Lung Cancer UPDATES
ESMO HIGHLIGTHS
17-21 SEPTIEMBRE 2021

Iniciativa científica de:
GECP
lung cancer research

Targeted therapies in advanced NSCLC
Small cell lung cancer and others

Dr. Juan Coves Sarto

Hospital universitario Son Llàtzer

2021 ESMO congress

1172 MO

Durvalumab consolidation in patients with stage III non-resecable NSCLC with driver genomic alterations

M. Riudavets[1], E. Auclin[2], M. Mosteiro[3], N. Dempsey[4], M. Majem[5], R. Lobefaro[6], R. López-Castro[7], J. Bosch-Barrera[8], S. Pilotto[9], E. Escalera[10], M. Tagliamento[11], J. Mosquera[12], G. Zalcman[13], E. Nadal[3], G. Lopes[4], D. Signorelli[6], R. Garcia-Campelo[12], B. Besse[1], D. Planchard[1], L. Mezquita[14]

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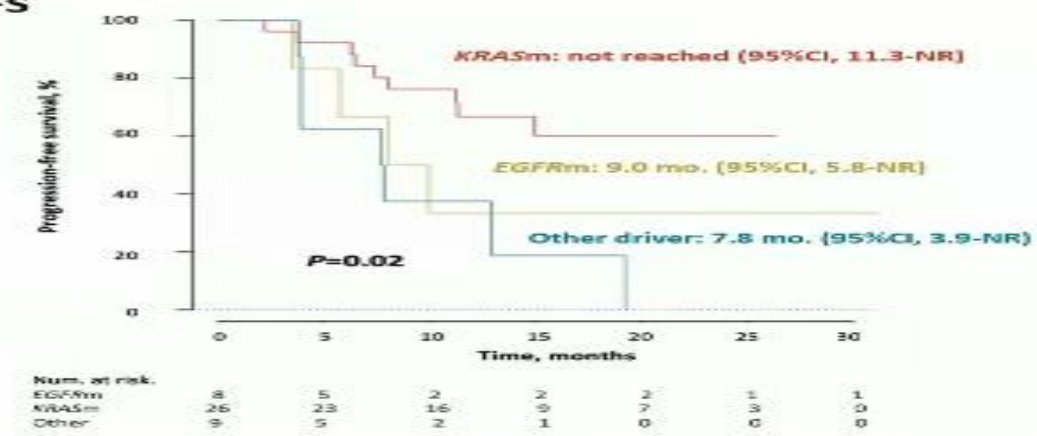
RESULTS (III/III), *Durvalumab outcomes by molecular subgroups*

Median FU: 18.5 mo. (95%CI, 16.9-21.0)

	Median PFS mo. (95% CI)	OS rate at 18 mo. % (95% CI)
Overall dGA (N=43)	14.9 (8.1-NR)	93.4 (84.7-100)
*KRAS*m (N=26)	NR (14.9-NR)	89.7 (76.8-100)
***KRAS*m G12C (N=8)**	**NR (11.3-NR)**	87.5 (67.3-100)
*EGFR*m (N=8)	9.0 (5.8-NR)	100 (NR-NR)
***EGFR*m del19/ex21 (N=6)**	**8.1 (5.8-NR)**	100 (NR-NR)
*BRAF*m (N=5)	3.9 (3.9-NR)	100 (NR-NR)
***BRAF*m *V600E* (N=4)**	**8.4 (3.9-NR)**	100 (NR-NR)
*ALK*r (N=4)	7.8 (7.7-NR)	100 (NR-NR)

PFS



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BEVERLY

Bevacizumab + erlotinib vs erlotinib alone as first-line treatment of pts with EGFR mutated advanced non squamous NSCLC. Final analysis of the multicenter, randomized, phase III BEVERLY trial.

Maria Carmela Piccirillo[1], Laura Bonanno[2], Marina Chiara Garassino[3], Claudio Dazzi[4], Luigi Cavanna[5], Giovanna Esposito[1], Marco Angelo Burgio[6], Francesco Rosetti[7], Simona Rizzato[8], Laura Arenare[1], Piera Gargiulo[1], Raimondo Di Liello[1], Filippo De Marinis[9], Lucio Crinò[6], Floriana Morgillo[10], Fortunato Ciardiello[10], Nicola Normanno[1], Ciro Gallo[10], Cesare Gridelli[11], Alessandro Morabito[1].

Study design

NSCLC
Untreated
Non-squamous
Activating EGFR mutation
Stage IIIB o IV
PS 0-2

→ **R**

1:1

Control arm
- **Erlotinib** 150 mg orally once daily

Experimental arm
- **Erlotinib** 150 mg orally once daily
- **Bevacizumab** 15 mg/kg iv every 21 days

Strata:
PS (0-1 vs 2)
Type of mutation (exon19 del vs 21 L858R mut vs others)
Centre

Treatment in both arms will be given until disease progression or unacceptable toxicity or patient's or physician's motivated decision to stop

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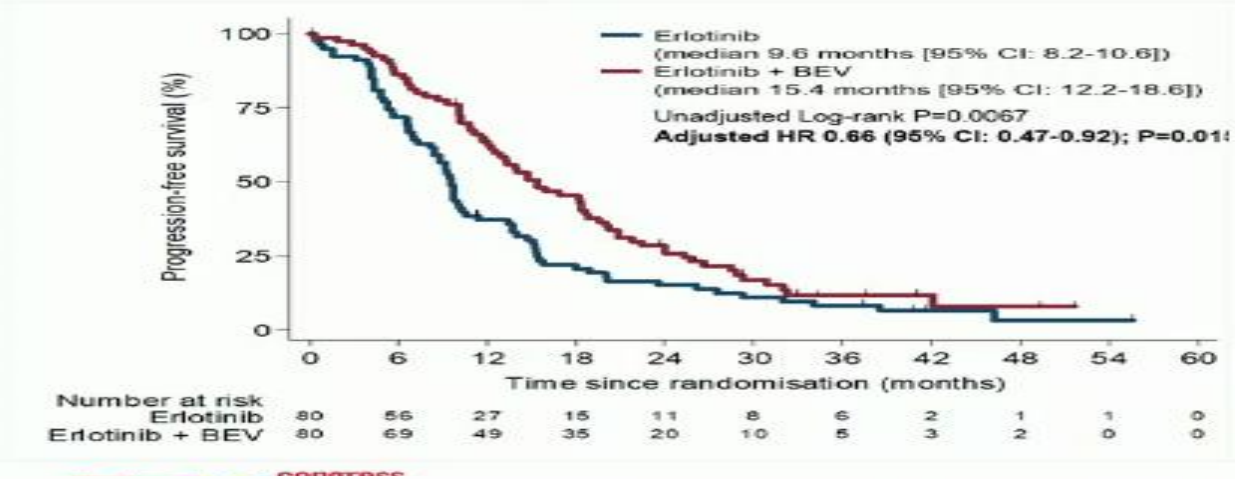
Progression-free survival

Investigator-assessed



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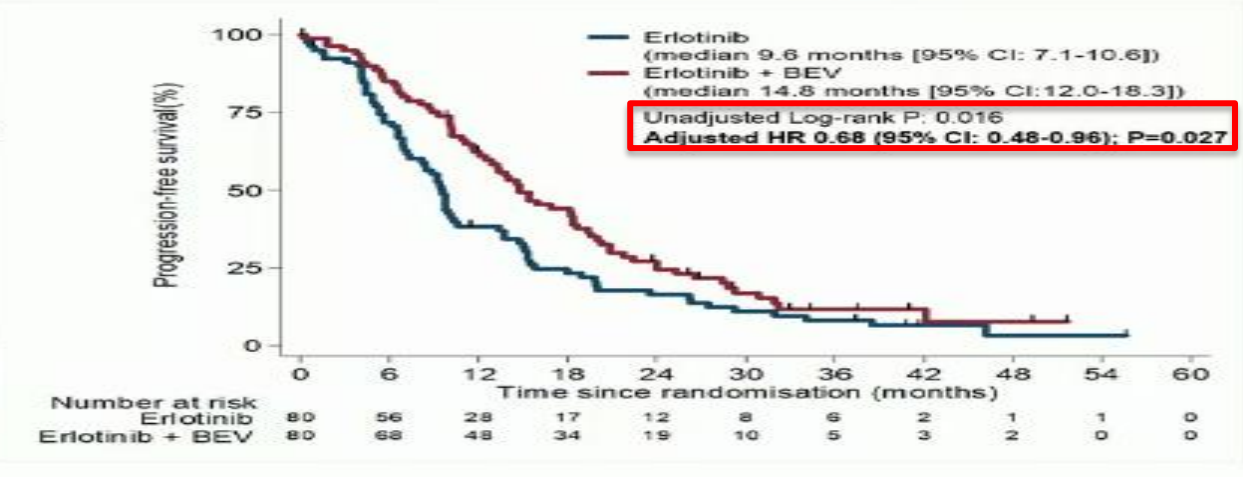

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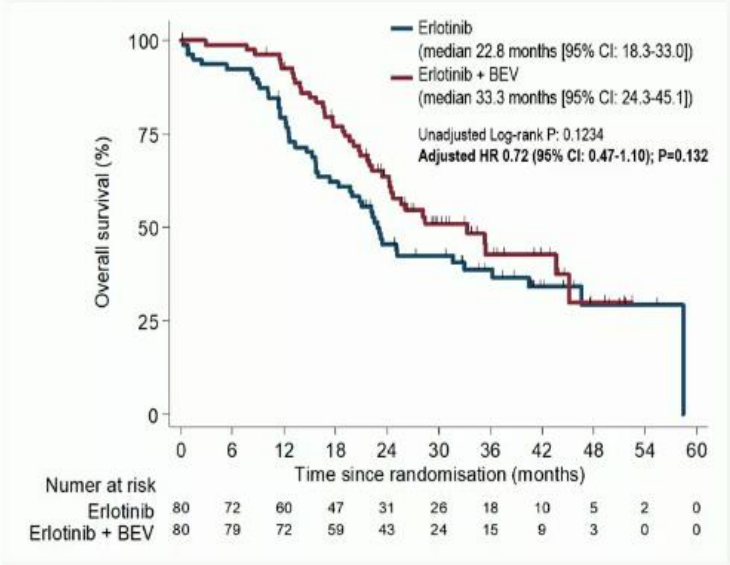
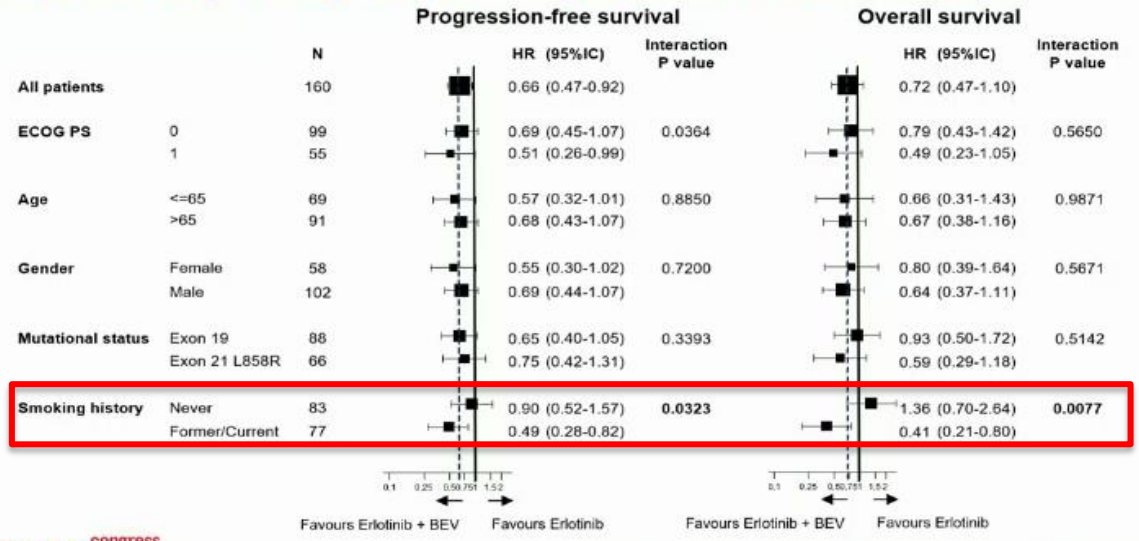
Overall survival



Exploratory subgroup analyses of PFS and OS



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Objective response rate

Investigator-assessed

	Erlotinib	Erlotinib + BEV	P
Responders (CR+PR)	**40 (50.0%)** 95%CI: 39.0%-60.9%	**56 (70.0%)** 95%CI: 60.0%-80.0%	**0.01**
CR	1 (1.3%)	1 (1.3%)	
PR	39 (48.8%)	55 (68.8%)	
SD	29 (36.3%)	18 (22.5%)	
PD	11 (13.8%)	6 (7.5%)	

Blinded independent centrally-reviewed

	Erlotinib	Erlotinib + BEV	P
Responders (CR+PR)	**43 (53.8%)** 95%CI: 42.8%-64.7%	**57 (71.3%)** 95%CI: 61.3%-81.2%	**0.02**
CR	1 (1.3%)	1 (1.3%)	
PR	42 (52.5%)	56 (70.0%)	
SD	26 (32.5%)	17 (21.3%)	
PD	11 (13.8%)	6 (7.5%)	

Safety

More frequent (>5%) or significantly different severe side effects

	Erlotinib				Erlotinib + BEV				P
	G 0-2	(%)	G≥3	(%)	G 0-2	(%)	G≥3	(%)	
Diarrhea	76	(96.2)	3	(3.8)	76	(95.0)	4	(5.0)	0.71
Fatigue	79	(100.0)	0	(0.0)	0	(0.0)	5	(6.3)	0.06
AST increased	75	(94.9)	4	(5.1)	79	(98.8)	1	(1.3)	0.21
Proteinuria	78	(98.7)	1	(1.3)	75	(93.8)	5	(6.3)	0.21
Hypertension	**75**	**(94.9)**	**4**	**(5.1)**	**61**	**(76.3)**	**19**	**(23.8)**	**0.001**
Thromboembolic event	78	(98.7)	1	(1.3)	76	(95.0)	4	(5.0)	0.37
Rash	**66**	**(83.5)**	**13**	**(16.5)**	**53**	**(66.3)**	**27**	**(33.8)**	**0.01**

One toxic death was reported with Erlotinib + BEV, due to intracranial haemorrhage.
Proteinuria was significantly more frequent with BEV (P=0.004) when considering all grades.

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Post-study anticancer therapies

	Erlotinib (N=79)	Erlotinib + BEV (N=80)
Discontinued study treatment, n (%)	78 (99)	71 (89)
No post-treatment anticancer therapy, n (%)¥	11 (14)	8 (11)
Missing Information¥	11 (14)	14 (20)
First post-treatment anticancer therapy, n (%)¶	56 (72)	49 (69)
Osimertinib	**32 (57)**	**24 (49)**
Erlotinib (out of the study)	7 (13)	8 (16)
Gefitinib	-	3 (6)
Platinum-based chemotherapy	16 (29)	13 (27)
Single agent chemotherapy	1 (2)	1 (2)

¥ percentages calculated on the proportion of patients who discontinued study treatment;
¶ percentages calculated on the proportion of patients who started a post-treatment anticancer therapy

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WJOG

Primary results of a randomized phase II study of osimertinib plus bevacizumab versus osimertinib monotherapy for untreated patients with non-squamous non-small-cell lung cancer harboring *EGFR* mutations; WJOG9717L study

UMIN000030206

On the behalf of West Japan Oncology Group
Hirotsugu Kenmotsu, Kazushige Wakuda, Keita Mori, Terufumi Kato, Shunichi Sugawara, Keisuke Kirita, Isamu Okamoto, Koichi Azuma, Kazumi Nishino, Shunsuke Teraoka, Ryo Koyama, Ken Masuda, Hidetoshi Hayashi, Ryo Toyozawa, Satoru Miura, Yuki Sato, Kazuhiko Nakagawa, Nobuyuki Yamamoto, Toshiaki Takahashi

WJOG9717L: Study Design

KEY ELIGIBILITY CRITERIA

- Non-squamous NSCLC harboring *EGFR* activating mutations
- Clinical stage IIIB, IIIC, IV, or recurrence after surgical resection
- Previously untreated
- ECOG PS 0-1
- Age 20- years
- Absence of symptomatic brain metastases

N=122

RANDOMIZED

1:1

Osimertinib (80 mg, daily) + Bevacizumab (15 mg/kg, q3w)

Osimertinib (80 mg , daily)

ENDPOINTS

- **Primary**
  - PFS by the BICRs*
- **Secondary**
  - PFS by investigators
  - Overall response rate
  - Overall survival
  - Adverse events

Stratification factors: Sex (female vs. male), Clinical stage (IIIB-IV vs. recurrence) *EGFR* mutation (Del19 deletion vs. L858R)

*BICRs; the blinded independent central reviewers

UMIN000010298; https://www.umin.ac.jp/

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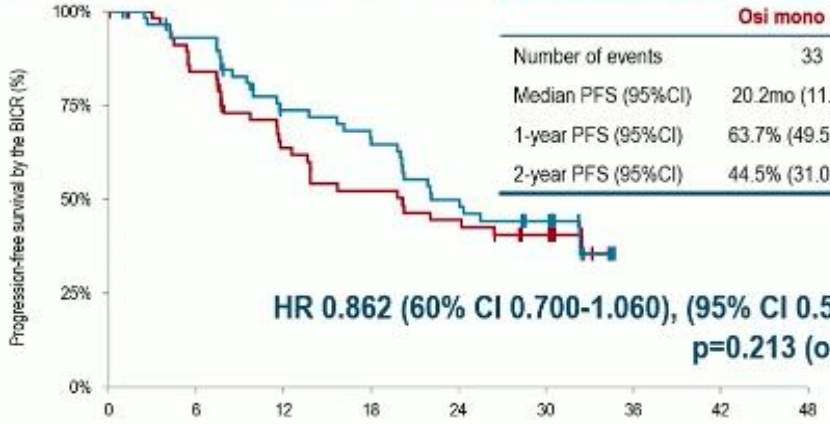
Primary Endpoint: PFS (ITT), assessed by BICRs



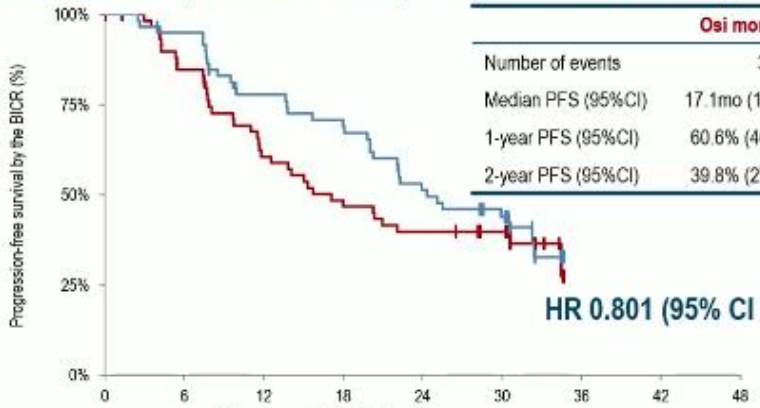
	Osi mono (n=61)	Osi+Bev (n=61)
Number of events	33	33
Median PFS (95%CI)	20.2mo (11.79-NE)	22.1mo (19.81-NE)
1-year PFS (95%CI)	63.7% (49.5-74.9%)	73.8% (60.4-83.3%)
2-year PFS (95%CI)	44.5% (31.0-57.2%)	49.8% (36.1-62.1%)

Median follow up; 30.4 mo

HR 0.862 (60% CI 0.700-1.060), (95% CI 0.531-1.397)
p=0.213 (one-sided)

Number at risk (number censored)							
Osimertinib monotherapy	61 (0)	47 (5)	34 (7)	27 (8)	23 (8)	17 (12)	0 (28)
Osimertinib plus bevacizumab	61 (0)	54 (3)	40 (6)	36 (6)	27 (6)	20 (10)	0 (28)

Secondary Endpoint: PFS (ITT), assessed by investigators



	Osi mono (n=61)	Osi+Bev (n=61)
Number of events	37	35
Median PFS (95%CI)	17.1mo (11.66-30.62)	24.3mo (20.01-32.36)
1-year PFS (95%CI)	60.6% (46.9-71.8%)	77.8% (64.9-86.5%)
2-year PFS (95%CI)	39.8% (27.3-52.0%)	51.3% (37.7-63.3%)

HR 0.801 (95% CI 0.504-1.272)

Number at risk (number censored)							
Osimertinib monotherapy	61 (0)	50 (2)	35 (3)	28 (3)	23 (3)	18 (8)	0 (24)
Osimertinib plus bevacizumab	61 (0)	56 (2)	44 (4)	40 (4)	29 (4)	21 (8)	0 (26)

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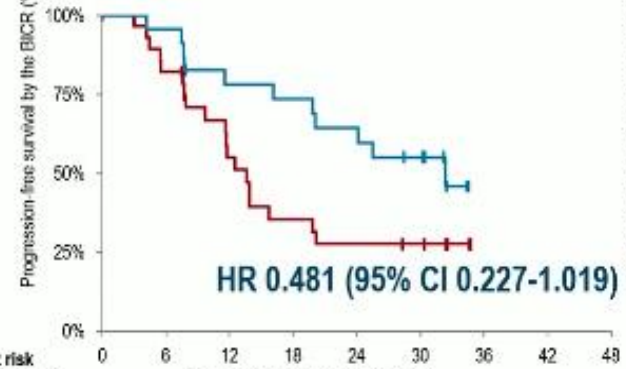
PFS assessed by BICRs, by smoking history

Ever-smoker

	Osi mono (n=31)	Osi+Bev (n=23)
Median PFS (95%CI)	13.6mo (7.8-19.9)	32.4mo (19.8-NE)

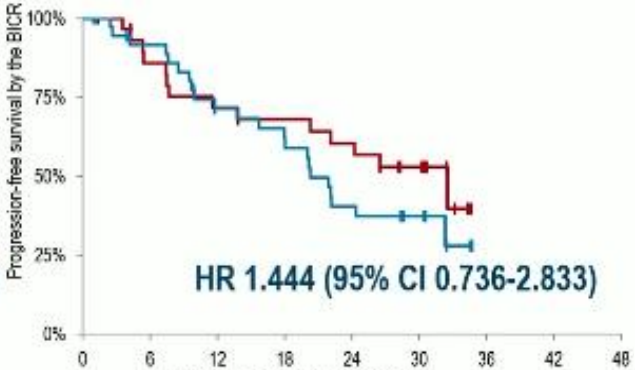


HR 0.481 (95% CI 0.227-1.019)

Number at risk (number censored)							
Osimertinib monotherapy	31 (0)	23 (3)	14 (5)	9 (5)	7 (5)	6 (6)	0 (12)
Osimertinib plus Bev	23 (0)	22 (0)	17 (1)	16 (1)	14 (1)	11 (2)	0 (12)

Never-smoker

	Osi mono (n=30)	Osi+Bev (n=38)
Median PFS (95%CI)	32.5mo (13.8-NE)	20.3mo (13.7-32.3)



HR 1.444 (95% CI 0.736-2.833)

	30 (0)	24 (2)	20 (2)	18 (3)	16 (3)	11 (6)	0 (16)
	38 (0)	32 (3)	23 (5)	20 (5)	13 (5)	9 (8)	0 (16)

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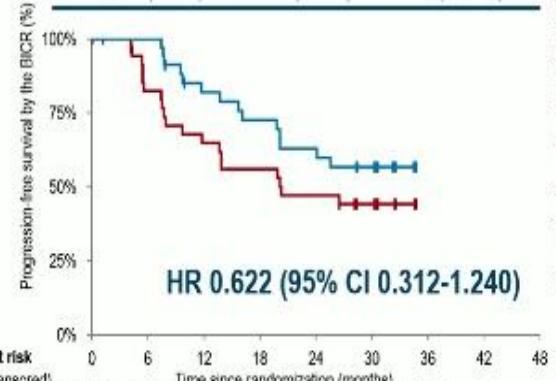
PFS assessed by BICRs, by *EGFR* mutation status

Del in exon 19

	Osi mono (n=36)	Osi+Bev (n=35)
Median PFS (95%CI)	20.3mo (9.6-NE)	NE (20.1-NE)

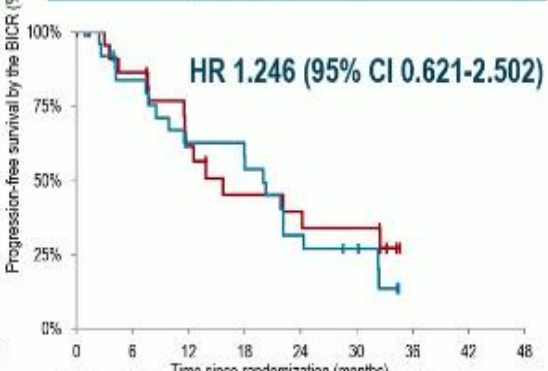


HR 0.622 (95% CI 0.312-1.240)

Number at risk (number censored)							
Osimertinib monotherapy	36 (0)	28 (2)	22 (2)	19 (2)	16 (2)	11 (6)	0 (17)
Osimertinib plus Bev	35 (0)	34 (1)	26 (3)	23 (3)	20 (3)	15 (6)	0 (21)

Leu858Arg in exon 21

	Osi mono (n=25)	Osi+Bev (n=26)
Median PFS (95%CI)	15.7mo (11.5-32.5)	20.0mo (8.5-24.4)



HR 1.246 (95% CI 0.621-2.502)

	25 (0)	19 (3)	12 (5)	8 (6)	7 (6)	6 (6)	0 (11)
	26 (0)	20 (2)	14 (3)	13 (3)	7 (3)	5 (4)	0 (7)

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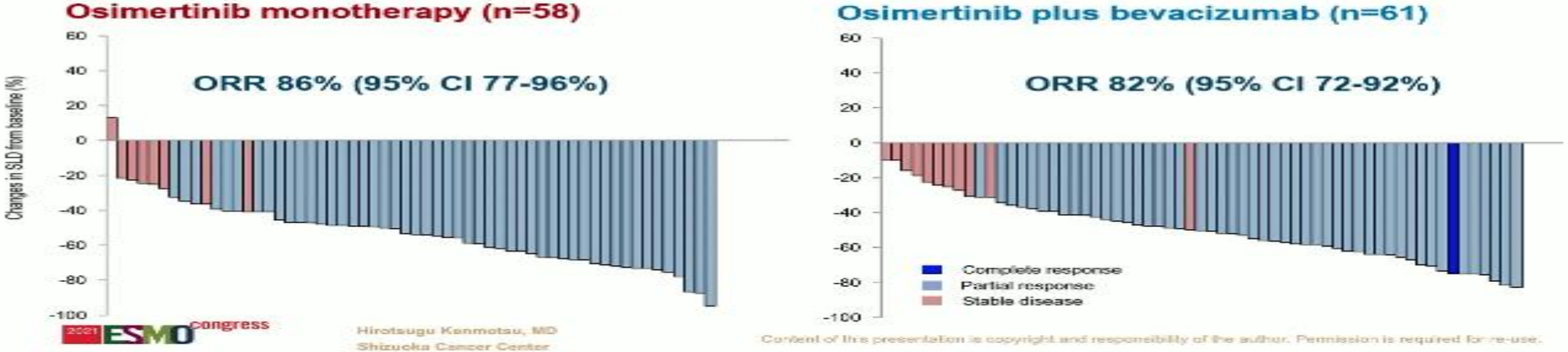
Secondary Endpoint: ORR (PPS), assessed by BICRs



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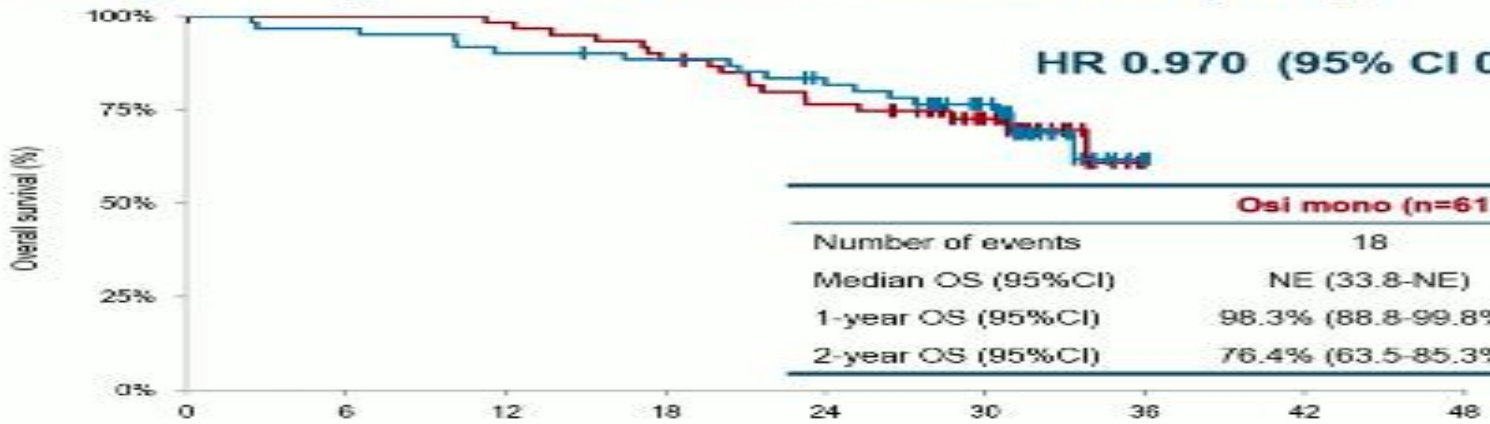
Secondary Endpoint: Overall survival (ITT)



	Osi mono (n=61)	Osi+Bev (n=61)
Number of events	18	18
Median OS (95%CI)	NE (33.8-NE)	NE (33.3-NE)
1-year OS (95%CI)	98.3% (88.8-99.8%)	90.2% (79.4-99.5%)
2-year OS (95%CI)	76.4% (63.5-85.3%)	81.7% (69.5-89.5%)

Number at risk
(number censored)

Osimertinib monotherapy	61 (0)	61 (1)	59 (1)	53 (1)	45 (2)	27 (18)	0 (43)	0 (43)
Osimertinib plus bevacizumab	61 (0)	59 (0)	55 (0)	53 (1)	47 (3)	34 (13)	1 (42)	0 (43)

Hirotsugu Kenmotsu, MD
Shizuoka Cancer Center

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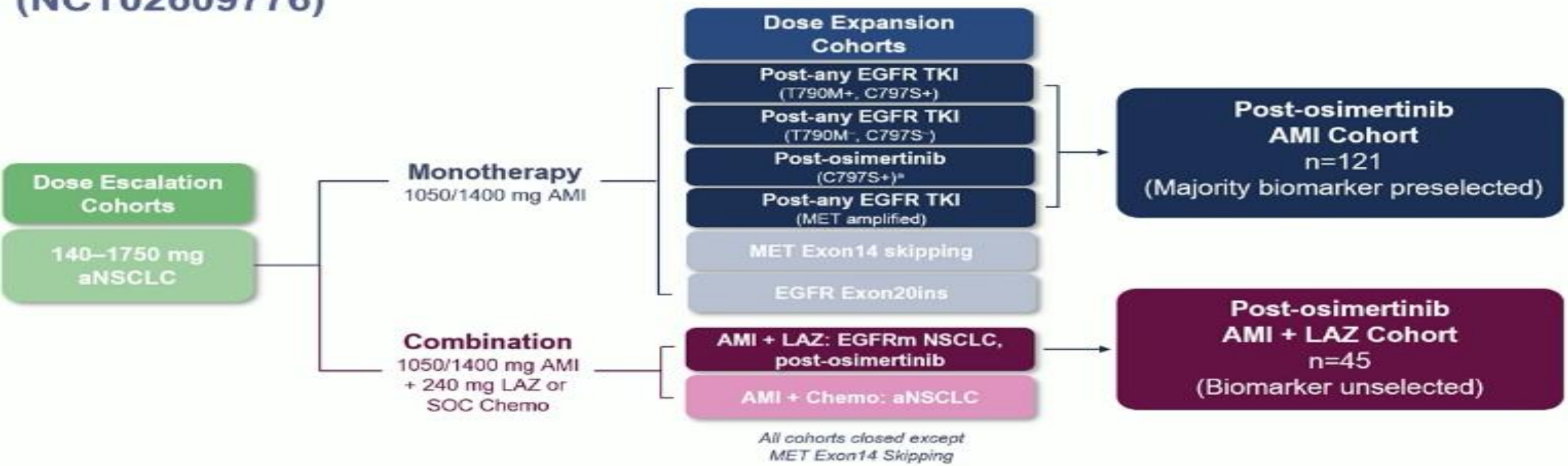
Amivantamab Monotherapy and in Combination with Lazertinib in Post-osimertinib EGFR-mutant NSCLC: Analysis from the CHRYSALIS Study

Natasha B. Leighl[1], Catherine A. Shu[2], Anna Minchom[3], Enriqueta Felip[4], Sophie Cousin[5], Byoung Chul Cho[6], Keunchil Park[7], Ji-Youn Han[8], Michael Boyer[9], Chee Khoon Lee[10], Victor Moreno[11], Pascale Tomasini[12], Santiago Viteri[13], John Xie[14], Jaime Mertz[14], Eunice Artis[14], Robert W. Schnepp[14], Roland E. Knoblauch[14], Meena Thayu[14], Jose Trigo[15]

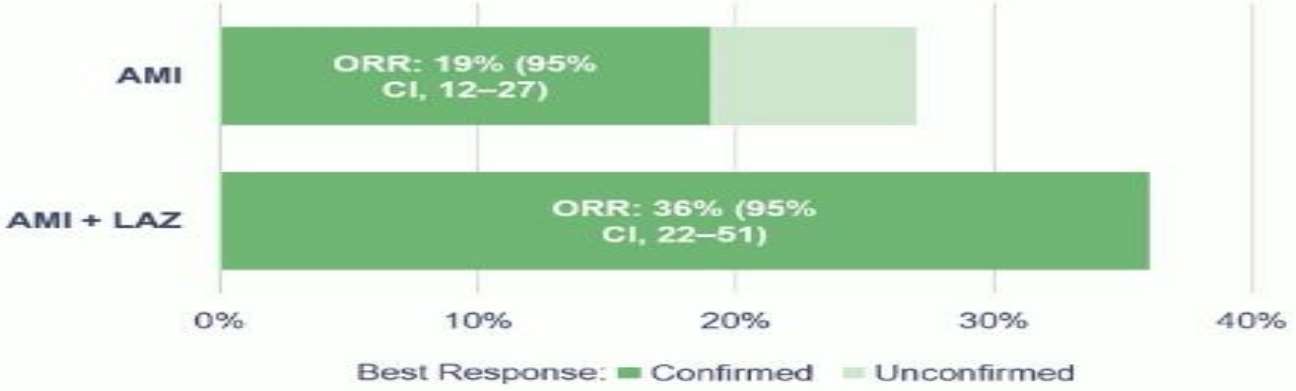
CHRYSALIS Study Design (NCT02609776)



19 April 2021 data cutoff
aThe first 33 patients were unselected before the cohort was amended to select only for C797S
AMI, amivantamab; chemo, chemotherapy; aNSCLC, advanced non-small cell lung cancer; EGFRm, epidermal growth factor receptor mutated; LAZ, lazertinib; NSCLC, non-small cell lung cancer; SOC, standard of care; TKI, tyrosine kinase inhibitor

Efficacy: AMI Monotherapy and AMI + LAZ

(descriptive cross-cohort analysis)



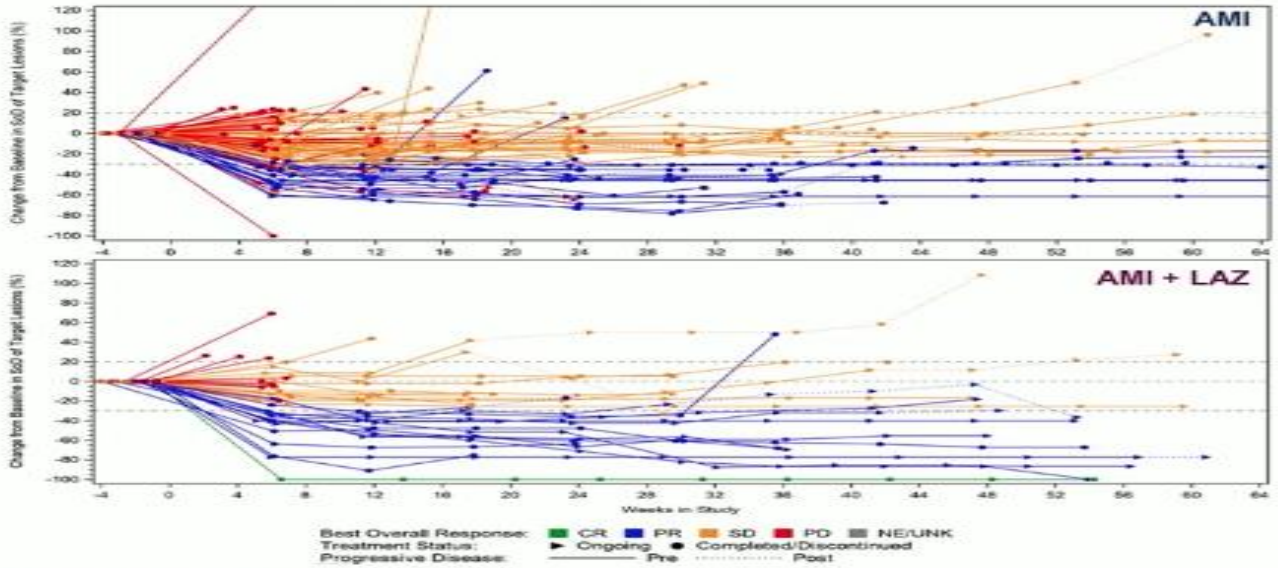
	AMI (n=121)	AMI + LAZ (n=45)
Best response[a]	27%	36%
Confirmed ORR* (95% CI)	**19%** (12–27)	**36%** (22–51)
CR	0	1 (2%)
PR	23 (19%)	15 (33%)
SD	53 (44%)	14 (31%)
PD	39 (32%)	11 (24%)
NE	6 (5%)	4 (9%)
mDOR (95% CI)	**5.9 mo** (4.2–12.6)	**9.6 mo** (5.3–NR)
CBR (95% CI)	48% (39–57)	64% (49–78)
mPFS (95% CI)	4.2 mo (3.2–5.3)	4.9 mo (3.7–9.5)
mF/U (range)	6.9 mo (0.7–38.6)	11.1 mo (1.0–15.0)

*ORR among patients with identified EGFR/MET-based osimertinib resistance was 18% for AMI and 47% for AMI + LAZ[1]

Addition of lazertinib to amivantamab was associated with numerically higher objective response rate and longer duration of response after progression on osimertinib

Responses over Time for AMI Monotherapy and AMI + LAZ

(descriptive cross-cohort analysis)



AMI (n=121):

- Median time on treatment = 3.7 mo (range, 0.03–32.2)
  - Among responders = 8.3 mo (range, 2.8–32.2)
- 39% had responses ≥6 months
- CNS progression[a] was documented among 17% of patients with 13% being new CNS lesions

AMI + LAZ (n=45):

- Median time on treatment = 5.6 mo (range, 0.5–14.8)
  - Among responders = 12.0 mo (range, 4.1–14.6)
- 69% had responses ≥6 months
- CNS progression[a] was documented among 7% of patients with 4% being new CNS lesions

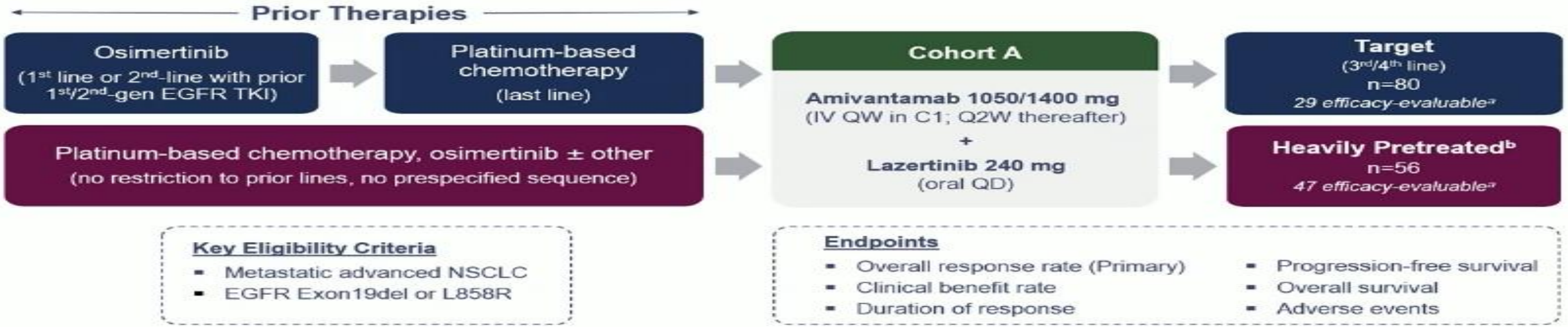
AMI plot is truncated at 64 weeks (x-axis) and 120% (y-axis). [a]CNS monitoring was performed per local standards
AMI, amivantamab; CNS, central nervous system; CR, complete response; LAZ, lazertinib; mo, month; NE, not evaluable; PD, progressive disease; PR, partial response; SD, stable disease; SoD, sum of diameters; UNK, unknown

2021 ESMO congress

Amivantamab Plus Lazertinib in Post-osimertinib, Post-platinum Chemotherapy EGFR-mutant Non-small Cell Lung Cancer (NSCLC): Preliminary Results from CHRYSALIS-2

Catherine A. Shu[1], Koichi Goto[2], Yuichiro Ohe[3], Benjamin Besse[4], Keunchil Park[5], Yongsheng Wang[6], Frank Griesinger[7], James Chih-Hsin Yang[8], Enriqueta Felip[9], Rachel E. Sanborn[10], Reyes Bernabe Caro[11], Joshua M. Bauml[12], Jun Chen[13], Elizabeth Fennema[13], Janine Mahoney[13], Leonardo Trani[13], Roland E. Knoblauch[13], Meena Thayu[13], Byoung Chul Cho[14]

CHRYSALIS-2 Study Design: Cohort A (NCT04077463)



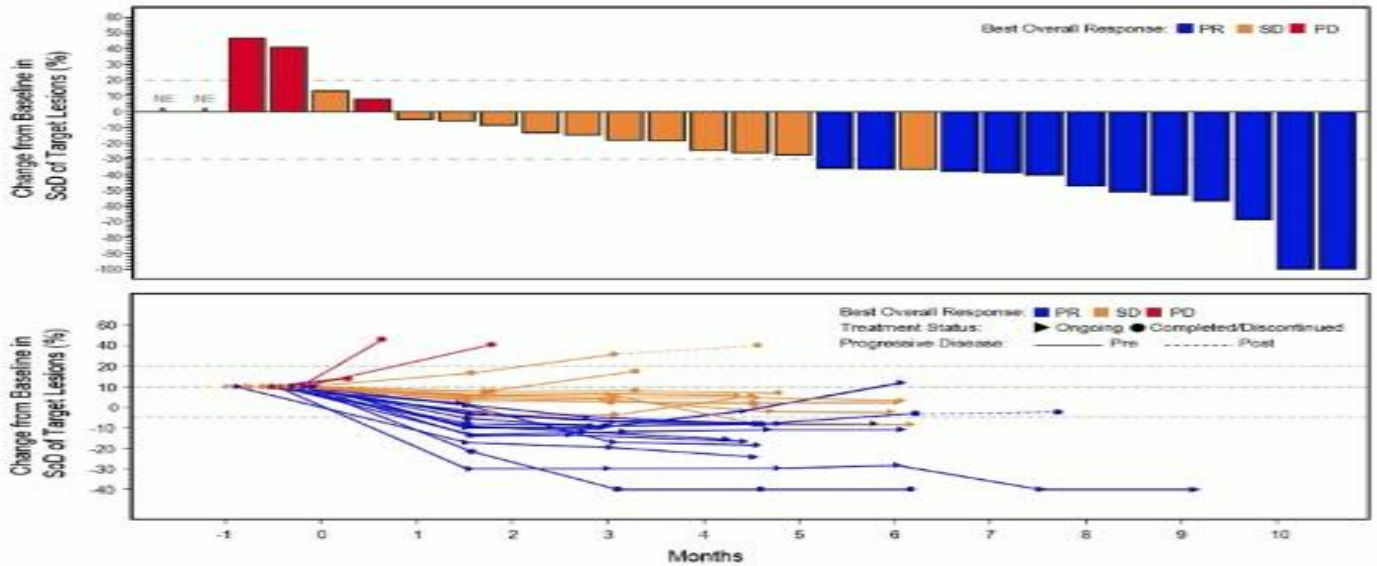
Key Eligibility Criteria

- Metastatic advanced NSCLC
- EGFR Exon19del or L858R

Endpoints

- Overall response rate (Primary)
- Clinical benefit rate
- Duration of response
- Progression-free survival
- Overall survival
- Adverse events

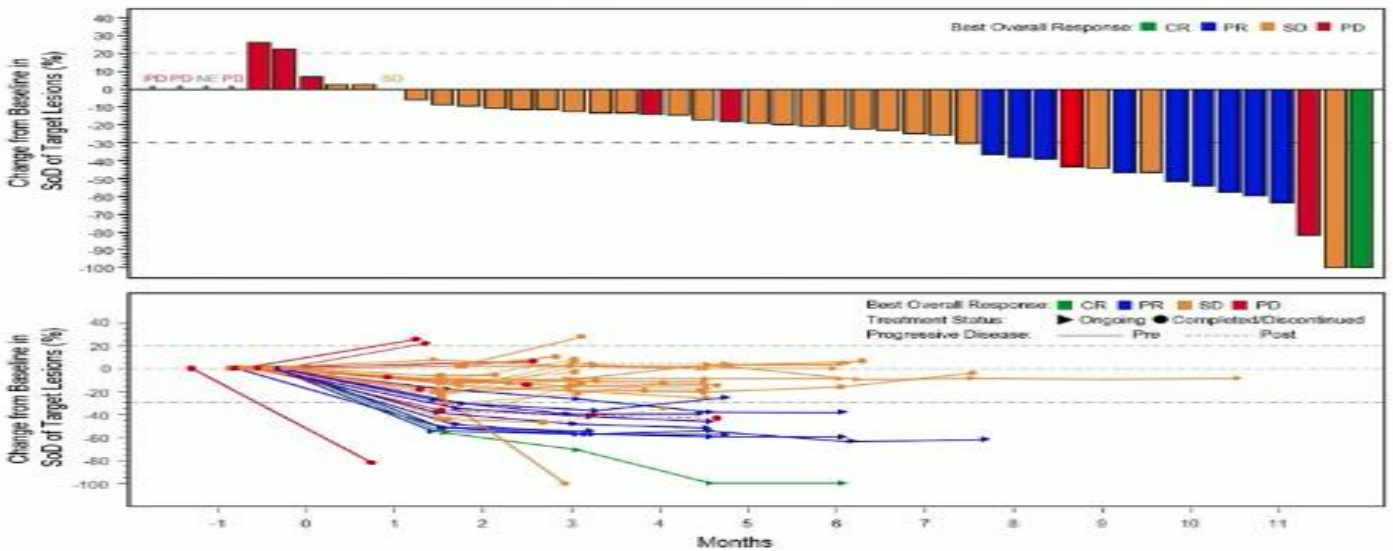
Target Population: Antitumor Activity of Amivantamab + Lazertinib



Among 29 efficacy-evaluable[a] patients at a median follow-up of 4.6 mo (range, 0.4–9.6):

- ORR = 41% (95% CI, 24–61)
- CBR = 69% (95% CI, 49–85)
- Median time on treatment = 4.2 mo (range, 0.03–8.4)
- Responses observed early
  - mTTR = 1.4 mo (range, 1.4–4.4)
- 8/12 patients who responded are progression-free and remain on treatment
- 5/12 patients with stable disease remain on treatment (longest at 6.9+ mo)

Heavily Pretreated: Antitumor Activity of Amivantamab + Lazertinib



Among 47 efficacy-evaluable[a] patients at a median follow-up of 4.5 mo (range, 0.3–9.7):

- ORR = 21% (95% CI, 11–36)
- CBR = 51% (95% CI, 36–66)
- Median time on treatment = 3.7 mo (range, 0.03–9.7)
- Responses observed early
  - mTTR = 1.5 mo (range, 1.3–4.2)
- 10/10 patients who responded are progression-free and remain on treatment
- 10/26 patients with stable disease remain on treatment (longest at 9.6+ mo)

[a]Patients who received at least one dose of study drug and were to have undergone at least 3 scheduled postbaseline disease assessments or discontinued treatment for any reason, including disease progression/death, prior to the clinical cutoff. CBR, clinical benefit rate (defined as CR, PR, or SD ≥11 weeks); CR, complete response; mo, month; mTTR, median time to first confirmed response; NE, not evaluable; ORR, overall response rate; PD, progressive disease; PR, partial response; SD, stable disease.

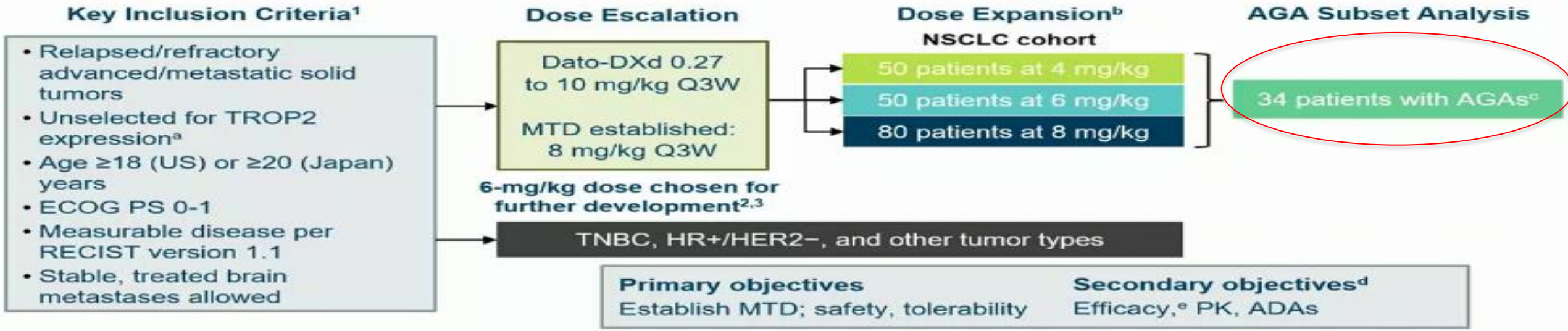
*Four patients did not have evaluable target lesion measurements in any postbaseline disease assessment; these four patients are not included in the spider plot.

2021 ESMO congress

Efficacy of Datopotamab Deruxtecan (Dato-DXd) in Patients With Advanced/Metastatic Non-Small Cell Lung Cancer (NSCLC) and Actionable Genomic Alterations (AGAs): Preliminary Results From the Phase 1 TROPION-PanTumor01 Study

Edward B. Garon,[1] Melissa L. Johnson,[2] Aaron E. Lisberg,[1] Alexander Spira,[3] Noboru Yamamoto,[4] Rebecca S. Heist,[5] Jacob M. Sands,[6] Kiyotaka Yoh,[7] Funda Meric-Bernstam,[8] Satoru Kitazono,[9] Jonathan Greenberg,[10] Fumiaki Kobayashi,[11] Yui Kawasaki,[11] Lori Jukofsky,[10] Kota Nakamura,[10] Toshio Shimizu[4]

TROPION-PanTumor01 Study Design



ADA, antidrug antibody; ECOG PS, Eastern Cooperative Oncology Group performance status; HER2, human epidermal growth factor receptor 2; HR, hormone receptor; MTD, maximum tolerated dose; PK, pharmacokinetics; Q3W, every 3 weeks; RECIST, Response Evaluation Criteria in Solid Tumors; TNBC, triple-negative breast cancer.

[a] Pretreatment tumor tissue was required for retrospective analysis of TROP2 expression. [b] Includes patients treated in the dose-escalation and dose-expansion portions. [c] AGAs were investigator reported. [d] Additional exploratory objectives include analyses of biomarkers associated with response. [e] Response assessments are based on RECIST 1.1.

1. ClinicalTrials.gov. Accessed August 26, 2021. https://clinicaltrials.gov/ct2/show/NCT03401385. 2. Meric-Bernstam F, et al. ASCO 2021. Abstract 9058. 3. Spira A, et al. WCLC 2020. Abstract 3407.

NSCLC With AGAs: Baseline Characteristics and Disposition

Characteristic	Dato-DXd n=34
Age, median (range), years	62 (42-80)
Weight, median (range), kg	60 (38-107)
Female, %	56
Nonsquamous histology, %	97
≥3 Prior lines of therapy, %	82
Previous systemic treatment, %	
Immunotherapy	41
Platinum-based chemotherapy	91
Tyrosine kinase inhibitor	85
Osimertinib	69[a]
Actionable genomic alterations, %	
EGFR mutation[b]	85
ALK fusion	9
ROS1 fusion	3
RET fusion	3

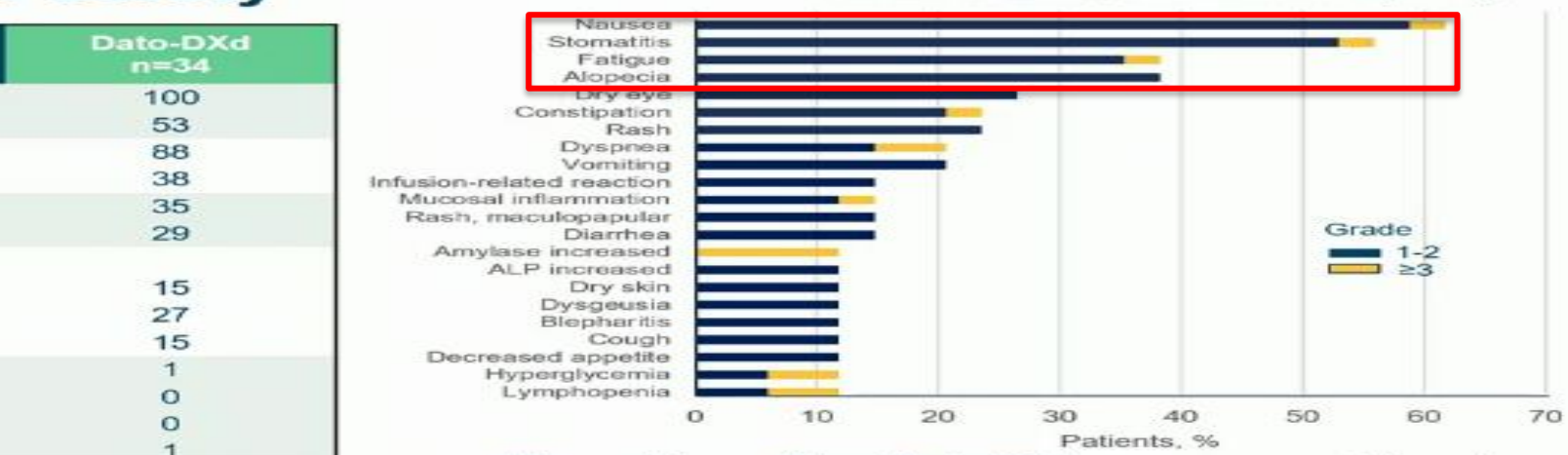
Treatment status	Dato-DXd n=34
Received study treatment, %	
4 mg/kg	24
6 mg/kg	29
8 mg/kg	47
Ongoing study treatment, %	12
Discontinued from study treatment, %	88
Progression[c]	65
Adverse event	15
Death	3
Other[d]	6
Duration on study, median (range), mo	13.4 (7-28)
Exposure, median (range), mo	5.8 (0.7-17.2)

Data cutoff: April 6, 2021.
RET, ret proto-oncogene ROS1, ROS proto-oncogene 1.
[a] Among patients with *EGFR* mutations. [b] Among those with *EGFR* mutations, 10% had exon 20 insertions. [c] Includes progressive disease per RECIST 1.1 and clinical progression. [d] Includes physician decision, withdrawal by patient, and other.

NSCLC With AGAs: Safety

Adverse events, n (%)	Dato-DXd n=34
TEAE, %	100
Grade ≥3	53
Drug-related TEAE, %	88
Grade ≥3	38
Serious TEAE, %	35
Grade ≥3	29
Dose adjustments, %	
TEAEs associated with discontinuation	15
TEAEs associated with dose interruption	27
TEAEs associated with dose reduction	15
ILD adjudicated as drug related, n[a]	1
Grade ≤2	0
Grade 3/4	0
Grade 5	1

TEAEs in ≥10% of Patients[b] (n=34)



- The safety profile of Dato-DXd was manageable and consistent with that observed in the overall NSCLC population in TROPION-PanTumor01; TEAEs were primarily nonhematologic

Data cutoff: April 6, 2021.
ALP, alkaline phosphatase; ILD, interstitial lung disease; TEAE, treatment-emergent adverse event.
[a] The case of adjudicated ILD occurred in a patient who received Dato-DXd 8 mg/kg. [b] Any grade TEAEs occurring in <10% of patients but with grade ≥3 occurring in ≥5% of patients included ulcerative keratitis.
Garon EB, et al. WCLC 2021. Abstract MA03.02.

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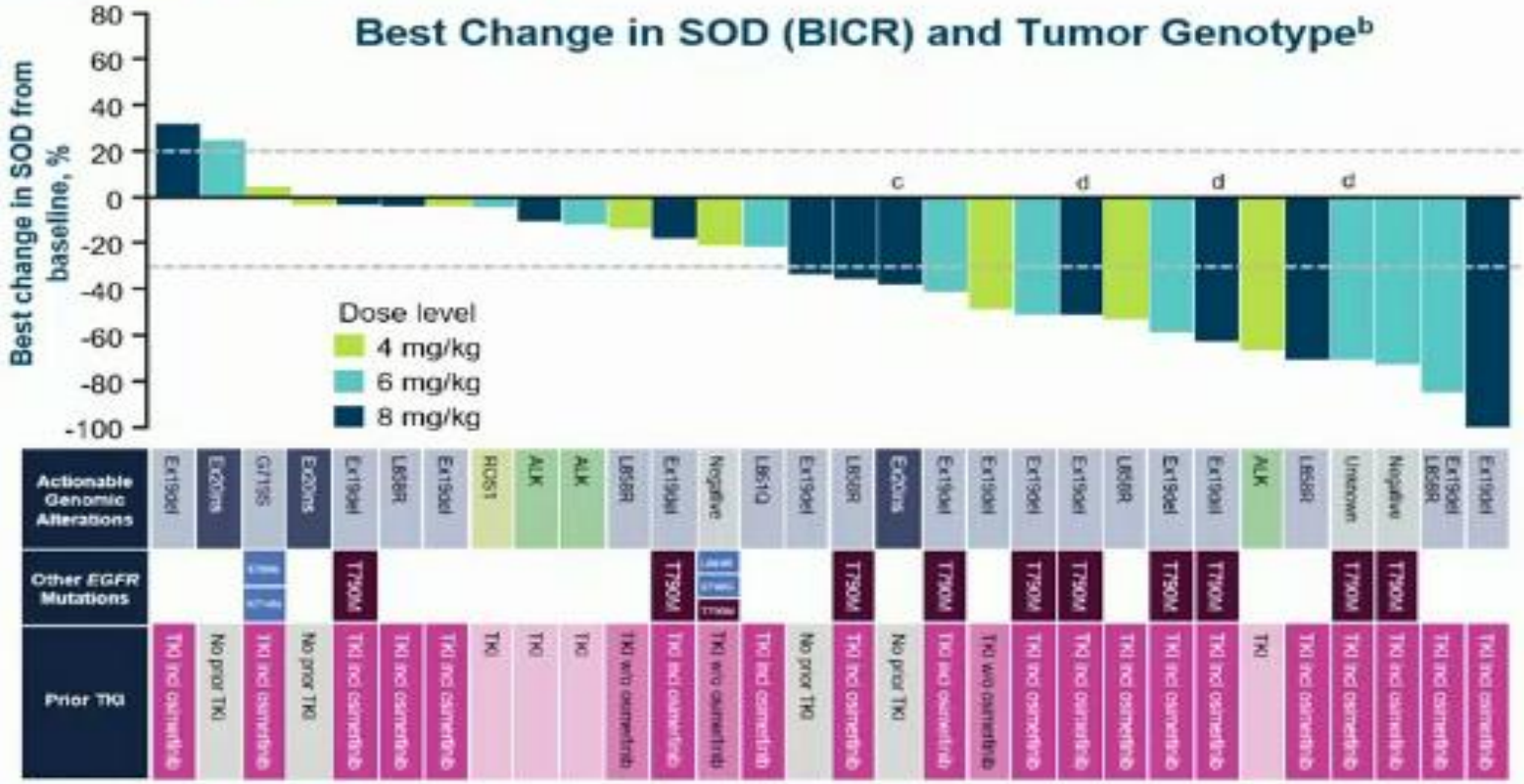
NSCLC With AGAs: Antitumor Activity

Best Overall Response (BICR)

Patients[a]	Dato-DXd n=34
ORR, n (%)	12 (35)
CR	0
PR	12 (35)
SD, n (%)	14 (41)
Non-CR/PD, n (%)	2 (6)
PD, n (%)	2 (6)
NE, n (%)	4 (12)
DOR, median (95% CI), mo	9.5 (3.3-NE)

- Clinical activity was observed in *EGFR* (Ex19del, L858R) including after osimertinib and across other AGAs

Best Change in SOD (BICR) and Tumor Genotype[b]



Data cutoff: April 6, 2021.

BICR, blinded independent central review; CR, complete response; DOR, duration of response; incl, including; NE, not evaluable; ORR, objective response rate; PD, progressive disease; PR, partial response; SOD, sum of diameters; SD, stable disease; w/o, without.

[a] Includes response-evaluable patients who had ≥1 postbaseline tumor assessment or discontinued treatment. [b] 4 patients were not included in the waterfall plot: 2 who did not have a target lesion per BICR and 2 who did not have on-study treatment images. [c] Patient NE. [d] Patients with unconfirmed PR.

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A randomized phase III study comparing cisplatin-pemetrexed with carboplatin-paclitaxel-bevacizumab in chemotherapy naïve patients with advanced *KRAS* mutated non-small cell lung cancer: NVALT22

NVALT22 Study design

Key Inclusion/Exclusion
- Age ≥ 18 years
- Pathologically confirmed advanced *KRAS* mutated NSCLC
- Chemotherapy naive
- Previous anti-PD(L1) therapy allowed
- Measurable disease (RECIST v1.1)
- ECOG PS 0-2
- Stable brain metastases allowed

RANDOMIZE 1:1

- C (AUC6) – P (200 mg/m2) – B (15 mg/kg), followed by B maintenance Q3W
- Cis (75 mg/m2) – Pem (500 mg/m2) followed by Pem maintenance Q3W

Primary endpoint:
- PFS

Secondary endpoints:
- ORR
- DCR
- OS

a) Stratification:
- *KRAS* mutation (G12C/G12V/other)
- ECOG PS (0-1/2)
- Brain metastases (yes/no)
- 2018: Prior anti-PD(L1) therapy (yes/no)

Sample size: 240

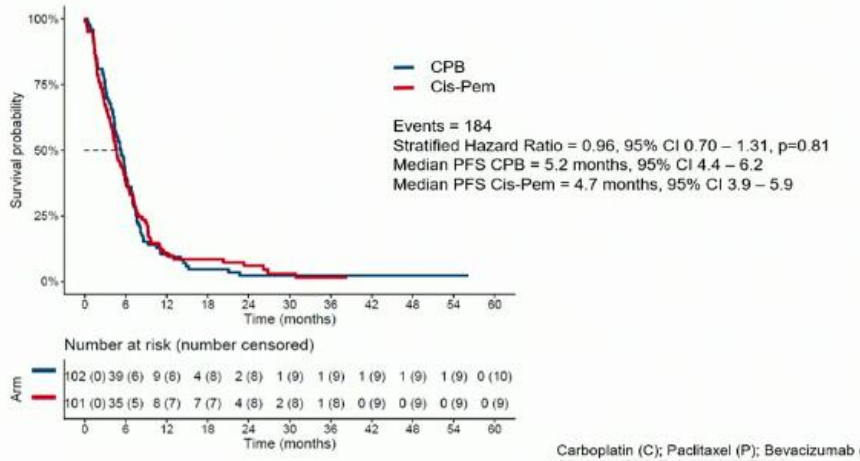
b) Response assessment (RECIST v1.1) Q6W

Inclusion from April 2016 to July 2021
Inclusion was closed prematurely due to slow accrual

Carboplatin (C); Paclitaxel (P); Bevacizumab (B)
Cisplatin (Cis); Pemetrexed (Pem)

NVALT22 Results: no difference in PFS

Investigator based Progression Free Survival



Carboplatin (C); Paclitaxel (P); Bevacizumab (B)
Cisplatin (Cis); Pemetrexed (Pem)

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Primary Data from DESTINY-Lung01: A Phase 2 Trial of Trastuzumab Deruxtecan (T-DXd) in Patients With *HER2*-Mutated (*HER2*m) Metastatic Non–Small Cell Lung Cancer (NSCLC)

Bob T. Li, MD, PhD, MPH[a], Egbert F. Smit, Yasushi Goto, Kazuhiko Nakagawa, Hibiki Udagawa, Julien Mazières, Misako Nagasaka, Lyudmila Bazhenova, Andreas N. Saltos, Enriqueta Felip, Jose M. Pacheco, Maurice Pérol, Luis Paz-Ares, Kapil Saxena, Ryota Shiga, Yingkai Cheng, Suddhasatta Acharyya, Javad Shahidi, David Planchard, Pasi A. Jänne

DESTINY-Lung01 Study Design

Multicenter, international, 2-cohort phase 2 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[a]
- ECOG PS of 0 or 1
- Locally reported *HER2* mutation (for Cohort 2)[b]

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

Cohort 1a: HER2-overexpressing[c] (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[d]

Secondary end points
- DOR
- PFS
- OS
- DCR
- Safety

Exploratory end point
- Biomarkers of response

Data cutoff: May 3, 2021
- 91 patients with *HER2*m 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%)

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

DCR, disease control rate; DOR, duration of response; ECOG, Eastern Cooperative Oncology Group; HER2, human epidermal growth factor receptor 2; ICR, independent central review; IHC, immunohistochemistry; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PS, performance status; q3w, every 3 weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumours version 1.1.

Demographics and Baseline Characteristics

	T-DXd (N = 91)
Age, median (range), years	60.0 (29.0-88.0)
Female, %	65.9
Race, %	
Asian	34.1
White	44.0
Black	1.1
Other	20.9
Region, %	
Asia	25.3
Europe	36.3
North America	38.5
ECOG PS, %	
0 | 1	25.3 | 74.7
***HER2* mutation, %**	
Kinase domain	93.4
Extracellular domain	6.6
Asymptomatic CNS metastases at baseline, %	36.3
Smoking status, %	
Never | Former | Current	57.1 | 40.7 | 2.2
History of prior lung resection, %	22.0

Confirmed ORR, Best Overall Response, and Dc

	Patients (N = 91)
Confirmed ORR[a], n (%)	**50 (54.9)** (95% CI, 44.2-65.4)
Best overall response, n (%)	
CR	**1 (1.1)**
PR	**49 (53.8)**
SD	**34 (37.4)**
PD	**3 (3.3)**
Not evaluable	**4 (4.4)**
DCR, n (%)	84 (92.3) (95% CI, 84.8-96.9)
Median DoR, months	9.3 (95% CI, 5.7-14.7)
Median follow up, months	13.1 (range, 0.7-29.1)

[a]Primary endpoint

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CR, complete response; DoR, duration of response; PD, progressive disease; PR, partial response; SD, stable disease.

Prior Therapies

	Patients (N = 91)
History of any prior systemic cancer therapy, n (%)	**90 (98.9)**
Prior lines of treatment, median (range)	2 (0-7)[a]
Prior treatment, n (%)	
Platinum-based therapy	86 (94.5)
Anti–PD-(L)1 therapy	60 (65.9)
Platinum-based and anti–PD-(L)1 therapy[b]	57 (62.6)
Docetaxel	18 (19.8)
HER2 TKI[c]	13 (14.3)

[a]One patient was enrolled without receiving prior cancer therapy
[b]Given separately or in combination
[c]Patients previously treated with a HER2 antibody or an antibody-drug conjugate were ineligible, but those who previously received a HER2 TKI such as afatinib, pyrotinib, or poziotinib were allowed

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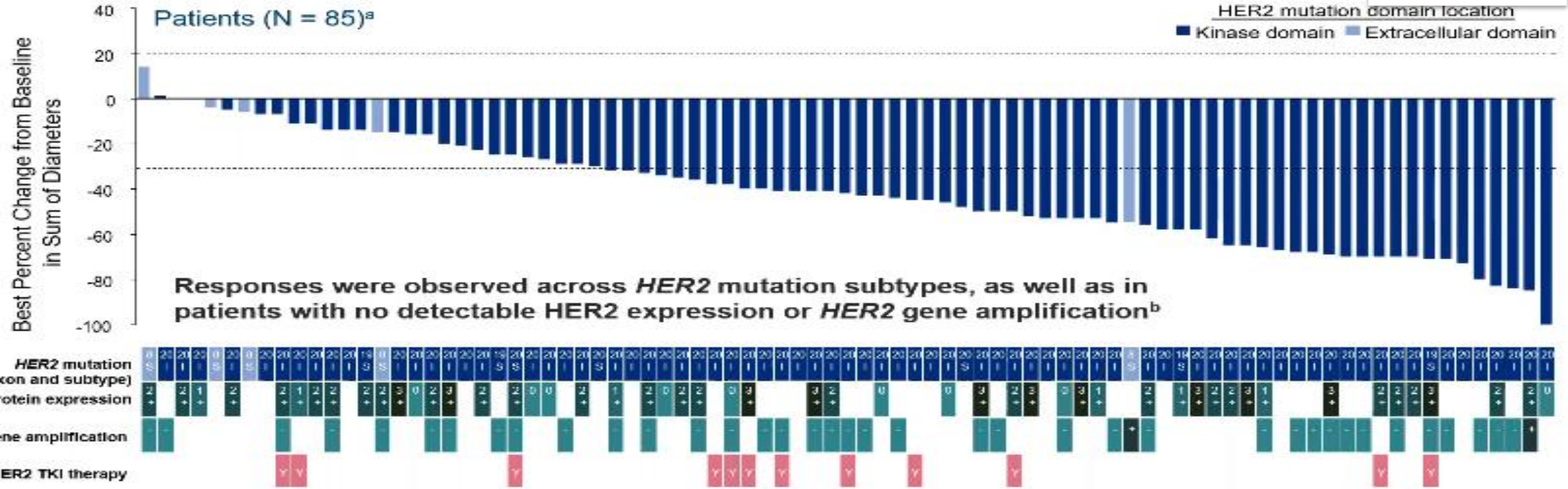
PD-(L)1, programmed cell death (ligand) 1; TKI, tyrosine kinase inhibitor.

DESTINY-Lung01

Best Percentage Change of Tumor Size From Bas



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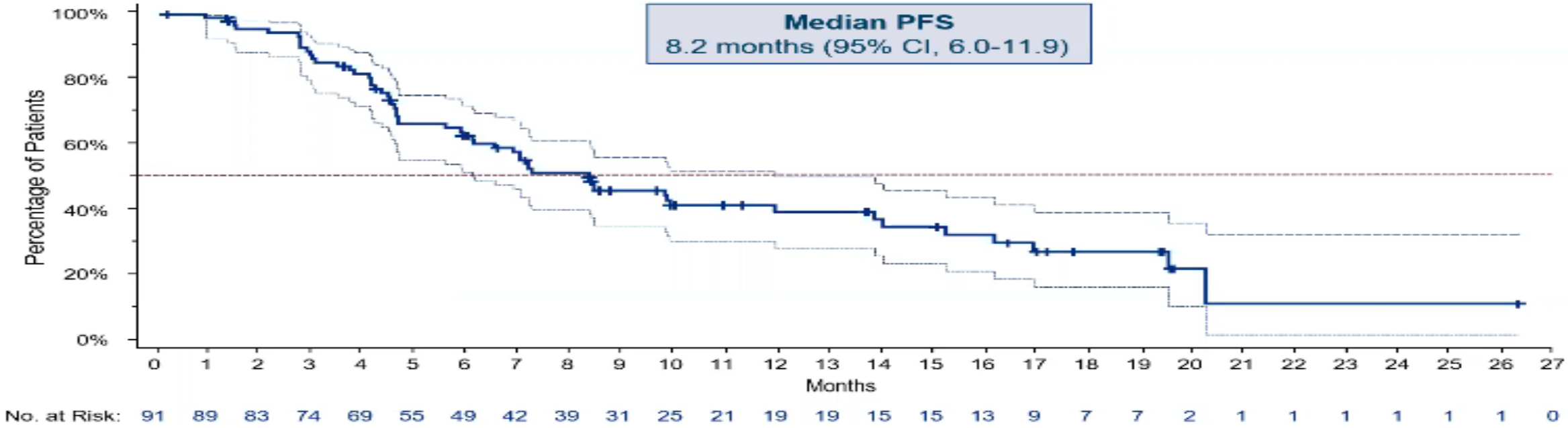
[a]Best change in tumor size by ICR for 85 of 91 patients for whom baseline and postbaseline data were available. Baseline is last measurement taken before enrollment. [b]The Oncomine™ Dx Target Test (Thermo Fisher Scientific) was used to confirm local HER2 mutation status and to determine HER2 amplification status. HER2 protein expression status was determined by immunohistochemistry using a modified PATHWAY anti HER2 (4B5) (Ventana Medical Systems, Inc.) assay. Shown is best (minimum) percentage change from baseline in the sum of diameters for all target lesions. (-), negative; (+), positive; I, insertion; N, no; S, substitution; Y, yes. Blank cells (except for the prior HER2 TKI therapy row) indicate patients whose tumor samples were not evaluable or assessed. The upper dashed horizontal line indicates a 20% increase in tumor size in the patients who had disease progression and the lower dashed line indicates a 30% decrease in tumor size (partial response).



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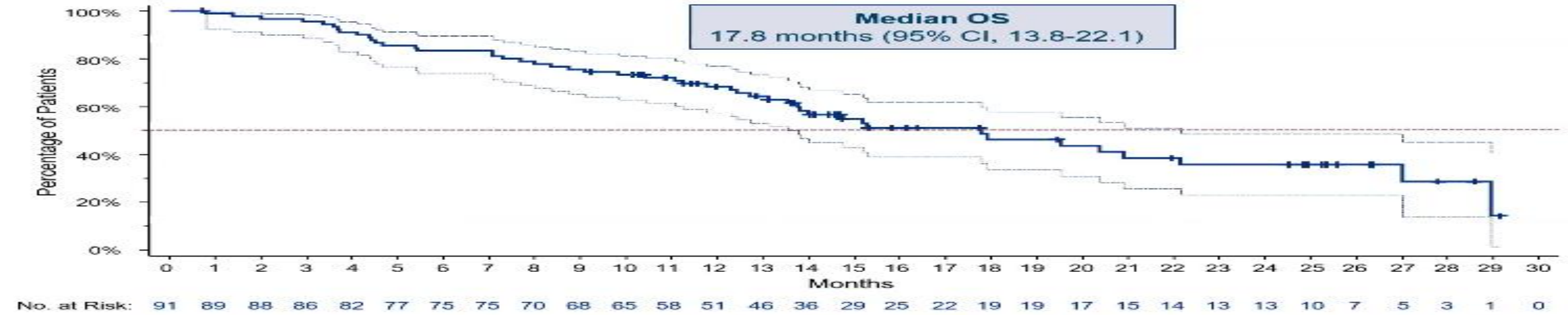
Median follow-up was 13.1 months (range, 0.7-29.1)
PFS assessed by ICR using RECIST v1.1., the median was based on Kaplan-Meier estimate, and 95% CI for median was computed using the Brookmeyer-Crowley method, and dashed lines indicate the 95% CI. Of 91 patients, 41 had progressive disease and 15 had died by the data cutoff date. Data for 35 patients were censored as indicated by tick marks; patients were censored if they discontinued treatment.

Overall Survival



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Median follow-up was 13.1 months (range, 0.7-29.1 months)
Dashed lines indicate the 95% CI. Of 91 patients, 47 had died by the data cutoff date. Data for 44 patients were censored as indicated by tick marks; patients

Overall Safety Summary

n (%)	Patients (N = 91)
Any drug-related TEAE	88 (96.7)
Drug-related TEAE Grade ≥3	42 (46.2)
Serious drug-related TEAE	18 (19.8)
Drug-related TEAE associated with discontinuation[a]	23 (25.3)
Drug-related TEAE associated with dose reduction	31 (34.1)
Drug-related TEAE associated with an outcome of death	2 (2.2)[c]

- Median treatment duration was 6.9 months (range, 0.7-26.4 months)
- The most common drug-related TEAEs associated with treatment discontinuation were investigator-reported pneumonitis (13.2%) and ILD (5.5%)
- The most common drug-related TEAEs associated with dose reduction were nausea (11.0%) and fatigue (8.8%)

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Relationship to study drug was determined by the treating investigator. [a]Pneumonitis (n = 12) and interstitial lung disease (n = 5) were among the drug-related TEAEs associated with discontinuation. [b]1 patient experienced grade 3 ILD as reported by investigator and died. The reported ILD was subsequently adjudicated as grade 5 by the interstitial lung disease adjudication committee.
ILD, interstitial lung disease; TEAE, treatment-emergent adverse event.

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Efficacy and Safety of Poziotinib in Treatment-naïve NSCLC Harboring HER2 exon 20 Mutations: A Multinational Phase 2 Study (ZENITH20-4)

Robin Cornelissen, MD

ZENITH20: Multi-cohort Global Clinical Trial

Completed

Cohort 1
Previously treated NSCLC with EGFR exon 20 insertions

Cohort 2
Previously treated NSCLC with HER2 exon 20 insertions

Cohort 3
First-line NSCLC with EGFR exon 20 insertions

Objectives

- **Primary**
  - Objective Response Rate (ORR)
- **Secondary**
  - Disease Control Rate (DCR)
  - Duration of Response (DOR)
  - Safety & Tolerability
- ORR based on Central independent imaging review

Cohort 4: Primary Endpoint Criteria: ORR 95% CI Lower Bound >20%

Treatment:
- 16 mg QD in first 48 patients (complete)
- 8 mg BID in subsequent patients (enrolling)

Enrolling

Cohort 4
First-line NSCLC with HER2 exon 20 insertions

Cohort 5
Exploratory Previously Treated or First-line NSCLC with EGFR or HER2 exon 20 insertions

Cohort 6
EGFR Osimertinib Failures

Cohort 7
Atypical EGFR or HER2 mutations

Preliminary safety and efficacy data from Cohort 4 QD dosing being presented here

Efficacy of QD Dosing

	All treated N=48
Objective Response Rate (ORR)[1]	21 (43.8%)
95% confidence interval	(29.5, 58.8)
Responses, n	
Complete response	1 (2.1%)
Partial response	20 (41.7%)
Stable disease	15 (31.3%)
Progressive disease	7 (14.6%)
Not evaluable	5 (10.4%)
Disease Control Rate (DCR), n	36 (75.0%)
ORR including unconfirmed response[2], n	23 (47.9%)
95% confidence interval	(33.3, 62.8)

[1]By RECIST v1.1; [2]Two additional response not confirmed by subsequent imaging in ≥4 weeks

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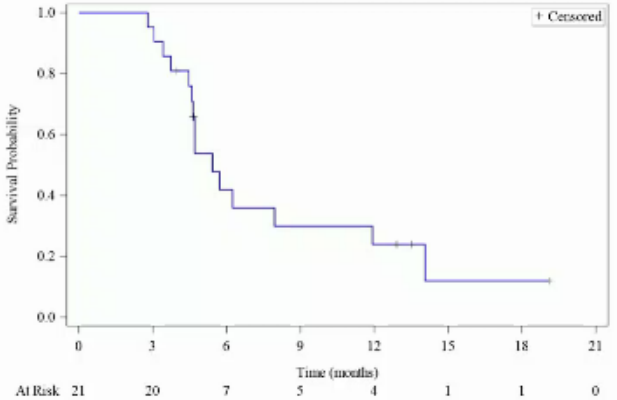
Duration of Response (DoR)

Median DoR (months) (range)	5.4 (2.8, >19.1)
Median follow up of response (months)	13.5
Response duration	
>6 months	42%
>12 months	24%



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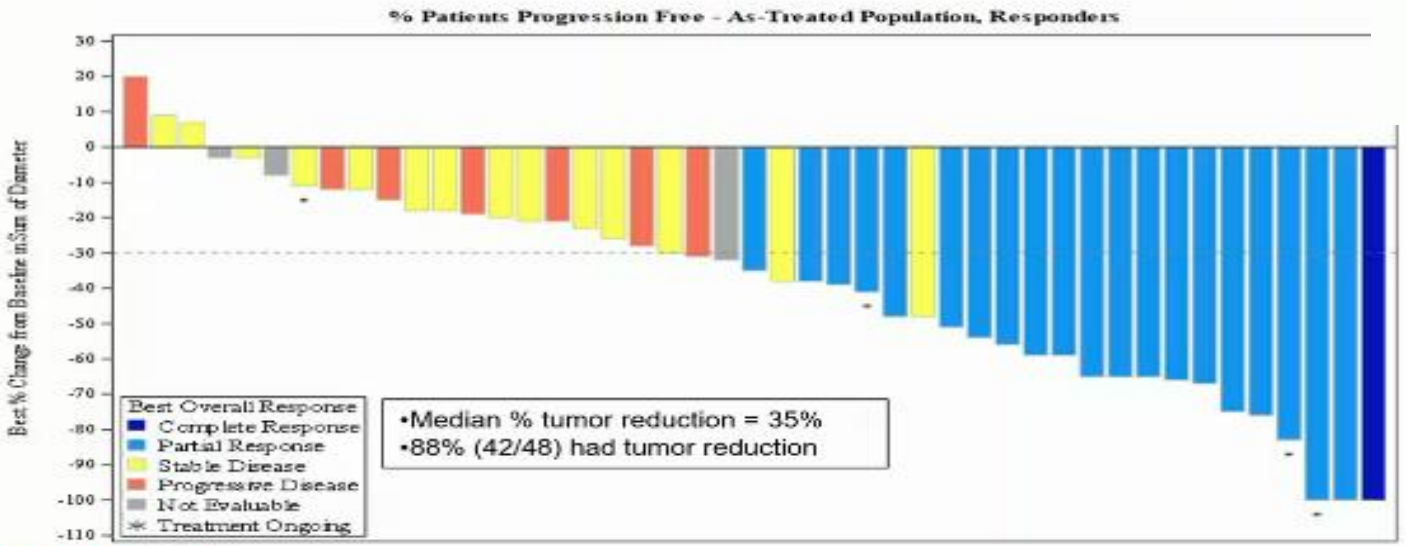
Best %Change from Baseline in Target Tumor Size



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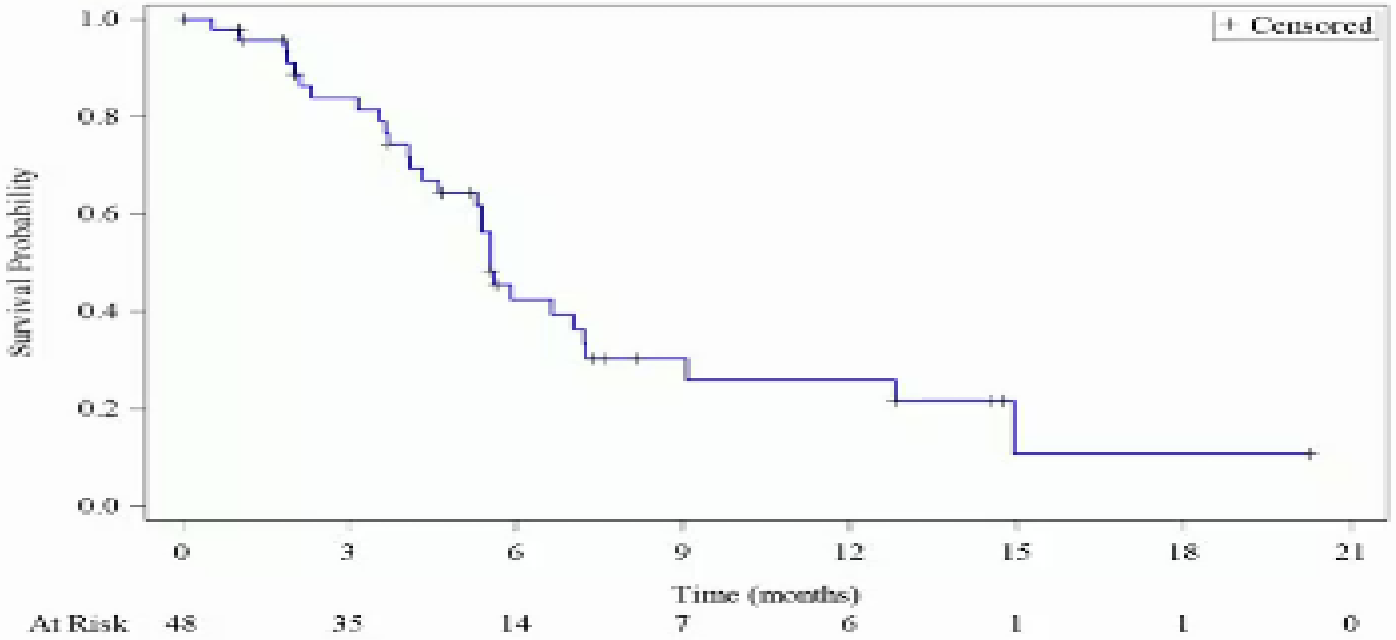
Progression-free-survival (PFS)

Median PFS (months) (range)	5.6 (0, >20.2)
PFS duration	
>6 months	42%
>12 months	26%



Exposure and Safety

	N=48
Treatment-related AE	48 (100%)
Treatment-related Serious AE	5 (10%)
Dose interruptions	42 (88%)
Dose reductions	37 (77%)
AE leading to permanent discontinuation	6 (13%)

	Any Grade	Grade 3	Grade 4 / 5
Diarrhea	40 (83)	7 (15)	0
Rash	34 (69)	17 (35)	0
Stomatitis / Mucosal Inflammation	39 (81)	10 (21)	0
Paronychia	22 (46)	4 (8)	0
Pneumonitis	2 (4)	1 (2)	0

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Durvalumab ± tremelimumab + platinum-etoposide in first-line extensive-stage SCLC (ES-SCLC): 3-year overall survival update from the Phase 3 CASPIAN study

Luis Paz-Ares,[1] Yuanbin Chen,[2] Niels Reinmuth,[3] Katsuyuki Hotta,[4] Dmytro Trukhin,[5] Galina Statsenko,[6] Maximilian J. Hochmair,[7] Mustafa Özgüroğlu,[8] Jun Ho Ji,[9] Oleksandr Voitko,[10] Artem Poltoratskiy,[11] Francesco Verderame,[12] Libor Havel,[13] Igor Bondarenko,[14] György Losonczy,[15] Nikolay Conev,[16] Helen Broadhurst,[17] Tapashi Dalvi,[18] Haiyi Jiang,[18] Jonathan W. Goldman[19]

[1]Hospital Universitario 12 de Octubre, Madrid, Spain; [2]Cancer & Hematology Centers of Western Michigan, Grand Rapids, MI, USA; [3]Asklepios Lung Clinic, Munich Gauting, Germany; [4]Okayama University Hospital, Okayama, Japan; [5]Odesa Regional Oncological Dispensary, Odesa, Ukraine; [6]Omsk Regional Cancer Center, Omsk, Russian Federation; [7]Karl Landsteiner Institute of Lung Research and Pulmonary Oncology, Klinik Ottakring, Wien, Austria; [8]Istanbul University–Cerrahpaşa, Cerrahpaşa School of Medicine, Istanbul, Turkey; [9]Samsung Changwon Hospital, Sungkyunkwan University School of Medicine, Changwon, South Korea; [10]Kyiv City Clinical Oncology Center, Kiev, Ukraine; [11]Petrov Research Institute of Oncology, St Petersburg, Russian Federation; [12]ASO Ospedale Santa Elisabetta Canicattì, Palermo, Italy; [13]Thoracic Hospital, First Faculty of Medicine, Charles University, Prague, Czech Republic; [14]Dnipropetrovsk Medical Academy, Dnipro, Ukraine; [15]Semmelweis University, Budapest, Hungary; [16]Medical Oncology, UMHAT St Marina, Varna, Bulgaria; [17]Pfizer Ireland Ltd, Aldwley Park, UK; [18]AstraZeneca, Gaithersburg, MD, USA; [19]David Geffen School of Medicine at UCLA, Los Angeles, CA, USA

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CASPIAN Study Design

Phase 3, global, randomised, open-label, active-controlled, multicentre study

- Treatment-naïve ES-SCLC
- WHO PS 0 or 1
- Asymptomatic or treated and stable brain metastases permitted
- Life expectancy ≥12 weeks
- Measurable disease per RECIST v1.1

N=805 (randomised)

1:1:1 (R)

Stratified by planned platinum (carboplatin vs cisplatin)

Durvalumab + EP* q3w for 4 cycles	Durvalumab q4w until PD
Durvalumab + tremelimumab + EP* q3w for 4 cycles	Durvalumab‡ q4w until PD
EP* q3w for up to 6 cycles†	Optional PCI†

Primary endpoint
- OS

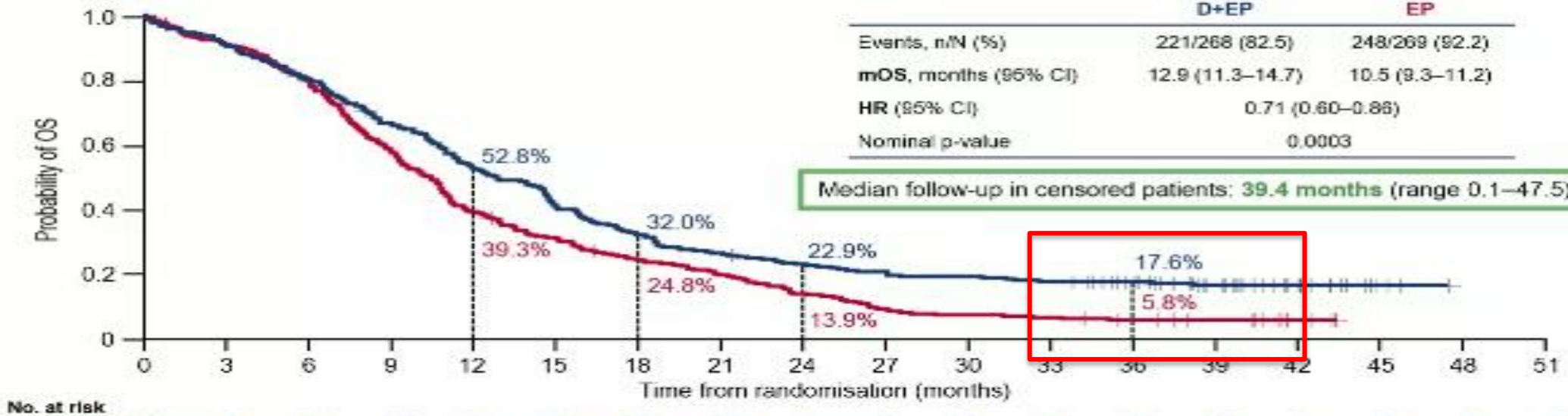
Secondary endpoints
- PFS §
- ORR §
- Safety & tolerability
- PROs

- Updated analysis of OS after median follow-up of approximately 3 years was a planned exploratory analysis
  - PFS and ORR data were not collected since the previous data cutoff
  - Serious AEs (including deaths) were analysed, but other safety data were not collected

*EP consists of etoposide 80–100 mg/m² with either carboplatin AUC 5–6 or cisplatin 75–80 mg/m², durvalumab dosed at 1500 mg, tremelimumab dosed at 75 mg; †Patients could receive an additional 2 cycles of EP (up to 6 cycles total) and PCI at the investigator's discretion; ‡Patients received an additional dose of tremelimumab post-EP; §By investigator assessment per RECIST v1.1

AEs, adverse events; AUC, area under the curve; CRR, objective response rate; PCI, prophylactic cranial irradiation; PD, disease progression; PFS, progression-free survival; PROs, patient-reported outcomes; PS, performance status; q3w, every 3 weeks; q4w, every 4 weeks; RECIST v1.1, Response Evaluation Criteria in Solid Tumors version 1.1

3-year Overall Survival Update: D+EP vs EP



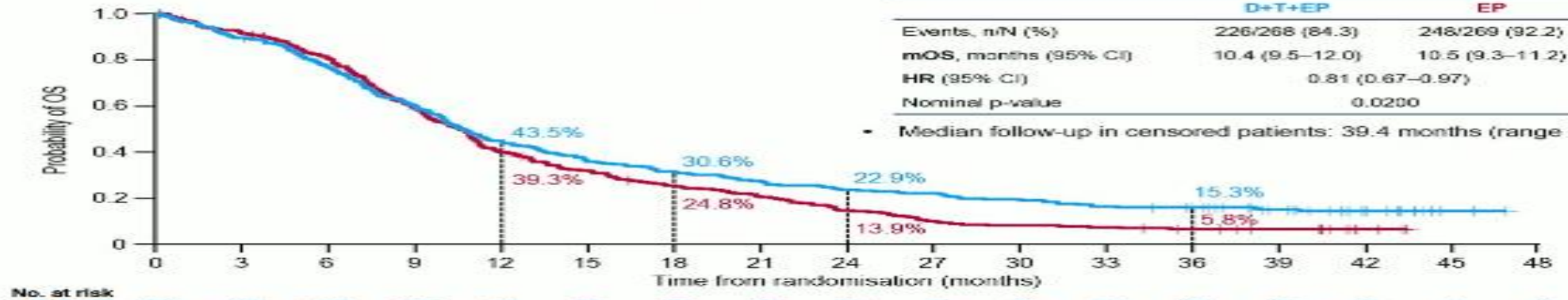
	D+EP	EP
Events, n/N (%)	221/268 (82.5)	248/269 (92.2)
mOS, months (95% CI)	12.9 (11.3–14.7)	10.5 (9.3–11.2)
HR (95% CI)	0.71 (0.60–0.86)	
Nominal p-value	0.0003	

Median follow-up in censored patients: 39.4 months (range 0.1–47.5)

No. at risk

D+EP	268	244	214	177	140	109	85	70	60	54	50	46	39	25	13	3	0	0
EP	269	243	212	156	104	82	64	51	36	24	19	17	13	10	3	0	0	0

3-year Overall Survival Update: D+T+EP vs EP



	D+T+EP	EP
Events, n/N (%)	226/268 (84.3)	248/269 (92.2)
mOS, months (95% CI)	10.4 (9.5–12.0)	10.5 (9.3–11.2)
HR (95% CI)	0.81 (0.67–0.97)	
Nominal p-value	0.0200	

- Median follow-up in censored patients: 39.4 months (range 0.1–47.5)

No. at risk

D+T+EP	268	238	200	156	114	92	80	70	60	56	48	41	37	26	11	2	0
EP	269	243	212	156	104	82	64	51	36	24	19	17	13	10	3	0	0

Data cutoff: 22 March 2021

Efficacy and safety of nivolumab for patients with pre-treated type B3 thymoma and thymic carcinoma: Results from the EORTC-ETOP NIVOTHYM phase II trial

Nicolas GIRARD, Santiago PONCE AIX, Susana CEDRES, Thierry BERGHMANS, Sjaak BURGERS, Anne-Claire TOFFART, Sanjay POPAT, Annelies JANSSENS, Radj GERVAIS, Monique HOCHSTENBAG, Mario SILVA, Irene A. BURGER, Helmut PROSCH, Rolf STAHEL, Anne-Sophie GOVAERTS, Alessia POCHESCI, Anouk NEVEN, Solange PETERS

EORTC-ETOP NIVOTHYM trial: Study Design

NIVOTHYM is an international multicenter phase II, 2-cohort, single-arm trial evaluating the use of nivolumab +/- ipilimumab in patients with advanced/relapsed type B3 thymoma or thymic carcinoma, after exposure of platinum-based chemotherapy

Cohort 1:
Nivolumab (240 mg IV Q2 weeks)

Final results reported

Cohort 2:
Nivolumab (240 mg IV Q2 weeks)
+ ipilimumab (1 mg/kg IV Q6 weeks)

Currently recruiting

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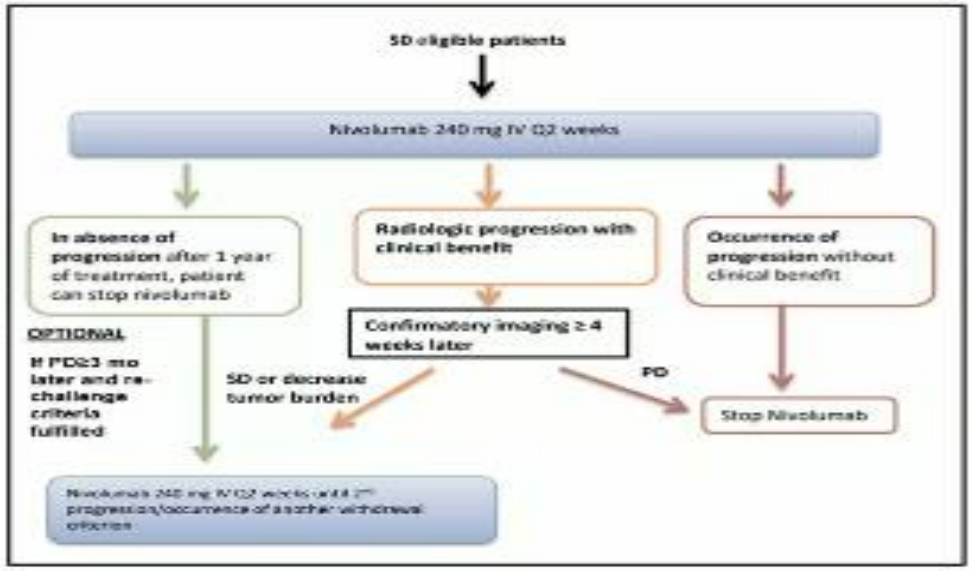
EORTC-ETOP NIVOTHYM: Endpoints and Statistics



Primary endpoint:
Progression Free Survival Rate at 6 months (PFSR-6, binary) per independent radiological review based on RECIST 1.1

Secondary endpoints:
- PFSR-6 per local investigator assessment
- Safety
- Overall response rate (ORR) and disease Control Rate (DCR)
- Progression Free survival (PFS)
- Overall survival (OS)

Statistical design
- Exclude a PFSR-6 of 40% (H0) or less under the alternative of a PFSR-6 of 60% (H1). The type I error is 10%, the power 90%
- Interim analysis for futility and efficacy

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EORTC-ETOP NIVOTHYM: Safety – safety population

	Grade 1 n (%)	Grade 2 n (%)	Grade 3 n (%)	Grade 4 n (%)	Grade 5 n (%)	Grade≥3 n (%)	Grade ≥1 n (%)
Worst grade – all AEs	4 (7)	18 (33)	26 (48)	5 (9)	1 (2)	32 (59)	54 (100)
Worst grade – treatment related AE	11 (20)	19 (35)	10 (19)	4 (7)	-	14 (26)	44 (81)

2021 ESMO congress
Nicolas Girard on behalf of EORTC-ETOP 1525 investigators
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EORTC-ETOP NIVOTHYM: PFSR-6 – per-protocol populatic

By central review – PRIMARY ENDPOINT

	Nivolumab (n=49) n (%)
PFSR-6	
Success	17 (35)
Failure	32 (65)
95% CI	22-50%
80% CI	26-45%
Reason for failure	
PD	24
Death without PD before 6 months	3
Start of new treatment before PD*	1
Unknown disease status	4

* Patient had PD according to local investigator and started new treatment

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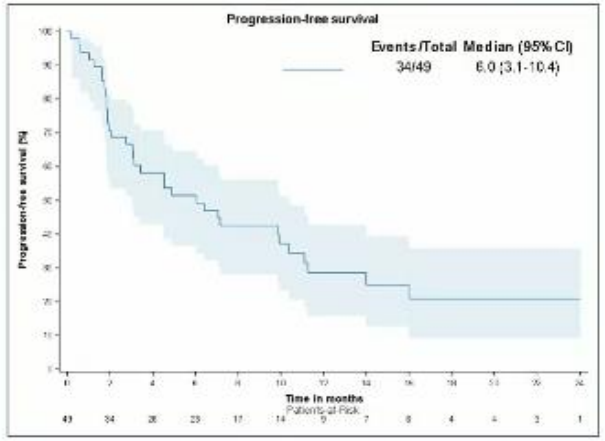
EORTC-ETOP NIVOTHYM: PFS – per-protocol population

	Nivolumab (n=49) n (%)
PFS status	
No event	15 (31)
Event	34 (69)

Survival rates % (95% CI)	
6 months	**52% (37-65)**
12 months	29% (16-43)
18 months	21% (9-36)

Note: In the PFS analysis, patients are censored if at least 2 consecutive disease assessments have been missed.



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EORTC-ETOP NIVOTHYM: Overall survival – per-protocol population

	Nivolumab (n=49) n (%)
Survival status	
Alive	33 (67)
Death	16 (33)
Reason for death	
PD	12
Other	2
Unknown	2

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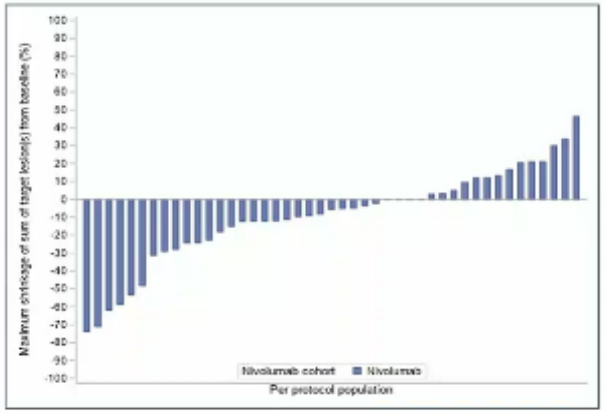
EORTC-ETOP NIVOTHYM: Response – per-protocol population

	Nivolumab (n=49) n (%)
Best overall response during treatment (investigator)	
Partial response (PR)	6 (12)
Stable disease (SD)	25 (51)
Progressive disease (PD)	13 (27)
Not evaluable	5 (10)
Response rate (RR=CR+PR)	12%
95% CI for RR	5-25%
Disease control rate (DCR=CR+PR+SD)	63%
95% CI for DCR	48-77%

* Only patients which are evaluable are presented on the waterfall plot



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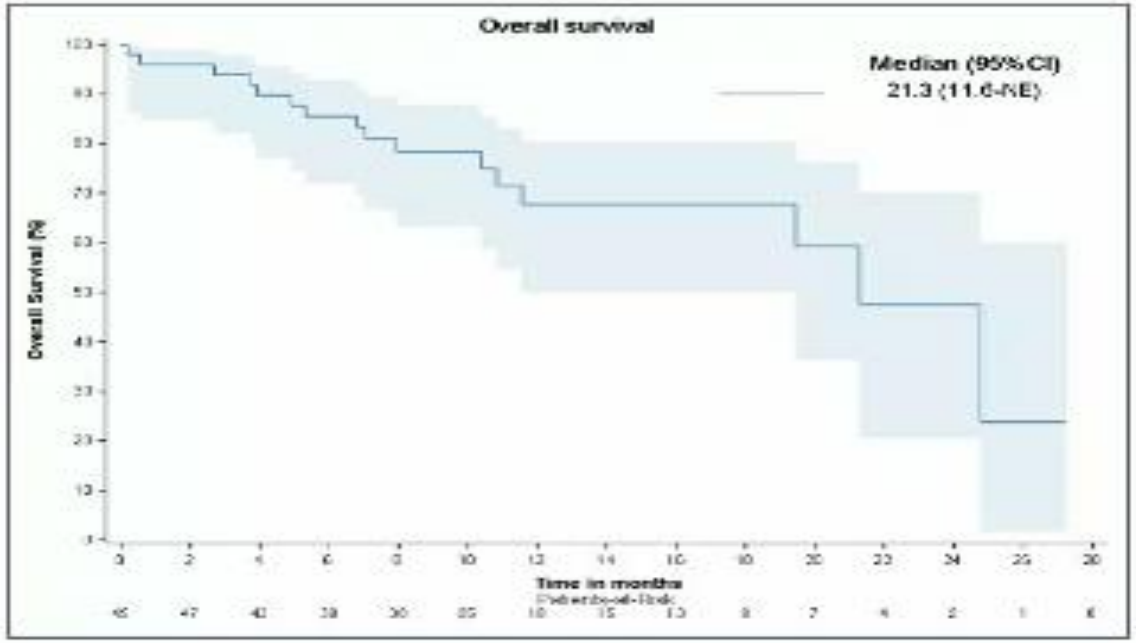
EORTC-ETOP NIVOTHYM: Overall survival – per-protocol population

	Nivolumab (n=49) n (%)
Survival status	
Alive	33 (67)
Death	16 (33)
Reason for death	
PD	12
Other	2
Unknown	2

Survival rates % (95% CI)	
6 months	86% (72-93)
12 months	68% (50-80)
18 months	68% (50-80)



2021 ESMO congress

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En resumen

- Bevacizumab no aporta beneficio en pacientes con EGFR mutados (a valorar el papel en la población fumadora.
- Amivantamab + Lazertinib postratamiento con osimertinib y en pacientes previamente tratados presenta buenos datos de respuesta y actividad en pacientes con mutación de EGFR. A la espera de resultados de estudios fase III.
- Trastuzumab deruxtecan y pozitinib afianzan datos en población con mutación HER 2
- Durvalumab presenta datos de supervivencia a 3 años en SCLC y sigue manteniendo beneficio con aumento de largos supervivientes
- Nivolumab en monoterapia no alcanza su objetivo primario en Timoma o carcinoma timico a la espera de resultados de la combinación con ipilimumab