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Anbenitamab plus chemotherapy for previously treated HER2-positive gastric or gastroesophageal carcinomas (GC/GEJC): Updated overall survival (OS) analysis of KC-WISE

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Background

In the prespecified interim progression-free survival (PFS) analysis of the KC-WISE, anbenitamab plus chemotherapy demonstrated clinically meaningful and statistically significant improvements in both PFS and OS compared with standard of care in patients with HER2-positive GC/GEJC who progressed on trastuzumab. Here we report the prespecified final PFS analysis and interim OS analysis of KC-WISE.

Methods

Patients with centrally confirmed HER2-positive GC/GEJC who had failed prior therapy containing trastuzumab were randomized to receive anbenitamab or placebo in combination with standard of care. A prespecified interim analysis of OS, a co-primary endpoint, was planned for when approximately 150 deaths had occurred. The cutoff date was July 15 2026.

Results

A total of 246 patients were randomized to receive anbenitamab (n=125) or control (n=121). The median duration of follow-up was 22.8 months in the anbenitamab group and 22.3 months in the control group. Overall, 157 deaths occurred, including 66 (52.8%) in the anbenitamab group and 91 (75.2%) in the control group. Median OS was 19.6 months with anbenitamab versus 9.6 months with control (hazard ratio [HR], 0.39; 95% confidence interval [CI], 0.28 to 0.54; $P < 0.0001$). The OS benefit was consistent across all prespecified subgroups. Median PFS, as assessed by independent review committee (IRC), was 7.1 months and 2.7 months, respectively (HR, 0.35; 95% CI, 0.26 to 0.48; $P < 0.0001$); similar results were observed for investigator-assessed PFS. Grade ≥ 3 treatment-related adverse events occurred in 69.4% of patients in the anbenitamab group and 47.9% in the control group, with the most common events being neutropenia (33.1% vs. 24.8%), leukopenia (27.4% vs. 25.6%), and anemia (24.2% vs. 12.4%). Treatment-related deaths were reported in no patients in the anbenitamab group and in 5 patients in the control group.

Conclusions

Anbenitamab plus chemotherapy significantly improved overall survival compared with standard of care in patients with HER2-positive GC/GEJC adenocarcinoma whose previous therapy containing trastuzumab had failed.

Clinical trial identification

NCT05427383.

Legal entity responsible for the study

Shanghai JMT-Bio Technology Co., Ltd.

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Disclosure

Y. Liu: Financial Interests, Personal, Full or part-time Employment: CSPC Pharmaceutical Group Limited. X. Wan: Financial Interests, Personal, Full or part-time Employment: CSPC Pharmaceutical Group Limited. Y. An: Financial Interests, Personal, Full or part-time Employment: CSPC Pharmaceutical Group Limited. K. Zou: Financial Interests, Personal, Full or part-time Employment: CSPC Pharmaceutical Group Limited. Z. Wu: Financial Interests, Personal, Full or part-time Employment: CSPC Pharmaceutical Group Limited. All other authors have declared no conflicts of interest.

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