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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

PHASE III CLINICAL TRIAL OF BECOTATUG (JMT101) IN COMBINATION WITH OSIMERTINIB FOR THE FIRST-LINE TREATMENT OF LOCALLY ADVANCED OR METASTATIC NSCLC HARBOURING EGFR EXON 20 INSERTION MUTATIONS ACHIEVES POSITIVE TOPLINE RESULTS

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 Phase III clinical trial of Becotatug (JMT101) (the “**Product**”) developed by the Group, in combination with osimertinib for the first-line treatment of locally advanced or metastatic non-small cell lung cancer (“**NSCLC**”) harbouring epidermal growth factor receptor (“**EGFR**”) exon 20 insertion mutations (EGFR ex20ins), has met its primary endpoint at a pre-specified interim analysis, achieving positive topline results. Compared with platinum-based chemotherapy in combination with pemetrexed, the treatment regimen of the Product in combination with osimertinib significantly prolonged the progression-free survival (“**PFS**”) of patients and demonstrated a trend of benefit in overall survival (OS).

The trial is a randomised, open-label, parallel-controlled Phase III clinical trial designed to compare the efficacy and safety of the Product in combination with osimertinib versus platinum-based chemotherapy in combination with pemetrexed in the first-line treatment of the aforementioned patients. The primary endpoint is PFS as assessed by the Independent Review Committee (IRC) in accordance with the Response Evaluation Criteria in Solid Tumours (RECIST 1.1). According to the pre-specified statistical analysis plan, as reviewed and resolved by the Independent Data Monitoring Committee (IDMC), the PFS benefit in the treatment group of the Product in combination with osimertinib met the pre-specified statistical superiority boundary for the interim analysis and was of clinical significance. In addition, this combination treatment regimen demonstrated a favourable safety profile.

About Becotatug (JMT101)

The Product is a high-affinity, humanised monoclonal antibody targeting EGFR. In combination with the EGFR tyrosine kinase inhibitor osimertinib, it serves as a chemotherapy-free, dual-targeted therapy regimen, acting simultaneously on the extracellular and intracellular EGFR signalling pathways, which reflects an innovative therapeutic approach that combines distinct mechanisms of action. Meeting the primary endpoint at the pre-specified interim analysis of this Phase III study provides pivotal clinical evidence for this chemotherapy-free, dual-targeted combination therapy regimen, and is expected to offer a new, potentially superior and chemotherapy-free first-line treatment option for such patients. The Group plans to present the results of this trial at upcoming academic conferences. Furthermore, pivotal Phase III clinical studies of the Product for indications such as the first-line treatment of locally advanced or metastatic non-squamous NSCLC with classical EGFR mutations, and advanced metastatic colorectal cancer that has failed at least two lines of standard therapies, are also ongoing.

About EGFR Exon 20 Insertion Mutation (EGFR ex20ins) Non-Small Cell Lung Cancer

Lung cancer is one of the most common malignant tumours globally and is also the malignant tumour with the highest incidence and mortality rates in China. NSCLC accounts for approximately 85% of lung cancer, among which EGFR mutations account for the highest proportion in the Chinese NSCLC population (approximately 40–50%), and EGFR exon 20 insertion mutation is the most common type of EGFR gene mutation other than classical EGFR mutations. EGFR ex20ins tumours have high mutational heterogeneity and a high proportion of brain metastasis, and often present with a higher tumour burden, resulting in a poor prognosis for patients. For patients with locally advanced or metastatic disease, there are unmet clinical needs such as prolonging the duration of disease control, improving long-term survival, and improving treatment tolerability.

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

Hong Kong, 24 September 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.