

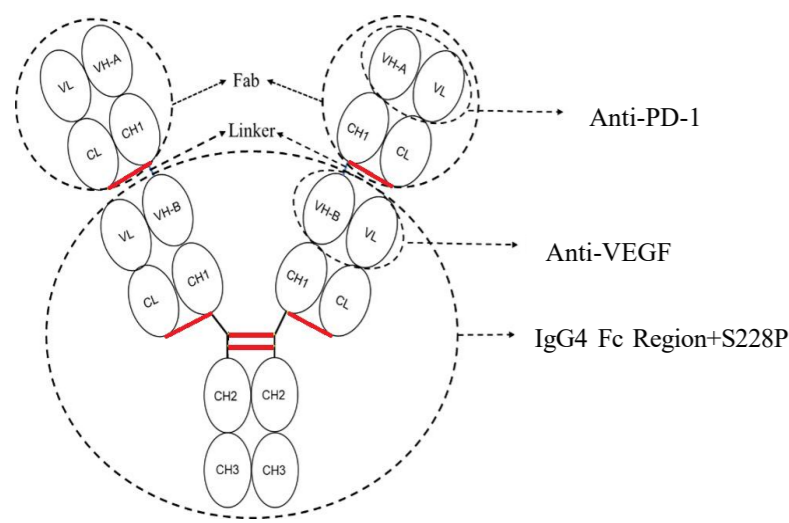
A phase II trial to evaluate the safety and efficacy of SSGJ-707, a bispecific antibody targeting PD-1 and VEGF, as a monotherapy in patients with advanced NSCLC

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BACKGROUND

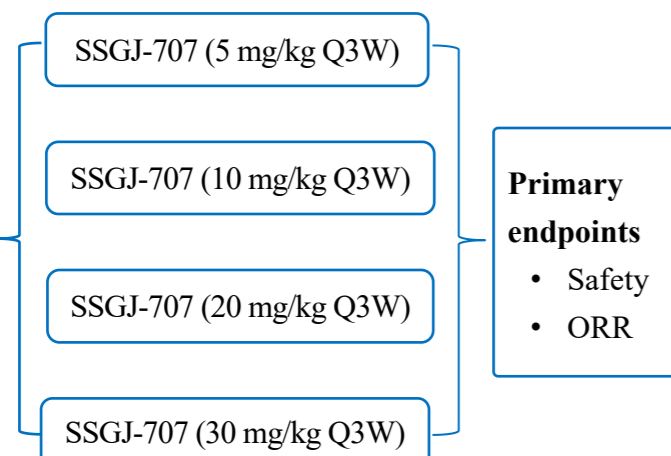
- SSGJ-707 is a recombinant humanized bispecific molecule built on IgG4 that targets the human programmed death 1 (PD-1) and vascular endothelial growth factor (VEGF).
- In the presence of VEGF, the affinity of SSGJ-707 for PD-1 was 100 fold increase.
- Here, we report the initial results from a phase II study of SSGJ-707 monotherapy in patients(pts) with advanced NSCLC.



METHODS

- This was an open-label, multi-center phase II study evaluating the safety and efficacy of SSGJ-707 monotherapy in pts with advanced NSCLC(SSGJ-707-NSCLC-II-01, NCT06361927).
- Pts with treatment naive advanced NSCLC (PD-L1 expression \geq 1% and without actionable genomic alterations) were enrolled to receive SSGJ-707 monotherapy until disease progression or unacceptable toxicity. The primary endpoint was safety and objective response rate (ORR) per RECIST v1.1 by investigator(Figure 1).

Figure 1: Study design



Participants

- As of data cut-off Mar 26, 2025, 83 pts with advanced NSCLC received SSGJ-707 at dose of 5mg/kg Q3W(n=31), 10mg/kg Q3W(n=34), 20mg/kg Q3W(n=12), 30mg/kg Q3W(n=6).
- Overall, 44.6% of pts had squamous cell carcinoma, 33.7% of pts had PD-L1 expression \geq 50%. See Table 1 for baseline characteristics.

Table 1. Baseline Characteristics

	5mg/kg Q3W (N=31)	10mg/kg Q3W (N=34)	20mg/kg Q3W (N=12)	30mg/kg Q3W (N=6)	Total (N=83)
Gender, n (%)					
Male	26 (83.9)	30 (88.2)	10 (83.3)	5 (83.3)	71 (85.5)
Female	5 (16.1)	4 (11.8)	2 (16.7)	1 (16.7)	12 (14.5)
ECOG PS, n (%)					
0	5 (16.1)	6 (17.6)	0	0	11 (13.3)
1	26 (83.9)	28 (82.4)	12 (100)	6 (100)	72 (86.7)
Age (years), n (%)					
<65	18 (58.1)	17 (50.0)	10 (83.3)	2 (33.3)	47 (56.6)
\geq 65	13 (41.9)	17 (50.0)	2 (16.7)	4 (66.7)	36 (43.4)
Smoking Status, n (%)					
Former or Current	22 (71.0)	28 (82.4)	10 (83.3)	6 (100)	66 (79.5)
Never	9 (29.0)	6 (17.6)	2 (16.7)	0	17 (20.5)
Clinical Stage, n (%)					
IIIB/IIIC	8 (25.8)	6 (17.6)	1 (8.3)	2 (33.3)	17 (20.5)
IV	23 (74.2)	28 (82.4)	11 (91.7)	4 (66.7)	66 (79.5)
Liver Metastasis, n (%)	1 (3.2)	3 (8.8)	0	1 (16.7)	5 (6.0)
Brain Metastasis, n (%)	0	5 (14.7)	2 (16.7)	0	7 (8.4)
Histology, n (%)					
Squamous	16 (51.6)	12 (35.3)	5 (41.7)	4 (66.7)	37 (44.6)
Non-squamous	15 (48.4)	22 (64.7)	7 (58.3)	2 (33.3)	46 (55.4)
PD-L1 TPS, n (%)					
\geq 50%	9 (29.0)	13 (38.2)	3 (25.0)	3 (50.0)	28 (33.7)
1-49%	22 (71.0)	21 (61.8)	9 (75.0)	3 (50.0)	55 (66.3)

Efficacy

- Among the 83 pts, 77 pts completed at least one efficacy evaluation. The ORR and DCR for each dose level of SSGJ-707 are shown in Table 2. Individual patient-level response is shown in Figure 2.
- SSGJ-707 10mg/kg Q3W demonstrated promising efficacy results in treatment naive advanced NSCLC. SSGJ-707 demonstrated promising efficacy results in both PD-L1 low and high subgroups, and in both squamous and non-squamous subgroups(Figure 3).

Table 2. Summary of efficacy outcomes

Response	5mg/kg Q3W (N=31)	10mg/kg Q3W (N=34)	20mg/kg Q3W (N=12)	30mg/kg Q3W (N=6)
ORR, n(%)	9/28(32%)	23/34(67.6%)*	6/11(55%)	1/4(25%)
Confirmed ORR, n(%)	9/28(32%)	22/34(64.7%)*	4/11(36.4%)	1/4(25%)
DCR, n(%)	24/28(86%)	33/34(97%)	10/11(91%)	3/4(75%)

* 1 PR pending for confirmation

RESULTS

Figure 2. Waterfall plots and Spider plots. Figure 2-A SSGJ-707 5mg/kg Q3W. Figure 2-B SSGJ-707 10mg/kg Q3W. Figure 2-C SSGJ-707 20mg/kg Q3W. Figure 2-D SSGJ-707 30mg/kg Q3W.

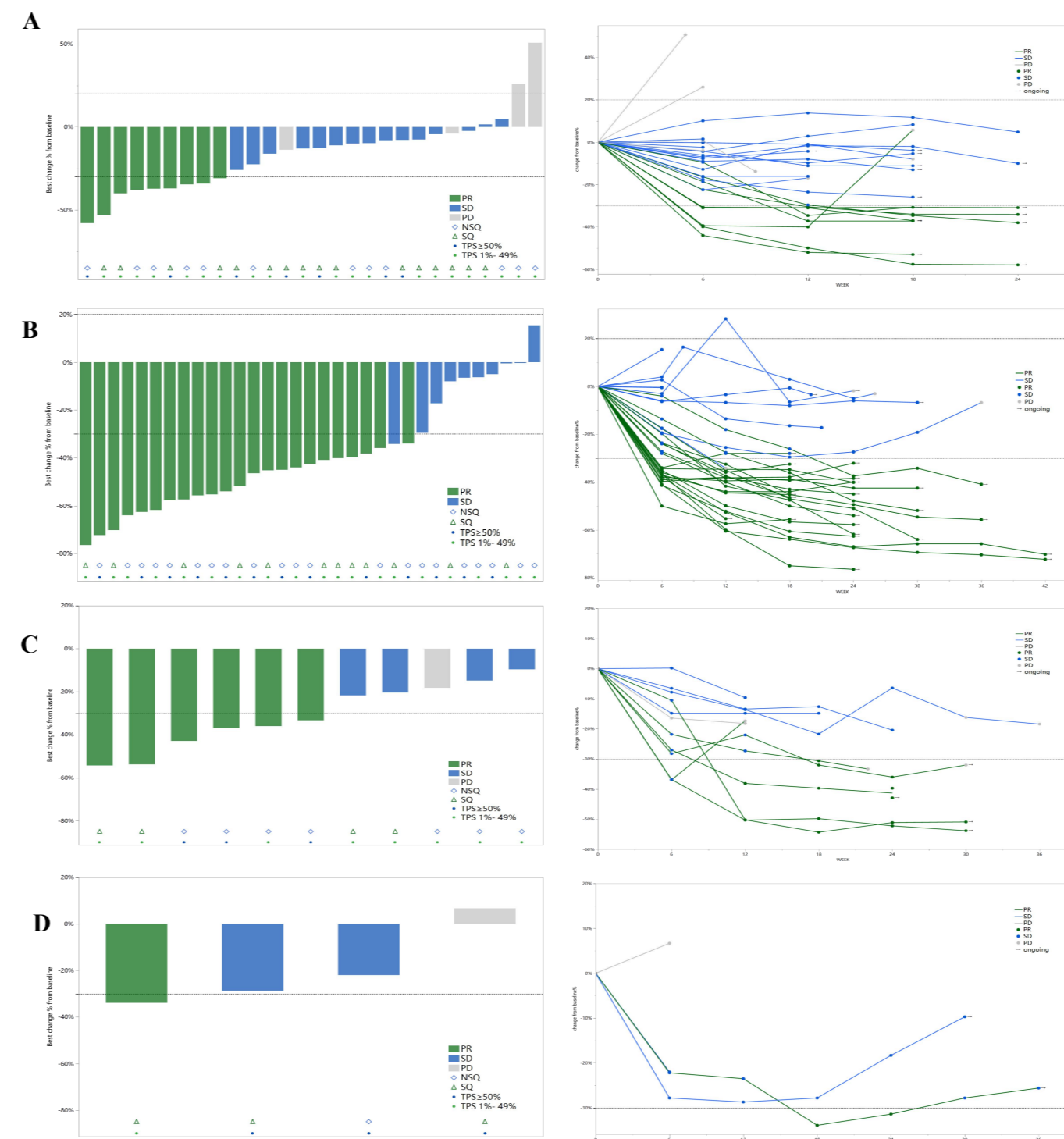
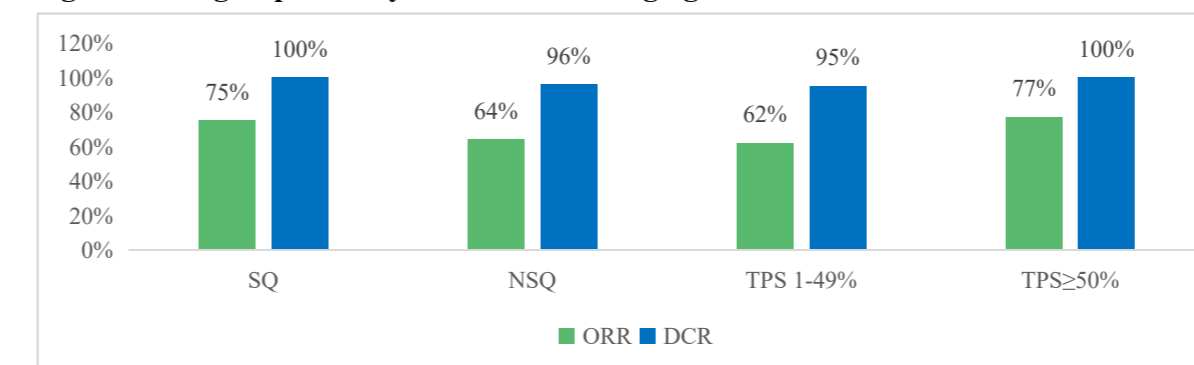


Figure 3. Subgroup Efficacy at SSGJ-707 10mg/kg Q3W



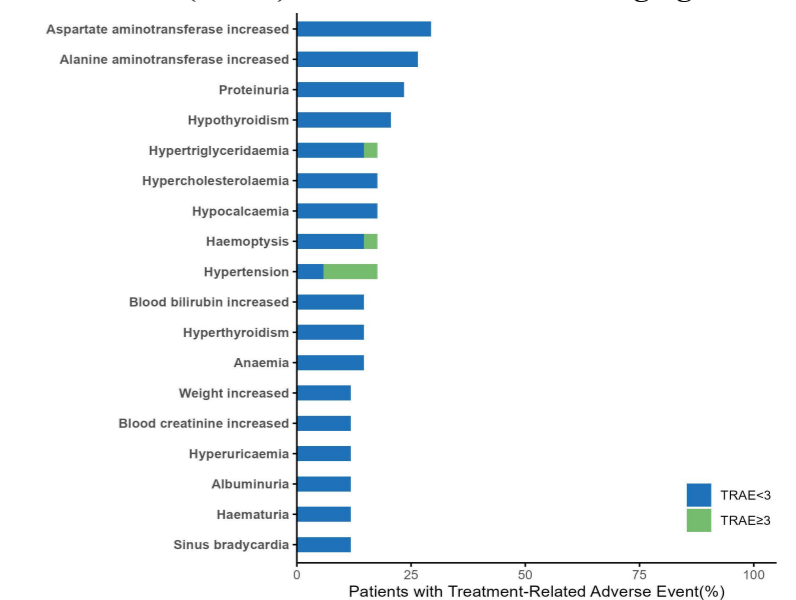
Safety

- Treatment related adverse events (TRAEs) are summarized in Table 3.
- The SSGJ-707 10mg/kg Q3W most common TRAEs(\geq 10% of patients) included aspartate aminotransferase increased, alanine aminotransferase increased, proteinuria, hypothyroidism, hypertriglyceridaemia, hypercholesterolaemia, hypocalcaemia, haemoptysis and hypertension(Figure 4).

Table 3. Summary of safety

	5 mg/kg Q3W (N=31)	10 mg/kg Q3W (N=34)	20 mg/kg Q3W (N=12)	30 mg/kg Q3W (N=6)	Total (N=83)
TRAE	25 (80.6%)	33 (97.1%)	12 (100%)	5 (83.3%)	75 (90.4%)
\geq Grade 3 TRAE	8 (25.8%)	8 (23.5%)	7 (58.3%)	4 (66.7%)	27 (32.5%)
TRSAE	7 (22.6%)	7 (20.6%)	5 (41.7%)	4 (66.7%)	23 (27.7%)
TRAE leading to drug discontinuation	4 (12.9%)	1 (2.9%)	1 (8.3%)	1 (16.7%)	7 (8.4%)
TRAE leading to death	0	0	1 (8.3%)	0	1 (1.2%)

Figure 4. Most Common(\geq 10%)TRAEs in SSGJ-707 10mg/kg Q3W



CONCLUSIONS

- SSGJ-707 has shown promising anti-tumor activity and an acceptable safety profile in patients with advanced NSCLC without actionable genomic alterations.
- Results of this analysis support further evaluation of SSGJ-707 monotherapy for the treatment-naive advanced NSCLC (PD-L1 expression \geq 1% and without actionable genomic alterations) in phase III trial.

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