The Implications of Recent Datasets for the Current and Future Management of Small Cell Lung Cancer — A 2024 World Conference on Lung Cancer Review Webinar

A CME/MOC-Accredited Live Webinar

Thursday, September 26, 2024
5:00 PM – 5:45 PM ET

Faculty

Jacob Sands, MD

Moderator

Neil Love, MD

RTP RESEARCH TO PRACTICE

Faculty

Jacob Sands, MD
Physician
Dana-Farber Cancer Institute
Assistant Professor
Harvard Medical School
Boston, Massachusetts

MODERATOR
Neil Love, MD
Research To Practice
Miami, Florida

Commercial Support

This activity is supported by an educational grant from Daiichi Sankyo Inc.

Dr Love — Disclosures

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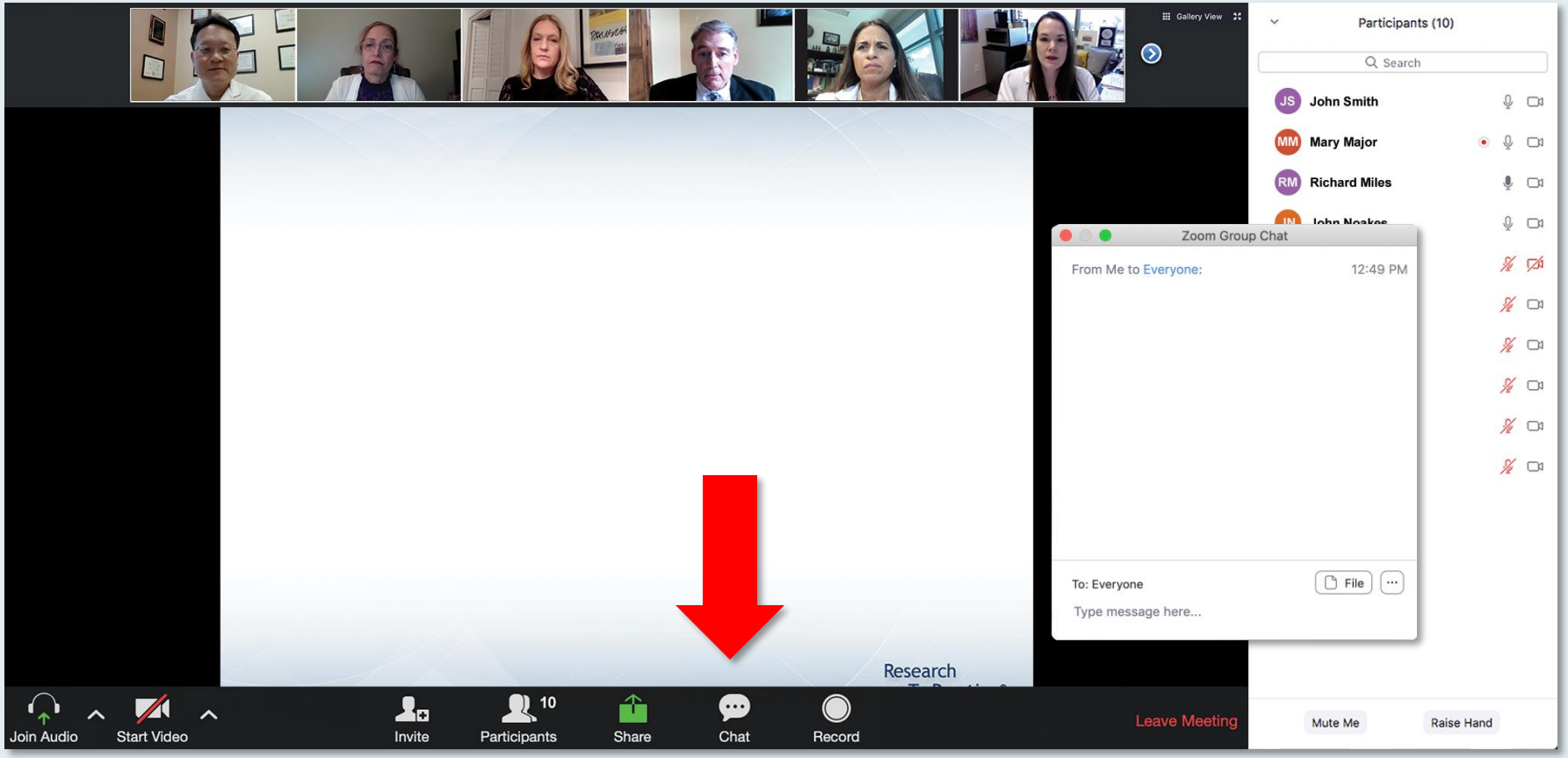

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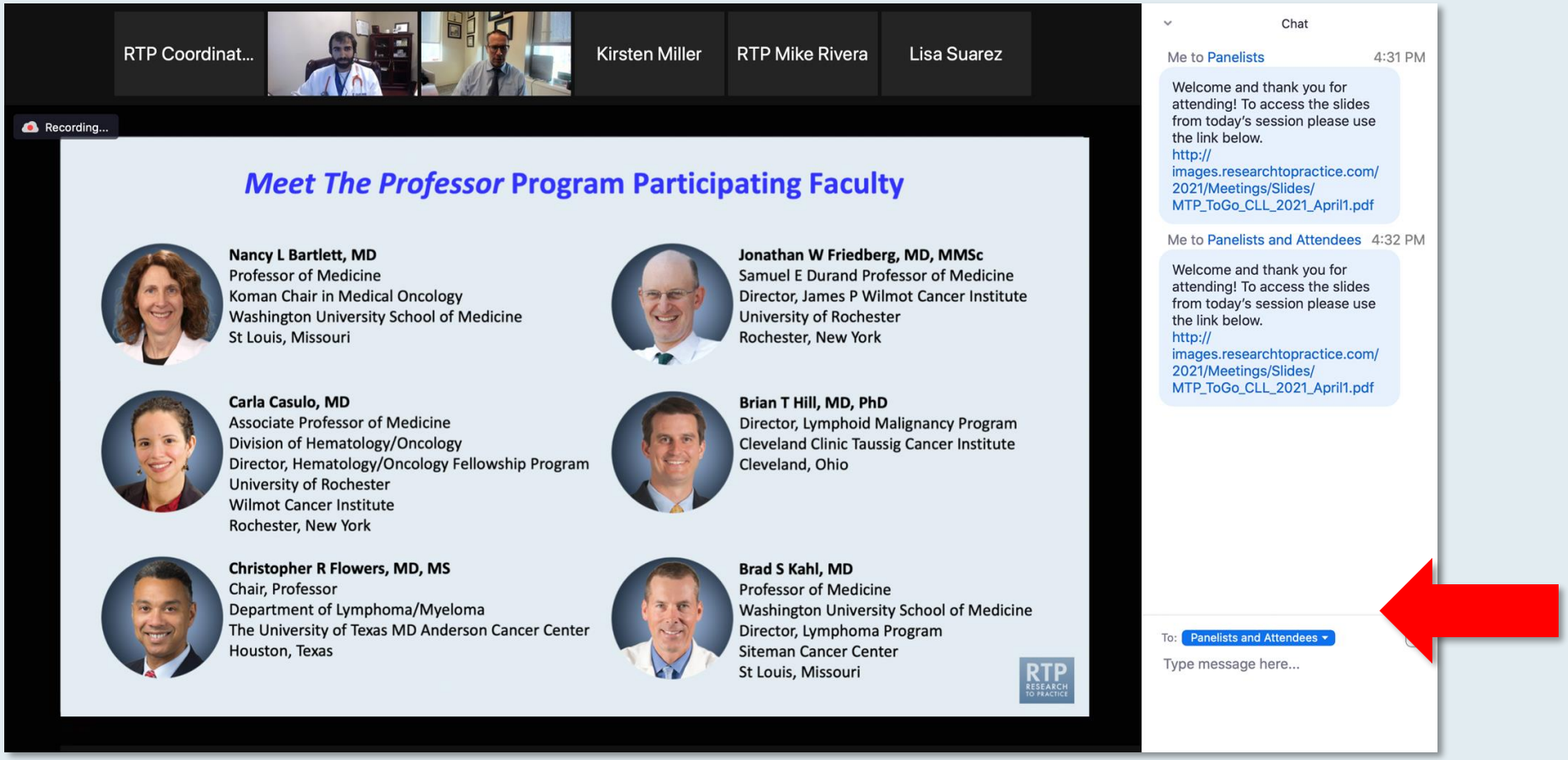

Drag the white line above the submission box up to create more space for your message.

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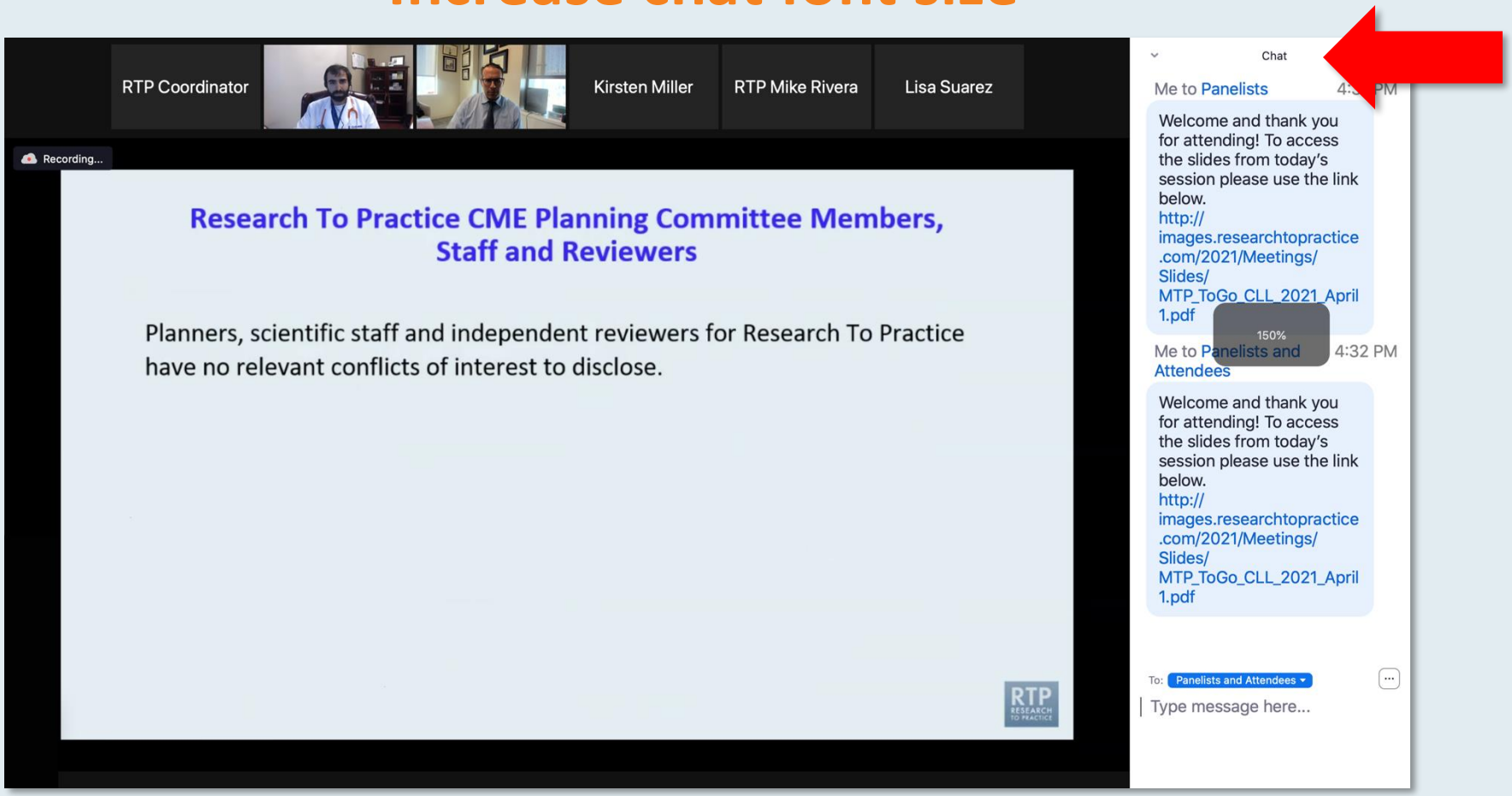

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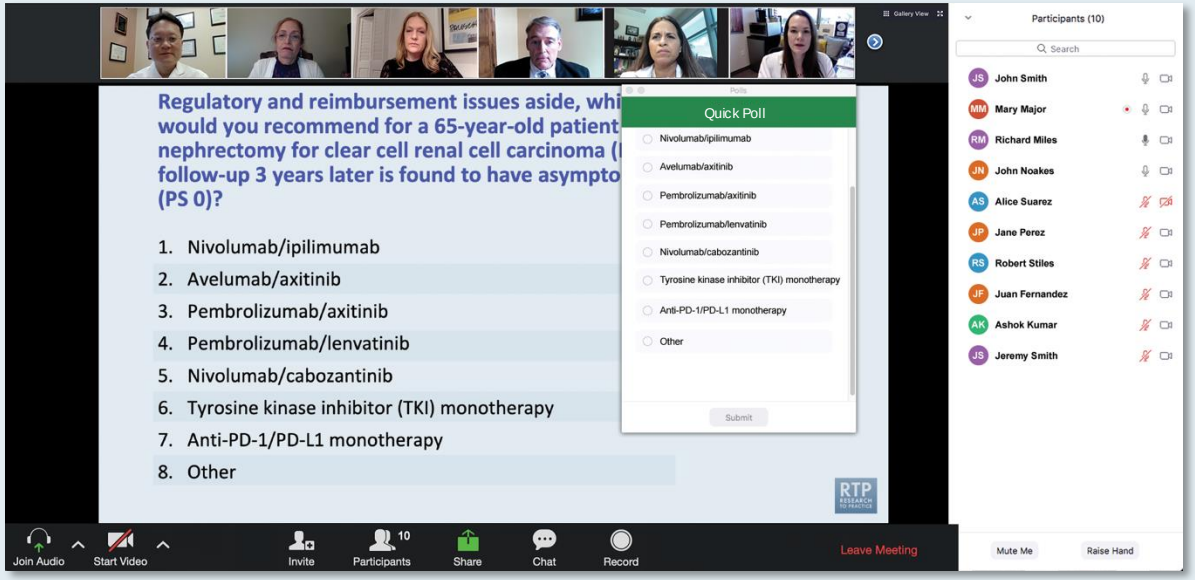

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Management of Small Cell Lung Cancer

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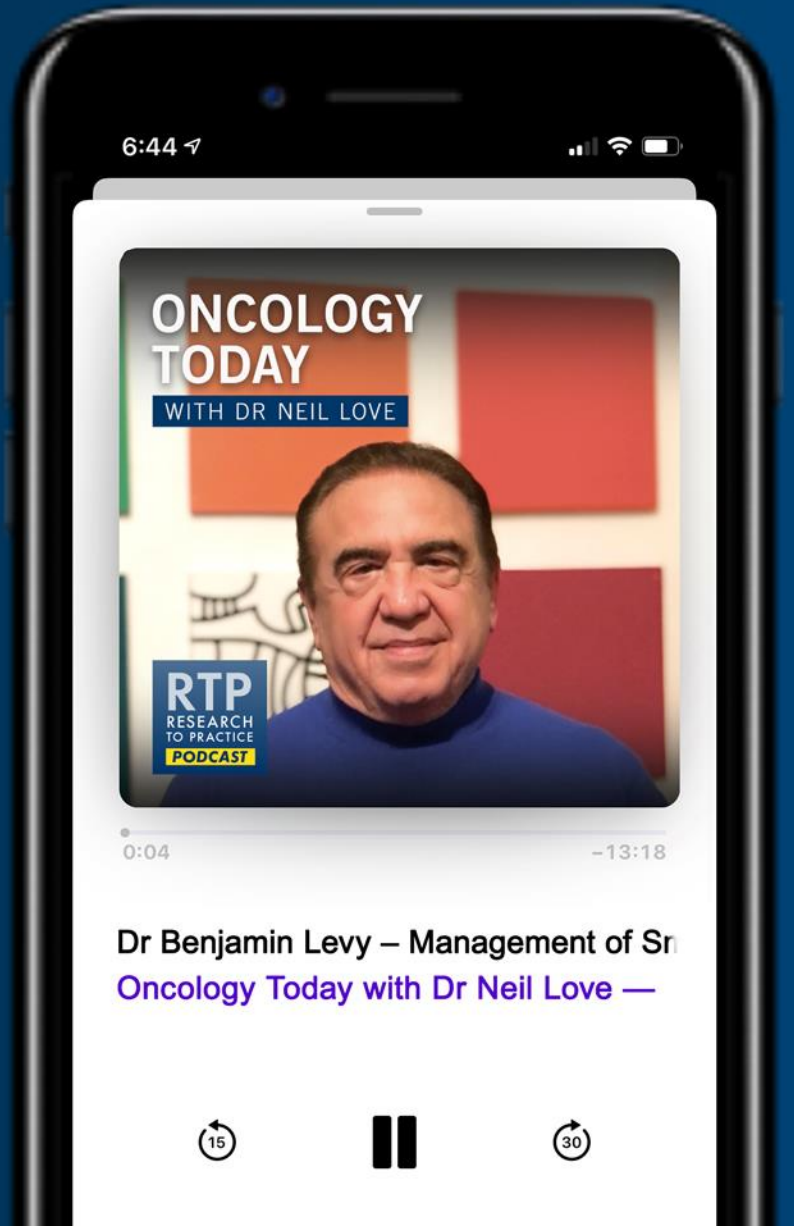

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Kevin Kalinsky, MD, MS

Moderator

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Tanios Bekaii-Saab, MD
Philip A Philip, MD, PhD, FRCP

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

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Seth Wander, MD, PhD

Prostate Cancer

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Preceding the 66th ASH Annual Meeting and Exposition

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7:30 AM – 9:00 AM PT

Chronic Lymphocytic Leukemia
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Moderated by Neil Love, MD

Thank you for joining us!

Information on how to obtain CME, ABIM MOC and ABS 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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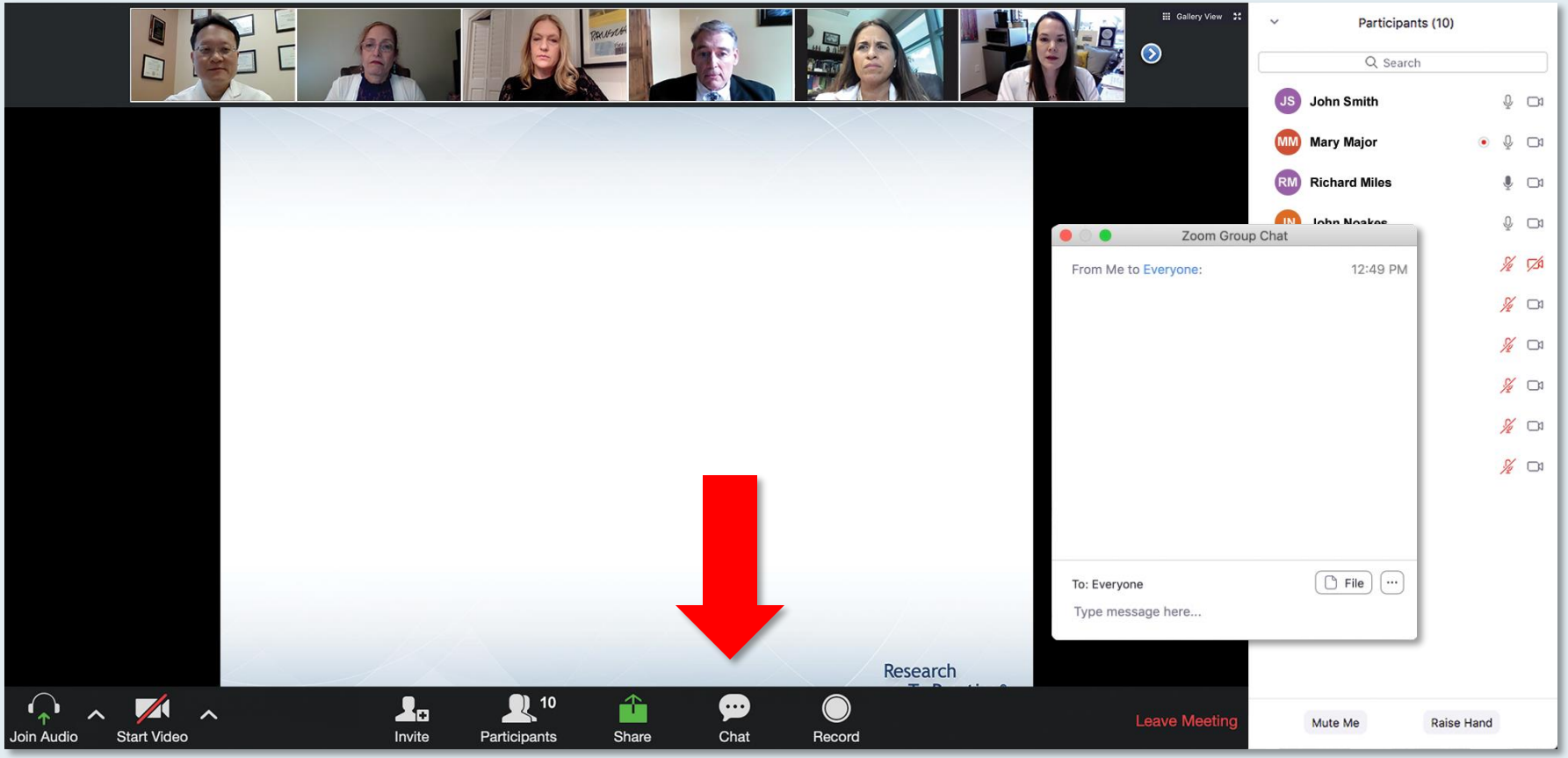

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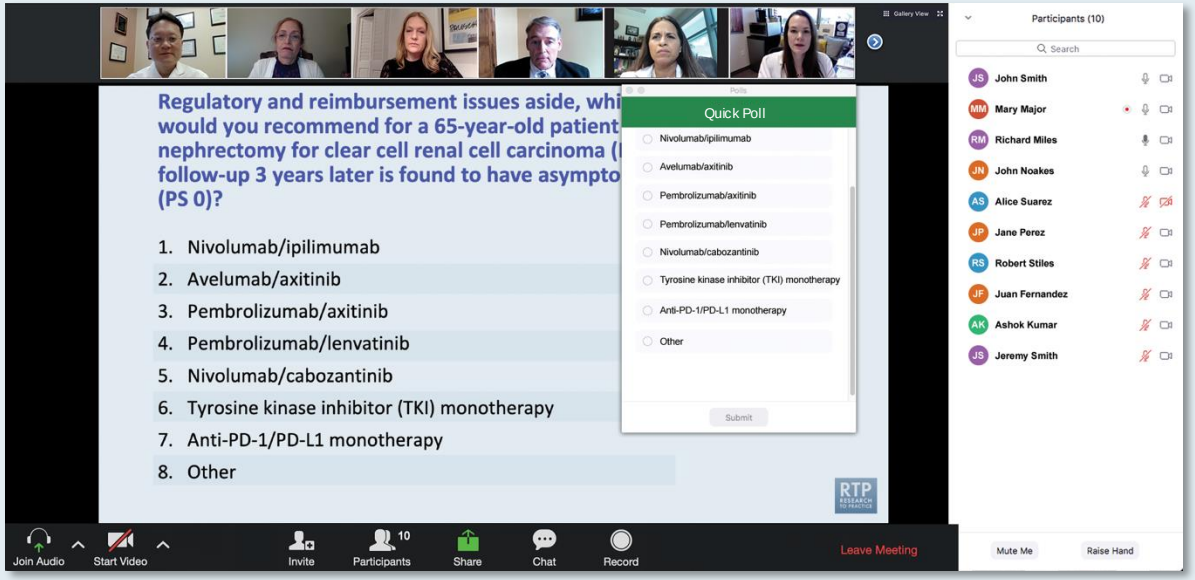

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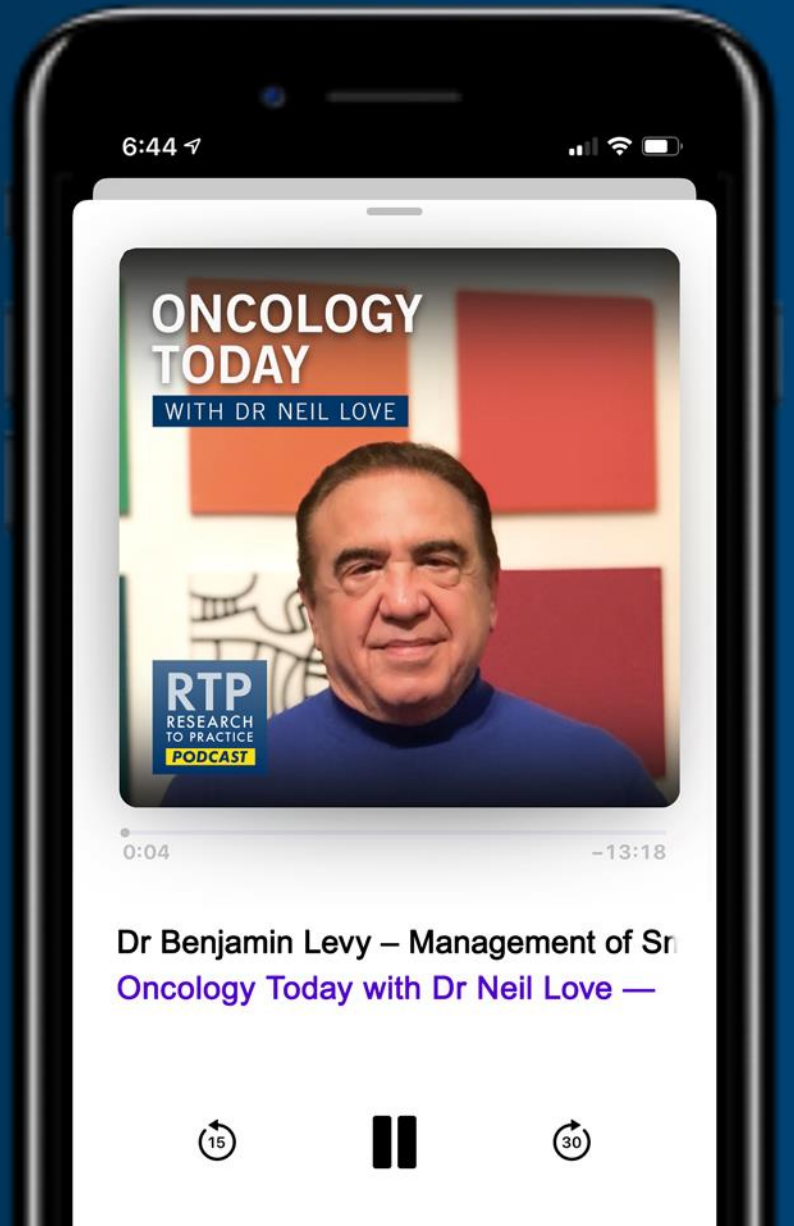

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Agenda

Introduction: A 66-Year-Old Man with a Lung Nodule on Lung Cancer Screening

Module 1: Current and Future Management of Small Cell Lung Cancer (SCLC)

Module 2: Other Relevant SCLC Abstracts from WCLC 2024

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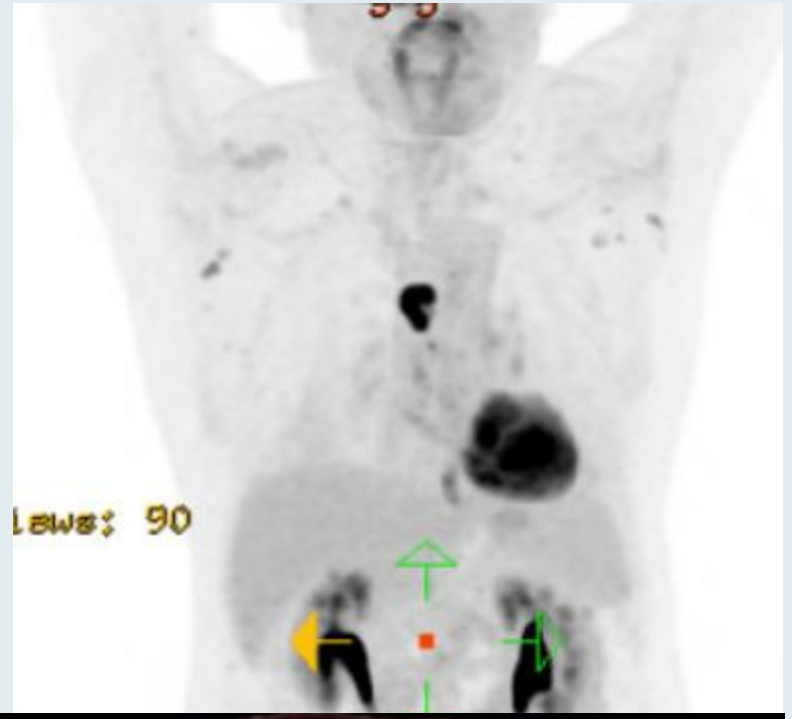
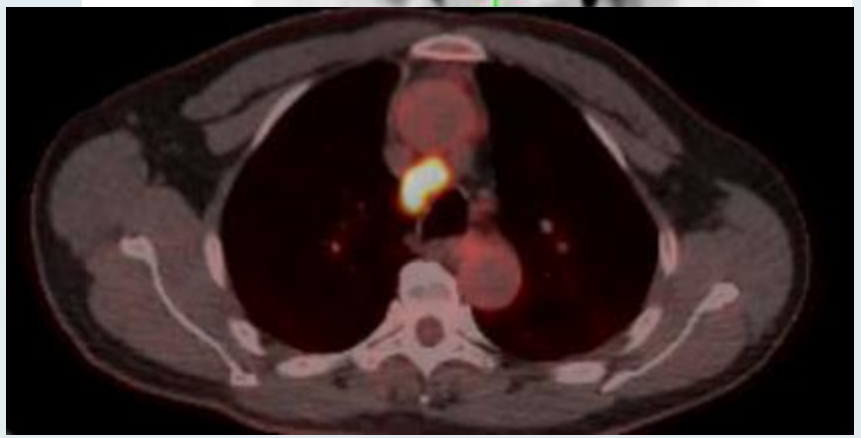
Clinical Case

- 66-yr old man who underwent lung screening at the recommendation of his PCP
- Right lung nodule and mediastinal adenopathy noted on scan
- PET/CT showed FDG avidity
- Biopsy demonstrated small cell lung cancer
- What treatment do you recommend?

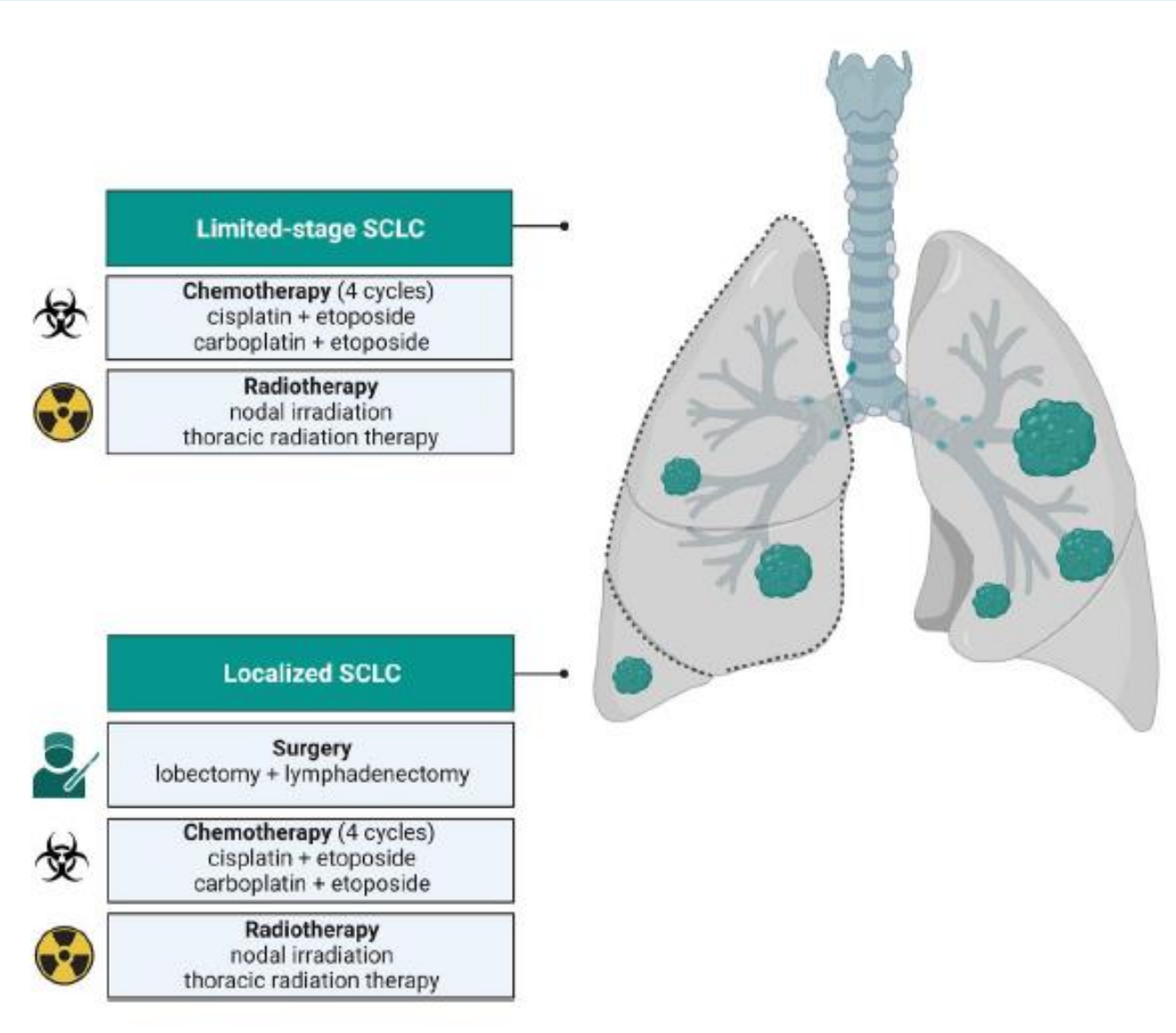




Clinical Case: Recurrence

- Was treated with cisplatin and etoposide concurrent with radiation followed by durvalumab
- About 6 months into treatment on durvalumab, CT scan showed metastatic recurrence at multiple sites, including liver, right adrenal, and 3 bone mets
- He is asymptomatic and continues to have good functional status
- Biopsy of liver met confirms recurrent SCLC
- What is next line treatment?

Therapeutic Approaches for Limited-Stage and Localized SCLC



Megyesfalvi Z et al. *CA Cancer J Clin* 2023;73:620-52.

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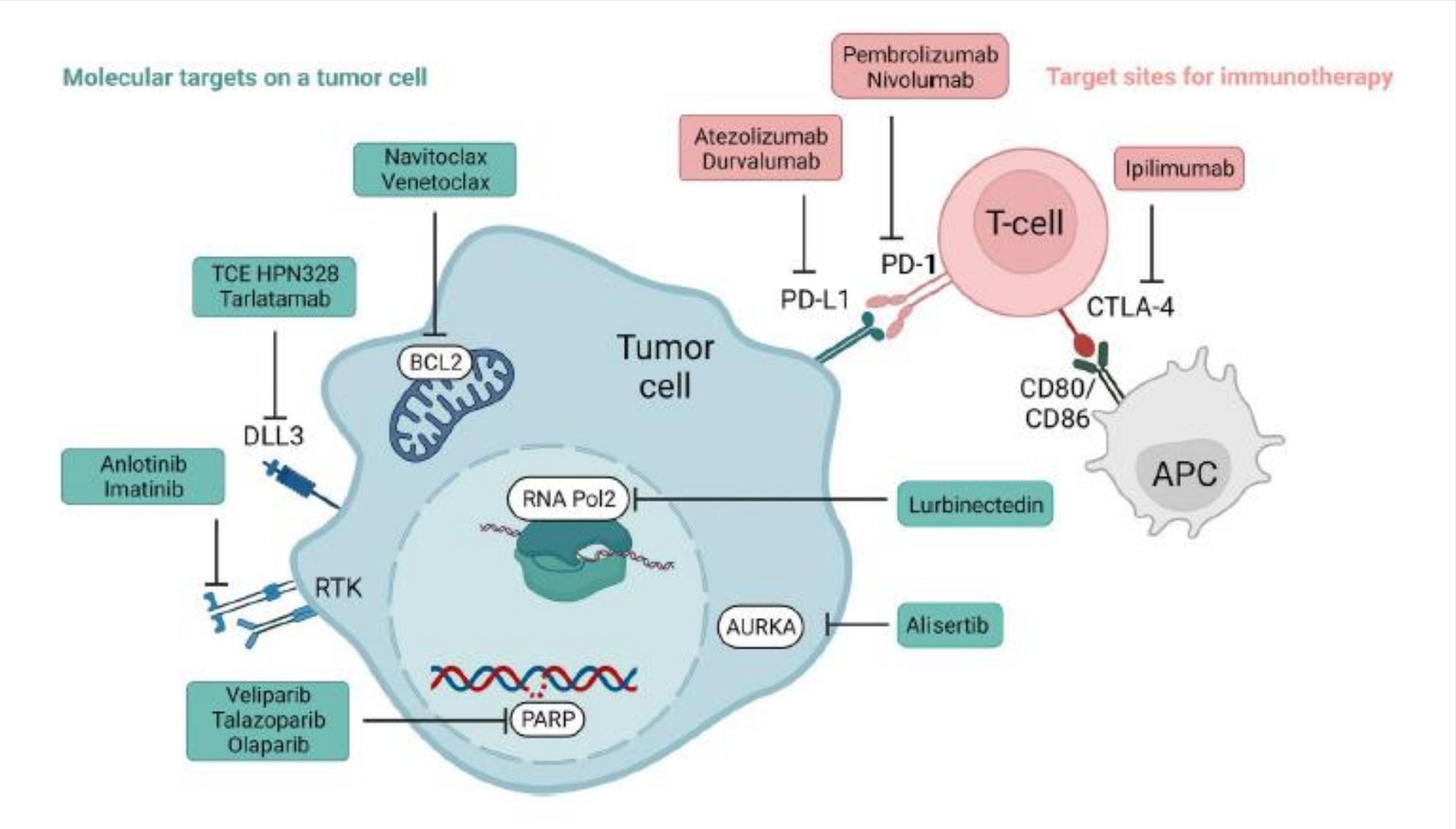
Molecular Targets in SCLC



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Jacob Sands, MD
Physician
Dana-Farber Cancer Institute
Assistant Professor
Harvard Medical School
Boston, Massachusetts

The NEW ENGLAND JOURNAL of MEDICINE

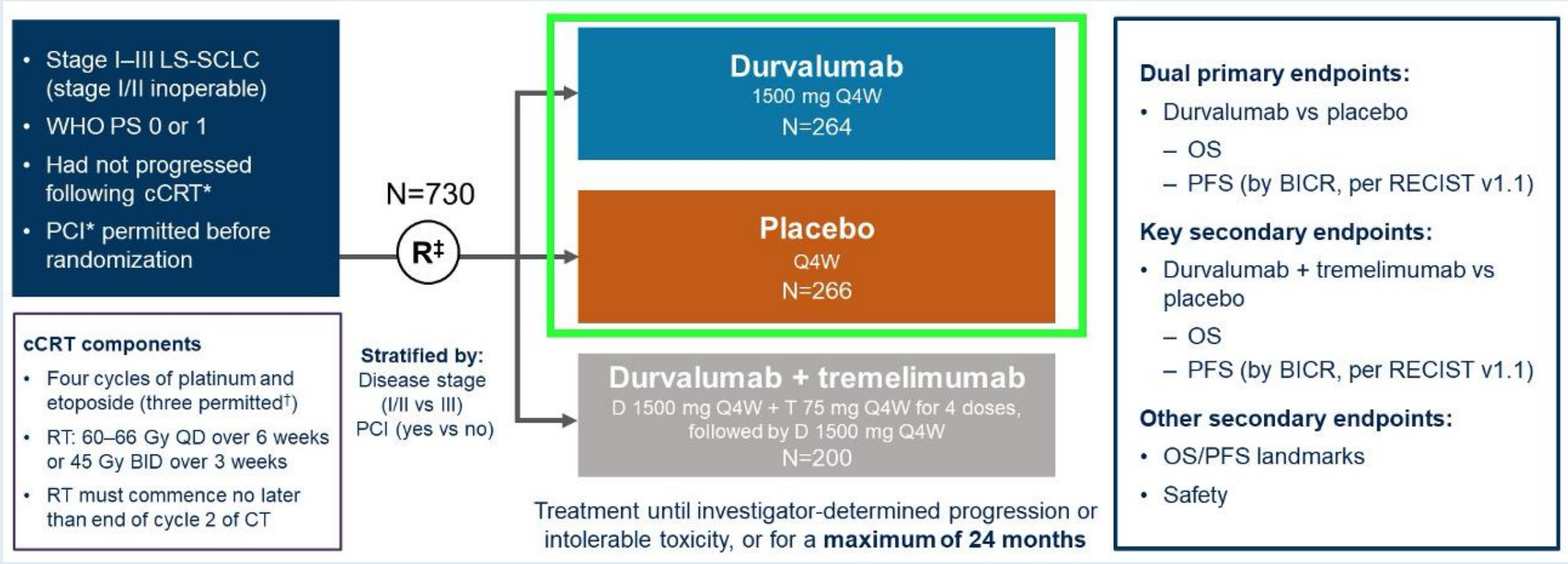
2024 September 13;[Online ahead of print]

ORIGINAL ARTICLE

Durvalumab after Chemoradiotherapy in Limited-Stage Small-Cell Lung Cancer

Y. Cheng, D.R. Spigel, B.C. Cho, K.K. Laktionov, J. Fang, Y. Chen, Y. Zenke, K.H. Lee, Q. Wang, A. Navarro, R. Bernabe, E.L. Buchmeier, J.W.-C. Chang, Y. Shiraishi, S.S. Goksu, A. Badzio, A. Shi, D.B. Daniel, N.T.T. Hoa, M. Zemanova, H. Mann, H. Gowda, H. Jiang, and S. Senan, for the ADRIATIC Investigators*

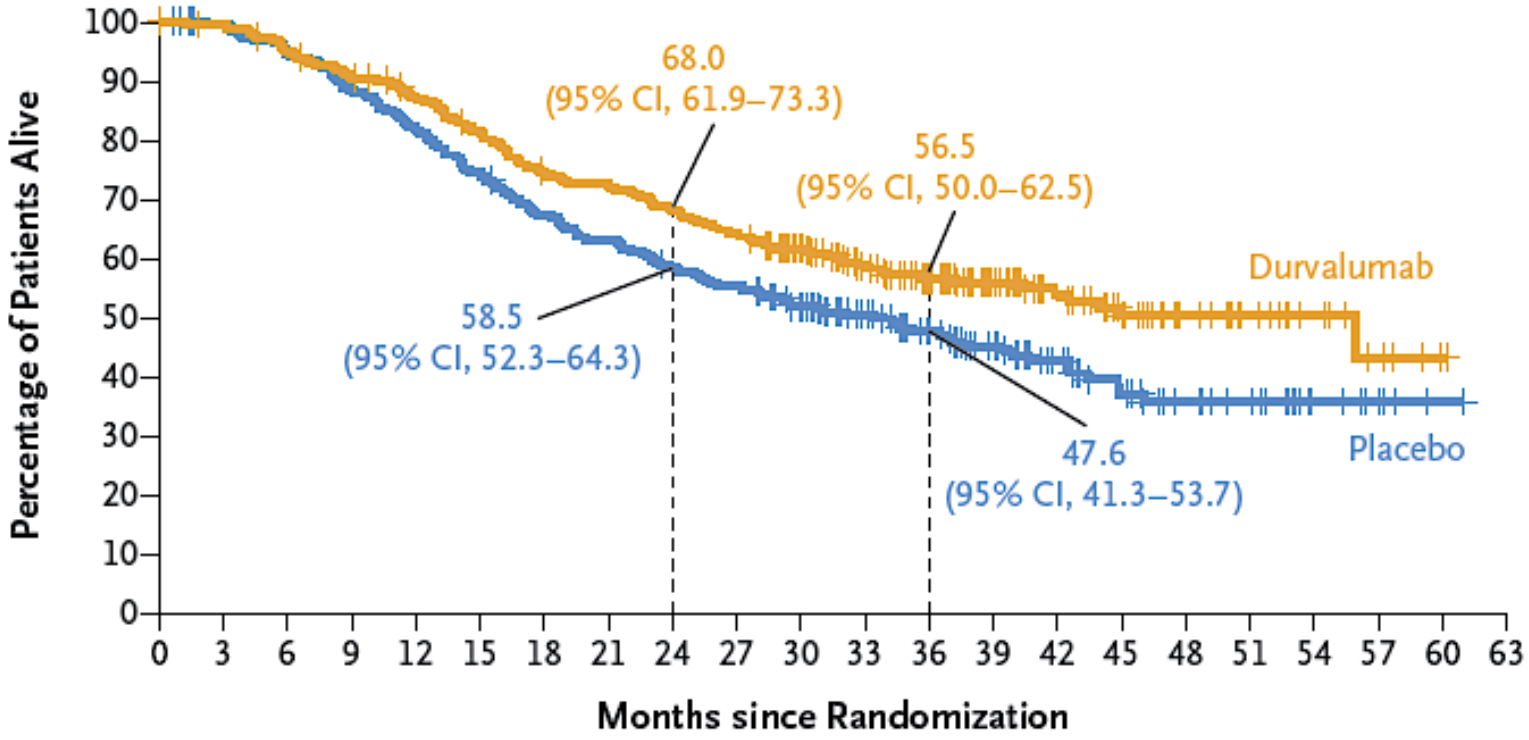
ADRIATIC Phase III Study Design



LS-SCLC = limited-stage small cell lung cancer; cCRT = concurrent chemoradiation therapy; PCI = prophylactic cranial irradiation; RT = radiation therapy; OS = overall survival; PFS = progression-free survival; BICR = blinded independent central review

Spigel DR et al. ASCO 2024;Abstract LBA5.

ADRIATIC: Overall Survival (Dual Primary Endpoint)

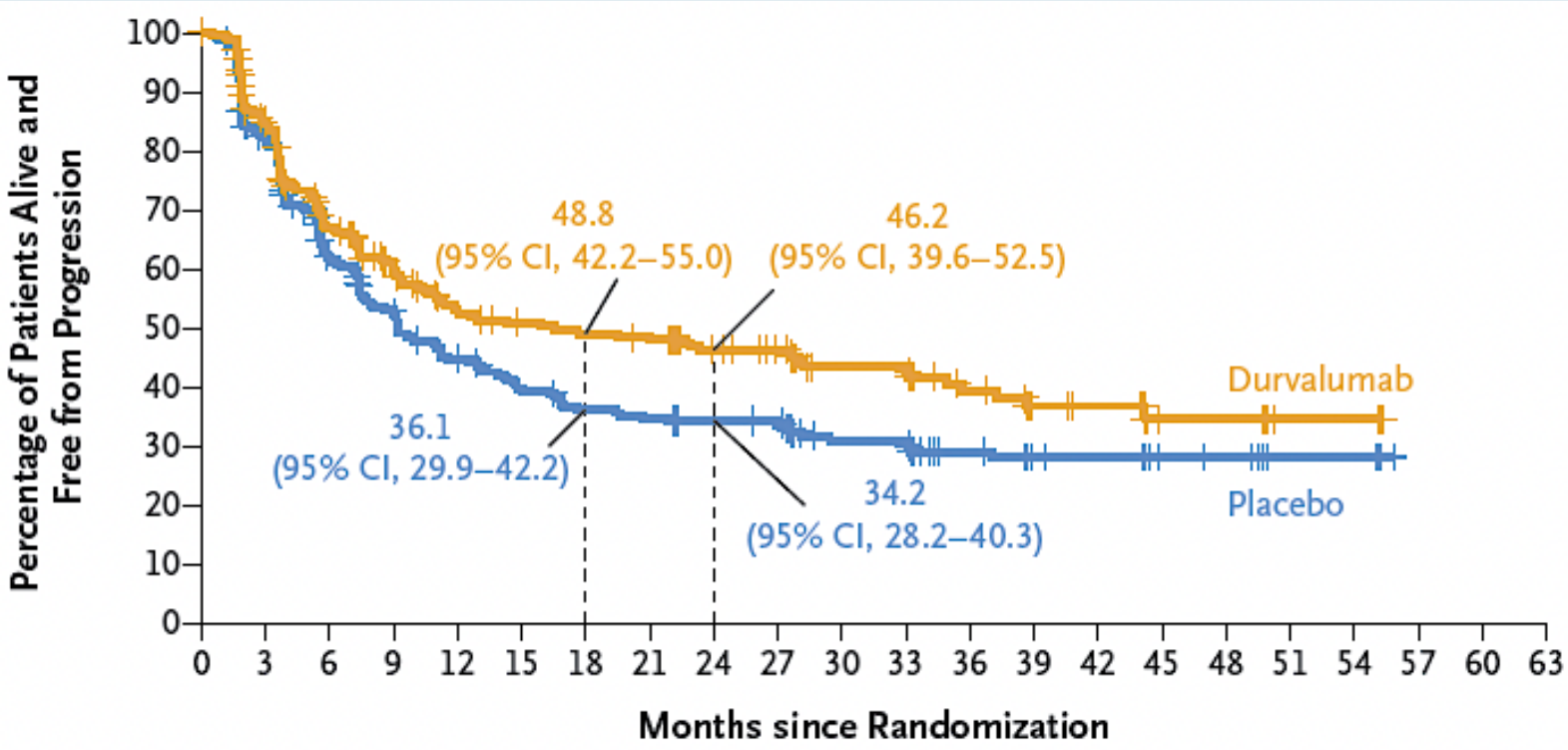


	No. of Deaths/ Total No. (%)	Median Overall Survival (95% CI)
		mo
Durvalumab	115/264 (43.6)	55.9 (37.3–NR)
Placebo	146/266 (54.9)	33.4 (25.5–39.9)

Stratified hazard ratio for death, 0.73 (98.321% CI, 0.54–0.98)
P=0.01

Cheng Y et al. *N Engl J Med* 2024 September 13;[Online ahead of print].

ADRIATIC: Progression-Free Survival (Dual Primary Endpoint)



	No. of Events/ Total No. (%)	Median Progression-free Survival (95% CI)
		mo
Durvalumab	139/264 (52.7)	16.6 (10.2–28.2)
Placebo	169/266 (63.5)	9.2 (7.4–12.9)

Stratified hazard ratio for disease progression or death, 0.76
(99.816% CI, 0.53–1.08)
(97.195% CI, 0.59–0.98)
P=0.02

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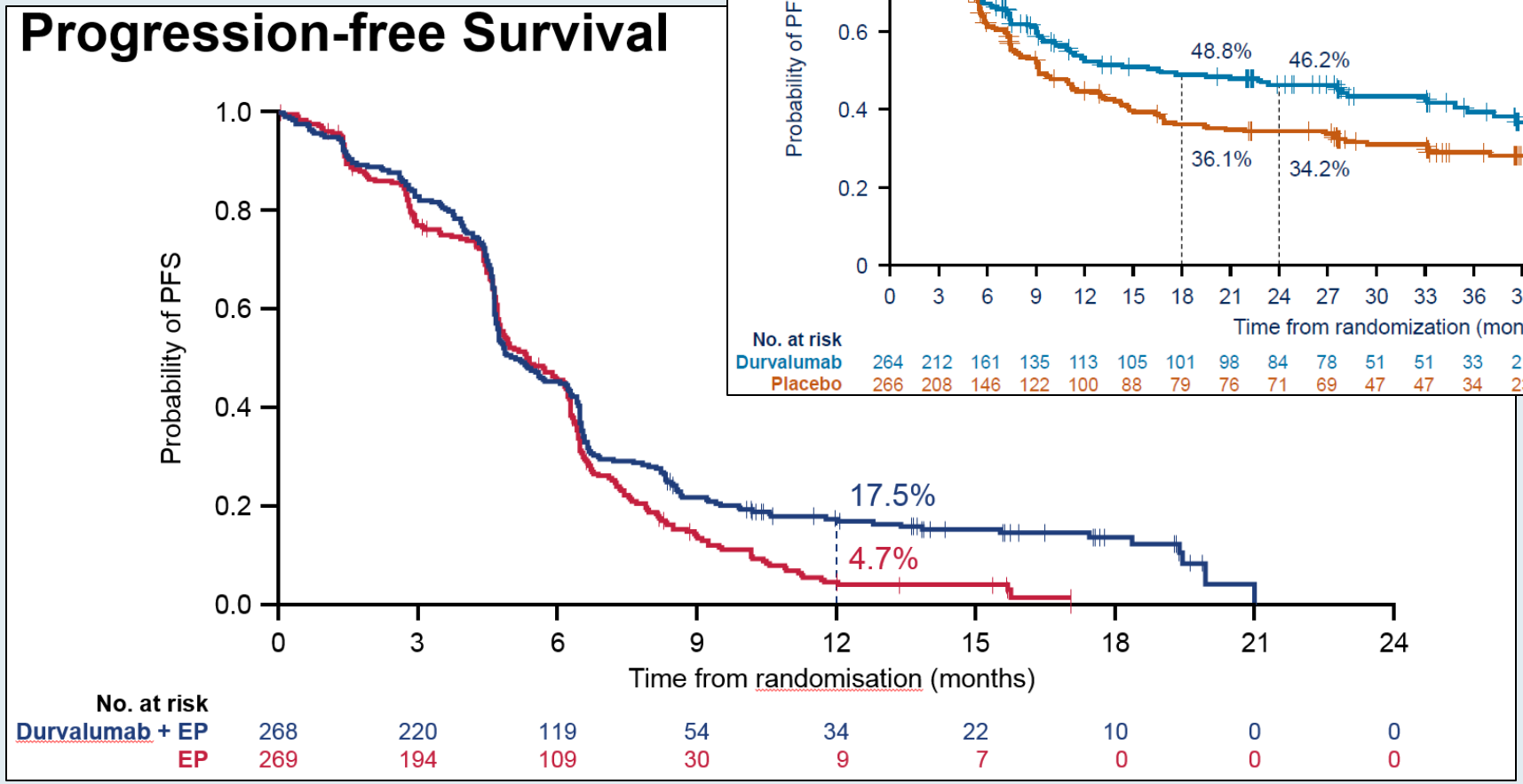
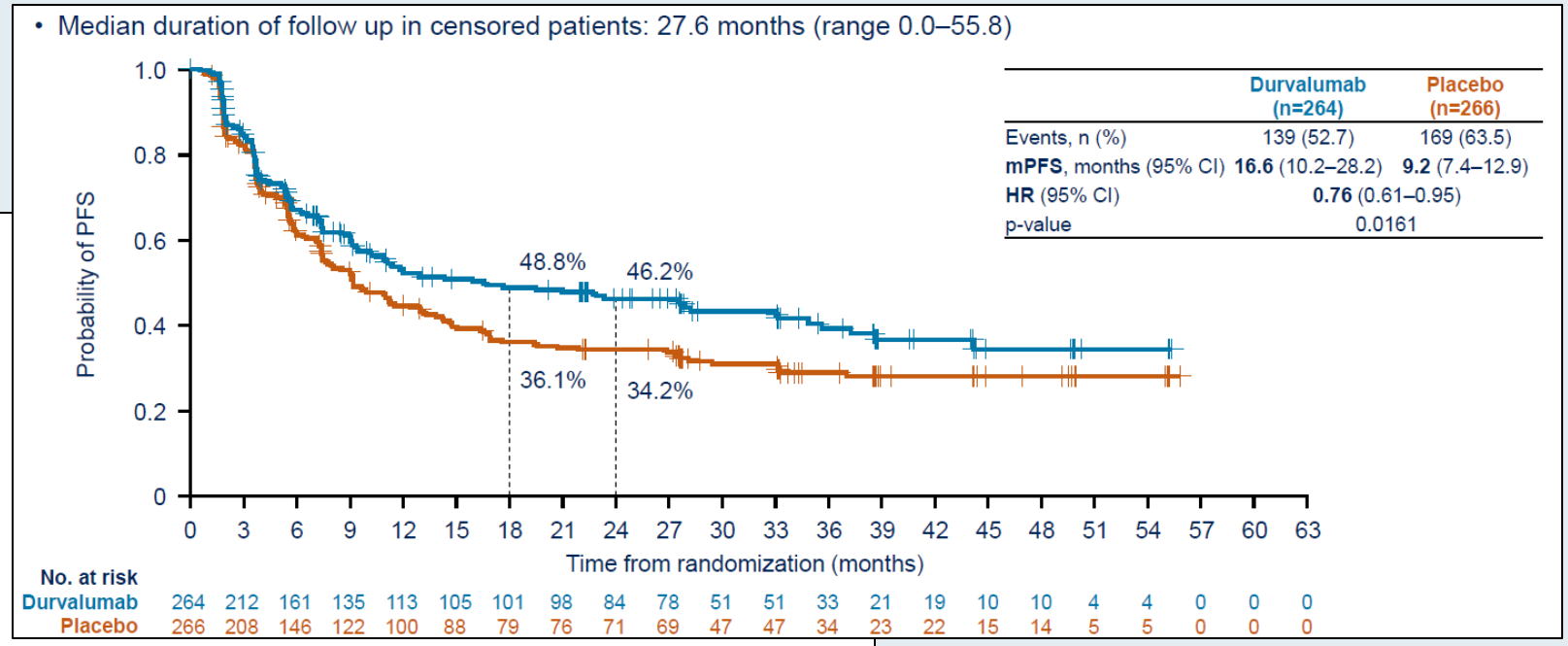
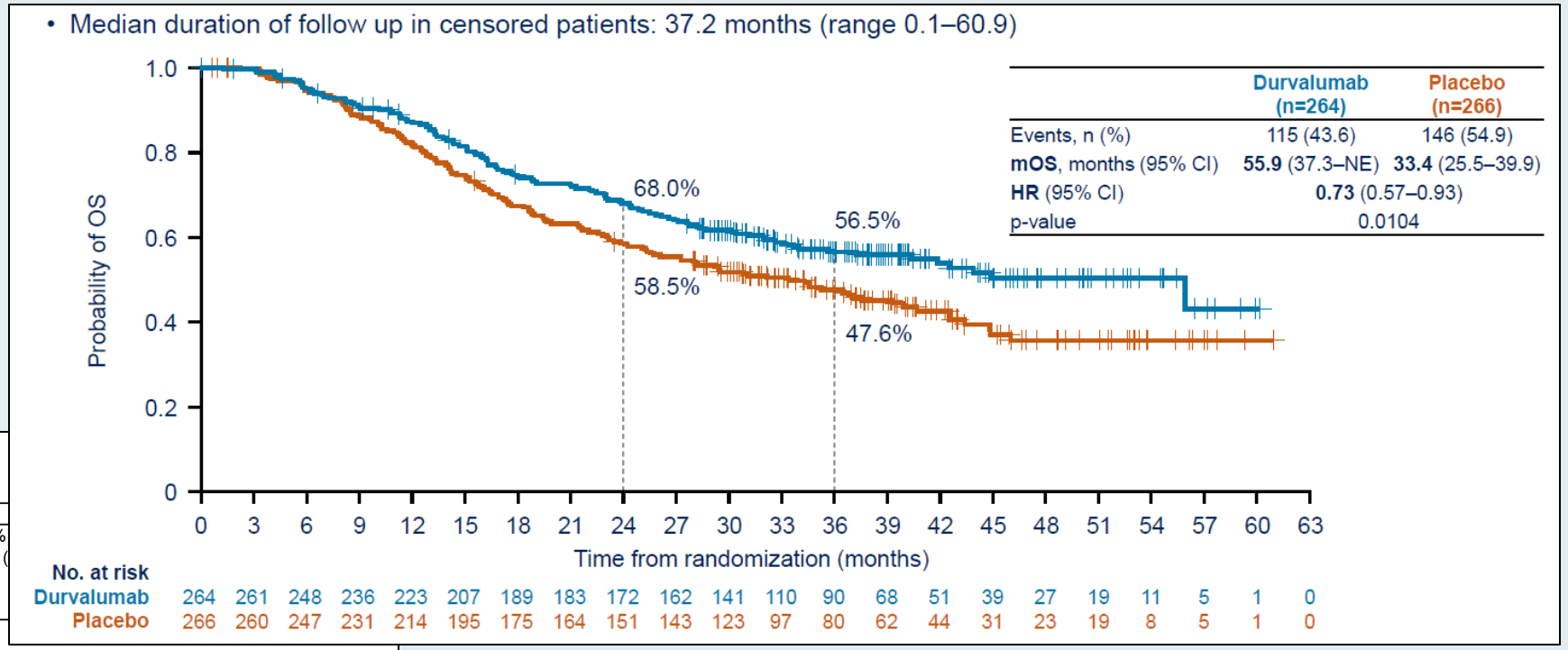
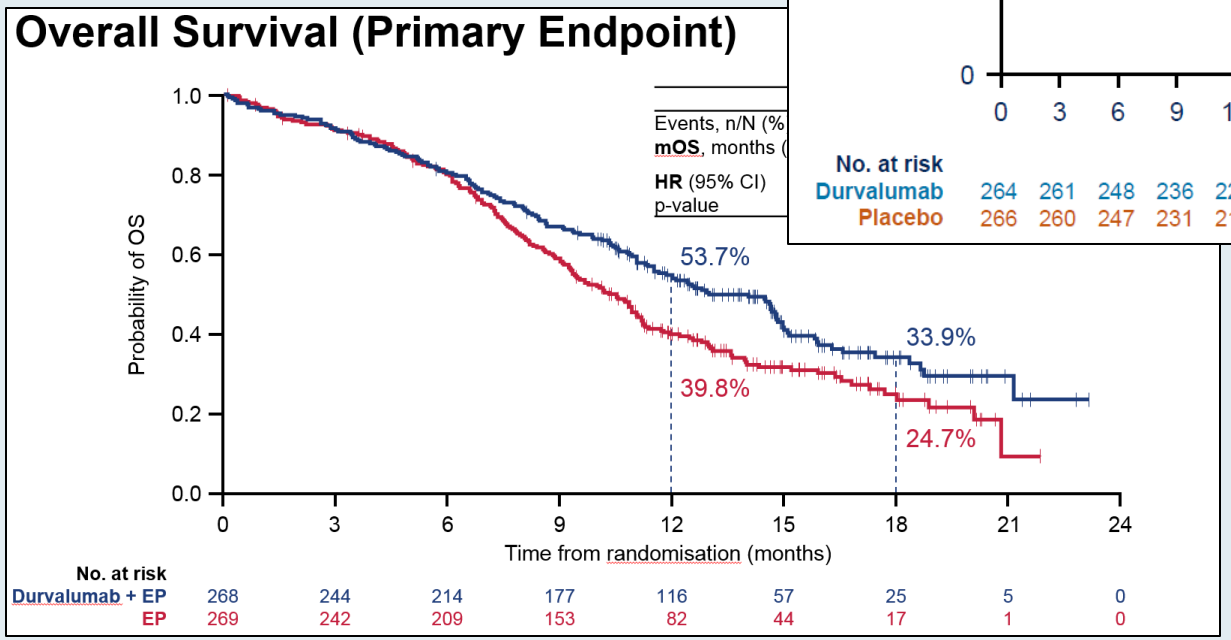
Progression-Free Survival Comparison with CASPIAN





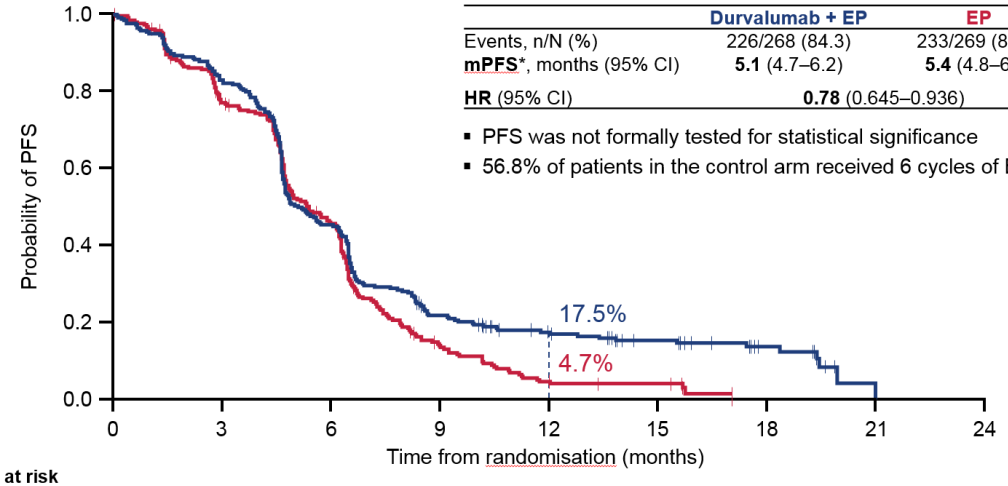
Overall Survival Comparison with CASPIAN





CASPIAN

Progression-free Survival

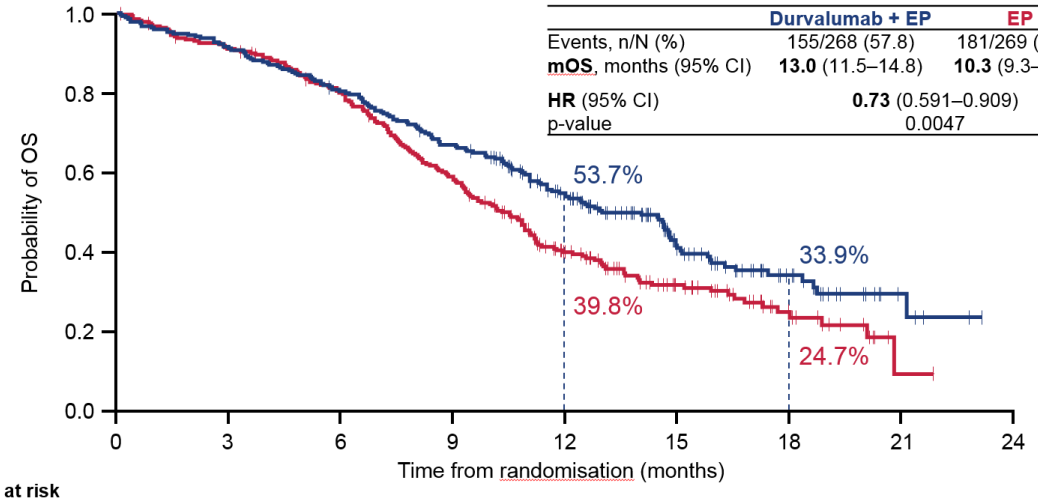


	Durvalumab + EP	EP
Events, n/N (%)	226/268 (84.3)	233/269 (86.6)
mPFS*, months (95% CI)	**5.1** (4.7–6.2)	**5.4** (4.8–6.2)
HR (95% CI)	**0.78** (0.645–0.936)	

- PFS was not formally tested for statistical significance
- 56.8% of patients in the control arm received 6 cycles of EP

No. at risk									
Durvalumab + EP	268	220	119	54	34	22	10	0	0
EP	269	194	109	30	9	7	0	0	0

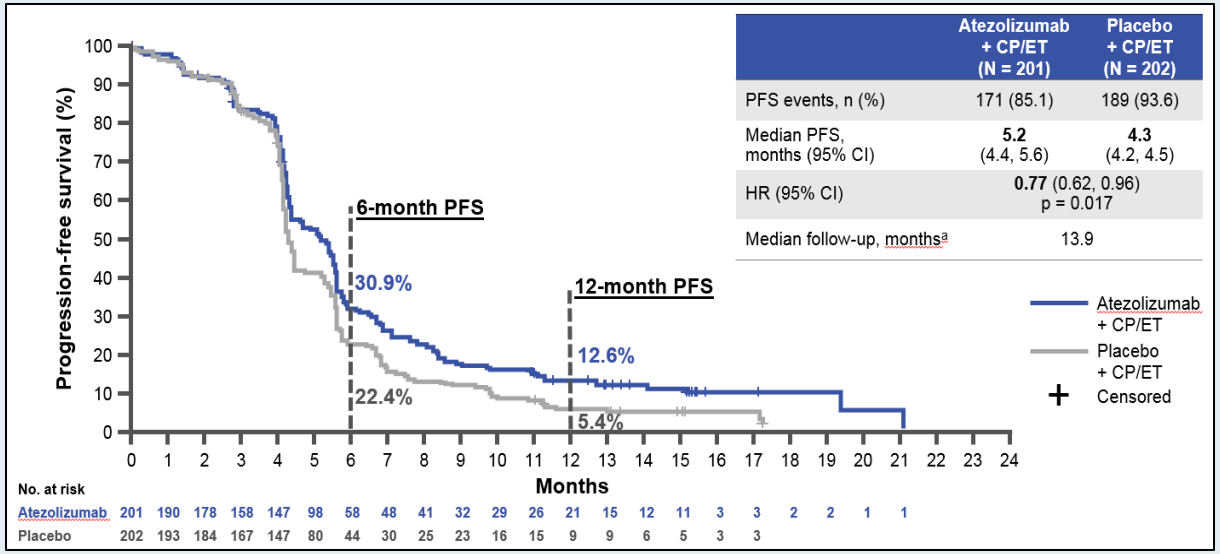
Overall Survival (Primary Endpoint)



	Durvalumab + EP	EP
Events, n/N (%)	155/268 (57.8)	181/269 (67.3)
mOS, months (95% CI)	**13.0** (11.5–14.8)	**10.3** (9.3–11.2)
HR (95% CI)	**0.73** (0.591–0.909)	
p-value	0.0047	

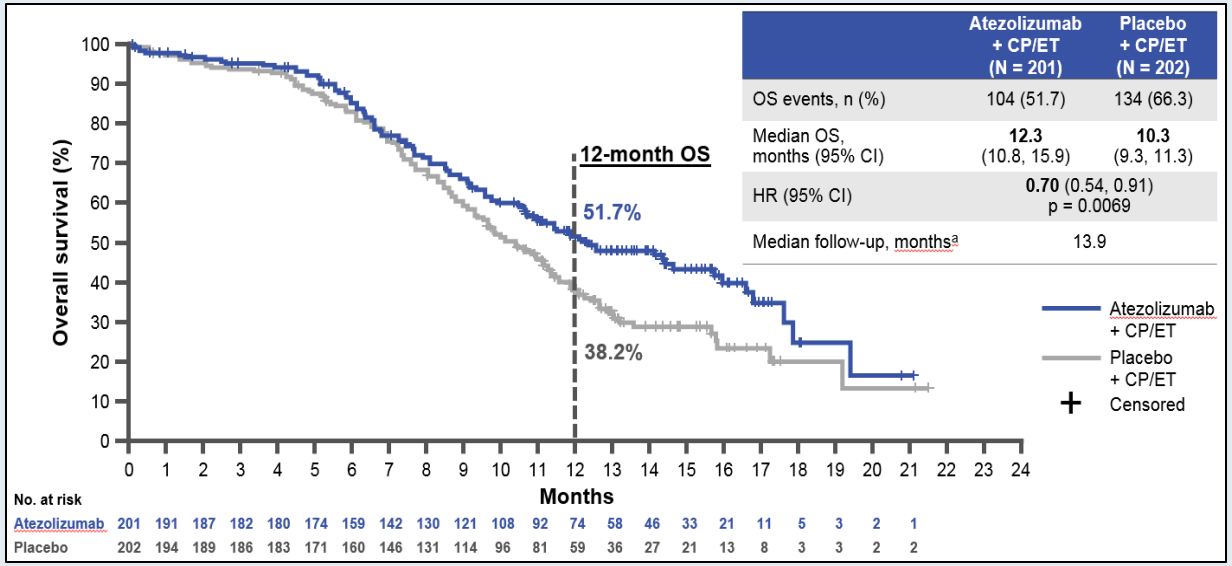
No. at risk									
Durvalumab + EP	268	244	214	177	116	57	25	5	0
EP	269	242	209	153	82	44	17	1	0

IMpower133



	Atezolizumab + CP/ET (N = 201)	Placebo + CP/ET (N = 202)
PFS events, n (%)	171 (85.1)	189 (93.6)
Median PFS, months (95% CI)	**5.2** (4.4, 5.6)	**4.3** (4.2, 4.5)
HR (95% CI)	**0.77** (0.62, 0.96) p = 0.017	
Median follow-up, months[a]	13.9	

No. at risk																								
Atezolizumab	201	190	178	158	147	98	58	48	41	32	29	26	21	15	12	11	3	3	2	2	1	1
Placebo	202	193	184	167	147	80	44	30	25	23	16	15	9	9	6	5	3	3				

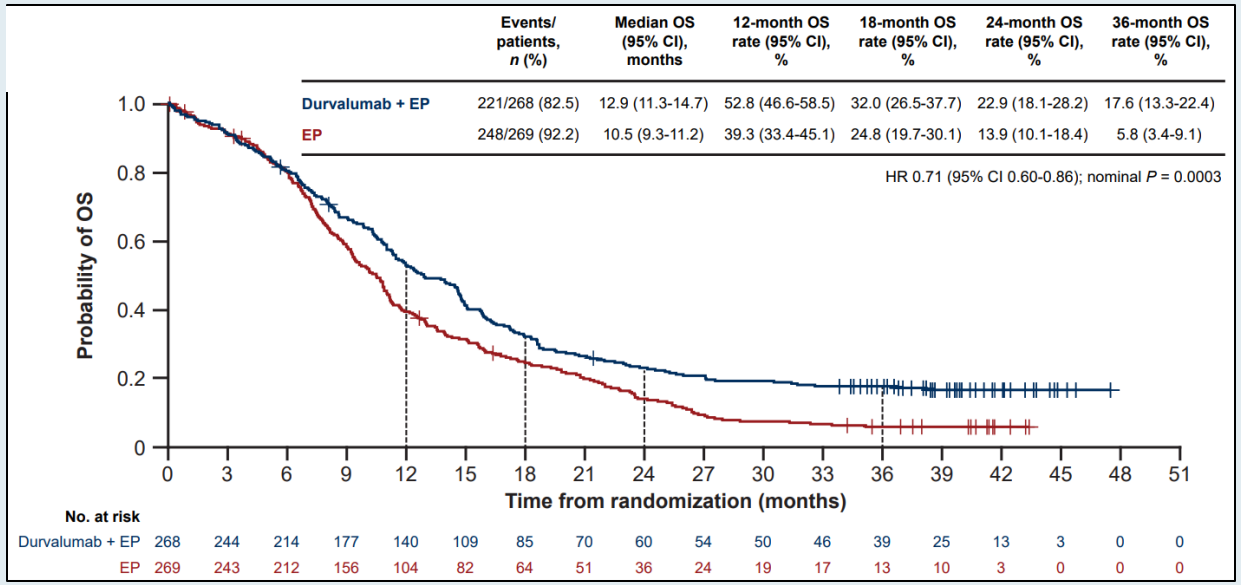


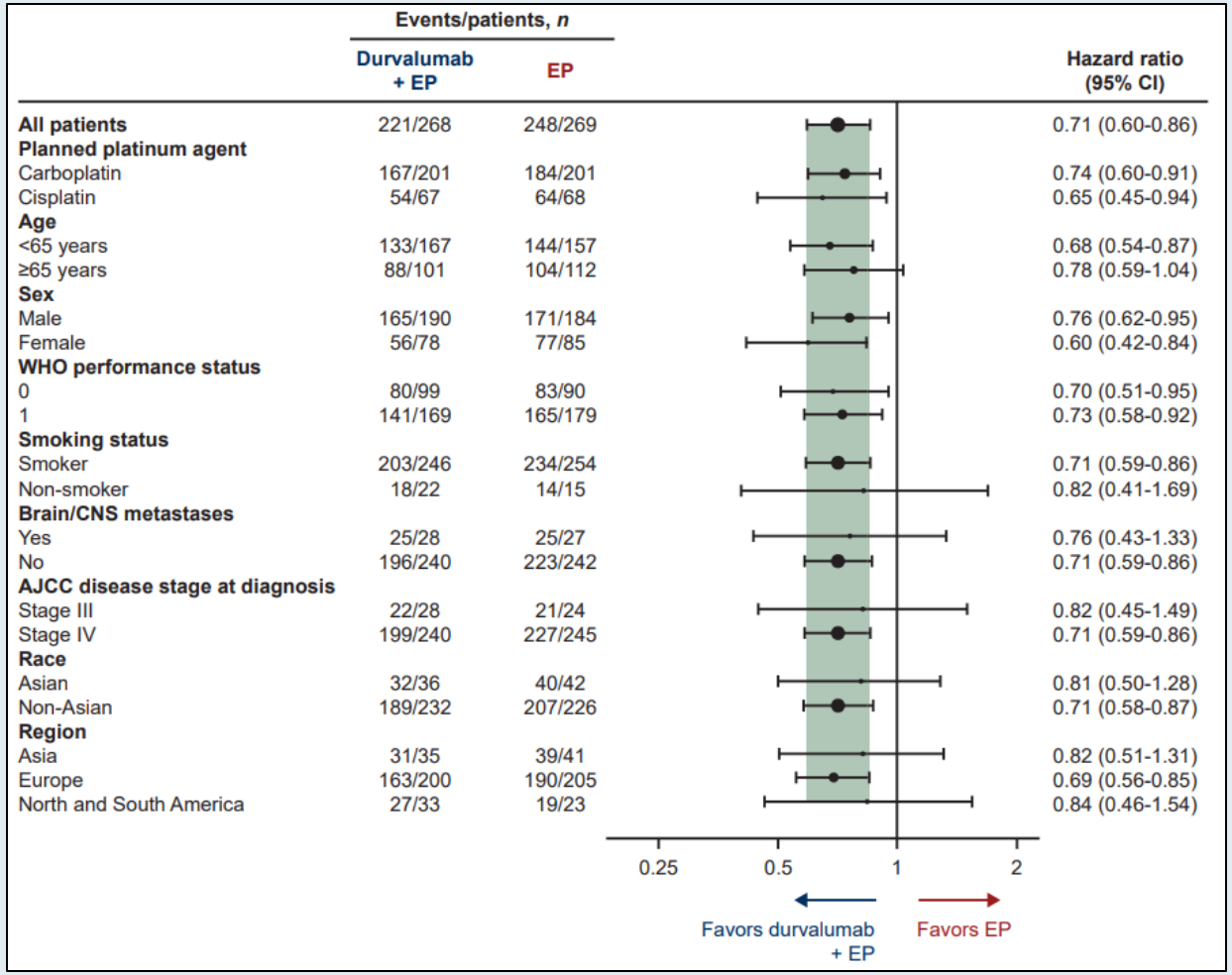
	Atezolizumab + CP/ET (N = 201)	Placebo + CP/ET (N = 202)
OS events, n (%)	104 (51.7)	134 (66.3)
Median OS, months (95% CI)	**12.3** (10.8, 15.9)	**10.3** (9.3, 11.3)
HR (95% CI)	**0.70** (0.54, 0.91) p = 0.0069	
Median follow-up, months[a]	13.9	

No. at risk																								
Atezolizumab	201	191	187	182	180	174	159	142	130	121	108	92	74	58	46	33	21	11	5	3	2	1
Placebo	202	194	189	186	183	171	160	146	131	114	96	81	59	36	27	21	13	8	3	3	2	2

Paz-Ares L et al. *Lancet* 2019;394(10212):1929-39. Horn L et al. *N Engl J Med* 2018;379(23):2220-9.

Updated OS Data for CASPIAN

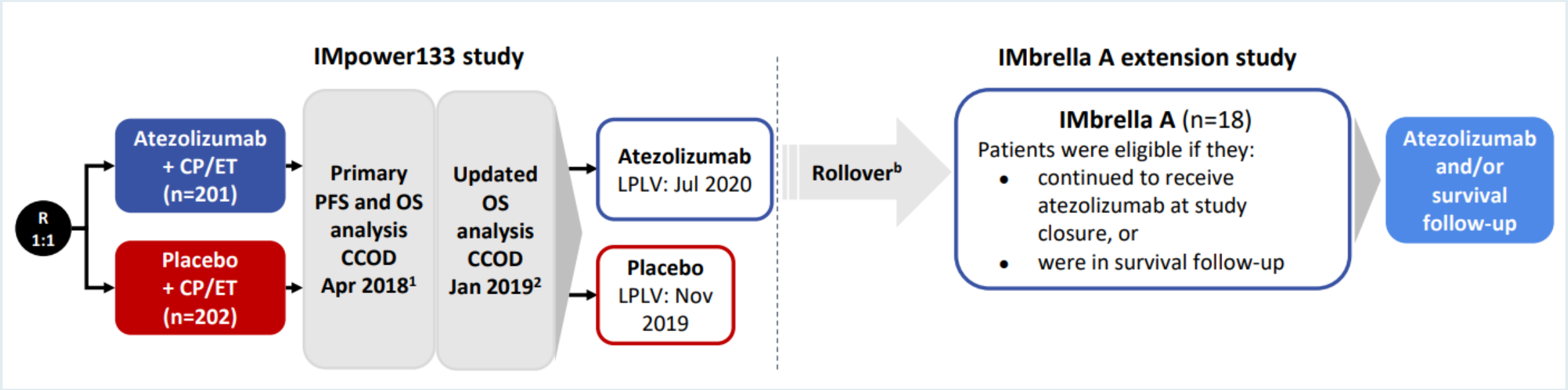




Paz-Ares L et al. ESMO Open. 2022;7(2):100408.

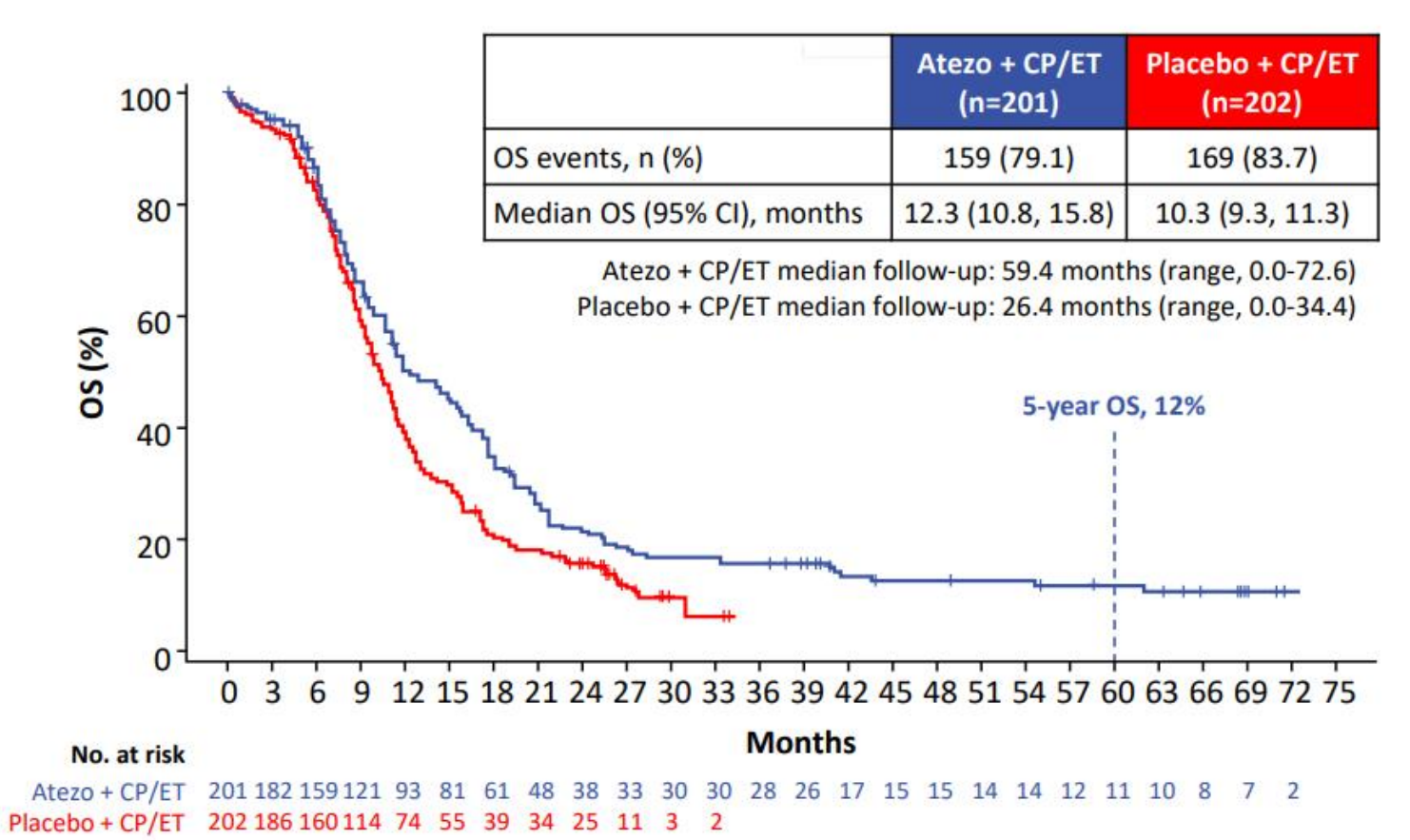
Updated OS Data for IMpower133

IMbrella A is an extension of IMpower133 that included long term responders to atezolizumab for ongoing treatment



Liu et al. WCLC 2023

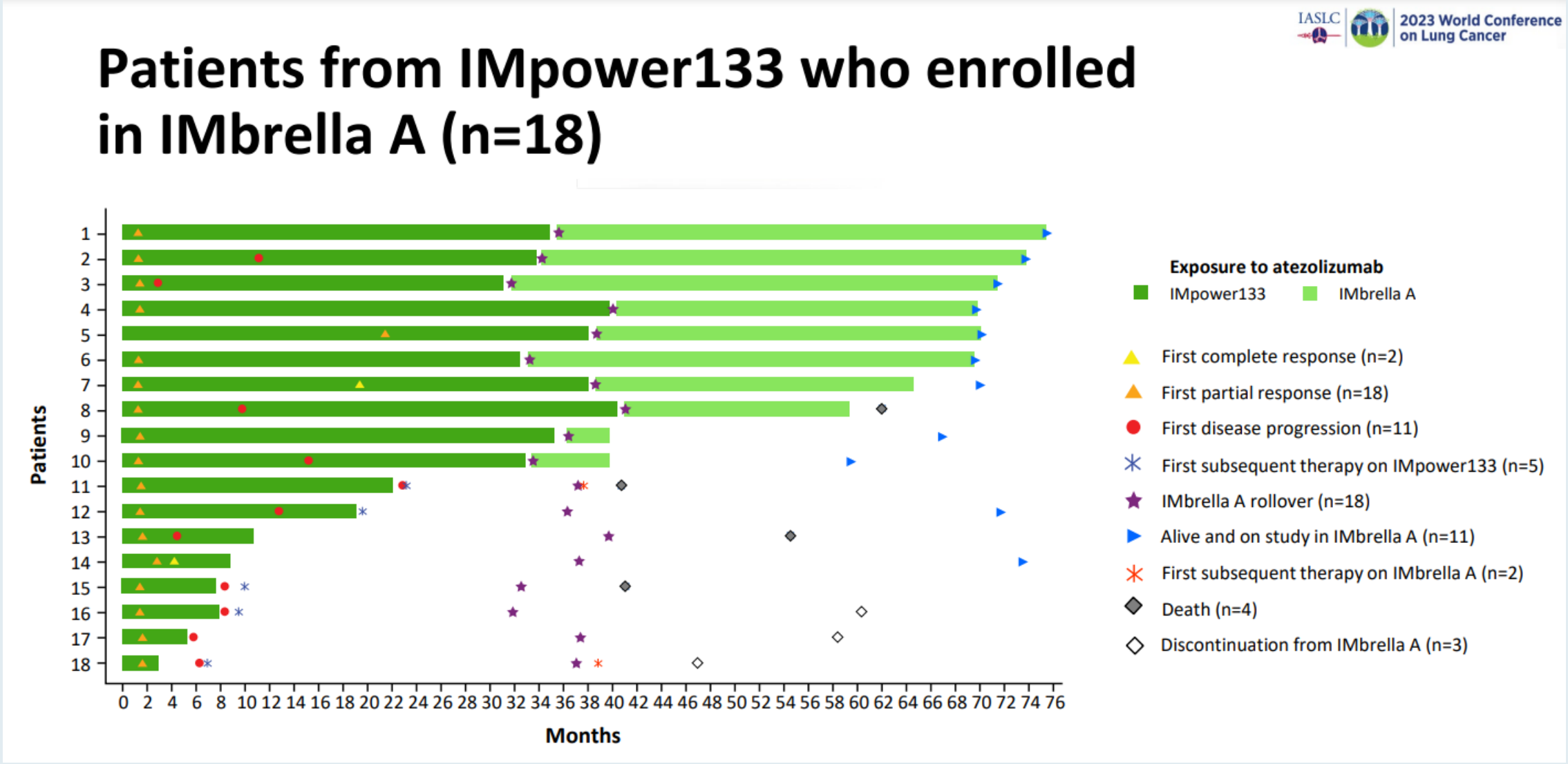
Updated OS Data for IMpower133



OS rate (95% CI), %	IMpower133 and IMbrella A Atezo + CP/ET (n=201)	IMpower133 only Placebo + CP/ET (n=202)
1-year	52% (45-59)	39% (32-46)
2-year	22% (16-28)	16% (11-21)
3-year	16% (11-21)	NE[a]
4-year	13% (8-18)	NE[a]
5-year	12% (7-17)	NE[a]

Liu et al. WCLC 2023

Updated OS Data for IMpower133



Liu et al. WCLC 2023

Questions?

FDA Grants Accelerated Approval to Tarlatamab for Extensive-Stage Small Cell Lung Cancer

Press Release: May 16, 2024

"On May 16, 2024, the Food and Drug Administration granted accelerated approval to tarlatamab-dlle for extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.

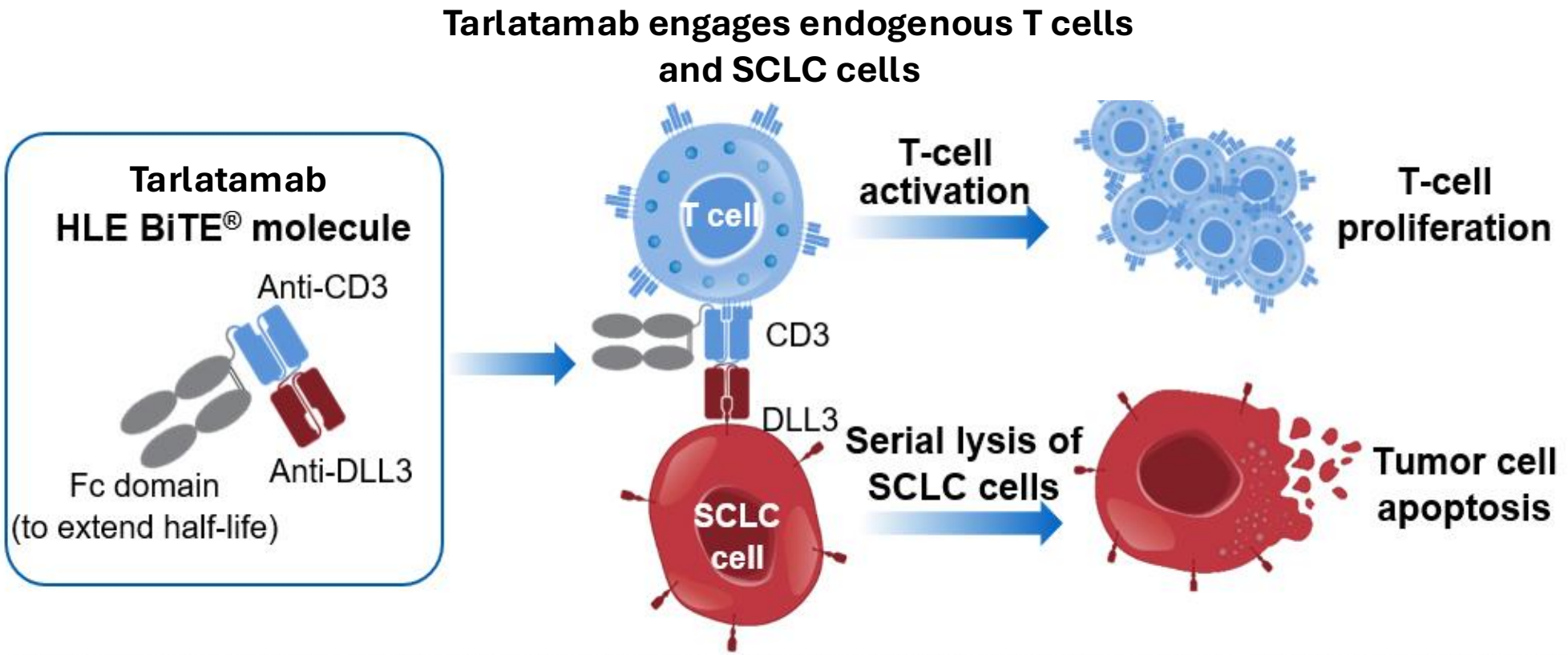
Efficacy was evaluated in 99 patients with relapsed/refractory ES-SCLC with disease progression following platinum-based chemotherapy enrolled in DeLLphi-301 [NCT05060016], an open-label, multicenter, multi-cohort study. Patients with symptomatic brain metastases, interstitial lung disease or non-infectious pneumonitis, and active immunodeficiency were excluded. Patients received tarlatamab until disease progression or unacceptable toxicity.

The major efficacy outcome measures were overall response rate (ORR) per RECIST 1.1 and duration of response (DOR), as assessed by blinded independent central review. ORR was 40% (95% CI: 31, 51) and median DOR was 9.7 months (range 2.7, 20.7+). Of the 69 patients with available data regarding platinum sensitivity status, the ORR was 52% (95% CI 32, 71) in 27 patients with platinum-resistant SCLC (defined as progression < 90 days after last dose of platinum therapy) and 31% (95% CI 18, 47) in 42 patients with platinum-sensitive SCLC (defined as progression ≥ 90 days after last dose of platinum therapy)."

https://www.fda.gov/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-tarlatamab-dlle-extensive-stage-small-cell-lung-cancer

RTP RESEARCH TO PRACTICE

Tarlatamab: A Half-life Extended BiTE® (bispecific T-cell engager) Immuno-oncology Therapy Targeting DLL3 for SCLC



CD, cluster of differentiation; DLL3, delta-like ligand 3; Fc, fragment crystallizable domain; HLE BiTE, half-life extended bispecific T-cell engager; SCLC, small cell lung cancer.

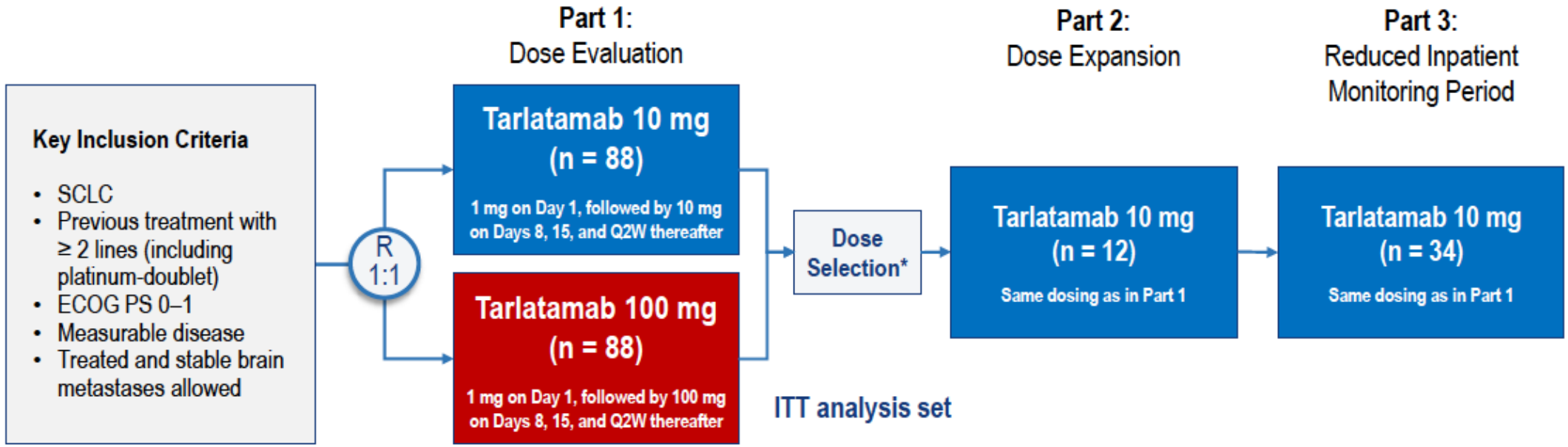
- The inhibitory notch ligand delta-like ligand 3 (DLL3) is aberrantly expressed on the surface of up to 85% of SCLC cells and minimally expressed in normal tissues.
- *In vitro* SCLC models have indicated a role for DLL3 in promoting tumor growth, migration, and invasion.

Stieglmaier J, et al. *Expert Opin Biol Ther*. 2015;15:1093-1099. Einsele H, et al. *Cancer.* 2020;126:3192-3201. Paz-Ares L, Champiat S, Lai WV, et al. *J Clin Oncol*. 2023;41(16):2893-2903.

Courtesy of Luis Paz-Ares, MD, PhD

DeLLphi-301 Phase II Study Design

- Phase 2, open-label study (NCT05060016)



Primary Endpoint: ORR per RECIST 1.1 by BICR

Secondary Endpoints Included: DOR, DCR, PFS per RECIST 1.1 by BICR, OS, TEAEs, tarlatamab serum concentrations

Data cutoff was January 12, 2024 for all efficacy and safety outcomes, except for OS. For OS, the data cutoff was May 16, 2024 to obtain mature OS data with a median follow-up of 20.7 months.

*Once 30 patients per dose level had the opportunity to confirm an objective response after the first post-treatment scan or ≥ 13 weeks of follow-up, whichever occurred first.

BICR, blinded independent central review; **DCR**, disease control rate; **DOR**, duration of response; **ECOG PS**, Eastern Cooperative Oncology Group performance status; **ITT**, intention-to-treat; **ORR**, objective response rate; **OS**, overall survival; **PFS**, progression-free survival; **Q2W**, every 2 weeks; **R**, randomization; **RECIST**, Response Evaluation Criteria in Solid Tumors; **SCLC**, small cell lung cancer; **TEAE**, treatment-emergent adverse event.

Sands J et al. WCLC 2024;Abstract OA10.03.

DeLLphi-301: Tarlatamab Anticancer Activity

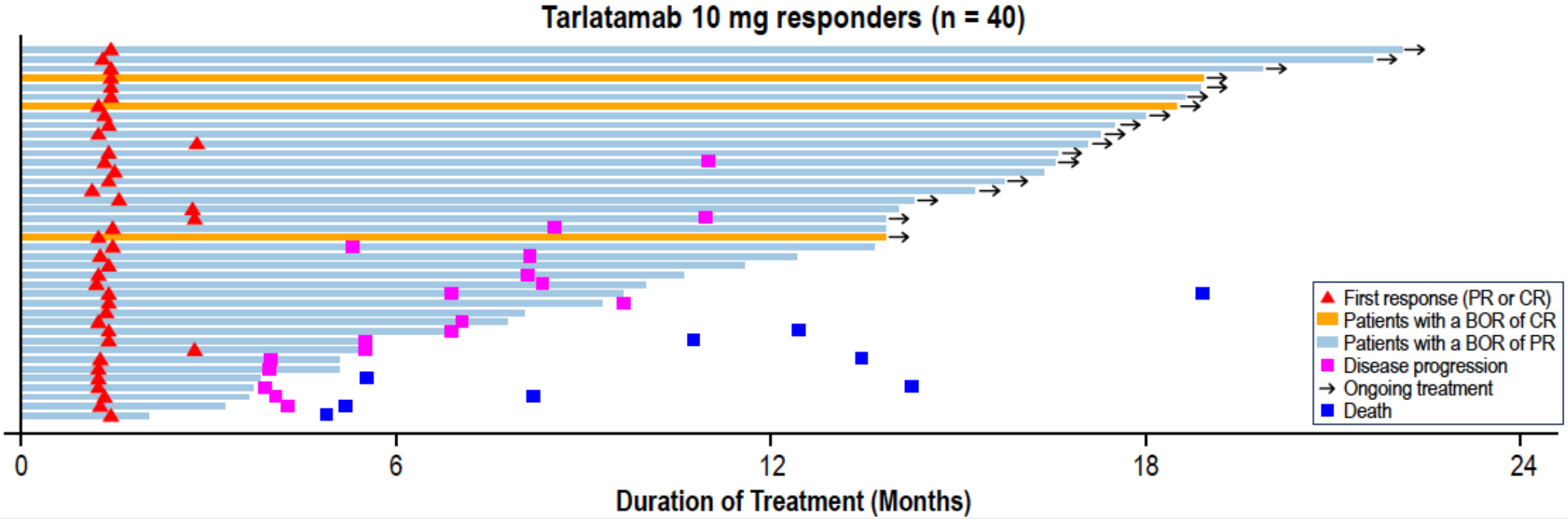
Outcome	Part 1 + 2 Tarlatamab 10 mg (N = 100)
Objective response rate, n (%) (95% CI for %)	40 (40) (30.3–50.3)
Complete response	3 (3)
Partial response	37 (37)
Stable disease	30 (30)
Progressive disease	20 (20)
Not evaluable / no post-baseline scan*	10 (10)
Disease control rate, n (%) (95% CI for %)	70 (70) (60.0–78.8)

Tarlatamab 10 mg demonstrated anti-cancer activity in heavily pretreated SCLC, with an ORR of 40%

Data cutoff, January 12, 2024. Median follow-up was 16.6 months. The efficacy analysis set consists of patients in Parts 1 and 2 (N = 100). One patient did not receive tarlatamab 10 mg but was included in the ITT analysis. Part 3 was a safety substudy and was not included in this response analysis. *Patients who were not evaluable or did not have post-baseline scans were considered non-responders for the response analysis.
CI, confidence interval; **ITT**, intention-to-treat; **ORR**, objective response rate; **SCLC**, small cell lung cancer.

Sands J et al. WCLC 2024;Abstract OA10.03.

DeLLphi-301: Duration of Response and Time on Treatment

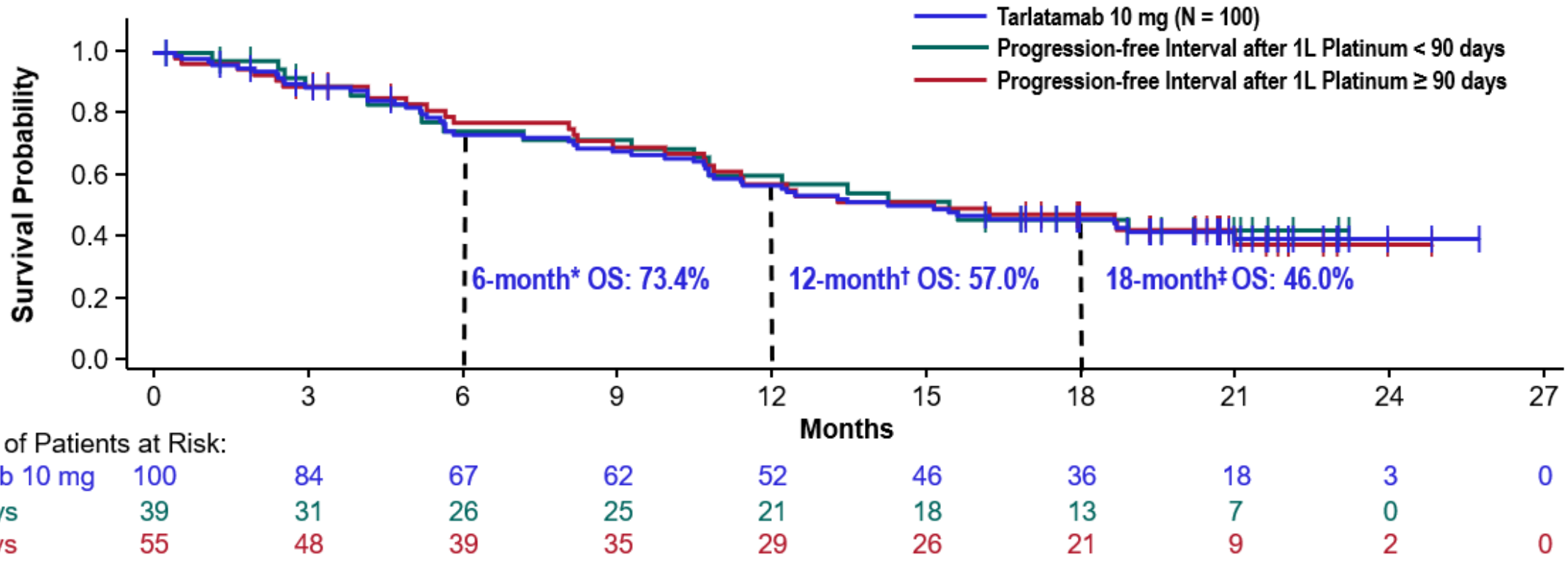


- Median time to response was 1.4 months (IQR, 1.3–1.4)
- Median DOR was 9.7 months (95% CI, 6.9–NE) with 17/40 (43%) of responses ongoing at data cutoff

Data cutoff was January 12, 2024. Median follow up for DOR was 15.1 months. The efficacy analysis set consists of patients in Parts 1 and 2 (N = 100). One patient did not receive tarlatamab 10 mg but was included in the ITT analysis. Part 3 was a safety sub-study and was not included in this response analysis. **BOR**, best overall response; **CR**, complete response; **DOR**, duration of response; **ITT**, intention-to-treat; **IQR**, interquartile range; **NE**, not estimable; **PR**, partial response.

Sands J et al. WCLC 2024;Abstract OA10.03.

DeLLphi-301: Overall Survival



Number of Patients at Risk:

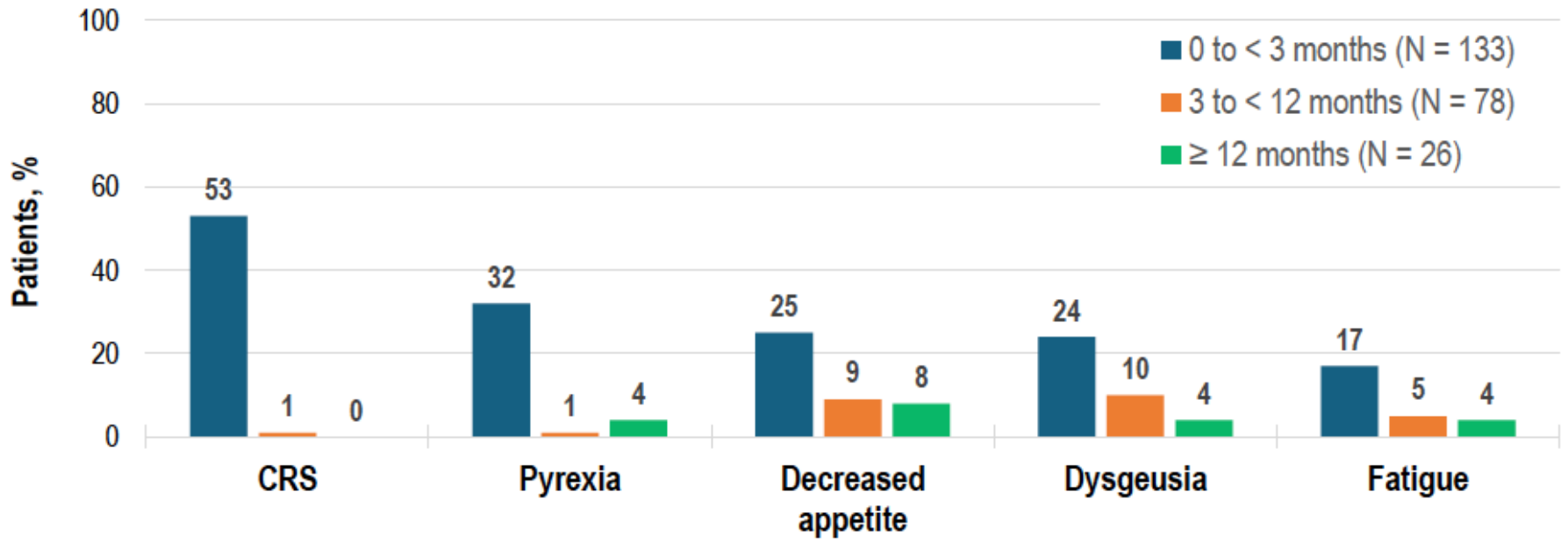
Tarlatamab 10 mg	100	84	67	62	52	46	36	18	3	0
< 90 days	39	31	26	25	21	18	13	7	0	
≥ 90 days	55	48	39	35	29	26	21	9	2	0

OS was similar regardless of progression-free interval after 1L platinum treatment (< 90 d vs ≥ 90 d)

Median follow-up for OS was 20.7 months. Data cutoff, May 16, 2024. The efficacy analysis set consists of patients in Parts 1 and 2 (N = 100). One patient did not receive tarlatamab 10 mg but was included in ITT analysis. Part 3 was a safety substudy and was not included in this response analysis. *95% CI, 63.2–81.2. †95% CI, 46.3–66.3. ‡95% CI, 35.6–55.8. Progression-free interval after first line platinum treatment is defined as days from the last first line platinum treatment to disease progression or start of second line treatment, whichever is earlier. **ITT,** intention-to-treat; **NE**, not estimable; **OS**, overall survival.

Sands J et al. WCLC 2024;Abstract OA10.03.

DeLLphi-301: Most Common Tarlatamab-Related AEs over Time



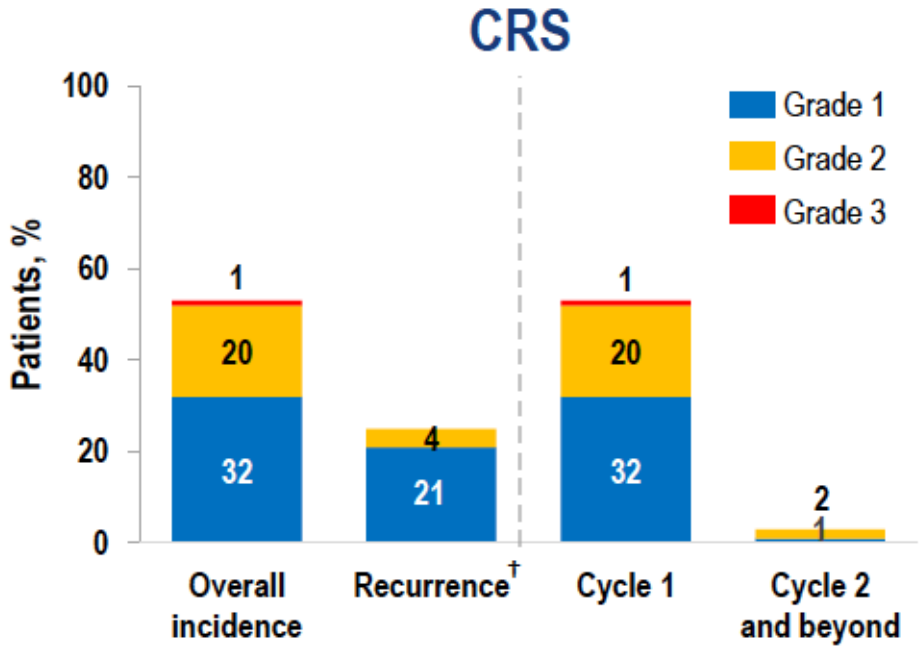
- TRAEs led to dose interruption in 16% and discontinuation in 4% of patients

Tarlatamab demonstrated long-term tolerability, with no new safety concerns

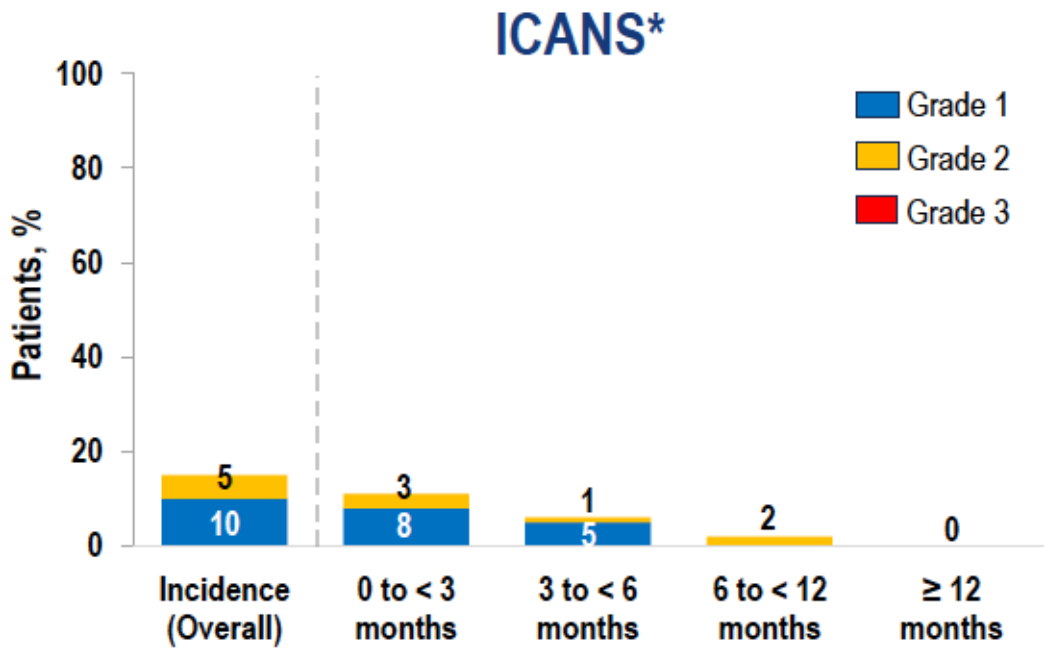
One patient did not receive tarlatamab 10 mg and was not included in the safety analyses. Most common TRAEs refer to TRAEs with overall incidence ≥ 17%. AEs were coded using MedDRA version 26.1. There was one fatal TRAE of respiratory failure, with contributing factors including baseline chronic obstructive pulmonary disease requiring supplemental oxygen, baseline compromised pulmonary functional reserve, concurrent grade 3 CRS and pneumonitis after cycle 1 day 1 treatment, and a decision against escalation to intensive care unit level of care. **AE**, adverse event; **CRS**, cytokine release syndrome; **MedDRA**, Medical Dictionary for Regulatory Activities; **TRAE**, tarlatamab-related AE.

Sands J et al. WCLC 2024;Abstract OA10.03.

DeLLphi-301: CRS and ICANS Incidence and Timing



Median time to resolution‡: 3 days (95% CI, 3–4)



Median time to resolution‡: 33 days§ (95% CI, 7–120)

- CRS primarily occurred after the first or second dose in cycle 1, with most events of grade 1 or 2
- ICANS* occurred infrequently, primarily with early onset (< 6 months) and all events of grade 1 or 2

*ICANS includes associated neurologic events based on a broad search using 61 selected preferred terms from MedDRA version 26.0. †A CRS event is considered a recurrent event if it occurred at a subsequent dose after the first CRS event during cycle 1. ‡Based on Kaplan-Meier estimates. TEAE data are reported. §Based on 22 events. **CI**, confidence interval; **CRS**, cytokine release syndrome; **ICANS**, immune effector cell–associated neurotoxicity syndrome; **MedDRA**, Medical Dictionary for Regulatory Activities.

Sands J et al. WCLC 2024;Abstract OA10.03.

Questions?

2024 World Conference on Lung Cancer | SEPTEMBER 7-10, 2024 SAN DIEGO, CA USA

Abstract OA04.03

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wclc2024.iaslc.org

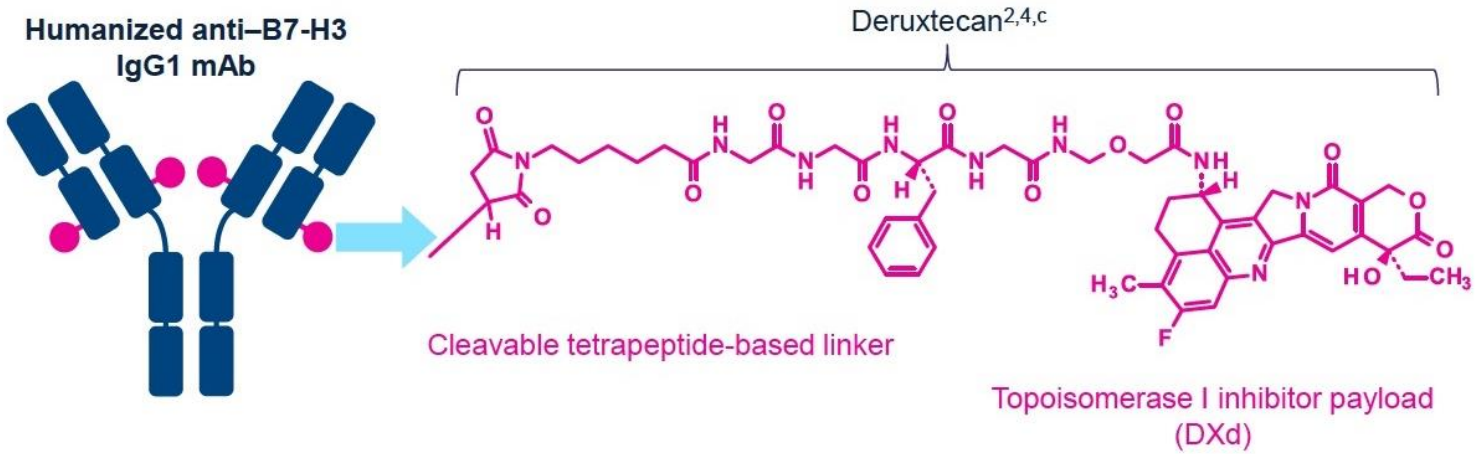
Ifinatamab deruxtecan (I-DXd) in extensive-stage small cell lung cancer (ES-SCLC): interim analysis of IDeate-Lung01

Charles M. Rudin,[1] Myung-Ju Ahn,[2] Melissa Johnson,[3] Christine L. Hann,[4] Nicolas Girard,[5] Makoto Nishio,[6] Ying Cheng,[7] Hidetoshi Hayashi,[8] Yu Jung Kim,[9] Alejandro Navarro,[10] Yuanbin Chen,[11] Tetsuya Sakai,[12] Meng Qian,[13] Juliette Godard,[14] Mei Tang,[13] Jasmeet Singh,[13] Luis Paz-Ares[15]

Ifinatamab Deruxtecan (I-DXd): A B7-H3-Targeted ADC

I-DXd is a B7-H3 (CD276)–directed ADC with 3 components[1–4]:

- A humanized anti–B7-H3 IgG1 mAb
- A tetrapeptide-based cleavable linker that covalently bonds antibody and payload
- A topoisomerase I inhibitor payload (an exatecan derivative, DXd)



The **mAb** directs the DXd ADC to the tumor cell.

1. Optimized drug-to-antibody ratio ≈4[4,a,b]

The **linker** binds the mAb to the payload.

2. Plasma-stable linker-payload[4,a]
3. Tumor-selective cleavable linker[4,a]

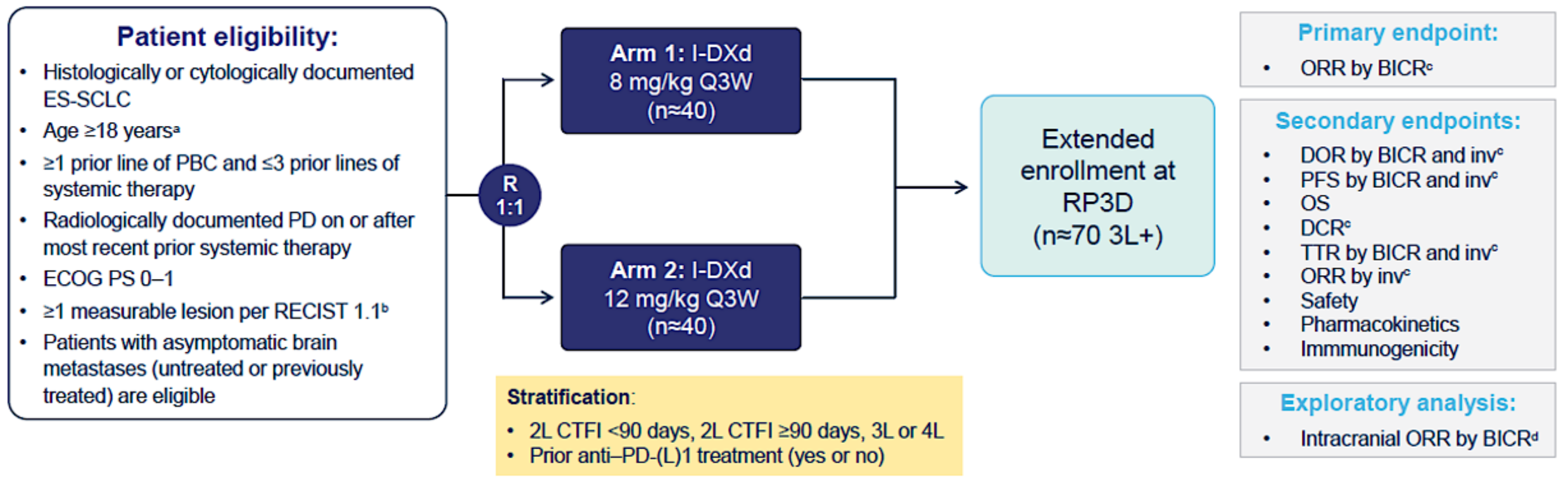
The **payload** induces cell death when delivered to the tumor.

4. Topoisomerase I inhibitor[2,4,a]
5. High potency[4,a]
6. Short systemic half-life[4,a,b]
7. Bystander antitumor effect[2,5,a]

[a]The clinical relevance of these features is under investigation. [b]Based on animal data. [c]Refers to the linker and payload.
ADC, antibody–drug conjugate; B7-H3, B7 homolog 3; CD276, cluster of differentiation 276; IgG1, immunoglobulin G1; mAb, monoclonal antibody.
1. Okajima D, et al. *Mol Cancer Ther*. 2021;20:2329–2340. 2. Nakada T, et al. *Chem Pharm Bull (Tokyo)*. 2019;67:173–185. 3. Ogitani Y, et al. *Clin Cancer Res*. 2016;22:5097–5108. 4. Yamato M, et al. *Mol Cancer Ther*. 2022;21:635–646.
5. Ogitani Y, et al. *Cancer Sci*. 2016;107:1039–1046.

Rudin CM et al. WCLC 2024;Abstract OA04.03.

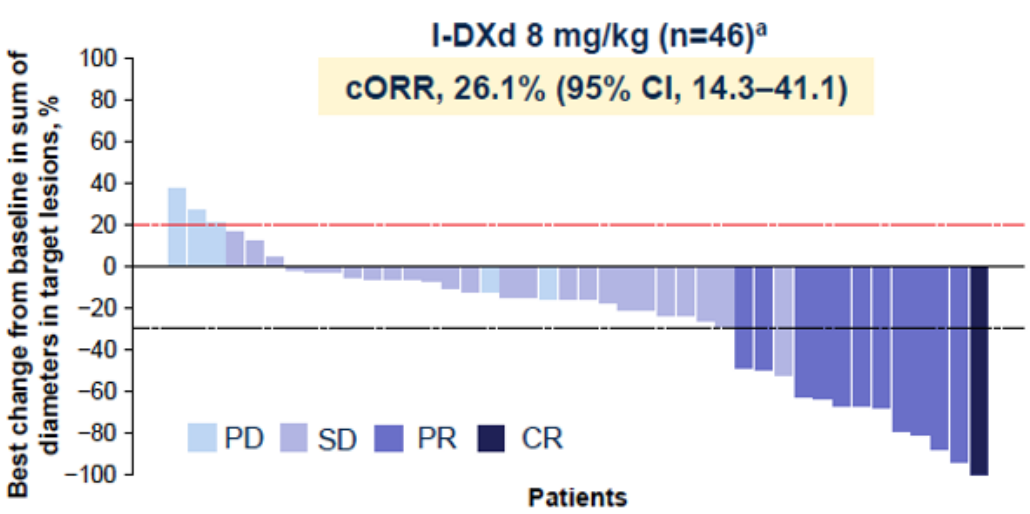
IDeate-Lung01: Phase II Study Design

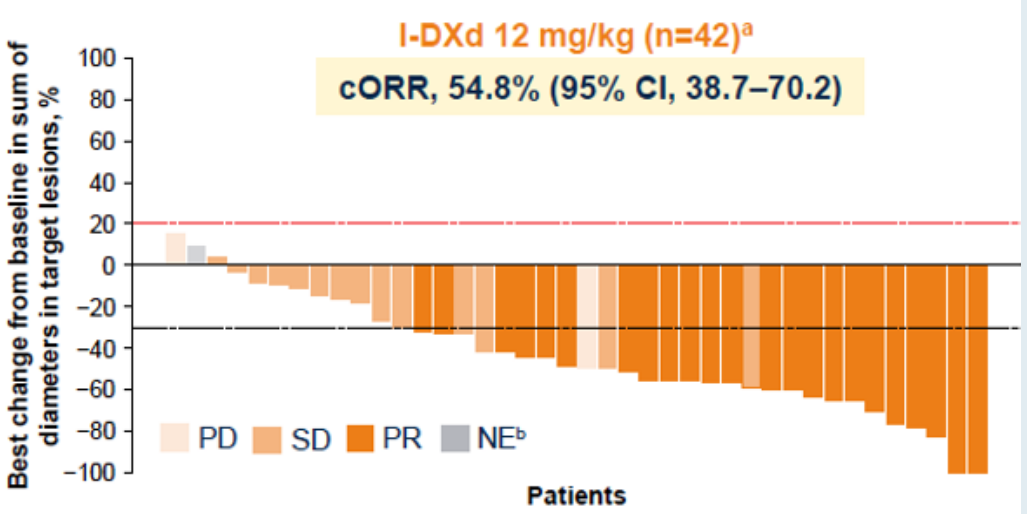


PBC = platinum-based chemotherapy; PD = progressive disease; CTFI = chemotherapy treatment-free interval; RP3D = recommended phase 3 dose; ORR = objective response rate; BICR = blinded independent central review; DOR = duration of response; DCR = disease control rate; TTR = time to response

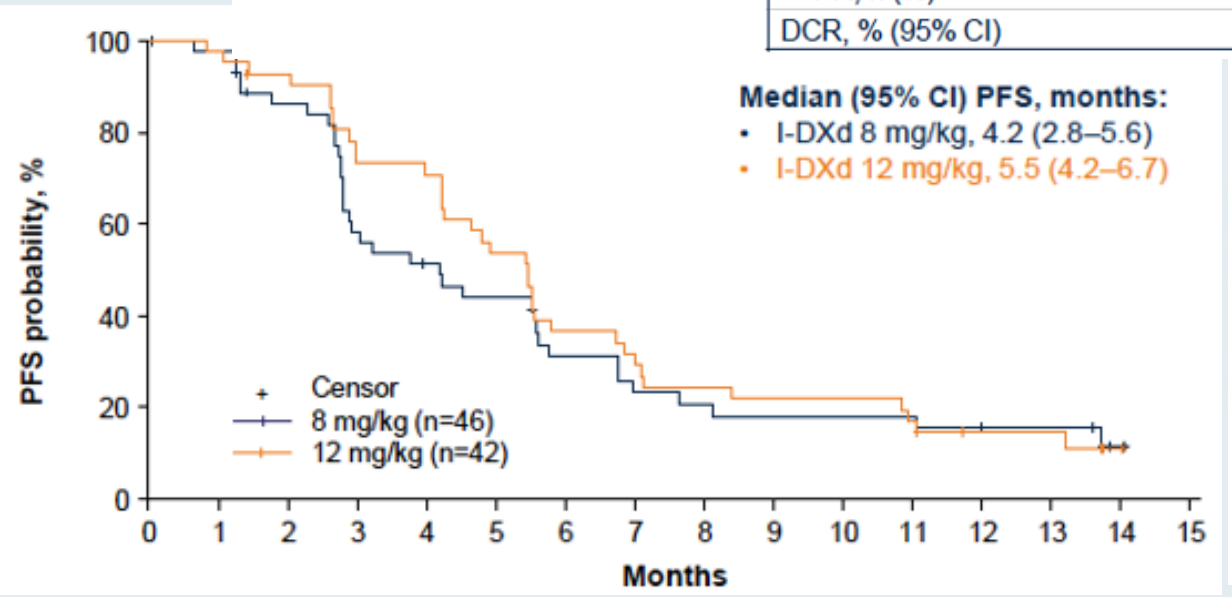
Rudin CM et al. WCLC 2024;Abstract OA04.03.

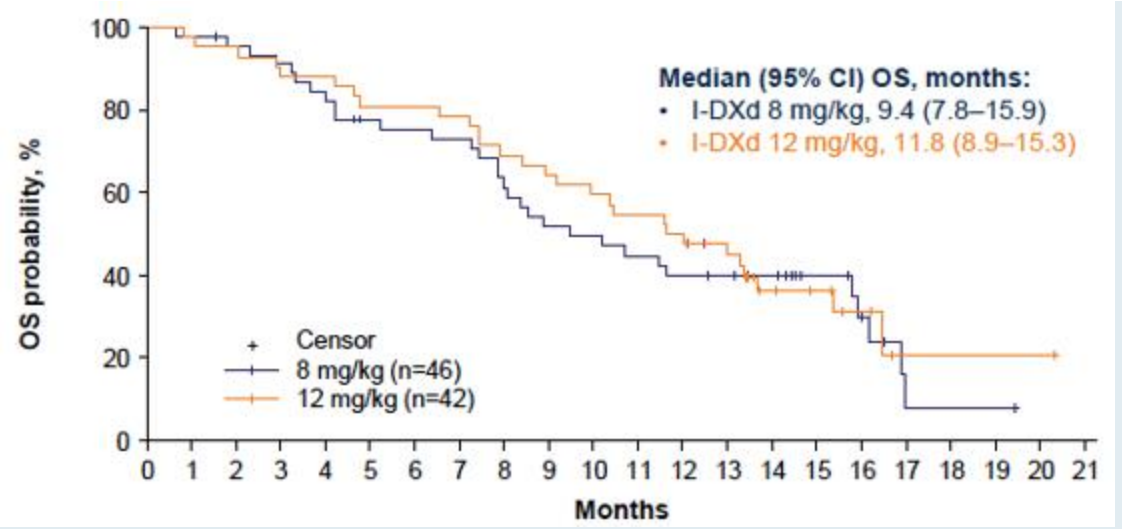
IDeate-Lung01: I-DXd was associated with rapid responses at both doses





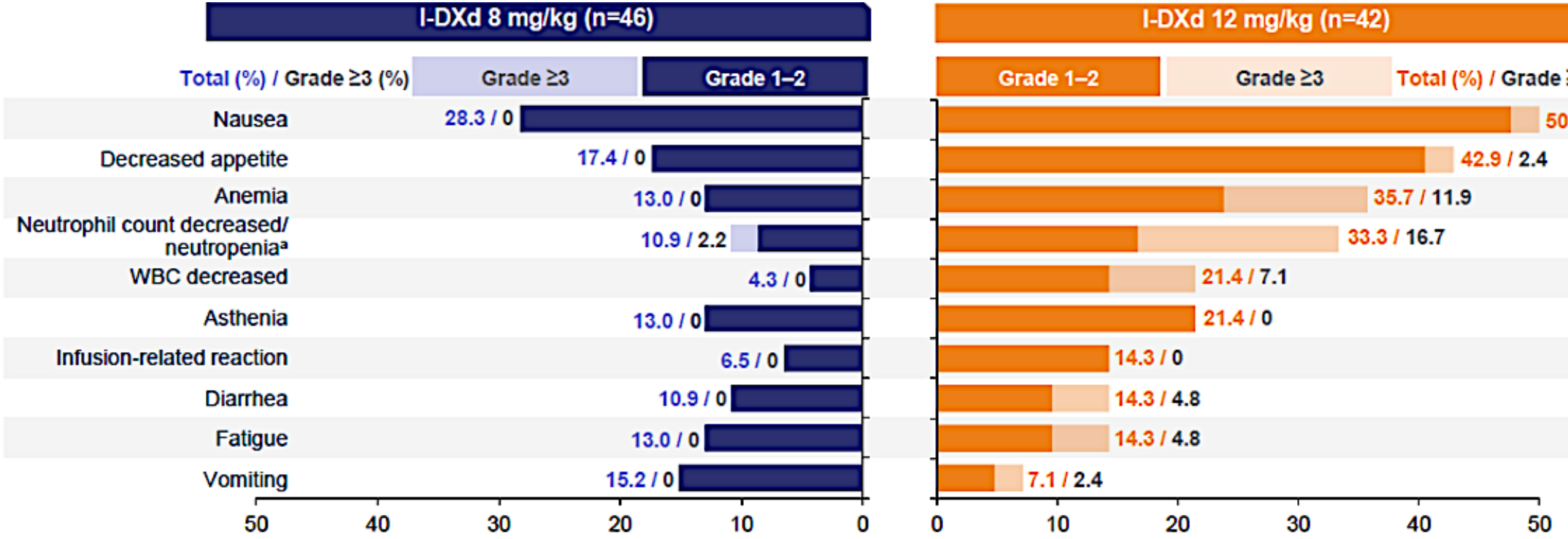
Confirmed response by BICR[c]	I-DXd 8 mg/kg n=46	I-DXd 12 mg/kg n=42
ORR, % (95% CI)	26.1 (14.3–41.1)	54.8 (38.7–70.2)
CR, n (%)	1 (2.2)	0
PR, n (%)	11 (23.9)	23 (54.8)
DCR, % (95% CI)	80.4 (66.1–90.6)	90.5 (77.4–97.3)





Rudin CM et al. WCLC 2024;Abstract OA04.03.

IDeate-Lung01: Most Common Treatment-Related Treatment-Emergent Adverse Events



ILD/pneumonitis adjudicated as treatment-related was reported in:

- Four (8.7%) patients in the 8-mg/kg cohort (Grade 2, n=3; Grade 5, n=1)
- Five (11.9%) patients in the 12-mg/kg cohort (Grade, 1 n=1; Grade 2, n=3; Grade 3, n=1)
- No ILD events were pending adjudication at the time of data cutoff

Rudin CM et al. WCLC 2024;Abstract OA04.03.

IDeate-Lung01: Interim Analysis Summary

- I-DXd demonstrated promising efficacy in patients with pretreated ES-SCLC; I-DXd 12 mg/kg had improved efficacy compared with the 8-mg/kg dose:
  - ORR was 54.8% vs 26.1%
  - Median PFS was 5.5 months vs 4.2 months
  - Median OS was 11.8 months vs 9.4 months
- The observed safety profile was generally manageable and I-DXd was well tolerated, with a higher frequency of TEAEs in the 12-mg/kg cohort than in the 8-mg/kg cohort; the safety profile was consistent with previous reports[1,2]
  - The most common treatment-related TEAEs were gastrointestinal and hematologic (most commonly nausea, decreased appetite, anemia, and decreased neutrophil count or neutropenia)
  - Patients receiving I-DXd 12 mg/kg had a longer treatment duration than those receiving 8 mg/kg (4.7 vs 3.5 months)
  - The majority of cases of adjudicated drug-related ILD were Grade 1 or 2
- I-DXd showed intracranial and systemic activity in a small subset of patients with brain target lesions at baseline; a full analysis of the subgroup of patients with brain metastases at baseline will be presented at the ESMO Congress 2024
- I-DXd 12 mg/kg has been selected as the RP3D for further clinical development, including in an ongoing Phase 3 study in patients with relapsed SCLC following only 1 prior line of therapy (IDeate-Lung02; NCT06203210)

Data cutoff: April 25, 2024. The median follow-up for 8-mg/kg and 12-mg/kg cohorts was 14.6 months (range, 0.6–17.0) and 15.3 months (range, 0.8–20.3) respectively.

ESMO, European Society for Medical Oncology; ES-SCLC, extensive-stage small cell lung cancer; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; RP3D, recommended Phase 3 dose; SCLC, small cell lung cancer; TEAE, treatment-emergent adverse event.

1. Johnson M, et al. Presented at the World Conference on Lung Cancer 2023. September 9–12, 2023. Singapore. Abstract 3258. 2. Patel MR, et al. Presented at the European Society for Medical Oncology Congress 2023. October 20–24, 2023. Madrid, Spain. Abstract 690P.

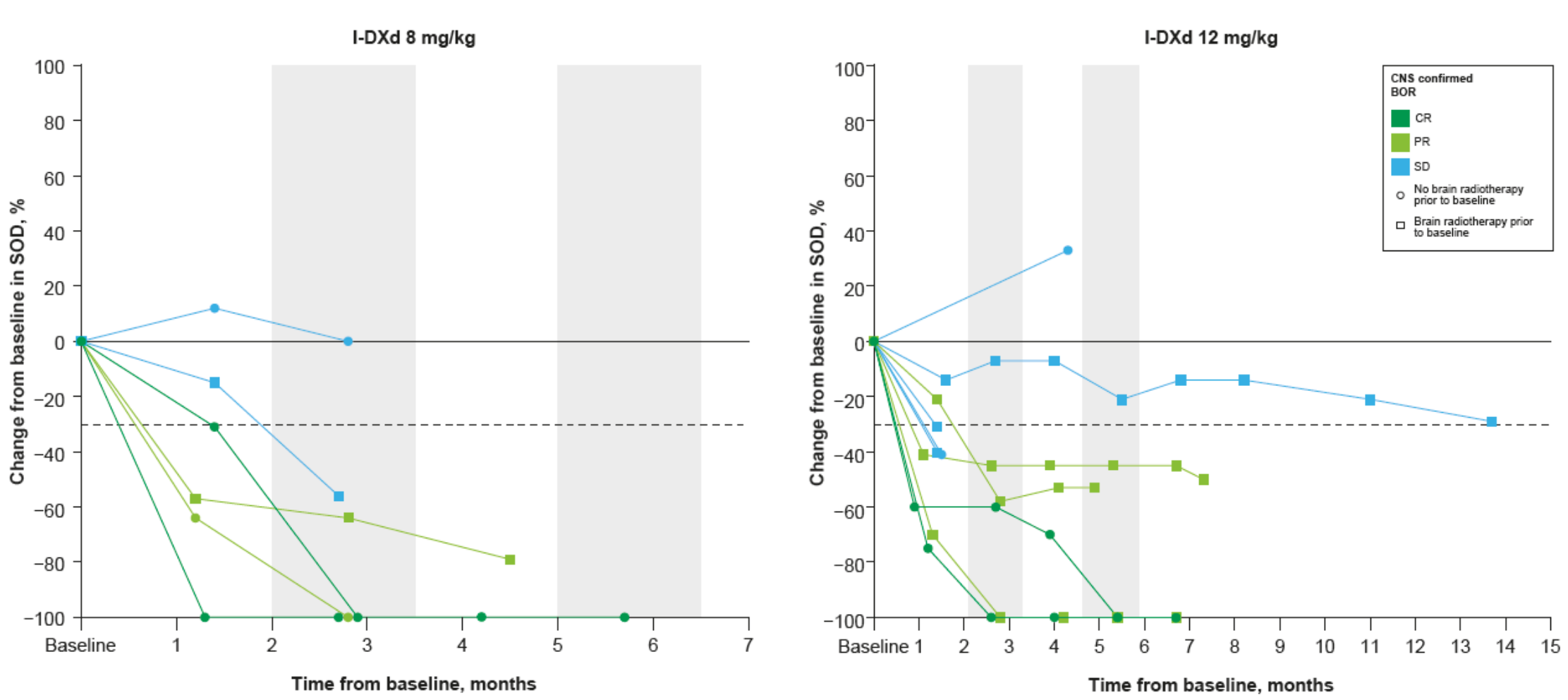
Rudin CM et al. WCLC 2024;Abstract OA04.03.

Intracranial Response in Patients (pts) with Baseline (BL) Brain Metastases (BM) and Extensive-Stage (ES) Small Cell Lung Cancer (SCLC) Treated with Ifinatamab Deruxtecan (I-DXd) in the IDeate-Lung01 Study

Johnson ML et al.

ESMO 2024;Abstract 1787P.

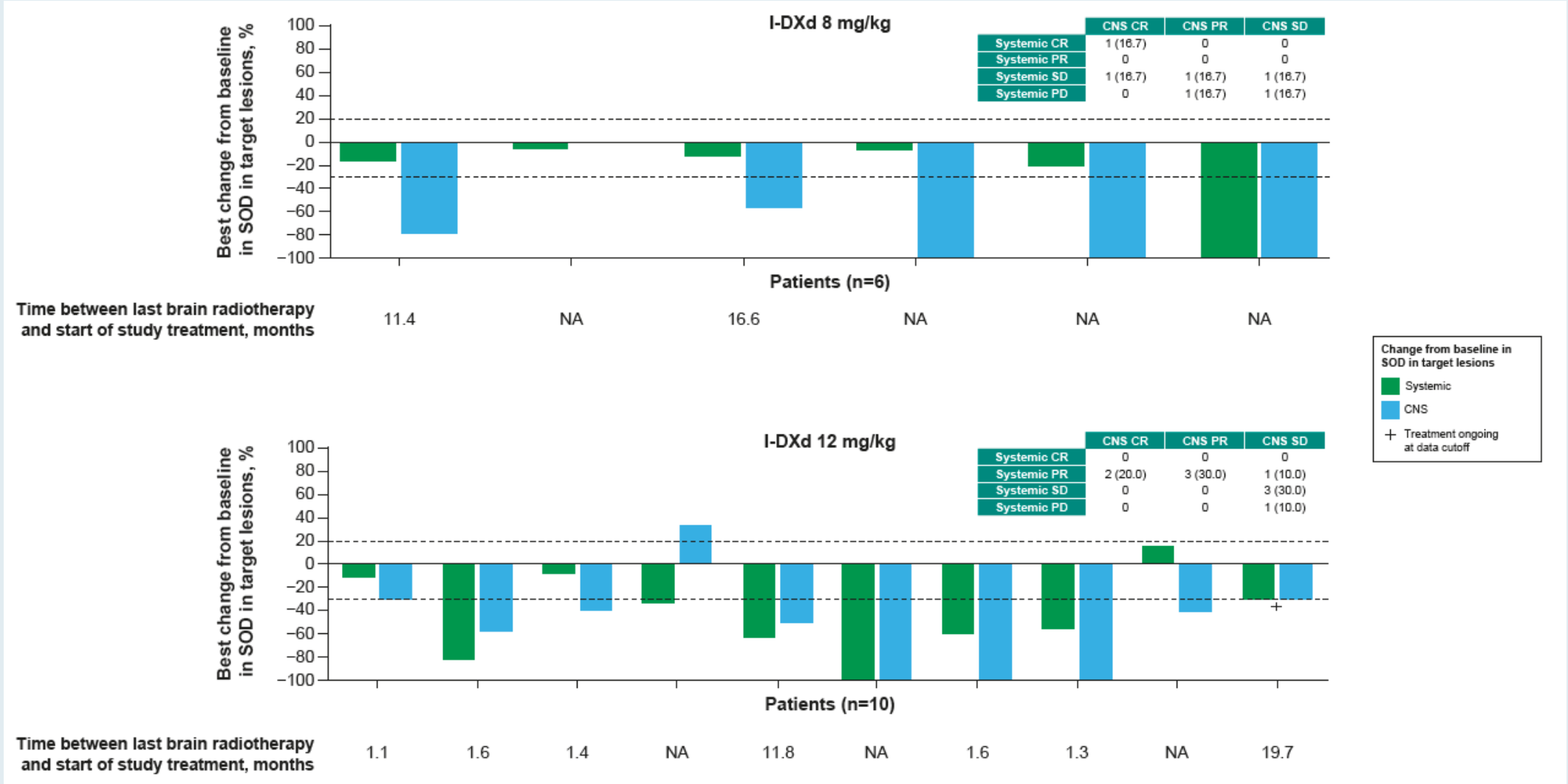
IDeate-Lung01: Change in CNS Target-Lesion Volume in Patients Who Received I-DXd at 2 Different Doses



SOD = sum of diameters

Johnson ML et al. ESMO 2024;Abstract 1787P.

IDeate-Lung01: Systemic and Intracranial Change from Baseline in SOD in Target Lesions in Patients Who Received I-DXd at 2 Different Doses



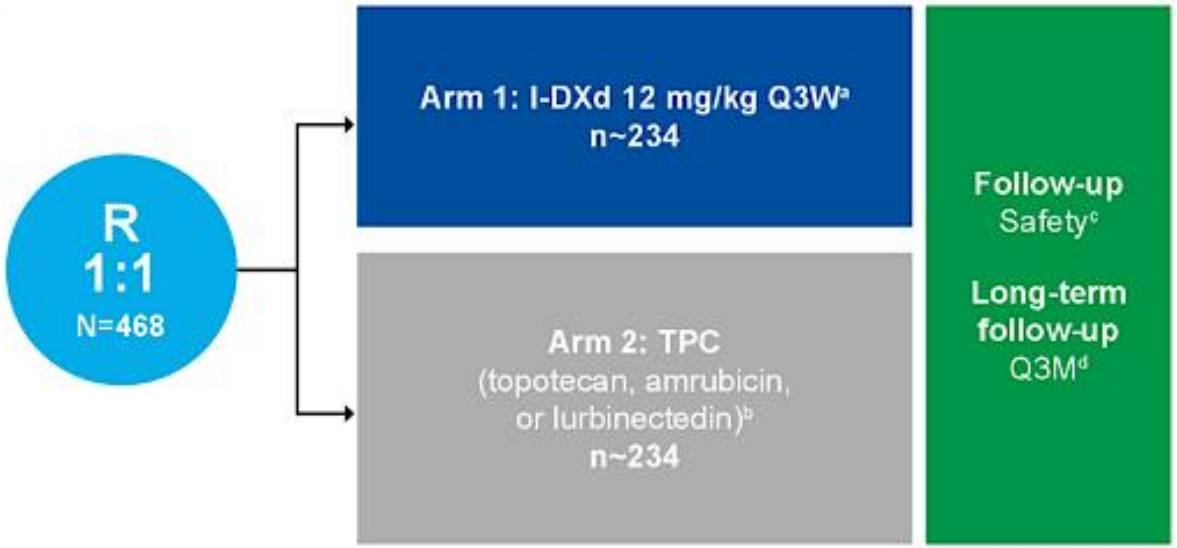
	CNS CR	CNS PR	CNS SD
Systemic CR	1 (16.7)	0	0
Systemic PR	0	0	0
Systemic SD	1 (16.7)	1 (16.7)	1 (16.7)
Systemic PD	0	1 (16.7)	1 (16.7)

	CNS CR	CNS PR	CNS SD
Systemic CR	0	0	0
Systemic PR	2 (20.0)	3 (30.0)	1 (10.0)
Systemic SD	0	0	3 (30.0)
Systemic PD	0	0	1 (10.0)

Johnson ML et al. ESMO 2024;Abstract 1787P.

IDeate-Lung02 Ongoing Phase III Trial Design

Key inclusion criteria	Key exclusion criteria
Histologically or cytologically documented SCLC	Prior treatment with orlotamab, enoblituzumab, or other B7-H3–targeted agents, including I-DXd
Age ≥18 years or minimal legal adult age (whichever is greater)	Prior discontinuation of an ADC that consists of an exatecan derivative (eg, trastuzumab deruxtecan) due to treatment-related toxicities
Received only 1 prior line of platinum-based therapy	Prior treatment with any of the comparators or a topoisomerase I inhibitor
≥1 measurable lesion per RECIST 1.1	Clinically active brain metastasis, spinal cord compression, or leptomeningeal carcinomatosis
Radiologically documented PD on or after platinum-based therapy	Clinically severe pulmonary compromise resulting from intercurrent pulmonary illnesses
ECOG PS 0–1	History of ILD/pneumonitis that required corticosteroids; current or suspected ILD/pneumonitis
Must provide adequate baseline tumor samples of sufficient quantity and quality	Uncontrolled or significant cardiovascular disease
Patients with asymptomatic brain metastases (untreated or previously treated) are eligible	Known, uncontrolled HIV infection; active or uncontrolled HBV or HCV infection; uncontrolled systemic bacterial, fungal, or viral infection; or active, known, or suspected autoimmune disease



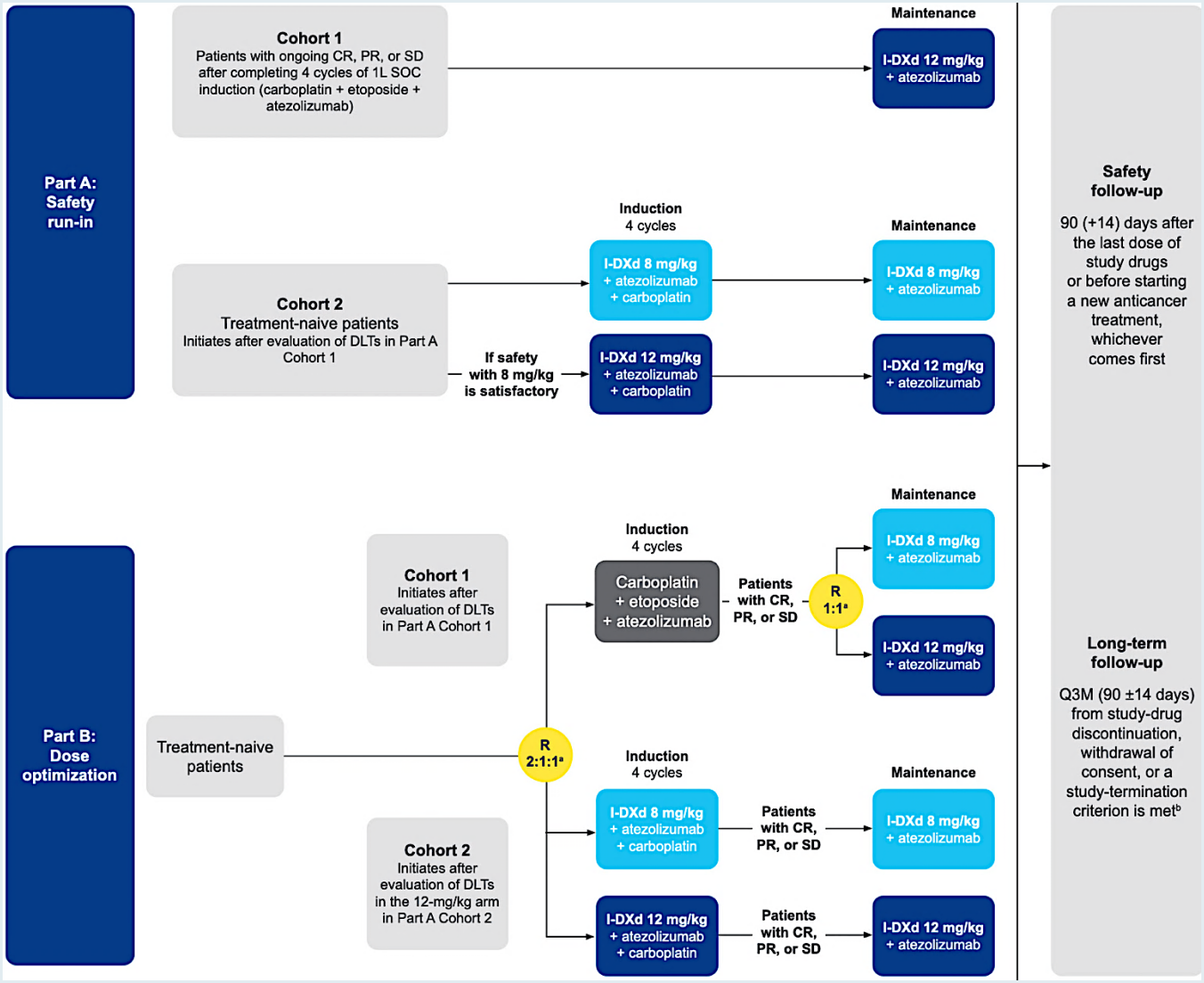
Stratification

Chemotherapy-free interval following 1L therapy (<90 vs ≥90 days)
TPC (topotecan vs amrubicin vs lurbinectedin)
Treatment with prior PD-(L)1 inhibitors (yes vs no)
Presence or history of asymptomatic brain metastases (yes vs no)

ILD = interstitial lung disease; TPC = treatment of physician's choice

Owonikoko TK et al. ASCO 2024;Abstract TPS8126. www.clinicaltrials.gov. NCT06203210. Accessed September 2024.

IDeate-Lung03: A Phase Ib/II Study of Ifinatamab Deruxtecan (I-DXd) and Atezolizumab with or without Carboplatin as First-Line Induction or Maintenance for Patients with Extensive-Stage Small Cell Lung Cancer



Primary endpoint: Safety (DLTs [Part A] and TEAEs [Parts A and B])

Key secondary endpoints: PFS, ORR, DCR, DOR, CBR, OS and others

General key inclusion criteria:

- Histologically or cytologically confirmed diagnosis of ES-SCLC requiring first-line therapy
- Age ≥18 years or minimal legal adult age (whichever is greater)
- ECOG performance status 0–1
- Patients with asymptomatic brain metastases (untreated or previously treated) are eligible

Rudin C et al. ESMO 2024;Abstract 1813TiP.

DLTs = dose-limiting toxicites; ORR = objective response rate; CBR = clinical benefit rate

Questions?

2024 ASCO ANNUAL MEETING

Abstract 8001

BEAT-SC: A randomized phase III study of bevacizumab or placebo in combination with atezolizumab and platinum-based chemotherapy in patients with extensive-stage small cell lung cancer

Yuichiro Ohe,[1] Baohui Han,[2] Makoto Nishio,[3] Satoshi Watanabe,[4] Xiubao Ren,[5] Shuji Murakami,[6] Nong Yang,[7] Isamu Okamoto,[8] Gaofeng Li,[9] Nobuyuki Katakami,[10] Xianling Liu,[11] Naoyuki Nogami,[12] Yuki Nakagawa,[13] Morihiko Hayashi,[14] Toshihiro Nanki,[15] Chunyu Qian,[16] Nobuyuki Yamamoto[17]

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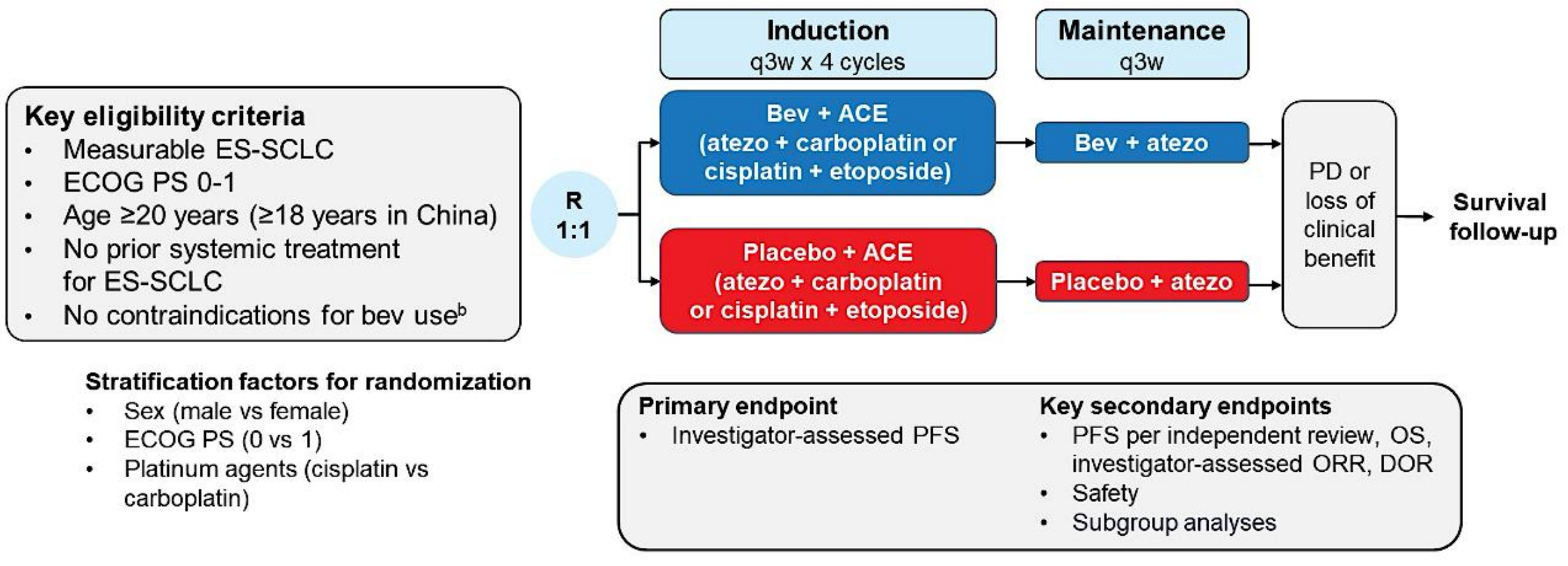
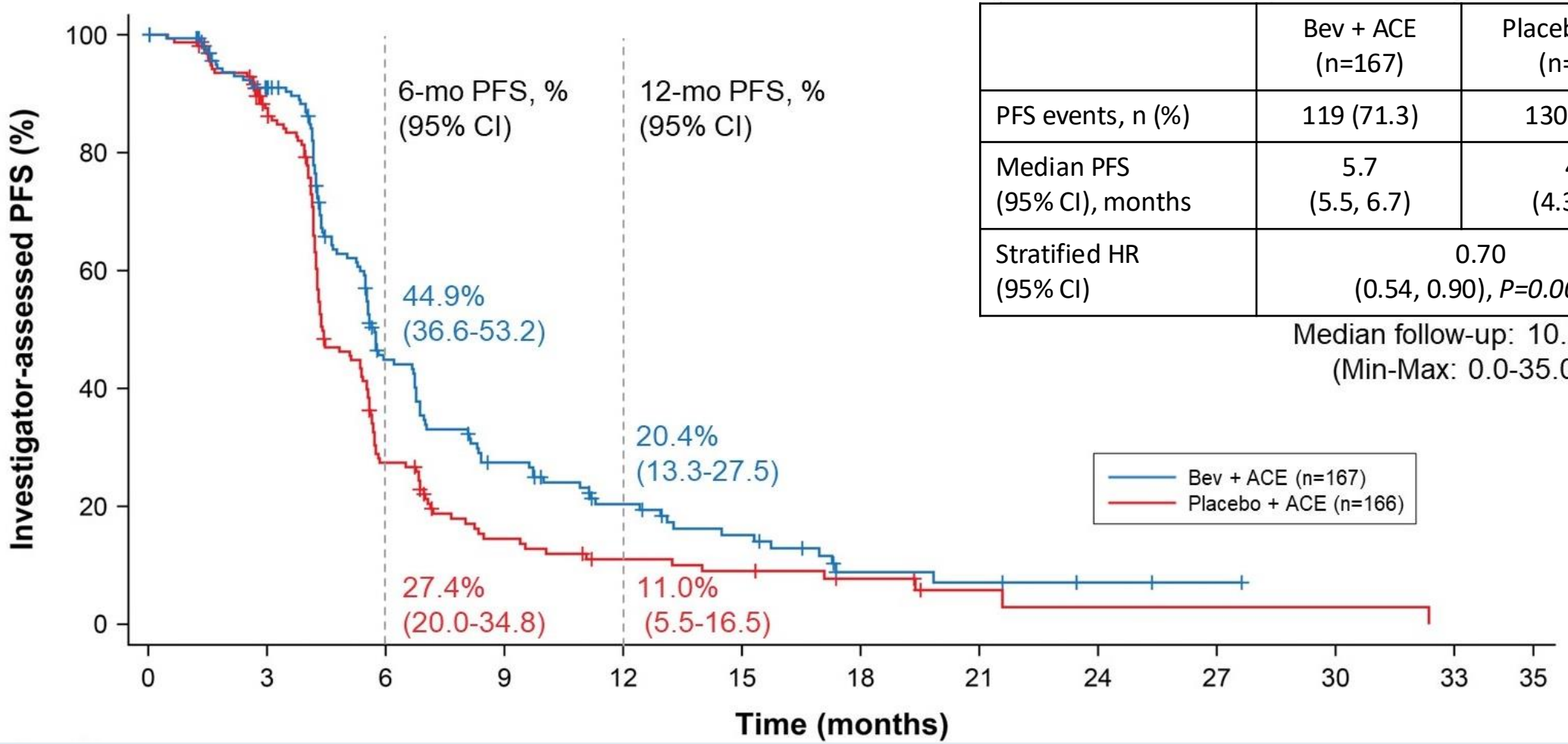
BEAT-SC Phase III Study Design



ORR = objective response rate

Ohe Y et al. ASCO 2024;Abstract 8001.

Phase III BEAT-SC: Investigator-Assessed PFS (Primary Endpoint)

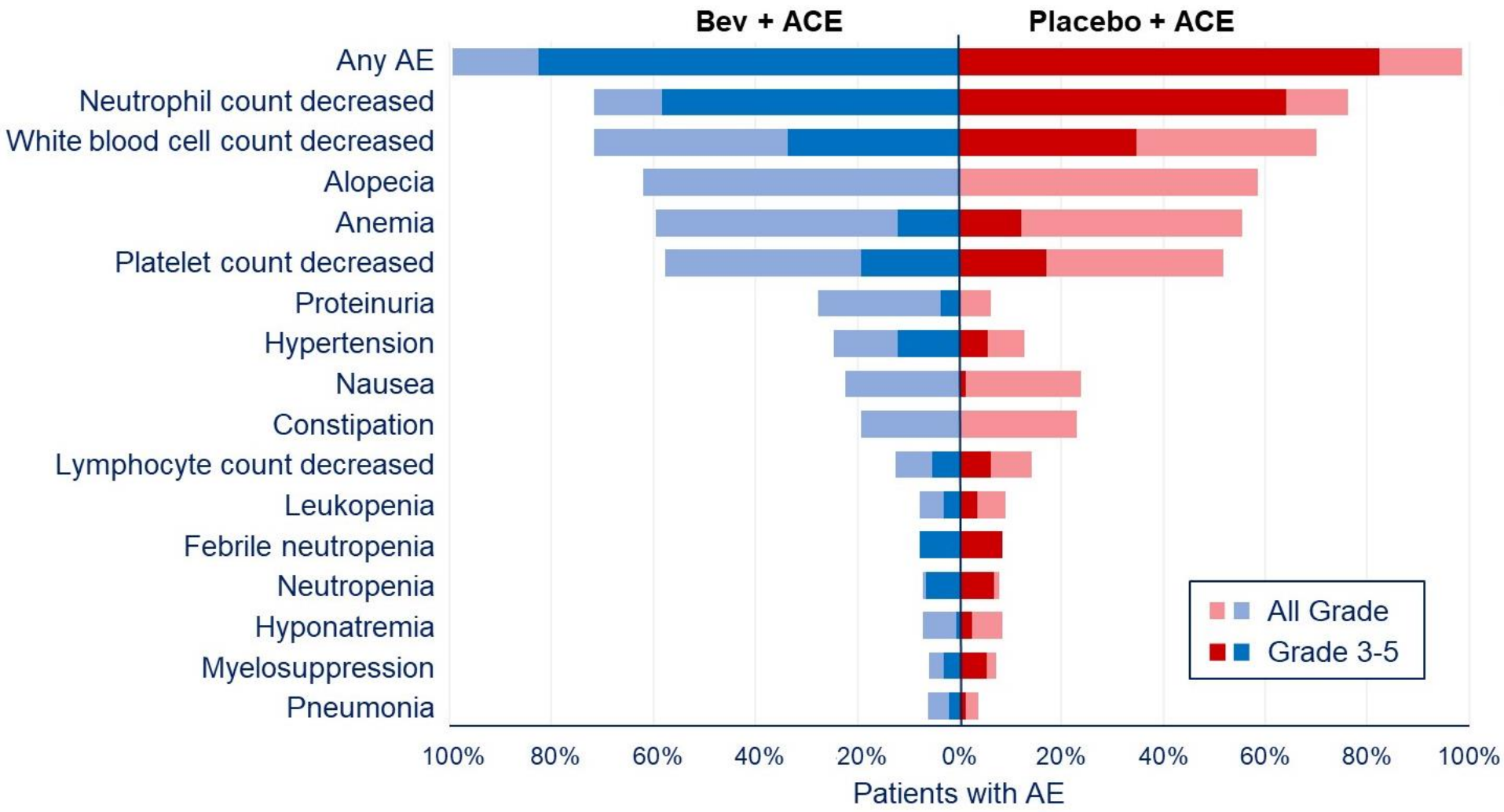


	Bev + ACE (n=167)	Placebo + ACE (n=166)
PFS events, n (%)	119 (71.3)	130 (78.3)
Median PFS (95% CI), months	5.7 (5.5, 6.7)	4.4 (4.3, 5.4)
Stratified HR (95% CI)	0.70 (0.54, 0.90), *P=0.0060*	

Median follow-up: 10.2 months
(Min-Max: 0.0-35.0 months)

Ohe Y et al. ASCO 2024;Abstract 8001.

Phase III BEAT-SC: Safety



- AEs occurring in ≥20% of patients in either arm (all grades) or in ≥2% in either arm (grades 3-5) are shown

Ohe Y et al. ASCO 2024;Abstract 8001.

Agenda

Introduction: A 66-Year-Old Man with a Lung Nodule on Lung Cancer Screening

Module 1: Current and Future Management of Small Cell Lung Cancer (SCLC)

Module 2: Other Relevant SCLC Abstracts from WCLC 2024

Other Key SCLC Abstracts from WCLC 2024

- Midde N et al. **Exposure-response analyses to support ph3 dose selection for I-DXd (ifinatamab deruxtecan) in extensive stage SCLC patients.** WCLC 2024;Abstract PT01.13.05.
- Dowlati A et al. **Sacituzumab govitecan as second-line treatment in patients with extensive stage small cell lung cancer.** WCLC 2024;Abstract OA04.04.
- Wang J et al. **Efficacy and safety of HS-20093 in extensive stage small cell lung cancer in a multicenter, phase 1 study (ARTEMIS-001).** WCLC 2024;Abstract OA04.06.
- Lau S et al. **Tarlatamab with a PD-L1 inhibitor as first-line maintenance after chemo-immunotherapy for ES-SLCLC: DeLLphi-303 phase 1b study.** WCLC 2024;Abstract OA10.04.

Other Key SCLC Abstracts from WCLC 2024

- Dowlati A et al. **DeLLphi-306 trial: A phase 3 study of tarlatamab after concurrent chemoradiotherapy in limited-stage small cell lung cancer.** WCLC 2024;Abstract PT01.13.02.
- Perol M et al. **Tarlatamab plus durvalumab as first-line maintenance in extensive-stage small cell lung cancer: DeLLphi-305 phase 3 trial.** WCLC 2024;Abstract PT01.13.02.
- Senan S et al. **Patient-reported outcomes (PROs) with consolidation durvalumab versus placebo following cCRT in limited-stage SCLC: ADRIATIC.** WCLC 2024;Abstract MA17.04.
- Qui M et al. **DLL3-targeted CAR-T therapy of small cell lung cancer utilizing circular RNA.** WCLC 2024;Abstract MA17.13.

Improving Outcomes with First-Line Endocrine-Based Therapy for Patients with HR-Positive, HER2-Negative Metastatic Breast Cancer

A CME/MOC-Accredited Live Webinar

Tuesday, October 8, 2024
5:00 PM – 6:00 PM ET

Faculty

Francois-Clement Bidard, MD, PhD
Kevin Kalinsky, MD, MS

Moderator

Neil Love, MD

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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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