

SSGJ-707, a PD-1/VEGF bispecific antibody, combined with platinum-based chemotherapy in first-line treatment of advanced non-small cell lung cancer: results from a phase 2 study

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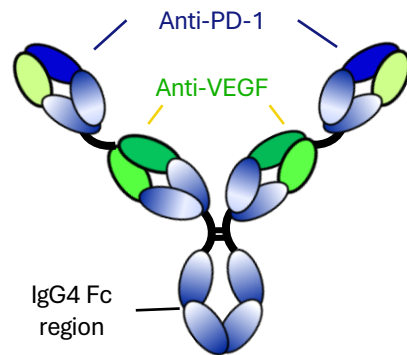
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40th Anniversary Annual Meeting & Pre-Conference Programs

SSGJ-707, a bispecific antibody targeting PD-1 and VEGF

- SSGJ-707 (PF-08634404) is a fully human immunoglobulin G4 bispecific antibody that targets PD-1 and VEGF¹
- SSGJ-707 monotherapy (10 mg/kg Q3W) demonstrated promising efficacy (confirmed ORR, 64.7%) and manageable safety (grade ≥ 3 TRAEs, 23.5%) in treatment-naive patients with NSCLC TPS $\geq 1\%$ ¹



SSGJ-707

(PF-08634404; 707)

**Bispecific Antibody With
Tetraivalent Structure:**
Each “arm” can bind both
VEGF and PD-1

Simultaneous Binding of PD-1 and VEGF Amplifies Therapeutic Potential Through:

Improved PD-1 inhibition through cooperative binding²

In the presence of VEGF, SSGJ-707 forms multimers to enhance binding and inhibition of PD-1

Inhibition of VEGF-driven angiogenesis and immunosuppression²

Functionally enhanced VEGF Fab arm normalizes tumor vasculature and reduces VEGF-related immune suppression

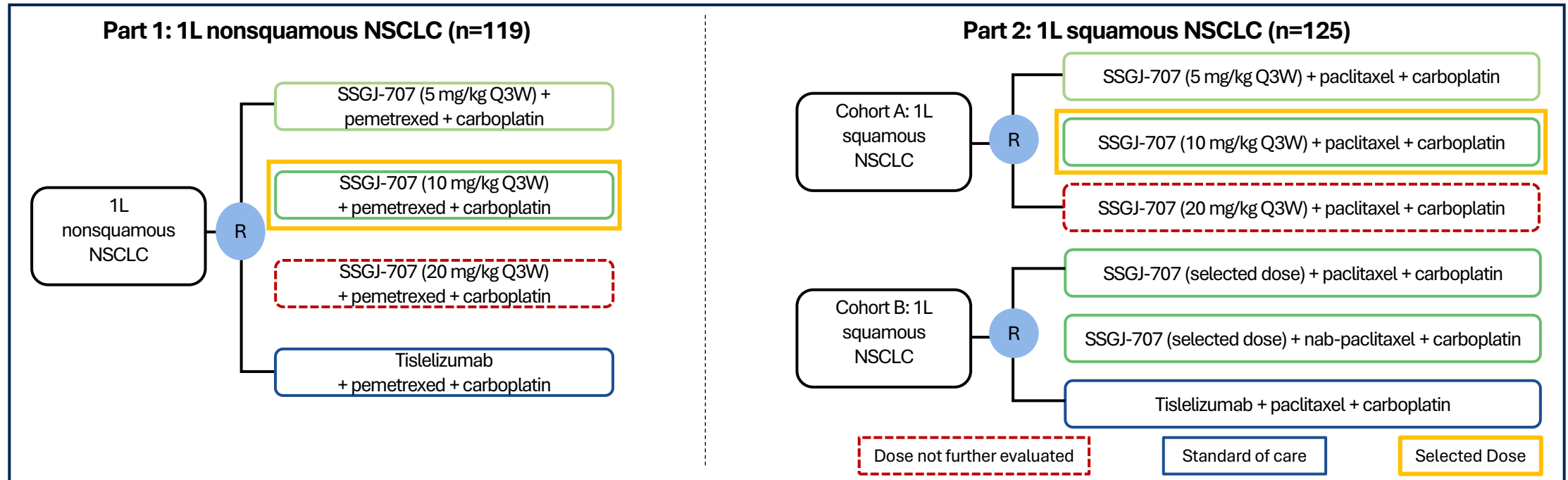
IgG4 backbone^{2,3}

IgG4 backbone is consistent with approved anti-PD-1 therapeutics

Here, we report safety and efficacy from the phase 2 study (NCT06412471) of SSGJ-707 combined with platinum-based chemotherapy in first-line NSCLC

Study design

- This is an open-label, multicenter, randomized phase 2 trial of SSGJ-707 or tislelizumab (anti-PD-1) combined with platinum-based chemotherapy for the treatment of patients with treatment-naive advanced NSCLC
- Primary objectives are to evaluate the safety, tolerability, and antitumor activity of different dosing regimens of SSGJ-707 combined with platinum-based chemotherapy
- Eligible patients have treatment-naive stage IIIB/C or stage IV NSCLC, regardless of PD-L1 expression, no AGAs, and ECOG PS 0-1



Baseline demographics and clinical characteristics

At the data cutoff of July 4, 2025, 119 patients with nonsquamous NSCLC and 125 with squamous NSCLC were enrolled in parts 1 and 2, respectively

	Part 1: Nonsquamous NSCLC (n=119)		Part 2: Squamous NSCLC (n=125)	
	SSGJ-707 (n=79)	Tislelizumab (n=40)	SSGJ-707 (n=98)	Tislelizumab (n=27)
Age ≥65 years, n (%)	36 (45.6)	20 (50.0)	54 (55.1)	13 (48.1)
Male, n (%)	54 (68.4)	33 (82.5)	83 (84.7)	25 (92.6)
ECOG PS of 1, n (%)	69 (87.3)	33 (82.5)	81 (82.7)	23 (85.2)
Smoking status, n (%)				
Former/current	53 (67.1)	30 (75.0)	81 (82.7)	21 (77.8)
Never	26 (32.9)	10 (25.0)	17 (17.3)	6 (22.2)
Clinical stage at study entry, n (%)				
Stage III	5 (6.3)	2 (5.0)	26 (26.5)	7 (25.9)
Stage IV	74 (93.7)	38 (95.0)	72 (73.5)	20 (74.1)
Liver metastases, n (%)	8 (10.1)	5 (12.5)	9 (9.2)	3 (11.1)
Brain metastases, n (%) ^a	18 (22.8)	8 (20.0)	8 (8.2)	4 (14.8)
PD-L1 expression level, n (%)				
TPS <1%	35 (44.3)	19 (47.5)	40 (40.8)	12 (44.4)
TPS 1-49%	20 (25.3)	15 (37.5)	40 (40.8)	12 (44.4)
TPS ≥50%	24 (30.4)	6 (15.0)	18 (18.4)	3 (11.1)

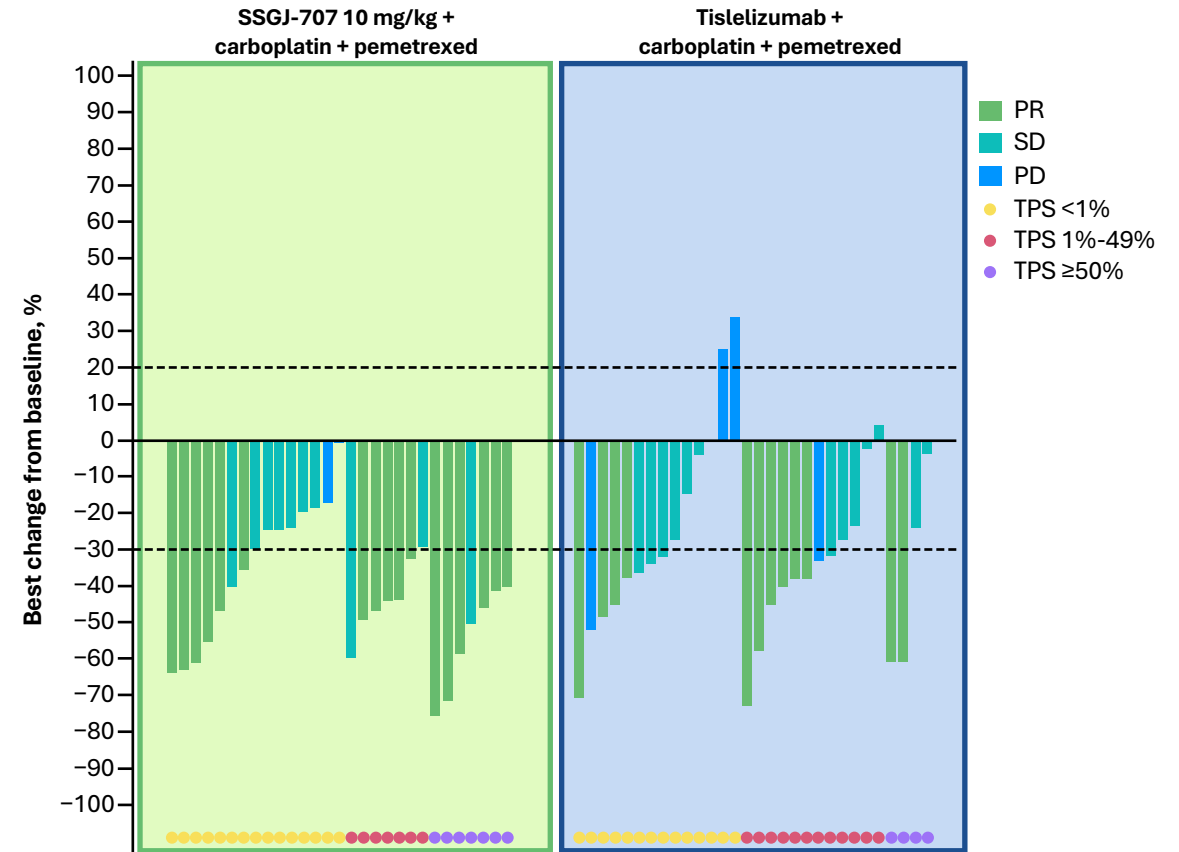
ECOG PS, Eastern Cooperative Oncology Group performance status; NSCLC, non-small cell lung cancer; PD-L1, programmed death ligand 1; TPS, tumor proportion score.
^aPreviously treated stable brain metastasis or asymptomatic, untreated brain metastases with long diameter ≤1.5 cm and without edema were allowed.

In nonsquamous NSCLC, confirmed ORRs with SSGJ-707 + chemotherapy are promising

Part 1: Nonsquamous NSCLC

	SSGJ-707 5 mg/kg + carboplatin + pemetrexed (n=30)	SSGJ-707 10 mg/kg + carboplatin + pemetrexed (n=29)	Tislelizumab + carboplatin + pemetrexed (n=31)
Confirmed ORR (95% CI), %^a	50.0 (31.3-68.7)	58.6 (38.9-76.5)	38.7 (21.8-57.8)
BOR, n (%)			
CR	0	0	0
PR	15 (50.0)	17 (58.6)	12 (38.7)
SD	14 (46.7)	11 (37.9)	14 (45.2)
PR pending ^b	1 (3.3)	3 (10.3)	3 (9.7)
PD	1 (3.3)	1 (3.4)	4 (12.9)
Not evaluated	0	0	1 (3.2)

Responses were observed independent of PD-L1 expression



BOR, best overall response; CR, complete response; NSCLC, non-small cell lung cancer; ORR, objective response rate; PD, progressive disease; PD-L1, programmed death ligand 1; PR, partial response; Q3W, every 3 weeks; SD, stable disease; TPS, tumor proportion score.

^aIncluded all patients in the enrolled analysis set who received any amount of drug and who had ≥1 postbaseline tumor evaluation. 37 patients had no postdose initial tumor assessment.

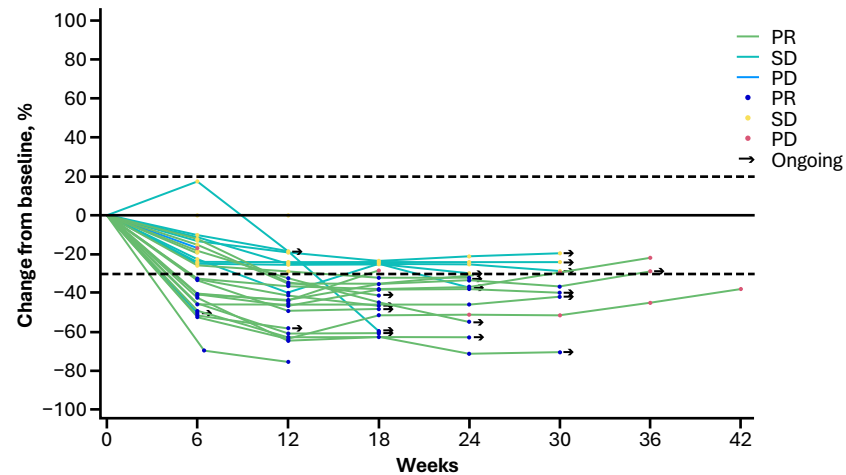
^bPatients with unconfirmed PRs that are awaiting confirmation and have the potential to become confirmed PRs.

In nonsquamous NSCLC, responses with SSGJ-707 + chemotherapy are durable

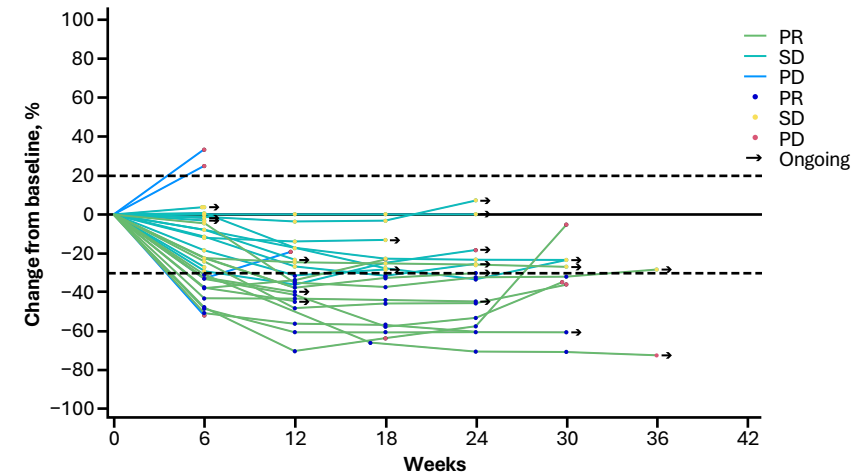
Part 1: Nonsquamous NSCLC

	SSGJ-707 5 mg/kg + carboplatin + pemetrexed (n=39)	SSGJ-707 10 mg/kg + carboplatin + pemetrexed (n=39)	Tislelizumab + carboplatin + pemetrexed (n=40)
Follow-up time, ^a median (95% CI), ^b months	6.3 (5.3-8.0)	6.1 (4.6-7.0)	6.1 (4.0-7.2)
No. of doses ^c administered, median (range)	8.0 (1-15)	5.0 (1-14)	5.5 (1-12)
DOR, median (95% CI), ^b months ^d	5.55 (3.09-NE)	6.87 (3.55-NE)	NE (2.63-NE)

SSGJ-707 10 mg/kg + carboplatin + pemetrexed (n=29)



Tislelizumab + carboplatin + pemetrexed (n=31)



DOR, duration of response; NE, not estimable; NSCLC, non-small cell lung cancer; PD, progressive disease; PR, partial response; SD, stable disease.

^aAt data cutoff of July 4, 2025; includes all enrolled patients who received SSGJ-707 at least once.

^bCalculated with the Kaplan-Meier method to estimate the median and Brookmeyer and Crowley method for 95% CIs.

^cFor SSGJ-707 or tislelizumab.

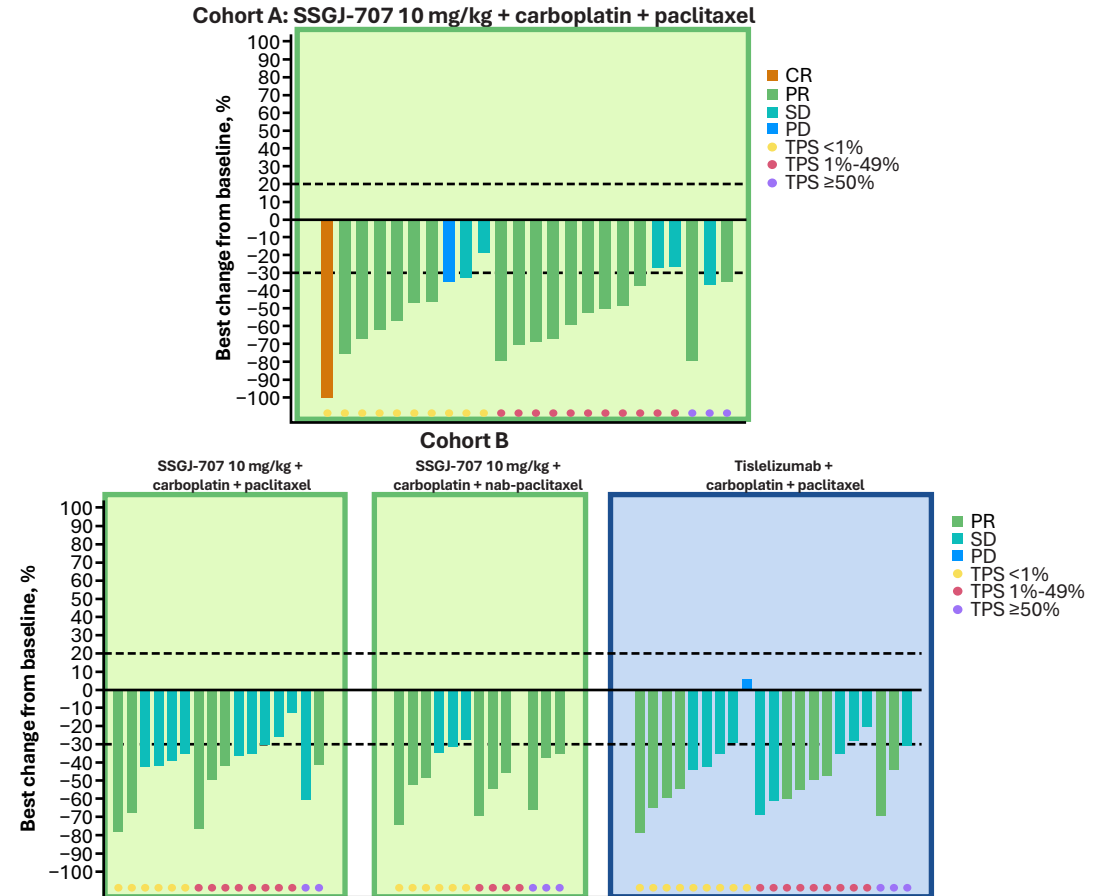
^dDOR was assessed in response evaluable patients; 15 in SSGJ-707 5 mg/kg, 17 in SSGJ-707 10 mg/kg, and 12 in tislelizumab groups.

In squamous NSCLC, confirmed ORRs with SSGJ-707 + chemotherapy are promising

Part 2: Squamous NSCLC

	Cohort A		Cohort B		
	SSGJ-707 5 mg/kg + carboplatin + paclitaxel (n=26)	SSGJ-707 10 mg/kg + carboplatin + paclitaxel (n=24)	SSGJ-707 10 mg/kg + carboplatin + paclitaxel (n=16)	SSGJ-707 10 mg/kg + carboplatin + nab-paclitaxel (n=13)	Tislelizumab + carboplatin + paclitaxel (n=21)
Confirmed ORR (95% CI), %^a	38.5 (20.2-59.4)	75.0 (53.3-90.2)	37.5 (15.2-64.6)	69.2 (38.6-90.9)	47.6 (25.7-70.2)
BOR, n (%)					
CR	0	1 (4.2)	0	0	0
PR	10 (38.5)	17 (70.8)	6 (37.5)	9 (69.2)	10 (47.6)
SD	16 (61.5)	5 (20.8)	10 (62.5)	4 (30.8)	10 (47.6)
PR pending ^b	4 (15.4)	0	7 (43.8)	1 (7.7)	6 (28.6)
PD	0	1 (4.2)	0	0	1 (4.8)
Not evaluated	0	0	0	0	0

Responses were observed independent of PD-L1 expression



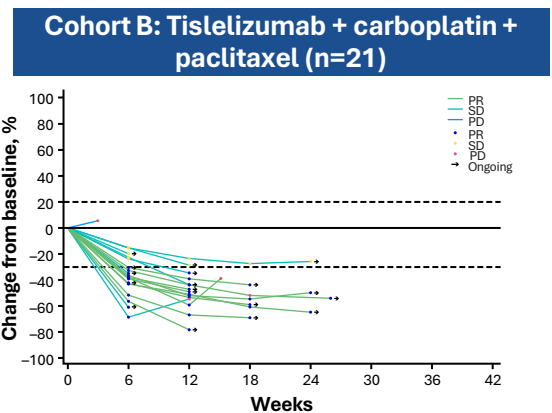
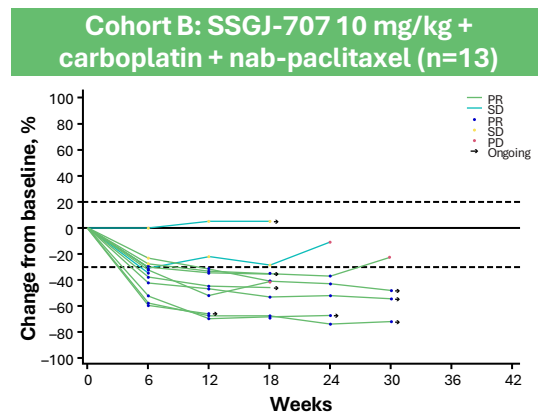
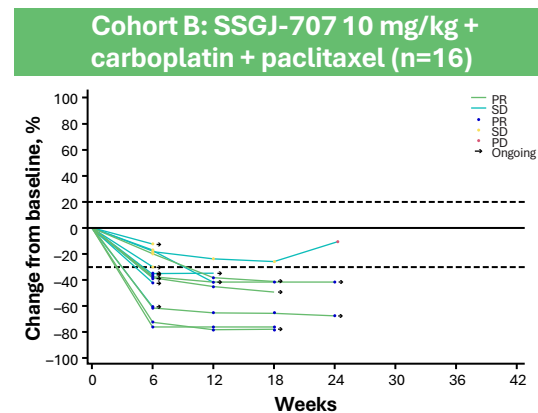
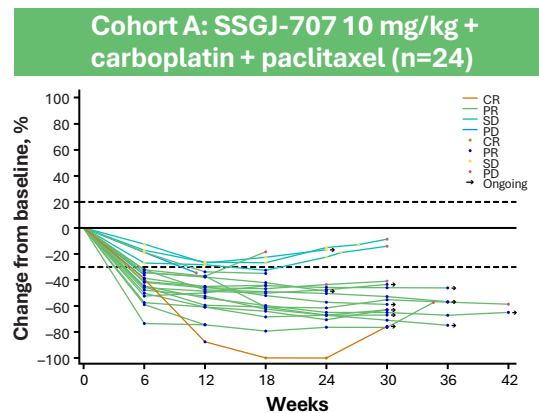
BOR, best overall response; CR, complete response; NSCLC, non-small cell lung cancer; ORR, objective response rate; PD, progressive disease; PD-L1, programmed death ligand 1; PR, partial response; SD, stable disease; TPS, tumor proportion score.

^aIncluded all patients in the enrolled analysis set who received any amount of drug and who had ≥1 postbaseline tumor evaluation. 37 patients had no postdose initial tumor assessment.

^bPatients with unconfirmed PRs that are awaiting confirmation and have the potential to become confirmed PRs.

In squamous NSCLC, responses with SSGJ-707 + chemotherapy are durable

	Part 2: Squamous NSCLC, Cohort A		Part 2: Squamous NSCLC, Cohort B		
	SSGJ-707 5 mg/kg + carboplatin + paclitaxel (n=30)	SSGJ-707 10 mg/kg + carboplatin + paclitaxel (n=27)	SSGJ-707 10 mg/kg + carboplatin + paclitaxel (n=25)	SSGJ-707 10 mg/kg + carboplatin + nab-paclitaxel (n=14)	Tislelizumab + carboplatin + pemetrexed (n=27)
Follow-up time, ^a median (95% CI), ^b months	7.9 (7.2-8.2)	7.9 (7.0-8.7)	2.8 (2.4-4.3)	5.5 (3.8-7.4)	3.3 (2.3-4.2)
No. of doses ^c administered, median (range)	8.5 (1-14)	8.0 (1-16)	4.0 (1-9)	6.0 (2-11)	4.0 (1-10)
DOR, median (95% CI), ^b months ^d	NE (NE-NE)	8.25 (6.7-NE)	NE (2.79-NE)	NE (2.79-NE)	NE (2.20-NE)



CR, complete response; DOR, duration of response; NE not estimable; NSCLC, non-small cell lung cancer; PD, progressive disease; PR, partial response; SD, stable disease

^aAt data cutoff of July 4, 2025; includes all enrolled patients who received SSGJ-707 at least once.

^bCalculated with the Kaplan-Meier method to estimate the median and Brookmeyer and Crowley for 95% CIs.

^cFor SSGJ-707 or tislelizumab.

^dDOR was assessed in response evaluable patients; cohort A: 10 patients in SSGJ-707 5 mg/kg and 18 in SSGJ-707 10 mg/kg, cohort B: 6 patients in SSGJ-707 + paclitaxel, 9 in SSGJ-707 + nab-paclitaxel, and 10 in tislelizumab groups.

Safety profile of SSGJ-707 + chemotherapy is manageable

	Part 1: Nonsquamous NSCLC and Part 2: Squamous NSCLC			
	SSGJ-707 5 mg/kg + chemotherapy (n=69)	SSGJ-707 10 mg/kg + chemotherapy (n=105)	SSGJ-707 20 mg/kg + chemotherapy ^a (n=3)	Tislelizumab + chemotherapy (n=67)
TRAE, n (%) ^b				
Any grade	57 (82.6)	95 (90.5)	3 (100)	56 (83.6)
Grade ≥3	26 (37.7)	41 (39.0)	3 (100)	22 (32.8)
Grade 5 ^c	0	3 (2.9)	0	1 (1.5)
SAE	13 (18.8)	17 (16.2)	2 (66.7)	15 (22.4)
Leading to discontinuation	0	2 (1.9)	0	1 (1.5)
VEGF-related AEs, n (%) ^d				
Any grade	26 (37.7)	43 (41.0)	2 (66.7)	11 (16.4)
Grade ≥3	4 (5.8)	9 (8.6)	0	1 (1.5)
irAE, n (%) ^e				
Any grade	7 (10.1)	15 (14.3)	1 (33.3)	11 (16.4)
Grade ≥3	1 (1.4)	5 (4.8)	1 (33.3)	4 (6.0)

Safety is consistent in nonsquamous and squamous NSCLC

AE, adverse event; irAE, immune-related AE; NSCLC, non-small cell lung cancer; SAE, serious AE; TEAE, treatment-emergent AE; TRAE, treatment-related AE; VEGF, vascular endothelial growth factor.

^aNo additional patients were included in this cohort based on safety and efficacy data at this dose from the monotherapy study.

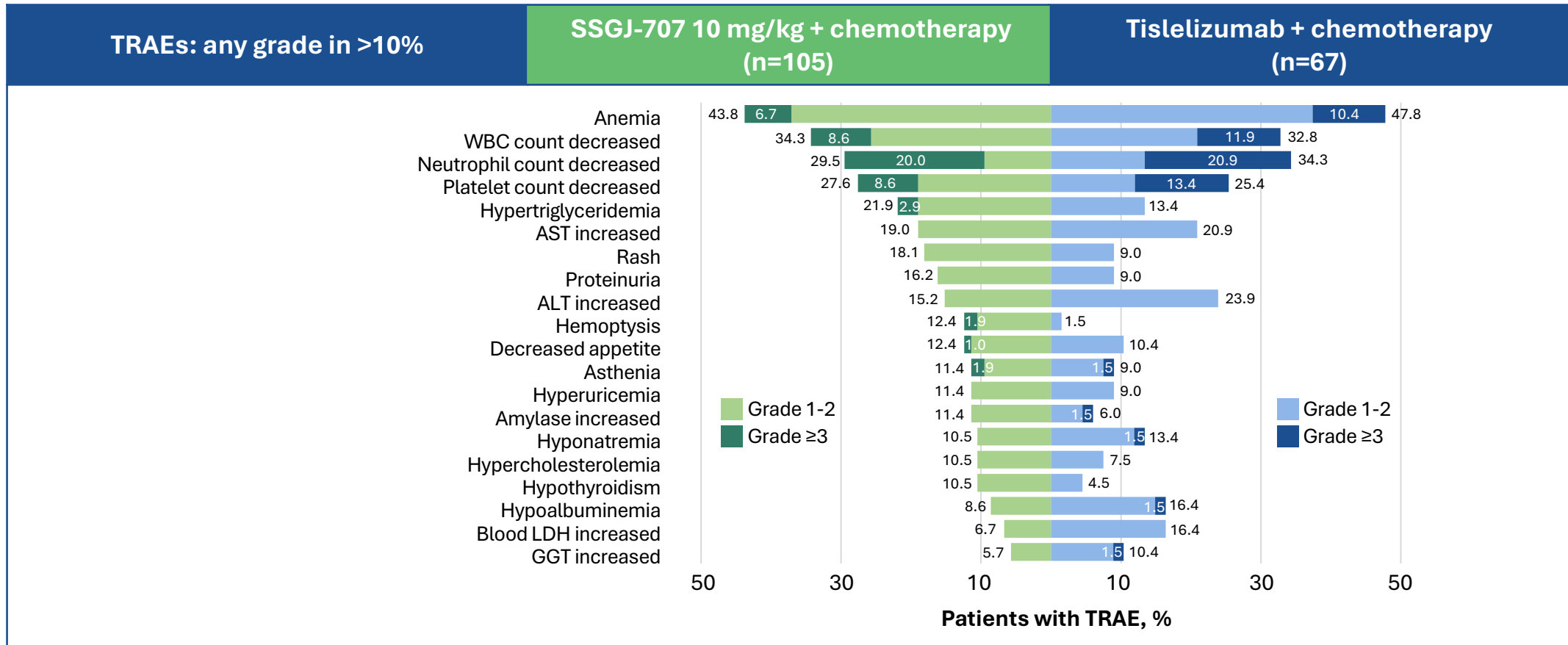
^bDefined as a TEAE that was "related" to SSGJ-707, "most possibly related" to SSGJ-707, "possibly related" to SSGJ-707, or for which relationship to SSGJ-707 was missing.

^cGrade 5 TRAEs consisted of hemoptysis (n=2) and death of unknown cause (n=1) in the SSGJ-707 group and death of unknown cause in the tislelizumab group.

^dDefined as gastrointestinal perforation and fistula, hemorrhage, thromboembolic event, hypertension, or proteinuria.

^eDefined as any TEAE that was potentially immune mediated and categorized as "related," "most possibly related," or "possibly related" to SSGJ-707 or tislelizumab.

AEs with SSGJ-707 + chemotherapy are consistent with the known safety profile of chemotherapy combined with PD-1 and angiogenesis inhibitors



Most VEGF- and immune-related AEs are grade 1/2 in severity

AE Categories Group preferred term	SSGJ-707 10 mg/kg + chemotherapy (n=105)		Tislelizumab + chemotherapy (n=67)	
	Any grade	Grade ≥3	Any grade	Grade ≥3
Any VEGF-related^a event (any grade in ≥5% of patients), n (%)	43 (41.0)	9 (8.6)	11 (16.4)	1 (1.5)
Hemorrhage	24 (22.9)	4 (3.8)	4 (6.0)	0
Extrapulmonary hemorrhage	14 (13.3)	2 (1.9)	3 (4.5)	0
Epistaxis	9 (8.6)	1 (1.0)	0	0
Hemoptysis	13 (12.4)	2 (1.9) ^b	1 (1.5)	0
Proteinuria	18 (17.1)	0	6 (9.0)	0
Blood pressure elevation	10 (9.5)	5 (4.8)	2 (3.0)	1 (1.5)
Categories Group preferred term	Any grade	Grade ≥3	Any grade	Grade ≥3
Any irAE^c (any grade in ≥3% of patients or any grade ≥3 AE), n (%)	15 (14.3)	5 (4.8)	11 (16.4)	4 (6.0)
Endocrine toxicity	8 (7.6)	0	4 (6.0)	0
Hypothyroidism	6 (5.7)	0	1 (1.5)	0
Hematologic toxicity	5 (4.8)	4 (3.8)	2 (3.0)	2 (3.0)
Decreased platelet count	5 (4.8)	4 (3.8)	2 (3.0)	2 (3.0)
Pulmonary toxicity	2 (1.9)	1 (1.0)	1 (1.5)	1 (1.5)
Immune-mediated lung disease	2 (1.9)	1 (1.0)	0	0
Interstitial lung disease	0	0	1 (1.5)	1 (1.5)
Dermatologic toxicity	1 (1.0)	0	4 (6.0)	0
Immune-mediated dermatitis	0	0	2 (3.0)	0
Rash	0	0	2 (3.0)	0

AE, adverse event; irAE, immune-related AE; TEAE, treatment-emergent AE; VEGF, vascular endothelial growth factor.

^aDefined as gastrointestinal perforation and fistula, hemorrhage, thromboembolic event, hypertension, or proteinuria.

^bTwo grade 5 treatment-related events of hemoptysis, 1 each in nonsquamous and squamous histology, occurred in patients with risk factors, eg, tumors with cavitation and necrosis, history of hemoptysis, thrombocytopenia.

^cDefined as any TEAE that was potentially immune mediated and categorized as "related," "most possibly related," or "possibly related" to SSGJ-707 or tislelizumab.

Conclusions

1

SSGJ-707 combined with platinum-based chemotherapy demonstrated promising efficacy in 1L treatment of patients with advanced NSCLC, independent of tumor histology and PD-L1 expression

2

SSGJ-707 combined with platinum-based chemotherapy demonstrated a manageable safety profile that was similar in non-squamous and squamous NSCLC

3

These results support initiation of the phase 3 pivotal trial of 707 10 mg/kg Q3W combined with chemotherapy in 1L NSCLC regardless of histology and PD-L1 expression

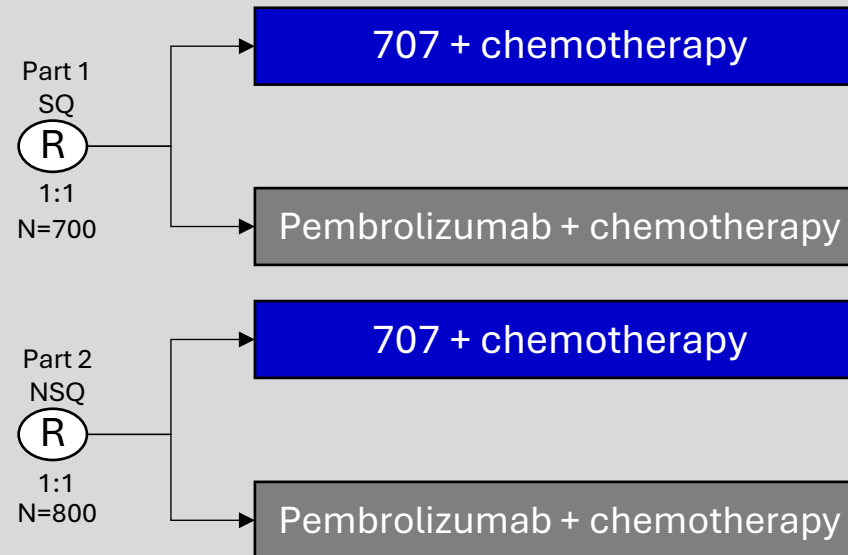
Phase 3 pivotal trial of 707 10 mg/kg combined with chemotherapy in first-line NSCLC (NCT07222566)

Eligibility

- Squamous or nonsquamous histology
- No prior systemic therapy for locally advanced or metastatic NSCLC
- No *EGFR*, *ALK*, or *ROS1* alterations and no other known AGAs
- ECOG PS 0 or 1
- No history of severe bleeding tendency or coagulation dysfunction
- No active CNS metastasis; treated brain metastasis or asymptomatic brain metastasis <1 cm permitted

Stratification factors for both parts:

- Brain metastasis present vs absent
- TPS <1% vs 1%-49% vs ≥50%
- East Asia vs rest of world



Dual primary endpoint

- OS
- PFS by BICR

Secondary endpoints

- ORR by BICR, DOR
- PRO
- Safety and tolerability
- PK and immunogenicity

AGA, actionable genomic alteration; ALK, anaplastic lymphoma kinase; BICR, blinded independent central review; CNS, central nervous system; DOR, duration of response; EGFR, epidermal growth factor receptor; ECOG PS, Eastern Cooperative Oncology Group performance status; NSCLC, non-small cell lung cancer; NSQ, nonsquamous; ORR, objective response rate; OS, overall survival; PFS, progression-free survival; PK, pharmacokinetics; PRO, patient-reported outcome; R, randomization; SQ, squamous; TPS, tumor proportion score.

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