The Implications of Recent Datasets for the Current and Future Use of Nontargeted Therapy for Metastatic Non-Small Cell Lung Cancer

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

Thursday, September 12, 2024

5:00 PM – 6:00 PM ET

Faculty

Edward B Garon, MD, MS

Luis Paz-Ares, MD, PhD

Moderator

Neil Love, MD

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Faculty

Edward B Garon, MD, MS
Professor
Director, Thoracic Oncology Program
Director, Signal Transduction and Therapeutics Research Program
David Geffen School of Medicine at UCLA
Jonsson Comprehensive Cancer Center
Los Angeles, California

Luis Paz-Ares, MD, PhD
Chair of the Medical Oncology Department
at the Hospital Universitario 12 de Octubre
Associate Professor at the
Universidad Complutense
Head of the Lung Cancer Unit
at the National Oncology Research Center
Madrid, Spain

MODERATOR
Neil Love, MD
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Miami, Florida

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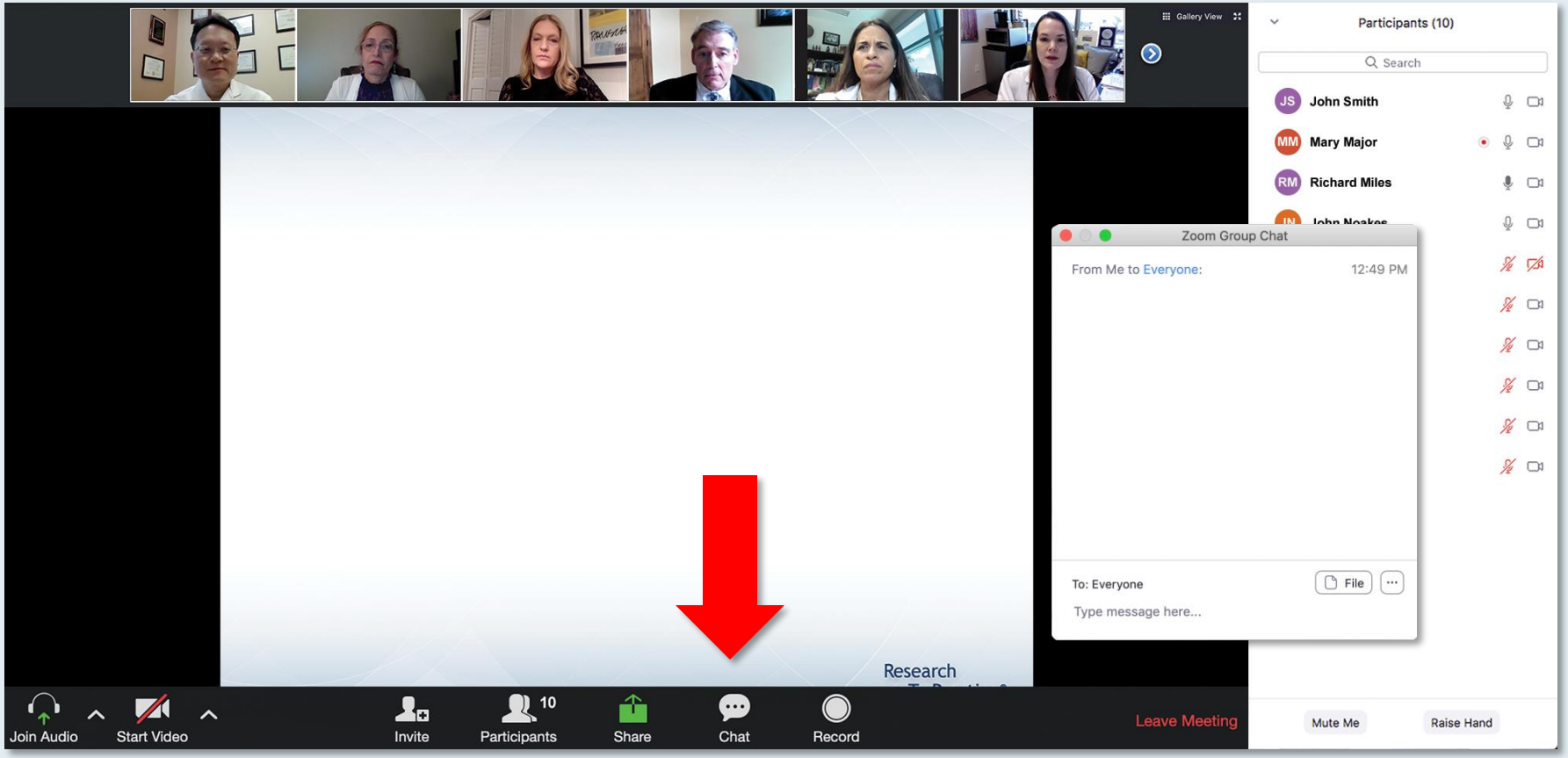

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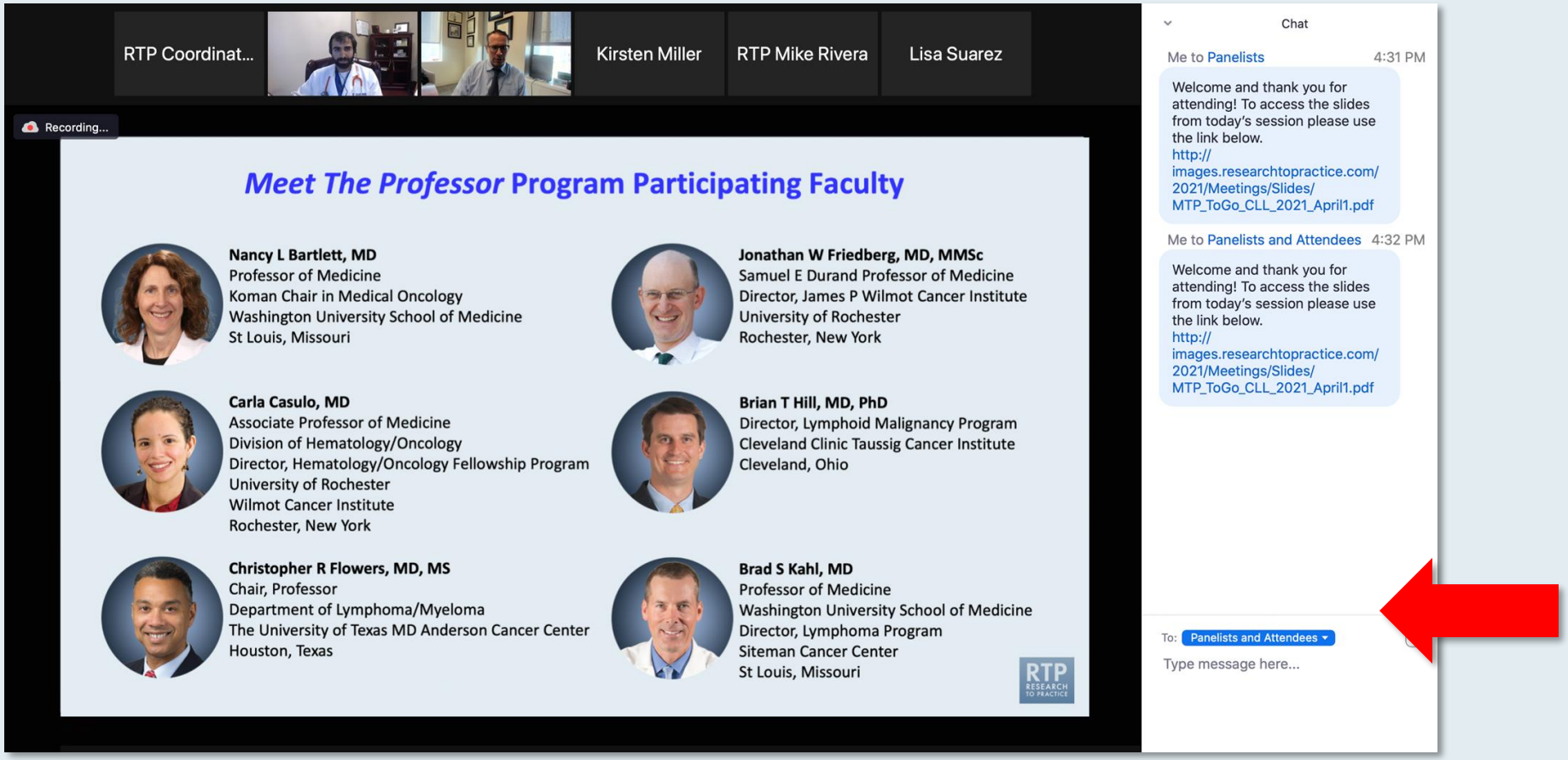

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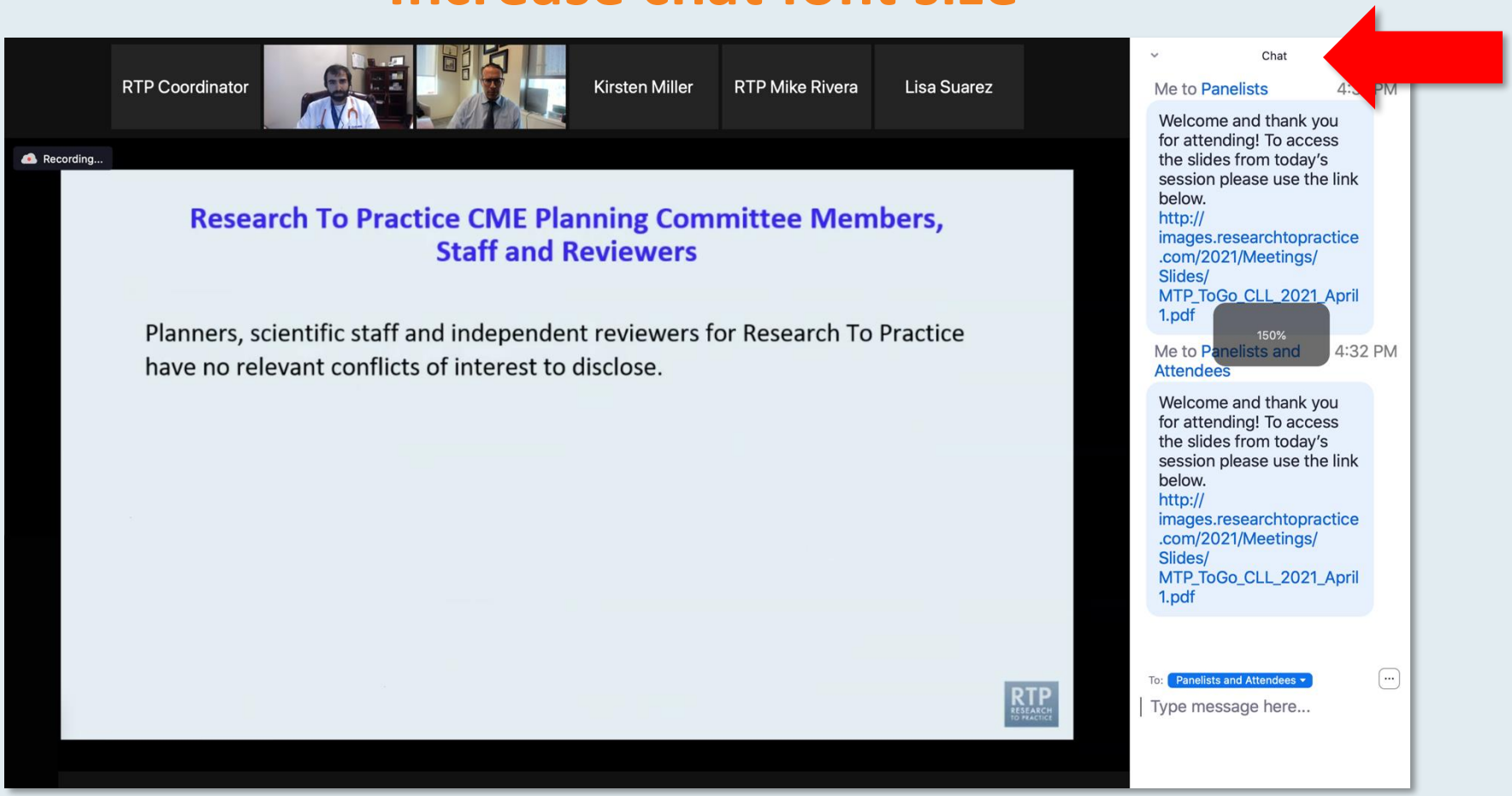

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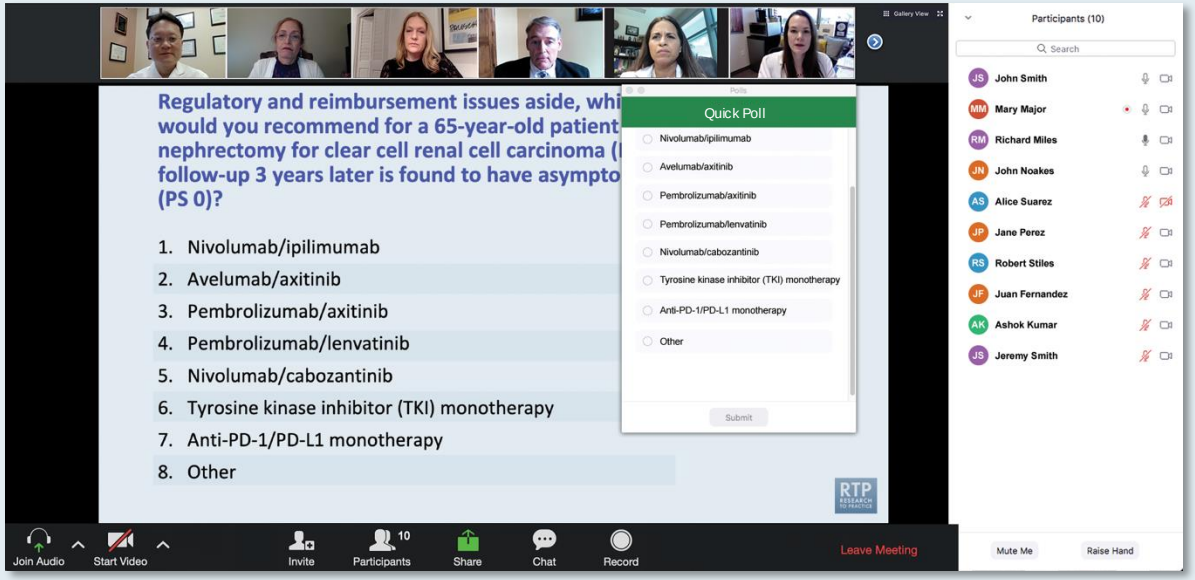

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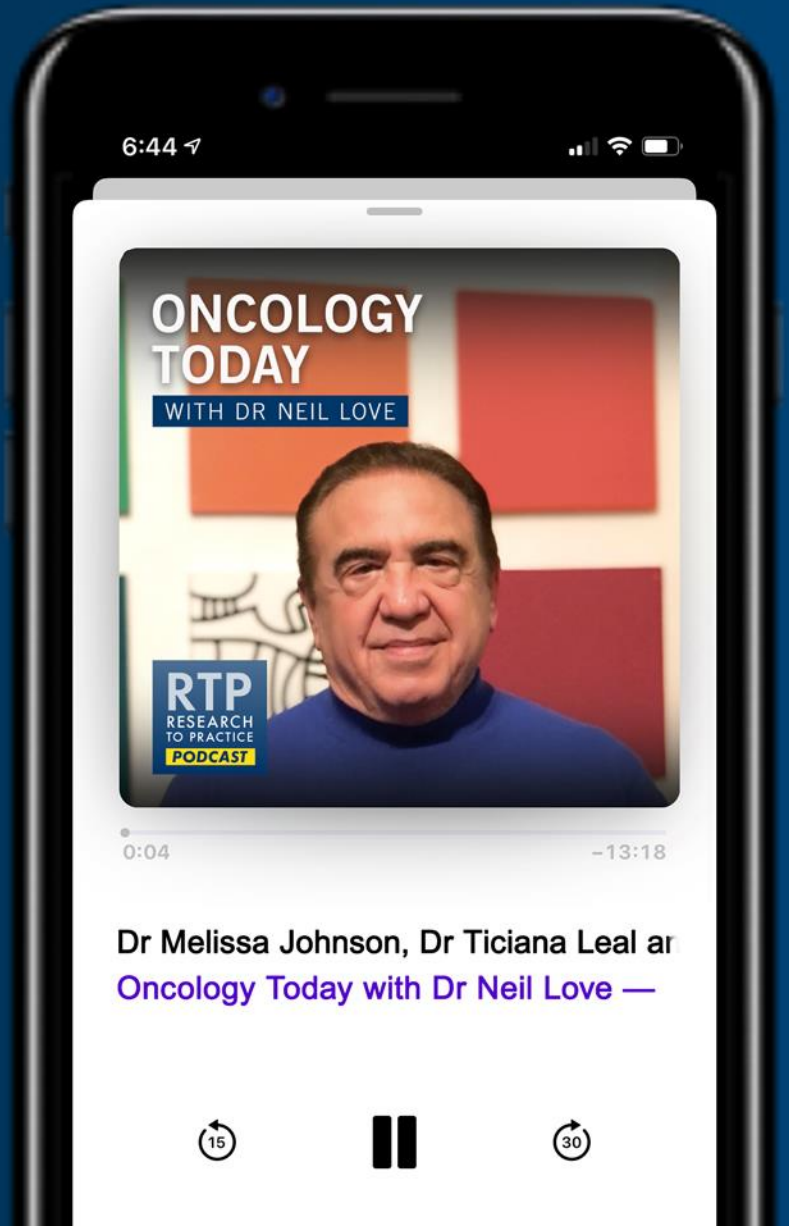

Meet The Professor: Optimizing the Management of Chronic Lymphocytic Leukemia

A CME/MOC-Accredited Live Webinar

Tuesday, September 17, 2024
5:00 PM – 6:00 PM ET

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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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Mrinal Gounder, MD

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RESEARCH TO PRACTICE

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

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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

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ER-Positive Breast Cancer

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Seth Wander, MD, PhD

Lung Cancer

Faculty

Joshua K Sabari, MD

Additional faculty to be announced.

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Fontainebleau Hotel, Miami Beach, Florida

Moderated by Neil Love, MD

Thank you for joining us!

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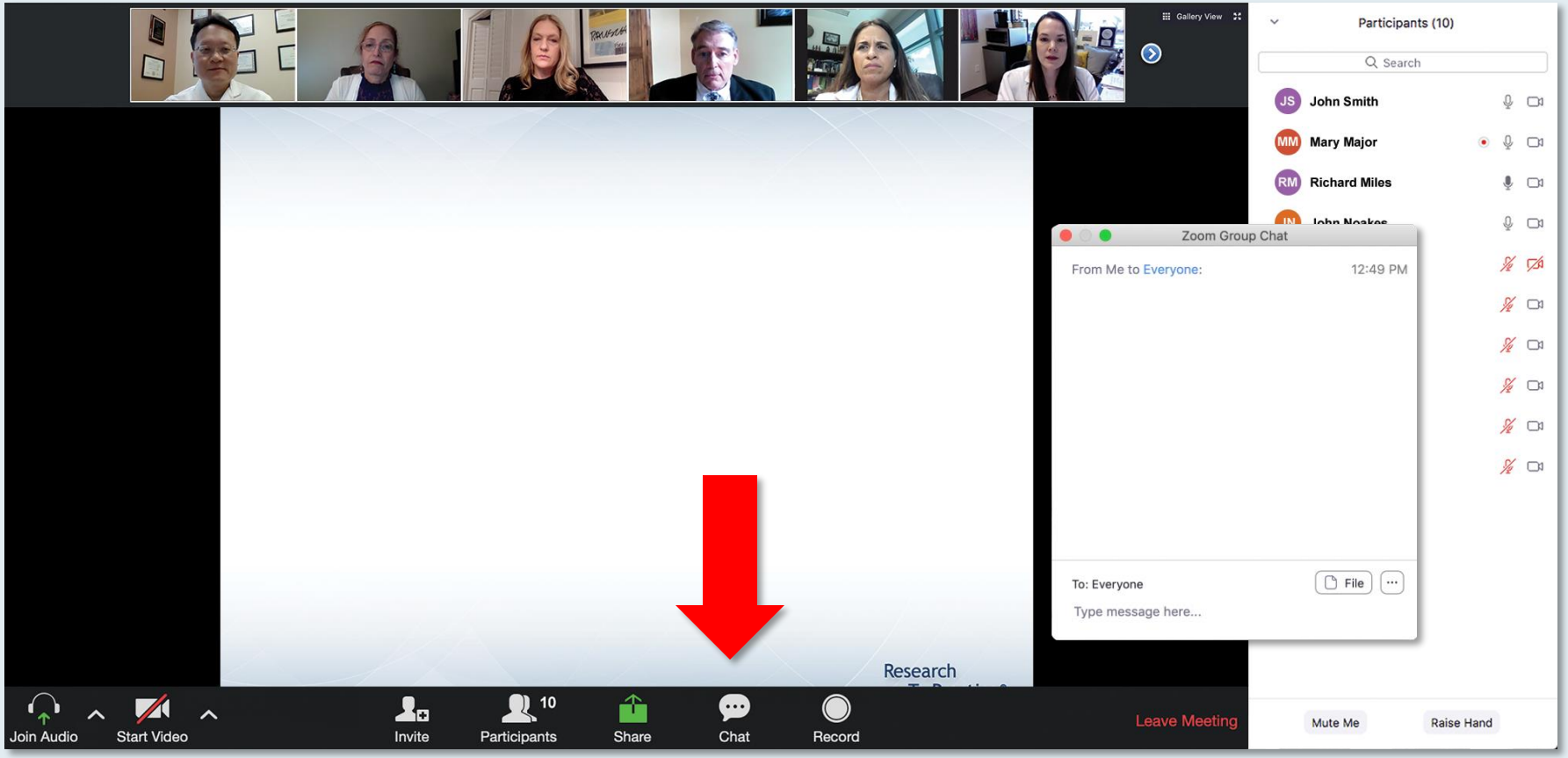

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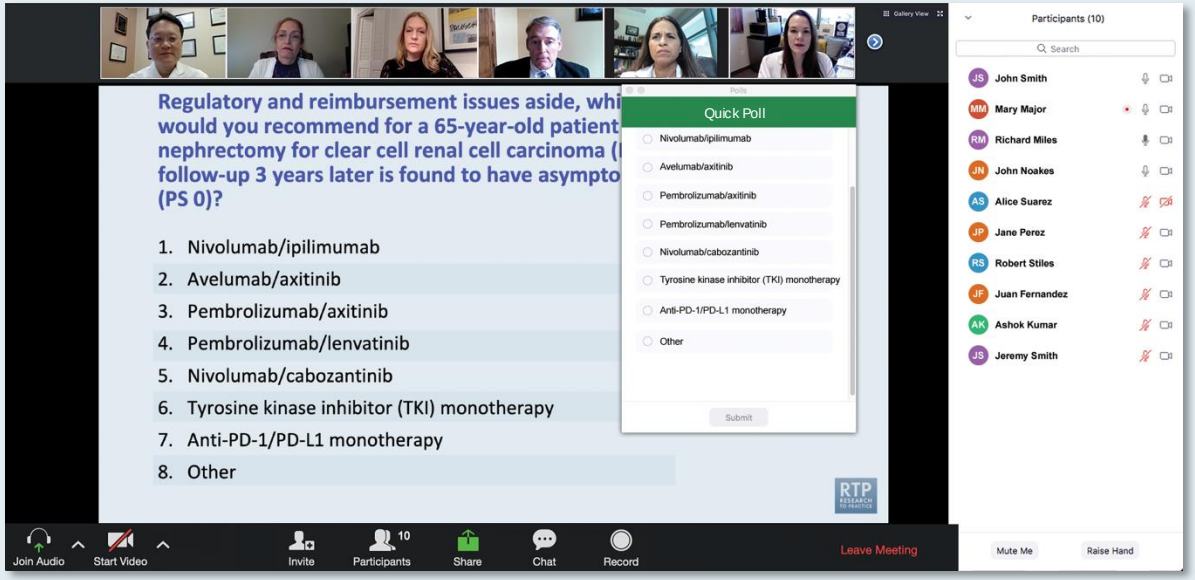

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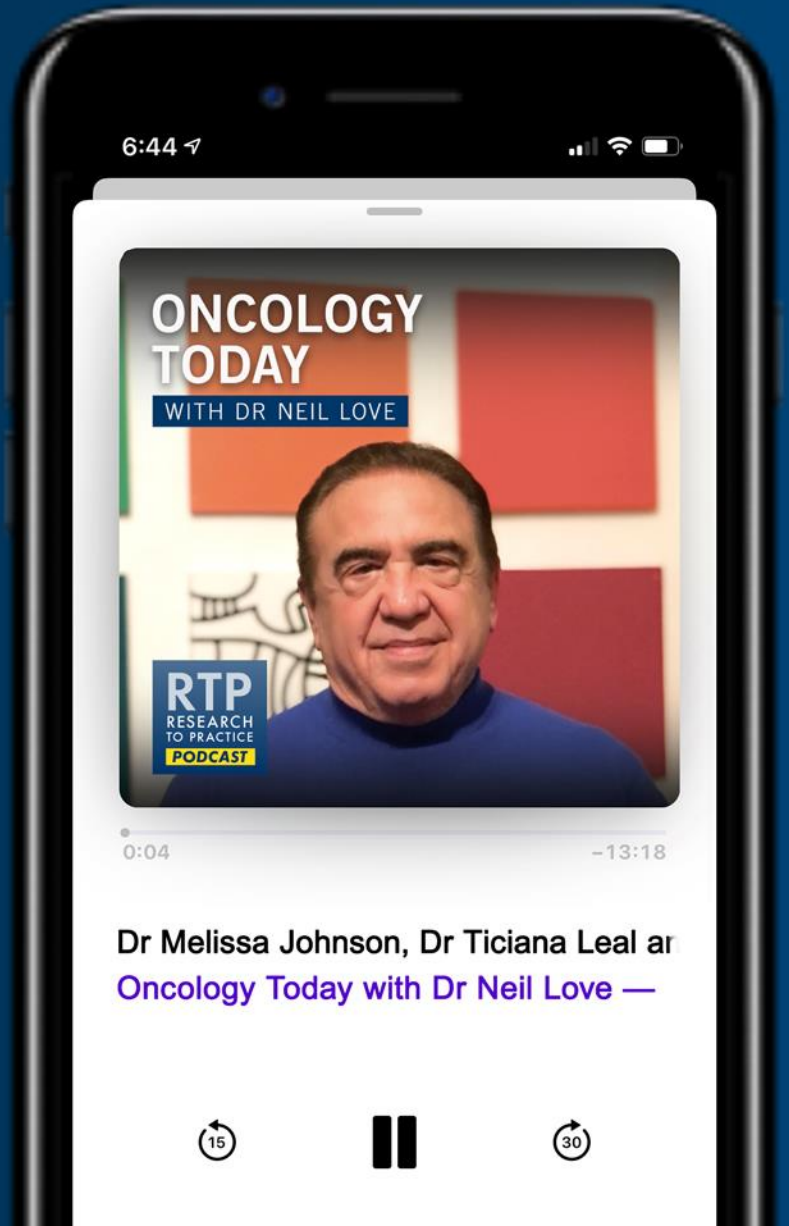

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Agenda

Introduction: Ivonescimab

Module 1: First-Line Therapy for Metastatic NSCLC without a Targetable Tumor Mutation — Dr Garon

Module 2: Promising Therapeutic Strategies for Patients with Progressive Metastatic NSCLC — Dr Paz-Ares

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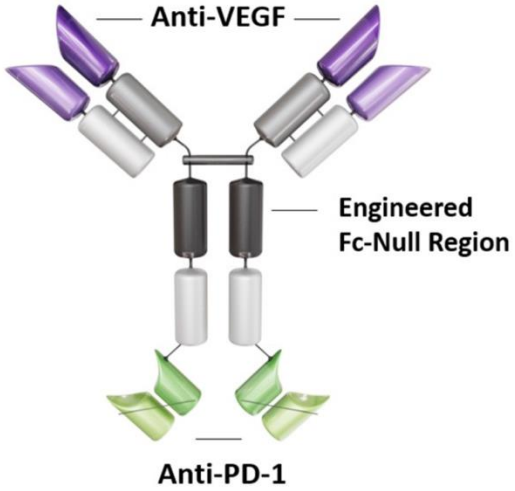
HARMONi-2: Phase 3 Study of Ivonescimab vs. Pembrolizumab as 1L Treatment for PD-L1-positive Advanced NSCLC – Study Design

Ivonescimab (AK112/SMT112) is an anti-PD-1/VEGF bispecific antibody displaying cooperative binding characteristics.

A randomized, double-blind, phase 3 study[a]



Patient Population

- Stage IIIB-IV aNSCLC
- No prior systemic therapy
- No *EGFR* mutations or *ALK* rearrangements
- ECOG PS 0 or 1
- PD-L1 TPS ≥1%

R 1:1

N=398

Ivonescimab
20 mg/kg Q3W (N=198)

Pembrolizumab
200 mg Q3W (N=200)

Treatment until no clinical benefit, unacceptable toxicity or up to 24 months

Stratification

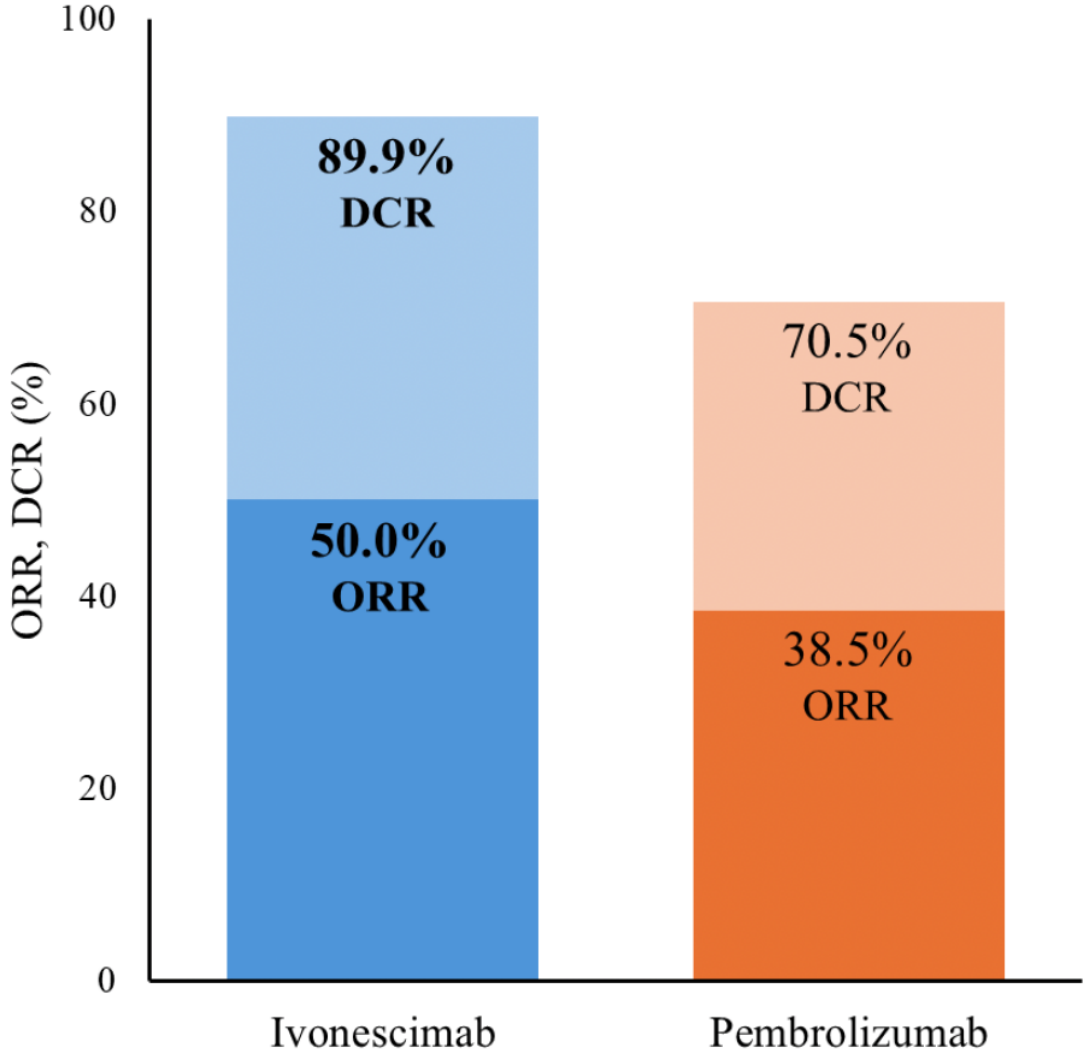
- Clinical stage (IIIB/C vs. IV)
- Histology (SQ vs. non-SQ)
- PD-L1 TPS (≥50% vs. 1-49%)

Endpoints

Primary: PFS by blind IRRC per RECIST v1.1
Secondary: OS, PFS assessed by INVs, ORR, DoR, TTR and safety
Exploratory: QoL

Zhang L et al. ASCO 2024;Abstract 8508.
Zhou C et al. WCLC 2024;Abstract PL02.04.

HARMONi-2: Phase 3 Study of Ivonescimab vs. Pembrolizumab as 1L Treatment for PD-L1-positive Advanced NSCLC – Response



	Ivonescimab (n = 198)	Pembrolizumab (n = 200)
ORR, %	**50.0**	38.5
(95% CI)	(42.8, 57.2)	(31.7, 45.6)
DCR, %	**89.9**	70.5
(95% CI)	(84.8, 93.7)	(63.7, 76.7)
Median DoR, mos	**NR**	NR
(95% CI)	(NE, NE)	(8.28, NE)

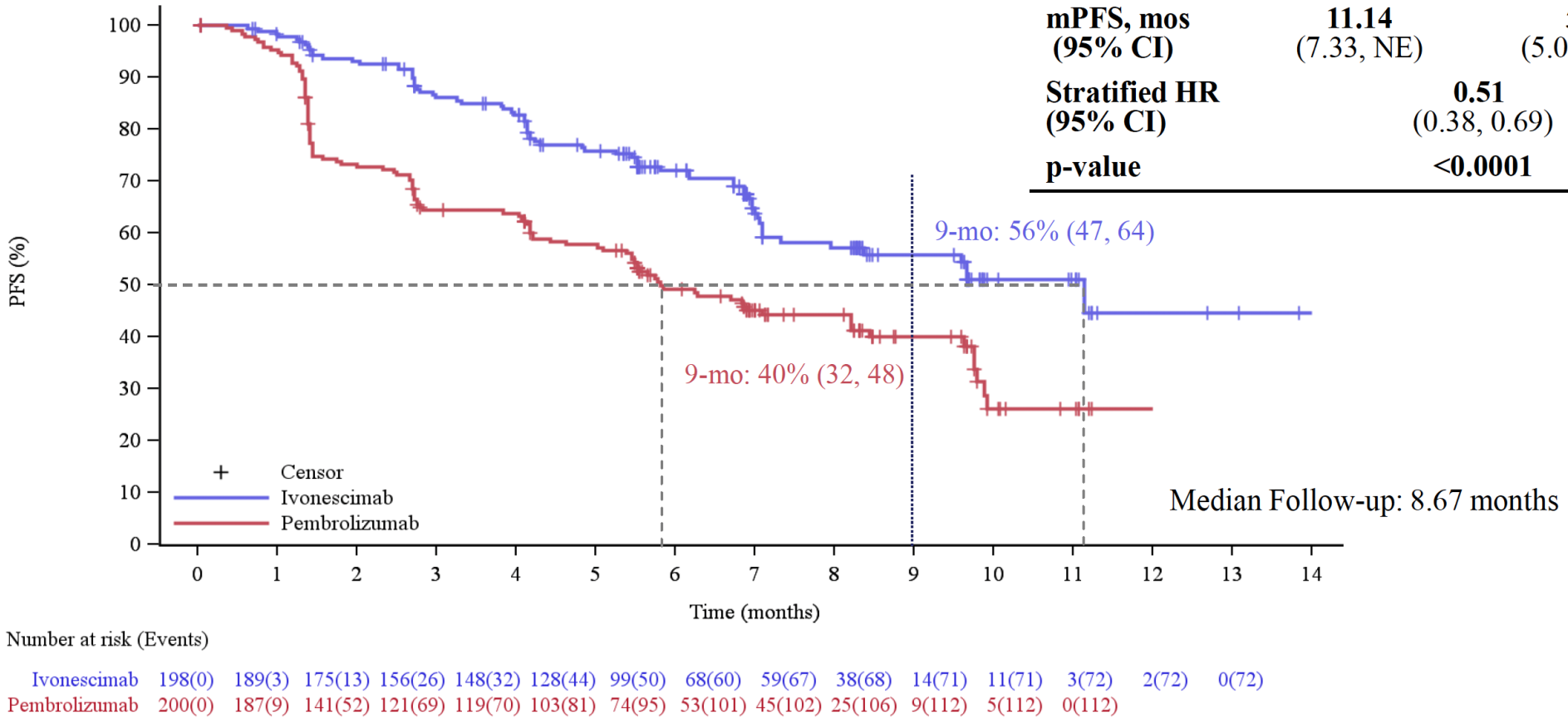
ORR and DCR were higher with ivonescimab vs. pembrolizumab.

Zhou C et al. WCLC 2024;Abstract PL02.04.

HARMONi-2: Phase 3 Study of Ivonescimab vs. Pembrolizumab as 1L Treatment for PD-L1-positive Advanced NSCLC – PFS

Primary endpoint: PFS per IRRC

	Ivonescimab (n = 198)	Pembrolizumab (n = 200)
mPFS, mos (95% CI)	**11.14** (7.33, NE)	5.82 (5.03, 8.21)
Stratified HR (95% CI)	**0.51** (0.38, 0.69)	
p-value	**<0.0001**	



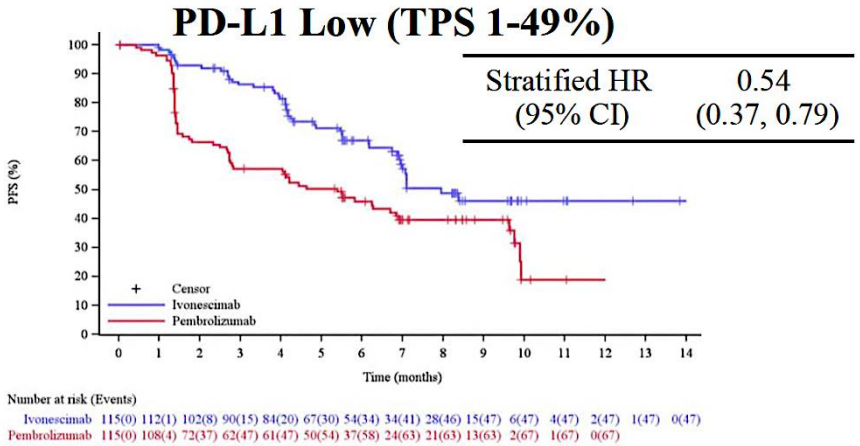
Ivonescimab demonstrated a statistically significant improvement in PFS vs. pembrolizumab with HR = 0.51, and a 5.3 months improvement in mPFS.

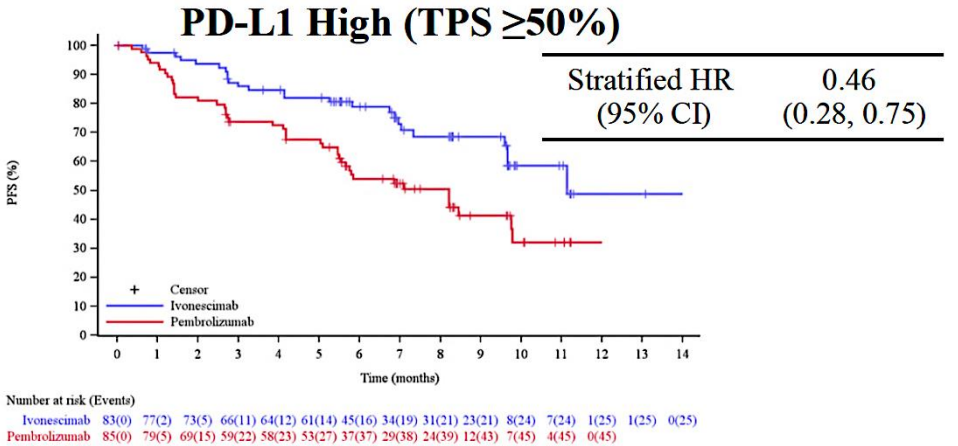
Zhou C et al. WCLC 2024;Abstract PL02.04.

HARMONi-2: Phase 3 Study of Ivonescimab vs. Pembrolizumab as 1L Treatment for PD-L1-positive Advanced NSCLC – Subgroups

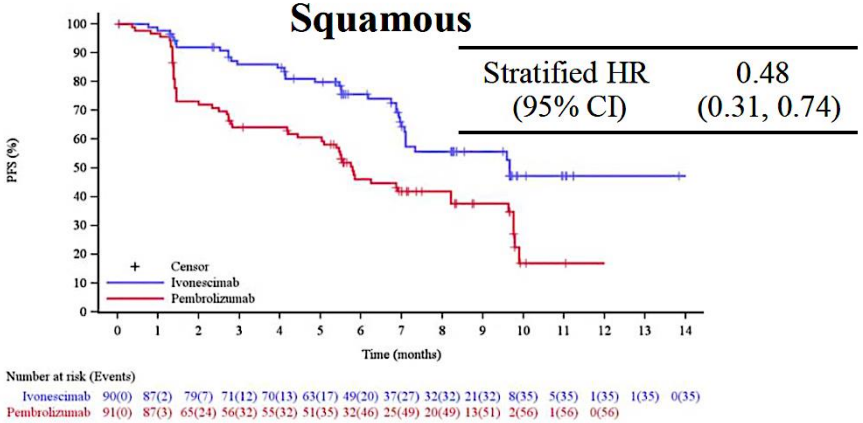
Key PFS Subgroup Analyses

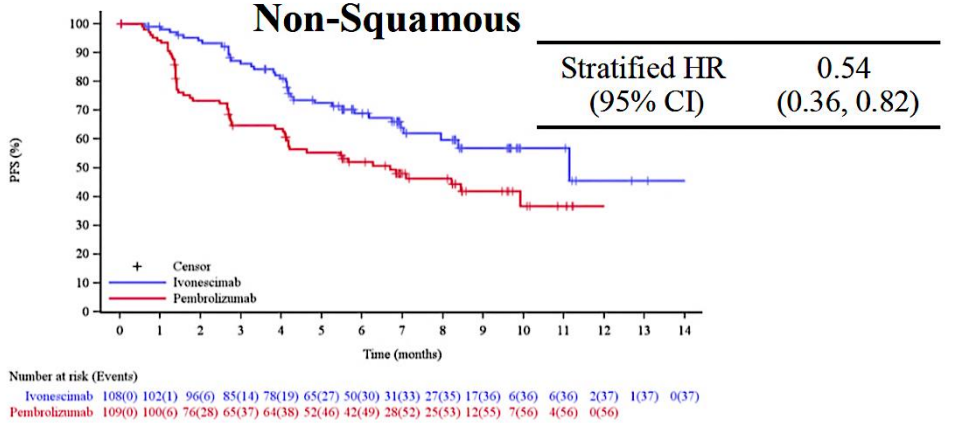
PD-L1 expression





NSCLC Histology





Ivonescimab showed meaningful improvement in PFS vs. pembrolizumab in patients with both low and high PD-L1, with squamous or non-squamous advanced NSCLC.

Zhou C et al. WCLC 2024;Abstract PL02.04.

HARMONi-2: Phase 3 Study of Ivonescimab vs. Pembrolizumab as 1L Treatment for PD-L1-positive Advanced NSCLC – Safety

TRAEs

Safety Summary, n (%)	Ivonescimab (n = 197[a])	Pembrolizumab (n = 199[a])
TRAEs (all grades)	177 (89.8)	163 (81.9)
Grade≥3	58 (29.4)	31 (15.6)
Serious TRAEs	41 (20.8)	32 (16.1)
Leading to discontinuation	3 (1.5)	6 (3.0)
Leading to death	1 (0.5)	2 (1.0)

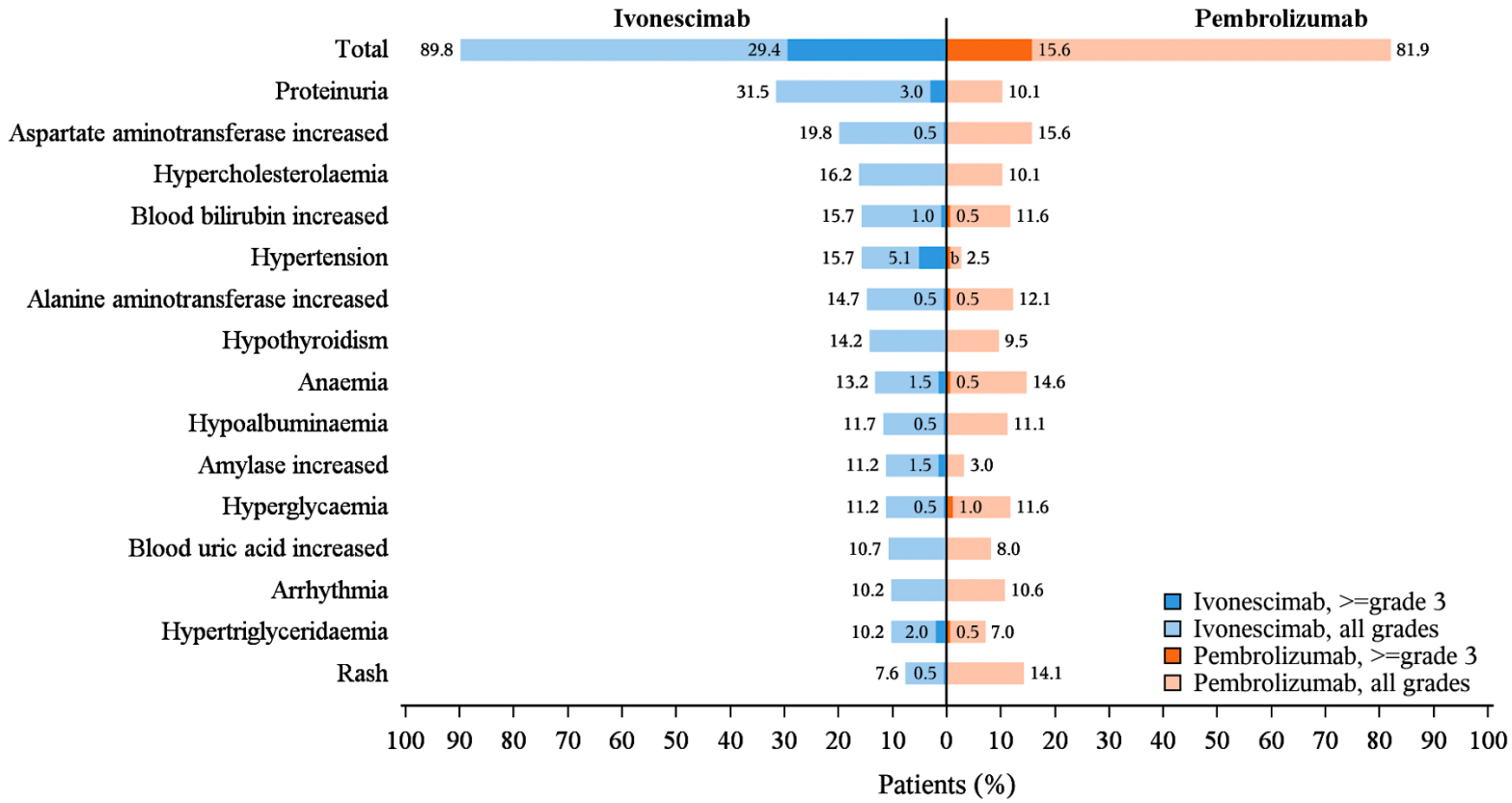
Ivonescimab showed a manageable safety profile, which was consistent with previous studies.

TRAEs in SQ Subgroup

Safety Summary, n (%)	Ivonescimab (n = 90[a])	Pembrolizumab (n = 91[a])
TRAEs (all grades)	77 (85.6)	73 (80.2)
Grade≥3	20 (22.2)	17 (18.7)
Serious TRAEs	17 (18.9)	17 (18.7)
Leading to discontinuation	2 (2.2)	3 (3.3)
Leading to death	0	1 (1.1)

Ivonescimab also demonstrated a tolerable safety profile in SQ patients.

The Most Common TRAEs (incidence ≥10%)



The differences in AEs were predominantly proteinuria, hypertension, and laboratory abnormalities.

Zhou C et al. 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)

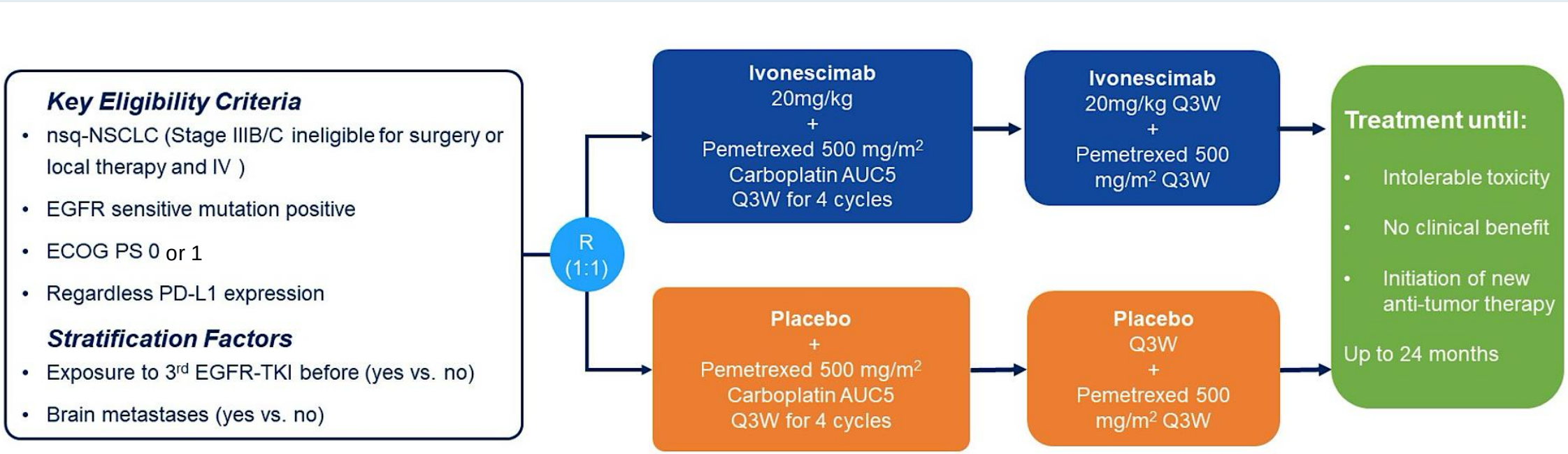
Li Zhang[1], Wenfeng Fang[1], Yuanyuan Zhao[1], Yongzhong Luo[2], Runxiang Yang[3], Yan Huang[1], Zhiyong He[4], Hui Zhao[5], Mingjun Li[6], Kai Li[7], Qibing Song[8], Xiaobo Du[9], Yulan Sun[10], Wei Li[11], Fei Xu[12], Zhiyu Wang[13], Kunning Yang[14], Yun Fan[15], Wenting Li[16], Michelle Xia[16]

[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

RTP RESEARCH TO PRACTICE

HARMONi-A Phase III Trial Design



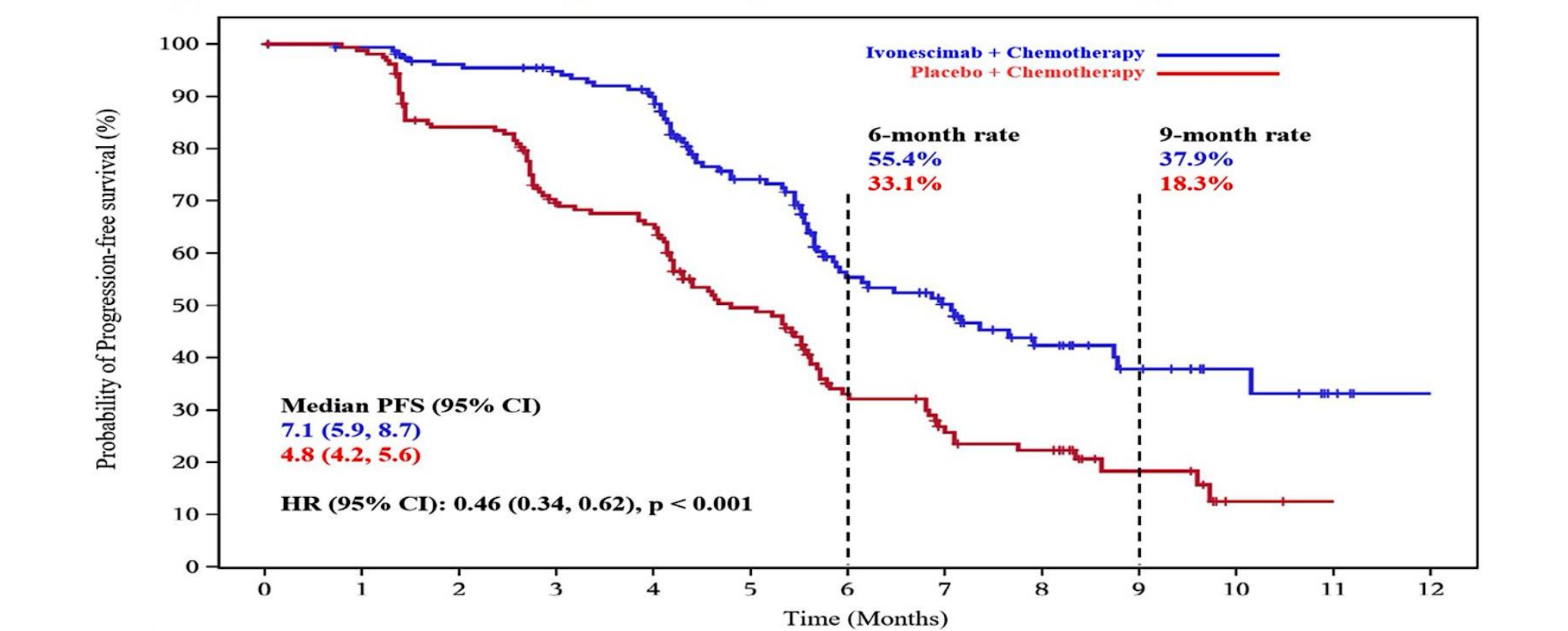
Endpoints

- 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

RTP RESEARCH TO PRACTICE

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: Ivonescimab

Module 1: First-Line Therapy for Metastatic NSCLC without a Targetable Tumor Mutation — Dr Garon

Module 2: Promising Therapeutic Strategies for Patients with Progressive Metastatic NSCLC — Dr Paz-Ares

Dr Garon - Case 1

- 92 year old woman with a prior extensive smoking history and distant history of ER+ Breast Cancer presented with a Chest X-ray obtained in the setting of a COVID infection
- Additional CT scans show evidence of a 4.3 cm RLL lung mass as well as a subcarinal mediastinal lymph node
- Bronchoscopy was performed, and she was found to have an adenocarcinoma involving both the mass and the lymph node
- NGS on the primary revealed no driver mutation and 6.4 mutations per megabase
- PD-L1 on the primary mass was 30% and the lymph nodes was 60%
- MRI Brain comes back with one 5mm and one 7mm metastasis

NSCLC without Actionable Mutations

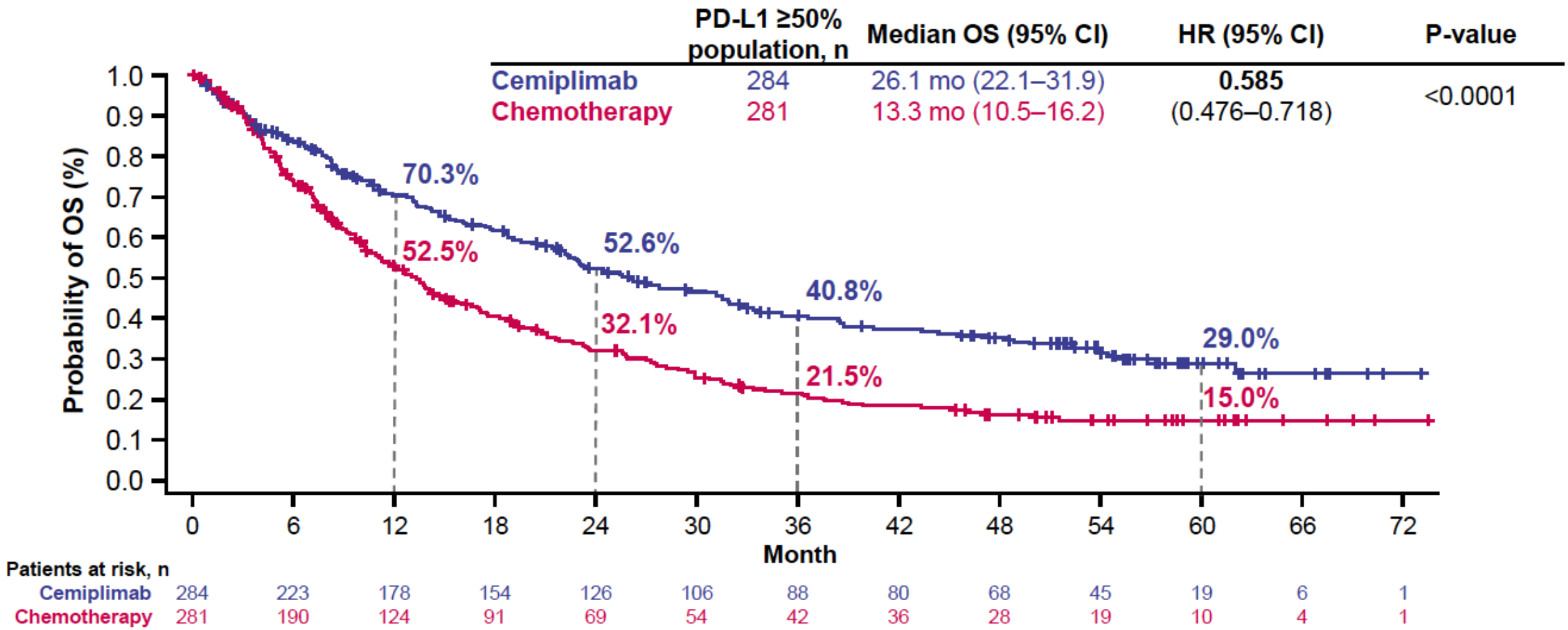
Edward B. Garon, MD, MS

Professor

David Geffen School of Medicine at UCLA

Los Angeles, CA

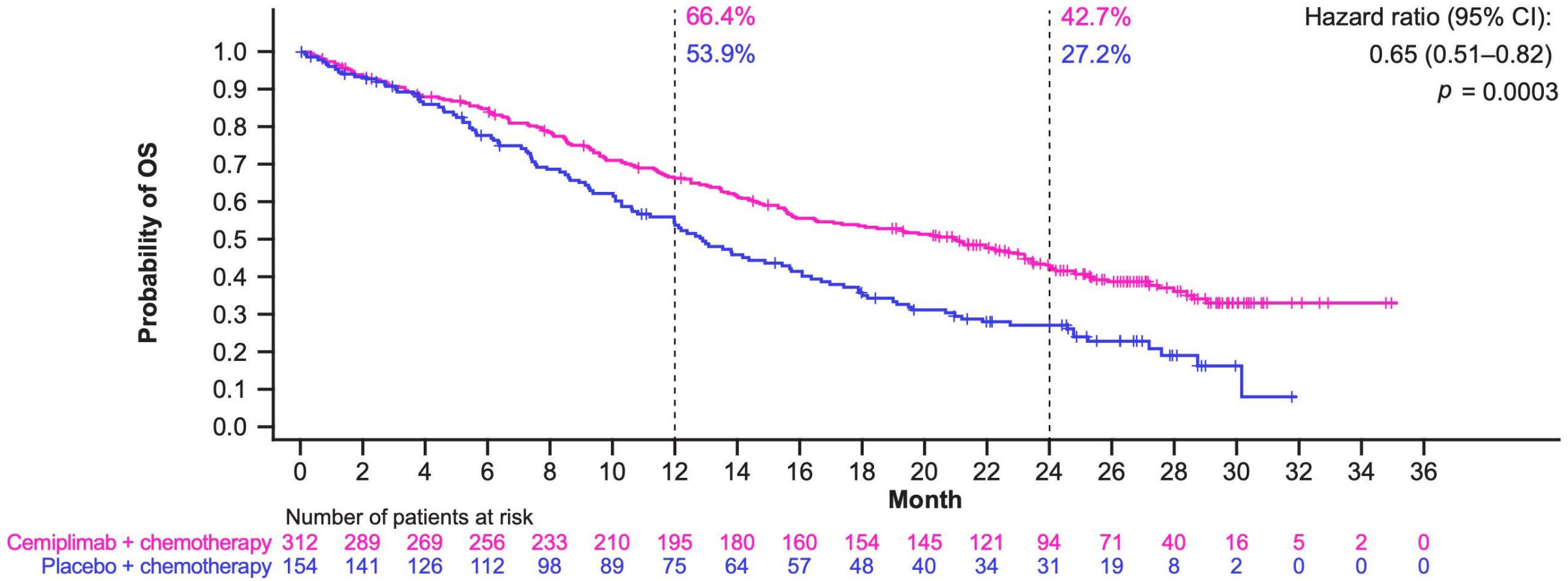
5-Year Update of EMPOWER-Lung 1



Kilickap S et al. WCLC 2024;Abstract OA11.06.

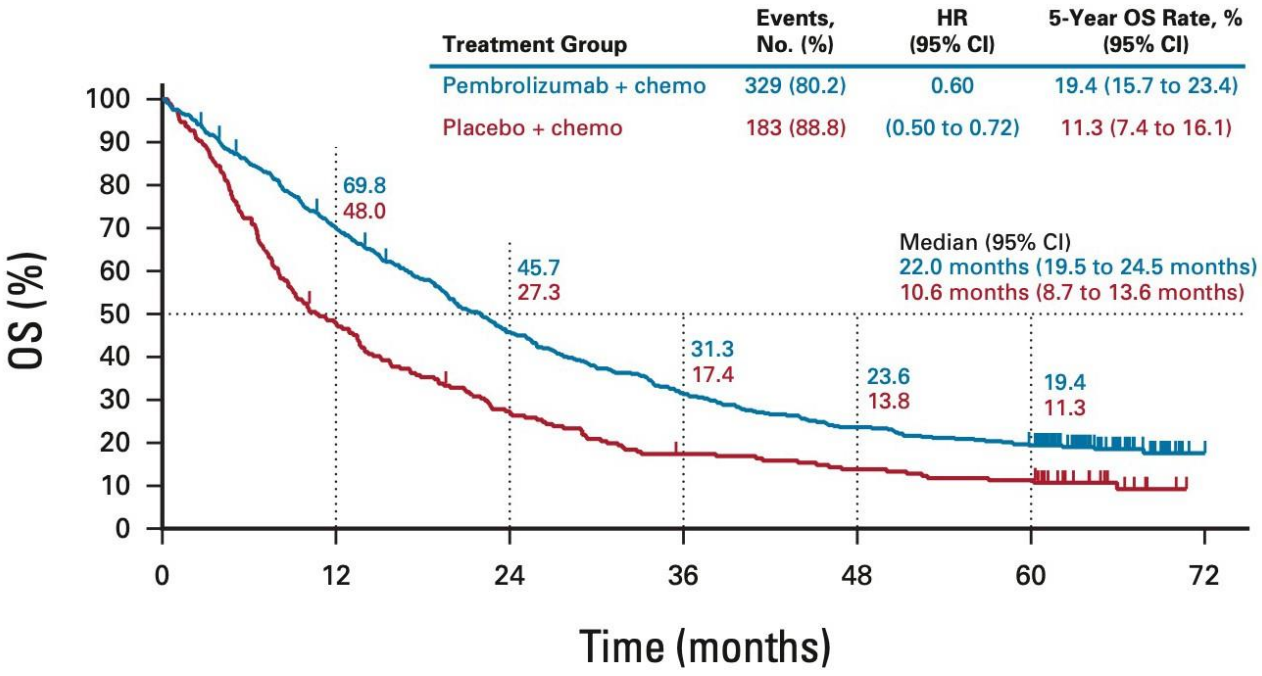
EMPOWER-Lung 3

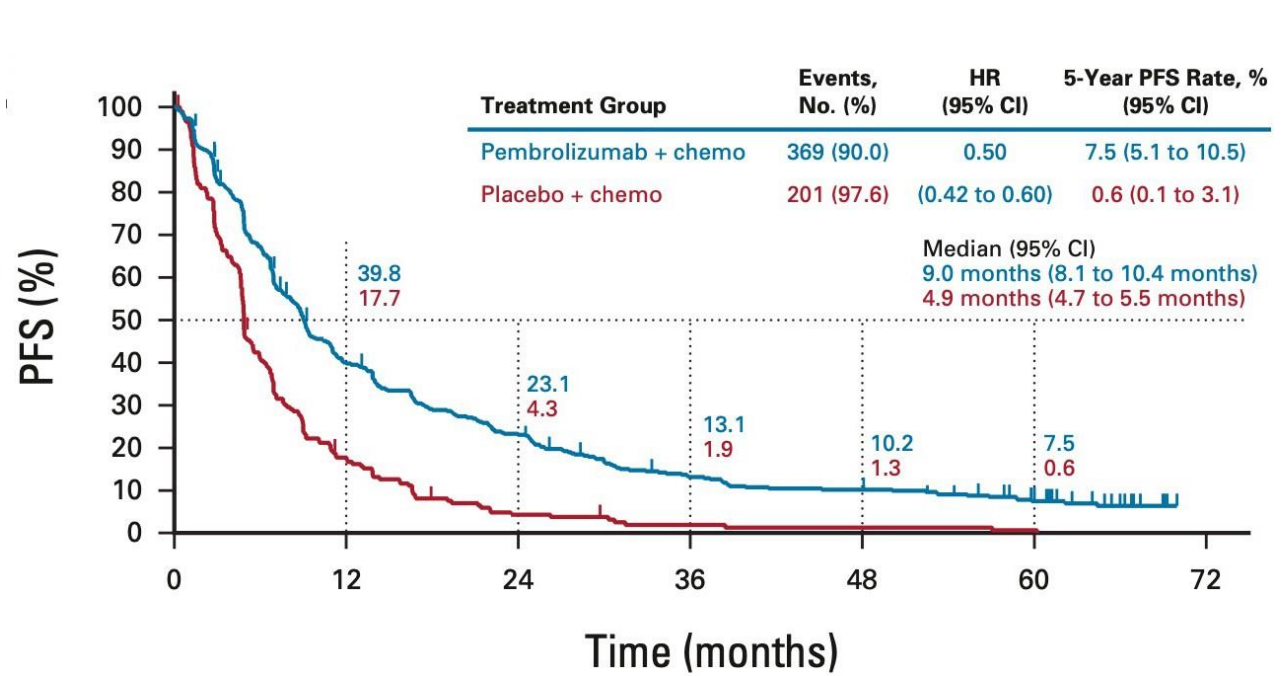
	Median OS (95% CI)
Cemiplimab + chemo	21.1 months (15.9–23.5)
Placebo + chemo	12.9 months (10.6–15.7)



Makharadze et al. *J Thorac Oncol* 2023;18(6):755-768.

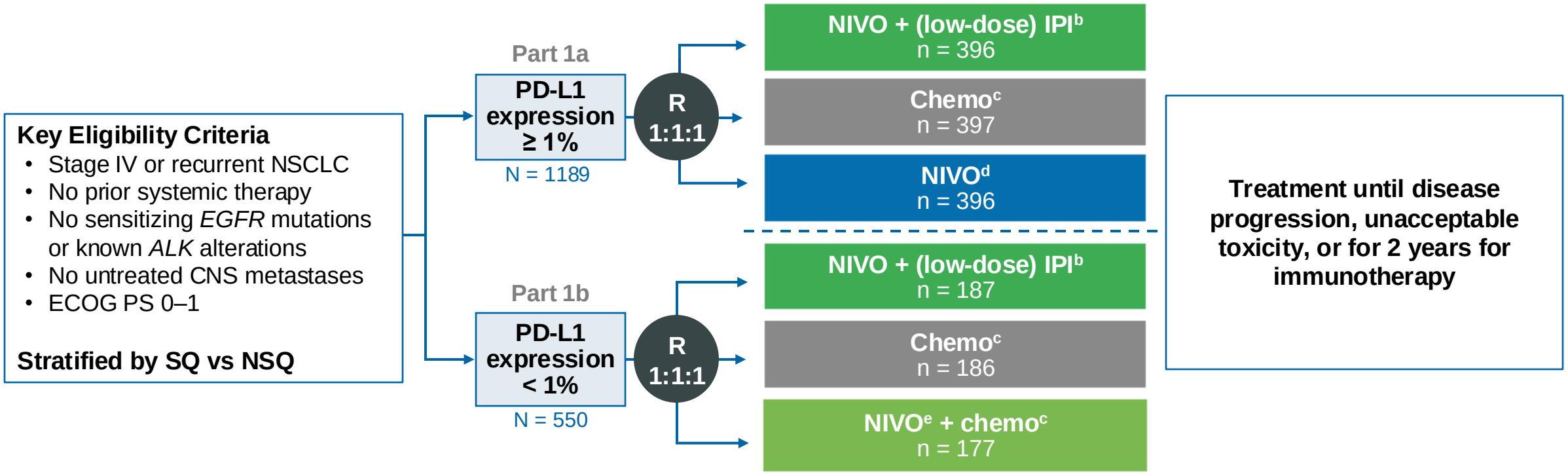
Pembrolizumab + Chemo (5-year outcomes)





Garassino et al. *J Clin Oncol* 2023;41(11):1992-1998.

CheckMate 227 Part 1 Study Design[a]



Independent co-primary endpoints: NIVO + IPI vs chemo

- PFS in high TMB (≥10 mut/Mb) population[f]
- OS in PD-L1 ≥ 1% population[g]

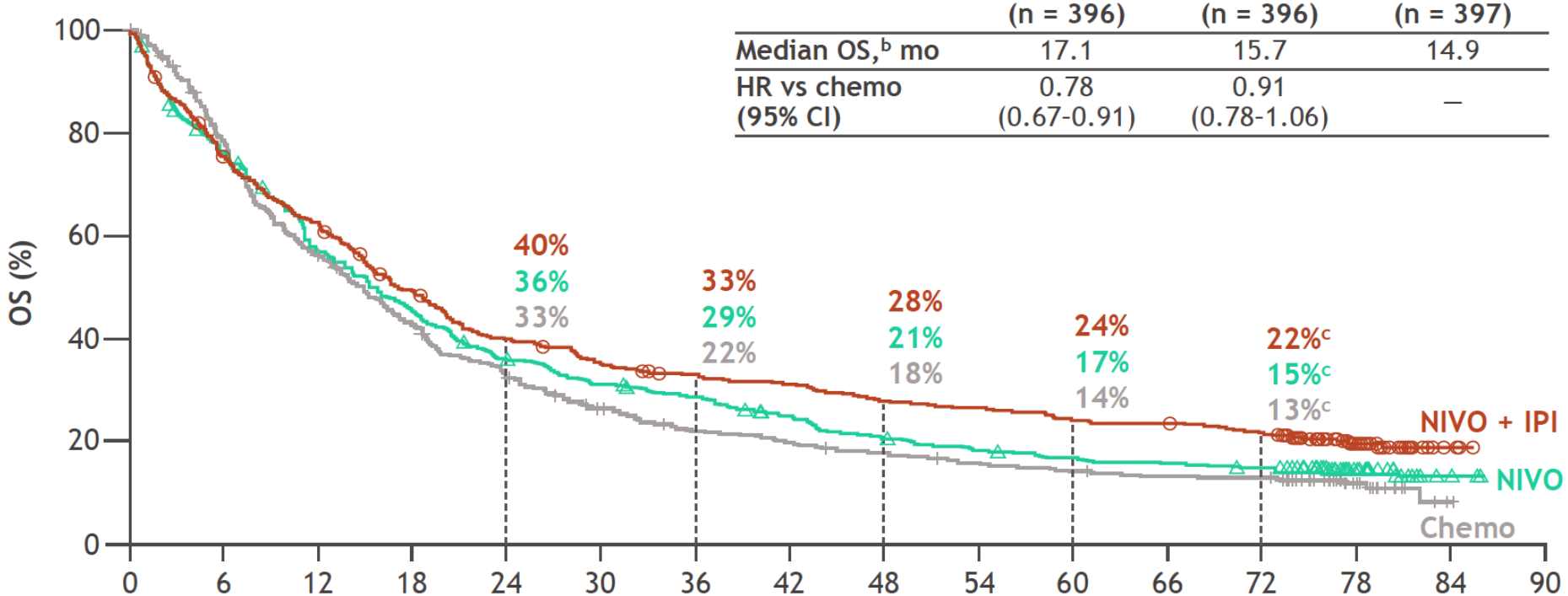
Secondary endpoints (PD-L1 hierarchy):

- PFS: **NIVO + chemo vs chemo** in PD-L1 < 1%
- OS: **NIVO + chemo vs chemo** in PD-L1 < 1%
- OS: **NIVO vs chemo** in PD-L1 ≥ 50%

Peters S. ESMO 2019

OS in patients with tumor PD-L1 ≥ 1%

	NIVO + IPI[a] (n = 396)	NIVO (n = 396)	Chemo (n = 397)
Median OS,[b] mo	17.1	15.7	14.9
HR vs chemo (95% CI)	0.78 (0.67-0.91)	0.91 (0.78-1.06)	—



No. at risk																
NIVO + IPI	396	296	246	192	154	134	123	116	104	99	90	88	80	36	4	0
NIVO	396	299	220	176	139	119	108	91	75	66	60	56	52	23	3	0
Chemo	397	306	218	166	126	98	80	72	63	56	50	46	45	16	1	0

- In an exploratory analysis of OS by histology in patients with tumor PD-L1 ≥ 1%, 6-year OS rates with NIVO + IPI vs chemo were 25% vs 16% (NSQ) and 14% vs 5% (SQ)[d]

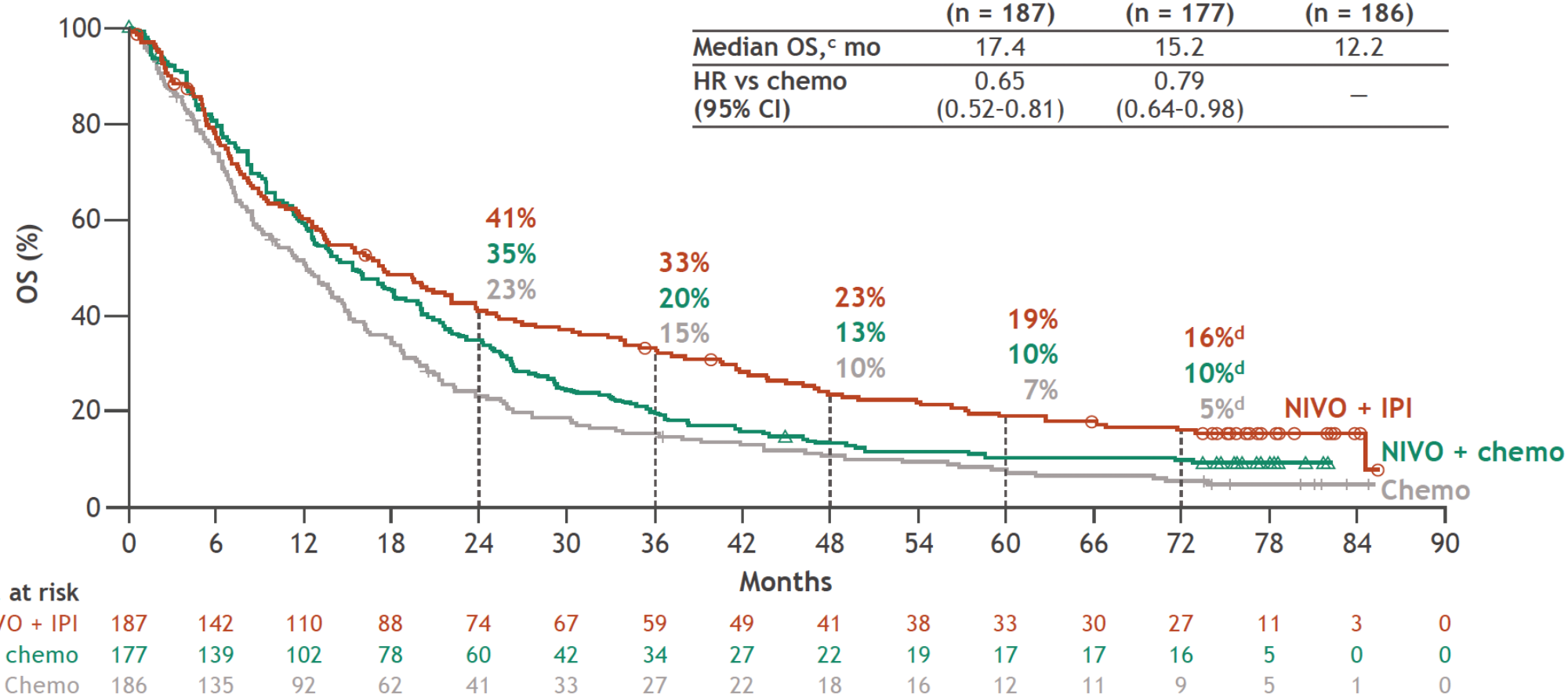
Minimum/median follow-up for OS: 73.5/78.8 months.

[a]NIVO + IPI vs NIVO OS HR was 0.86 (95% CI, 0.74-1.01). [b]Median OS 95% CIs were 15.0-20.2 (NIVO + IPI), 13.3-18.1 (NIVO), and 12.7-16.7 (chemo). [c]6-year OS rate 95% CIs were 18-26 (NIVO + IPI), 12-19 (NIVO), and 10-17 (chemo). [d]NIVO + IPI vs chemo OS HRs were 0.83 (95% CI, 0.68-1.00; NSQ) and 0.70 (95% CI, 0.53-0.92; SQ).

Ramalingam et al. WCLC 2023;Abstract OA14.03.

OS in patients with tumor PD-L1 < 1%[a]

	NIVO + IPI[b] (n = 187)	NIVO + chemo (n = 177)	Chemo (n = 186)
Median OS,[c] mo	17.4	15.2	12.2
HR vs chemo (95% CI)	0.65 (0.52-0.81)	0.79 (0.64-0.98)	—



No. at risk																
NIVO + IPI	187	142	110	88	74	67	59	49	41	38	33	30	27	11	3	0
NIVO + chemo	177	139	102	78	60	42	34	27	22	19	17	17	16	5	0	0
Chemo	186	135	92	62	41	33	27	22	18	16	12	11	9	5	1	0

- In an exploratory analysis of OS by histology in patients with tumor PD-L1 < 1%, 6-year OS rates with NIVO + IPI vs chemo were 15% vs 6% (NSQ) and 18% and 4% (SQ)[e]

Minimum/median follow-up for OS: 73.5/78.8 months.

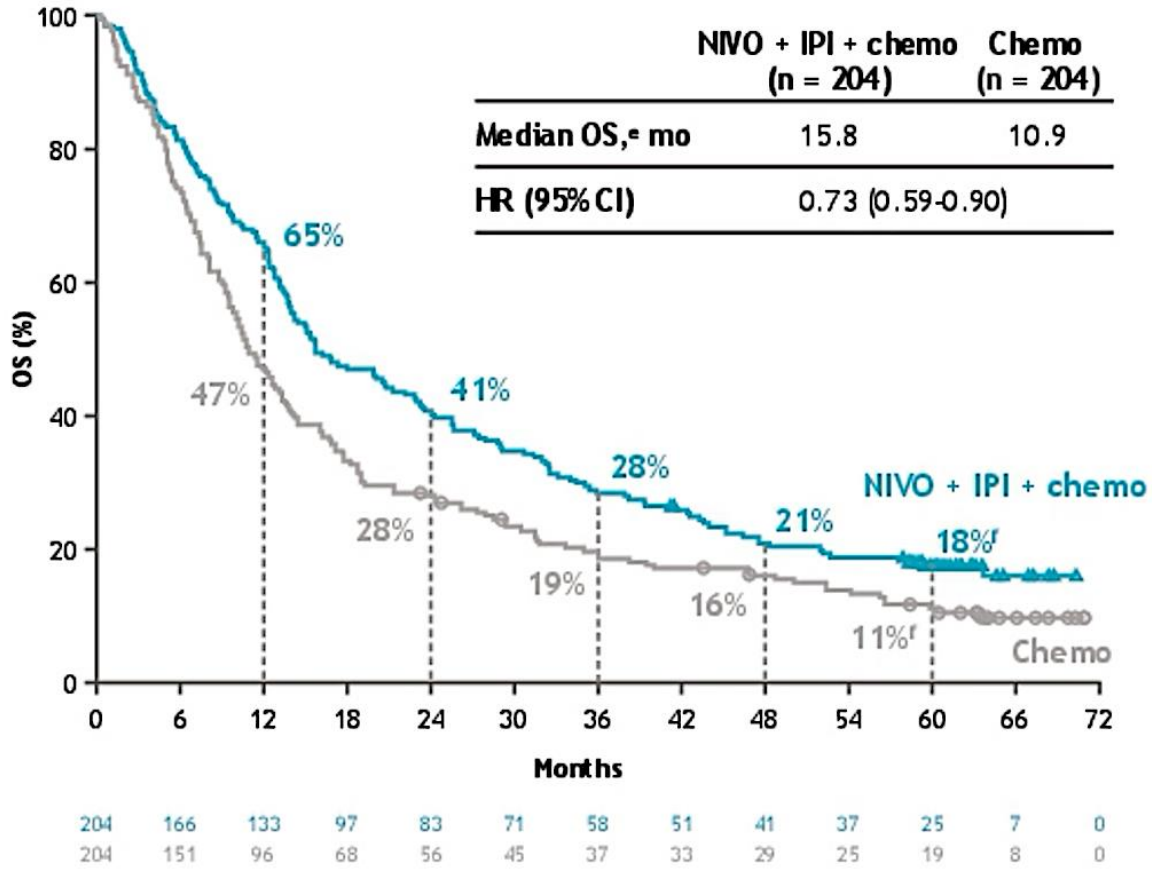
[a]6-year OS rates in the combined tumor PD-L1 ≥ 1% and < 1% population were 20% (95% CI, 17-23; NIVO + IPI) and 11% (95% CI, 8-13; chemo). [b]NIVO + IPI vs NIVO + chemo OS HR was 0.80 (95% CI, 0.64-1.00). [c]Median OS 95% CIs were 13.2-22.0 (NIVO + IPI), 12.3-19.8 (NIVO + chemo), and 9.2-14.3 (chemo). [d]6-year OS rate 95% CIs were 11-22 (NIVO + IPI), 6-15 (NIVO + chemo), and 3-9 (chemo). [e]NIVO + IPI vs chemo OS HRs were 0.69 (95% CI, 0.54-0.89; NSQ) and 0.52 (95% CI, 0.34-0.82; SQ).

Ramalingam et al. WCLC 2023;Abstract OA14.03.

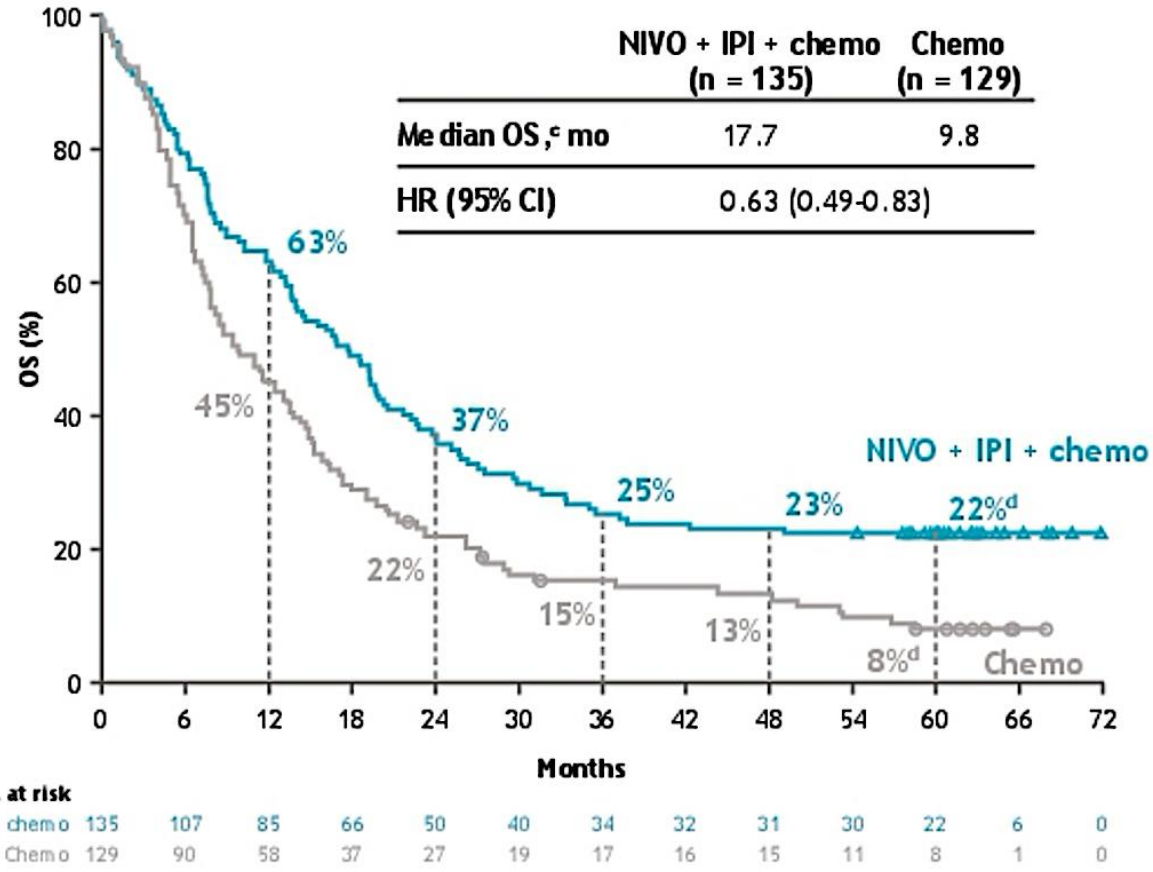
CheckMate 9LA: 5-Year Update

OS in subgroups by PD-L1 expression

PD-L1 ≥ 1%



PD-L1 < 1%

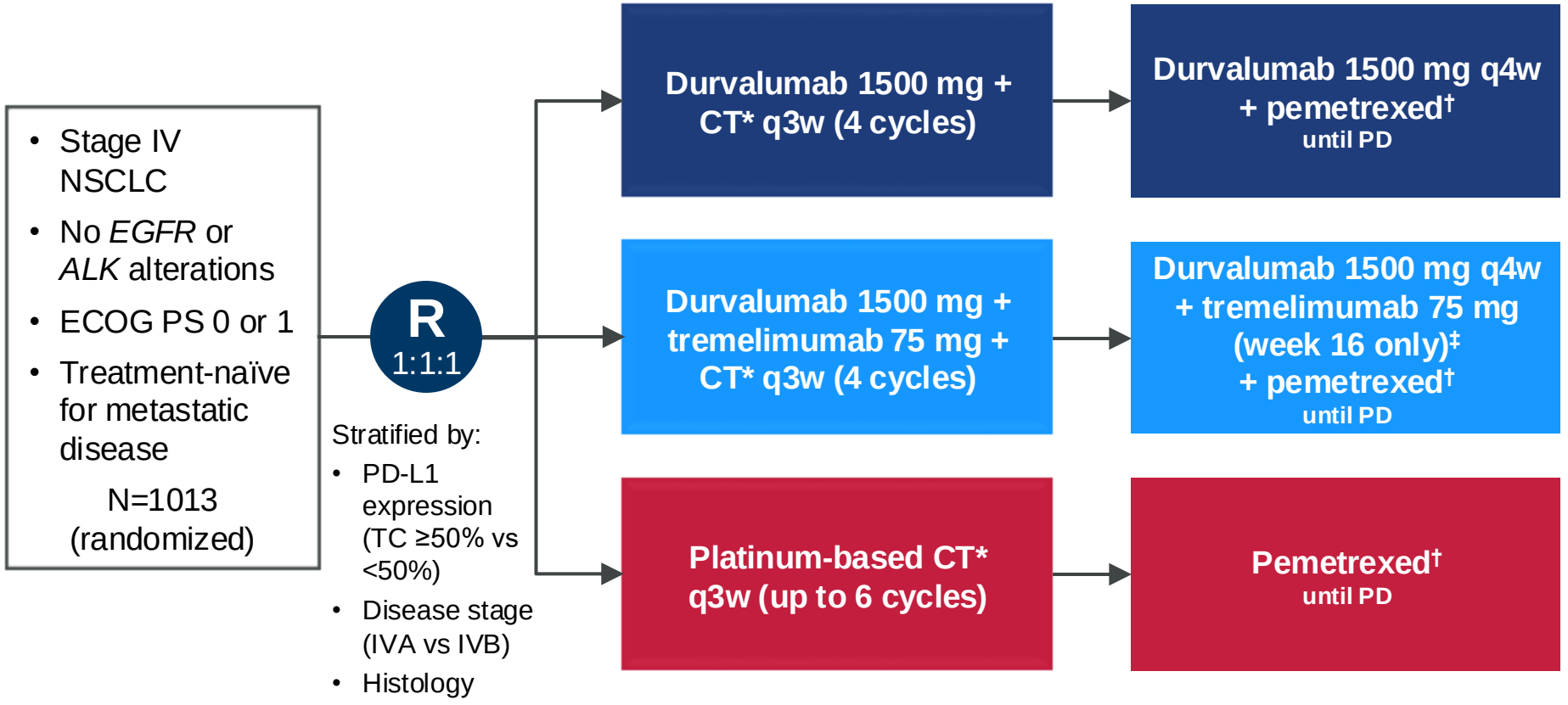


Reck M et al. ASCO 2024;Abstract 8560.

POSEIDON Study Design

Johnson ML. ASCO 2021

Phase 3, global, randomized, open-label, multicenter study



Primary endpoints
- PFS by BICR (D+CT vs CT)
- OS (D+CT vs CT)

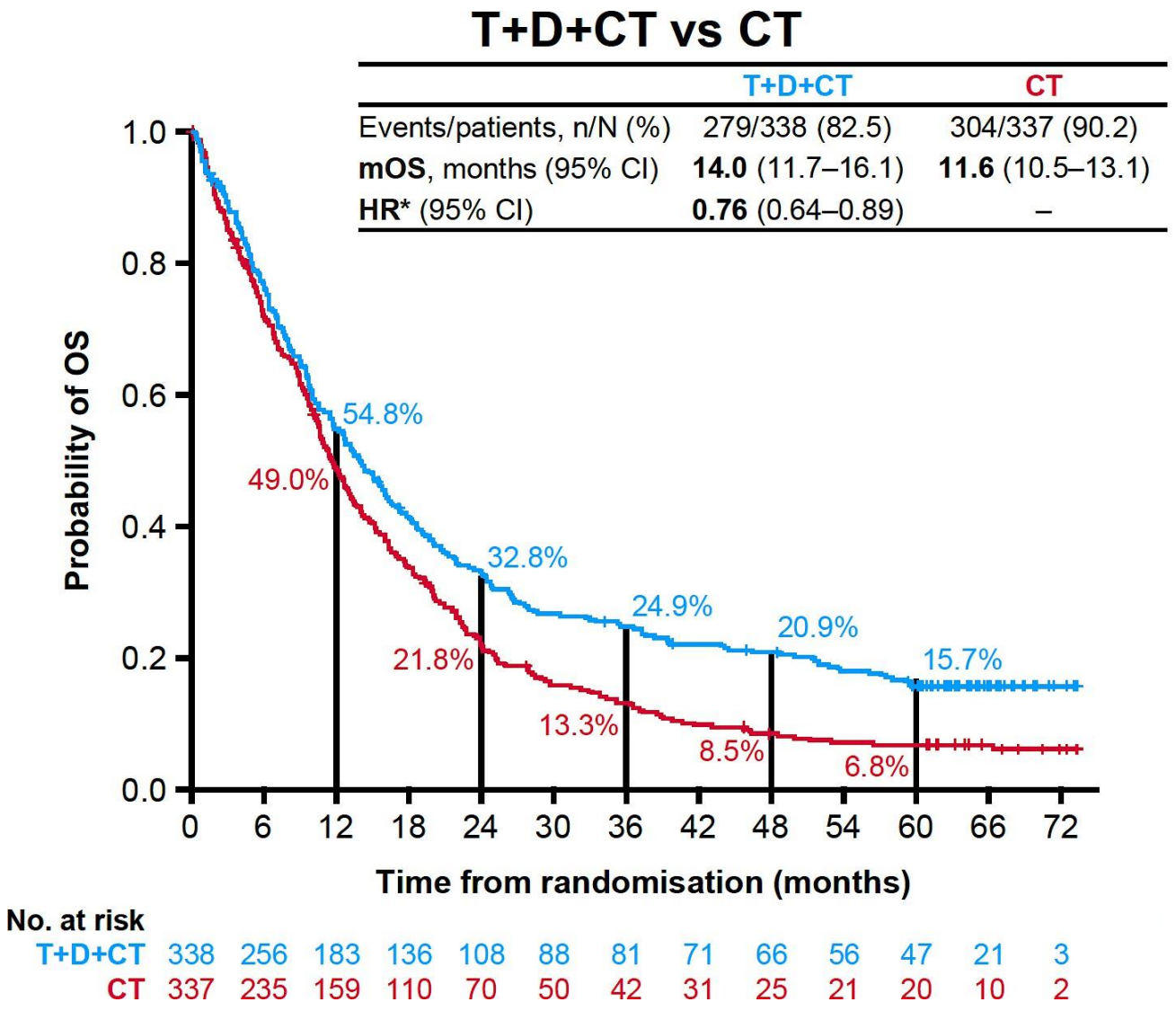
Key secondary endpoints
- PFS by BICR (D+T+CT vs CT)
- OS (D+T+CT vs CT)
- OS in patients with bTMB ≥20 mut/Mb (D+T+CT vs CT)

Additional secondary endpoints
- ORR, DoR, and BOR by BICR
- PFS at 12 months
- HRQoL
- Safety and tolerability

*CT options: gemcitabine + carboplatin/cisplatin (squamous), pemetrexed + carboplatin/cisplatin (non-squamous), or nab-paclitaxel + carboplatin (either histology); †Patients with non-squamous histology who initially received pemetrexed during first-line treatment only (if eligible); ‡Patients received an additional dose of tremelimumab post CT (5th dose)

BICR, blinded independent central review; BOR, best objective response; bTMB, blood tumor mutational burden; D, durvalumab; DoR, duration of response; ECOG, Eastern Cooperative Oncology Group; HRQoL, health-related quality of life; Mb, megabase; mut, mutations; ORR, objective response rate; OS, overall survival; PD, progressive disease; PFS, progression-free survival; PS, performance status; q3w, every 3 weeks; q4w, every 4 weeks; T, tremelimumab; TC, tumor cell

Durvalumab + Tremelimumab + CT vs CT: 5-year OS



Peters et al. ESMO IO 2023;Abstract LBA3.

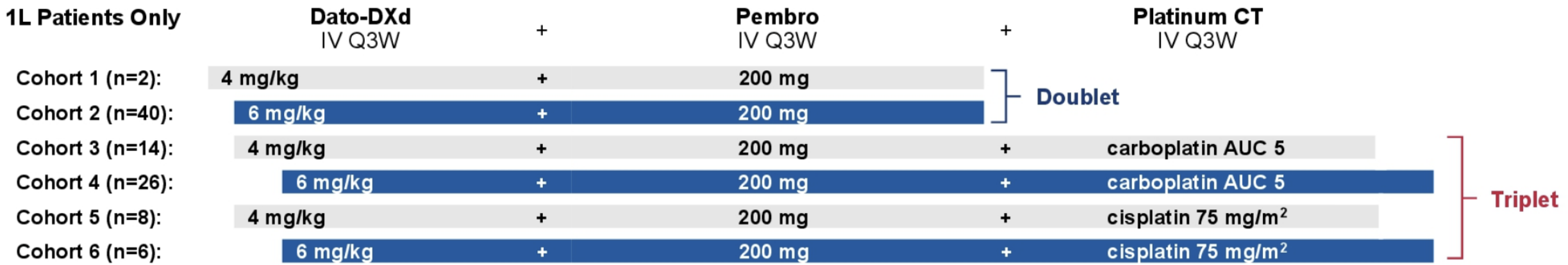
Questions?

TROPION-Lung02: Datopotamab deruxtecan (Dato-DXd) plus pembrolizumab +/- chemotherapy as 1L therapy for NSCLC

Key eligibility criteria

- **Advanced/metastatic NSCLC**
- **Dose escalation**[b]: ≤2 lines of prior therapy[c]
- **Dose expansion**
  - ≤1 line of platinum CT (cohorts 1 and 2)[c]
  - Treatment-naive (cohort 2; enrollment after June 30, 2022)[c]
  - Treatment-naive (cohorts 3–6)[c]

Data cutoff: October 31, 2023.



Levy BP et al. ASCO 2024

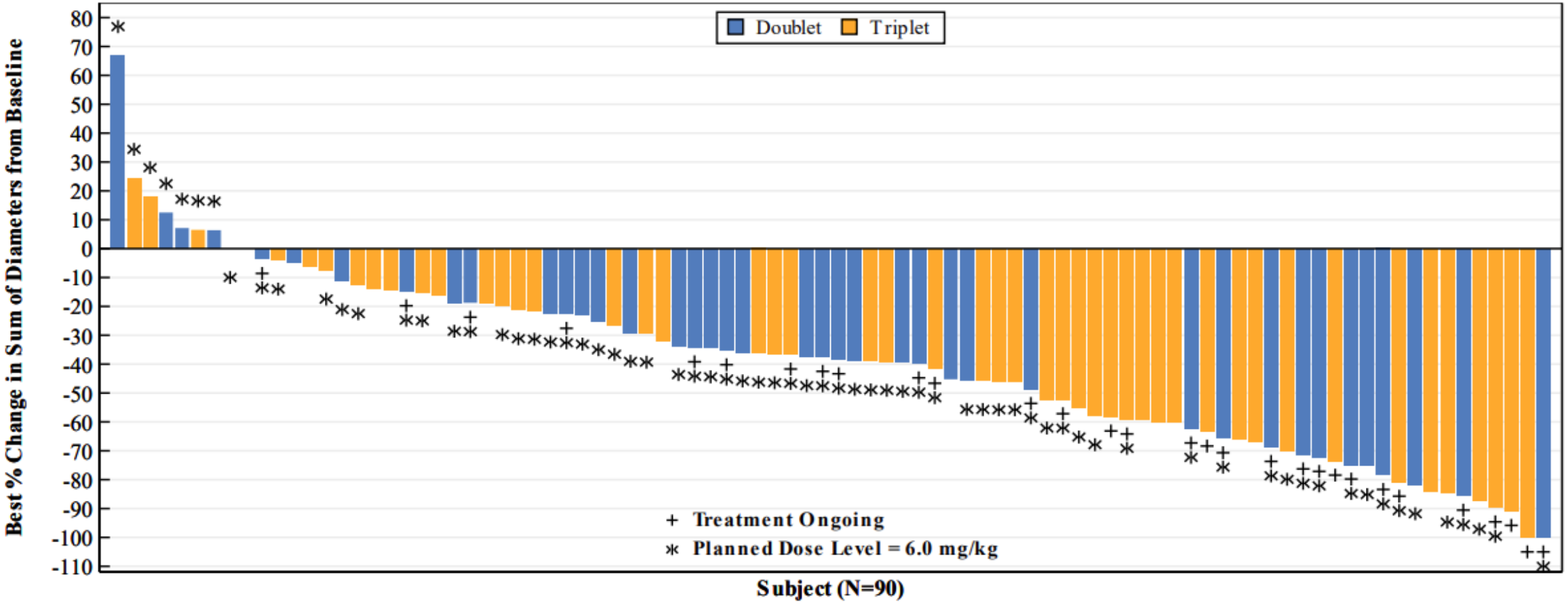
TROPION-Lung02: Datopotamab plus pembrolizumab +/- chemo

Efficacy outcomes in 1L patients, overall and by PD-L1 status[a,b]

	All 1L (n=96)		1L PD-L1 <1% (n=34)		1L PD-L1 1–49% (n=42)		1L PD-L1 ≥50% (n=20)	
	Doublet (n=42)	Triplet (n=54)	Doublet (n=18)	Triplet (n=16)	Doublet (n=19)	Triplet (n=23)	Doublet (n=5)	Triplet (n=15)
ORR, n (%)	22 (52)	30 (56)	8 (44)	5 (31)	9 (47)	17 (74)	5 (100)	8 (53)
[95% CI]	[36–68]	[41–69]	[22–69]	[11–59]	[24–71]	[52–90]	[48–100]	[27–79]
BOR, n (%)								
CR	1 (2)	1 (2)	1 (6)	0	0	1 (4)	0	0
PR	21 (50)	29 (54)	7 (39)	5 (31)	9 (47)	16 (70)	5 (100)	8 (53)
SD	15 (36)	18 (33)	8 (44)	10 (63)	7 (37)	3 (13)	0	5 (33)
PD	3 (7)	2 (4)	1 (6)	1 (6)	2 (11)	1 (4)	0	0
NE	2 (5)	4 (7)	1 (6)	0	1 (5)	2 (9)	0	2 (13)
DCR, n (%)	37 (88)	48 (89)	16 (89)	15 (94)	16 (84)	20 (87)	5 (100)	13 (87)
[95% CI]	[74–96]	[77–96]	[65–99]	[70–100]	[60–97]	[66–97]	[48–100]	[60–98]
Median TTR, months	1.4	1.4	1.4	1.5	1.5	1.4	1.4	1.5
[Range]	[1.2–7.0]	[1.2–9.6]	[1.2–6.9]	[1.2–9.6]	[1.2–7.0]	[1.2–7.0]	[1.3–2.8]	[1.2–8.3]
Median DoR, months	NE	12.9	NE	12.9	12.0	14.6	NE	18.1
[95% CI]	[9.7–NE]	[5.7–NE]	NE	[4.1–NE]	[4.2–NE]	[4.2–NE]	[5.5–NE]	[4.1–NE]

Levy BP et al.
ASCO 2024

Best Overall Tumor Change From Baseline in 1L Patients- Datopotamab Deruxtecan + IO regimens

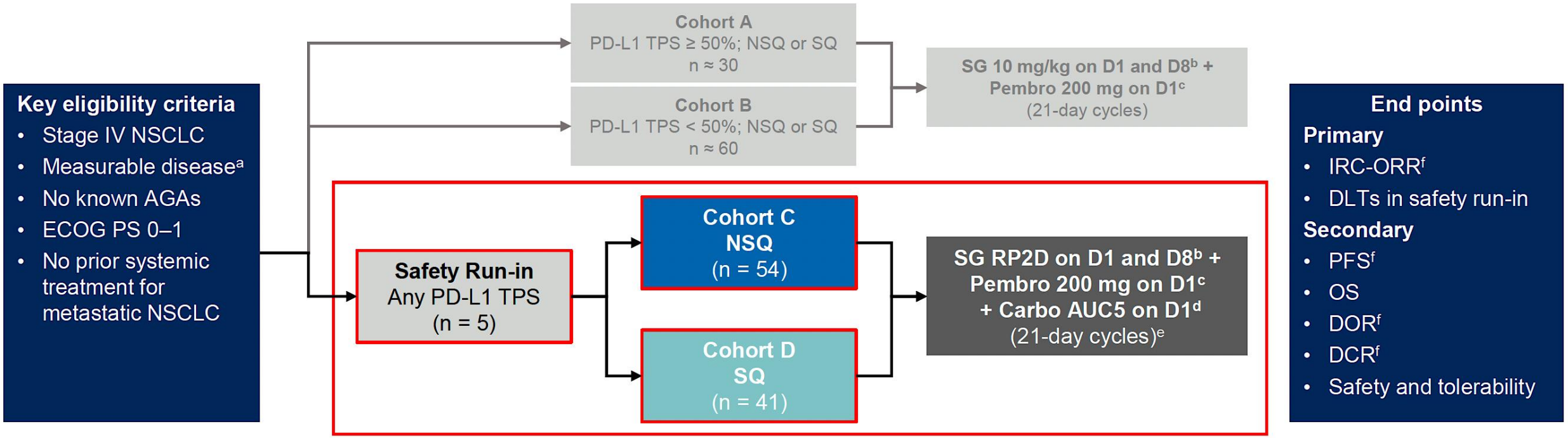


Patients with no baseline target lesions or no postbaseline tumor assessments were excluded from the waterfall plot.

Levy BP et al. ASCO 2024

Sacituzumab Govitecan + Pembro + Carboplatin in 1L mNSCLC

EVOKE-02: A Global, Open-Label, Multicohort Phase 2 Study



Data cutoff: 03 June 2024

	Cohort C (NSQ) (n = 51)[g]	Cohort D (SQ) (n = 41)
Follow-up, median (range), months	14.5 (12.2–22.3)	14.2 (11.0–23.0)

Gray et al. WCLC24; Abstract OA-08-07.

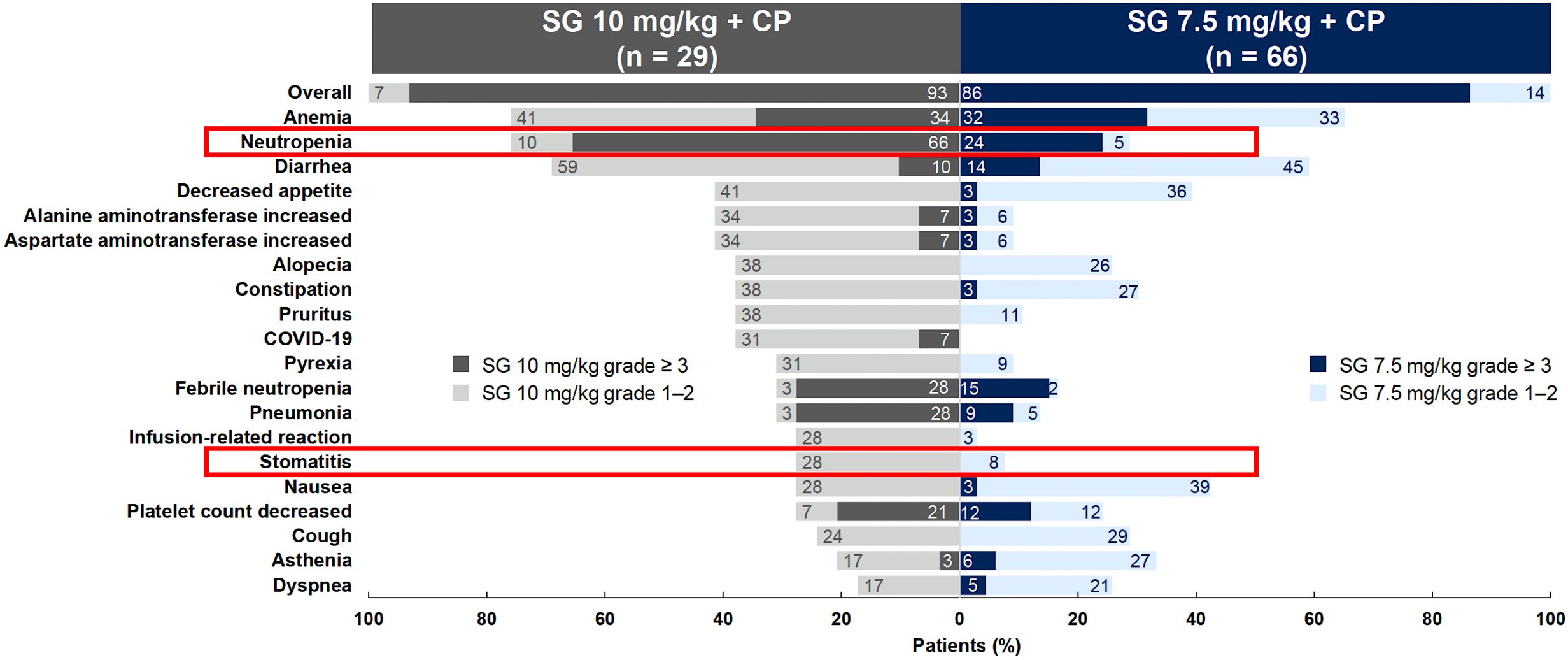
EVOKE-02: Sacituzumab + Pembro + Carboplatin – Efficacy

	Cohort C (NSQ) SG + CP (n = 51)[b]	Cohort D (SQ) SG + CP (n = 41)
Follow-up, median (range), months	14.5 (12.2–22.3)	14.2 (11.0–23.0)
ORR, % (95% CI)	45.1 (31.1–59.7)	39.0 (24.2–55.5)
Partial response, n (%)	23 (45.1)	16 (39.0)
Stable disease, n (%)	16 (31.4)	17 (41.5)
Progressive disease, n (%)	5 (9.8)	3 (7.3)
Not evaluable, n (%)	7 (13.7)	5 (12.2)
Time to response, median (range), months	2.7 (1.2–7.2)	1.5 (1.2–5.8)
DOR, median (95% CI), months	NR (3.2–NR)	11.5 (5.6–NR)
PFS, median (95% CI), months	8.1 (5.2–15.0)	8.3 (4.3–11.2)
PFS rate at 6 months, % (95% CI)	53.7 (37.8–67.2)	64.6 (46.0–78.2)

	PD-L1 TPS < 1% SG + CP (n = 44)	PD-L1 TPS 1–49% SG + CP (n = 36)	PD-L1 TPS ≥ 50% SG + CP (n = 12)
ORR, % (95% CI)	43.2 (28.3–59.0)	33.3 (18.6–51.0)	66.7 (34.9–90.1)
Partial response, n (%)	19 (43.2)	12 (33.3)	8 (66.7)
Stable disease, n (%)	15 (34.1)	16 (44.4)	2 (16.7)
Progressive disease, n (%)	3 (6.8)	4 (11.1)	1 (8.3)
Not evaluable, n (%)	7 (15.9)	4 (11.1)	1 (8.3)
PFS, median (95% CI), months	8.3 (5.2–15.0)	6.8 (4.0–10.7)	NR (1.9–NR)

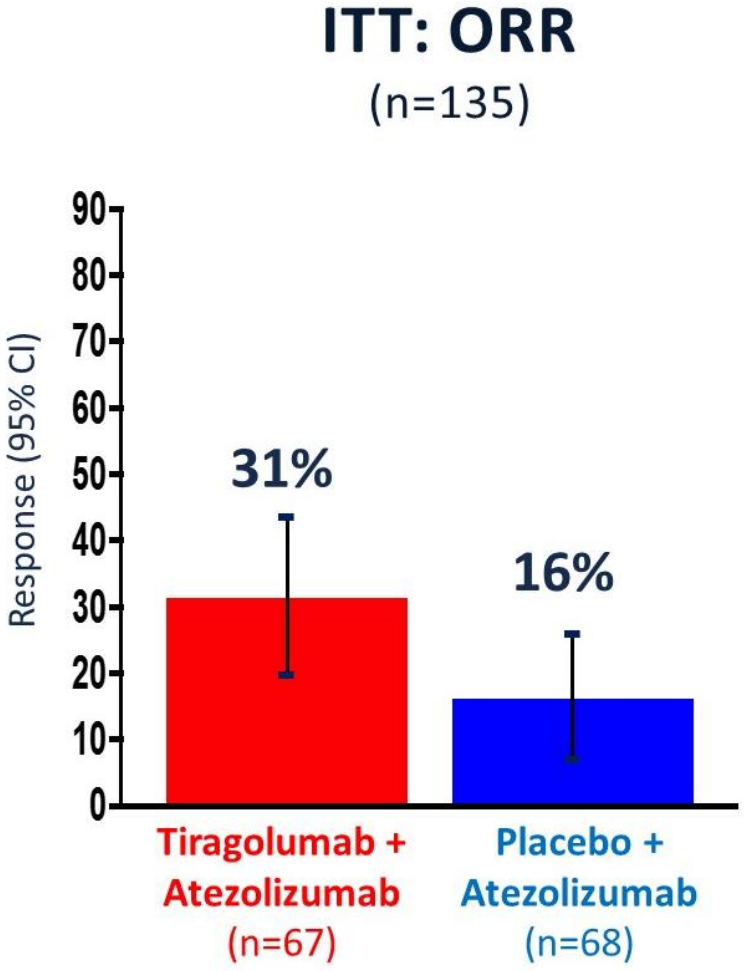
Gray et al. WCLC24; Abstract OA-08-07.

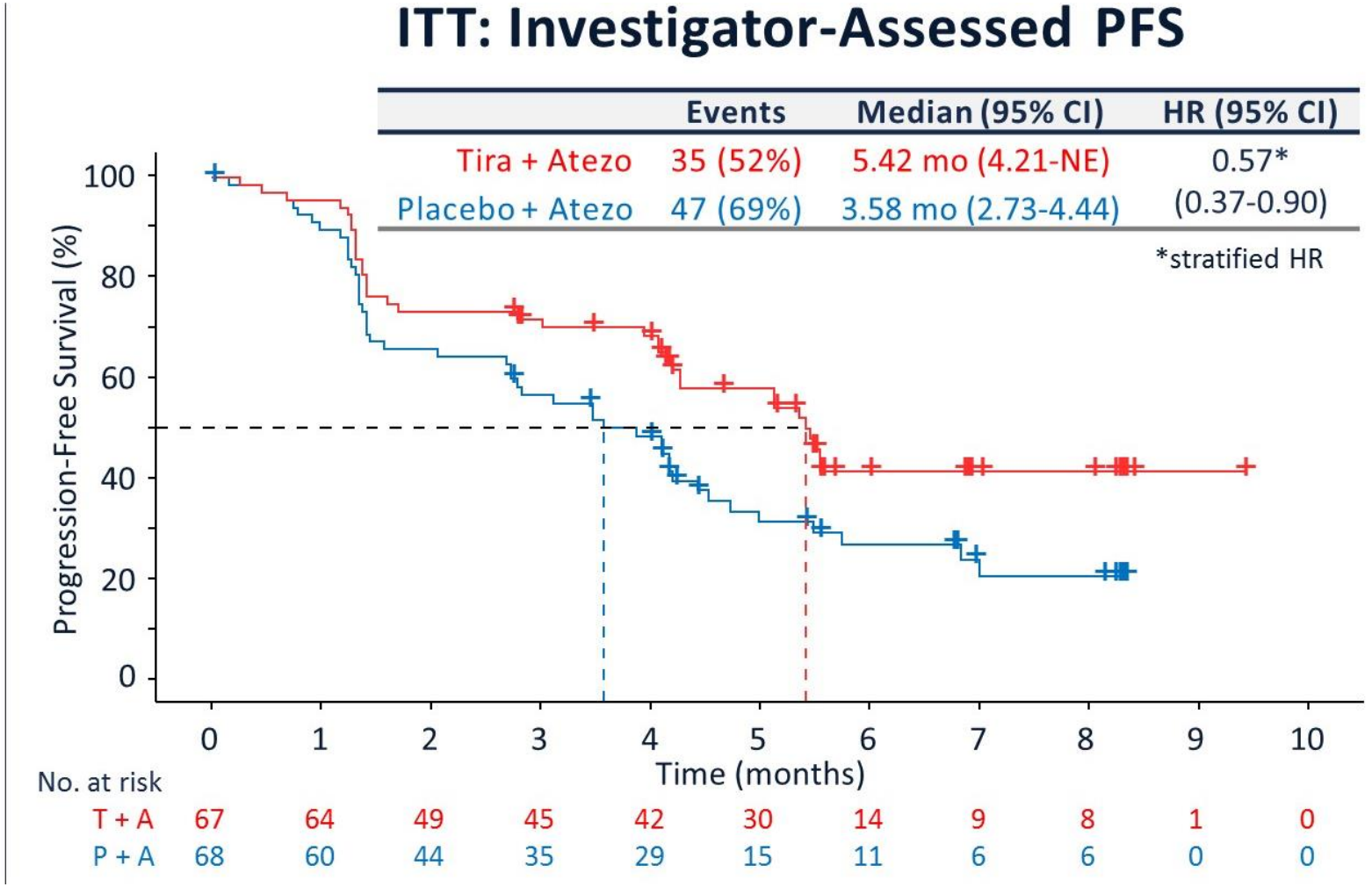
EVOKE-02: Sacituzumab + Pembro + Carboplatin – Safety



Gray et al. WCLC24; Abstract OA-08-07.

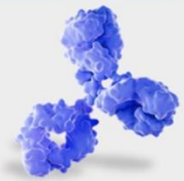
Tiragolumab (Anti-TIGIT) + Atezolizumab



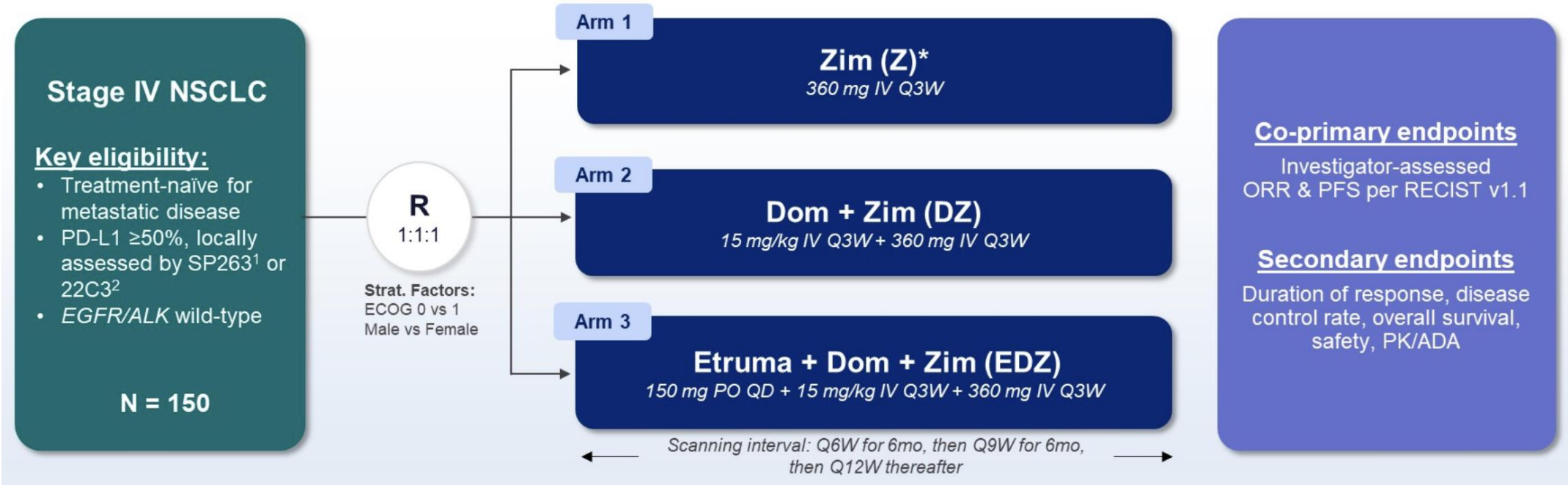


Rodriguez-Abreu D et al. ASCO 2020. Abstract 9503.

ARC-7: Phase 2 study of domvanalimab + zimberelimab ± etrumadenant vs. zimberelimab in 1L, metastatic, PD-L1-high NSCLC

Zimberelimab (Zim) anti-PD-1 mAb	Domvanalimab (Dom) Fc-silent anti-TIGIT mAb	Etrumadenant (Etruma) A2R antagonist
		

- ARC-7 (NCT04262856) is a randomized Ph2 study evaluating whether the addition of domvanalimab +/- etrumadenant augments the activity of zimberelimab in PD-L1 high, metastatic NSCLC



Johnson M et al. ASCO 2023;Abstract 397600.

ARC-7: Domvanalimab + zimberelimab ± etrumadenant vs. zimberelimab in 1L, metastatic, PD-L1-high NSCLC – Response

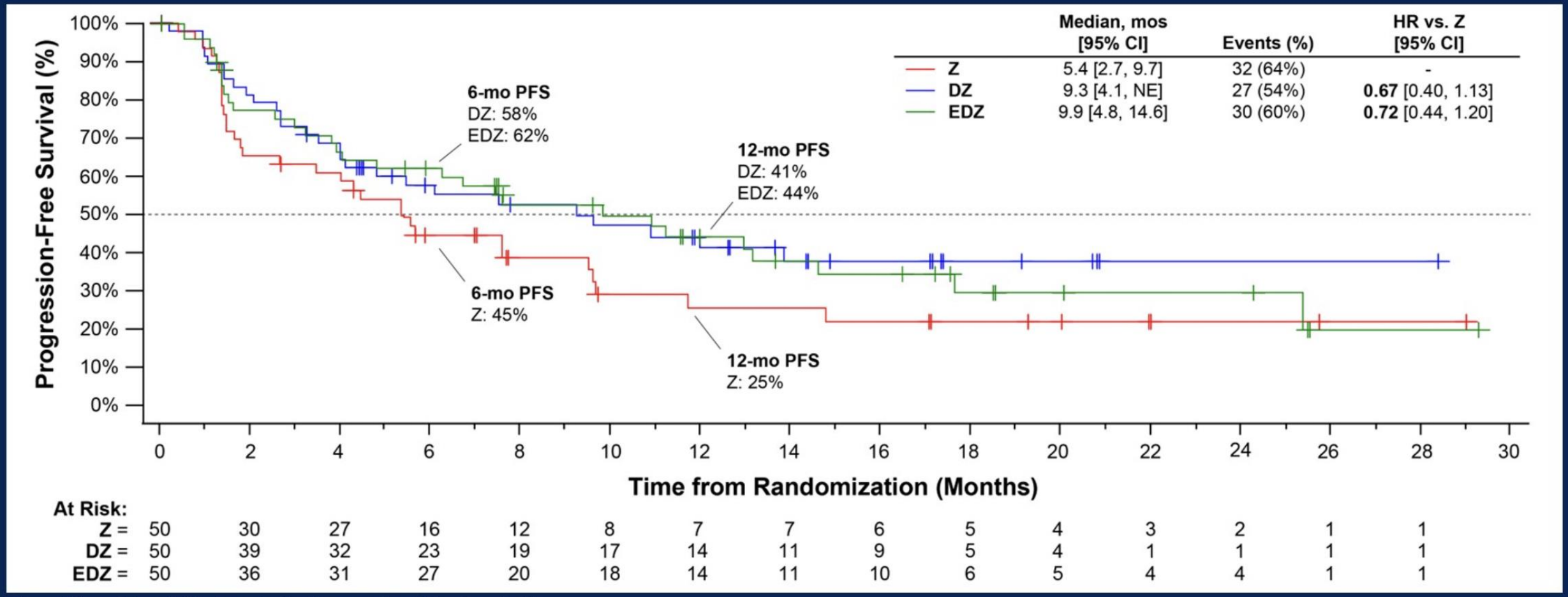
mITT, n (%)	Arm 1 (Z) (n=50)	Arm 2 (DZ) (n=50)	Arm 3 (EDZ) (n=50)
ORR, Confirmed + Pending [95% CI]	**15 (30%)** [17.9%, 44.6%]	**20 (40%)** [26.4%, 54.8%]	**22 (44%)** [30%, 58.7%]
Complete Response	1 (2%)	1 (2%)	0 (0%)
Partial Response - confirmed	14 (28%)	18 (36%)	22 (44%)
Partial Response - pending	0 (0%)	1 (2%)	0 (0%)
Stable Disease	16 (32%)	18 (36%)	16 (32%)
Progressive Disease	12 (24%)	4 (8%)	7 (14%)
Not evaluable	7 (14%)	8 (16%)	5 (10%)

CI: confidence interval; mITT: modified intent-to-treat population

Johnson M et al. ASCO 2023;Abstract 397600.

ARC-7: Domvanalimab + zimberelimab ± etrumadenant vs. zimberelimab in 1L, metastatic, PD-L1-high NSCLC – PFS

Zim Monotherapy vs. Dom-containing arms



CI: confidence interval; HR: hazard ratio; Mos: months; NE: not evaluable

Johnson M et al. ASCO 2023;Abstract 397600.

ARC-7: Domvanalimab + zimberelimab ± etrumadenant vs. zimberelimab in 1L, metastatic, PD-L1-high NSCLC – Safety

mITT, n (%)	Arm 1 (Z) (n=50)	Arm 2 (DZ) (n=50)	Arm 3 (EDZ) (n=50)
Any TEAEs	50 (100%)	49 (98%)	49 (98%)
Grade ≥3 TEAE	32 (64%)	23 (46%)	30 (60%)
Grade 5, related to study treatment*	1 (2%)	1 (2%)	2 (4%)
Serious TEAE	28 (56%)	17 (34%)	26 (52%)
TEAEs leading to study drug discontinuation	14 (28%)	9 (18%)	9 (18%)
Immune-related TEAE	24 (48%)	25 (50%)	33 (66%)
Infusion-related Reactions	2 (4%)	2 (4%)	6 (12%)
Median Treatment Duration, weeks (range)	16.9 (0, 103)	26.2 (0, 130)	36.1 (2, 130)

Designation of immune-related TEAEs based on basket of Preferred Terms. TEAE: treatment-emergent adverse event; *Per Physician assessment

- Most common TEAEs (≥15% overall) were nausea, fatigue, constipation, dyspnea, pneumonia, decreased appetite and diarrhea. Grade ≥3 events occurring in ≥5% of patients were pneumonia (12%) and anemia (7%)
- Most common immune-related TEAEs (>10% overall) were rash (13%), pneumonitis (11%), and pruritus (11%)
  - No clear increase in rates of pneumonitis in dom-containing arms compared to zim alone

Johnson M et al. ASCO 2023;Abstract 397600.

Questions?

Dr Garon - Case 2

- 64 year old man with a long smoking history
- Presents with hemoptysis
- Imaging shows an 8.5 cm mass in the lung along with bilateral adrenal nodules and bone metastases
- Biopsy shows squamous cell carcinoma of the lung
- PD-L1 <1%, TMB 7.3 mut/MB
- No targetable mutation, but STK11 mutation

Agenda

Introduction: Ivonescimab

Module 1: First-Line Therapy for Metastatic NSCLC without a Targetable Tumor Mutation — Dr Garon

Module 2: Promising Therapeutic Strategies for Patients with Progressive Metastatic NSCLC — Dr Paz-Ares

Dr Paz-Ares: Clinical Case

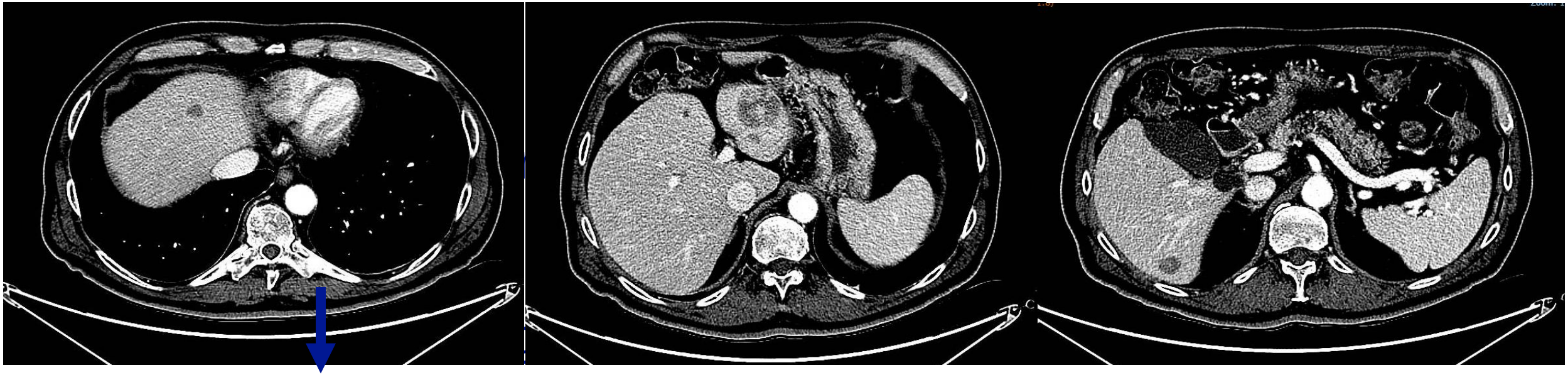
- 68 yo male
- PMH:
  - Active smoker (60 y/p)
  - COPD
- January 2021
  - Right lung nodule (RML)
  - Lobectomy (RML) + Mediastinal Lymphadenectomy (R0)
  - Large Cell Carcinoma
  - pT2 (1,7 cm; pleura) pN0 M0
- Follow Up

Dr Paz-Ares: Clinical Case

- 68 yo male
- PMH:
  - Active smoker (60 y/p)
  - COPD
- January 2021-
  - Resected stage I LCC
- May 2021
  - Liver relapse (Histologically confirmed)
  - Platin-Pemetrexed-Nivolumab-Experimental IO x 1 year (SD)
- June 2022
  - Brain and Liver relapse
  - Holocraneal radiation

Dr Paz-Ares: Clinical Case

- 68 yo male
- PMH:

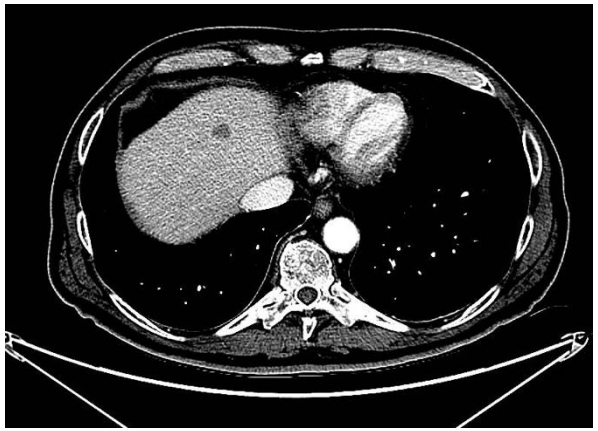


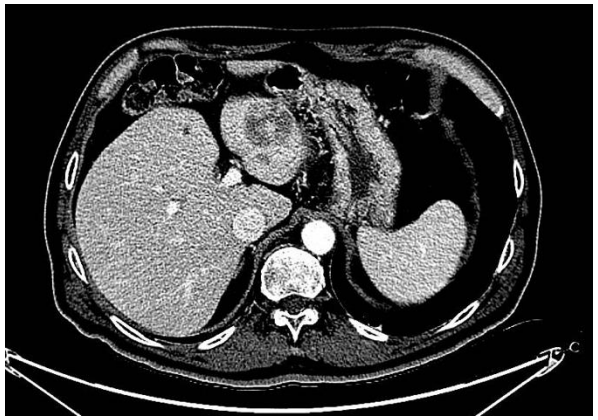
- May 2021
  - Liver relapse (Histologically confirmed)
  - Platin-Pemetrexed-Nivolumab-Experimental IO x 1 year (SD)
- June 2022
  - Brain and Liver relapse
  - Holocraneal radiation

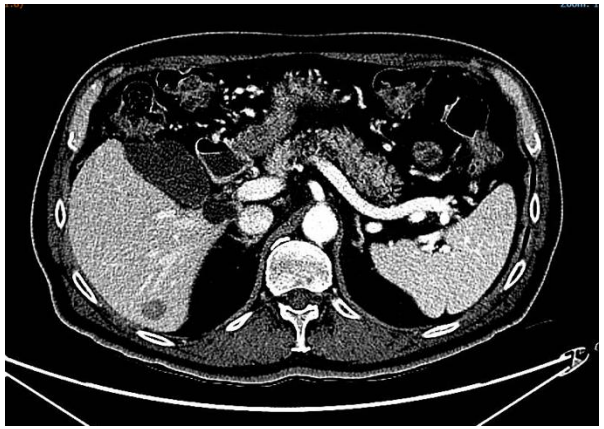
What would you do?

Dr Paz-Ares: Clinical Case

July 2022

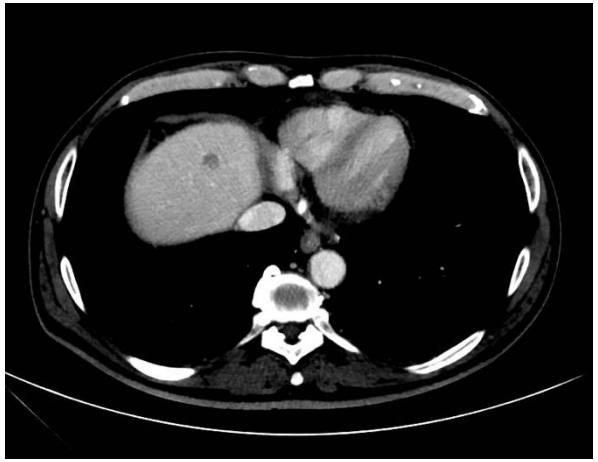


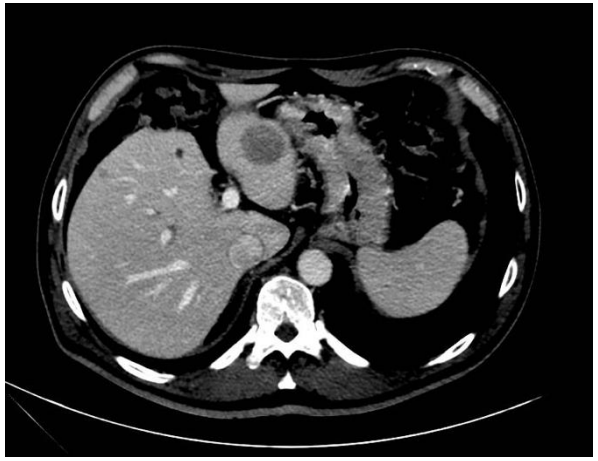


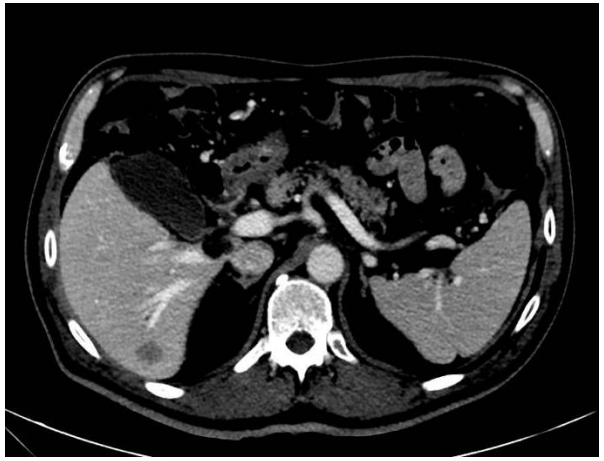


Sacituzumab Govitecan x 4

October 2022







Dr Paz-Ares: Clinical Case

- **Follow Up**
  - 32 cycles up to August 22, 2024
  - Ongoing SD
  - 2 dose reductions due to (neutropenia)
  - Safety: G1 diarrhea, Nausea and Grade 4 neutropenia

Hospital Universitario 12 de Octubre

SaludMadrid

cnio SPANISH NATIONAL CANCER RESEARCH CENTRE

UNIVERSIDAD COMPLUTENSE MADRID

Promising Therapeutic Strategies for Patients with Progressive Metastatic NSCLC

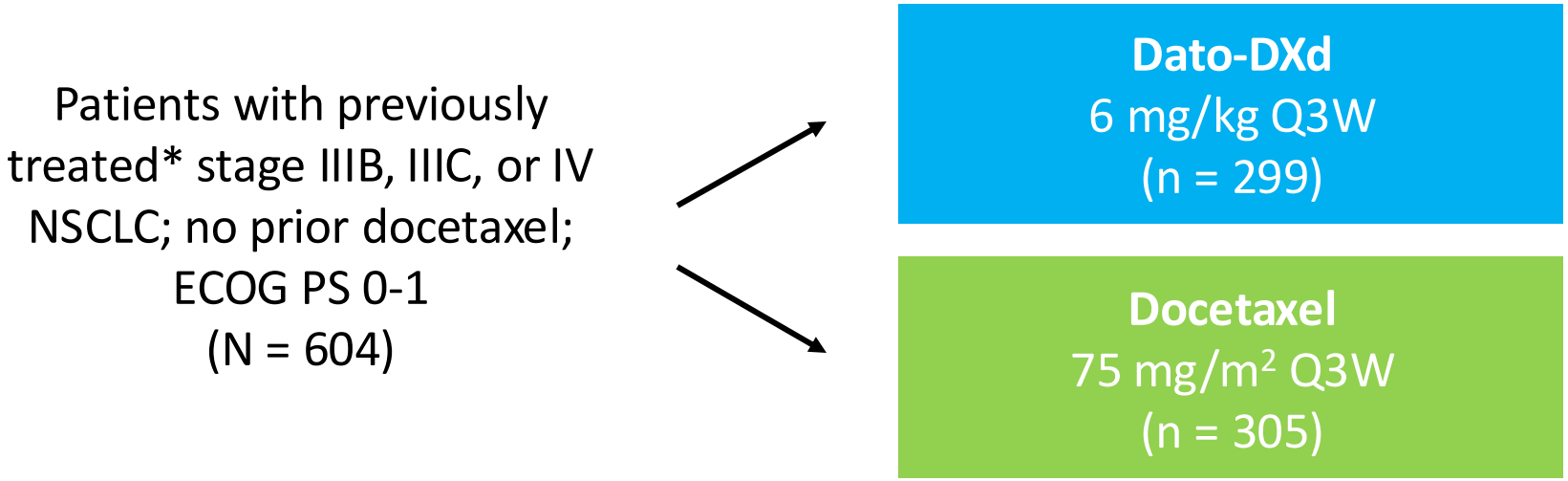
Luis Paz-Ares

Hospital Universitario 12 de Octubre

Madrid, Spain

TROPION-Lung01: Dato-DXd vs Docetaxel in Previously Treated Advanced NSCLC With or Without AGAs

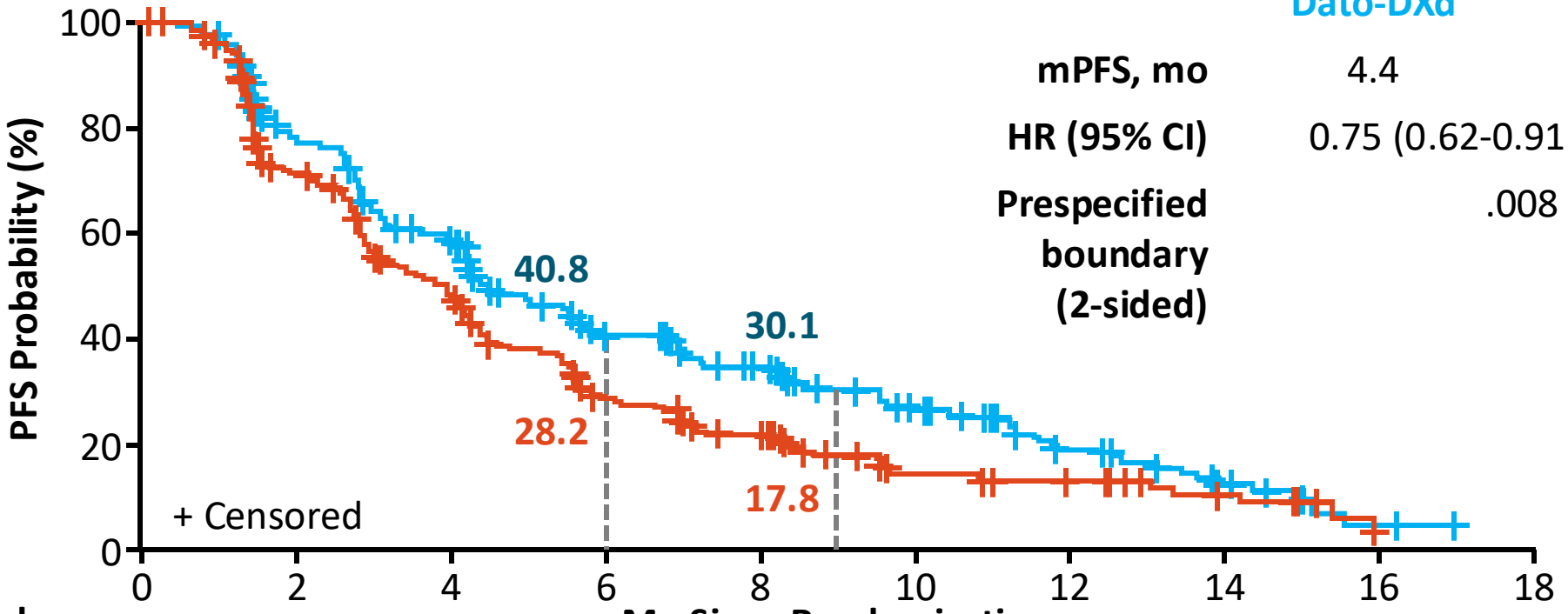
- Global, randomized, open-label phase III trial



- **Dual primary endpoints**: PFS (BICR), OS
- **Secondary endpoints**: ORR (BICR), DoR (BICR), safety

Lisberg. ESMO 2023. Abstr LBA12.

TROPION-Lung01: Efficacy in ITT Population



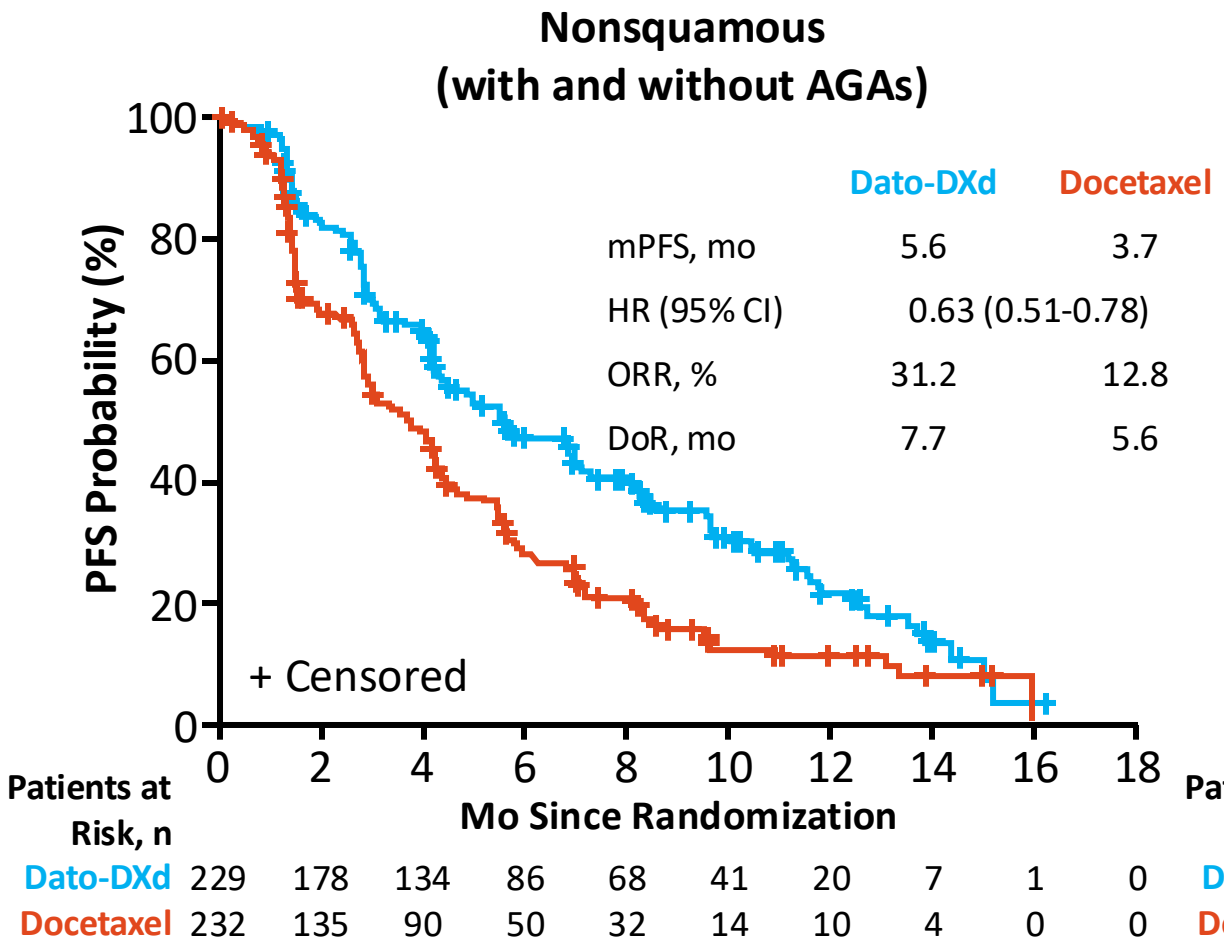
	Dato-DXd	Docetaxel
mPFS, mo	4.4	3.7
HR (95% CI)	0.75 (0.62-0.91; *P* = .004)	
Prespecified boundary (2-sided)	.008	

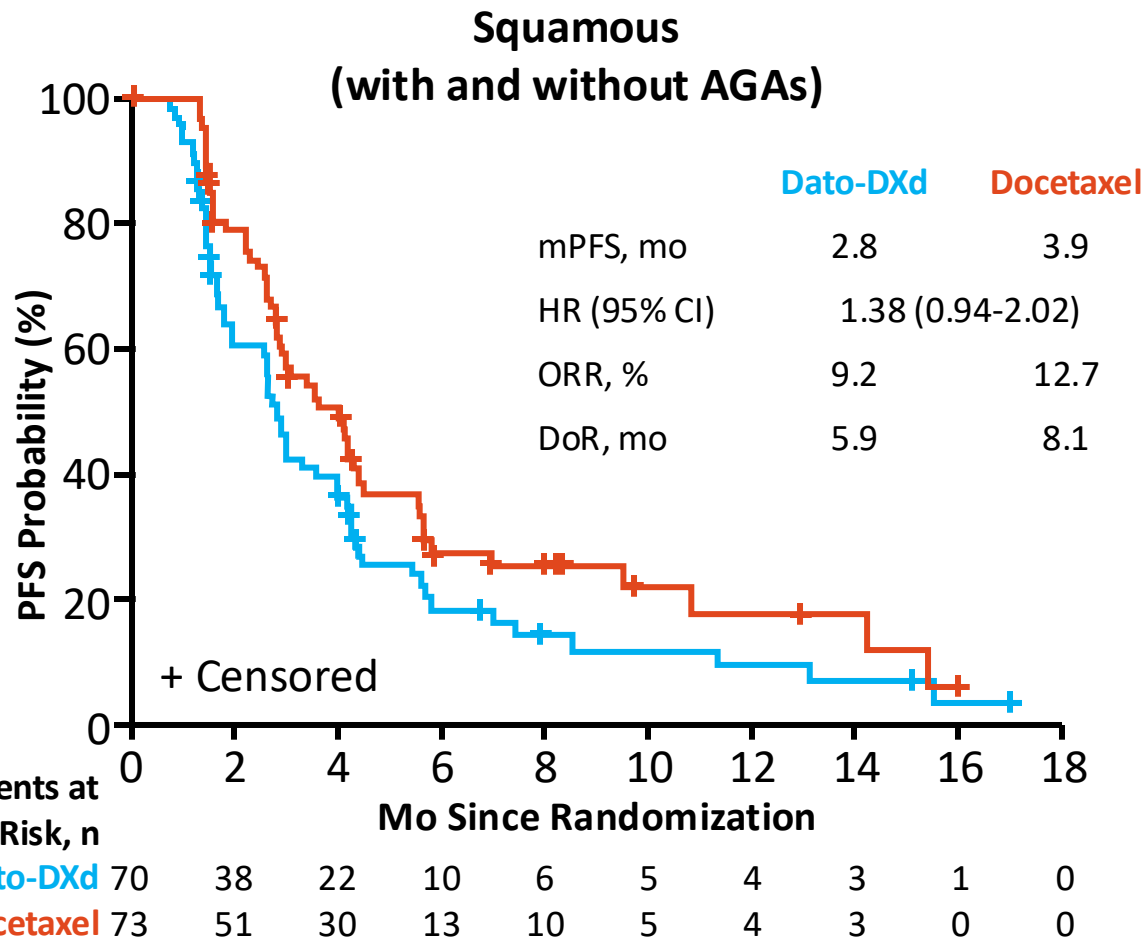
Patients at Risk, n										
Dato-DXd	299	216	156	96	74	46	24	10	2	0
Docetaxel	305	186	120	63	42	19	14	7	0	0

Response	Dato-DXd	Docetaxel
ORR, %	26.4	12.8
DoR, mo (95% CI)	7.1 (5.6-10.9)	5.6 (5.4-8.1)

Lisberg. ESMO 2023. Abstr LBA12.

TROPION-Lung01: Efficacy by Histology



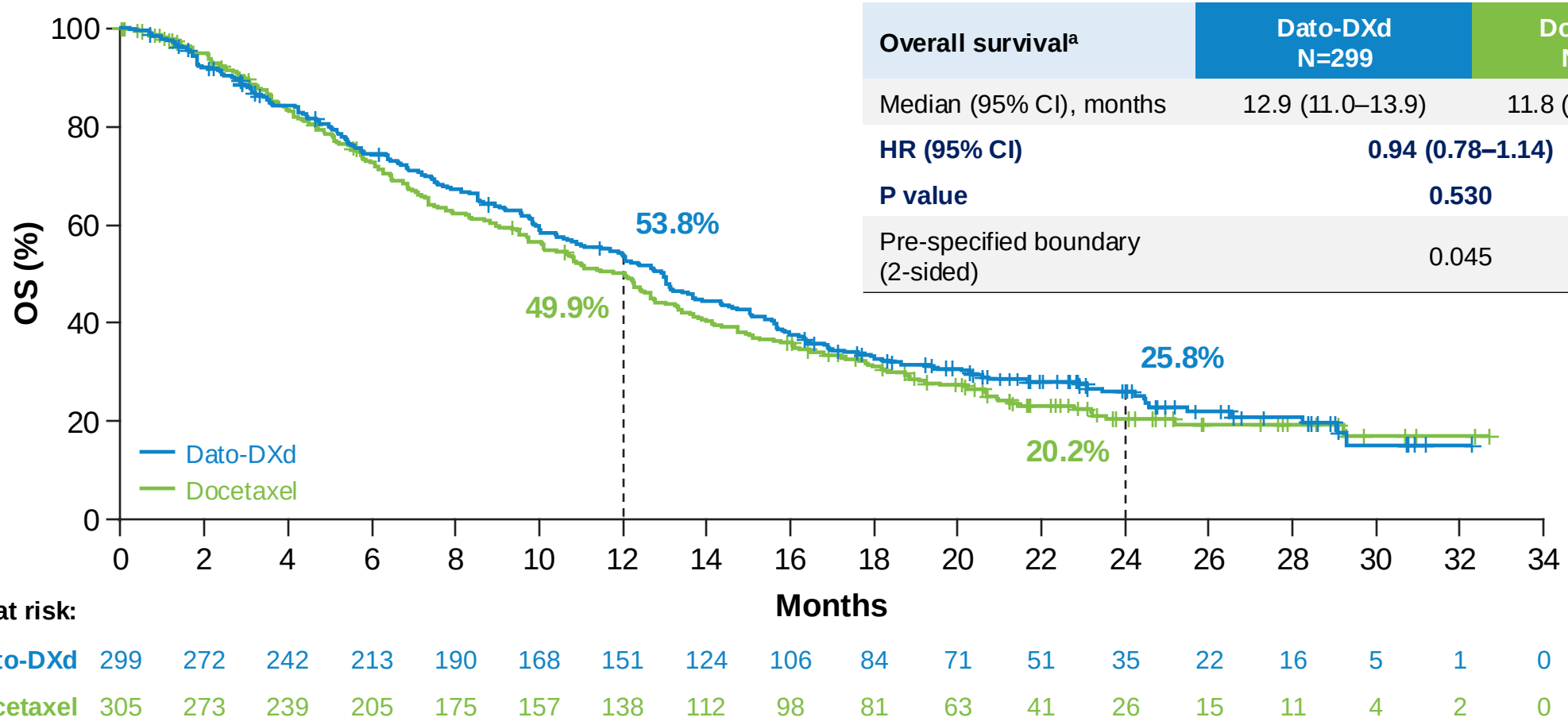


HR for PFS for nonsquamous without AGAs: 0.71 (0.56-0.91)

Lisberg. ESMO 2023. Abstr LBA12.

Overall survival: ITT

TROPION-Lung01



Overall survival[a]	Dato-DXd N=299	Docetaxel N=305
Median (95% CI), months	12.9 (11.0–13.9)	11.8 (10.0–12.8)
HR (95% CI)	**0.94 (0.78–1.14)**	
P value	**0.530**	
Pre-specified boundary (2-sided)	0.045	

No. at risk:

Dato-DXd	299	272	242	213	190	168	151	124	106	84	71	51	35	22	16	5	1	0
Docetaxel	305	273	239	205	175	157	138	112	98	81	63	41	26	15	11	4	2	0

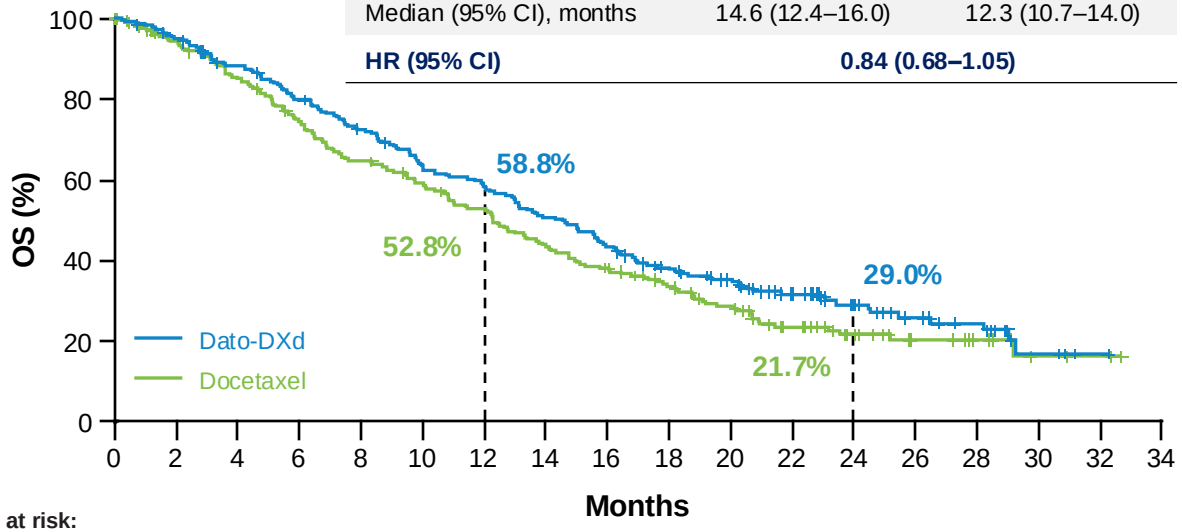
[a]Median (95% CI) OS follow-up was 23.1 (22.0, 24.8) months for Dato-DXd and 23.1 (21.7, 24.2) months for docetaxel. [b]At primary OS analysis (data cutoff: March 1, 2024), 433 OS events (IF) were observed.
CI, confidence interval; Dato-DXd, datopotamab deruxtecan; HR, hazard ratio; IF, information fraction; ITT, intention to treat; OS, overall survival.

Overall survival by histology

TROPION-Lung01

Nonsquamous

Overall survival	Dato-DXd (N=234)	Docetaxel (N=234)
Median (95% CI), months	14.6 (12.4–16.0)	12.3 (10.7–14.0)
HR (95% CI)	0.84 (0.68–1.05)	

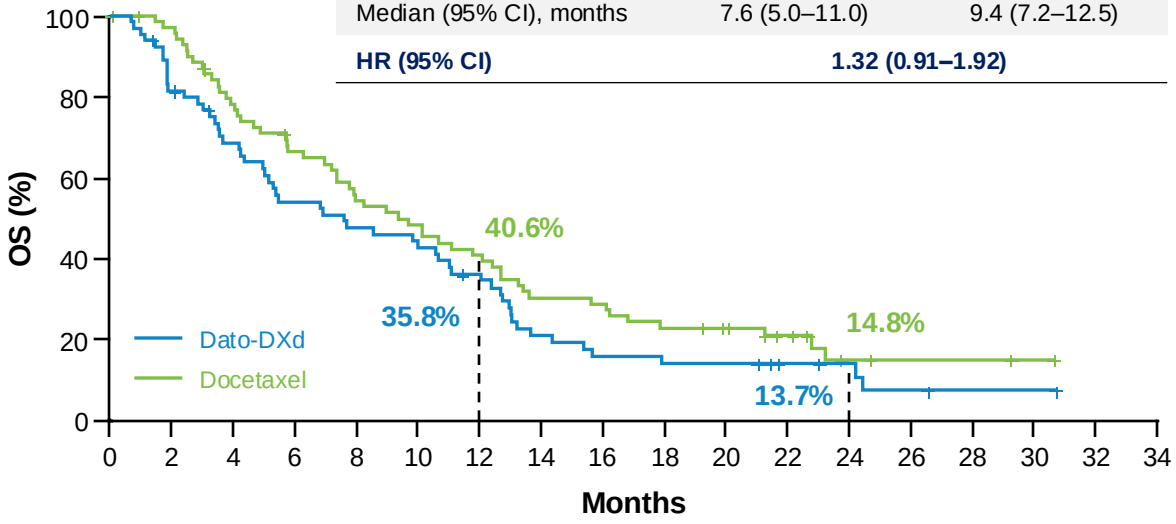


No. at risk:

Dato-DXd	234	220	200	180	161	141	130	112	97	76	63	46	31	20	15	4	1	0
Docetaxel	234	206	186	161	139	125	111	92	79	66	50	32	22	12	8	3	2	0

Squamous

Overall survival	Dato-DXd (N=65)	Docetaxel (N=71)
Median (95% CI), months	7.6 (5.0–11.0)	9.4 (7.2–12.5)
HR (95% CI)	1.32 (0.91–1.92)	



	65	52	42	33	29	27	21	12	9	9	9	5	4	2	1	1	0	0
	71	67	53	44	36	32	27	20	19	15	13	9	4	3	3	1	0	0

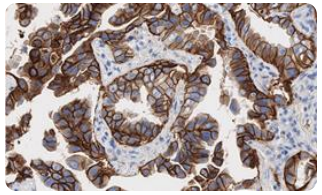
- In patients with NSQ histology, 16% risk reduction for death and 2.3-month improvement in median OS with Dato-DXd
- OS improvements were seen regardless of actionable genomic alteration status[a]:
  - **Present**: 15.6 vs 9.8 months (HR [95% CI], 0.65 [0.40–1.08]); **Absent:** 13.6 vs 12.3 months (HR [95% CI], 0.89 [0.70–1.13])

Data cutoff: March 1, 2024.
[a]Percentages are based on the number of patients in the respective actionable genomic alteration subsets. Values were calculated based on patient data in the electronic case report forms.
CI, confidence interval; Dato-DXd, datopotamab deruxtecan; HR, hazard ratio; NSQ, nonsquamous; OS, overall survival.

TROP2 Normalized Membrane Ratio (NMR) measured by Quantitative Continuous Scoring (QCS)

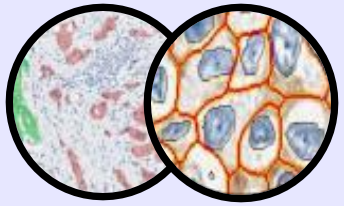
QCS is a novel, fully-supervised computational pathology approach that precisely quantifies and locates targets like TROP2

1 IHC with TROP2 Assay



2 Whole Slide Imaging

3 Automated Image Analysis (QCS)

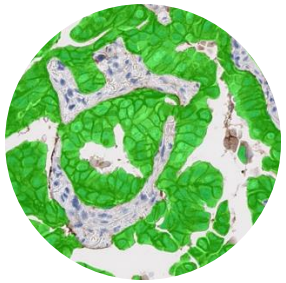


4 Patient Biomarker Status Determination

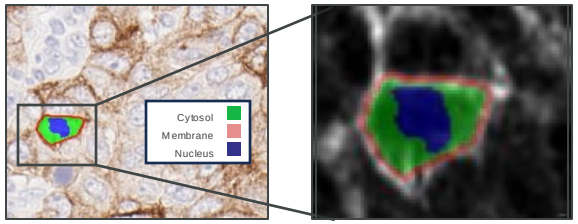
\+ ≥75% of tumor cells with TROP2 NMR ≤0.56

\- <75% of tumor cells with TROP2 NMR ≤0.56

Differentiates tumor from non-tumor



Measures OD in each tumor cell



Membrane and cytoplasm optical density (OD)

Calculates TROP2 NMR for every tumor cell

$$\frac{\text{Membrane OD}}{\text{Membrane OD + Cytoplasm OD}}$$

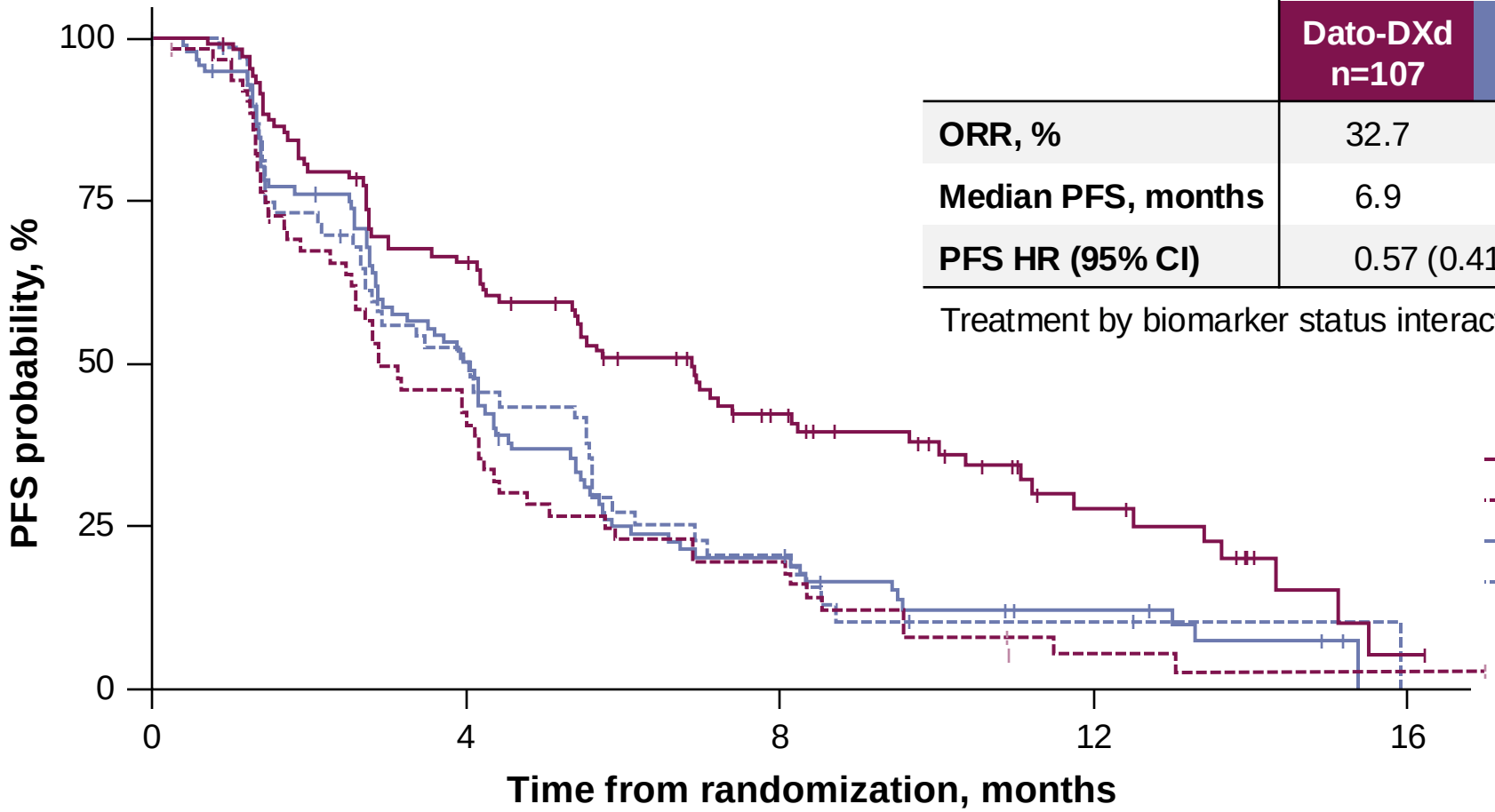
Lower NMR → higher cytoplasm proportion

OD, optical density (a measure of staining intensity).

Efficacy by TROP2 QCS-NMR Status

TROP2 QCS-NMR positivity is predictive for longer PFS with Dato-DXd in the biomarker-evaluable population

Biomarker-evaluable population, n=352



	TROP2 QCS-NMR+		TROP2 QCS-NMR–	
	Dato-DXd n=107	Docetaxel n=107	Dato-DXd n=65	Docetaxel n=73
ORR, %	32.7	10.3	16.9	15.1
Median PFS, months	6.9	4.1	2.9	4.0
PFS HR (95% CI)	0.57 (0.41–0.79)		1.16 (0.79–1.70)	

Treatment by biomarker status interaction: p=0.0063

Data cutoff: March 29 2023

Questions?

EVOKE-01: Sacituzumab Govitecan vs Docetaxel in Adv NSCLC Previously Treated With Platinum and ICI

- Open-label, multicenter, randomized phase III trial[1,2]

Stratified by histology (sq vs nonsq), response to last prior immune therapy (PD/SD vs CR/PR), receipt of prior targeted therapy for AGA (yes vs no)

Adults with stage IV NSCLC with radiographic PD after platinum-based CT and ICI therapy; ≥1 targeted tx for AGAs; testing for *EGFR, ALK,* PD-L1 required, testing for other AGAs recommended; ECOG PS 0/1; no active CNS metastases and/or carcinomatous meningitis (N = 520)

Sacituzumab Govitecan
10 mg/kg IV on Day 1, 8
21-day cycle

Docetaxel
75 mg/m^2 IV on Day 1
21-day cycle

Tx continued until PD or unacceptable toxicity.

EVOKE-01 did not meet its primary endpoint of OS, but did show numerical improvement, including in both nonsq and sq disease as well as those nonresponsive to last prior therapy[3]

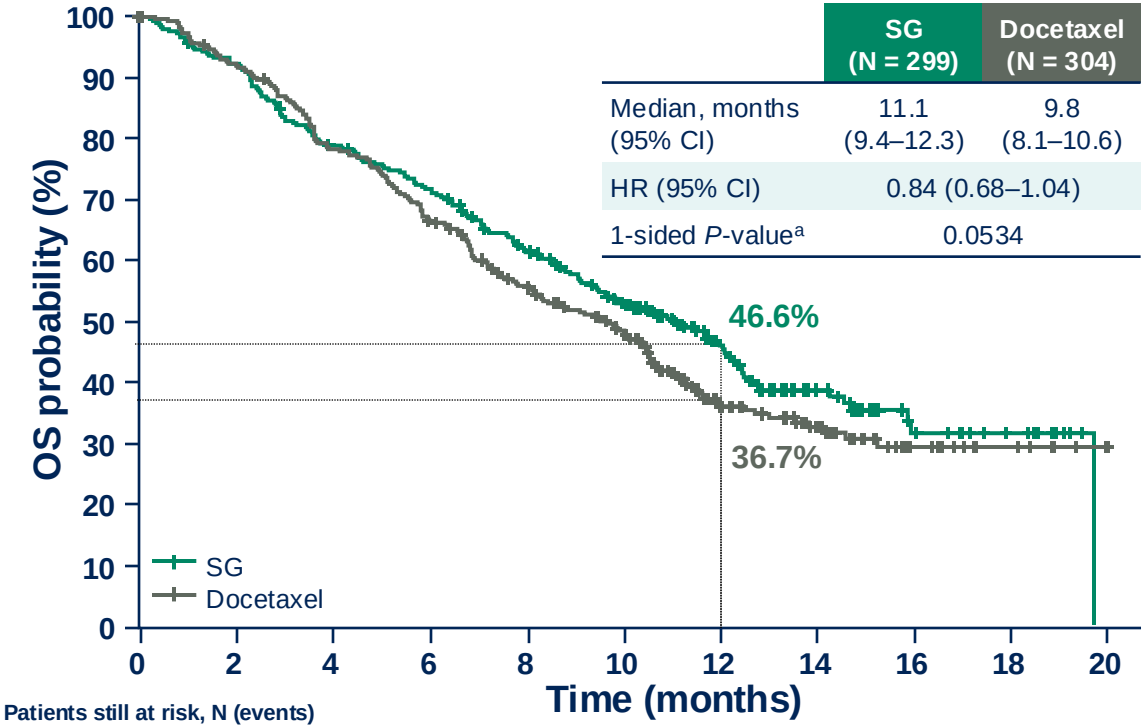
- **Primary endpoint:** OS
- **Secondary endpoints:** PFS, ORR, DoR, DCR by inv per RECIST v1.1, safety, QoL

1. Garassino. ASCO 2023. Abstr TPS9149. 2. NCT05089734.
3. Press release (Jan 22, 2024); data presentation at upcoming medical meeting awaited.

Background: EVOKE-01 Primary Results[1]

- There was a clinically meaningful OS improvement favoring SG over docetaxel patients with mNSCLC non-responsive (SD/PD) to their last anti-PD-(L)1–containing regimen
  - Here we discuss this subgroup

OS: ITT

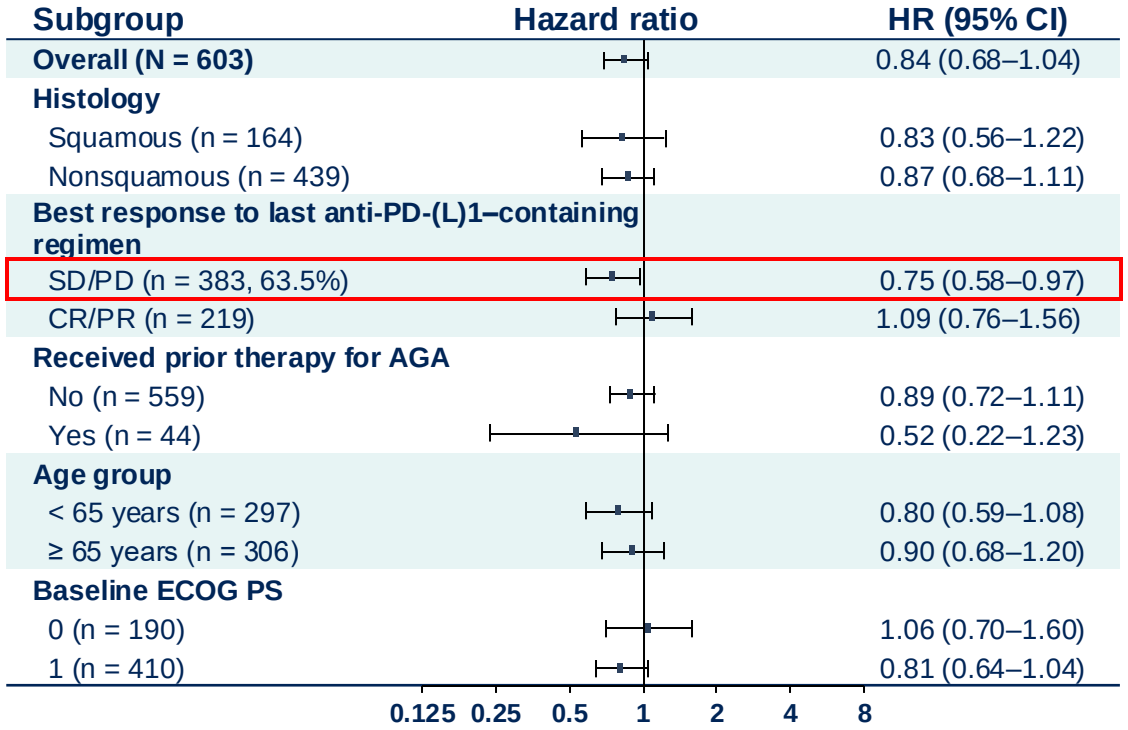


	SG (N = 299)	Docetaxel (N = 304)
Median, months (95% CI)	11.1 (9.4–12.3)	9.8 (8.1–10.6)
HR (95% CI)	0.84 (0.68–1.04)	
1-sided *P*-value[a]	0.0534	

Patients still at risk, N (events)

SG	299 (0)	275 (23)	234 (63)	212 (83)	175 (112)	140 (137)	76 (150)	40 (162)	17 (166)	10 (167)	0 (168)
Docetaxel	304 (0)	277 (23)	234 (65)	201 (98)	158 (131)	128 (151)	64 (178)	41 (184)	15 (187)	7 (187)	2 (187)

OS: Key Subgroups

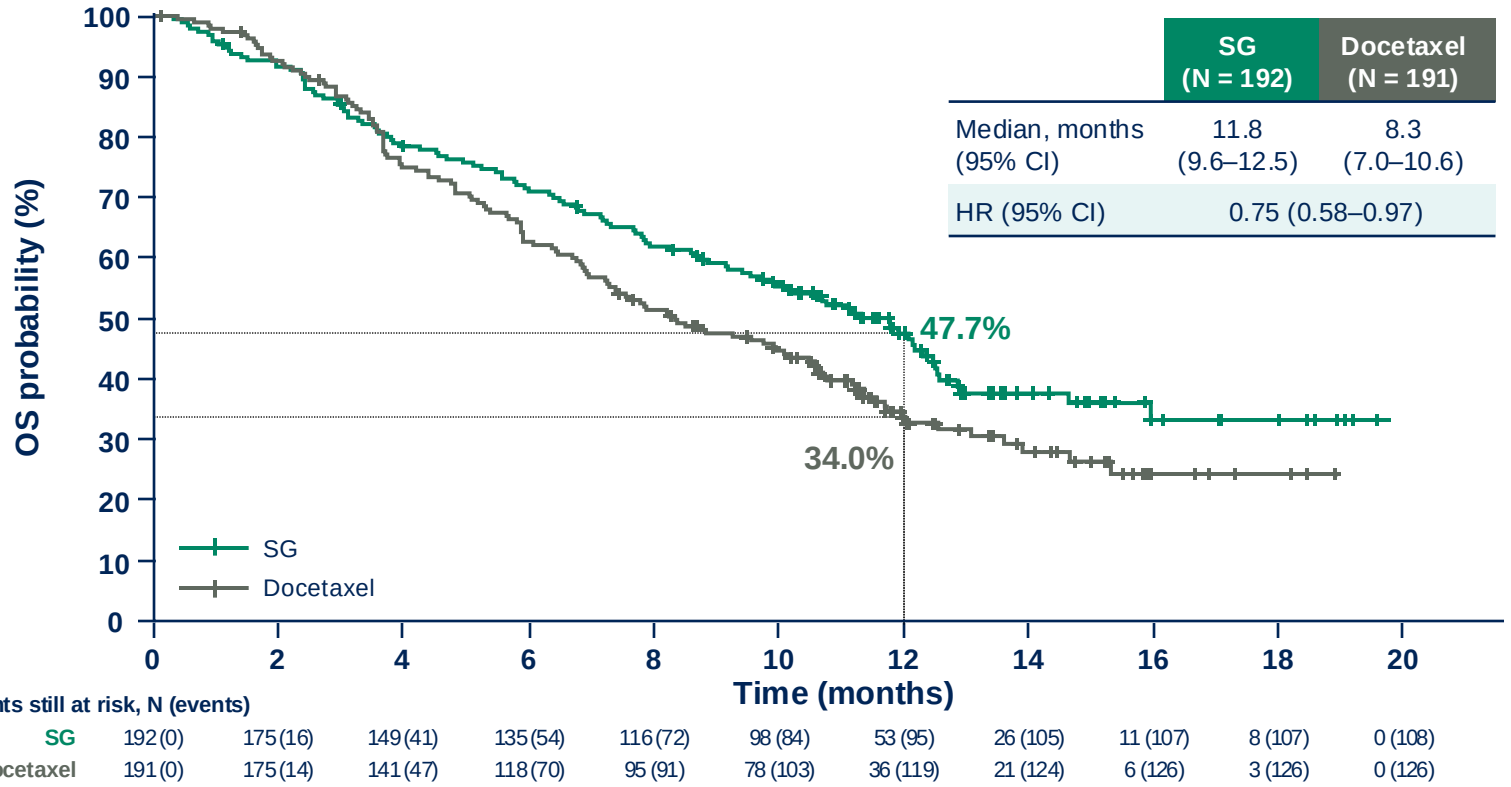


[a]1-sided *P*-value for significance was $P \leq 0.0223$. AGA, actionable genomic alteration; CI, confidence interval; CR, complete response; ECOG PS, Eastern Cooperative Oncology Group performance status; HR, hazard ratio; ITT, intent-to-treat; mNSCLC, metastatic non-small cell lung cancer OS, overall survival; PD, progressive disease; PD-(L)1, programmed death (ligand) 1; PR, partial response; SD, stable disease; SG, sacituzumab govitecan. 1. Paz-Ares LG, et al. J Clin Oncol. 2024; JCO.24.00733 DOI:10.1200/JCO.24.00733.

Efficacy: Non-Responsive (SD/PD) to Last Anti-PD-(L)1–Containing Regimen

SG had a 3.5-month median OS improvement over docetaxel among the subgroup of patients with non-responsive (SD/PD) disease

OS[1]



	SG (N = 192)	Docetaxel (N = 191)
Median, months (95% CI)	11.8 (9.6–12.5)	8.3 (7.0–10.6)
HR (95% CI)	0.75 (0.58–0.97)	

Patients still at risk, N (events)

SG	192 (0)	175 (16)	149 (41)	135 (54)	116 (72)	98 (84)	53 (95)	26 (105)	11 (107)	8 (107)	0 (108)
Docetaxel	191 (0)	175 (14)	141 (47)	118 (70)	95 (91)	78 (103)	36 (119)	21 (124)	6 (126)	3 (126)	0 (126)

PFS and Response

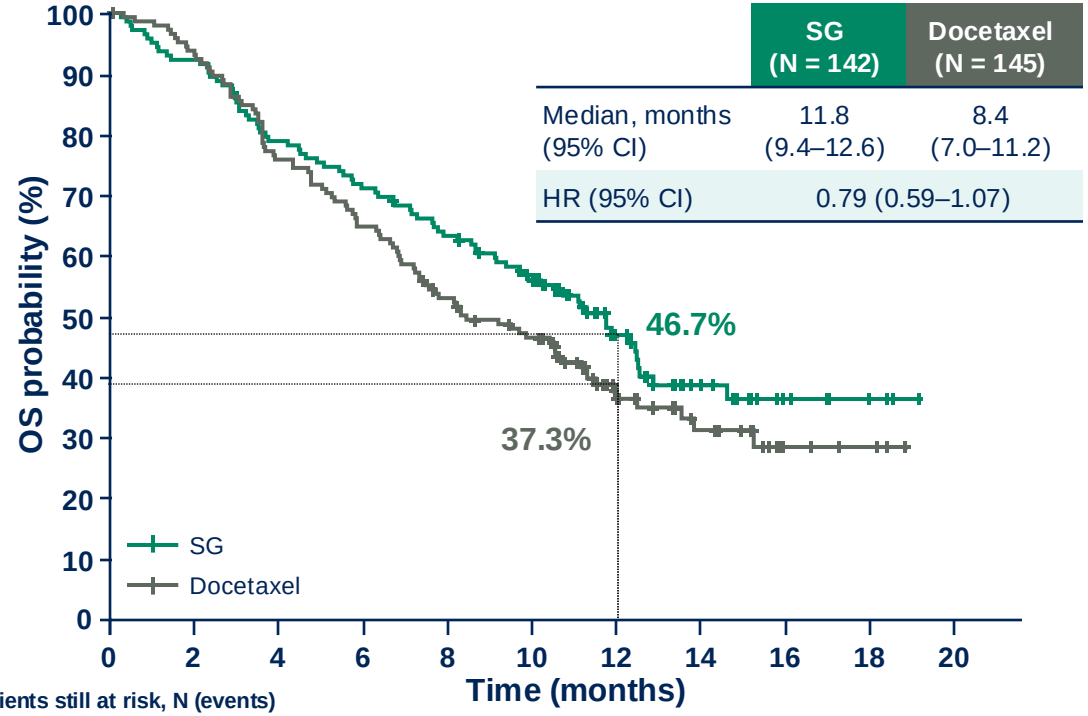
	SG (N = 192)	Docetaxel (N = 191)
Median PFS,[a] months (95% CI)	4.2 (3.0–5.3)	3.7 (2.9–4.2)
HR (95% CI)	0.88 (0.70–1.10)	
ORR,[a] % (95% CI)	12.5 (8.2–18.0)	16.2 (11.3–22.2)

[a]By investigator assessment per Response Evaluation Criteria in Solid Tumors version 1.1. CI, confidence interval; HR, hazard ratio; ORR, objective response rate; OS, overall survival; PD, progressive disease; PD-(L)1, programmed death (ligand) 1; PFS, progression-free survival; SD, stable disease; SG, sacituzumab govitecan. 1. Paz-Ares LG, et al. J Clin Oncol. 2024; JCO.24.00733 DOI:10.1200/JCO.24.00733.

Overall Survival: Non-Responsive (SD/PD) to Last Anti-PD-(L)1–Containing Regimen, by Histology

SG had an OS improvement over docetaxel in both nonsquamous and squamous histologies

Nonsquamous[1]

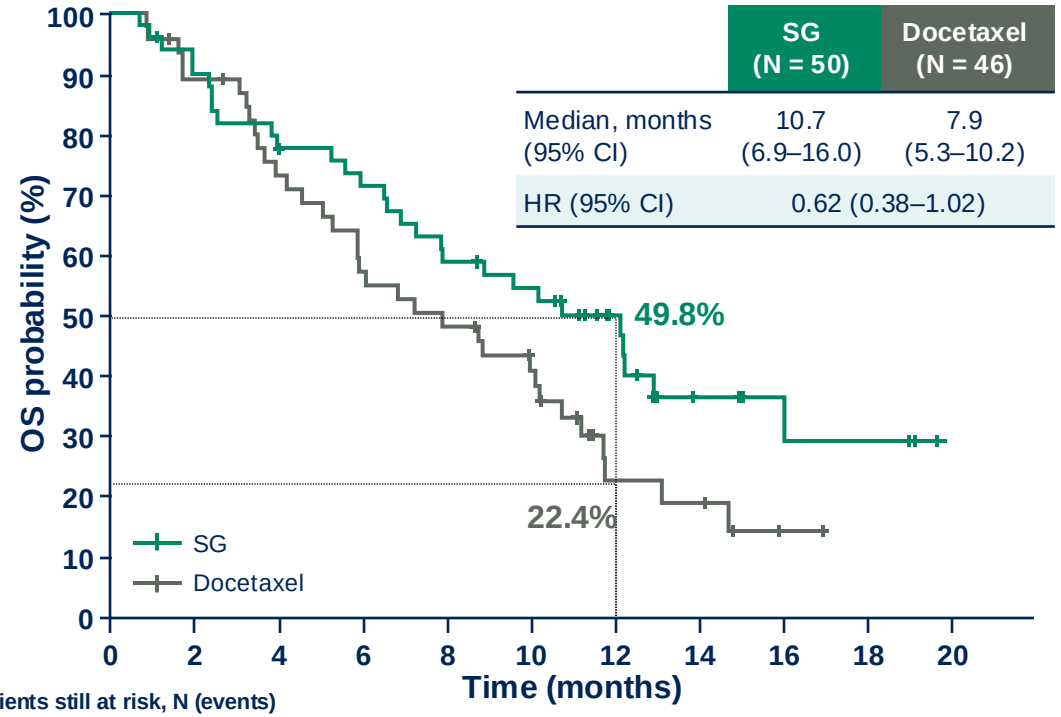


	SG (N = 142)	Docetaxel (N = 145)
Median, months (95% CI)	11.8 (9.4–12.6)	8.4 (7.0–11.2)
HR (95% CI)	0.79 (0.59–1.07)	

Patients still at risk, N (events)

SG	142 (0)	131 (11)	111 (30)	101 (40)	88 (52)	73 (62)	38 (71)	19 (77)	7 (78)	4 (78)	0 (78)
Docetaxel	145 (0)	135 (9)	109 (35)	93 (51)	74 (68)	62 (77)	30 (87)	16 (91)	5 (92)	3 (92)	0 (92)

Squamous[1]



	SG (N = 50)	Docetaxel (N = 46)
Median, months (95% CI)	10.7 (6.9–16.0)	7.9 (5.3–10.2)
HR (95% CI)	0.62 (0.38–1.02)	

Patients still at risk, N (events)

SG	50 (0)	44 (5)	38 (11)	34 (14)	28 (20)	25 (22)	15 (24)	7 (28)	4 (29)	4 (29)	0 (30)
Docetaxel	46 (0)	40 (5)	32 (12)	25 (19)	21 (23)	16 (26)	6 (32)	5 (33)	1 (34)		

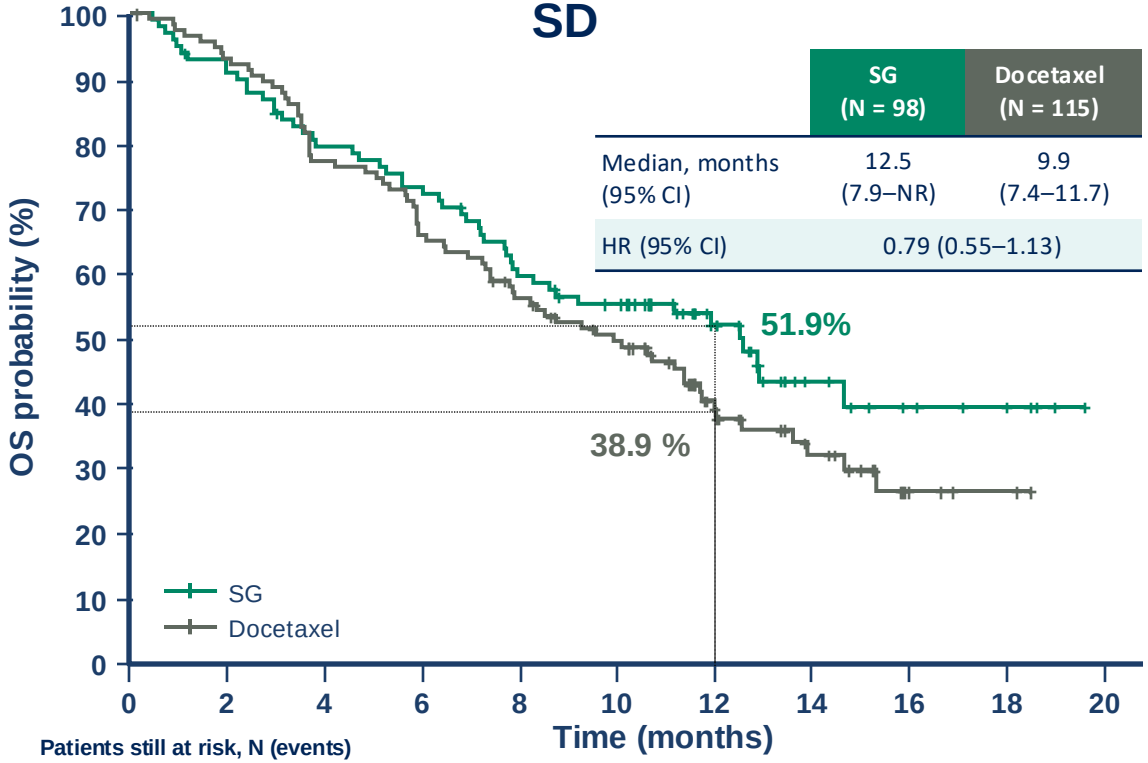
CI, confidence interval; HR, hazard ratio; OS, overall survival; PD, progressive disease; PD-(L)1, programmed death (ligand) 1; SD, stable disease; SG, sacituzumab govitecan. 1. Paz-Ares LG, et al. J Clin Oncol. 2024; JCO.24.00733 DOI:10.1200/JCO.24.00733.

Overall Survival: SD or PD as Best Response to Last Anti-PD-(L)1–Containing Regimen

SG had an OS improvement over docetaxel in both SD and PD subgroups

SD

	SG (N = 98)	Docetaxel (N = 115)
Median, months (95% CI)	12.5 (7.9–NR)	9.9 (7.4–11.7)
HR (95% CI)	0.79 (0.55–1.13)	

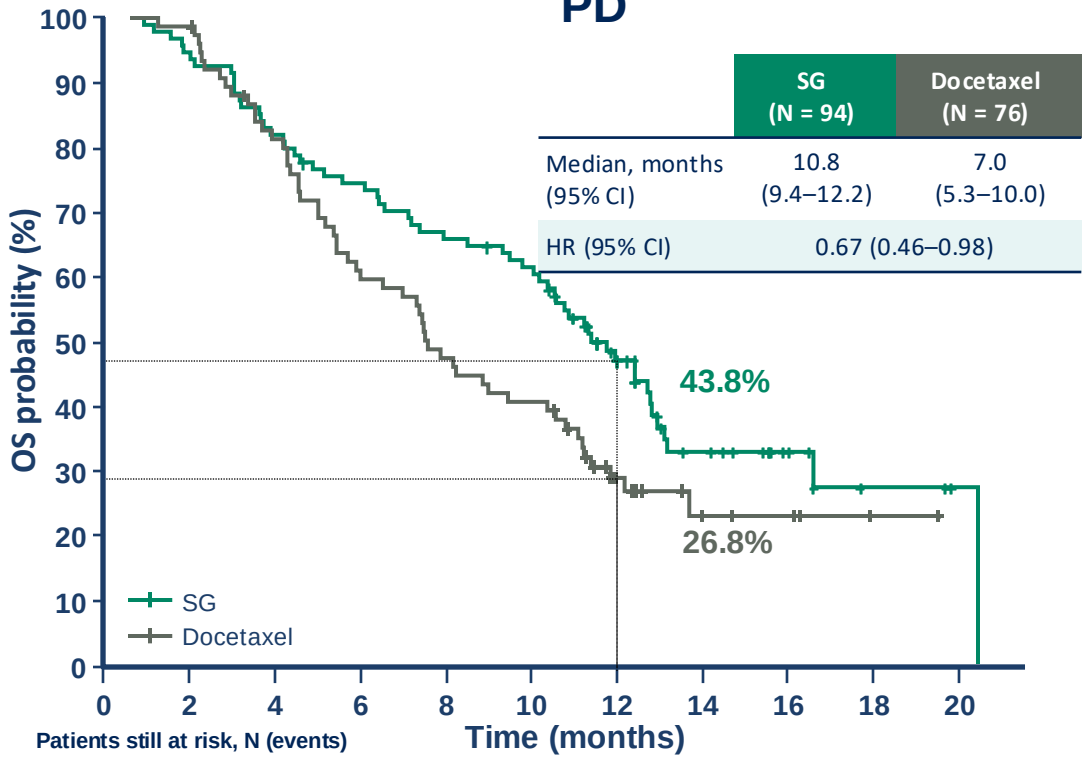


Patients still at risk, N (events)

SG	98 (0)	88 (9)	76 (20)	70 (26)	56 (39)	49 (43)	28 (45)	12 (49)	7 (50)	5 (50)	0 (50)
Docetaxel	115 (0)	106 (8)	88 (26)	75 (39)	62 (50)	51 (57)	27 (66)	16 (70)	4 (72)	2 (72)	

PD

	SG (N = 94)	Docetaxel (N = 76)
Median, months (95% CI)	10.8 (9.4–12.2)	7.0 (5.3–10.0)
HR (95% CI)	0.67 (0.46–0.98)	



Patients still at risk, N (events)

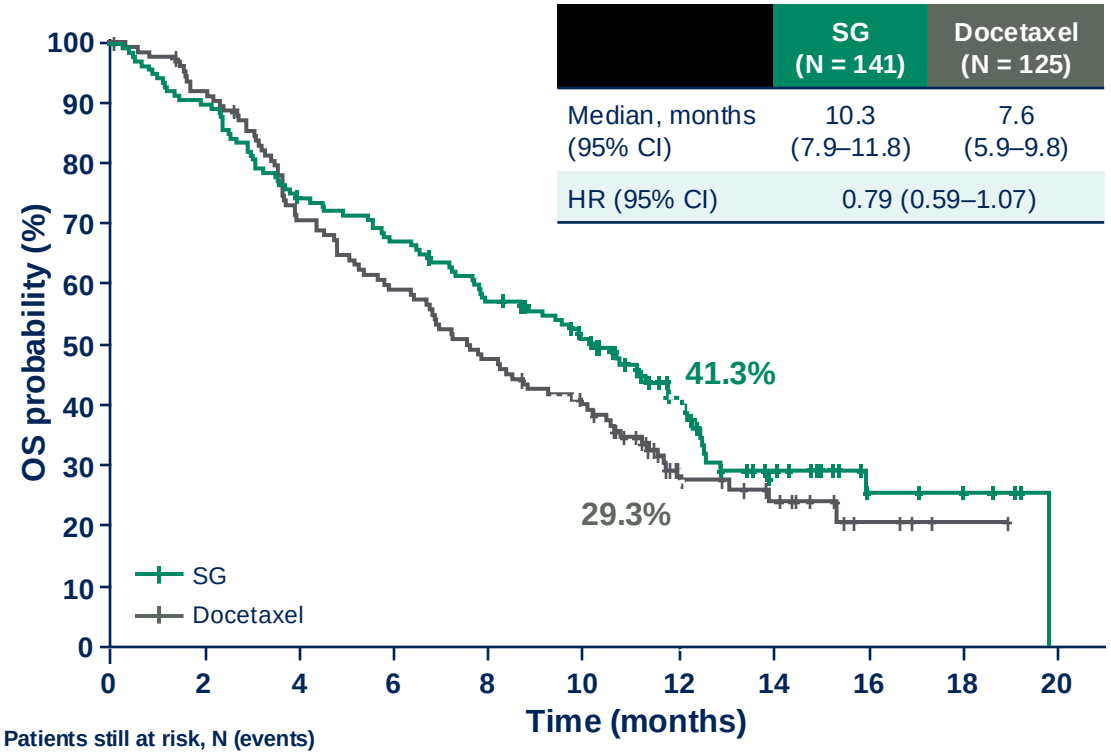
SG	94 (0)	87 (7)	73 (21)	65 (28)	60 (33)	49 (41)	25 (50)	14 (56)	4 (57)	3 (57)	0 (58)
Docetaxel	76 (0)	69 (6)	53 (21)	43 (31)	33 (41)	27 (46)	9 (53)	5 (54)	2 (54)	1 (54)	

CI, confidence interval; HR, hazard ratio; OS, overall survival; PD, progressive disease; PD-(L)1, programmed death (ligand) 1; SD, stable disease; SG, sacituzumab govitecan.

Overall Survival Analysis: SD/PD to Last Anti-PD-(L)1–Containing Regimen

PD or SD (<6 months on treatment) or SD (≥ 6 months on treatment) per SITC criteria[a]

Primary resistance[b] to last anti-PD-(L)1–containing regimen

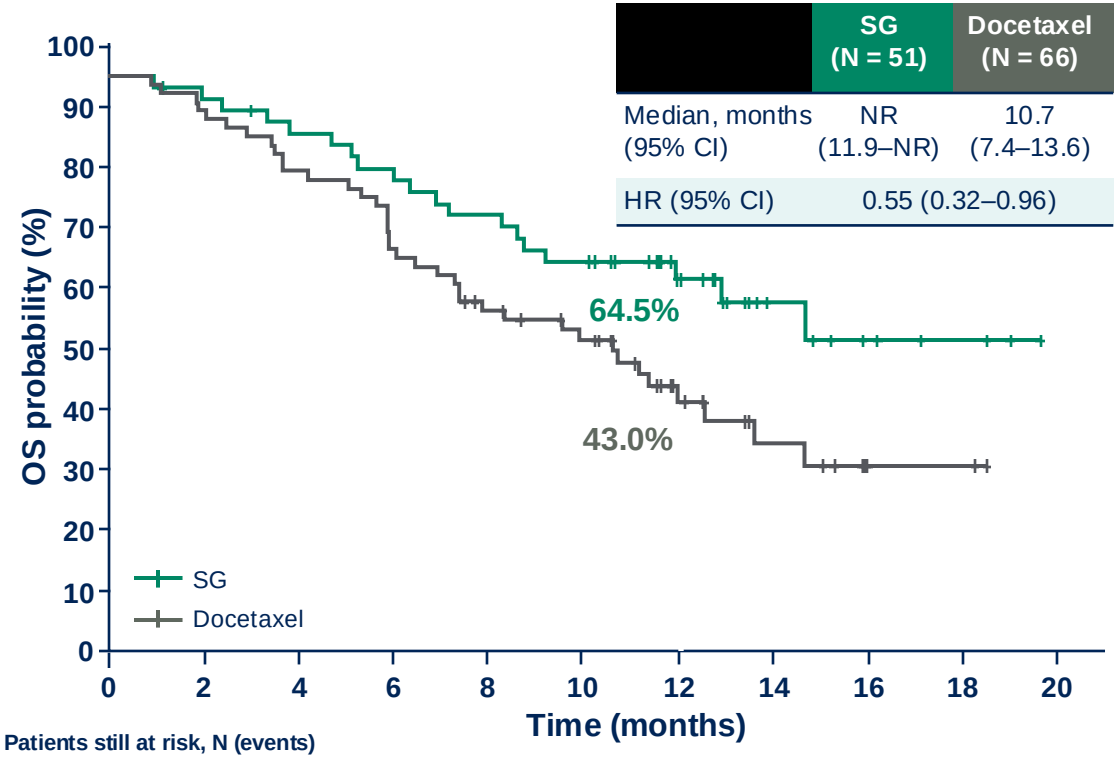


	SG (N = 141)	Docetaxel (N = 125)
Median, months (95% CI)	10.3 (7.9–11.8)	7.6 (5.9–9.8)
HR (95% CI)	0.79 (0.59–1.07)	

Patients still at risk, N (events)

SG	141 (0)	127 (14)	105 (36)	94 (46)	79 (60)	65 (68)	32 (78)	17 (87)	6 (88)	5 (88)	0 (89)
Docetaxel	125 (0)	113 (10)	86 (36)	72 (50)	58 (64)	47 (73)	20 (84)	12 (87)	4 (88)	1 (88)	

Secondary resistance[c] to last anti-PD-(L)1–containing regimen



	SG (N = 51)	Docetaxel (N = 66)
Median, months (95% CI)	NR (11.9–NR)	10.7 (7.4–13.6)
HR (95% CI)	0.55 (0.32–0.96)	

Patients still at risk, N (events)

SG	51 (0)	48 (2)	44 (5)	41 (8)	37 (12)	33 (16)	21 (17)	9 (18)	5 (19)	3 (19)	0 (19)
Docetaxel	66 (0)	62 (4)	55 (11)	46 (20)	37 (27)	31 (30)	16 (35)	9 (37)	2 (38)	2 (38)	

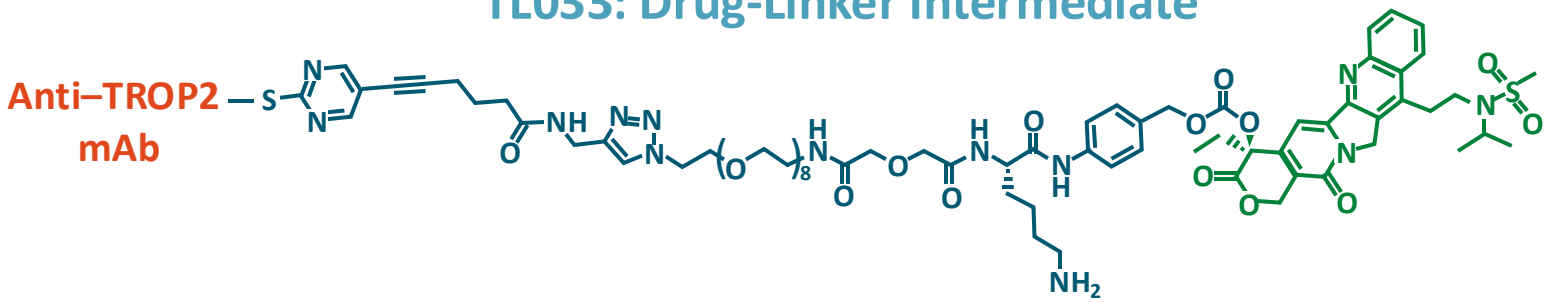
[a]Resistance per SITC-based criteria for immune-checkpoint inhibitor combinations.[1] [b]Patients with PD or SD (<6 months on treatment). [c]Patients with SD (≥6 months on treatment). CI, confidence interval; HR, hazard ratio; NR, not reached; OS, overall survival; PD, progressive disease; PD-(L)1, programmed death (ligand) 1; SD, stable disease. 1. Kluger HM, et al. J Immunother Cancer 2020;8:e000398

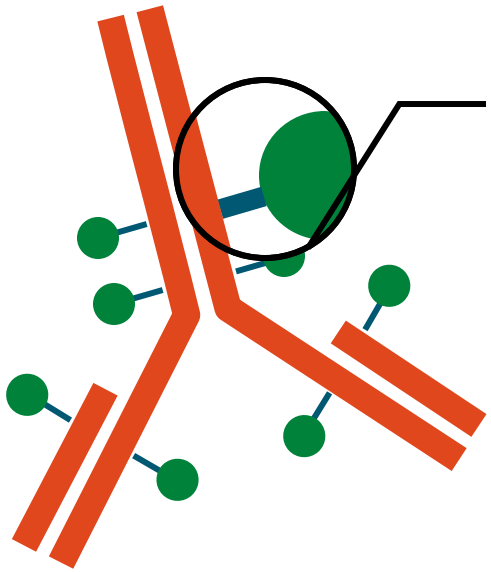
Sacituzumab Tirumotecan (MK-2870; SKB264): TROP2-Targeted ADC

Humanized RS7 Antibody

- Targets TROP2
- Type: hRS7 IgG1
- High affinity targeting

TL033: Drug-Linker Intermediate





Sulfonyl Pyrimidine-CL2A-Carbonate Linker

- Irreversible, cysteine conjugation
- High DAR (~7.4:1)
- Designed to balance stability in circulation with intracellular release of payload

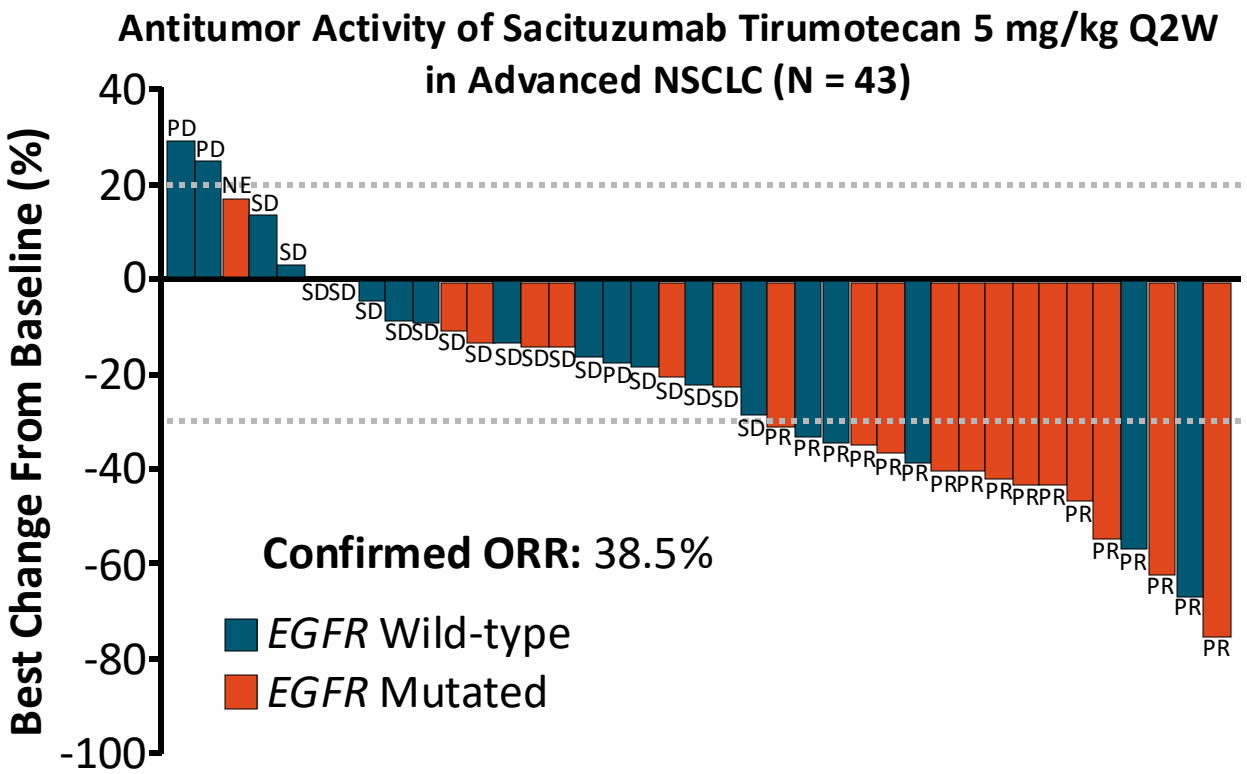
KL610023 (T030) Payload

- Novel topoisomerase I inhibitor (Belotecan-derivative)
- T030 released by hydrolysis
- Moderate cytotoxicity

Bystander effect: In acidic environment, carbonate linker releases T030 from anti-TROP2 antibody and diffuses into neighboring TROP2-negative cells

Cheng. Front Oncol. 2022;12:1589. Fang. ASCO 2023. Abstr 9114.

Phase I/II MK-2870-001 Trial: NSCLC Cohort



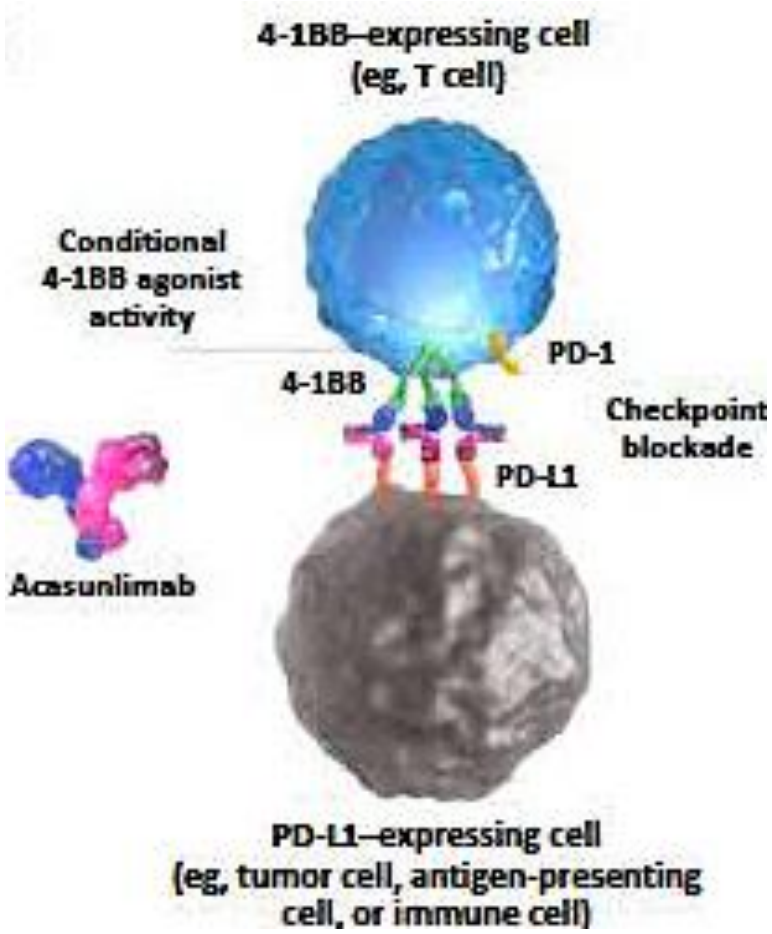
Response, %	*EGFR*mut (n = 22)	*EGFR* WT (n = 21)	All NSCLC (N = 43)
ORR	26.3	60.0	43.6
Confirmed ORR	21.1	55.0	38.5

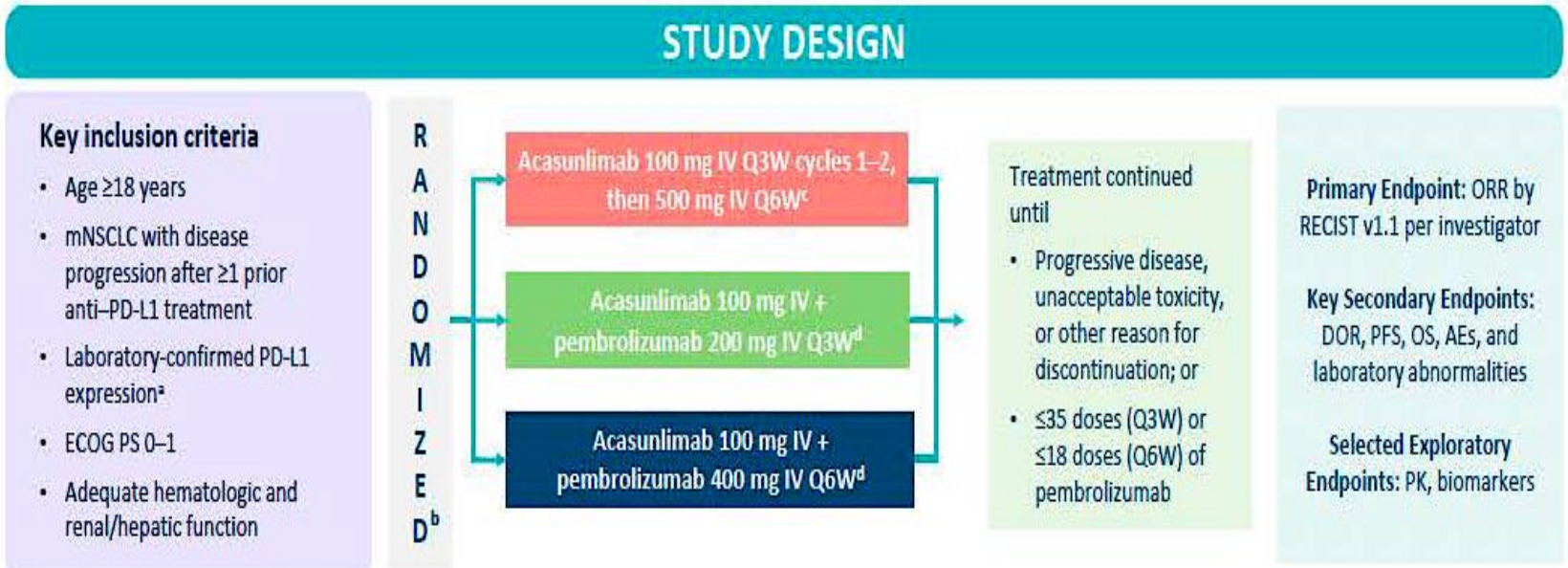
TRAE, n (%)	NSCLC Cohort (N = 43)	
	All Grades	≥ Grade 3
Any TRAE	41 (95.3)	29 (67.4)
▪ Associated with dose delay	21 (48.8)	17 (39.5)
▪ Associated with dose reduction	10 (23.3)	9 (20.9)
▪ Associated with discontinuation	0	0
Treatment-related serious AE	9 (20.9)	9 (20.9)
TRAE associated with death	0	0
TRAE in ≥20% of Patients, n (%)		
Anemia	31 (72.1)	13 (30.2)
Decreased WBC count	24 (55.8)	10 (23.3)
Alopecia	23 (53.5)	0
Decreased neutrophil count	23 (53.5)	14 (32.6)
Stomatitis	21 (48.8)	4 (9.3)
Rash	17 (39.5)	3 (7.0)
Nausea	16 (37.2)	0
Decreased appetite	15 (34.9)	0
Vomiting	14 (32.6)	2 (4.7)
Decreased platelet count	10 (23.3)	1 (2.3)
Hypoalbuminemia	9 (20.3)	0

Fang. ASCO 2023. Abstr 9114.

Questions?

Acasunlimab (DuoBody PD-L1-4-1BB) alone or in combination with Pembrolizumab in pre-treated NSCLC



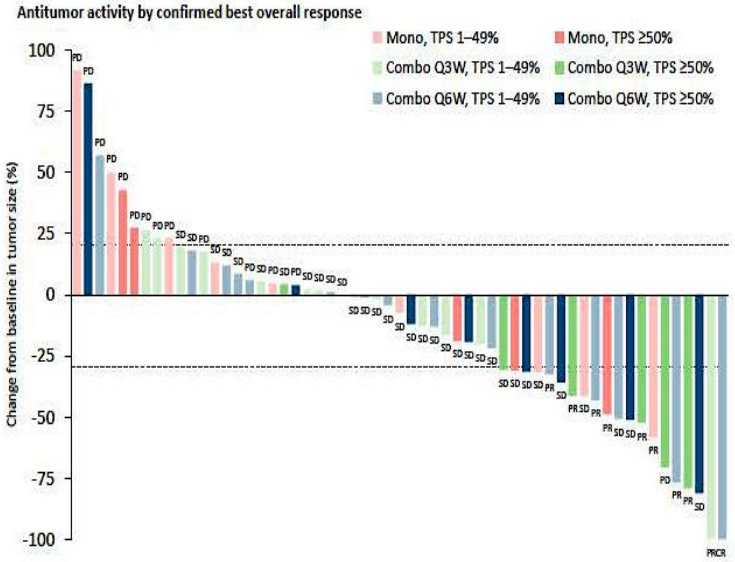


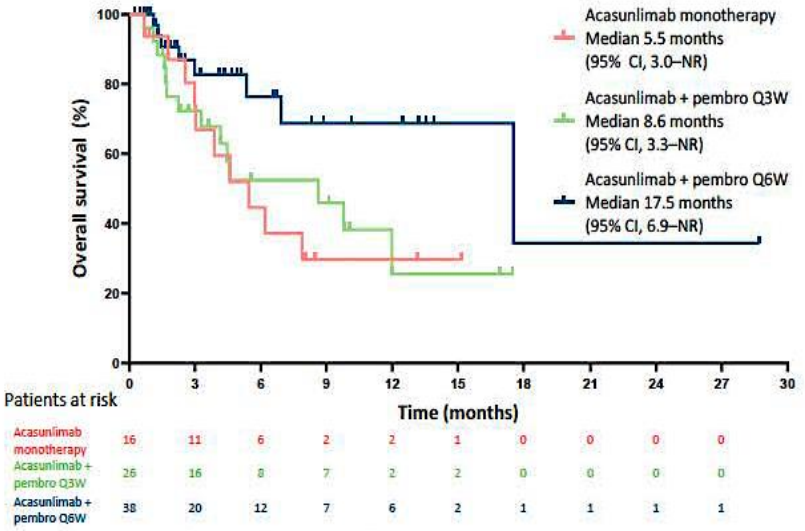
Aerts J et al. ASCO 2024.

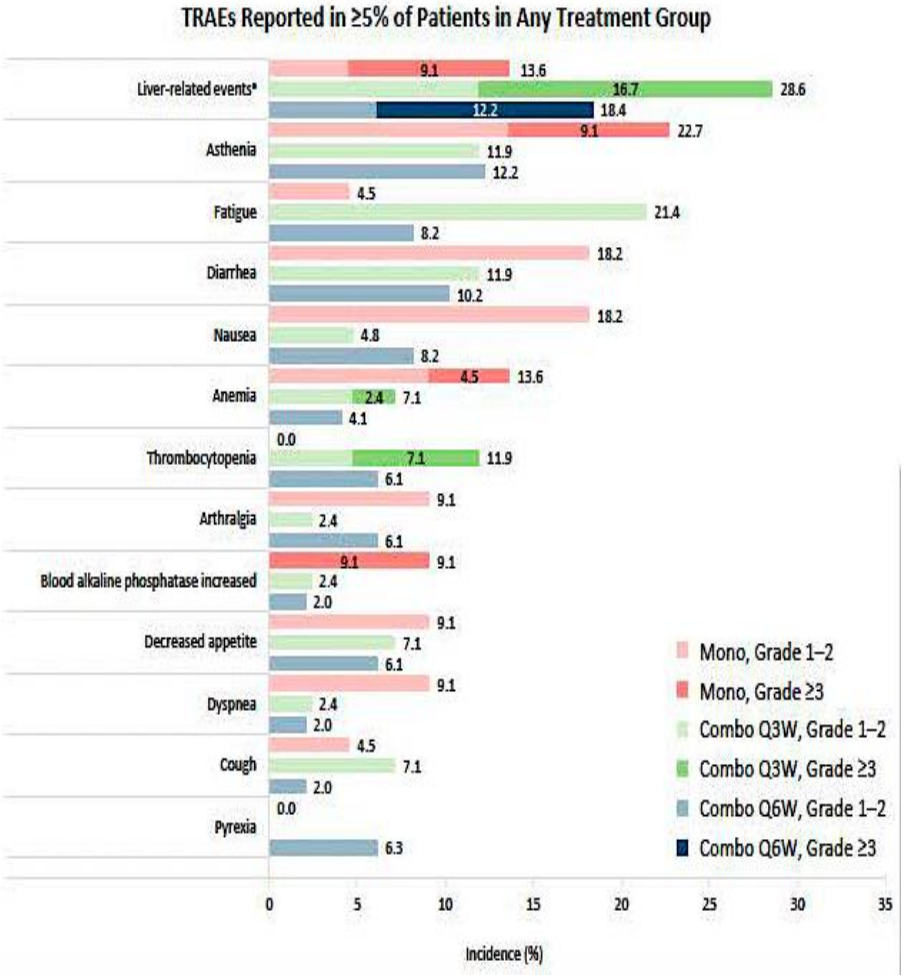
Acasunlimab (DuoBody PD-L1-4-1BB) alone or in combination with Pembrolizumab in pre-treated NSCLC (PD-L1 + subset)

	Acasunlimab Monotherapy	Acasunlimab + Pembro Q3W	Acasunlimab + Pembro Q6W
Unconfirmed ORR, % (n/n)	31.3 (5/16)	20.8 (5/24)	29.6 (8/27)
Confirmed ORR, % (n/n)	12.5 (2/16)	18.2 (4/22)	16.7 (4/24)
Confirmed DCR, % (n/n)	50.0 (8/16)	59.1 (13/22)	75.0 (18/24)
Median DOR, mo (95% CI)	2.0 (1.6–NR)	5.2 (3.5–NR)	NR (NR–NR)
6-month PFS rate, %	0	14	34
12-month OS rate, % (95% CI)	30 (9–54)	26 (6–52)	69 (43–85)

NR, not reached. Data cutoff: March 22, 2024. Centrally confirmed PD-L1+ patients are shown.







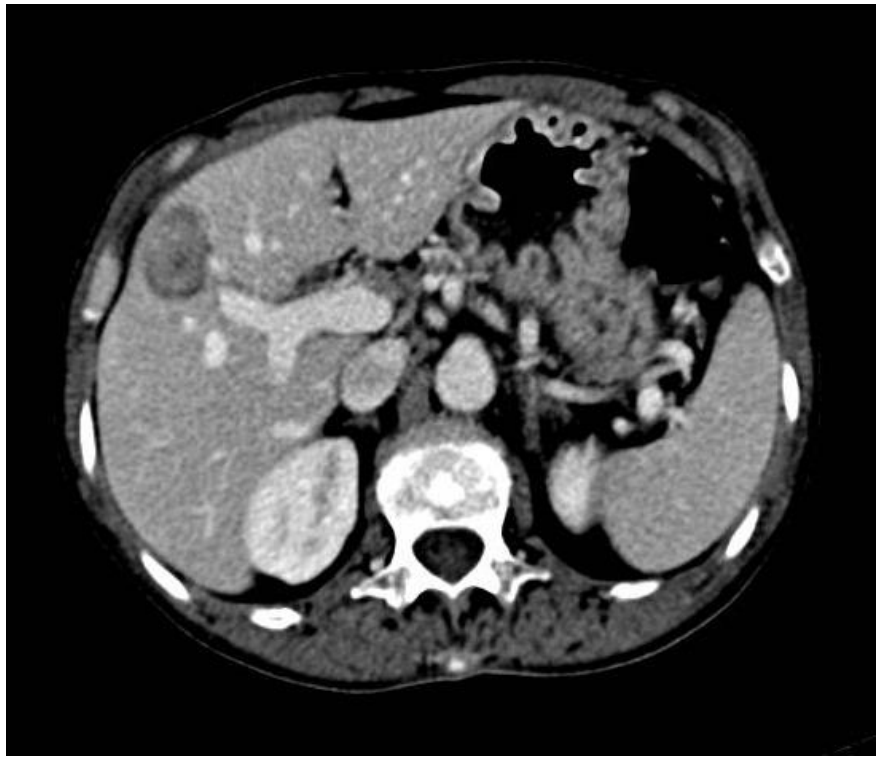
Aerts J et al. ASCO 2024.

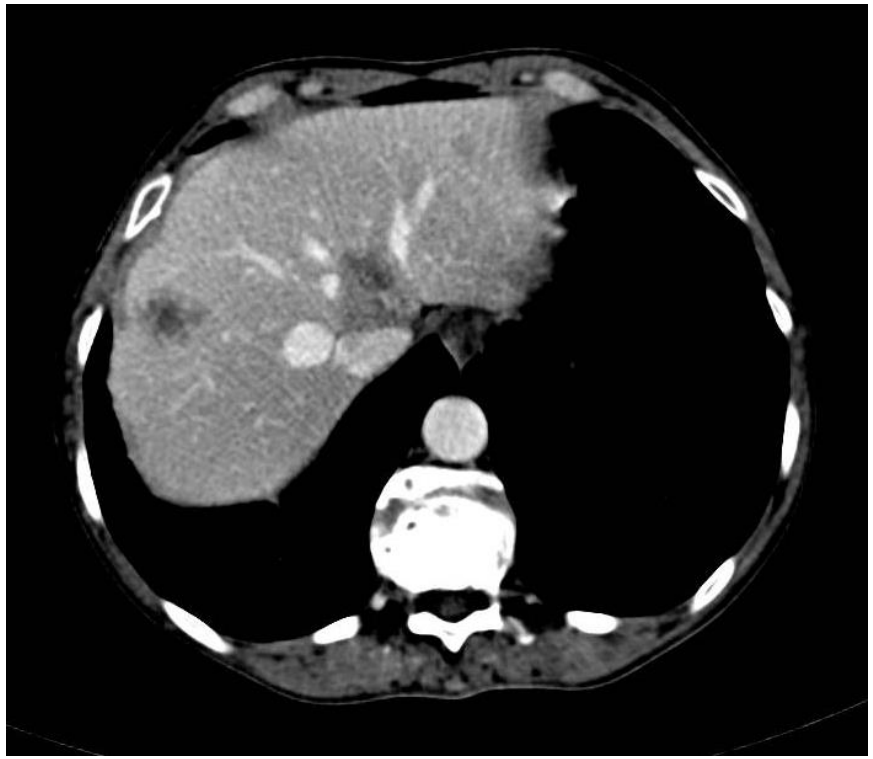
Questions?

Dr Paz-Ares: Clinical Case II

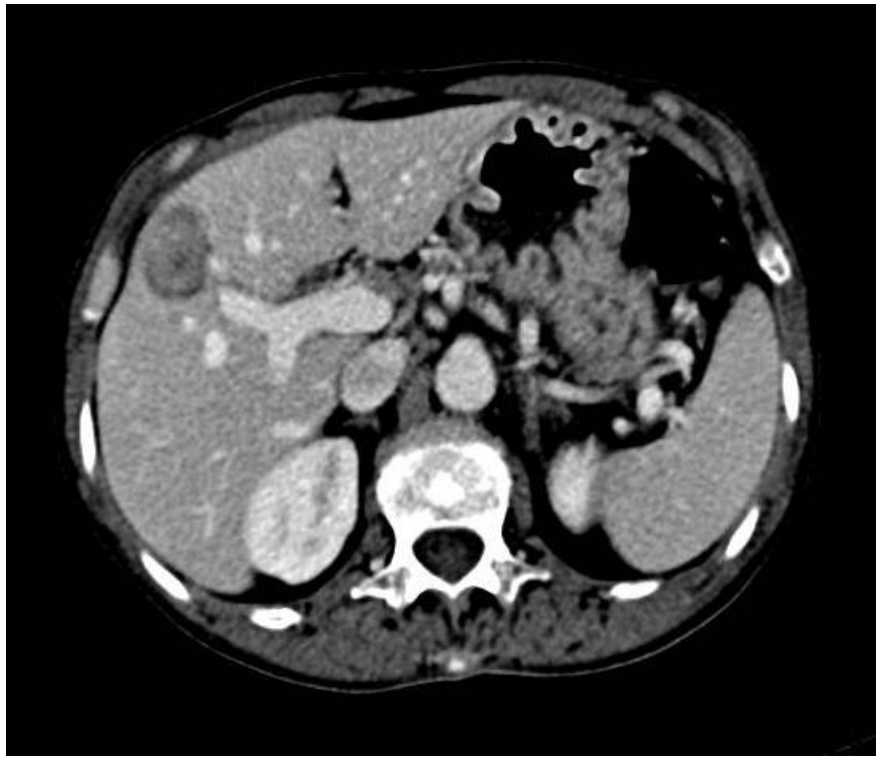
- 61 yo female
- PMH:
  - Prior smoker until 2018 (35 y/p)
  - Neurosensorial hypoacusia
- November 2018
  - Lung adenocarcinoma
  - Lobectomy (RUL) + Mediastinal Lymphadenectomy (R0)
  - Adenocarcinoma; NGS: P53 mutant, EGFR amplification
  - pT1b (1,2 cm) pN1 M0; PD-L1+ TPS 35%
  - Adjuvant treatment: Carboplatin-vinorelbine x 4
- March 2021
  - Systemic relapse (Liver, Brain)
  - WBRT
  - Carboplatin-Pemetrexed-Pembrolizumab x 2: PD (Liver)

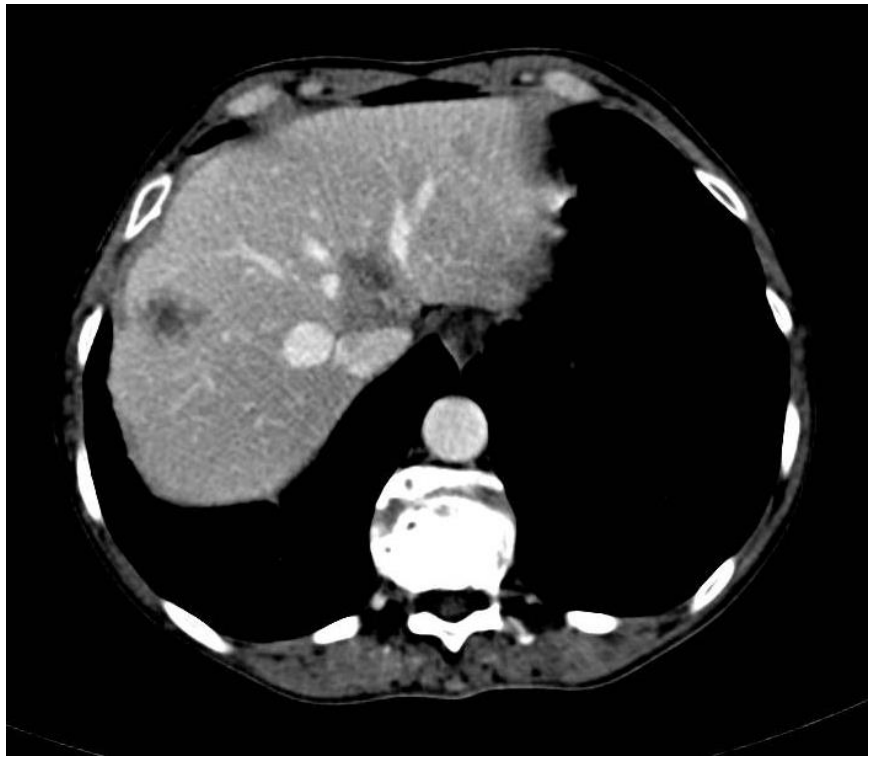
Dr Paz-Ares: Clinical Case II





Dr Paz-Ares: Clinical Case II

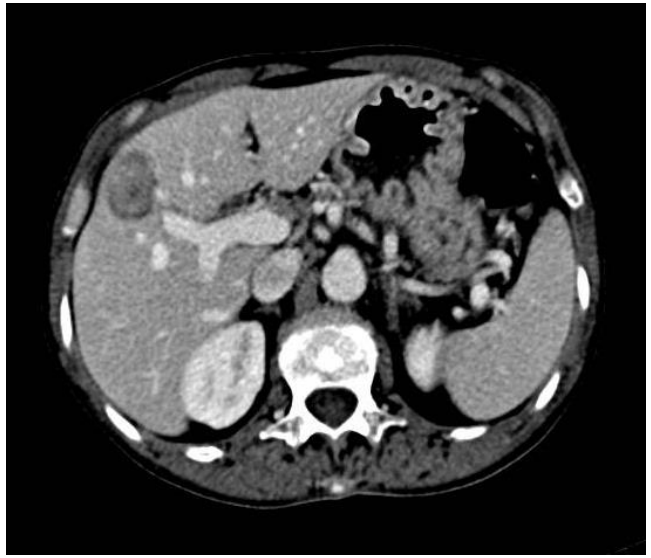


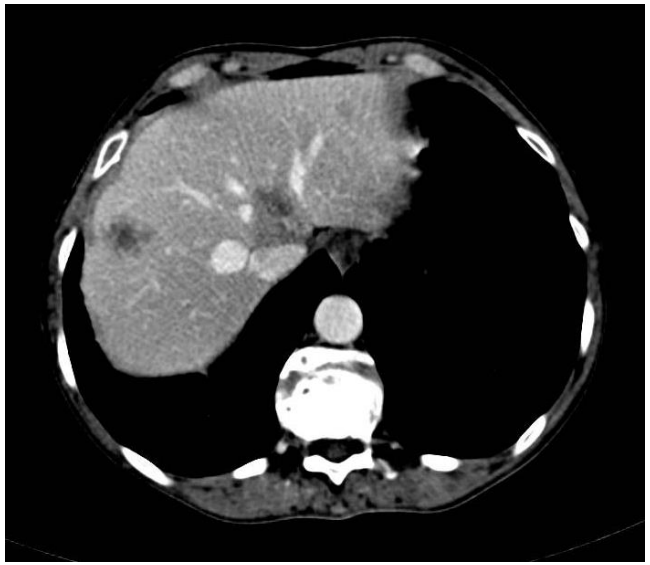


PD to 1L Chemo-IO: What would you do?

June

2021

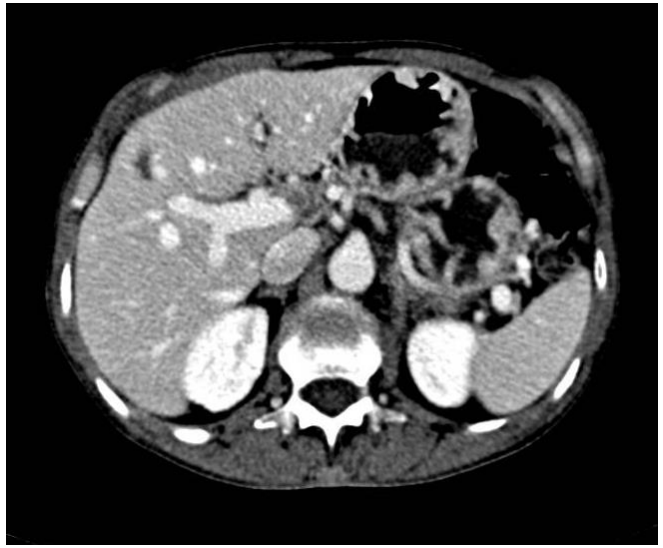


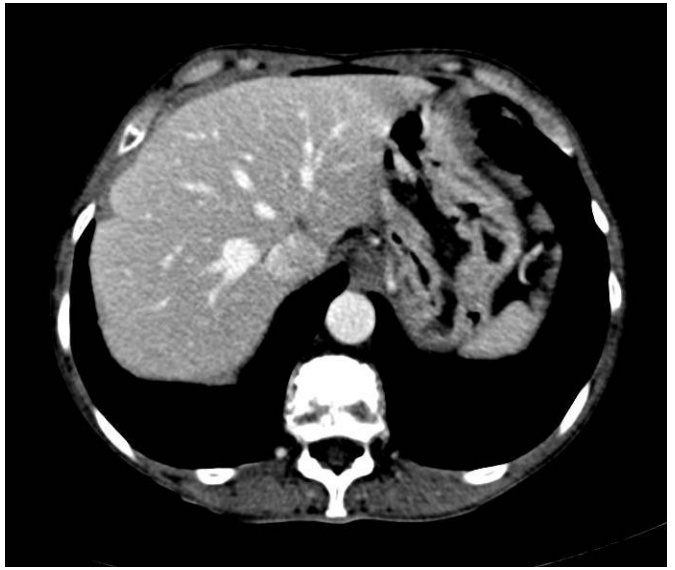


Datopotamab Deruxtecan x 4

October

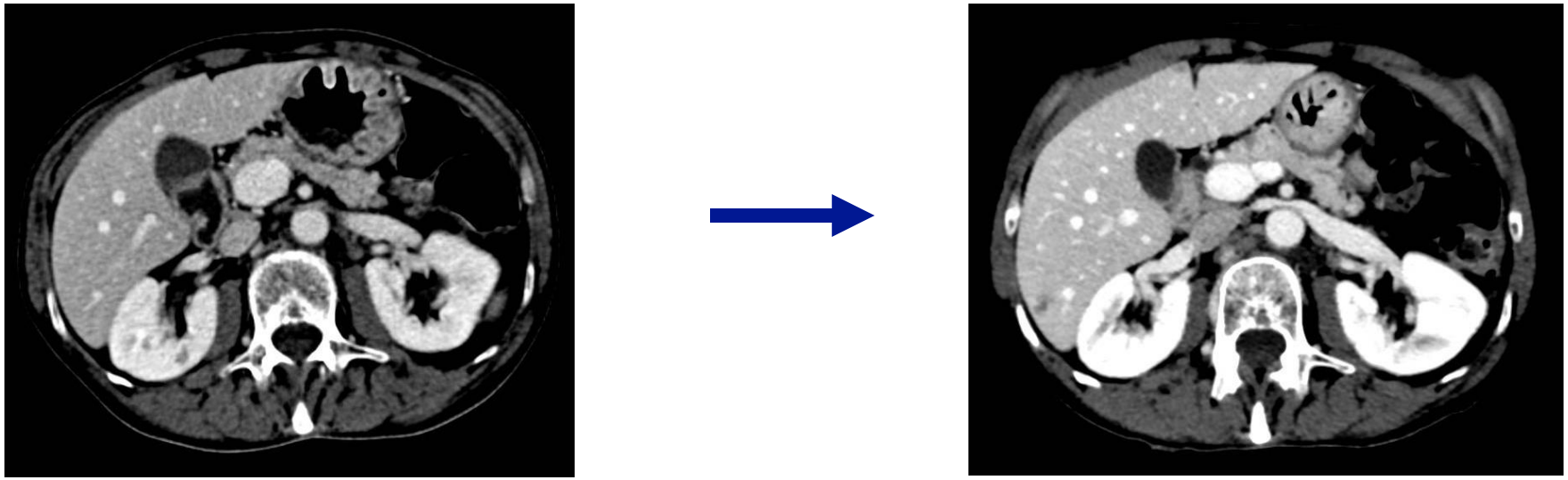
2021





Dr Paz-Ares: Clinical Case II

- **Follow Up**
  - 19 cycles up to August 22, 2022
  - Safety: G1 mucositis, Nausea and Grade 3 neutropenia



Dr Paz-Ares: Clinical Case II

- **Follow Up**
  - 19 cycles up to August 22, 2022
  - Safety: G1 mucositis, Nausea and Grade 3 neutropenia

- **Subsequent Therapy**
  - August 2022: Paclitaxel-Bevacizumab - PR
  - March 2023: Phase I trial - PD
  - July 2023: Gemcitabine - PD
  - September 2023: Vinorelbine NE
- **Exitus: December 2023**

Meet The Professor: Optimizing the Management of Chronic Lymphocytic Leukemia

A CME/MOC-Accredited Live Webinar

Tuesday, September 17, 2024
5:00 PM – 6:00 PM ET

Faculty

Matthew S Davids, MD, MMSc

Moderator

Neil Love, MD

RTP
RESEARCH TO PRACTICE

Thank you for joining us!

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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.

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