Universiteit Antwerpen

UZA

POST ASCO 2026

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1.
NSCLC m+, no AGA

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ABSTRACTS

- 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.
- Phase 2 data from ROSETTA Lung-02: a global, randomized, phase 2/3 trial of pumitamig (PD-L1 x VEGF-A bsAb) + chemotherapy in 1L NSCLC.
- A Randomized, Open-label, Parallel-controlled Phase 3 Trial of Benmelstobart plus Chemotherapy and Anlotinib for First-line Treatment of advanced Non-squamous Non-Small Cell Lung Cancer (nsq-NSCLC).
- Tremelimumab + durvalumab + chemotherapy vs pembrolizumab + chemotherapy in 1L non-squamous metastatic NSCLC with *STK11*, *KEAP1* and/or *KRAS* mutations: Interim analysis of the phase 2b TRITON study.

- Sacituzumab tirumotecan (sac-TMT) plus pembrolizumab versus pembrolizumab as first-line treatment for PD-L1-positive advanced non-small cell lung cancer (NSCLC): results from the randomized phase 3 OptiTROP-Lung05 study.

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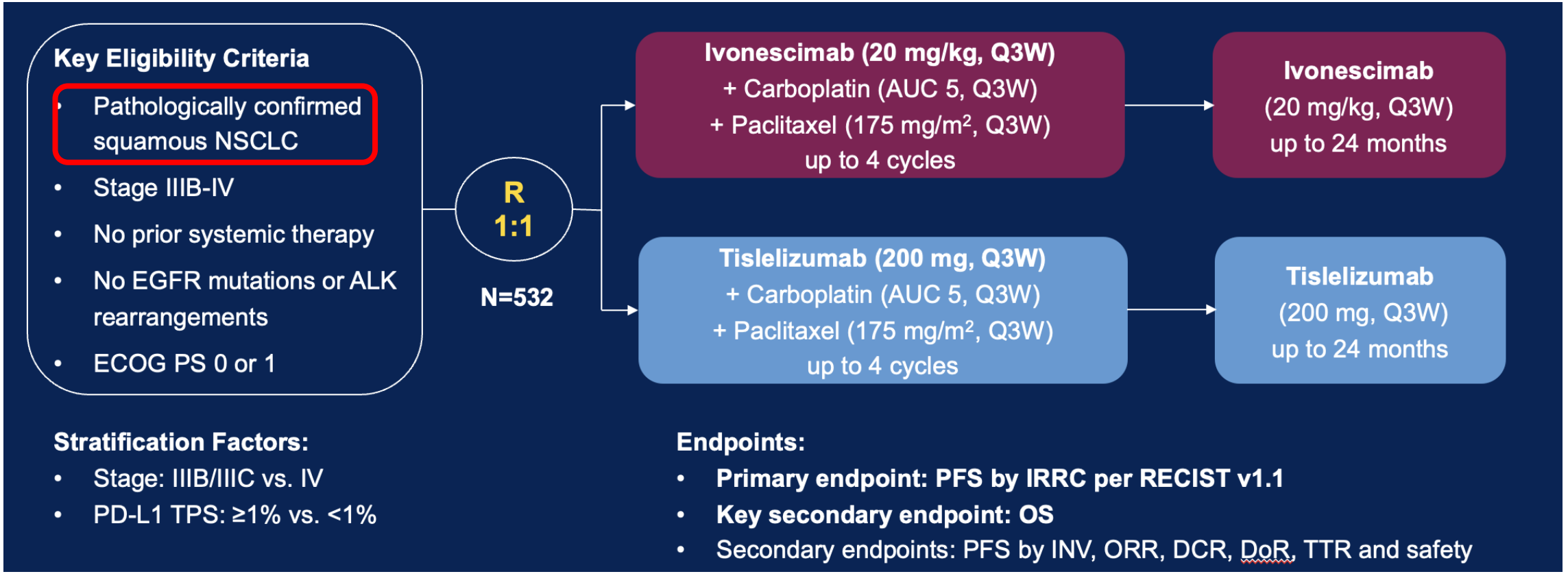
HARMONi-6: study design



Primary endpoint was previously reported: Chen Z. Lancet 2025.
Anti-VEGF in squamous NSCLC: ramucirumab (REVEL): Garon EB. Lancet 2014.
Ivonescimab is a bispecific Ab targeting PD-1 and VEGF. Tislelizumab is a monoclonal Ab targeting PD-1.
100% Chinese population.

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HARMONi-6: patient characteristics

Characteristics, n(%)		Ivonescimab + chemo (N=266)	Tislelizumab + chemo (N=266)
Age, years	< 65	135 (50.8)	139 (52.3)
	≥ 65	131 (49.2)	127 (47.7)
Sex	Male	256 (96.2)	238 (89.5)
	Female	10 (3.8)	28 (10.5)
ECOG PS*	0	42 (15.8)	42 (15.8)
	1	224 (84.2)	222 (83.5)
Smoking history	Never	21 (7.9)	37 (13.9)
	Current/Former	245 (92.1)	229 (86.1)
Disease stage	IIIB/IIIC	21 (7.9)	20 (7.5)
	IV	245 (92.1)	246 (92.5)
Tumor characteristics	Central type	178 (66.9)	158 (59.4)
	Major blood vessel encasement	49 (18.4)	44 (16.5)
	With cavity	24 (9.0)	23 (8.6)
	With hemoptysis history	86 (32.3)	79 (29.7)
PD-L1 TPS	<1%	105 (39.5)	105 (39.5)
	≥ 1%	161 (60.5)	161 (60.5)
	1-49%	112 (42.1)	99 (37.2)
	≥ 50%	49 (18.4)	62 (23.3)
Metastases sites	≥3 metastatic sites	42 (15.8)	39 (14.7)
	Liver metastases	28 (10.5)	45 (16.9)
	Brain metastases	9 (3.4)	17 (6.4)

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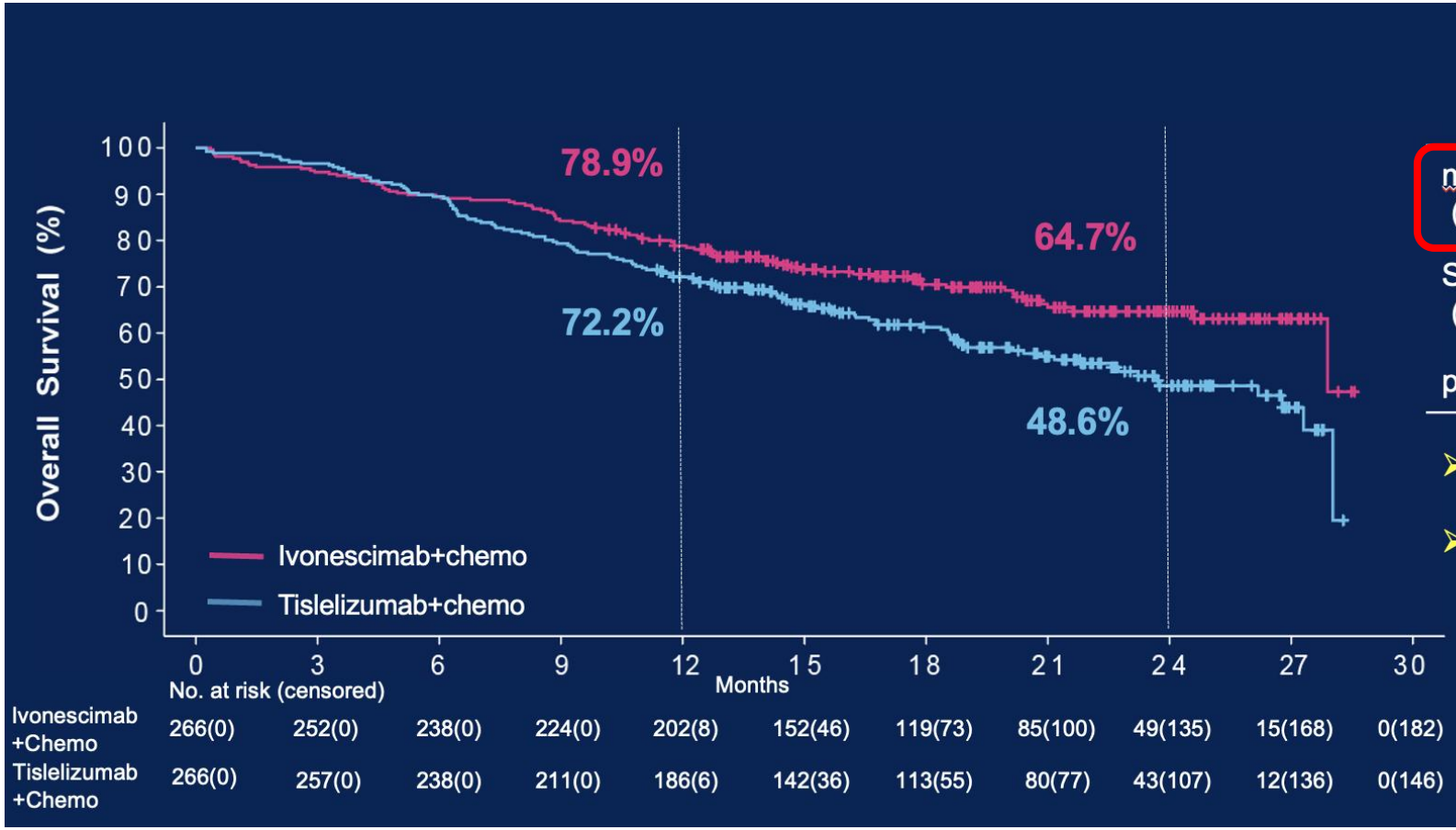
HARMONi-6: key secondary endpoint



	Ivonescimab + chemo (N=266)	Tislelizumab + chemo (N=266)
mOS, months (95% CI)	27.89 (27.89, NE)	23.69 (20.11, NE)
Stratified HR (95% CI)	0.66 (0.50, 0.87)	
p-value	0.0017	

- OS significance boundary: 0.0049
- The median OS in the ivonescimab group would have not been reached without the last single event

- Data cutoff date: Feb 27, 2026
- Median Follow-up: 21.36 months

Primary endpoint (PFS): 11.9 m vs. 6.1 m.

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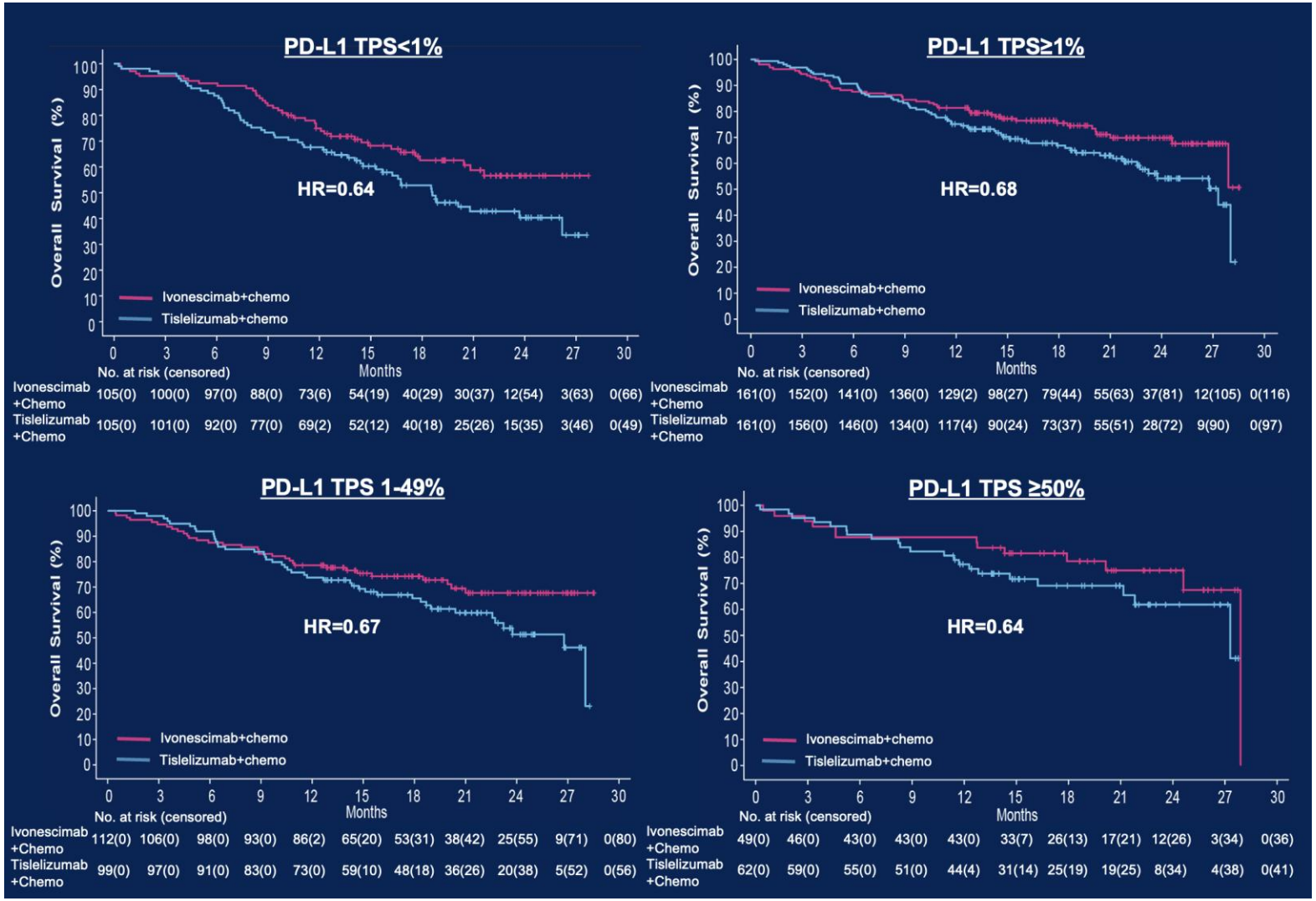
HARMONi-6: subgroup analysis



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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. Chen Z et al.

HARMONi-6: adverse events

	Ivonescimab + chemo (N=266)	Tislelizumab + chemo (N=265)
TRAE	264 (99.2)	263 (99.2)
Grade ≥ 3 TRAE	**184 (69.2)**	**156 (58.9)**
Serious TRAE	110 (41.4)	91 (34.3)
Leading to ivonescimab or tislelizumab discontinuation	14 (5.3)	12 (4.5)
Leading to death	10 (3.8)	11 (4.2)
Grade ≥ 3 irAE#	**34 (14)**	**36 (14)**

In comparison: pembrolizumab + chemo in KN-407 (Paz-Ares L. N Engl J Med 2018):
-- G3+ AE: 69.8%.
-- Discontinuation rate: 17.3%
-- G5 AE: 3.6%.

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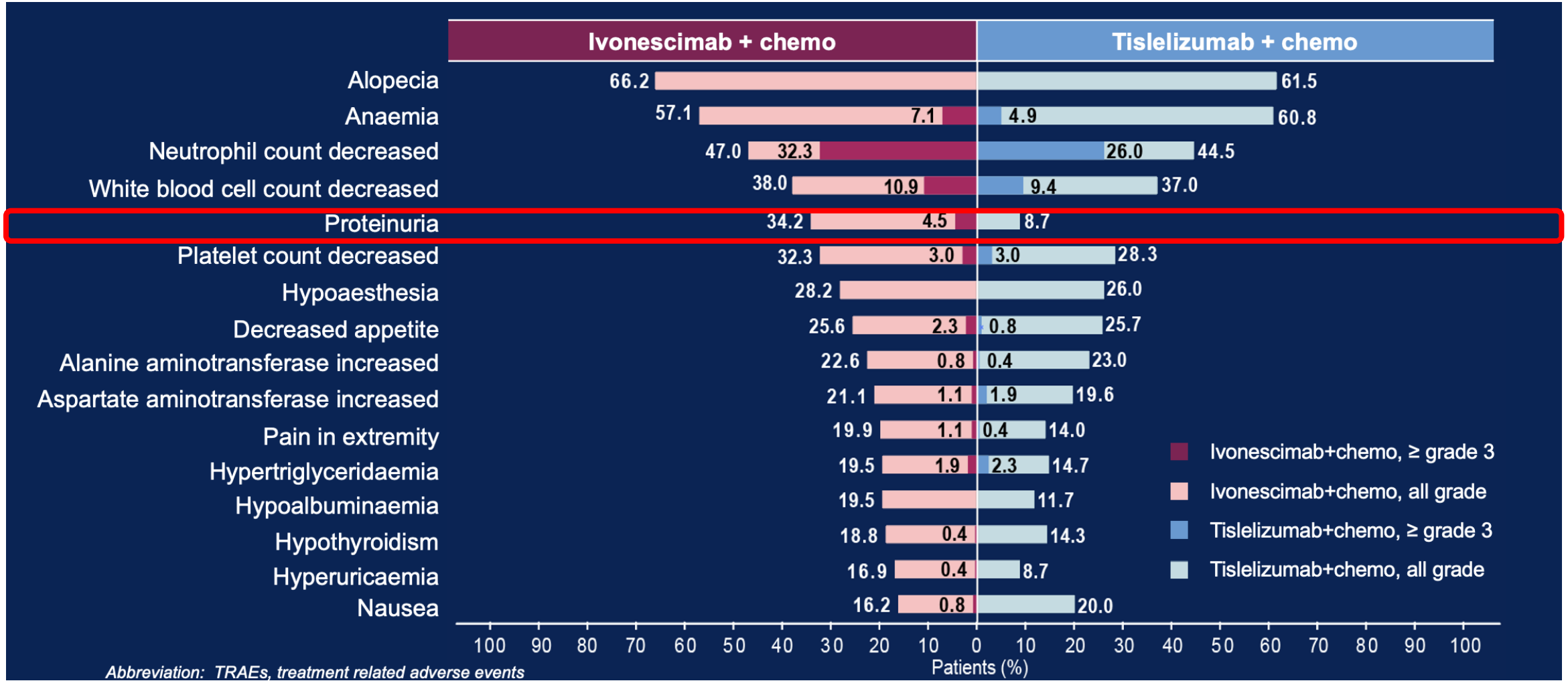
HARMONi-6: AE in >15% of patients



Abbreviation: TRAEs, treatment related adverse events

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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. Chen Z et al.

HARMONi-6: AE related to anti-VEGF

Possibly VEGF-Related AEs#	Ivonescimab + chemo (N=266)				Tislelizumab + chemo (N=265)			
	Any Grade	Grade 1	Grade 2	Grade ≥3	Any Grade	Grade 1	Grade 2	Grade ≥3
Proteinuria	113 (42.5)	35 (13.2)	60 (22.6)	**18 (6.8)**	34 (12.8)	26 (9.8)	8 (3.0)	**0**
Haemorrhage	**66 (24.8)**	**39 (14.7)**	**20 (7.5)**	**7 (2.6)**	**32 (12.1)**	**24 (9.1)**	**6 (2.3)**	**2 (0.8)**
Hypertension	39 (14.7)	7 (2.6)	22 (8.3)	**10 (3.8)**	15 (5.7)	3 (1.1)	7 (2.6)	**5 (1.9)**
Arterial thromboembolism	4 (1.5)	1 (0.4)	0	**3 (1.1)**	0	0	0	**0**
Venous thromboembolism	2 (0.8)	0	2 (0.8)	**0**	3 (1.1)	0	2 (0.8)	**1 (0.4)**
Fistula	1 (0.4)	0	1 (0.4)	**0**	0	0	0	**0**

Phase 3 HARMONi-3: ivonescimab + chemo vs. Pembrolizumab + chemo in NSQ and SQ NSCLC currently recruiting internationally.

HARMONi-6 recently published: Lu S et al. Lancet 2026.

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ROSETTA Lung-02: study design

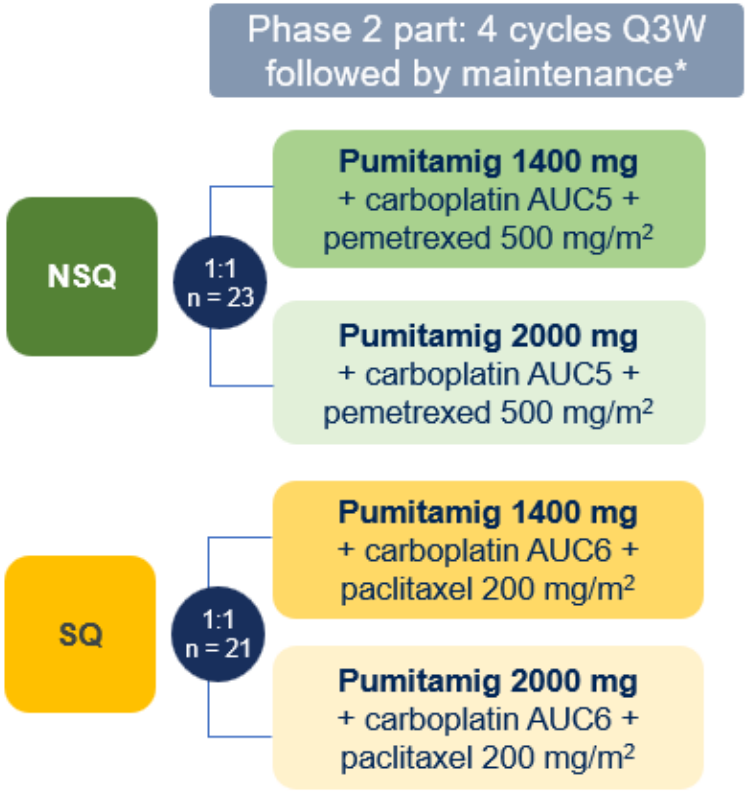
Key eligibility criteria

- Histologically or cytologically confirmed stage IIIB/IIIC or IV NSCLC without actionable genomic alterations
- No previous systemic therapy for NSCLC
- ≥1 measurable lesion per RECIST v1.1
- ECOG PS 0–1
- Any PD-L1 status

Phase 2 primary endpoints

- Safety, ORR, best percentage change in tumor size

Data cut-off was April 13, 2026
Median follow-up (range) was 9.0 months (0.0–12.8) overall



		All NSCLC N = 44
Age, years, median (range)		66.0 (41–87)
Sex, n (%)	Female	15 (34.1)
Race, n (%)	White	28 (63.6)
	Asian	15 (34.1)
	Black	1 (2.3)
Histology, n (%)	NSQ	23 (52.3)
	SQ	21 (47.7)
Smoker, n (%)	Never	3 (6.8)
	Former	37 (84.1)
	Current	4 (9.1)
ECOG PS, n (%)	0	17 (38.6)
	1	27 (61.4)
Brain metastasis, n (%)	Present	4 (9.1)
Liver metastasis, n (%)	Present	6 (13.6)

PD-L1 TPS, † %	NSQ	SQ	All
<1%	**78.9**	35.3	58.3
1–49%	5.3	47.1	25.0
≥50%	15.8	17.6	16.7

Pumitamig is a bispecific Ab targeting PD-L1 and VEGF-A.

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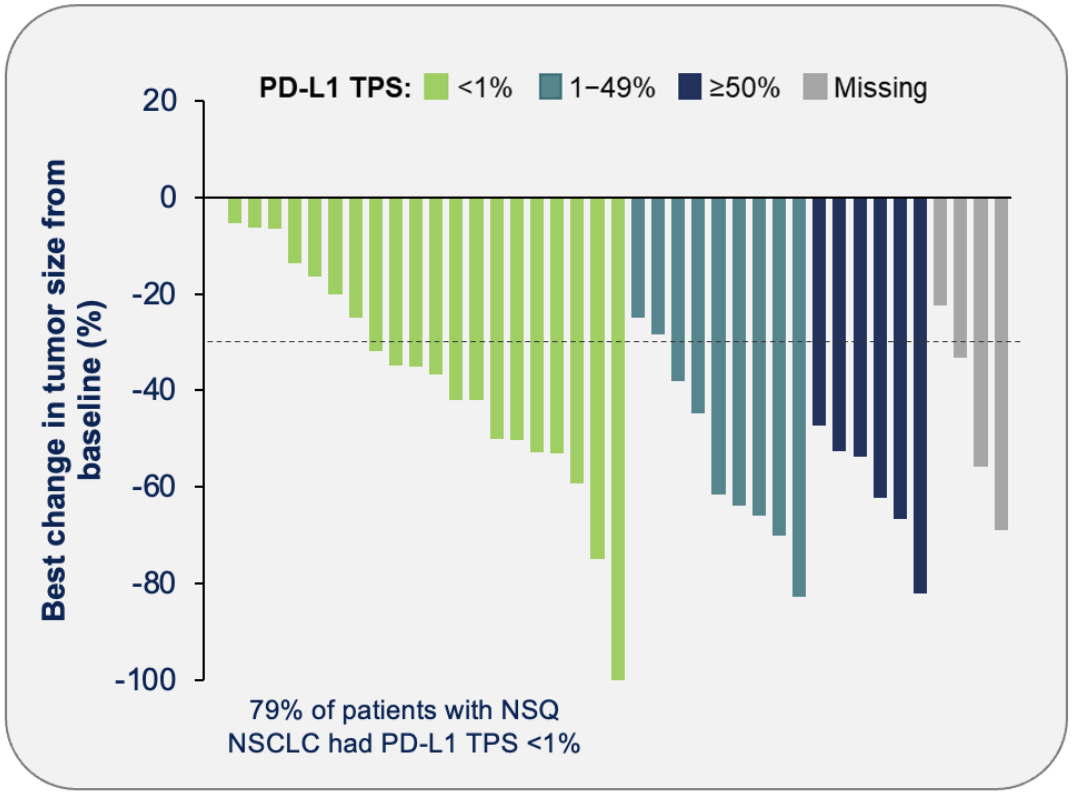
ROSETTA Lung-02: primary endpoint (ORR)

	Overall NSCLC (NSQ + SQ)				
	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)



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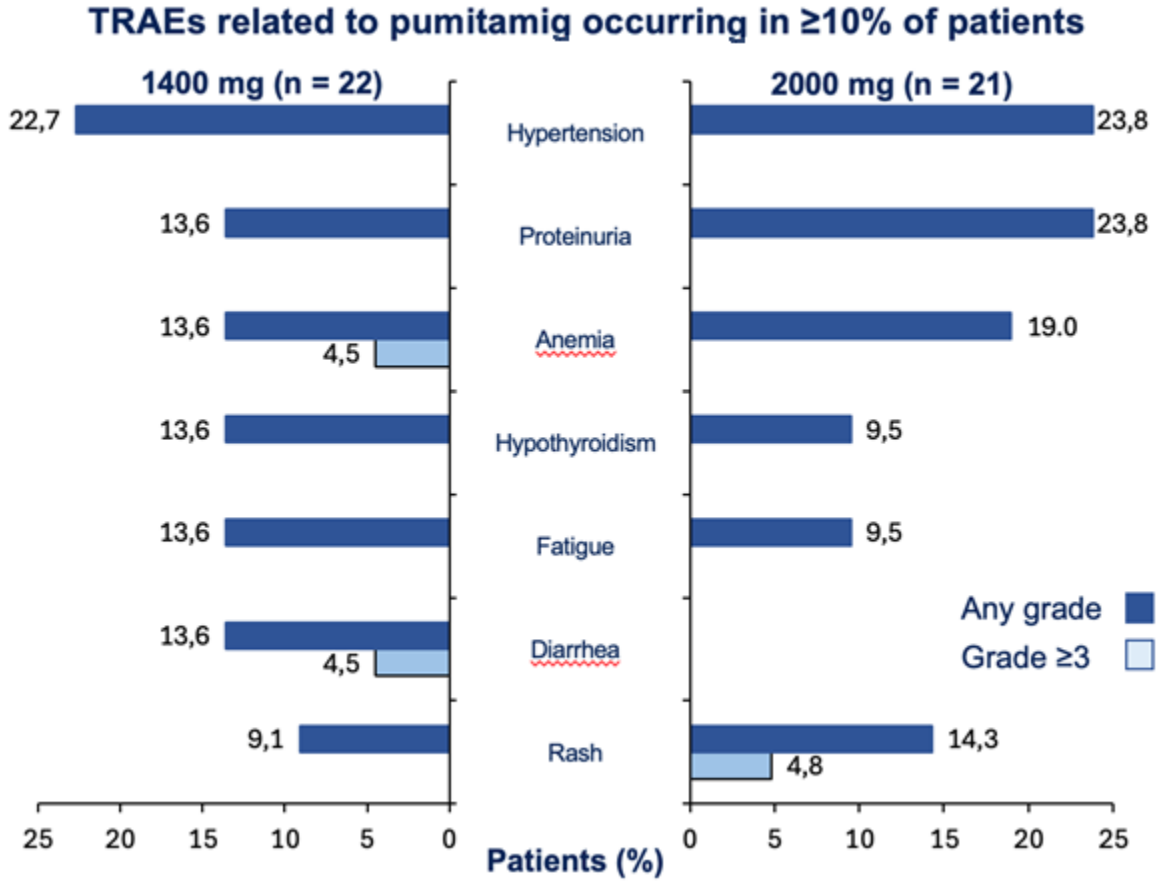
ROSETTA Lung-02: adverse events

	NSQ (n = 22)	SQ (n = 21)	Overall (N = 43)
Any TRAE, n (%)	19 (86.4)	21 (100.0)	40 (93.0)
Grade ≥3	8 (36.4)	13 (61.9)	21 (48.8)
Pumitamig-related TRAE, n (%)	14 (63.6)	19 (90.5)	33 (76.7)
Grade ≥3	4 (18.2)	6 (28.6)	10 (23.3)
TRAE leading to discontinuation, n (%)	3 (13.6)	5 (23.8)	8 (18.6)
Pumitamig-related	1 (4.5)	3 (14.3)	4 (9.3)
TRAE leading to death, n (%)	0	1 (4.8)*	1 (2.3)*
Pumitamig-related	0	1 (4.8)*	1 (2.3)*
Any irAE TEAE , n (%)	8 (36.4)	8 (38.1)	16 (37.2)
Grade ≥3	1 (4.5)	1 (4.8)	2 (4.7)
VEGF-related TEAEs, n (%)	10 (45.5)	14 (66.7)	24 (55.8)
Grade ≥3	1 (4.5)	1 (4.8)	2 (4.7)
Hemorrhage/bleeding TEAEs, n (%)	2 (9.1)	7 (33.3)	9 (20.9)
Grade ≥3	0	1 (4.8)‡	1 (2.3)‡



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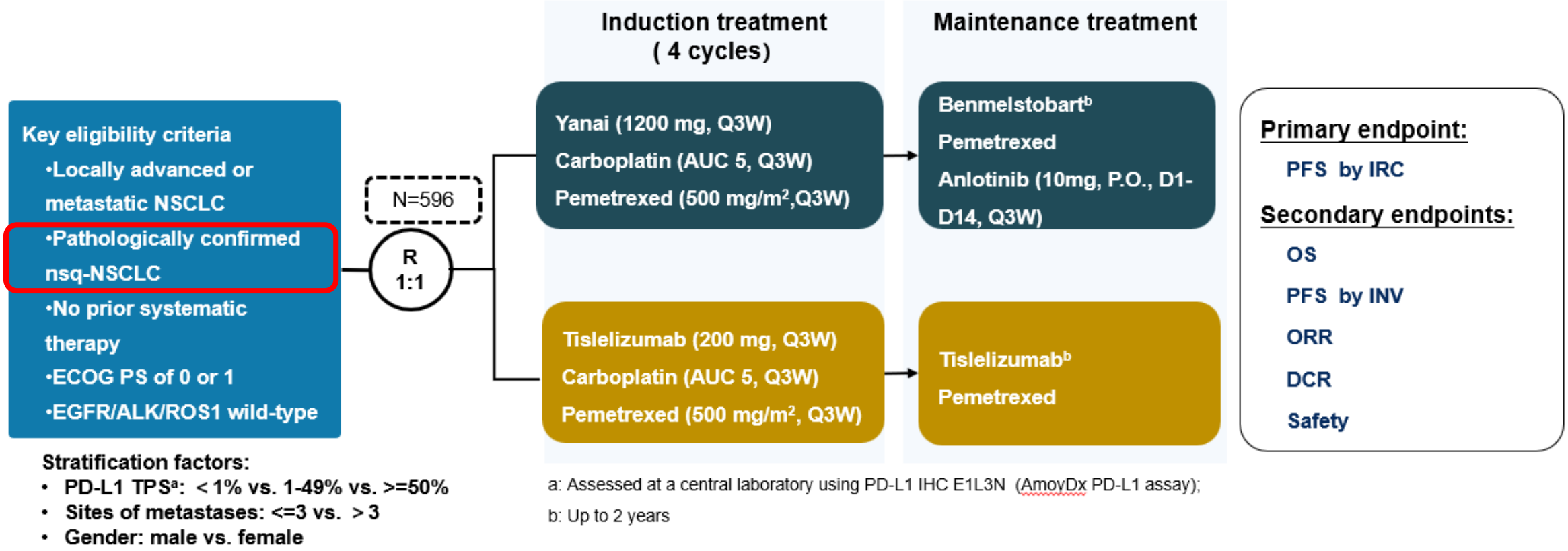
Phase 2 data from ROSETTA Lung-02: a global, randomized, phase 2/3 trial of pumitamig (PD-L1 x VEGF-A bsAb) + chemotherapy in 1L NSCLC. Peters S et al.

TQB2450-III-11: study design



Stratification factors:

- **PD-L1 TPS[a]: < 1% vs. 1-49% vs. >=50%**
- **Sites of metastases: <=3 vs. > 3**
- **Gender: male vs. female**

a: Assessed at a central laboratory using PD-L1 IHC E1L3N (AmoyDx PD-L1 assay);

b: Up to 2 years

Benmelstobart is a monoclonal Ab targeting PD-L1.
Tislelizumab is a monoclonal Ab targeting PD-1.
Anlotinib is a TKI targeting VEGF, PDGFR, FGFR, c-KIT and RET.

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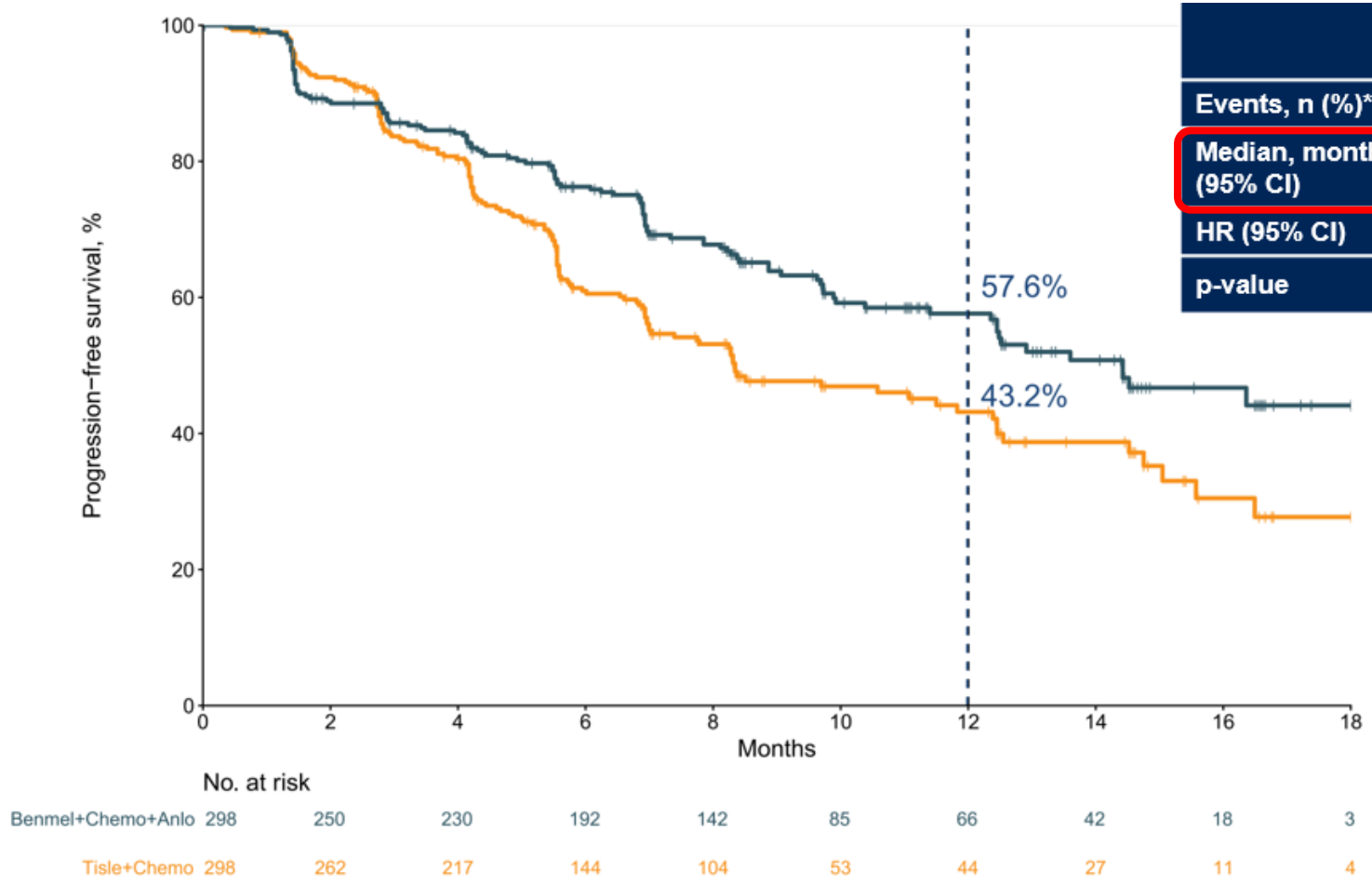
TQB2450-III-11: primary endpoint (PFS)



	Benmel + Chemo & Anlo (N=298	Tisle +Chemo (N=298)
Events, n (%)*	113	144
Median, months (95% CI)	14.42(12.35,NE)	8.34(6.97,12.39)
HR (95% CI)	0.67(0.52,0.86)	
p-value	0.0017	

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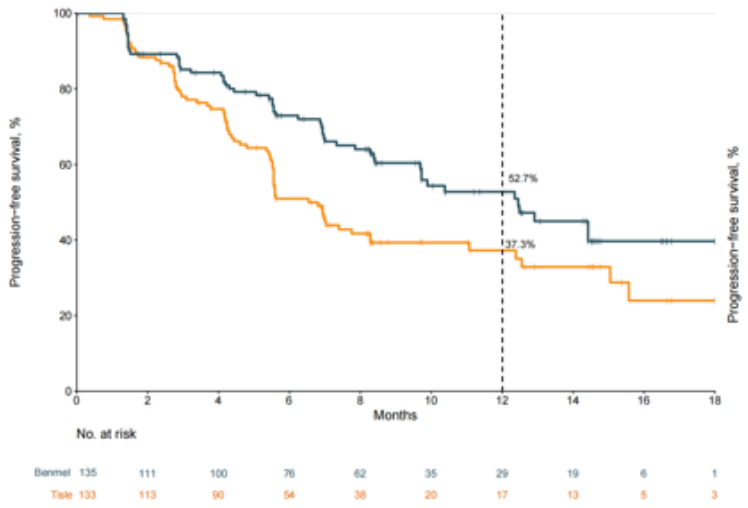
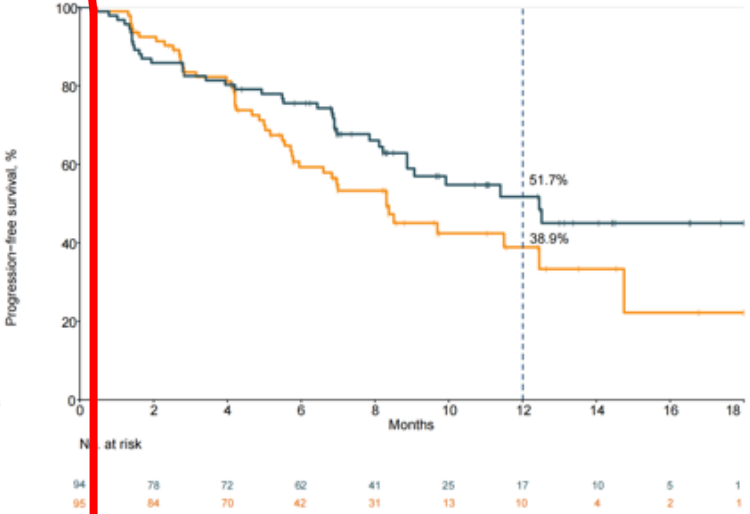
TQB2450-III-11: subgroup analysis

PD-L1 <1%



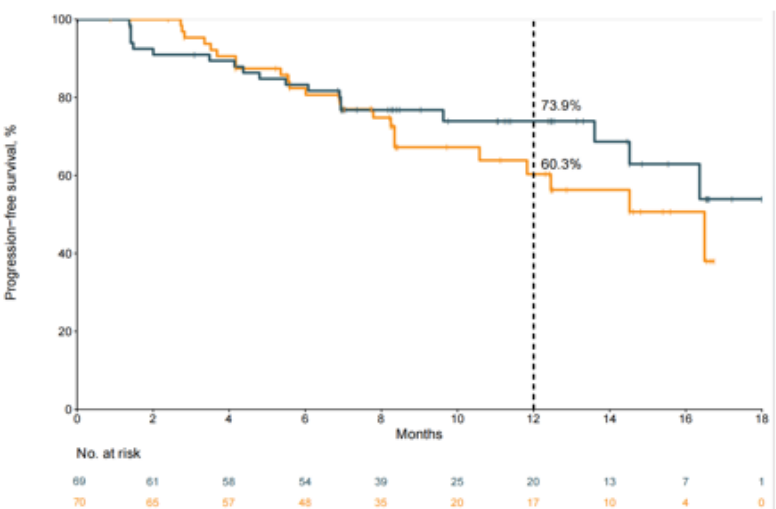
	Benmel + Chemo & Anlo	Tisle +Chemo
Median, months (95% CI)	12.45(9.69,NR)	6.54(5.52,8.28)
HR (95% CI)	0.61(0.43,0.86)	

PD-L1 1-49%



	Benmel + Chemo & Anlo	Tisle +Chemo
	12.45(8.87,NR)	8.31(5.78,12.45)
	0.69(0.45,1.06)	

PD-L1 ≥50%



	Benmel + Chemo & Anlo	Tisle +Chemo
	NR(14.52,NR)	16.49(10.52,NR)
	0.75(0.41,1.39)	

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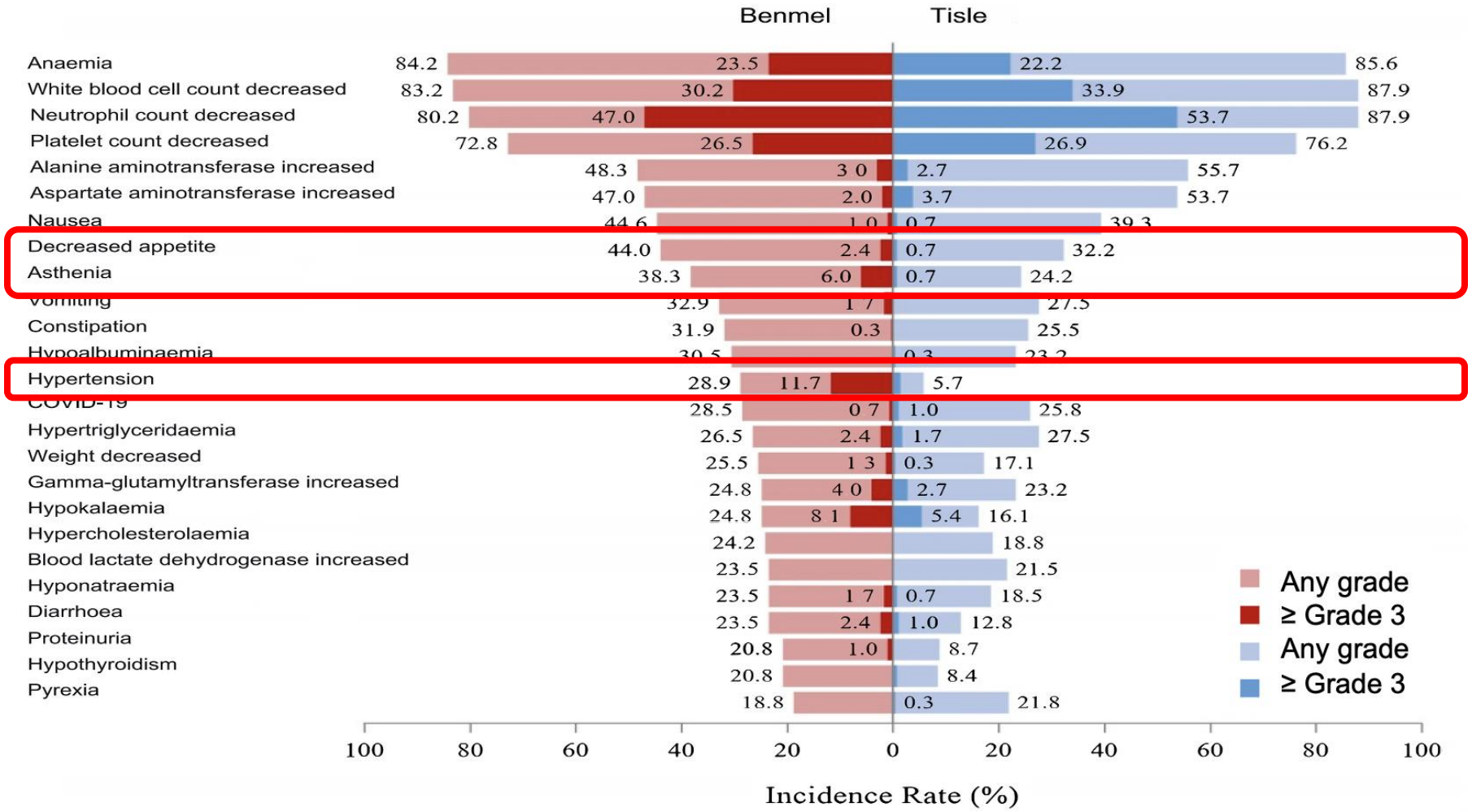
TQB2450-III-11: AE in >20% of patients



G3+ AE in 78.2% (AB) vs. 73.5% (T), similar discontinuation rate.

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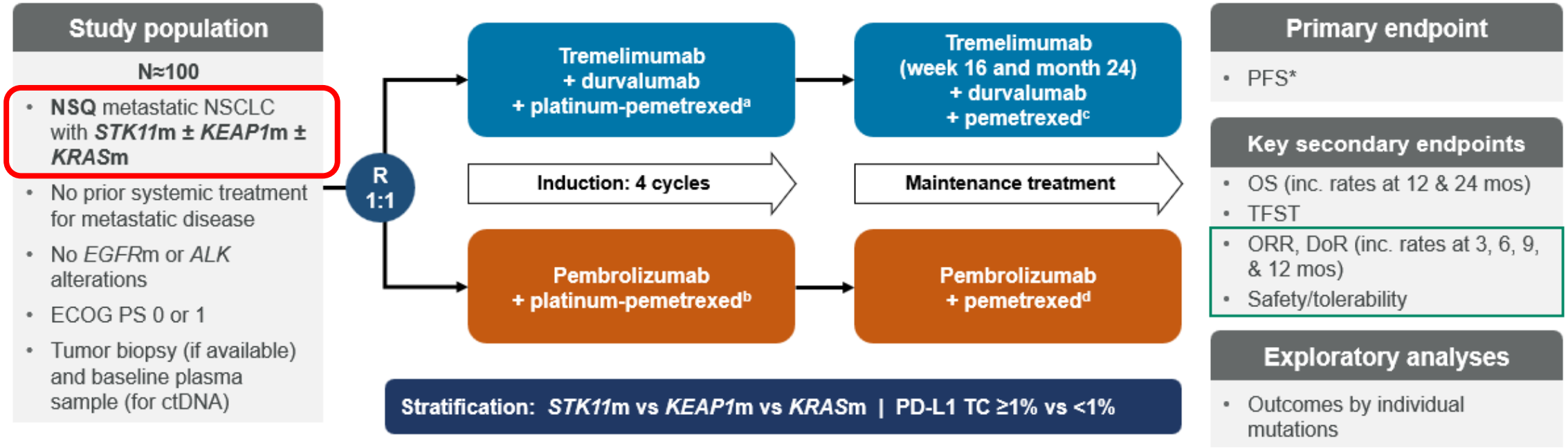
TRITON: study design



KEAP-1 and STK11 mutations are present in 15% and 20% of NSQ NSCLC. They are associated with poor outcome in IO +/- CT, even more in KRASm+ NSCLC.

POSEIDON suggests additional effect of tremelimumab in this population (Johnson ML. J Clin Oncol 2023).

Tremelimumab is a monoclonal antibody targeting CTLA-4.

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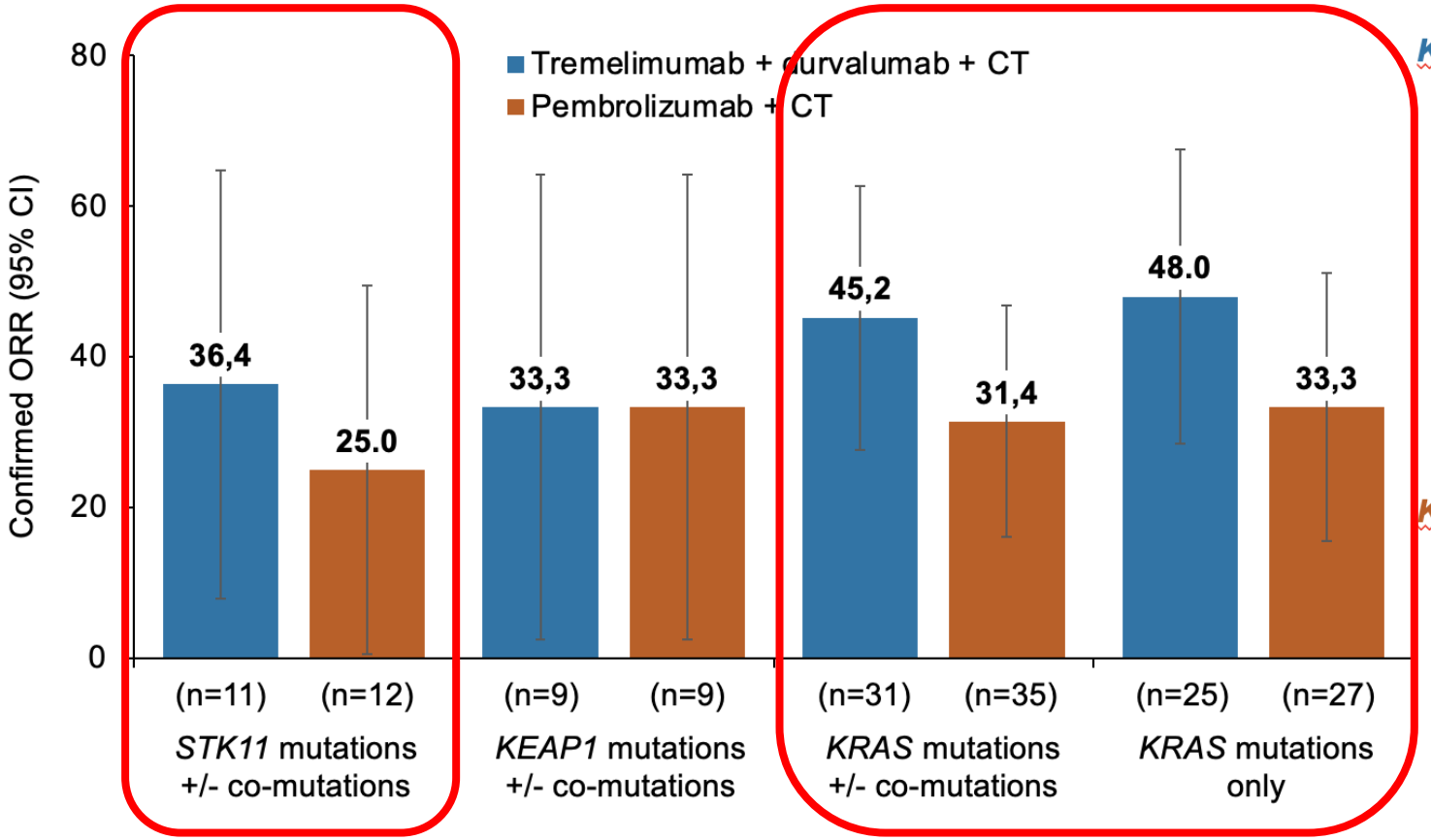
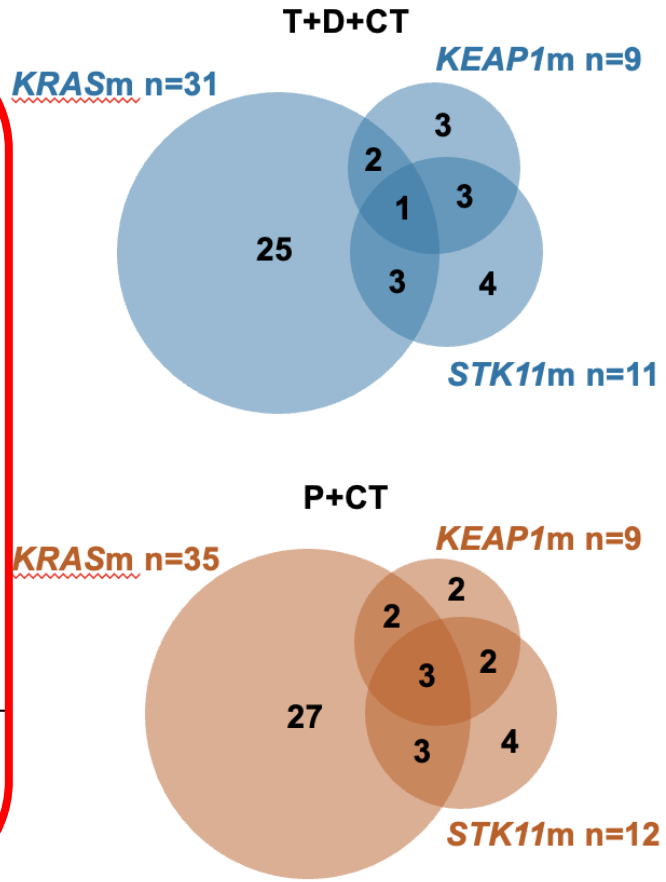
TRITON: key secondary endpoint (ORR)





ORR in the overall population was 39.0% vs. 34.9%. mDOR was 6.4 m.

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Tremelimumab + durvalumab + chemotherapy vs pembrolizumab + chemotherapy in 1L non-squamous metastatic NSCLC with *STK11*, *KEAP1* and/or *KRAS* mutations: Interim analysis of the phase 2b TRITON study. Skoulidis F et al.

TRITON: adverse events

	D+T+CT n=41	P+CT n=43
Median (range) safety follow-up for D/P, months	5.6 (0.0–14.0)	5.1 (0.0–17.5)
Any-grade all-cause AEs, n (%)	41 (100)	42 (97.7)
Grade 3/4 AEs*	31 (75.6)	27 (62.8)
Serious AEs	26 (63.4)	26 (60.5)
AEs leading to treatment discontinuation†	1 (2.4)	2 (4.7)
AEs leading to death	2 (4.9)	5 (11.6)
Any-grade treatment-related AEs‡, n (%)	36 (87.8)	38 (88.4)
Grade 3/4 AEs*	17 (41.5)	18 (41.9)
Serious AEs	11 (26.8)	11 (25.6)
AEs leading to treatment discontinuation†	1 (2.4)	2 (4.7)
AEs leading to death	0	1 (2.3)§
Any imAEs¶, n (%)	6 (14.6)	7 (16.3)
Grade 3/4 imAEs	0	3 (7.0)

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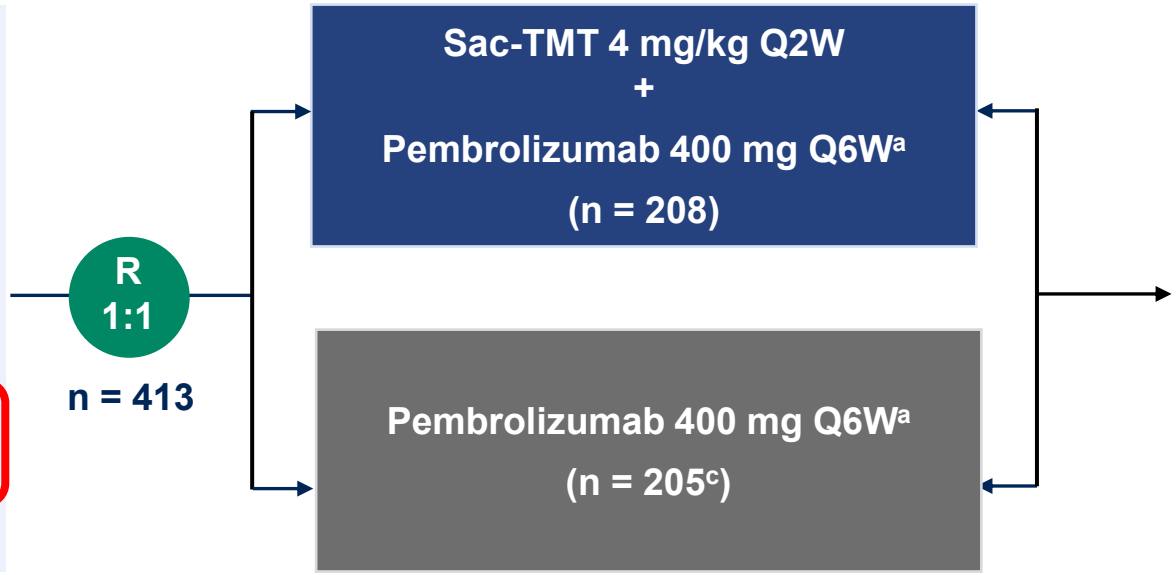
OptiTROP-Lung05: study design

Key Eligibility

- Locally advanced (stage IIIB/IIIC) or metastatic (stage IV) NSCLC
- No prior systemic antitumor therapy
- No sensitizing *EGFR* or *ALK* alteration
- PD-L1 TPS≥ 1% (IHC 22C3, central lab)
- ECOG score 0 or 1



Endpoints [b]

Primary

- PFS assessed by BICR

Secondary

- OS (key secondary endpoint)
- PFS assessed by investigator
- ORR, DCR, DOR, etc.
- Safety

Sacituzumab is a monoclonal Ab targeting TROP 2. Tirumotecan is a topoisomerase I inhibitor.

Phase 2 OptiTROP-Lung01: sac-TMT + tagitanlimab (Hong S. Nature Med 2025): PFS 15.4 m-NR.

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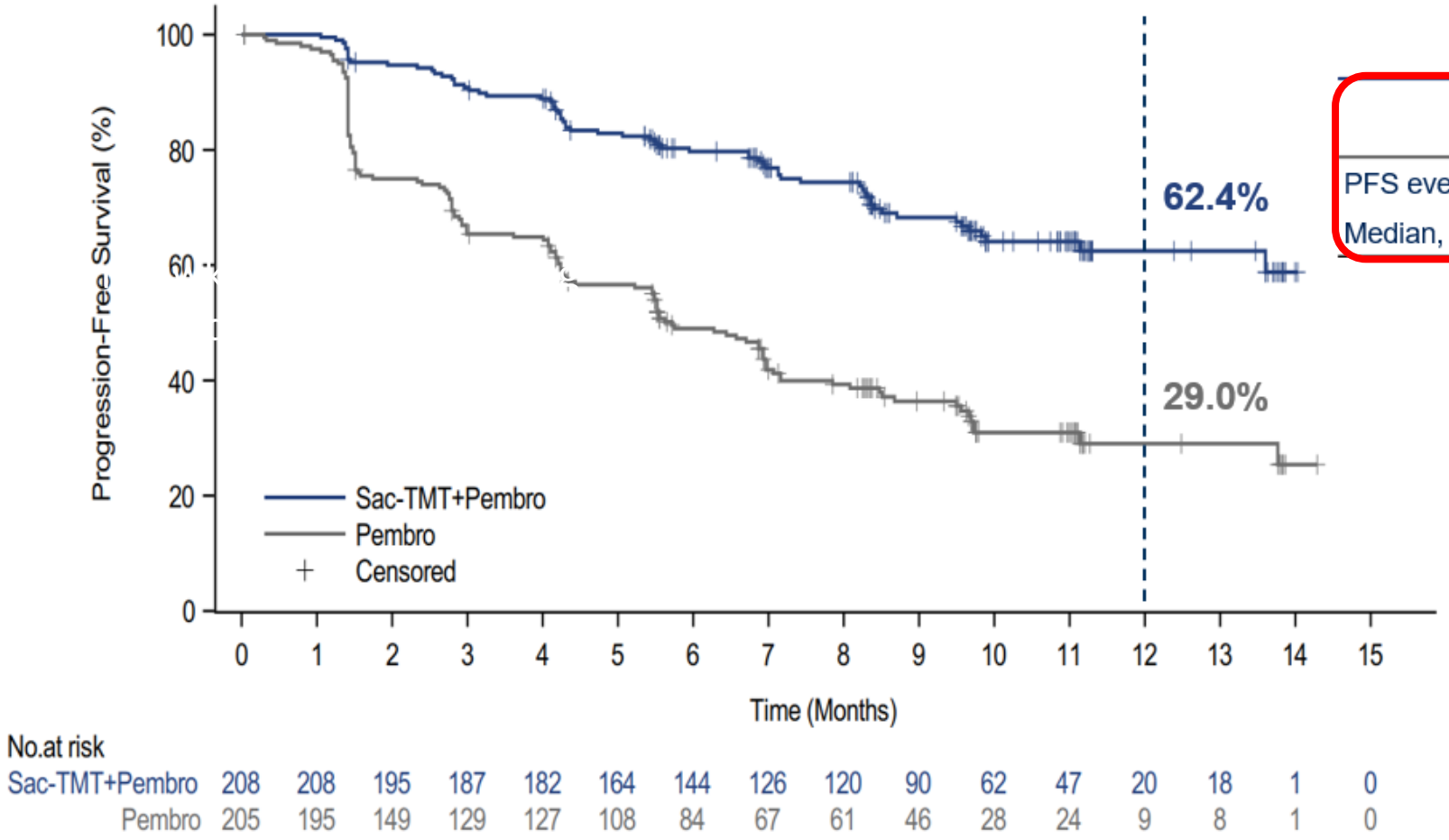
OptiTROP-Lung05: primary endpoint (PFS)



	Sac-TMT + Pembro (n = 208)	Pembro (n = 205)
PFS events, n (%)	66 (31.7)	128 (62.4)
Median, mo (95%CI)	NR (13.6, NE)	5.7 (4.3, 7.0)

HR 0.35 (95%CI: 0.26, 0.47)

***p* < 0.0001[a]**

EVOKE-03 (sac-govitecan) showed no difference in mPFS according to a press release from MSD and Gilead.

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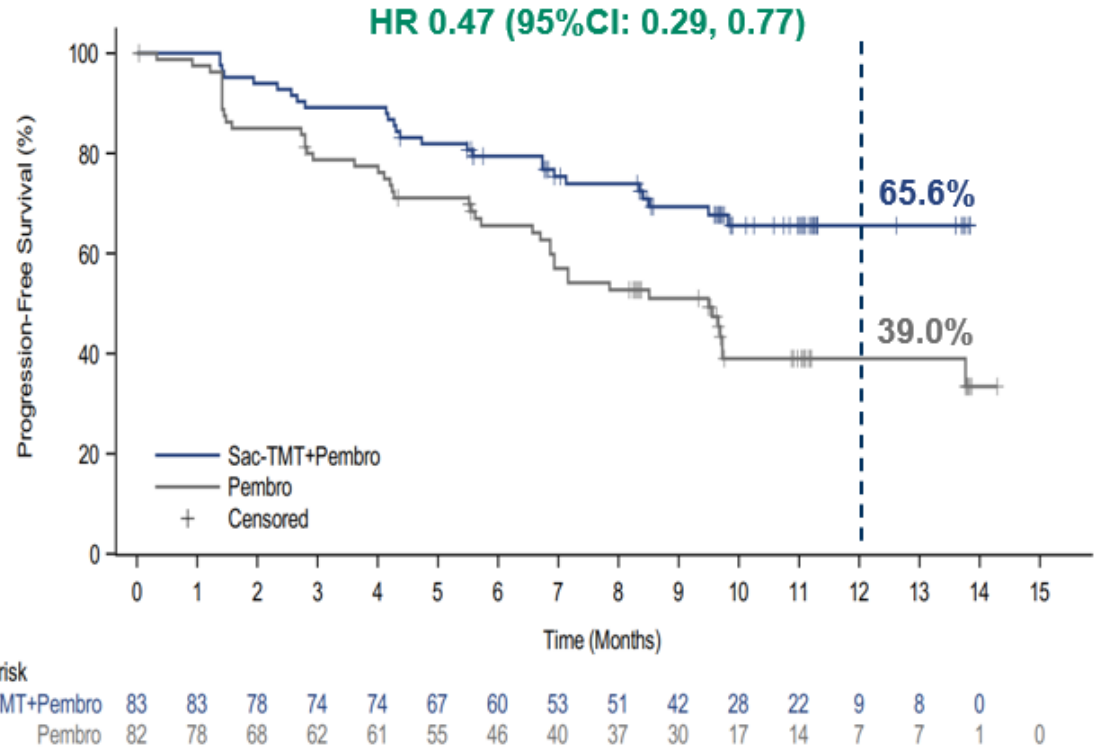
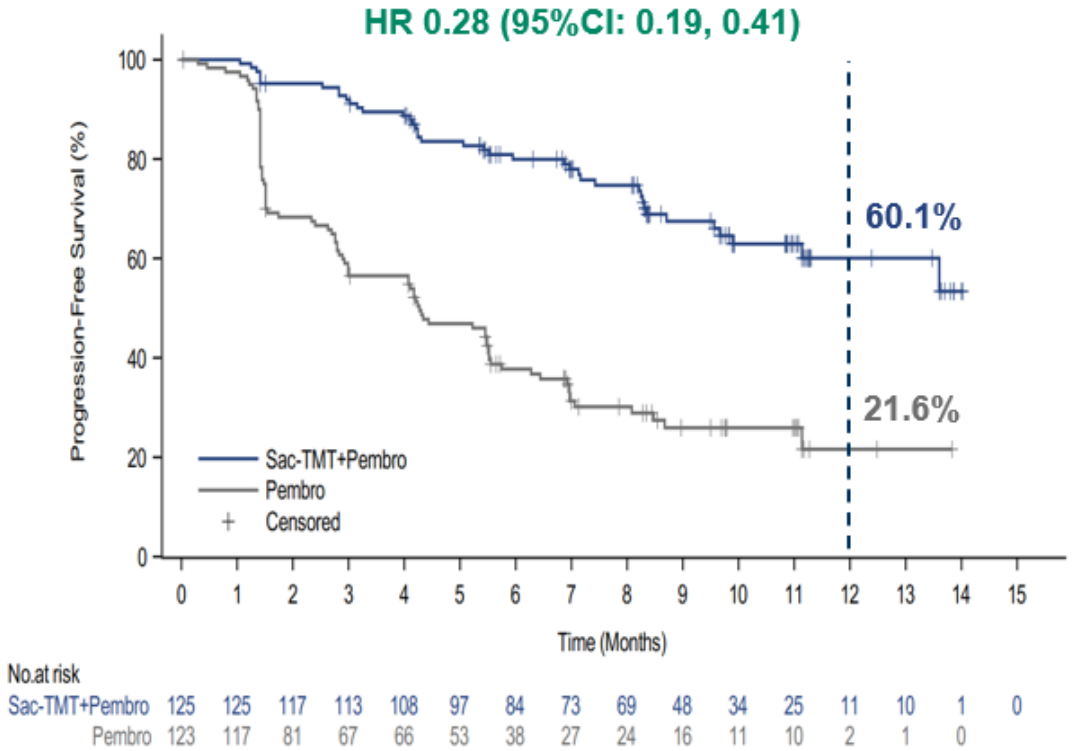
Sacituzumab tirumotecan (sac-TMT) plus pembrolizumab versus pembrolizumab as first-line treatment for PD-L1-positive advanced non-small cell lung cancer (NSCLC): results from the randomized phase 3 OptiTROP-Lung05 study. Zhou C et al.

OptiTROP-Lung05: subgroup analysis

TPS ≥ 50%	Sac-TMT + Pembro (n = 83)	Pembro (n = 82)
PFS events, n (%)	26 (31.3)	44 (53.7)
Median, mo (95%CI)	NR (NE, NE)	9.5 (6.9, 13.8)



TPS 1-49%	Sac-TMT + Pembro (n = 125)	Pembro (n = 123)
PFS events, n (%)	40 (32.0)	84 (68.3)
Median, mo (95%CI)	NR (11.1, NE)	4.3 (2.9, 5.5)



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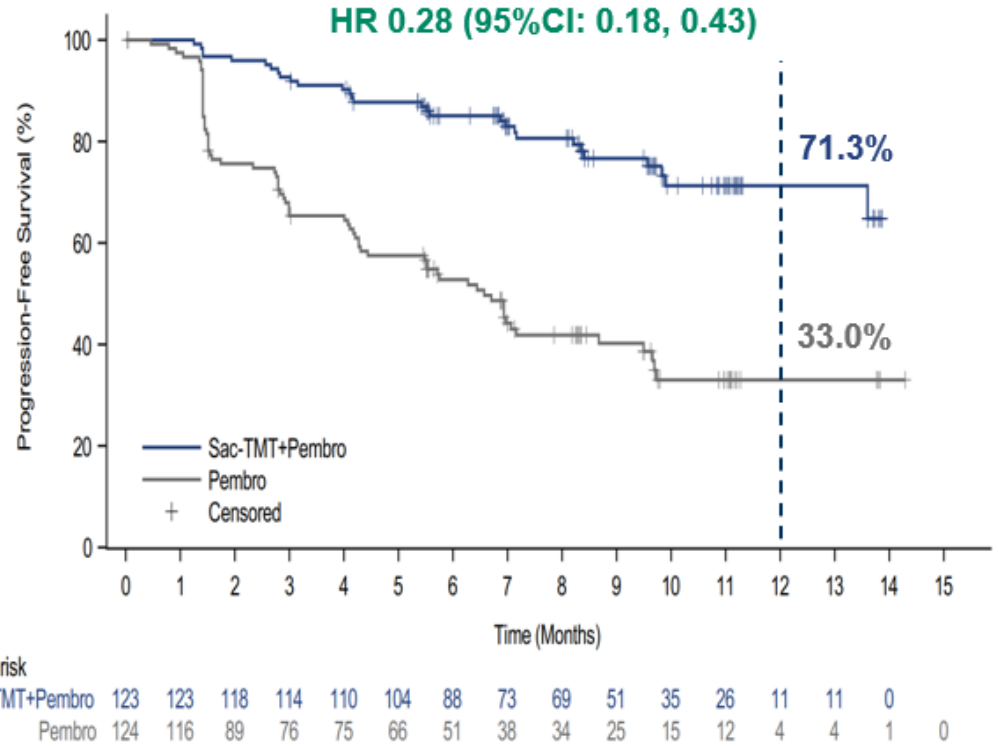
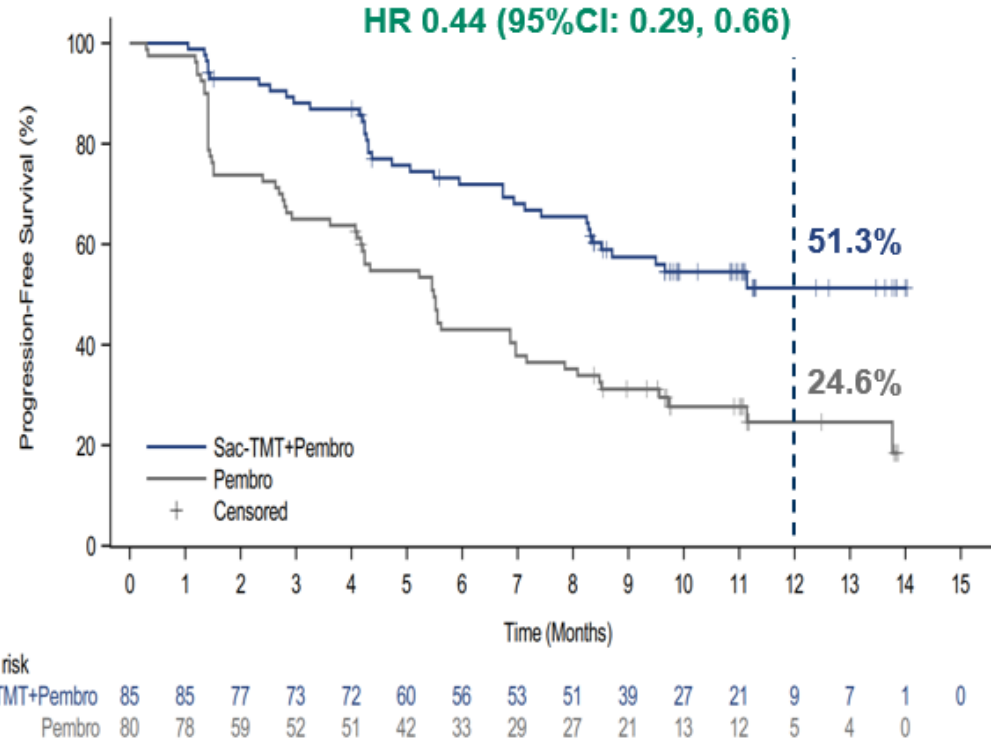
Sacituzumab tirumotecan (sac-TMT) plus pembrolizumab versus pembrolizumab as first-line treatment for PD-L1-positive advanced non-small cell lung cancer (NSCLC): results from the randomized phase 3 OptiTROP-Lung05 study. Zhou C et al.

OptiTROP-Lung05: subgroup analysis

Non-Squamous	Sac-TMT + Pembro (n = 123)	Pembro (n = 124[a])
PFS events, n (%)	29 (23.6)	70 (56.5)
Median, mo (95%CI)	NR (13.6, NE)	6.6 (4.3, 8.7)



Squamous	Sac-TMT + Pembro (n = 85)	Pembro (n = 80)
PFS events, n (%)	37 (43.5)	58 (72.5)
Median, mo (95%CI)	NR (8.3, NE)	5.5 (4.1, 7.0)



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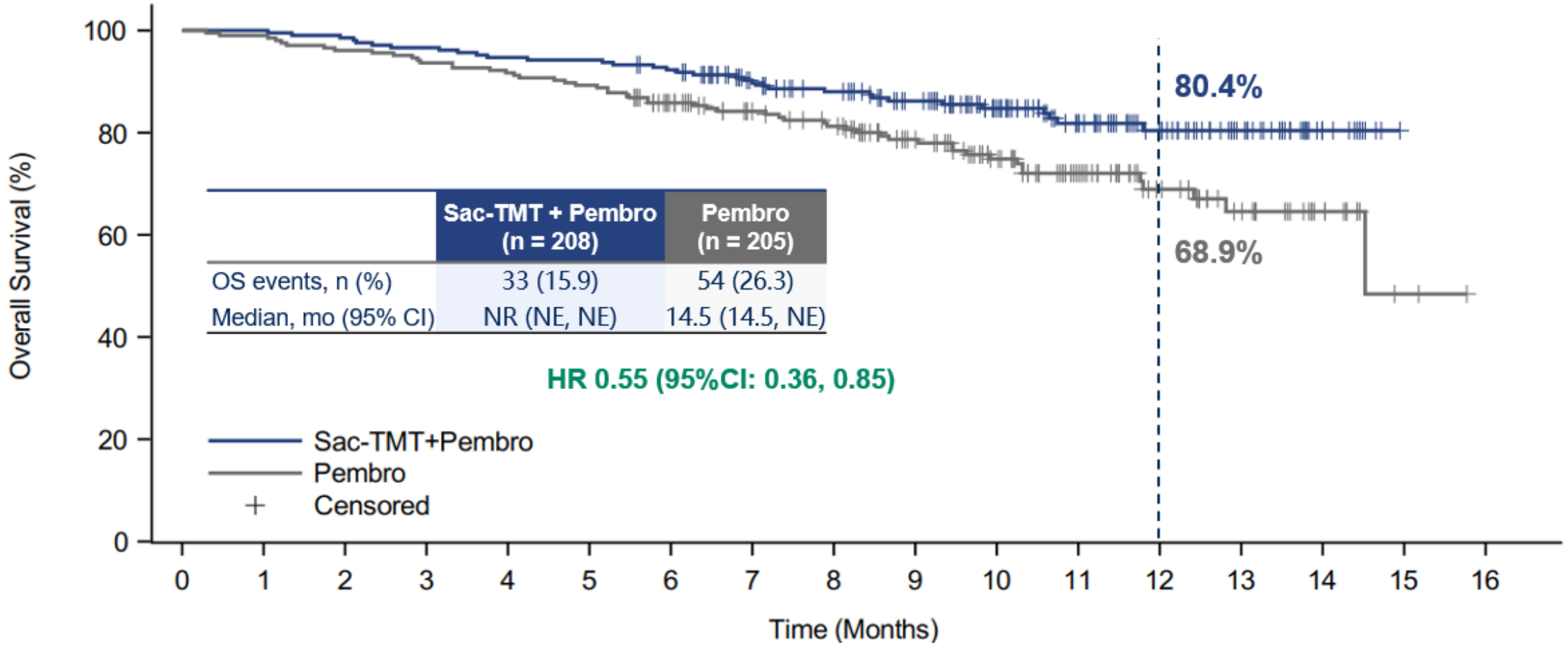
Sacituzumab tirumotecan (sac-TMT) plus pembrolizumab versus pembrolizumab as first-line treatment for PD-L1-positive advanced non-small cell lung cancer (NSCLC): results from the randomized phase 3 OptiTROP-Lung05 study. Zhou C et al.

OptiTROP-Lung05: secondary enpoint (OS)



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Sacituzumab tirumotecan (sac-TMT) plus pembrolizumab versus pembrolizumab 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.

OptiTROP-Lung05: adverse events

Event, n (%)	Sac-TMT + Pembro (n = 208)		Pembro (n = 204)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Treatment-emergent AEs	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/ pembro	8 (3.8) / 11 (5.3)	—	10 (4.9)	—
Led to death	5 (2.4)	—	13 (6.4)	—
Common TEAEs[a]				
Anemia	182 (87.5)	19 (9.1)	55 (27.0)	2 (1.0)
Alopecia	137 (65.9)	0	6 (2.9)	0
White blood cell 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
Decreased appetite	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)

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Sacituzumab tirumotecan (sac-TMT) plus pembrolizumab versus pembrolizumab 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.

2.
Surgery and radiotherapy in lung cancer

PRESENTED BY: Jo Raskin MD
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ABSTRACTS

- **Complex segmentectomy versus lobectomy in small-sized peripheral non-small cell lung cancer: : a post-hoc supplemental analysis of a multicenter, open-label, phase 3 trial (JCOG0802/WJOG4607L.**

- **Neoadjuvant fractionated stereotactic radiotherapy followed by surgical resection for brain metastases. A multicenter, single arm phase II trial (NEO-TACTICS).**
- **Final results of a randomized, controlled, phase 3 trial comparing resection and post-operative stereotactic radiation versus resection and cesium-131 tile-based radiation for treatment of newly diagnosed brain metastases.**

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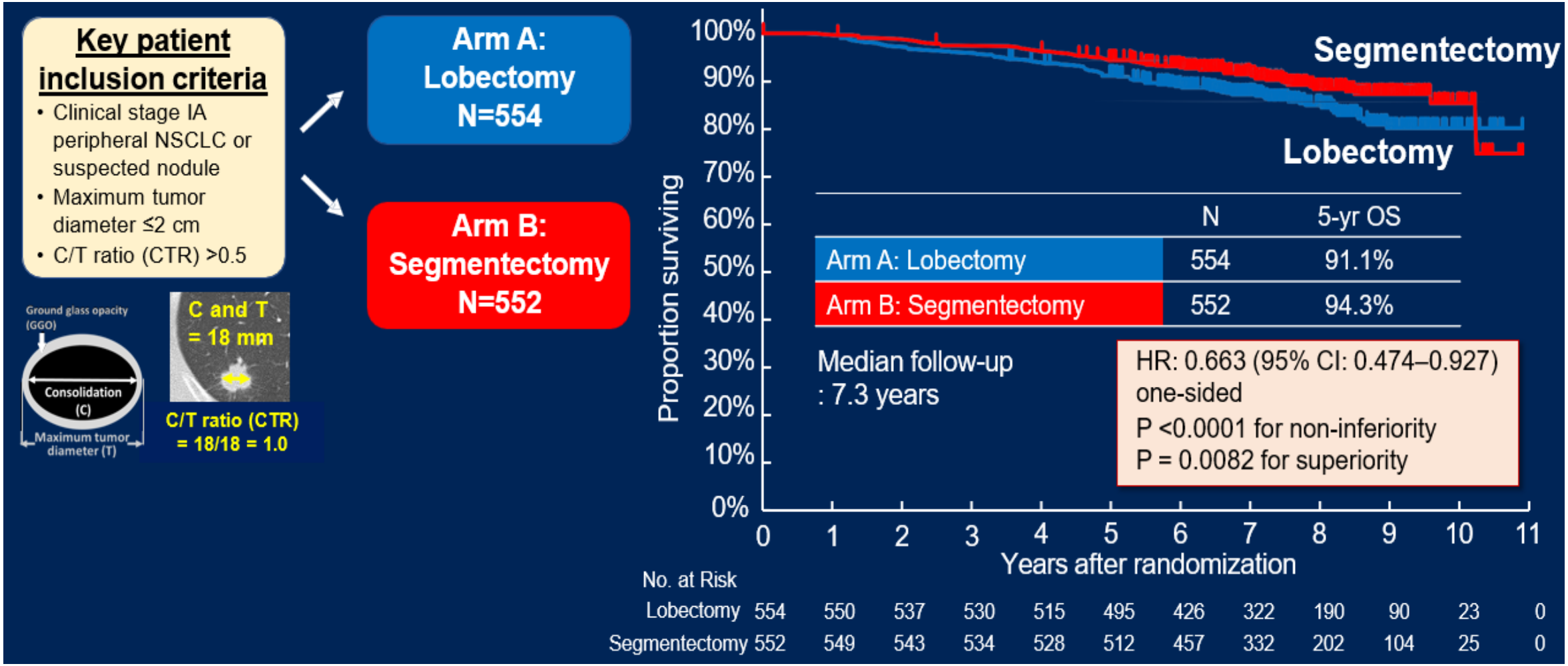
JCOG0802: study design



Published as: Saji H. Lancet 2022.

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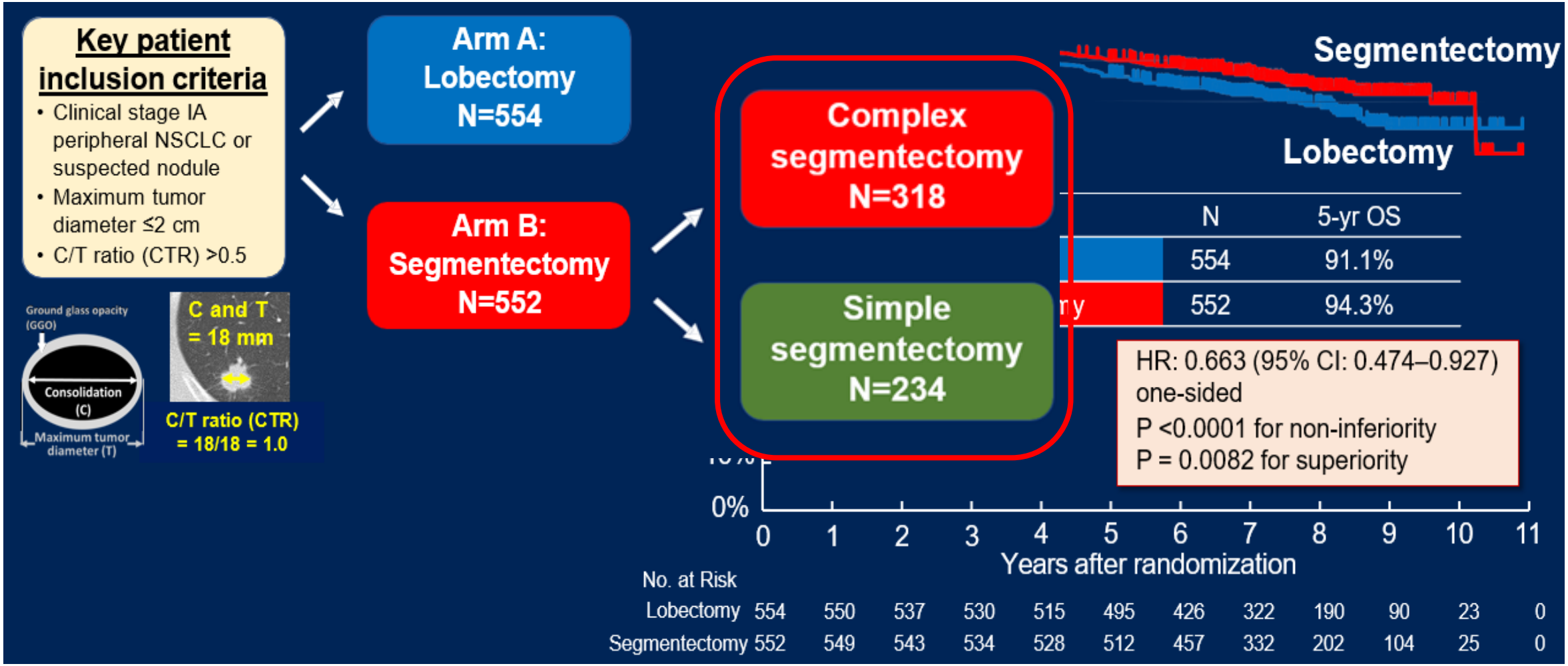
JCOG0802: study design



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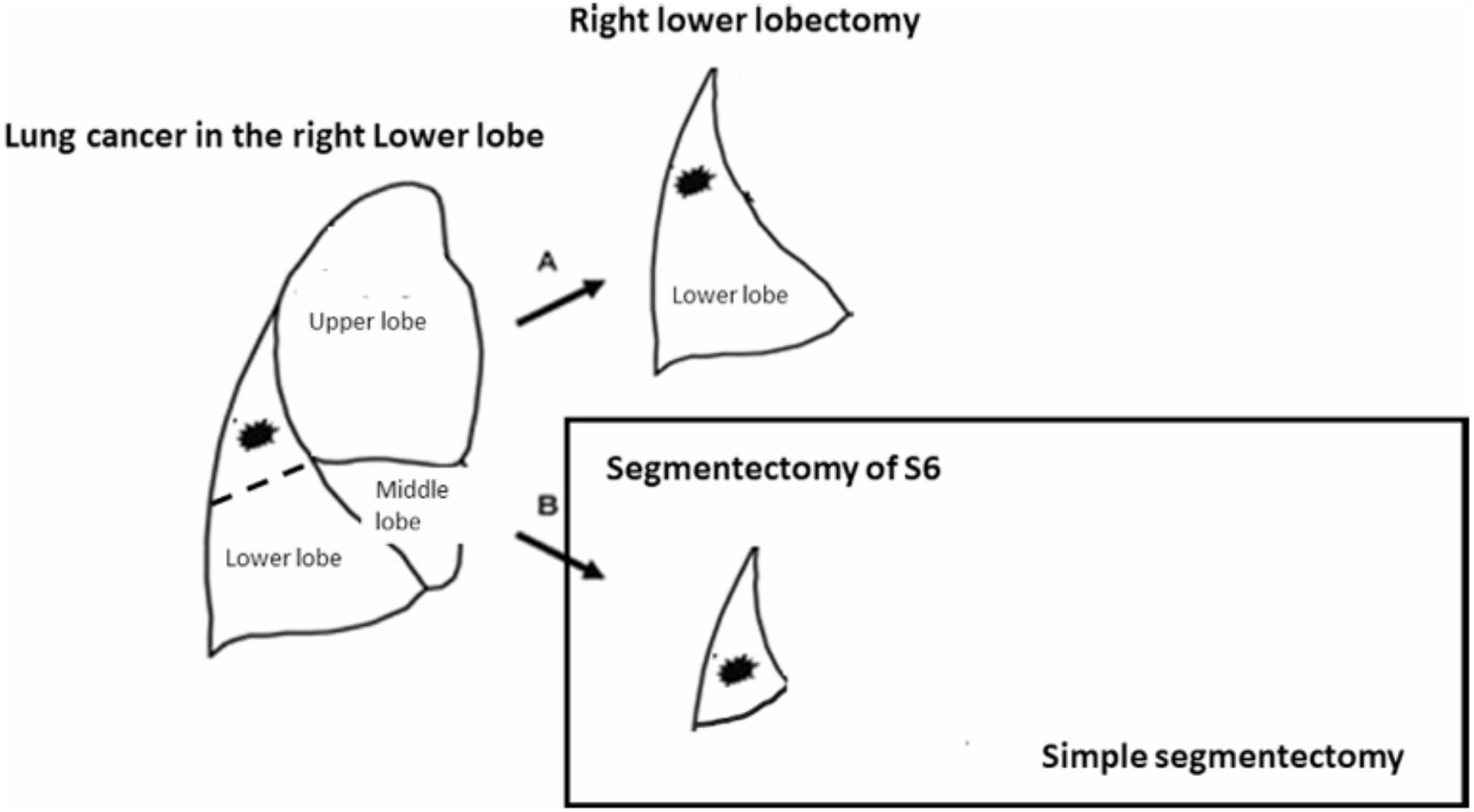
JCOG0802: simple segmentectomy



Suzuki K. J Thorac Cardiovasc Surg 2019

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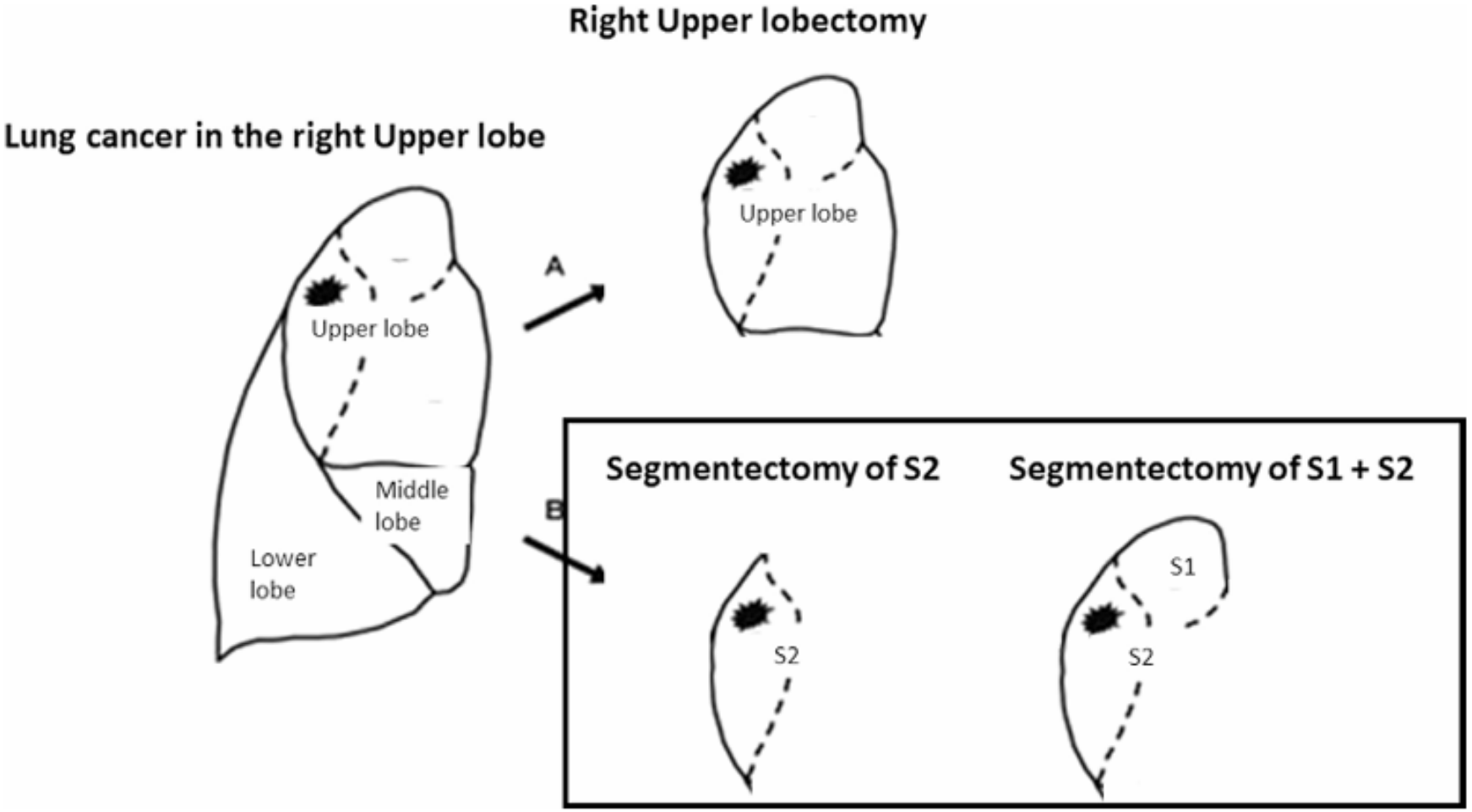
Complex segmentectomy versus lobectomy in small-sized peripheral non-small cell lung cancer. Kamigaichi A et al.

JCOG0802: complex segmentectomy



Suzuki K. J Thorac Cardiovasc Surg 2019

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Complex segmentectomy versus lobectomy in small-sized peripheral non-small cell lung cancer. Kamigaichi A et al.

JCOG0802: patient characteristics

	Lobectomy N=554	Complex Segmentectomy N=318	Simple Segmentectomy N=234
Median age (IQR)	67 (61-72)	68 (61-73)	65.5 (60-72)
Sex, male (%)	293 (52.9)	160 (50.3)	130 (55.6)
Smoking history, yes (%)	308 (55.6)	177 (55.7)	131 (56.0)
Median maximum tumor size, cm (IQR)	1.6 (1.3-1.8)	1.5 (1.3-1.8)	1.6 (1.4-1.8)
CT findings, pure solid (%)	274 (49.5)	149 (46.9)	130 (55.6)
Median FEV1.0, mL (IQR)	2260 (1870-2690)	2280 (1960-2710)	2285 (1960-2760)
Median FVC, mL (IQR)	3120 (2580-3710)	3075 (2570-3700)	3110 (2660-3680)
Median surgical time, min (IQR)	174 (140-216)	216.5 (175-270)	182 (150-233)
Median bleeding ,mL (IQR)	44.5 (20-95)	55 (25-125)	40 (20-99)
Histology, ad/others (%)	485 (87.5) / 69 (12.5)	279 (87.7) / 39 (12.3)	204 (87.2) / 30 (12.8)
Nodal metastasis, p-N1/N2 (%)	16 (2.9) / 15 (2.7)	11 (3.5) / 11 (3.5)	6 (2.6) / 6 (2.6)
Median surgical margin ,cm (IQR)	4.0 (3.0-5.0)	2.2 (1.5-3.0)	2.5 (1.9-3.5)

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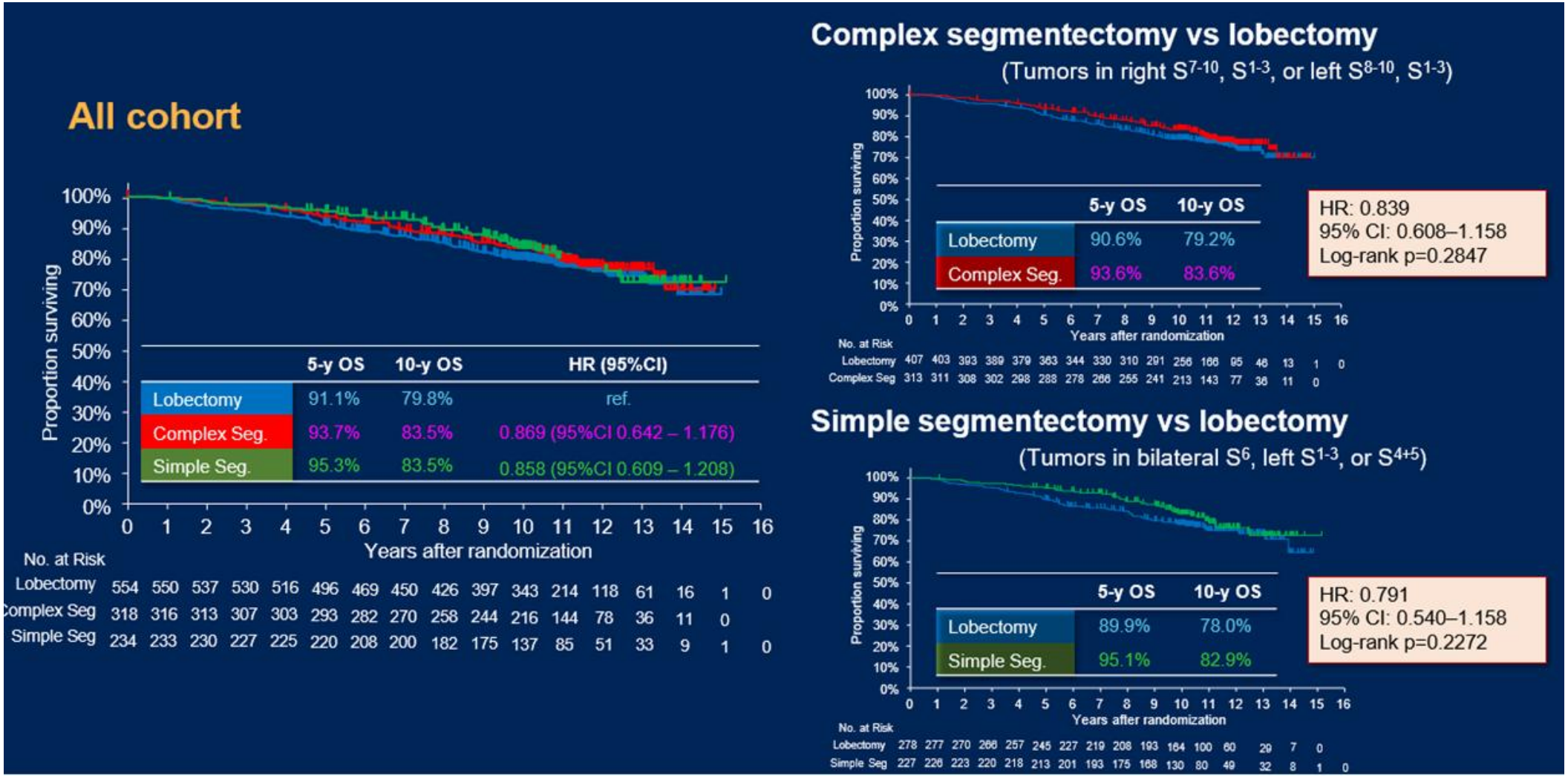
JCOG0802: location-adjusted overall survival



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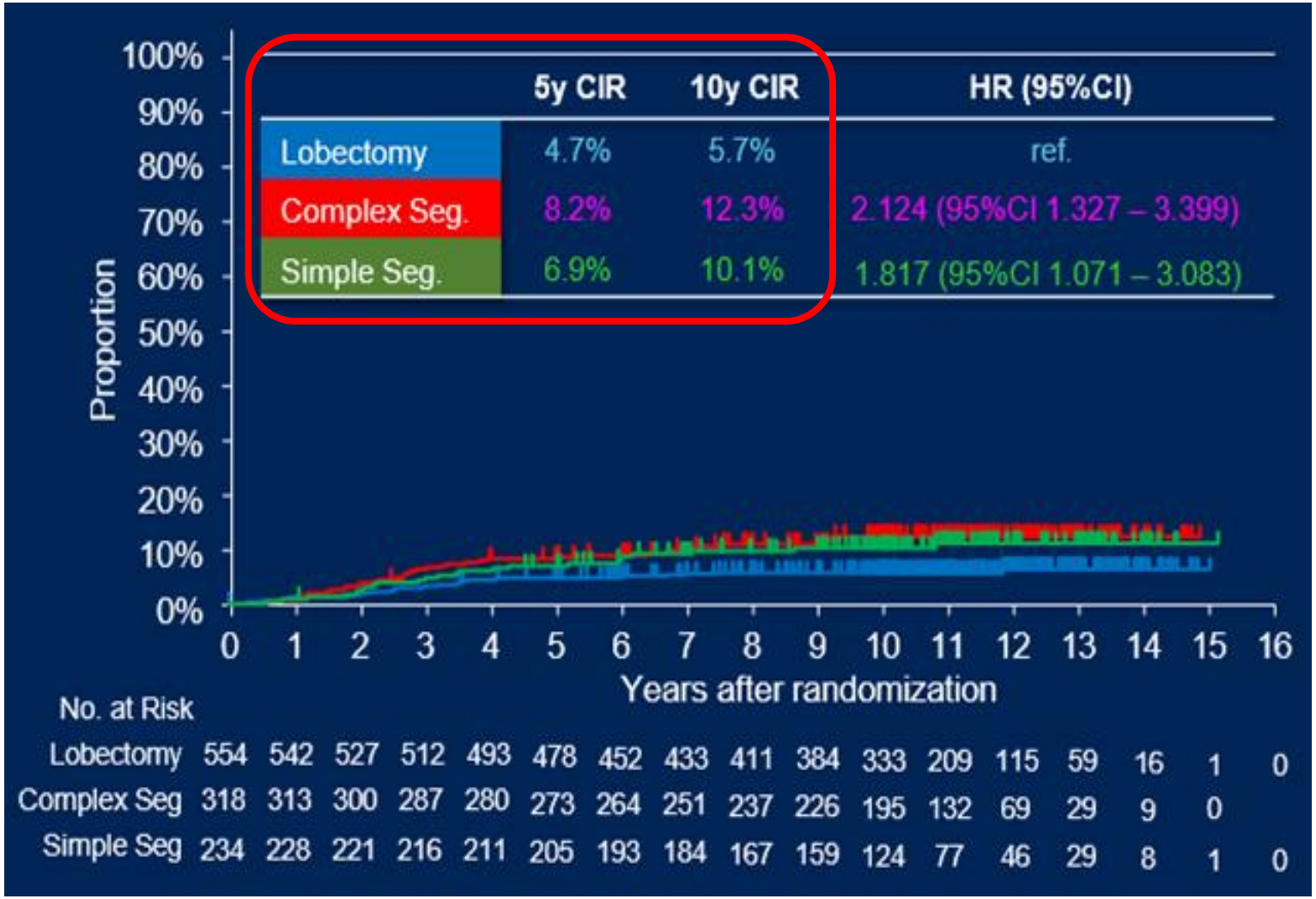
Complex segmentectomy versus lobectomy in small-sized peripheral non-small cell lung cancer. Kamigaichi A et al.

JCOG0802: locoregional relapse



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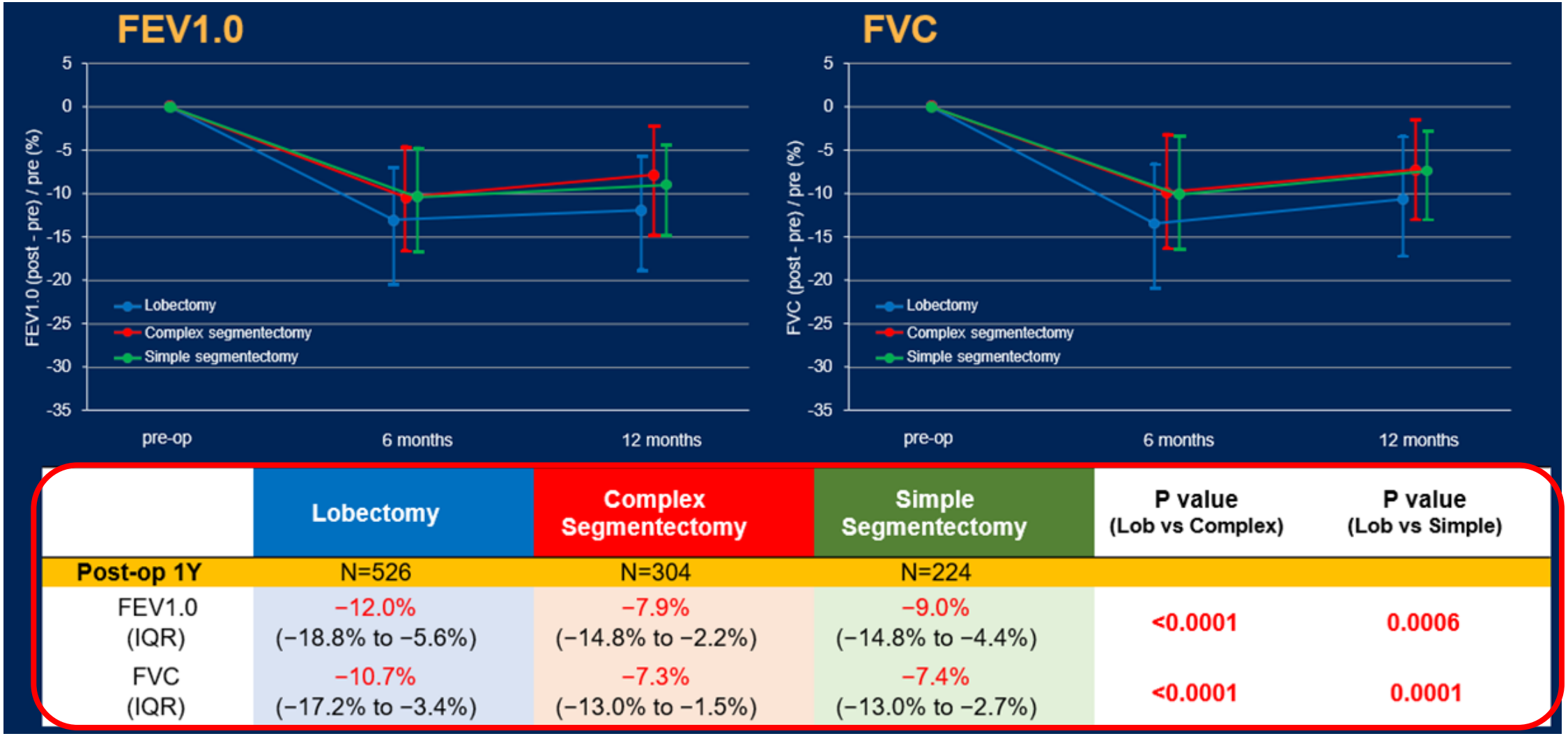
Complex segmentectomy versus lobectomy in small-sized peripheral non-small cell lung cancer. Kamigaichi A et al.

JCOG0802: impact on pulmonary function



	Lobectomy	Complex Segmentectomy	Simple Segmentectomy	P value (Lob vs Complex)	P value (Lob vs Simple)
Post-op 1Y	N=526	N=304	N=224		
FEV1.0 (IQR)	−12.0% (−18.8% to −5.6%)	−7.9% (−14.8% to −2.2%)	−9.0% (−14.8% to −4.4%)	<0.0001	0.0006
FVC (IQR)	−10.7% (−17.2% to −3.4%)	−7.3% (−13.0% to −1.5%)	−7.4% (−13.0% to −2.7%)	<0.0001	0.0001

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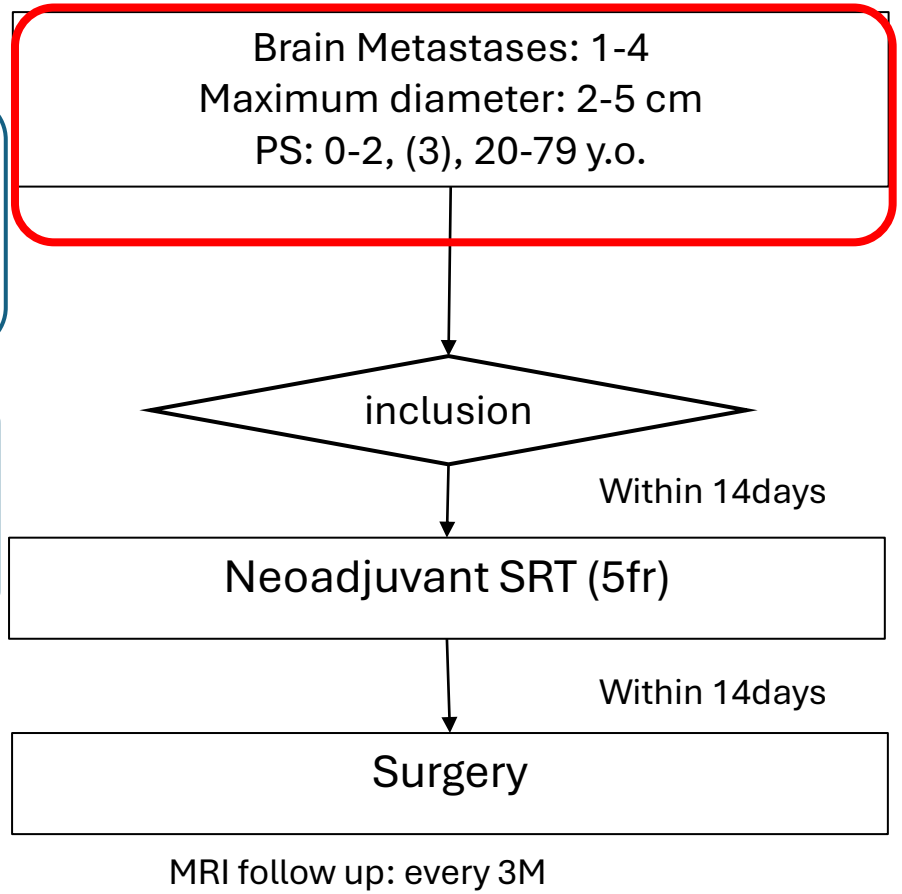
Complex segmentectomy versus lobectomy in small-sized peripheral non-small cell lung cancer. Kamigaichi A et al.

NEOTACTICS: study design

primary endpoint:
local recurrence @ 6M

secondary endpoints:
OS, ic-PFS, LR, RN, LMD, DBF, AE, cognitive EP

RN = radiation necrosis
LR = local recurrence
DBF = distant brain failure
LMD = leptomeningeal disease



1 index m+ for surgery: 2-5 cm

up to 3 m+ <2 cm for SRT

Primary cancer	N	(%)
NSCLC	23	(41.8)
Breast	12	(21.8)
Colon	11	(20)
Esophagus	3	(5.5)
Kidney	2	(3.6)
Uterus cervical	2	(3.6)
Uterus body	1	(1.8)
Gastric	1	(1.8)

Preoperative SRT is feasible (Yeboa DN. JAMA Oncol 2025).

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NEOTACTICS: primary/secondary endpoints

local recurrence
4.3% @6M
16.4% @12M

compare to: 15-20% en 28-40%*

leptomeningeal disease
0.0% @6M
0.0% @12M

compare to: 8.3% @12M*

distant brain failure
14.0% @6M
18.1% @12M

intracranial PFS
72.5% @6M
64.4% @12M

compare to: 4.0-6.4 m*

radiation necrosis**
5.9% @6M
8.0% @12M

compare to: 14.6% @12M*

overall survival
86.3% @6M
72.5% @12M

*** Historical data from diverse trials.**
**** Asymptomatic RN (there was no symptomatic RN).**

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NEOTACTICS: adverse events

cognitive function

generally preserved in most patients

a decline of ≥ 1 point in MMSE from baseline:

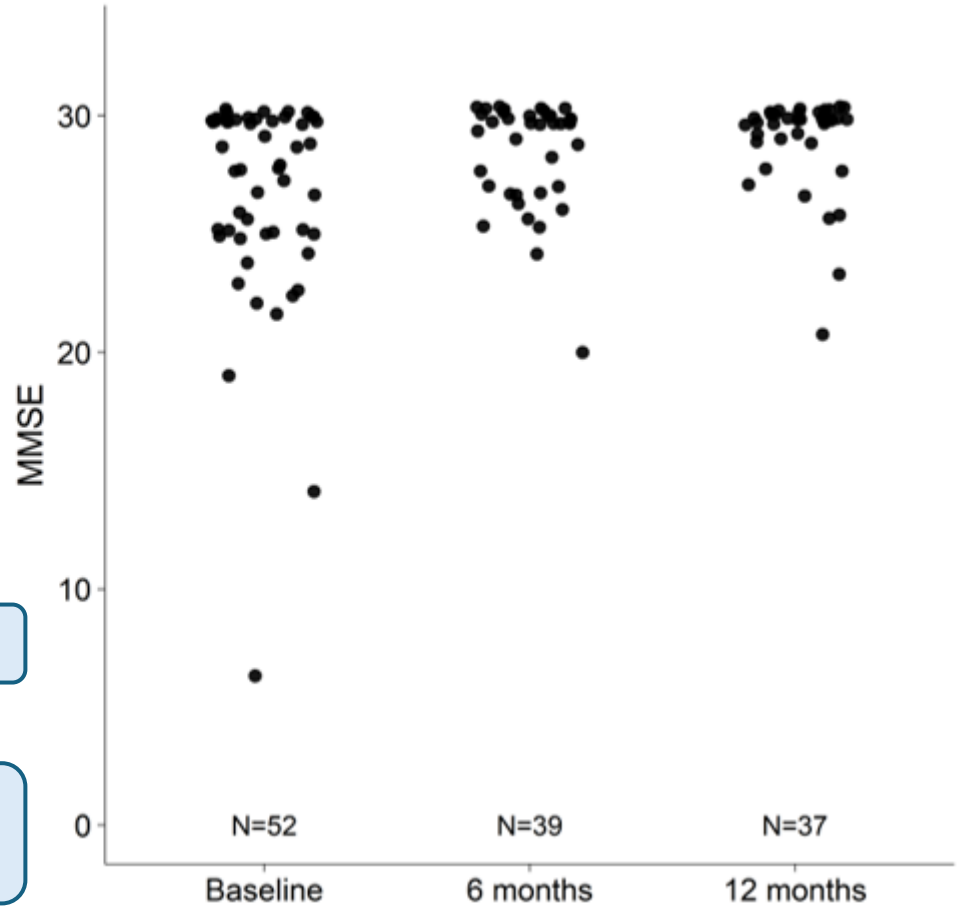
- 15.4% (6m)
- 9.6% (12m)

a decline of ≥ 3 points

- < 4% (6m, 12m)

G3+ AE in 5.3%

median time to surgery
4 days [0-13]



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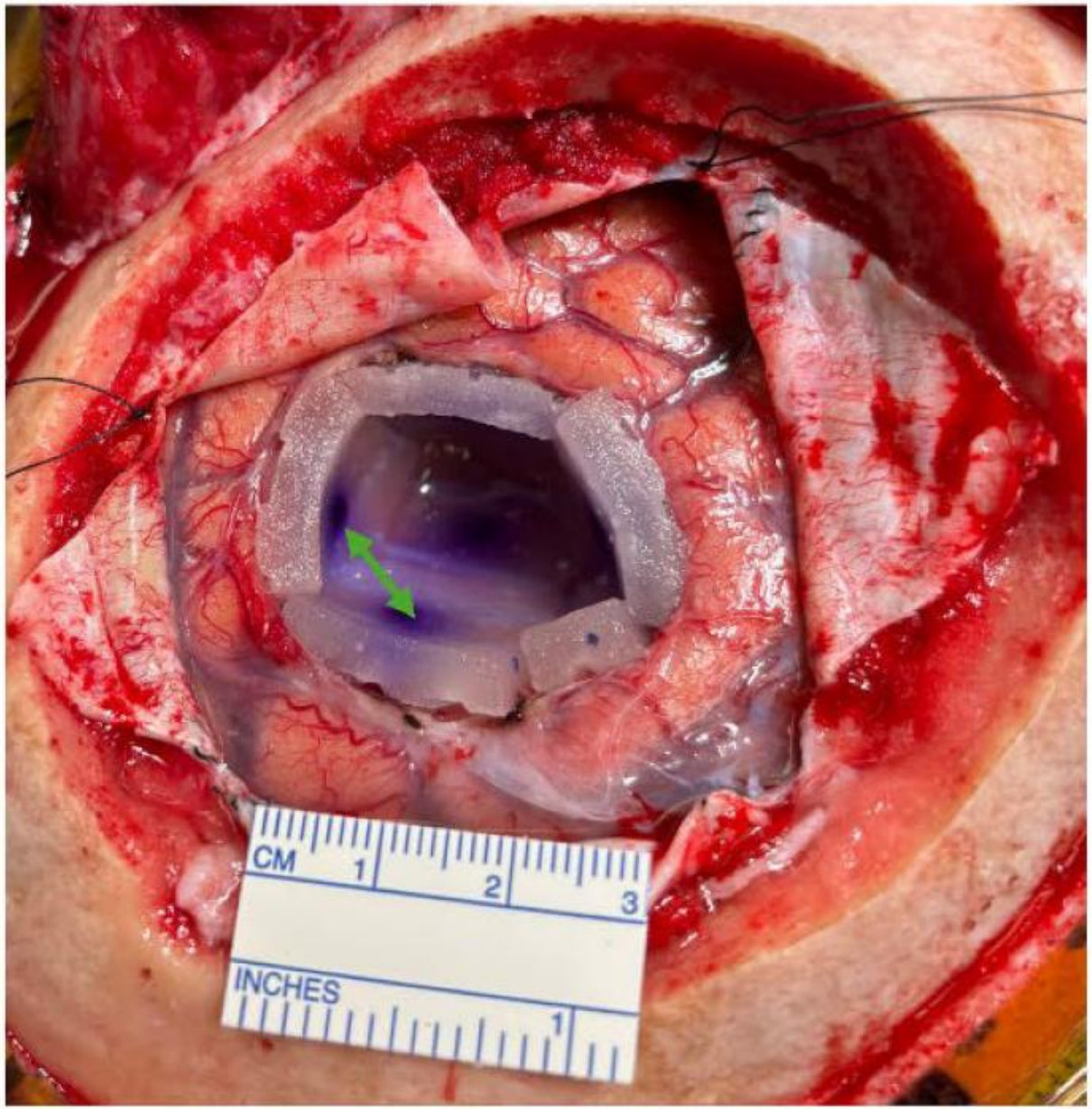
Neoadjuvant fractionated stereotactic radiotherapy followed by surgical resection for brain metastases. A multicenter, single arm phase II trial (NEO-TACTICS). Mitsuya K et al.



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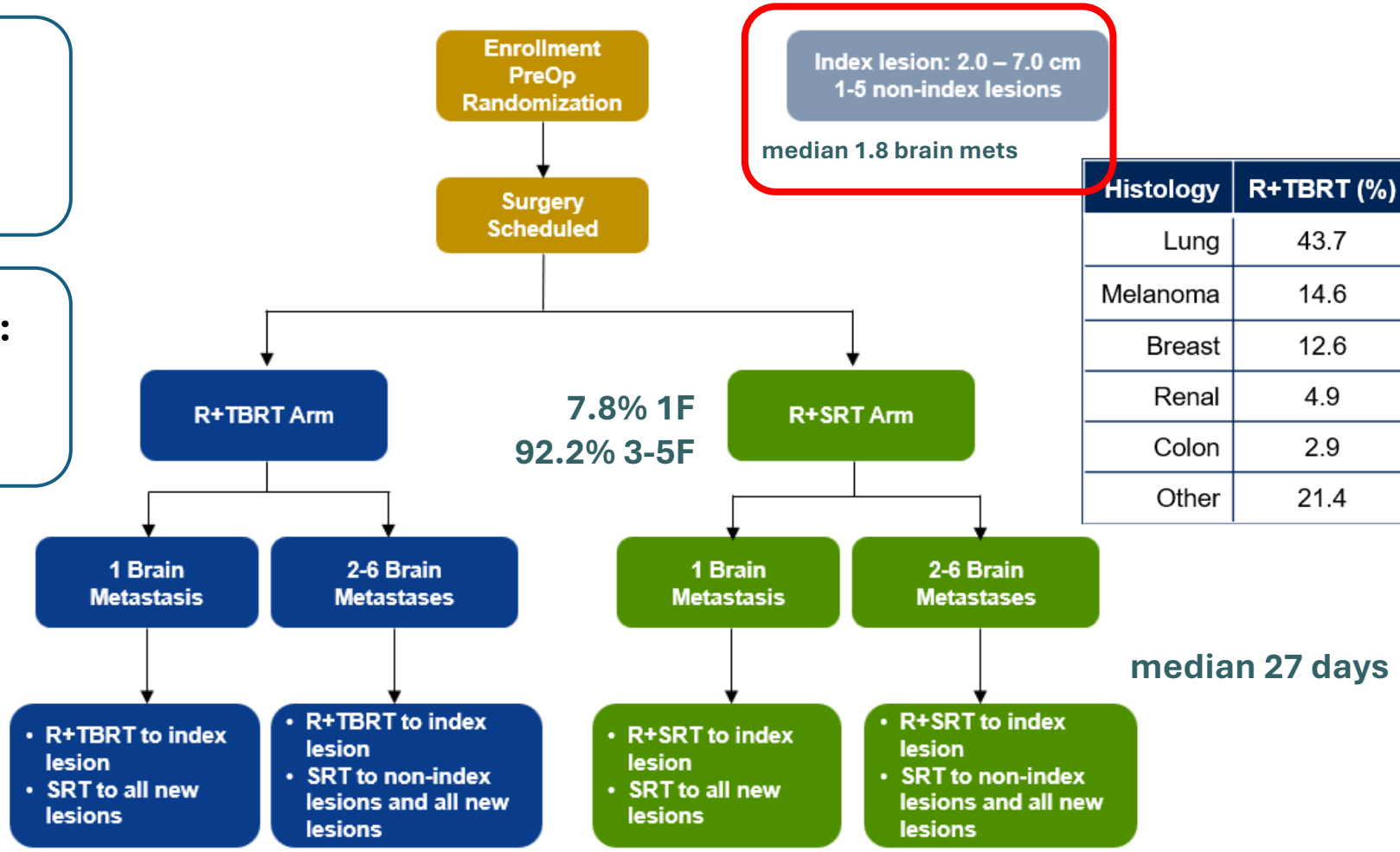
WEINBERG: study design

primary endpoint:
time-to-SBR
SB-RFS

secondary endpoints:
OS, functional status, QoL, AE, LMD, RN

SBR = surgical bed recurrence
RFS = recurrence free survival
TBRT = tiles based radiotherapy



Histology	R+TBRT (%)	R+SRT (%)
Lung	43.7	45.5
Melanoma	14.6	10.9
Breast	12.6	8.9
Renal	4.9	5.0
Colon	2.9	5.9
Other	21.4	23.8

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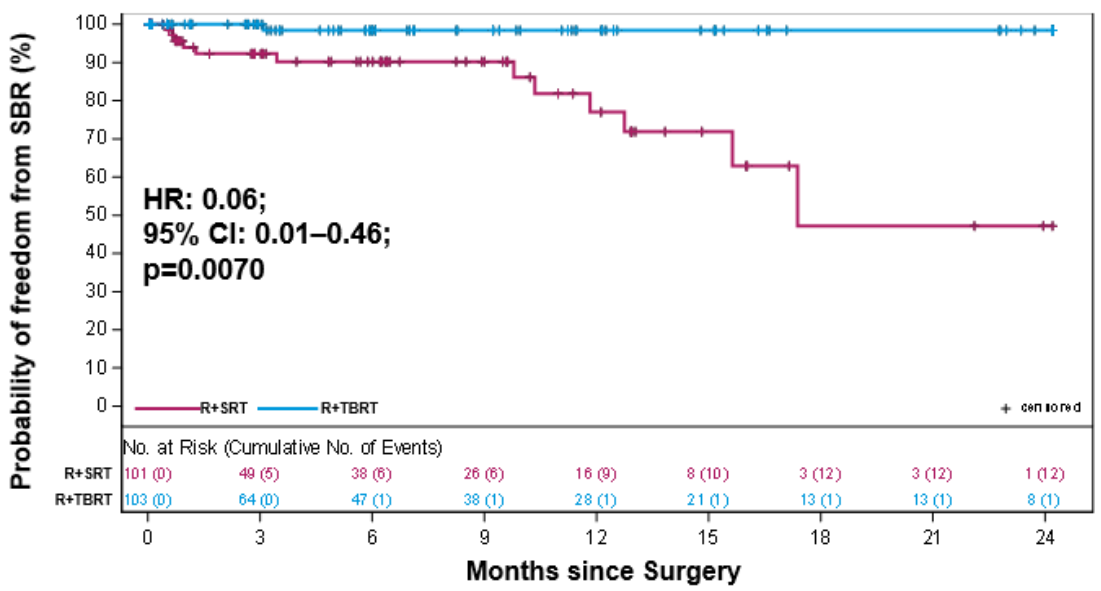
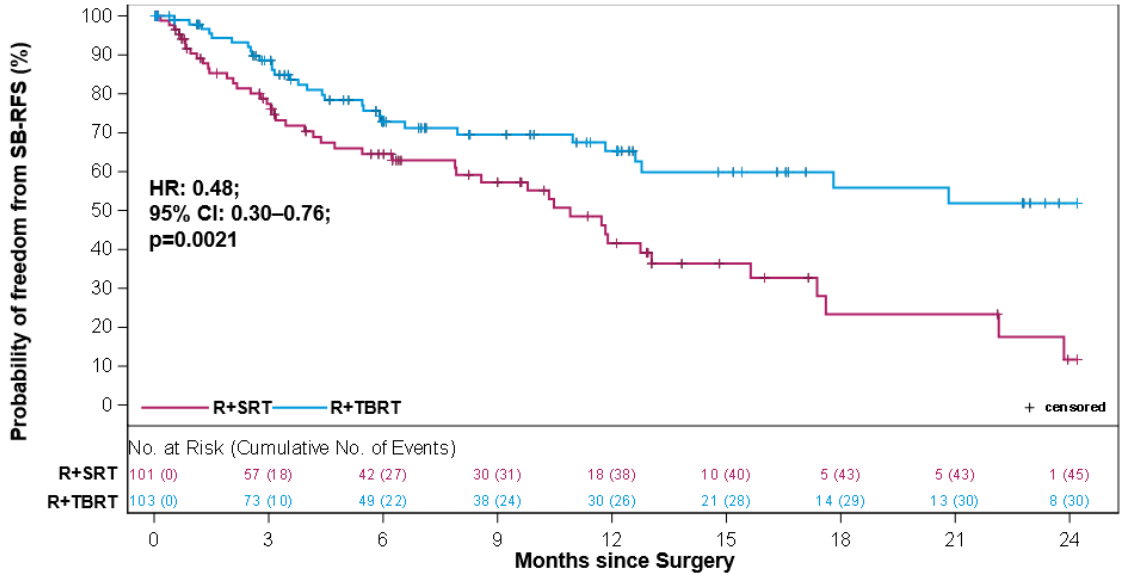
WEINBERG: primary endpoint (time-to-SBR)





median time-to-SBR
NR vs. 17.4 m
---
incidence of SBR @12M
1.3% vs. 15.4%

median SB-RFS
NR vs. 10.9 m

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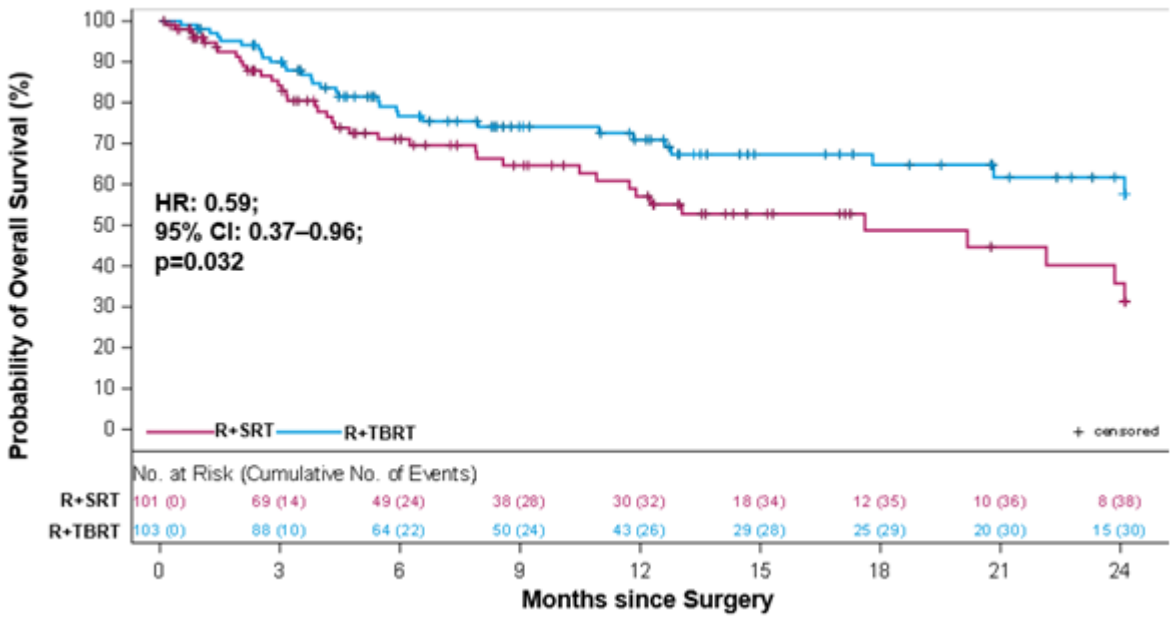
WEINBERG: secondary endpoints



time-to-DBF
no difference

G3 AE
18.1% vs. 19.3%

KPS, Barthel-ADL, FACT-BR
no difference

DBF = distant brain failure

median overall survival
42.5 m vs. 17.6 m

24m-OS
61.7% vs. 35.7%

leptomeningeal disease
no difference
---
radiation necrosis
no difference

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3.
Small cell lung cancer

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ABSTRACTS

- Autologous natural killer cell infusion as consolidation therapy after first-line chemoradiotherapy for limited-stage small-cell lung cancer: A cohort analysis of a randomized phase II study (NCT03410368).

- LuSato-1: Phase I study of 177Lu-SSO110 with 68Ga-SSO120 companion imaging in patients with extensive stage small cell lung cancer (ES-SCLC) on maintenance treatment with immune checkpoint inhibition (ICI).
- Concurrent thoracic radiotherapy, chemotherapy and durvalumab in ES SCLC - a phase III trial.

- Intracranial efficacy of tarlatamab versus chemotherapy as second-line treatment for small cell lung cancer: DeLLphi-304 phase 3 post hoc analysis.
- Efficacy and safety of ivonescimab combined with liposomal irinotecan as second-line treatment for small-cell lung cancer (SCLC) : results from a multicenter phase 2 study (VICTORY).
- ABBV-706 as monotherapy and in combination with budigalimab in patients with relapsed/refractory small cell lung cancer.

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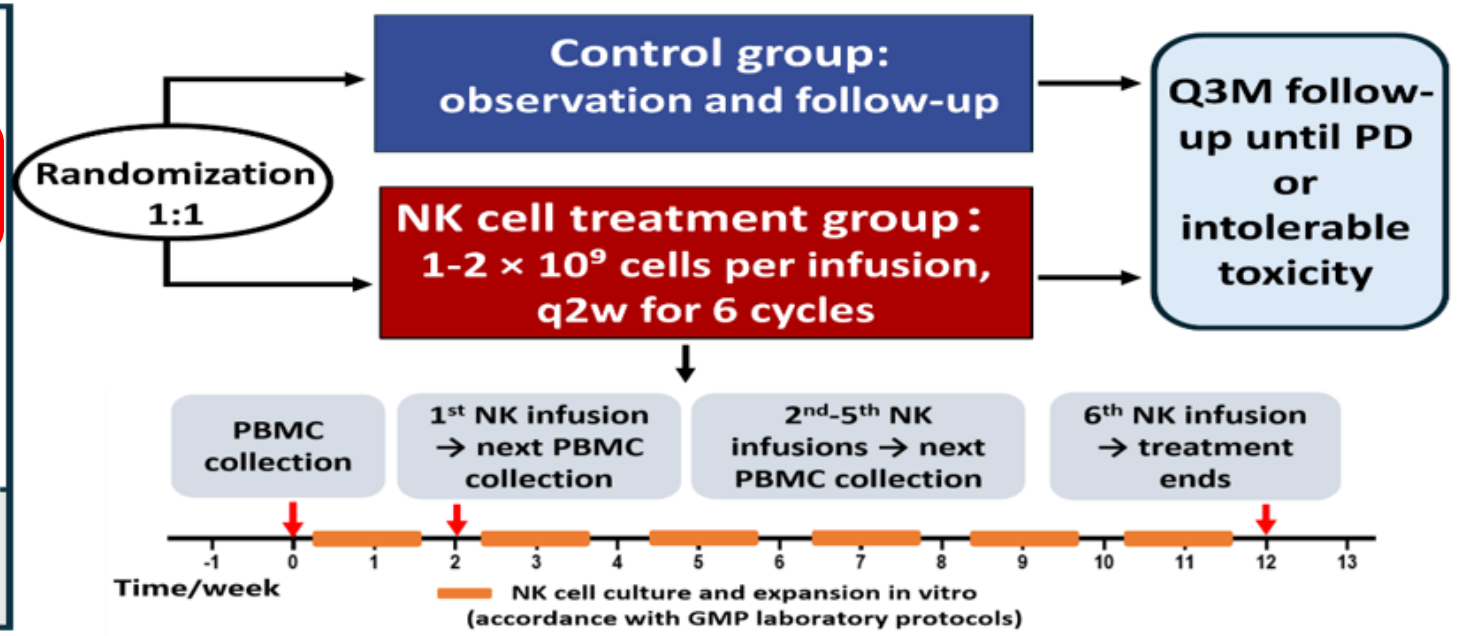
CUI: study design

Key Eligibility Criteria

- Patients with pathologically diagnosed LS-SCLC;
- Patients who have completed standard first-line chemoradiotherapy with efficacy evaluation of CR, PR, or SD;
- Age ≥ 18 years;
- ECOG PS 0 or 1;
- Adequate organ function;
- Hemoglobin (Hgb) ≥ 60 g/L;
- No contraindications for apheresis and cell separation;

Stratification factors

- TNM stage (I-II or III)
- Prophylactic cranial irradiation (yes or no)



95% stage III
67% ECOG 0
-- 52% vs. 77% male
-- 48% vs. 27% never smokers
-- 48% SD vs. 27% SD
-- 19% vs. 14% CTFI <1m

End points

- **Primary:** PFS
- **Secondary:** OS, 12- and 24-month PFS rate, 24- and 36-month OS rates and safety.

PRESENTED BY: Jo Raskin MD
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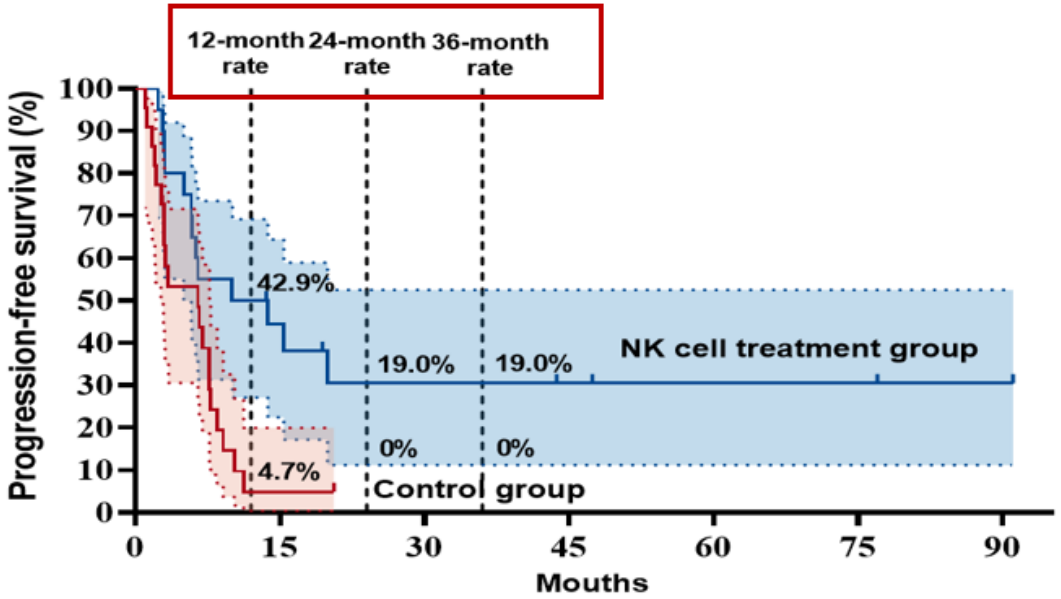
Autologous natural killer cell infusion as consolidation therapy after first-line chemoradiotherapy for limited-stage small-cell lung cancer: A cohort analysis of a randomized phase II study (NCT03410368). Cui J et al.

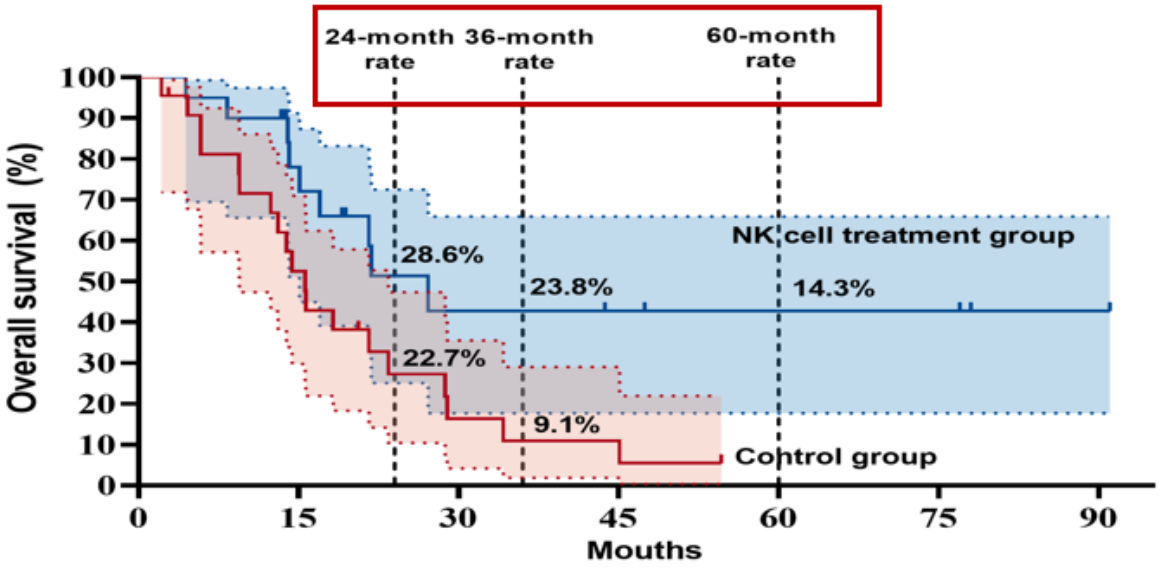
CUI: primary (PFS) and secondary (OS) endpoints

33/43 (data maturity, 76.7%) patients had PD



	No. of Events/ Total No. (%)	Median, mouths
NK cell treatment group (n=21)	13/21 (61.9)	11.9
Control group (n=22)	20/22 (90.9)	6.5

28 out of 43 (data maturity, 65.1%) patients had died



	No. of Deaths/ Total No. (%)	Median, mouths
NK cell treatment group (n=21)	9/21 (42.9)	27.1
Control group (n=22)	19/22 (86.4)	15.6

* Stratified hazard ratio for death, HR 0.41 (95%CI 0.19-0.87), P = 0.02

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CUI: adverse events

Events	NK cell treatment group (N=19)		Control group (N=21)	
	Any Grade	Grade 3 or 4	Any Grade	Grade 3 or 4
	number of patients (percent)			
Any adverse event of any cause	10 (52.6)	2 (10.5)	11 (52.4)	3 (14.3)
Any event leading to discontinuation	0	0	0	0
Abnormal lung function				
Radiation pneumonitis	1 (5.3)	1 (5.3)	2 (9.5)	0
Abnormal liver function				
Hypoalbuminemia	3 (15.8)	0	4 (19.0)	0
Total bile acid increased	1 (5.3)	0	2 (9.5)	0
Aspartate aminotransferase increased	1 (5.3)	0	1 (4.8)	0
Gamma glutamyl transpeptidase increased	1 (5.3)	0	0	0
Abnormal renal function				
Creatinine increased	1 (5.3)	0	1 (4.8)	0
Uric acid increased	1 (5.3)	0	1 (4.8)	0
Urine protein	1 (5.3)	0	0	0
Urinary tract infection	1 (5.3)	0	1 (4.8)	0
Cardiac function abnormal				
Occasional ventricular/atrial extrasystoles	1 (5.3)	0	0	0
Abnormal glucose and lipid metabolism				
Cholesterol increased	1 (5.3)	0	0	0
Triglyceride increased	3 (15.8)	1 (5.3)	2 (9.5)	0
Low-density lipoprotein cholesterol increased	3 (15.8)	0	2 (9.5)	0
Low-density lipoprotein increased	1 (5.3)	0	2 (9.5)	0
Blood system disorders				
Anemia	3 (15.8)	0	6 (28.6)	0
Thrombocytopenia	1 (5.3)	0	1 (4.8)	0
Lymphocyte count decreased	1 (5.3)	0	0	0
Leukopenia/neutropenia	3 (15.8)	0	9 (42.9)	3 (14.3)
Otitis media secretory				
Otitis media with effusion	1 (5.3)	0	0	0

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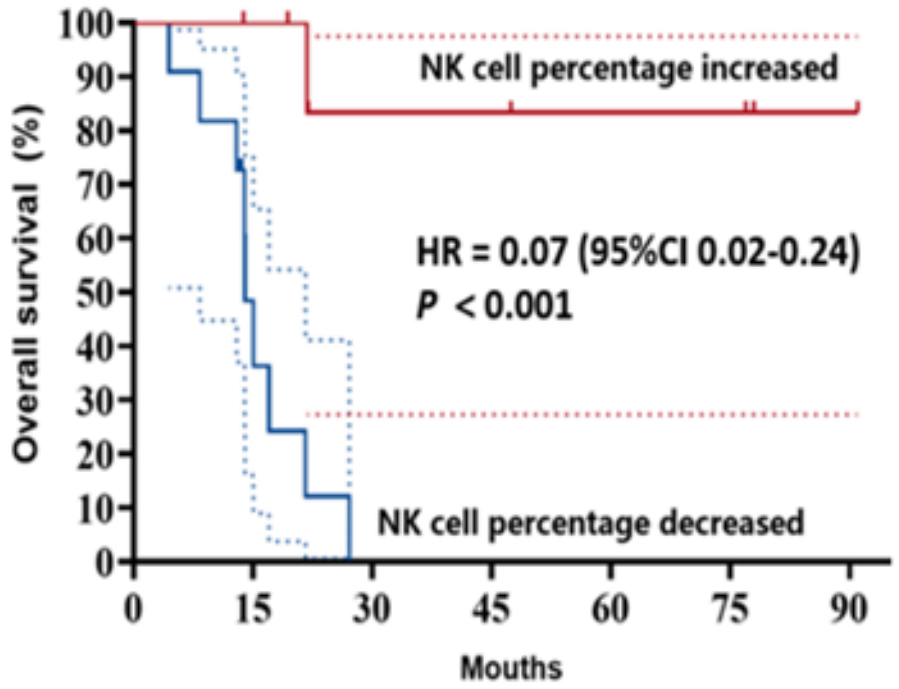
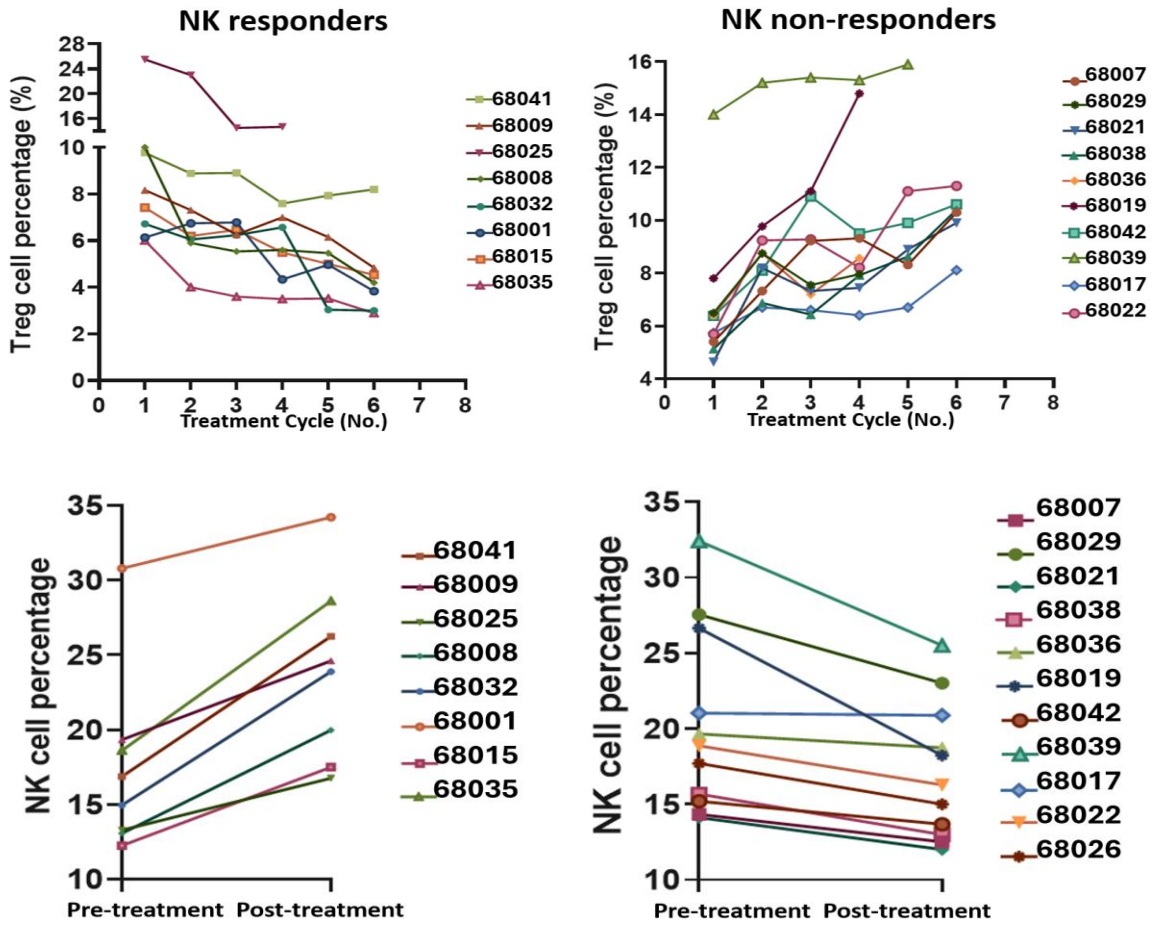
CUI: biomarkers



Combination with IO? Durvalumab = SOC.

NK responders: high baseline NK and CD8+ TME + low Treg and TAM.



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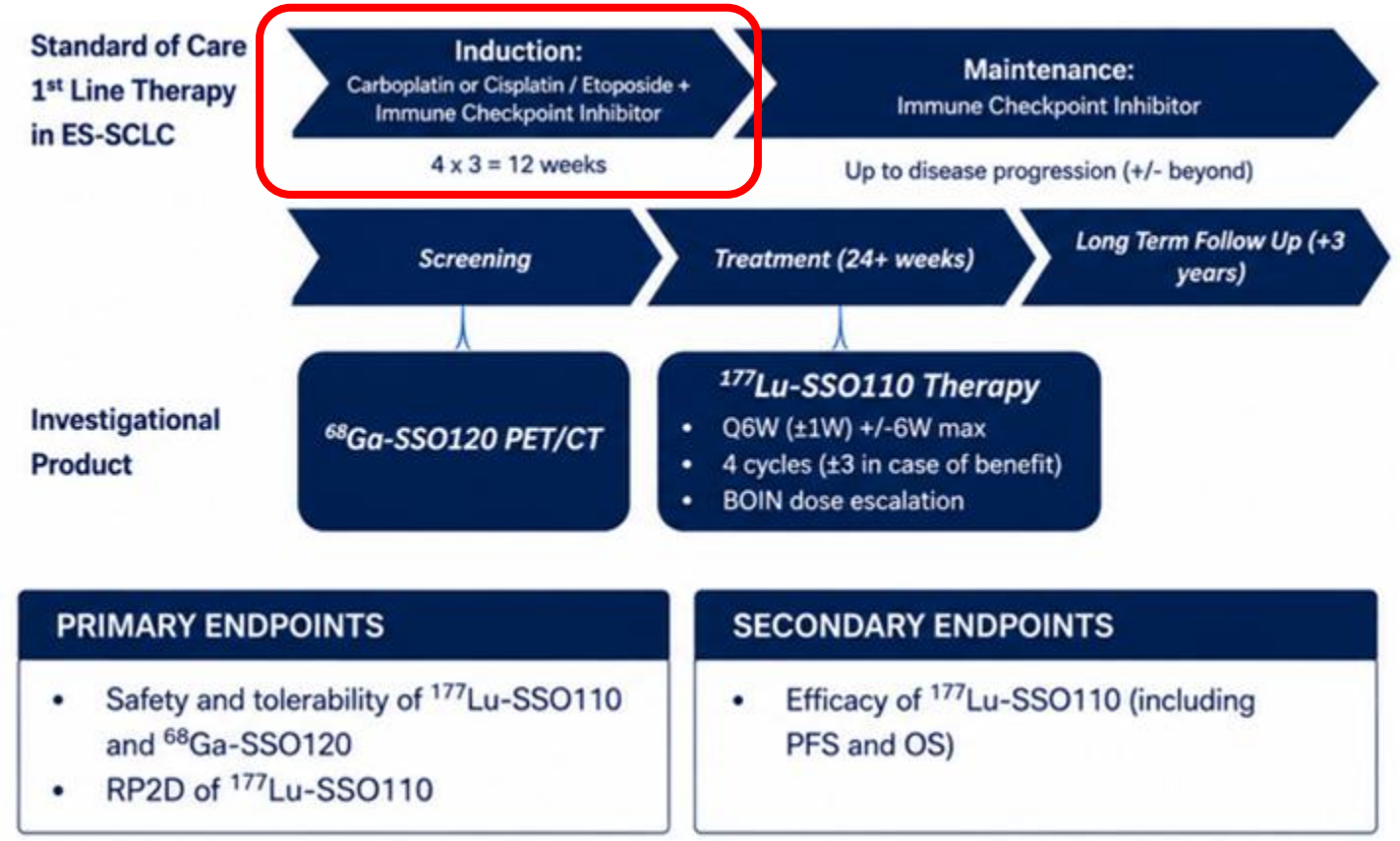
LuSATO-1: study design



	Number of patients N= 20
Sex	
Male, n (%)	9 (45%)
Female, n (%)	11 (55%)
Age	
Median age (range)	64 (47 – 83)
Age < 65 years	9 (45%)
Age ≥ 65 years	11 (55%)
Race, n (%)	
White	19 (95%)
Asian	1 (5%)
Brain metastases, n (%)	
Yes	5 (25%)
No	15 (75%)
Liver metastases, n (%)	
Yes	12 (60%)
No	8 (40%)
ECOG PS Status	
0	6 (30%)
1	14 (70%)
Smoking Status	
Never	0 (0%)
Current	2 (10%)
Previous	18 (90%)

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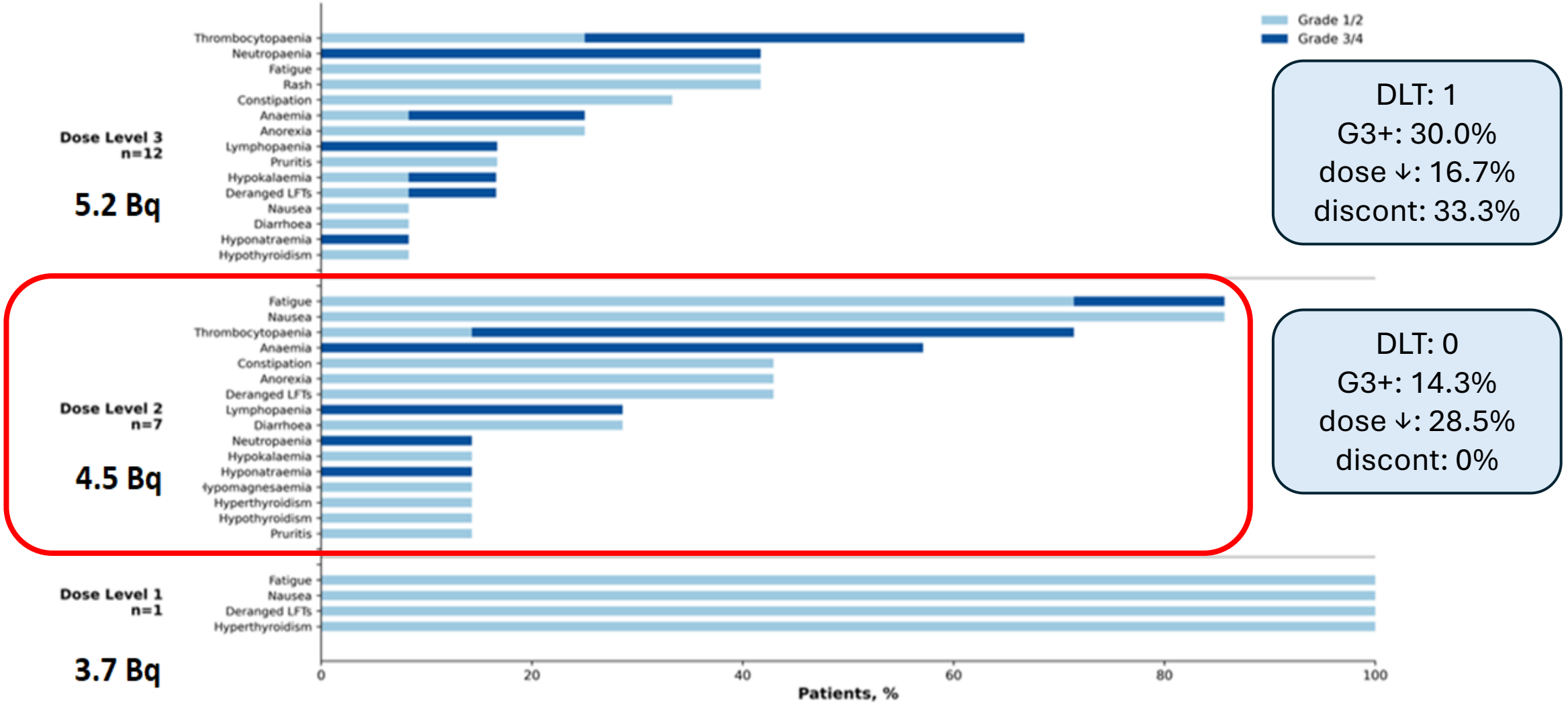
LuSATO-1: primary endpoint (safety)



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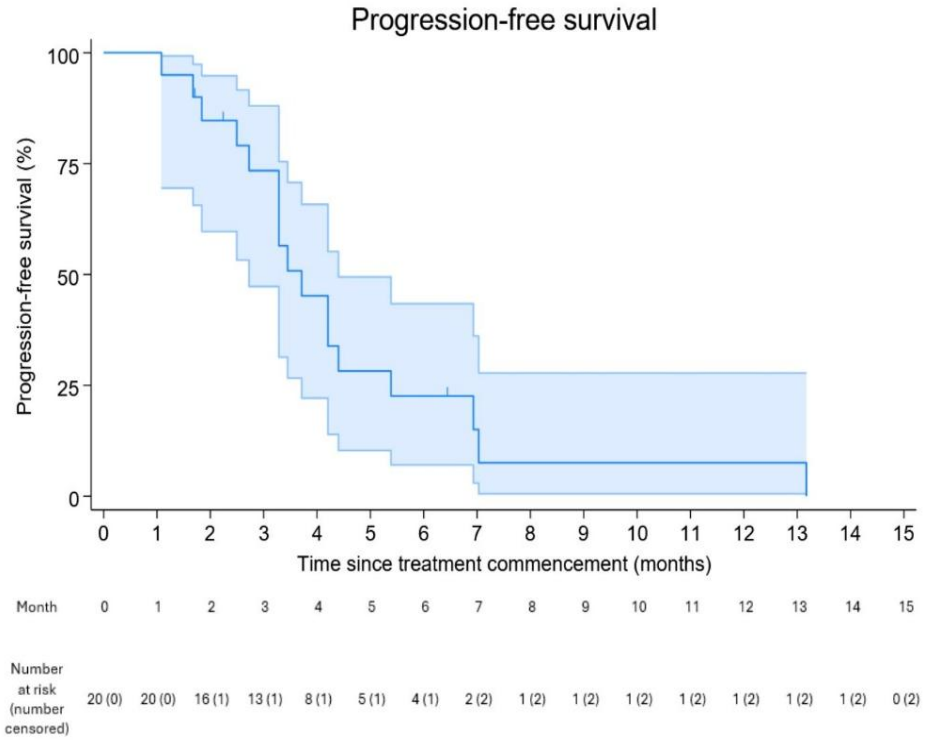
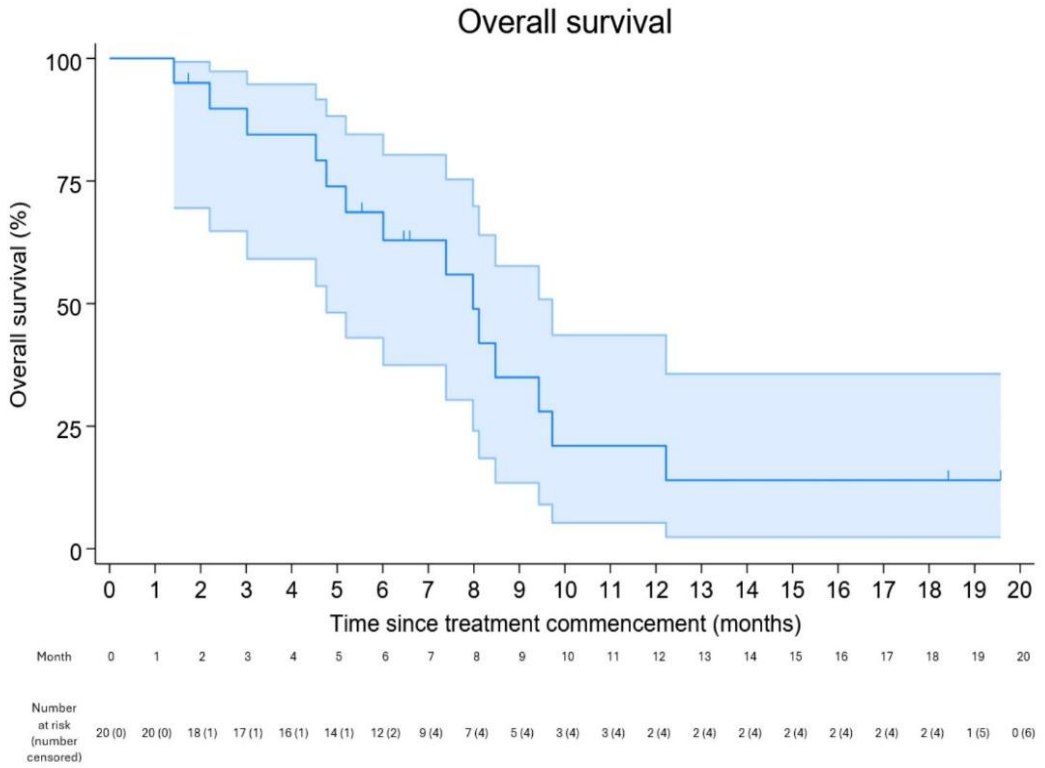
LuSato-1: Phase I study of 177Lu-SSO110 with 68Ga-SSO120 companion imaging in patients with extensive stage small cell lung cancer (ES-SCLC) on maintenance treatment with immune checkpoint inhibition (ICI). Arunalanda S et al.

LuSATO-1: secondary endpoints (PFS, OS)



mPFS from C1 maintenance:
3.7 m [2.5-5.4]



mOS from C1 maintenance:
8.0 m [4.8-9.7]

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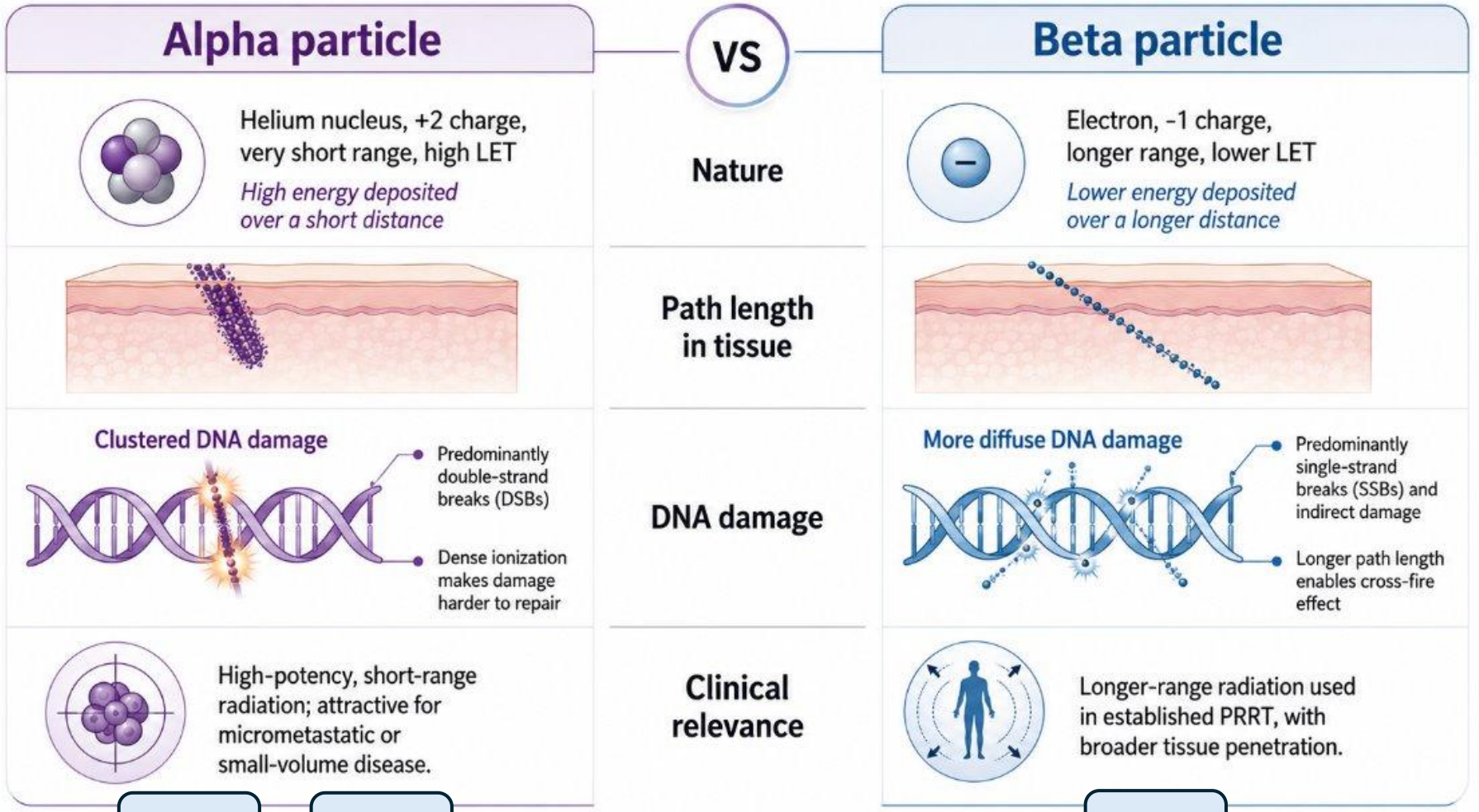
LuSato-1: Phase I study of 177Lu-SSO110 with 68Ga-SSO120 companion imaging in patients with extensive stage small cell lung cancer (ES-SCLC) on maintenance treatment with immune checkpoint inhibition (ICI). Arunalanda S et al.

LuSATO-1: future perspectives



Singh S. ASCO 2026 discussant

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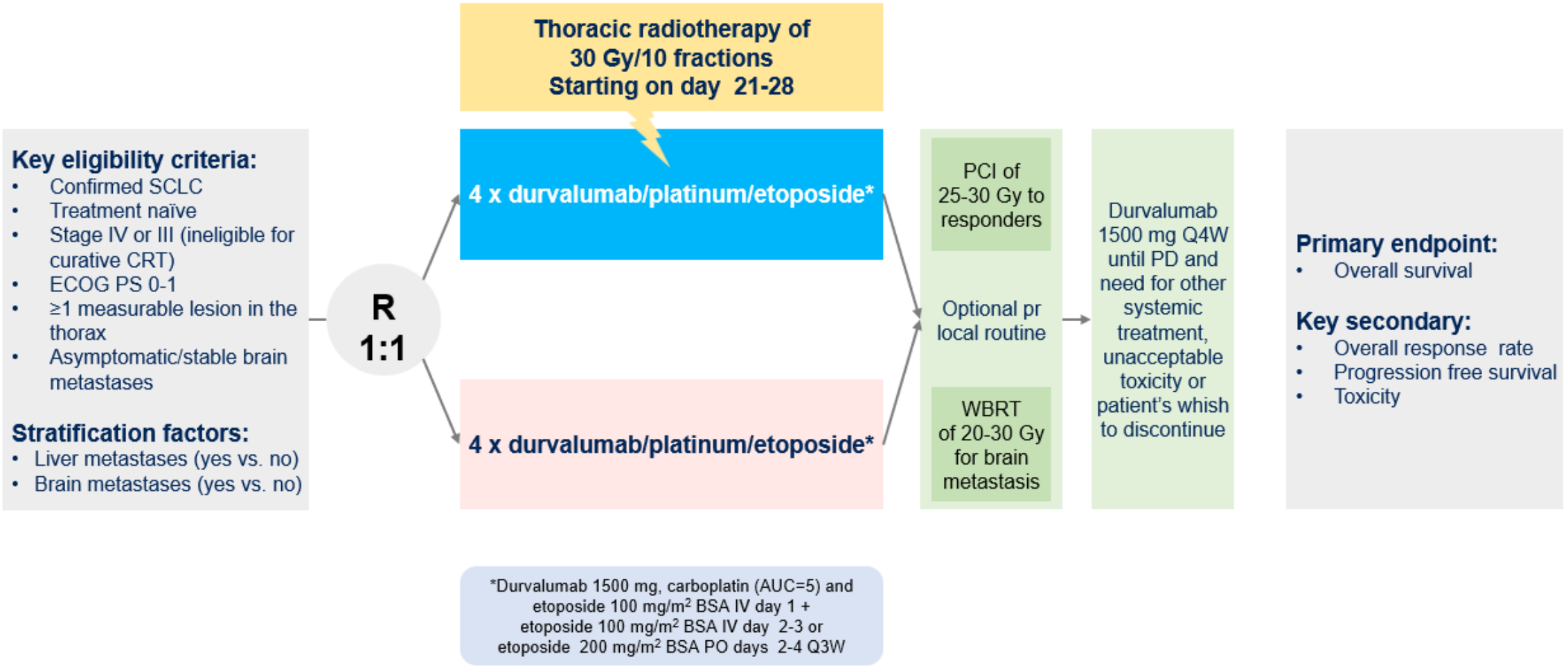
LuSato-1: Phase I study of 177Lu-SSO110 with 68Ga-SSO120 companion imaging in patients with extensive stage small cell lung cancer (ES-SCLC) on maintenance treatment with immune checkpoint inhibition (ICI). Arunalanda S et al.

GRØNBERG: study design



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GRØNBERG: patient characteristics

		Chemoimmunotherapy plus TRT (n=115)		Chemoimmunotherapy (n=113)	
		n	%	n	%
Age, years	Median (range)	68 (40-83)		67 (39-84)	
	≥ 70 years	49	42.6%	45	39.8%
Sex	Female	58	50.4%	57	50.4%
ECOG PS	0	37	32.2%	49	43.4%
	1	77	67.0%	64	56.6%
	Missing	1	0.9%	-	-
TNM v8 stage	III	5	4.3%	4	3.5%
	IV	110	95.7%	109	96.5%
Liver metastases		45	39.1%	46	40.7%
Brain metastases		33	28.7%	31	27.4%

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GRØNBERG: study treatment

	Chemoimmunotherapy plus TRT (n=115)		Chemoimmunotherapy (n=113)	
	n	%	n	%
Surgery/SRS/WBRT for brain mets before chemo-I	6	5.2%	8	7.1%
Mean no. of chemotherapy-courses	3.6		3.7	
Four chemotherapy-courses	89	77.4%	100	88.5%
Median no. of durvalumab-courses (range)	6 (1-30)		6 (1-30)	
≥1 year of durvalumab	10	8.7%	12	10.6%
Thoracic radiotherapy	105*	91.3%	2**	1.8%
Prophylactic cranial irradiation after chemo-I	11	9.6%	8	7.1%
Whole brain radiotherapy after chemo-I	7	6.1%	8	7.1%

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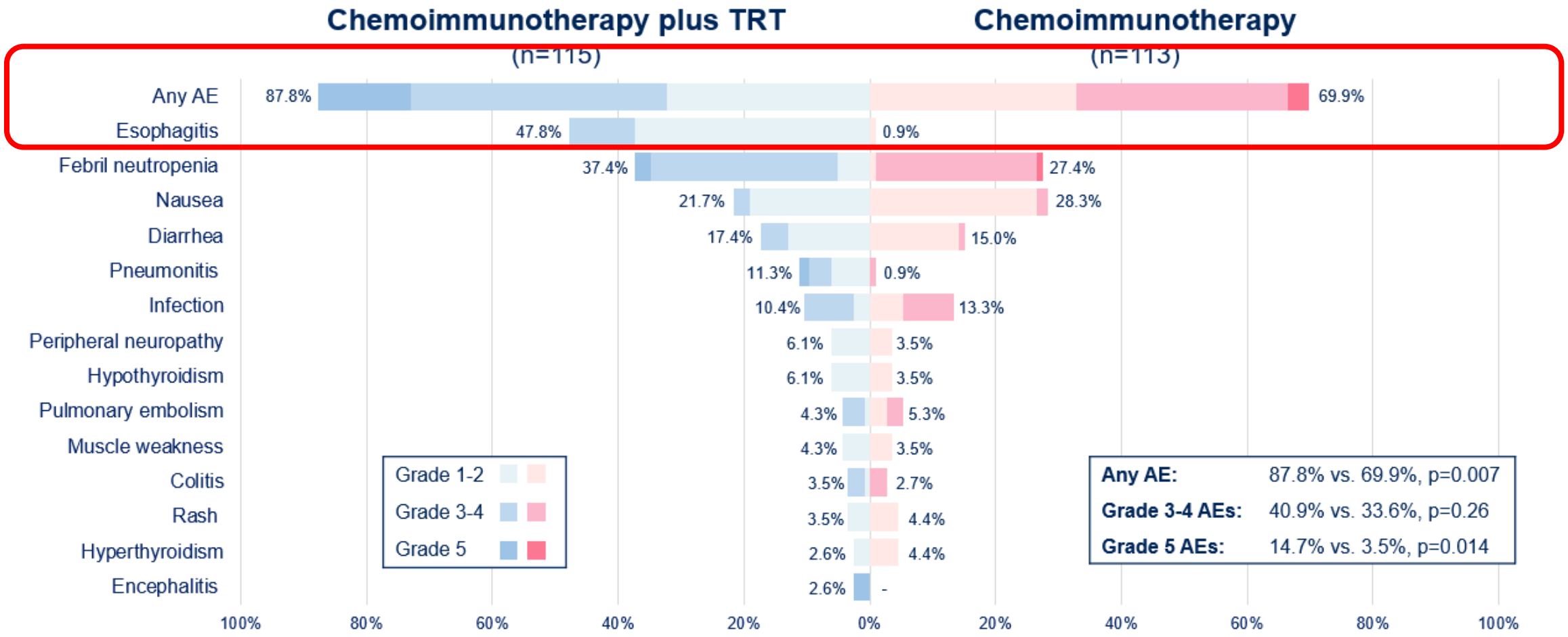
GRØNBERG: adverse events



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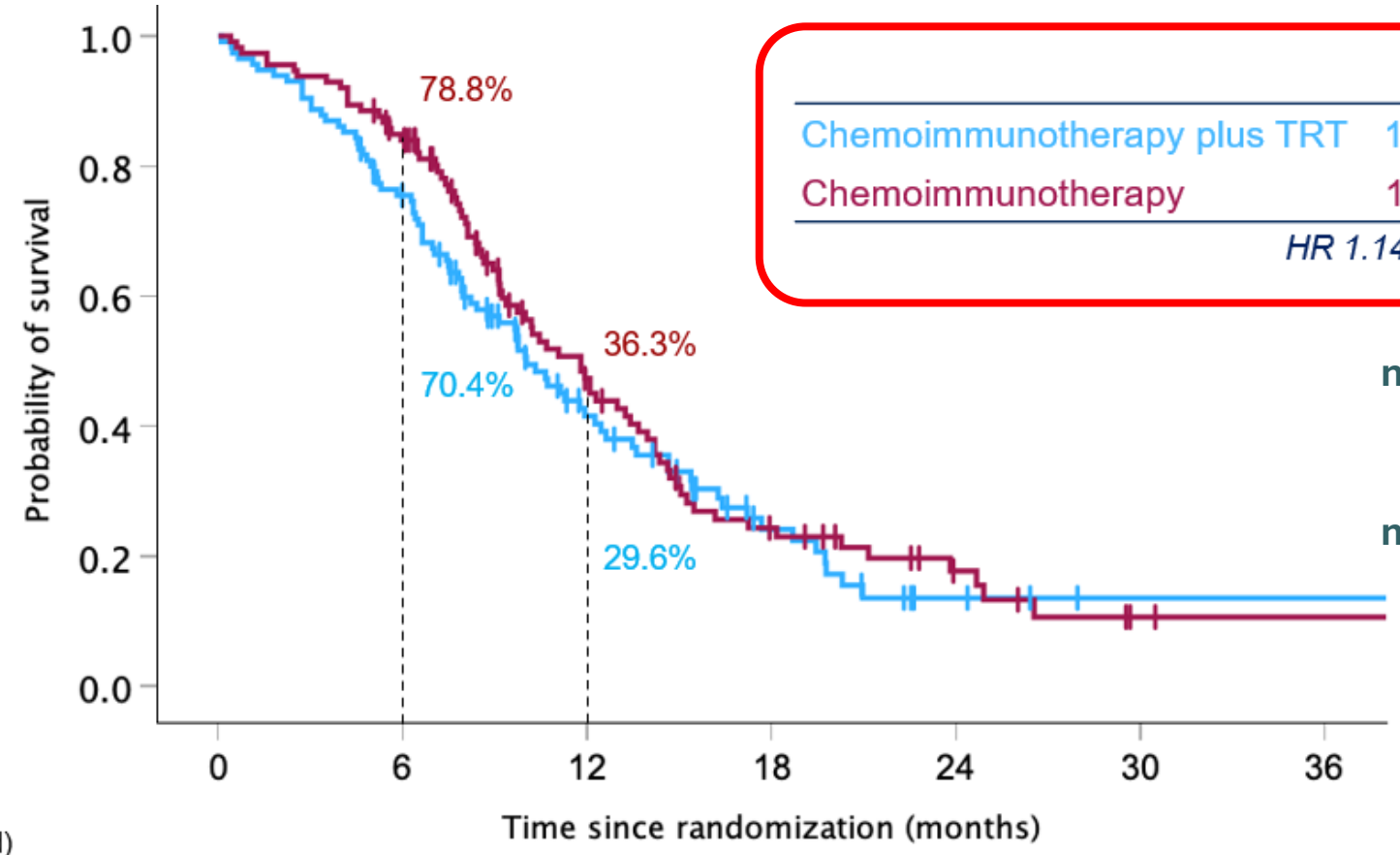
Concurrent thoracic radiotherapy, chemotherapy and durvalumab in ES SCLC - a phase III trial. Grønberg BH et al.

GRØNBERG: primary endpoint (OS)



	Median	95% CI
Chemoimmunotherapy plus TRT	10.0 months	8.3 – 11.7
Chemoimmunotherapy	11.8 months	10.0 – 13.6

HR 1.14, 95% CI 0.84 – 1.56, p=0.40

no subgroup with OS benefit.

mPFS 5.1 m vs. 5.0 m.

Number at risk (censored)

Chemoimmunotherapy plus 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)

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Concurrent thoracic radiotherapy, chemotherapy and durvalumab in ES SCLC - a phase III trial. Grønberg BH et al.

GRØNBERG: treatment at relapse

	Chemoimmunotherapy plus TRT (n=115)		Chemoimmunotherapy (n=113)	
	n	%	n	%
Systemic therapy	47	40.1%	67	59.3%
Carboplatin plus etoposide or irinotecan	21	18.3%	22	19.5%
Carboplatin/etoposide plus durvalumab or atezolizumab	-	-	2	1.8%
Cyclophosphamide/adriamycin/vincristine	8	7.0%	13	11.5%
Topotecan or lurbinectedin	3	2.6%	2	1.8%
Tarlatamab	-	-	2	1.8%
Unknown	15	13.0%	30	26.5%
Radiotherapy	36	31.3%	35	31.0%
Thoracic radiotherapy	1	0.9%	13	11.5%
Whole brain radiotherapy	8	7.0%	7	6.2%
Stereotactic radiosurgery	2	1.7%	-	-

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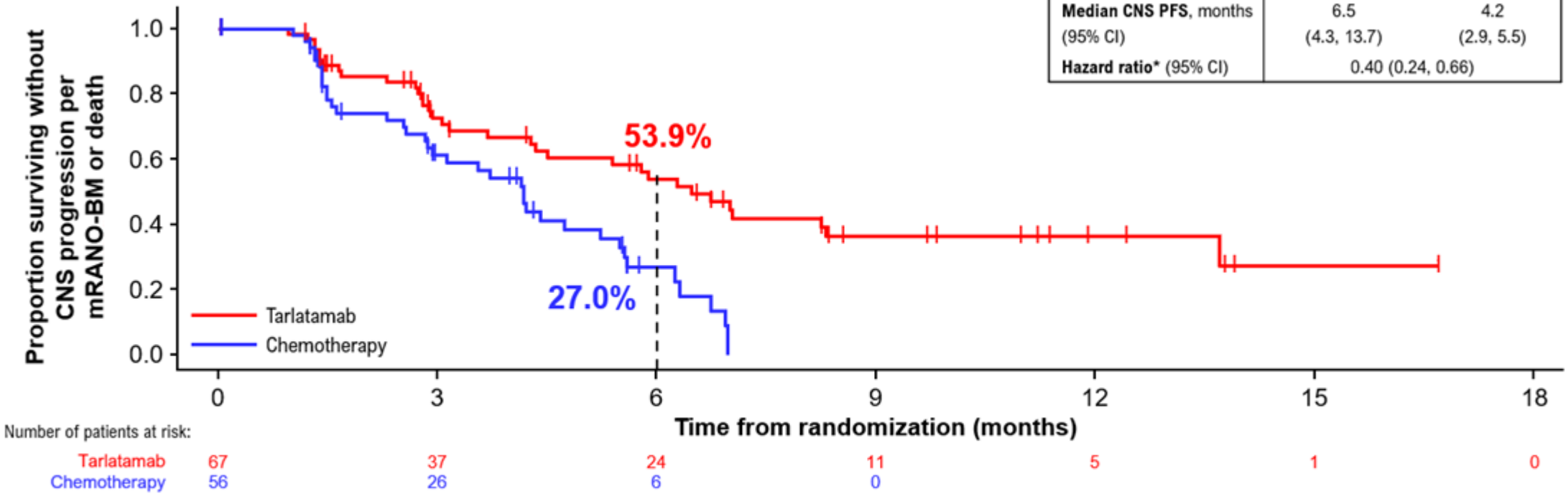
DeLLphi-304: secondary endpoint (CNS-PFS)

mRANO-BM analysis by BICR

Patients with ≥ 1 brain metastases at baseline per mRANO-BM by BICR and ≥ 1 post-baseline scan

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



Among patients with brain metastases, treatment with tarlatamab reduced the risk of CNS disease progression or death by 60% compared to chemotherapy.

DeLLphi-304: mPFS 4.2 m vs. 3.2 m | mOS 13.6 m vs. 8.3 m (Mountzios G. N Engl J Med 2025).

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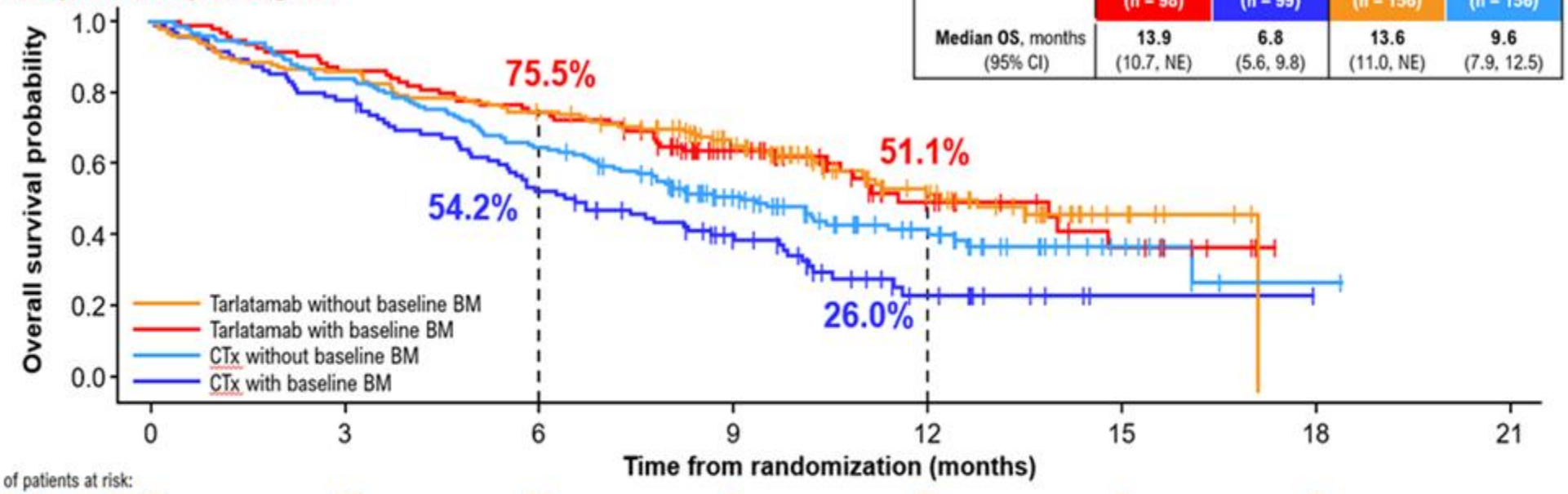
Intracranial efficacy of tarlatamab versus chemotherapy as second-line treatment for small cell lung cancer: DeLLphi-304 phase 3 post hoc analysis. Mountzios G et al.

DeLLphi-304: secondary endpoint (CNS-PFS)

Patients with or without brain metastases at baseline per RECIST by investigator

	Tarlatamab with BM (n = 98)	CTx with BM (n = 99)	Tarlatamab w/o BM (n = 156)	CTx w/o BM (n = 156)
Median OS, months (95% CI)	**13.9** (10.7, NE)	**6.8** (5.6, 9.8)	**13.6** (11.0, NE)	**9.6** (7.9, 12.5)



Number of patients at risk:

Tarlatamab without baseline BM	156	135	118	86	39	8	0
Tarlatamab with baseline BM	98	85	74	45	21	9	0
CTx without baseline BM	156	132	103	64	32	8	1	0
CTx with baseline BM	99	78	53	33	10	1	1	0

Median follow-up: 11.4 months (tarlatamab) and 11.5 months (chemotherapy)

Treatment with tarlatamab reduced the risk of death by 49% in patients with brain metastases vs chemotherapy (HR 0.51 [95% CI: 0.34, 0.74]).

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Intracranial efficacy of tarlatamab versus chemotherapy as second-line treatment for small cell lung cancer: DeLLphi-304 phase 3 post hoc analysis. Mountzios G et al.

DeLLphi-304: secondary endpoint (CNS-PFS)

	Tarlatamab (n = 98)*	Chemotherapy (n = 93)*
Treatment-emergent AE, n (%)		
Grade ≥ 3 AEs	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)
Treatment-related AEs, n (%)		
Grade ≥ 3 AE	25 (25.5)	61 (65.6)
Serious AEs	28 (28.6)	33 (35.5)
Leading to dose interruption and/or reduction†	18 (18.4)	51 (54.8)
Leading to discontinuation	2 (2.0)	6 (6.5)
Fatal AEs	0	2 (2.2)

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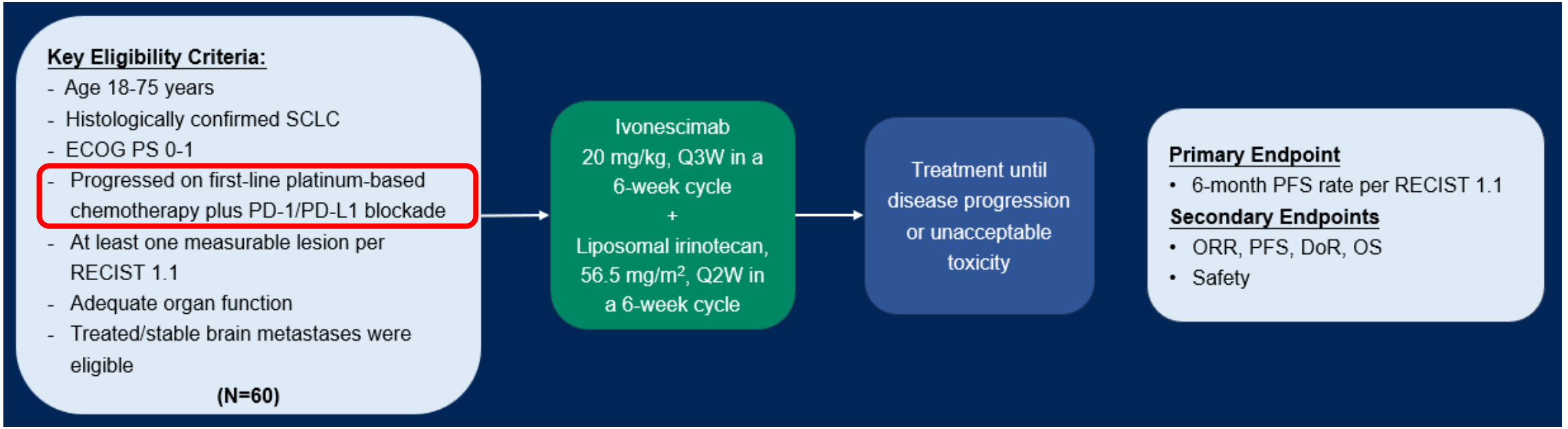
VICTORY: study design



Phase 1b in 1L (N=35): ORR 80% | mPFS 6.9 m (Cui J. Signal Transduct Target Ther 2024).

Ivonescimab is a bispecific Ab targeting PD-1 and VEGF.

Liposomal irinotecan is a smaller molecule, leads to better tumour penetration, prolonged exposure and reduced systemic toxicity.

Cui J. Signal Transduct Target Ther 2024

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VICTORY: primary (PFS_{6m}) and secondary (ORR) EP

	Total (N=60)	Platinum-Sensitive CFI ≥90 Days § (N=38)	Platinum-Resistant CFI <90 Days § (N=22)
Best Overall Response (BOR), n (%)			
PR	39 (65.0)	26 (68.4)	13 (59.1)
Confirmed PR	37 (61.7)	24 (63.2)	13 (59.1)
SD	19 (31.7)	10 (26.3)	9 (40.9)
PD	2 (3.3)	2 (5.2)	0
cORR, % (95% CI)	**61.7 (48.2, 73.9)**	**63.2 (46.0, 78.2)**	**59.1 (36.4, 79.3)**
DCR, % (95% CI)	96.7 (88.5, 99.6)	94.7 (82.3, 99.4)	100 (84.6, 100)
DoR, m (95% CI)	7.3 (5.9, 10.2)	8.6 (5.9, 10.2)	6.7 (2.8, 13.8)
Median PFS, m (95% CI)	8.1 (6.5, 10.0)	8.3 (6.3, 11.2)	7.7 (4.4, 9.8)
PFS rate at 6 m, %(95% CI)	**69.1 (55.5, 79.3)**	**69.5 (51.7, 82.0)**	**68.2 (44.6, 83.4)**
PFS rate at 12 m, %(95% CI)	25.7 (13.4, 39.8)	25.0 (9.6, 44.1)	24.8 (8.4, 45.7)

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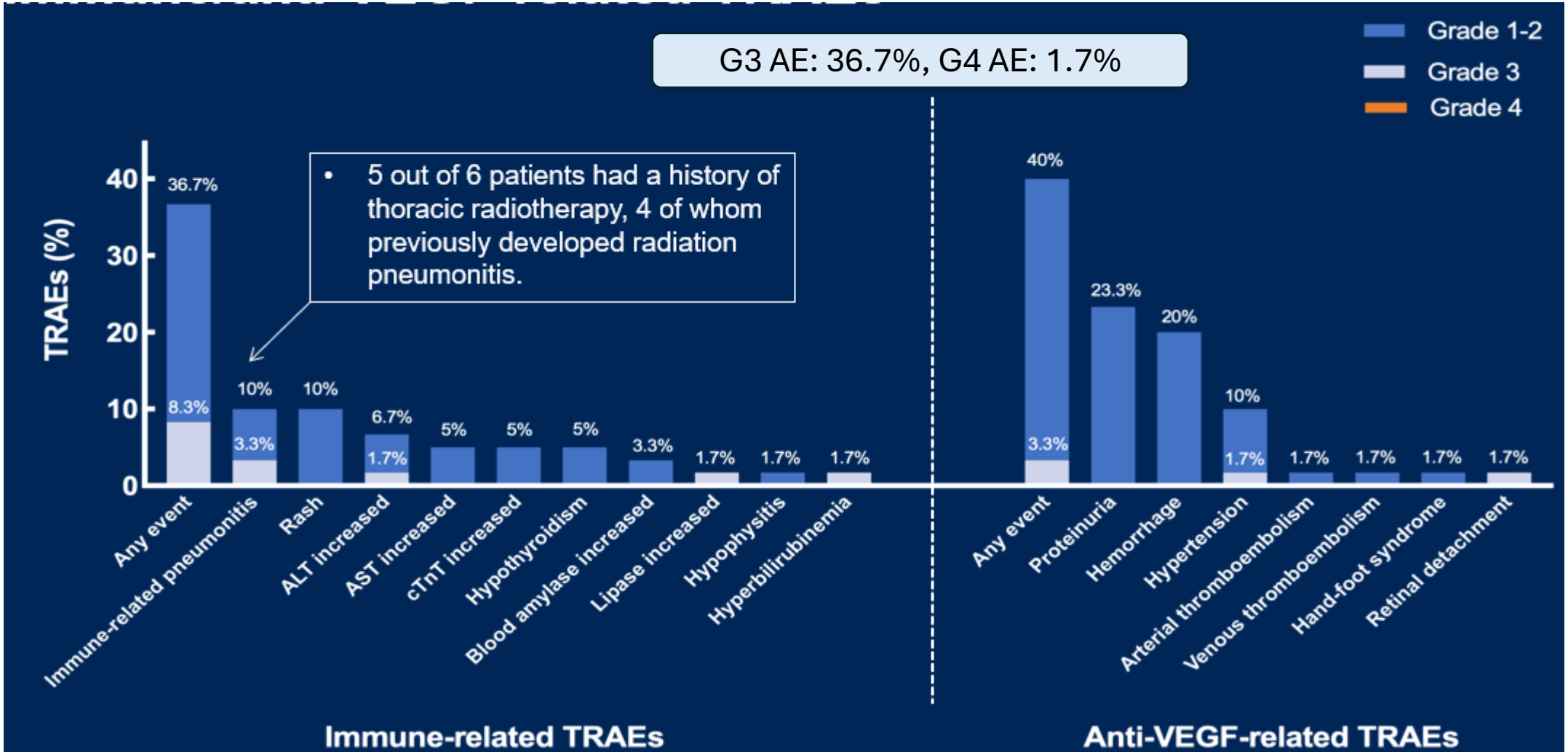
Efficacy and safety of ivonescimab combined with liposomal irinotecan as second-line treatment for small-cell lung cancer (SCLC) : results from a multicenter phase 2 study (VICTORY). Chen K et al.

VICTORY: primary (PFS_{6m}) and secondary (ORR) EP



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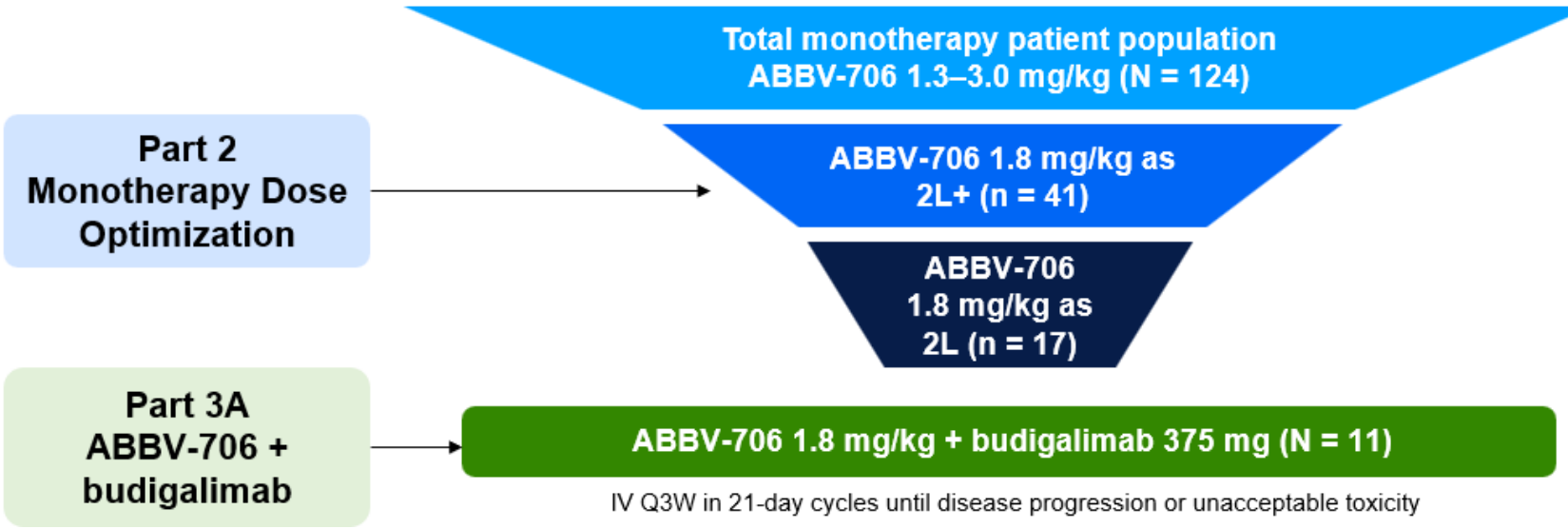
Efficacy and safety of ivonescimab combined with liposomal irinotecan as second-line treatment for small-cell lung cancer (SCLC) : results from a multicenter phase 2 study (VICTORY). Chen K et al.

BYERS: study design



Endpoints:

Primary:
- Safety and tolerability, PK, RP2D

Secondary:
- ORR, DOR, PFS, OS, clinical benefit

Exploratory:
- SEZ6 by IHC, predictive biomarkers

ABVV-706 is an ADC targeting SEZ6.

Phase 1 ABVV-706 monotherapy showed an ORR of 58% (Byers LA. WCLC 2025).

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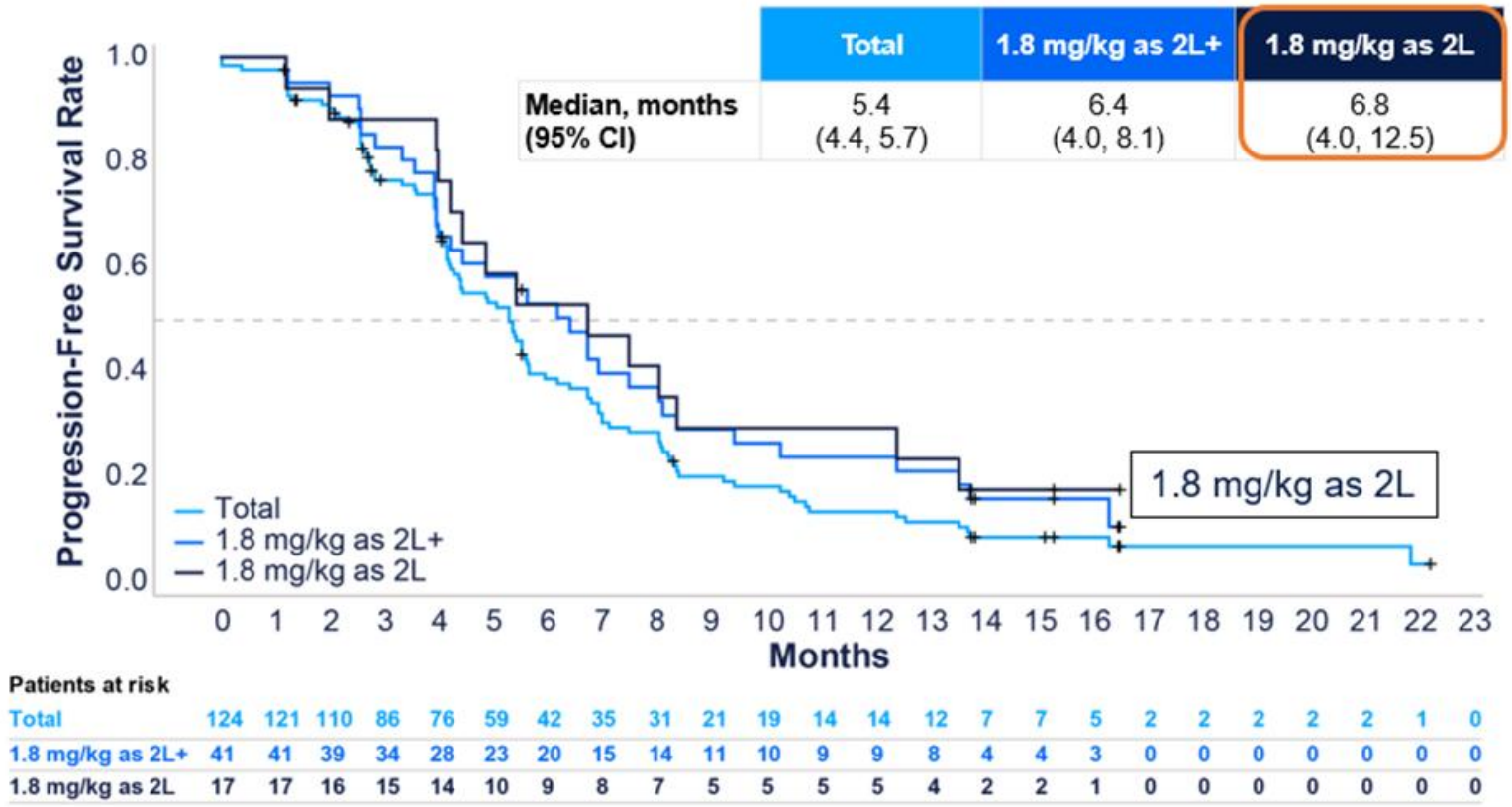
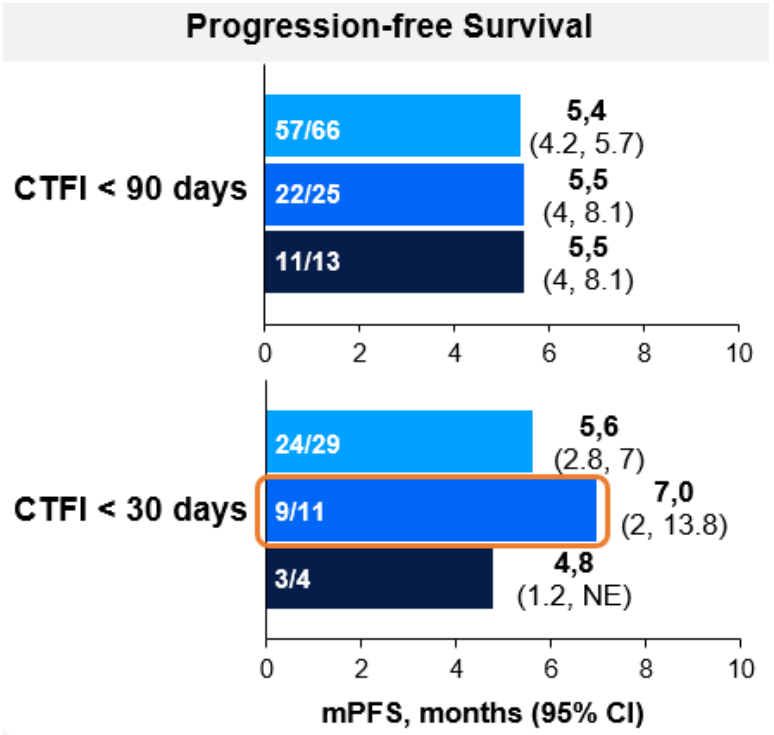
BYERS: secondary endpoint (PFS)





Published as: Byers LA. Nature Med 2026.

mOS: 14.3 m in 2L | 12.4 m in 2L+

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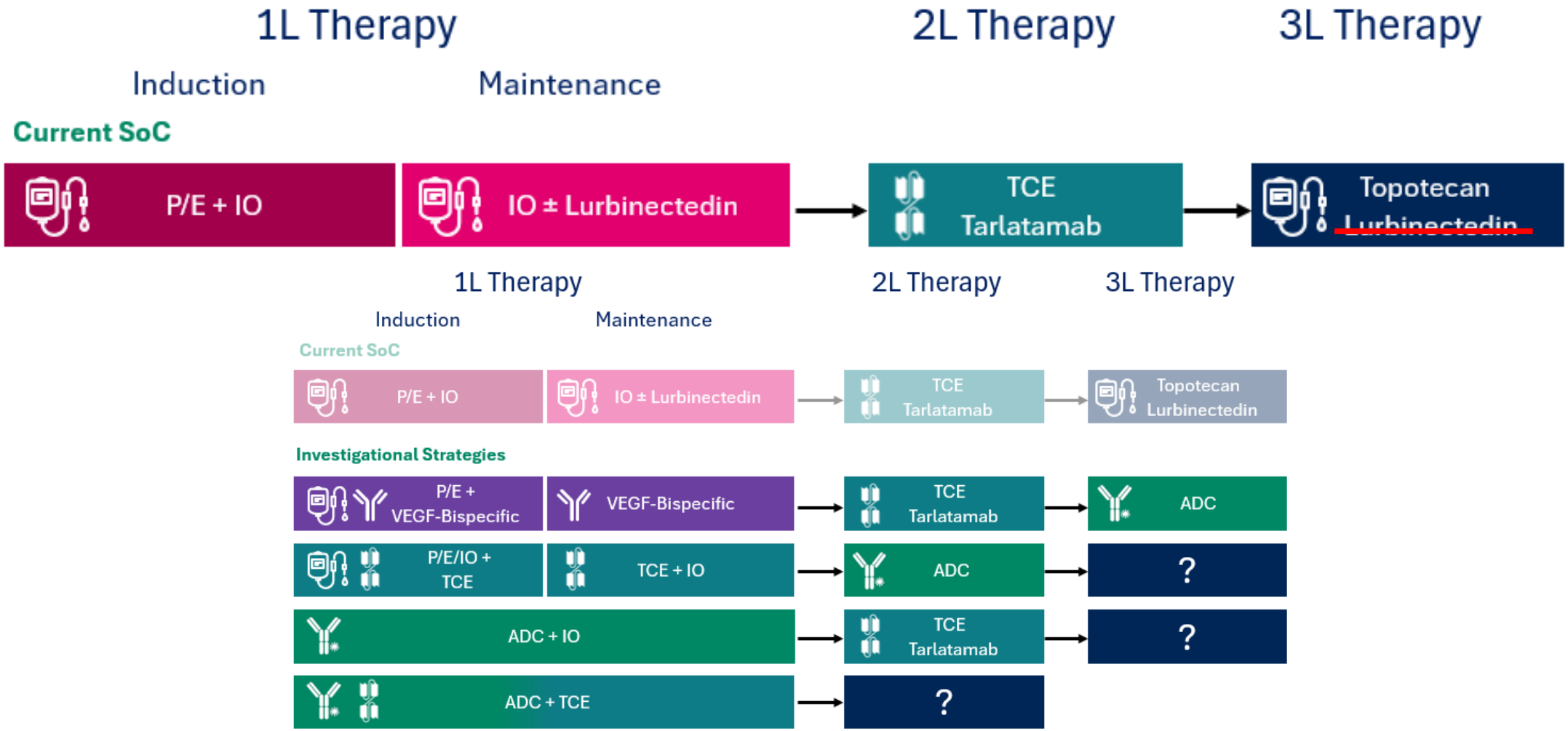
FUTURE PERSPECTIVES IN SCLC



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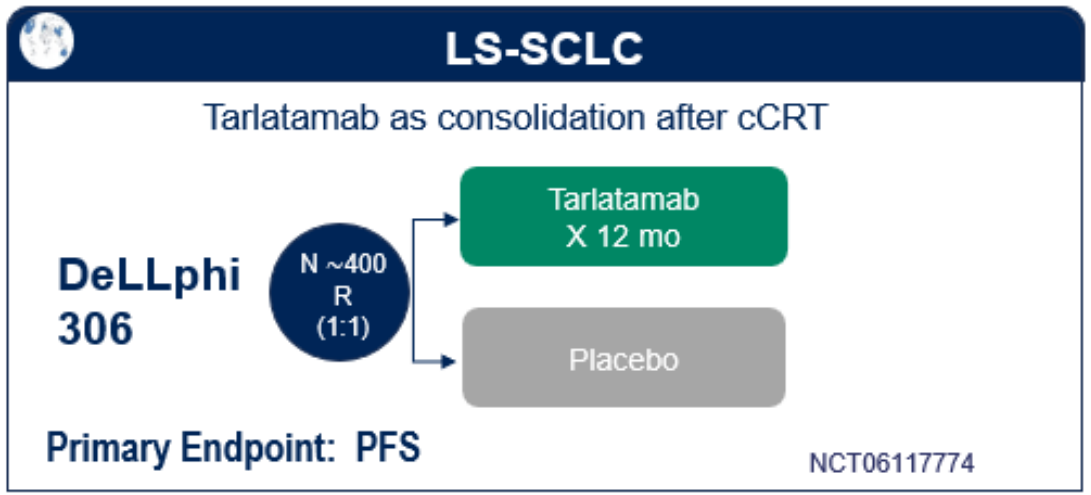
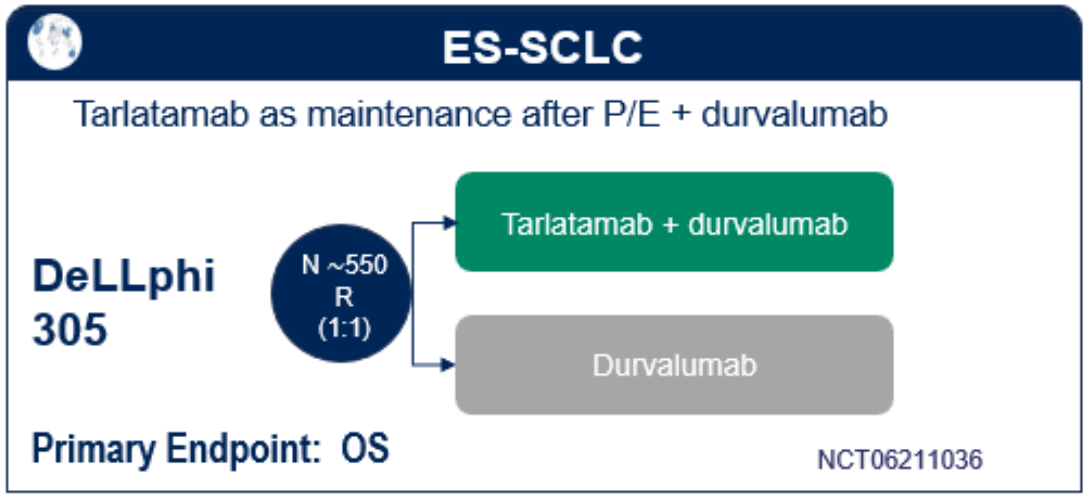
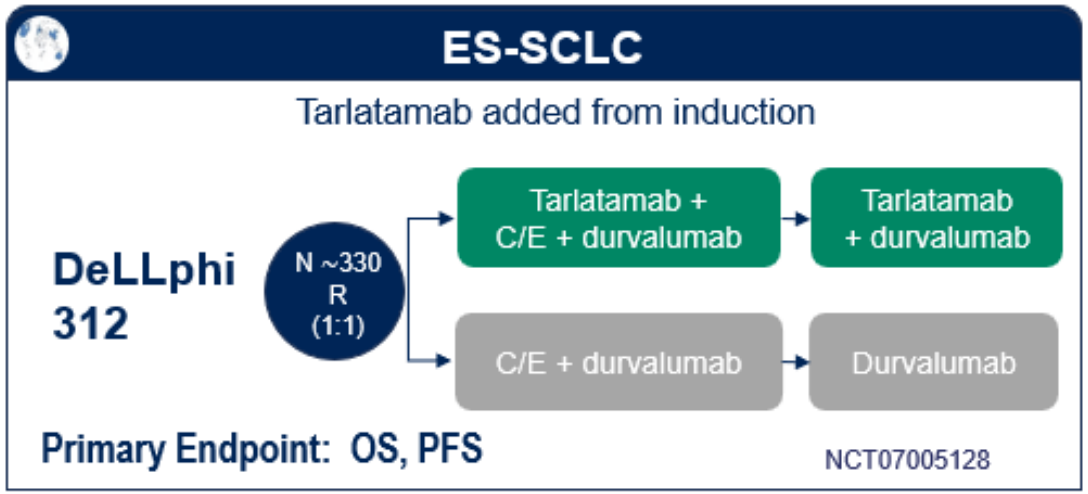
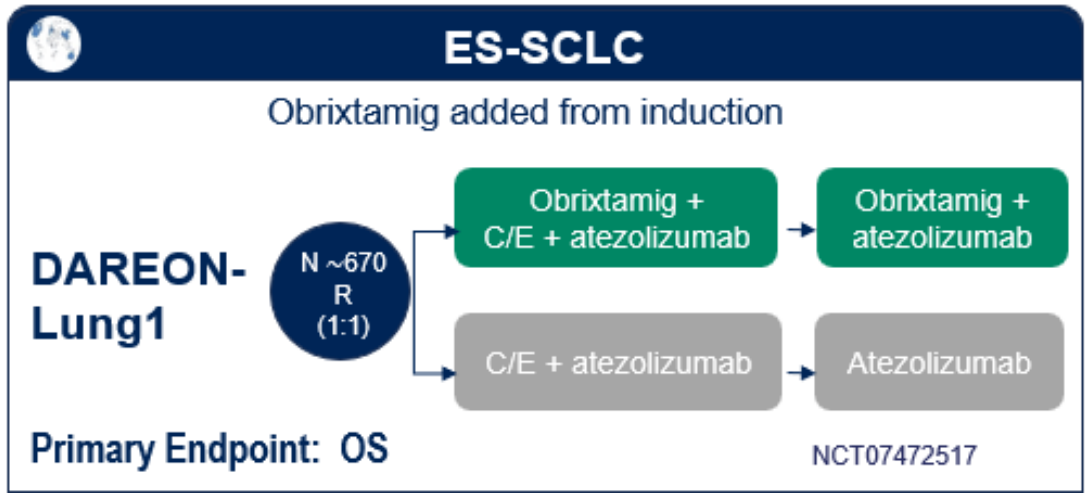
FUTURE PERSPECTIVES IN SCLC









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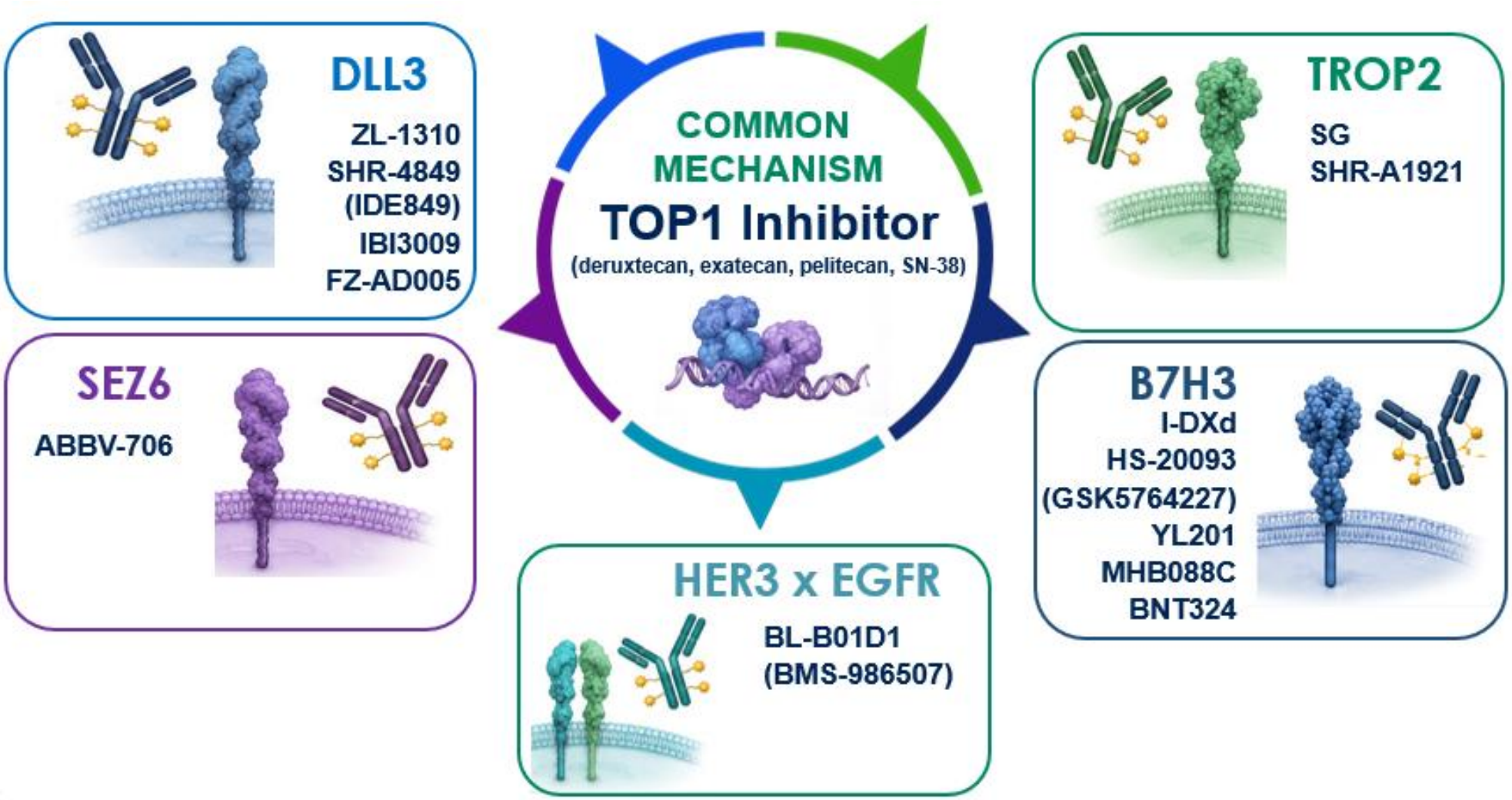
FUTURE PERSPECTIVES IN SCLC



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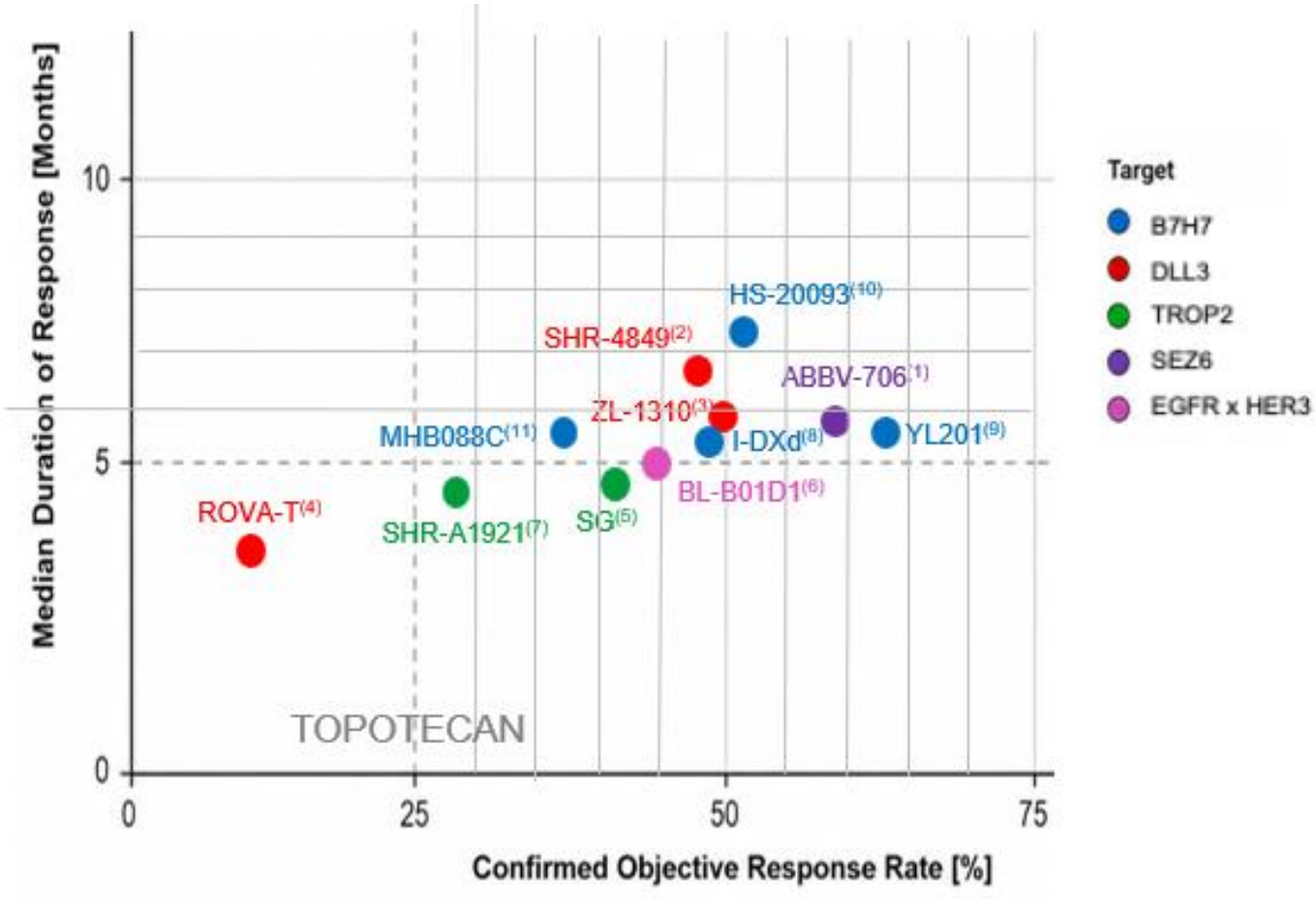
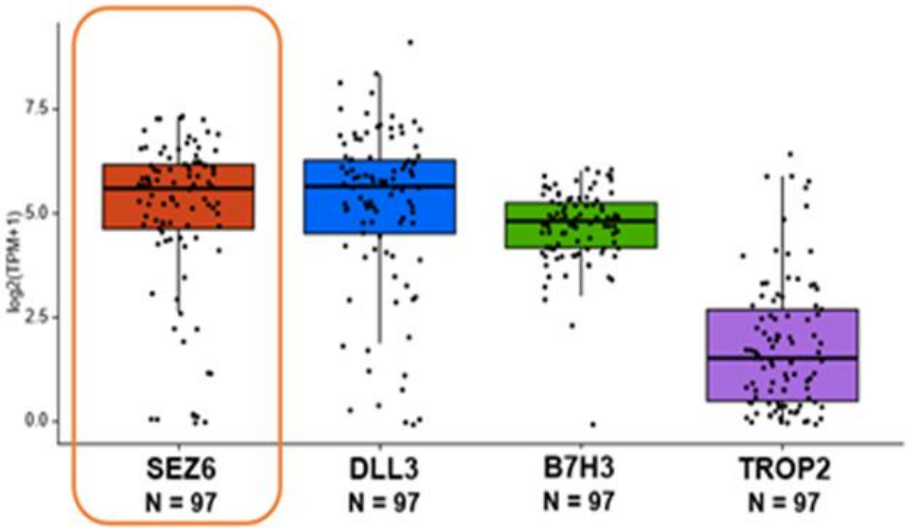
FUTURE PERSPECTIVES IN SCLC





SEZ6 tumor expression is prevalent in patients with SCLC (93% of patients above a 1+, 1% cutoff by IHC)[a]

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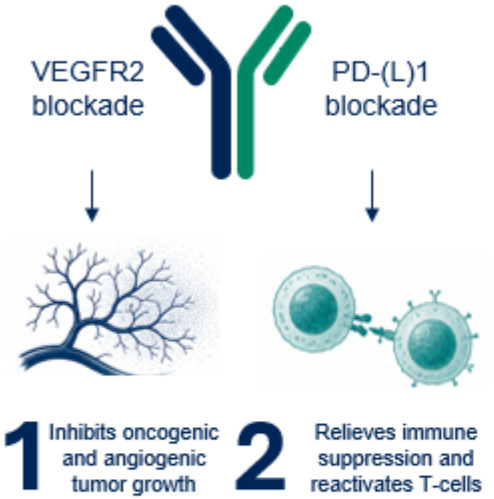
FUTURE PERSPECTIVES IN SCLC

DUAL MODULATION OF TME



1 Inhibits oncogenic and angiogenic tumor growth

2 Relieves immune suppression and reactivates T-cells

EARLY CLINICAL ACTIVITY IN 1L + C/E

Trial	cORR	mPFS
PUMITAMIG (BNT327) + C/E[1] (N = 43)	76%	6.8 mo
IVONESCIMAB + C/E[2] (N = 35)	80%	6.9 mo

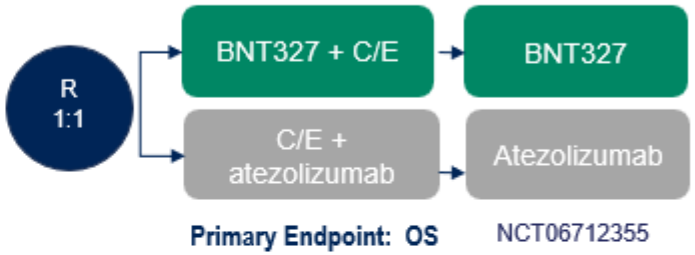
No major hemoptysis signal observed

HISTORICAL BENCHMARK (1L ES-SCLC)[3-4] Impower133 | CASPIAN

ORR	mPFS
~ 60-65%	~ 5 mo

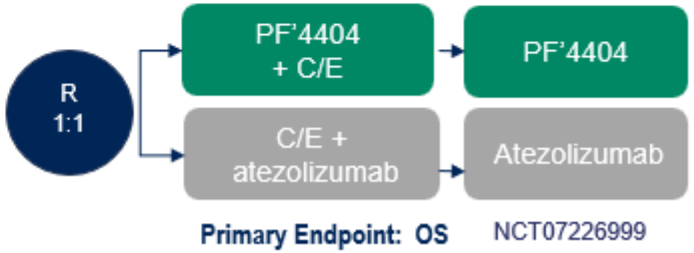
ONGOING PHASE IN 1L ES-SCLC

ROSETTA Lung-01



Primary Endpoint: OS NCT06712355

Symbiotic-Lung-04



Primary Endpoint: OS NCT07226999

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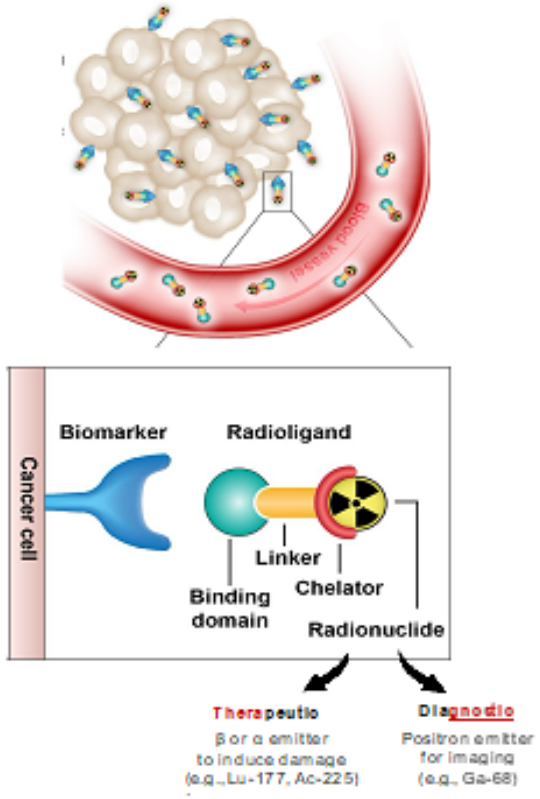
FUTURE PERSPECTIVES IN SCLC



Target	Ligand Construct	Therapeutic Radionuclide	Theranostic Pair	PET Imaging Tracer	Setting in ES-SCLC	Phase Development
DLL3	ABD-147	^{225}Ac (α)	✗	-	2 L R/R	I
DLL3	RYZ101	^{225}Ac (α)	✗	-	1L + Chemo/IO	FIH
SSTR2	DOTATATE	^{177}Lu (β$^-$)	✓	^{68}Ga-DOTATATE	1L + Chemo/IO	I/II
SSTR2	Satoreotide	^{177}Lu (β$^-$)	✓	^{68}Ga-SSO120	Maintenance + IO	I (LuSato-1)
SSTR2	Satoreotide	^{225}Ac (α)	✓	^{68}Ga-SSO120	Maintenance + IO	I/II (SANTANA-225)

Operational logistics infrastructure

Long-term marrow/renal toxicity

Optimal integration with evolving standards

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4.
Supportive care

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ABSTRACTS

- The efficacy and safety of add-on ruxolitinib for patients with severe checkpoint inhibitor pneumonitis management with corticosteroids: A multicenter, open-label, randomised phase 2 trial.
- Vitamin D Insufficiency and Risk of Taxane-Induced Peripheral Neuropathy: Results from SWOG S1714.
- An international phase III randomized, double-blind, double-dummy trial comparing duloxetine and pregabalin for opioid-refractory neuropathic cancer pain.
- Nationwide Randomized, Phase III, Placebo-Controlled Trial of Bupropion for Cancer-Related Fatigue.
- DESCEND Study: Reducing or omitting dexamethasone with NEPA and olanzapine for prevention of chemotherapy-induced nausea and vomiting (CINV)
  in highly emetogenic chemotherapy: a randomized non-inferiority phase III trial.

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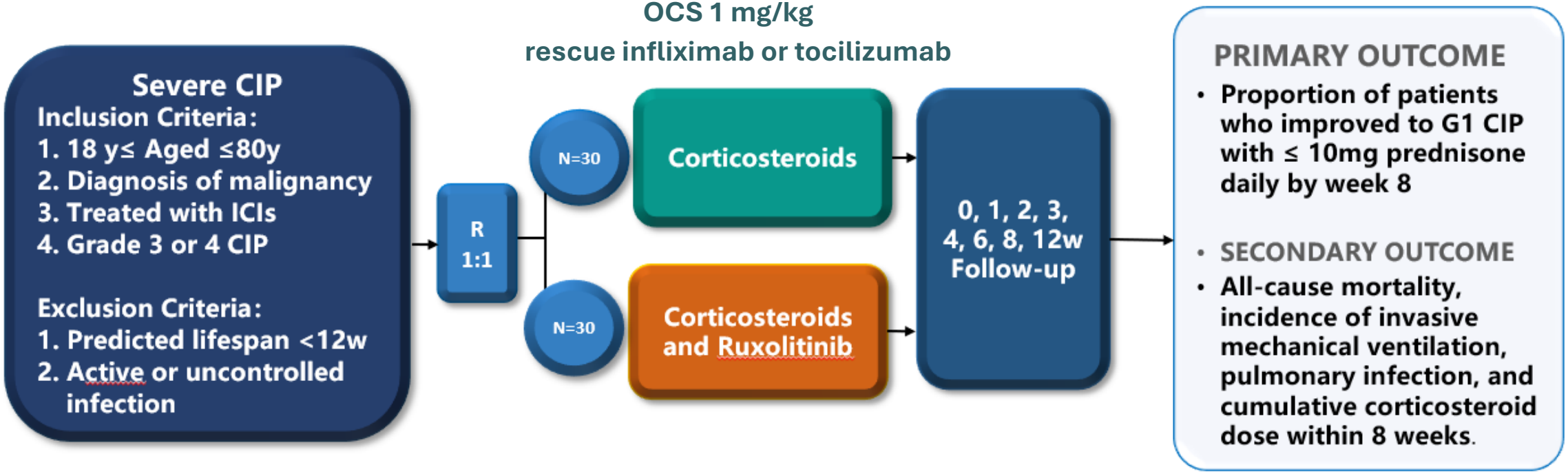
IMMUNERELATED PNEUMONITIS



no differences in PD-1/PD-L1, G3/G4, lung cancer/other cancer

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IMMUNERELATED PNEUMONITIS

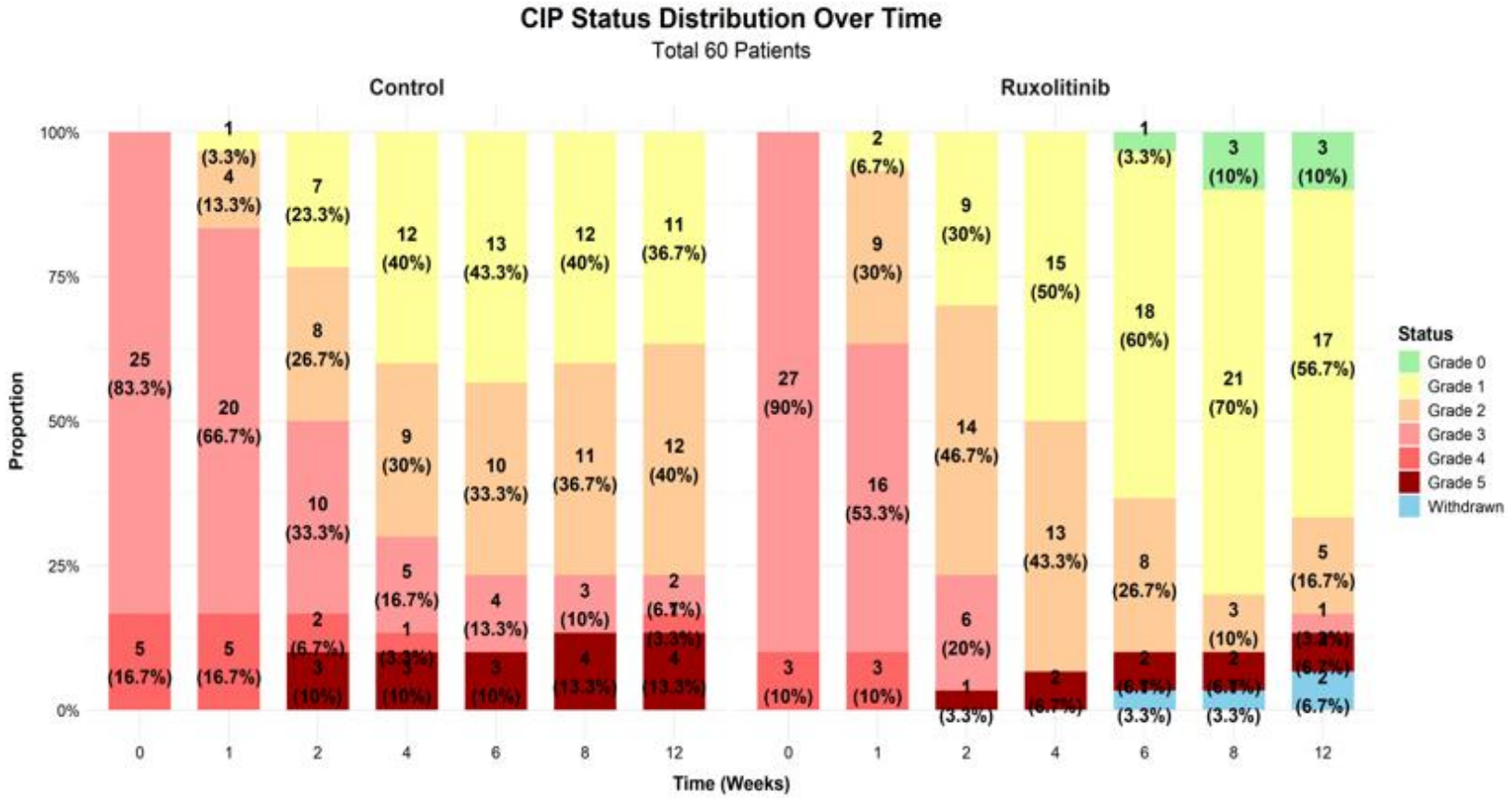

Figure 2. Distribution of CIP Severity Over Time by Treatment Group

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The efficacy and safety of add-on ruxolitinib for patients with severe checkpoint inhibitor pneumonitis management with corticosteroids: A multicenter, open-label, randomised phase 2 trial. Xu Y et al.

TAXANE-INDUCED NEUROPATHY

Paclitaxel | Docetaxel

1M patients annually

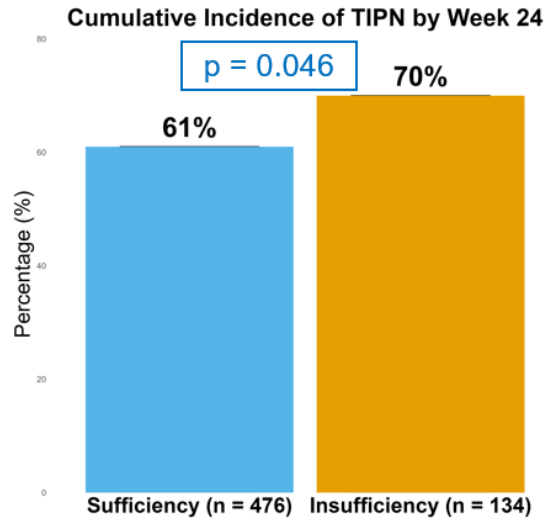
breast, ovarian, lung, GI, genitourinary, prostate, and head and neck cancers

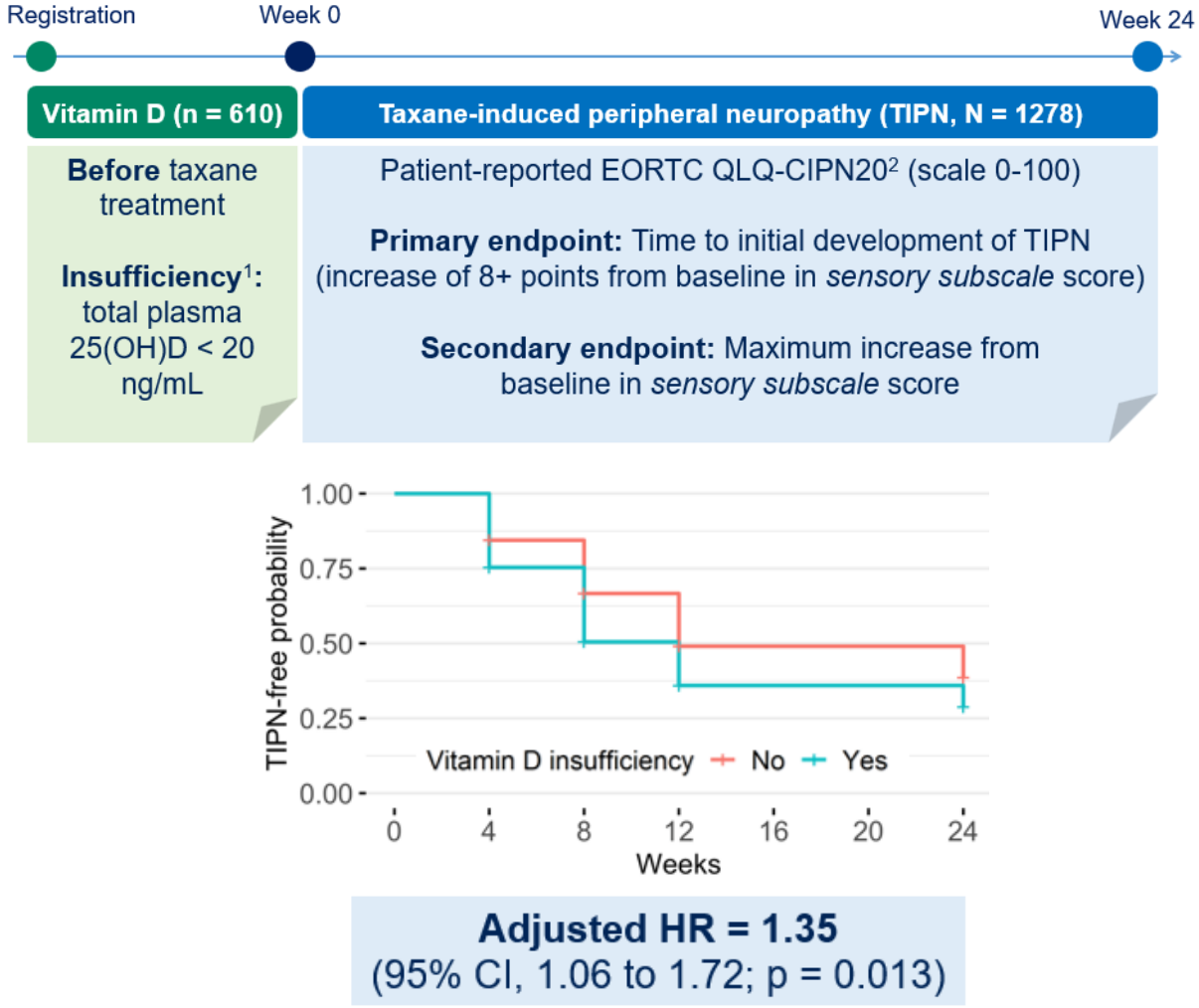
70%
experience **TIPN** among taxane-treated patients

40-60%
continue to experience symptoms **after 3 years**

1/4
delay, **decrease**, and **discontinue** taxanes

90% breast cancer





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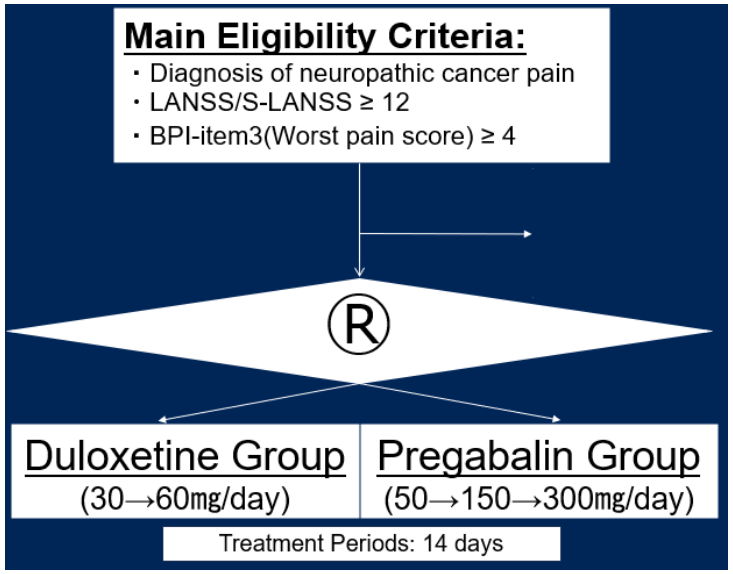
Vitamin D Insufficiency and Risk of Taxane-Induced Peripheral Neuropathy: Results from SWOG S1714. Nguyen-Hoang N et al.

OPIOID-REFRACTORY CANCER PAIN



no PNP

no spinal cord compression

Items	Duloxetine group (N = 74)	Pregabalin group (N = 73)
Age (yrs) Mean (SD)	62.0(10.9)	61.2(13.3)
Sex N (%)		
Males	47(63.5)	47(64.4)
Females	27(36.5)	26(35.6)
Country of enrollment N (%)		
Australia	9(12.2)	7(9.6)
Japan	65(87.8)	66(90.4)
Primary tumor sites n (%)		
Lung	20(27.0)	33(45.2)
Esophagus, stomach, colon	13(17.6)	8(11.0)
Hepatobiliary tract and pancreas	6(8.1)	4(5.5)
Head and neck	4(5.4)	6(8.2)
Breast	4(5.4)	6(8.2)
Uterus/ovary	5(6.8)	2(2.7)
Prostate, kidney, bladder	5(6.8)	3(4.1)
Others	17(23.0)	11(15.1)
Mean worst pain score (BPI item 3)	7.23	7.04

Between-Group Differences in BPI Item 3 (Worst Pain) Scores

Analysis	Duloxetine Mean (95% CI)	Pregabalin Mean (95% CI)	Mean Difference (95% CI)	P value (2sided t-test)
Main analysis	5.62 (5.00 - 6.24)	5.45 (4.85 - 6.06)	0.17 (-0.69 - 1.03)	0.70
Sensitivity analysis	5.59 (4.99 - 6.19)	5.45 (4.85 - 6.04)	0.14 (-0.70 - 0.99)	0.74

No significant difference was observed between duloxetine and pregabalin group

Adverse events worse than baseline	Duloxetine Group (N = 74)			Pregabalin Group (N = 72)		
	Grade 1	Grade 2	Grade 3	Grade 1	Grade 2	Grade 3
Nausea	15 (20%)	13 (18%)	5 (7%)	4 (6%)	0	0
Vomiting	5 (7%)	4 (5%)	3 (4%)	1 (1%)	0	0
Decreased appetite	9 (12%)	12 (16%)	5 (7%)	5 (7%)	3 (4%)	0
Dry mouth	5 (7%)	4 (5%)	2 (3%)	5 (7%)	0	0
Fatigue	9 (12%)	8 (11%)	3 (4%)	6 (8%)	1 (1%)	0
Somnolence	22 (30%)	8 (11%)	1 (1%)	21 (29%)	7 (10%)	0
Dizziness	9 (12%)	3 (4%)	1 (1%)	7 (10%)	6 (8%)	0
Peripheral edema	3 (4%)	0	1 (1%)	6 (8%)	1 (1%)	0

Duloxetine:①Nausea ②Somnolence ③Decreased appetite ④Fatigue ⑤Dizziness
Pregabalin:①Somnolence ②Dizziness ③Decreased appetite ④Peripheral edema ⑤ Fatigue

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An international phase III randomized, double-blind, double-dummy trial comparing duloxetine and pregabalin for opioid-refractory neuropathic cancer pain. Matsuoka H et al.

CANCER-RELATED FATIGUE

ELIGIBILITY

- Adults, any cancer, any stage
- Worst fatigue ≥4 / 10 in past week
- Completed surgery/RT/IV therapy ≥2 months prior
- Concurrent hormonal, targeted, and other supportive therapies allowed
- No bupropion contraindications

→

1:1 RANDOMIZATION

Stratified by:
- Study site
- Prior chemotherapy
- Metastatic disease
- Current oral/targeted/hormonal therapy

→

BUPROPION XL

150 mg wk 1 → 300 mg wks 2-12 → 150 mg wk 13

Over-encapsulated to maintain blinding

PLACEBO

Matching over-encapsulated lactose capsules

Identical schedule

PRIMARY OUTCOME & ANALYSIS

Primary endpoints

FACIT-F Fatigue subscale at 12 weeks
- *13 items, 0–52; higher = less fatigue*

Tolerability
- *Pill count, incidence of CTCAE grade 2 or above toxicity, self-reported insomnia, and early discontinuation*

Analysis

ANCOVA, baseline FACIT-F as covariate
Site as random effect (per protocol)
Intent-to-treat

Power

90% to detect d = 0.30
(3-point MCID on FACIT-F)
α = 0.05 two-sided

CANCER & TREATMENT

	Bupr	Plac	*p*
Breast cancer	75%	73%	*0.81*
Stage 0–II	70%	69%	*0.41*
Prior chemotherapy	66%	63%	*0.50*
Prior radiation	66%	74%	*0.05*

>80% female

BASELINE FATIGUE

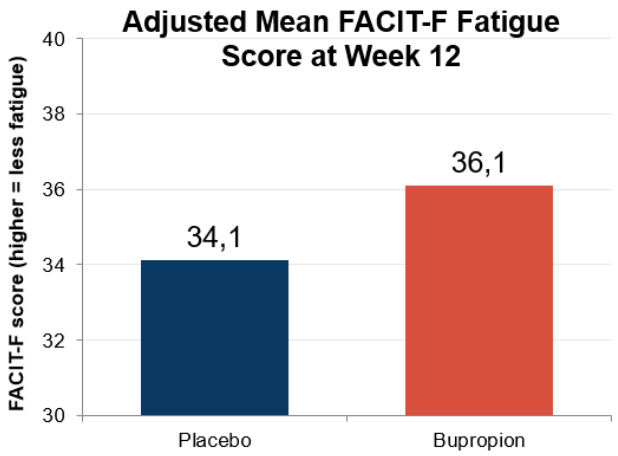
Identical between arms

25.6

FACIT-F at baseline

Bupropion: **25.6 (9.5)**

Placebo: **25.6 (10.1)**



KEY RESULT

+2.01

points on FACIT-F favoring bupropion

p = 0.03 **d = 0.23**

95% CI for group difference
0.15 to 3.86 points

Both arms improved from baseline (~25.6);
bupropion improved more

no difference in G2+ AE

SMOKING STATUS

Prespecified moderator

Interaction p = 0.060

Ever-smokers
+4.24 points, p = 0.005

Never-smokers
+0.58 points, p = 0.63

Bupropion resulted in greater improvements in fatigue among study participants who were current or past smokers

PRESENTED BY: Jo Raskin MD

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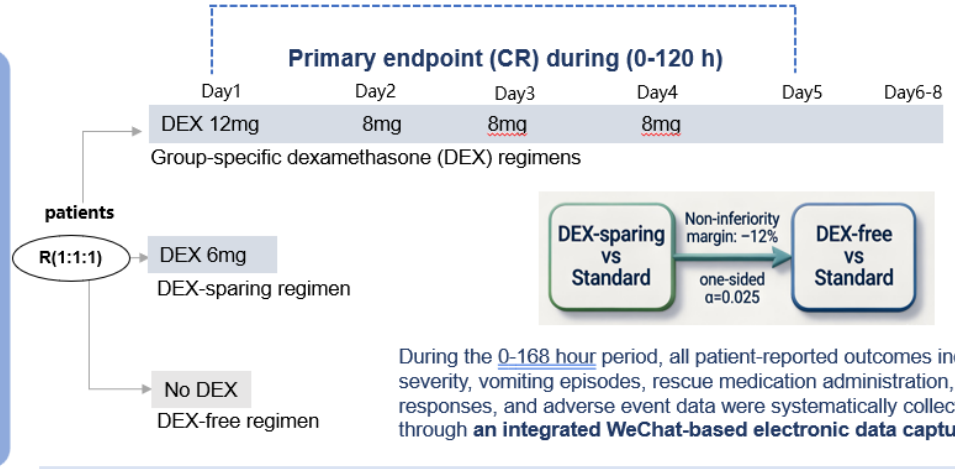
Nationwide Randomized, Phase III, Placebo-Controlled Trial of Bupropion for Cancer-Related Fatigue. Peppone L et al.

CHEMOTHERAPY-INDUCED NAUSEA

Key inclusion criteria

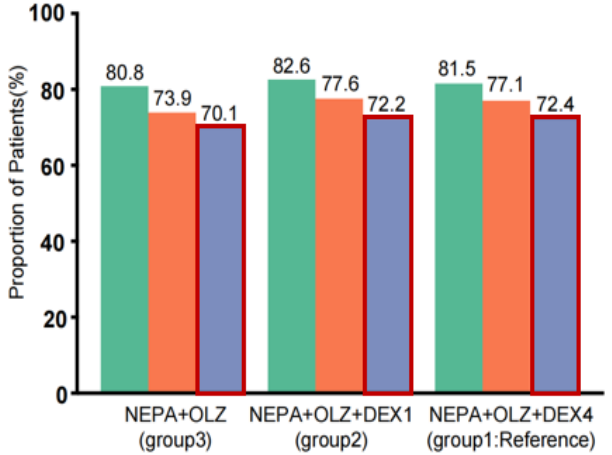
- Aged ≥18 years with histologically or cytologically confirmed malignant solid tumors,
- Scheduled to receive HEC
- No antiemetic or investigational agent use within 3 weeks prior
- ECOG PS ≤2
- Life expectancy ≥12 weeks

Simple randomization was applied within strata defined by **sex (male vs female) and age (≥55 years vs <55 years)**

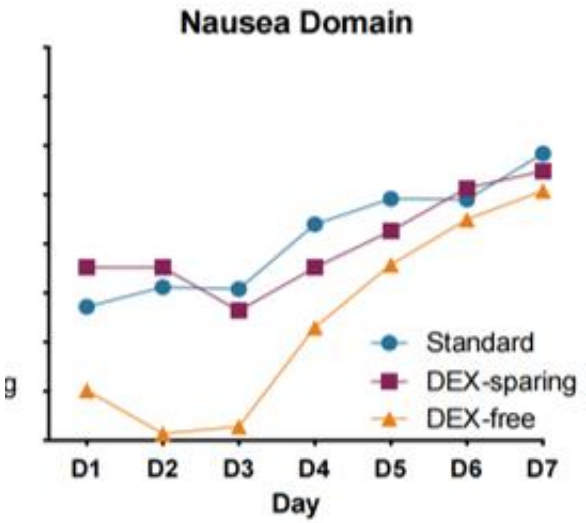


During the 0-168 hour period, all patient-reported outcomes including nausea severity, vomiting episodes, rescue medication administration, FLIE questionnaire responses, and adverse event data were systematically collected and managed through **an integrated WeChat-based electronic data capture system**

All patients received **NEPA** orally 1 hour before chemotherapy on day 1 and **OLZ** 5 mg orally once daily on days 1-4



HEC: carboplatin, tras-dxd, sac-gov, dat-dxd



Side effects	Standard (N=217)	DEX-sparing (N=213)	DEX-free (N=214)
Agitation/Anxiety		0.004	<0.001
Facial rash/acne		0.066	<0.001
Hiccups		<0.001	<0.001
Indigestion/heartburn or reflux		<0.001	<0.001
Insomnia		<0.001	<0.001

stratified Risk difference	group2-group1	group3-group1
Acute	1.1%(-6.2%-8.4%)	-0.6%(-8.1%-6.8%)
Delayed	0.4%(-7.6%-8.4%)	-3.2%(-11.4%-5.0%)
Overall	-0.2%(-8.7%-8.5%)	-2.2%(-10.7%-6.4%)
	$P_{non\text{-}inferiority}$=0.005	$P_{non\text{-}inferiority}$=0.014

Acute(0-24h) Delayed(24-120h) Overall(0-120h)

Non-inferiority margin set at -12%

DESCEND Study: Reducing or omitting dexamethasone with NEPA and olanzapine for prevention of chemotherapy-induced nausea and vomiting (CINV) in highly emetogenic chemotherapy: a randomized non-inferiority phase III trial. Zhang J et al.

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Questions?

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