The Implications of Recent Datasets for the Current and Future Management of Non-Small Cell Lung Cancer with EGFR Mutations

A CME/MOC-Accredited Live Webinar in Conjunction with the IASLC 2024 World Conference on Lung Cancer

Tuesday, September 10, 2024

9:00 PM – 10:00 PM ET (6:00 PM – 7:00 PM PT)

Faculty

Joshua K Sabari, MD

Helena Yu, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

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Assistant Professor of Medicine
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Perlmutter Cancer Center
New York, New York

MODERATOR
Neil Love, MD
Research To Practice
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Helena Yu, MD
Medical Oncologist
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Commercial Support

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Dr Love — Disclosures

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Data and Safety Monitoring Board/Committee	Janssen Biotech Inc
Research Funding to My Institution	AstraZeneca Pharmaceuticals LP, Black Diamond Therapeutics Inc, Blueprint Medicines, Cullinan Therapeutics, Daiichi Sankyo Inc, Erasca, Janssen Biotech Inc, Novartis, Pfizer Inc

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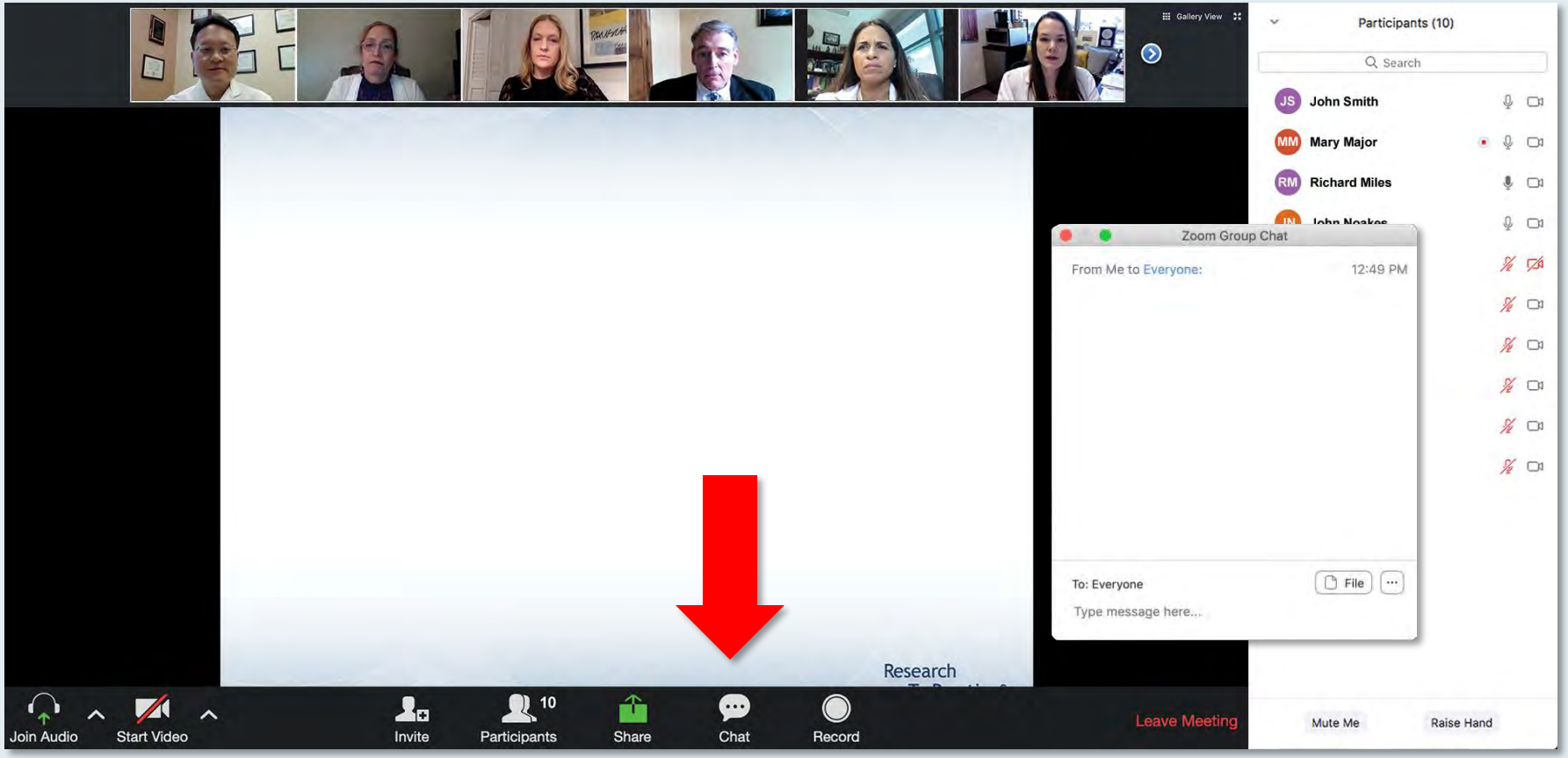

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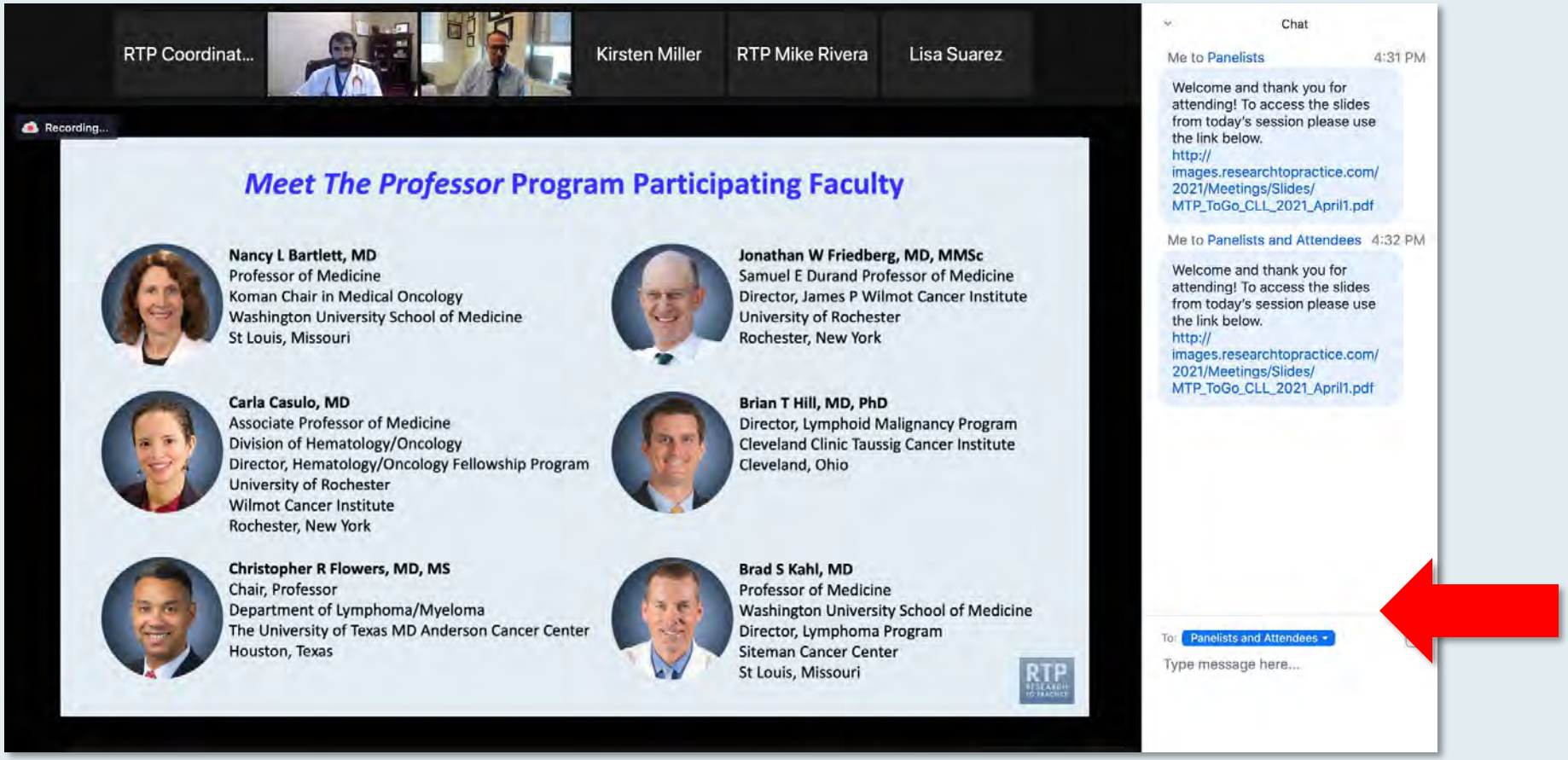

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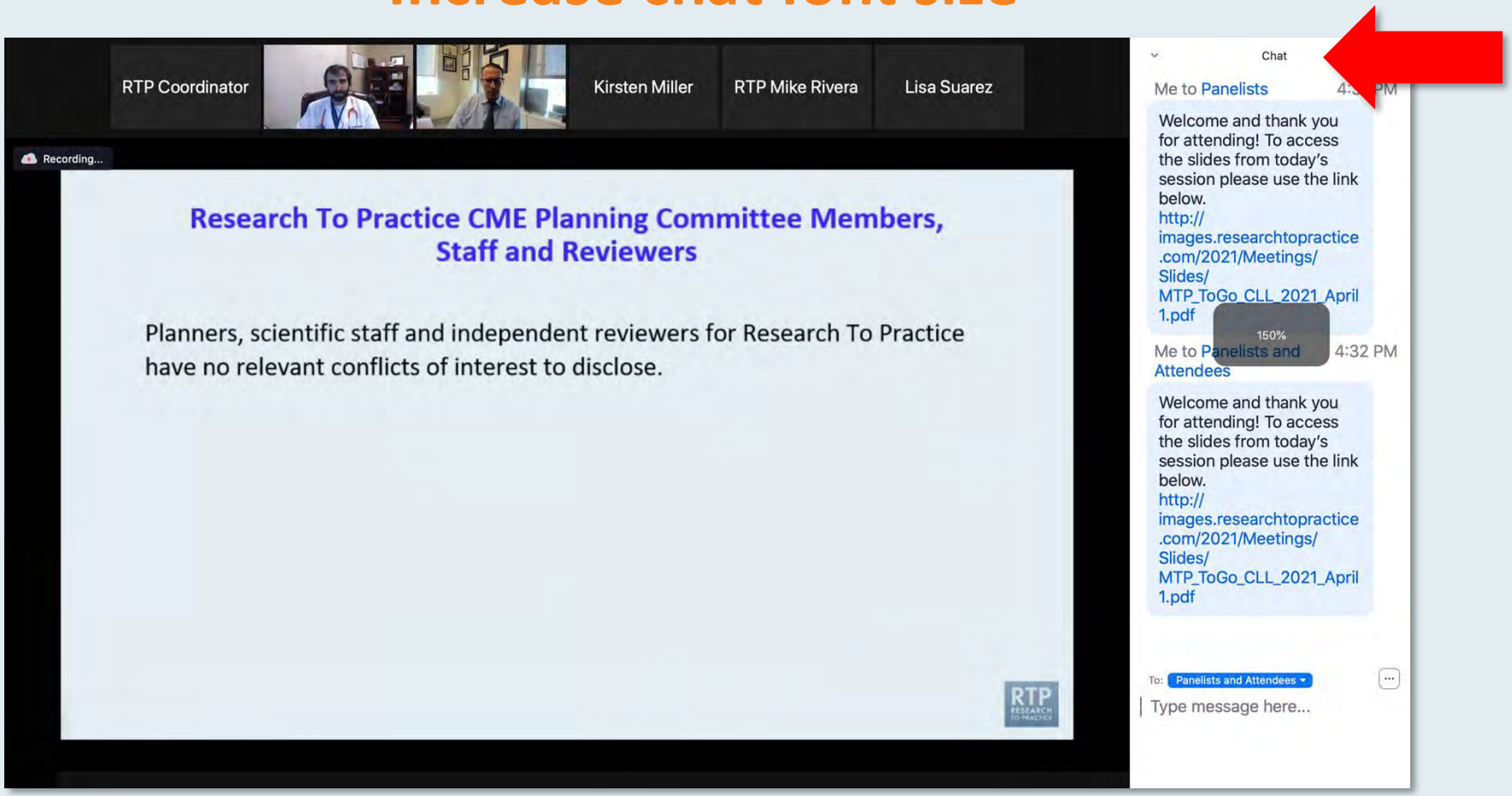

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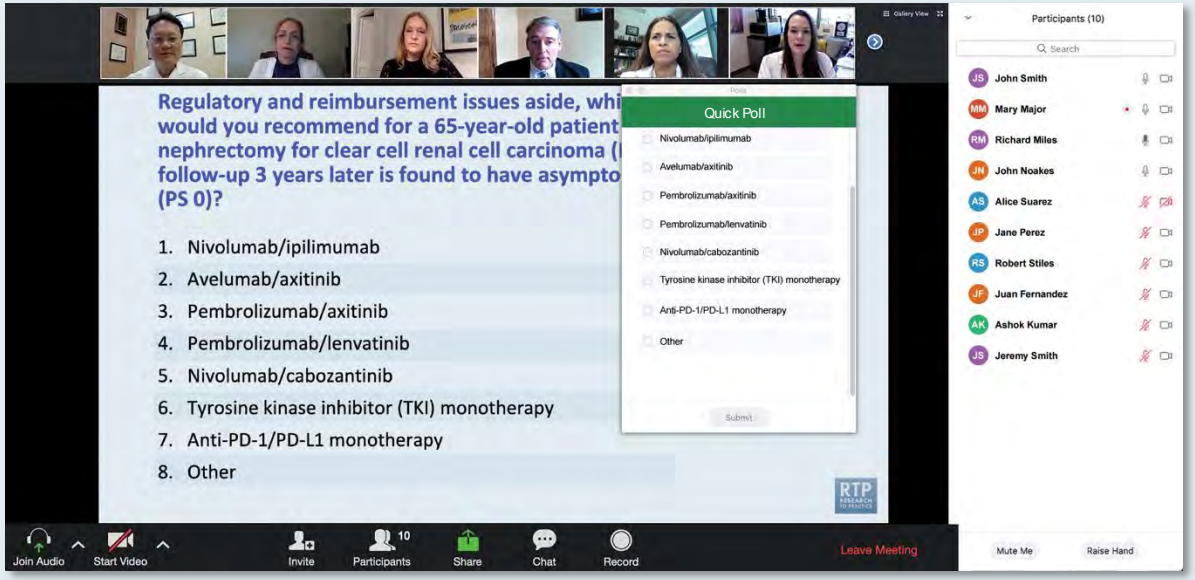

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UCLA HEALTH

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Moderator

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RESEARCH TO PRACTICE

Practical Perspectives: Optimizing Diagnosis and Treatment for Patients with Desmoid Tumors

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Tuesday, September 24, 2024
5:00 PM – 6:00 PM ET

Faculty

Thierry Alcindor, MD, MSc
Mrinal Gounder, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Practical Perspectives: Optimizing the Role of BTK Inhibitors in the Management of Mantle Cell Lymphoma

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5:00 PM – 6:00 PM ET

Faculty

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Michael Wang, MD

Moderator

Neil Love, MD

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Data + Perspectives: Clinical Investigators Explore the Application of Recent Datasets in Current Oncology Care

A Multitumor Hybrid Symposium in Partnership with Florida Cancer Specialists & Research Institute

Saturday, October 26, 2024

ER-Positive Breast Cancer

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Additional faculty to be announced.

Lung Cancer

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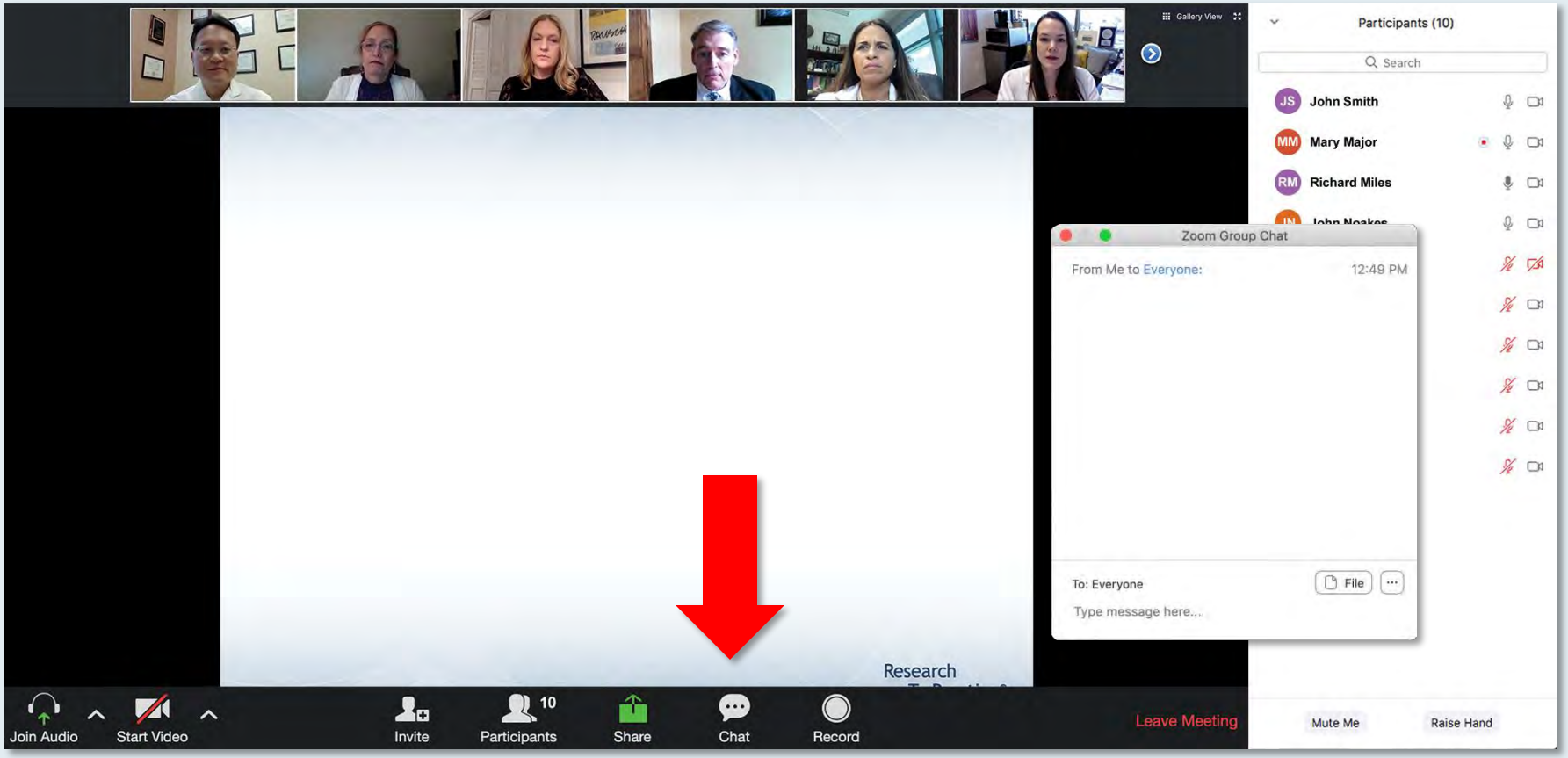

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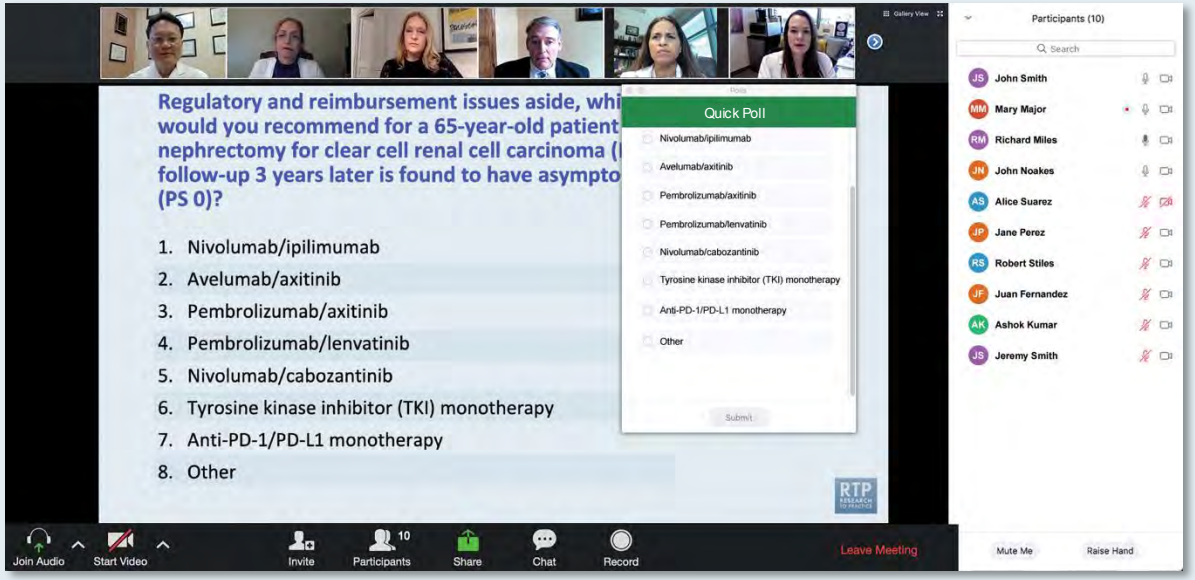

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Introduction: Checkpoint Inhibitors and EGFR-Mutated Lung Cancer

Module 1: Current Management of Metastatic Non-Small Cell Lung Cancer (NSCLC) with EGFR Mutations — Dr Sabari

Module 2: Novel Therapeutic Approaches for NSCLC Harboring EGFR Mutations — Dr Yu

Agenda

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Ivonescimab Head-to-Head Phase III Data Against Pembrolizumab Unveiled at WCLC 2024

Press Release: September 8, 2024

Head-to-head clinical data from the Phase III HARMONi-2 study comparing ivonescimab monotherapy to pembrolizumab monotherapy as a first-line treatment for PD-L1-positive (PD-L1 TPS ≥1%) locally advanced or metastatic non-small cell lung cancer (NSCLC) were presented today as a Late-Breaking Abstract with an oral presentation at the IASLC 2024 World Conference on Lung Cancer. In the ITT population, ivonescimab demonstrated a median progression-free survival of 11.14 months compared to 5.82 months for pembrolizumab. The PFS hazard ratio was 0.51 ($P < 0.0001$), indicating a significant 49% reduction in the risk of disease progression or death. Ivonescimab significantly improved the objective response rate (ORR) and disease control rate (DCR) compared to pembrolizumab in the first-line treatment of PD-L1-positive NSCLC. The ORR for ivonescimab was 50.0%, versus 38.5% for pembrolizumab, while the DCR was 89.9% for ivonescimab versus 70.5% for pembrolizumab. Subgroup analyses revealed that ivonescimab outperformed pembrolizumab across various factors, including age, sex, ECOG performance status, PD-L1 expression, histological type and the presence of liver or brain metastases. This is the first randomized Phase III study to demonstrate a clinically significant improvement in efficacy with a novel drug compared to pembrolizumab for NSCLC. Overall survival data were not yet mature at the time of the data cutoff and will be evaluated in the future.

Based on this study, a supplemental New Drug Application (sNDA) for ivonescimab monotherapy as first-line treatment for PD-L1-positive NSCLC has been submitted and granted priority review. Additionally, a Phase III clinical study of ivonescimab combined with chemotherapy versus tislelizumab combined with chemotherapy as first-line treatment for squamous NSCLC is ongoing. The HARMONi study, an international multicenter Phase III clinical study, is investigating ivonescimab combined with chemotherapy for EGFR-mutated, locally advanced or metastatic nonsquamous NSCLC that has progressed after third-generation EGFR-TKI therapy.

https://www.prnewswire.com/news-releases/akesos-ivonescimab-head-to-head-phase-iii-data-against-pembrolizumab-unveiled-at-wclc-2024-302241266.html

Phase 3 Study of Ivonescimab (AK112) vs. Pembrolizumab as First-line Treatment for PD-L1-positive Advanced NSCLC: HARMONi-2

C. Zhou[1,2], J. Chen[3], L. Wu[3], L. Wang[1], A. Xiong[1], B. Liu[4], J. Yao[5], H. Zhong[6], J. Li[7], Y. Cheng[8], Y. Sun[9], H. Ge[10], Q. Shi[11], M. Zhou[12], Z. Han[13], J. Wang[14], Q. Bu[15], Y. Zhao[16], J. Chen[17], J. Yang[18], M. Xia[18]

WCLC 2024;Abstract PL02.04

JAMA | Original Investigation

Ivonescimab Plus Chemotherapy in Non–Small Cell Lung Cancer With *EGFR* Variant
A Randomized Clinical Trial

HARMONi-A Study Investigators

Zhang L et al. *JAMA* 2024;332(7):561-570.

2024 ASCO ANNUAL MEETING

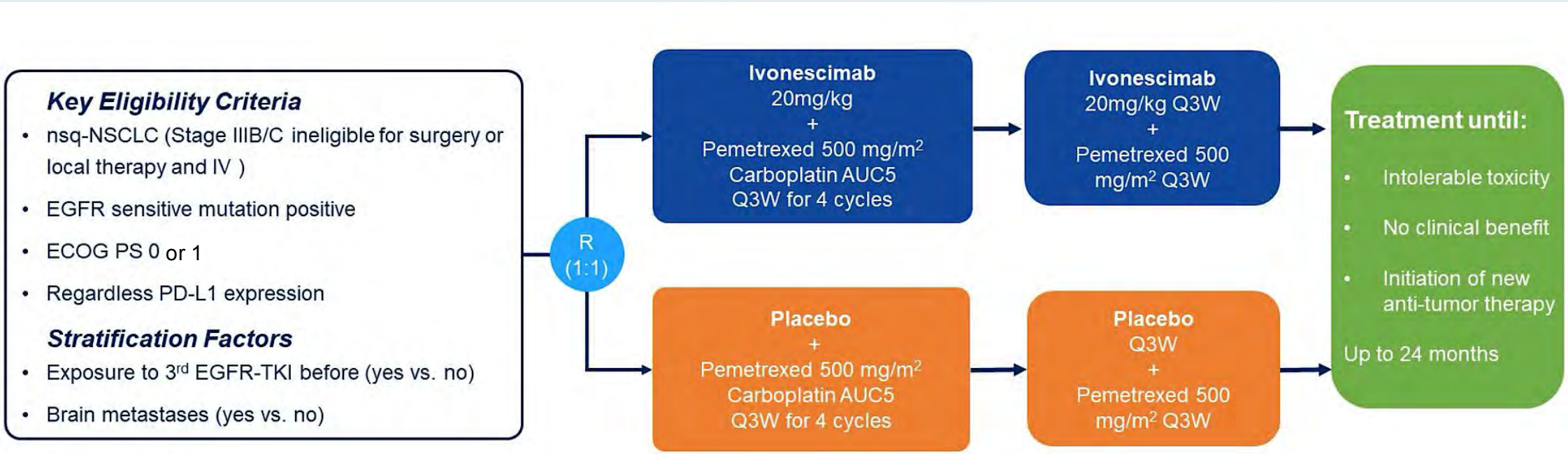
Ivonescimab combined with chemotherapy in patients with EGFR-mutant non-squamous non-small cell lung cancer who progressed on EGFR-TKIs treatment: a randomized, double-blind, multi-center, phase 3 trial (HARMONi-A study)

Li Zhang[1], Wenfeng Fang[1], Yuanyuan Zhao[1], Yongzhong Luo[2], Runxiang Yang[3], Yan Huang[1], Zhiyong He[4], Hui Zhao[5], Mingjun Li[6], Kai Li[7], Qibing Song[8], Xiaobo Du[9], Yulan Sun[10], Wei Li[11], Fei Xu[12], Zhiyu Wang[13], Kunning Yang[14], Yun Fan[15], Wenting Li[16], Michelle Xia[16]

[1]Sun Yat-sen University Cancer Center, Guangzhou, China; [2]Hunan Cancer Hospital, Changsha, China; [3]Yunnan Cancer Hospital, Kunming, China; [4]Fujian Provincial Tumor Hospital, Fuzhou, China; [5]The Second Hospital of Anhui Medical University, Hefei, China; [6]The First Affiliated Hospital of Zhengzhou University, Zhengzhou, China; [7]Tianjin Medical University Cancer Institute&Hospital, Tianjin, China; [8]Renmin Hospital of Wuhan University, Wuhan, China; [9]Mianyang Central Hospital, Mianyang, China; [10]Shandong Cancer Prevention and Treatment Institute, Jinan, China; [11]The First Affiliated Hospital of Bengbu Medical University, Bengbu, China; [12]The First Affiliated Hospital of Nanchang University, Nanchang, China; [13]The Fourth Hospital of Hebei Medical University, Shijiazhuang, China; [14]Weifang No.2 People's Hospital, Weifang, China; [15]Zhejiang Cancer Hospital, Hangzhou, China; [16]Akeso Biopharma, Inc., Zhongshan, China

Abstract 8508

HARMONi-A Phase III Trial Design



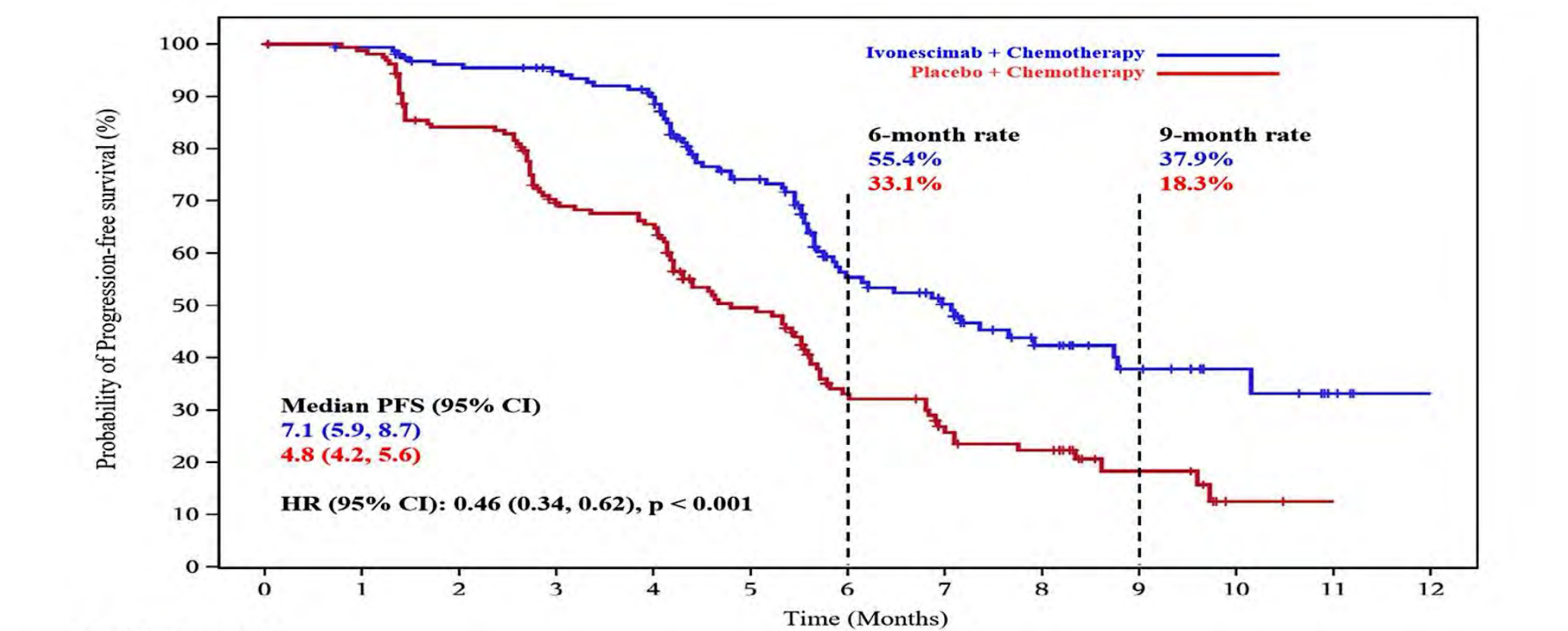
Endpoints

- Primary: Progression-free survival by independent radiologic review committee (IRRC)
- Secondary: Overall survival, Response rate, Duration of response, Time to response and Safety

ClinicalTrials.gov, NCT05184712; NSCLC, non-small cell lung carcinoma; EGFR, epidermal growth factor receptor; ECOG, Eastern Cooperative Oncology Group; TKI, tyrosine-kinase inhibitor; Q3W, every 3 weeks.

Zhang L et al. ASCO 2024;Abstract 8508.

HARMONi-A Primary Endpoint: Progression-Free Survival (PFS) with Ivonescimab and Chemotherapy for Patients with EGFR Mutation-Positive NSCLC and Disease Progression on EGFR TKIs



HR and P-value were stratified by previous 3rd Gen EGFR-TKI ues (yes vs. no) and presence of brain metastases (yes vs. no), and were calculated with stratified Cox model and log rank test. The two-sided P-value boundary is 0.024 as calculated using Lan-Demets spending function with O'Brien-Fleming approximation.
HR, hazard ratio; CI, confidence interval; IRRC, independent radiology review committee.

Zhang L et al. ASCO 2024;Abstract 8508.

TKIs = tyrosine kinase inhibitors

HARMONi-A: Adverse Events of Special Interest

Categories	Ivonescimab + Chemotherapy (N=161)		Placebo + Chemotherapy (N=161)	
Preferred Term, n(%)	Any grade	Grade ≥ 3	Any grade	Grade ≥ 3
AESI	48 (29.8)	5 (3.1)	25 (15.5)	4 (2.5)
Proteinuria	28 (17.4)	1 (0.6)	13 (8.1)	0
Haemorrhage	11 (6.8)	0	8 (5.0)	0
Urinary occult blood positive	4 (2.5)	0	3 (1.9)	0
Haemoptysis	2 (1.2)	0	0	0
Epistaxis	3 (1.9)	0	1 (0.6)	0
Mouth haemorrhage	1 (0.6)	0	0	0
Gastrointestinal haemorrhage	0	0	1 (0.6)	0
Gingival bleeding	1 (0.6)	0	0	0
Eye haemorrhage	1 (0.6)	0	2 (1.2)	0
Vaginal haemorrhage	0	0	1 (0.6)	0
Occult blood positive	0	0	1 (0.6)	0
Hypertension	13 (8.1)	3 (1.9)	5 (3.1)	3 (1.9)
Arterial thromboembolism	1 (0.6)	0	1 (0.6)	1 (0.6)
Cardiac failure congestive	1 (0.6)	1 (0.6)	0	0

Zhang L et al. ASCO 2024;Abstract 8508.

Agenda

Introduction: Checkpoint Inhibitors and EGFR-Mutated Lung Cancer

Module 1: Current Management of Metastatic Non-Small Cell Lung Cancer (NSCLC) with EGFR Mutations — Dr Sabari

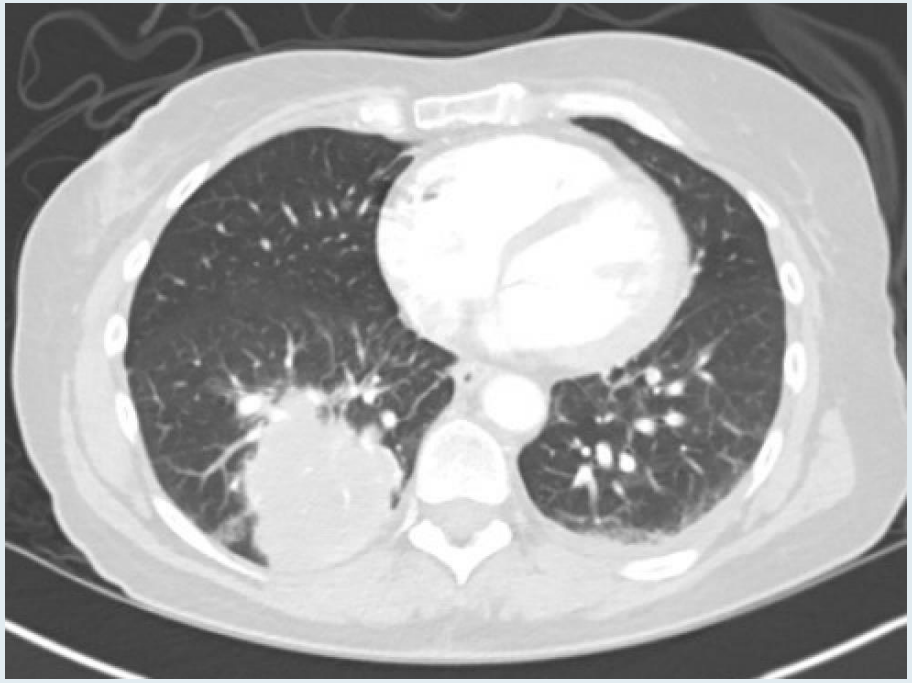
Module 2: Novel Therapeutic Approaches for NSCLC Harboring EGFR Mutations — Dr Yu

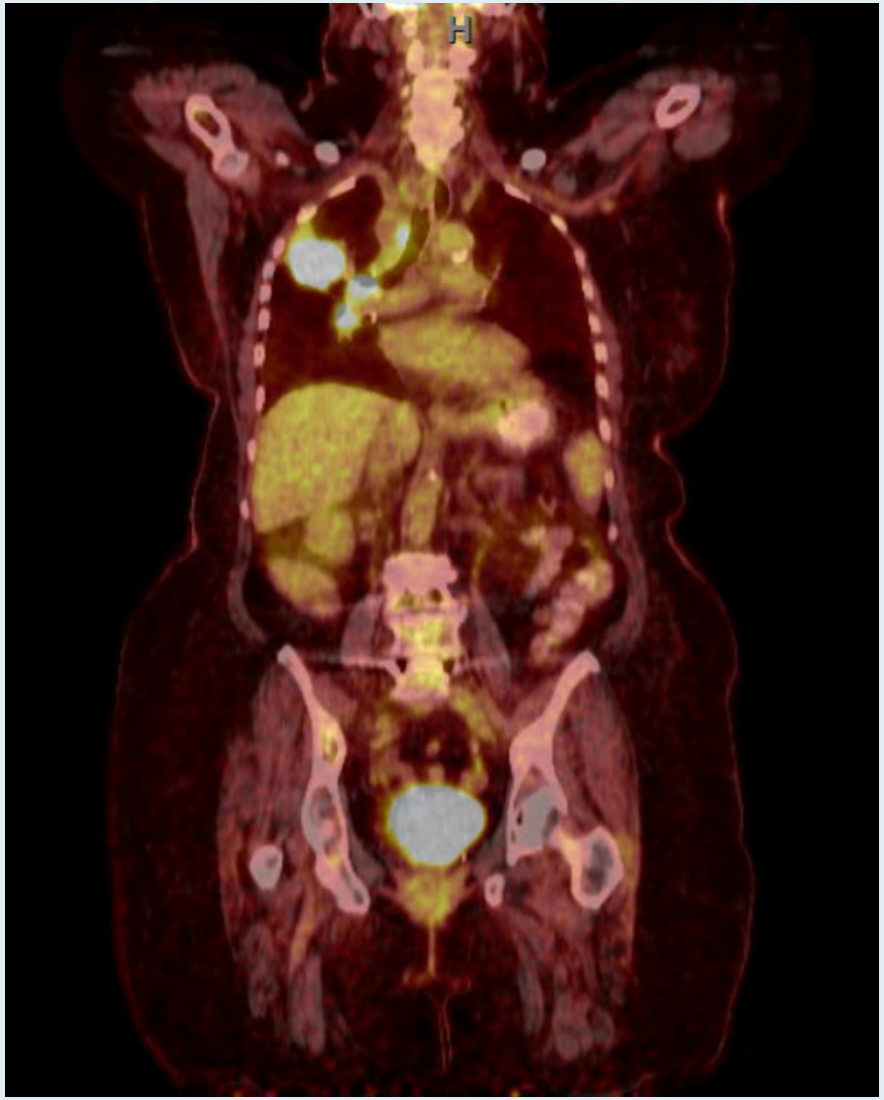
Case Presentation – Dr Sabari: 52-year-old woman

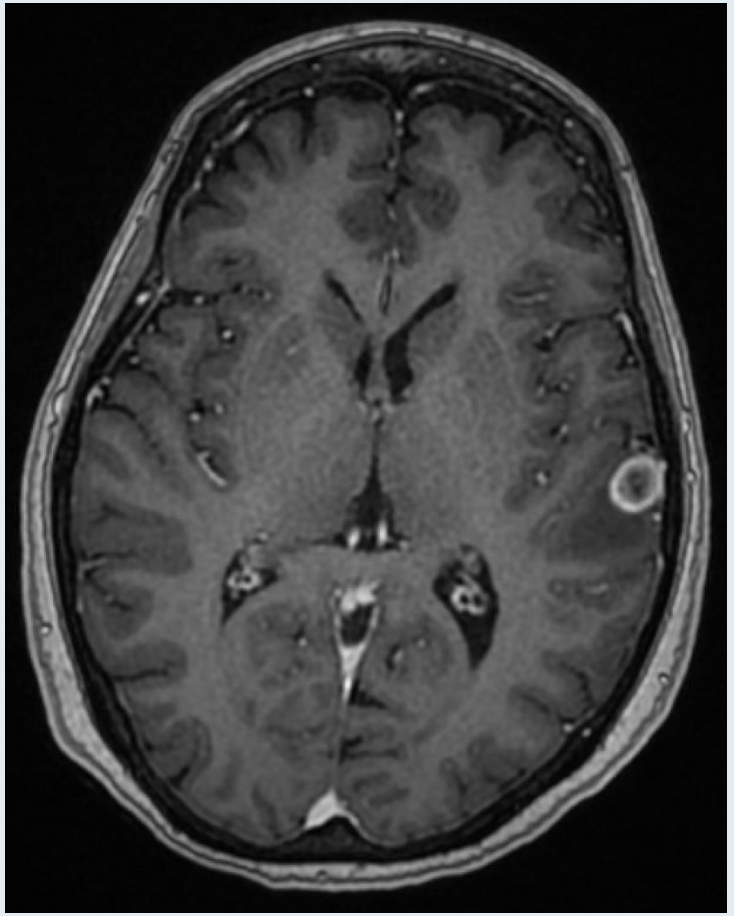
- 52-year-old woman with cough and shortness of breath x 2 months
- Presented to PCP who obtained a CXR which revealed a right upper lobe opacity
  - PMHx: former 5 pack-year smoker

Case Presentation – Dr Sabari: 52-year-old woman (continued)

Imaging







Case Presentation – Dr Sabari: 52-year-old woman (continued)

Plasma NGS identifies an EGFR L858R mutation

Summary of Detected Somatic Alterations, Immunotherapy Biomarkers & Associated Treatment Options

KEY ✓ Approved in indication ~ Approved in other indication ✗ Lack of response

Detected Alteration(s) / Biomarker(s)	Associated FDA-approved therapies	Clinical trial availability (see page 3)	% cfDNA or Amplification
EGFR L858R	✓ Afatinib, Dacomitinib, Erlotinib, Erlotinib+ramucirumab, Gefitinib, Osimertinib ~ Amivantamab	Yes	0.3%

Case Presentation – Dr Sabari: 52-year-old woman (continued)

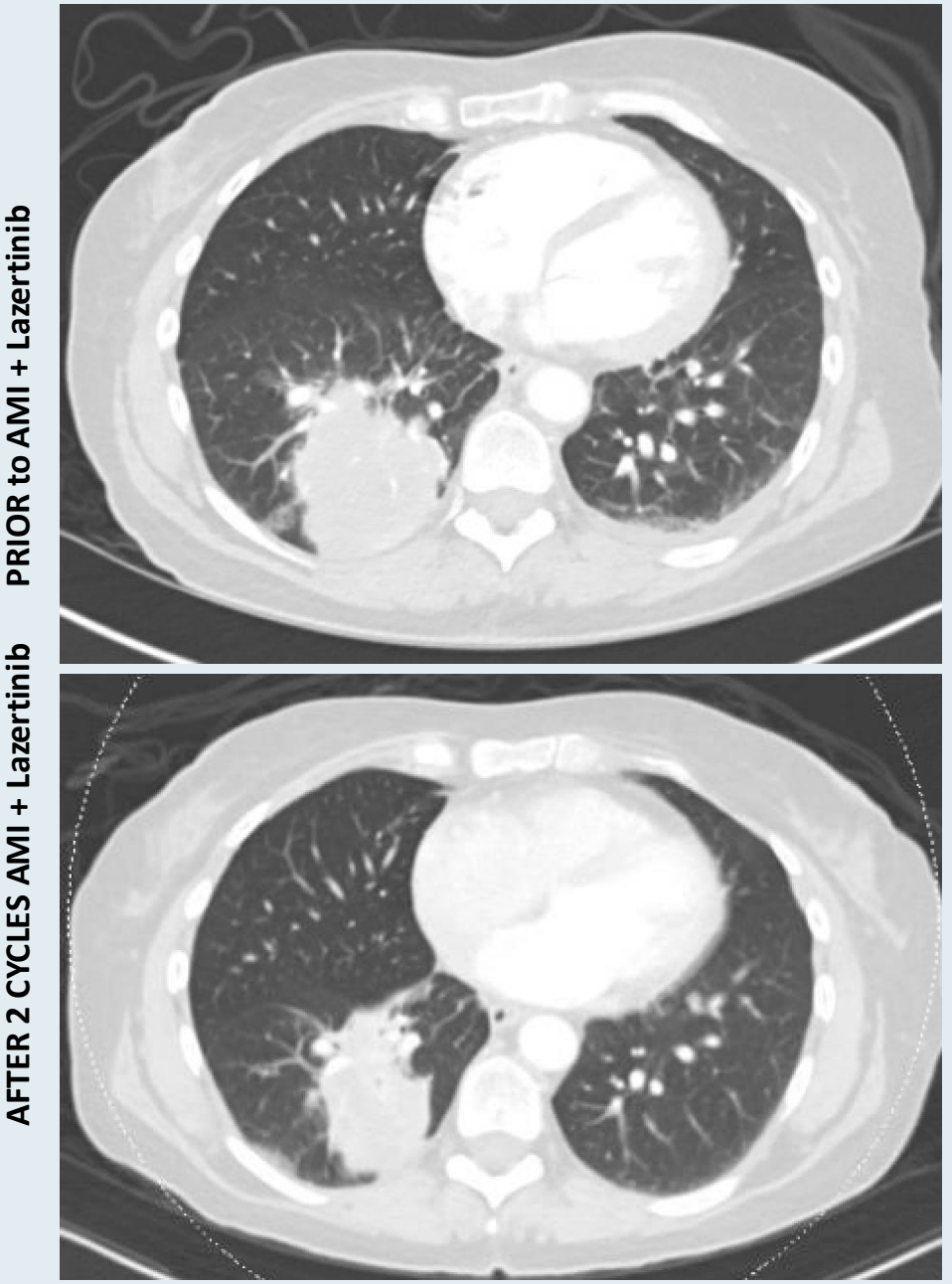
Systemic Treatment

- **Initiated 1L Amivantamab and Lazertinib**

Case Presentation – Dr Sabari: 52-year-old woman (continued)

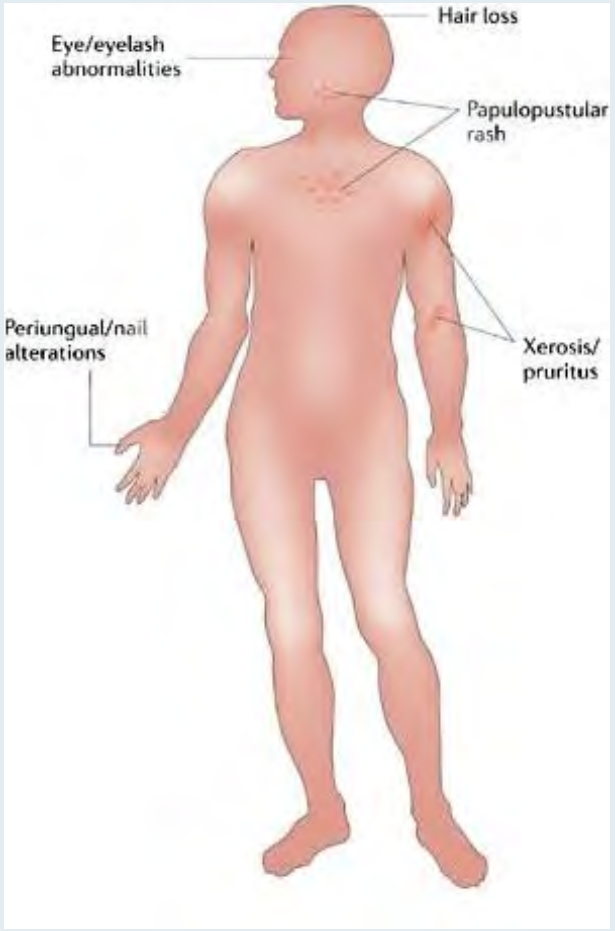
Systemic Treatment

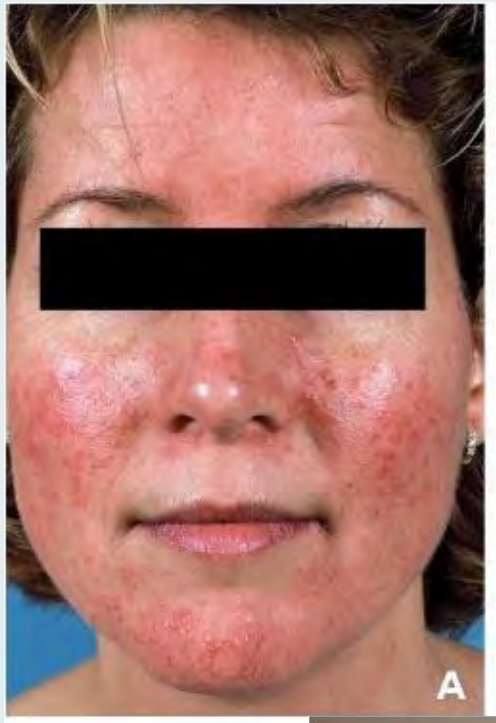
- **Initiated 1L Amivantamab and Lazertinib**
  - Despite a grade 2 IRR on C1D1, she tolerated amivantamab well with grade 1 rash and grade 1 edema
  - First restaging scans showed reduction in the RLL mass

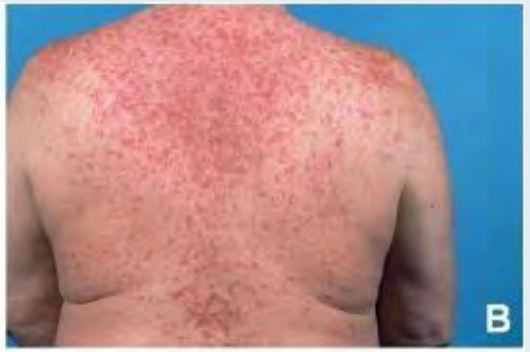


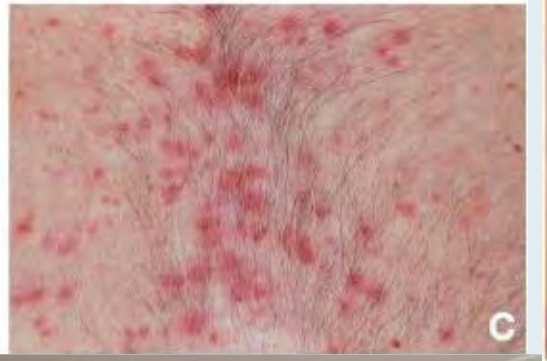
EGFR inhibition-mediated cutaneous toxicities

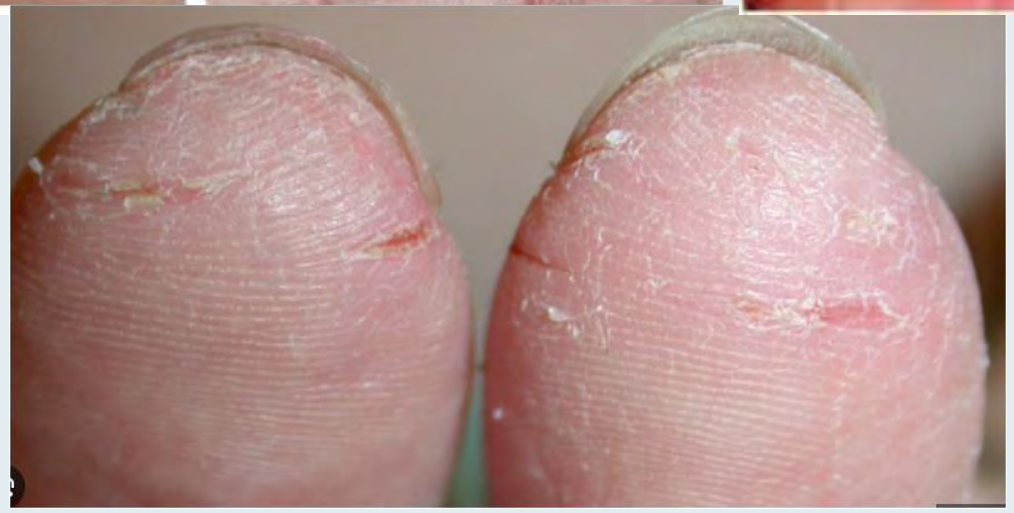
Cutaneous









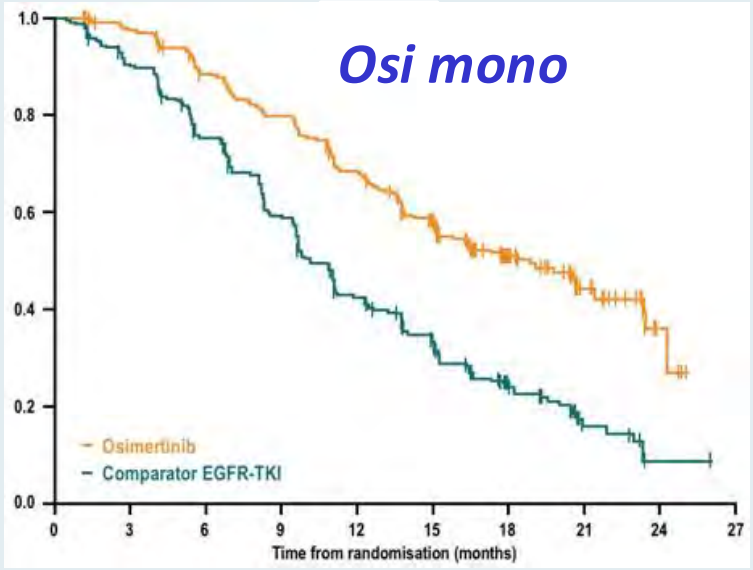


Current Management of Metastatic Non-Small Cell Lung Cancer (NSCLC) with EGFR Mutations

Joshua K Sabari, MD
Attending Physician
Thoracic Medical Oncology
Assistant Professor of Medicine
NYU Langone Health
Perlmutter Cancer Center
New York, New York

Options for First-Line Treatment for NSCLC with EGFR Mutations

FLAURA

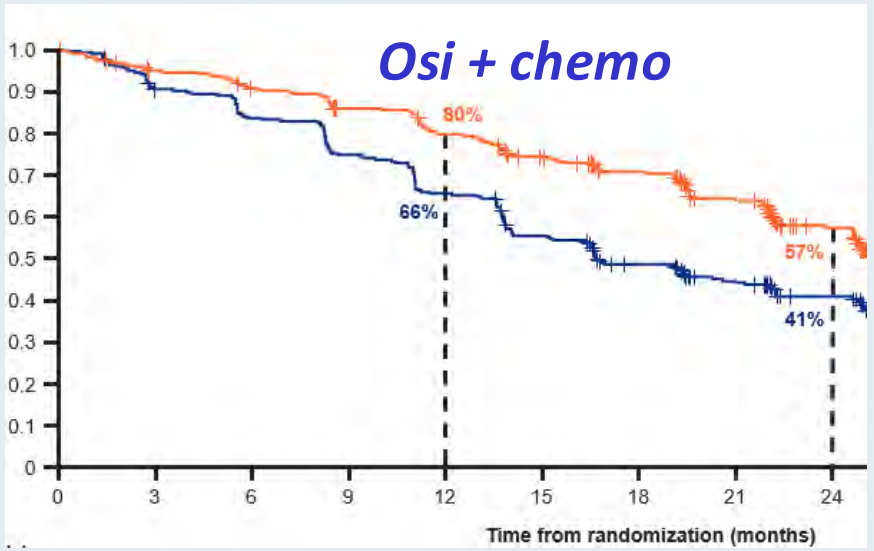


Progression-free survival

Osimertinib 18.9 mo

1st gen TKI 10.2 mo

FLAURA2

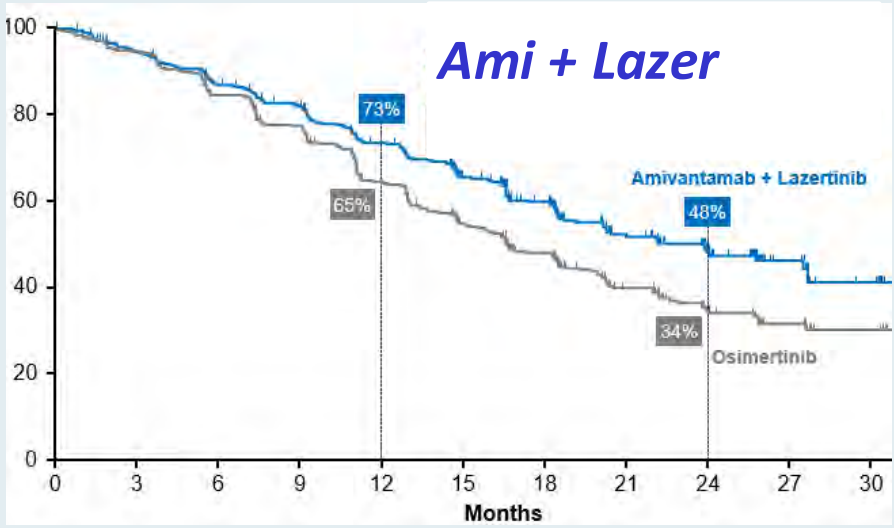


Progression-free survival

Osi + chemo 25.5 mo

Osimertinib 16.7 mo

MARIPOSA



Progression-free survival

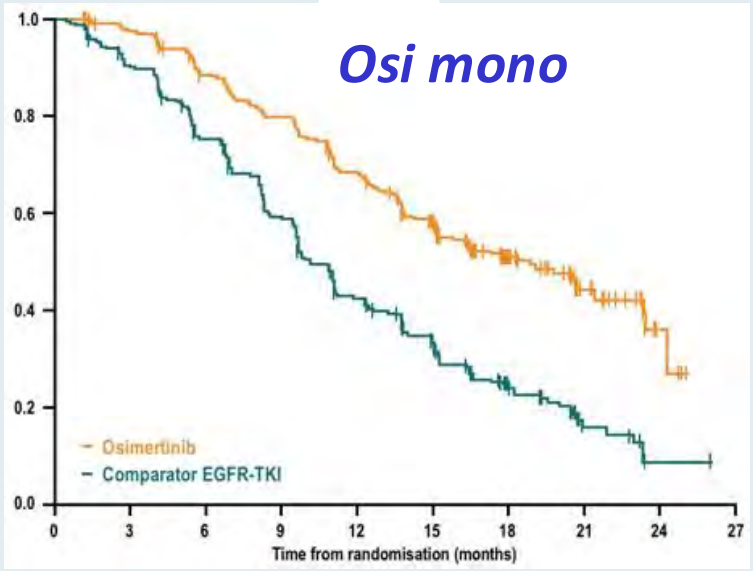
Ami + Laz 23.7 mo

Osimertinib 16.6 mo

Soria J-C et al. *N Engl J Med* 2018;378(2):113-25; Planchard D et al. *N Engl J Med* 2023;389(21):1935-48; Cho BC et al. *N Engl J Med* 2024 June 26;[Online ahead of print].

Options for First-Line Treatment for NSCLC with EGFR Mutations

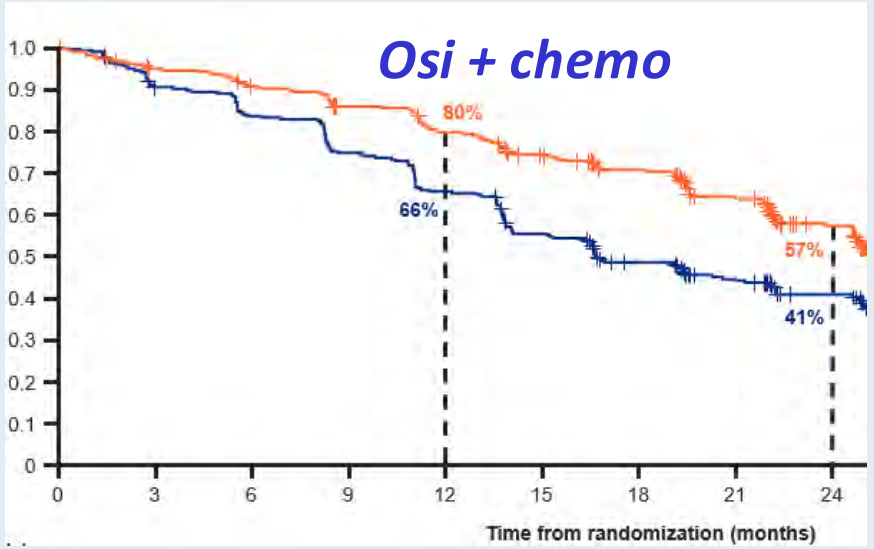
FLAURA



Progression-free survival
Osimertinib 18.9 mo
1st gen TKI 10.2 mo

Overall Survival
Osimertinib 38.6mo
1st gen TKI 31.8mo

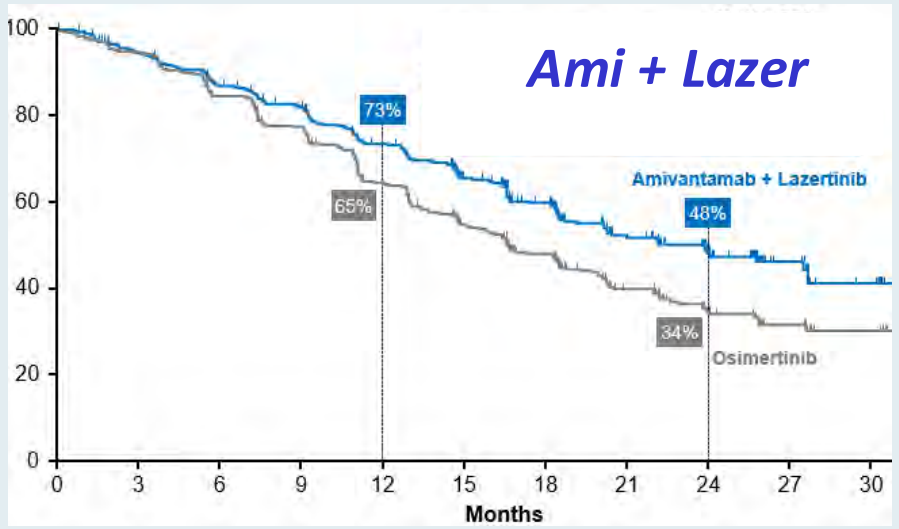
FLAURA2



Progression-free survival
Osi + chemo 25.5 mo
Osimertinib 16.7 mo

Overall Survival
Osimertinib + Chemo NR
Osimertinib 36.7mo

MARIPOSA

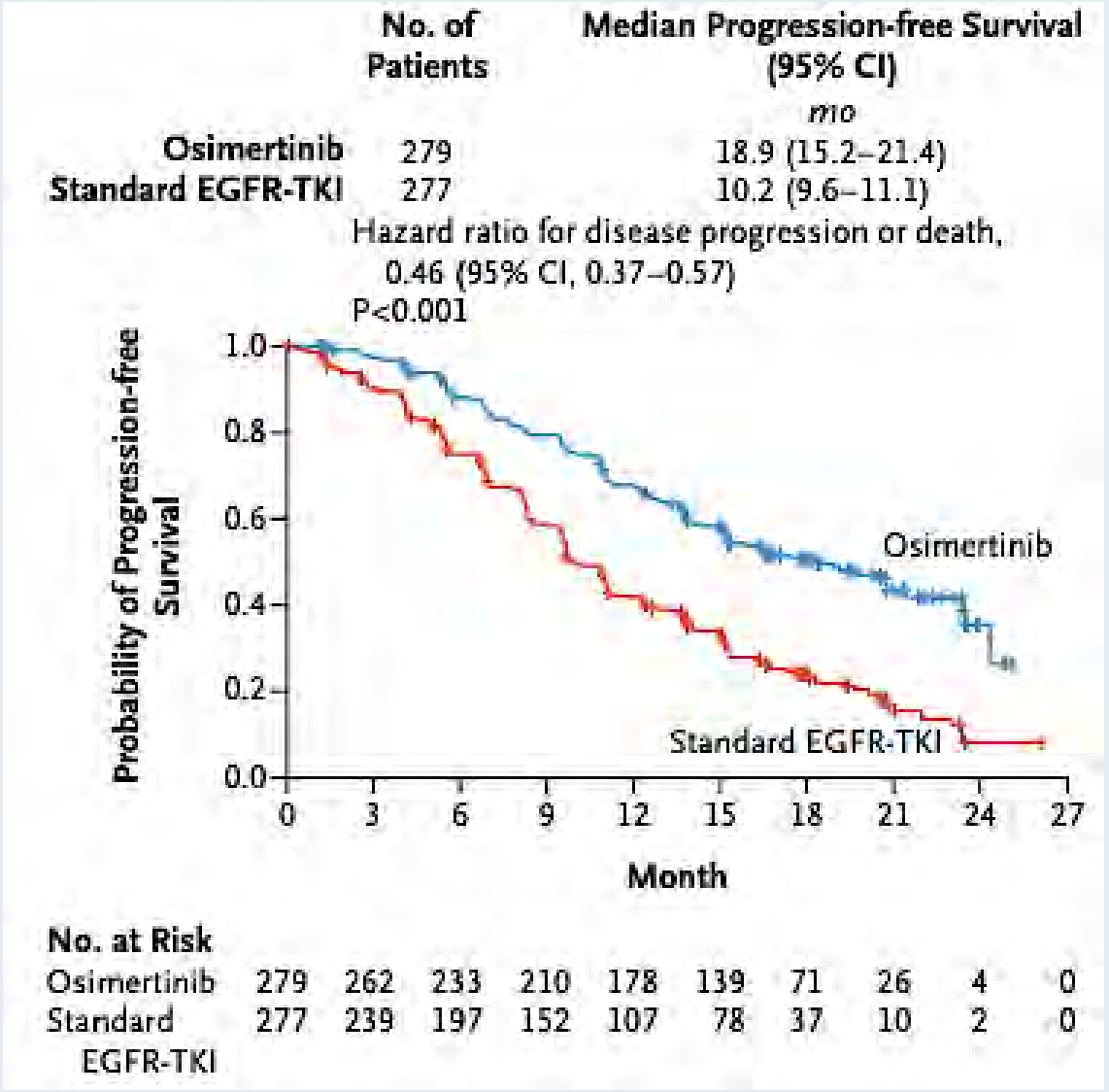


Progression-free survival
Ami + Laz 23.7 mo
Osimertinib 16.6 mo

Overall Survival
Ami + Laz NR
Osimertinib 37.3mo

Soria J-C et al. *N Engl J Med* 2018;378(2):113-25; Valdiviezo N et al. ELCC 2024;Abstract 4O; Gadgeel S et al. WCLC 2024;Abstract OA02.03.

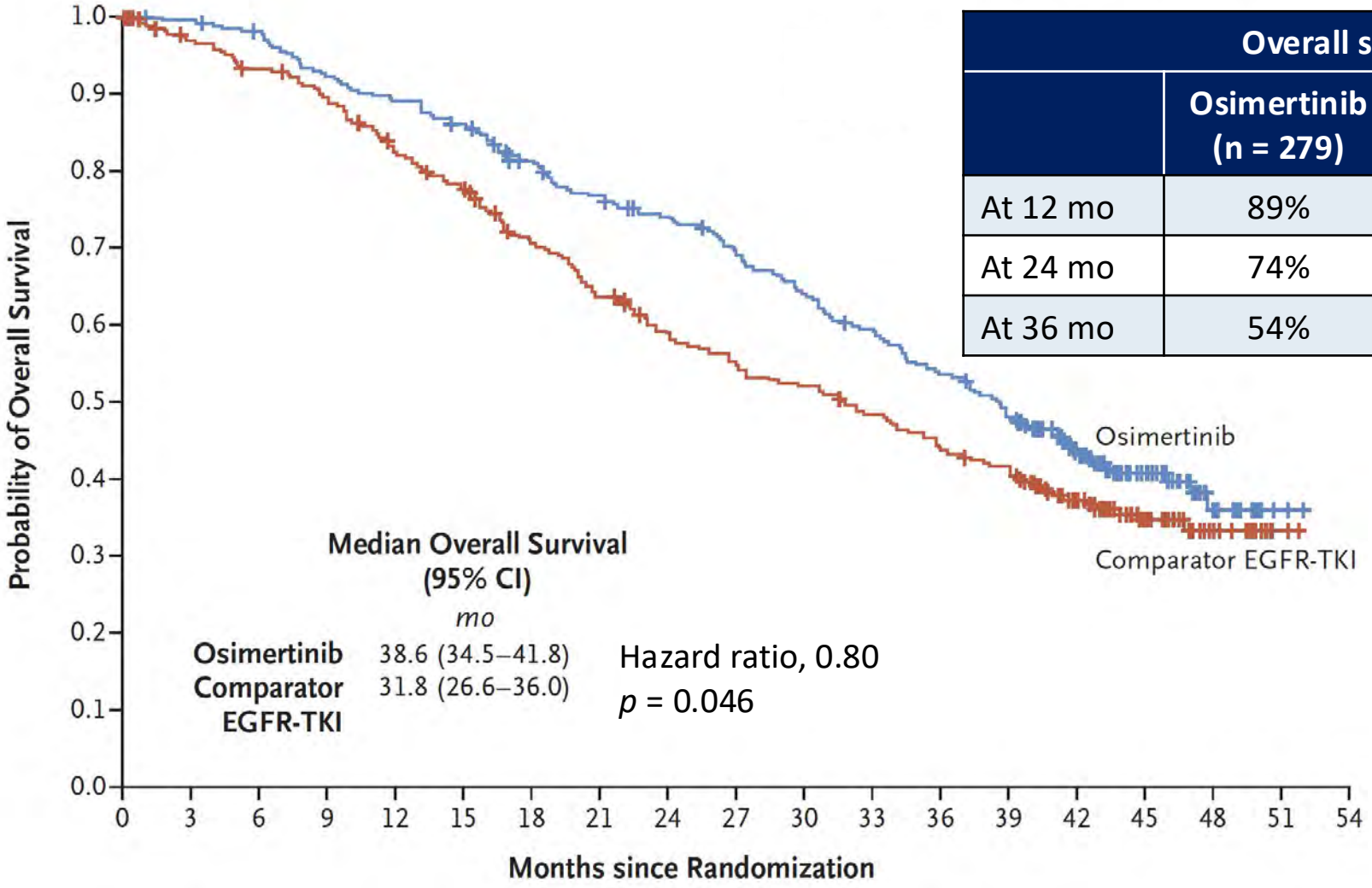
FLAURA Trial Primary Endpoint: Progression-Free Survival with Osimertinib for Advanced NSCLC with EGFR Mutations



Soria J-C et al. *N Engl J Med* 2018;378(2):113-25.

TKI = tyrosine kinase inhibitor

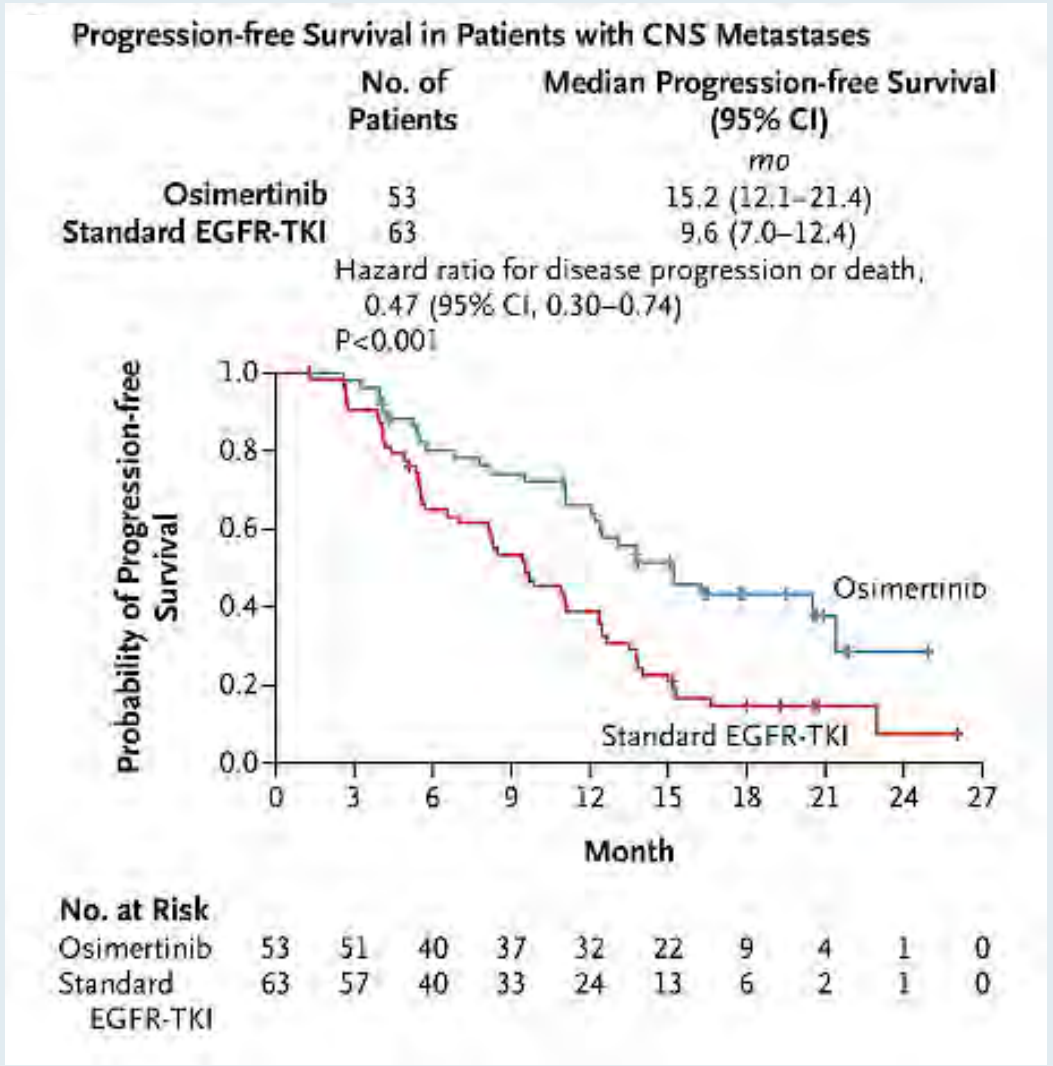
FLAURA: Overall Survival with Osimertinib for Advanced NSCLC with EGFR Mutations

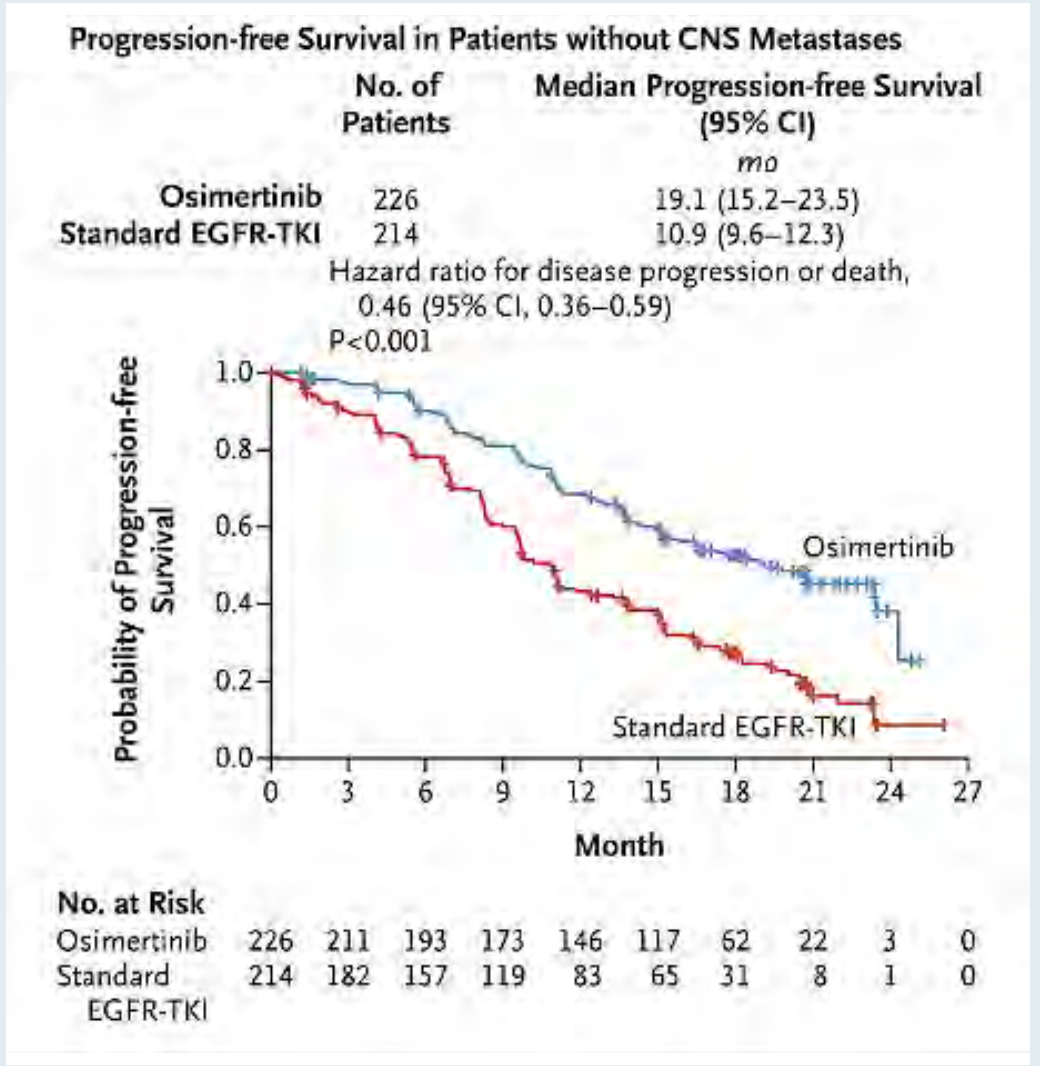


Overall survival		
	Osimertinib (n = 279)	Comparator EGFR TKI (n = 277)
At 12 mo	89%	83%
At 24 mo	74%	59%
At 36 mo	54%	44%

Ramalingam SS et al. *N Engl J Med* 2020;382(1):41-50.

FLAURA: Progression-Free Survival with Osimertinib for Advanced NSCLC with EGFR Mutations with or without CNS Metastases





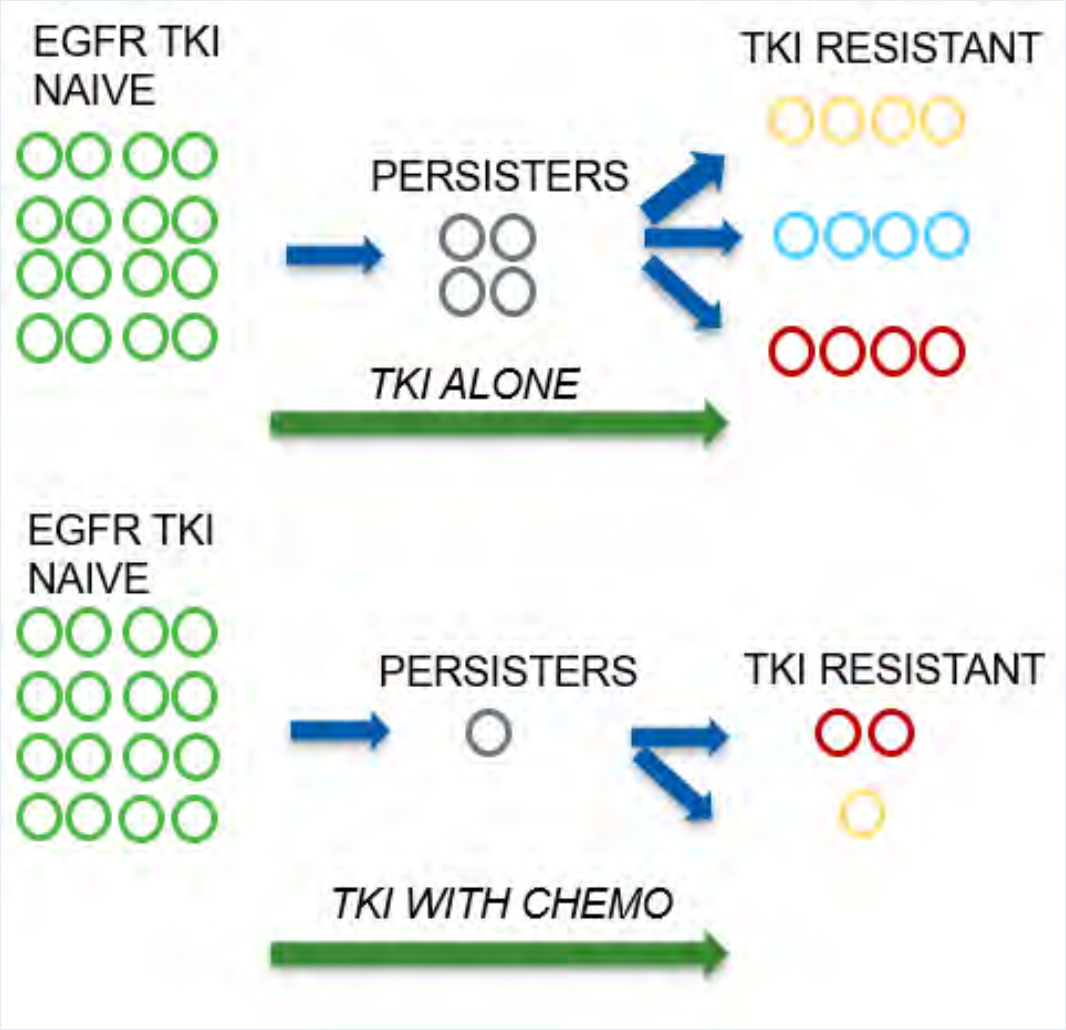
Soria J-C et al. *N Engl J Med* 2018;378(2):113-25.

First-Line Combination Therapies — Benefit

- To combine two active therapies, there needs to be clear improvement in PFS more than the sum of sequencing OR improvement in overall survival.

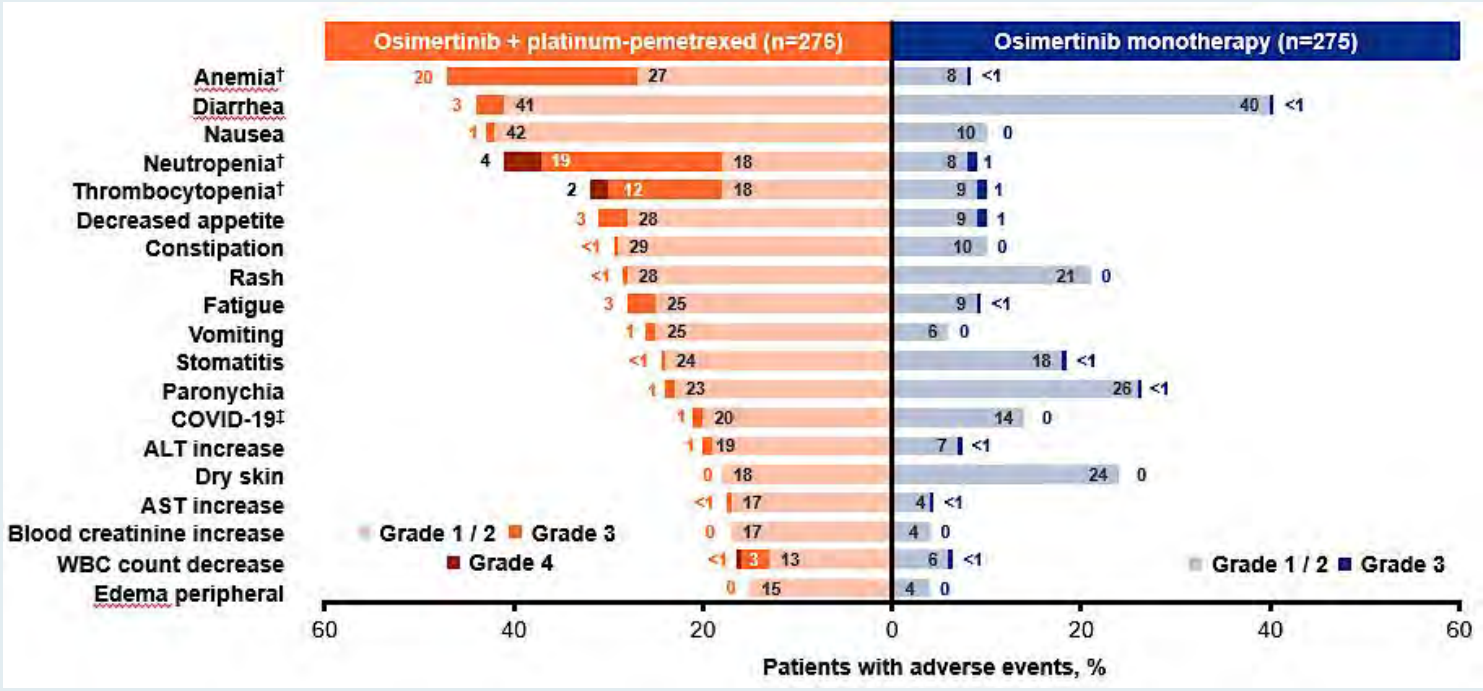
- Combination studies demonstrated improved PFS above additive sequencing, suggesting that further eradication of persistent subclones changes natural history

- Allow more patients to receive both therapies (2L drop off of treatment ~30%)



First-Line Combinations — Cost

- Toxicity – more toxicity and for longer
- Quality of life – intravenous therapy every 2-3 weeks
- Financial cost to patient and healthcare system
- Over-treatment – there is significant heterogeneity in response to osimertinib and many would do well with osimertinib monotherapy



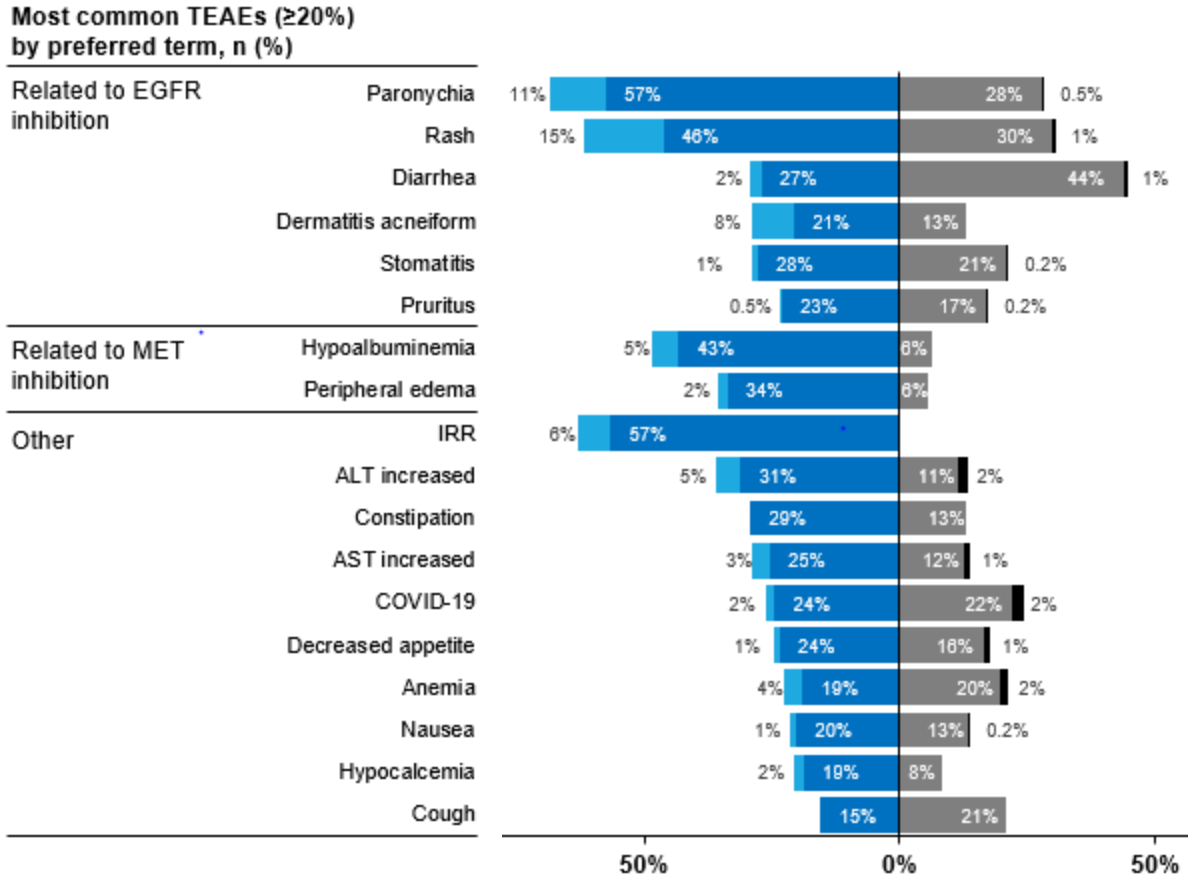
Patients with AEs, n (%)*	Osimertinib + platinum-pemetrexed (n=276)	Osimertinib monotherapy (n=275)
AE any cause	**276 (100)**	**268 (97)**
Any AE Grade ≥3	176 (64)	75 (27)
Any serious AE	104 (38)	53 (19)
Any AE leading to discontinuation	132 (48)	17 (6)
AE possibly causally related to treatment†	**269 (97)**	**241 (88)**
Any AE Grade ≥3	146 (53)	29 (11)
Causally related to osimertinib / carboplatin or cisplatin / pemetrexed	81 (29) / 104 (38) / 130 (47)	29 (11) / NA / NA
Any AE leading to death	5 (2)	1 (<1)

First-Line Combinations — Cost (Continued)

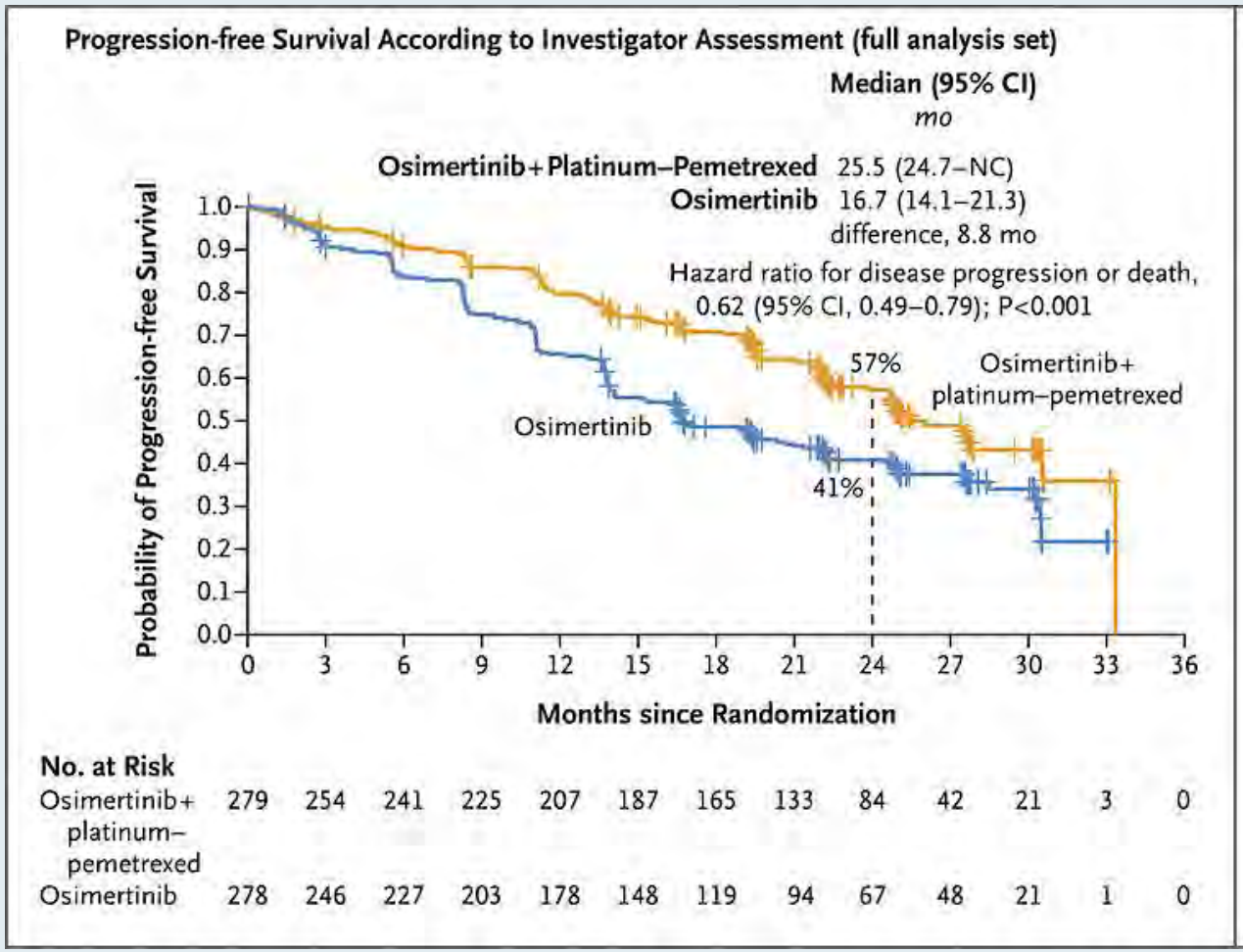
- Toxicity – more toxicity and for longer
- Quality of life – intravenous therapy every 2-3 weeks
- Financial cost to patient and healthcare system
- Over-treatment – there is significant heterogeneity in response to osimertinib and many would do well with osimertinib monotherapy

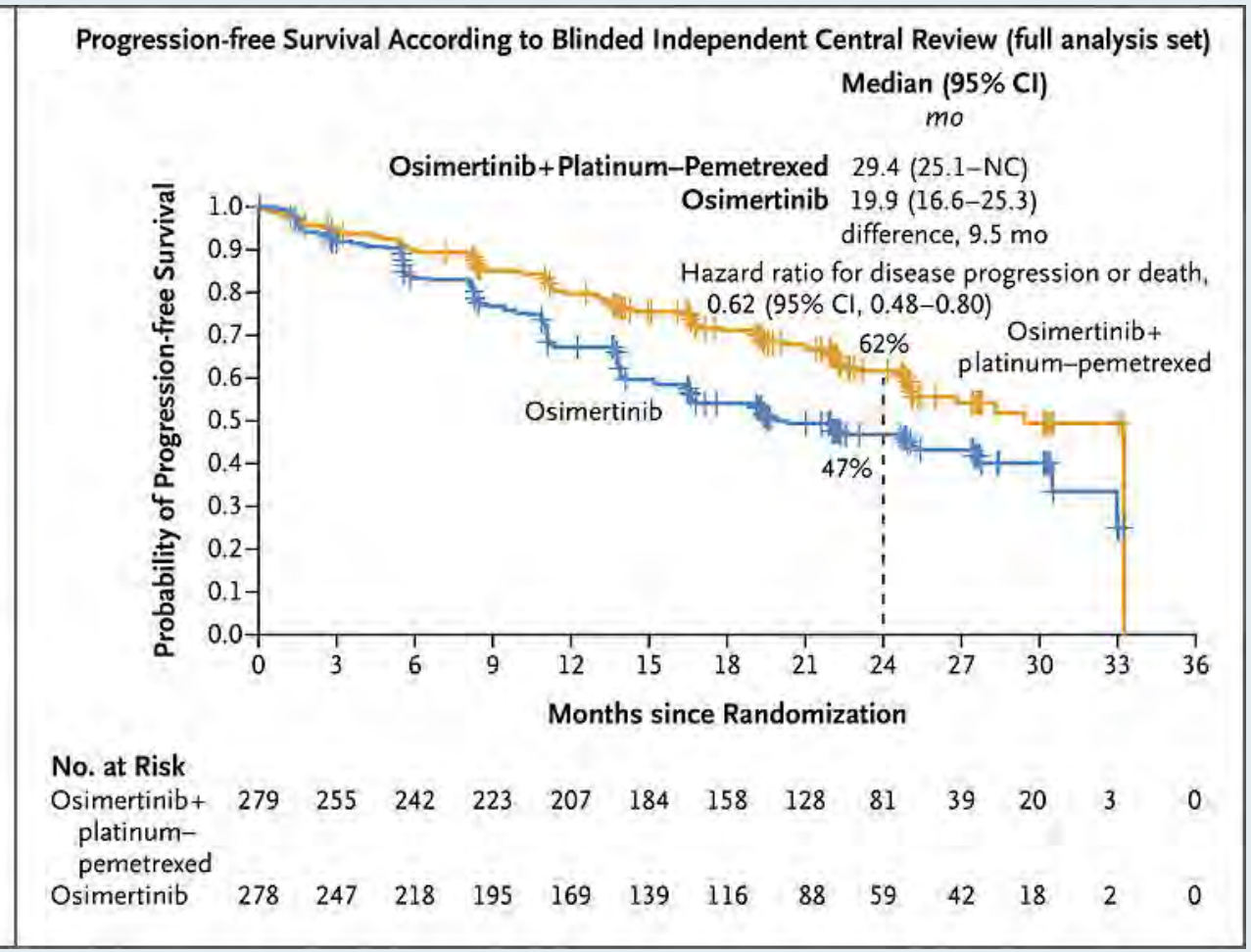
Any AE leading to treatment:		
Interruptions of any agent	350 (83)	165 (39)
Reductions of any agent	249 (59)	23 (5)
Discontinuations of any agent	147 (35)	58 (14)

	Amivantamab + Lazertinib (n=421)	Osimertinib (n=428)
Any VTE, n (%)	157 (37)	39 (9)
Grade 1	5 (1)	0
Grade 2	105 (25)	24 (6)
Grade 3	43 (10)	12 (3)



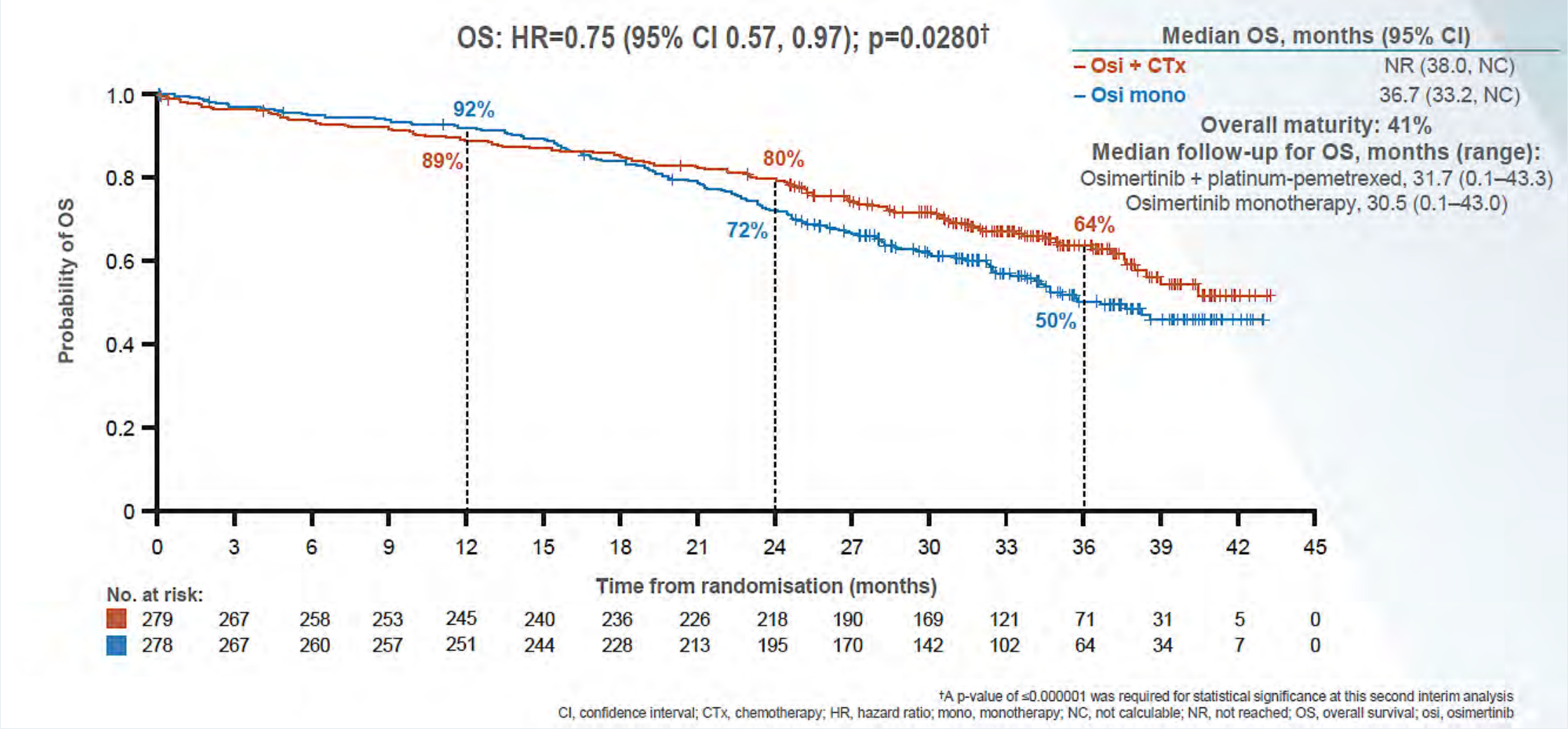
FLAURA2 Trial: Progression-Free Survival with Osimertinib and Chemotherapy for Advanced NSCLC with EGFR Mutations





Planchard D et al. *N Engl J Med* 2023;389(21):1935-48.

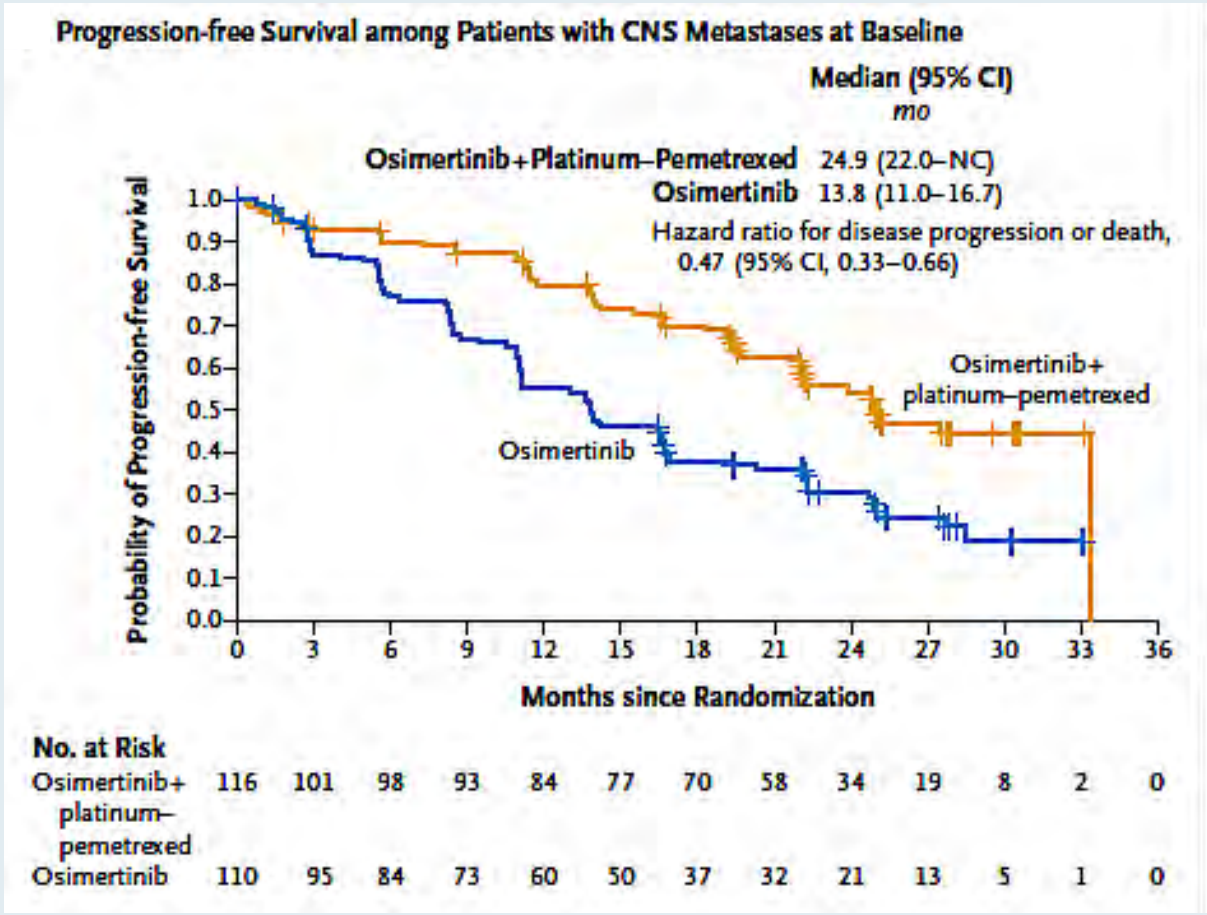
FLAURA2: Second Interim Overall Survival (OS) Analysis with Osimertinib and Chemotherapy for Advanced NSCLC with EGFR Mutations

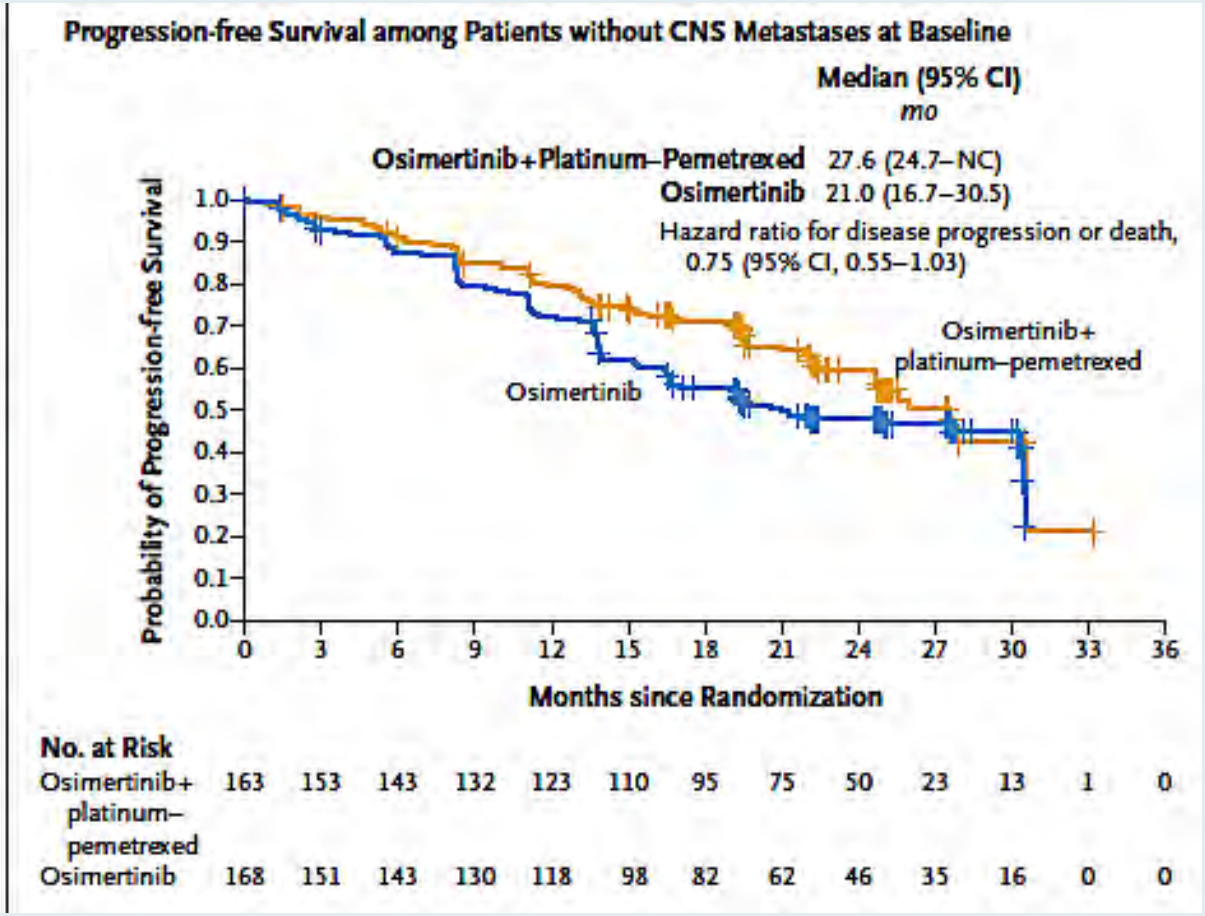


†A p-value of ≤0.000001 was required for statistical significance at this second interim analysis
CI, confidence interval; CTx, chemotherapy; HR, hazard ratio; mono, monotherapy; NC, not calculable; NR, not reached; OS, overall survival; osi, osimertinib

Valdiviezo N et al. ELCC 2024;Abstract 4O.

FLAURA2: Progression-Free Survival with Osimertinib and Chemotherapy for Advanced NSCLC with EGFR Mutations with and without CNS Metastases

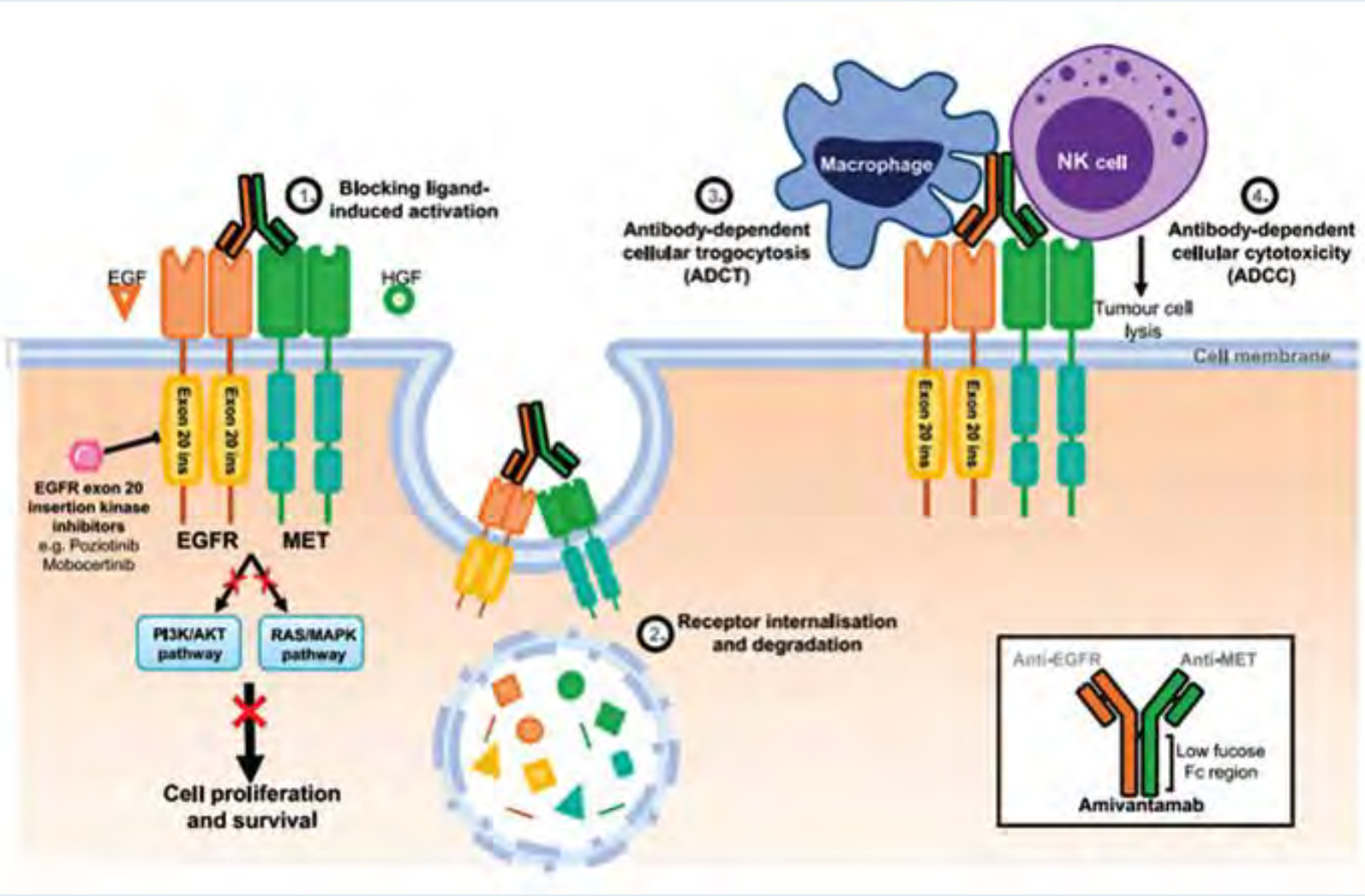




Planchard D et al. *N Engl J Med* 2023;389(21):1935-48.

Questions?

Amivantamab Mechanism of Action

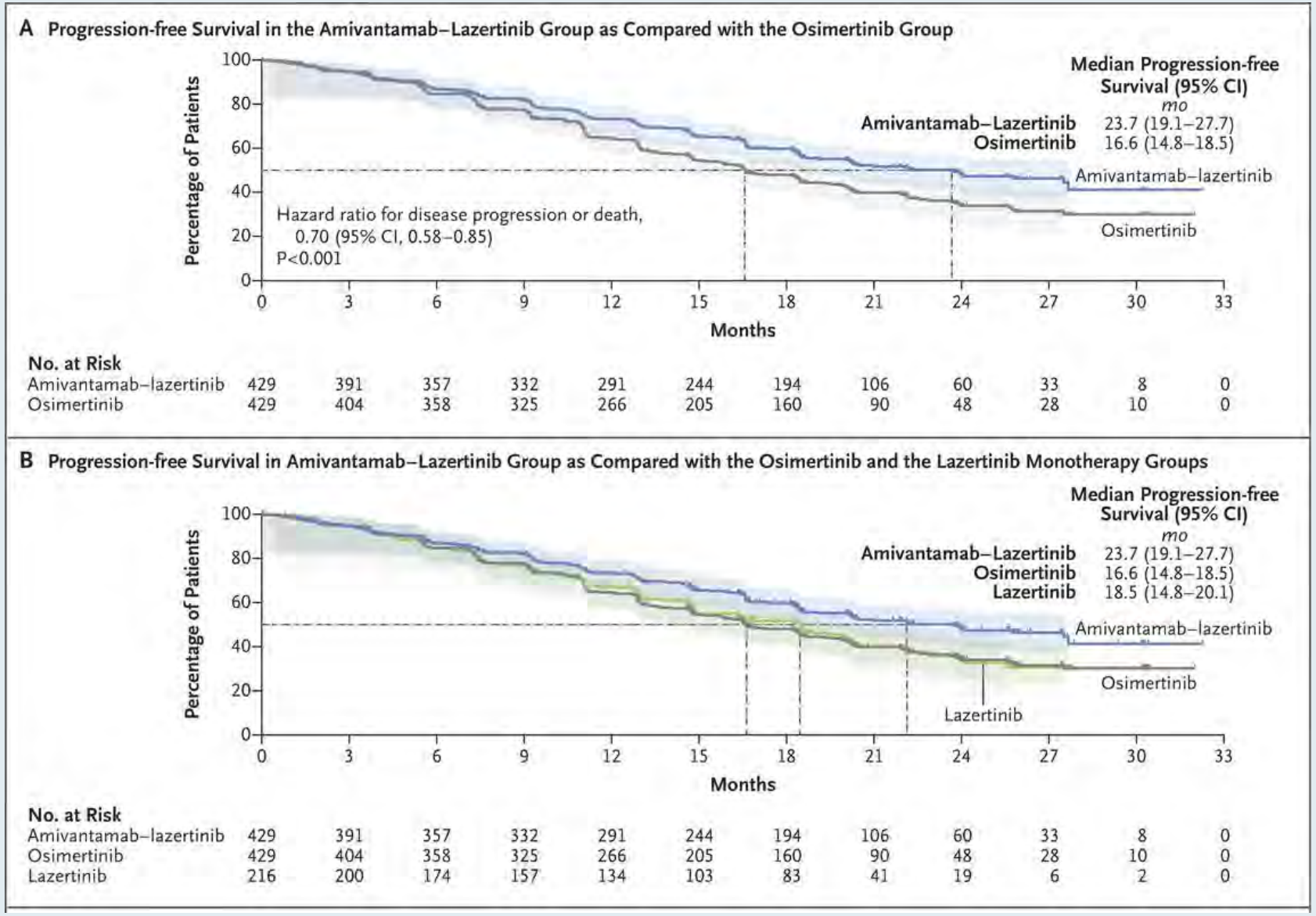


- Secondary resistance is a major cause of TKI resistance (secondary EGFR mutations and met mutations/amp)

Courtesy of Alexander I Spira, MD, PhD

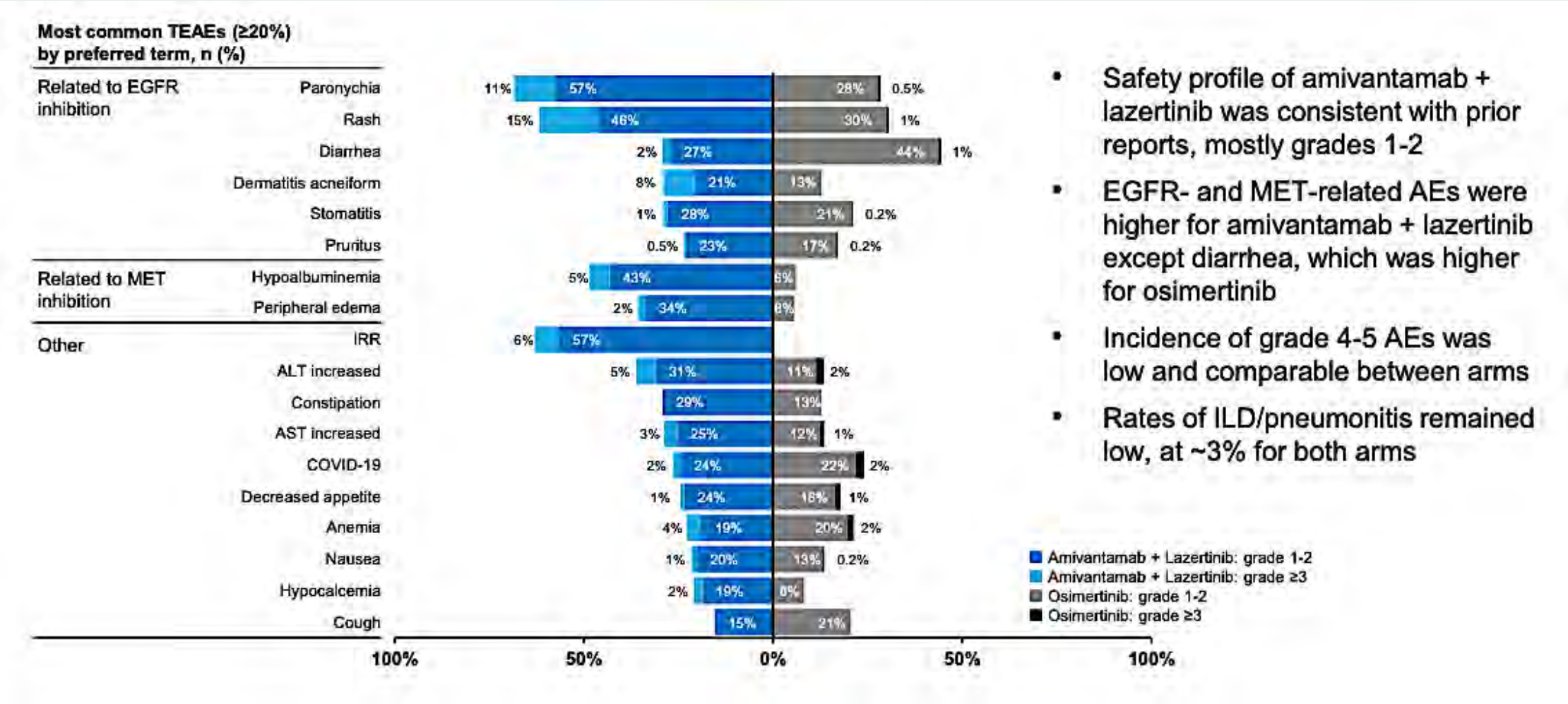
RTP RESEARCH TO PRACTICE

MARIPOSA Trial: Progression-Free Survival with Amivantamab and Lazertinib for Previously Untreated Advanced NSCLC with EGFR Mutations



Cho BC et al. *N Engl J Med* 2024 June 26;[Online ahead of print].

MARIPOSA: Safety Profile with Amivantamab and Lazertinib for Previously Untreated Advanced NSCLC with EGFR Mutations



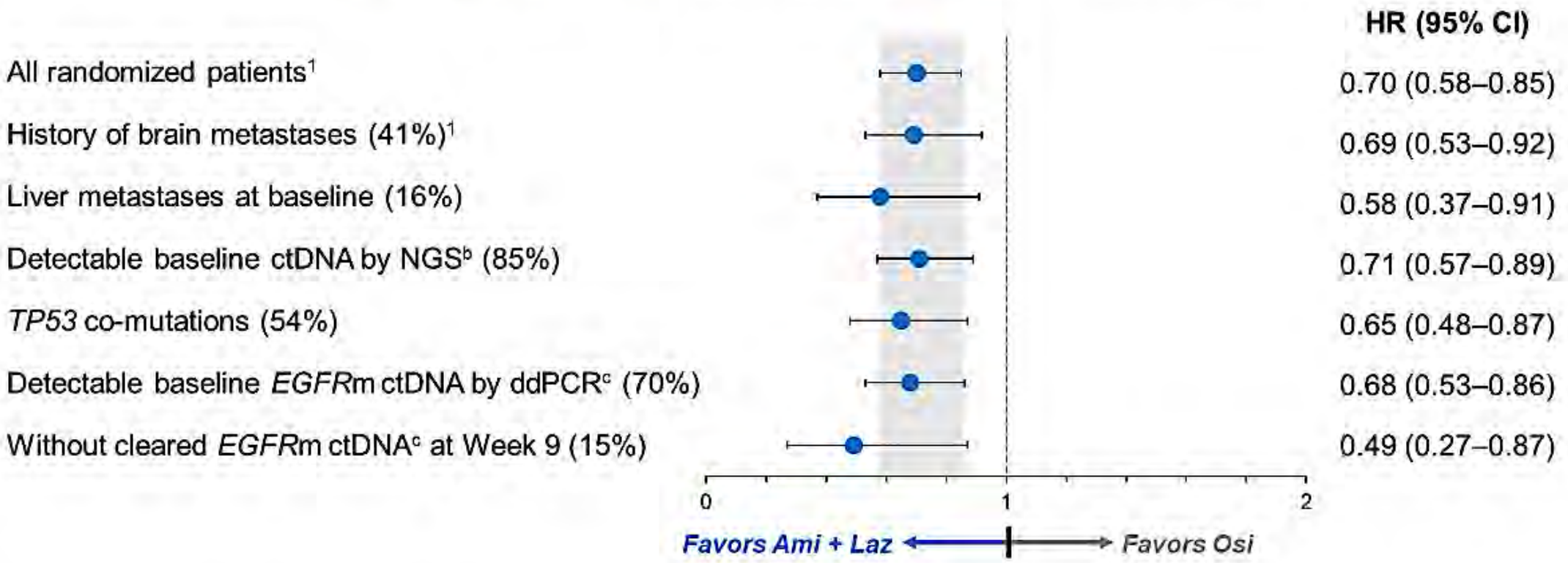
- Safety profile of amivantamab + lazertinib was consistent with prior reports, mostly grades 1-2
- EGFR- and MET-related AEs were higher for amivantamab + lazertinib except diarrhea, which was higher for osimertinib
- Incidence of grade 4-5 AEs was low and comparable between arms
- Rates of ILD/pneumonitis remained low, at ~3% for both arms

TEAEs = treatment-emergent adverse events; IRR = infusion-related reaction; AEs = adverse events; ILD = interstitial lung disease

Cho BC et al. ESMO 2023;Abstract LBA14; Cho BC et al. *N Engl J Med* 2024 June 26;[Online ahead of print].

MARIPOSA: Progression-Free Survival for Patients with High-Risk Features

In the MARIPOSA study, 89% of patients had ≥1 high-risk feature detected at baseline[a]



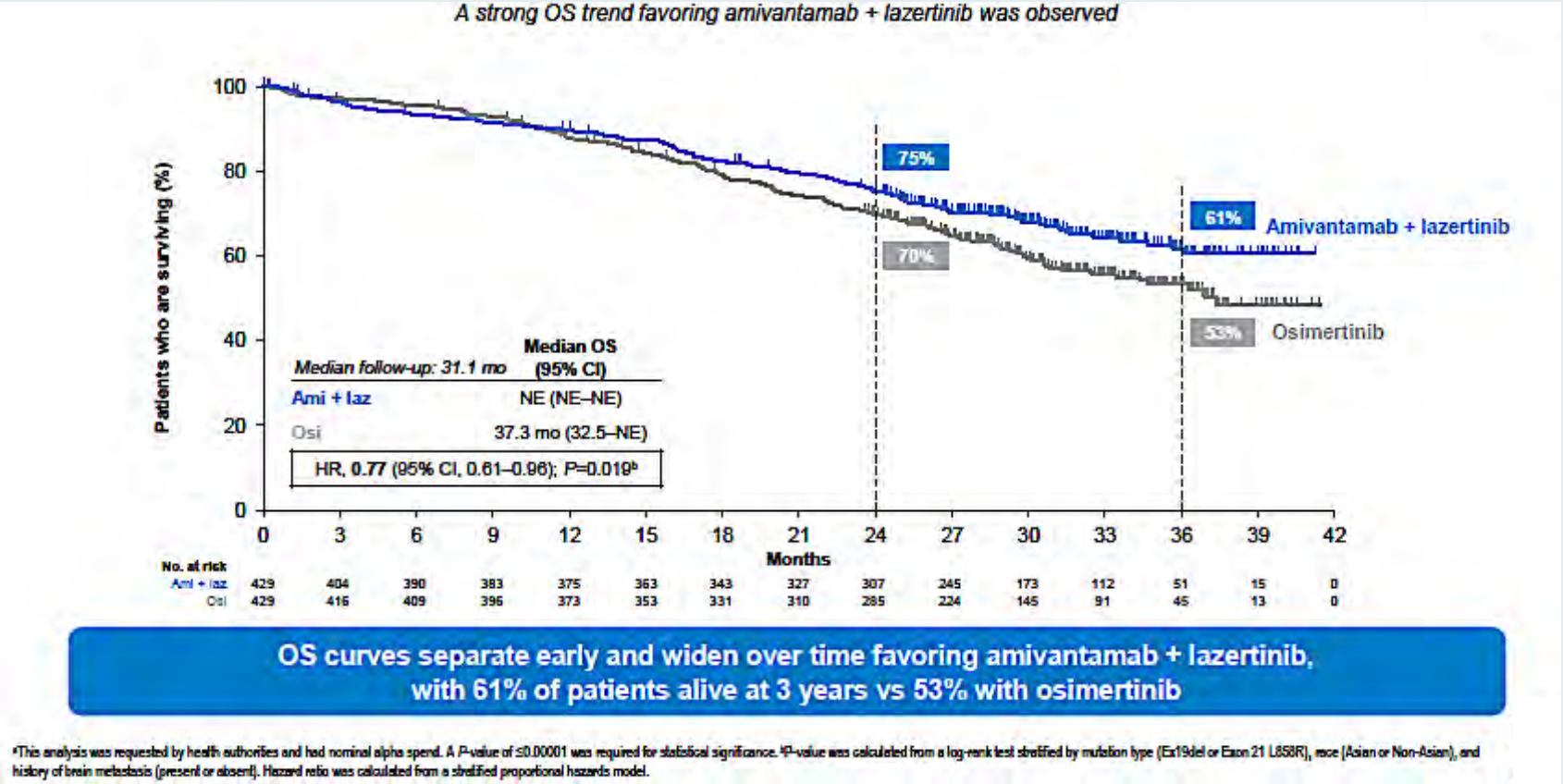
[a]Patients with analyzable ctDNA by NGS at baseline were included in this pooled analysis. High-risk features included baseline detectable ctDNA by NGS or baseline metastases of the liver or brain. For patients with detectable ctDNA, it was assumed that *TP53* co-mutations would be identified if present. [b]Pathogenic mutations were detected with the Guardant Health G360® panel. [c]Ex19del and L858R by Biodesix ddPCR.

Ami, amivantamab; ctDNA, circulating tumor DNA; ddPCR, droplet digital polymerase chain reaction; Ex19del, Exon 19 deletion; Laz, lazertinib; NGS, next-generation sequencing.

1. Cho BC, et al. Presented at the European Society for Medical Oncology (ESMO) Congress; October 20-24, 2023. Madrid, Spain. LBA14.

Felip E et al. ASCO 2024;Abstract 8504.

MARIPOSA: Longer Follow-Up with First-Line Amivantamab and Lazertinib for Advanced NSCLC with EGFR Mutations



- Three-year intracranial PFS was double for amivantamab with lazertinib versus osimertinib (38% vs 18%)
- Amivantamab with lazertinib showed a favorable trend for intracranial duration of response (NE vs 24.4 months)
- Postprogression outcomes (time to deterioration, time to symptomatic progression, progression-free survival after first subsequent therapy) were significantly improved with first-line amivantamab and lazertinib versus osimertinib

Gadgeel S et al. WCLC 2024;Abstract OA02.03.

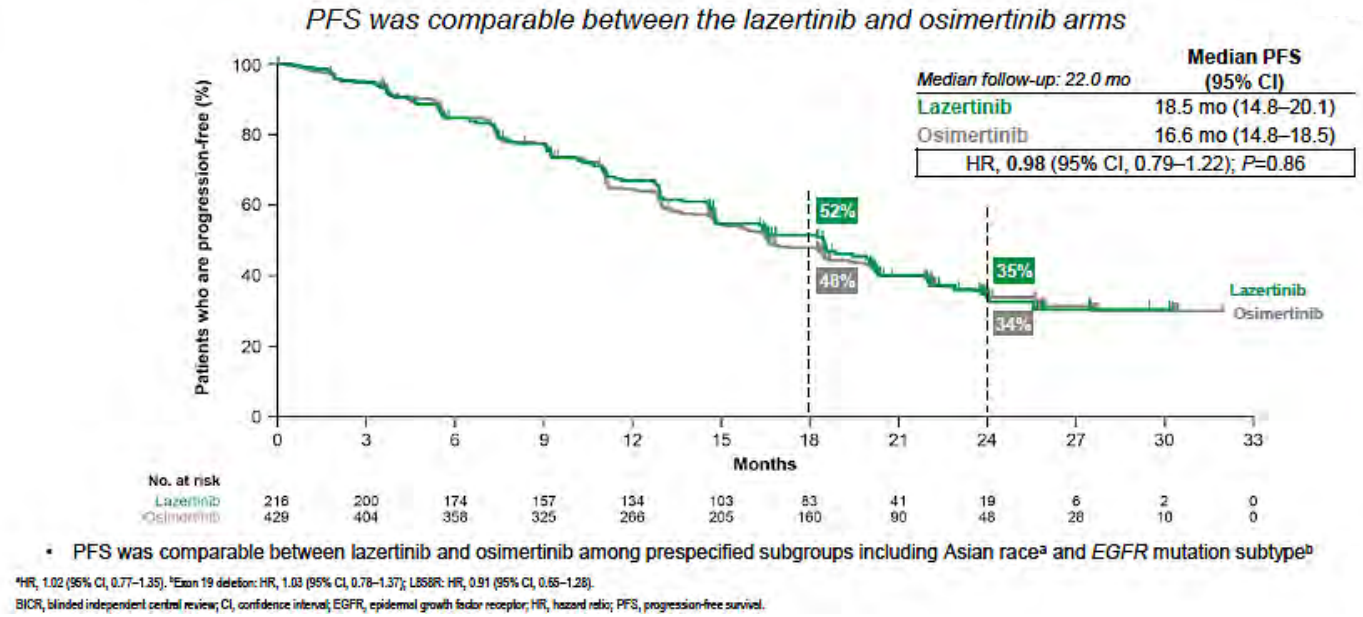
MARIPOSA: Efficacy Data — Long-Term Follow-Up

- As of May 13, 2024 (median follow-up, 31.1 months), 44% (185/421) and 34% (145/428) of patients were still receiving treatment in the amivantamab-lazertinib and osimertinib arms, respectively.

Endpoint, median months (95% CI)	Amivantamab-lazertinib (n = 429)	Osimertinib (n = 429)	Treatment effect (95% CI)	Nominal *p*-value
OS	NE (NE-NE)	37.3 (32.5 – NE)	HR 0.77 (0.61 – 0.96)	0.019
at 24 months, % (95% CI)	75 (71-79)	70 (65-74)	—	—
at 36 months, % (95% CI)	61 (56-67)	53 (47-59)	—	—
TTD	26.3 (22.3-30.4)	22.6 (20.3-24.5)	HR, 0.80 (0.68-0.96)	0.014
TTST	30.0 (26.3-36.0)	24.0 (22.5-26.2)	HR, 0.77 (0.65-0.93)	0.005
PFS2	NE (36.0-NE)	32.4 (29.3-NE)	HR, 0.73 (0.59 -0.91)	0.004
Intracranial PFS	24.9 (20.1-34.7)	22.2 (18.4-26.1)	HR, 0.82 (0.62--1.09)	0.165
at 24 months, % (95% CI)	51 (43-58)	48 (40-56)	—	—
at 36 months, % (95% CI)	38 (28-47)	18 (11-28)	—	—

Gadgeel S et al. WCLC 2024;Abstract OA02.03.

MARIPOSA: Exploratory Analysis of Lazertinib versus Osimertinib



- PFS was comparable between lazertinib and osimertinib among prespecified subgroups including Asian race[a] and *EGFR* mutation subtype[b]

[a]HR, 1.02 (95% CI, 0.77–1.35). [b]Exon 19 deletion: HR, 1.03 (95% CI, 0.78–1.37); L858R: HR, 0.91 (95% CI, 0.65–1.28).
BICR, blinded independent central review; CI, confidence interval; EGFR, epidermal growth factor receptor; HR, hazard ratio; PFS, progression-free survival.

BICR-assessed response, n (%)[a]	Osimertinib (n=429)	Lazertinib (n=216)
ORR		
All responders	85% (95% CI, 81–88)	83% (95% CI, 77–88)
Confirmed responders	76% (95% CI, 71–80)	75% (95% CI, 68–80)
Best response[b]		
CR	15 (4)	9 (4)
PR	335 (81)	168 (79)
SD	42 (10)	23 (11)
PD	11 (3)	9 (4)
NE	11 (3)	5 (2)
Median DoR[c]	16.8 mo (95% CI, 14.8–18.5)	16.6 mo (95% CI, 14.8–20.2)
Ongoing responses	151 of 314 (48)	77 of 160 (48)

- Lazertinib demonstrated comparable efficacy versus osimertinib across all clinical endpoints, including in high-risk subgroups
- Lazertinib demonstrated lower rates of QT interval prolongation, cardiomyopathy, diarrhea, thrombocytopenia and neutropenia, and higher rates of rash, muscle spasms and paresthesia compared to osimertinib

Lee S-H et al. WCLC 2024;Abstract OA02.05.

Amivantamab plus Lazertinib vs Osimertinib in First-Line, EGFR-Mutant Advanced NSCLC: Patient-Relevant Outcomes from MARIPOSA

Nguyen D et al.
WCLC 2024;Abstract MA12.07
Tuesday, September 10, 2024
1:55 PM – 2:00 PM PDT

Preventing Infusion-Related Reactions with Intravenous Amivantamab: Primary Results from SKIPPirr, a Phase 2 Study

Lopes G et al.
WCLC 2024;Abstract MA12.08
Tuesday, September 10, 2024
2:00 PM – 2:05 PM PDT

Clinical Cases

Should we treat these patients the same?
What factors can we use to risk-adapt treatment?

76 yo, EGFR ex19 deletion only
Asymptomatic
Oligometastatic disease
Thoracic only disease
Slow growing
ctDNA neg

Median PFS on
1L osimertinib

18.9 months

45 yo, EGFR L858R, TP53, RB1
High symptom burden
Fast growing
Diffuse mets including brain, liver, bone
Large tumor burden

Clinical Cases

Should we treat these patients the same?
What factors can we use to risk-adapt treatment?

Osimertinib Alone

76 yo, EGFR ex19 deletion only
Asymptomatic
Oligometastatic disease
Thoracic only disease
Slow growing
ctDNA neg

Ami + Lazertinib

Chemo + Osimertinib

45 yo, EGFR L858R, TP53, RB1
High symptom burden
Fast growing
Diffuse mets including brain, liver, bone
Large tumor burden

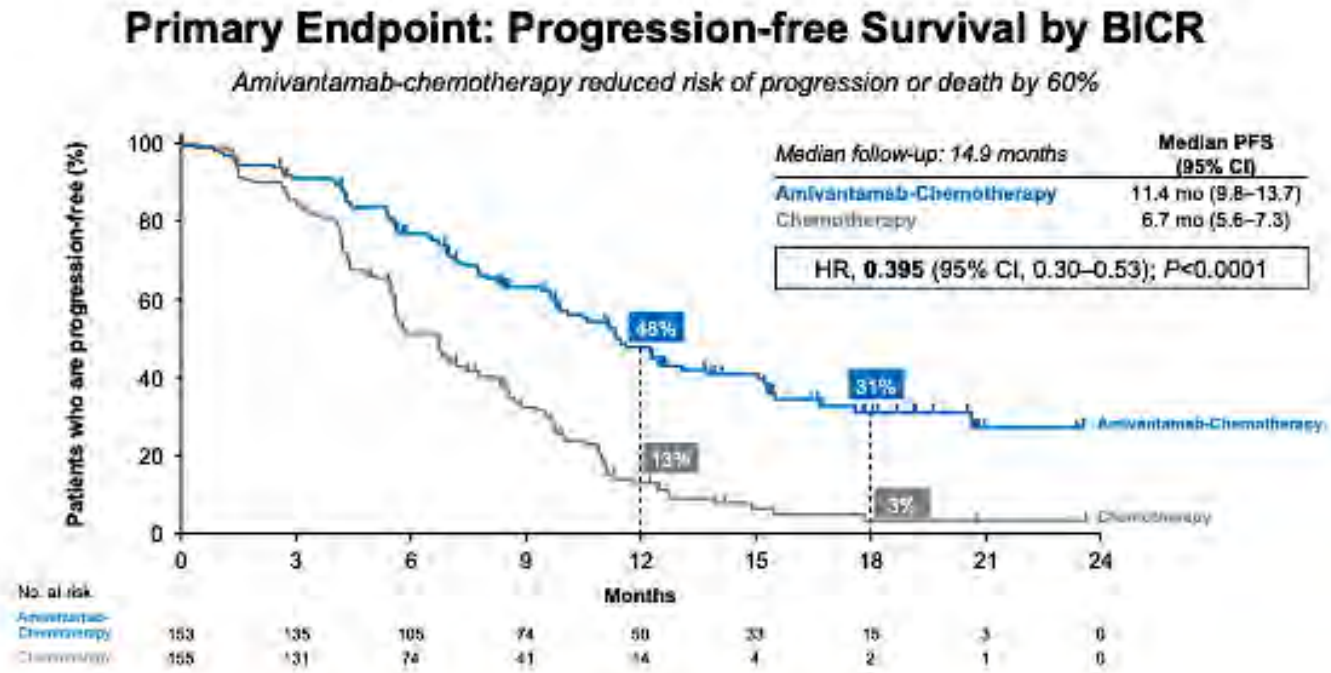
Median PFS on
1L osimertinib

↓

18.9 months

Questions?

PAPILLON Trial: First-Line Amivantamab and Chemotherapy for NSCLC with EGFR Exon 20 Insertion Mutations



	Amivantamab-Chemo	Chemo	
ORR	73% (95% CI, 65-80)	47% (95% CI, 39-56)	
mPFS	11.4 mo (9.8-13.7)	6.7 (95% CI, 5.6-7.3)	HR 0.395 (95% CI, 0.30-0.53)
[OS (interim)*	*NE*	*24.4 mo (95% CI, 22.1-NE)*	*HR 0.675 (95% CI, 0.42-1.09)]*

BICR = blinded independent central review; ORR = objective response rate; mPFS = median progression-free survival

Zhou C et al. *N Engl J Med* 2023;389(22):2039-51; Girard N et al. ESMO 2023;Abstract LBA5.

PAPILLON: Safety with First-Line Amivantamab and Chemotherapy for NSCLC with EGFR Exon 20 Insertion Mutations

Most common AEs of any cause by preferred term (≥20%), n (%)	Amivantamab-Chemotherapy (n=151)		Chemotherapy (n=155)	
	All grades	Grade ≥3	All grades	Grade ≥3
Associated with EGFR inhibition				
Paronychia	85 (56)	10 (7)	0	0
Rash	81 (54)	17 (11)	12 (8)	0
Dermatitis acneiform	47 (31)	6 (4)	5 (3)	0
Stomatitis	38 (25)	2 (1)	9 (6)	0
Diarrhea	31 (21)	5 (3)	20 (13)	2 (1)
Associated with MET inhibition				
Hypoalbuminemia	62 (41)	6 (4)	15 (10)	0
Peripheral edema	45 (30)	2 (1)	16 (10)	0
Other				
Neutropenia	89 (59)	50 (33)	70 (45)	35 (23)
Anemia	76 (50)	16 (11)	85 (55)	19 (12)
Infusion-related reaction	63 (42)	2 (1)	2 (1)	0
Constipation	60 (40)	0	47 (30)	1 (1)
Leukopenia	57 (38)	17 (11)	50 (32)	5 (3)
Nausea	55 (36)	1 (1)	65 (42)	0
Thrombocytopenia	55 (36)	15 (10)	46 (30)	16 (10)
Decreased appetite	54 (36)	4 (3)	43 (28)	2 (1)
Alanine aminotransferase increased	50 (33)	6 (4)	56 (36)	2 (1)
Aspartate aminotransferase increased	47 (31)	1 (1)	51 (33)	1 (1)
COVID-19	36 (24)	3 (2)	21 (14)	1 (1)
Hypokalemia	32 (21)	13 (9)	13 (8)	2 (1)
Vomiting	32 (21)	5 (3)	29 (19)	1 (1)

- EGFR- and MET-related AEs were increased with amivantamab-chemotherapy, primarily grade 1-2
- Chemotherapy-associated hematologic and GI toxicities were comparable except for neutropenia
- Neutropenia was transient; majority of events were not serious, with low rates of discontinuations
- Pneumonitis was reported in 4 (3%) patients in the amivantamab-chemotherapy arm

Zhou C et al. *N Engl J Med* 2023;389(22):2039-51; Girard N et al. ESMO 2023;Abstract LBA5.

Agenda

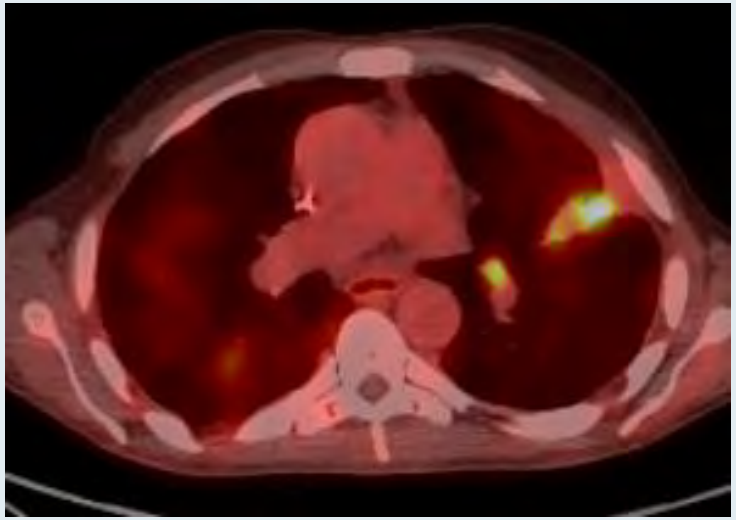
Introduction: Checkpoint Inhibitors and EGFR-Mutated Lung Cancer

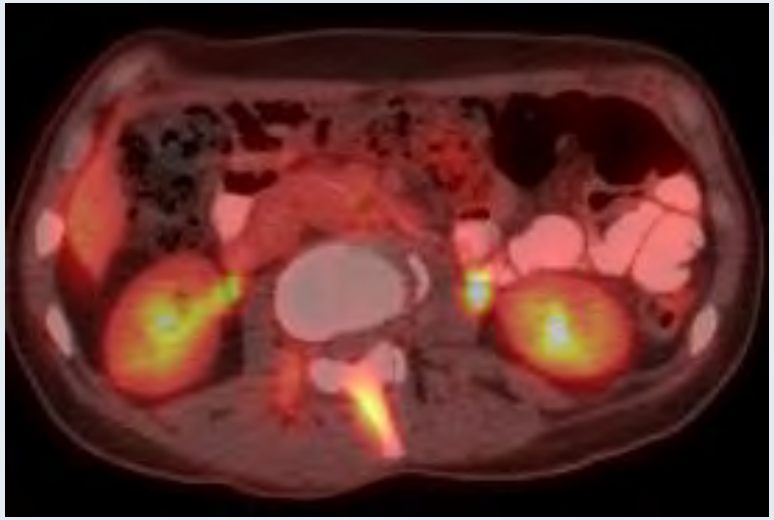
Module 1: Current Management of Metastatic Non-Small Cell Lung Cancer (NSCLC) with EGFR Mutations — Dr Sabari

Module 2: Novel Therapeutic Approaches for NSCLC Harboring EGFR Mutations — Dr Yu

Case Presentation – Dr Yu: 58-year-old woman with recent disease progression on first-line osimertinib

58 yo woman was initially diagnosed March 2023 with stage 4 EGFR-mutant lung cancer with metastases to bone and lymph node and started on osimertinib monotherapy in April 2023. She did well until June 2024 when follow-up CT scan showed a new L lung mass and a new T12/L1 vertebral metastasis. Repeat biopsy of the liver metastases confirmed the EGFR L858R mutation, but no acquired additional alterations were present.





What treatment options would be appropriate for this patient?

Case Presentation – Dr Yu: 58-year-old woman with recent disease progression on first-line osimertinib (continued)

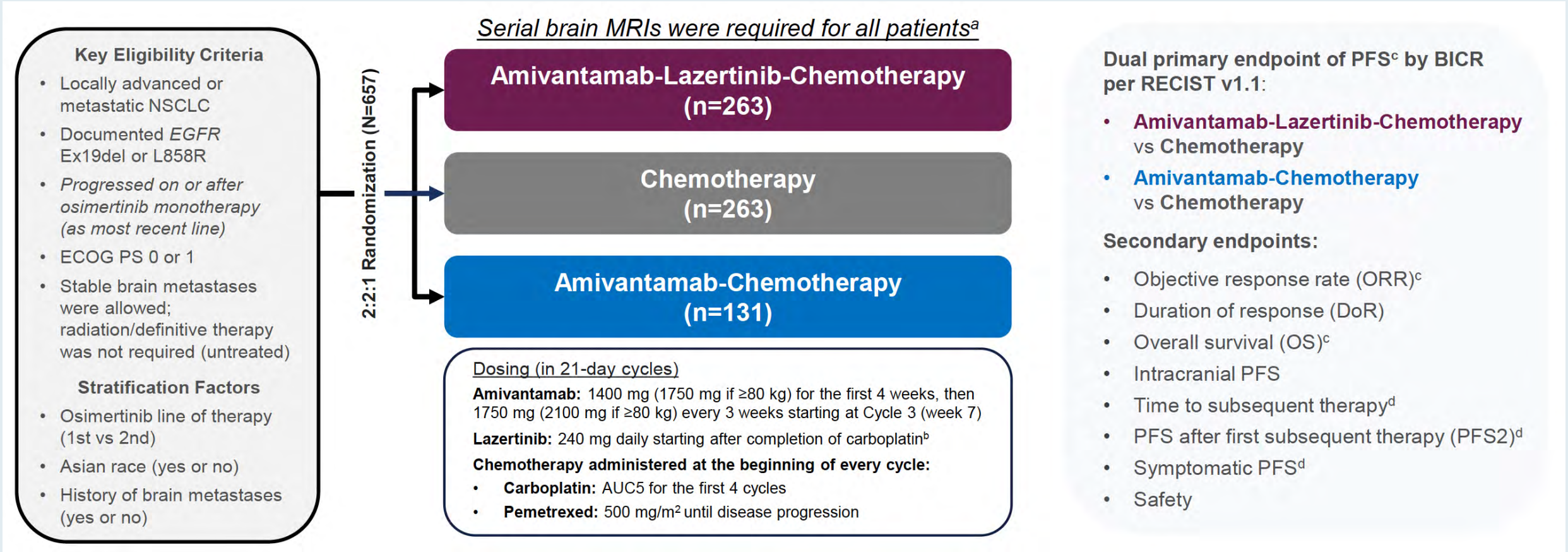
We discussed various options for treatment, which included platinum doublet chemotherapy alone versus chemotherapy with amivantamab. The patient wished to be as aggressive as possible with treatment, and we went ahead with carboplatin, pemetrexed and amivantamab.

She did well, with initial scans after 2 cycles showing response to therapy with shrinkage of her lung metastases and improved bone discomfort. She did have to delay one cycle due to neutropenia (ANC 1.1) and has noticed a bit of a scalp rash and acneiform rash on her chest and back, grade 2. It's been 3 months and she continues to do well on treatment.

Novel Therapeutic Approaches for NSCLC Harboring EGFR Mutations

Helena Yu, MD
Medical Oncologist
Associate Attending
Memorial Sloan Kettering Cancer Center
New York, New York

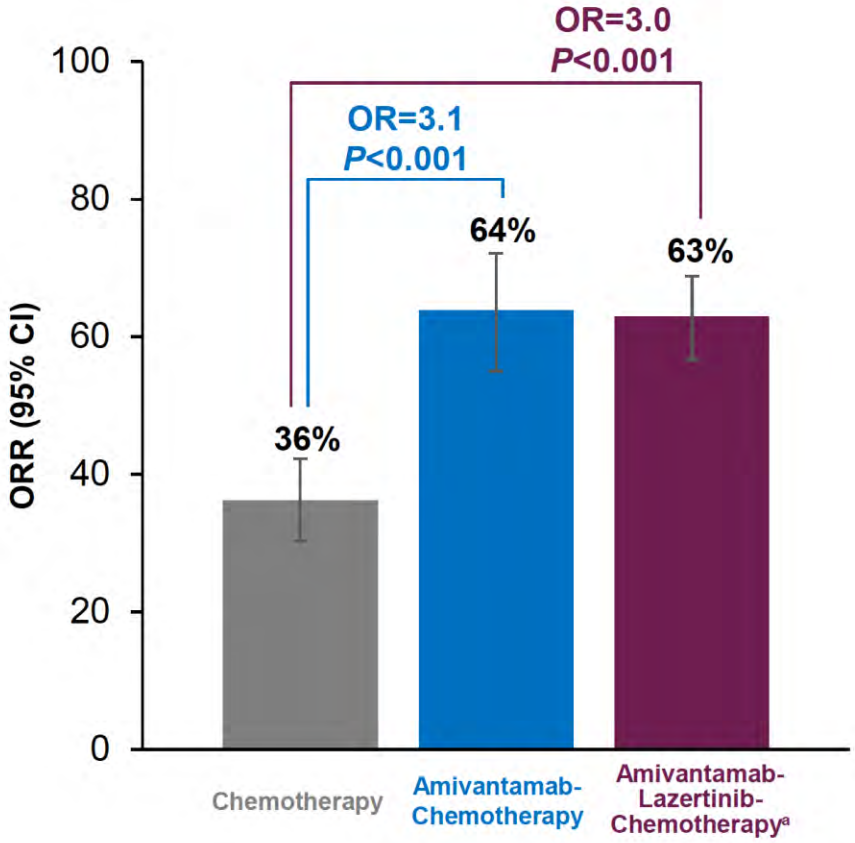
MARIPOSA-2 Study Design



NSCLC = non-small cell lung cancer; PFS = progression-free survival; BICR = blinded independent central review

Passaro A et al. ESMO 2023;Abstract LBA15.

MARIPOSA-2: Response Data



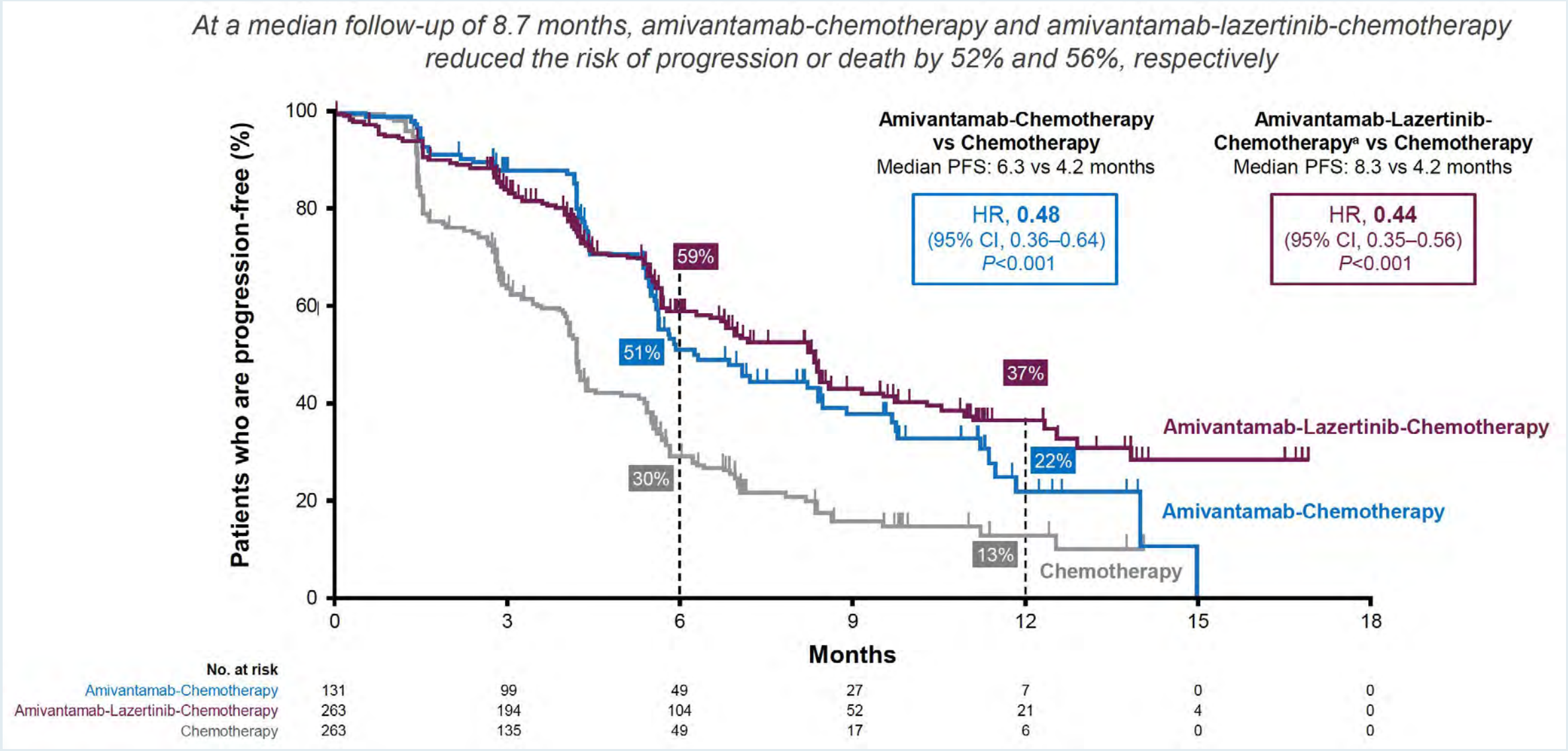
BICR-assessed Response, n (%)[b]	Chemotherapy (n=263)	Amivantamab-Chemotherapy (n=131)	Amivantamab-Lazertinib-Chemotherapy (n=263)
Best Response			
CR	1 (0.4)	2 (2)	6 (2)
PR	93 (36)	81 (62)	157 (61)
SD	82 (32)	30 (23)	61 (24)
PD	52 (20)	10 (8)	14 (5)
NE/UNK	32 (12)	7 (5)	21 (8)
Median DoR[c]	5.6 mo (95% CI, 4.2–9.6)	6.9 mo (95% CI, 5.5–NE)	9.4 mo (95% CI, 6.9–NE)

ORR = objective response rate; CR = complete response; PR = partial response; SD = stable disease; PD = progressive disease; NE/UNK = not evaluable/unknown

Passaro A et al. ESMO 2023;Abstract LBA15. Passaro A et al. *Ann Oncol* 2024;35(1):77-90.

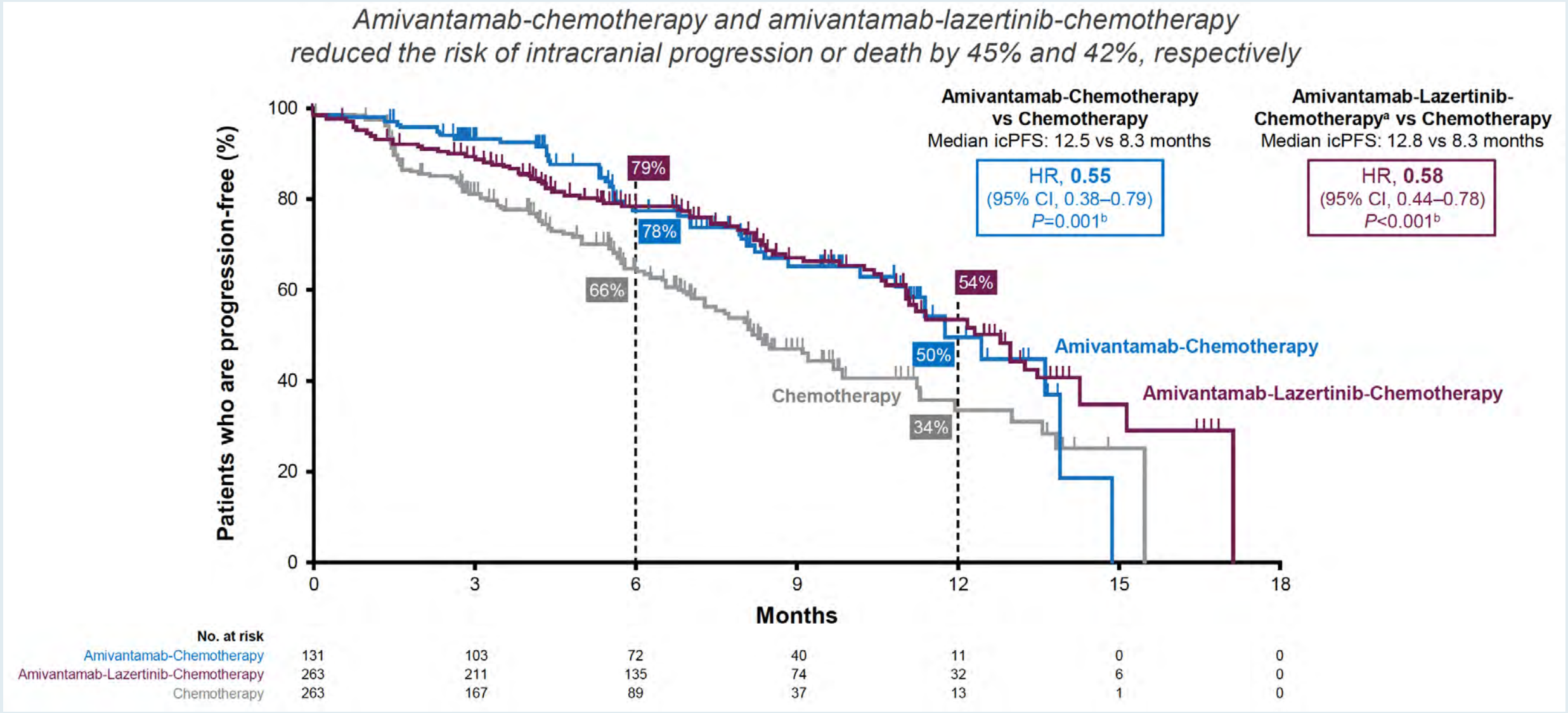
MARIPOSA-2: PFS by BICR

At a median follow-up of 8.7 months, amivantamab-chemotherapy and amivantamab-lazertinib-chemotherapy reduced the risk of progression or death by 52% and 56%, respectively



Passaro A et al. ESMO 2023;Abstract LBA15. Passaro A et al. *Ann Oncol* 2024;35(1):77-90.

MARIPOSA-2: Intracranial PFS by BICR



Passaro A et al. ESMO 2023;Abstract LBA15. Passaro A et al. *Ann Oncol* 2024;35(1):77-90.

MARIPOSA-2: Safety Profile

Most common TEAEs (≥25%) by preferred term, n (%)	Chemotherapy (n=243)		Amivantamab-Chemotherapy (n=130)		Amivantamab-Lazertinib-Chemotherapy[a] (n=263)	
	All grades	Grade ≥3	All grades	Grade ≥3	All grades	Grade ≥3
Associated with EGFR inhibition						
Paronychia	1 (0.4)	0	48 (37)	3 (2)	133 (51)	11 (4)
Rash	12 (5)	0	56 (43)	8 (6)	126 (48)	17 (6)
Stomatitis	21 (9)	0	41 (32)	1 (1)	120 (46)	24 (9)
Diarrhea	16 (7)	1 (0.4)	18 (14)	1 (1)	68 (26)	10 (4)
Associated with MET inhibition						
Hypoalbuminemia	21 (9)	1 (0.4)	29 (22)	3 (2)	104 (40)	12 (5)
Peripheral edema	15 (6)	0	42 (32)	2 (2)	85 (32)	1 (0.4)
Associated with Chemotherapy						
Neutropenia	101 (42)	52 (21)	74 (57)	59 (45)	181 (69)	144 (55)
Thrombocytopenia	72 (30)	22 (9)	57 (44)	19 (15)	158 (60)	96 (37)
Anemia	97 (40)	23 (9)	51 (39)	15 (12)	141 (54)	48 (18)
Leukopenia	68 (28)	23 (9)	37 (28)	26 (20)	106 (40)	71 (27)
Other						
Infusion-related reaction	1 (0.4)	0	76 (58)	7 (5)	148 (56)	9 (3)
Nausea	90 (37)	2 (1)	58 (45)	1 (1)	131 (50)	16 (6)
Constipation	72 (30)	0	50 (38)	1 (1)	96 (37)	3 (1)
Decreased appetite	51 (21)	3 (1)	40 (31)	0	85 (32)	7 (3)
Vomiting	42 (17)	1 (0.4)	32 (25)	1 (1)	76 (29)	10 (4)
Fatigue	47 (19)	4 (2)	36 (28)	4 (3)	69 (26)	15 (6)
Asthenia	40 (16)	5 (2)	34 (26)	1 (1)	67 (25)	14 (5)
Alanine aminotransferase increased	67 (28)	10 (4)	26 (20)	7 (5)	55 (21)	14 (5)
AESIs by grouped term, n (%)						
Rash[b]	30 (12)	0	92 (71)	13 (10)	197 (75)	40 (15)
VTE[c]	11 (5)	7 (3)	13 (10)	3 (2)	58 (22)	17 (6)
ILD	0	0	2 (2)	1 (1)	7 (3)	5 (2)

TEAE = treatment-emergent adverse event; VTE = venous thromboembolism; ILD = interstitial lung disease

Passaro A et al. ESMO 2023;Abstract LBA15. Passaro A et al. *Ann Oncol* 2024;35(1):77-90.

PALOMA-3 Study Design and Response Data

Key eligibility criteria

- Locally advanced or metastatic NSCLC
- Disease had progressed on or after osimertinib and platinum-based chemotherapy, irrespective of order
- Documented *EGFR* Ex19del or L858R
- ECOG PS 0–1

Stratification factors

- Brain metastases (yes or no)
- *EGFR* mutation type (Ex19del vs L858R)
- Race (Asian vs non-Asian)
- Type of last therapy (osimertinib vs chemotherapy)

1:1 randomization (N=418)

SC Amivantamab + Lazertinib (n=206)

IV Amivantamab + Lazertinib (n=212)

Dosing (in 28-day cycles)

SC Amivantamab[a,b] (co-formulated with rHuPH20 and administered by manual injection): 1600 mg (2240 mg if ≥80 kg) weekly for the first 4 weeks, then every 2 weeks thereafter

IV Amivantamab[b]: 1050 mg weekly (1400 mg if ≥80 kg) for the first 4 weeks, then every 2 weeks thereafter

Lazertinib: 240 mg PO daily

Prophylactic anticoagulation recommended for the first 4 months of treatment

Co-primary endpoints[c]**:**

- C_{trough} (noninferiority)[d]
- C2 AUC (noninferiority)[e]

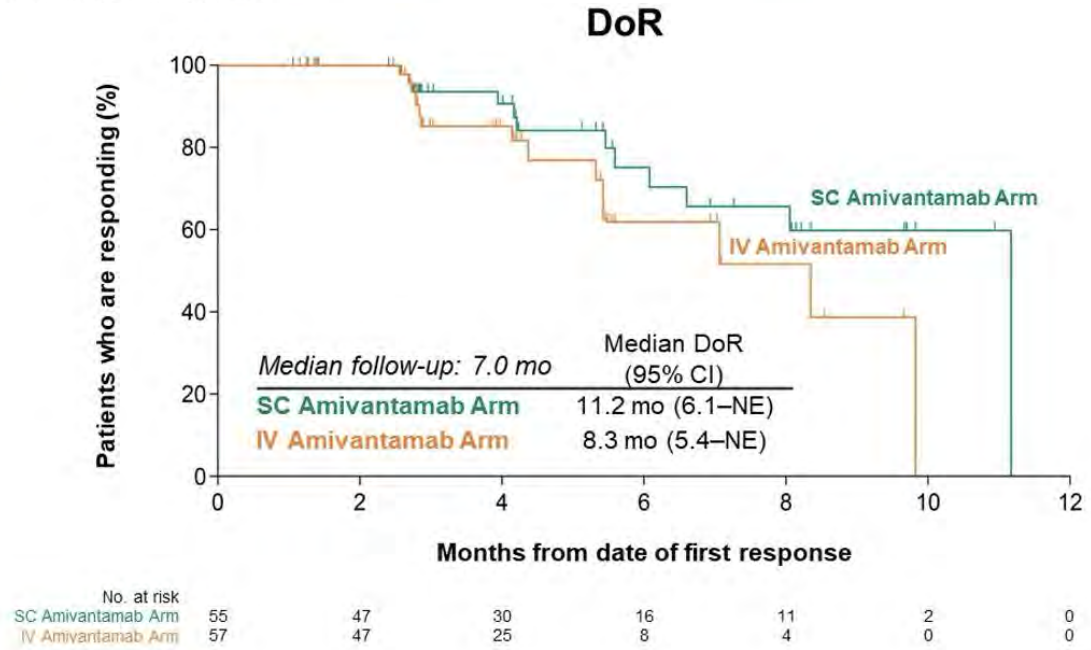
Secondary endpoints:

- ORR (noninferiority)
- PFS (superiority)
- DoR
- Patient satisfaction[f]
- Safety

Exploratory endpoints:

- OS

	SC Amivantamab Arm (n=206)	IV Amivantamab Arm (n=212)
ORR, % (95% CI)[a]		
All responders	**30 (24–37)**	**33 (26–39)**
	Relative risk, 0.92 (95% CI, 0.70–1.23); *P*=0.001	
Confirmed responders	**27 (21–33)**	**27 (21–33)**
	Relative risk, 0.99 (95% CI, 0.72–1.36); *P*<0.001	
Best response, n (%)		
CR	1 (0.5)	1 (0.5)
PR	61 (30)	68 (32)
SD	93 (45)	81 (38)
PD	37 (18)	42 (20)
Not evaluable	14 (7)	20 (9)
DCR, % (95% CI)[b]	**75 (69–81)**	**71 (64–77)**
Median time to response (range), mo	**1.5 (1.2–6.9)**	**1.5 (1.2–9.9)**

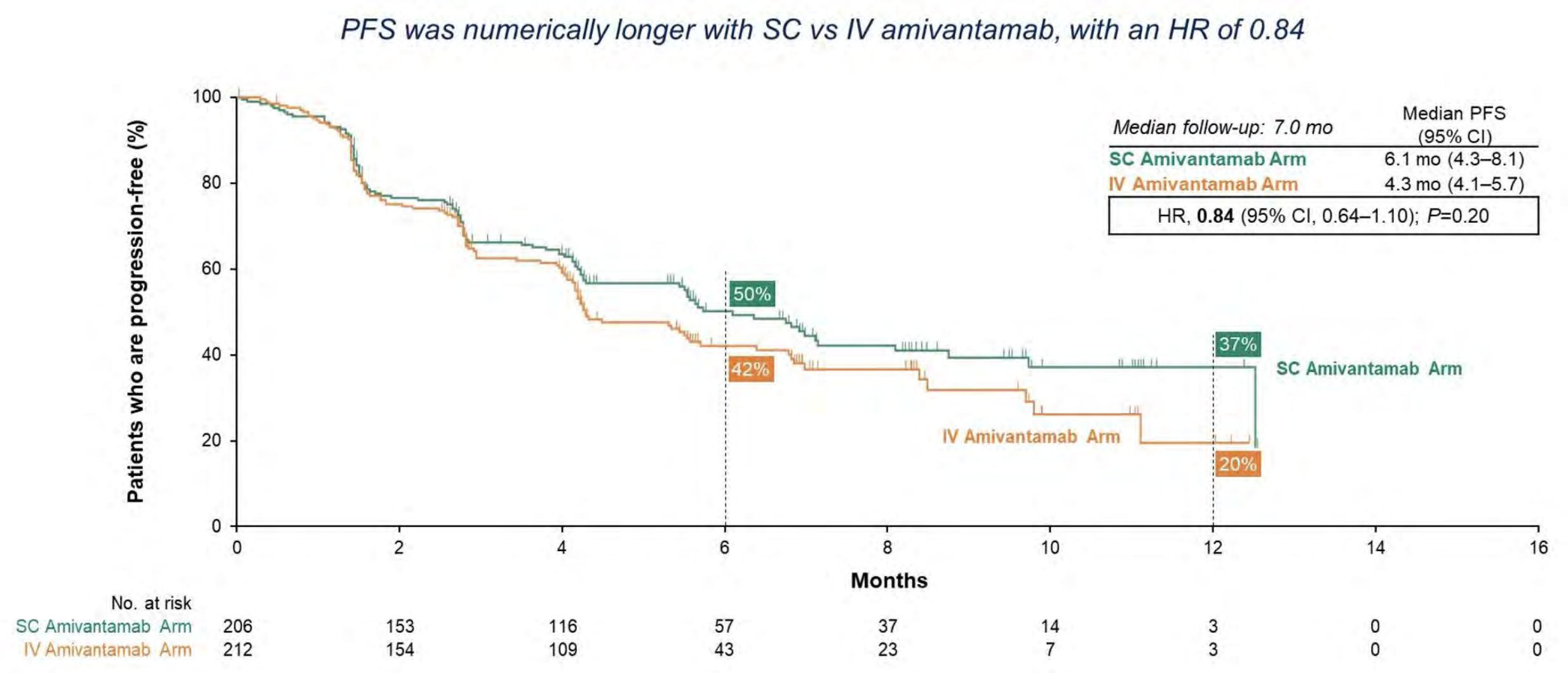


Leighl NB et al. ASCO 2024;Abstract LBA8505.

DCR = disease control rate

RTP RESEARCH TO PRACTICE

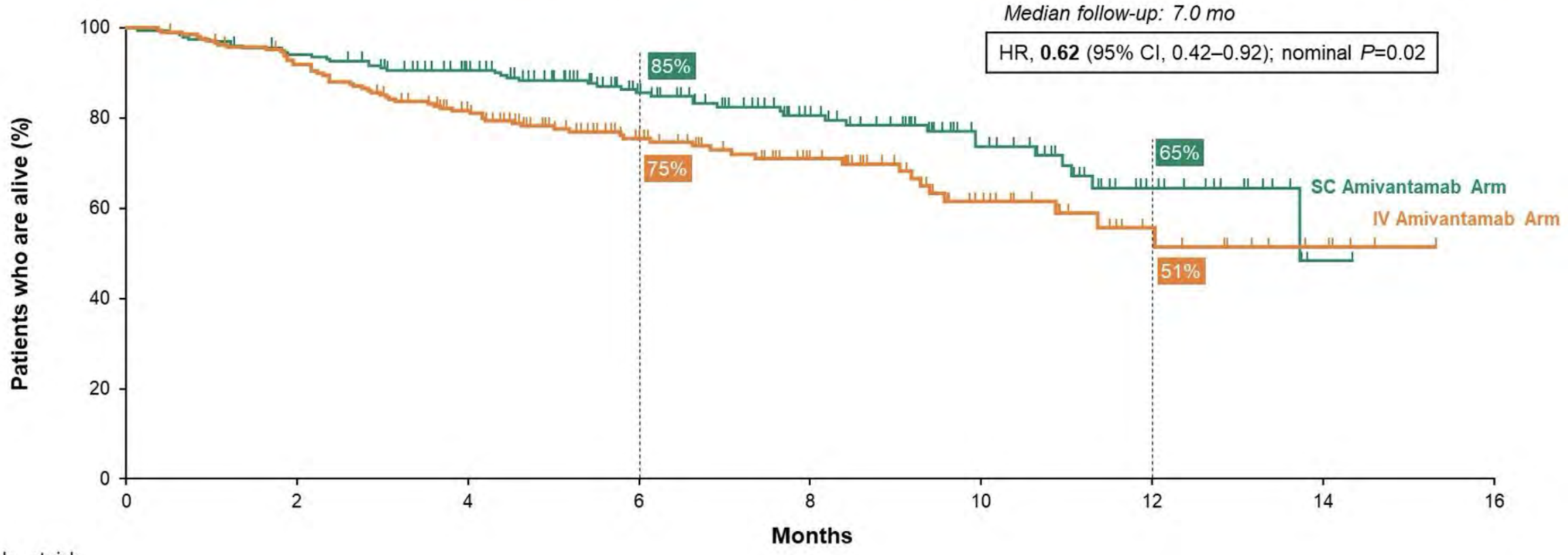
PALOMA-3: PFS Outcomes



Leighl NB et al. ASCO 2024;Abstract LBA8505.

PALOMA-3: OS Outcomes

There was an OS benefit associated with SC amivantamab, with an HR of 0.62 compared to the IV amivantamab arm[a]

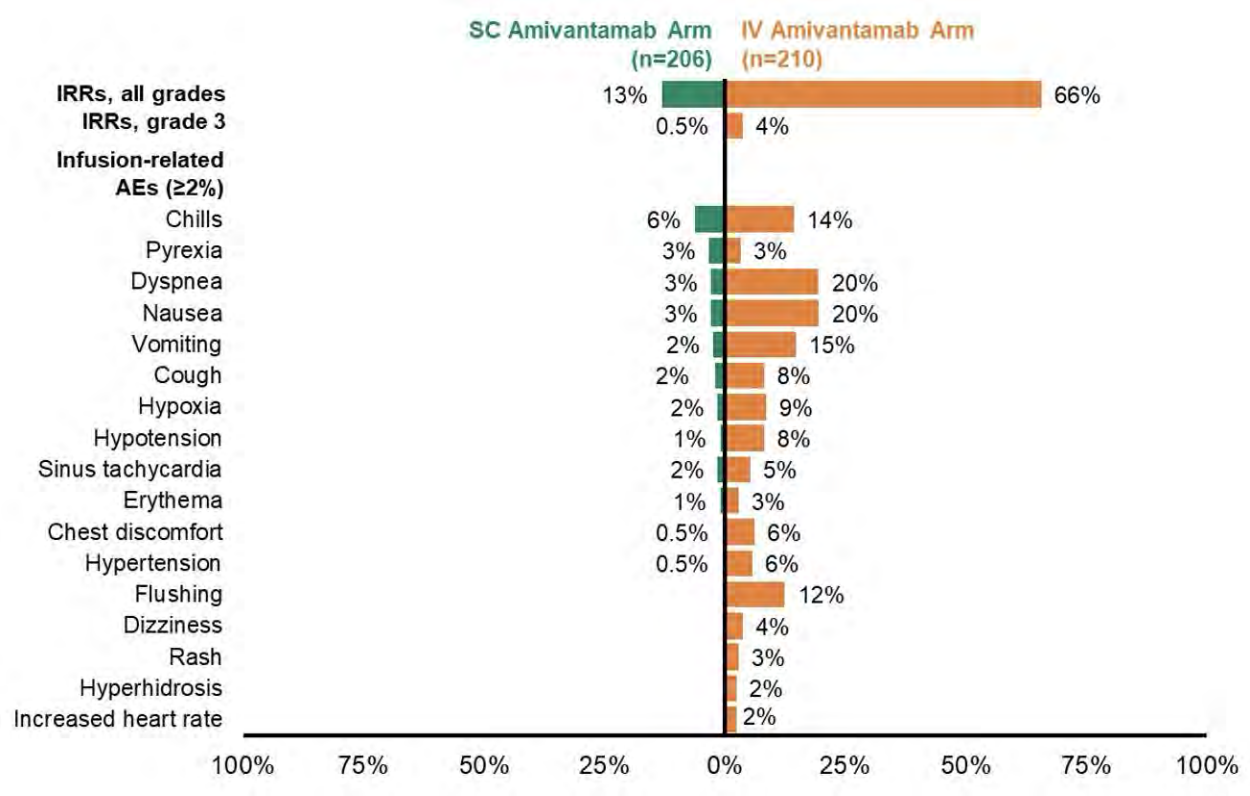


No. at risk									
SC Amivantamab Arm	206	192	163	109	71	36	10	0	0
IV Amivantamab Arm	212	191	144	92	51	24	10	1	0

Leighl NB et al. ASCO 2024;Abstract LBA8505.

PALOMA-3: Safety Profile

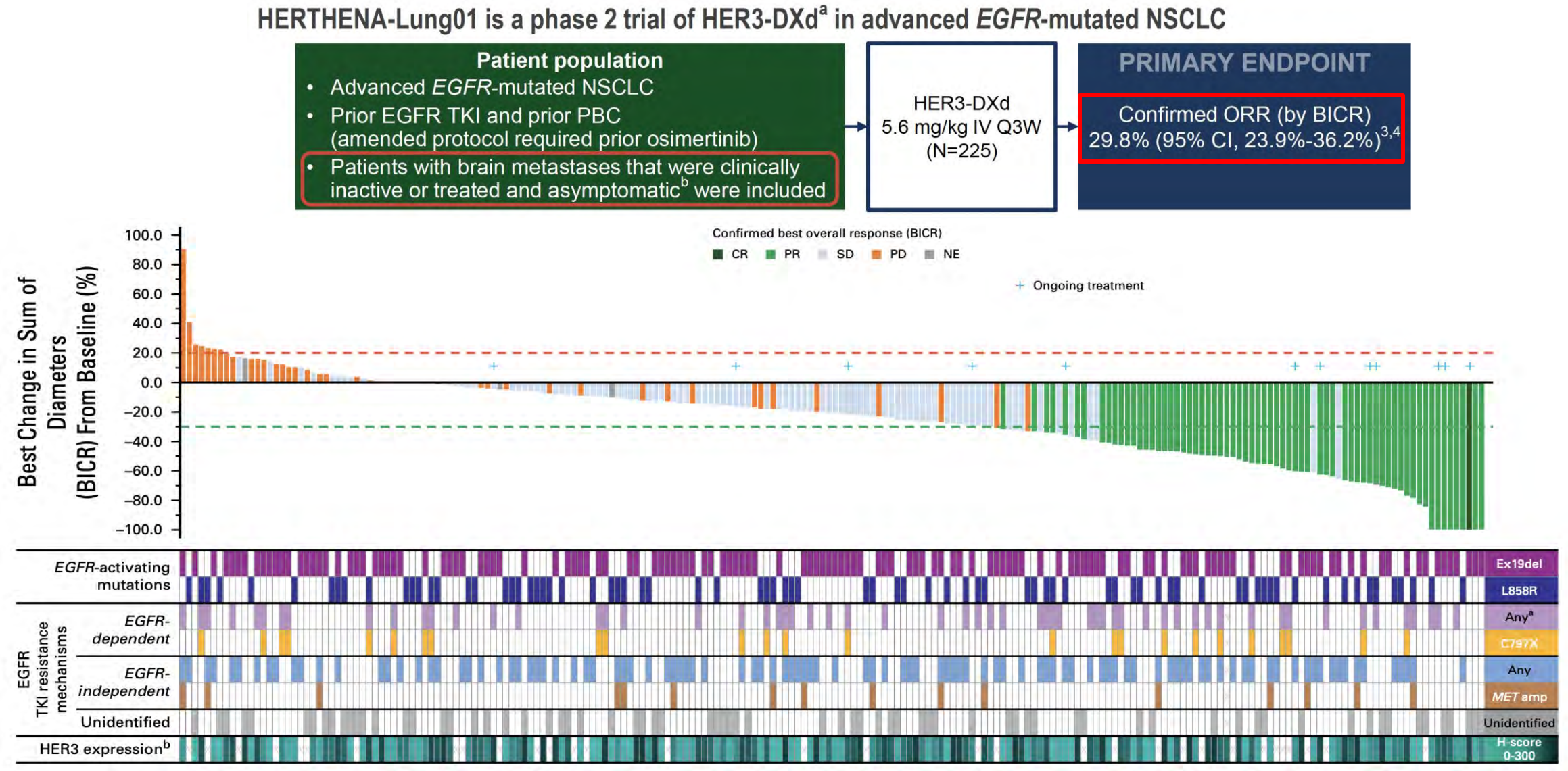
Most common AEs of any cause by preferred term (≥20%), n (%)	SC Amivantamab Arm (n=206)		IV Amivantamab Arm (n=210)	
	All grades	Grade ≥3	All grades	Grade ≥3
Associated with EGFR inhibition				
Paronychia	111 (54)	8 (4)	108 (51)	3 (1)
Rash	95 (46)	8 (4)	91 (43)	8 (4)
Dermatitis acneiform	64 (31)	18 (9)	69 (33)	12 (6)
Stomatitis	57 (28)	1 (0.5)	69 (33)	5 (2)
Diarrhea	43 (21)	3 (1)	39 (19)	2 (1)
Associated with MET inhibition				
Hypoalbuminemia	96 (47)	9 (4)	77 (37)	8 (4)
Peripheral edema	52 (25)	6 (3)	58 (28)	1 (0.5)



AEs = adverse events;
IRRs = infusion-related reactions

Leighl NB et al. ASCO 2024;Abstract LBA8505.

HERTHENA-Lung01 Study Design and Response Data

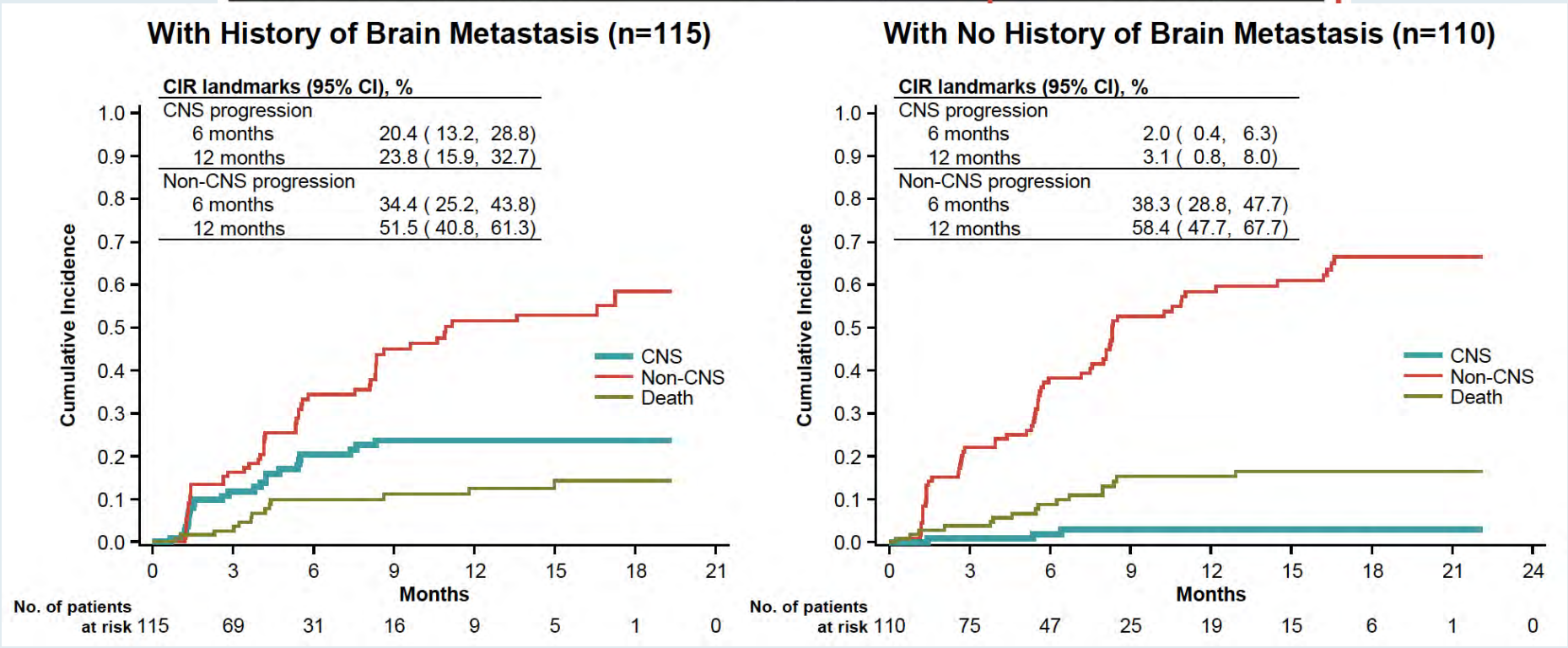


TKI = tyrosine kinase inhibitor; PBC = platinum-based chemotherapy

Yu HA et al. *J Clin Oncol* 2023;41(35):5363-75. Johnson M et al. ESMO 2023;Abstract 1319MO.

HERTHENA-Lung01: Intracranial Efficacy

Responses by CNS BICR[a]	All patients with baseline BM by CNS BICR (n=95)	Patients whose baseline BM had not been irradiated (n=30)[b]
CNS cORR, n (%) [95% CI]	19 (20.0) [12.5, 29.5]	10 (33.3) [17.3-52.8]
CR, n (%)	15 (15.8)	9 (30.0)[c]
PR, n (%)	4 (4.2)	1 (3.3)
SD/non-CR/non-PD, n (%)	57 (60.0)	13 (43.3)
PD, n (%)	13 (13.7)	4 (13.3)
NE, n (%)	6 (6.3)	3 (10.0)
CNS DCR (95% CI), %	80.0 (70.5, 87.5)	76.7 (57.7-90.1)
CNS DOR, median (95% CI), mo	9.2 (8.1-11.1)	8.4 (5.8-9.2)

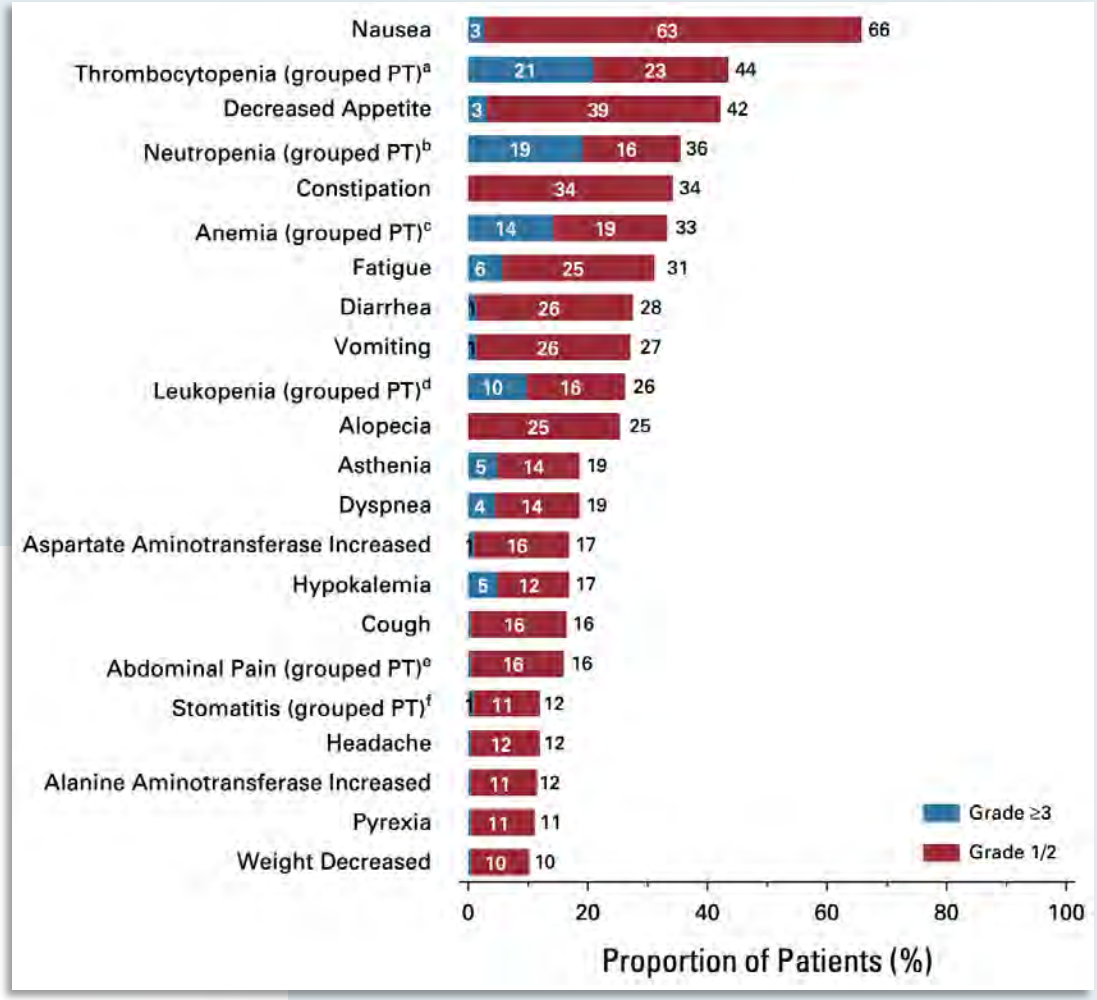


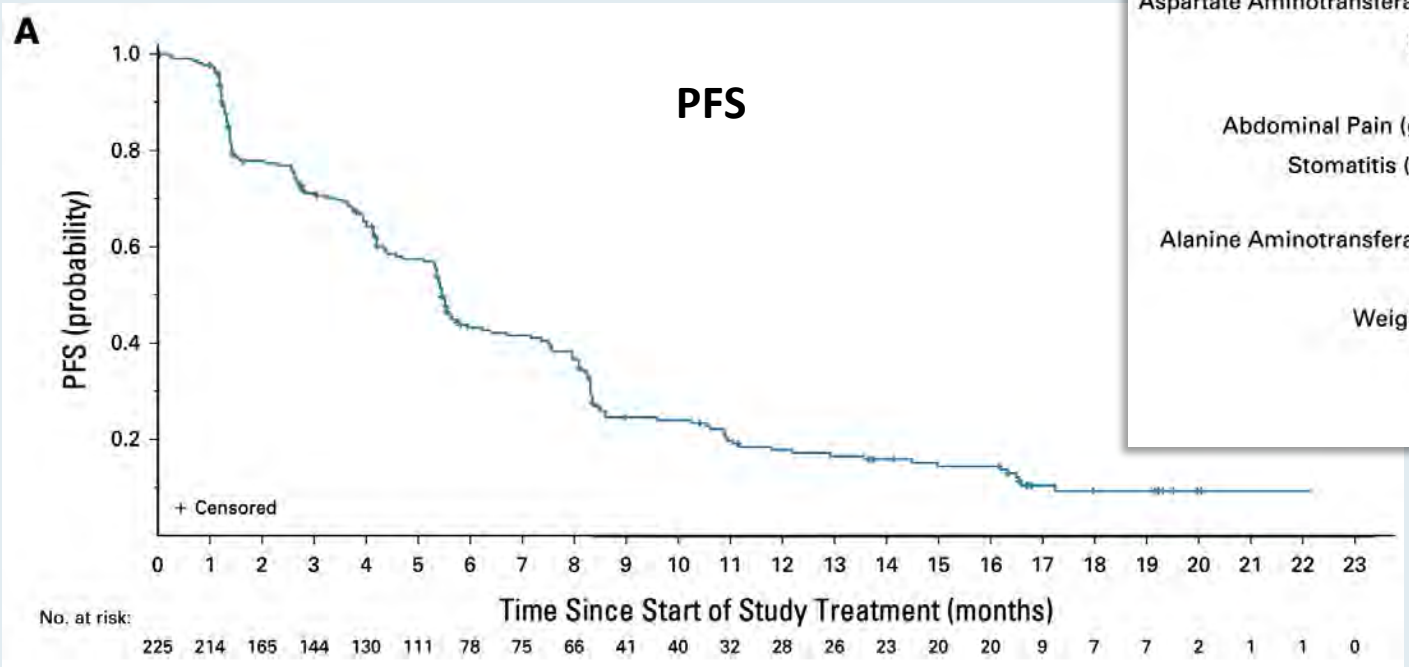
Johnson M et al. ESMO 2023;Abstract 1319MO.

BM = brain metastasis

HERTHENA-Lung01: Efficacy Outcomes and Safety

Median PFS of 5.5 months (95% CI, 5.1 to 5.9)
Median OS of 11.9 months (95% CI, 11.2 to 13.1)





Yu HA et al. *J Clin Oncol* 2023;41(35):5363-75.

TROPION-Lung05 Study Design and Patient Demographics

Screening

Key inclusion criteria

- Stage IIIB, IIIC, or IV NSCLC
- Presence of ≥1 actionable genomic alteration (*EGFR*, *ALK*, *ROS1*, *NTRK*, *BRAF*, *MET* exon 14 skipping, or *RET*)
- ECOG PS of 0 or 1
- ≥1 line of targeted therapy
- 1 or 2 prior cytotoxic agent–containing therapies including platinum-based therapy in the metastatic setting
- Radiographic disease progression after targeted therapy

Treatment

Dato-DXd
6 mg/kg
Q3W

Endpoints[a]

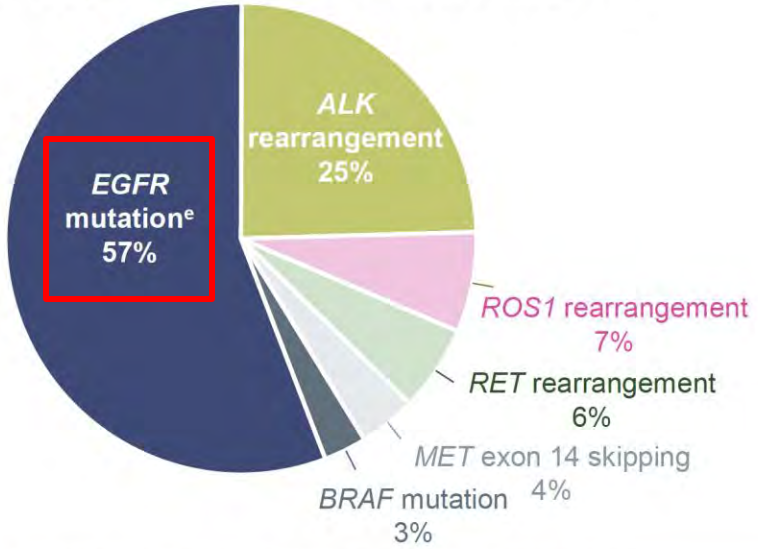
Primary: ORR by BICR

Secondary:

- By BICR and investigator: DOR, DCR, CBR, PFS, TTR
- By investigator: ORR
- OS, safety, PK, immunogenicity

Demographic characteristics	Dato-DXd (N=137)
Median age (range), years	60 (29-79)
Female, n (%)	83 (61)
Histology, n (%)	
Adenocarcinoma	130 (95)
History of brain metastasis, n (%)[a]	70 (51)
Median prior lines of therapy for adv/met disease	3
Prior lines of therapy, n (%)	137 (100)
≥3 prior lines of therapy for adv/met disease	98 (72)
Prior platinum chemotherapy	137 (100)
Prior anti–PD-1/anti–PD-L1 immunotherapy	49 (36)
≥2 prior lines of targeted therapies for indicated genomic alteration	82 (60)

Relative Frequency of Genomic Alterations[b-d]



Disposition

At the time of data cutoff (December 14, 2022):

- Median (range) treatment duration was 4 (1-21) months
- 60 participants (44%) were ongoing in study
- 20 participants (15%) were ongoing on study treatment

Paz-Ares L et al. ESMO 2023;Abstract 1314MO.

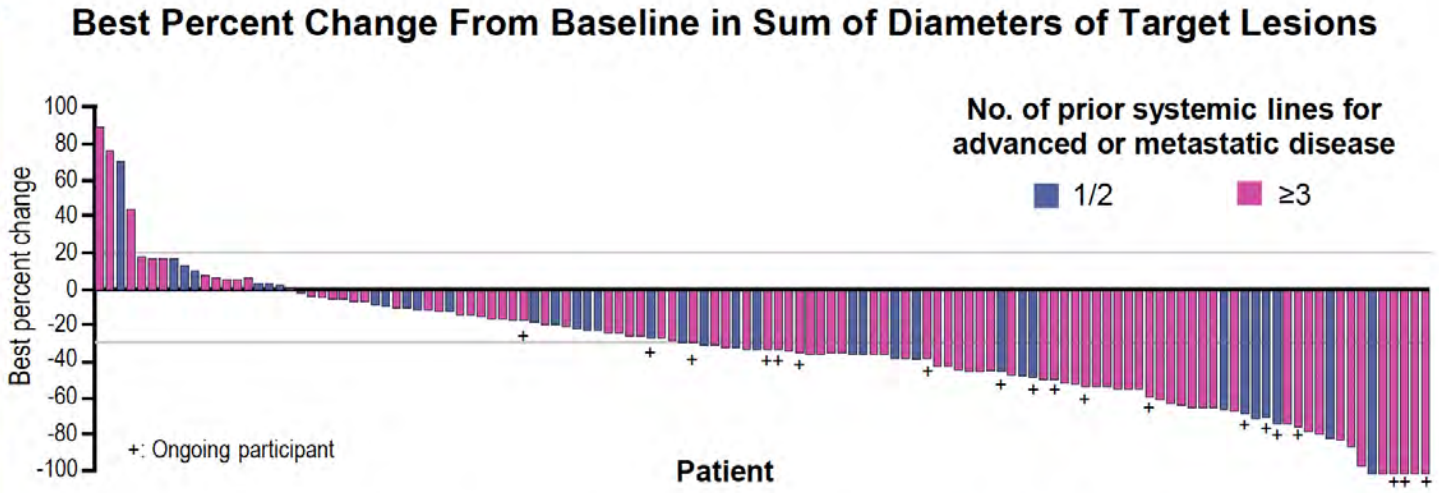
CBR = clinical benefit rate; TTR = time to response; PK = pharmacokinetics

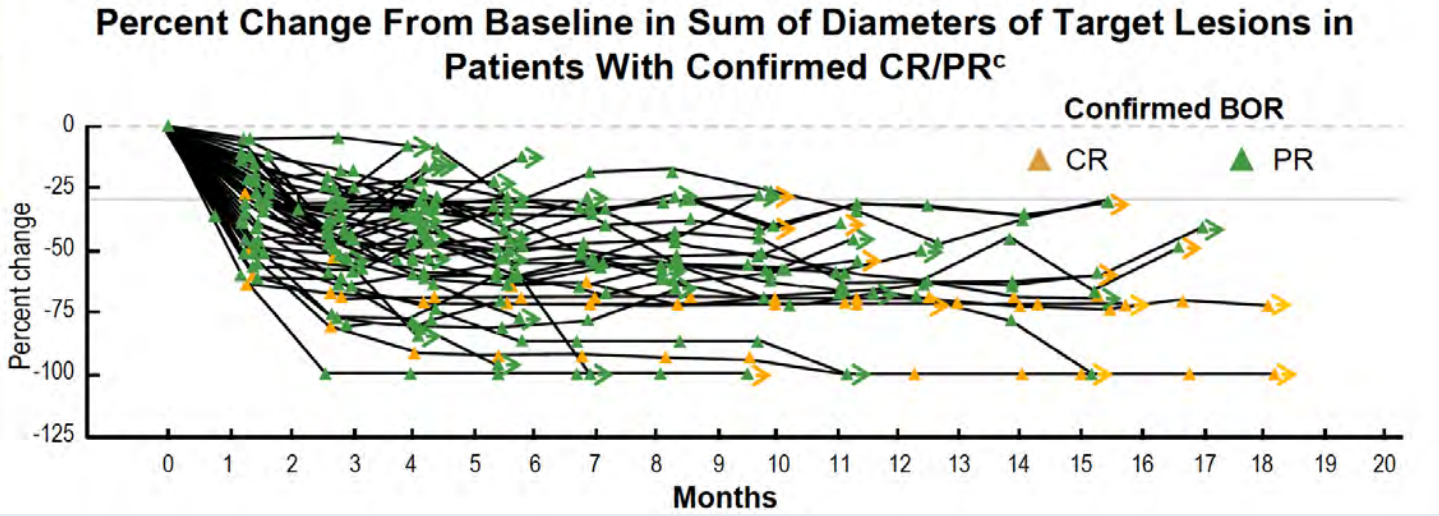
TROPION-Lung05: Efficacy Outcomes

Response per BICR	All treated patients (N=137)	Patients with *EGFR* mutations (N=78)	Patients with *ALK* rearrangement (N=34)
ORR confirmed, n (%) [95% CI][a]	49 (35.8) [27.8-44.4]	34 (43.6) [32.4-55.3]	8 (23.5) [10.7-41.2]
Median DOR (95% CI), months	7.0 (4.2-9.8)	7.0 (4.2-10.2)	7.0 (2.8-8.4)
DCR confirmed, n (%) [95% CI][a]	108 (78.8) [71.0-85.3]	64 (82.1) [71.7-89.8]	25 (73.5) [55.6-87.1]
Median PFS, (95% CI), months[b]	5.4 (4.7-7.0)	5.8 (5.4-8.3)	4.3 (2.6-6.9)

BOR: In the overall population (N=137), 4 patients (3%) achieved a CR and 45 (33%) achieved a PR

***EGFR* subset:** Among patients with sensitizing or T790M mutations (N=68), the ORR was 49.1% in those previously treated with osimertinib





BOR = best objective response

Paz-Ares L et al. ESMO 2023;Abstract 1314MO.

TROPION-Lung05: Intracranial Efficacy

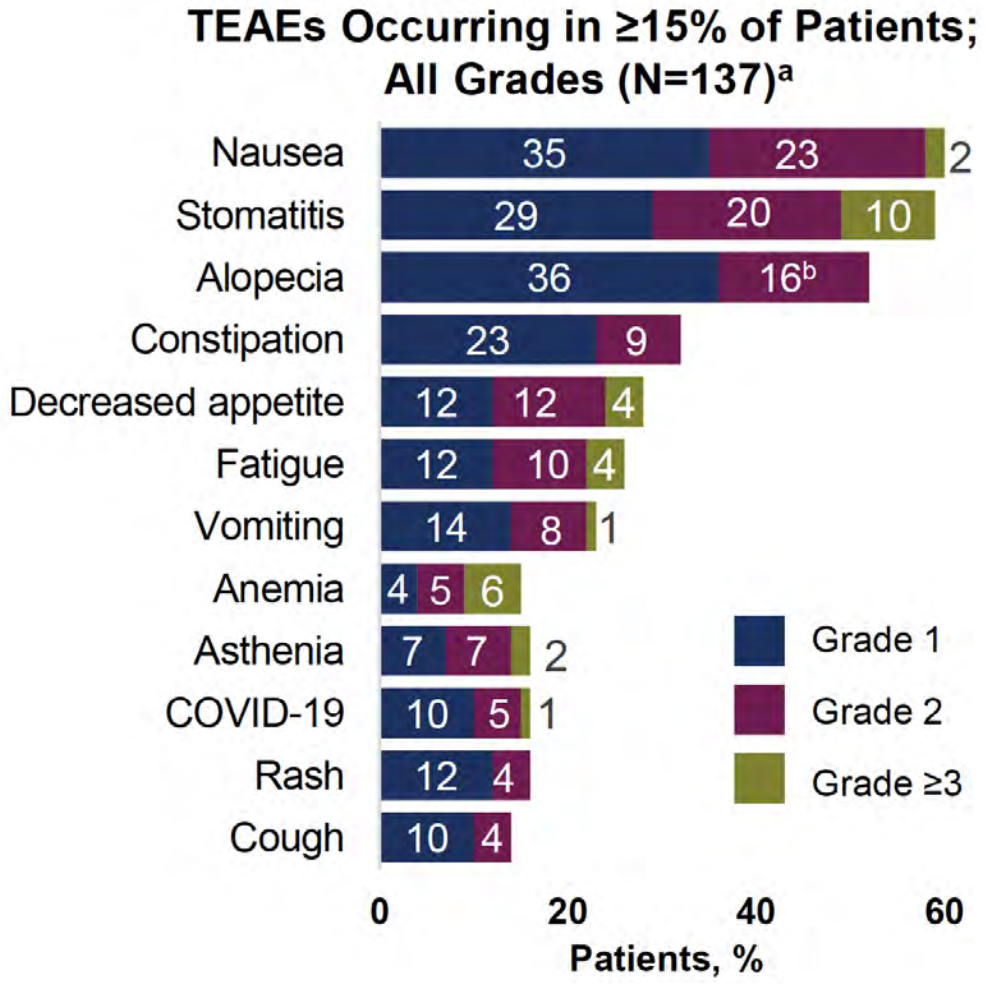
Response with confirmation[a]	With BL brain mets (N=53)	Without BL brain mets (N=84)
ORR,[b] n (%) [95% CI][c]	15 (28) [17–42]	34 (40) [30–52]
CR	0	4 (5)
PR	15 (28)	30 (36)
SD	21 (40)	35 (42)
Non-CR/Non-PD	2 (4)	1 (1)
PD	10 (19)	9 (11)
NE	5 (9)	5 (6)
DCR,[d] n (%) [95% CI][c]	38 (72) [58–83]	70 (83) [74–91]
CBR,[e] n (%) [95% CI][c]	21 (40) [27–54]	43 (51) [40–62]
PFS,[f] median, [95% CI][c] months	5.4 [3.1–7.0]	5.6 [4.9–8.3]

Response with confirmation[a]	Total (N=18)	With *EGFR* mutations (N=11)	Without *EGFR* mutations (N=7)	With *ALK* rearrangements (N=5)[b]
IC BOR, n (%)				
CR	0	0	0	0
PR	4 (22)	2 (18)	2 (29)	1 (20)
SD	9 (50)	5 (45)	4 (57)	4 (80)
PD	2 (11)	1 (9)	1 (14)	0
NE	3 (17)[c]	3 (27)[c]	0	0
IC ORR,[d] n (%) [95% CI][e]	4 (22) [6–48]	2 (18) [2–52]	2 (29) [4–71]	1 (20) [1–72]
IC DCR,[f] n (%) [95% CI][e]	13 (72) [47–90]	7 (64) [31–89]	6 (86) [42–100]	5 (100) [48–100]
IC CBR,[g] n (%) [95% CI][e]	8 (44) [22–69]	4 (36) [11–69]	4 (57) [18–90]	3 (60) [15–95]

Lisberg A et al. ASCO 2024;Abstract 8593.

BL = baseline; IC = intracranial

TROPION-Lung05: Safety Profile



- 137 patients (100%) experienced **TEAEs** (grade ≥3, 47%)
  - 129 (94%) experienced **treatment-related TEAEs** (grade ≥3, 29%)
  - 34 (25%) experienced **serious AEs** (grade ≥3, 5%)
- 30 (22%), 13 (10%), and 2 (2%) patients experienced TEAEs associated with **dose reduction, dose withdrawal, and death**,[c] respectively

AESI Incidence by Grade[d]

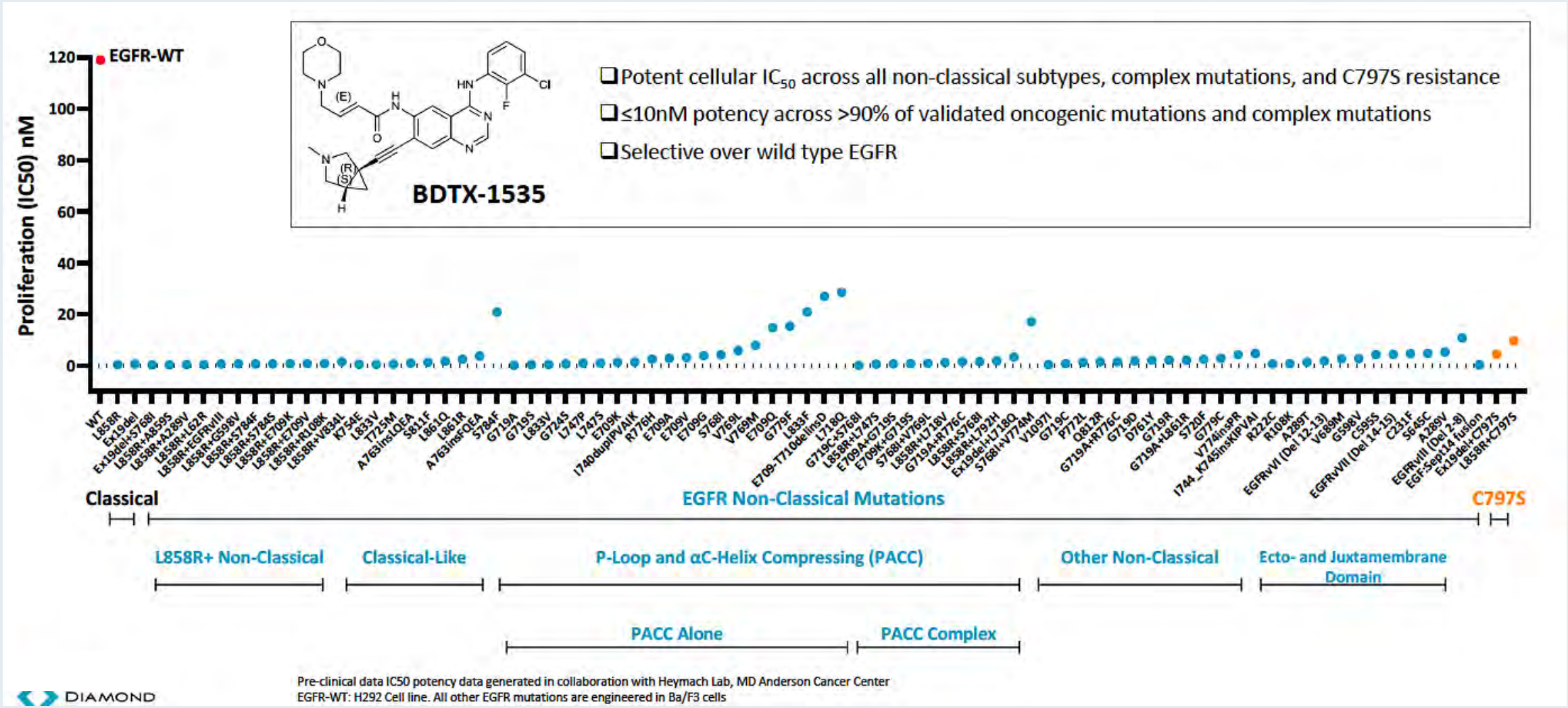
n (%)	Total	Grade 1	Grade 2	Grade ≥3
Oral mucositis/stomatitis	90 (66)	45 (33)	30 (22)	15 (11)
Ocular surface toxicity[e]	36 (26)	26 (19)	7 (5)	3 (2)[f]
IRR	22 (16)	15 (11)	7 (5)	0
Adjudicated drug-related ILD	5 (4)	1 (1)	3 (2)	1 (1)[g]

AESI = adverse event of special interest

Paz-Ares L et al. ESMO 2023;Abstract 1314MO.

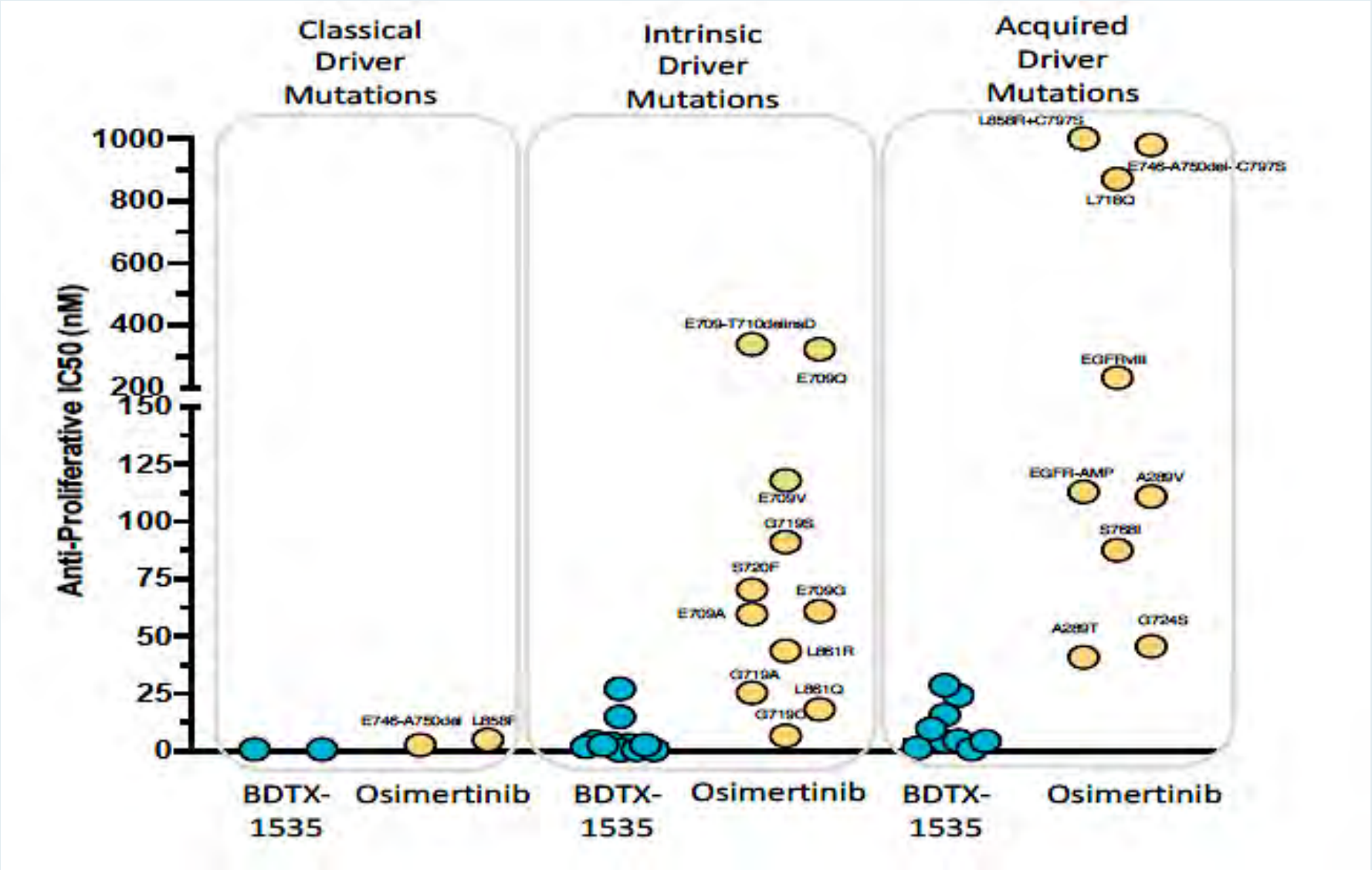
Questions?

BDTX-1535 Inhibits EGFR Classical (Exon 19 Deletion and L858R) and Nonclassical Mutations and Spares EGFR Wild Type (EGFR-WT)



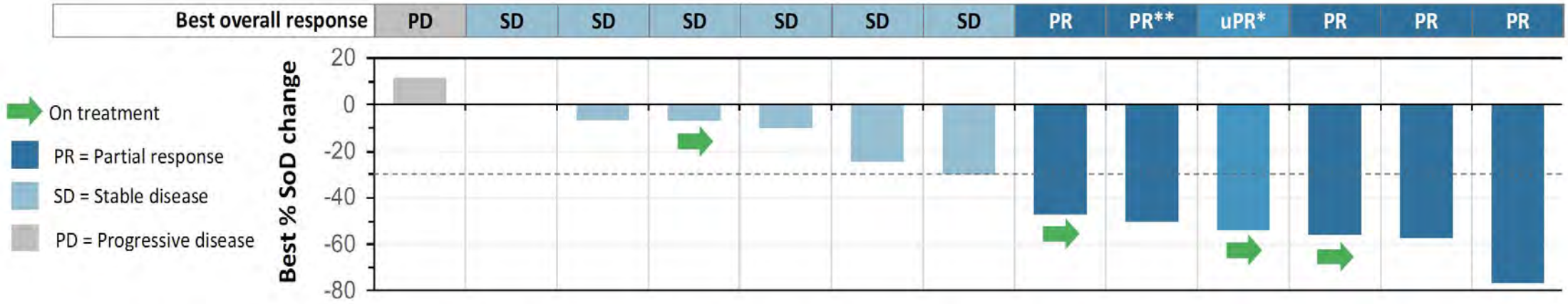
Dardenne E et al. AACR 2024;Abstract 1229.

BDTX-1535 Inhibits EGFR Classical, Intrinsic and Acquired Driver Mutations in Comparison to Osimertinib for NSCLC



O'Connor M et al. AACR 2023 poster.

Phase I Study of BDTX-1535 for Patients with NSCLC and Glioblastoma: Responses in the NSCLC Cohort



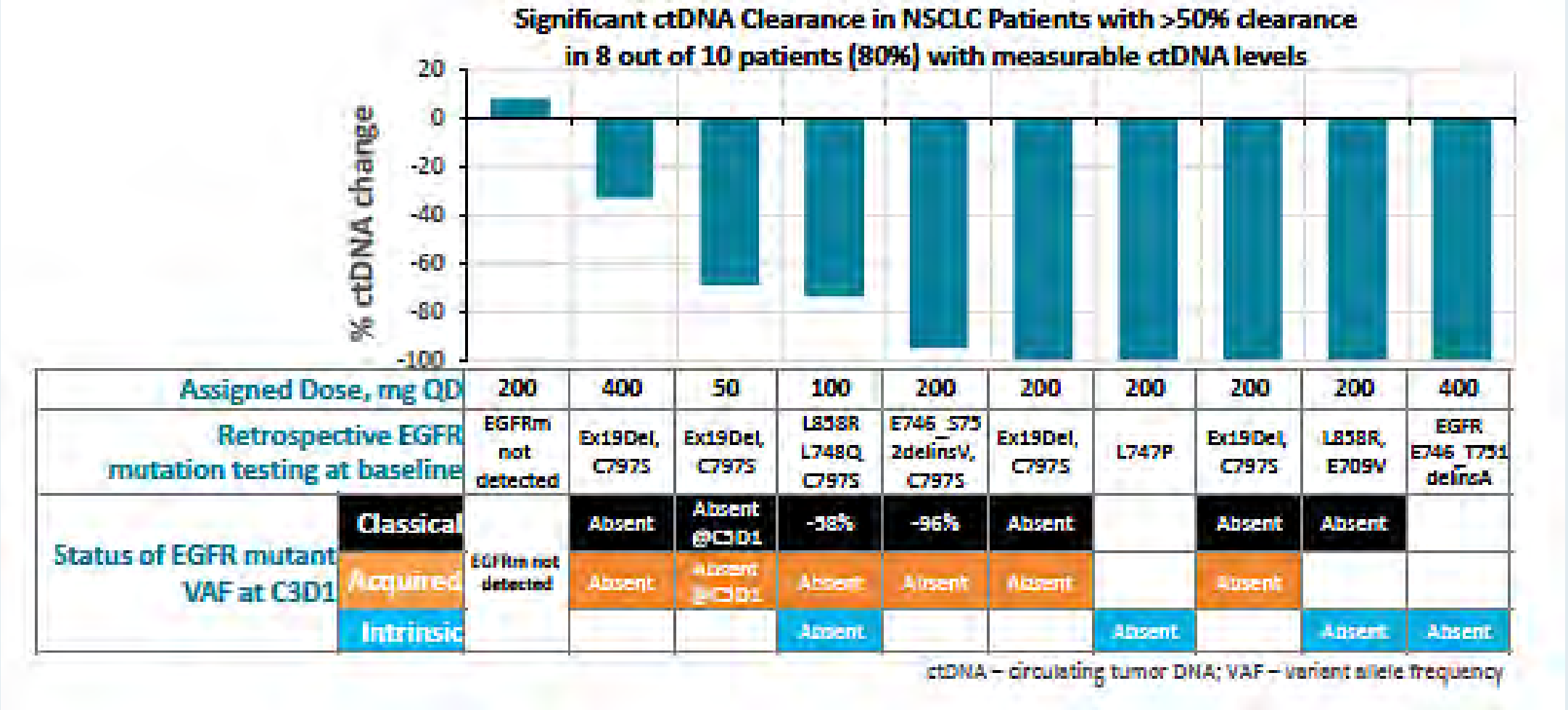
Assigned dose level, mg QD		300	400	200	200	200	200	400	400	300	200	200	300	100
EGFR mutation (retrospective central testing)	Classical	L858R		Ex19del	L858R#	Ex19del	Ex19del		Ex19del	Ex19del	L858R		L858R	L858R
	Non-classical	L833V	G719A		E709V#		G724S	S768I			E709V	L747P		L718Q
	Acquired	C797S		C797S		C797S	C797S		C797S	C797S			C797S	C797S
Prior lines of therapy	1st line	Osi	Osi	Osi	Gefi	Osi	Osi	Erlo	CPI	Osi	Osi	Osi	C	Osi
	2nd line	Daco, Osi	C		C	CPI, C		C	Osi	Osi+Gefi	C	CPI/C	Osi	
	>2 line	CPI, C	Afa						C	BLU-701		C	C	

Efficacy-Evaluable Patients
5 cPR, 1 uPR of 13 by RECIST
5 cPR, 1 uPR of 11 by RECIST post osimertinib

Osi = Osimertinib; Afa = Afatinib; Gefi = Gefitinib; Daco = Dacomitinib; Erlo = Erlotinib; CPI = Checkpoint inhibitor, C = Chemotherapy; # - mutations were absent on confirmatory test; * uPR=unconfirmed partial response-patient had a PR on a post baseline scan, but a radiologist was unable to confirm a response on a subsequent scan; this patient remains on study treatment without evidence of PD. **%SoD was updated to -50% from prior data release
24July2023 BDTX-1535-101 clinical data extract
Data adapted from Poster at EORTC/AACR/NCI International Conference on Molecular Targets and Cancer Therapeutics October 2023

Dardenne E et al. AACR 2024;Abstract 1229.

Phase I Study of BDTX-1535 for Patients with NSCLC and Glioblastoma: Clearance of EGFR VAF and ctDNA in NSCLC

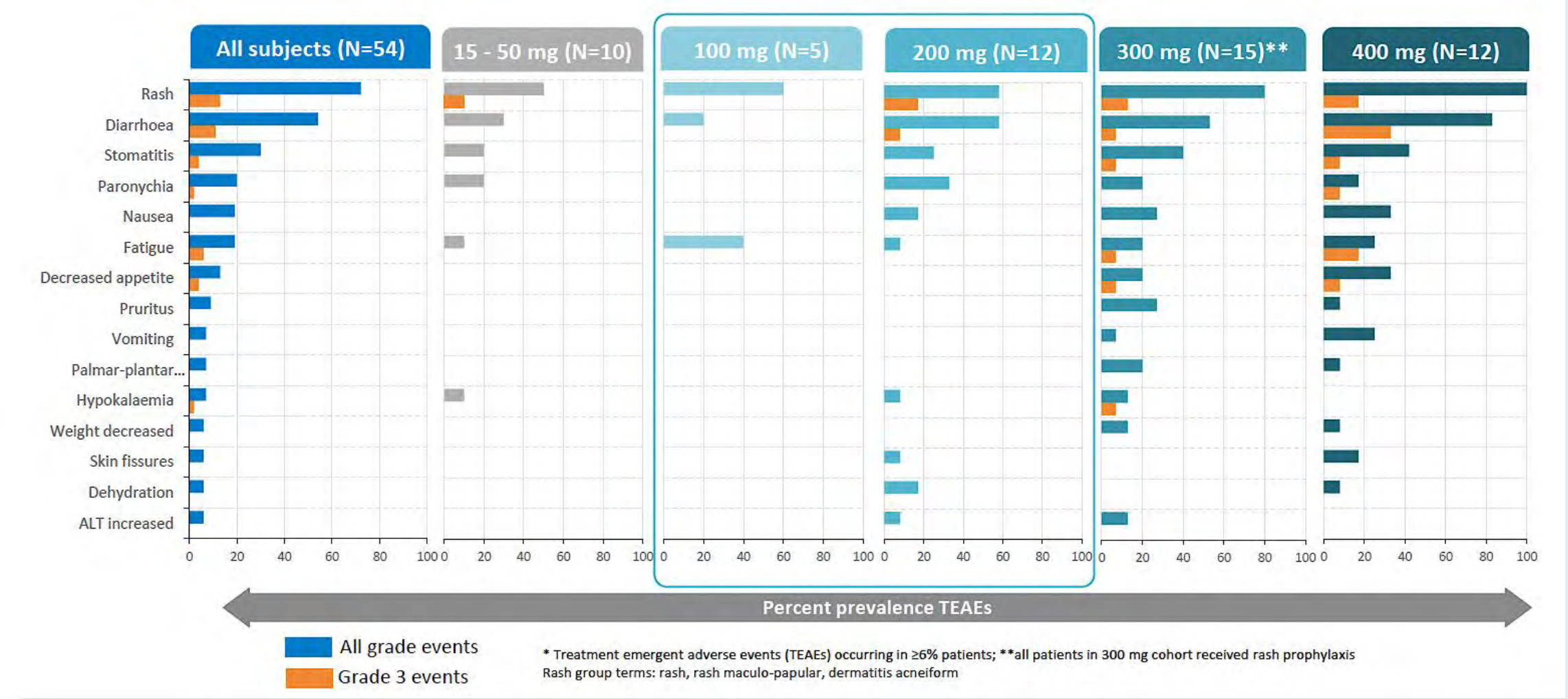


Assigned Dose, mg QD		200	400	50	100	200	200	200	200	200	400
Retrospective EGFR mutation testing at baseline		EGFRm not detected	Ex19Del, C797S	Ex19Del, C797S	L858R L748Q C797S	E746_S75 2delinsV, C797S	Ex19Del, C797S	L747P	Ex19Del, C797S	L858R, E709V	EGFR E746_T751 delinsA
Status of EGFR mutant VAF at C3D1	Classical	EGFRm not detected	Absent	Absent @C3D1	-38%	-96%	Absent		Absent	Absent	
	Acquired		Absent	Absent @C3D1	Absent	Absent	Absent		Absent		
	Intrinsic				Absent			Absent		Absent	Absent

ctDNA – circulating tumor DNA; VAF – variant allele frequency

Yu H et al. AACR-NCI-EORTC 2023;Abstract 35817.

Phase I Study of BDTX-1535 for Patients with NSCLC and Glioblastoma: Treatment-Emergent Adverse Events



Yu H et al. AACR-NCI-EORTC 2023;Abstract 35817.

Questions?

FURTHER: A Global, Randomized Study of Firmonertinib at Two Dose Levels in TKI-Naive, Advanced NSCLC with EGFR PACC Mutations

Wang J et al.
WCLC 2024;Abstract PL04.07
Monday, September 9, 2024
8:58 AM – 9:05 AM PDT

Osimertinib with or without Savolitinib as 1L in de Novo MET Aberrant, EGFRm Advanced NSCLC (CTONG 2008): A Phase II Trial

Yang J et al.
WCLC 2024;Abstract PL04.10
Monday, September 9, 2024
9:17 AM – 9:24 AM PDT

Select Novel Therapies for Advanced NSCLC with EGFR Mutations

Agent	Clinical trial	EGFR mutation	ORR	CNS ORR	Median PFS
Aumolertinib	AENEAS	Exon 19 deletion Exon 21 L858R	74%	83%	19.3 mo
Firmonertinib (formerly furmonertinib)	FURLONG	Exon 19 deletion Exon 21 L858R	89%	91%	20.8 mo
Befotertinib	NCT04206072	Exon 19 deletion Exon 21 L858R	67%	70%	22.1 mo
Firmonertinib (formerly furmonertinib)	FAVOUR	Exon 20 insertion	TN 240 mg 79% PT 240 mg 46% PT 160 mg 39%	NR	NR
Sunvozertinib	WU-KONG1	Exon 20 insertion	45%	NR	NR
Zipalertinib	REZILIENT1	Exon 20 insertion	38%	1 of 3 patients with target CNS lesion achieved PR	NR

TN = treatment naïve; PT = previously treated; NR = not reported

Lu S et al. *J Clin Oncol* 2022;40:3162-71; Lu S et al. ASCO 2022;Abstract 9096; Shi Y et al. *J Thorac Oncol* 2022;17:1297-305; Shi Y et al. *Lancet Respir Med* 2022;10;1019-28; Lu S et al. *Lancet Respir Med* 2023;11:905-15; Han B et al. WCLC 2023;Abstract OA03.04; Yang YC-H et al. ASCO 2024;Abstract 8513; Piotrowska Z et al. *J Clin Oncol* 2023;41(26):4218-25.

Case Presentation – Dr Yu: 64-year-old man with recent disease progression on chemotherapy

48 yo man with a diagnosis of stage 4 lung cancer in 2020. He initially was treated with osimertinib, and had an excellent response to treatment that lasted for 20 months. He had radiation to his L humerus as a site of oligoprogression, then continued on osimertinib for another 8 months. In July 2022, he began treatment with carboplatin and pemetrexed for progressive disease in the lungs bilaterally. He initially responded, but in Feb 2023 had further disease progression in the lungs while on pemetrexed maintenance. Repeat biopsy of his lung identified the EGFR ex19 deletion and a new KRAS G12D alteration.

What treatment options would be appropriate for this patient if all were approved and reimbursable?

1. Osimertinib 80 mg + sotorasib 960 mg daily
2. Retrial of carboplatin/pemetrexed
3. Carboplatin/pemetrexed/amivantamab
4. Patritumab deruxtecan

Case Presentation – Dr Yu: 64-year-old man with recent disease progression on chemotherapy (continued)

Since he had just come off chemotherapy, and there are no targetable treatments for KRAS G12D, we decided to proceed with patritumab deruxtecan.

He did well with treatment. He had grade 2 leukopenia and thrombocytopenia on C2D1 that improved with a 3-day dose hold. He has noticed some hair loss and nausea for 3 days post-treatment but otherwise has tolerated treatment well. Repeat scans after 3 cycles indicated stable disease on treatment with some minor shrinkage of some of his pulmonary nodules. It's been 7 months and he continues to do well on treatment.

The Implications of Recent Datasets for the Current and Future Management of Non-Small Cell Lung Cancer with Actionable Targets Beyond EGFR

A CME/MOC-Accredited Live Webinar in Conjunction with the IASLC 2024 World Conference on Lung Cancer

Wednesday, September 11, 2024

5:00 PM – 6:00 PM ET

Faculty

Ibiayi Dagogo-Jack, MD

Corey J Langer, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

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Information on how to obtain CME, ABIM MOC and ABS credit is provided in the Zoom chat room. Attendees will also receive an email in 1 to 3 business days with these instructions.