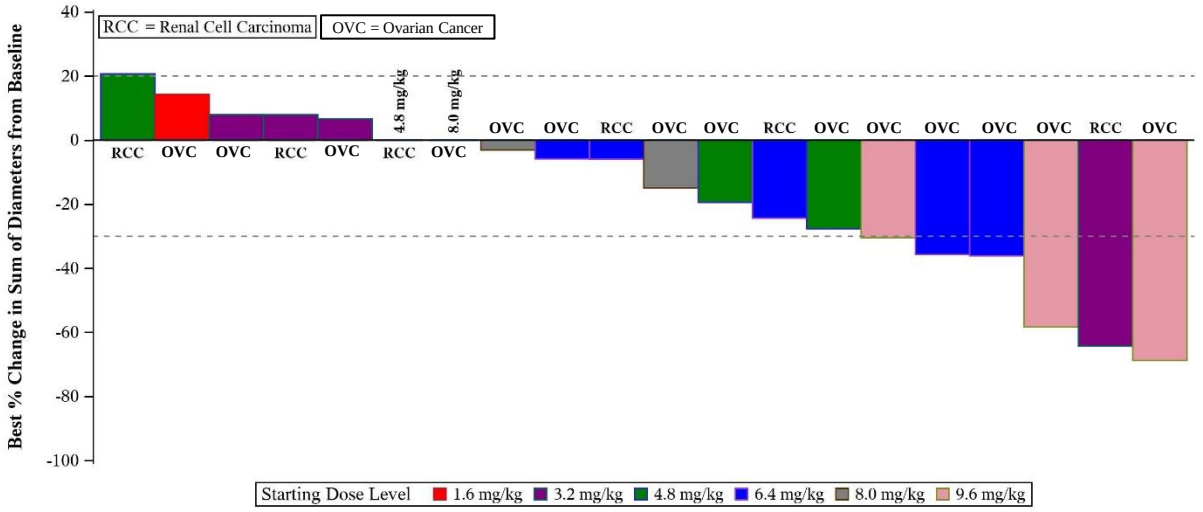
CI: confidence interval, ESCC: esophageal squamous cell carcinoma, ESMO: European Society for Clinical Oncology, mCRPC: metastatic castration-resistant prostate cancer, NSCLC: non-small cell kung cancer, ORR: objective response rate, PR: partial response, RECIST: Response Evaluation Criteria in Solid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

DS-6000

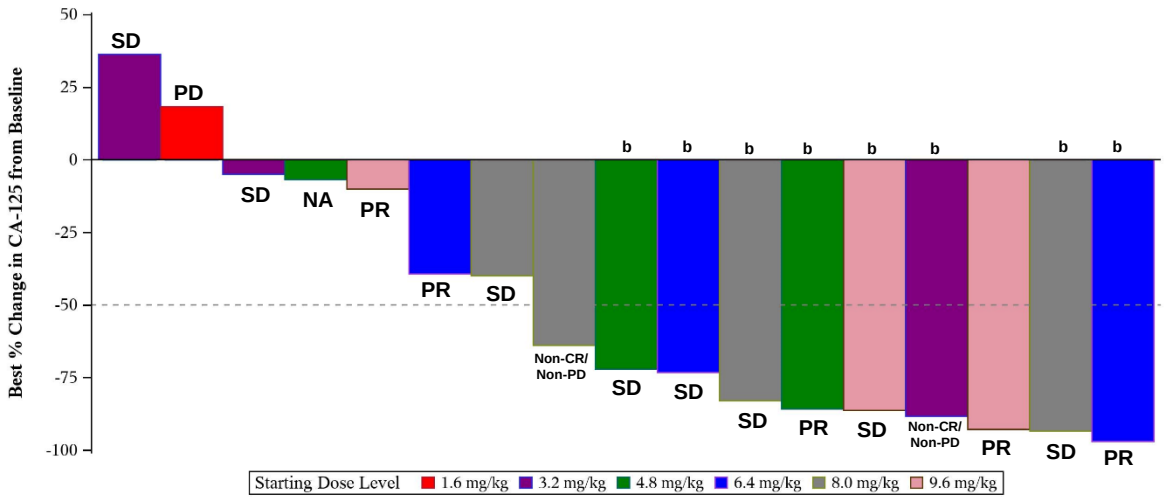
Encouraging data supports further development

Ph1 dose-escalation data presented at ASCO 2022

Efficacy (OVC, RCC)



Change from baseline in CA-125* levels (OVC)



- DS-6000 is **generally well tolerated**. Escalation part is completed.
- **Encouraging efficacy** in heavily pre-treated patients with platinum-resistant OVC and RCC
- Dose-expansion is on-going in OVC and RCC

Encouraging efficacy and manageable safety data supports further development in OVC and RCC

Data cutoff: February 25, 2022. The best tumor responses (PR/SD/non-CR/Non-PD/PD) on the graph are based on the single tumor assessment.
[a] Patients with baseline CA-125 value and ≥1 postbaseline CA-125 value were included. [b] According to the GCIG criteria, patients can be evaluated for response only if they have a baseline sample that is ≥2 × the upper limit of normal obtained within 2 weeks prior to starting treatment. CA-125 response is defined as a ≥50% reduction in CA-125 levels from a pretreatment sample. The response must be confirmed and maintained for ≥28 days.

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

ASCO: American Society of Clinical Oncology, NA: not available, OVC: ovarian cancer, PD: progressive disease, PR: partial response, RCC: renal cell carcinoma, SD: stable disease

Quizartinib

Changing SOC for newly-diagnosed *FLT3*-ITD AML

QuANTUM-First results presented at EHA 2022 Presidential Symposium

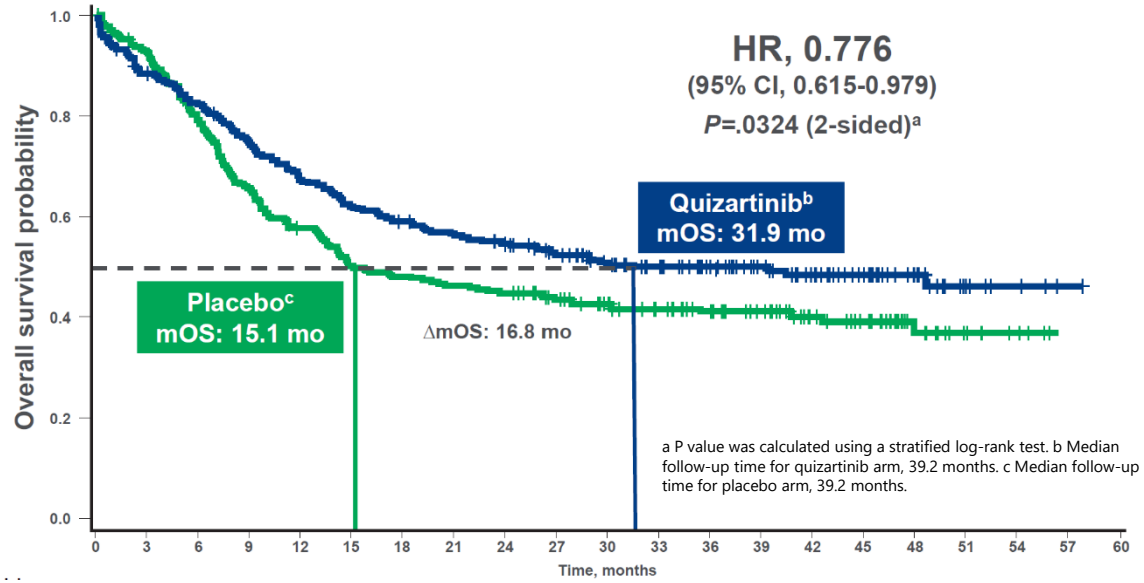
Daiichi-Sankyo

- Population: newly diagnosed *FLT3*-ITD(+) AML; poor prognosis with high-risk of relapse
- Quizartinib: more potent and selective FLT3i
- Demonstrated statistically significant and **clinically meaningful OS improvement** vs. chemotherapy alone
- **No new safety signals** were observed

- **NDA submitted based on the QuANTUM-First results and currently under review in US, Europe and Japan***
  - FDA granted **Priority Review**, PDUFA date in Apr 23, 2023
- **New data to be presented at ASH 2022**

* Quizartinib is already on the market in Japan as VANFLYTA® for relapsed or refractory FLT3-ITD AML.

Primary Endpoint: OS



Safety

- Rates of grade≥3 TEAEs were similar for both arms
- The most commo grade≥3 TEAEs (quizartinib, placebo) were febrile neutropenia (43.4%, 41.0%), neutropenia (18%, 8.6%), hypokalemia (18.9%, 16.4%), and pneumonia (11.7%, 12.7%)
- 0.8% of patients discontinued quizartinib due to QT prolongation

AML: acute myeloid leukemia, ASH: American Society of hematology, CI: confidence interval, EHA: European Hematology Association, HR: hazard ratio, OS: overall survival, PDUFA: prescription drug user fee act, mo: month, SOC: standard of care, TEAEs: treatment emergent adverse events

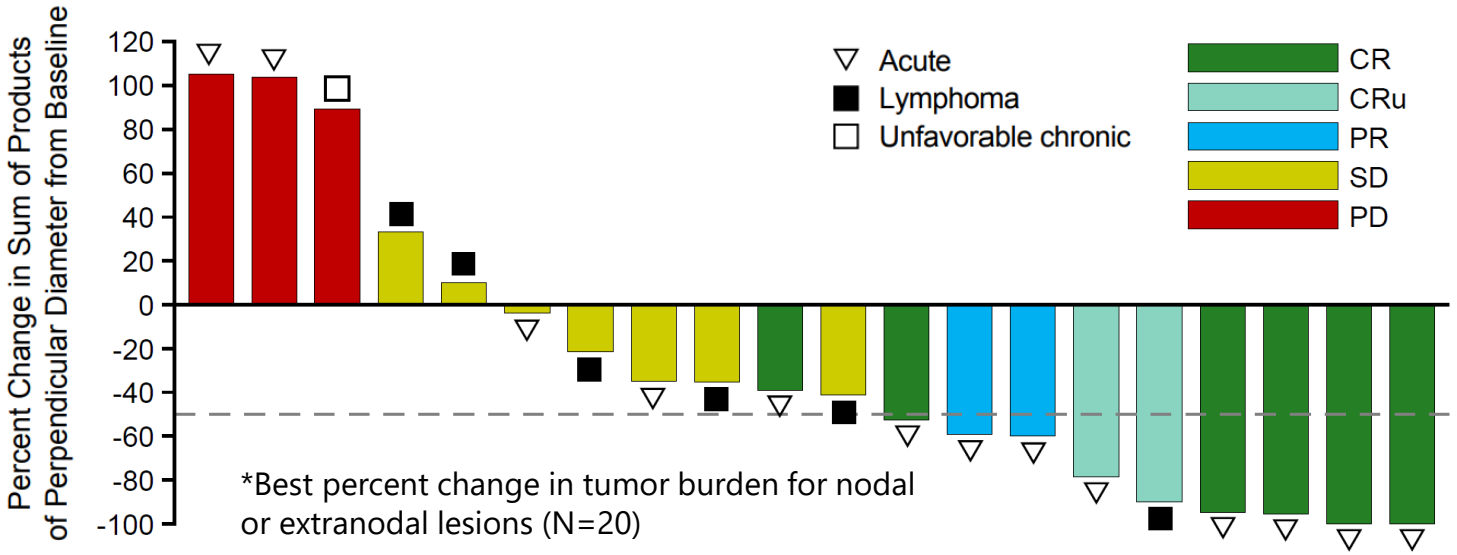
EZHARMIA®

World first EZH1/EZH2 dual inhibitor approved for adult T-cell leukemia-lymphoma

Daiichi-Sankyo

- Approved in Japan based on pivotal Ph2 where **EZHARMIA® (valemetostat)** demonstrated **48% ORR** including 20% CR and 28% PR
- A new treatment option for patients with r/r ATLL, a rare and aggressive disease with poor prognosis
- On-going development in other T-cell or B-cell lymphomas, and in solid tumors

Efficacy in Ph2 study*

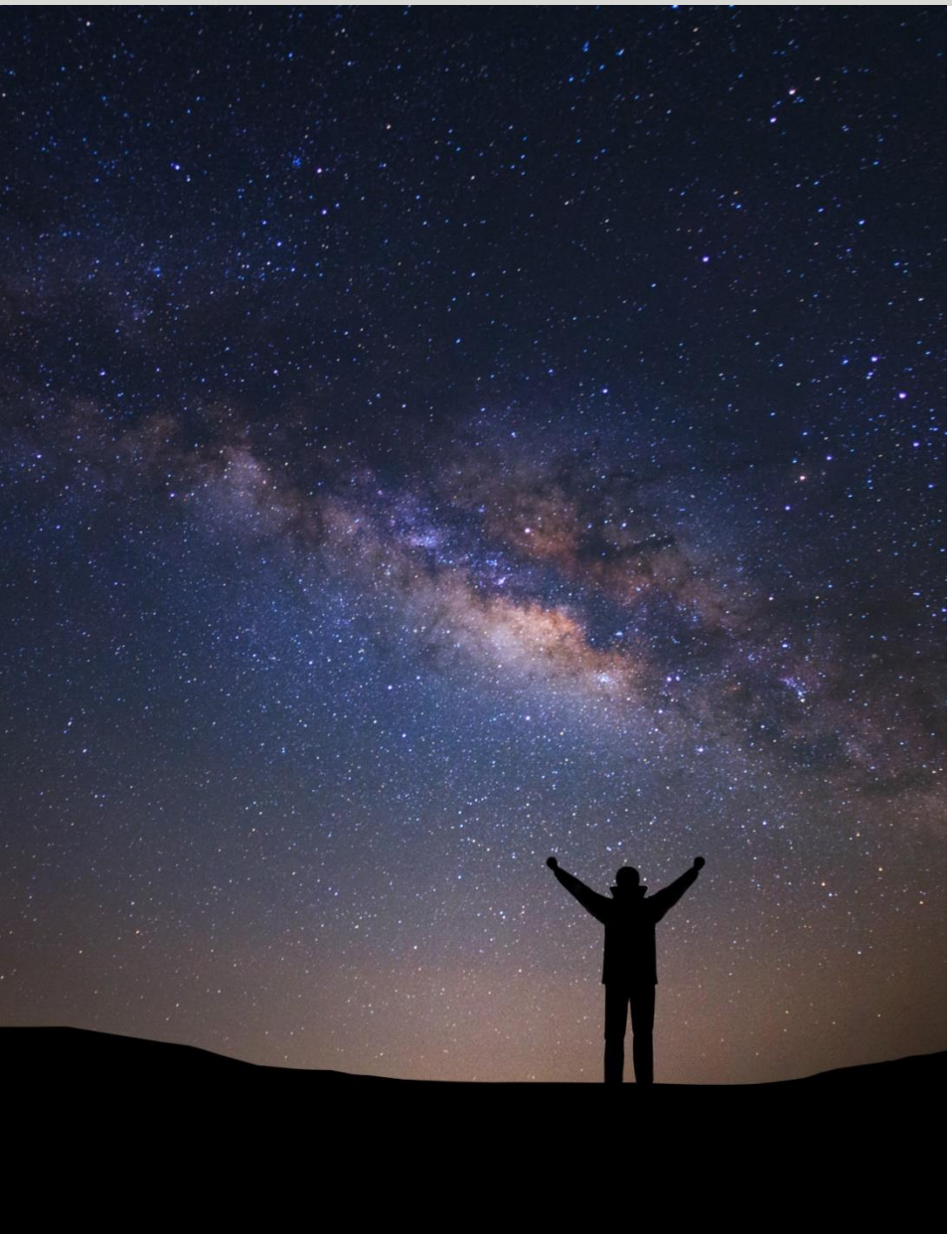


Safety in Ph2 study

- The most common grade ≥3 TEAEs were platelet count decreased (32%), anemia (32%), lymphocyte count decreased (16%), neutrophil count decreased (12%), white blood cell count decreased (12%), and decreased appetite (8%) in 25 patients
- Dose interruption, reduction or discontinuation due to adverse events occurred in 20%, 8% and 8% patients, respectively
- No treatment-related deaths occurred

Ph2 study data presented at ASH 2021 and published on Blood, Sep 23, 2022
https://doi.org/10.1182/blood.2022016862
ATLL: adult T-cell leukemia-lymphoma, CR: complete response, CRu: unconfirmed complete response, ORR: overall response, PD: progressive disease, PR: partial response, r/r: relapse or refractory, SD: stable disease, TEAEs: treatment-emergent adverse events

Next steps of Rising Stars and Hematology



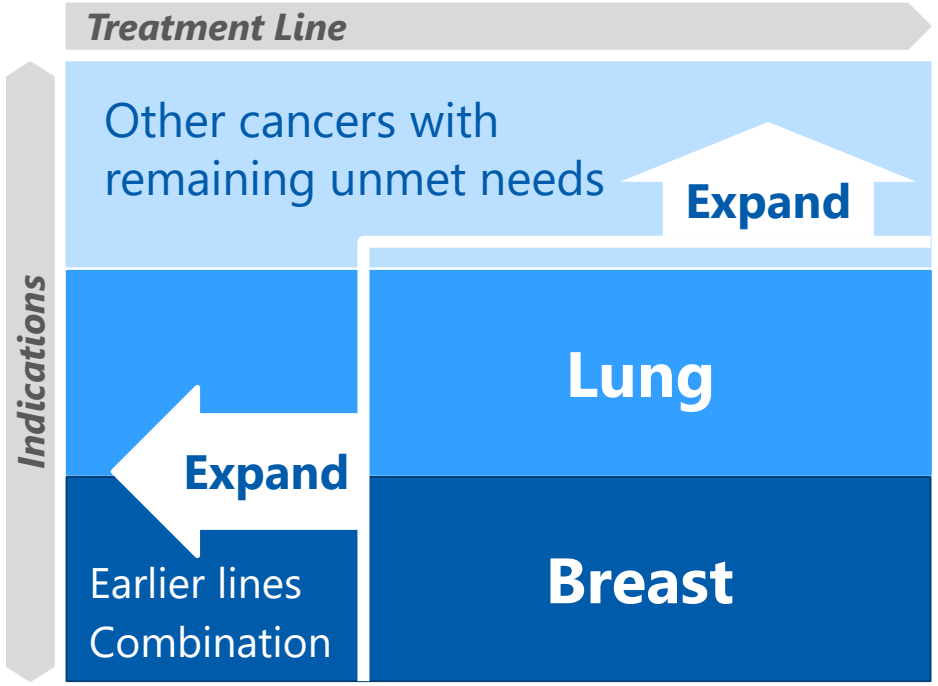
- **Accelerate development of DS-7300**
  - Evaluate optimum dose in on-going Ph2 study in extensive-stage **SCLC**, a potential first indication
  - Continue to evaluate potential in multiple types of solid tumors
- Continue to **evaluate potential of DS-6000** in OVC and RCC for the next step
- Expect regulatory approval of **quizartinib** for *FLT3*-ITD AML 1L in 1H FY2023
- Continue to develop and explore potential of **valemetostat (EZHARMIA®)** in broader indications

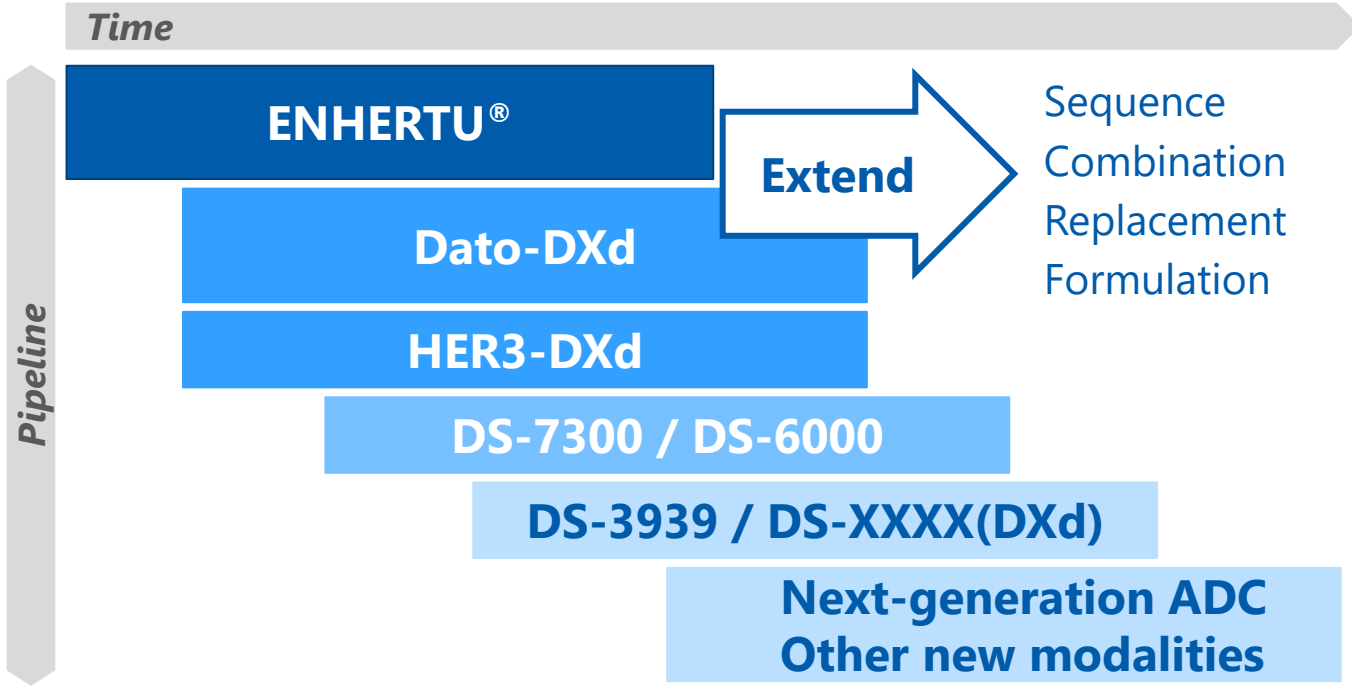
AML: acute myeloid leukemia, OVC: ovarian cancer, RCC: renal cell carcinoma, SCLC: small cell lung cancer

Agenda

1. Opening
2. Clinical Progress
3. **R&D Strategy**
4. Closing
5. Q&A

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

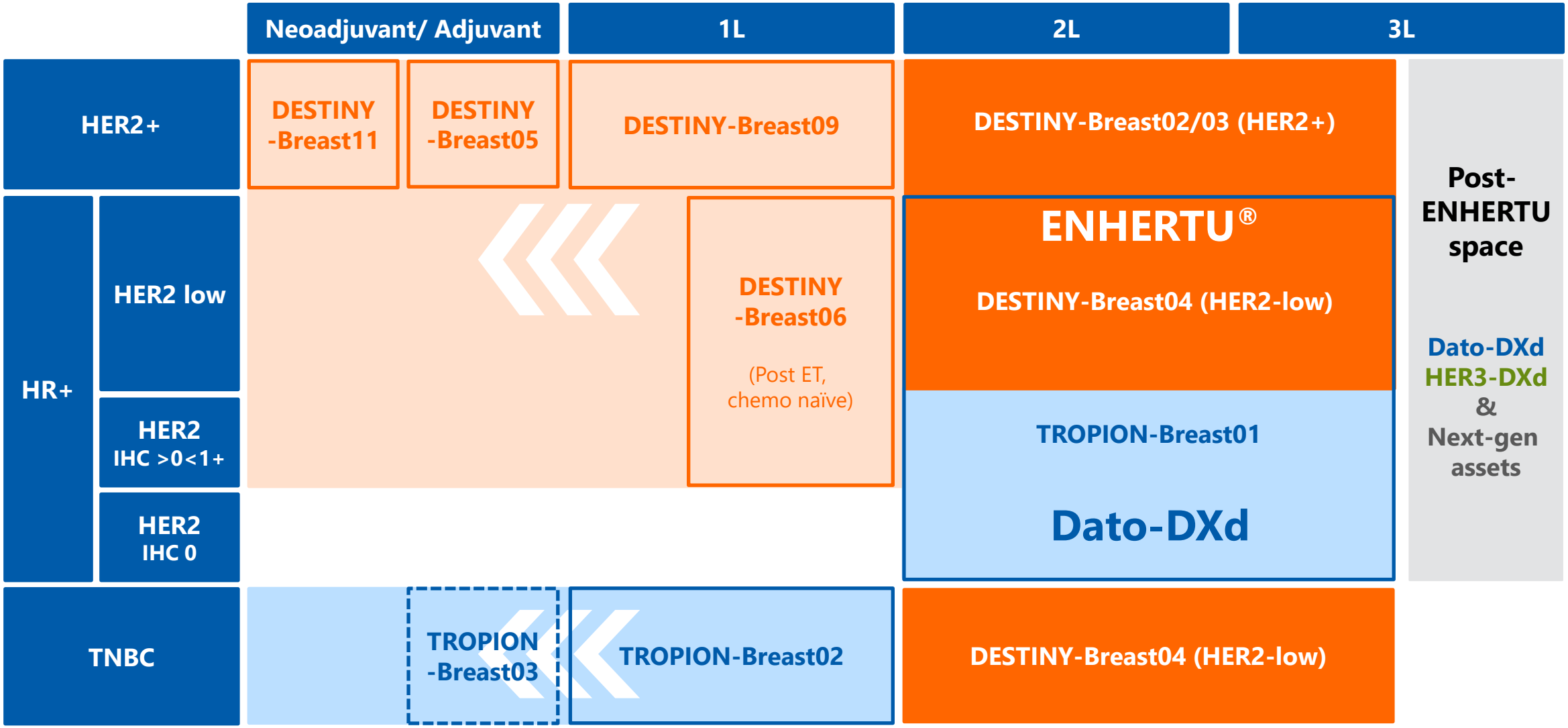
- Address unmet needs **after ENHERTU®** treatment
- Seek effective **treatment sequencing** between DXd-ADCs or novel assets including next-generation/new-concept ADCs
- Propose **novel combinations** to enhance efficacy

Our Breast Cancer Strategy

Build on our leadership in breast cancer to deliver additional novel treatment options to improve patient outcomes for a broad set of distinct patient segments

- Establish our assets as **a foundational treatment** across the disease spectrum from early to metastatic setting
- Identify opportunities to maximize the benefit of our assets through **combination** and **sequencing** therapies
- Provide suitable treatment options by understanding the underlying biology of HER2-negative breast cancers

Establish and expand DXd-ADCs to address the broader spectrum of Breast Cancer



Launched | On-going study | Planning study

Pivotal studies only, not exhaustive

ET: endocrine therapy, HR: hormone receptor, TNBC: triple-negative breast cancer

* The numbers of treatment line in HR+ BC is chemotherapy lines after ET

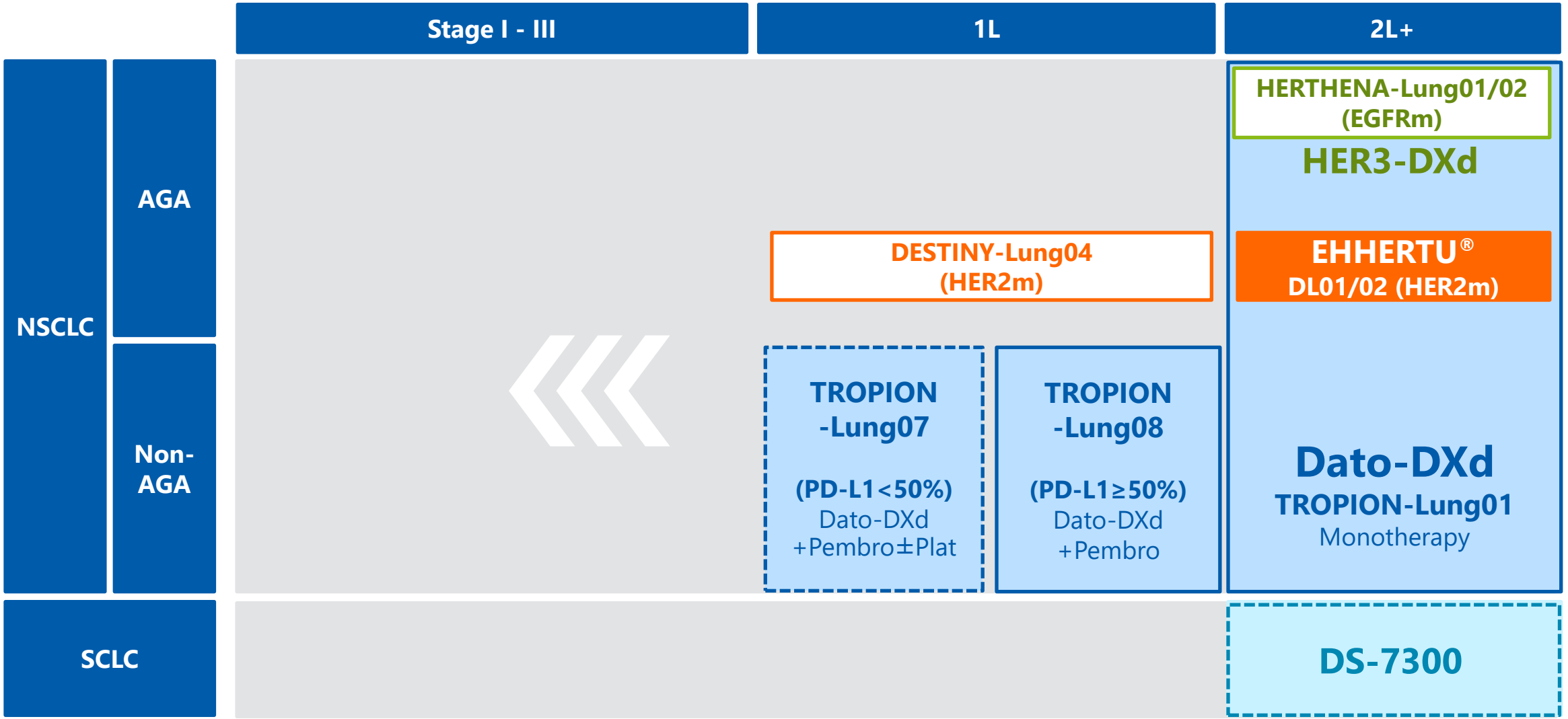
Our Lung Cancer Strategy

Leverage the depth of our portfolio to deliver novel treatment options with a clear clinical benefit to meet evolving unmet needs in lung cancer for a broad set of distinct patient segments

- Provide superior 2L+ treatments and differentiated combinations in **metastatic NSCLC with DXd-ADC as the foundational treatment**
- Leverage the innovation in DXd-ADC **to move into early-stage NSCLC**
- Identify **novel therapeutic approaches for extensive-stage SCLC** to address significant unmet need

NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer

Establish and expand DXd-ADCs as new treatment options in Lung Cancer



AGA: actionable genomic alteration, NSCLC: non-small cell lung cancer, SCLC: small cell lung cancer

Combinations to expand DXd-ADC's opportunity

Daiichi-Sankyo

Combinations in on-going study (examples, not exhaustive)

Ph1 or Ph2 | Ph3

DXd ADC +

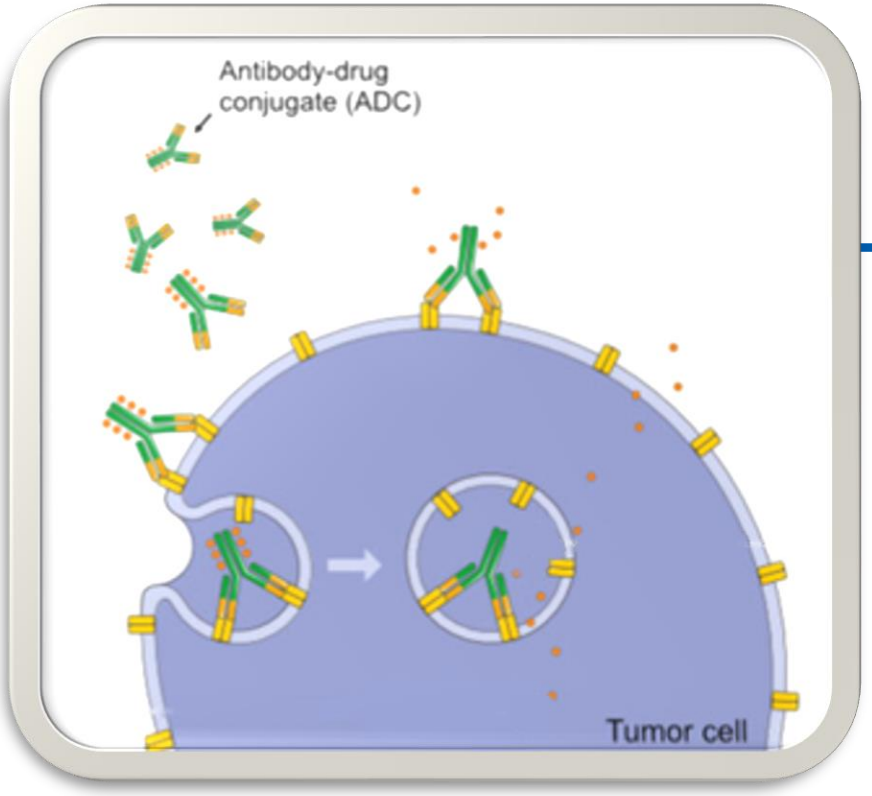
		Ph1 or Ph2	Ph3
Checkpoint Inhibitor	pembrolizumab	TROPION-Lung02	
		TROPION-Lung08	TROPION-Lung07
	durvalumab	DESTINY-Breast07	DESTINY-Breast08, BEGONIA
		TROPION-Breast03	
		DESTINY-Lung03	TROPION-Lung04, HUDSON
Targeted Therapy	pertuzumab	DESTINY-Breast09	DESTINY-Breast11
	tucatinib	DESTINY-Breast07	
	capivasertib	DESTINY-Breast08	
	osimertinib	ORCHARD	U31402-A-U103

+ **Internal Assets**

- **ENHERTU® + valemetostat in HER2-low BC** (FSD in 2H FY2022 in collaboration with MDACC)
- **Novel asset with undisclosed MoA** (FSD in 1H FY2023)
- More potential combo partners in preclinical pipeline

FSD: first subject dosed, MDACC: MD Anderson Cancer Center, MoA: mechanism of action

Translational Science supports our combo/sequencing strategy



Mechanism of Resistance to ADCs

Target-mediated resistance

Low/Loss of antigen expression, etc.

» **Supports sequencing of DXd-ADC**

Payload-mediated resistance

Alterations in payload-related mechanisms, e.g., Topo1, efflux pumps, etc.

» **Opportunity for novel assets or combinations**

Accumulating knowledge of **cross-DXd-ADC translational science** is deepening our understanding of **mechanisms of resistance** and potential for **rational combinations**

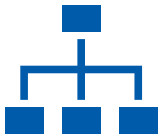
Agenda

1. Opening
2. Clinical Progress
3. R&D Strategy
4. **Closing**
5. Q&A

Creating “One Global R&D” to deliver our strong pipeline

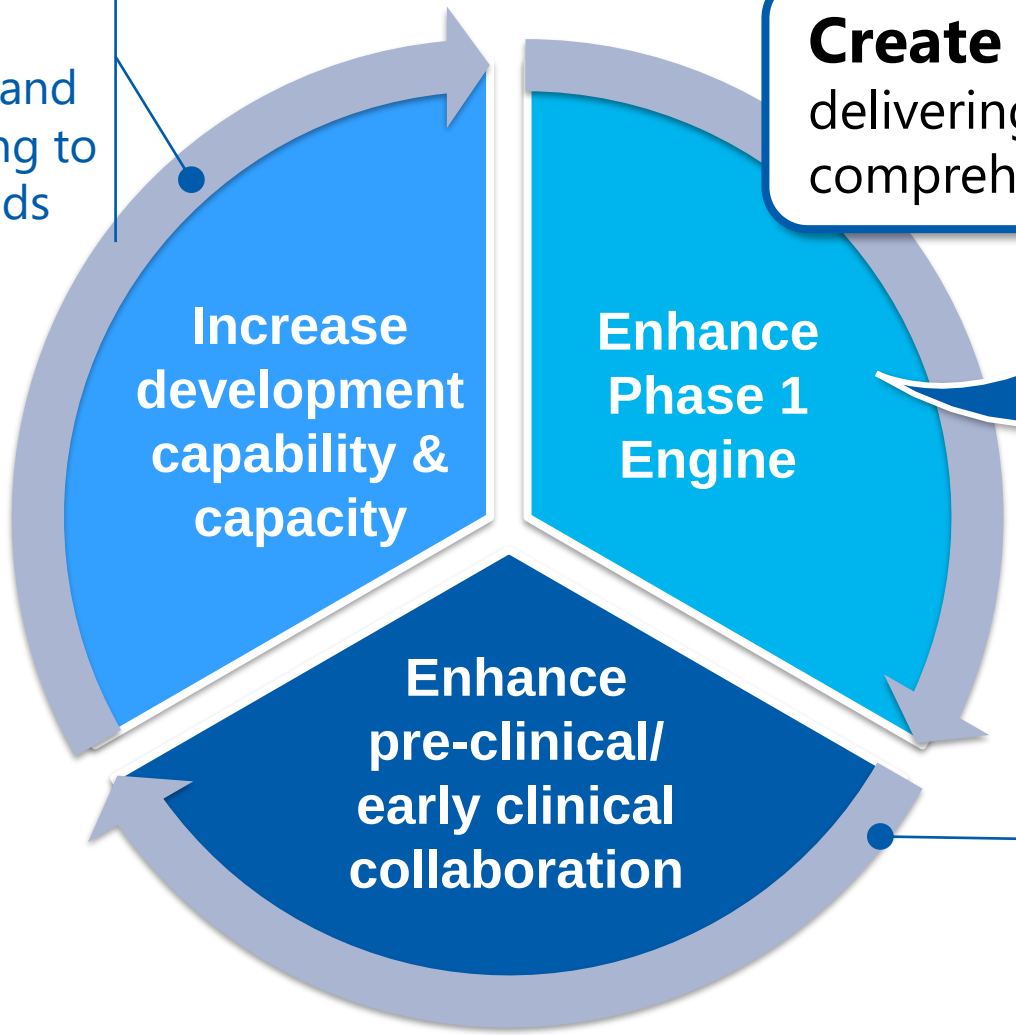
Achievements in 2022 (examples)

- **Streamlined governance** for quick and quality decisions
- **Reorganized** East-West mirror model to unified global functions
- **Unified Clinical Scientists** under one global function to enhance capability to secure scientific validity and quality of clinical trials
- **Assembled Team Leaders** of development projects in one organization and integrated under the same global function as Asset & Portfolio Management to reinforce project promotion
- **Established Therapeutic Area Strategy function** to optimize strategy to address patient needs
- **Reinforcing talents and capabilities** in development especially for early stage
- **Integrated Discovery Research** of Oncology and Specialty-Medicine under one leadership



Plan to enhance Research to Development capability

Shifting to optimum balance of insourcing and outsourcing responding to dynamic portfolio needs



Create Phase 1 Center of Excellence
delivering high quality, high throughput, comprehensive and cost-efficient Ph1 studies

Cross-functional and cross-asset collaborations among preclinical, precision medicine and early clinical functions in science and strategy

Daiichi Sankyo R&D toward 2025 and beyond

Expectations by FY2025

>8

Start Phase 1 of novel assets including new-concept ADC

>6

Evaluate PoC or early signals from new assets including next-generation ADC

>12

Submit BLA/NDA for new indications of DXd-ADC etc.

~FY2030

To be an innovative global healthcare company contributing to the sustainable development of society

Top 10 in Oncology

ADC: antibody-drug conjugate, BLA: Biologic License Application, NDA: New Drug Application, PoC: proof of concept

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. Opening
2. Clinical Progress
3. R&D Strategy
4. Closing
5. **Q&A**

Appendix

FY2022 News Flow

As of Dec 2022

Regulatory decisions

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

Planned regulatory submissions

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

Key data readouts

Dato-DXd	TROPION-Lung01*: NSCLC, 2/3L, Ph3 • FY2022 H2
HER3-DXd	**HERTHENA-Lung01*: EGFR mutated NSCLC, 3L, Registrational Ph2** • **FY2022 H2**

Planned pivotal study initiation

Dato-DXd	TROPION-Lung07: non-squamous NSCLC w/o actionable genomic alterations, PD-L1 <50% 1L (pembrolizumab combo), Ph3 • FY2022 H2
Dato-DXd	**TROPION-Breast03: TNBC, adjuvant** (durvalumab combo), Ph3** • **FY2022 Q3**

Bold: update from FY2022 Q2

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

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

*Event-driven study

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

Major R&D Milestones (3ADCs)

As of Dec 2022

Project	Target Indication [phase, study name]	FY2022 H1	FY2022 H2	FY2023
ENHERTU®	BC • HER2+, 2L [P3, DESTINY-Breast03]	• Approved (US/EU)	**• Approved (JP)**	
	BC • HER2 low, post chemo [P3, DESTINY-Breast04]	• Filing accepted (JP/EU/China) • Approved (US)		• Approval anticipated (JP/EU)
	BC • HER2 low, chemo naïve [P3, DESTINY-Breast06]			• TLR anticipated
	GC • HER2+, 2L [P2, DESTINY-Gastric02, EU]		• Approval anticipated (EU)	
	NSCLC • HER2 mutant, 2L [P2, DESTINY-Lung01, 02]	• Approved (US)	• Filing anticipated (JP/EU)	
	CRC • HER2+, 3L [P2, DESTINY-CRC02]		**• TLR anticipated**	
Dato-DXd	NSCLC • 2/3L [P3, TROPION-Lung01]		• TLR anticipated	
	NSCLC • 1L [P3, TROPION-Lung07]		• Study start planned	
	BC **• TNBC, adjuvant* [P3, TROPION-Breast03]**		**• Study start planned**	
HER3-DXd	NSCLC • EGFR mutated, 3L [Registrational P2, HERTHENA-Lung01]		**• TLR anticipated**	

Bold: update from FY2022 Q2 BC: breast cancer, CRC: colorectal cancer, GC: gastric cancer, NSCLC: non-small cell lung cancer, TLR: Top Line Results, TNBC: triple-negative breast cancer

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

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

Major R&D Milestones (Alpha)

As of Dec 2022

Project	Target Indication [phase, study name]	FY2022 H1	FY2022 H2	FY2023
Quizartinib	• AML, 1L [P3, JP/US/EU]	• Filing accepted (JP/EU)	Filing accepted (US)	• Approval anticipated (JP/US/EU)
DS-1211	• PXE [P2, US/EU]		**• Study started**	
DS-5670	• COVID-19 mRNA vaccine, booster vaccination [P1/2/3, JP]		**• TLR obtained** • Filing anticipated (JP)	

Bald: update from FY2022 Q2 AML: acute myeloid leukemia, IA: interim analysis, PXE: pseudoxanthoma elasticum, TLR: Top Line Results

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

Major R&D Pipeline: 3ADCs

As of Dec 2022

Phase 1	Phase 2	Phase 3	Filed
(US/EU/Asia) HER2+ BC 2L~/1L DESTINY-Breast07	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	(JP/US/EU/Asia) HER2+ BC 3L DESTINY-Breast02	(China) HER2+ BC 2L DESTINY-Breast03
(US/EU/Asia) HER2 low BC Chemo naïve/ post chemo DESTINY-Breast08	(CN) HER2+ GC 3L DESTINY-Gastric06	(JP/US/EU/Asia) HER2+ BC adjuvant* DESTINY-Breast05	(EU) HER2+ GC 2L DESTINY-Gastric02
(JP/US/EU/Asia) HER2+ GC combo, 2L~/1L DESTINY-Gastric03	(JP/US/EU) HER2+ or HER2 mutant NSCLC 2L~ DESTINY-Lung01	(JP/US/EU/Asia) HER2 low BC chemo naïve DESTINY-Breast06	(JP/EU/China) HER2 low BC post chemo DESTINY-Breast04
(EU/Asia) HER2+ NSCLC (durvalumab combo) 1L DESTINY-Lung03	(JP/US/EU/Asia) HER2 mutant NSCLC 2L~ DESTINY-Lung02	(JP/US/EU/Asia) HER2+ BC 1L DESTINY-Breast09	
(US/EU) BC, bladder (nivolumab combo)	(CN) HER2 mutant NSCLC 2L~ DESTINY-Lung05	(JP/US/EU/Asia) HER2+ BC neoadjuvant DESTINY-Breast11	
(US/EU) BC, NSCLC (pembrolizumab combo)	(US/EU/Asia) NSCLC (durvalumab combo) 2L~ HUDSON	(JP/EU/Asia) HER2+ GC 2L DESTINY-Gastric04	
(US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(JP/US/EU) HER2+ CRC 3L DESTINY-CRC01	(JP/US/EU/Asia) NSCLC (w/ HER2 exon 19 or exon 20 mutation) 1L DESTINY-Lung04	
	(JP/US/EU/Asia) HER2+ CRC 3L DESTINY-CRC02	(JP/US/EU/Asia) NSCLC 2/3L TROPION-Lung01	
	(JP/US/EU/Asia) HER2 mutant tumor DESTINY-PanTumor02	(JP/US/EU/Asia) NSCLC (w/o actionable mutation, pembro combo) 1L TROPION-Lung07 (in prep.)	
	(US/EU/Asia) HER2 expressing tumor DESTINY-PanTumor02	(JP/US/EU/Asia) NSCLC (w/o actionable mutation, pembro combo) 1L TROPION-Lung08	
		(JP/US/EU/Asia) HR+ BC 2/3L TROPION-Breast01	
		(JP/US/EU/Asia) TNBC 1L TROPION-Breast02	
		(JP/US/EU/Asia) TNBC adjuvant** TROPION-Breast03 (in prep.)	
		(JP/US/EU/Asia) EGFR mutated NSCLC 2L HERTHENA-Lung02	

Phase 1	Phase 2	Phase 3
(JP/US) NSCLC, TNBC, HR+ BC, SCLC, GC, urothelial, esophageal, prostate, etc. TROPION-PanTumor01	(JP/US/EU/Asia) endometrial, ovarian, prostate cancer, GC, CRC combo TROPION-PanTumor03	
(CN) NSCLC, TNBC TROPION-PanTumor02	(JP/US/EU/Asia) NSCLC (w/ actionable mutation) TROPION-Lung05	
(JP/US/EU/Asia) NSCLC (pembrolizumab combo) TROPION-Lung02	(US/EU/Asia) TNBC (durvalumab combo) BEGONIA	
(JP/US/EU) NSCLC (durvalumab combo) TROPION-Lung04	(JP/US/EU/Asia) EGFR mutated NSCLC 2L (osimertinib combo) ORCHARD	
(JP/US/EU/Asia) solid tumors (AZD5305 combo) PETRA	(JP/US/EU/Asia) EGFR mutated NSCLC 3L HERTHENA-Lung01	
(JP/US/EU/Asia) NSCLC		
(JP/US) EGFR mutated NSCLC (osimertinib combo)		
(JP/US) HER3+ BC		

ENHERTU®

Dato-DXd

HER3-DXd

Project in oncology that is planned to be submitted for approval in some countries/regions based on the results of phase 2 trials

Breakthrough Designation (US) Orphan drug designation (JP)

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

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

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

Major R&D Pipeline: Alpha

As of Dec 2022

Phase 1	Phase 2	Phase 3	Filed
DS-7300 (JP/US) B7-H3-directed ADC ESCC, CRPC, squamous NSCLC, SCLC, etc.	Valemetostat (DS-3201)(JP/US/EU/Asia) EZH1/2 inhibitor PTCL	Pexidartinib (JP/Asia) CSF-1/KIT/FLT3 inhibitor Tenosynovial giant cell tumor	Quizartinib (JP/US/EU) FLT3 inhibitor AML 1L
DS-6000 (JP/US) CDH6-directed ADC Renal cell carcinoma, ovarian cancer	Valemetostat (DS-3201) (EU) EZH1/2 inhibitor BCL	Esaxerenone (JP) MR blocker Diabetic nephropathy	VN-0107/MEDI3250 (JP) Live attenuated influenza vaccine nasal spray
DS-1055 (JP/US) Anti-GARP antibody Solid tumors	DS-1001 (JP) Mutant IDH1 inhibitor Glioma	VN-0102/JVC-001 (JP) Measles mumps rubella combined vaccine	
DS-1594 (US) Menin-MLL binding inhibitor AML, ALL	DS-7300 (JP/US/EU/Asia) B7-H3-directed ADC ES-SCLC	DS-5670 (JP) COVID-19 mRNA vaccine COVID-19 (booster vaccination)	
DS-9606 (US/EU) Target undisclosed ADC Solid tumors	DS-5141 (JP) ENA oligonucleotide DMD	DS-5670 (JP) COVID-19 mRNA vaccine COVID-19 (primary vaccination, adults)	
DS-6016 (JP) Anti-ALK2 antibody FOP	DS-1211 (US/EU) TNAP inhibitor Pseudoxanthoma elasticum	DS-5670 (JP) COVID-19 mRNA vaccine, COVID-19 (primary vaccination, 12 to 17 aged children) (in prep.)	
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)		
DS-2325 (US) KLK5 inhibitor Netherton syndrome	VN-0200 (JP) RS virus vaccine RS virus infection		

Oncology

Specialty medicine

Vaccine

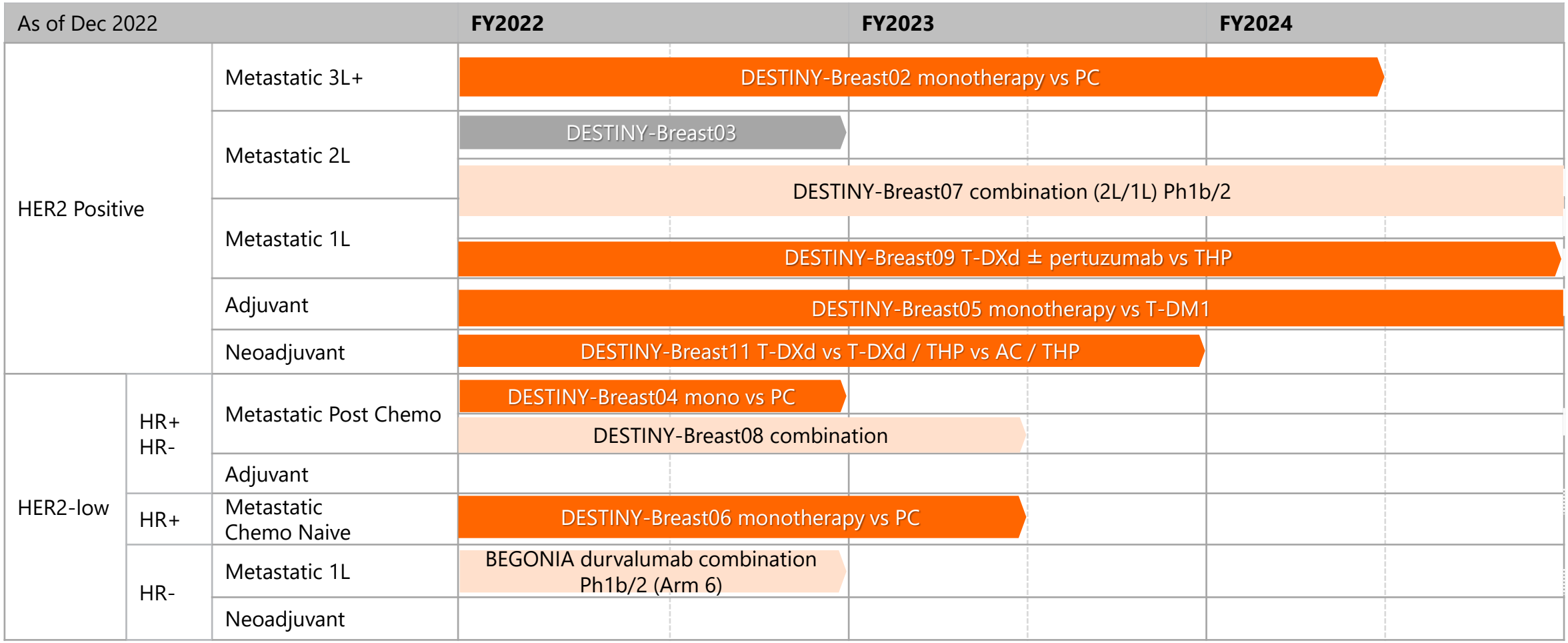
Project in oncology that is planned to be submitted for approval in some countries/regions based on the results of phase 2 trials

SAKIGAKE Designation (JP)

Orphan drug designation (JP/US/EU)

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

ENHERTU®: Clinical Development Plan | Breast cancer



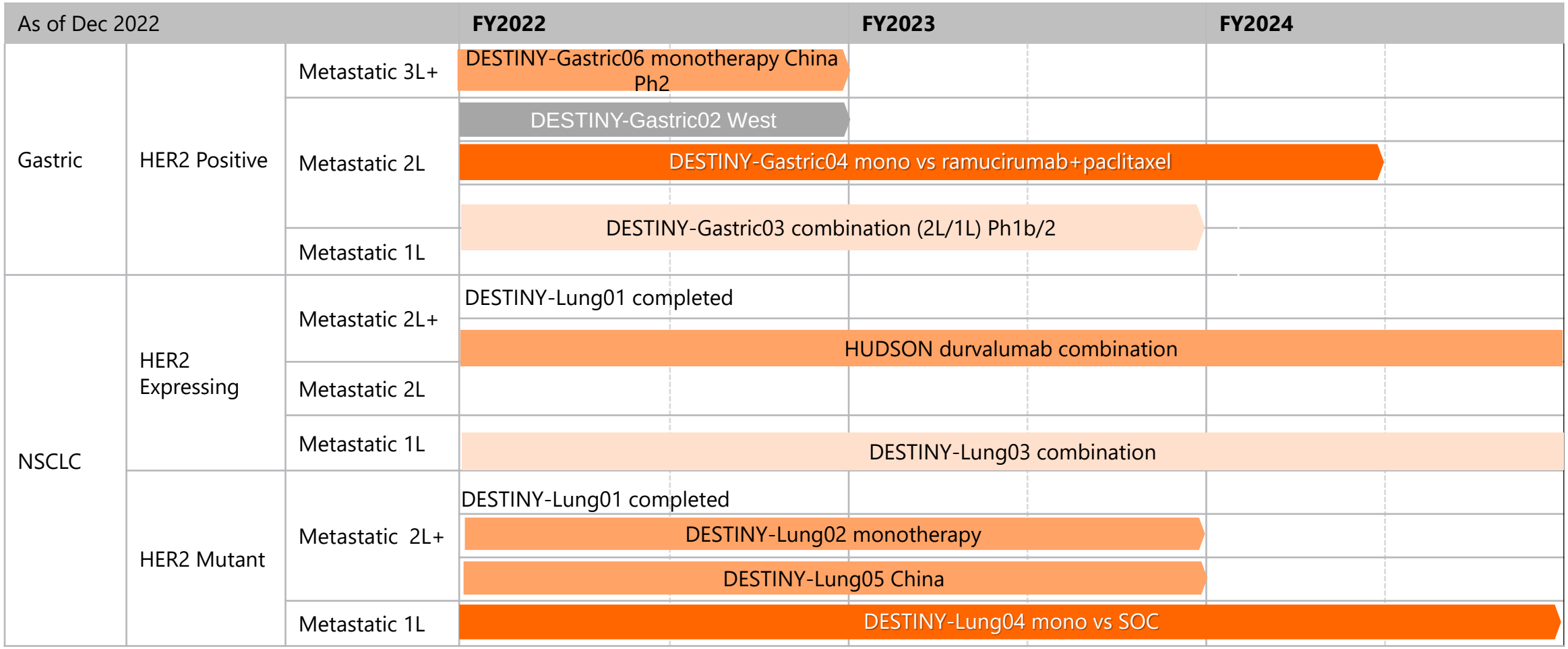
*Adjuvant therapy for patients with HER2+ early BC with high risk of disease recurrence who have residual invasive disease after receiving neoadjuvant therapy

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

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



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

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

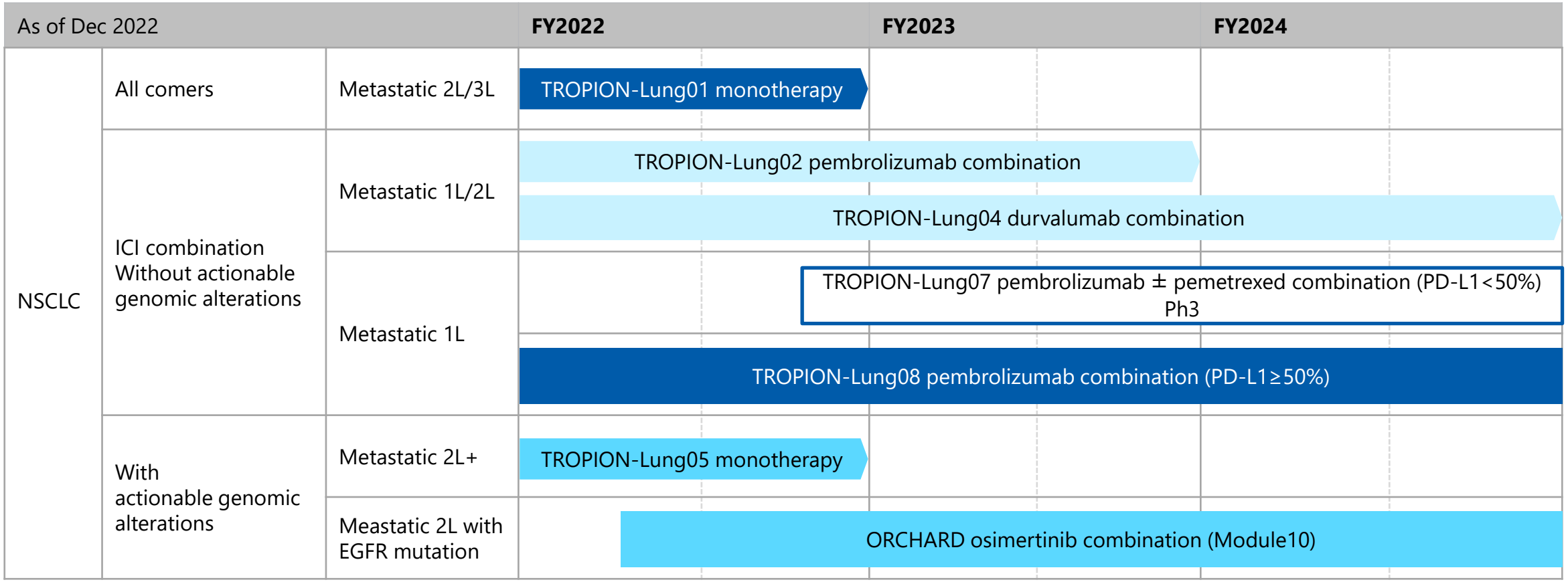
As of Dec 2022			FY2022	FY2023	FY2024
CRC	HER2 Expressing	Metastatic 3L	DESTINY-CRC02 monotherapy		
Other Tumors/ multiple tumors	HER2 Expressing	Metastatic 2L	Pembrolizumab combination (breast, NSCLC)		
			DESTINY-PanTumor02		
	HER2 Mutant	Metastatic 2L	DESTINY-PanTumor01		
			PETRA AZD5305 combination Ph1/2a (Module 4)		

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

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

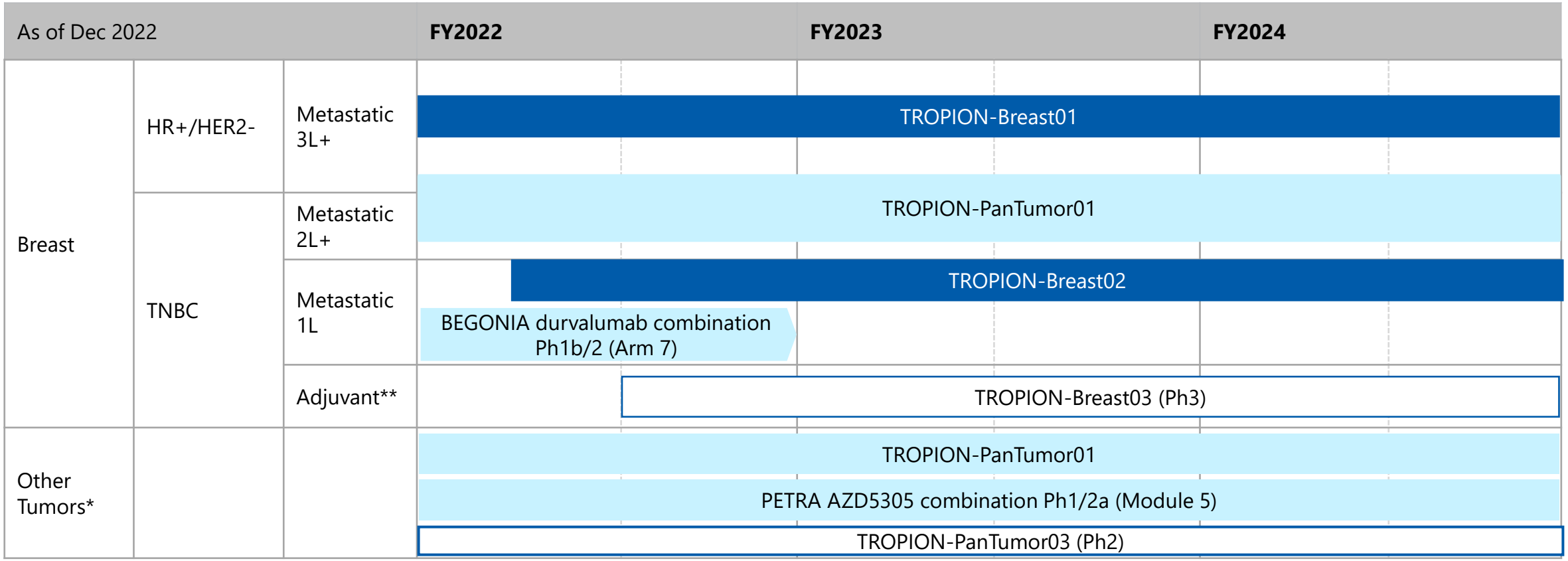


Ph 1 ongoing | Ph 2 ongoing | Ph 3 ongoing | New | Completed

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



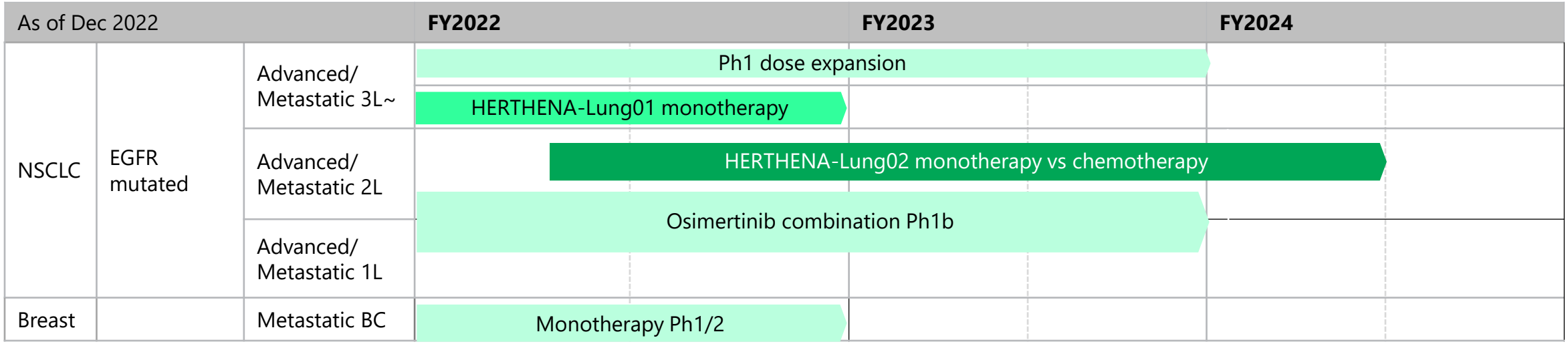
*Other tumors are gastric, esophageal, urothelial, SCLC, endometrial, CRPC, etc. Inclusion of these tumors is based upon TROP2 expression as well as preclinical and other evidence that Dato-DXd may be effective.
**Adjuvant therapy for patients with TNBC with residual disease after neoadjuvant therapy

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

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



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

BC: breast cancer, NSCLC: non small cell lung cancer

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