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Letter from Prof Rolf Stahel

Dear Colleagues

It is my pleasure to present this ETOP slide set which has been designed to highlight and summarise key findings in thoracic cancers from the major congresses in 2025. This slide set specifically focuses on the **2026 ASCO Annual Meeting** and is available in 3 languages – English, Chinese and Japanese.

The area of clinical research in oncology is a challenging and continually changing environment. Within this environment we all value access to scientific data and research which helps to educate and inspire further advancements in our roles as scientists, clinicians and educators. I hope you find this review of the latest developments in thoracic cancers of benefit to you in your practice. If you would like to share your thoughts with us, we would welcome your comments. Please send any correspondence to etop@etop.eu-org.

I would like to thank our ETOP members Drs Enriqueta Felip, Solange Peters, Martin Reck and Egbert Smit for their roles as Editors – for prioritising abstracts and reviewing slide content. The slide set you see before you would not be possible without their commitment and hard work.

Finally, we are also very grateful to Lilly Oncology for their financial, administrative and logistical support in the realisation of this complex yet rewarding activity.

Yours sincerely,
Rolf Stahel
President, ETOP Foundation Council

ETOP Medical Oncology Slide Deck Editors 2026

Focus: biomarkers (all stages)

Dr Enriqueta Felip

Oncology Department, Vall d'Hebron University Hospital, Barcelona, Spain

Focus: early and locally advanced NSCLC (stages I–III)

Dr Egbert Smit

Netherlands Cancer Institute, Antoni van Leeuwenhoek Hospital, Amsterdam, Netherlands

Focus: advanced NSCLC (not radically treatable stage III & stage IV)

Dr Solange Peters

Multidisciplinary Oncology Center, Lausanne Cancer Center, Lausanne, Switzerland

Focus: other malignancies, SCLC, mesothelioma, rare tumors

Dr Martin Reck

Department of Thoracic Oncology, Hospital Grosshansdorf, Grosshansdorf, Germany

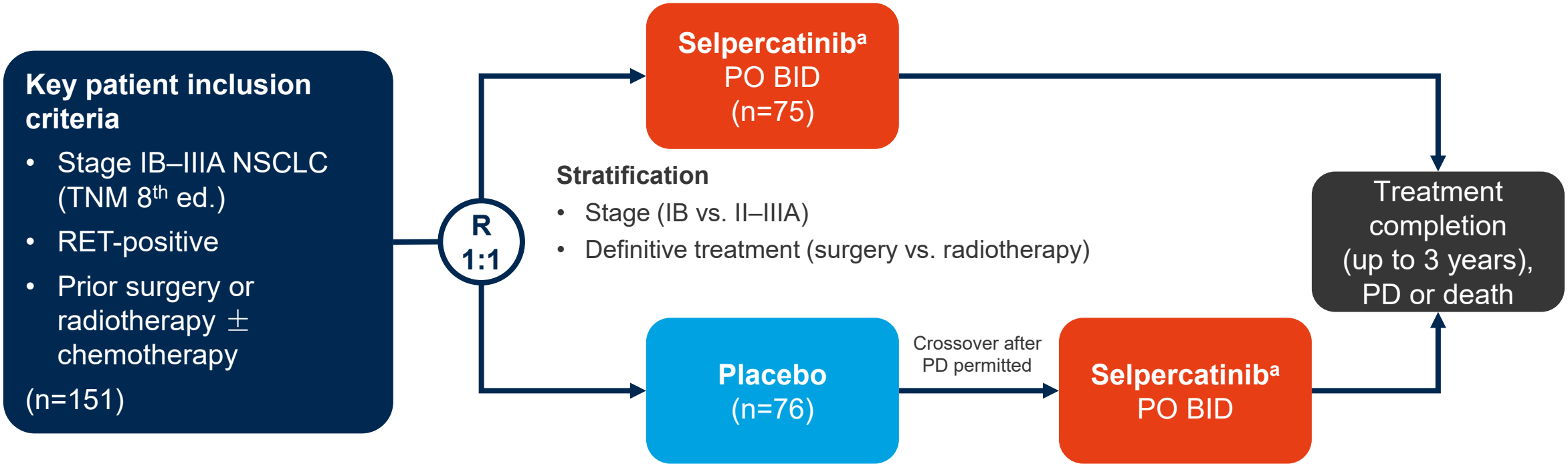
Contents

- Early stage and locally advanced NSCLC – Stages I, II and III
- Advanced NSCLC – Not radically treatable stage III and stage IV
  - Immunotherapy
  - Targeted therapies
  - ADCs and other therapies
- Other malignancies
  - SCLC, mesothelioma and thymic epithelial tumors
- Genomics

Early stage and locally advanced NSCLC – Stages I, II and III

LBA3: Event-free survival with adjuvant selpercatinib in stage IB-IIIA RET fusion-positive NSCLC: Primary results of the phase 3 LIBRETTO-432 trial – Goldman JW, et al

- **Study objective**
  - To evaluate the EFS with adjuvant selpercatinib in patients with stage IB-IIIA RET fusion-positive NSCLC



Primary endpoints

- EFS (investigator-assessed) in stage II–IIIA population

Secondary endpoints

- EFS in stage II–IIIA population (BICR-assessed), EFS in stage IB–IIIA population, OS, safety

[a]Participants ≥50 mg: selpercatinib 160 mg; participants <50 mg: selpercatinib 120 mg.

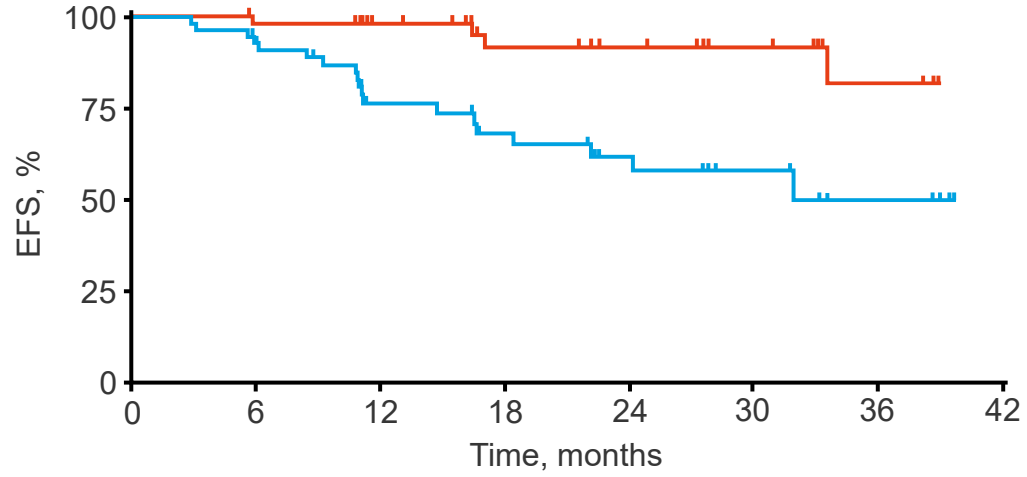
Goldman JW, et al. J Clin Oncol 2026;44(suppl):Abstr LBA3

LBA3: Event-free survival with adjuvant selpercatinib in stage IB-IIIA RET fusion-positive NSCLC: Primary results of the phase 3 LIBRETTO-432 trial – Goldman JW, et al

- **Key results**

Investigator-assessed EFS (stage II–IIIA)

	Selpercatinib (n=54)	Placebo (n=55)
Events, n	4	19
24-month EFS, rate (95%CI)	91.5 (75.4, 97.2)	61.1 (44.2, 74.3)
HR (95%CI); p-value	0.172 (0.058, 0.509); 0.0003	



Investigator-assessed EFS (stage IB–IIIA)

	Selpercatinib (n=75)	Placebo (n=76)
Events, n	4	20
24-month EFS, rate (95%CI)	93.8 (81.5, 98.0)	69.6 (55.5, 80.1)
HR (95%CI); p-value	0.165 (0.056, 0.485); 0.0002	

Overall survival

	Selpercatinib (n=54)	Placebo (n=55)
Median follow-up, mo (IQR)	25 (13.9, 33.2)	27 (15.8, 34.1)
On treatment, n (%)	30 (55.6)	24 (43.6)
Off treatment, n (%)	24 (44.4)	31 (56.4)
Death, n	0	3

LBA3: Event-free survival with adjuvant selpercatinib in stage IB-IIIA RET fusion-positive NSCLC: Primary results of the phase 3 LIBRETTO-432 trial – Goldman JW, et al

- **Key results (cont.)**

TEAEs, n, %	Selpercatinib (n=75)	Placebo (n=76)
Any	75 (100)	74 (97.4)
Grade ≥3	50 (66.7)	18 (23.7)
Led to study treatment discontinuation[a]	13 (17.3)	1 (1.3)
Led to dose modifications	66 (88.0)	35 (46.1)
Dose interruptions	58 (77.3)	20 (26.3)
Dose reductions	41 (54.7)	6 (7.9)
Serious in ≥1	17 (22.7)	10 (13.2)
Serious led to discontinuation	2 (2.7)	1 (1.3)

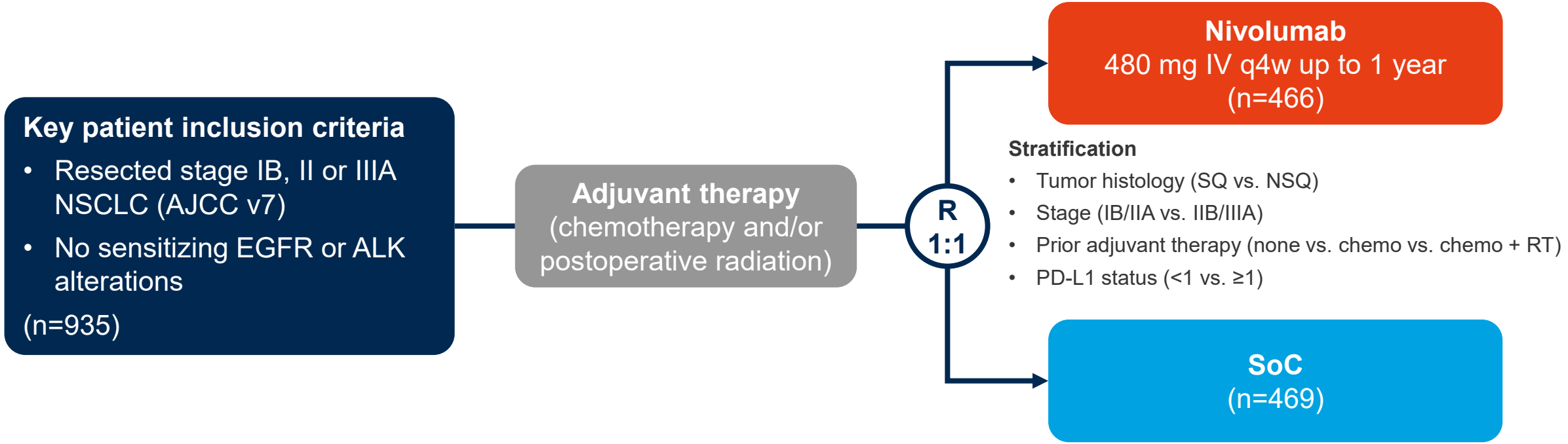
	Selpercatinib (n=75)		Placebo (n=76)	
TEAEs, n, %	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Patients with ≥1 (≥20%)	75 (100)	50 (66.7)	74 (97.4)	18 (23.7)
ALT increased	47 (62.7)	13 (17.3)	14 (18.4)	1 (1.3)
AST increased	45 (60.0)	14 (18.7)	12 (15.8)	2 (2.6)
Diarrhea	29 (38.7)	3 (4.0)	13 (17.1)	0
Dry mouth	30 (40.0)	0	12 (15.8)	0
Cough	20 (26.7)	0	18 (23.7)	0
Bilirubin increased	20 (26.7)	1 (1.3)	11 (14.5)	0
Hypertension	23 (30.7)	8 (10.7)	8 (10.5)	2 (2.6)
Constipation	17 (22.7)	0	10 (13.2)	0
Hyperuricemia	15 (20.0)	0	8 (10.5)	0

- **Conclusions**
  - In patients with stage IB–IIIA RET fusion-positive NSCLC, adjuvant selpercatinib significantly prolonged EFS versus placebo with a safety profile consistent with prior findings

[a]Most common reason for selpercatinib discontinuation: ALT increased (n=4); AST increased (n=2); interstitial lung disease (n=2).

8000: Randomized phase III study of nivolumab after surgery and adjuvant chemotherapy in NSCLC (ECOG-ACRIN EA5142, ALCHEMIST) – Chaft JE, et al

- **Study objective**
  - To evaluate the efficacy and safety of nivolumab after surgery and adjuvant chemotherapy in patients with NSCLC



Primary endpoints

- DFS (all patients and PD-L1 high ≥50%), OS

Secondary endpoints

- DFS in prespecified subsets, safety

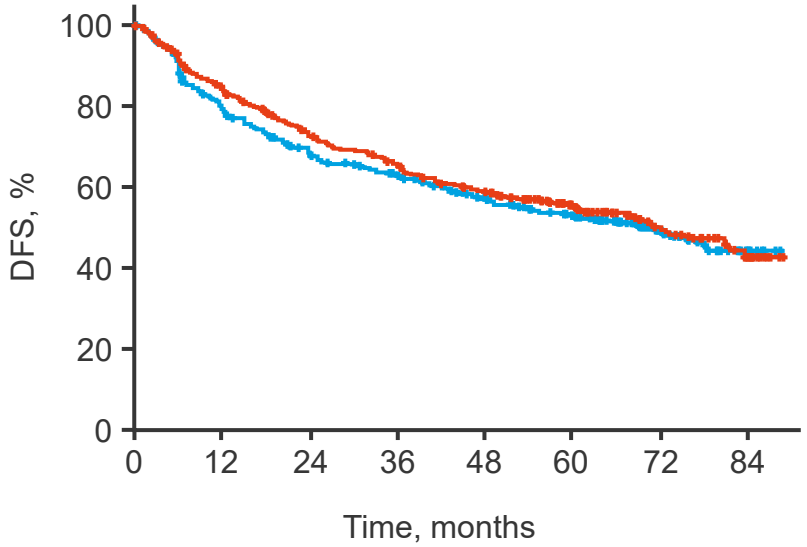
8000: Randomized phase III study of nivolumab after surgery and adjuvant chemotherapy in NSCLC (ECOG-ACRIN EA5142, ALCHEMIST) – Chaft JE, et al

- **Key results**

Disease-free survival

ITT

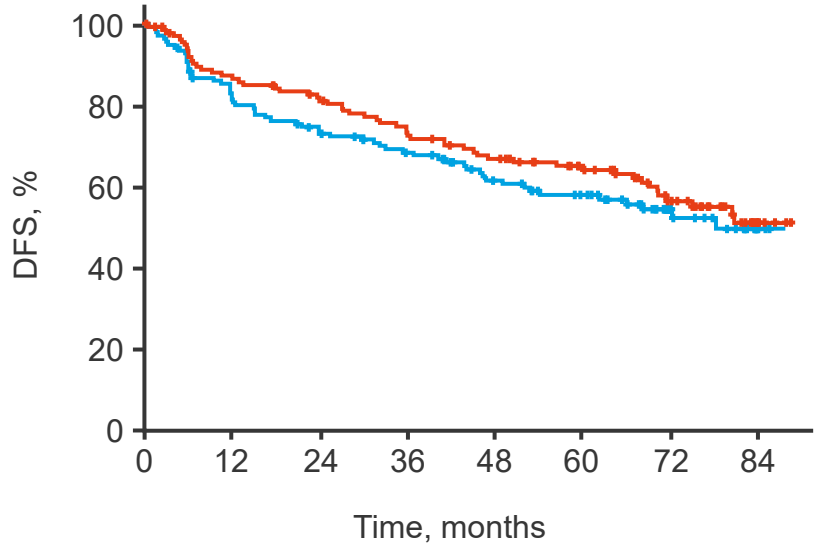
	Nivolumab (n=466)	SoC (n=469)
mDFS, mo	71.3	68.8
HR (95%CI); p-value	0.97 (0.81, 1.17); 0.39	



No. at risk								
Nivolumab	466	365	305	271	236	200	118	41
SoC	469	355	300	263	225	192	115	43

PD-L1 ≥50%

	Nivolumab (n=136)	SoC (n=137)
mDFS, mo	89.9	78.5
HR (95%CI); p-value	0.86 (0.59, 1.25); 0.43	



No. at risk								
Nivolumab	136	112	102	90	80	67	45	17
SoC	137	105	93	82	67	57	31	12

Chaft JE, et al. J Clin Oncol 2026;44(suppl):Abstr 8000

8000: Randomized phase III study of nivolumab after surgery and adjuvant chemotherapy in NSCLC (ECOG-ACRIN EA5142, ALCHEMIST) – Chaft JE, et al

- **Key results (cont.)**

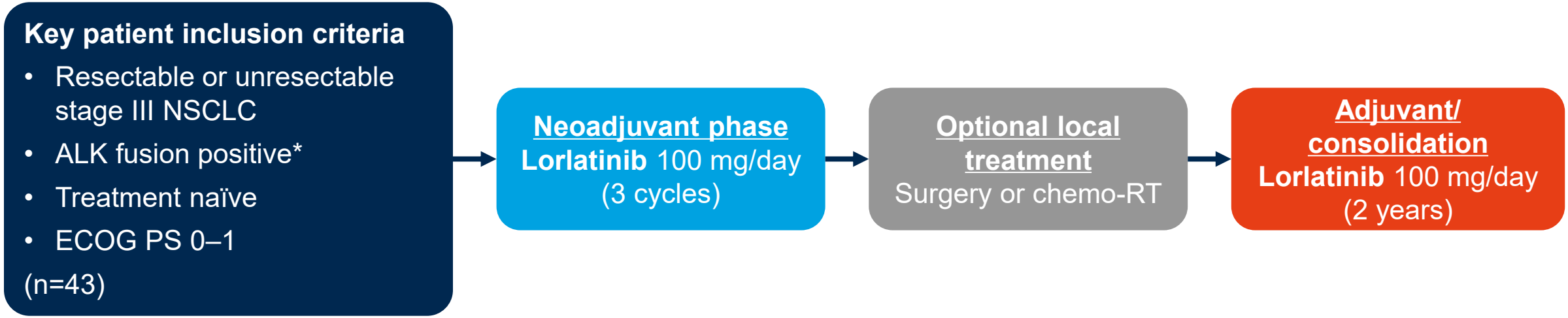
Overall survival	Nivolumab	SoC
ITT, n	466	469
HR (95%CI)	1.02 (0.82, 1.26)	
PD-L1 ≥50%	136	137
HR (95%CI)	0.82 (0.53, 1.28)	

TRAE occurring in ≥1 of patients, n (%)	Grade 3	Grade 4	Grade 5
Lymphocyte count decreased	5 (1)	—	—
Dyspnea	8 (2)	—	—
Hypoxia	5 (1)	—	1 (<1)
Pneumonitis	15 (3)	1 (<1)	1 (<1)
Colitis/proctitis	4 (1)	1 (<1)	—
Diarrhea	11 (2)	—	—
AST increased	7 (2)	—	—
Lung infection	5 (1)	—	—
Maculopapular rash	9 (2)	—	—
Pruritus	4 (1)	—	—
Hypertension	4 (1)	—	—
Adrenal insufficiency	6 (1)	1 (<1)	—
Fatigue	7 (2)	—	—
Hyponatremia	5 (1)	2 (<1)	—

- **Conclusions**
  - In patients with resected EGFR/ALK-negative NSCLC, adjuvant nivolumab failed to show improvement in DFS or OS compared with standard of care

8002: Neoadjuvant lorlatinib in stage III NSCLC harboring ALK fusion: A phase 2 multicenter study (LORIN) – Zhang C, et al

- **Study objective**
  - To evaluate the efficacy and safety of neoadjuvant lorlatinib in patients with stage III ALK fusion-positive NSCLC



Primary endpoint

- pCR (IASLC)

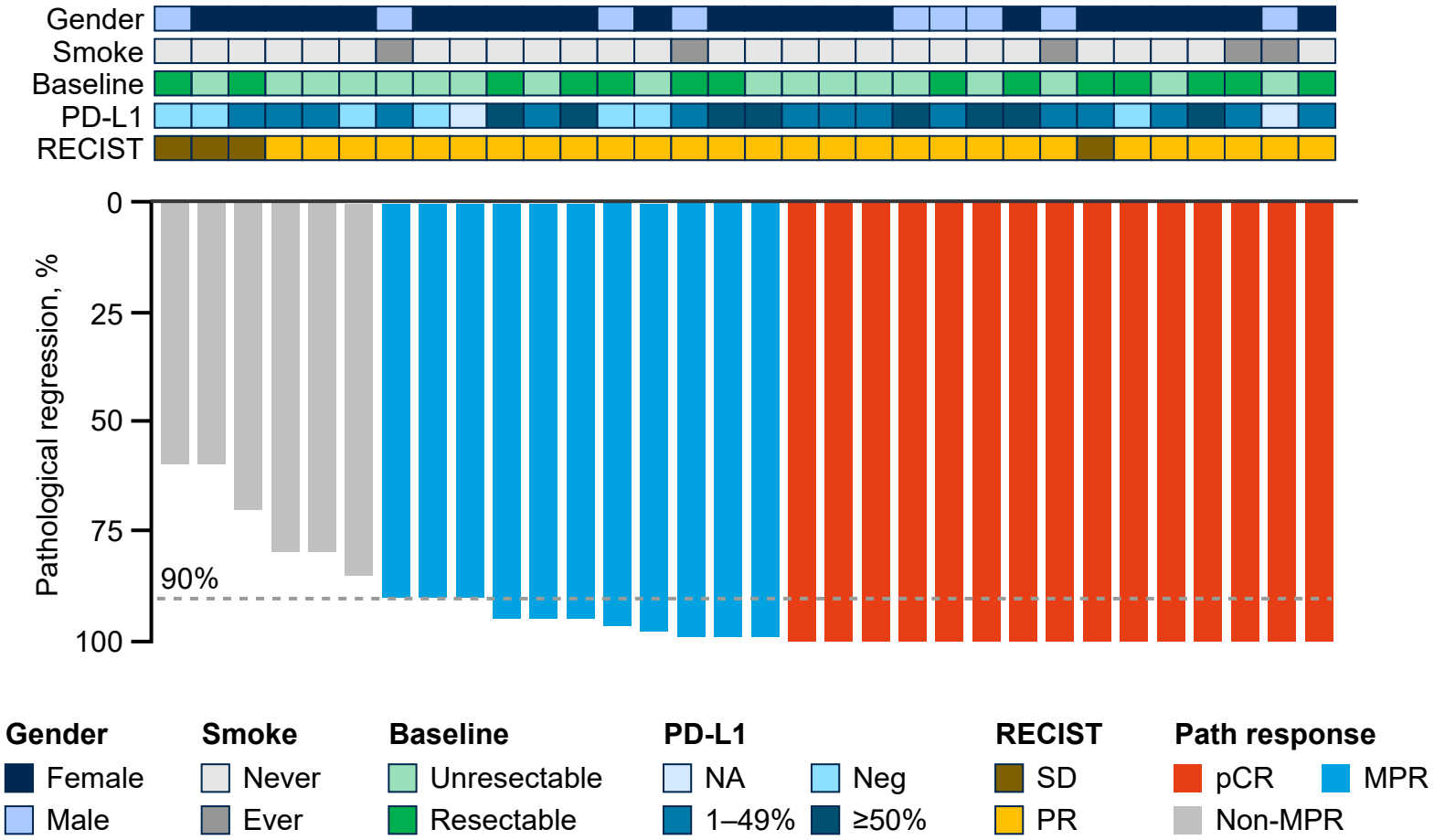
Secondary endpoints

- MPR (IASLC), ORR, EFS, OS, safety

*IHC, FISH or NGS.

8002: Neoadjuvant lorlatinib in stage III NSCLC harboring ALK fusion: A phase 2 multicenter study (LORIN) – Zhang C, et al

- **Key results**



	n=32
pCR, n/N (%) [95%CI]	15/32 (46.9) [29.1, 65.2]
MPR, n/N (%)	26/32 (81.3)
Median/mean RVT, %	1/7
Resectability, pCR/MPR, %	
Resectable	50/86
Unresectable	44/78

Objective response, n (%)	n=43
ORR	36 (84)
PR	36 (84)
SD	7 (16)

8002: Neoadjuvant lorlatinib in stage III NSCLC harboring ALK fusion: A phase 2 multicenter study (LORIN) – Zhang C, et al

- **Key results (cont.)**

TRAEs in neoadjuvant phase, n (%)	n=43
Any	43 (100)
Grade 3–4	10 (23)
Led to dose reduction	7 (16)
Led to discontinuation	1[a] (2)

TRAEs in adjuvant/consolidation phase, n (%)	n=34
Any	32 (94)
Grade 3–4	7 (21)
Led to dose reduction	8 (24)
Led to treatment switch (to alectinib)	4 (12)

	Neoadjuvant phase	
TRAEs, n (%)	Any	Grade 3–4
Hypertriglyceridemia	33 (77)	6 (14)
Hypercholesterolemia	30 (70)	5 (12)
Edema	21 (49)	3 (7)
Weight increased	20 (46)	4 (9)
Peripheral neuropathy	12 (28)	1 (2)
Constipation	9 (21)	-
Nausea	8 (19)	-
Cognitive effect	8 (19)	-
ALT increased	6 (14)	-
Rash	5 (12)	-
Anemia	4 (9)	-

- **Conclusions**
  - In patients with stage III ALK fusion-positive NSCLC, neoadjuvant lorlatinib provided high pathological response rates and enabled surgical resection in a proportion of cases (≈75% of the ITT population, including those with initially unresectable disease), and no new safety signals were observed

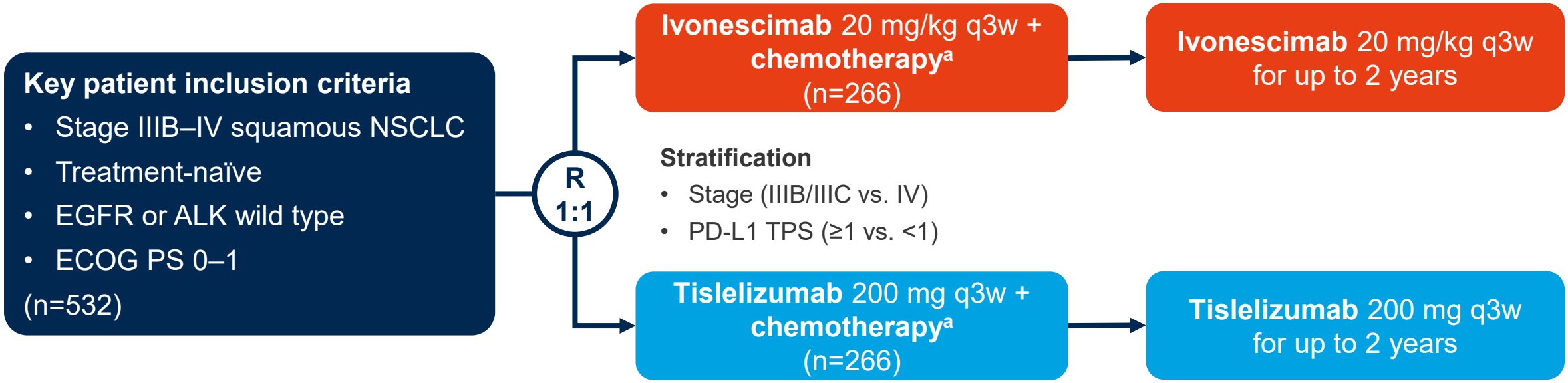
[a]Patient discontinued due to grade 3 ILD.

Advanced NSCLC – Not radically treatable stage III and stage IV

Immunotherapy

LBA4: Ivonescimab plus chemotherapy versus tislelizumab plus chemotherapy in previously untreated advanced squamous non–small cell lung cancer: Overall survival results of the phase 3 HARMONi-6 trial – Lu S, et al

- **Study objective**
  - To evaluate OS at a pre-specified interim analysis with 1L ivonescimab + chemotherapy vs tislelizumab + chemotherapy in patients with advanced squamous NSCLC



Primary endpoints

- PFS (IRRC, RECIST v1.1)

Secondary endpoints

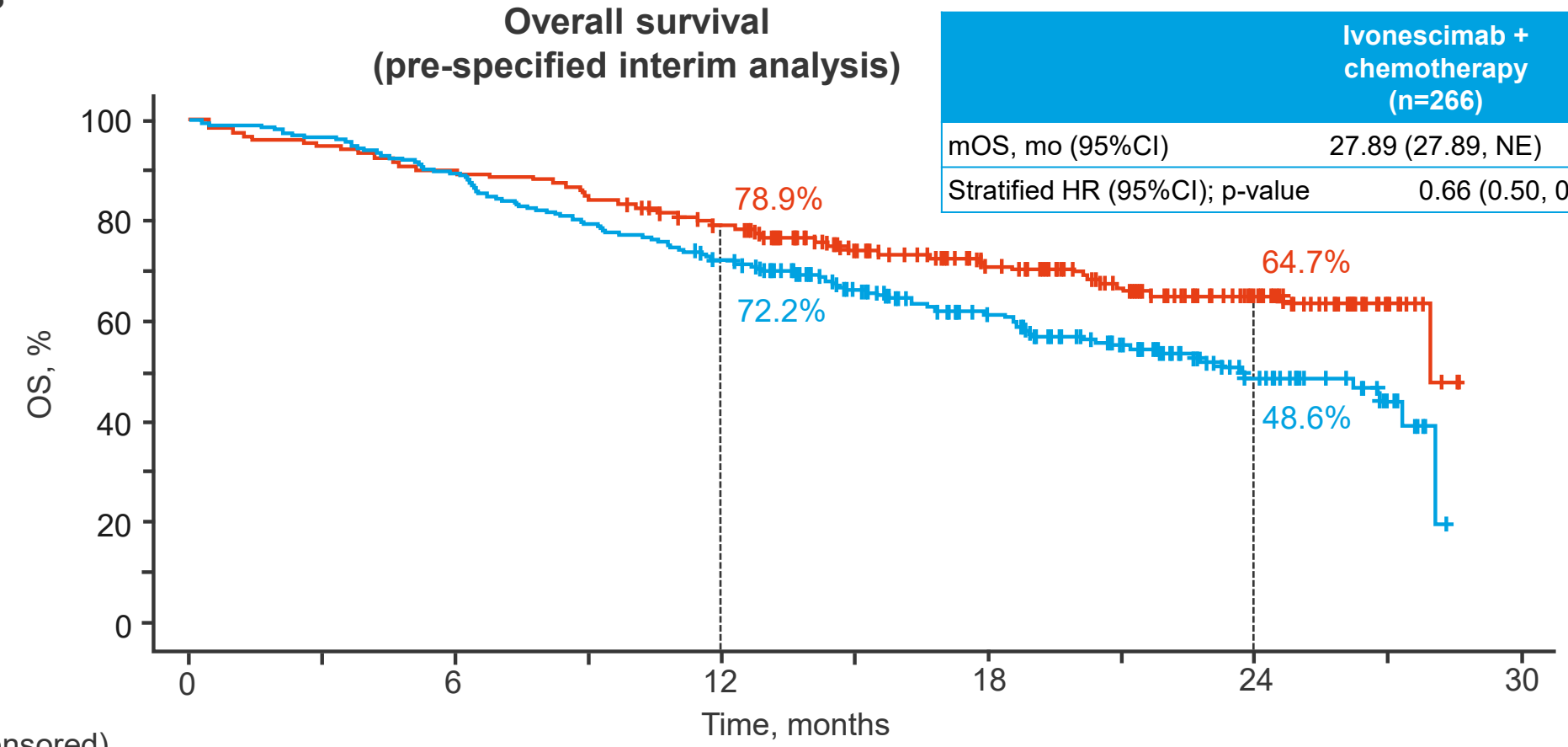
- OS, PFS (investigator-assessed), ORR, DCR, DoR, TTR, safety

[a]Carboplatin AUC5 q3w + paclitaxel 175 mg/m^2 q3w (up to 4 cycles).

Lu S, et al. J Clin Oncol 2026;44(suppl):Abstr LBA4

LBA4: Ivonescimab plus chemotherapy versus tislelizumab plus chemotherapy in previously untreated advanced squamous non–small cell lung cancer: Overall survival results of the phase 3 HARMONi-6 trial – Lu S, et al

- **Key results**



	Ivonescimab + chemotherapy (n=266)	Tislelizumab + chemotherapy (n=266)
mOS, mo (95%CI)	27.89 (27.89, NE)	23.69 (20.11, NE)
Stratified HR (95%CI); p-value	0.66 (0.50, 0.87); 0.0017	

No. at risk (censored)

Ivonescimab + chemo	266 (0)	252 (0)	238 (0)	224 (0)	202 (8)	152 (46)	119 (73)	85 (100)	49 (135)	15 (168)	0 (182)
Tislelizumab + chemo	266 (0)	257 (0)	238 (0)	211 (0)	186 (6)	142 (36)	113 (55)	80 (77)	43 (107)	12 (136)	0 (146)

Median follow-up: 21.36 months.

Lu S, et al. J Clin Oncol 2026;44(suppl):Abstr LBA4

LBA4: Ivonescimab plus chemotherapy versus tislelizumab plus chemotherapy in previously untreated advanced squamous non–small cell lung cancer: Overall survival results of the phase 3 HARMONi-6 trial – Lu S, et al

- **Key results (cont.)**

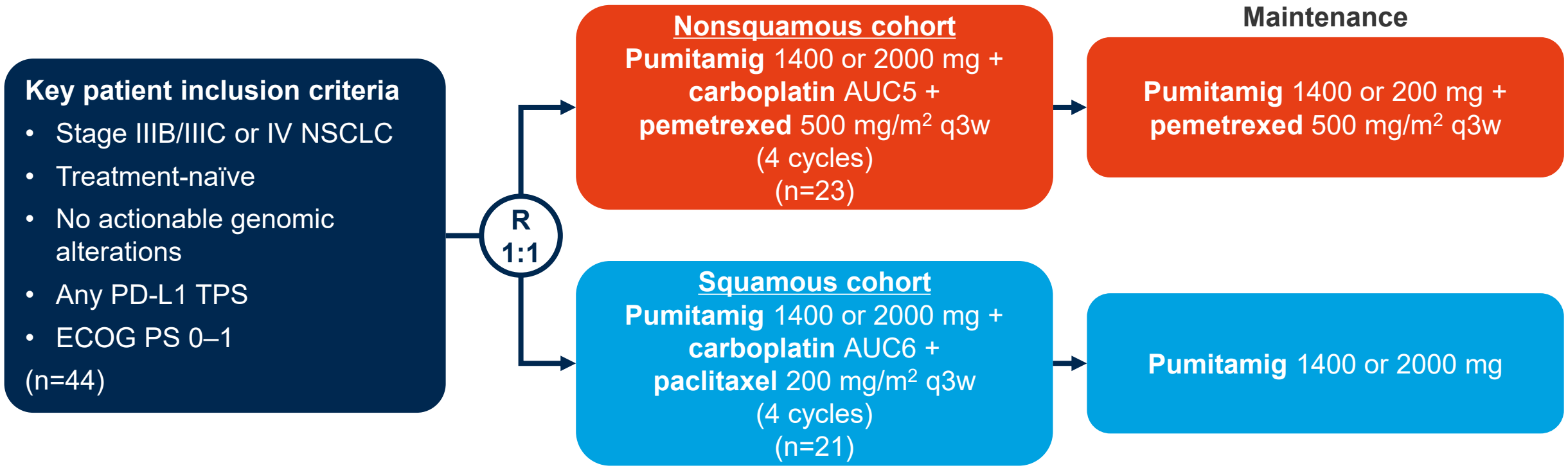
AEs, n (%)	Ivonescimab + chemotherapy (n=266)	Tislelizumab + chemotherapy (n=265)
TRAE	264 (99.2)	263 (99.2)
Grade ≥3	184 (69.2)	156 (58.9)
Serious	110 (41.4)	91 (34.3)
Led to treatment discontinuation	14 (5.3)	12 (4.5)
Led to death	10 (3.8)	11 (4.2)
Grade ≥3 irAE	34 (14)	36 (14)

TRAEs occurring in ≥15% of patient, %	Ivonescimab + chemo		Tislelizumab + chemo	
	All grade	Grade ≥3	All grade	Grade ≥3
Alopecia	66.2	-	61.5	-
Anemia	57.1	7.1	60.8	4.9
Neutrophil count decreased	47.0	32.3	44.5	26.0
White blood cell count decreased	38.0	10.9	37.0	9.4
Proteinuria	34.2	4.5	18.7	-
Platelet count decreased	32.3	3.0	28.3	3.0
Hypoesthesia	28.2	-	26.0	-
Appetite decreased	25.6	2.3	25.7	0.8
ALT increased	22.6	0.8	23.0	0.4
AST increased	21.1	1.1	19.6	1.9
Pain in extremity	19.9	1.1	14.0	0.4
Hypertriglyceridemia	19.5	1.9	14.7	2.3
Hypoalbuminemia	19.5	-	11.7	-
Hypothyroidism	18.8	0.4	14.3	-
Hyperuricemia	16.9	0.4	18.7	-
Nausea	16.2	0.8	20.0	-

- **Conclusions**
  - In Chinese patients with advanced squamous NSCLC, 1L ivonescimab + chemotherapy significantly prolonged OS compared with tislelizumab + chemotherapy at a pre-specified interim analysis with a manageable safety profile and low frequency of VEGF-related adverse events

8513: Phase 2 data from ROSETTA Lung-02, a global randomized phase 2/3 trial of pumitamig (PD-L1 × VEGF-A bsAb) + chemotherapy in 1L NSCLC – Peters S, et al

- **Study objective**
  - To evaluate the efficacy and safety of 1L pumitamig (a bispecific PD-L1/VEGF-A antibody) + chemotherapy in patients with NSCLC



Primary endpoints

- ORR, tumor size, safety

Secondary endpoints

- DoR, DCR

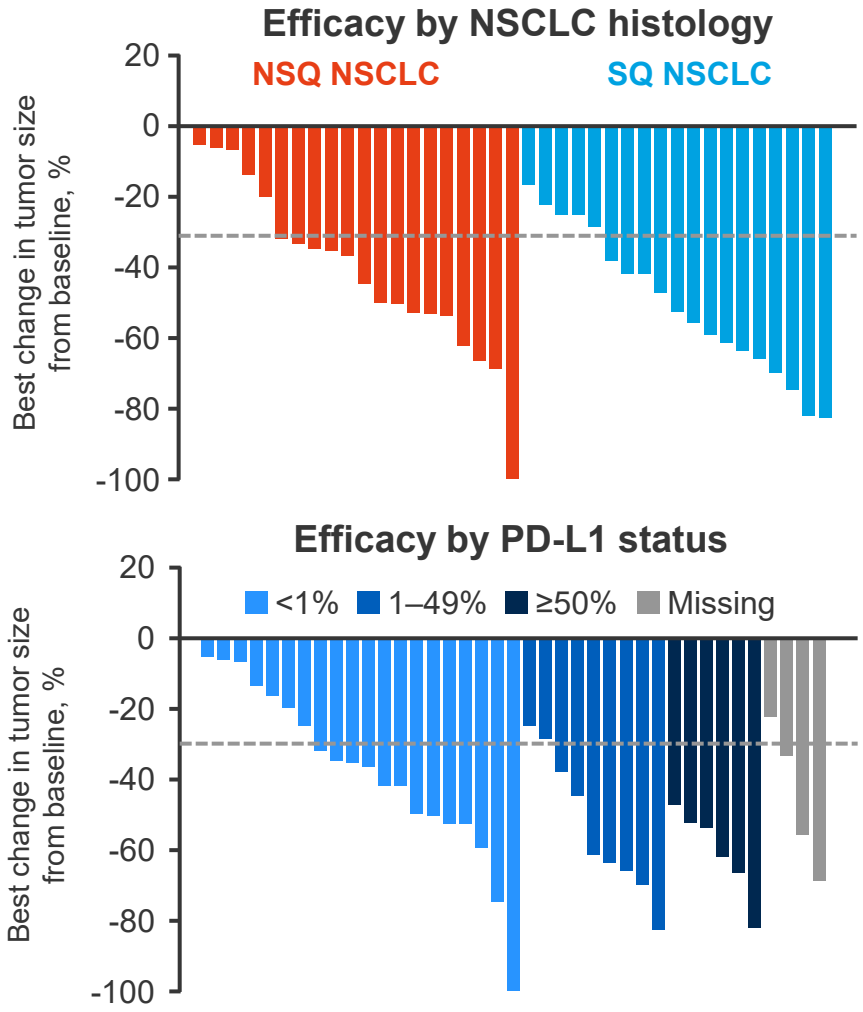
Median follow-up (range): 9.0 months (0–12.8).

8513: Phase 2 data from ROSETTA Lung-02, a global randomized phase 2/3 trial of pumitamig (PD-L1 × VEGF-A bsAb) + chemotherapy in 1L NSCLC – Peters S, et al

- **Key results**

	Nonsquamous cohort			Squamous cohort		
	1400 mg (n=11)	2000 mg (n=10)	Overall (n=21)	1400 mg (n=11)	2000 mg (n=8)	Overall (n=19)
uORR, % (95%CI)	81.8 (48.2, 97.7)	60.0 (26.2, 87.8)	71.4 (47.8, 88.7)	81.8 (48.2, 97.7)	62.5 (24.5, 91.5)	73.7 (48.8, 90.9)
cORR, % (95%CI)	63.6 (30.8, 89.1)	50.0 (18.7, 81.3)	57.1 (34.0, 78.2)	72.7 (39.0, 94.0)	62.5 (24.5, 91.5)	68.4 (43.4, 87.4)
cBOR, n (%)						
CR	0	0	0	0	1 (12.5)	1 (5.3)
PR	7 (63.6)	5 (50.0)	12 (57.1)	8 (72.7)	4 (50.0)	12 (63.2)
SD	4 (36.4)	5 (50.0)	9 (42.9)	3 (27.3)	3 (37.5)	6 (31.6)
cDCR, % (95%CI)	100 (71.5, 100)	100 (69.2, 100)	100 (83.9, 100)	100 (71.5, 100)	100 (63.1, 100)	100 (82.4, 100)

All NSCLC by PD-L1 status	TPS <1 (n=21)	TPS 1–49 (n=9)	TPS ≥50 (n=6)	Missing (n=4)	Overall (n=40)
uORR, (95%CI)	61.9 (38.4, 81.9)	77.8 (40.0, 97.2)	100.0 (54.1, 100.0)	75.0 (19.4, 99.4)	72.5 (56.1, 85.4)
cORR, (95%CI)	47.6 (25.7, 70.2)	77.8 (40.0, 97.2)	100.0 (54.1, 100.0)	50.0 (6.8, 93.2)	62.5 (45.8, 77.3)
cBOR, n (%)					
CR	0	1 (11.1)	0	0	1 (2.5)
PR	10 (47.6)	6 (66.7)	6 (100.0)	2 (50.0)	24 (60.0)
SD	11 (52.4)	2 (22.2)	0	2 (50.0)	15 (37.5)



Peters S, et al. J Clin Oncol 2026;44(suppl):Abstr 8513

8513: Phase 2 data from ROSETTA Lung-02, a global randomized phase 2/3 trial of pumitamig (PD-L1 × VEGF-A bsAb) + chemotherapy in 1L NSCLC – Peters S, et al

- **Key results (cont.)**

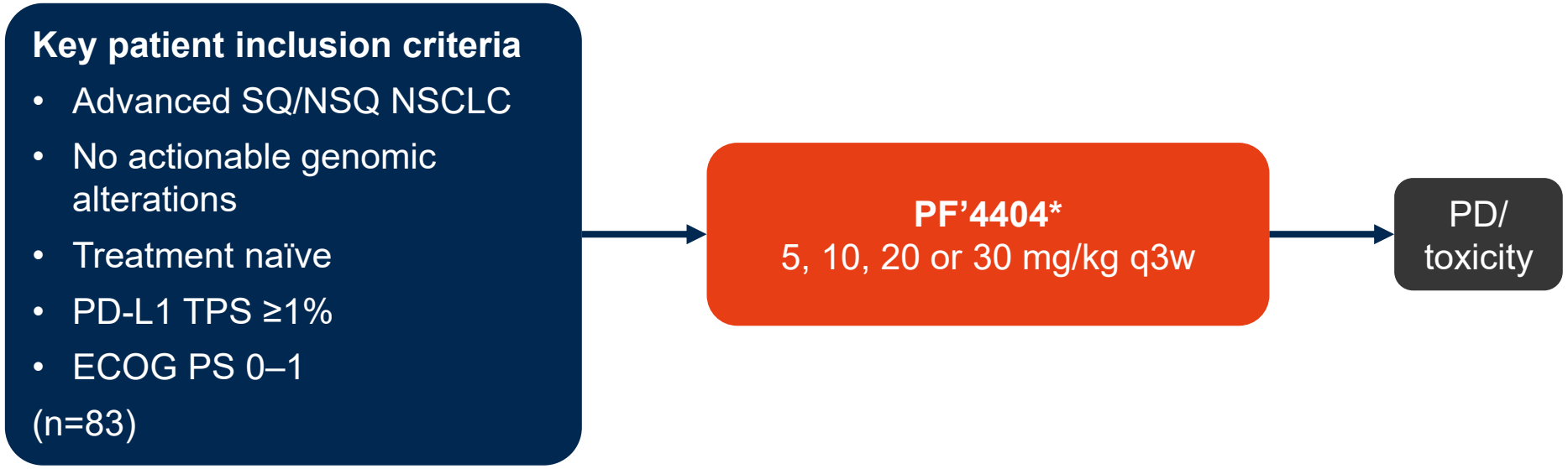
TRAEs, n (%)	Nonsquamous cohort (n=22)	Squamous cohort (n=21)	Overall (n=43)
Any	19 (86.4)	21 (100)	40 (93.0)
Grade ≥3	8 (36.4)	13 (61.9)	21 (48.8)
Pumitamig-related	14 (63.6)	19 (90.5)	33 (76.7)
Grade ≥3	4 (18.2)	6 (28.6)	10 (23.3)
Led to discontinuation	3 (13.6)	5 (23.8)	8 (18.6)
Pumitamig-related	1 (4.5)	3 (14.3)	4 (9.3)
Led to death	0	1 (4.8)	1 (2.3)
Pumitamig-related	0	1 (4.8)	1 (2.3)

TEAEs, n (%)	Nonsquamous cohort (n=22)	Squamous cohort (n=21)	Overall (n=43)
Any irAE	8 (36.4)	8 (38.1)	16 (37.2)
Grade ≥3	1 (4.5)	1 (4.8)	2 (4.7)
VEGF-related	10 (45.5)	14 (66.7)	24 (55.8)
Grade ≥3	1 (4.5)	1 (4.8)	2 (4.7)
Hemorrhage/bleeding	2 (9.1)	7 (33.3)	9 (20.9)
Grade ≥3	0	1 (4.8)	1 (2.3)

- **Conclusions**
  - In patients with advanced NSCLC, 1L pumitamig + chemotherapy demonstrated consistent antitumor activity across histologies and PD-L1 subgroups with a manageable safety profile

8514: Updated results from a phase 2 trial of SSGJ-707 (PF-08634404), a PD-1/VEGF bispecific antibody, as monotherapy in patients with advanced non-small cell lung cancer (NSCLC) – Wu L, et al

- **Study objective**
  - To evaluate updated efficacy and safety of PF'4404 (a bispecific PD-L1/VEGF antibody, also known as PF-08634404 or SSGJ-707) in patients with advanced NSCLC



Primary endpoints

- ORR (RECIST v1.1)

Secondary endpoints

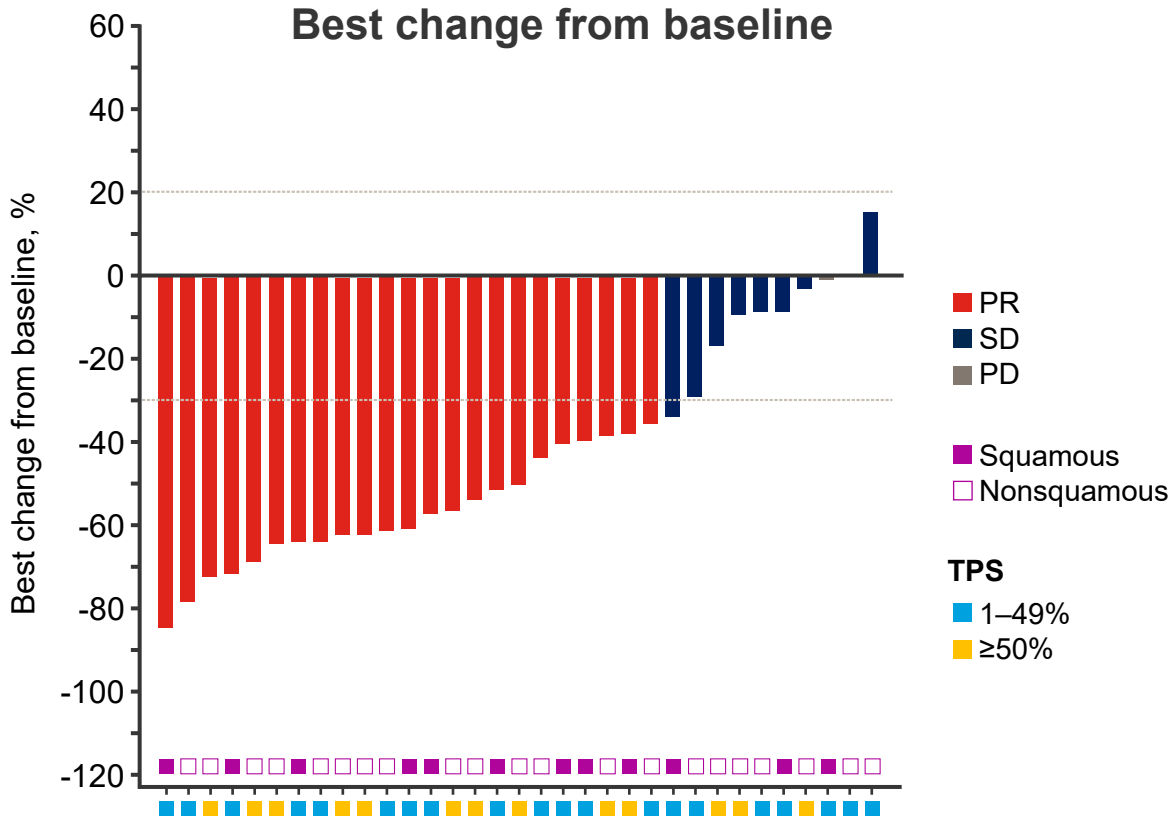
- DoR, PFS, OS, ctDNA, safety

*RP3D PF'4404 10 mg/kg q3w.

8514: Updated results from a phase 2 trial of SSGJ-707 (PF-08634404), a PD-1/VEGF bispecific antibody, as monotherapy in patients with advanced non-small cell lung cancer (NSCLC) – Wu L, et al

- **Key results**

	PF'4404 10 mg/kg (n=34)
cORR, % (95%CI)	67.6 (49.5, 82.6)
BOR, n (%) PR SD PD	 23 (67.6) 10 (29.4) 1 (2.9)
DCR, % (95%CI)	97.1 (84.7, 99.9)
DoR, % (95%CI)	18.0 (10.9, NE)
mPFS, mo (95%CI)	12.4 (8.2, NE)
Events, n	19
12-mo PFS rate, % (95%CI)	55.6 (36.7, 70.9)



8514: Updated results from a phase 2 trial of SSGJ-707 (PF-08634404), a PD-1/VEGF bispecific antibody, as monotherapy in patients with advanced non-small cell lung cancer (NSCLC) – Wu L, et al

- **Key results (cont.)**

	Nonsquamous (n=22)	Squamous (n=12)	TPS 1–49% (n=21)	TPS ≥50% (n=13)
cORR, % (95%CI)	63.6 (40.7, 82.8)	75.0 (42.8, 94.5)	61.9 (38.4, 81.9)	76.9 (46.2, 95.0)
BOR, n (%)				
PR	14 (63.6)	9 (75.0)	13 (61.9)	10 (76.9)
SD	7 (31.8)	3 (25.0)	7 (33.3)	3 (23.1)
PD	1 (4.5)	0	1 (4.8)	0
mPFS, mo (95%CI)	12.4 (8.2, NE)	8.9 (2.7, NE)	9.6 (7.6, NE)	15.8 (5.9, NE)

Correlation between ctDNA clearance and PFS	N	Events, n (%)	mPFS, mo (95%CI)
Detected at C1D1/Not detected at C3D1	19	5 (26.3)	NR (12.4, NR)
Detected at C1D1/ Detected at C3D1	33	23 (69.7)	7.6 (5.6, 9.4)

AEs, n (%)	All patients (n=83)	10 mg/kg (n=34)
TRAEs		
Any grade	77 (92.8)	34 (100)
Grade ≥3	36 (43.4)	15 (44.1)
Grade 5	2 (2.4)[a]	0
Serious	31 (37.3)	10 (29.4)
Led to discontinuation	7 (8.4)[b]	1 (2.9)[c]
VEGF-related AEs		
Any grade	52 (62.7)	25 (73.5)
Grade ≥3	15 (18.1)	5 (14.7)
irAEs		
Any grade	32 (38.6)	17 (50.0)
Grade ≥3	7 (8.4)	2 (5.9)[d]

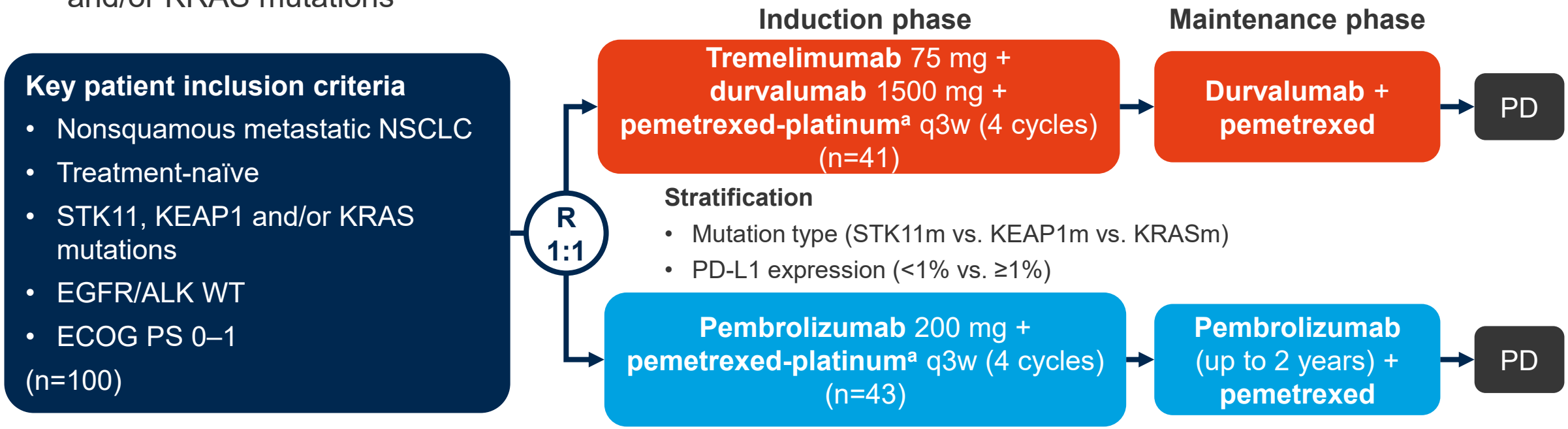
- **Conclusions**
  - In Chinese patients with advanced NSCLC, PF'4404 monotherapy provided encouraging antitumor activity across subgroups with a manageable safety profile

[a]Grade 5 TRAEs consisted of hemoptysis (n=1) and death from unknown cause (n=1). [b]Hemoptysis (n=4), pneumonia (n=1), ALT increased (n=1), diabetic ketoacidosis (n=1). [c]Hemoptysis. [d]Abnormal hepatic function (n=1), rash (n=2).

Wu L, et al. J Clin Oncol 2026;44(suppl):Abstr 8514

8515: Tremelimumab (T) + durvalumab (D) + chemotherapy (CT) vs pembrolizumab (P) + CT in 1L non-squamous (NSQ) metastatic NSCLC (mNSCLC) with STK11, KEAP1, and/or KRAS mutations (mut): Interim analysis (IA) of the phase 2b TRITON study – Skoulidis F, et al

- **Study objective**
  - To evaluate the efficacy and safety of 1L tremelimumab + durvalumab + chemotherapy compared with pembrolizumab + chemotherapy in patients with nonsquamous metastatic NSCLC with STK11, KEAP1 and/or KRAS mutations



Primary endpoints

- PFS* (investigator-assessed, RECIST v1.1)

Secondary endpoints

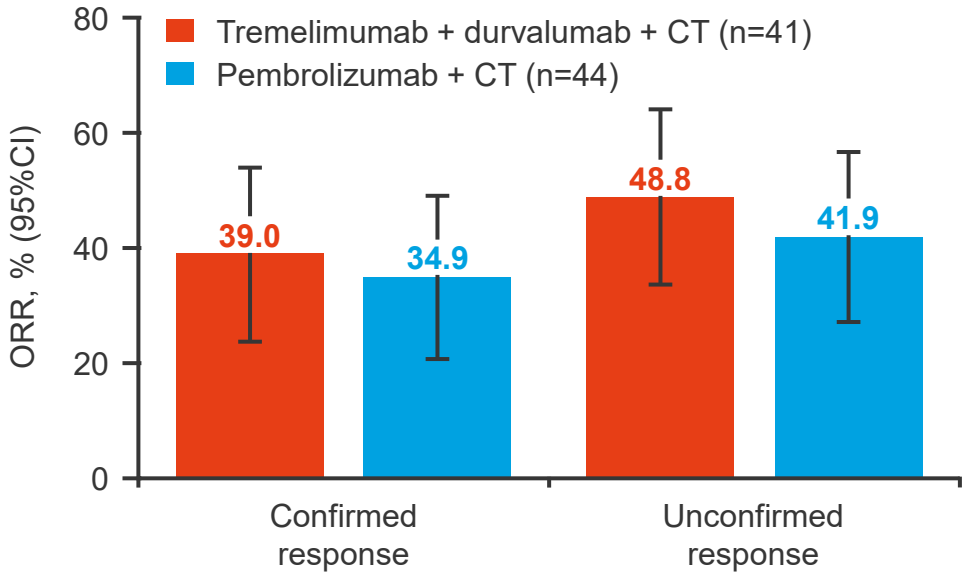
- OS, ORR, DoR, time to subsequent treatment, safety

*TRITON was resized due to challenges with enrollment; consequently, the study was amended from phase 3b to 2b and the primary endpoint was changed from OS to PFS. [a]Platinum (carboplatin AUC 5/6 or cisplatin 75 mg/m²) + pemetrexed 500 mg/m² q3w for up to 4 cycles.

8515: Tremelimumab (T) + durvalumab (D) + chemotherapy (CT) vs pembrolizumab (P) + CT in 1L non-squamous (NSQ) metastatic NSCLC (mNSCLC) with STK11, KEAP1, and/or KRAS mutations (mut): Interim analysis (IA) of the phase 2b TRITON study – Skoulidis F, et al

- **Key results**

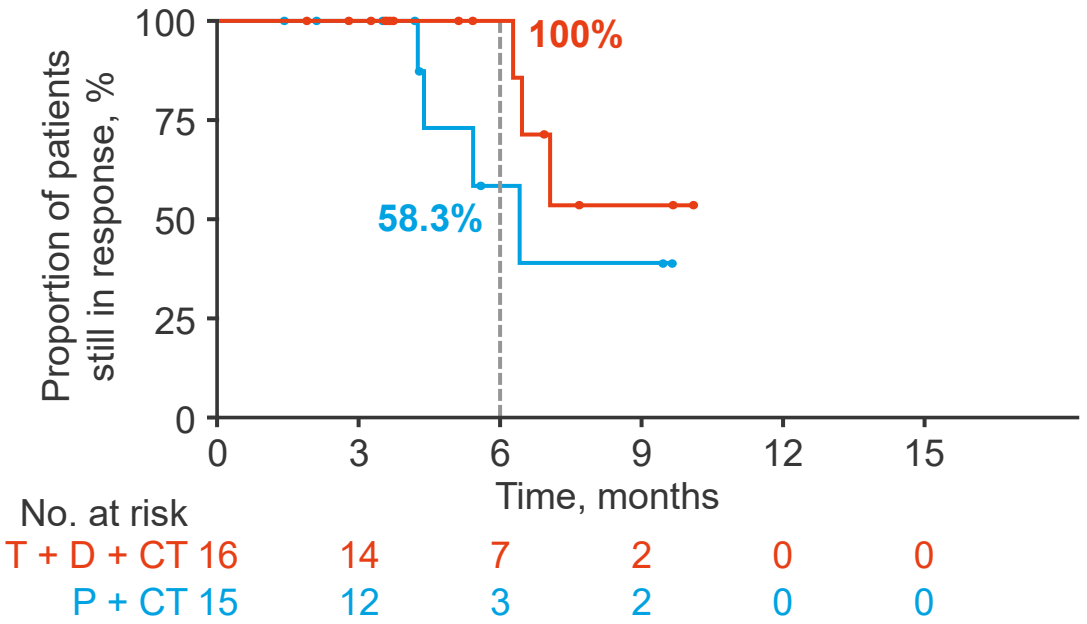
Overall response rate



	STK11m ± co-mutations		KEAP1m ± co-mutations		KRASm ± co-mutations		KRASm only	
	T + D + CT (n=11)	P + CT (n=12)	T + D + CT (n=9)	P + CT (n=9)	T + D + CT (n=31)	P + CT (n=35)	T + D + CT (n=25)	P + CT (n=27)
cORR, %	36.4	25.0	33.3	33.3	45.2	31.4	48.0	33.3

Duration of response

	T + D + CT	P + CT
Events, n	16	15
Median DoR, mo (95%CI)	NR (6.3, NR)	6.4 (4.2, NR)



8515: Tremelimumab (T) + durvalumab (D) + chemotherapy (CT) vs pembrolizumab (P) + CT in 1L non-squamous (NSQ) metastatic NSCLC (mNSCLC) with STK11, KEAP1, and/or KRAS mutations (mut): Interim analysis (IA) of the phase 2b TRITON study – Skoulidis F, et al

- **Key results (cont.)**

	D + T + CT (n=41)	P + CT (n=43)
Median follow-up, months (range)	5.6 (0–14.0)	5.1 (0–17.5)
Any grade all-cause AEs, n (%)	41 (100)	42 (97.7)
Grade 3/4	31 (75.6)	27 (62.8)
Serious	26 (63.4)	26 (60.5)
Led to treatment discontinuation	1 (2.4)	2 (4.7)
Led to death	2 (4.9)	5 (11.6)

AEs, n (%)	D + T + CT (n=41)	P + CT (n=43)
TRAEs		
Any grade	36 (87.8)	38 (88.4)
Grade 3/4	17 (41.5)	18 (41.9)
Serious	11 (26.8)	11 (25.6)
Led to treatment discontinuation	1 (2.4)	2 (4.7)
Led to death	0	1 (2.3)[a]
Any imAEs	6 (14.6)	7 (16.3)
Grade 3/4	0	3 (7.0)

- **Conclusions**
  - In patients with nonsquamous metastatic NSCLC harboring STK11, KEAP1, and/or KRAS mutations, 1L tremelimumab + durvalumab + chemotherapy showed antitumor activity comparable to pembrolizumab-based therapy with a safety profile consistent with previous findings

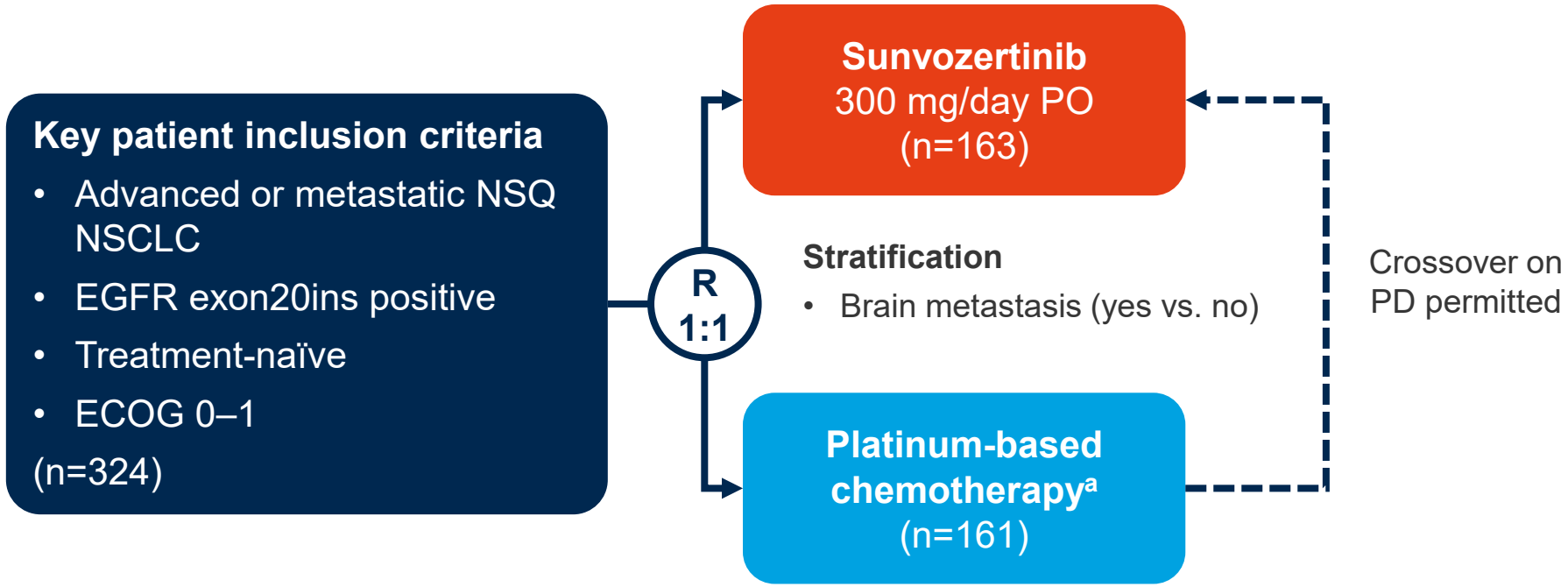
[a]Death due to sepsis.

Advanced NSCLC – Not radically treatable stage III and stage IV

Targeted therapies

LBA8500: Sunvozertinib monotherapy versus platinum-based chemotherapy as first-line treatment for advanced NSCLC with EGFR exon20ins: Primary analysis of a multinational phase 3 randomized study (WU-KONG28) – Heymach JV, et al

- **Study objective**
  - To evaluate the efficacy and safety of 1L sunvozertinib compared with platinum-based chemotherapy in patients with advanced NSCLC and EGFR exon20ins



Primary endpoints
- PFS (BICR)

Secondary endpoints
- OS, ORR, DCR, DoR, PK, safety

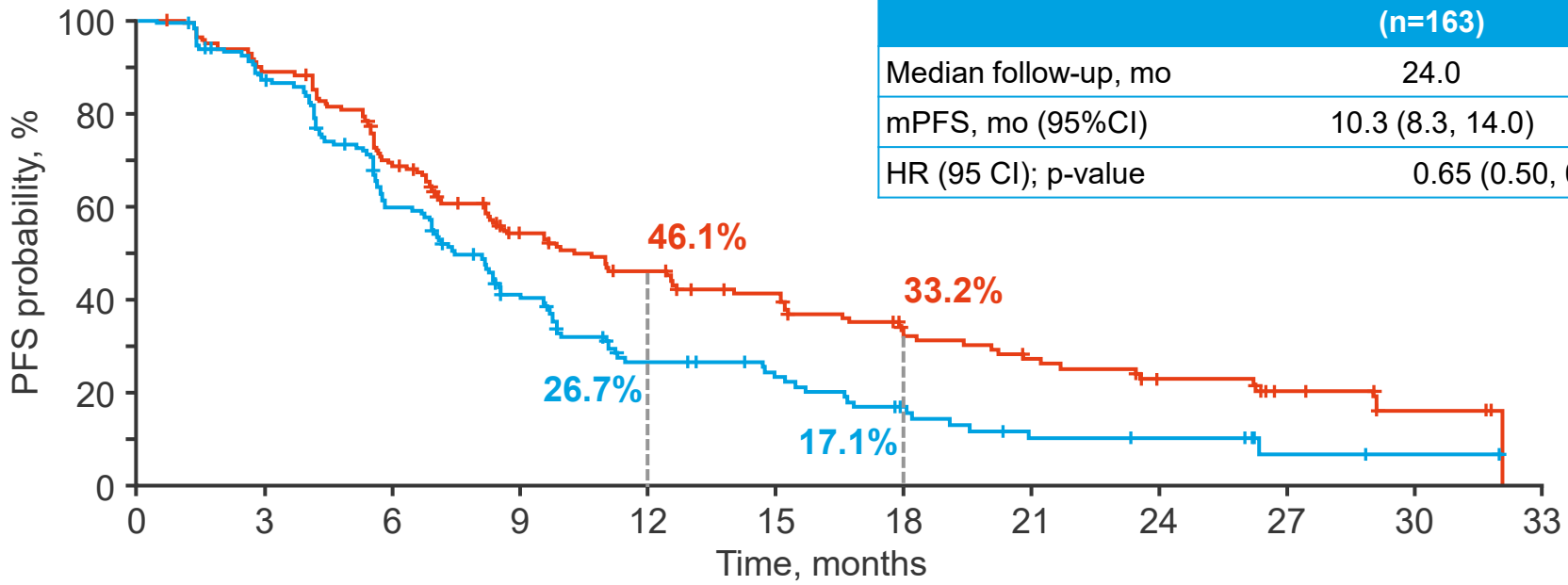
Exploratory endpoints
- PFS2

[a]Carboplatin AUC5 + pemetrexed 500 mg/m^2 q3w (6 cycles), followed by pemetrexed maintenance therapy.

LBA8500: Sunvozertinib monotherapy versus platinum-based chemotherapy as first-line treatment for advanced NSCLC with EGFR exon20ins: Primary analysis of a multinational phase 3 randomized study (WU-KONG28) – Heymach JV, et al

- **Key results**

Progression-free survival (BICR)



	Sunvozertinib (n=163)	Chemotherapy (n=161)
Median follow-up, mo	24.0	18.0
mPFS, mo (95%CI)	10.3 (8.3, 14.0)	7.5 (6.7, 8.5)
HR (95 CI); p-value	0.65 (0.50, 0.85); 0.0008	

No. at risk

Sunvozertinib	163	143	108	74	60	48	34	26	18	9	3	0
Chemotherapy	161	128	84	51	28	22	14	7	6	2	1	0

Heymach JV, et al. J Clin Oncol 2026;44(suppl):Abstr LBA8500

LBA8500: Sunvozertinib monotherapy versus platinum-based chemotherapy as first-line treatment for advanced NSCLC with EGFR exon20ins: Primary analysis of a multinational phase 3 randomized study (WU-KONG28) – Heymach JV, et al

- **Key results**

Outcomes	Sunvozertinib (n=163)	Chemotherapy (n=161)
BOR rate, % (95%CI)	68.1 (60.4, 75.2)	35.4 (28.0, 43.3)
Confirmed ORR, % (95%CI)	58.9 (50.9, 66.5)	31.1 (24.0, 38.8)
OR (95%CI); p-value	3.2 (2.0, 5.0); <0.0001	
Median tumor shrinkage, %	42.1	24.7
DCR, % (95%CI)	94.5 (89.8, 97.4)	85.7 (79.3, 90.7)
mPFS2, mo (95%CI)	21.7 (16.1, 24.3)	15.5 (13.4, 18.6)
HR (95%CI); p-value	0.70 (0.52, 0.95); 0.0111	
Median follow-up, mo	23.6	24.1
Interim mOS, mo (95%CI)	29.8 (21.8, NE)	28.8 (20.7, NE)
Median follow-up, mo	26.1	26.7
	n=96	n=50
mDoR, mo (95%CI)	11.2 (8.2, 13.9)	7.1 (6.9, 11.1)

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LBA8500: Sunvozertinib monotherapy versus platinum-based chemotherapy as first-line treatment for advanced NSCLC with EGFR exon20ins: Primary analysis of a multinational phase 3 randomized study (WU-KONG28) – Heymach JV, et al

- **Key results (cont.)**

TRAEs, n (%)	Sunvozertinib (n=163)	Chemotherapy (n=150)
Any	163 (100)	146 (97.3)
Grade ≥3	100 (61.3)	74 (49.3)
Serious	30 (18.4)	19 (12.7)
Led to dose interruption	74 (45.4)	41 (27.3)
Led to dose reduction	66 (40.5)	36 (24.0)
Led to treatment discontinuation	12 (7.4)	17 (11.3)
Led to death	0	1 (0.7)[a]

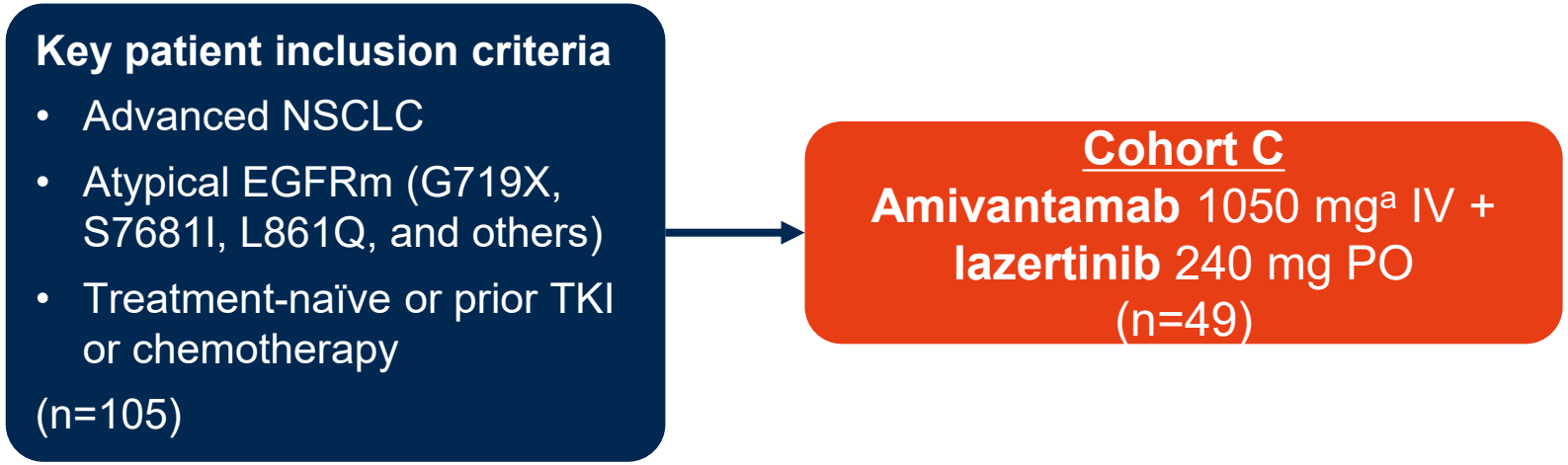
Common TRAEs occurring in ≥30%, n (%)	Sunvozertinib (n=163)		Chemotherapy (n=150)	
	All grade	Grade 3	All grade	Grade 3
Any	163 (100)	100 (61.3)	146 (97.3)	74 (49.3)
Diarrhea	137 (84.0)	22 (13.5)	15 (10.0)	0
Blood creatine phosphokinase increased	90 (55.2)	33 (10.2)	5 (3.3)	1 (0.7)
Rash	84 (51.5)	1 (0.6)	8 (5.3)	0
Paronychia	79 (48.5)	6 (3.7)	0	0
Anemia	75 (46.0)	10 (6.1)	91 (60.7)	15 (10.0)
Weight decreased	56 (34.4)	5 (3.1)	15 (10.0)	1 (0.7)
Appetite decreased	52 (31.9)	1 (0.6)	39 (26.0)	2 (1.3)
Blood creatine increased	50 (30.7)	1 (0.6)	12 (8.0)	0
Nausea	38 (23.3)	3 (1.8)	66 (44.0)	2 (1.3)
AST increased	35 (21.5)	3 (1.8)	52 (34.7)	1 (0.7)
ALT increased	25 (15.3)	2 (1.2)	50 (33.3)	2 (1.3)
Neutrophil count decreased	22 (13.5)	5 (2.5)	68 (45.3)	28 (18.7)
WBC count decreased	20 (12.3)	1 (0.6)	58 (38.7)	10 (6.7)

- **Conclusions**
  - In treatment-naïve patients with advanced NSCLC and EGFR exon20ins, 1L sunvozertinib significantly improved PFS and response outcomes compared with platinum-based chemotherapy, with a manageable safety profile

[a]Pneumonia.

8501: Overall survival of first-line amivantamab plus lazertinib in atypical EGFR-mutated advanced non-small cell lung cancer (NSCLC): Updated results from the CHRYSALIS-2 study – Neal JW, et al

- **Study objective**
  - To evaluate OS with amivantamab + lazertinib in patients with atypical EGFRm advanced NSCLC



Primary endpoint

- ORR (investigator-assessed, RECIST v1.1)

Secondary endpoints

- CBR, DoR, PFS, OS, safety

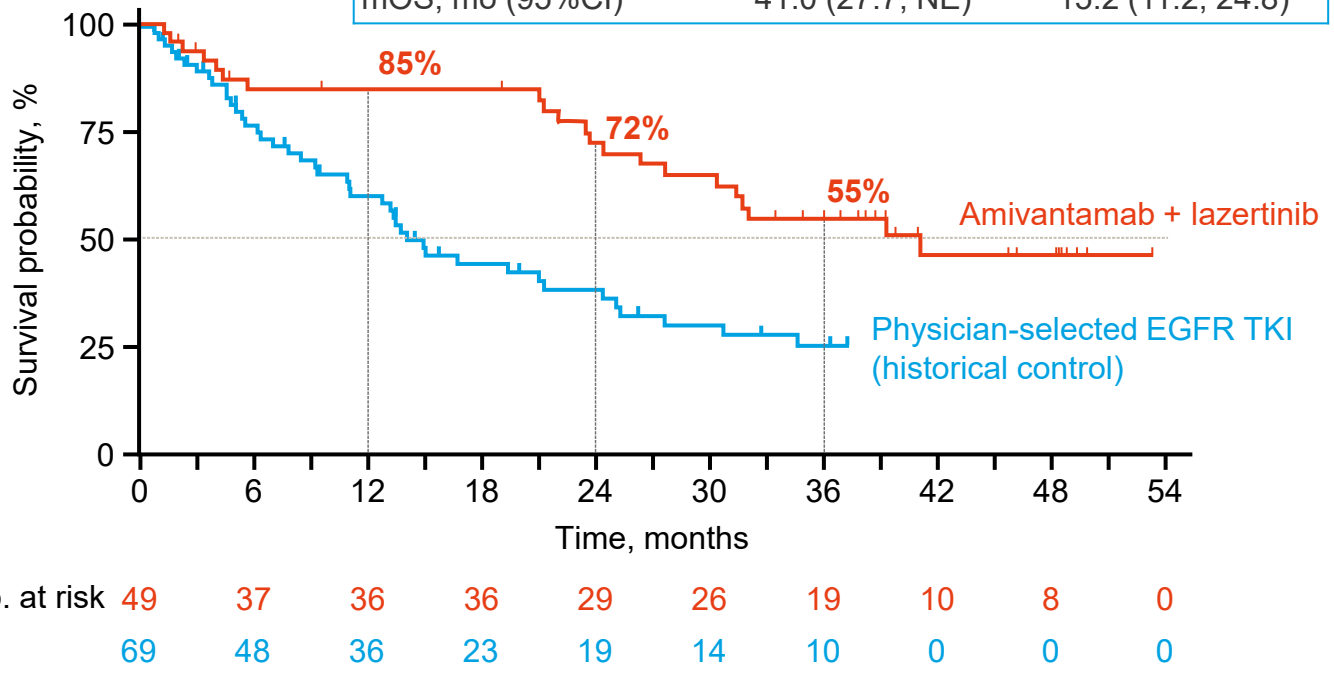
[a]1400 mg if ≥80 kg.

8501: Overall survival of first-line amivantamab plus lazertinib in atypical EGFR-mutated advanced non-small cell lung cancer (NSCLC): Updated results from the CHRYSALIS-2 study – Neal JW, et al

- **Key results**

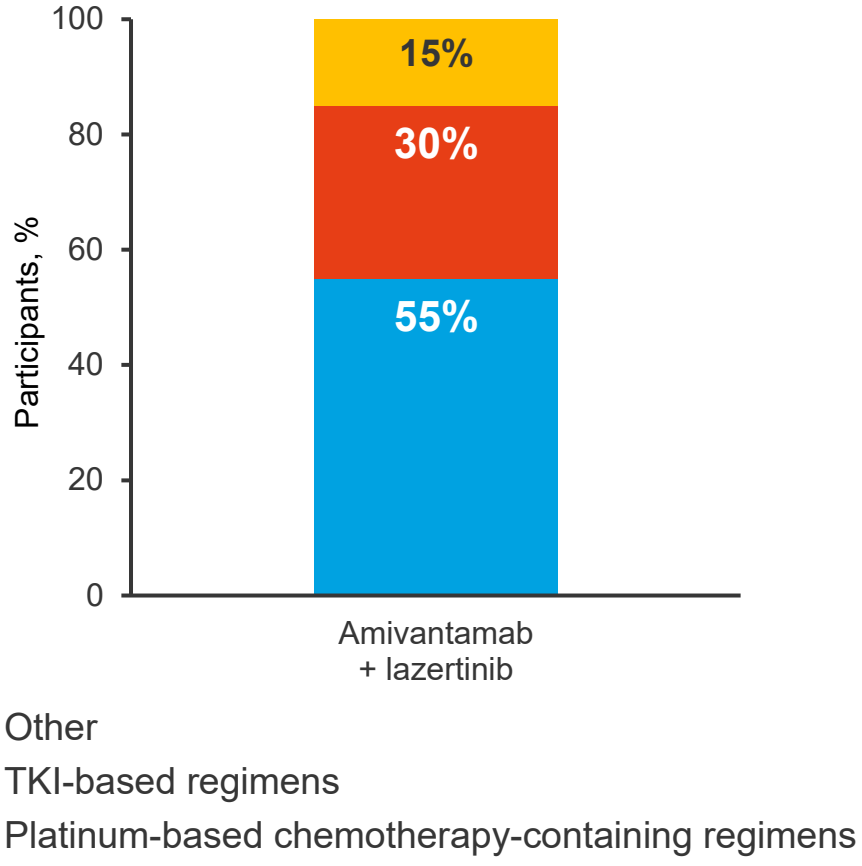
Overall survival vs. real-world cohort of atypical EGFR[a]

	Amivantamab + lazertinib	Physician-selected EGFR TKI
Median follow-up, mo	31.3	13.4
mOS, mo (95%CI)	41.0 (27.7, NE)	15.2 (11.2, 24.8)



No. at risk										
Amivantamab + lazertinib	49	37	36	36	29	26	19	10	8	0
Physician-selected EGFR TKI (historical control)	69	48	36	23	19	14	10	0	0	0

Subsequent therapy (n=20)



[a]Real-world data were obtained from the FH/FMI CGDB between 1st January and 31st March 2024.

8501: Overall survival of first-line amivantamab plus lazertinib in atypical EGFR-mutated advanced non-small cell lung cancer (NSCLC): Updated results from the CHRYSALIS-2 study – Neal JW, et al

- **Key results (cont.)**

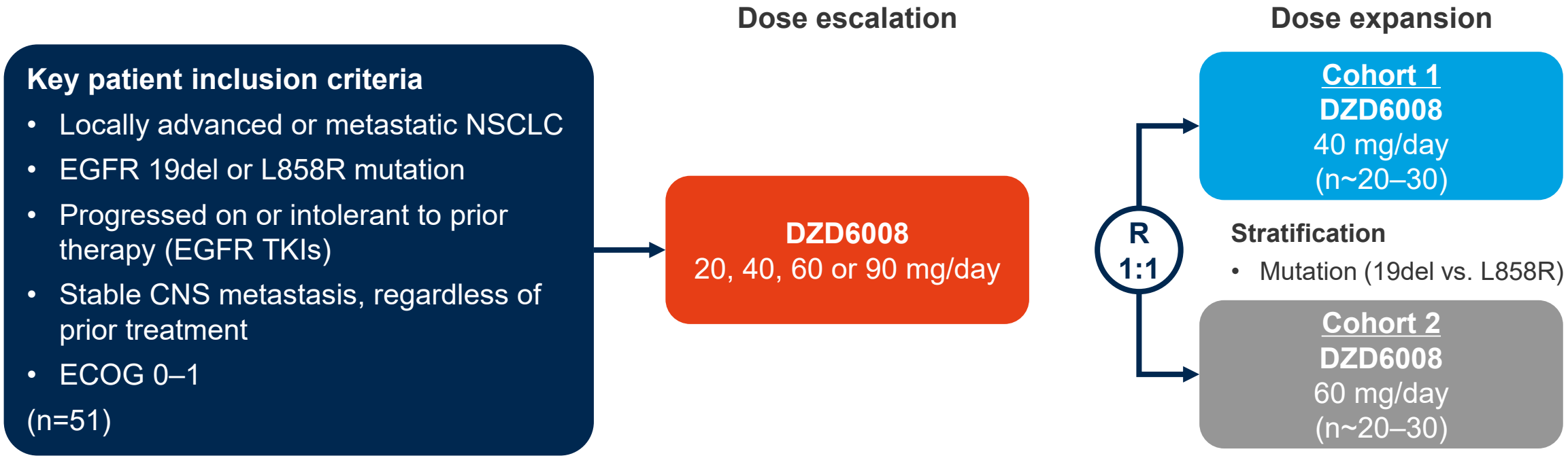
AEs, n (%)	All grades	Grade ≥3
Related to EGFR inhibition		
Paronychia	38 (78)	4 (8)
Rash	32 (65)	7 (14)
Diarrhea	17 (35)	0
Stomatitis	17 (35)	0
Pruritus	15 (31)	0
Related to MET inhibition		
Hypoalbuminemia	30 (61)	3 (6)
Peripheral edema	20 (41)	1 (2)

AEs, n (%)	All grades	Grade ≥3
Other		
Infusion-related reaction	30 (61)	3 (6)
ALT increased	26 (53)	2 (4)
AST increased	24 (49)	1 (2)
Hypocalcemia	23 (47)	0
COVID-19	20 (41)	1 (2)
Nausea	15 (31)	1 (2)
Constipation	15 (31)	0

- **Conclusions**
  - In patients with previously untreated advanced atypical EGFRm NSCLC, 1L amivantamab + lazertinib provided promising OS results with no new safety signals observed

8520: DZD6008, a fourth-generation EGFR TKI, in pretreated NSCLC patients with EGFR C797X mutations: Results from phase 1/2 studies – Wang M, et al

- **Study objective**
  - To evaluate the efficacy and safety of DZD6008 (an EGFR TKI) in previously treated patients with EGFR C797X mutations in the TIAN-SHAN1/2 study



Primary endpoint

- Dose escalation: Safety
- Dose expansion: ORR (investigator-assessed, RECIST v1.1)

Secondary endpoints

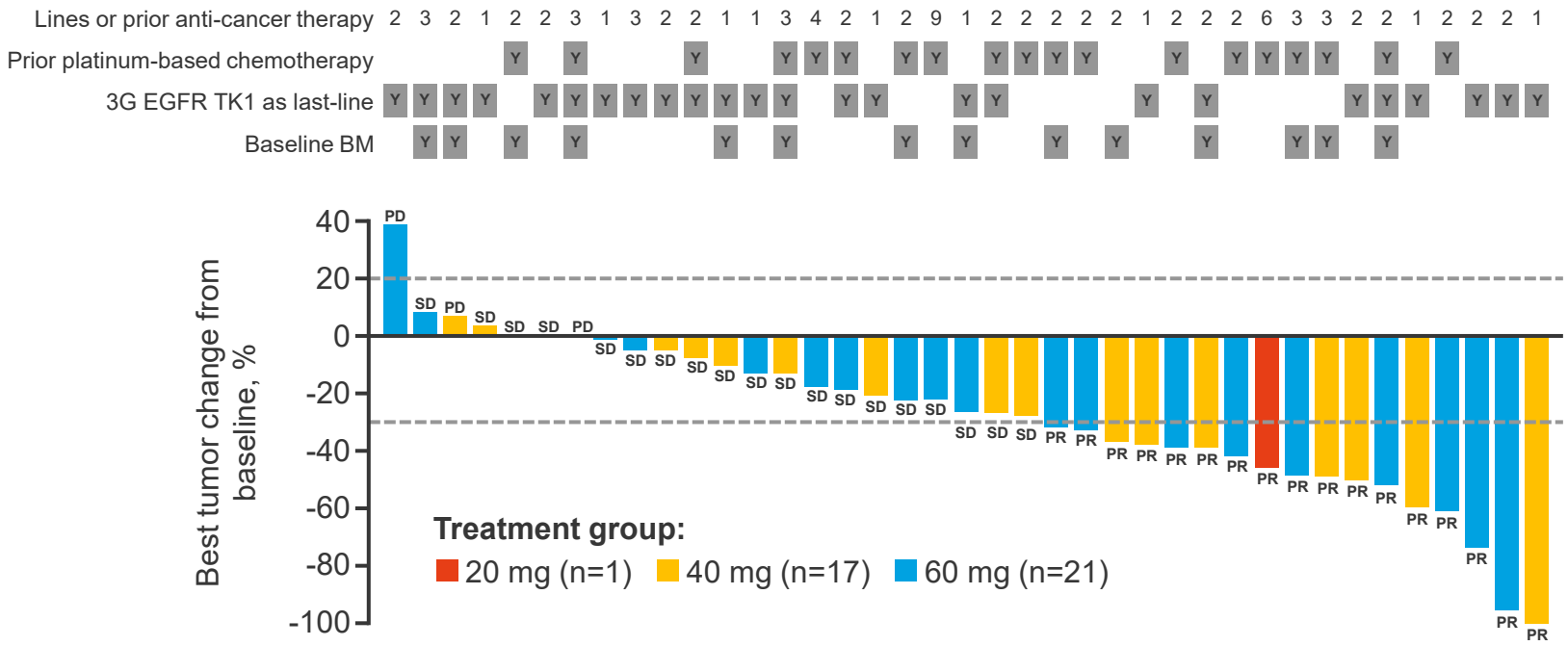
- PFS, DoR, DCR, OS

8520: DZD6008, a fourth-generation EGFR TKI, in pretreated NSCLC patients with EGFR C797X mutations: Results from phase 1/2 studies – Wang M, et al

- **Key results**

	DZD6008 40 mg (n=17)	DZD6008 60 mg (n=21)
ORR, n (%) [95%CI]	7 (41.2) [18.4, 67.1]	9 (42.9) [21.8, 66.0]
DCR, n (%) [95%CI]	16 (94.1) [71.2, 99.9]	19 (90.5) [69.6, 98.8]
BOR, n (%)		
PR	7 (41.2)	9 (42.9)
SD	9 (52.9)	10 (47.6)
PD	1 (5.9)	2 (9.5)
6-month PFS, (95%CI)	70.6 (38.9, 88.0)	61.8 (35.8, 79.8)
Median follow-up, mo	6.1	5.7

Best tumor change from baseline



Wang M, et al. J Clin Oncol 2026;44(suppl):Abstr 8520

8520: DZD6008, a fourth-generation EGFR TKI, in pretreated NSCLC patients with EGFR C797X mutations: Results from phase 1/2 studies – Wang M, et al

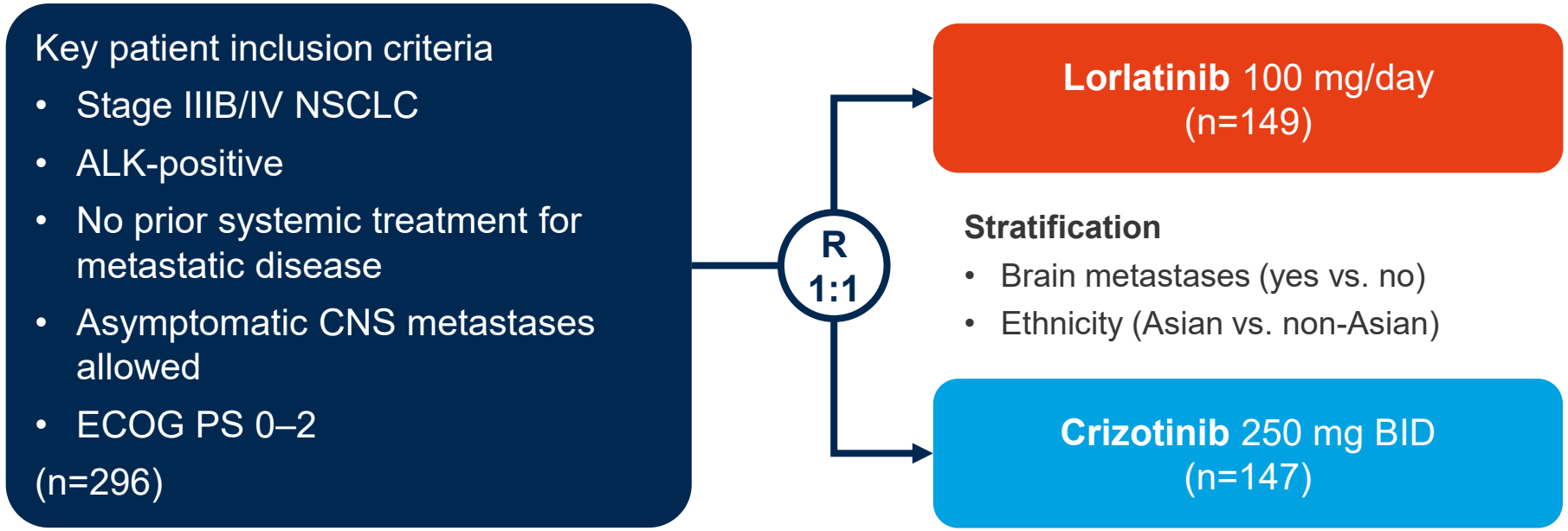
- **Key results (cont.)**

	20 mg (n=2)		40 mg (n=24)		60 mg (n=24)		90 mg (n=1)		All (n=51)	
TEAEs occurring in ≥20%, n (%)	All grade	Grade ≥3	All grade	Grade ≥3	All grade	Grade ≥3	All grade	Grade ≥3	All grade	Grade ≥3
Any	2 (100)	1 (50.0)	22 (91.7)	9 (37.5)	24 (100)	10 (41.7)	0	0	48 (94.1)	20 (39.2)
Anemia	1 (50.0)	0	18 (75.0)	1 (4.2)	20 (83.3)	4 (16.7)	0	0	39 (76.5)	5 (9.8)
Blood bilirubin increased	0	0	7 (29.2)	0	12 (50.0)	1 (4.2)	0	0	19 (37.3)	1 (2.0)
AST increased	0	0	8 (33.3)	0	10 (41.7)	1 (4.2)	0	0	18 (35.3)	1 (2.0)
ALT increase	0	0	6 (25.0)	0	9 (37.5)	1 (4.2)	0	0	15 (29.4)	1 (2.0)
Blood creatine phosphokinase increased	1 (50.0)	0	4 (16.7)	0	7 (29.2)	0	0	0	12 (23.5)	0
Blood creatinine increased	0	0	8 (33.3)	0	4 (16.7)	0	0	0	12 (23.5)	0
Appetite decreased	1 (50.0)	0	4 (16.7)	0	7 (29.2)	1 (4.2)	0	0	12 (23.5)	1 (2.0)

- **Conclusions**
  - In previously treated patients with NSCLC and EGFR C797X mutations, DZD6008 showed encouraging antitumor intracranial activity with a manageable safety profile

8502: Lorlatinib vs crizotinib as first-line treatment for advanced ALK+ non-small cell lung cancer: 7-year update from the phase 3 CROWN study – Mok TSK, et al

- **Study objective**
  - To evaluate the long-term efficacy and safety of 1L lorlatinib compared with crizotinib in patients with ALK+ NSCLC



Primary endpoint

- PFS (BICR, RECIST v1.1)

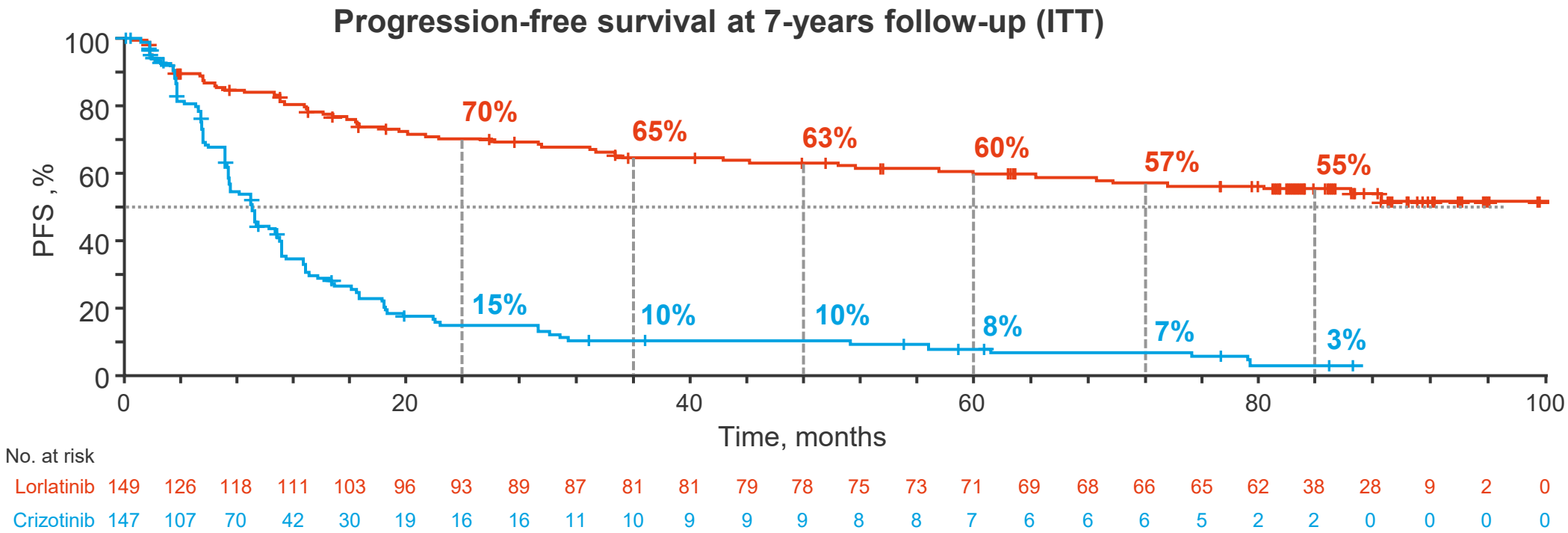
Secondary endpoints

- OS, PFS (investigator-assessed), ORR, DoR, intracranial ORR, intracranial TTP, intracranial DoR, QoL, safety

Mok TSK, et al. J Clin Oncol 2026;44(suppl):Abstr 8502

8502: Lorlatinib vs crizotinib as first-line treatment for advanced ALK+ non-small cell lung cancer: 7-year update from the phase 3 CROWN study – Mok TSK, et al

- **Key results**



	Lorlatinib (n=149)	Crizotinib (n=147)
Events, n	62	119
Median follow-up, mo (95%CI)	83.0 (81.2, 86.3)	77.2 (36.8, NE)
mPFS, mo (95%CI)	NR (68.5, NR)	9.1 (7.4, 10.9)
HR (95%CI)	0.19 (0.13, 0.26)	

Conditional PFS beyond 2 years	PFS estimate, %
2-year PFS rate	70
7-year PFS rate	55
Conditional PFS (7Y/2Y)[a]	79

[a]Estimated as the ratio of the Kaplan-Meier PFS estimate at 7 and 2 years.

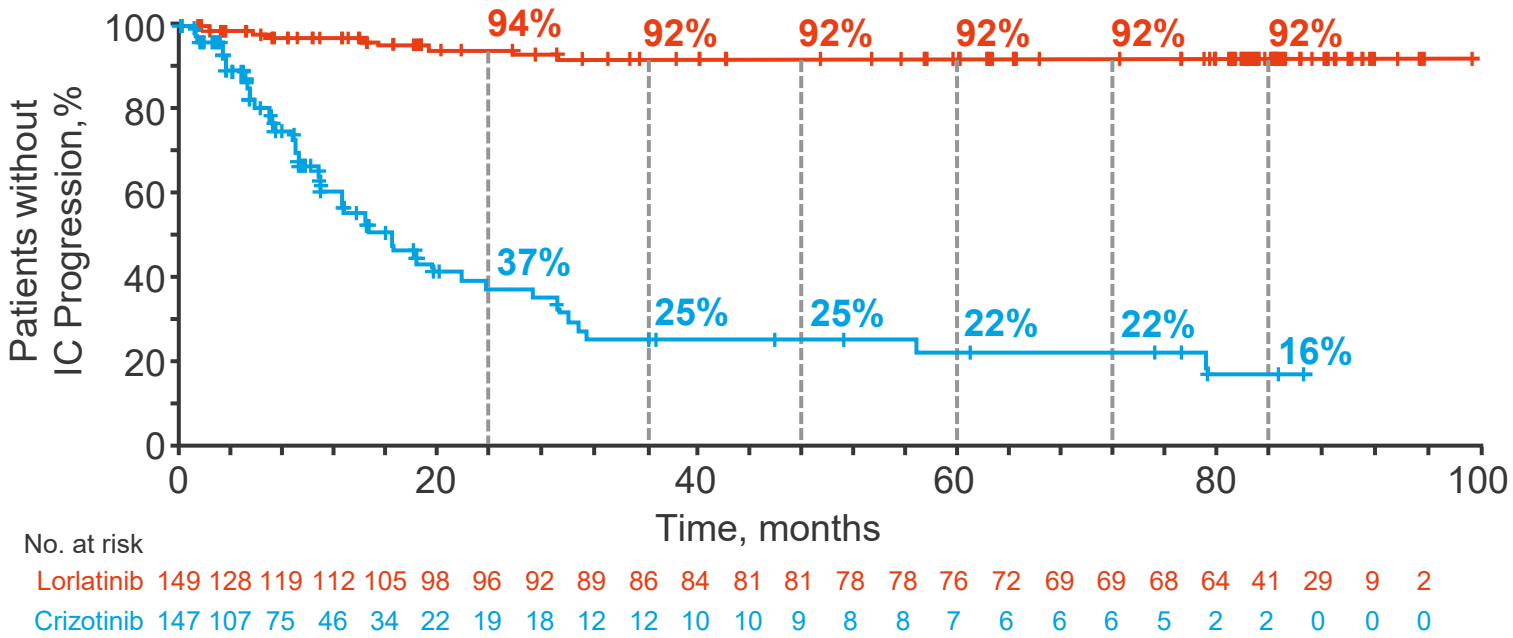
Mok TSK, et al. J Clin Oncol 2026;44(suppl):Abstr 8502

8502: Lorlatinib vs crizotinib as first-line treatment for advanced ALK+ non-small cell lung cancer: 7-year update from the phase 3 CROWN study – Mok TSK, et al

- **Key results**

Time to intracranial progression in the ITT population

	Lorlatinib (n=149)	Crizotinib (n=147)
Events, n	9	66
Median time to intracranial progression, mo (95%CI)	NR (NR, NR)	16.4 (12.7, 21.9)
HR (95%CI)	0.06 (0.03, 0.12)	



Time to intracranial progression with baseline brain metastases

	Lorlatinib (n=35)	Crizotinib (n=147)
Events, n	5	26
Median time to intracranial progression, mo (95%CI)	NR (NR, NR)	7.2 (3.7, 11.0)
HR (95%CI)	0.03 (0.01, 0.13)	

Time to intracranial progression without baseline brain metastases

	Lorlatinib (n=114)	Crizotinib (n=109)
Events, n	4	40
Median time to intracranial progression, mo (95%CI)	NR (NR, NR)	23.9 (16.4, 30.8)
HR (95%CI)	0.04 (0.02, 0.12)	

8502: Lorlatinib vs crizotinib as first-line treatment for advanced ALK+ non-small cell lung cancer: 7-year update from the phase 3 CROWN study – Mok TSK, et al

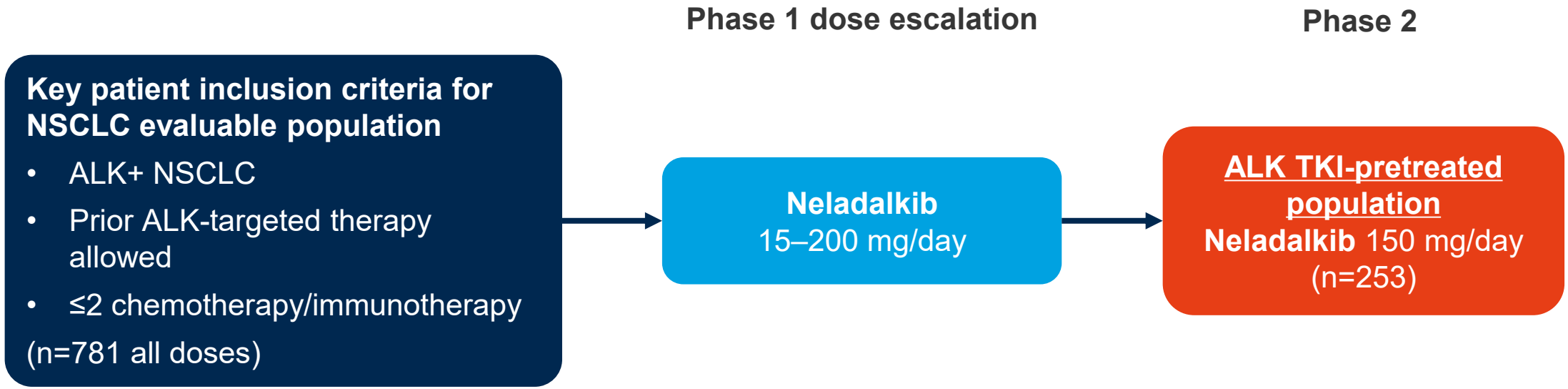
- **Key results (cont.)**

AEs of special interest, %	Lorlatinib	Crizotinib
Edema	58	43
Hypertriglyceridemia	71	6
Hypercholesterolemia	73	4
Peripheral neuropathy	46	16
Weight gain	45	13
Cognitive effects	30	7
Mood effects	21	7
Speech effects	6	0
Psychotic effects	5	1

- **Conclusions**
  - In patients with advanced ALK-positive NSCLC, 1L lorlatinib provided sustained, long-term disease and CNS control with durable PFS and no new safety events over the extended follow-up

8503: ALKOVE-1: Efficacy and safety of neladalkib in patients with advanced ALK+ NSCLC – Lin JJ, et al

- **Study objective**
  - To evaluate the efficacy and safety of neladalkib (an ALK-selective, TRK-sparing TKI) in patients with ALK+ advanced NSCLC



Primary endpoint

- ORR (BICR)

Secondary endpoints

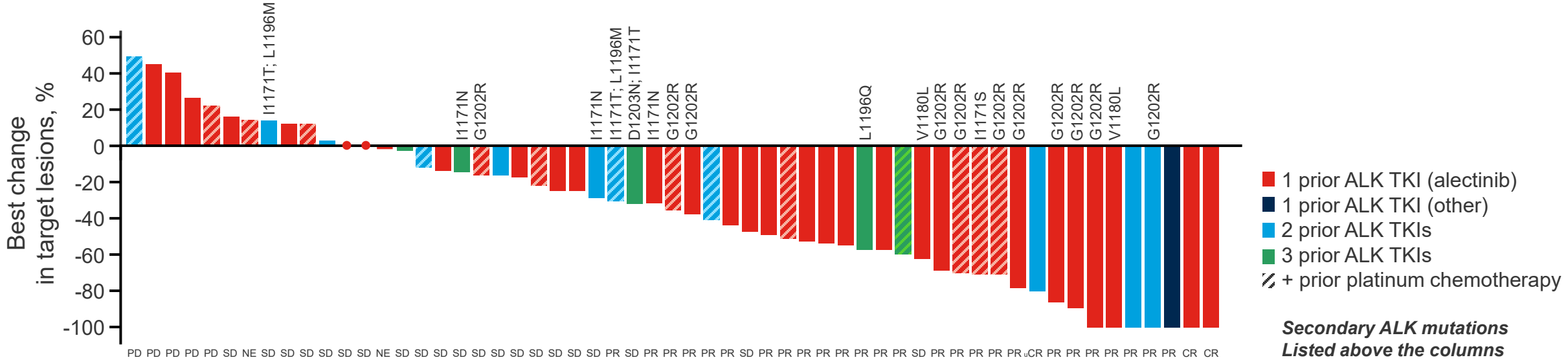
- DoR, TTR, PFS, OS, intracranial activity, PK, safety

8503: ALKOVE-1: Efficacy and safety of neladalkib in patients with advanced ALK+ NSCLC – Lin JJ, et al

- **Key results**

Objective response in ALK TKI-pretreated patients

	Any prior ALK TKI (1–5 prior ALK TKIs ± chemotherapy) (n=253)	Lorlatinib-naïve (1–3 prior ALK TKIs ± chemotherapy) (n=63)	Lorlatinib-experienced (1–5 prior ALK TKIs ± chemotherapy) (n=190)
ORR, n (%) [95%CI]	79 (31) [26, 37]	29 (46) [33, 59]	50 (26) [20, 33]
CR, n (%)	6 (2)	3 (5)	3 (2)
mPFS, mo (95%CI)	5.7 (4.4, 6.5)	14.5 (4.8, NE)	4.6 (2.8, 6.2)



Median duration of follow-up: 11.3 months.

Lin JJ, et al. J Clin Oncol 2026;44(suppl):Abstr 8503

8503: ALKOVE-1: Efficacy and safety of neladalkib in patients with advanced ALK+ NSCLC – Lin JJ, et al

- **Key results (cont.)**

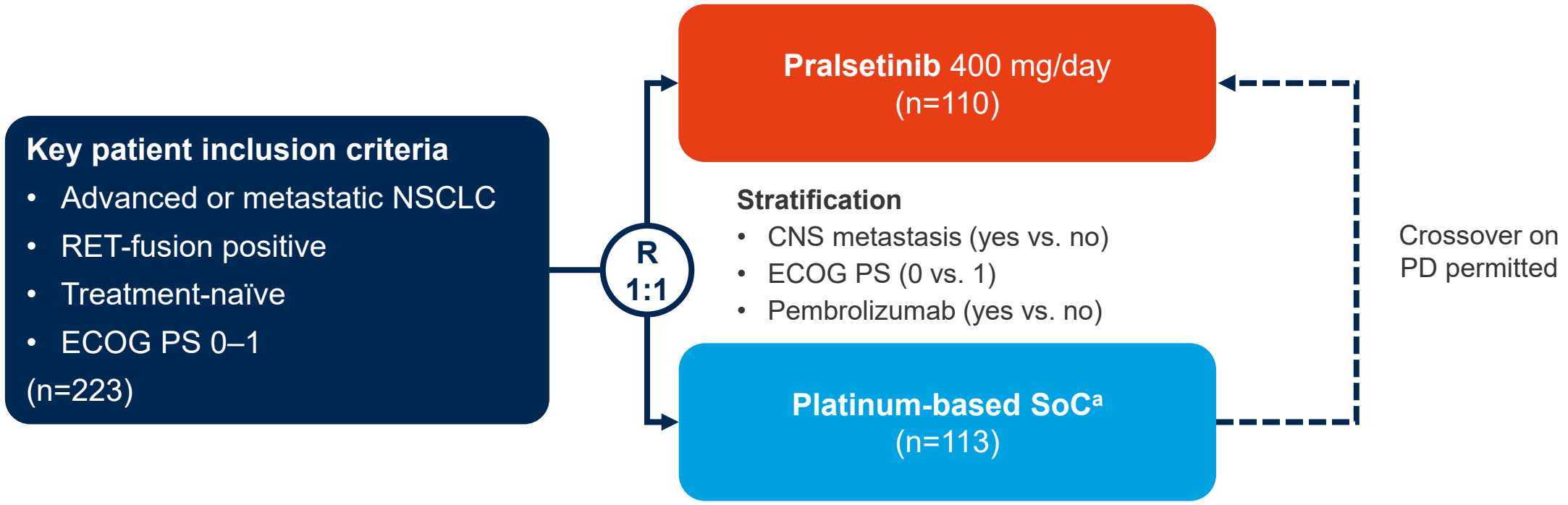
Intracranial activity	Any prior ALK TKI ± chemotherapy (n=92)	Lorlatinib-naive ± chemotherapy (n=24)	Lorlatinib-experienced ± chemotherapy (n=68)
ORR, n (%) [95%CI]	29 (32) [22, 42]	15 (63) [41, 81]	14 (21) [12, 32]
CR, n (%)	12 (13)	5 (21)	7 (10)
DoR ≥6 mo, % (95%CI)	81 (59, 91)	92 (57, 99)	71 (41, 88)
DoR ≥12 mo, % (95%CI)	71 (48, 85)	92 (57, 99)	55 (26, 77)
DoR ≥18 mo, % (95%CI)	71 (48, 85)	92 (57, 99)	55 (26, 77)

TEAEs occurring in ≥15% of TKI-naïve or -pretreated patients, n (%)	Neladalkib 150 mg (n=656)	
	Any grade	Grade ≥3
ALT increased	47	20
AST increased	44	16
Constipation	28	0.2
Dysgeusia	23	0
Peripheral edema	18	0.3
Cough	16	0.5
Nausea	16	0.8

- **Conclusions**
  - In pretreated patients with advanced ALK-positive NSCLC, neladalkib demonstrated encouraging antitumor and intracranial activity, including in heavily pretreated populations, and was generally well-tolerated

8504: Efficacy and safety of pralsetinib as first-line treatment of RET fusion–positive advanced or metastatic non–small cell lung cancer (NSCLC): The phase 3 AcceleRET-Lung study – Popat S, et al

- **Study objective**
  - To evaluate the efficacy and safety of 1L pralsetinib in patients with RET fusion-positive advanced or metastatic NSCLC



Primary endpoints

- PFS (investigator-assessed, RECIST v1.1)

Secondary endpoints

- ORR, DoR, OS, CBR, DCR, safety

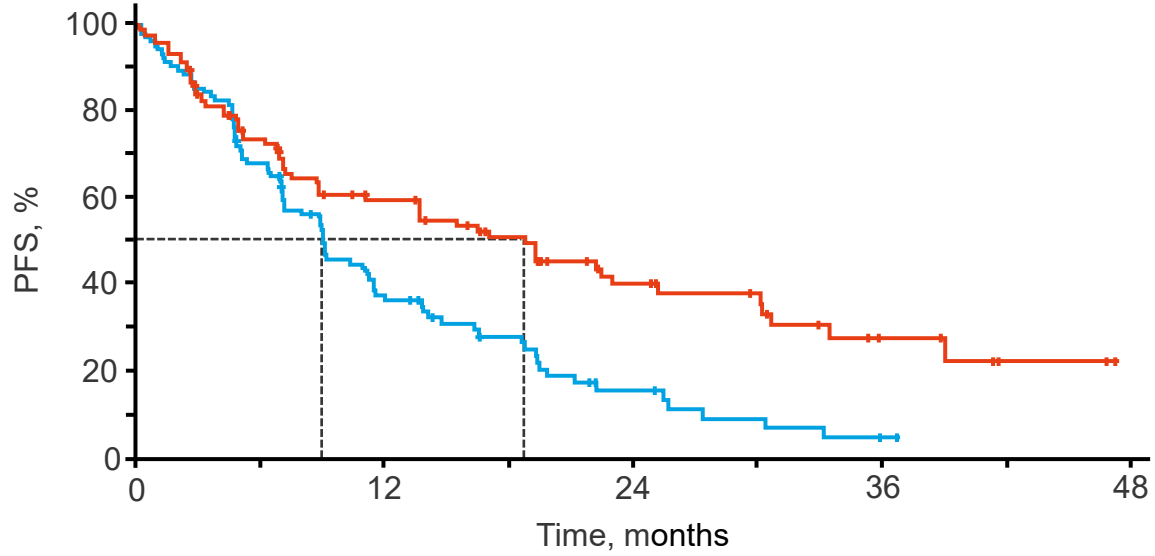
[a]Nonsquamous: carboplatin/cisplatin + pemetrexed ± pembrolizumab. Squamous: carboplatin/cisplatin + gemcitabine, or pembrolizumab + carboplatin + paclitaxel/nab-paclitaxel.

8504: Efficacy and safety of pralsetinib as first-line treatment of RET fusion–positive advanced or metastatic non–small cell lung cancer (NSCLC): The phase 3 AcceleRET-Lung study – Popat S, et al

- **Key results**

Progression-free survival

	Pralsetinib (n=110)	SoC (n=113)
mPFS, mo (95%CI)	18.7 (11.1, 25.2)	9.0 (7.1, 11.5)
HR (95%CI); p-value[a]	0.59 (0.42, 0.84); 0.0027	
Median duration of follow-up, mo (95%CI)	20.5 (17.5, 23.2)	16.0 (13.7, 20.9)



Outcomes	Pralsetinib	SoC
ORR, n	110	113
ORR, % (95%CI)	65.5 (55.79, 74.26)	41.6 (32.40, 51.24)
Difference in ORR (95%CI)	23.9 (10.3, 37.5)	
OR (95%CI)	2.81 (1.61, 4.93)	
p-value[b]	0.0002	
DoR, n	72	47
mDoR, mo (95%CI)	20.6 (17.2, 31.8)	9.7 (7.6, 15.9)
HR (95%CI); p-value[a]	0.48 (0.28, 0.80); 0.0043	

[a]Log-rank. [b]Cochran-Mantel-Haenszel.

8504: Efficacy and safety of pralsetinib as first-line treatment of RET fusion–positive advanced or metastatic non–small cell lung cancer (NSCLC): The phase 3 AcceleRET-Lung study – Popat S, et al

- **Key results (cont.)**

AEs, n (%)	Pralsetinib (n=108)	SoC (n=104)
Patients with ≥1	108 (100)	104 (100)
Treatment-related	101 (93.5)	96 (92.3)
Serious	67 (62.0)	38 (36.5)
Treatment-related	23 (21.3)	9 (8.7)
Grade 3–5	84 (77.8)	60 (57.7)
Led to deaths	16 (14.8)	5 (4.8)
Deaths due to infections	8 (7.4)	0
Grade ≥3 QT prolongation	3 (2.8)	0
Led to withdrawal	18 (16.7)	25 (24.0)
Led to dose modification/interruption	80 (74.1)	57 (54.8)

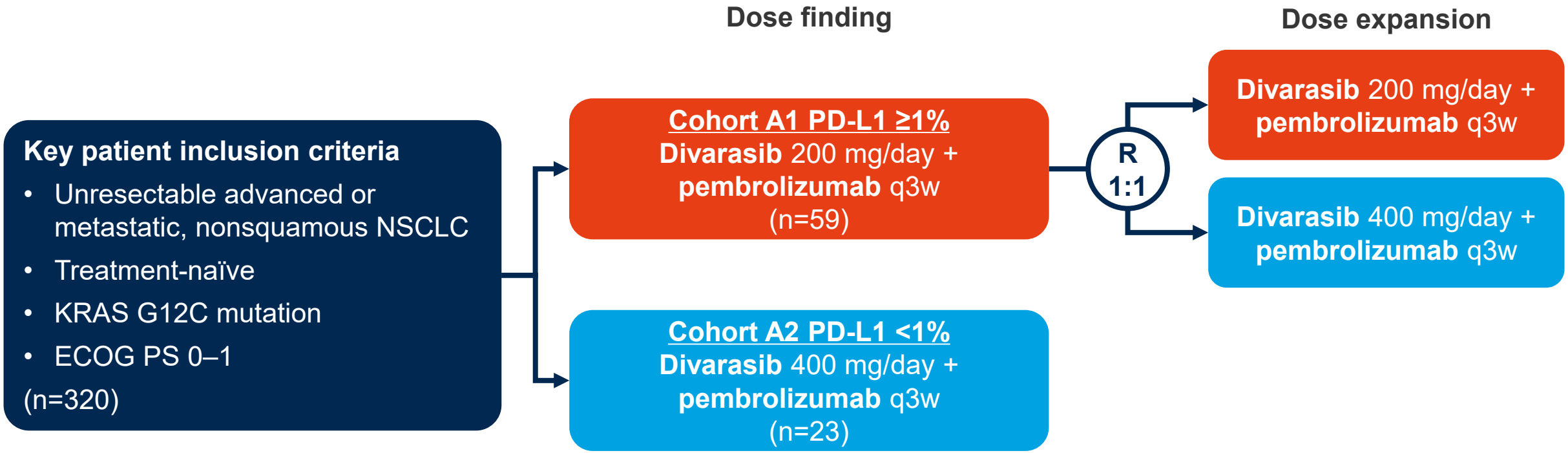
Infection-related AEs[a]	Pralsetinib (n=108)	SoC (n=104)
Any grade, n (%)	77 (71.3)	54 (51.9)
Grade ≥3, n (%)	31 (28.7)	10 (9.6)
Months to first severe infection, mean (SD)	6.2 (8.0)	5.1 (5.8)
Fatal infection events, n (%)	8 (7.4)	0
Any grade opportunistic infections, n (%)	10 (9.3)	1 (1.0)
Grade ≥3 opportunistic infections, n (%)	7 (6.5)	0

- **Conclusions**
  - In patients with advanced RET fusion-positive NSCLC, 1L pralsetinib significantly improved PFS along with higher response outcomes compared with SoC, and severe infections could be managed using increased monitoring

[a]Protocol amended (October 2024) updated guidance on infection monitoring and pralsetinib dose modification based on AE severity.

8510: First-line (1L) divarasib plus pembrolizumab (pembro) in advanced or metastatic KRAS G12C+ non–small cell lung cancer (NSCLC): Results from the Krascendo-170 study – Skoulidis F, et al

- **Study objective**
  - To evaluate efficacy and safety of 1L divarasib + pembrolizumab in patients with KRAS G12C-mutant advanced or metastatic NSCLC



Primary endpoint

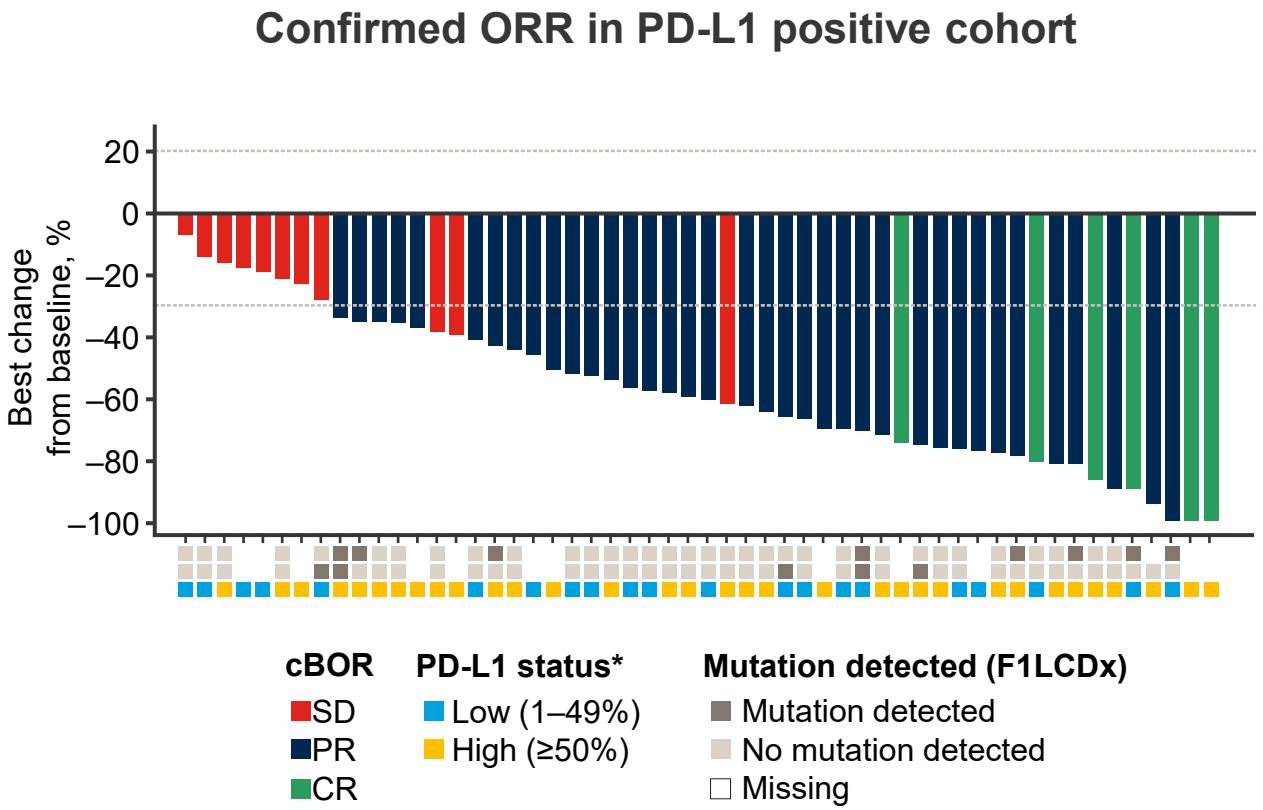
- Safety

Secondary endpoints

- ORR, PFS, DoR, PK, PRO

8510: First-line (1L) divarasib plus pembrolizumab (pembro) in advanced or metastatic KRAS G12C+ non–small cell lung cancer (NSCLC): Results from the Krascendo-170 study – Skoulidis F, et al

- **Key results**



PD-L1 positive cohort	Divarasib + pembrolizumab (n=59)
Confirmed ORR, n (%) [95%CI]	43 (72.9) [59.7, 83.6]
BOR, n (%)	
CR	6 (10.2)
PR	37 (62.7)
SD	11 (18.6)
NE	5 (8.5)
Median time to first response, days (range)	43 (36–164)
Median DoR, mo (95%CI)	NE (14.5, NE)
mPFS, mo (95%CI)	19.3 (12.4, NE)
6-mo PFS rate, % (95%CI)	83.5 (73.6, 93.3)

8510: First-line (1L) divarasib plus pembrolizumab (pembro) in advanced or metastatic KRAS G12C+ non–small cell lung cancer (NSCLC): Results from the Krascendo-170 study – Skoulidis F, et al

- **Key results (cont.)**

PD-L1 negative cohort	Divarasib + pembrolizumab (n=23)
Unconfirmed ORR, n (%) [95%CI]	16 (69.6) [47.1, 86.8]
BOR, n (%)	
PR	16 (69.6)
SD	4 817.4)
PD	1 (4.3)
NE	2 (8.7)
Median time to first response, days (range)	40.5 (36–120)

Safety in Cohorts A1 and A2, n (%)	Divarasib + pembrolizumab (n=78)[a]
Any grade AE	78 (100)
Grade ≥3	60 (76.9)[a]
Serious	39 (50.0)
Any grade TRAE	77 (98.7)
Grade 3–4	51 (65.4)
Serious	22 (28.2)
Led to divarasib dose reduction	41 (52.6)
Led to dose interruption	54 (69.2)
Led to study treatment discontinuation	10 (12.8)

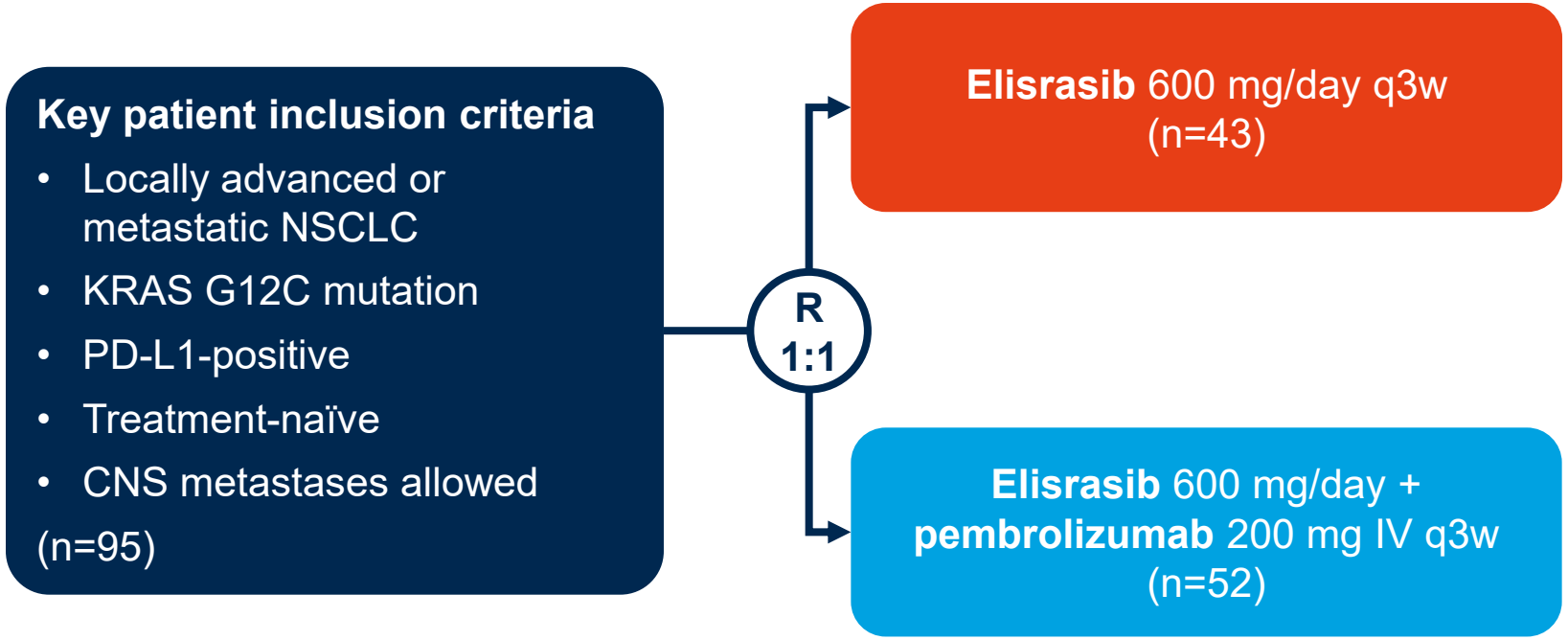
TRAEs occurring in ≥20% in Cohorts A1 and A2, n (%)	Divarasib + pembrolizumab (n=78)	
	Any grade	Grade 3–4
Diarrhea	58 (74.4)	14 (17.9)
Nausea	50 (64.1)	1 (1.3)
Vomiting	36 (46.2)	1 (1.3)
ALT increased	41 (52.6)	18 (23.1)
AST increased	38 (48.7)	14 (17.9)
Lipase increased	23 (29.5)	7 (9.0)
Appetite decreased	24 (30.8)	0
Amylase increased	16 (20.5)	3 (3.8)

- **Conclusions**
  - In patients with advanced KRAS G12C-mutant NSCLC, 1L divarasib + pembrolizumab demonstrated encouraging antitumor activity across PD-L1 subgroups with a manageable safety profile

[a]Four patients had grade 5 AEs.

8511: Elisrasib (D3S-001), a next-generation GDP-bound KRAS G12C inhibitor, as first-line therapy for KRAS G12C mutation–positive non–small cell lung cancer (NSCLC) – Lu S, et al

- **Study objective**
  - To evaluate the efficacy and safety of 1L elisrasib, a GDP-bound KRAS G12C inhibitor, in patients with KRAS G12C-mutant NSCLC



Endpoints

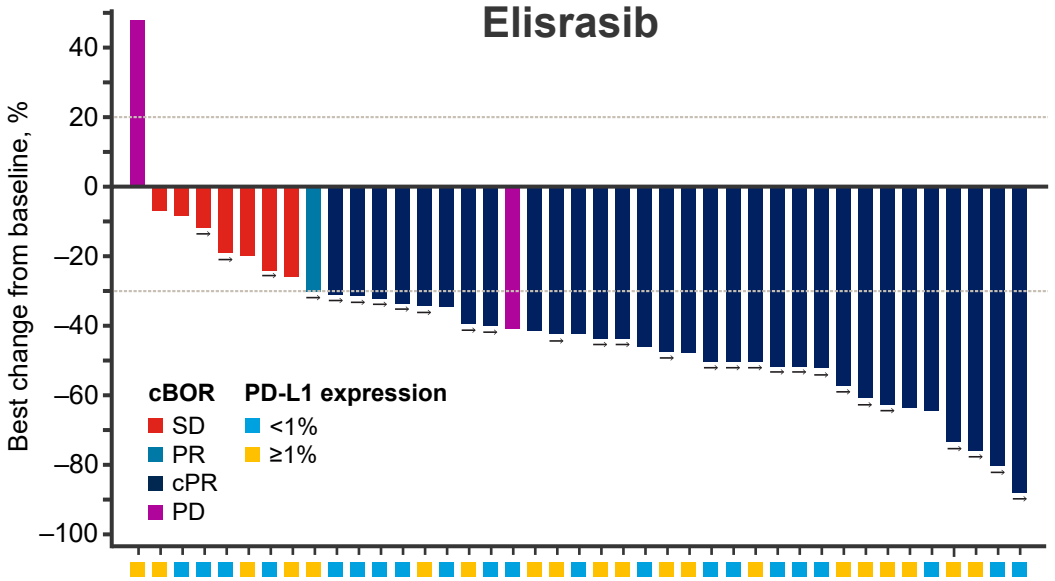
- Safety, efficacy, PK, biomarkers

8511: Elisrasib (D3S-001), a next-generation GDP-bound KRAS G12C inhibitor, as first-line therapy for KRAS G12C mutation–positive non–small cell lung cancer (NSCLC) – Lu S, et al

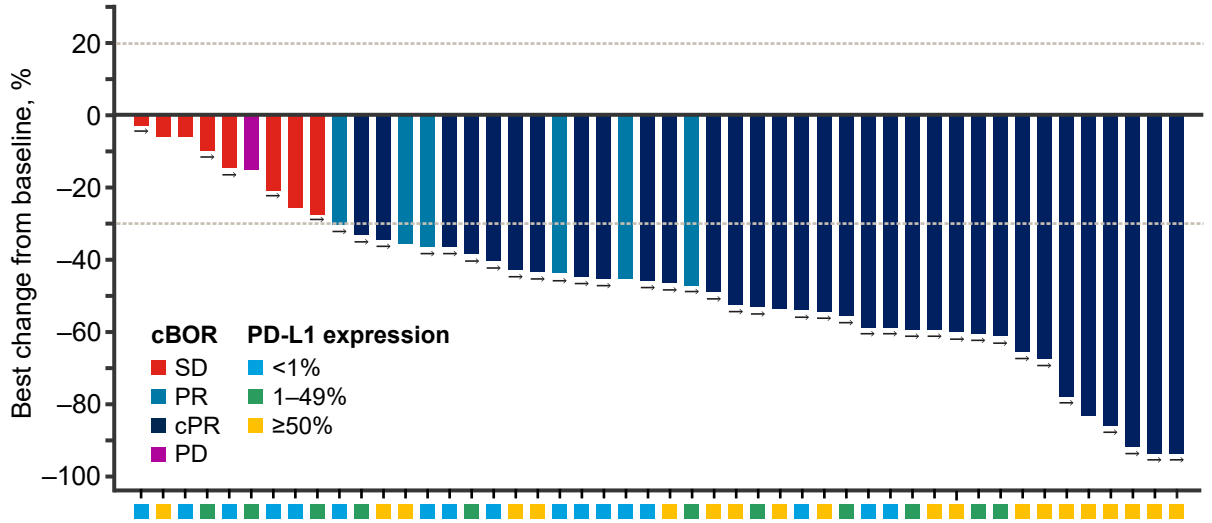
- **Key results**

Overall response rate

Elisrasib



Elisrasib + pembrolizumab



	PD-L1 <1% (n=21)	PD-L1 ≥1% (n=20)	Total (n=41)
ORR, n (%)	16 (76.2)	16 (80.0)	32 (78.0)
Confirmed ORR	13 (61.9)	15 (75.0)	28 (68.3)
DCR, n (%)	20 (95.2)	19 (95.0)	39 (95.1)

	PD-L1 <1% (n=17)	PD-L1 1–49% (n=11)	PD-L1 ≥50% (n=20)	Total (n=48)
ORR, n (%)	12 (70.6)	8 (72.7)	19 (95.0)	39 (81.3)
Confirmed ORR	8 (47.1)	7 (63.6)	17 (85.0)	32 (66.7)
DCR, n (%)	17 (100)	10 (90.9)	20 (100)	47 (97.9)

8511: Elisrasib (D3S-001), a next-generation GDP-bound KRAS G12C inhibitor, as first-line therapy for KRAS G12C mutation–positive non–small cell lung cancer (NSCLC) – Lu S, et al

- **Key results (cont.)**

Outcomes	Elisrasib	Elisrasib + pembrolizumab
mDoR, mo (95%CI)	NR (6.5, NR)	NR (7.0, NR)
mPFS, mo (95%CI)	12.4 (6.8, NR)	NR (8.4, NR)

TRAEs, n (%)	Elisrasib (n=43)	Elisrasib + pembrolizumab (n=52)
Any	41 (95.3)	48 (92.3)
Grade ≥3	3 (7.0)	17 (32.7)
Serious	1 (2.3)	9 (17.3)
Led to discontinuation of elisrasib	0	1 (1.9)
Led to discontinuation of pembrolizumab	-	5 (9.6)
Led to dose reduction of elisrasib	0	12 (23.1)
Led to dose interruption of elisrasib	4 (9.3)	26 (50.0)
Led to dose delay of pembrolizumab	-	22 (42.3)

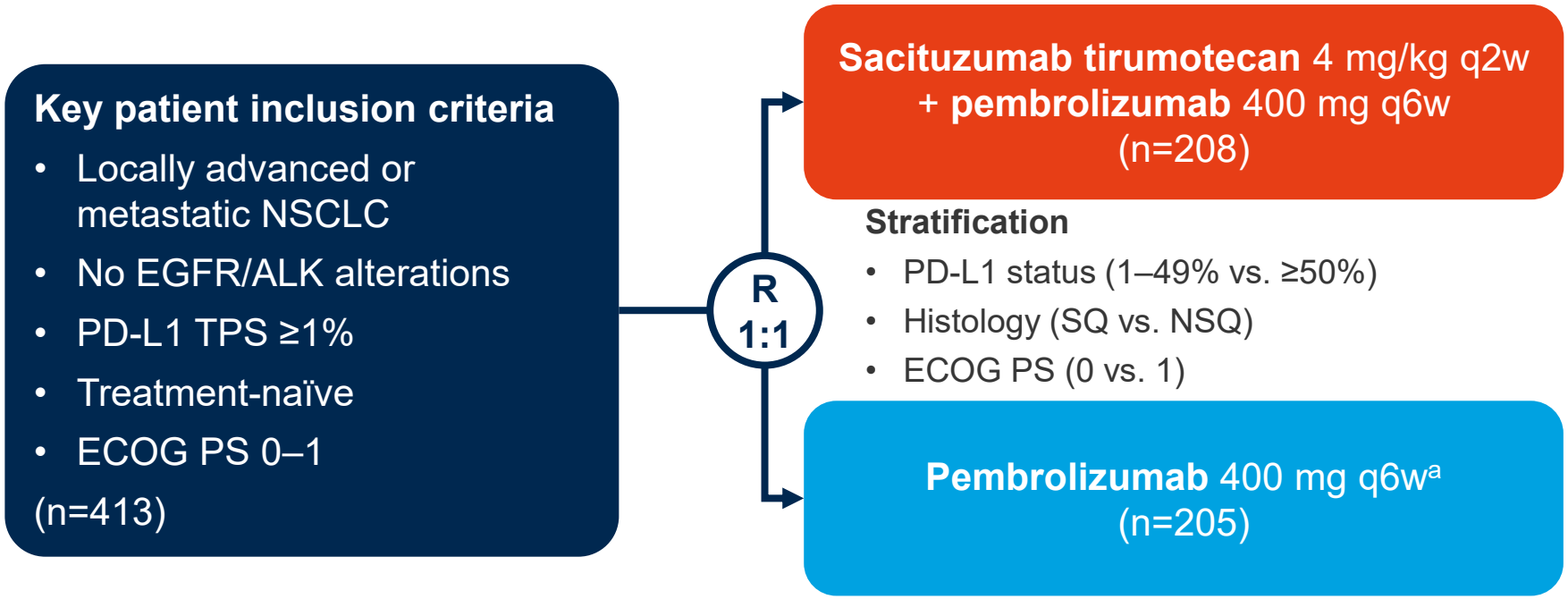
- **Conclusions**
  - In patients with KRAS G12C-mutant advanced NSCLC, elisrasib alone or combined with pembrolizumab demonstrated encouraging antitumor activity across PD-L1 subgroups with a manageable safety profile

Advanced NSCLC – Not radically treatable stage III and stage IV

ADCs and other therapies

8506: Sacituzumab tirumotecan (sac-TMT) plus pembrolizumab (P) versus pembrolizumab (P) as first-line treatment for PD-L1–positive advanced non-small cell lung cancer (NSCLC): Results from the randomized phase 3 OptiTROP-Lung05 study – Zhou C, et al

- **Study objective**
  - To evaluate the efficacy and safety of 1L sacituzumab tirumotecan + pembrolizumab compared with pembrolizumab in patients with PD-L1-positive advanced NSCLC



Primary endpoints

- PFS (BICR)

Secondary endpoints

- OS, PFS (investigator-assessed), ORR, DCR, DoR, safety

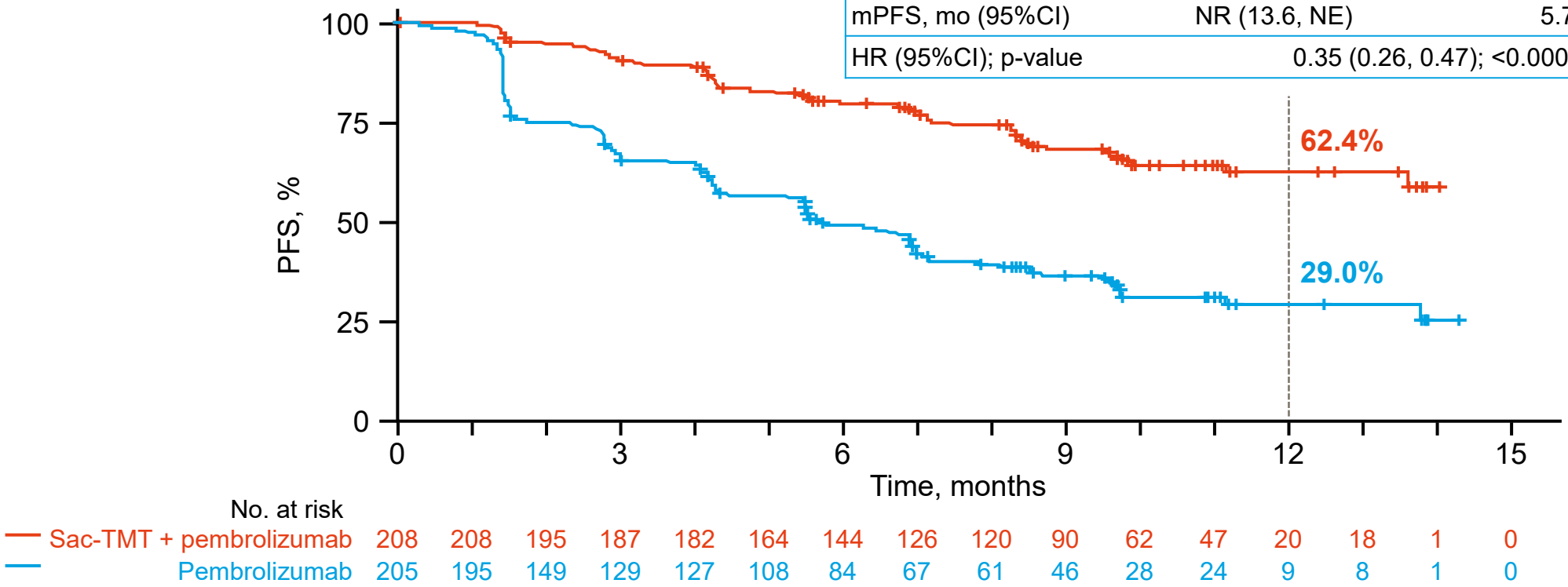
[a]Maximum 18 cycles.

8506: Sacituzumab tirumotecan (sac-TMT) plus pembrolizumab (P) versus pembrolizumab (P) as first-line treatment for PD-L1–positive advanced non-small cell lung cancer (NSCLC): Results from the randomized phase 3 OptiTROP-Lung05 study – Zhou C, et al

- **Key results**

Progression-free survival (BICR)

	Sac-TMT + pembrolizumab (n=208)	Pembrolizumab (n=205)
Events, n (%)	66 (31.7)	128 (62.4)
mPFS, mo (95%CI)	NR (13.6, NE)	5.7 (4.3, 7.0)
HR (95%CI); p-value	0.35 (0.26, 0.47); <0.0001[a]	



[a]Updated efficacy boundary corresponding to actual PFS events of 194: 0.0174 (2-sided).

Zhou C, et al. J Clin Oncol 2026;44(suppl):Abstr 8506

8506: Sacituzumab tirumotecan (sac-TMT) plus pembrolizumab (P) versus pembrolizumab (P) as first-line treatment for PD-L1–positive advanced non-small cell lung cancer (NSCLC): Results from the randomized phase 3 OptiTROP-Lung05 study – Zhou C, et al

- **Key results**

PFS by PD-L1 expression and histology	Sac-TMT + pembrolizumab (n=208)	Pembrolizumab (n=205)
TPS ≥50%, n	83	82
Events, n (%)	26 (31.3)	44 (53.7)
mPFS, mo (95%CI)	NR (NE, NE)	9.5 (6.9, 13.8)
HR (95%CI)	0.47 (0.29, 0.77)	
TPS 1–49%, n	125	123
Events, n (%)	40 (32.0)	84 (68.3)
mPFS, mo (95%CI)	NR (11.1, NE)	4.3 (2.9, 5.5)
HR (95%CI)	0.28 (0.19, 0.41)	
Nonsquamous, n	123	124
Events, n (%)	29 (23.6)	70 (56.5)
mPFS, mo (95%CI)	NR (13.6, NE)	6.6 (4.3, 8.7)
HR (95%CI)	0.28 (0.18, 0.43)	
Squamous, n	85	80
Events, n (%)	37 (43.5)	58 (72.5)
mPFS, mo (95%CI)	NR (8.3, NE)	5.5 (4.1, 7.0)
HR (95%CI)	0.44 (0.29, 0.66)	

OS	Sac-TMT + pembrolizumab (n=208)	Pembrolizumab (n=205)
OS events, n (%)	33 (15.9)	54 (26.3)
mOS, mo (95%CI)	NR (NE, NE)	14.5 (14.5, NE)
HR (95%CI)	0.55 (0.36, 0.85)	

Outcomes, %	Sac-TMT + pembrolizumab	Pembrolizumab
ORR		
ITT	70.2	42.0
Difference in ORR	28.3	
TPS ≥50%	80.7	60.5
TPS 1–49%	63.2	30.1
Deep response rate (≥50% SLD reduction)		
ITT	49.0	25.9
Difference in ORR	23.2	
TPS ≥50%	62.7	40.7
TPS 1–49%	40.0	16.3
DoR	77.7	59.4
HR (95%CI)	0.47 (0.27, 0.82)	

8506: Sacituzumab tirumotecan (sac-TMT) plus pembrolizumab (P) versus pembrolizumab (P) as first-line treatment for PD-L1–positive advanced non-small cell lung cancer (NSCLC): Results from the randomized phase 3 OptiTROP-Lung05 study – Zhou C, et al

- **Key results (cont.)**

	Sac-TMT + pembro (n=208)		Pembrolizumab (n=204)	
TEAEs, n (%)	Any grade	Grade ≥3	Any grade	Grade ≥3
Any	207 (99.5)	115 (55.3)	178 (87.3)	64 (31.4)
Serious	81 (38.9)	—	59 (28.9)	—
Led to discontinuation of sac-TMT/pembrolizumab	8 (3.8)/ 11 (5.3)	—	10 (4.9)	—
Led to death	5 (2.4)	—	13 (6.4)	—

	Sac-TMT + pembro (n=208)		Pembrolizumab (n=204)	
TEAEs in ≥20% of patients, n (%)	Any grade	Grade ≥3	Any grade	Grade ≥3
Anemia	182 (87.5)	19 (9.1)	55 (27.0)	2 (1.0)
Alopecia	137 (65.9)	0	6 (2.9)	0
WBC count decreased	96 (46.2)	18 (8.7)	5 (2.5)	1 (0.5)
Neutrophil count decreased	93 (44.7)	36 (17.3)	3 (1.5)	1 (0.5)
Stomatitis	84 (40.4)	11 (5.3)	3 (1.5)	0
Appetite decreased	73 (35.1)	2 (1.0)	27 (13.2)	0
Weakness	71 (34.1)	8 (3.8)	23 (11.3)	2 (1.0)
Nausea	70 (33.7)	0	11 (5.4)	0
Hypoalbuminemia	61 (29.3)	0	35 (17.2)	0
Weight decreased	56 (26.9)	1 (0.5)	19 (9.3)	1 (0.5)
ALT increased	55 (26.4)	1 (0.5)	33 (16.2)	0
Rash	50 (24.0)	6 (2.9)	33 (16.2)	1 (0.5)

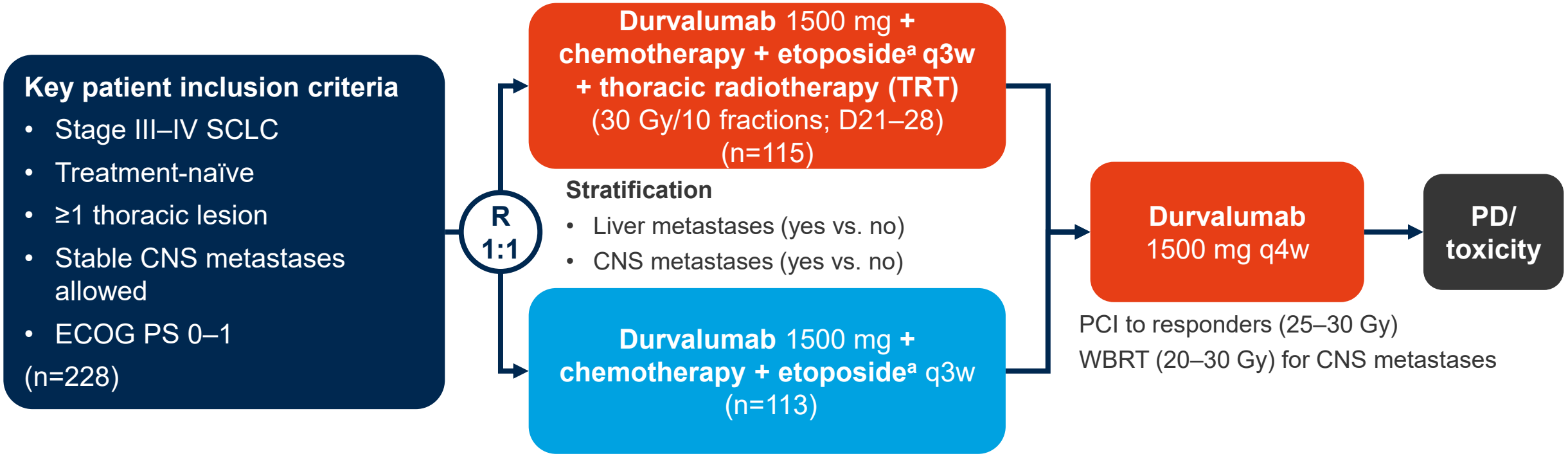
- **Conclusions**
  - In Chinese patients with PD-L1-positive advanced NSCLC, sacituzumab tirumotecan + pembrolizumab demonstrated a significant improvement in PFS with benefit across subgroups compared with pembrolizumab alone, and no new safety signals were observed

Other malignancies

SCLC, mesothelioma and thymic epithelial tumors

LBA8005: Concurrent thoracic radiotherapy (TRT), platinum/etoposide chemotherapy, and durvalumab immunotherapy in extensive-stage (ES) small cell lung cancer (SCLC): A phase III trial – Gronberg BH, et al

- **Study objective**
  - To evaluate the efficacy and safety of concurrent thoracic radiotherapy, platinum/etoposide chemotherapy + durvalumab in patients with extensive-stage SCLC



Primary endpoint

- OS

Secondary endpoints

- ORR, PFS, safety

[a]Carboplatin AUC5 + etoposide 100 mg/m² BSA IV (D1), followed by etoposide 100 mg/m² BSA IV (D2–3) or etoposide 200 mg/m² BSA PO (D2–4) for 4 cycles.

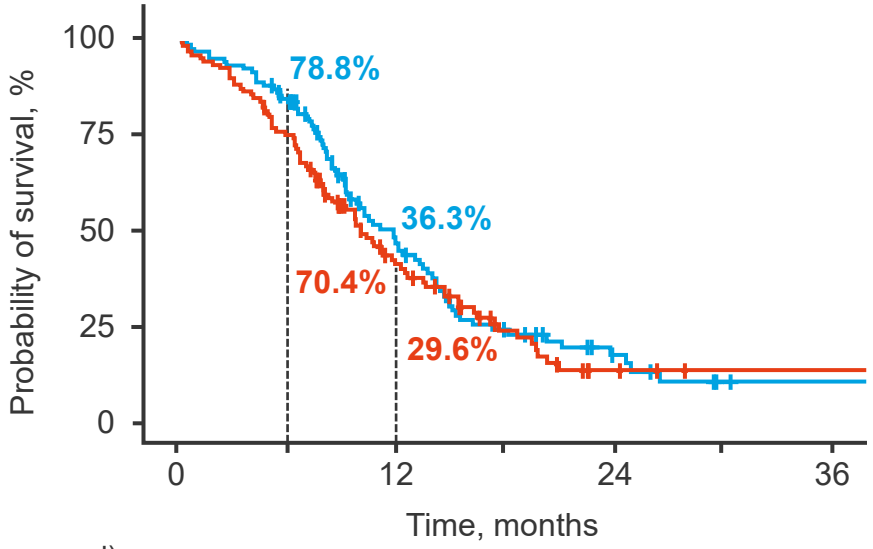
Gronberg BH, et al. J Clin Oncol 2026;44(suppl):Abstr LBA8005

LBA8005: Concurrent thoracic radiotherapy (TRT), platinum/etoposide chemotherapy, and durvalumab immunotherapy in extensive-stage (ES) small cell lung cancer (SCLC): A phase III trial – Gronberg BH, et al

- **Key results**

Overall survival

	Chemo-IO + TRT (n=115)	Chemo-IO (n=113)
mOS, mo (95%CI)	10.0 (8.3, 11.7)	11.8 (10.0, 13.6)
HR (95%CI); p-value	1.14 (0.84, 1.56); 0.40	



No. at risk (censored)							
Chemoimmunotherapy + TRT	115	83 (4)	35 (18)	14 (26)	4 (30)	1 (33)	1 (34)
Chemoimmunotherapy	113	92 (3)	41 (19)	18 (23)	8 (29)	2 (32)	1 (34)

	Chemo-IO + TRT	Chemo-IO
All, n	115	113
mPFS, mo (95%CI)	5.1 (4.7, 5.4)	5.0 (4.6, 5.4)
HR (95%CI); p-value	1.10 (0.84, 1.45); 0.49	
Patients who completed 4 chemo-IO cycles, n	89	100
mPFS, mo (95%CI)	11.9 (9.7, 14.1)	12.1 (9.4, 14.8)
HR (95%CI); p-value	1.02 (0.72, 1.44); 0.92	
Patients without brain/liver metastases, n	46	45
mPFS, mo (95%CI)	11.9 (6.2, 17.7)	13.2 (10.4, 16.1)
HR (95%CI); p-value	1.10 (0.65, 1.87); 0.72	

Response, n (%)	Chemo-IO + TRT (n=115)	Chemo-IO (n=113)
ORR	91 (79.1)	95 (84.1)
p-value	0.34	
BOR		
CR	5 (4.3)	3 (2.7)
PR	86 (74.8)	92 (81.4)
SD	8 (7.0)	9 (8.0)
PD	5 (4.3)	2 (1.8)
NE	11 (9.6)	7 (6.2)

LBA8005: Concurrent thoracic radiotherapy (TRT), platinum/etoposide chemotherapy, and durvalumab immunotherapy in extensive-stage (ES) small cell lung cancer (SCLC): A phase III trial – Gronberg BH, et al

- **Key results (cont.)**

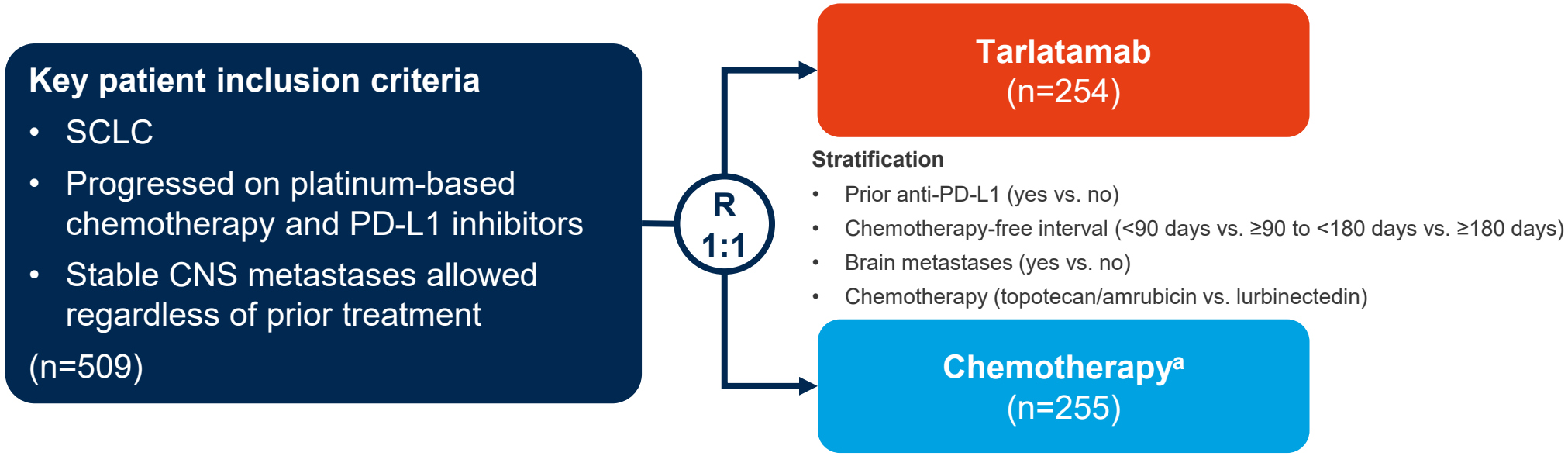
n, %	Chemo-IO + TRT (n=115)	Chemo-IO (n=113)
Disease progression	94 (81.7)	95 (84.1)
Cause of death	80 (69.6)	79 (69.9)
PD	63 (54.8)	75 (66.4)
AE during study period	15 (13.0)	2 (1.8)
AE during 2L	1 (0.9)	1 (0.9)
Euthanasia	1 (0.9)	1 (0.9)

AEs, %	Chemo-IO + TRT (n=115)	Chemo-IO (n=113)
Any	87.8	69.9
Esophagitis	47.8	0.9
Febrile neutropenia	37.4	27.4
Nausea	21.7	28.3
Diarrhea	17.4	15.0
Pneumonitis	11.3	0.9
Infection	10.4	13.3
Peripheral neuropathy	6.1	3.5
Hypothyroidism	6.1	3.5
Pulmonary embolism	4.3	5.3
Muscle weakness	4.3	3.5
Colitis	3.5	2.7
Rash	3.5	4.4
Hyperthyroidism	2.6	4.4
Encephalitis	2.6	0

- **Conclusions**
  - In patients with extensive-stage SCLC receiving 1L chemoimmunotherapy, the addition of concurrent thoracic radiotherapy did not improve OS or PFS compared with systemic therapy alone and was associated with a higher rate of AEs

8006: Intracranial efficacy of tarlatamab versus chemotherapy (CTx) as second-line (2L) treatment for small cell lung cancer (SCLC): DeLLphi-304 phase 3 post hoc analysis – Mountzios GS, et al

- **Study objective**
  - To evaluate the intracranial efficacy of 2L tarlatamab compared with chemotherapy in patients with SCLC



Primary endpoint

- OS

Secondary endpoints

- PFS, ORR, DCR, DoR, PRO, safety

Exploratory analysis

- CNS PFS (investigator-assessed), CNS ORR, CNS DoDC

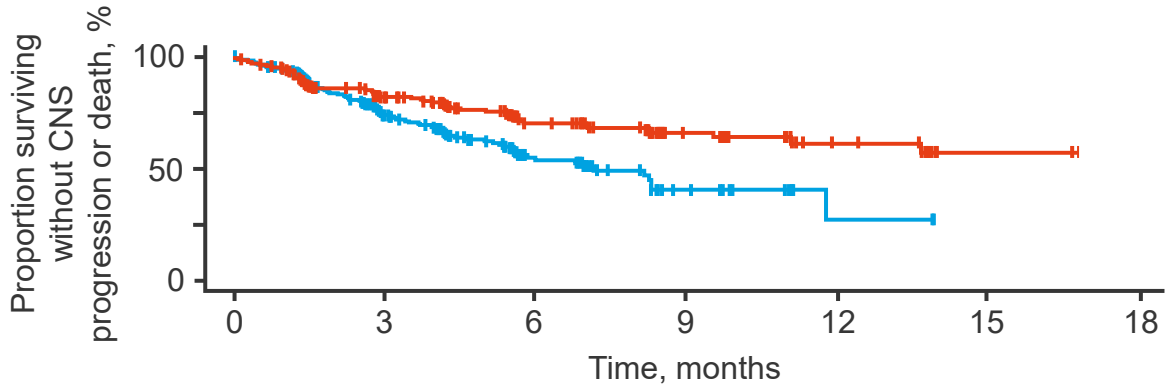
[a]Topotecan was used in all countries excluding Japan; lurbinectedin in Australia, Canada, Republic of Korea, Singapore and the United States; amrubicin in Japan.

8006: Intracranial efficacy of tarlatamab versus chemotherapy (CTx) as second-line (2L) treatment for small cell lung cancer (SCLC): DeLLphi-304 phase 3 post hoc analysis – Mountzios GS, et al

- **Key results**

CNS PFS in all patients

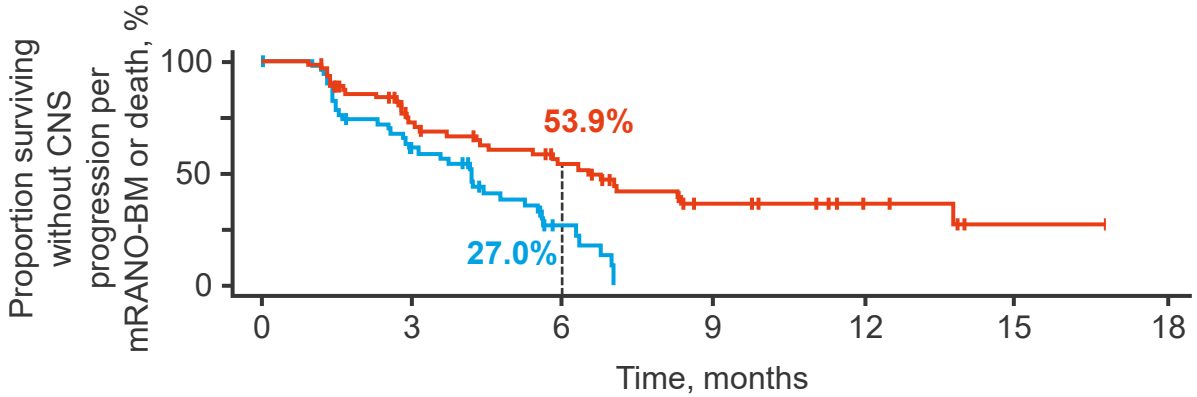
	Tarlatamab (n=254)	Chemotherapy (n=255)
Median CNS PFS, mo (95%CI)	NE (13.7, NE)	7.2 (5.6, NE)
HR (95%CI)	0.54 (0.39, 0.75)	



No. at risk							
Tarlatamab	254	142	74	36	17	2	0
Chemotherapy	255	119	47	13	2	0	

CNS PFS in patients with ≥1 brain metastasis at baseline (mRANO-BM by BICR)[a]

	Tarlatamab (n=67)	Chemotherapy (n=56)
Median CNS PFS, mo (95%CI)	6.5 (4.3, 13.7)	4.2 (2.9, 5.5)
HR (95%CI)	0.40 (0.24, 0.66)	



No. at risk							
Tarlatamab	67	37	24	11	5	1	0
Chemotherapy	56	26	6	0			

[a]CNS lesion(s) ≥10 mm in diameter.

8006: Intracranial efficacy of tarlatamab versus chemotherapy (CTx) as second-line (2L) treatment for small cell lung cancer (SCLC): DeLLphi-304 phase 3 post hoc analysis – Mountzios GS, et al

- **Key results (cont.)**

Intracranial outcomes	Tarlatamab (n=67)	Chemo (n=56)
BOR, n (%)		
CR, n (%) [95%CI]	10 (14.9) [7.4, 25.7]	3 (5.4) [1.1, 14.9]
Non-CR/non-PD	42 (62.7)	37 (66.1)
PD	13 (19.4)	16 (28.6)
NE	2 (3.0)	0
DCR, n (%) [95% CI]	52 (77.6) [65.8, 86.9]	40 (71.4) [57.8, 82.7]
Tumor shrinkage ≥30%, n/N (%)	9/16 (56.3)	5/13 (38.5)

TEAEs, n (%)	Tarlatamab (n=98)	Chemo (n=93)
Grade ≥3	53 (54.1)	81 (87.1)
TEAEs of interest, any grade		
Neurological events (excluding dysgeusia)	45 (45.9)	41 (44.1)
Dysgeusia	23 (23.5)	3 (3.2)
Neutropenia	7 (7.1)	30 (32.3)

TRAEs, n (%)	Tarlatamab (n=98)	Chemo (n=93)
Grade ≥3	25 (25.5)	61 (65.6)
Serious	28 (28.6)	33 (35.5)
Led to dose interruption and/or reduction[a]	18 (18.4)	51 (54.8)
Led to discontinuation	2 (2.0)	6 (6.5)
Led to death	0	2 (2.2)

- **Conclusions**
  - In patients with SCLC, tarlatamab reduced the risk of CNS progression and prolonged OS compared with chemotherapy, with a manageable safety profile

8008: ABBV-706 as monotherapy and in combination with budigalimab in patients with relapsed/refractory (R/R) small cell lung cancer (SCLC) – Byers LA, et al

- **Study objective**
  - To evaluate the efficacy and safety of ABBV-706 alone or combined with budigalimab in patients with relapsed or refractory SCLC

Key patient inclusion criteria

- R/R SCLC
- Stable CNS metastasis allowed
- ≥ 1 prior platinum-based chemotherapy
- Tumor tissue available
- ECOG PS 0–1

Part 2: Monotherapy dose optimization
ABBV-706 1.3–3.0 mg/kg q3w
(n=124)

Part 3A:
ABBV-706 1.8 mg/kg q3w +
budigalimab 375 mg IV q3w
(n=11)

Primary endpoints

- Safety, tolerability, PK, RP2D

Secondary endpoints

- ORR, DoR, PFS, OS, clinical benefit

Exploratory analysis

- SEZ6 by IHC, predictive biomarkers

Byers LA, et al. J Clin Oncol 2026;44(suppl):Abstr 8008

8008: ABBV-706 as monotherapy and in combination with budigalimab in patients with relapsed/refractory (R/R) small cell lung cancer (SCLC) – Byers LA, et al

- **Key results**

Safety	Total (n=124)	1.8 mg/kg as 2L+ (n=41)	1.8 mg/kg as 2L (n=17)	1.8 mg/kg + Budi (n=11)
Median duration of treatment, mo (range)	4.8 (0.4–25.3)	6.2 (0.7–18.1)	7.6 (1.4–18.1)	8.3 (0.7–9.9)
Median relative dose intensity, %	96.1	98.9	98.8	85.1
Median follow-up time, mo	16.2	16.4	16.1	9.1
TRAEs, n (%)				
Any grade	115 (92.7)	36 (87.8)	16 (94.1)	10 (90.9)
Grade ≥3	75 (60.5)	22 (53.7)	9 (52.9)	5 (45.5)
Serious	18 (14.5)	7 (17.1)	4 (23.5)	1 (9.1)
Led to dose interruption	55 (44.4)	13 (31.7)	5 (29.4)	7 (63.6)
Led to dose reduction	34 (27.4)	8 (19.5)	6 (35.3)	4 (36.4)
Led to discontinuation	10 (8.1)	5 (12.2)	2 (11.8)	0
Led to death	3 (2.4)	3 (7.3)	1 (5.9)	0

8008: ABBV-706 as monotherapy and in combination with budigalimab in patients with relapsed/refractory (R/R) small cell lung cancer (SCLC) – Byers LA, et al

- **Key results (cont.)**

Efficacy outcomes	ABBV-706 monotherapy		
	Total (n=124)	1.8 mg/kg as 2L+ (n=41)	1.8 mg/kg as 2L (n=17)
Confirmed ORR, n (%)	65 (52)	23 (56)	14 (82)
ORR by CTFI, n/N (%)			
CTFI ≥90 days	22/44 (50)	7/12 (58)	4/4 (100)
CTFI <90 days	35/64 (55)	14/25 (56)	10/13 (77)
CTFI <30 days	14/27 (52)	5/11 (46)	2/4 (50)
Confirmed CBR, n (%)	111 (90)	39 (95)	16 (94)
mDoR, mo (95%CI)	5.3 (4.1, 6.7)	5.9 (3.6, 11.1)	6.6 (3.1, 12.5)
mPFS, mo (95%CI)	5.4 (4.4, 5.7)	6.4 (4.0, 8.1)	6.8 (4.0, 12.5)
mOS, mo (95%CI)	11.3 (9.1, 14.8)	12.4 (8.2, 17.3)	14.3 (7.8, NE)

Efficacy outcomes	ABBV-706 1.8 mg/kg + Budi (n=11)
Confirmed ORR, n (%) [95%CI]	6 (54.5) [23.4, 83.3]
Confirmed BOR, n (%)	
PR	6 (54.5)
SD	3 (27.3)
PD	1 (9.1)
NE	1 (9.1)
Confirmed CBR, n (%)	9 (81.8)
mDoR, mo (95%CI)	6.7 (5.5, NE)
mPFS, mo (95%CI)	8.1 (1.4, NE)
mOS, mo (95%CI)	NR (2.5, NE)

- **Conclusions**
  - In patients with relapsed or refractory SCLC, ABBV-706 alone or combined with budigalimab demonstrated encouraging antitumor activity and survival outcomes with a manageable safety profile

3010: Phase Ib results from the phase Ib/II study of [177Lu]Lu-DOTA-TATE in combination with standard of care as a first-line treatment for pts with extensive-stage small cell lung cancer – Liu S, et al

- **Study objective**
  - To evaluate the efficacy and safety of 1L ^{177}Lu-DOTATATE + SoC in patients with extensive-stage SCLC

Key patient inclusion criteria
- Extensive-stage SCLC
- SSTR-positive lesions
- Treatment-naïve
- ECOG PS 0–1

(n=29)

Dose escalation

^{177}Lu-DOTATATE 3.70–7.40 GBq + carboplatin + etoposide + anti-PD-(L)1[a]

Primary endpoints
- DLTs, safety

Secondary endpoints
- ORR, DoR, PFS

[a]Induction phase: ^{177}Lu-DOTATATE (Cycles 2 and 4) + tislelizumab 200 mg or atezolizumab 1200 mg q3w + carboplatin AUC5 (D1 q3w) + etoposide 100 mg/m² (D1–3 q3w). Maintenance phase: ^{177}Lu-DOTATATE + tislelizumab 200 mg or atezolizumab 1200 mg q3w.

Liu S, et al. J Clin Oncol 2026;44(suppl):Abstr 3010

3010: Phase Ib results from the phase Ib/II study of [177Lu]Lu-DOTA-TATE in combination with standard of care as a first-line treatment for pts with extensive-stage small cell lung cancer – Liu S, et al

- **Key results**

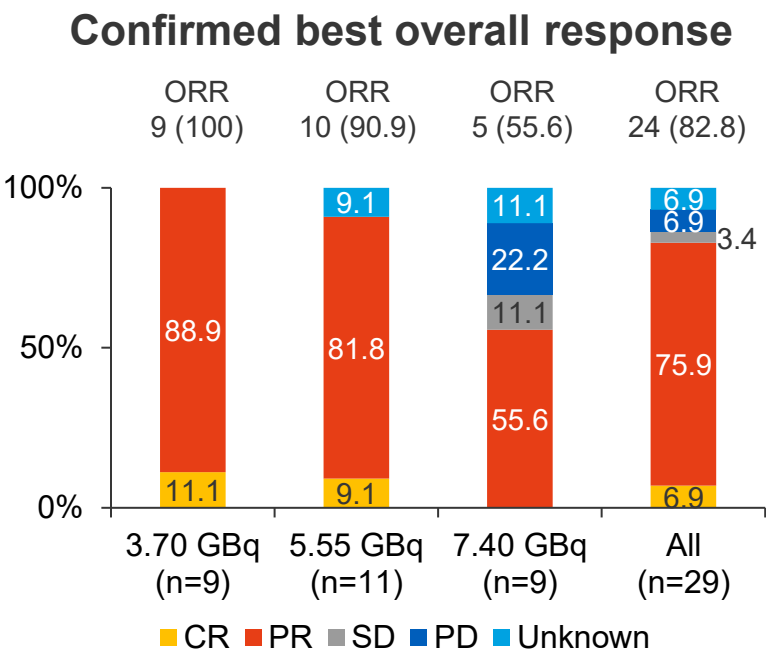
	3.70 GBq (n=9)	5.55 GBq (n=11)	7.40 GBq (n=9)	All (n=29)
Median ^{177}Lu-DOTATATE duration of exposure, months (range)	4.1 (3–6)	4.6 (2–5)	3.4 (1–6)	4.1 (1–6)
Any AE, n (%)	9 (100)	11 (100)	9 (100)	29 (100)
Grade ≥3	9 (100)	11 (100)	9 (100)	29 (100)
TRAEs (any treatment), n (%)	9 (100)	11 (100)	9 (100)	29 (100)
Grade ≥3	8 (88.9)	8 (72.7)	9 (100)	25 (86.2)
TRAEs (related to ^{177}Lu-DOTATATE), n (%)	8 (88.9)	9 (81.8)	8 (88.9)	25 (86.2)
Grade ≥3	5 (55.6)	4 (36.4)	8 (88.9)	17 (58.6)
SAE, n (%)	6 (66.7)	7 (63.6)	8 (88.9)	21 (72.4)
Patients with ≥1 AE led to discontinuation of any treatment, n (%)	3 (33.3)	3 (27.3)	1 (11.1)	7 (24.1)
Patients with ≥1 DLT event, n (%)	0	0	0	0
Death due to an AE[a], n (%)	2 (22.2)	0	0	2 (6.9)
Cardiac failure	1 (11.1)	0	0	1 (3.4)
Large intestinal hemorrhage	1 (11.1)	0	0	1 (3.4)

[a]There were two deaths due to AEs, which were not considered to be treatment-related.

3010: Phase Ib results from the phase Ib/II study of [177Lu]Lu-DOTA-TATE in combination with standard of care as a first-line treatment for pts with extensive-stage small cell lung cancer – Liu S, et al

- **Key results (cont.)**

AEs occurring in ≥30% of patients, n (%)	3.70 GBq (n=9)		5.55 GBq (n=11)		7.40 GBq (n=9)		All (n=29)	
	All grade	Grade ≥3	All grade	Grade ≥3	All grade	Grade ≥3	All grade	Grade ≥3
≥1 AE, regardless of causality	9 (100)	9 (100)	11 (100)	11 (100)	9 (100)	9 (100)	29 (100)	29 (100)
Anemia	8 (88.9)	3 (33.3)	6 (54.5)	2 (18.2)	6 (66.7)	5 (55.6)	20 (69.0)	10 (34.5)
Thrombocytopenia	6 (66.7)	6 (66.7)	7 (63.6)	5 (45.5)	7 (77.8)	7 (77.8)	20 (69.0)	18 (62.1)
Nausea	6 (66.7)	0	7 (63.6)	0	2 (22.2)	0	15 (51.7)	0
Neutropenia	2 (22.2)	0	6 (54.5)	5 (45.5)	6 (66.7)	4 (44.4)	14 (48.3)	9 (31.0)
Lymphopenia	2 (22.2)	1 (11.1)	3 (27.3)	3 (27.3)	6 (66.7)	5 (55.6)	11 (37.9)	9 (31.0)
Asthenia	2 (22.2)	0	4 (36.4)	0	4 (44.4)	1 (11.1)	10 (34.5)	1 (3.4)
Alopecia	3 (33.3)	0	4 (36.4)	0	1 (11.1)	0	8 (27.6)	0
Fatigue	3 (33.3)	0	2 (18.2)	0	3 (33.3)	0	8 (27.6)	0
Hypomagnesemia	3 (33.3)	0	4 (36.4)	0	0	0	7 (24.1)	0
Diarrhea	3 (33.3)	0	1 (9.1)	0	2 (22.2)	0	6 (20.7)	0
Hyponatremia	1 (11.1)	0	1 (9.1)	1 (9.1)	4 (44.4)	4 (44.4)	6 (20.7)	5 (17.2)
Lymphocyte count decreased	5 (55.6)	5 (55.6)	1 (9.1)	1 (9.1)	0	0	6 (20.7)	6 (20.7)
WBC count decreased	4 (44.4)	3 (33.3)	1 (9.1)	0	1 (11.1)	1 (11.1)	6 (20.7)	4 (13.8)



- **Conclusions**
  - In treatment-naïve patients with extensive-stage SCLC, 1L ^{177}Lu-DOTATATE + chemoimmunotherapy showed a consistent safety profile across all doses and the efficacy outcomes appear to comparable to previous findings for SoC alone with no additional benefit of ^{177}Lu-DOTATATE

Liu S, et al. J Clin Oncol 2026;44(suppl):Abstr 3010