Second Opinion: Investigators Provide Perspectives on the Current and Future Management of Small Cell Lung Cancer

Saturday, May 30, 2026
7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)

Faculty

Anne Chiang, MD, PhD
Apar Kishor Ganti, MD, MS
Luis Paz-Ares, MD, PhD

Moderator

Misty Dawn Shields, MD, PhD

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Dr Ganti — Disclosures
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Contributing Clinical Investigators

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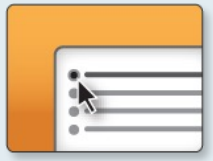

Answer Survey Questions: Complete the pre- and postmeeting surveys. Survey questions will be discussed throughout the meeting.

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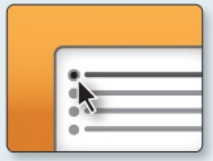

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About the Enduring Program

- The live meeting is being video and audio recorded.
- The proceedings from today will be edited and developed into an enduring web-based program. An email will be sent to all attendees when the activity is available.
- To learn more about our education programs, visit our website, **www.ResearchToPractice.com**

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Friday May 29	**Gastroesophageal Cancers** 11:30 AM – 1:00 PM CT (12:30 PM – 2:00 PM ET)
	Non-Small Cell Lung Cancer 6:30 PM – 8:30 PM CT (7:30 PM – 9:30 PM ET)
	Chronic Lymphocytic Leukemia 6:30 PM – 8:30 PM CT (7:30 PM – 9:30 PM ET)
	Colorectal Cancer 6:30 PM – 8:00 PM CT (7:30 PM – 9:00 PM ET)
Saturday May 30	**Ovarian Cancer** 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
	Prostate Cancer 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
	Small Cell Lung Cancer 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
Sunday May 31	**Oral SERDs and Agents Targeting the PI3K/AKT/mTOR Pathway for Breast Cancer** 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
	Endometrial Cancer 7:00 PM – 8:30 PM CT (8:00 PM – 9:30 PM ET)
	CAR T-Cell Therapy and Bispecific Antibodies for Non-Hodgkin Lymphoma 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
Monday June 1	**ADCs for Breast Cancer** 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
	Novel Therapies for Non-Hodgkin Lymphoma 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
	Relapsed/Refractory Multiple Myeloma 7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)
Tuesday June 2	**Myelofibrosis (Webinar)**

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Moderator

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Second Opinion

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Agenda

Module 1: Optimizing First-Line and Maintenance Therapy for Extensive-Stage Small Cell Lung Cancer (SCLC) — Dr Shields

Module 2: Management of Relapsed/Refractory SCLC — Dr Paz-Ares

Module 3: Ongoing Investigation and Potential Role of Antibody-Drug Conjugates in SCLC — Dr Chiang

Module 4: Management of Limited-Stage SCLC — Dr Ganti

Agenda

Module 1: Optimizing First-Line and Maintenance Therapy for Extensive-Stage Small Cell Lung Cancer (SCLC) — Dr Shields

Module 2: Management of Relapsed/Refractory SCLC — Dr Paz-Ares

Module 3: Ongoing Investigation and Potential Role of Antibody-Drug Conjugates in SCLC — Dr Chiang

Module 4: Management of Limited-Stage SCLC — Dr Ganti

Optimizing First-Line and Maintenance Therapy for Extensive-Stage Small Cell Lung Cancer

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Associate Member, Experimental & Developmental Therapeutics

May 30, 2026

INDIANA UNIVERSITY
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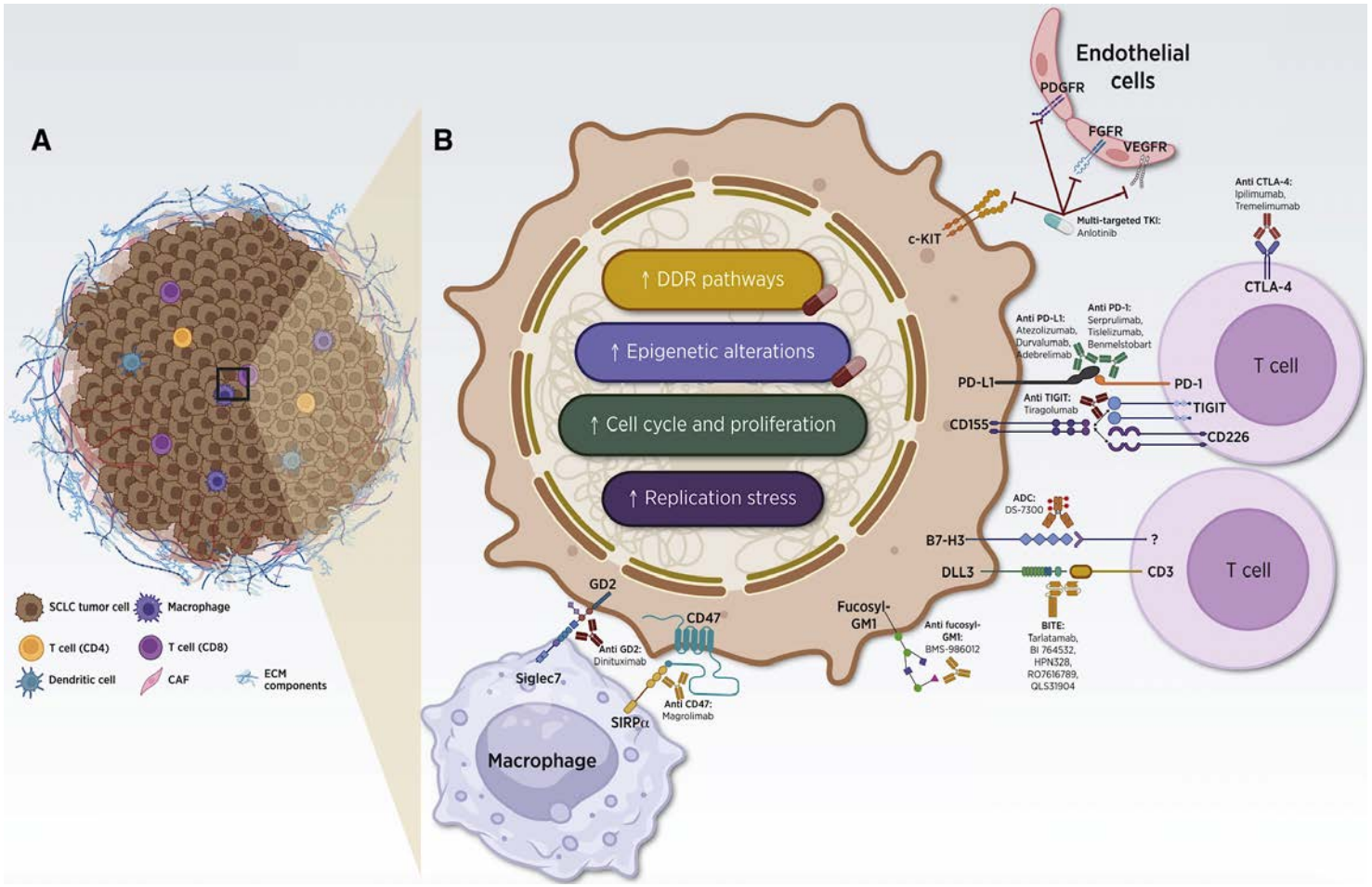
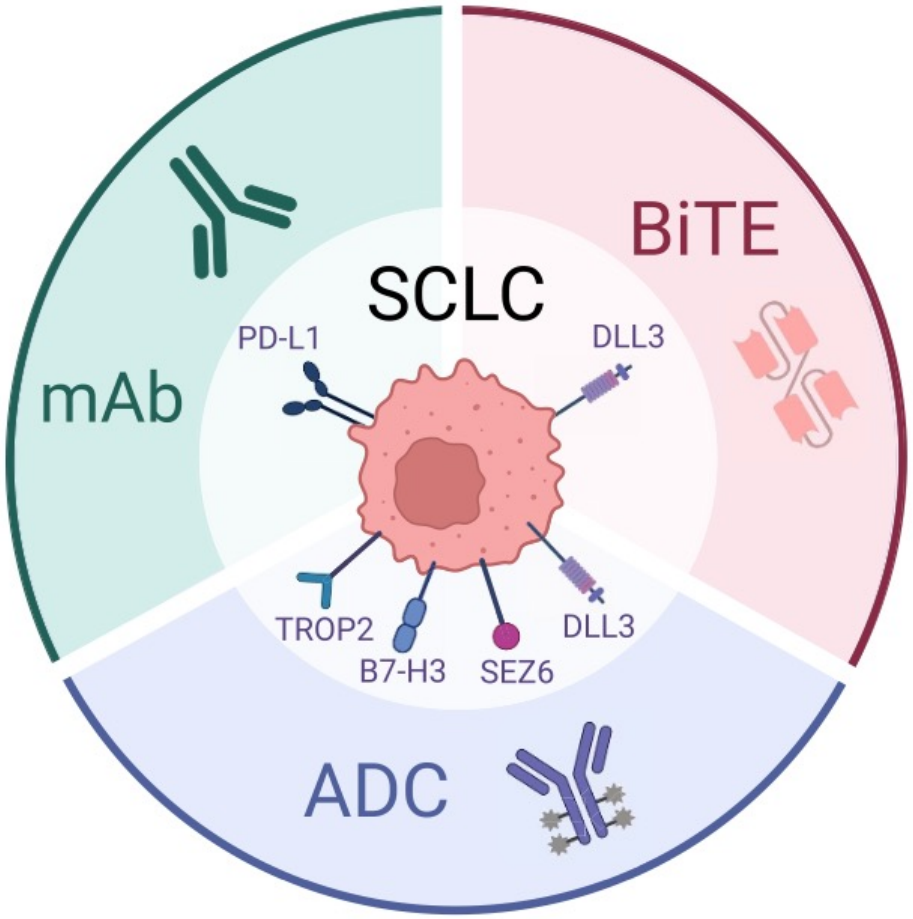
NCI Comprehensive Cancer Center
A Cancer Center Designated by the National Cancer Institute

NCCN National Comprehensive Cancer Network®
Member Institution

Era of Scientific Revolution for SCLC

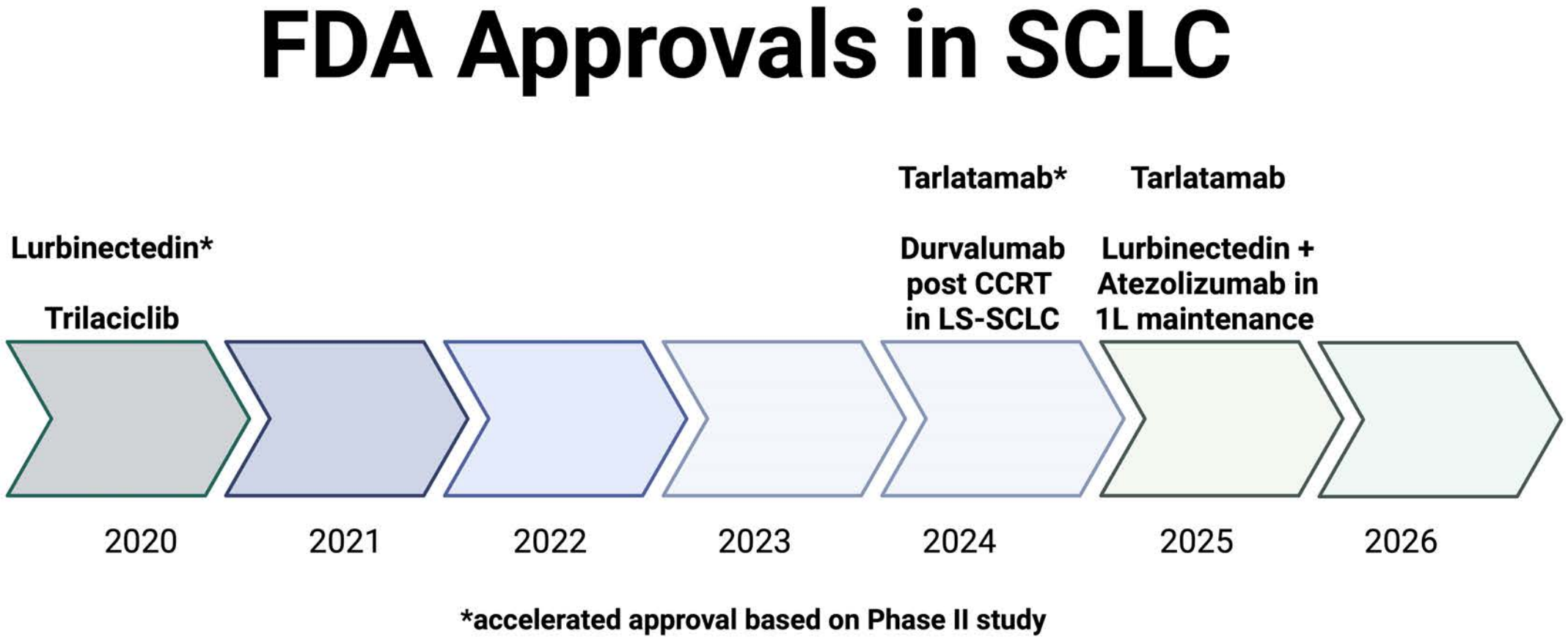


Zugazgoitia, et al. *Clin Cancer Res.* 2024.

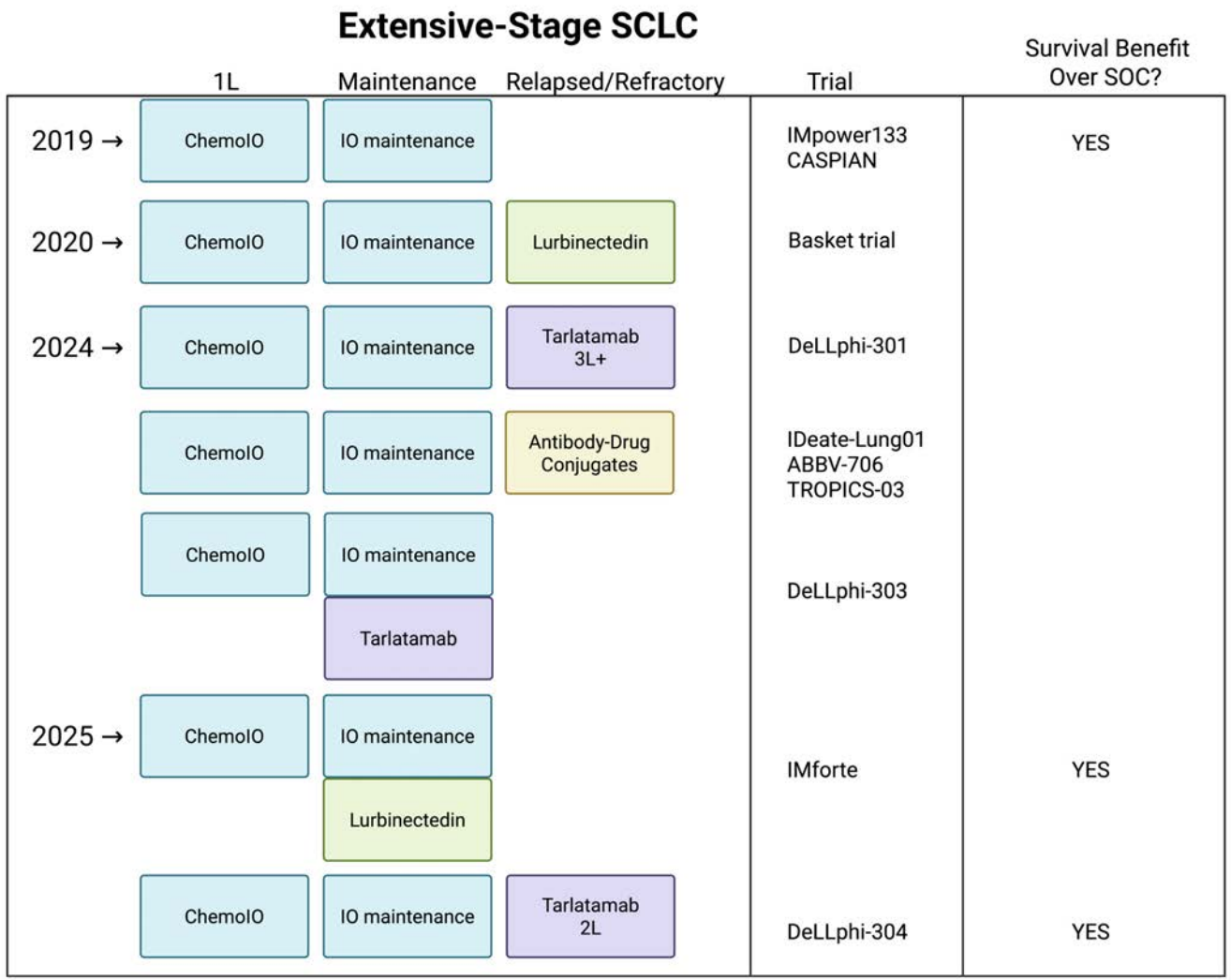


Shields, Chiang, Byers. *Cancer.* 2025.

Tangible Progress in SCLC



Plethora of Options: What Is the RIGHT Sequence?



Horn, et al. *NEJM* 2018
Paz-Ares, et al. *Lancet* 2019/ESMO Open 2022

Trigo, et al. *Lancet Oncol* 2020

Ahn, et al. *NEJM* 2023

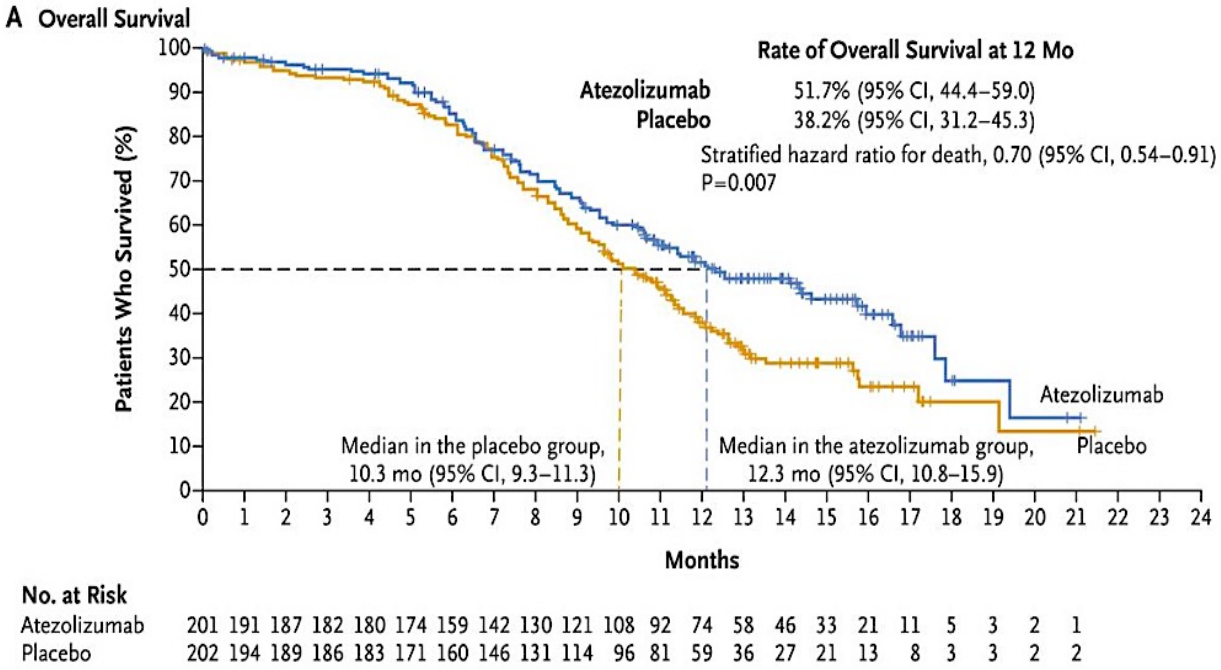
Rudin, et al. *J Clin Oncol* 2026
Cooper, et al. ASCO 2025, Abstract 105
Dowlati, et al. *J Thorac Oncol* 2025

Paulson, et al. *Lancet Oncol* 2025

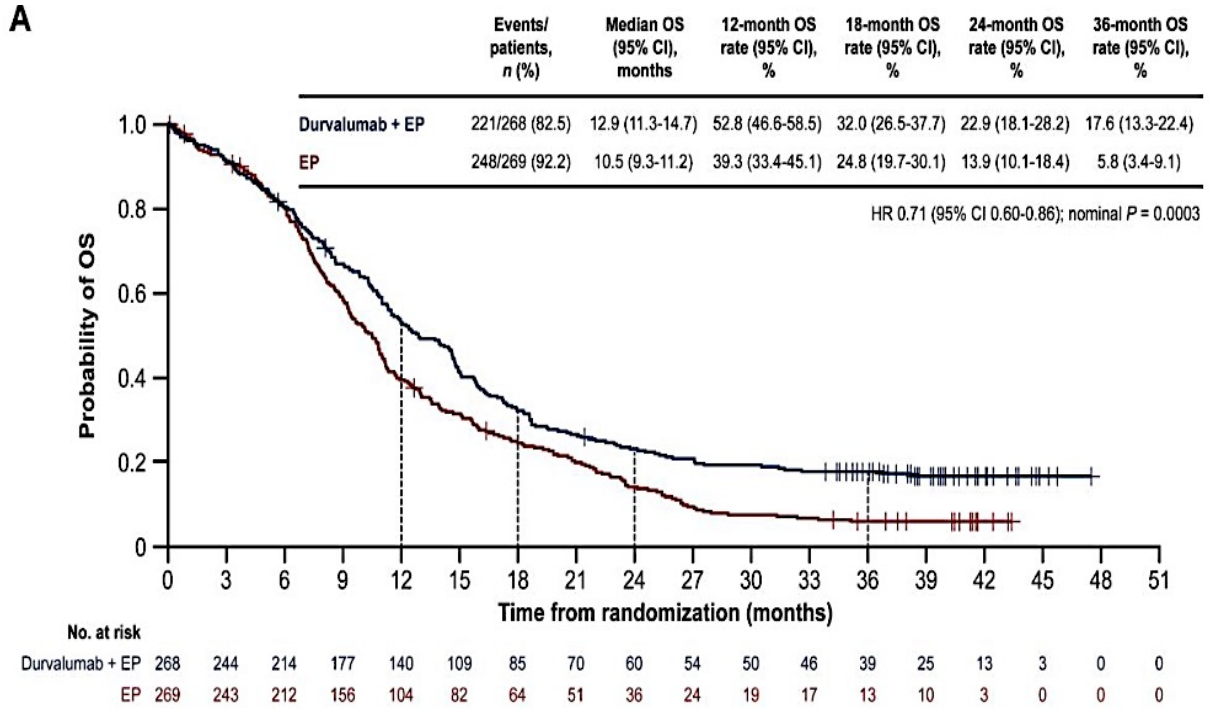
Paz-Ares, et al. *Lancet* 2025

Mountzios, et al. *NEJM* 2025

Chemoimmunotherapy: Standard of Care for 1L ES-SCLC Since 2019



IMpower133



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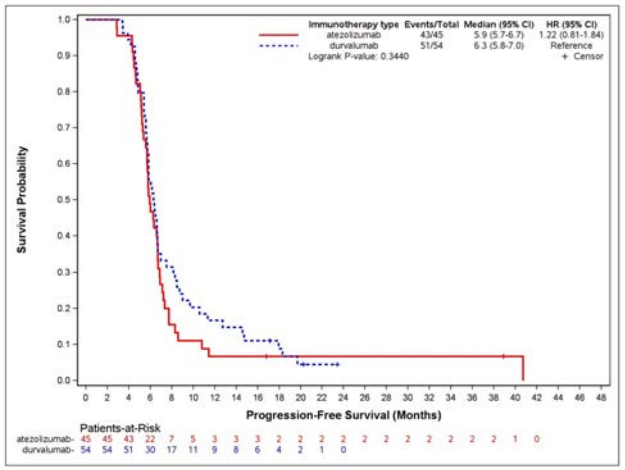
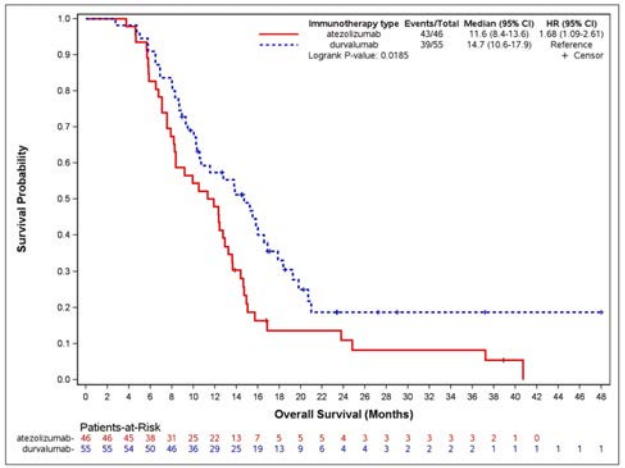
Horn, et al. *NEJM* 2018; Paz-Ares, et al. *Lancet* 2019/ESMO Open 2022.

Does the Choice of IO Agent Matter in 1L ES-SCLC?

PFS

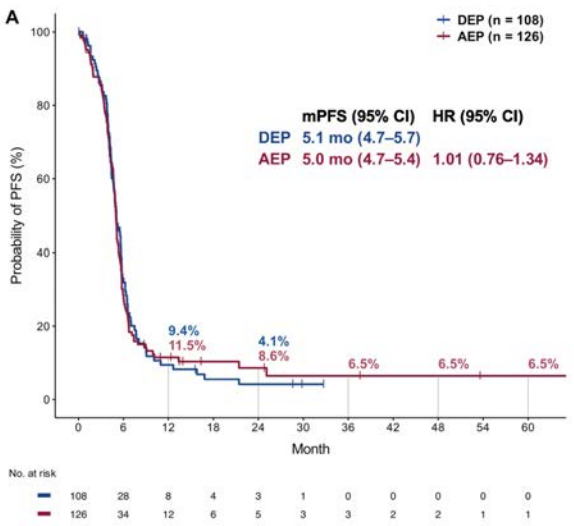


OS

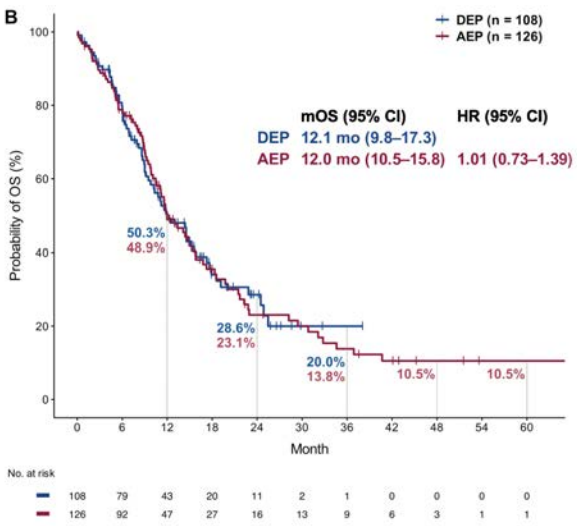


Vince, et al. *Lung Cancer* 2024.

PFS



OS



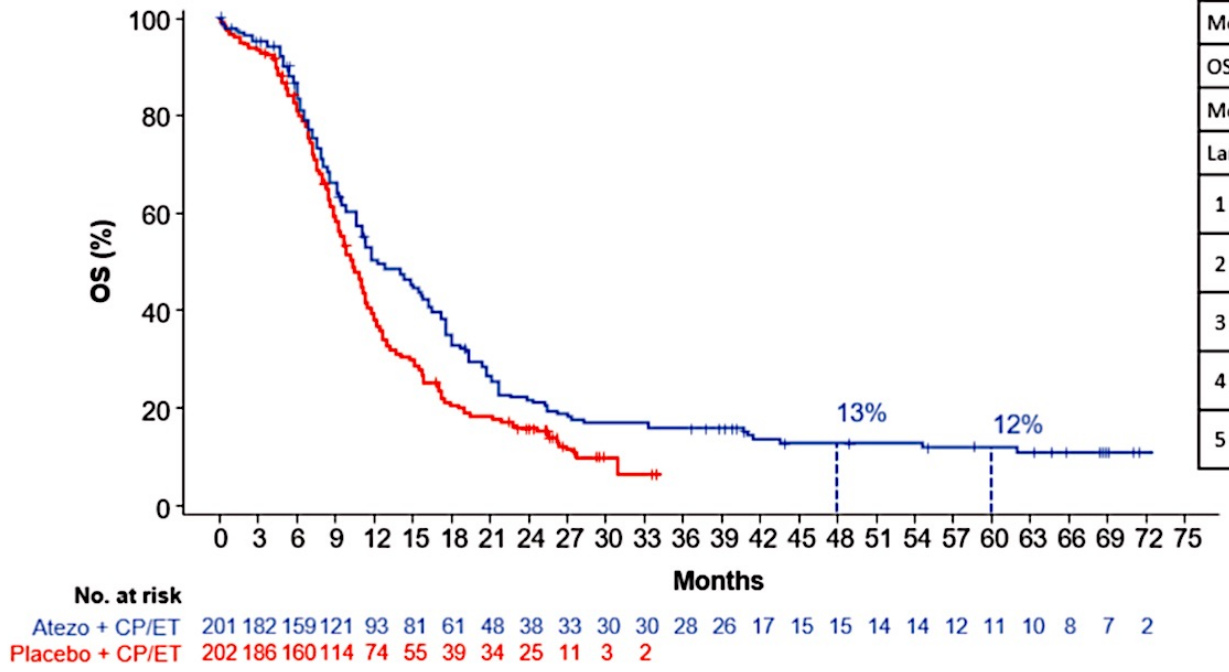
Aiba, et al. *Lung Cancer* 2026.

Durvalumab with superior OS

No significant difference in OS

Are There Long-Term IO Responders in ES-SCLC? Yes!

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

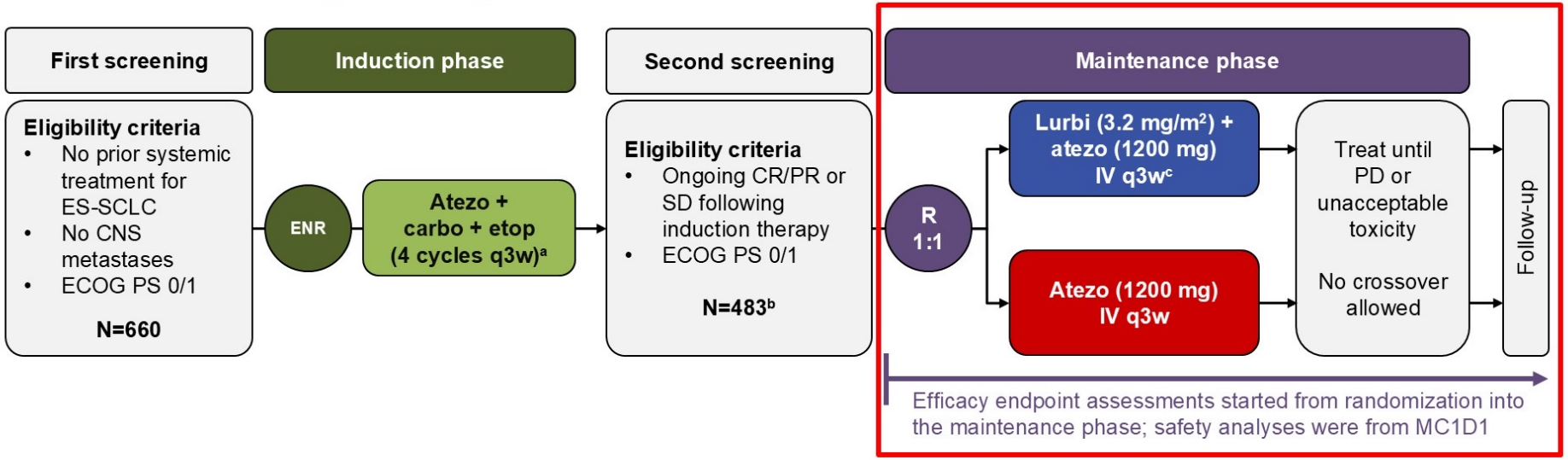


	Atezo + CP/ET (n=201)	Placebo + CP/ET (n=202)
Median follow-up (range), months	59.4 (0.0-72.6)	26.4 (0.0-34.4)
OS events, n (%)	159 (79.1)	169 (83.7)
Median OS (95% CI), months	12.3 (10.8-15.8)	10.3 (9.3-11.3)
Landmark OS estimate (95% CI)		
1 year	52% (45%-59%)	39% (32%-46%)
2 year	22% (16%-28%)	16% (11%-21%)
3 year	16% (11%-21%)	NE[a]
4 year	13% (8%-18%)	NE[a]
5 year	12% (7%-17%)	NE[a]

Reck, et al. *Lung Cancer*. 2024.

Can We Intensify IO Maintenance with Lurbinectedin?

IMforte study design



Stratification factors for randomization
- ECOG PS (0/1)
- LDH (≤ULN/>ULN)
- Presence of liver metastases (Y/N) at induction BL
- Prior receipt of PCI (Y/N)

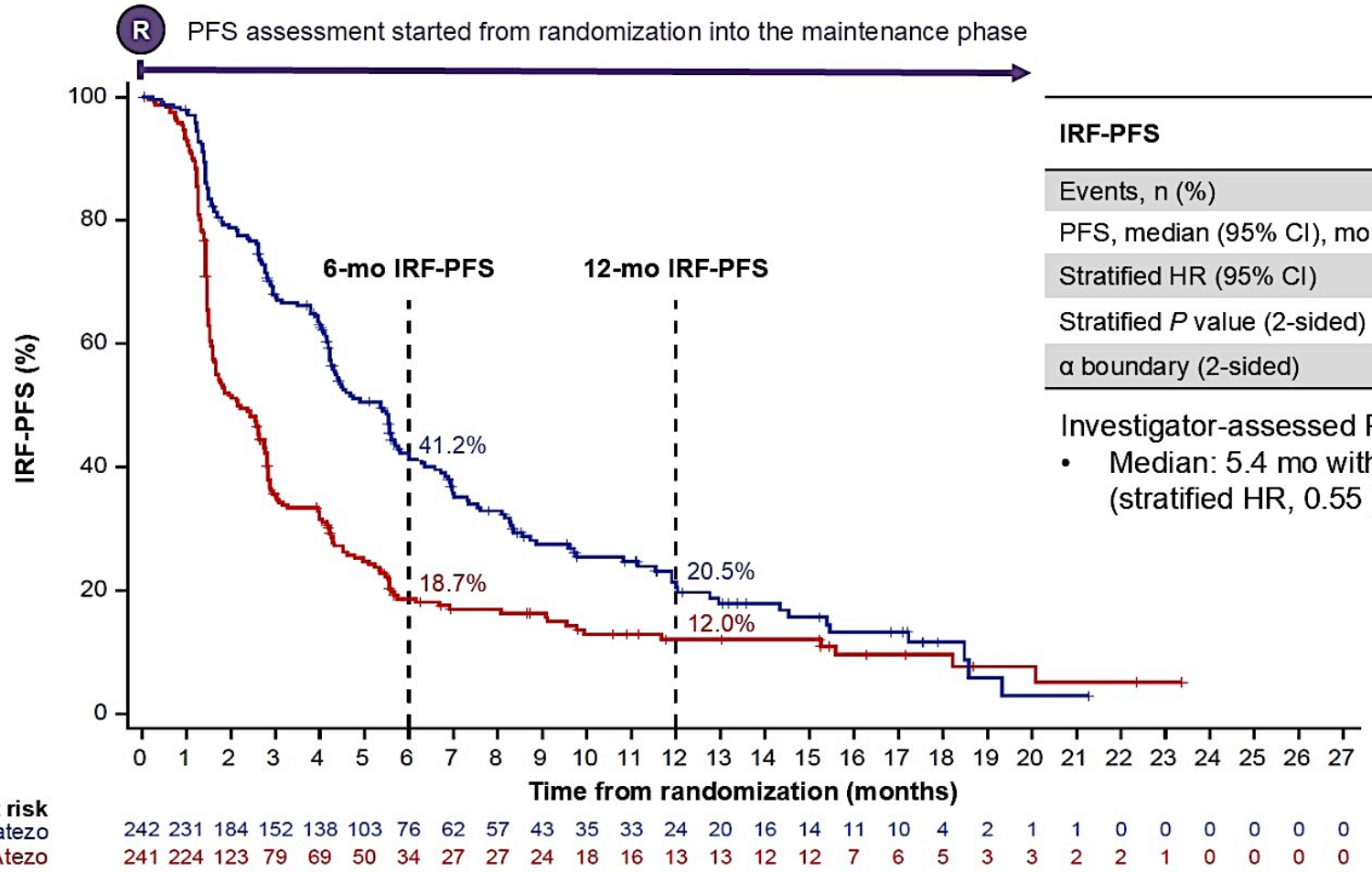
Primary endpoints
IRF-PFS and OS

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.

IRF-PFS from randomization into maintenance phase



IRF-PFS	Lurbi + atezo (n=242)	Atezo (n=241)
Events, n (%)	174 (71.9)	202 (83.8)
PFS, median (95% CI), mo	5.4 (4.2, 5.8)	2.1 (1.6, 2.7)
Stratified HR (95% CI)	**0.54 (0.43, 0.67)**	
Stratified *P* value (2-sided)	<0.0001	
α boundary (2-sided)	0.001	

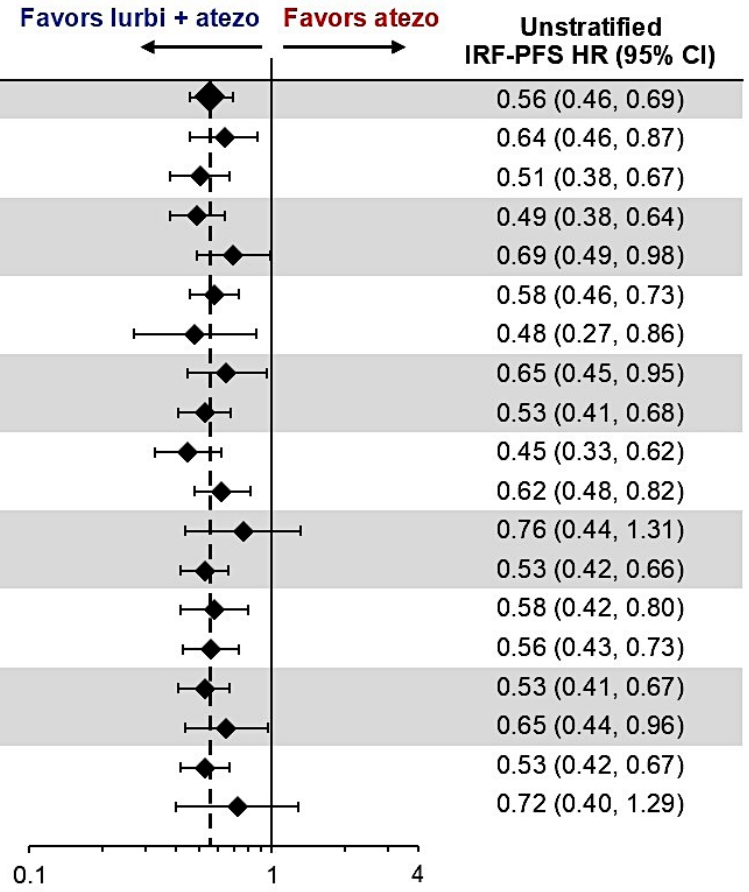
Investigator-assessed PFS was consistent with IRF-PFS

- Median: 5.4 mo with lurbi + atezo and 2.7 mo with atezo (stratified HR, 0.55 [95% CI: 0.45, 0.68])

Clinical cutoff: July 29, 2024; median survival follow-up: 15.0 mo (minimum follow-up: 3.0 mo).
CI, confidence interval; HR, hazard ratio.

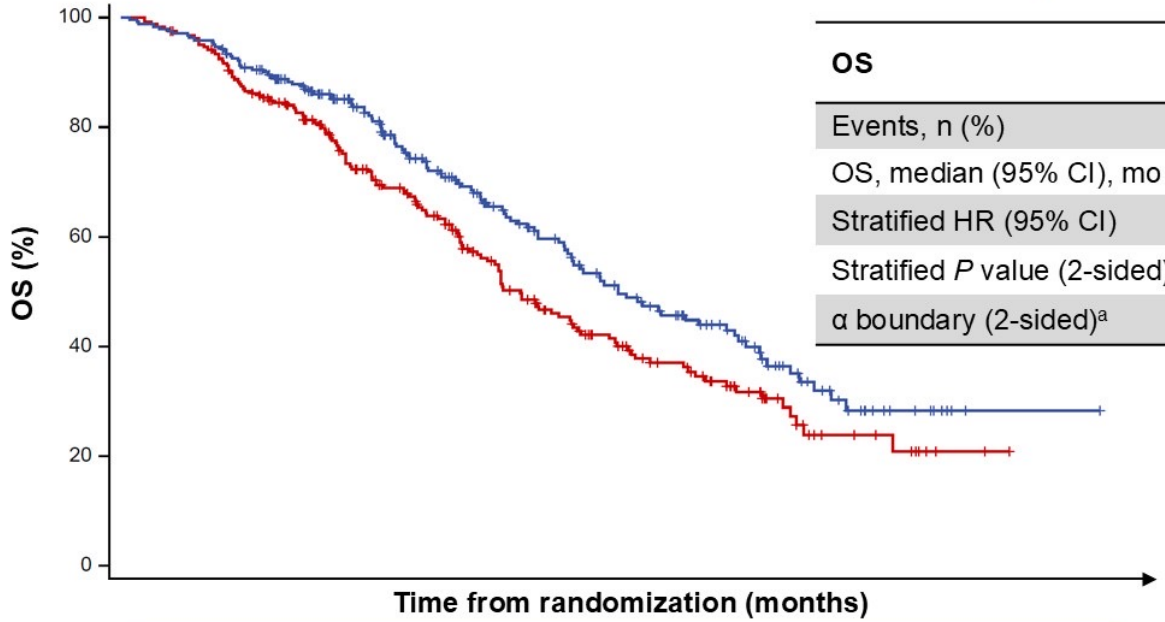
IRF-PFS subgroup analysis

Baseline risk factors		Events/patients, n/N		Unstratified IRF-PFS HR (95% CI)
		Lurbi + atezo	Atezo	
All patients		174/242	202/241	0.56 (0.46, 0.69)
Age, years	<65	86/118	73/90	0.64 (0.46, 0.87)
	≥65	88/124	129/151	0.51 (0.38, 0.67)
Sex	Male	110/151	131/151	0.49 (0.38, 0.64)
	Female	64/91	71/90	0.69 (0.49, 0.98)
Race[a]	White	140/195	167/199	0.58 (0.46, 0.73)
	Asian	22/31	26/31	0.48 (0.27, 0.86)
Tobacco use history[a]	Current	61/88	57/73	0.65 (0.45, 0.95)
	Previous	107/147	141/163	0.53 (0.41, 0.68)
Liver metastases at induction BL[b]	Yes	75/100	87/94	0.45 (0.33, 0.62)
	No	99/142	115/147	0.62 (0.48, 0.82)
Prior PCI[b]	Yes	25/34	29/37	0.76 (0.44, 1.31)
	No	149/208	173/204	0.53 (0.42, 0.66)
ECOG PS[b]	0	76/105	82/102	0.58 (0.42, 0.80)
	1	98/137	120/139	0.56 (0.43, 0.73)
LDH[b]	≤ULN	123/176	150/179	0.53 (0.41, 0.67)
	>ULN	51/66	52/62	0.65 (0.44, 0.96)
Response to induction therapy[a,c]	CR/PR	143/206	176/213	0.53 (0.42, 0.67)
	SD	26/28	23/25	0.72 (0.40, 1.29)



Clinical cutoff: July 29, 2024; median survival follow-up: 15.0 mo (minimum follow-up: 3.0 mo).
[a] Data from subgroups with small numbers are not displayed. [b] Stratification factor for randomization; data determined from electronic case-report forms. [c] n=236 in the lurbi + atezo arm and n=240 in the atezo arm; 7 randomized patients did not have a maintenance screening tumor assessment.

OS from randomization into maintenance phase



OS	Lurbi + atezo (n=242)	Atezo (n=241)
Events, n (%)	113 (46.7)	136 (56.4)
OS, median (95% CI), mo	13.2 (11.9, 16.4)	10.6 (9.5, 12.2)
Stratified HR (95% CI)	**0.73 (0.57, 0.95)**	
Stratified *P* value (2-sided)	0.0174	
α boundary (2-sided)[a]	0.0313	

Induction treatment
Atezo + carbo + etop

3.2 months[a]

R

Maintenance treatment
Lurbi + atezo
Median OS from randomization: 13.2 months

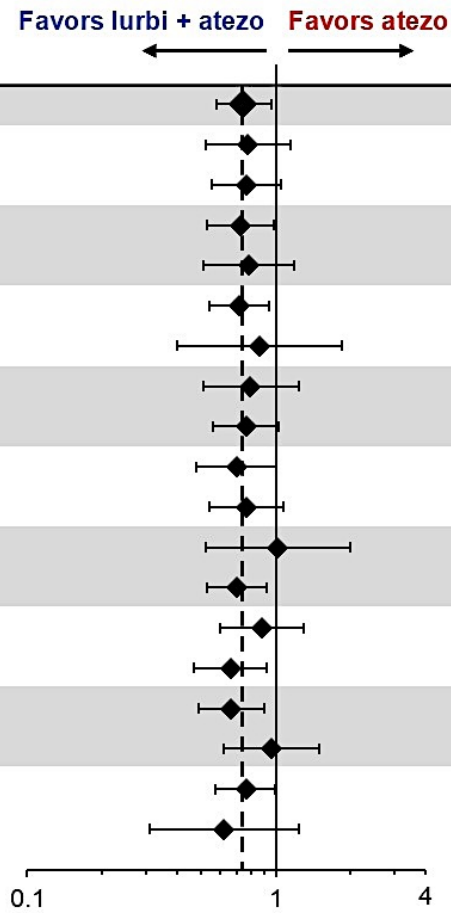
Maintenance treatment
Atezo
Median OS from randomization: 10.6 months

IMforte results do not include time on induction treatment

[a] Median time from start of induction treatment to randomization was analyzed for 483 randomized patients. Note: 660 patients were enrolled into the induction phase, out of whom 177 patients were not randomized into the maintenance phase.

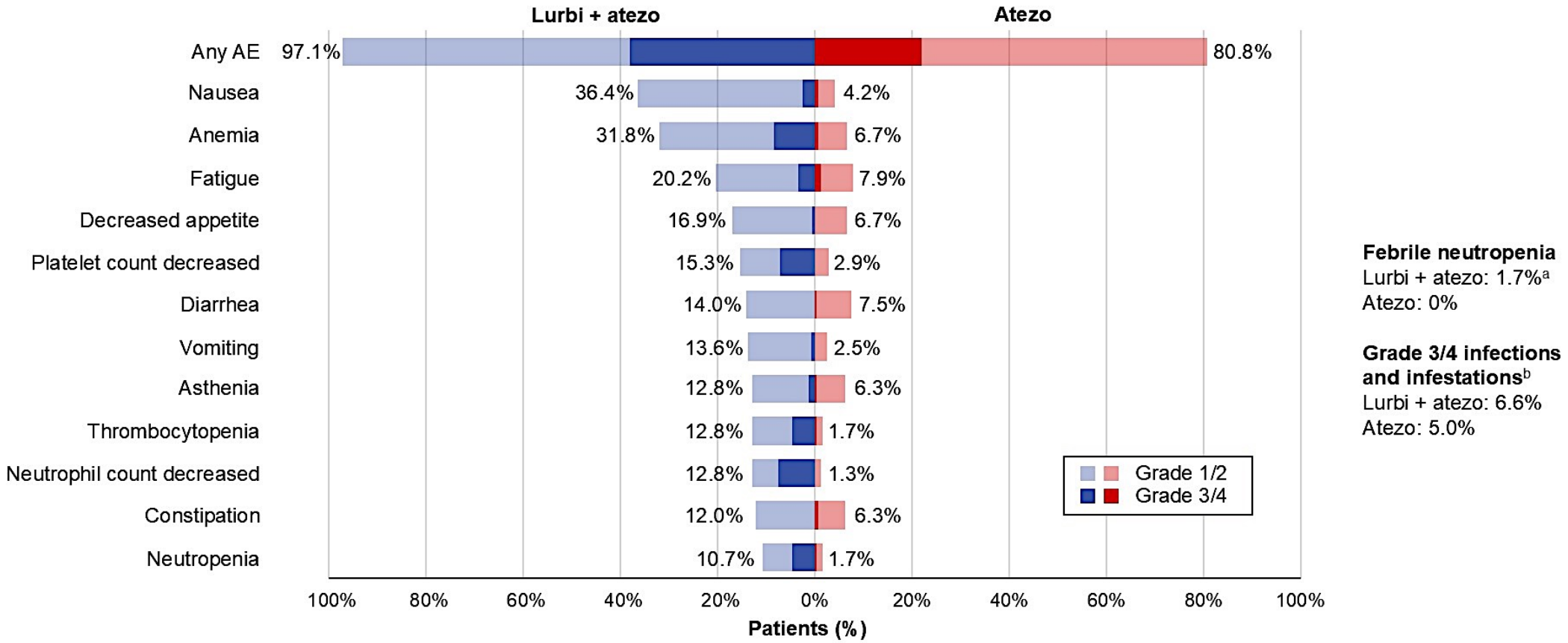
OS subgroup analysis

Baseline risk factors		Events/patients, n/N		Unstratified OS HR (95% CI)
		Lurbi + atezo	Atezo	
All patients		113/242	136/241	0.74 (0.58, 0.96)
Age, years	<65	53/118	49/90	0.77 (0.52, 1.14)
	≥65	60/124	87/151	0.76 (0.55, 1.05)
Sex	Male	75/151	88/151	0.72 (0.53, 0.98)
	Female	38/91	48/90	0.78 (0.51, 1.19)
Race[a]	White	92/195	118/199	0.71 (0.54, 0.94)
	Asian	13/31	14/31	0.86 (0.40, 1.84)
Tobacco use history[a]	Current	38/88	39/73	0.79 (0.51, 1.24)
	Previous	72/147	94/163	0.76 (0.56, 1.03)
Liver metastases at induction BL[b]	Yes	55/100	63/94	0.70 (0.48, 1.00)
	No	58/142	73/147	0.76 (0.54, 1.07)
Prior PCI[b]	Yes	16/34	18/37	1.02 (0.52, 2.00)
	No	97/208	118/204	0.70 (0.53, 0.92)
ECOG PS[b]	0	51/105	53/102	0.88 (0.60, 1.29)
	1	62/137	83/139	0.66 (0.47, 0.92)
LDH[b]	≤ULN	72/176	97/179	0.66 (0.49, 0.90)
	>ULN	41/66	39/62	0.96 (0.62, 1.50)
Response to induction therapy[a,c]	CR/PR	92/206	115/213	0.76 (0.57, 0.99)
	SD	17/28	18/25	0.62 (0.31, 1.24)



Clinical cutoff: July 29, 2024; median survival follow-up: 15.0 mo (minimum follow-up: 3.0 mo).
[a] Data from subgroups with small numbers are not displayed. [b] Stratification factor for randomization; data determined from electronic case-report forms. [c] n=236 in the lurbi + atezo arm and n=240 in the atezo arm; 7 randomized patients did not have a maintenance screening tumor assessment.

All-cause AEs with incidence ≥10% in either arm



Febrile neutropenia
Lurbi + atezo: 1.7%[a]
Atezo: 0%

Grade 3/4 infections and infestations[b]
Lurbi + atezo: 6.6%
Atezo: 5.0%

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).

Tarlatamab (DLL3xCD3)

Phase 2 DeLLphi-301 (NCT05060016)

Randomized to one of two cohorts:

10 mg or 100 mg dose

ORR: 40% (10 mg), 32% (100 mg)

Accelerated approval (May 2024)

Full regulatory approval (Nov 2025)

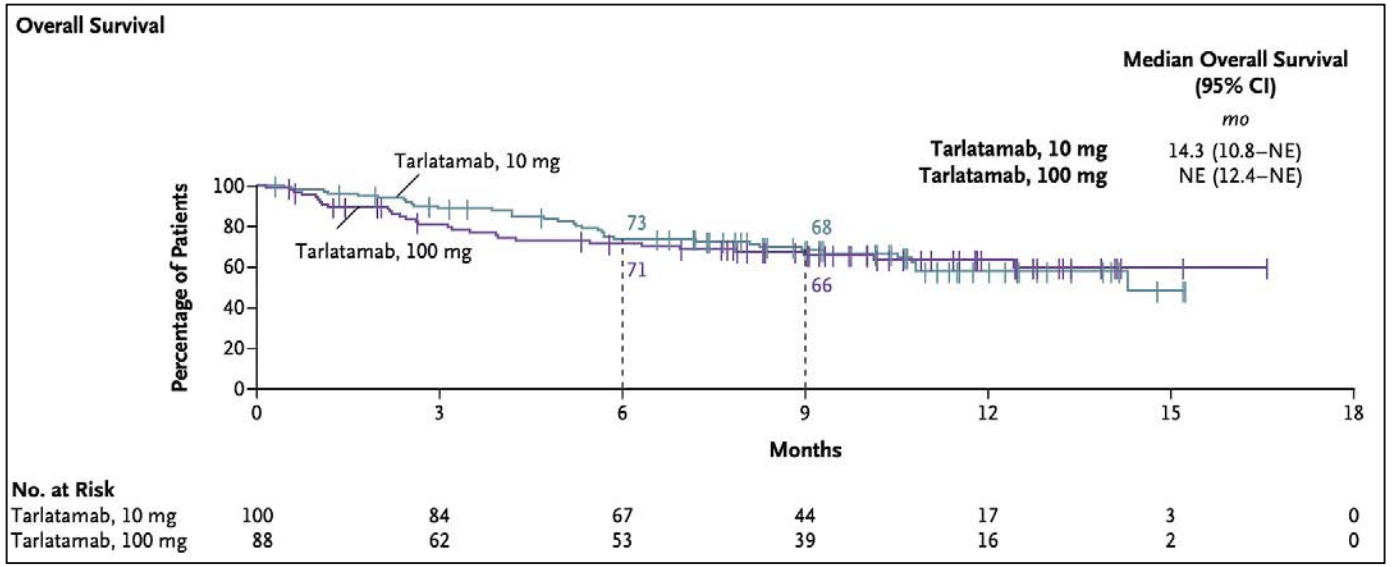
Following platinum-based therapies (2L+)

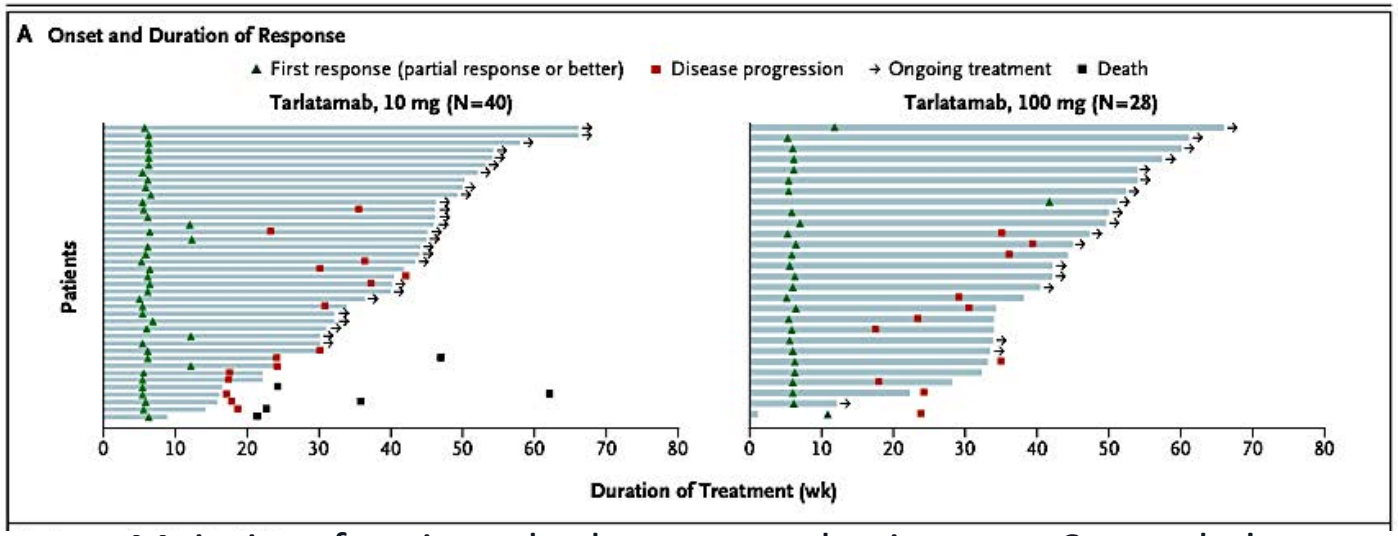
FDA Boxed Warning:

Cytokine release syndrome

Neurotoxicity

C1D1 & C1D8 require 22-24h observation





Majority of patients had responses lasting over 6 months!

Ahn, et al. *NEJM*. 2023.

Phase 1b study of tarlatamab with anti-PD-L1 as 1L maintenance for ES-SCLC: DeLLphi 303 Study[a]

DeLLphi 303

1L Chemo-IO

Platinum-etoposide + anti-PD-L1[c]

(4-6 cycles)

Enrollment

Key Inclusion Criteria

- ✓ No disease progression following 4–6 cycles of 1L chemo-IO
- ✓ ECOG PS 0 or 1
- ✓ Patients with treated and asymptomatic brain metastases were permitted
- ✓ No active autoimmune disease or disease requiring immunosuppressive therapy[d]

Non-randomized[e]

Switching to a different anti-PD-L1 than that received in 1L chemo-IO was permitted

1L Maintenance[b]

Tarlatamab (10 mg IV Q2W) + Atezolizumab (1680 mg IV Q4W) n = 48

Tarlatamab (10 mg IV Q2W) + Durvalumab (1500 mg IV Q4W) n = 40

Primary Endpoints[f]: Dose-limiting toxicities[g], treatment-emergent and treatment-related adverse events
Secondary Endpoints[h]: Progression-free survival, overall survival, objective response rate, duration of response, and disease control

[a]Cohorts 5, 6, and 8; NCT05361395. [b]Maintenance therapy commenced within 8 weeks of the start of the last cycle of 1L chemo-IO. [c]Patients without access to 1L anti-PD-L1 were allowed. [d]Patients with active autoimmune disease requiring systemic treatment (except replacement therapy) within the past 2 years were excluded. [e]Patients were allocated to treatment arms in a non-randomized manner based on slot availability. [f]Also included vital signs, electrocardiograms, and clinical laboratory tests [g]Dose-limiting toxicities were assessed for cohort 5 only. [h]Also included serum concentrations of tarlatamab, quantification of biomarker expression, and incidence of anti-tarlatamab antibody formation. **1L:** first-line; **chemo-IO:** chemo-immunotherapy; **ECOG PS:** Eastern Cooperative Oncology Group performance status; **ES-SCLC:** extensive-stage small cell lung cancer; **IV:** intravenous; **PD-L1:** programmed death-ligand 1; **Q2W:** once every 2 weeks; **Q4W:** once every 4 weeks.

SABCS 2025, Abstract OA13.01.

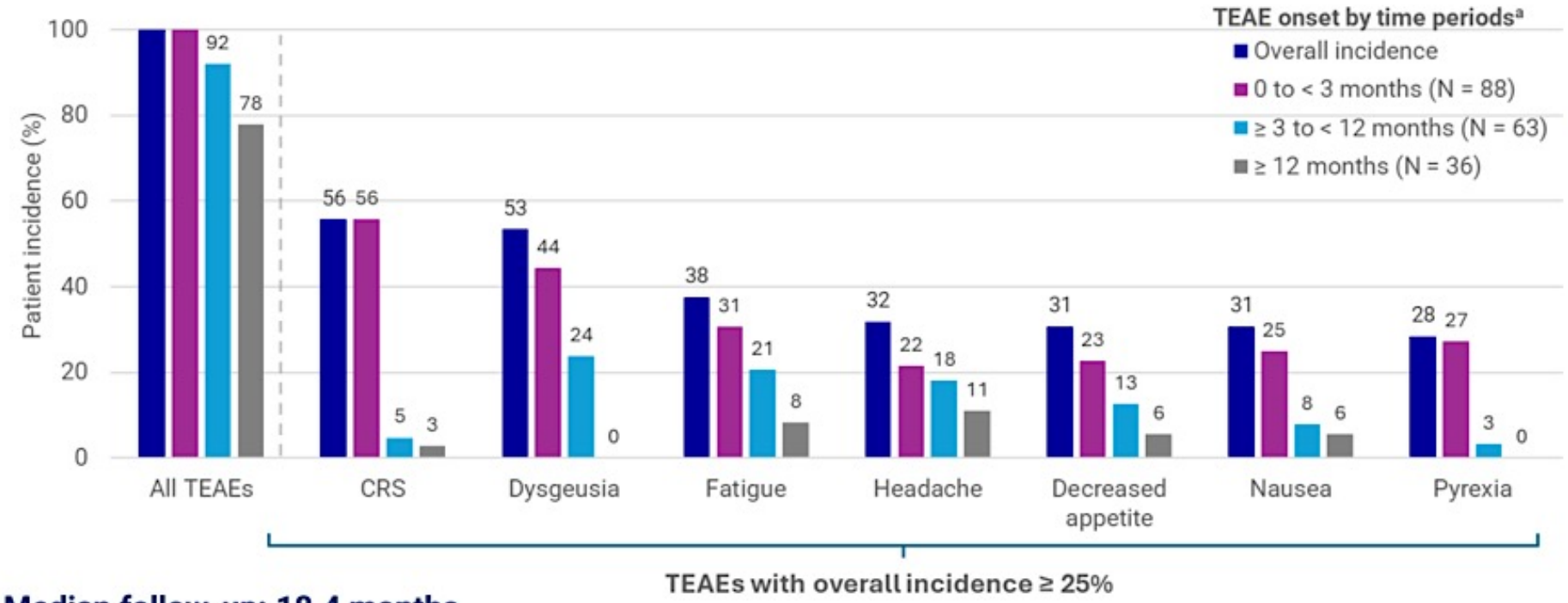
Baseline characteristics of patients receiving 1L maintenance therapy

Characteristics	Tarlatamab + Atezolizumab (n = 48)	Tarlatamab + Durvalumab (n = 40)	Overall Tarlatamab + Anti-PD-L1 (N = 88)
Age, median (range), years	64 (27–79)	64 (37–85)	**64 (27–85)**
Male, %	67	58	**63**
Race (Asian/White/Other), %	19/71/10	20/70/10	**19/70/10**
ECOG PS (0/1), %	38/63	45/55	**41/59**
Median sum of lesion diameters, mm	29.2	37.0	**33.0**
Smoking history (never/current/former), %	2/23/75	8/25/68	**5/24/72**
Disease stage at initial diagnosis (limited/extensive/missing), %	15/81/4	10/90/0	**13/85/2**
Prior no. of 1L EP cycles, (4/5/6), %	83/10/6	83/3/15	**83/7/10**
Prior anti-PD-L1, %	88	88	**88**
Prior radiotherapy, %	25	35	**30**
Presence of brain[a]/liver metastases, %	19/31	33/43	**25/36**
Median time from start of 1L chemo-IO to 1LM, months (range)	3.6 (2.9–5.8)	3.5 (2.9–5.4)	**3.6 (2.9–5.8)**

[a]All patients had received prior treatment for brain metastases.
1L: first-line; **1LM:** first-line maintenance; **chemo-IO:** chemo-immunotherapy; **ECOG PS:** Eastern Cooperative Oncology Group performance status; **EP:** etoposide-platinum; **PD-L1:** programmed death-ligand 1.

SABCS 2025, Abstract OA13.01.

Incidence of treatment-emergent adverse events decreased over time, supporting long-term tolerability



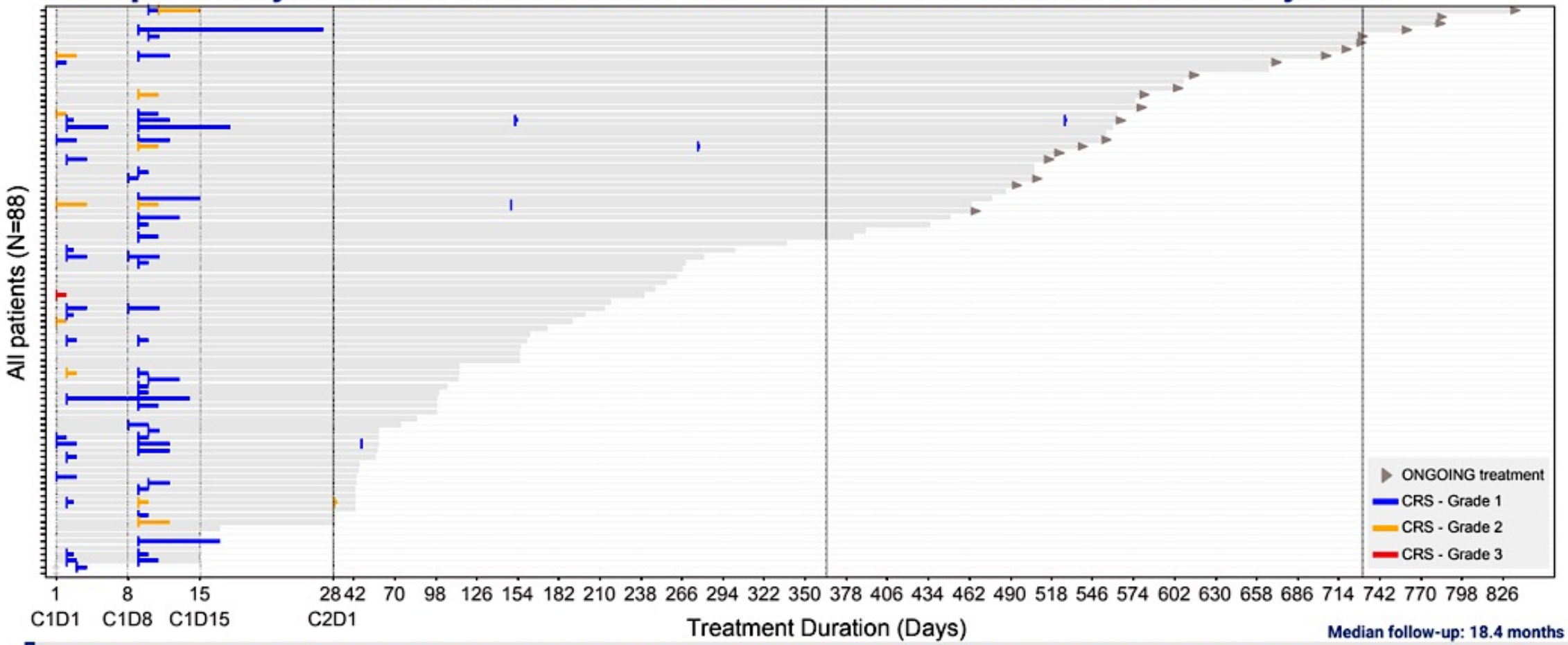
- **ICANS occurred in 5 (6%) patients, all with early onset (< 3 months)**
  - **All events were grade 1-2 and resolved with supportive care**

Median follow-up: 18.4 months

Tarlatamab in combination with anti-PD-L1 had a manageable safety profile.

[a]The patient incidence of TEAE onset by time periods (0 to < 3 months, ≥ 3 to < 12 months, ≥ 12 months) was assessed. **CRS:** cytokine release syndrome; **ICANS:** immune effector cell-associated neurotoxicity syndrome; **TEAE:** treatment-emergent adverse event.

CRS primarily occurred after the first or second tarlatamab dose in cycle 1

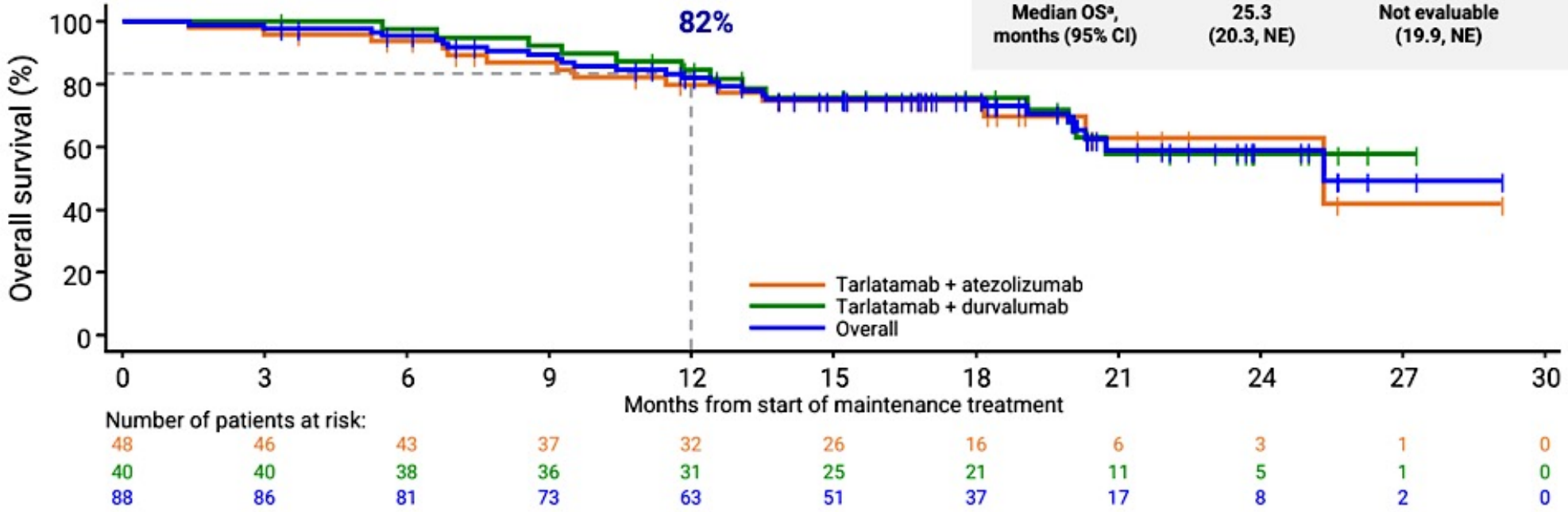


CRS occurred in 49 (56%) of patients, with most events grade 1 (43%) or grade 2 (11%); all CRS events resolved.

CRS (grade 1) led to tarlatamab interruption in one patient . Tarlatamab dose was reduced (i.e., repeat step dosing) in one patient with grade 3 CRS. No CRS events of grade 4 or 5 occurred. The four CRS events after 3 months occurred with tarlatamab rechallenge. **CRS**: cytokine release syndrome.

Overall survival with addition of tarlatamab to anti-PD-L1 as 1L maintenance therapy

	Tarlatamab+ Atezolizumab	Tarlatamab+ Durvalumab	Overall Tarlatamab + Anti-PD-L1
Median OS[a], months (95% CI)	25.3 (20.3, NE)	Not evaluable (19.9, NE)	25.3 (20.3, NE)



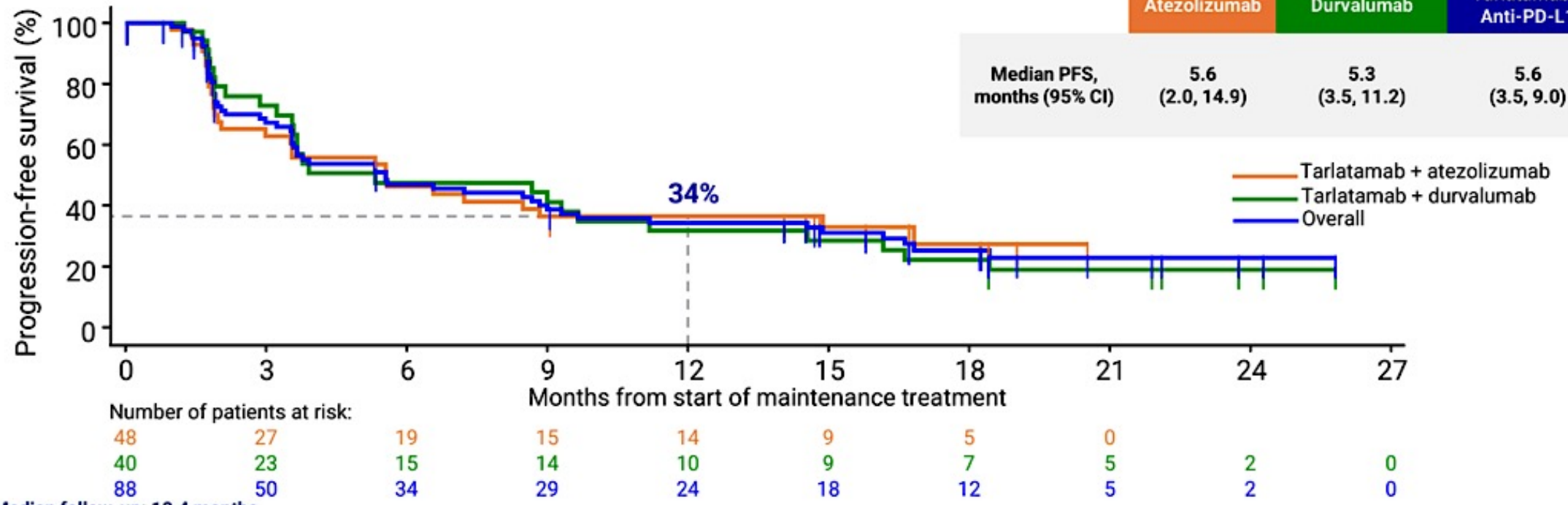
With a median follow-up time of 18.4 months, tarlatamab with anti-PD-L1 as 1L maintenance therapy led to a median OS of 25.3 months (95% CI, 20.3, NE).

[a]The median OS is immature and will continue to evolve with longer follow-up time. **1L:** first-line; **CI:** confidence interval; **NE:** not evaluable; **OS:** overall survival; **PD-L1:** programmed death-ligand 1.

SABCS 2025, Abstract OA13.01.

Progression free survival with addition of tarlatamab to anti-PD-L1 as 1L maintenance therapy

	Tarlatamab+ Atezolizumab	Tarlatamab+ Durvalumab	Overall Tarlatamab + Anti-PD-L1
Median PFS, months (95% CI)	5.6 (2.0, 14.9)	5.3 (3.5, 11.2)	5.6 (3.5, 9.0)



Number of patients at risk:

48	27	19	15	14	9	5	0		
40	23	15	14	10	9	7	5	2	0
88	50	34	29	24	18	12	5	2	0

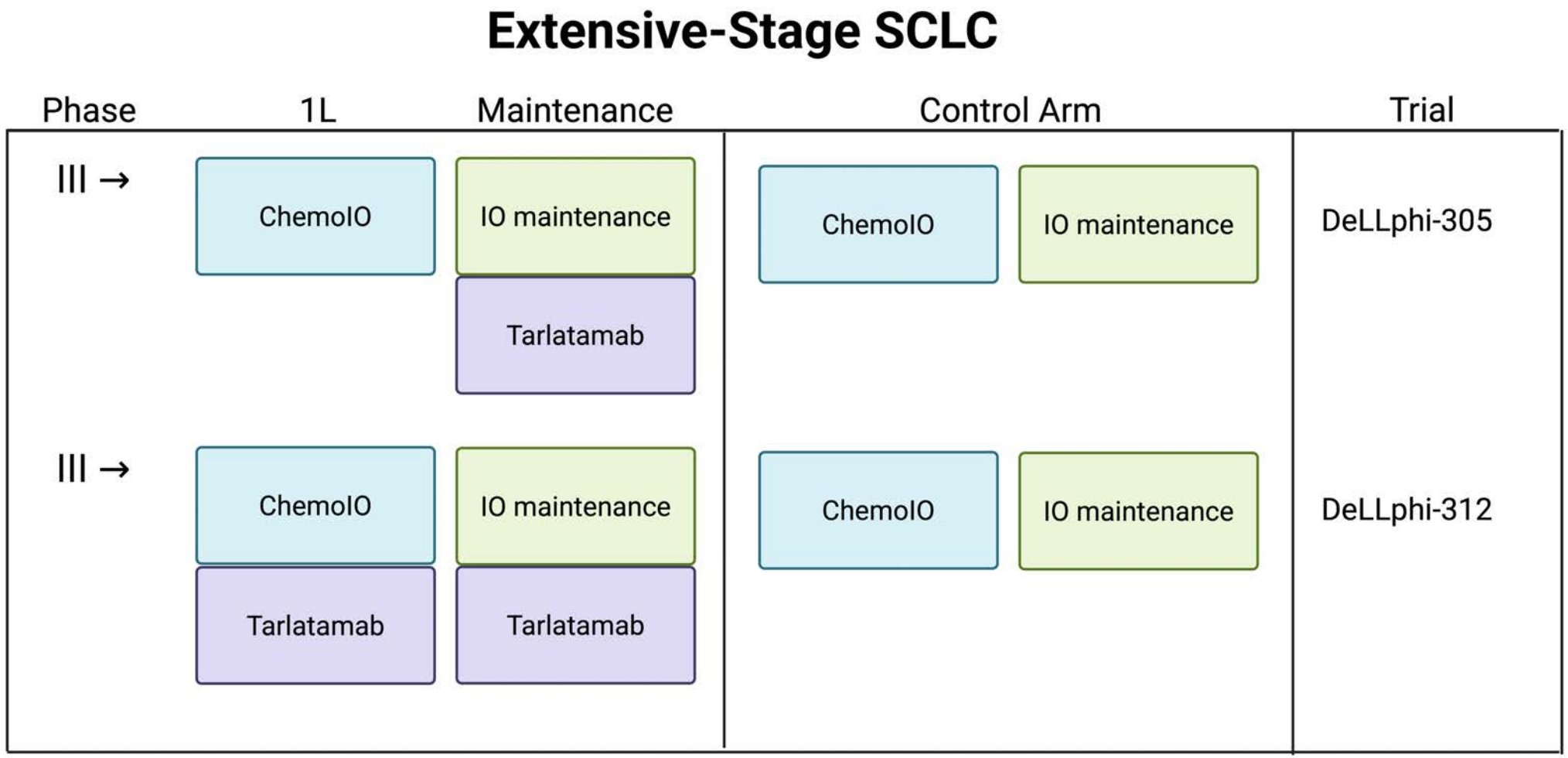
Median follow-up: 18.4 months

Tarlatamab with anti-PD-L1 as 1L maintenance therapy led to a median PFS of 5.6 months (95% CI, 3.5, 9.0).

1L: first-line; **CI:** confidence interval; **PD-L1:** programmed death-ligand 1; **PFS:** progression-free survival.

SABCS 2025, Abstract OA13.01.

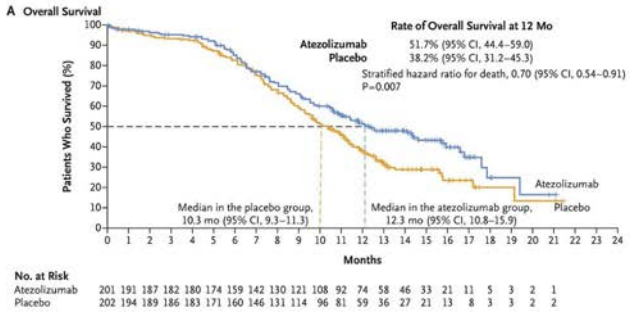
Ongoing Phase 3 Trials with Tarlatamab in SCLC



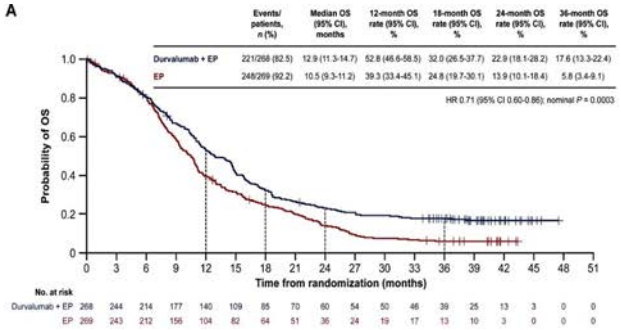
https://clinicaltrials.gov/study/NCT06211036; https://clinicaltrials.gov/study/NCT07005128.

Can NE Subtyping Help Inform Treatments after 1L ChemoIO?

IMpower133

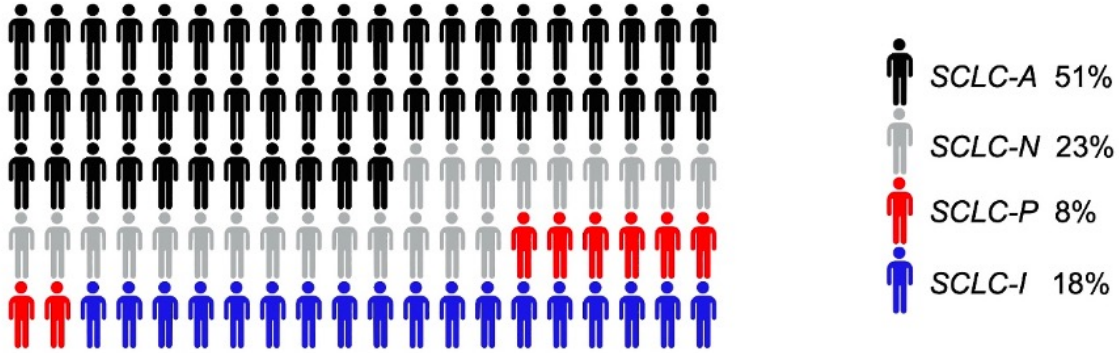


CASPIAN



Horn, et al. *NEJM* 2018; Paz-Ares, et al. *Lancet* 2019/ESMO Open 2022.

Neuroendocrine Subtype Distribution of Treatment-Naïve Extensive-Stage SCLC



S2409-PRISM: A Multicohort **PR**ec**I**sion **S**CLC Subtype **M**aintenance Phase II Trial of Immunotherapy Versus Biomarker-Directed Novel Agents in Combination with Immunotherapy in Extensive Stage Small Cell Lung Cancer (ES-SCLC)

Step 1: Tissue screening & Induction (n=~900)

- ES-SCLC Screening
- Tissue available for testing
- Asymptomatic or Stable Treated Brain Lesions
- Allows consent after initial cycle for tissue screening

Step 2: Randomization (n=312)

Subtypes A/N, SLFN11 pos or Subtype P N=134	Immunotherapy + PARP inhibitor / Immunotherapy
Subtypes A/N, SLFN11 neg N=84	Immunotherapy + ATR inhibitor / Immunotherapy
Subtype I N=84	Immunotherapy + NK activator / Immunotherapy

Primary Endpoints: PFS

Secondary Endpoints: OS, Frequency, Severity of Adverse Events

SWOG CANCER RESEARCH NETWORK

NCI National Clinical Trials Network a National Cancer Institute program · NCI Community Oncology Research Program

Shields, Chiang, Byers. *Cancer.* 2025.

Questions Remain for ES-SCLC:

- **Does the IO backbone for 1L chemoIO impact outcomes?**

No difference in Phase 3 studies (IMpower133, CASPIAN), RWD is mixed/unclear.

- **Maintenance strategies with similar PFS benefit (possible differential OS benefit)?**

Lurbinectedin (Phase 3) vs. tarlatamab (Phase 1b; Phase 3 DeLLphi-305, in progress).

- **Management of brain metastases?**

Avoid lurbinectedin, choose agents with intracranial activity & limit XRT to SRS.

- **Can knowledge of NE subtypes personalize maintenance strategies?**

SWOG S2409 PRISM will address.

Second Opinion

Ticiana Leal, MD

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

Discussion Questions

How are you incorporating the strategy evaluated in the IMforte trial into your day-to-day practice? Do you discuss this approach with all patients at the diagnosis of ES-SCLC, or do you wait until the completion of induction therapy to gauge response, tolerability, etc?

Are there circumstances in which you prefer atezolizumab/carboplatin/etoposide over durvalumab/platinum/etoposide or vice versa for your patients with newly diagnosed ES-SCLC? Would you be comfortable combining lurbinectedin with durvalumab in the maintenance setting for a patient with ES-SCLC who received induction therapy with durvalumab/platinum/etoposide?

Discussion Questions (Continued)

What has been your experience with the tolerability of lurbinectedin in the up-front maintenance setting? How frequently have you had to employ dose holds or dose modifications? What is your approach to the use of prophylactic G-CSF? Has this generally been effective for maintaining patients on therapy?

Second Opinion

Charu Aggarwal, MD

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

Discussion Questions

How would you proceed in the case of Dr Aggarwal's patient? Do you recommend lurbinectedin maintenance to your patients with ES-SCLC and brain metastases given that they were excluded from the IMforte trial?

How would you approach the initiation of lurbinectedin maintenance for a patient with disease-related complications that render them too unwell to start at the beginning of the maintenance phase? Would you consider adding it later?

Do you recommend consolidation radiation therapy after first-line chemoimmunotherapy for any of your patients with ES-SCLC? If so, which ones, and how do you sequence the immunotherapy and the radiation therapy?

Agenda

Module 1: Optimizing First-Line and Maintenance Therapy for Extensive-Stage Small Cell Lung Cancer (SCLC) — Dr Shields

Module 2: Management of Relapsed/Refractory SCLC — Dr Paz-Ares

Module 3: Ongoing Investigation and Potential Role of Antibody-Drug Conjugates in SCLC — Dr Chiang

Module 4: Management of Limited-Stage SCLC — Dr Ganti

CENTRO INTEGRAL DE CÁNCER
Comprehensive Cancer Center
SaludMadrid
12 de Octubre

cnio SPANISH NATIONAL CANCER RESEARCH CENTRE

UNIVERSIDAD COMPLUTENSE MADRID

Small Cell Lung Cancer:

Management of Relapsed/Refractory (R/R) disease

Luis Paz-Ares

CCC & Hospital Universitario 12 de Octubre

Agenda

- Lurbinectedin
  - Monotherapy and combos
- TCEs
  - Tarlatamab
  - Others

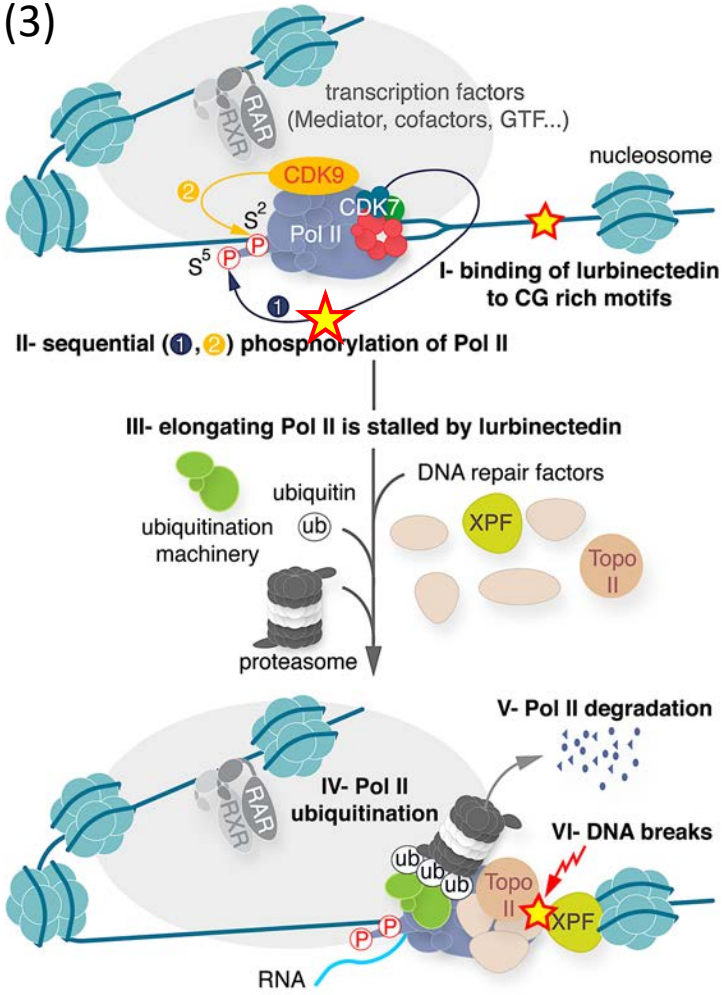
Agenda

- **Lurbinectedin**
  - **Monotherapy and combos**
- **TCEs**
  - **Tarlatamab**
  - **Others**

Lurbinectedin

- FDA grants accelerated approval to lurbinectedin for SCLC based on efficacy shown in multicohort clinical trial (PM1183-B-005-14, NCT02454972)[(1)]
- Second-line treatment option for metastatic and recurrent SCLC[(2)].

(3)

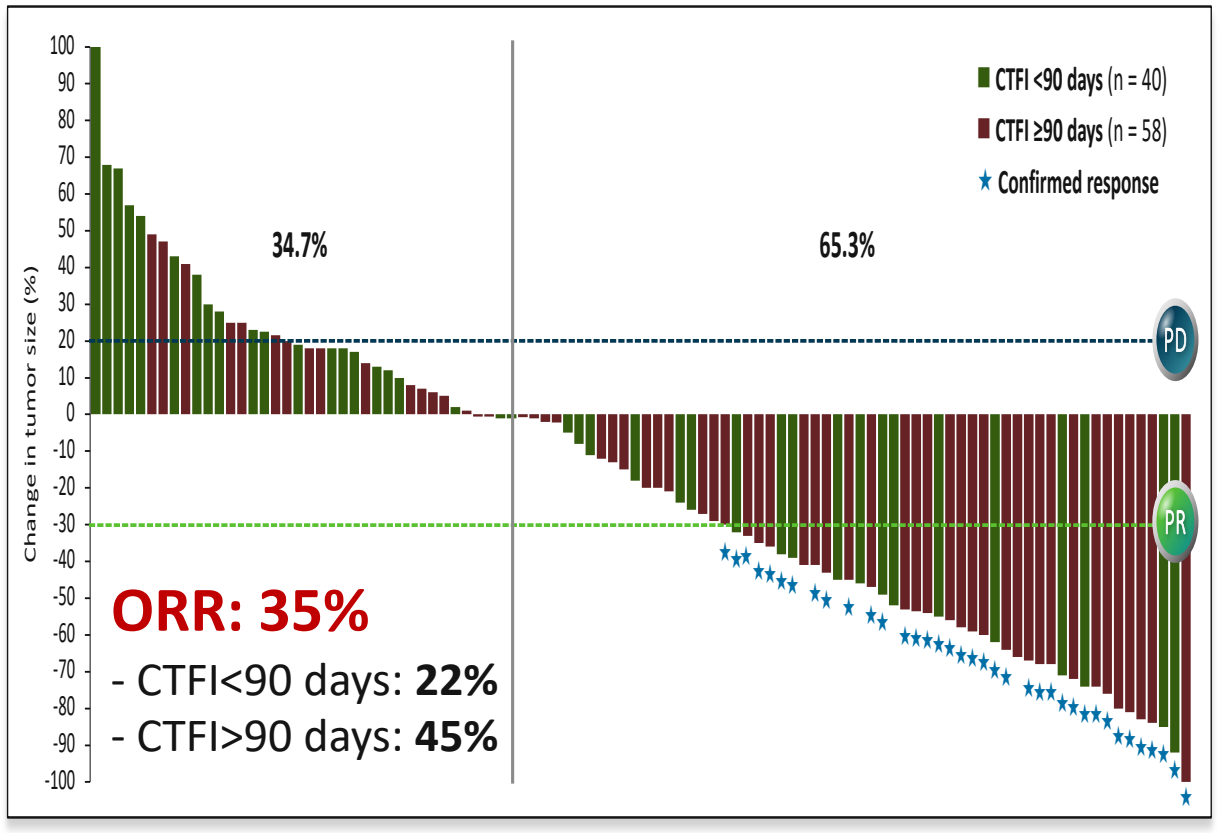


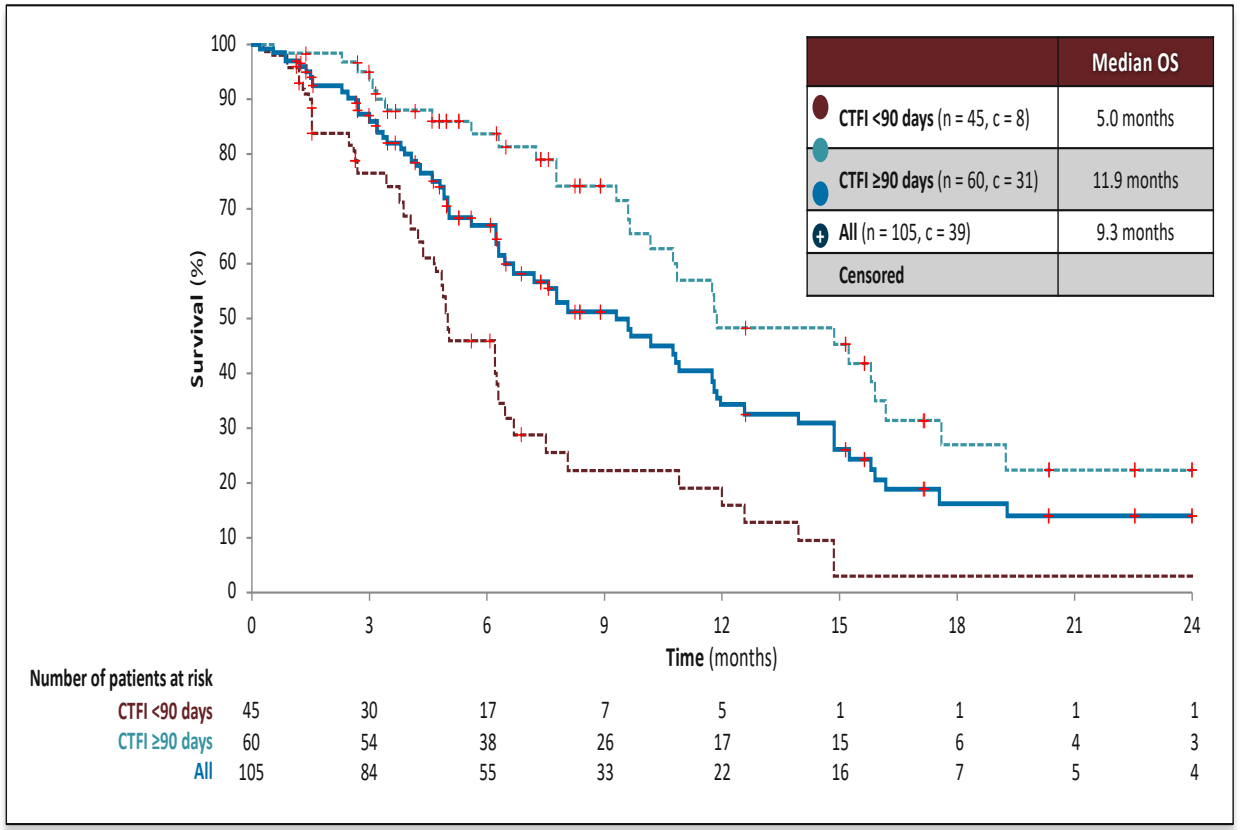
Mechanism of action[(3)]

- Lurbinectedin binds to DNA at CG-rich regions near promoters of protein-coding genes.
- Lurbinectedin stalls RNA Pol II and promotes phosphorylation of RNA Pol II.
- Phosphorylated RNA Pol II is target of ubiquitin-proteasome degradation at site of transcription → **Transcription Inhibition** → **Tumour growth arrest**.
- Macro-complex of RNA Pol II/Proteasome Degradation Machinery promotes double stranded DNA breaks → **DNA Damage Repair Overstressed** → **Apoptosis**.

(1) Singh et al., 2021, *Clinical Cancer Reseach.* (2) Patel et al., 2021, *Therapeutic Advances in Medical Oncology.*
(3) Santamaría Nuñez et al., 2016, *Molecular cancer therapeutics.*

Lurbinectedin basket trial – SCLC Cohort (Pretreated)

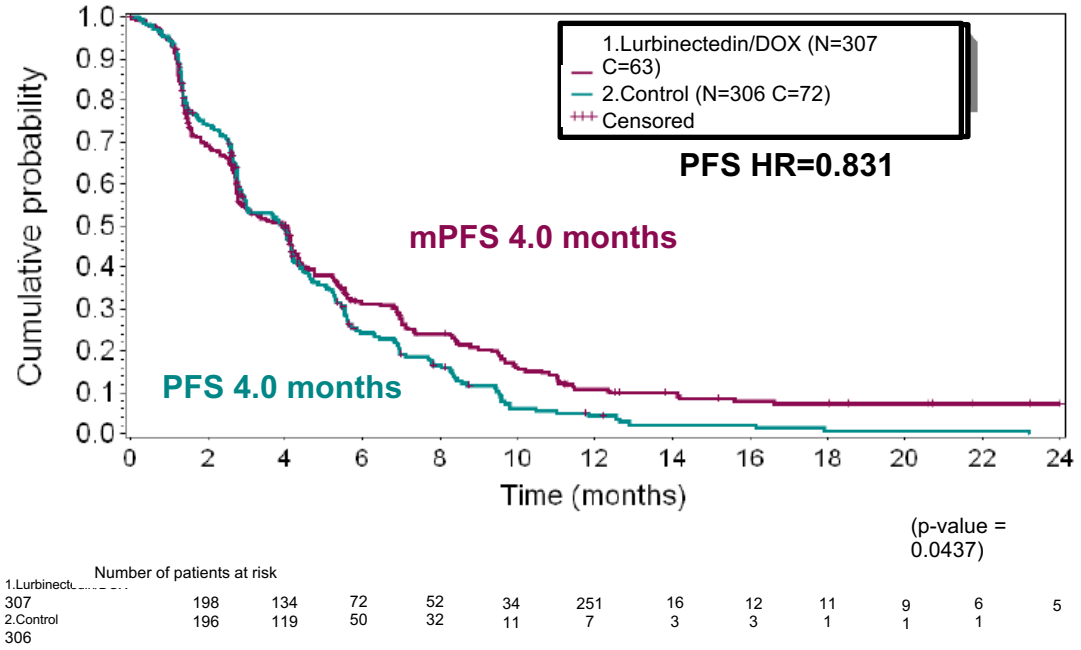




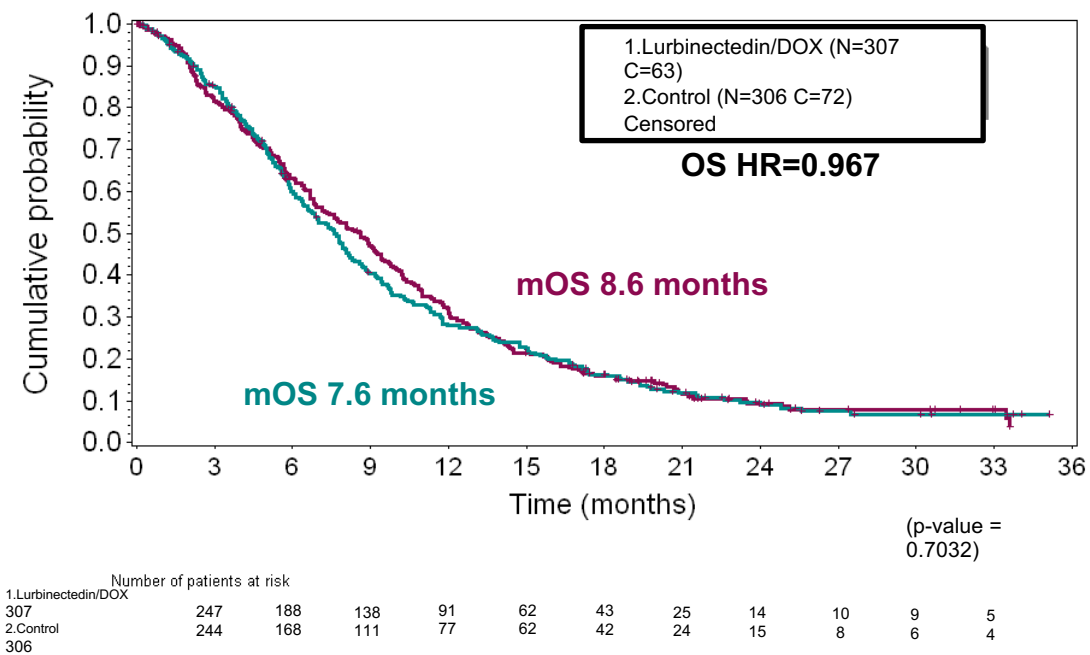
Trigo J, et al. Lancet Oncol. 2020;21(5):645-654..

Atlantis Trial: Lurbinectedin plus Doxorubicin
No impact in OS or PFS

Progression-freeSurvival

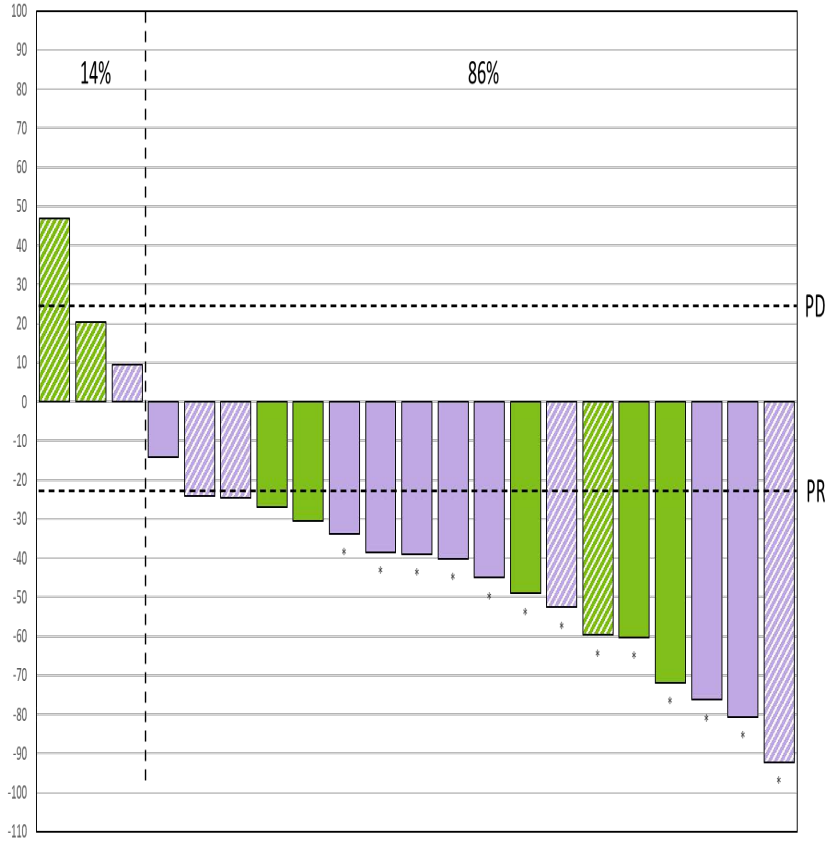


Overall Survival

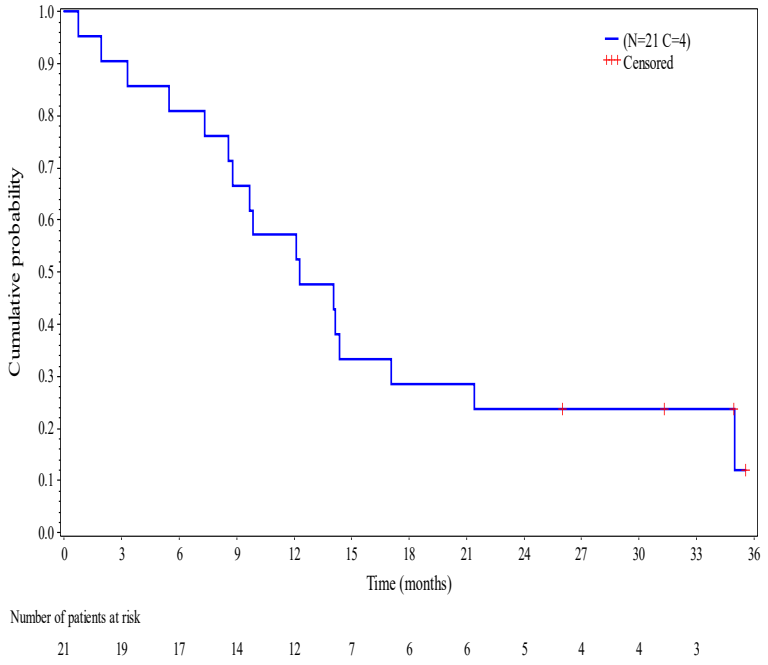


Paz-Ares et al. WCLC 2021 (PL02.03), S Poncet et al. Lancet Resp Med 2023

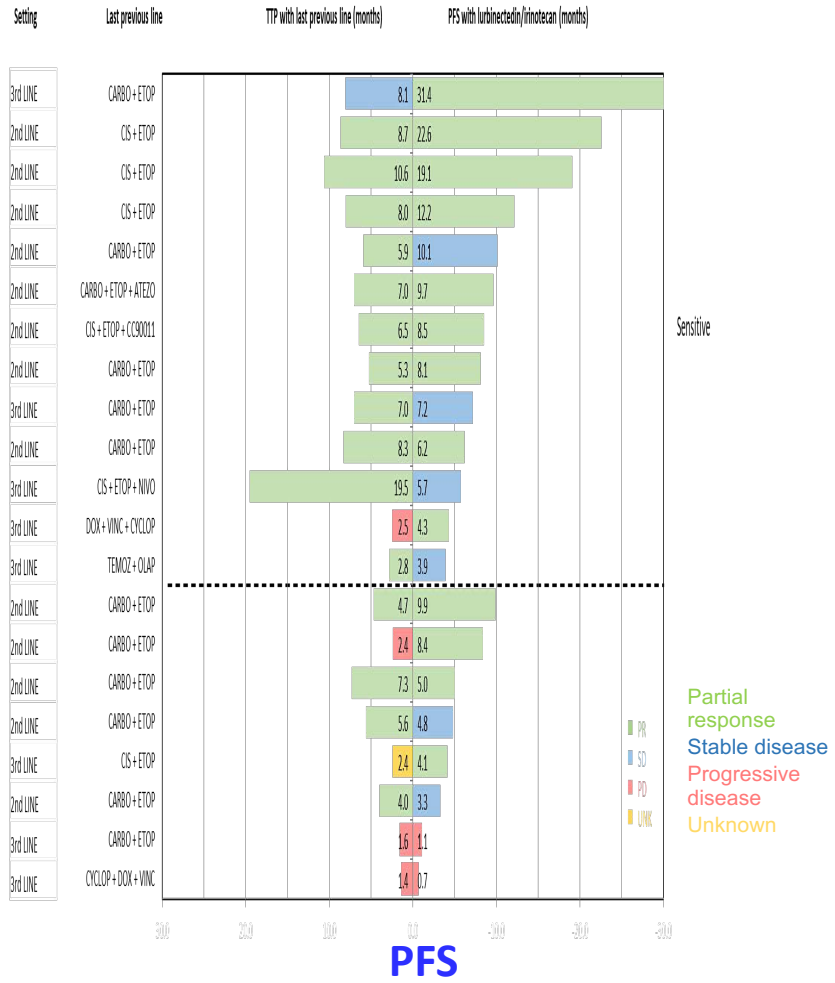
Lurbinectedin plus Irinotecan Phase I-II trial



N =21
ORR 61,9%



Median OS
12,3 months



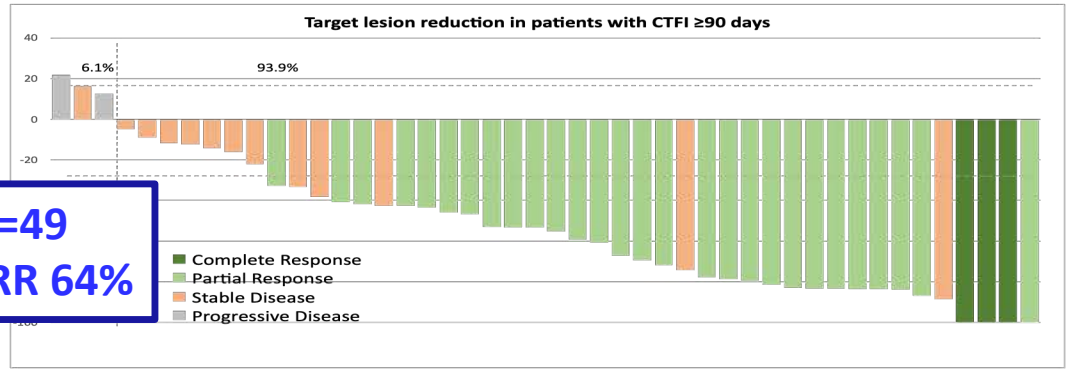
PFS

Ponce,.Paz-Ares JTO 2026

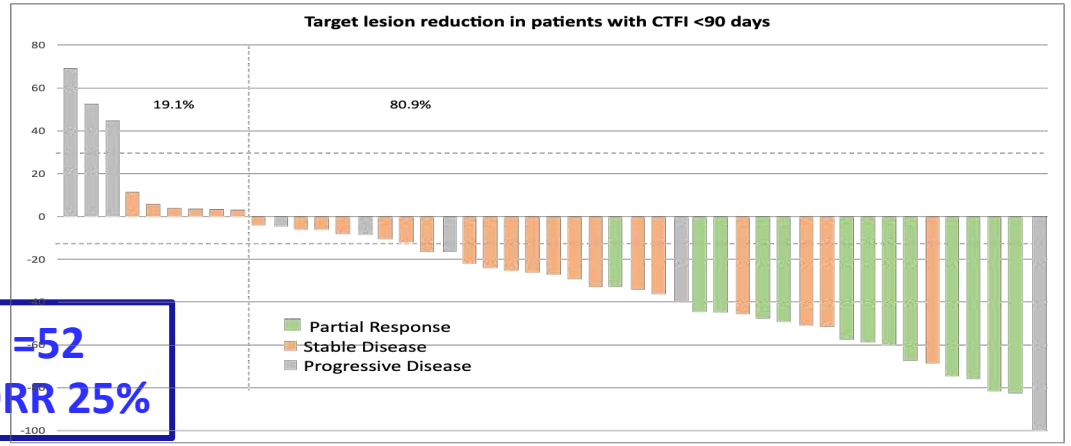
Lurbinectedin plus Irinotecan Phase II trial

	All pts (n=101)	CTFI<90 d (n=52)	CTFI≥90 d (n=49)	CTFI>30 d (n=74)
ORR by IRC, % (95% CI)	43.6 (33.7-53.8)	25.0 (14.0-38.9)	63.3 (48.3-76.6)	52.7 (40.7-64.4)
DoR by IRC (mo), median (95% CI)	7.1 (4.6-9.4)	6.9 (3.9-7.6)	8.2 (4.4-12.4)	7.6 (4.6-9.7)
PFS by IRC (mo), median (95% CI)	4.7 (3.8-5.7)	3.3 (2.6-5.0)	5.7 (4.2-8.3)	5.0 (4.1-7.2)
OS (mo), median (95% CI)	9.6 (7.8-13.4)	7.5 (3.5-8.8)	14.0 (10.1-21.4)	12.7 (9.1-14.1)
OS rate at 12 mo, % (95% CI)	43.4 (33.4-53.4)	25.3 (13.2-37.5)	63.1 (49.1-77.2)	52.0 (40.3-63.8)

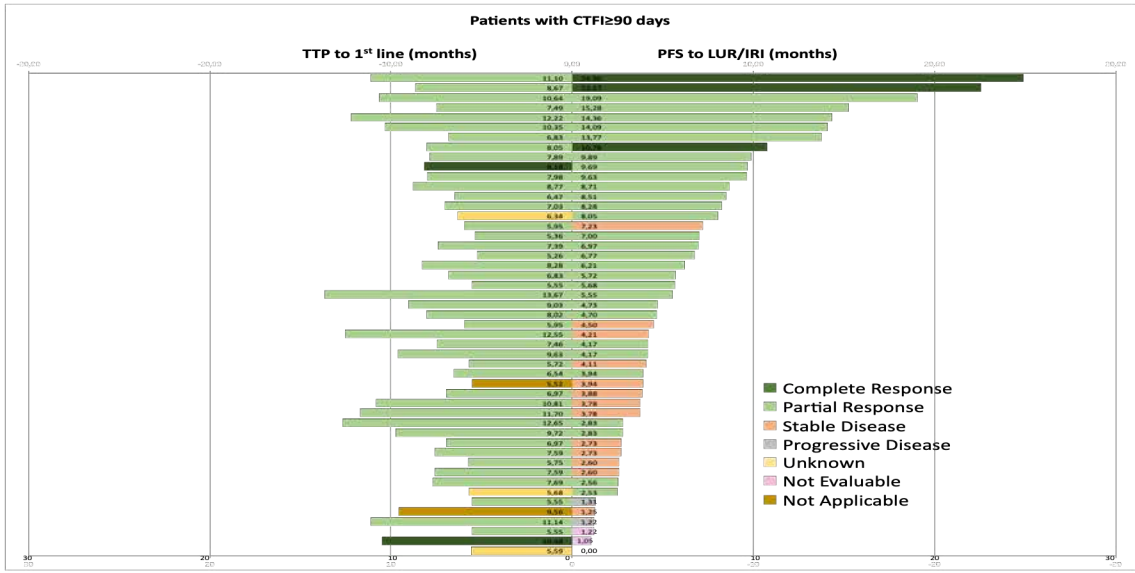
CI, confidence interval; CTFI, chemotherapy-free interval; d, days; DoR, duration of response; mo, months; ORR, overall response rate; OS, overall survival; PFS, progression free survival.

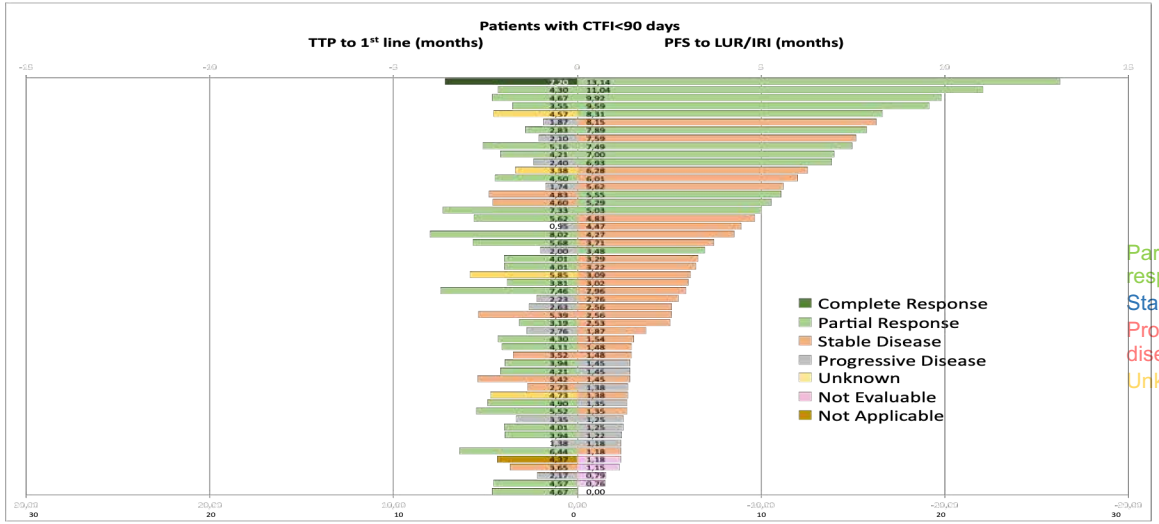


N =49
ORR 64%



N =52
ORR 25%





Paz-Ares et al. ASCO 2024

Lagoon trial design

- Relapsed SCLC
- One prior platinum containing regimen
- CTFI ≥30 days
- ECOG 0-2

Stratification Factors

- CTFI (≥ 90 days, <90 days)
- Prior PD-L1/PD-1 (Y/N)
- LDH (> ULN or ≤ ULN)
- CNS involvement (Y/N)
- Investigator´s preference of the control arm

Randomization
1:1:1
705 patients

Arm A

Lurbinectedin 3.2 mg/m^2 every 3 weeks

Arm B

Lurbinectedin 2 mg/m^2 every 3 weeks
+ Irinotecan 75 mg/m^2 D1,8 q3wks
+ G-CSF

Arm C - Physician's choice

Topotecan oral 2.3 mg/m^2 d1-5 q3wks
or
Topotecan IV 1.5 mg/m^2 d1-5 q3wks
or
Irinotecan 350 mg/m^2 d1 q3wks

Primary Endpoint:
Overall Survival
Arm A vs. C
90% powered to deliver
HR 0.81

https://clinicaltrials.gov/ct2/show/NCT05153239

2SMALL Trial (Lurbe + Atezo)

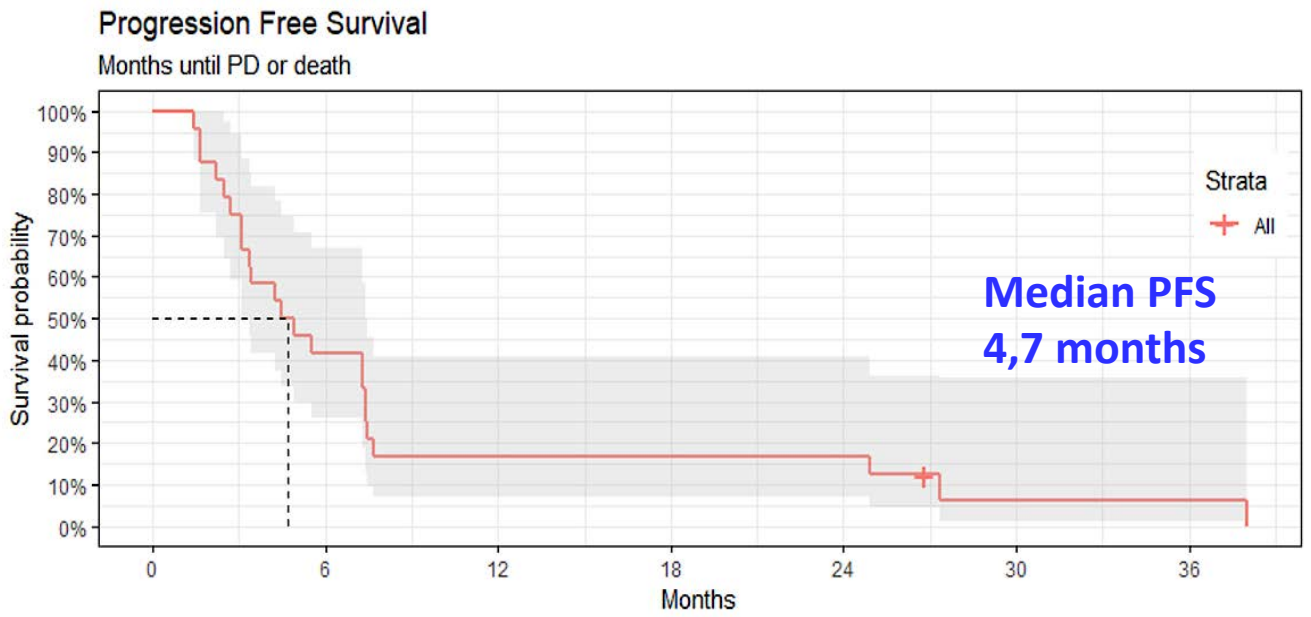
Phase II

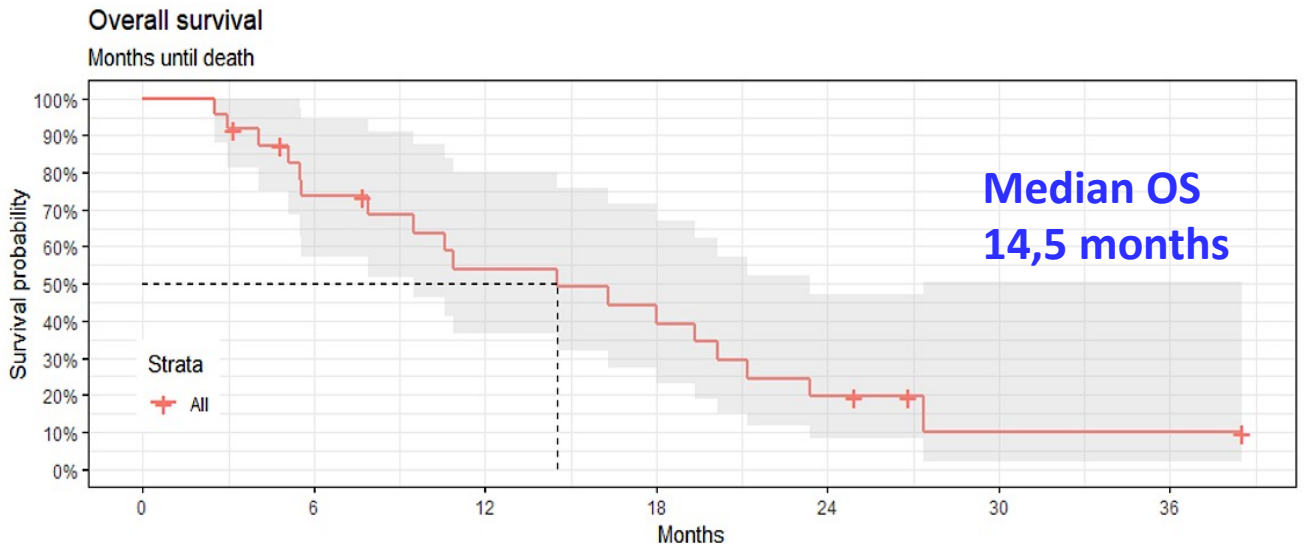
	2SMALL (NCT02454972)	Lurbinectedin as second-line treatment in SCLC (NCT02454972)
Best response	**N (%)**	
Complete Response	3 (12.5)	0 (0.0)
Partial Response	13 (54.17)	38 (36.2)
Stable Disease	5 (20.83)	34 (32.4)
Progression Disease	3 (12.5)	28 (26.7)
Total	24 (100)	105 (100)

Overall Response Rate	**N (%) [95% CI]**	
ORR	16 **(66.67%)**	38 **(36.2%)**

Progression Free Survival	**Median Months (95% CI)**	
PFS	**4.7** (3.37 - 7.4)	**3.7** (2.6 to 4.3)

Overall Survival	**Median Months (95% CI)**	
OS	**14.5** (9.5 - 23.4)	**8.1** (6.5 to 10.9)

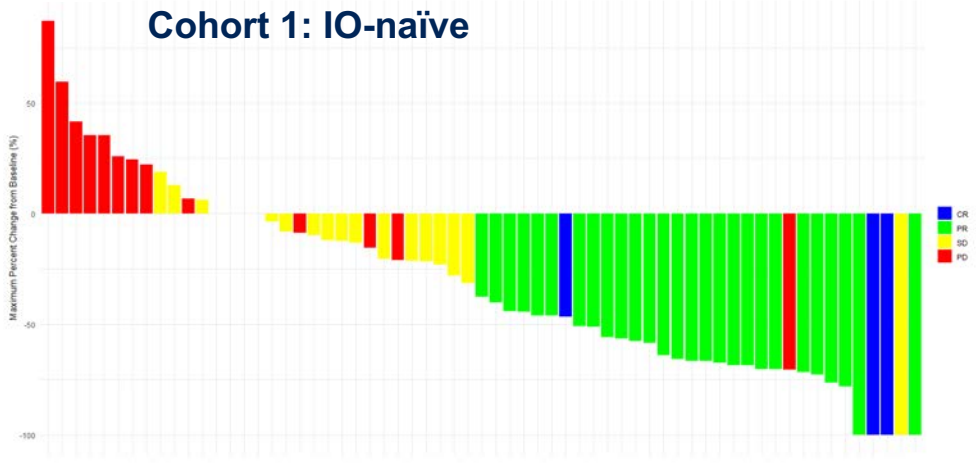


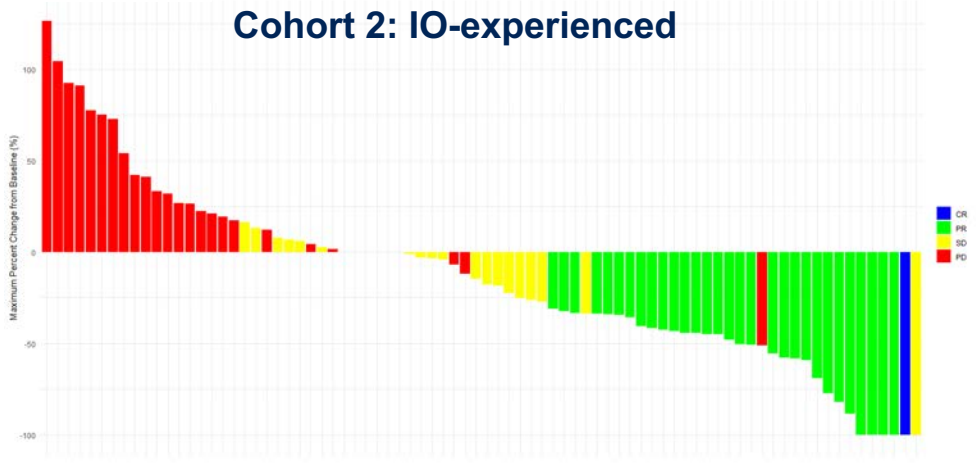


S Ponce et al. SITC 2021

2SMALL Phase II Trial - Response

	Cohort 1 IO-naïve (n=68)	Cohort 2 IO-experienced (n= 83)	TOTAL n=151	Platinum - sensitive CTFI ≥90 days (n=92)	Platinum - resistant CTFI 30 to <90 days (n=59)
ORR n, % (95% CI)	30, 44.1% (32.3 - 56.6 %)	31, 37.3% (27.2 - 48.7%)	61, 40.4% (32.6 - 48.7%)	40, 43.5% (33.3 - 54.2%)	21, 35.6% (23.9% - 49.2%)
DoR, mo (95% CI) Median	5.6 (3.9 - 7.5)	3.97 (3 - 4.4)	4.1 (3.3 - 5.6)	4.4 (3.3 - 7.0)	4.07 (2.9 - 6.0)
DCR (CR+PR+SD)	51 (75%)	56 (67.5%)	107 (70.9%)	66 (71.7%)	41 (69.5%)





Santiago Ponce Aix MD

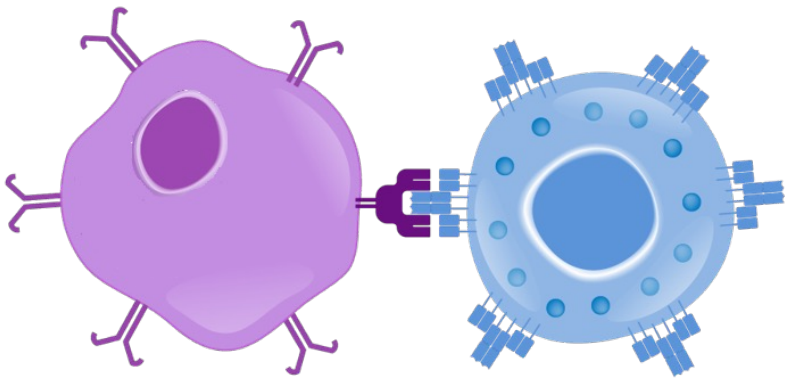
S Ponce et al. ASCO 2025

Agenda

- Lurbinectedin
  - Monotherapy and combos
- **TCEs**
  - **Tarlatamab**
  - **Others**

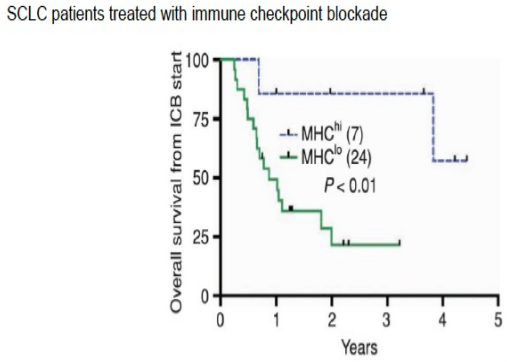
SCLC – Antigen presentation

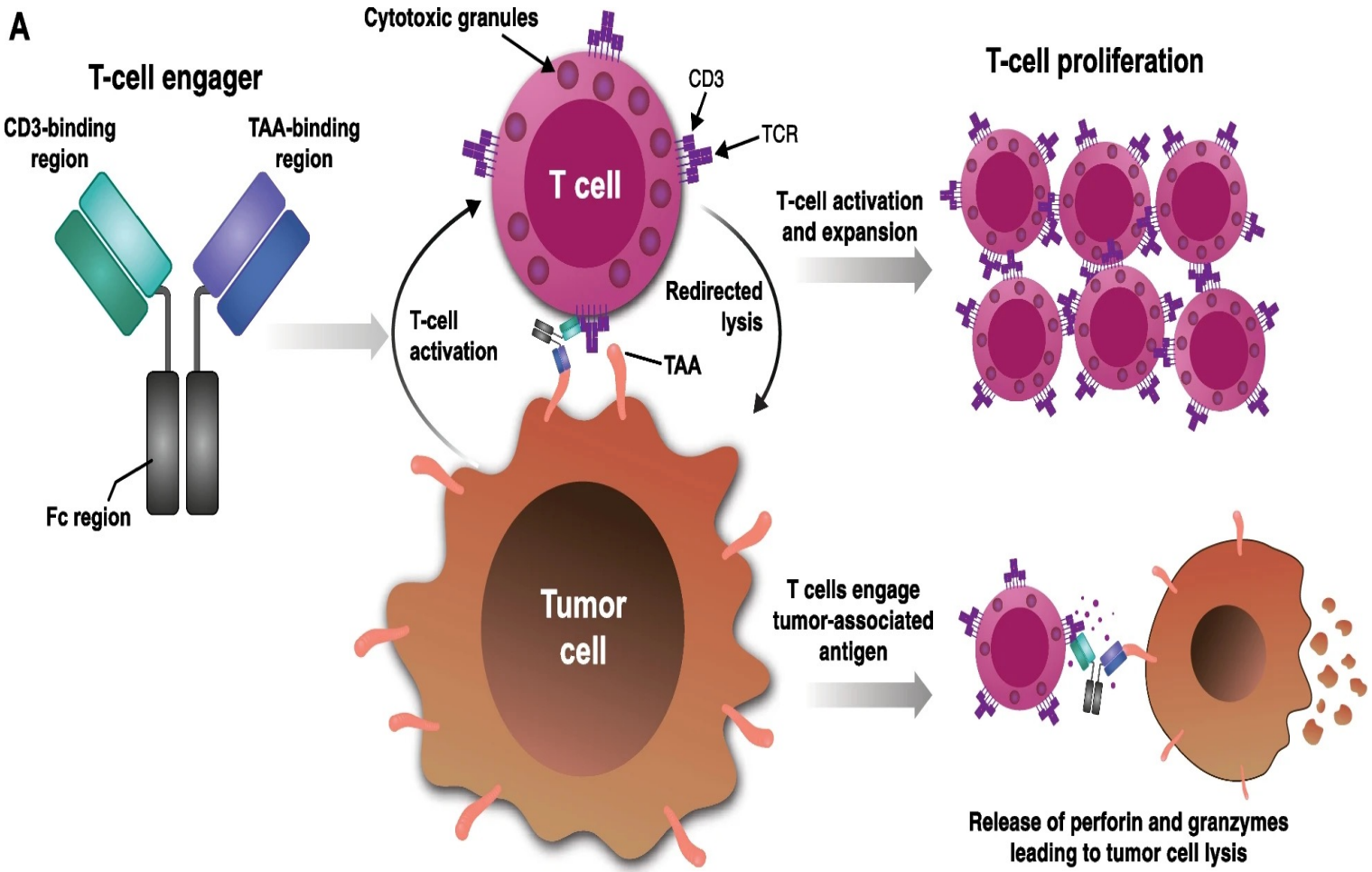
Normal Immune Recognition



Antigen presentation by MHC and recognition by TCR

Relevance of MHC-I downregulation on IO Resistance





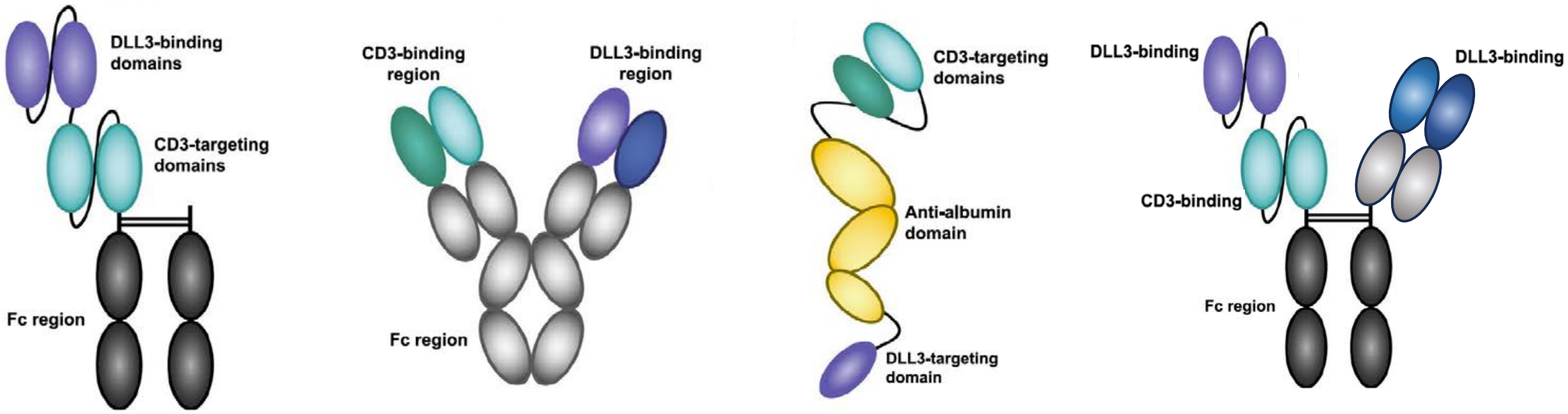
Mahadevan et al. Clin Cancer Res 2024

Rudin et al. Journal of Hematology & Oncology 2023; Sharma et al., Cancer Res 2017

T-cell engagers: many BiTEs, similar flavors

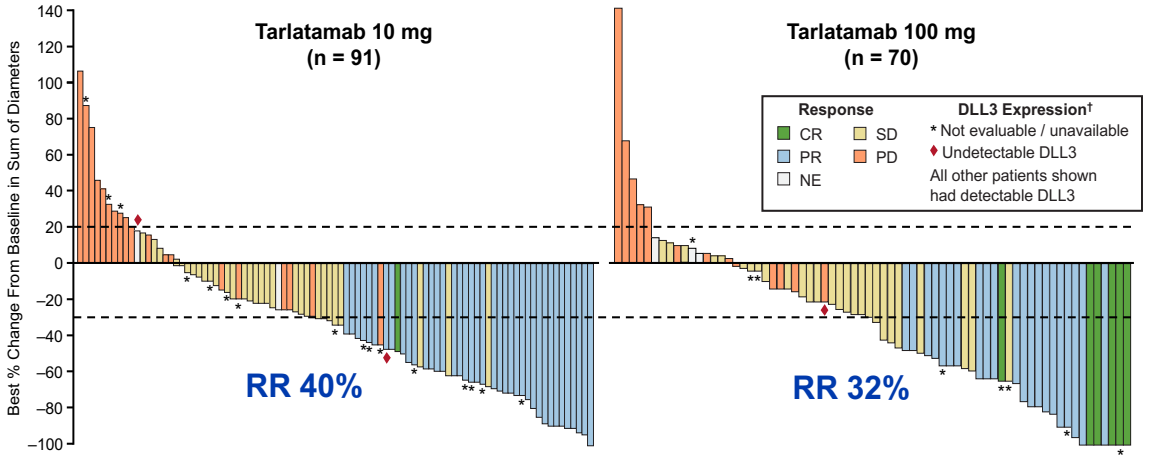
Bispecifics | **Trispecifics**

Tarlatamab | **Obrixtamig** | **Gocatamig** | **Alveltamig**

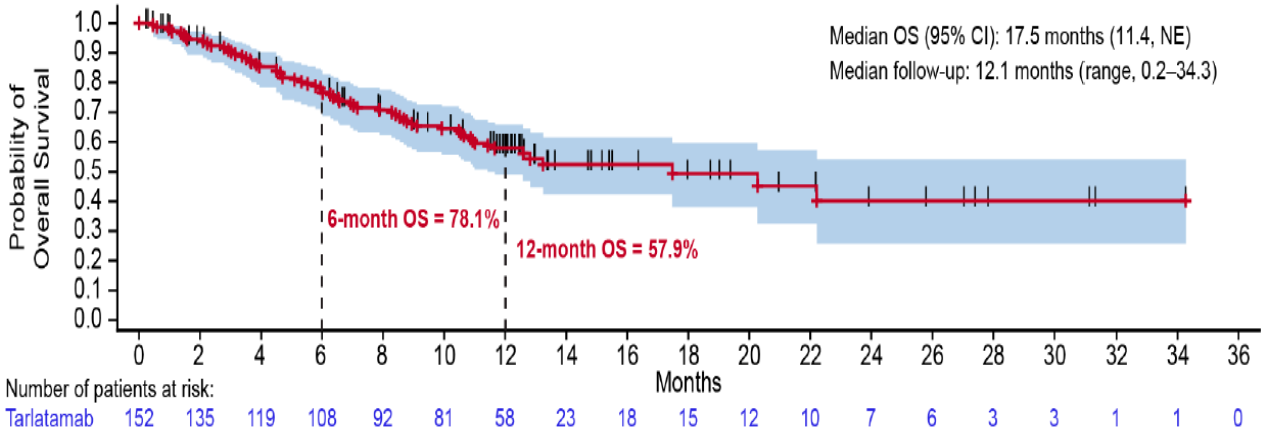


Rudin et al., ***J Hematol Oncol*** 2023 (modified)

Tarlatamab- Dellphi 300 & 301 Trials in pretreated patients



Responses were observed regardless of DLL3 expression, as well as in patients without evaluable tumor tissue



Most Common TEAEs in ≥ 20% of Patients, n (%)	Part 1 + 2 Tarlatamab 10 mg (n = 99)	Part 1 Tarlatamab 100 mg (n = 87)	Part 3 Tarlatamab 10 mg (n = 34)
CRS	49 (49)	53 (61)	19 (56)
Grade 1–2	49 (49)	48 (55)	18 (53)
≥ Grade 3	0	5 (6)	1 (3)
Decreased appetite	25 (25)	38 (44)	13 (38)
Pyrexia	38 (38)	29 (33)	8 (24)
Constipation	28 (28)	22 (25)	8 (24)
Anemia	26 (26)	22 (25)	9 (26)
Asthenia	20 (20)	21 (24)	10 (29)
Dysgeusia	24 (24)	12 (14)	14 (41)
Fatigue	21 (21)	17 (20)	9 (26)

Paz-Ares et al. ESMO 2023 & NEJM 2023; HD Hummel et al., ELCC 2024

Tarlatamab - Brain Metastases

Baseline brain metastases:	Tarlatamab 10 mg Q2W* (n = 100)†	
	Yes (n = 23)	No (n = 77)
ORR, % (95% CI)	52 (30.6–73.2)	38 (26.9–49.4)
Median DOR, months (range)	NE (2.7–12.2+)	NE (2.4–12.4+)
DOR probability at 12 months, KM estimate, % (95% CI)	55 (22.2–78.5)	50 (29.2–67.7)
Median PFS, months (95% CI)	6.7 (2.8–NE)	4.0 (2.8–5.6)
Median OS‡, months (95% CI)	14.3 (14.3–NE)	NE (9.3–NE)

Tarlatamab demonstrated durable response with promising survival regardless of the presence of treated, stable brain metastases at baseline

Paz-Ares et al. NEJM 2023 & MA Dingemans et al., ASCO 2024

DeLLphi 304 trial

Randomized, controlled, phase 3 DeLLphi-304 study (NCT05740566)

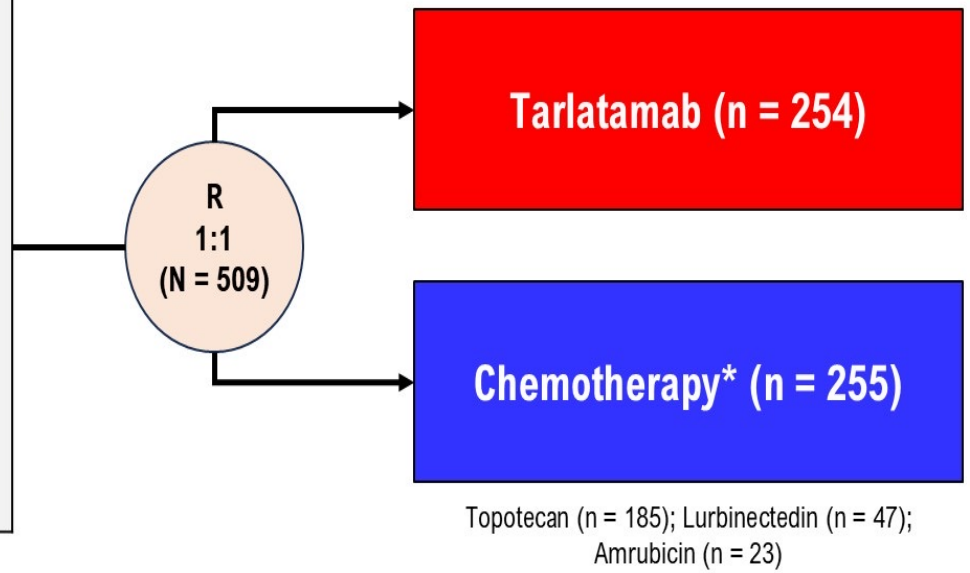
DeLLphi 304

Key inclusion criteria

- Histologically or cytologically confirmed SCLC
- Progression after 1L platinum-based chemotherapy +/- anti-PD-(L)1
- ECOG PS 0 or 1
- Asymptomatic, treated or untreated brain metastases

Randomization stratified by

- Prior anti-PD-(L)1 exposure (yes/no)
- Chemotherapy-free interval (< 90 days vs ≥ 90 to < 180 days vs ≥ 180 days)
- Presence of (previous/current) brain metastases (yes/no)
- Intended chemotherapy (topotecan/amrubicin vs lurbinectedin)



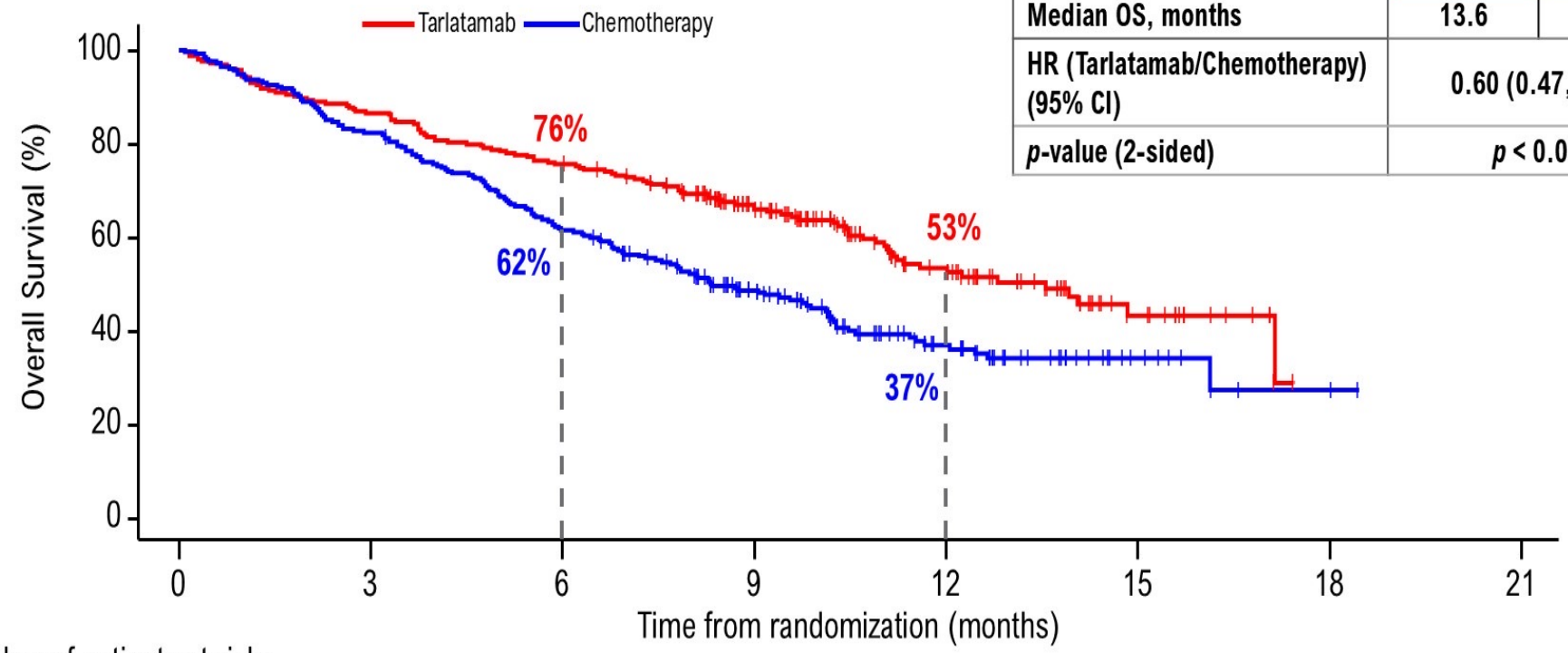
Primary Endpoint: Overall survival
Key Secondary Endpoints: Progression-free survival, patient-reported outcomes
Other Secondary Endpoints: Objective response, disease control, duration of response, safety

C Rudin et al ASCO & NEJM 2025

DeLLphi 304 trial

DeLLphi-304 met its primary endpoint with tarlatamab demonstrating superior overall survival over chemotherapy

	Tarlatamab (n = 254)	Chemotherapy (n = 255)
Median OS, months	13.6	8.3
HR (Tarlatamab/Chemotherapy) (95% CI)	0.60 (0.47, 0.77)	
p-value (2-sided)	*p* < 0.001	



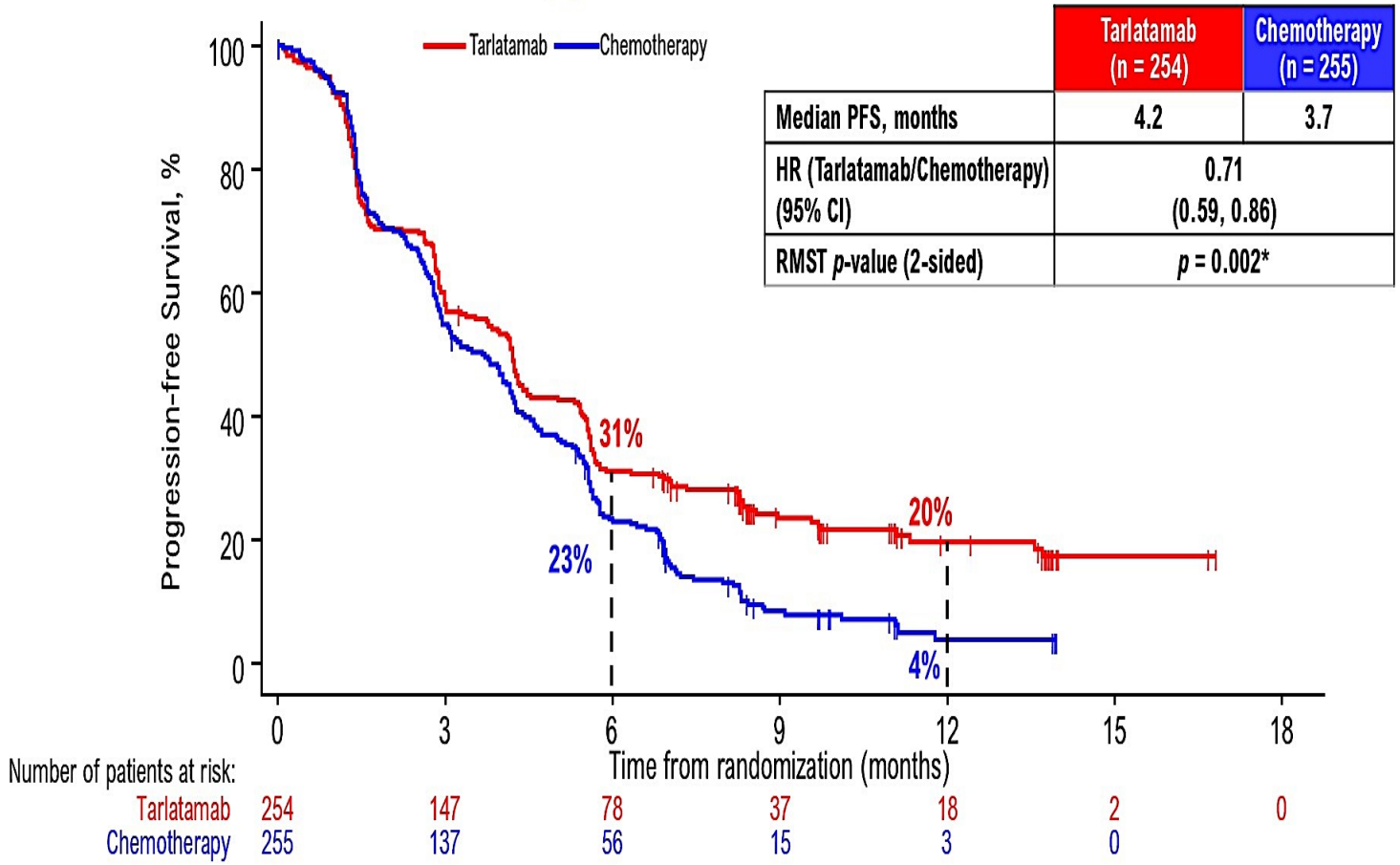
Number of patients at risk:

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

C Rudin et al ASCO & NEJM 2025

DeLLphi 304 trial

Progression-free survival was significantly longer with tarlatamab vs chemotherapy

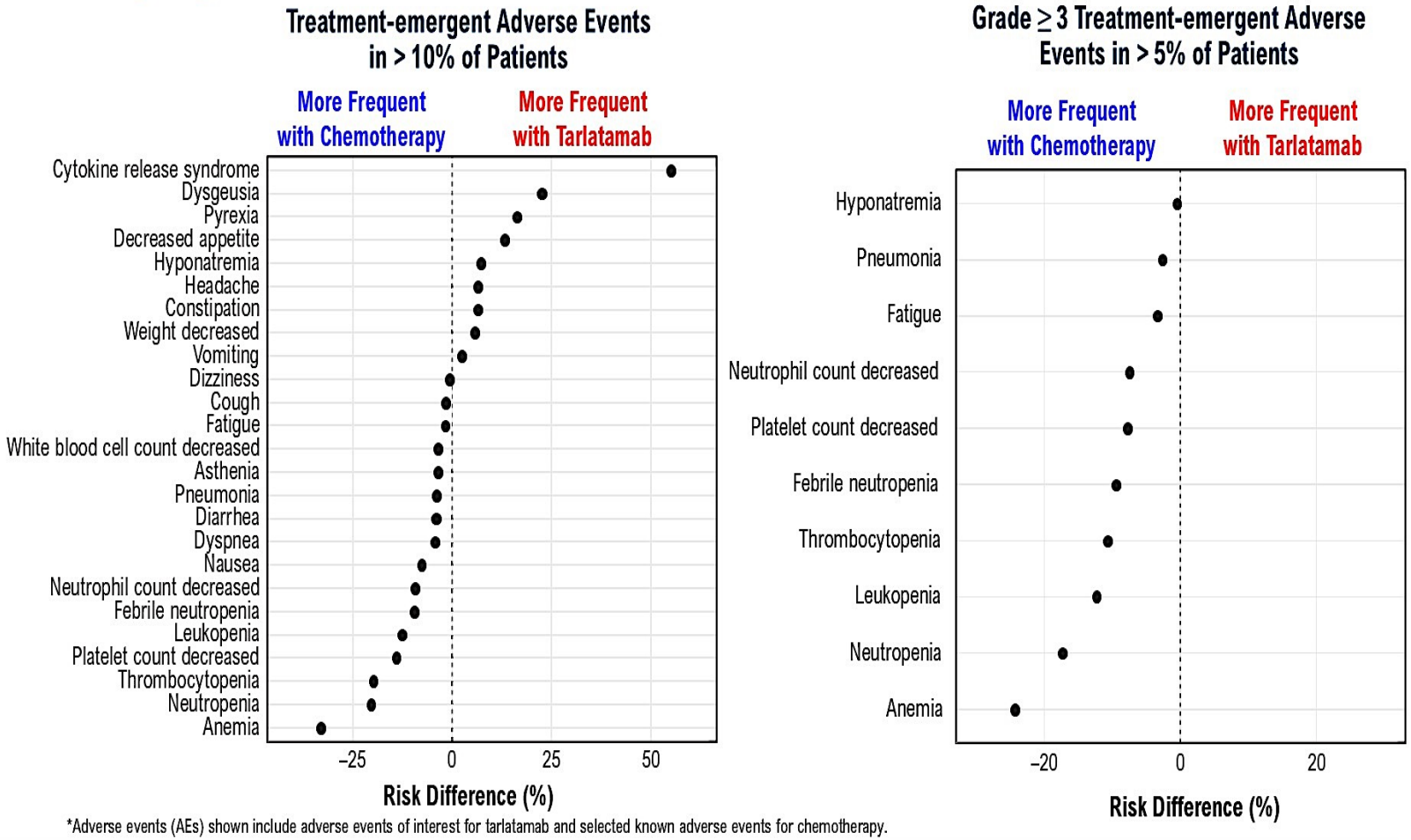


	Tarlatamab (n = 254)	Chemotherapy (n = 255)
Median PFS, months	4.2	3.7
HR (Tarlatamab/Chemotherapy) (95% CI)	0.71 (0.59, 0.86)	
RMST *p*-value (2-sided)	*p* = 0.002*	

C Rudin et al ASCO & NEJM 2025

DeLLphi 304 trial

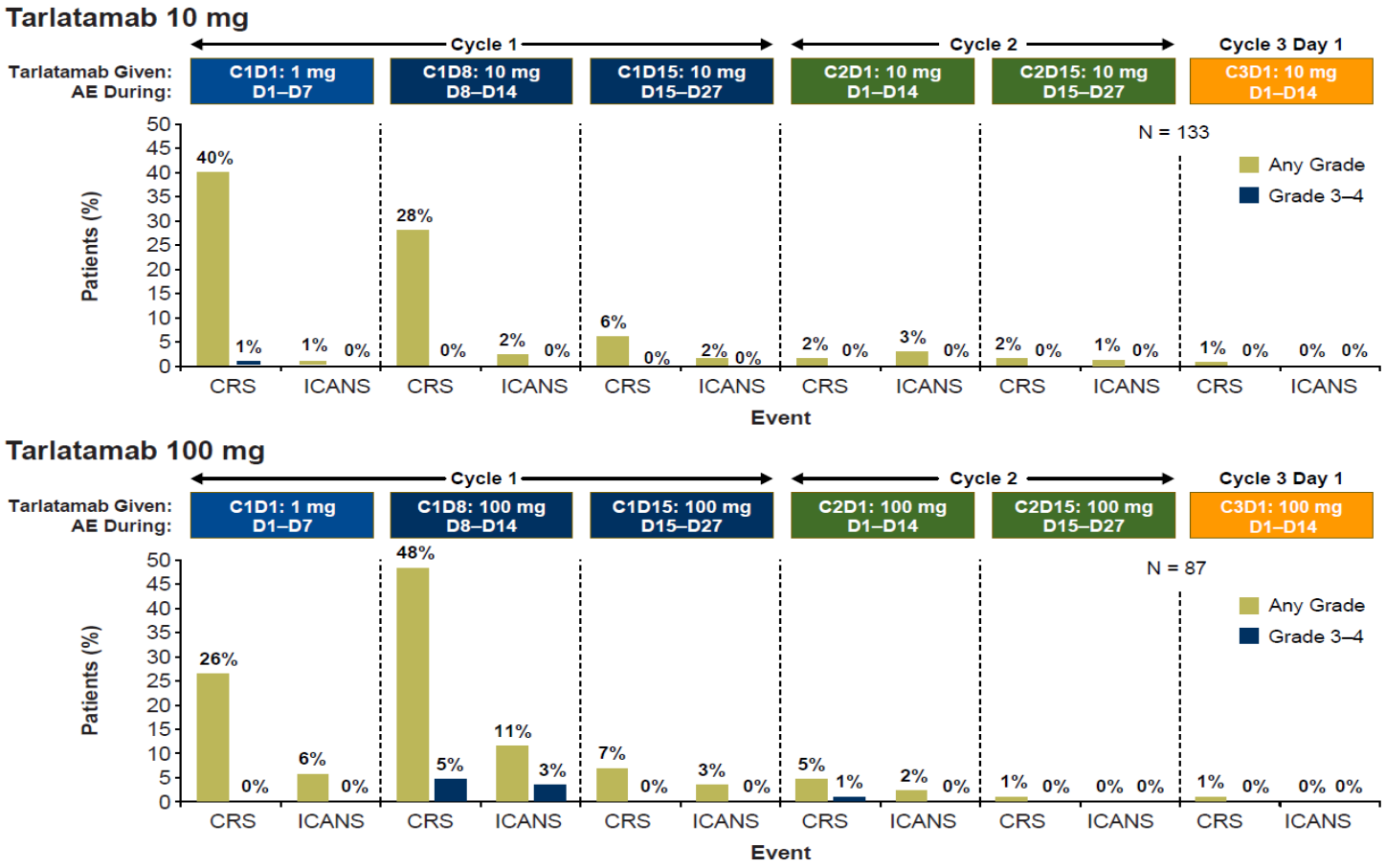
Patients treated with tarlatamab experienced lower incidence of high-grade AEs



*Adverse events (AEs) shown include adverse events of interest for tarlatamab and selected known adverse events for chemotherapy.

C Rudin et al ASCO & NEJM 2025

CRS and Immune Effector Cell-associated Neurotoxicity Syndrome (ICANS)*



- CRS was largely confined to the first or second dose, primarily grade 1–2
- ICANS* occurred infrequently overall, predominantly with 100 mg tarlatamab

Additional Interventions for CRS:

Patients receiving tarlatamab, n (%)	10 mg (n = 133)	100 mg (n = 87)
Tocilizumab	7 (5)	9 (10)
Supplemental oxygen	11 (8)	8 (9)
Vasopressor support	1 (1)	1 (1)

*ICANS includes associated neurologic events based on a broad search using 61 selected preferred terms from MedDRA version 26.0.
AE, adverse event; **C**, cycle; **CRS**, cytokine release syndrome; **D**, day; **ICANS**, immune effector cell-associated neurotoxicity syndrome.

Ahn et al., NEJM 2023

CRS

CRS, n (%)	Parts 1–3 Tarlatamab 10 mg (n = 133)	Part 1 Tarlatamab 100 mg (n = 87)
All Grades	68 (51)	53 (61)
Grade 1	40 (30)	28 (32)
Grade 2	27 (20)	20 (23)
Grade 3	1 (1)	5 (6)

Timing and resolution

- Median onset following last tarlatamab dose: 13 hours (IQR: 8–27)
- Median duration: 4 days (range, 2–6)
- Resolution in 98% of cases

CRS Recurrence

- 24% of patients had another CRS event

(primarily Grade 1) with a subsequent dose

Dose interruption

- 10 mg group: 4 patients (3%)
- 100 mg group: 8 patients (9%)

ICANS

AE of interest, n (%)	Parts 1 + 2 Tarlatamab 10 mg (n = 99)	Part 1 Tarlatamab 100 mg (n = 87)	Part 3 Tarlatamab 10 mg (n = 34)
ICANS and associated neurologic events*			
Overall	7 (7)	24 (28)	4 (12)
Grade ≥ 3 severity	0	4 (5)	0
Serious	2 (2)	11 (13)	2 (6)
Leading to tarlatamab discontinuation	1 (1)	1 (1)	0
Fatal	0	0	0

Timing and resolution

- Median onset after last tarlatamab dose: 5 days
  Median time to resolution: 6.5 days (range, 4–17)

Dose interruption

- 10 mg group: 1 patient (1%)
- 100 mg group: 4 patients (6%)

Ahn et al., NEJM 2023; Paz-Ares AACR 2024

Tarlatamab Management Guidelines - CRS

	Grade 1	Grade 2	Grade 3	Grade 4
Diagnosis	Fever	Hypotension responding to fluids Need for low flow oxygen	Hypotension not responsive to fluids Need for high flow oxygen	Hypotension requiring multiple vasopressors Need for positive pressure
Management	Antipiretics, Dexam.? Consider cultures and antibiotics Alert ICU	IV fluids Oxygen Dexam. Tocilizumab ?? ICU ??	Oxygen Vasopressor Dexam. Tocilizumab ICU	Positive pressure Vasopressors Dexame. Tocilizumab ICU

Tarlatamab Management Guidelines - ICANS

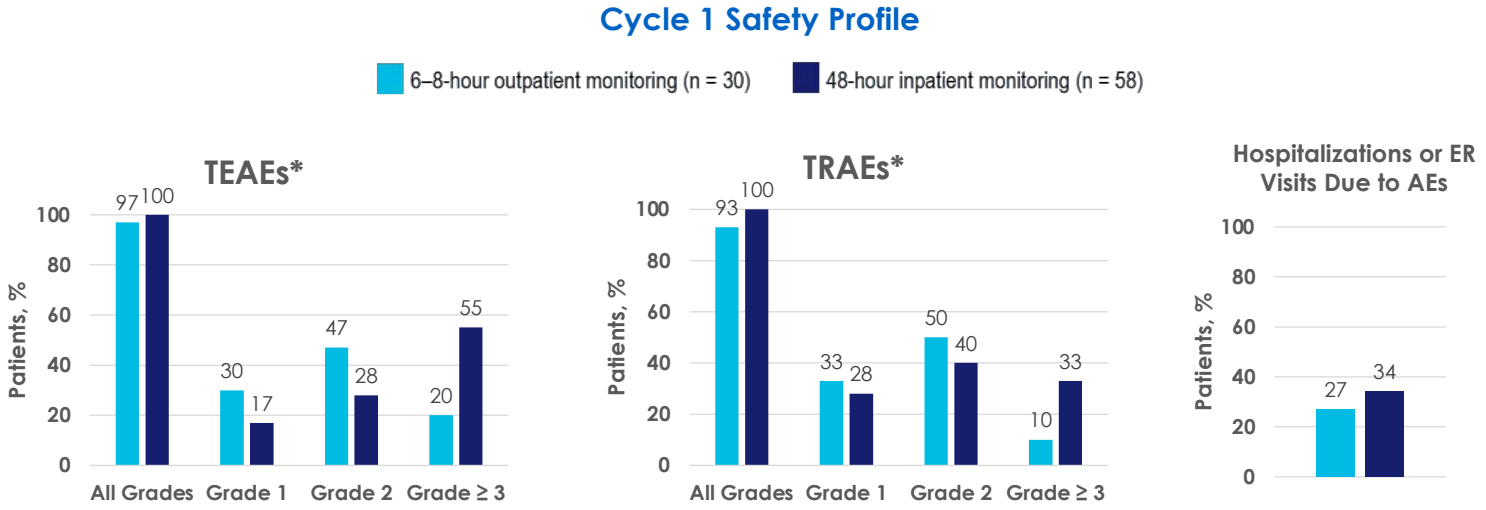
ICE Parameter	Scoring Points
Orientation	4
Naming	3

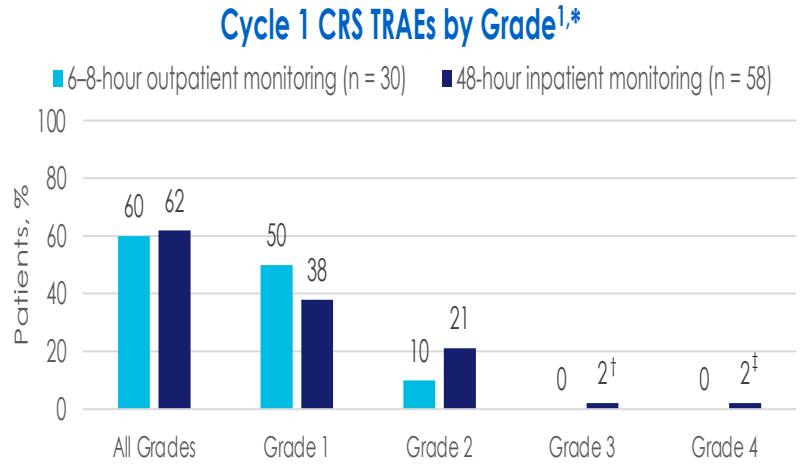
ICE Parameter	Scoring Points
Following commands	1
Writing	1
Attention	1

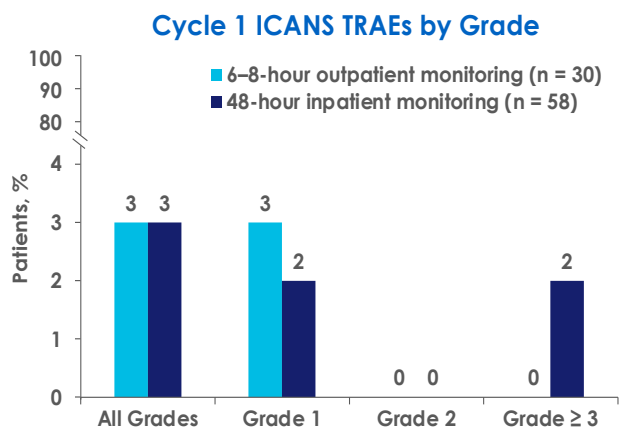
	Grade 1	Grade 2	Grade 3	Grade 4
Diagnosis	ICE 7-9 Awake	ICE 3-6 Awake to voices	ICE 0-2 Awake to tactile stimulus Seizures (Responsive) Local edema?	Unarousable Life-threatening seizures Diffuse edema Focal motor weakness
Management	Supportive If grade 2-3 CRS Tocilizumab	Dexamethasone If grade 2-3 CRS Tocilizumab and consider UCI	Dexamethasone/6 h Neuroimaging every 2-3 days Antiepileptics as needed Consider anti IL-6 therapy, particularly if CRS	Dexamethasone/6 h Neuroimaging every 2-3 days Antiepileptics as needed Consider anti IL-6 therapy, particularly if CRS

Tarlatamab into Clinical Practice

- Step dosing, steroids, hydration
- Admission for initial infusions
- Expert teams – expedite circuits
- Education on TCEs, safety profile (CRS, ICANS) and management
- Optimize AE prevention (SC preparations,…)



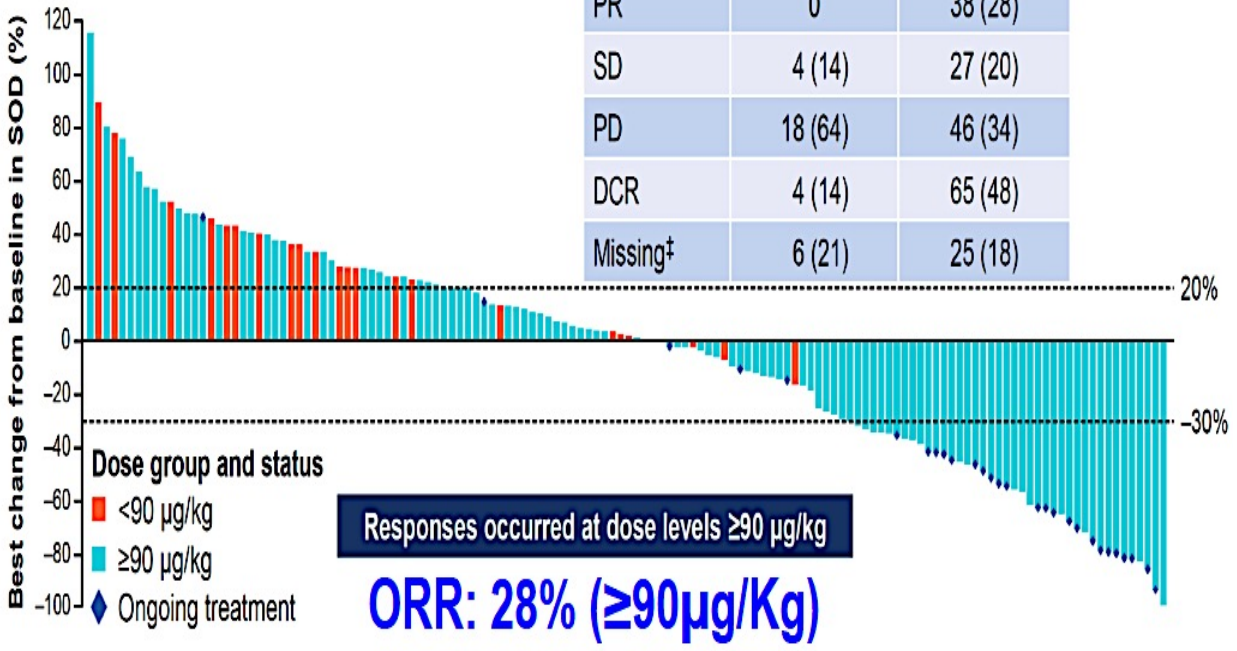




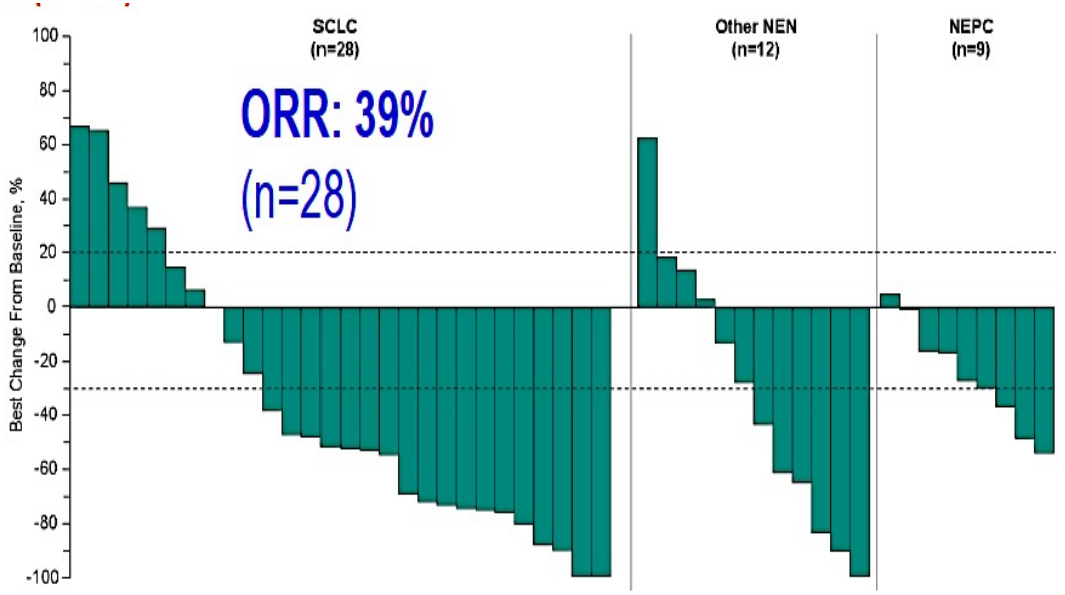
Ahn et al., NEJM 2023; Wermke et al. ASCO 2023; Chiang AC, et al. ESMO Open. 2025;10:104538.

Obrixtamig (BI764532)

Response n, (%)*	All patients (<90 µg/kg) n=28†	All patients (≥90 µg/kg) n=136†
PR	0	38 (28)
SD	4 (14)	27 (20)
PD	18 (64)	46 (34)
DCR	4 (14)	65 (48)
Missing‡	6 (21)	25 (18)



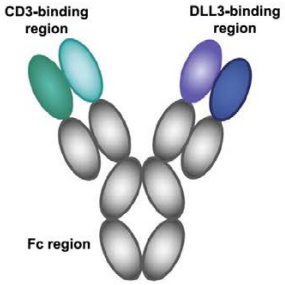
MK 6070 (HPN328): 12-24 mg

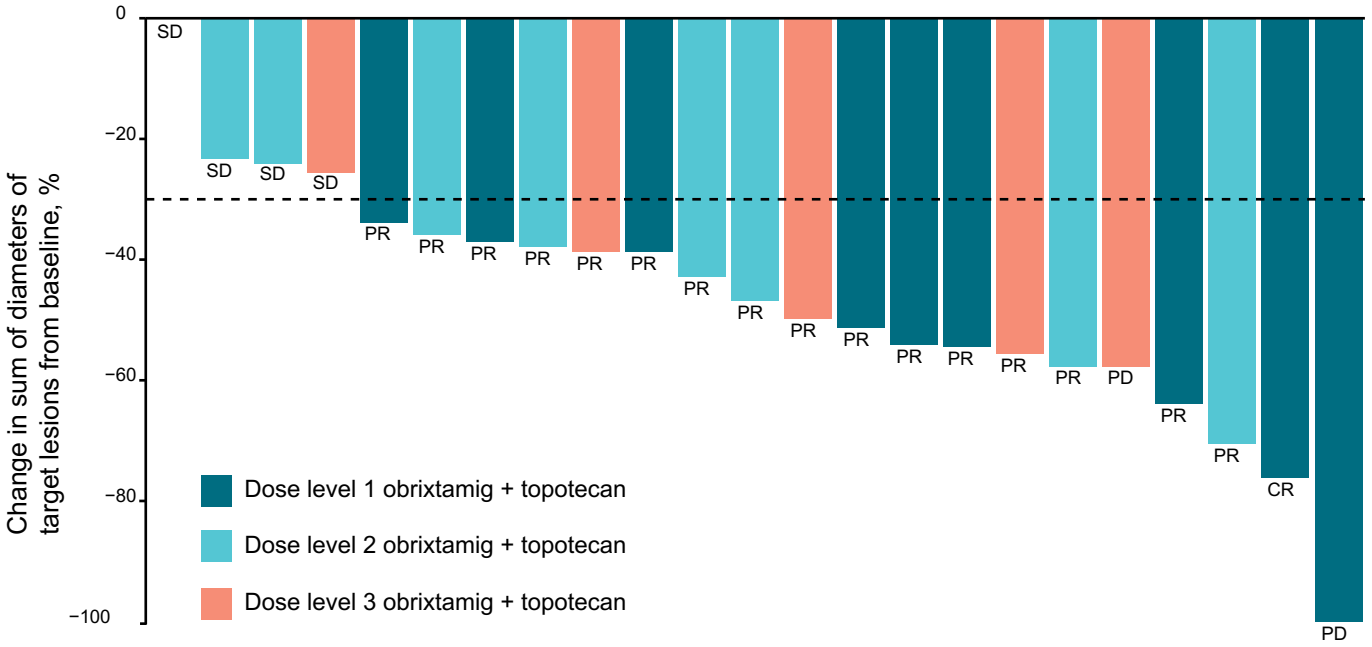


	SCLC n=28	Other NEN† n=13
RECIST v1.1		
ORR	11 (39%)	6 (46%)
DCR	20 (71%)	6 (46%)
Extracranial response per RECIST v1.1§		
ORR	14 (50%)	6 (46%)
DCR	21 (75%)	6 (46%)

H Beltran et al. ASCO 2024

Obrixtamig + topotecan (DAREON-9) in 2L+ ES-SCLC



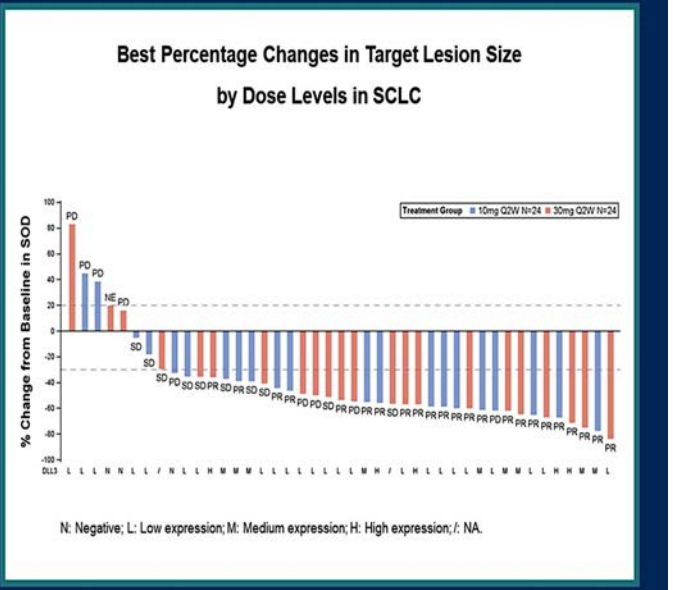


Efficacy endpoint	N=23
Best overall response, n (%)	
CR	1 (4)
PR	15 (65)
SD	4 (17)
PD	2 (9)
Confirmed ORR, % (95% CI)	69 (39–91)
DCR, % (95% CI)	87 (66–97)

Second Generation DLL3 TCEs: ZG006

Antitumor Activity as Assessed by IRC

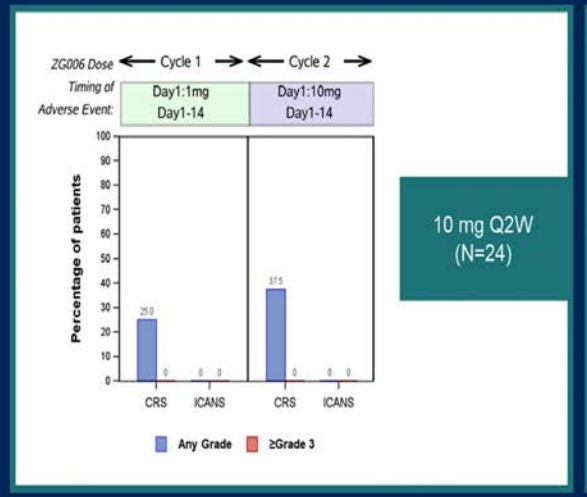
	10 mg Q2W (N=24)	30 mg Q2W (N=24)
BOR		
CR, n (%)	0	0
PR, n (%)	15 (62.5)	14 (58.3)
SD, n (%)	2 (8.3)	2 (8.3)
PD, n (%)	6 (25.0)	6 (25.0)
NE, n (%)	1 (4.2)	2 (8.3)
ORR*, n (%) 95% CI	15 (62.5) (40.6, 81.2)	14 (58.3) (36.6, 77.9)
DCR*, n (%) 95% CI	17 (70.8) (48.9, 87.4)	16 (66.7) (44.7, 84.4)

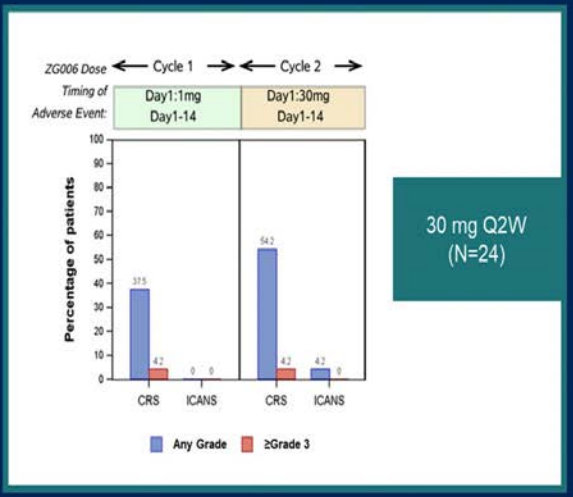


N: Negative; L: Low expression; M: Medium expression; H: High expression; /: NA.

CR: Complete Response; PR: Partial Response; SD: Stable Disease; PD: Progressive Disease; BOR: Best Overall Response; *: Non-confirmed

CRS and ICANS on Treatment

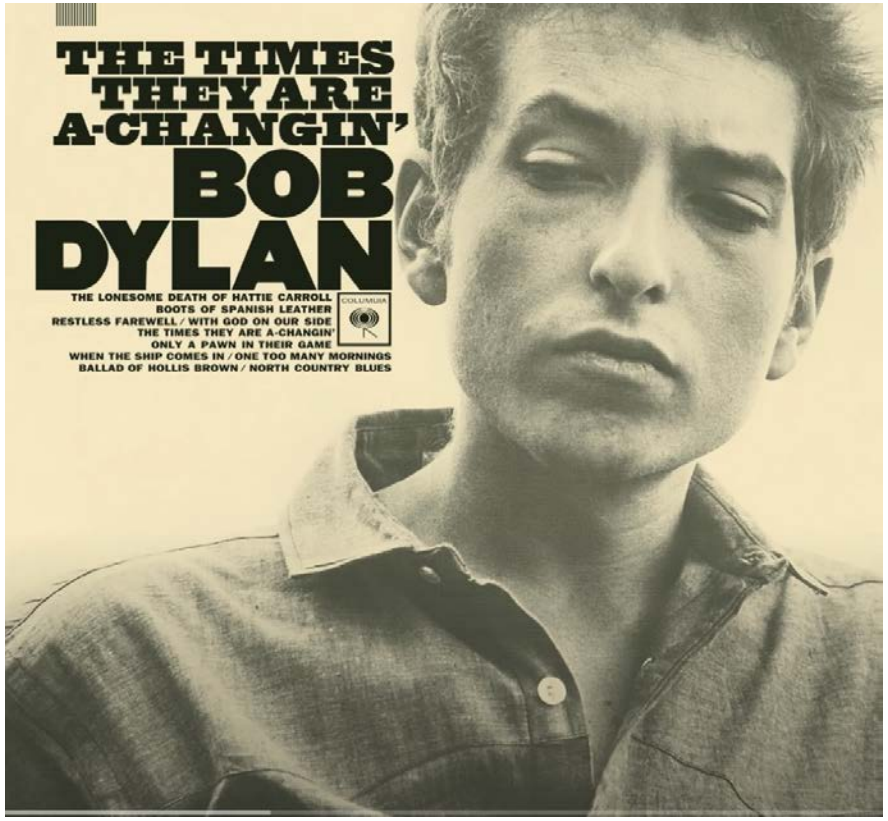




- Most CRS events were Grade 1-2 in severity, and resolved quickly after symptomatic treatment
- The incidence of CRS and ICANS according to severity by the treatment cycle showed most CRS events occurred during the 1st to 2nd dosing cycle
- The median time of onset was 12.6 to 24.1 hours with a duration of 38.5 to 50.9 hours
- Grade ≥3 CRS occurred in only 2 patients at 30 mg dose group

› X Al et al. ASCO 2025

Take home: Times are a changin´in SCLC!!



- Lurbinectedin plus atezolizumab represents a new standard in the maintenance treatment of SCLC
- TCEs (Tarlatamab) are revolutionizing the treatment and natural history of advanced SCLC (now in the 2nd line context but likely soon in front line therapy)
- Bispecifics and ADCs have promising activity and their incorporation may be easier in the post-TCEs scenario

Second Opinion

Ticiana Leal, MD

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

Discussion Questions

How are you currently selecting patients for treatment with tarlatamab? What has been your experience implementing tarlatamab in clinical practice? What advice would you offer an oncologist in community practice who is going to begin administering tarlatamab for the first time?

For a patient with bulky disease, do you think it's necessary to employ a cytotoxic agent (eg, lurbinectedin) as a bridge to tarlatamab? What do you do in your own practice? What cytoreductive approach would you use if a patient had already received lurbinectedin in the first-line maintenance setting?

For a patient who does not receive lurbinectedin maintenance, where in the treatment sequence are you integrating the agent? Have you observed meaningful response to this agent following progression on tarlatamab?

Second Opinion

Charu Aggarwal, MD

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

Discussion Questions

How do you typically approach monitoring for CRS and neurotoxicity for patients receiving tarlatamab? How long do you observe patients after infusion of later cycles, after the highest risk of CRS has passed?

How do you manage dysgeusia with tarlatamab? Do you offer dose holds or treatment holidays for patients who are responding well but experiencing tolerability issues?

Agenda

Module 1: Optimizing First-Line and Maintenance Therapy for Extensive-Stage Small Cell Lung Cancer (SCLC) — Dr Shields

Module 2: Management of Relapsed/Refractory SCLC — Dr Paz-Ares

Module 3: Ongoing Investigation and Potential Role of Antibody-Drug Conjugates in SCLC — Dr Chiang

Module 4: Management of Limited-Stage SCLC — Dr Ganti

Ongoing Investigation and Potential Role of Antibody-Drug Conjugates in SCLC

Yale NewHaven Health
Smilow Cancer Hospital

Yale CANCER CENTER

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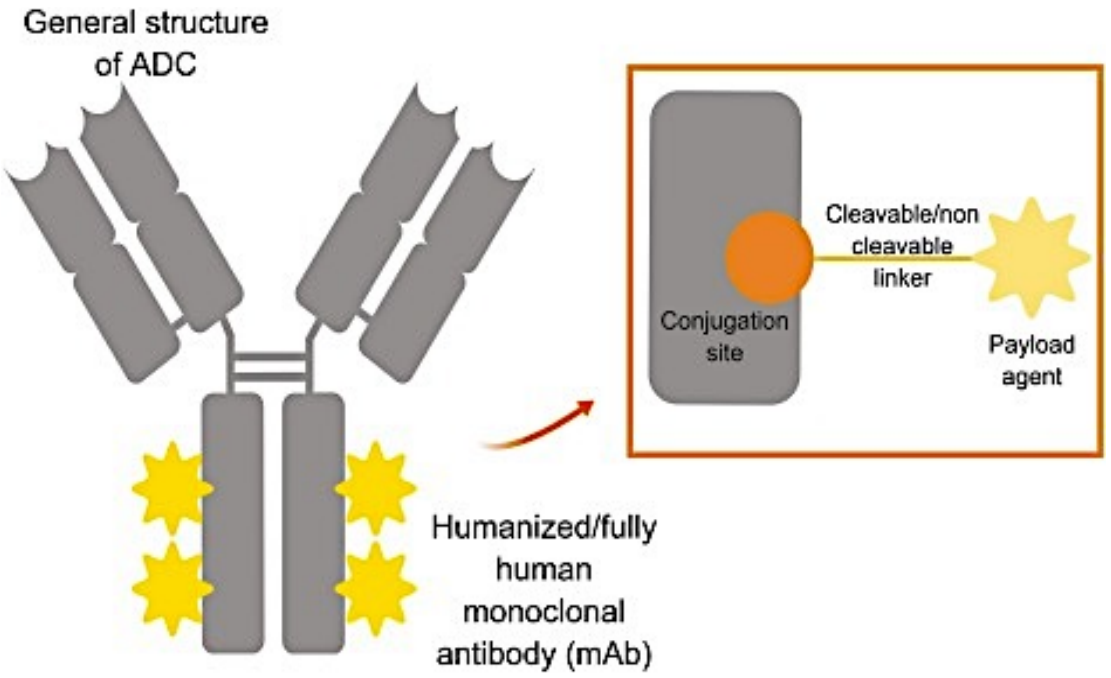
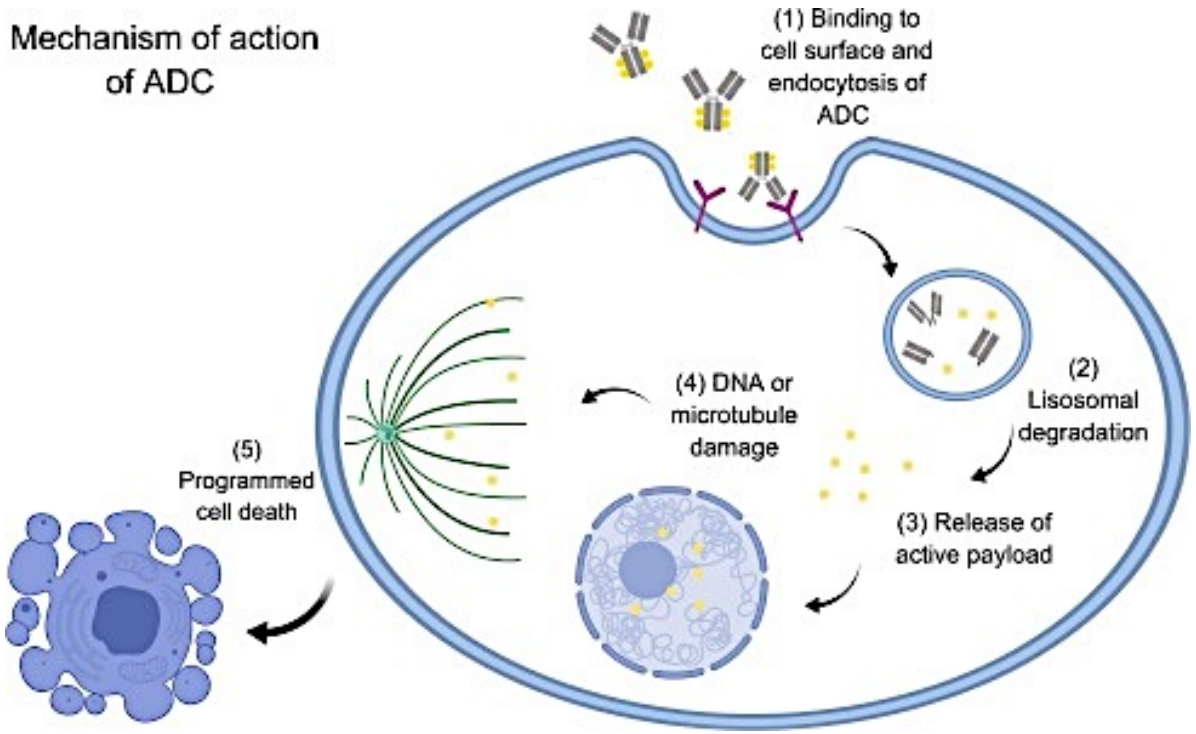
Associate Professor, Division of Thoracic Medical Oncology
Yale University School of Medicine
Associate Yale Cancer Center Director

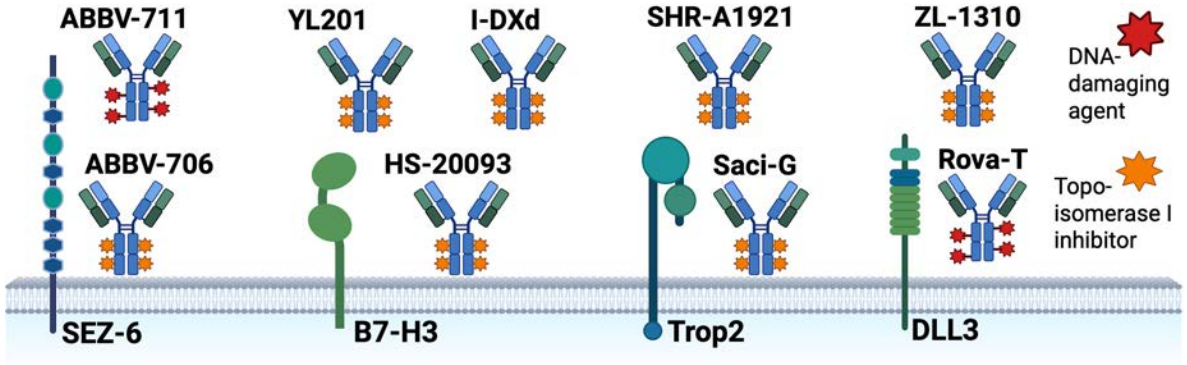
Targeting Tumors: Antibody Drug Conjugates (ADCs)





Ricciuti, B, et al, Sem Cancer Biol 2021, 69:268-278

SCLC ADC Agents



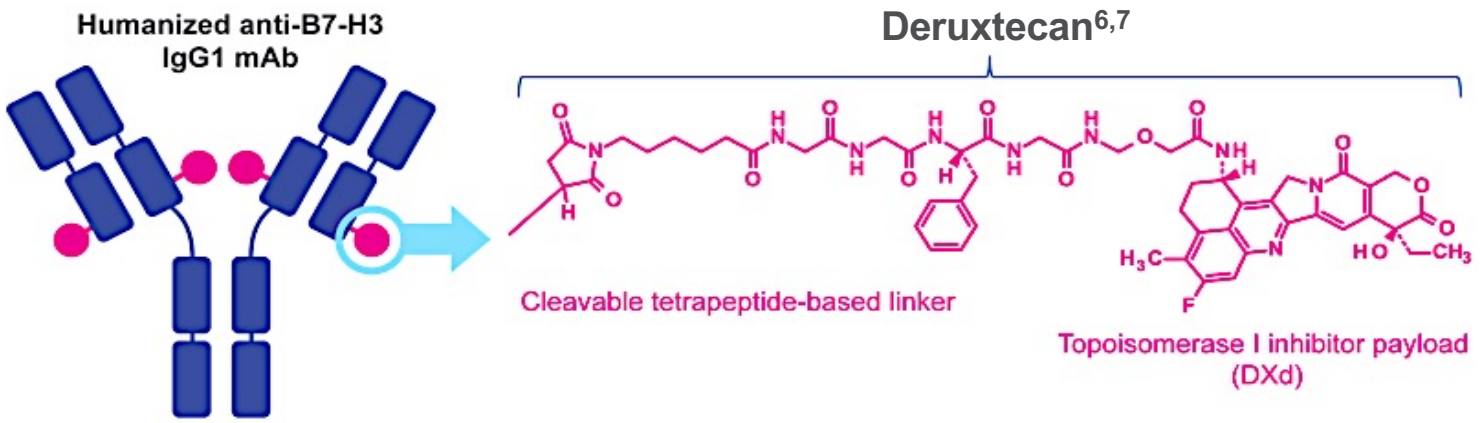
	SEZ-6		B7-H3			Trop2		DLL3	
	ABBV-711	**ABBV-706**	**YL201**	**I-DXd**	**HS-20093**	**SHR-A1921**	**Saci-G**	**Rova-T**	**ZL-1310**
Antibody	SC17	SC17	Proprietary	Ifinatamab	Proprietary	Proprietary	Sacituzumab	Rovalpituzumab	Zocilurtatug
Payload	Calicheamicin	Top1 inhibitor	Top1 inhibitor (Camptothecin derivative)	Deruxtecan	TOP1i	SHR9265 (TOP1i)	Govitecan (SN38)	Tesirine (PBD)	Pelitecan (TOP1i)
DAR	2	6	8	4	4	4	7.6	2	8
Linker	Noncleavable	Proprietary	Protease-cleavable*	Plasma stable, Protease-cleavable	Protease-cleavable	Cleavable	Hydrolysable	Protease-cleavable	Cleavable tri-peptide

Sethakorn N, Chiang AC. 2026 Cancers, manuscript accepted

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

- B7 homologue 3 (B7-H3) is overexpressed in a wide range of cancer types, and is associated with disease progression and lower overall survival[1-5]

DS-7300 is a B7-H3 (CD276)-directed ADC composed of 3 components



- Payload mechanism of action: topoisomerase I inhibitor[6-11,a]
- High potency of payload[7,a]
- Optimized drug-to-antibody ratio ≈ 4[6-8,10,a]
- Payload with short systemic half-life[7,8,a,b]
- Stable linker-payload[7,8,11,a]
- Tumor-selective cleavable linker[7-12,a]
- Bystander antitumor effect[7,13,a]

ADC, antibody-drug conjugate; B7-H3, B7 homologue 3.
[a] The clinical relevance of these features is under investigation. [b] Based on animal data.
1. Yamato M, et al. AACR-NCI-EORTC 2020. Abstract 28. 2. Dong P, et al. *Front Oncol*. 2018;8:264. 3. Picarda E, et al. *Clin Cancer Res*. 2016;22(14):3425-3431. 4. Bendell JC, et al. *J Clin Oncol*. 2020;39(15 suppl 1). Abstract TPS3646. 5. Kontos F, et al. *Clin Cancer Res*. 2021;27(5):1227-1235. 6. Okajima D, et al. *Mol Cancer Ther*. 2021;(12):2329-2340. 7. Nakada T, et al. *Chem Pharm Bull (Tokyo)*. 2019;67(3):173-185. 8. Ogitani Y, et al. *Clin Cancer Res*. 2016;22(20):5097-5108. 9. Yamato M, et al. AACR-NCI-EORTC 2020. Abstract 28. 10. Hashimoto Y, et al. *Clin Cancer Res*. 2019;25(23):7151-7161. 11. Koganemaru S, et al. *Mol Cancer Ther*. 2019;18(11):2043-2050. 12. Haratani K, et al. *J Clin Invest*. 2020;130(1):374-388. 13. Ogitani Y, et al. *Cancer Sci*. 2016;107(7):1039-1046.

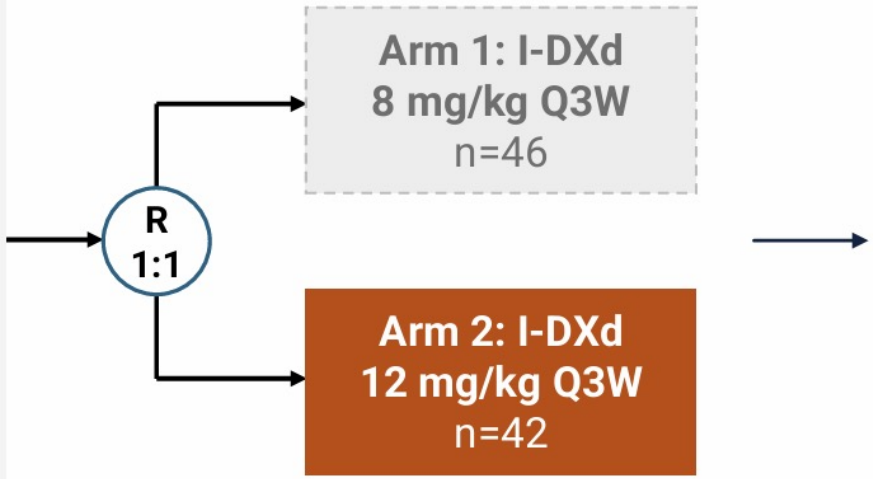
IDeate-Lung01 study design

Phase 2, multicenter, randomized, open-label study (NCT05280470)

Patient eligibility

- Histologically or cytologically documented ES-SCLC
- Age ≥18 years[a]
- ≥1 prior line of PBC and ≤3 prior lines of systemic therapy
- Radiologically documented PD on or after most recent prior systemic therapy
- ECOG PS 0–1
- ≥1 measurable lesion per RECIST 1.1[b]
- Patients with asymptomatic brain metastases (untreated or previously treated) were eligible

Part 1: Dose optimization



Stratification factors:

- 2L CTFI <90 days; 2L CTFI ≥90 days; 3L or 4L
- Prior anti–PD-(L)1 treatment (yes or no)

Part 2: Extension

I-DXd 12 mg/kg Q3W
n=95

Primary endpoint

- ORR by BICR[c]

Secondary endpoints

- DOR by BICR and inv[c]
- PFS by BICR and inv[c]
- OS
- DCR by BICR and inv[c]
- TTR by BICR and inv[c]
- ORR by inv[c]
- Safety
- Pharmacokinetics
- Immunogenicity

Exploratory analysis

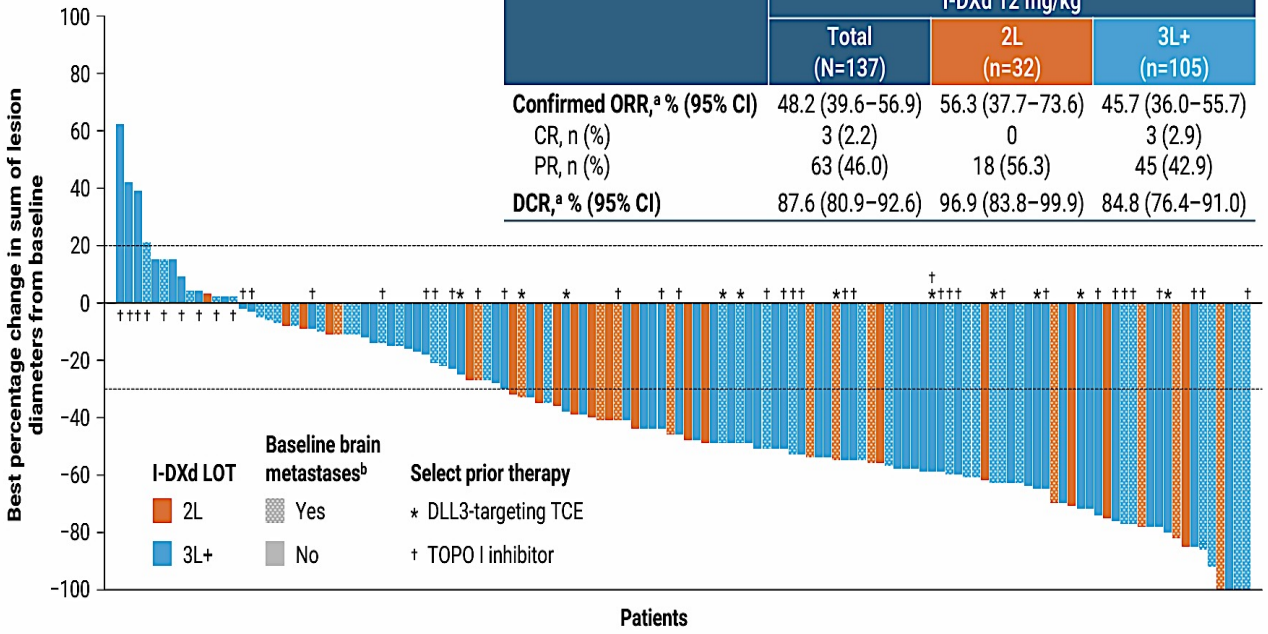
- Intracranial ORR by BICR[d]

[a]Or local legal age of consent. [b]Patients must also have ≥1 lesion that has not been irradiated and is amenable to biopsy. [c]Per RECIST 1.1. [d]Assessed 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; CNS, central nervous system; 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; TTR, time to response.

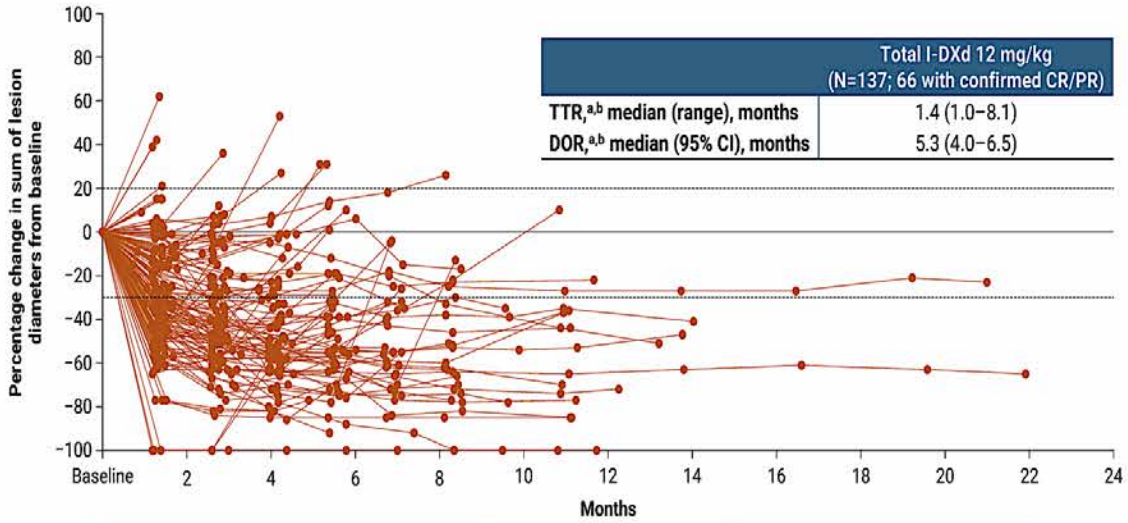
Ideate-Lung01 Clinical Outcomes

I-DXd 12 mg/kg demonstrated promising antitumor activity

	I-DXd 12 mg/kg		
	Total (N=137)	2L (n=32)	3L+ (n=105)
Confirmed ORR,[a] % (95% CI)	48.2 (39.6–56.9)	56.3 (37.7–73.6)	45.7 (36.0–55.7)
CR, n (%)	3 (2.2)	0	3 (2.9)
PR, n (%)	63 (46.0)	18 (56.3)	45 (42.9)
DCR,[a] % (95% CI)	87.6 (80.9–92.6)	96.9 (83.8–99.9)	84.8 (76.4–91.0)



Responses with I-DXd 12 mg/kg were rapid and durable



	Total I-DXd 12 mg/kg (N=137; 66 with confirmed CR/PR)
TTR,[a,b] median (range), months	1.4 (1.0–8.1)
DOR,[a,b] median (95% CI), months	5.3 (4.0–6.5)

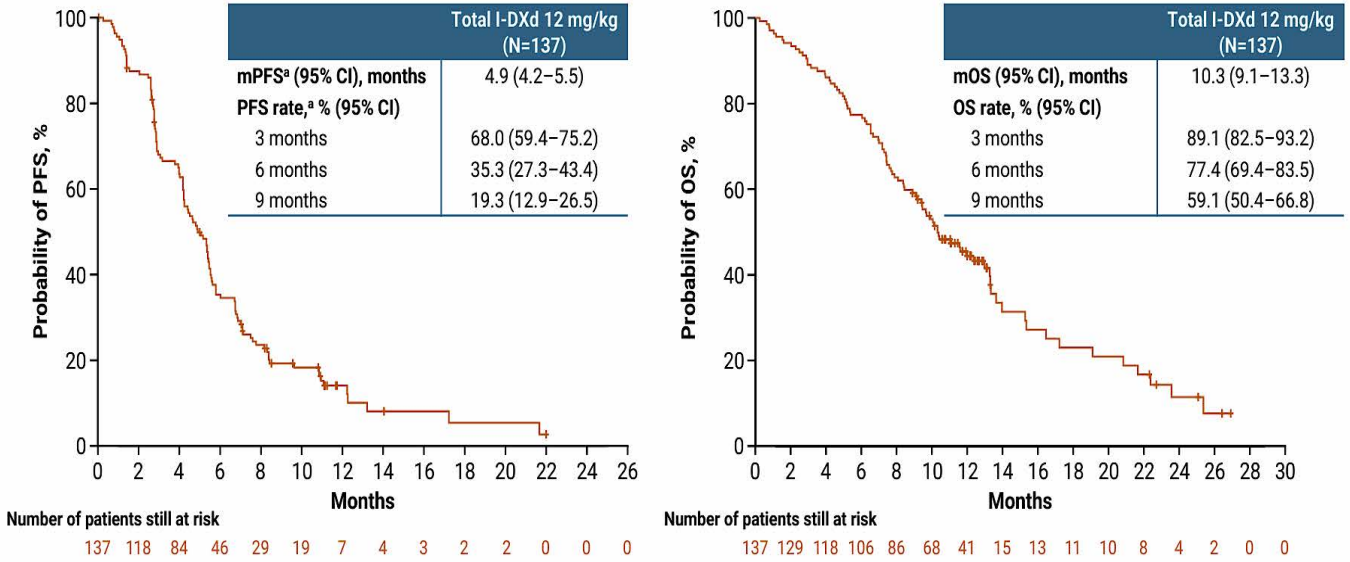
Among patients who received I-DXd 12 mg/kg as 2L therapy (n=32), median TTR was 1.4 months (range, 1.2–4.0) and median DOR was 7.2 months (95% CI, 3.6–NE)

Data cutoff: March 3, 2025.
Tumor assessments were performed every 6 weeks (±7 days) in the first 36 weeks and every 12 weeks (±7 days) thereafter, until disease progression, death, loss to follow-up, or withdrawal of consent, whichever occurred first.
[a]Assessed by BICR per RECIST 1.1. [b]Patients with confirmed objective response.
2L, second-line; BICR, blinded independent central review; CI, confidence interval; CR, complete response; DOR, duration of response; NE, not estimable; PR, partial response; RECIST 1.1, Response Evaluation Criteria in Solid Tumours, version 1.1; TTR, time to response.

Ahn MJ et al. WCLC 2025

Phase II: Ideate-Lung01 Clinical Outcomes

mPFS was 4.9 months and mOS was 10.3 months with I-DXd 12 mg/kg

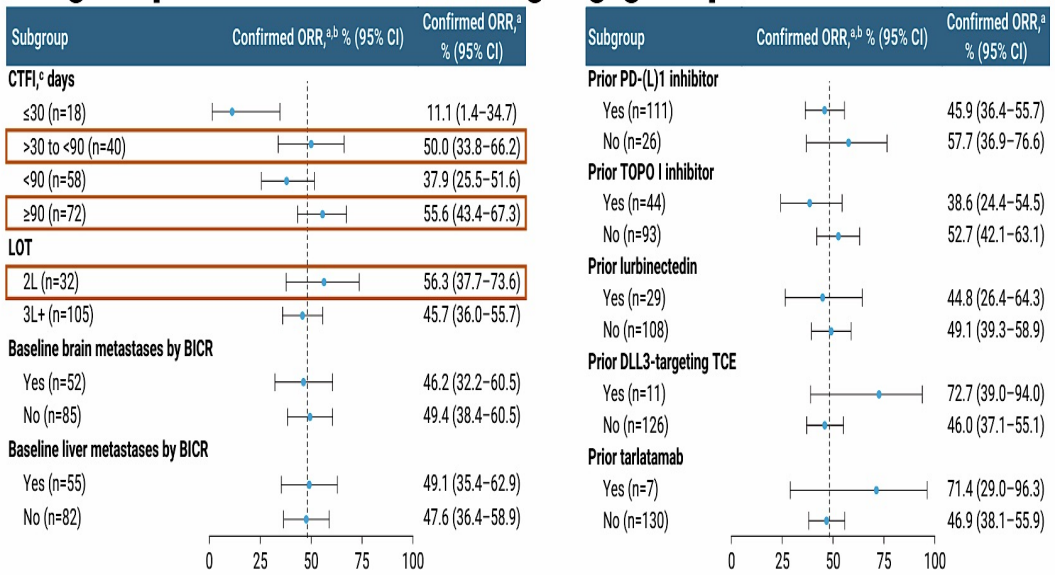


	Total I-DXd 12 mg/kg (N=137)
mPFS[a] (95% CI), months	4.9 (4.2–5.5)
PFS rate,[a] % (95% CI)	
3 months	68.0 (59.4–75.2)
6 months	35.3 (27.3–43.4)
9 months	19.3 (12.9–26.5)

	Total I-DXd 12 mg/kg (N=137)
mOS (95% CI), months	10.3 (9.1–13.3)
OS rate, % (95% CI)	
3 months	89.1 (82.5–93.2)
6 months	77.4 (69.4–83.5)
9 months	59.1 (50.4–66.8)

Among patients who received I-DXd 12 mg/kg as 2L therapy (n=32), mPFS was 5.6 months (95% CI, 3.9–8.1) and mOS was 12.0 months (95% CI, 7.3–19.1)

I-DXd demonstrated clinically meaningful benefit across subgroups of the total 12-mg/kg group



- The total 12-mg/kg population included 18 (13.1%) patients with CTFI ≤30 days; as expected, confirmed ORR was low in this population
- In 65 patients with baseline brain metastases identified using CNS BICR, CNS confirmed ORR was 46.2% (95% CI, 33.7–59.0)[d]

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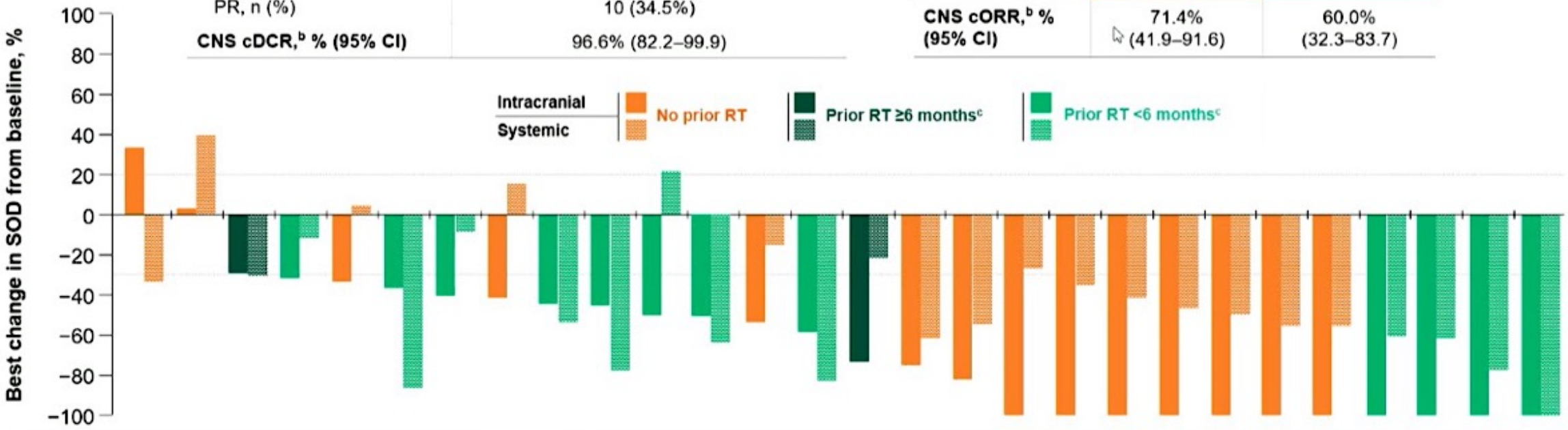
I-DXd demonstrated promising responses in patients with brain target lesions[a]

	With baseline brain target lesions (n=29)
CNS cORR,[b] % (95% CI)	65.5% (45.7–82.1)
CR, n (%)	9 (31.0%)
PR, n (%)	10 (34.5%)
CNS cDCR,[b] % (95% CI)	96.6% (82.2–99.9)

	No prior RT (n=14)	With prior RT (n=15)
CNS cORR,[b] % (95% CI)	71.4% (41.9–91.6)	60.0% (32.3–83.7)



Concordance between systemic and CNS **objective response: 69.0%**

Data cutoff: March 3, 2025.

[a]Only patients with measurable disease at baseline and ≥1 post-baseline assessment are included in the plot (n=28); 1 patient was excluded due to a lack of post-baseline assessment. [b]By CNS BICR using a version of RECIST 1.1 modified for assessment of CNS tumors. [c]Time from last RT of brain until first dose of study treatment.

BICR, blinded independent central review; cDCR, confirmed disease control rate; CI, confidence interval; CNS, central nervous system; cORR, confirmed objective response rate; CR, complete response; PR, partial response; RECIST 1.1, Response Evaluation Criteria in Solid Tumours, version 1.1; RT, radiotherapy; SOD, sum of diameters.

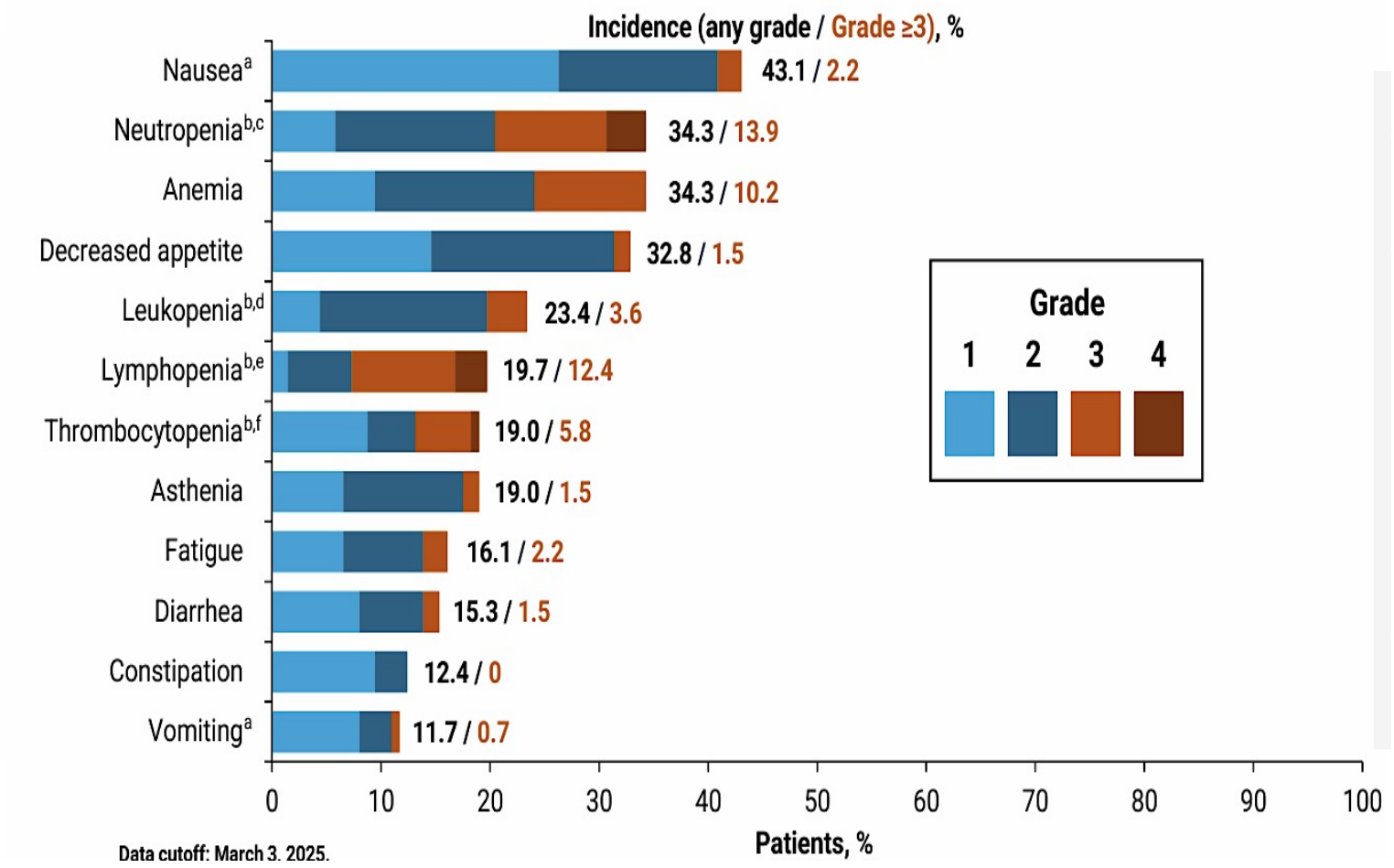
BERLIN 2025 ESMO congress

Rocha P et al. ESMO 2025

Phase II: Ideate-Lung01 Safety

The safety profile of I-DXd 12 mg/kg was manageable

	Total I-DXd 12 mg/kg (N=137)
Median treatment duration,[a] months (range)	4.8 (0.7–22.7)
Median cycles, n (range)	7.0 (1.0–32.0)
Any-grade TRAEs, n (%)	123 (89.8)
Grade ≥3	50 (36.5)
Associated with dose delay	35 (25.5)
Associated with dose reduction	21 (15.3)
Associated with treatment discontinuation[b]	13 (9.5)
Associated with death[c]	6 (4.4)



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Interstitial Lung Disease (ILD) with I-DXd

- Among the most common TRAEs, the majority were Grade 1 or 2
- Adjudicated treatment-related ILD/pneumonitis was reported in 17 (12.4%) patients:
  - Grade 1 or 2, n=11 (8.0%)
  - Grade 3, n=4 (2.9%)
  - Grade 5, n=2 (1.5%)[g]
- No ILD events were pending adjudication at data cutoff

Dec 18, 2025
Voluntary clinical hold on ongoing Phase 3 trial due to higher incidence of grade 5 ILD.

January 13, 2026
Clinical hold lifted.

The manufacturers have implemented "additional strategies" to mitigate the risk of pneumonitis and ILD. These strategies include "stricter trial enrollment eligibility criteria" and "more frequent review of unblinded efficacy and safety data."

The manufacturers have also implemented additional training for investigators and clinical study staff.

Ahn MJ et al. WCLC 2025
https://www.fiercebiotech.com/biotech/patient-deaths-prompt-partial-hold-daiichi-mercks-global-phase-3-adc-program
https://www.biospace.com/drug-development/patient-deaths-put-merck-daiichi-sankyos-antibody-drug-conjugate-on-hold

I-DXd Currently Under FDA Review

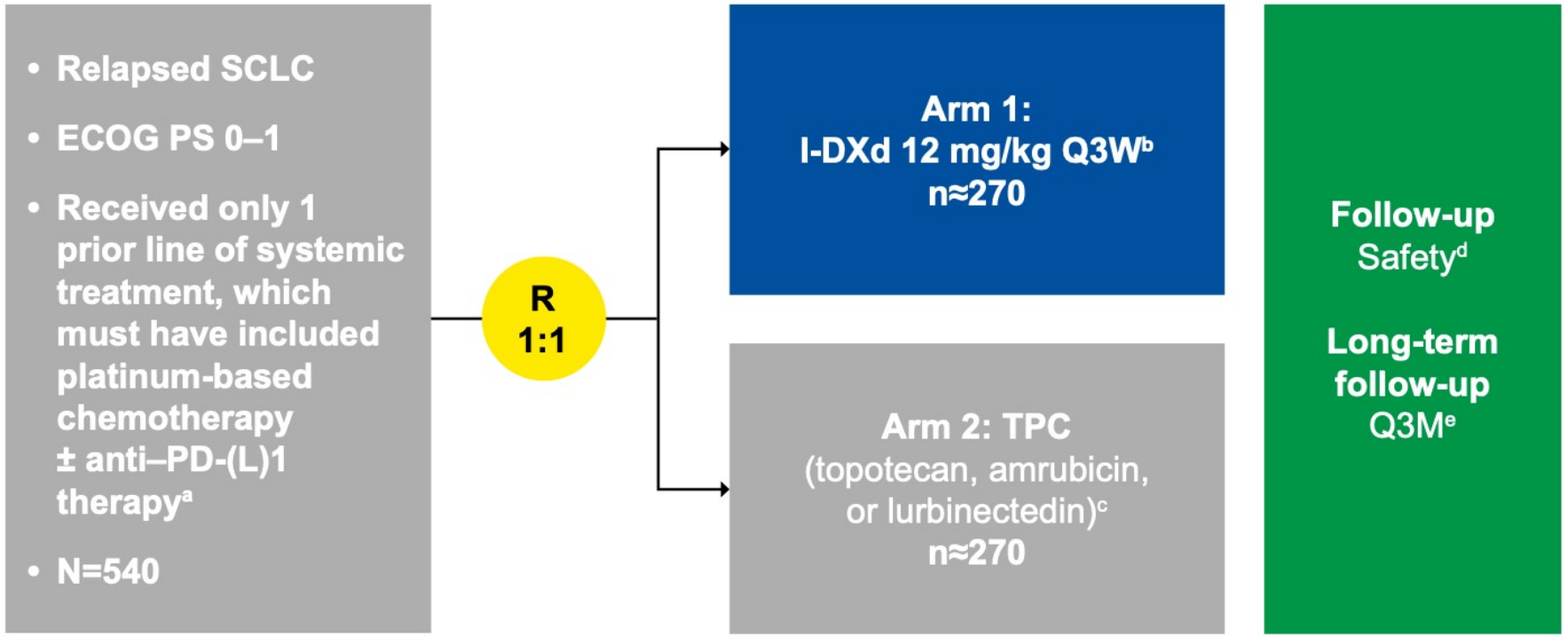
Ifinatamab Deruxtecan Granted Priority Review in the U.S. for Adult Patients with Previously Treated Extensive-Stage Small Cell Lung Cancer who Experienced Disease Progression on or After Platinum-Based Chemotherapy

Based on results from IDeate-Lung01 Phase 2 trial, with support from IDeate-PanTumor01 Phase 1/2 trial.

If approved, ifinatamab deruxtecan would be a first-in-class B7-H3 directed DXd antibody drug conjugate for these patients.

https://www.merck.com/news/ifinatamab-deruxtecan-granted-priority-review-in-the-u-s-for-adult-patients-with-previously-treated-extensive-stage-small-cell-lung-cancer-who-experienced-disease-progression-on-or-after-platinum-bas/

IDeate-Lung02: Phase 3 Study of I-DXd in Relapsed SCLC



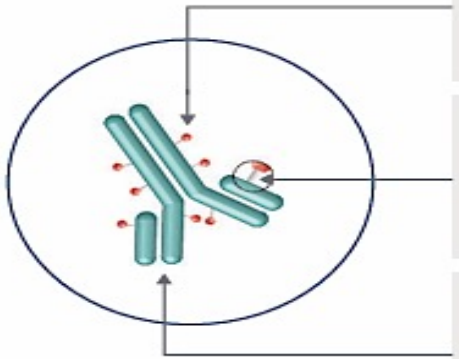
Stratification

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)

Hayashi H et al. Japanese Society of Medical Oncology 2025 Annual Meeting; Abstract P93-5.

Sacituzumab Govitecan: MOA

Figure 1. SG Mechanism of Action

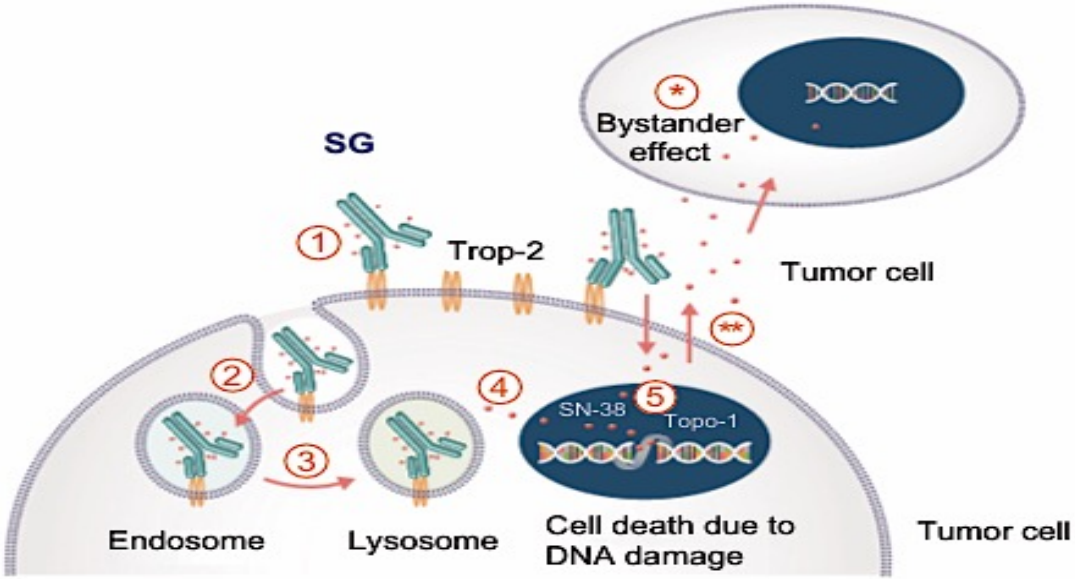


SN-38 payload
- SN-38 is more potent than the parent compound, irinotecan (Topo-1 inhibitor)
- SN-38 is rapidly internalized and efficiently released to the tumor with minimized effect on healthy tissues

Linker for SN-38
- pH-sensitive, hydrolyzable linker for SN-38 release in targeted tumor cells and tumor microenvironment, allowing bystander effect
- High drug-to-antibody ratio (7.6:1)[8]

Humanized anti–Trop-2 antibody
- Binds with high (K_D = 0.3 nM) affinity to Trop-2, an epithelial antigen expressed on many solid tumors[9]

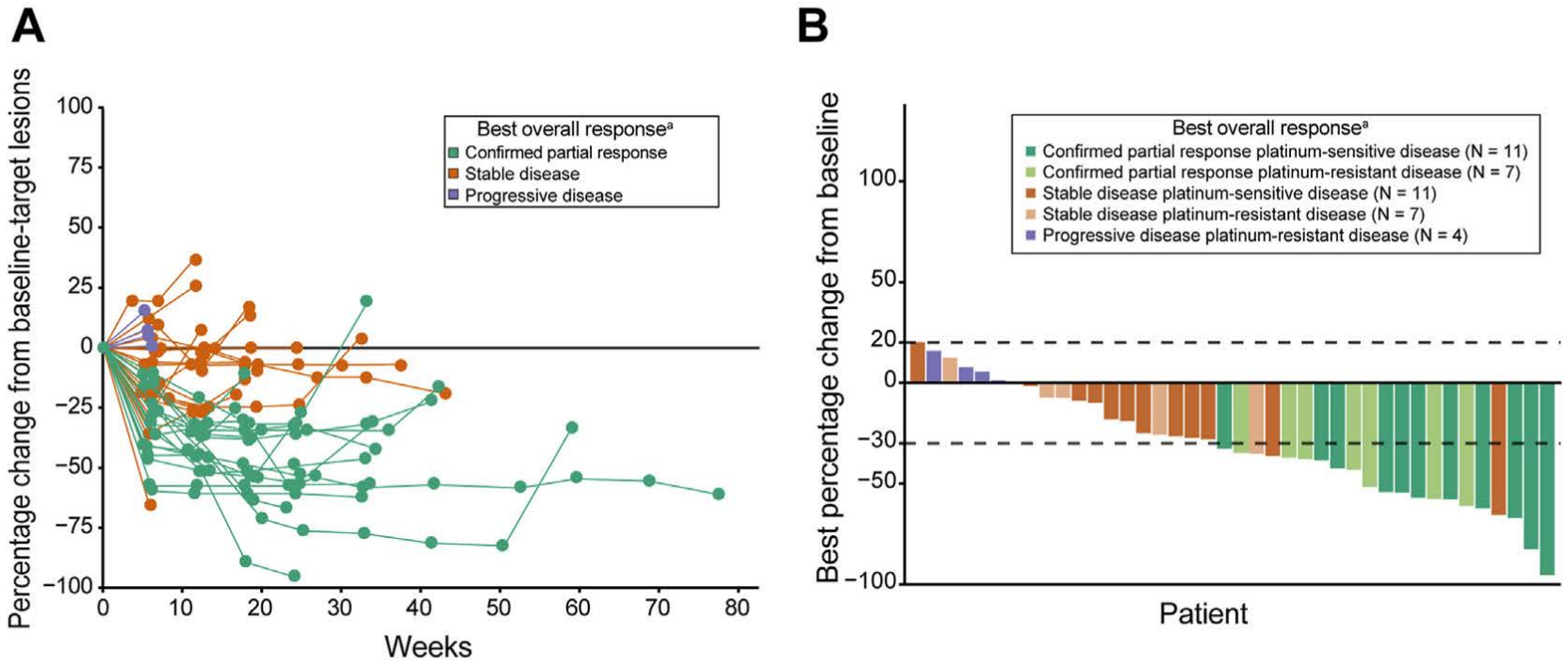
① Binding
② Internalization
③ Lysosomal degradation
④ Intracellular trafficking
⑤ Cell cytotoxicity
* Bystander effect on adjacent tumor cells
** SN-38 release and DNA damage



SG, sacituzumab govitecan; Topo-1, topoisomerase I; Trop-2, trophoblast cell surface antigen 2.

Dowlati, et al, WCLC 2025

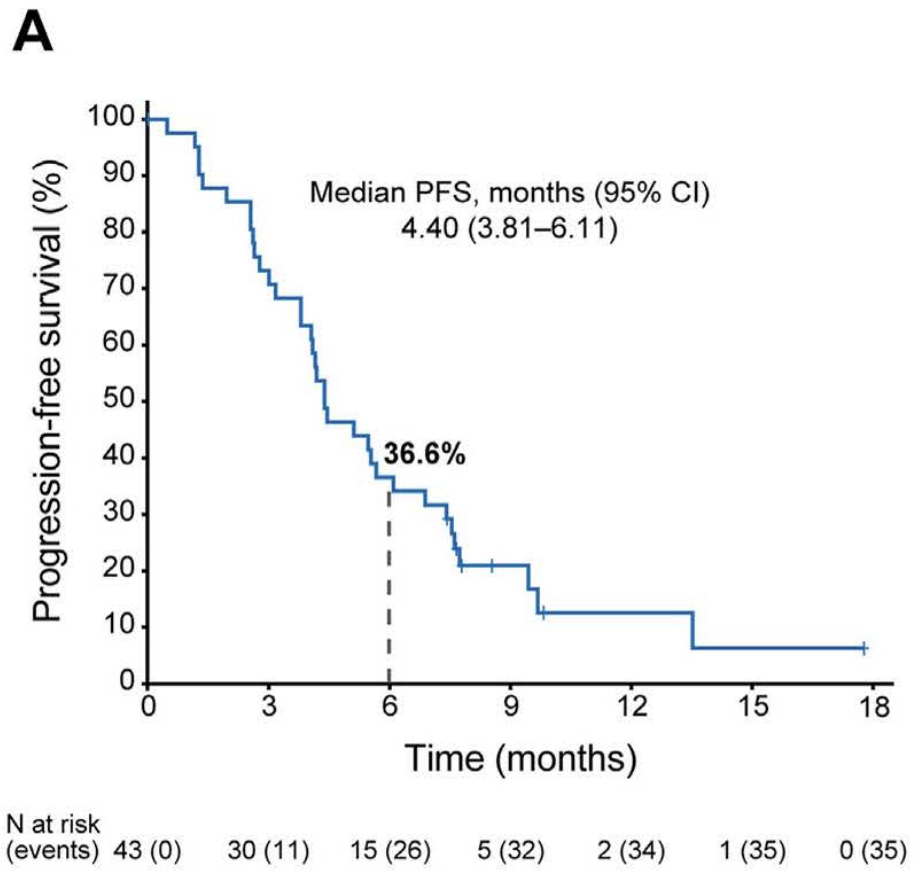
Ph2 TROPiCS-03: Sacituzumab Govitecan (SG) as 2L in SCLC Cohort

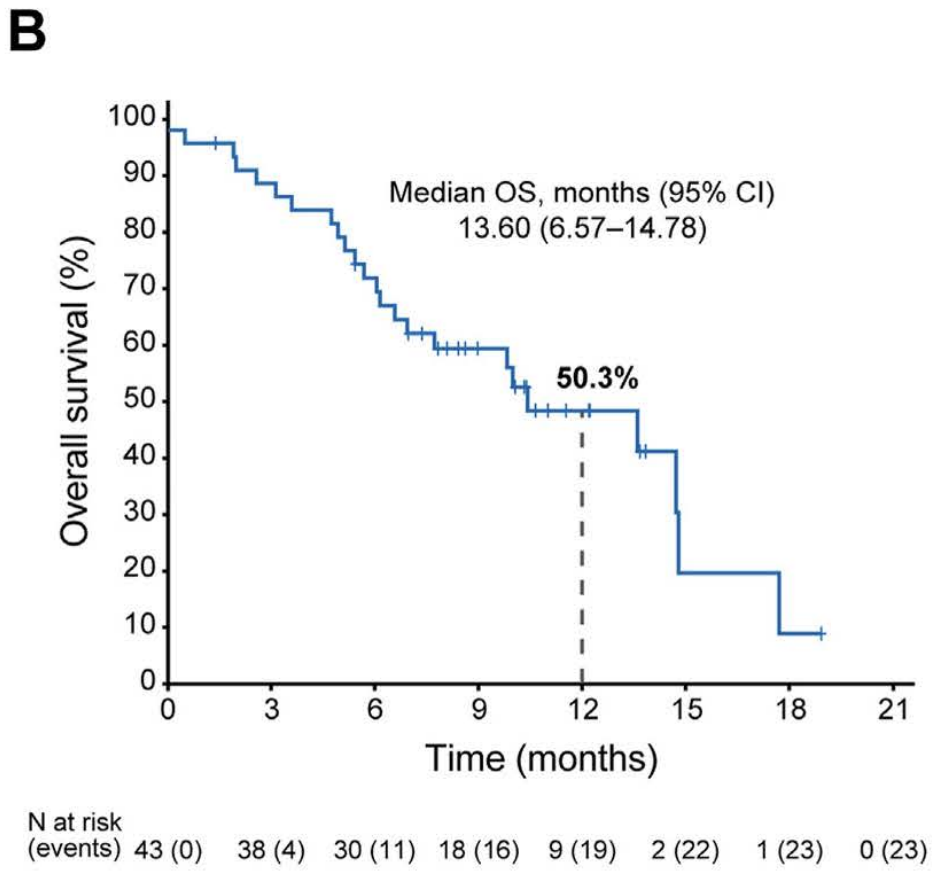


- TROPiCS-03 (NCT03964727) open-label phase 2 basket study of solid tumors
- Pts with ES-SCLC that progressed after 1L chemoIO
- Received SG 10 mg/kg on D1, D8 of 21 day cycle
- n=43
- ORR 41.9%
- mDOR: 4.73 mo

Dowlati, Chiang et al, JTO June 2025

Ph2 TROPiCS-03: Sacituzumab Govitecan (SG) as 2L in SCLC Cohort





Dowlati, Chiang et al, JTO June 2025

Ph2 TROPiCS-03: Sacituzumab Govitecan (SG) as 2L in SCLC Cohort

Table 3. Safety Summary

TEAEs	Patients (N = 43)	
Event	Any Grade	Grade ≥ 3
TEAEs, n (%)[a,b]	43 (100.0)	32 (74.4)
TEAEs reported in ≥10% of patients		
Diarrhea	33 (76.7)	4 (9.3)
Fatigue	26 (60.5)	1 (2.3)
Neutropenia	24 (55.8)	19 (44.2)
Constipation	18 (41.9)	0
Nausea	17 (39.5)	0
Alopecia	13 (30.2)	0
Anemia	13 (30.2)	2 (4.7)
Decreased appetite	10 (23.3)	0
Abdominal pain	8 (18.6)	0
Hypomagnesemia	7 (16.3)	0
Rash	7 (16.3)	0
Vomiting	7 (16.3)	0
Dizziness	6 (14.0)	0
Dysgeusia	6 (14.0)	0
Stomatitis	6 (14.0)	2 (4.7)
COVID-19	5 (11.6)	0
Cough	5 (11.6)	0
Hypokalemia	5 (11.6)	0
Hyponatremia	5 (11.6)	3 (7.0)
Hypotension	5 (11.6)	1 (2.3)
Edema peripheral	5 (11.6)	0
Treatment related[c]	42 (97.7)	26 (60.5)
TEAEs leading to treatment discontinuation	0	
Treatment related[c]	0	
TEAEs leading to death	3 (7.0)	
Treatment related[d]	1 (2.3)	
TEAEs leading to dose reduction	16 (37.2)	
TEAEs leading to treatment interruption	30 (69.8)	

Dowlati, Chiang et al, JTO June 2025

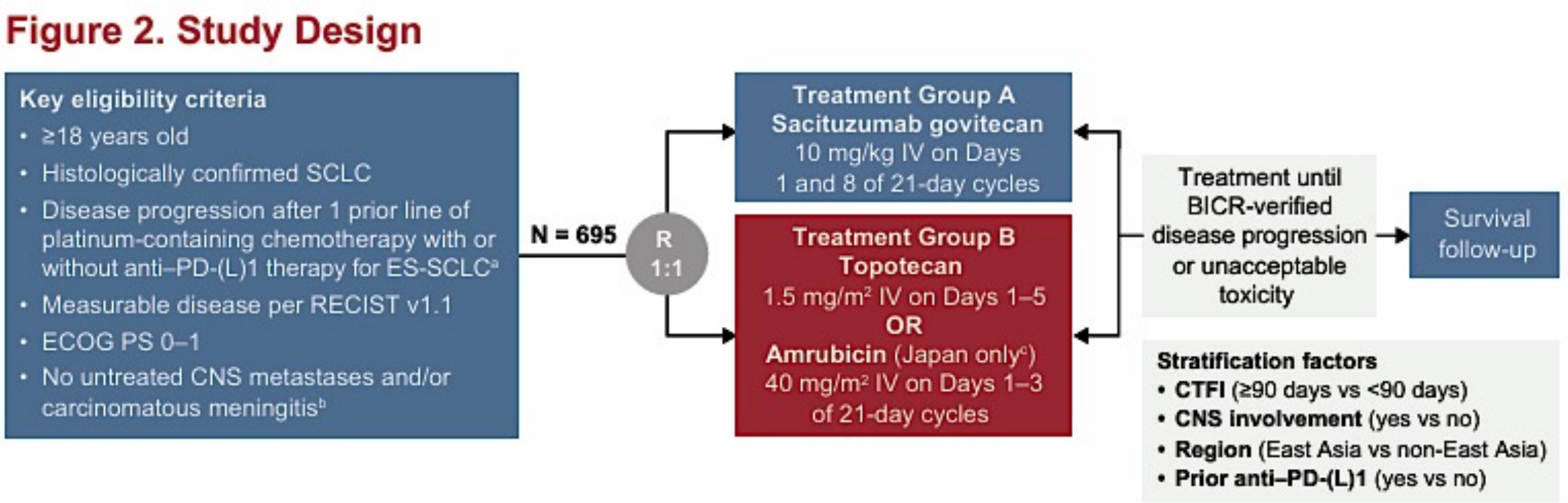
SG Granted FDA Breakthrough Therapy in ES-SCLC

U.S. FDA Grants Breakthrough Therapy Designation to sacituzumab govitecan for Second-Line Treatment of Extensive-Stage Small Cell Lung Cancer

The Breakthrough Therapy Designation is based on results from the global Phase 2 TROPiCS-03 study ES-SCLC cohort, which showed encouraging results with SG as a second-line treatment for ES-SCLC.

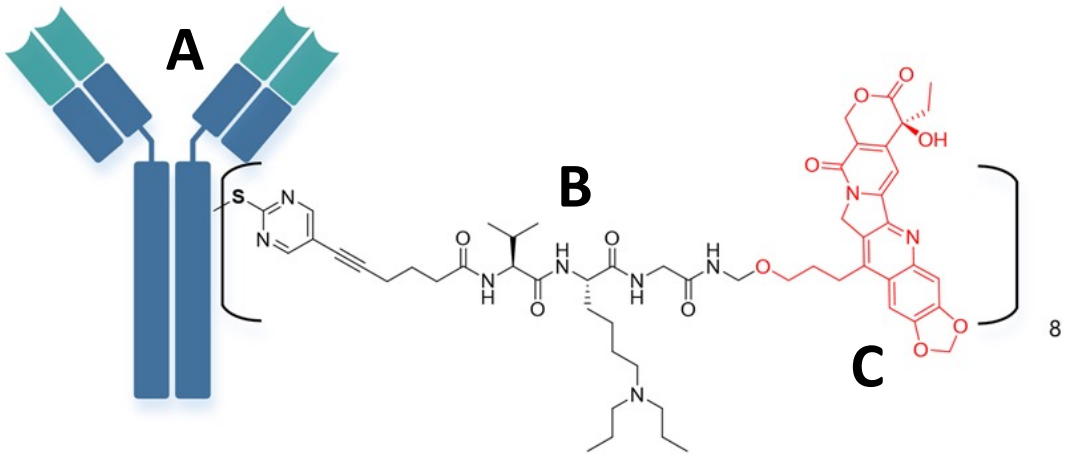
https://www.gilead.com/news/news-details/2024/us-fda-grants-breakthrough-therapy-designation-to-trodelvy-sacituzumab-govitecan-hziy-for-second-line-treatment-of-extensive-stage-small-cell-lung-cancer

Ongoing Ph3 EVOKE-SCLC-04 (NCT06801834)



ZL-1310: Delta-Like Ligand 3 (DLL3) Targeting Antibody Drug Conjugate (ADC)

- DLL3 is a neuroendocrine-specific antigen that is a validated target and is highly expressed in small cell lung cancer (SCLC), an indication with a high unmet medical need[1-3]
- ZL-1310 is a novel DLL3-targeting ADC developed using the camptothecin derivative-based TMALIN® (Tumor Microenvironment-Activable LINker-payload) platform[4]
  - Efficient payload delivery to the targeted cells with DAR=8
  - Potent bystander killing mediated by the Topo-1 inhibitor payload C24
  - TME-specific payload release and accumulation, minimizing systemic toxicity



A: Humanized anti-DLL3 IgG1 mAb
B: Cleavable tripeptide-based linker
C: Camptothecin derivative payload, C24

DLL3: delta-like ligand 3; DAR: drug-to-antibody ratio; Ig: immunoglobulin; mAb: monoclonal antibody; TME: tumor microenvironment

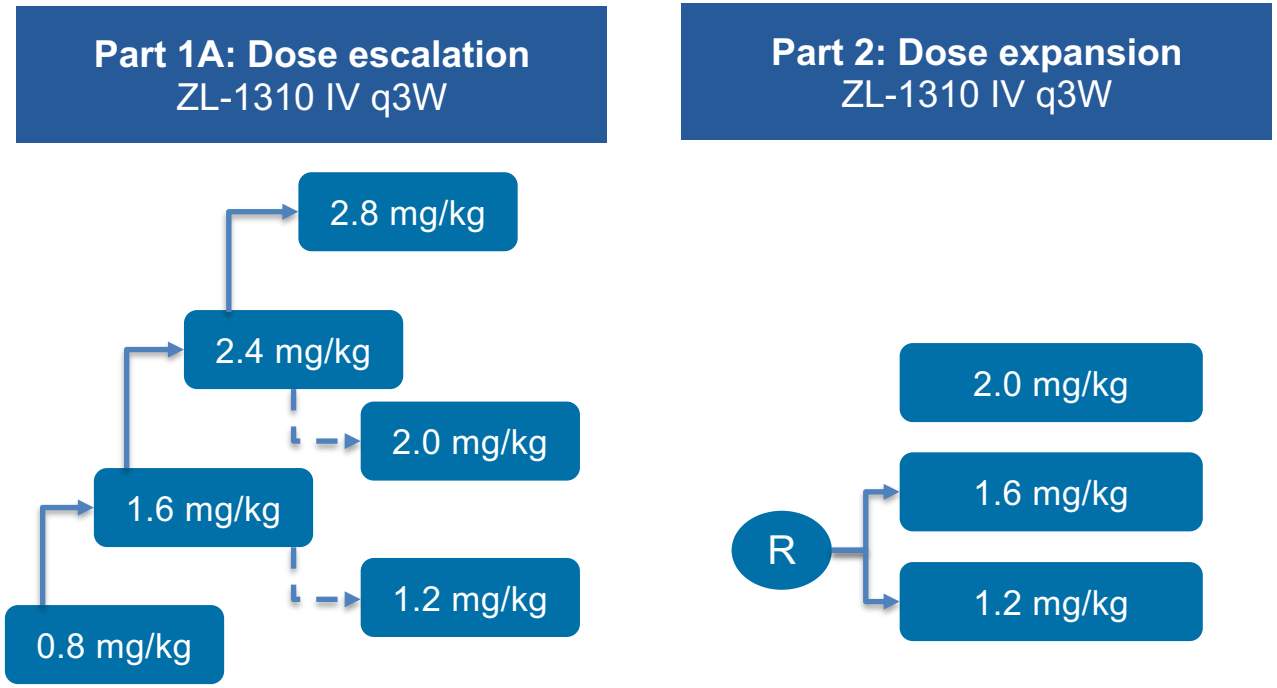
1. Sabari JK, et al. Nat Rev Clin Oncol. 2017;14(9):549–61. 2. Saunders LR, et al. Sci Transl Med. 2015;7(302):302ra136. 3. Petrelli F, et al. Mol Clin Oncol. 2021;15(4):218. 4. Liu LN, et al. Poster presented at: ELCC; March 22, 2024; Prague, Czech Republic.

ZL-1310-001: Study Overview (NCT06179069)

- Phase I, open-label, dose-escalation and expansion study of ZL-1310 as **monotherapy** and in combination with atezolizumab or atezolizumab and carboplatin in SCLC
- Preliminary data was previously reported.[1] Data reported here are an update from the ongoing **monotherapy parts**
  - **115 patients** dosed across dose escalation and expansion cohorts
    - **102 patients** had the opportunity of at least 1 post baseline scan for response assessment per RECIST v1.1 (Efficacy Evaluable Population) with median follow-up time 7.1 months

Patients with metastatic or extensive-stage SCLC with ≥ 1 prior platinum-based chemotherapy regimen

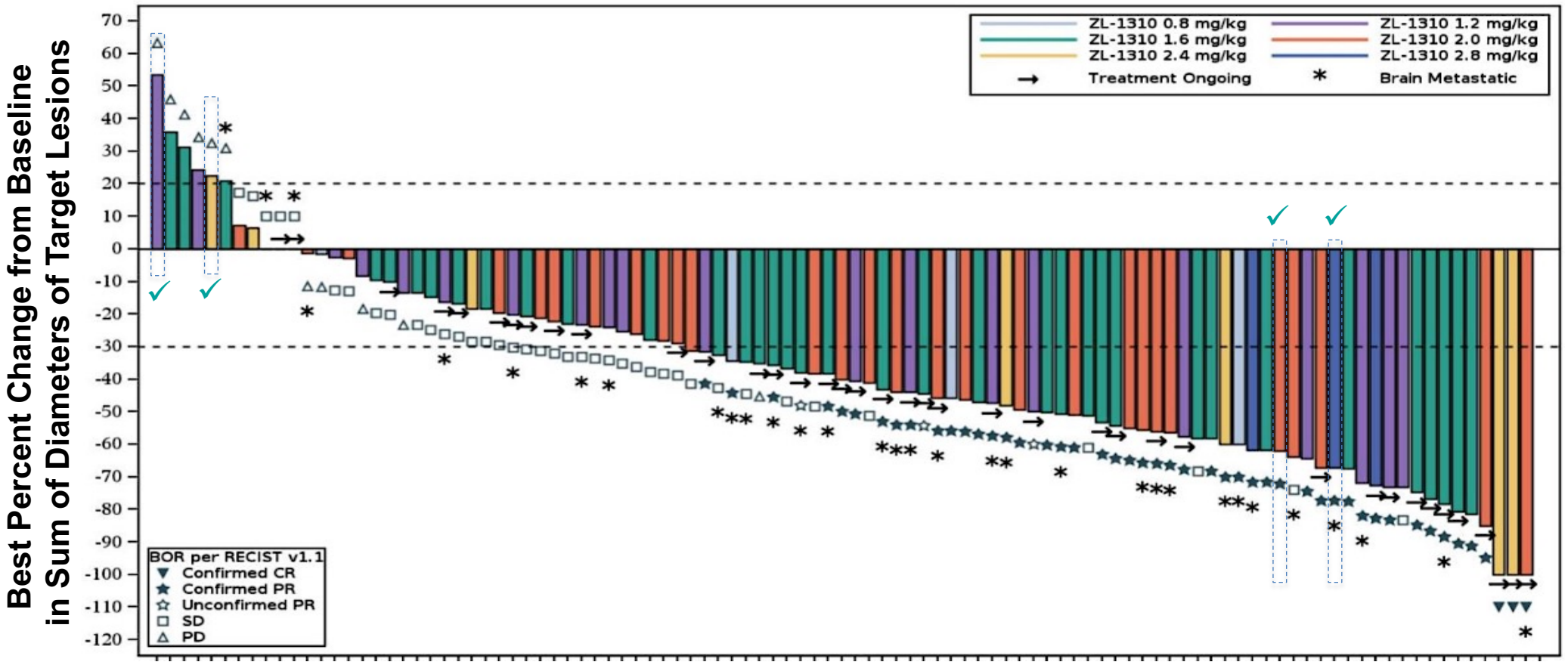
- Asymptomatic brain metastasis (treated or untreated) allowed
- Prior DLL3-targeted therapy allowed
- Archival biopsy collected for retrospective DLL3 testing
- ECOG PS 0-1



Data cut-off: September 15, 2025. IV: intravenous; q3W: once every 3 weeks; PS: Performance Status; R: randomization; RECIST v1.1: Response Evaluation Criteria in Solid Tumors version 1.1; SCLC: small cell lung cancer;

1. Patel, M.R. et al. JCO 2025, 43, 3041, ASCO 2025.

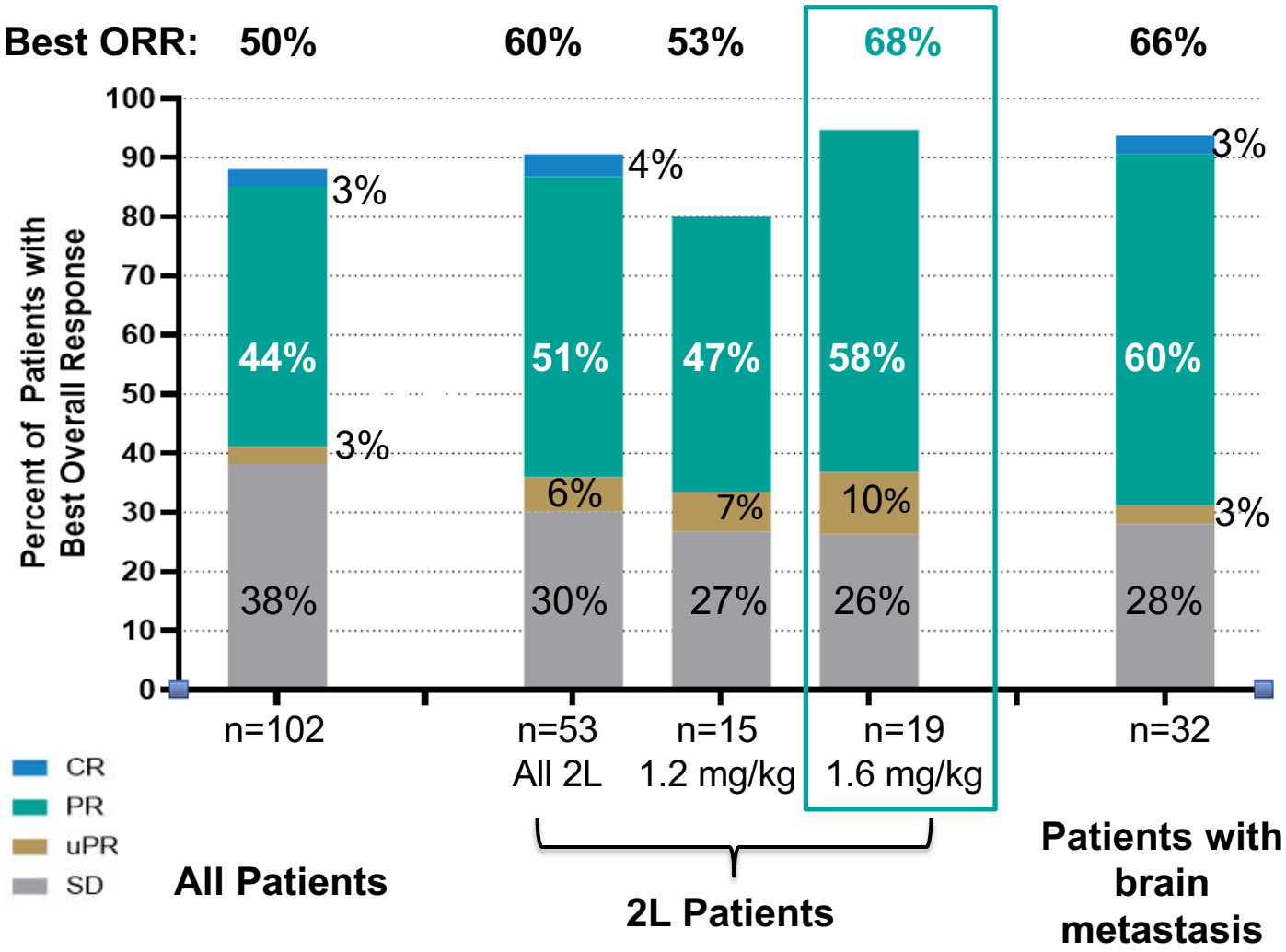
Target Tumor Regression Observed Across Dose Levels and In Patients with Brain Metastasis At Baseline



Pts received a median of 6 treatment cycles (range 1-22) of ZL-1310

✓ Of the 76 pts with tumor tissue samples available, four (4/76, 5.3%) were found to be DLL3-negative (IHC=0) by retrospective immunohistochemistry analysis via central laboratory

Best Overall Response per RECIST v1.1 by Investigator: Efficacy Evaluable Population



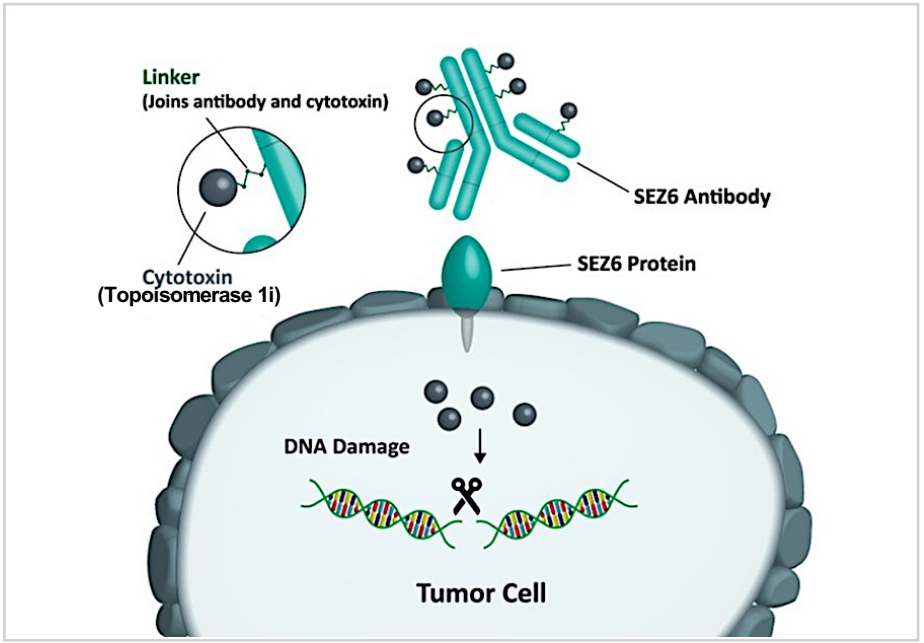
- High response rate observed in patients with brain metastasis at baseline
  - Including 8/10 (80%) ORR for patients without prior brain radiotherapy
- Higher response rate for less heavily treated patients; retained activity after DLL3-targeted therapy
  - 40% ORR (1 CR, 3 PR) in 10 with prior DLL3-targeted T-cell engagers
  - 43% ORR (1 CR, 2 PR) in 7 with prior tarlatamab
- Activity observed at both ongoing dose expansion levels
- Estimated median DoR: 6.1 mo.
  (48/102 confirmed responders)

Data cut-off: September 15, 2025. CR: Complete Response; DoR = duration of response; mo.: months; PR: partial response; uPR: partial response observed, and follow-up is ongoing in this patient (response to be confirmed); Best ORR: confirmed overall response rate (ORR: CR + PR) + uPR for patients ongoing; SD: Stable Disease

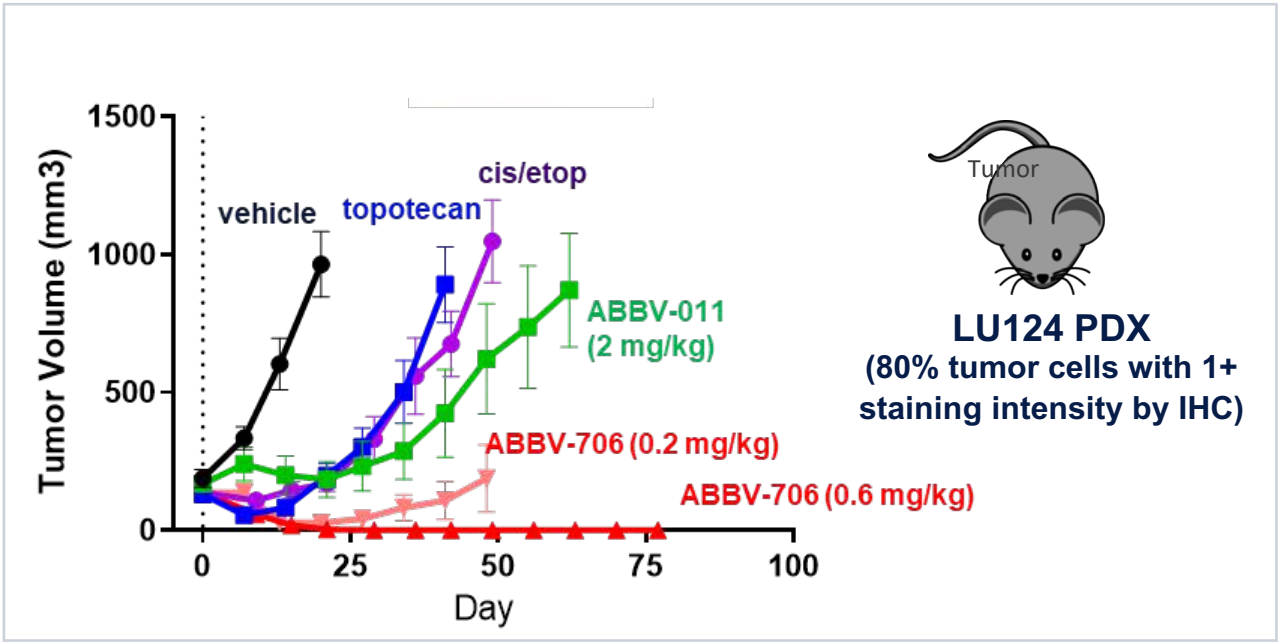
ABBV-706: SEZ6-targeting ADC

- SEZ6-targeting antibody, conjugated to a topoisomerase 1 inhibitor (Top1i) payload with sub-nM cytotoxic activity
- Drug-to-antibody ratio of 6 with stable attachment via a valine-alanine cathepsin cleavable linker
- Tumor-targeted delivery of Top1i[1] with potential for bystander killing of neighboring cancer cells
- Superior antitumor activity vs chemotherapy and ABBV-011, in a SEZ6-expressing SCLC murine model

ABBV-706 Mechanism of Action



ABBV-706 Preclinical Activity – SCLC (SEZ6+) PDX



ADC, antibody-drug conjugate; cis, cisplatin; etop, etoposide; IHC, immunohistochemistry; nM, nanomolar; PDX, patient-derived xenograft; SCLC, small cell lung cancer; SEZ6, seizure-related homolog protein 6.

1. Han S, et al. *Pharmaceutics*. 2022;14:1707.

ABBV-706 SEZ6 Antibody-Drug Conjugate (ADC) in Relapsed/Recurrent SCLC Patients

Efficacy in patients with R/R SCLC

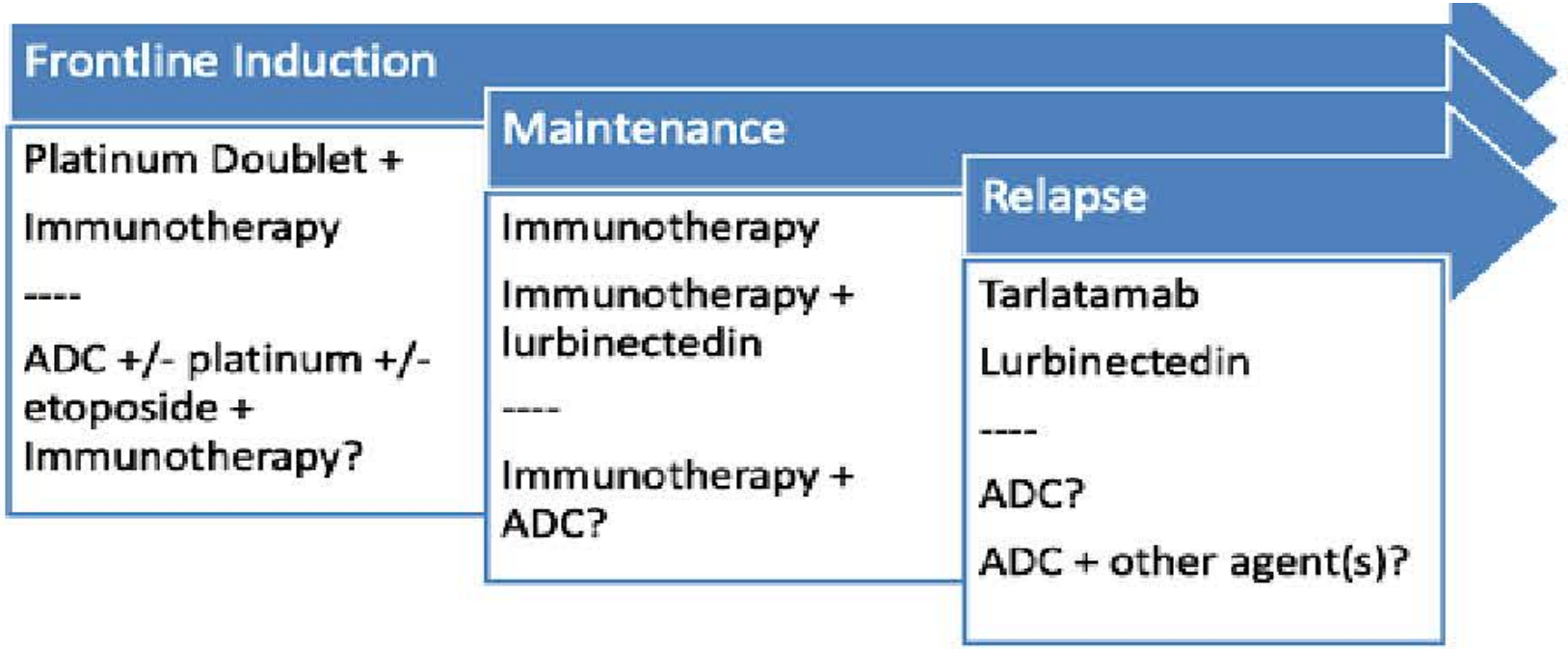
Outcome	1.8 mg/kg (n = 41)	2.5 mg/kg (n = 39)
ORR,* %	**56.1**	**59.0**
1 prior LOT	*81.3*	*71.4*
Top1i naïve	*62.1*	*64.3*
Brain metastasis	*62.5*	*50.0*
Median DOR,† mo [95% CI]	**6.2** [4.2, NE]	**4.4** [3.5, 6.9]
PFS, mo [95% CI]	**6.8** [4.0, 8.2]	**5.6** [4.4, 7.0]

Safety in patients with R/R SCLC

TRAE	1.8 mg/kg (n = 41)	2.5 mg/kg (n = 39)
Any-grade TRAE, %	**85**	**95**
Anemia	*51*	*74*
Fatigue	*34*	*39*
Grade ≥3 TRAE, %	**49**	**77**
Anemia	39	62
Neutrophils Decreased	17	31
TRAEs leading to dose discontinuation, %	**9** (of all patients)	
Adjudicated ILD rate, %	**9** (of all patients)	

- The SEZanne ph2 trial (NCT07155174) randomizes 1L SCLC patients to ADC+ immunotherapy (platinum free) vs platinum doublet/immunotherapy!

ADCs in SCLC: Future Questions



- Will ADCs be approved in the near future in ≥ 2L (likely)?
- What is the role of ADCs in 1L or maintenance therapy replacing or in combination with current SOC?
- What are mechanisms of resistance to ADCs?
- What is the ideal sequencing of therapies?

Sethakorn, Chiang, Cancers, manuscript accepted

Second Opinion

Ticiana Leal, MD

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

Discussion Questions

Given available research findings and your own clinical experience, would you like to have access to I-DXd today? If so, where would you likely sequence this agent?

Given its availability for breast cancer, are there any circumstances in which you would attempt to access sacituzumab govitecan for a patient with SCLC today? Are you optimistic that we will be using this agent soon for SCLC?

Discussion Questions (Continued)

How is I-DXd tolerated relative to other ADCs that are used in lung cancer (eg, trastuzumab deruxtecan, datopotamab deruxtecan)? Is the risk of ILD increased in patients with SCLC given that many of them have a smoking history and significant pulmonary comorbidities?
If I-DXd were available today, how would you approach monitoring for ILD to ensure safe delivery?

If multiple ADCs eventually reach the clinic, how do you envision sequencing them? Given that both I-DXd and sacituzumab govitecan have topoisomerase I payloads, will you be comfortable employing both of them for the same patient?

Second Opinion

Charu Aggarwal, MD

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

Discussion Questions

What would you recommend next for this patient?

How do you generally approach treatment for patients with EGFR-mutated NSCLC who experience transformation to SCLC? Do you still treat the EGFR component?

When EGFR-mutated NSCLC transforms to SCLC, does it become more responsive to immunotherapy? Have other commonly employed SCLC treatments been evaluated specifically for patients with SCLC transformation? Are any of them particularly effective?

Agenda

Module 1: Optimizing First-Line and Maintenance Therapy for Extensive-Stage Small Cell Lung Cancer (SCLC) — Dr Shields

Module 2: Management of Relapsed/Refractory SCLC — Dr Paz-Ares

Module 3: Ongoing Investigation and Potential Role of Antibody-Drug Conjugates in SCLC — Dr Chiang

Module 4: Management of Limited-Stage SCLC — Dr Ganti

Management of Limited Stage Small Cell Lung Cancer

Apar Kishor Ganti, MD, MS, FACP
Professor of Medicine
VA Nebraska Western Iowa Health Care System
Division of Oncology-Hematology
University of Nebraska Medical Center

University of Nebraska Medical Center

Introduction

- Neuroendocrine tumor
- ~15% of lung cancer
- M:F = 1:1
  - Incidence decreasing overall, but increasing in women
  - Proportion of women: 28% in 1973, 50% in 2002
- 5th leading cause of US cancer deaths
  - ~34,000 new cases per year

- Almost exclusively in those with smoking history
  - High burden in veteran populations
  - Never-smokers:
    - 2.9% of lung cancer in women
    - 0% of lung cancer in men
- Highly responsive to chemotherapy and radiotherapy, but relapses common
- 5-yr survival – 3-8% of all patients; 10-13% in patients with limited disease

Staging

- Staging workup
  - CT chest/abdomen/pelvis
  - Brain MRI
  - PET scan to rule out distant metastases

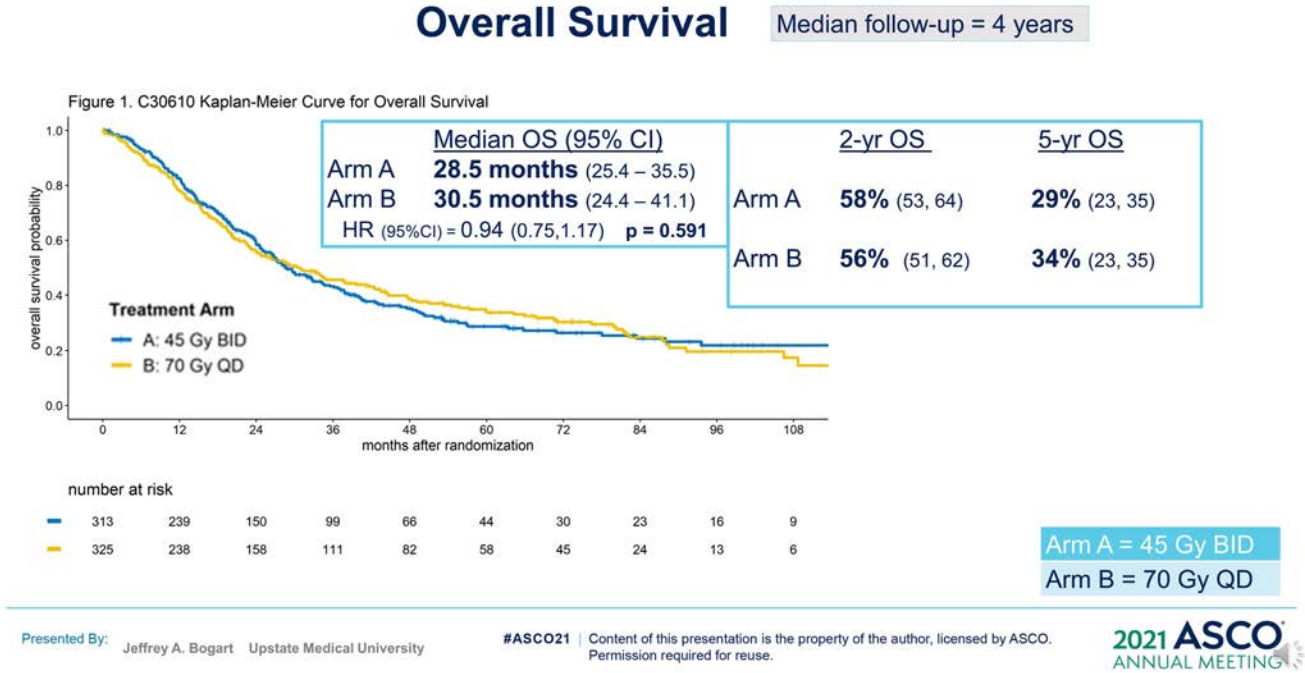
TNM Staging	VA Staging	Incidence (%)
T1-T2, N0, M0 (stage I)	Limited stage	~ 5
T any, N any, M0 (stage I-III)	Limited stage; disease burden contained within radiation field	~ 30
T any, N any, M1 (stage IV)	Extensive stage; disease burden beyond radiation field	~ 65

Treatment

- Limited stage (Goal = CURE)
  - Combination chemotherapy + TRT
    - Chemotherapy - platinum + etoposide
    - TRT moderately improves survival in patients with LS-SCLC treated with combination chemotherapy

Radiation in SCLC - CALGB 30610

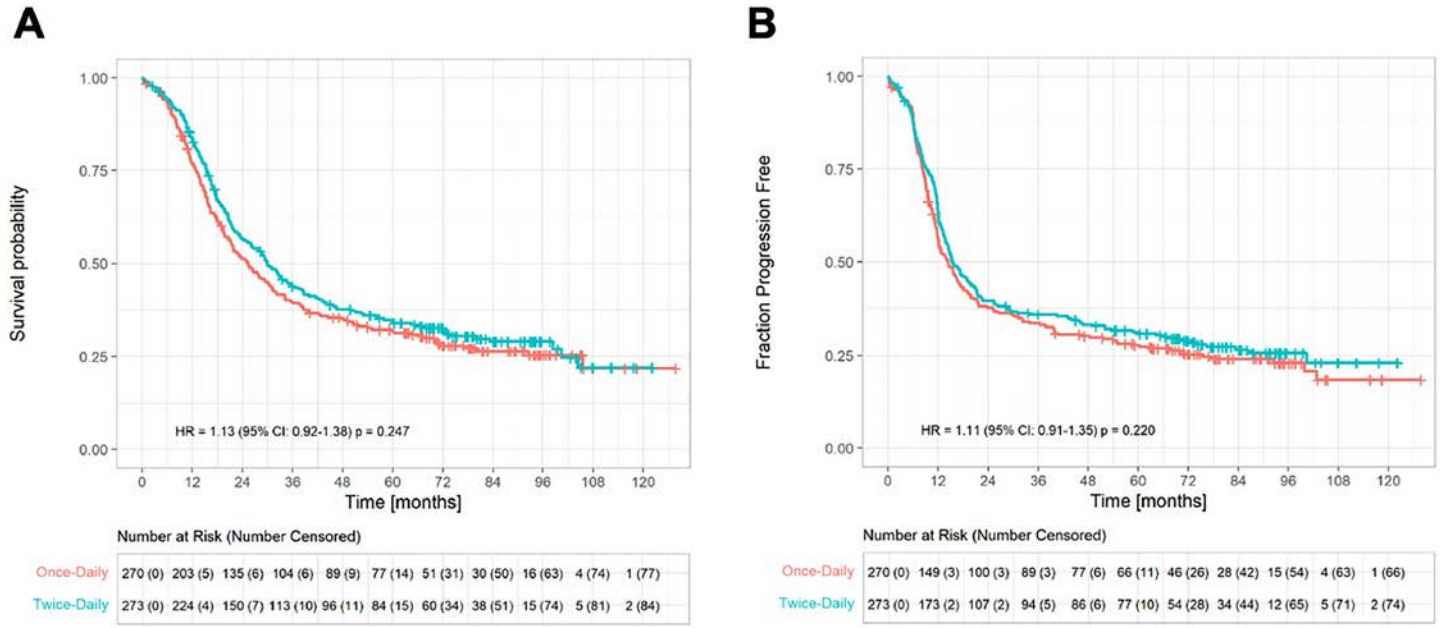
- 638 patients with LS-SCLC; PS - 0-2.
- 1:1:1 randomization to 45 Gy BID over 3 weeks, 70 Gy QD over 7 weeks, 61.2 Gy concomitant boost (CB) over 5 weeks.
- TRT - starting with 1st or 2nd (of 4 total) chemotherapy cycles.
- Primary endpoint - OS



Bogart J. J Clin Oncol. 2023;41:2394-2402.

Radiation in SCLC - CONVERT

- 547 patients with LS-SCLC; PS - 0-1.
- 1:1 randomization to 45 Gy BID over 3 weeks or 66 Gy QD over 6.5 weeks starting C1, D22.
- 4-6 cycles of cisplatin-etoposide
- Primary endpoint - OS

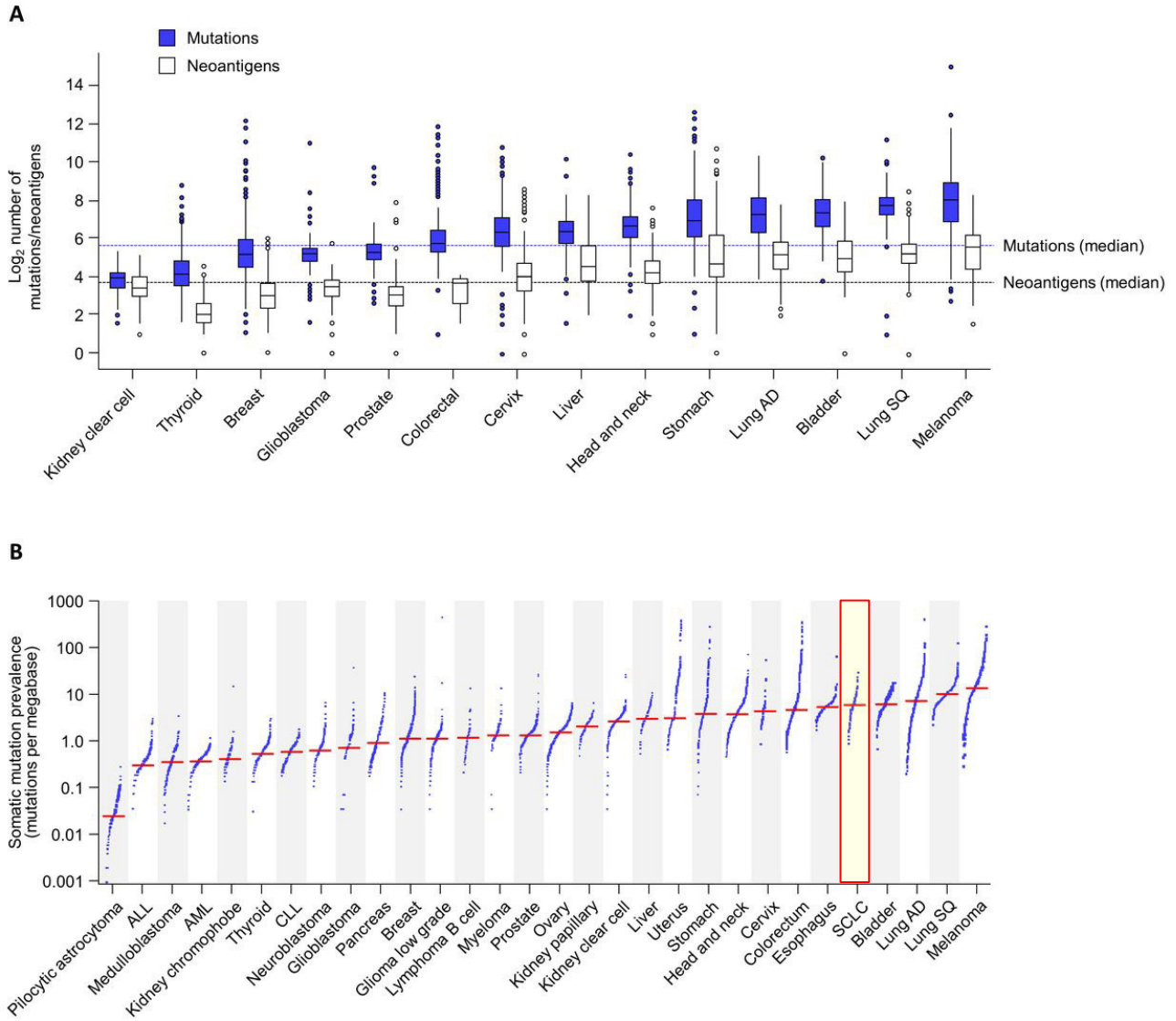


Median OS –

- QD: 25.4 months (95% CI, 21.1-30.9)
- BID: 30.0 months (95% CI, 25.3-36.5)

Walls GM. Int J Radiat Oncol Biol Phys. 2024;119(5):1386-1390.

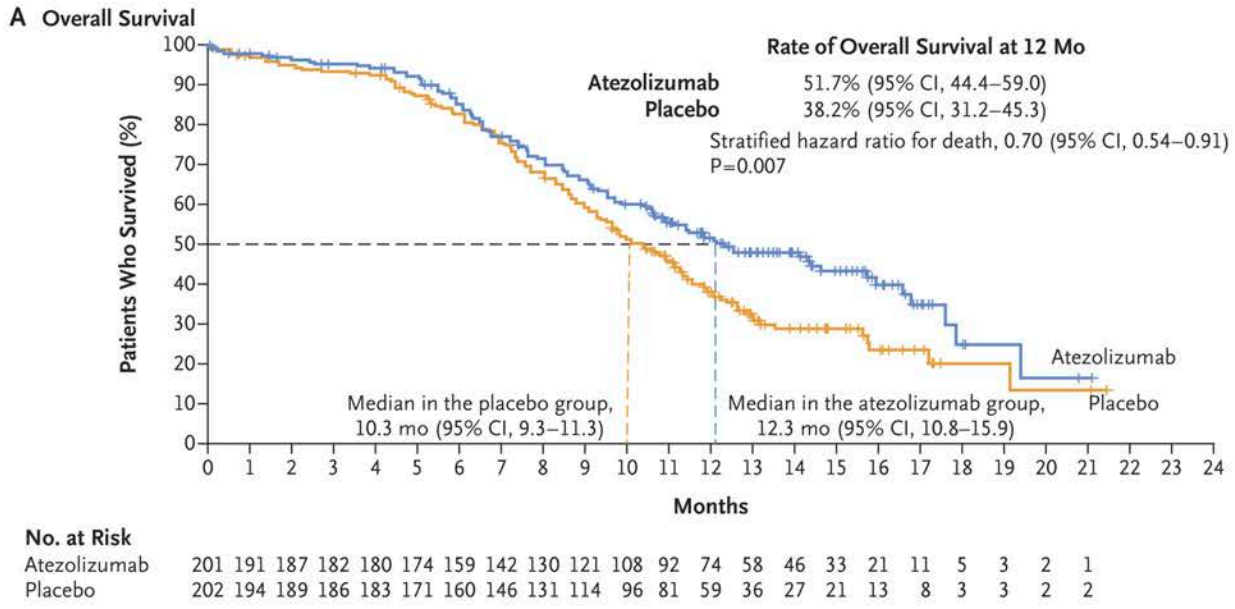
Rationale for IO
High Tumor Mutation Burden



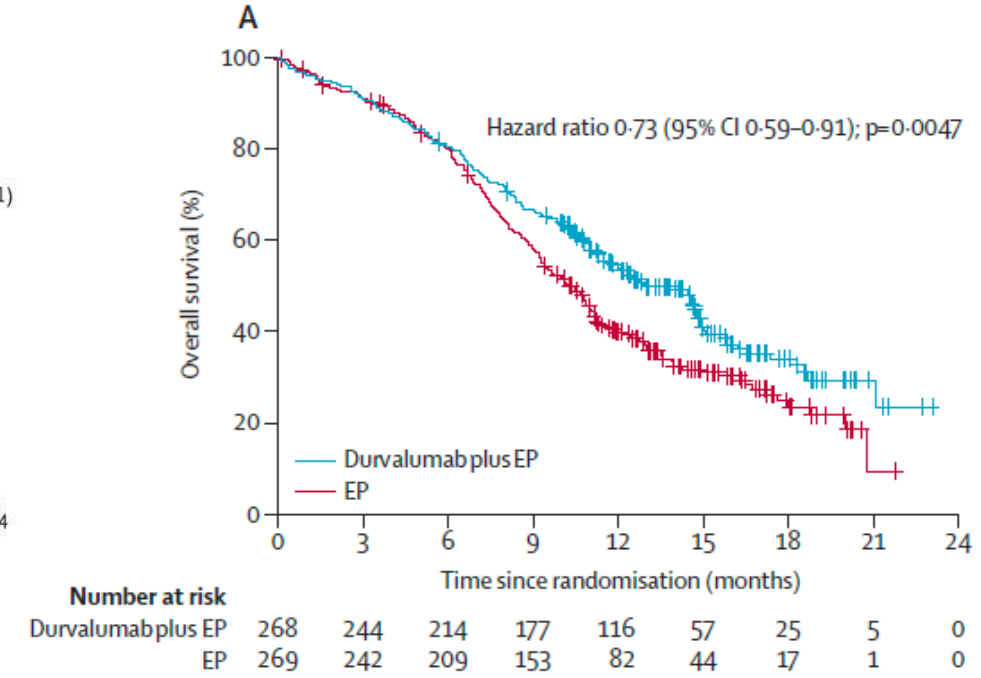
Büttner R. ESMO Open 2019;4:e000442.

Treatment – ES-SCLC

- Two trials: IMpower133 and CASPIAN



Carboplatin+ etoposide+ atezolizumab



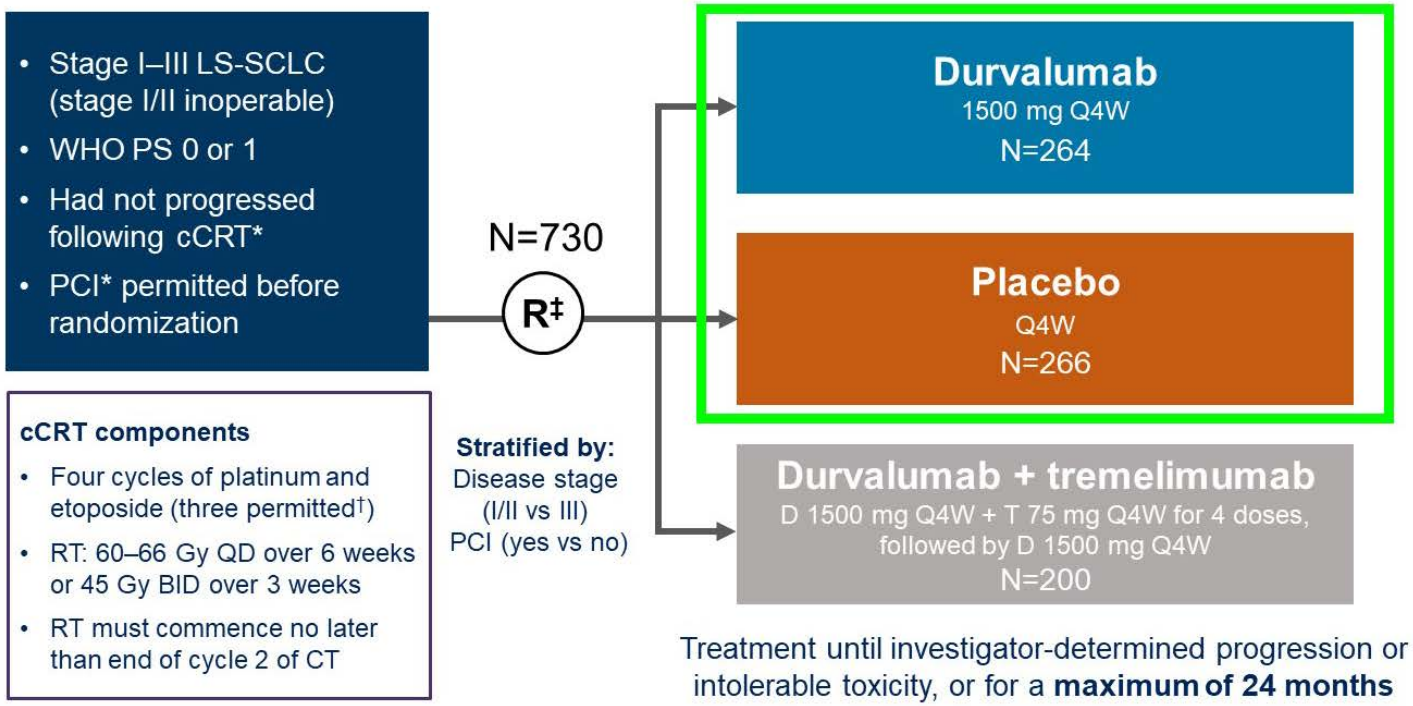
Platinum+ etoposide+ durvalumab

Horn L. N Engl J Med 2018; 379:2220-2229
Paz-Ares L. Lancet 2019; 394: 1929–39

LS-SCLC - ADRIATIC

ADRIATIC study design

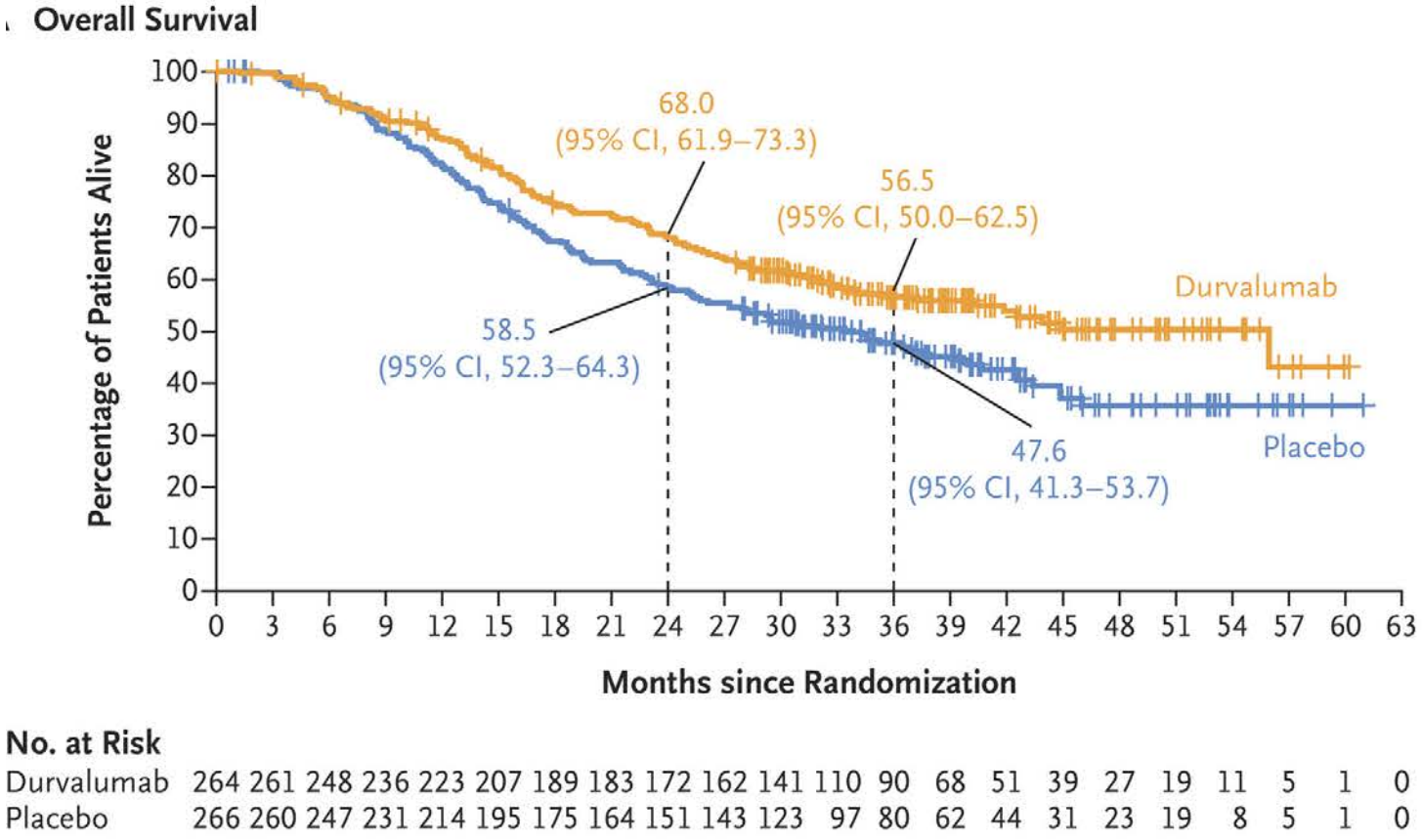
Phase 3, randomized, double-blind, placebo-controlled, multicenter, international study (NCT03703297)



*cCRT and PCI treatment, if received per local standard of care, must have been completed within 1–42 days prior to randomization.
†If disease control was achieved and no additional benefit was expected with an additional cycle of chemotherapy, in the opinion of the investigator.
‡The first 600 patients were randomized in a 1:1:1 ratio to the 3 treatment arms; subsequent patients were randomized 1:1 to either durvalumab or placebo.

Cheng Y. N Engl J Med 2024;391:1313-1327

ADRIATIC – Efficacy Results



	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)

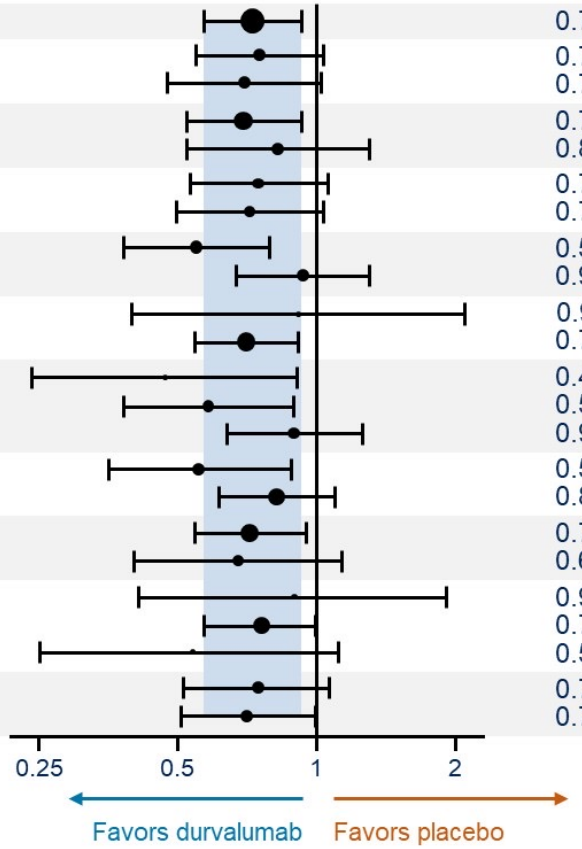
Stratified hazard ratio for death, 0.73 (98.321% CI, 0.54–0.98)
P=0.01

Cheng Y. N Engl J Med 2024;391:1313-1327

ADRIATIC – Efficacy Results

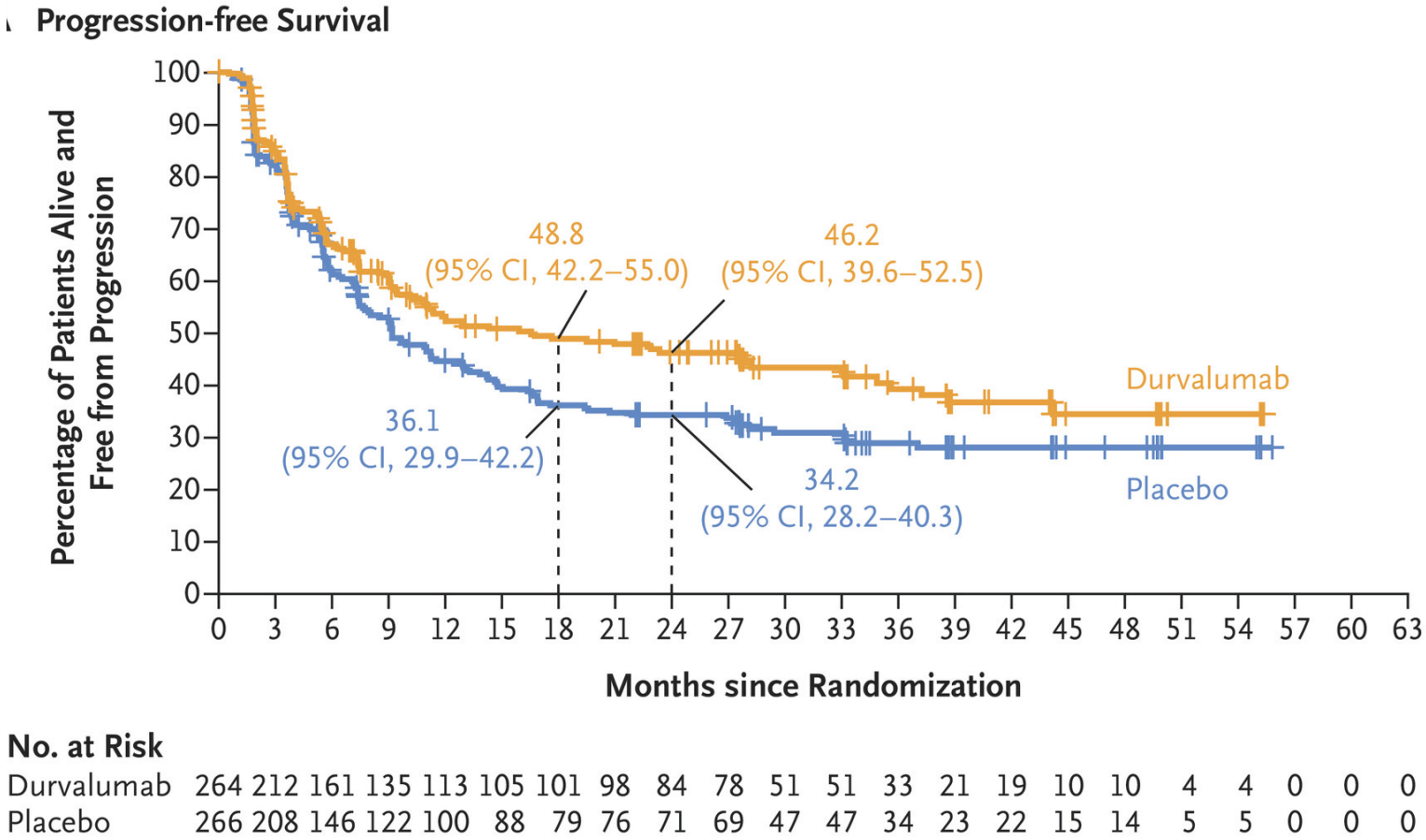
OS subgroup analysis

		Events/Patients n/N		HR (95% CI)
		Durvalumab	Placebo	
All patients		115/264	146/266	0.73 (0.57–0.93)
Age	<65 years	69/160	83/162	0.76 (0.55–1.04)
	≥65 years	46/104	63/104	0.70 (0.48–1.02)
Sex	Male	79/178	108/188	0.70 (0.52–0.93)
	Female	36/86	38/78	0.83 (0.52–1.31)
Race	White	60/130	77/137	0.75 (0.53–1.05)
	Asian	53/131	64/121	0.72 (0.50–1.04)
WHO performance status	0	48/133	74/131	0.55 (0.38–0.79)
	1	67/131	72/135	0.94 (0.67–1.31)
AJCC disease stage at diagnosis	I/II	11/33	12/34	0.92 (0.40–2.11)
	III	104/231	134/232	0.71 (0.55–0.91)
Time from end of cCRT* to randomization	<14 days	14/32	24/32	0.47 (0.24–0.91)
	≥14 days to <28 days	37/79	51/80	0.59 (0.38–0.90)
	≥28 days	64/153	71/154	0.90 (0.64–1.27)
Prior chemotherapy regimen	Carboplatin-etoposide	31/ 91	46/88	0.56 (0.35–0.89)
	Cisplatin-etoposide	84/173	100/178	0.82 (0.61–1.10)
Prior radiation schedule	Once daily	92/195	107/187	0.72 (0.55–0.95)
	Twice daily	23/69	39/79	0.68 (0.40–1.14)
Best response to prior cCRT	Complete response	12/31	15/34	0.90 (0.41–1.92)
	Partial response	88/191	116/200	0.76 (0.57–1.00)
	Stable disease	15/42	15/32	0.54 (0.25–1.13)
Prior PCI	Yes	53/142	67/143	0.75 (0.52–1.07)
	No	62/122	79/123	0.71 (0.51–0.99)



*End of chemotherapy or radiotherapy, whichever was latest.
Intention-to-treat analysis stratified, subgroup analyses unstratified. Not all prespecified subgroups are included in the plot.
Size of circle is proportional to number of events across both arms.

ADRIATIC – Efficacy Results



	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)

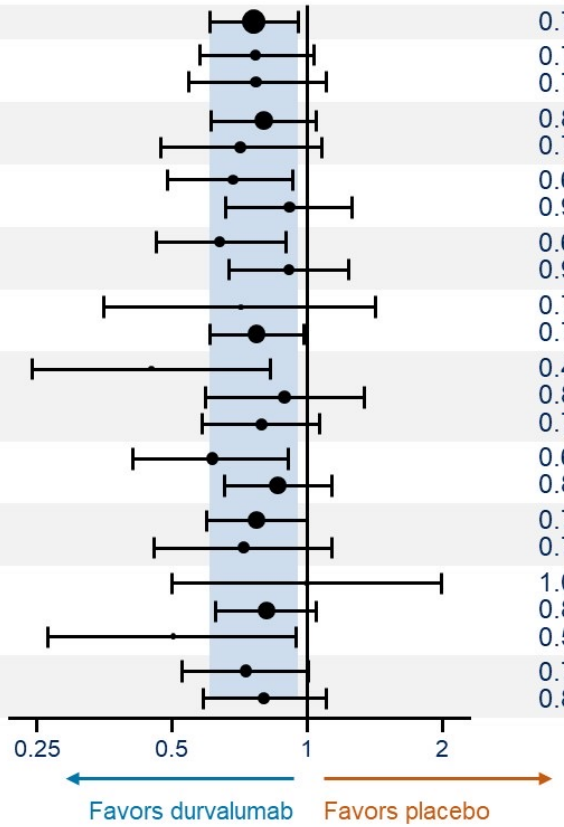
Stratified hazard ratio for disease progression or death, 0.76
(99.816% CI, 0.53–1.08)
(97.195% CI, 0.59–0.98)
P=0.02

Cheng Y. N Engl J Med 2024;391:1313-1327

ADRIATIC – Efficacy Results

PFS subgroup analysis

		Events/Patients n/N		HR (95% CI)
		Durvalumab	Placebo	
All patients		139/264	169/266	0.76 (0.61–0.95)
Age	<65 years	83/160	98/162	0.77 (0.58–1.03)
	≥65 years	56/104	71/104	0.77 (0.54–1.10)
Sex	Male	96/178	120/188	0.80 (0.61–1.04)
	Female	43/86	49/78	0.71 (0.47–1.08)
Race	White	65/130	90/137	0.68 (0.49–0.93)
	Asian	72/131	75/121	0.91 (0.66–1.26)
WHO performance status	0	60/133	82/131	0.64 (0.46–0.90)
	1	79/131	87/135	0.91 (0.67–1.24)
AJCC disease stage at diagnosis	I/II	14/33	19/34	0.71 (0.35–1.42)
	III	125/231	150/232	0.77 (0.61–0.98)
Time from end of cCRT* to randomization	<14 days	18/32	27/32	0.45 (0.24–0.83)
	≥14 days to <28 days	43/79	50/80	0.89 (0.59–1.34)
	≥28 days	78/153	92/154	0.79 (0.58–1.07)
Prior chemotherapy regimen	Carboplatin-etoposide	44/91	57/88	0.61 (0.41–0.90)
	Cisplatin-etoposide	95/173	112/178	0.86 (0.65–1.13)
Prior radiation schedule	Once daily	108/195	122/187	0.77 (0.60–1.00)
	Twice daily	31/69	47/79	0.72 (0.45–1.13)
Best response to prior cCRT	Complete response	15/31	18/34	1.00 (0.50–1.99)
	Partial response	106/191	130/200	0.81 (0.62–1.04)
	Stable disease	18/42	21/32	0.50 (0.26–0.94)
Prior PCI	Yes	65/142	84/143	0.73 (0.53–1.01)
	No	74/122	85/123	0.80 (0.59–1.09)



*End of chemotherapy or radiotherapy, whichever was latest.
Intention-to-treat analysis stratified, subgroup analyses unstratified. Not all prespecified subgroups are included in the plot.
Size of circle is proportional to number of events across both arms.

ADRIATIC – Safety Results

- Grade 3-4 AEs: Durvalumab - 24.4%; placebo – 24.2%
- Pneumonitis or Radiation pneumonitis: Durvalumab – 38.2% (grade 3-4 – 3.1%); placebo – 30.2% (grade 3-4 – 2.6%)
- AE resulting in drug discontinuation: durvalumab - 11.5%; placebo - 5.7%
- IRAE: durvalumab - 32.1%; placebo - 10.2%
  - Hypothyroid events: 13.7% vs. 3.4%
  - Pneumonitis: 11.8% vs. 3.0%

Cheng Y. N Engl J Med 2024;391:1313-1327

ADRIATIC – Unmet needs

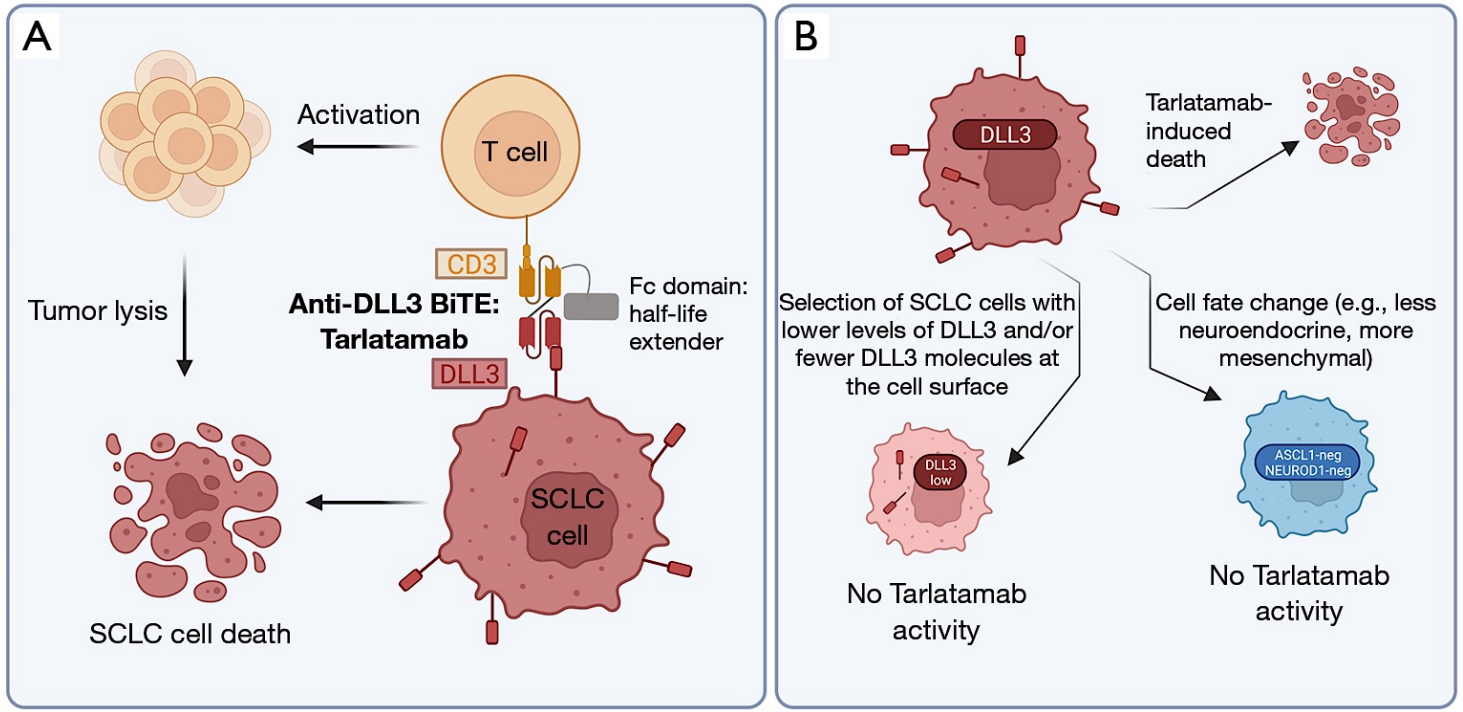
- Role of durvalumab after sequential chemotherapy and radiation
- Efficacy in PS 2 patients

ALBORAN study

- IIIB study in Spain (NCT06992609)
- To assess the safety and effectiveness of durvalumab in real world like LS-SCLC population
- Key eligibility criteria
  - Inclusion criteria
    - LS-SCLC patients with ECOG **0-2**
    - **Concurrent or sequential** chemoradiation with platinum-etoposide and either QD or BID XRT without progression
    - Adequate organ function
  - Exclusion criteria
    - Mixed SCLC and NSCLC
    - Grade ≥2 pneumonitis
    - H/O allogeneic organ transplantation or autoimmune/inflammatory disorders

Tarlatamab

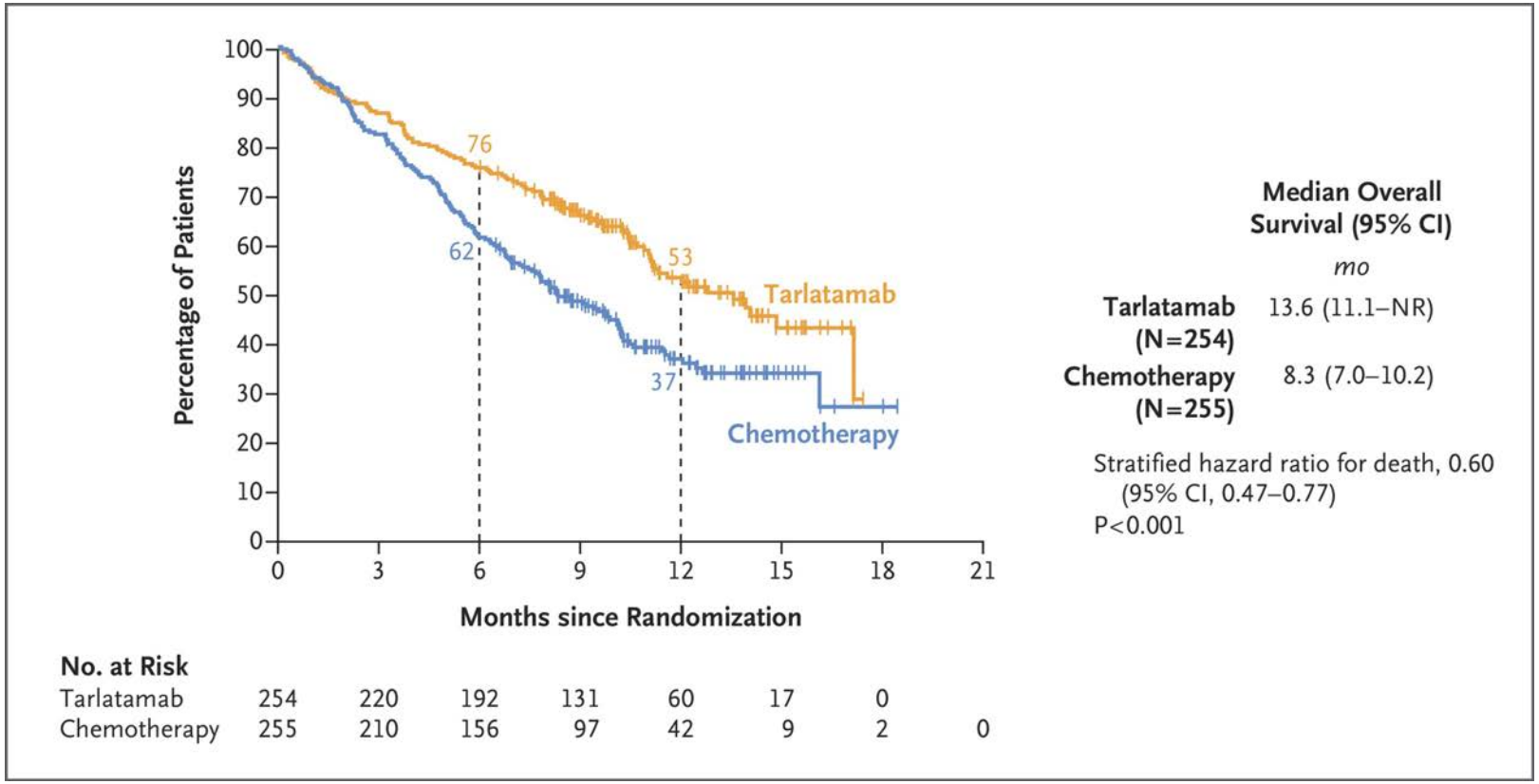
- Notch ligand delta-like ligand 3 (DLL3) - aberrantly expressed on surface of SCLC cells
- Tarlatamab - bispecific T cell engager binds DLL3 and CD3 - T cell-mediated tumor lysis



Sabari JK. *Nat Rev Clin Oncol.* 2017;14:549-561.
Saunders LR. *Sci Transl Med.* 2015;7:302ra136.
Apaydin AA. Transl Lung Cancer Res. 2023 May 31;12(5):948-952.
Leonetti A. *Cell Oncol (Dordr).* 2019;42:261-273.
Giffin MJ. *Clin Cancer Res.* 2021;27:1526-1537.

Tarlatamab – DeLLphi-304

- Randomized phase 3 study
- Tarlatamab vs. Chemotherapy (topotecan, lurbinectedin, amrubicin)



Mountzios G. N Engl J Med 2025;393:349-361.

DeLLphi-306

- Phase 3 (NCT06117774) randomized, double-blind, placebo-controlled study evaluating tarlatamab as consolidation therapy for patients with LS-SCLC
- Sample size - 400
- Primary objective: PFS based on BICR; OS.
- Key Secondary endpoints:
  - Investigator assessed PFS
  - CR rate
  - Time to progression
  - TEAE
- Intervention:
  - Tarlatamab or placebo on Cycle 1 Day 1, 8 and 15; then every 2 weeks

DeLLphi-306

- Key Eligibility Criteria
  - Inclusion Criteria
    - Diagnosed and treated for LS-SCLC with concurrent chemoradiotherapy.
    - No evidence of progression per RECIST 1.1.
    - Performance Status (PS) of 0 or 1.
    - Minimum life expectancy of 12 weeks.
    - Adequate organ function.
    - Toxicities attributed to concurrent chemoradiotherapy resolved to grade ≤ 1
  - Exclusion Criteria
    - Transformed non-small-cell lung cancer (NSCLC) or mixed SCLC NSCLC histology.
    - Interstitial lung disease or active, non-infectious pneumonitis
    - History of other malignancy within the past 2 years, with certain exceptions.
    - History of solid organ transplantation.
    - AMI and/or symptomatic CHF (NYHA > class II) within 6 months
    - Arterial thrombosis within 6 months.
    - HIV and hepatitis infection
    - Sequential chemotherapy and thoracic radiotherapy
    - Prior therapy with any selective DLL3 inhibitor

Conclusions

- Limited disease – concurrent chemoradiation followed by maintenance durvalumab is the current SOC
- Tarlatamab – ongoing studies in this area

Second Opinion

Ticiana Leal, MD

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

Discussion Questions

What would you recommend for this patient?

How do you think through treatment for patients with SCLC and well-compensated paraneoplastic syndromes? Are you comfortable using immunotherapy for these patients given that they were excluded from many of the pivotal trials?

What recommendations were recently added to the NCCN guidelines for SCLC specifically related to the diagnosis and management of LEMS, and what are their implications for routine patient care?

Second Opinion

Charu Aggarwal, MD

Neil Love, MD

RTP
RESEARCH
TO PRACTICE

Discussion Questions

What would you have recommended for this patient with localized SCLC that's been resected? Do you offer patients in this situation adjuvant immunotherapy, and if so, for how long? Do you offer them radiation therapy in the absence of high-risk features?

For patients with more typical presentations of LS-SCLC, how do you decide whether to add an immune checkpoint inhibitor after CRT? Are you doing this in all or most cases? When, if ever, would you not?

Second Opinion: Investigators Provide Perspectives on the Current and Future Management of Small Cell Lung Cancer

Saturday, May 30, 2026
7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)

Faculty

Anne Chiang, MD, PhD
Apar Kishor Ganti, MD, MS
Luis Paz-Ares, MD, PhD

Moderator

Misty Dawn Shields, MD, PhD

RTP
RESEARCH
TO PRACTICE

Consensus or Controversy? Documenting and Discussing Investigators' Approaches to the Use of Oral SERDs and Agents Targeting the PI3K/AKT/mTOR Pathway in Breast Cancer

A CME Symposium Held Adjunct with the 2026 ASCO® Annual Meeting

Sunday, May 31, 2026

7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)

Faculty

Sara A Hurvitz, MD, FACP
Erica Mayer, MD, MPH, FASCO
Joyce O'Shaughnessy, MD
Nicholas Turner, MD, PhD

Moderator

Sara M Tolaney, MD, MPH

RTP RESEARCH TO PRACTICE

What Clinicians Want to Know: Addressing Community Oncologists' Questions About the Current and Future Management of Endometrial Cancer

A CME Symposium Held Adjunct with the 2026 ASCO® Annual Meeting

Sunday, May 31, 2026

7:00 PM – 8:30 PM CT (8:00 PM – 9:30 PM ET)

Faculty

Floor J Backes, MD

Brian M Slomovitz, MD

Moderator

Shannon N Westin, MD, MPH, FASCO, FACOG

RTP RESEARCH TO PRACTICE

What Clinicians Want to Know: Addressing Community Oncologists' Questions About the Roles of CAR T-Cell Therapy and Bispecific Antibodies in the Management of Non-Hodgkin Lymphoma

A CME Symposium Held Adjunct with the 2026 ASCO® Annual Meeting

Sunday, May 31, 2026

7:00 PM – 9:00 PM CT (8:00 PM – 10:00 PM ET)

Faculty

Joshua Brody, MD

Manali Kamdar, MD, MBBS

Tycel Phillips, MD, FASCO

Jason Westin, MD, MS, FACP, FASCO

Moderator

Jeremy S Abramson, MD, MMSc

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Thank you for joining us!
Your feedback is very important to us.

Please complete the survey currently up on the iPads for attendees in the room and on Zoom for those attending virtually. The survey will remain open up to 5 minutes after the meeting ends.

How to Obtain CME Credit

In-person attendees: Please refer to the program syllabus for the CME credit link or QR code. Online/Zoom attendees: The CME credit link is posted in the chat room.

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