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CSPC PHARMACEUTICAL GROUP LIMITED

石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1093)

VOLUNTARY ANNOUNCEMENT

UPDATED OVERALL SURVIVAL (OS) RESULTS FROM A PHASE III CLINICAL STUDY OF ANBENITAMAB FOR THE TREATMENT OF HER2-POSITIVE ADVANCED GASTRIC CANCER/GASTRO-OESOPHAGEAL JUNCTION ADENOCARCINOMA PRESENTED AS A RAPID ORAL PRESENTATION AT THE ESMO CONGRESS 2026

The Board of Directors (the “**Board**”) of CSPC Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that the updated overall survival (“**OS**”) analysis results from a Phase III clinical study (Study No.: KC-WISE) of Anbenitamab Injection (brand name: Ennituo (恩尼妥®)), co-developed by the Group and Jiangsu Alphamab Oncology Co., Ltd., in combination with chemotherapy for the treatment of patients with human epidermal growth factor receptor 2 (“**HER2**”)-positive advanced gastric cancer/gastroesophageal junction adenocarcinoma (“**GC/GEJA**”) who have failed prior trastuzumab treatment, have been selected as a Late-breaking Abstract (LBA) and were presented as a Rapid Oral Presentation at the European Society for Medical Oncology (“**ESMO**”) Congress 2026 on 23 October 2026.

STUDY OVERVIEW

The KC-WISE study is a randomised, double-blind, controlled, multicentre Phase III clinical study (NCT05427383) led by Professor Xu Jianming from the Chinese People’s Liberation Army General Hospital as the principal investigator and sponsored by the Group, aiming to conduct a head-to-head comparison of the efficacy and safety of Anbenitamab in combination with chemotherapy versus standard of care in patients with HER2-positive GC/GEJA who have failed prior trastuzumab treatment. A total of 246 trial participants were randomly enrolled in the study, including 125 in the Anbenitamab group and 121 in the control group. As at the data cut-off date of 15 July 2026, the median follow-up time for the two groups reached 22.8 months and 22.3 months, respectively.

STUDY RESULTS

Efficacy:

- A total of 157 death events occurred in the two groups, including 66 (52.8%) in the Anbenitamab group and 91 (75.2%) in the control group. The median overall survival (mOS) of the Anbenitamab group reached 19.6 months, which was significantly superior to 9.6 months of the control group (hazard ratio (“**HR**”)=0.39; 95% confidence interval (“**CI**”): 0.28–0.54; $P<0.0001$), representing a substantial reduction of 61% in the risk of death compared with the standard of care. Subgroup analysis demonstrated that the OS benefit was consistent across all prespecified subgroups.
- As assessed by the Independent Review Committee (“**IRC**”), the median progression-free survival (mPFS) for the Anbenitamab group and the control group was 7.1 months and 2.7 months, respectively (HR=0.35; 95% CI: 0.26–0.48; $P<0.0001$); the PFS results assessed by the investigators were similar to the IRC assessed conclusions, further verifying that this regimen can significantly delay disease progression.

Safety:

- The most common Grade $\geq$ 3 treatment-emergent adverse events (TEAEs) in the Anbenitamab group and the control group included neutropenia (33.1% vs 24.8%), leukopenia (27.4% vs 25.6%), and anaemia (25.8% vs 14.0%).
- No treatment-related death events occurred in the Anbenitamab group, whereas 5 treatment-related death events were reported in the control group. Overall, the Anbenitamab group demonstrated a favourable safety profile with manageable risks.

STUDY CONCLUSION

The updated OS data presented at the ESMO Congress 2026 further confirmed that Anbenitamab in combination with chemotherapy for the second-line and beyond treatment of patients with HER2-positive advanced GC/GEJA provides significant benefits in both short-term tumour shrinkage and long-term survival, with an overall manageable safety profile, which is expected to reshape the clinical treatment landscape for HER2-positive advanced GC/GEJA.

ABOUT ANBENITAMAB INJECTION (ENNITUO (恩尼妥®))

Anbenitamab is a HER2 bispecific antibody targeting two non-overlapping epitopes of HER2. It can simultaneously bind to two non-overlapping epitopes of HER2, blocking the HER2 signalling. Through antibody-induced receptor clustering, it enhances antibody-dependent cell-mediated cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC) effects while promoting HER2 receptor endocytosis and downregulating cell-surface HER2 receptors.

Based on the previous breakthrough interim analysis results of PFS from the KC-WISE study, Anbenitamab Injection (Ennituo (恩尼妥®)) was approved for marketing by the National Medical Products Administration (NMPA) of the People’s Republic of China in May 2026, in combination with chemotherapy for the second-line and beyond treatment of patients with HER2-positive advanced GC/GEJA.

The Group is the sole marketing authorisation holder (MAH) of Anbenitamab injection (Ennituo (恩尼妥[®])) for the approved indications in Chinese Mainland and the sole owner of the Ennituo (恩尼妥[®]) trademark. As an independent sponsor, the Group has taken overall responsibility for leading the clinical development design and end-to-end management of Anbenitamab injection (Ennituo (恩尼妥[®])). Leveraging on a mature incubation ecosystem, efficient clinical operation capabilities, comprehensive resource coordination mechanisms, and a well-established commercialisation system, the Group is expected to rapidly integrate full-chain advantages to bring the product to market.

By order of the Board
CSPC Pharmaceutical Group Limited
CAI Dong Chen
Chairman

Hong Kong, 26 October 2026

As at the date of this announcement, the Board comprises Mr. CAI Dong Chen, Dr. CAI Lei, Mr. WEI Qingjie, Mr. ZHANG Cuilong, Mr. WANG Zhenguo, Dr. LI Chunlei, Dr. YAO Bing, Mr. CAI Xin, Mr. CHEN Weiping, Mr. QU Zhiyong and Mr. ZHANG Yiwei as Executive Directors; and Mr. WANG Bo, Mr. CHEN Chuan, Prof. WANG Hongguang, Mr. AU Chun Kwok Alan, Mr. LAW Cheuk Kin Stephen and Ms. LI Quan as Independent Non-executive Directors.