Investor science conference call: European Society for Medical Oncology (ESMO) Congress 2021

Conference call for investors and analysts

20 September 2021

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Speakers

Dr Sara Hurvitz
Senior Investigator,
DESTINY-Breast03 and Professor at David Geffen School of Medicine at UCLA

Susan Galbraith
Executive Vice President,
Oncology R&D

Dave Fredrickson
Executive Vice President,
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Cristian Massacesi
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Sunil Verma
Vice President,
Oncology R&D, Late-Stage Development Breast Cancer

Chris Sheldon
Vice President,
Head of Investor Relations

Agenda

1. Introduction: AstraZeneca @ ESMO 2021
2. *Enhertu* (T-DXd) Phase III DESTINY-Breast03 trial
3. What's next for *Enhertu*?
4. ESMO 2021 other highlights: *Enhertu* and *Imfinzi*
5. Closing and Q&A

1

Introduction

Susan Galbraith

Executive Vice President,
Oncology R&D

Comprehensive portfolio to combat cancer

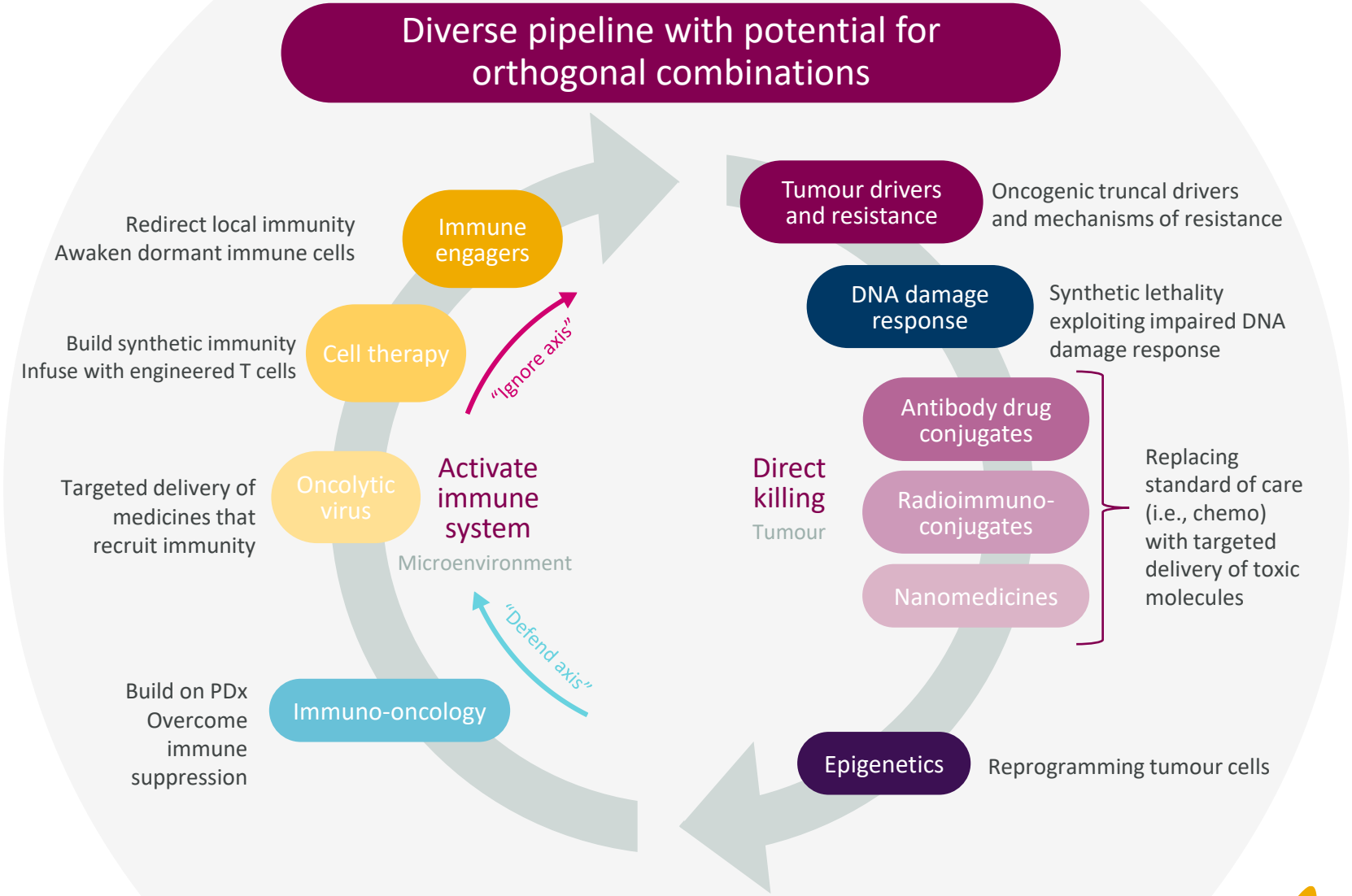
ENHERTU®
fam-trastuzumab deruxtecan-nxki
20 mg/mL INJECTION FOR INTRAVENOUS USE

IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL

Lynparza™
olaparib

TAGRISSO®
osimertinib

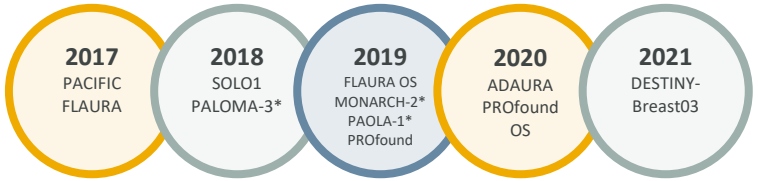
CALQUENCE®
(acalabrutinib) 100 mg capsules



Source: AstraZeneca.

ESMO 2021

5 years of Presidential Symposia/Presentations



65 abstracts with 20 oral presentations

- **One** Presidential presentation
- **Eight** Proffered paper oral presentations
- **11** Mini oral presentations
- **45** Posters
- **65** Abstracts

Data highlights

- ***Enhertu* in breast cancer**
  DESTINY-Breast03
- ***Enhertu* in other cancers**
  DESTINY-Gastric02, DESTINY-Lung01
- ***Imfinzi***
  COAST, CASPIAN, PACIFIC-R
- *Tagrisso, Lynparza,*
  datopotamab deruxtecan and capivasertib

*Alliance presentations. Source: ESMO 2021 accepted abstracts. 23 additional presentations at ESMO 2021 will feature AstraZeneca medicines and potential new medicines but were not supported by AstraZeneca.

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Enhertu (T-DXd) DESTINY-Breast03

Dr Sara Hurvitz

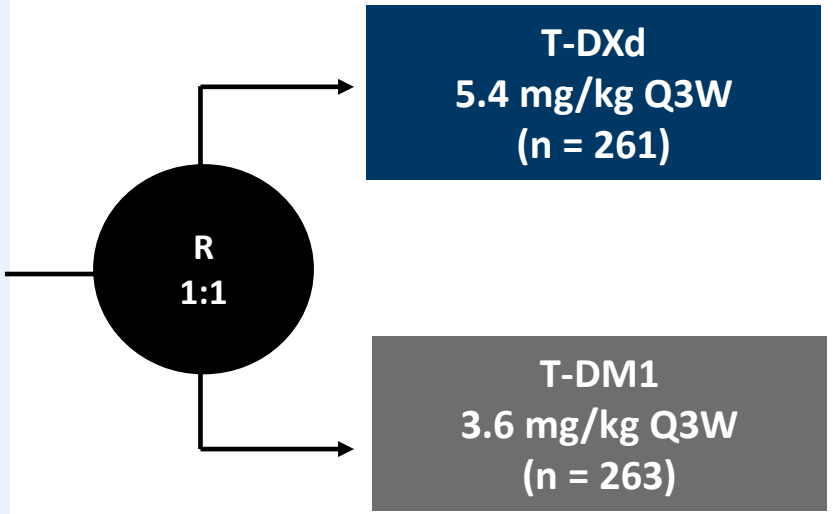
Senior Investigator,
DESTINY-Breast03
Phase III trial

DESTINY-Breast03: first randomised phase III trial of T-DXd

An open-label, multicentre study (NCT03529110)

Patients
- Unresectable or metastatic HER2-positive[1] breast cancer
- Previously treated with trastuzumab and taxane in advanced/metastatic setting[2]
- Could have clinically stable, treated brain metastases

Stratification factors
- Hormone receptor status
- Prior treatment with pertuzumab
- History of visceral disease



Primary endpoint
- PFS (BICR)

Key secondary endpoint
- OS

Secondary endpoints
- ORR (BICR and investigator)
- DOR (BICR)
- PFS (investigator)
- Safety

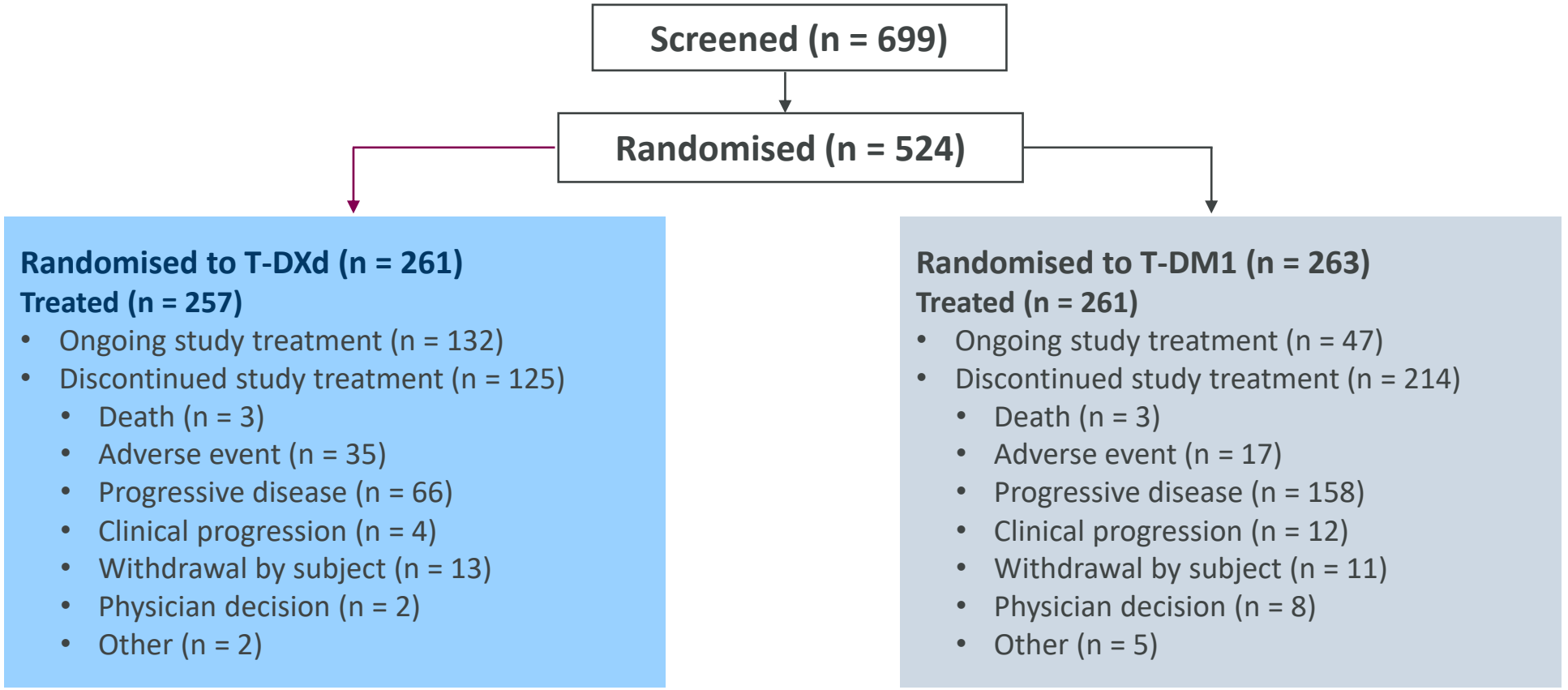
Interim analysis for PFS (data cutoff: May 21, 2021)
- Efficacy boundary for superiority: $P < 0.000204$ (based on 245 events)
- IDMC recommendation to unblind study (July 30, 2021)

Key secondary endpoint, OS: boundary for efficacy: $P < 0.000265$ (based on 86 events)

T-DXd, trastuzumab deruxtecan; T-DM1, ado-trastuzumab emtansine; BICR, blinded independent central review; DOR, duration of response; HER2, human epidermal growth factor receptor 2; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; Q3W, every 3 weeks.

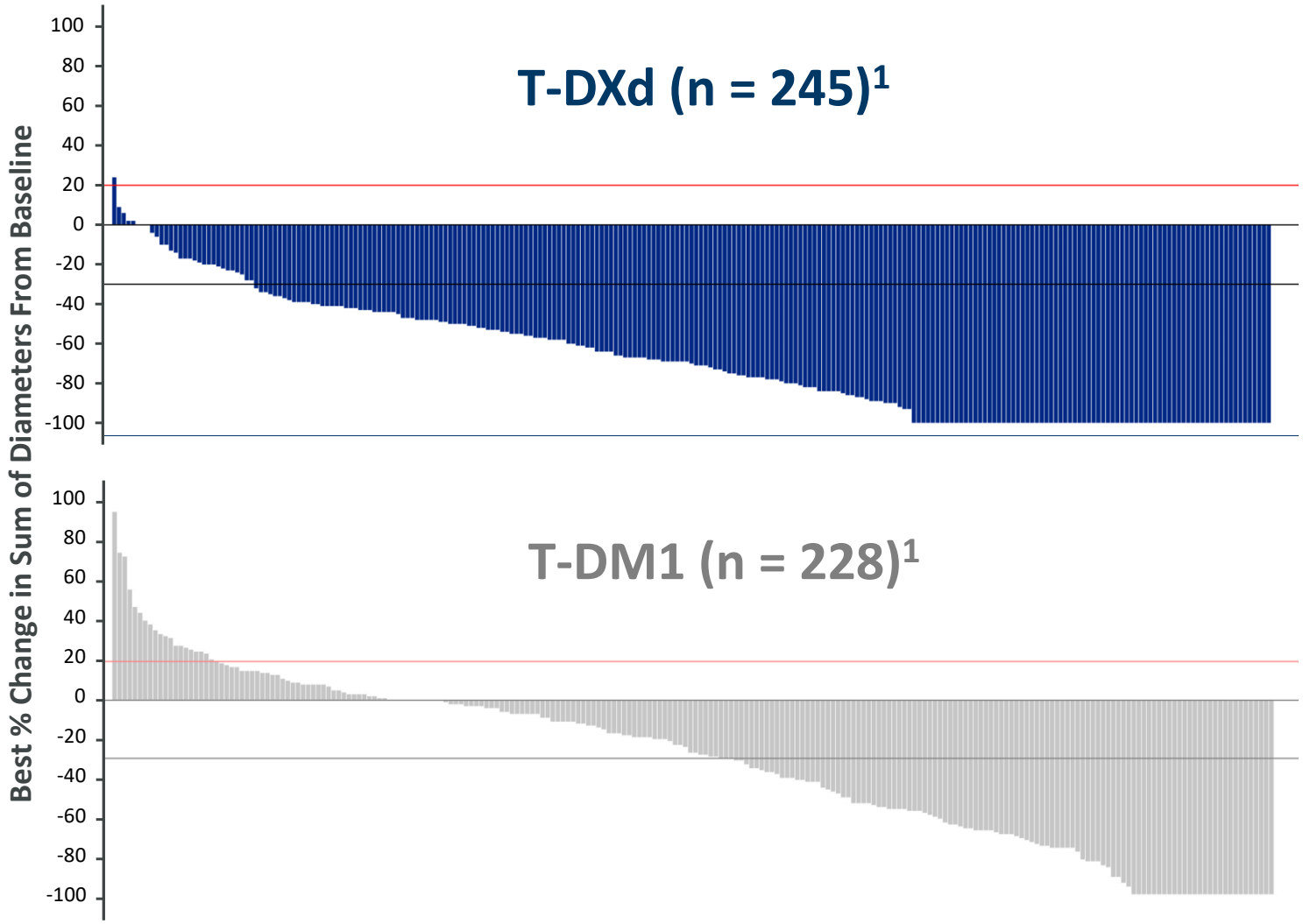
1. HER2 IHC3+ or IHC2+/ISH+ based on central confirmation. 2. Progression during or <6 months after completing adjuvant therapy involving trastuzumab and taxane.

Patient disposition



Median follow up for T-DXd was 16.2 months and for T-DM1 was 15.3 months

Efficacy: confirmed ORR and best overall response



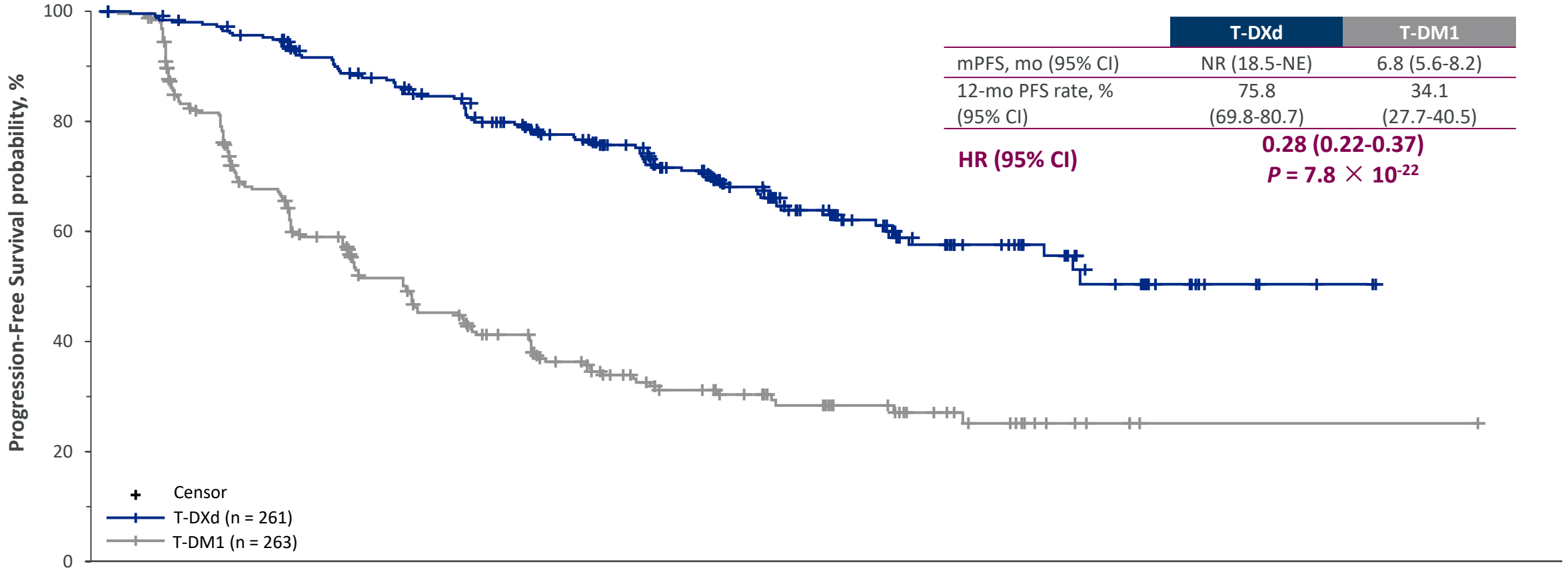
	T-DXd (n = 261)	T-DM1 (n = 263)
Confirmed ORR		
n (%)[2]	208 **(79.7)**	90 **(34.2)**
[95% CI]	[74.3-84.4]	[28.5-40.3]
	P < .0001	
CR	42 **(16.1)**	23 **(8.7)**
PR	166 **(63.6)**	67 **(25.5)**
SD	44 (16.9)	112 (42.6)
PD	3 (1.1)	46 (17.5)
Not evaluable	6 (2.3)	15 (5.7)
CR + PR + SD (DCR)	252 (96.6)	202 (76.8)

CI, confidence interval; CR, complete response; DCR, disease control rate; PD, progressive disease; PR, partial response; SD, stable disease.

1. Only subjects with measurable disease at baseline and at least one postbaseline target lesion assessment are included. 2. Based on BICR.

Red line at 20% indicates progressive disease; black line at -30% indicates partial response.

Primary endpoint: PFS by BICR



	T-DXd	T-DM1
mPFS, mo (95% CI)	NR (18.5-NE)	6.8 (5.6-8.2)
12-mo PFS rate, % (95% CI)	75.8 (69.8-80.7)	34.1 (27.7-40.5)
HR (95% CI)	**0.28 (0.22-0.37)**	
	***P* = 7.8 × 10^{-22}**	

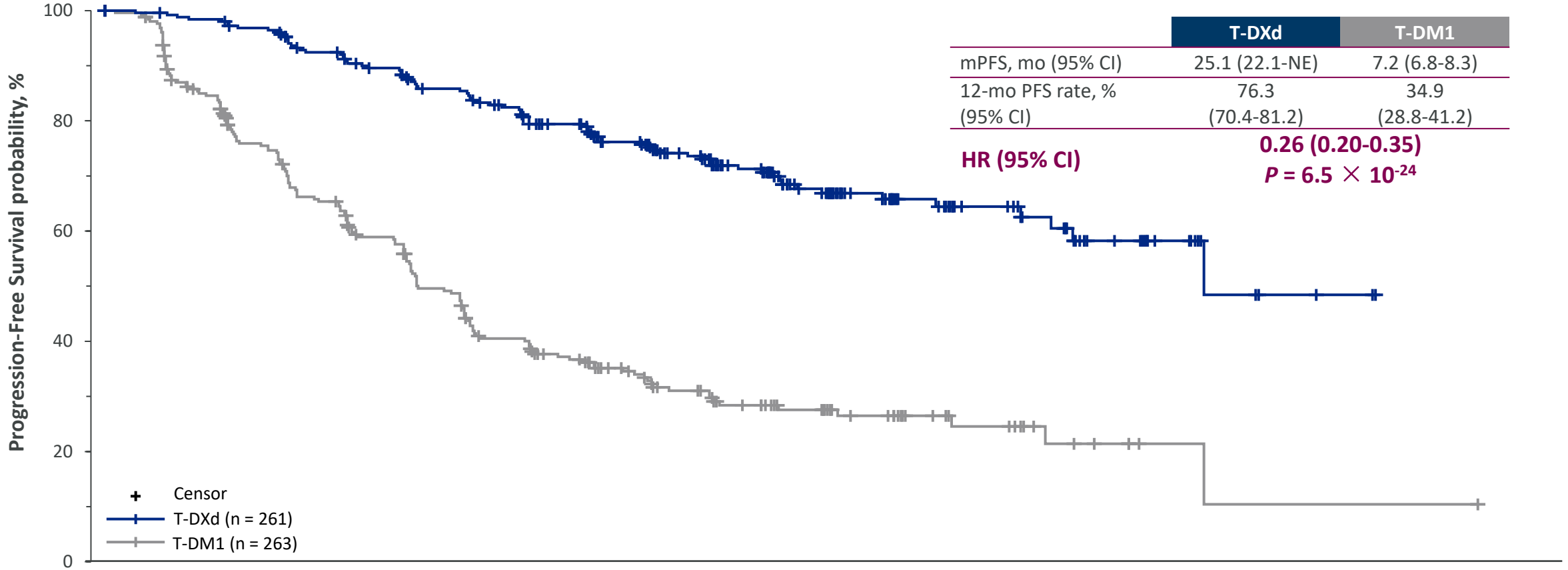
Patients Still at Risk:

T-DXd (261)	261	256	250	244	240	224	214	202	200	183	168	164	150	132	112	105	79	64	53	45	36	29	25	19	10	6	5	3	2	0	0	0	0
T-DM1 (263)	263	252	200	163	155	132	108	96	93	78	65	60	51	43	37	34	29	23	21	16	12	8	6	4	1	1	1	1	1	1	1	1	0

Median PFS follow up for T-DXd was 15.5 months (range, 15.1-16.1) and for T-DM1 was 13.9 months (range, 11.8-15.1).

HR hazard ratio; INV, investigator; mo, month; NE, not estimable; NR, not reached.

Secondary Endpoint: PFS by investigator assessment



	T-DXd	T-DM1
mPFS, mo (95% CI)	25.1 (22.1-NE)	7.2 (6.8-8.3)
12-mo PFS rate, % (95% CI)	76.3 (70.4-81.2)	34.9 (28.8-41.2)

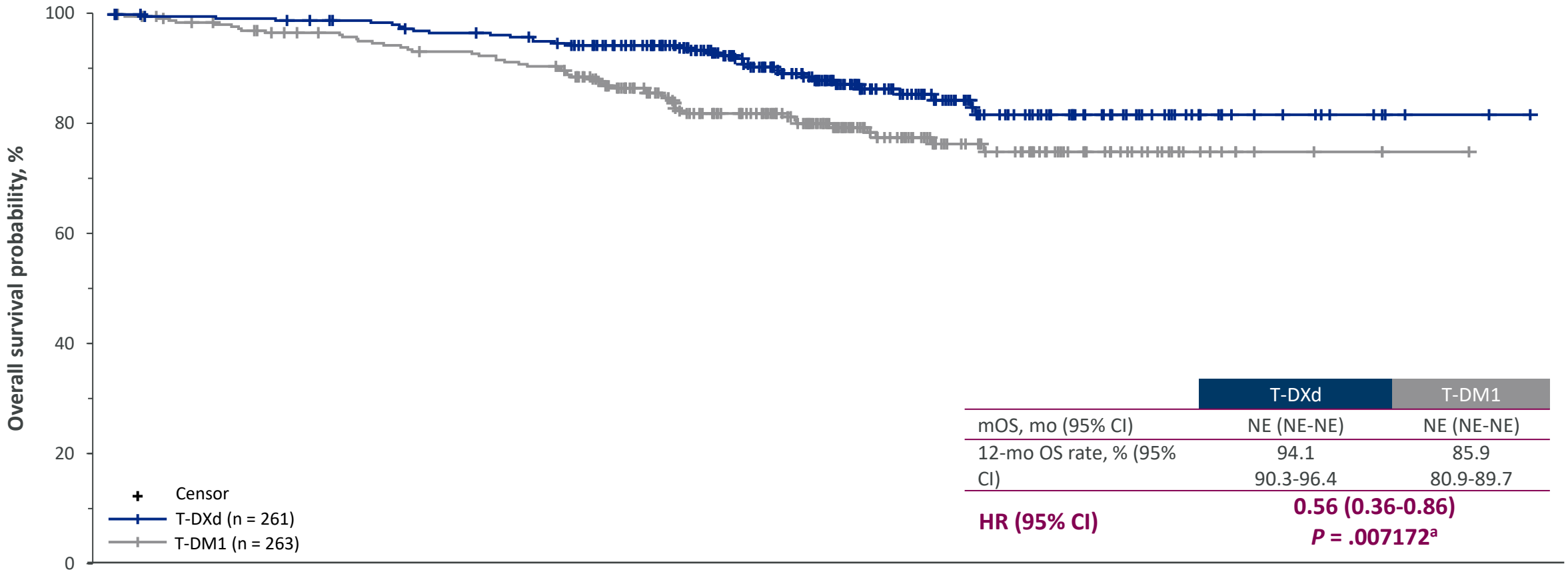
HR (95% CI) **0.26 (0.20-0.35)**

***P* = 6.5 × 10^{-24}**

Patients Still at Risk:

T-DXd (261)	261	256	250	244	240	224	214	202	200	183	168	164	150	132	112	105	79	64	53	45	36	29	25	19	10	6	5	3	2	0	0	0	0
T-DM1 (263)	263	252	200	163	155	132	108	96	93	78	65	60	51	43	37	34	29	23	21	16	12	8	6	4	1	1	1	1	1	1	1	1	0

Key secondary endpoint: overall survival



	T-DXd	T-DM1
mOS, mo (95% CI)	NE (NE-NE)	NE (NE-NE)
12-mo OS rate, % (95% CI)	94.1 90.3-96.4	85.9 80.9-89.7
HR (95% CI)	**0.56 (0.36-0.86)** ***P* = .007172[a]**	

Patients Still at Risk:

T-DXd (261)	261	256	250	244	240	224	214	202	200	183	168	164	150	132	112	105	79	64	53	45	36	29	25	19	10	6	5	3	2	0	0	0	0	0
T-DM1 (263)	263	252	200	163	155	132	108	96	93	78	65	60	51	43	37	34	29	23	21	16	12	8	6	4	1	1	1	1	1	1	1	1	0	0

Early OS data with relatively few events (33 in the T-DXd arm, 53 in the T-DM1 arm)

a) *P* = .007172, but does not cross pre-specified boundary of *P* < .000265

Drug-related TEAEs in ≥20% of patients

System Organ Class Preferred term, n (%)	T-DXd (n = 257)		T-DM1 (n = 261)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Blood and lymphatic system disorders				
Neutropenia[1]	110 (42.8)	49 (19.1)	29 (11.1)	8 (3.1)
Anemia[2]	78 (30.4)	15 (5.8)	37 (14.2)	11 (4.2)
Leukopenia[3]	77 (30.0)	17 (6.6)	20 (7.7)	1 (0.4)
Thrombocytopenia[4]	64 (24.9)	18 (7.0)	135 (51.7)	65 (24.9)
Gastrointestinal disorders				
Nausea	187 (72.8)	17 (6.6)	72 (27.6)	1 (0.4)
Vomiting	113 (44.0)	4 (1.6)	15 (5.7)	1 (0.4)
Diarrhea	61 (23.7)	1 (0.4)	10 (3.8)	1 (0.4)
Constipation	58 (22.6)	0	25 (9.6)	0
General disorders				
Fatigue[5]	115 (44.7)	13 (5.1)	77 (29.5)	2 (0.8)
Investigations				
AST increased	60 (23.3)	2 (0.8)	97 (37.2)	13 (5.0)
ALT increased	50 (19.5)	4 (1.6)	71 (27.2)	12 (4.6)
Metabolism and nutrition disorders				
Decreased appetite	67 (26.1)	3 (1.2)	33 (12.6)	0
Skin and subcutaneous tissue disorders				
Alopecia[6]	93 (36.2)	1 (0.4)	6 (2.3)	0

Most drug-related TEAEs were gastrointestinal or haematological in nature

Adverse events were managed according to the protocol. TEAE, Treatment emergent adverse events.

1. This category includes the preferred terms neutrophil count decreased and neutropenia 2. This category includes the preferred terms hamoglobin decreased, red blood cell count decreased, anemia, and hematocrit decreased 3. This category includes the preferred terms white blood cell count decreased and leukopenia 4.Tthis category includes platelet count decreased and thrombocytopenia 5. This category includes the preferred terms fatigue, asthenia, and malaise 6. Grade 1 alopecia: T-DXd = 26.5%, T-DM1 = 2.3%; grade 2, T-DXd = 9.3%.

Adverse events of special interest

Adjudicated as drug-related ILD/pneumonitis[1], n (%)						
n (%)	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**	**Any Grade**
T-DXd (n = 257)	7 (2.7)	18 (7.0)	2 (0.8)	0	0	27 (10.5)
T-DM1 (n = 261)	4 (1.5)	1 (0.4)	0	0	0	5 (1.9)

- There were no grade 4 or 5 adjudicated drug-related ILD/pneumonitis events observed with T-DXd

LVEF, n (%)						
n (%)	**Grade 1**	**Grade 2**	**Grade 3**	**Grade 4**	**Grade 5**	**Any Grade**
T-DXd (n = 257)	1 (0.4)[2]	6 (2.3)[3]	0	0	0	7 (2.7)
T-DM1 (n = 261)	0	1 (0.4)[3]	0	0	0	1 (0.4)

- In the T-DXd arm, all LVEF adverse events reported were asymptomatic and no cases of cardiac failure occurred

ILD, interstitial lung disease; LVEF, left-ventricular ejection fraction.

1. Patients with prior history of ILD/pneumonitis requiring steroids were excluded 2. Left ventricular dysfunction 3. Decreased ejection fraction.

Conclusions

In the first randomised Phase III trial in breast cancer, T-DXd demonstrated:

Highly clinically meaningful and statistically significant improvement in PFS compared with T-DM1 in patients with HER2-positive mBC

- PFS HR of 0.28 ($P = 7.8 \times 10^{-22}$)
- Consistent benefit seen across key subgroups and efficacy endpoints, with a confirmed ORR for T-DXd of 79.7% vs 34.2% for T-DM1 (CR, 16.1% vs 8.7%)

Encouraging OS trend at the time of first interim analysis

- 12-month OS rate for T-DXd was 94.1% vs 85.9% for T-DM1

A safety profile that is comparable between the two arms

- Similar rates of all grade and grade ≥3 drug-related TEAEs between arms
- There were no grade 4 or 5 ILD/pneumonitis events in either arm

These data support T-DXd becoming the standard of care for 2L HER2-positive mBC

mBC, metastatic breast cancer.

T-DXd transforms the treatment paradigm

for patients with metastatic HER2+ breast cancer

Second-line monotherapy data that rivals first-line current standard triplet therapy

Consistency across all sub-groups

Improved safety profile

1L **Trastuzumab + pertuzumab + taxane,**
CLEOPATRA[1] : mPFS = 18.7 months

1L **T-DM1 + pertuzumab,**
MARIANNE[2]: mPFS = 15.2 months

2L **T-DXd**
DESTINY-Breast03[3]: mPFS = not yet reached
Investigator-assessed PFS: 25.1 months

2L+ **T-DM1, EMILIA[4]:**
mPFS = 9.6 months

3L+ **T-DXd**
DESTINY-Breast01[5]: mPFS = 19.4 months

1. Swain SM, Baselga J et al. *N Engl J Med*. 2015;372:724-34. 2. Perez J et al. Expert Opin Biol Ther. 2021;21:811-24 3. Cortés, J, Presented at ESMO 2021, Abstract LBA1 on 18 September 2021. 4. Verma S et al. *N Engl J Med.* 2012;367:1783-91 5. DB01: Modi S et al. Presented at San Antonio Breast Cancer Symposium. 2020. Poster PD3-06.

3

What's next for *Enhertu*?

Dave Fredrickson

Executive Vice President,
Oncology Business Unit

Enhertu: a new standard of care

for patients with HER2-positive metastatic breast cancer

Today: 3rd-line+ mBC

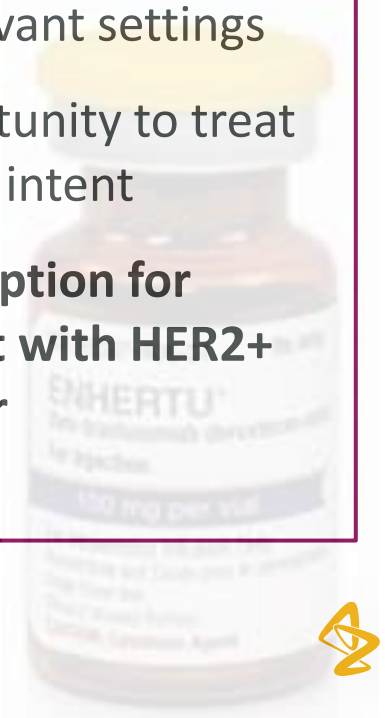
- Strong launch trajectory: market leader in every major country launched[1]
- >7,000 patients treated to date
- Partnering with healthcare practitioners with treatment-specific guidance

2022: 2nd-line mBC

- DESTINY-Breast03: **unprecedented benefit** in 2nd line
- Consistent efficacy across all sub-groups
- Safety profile and prolonged PFS benefit supports extended duration on therapy

Future: earlier settings, combinations

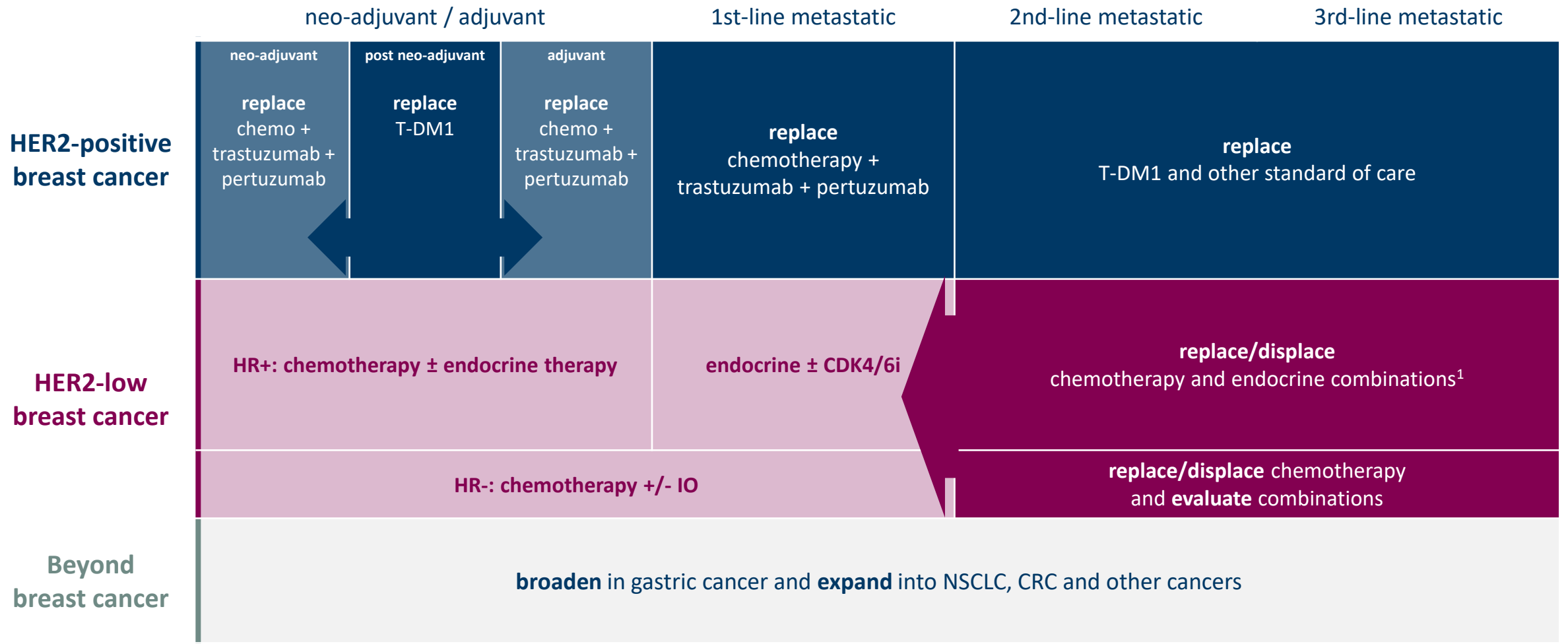
- Efficacy and safety profile support development in 1st line and adjuvant settings
- Opens opportunity to treat with curative intent
- **An *Enhertu* option for every patient with HER2+ breast cancer**



1. UK National Health Service – Cancer Drugs Fund, AstraZeneca market studies.

Enhertu in breast cancer and beyond

Opportunities across treatment settings



HR = hormone-receptor positive; CDK4/6i = cyclin-dependent kinase 4/6 inhibitor; HR- = hormone-receptor negative; IO = immuno-oncology. NSCLC = non-small cell lung cancer; CRC = colorectal cancer.

1. in endocrine therapy refractory/resistant patients.

4

Other ESMO 2021 highlights - *Enhertu* and *Imfinzi*

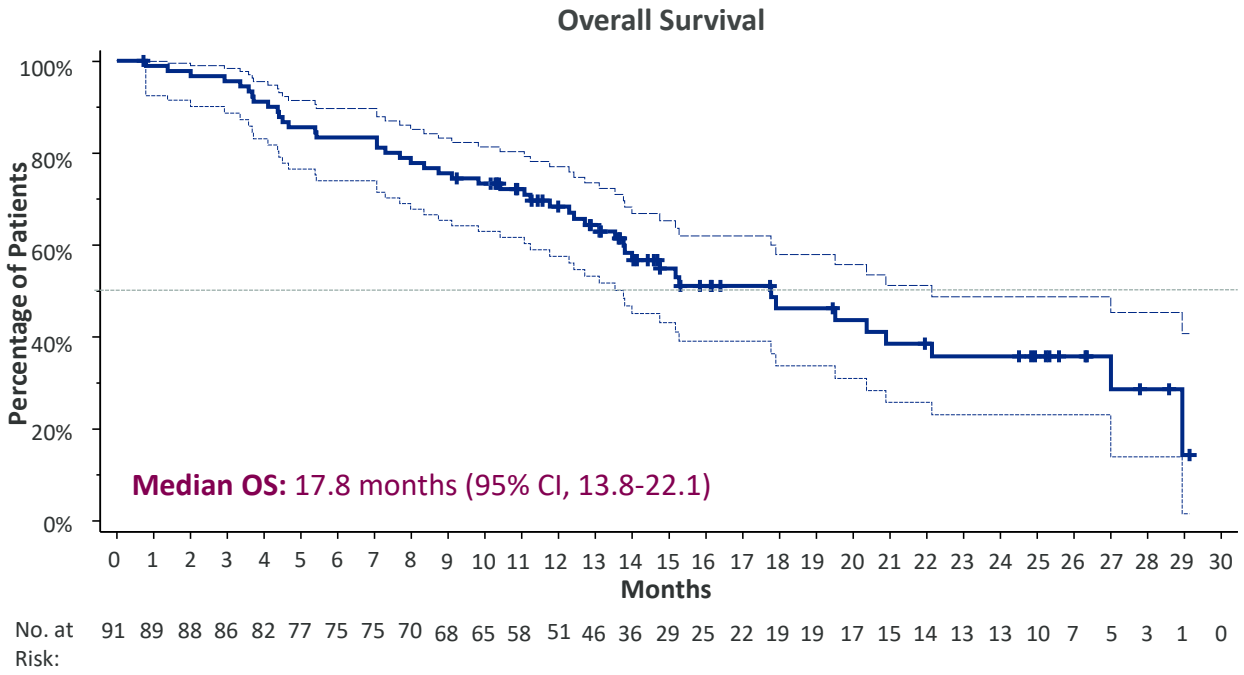
Susan Galbraith

Executive Vice President,
Oncology R&D

Enhertu: extending clinical benefit to other cancers

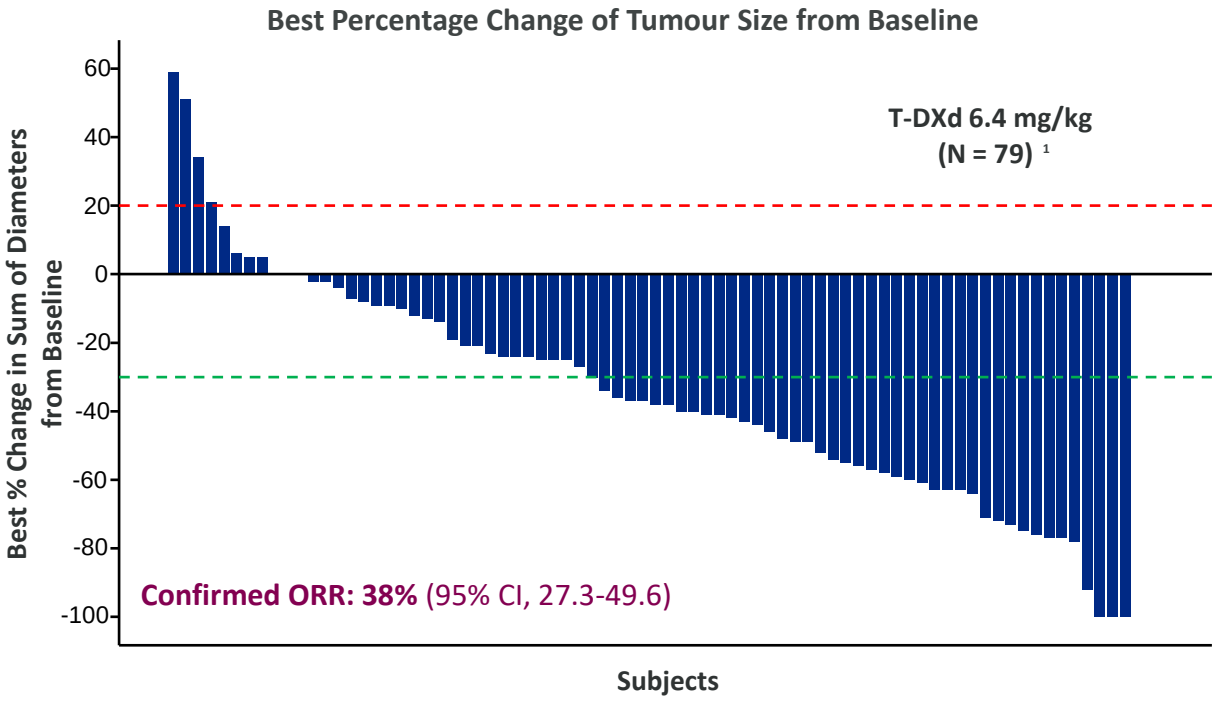
Phase II DESTINY-Lung01

Robust and durable anti-cancer activity in patients with previously treated HER2m NSCLC



Phase II DESTINY-Gastric02

Efficacy results demonstrate clinically meaningful and durable responses



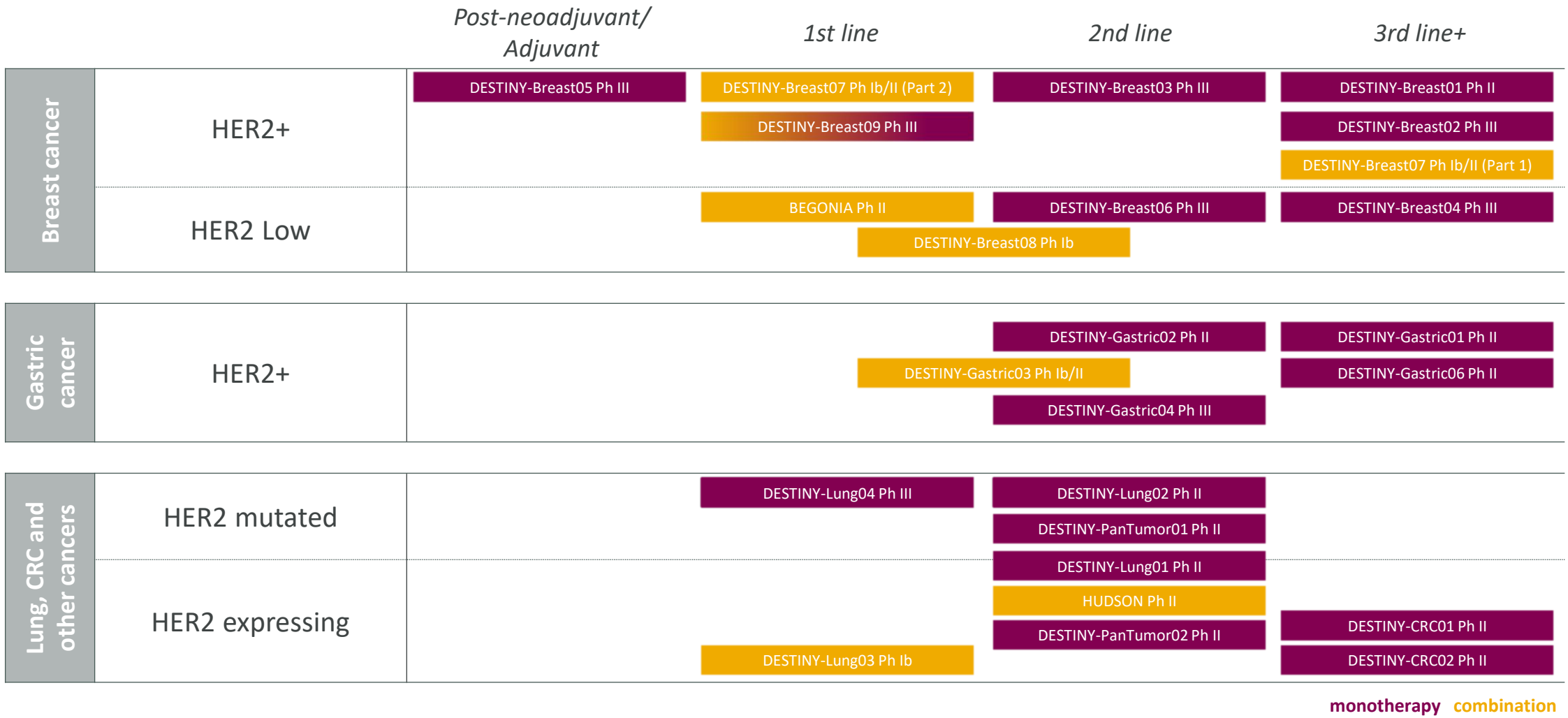
Median PFS follow-up for T-DXd was 15.5 months (range, 15.1-16.1) and for T-DM1 was 13.9 months (range, 11.8-15.1)

Dashed lines indicate the 95% CI. Of 91 patients, 47 had died by the cutoff date.

Data for 44 patients were censored as indicated by tick marks; patients were censored if they discounted treatment.

Enhertu: an extensive clinical development programme

Focusing on HER2+ and HER2-low breast cancer and other cancers



Imfinzi in Stage III, unresectable non-small cell lung cancer

Cementing leadership in this potentially curative setting

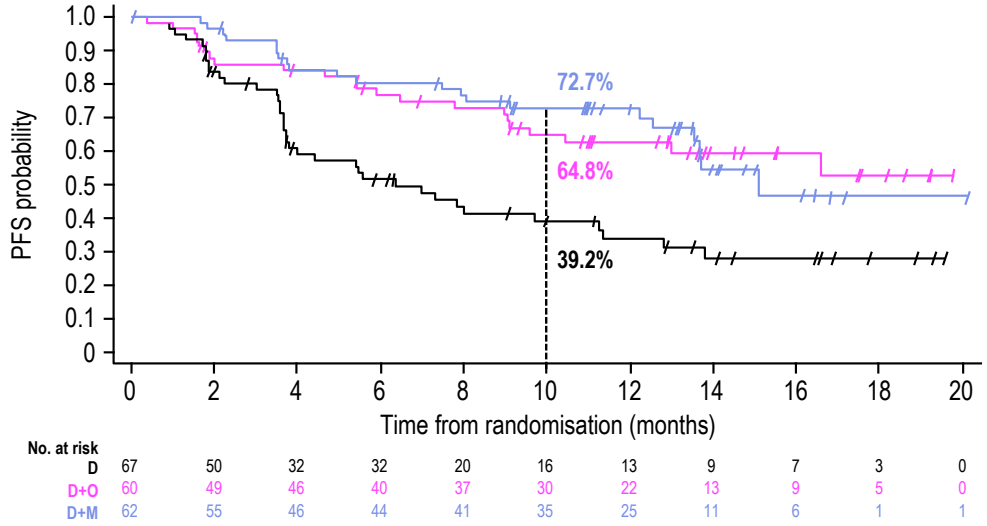
PACIFIC-R: Real world PFS

Imfinzi after CRT for a median duration of ~11 months is effective in a large, real-world cohort of patients with unresectable Stage III NSCLC

	PACIFIC-R FAS	PACIFIC trial (durva. arm)[1]
PFS	N=1,399	N=476
Total events, N (%)	737 (52.7)	268 (56.3)[†]
Progression per RECIST	456 (32.6)	
Progression per physician assessment	170 (12.2)	
	30 (2.1)	
Progression, assessment unknown	81 (5.8)	
Deaths in absence of progression		
Median PFS, months	**21.7**	**16.9**
95% CI	19.2–24.5	13.0–23.9
PFS rate, %		
12 months	62.4	55.7
24 months	48.2	45.0

COAST: PFS by investigator's analysis

First randomised Phase II to show evidence of improved outcomes with novel IO combinations in the PACIFIC setting



	D	D+O	D+M
Events/patients, n	38/67	22/60	21/62
mPFS, months (95% CI)[1]	**6.3** (3.7–11.2)	**NR** (10.4–NE)	**15.1** (13.6–NE)
HR (95% CI)[2,3]	–	**0.44** (0.26–0.75)	**0.65** (0.49–0.85)

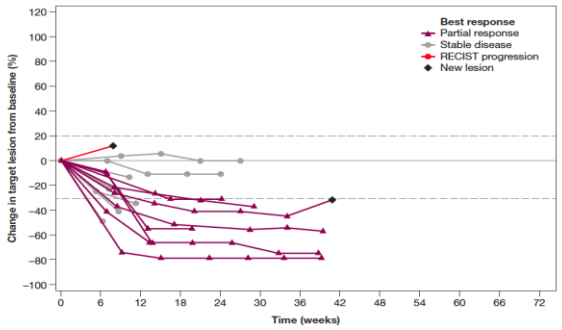
1. Spigel DR, et al. *J Clin Oncol* 2021;39(15_suppl):8511.
*Range for median follow-up duration = 0–35.6 months; [†]In the PACIFIC trial, PFS was assessed by BICR per RECIST v1.1; [‡] Per local regulations. FAS, full analysis set; rw, real-world; UK, United Kingdom.

Data cut-off: 17 May 2021 (median follow-up of 11.5 months; range, 0.4–23.4) D, durvalumab; M, monalizumab; O, oleclumab.
1. Interim analysis performed when all patients had a 10mth min potential follow-up; Kaplan-Meier estimates for PFS, PFS rate and 95% CIs 2. PFS HR and 95% CI estimated by Cox regression model, stratified by histology (adenocarcinoma and non-adenocarcinoma) 3. Compared with the 67 and 64 patients in the D arm enrolled concurrently with patients in the D+O and D+M arms, respectively.

Imfinzi: extending IO leadership through portfolio combinations

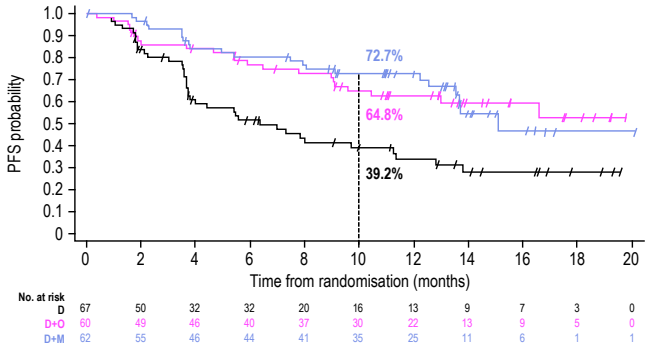
ADCs

POC: BEGONIA mBC 1L HER2-low/HR-



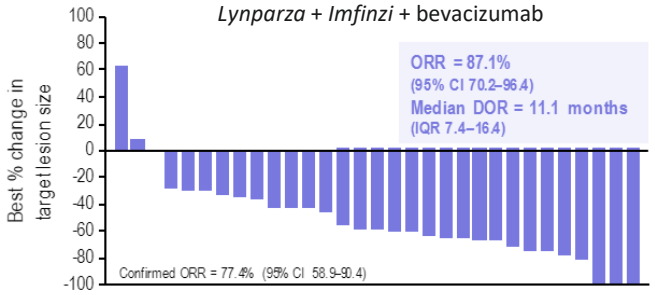
CD73, NKG2A

POC: COAST – Stg III UR NSCLC (below) / Study 5 (PDAC)



PARP inhibitor

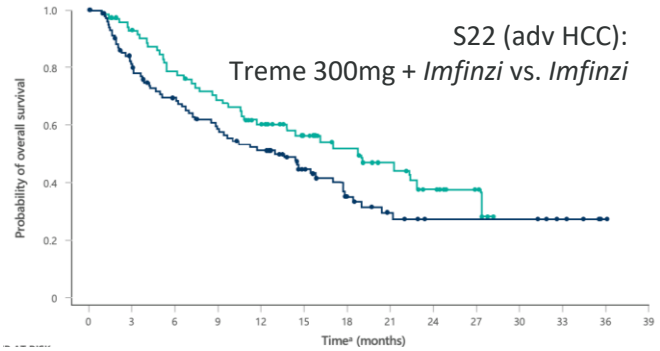
POC: MEDIOLA BRCAwt PSR ovarian (below) / BAYOU (UC)



CTLA4

POC: POSEIDON (adv NSCLC)/Study 22 (HCC)/MEDI5752 Ph II

S22 (adv HCC):
Treme 300mg + *Imfinzi* vs. *Imfinzi*



TIGIT

ARCUS BIOSCIENCES

Imfinzi + domvanalimab

Phase III (PACIFIC-8)

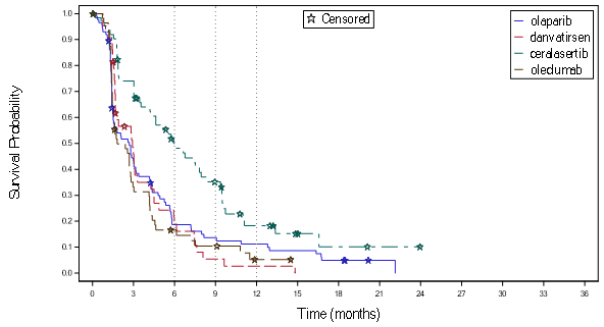
compugen
FROM CODE TO CURE™

AZD2936

Phase I/II (ARTEMIDE-01)

ATR inhibitor

POC: PDx relapse – HUDSON adv NSCLC (below) / VIKTORY adv M



ADCs = antibody drug conjugates; CD73 = cluster of differentiation 73; NKG2A = natural killer group 2 member A; PARPi = poly (ADP-ribose) polymerase; CTLA4 = cytotoxic T-lymphocyte-associated protein 4; HCC = hepatocellular carcinoma; TIGIT = T cell immunoreceptor with Ig and ITIM domains; ATR = ataxia telangiectasia and rad3-related; POC = proof of concept; UR = unresectable; NSCLC = non small cell lung cancer; BRCAwt = breast cancer gene wildtype; PSR = platinum sensitive relapsed; PDAC = pancreatic ductal adenocarcinoma; UC = urothelial cancer; adv = advanced.

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Closing and Q&A

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A

Appendix

Enhertu: DESTINY-Lung01 trial design

Multi-centre, international, 2-cohort Phase II trial (NCT03505710)

Key eligibility criteria

- Unresectable/metastatic nonsquamous NSCLC
- Relapsed from or is refractory to standard treatment
- Measurable disease by RECIST v1.1
- Asymptomatic CNS metastases at baseline[1]
- ECOG PS of 0 or 1
- Locally reported HER2 mutation (for Cohort 2)[2]

Cohort 1: HER2-overexpressing[3] (IHC 3+ or IHC 2+) T-DXd 6.4 mg/kg q3w N = 49

Cohort 1a: HER2-overexpressing[3] (IHC 3+ or IHC 2+) T-DXd 5.4 mg/kg q3w N = 41

Cohort 2: HER2-mutated T-DXd 6.4 mg/kg q3w N = 42

Cohort 2 expansion: HER2-mutated T-DXd 6.4 mg/kg q3w N = 49

Primary end point

- Confirmed ORR by ICR[4]

Secondary end points

- DOR
- PFS
- OS
- DCR
- Safety

Exploratory end point

- Biomarkers of response

Data cutoff: May 3, 2021

- 91 patients with HER2m NSCLC were enrolled and treated with T-DXd
- 15 patients (16.5%) remain on treatment to date
- 76 patients (83.5%) discontinued, primarily for progressive disease (37.4%) and adverse events (29.7%)

1. Patients with asymptomatic brain metastases not requiring ongoing steroid or anticonvulsant therapy were allowed to enrol 2. HER2 mutation documented solely from a liquid biopsy could not be used for enrolment 3. HER2 overexpression without known HER2 mutation was assessed by local assessment of archival tissue and centrally confirmed 4. Per RECIST v1.1

ECOG PS = Eastern Cooperative Oncology Group performance status; ICR = independent central review; IHC = immunohistochemistry; q3w, every 3 weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1.

Enhertu: DESTINY-Gastric02 trial design

Open-label, multicentre Phase II trial in Western patients with HER2+ gastric or GEJ cancer (NCT04014075)

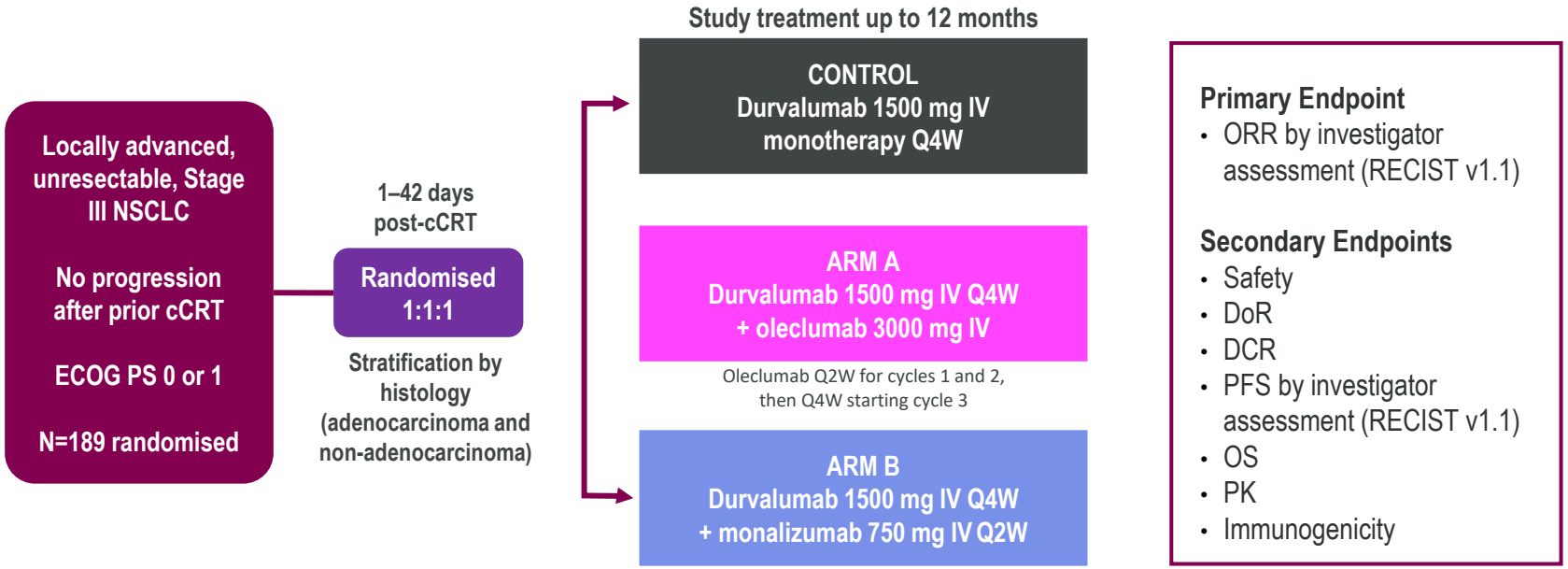
- DESTINY-Gastric02 is the first study focused only on second-line T-DXd monotherapy in Western patients with HER2+ gastric/GEJ cancer who have progressed on a trastuzumab-containing regimen
- It is the follow-on study to DESTINY-Gastric01, which evaluated T-DXd third-line or later in Asian patients[3]
- Patients were enrolled in Europe (Belgium, Great Britain, Italy, Spain) and the United States (data cutoff: April 9, 2021)

1. Enrollment of 80 patients was planned; actual enrollment was 79 patients 2. Other secondary endpoints were ORR, PFS, and DOR by investigator assessment, pharmacokinetics, anti-drug antibodies, and patient-reported outcomes 3. Shitara K et al. *N Engl J Med.* 2020;382:2419-30.

GEJ = gastroesophageal junction; ISH = in situ hybridisation.

Imfinzi: COAST trial design

A Phase II, randomised open-label trial

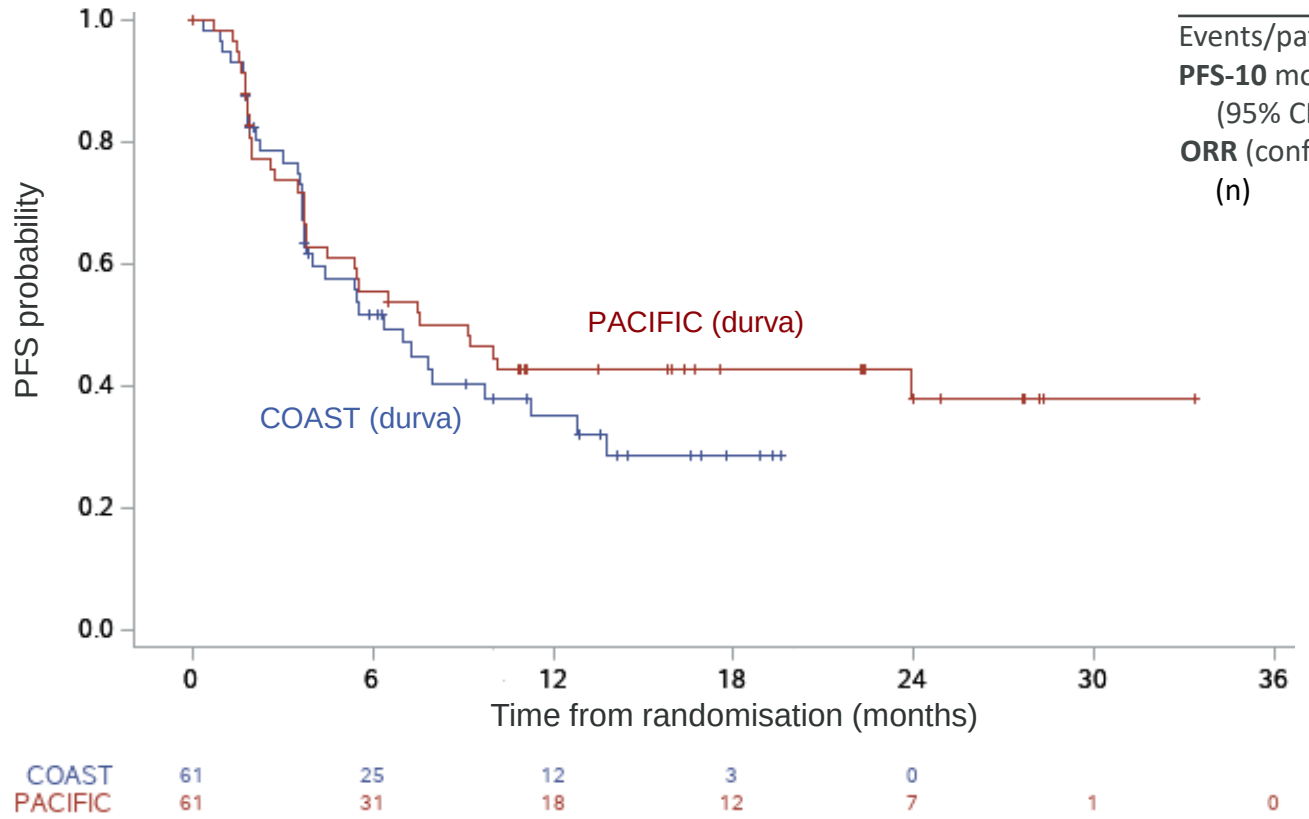


- A planned sample size of 60 patients per arm was designed to provide acceptable precision in estimating antitumour activities in an early phase setting
- Between Jan 2019 and Jul 2020, 189 patients were randomised of whom 186 received D (n=66), D+O (n=59) or D+M (n=61)
- As of 17 May 2021, all patients had a minimum of 10 months potential follow-up and the median actual follow-up was 11.5 months (range, 0.4–23.4; all patients)

IV = intravenous; PK = pharmacokinetics.

Imfinzi: Propensity score matching of COAST (durvalumab arm) with PACIFIC (durvalumab arm)

- **Matching variables**: Age (<75, ≥75), Race (Asian, Other), Prior therapy (Carboplatin, Cisplatin), Time from last radiation to randomisation (<14 days, ≥14 days), Best response to prior therapies (PR, SD) and Disease stage at entry (IIIA, IIIB, IIIC)



	COAST (D)	PACIFIC (D)
Events/patients, n	32/61	31/60
PFS-10 months	**38.0%**	**44.6%**
(95% CI)	(24.5–51.3%)	(31.3-57.1%)
ORR (conf + unconf), **%**	**24.6%**	**24.6%**
(n)	(15)	(15)

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