

What Clinicians Want to Know: First-Line and Maintenance Therapy for Patients with Extensive-Stage Small Cell Lung Cancer

A CME/MOC-Accredited Live Webinar

Tuesday, November 11, 2025

5:00 PM – 6:00 PM ET

Faculty

Luis Paz-Ares, MD, PhD

Misty Dawn Shields, MD, PhD

Moderator

Neil Love, MD

Faculty



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

Research To Practice
Miami, Florida



Misty Dawn Shields, MD, PhD

Assistant Professor of Clinical Medicine
Indiana University School of Medicine
Adjunct Assistant Professor of Medical and Molecular Genetics
Associate Member, Experimental and Developmental Therapeutics
Department of Medicine, Division of Hematology/Oncology, Thoracic Oncology
Indiana University Melvin and Bren Simon Comprehensive Cancer Center
Indianapolis, Indiana

Commercial Support

This activity is supported by educational grants from Genentech, a member of the Roche Group, and Jazz Pharmaceuticals Inc.

Dr Love — Disclosures

Dr Love is president and CEO of Research To Practice. Research To Practice receives funds in the form of educational grants to develop CME activities from the following companies: Aadi Bioscience, AbbVie Inc, ADC Therapeutics, Agendia Inc, Alexion Pharmaceuticals, Amgen Inc, Array BioPharma Inc, a subsidiary of Pfizer Inc, Arvinas, Astellas, AstraZeneca Pharmaceuticals LP, Aveo Pharmaceuticals, Bayer HealthCare Pharmaceuticals, BeOne, Black Diamond Therapeutics Inc, Blueprint Medicines, Boehringer Ingelheim Pharmaceuticals Inc, Bristol Myers Squibb, Clovis Oncology, Coherus BioSciences, Corcept Therapeutics Inc, CTI BioPharma, a Sobi Company, Daiichi Sankyo Inc, Eisai Inc, Elevation Oncology Inc, Exact Sciences Corporation, Exelixis Inc, Genentech, a member of the Roche Group, Genmab US Inc, Geron Corporation, Gilead Sciences Inc, GSK, Helsinn Therapeutics (US) Inc, Hologic Inc, ImmunoGen Inc, Incyte Corporation, Ipsen Biopharmaceuticals Inc, Jazz Pharmaceuticals Inc, Johnson & Johnson, Karyopharm Therapeutics, Kite, A Gilead Company, Kura Oncology, Legend Biotech, Lilly, MEI Pharma Inc, Merck, Mersana Therapeutics Inc, Mirati Therapeutics Inc, Mural Oncology Inc, Natera Inc, Novartis, Novartis Pharmaceuticals Corporation on behalf of Advanced Accelerator Applications, Novocure Inc, Nuvalent, Pfizer Inc, Pharmacyclics LLC, an AbbVie Company, Puma Biotechnology Inc, Regeneron Pharmaceuticals Inc, Rigel Pharmaceuticals Inc, R-Pharm US, Sanofi, Seagen Inc, Servier Pharmaceuticals LLC, SpringWorks Therapeutics Inc, Stemline Therapeutics Inc, Sumitomo Pharma America, Syndax Pharmaceuticals, Taiho Oncology Inc, Takeda Pharmaceuticals USA Inc, TerSera Therapeutics LLC, and Tesaro, A GSK Company.

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Planners, scientific staff and independent reviewers for Research To Practice have no relevant conflicts of interest to disclose.

Dr Paz-Ares — Disclosures

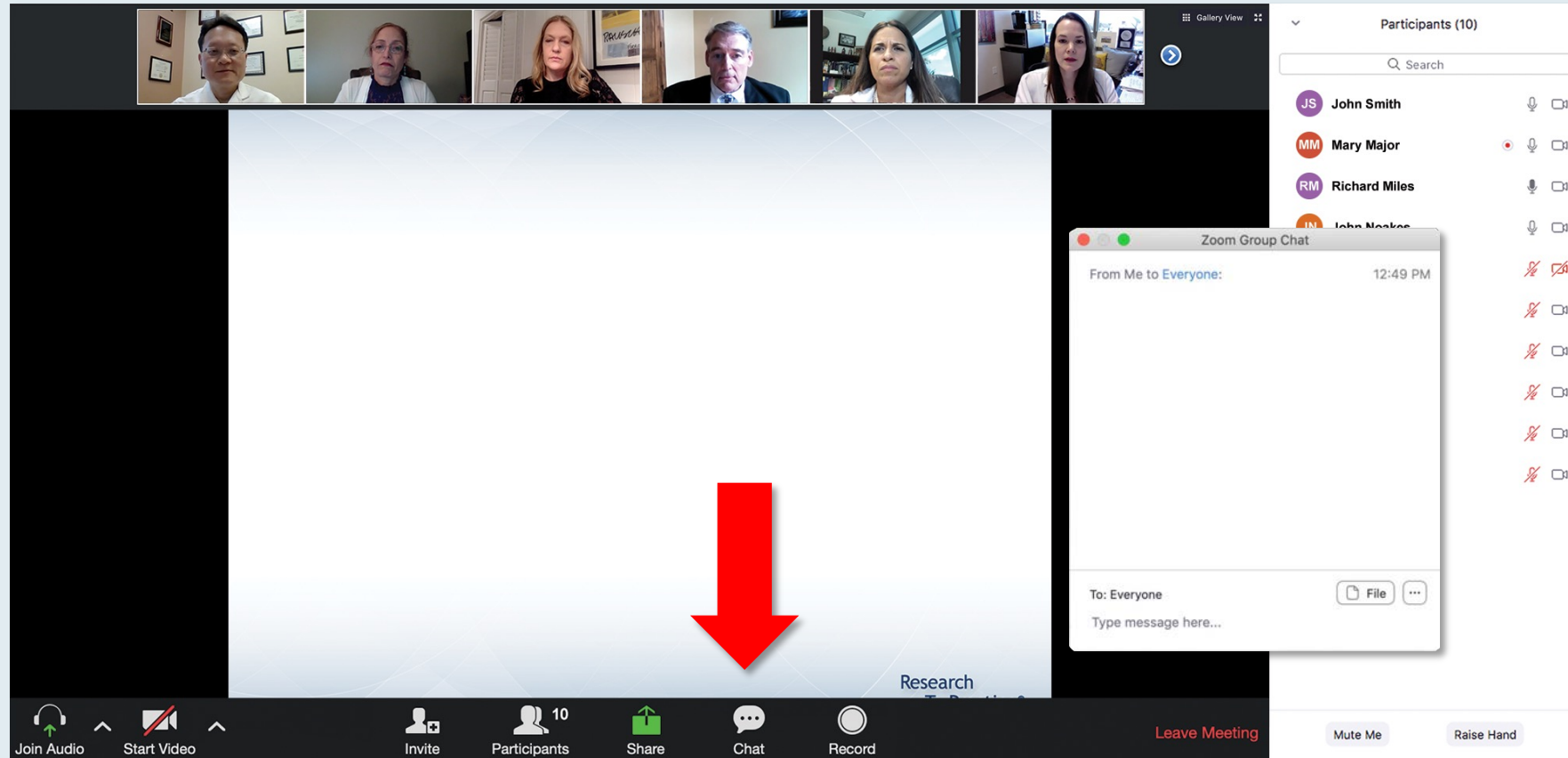
Advisory Committees	AstraZeneca Pharmaceuticals LP, Bristol Myers Squibb, MSD
Founder and Board Member	Altum Sequencing, STAb Therapeutics
Speakers Bureaus	AbbVie Inc, Amgen Inc, AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, BeOne, BioNTech SE, Boehringer Ingelheim Pharmaceuticals Inc, Bristol Myers Squibb, Daiichi Sankyo Inc, Genmab US Inc, Ipsen Biopharmaceuticals Inc, Janssen Biotech Inc, Jazz Pharmaceuticals Inc, Johnson & Johnson, Lilly, Merck, Mirati Therapeutics Inc, Moderna, MSD, Novartis, Pfizer Inc, PharmaMar, RayzeBio Inc, Regeneron Pharmaceuticals Inc, Roche Laboratories Inc

Dr Shields — Disclosures

Steering Committees	AstraZeneca Pharmaceuticals LP
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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.

We Encourage Clinicians in Practice to Submit Questions



Feel free to submit questions now before the program begins and throughout the program.

Familiarizing Yourself with the Zoom Interface

Expand chat submission box

The screenshot displays a Zoom meeting interface. At the top, there's a header bar with participant names: RTP Coordinat..., Kirsten Miller, RTP Mike Rivera, and Lisa Suarez. Below this, a slide titled "Meet The Professor Program Participating Faculty" is shown. The slide lists six faculty members with their photos and titles:

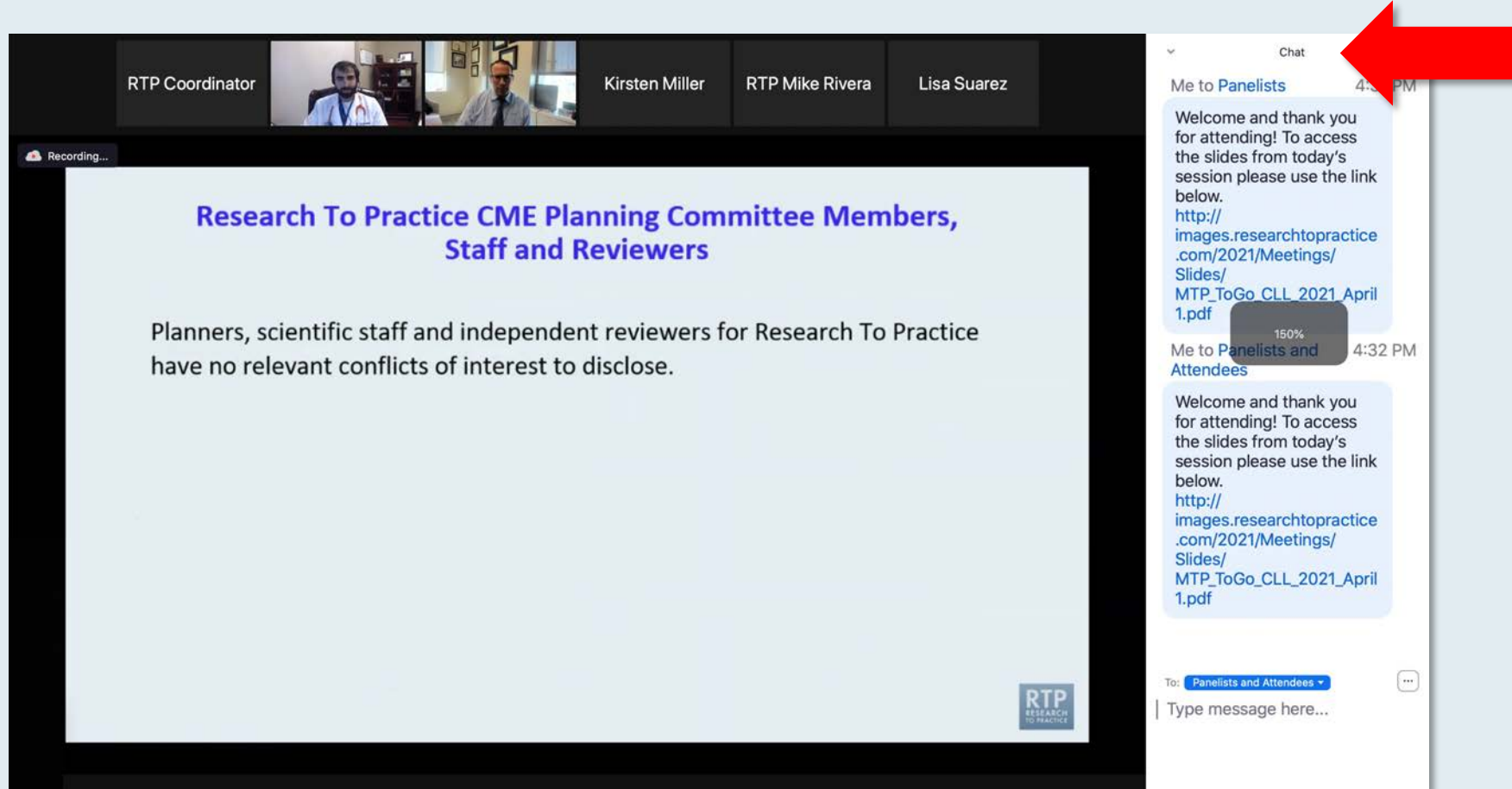
- Nancy L Bartlett, MD**
Professor of Medicine
Koman Chair in Medical Oncology
Washington University School of Medicine
St Louis, Missouri
- Jonathan W Friedberg, MD, MMSc**
Samuel E Durand Professor of Medicine
Director, James P Wilmot Cancer Institute
University of Rochester
Rochester, New York
- Carla Casulo, MD**
Associate Professor of Medicine
Division of Hematology/Oncology
Director, Hematology/Oncology Fellowship Program
University of Rochester
Wilmot Cancer Institute
Rochester, New York
- Brian T Hill, MD, PhD**
Director, Lymphoid Malignancy Program
Cleveland Clinic Taussig Cancer Institute
Cleveland, Ohio
- Christopher R Flowers, MD, MS**
Chair, Professor
Department of Lymphoma/Myeloma
The University of Texas MD Anderson Cancer Center
Houston, Texas
- Brad S Kahl, MD**
Professor of Medicine
Washington University School of Medicine
Director, Lymphoma Program
Siteman Cancer Center
St Louis, Missouri

On the right side, a chat window is open. It shows two messages from "Me to Panelists" and "Me to Panelists and Attendees". At the bottom of the chat window, there's a "To:" dropdown menu set to "Panelists and Attendees" and a text input field labeled "Type message here...". A red arrow points to the white line above this input field, indicating where to drag to expand the box.

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

Familiarizing Yourself with the Zoom Interface

Increase chat font size



**Press Command (for Mac) or Control (for PC) and the + symbol.
You may do this as many times as you need for readability.**

Clinicians in the Audience, Please Complete the Pre- and Postmeeting Surveys

The screenshot shows a Zoom meeting window. At the top, a row of seven participant video thumbnails is visible. The main content area on the left displays a presentation slide with the following text:
Meet The Professionals
Optimizing the Selection and Management of Therapy for Patients with Gastrointestinal Cancer
Wednesday, August 25, 2022
5:00 PM – 6:00 PM EST
Faculty
Wells A Messersmith, MD
Moderator
Neil Love, MD
The RTP Research to Practice logo is in the bottom right corner of the slide. A 'Quick Survey' pop-up window is centered over the slide, listing several treatment combinations with radio button options. To the right of the main content area is a 'Participants (10)' sidebar showing a list of names with their respective status icons (mute, video on/off). At the bottom of the window is a standard Zoom toolbar with icons for Join Audio, Start Video, Invite, Participants, Share, Chat, Record, and a red 'Leave Meeting' button.

Quick Survey

- ☐ Ceritinib +/- dexamethasone
- ☐ Pomalidomide +/- dexamethasone
- ☐ Ceritinib + pomalidomide +/- dexamethasone
- ☐ Elotuzumab + lenalidomide +/- dexamethasone
- ☐ Elotuzumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + lenalidomide +/- dexamethasone
- ☐ Daratumumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + bortezomib +/- dexamethasone
- ☐ Isaxozim + Rd
- ☐ Other

Participants (10)

- JS John Smith
- MM Mary Major
- RM Richard Miles
- JN John Noakes
- AS Alice Suarez
- JP Jane Perez
- RS Robert Stiles
- JF Juan Fernandez
- AK Ashok Kumar
- JS Jeremy Smith

This screenshot shows the same Zoom meeting window as the previous one, but the main content area now displays a different slide. The slide text reads:
Regulatory and reimbursement issues aside, which treatment would you recommend for a 65-year-old patient with clear cell renal cell carcinoma (ccRCC) if a follow-up 3 years later is found to have asymptomatic (PS 0)?
Below the question is a numbered list of eight options. A 'Quick Poll' pop-up window is overlaid on the right side of the slide, showing the same list of options with radio button selection fields. The 'Participants (10)' sidebar and the bottom Zoom toolbar remain the same as in the previous screenshot.

Quick Poll

1. Nivolumab/ipilimumab
2. Avelumab/axitinib
3. Pembrolizumab/axitinib
4. Pembrolizumab/lenvatinib
5. Nivolumab/cabozantinib
6. Tyrosine kinase inhibitor (TKI) monotherapy
7. Anti-PD-1/PD-L1 monotherapy
8. Other

Quick Poll

- ☐ Nivolumab/ipilimumab
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Small Cell Lung Cancer — Expert Perspectives on Actual Patient Cases



DR STEPHEN V LIU
GEORGETOWN UNIVERSITY HOSPITAL



DR CHARLES RUDIN
MEMORIAL SLOAN KETTERING CANCER CENTER



Cancer Q&A: Understanding the Role and Reality of CAR (Chimeric Antigen Receptor) T-Cell Therapy for Non-Hodgkin Lymphoma

A CME/MOC-Accredited Webinar Developed in Partnership with CancerCare®

**Wednesday, November 12, 2025
5:00 PM – 6:00 PM ET**

Faculty

**Jeremy S Abramson, MD, MMSc
Loretta J Nastoupil, MD**

Moderator

Neil Love, MD

Cancer Conference Update: 2025 ESMO Annual Meeting — Breast Cancer Highlights

CME/MOC-Accredited Live Webinar

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**Professor Giuseppe Curigliano, MD, PhD
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Practical Perspectives: Clinical Investigators Review Actual Cases of Patients with Advanced Gastroesophageal Cancers

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Yelena Y Janjigian, MD

Moderator

Neil Love, MD

Preventing and Managing Toxicities Associated with Antibody-Drug Conjugates in the Management of Metastatic Breast Cancer

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5:00 PM – 6:00 PM ET

Faculty

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Rita Nanda, MD

Moderator

Neil Love, MD

Exciting CME Events You Do Not Want to Miss

A Friday Satellite Symposium Series Preceding the 67th ASH Annual Meeting

Friday, December 5, 2025

Acute Myeloid Leukemia

7:30 AM – 9:30 AM ET

**Myelofibrosis and
Systemic Mastocytosis**

3:15 PM – 5:15 PM ET

Chronic Lymphocytic Leukemia

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Cases from the Community: Investigators Discuss the Optimal Management of Breast Cancer

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November 2025 to April 2026

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Save The Date

Fifth 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, April 24 to 26, 2026

The Ritz-Carlton Orlando, Grande Lakes | Orlando, Florida

Moderated by Neil Love, MD

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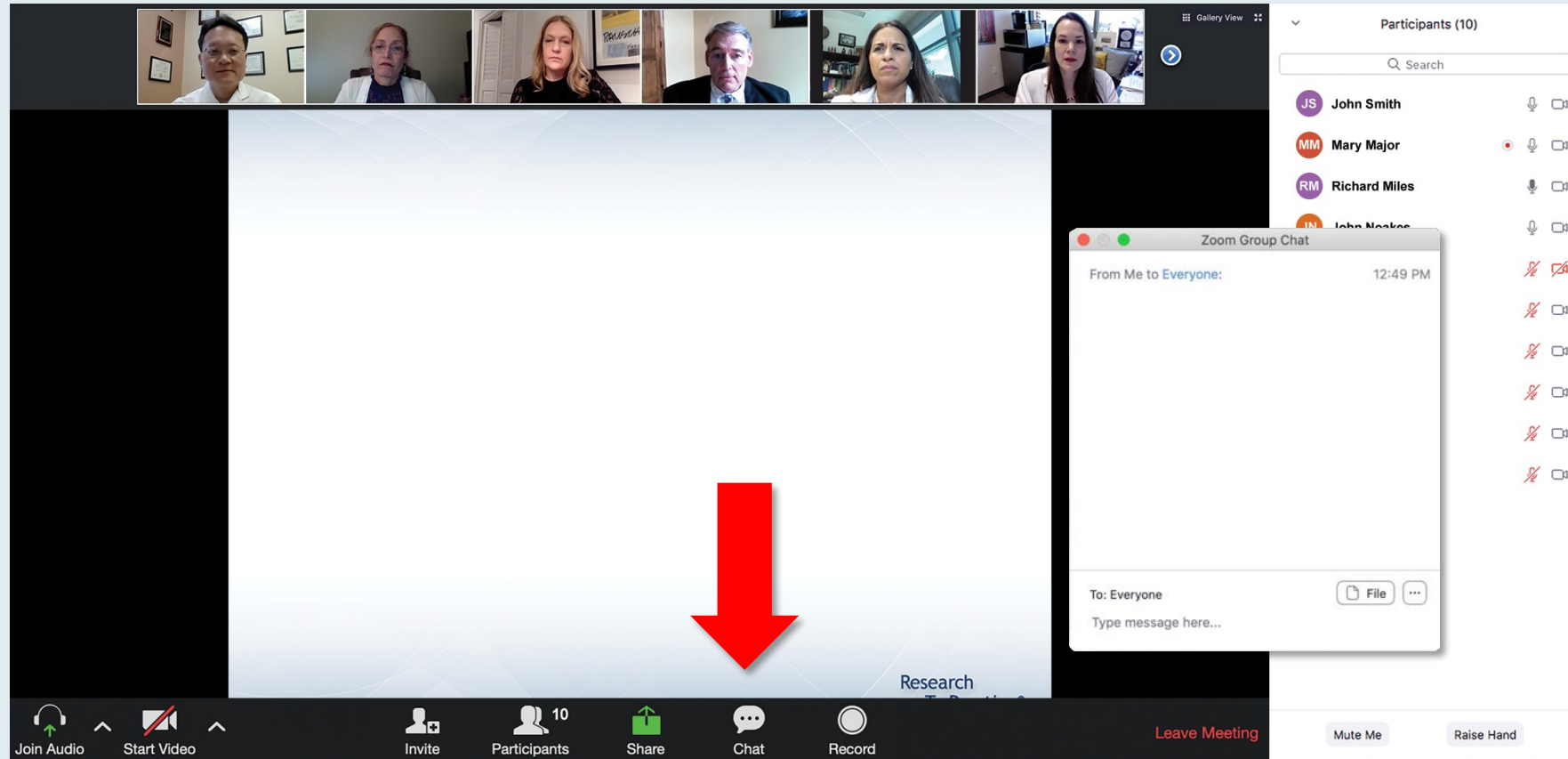
Research To Practice
Miami, Florida



Misty Dawn Shields, MD, PhD

Assistant Professor of Clinical Medicine
Indiana University School of Medicine
Adjunct Assistant Professor of Medical and Molecular Genetics
Associate Member, Experimental and Developmental Therapeutics
Department of Medicine, Division of Hematology/Oncology, Thoracic Oncology
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Quick Survey

- ☐ Capecitabine +/- docetaxel
- ☐ FOLFIRI +/- docetaxel
- ☐ Capecitabine + pomalidomide +/- dexamethasone
- ☐ Eribulin + pomalidomide +/- dexamethasone
- ☐ Eribulin + pomalidomide +/- dexamethasone
- ☐ Daratumumab + lenalidomide +/- dexamethasone
- ☐ Daratumumab + pomalidomide +/- dexamethasone
- ☐ Daratumumab + bortezomib +/- dexamethasone
- ☐ Isotretinoin + Rd
- ☐ Other

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Small Cell Lung Cancer — Expert Perspectives on Actual Patient Cases



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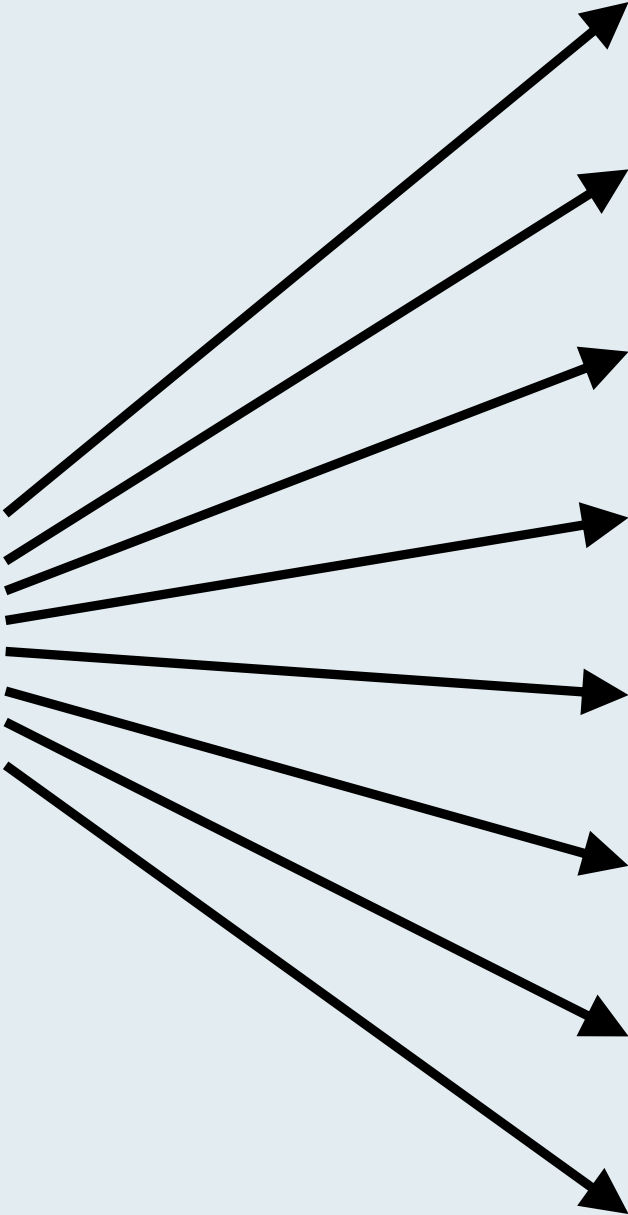
The Ritz-Carlton Orlando, Grande Lakes | Orlando, Florida

Moderated by Neil Love, MD

RTP Content Distribution Platform

9-28-24 to 9-28-25

	Year	Month
Total (hours)	280	24
Recordings	93	7
Webinars	41	4
Cases	62	5
Meetings	84	7
Final	218	18



- Podcast
- Streaming Platforms
(YouTube, Spotify)
- Email
- Social Media
- App
- Website
- Text Messages
- QR Code Cards

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Dr Shields — Disclosures

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Dr Love — Disclosures

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**What Clinicians Want to Know:
First-Line and Maintenance Therapy for
Patients with Extensive-Stage Small Cell Lung Cancer**

**Survey of 50 US-Based General Medical Oncologists
November 1-10, 2025**

Up-Front Treatment of Extensive-Stage Small Cell Lung Cancer

Introduction: Tail on the Curve?

Module 1: First-Line Chemoimmunotherapy

Module 2: Maintenance Lurbinectedin

Module 3: Second-Line Treatment, Tarlatamab

Module 4: Ongoing Research

Up-Front Treatment of Extensive-Stage Small Cell Lung Cancer

Introduction: Tail on the Curve?

Module 1: First-Line Chemoimmunotherapy

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Module 3: Second-Line Treatment, Tarlatamab

Module 4: Ongoing Research

Integrating New Advances into the Care of Patients with Cancer

**A Multitumor Symposium in Partnership
with the American Oncology Network**

CME/MOC, NCPD and ACPE Accredited

**Saturday, November 8, 2025
10:00 AM – 3:00 PM CT**

Lung Cancer Faculty



Justin F Gainor, MD

Director, Center for Thoracic Cancers Program

Director of Targeted Immunotherapy in the Henri and Belinda Termeer

Center for Targeted Therapies

Massachusetts General Hospital

Associate Professor of Medicine

Harvard Medical School

Boston, Massachusetts



Misty Dawn Shields, MD, PhD

Assistant Professor of Clinical Medicine

Indiana University School of Medicine

Adjunct Assistant Professor of Medical and Molecular Genetics

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Department of Medicine, Division of

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Indiana University Melvin and Bren Simon

Comprehensive Cancer Center

Indianapolis, Indiana



Corey J Langer, MD

Director of Thoracic Oncology

Abramson Cancer Center

Professor of Medicine

Perelman School of Medicine

University of Pennsylvania

Philadelphia, Pennsylvania



MODERATOR

Stephen "Fred" Divers, MD

Chief Medical Officer

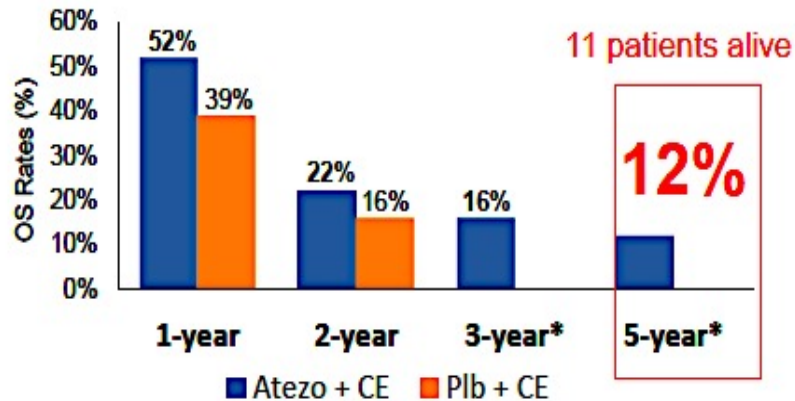
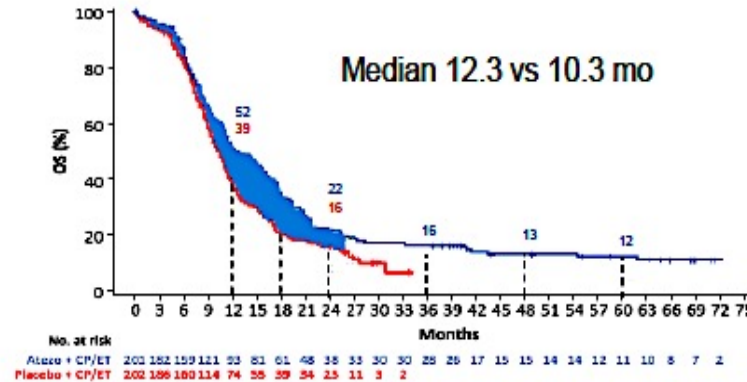
American Oncology Network

Hot Springs, Arkansas

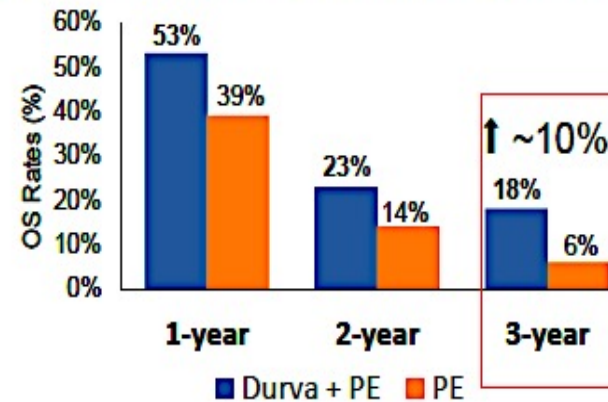
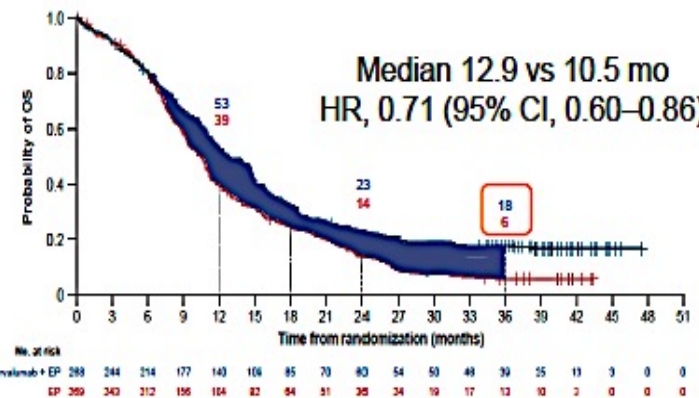


Pivotal Trials of ICLs in ES SCLC – Long term outcome

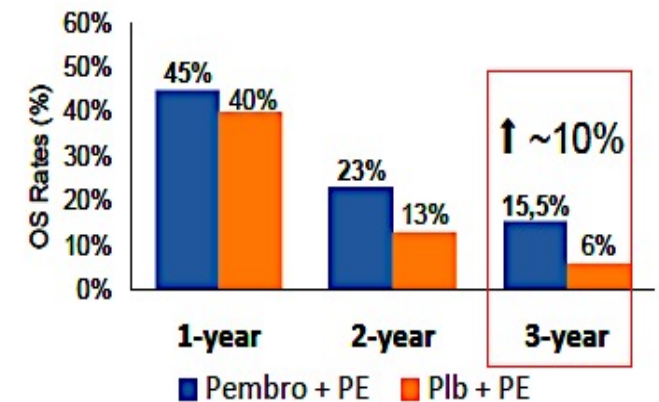
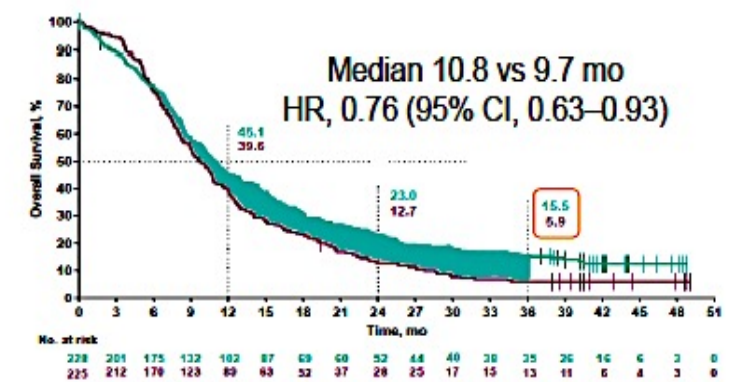
IMpower133 and IMbrella A
Atezolizumab + CP/ET vs CP/ET + Plb¹⁻²



CASPIAN
Durvalumab + P/ET vs P/ET³⁻⁴



KEYNOTE-604
Pembrolizumab + P/ET vs P/ET + Plb⁵⁻⁶



CP, carboplatin; ET, etoposide; P, platinum; Plb, placebo; NE, not estimable. * OS rates at 3-5 years were not estimable in the control arm as rollover to IMbrella A was not permitted.

1.- Horn L, et al. N Engl J Med 2018; 2.- Liu S, et al. OA01.04, WCLC 2023; 3.- Paz-Ares L, et al. Lancet 2019; 4.- Paz-Ares L, et al. ESMO Open 2022; 5.- Rudin CM, et al. J Clin Oncol 2020; 6.- Rudin CM, et al. WCLC 2022

2:38



ChatGPT



the limited field (e.g., distant metastases).

Treatment:

- **Systemic chemotherapy** (platinum + etoposide or carboplatin + etoposide)
- **Immunotherapy** (e.g., atezolizumab or durvalumab) added to frontline therapy has modestly improved outcomes
- **Radiation** sometimes used for symptom control or consolidative thoracic therapy in responders

Outcomes:

- **Median survival:** 9–12 months
- **2-year survival:** ~5–10%
- **5-year survival (functional "cure"):** <2%



Ask anything



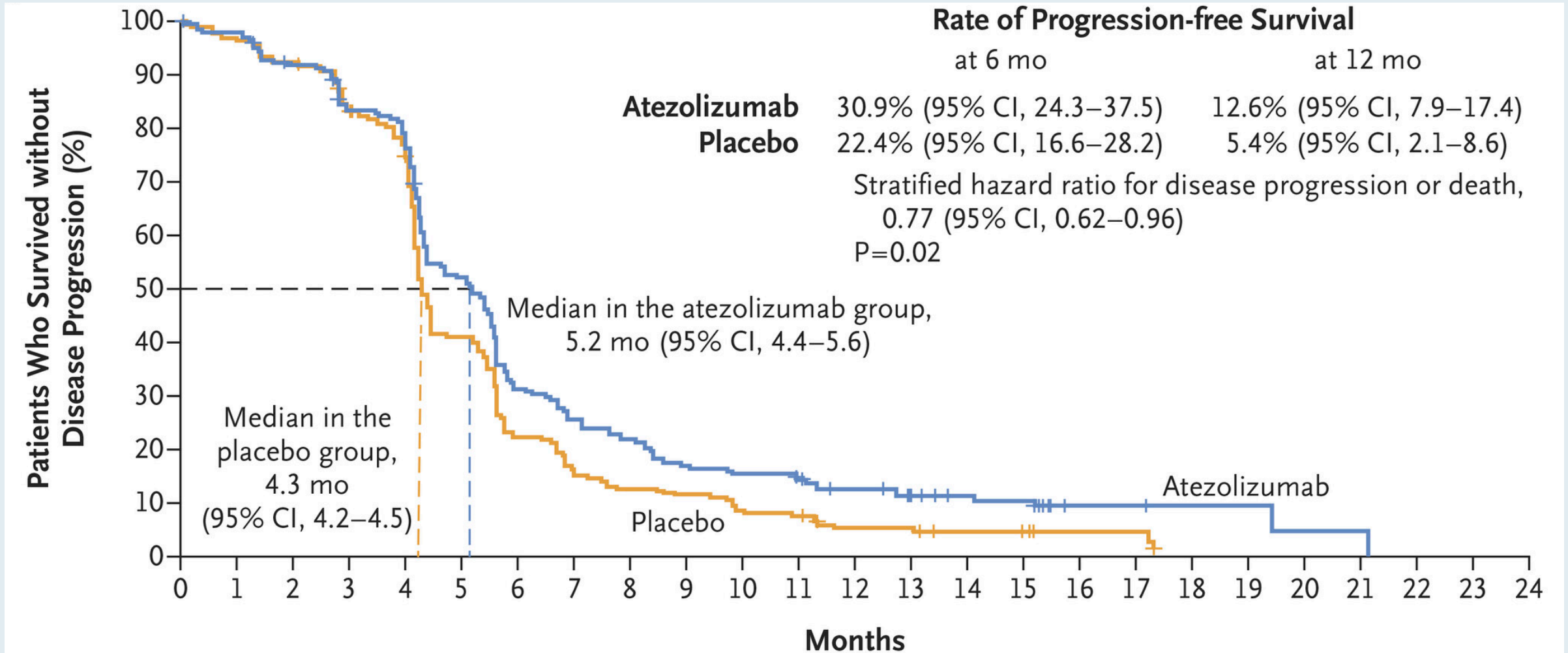
What is the cure rate for extensive stage small cell lung Cancer?

✓ Finished thinking

Extensive-stage small cell lung cancer (ES-SCLC) is rarely curable, with long-term survival being exceptional; the 5-year cure rate is less than 5%. Most patients experience relapse after initial response to therapy, and the disease is generally managed with palliative intent rather than curative.^[1-4]

Median overall survival for ES-SCLC with current first-line chemoimmunotherapy regimens (platinum/etoposide plus atezolizumab or durvalumab) is approximately 12–13 months, with 1-year survival rates around 50% and 2-year survival rates below 20%. For example, the IMpower133 trial reported a median OS of 12.3 months with atezolizumab plus chemotherapy, and the CASPIAN trial found a median OS of 13.0 months with durvalumab plus chemotherapy.^{[3][5-7]} Real-world and clinical trial data consistently show that **long-term survival (cure) is extremely rare**; most patients succumb to progressive disease within a few years.^{[1-2][4][6]}

Phase III IMpower133 Trial: Primary Progression-Free Survival with Atezolizumab/Carboplatin/Etoposide (ITT Population)



ITT = intention to treat

Five-year survival in patients with ES-SCLC treated with atezolizumab in IMpower133: IMbrella A extension study results

Stephen V. Liu,¹ Rafal Dziadziuszko,² Shunichi Sugawara,³ Steven Kao,⁴ Maximilian Hochmair,⁵ Florian Huemer,⁶ Gilberto de Castro, Junior,⁷ Libor Havel,⁸ Reyes Bernabé Caro,⁹ György Losonczy,¹⁰ Jong-Seok Lee,¹¹ Dariusz Kowalski,¹² Zoran Andric,¹³ Raffaele Califano,¹⁴ Andrea Veatch,¹⁵ Gregory Gerstner,¹⁶ Marta Batus,¹⁷ Stefanie Morris,¹⁸ Monika Kaul,¹⁹ Madeena Siddiqui,¹⁹ Huafei Li,²⁰ Wei Zhang,¹⁹ Barzin Nabet,¹⁹ Martin Reck²¹

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Presented by: Stephen V. Liu

<https://r.13/612nd>

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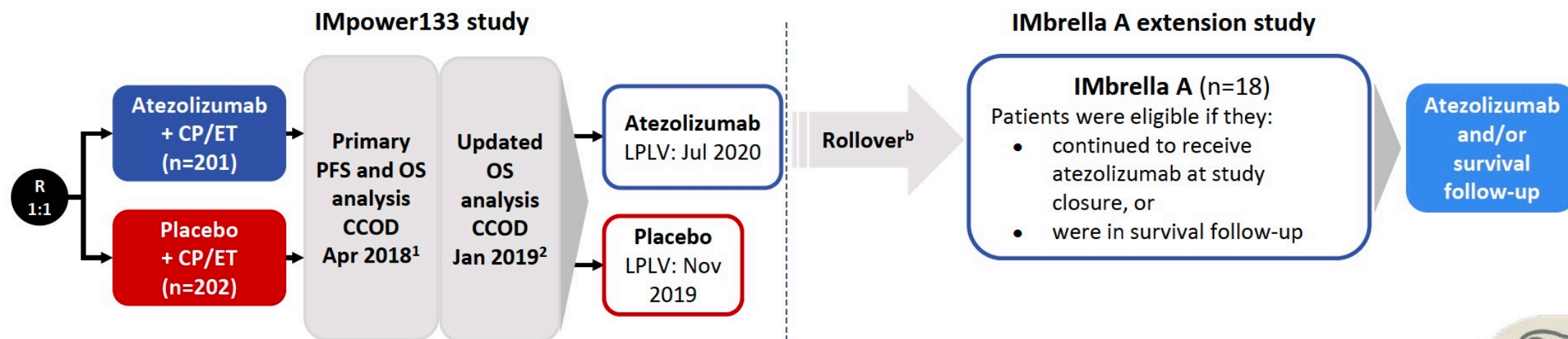
journal homepage: www.elsevier.com/locate/lungcan

Five-year survival in patients with extensive-stage small cell lung cancer treated with atezolizumab in the Phase III IMpower133 study and the Phase III IMbrella A extension study

Martin Reck^{a,*}, Rafal Dziadziuszko^b, Shunichi Sugawara^c, Steven Kao^d, Maximilian Hochmair^e, Florian Huemer^f, Gilberto de Castro Jr^g, Libor Havel^{h,1}, Reyes Bernabé Caroⁱ, György Losonczy^j, Jong-Seok Lee^k, Dariusz M. Kowalski^l, Zoran Andric^m, Raffaele Califanoⁿ, Andrea Veatch^o, Gregory Gerstner^p, Marta Batus^q, Stefanie Morris^r, Monika Kaul^s, Vaikunth Cuchelkar^t, Huafei Li^u, Bradford J. Danner^v, Barzin Y. Nabet^w, Stephen V. Liu^x

Phase III IMpower133 Study Design (IMbrella A Extension Study)

- IMbrella A is an open-label, non-randomised, multicentre extension and long-term observational study
- Patients in the IMpower133 control arm were not eligible for enrollment in IMbrella A
- Rollover from IMpower133 to IMbrella A for patients treated with atezolizumab in IMpower133 occurred between December 2019 and July 2020
- We report a merged analysis from IMpower133 and IMbrella A with a CCOD of 16 March 2023

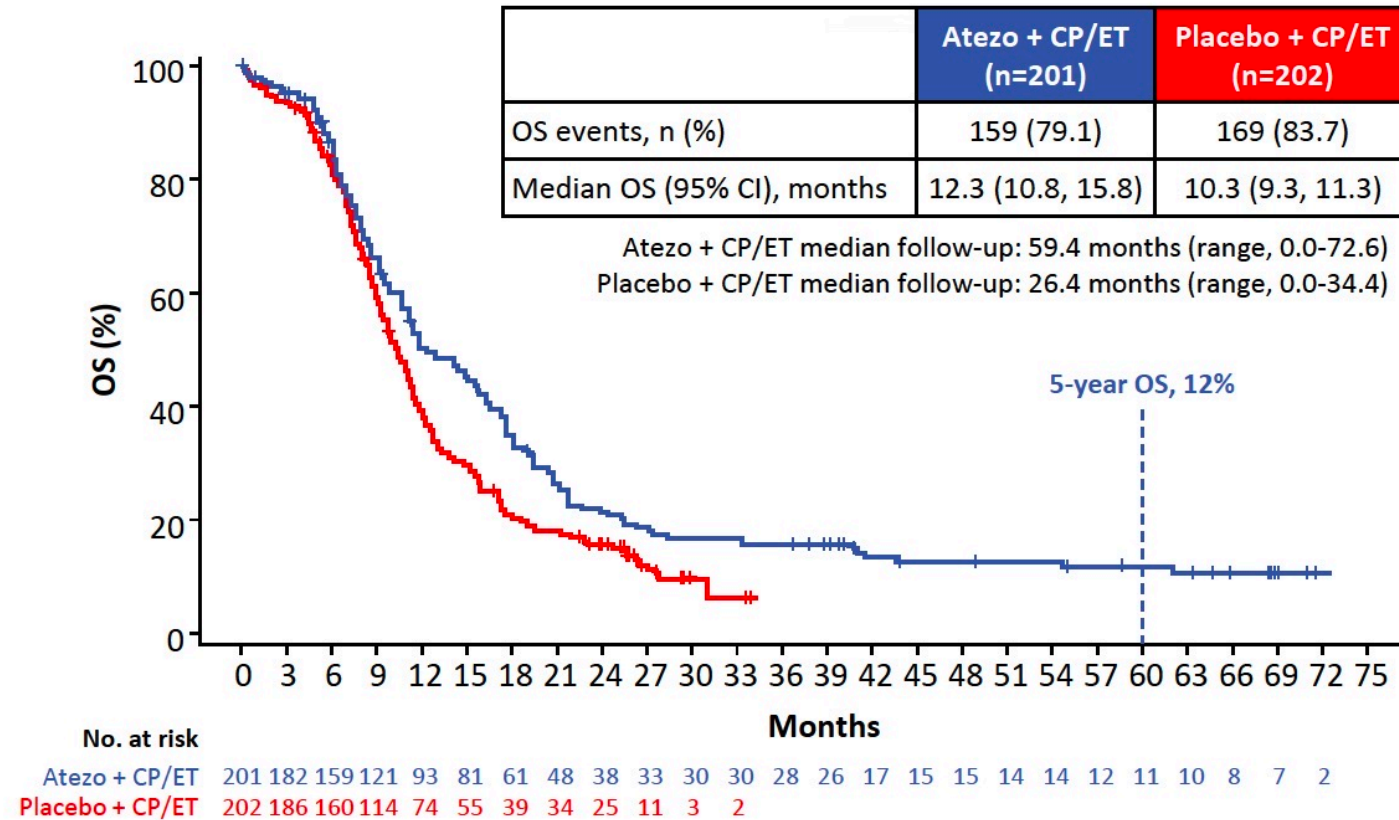


Atezolizumab, 1200 mg IV, Day 1; CP, AUC 5 mg/mL/min IV, Day 1; ET, 100 mg/m² IV, Days 1–3. CCOD, clinical cutoff date; LPLV, last patient, last visit. ^a IMbrella A (NCT03148418) allowed rollover from other Roche/Genentech-sponsored atezolizumab trials; only results from patients who rolled over from IMpower133 are reported.

^b Eight patients who were alive did not rollover to IMbrella A (censored). 1. Horn L, et al. N Engl J Med 2018;379:2220-92; 2. Liu SV, et al. J Clin Oncol 2021; 39:619-30.



Merged Analysis of IMpower133 and IMbrella A: Long-Term OS



	IMpower133 and IMbrella A Atezo + CP/ET (n=201)	IMpower133 only Placebo + CP/ET (n=202)
OS rate (95% CI), %		
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

Clinical cutoff date: 16 March 2023. NE, not estimable. ^a OS rates were NE in the control arm as rollover to IMbrella A was not permitted.

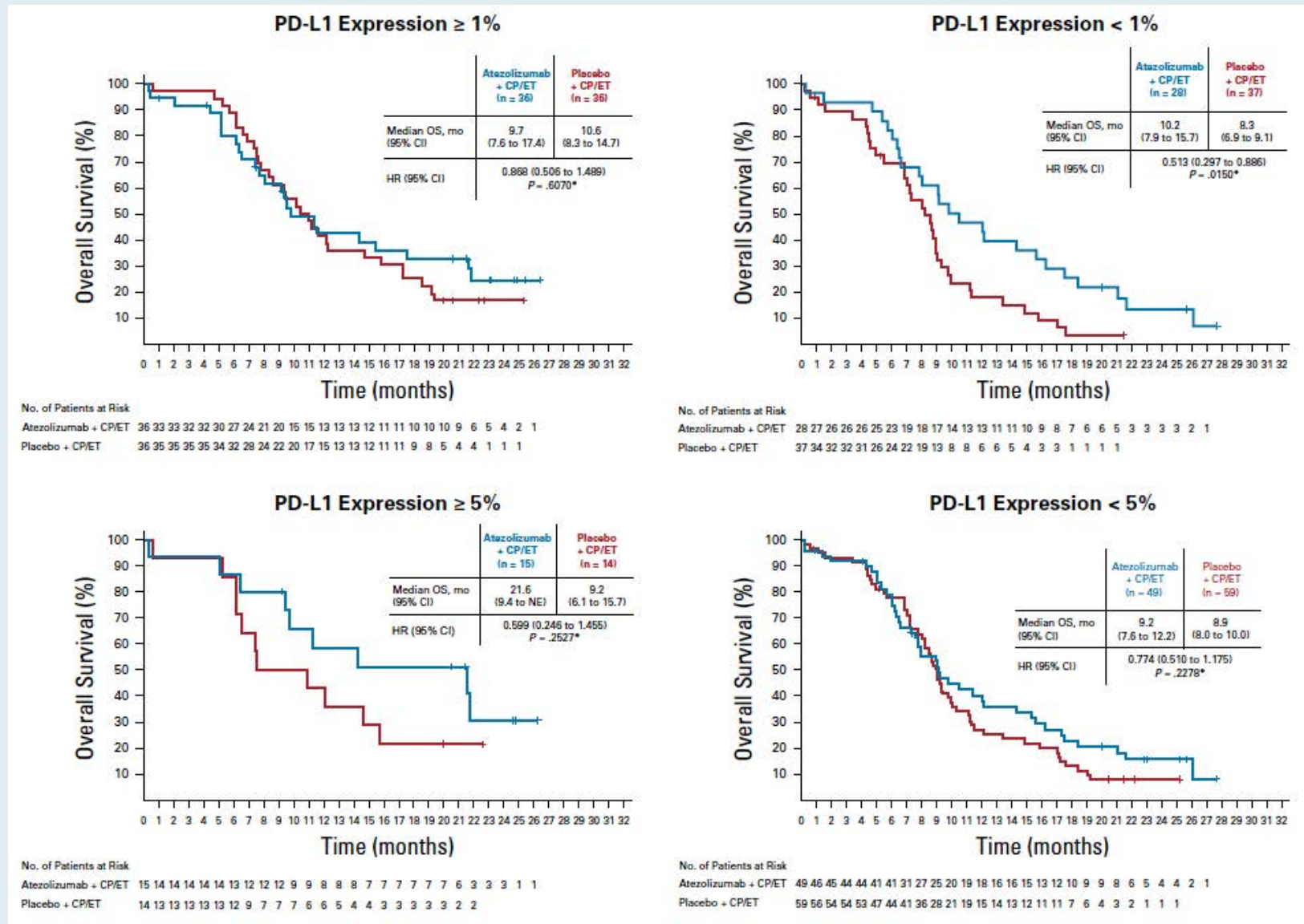
NE = not evaluable

Merged Analysis of IMpower133 and IMbrella A: Authors' Conclusions

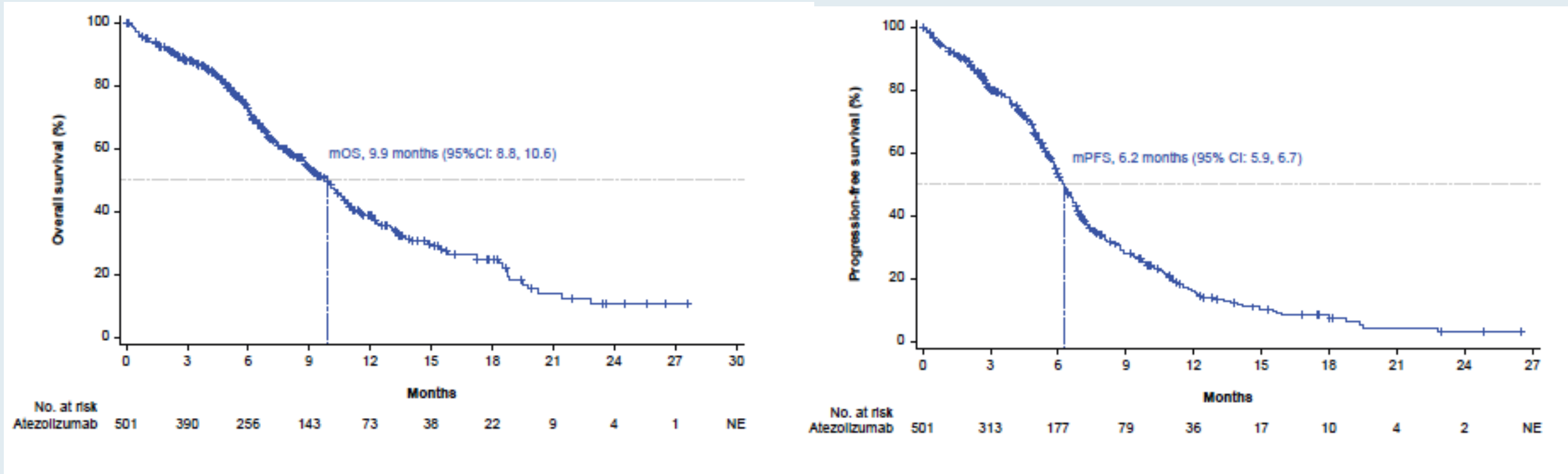
- These data from IMpower133 and IMbrella A provide the first report of 5-year survival outcomes for patients who received first-line cancer immunotherapy with chemotherapy for ES-SCLC
 - 5-year survival in the atezolizumab + CP/ET arm was 12%
 - The OS data compare favorably with historical 5-year OS rates of $\approx 2\%$ for patients with ES-SCLC treated with chemotherapy alone, although patient numbers were limited
- The long-term safety profile of atezolizumab + CP/ET in IMbrella A is encouraging considering the low incidence of serious AEs and AEs of special interest
 - Notably, late onset immune-mediated toxicities were rare and manageable
- These outcomes demonstrate the potential for durable survival benefit up to 5 years with atezolizumab + CP/ET

ES-SCLC = extensive-stage small cell lung cancer; AEs = adverse events

Phase III IMpower133: OS by PD-L1 Expression with Atezolizumab/Carboplatin/Etoposide



IMreal Study Cohort 4: Efficacy and Safety for Patients with ES-SCLC Receiving First-Line Atezolizumab and Carboplatin/Etoposide Under Real-World Conditions



- The safety profile of atezolizumab was consistent with that in the IMpower133 study, and no new or unexpected safety signals were observed.

mOS = median overall survival; mPFS = median progression-free survival

IMreal Cohort 4: Authors' Conclusions

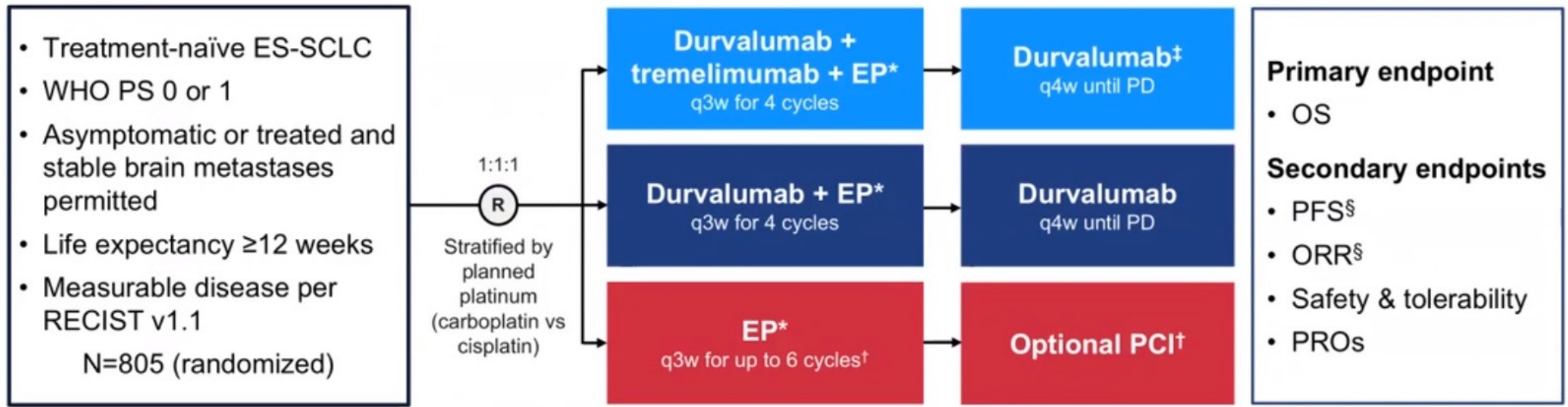
- After a median time of 6.1 months on study for Cohort 4 of the IMreal study, mOS was slightly shorter and mPFS was slightly longer compared with the Phase III IMpower133 study^{4,7}
 - These slight differences may be attributed to patient baseline characteristics that are reflective of an advanced SCLC population in clinical practice
- The safety profile of atezolizumab was consistent with that of the IMpower133 study, and no new or unexpected safety signals were observed⁴
- IMreal Cohort 4 provides data from patients treated in routine clinical practice, supporting the use of atezolizumab combined with carboplatin and etoposide as a first-line treatment for patients with ES-SCLC
- The IMreal study is ongoing and more mature data, including the final analysis, for Cohort 4 are expected in 2025

 Download Full Issue

Durvalumab, with or without tremelimumab, plus platinum-etoposide in first-line treatment of extensive-stage small-cell lung cancer: 3-year overall survival update from CASPIAN

[L. Paz-Ares](#) ¹  · [Y. Chen](#)² · [N. Reinmuth](#)³ · [K. Hotta](#)⁴ · [D. Trukhin](#)⁵ · [G. Statsenko](#)⁶ ·
[M.J. Hochmair](#)⁷ · [M. Özgüroğlu](#)⁸ · [J.H. Ji](#)⁹ · [M.C. Garassino](#)^{10,11} · [O. Voitko](#)¹² · [A. Poltoratskiy](#)¹³ ·
[E. Musso](#)¹⁴ · [L. Havel](#)¹⁵ · [I. Bondarenko](#)¹⁶ · [G. Losonczy](#)¹⁷ · [N. Conev](#)¹⁸ · [H. Mann](#)¹⁹ · [T.B. Dalvi](#)²⁰
· [H. Jiang](#)²⁰ · [J.W. Goldman](#)²¹ [Show less](#)

Phase III CASPIAN Study Design



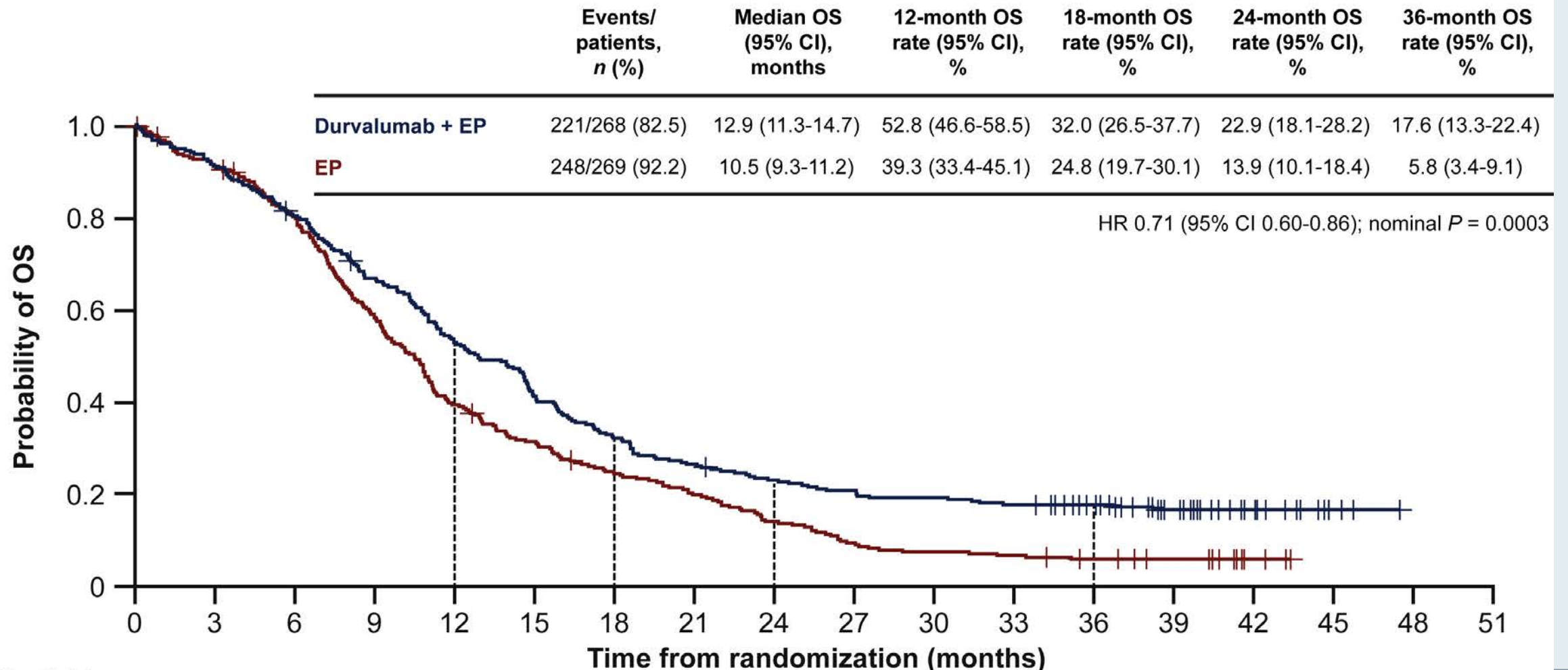
*EP consists of etoposide 80–100 mg/m² with either carboplatin AUC 5–6 or cisplatin 75–80 mg/m², durvalumab dosed at 1500 mg, tremelimumab dosed at 75 mg

†Patients could receive an additional 2 cycles of EP (up to 6 cycles total) and PCI at the investigator's discretion

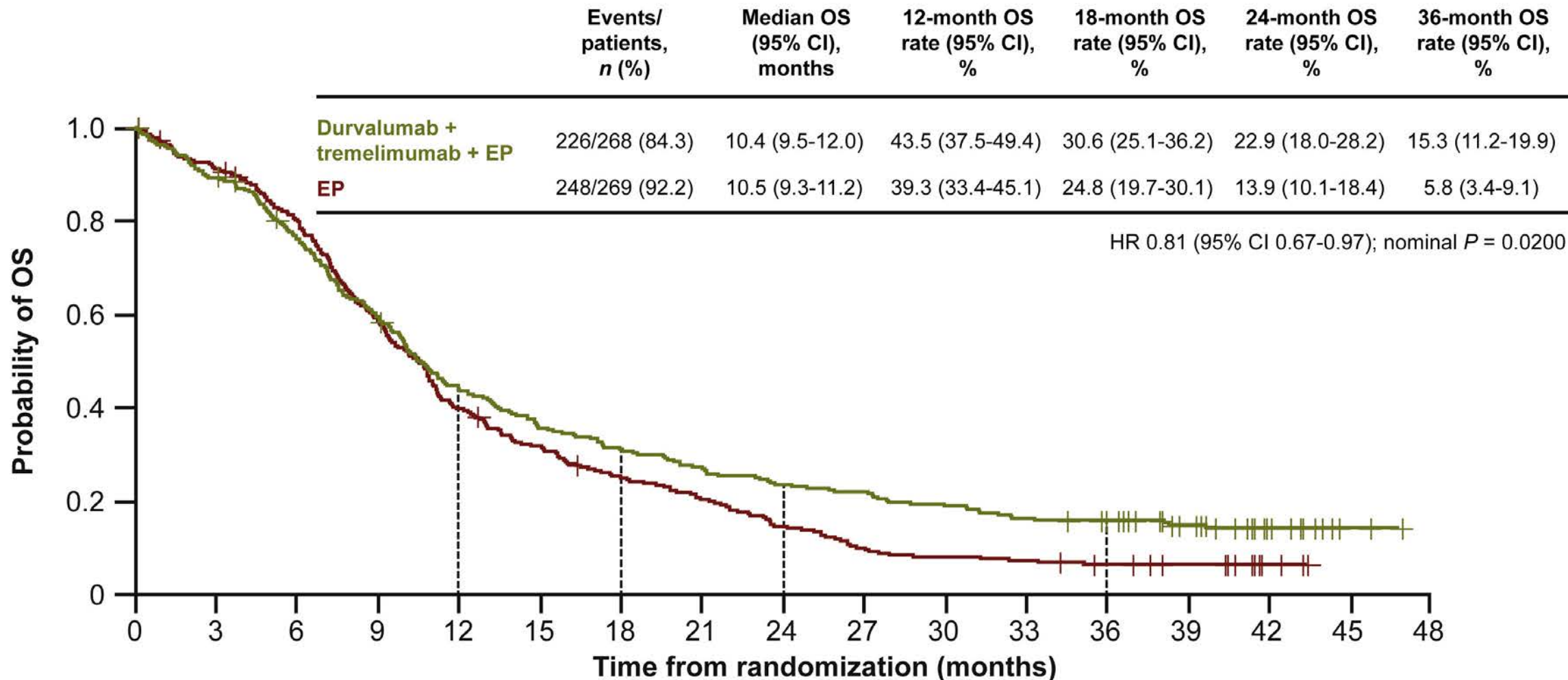
‡Patients received an additional dose of tremelimumab post-EP; §By investigator assessment per RECIST v1.1

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

Phase III CASPIAN: OS (ITT Population) Durvalumab/EP versus EP



Phase III CASPIAN: OS (ITT Population) Durvalumab/Tremelimumab/EP versus EP



Phase III CASPIAN: Serious Adverse Events

	Durvalumab + EP (n = 265)	Durvalumab + tremelimumab + EP (n = 266)	EP (n = 266)
Any serious adverse event, n (%) ^a	86 (32.5)	126 (47.4)	97 (36.5)
Febrile neutropenia	12 (4.5)	11 (4.1)	12 (4.5)
Pneumonia	6 (2.3)	16 (6.0)	11 (4.1)
Anemia	5 (1.9)	9 (3.4)	12 (4.5)
Thrombocytopenia	1 (0.4)	6 (2.3)	9 (3.4)
Hyponatremia	2 (0.8)	9 (3.4)	4 (1.5)
Neutropenia	2 (0.8)	5 (1.9)	7 (2.6)
Diarrhea	2 (0.8)	7 (2.6)	4 (1.5)
Pneumonitis	3 (1.1)	5 (1.9)	3 (1.1)
Pancytopenia	4 (1.5)	2 (0.8)	3 (1.1)
Pulmonary embolism	1 (0.4)	7 (2.6)	0
Chronic obstructive pulmonary disease	3 (1.1)	2 (0.8)	1 (0.4)
Death	0	4 (1.5)	2 (0.8)
Vomiting	0	3 (1.1)	3 (1.1)
Atrial fibrillation	2 (0.8)	3 (1.1)	0
Colitis	0	5 (1.9)	0
Dyspnea	0	2 (0.8)	3 (1.1)
Inappropriate antidiuretic hormone secretion	0	5 (1.9)	0
Enterocolitis	0	4 (1.5)	0
Hyperglycemia	1 (0.4)	3 (1.1)	0
Lower respiratory tract infection	1 (0.4)	3 (1.1)	0
Sepsis	3 (1.1)	0	1 (0.4)
Cerebrovascular accident	0	0	3 (1.1)
Hepatitis	0	3 (1.1)	0
Hypokalemia	0	0	3 (1.1)
Septic shock	3 (1.1)	0	0

CASPIAN: Authors' Conclusions

“In conclusion, durvalumab plus EP demonstrated sustained OS benefit over EP with a well-tolerated safety profile after median follow-up of >3 years, consistent with previous analyses. Three times more patients were estimated to be alive at 3 years when treated with durvalumab plus EP versus EP alone, with the majority still receiving durvalumab at DCO [data cutoff], further establishing durvalumab plus EP as the standard of care for the first-line treatment of ESSCLC.”

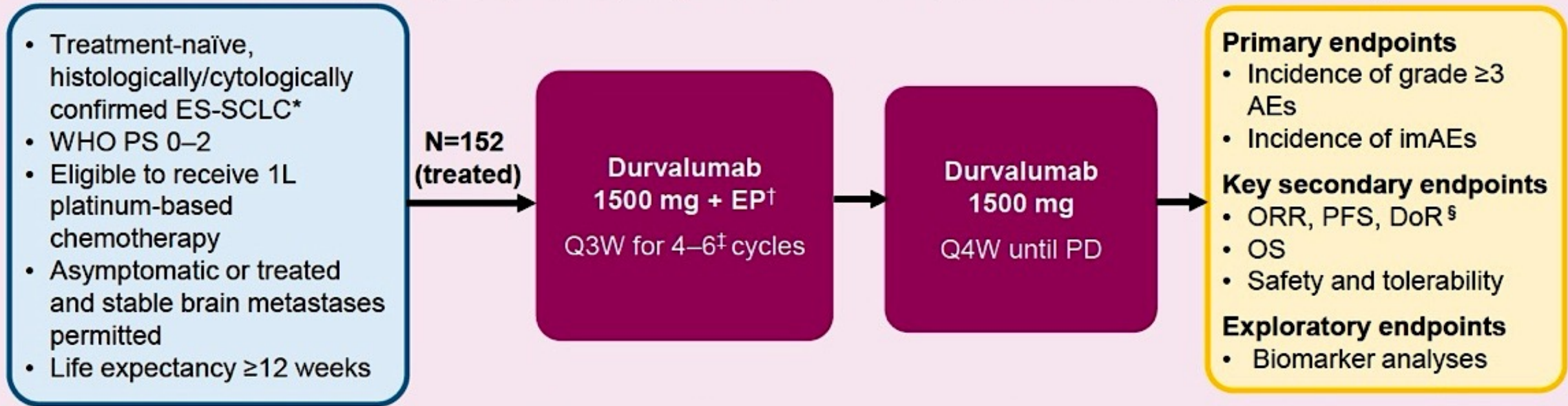
Poster 299P

First-line durvalumab + platinum-etoposide in patients with extensive-stage SCLC: Final results and exploratory biomarker analyses from LUMINANCE

Niels Reinmuth¹, Mustafa Özgüroğlu², Natasha B. Leigh³, Vito Longo⁴, Ilhan Hacibekiroglu⁵, Jaromir Roubec⁶, Mehmet Ali Nahit Şendur⁷, Emilio Bria⁸, Irfan Cicin⁹, Saadettin Kilickap¹⁰, Silvia Novello¹¹, Petr Opalka¹², Rossitza K. Ruseva¹³, Susanne Lang¹⁴, Ugochinyere Emeribe¹⁵, Mingchao Xie¹⁶, Yashaswi Shrestha¹⁷, Natalia Donner¹⁸, Filippo de Marinis¹⁹

ELCC 2025

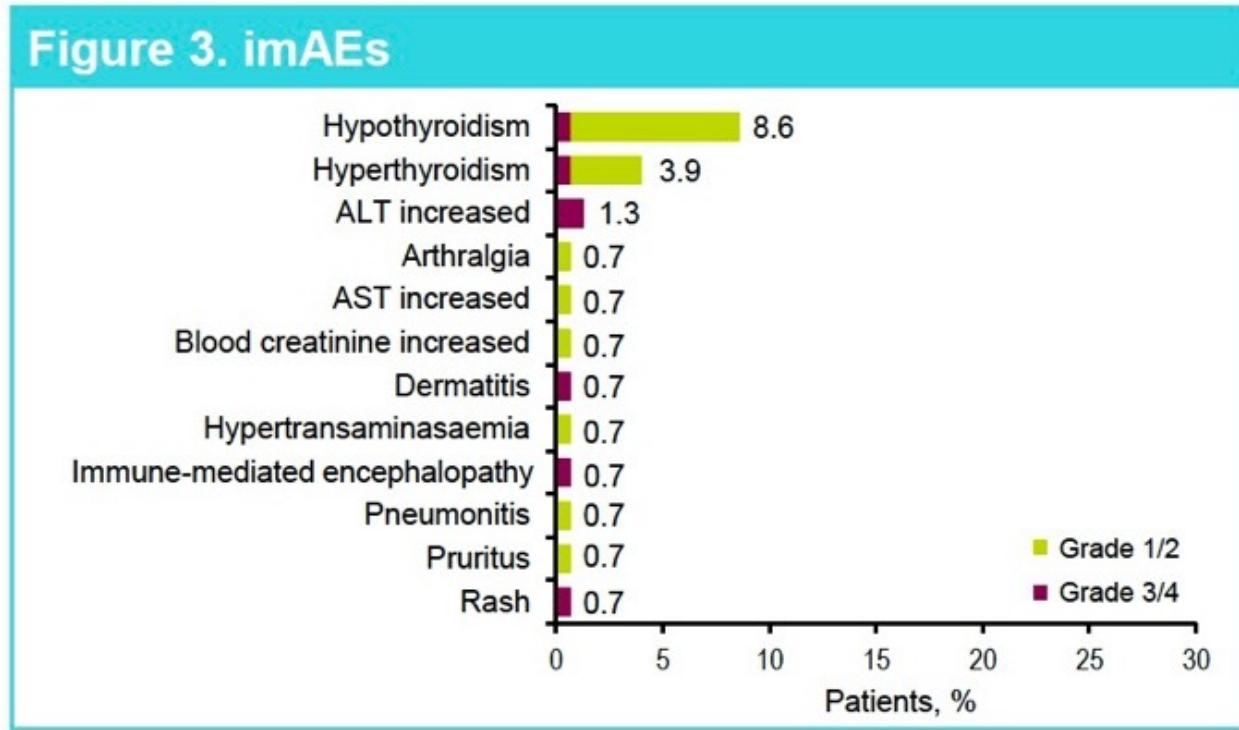
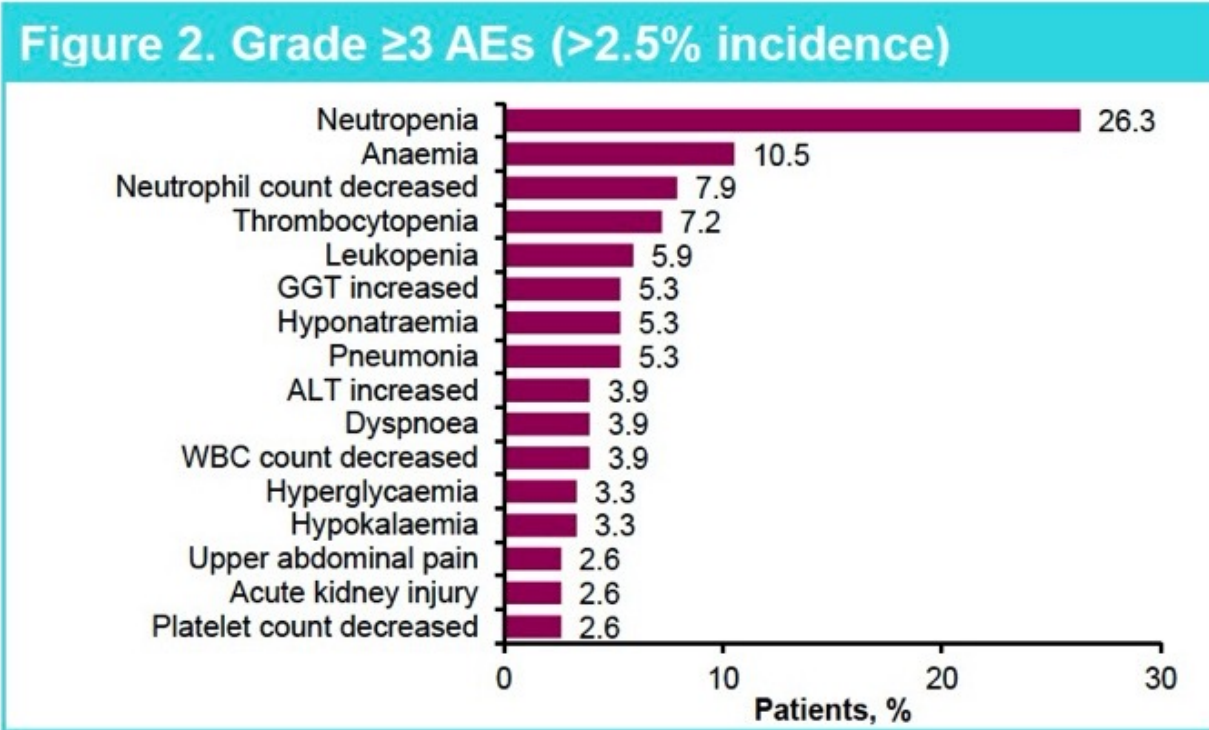
Phase IIIb LUMINANCE Study Design



*Patients who received prior curative intent chemoradiotherapy for LS-SCLC were eligible if they had experienced a treatment-free interval of ≥6 months at the time of diagnosis of ES-SCLC; 3 patients were enrolled following recurrence of LS-SCLC; [†]Investigator's choice of carboplatin or cisplatin + etoposide; [‡]Investigator decision. [§]Investigator-assessed per RECIST v1.1.

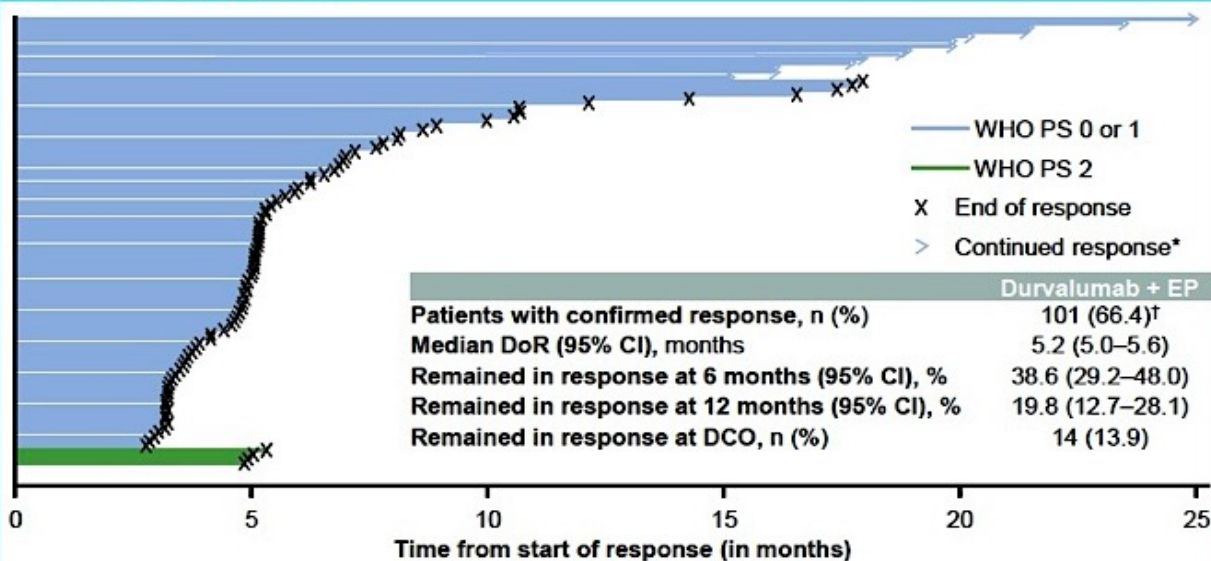
EP = etoposide/platinum

Phase IIb LUMINANCE Primary Endpoints: Incidence of AEs and Immune-mediated AEs (imAEs)



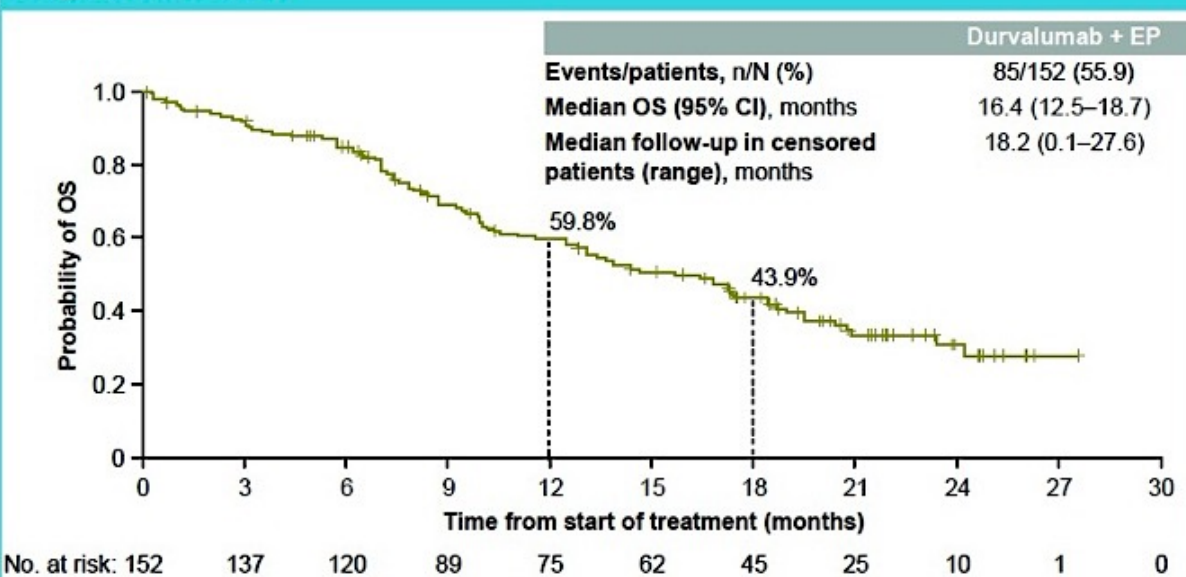
Phase IIb LUMINANCE Key Secondary Endpoints: Duration of Response (DoR), OS

Figure 4. DoR



*DoR calculated using PFS censoring time at DCO; [†]Four out of five patients with WHO PS 2 had a response

Figure 5. OS



Phase IIIb LUMINANCE: Authors' Conclusions

Conclusions

- Safety and efficacy results from the final analysis of LUMINANCE were consistent with those observed in the primary analysis and in the phase 3 CASPIAN study.^{1,5}
 - The most common grade ≥ 3 AEs were haematological (typically associated with chemotherapy); the rate of imAEs was low.
 - With greater maturity, median OS was 16.4 months and the OS rate at 18 months was 43.9%.
- Though limited by a lack of a control arm, CD8, MHC I and PD-L1 analyses were consistent with CASPIAN.⁶
- ctDNA was evaluable in most patients and data support further investigation of the potential of TMeF as a biomarker of treatment outcomes in SCLC.
- These results further support the use of durvalumab plus EP as 1L treatment for patients with ES-SCLC.

ctDNA = circulating tumor DNA; TMeF = tumor methylated fraction

Conclusions and Challenges in SCLC

- In limited stage SCLC, Consolidation with Durvalumab for up to 2 yrs is the SOC with ~ 10-12% absolute improvement in long term OS
- The addition of CPIs to standard EP chemo in Ext stage SCLC has led to 5 yr OS rates $\geq 10\%$
- Lurbinectedin combined with atezolizumab in the maintenance setting in ES-SCLC has led to statistically significant and clinically meaningful improvements in PFS and OS, albeit heightened toxicity
- Tarlatamab is the New SOC in 2L SCLC dramatically displacing lurbinectedin and topotecan based on unprecedented RR%, PFS and OS advantages
- Role of ADCs will be determined in the next 12-24 mos
- We lack clear biomarkers and reproducible targets

Up-Front Treatment of Extensive-Stage Small Cell Lung Cancer

Module 1: First-Line Chemoimmunotherapy

General Questions

Patients with Tumor-Related Complications

Patients with Comorbidities

Management of Transformed Non-Small Cell Lung Cancer; Prostate Cancer

General Questions

- **Atezo vs durva — any efficacy or safety differences?**
- **Cisplatin vs carboplatin — does it matter?**
- **What to offer if platinum ineligible?**
- **Tumor lysis syndrome?**
- **Trilaciclib for myeloprotection?**
- **Consolidative thoracic RT?**
- **Role of ipilimumab/nivolumab?**

General Questions

- IO rechallenge after autoimmune complications (pneumonitis, diabetes, adrenal insufficiency, cardiomyopathy, arthritis)
- Patient on chemo-IO: diarrhea differential — chemo, infection, or ICI colitis?
- Do immune toxicities correlate with higher response rates?
- Do prior IO toxicities predict CRS/ICANS with tarlatamab?
- IO in transplant recipient

General Questions

- **Prophylactic cranial irradiation (PCI) vs MRI surveillance**
- **Surgery for solitary brain met — any role in SCLC?**
- **Consolidative thoracic RT during maintenance IO $\pm$ lurbinectedin?**
- **Management of transformed NSCLC (prostate cancer)?**

General Questions

- **Oligometastatic disease — when to use systemic vs local therapy?**
- **Patient with LS-SCLC developed brain metastases 2 mo after chemoRT (no systemic disease) — other options besides radiation?**
- **After definitive CRT + IO (ADRIATIC strategy) — what to do at progression?**

General Questions

- **Role of MRD testing for early progression detection and 2L initiation**
- **Benefits of smoking cessation — outcome impact**
- **Intrabronchial tumor debulking — data and indications**

Patients with Tumor-Related Complications

- Patient with hyponatremia and seizures at diagnosis, good initial response for 2 years, then recurrence with pancreatic lesion (SCLC) and recurrent SIADH → improved after 2 cycles of lurbinectedin.
- SIADH with persistent low sodium — management challenges
- Refractory SIADH management (salt tablets, fluid restriction?)
- Contraindications to IO in autoimmune paraneoplastic syndromes
- Does neurologic paraneoplastic disease resolve with treatment?

Patients with Tumor-Related Complications

- **SCLC with SVC syndrome: whether to start systemic therapy or radiation first**
- **Stage dependency: limited vs extensive SCLC in SVC management**
- **Venous access issues in SVC setting**
- **Community challenges: inpatient RT often unavailable → start inpatient chemo + plan outpatient RT**
- **IVC stenting — any role or parallels to SVC?**
- **Role of prophylactic or consolidative RT after resolution of SVC**

Patients with Comorbidities

- 80-year-old female with COPD (EF 30%), CKD (eGFR 30 mL/min), ischemic cardiomyopathy, diabetes and ES-SCLC → what is the most appropriate front-line approach?
- Young female heavy smoker with COPD on frequent steroids for exacerbations — would you include IO in stage IV SCLC?
- Steroid use (eg, COPD exacerbations) — does it compromise IO efficacy?
- 62-year-old female ex-smoker with S-SCLC and myasthenia gravis — would you consider IO in this autoimmune paraneoplastic setting?
- IOs in patients with autoimmune disease

Up-Front Treatment of Extensive-Stage Small Cell Lung Cancer

Introduction: Tail on the Curve?

Module 1: First-Line Chemoimmunotherapy

Module 2: Maintenance Lurbinectedin

Data Review: IMforte Trial

Clinical Discussion

FDA Approves Lurbinectedin in Combination with Atezolizumab or Atezolizumab and Hyaluronidase-Tqjs for ES-SCLC

Press Release: October 2, 2025

“On October 2, 2025, the Food and Drug Administration approved lurbinectedin in combination with atezolizumab or atezolizumab and hyaluronidase-tqjs for the maintenance treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) whose disease has not progressed after first-line induction therapy with atezolizumab or atezolizumab and hyaluronidase-tqjs, carboplatin, and etoposide.

Efficacy was evaluated in IMforte (NCT05091567), a randomized, multicenter, open-label trial in patients receiving first-line treatment for ES-SCLC. In IMforte, 483 patients with ES-SCLC whose disease had not progressed after completion of four cycles of atezolizumab, carboplatin, and etoposide (induction treatment) were randomized (1:1) to receive either lurbinectedin in combination with atezolizumab administered intravenously (IV) or atezolizumab IV alone until disease progression or unacceptable toxicity.”

Lurbinectedin + atezolizumab as first-line maintenance treatment in patients with extensive-stage small cell lung cancer: Primary results of the Phase 3 IMforte trial

Luis Paz-Ares,¹ Hossein Borghaei,² Stephen V. Liu,³ Solange Peters,⁴ Roy S. Herbst,⁵ Katarzyna Stencel,⁶ Margarita Majem,⁷ Grzegorz Czyżewicz,⁸ Reyes Bernabé Caro,⁹ Ki Hyeon Lee,¹⁰ Melissa L. Johnson,¹¹ Nuri Karadurmus,¹² Christian Grohé,¹³ Vaikunth Cuchelkar,¹⁴ Vilma Graupner,¹⁵ Monika Kaul,¹⁴ Ya-Chen Lin,¹⁴ Debasis Chakrabarti,¹⁶ Kamalnayan Bhatt,¹⁶ Martin Reck¹⁷

¹Hospital Universitario 12 de Octubre, H12O-CNIO Lung Cancer Unit, Universidad Complutense and Ciberonc, Madrid, Spain; ²Fox Chase Cancer Center, Philadelphia, PA, USA; ³Lombardi Comprehensive Cancer Center, Georgetown University, Washington, DC, USA; ⁴University Hospital CHUV, Lausanne, Switzerland; ⁵Yale School of Medicine, New Haven, CT, USA; ⁶Wielkopolska Center of Pulmonology and Thoracic Surgery of Eugenia and Janusz Zeyland, Poznan, Poland; ⁷Hospital de la Santa Creu i Sant Pau, Barcelona, Spain; ⁸The John Paul II Specialist Hospital, Kraków, Poland; ⁹Hospital Universitario Virgen del Rocío, Seville, Spain; ¹⁰Chungbuk National University Hospital, Cheongju, South Korea; ¹¹Tennessee Oncology, Sarah Cannon Research Institute, Nashville, TN, USA; ¹²University of Health Sciences, Gülhane Training and Research Hospital, Ankara, Türkiye; ¹³Klinik für Pneumologie, Evangelische Lungenklinik Berlin, Berlin, Germany; ¹⁴Genentech Inc, South San Francisco, CA, USA; ¹⁵F. Hoffmann-La Roche Ltd, Basel, Switzerland; ¹⁶Jazz Pharmaceuticals plc, Dublin, Ireland; ¹⁷Lung Clinic Grosshansdorf, Airway Research Center North, German Center of Lung Research, Grosshansdorf, Germany

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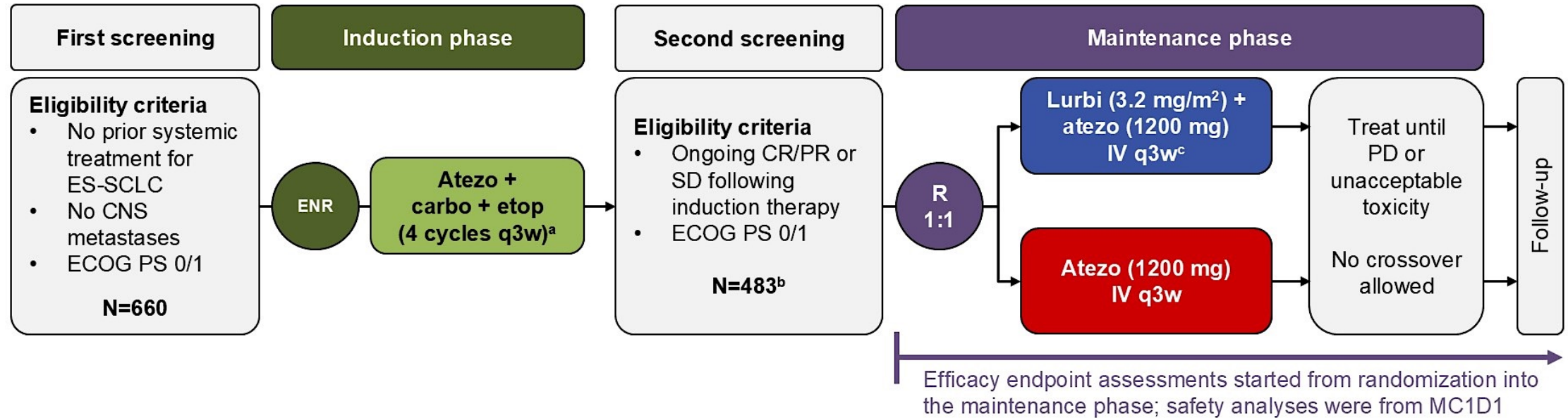
Articles

Efficacy and safety of first-line maintenance therapy with lurbinectedin plus atezolizumab in extensive-stage small-cell lung cancer (IMforte): a randomised, multicentre, open-label, phase 3 trial



Luis Paz-Ares, Hossein Borghaei, Stephen V Liu, Solange Peters, Roy S Herbst, Katarzyna Stencel, Margarita Majem, Mehmet Ali Nahit Şendur, Grzegorz Czyżewicz, Reyes Bernabé Caro, Ki Hyeon Lee, Melissa L Johnson, Nuri Karadurmus, Christian Grohé, Sofia Baka, Tibor Csősz, Jin Seok Ahn, Raffaele Califano, Tsung-Ying Yang, Yasemin Kemal, Marcus Ballinger, Vaikunth Cuchelkar, Vilma Graupner, Ya-Chen Lin, Debasis Chakrabarti, Kamalnayan Bhatt, George Cai, Robert Iannone, Martin Reck, for the IMforte investigators*

Phase III IMforte Study Design



Stratification factors for randomization

- ECOG PS (0/1)
- LDH ($\leq$ ULN/ $>$ ULN)
- Presence of liver metastases (Y/N) at induction BL
- Prior receipt of PCI (Y/N)

Primary endpoints

IRF-PFS and OS

Secondary endpoints included

INV-PFS, ORR, DOR, and safety

Last patient randomized: April 30, 2024
Clinical cutoff: July 29, 2024

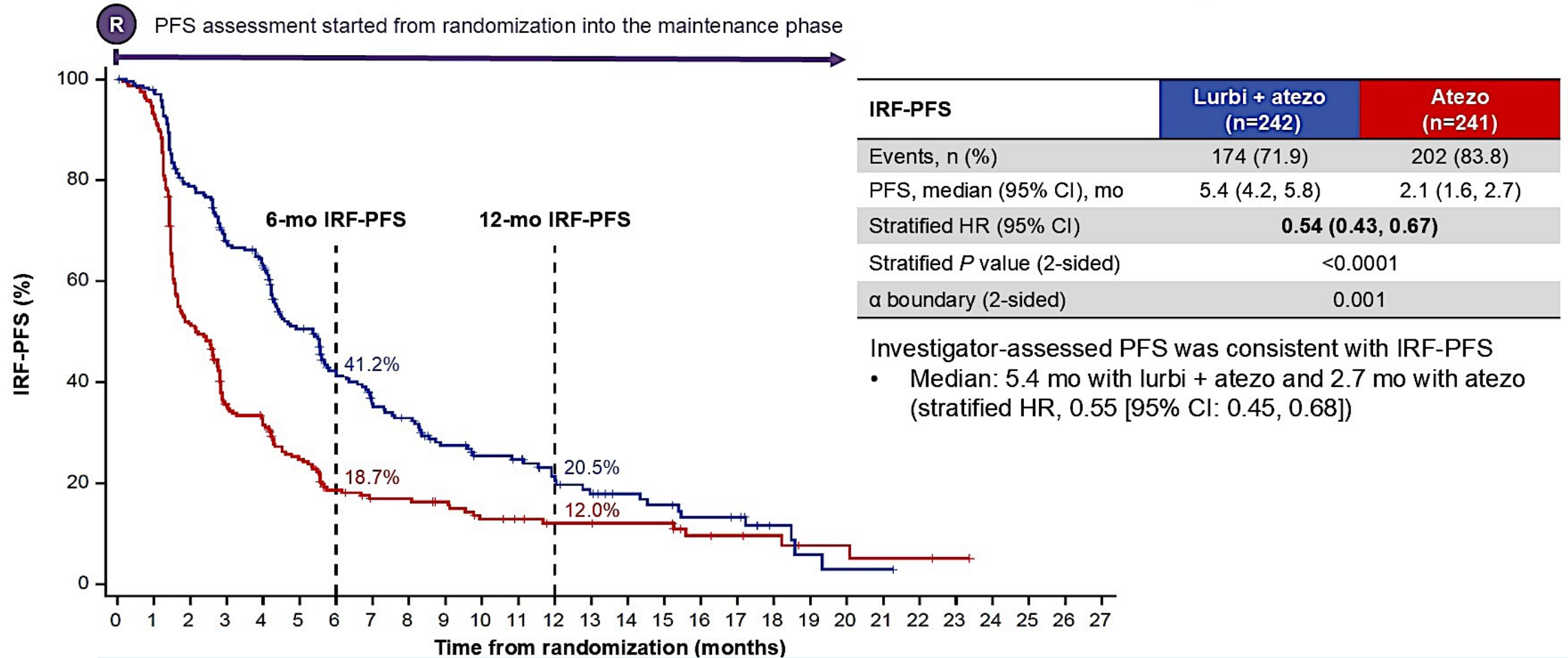
ClinicalTrials.gov ID: NCT05091567.

^a Administered per standard dose. ^b 73% of patients continued from induction to maintenance. ^c With prophylactic granulocyte colony-stimulating factor and anti-emetics.

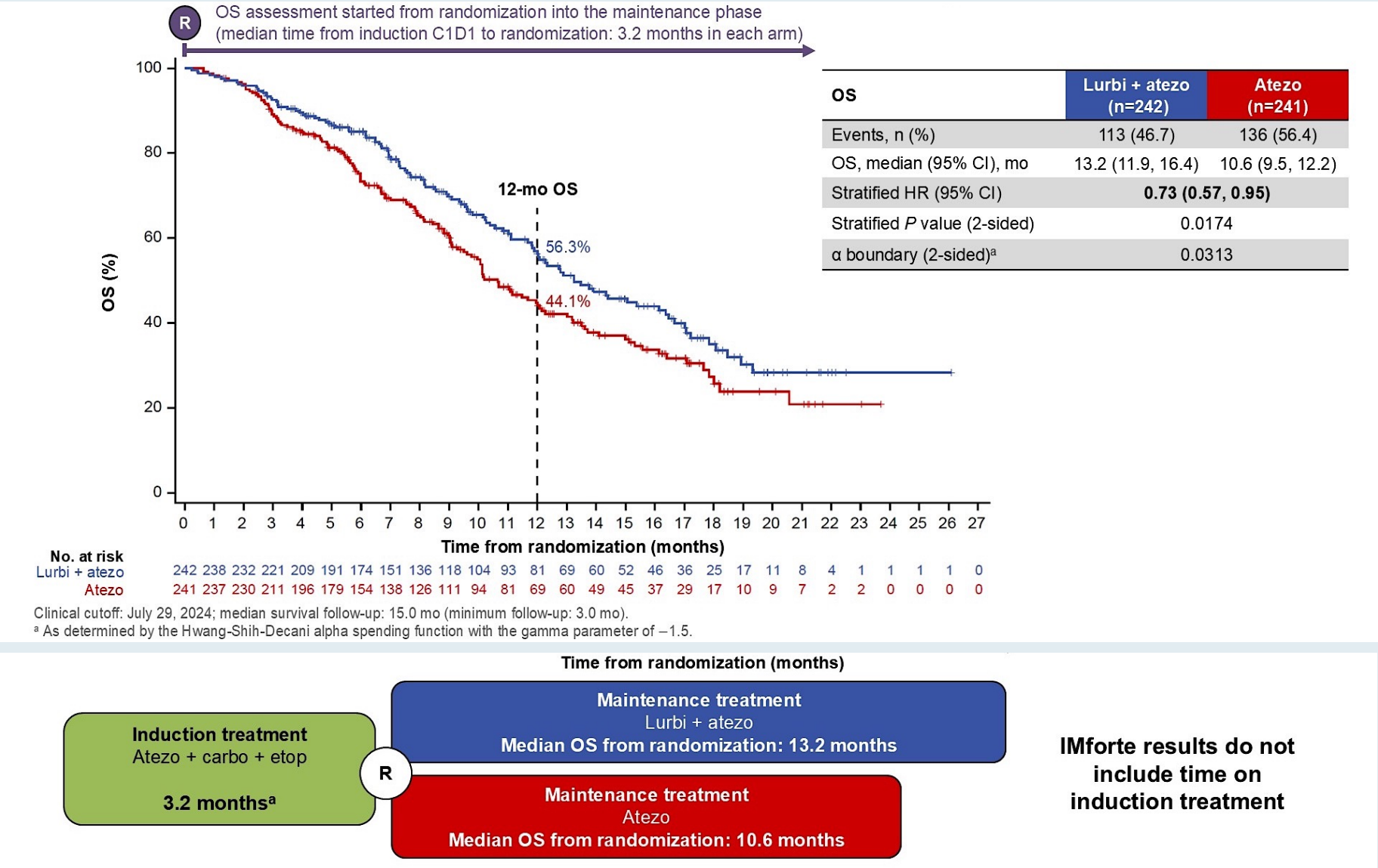
atezo, atezolizumab; BL, baseline; carbo, carboplatin; CNS, central nervous system; ECOG PS, Eastern Cooperative Oncology Group performance status; ENR, enrollment; etop, etoposide; INV-PFS, investigator-assessed PFS; IRF-PFS, independent review facility-assessed PFS; IV, intravenously; LDH, lactate dehydrogenase; lurbi, lurbinectedin; MC1D1, maintenance Cycle 1 Day 1; PCI, prophylactic cranial irradiation; q3w, every 3 weeks; R, randomization; ULN, upper limit of normal; Y/N, yes/no.

CR =complete response; PR = partial response; SD = stable disease

Phase III IMforte: Independent Review Facility-Assessed PFS (IRF-PFS)



IMforte: Overall Survival (OS) from Randomization into Maintenance Phase



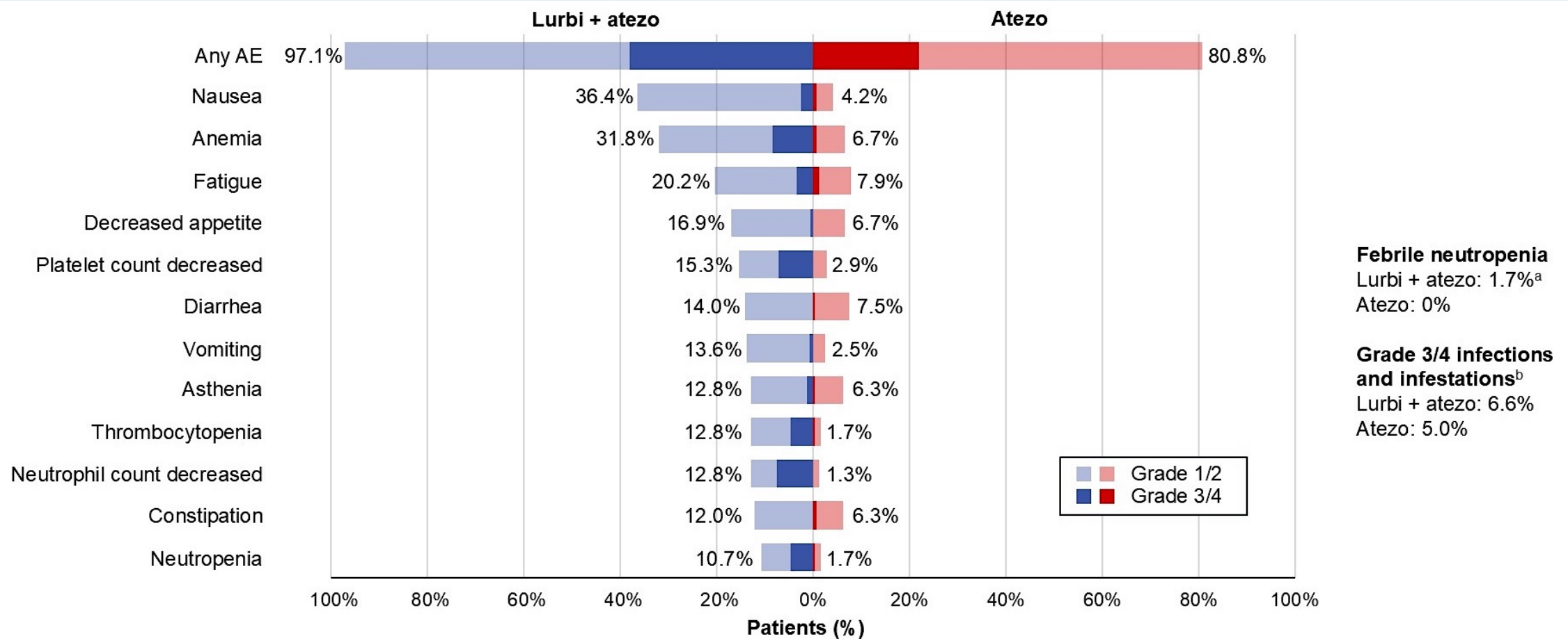
Phase III IMforte: Confirmed IRF-Assessed Objective Response Rate (ORR), DoR

- Background: At the time of randomization, 88% of patients had CR/PR and 11% had SD to induction therapy
 - Tumor response in the maintenance phase was assessed against maintenance baseline

Patients with measurable disease ^a	Lurbi + atezo (n=175)	Atezo (n=182)
Confirmed objective response, n (%) (95% CI)^b	34 (19.4) (13.9, 26.1)	19 (10.4) (6.4, 15.8)
Difference in ORR (95% CI), %	9.0 (1.1, 16.9)	
CR, n (%)	4 (2.3)	1 (0.5)
PR, n (%)	30 (17.1)	18 (9.9)
SD, n (%)	96 (54.9)	68 (37.4)
PD, n (%)	34 (19.4)	87 (47.8)
Missing or non-evaluable, n (%)	11 (6.3)	8 (4.4)
DOR^c		
Responders with an event/responders, n (%)	14/34 (41.2)	11/19 (57.9)
Median DOR (95% CI), mo	9.0 (5.5, NE)	5.6 (4.2, NE)

Clinical cutoff: July 29, 2024. ^a Measurable disease was not an inclusion criterion to enter the maintenance phase. ^b The confirmed ORR was defined as the proportion of randomized patients with a CR or PR on two consecutive occasions ≥ 4 weeks apart after randomization and was assessed in patients who had measurable disease at maintenance baseline. ^c DOR was assessed in patients who had a confirmed objective response in the maintenance phase. NE, not estimable.

IMforte: All-Cause Adverse Events (AEs) with Incidence $\geq 10\%$ in Either Arm



Clinical cutoff: July 29, 2024. Percentage labels represent all-grade AEs, including Grade 5 AEs. Grade 5 AEs occurred in 12 (5.0%) patients in the lurbi + atezo arm and 6 (2.5%) patients in the atezo arm.

^a Includes 1 Grade 5 AE. ^b Grade 5 infections: lurbi + atezo arm (n=6 [2.5%]): COVID-19 pneumonia, pneumonia, pneumonia viral, sepsis, septic shock, and vascular device infection (n=1 each); atezo arm (n=4 [1.7%]): pneumonia (n=2), abscess intestinal, and sepsis (n=1 each).

IMforte: Authors' Conclusions

- IMforte demonstrated a statistically significant and clinically meaningful improvement in IRF-PFS and OS with 1L maintenance treatment with lurbinectedin + atezolizumab vs atezolizumab in patients with ES-SCLC
 - Stratified IRF-PFS HR: 0.54 (95% CI: 0.43, 0.67); $P < 0.0001$
 - Stratified OS HR: 0.73 (95% CI: 0.57, 0.95); $P = 0.0174$
- IRF-PFS and OS benefit with lurbinectedin + atezolizumab was generally consistent across the majority of subgroups
- Despite the higher rate of Grade 3/4 AEs and SAEs, there were no new or unexpected safety signals with lurbinectedin + atezolizumab
 - The safety profile was predictable, with mostly low-grade AEs and low treatment discontinuation rates
 - There was no clinically meaningful increase in immune-related AEs
- IMforte is the first Phase 3 study to show PFS and OS improvement with 1L maintenance treatment for ES-SCLC, highlighting the potential of lurbinectedin + atezolizumab to become a new standard of care for 1L maintenance therapy in patients with this aggressive and difficult-to-treat disease

Breaking New Ground in Small Cell Lung Cancer: BiTE, TriTE and Chemoimmunotherapy

Abstracts LBA8008 (DeLLphi-304), 8006 (IMforte), and 8007 (ZG006)

Catherine B. Meador, MD PhD

Center for Thoracic Cancers, Massachusetts General Hospital

Harvard Medical School, Boston, MA, USA

IMforte: Conclusions and Practice Implications

- OS improved by adding lurbinectedin to 1L chemo+ICI in ES-SCLC in patients without progression after chemo
- However.... toxicity is not trivial
- Practice-changing data, but patient selection for this regimen will be key
 - Better biomarkers?¹
 - SCLC subtypes?²
 - Role of ctDNA?³

¹Chakraborty et al., Clin Cancer Res 2023; Kundu et al., Transl Lung Cancer Res 2021

² Gay et al., Cancer Cell 2021; Rudin et al., J Thorac Oncol 2023

³ Sivapalan et al., Clin Cancer Res 2023; Valenza et al., Ann Oncol 2025

ICI = immune checkpoint inhibitor

Maintenance Lurbinectedin

- Is maintenance lurbinectedin now standard?
- How do clinicians adjust dosing/frequency for toxicity?
- Who are optimal candidates (fit vs comorbid, platinum sensitive vs refractory)?
- Are there subsets (good PS, younger, low burden) most likely to benefit?
- How long should therapy continue — indefinite or capped?
- When to stop one of the agents (lurbinectedin vs IO)?

Maintenance Lurbinectedin

- Can this be used with durvalumab instead of atezo?
- Would you switch durva-treated patients to atezo + lurbi?
- What are the expected toxicities (hematologic, fatigue, neuropathy, hepatic)?
- Rates of myelotoxicity, neutropenia, fatigue, discontinuation

Up-Front Treatment of Extensive-Stage Small Cell Lung Cancer

Introduction: Tail on the Curve?

Module 1: First-Line Chemoimmunotherapy

Module 2: Maintenance Lurbinectedin

Module 3: Second-Line Treatment, Tarlatamab

Data Review: DeLLphi-304 Trial

Clinical Discussion

Tarlatamab versus chemotherapy as second-line treatment for small cell lung cancer (SCLC): primary analysis of the phase 3 DeLLphi-304 study

Charles M. Rudin, Giannis S. Mountzios, Longhua Sun, Byoung Chul Cho, Umut Demirci, Sofia Baka, Mahmut Gumus, Antonio Lugini, Tudor-Eliade Ciuleanu, Myung-Ju Ahn, Pedro Rocha, Bo Zhu, Fiona Blackhall, Tatsuya Yoshida, Taofeek K. Owonikoko, Luis Paz-Ares, Shuang Huang, Diana Gauto, Gonzalo Recondo, Martin Schuler

Speaker: **Charles M. Rudin, MD, PhD**, Fiona and Stanley Druckenmiller Center for Lung Cancer Research, Memorial Sloan Kettering Cancer Center, New York, USA.

THE NEW ENGLAND JOURNAL of MEDICINE

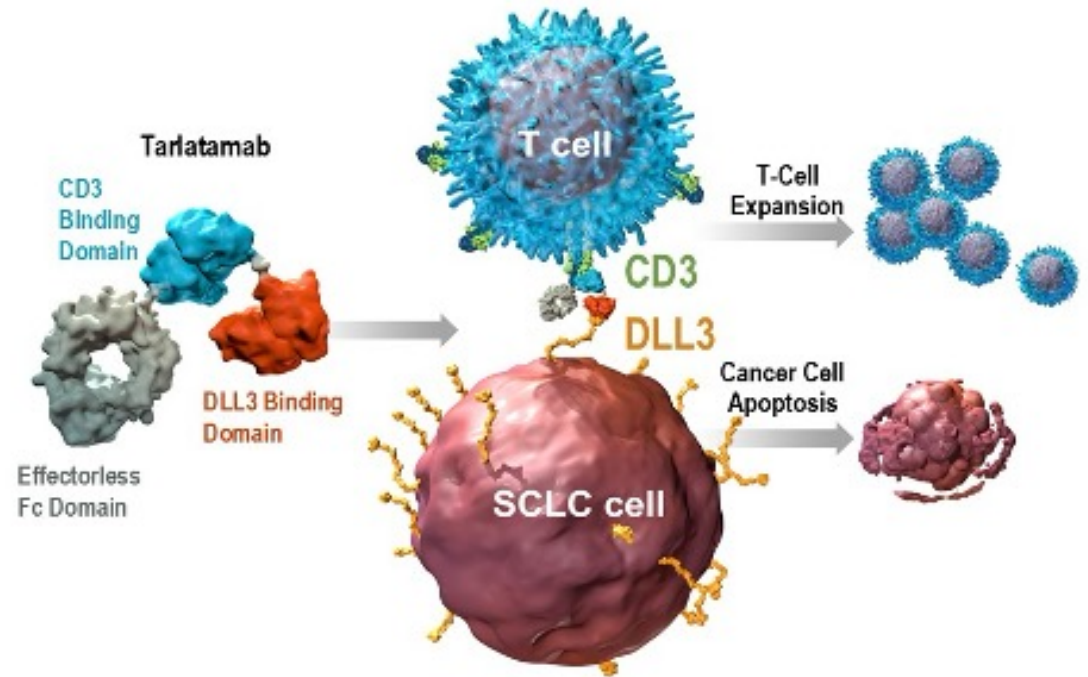
ORIGINAL ARTICLE

Tarlatamab in Small-Cell Lung Cancer after Platinum-Based Chemotherapy

Giannis Mountzios, M.D., Ph.D.,¹ Longhua Sun, M.D.,²
Byoung Chul Cho, M.D., Ph.D.,³ Umut Demirci, M.D., Ph.D.,⁴
Sofia Baka, M.D., Ph.D.,⁵ Mahmut Gümüş, M.D.,⁶ Antonio Lugini, M.D.,⁷
Bo Zhu, M.D., Ph.D.,⁸ Yan Yu, M.D.,⁹ Ippokratis Korantzis, M.D., Ph.D.,¹⁰
Ji-Youn Han, M.D., Ph.D.,¹¹ Tudor-Eliade Ciuleanu, M.D., Ph.D.,¹²
Myung-Ju Ahn, M.D., Ph.D.,¹³ Pedro Rocha, M.D., Ph.D.,¹⁴
Julien Mazières, M.D., Ph.D.,¹⁵ Sally C.M. Lau, M.D., M.P.H.,¹⁶
Martin Schuler, M.D.,^{17,18} Fiona Blackhall, M.D., Ph.D.,¹⁹
Tatsuya Yoshida, M.D., Ph.D.,²⁰ Taofeek K. Owonikoko, M.D., Ph.D.,²¹
Luis Paz-Ares, M.D., Ph.D.,²² Tony Jiang, Ph.D.,²³ Ali Hamidi, M.D.,²³
Diana Gauto, M.D.,²³ Gonzalo Recondo, M.D., Ph.D.,²³
and Charles M. Rudin, M.D., Ph.D.,²⁴ for the DeLLphi-304 Investigators*

DeLLphi-304 Background

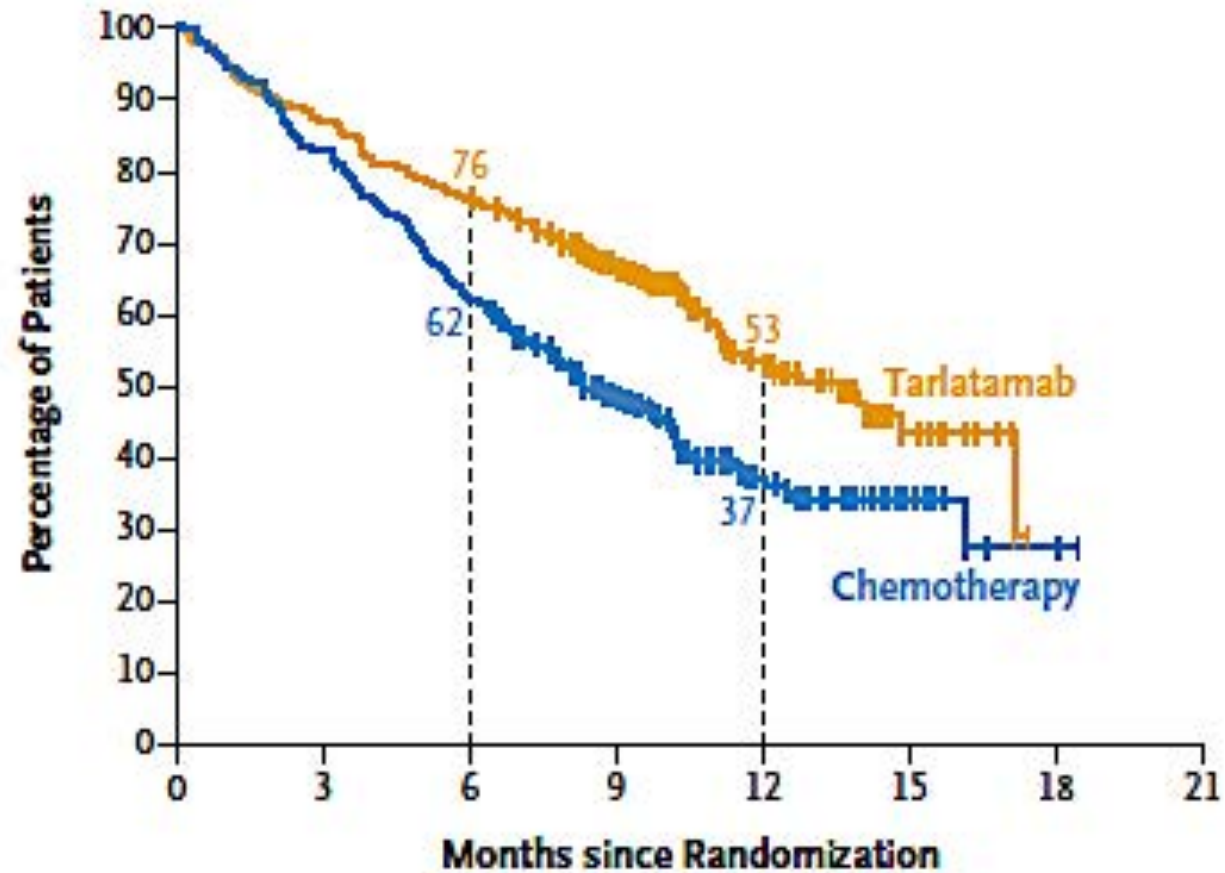
- Tarlatamab is a bispecific T-cell engager immunotherapy that directs cytotoxic T cells to DLL3-expressing SCLC cells resulting in tumor cell lysis¹
- Tarlatamab demonstrated durable anticancer efficacy in patients with previously treated SCLC^{2,3}
- Survival with current 2L chemotherapy options is modest and is also associated with substantial hematological toxicity⁴⁻⁶
- The DeLLphi-304 study was conducted to assess whether tarlatamab could improve survival for patients with SCLC whose disease had progressed or recurred following one line of platinum-based chemotherapy⁷



We present results from the first planned interim analysis of the phase 3 DeLLphi-304 trial comparing tarlatamab to chemotherapy for 2L treatment of SCLC

2L, second-line; CD3, cluster of differentiation 3; DLL3, delta-like ligand 3; Fc, fragment crystallizable region; SCLC, small cell lung cancer.

DeLLphi-304 Primary Endpoint: Overall Survival

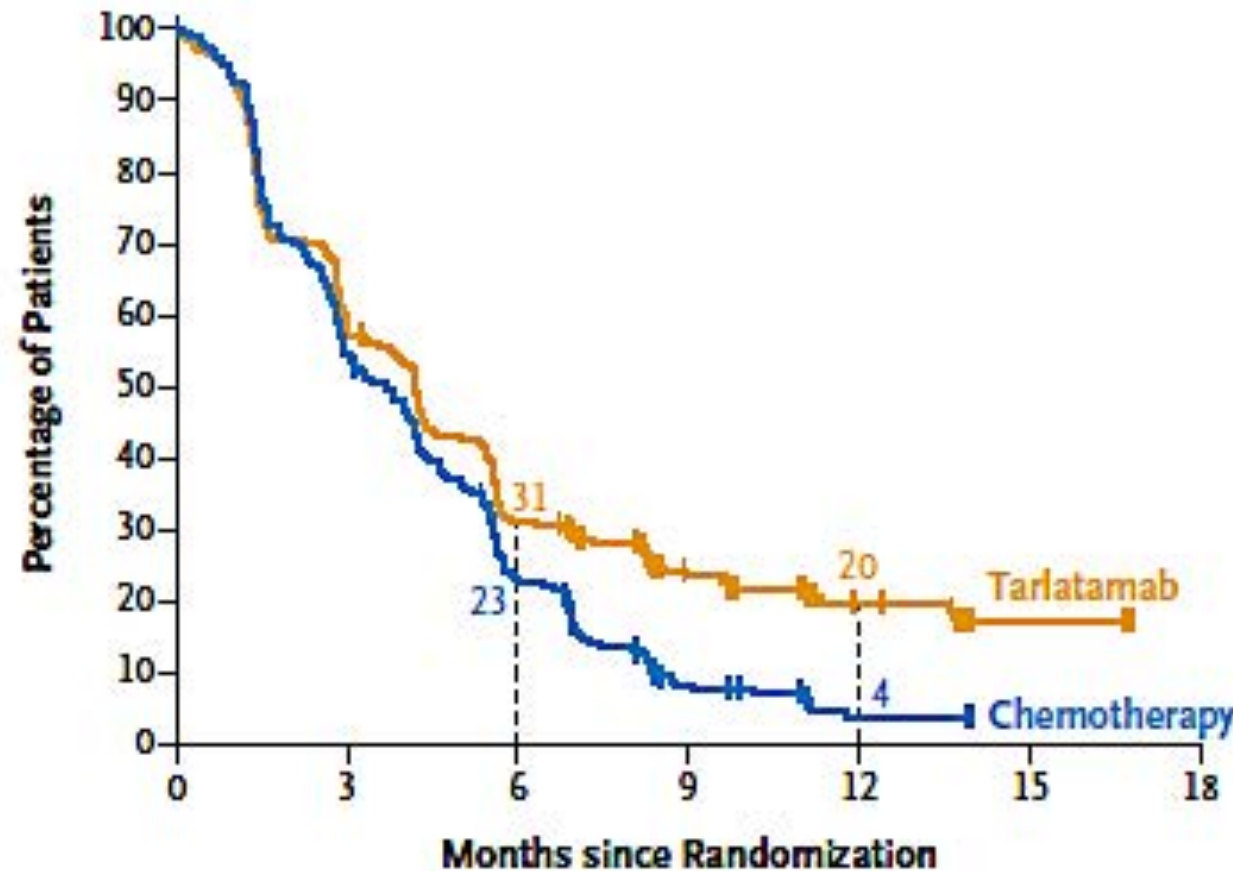


	Median Overall Survival (95% CI) mo
Tarlatamab (N=254)	13.6 (11.1–NR)
Chemotherapy (N=255)	8.3 (7.0–10.2)
Stratified hazard ratio for death, 0.60 (95% CI, 0.47–0.77)	
P<0.001	

No. at Risk

Tarlatamab	254	220	192	131	60	17	0	0
Chemotherapy	255	210	156	97	42	9	2	0

DeLLphi-304: Progression-Free Survival

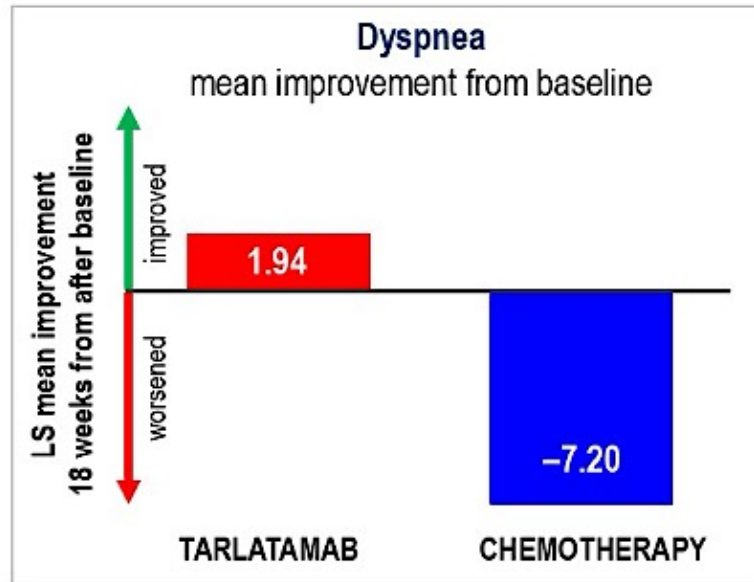


No. at Risk

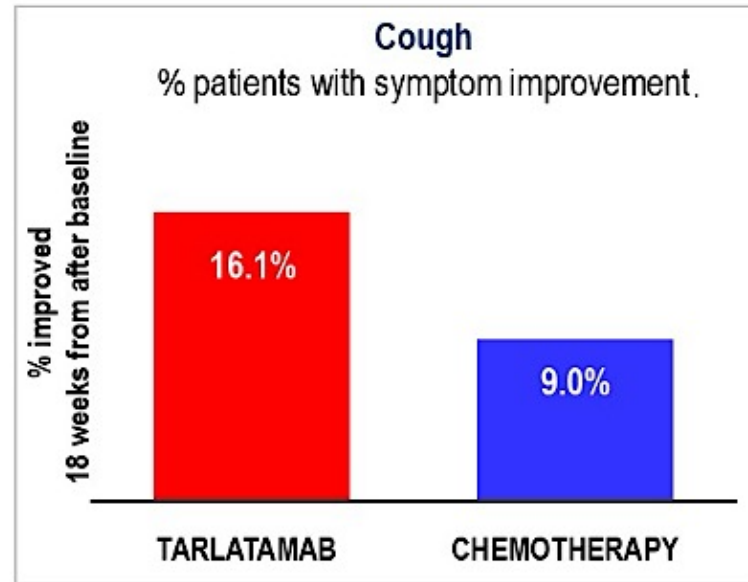
Tarlatamab	254	147	78	37	18	2	0
Chemotherapy	255	137	56	15	3	0	

RMST = restricted mean survival time

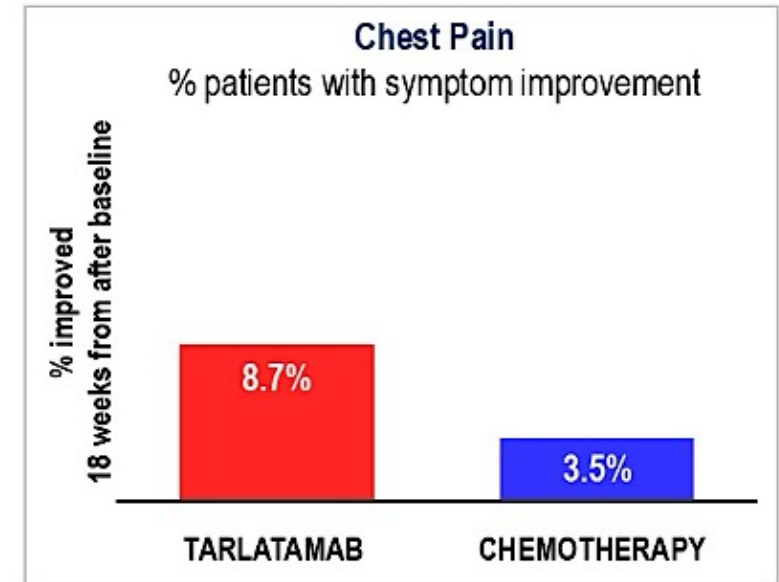
DeLLphi-304: Symptom Change from Baseline



LS mean difference = -9.14*
95% CI (-12.64, -5.64)
 $p < 0.001$



Odds ratio = 2.04*
95% CI (1.17, 3.55)
 $p = 0.012$



Odds ratio = 1.84*
95% CI (0.89, 3.81)
 $p = 0.1$
(Did not meet statistical significance)

The mean difference in the change after 18 weeks in the physical functioning score (10.35 points [95% CI: 6.00 to 14.69]) and the global health status score (8.93 points [95% CI: 5.04 to 12.83]) trended in favor of tarlatamab. *Similar results were observed when the sensitivity analyses were carried out incorporating a more conservative estimand (i.e., treatment policy strategy) for change from baseline after 18 weeks in **dyspnea** (mean difference, -6.19; [95% CI, -8.88 to -3.49]), **cough** (odds ratio, 1.48 [95% CI, 1.08 to 2.02]), **chest pain** (odds ratio, 1.21 [95% CI, 0.80 to 1.82]).

LS = least squares

DeLLphi-304: Tarlatamab Safety Profile

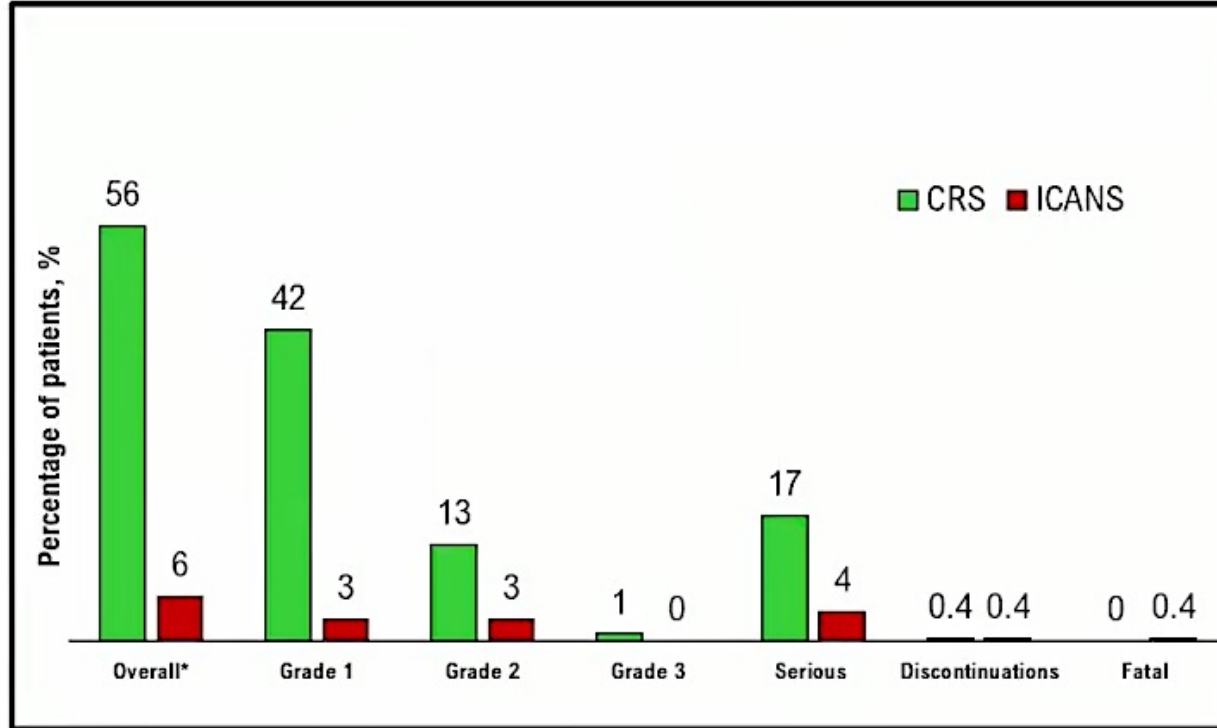
	Tarlatamab (n = 252)*	Chemotherapy (n = 244)*
Median duration of treatment , months, (range)	4.2 (< 1–17)	2.5 (< 1–15)
All grade, TEAEs , n (%)	249 (99)	243 (100)
All grade, TRAEs n (%)	235 (93)	223 (91)
Grade ≥ 3 TRAEs, n (%)	67 (27)	152 (62)
Serious TRAEs, n (%)	70 (28)	75 (31)
TRAEs leading to dose interruption and/or dose reduction, n (%)	48 (19)	134 (55)
TRAEs leading to discontinuation, n (%)	7 (3)	15 (6)
Treatment-related grade 5 events[†] , n (%)	1 (0.4)	4 (2)

*Safety analysis set (all patients who received at least one dose of study treatment). [†]The single grade 5 TRAE observed with tarlatamab was attributed to ICANS in the setting of progressive neurological decline concurrent with persistent fever, hypoxemia, and hypotension. Grade 5 TRAEs observed with chemotherapy were attributed to general physical health deterioration (n = 1), pneumonia (n = 1), respiratory tract infection (n = 1), and tumor lysis syndrome (n = 1).

ICANS, immune effector cell-associated neurotoxicity syndrome; **TEAE**, treatment-emergent adverse event; **TRAE**, treatment-related adverse event.

DeLLphi-304: CRS and ICANS Events

Treatment-emergent CRS and ICANS with tarlatamab



CRS with first two infusions

Tarlatamab (N = 252)	Minimum required monitoring duration	
	6 - 8 Hours (n = 43)	48 Hours (n = 209)
Treatment emergent CRS, n (%)*	16 (37)	125 (60)
Grade 1	12 (28)	94 (45)
Grade 2	4 (9)	28 (13)
Grade 3	0 (0)	3 (1)
Serious adverse events	3 (7)	39 (19)
Leading to discontinuation of IP	0 (0)	1 (0.5)
Median time to intervention from last tarlatamab dose (hours)	17	27

*Grade 4 CRS or ICANS events were not observed. A single grade 5 treatment-related adverse event observed with tarlatamab was attributed to ICANS in the setting of progressive neurological decline concurrent with persistent fever, hypoxemia, and hypotension.

CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; IP, investigational product.

DeLLphi-304: Authors' Conclusions

In the phase 3 DeLLphi-304 randomized controlled trial evaluating tarlatamab versus chemotherapy in patients with SCLC whose disease had progressed or recurred following one line of platinum-based chemotherapy with or without immune-checkpoint inhibitor:

- ✓ Tarlatamab treatment achieved a 40% reduction in the risk of death compared to chemotherapy
- ✓ Benefit extended to those with poor prognostic factors such as platinum resistance and brain metastases
- ✓ Tarlatamab improved patient reported symptoms of dyspnea and cough compared with chemotherapy
- ✓ Tarlatamab was well tolerated with a lower incidence of high-grade adverse events and a lower incidence of adverse events that led to treatment discontinuations
- ✓ CRS and ICANS were mostly grade 1 or 2 in severity and generally manageable

- ***The superior survival outcomes coupled with the favorable patient-reported outcomes and safety profile affirm tarlatamab as the standard of care for 2L treatment of SCLC***
- ***The DeLLphi-304 study establishes a new paradigm for bispecific T-cell engager immunotherapy in lung cancer***

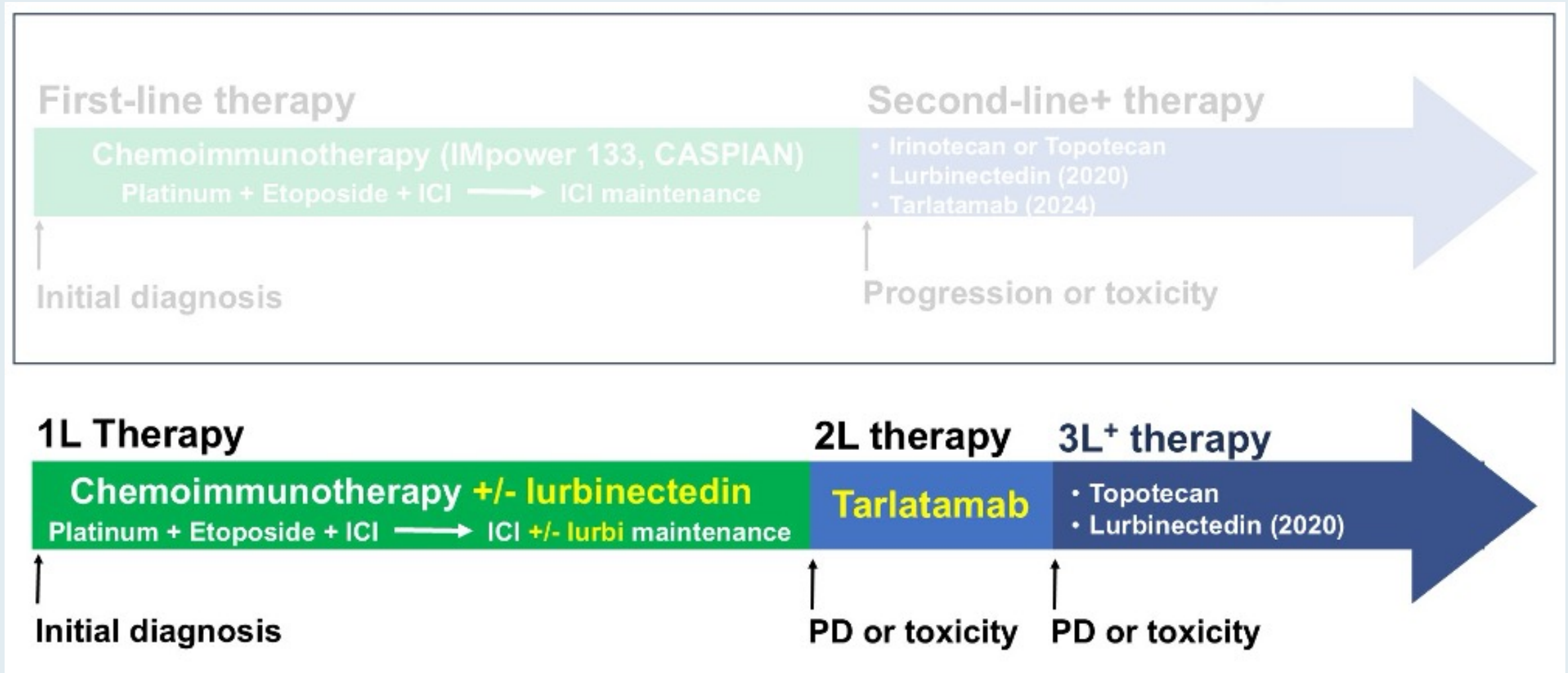
2L, second line; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; SCLC, small cell lung cancer.

Evolving Management Strategies for Cytokine Release Syndrome (CRS)

1. Learn from the (years of) experience of our malignant hematology colleagues – established monitoring protocols and resources
2. Explore alternative care settings during CRS risk window:
 - Home hospital 

☐ NCT06957314 Recruiting New
A Study of Hospital-at-Home for People Receiving Tarlatamab
 - Outpatient (with medical equipment, 24/7 caregivers, and education)
3. Establish better predictive biomarkers – understand which patients are at highest risk for grade 2+ CRS

ES-SCLC: Current Treatment Landscape



Second-Line Treatment: Tarlatamab

- Sequencing of lurbinectedin and tarlatamab
- 71-year-old man with ES-SCLC: PR to carbo/etoposide/atezolizumab — maintenance atezo/lurbinectedin; progressed at 6 months? Platinum rechallenge vs tarlatamab?
- Is platinum sensitivity still relevant in the tarlatamab era?
- Use in inpatient vs outpatient setting — safety data, monitoring

Second-Line Treatment: Tarlatamab

- **How to administer tarlatamab safely without inpatient induction**
- **CRS management and learning curve for staff**
- **Step-up dosing protocols — can these be outpatient?**
- **Trials for community accessibility (to avoid mandatory hospitalization)**
- **Challenges and toxicity profiles — managing side effects**
- **Use as 1L or maintenance — ongoing trials or rationale**

Up-Front Treatment of Extensive-Stage Small Cell Lung Cancer

Introduction: Tail on the Curve?

Module 1: First-Line Chemoimmunotherapy

Module 2: Maintenance Lurbinectedin

Module 3: Second-Line Treatment, Tarlatamab

Module 4: Ongoing Research

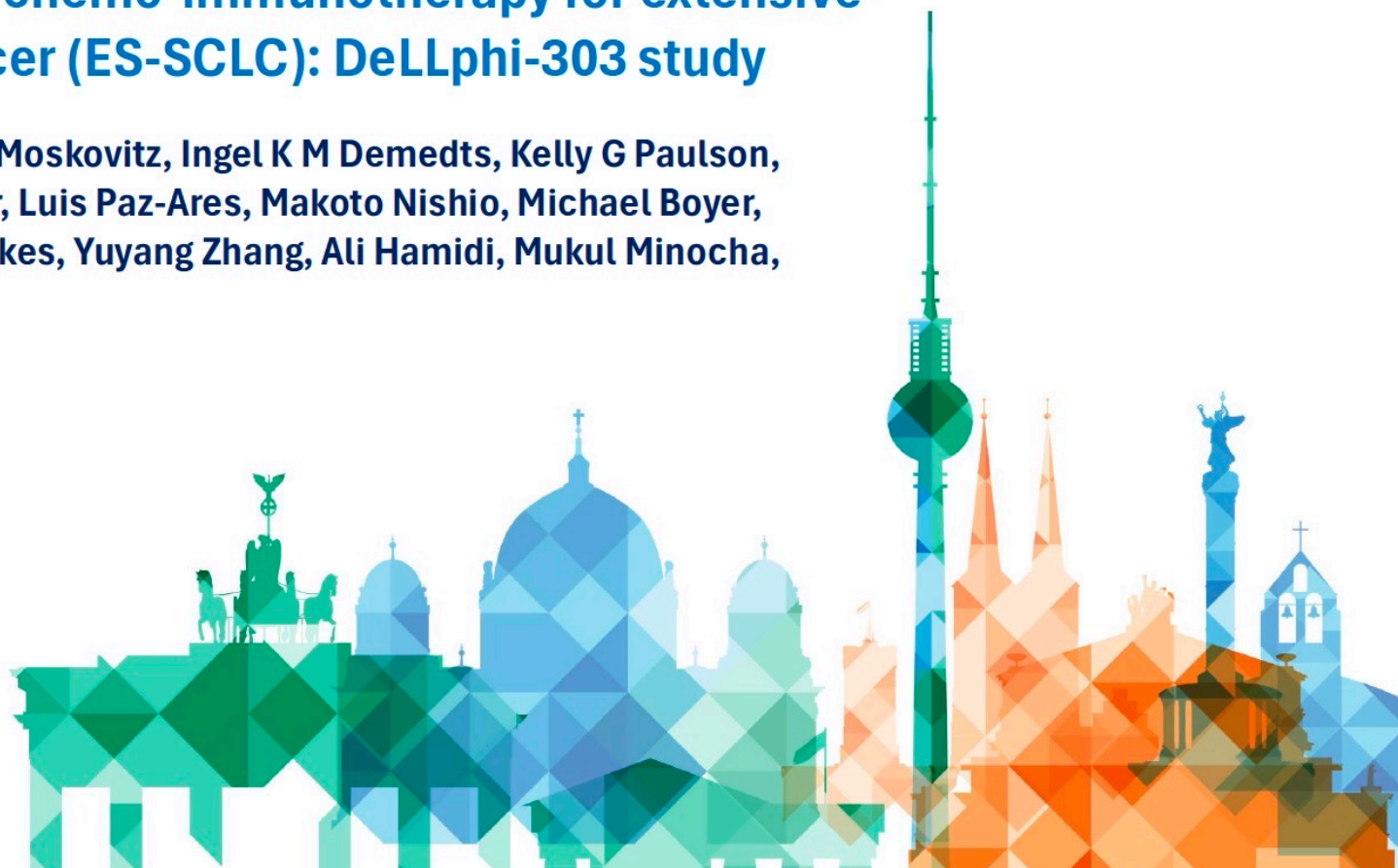
Tarlatamab with first-line chemo-immunotherapy for extensive-stage small cell lung cancer (ES-SCLC): DeLLphi-303 study

Martin Wermke, Sally C M Lau, Mor Moskovitz, Ingel K M Demedts, Kelly G Paulson, Aurélie Swalduz, Cornelius F Waller, Luis Paz-Ares, Makoto Nishio, Michael Boyer, James Chih-Hsin Yang, Amanda Parkes, Yuyang Zhang, Ali Hamidi, Mukul Minocha, Pedro Rocha

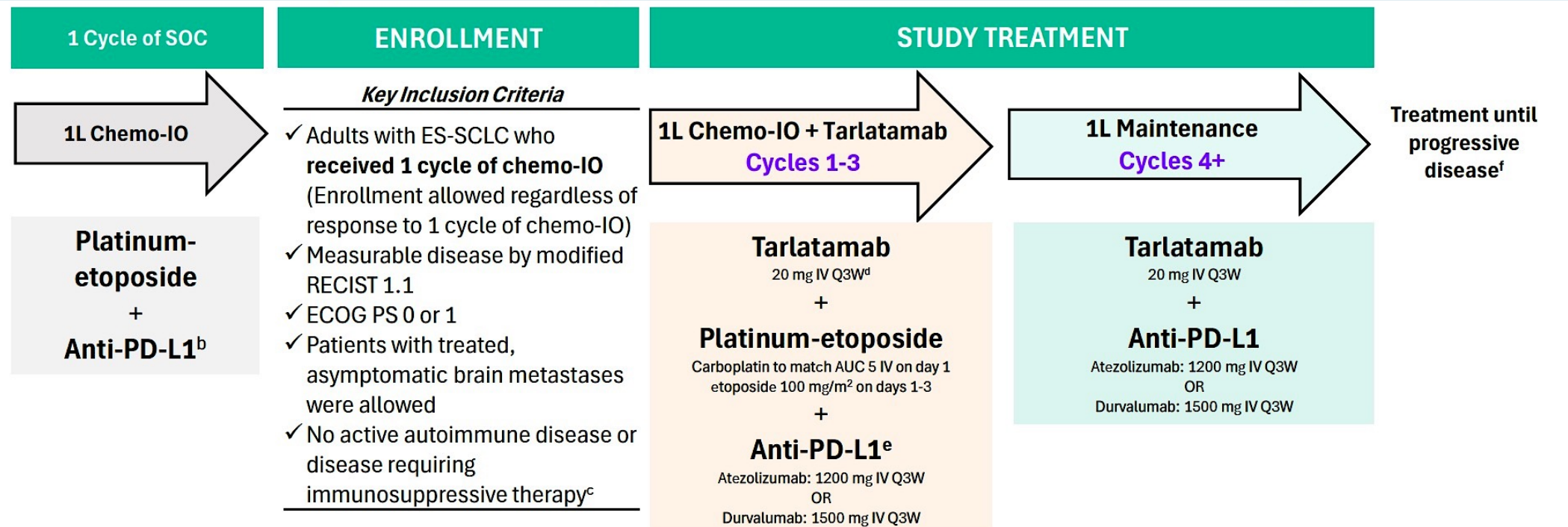
Presenter: Martin Wermke, MD

NCT/UCC Early Clinical Trial Unit, Medical Clinic and Poliklinik I, TU Dresden, Medical Faculty and University Hospital C.-G. Carus Dresden, Germany

18 October 2025



Phase Ib DeLLphi-303 Study Design



Primary Endpoints^g: Dose-limiting toxicities^h, treatment-emergent and treatment-related adverse events

Secondary Endpointsⁱ: Objective response, duration of response, disease control, PFS, and OS

^aOnly data for cohorts 2.1, -2.1, 4, and 7 investigating tarlatamab in combination with 1L chemo-immunotherapy and anti-PD-L1 maintenance therapy are presented. ^bPatients without access to anti-PD-L1 were allowed. ^cPatients with active autoimmune disease requiring systemic treatment (except replacement therapy) within the past 2 years were excluded. ^dTarlatamab was administered with step dosing: 1 mg on cycle 1 day 1 followed by tarlatamab 20 mg Q3W. For patients in cohort -2.1 (n=7), step dosing began on cycle 1 day 8. ^ePatients received either atezolizumab or durvalumab in a non-randomized manner; switch to a different PD-L1 inhibitor from that received with SOC before study start was allowed. ^fTreatment beyond progressive disease allowed if clinical benefit per investigator. ^gAlso included vital signs, electrocardiograms, and clinical laboratory tests ^hDLTs were assessed in cohorts 2.1 and -2.1 only. ⁱAlso included serum concentrations of tarlatamab. **1L:** first-line; **AUC:** area under curve; **chemo-IO:** chemo-immunotherapy; **ECOG PS:** Eastern Cooperative Oncology Group performance status; **LS-SCLC:** limited stage small cell lung cancer; **IV:** intravenous; **OS:** overall survival; **PFS:** progression-free survival; **PD-L1:** programmed death-ligand 1; **RECIST:** Response Evaluation Criteria in Solid Tumors; **SOC:** standard-of-care.

Martin Wermke, MD | Tarlatamab with 1L chemo-immunotherapy for extensive-stage small cell lung cancer (ES-SCLC): DeLLphi-303 study



Phase Ib DeLLphi-303 Primary Endpoint: Safety Summary

	Tarlatamab + EP + atezolizumab n = 56	Tarlatamab + EP + durvalumab n = 40	Overall N = 96 ^a
Median duration of treatment, weeks (IQR)	46 (16–60)	30 (12–62)	46 (14–60)
Median study follow-up, months (95% CI)	12.5 (11.3, 14.7)	14.8 (13.2, 15.0)	13.8 (12.5, 15.0)
Dose-limiting toxicities ^b , n (%)	3 (5)	0	3 (3)
Treatment-emergent AEs ^c , n (%)	56 (100)	40 (100)	96 (100)
Treatment-related AEs, n (%)	56 (100)	40 (100)	96 (100)
Grade 3	26 (46)	15 (38)	41 (43)
Grade 4	21 (38)	13 (33)	34 (35)
Fatal TRAEs	0	1 (3) ^d	1 (1)

- Tarlatamab-related AEs led to tarlatamab discontinuation in 6% of patients^e, with no deaths
- Immune-related adverse events^f, excluding CRS and ICANS and associated neurological events, were rare (2%)

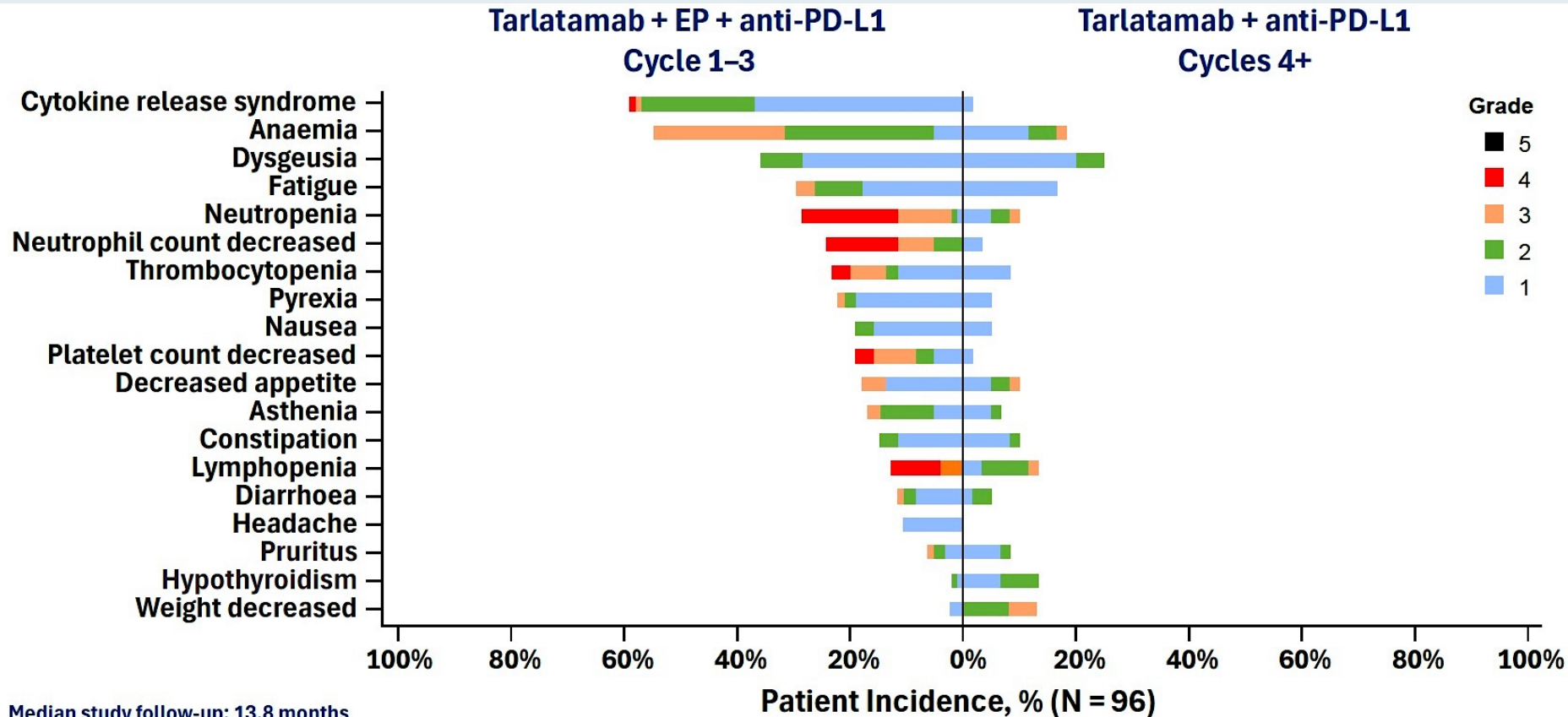
Overall, the addition of tarlatamab to chemo-immunotherapy demonstrated a manageable safety profile, consistent with the safety profiles of each individual agent.

^aOne patient from cohort -2.1 received atezolizumab on cycle 1 day 1 but withdrew before receiving tarlatamab on cycle 1 day 8. ^bDose limiting toxicities included ICANS (n = 1), platelet count decrease (n = 1), and thrombocytopenia (n = 1). ^cFatal TEAEs included pneumonia (n = 1), pneumonia aspiration (n = 1), and septic shock (n = 1). ^dSeptic shock attributed by the investigator as related to etoposide-carboplatin chemotherapy. ^eDiscontinuations include: immune effector cell-associated neurotoxicity syndrome (n = 1), cytokine release syndrome (n = 1), myocardial infarction (n = 1), arthritis allergic, dermatitis allergic, and osteoarthritis (n = 1), hepatitis (n = 1), decreased appetite (n = 1). ^fImmune-related adverse events, defined using MedDRA SMQ narrow search excluding CRS and ICANS and associated neurological events, included autoimmune hypothyroidism (n = 1) and polymyalgia rheumatica (n = 1). AE: adverse event; Chemo-IO: chemo-immunotherapy; EP: etoposide-carboplatin chemotherapy; IQR: interquartile range; TEAE: treatment-emergent adverse events; TRAE: treatment-related adverse events.

Martin Wermke, MD | Tarlatamab with 1L chemo-immunotherapy for extensive-stage small cell lung cancer (ES-SCLC): DeLLphi-303 study



Phase Ib DeLLphi-303: Timing of TRAEs (Primary Endpoint)



Median study follow-up: 13.8 months

- The most common TRAEs primarily occurred during the first 3 cycles when carboplatin-etoposide chemotherapy was administered
- The observed safety profile was consistent with that reported for the individual treatment components (EP/anti-PD-L1/tarlatamab)

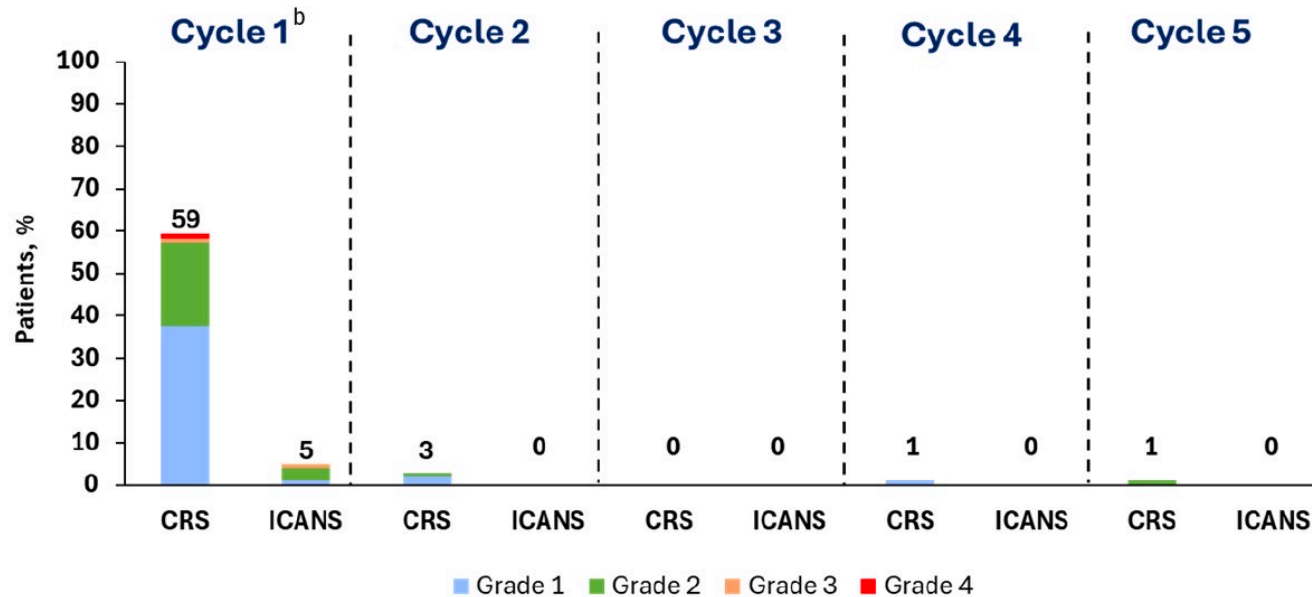
^aTRAEs related to EP, anti-PD-1, and/or tarlatamab with patient incidence $\geq 10\%$ are shown.

Chemo-IO: chemo-immunotherapy; EP: etoposide-carboplatin chemotherapy; PD-L1: programmed cell death-ligand 1; TRAE: treatment-related adverse event.

Martin Wermke, MD | Tarlatamab with 1L chemo-immunotherapy for extensive-stage small cell lung cancer (ES-SCLC): DeLLphi-303 study



Phase Ib DeLLphi-303: Treatment-Emergent CRS, ICANS



- CRS and ICANS were associated with a low rate of
 - tarlatamab dose interruptions (CRS and ICANS: 1% each)
 - tarlatamab discontinuations (CRS and ICANS: 1% each)
- There were no fatalities related to CRS or ICANS
- The median time to onset of CRS from last prior dose of tarlatamab was 13.3 hours (IQR: 8.0–19.3)
- The median time to onset of ICANS from last prior dose of tarlatamab was 5 days (IQR: 3.0–5.0)

Median study follow-up: 13.8 months

- **CRS and ICANS events occurred primarily during cycle 1 of tarlatamab administration and were mostly low grade (grades 1–2) events**
- **All CRS and ICANS events resolved**

^aTreatment-emergent events by worst grade reported. ^bGrade 4 CRS event was due to use of bilevel positive airway pressure in a patient with concurrent grade 3 pneumonia with positive sputum cultures. CRS: cytokine release syndrome; ICANS: immune effector cell-associated neurotoxicity syndrome; IQR: interquartile range.

Martin Wermke, MD | Tarlatamab with 1L chemo-immunotherapy for extensive-stage small cell lung cancer (ES-SCLC): DeLLphi-303 study



Phase Ib DeLLphi-303: Responses

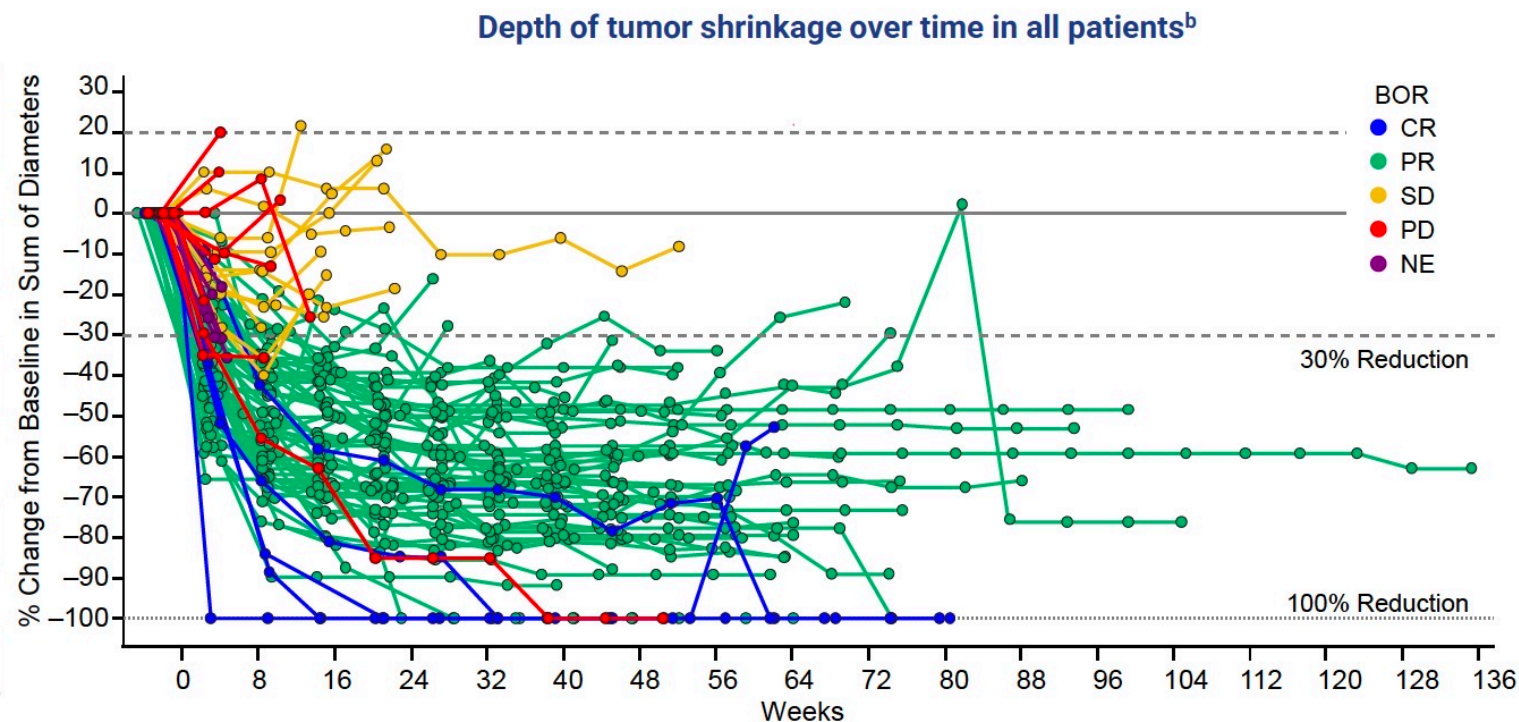
Overall N = 96	
ORR ^a , n (%)	68 (71)
95% CI	61–80
CR	5 (5)
PR	63 (66)
SD	11 (11)
PD	8 (8)
NE/no post-baseline scan	9 (9)
mDOR, mos (95% CI)	11.0 (8.5, NE)
DCR, % (95% CI)	82 (73–89)
mDoDC, mos (95% CI)	10.7 (7.7–18.8)

Median study follow-up: 13.8 months

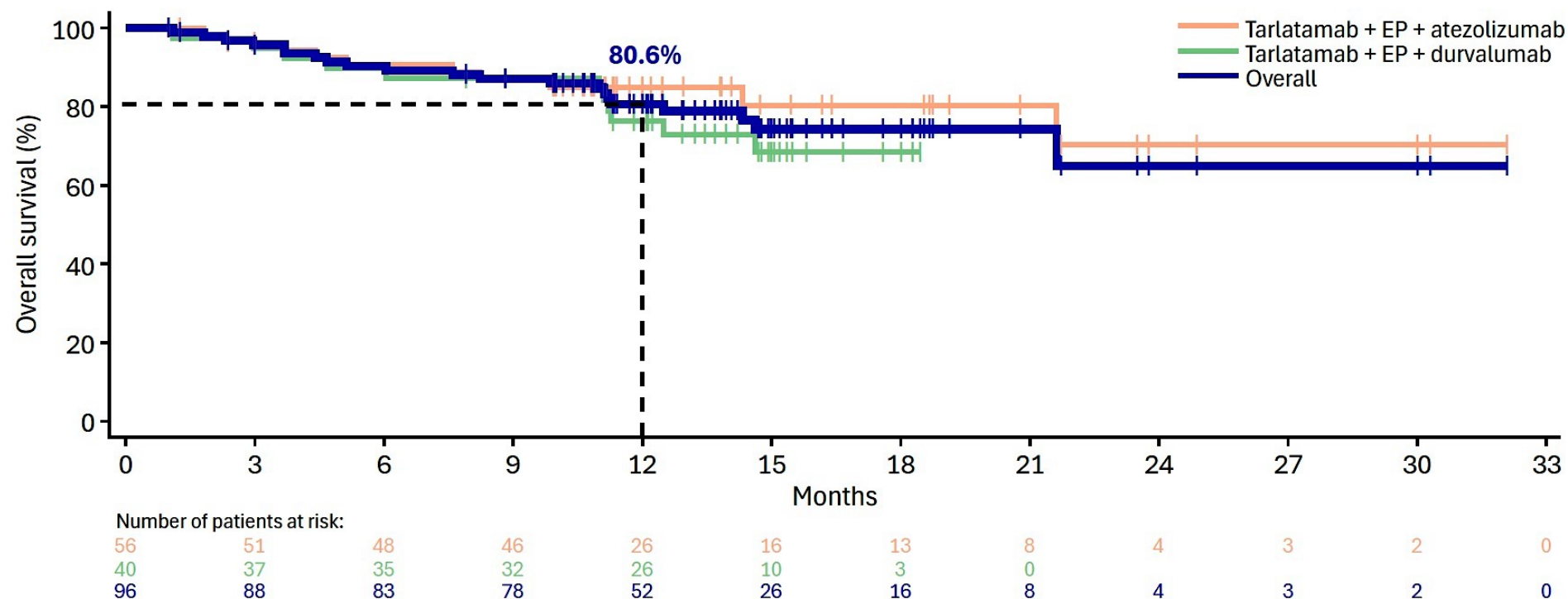
- From a baseline scan after 1 cycle of SOC 1L chemo-IO, addition of tarlatamab to 1L ES-SCLC therapy resulted in
 - ORR of 71%, with median duration of response of 11.0 months
 - Disease control sustained for ≥ 52 weeks in 39% of patients
 - Ongoing responses in 49% of patients at data cutoff with data continuing to mature

^aFor objective response endpoints, patients with missing response data (eg, no baseline assessment, missing post-baseline assessment) were treated as non-responders and included in the denominator. ^bOne patient did not have a post-baseline scan and is not included in the spider plot. Nine patients had 100% reduction in target lesions, including one patient with 100% reduction in target lesions and BOR of PD due to new lesions. 1L: first-line; Chemo-IO: chemo-immunotherapy; CR: complete response; DCR: disease control rate; EP: etoposide-carboplatin chemotherapy; mDoDC: median duration of disease control; mDOR: median duration of response; mos: months; NE: not evaluable; ORR: objective response rate; PD: progressive disease; PR: partial response; SD: stable disease.

Martin Wermke, MD | Tarlatamab with 1L chemo-immunotherapy for extensive-stage small cell lung cancer (ES-SCLC): DeLLphi-303 study



Phase Ib DeLLphi-303: Overall Survival



Median study follow-up: 13.8 months

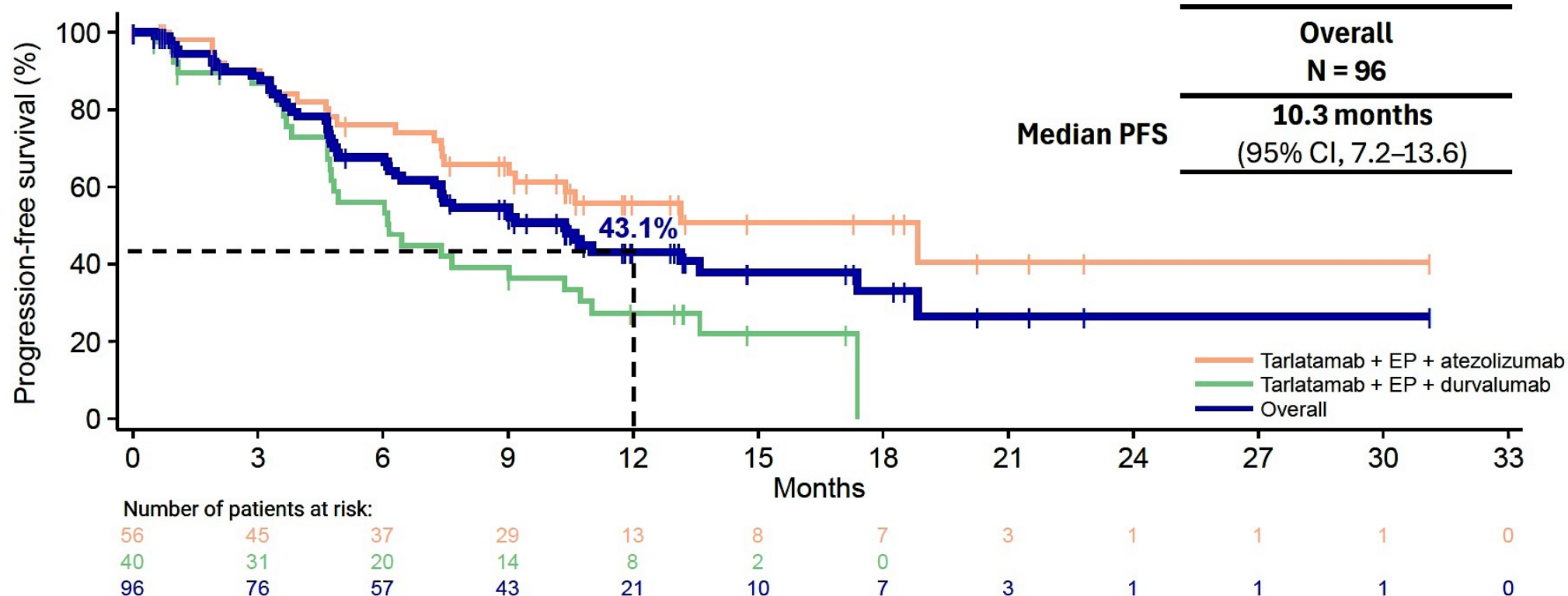
- Starting from the first dose of study treatment, the Kaplan-Meier estimate of OS at 12 months was 80.6%.
- The median OS was not yet estimable.

^aGiven allocation between the atezolizumab and durvalumab subgroups was not randomized thus resulting in imbalances in baseline characteristics, comparisons cannot be made between the anti-PD-L1 agents. 1L: first-line; Chemo-IO: chemo-immunotherapy; CI: confidence interval; EP: etoposide-carboplatin chemotherapy; OS: overall survival; SOC: standard-of-care



Martin Wermke, MD | Tarlatamab with 1L chemo-immunotherapy for extensive-stage small cell lung cancer (ES-SCLC): DeLLphi-303 study

Phase Ib DeLLphi-303: Progression-Free Survival



- Starting from the first dose of study treatment, the median PFS was 10.3 months
- The Kaplan-Meier estimate of PFS at 12 months was 43.1% (95% CI, 32.0– 53.7)

^aGiven allocation between the atezolizumab and durvalumab subgroups was not randomized thus resulting in imbalances in baseline characteristics, comparisons cannot be made between the anti-PD-L1 agents. 1L: first-line; Chemo-IO: chemo-immunotherapy; CI: confidence interval; PFS: progression-free survival, SOC: standard-of-care



Martin Wermke, MD | Tarlatamab with 1L chemo-immunotherapy for extensive-stage small cell lung cancer (ES-SCLC): DeLLphi-303 study

Phase Ib DeLLphi-303: Authors' Conclusions

Tarlatamab in combination with 1L chemo-immunotherapy and anti-PD-L1 maintenance therapy:

- **Demonstrated a manageable safety profile, consistent with the individual treatments**
 - CRS and ICANS predominantly occurred during cycle 1 and were mostly low grade (grade 1 or 2)
 - No tarlatamab-related fatal events
 - Incidence of neutropenia and thrombocytopenia with tarlatamab added to 1L SOC were comparable to that seen with SOC^{3,4}
- **Encouraging response rate, durability of response, and survival outcomes from a baseline scan obtained at study start following 1 cycle of standard of care chemo-immunotherapy**
 - Objective response rate of 71% with median duration of response of 11.0 months
 - Disease control rate of 82% with disease control sustained for ≥ 52 weeks in 39% of patients
 - Median OS was not yet reached; the Kaplan-Meier estimate of OS at 12 months was 81%, and median PFS was 10.3 months

The combination of tarlatamab with 1L chemo-IO and anti-PD-L1 maintenance therapy for ES-SCLC demonstrated a manageable safety profile with encouraging initial survival outcomes, supporting further investigation of this combination in the phase 3 DeLLphi-312 study (NCT07005128).

1L: first-line; **chemo-IO:** chemo-immunotherapy; **CRS:** cytokine release syndrome; **ES-SCLC:** extensive stage small cell lung cancer; **ICANS:** immune effector cell-associated neurotoxicity syndrome; **OS:** overall survival; **PD-L1:** programmed death-ligand 1; **PFS:** progression-free survival; **SOC:** standard-of-care.

Martin Wermke, MD | Tarlatamab with 1L chemo-immunotherapy for extensive-stage small cell lung cancer (ES-SCLC): DeLLphi-303 study



The Road Ahead: Tarlatamab

Is earlier tarlatamab better (e.g. first-line ES-SCLC, or LS-SCLC)?

DeLLphi trial #	Phase	Indication	Design	Recruiting?	Trial ID
303	1b	1L ES-SCLC	Tarlatamab + standard therapy	N	NCT05037847
305	3	1L ES-SCLC maintenance	Tarlatamab + durva vs. durva alone	Y	NCT06502977
306	3	LS-SCLC post-chemoRT	Tarlatamab vs. placebo	Y	NCT06117774
310	1b	1L ES-SCLC maintenance	Tarlatamab + YL201 + atezo or durva	Y	NCT06898957

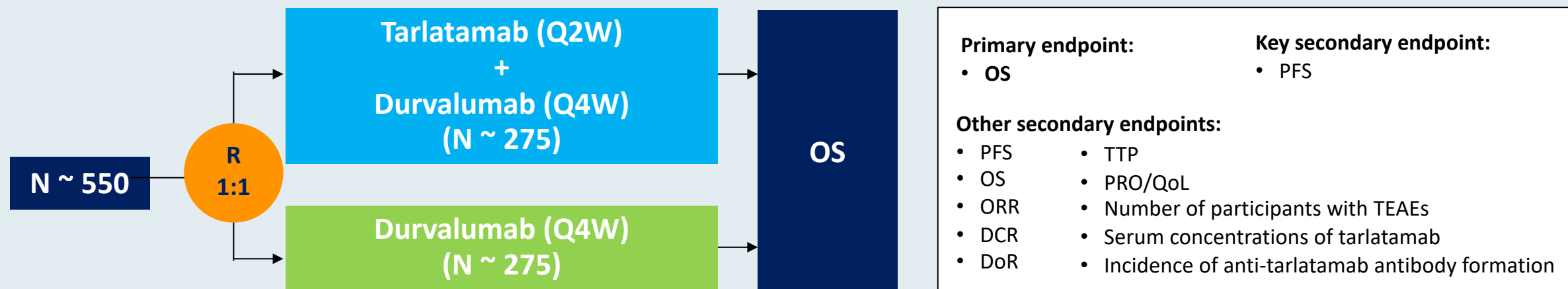
Is tarlatamab more effective in combination?

DeLLphi trial #	Phase	Indication	Design	Recruiting?	Trial ID
302	1b	2L+ SCLC	Tarlatamab + anti-PD-1 therapy	Y	NCT04184050
305	3	1L ES-SCLC maintenance	Tarlatamab + durva vs. durva alone	Y	NCT06502977
310	1b	2L SCLC	Tarlatamab + YL201	Y	NCT06898957
		1L ES-SCLC maintenance	Tarlatamab + YL201 + atezo or durva		

LS-SCLC = limited-stage small cell lung cancer

Phase III DeLLphi-305 Trial: Tarlatamab with Durvalumab as First-Line Maintenance in ES-SCLC

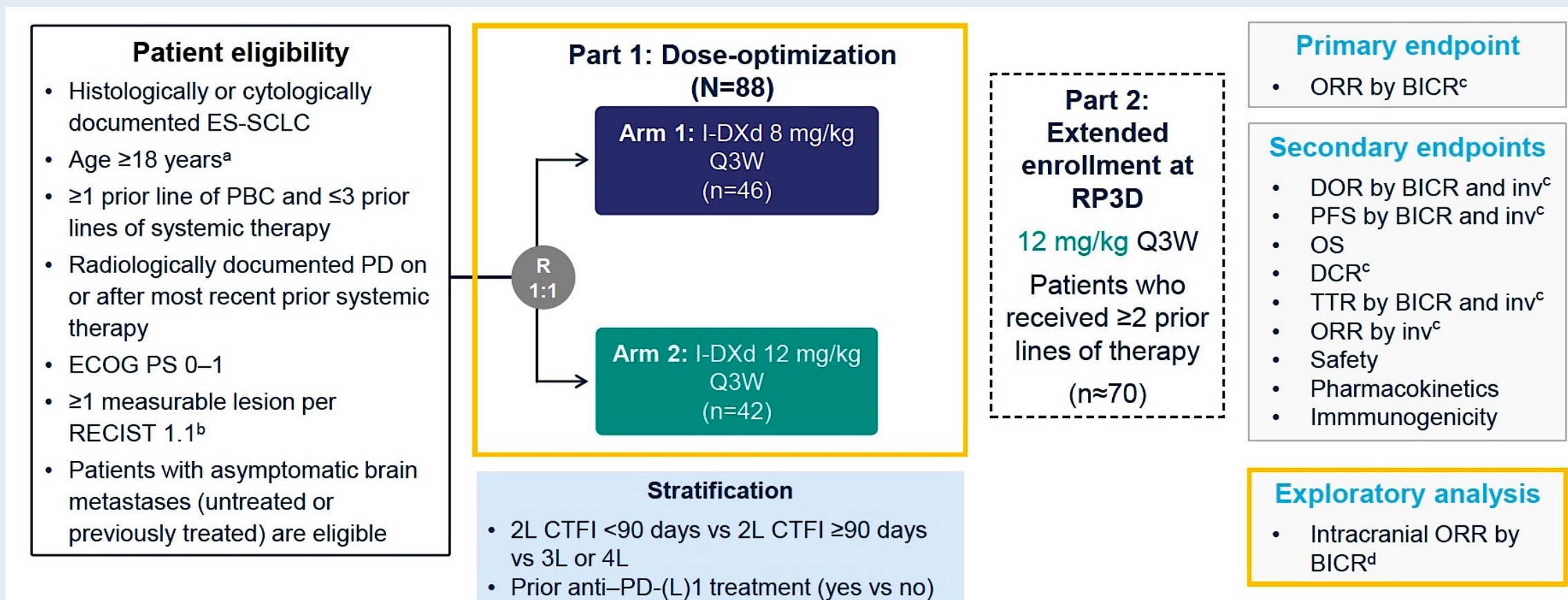
Trial Identifier: NCT06211036



Key inclusion criteria: Patients aged ≥ 18 years with ECOG PS of 0 to 1 and histologically or cytologically confirmed ES-SCLC who completed 3-4 cycles of platinum-etoposide chemotherapy with concurrent durvalumab without progression

Key exclusion criteria: Symptomatic CNS metastases or leptomeningeal disease; active systemic infections; active HIV and/or hepatitis B/C; prior therapy targeting DLL3

Phase II IDeate-Lung01 Study Design



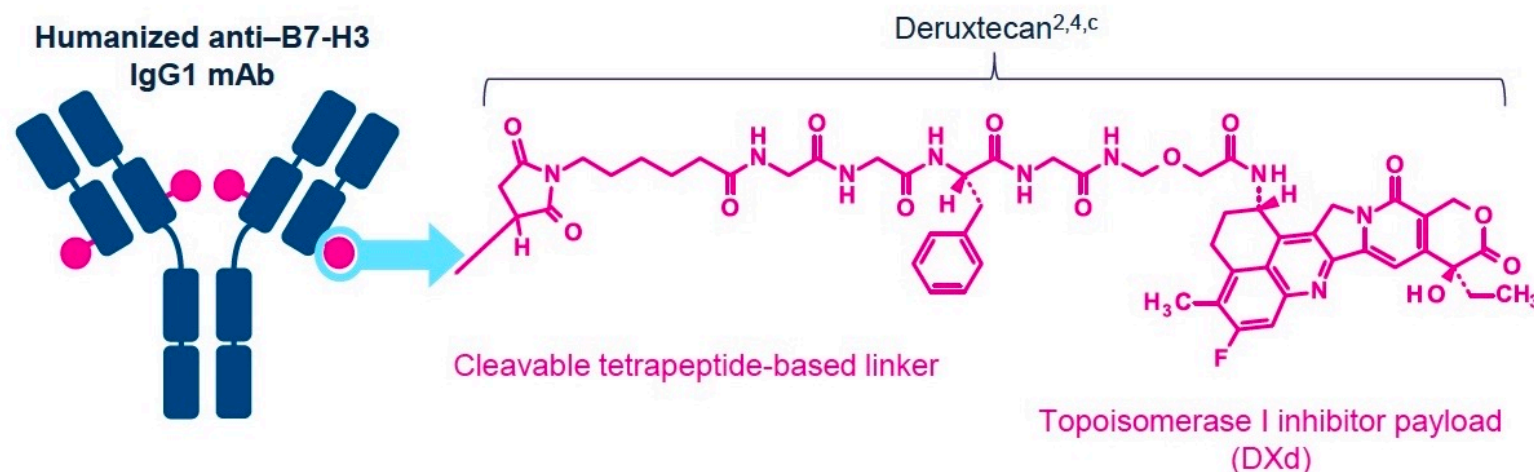
^aOr local legal age of consent. ^bPatients must also have ≥1 lesion that has not been irradiated and is amenable to biopsy. ^cAssessed by RECIST 1.1. ^dAssessed using a version of RECIST 1.1 modified for assessment of CNS tumors. 2L, second-line; 3L, third-line; 4L, fourth-line; BICR, blinded independent central review; CTFI, chemotherapy-free interval; DCR, disease control rate; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; ES-SCLC, extensive-stage small cell lung cancer; inv, investigator; ORR, objective response rate; OS, overall survival; PBC, platinum-based chemotherapy; PD, progressive disease; PD-(L)1; programmed death (ligand) 1; PFS, progression-free survival; Q3W, every 3 weeks; R, randomization; RECIST 1.1, Response Evaluation Criteria in Solid Tumours, version 1.1; RP3D, recommended Phase 3 dose; TTR, time to response.

I-DXd = ifinatamab deruxtecan

Ifinatamab Deruxtecan (I-DXd)

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 $\approx 4^{4,a,b}$

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}

^aThe clinical relevance of these features is under investigation. ^bBased on animal data. ^cRefers to the linker and payload.

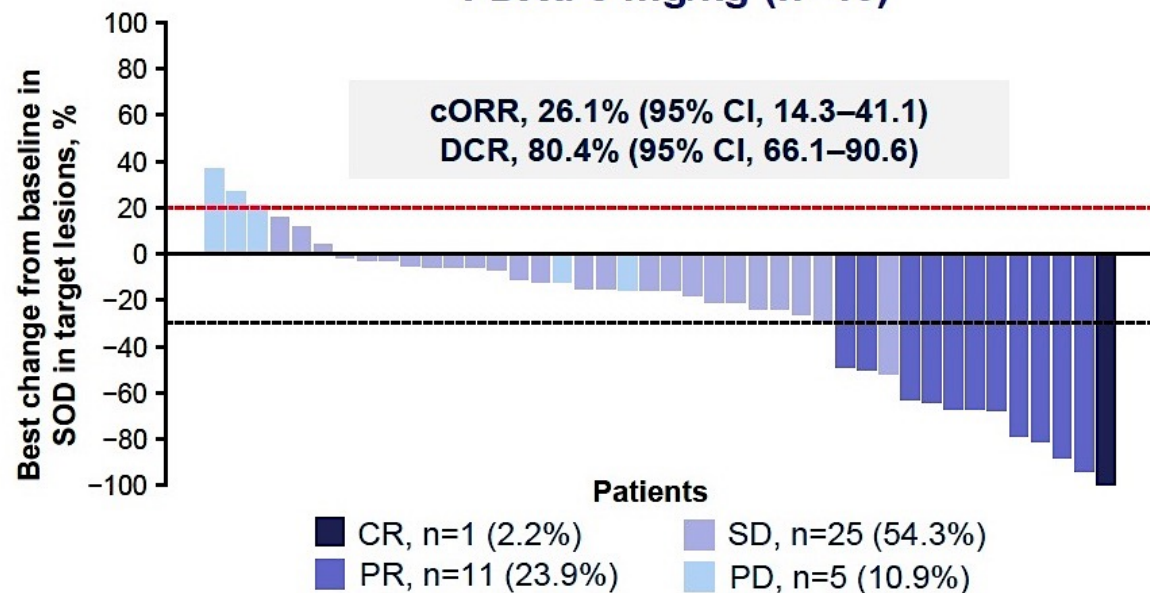
ADC, antibody–drug conjugate; B7-H3, B7 homolog 3; CD276, cluster of differentiation 276; IgG1, immunoglobulin G1; mAb, monoclonal antibody.

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.

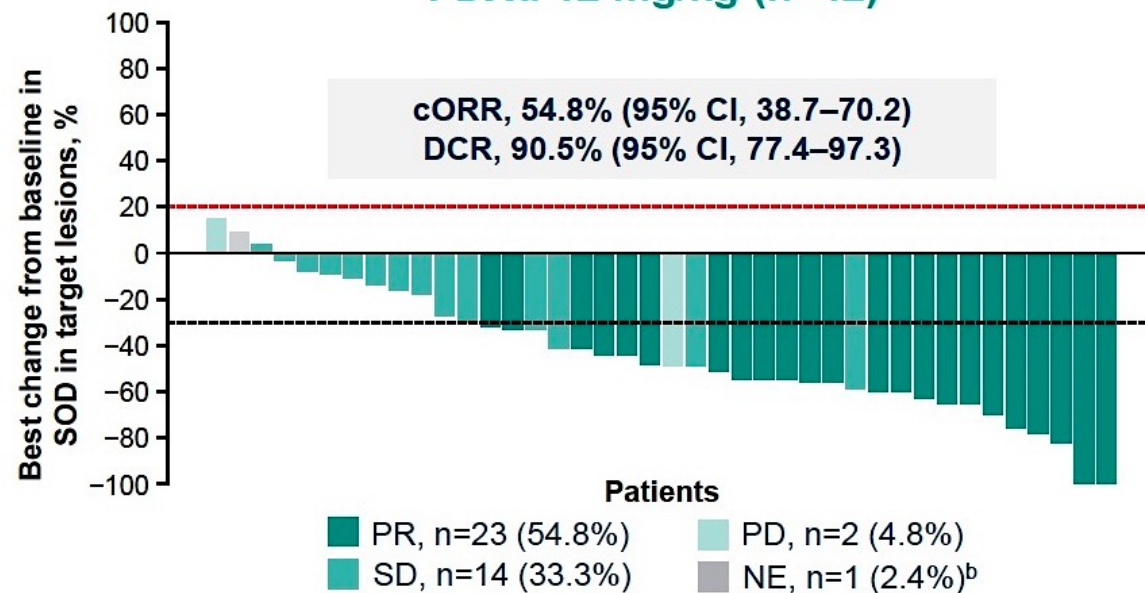
5. Ogitani Y, et al. *Cancer Sci.* 2016;107:1039–1046.

IDeate-Lung01: Responses

I-DXd 8 mg/kg (n=46)^a



I-DXd 12 mg/kg (n=42)^a



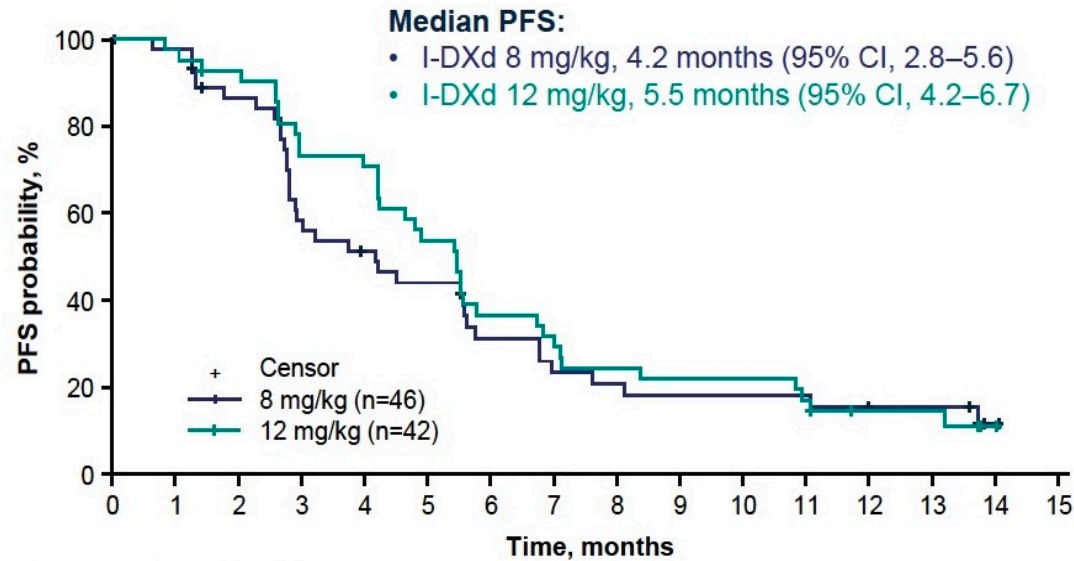
Data cutoff: April 25, 2024. Median follow-up for the 8-mg/kg and 12-mg/kg cohorts was 14.6 (range, 0.6–17.0) months and 15.3 (range, 0.8–20.3) months, respectively.

^aOnly patients with measurable disease at baseline and ≥ 1 post-baseline tumor scan were included in the waterfall plot: in the I-DXd 8-mg/kg cohort (n=42), 2 patients died and 2 patients withdrew consent before the Week 6 assessment; in the 12-mg/kg cohort (n=40), 1 patient died before the Week 6 assessment, and 1 patient did not have target lesions at baseline. ^bThis patient has a BOR of NE because the only post-baseline tumor scan was conducted outside the designated time window; the timepoint response was SD.

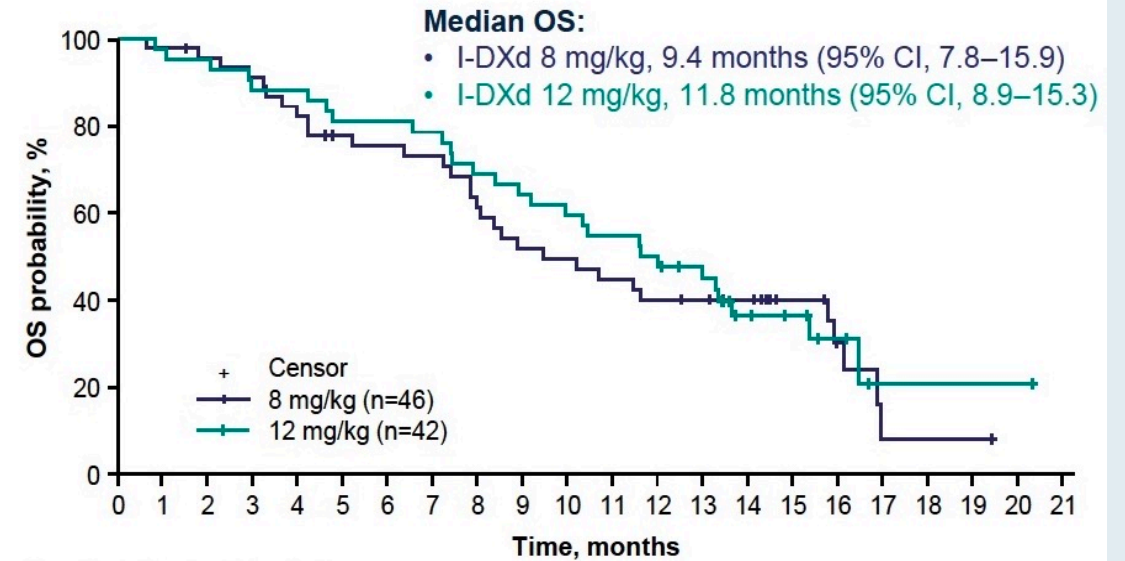
BICR, blinded independent central review; BOR, best overall response; CI, confidence interval; cORR, confirmed objective response rate; CR, complete response; DCR, disease control rate; NE, not evaluable; ORR, objective response rate; PD, progressive disease; PR, partial response; SD, stable disease; SOD, sum of diameters.

IDeate-Lung01: Survival

PFS



OS



Data cutoff: April 25, 2024. Median follow-up for the 8-mg/kg and 12-mg/kg cohorts was 14.6 (range, 0.6–17.0) months and 15.3 (range, 0.8–20.3) months, respectively.
CI, confidence interval; OS, overall survival; PFS, progression-free survival.

IDeate-Lung01: Intracranial Activity of I-DXd

	Patients with brain metastases at baseline		Subset of patients with brain target lesions	
	8 mg/kg (n=19)	12 mg/kg (n=18)	8 mg/kg (n=6)	12 mg/kg (n=10)
CNS efficacy				
CNS confirmed ORR,^a % (95% CI)	36.8 (16.3–61.6)	38.9 (17.3–64.3)	66.7 (22.3–95.7)	50.0 (18.7–81.3)
CNS confirmed BOR,^a n (%)				
CR	5 (26.3)	4 (22.2)	2 (33.3)	2 (20.0)
PR	2 (10.5) ^b	3 (16.7) ^b	2 (33.3)	3 (30.0)
SD or non-CR/non-PD ^c	8 (42.1)	10 (55.6)	2 (33.3)	5 (50.0)
PD	1 (5.3)	0	0	0
Not evaluable	3 (15.8)	1 (5.6)	0	0
CNS confirmed DCR,^{a,d} % (95% CI)	78.9 (54.4–93.9)	94.4 (72.7–99.9)	100 (54.1–100.0)	100 (69.2–100.0)
CNS DOR, median (95% CI),^a months	4.3 (3.3–NE)	7.4 (3.0–NE)	3.9 (3.3–NE)	6.5 (3.0–NE)
CNS TTR, median (range),^a months	1.4 (1.2–1.5)	1.2 (0.9–2.8)	1.3 (1.2–1.4)	1.2 (0.9–2.8)
Systemic efficacy				
Systemic confirmed ORR,^e % (95% CI)	26.3 (9.1–51.2)	61.1 (35.7–82.7)	16.7 (0.4–64.1)	60.0 (26.2–87.8)
Concordance between systemic and CNS objective response,^f %	78.9	77.8	NR	NR

Data cutoff: April 25, 2024.

^aAssessed by BICR, using a version of RECIST 1.1 modified for assessment of CNS tumors. ^bAll patients with PR had target lesions at baseline. ^cOnly patients without baseline brain target lesions could have response classified as “non-CR/non-PD.” ^dCR + PR + SD + non-CR/non-PD. ^eBy BICR per RECIST 1.1. ^fPercentage of patients with both CNS and systemic objective response, and with neither CNS nor systemic objective response.

BICR, blinded independent central review; BOR, best overall response; CI, confidence interval; CNS, central nervous system; CR, complete response; DCR, disease control rate; DOR, duration of response; NE, not estimable; NR, not reported; ORR, objective response rate; PD, progressive disease; PR, partial response; RECIST 1.1, Response Evaluation Criteria in Solid Tumours, version 1.1; SD, stable disease; TTR, time to response.

IDEATE-LUNG01: Authors' Conclusions

- I-DXd demonstrated promising efficacy in patients with pretreated ES-SCLC, with greater efficacy observed at the 12-mg/kg dose level compared with 8 mg/kg:
 - ORR, 54.8% vs 26.1%; median PFS, 5.5 months vs 4.2 months; median OS, 11.8 months vs 9.4 months
- I-DXd was generally well tolerated and demonstrated a manageable safety profile that was consistent with previous reports; the occurrence of TEAEs was dose-dependent, with a higher incidence reported in the 12-mg/kg cohort than in the 8-mg/kg cohort
 - 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
- Among the 37 patients with baseline brain metastases, CNS confirmed ORR was 37.8%; all 16 patients with brain target lesions at baseline achieved CNS disease control
- The safety profile of I-DXd was generally comparable between patients with and without baseline brain metastases, and was consistent with the overall population
- I-DXd 12 mg/kg has been selected as the RP3D for further clinical development, including in an ongoing Phase 3 trial in patients with relapsed SCLC who have received only 1 prior line of systemic treatment, which must have included PBC (IDEATE-LUNG02; NCT06203210)

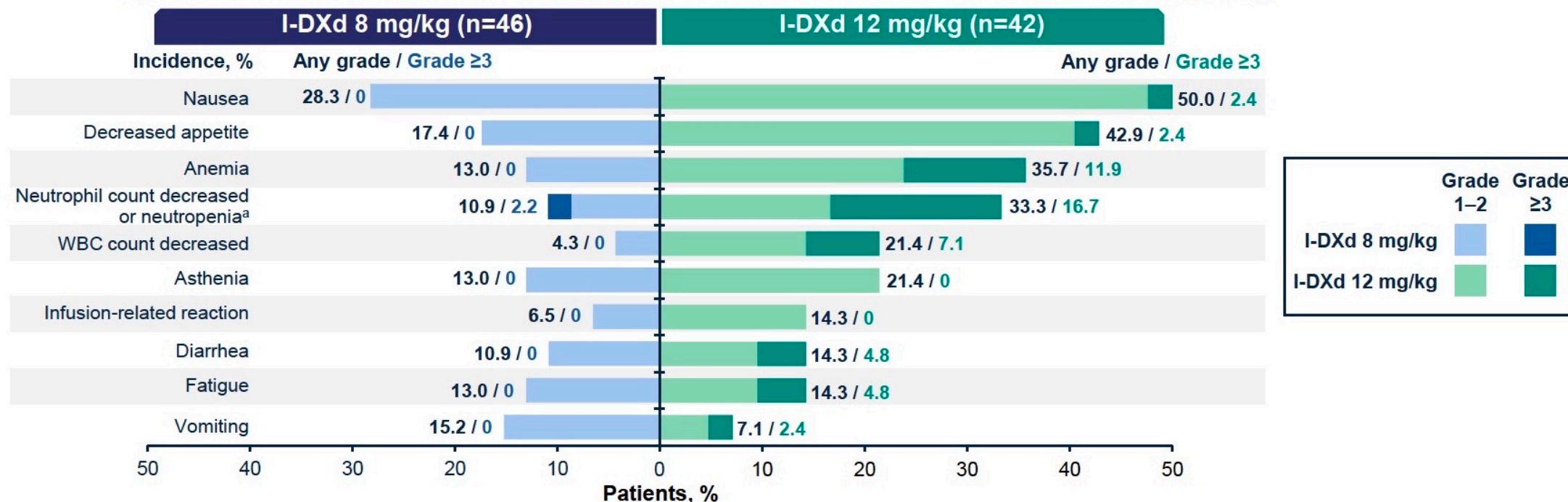
Data cutoff: April 25, 2024.

CNS, central nervous system; ES-SCLC, extensive-stage small cell lung cancer; ILD, interstitial lung disease; ORR, objective response rate; OS, overall survival; PBC, platinum-based chemotherapy; PFS, progression-free survival; RP3D, recommended Phase 3 dose; SCLC, small cell lung cancer; TEAE, treatment-emergent adverse event.



IDEATE-Lung01: Adverse Events

Treatment-related TEAEs reported in ≥10% of the total dose-optimization population

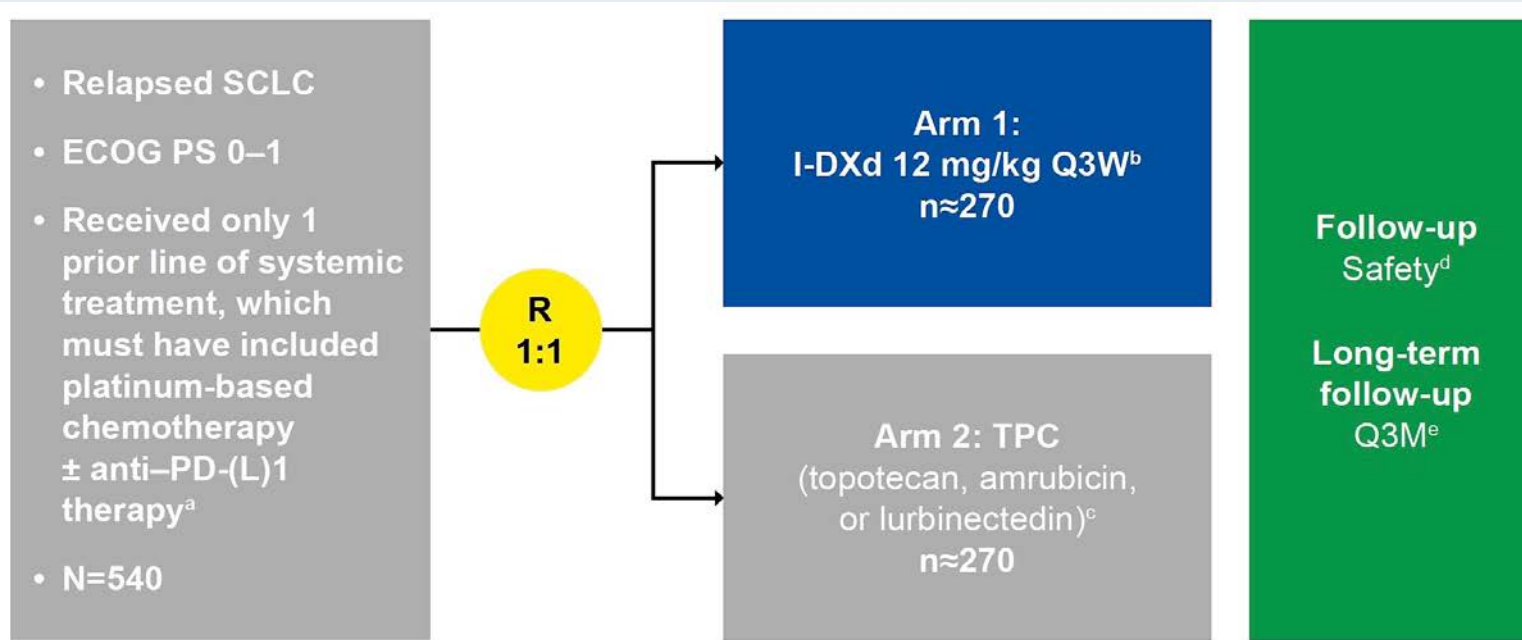


- ILD/pneumonitis adjudicated as treatment-related^b was reported in:
 - Four (8.7%) of 46 patients in the **8-mg/kg** cohort (Grade 2, n=3; Grade 5, n=1)
 - Five (11.9%) of 42 patients in the **12-mg/kg** cohort (Grade 1, n=1; Grade 2, n=3; Grade 3, n=1)

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.

^aTEAEs associated with preferred terms neutrophil count decreased and neutropenia have been combined; no patients in either cohort were reported to have febrile neutropenia. ^bNo ILD events are pending adjudication at the time of data cutoff. ILD, interstitial lung disease; TEAE, treatment-emergent adverse event; WBC, white blood cell.

Phase III IDeate-Lung02 Study



Stratification

CTFI 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)

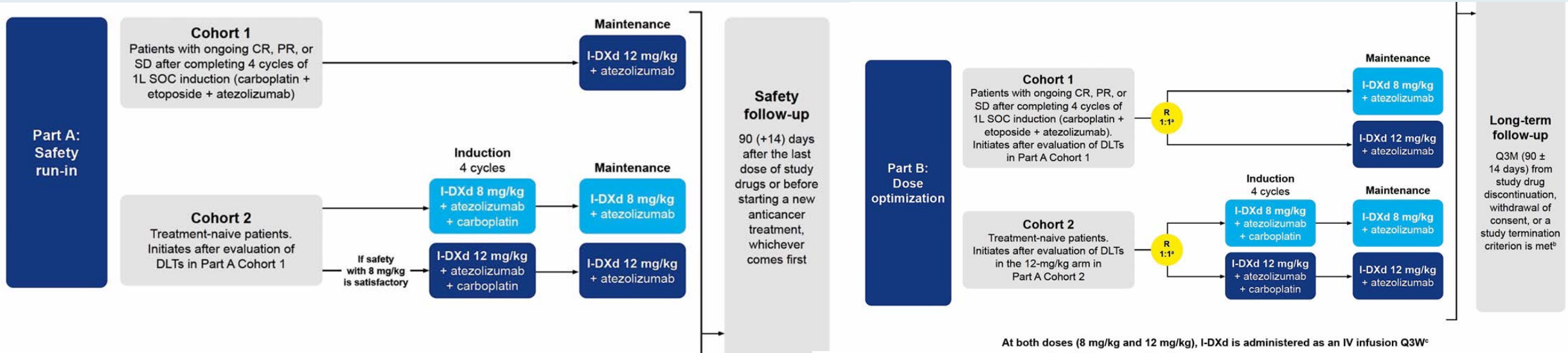
Primary endpoints: ORR, OS

Secondary endpoints: ORR, PFS, DOR, DCR, TTR, PROs, Safety, Immunogenicity, Pharmacokinetics, Relationship between B7-H3 expression and outcomes

^a≥80% of patients are expected to have received prior anti-PD-(L)1 therapy. ^bUntil PD, unacceptable toxicity, loss to follow-up, consent withdrawal, death, or other reason. ^cComparator treatments will only be utilized in countries where they are approved in second and subsequent LoTs for patients with SCLC who progressed on or after platinum-based therapy; ≥70% of patients in the comparator group will receive topotecan.

^dSafety follow-up visit will occur 40 days (+7 days) after the last dose. ^eLong-term follow-up will occur to assess survival; assess tumor progression until PD for patients discontinuing for reasons other than PD; and to collect information on further anticancer treatments, Q3M (90 ±14 days) from study-drug discontinuation (end of treatment), withdrawal of consent, or from when a study-termination criterion is met.

Phase Ib/II IDeate-Lung03 Study



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

Secondary endpoints: PFS, ORR, DCR, DOR, CBR, TTR, Best percentage change in sum of diameters of measurable tumors, OS, Pharmacokinetics, Immunogenicity

^aRandomization stratified by lactate dehydrogenase ($\leq$ ULN vs ULN) and ECOG performance status (0 vs 1), as determined at induction baseline. ^bLong-term follow-up will occur to assess survival and tumor progression until PD for patients who discontinue treatment for reasons other than PD, and to collect information on further anticancer treatments. ^cAtezolizumab is administered as an IV infusion Q3W at a dose of 1,200 mg; carboplatin is administered as an IV infusion Q3W, AUC 5; etoposide is administered as an IV infusion Q3W on Day 1 to Day 3 at a dose of 100 mg/m².

Ongoing Research

- **When will ifinatamab deruxtecan be FDA approved? CNS activity?**
- **Sequencing of lurbinectedin, tarlatamab and ifinatamab deruxtecan**

Cancer Q&A: Understanding the Role and Reality of CAR (Chimeric Antigen Receptor) T-Cell Therapy for Non-Hodgkin Lymphoma

A CME/MOC-Accredited Webinar Developed in Partnership with CancerCare®

**Wednesday, November 12, 2025
5:00 PM – 6:00 PM ET**

Faculty

**Jeremy S Abramson, MD, MMSc
Loretta J Nastoupil, MD**

Moderator

Neil Love, MD

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