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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 **2025 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 2025

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

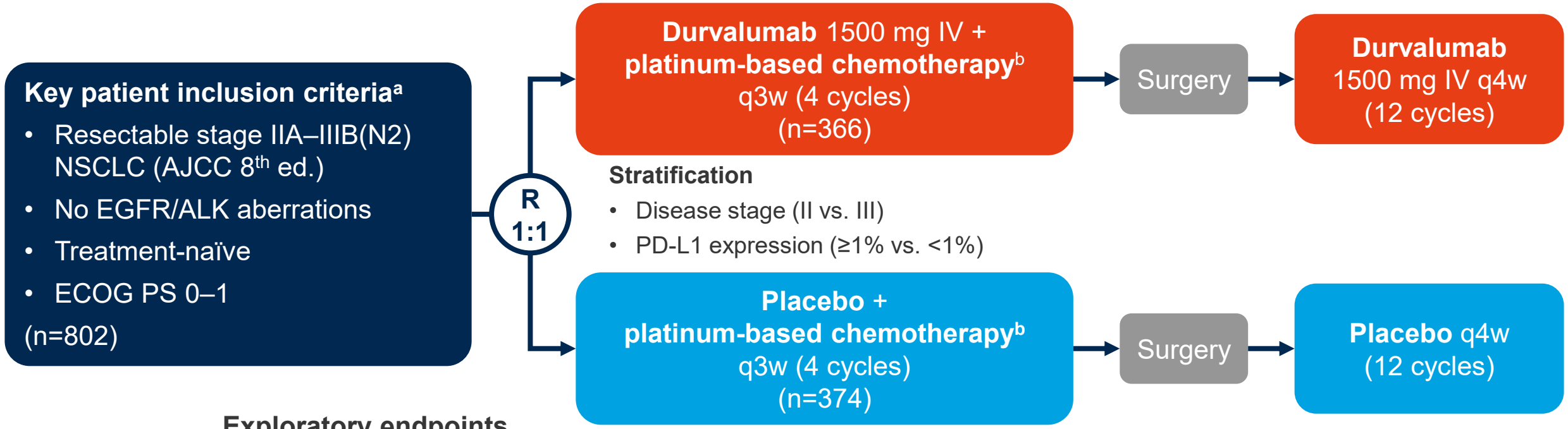
Contents

- 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

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

8009: Association of post-surgical MRD status with neoadjuvant ctDNA dynamics, genomic mutations, and clinical outcomes in patients with resectable NSCLC (R-NSCLC) from the phase 3 AEGEAN trial – Reck M, et al

- **Study objective**
  - To evaluate the associations between post-surgical MRD status and neoadjuvant ctDNA dynamics, genomic mutations and clinical outcomes in patients with resectable NSCLC in the phase 3 AEGEAN trial



Exploratory endpoints

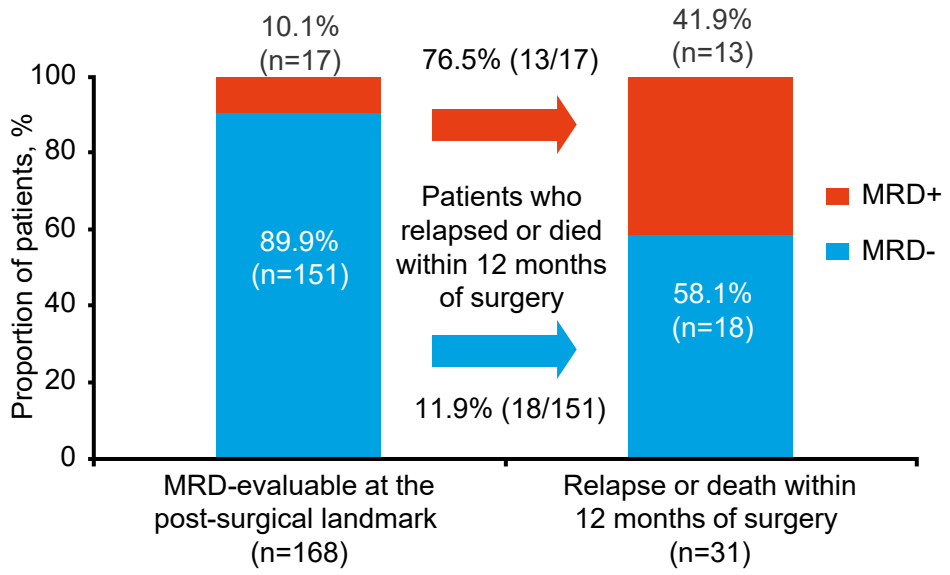
- Association between ctDNA clearance and pathological response[c] and EFS

[a]The protocol was amended to exclude patients with T4 tumors (not based on size, n=1); [b]nonsquamous: cisplatin + pemetrexed or carboplatin + pemetrexed. Squamous: carboplatin + paclitaxel or cisplatin + gemcitabine (or carboplatin + gemcitabine for patients with comorbidities/unable to tolerate cisplatin); [c]pCR and MPR were evaluated centrally per IASLC recommendations.

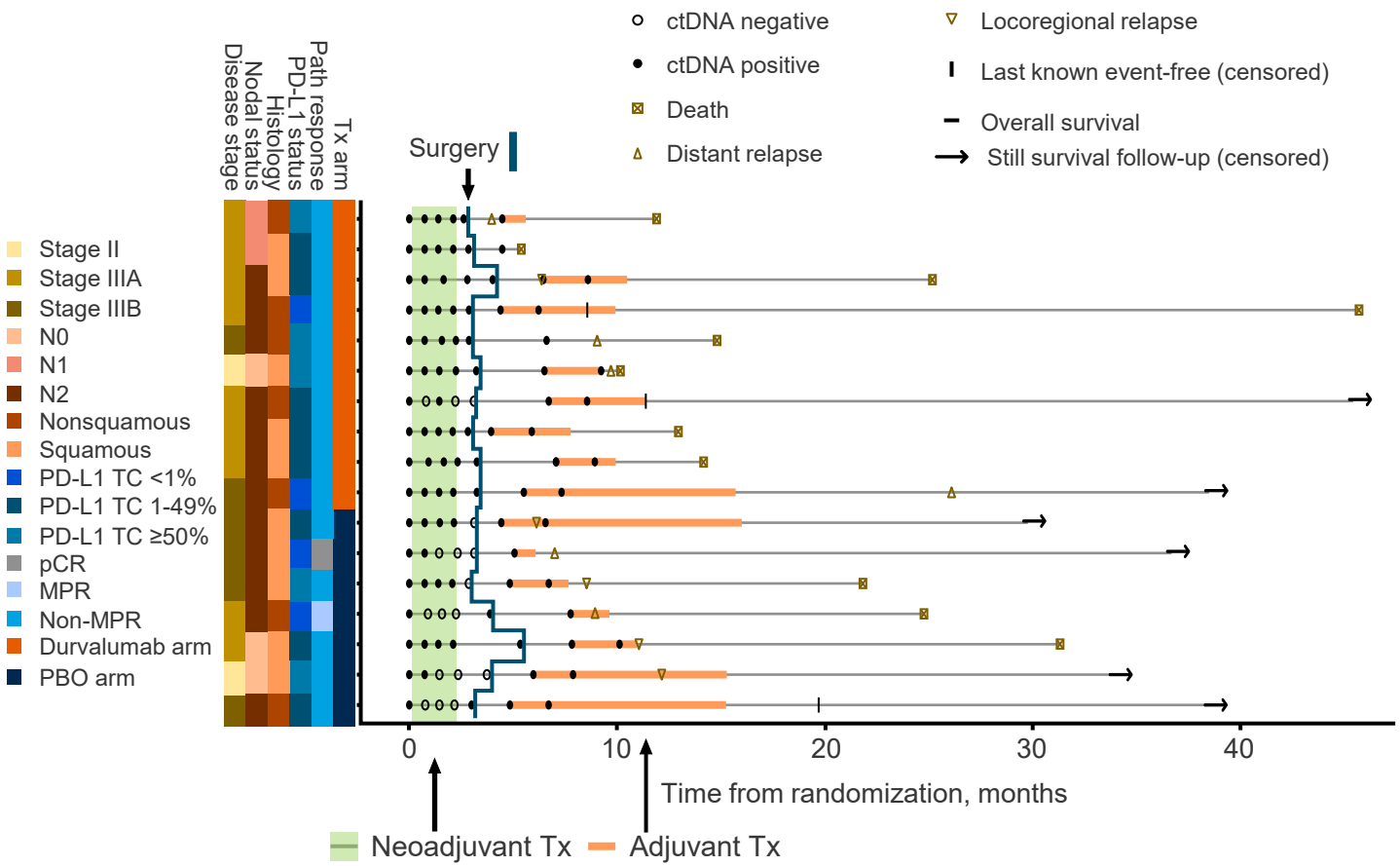
8009: Association of post-surgical MRD status with neoadjuvant ctDNA dynamics, genomic mutations, and clinical outcomes in patients with resectable NSCLC (R-NSCLC) from the phase 3 AEGEAN trial – Reck M, et al

- **Key results**

Response, n (%)	Durvalumab arm		PBO arm	
	MRD+ (n=10)	MRD- (n=78)	MRD+ (n=7)	MRD- (n=73)
pCR	0	25 (32.1)	1 (14.3)	3 (4.1)
No pCR	10 (100)	53 (67.9)	6 (85.7)	70 (95.9)
MPR	0	42 (53.8)	2 (28.6)	14 (19.2)
Non-MPR	10 (100)	36 (46.2)	5 (71.4)	59 (80.8)



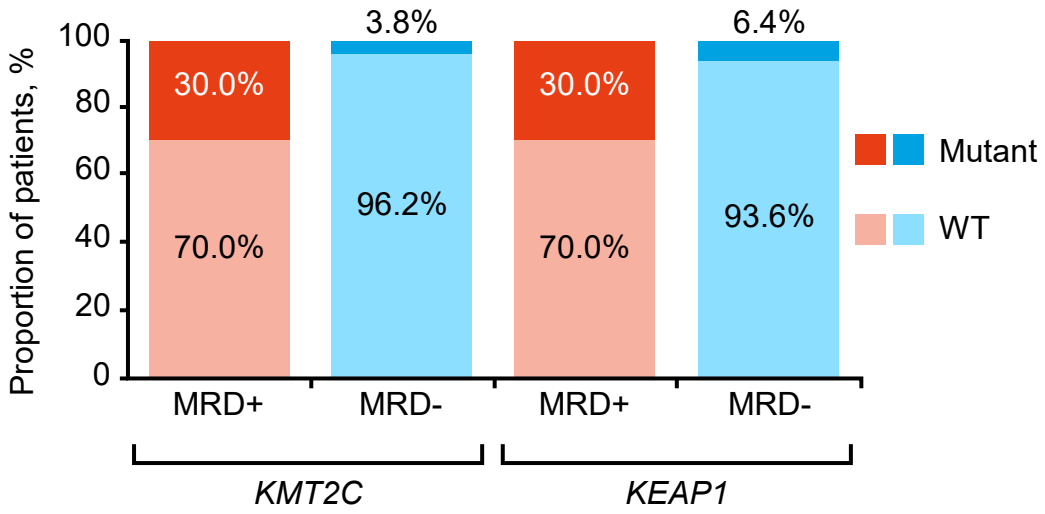
Swimmer Plot of MRD+ patients during perioperative therapy (n=17)



8009: Association of post-surgical MRD status with neoadjuvant ctDNA dynamics, genomic mutations, and clinical outcomes in patients with resectable NSCLC (R-NSCLC) from the phase 3 AEGEAN trial – Reck M, et al

- **Key results (cont.)**

Prevalence of KMT2C and KEAP1 mutations in MRD-evaluable patients within the D arm



EFS by *KMT2C* and *KEAP1* mutations status

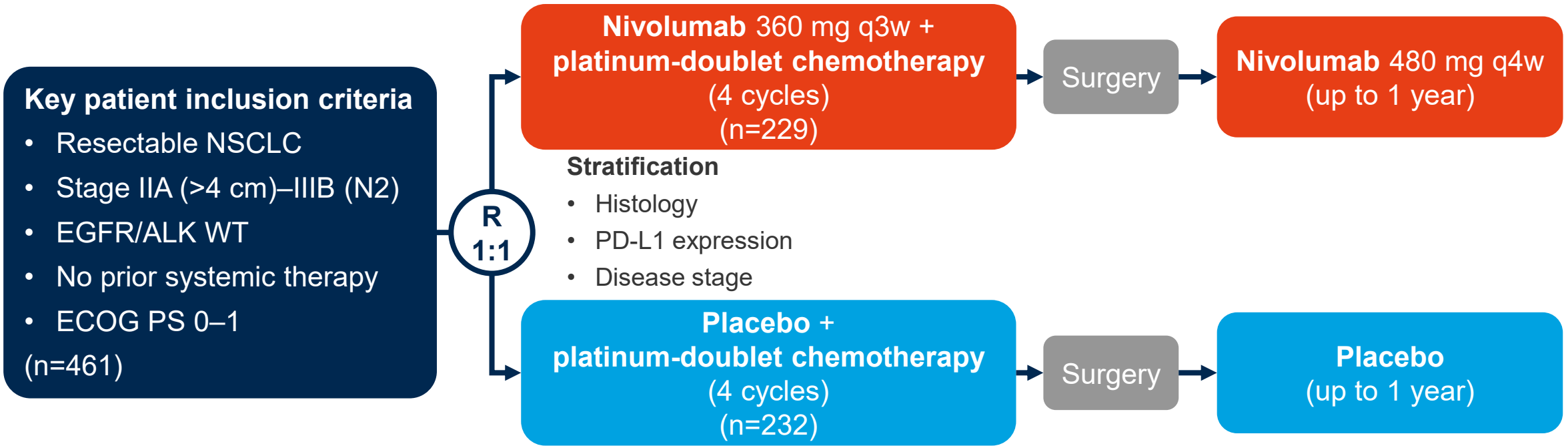
KMT2C	Durvalumab arm	PBO arm
EFS, HR (95%CI) for *KMT2Cwt* vs. *KMT2Cm*	0.28 (0.12, 0.62)	0.96 (0.46, 2.02)
EFS, HR (95%CI) for the D vs. PBO arm (*KMT2Cwt*)	0.52 (0.35, 0.78)	-
EFS, HR (95%CI) for the D vs. PBO arm (*KMT2Cm*)	2.03 (0.70, 5.91)	-

KEAP1	Durvalumab arm	PBO arm
EFS, HR (95%CI) for *KMT2Cwt* vs. *KMT2Cm*	0.57 (0.25, 1.27)	1.41 (0.35, 5.78)
EFS, HR (95%CI) for the D vs. PBO arm (*KEAP1wt*)	0.54 (0.36, 0.79)	-
EFS, HR (95%CI) for the D vs. PBO arm (*KEAP1m*)	1.39 (0.29, 6.77)	-

- **Conclusions**
  - In this exploratory analysis, MRD was associated with worse prognosis compared with patients without MRD
  - Patients with *KMT2C* and *KEAP1* mutations may have reduced benefit from immunotherapy

LBA8010: Perioperative nivolumab (NIVO) vs placebo (PBO) in patients (pts) with resectable NSCLC: updated survival and biomarker analyses from CheckMate 77T – Provencio M, et al

- **Study objective**
  - To evaluate the updated efficacy and safety of perioperative nivolumab in patients with resectable NSCLC in the CheckMate 77T trial



Primary endpoint

- EFS (RECIST v1.1, BICR)

Secondary endpoints

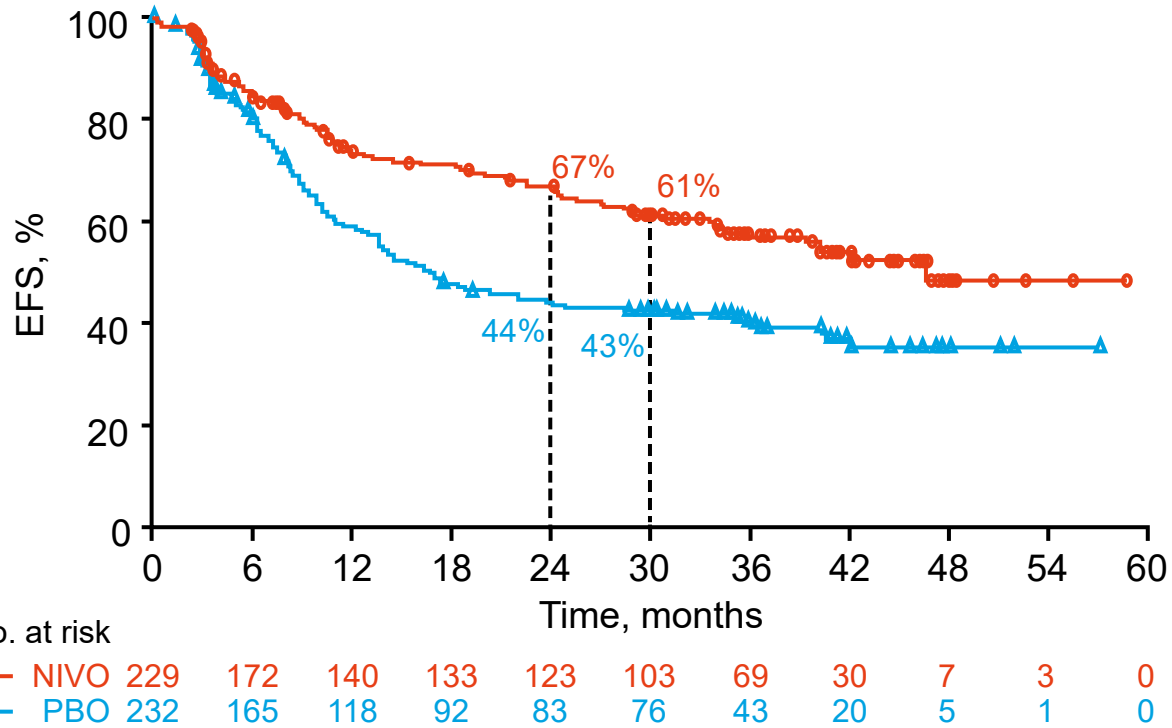
- pCR, MPR, OS, safety

LBA8010: Perioperative nivolumab (NIVO) vs placebo (PBO) in patients (pts) with resectable NSCLC: updated survival and biomarker analyses from CheckMate 77T – Provencio M, et al

- **Key results**

EFS

	Nivolumab (n=229)	Placebo (n=232)
Median EFS, mo (95%CI)	46.6 (35.8, NR)	16.9 (13.6, 28.2)
HR (95%CI)	0.61 (0.46, 0.80)	



EFS by tumor mutation status

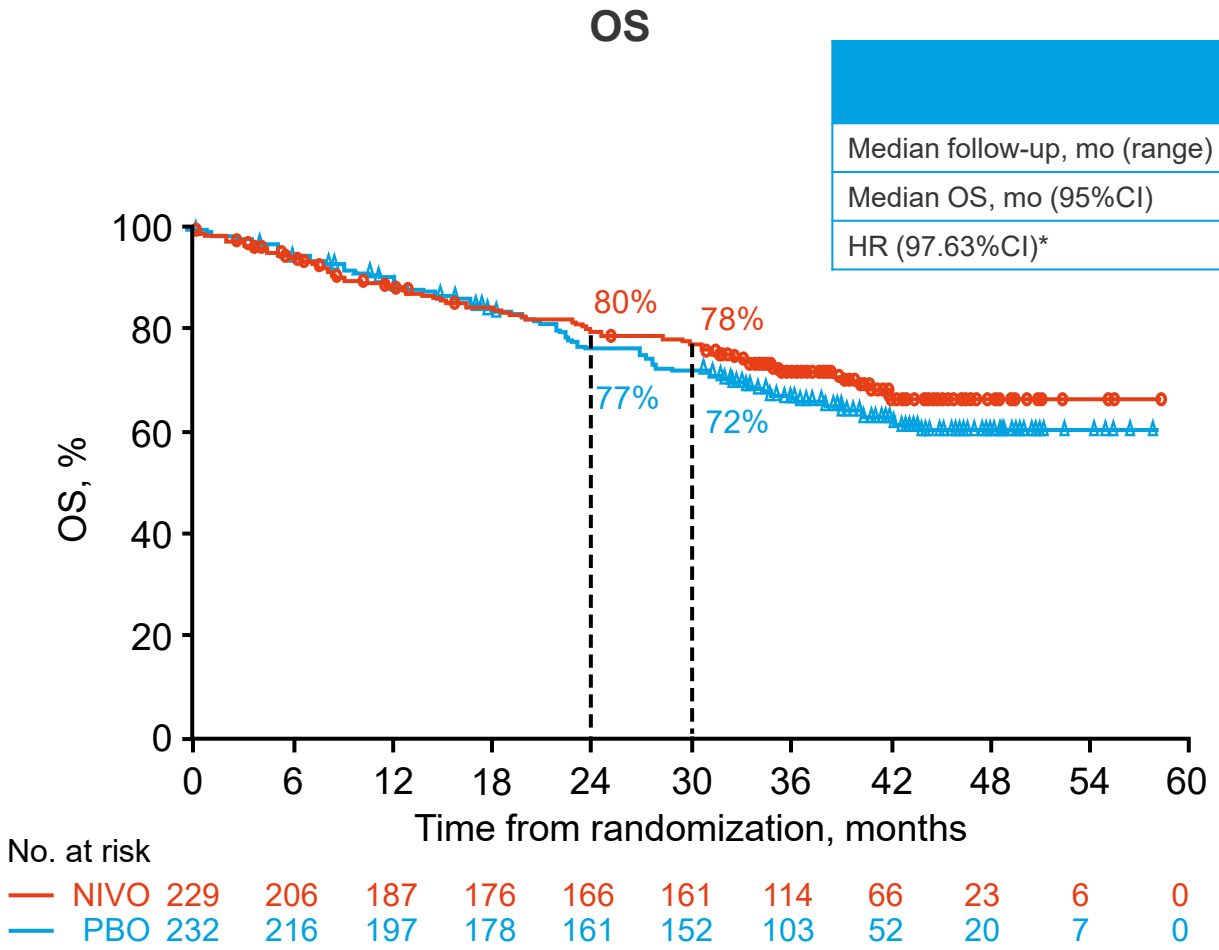
	Nivolumab	Placebo
KRASm ± KEAP1m ±STK11m, n	33	34
Median EFS, mo (95%CI)	28.9 (13.2, NR)	10.5 (18.8, 31.4)
HR (95%CI)	0.63 (0.32, 1.23)	
KRASwt ± KEAP1wt ±STK11wt, n	65	58
Median EFS, mo (95%CI)	NR (29.0, NR)	17.0 (10.8, NR)
HR (95%CI)	0.65 (0.39, 1.10)	

	Nivolumab (n=229)	Placebo (n=232)
Median OS, mo (95%CI)	NR (NR, NR)	NR (NR, NR)
HR (97.6%CI)	0.85 (0.58, 1.25)	

Database lock date: December 16, 2024.

LBA8010: Perioperative nivolumab (NIVO) vs placebo (PBO) in patients (pts) with resectable NSCLC: updated survival and biomarker analyses from CheckMate 77T – Provencio M, et al

- **Key results**



	Nivolumab (n=229)	Placebo (n=232)
Median follow-up, mo (range)	41.0 (31.3–59.8)	
Median OS, mo (95%CI)	NR (NR, NR)	NR (NR, NR)
HR (97.63%CI)*	0.85 (0.58, 1.25)	

*HR 0.85 (95%CI 0.61, 1.18). Significance boundary for OS not met at this interim analysis.

LBA8010: Perioperative nivolumab (NIVO) vs placebo (PBO) in patients (pts) with resectable NSCLC: updated survival and biomarker analyses from CheckMate 77T – Provencio M, et al

- **Key results (cont.)**

EFS by ctDNA clearance and pCR status

Nivolumab	ctDNA CL + pCR vs ctDNA CL + no pCR	ctDNA CL + pCR vs No ctDNA CL + no pCR	ctDNA CL + no pCR vs No ctDNA CL + no pCR
HR (95%CI)	0.29 (0.10, 0.85)	0.23 (0.08, 0.65)	0.70 (0.31, 1.59)

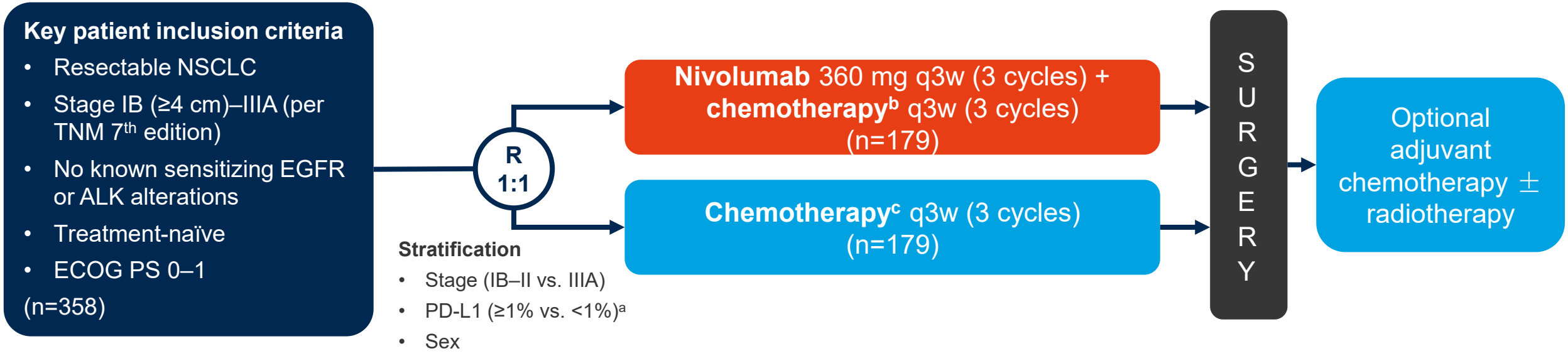
Placebo	ctDNA CL + pCR vs ctDNA CL + no pCR	ctDNA CL + pCR vs No ctDNA CL + no pCR	ctDNA CL + no pCR vs No ctDNA CL + no pCR
HR (95%CI)	NC	NC	0.77 (0.39, 1.54)

	Nivolumab (n=228)		Placebo (n=230)	
AEs, n (%)	Any grade	Grade 3–4	Any grade	Grade 3–4
All AEs	222 (97)	107 (47)	225 (98)	98 (43)
TRAEs	203 (89)	73 (32)	200 (87)	58 (25)
AEs led to discontinuation	57 (25)	32 (14)	25 (11)	14 (6)
TRAEs led to discontinuation	44 (19)	25 (11)	17 (7)	11 (5)
All SAEs	96 (42)	65 (28)	71 (31)	46 (20)
Treatment-related SAEs	43 (19)	31 (14)	22 (10)	13 (6)
Treatment-related death	2 (1)		0	

- **Conclusions**
  - In patients with resectable NSCLC, perioperative nivolumab continued to show robust and durable responses with a manageable safety profile, regardless of tumor mutation status

LBA8000: Overall survival with neoadjuvant nivolumab (NIVO) + chemotherapy (chemo) in patients with resectable NSCLC in CheckMate 816 – Forde PM, et al

- **Study objective**
  - To evaluate the OS of neoadjuvant nivolumab + chemotherapy in patients with resectable NSCLC in the phase 3 CheckMate 816 trial



Primary endpoints

- pCR (BIPR), EFS (BICR)

Secondary endpoints

- OS, MPR (BIPR), TTDM

[a]Determined by the PD-L1 28-8 pharmDx assay; [b]pemetrexed + cisplatin or paclitaxel + carboplatin for nonsquamous and gemcitabine + cisplatin or paclitaxel + carboplatin for squamous; [c]vinorelbine or docetaxel or gemcitabine + cisplatin for squamous and pemetrexed + cisplatin for nonsquamous, or paclitaxel + carboplatin.

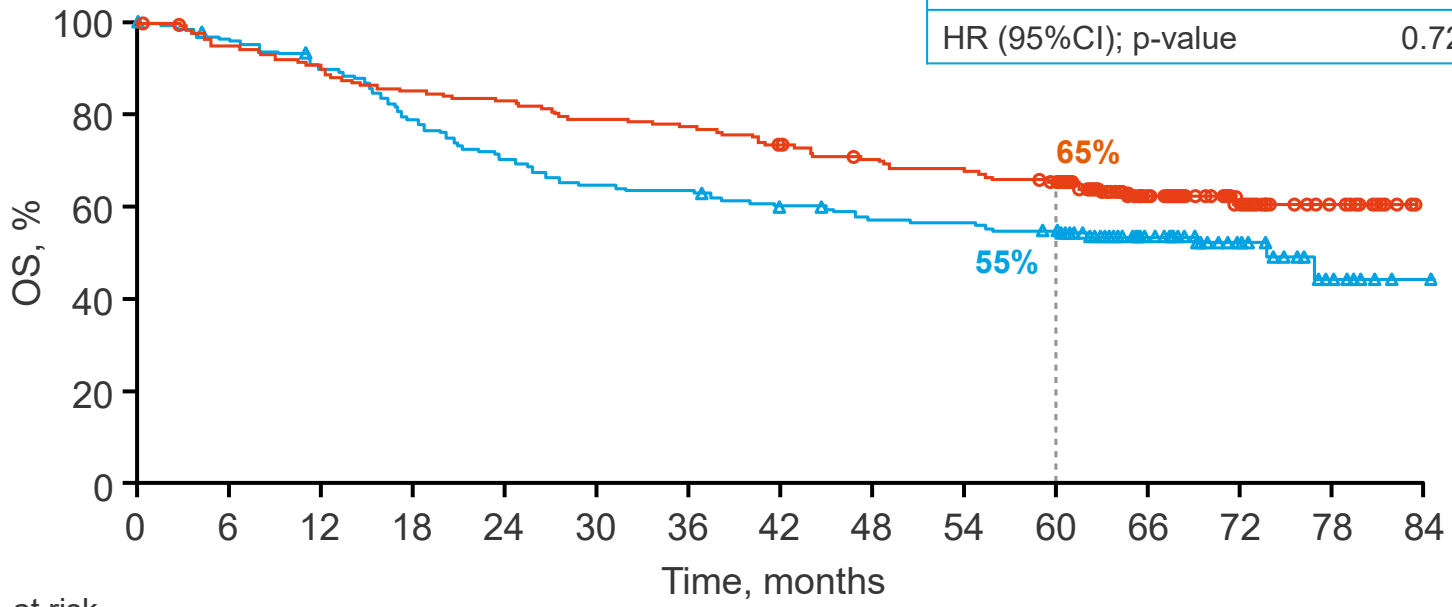
Forde PM, et al. J Clin Oncol 2025;43(suppl):Abstr LBA8000

LBA8000: Overall survival with neoadjuvant nivolumab (NIVO) + chemotherapy (chemo) in patients with resectable NSCLC in CheckMate 816 – Forde PM, et al

- **Key results**

Final analysis: OS

	Nivolumab + Chemo (n=179)	Chemo (n=179)
Median OS, mo	NR	73.7
HR (95%CI); p-value	0.72 (0.523, 0.998); 0.0479	



No. at risk

Nivolumab + chemotherapy	179	168	159	151	147	140	137	129	122	117	111	67	29	9	0
Chemotherapy	179	170	159	139	124	114	112	104	98	97	91	58	29	6	1

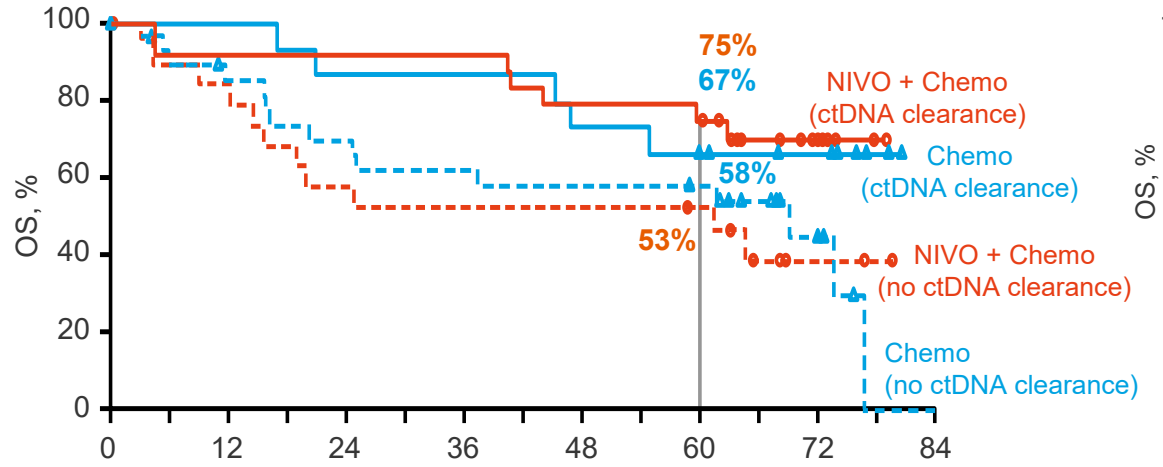
Forde PM, et al. J Clin Oncol 2025;43(suppl):Abstr LBA8000

LBA8000: Overall survival with neoadjuvant nivolumab (NIVO) + chemotherapy (chemo) in patients with resectable NSCLC in CheckMate 816 – Forde PM, et al

- **Key results (cont.)**

OS by ctDNA clearance status

	Nivolumab + chemotherapy		Chemotherapy	
	ctDNA CL	No ctDNA CL	ctDNA CL	No ctDNA CL
Median OS, mo	NR	61.5	NR	69.2
HR (95%CI)	0.38 (0.15, 1.00)		0.39 (0.14, 1.11)	

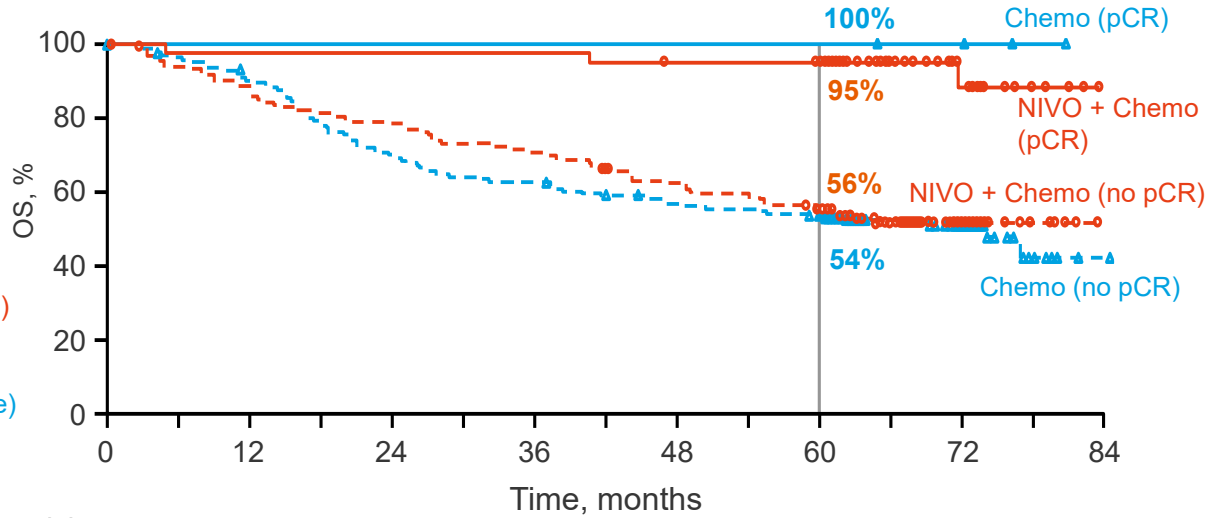


No. at risk

ctDNA clearance	24	22	22	22	22	22	22	20	19	19	18	11	6	1	0
ctDNA clearance	15	15	15	14	13	13	13	13	11	11	9	8	7	2	0
No ctDNA clearance	19	17	16	13	11	10	10	10	10	10	9	4	2	1	0
No ctDNA clearance	28	24	22	19	18	16	16	15	15	15	14	9	5	0	0

OS by pCR status

	Nivolumab + chemotherapy		Chemotherapy	
	pCR	No pCR	pCR	No pCR
Median OS, mo	NR	NR	NR	73.7
HR (95%CI)	0.11 (0.04, 0.36)		-	



No. at risk

pCR	43	42	42	42	42	42	42	41	40	40	39	25	13	4	0
pCR	4	4	4	4	4	4	4	4	4	4	4	3	3	1	0
No pCR	136	126	117	109	105	98	95	88	82	77	72	42	16	5	0
No pCR	75	166	155	135	120	110	108	100	94	93	87	55	26	5	1

LBA8000: Overall survival with neoadjuvant nivolumab (NIVO) + chemotherapy (chemo) in patients with resectable NSCLC in CheckMate 816 – Forde PM, et al

- **Key results (cont.)**

5-year EFS	NIVO + Chemo (n=179)	Chemo (n=179)
Median EFS, mo	59.6	21.1
HR (95%CI)	0.68 (0.51, 0.91)	

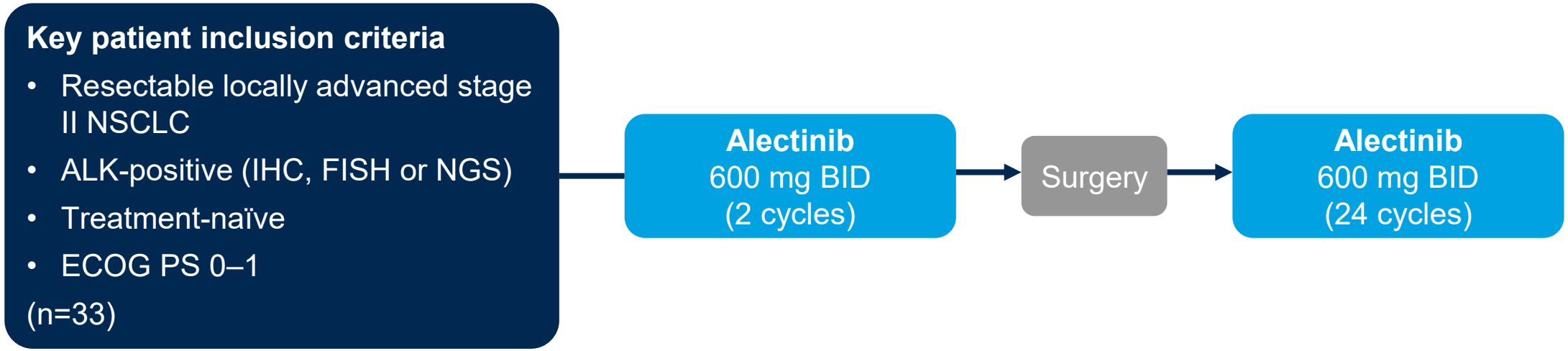
	NIVO + Chemo		Chemo	
	pCR	No pCR	pCR	No pCR
Median EFS, mo	NR	27.8	NR	20.8
HR (95%CI)	0.14 (0.06, 0.33)		-	

	Nivo + chemo (n=176)		Chemotherapy (n=176)	
AEs, n (%)	Any grade	Grade 3–4	Any grade	Grade 3–4
All AEs	165 (94)	76 (43)	173 (98)	79 (45)
TRAEs	147 (84)	63 (36)	159 (90)	67 (38)
AEs led to discontinuation	18 (10)	10 (6)	20 (11)	7 (4)
TRAEs ledi to discontinuation	18 (10)	10 (6)	17 (10)	6 (3)
SAEs	30 (17)	19 (11)	24 (14)	17 (10)
Treatment-related SAEs	21 (12)	15 (8)	18 (10)	14 (8)
Surgery-related AEs	67 (45)	17 (11)	66 (49)	20 (15)
TRAEs leading to death	0		3 (2)	

- **Conclusions**
  - In patients with resectable NSCLC, nivolumab + chemotherapy demonstrated a statistically significant long-term survival benefit over chemotherapy alone, with a manageable safety profile
  - Exploratory analyses showed that ctDNA and pCR status may correlate with treatment response and harbor a prognostic impact

8015: Alectinib as neoadjuvant treatment in potentially resectable stage III ALK-positive NSCLC: Final analysis of ALNEO phase II trial (GOIRC-01-2020-ML42316) – Tiseo M, et al

- **Study objective**
  - To evaluate the final efficacy and safety of neoadjuvant alectinib in patients with potentially resectable stage II ALK-positive NSCLC in the phase 2 ALNEO trial



Primary endpoint

- MPR (≤10% viable tumor) by BICR

Secondary endpoints

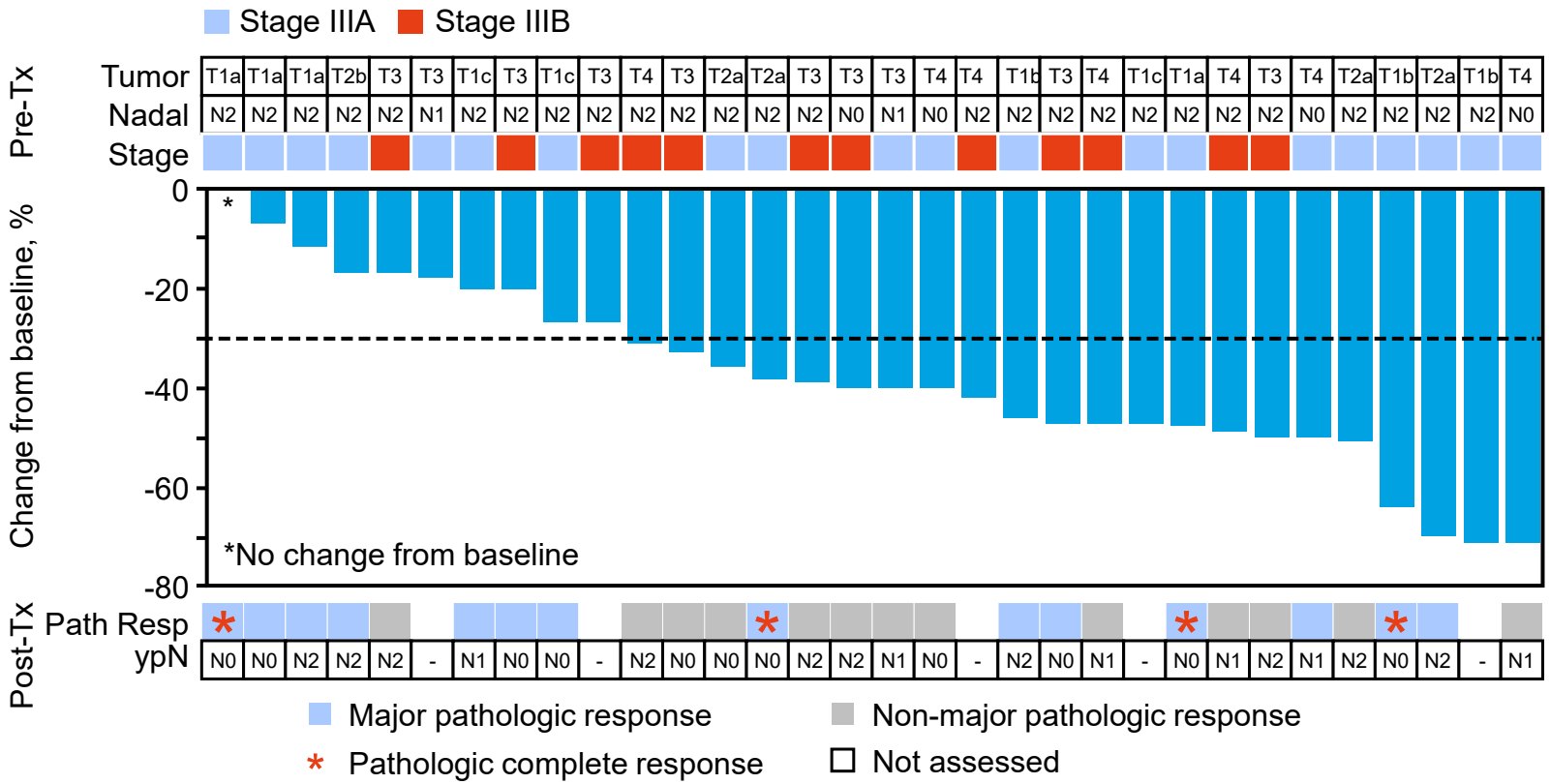
- pCR, ORR, EFS, DFS, OS, safety

8015: Alectinib as neoadjuvant treatment in potentially resectable stage III ALK-positive NSCLC: Final analysis of ALNEO phase II trial (GOIRC-01-2020-ML42316) – Tiseo M, et al

- **Key results**

Pathologic response	Alectinib (n=33)
MPR (≤10% viable tumor), n (%) [90%CI]	14 (42) [28, 58]
Non-MPR (>10% viable tumor), n (%)	13 (40)
pCR, n (%) [95%CI]	4 (12) [3, 28]
Not assessed, n (%)	6 (18)

Objective response, n (%)[a]	N=33
CR	0
PR	22 (67)
SD	10 (30)
PD	1 (3)[b]
ORR	**22 (67)**



[a]At pre-surgical evaluation; [b]not evaluated (clinical progression).

8015: Alectinib as neoadjuvant treatment in potentially resectable stage III ALK-positive NSCLC: Final analysis of ALNEO phase II trial (GOIRC-01-2020-ML42316) – Tiseo M, et al

- **Key results (cont.)**

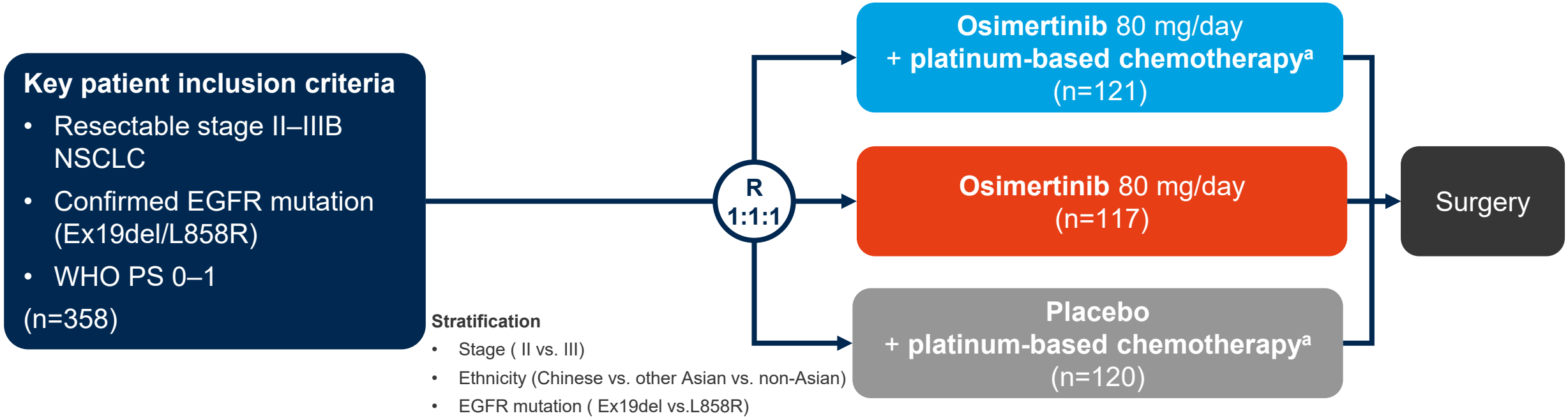
TRAEs in neoadjuvant phase, n (%)	Alectinib (n=33)
Any	33 (100)
Grade 3	3 (9)
Leding to dose reduction	2 (6)
Led to discontinuation	0

TRAEs in adjuvant phase, n (%)	Alectinib (n=26)
Any	26 (100)
Grade 3	3 (12)
Leding to dose reduction	7 (27)
Led to discontinuation	1 (4)

- **Conclusions**
  - In patients with resectable ALK-positive NSCLC, neoadjuvant alectinib showed promising antitumor activity with a manageable safety profile

8001: Neoadjuvant (neoadj) osimertinib (osi) ± chemotherapy (CT) vs CT alone in resectable (R) epidermal growth factor receptor-mutated (EGFRm) NSCLC: NeoADAURA – Chaft JE, et al

- **Study objective**
  - To evaluate the efficacy and safety of neoadjuvant osimertinib ± chemotherapy in patients with resectable EGFR-mutant NSCLC in the NeoADAURA trial



Primary endpoint

- MPR (BICR)

Secondary endpoints

- EFS, pCR, nodal downstaging, safety

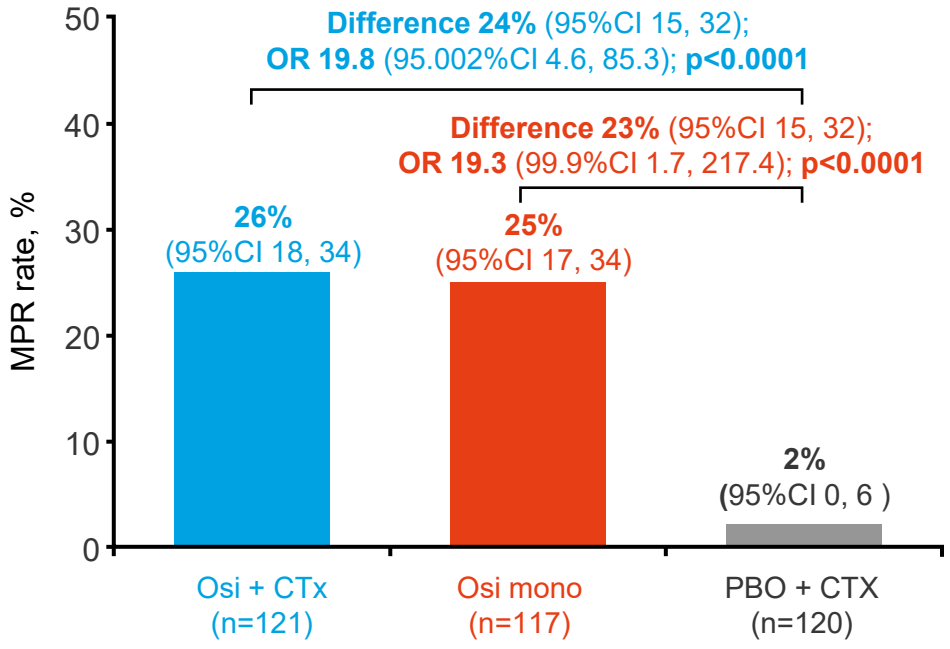
[a]Carboplatin AUC5 or cisplatin 75 mg/m^2 + pemetrexed 500 mg/m^2 q3w, 3 cycles.

Chaft JE, et al. J Clin Oncol 2025;43(suppl):Abstr 8001

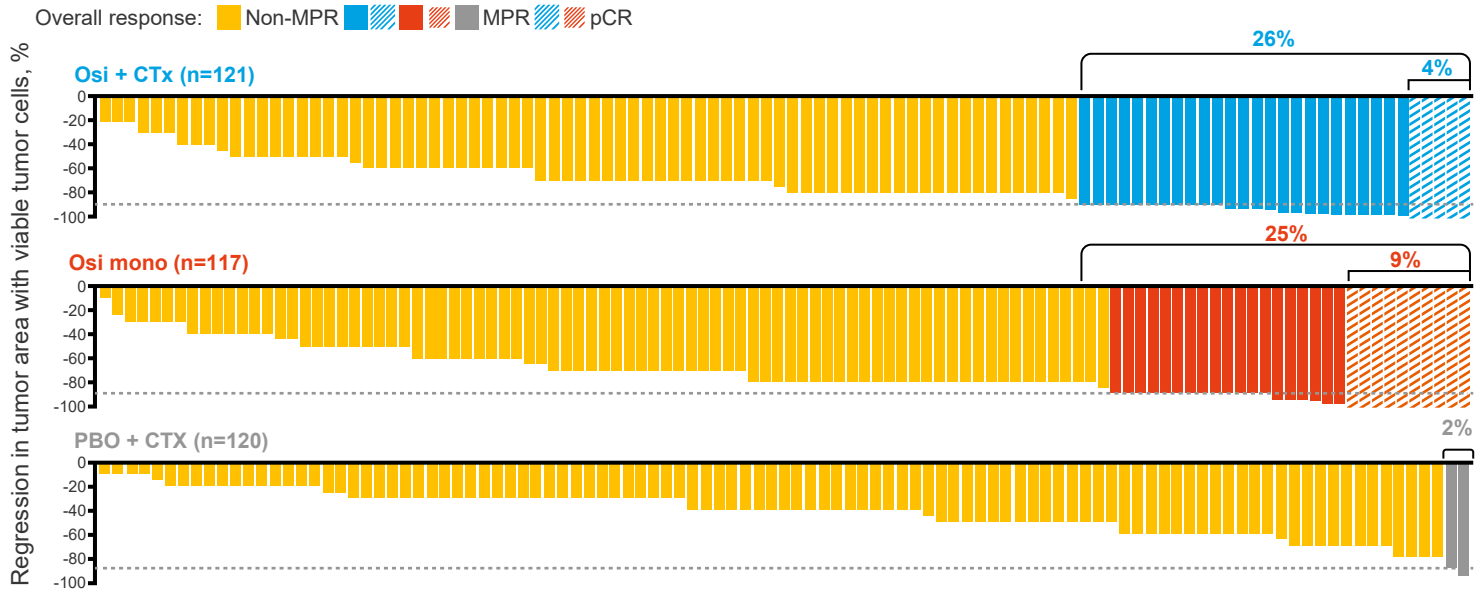
8001: Neoadjuvant (neoadj) osimertinib (osi) ± chemotherapy (CT) vs CT alone in resectable (R) epidermal growth factor receptor-mutated (EGFRm) NSCLC: NeoADAURA – Chaft JE, et al

- **Key results**

Major pathological response



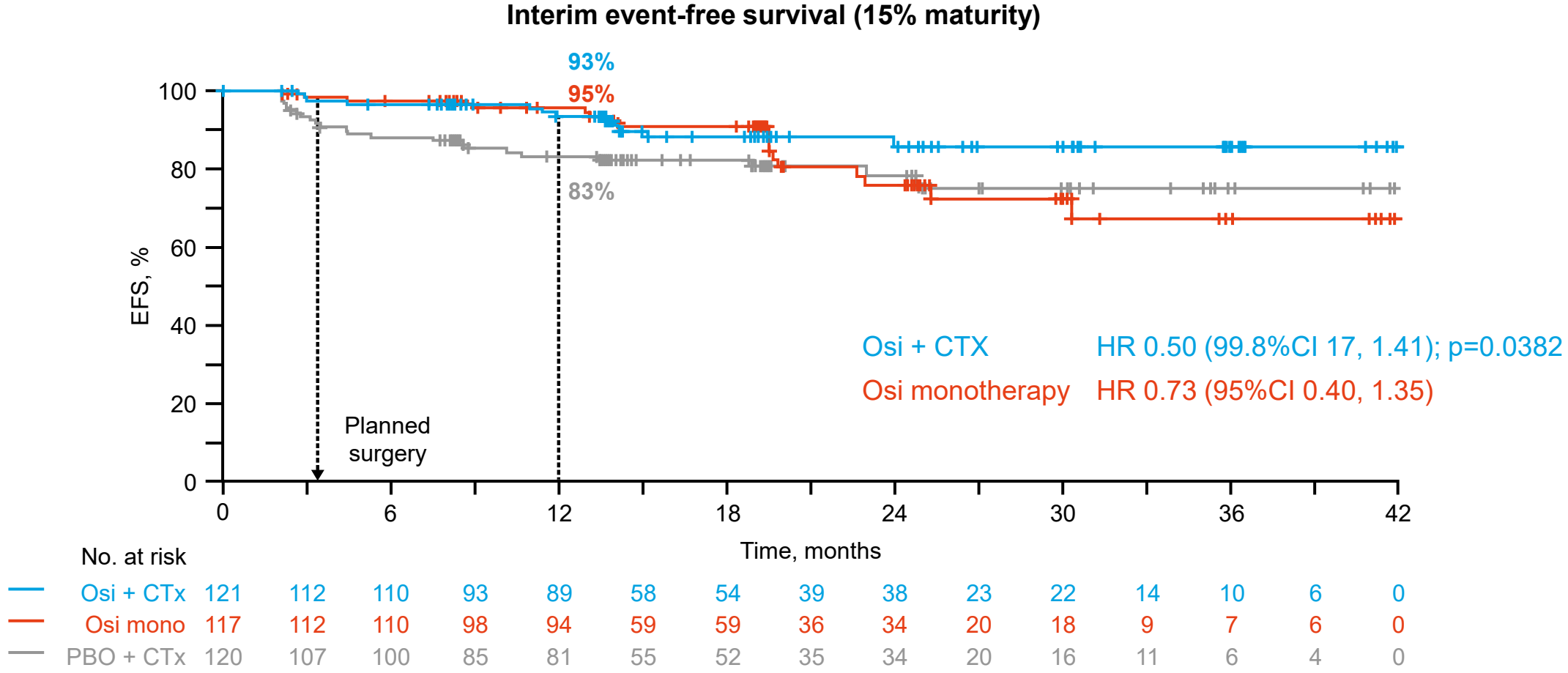
Depth of pathological response



Chaft JE, et al. J Clin Oncol 2025;43(suppl):Abstr 8001

8001: Neoadjuvant (neoadj) osimertinib (osi) ± chemotherapy (CT) vs CT alone in resectable (R) epidermal growth factor receptor-mutated (EGFRm) NSCLC: NeoADAURA – Chaft JE, et al

- **Key results (cont.)**



Chaft JE, et al. J Clin Oncol 2025;43(suppl):Abstr 8001

8001: Neoadjuvant (neoadj) osimertinib (osi) ± chemotherapy (CT) vs CT alone in resectable (R) epidermal growth factor receptor-mutated (EGFRm) NSCLC: NeoADAURA – Chaft JE, et al

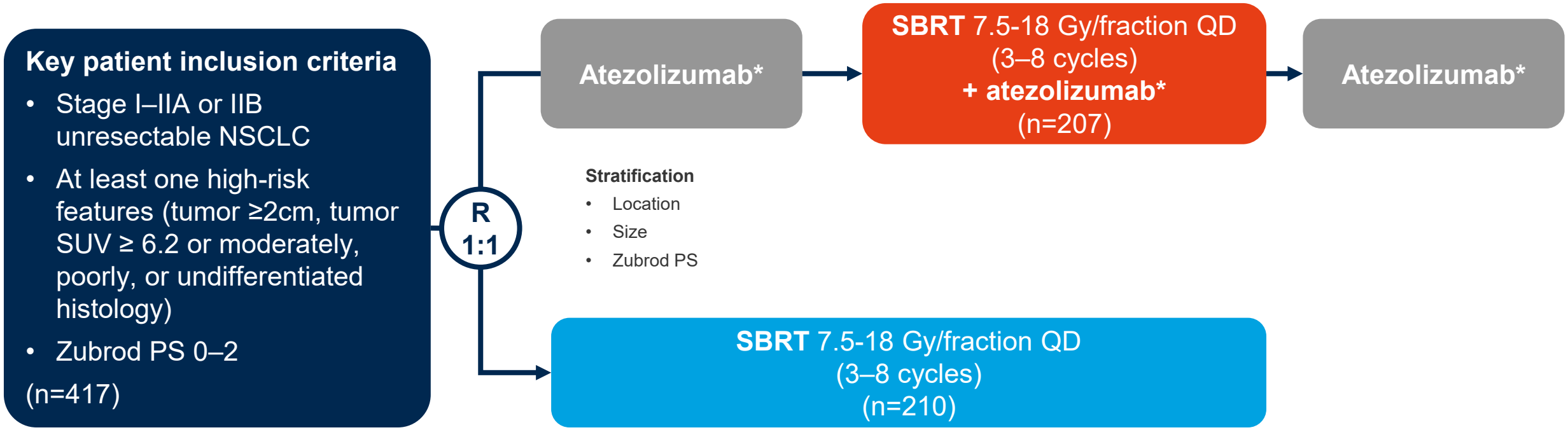
- **Key results (cont.)**

Safety (neoadjuvant period), n (%)	Osi + chemo (n=119)	Osi mono (n=117)	Placebo + chemo (n=120)
Any AEs			
Any/Grade ≥3	110 (92)/43 (36)	104 (89)/15 (13)	111 (93)/40 (33)
Serious	24 (20)	13 (11)	24 (20)
Led to discontinuation of any study drug	11 (9)	3 (3)	6 (5)
Osi or placebo/chemotherapy discontinuation	2 (2)/10 (8)	3 (3)/-	2 (2)/6 (5)
TRAEs			
Any/Grade ≥3	103 (87)/34 (29)	71 (61)/5 (4)	98 (82)/27 (23)
Grade ≥3 possibly causally related to osi or placebo/chemotherapy	20 (17)/33 (28)	5 (4)/-	12 (10)/27 (23)
Serious	9 (8)	2 (2)	10 (8)

- **Conclusions**
  - In patients with resectable EGFR-mutant NSCLC, neoadjuvant osimertinib, with or without chemotherapy, significantly improved MPR rates over chemotherapy alone and had a manageable safety profile
  - Longer EFS and OS follow-up are needed across all treatment arms

8003: SWOG/NRG S1914: Randomized phase III trial of induction/consolidation atezolizumab + SBRT versus SBRT alone in high risk, early-stage NSCLC – Daly ME, et al

- **Study objective**
  - To evaluate the efficacy and safety of atezolizumab + SBRT vs SBRT alone in patients with high-risk, early-stage NSCLC in the phase 3 SWOG/NRG S1914 trial



Primary endpoint

- OS

Secondary endpoints

- PFS

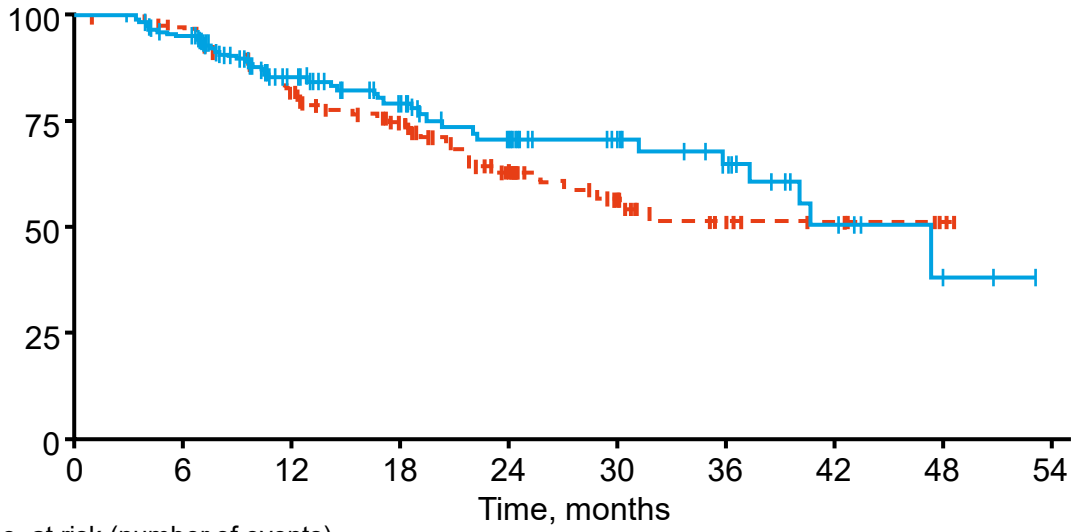
*Atezolizumab 1200 mg IV q3w x8 cycles in total (6 months).

8003: SWOG/NRG S1914: Randomized phase III trial of induction/consolidation atezolizumab + SBRT versus SBRT alone in high risk, early-stage NSCLC – Daly ME, et al

- **Key results**

Progression-free survival

	Atezolizumab + SBRT (n=202)	SBRT (n=201)
Events, n	51	43
2-year rate, % (95%CI)	62.7 (52.5, 71.3)	70.4 (60.4, 78.4)
HR (95% CI); p-value	1.14 (0.75, 1.73); 0.73	

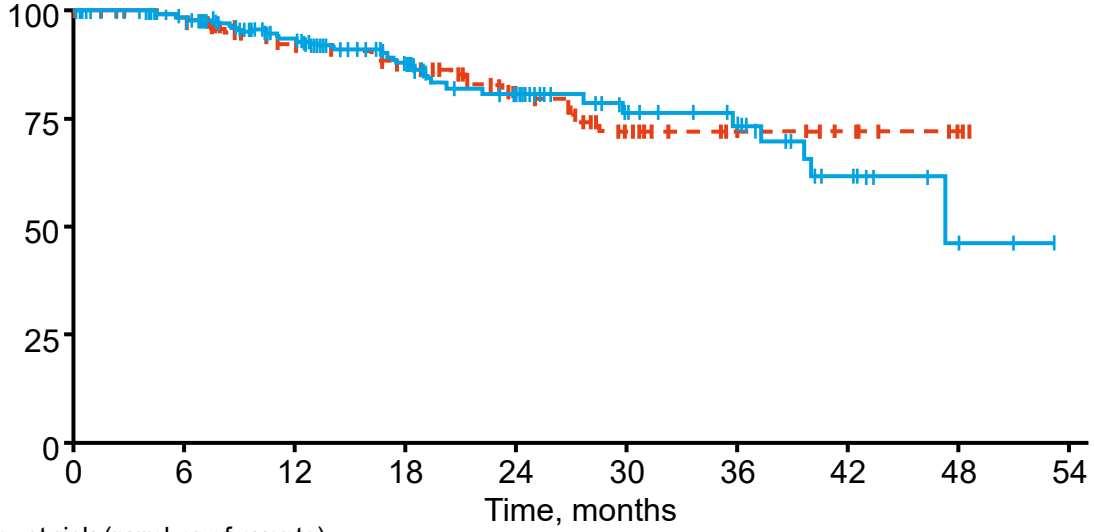


No. at risk (number of events)

Atezolizumab + SBRT	202 (0)	176 (6)	109 (29)	69 (37)	41 (46)	24 (49)	15 (51)	10 (51)	3 (51)	0 (51)
SBRT	201 (0)	176 (10)	110 (25)	72 (31)	47 (37)	28 (37)	20 (39)	10 (42)	3 (43)	0 (43)

Overall survival

	Atezolizumab + SBRT (n=202)	SBRT (n=201)
Events, n	28	30
2-year rate, % (95%CI)	81.2 (72.4, 87.4)	80.5 (71.5, 87.0)
HR (95% CI); p-value	1.02 (0.60, 1.73); 0.54	



No. at risk (number of events)

Atezolizumab + SBRT	202 (0)	183 (2)	127 (13)	92 (18)	57 (23)	30 (28)	20 (28)	11 (28)	6 (28)	0 (28)
SBRT	201 (0)	185 (3)	133 (11)	90 (17)	59 (23)	34 (25)	24 (26)	13 (29)	3 (30)	0 (30)

Daly ME, et al. J Clin Oncol 2025;43(suppl):Abstr 8003

8003: SWOG/NRG S1914: Randomized phase III trial of induction/consolidation atezolizumab + SBRT versus SBRT alone in high risk, early-stage NSCLC – Daly ME, et al

- **Key results (cont.)**

AEs, n (%)	A + SBRT (n=194)	SBRT (n=191)
Grade 2	6 (31)	16 (8)
Grade 3	21 (11)	3 (2)
Grade 4	1 (<1)	1 (<1)
Grade 5	1 (<1)	0

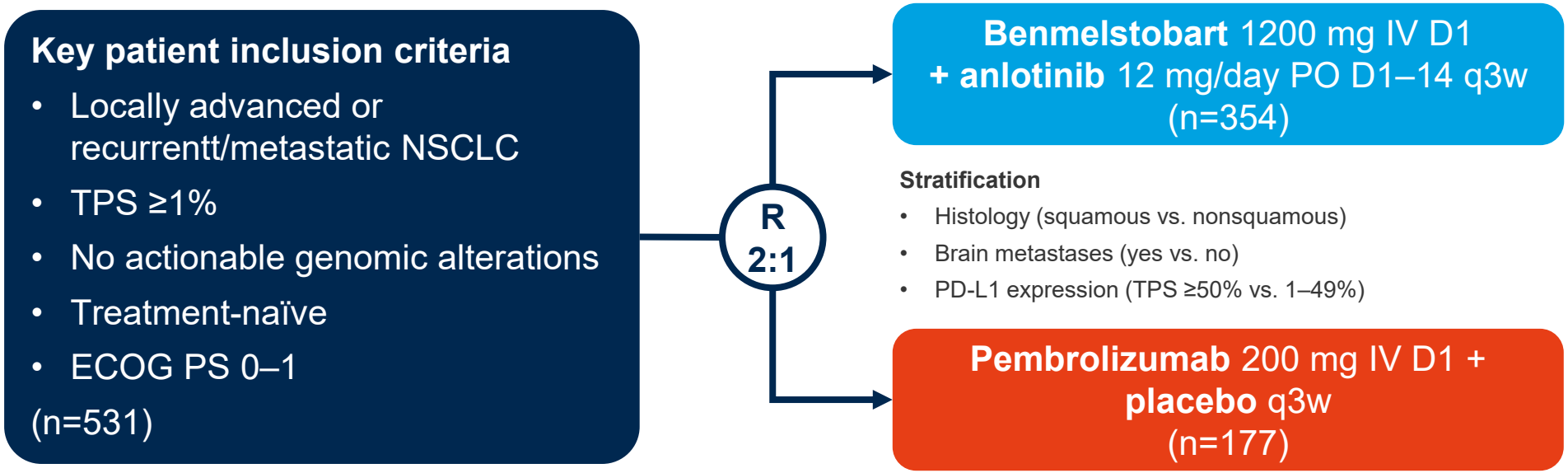
- **Conclusions**
  - In patients with high-risk, early-stage NSCLC, 8 cycles of atezolizumab + SBRT (induction, concurrent and consolidation) failed to improve survival compared with SBRT alone and no new safety signals were observed

Advanced NSCLC
Not radically treatable stage III and stage IV

Immunotherapy

LBA8502: CAMPASS: Benmelstobart in combination with anlotinib vs pembrolizumab in the first-line treatment of advanced non-small cell lung cancer (aNSCLC): A randomized, single-blind, multicenter phase 3 study – Han B, et al

- **Study objective**
  - To evaluate the efficacy and safety of 1L benmelstobart (PD-L1 inhibitor) + anlotinib vs pembrolizumab in PD-L1+ patients with advanced NSCLC in the phase 3 CAMPASS trial



Primary endpoint

- PFS (IRC, RECIST v1.1)

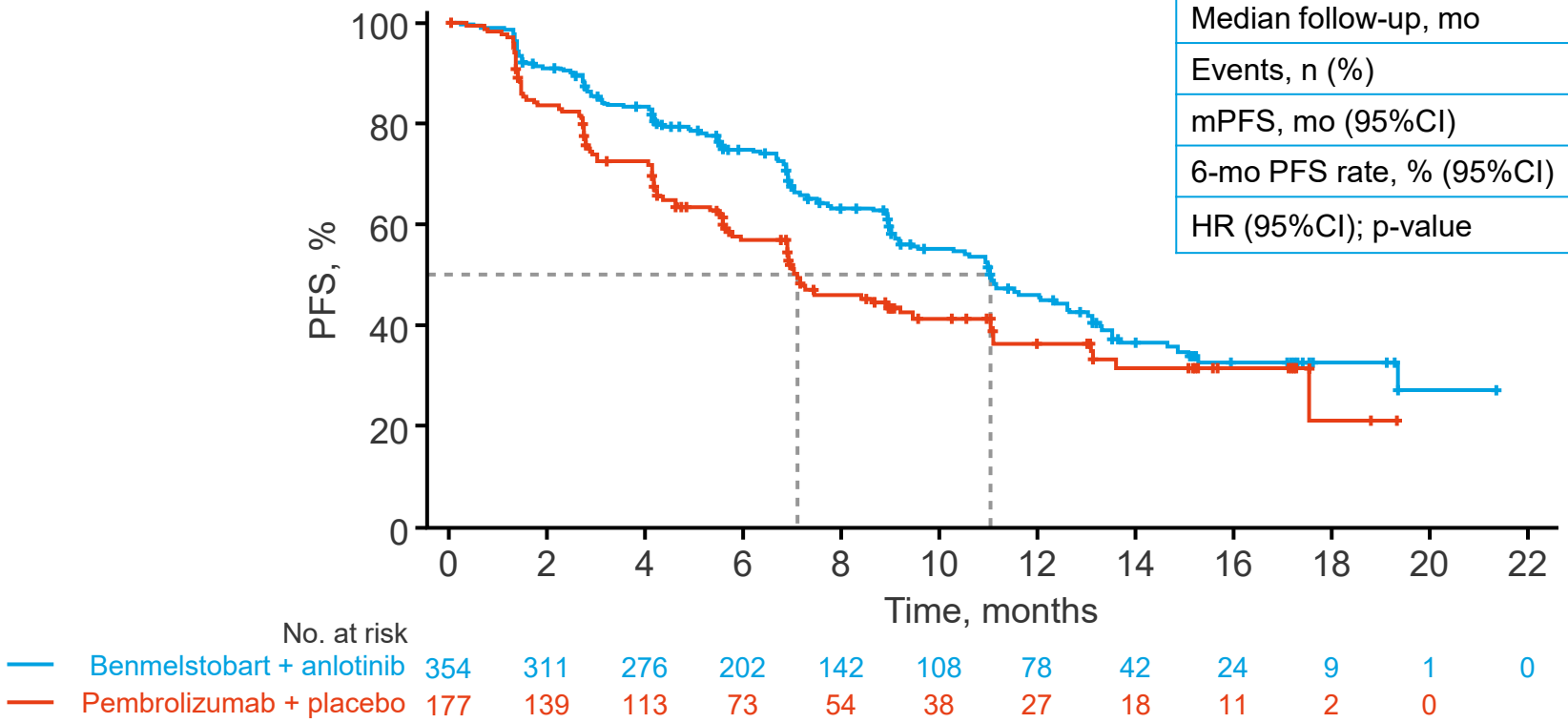
Secondary endpoints

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

LBA8502: CAMPASS: Benmelstobart in combination with anlotinib vs pembrolizumab in the first-line treatment of advanced non-small cell lung cancer (aNSCLC): A randomized, single-blind, multicenter phase 3 study – Han B, et al

- **Key results**

PFS by IRC

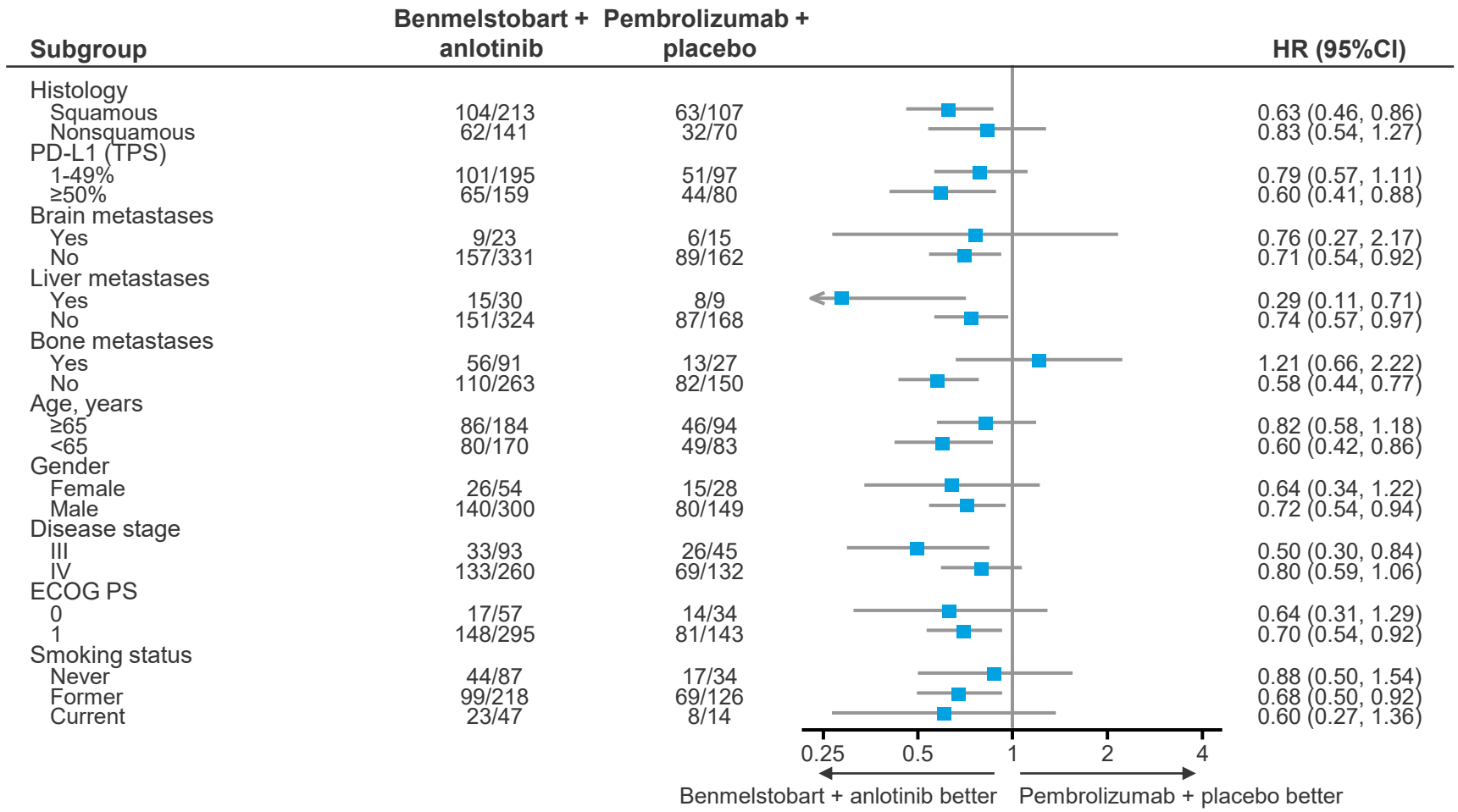


	Benmelstobart + anlotinib (n=354)	Pembrolizumab + placebo (n=177)
Median follow-up, mo	11.4	10.6
Events, n (%)	166 (46.9)	95 (53.7)
mPFS, mo (95%CI)	11.0 (9.2, 12.6)	7.1 (5.8, 9.5)
6-mo PFS rate, % (95%CI)	74.7 (69.6, 79.0)	56.8 (48.6, 64.2)
HR (95%CI); p-value	0.70 (0.54, 0.90); 0.0057	

LBA8502: CAMPASS: Benmelstobart in combination with anlotinib vs pembrolizumab in the first-line treatment of advanced non-small cell lung cancer (aNSCLC): A randomized, single-blind, multicenter phase 3 study – Han B, et al

- **Key results (cont.)**

PFS subgroup analyses



LBA8502: CAMPASS: Benmelstobart in combination with anlotinib vs pembrolizumab in the first-line treatment of advanced non-small cell lung cancer (aNSCLC): A randomized, single-blind, multicenter phase 3 study – Han B, et al

- **Key results (cont.)**

Outcomes	Benmelstobart + anlotinib (n=354)	Pembrolizumab + placebo (n=177)
BOR, n (%)		
CR	1 (0.3)	1 (0.6)
PR	202 (57.1)	69 (39.0)
SD	101 (28.5)	70 (39.5)
PD	36 (10.2)	27 (15.3)
NE	14 (4.0)	10 (5.6)
ORR, n (%) [95%CI]	203 (57.3) [52.0, 62.6]	70 (39.5) [32.3, 47.2]
Odds ratio (95%CI); p-value[a]	2.08 (1.43, 3.01); 0.0001	
DCR, n (%) [95%CI]	304 (85.9) [81.8, 89.3]	140 (79.1) [72.4, 84.8]
p-value[a]	0.047	

AEs, n, %	Benmelstobart + anlotinib (n=352)	Pembrolizumab + placebo (n=176)
TRAEs		
Any	346 (98.3)	155 (88.1)
≥Grade 3	206 (58.5)	51 (29.0)
Serious	89 (25.3)	37 (21.0)
Led to any discontinuation	25 (7.1)	14 (8.0)
Led to death	5 (1.4)	4 (2.3)
irAEs	151 (42.9)	70 (39.8)
≥Grade 3	38 (10.8)	22 (12.5)

- **Conclusions**
  - In patients with advanced NSCLC, 1L benmelstobart + anlotinib prolonged PFS compared to pembrolizumab alone, particularly in patients with high PD-L1 (≥50%) levels and showed a manageable safety profile
  - Extended follow-up is needed to achieve mature OS outcomes

[a]Chi-square or Fisher's exact probability.

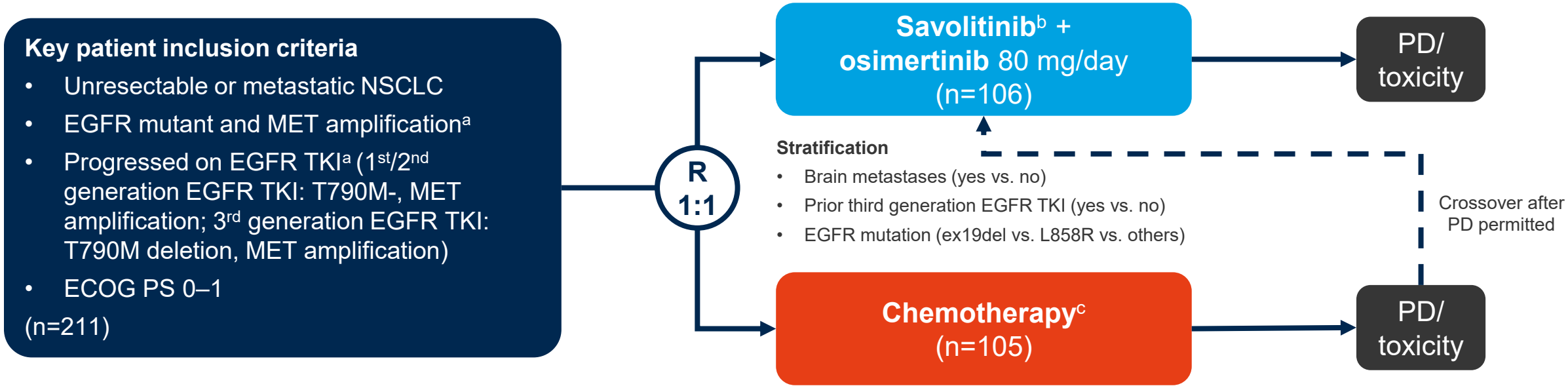
Han B, et al. J Clin Oncol 2025;43(suppl):Abstr LBA8502

Advanced NSCLC
Not radically treatable stage III and stage IV

Targeted therapies

LBA8505: Savolitinib (Savo) combined with osimertinib (osi) versus chemotherapy (chemo) in EGFR-mutant (EGFRm) and MET-amplification (METamp) advanced NSCLC after disease progression (PD) on EGFR tyrosine kinase inhibitor (TKI): Results from a randomized phase 3 SACHI study – Lu S, et al

- **Study objective**
  - To evaluate the efficacy and safety of savolitinib + osimertinib in patients with EGFR-mutant and MET-amplified advanced NSCLC following disease progression on an EGFR TKI in the phase 3 SACHI trial



Primary endpoint

- PFS (investigator)

Secondary endpoints

- PFS (IRC), ORR, DCR, DoR, TTR, OS, safety

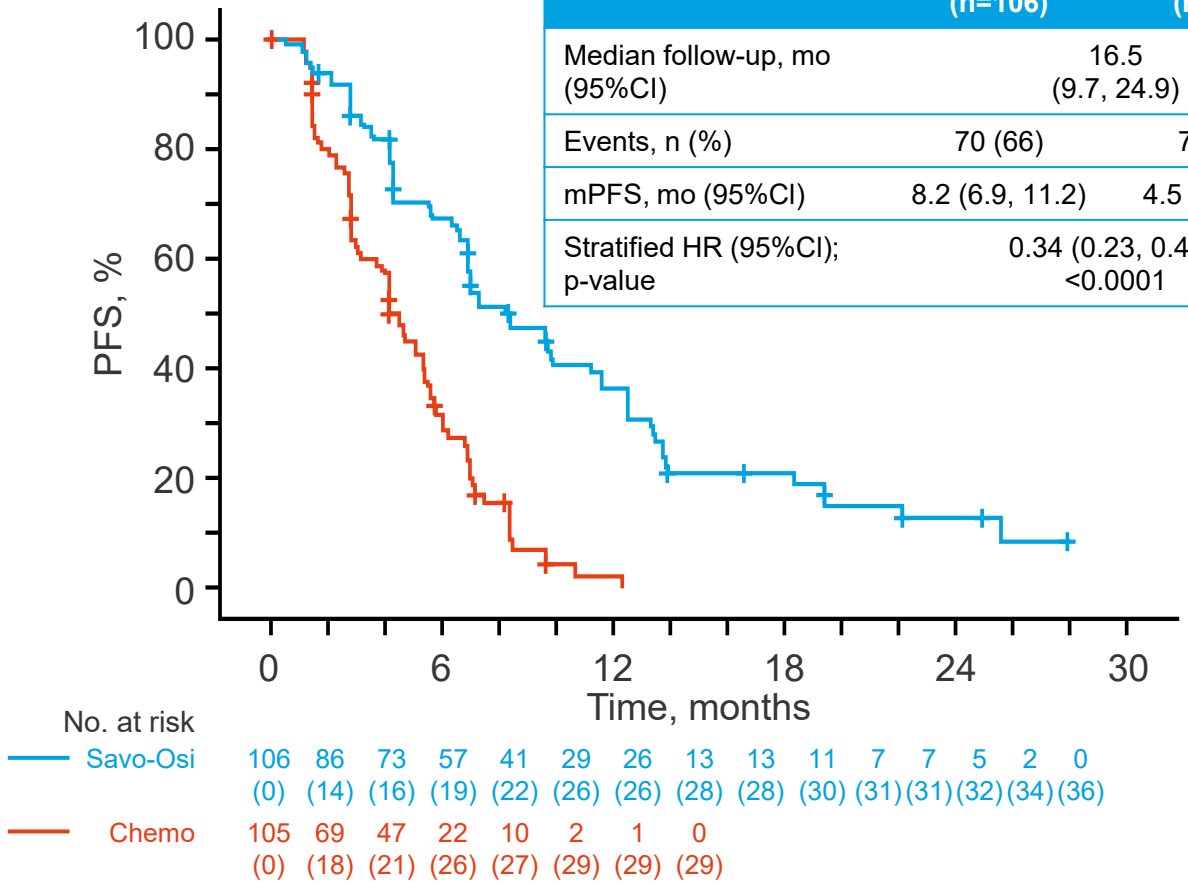
[a]Post 1st/2nd generation EGFR-TKI: MET copy number ≥5 or MET/CEP7 ≥2; post 3rd generation EGFR-TKI: MET copy number ≥10. MET amplification confirmed by central laboratory (FISH+). [b]400 mg/day: body weight <50 kg; 600 mg/day: body weight ≥50 kg; [c]platinum + pemetrexed (4–6 cycles) then pemetrexed.

Lu S, et al. J Clin Oncol 2025;43(suppl):Abstr LBA8505

LBA8505: Savolitinib (Savo) combined with osimertinib (osi) versus chemotherapy (chemo) in EGFR-mutant (EGFRm) and MET-amplification (METamp) advanced NSCLC after disease progression (PD) on EGFR tyrosine kinase inhibitor (TKI): Results from a randomized phase 3 SACHI study – Lu S, et al

- **Key results**

PFS in the ITT population



	Savo-Osi (n=106)	Chemo (n=105)
Median follow-up, mo (95%CI)	16.5 (9.7, 24.9)	
Events, n (%)	70 (66)	76 (72)
mPFS, mo (95%CI)	8.2 (6.9, 11.2)	4.5 (3.0, 5.4)
Stratified HR (95%CI); p-value	0.34 (0.23, 0.49); <0.0001	

PFS by subgroups

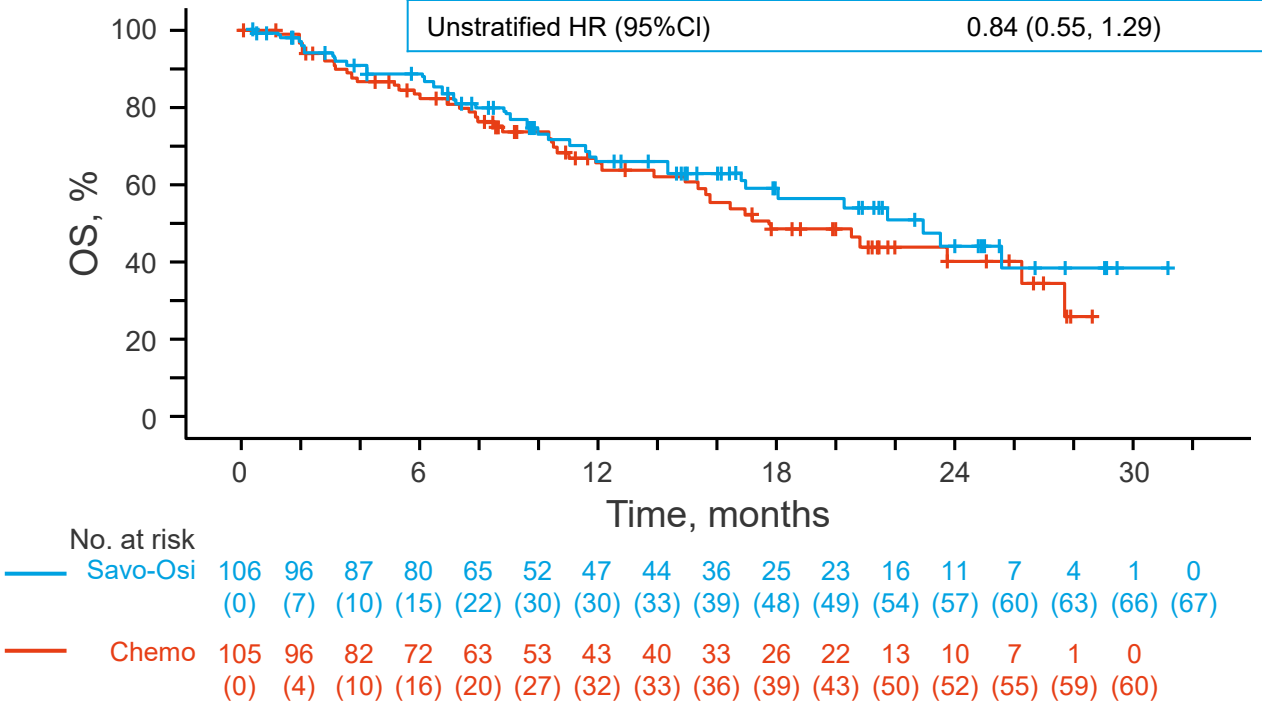
PFS by subgroups	Savo-Osi	Chemo
Prior first/second generation EGFR TKI, n	69	68
Median follow-up, mo (95%CI)	13. (8.3, 22.1)	
Events, n (%)	40 (58)	44 (65)
mPFS, mo, (95%CI)	9.8 (6.9, 12.5)	5.4 (4.2, 6.0)
Unstratified HR (95%CI); p-value	0.34 (0.21, 0.56); <0.0001	
Prior third generation EGFR TKI, n	37	37
Median follow-up, mo (95%CI)	24.9 (6.6, NE)	
Events, n (%)	30 (81)	32 (86)
mPFS, mo, (95%CI)	6.9 (4.2, 9.7)	3.0 (2.7, 4.6)
Unstratified HR (95%CI); p-value	0.32 (0.18, 0.57); <0.0001	
With brain metastases, n	38	39
Events, n (%)	28 (74)	31 (79)
mPFS, mo, (95%CI)	6.9 (4.3, 9.8)	4.7 (2.8, 5.6)
Unstratified HR (95%CI); p-value	0.40 (0.23, 0.71); 0.0011	
Without brain metastases, n	68	66
Events, n (%)	42 (62)	45 (68)
mPFS, mo, (95%CI)	9.6 (6.9, 12.5)	4.2 (2.9, 5.6)
Unstratified HR (95%CI); p-value	0.30 (0.18, 0.48); <0.0001	

LBA8505: Savolitinib (Savo) combined with osimertinib (osi) versus chemotherapy (chemo) in EGFR-mutant (EGFRm) and MET-amplification (METamp) advanced NSCLC after disease progression (PD) on EGFR tyrosine kinase inhibitor (TKI): Results from a randomized phase 3 SACHI study – Lu S, et al

- **Key results (cont.)**

OS in the ITT population

	Savo-Osi (n=106)	Chemo (n=105)
Median follow-up, mo (95%CI)	17.7 (15.3, 19.8)	
Events, n (%)	39 (37)	45 (43)
mOS, mo (95%CI)	22.9 (16.8, NE)	17.7 (14.9, 26.3)
Unstratified HR (95%CI)	0.84 (0.55, 1.29)	



	Savo-Osi (n=106)	Chemo (n=105)
ORR, %(95%CI)	58 (49, 68)	34 (25, 44)
Stratified OR (95%CI); p-value	2.74 (1.50, 4.98); 0.0004	
DCR, % (95%CI)	89 (81, 94)	67 (57, 76)
Stratified OR (95%CI); p-value	3.98 (1.81, 8.82); 0.0001	
Median DoR, mo (95%CI)	8.4 (5.9, 11.1)	3.2 (2.8, 4.2)

Lu S, et al. J Clin Oncol 2025;43(suppl):Abstr LBA8505

LBA8505: Savolitinib (Savo) combined with osimertinib (osi) versus chemotherapy (chemo) in EGFR-mutant (EGFRm) and MET-amplification (METamp) advanced NSCLC after disease progression (PD) on EGFR tyrosine kinase inhibitor (TKI): Results from a randomized phase 3 SACHI study – Lu S, et al

- **Key results (cont.)**

AEs, n, %	Savolitinib + osimertinib (n=106)	Chemotherapy (n=96)
At least one TEAEs	104 (98)	92 (96)
Grade ≥3	60 (57)	55 (57)
Led to dose modification of any drug	58 (55)	51 (53)
Led to dose discontinuation of any drug	9 (8)	8 (8)
Serious TEAEs	40 (38)	27 (28)
At least one TRAEs	103 (97)	91 (95)
Grade ≥3	48 (45)	46 (48)
Led to dose modification of any drug	50 (47)	38 (40)
Led to dose discontinuation of any drug	6 (6)	8 (8)
Serious TRAEs	29 (27)	21 (21)
Death during treatment cycles	11 (10)	7 (7)

Conclusions

- In patients with EGFR-mutant and MET-amplified advanced NSCLC, savolitinib + osimertinib provided a significant PFS benefit over chemotherapy and was well tolerated
- The analysis was not mature for OS

8500: First-line adagrasib (ADA) with pembrolizumab (PEMBRO) in patients (pts) with advanced/metastatic KRASG12C-mutated non-small cell lung cancer (NSCLC) from the phase 2 portion of the KRYSTAL-7 study – Jänne PA, et al

- **Study objective**
  - To evaluate the efficacy and safety of 1L adagrasib + pembrolizumab in patients with KRAS G12C-mutant advanced or metastatic NSCLC in the phase 2 portion of the KRYSTAL-7 trial

Key patient inclusion criteria

- Advanced, unresectable or metastatic NSCLC
- KRAS G12C mutant
- No prior treatment
- CNS metastases allowed

(n=150)

→ **Adagrasib** 400 mg PO BID + **pembrolizumab** 200 mg IV q3w

Primary endpoint

- ORR (investigator, RECIST v1.1)

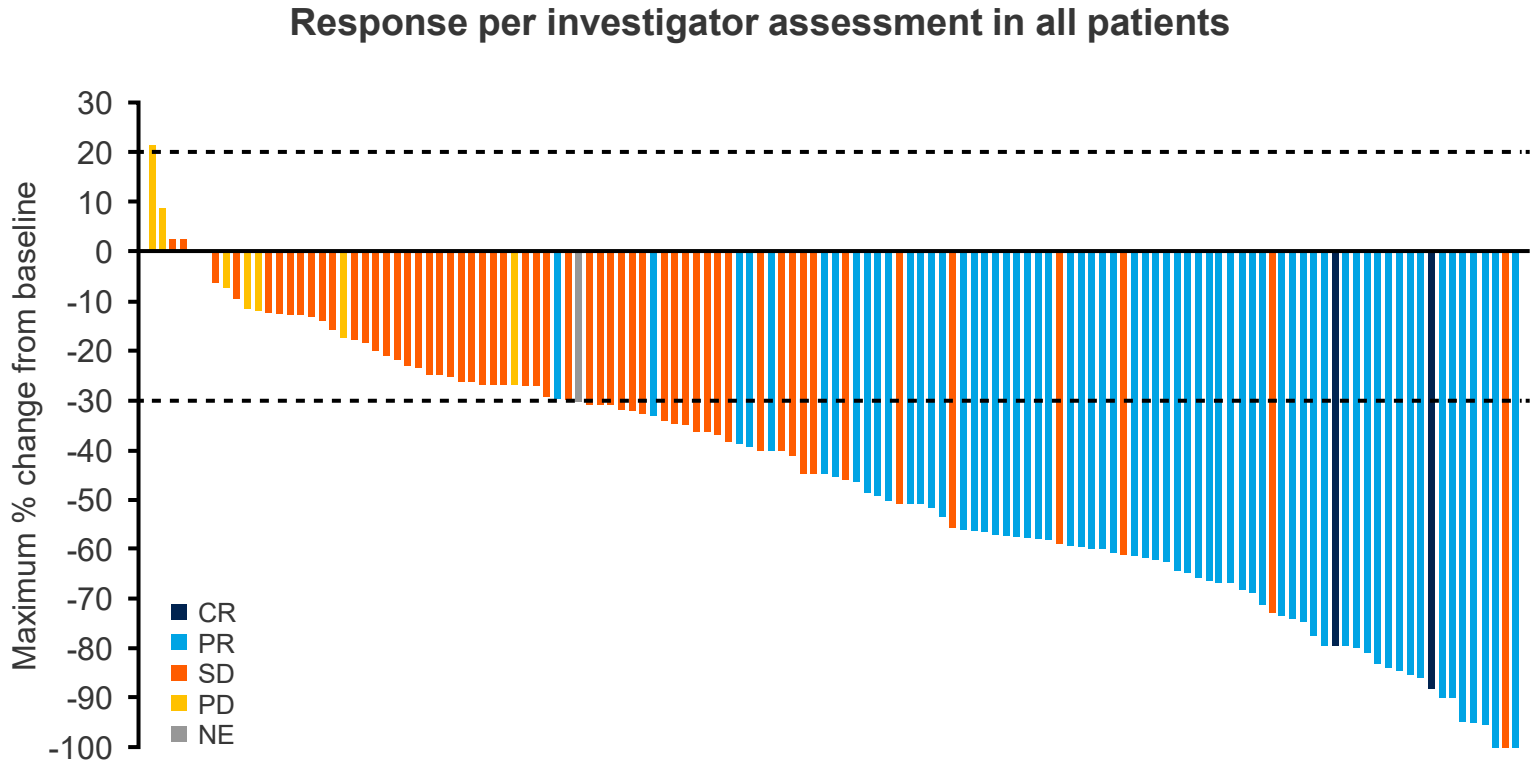
Secondary endpoints

- DoR, PFS, OS and safety

8500: First-line adagrasib (ADA) with pembrolizumab (PEMBRO) in patients (pts) with advanced/metastatic KRASG12C-mutated non-small cell lung cancer (NSCLC) from the phase 2 portion of the KRYSTAL-7 study – Jänne PA, et al

- **Key results**

	All patients (n=149)
ORR, n (%) [95%CI]	66 (44) [36, 53]
BOR, n (%)	
CR	2 (1)
PR	64 (43)
SD	55 (37)
PD	12 (8)
NE	16 (11)
DCR, n (%) [95%CI]	121 (81) [74, 87]



8500: First-line adagrasib (ADA) with pembrolizumab (PEMBRO) in patients (pts) with advanced/metastatic KRASG12C-mutated non-small cell lung cancer (NSCLC) from the phase 2 portion of the KRYSTAL-7 study – Jänne PA, et al

- **Key results (cont.)**

	All patients (n=149)
mPFS, mo (95%CI)	11.0 (5.8, 14.0)
Events, n (%)	83 (56)
mOS, mo (95%CI)	18.3 (14.3, NE)
Events, n (%)	73 (49)

	PD-L1 <1% (n=39)	PD-L1 1–49% (n=27)	PD-L1 ≥50% (n=38)
mPFS, mo (95%CI)	8.2 (2.7, 13.6)	13.5 (2.3, NE)	27.7 (9.6, NE)
Events, n (%)	27 (69)	15 (56)	17 (45)
mOS, mo (95%CI)	15.5 (9.6, NE)	14.3 (8.3, NE)	NR (19.4, NE)
Events, n (%)	22 (56)	14 (52)	13 (34)

AEs, n (%)	PD-L1 <50% (n=95)	PD-L1 ≥50% (n=54)	All patients (n=149)
TRAEs			
Any grade	91 (96)	50 (93)	141 (95)
Grade 3	54 (57)	32 (59)	86 (58)
Grade 4	13 (14)	3 (6)	16 (11)
Grade 5	3 (3)	0	3 (2)*
TRAEs led to			
Adagrasib dose interruption	65 (68)	35 (65)	100 (67)
Adagrasib dose reduction†	50 (53)	22 (41)	72 (48)
Adagrasib discontinuation	5 (5)	5 (9)	10 (7)
Pembrolizumab dose reduction	19 (20)	6 (11)	25 (17)
Adagrasib + pembrolizumab discontinuation	7 (7)	3 (6)	10 (7)
Any grade irAEs	23 (24)	10 (19)	33 (22)

*Pneumonitis (n=1), pneumonia (n=2); †ALT increased (11%), AST increased (7%), nausea (7%), and lipase increased (5%).

Jänne PA, et al. J Clin Oncol 2025;43(suppl):Abstr 8500

8500: First-line adagrasib (ADA) with pembrolizumab (PEMBRO) in patients (pts) with advanced/metastatic KRASG12C-mutated non-small cell lung cancer (NSCLC) from the phase 2 portion of the KRYSTAL-7 study – Jänne PA, et al

- **Key results (cont.)**

	All patients (n=149)				
Hepatic TRAEs, n (%)	Any grade	Grade 1	Grade 2	Grade 3	Grade 4
Any	88 (59)	25 (17)	20 (13)	41 (28)	2 (1)
Occurring in ≥4% of patients					
ALT increased	59 (40)	23 (15)	19 (13)	16 (11)	1 (<1)
AST increased	53 (36)	20 (13)	12 (8)	19 (13)	2 (1)
Blood ALP increase	29 (19)	12 (8)	7 (5)	10 (7)	0
GGT increase	10 (7)	2 (1)	2 (1)	6 (4)	0
Blood bilirubin increase	6 (4)	4 (3)	1 (<1)	1 (<1)	0
Abnormal hepatic function	6 (4)	3 (2)	1 (<1)	2 (1)	0
Hepatitis	6 (4)	0 (0)	3 (2)	3 (2)	0

Hepatic TRAEs led to, n (%)	All patients (n=149)
Adagrasib discontinuation only	2 (1)*
Pembrolizumab discontinuation only	9 (6)†
Adagrasib and pembrolizumab discontinuation	1 (<1)‡

- **Conclusions**
  - In patients with KRAS G12C-mutant advanced or metastatic NSCLC, 1L adagrasib + pembrolizumab demonstrated encouraging antitumor activity with a manageable safety profile

*Grade 3 ALT increase and Grade 4 ALT increase (n=1, each). †AST increase (n=4), ALT increase (n=4), blood ALP increase (n=2), hepatic enzyme increased, abnormal hepatic function, hepatitis, immune-mediated hepatic disorder, and liver function test increase (n=1, each). ‡Grade 4 AST increase (n=1).

8519: Safety and efficacy of olomorasib + immunotherapy in first-line treatment of patients with KRAS G12C-mutant advanced NSCLC: Update from the LOXO-RAS-20001 trial – Dragnev KH, et al

- **Study objective**
  - To evaluate the updated efficacy and safety of 1L olomorasib + immunotherapy in patients with KRAS G12C-mutant advanced NSCLC in the LOXO-RAS-20001 trial

Key patient inclusion criteria

- Advanced NSCLC
- KRAS G12C mutant
- Any PD-L1 expression

Part G

- Treatment-naïve

Part B4

- Received prior treatment

(n=48)

Part G: 1L NSCLC
Olomorasib 50 or 100 mg BID + **pembrolizumab** 200 mg q3w (n=43)

Part B4: Line-agnostic NSCLC
Olomorasib 50 or 100 mg BID + **pembrolizumab** 200 mg q3w (1L, n=5)

Stratification

- Olomorasib dose (50 vs. 100 mg BID)
- PD-L1 (0–49% vs. ≥50)

Primary endpoint

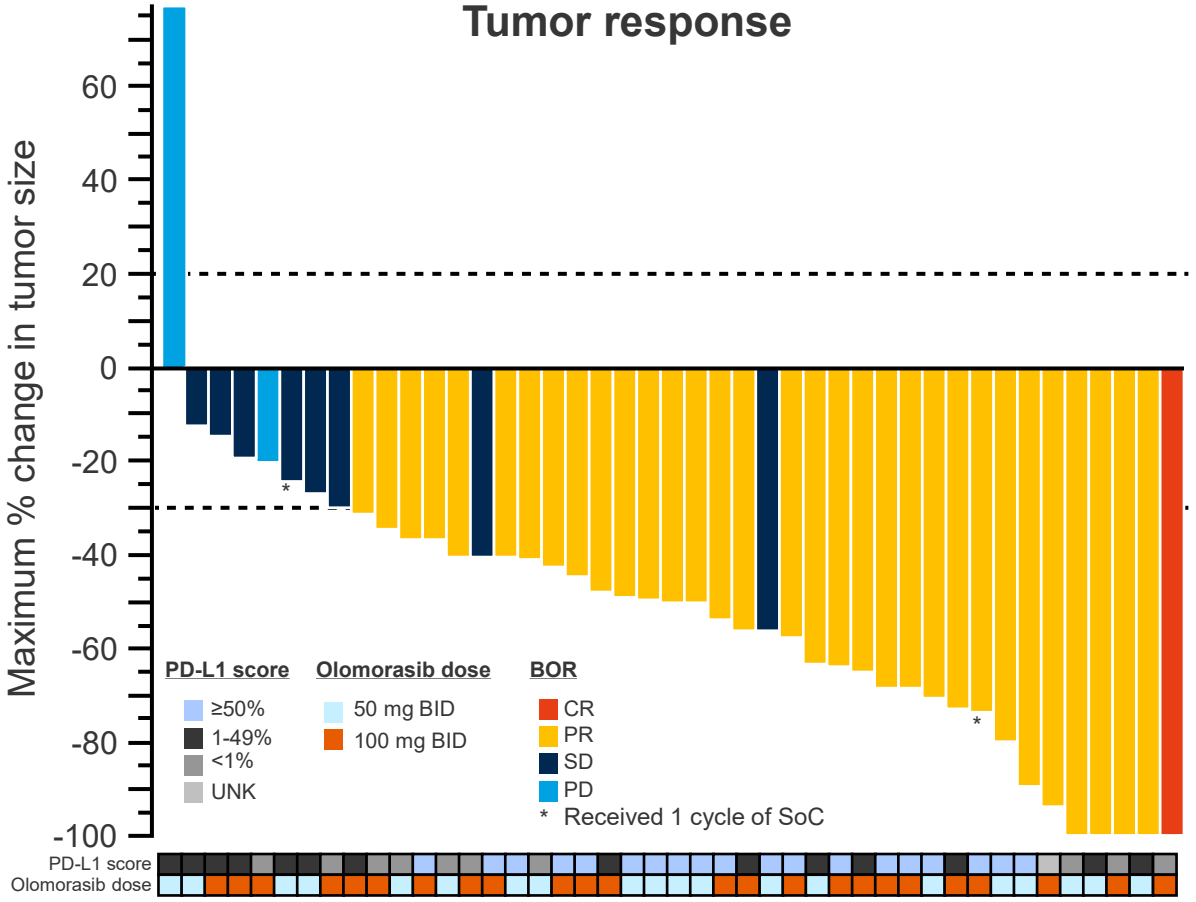
- Safety

Secondary endpoints

- MTD, R2PD, PK, ORR, DCR, PFS, DoR

8519: Safety and efficacy of olomorasib + immunotherapy in first-line treatment of patients with KRAS G12C-mutant advanced NSCLC: Update from the LOXO-RAS-20001 trial – Dragnev KH, et al

- **Key results**



	Olomorasib + pembrolizumab	
	All (n=46)	PD-L1 ≥50% (n=20)
BOR, n (%)		
CR	1 (2)	0
PR	33 (72)	18 (90)
SD	8 (17)	1 (5)
PD	3 (7)	1 (5)
NE	1 (2)	0
ORR, % (95%CI)	74 (58.9, 85.7)	90 (68.3, 98.8)
DCR, % (95%CI)	91 (79.2, 97.6)	95 (75.1, 99.9)
mDoR, mo (95%CI)	NE (10.5, NE)	NE (10.5, NE)
mPFS, mo (95%CI)	NE (12.0, NE)	NE (12.0, NE)
6-mo PFS rate, % (95%CI)	80.2 (64.1, 89.6)	89.7 (64.8, 97.3)
12-mo PFS rate, % (95%CI)	66.7 (40.9, 83.2)	59.8 (8.2, 90.0)

8519: Safety and efficacy of olomorasib + immunotherapy in first-line treatment of patients with KRAS G12C-mutant advanced NSCLC: Update from the LOXO-RAS-20001 trial – Dragnev KH, et al

- **Key results (cont.)**

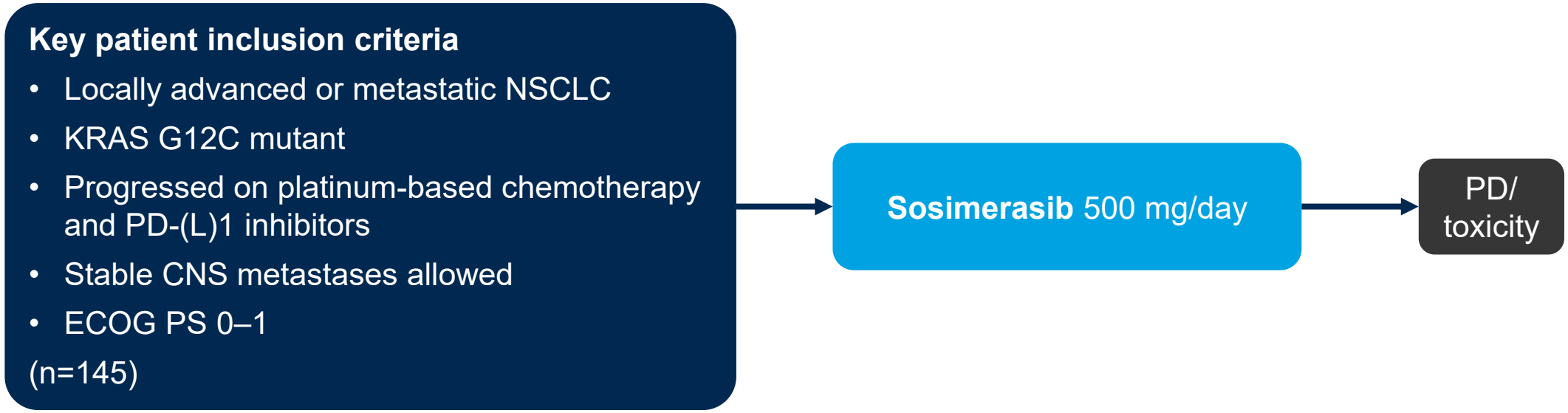
	Olomorasib 50 or 100 mg BID + pembrolizumab (n=48)			
	TEAEs ≥10%		TRAEs	
AEs, n (%)	Any grade	Grade ≥3	Any grade	Grade 3
Any AE	45 (93.8)	26 (54.2)	43 (89.6)	17 (35.4)
Diarrhea	20 (41.7)	4 (8.3)	17 (35.4)	4 (8.3)
ALT increased	16 (33.3)	11 (22.9)	14 (29.2)	11 (22.9)
AST increased	14 (29.2)	7 (14.9)	14 (29.2)	7 (14.6)
Nausea	13 (27.1)	-	9 (18.8)	-
Fatigue	11 (29.9)	-	7 (14.6)	-
Vomiting	10 (20.8)	-	6 (12.5)	-
Appetite decreased	8 (16.7)	1 (2.1)	6 (12.5)	-
Pruritus	9 (18.8)	-	7 (14.6)	-

	Olomorasib 50 or 100 mg BID + pembrolizumab (n=48)			
	TEAEs ≥10%		TRAEs	
AE, n (%) (cont'd)	Any grade	Grade ≥3	Any grade	Grade 3
Abdominal pain	9 (18.8)	-	3 (6.3)	-
Peripheral edema	8 (16.7)	1 (2.1)	2 (4.3)	-
Constipation	7 (14.6)	1 (2.1)	1 (2.1)	-
Arthralgia	7 (14.6)	1 (2.1)	2 (4.2)	-
Dyspnea	6 (12.5)	2 (4.2)	-	-
Anemia	5 (10.4)	1 (2.1)	2 (4.2)	-
Cough	5 (10.4)	-	-	-
Dizziness	5 (10.4)	-	-	-
Hypertension	5 (10.4)	1 (2.1)	1 (2.1)	1 (2.1)

- **Conclusions**
  - In patients with KRAS G12C-mutant NSCLC, 1L olomorasib + pembrolizumab demonstrated encouraging antitumor activity at any dose and regardless PD-L1 expression; no new safety signals were observed

8520: Sosimerasib monotherapy in patients with previously treated KRAS G12C–mutated non-small cell lung cancer: Primary results of a phase 2 study – Wang J, et al

- **Study objective**
  - To evaluate the efficacy and safety of sosimerasib (KRAS inhibitor) in previously treated patients with KRAS G12C-mutant NSCLC in a phase 2 trial



Primary endpoint

- ORR (IRC, RECIST v1.1)

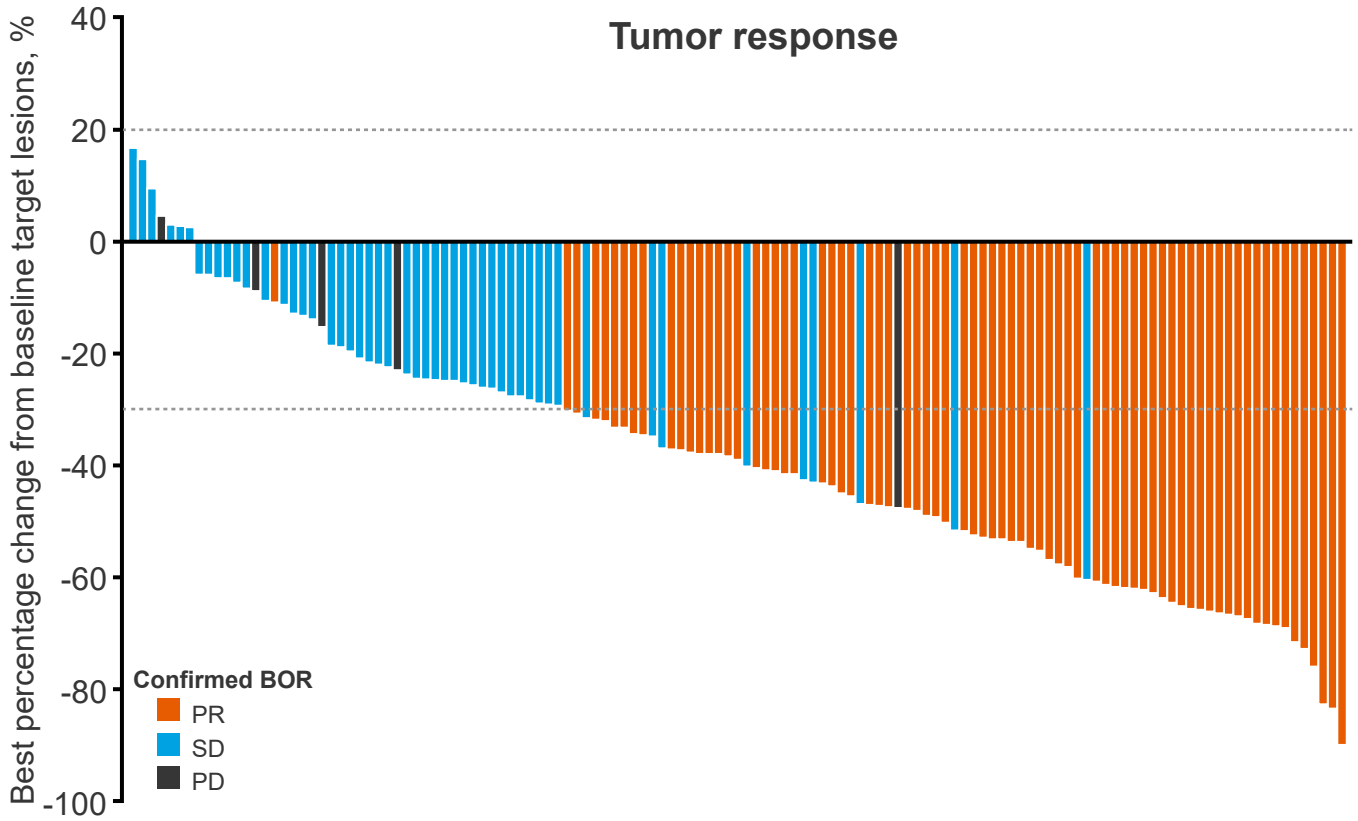
Secondary endpoints

- DoR, DCR, TTR, PFS, OS, safety

8520: Sosimerasib monotherapy in patients with previously treated KRAS G12C–mutated non-small cell lung cancer: Primary results of a phase 2 study – Wang J, et al

- **Key results**

Response (IRC)	Sosimerasib (n=145)
Median follow-up, mo	6.8
Confirmed BOR, n (%)	
PR	76 (52.4)
SD	51 (35.2)
Non-CR/non-PD	8 (5.5)
PD	5 (3.4)
Confirmed ORR, % (95%CI)	52.4 (44.0, 60.8)



Wang J, et al. J Clin Oncol 2025;43(suppl):Abstr 8520

8520: Sosimerasib monotherapy in patients with previously treated KRAS G12C–mutated non-small cell lung cancer: Primary results of a phase 2 study – Wang J, et al

- **Key results (cont.)**

Response (IRC)	Sosimerasib (n=145)
Median follow-up, mo	6.8
DCR, % (95%CI)	87.6 (81.1, 92.5)
mTTR, mo (range)	1.4 (1.2–8.4)
mDoR, mo (95%CI)	NA (5.4, NA)
PFS	
Events, n (%)	62 (42.8)
mPFS, mo (95%CI)	7.2 (5.6, NA)
6-mo PFS rate, % (95%CI)	56.7 (47.5, 65.0)
OS	
Deaths, n (%)	31 (21.4)
mOS, mo (95%CI)	NA (NA, NA)
6-mo OS rate, % (95%CI)	86.6 (79.8, 81.3)

TRAEs, n (%)	Sosimerasib (n=145)
Any	138 (95.2)
Grade ≥3	58 (40.0)
Serious	21 (14.5)
Led to interruption	35 (14.5)
Led dose reduction	15 (10.3)
Led to discontinuation	3 (2.1)

- **Conclusions**
  - In patients with KRAS G12C-mutant NSCLC, sosimerasib demonstrated an encouraging antitumor activity with a manageable safety profile

3013: A first-in-human phase I/II study of GFH375, a highly selective and potent oral KRAS G12D inhibitor in patients with KRAS G12D mutant advanced solid tumors – Ai X, et al

- **Study objective**
  - To evaluate the preliminary efficacy and safety of GFH375 (KRAS G12D inhibitor) in patients with KRAS G12D-mutant advanced solid tumors

Key patient inclusion criteria
- Advanced solid tumors
- KRAS G12D mutant
- Prior treatment with standard therapies
- ECOG PS 0–1

(n=62)

Phase 1: Dose escalation and expansion

GFH375

300 mg BID
900 mg QD
750 mg QD
600 mg QD
400 mg QD
200 mg QD
100 mg QD

Phase 2: Indication expansion

Cohort 1: NSCLC
Cohort 2: PDAC
Cohort 3: CRC
Cohort 4: Other

Phase 1 endpoints
- Safety, MTD, RP2D, antitumor activity, PK, biomarkers

Phase 2 endpoints
- ORR, DoR, DCR, PFS (RECIST, v1.1), OS, safety, biomarkers

Ai X, et al. J Clin Oncol 2025;43(suppl):Abstr 3013

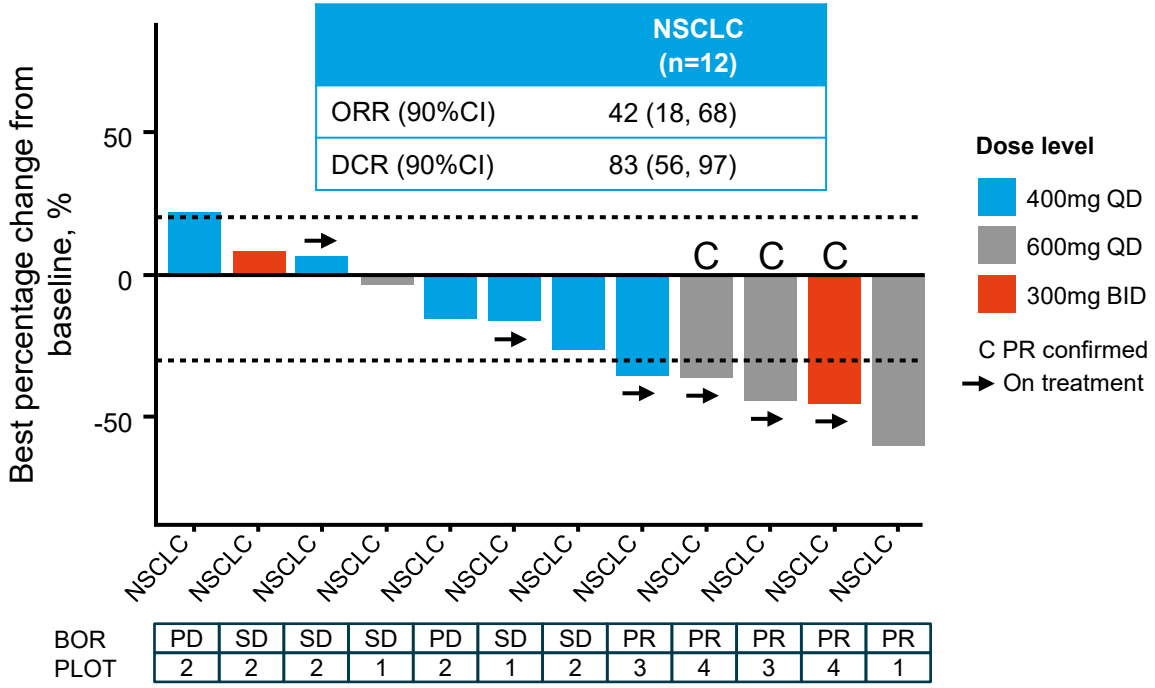
3013: A first-in-human phase I/II study of GFH375, a highly selective and potent oral KRAS G12D inhibitor in patients with KRAS G12D mutant advanced solid tumors – Ai X, et al

- **Key results**

Best percentage change in sum of target lesion measurements

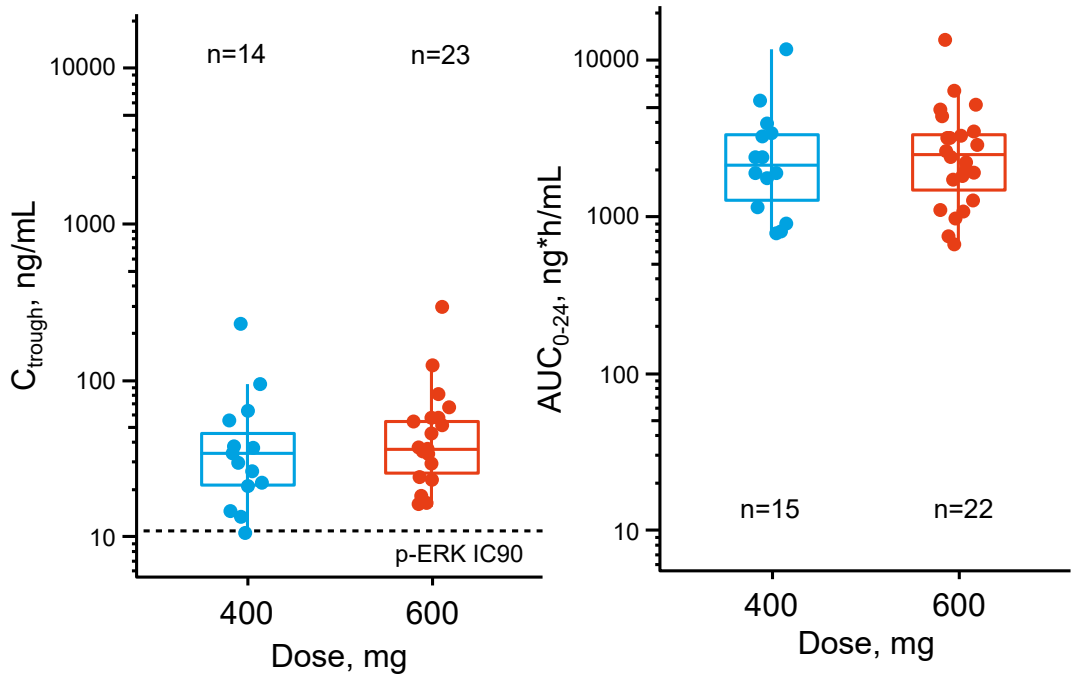
	All patients (n=52)	400 mg QD + 600 mg QD + 300 mg BID (n=43)
ORR (90%CI)	38 (27, 51)	42 (29, 56)
DCR (90%CI)	90 (81, 96)	91 (80, 97)

	NSCLC (n=12)
ORR (90%CI)	42 (18, 68)
DCR (90%CI)	83 (56, 97)



BOR	PD	SD	SD	SD	PD	SD	SD	PR	PR	PR	PR	PR
PLOT	2	2	2	1	2	1	2	3	4	3	4	1

Exposure of GFH375



3013: A first-in-human phase I/II study of GFH375, a highly selective and potent oral KRAS G12D inhibitor in patients with KRAS G12D mutant advanced solid tumors – Ai X, et al

- **Key results (cont.)**

TRAEs, n (%)	All patients (n=162)		400 mg QD + 600 mg QD + 300 mg BID (n=43)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Any	62 (100)	18 (29)	49 (100)	15 (31)
Led to dose reduction	7 (11)	3 (5)	5 (10)	1 (2)
Led to interruption	13 (21)	7 (11)	9 (18)	6 (12)
Led to discontinuation	2 (3)	2 (3)	2 (4)	2 (4)
Serious	6 (10)	5 (8)	5 (10)	4 (8)

TRAEs occurring in ≥20% of patients, n (%)	All patients (n=162)		400 mg QD + 600 mg QD + 300 mg BID (n=43)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Diarrhea	43 (69)	3 (5)	34 (69)	2 (4)
Nausea	42 (68)	0	34 (69)	0
Vomiting	38 (61)	1 (2)	29 (59)	1 (2)
Anemia	32 (52)	0	26 (53)	0
Appetite decreased	24 (39)	0	20 (41)	0
Neutrophil count decreased	21 (34)	5 (8)	17 (35)	4 (8)
WBC count decreased	20 (32)	1 (2)	15 (31)	1 (2)
AST increased	20 (32)	1 (2)	16 (33)	0
Hypoalbuminemia	17 (27)	0	12 (24)	0
Asthenia	17 (27)	1 (2)	15 (31)	1 (2)
ALT increase	15 (24)	0	13 (27)	0

- **Conclusions**
  - In patients with KRAS G12D-mutant advanced solid tumors, GFH375 once daily showed a tolerable safety profile and promising initial tumor activity

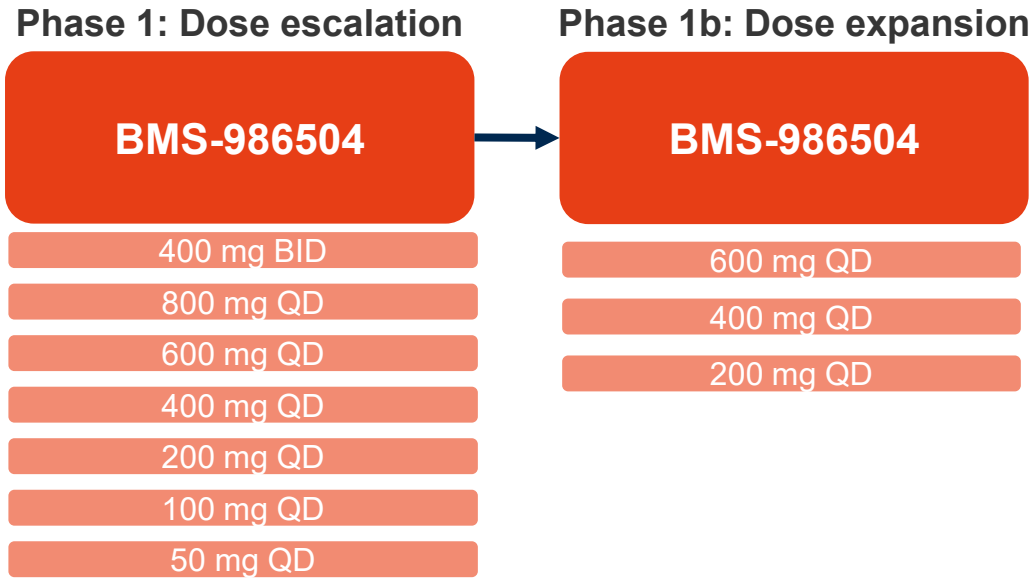
3011: BMS-986504 in patients (pts) with advanced solid tumors with homozygous MTAP deletion (MTAP-del): Clinical update and first report of pharmacokinetics (PK) and pharmacodynamic (PD) analyses from CA240-0007 – Arbour KC, et al

- **Study objective**
  - To evaluate the preliminary efficacy and safety of BMS-986504 (PRMT5/inhibitor) in patients with homozygous MTAP-deleted advanced solid tumors in the CA240-0007 trial

Key patient inclusion criteria

- Advanced solid tumors*
- Homozygous MTAP deletion
- Progressed on or after previous treatment

(n=163)



Primary endpoint

- Safety

Secondary endpoints

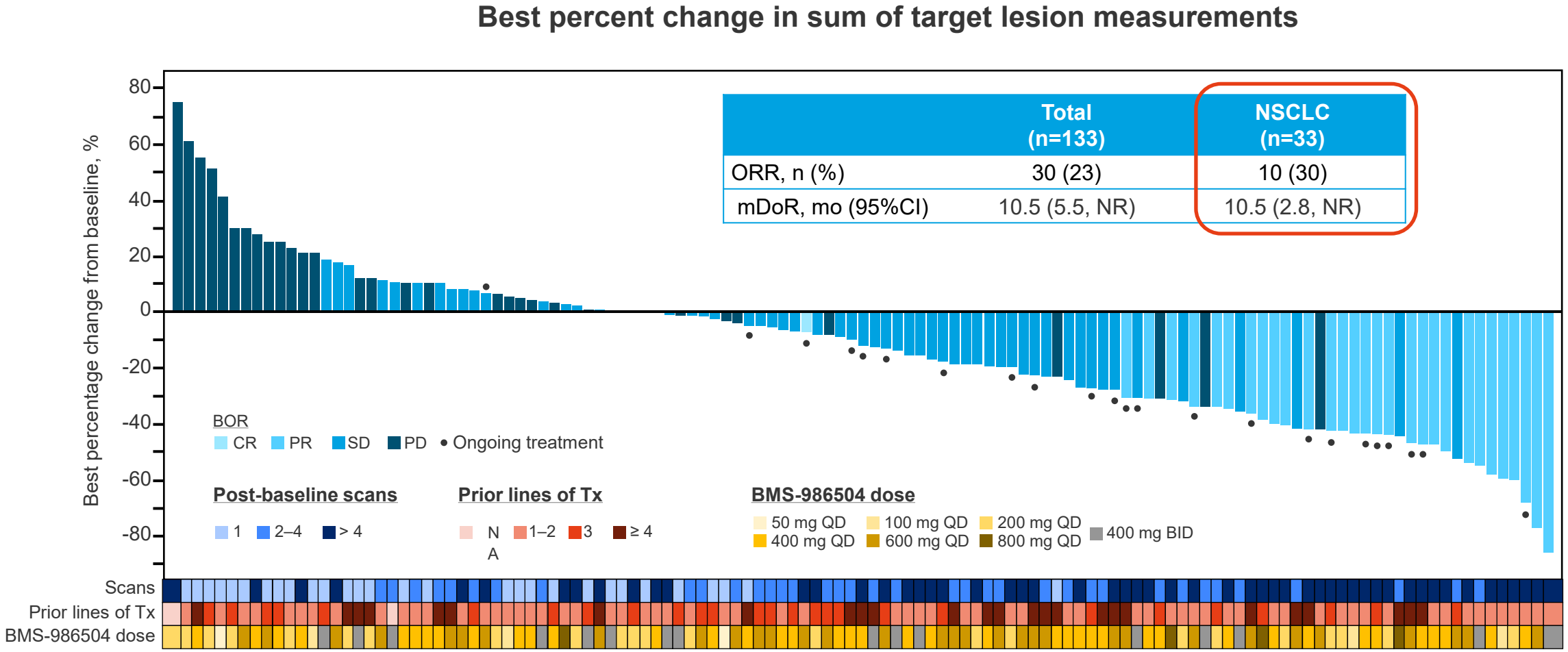
- Pharmacokinetics, efficacy, pharmacodynamics

*NSCLC, PDAC, cholangiocarcinoma, mesothelioma, MPNST, HNSCC, breast cancer, melanoma, other.

Arbour KC, et al. J Clin Oncol 2025;43(suppl):Abstr 3011

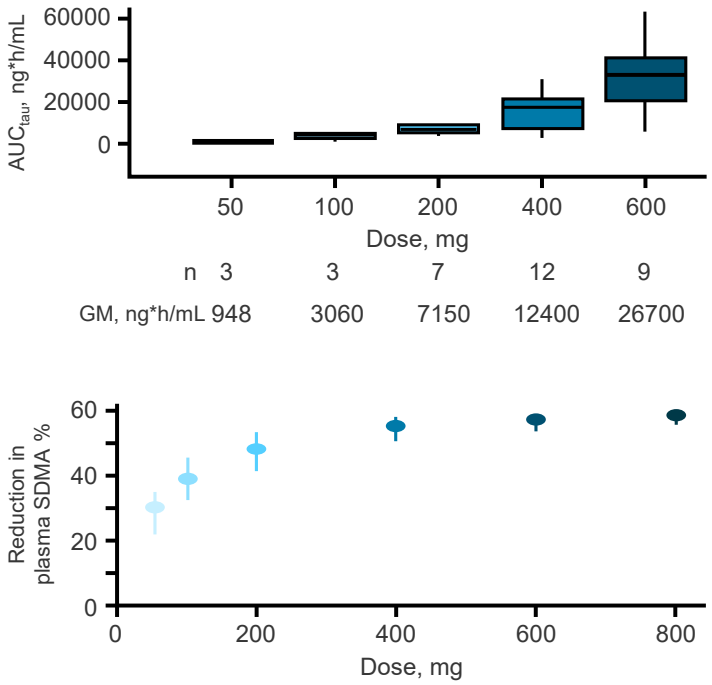
3011: BMS-986504 in patients (pts) with advanced solid tumors with homozygous MTAP deletion (MTAP-del): Clinical update and first report of pharmacokinetics (PK) and pharmacodynamic (PD) analyses from CA240-0007 – Arbour KC, et al

- **Key results**



3011: BMS-986504 in patients (pts) with advanced solid tumors with homozygous MTAP deletion (MTAP-del): Clinical update and first report of pharmacokinetics (PK) and pharmacodynamic (PD) analyses from CA240-0007 – Arbour KC, et al

- **Key results (cont.)**



n (%)	Total (n=163) Any grade	Grade ≥3
TEAEs	157 (96)	78 (48)
Led to discontinuation	6 (4)	
Serious	47 (29)	
TRAEs	125 (77)	21 (13)
Leding to discontinuation	4 (2)	
Serious	6 (4)	

- **Conclusions**
  - In patients with homozygous MTAP-deleted advanced solid tumors, including NSCLC, BMS-986504 demonstrated encouraging antitumor activity and was well tolerated

Advanced NSCLC
Not radically treatable stage III and stage IV

ADC and other therapies

8501: TROPION-Lung02: Datopotamab deruxtecan (Dato-DXd) plus pembrolizumab (pembro) with or without platinum chemotherapy (Pt-CT) as first-line (1L) therapy for advanced non-small cell lung cancer (aNSCLC) – Levy BP, et al

- **Study objective**
  - To evaluate the efficacy and safety of 1L datopotamab deruxtecan + pembrolizumab ± platinum chemotherapy in patients with advanced NSCLC in the phase 1b TROPION-Lung02 trial

Key patient inclusion criteria

- Advanced or metastatic NSCLC
- Dose escalation: ≤2 lines of prior therapy
- Dose expansion: ≤1 line of platinum-based chemotherapy (Cohorts 1 and 2) and no prior therapy (Cohorts 3–6)

- **Cohort 1**: Dato-DXd 4 mg/kg + pembrolizumab[a] IV q3w (n=2)
- **Cohort 2**: Dato-DXd 6 mg/kg + pembrolizumab[a] IV q3w (n=40)
- **Cohort 3**: Dato-DXd 4 mg/kg + pembrolizumab[a] + carboplatin AUC5 IV q3w (n=14)
- **Cohort 4**: Dato-DXd 6 mg/kg + pembrolizumab[a] + carboplatin AUC5 IV q3w (n=26)
- **Cohort 5**: Dato-DXd 4 mg/kg + pembrolizumab[a] + cisplatin 75 mg/m^2 IV q3w (n=8)
- **Cohort 6**: Dato-DXd 6 mg/kg + pembrolizumab[a] + cisplatin 75 mg/m^2 IV q3w (n=6)

Primary endpoint

- Safety

Secondary endpoints

- Efficacy, PK, immunogenicity

[a]Pembrolizumab 200 mg and treatments administered sequentially at the same visit.

Levy BP, et al. J Clin Oncol 2025;43(suppl):Abstr 8501

8501: TROPION-Lung02: Datopotamab deruxtecan (Dato-DXd) plus pembrolizumab (pembro) with or without platinum chemotherapy (Pt-CT) as first-line (1L) therapy for advanced non-small cell lung cancer (aNSCLC) – Levy BP, et al

- **Key results**

AEs, n (%)	Doublet (n=42)	Triplet (n=54)
TRAEs	39 (92.9)	54 (100)
Grade ≥3	17 (40.5)	30 (55.6)
TRAEs led to		
Dose reduction of any drug	8 (19.0)	14 (25.9)
Dose reduction of Dato-DXd	8 (19.0)	7 (13.0)
Discontinuation of any drug	14 (33.3)	20 (37.0)
Discontinuation of Dato-DXd	13 (31.0)	16 (29.6)
Serious TRAEs	5 (11.9)	12 (22.2)
Grade ≥3	4 (9.5)	9 (16.7)
AESIs		
Oral mucositis/stomatitis	26 (61.9)	22 (40.7)
Grade 3	2 (4.8)	1 (1.9)
Adjudicated drug-related ILD/pneumonitis	11 (26.2)	14 (25.9)
Grade 3	2 (4.8)	1 (1.9)
Ocular surface events	9 (21.4)	18 (33.3)
Grade 3	1 (2.4)	2 (3.7)

TRAEs occurring in ≥20% of patients, %	Doublet		Triplet	
	G 1–2	G≥3	G 1–2	G≥3
Stomatitis	52	5	28	2
Nausea	40	0	37	6
Anemia	10	2	33	13
Appetite decreased	17	2	30	0
Pneumonitis	21	2	24	0
Increased amylase	14	14	9	9
Fatigue	14	2	22	6
Alopecia	33	0	13	0
Pruritus	26	0	11	0
Vomiting	7	0	26	0
Constipation	24	0	11	0
Platelet count decreased	0	0	26	4
Blood creatine increased	7	0	20	2
Rash	21	0	11	0
Neutropenia	2	0	11	13
Neutrophil count decreased	0	0	11	15

8501: TROPION-Lung02: Datopotamab deruxtecan (Dato-DXd) plus pembrolizumab (pembro) with or without platinum chemotherapy (Pt-CT) as first-line (1L) therapy for advanced non-small cell lung cancer (aNSCLC) – Levy BP, et al

- **Key results (cont.**

Response	Doublet (n=42)	Triplet (n=54)
Confirmed ORR, n (%) [95%CI]	23 (54.8) [38.7, 70.2]	30 (55.6) [41.4, 69.1]
mDoR, months (95%CI)	20.1 (9.7, NE)	13.7 (5.7, NE)
DCR, n (%) [95%CI]	37 (88.1) [74.4, 96.0]	48 (88.9) [77.4, 95.8]
mTTR, mo (range)	1.4 (1.2–7.0)	1.4 (1.2–9.6)
mPFS, mo (95%CI)	11.2 (8.2, 21.3)	6.8 (5.5, 11.1)
mOS, mo (95%CI)	NE (19.2, NE)	17.4 (9.1, NE)

	Doublet		Triplet	
Response by PD-L1 status	PD-L1 <50% (n=30)	PD-L1 ≥50% (n=5)	PD-L1 <50% (n=40)	PD-L1 ≥50% (n=10)
Confirmed ORR, % (95%CI)	53.3 (34.3, 71.7)	100 (47.8, 100)	55.0 (38.5, 70.7)	60.0 (26.2, 87.8)
BOR, %				
CR PR	3.3 50.0	0 100	2.5 52.5	10.0 50.0
DoR, mo (95%CI)	12.0 (8.0, NE)	NE (5.5, NE)	14.6 (5.3, NE)	NE (4.1, NE)
DCR, % (95%CI)	96.7 (82.8, 99.9)	100 (47.8, 100)	87.5 (73.2. 95.8)	90.0 (55.5, 99.7)
mPFS, mo (95%CI)	11.1 (7.2, 13.3)	NE (8.3, NE)	6.4 (5.5, 13.2)	6.8 (0.8, NE)
mOS, mo (95%CI)	NE (19.2, NE)	NE (12.6, NE)	13.3 (7.7, NE)	NE (0.8, NE)

8501: TROPION-Lung02: Datopotamab deruxtecan (Dato-DXd) plus pembrolizumab (pembro) with or without platinum chemotherapy (Pt-CT) as first-line (1L) therapy for advanced non-small cell lung cancer (aNSCLC) – Levy BP, et al

- **Key results (cont.)**

Doublet efficacy by TROP2 NMR	Doublet (n=16)	Triplet (n=16)	1L ITT (n=42)
mPFS, mo (95%CI)	21.3 (10.2, NE)	10.9 (4.2, 13.4)	11.2 (8.2, 21.3)
HR (95%CI)	0.50 (0.19, 1.29)		-
mOS, mo (95%CI)	NE (26.2, NE)	NE (14.3, NE)	NE (19.2, NE)
HR (95%CI)	0.35 (0.07, 1.72)		-
ORR, %	68.8	62.5	54.8

TRiplet efficacy by TROP2 NMR	Doublet (n=21)	Triplet (n=23)	1L ITT (n=54)
mPFS, mo (95%CI)	8.2 (5.6, NE)	5.5 (3.0, 13.2)	6.8 (5.5, 11.1)
HR (95%CI)	0.67 (0.33, 1.36)		-
mOS, mo (95%CI)	26.9 (7.1, NE)	13.3 (6.4, NE)	17.4 (9.1, NE)
HR (95%CI)	0.71 (0.31, 1.59)		
ORR, %	61.9	52.2	55.6

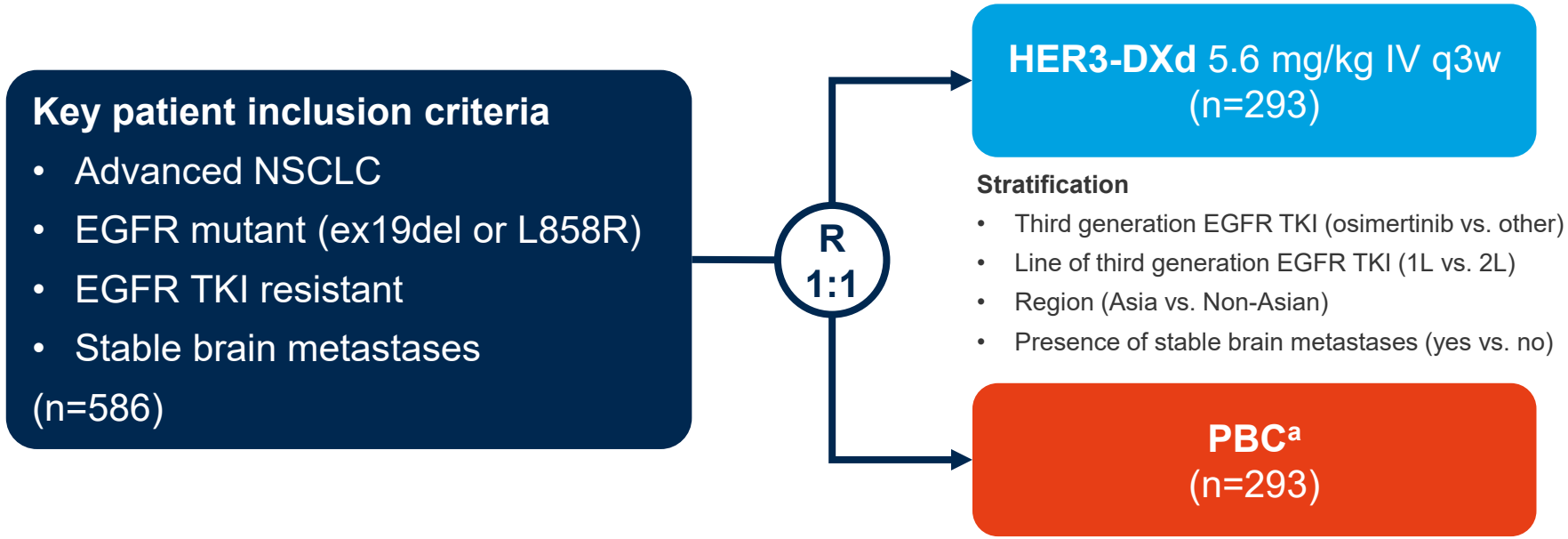
- **Conclusions**
  - In patients with advanced NSCLC, 1L datopotamab deruxtecan + pembrolizumab continued to show antitumor activity and was well tolerated. The additional benefit of platinum chemotherapy remains to be determined, and it was associated with higher frequencies of adverse events
  - Patients with a TROP2 expression by TROP2 NMR* showed longer survival outcomes than those with TROP2 NMR-

*TROP2 normalized membrane ratio (NMR) as measured by quantitative continuous scoring reflects the expression of TROP2 in the membrane relative to the total TROP2 (membrane and cytoplasm).

Levy BP, et al. J Clin Oncol 2025;43(suppl):Abstr 8501

8506: Patritumab deruxtecan (HER3-DXd) in resistant EGFR-mutated (EGFRm) advanced non-small cell lung cancer (NSCLC) after a third-generation EGFR TKI: The phase 3 HERTHENA-Lung02 study – Mok TSK, et al

- **Study objective**
  - To evaluate the efficacy and safety of patritumab deruxtecan in patients with resistant EGFR-mutant advanced NSCLC following a third-generation EGFR TKI in the phase 3 HERTHENA-Lung02 trial



Primary endpoint

- PFS (BICR, RECIST v1.1)

Secondary endpoints

- OS, intracranial PFS, safety

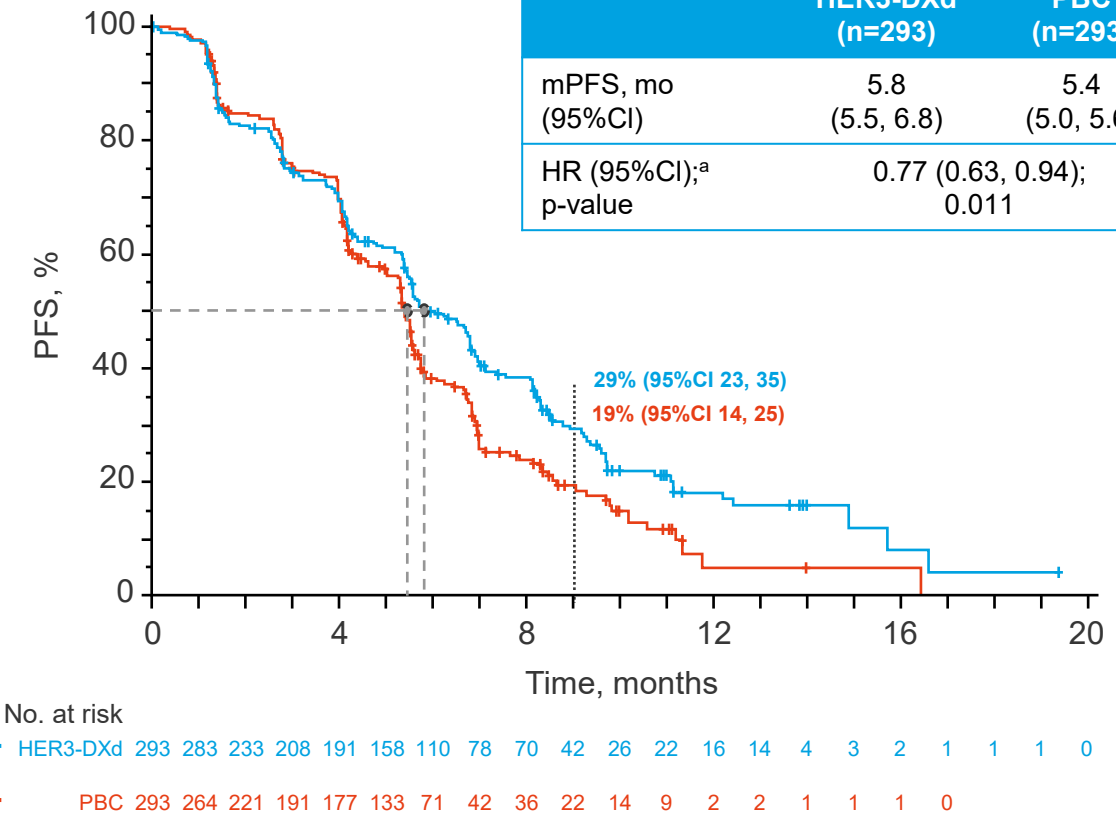
[a]Cisplatin 75 mg/m^2 or carboplatin AUC5 q3w (4 cycles) + pemetrexed 500 mg/m^2 q3w.

8506: Patritumab deruxtecan (HER3-DXd) in resistant EGFR-mutated (EGFRm) advanced non-small cell lung cancer (NSCLC) after a third-generation EGFR TKI: The phase 3 HERTHENA-Lung02 study – Mok TSK, et al

- **Key results**

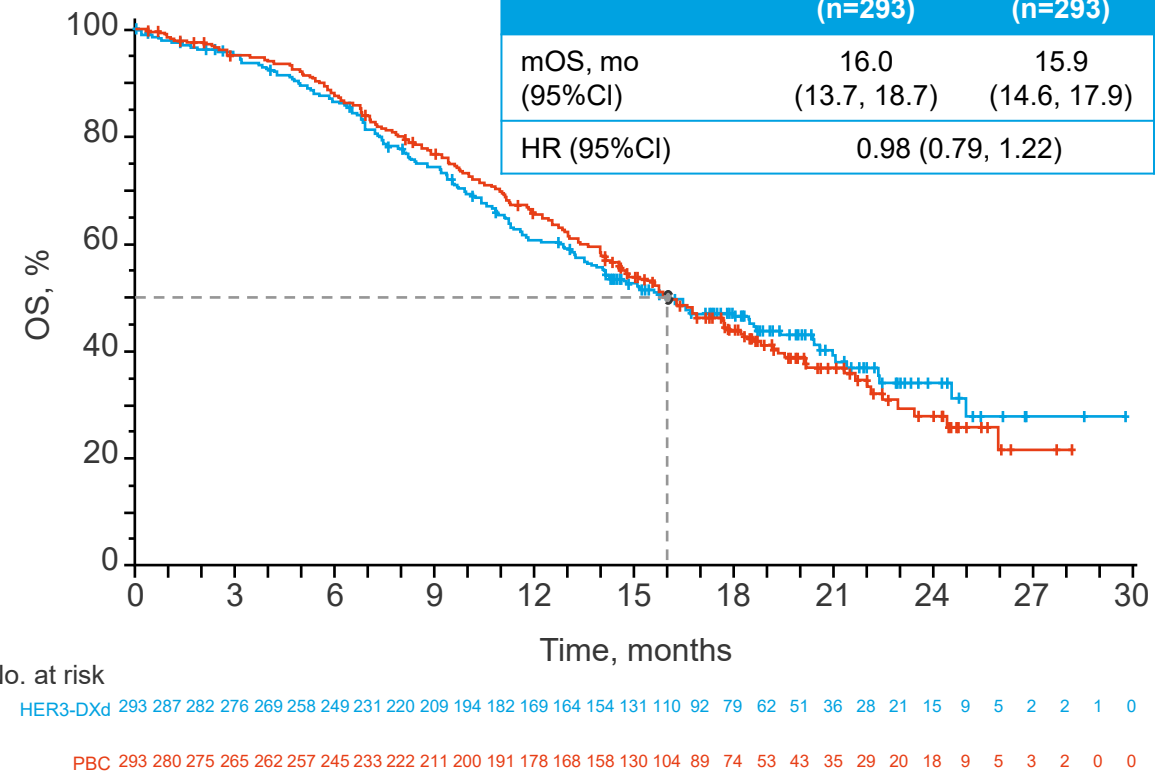
Progression-free survival

	HER3-DXd (n=293)	PBC (n=293)
mPFS, mo (95%CI)	5.8 (5.5, 6.8)	5.4 (5.0, 5.6)
HR (95%CI);[a] p-value	0.77 (0.63, 0.94); 0.011	



Overall survival

	HER3-DXd (n=293)	PBC (n=293)
mOS, mo (95%CI)	16.0 (13.7, 18.7)	15.9 (14.6, 17.9)
HR (95%CI)	0.98 (0.79, 1.22)	



[a]Cox proportional model stratified by stratification factors; [b]stratified Log-rank test.

Mok TSK, et al. J Clin Oncol 2025;43(suppl):Abstr 8506

8506: Patritumab deruxtecan (HER3-DXd) in resistant EGFR-mutated (EGFRm) advanced non-small cell lung cancer (NSCLC) after a third-generation EGFR TKI: The phase 3 HERTHENA-Lung02 study – Mok TSK, et al

- **Key results (cont.)**

Response by BICR (RECIST)	HER3-DXd (n=293)	PBC (n=293)
Confirmed ORR, % (95%CI)	35.2 (29.7, 40.9)	25.3 (20.4, 30.6)
BOR, n (%)		
CR	1 (0.3)	3 (1.0)
PR	102 (34.8)	71 (24.2)
SD	133 (45.4)	148 (50.5)
PD	40 (13.7)	35 (11.9)
NE	17 (5.8)	36 (12.3)
BOR confirmed, n (%)	2 (0.7)	2 (0.7)
DCR, n (95%CI)	80.5 (75.5, 84.9)	75.8 (70.4, 80.6)
mTTR, mo (range)	1.5 (0.3–8.1)	1.5 (1.2–6.9)
mDoR, mo (95%CI)	5.7 (5.1, 7.3)	5.4 (4.1, 5.6)

Intracranial response by CNS BICR per CNS (RECIST)	HER3-DXd (n=105)	PBC (n=95)
Confirmed ORR, % (95%CI)	19.0 (12.0, 27.9)	11.6 (5.9, 19.8)
BOR, n (%)		
CR	13 (12.4)	4 (4.2)
PR	7 (6.7)	7 (7.4)
SD	52 (49.5)	47 (49.5)
PD	27 (25.7)	26 (27.4)
NE	6 (5.7)	11 (11.6)
BOR confirmed, n (%)	2 (1.9)	0
Intracranial DCR, n (95%CI)	68.6 (58.8, 77.3)	61.1 (50.5, 70.9)
Median intracranial TTR, mo (range)	2.1 (1.2–6.9)	2.6 (1.2–4.7)
Median intracranial DoR, mo (95%CI)	4.5 (4.1, NE)	4.2 (2.4, NE)
Prior radiation to the brain, n (%)	39 (37.1)	36 (37.9)

8506: Patritumab deruxtecan (HER3-DXd) in resistant EGFR-mutated (EGFRm) advanced non-small cell lung cancer (NSCLC) after a third-generation EGFR TKI: The phase 3 HERTHENA-Lung02 study – Mok TSK, et al

- **Key results (cont.)**

TEAEs, n (%)	HER3-DXd (n=290)	PBC (n=280)
Any	290 (100)	277 (98.9)
Grade ≥3	211 (72.8)	160 (57.1)
Treatment-related Grade ≥3	168 (57.9)	129 (46.1)
Serious	124 (42.8)	80 (28.6)
Treatment-related serious	65 (22.4)	35 (12.5)
Led to treatment discontinuation	33 (11.4)	27 (9.6)
Led to dose reduction	94 (32.4)	59 (21.1)
Led to dose interruption	131 (45.2)	105 (37.5)
Led to death	22 (7.6)	14 (5.0)
Treatment-related led to death	4 (1.4)	1 (0.4)

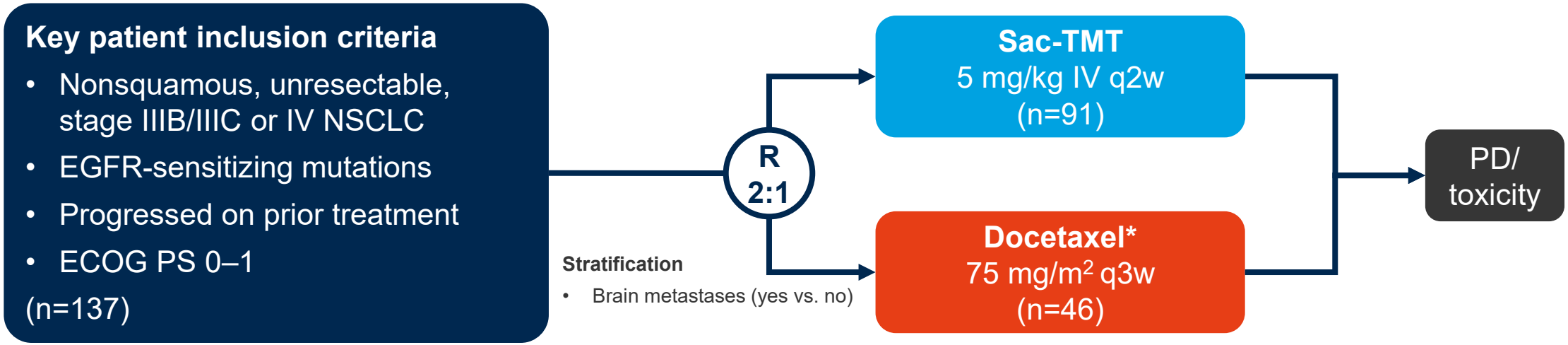
	HER3-DXd (n=290)		PBC (n=280)	
ILD adjudication, n (%)	Adjudicated as ILD	Adjudicated as treatment-related ILD	Adjudicated as ILD	Adjudicated as treatment-related ILD
Grade 1	2 (0.7)	2 (0.7)	0	0
Grade 2	10 (3.4)	9 (3.1)	0	0
Grade 3	1 (0.3)	1 (0.3)	0	0
Grade 4	0	0	0	0
Grade 5	2 (0.7)	2 (0.7)	0	0
Total ILD	15 (5.2)	14 (4.8)	0	0

- **Conclusions**
  - In patients with resistant EGFR-mutant advanced NSCLC, patritumab deruxtecan significantly reduced the risk of progression, showed intracranial activity, and had a manageable safety profile
  - In the third interim analysis, patritumab deruxtecan failed to demonstrate an OS advantage over chemotherapy

Mok TSK, et al. J Clin Oncol 2025;43(suppl):Abstr 8506

8507: Sacituzumab tirumotecan (sac-TMT) in patients (pts) with previously treated advanced EGFR-mutated non-small cell lung cancer (NSCLC): Results from the randomized OptiTROP-Lung03 study – Zhang L, et al

- **Study objective**
  - To evaluate the efficacy and safety of sacituzumab tirumotecan in previously treated patients with EGFR-mutant advanced NSCLC in the OptiTROP-Lung03 trial



Primary endpoint

- ORR (BICR)

Secondary endpoints

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

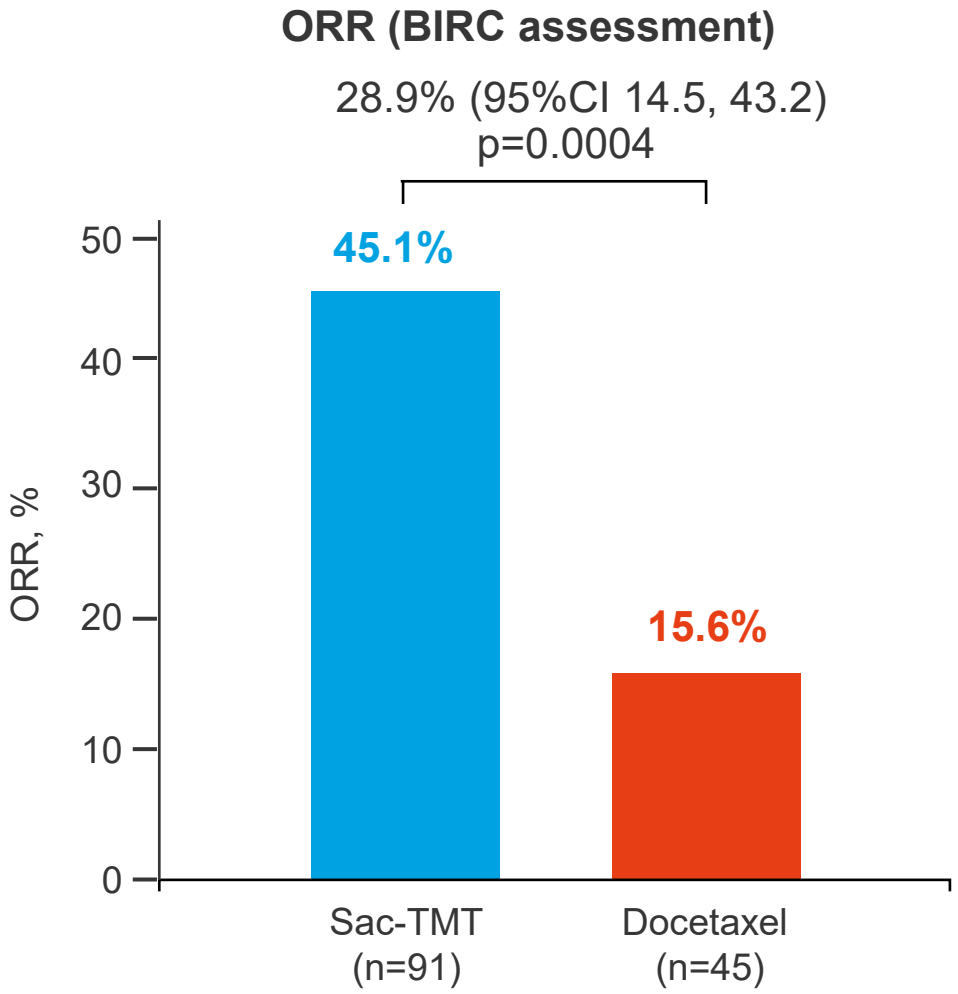
*Patients were allowed to switch treatment following independent verification of PD.

Zhang L, et al. J Clin Oncol 2025;43(suppl):Abstr 8507

8507: Sacituzumab tirumotecan (sac-TMT) in patients (pts) with previously treated advanced EGFR-mutated non-small cell lung cancer (NSCLC): Results from the randomized OptiTROP-Lung03 study – Zhang L, et al

- **Key results**

	Sac-TMT (n=91)	Docetaxel (n=45)
ORR, n (%) [95%CI]	41 (45.1) [34.6, 55.8]	7 (15.6) [6.5, 29.5]
Difference (95%CI)	28.9 (14.5, 43.2)	
One-sided p-value	0.0004	
DCR, n (%) [95%CI]	75 (82.4) [73.0, 89.6]	27 (60.0) [44.3, 74.3]
Difference (95%CI)	22.3 (6.0 38.7)	
DoR, n (%)	26 (63.4)	6 (85.7)
mDoR, mo (95%CI)	7.0 (5.4, 9.1)	5.1 (3.1, NE)



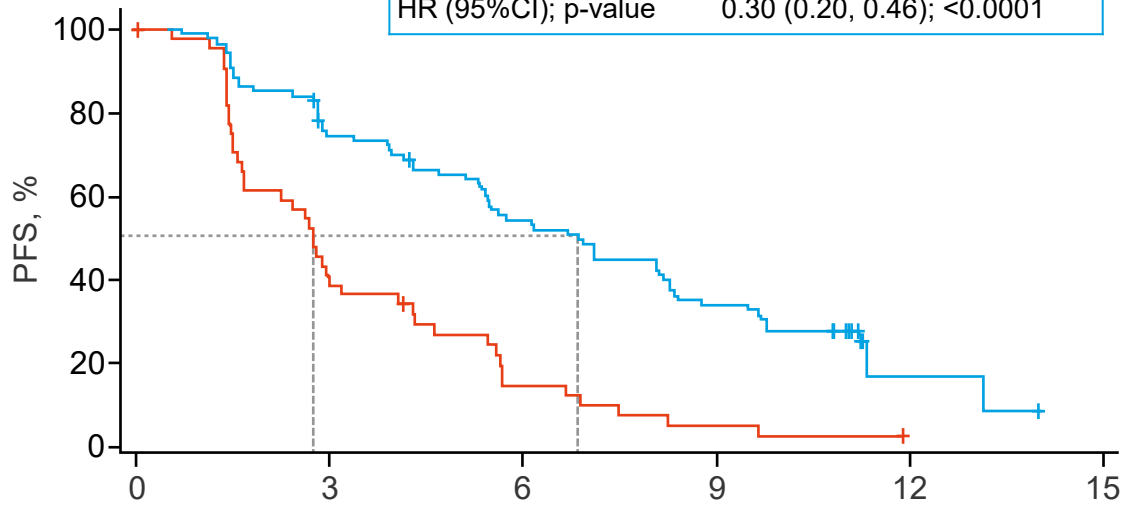
Zhang L, et al. J Clin Oncol 2025;43(suppl):Abstr 8507

8507: Sacituzumab tirumotecan (sac-TMT) in patients (pts) with previously treated advanced EGFR-mutated non-small cell lung cancer (NSCLC): Results from the randomized OptiTROP-Lung03 study – Zhang L, et al

- **Key results**

Progression-free survival

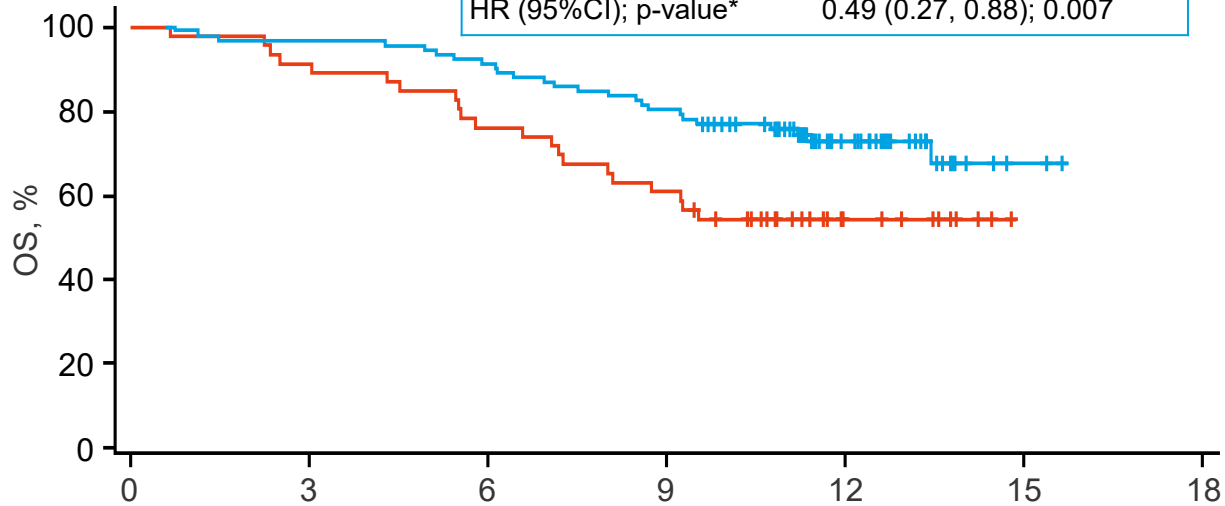
	Sac-TMT (n=91)	Docetaxel (n=46)
Events, n (%)	64 (70.3)	42 (91.3)
mPFS, mo (95% CI)	6.9 (5.4, 8.2)	2.8 (1.6, 4.1)
6-mo PFS rate, %	54.2	14.6
HR (95%CI); p-value	0.30 (0.20, 0.46); <0.0001	



No. at risk						
Sac-TMT	91	63	45	28	2	0
Docetaxel	46	17	6	2	0	

Overall survival

	Sac-TMT (n=91)	Docetaxel (n=46)
Events, n (%)	25 (27.5)	21 (45.7)
mOS, mo (95% CI),	NR (NE, NE)	NR (8.0, NE)
12-mo OS rate, %	72.8	54.3
HR (95%CI); p-value*	0.49 (0.27, 0.88); 0.007	



No. at risk						
Sac-TMT	91	88	83	73	39	2	0
Docetaxel	46	42	35	28	10	0	

*Based on interim analysis, one-sided p-value was inferior to the pre-specified efficacy boundary to achieve statistically significant improvement.

8507: Sacituzumab tirumotecan (sac-TMT) in patients (pts) with previously treated advanced EGFR-mutated non-small cell lung cancer (NSCLC): Results from the randomized OptiTROP-Lung03 study – Zhang L, et al

- **Key results (cont.)**

TROP2 expression levels	Sac-TMT (n=76)	Docetaxel (n=33)
TROP2 high, n (%)	46 (60.5)	18 (54.5)
cORR, n (%) [95%CI]	26 (56.5) [41.1, 71.1]	4 (22.2) [6.4, 47.6]
Difference (95%CI)	34.3 (10.3, 58.3)	
TROP2 high, n (%)	30 (39.5)	15 (45.5)
cORR, n (%) [95%CI]	11 (36.7) [19.9, 56.1]	2 (13.3) [1.7, 40.5]
Difference (95%CI)	22.3 (−1.0, 47.7)	

TRAEs, n (%)	Sac-TMT (n=91)	Docetaxel (n=46)
Any	89 (97.8)	45 (97.8)
Grade ≥3	51 (56.0)	33 (71.7)
Serious	15 (16.5)	19 (41.3)
Led to dose reduction	29 (31.9)	20 (43.5)
Led to dose interruption	32 (35.2)	13 (28.3)
Led to dose treatment discontinuation	0	1 (2.2)

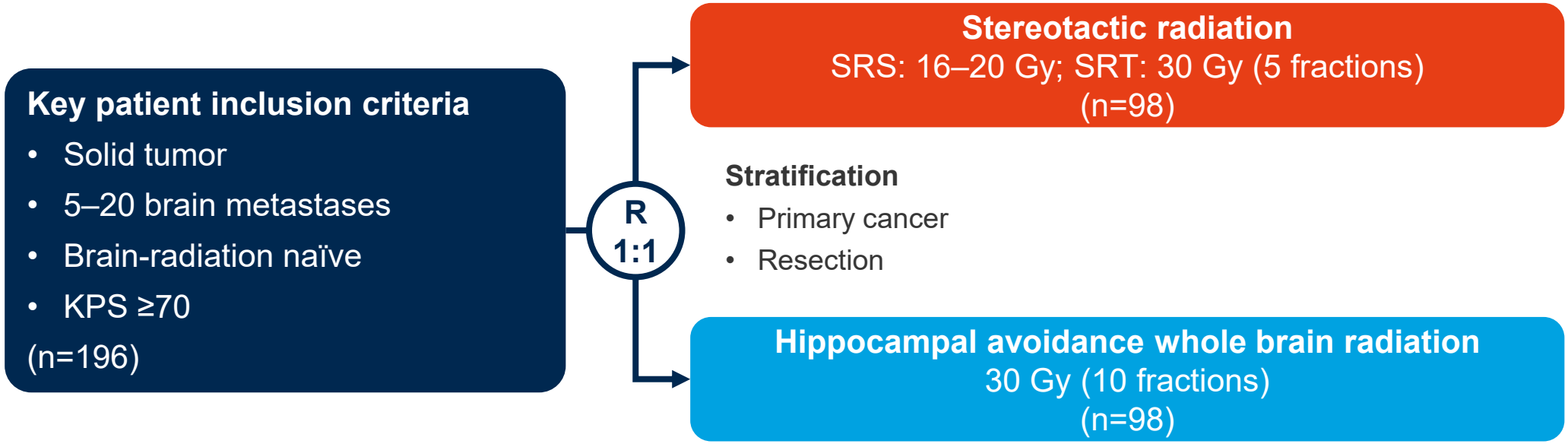
- **Conclusions**
  - In patients with EGFR-mutant advanced NSCLC, sacituzumab tirumotecan demonstrated significant improvements in tumor response, PFS and OS compared to docetaxel, with no new safety findings observed

Other malignancies

SCLC, mesothelioma and thymic epithelial tumors

2011: Stereotactic radiation (SRS/SRT) versus hippocampal avoidance whole brain radiation (HA/WBRT) in patients with 5/20 brain metastases: A multicenter, phase 3 randomized trial – Aizer A, et al

- **Study objective**
  - To evaluate the quality of life with stereotactic radiation (SRS/SRT) compared with whole brain radiation (WBRT) in patients with brain metastases secondary to a solid tumor



Primary endpoints

- 6-month average of patient-reported symptom severity and interference (MDASI-BT)

Secondary endpoints

- Performance status, ability to complete daily activities, neurocognitive function, OS

2011: Stereotactic radiation (SRS/SRT) versus hippocampal avoidance whole brain radiation (HA/WBRT) in patients with 5/20 brain metastases: A multicenter, phase 3 randomized trial – Aizer A, et al

- **Key results**

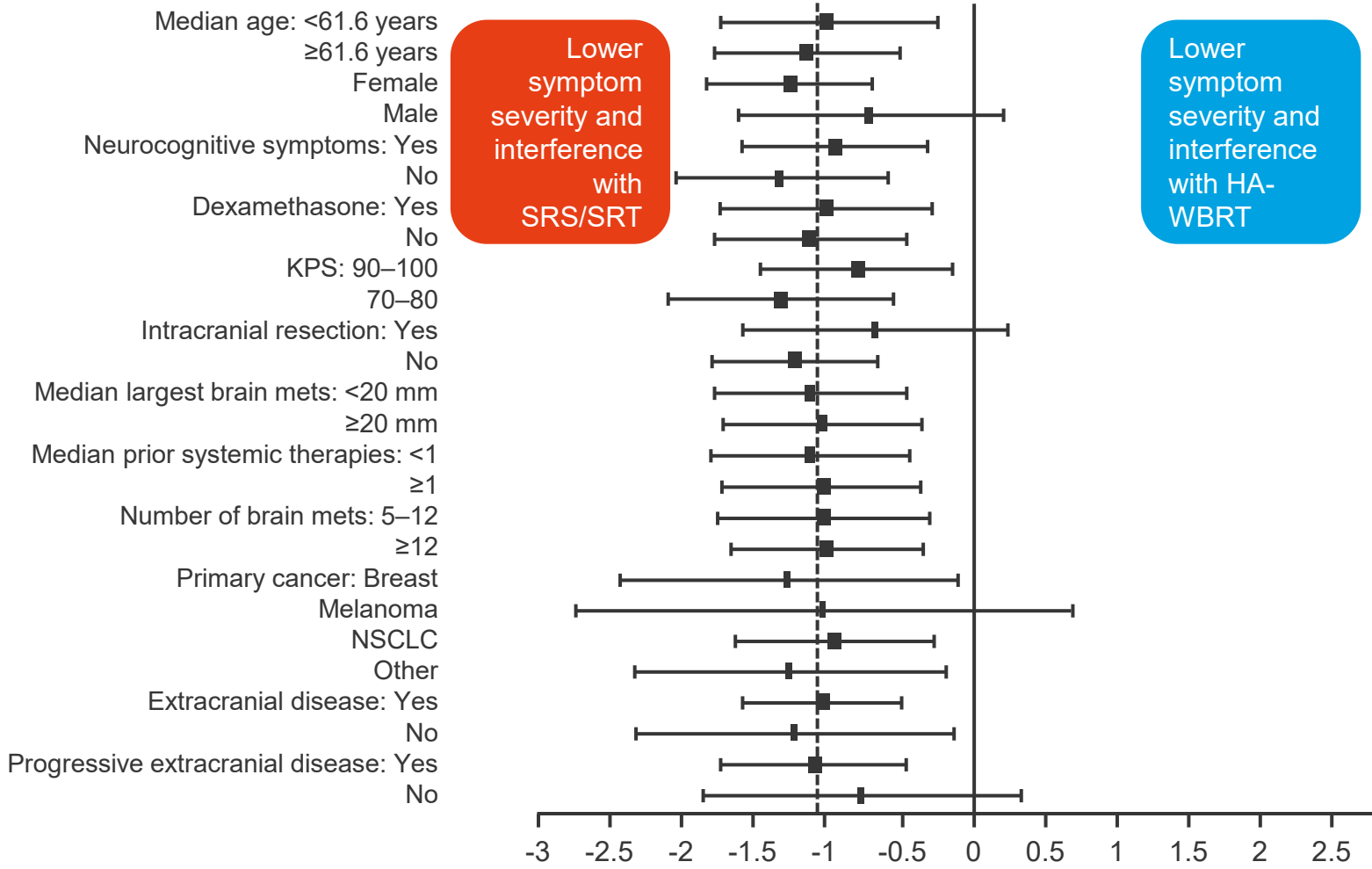
MDASI-BT symptom severity

	SRS/SRT	HA-WBRT	p-value
Baseline, mean	2.19	1.90	0.20
Post baseline minus baseline (weighted, mean)	−0.03	0.59	
Difference		−0.62	<0.001

MDASI-BT symptom interference

	SRS/SRT	HA-WBRT	p-value
Baseline, mean	3.49	3.18	0.40
Post baseline minus baseline (weighted, mean)	−0.62	0.89	
Difference		−1.50	<0.001

Post-baseline averaged MDASI-BT symptom severity and interference

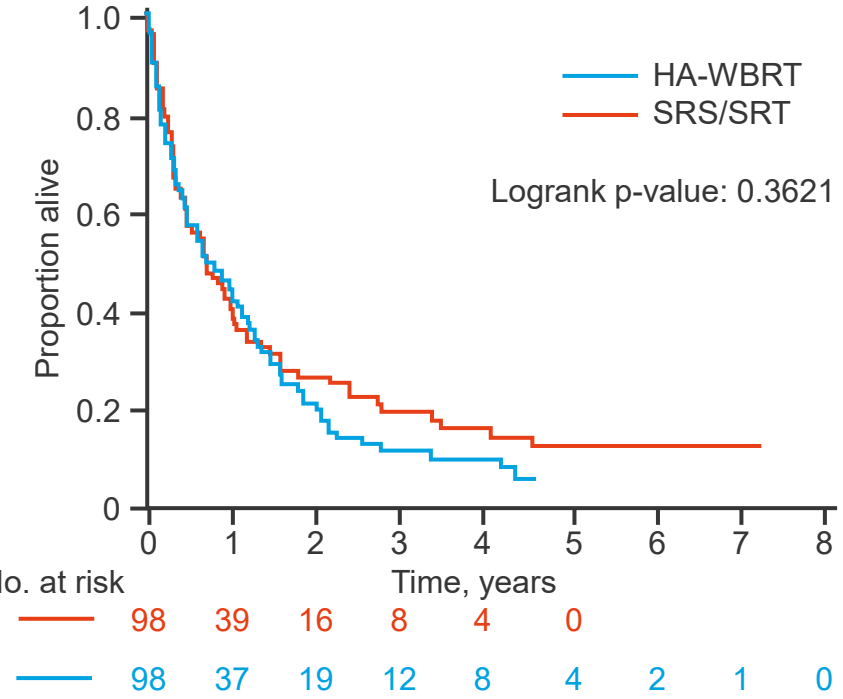


Aizer A, et al. J Clin Oncol 2025;43(suppl):Abstr 2011

2011: Stereotactic radiation (SRS/SRT) versus hippocampal avoidance whole brain radiation (HA/WBRT) in patients with 5/20 brain metastases: A multicenter, phase 3 randomized trial – Aizer A, et al

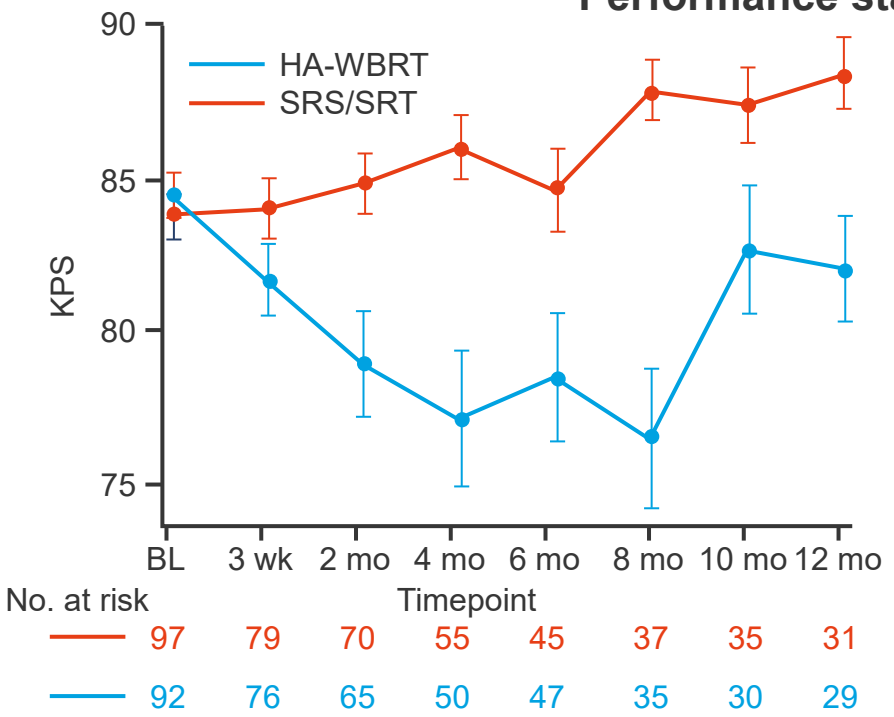
- **Key results (cont.)**

Overall survival



	SRS/SRT	HA-WBRT
mOS, mo (95%CI)	8.3 (5.9, 12.3)	8.5 (5.9, 13.9)
12-mo OS, % (95%CI)	41.1 (31.3, 50.7)	42.8 (32.7, 52.6)

Performance status



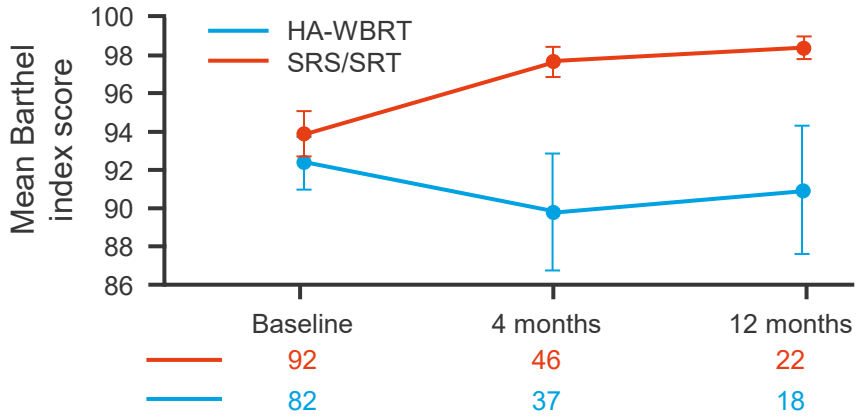
	Difference (95%CI) between SRS/SRT and HA-WBRT	p-value
Baseline	−0.87 (−2.91, 1.18)	0.41
3 weeks	2.89 (−0.09, 5.87)	0.06
2 months	6.53 (2.77, 10.28)	0.001
4 months	9.51 (5.12, 13.90)	<0.001
6 months	7.51 (2.87, 12.14)	0.002
8 months	11.80 (7.29, 16.32)	<0.001
10 months	7.76 (3.55, 11.98)	<0.001
12 months	8.64 (4.62, 12.66)	<0.001

Aizer A, et al. J Clin Oncol 2025;43(suppl):Abstr 2011

2011: Stereotactic radiation (SRS/SRT) versus hippocampal avoidance whole brain radiation (HA/WBRT) in patients with 5/20 brain metastases: A multicenter, phase 3 randomized trial – Aizer A, et al

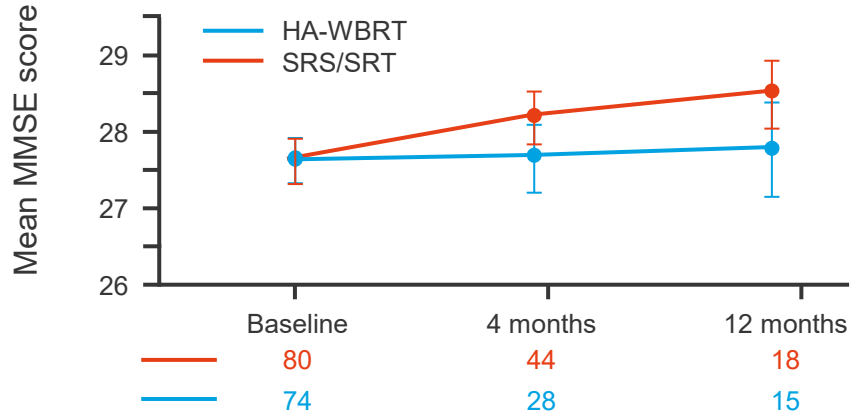
- **Key results (cont.)**

Functional independence



	p-value
Baseline	0.39
4 months	0.02
12 months	0.02

General neurocognition (MMSE testing)

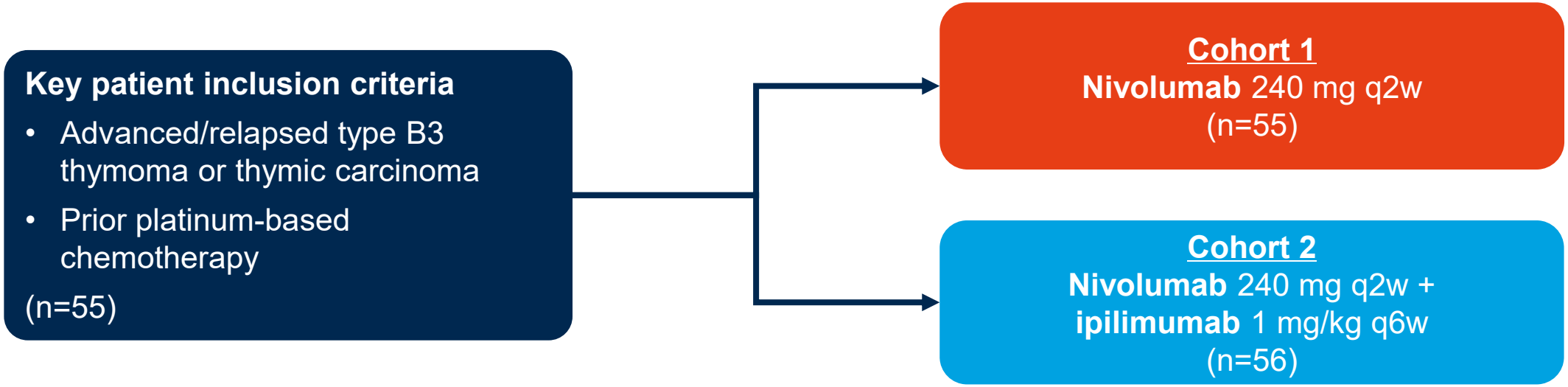


	p-value
Baseline	0.99
4 months	0.33
12 months	0.21

- **Conclusions**
  - In patients with 5–20 brain metastases secondary to a solid tumor, SRS/SRT provided improved symptom control and less interference with daily function compared with HA-WBRT, without compromising OS
  - These findings support SRS/SRT as the standard of care in this population

8016: Efficacy and safety of nivolumab plus ipilimumab for patients with pre-treated type B3 thymoma and thymic carcinoma: Results from the EORTC-ETOP NIVOTHYM phase II trial – Girard N, et al

- **Study objective**
  - To evaluate the efficacy and safety of 2L nivolumab + ipilimumab in previously treated patients with advanced type B3 thymoma or thymic carcinoma in the phase 2 NIVOTHYM trial



Primary endpoint

- 6-mo PFS rate (RECIST v1.1)

Secondary endpoints

- PFS, OS, safety

8016: Efficacy and safety of nivolumab plus ipilimumab for patients with pre-treated type B3 thymoma and thymic carcinoma: Results from the EORTC-ETOP NIVOTHYM phase II trial – Girard N, et al

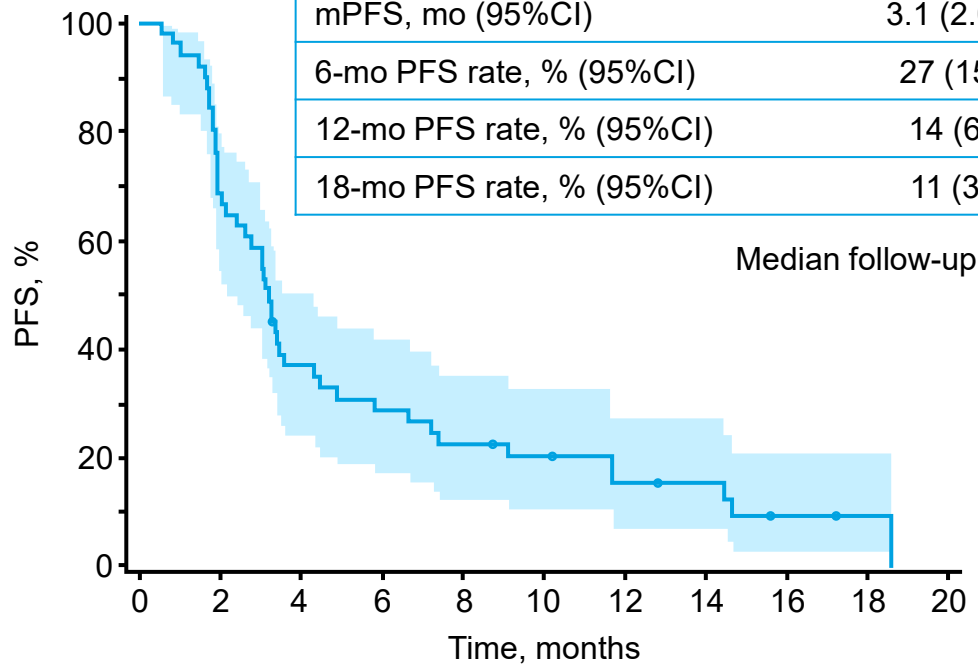
- **Key results**

	Nivolumab + ipilimumab (n=51)
6-mo PFS rate (BICR), n (%)	
Failure	40 (78)
Success	11 (22)
Reason failure at 6 months, n (%)	
PD	27 (68)
Death before PD	3 (8)
Start further therapy before PD	4 (10)
Missing disease evaluation at 6 mo	6 (15)

Progression-free survival

	Nivolumab + ipilimumab (n=51)
mPFS, mo (95%CI)	3.1 (2.0, 3.6)
6-mo PFS rate, % (95%CI)	27 (15, 41)
12-mo PFS rate, % (95%CI)	14 (6, 27)
18-mo PFS rate, % (95%CI)	11 (3, 23)

Median follow-up: 16.1 mo



8016: Efficacy and safety of nivolumab plus ipilimumab for patients with pre-treated type B3 thymoma and thymic carcinoma: Results from the EORTC-ETOP NIVOTHYM phase II trial – Girard N, et al

- **Key results (cont.)**

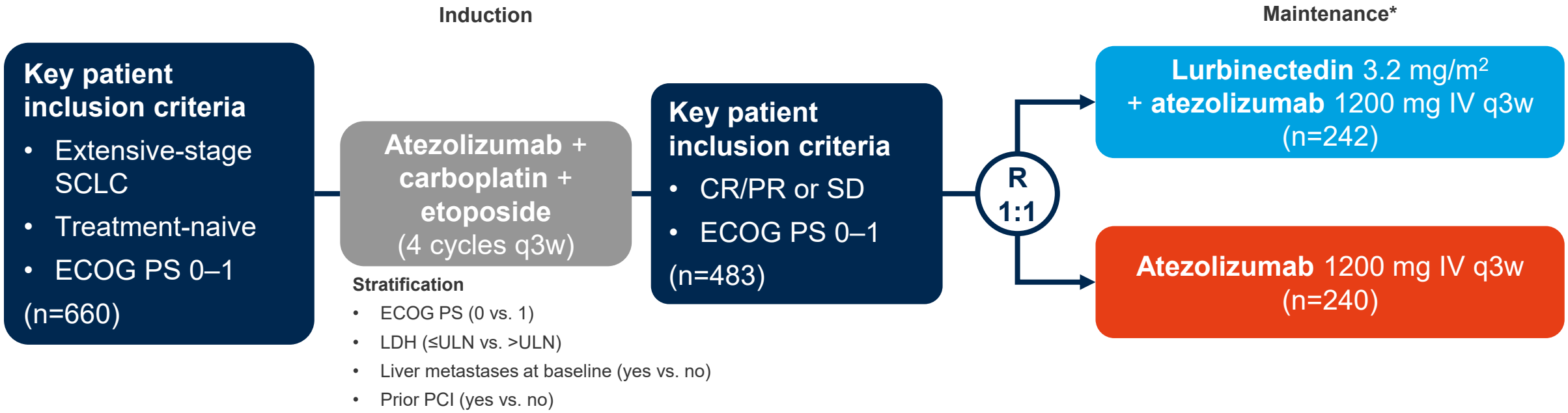
	Nivolumab + ipilimumab (n=51)
mOS, mo (95%CI)	22.0 (16.6, NE)
6-mo OS rate, % (95%CI)	84 (71, 92)
12-mo OS rate, % (95%CI)	75 (60, 85)
18-mo OS rate, % (95%CI)	65 (47, 78)
BOR, n (%)	
PR	8 (16)
SD	22 (43)
PD	18 (35)
NE	3 (6)
DCR, %	59

AEs, n (%)	Nivolumab + ipilimumab (n=56)
Maximal grade of AEs	
Grade 1–2	29 (52)
Grade 3–4	27 (48)
Grade ≥3 TRAE	16 (29)
Myocarditis	2 (4)
Colitis	4 (8)
Infusion-related rection/allergy	2 (4)
Skin rash	2 (4)

- **Conclusions**
  - In patients with advanced type B3 thymoma or thymic carcinoma, 2L nivolumab + ipilimumab failed to improve survival outcomes compared with ipilimumab monotherapy

8006: Lurbinectedin (lurbi) + atezolizumab (atezo) as first-line (1L) maintenance treatment (tx) in patients (pts) with extensive-stage small cell lung cancer (ES-SCLC): Primary results of the phase 3 IMforte trial – Paz-Ares LG, et al

- **Study objective**
  - To evaluate the efficacy and safety of 1L maintenance with lurbinectedin + atezolizumab in patients with extensive-stage SCLC in the phase 3 IMforte trial



Primary endpoints

- PFS (investigator), OS

Secondary endpoints

- ORR, DoR, safety

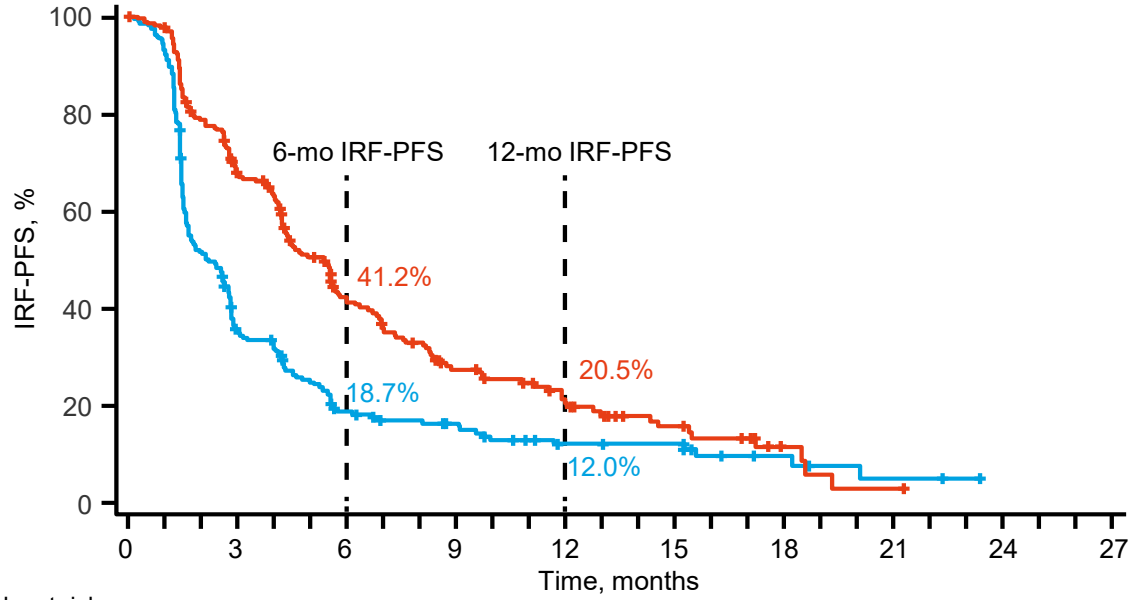
*Efficacy endpoints assessed from randomization.

8006: Lurbinectedin (lurbi) + atezolizumab (atezo) as first-line (1L) maintenance treatment (tx) in patients (pts) with extensive-stage small cell lung cancer (ES-SCLC): Primary results of the phase 3 IMforte trial – Paz-Ares LG, et al

- **Key results**

Progression-free survival

	Lurbinectedin + atezolizumab (n=242)	Atezolizumab (n=241)
Events, n (%)	174 (71.9)	202 (83.8)
mPFS, mo (95%CI)	5.4 (4.2, 5.8)	2.1 (1.6, 2.7)
Stratified HR (95%CI); p-value (2-sided)	0.54 (0.43, 0.67); <0.0001	

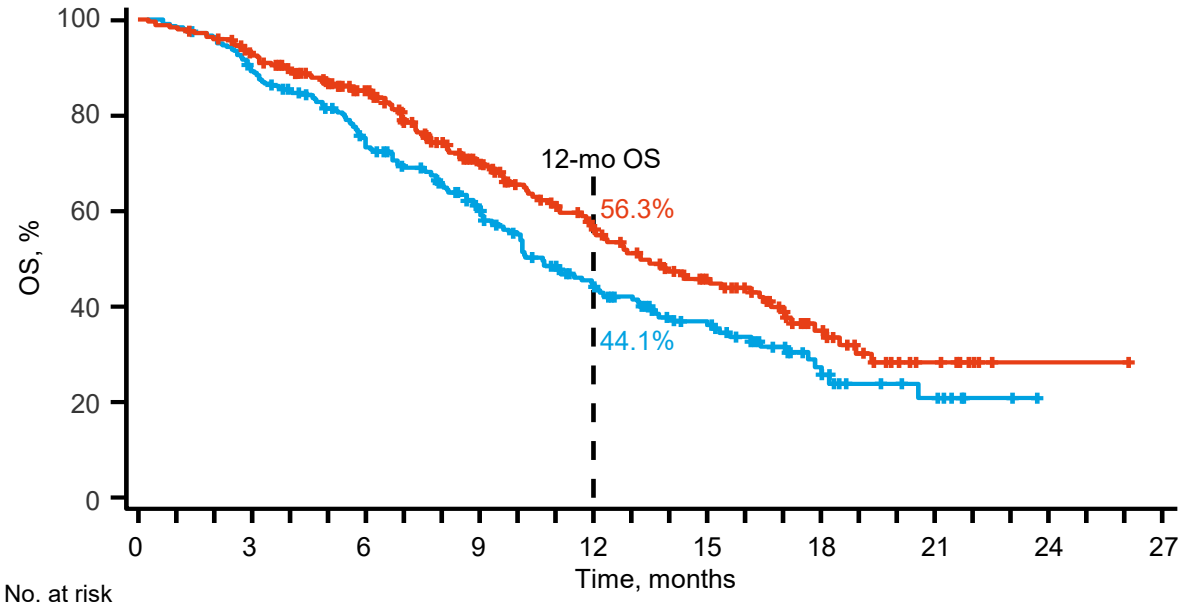


No. at risk

Lurbinectedin + atezo	242	231	184	152	138	103	76	62	57	43	35	33	24	20	16	14	11	10	4	2	1	1	0	0	0	0	0
Atezo	241	224	123	79	69	50	34	27	27	24	18	16	13	13	12	12	7	6	5	3	3	2	2	1	0	0	0

Overall survival

	Lurbinectedin + atezolizumab (n=242)	Atezolizumab (n=241)
Events, n (%)	113 (46.7)	136 (56.4)
mOS, mo (95%CI)	13.2 (11.9, 16.4)	10.6 (9.5, 12.2)
Stratified HR (95%CI); p-value (2-sided)	0.73 (0.57, 0.95); 0.0174	



No. at risk

Lurbinectedin + atezo	242	238	232	221	209	191	174	151	136	118	104	93	81	69	60	52	46	36	25	17	11	8	4	1	1	1	1	0
Atezo	241	237	230	211	196	179	154	138	126	111	94	81	69	60	49	45	37	29	17	10	9	7	2	2	0	0	0	0

Paz-Ares LG, et al. J Clin Oncol 2025;43(suppl):Abstr 8006

8006: Lurbinectedin (lurbi) + atezolizumab (atezo) as first-line (1L) maintenance treatment (tx) in patients (pts) with extensive-stage small cell lung cancer (ES-SCLC): Primary results of the phase 3 IMforte trial – Paz-Ares LG, et al

- **Key results (cont.)**

	Lurbi + atezo (n=175)	Atezo (n=182)
Confirmed objective response, n (%) [95%CI]	34 (19.4) [13.9, 26.1]	19 (10.4) [6.4, 15.8]
Difference in ORR, % (95%CI)	9.0 (1.1, 16.9)	
BOR, n (%)		
CR	4 (2.3)	1 (0.5)
PR	30 (17.1)	18 (9.9)
SD	96 (54.9)	68 (37.4)
PD	34 (19.4)	87 (47.8)
NE	11 (6.3)	8 (4.4)
DoR		
Responders with an event/responders, n (%)	14/34 (41.2)	11/19 (57.9)
mDoR, mo (95%CI)	9.0 (5.5, NE)	5.6 (4.2, NE)

8006: Lurbinectedin (lurbi) + atezolizumab (atezo) as first-line (1L) maintenance treatment (tx) in patients (pts) with extensive-stage small cell lung cancer (ES-SCLC): Primary results of the phase 3 IMforte trial – Paz-Ares LG, et al

- **Key results (cont.)**

AEs, n (%)	atezolizumab (n=242)	Atezolizumab (n=240)
Any AEs	235 (97.1)	194 (80.8)
AEs grade 3–4	92 (38.0)	53 (22.1)
TRAEs grade 3–4	62 (25.6)	14.0 (5.8)
AEs grade 5	12 (5.0)	6 (2.5)
TRAEs grade 5	2 (0.8)	1 (0.4)
SAEs	75 (31.0)	41 (17.1)
AEs led to discontinuation of any study drug	15 (6.2)	8 (3.3)
TRAEs led to interruption/modification of any study drug	92 (38.0)	33 (13.8)

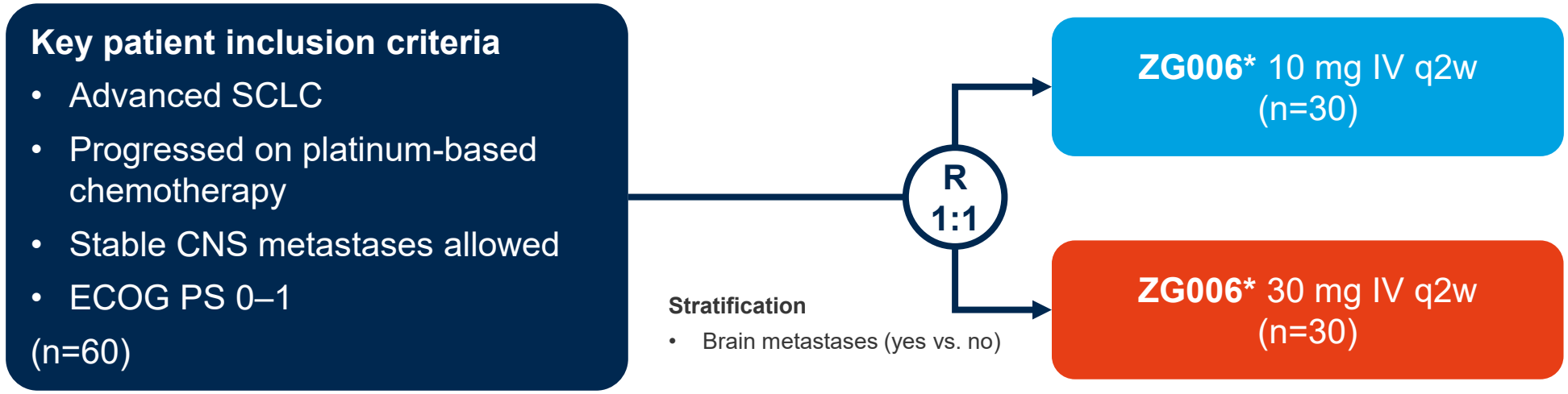
AESIs, n (%)	Lurbinectedin + atezolizumab (n=242)	Atezolizumab (n=240)
Lurbinectedin	93 (38.4)	62 (25.8)
Grade 5	7 (2.9)	4 (1.7)
Atezolizumab	76 (31.4)	54 (22.5)
Grade 5	0	0
Atezolizumab requiring corticosteroids	40 (16.5)	18 (7.5)

- **Conclusions**
  - In patients with extensive-stage SCLC, 1L maintenance with lurbinectedin + atezolizumab provided a significant PFS and OS benefit over atezolizumab maintenance alone
  - No new safety signals were observed

Paz-Ares LG, et al. J Clin Oncol 2025;43(suppl):Abstr 8006

8007: A phase 2 dose expansion study of ZG006, a trispecific T cell engager targeting CD3/DLL3/DLL3, as monotherapy in patients with advanced small cell lung cancer – Ai X, et al

- **Study objective**
  - To evaluate the preliminary efficacy and safety of ZG006 (trispecific T cell engager) in patients with advanced SCLC in a phase 2 trial



Primary endpoint

- ORR

Secondary endpoints

- PFS, DoR, OS, safety

*Priming dose of 1 mg given on Day 1, followed by target dose from C2D1.

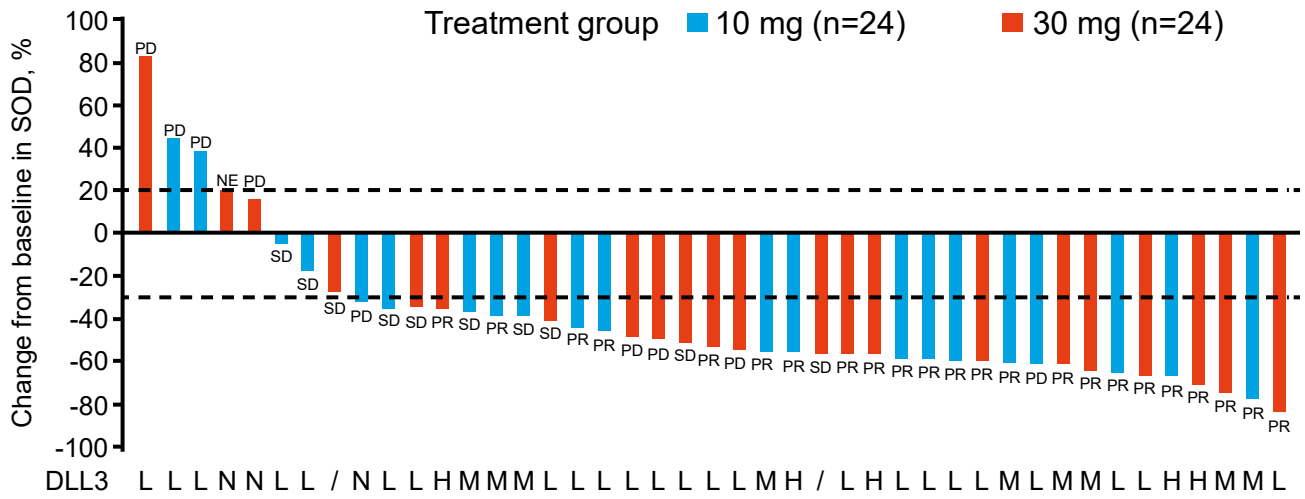
Ai X, et al. J Clin Oncol 2025;43(suppl):Abstr 8007

8007: A phase 2 dose expansion study of ZG006, a trispecific T cell engager targeting CD3/DLL3/DLL3, as monotherapy in patients with advanced small cell lung cancer – Ai X, et al

- **Key results**

Response	ZG006 10 mg (n=24)	ZG006 30 mg (n=24)
BOR, n (%)		
PR	15 (62.5)	14 (58.3)
SD	2 (8.3)	2 (8.3)
PD	6 (25.0)	6 (25.0)
NE	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]

Best percentage changes in target lesion size by dose levels in SCLC



N, negative; L, low expression; M, medium expression; H, high expression; /, NA

8007: A phase 2 dose expansion study of ZG006, a trispecific T cell engager targeting CD3/DLL3/DLL3, as monotherapy in patients with advanced small cell lung cancer – Ai X, et al

- **Key results (cont.)**

AEs, n (%)	ZG006 10 mg (n=24)	ZG006 30 mg (n=24)
Any TEAEs	24 (100)	24 (100)
Any TRAEs	24 (100)	24 (100)
TEAE grade ≥3	7 (29.2)	11 (45.8)
TRAE grade ≥3	5 (20.8)	9 (37.5)
SAEs	9 (37.5)	9 (37.5)
Treatment-related SAEs	5 (20.8)	8 (33.3)
TRAEs led to interruption and/or reduction	3 (12.5)	7 (29.2)
TRAEs led to discontinuation	0	0
TRAEs led to death	0	1 (4.2)

Treatment-emergent CRS and ICANS, %	ZG006 10 mg (n=24)		ZG006 30 mg (n=24)	
	1 mg (Cycle 1; D1–14)	10 mg (Cycle 2; D1–14)	1 mg (Cycle 1; D1–14)	30 mg (Cycle 2; D1–14)
CRS				
Any grade	25.0	37.5	37.5	54.2
Grade ≥3	0	0	4.2	4.2
ICANS				
Any grade	0	0	0	4.2
Grade ≥3	0	0	0	0

- **Conclusions**
  - In patients with advanced SCLC, ZG006 showed promising antitumor activity at both doses although there was a higher rate of specific side effects at the dose of 30 mg

LBA8008: Tarlatamab versus chemotherapy (CTx) as second-line (2L) treatment for small cell lung cancer (SCLC): Primary analysis of Ph3 DeLLphi-304 – Rudin CM, et al

- **Study objective**
  - To evaluate the efficacy and safety of 2L tarlatamab in patients with SCLC in the phase 3 DeLLphi-304 trial

Key patient inclusion criteria

- SCLC
- Progressed on platinum-based chemotherapy and PD-(L)1 inhibitors
- Stable CNS metastases allowed
- ECOG PS 0–1

(n=509)

R 1:1

Tarlatamab (n=254)

Chemotherapy[a] (n=255)

Stratification

- Prior anti-PD-L1 (yes vs. no)
- Chemotherapy-free interval (<90 days vs. ≥90 to <180 days vs. ≥180 days)
- Brain metastases (yes vs. no)
- Chemotherapy (topotecan/amrubicin vs. lurbinectedin)

Primary endpoint

- OS

Secondary endpoints

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

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

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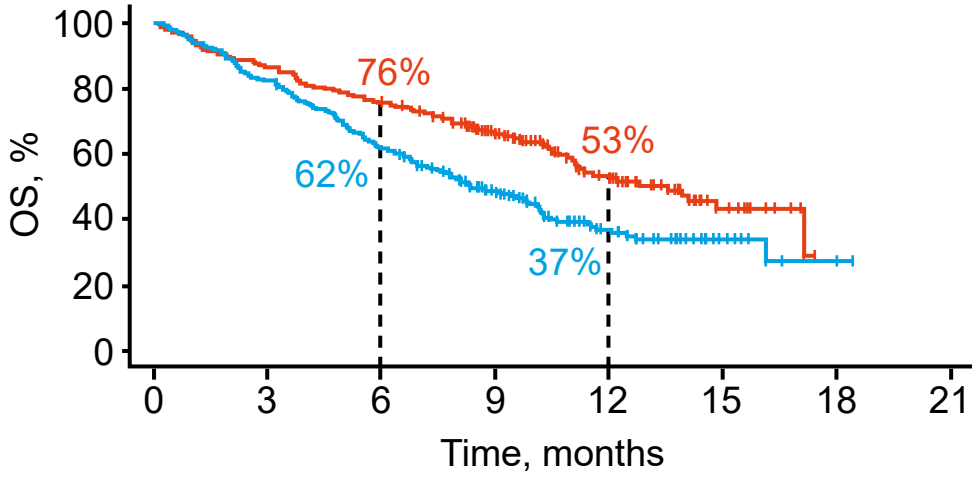
- **Key results**

OS

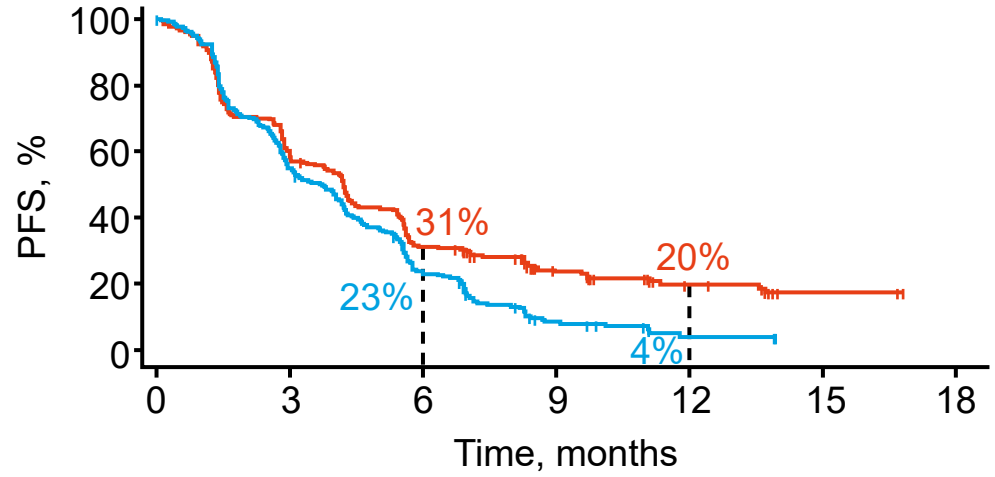
	Tarlatamab (n=254)	Chemotherapy (n=255)
mOS, mo	13.6	8.3
HR (95%CI); p-value (2-sided)[a]	0.60 (0.47, 0.77); <0.001	



No.at risk							
Tarlatamab	254	220	192	131	60	17	0
Chemotherapy	255	210	156	97	42	9	2	0

PFS

	Tarlatamab (n=254)	Chemotherapy (n=255)
mPFS, mo	4.2	3.7
HR (95%CI); RMST p-value (2-sided)	0.71 (0.59, 0.86); 0.002[b]	



No. at risk							
Tarlatamab	254	147	78	37	18	2	0
Chemotherapy	255	137	56	15	3	0	

[a]Log-rank test; [b]the restricted mean PFS in the tarlatamab and the chemotherapy group was 5.3 and 4.3 months, respectively, resulting in statistically significant improvement of the tarlatamab group over chemotherapy group.

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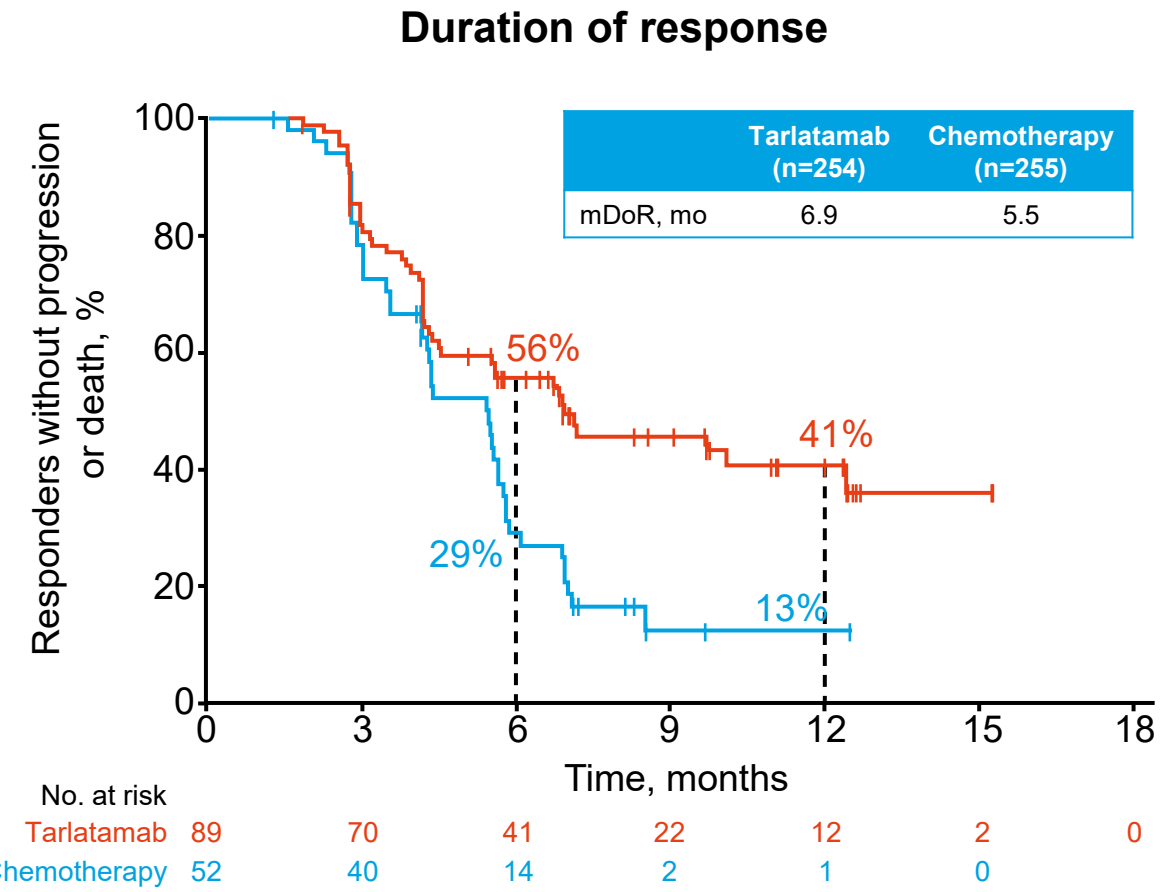
- **Key results (cont.)**

	Tarlatamab (n=254)	Chemotherapy (n=255)
BOR, n (%)		
CR	3 (1)	0
PR	86 (34)	52 (20)
SD	84 (33)	112 (44)
PD	56 (22)	50 (20)
NE	25 (10)	41 (16)
ORR, % (95%CI)	35 (29, 41)	20 (16, 26)
mDoR, mo	6.9	5.5
mTTR, mo	1.5	1.4
Ongoing response at data cut-off, n (%)[a]	42 (47)	8 (15)



[a]Percentage of total number of responders.

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- **Key results (cont.)**

Symptoms after 18 weeks from baseline	Tarlatamab	Chemotherapy
Mean improvement of dyspnea from baseline	1.94	−7.20
LSM difference (95%CI); p-value	−9.14 (−12.64, −5.64); p<0.001	
Patients with cough improved, %	16.1	9.0
OR (95%CI); p-value	2.04 (1.17, 3.55); p=0.012	
Patients with chest pain improved, %	8.7	3.5
OR (95%CI); p-value	1.84 (0.89, 3.81); p=0.1	

AEs, n (%)	Tarlatamab (n=252)	Chemotherapy (n=244)
Any TEAEs	249 (99)	243 (100)
Any TRAEs	235 (93)	223 (91)
Grade ≥3	67 (27)	152 (62)
Serious	70 (28)	75 (31)
Led to interruption and/or reduction	48 (19)	134 (55)
Led to discontinuation	7 (3)	15 (6)
Grade 5[a]	1 (0.4)	4 (2)

Treatment-emergent CRS and ICANS with tarlatamab, %	CRS	ICANS
Overall	56	6
Grade 1	42	3
Grade 2	13	3
Grade 3	1	0
Serious	17	4

- **Conclusions**
  - In patients with SCLC, 2L tarlatamab provided a significant OS and PFS benefit as well as a superior response rate over chemotherapy alone, with a manageable safety profile and improved PROs such as cough and dyspnea

[a]One grade 5 with tarlatamab was attributed to ICANS in the setting of progressive neurological decline; Grade 5 TRAEs observed with chemotherapy were attributed to general physical health deterioration.