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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

**RESULTS FROM A PHASE III CLINICAL STUDY OF ANBENITAMAB IN
COMBINATION WITH DOCETAXEL FOR INJECTION (ALBUMIN-BOUND) (HB1801)
FOR THE FIRST-LINE TREATMENT OF
HER2-POSITIVE ADVANCED BREAST CANCER PRESENTED
AS A PROFFERED PAPER PRESENTATION
AT THE ESMO CONGRESS 2026 AND SIMULTANEOUSLY PUBLISHED
IN THE NEW ENGLAND JOURNAL OF MEDICINE**

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 interim analysis results from a Phase III clinical study (Study No.: HEALER) of Anbenitamab Injection (brand name: Ennituo (恩尼妥®)), co-developed by the Group and Jiangsu Alphamab Oncology Co., Ltd., in combination with Docetaxel for Injection (Albumin-bound) (“**HB1801**”) for the first-line treatment of human epidermal growth factor receptor 2 (“**HER2**”)-positive advanced breast cancer, have been selected as a Late-breaking Abstract and were presented as a Proffered Paper Presentation at the European Society for Medical Oncology (“**ESMO**”) Congress 2026 on 24 October 2026. The study was published simultaneously as an original article in *The New England Journal of Medicine* (“**NEJM**”), making it the first clinical achievement in the field of breast cancer from the Chinese Mainland published in the NEJM.

For a long time, trastuzumab in combination with pertuzumab and taxanes (the “**THP regimen**”) has been the first-line standard treatment for HER2-positive advanced breast cancer. However, approximately half of the patients experience disease progression within two years, highlighting an urgent clinical need for better treatment options.

STUDY OVERVIEW

The HEALER study is a randomised, open-label Phase III clinical study sponsored by the Group and led by Academician Xu Binghe, conducted across 76 centres in China, aiming to compare the efficacy and safety of the Anbenitamab plus HB1801 regimen versus the standard THP regimen as a first-line treatment for HER2-positive advanced breast cancer. A total of 885 patients with HER2-positive advanced breast cancer who had not received prior chemotherapy or anti-HER2 targeted therapy in the advanced setting were enrolled and randomly assigned in a 1:1 ratio to either the experimental group (Anbenitamab plus HB1801) or the control group (THP group). The primary endpoint was progression-free survival (“**PFS**”) assessed by a Blinded Independent Review Committee (“**BIRC**”) based on the Response Evaluation Criteria in Solid Tumours (RECIST 1.1).

STUDY RESULTS

The interim analysis results presented at the ESMO Congress 2026 showed:

Efficacy:

- As assessed by the BIRC, the PFS of the Anbenitamab plus HB1801 group was significantly superior to that of the THP group, with 24-month PFS rates of 58.5% vs 34.4%, respectively, representing a 54% reduction in the risk of disease progression or death (hazard ratio (“**HR**”) = 0.46, 95% confidence interval (“**CI**”): 0.37–0.56, $P=6.37\times 10^{-15}$). This benefit was consistent across all prespecified subgroups, including patients who had previously received trastuzumab treatment (HR=0.47) and patients with visceral metastases (HR = 0.47).
- Regarding secondary endpoints, the trend of PFS benefit assessed by the investigators was consistent with the BIRC results (HR=0.52). As assessed by the BIRC, the objective response rate (ORR) of the Anbenitamab plus HB1801 group reached 87.6%, which was significantly higher than the 73.4% in the THP group. Furthermore, the median duration of response (“**mDoR**”) had not yet been reached in the Anbenitamab plus HB1801 group, whereas the mDoR for the THP group was 16.6 months. The Anbenitamab plus HB1801 group demonstrated a better response rate and a more durable response time compared with the THP group.

Safety:

- The incidence of Grade $\geq$ 3 adverse events was 45.9% in the Anbenitamab plus HB1801 group and 34.4% in the THP group. The most common Grade $\geq$ 3 adverse events were primarily haematological toxicities, including neutropenia (13.1% vs 8.4%) and leukopenia (9.7% vs 5.5%).
- The Anbenitamab plus HB1801 group had a low incidence of treatment discontinuation due to treatment-emergent adverse events (TEAEs) (5.2% vs 3.4%), demonstrating good tolerability. Notably, although the overall incidence of diarrhoea in the Anbenitamab plus HB1801 group was slightly higher than that in the THP group, Grade $\geq$ 3 diarrhoea accounted for only 2.3%, and no subjects discontinued treatment due to diarrhoea.
- In terms of cardiotoxicity, the incidences of left ventricular dysfunction and decreased ejection fraction in the Anbenitamab plus HB1801 group were 2.9% and 8.1%, respectively, with Grade $\geq$ 3 events being 0.5% and 1.8%, respectively. This is consistent with the known safety profile of traditional anti-HER2 targeted therapies, and no new safety risk signals were identified.

STUDY CONCLUSION

The results of the HEALER study confirmed that compared with the existing standard THP regimen, the Anbenitamab plus HB1801 regimen significantly improved the first-line PFS of HER2-positive advanced breast cancer, with an overall manageable safety profile. The study provides high-quality evidence-based medical evidence for this novel combination therapy, which is expected to become a new option for the first-line treatment of HER2-positive advanced breast cancer.

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, blocking HER2 signalling; through antibody-induced receptor clustering, it enhances antibody-dependent cell-mediated cytotoxicity (ADCC) and complement-dependent cytotoxicity (CDC) effects, while simultaneously promoting HER2 receptor endocytosis and downregulating cell-surface HER2 receptors.

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.

ABOUT HB1801

HB1801 is an albumin-bound docetaxel independently developed by the Group, which encapsulates docetaxel in human serum albumin. As it does not contain polysorbate 80 (Tween-80) or ethanol, it has the following advantages compared with docetaxel injection: (1) Safety: it requires no steroid premedication and can be administered rapidly at a high concentration, with higher safety and patient treatment compliance; (2) Efficacy: it shows significant effects in multiple preclinical tumour models and early-stage clinical studies, allowing for higher doses in clinical practice to further improve efficacy.

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.