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Preliminary results from a phase II study evaluating the safety and efficacy of JS207, a bispecific antibody targeting PD-1 and VEGF-A, in combination with JS007 (Anti-CTLA-4) as first-line treatment in patients with advanced hepatocellular carcinoma

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INTRODUCTION

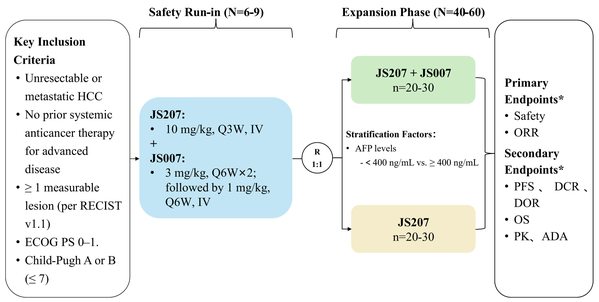
- JS207, a bispecific antibody targeting PD-1 and VEGF-A, has demonstrated promising therapeutic efficacy in phase I studies [1].
- This Phase II study (NCT06954467) aimed to evaluate the safety and efficacy of JS207 in combination with JS007, an antibody targeting CTLA-4, for the first-line treatment of advanced hepatocellular carcinoma (HCC).
- Here, we present the preliminary results from the patients treated with the combination of JS207 and JS007.

[1] Yu J, et al. A Phase I study of JS207, a PD-1/VEGF bispecific antibody, in patients with advanced malignancies. Ann Oncol. Volume 36, Supplement 4, S2185-S2186, December 2025

STUDY DESIGN

- This study included a safety run-in period, enrolling 6 to 9 patients to determine the recommended dose of JS007 for the randomized expansion phase which planned to enroll 40 to 60 patients.

Figure 1. JS207-006-II-HCC Study Design



*The tumor imaging assessments are performed by investigators in accordance with RECIST v1.1.
HCC, Hepatocellular Carcinoma; RECIST, Response Evaluation Criteria In Solid Tumors; ECOG, Eastern Cooperative Oncology Group Performance Status; Q3W, once every 3 weeks; IV, intravenous; Q6W, once every 6 weeks; AFP, Alpha-fetoprotein; ORR, Objective Response Rate; PFS, Progression Free Survival; DCR, Disease Control Rate; DOR, Duration of Response; OS, Overall survival; PK, Pharmacokinetics; ADA, Anti-drug Antibody.

- Patients with histologically or cytologically confirmed unresectable or metastatic HCC who had not previously received any systemic anticancer therapy were eligible.
- The primary endpoints included safety and the objective response rate (ORR).

RESULTS

Baseline Characteristics

- As of March 20, 2026, a total of 26 patients received combination therapy of JS207 plus JS007, including 7 patients in safety run-in period and 19 patients in the randomized expansion phase.
- Of those patients, 92.3% were male, 57.7% were under 65 years of age, 53.8% had an ECOG performance status score of 0.
- The baseline characteristics of the patients are shown in Table 1.

Table 1. Baseline characteristics

	JS207 + JS007 N=26, n (%)
Age, n (%)	
< 65	15 (57.7)
≥ 65	11 (42.3)
Sex, n (%)	
Female	2 (7.7)
Male	24 (92.3)
ECOG, n (%)	
0	14 (53.8)
1	12 (46.2)
BCLC stage, n (%)	
Stage B	8 (30.8)
Stage C	18 (69.2)
Child-Pugh grade, n (%)	
Class A	20 (76.9)
Class B	6 (23.1)
MVI, n (%)	
No	18 (69.2)
Yes	8 (30.8)
AFP category, n (%)	
< 400 ng/mL	18 (69.2)
≥ 400 ng/mL	8 (30.8)

ECOG, Eastern Cooperative Oncology Group Performance Status; BCLC, Barcelona Clinic Liver Cancer; MVI, Microvascular Invasion; AFP, Alpha-fetoprotein.

Safety

- No dose-limiting toxicities were observed during the safety run-in period.
- The recommended dose of JS007 for the expansion phase was determined to be 3 mg/kg every 6 weeks (Q6W) for two doses, followed by 1 mg/kg Q6W thereafter.
- Treatment-related adverse events (TRAEs) occurred in 88.5% of patients, with Grade ≥ 3 TRAEs reported in 19.2% of patients.
- The most common treatment-emergent adverse evens (TEAEs) were increased aspartate aminotransferase (53.8%) and pyrexia (46.2%).
- A summary of safety data is presented in Table 2, and the most common TEAEs are listed in Table 3.

Table 2. Summary of safety

	JS207 + JS007 N=26, n (%)
TEAE	23 (88.5)
TRAE	23 (88.5)
Grade ≥ 3 TEAE	6 (23.1)
Grade ≥ 3 TRAE	5 (19.2)
SAE	6 (23.1)
TRSAE	6 (23.1)
TEAE Leading to JS207 or JS007 Interruption	8 (30.8)
TEAE Leading to JS207 or JS007 Termination	2 (7.7)
TEAE Leading to Death	0
irAE	7 (26.9)
JS207 related	7 (26.9)
JS007 related	0

TEAE, Treatment-Emergent Adverse Event; TRAE, Treatment-Related Adverse Event; SAE, Serious Adverse Event, ; TRSAE, Treatment-Related Serious Adverse Event, irAE, immune-related Adverse Event.

Table 3. Most common TEAEs (incidence ≥ 15%)

Preferred Term	JS207 + JS007 N=26, n (%)
Aspartate aminotransferase increased	14 (53.8)
Pyrexia	12 (46.2)
Alanine aminotransferase increased	10 (38.5)
Anaemia	9 (34.6)
Rash	9 (34.6)
Platelet count decreased	7 (26.9)
Hypoalbuminaemia	7 (26.9)
Blood bilirubin increased	5 (19.2)
Proteinuria	5 (19.2)
White blood cell count decreased	4 (15.4)
Blood alkaline phosphatase increased	4 (15.4)
Hyponatraemia	4 (15.4)

Efficacy

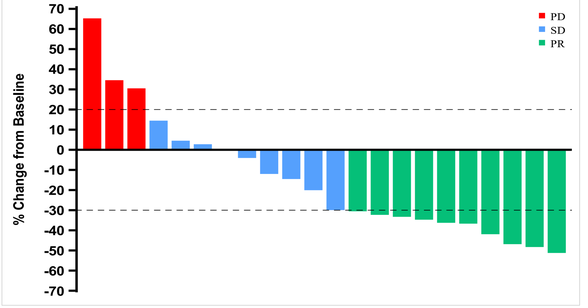
- Among evaluable patients, the ORR was 45.5% and the disease control rate (DCR) was 86.4%, respectively.
- The best overall responses in evaluable patients is summarized in Table 4. Best percent changes from baseline in target lesions are shown in Figure 2.

Table 4. Best overall response in the evaluable patients

	JS207 + JS007
Evaluable Patients, n	22
PR	10
SD	9
PD	3
ORR (%)	45.5%
DCR (%)	86.4%

PR, Partial Response; SD, Stable Disease; PD, Progressive Disease; ORR, Objective Response Rate; DCR, Disease Control Rate.

Figure 2. Best Percent Change from Baseline



CONCLUSION

- The enrollment is still ongoing, with limited follow-up. The combination of JS207 and JS007 as first-line treatment for advanced HCC was well tolerated, and has demonstrated an encouraging efficacy, with an ORR of 45.5%.
- These findings provide preliminary evidence of the synergistic efficacy of JS207 and JS007 in combination for the first-line treatment of HCC.

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