Iniciativa científica de:

GECP lung cancer research

Lung Cancer UPDATES

WCLC HIGHLIGHTS

12 - 15 **SEPTIEMBRE** 2026

Seoul, Republic of South Korea



#WCLCUPDATES

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Cáncer de pulmón no microcítico avanzado sin driver

Aitor Azkárate Martínez

IASLC

2026 World Conference on Lung Cancer

SEPTEMBER 12 – 15, 2026 | SEOUL, REPUBLIC OF KOREA

Primary Results From Phase 3 EVOKE-03/KEYNOTE D46: Sacituzumab Govitecan + Pembrolizumab in PD-L1 TPS ≥50% Metastatic NSCLC

Giannis Mountzios, MD, MSc, PhD

EVOKE-03/KEYNOTE D46 Study Design

Key eligibility criteria

- Stage IV NSCLC (AJCC 8th)
- No prior systemic treatment for mNSCLC
- ECOG PS 0 or 1
- PD-L1 TPS ≥50%
- No ILD
- No untreated or unstable brain metastases
- EGFR/ALK/ROS-1–negative disease

Stratification

- ECOG PS (0 or 1)
- Predominant tumor histology (squamous or non-squamous)
- Geographic region (East Asia vs Western Europe/North America/Australia vs Rest of World)

Randomized
1:1
N = 620

Sacituzumab govitecan
10 mg/kg
D1, D8, Q3W
+
Pembrolizumab 200 mg
IV D1 Q3W
35 cycles

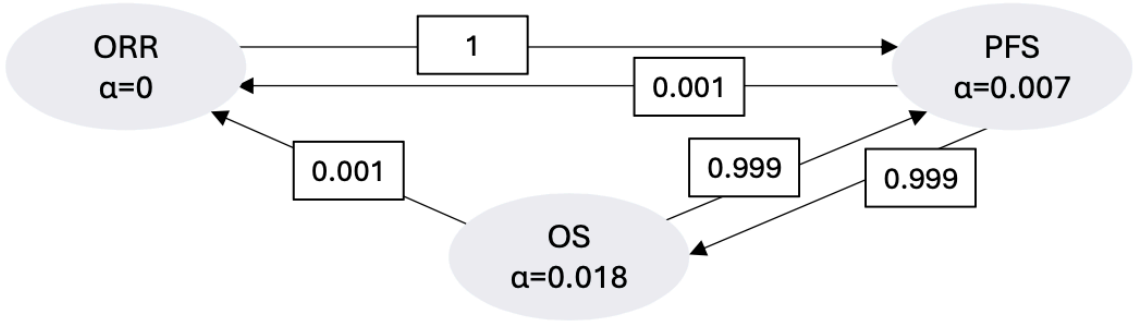
Pembrolizumab 200 mg
IV D1 Q3W
35 cycles

Primary endpoints

- PFS[a]
- OS

Secondary endpoints

- ORR[a]
- DOR[a]
- PROs
- Safety

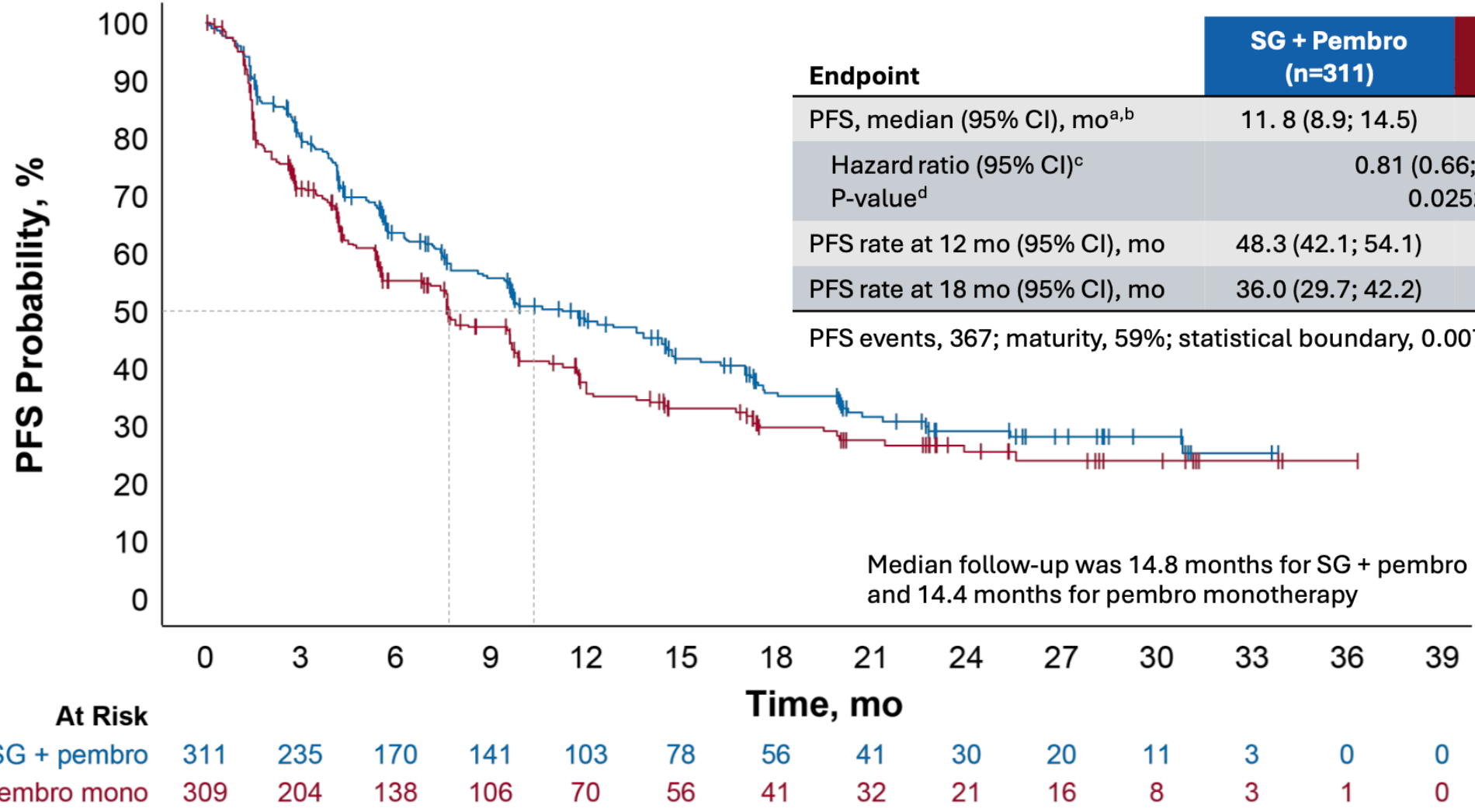


Baseline Demographics and Disposition

Characteristic[a]	SG + Pembro (n=311)[b]	Pembro (n=309)[b]
Median age (range), y	67 (34–87)	68 (37–86)
Male, n (%)	219 (70.4)	224 (72.5)
Geographical region[c]		
East Asia	114 (36.7)	116 (37.5)
Western Europe/North America/Australia	60 (19.3)	58 (18.8)
Rest of world	137 (44.1)	135 (43.7)
ECOG PS		
0	107 (34.4)	108 (35.0)
1	204 (65.6)	201 (65.0)
Histology		
Squamous	96 (30.9)	96 (31.1)
Non-squamous	215 (69.1)	213 (68.9)
Smoking status		
Never smoker	52 (16.7)	53 (17.2)
Current/former smoker	259 (83.3)	256 (82.8)
Cancer stage		
IIIC	1 (0.3)	0 (0.0)
IVA	158 (50.8)	168 (54.4)
IVB	152 (48.9)	141 (45.6)
Brain metastasis	27 (8.7)	30 (9.7)
Liver metastasis	49 (15.8)	49 (15.9)

All data are n (%) unless otherwise stated.

Progression-Free Survival in the ITT Population – Primary Analysis



Endpoint	SG + Pembro (n=311)	Pembro (n=309)
PFS, median (95% CI), mo[a,b]	11. 8 (8.9; 14.5)	7.7 (5.6; 9.7)
Hazard ratio (95% CI)[c] P-value[d]	0.81 (0.66; 1.00) 0.0252	
PFS rate at 12 mo (95% CI), mo	48.3 (42.1; 54.1)	36.9 (30.9; 42.9)
PFS rate at 18 mo (95% CI), mo	36.0 (29.7; 42.2)	29.9 (24.0; 36.1)

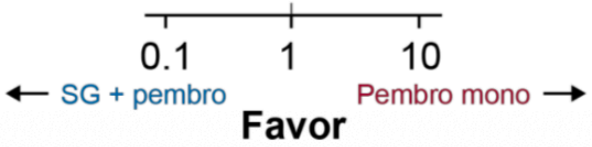
PFS events, 367; maturity, 59%; statistical boundary, 0.007

Median follow-up was 14.8 months for SG + pembro and 14.4 months for pembro monotherapy

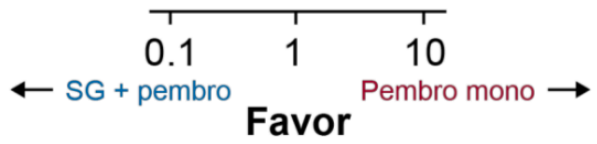
BICR, blinded independent centralized review; mono, monotherapy; ECOG PS, Eastern Cooperative Oncology Group Performance Score; ITT, intention-to-treat; mo, months; pembro, pembrolizumab; PFS, progression-free survival; RECIST, Response Evaluation Criteria in Solid Tumors; SG, sacituzumab govitecan.

Progression-Free Survival Sub-Group Analyses

	#Events/N SG + Pembro	#Events/N Pembro mono	Hazard Ratio (95% CI)
Overall	179/311	188/309	0.81 (0.66; 1.00)
Age, years			
<65	68/126	75/120	0.65 (0.47; 0.91)
≥65	111/185	113/189	0.91 (0.70; 1.18)
Sex			
Male	129/219	138/224	0.83 (0.66; 1.06)
Female	50/92	50/85	0.70 (0.47; 1.04)
Race			
White	109/176	104/168	0.89 (0.68; 1.16)
All others	70/135	84/141	0.69 (0.51; 0.96)
Geographic Region			
East Asia	59/114	67/116	0.68 (0.48; 0.97)
Western Europe/ North America/Australia	41/60	33/58	1.20 (0.76; 1.89)
Rest of the world	79/137	88/135	0.76 (0.56; 1.03)
Baseline ECOG PS			
0	46/107	56/108	0.73 (0.50; 1.08)
1	133/204	132/201	0.81 (0.64; 1.03)



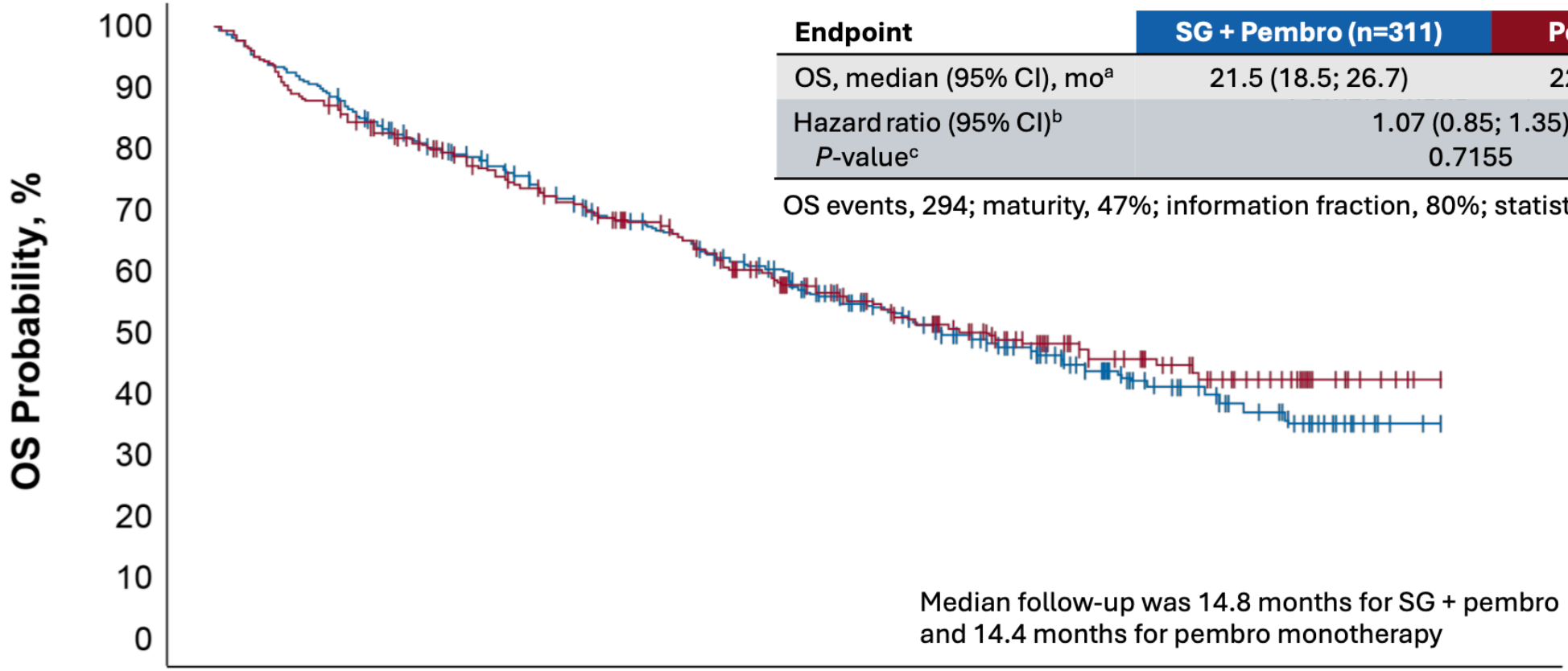
	#Events/N SG + Pembro	#Events/N Pembro mono	Hazard Ratio (95% CI)
Predominant Tumor Histology			
Squamous	69/96	61/96	1.11 (0.78; 1.56)
Non-squamous	110/215	127/213	0.70 (0.54; 0.90)
Smoking Status			
Never smoker	34/52	41/53	0.59 (0.37; 0.93)
Former/current smoker	145/259	147/256	0.85 (0.67; 1.07)
Baseline Brain Metastasis Status			
Yes	19/27	17/30	
No	160/284	171/279	0.77 (0.62; 0.95)
Baseline Liver Metastasis Status			
Yes	38/49	33/49	0.92 (0.58; 1.47)
No	141/262	155/260	0.76 (0.61; 0.96)



Overall Survival in the ITT Population – Interim Analysis

Endpoint	SG + Pembro (n=311)	Pembro (n=309)
OS, median (95% CI), mo[a]	21.5 (18.5; 26.7)	22.8 (18.7; 29.0)
Hazard ratio (95% CI)[b]	1.07 (0.85; 1.35)	
P-value[c]	0.7155	

OS events, 294; maturity, 47%; information fraction, 80%; statistical boundary, 0.008



Median follow-up was 14.8 months for SG + pembro and 14.4 months for pembro monotherapy

At Risk														
SG + pembro	311	282	243	214	180	153	123	95	71	46	27	14	1	0
Pembro mono	309	272	237	205	178	148	120	91	69	47	29	11	1	0

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Overall Survival Analysis From HARMONi-2: Ivonescimab vs Pembrolizumab as First-line Treatment for PD-L1-Positive NSCLC

Patient Population
Locally advanced or metastatic (IIIB-IV) NSCLC

Key Eligibility Criteria

- PD-L1 TPS ≥1%
- No prior systemic therapy
- No *EGFR* mutations or *ALK* alterations
- ECOG PS 0 or 1

Stratification Factors

- Clinical stage (IIIB/C vs IV)
- Histology (SQ vs non-SQ)
- PD-L1 TPS (≥50% vs 1-49%)

R 1:1

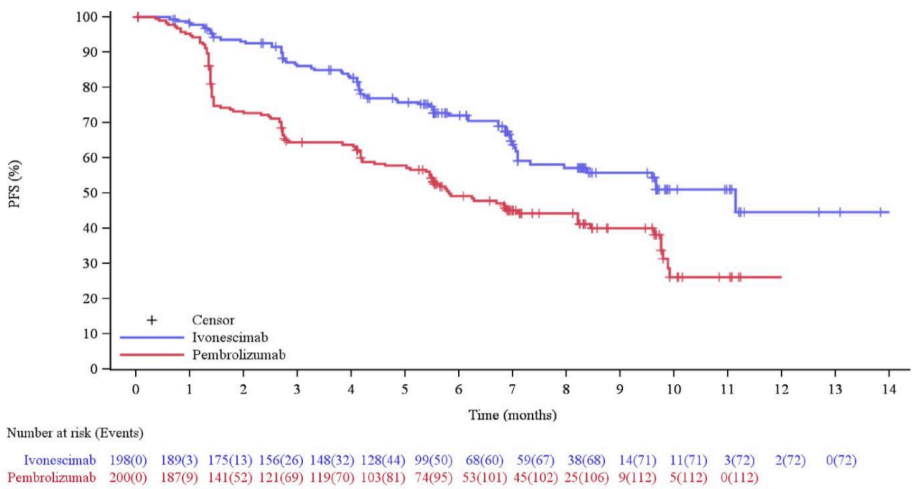
N=398

- **Ivonescimab** 20 mg/kg Q3W (N=198)
- **Pembrolizumab** 200 mg Q3W (N=200)

Treatment until no clinical benefit, unacceptable toxicity or up to 24 months

Endpoints

- **Primary endpoint:** PFS by blind IRRC per RECIST v1.1
- **Key Secondary endpoint : OS**
- **Secondary endpoints:** PFS assessed by INVs, ORR, DoR, TTR and safety



	Ivonescimab (n = 198)	Pembrolizumab (n = 200)
ORR, % (95% CI)	50.0 (42.8, 57.2)	38.5 (31.7, 45.6)
DCR, % (95% CI)	89.9 (84.8, 93.7)	70.5 (63.7, 76.7)
mPFS, mo (95% CI)	11.1 (7.33, NE)	5.8 (5.03, 8.21)
Stratified HR (95% CI)	0.51 (0.38, 0.69)	
p-value	<0.0001	

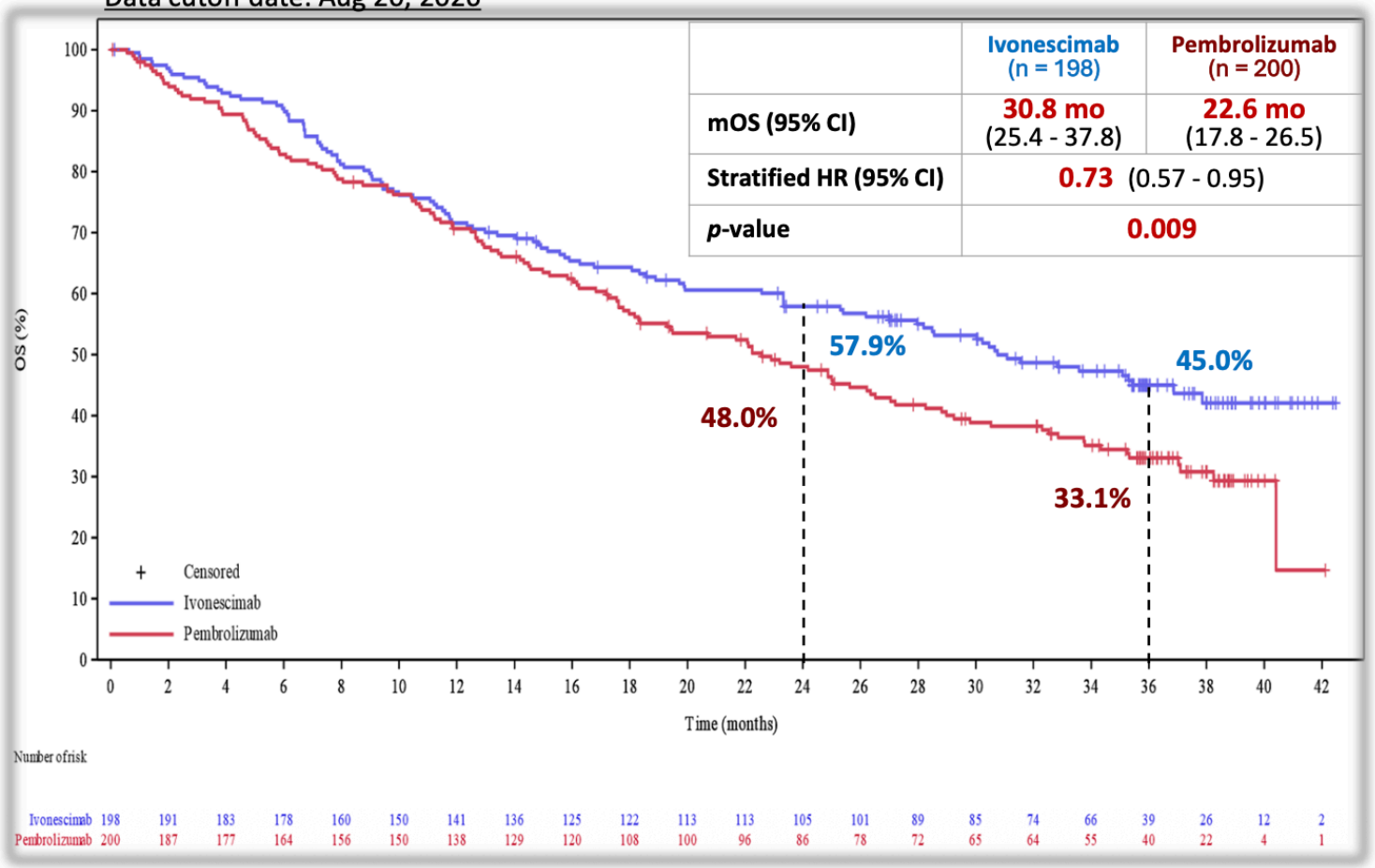
Median follow-up: 8.7 months

Data cutoff date: Jan 29, 2024

Overall survival

➢ Ivonescimab demonstrated a statistically significant improvement in OS with a median follow-up of 36.0 months

Data cutoff date: Aug 20, 2026



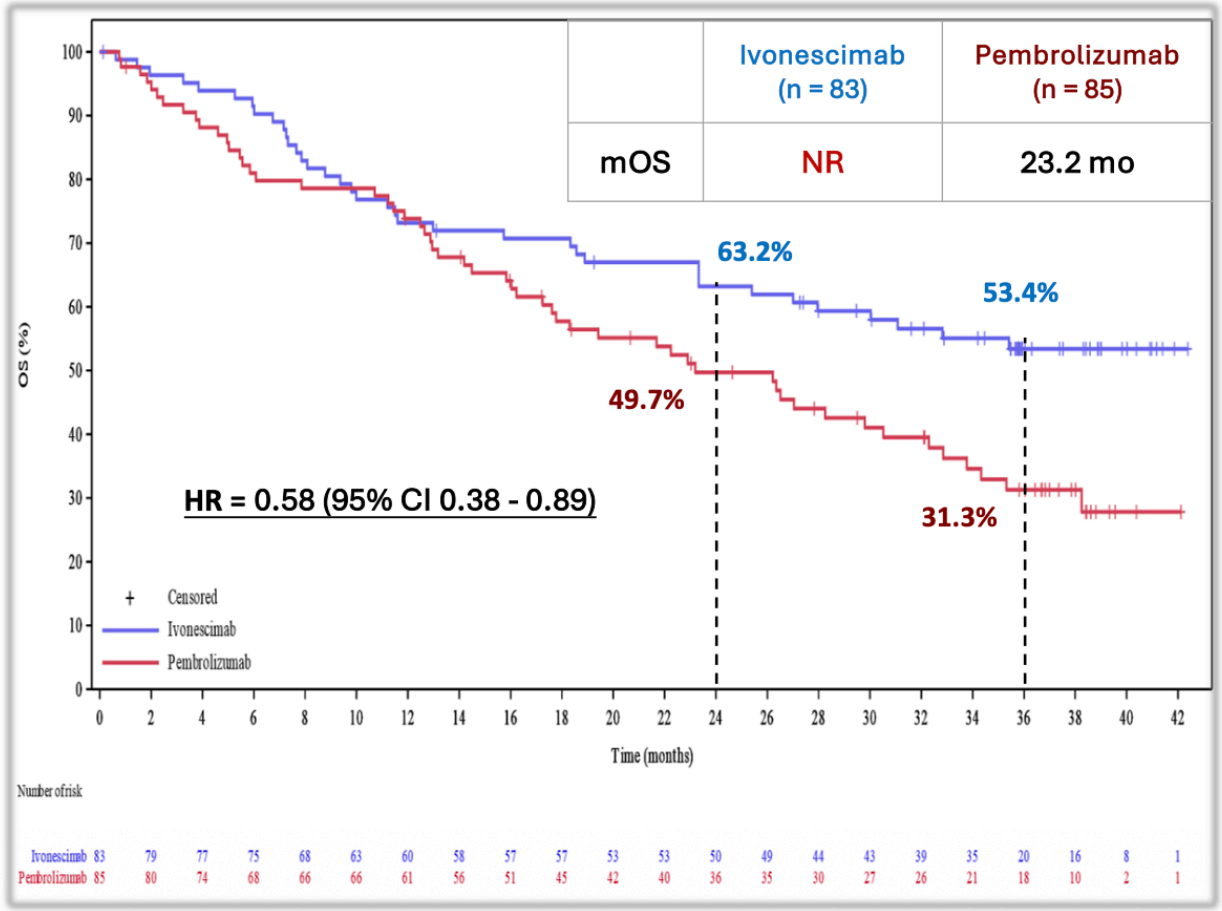
OS rate (%)	HARMONi-2		KN-042 China study [1]
	Ivonescimab (n = 198)	Pembrolizumab (n = 200)	Pembrolizumab (n = 128)
24-mo	57.9%	48.0%	43.8%
36-mo	45.0%	33.1%	28.1%

1. Yilong Wu et al. Five-year outcomes of pembrolizumab versus chemotherapy in Chinese patients with non-small-cell lung cancer and programmed cell death ligand 1 tumor proportion score ≥1%: KEYNOTE-042 China study. Int. J. Cancer. 2026;158:2429–2439.

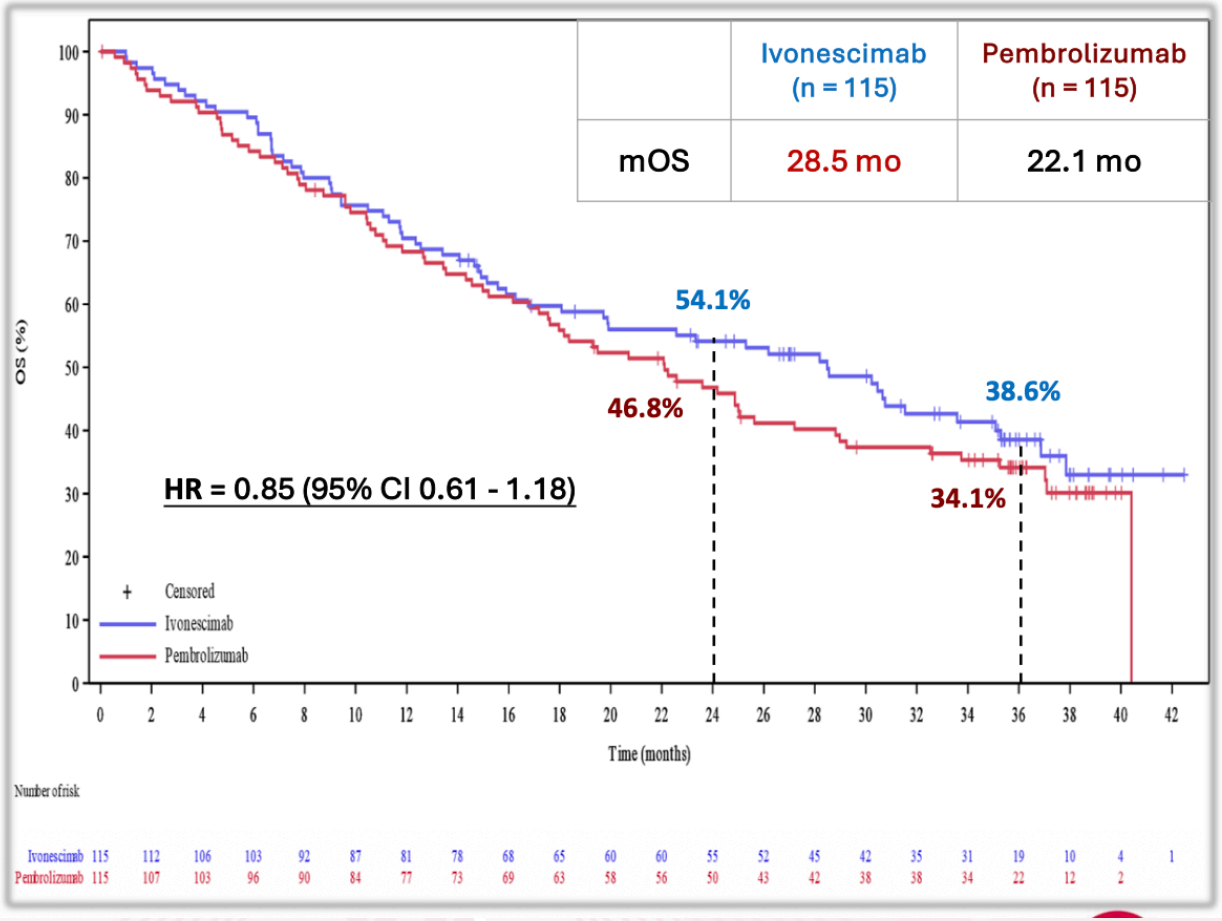
Overall survival by PD-L1 expression level

➢ OS benefit with ivonescimab was consistent in both PD-L1 High and PD-L1 Low expressors

PD-L1 High (TPS ≥50%)



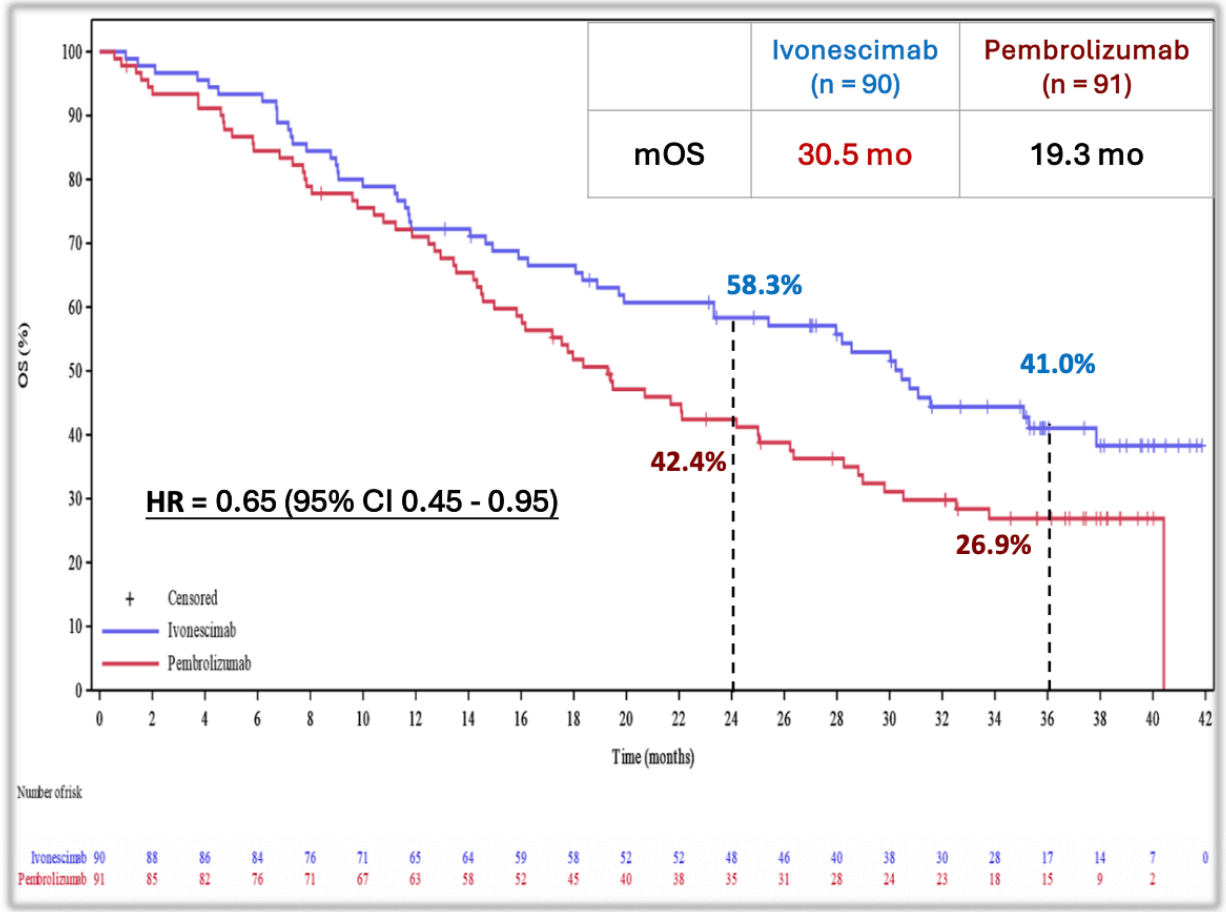
PD-L1 Low (TPS 1-49%)



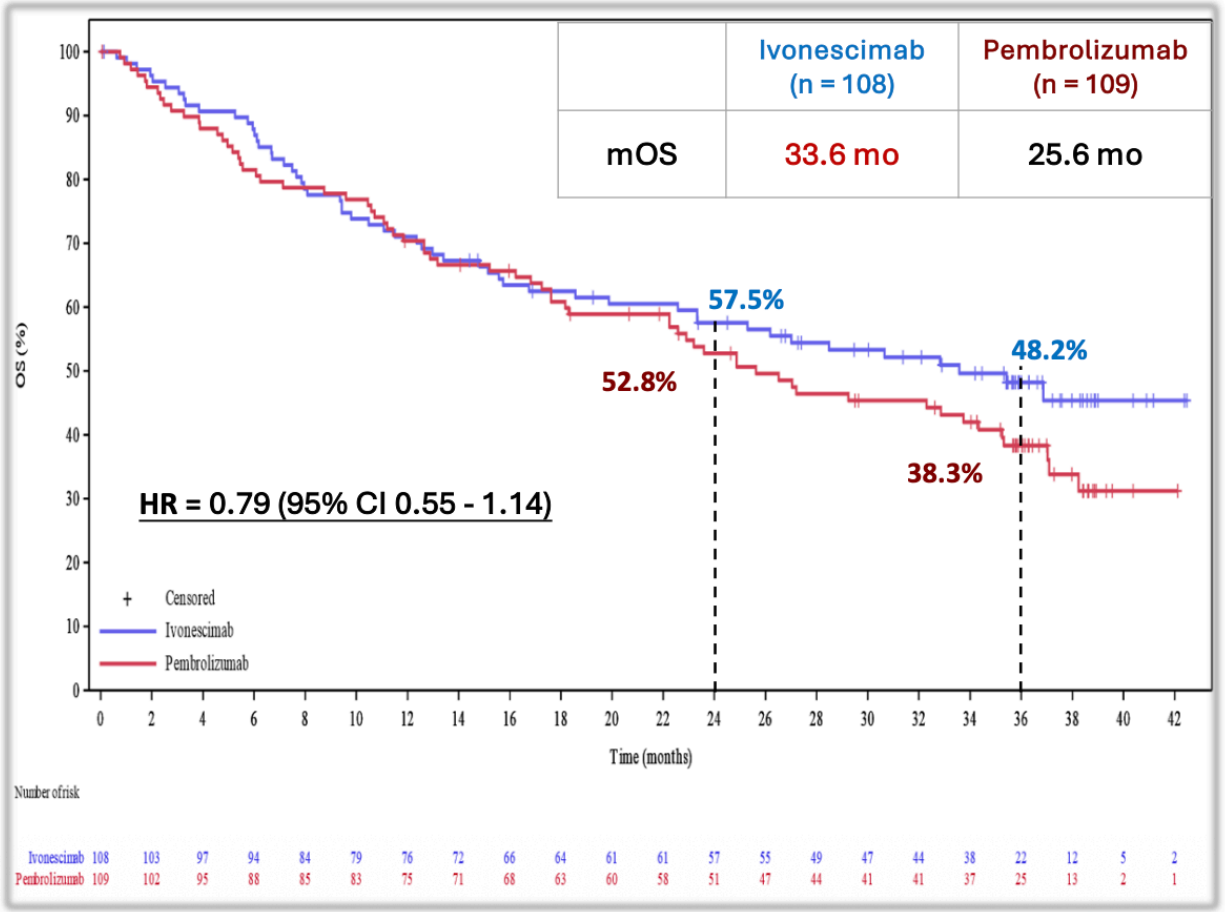
Overall survival by histology

➢ OS benefit with ivonescimab was consistent in both squamous and non-squamous histology

Squamous



Non-Squamous

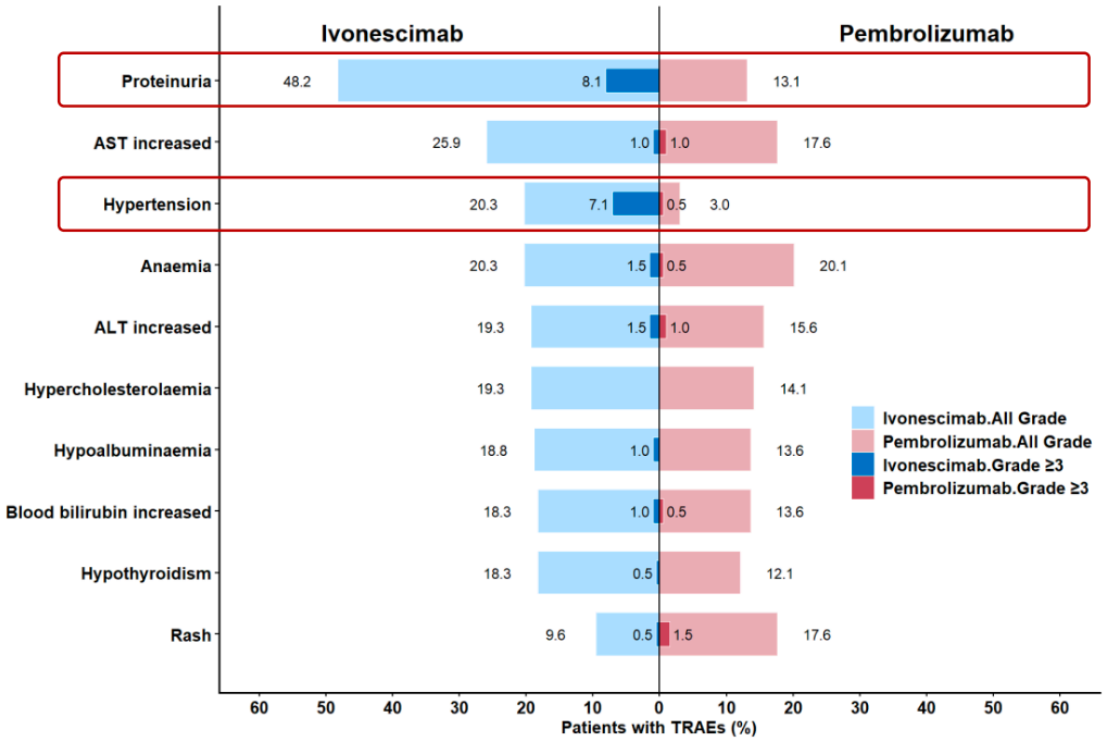


Safety summary

TRAE summary, n (%)	Ivonescimab (n = 197 [a])	Pembrolizumab (n = 199 [a])
TRAEs (all grade)	184 (93.4)	169 (84.9)
Grade ≥ 3 TRAEs	82 (41.6)	43 (21.6)
Serious TRAEs	59 (29.9)	43 (21.6)
Leading to discontinuation	8 (4.1)	10 (5.0)
Leading to death	1 (0.5)	3 (1.5)

Possible VEGF-related AEs [b], n (%)	Ivonescimab (n = 197 [a])		Pembrolizumab (n = 199 [a])	
	All grade	Grade ≥ 3	All grade	Grade ≥ 3
Proteinuria	95 (48.2)	16 (8.1)	26 (13.1)	0
Hypertension	40 (20.3)	14 (7.1)	6 (3.0)	1 (0.5)
Haematuria	18 (9.1)	0	17 (8.5)	0
Haemoptysis	13 (6.6)	0	7 (3.5)	1 (0.5)
Epistaxis	3 (1.5)	0	0	0
Gingival bleeding	2 (1.0)	0	0	0
Cerebral infarction	2 (1.0)	2 (1.0)	1 (0.5)	0

Most common TRAEs (incidence ≥ 15%)



The median duration of exposure:

14.0 cycles (ivonescimab) vs 10.0 cycles (pembrolizumab)

- ✓ No new safety signals
- ✓ No apparent increase in bleeding risk

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Gotistobart vs Docetaxel in Metastatic Squamous NSCLC After PD-(L)1 Progression: Updated Overall Survival of the Stage 1 of PRESERVE-003

Rama Balaraman,[1] Byoung Chul Cho,[2] Hua-Jun Chen,[3] Adewale Fawole,[4] Xinmin Yu,[5] Zhi-gang Liu,[6] Jiliang Zhang,[7] John Hamm,[8] Wu Long,[9] Bin Yang,[10] Jennifer Leddon,[11] Yanjing Huang,[12] Pinhua Pan,[13] Svetlana Shpyro,[14] Qiong Wang,[15] Ugur Sahin,[14] Sergey Efuni,[16] Shiling Song,[16] Pan Zheng,[16] Yang Liu,[16] Kai He,[17] Tianhong Li,[18] Mark A. Socinski,[19] Yi-Long Wu[3]

Unmet medical need in 2L+ sqNSCLC

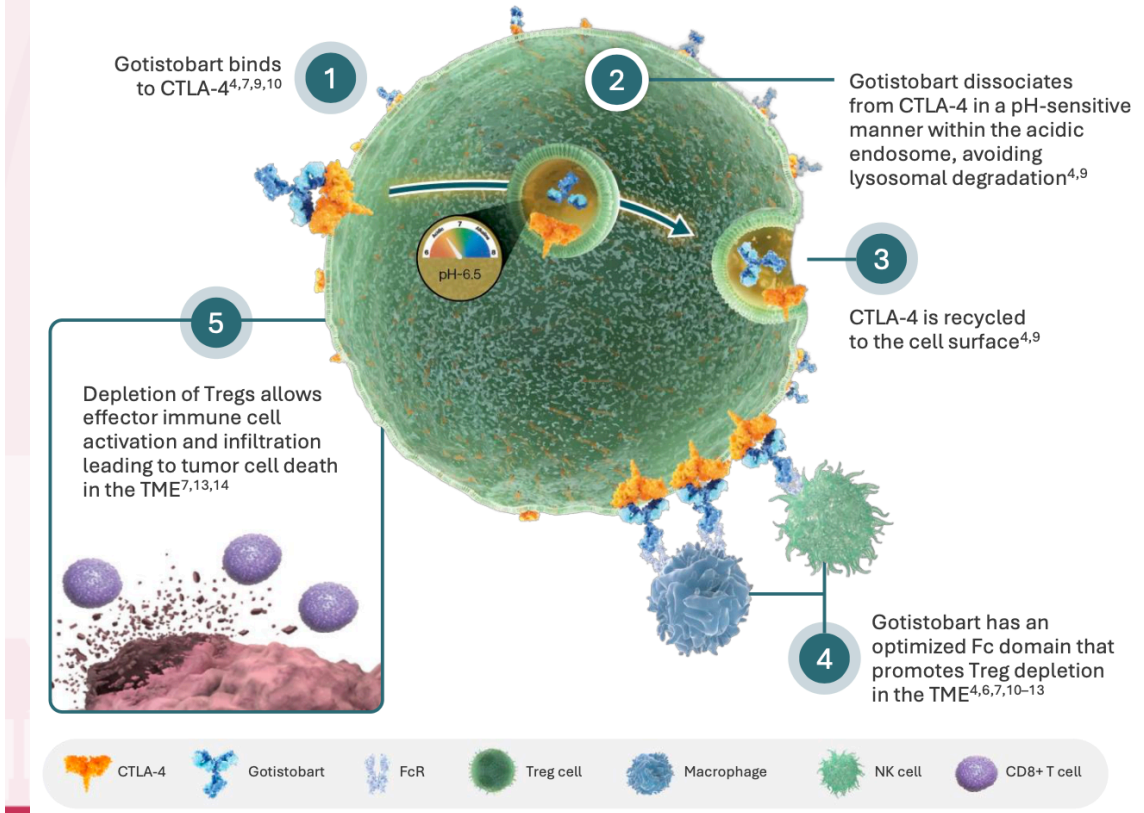
- Limited use of targeted therapies in sqNSCLC
- Docetaxel monotherapy: median OS ~8.0–9.4m, ORR 10.5–12.7%[1–3]
- Multiple trials have failed in the 2L+ metastatic sqNSCLC setting

Gotistobart: novel anti-CTLA-4 with differentiated MoA

- pH-sensitive: preserves/enriches CTLA-4 on tumor-infiltrating regulatory T cells (Tregs)
- Optimized Fc domain enhances intratumoral Treg depletion with minimal peripheral immune activation[4–7]

Gotistobart demonstrated efficacy in 2L+ sqNSCLC

- Gotistobart demonstrated a clinically meaningful OS benefit and durable antitumor activity versus docetaxel in Stage 1 of the PRESERVE-003 Phase 3 trial in patients with sqNSCLC who had progressed on PD-(L)1 inhibitors[8,9]



PRESERVE-003: 2-stage, randomized, multicenter, international Phase 3 trial

PRESERVE 003

This presentation includes data from non-pivotal patients with sqNSCLC. Demographic information is available via the QR code

- ≥18 years of age, Stage 3 & 4, metastatic NSCLC
- Prior PD-(L)1
- Prior platinum-based chemotherapy
- Prior IO–IO allowed
- RECIST 1.1 measurable lesions

R* n=217

Stage 1: Non-pivotal part (enrollment completed)

- **Gotistobart** 3 mg/kg, Q3W (n=10)
- **Gotistobart 6 mg/kg** with 2 loading doses of 10 mg/kg, Q3W (n=103)
- **Docetaxel** 75 mg/m^2, Q3W (n=104)

Stage 2: Pivotal part (sqNSCLC only)

R (1:1) n=414

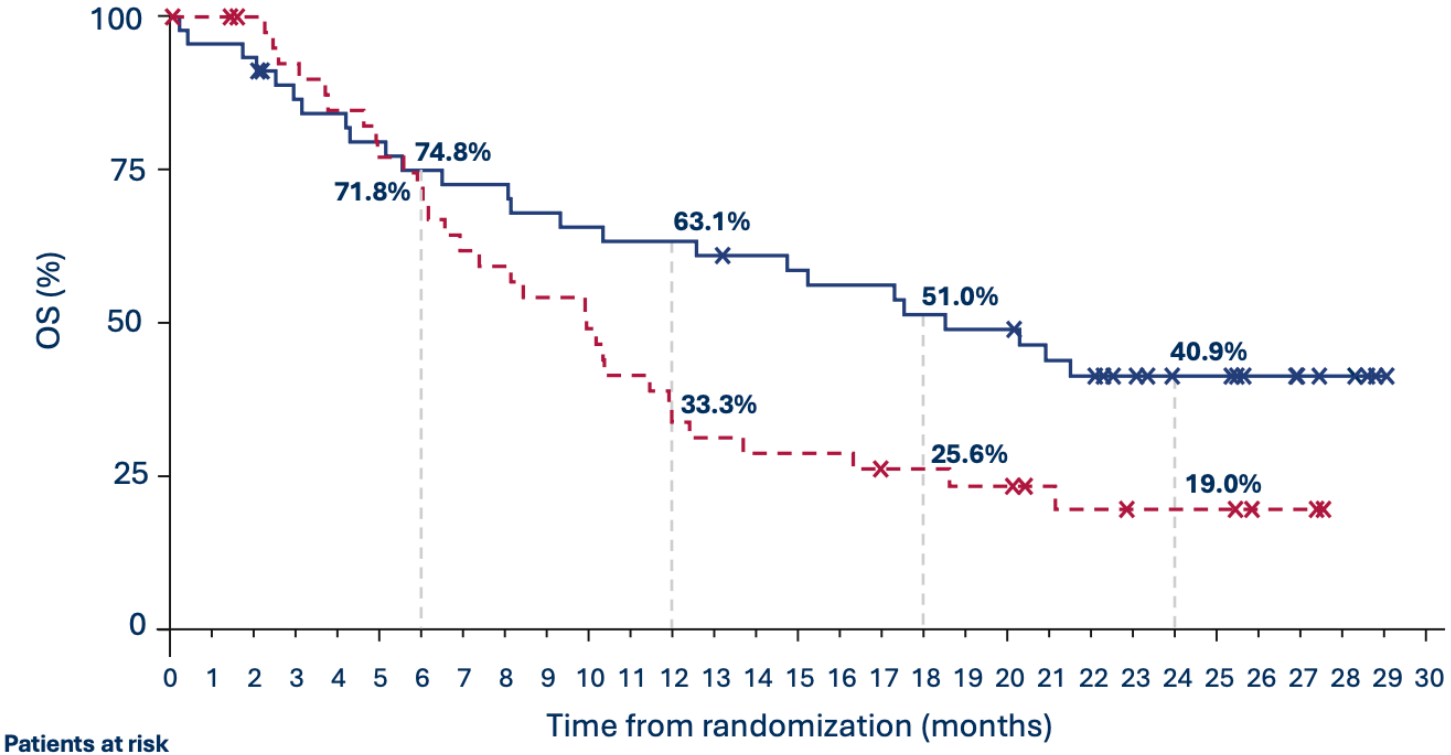
- **Gotistobart 6 mg/kg** with 2 loading doses of 10 mg/kg, Q3W
- **Docetaxel** 75 mg/m^2, Q3W

• **Primary endpoint:** OS. • **Secondary endpoints:** ORR and PFS (both investigator-assessed per RECIST 1.1); safety (treatment-emergent AEs, treatment related AEs, irAEs, and AEs leading to discontinuation). • **Exploratory endpoints:** PK and E–R relationship

We report updated median OS, PK, and E-R analysis from the non-pivotal part.

Median OS in patients with sqNSCLC

With a median follow-up of 25.4 months, median OS was 18.5 months with gotistobart versus 10.0 months with docetaxel (HR=0.56 [95% CI: 0.33, 0.95])



	Gotistobart (n=45)	Docetaxel (n=42)
Events, n (%)	25 (55.6)	31 (73.8)
Alive, n (%)*	16 (35.6)	7 (16.7)
Median OS, months (95% CI)	**18.5 (9.3, NE)**	**10.0 (6.2, 12.0)**
HR (95% CI)	**0.56 (0.33, 0.95); Nominal 2-sided *p*=0.0295†**	
Median duration of follow-up, months (Q1, Q3)‡	25.4 (22.5, 27.5)	25.5 (20.1, 27.4)

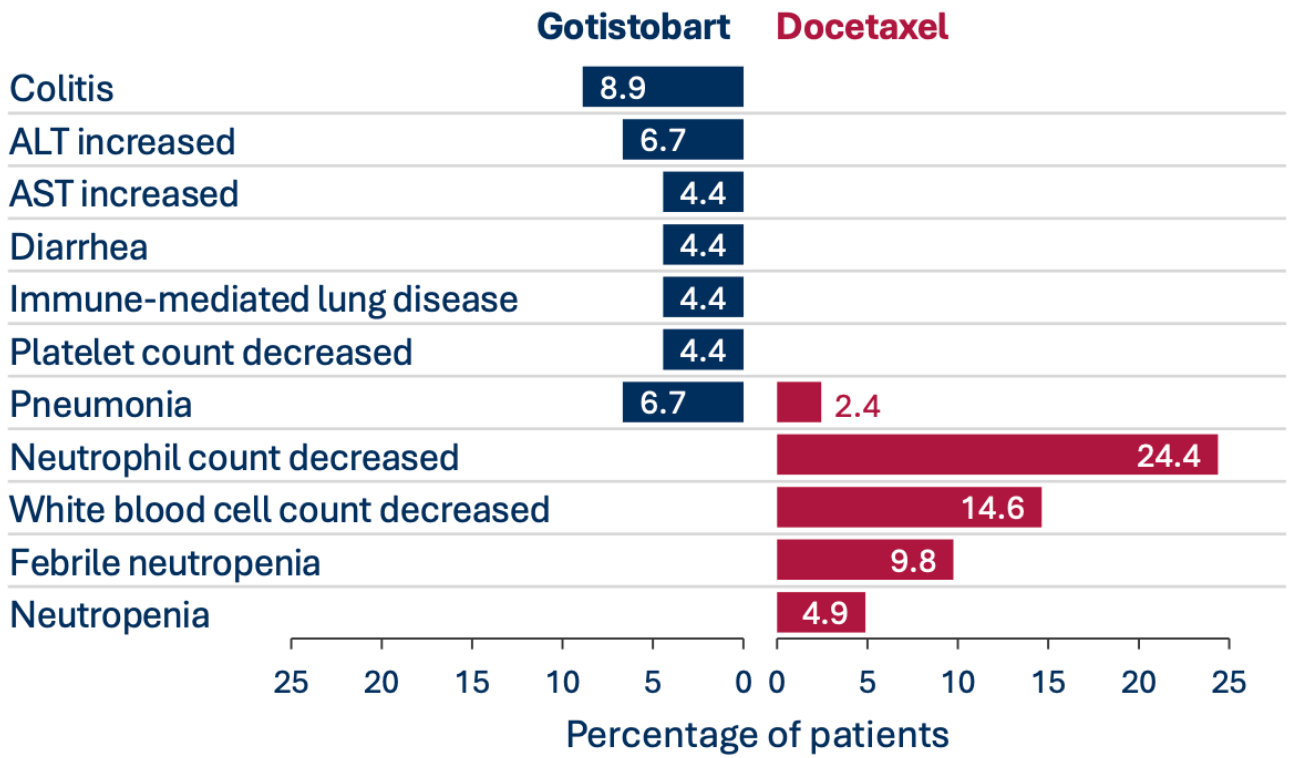
Safety summary

- Safety profile consistent with the expected safety profiles of an immunotherapy versus chemotherapy, with no new or unexpected toxicities
- AEs were non-overlapping: gotistobart events were mainly immune-related or inflammatory, while docetaxel events were predominantly hematologic toxicities

Treatment-related AEs

n (%)	Gotistobart (n=45)	Docetaxel (n=42)
Any grade	38 (84.4)	37 (90.2)
Grade ≥3	20 (44.4)	20 (48.8)
Serious	20 (44.4)	12 (29.3)
Led to treatment discontinuation	7 (15.6)	2 (4.9)
Led to death	0	0

Grade ≥3 treatment-related AEs (in ≥2 patients in either arm)



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Phase II Study of SYS6010 Plus Enlonstobart in Actionable Genomic Alteration-Negative Advanced Non-Small Cell Lung Cancer

Wei Li

Study Objective & Design (the randomized part focus on patients with AGA-negative NSCLC)

Key Eligibility Criteria

- Aged 18-75 years;
- Pathologically confirmed NSCLC
- Treatment-naïve to systemic therapy (prior adjuvant/neoadjuvant therapy allowed if progression occurred ≥6 months after completion);
- Without actionable genomic alterations* ;
- At least one measurable lesion per RECIST v1.1;
- ECOG PS 0-1;
- Life expectancy ≥3 months.

N=60-200

R
1:1

Stratification by PD-L1 TPS (≥1% vs <1%)

Arm 1
SYS6010 4.2mg/kg + SG001 360 mg
Q3W

Arm 2
SYS6010 3.6mg/kg + SG001 240 mg
Q2W

Primary Endpoints:

- Safety/tolerability
- Investigator-assessed ORR per RECIST 1.1

Secondary Endpoints:

- DCR, PFS, DoR, OS

Primary Endpoint: Safety Profile

	Arm 1 (N=62)	Arm 2 (N=61)	Total (N=123)
TEAE			
Any grade	62 (100)	60 (98.4)	122 (99.2)
Grade ≥ 3	34 (54.8)	36 (59.0)	70 (56.9)
Serious	21 (33.9)	21 (34.4)	42 (34.1)
Leading to death	2 (3.2)	3 (4.9)	5 (4.1)
Leading to discontinuation	6 (9.7)	5 (8.2)	11 (8.9)
Leading to dose reduction	7 (11.3)	5 (8.2)	12 (9.8)
TRAE			
Any grade	62 (100)	60 (98.4)	122 (99.2)
Grade ≥ 3	32 (51.6)	32 (52.5)	64 (52.0)
Serious	18 (29.0)	14 (23.0)	32 (26.0)
Leading to death	0	1 (1.6)	1 (0.8)
Leading to discontinuation	6 (9.7)	5 (8.2)	11 (8.9)
Leading to dose reduction	7 (11.3)	5 (8.2)	12 (9.8)

Cut-off date: July 13, 2026. Data are presented as n (%).

Median follow-up period

10.8 months (IQR, 7.2-12.8)

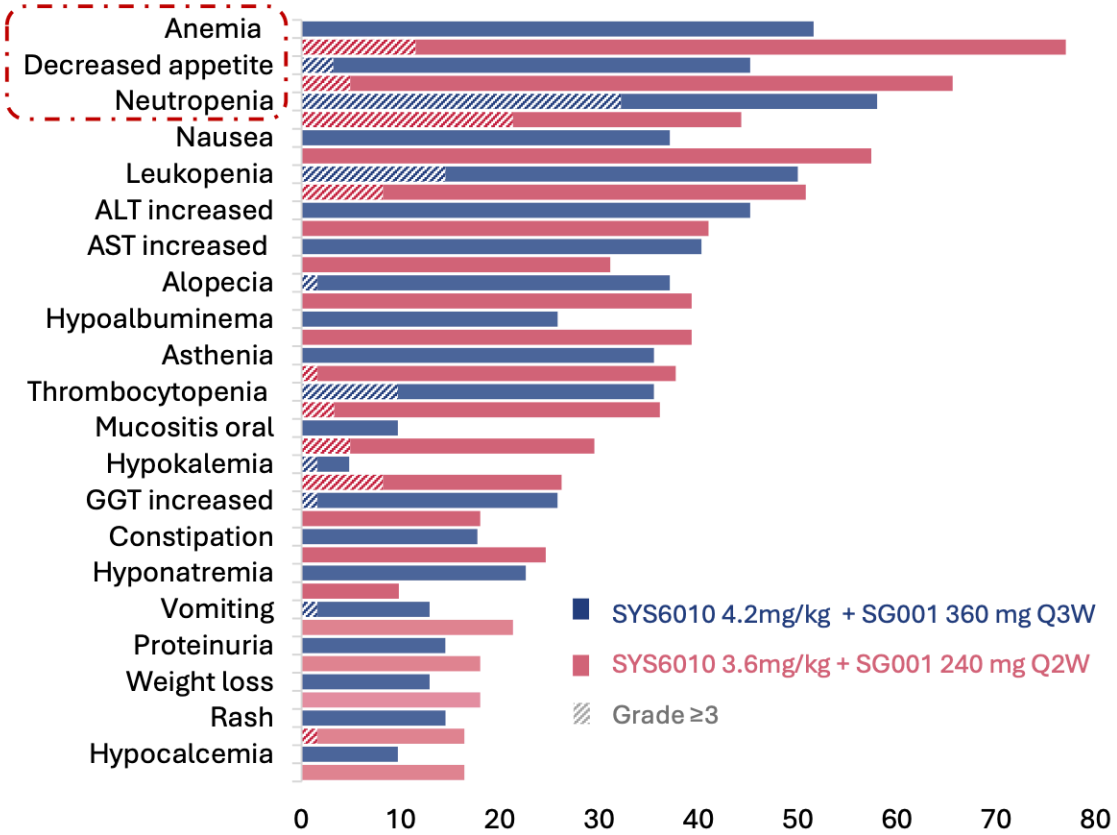
Median treatment duration

Arm 1: 25.1 weeks (IQR, 12.1-38.3)

Arm 2: 26.0 weeks (IQR, 12.1-40.1)

The overall safety profile was similar between the two Arms.

Primary Endpoint: Safety Profile



TRAEs with an incidence of ≥15% in either arm

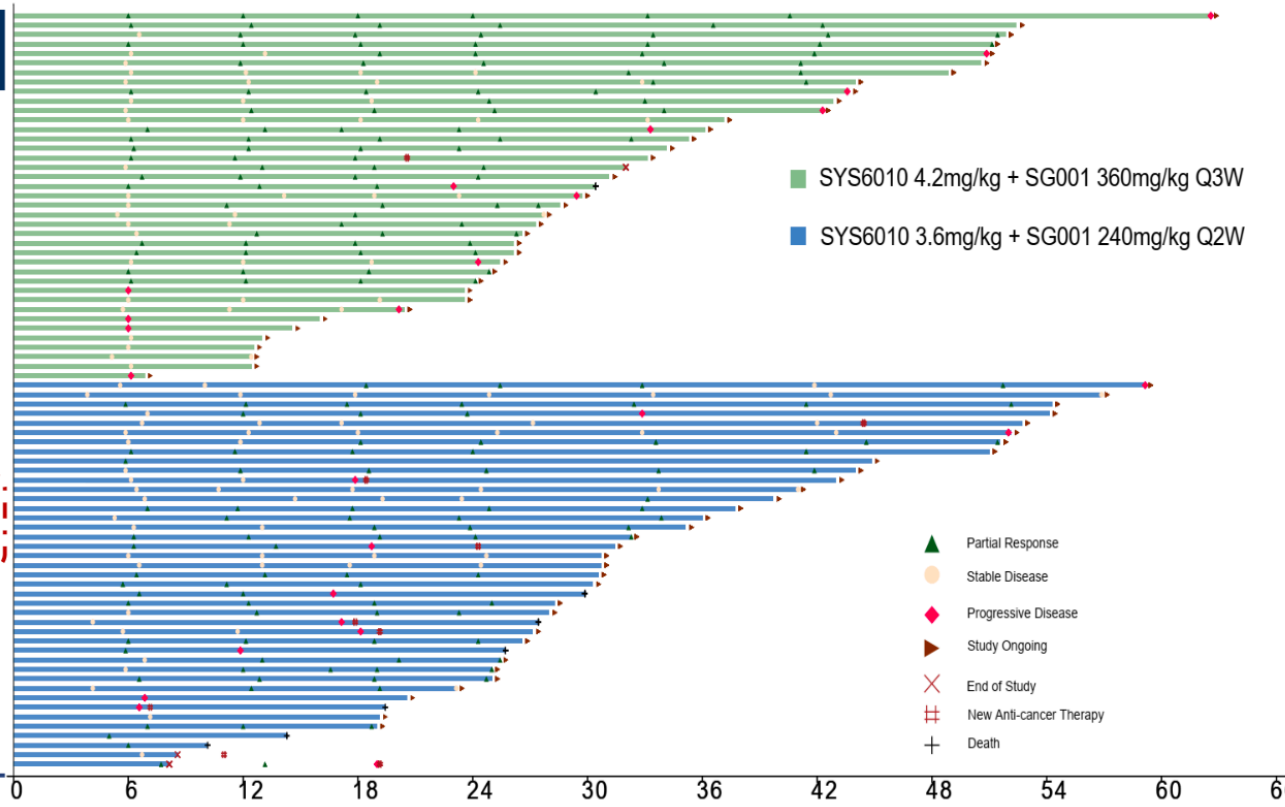
- The most common TRAEs were hematologic and gastrointestinal in nature.
- Most TRAEs were grade 1–2 in severity.

	Arm 1 (n=62)		Arm 2 (n=61)	
	All grade	Grade ≥3	All grade	Grade ≥3
Adverse events of interest, n (%)				
Rash	9 (14.5)	0	10 (16.4)	1 (1.6)
Mucositis oral	6 (9.7)	0	18 (29.5)	3 (4.9)
ILD / pneumonitis (including immune-related)	8 (12.9)	2 (3.2)	4 (6.6)	1 (1.6)
Most common grade ≥3 TRAEs, n (%)				
Neutropenia	36 (58.1)	20 (32.3)	27 (44.3)	13 (21.3)
Leukopenia	31 (50.0)	9 (14.5)	31 (50.8)	5 (8.2)
Anemia	32 (51.6)	0	47 (77.0)	7 (11.5)

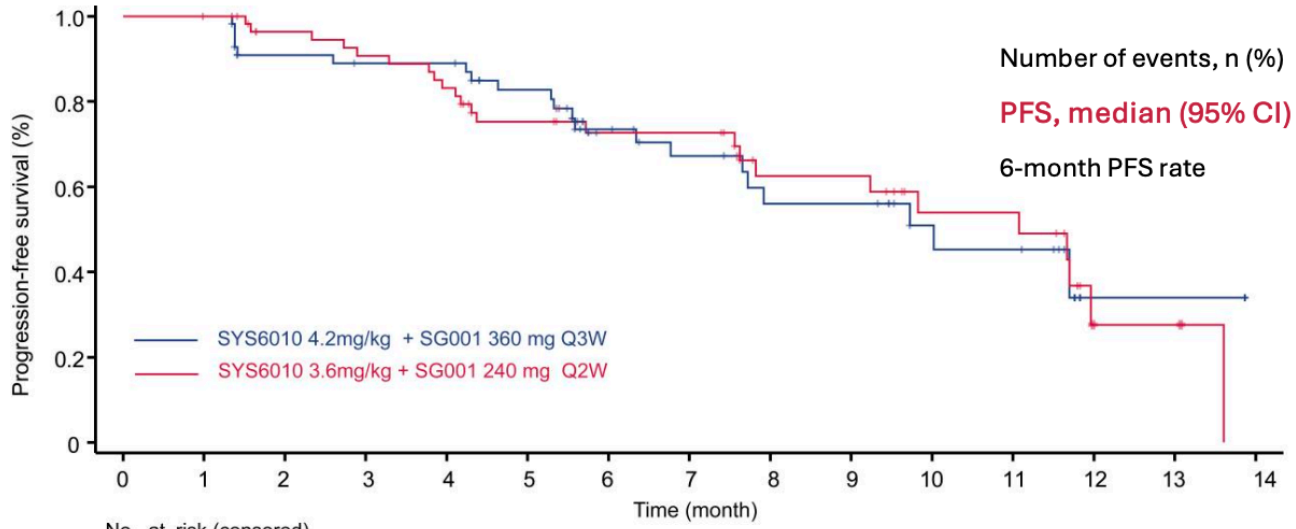
The confirmed ORR achieved **58.9%** in patients treated with SYS6010 4.2mg/kg + SG001 360 mg Q3W

An additional patient in this arm achieved a PR that remained unconfirmed pending the 4-week assessment.

	Arm 1 (N=56)	Arm 2 (N=59)
BOR, n (%)		
Confirmed CR	1 (1.8)	0
Unconfirmed CR	0	0
Confirmed PR	32 (57.1)	29 (49.2)
Unconfirmed PR	1 (1.8)	6 (10.2)
SD	14 (25.0)	19 (32.2)
PD	6 (10.7)	4 (6.8)
Confirmed ORR , % (95% CI)	**58.9 (45.0, 71.9)**	**49.2 (35.9, 62.5)**
Unconfirmed ORR, % (95% CI)	60.7 (46.8, 73.5)	59.3 (45.8, 71.9)
DCR, % (95% CI)	85.7 (73.8, 93.6)	84.7 (73.0, 92.8)



Secondary Time-to-event Endpoints



No. at risk (censored)

SYS6010 4.2mg/kg + SG001 360 mg Q3W	56 (0)	56 (0)	47 (4)	45 (5)	45 (5)	38 (9)	26 (17)	21 (20)	15 (23)	15 (23)	9 (28)	8 (28)	1 (34)	1 (34)	0 (35)
SYS6010 3.6mg/kg + SG001 240 mg Q2W	59 (0)	58 (1)	51 (6)	48 (6)	44 (6)	36 (10)	25 (20)	25 (20)	17 (25)	17 (25)	11 (29)	11 (29)	2 (34)	2 (34)	0 (35)

	SYS6010 4.2mg/kg + SG001 360 mg Q3W (n=56)	SYS6010 3.6mg/kg + SG001 240 mg Q2W (n=59)
Number of events, n (%)	21 (37.5)	24 (40.7)
PFS, median (95% CI)	10.0 (7.7, NR)	11.1 (7.8, 12.0)
6-month PFS rate	73.5 (58.5, 83.8)	72.7 (58.0, 82.9)

- Median PFS was **comparable** between the two arms, both of which were ≥10 months.
- Median DoR was not reached in Arm 1 and was 9.4 months (95% CI: 6.24–NR) in Arm 2.
- Overall survival data were immature at the time of analysis.

Subgroup Analysis for Investigator-assessed ORR

Antitumor activity across

- **Squamous and non-squamous** histologies (particularly in non-squamous)
- **PD-L1-positive and negative** subgroups (particularly in TPS ≥50%)

	SYS6010 4.2mg/kg + SG001 360 mg Q3W			SYS6010 3.6mg/kg + SG001 240 mg Q2W		
Subgroups	**No. of patients**	**Confirmed ORR, % (95%CI)**	**Unconfirmed ORR, % (95%CI)**	**No. of patients**	**Confirmed ORR, % (95%CI)**	**Unconfirmed ORR, % (95%CI)**
Histology						
Non-squamous NSCLC	39	64.1 (47.2, 78.8)	66.7 (49.8, 80.9)	41	56.1 (39.8, 71.5)	68.3 (51.9, 81.9)
Squamous NSCLC	17	47.1 (23.0, 72.2)	47.1 (23.0, 72.2)	18	33.3 (13.3, 59.0)	38.9 (17.3, 64.3)
PD-L1 expression						
TPS < 1%	15	60.0 (32.3, 83.7)	60.0 (32.3, 83.7)	21	23.8 (8.2, 47.2)	33.3 (14.6, 57.0)
TPS ≥ 1%	41	58.5 (42.1, 73.7)	61.0 (44.5, 75.8)	38	63.2 (46.0, 78.2)	73.7 (56.9, 86.6)
TPS ≥ 50%	18	77.8 (52.4, 93.6)	77.8 (52.4, 93.6)	17	82.4 (56.6, 96.2)	88.2 (63.6, 98.5)

Subgroup Analysis for Investigator-assessed ORR

Pronounced activity was observed in **PD-L1-positive** AGA-negative NSCLC patients, especially those with **TPS ≥50%**, across both squamous and non-squamous histologies.

	SYS6010 4.2mg/kg + SG001 360 mg Q3W			SYS6010 3.6mg/kg + SG001 240 mg Q2W		
Subgroups	**No. of patients**	**Confirmed ORR, % (95%CI)**	**Unconfirmed ORR, % (95%CI)**	**No. of patients**	**Confirmed ORR, % (95%CI)**	**Unconfirmed ORR, % (95%CI)**
PD-L1 expression in non-squamous NSCLC						
TPS < 1%	10	60.0 (26.2, 87.8)	60.0 (26.2, 87.8)	14	28.6 (8.4, 58.1)	42.9 (17.7, 71.1)
TPS ≥ 1%	29	65.5 (45.7, 82.1)	69.0 (49.2, 84.7)	27	70.4 (49.8, 86.3)	81.5 (61.9, 93.7)
TPS ≥ 50%	11	81.8 (48.2, 97.7)	81.8 (48.2, 97.7)	12	91.7 (61.5, 99.8)	100 (73.5, 100.0)
PD-L1 expression in squamous NSCLC						
TPS < 1%	5	60.0 (14.7, 94.7)	60.0 (14.7, 94.7)	7	14.3 (0.4, 57.9)	14.3 (0.4, 57.9)
TPS ≥ 1%	12	41.7 (15.2, 72.3)	41.7 (15.2, 72.3)	11	45.5 (16.8, 76.6)	54.5 (23.4, 83.3)
TPS ≥ 50%	7	71.4 (29.0, 96.3)	71.4 (29.0, 96.3)	5	60.0 (14.7, 94.7)	60.0 (14.7, 94.7)

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Phase II study of Opamtistomig (LBL-024), a PD-L1/4-1BB Bispecific Antibody Plus Chemotherapy in First-line Advanced NSCLC

Yan Huang, Yu Zhang, Weiguo Xu, Zhiye Zhang, Junmei Jia, Tienan Yi, Baohua Lu, Yuhui Xu, Yuli Wang, Xueqiang Zhu, Xicheng Wang, Zhihua Liu, Chunhao Niu, Bin Fan, Shengli Cai, Li Zhang

Study Design

Non-squamous NSCLC

Opamtistomig (15 mg/kg) + Pemetrexed (500 mg/m^2) + Carboplatin (AUC 5), Q3W; 4–6 cycles

→ Opamtistomig (15 mg/kg) + Pemetrexed (500 mg/m^2), Q3W; up to disease progression or unacceptable toxicity or 2 years

Squamous NSCLC

Opamtistomig (15 mg/kg) + Paclitaxel (175 mg/m^2) + Carboplatin (AUC 5), Q3W; 4–6 cycles

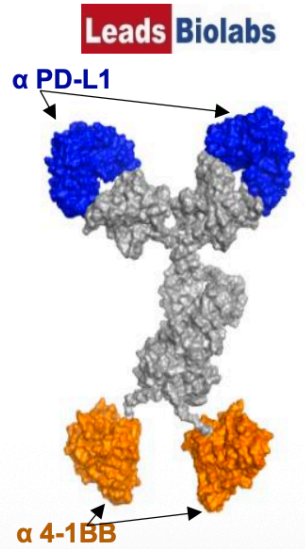
→ Opamtistomig (15 mg/kg), Q3W; up to disease progression or unacceptable toxicity or 2 years

Endpoints

Primary endpoint: ORR (based on RECIST 1.1)

Secondary endpoints: DCR , DOR , PFS , OS , Safety, PK, Immunogenicity

EP-NEC: Extrapulmonary Neuroendocrine Carcinoma; NSCLC: Non-Small Cell Lung Cancer; BTC: Biliary Tract Cancer



Baseline and Demographics Characteristics

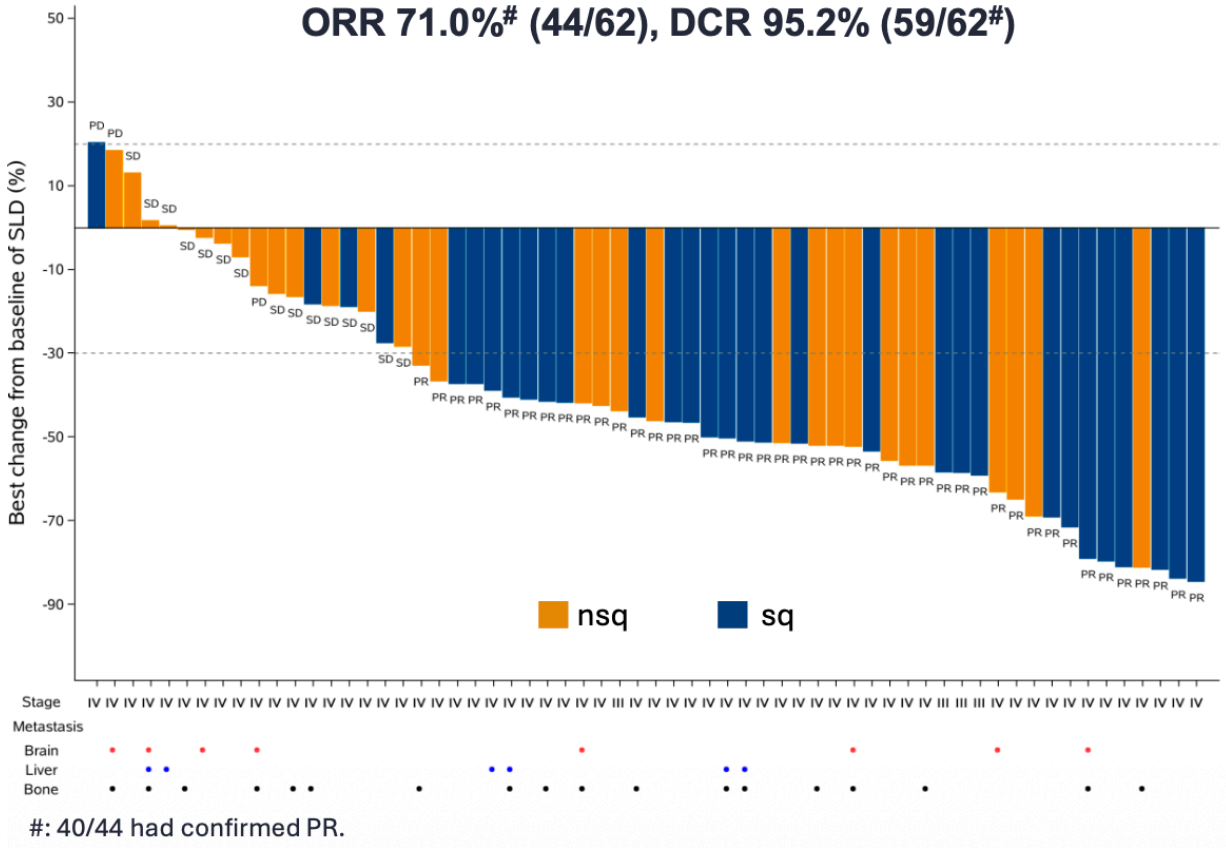
- As of July 1, 2026, 63 treatment-naïve NSCLC patients (31 nsq and 32 sq) were enrolled with a median follow-up of 7.1 months (6.9 months for nsq and 7.4 months for sq).
- Over 90% had stage IV disease; the proportions of patients with PD-L1 TPS ≥1% were 35.5% (nsq) and 43.8% (sq), respectively.

Characteristics, n (%)	nsq-NSCLC (n=31)	sq-NSCLC (n=32)
Age (years), median (range)	63.0 (40-75)	62.0 (36-72)
<65	17 (54.8)	21 (65.6)
≥65	14 (45.2)	11 (34.4)
Male, n (%)	25 (80.6)	31 (96.9)
ECOG PS, n (%)		
0	6 (19.4)	7 (21.9)
1	25 (80.6)	25 (78.1)
Smoking status, n (%)		
Former	19 (61.3)	20 (62.5)
Current	5 (16.1)	8 (25.0)
Never	7 (22.6)	4 (12.5)
Clinical state, n (%)		
IIIB/IIIC	1 (3.2)	3 (9.4)
IV	30 (96.8)	29 (90.6)

Characteristics, n (%)	nsq-NSCLC (n=31)	sq-NSCLC (n=32)
Metastatic site, n (%)		
Brain	7 (22.6)	1 (3.1)
Liver	2 (6.5)	4 (12.5)
Bone	11 (35.5)	8 (25.0)
PD-L1 expression status (TPS), n (%)		
<1%	17 (54.8)	17 (53.1)
≥1%	11 (35.5)	14 (43.8)
1-49%	7 (22.6)	8 (25.0)
≥50%	4 (12.9)	6 (18.8)
Unknown	3 (9.7)	1 (3.1)

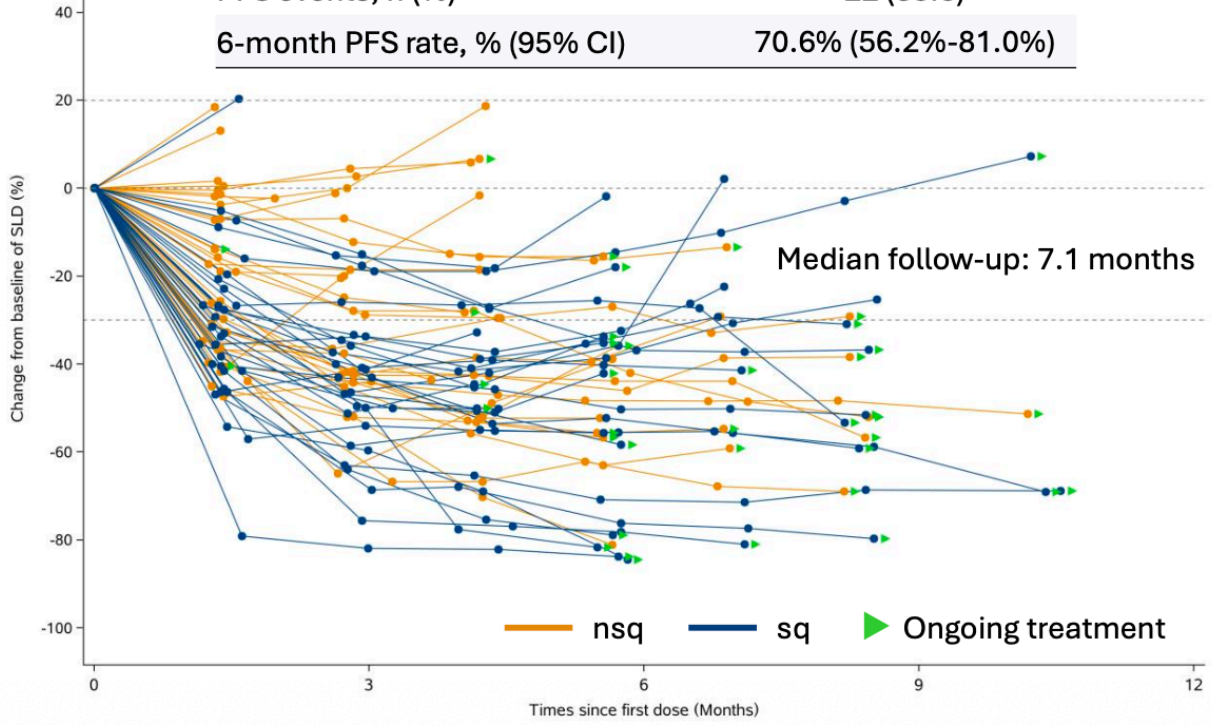
Efficacy in NSCLC

- Among the efficacy-evaluable population, the overall ORR was 71.0%.
- PFS data were not mature, with an event rate of only 35.5%. The 6-month PFS rate was 70.6%.



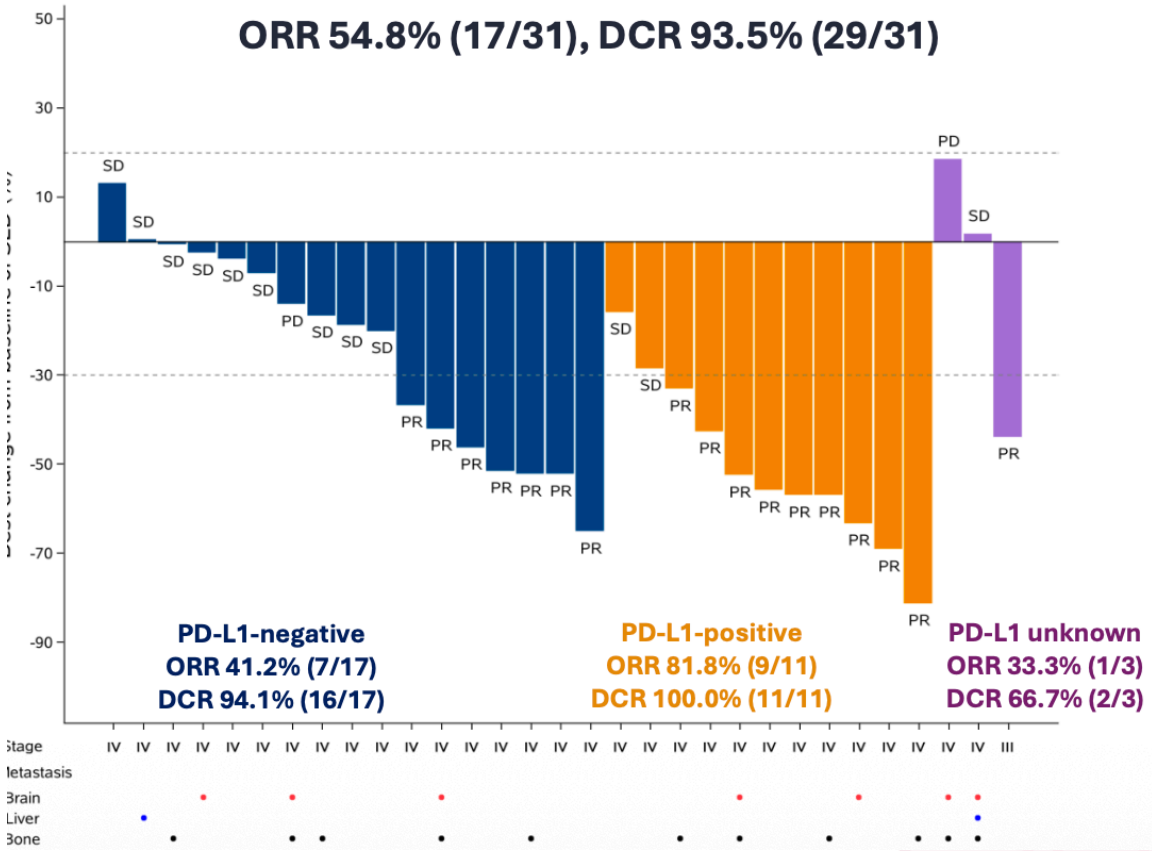
#: 40/44 had confirmed PR.

	Total (N=62)
PFS events, n (%)	22 (35.5)
6-month PFS rate, % (95% CI)	70.6% (56.2%-81.0%)

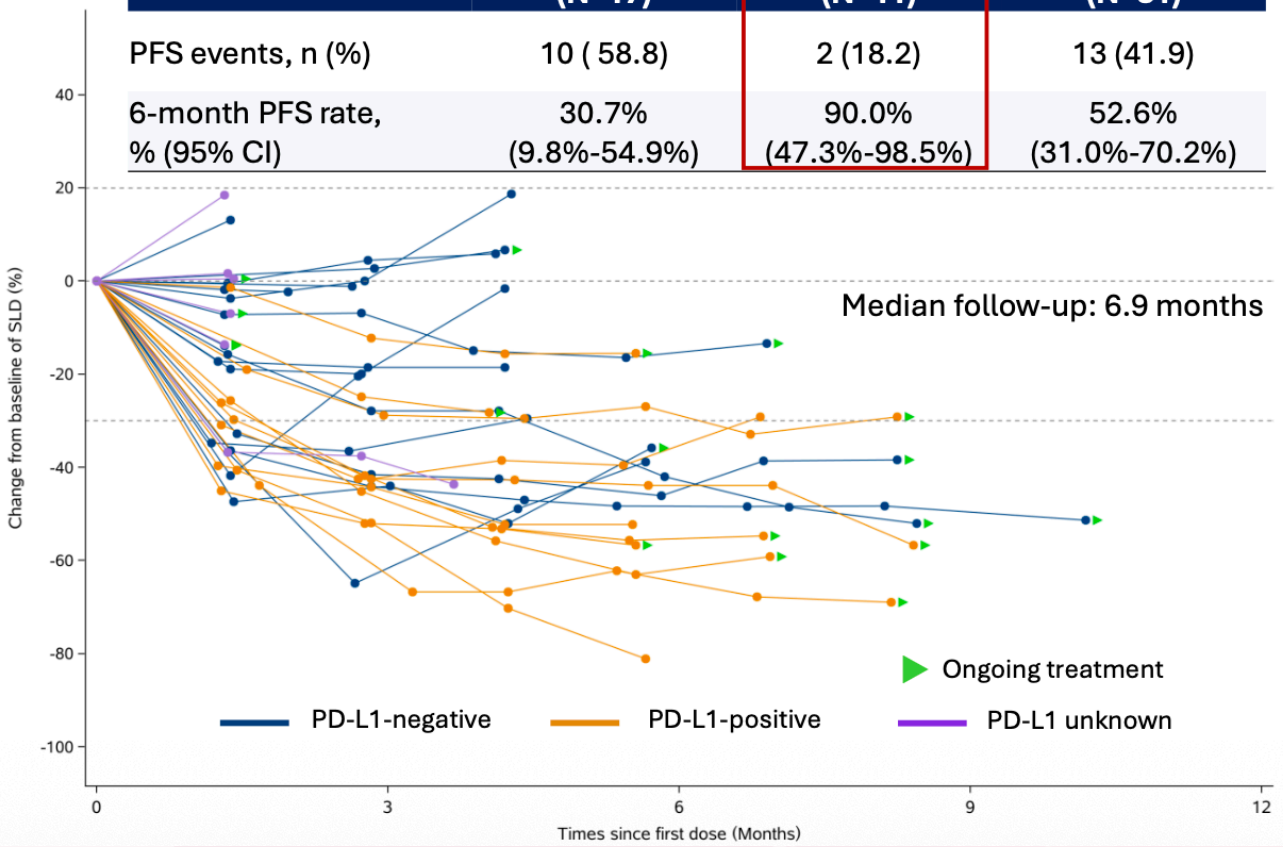


Efficacy in nsq-NSCLC

- Among the efficacy-evaluable population, the overall ORR was 54.8%, increasing to 81.8% in PD-L1-positive patients.
- PFS data were not mature, with an event rate of only 41.9%. Notably, the 6-month PFS rate reached 90% among PD-L1-positive patients.



	PD-L1 negative (N=17)	PD-L1 positive (N=11)	Total (N=31)
PFS events, n (%)	10 (58.8)	2 (18.2)	13 (41.9)
6-month PFS rate, % (95% CI)	30.7% (9.8%-54.9%)	90.0% (47.3%-98.5%)	52.6% (31.0%-70.2%)



	Total (n=63)
TEAE	61 (96.8)
TRAE	60 (95.2)
SAE	21 (33.3)
Treatment-related SAE	18 (28.6)
Grade ≥3 TEAE	42 (66.7)
Grade ≥3 TRAE	40 (63.5)
TEAE leading to death	2 (3.2)[#]
TRAE leading to death	2 (3.2)
TEAE leading to permanent discontinuation	10 (15.9)
TRAE leading to permanent discontinuation	10 (15.9)
Immune-related AE (irAE)	2 (3.2)[*]
Grade ≥3 irAE	2 (3.2)
Infusion-related reaction (IRR)	10 (15.9)
Grade ≥3 IRR	1 (1.6)

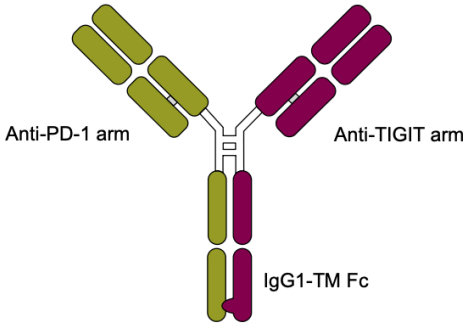
Most common TEAEs (≥25%)	Total (n=63)	
	Any Grade	≥ Grade 3
Anemia	46 (73.0)	10 (15.9)
Platelet count decreased	36 (57.1)	10 (15.9)
White blood cell count decreased	33 (52.4)	7 (11.1)
Neutrophil count decreased	30 (47.6)	16 (25.4)
Hypoalbuminaemia	20 (31.7)	0 (0.0)
Alanine aminotransferase increased	19 (30.2)	1 (1.6)
Constipation	19 (30.2)	0 (0.0)
Asthenia	17 (27.0)	0 (0.0)
Aspartate aminotransferase increased	16 (25.4)	0 (0.0)
Hypoaesthesia	16 (25.4)	1 (1.6)

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Updated efficacy results of rilvegostomig for checkpoint inhibitor (CPI)-naïve metastatic non-small-cell lung cancer (mNSCLC)

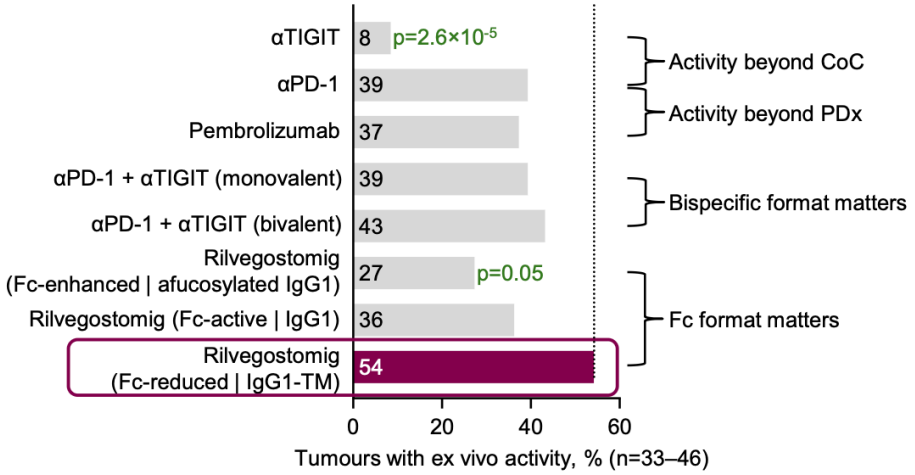
Byoung Chul Cho,[1] T. Jeroen N. Hiltermann,[2] Hiroki Izumi,[3] Mariana Brandão,[4] Sulene Cunha,[5] Pongwut Danchaivijitr,[6] Enriqueta Felip,[7] Gwo Fuang Ho,[8] Konstantinos Leventakos,[9] Yongsheng Li,[10] Shunichi Sugawara,[11] Pei Jye Voon,[12] Els Wauters,[13] Tsung-Ying Yang,[14] Tatsuya Yoshida,[15] Huifang (Ariel) Chen,[16] Ikbel Achour,[17] Steve Colebrook,[18] Negar Hamidi,[17] Nelson Liu,[16] Yongsheng Wang[19]

Anti-PD-1 / anti-TIGIT DuetMab[1]



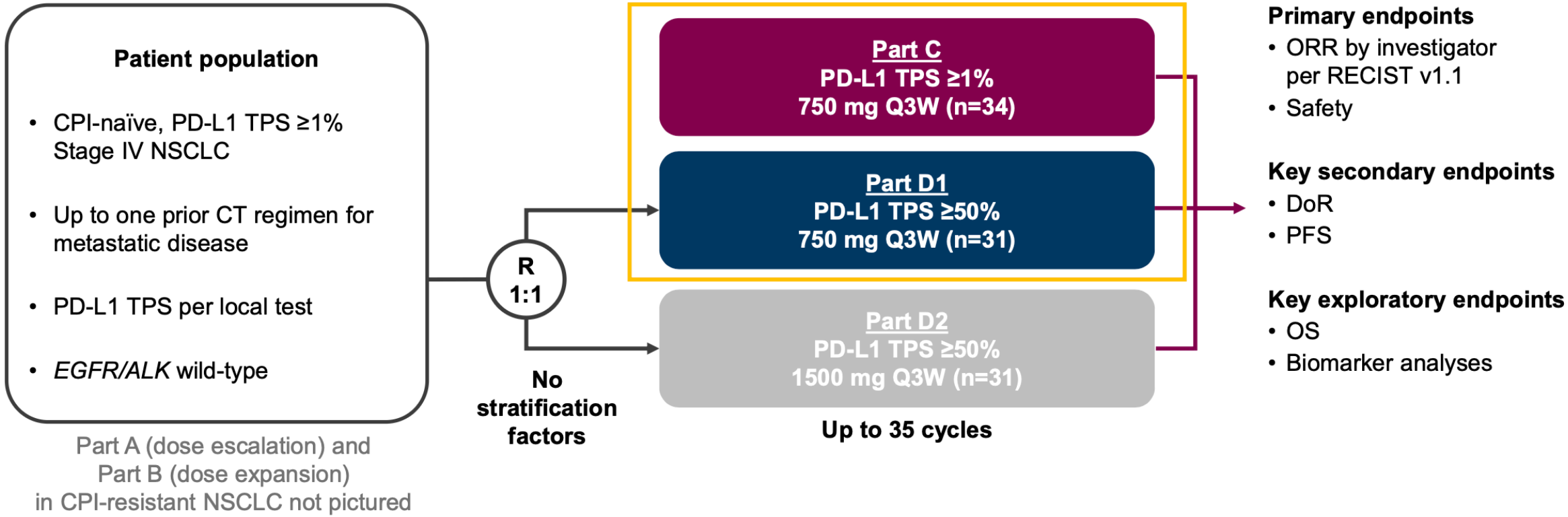
- The **bispecific format enables coordinated PD-1 and TIGIT blockade** on the same immune effector cells[2]
- Reduced Fc function by triple mutation minimizes ADCC/ADCP activity, reducing unwanted depletion of TIGIT-expressing immune effector cells[2]

Antitumour activity according to IFNγ positivity in resected NSCLC tumours[1]



- Rilvegostomig induces greater ex vivo activity compared with anti-PD-1/TIGIT co-administrations and Fc-active formulations[2,3]

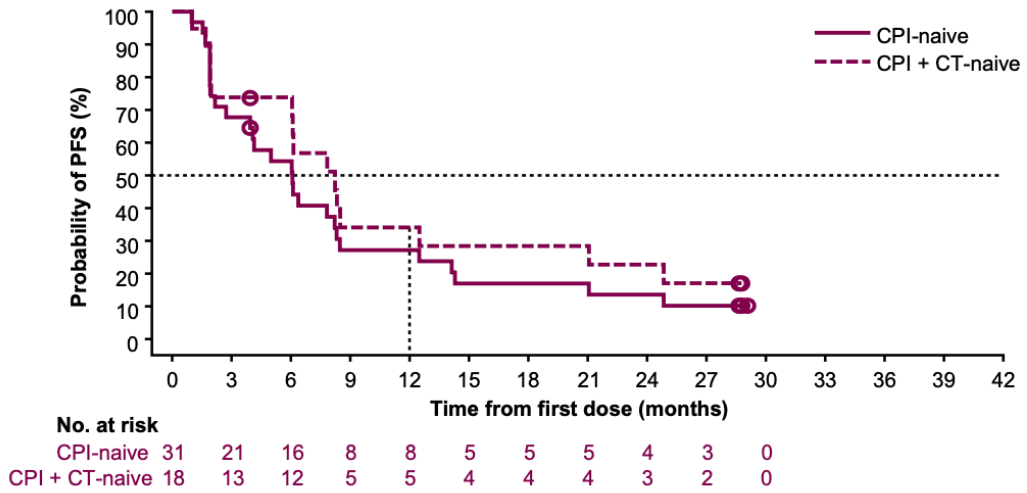
ARTEMIDE-01: First-in-human study of rilvegostomig (NCT04995523)



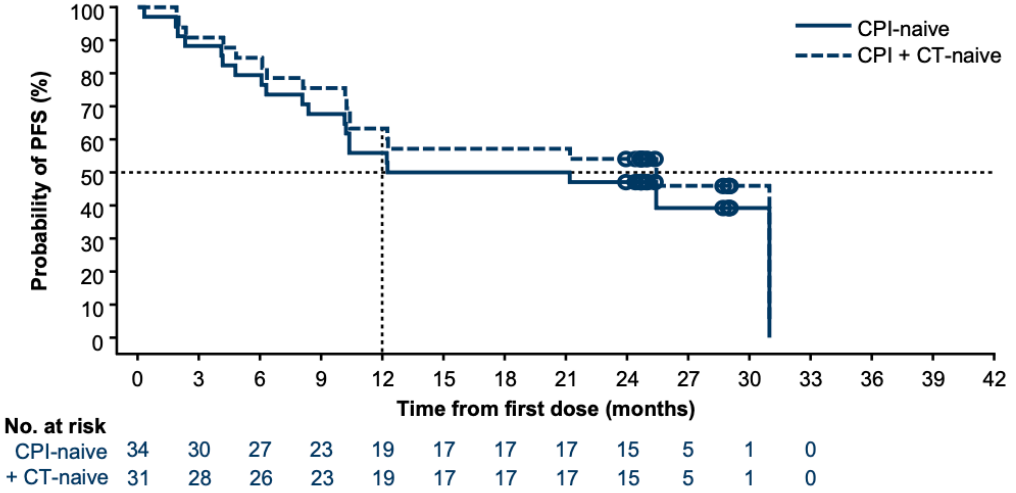
- We report updated safety and efficacy results in CPI-naïve metastatic NSCLC in Parts C and D1

ARTEMIDE-01: PFS benefit in both PD-L1 subgroups

PD-L1 TPS 1–49% (n=31)



PD-L1 TPS ≥50%(n=34)

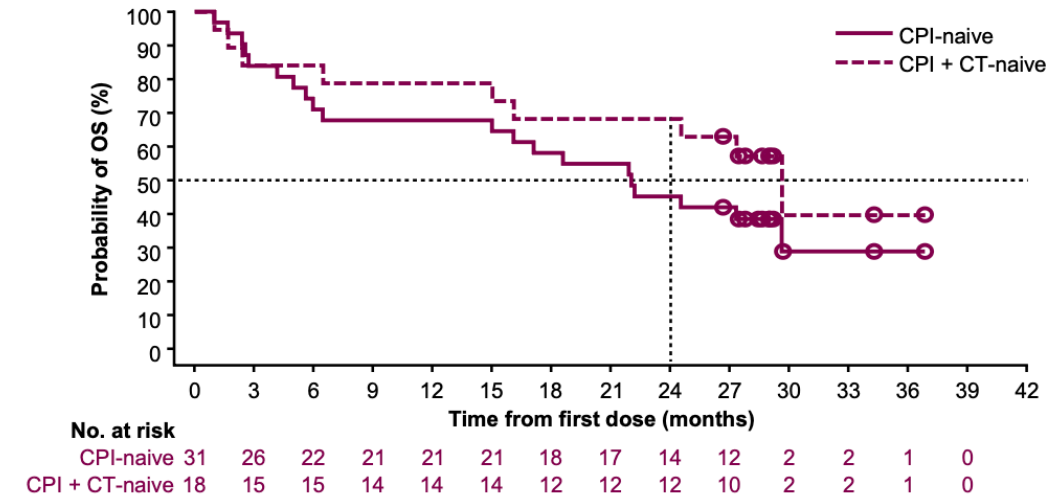


	PD-L1 TPS 1–49%*		PD-L1 TPS ≥50%*	
	CPI-naïve (n=31)	CPI + CT-naïve (n=18)	CPI-naïve (n=34)	CPI + CT-naïve (n=31)
Events, n (%)	27 (87.1)	15 (83.3)	20 (58.8)	17 (54.8)
Median PFS, months (95% CI)	6.1 (2.7–8.3)	7.8 (1.9–12.5)	16.7 (8.4–NC)	25.4 (10.2–NC)
12-month PFS, % (95% CI)	27.2 (12.9–43.6)	30.1 (11.1–52.0)	55.9 (37.8–70.6)	61.3 (42.0–75.8)

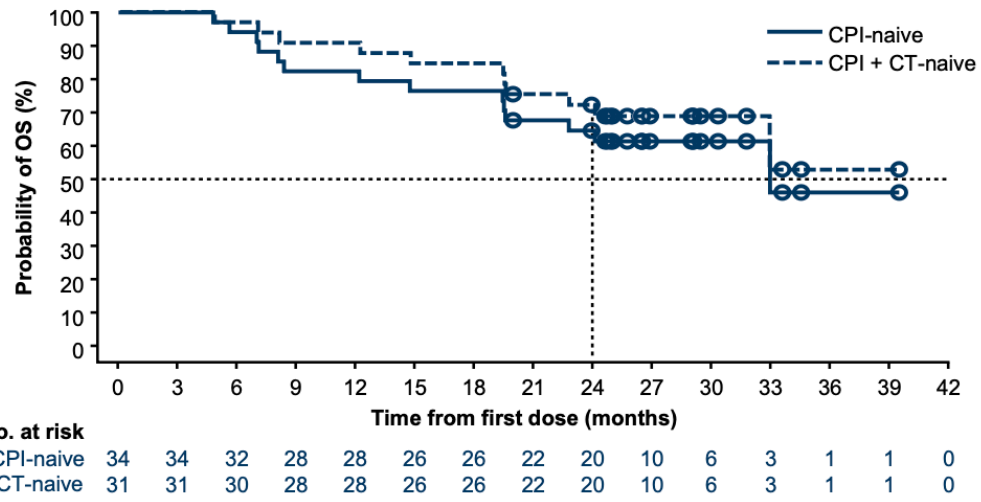
Data cutoff: 27 March 2026. *Based on local testing.
CI, confidence interval; CPI, checkpoint inhibitor; CT, chemotherapy; NC, not calculable; PD-L1, programmed cell death ligand-1; PFS, progression-free survival; TPS, tumour proportion score

ARTEMIDE-01: Encouraging first OS results

PD-L1 TPS 1–49% (n=31)



PD-L1 TPS ≥50% (n=34)



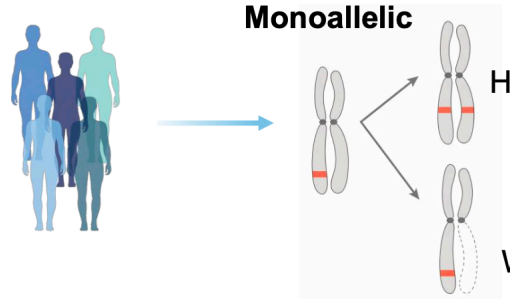
	PD-L1 TPS 1–49%*		PD-L1 TPS ≥50%*	
	CPI-naïve (n=31)	CPI + CT-naïve (n=18)	CPI-naïve (n=34)	CPI + CT-naïve (n=31)
Events, n (%)	20 (64.5)	9 (50.0)	14 (41.2)	11 (35.5)
Median OS, months (95% CI)	22.0 (6.5–29.6)	29.6 (15.0–NC)	33.0 (19.6–NC)	NA (24.1–NC)
24-month OS, % (95% CI)	45.2 (27.4–61.4)	66.7 (40.4–83.4)	64.6 (46.1–78.1)	70.8 (51.4–83.6)

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Biallelic inactivation of KEAP1/STK11 predicts benefit to dual PD-(L)1/CTLA4 immune checkpoint blockade in non-small cell lung cancers

Mark Y. Jeng, Maria Perry, Michael Rafizadeh, Alessandro Di Federico, Marc Ladanyi, Andre Arfe, Sarah Cascarino, Greg Riely, Mark Awad, Charlie Rudin, Chaitanya Bandlamudi, Adam Schoenfeld

Assess role of *KEAP1/STK11* zygosity status on patients treated with Dual-ICB vs Single-ICB



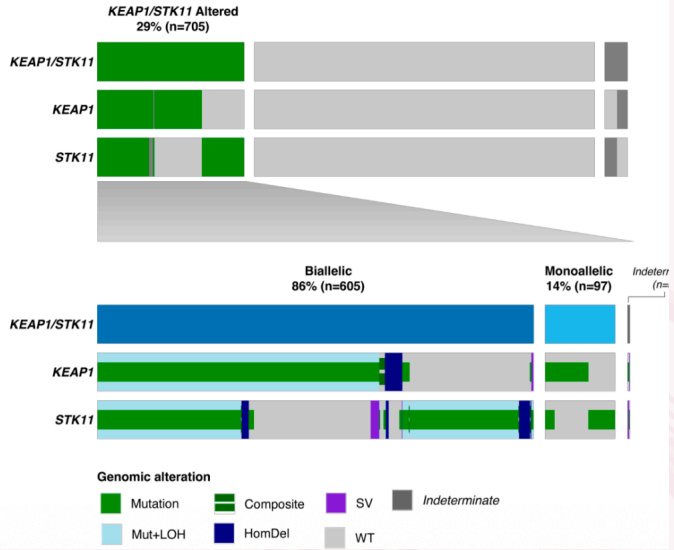
Patient Population

>2400 patients with advanced NSCLC and MSK-IMPACT treated with ICB

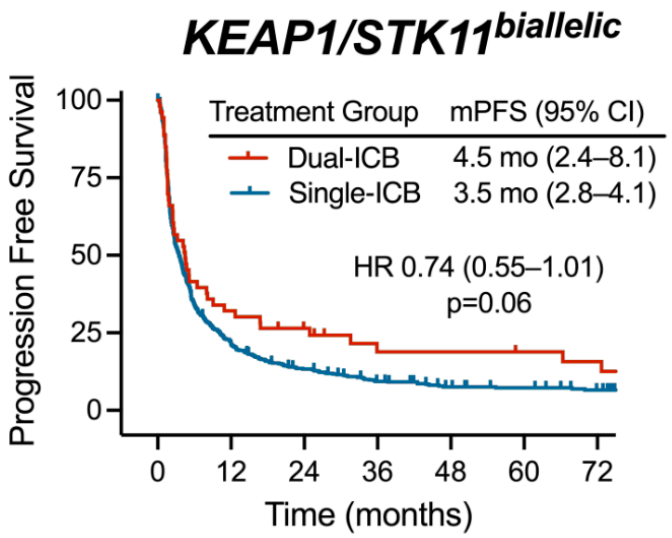
Zygosity Status

Allele-specific copy number assessment via FACETS

(Zucker et al., Cell 2025)

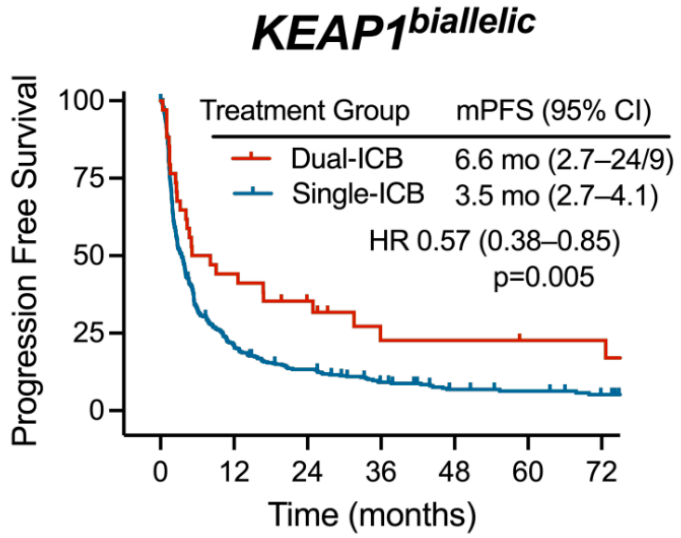


Dual-ICB improves PFS in patients with biallelic inactivation of *KEAP1* (*KEAP1*$^{\text{biallelic}}$)



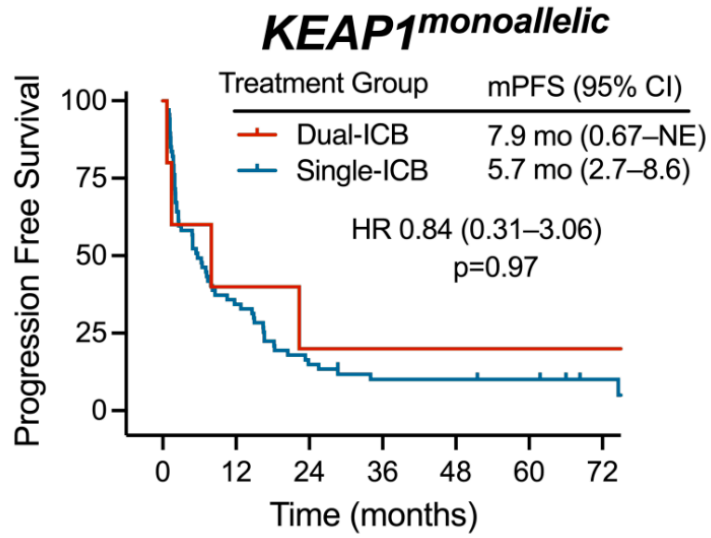
Number at risk

Dual-ICB +/- chemo	53	17	12	7	7	6	5
Single-ICB +/- chemo	551	117	67	42	28	23	16



Number at risk

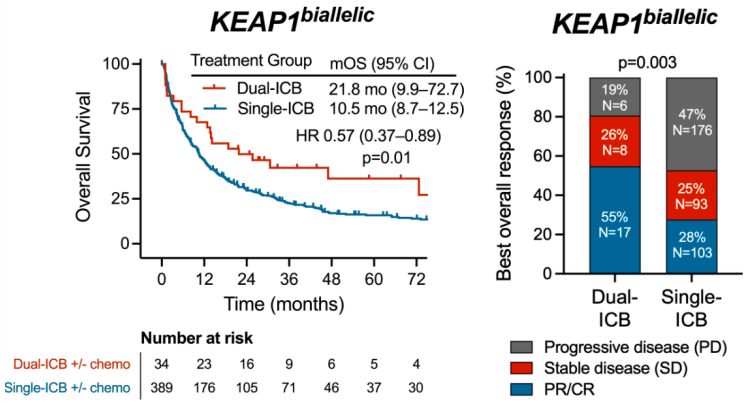
Dual-ICB +/- chemo	34	15	10	5	5	4	4
Single-ICB +/- chemo	388	80	48	28	16	13	8

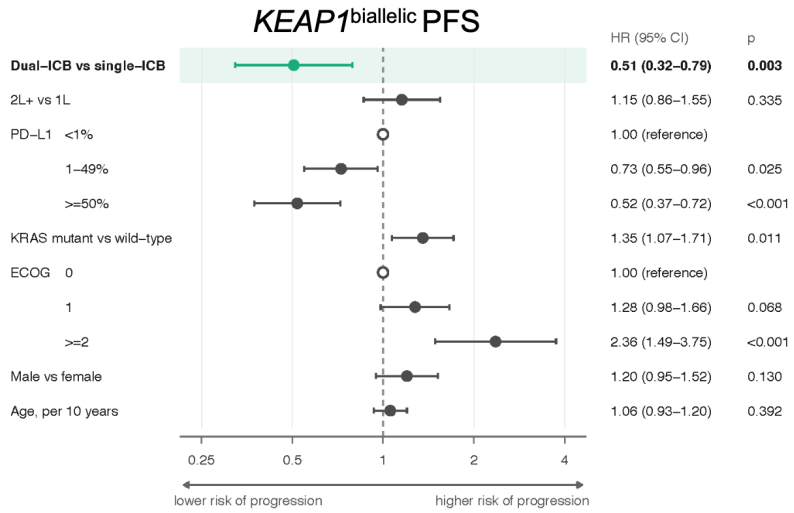


Number at risk

Dual-ICB +/- chemo	5	2	1	1	1	1	1
Single-ICB +/- chemo	67	23	10	6	6	5	2

Dual-ICB improves overall survival (OS) and overall response rate (ORR) for KEAP1 biallelic





KRAS and PD-L1 status also contribute

CONCLUSIONES

Biallelic inactivation occurs often (86%) in KEAP1/STK11 mutations

- Dual-ICB improves outcomes in patients with biallelic inactivation of KEAP1
- mPFS 6.6 vs 3.5 months, mOS 21.8 vs 10.5 months, ORR 55% vs 28%
- Additional factors include KRAS and PD-L1 status
- Validation in larger and prospective cohorts is necessary
- Gene zygosity status is not widely reported, but is an important factor to consider for KEAP1/STK11 and others (e.g. MTAP, SMARCA4)


Gracias