Meet The Professor

Current and Future Use of Nontargeted Therapy for Metastatic Non-Small Cell Lung Cancer — A 2024 World Conference on Lung Cancer Review

A CME/MOC-Accredited Live Webinar

Tuesday, November 19, 2024

5:00 PM – 6:00 PM ET

Faculty

Heather Wakelee, MD, FASCO

Moderator

Neil Love, MD

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Commercial Support

This activity is supported by educational grants from AstraZeneca Pharmaceuticals LP, Bristol Myers Squibb, Daiichi Sankyo Inc, Genmab US Inc, Gilead Sciences Inc, and Regeneron Pharmaceuticals Inc.

Dr Love — Disclosures

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Dr Wakelee — Disclosures
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Advisory Committees	BeiGene Ltd, GSK, IO Biotech, OncoC4
Consulting Agreements (All Unpaid)	AstraZeneca Pharmaceuticals LP, Bristol Myers Squibb, Genentech, a member of the Roche Group, Merck
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This educational activity contains discussion of non-FDA-approved uses of agents and regimens. Please refer to official prescribing information for each product for approved indications.

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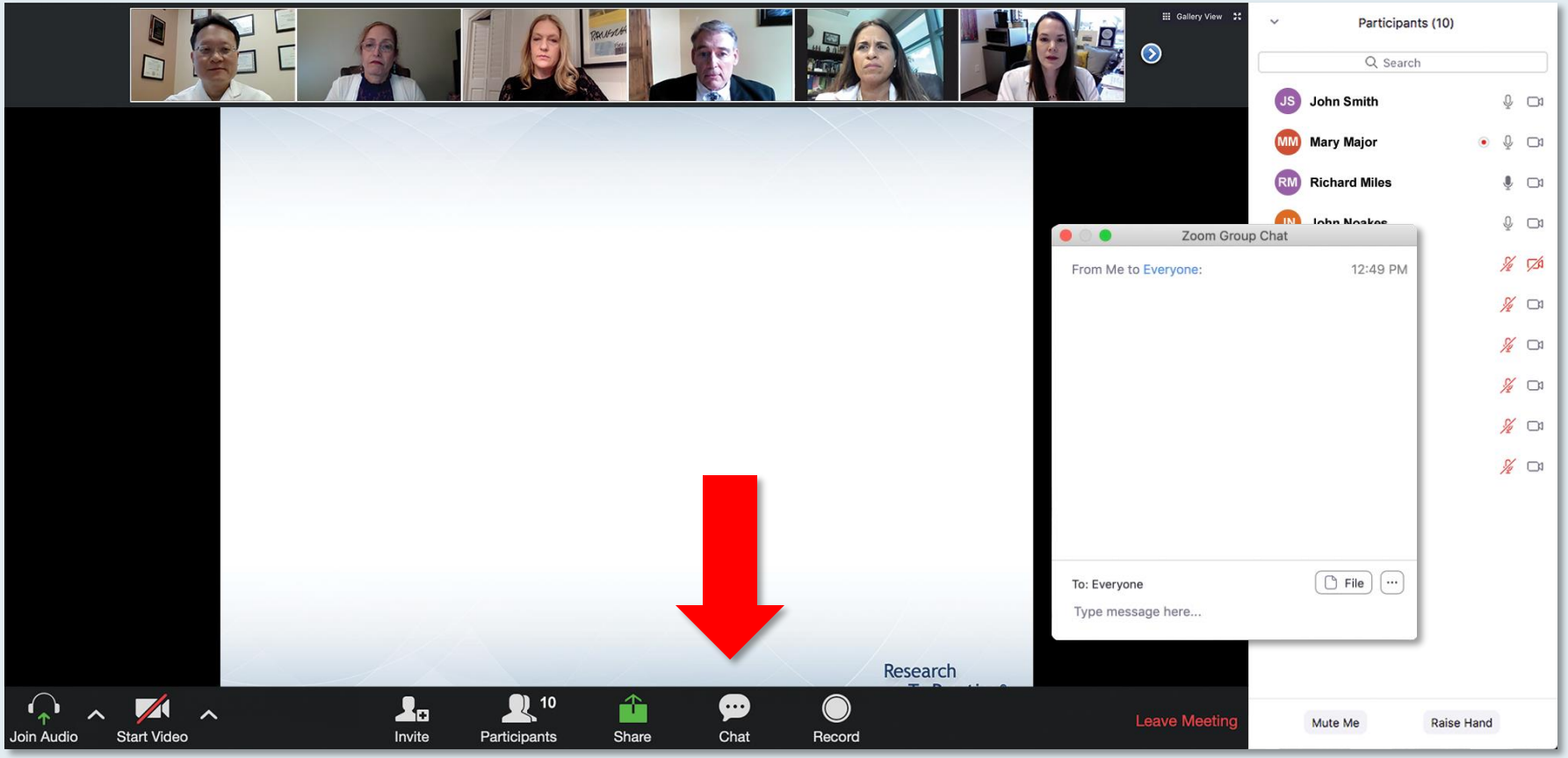
We Encourage Clinicians in Practice to Submit Questions



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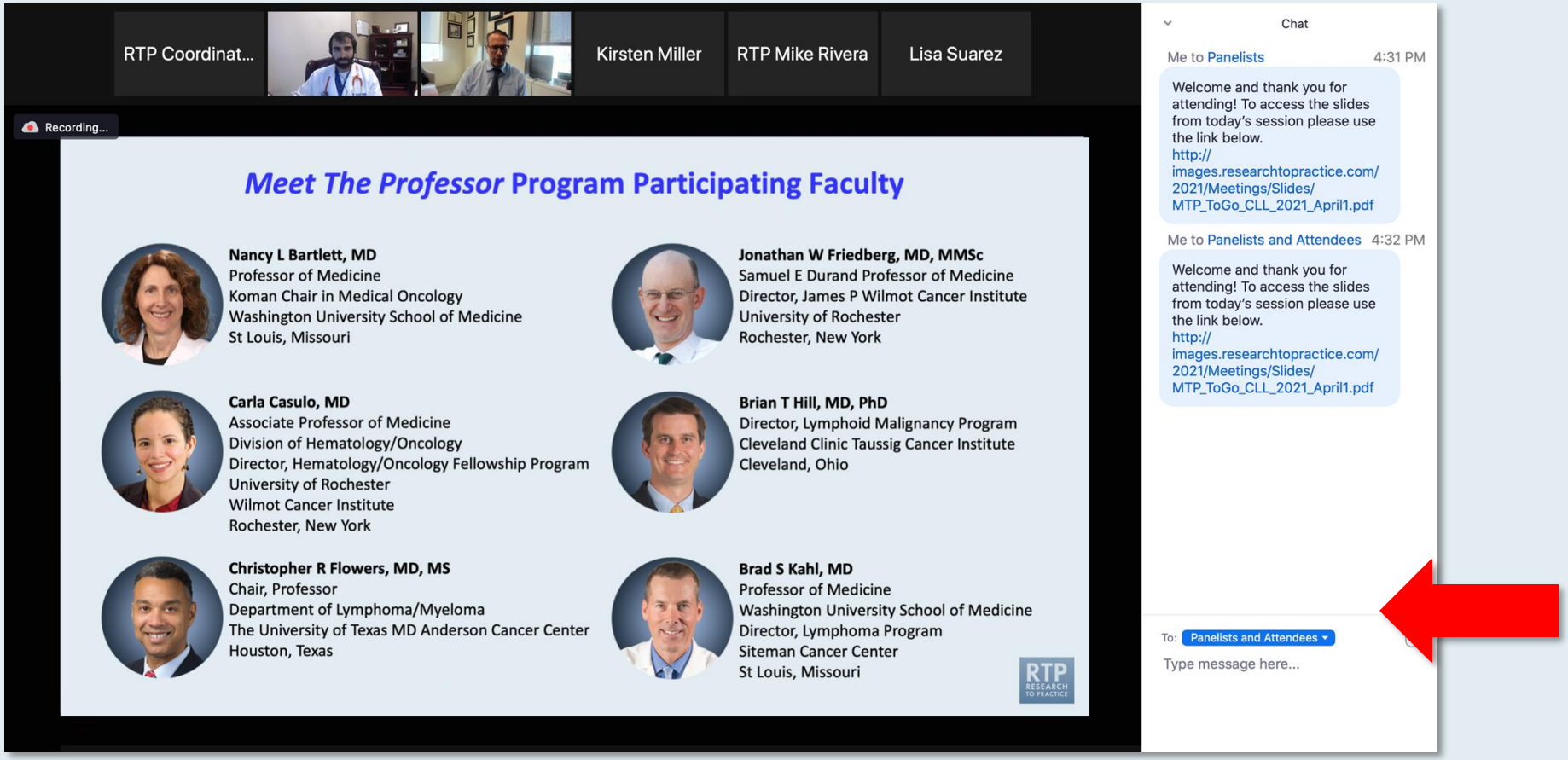
Familiarizing Yourself with the Zoom Interface

Expand chat submission box



Drag the white line above the submission box up to create more space for your message.

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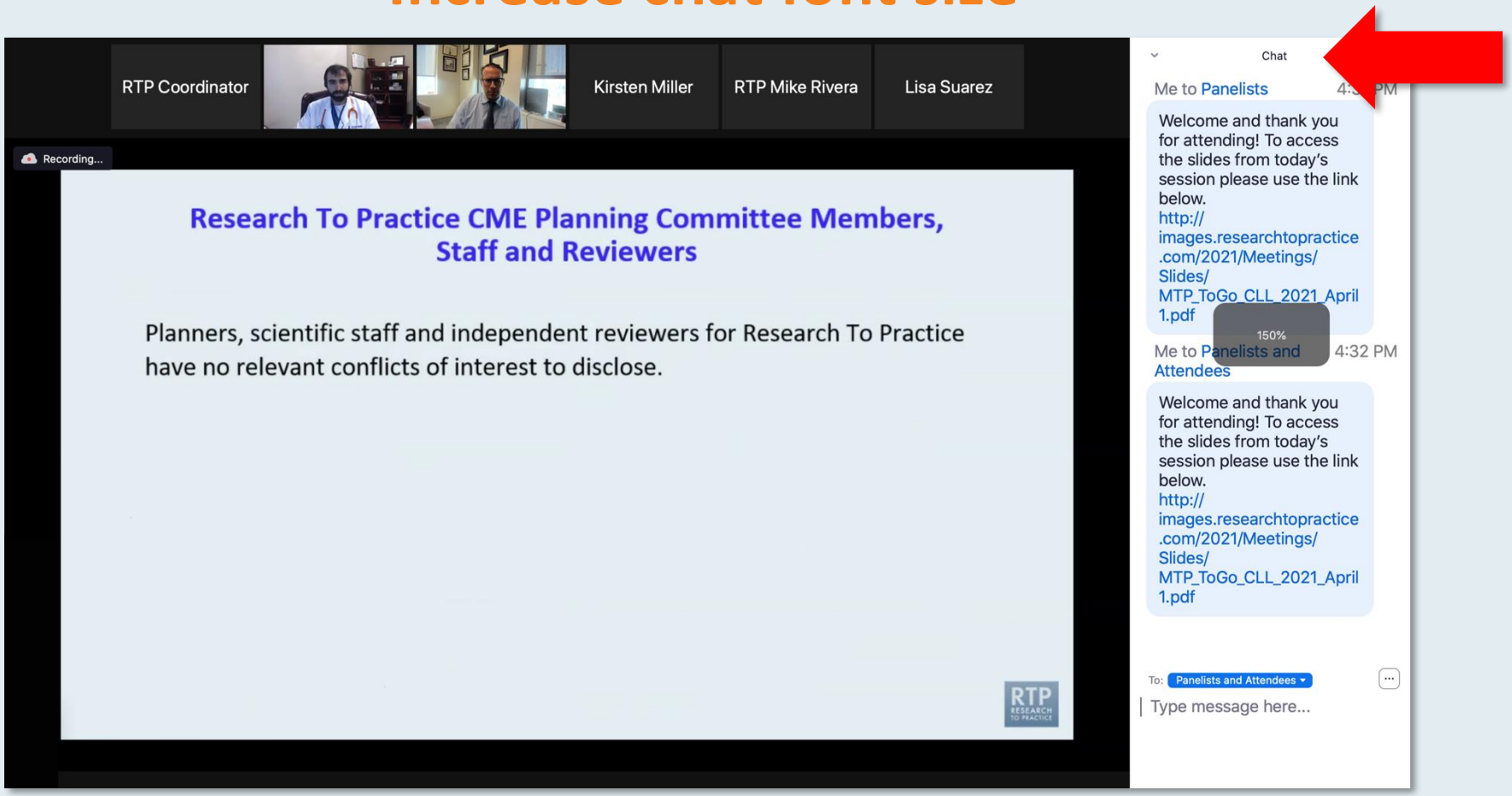
Increase chat font size



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You may do this as many times as you need for readability.

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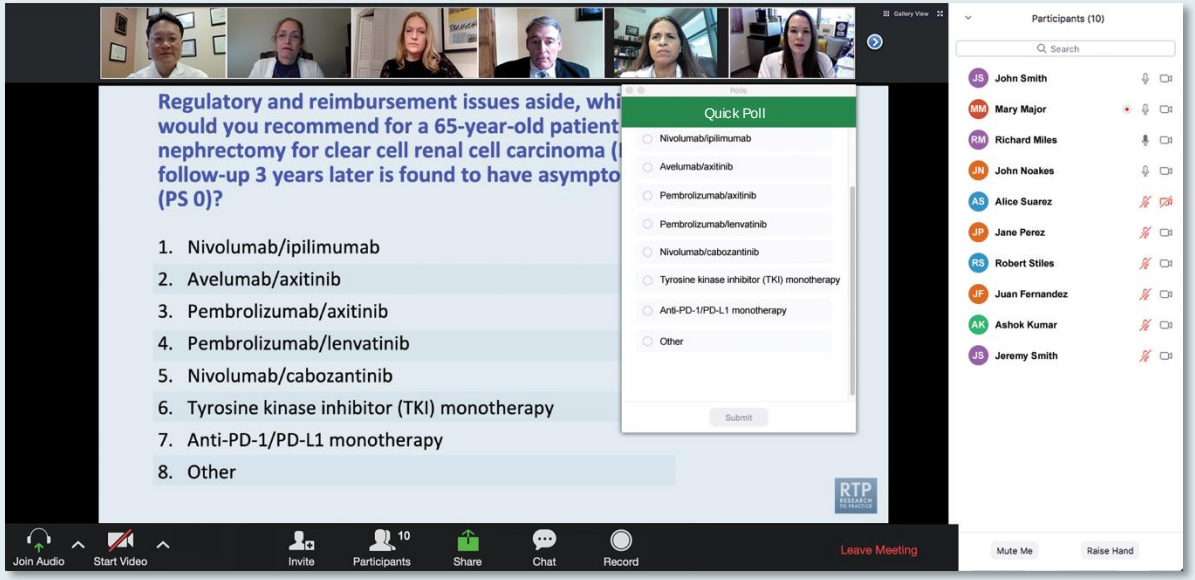

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WITH DR NEIL LOVE

Special Edition — Key Presentations on Lung Cancer from Recent Major Conferences

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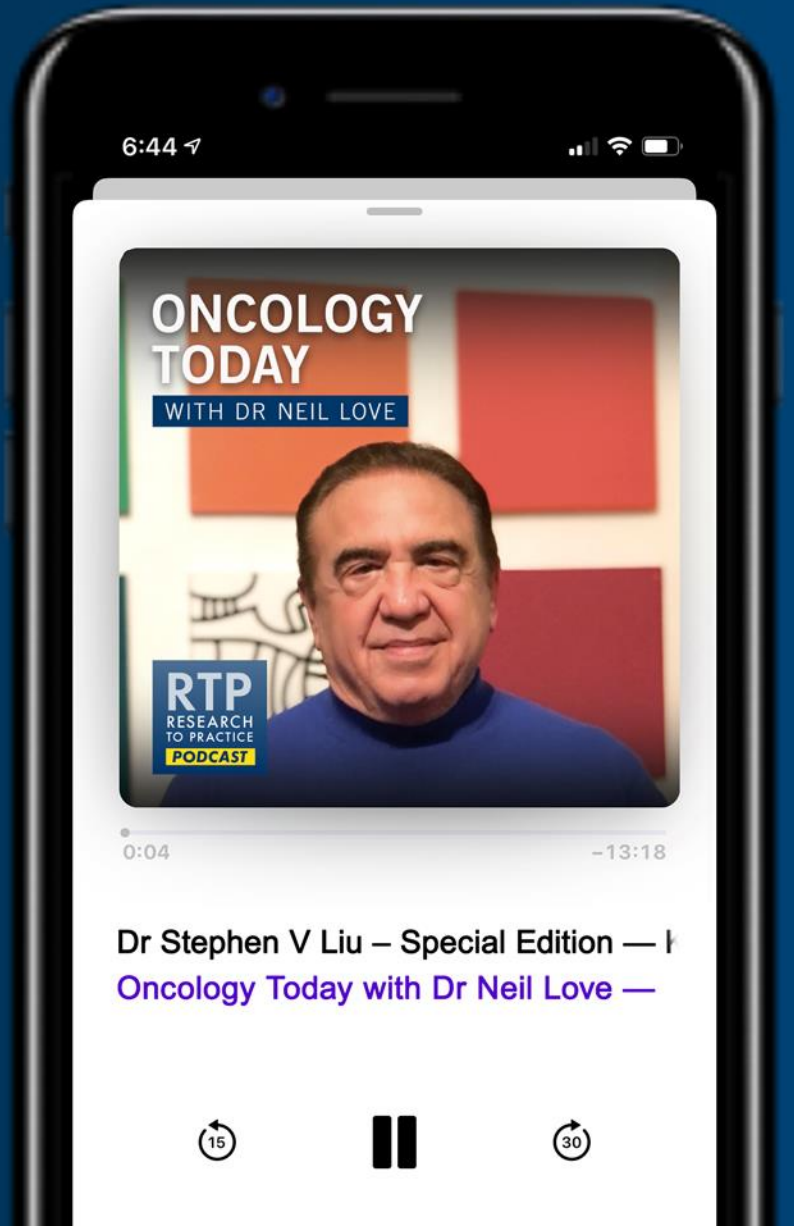

What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Hematologic Cancers

A CME Friday Satellite Symposium and Webcast Series
Preceding the 66th ASH Annual Meeting and Exposition

Friday, December 6, 2024

Chronic Myeloid Leukemia
7:30 AM – 9:00 AM PT

Chronic Lymphocytic Leukemia
7:30 AM – 9:30 AM PT

CAR T-Cell Therapy and Bispecific Antibodies in Lymphoma
11:30 AM – 1:30 PM PT

Myelofibrosis
11:30 AM – 1:30 PM PT

Acute Myeloid Leukemia
3:15 PM – 5:15 PM PT

Multiple Myeloma
3:15 PM – 5:15 PM PT

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Rounds with the Investigators: Compelling Teaching Cases Focused on the Management of Breast Cancer

A 3-Part CME Hybrid Satellite Symposium Series in Partnership with the 2024 San Antonio Breast Cancer Symposium®

HER2-Low and HER2-Ultralow Breast Cancer

Tuesday, December 10, 2024

7:15 PM – 8:45 PM CT

New Developments in Endocrine Treatment for Breast Cancer

Wednesday, December 11, 2024

7:15 PM – 9:15 PM CT

Management of Metastatic Breast Cancer

Thursday, December 12, 2024

7:00 PM – 9:00 PM CT

Moderator

Neil Love, MD

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Save The Date

Fourth Annual
National General Medical Oncology Summit

A Multitumor CME/MOC-, NCPD- and ACPE-Accredited Educational Conference Developed in Partnership with Florida Cancer Specialists & Research Institute

Friday to Sunday, February 28 to March 2, 2025

Fontainebleau Hotel, Miami Beach, Florida

Moderated by Neil Love, MD

Thank you for joining us!

Information on how to obtain CME and ABIM MOC credit will be provided at the conclusion of the activity in the Zoom chat room. Attendees will also receive an email in 1 to 3 business days with these instructions.

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Professor of Medicine/Chief, Division of Oncology

Stanford University School of Medicine

Deputy Director, Stanford Cancer Institute

Stanford, California

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Winston Chen and Phyllis Huang Professor
Professor of Medicine/Chief, Division of Oncology
Stanford University School of Medicine
Deputy Director, Stanford Cancer Institute
Past President, International Association for the Study of Lung Cancer (IASLC)
Stanford, California

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

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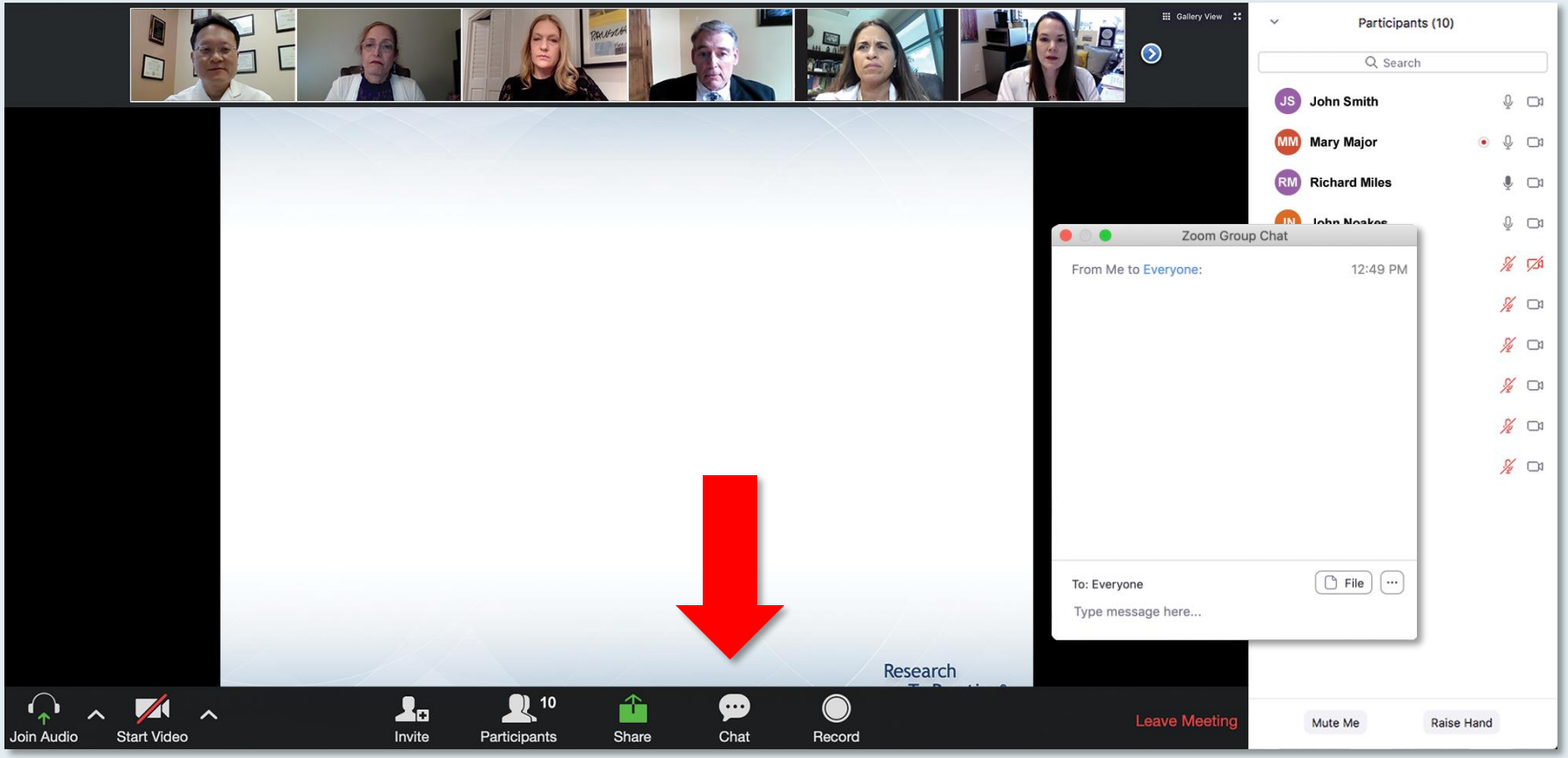

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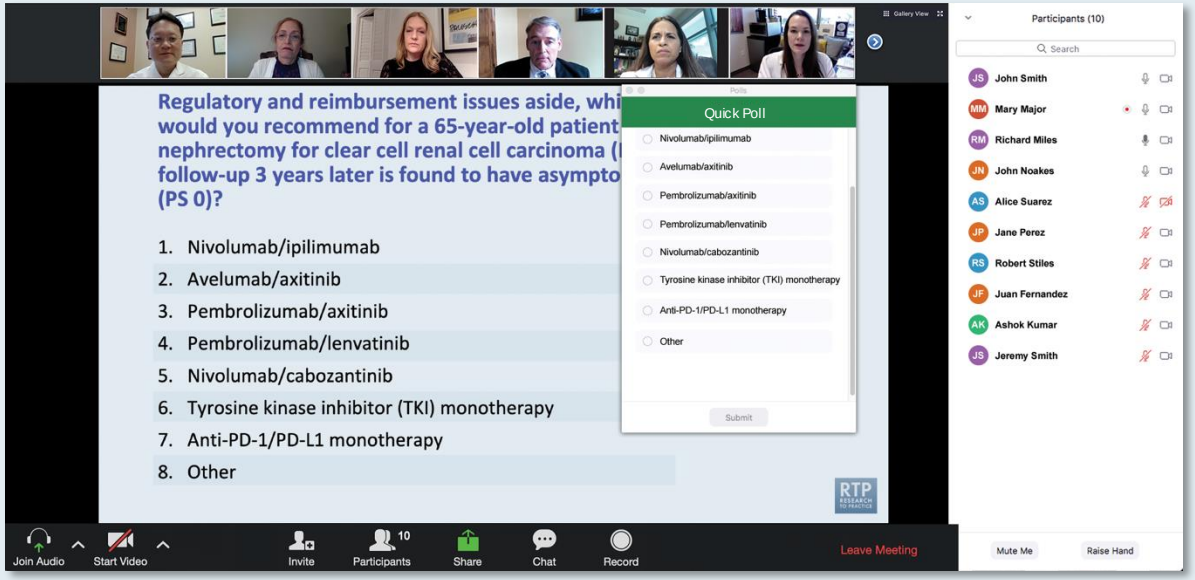

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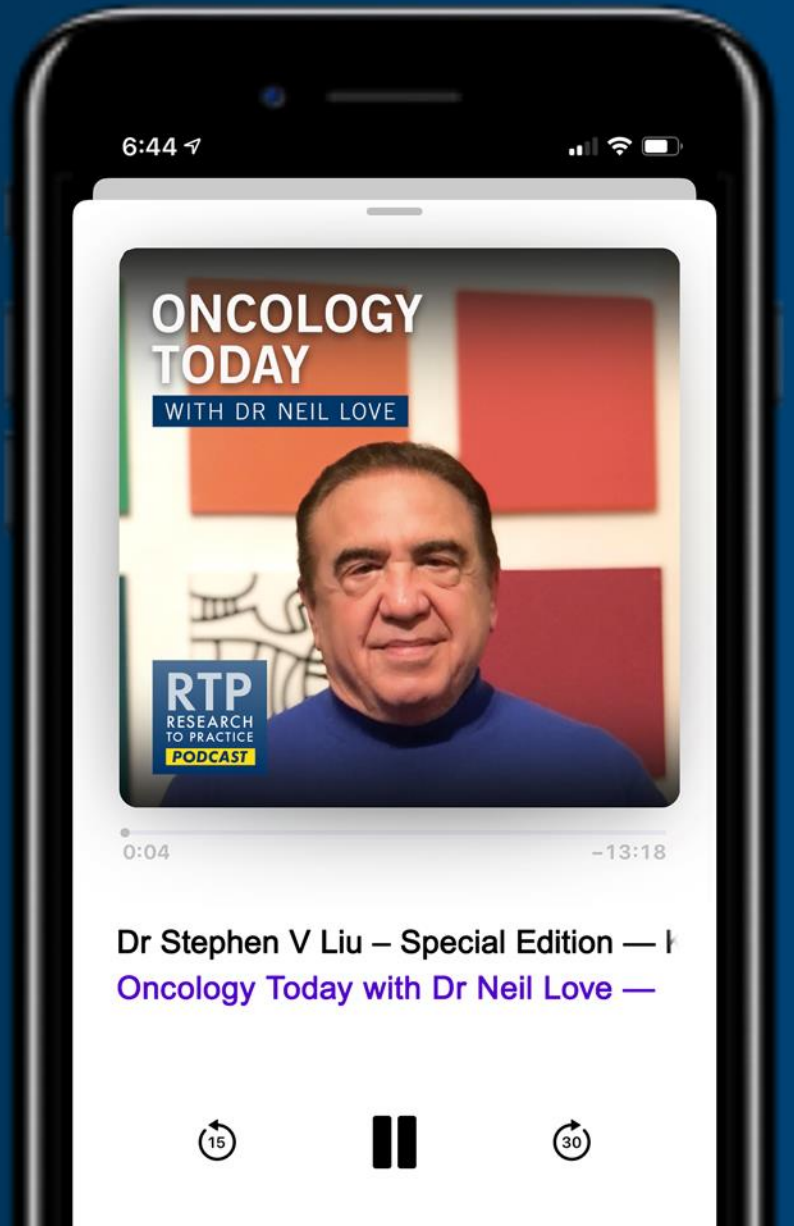

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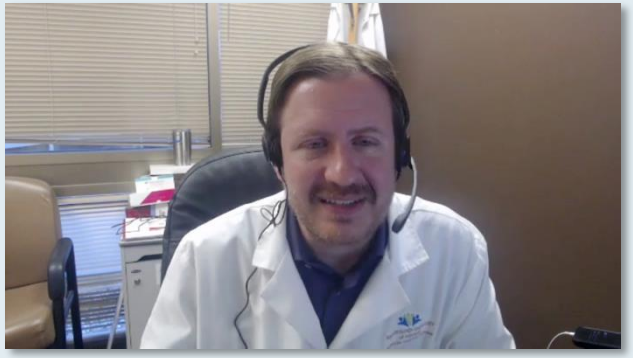
Contributing General Medical Oncologists

Zanetta S Lamar, MD
Florida Oncology and Hematology
American Oncology Partners
Naples, Florida

Taral Patel, MD
Zangmeister Cancer Center
Columbus, Ohio



Brian P Mulherin, MD
Hematology Oncology of Indiana
Indianapolis, Indiana

Priya Rudolph, MD, PhD
Georgia Cancer Specialists
Athens, Georgia

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Meet The Professor with Dr Wakelee

Module 1: Case Presentations – Part 1

Module 2: Current and Emerging Immunotherapeutic Strategies for Metastatic Non-Small Cell Lung Cancer (mNSCLC)

Module 3: Case Presentations – Part 2

Module 4: Antibody-Drug Conjugates and Other Management Approaches for mNSCLC without Actionable Genomic Alterations

Module 5: Case Presentations – Part 3

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Module 1: Case Presentations – Part 1

- Dr Mulherin: 59-year-old man with metastatic carcinoma of the lung, no AGA, PD-L1-negative
- Dr Patel: 62-year-old man with metastatic squamous cell carcinoma of the lung, PD-L1-negative
- Dr Rudolph: 67-year-old man presenting with metastatic adenocarcinoma of the lung, multiple bone metastases, no AGA; PD-L1 20%; enrolled on ECOG-EA5163

Dr Brian P Mulherin
(Indianapolis, Indiana)

Case Presentation: 59-year-old man with metastatic carcinoma of the lung, no AGA , PD-L1-negative

Dr Taral Patel
(Columbus, Ohio)

Case Presentation: 62-year-old man with metastatic squamous cell carcinoma of the lung, PD-L1-negative

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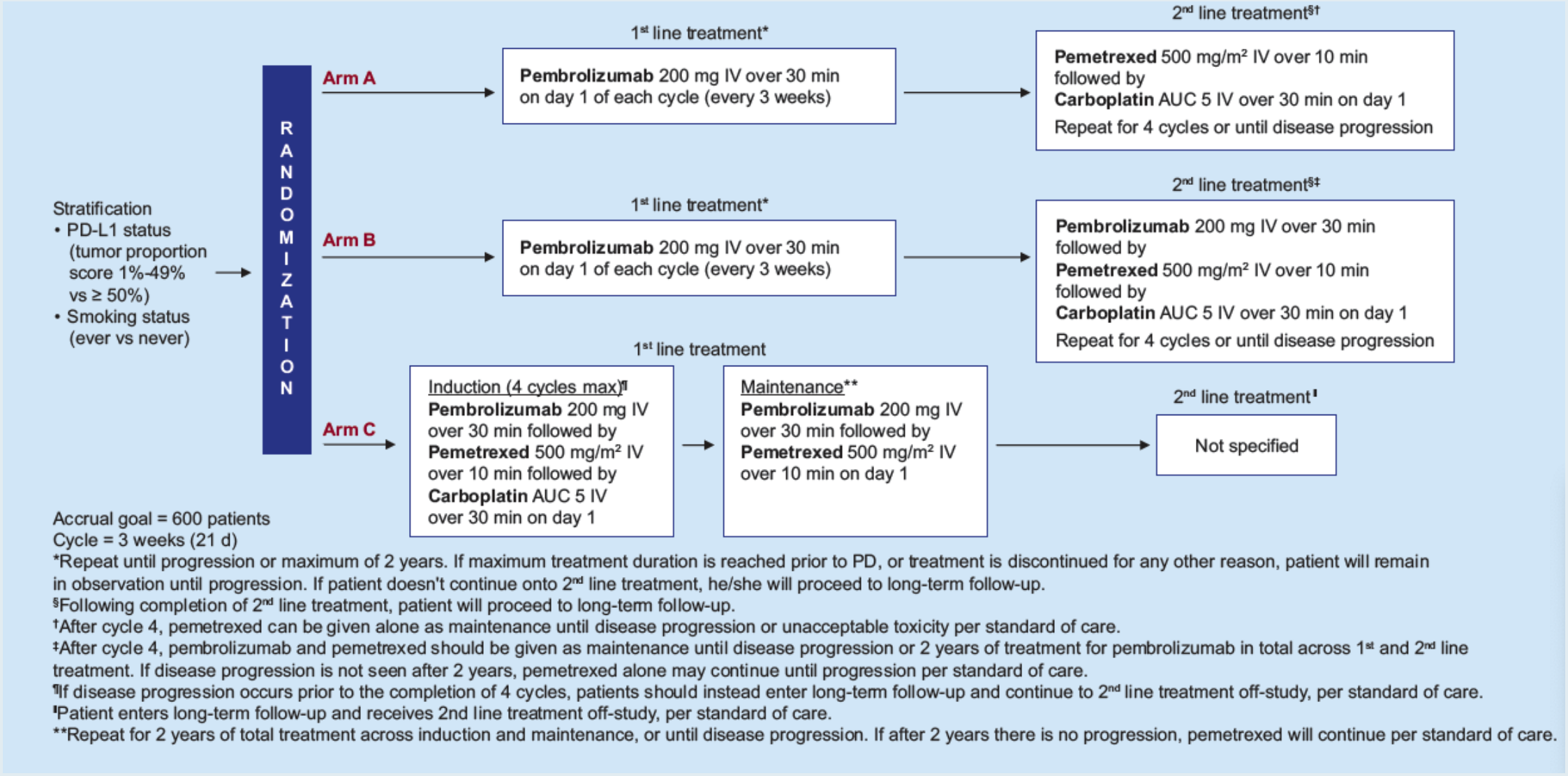
ECOG-EA5163/INSIGNA Phase III Trial Design



Accrual goal = 600 patients
Cycle = 3 weeks (21 d)

*Repeat until progression or maximum of 2 years. If maximum treatment duration is reached prior to PD, or treatment is discontinued for any other reason, patient will remain in observation until progression. If patient doesn't continue onto 2nd line treatment, he/she will proceed to long-term follow-up.

§Following completion of 2nd line treatment, patient will proceed to long-term follow-up.

†After cycle 4, pemetrexed can be given alone as maintenance until disease progression or unacceptable toxicity per standard of care.

‡After cycle 4, pembrolizumab and pemetrexed should be given as maintenance until disease progression or 2 years of treatment for pembrolizumab in total across 1st and 2nd line treatment. If disease progression is not seen after 2 years, pemetrexed alone may continue until progression per standard of care.

¶If disease progression occurs prior to the completion of 4 cycles, patients should instead enter long-term follow-up and continue to 2nd line treatment off-study, per standard of care.

‖Patient enters long-term follow-up and receives 2nd line treatment off-study, per standard of care.

**Repeat for 2 years of total treatment across induction and maintenance, or until disease progression. If after 2 years there is no progression, pemetrexed will continue per standard of care.

AUC = area under curve; PD = progressive disease

https://ecog-acrin.org/wp-content/uploads/2021/03/EA5163-pocket-reference-card.pdf.

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Case Presentation: 67-year-old man presenting with metastatic adenocarcinoma of the lung, multiple bone metastases, no AGA; PD-L1 20%; enrolled on ECOG-EA5163

Dr Priya Rudolph (Athens, Georgia)

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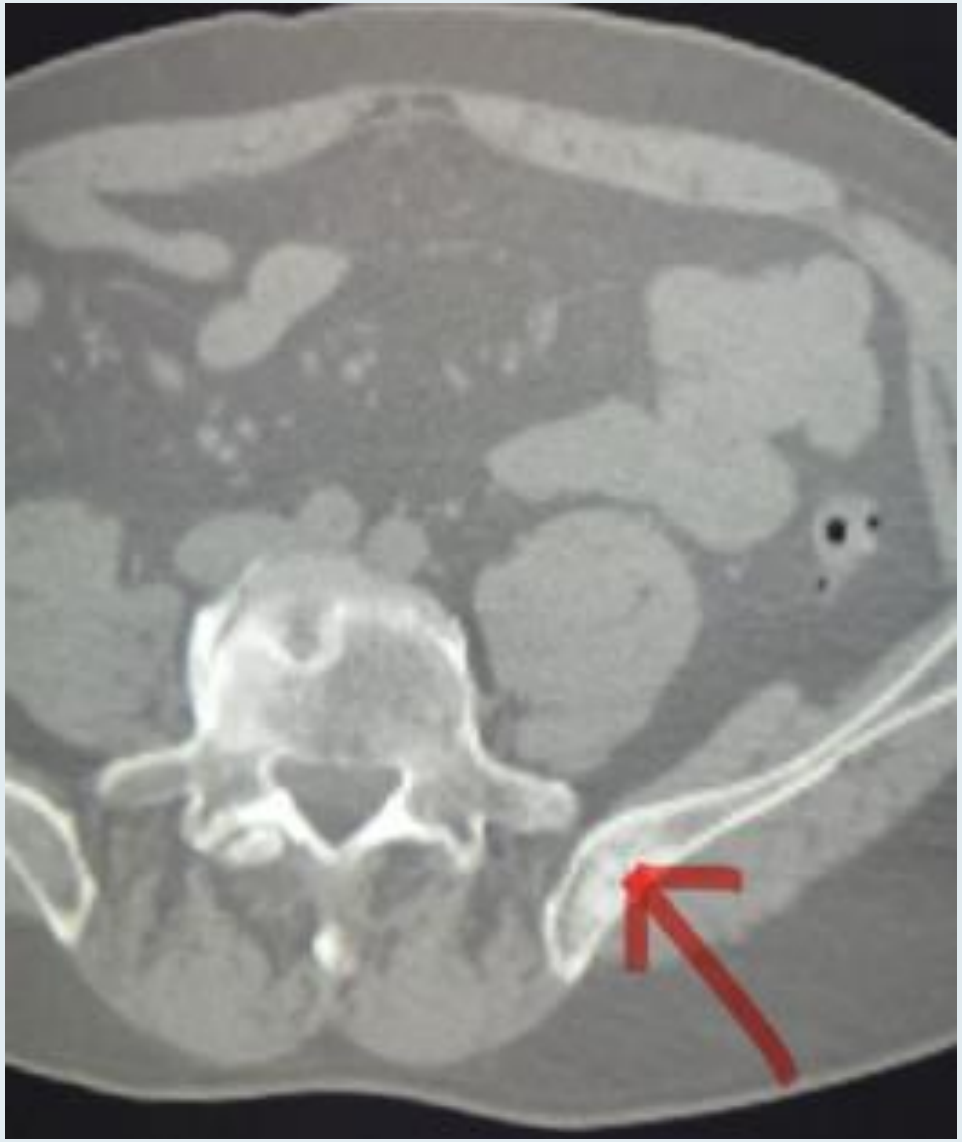
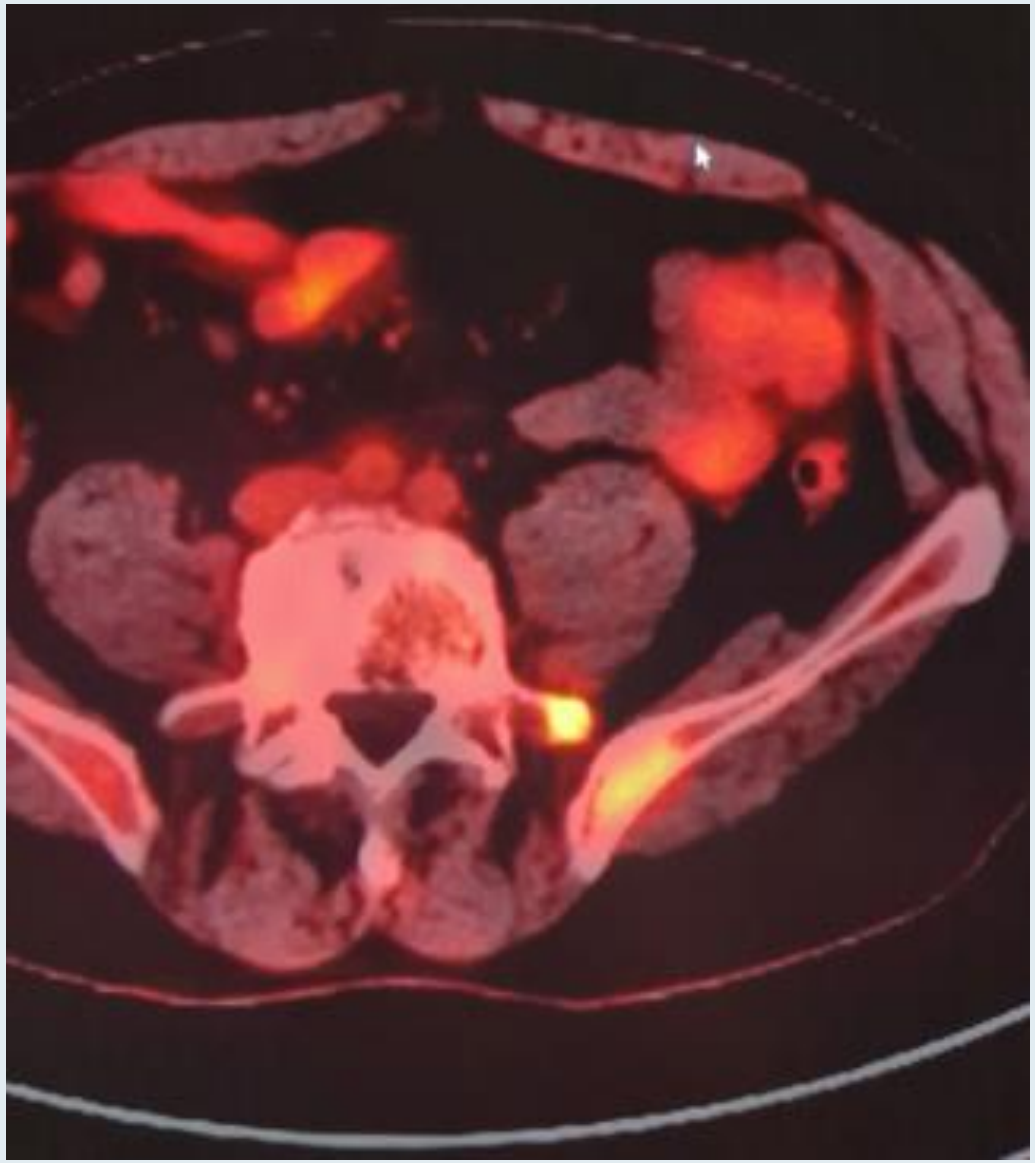
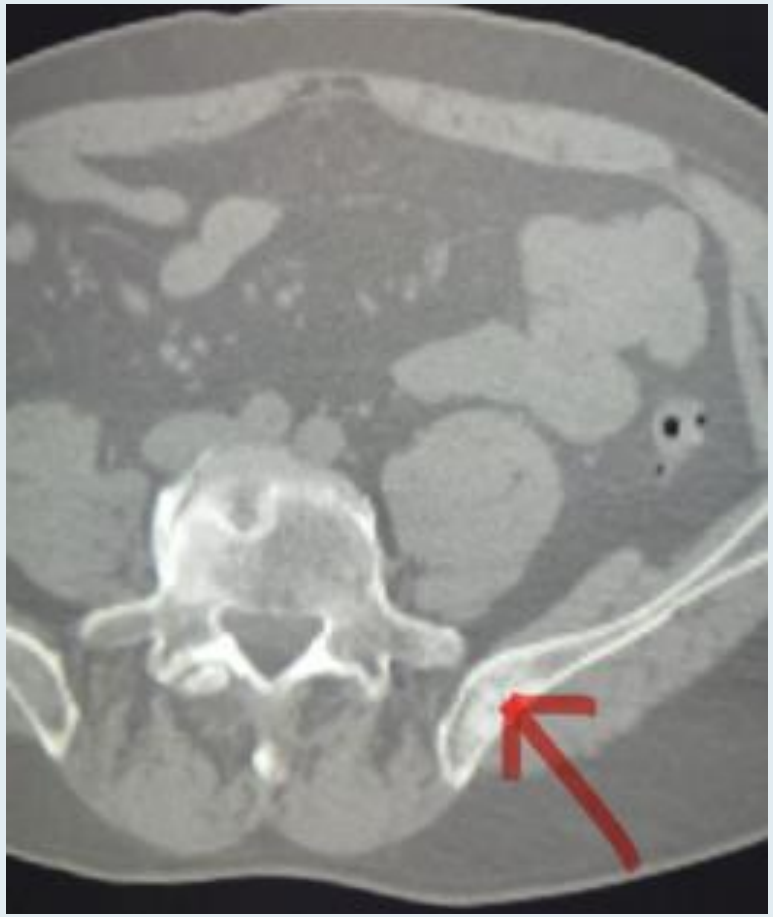
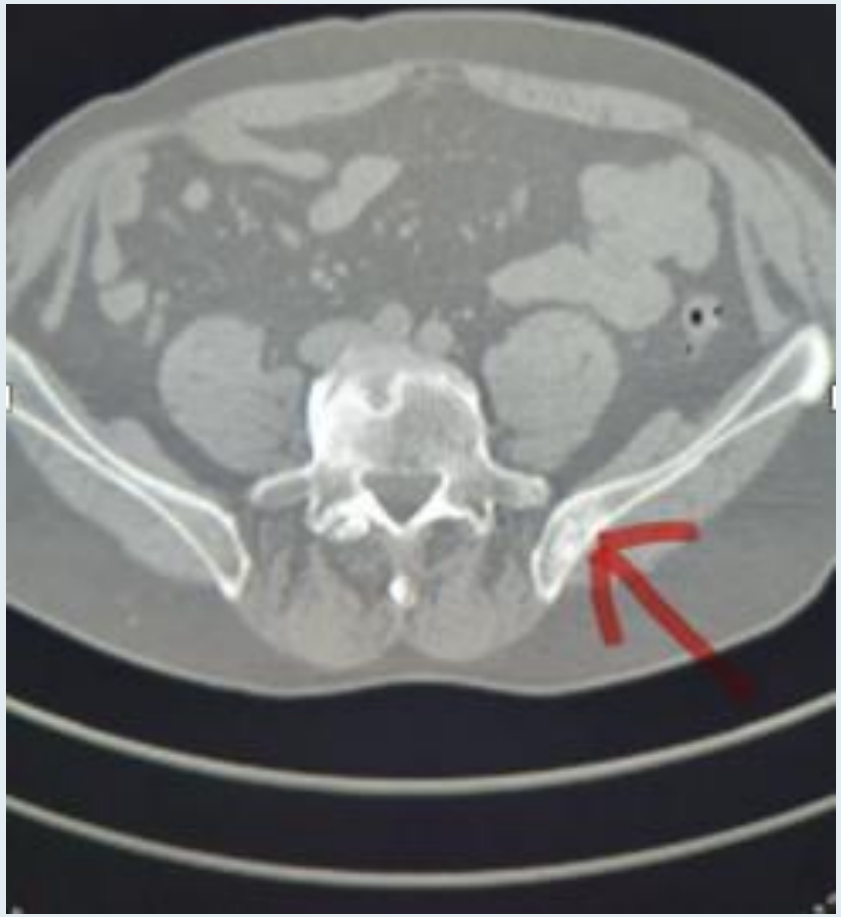




Pretreatment



Post-treatment



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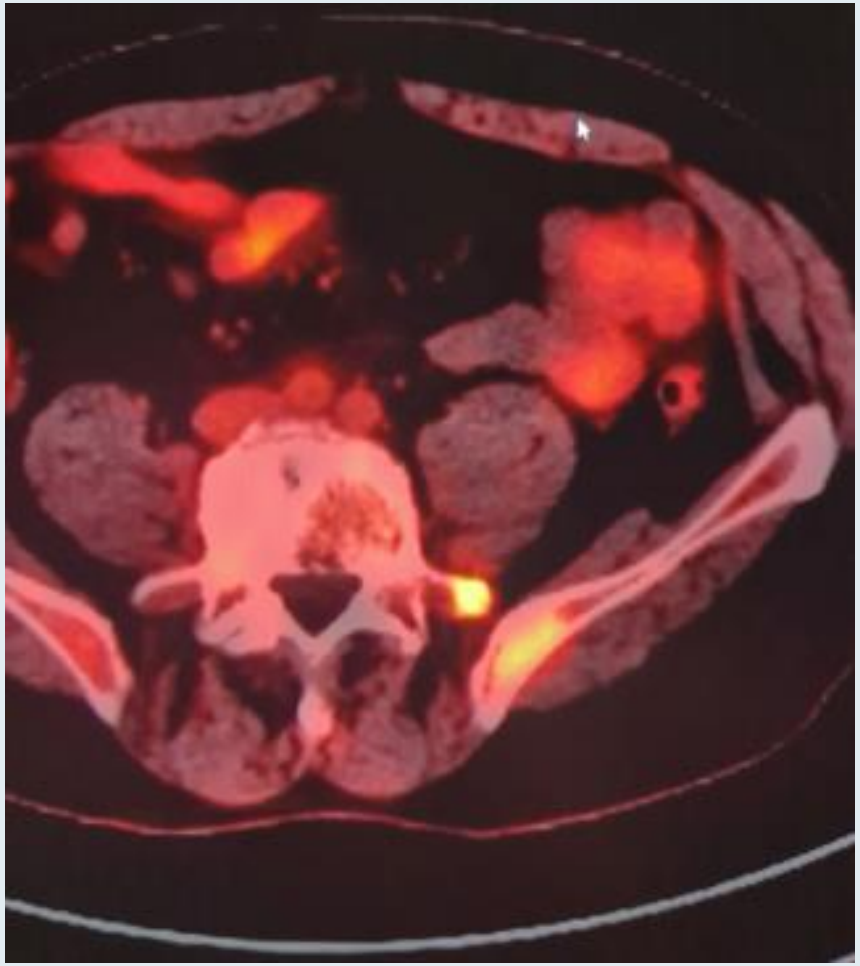

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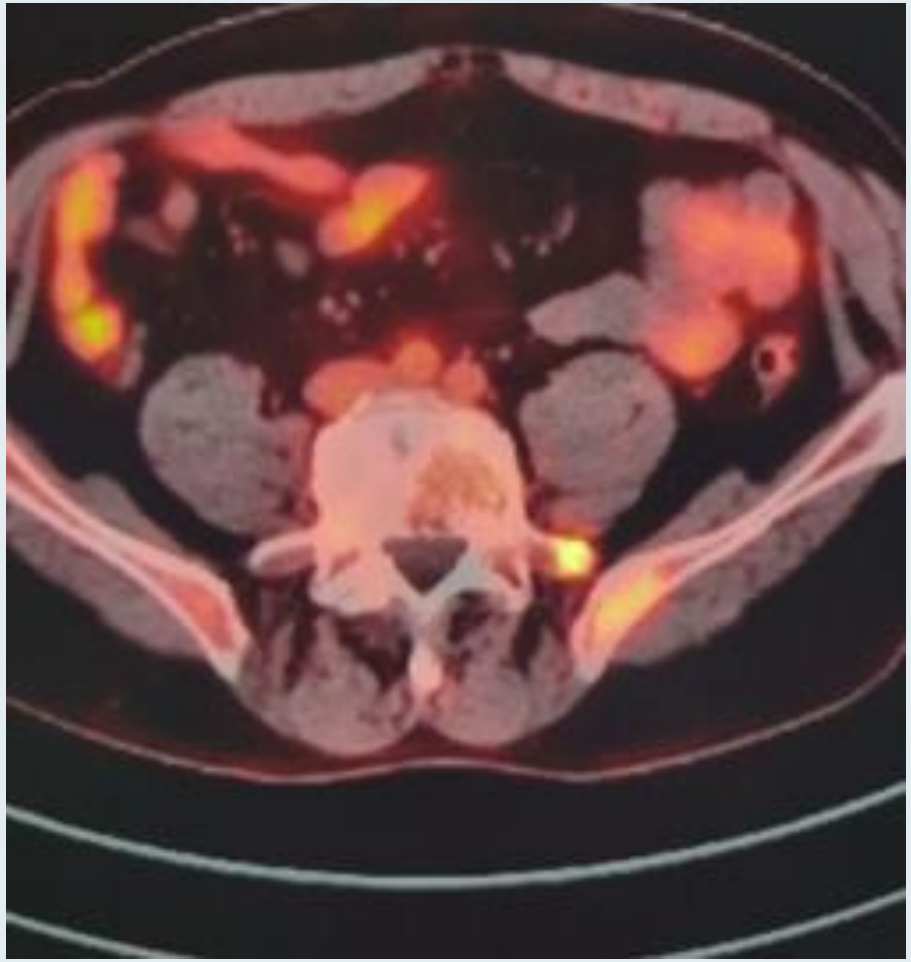

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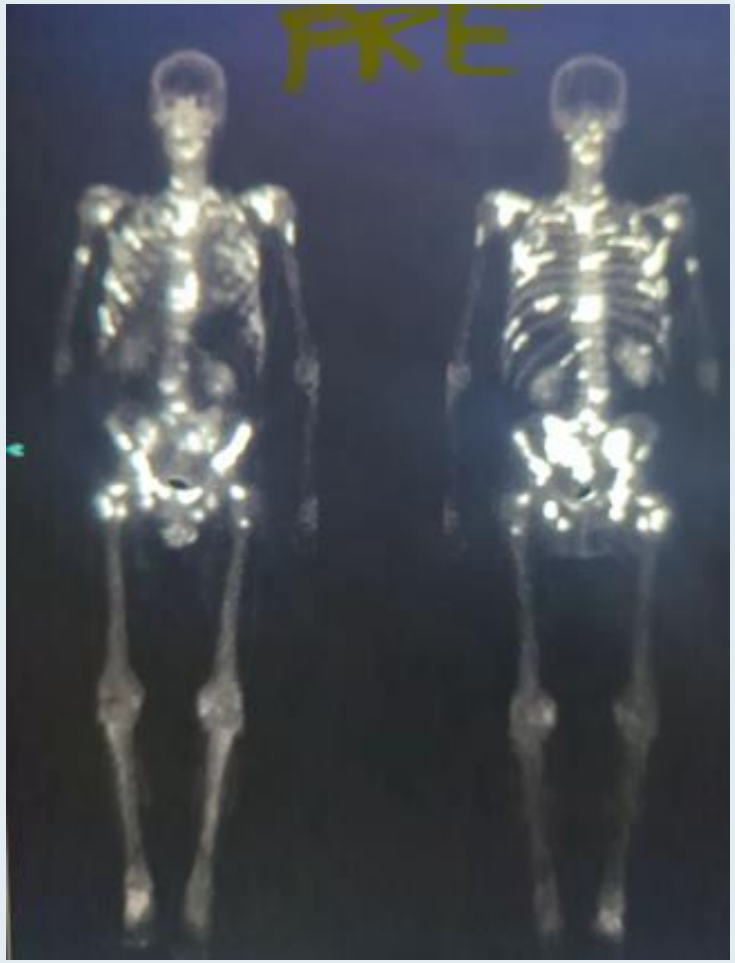

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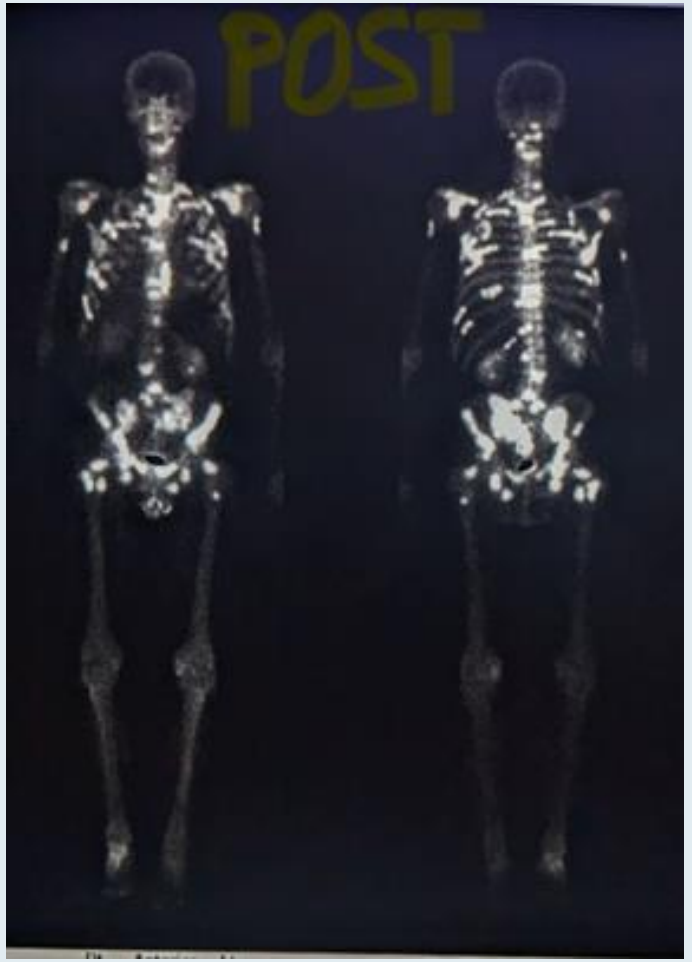

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Case Presentation: 67-year-old man presenting with metastatic adenocarcinoma of the lung, multiple bone metastases, no AGA; PD-L1 20%; enrolled on ECOG-EA5163 (continued)

Dr Priya Rudolph (Athens, Georgia)

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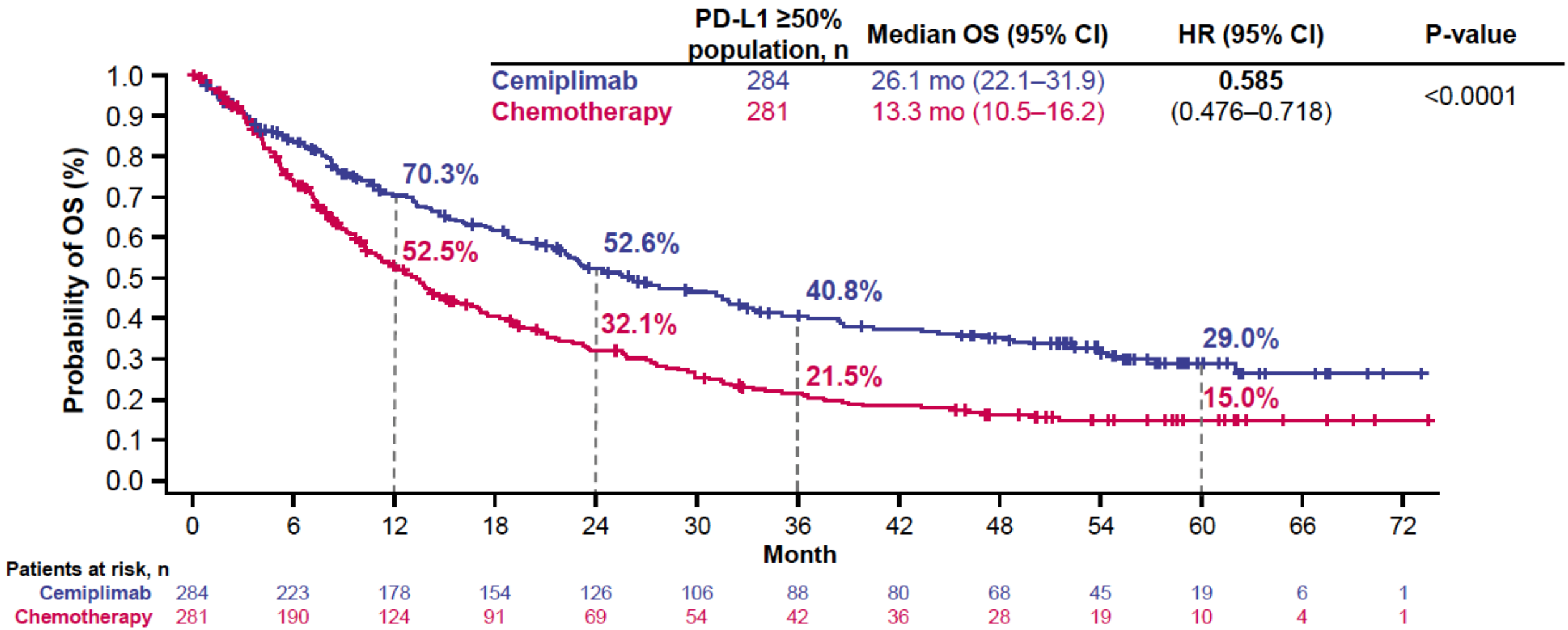
5-Year Update of EMPOWER-Lung 1

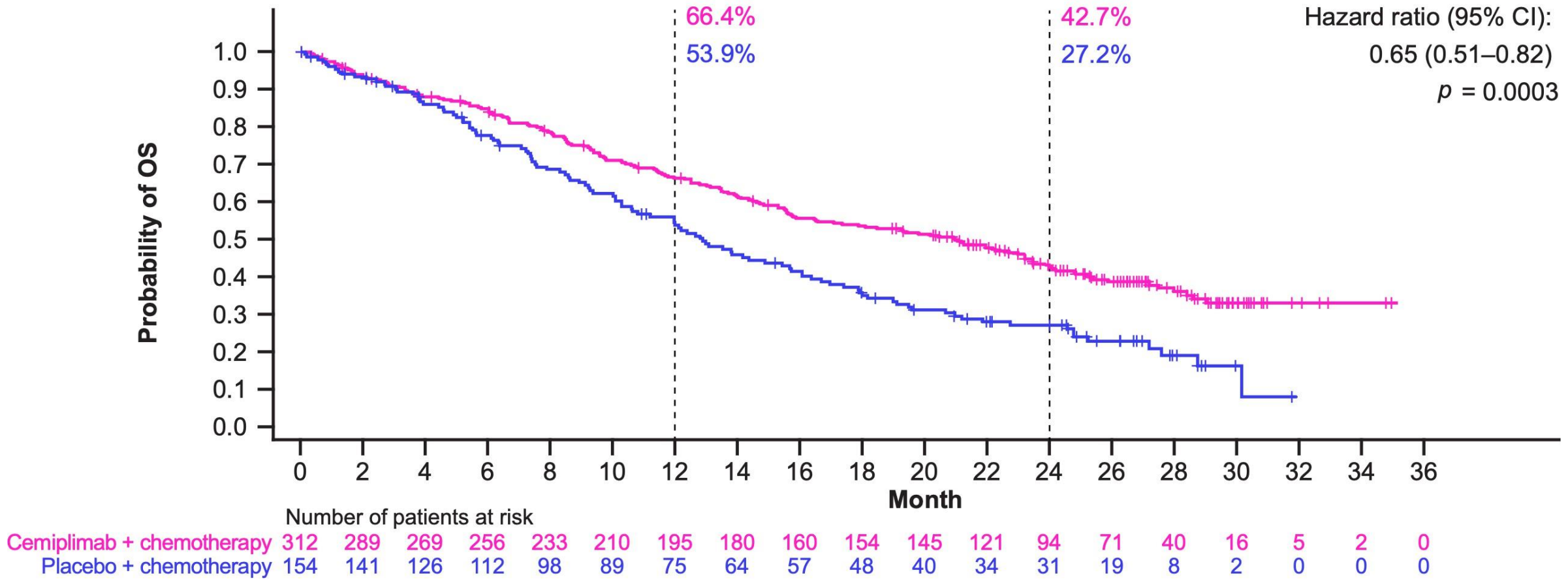


Courtesy of Edward B Garon, MD, MS.

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

EMPOWER-Lung 3

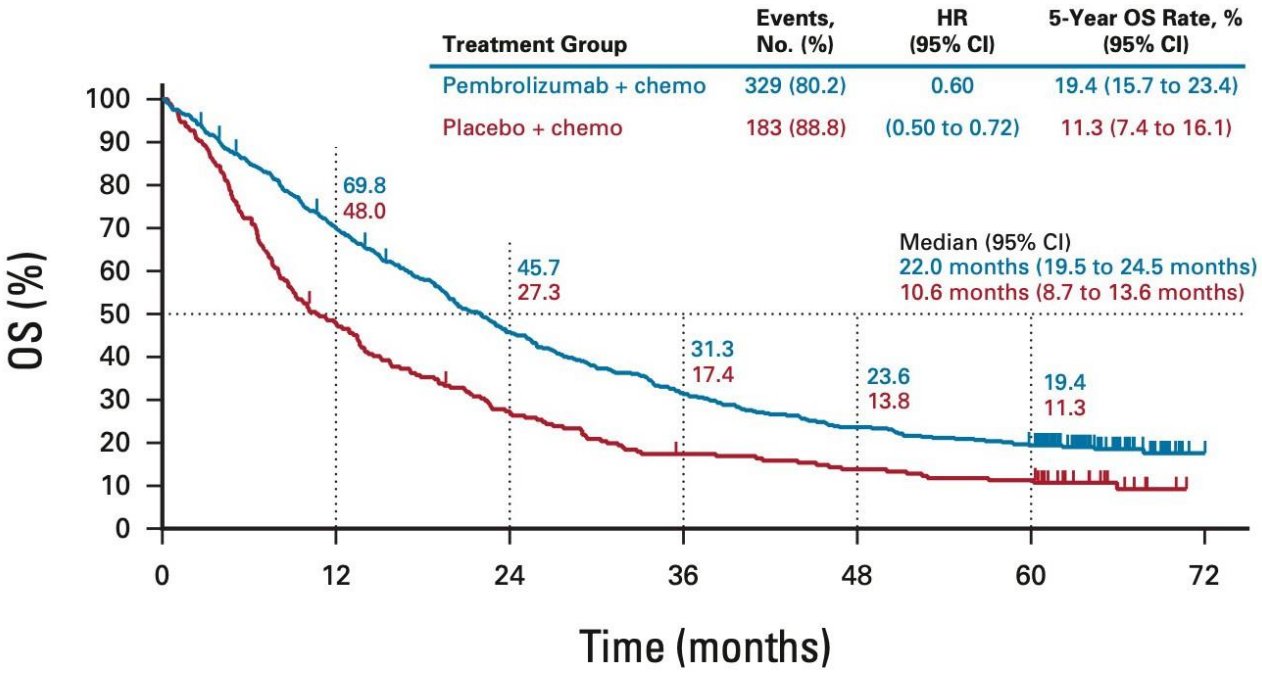
	Median OS (95% CI)
Cemiplimab + chemo	21.1 months (15.9–23.5)
Placebo + chemo	12.9 months (10.6–15.7)

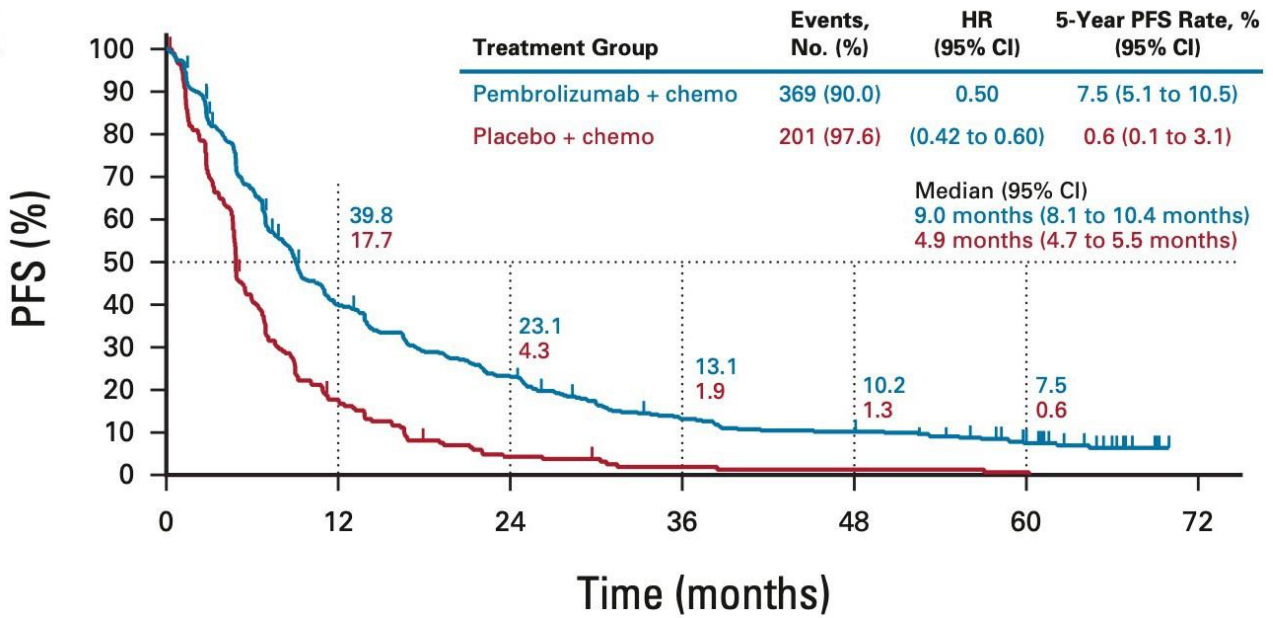


Courtesy of Edward B Garon, MD, MS.

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

Pembrolizumab + Chemo (5-year outcomes)





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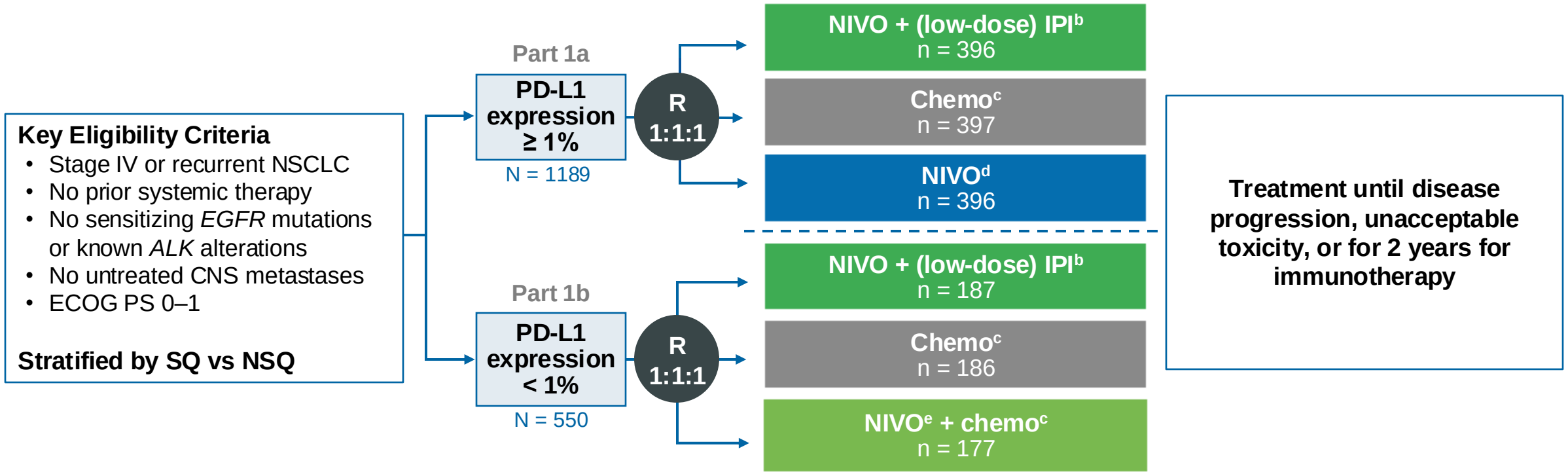
Garassino et al. *J Clin Oncol* 2023;41(11):1992-1998.

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):

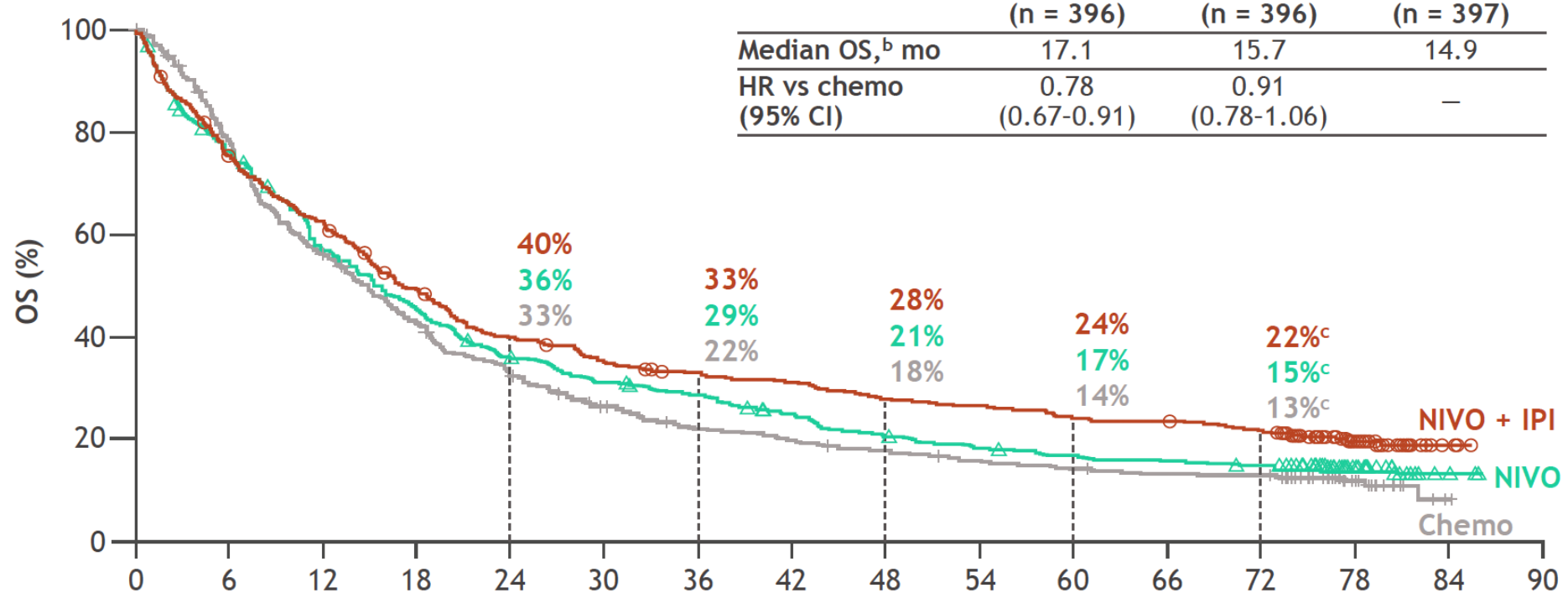
- PFS: **NIVO + chemo vs chemo** in PD-L1 < 1%
- OS: **NIVO + chemo vs chemo** in PD-L1 < 1%
- OS: **NIVO vs chemo** in PD-L1 ≥ 50%

Courtesy of Edward B Garon, MD, MS.

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.

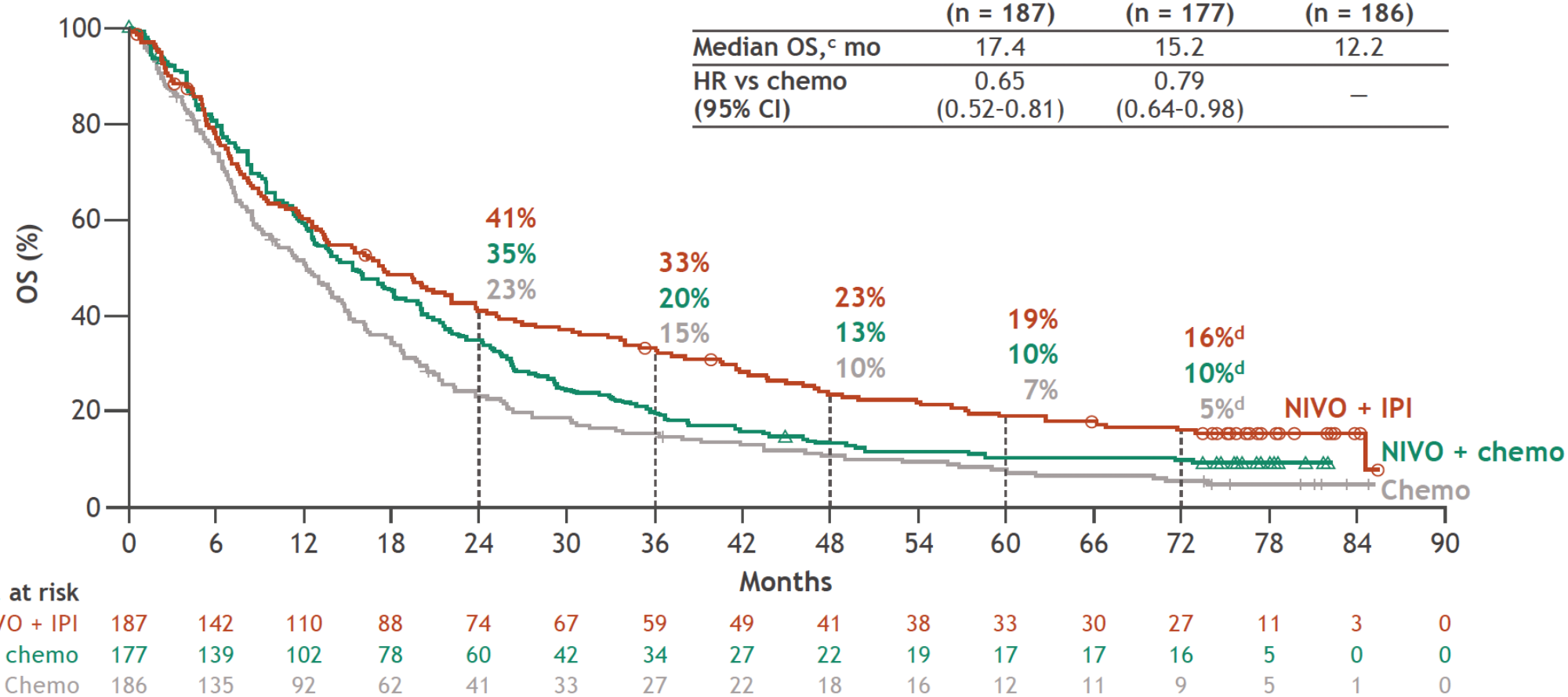
[a]NIVO + IPI vs NIVO OS HR was 0.86 (95% CI, 0.74-1.01). [b]Median OS 95% CIs were 15.0-20.2 (NIVO + IPI), 13.3-18.1 (NIVO), and 12.7-16.7 (chemo). [c]6-year OS rate 95% CIs were 18-26 (NIVO + IPI), 12-19 (NIVO), and 10-17 (chemo). [d]NIVO + IPI vs chemo OS HRs were 0.83 (95% CI, 0.68-1.00; NSQ) and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

Courtesy of Edward B Garon, MD, MS.

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).

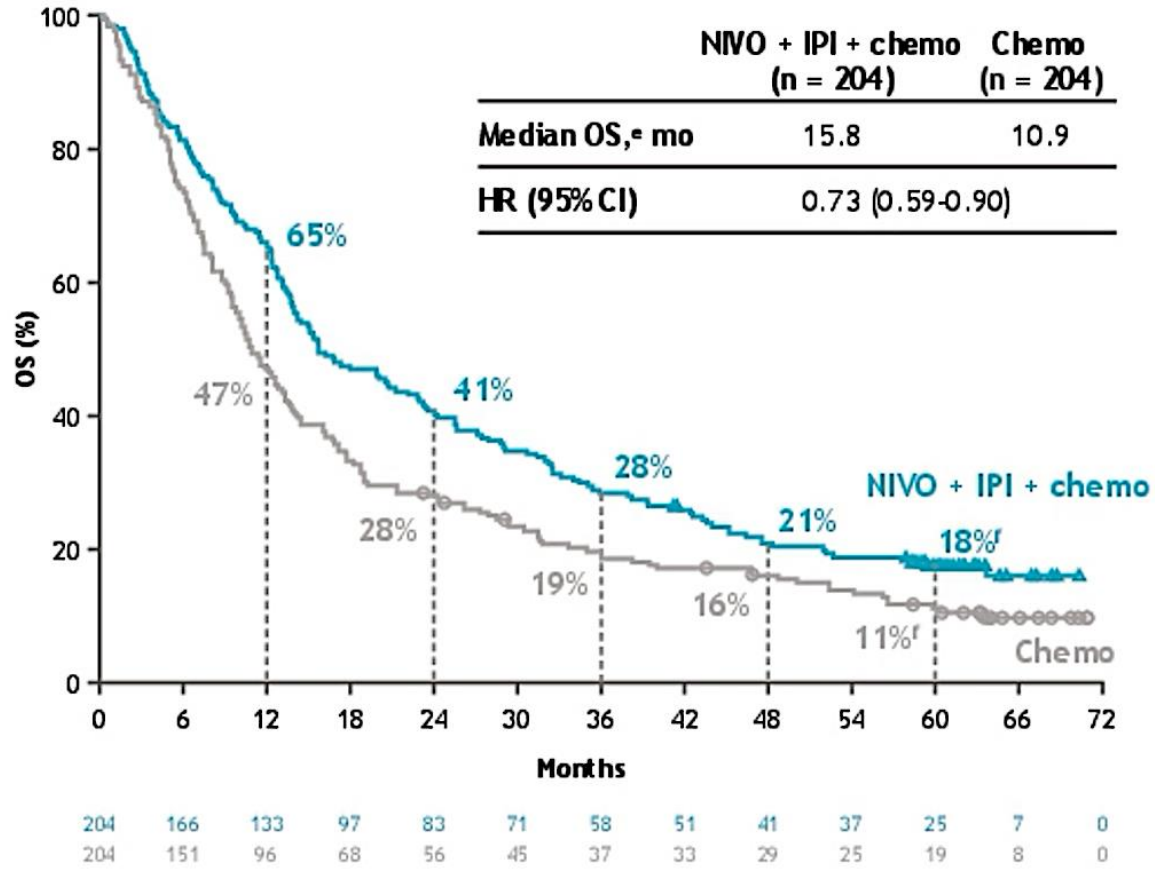
Courtesy of Edward B Garon, MD, MS.

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

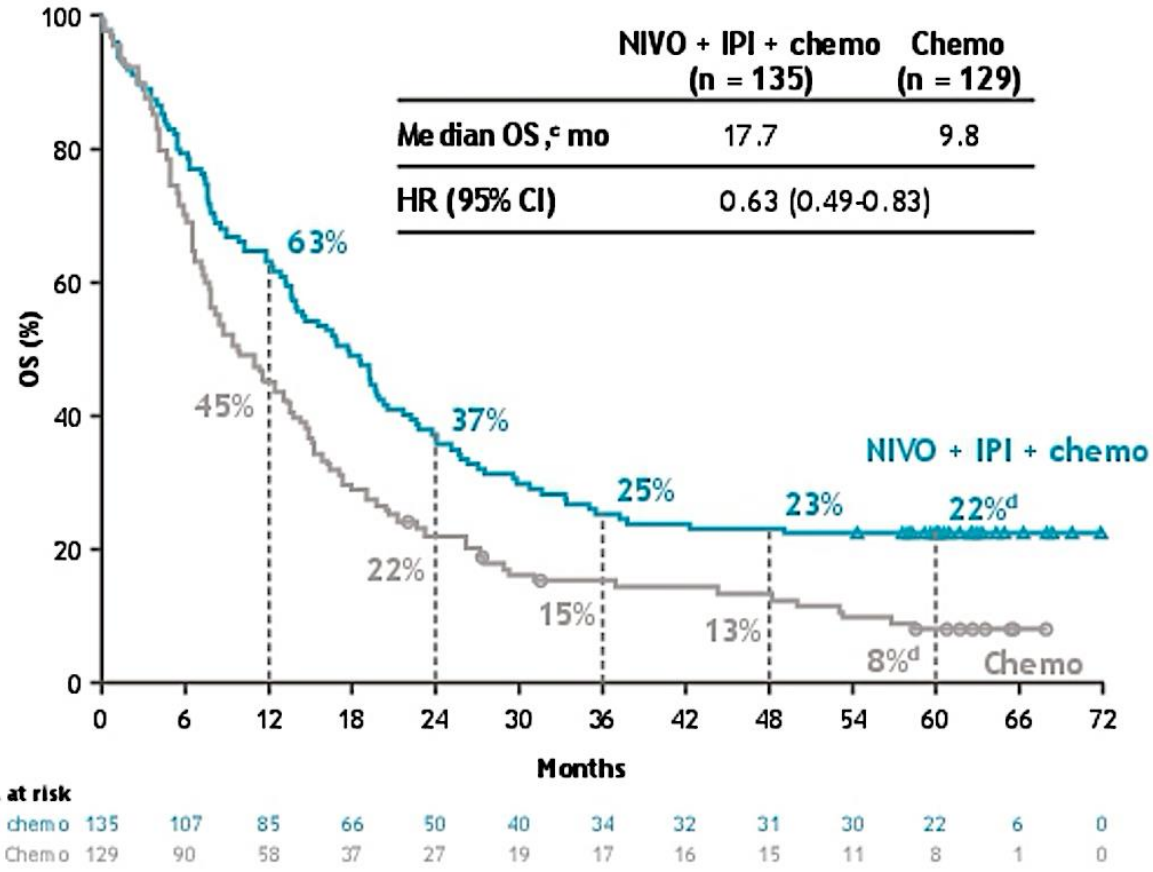
CheckMate 9LA: 5-Year Update

OS in subgroups by PD-L1 expression

PD-L1 ≥ 1%



PD-L1 < 1%



Courtesy of Edward B Garon, MD, MS.

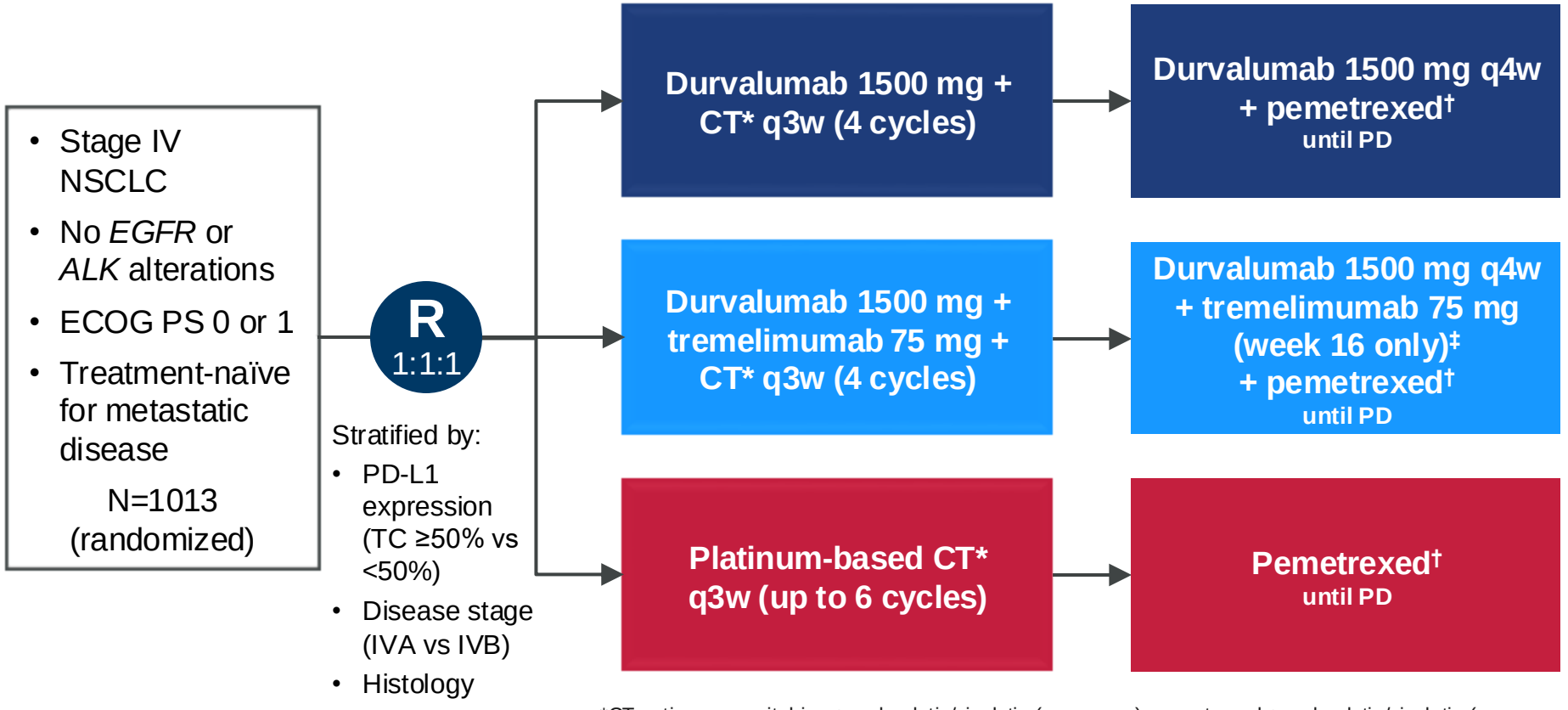
Reck M et al. ASCO 2024;Abstract 8560.

POSEIDON Study Design

Johnson ML. ASCO 2021

Courtesy of Edward B Garon, MD, MS.

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



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

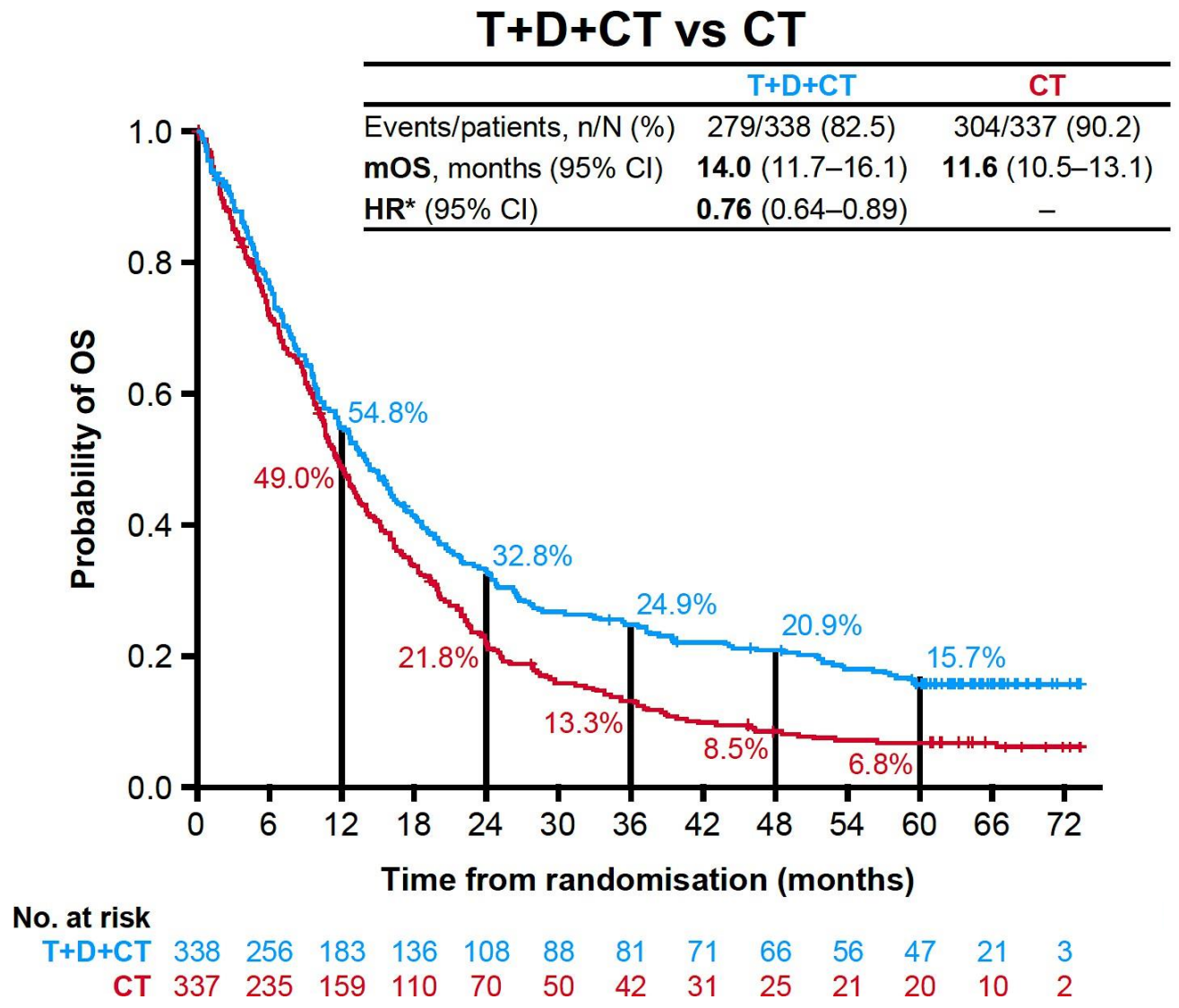
Key secondary endpoints
- PFS by BICR (D+T+CT vs CT)
- OS (D+T+CT vs CT)
- OS in patients with bTMB ≥20 mut/Mb (D+T+CT vs CT)

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



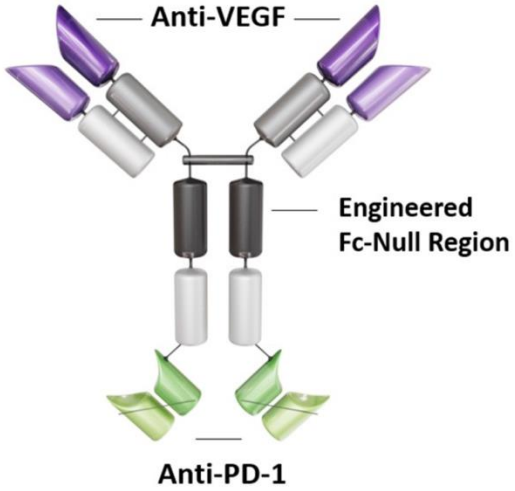
Courtesy of Edward B Garon, MD, MS.

Peters et al. ESMO IO 2023;Abstract LBA3.

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

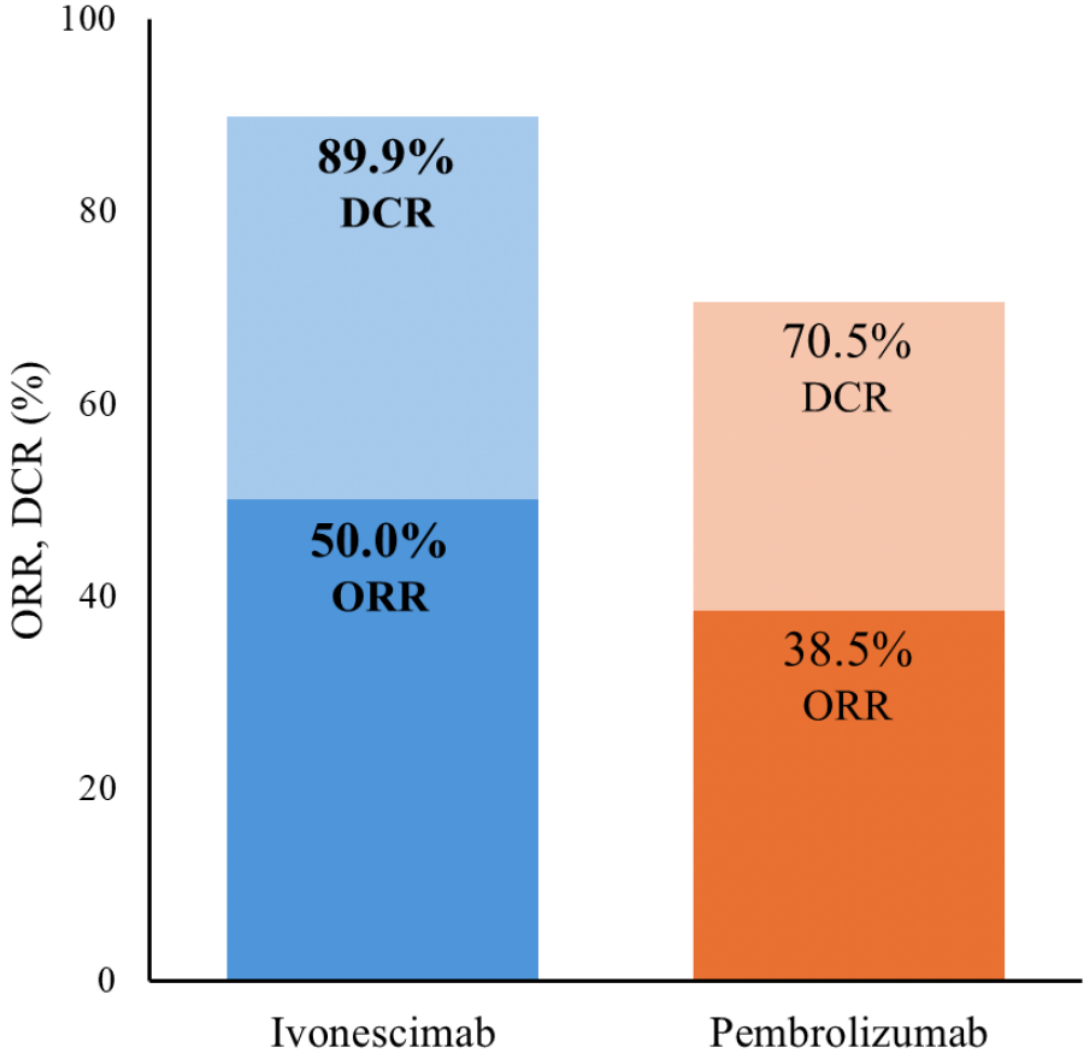
- Clinical stage (IIIB/C vs. IV)
- Histology (SQ vs. non-SQ)
- PD-L1 TPS (≥50% vs. 1-49%)

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)

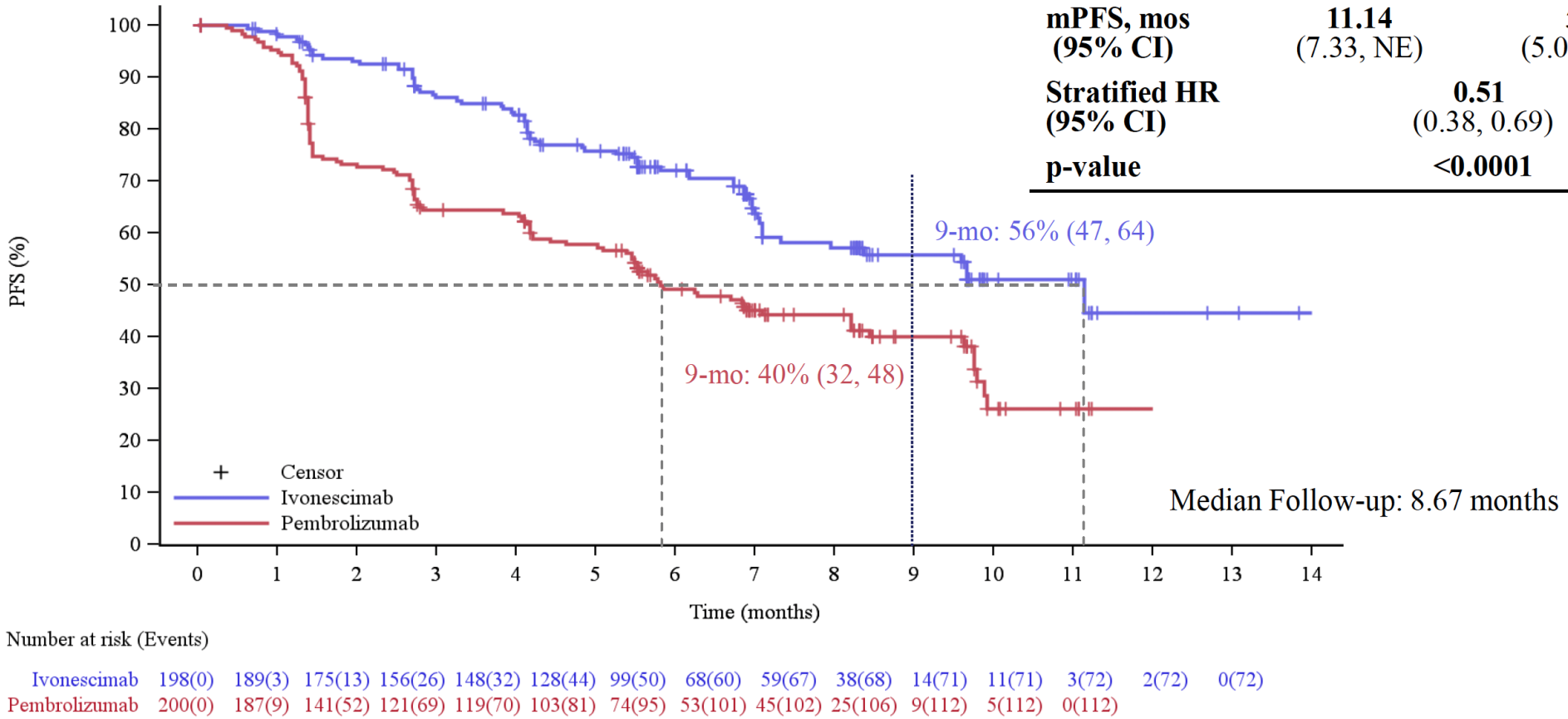
ORR and DCR were higher with ivonescimab vs. pembrolizumab.

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**	



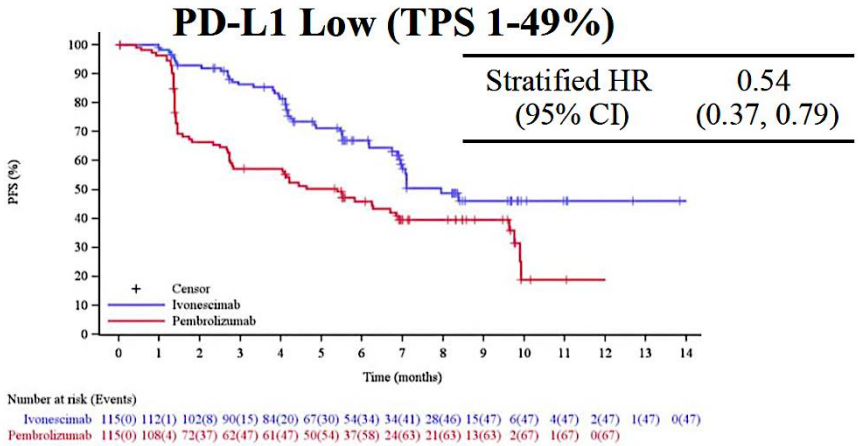
Ivonescimab demonstrated a statistically significant improvement in PFS vs. pembrolizumab with HR = 0.51, and a 5.3 months improvement in mPFS.

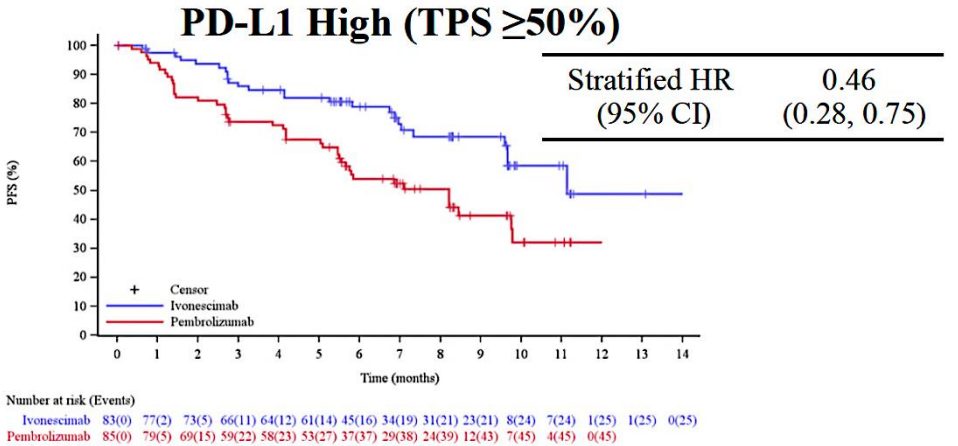
Zhou C et al. WCLC 2024;Abstract PL02.04.

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

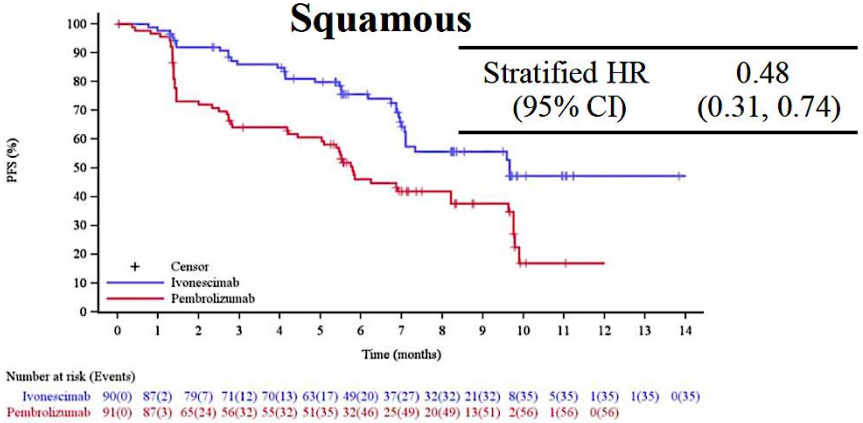
Key PFS Subgroup Analyses

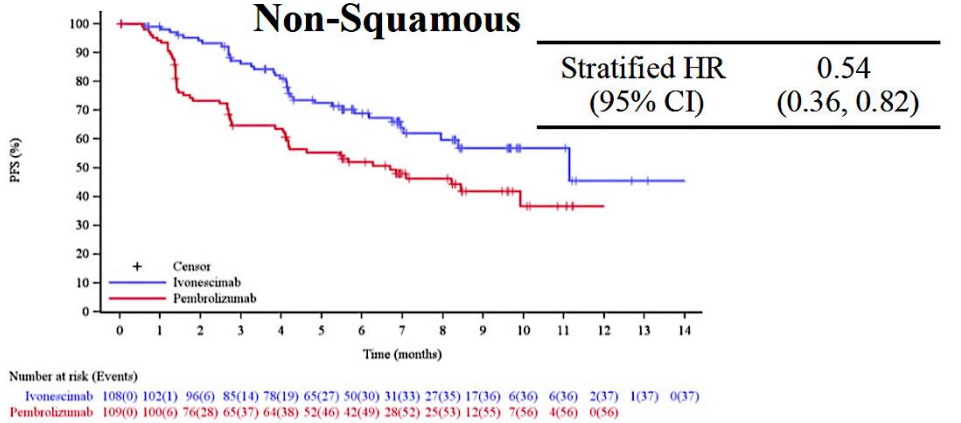
PD-L1 expression





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)

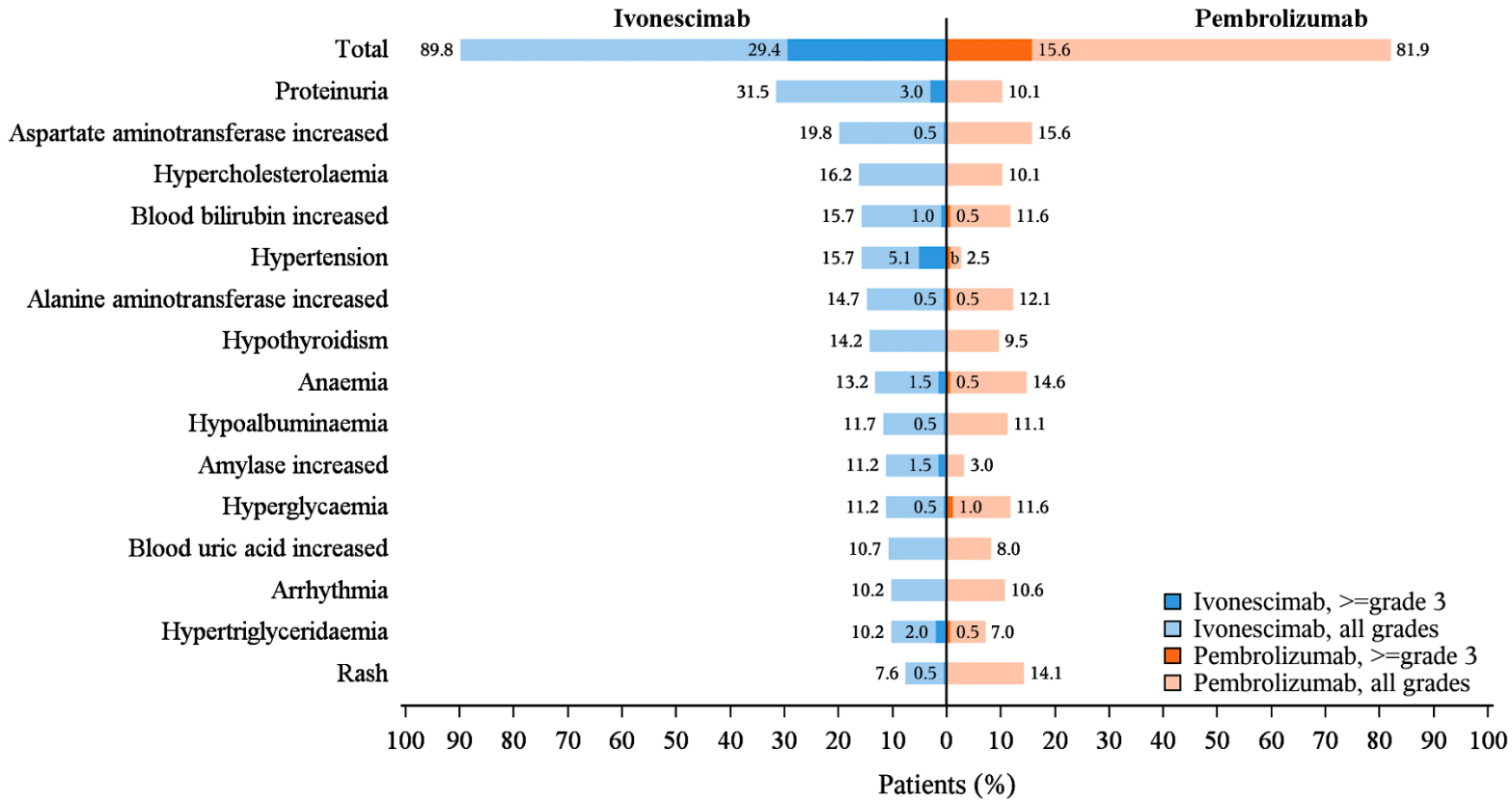
Ivonescimab showed a manageable safety profile, which was consistent with previous studies.

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.

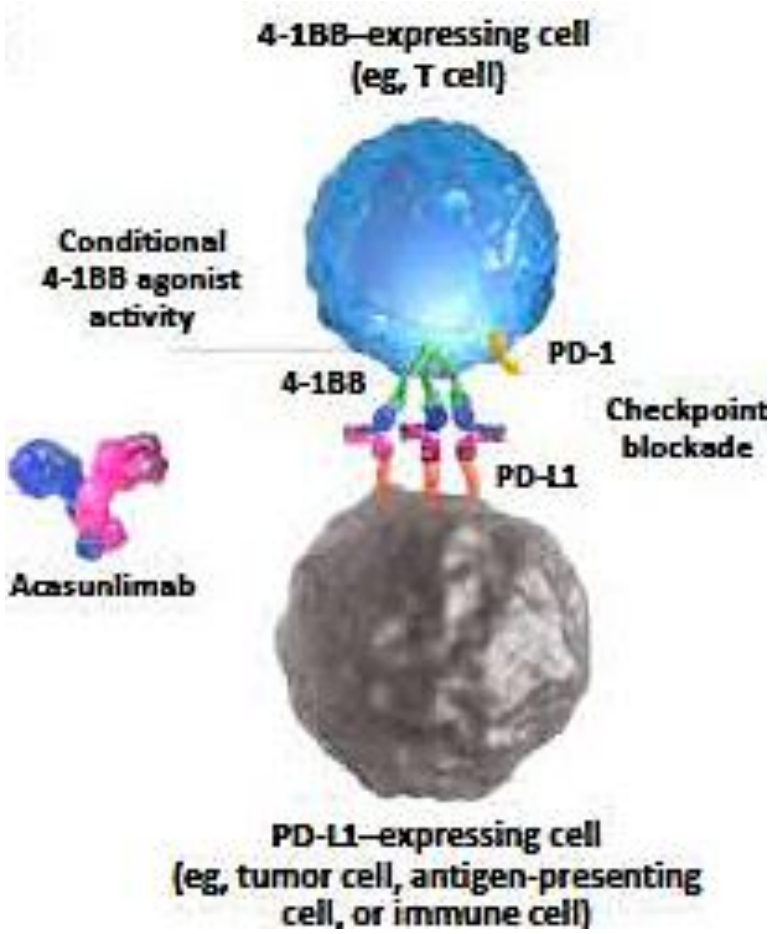
The Most Common TRAEs (incidence ≥10%)

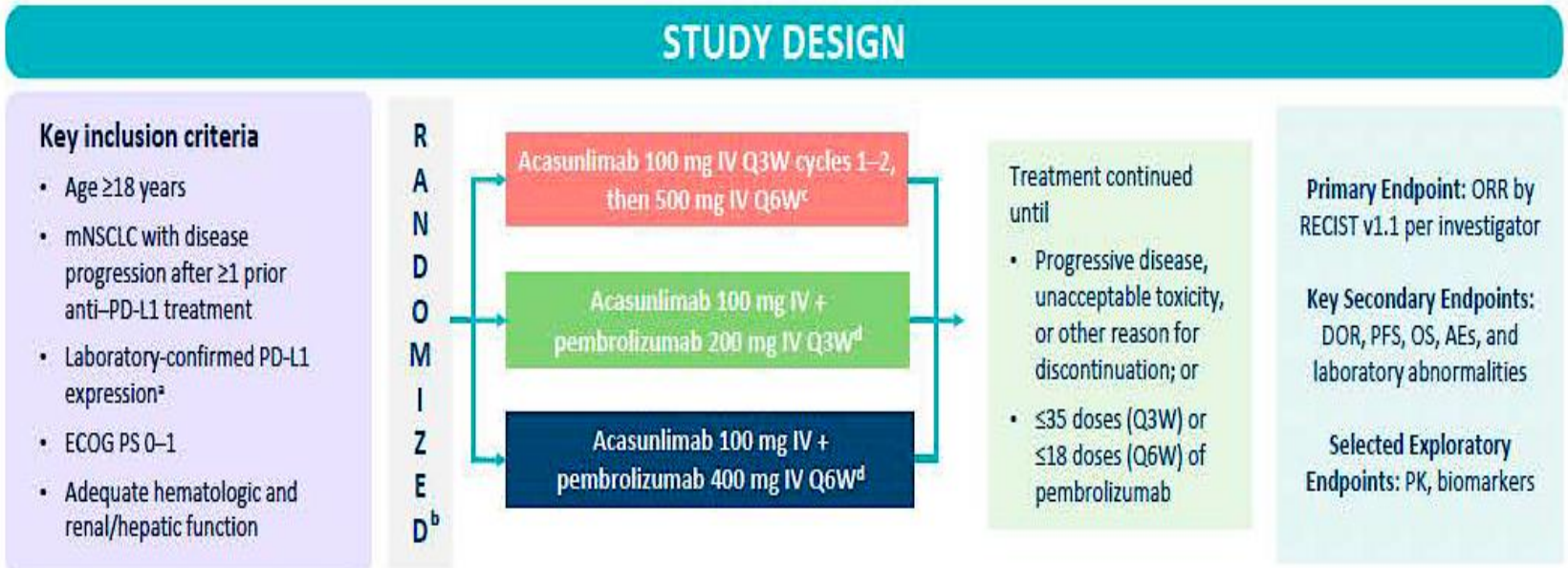


The differences in AEs were predominantly proteinuria, hypertension, and laboratory abnormalities.

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

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





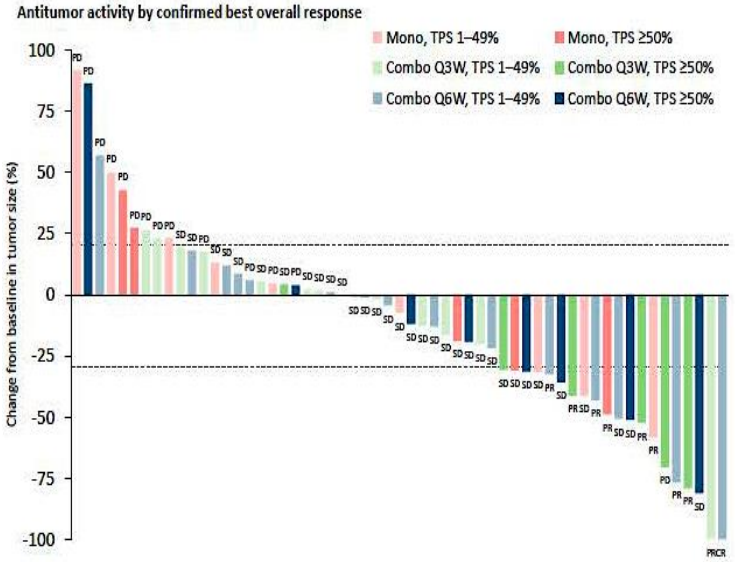
Aerts J et al. ASCO 2024.

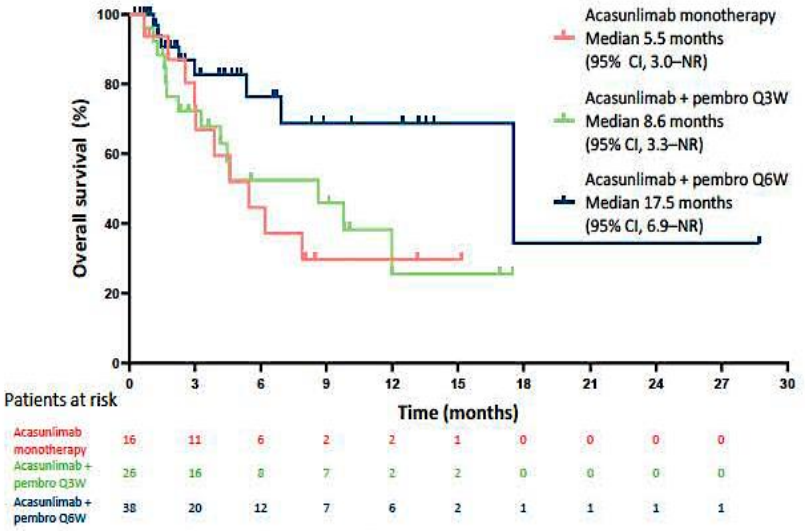
Courtesy of Luis Paz-Ares, MD, PhD

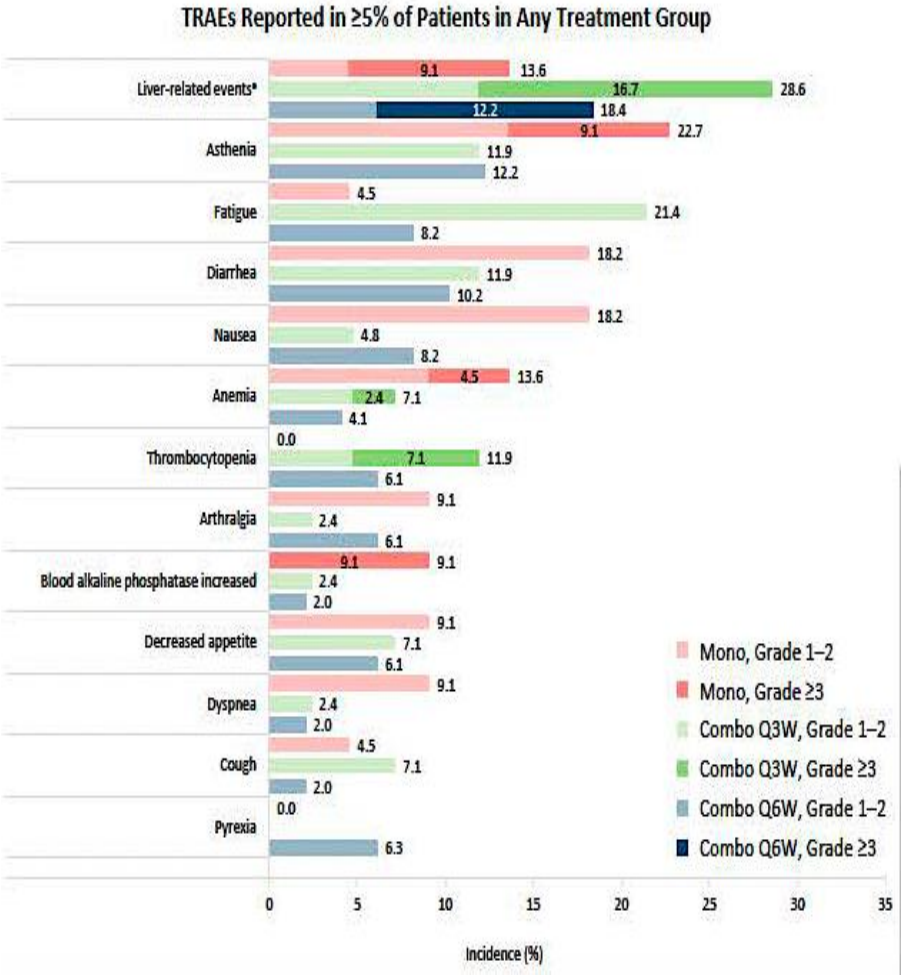
Acasunlimab (DuoBody PD-L1-4-1BB) alone or in combination with Pembrolizumab in pre-treated NSCLC (PD-L1 + subset)

	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.

Courtesy of Luis Paz-Ares, MD, PhD

Meet The Professor with Dr Wakelee

Module 3: Case Presentations – Part 2

- Dr Rudolph: 63-year-old African American man with 6.2-cm squamous cell carcinoma of right upper lung receives neoadjuvant treatment as per CheckMate 816
- Dr Lamar: 69-year-old man with pT2aN0 invasive adenocarcinoma of the right lower lung, no AGA; PD-L1 5%

Case Presentation: 63-year-old African American man with 6.2-cm squamous cell carcinoma of right upper lung receives neoadjuvant treatment as per CheckMate 816

Dr Priya Rudolph (Athens, Georgia)

RTP RESEARCH TO PRACTICE

Case Presentation: 69-year-old man with pT2aN0 invasive adenocarcinoma of the right lower lung, no AGA; PD-L1 5%

Dr Zanetta S Lamar (Naples, Florida)

RTP
RESEARCH
TO PRACTICE

Meet The Professor with Dr Wakelee

Module 1: Case Presentations – Part 1

Module 2: Current and Emerging Immunotherapeutic Strategies for Metastatic Non-Small Cell Lung Cancer (mNSCLC)

Module 3: Case Presentations – Part 2

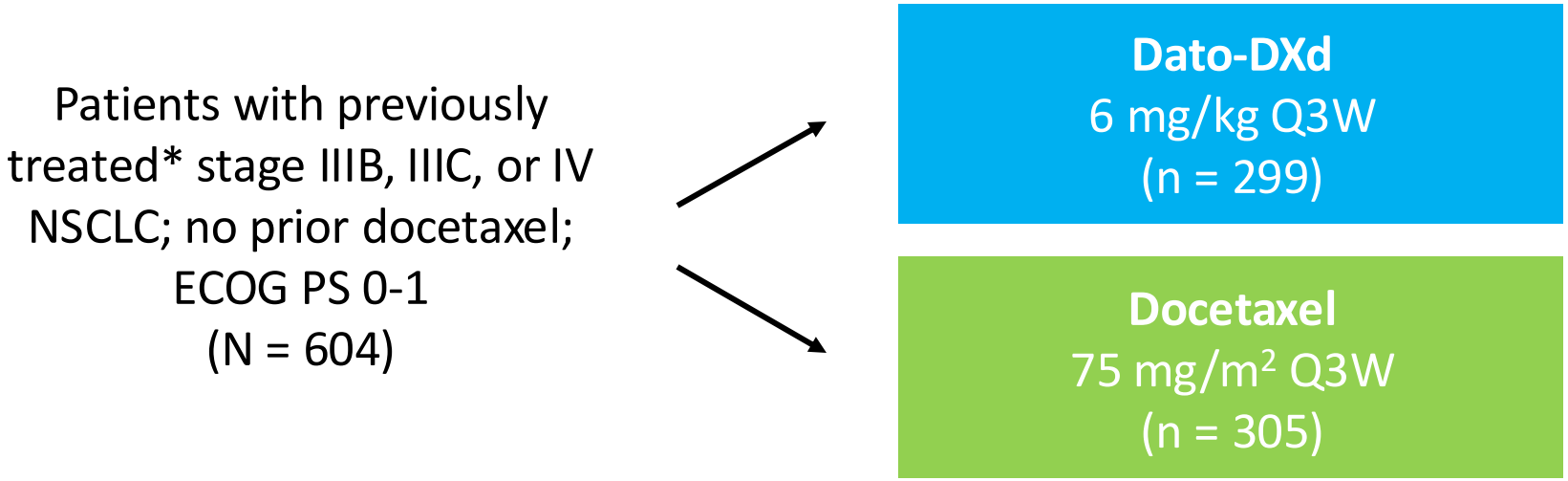
Module 4: Antibody-Drug Conjugates and Other Management Approaches for mNSCLC without Actionable Genomic Alterations

Module 5: Case Presentations – Part 3

RTP RESEARCH TO PRACTICE

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

- Global, randomized, open-label phase III trial

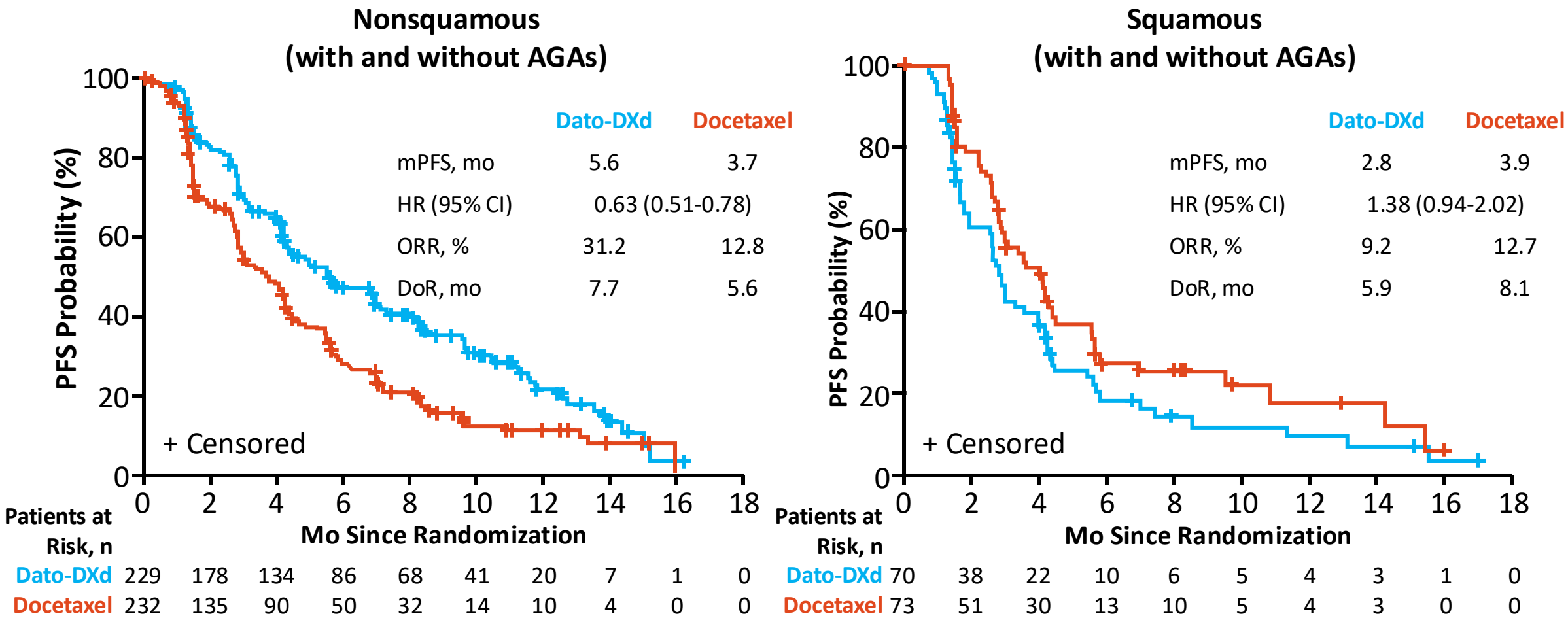


- **Dual primary endpoints**: PFS (BICR), OS
- **Secondary endpoints**: ORR (BICR), DoR (BICR), safety

Lisberg. ESMO 2023. Abstr LBA12.

Courtesy of Luis Paz-Ares, MD, PhD

TROPION-Lung01: Efficacy by Histology



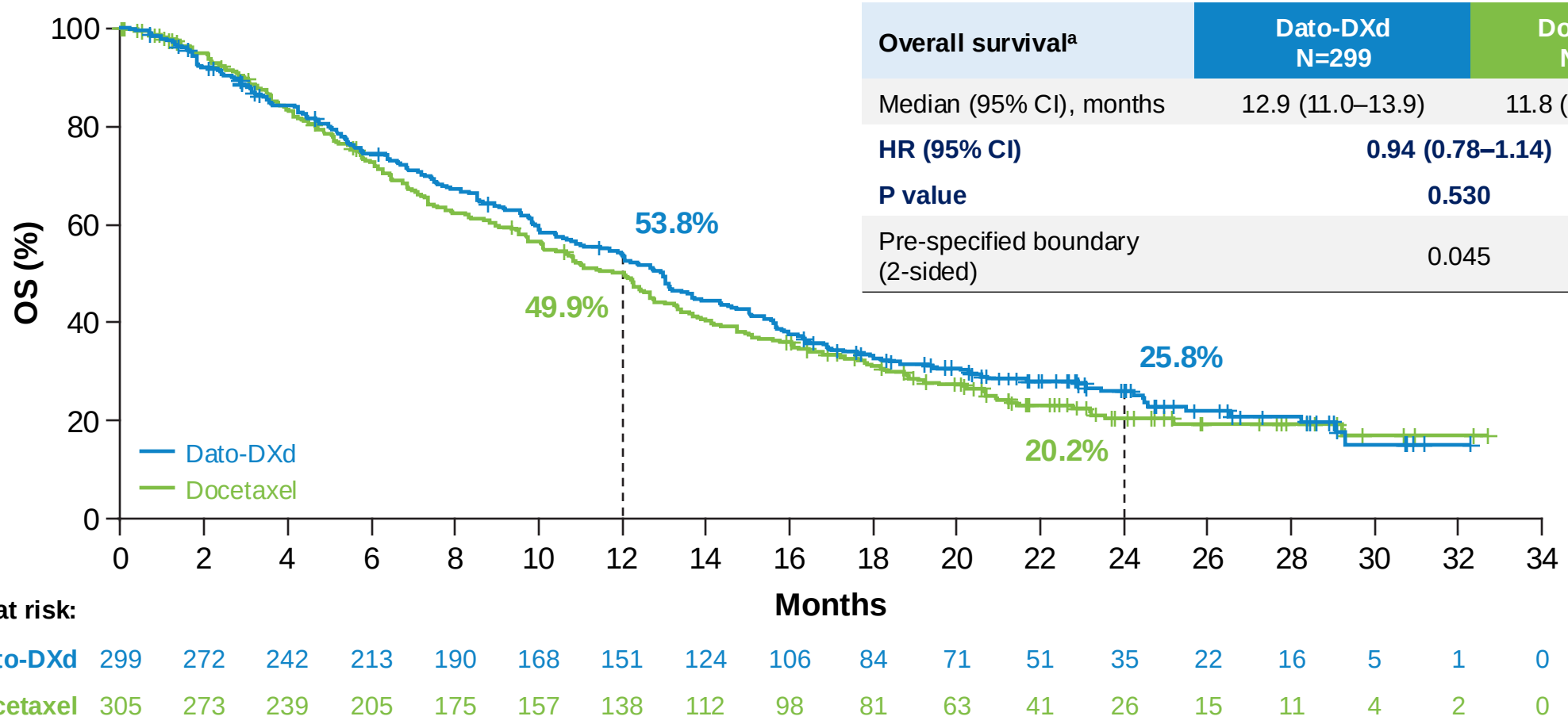
HR for PFS for nonsquamous without AGAs: 0.71 (0.56-0.91)

Lisberg. ESMO 2023. Abstr LBA12.

Courtesy of Luis Paz-Ares, MD, PhD

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.

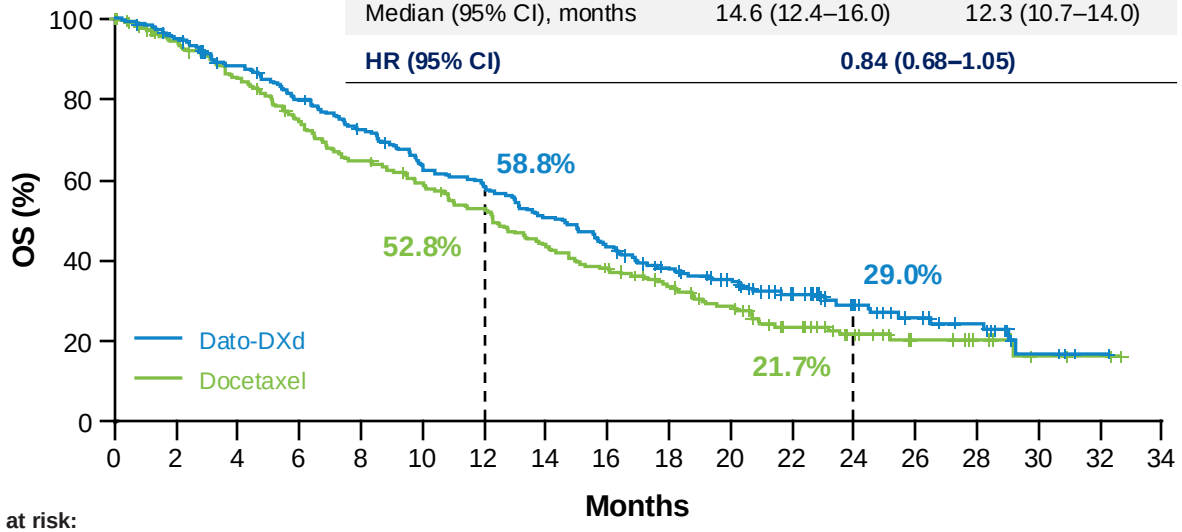
Courtesy of Luis Paz-Ares, MD, PhD

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)	

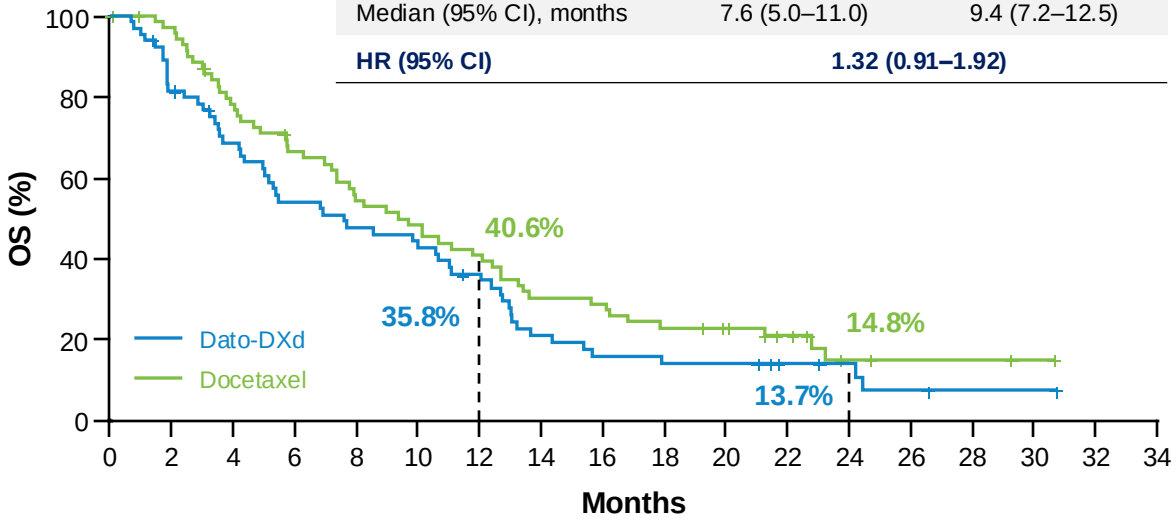


No. at risk:

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.

Courtesy of Luis Paz-Ares, MD, PhD

Datopotamab Deruxtecan: New Biologics License Application Submitted for Accelerated Approval for Previously Treated Advanced NSCLC with EGFR Mutations

Press Release: November 12, 2024

"[The manufacturers] have submitted a new Biologics License Application (BLA) for accelerated approval in the US for datopotamab deruxtecan (Dato-DXd) for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor-mutated (EGFR) non-small cell lung cancer (NSCLC) who have received prior systemic therapies, including an EGFR-directed therapy.

The companies have voluntarily withdrawn the BLA in the US for datopotamab deruxtecan for patients with advanced or metastatic nonsquamous NSCLC based on the TROPION-Lung01 Phase III trial.

The decision to submit a new BLA for EGFR-mutated NSCLC and withdraw the previously submitted BLA for nonsquamous NSCLC was informed by feedback from the US Food and Drug Administration (FDA).

The new BLA is based on results from the TROPION-Lung05 Phase II trial and supported by data from the TROPION-Lung01 Phase III and TROPION-PanTumor01 Phase I trials."

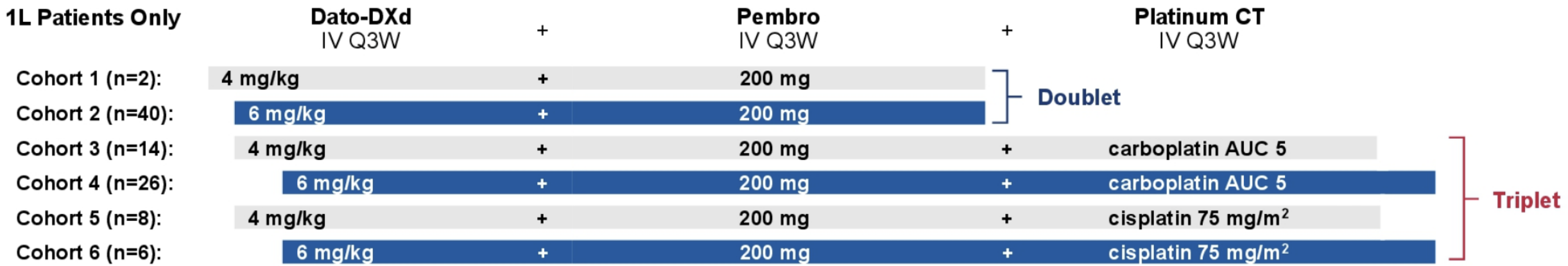
https://www.astrazeneca.com/media-centre/press-releases/2024/dato-dxd-new-bla-submitted-nsq-bla-withdrawn.html

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]

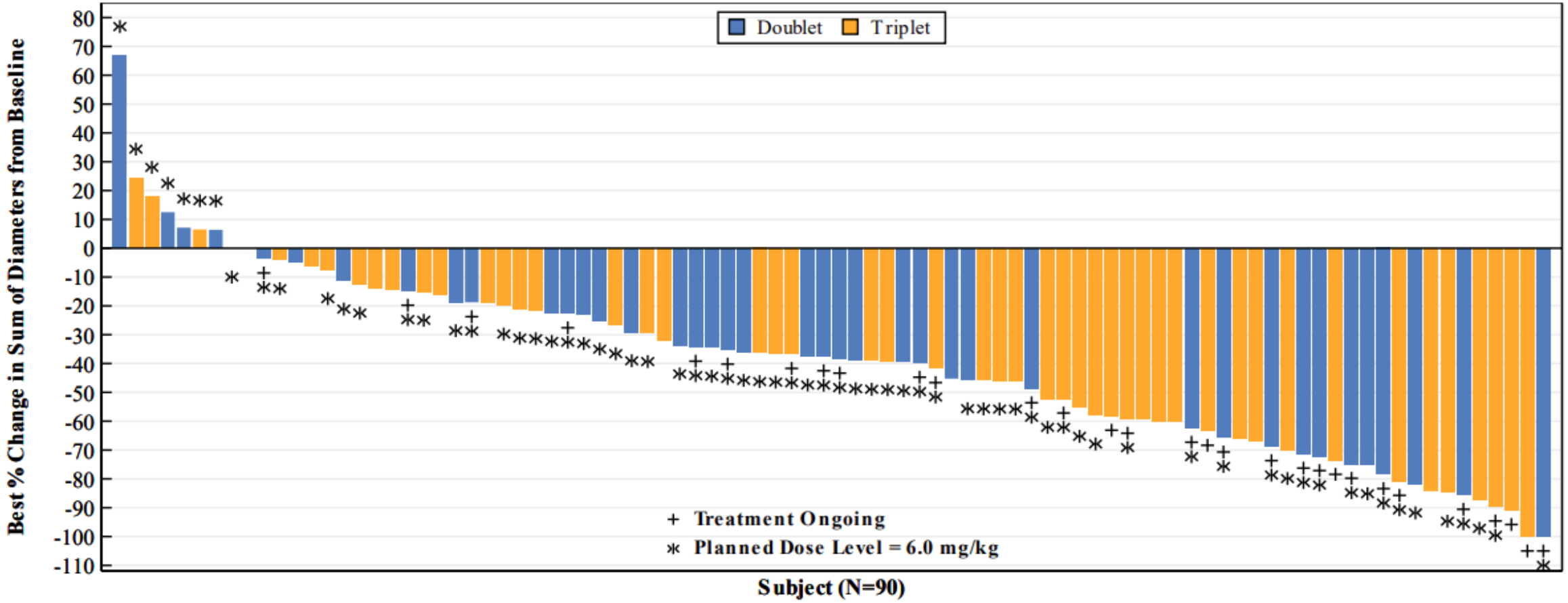
Data cutoff: October 31, 2023.



Courtesy of Edward B Garon, MD, MS.

Levy BP et al. ASCO 2024

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

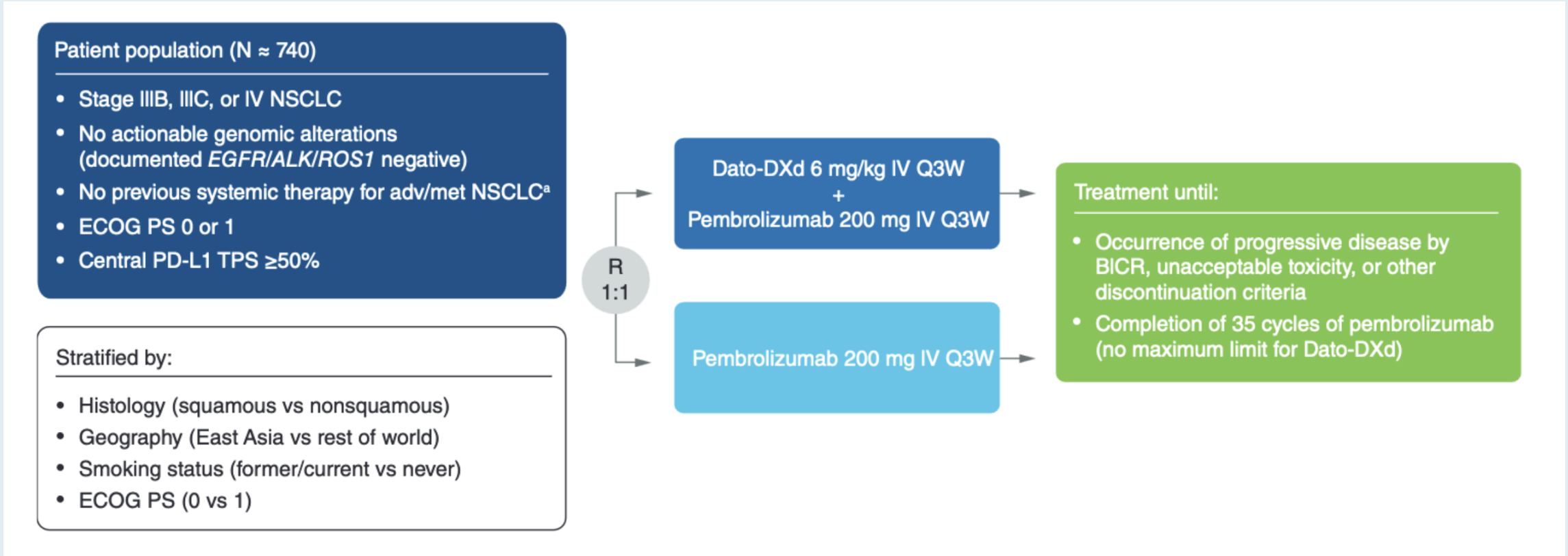


Patients with no baseline target lesions or no postbaseline tumor assessments were excluded from the waterfall plot.

Courtesy of Edward B Garon, MD, MS.

Levy BP et al. ASCO 2024

TROPION-Lung08: A Phase III Study of Datopotamab Deruxtecan and Pembrolizumab as First-Line Therapy for Advanced NSCLC



Levy BP et al. *Future Oncol* 2023;19(21):1461-72.

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

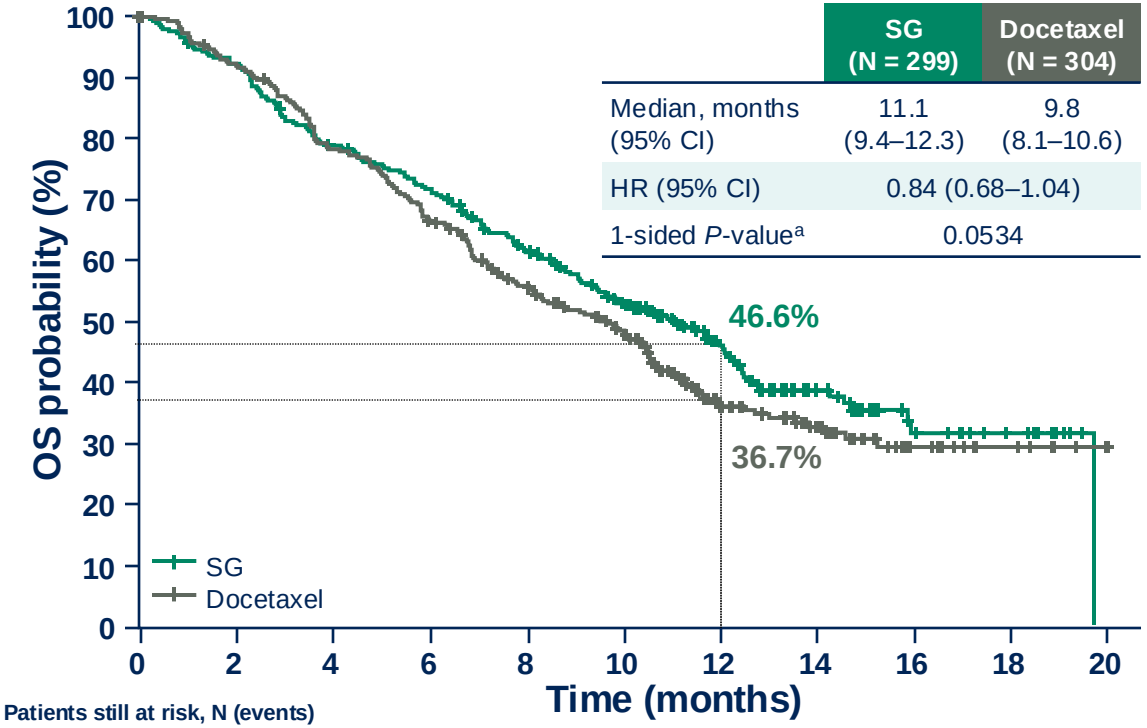
1. Garassino. ASCO 2023. Abstr TPS9149. 2. NCT05089734.
3. Press release (Jan 22, 2024); data presentation at upcoming medical meeting awaited.

Courtesy of Luis Paz-Ares, MD, PhD

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

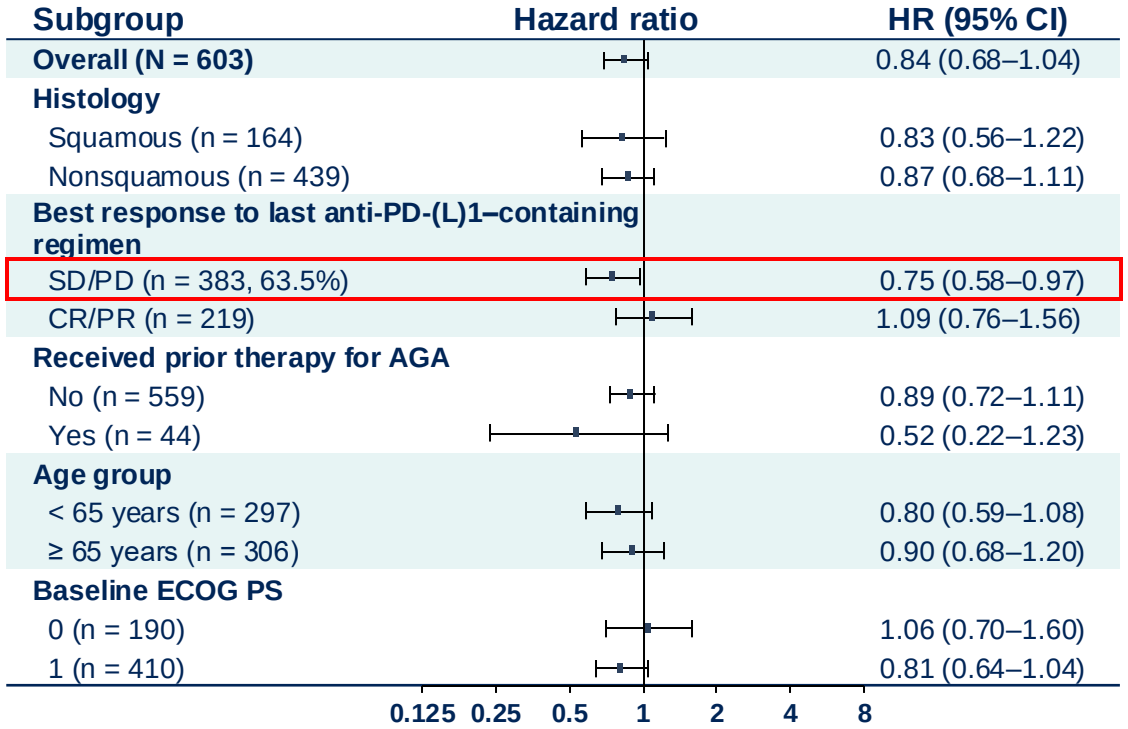


	SG (N = 299)	Docetaxel (N = 304)
Median, months (95% CI)	11.1 (9.4–12.3)	9.8 (8.1–10.6)
HR (95% CI)	0.84 (0.68–1.04)	
1-sided *P*-value[a]	0.0534	

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.

Courtesy of Luis Paz-Ares, MD, PhD

Sacituzumab Govitecan + Pembro + Carboplatin in 1L mNSCLC

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

Key eligibility criteria
- Stage IV NSCLC
- Measurable disease[a]
- No known AGAs
- ECOG PS 0–1
- No prior systemic treatment for metastatic NSCLC

Cohort A
PD-L1 TPS ≥ 50%; NSQ or SQ
n ≈ 30

Cohort B
PD-L1 TPS < 50%; NSQ or SQ
n ≈ 60

Safety Run-in
Any PD-L1 TPS
(n = 5)

Cohort C
NSQ
(n = 54)

Cohort D
SQ
(n = 41)

SG 10 mg/kg on D1 and D8[b] + Pembro 200 mg on D1[c]
(21-day cycles)

SG RP2D on D1 and D8[b] + Pembro 200 mg on D1[c] + Carbo AUC5 on D1[d]
(21-day cycles)[e]

End points

Primary
- IRC-ORR[f]
- DLTs in safety run-in

Secondary
- PFS[f]
- OS
- DOR[f]
- DCR[f]
- Safety and tolerability

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)

Courtesy of Edward B Garon, MD, MS.

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

EVOKE-02: Sacituzumab + Pembro + Carboplatin – Efficacy

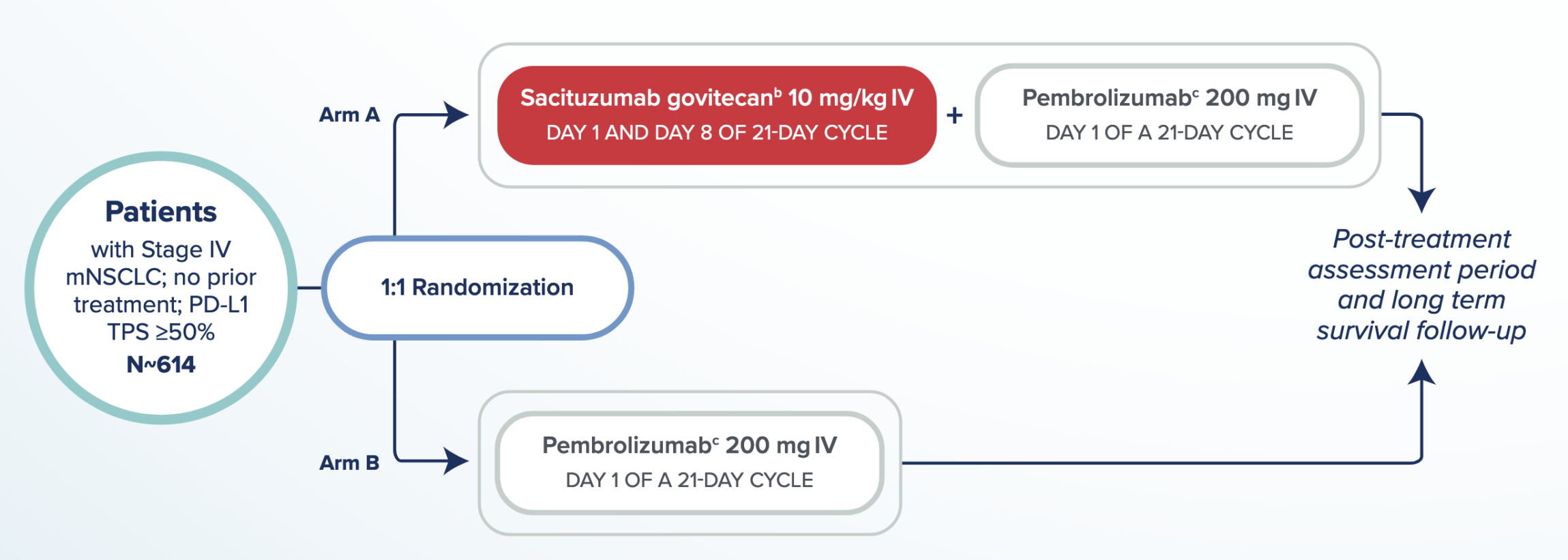
	Cohort C (NSQ) SG + CP (n = 51)[b]	Cohort D (SQ) SG + CP (n = 41)
Follow-up, median (range), months	14.5 (12.2–22.3)	14.2 (11.0–23.0)
ORR, % (95% CI)	45.1 (31.1–59.7)	39.0 (24.2–55.5)
Partial response, n (%)	23 (45.1)	16 (39.0)
Stable disease, n (%)	16 (31.4)	17 (41.5)
Progressive disease, n (%)	5 (9.8)	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)

Courtesy of Edward B Garon, MD, MS.

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

EVOKE-03: An Open-Label, Multicenter, Phase III Randomized Study of Pembrolizumab with Sacituzumab Govitecan versus Pembrolizumab Monotherapy as First-Line Treatment for PD-L1 TPS ≥50% mNSCLC



https://www.gileadkiteoncology.com/ash23/pdf/US/EVOKE-03.pdf

FDA Approves Tumor Treating Fields for the Treatment of Metastatic NSCLC

Press Release: October 15, 2024

The FDA has approved tumor treating fields (TTFields) for concurrent use with PD-1/PD-L1 inhibitors or docetaxel in the treatment of metastatic NSCLC in adult patients who have experienced disease progression on or after a platinum-based regimen.

Approval was based on results of the Phase III LUNAR trial that compared TTFields concurrent with PD-1/PD-L1 inhibitors or docetaxel (experimental arm) to PD-1/PD-L1 inhibitors or docetaxel alone (control arm) for patients with metastatic NSCLC progressing during or after platinum-based therapy.

The primary endpoint of the study was achieved demonstrating a statistically significant and clinically meaningful 3.3-month (p = 0.04) extension in median overall survival (OS) for patients who received TTFields concurrently with a PD-1/PD-L1 inhibitor or docetaxel (n = 145). The group treated with TTFields concurrently with a PD-1/PD-L1 inhibitor or docetaxel had a median OS of 13.2 months (95% CI, 10.3 to 15.5 months) compared to a median OS of 9.9 months (95% CI, 8.2 to 12.2 months) in the group who received a PD-1/PD-L1 inhibitor or docetaxel (n = 146).

https://www.novocure.com/fda-approves-novocures-optune-lua-for-the-treatment-of-metastatic-non-small-cell-lung-cancer/

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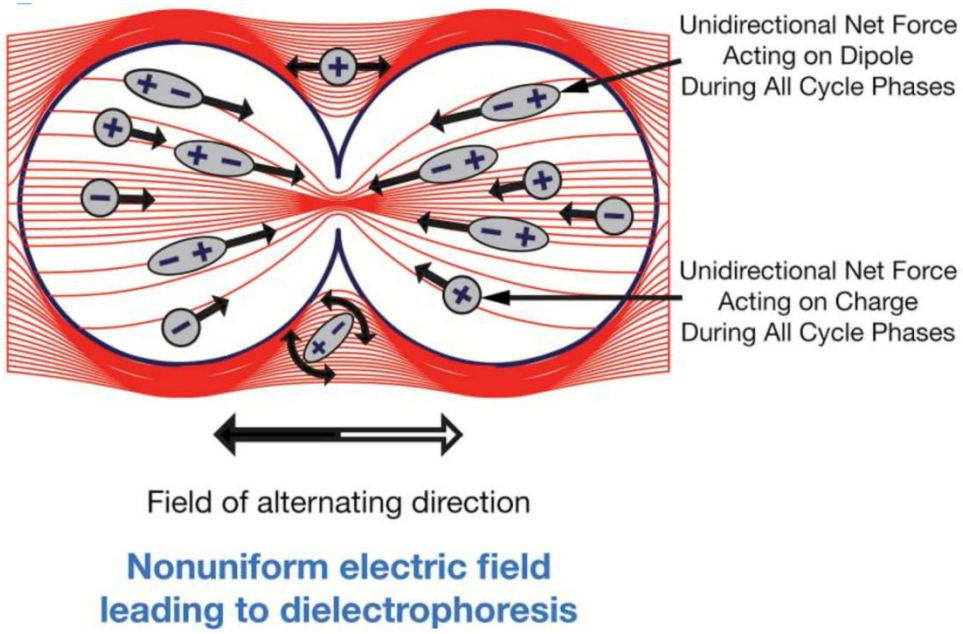
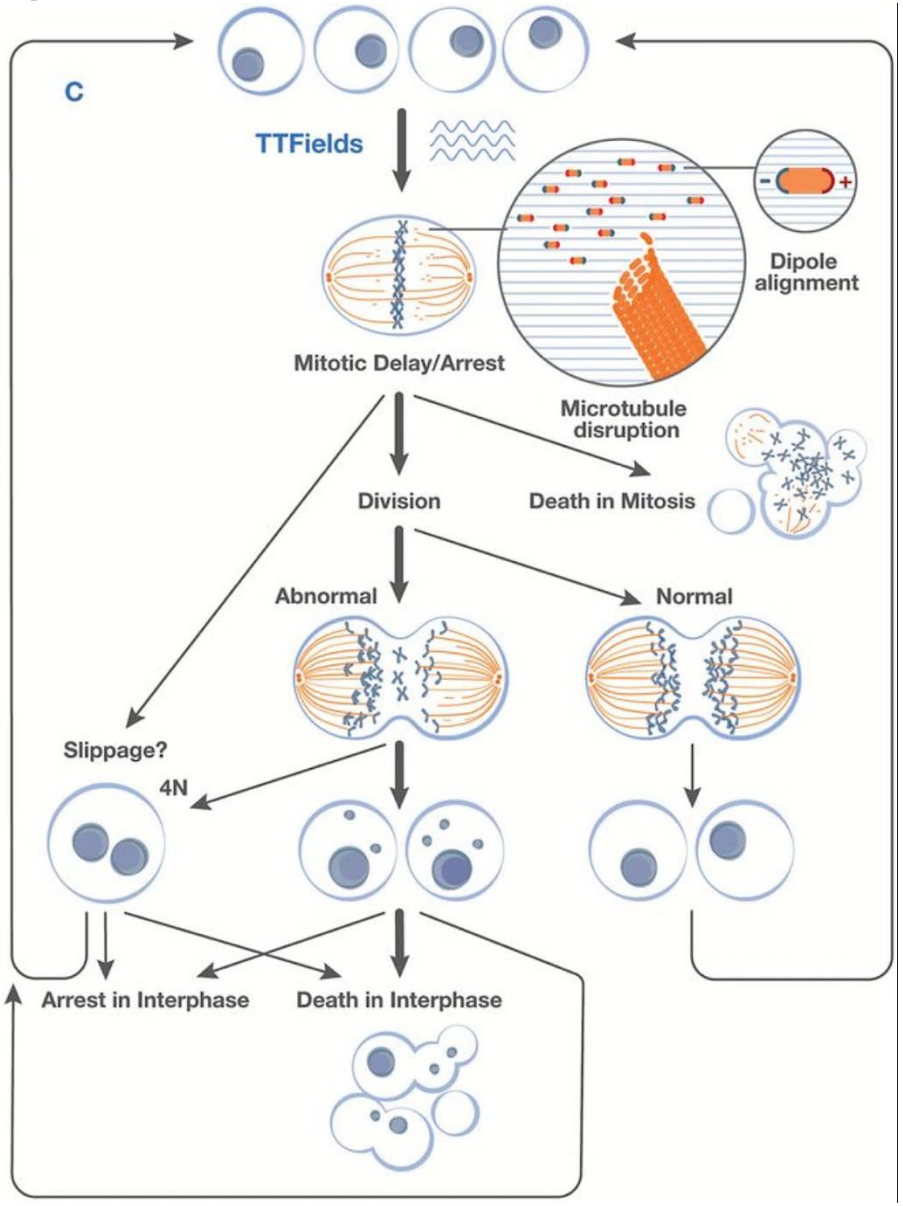
Tumor Treating Fields (TTFields): Mechanism of Action

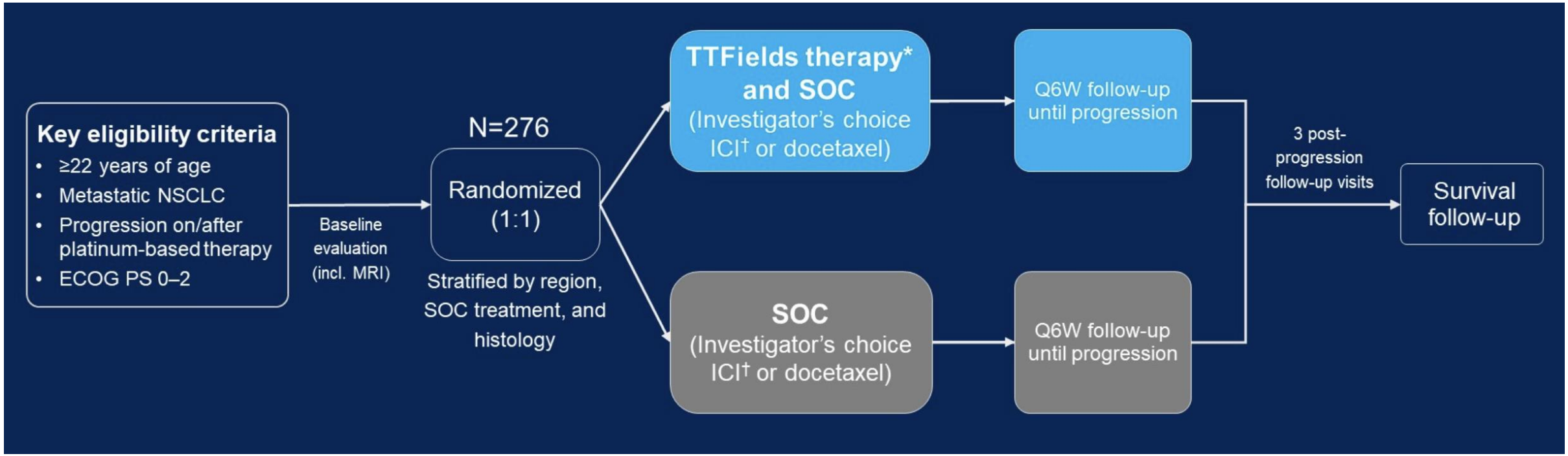




Hottinger AF et al. *Neuro Oncol* 2016;18(10):1338-49.

Courtesy of Ticiana Leal, MD

LUNAR: A Phase III Study of TTFields for Metastatic Non-Small Cell Lung Cancer (mNSCLC) Progressing on Platinum



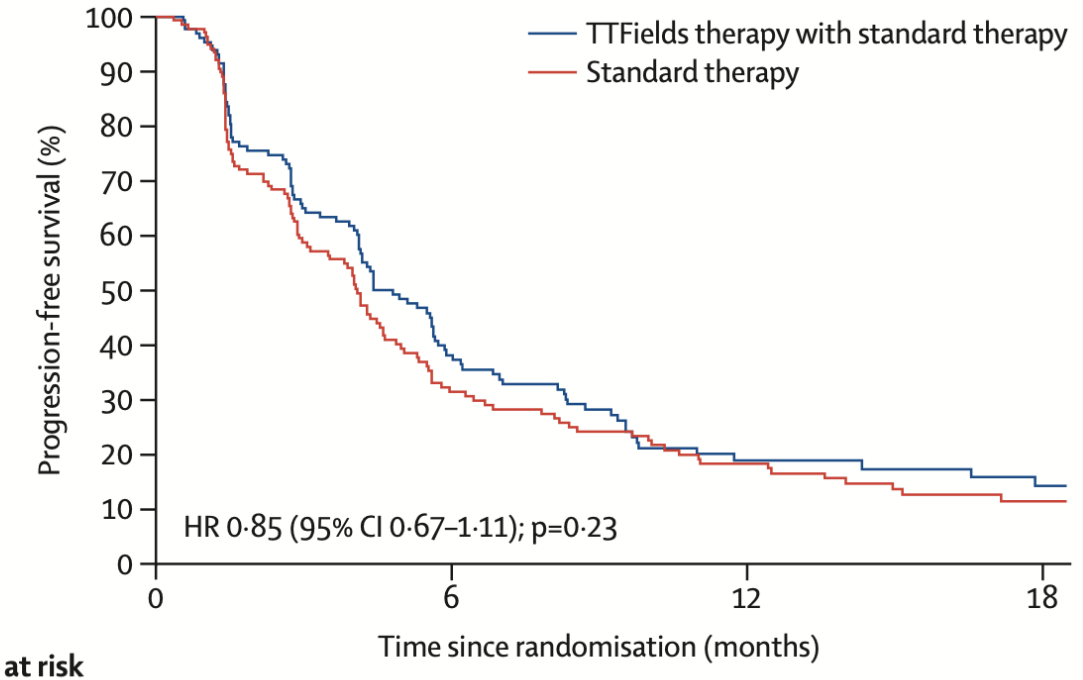
SOC = standard of care; ICI = immune checkpoint inhibitor

Leal T et al. ASCO 2023;Abstract LBA9005. Leal T et al. *Lancet Oncol* 2023;24(9):1002-17.

Courtesy of Ticiana Leal, MD

LUNAR: Response and Progression-Free Survival Outcomes

	TTFields therapy with standard therapy group (n=137)	Standard therapy group (n=139)
Patients with at least one post-baseline scan, n	122	127
Overall response, n (%; 95% CI)	28 (20·4%; 14·0–28·2)	24 (17·3%; 11·4–24·6)
Best overall response, n (%)		
Complete response	4 (3%)	1 (1%)
Partial response	24 (18%)	23 (17%)
Stable disease	67 (49%)	65 (47%)
Progressive disease	24 (18%)	36 (26%)
Not evaluable	3 (2%)	2 (1%)

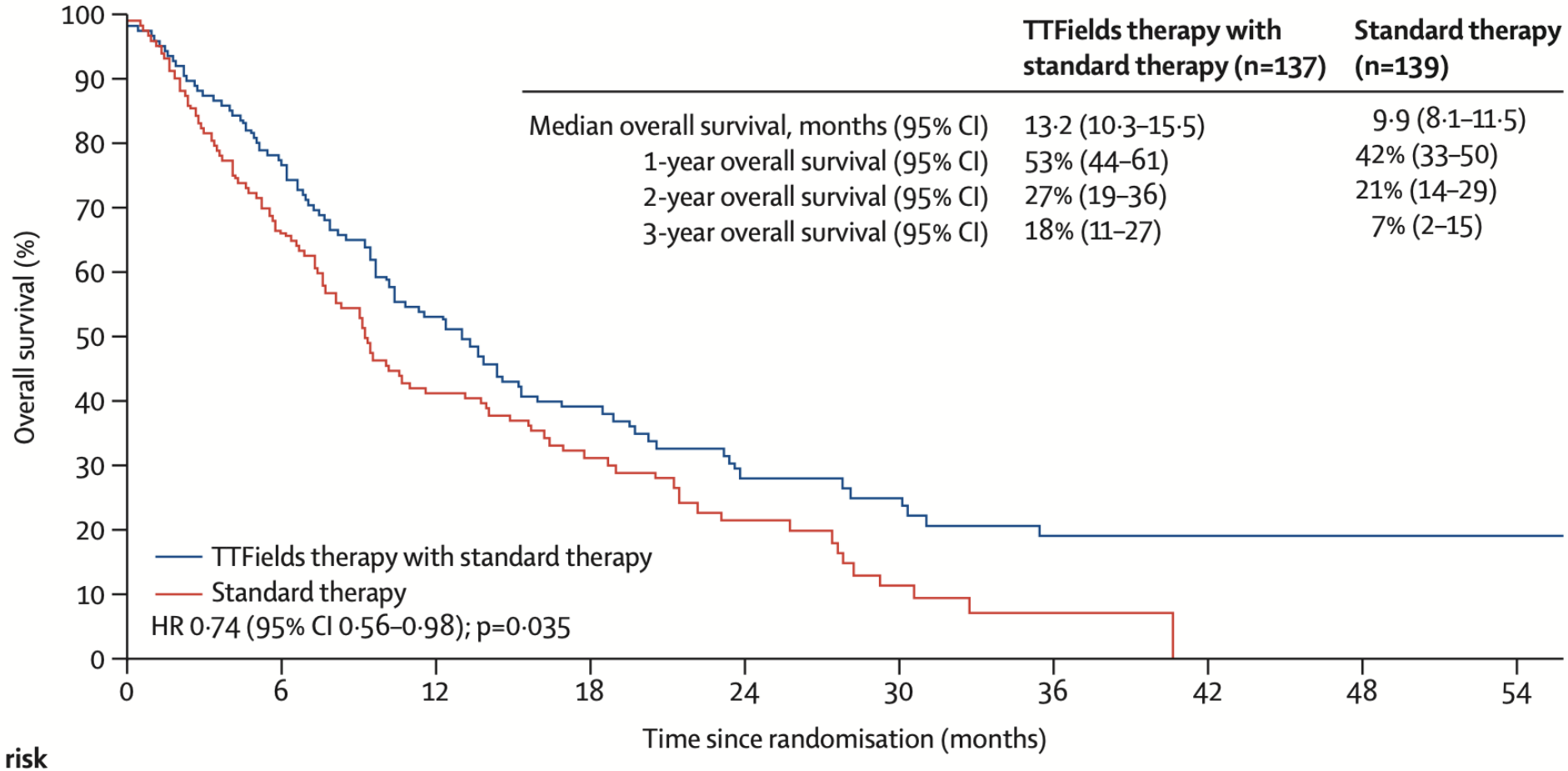


Number at risk (number censored)				
TTFields therapy with standard therapy	137 (0)	44 (17)	17 (24)	9 (29)
Standard therapy	139 (0)	40 (8)	21 (11)	9 (16)

Leal T et al. ASCO 2023;Abstract LBA9005. Leal T et al. *Lancet Oncol* 2023;24(9):1002-17.

Courtesy of Ticiana Leal, MD

LUNAR: Overall Survival Outcomes in the Intention-to-Treat Population



	TTFields therapy with standard therapy (n=137)	Standard therapy (n=139)
Median overall survival, months (95% CI)	13·2 (10·3–15·5)	9·9 (8·1–11·5)
1-year overall survival (95% CI)	53% (44–61)	42% (33–50)
2-year overall survival (95% CI)	27% (19–36)	21% (14–29)
3-year overall survival (95% CI)	18% (11–27)	7% (2–15)

Number at risk (number censored)										
TTFields therapy with standard therapy	137 (0)	100 (9)	62 (15)	36 (26)	22 (30)	16 (34)	11 (35)	9 (37)	5 (41)	3 (43)
Standard therapy	139 (0)	96 (2)	54 (5)	32 (16)	16 (23)	7 (27)	3 (28)	0 (30)	0 (30)	0 (30)

Leal T et al. ASCO 2023;Abstract LBA9005; *Lancet Oncol* 2023;24(9):1002-17.

Courtesy of Ticiana Leal, MD

LUNAR: Safety Outcomes

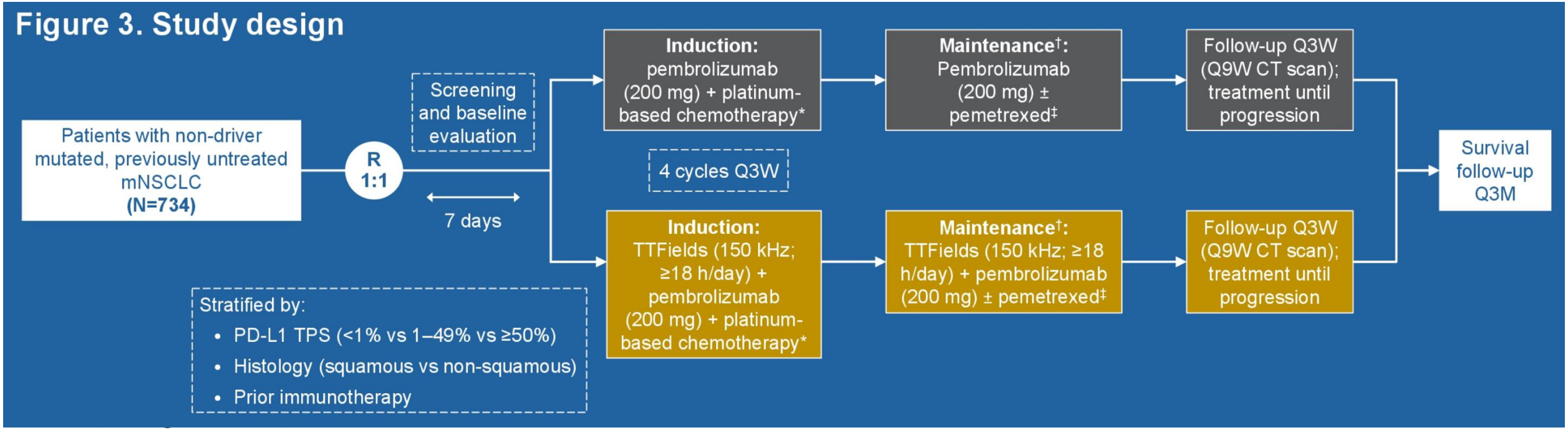
	TTFields + SOC (n=133)		SOC (n=134)	
	All grades	**Grade ≥3**	**All grades**	**Grade ≥3**
Any AE*	97%	59%	91%	56%
Most frequent AEs				
Dermatitis	**43%**	**2%**	**2%**	**0%**
Fatigue	28%	4%	37%	8%
Musculoskeletal pain	36%	3%	27%	4%
Dyspnea	20%	7%	25%	3%
Anemia	23%	8%	22%	8%
Diarrhea	19%	2%	19%	0%
Cough	18%	0%	19%	1%
Nausea	19%	0%	16%	1%
Leukopenia	17%	14%	18%	14%
Pneumonia	15%	11%	17%	11%
Alopecia	10%	0%	17%	1%
Respiratory tract infection	15%	3%	16%	0%
Localized edema	15%	1%	16%	2%
Any serious AE	53%		38%	
Any AE leading to discontinuation	36%		20%	
Any AE leading to death	10%		8%	

AE = adverse event

Leal T et al. ASCO 2023;Abstract LBA9005; *Lancet Oncol* 2023;24(9):1002-17.

Courtesy of Ticiana Leal, MD

LUNAR-2: Front-Line TTFields with ICI and Chemotherapy for mNSCLC



Inclusion criteria

- Histologically/cytologically confirmed stage IV NSCLC
- No prior systemic treatment for mNSCLC
- Evaluable (measurable or non-measurable) disease in the thorax per RECIST v1.1
- ≥18 years old (≥22 years in the US)
- ECOG PS 0–1

Endpoints

Primary*	• OS and PFS per RECIST v1.1 as assessed by a BICR
Secondary	• OS and PFS (by histology and PD-L1 TPS) per RECIST v1.1 as assessed by BICR • ORR, DoR, and DCR (all per RECIST v1.1 as assessed by BICR and by investigator) • PFS rates at 6, 12, 24 and 36 months per RECIST v1.1 as assessed by BICR • 1-, 2-, and 3-year survival rates • Safety profile
Exploratory	• PFS and OS according to in-field or out-of-field location of the disease

TPS = tumor proportion score; OS = overall survival; PFS = progression-free survival; BICR = blinded independent central review; ORR = objective response rate; DoR = duration of response; DCR = disease control rate

Eaton M et al. ASCO 2024;Abstract TPS8665.

Courtesy of Ticiana Leal, MD

Meet The Professor with Dr Wakelee

Module 5: Case Presentations – Part 3

- Dr Rudolph: 62-year-old woman diagnosed in 2014 with metastatic adenocarcinoma of the lung and treated on ECOG 5508 (carboplatin/paclitaxel/bevazicumab) receives nivolumab on progression
- Dr Rudolph: 81-year-old man with metastatic adenocarcinoma of the lung, PD-L1-negative, no AGA, TMB 44 mut/Mb, is treated with carboplatin/paclitaxel/atezolizumab/bevacizumab followed by atezolizumab/bevacizumab maintenance

Case Presentation: 62-year-old woman diagnosed in 2014 with metastatic adenocarcinoma of the lung and treated on ECOG 5508 (carboplatin/paclitaxel/bevazicumab) receives nivolumab on progression

Dr Priya Rudolph (Athens, Georgia)

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Case Presentation: 81-year-old man with metastatic adenocarcinoma of the lung, PD-L1-negative, no AGA, TMB 44 mut/Mb, is treated with carboplatin/paclitaxel/ atezolizumab/bevacizumab followed by atezolizumab/ bevacizumab maintenance

Dr Priya Rudolph (Athens, Georgia)

Contributing General Medical Oncologists

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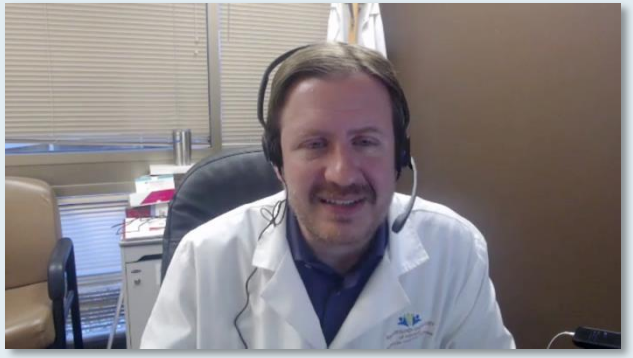
American Oncology Partners
Naples, Florida

Taral Patel, MD
Zangmeister Cancer Center
Columbus, Ohio



Brian P Mulherin, MD
Hematology Oncology of Indiana
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Priya Rudolph, MD, PhD
Georgia Cancer Specialists
Athens, Georgia

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What Clinicians Want to Know: Addressing Current Questions and Controversies in the Management of Hematologic Cancers

A CME Friday Satellite Symposium and Webcast Series
Preceding the 66th ASH Annual Meeting and Exposition

Friday, December 6, 2024

Chronic Myeloid Leukemia
7:30 AM – 9:00 AM PT

Chronic Lymphocytic Leukemia
7:30 AM – 9:30 AM PT

CAR T-Cell Therapy and Bispecific Antibodies in Lymphoma
11:30 AM – 1:30 PM PT

Myelofibrosis
11:30 AM – 1:30 PM PT

Acute Myeloid Leukemia
3:15 PM – 5:15 PM PT

Multiple Myeloma
3:15 PM – 5:15 PM PT

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Thank you for joining us!

Please take a moment to complete the survey currently up on Zoom. Your feedback is very important to us. The survey will remain open for 5 minutes after the meeting ends.

Information on how to obtain CME and ABIM MOC 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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