Passion for Innovation.
Compassion for Patients.™

Daiichi-Sankyo

R&D Day

DAIICHI SANKYO CO., LTD.

December 12th, 13th 2022

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Participants

Presenters

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Joining for Q&A session

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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

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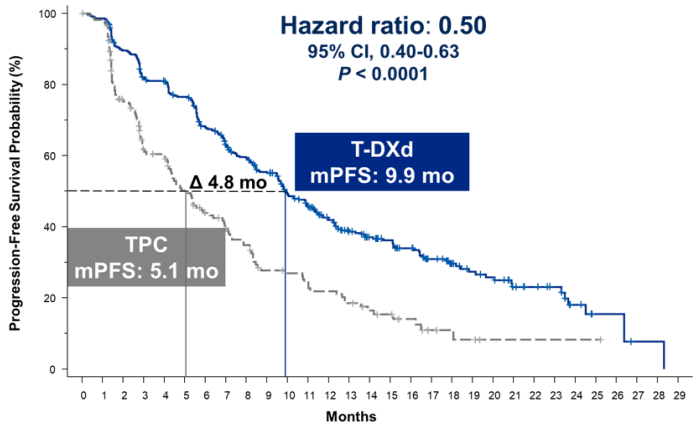
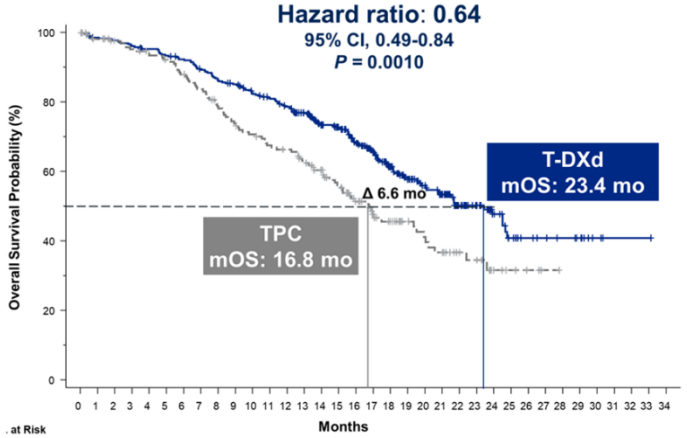
PFS in all patients with HR+ or HR-/HER2 low BC

- **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



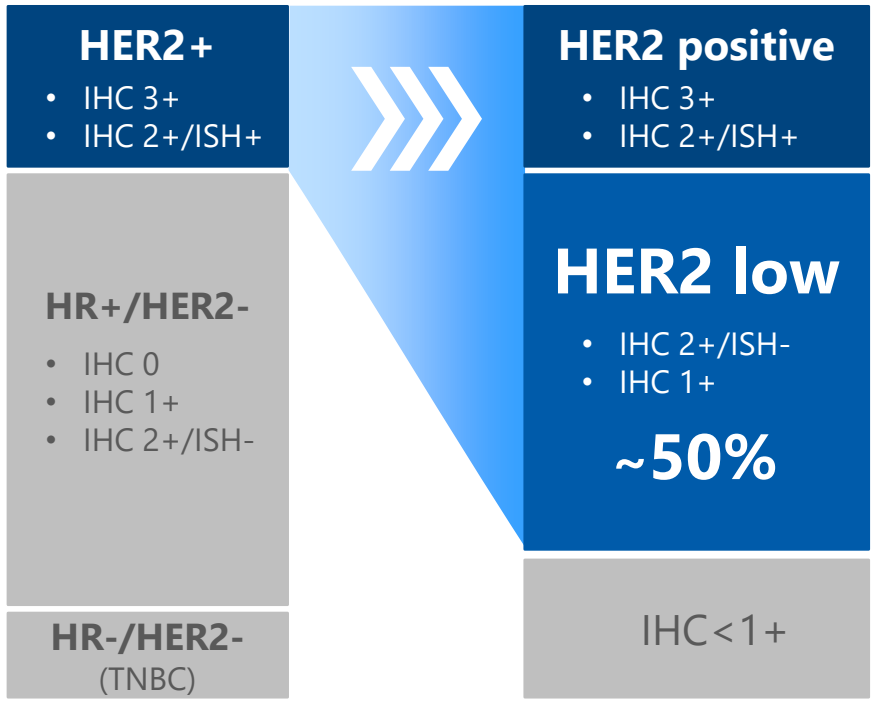
Safety Summary

- 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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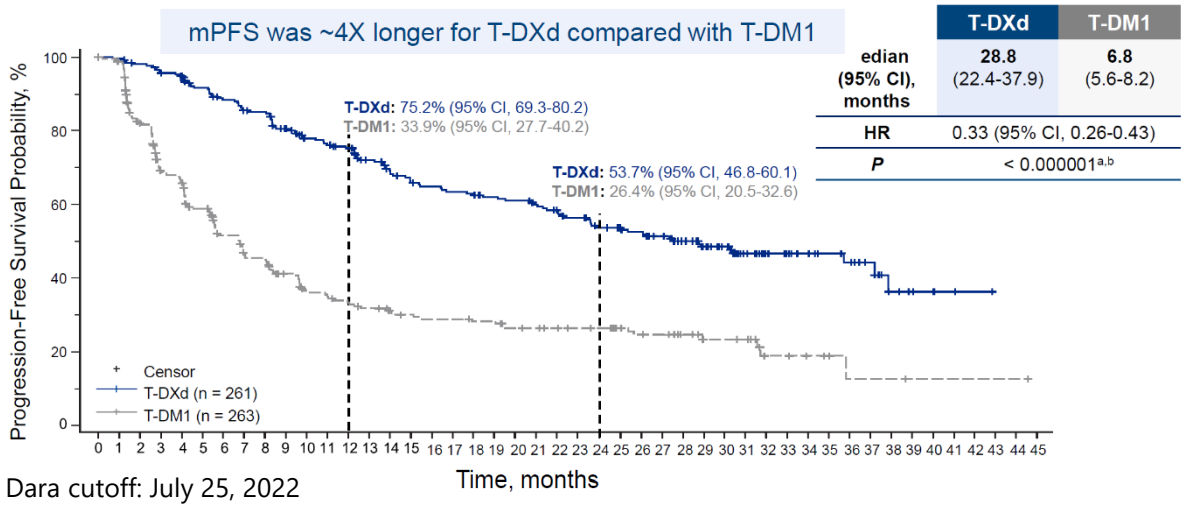
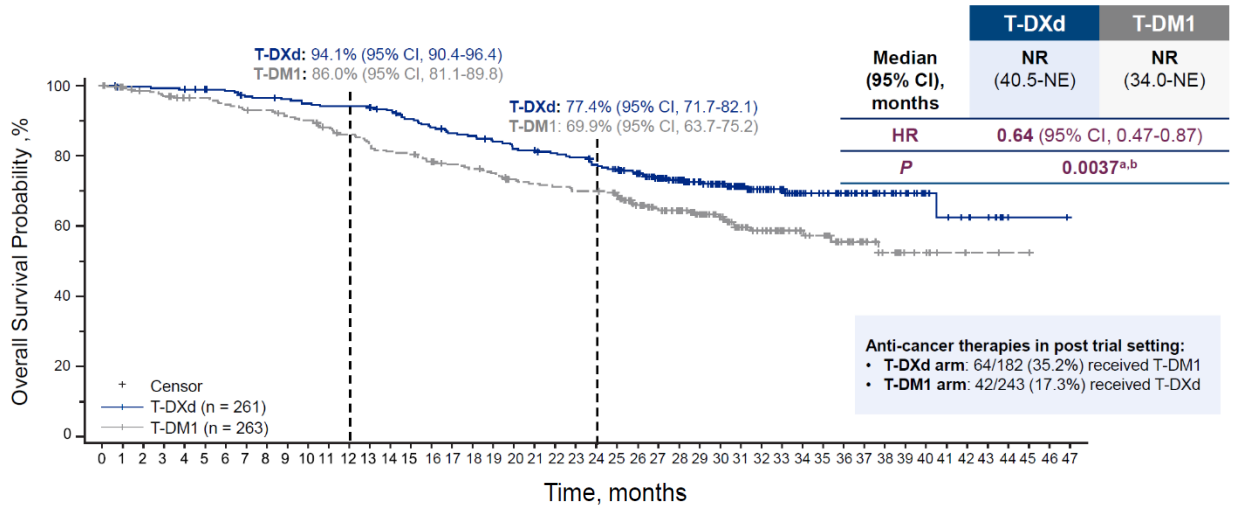
Updated PFS in HER2+ BC, 2L



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)

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(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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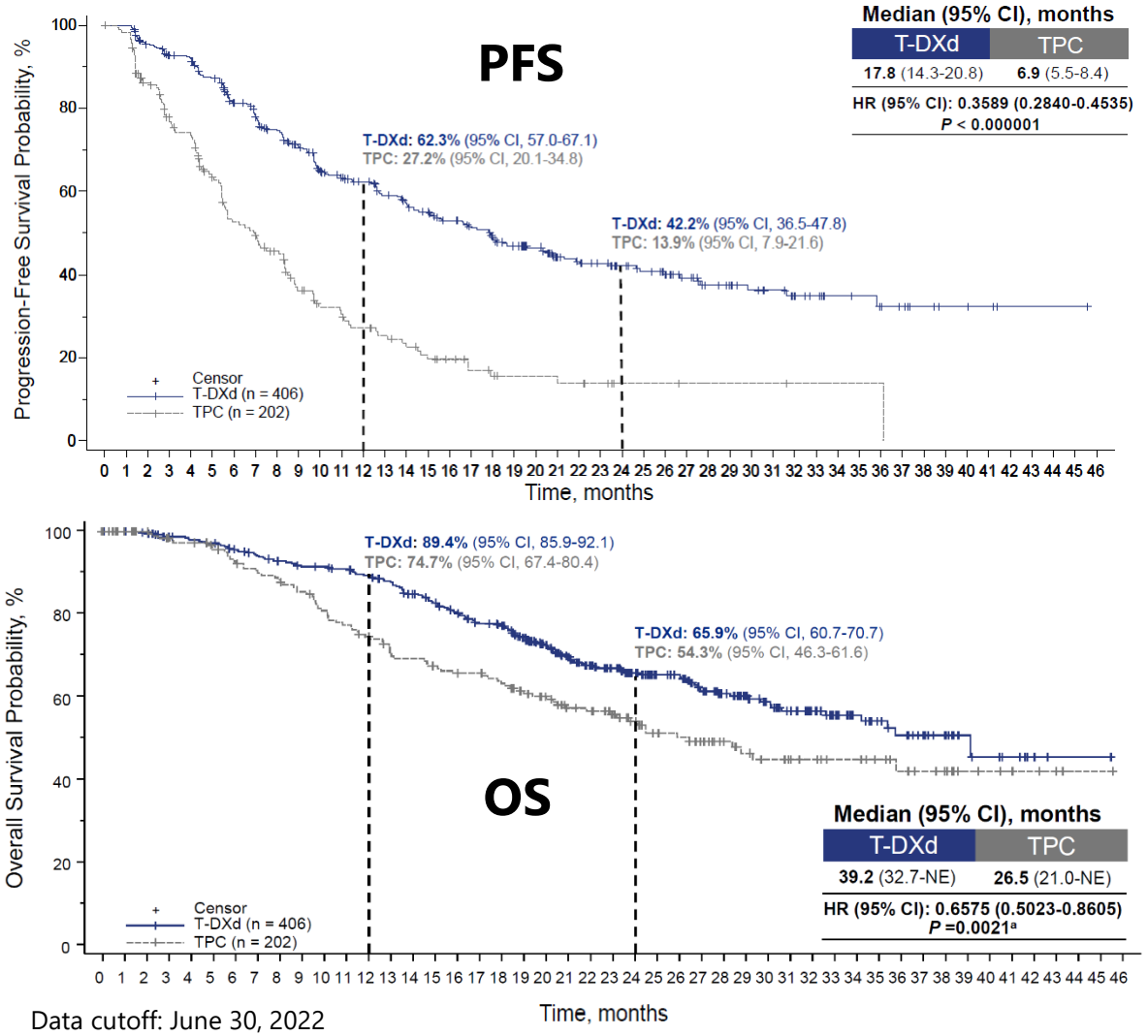
PFS and OS in HER2+ BC 3L+



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%)

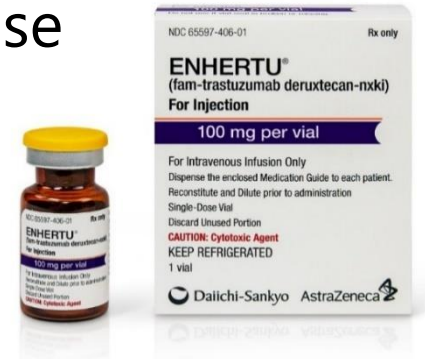
The results confirms the favorable benefit/risk profile of T-DXd in HER2+ BC as previously demonstrated by DESTINY-Breast01

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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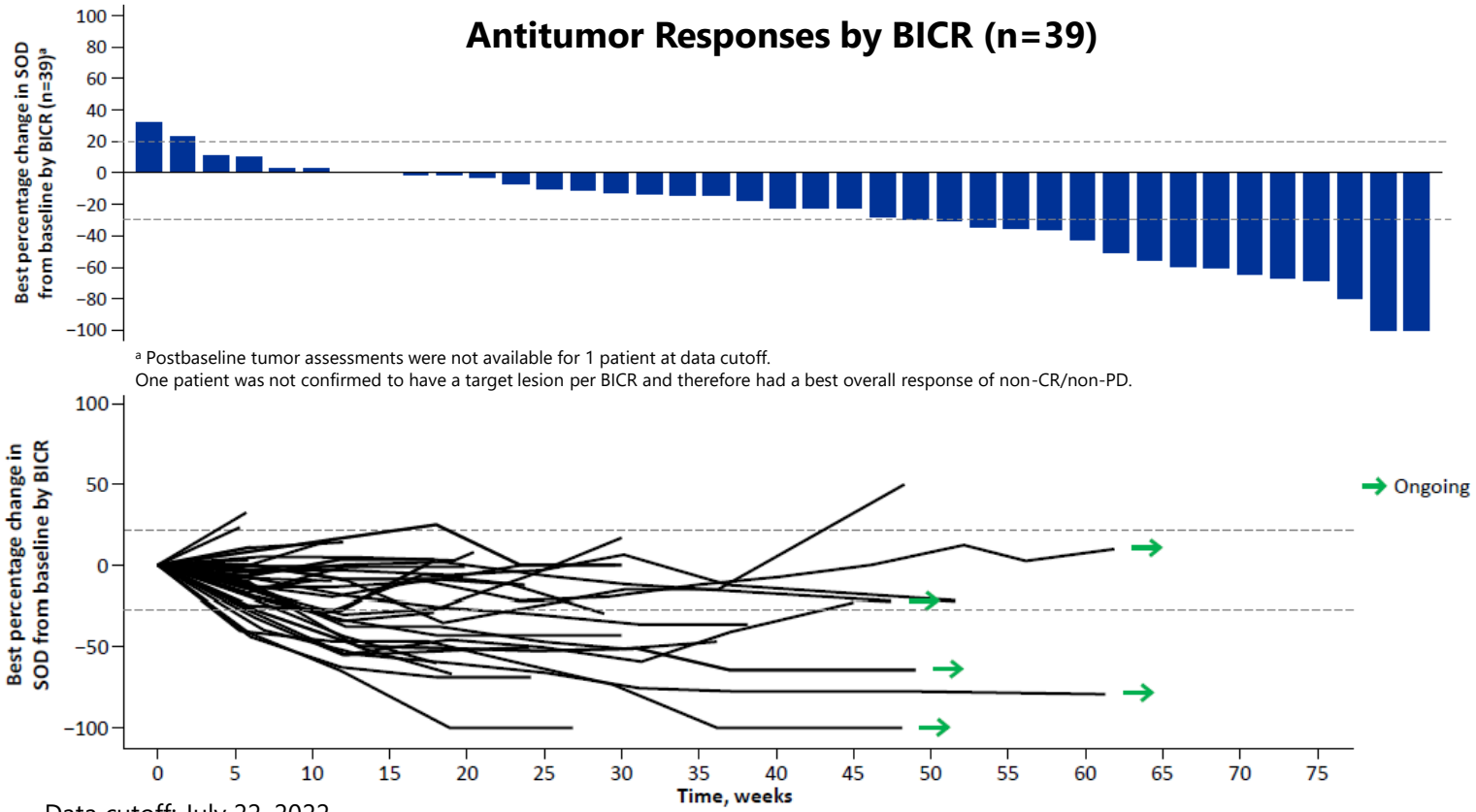
Efficacy



[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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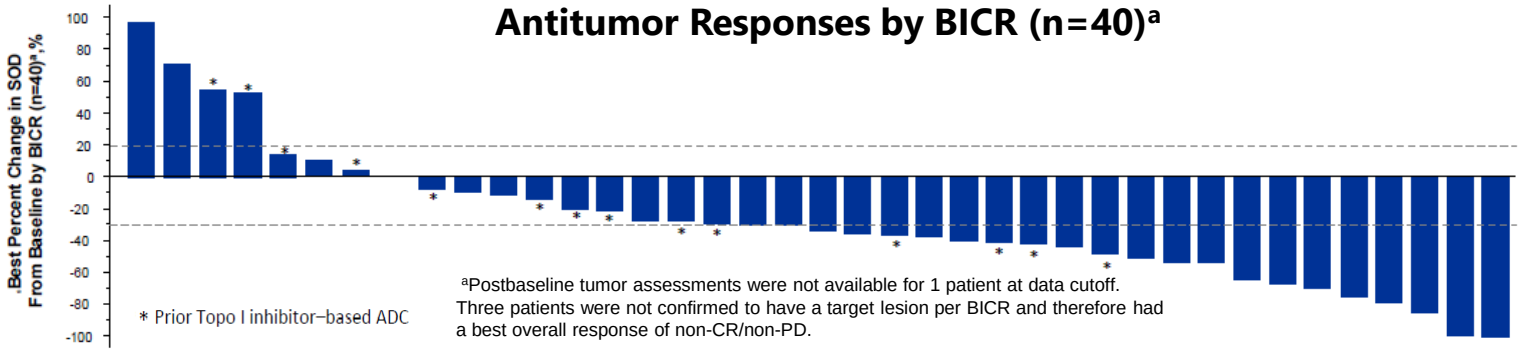
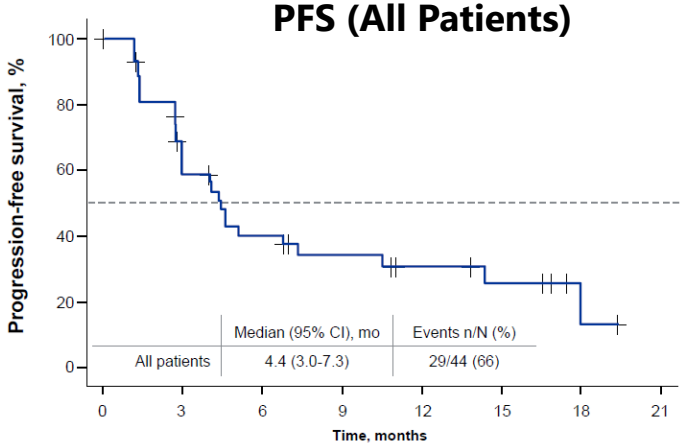
Efficacy

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

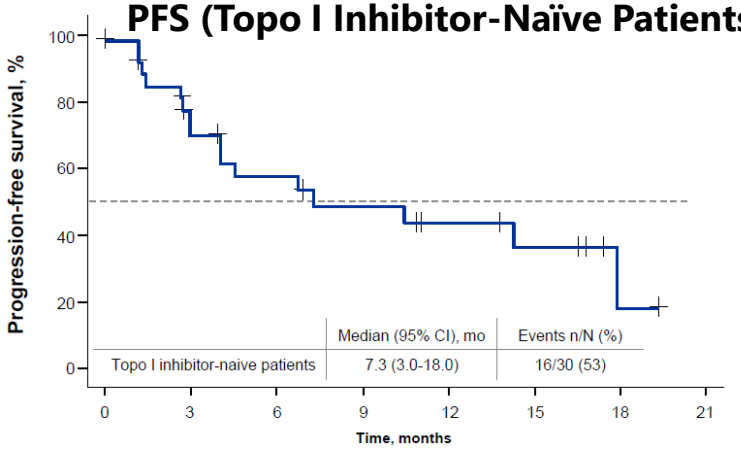


[a]Postbaseline tumor assessments were not available for 1 patient at data cutoff. Three patients were not confirmed to have a target lesion per BICR and therefore had a best overall response of non-CR/non-PD.

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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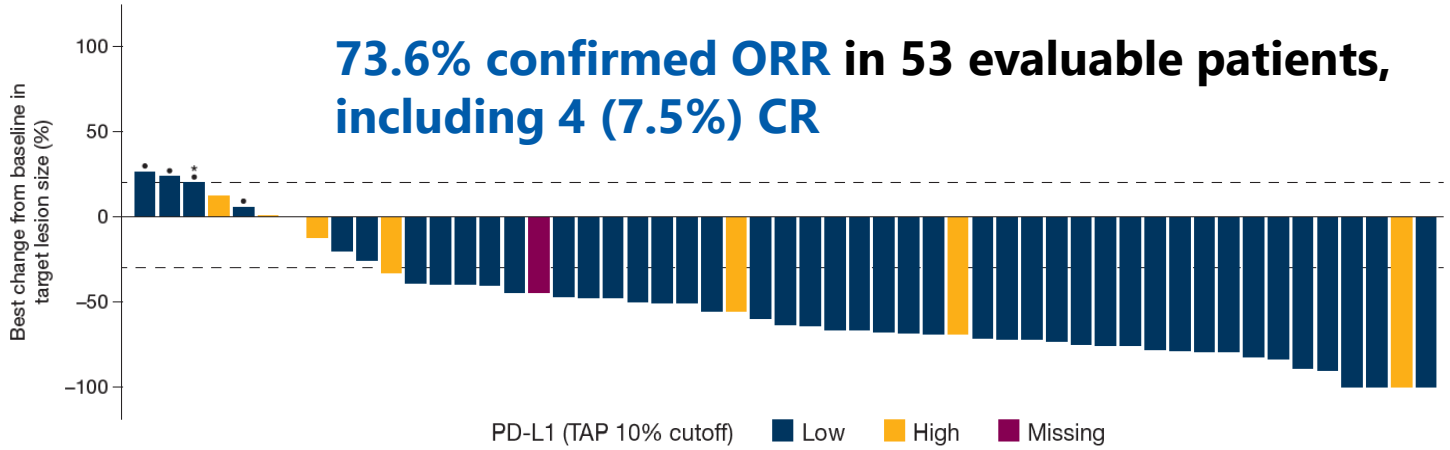
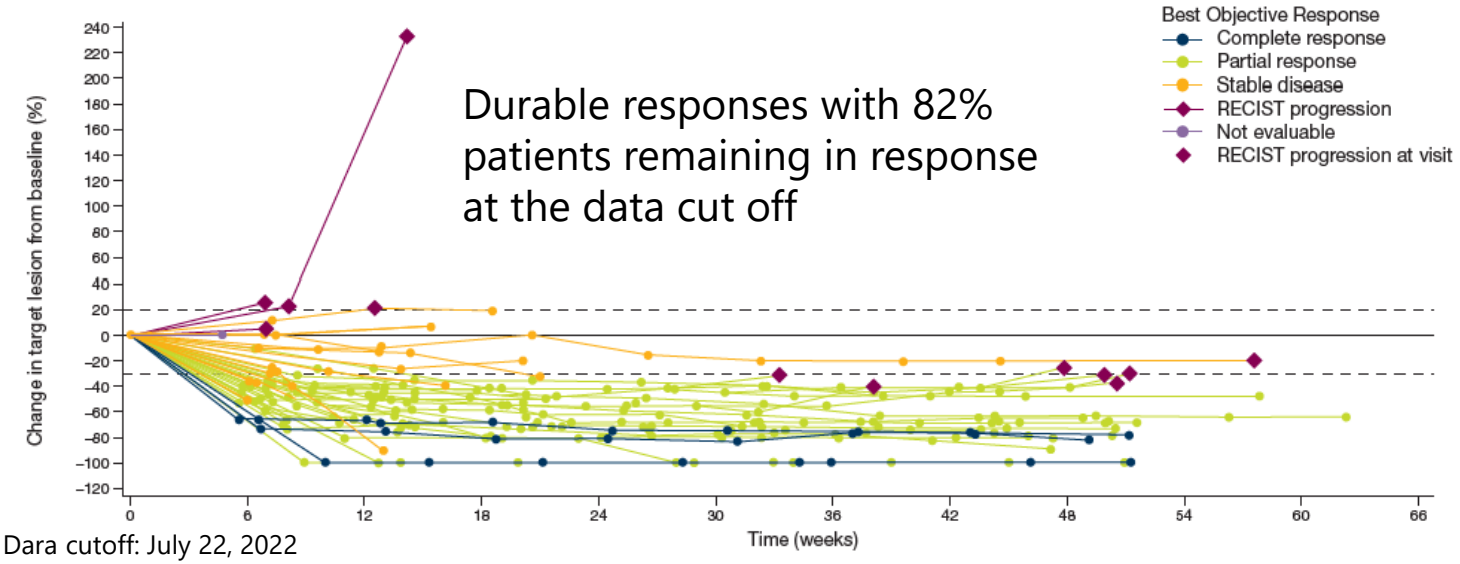
Efficacy

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

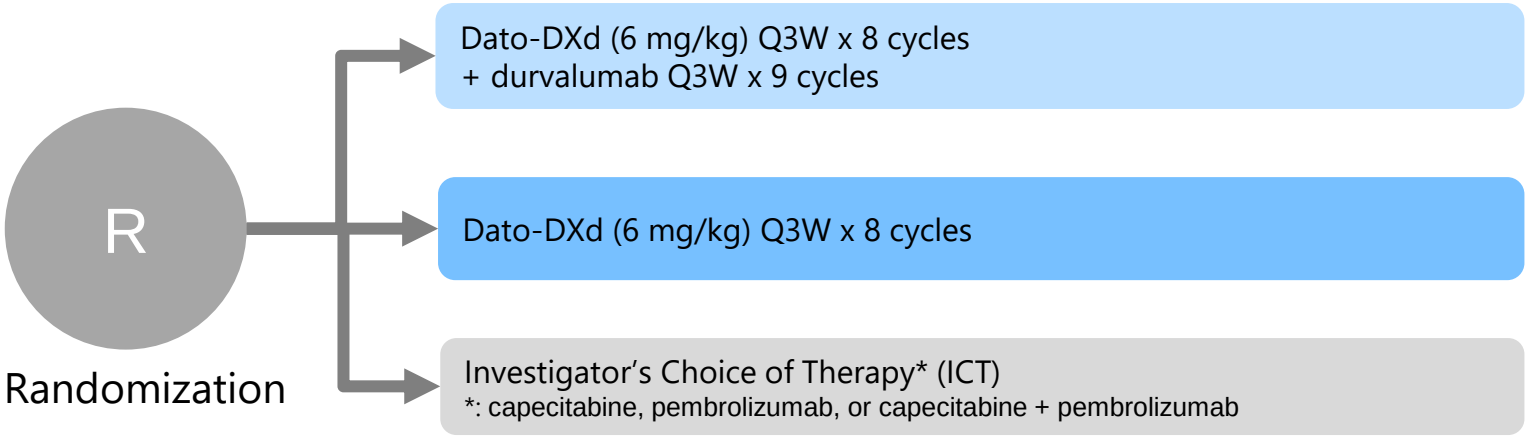
Dato-DXd

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

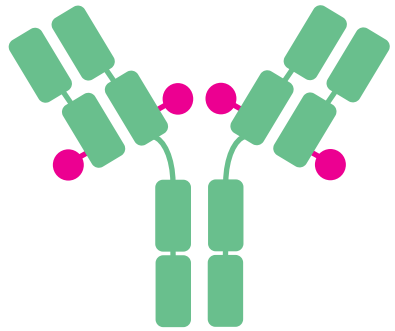
■ Primary endpoint:	Dato + durva vs ICT: iDFS
■ Secondary endpoint:	Dato + durva vs ICT: DDFS, OS
	Dato vs ICT: iDFS, DDFS, OS
	Dato + durva vs Dato: iDFS, DDFS
	Dato + durva vs ICT (subset*): iDFS, DDFS, PROs, PK, immunogenicity, safety

* 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

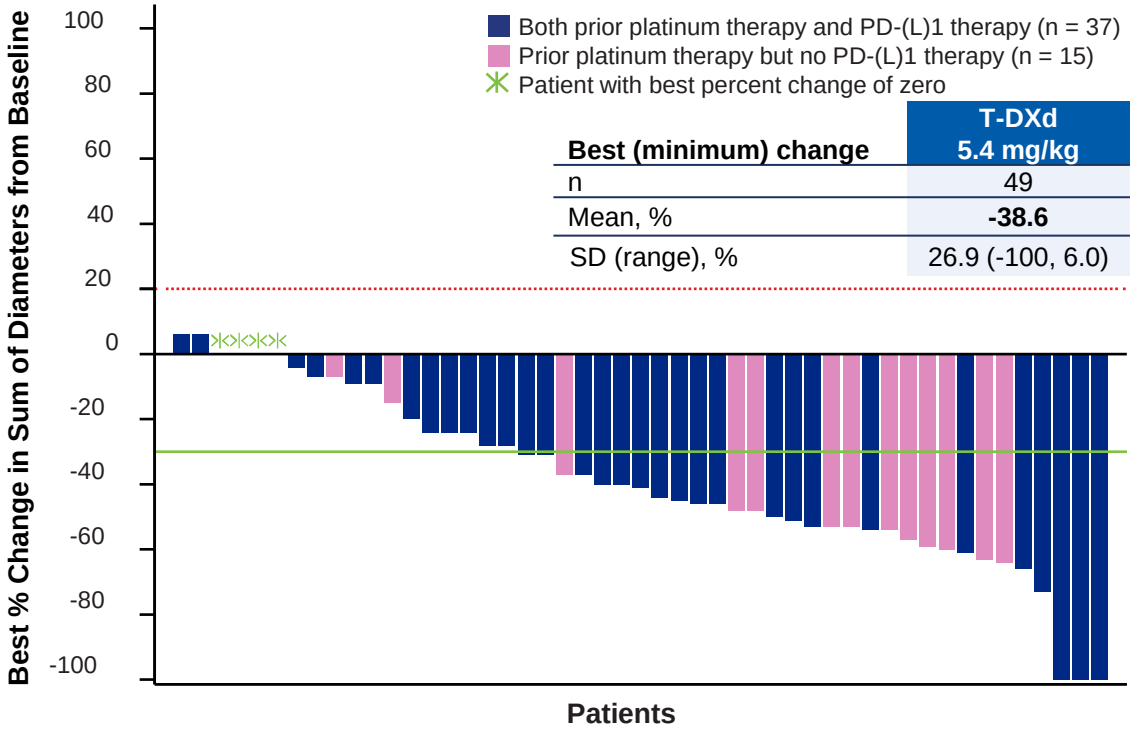
ENHERTU®

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

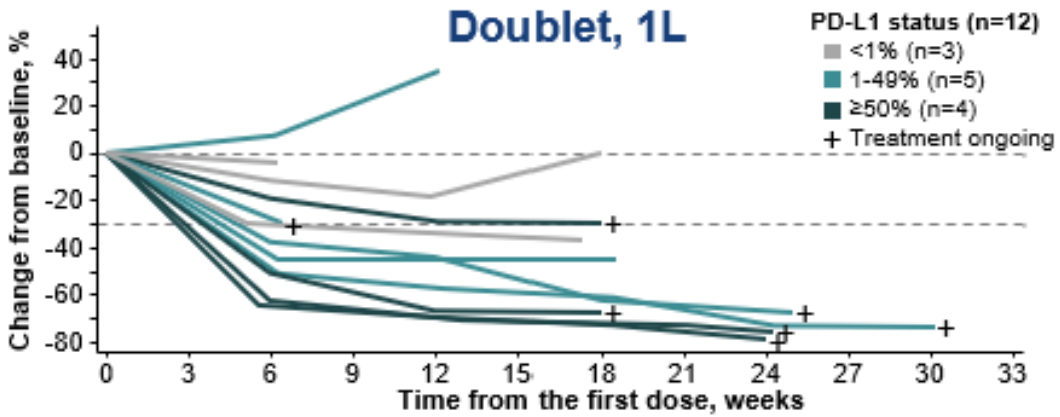
Dato-DXd

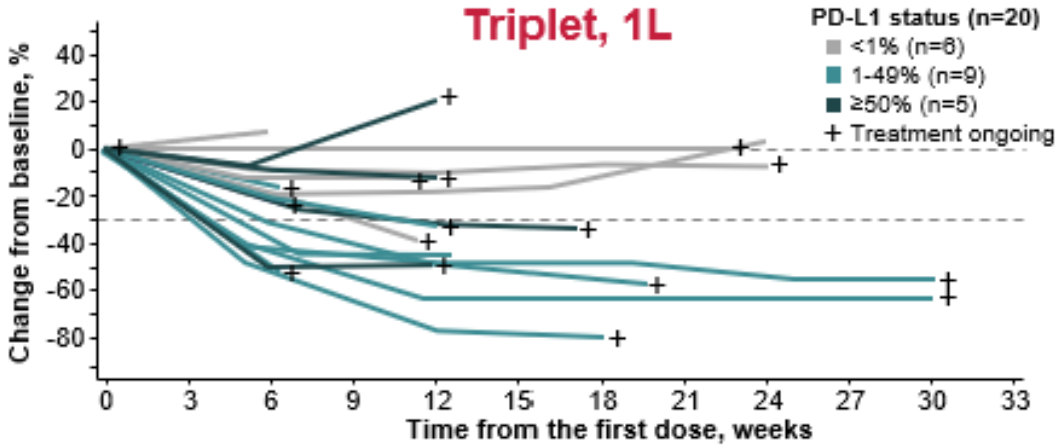
Data supports further development in 1L NSCLC

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

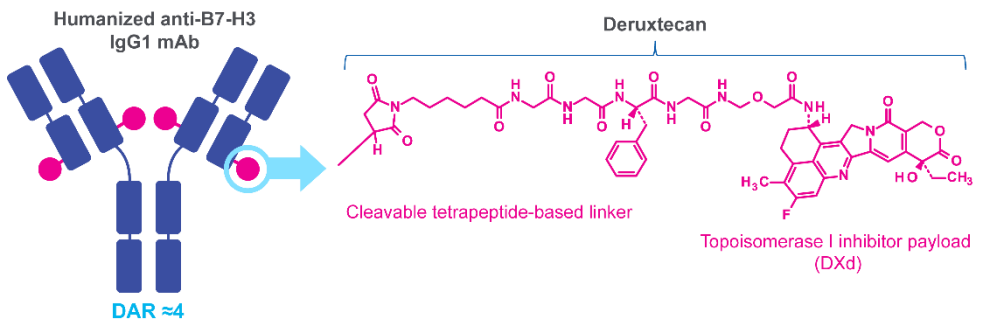
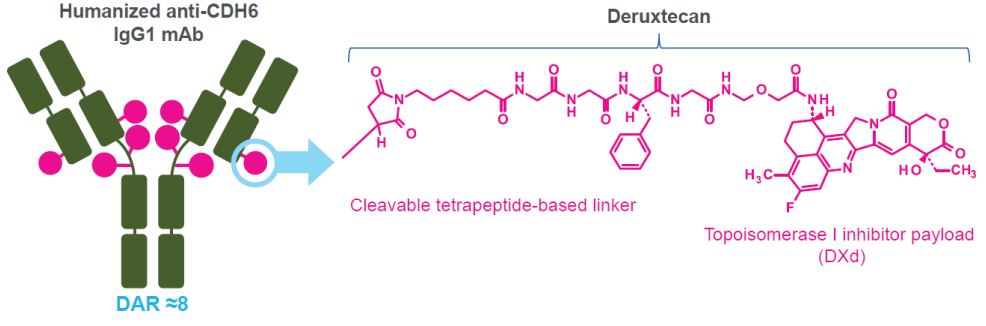
Lung Cancer Summary

- **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

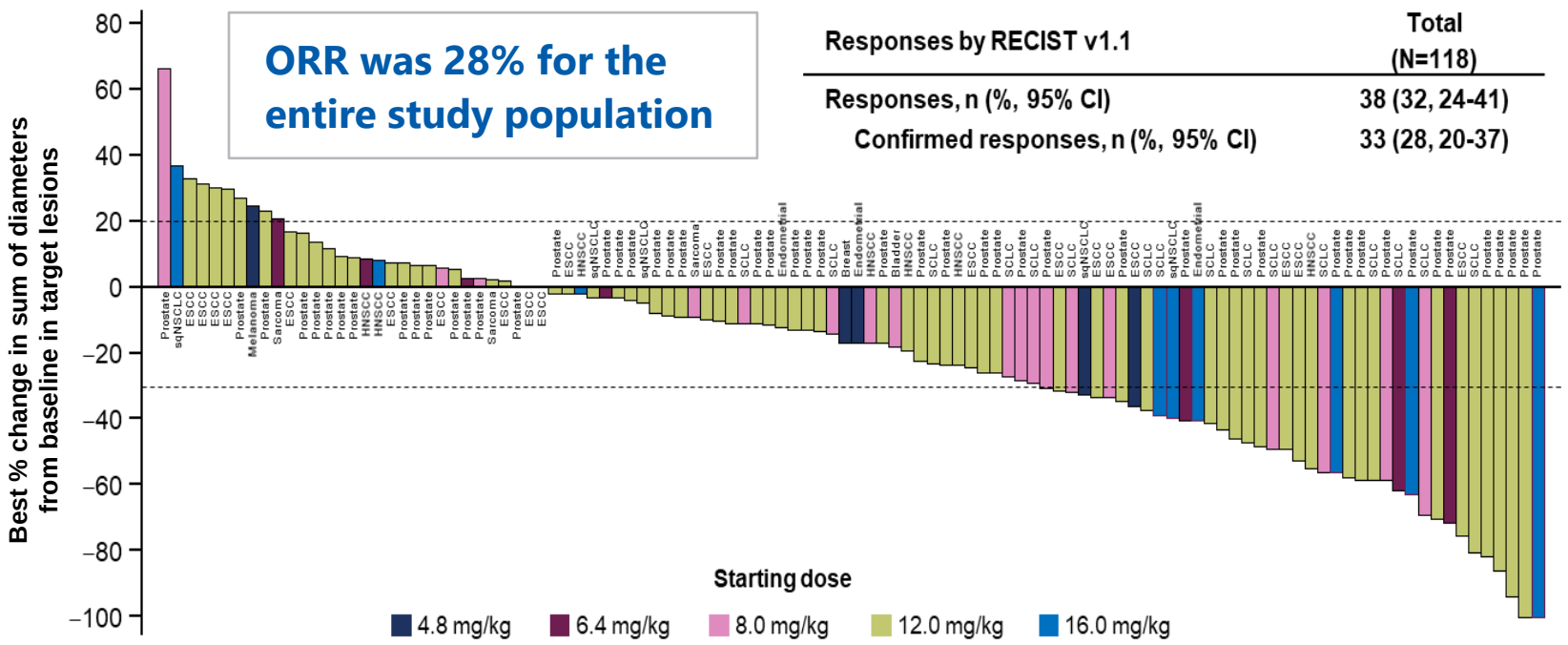
DS-7300

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

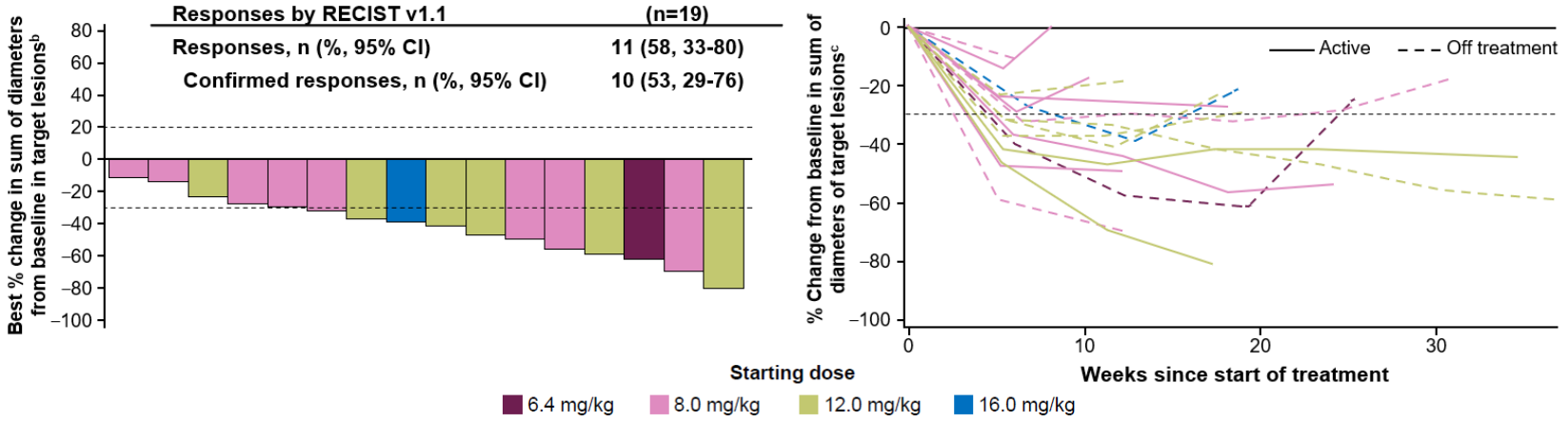
DS-7300

Promising efficacy in multiple cancer types

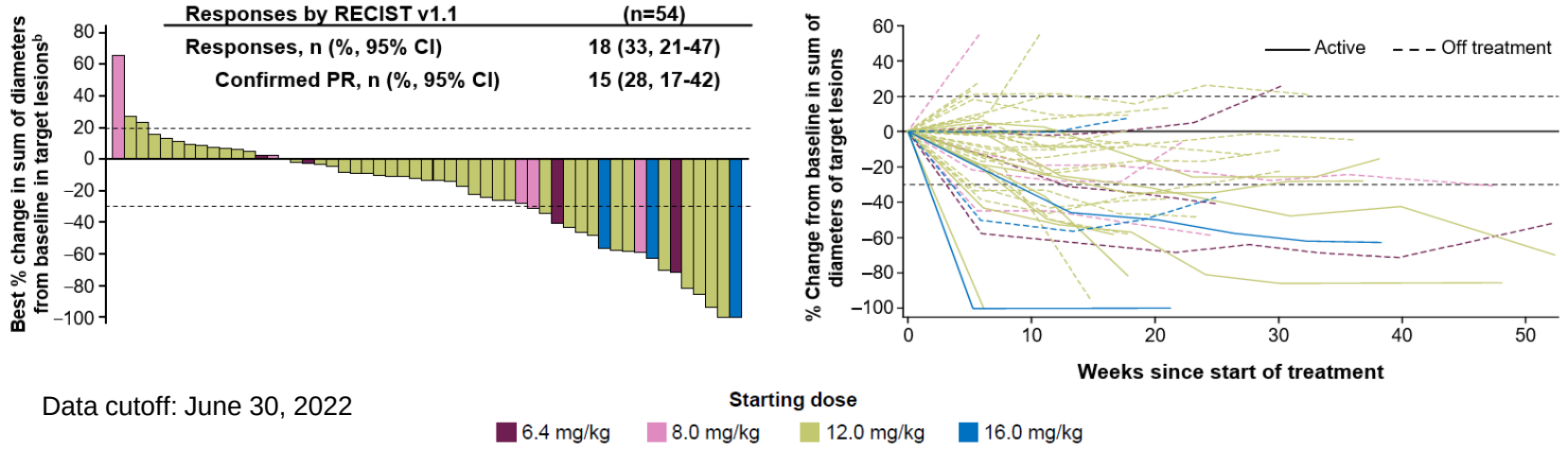
Ph1/2 interim analysis data presented at ESMO 2022 (2/2)

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

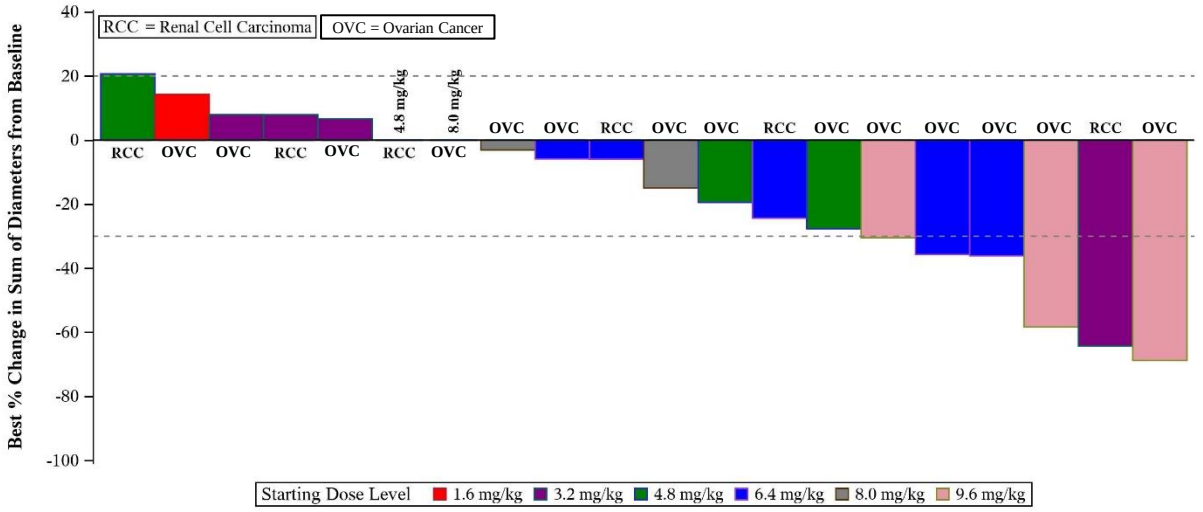
CI: confidence interval, ESCC: esophageal squamous cell carcinoma, ESMO: European Society for Clinical Oncology, mCRPC: metastatic castration-resistant prostate cancer, NSCLC: non-small cell kung cancer, ORR: objective response rate, PR: partial response, RECIST: Response Evaluation Criteria in Solid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

DS-6000

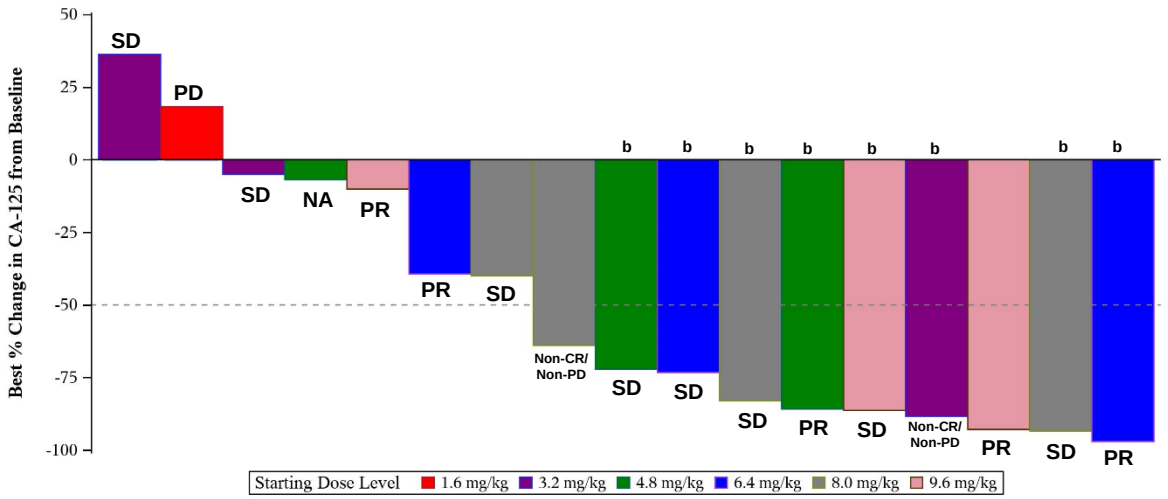
Encouraging data supports further development

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

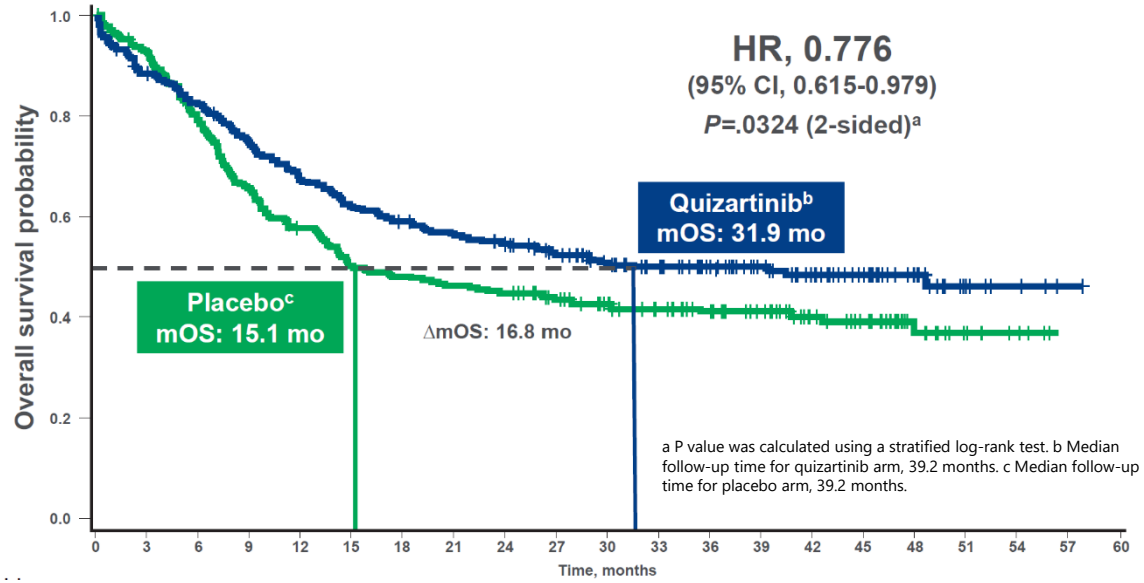
Daiichi-Sankyo

- 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

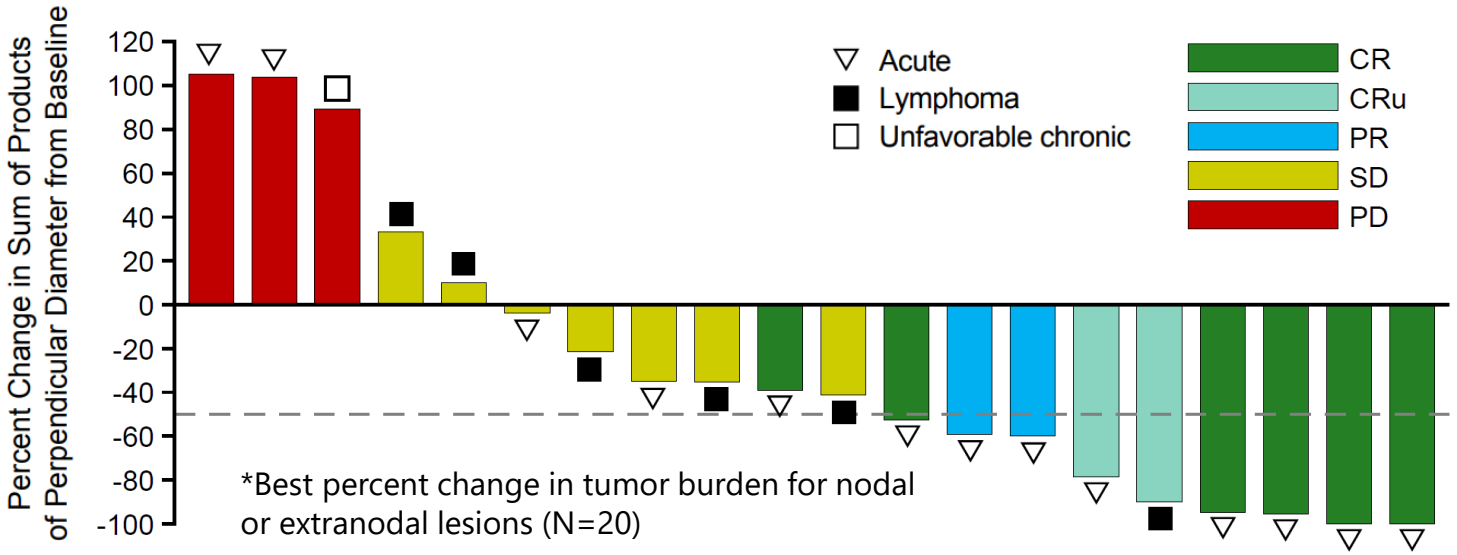
EZHARMIA®

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*

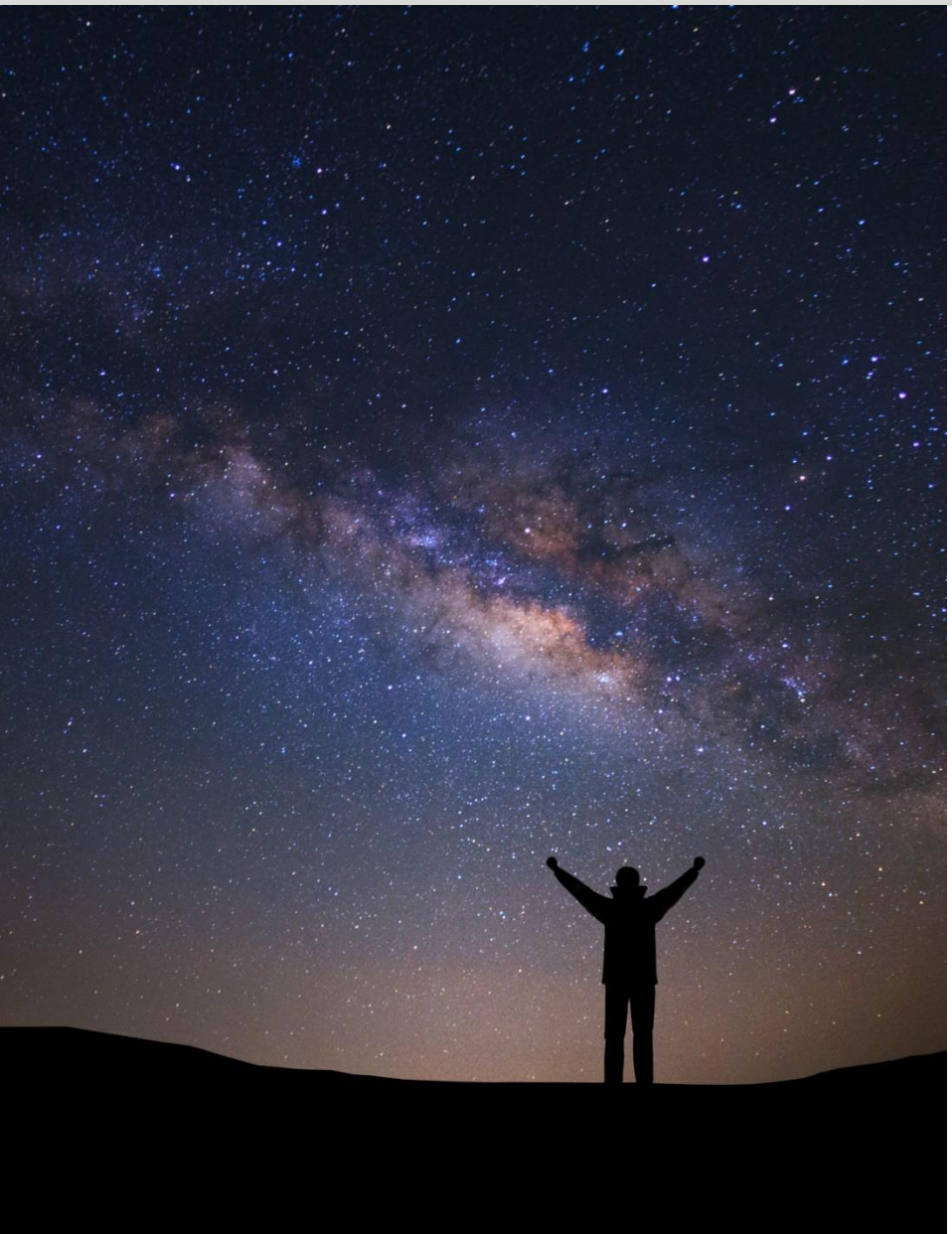


Safety in Ph2 study

- 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



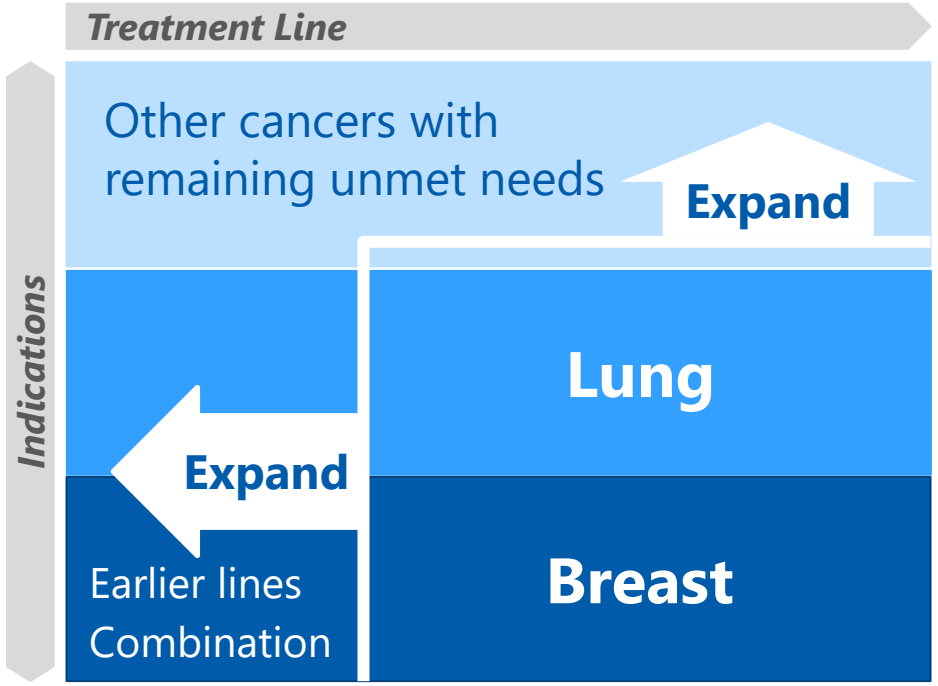
- **Accelerate development of DS-7300**
  - Evaluate optimum dose in on-going Ph2 study in extensive-stage **SCLC**, a potential first indication
  - Continue to evaluate potential in multiple types of solid tumors
- Continue to **evaluate potential of DS-6000** in OVC and RCC for the next step
- Expect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

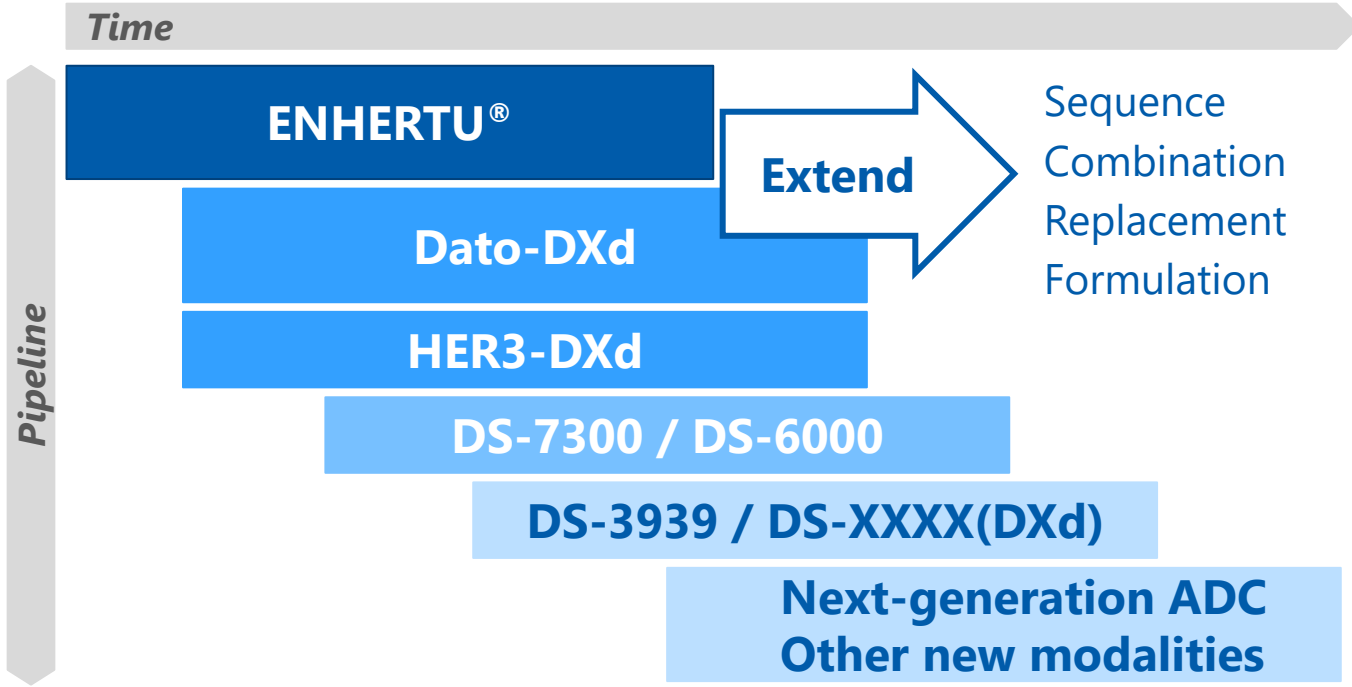
AML: acute myeloid leukemia, OVC: ovarian cancer, RCC: renal cell carcinoma, SCLC: small cell lung cancer

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

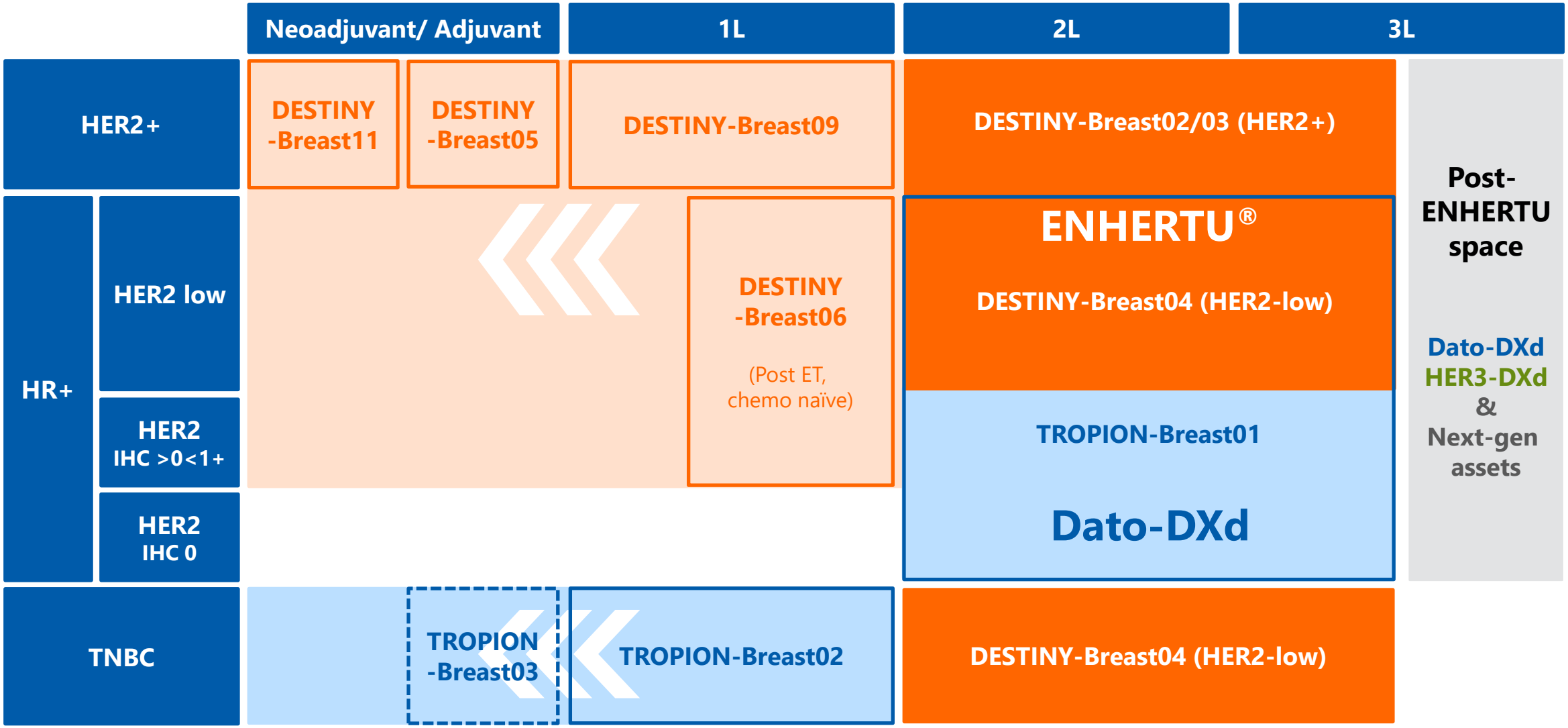
- Address unmet needs **after ENHERTU®** treatment
- Seek effective **treatment sequencing** between DXd-ADCs or novel assets including next-generation/new-concept ADCs
- Propose **novel combinations** to enhance efficacy

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

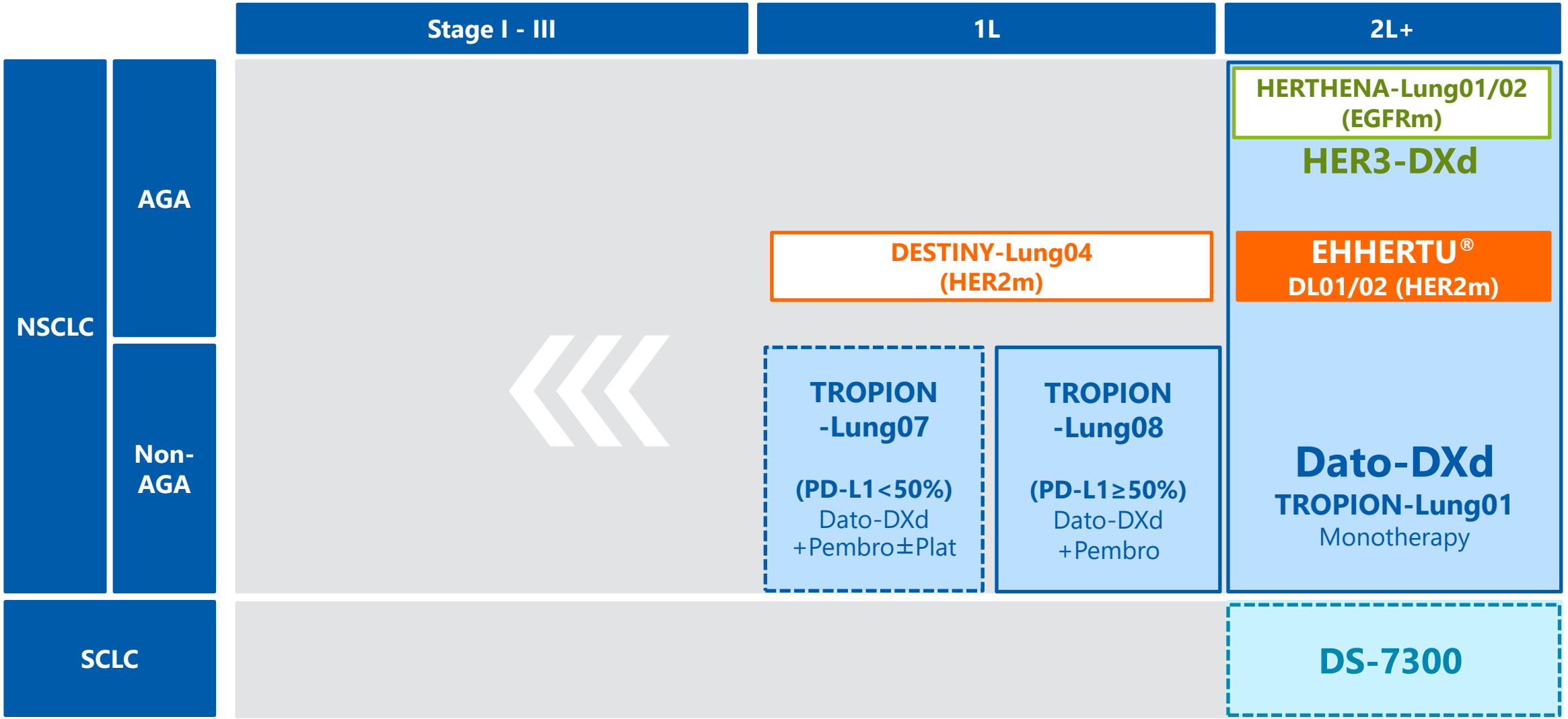
Our Lung Cancer Strategy

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 +

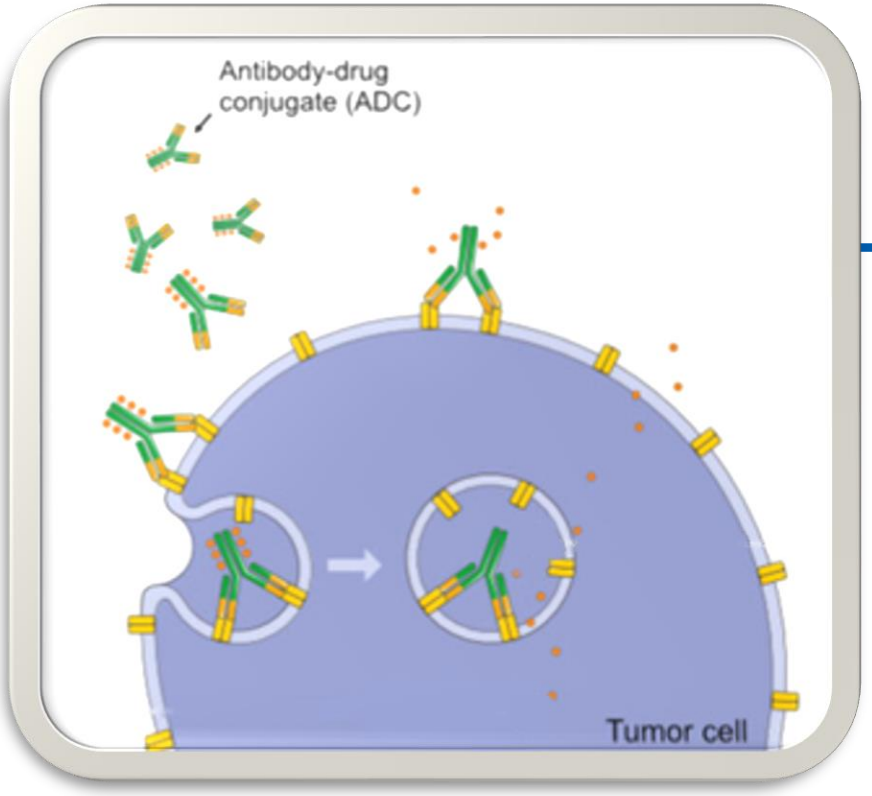
		Ph1 or Ph2	Ph3
Checkpoint Inhibitor	pembrolizumab	TROPION-Lung02	
		TROPION-Lung08	TROPION-Lung07
	durvalumab	DESTINY-Breast07	DESTINY-Breast08, BEGONIA
		TROPION-Breast03	
		DESTINY-Lung03	TROPION-Lung04, HUDSON
Targeted Therapy	pertuzumab	DESTINY-Breast09	DESTINY-Breast11
	tucatinib	DESTINY-Breast07	
	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
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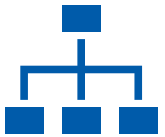
3. R&D Strategy
4. **Closing**
5. Q&A

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

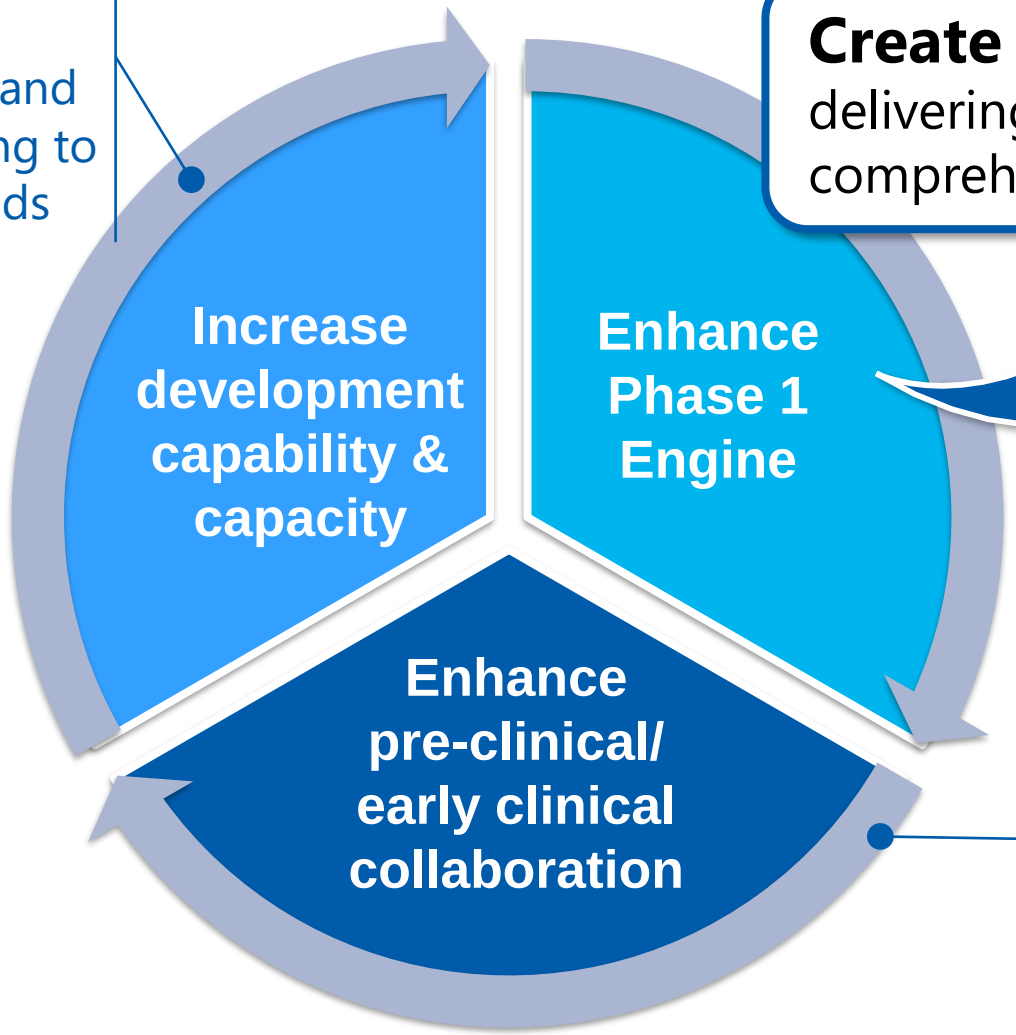
Achievements in 2022 (examples)

- **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

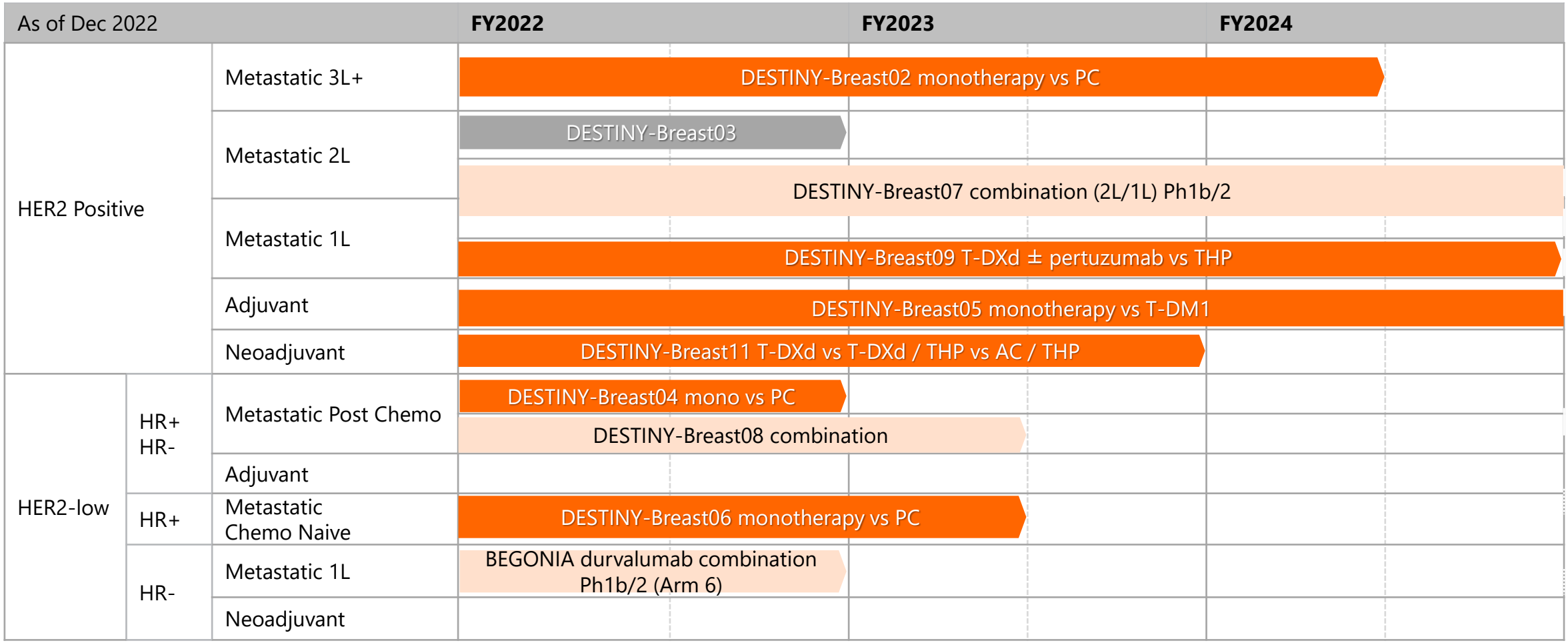
Project in oncology that is planned to be submitted for approval in some countries/regions based on the results of phase 2 trials

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



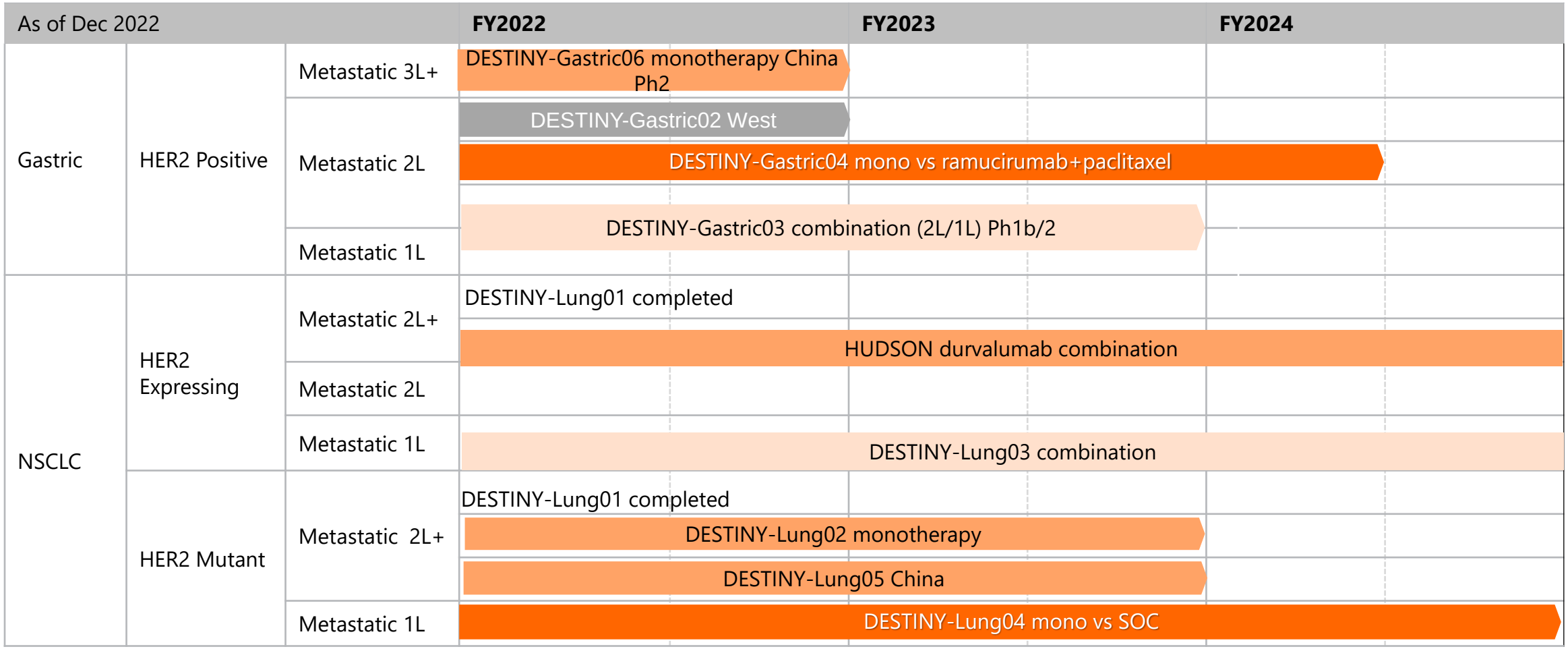
*Adjuvant therapy for patients with HER2+ early BC with high risk of disease recurrence who have residual invasive disease after receiving neoadjuvant therapy

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

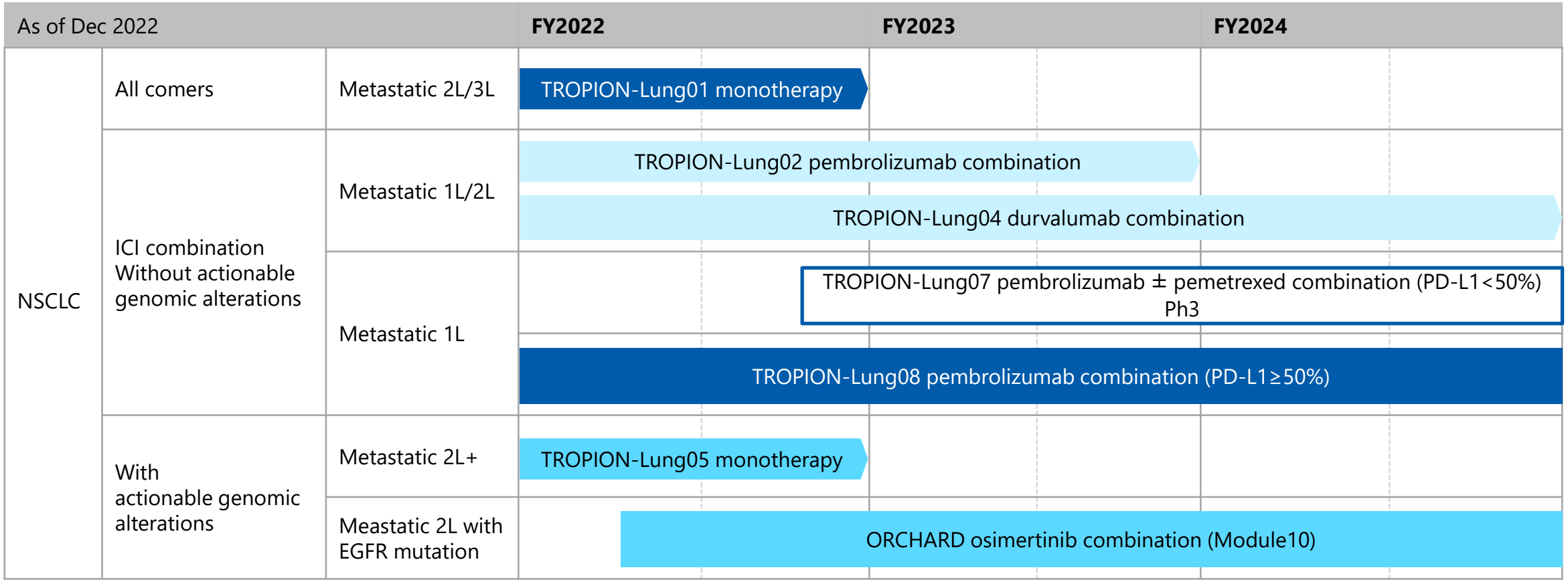
As of Dec 2022			FY2022	FY2023	FY2024
CRC	HER2 Expressing	Metastatic 3L	DESTINY-CRC02 monotherapy		
Other Tumors/ multiple tumors	HER2 Expressing	Metastatic 2L	Pembrolizumab combination (breast, NSCLC)		
			DESTINY-PanTumor02		
	HER2 Mutant	Metastatic 2L	DESTINY-PanTumor01		
			PETRA AZD5305 combination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

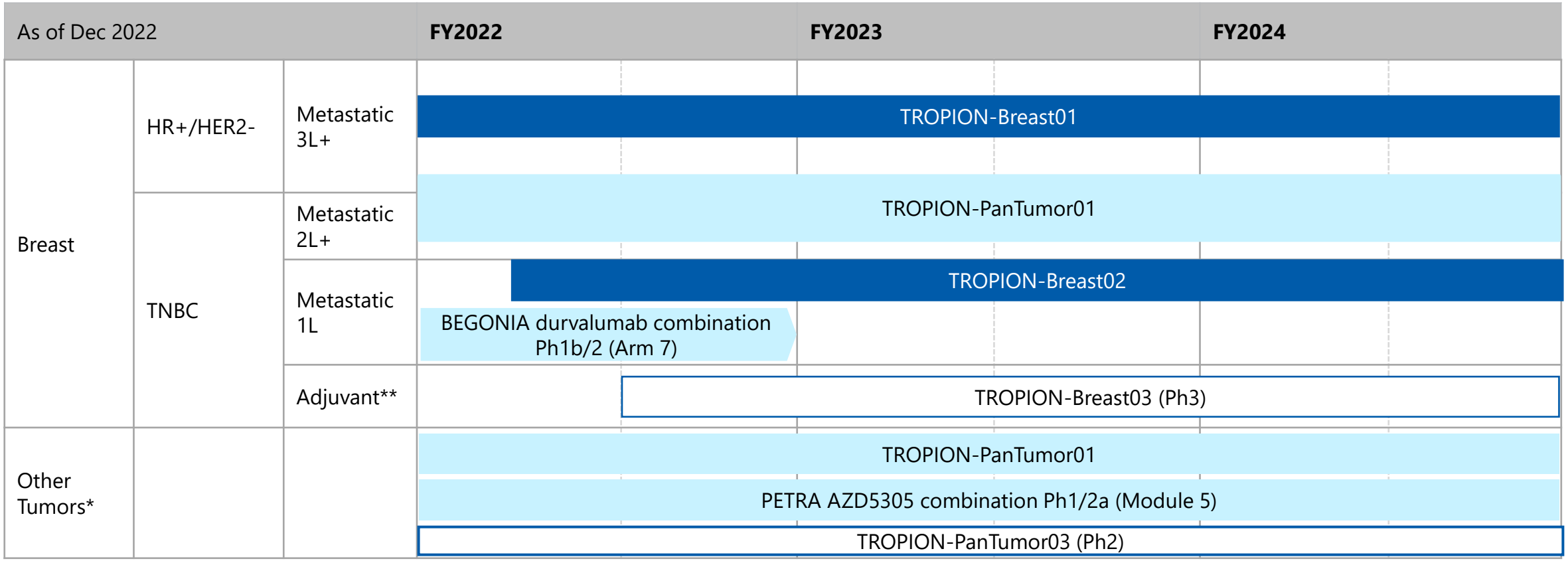


Ph 1 ongoing | Ph 2 ongoing | Ph 3 ongoing | New | Completed

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



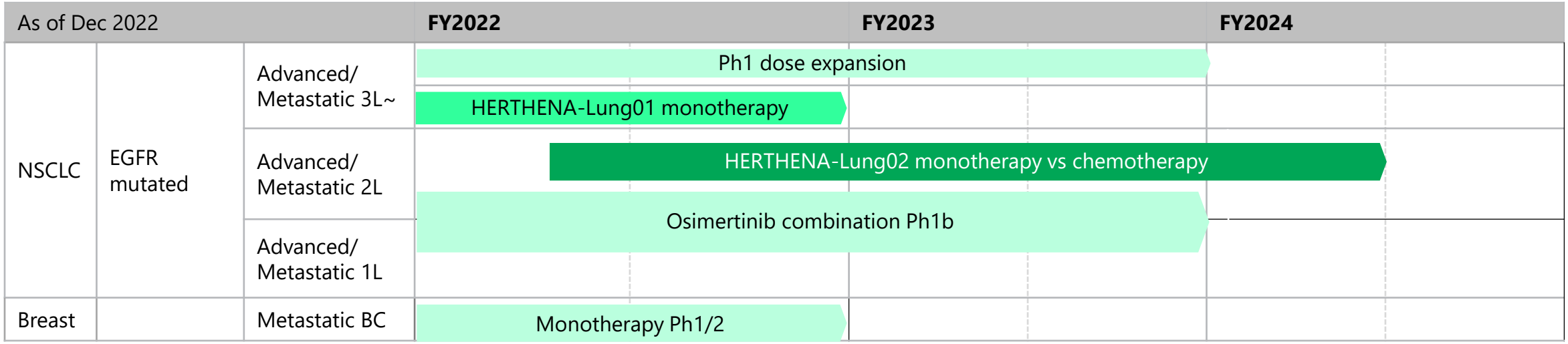
*Other tumors are gastric, esophageal, urothelial, SCLC, endometrial, CRPC, etc. Inclusion of these tumors is based upon TROP2 expression as well as preclinical and other evidence that Dato-DXd may be effective.
**Adjuvant therapy for patients with TNBC with residual disease after neoadjuvant therapy

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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