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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

BATOCLIMAB INJECTION (SUBCUTANEOUS INJECTION) OBTAINS DRUG REGISTRATION CERTIFICATE FROM THE NMPA

The Board of Directors (the “**Board**”) of CSPC Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that Batoclimab Injection (Subcutaneous Injection) (trade name: Enlida[®](恩力達[®])) (the “**Product**”), in-licensed by CSPC NBP Pharmaceutical Co., Ltd.* (石藥集團恩必普藥業有限公司), a subsidiary of the Company, from Harbour Biomed (Shanghai) Co., Ltd.* (和鉑醫藥(上海)有限責任公司), has obtained the drug registration certificate issued by the National Medical Products Administration of the People’s Republic of China (the “**NMPA**”) for use in combination with conventional drugs for the treatment of generalised myasthenia gravis (“**gMG**”) in adult patients who are anti-acetylcholine receptor (“**AChR**”) antibody positive.

gMG is a rare, chronic autoimmune neuromuscular disease mediated by autoantibodies that impair neuromuscular junction transmission, thereby leading to skeletal muscle weakness. The disease can significantly affect patients’ ability to work and quality of life and, in severe cases, may trigger a potentially life-threatening myasthenic crisis. Existing treatment options include cholinesterase inhibitors, glucocorticoids and other immunosuppressive drugs, but there remain unmet clinical needs in terms of efficacy, safety, accessibility and cost.

The Product is a fully human monoclonal antibody targeting the neonatal Fc receptor (“**FcRn**”). By blocking FcRn-mediated recycling of immunoglobulin G (“**IgG**”) antibodies, it accelerates the degradation of pathogenic IgG autoantibodies. It is also the first anti-FcRn therapy to complete its full clinical development for patients with gMG in China.

The approval is mainly supported by positive results from a pivotal Phase III clinical trial conducted at 27 study centres in China. The main study population comprised adult patients with gMG who were positive for AChR antibodies or muscle-specific tyrosine kinase (MuSK) antibodies. The primary endpoint was the proportion of patients achieving sustained improvement in the Myasthenia Gravis Activities of Daily Living (“MG-ADL”) score during the first treatment cycle. Sustained improvement was defined as a reduction of at least three points from baseline in the MG-ADL score that persisted for at least four weeks.

The study results showed that 58.2% of patients in the batoclimab subcutaneous injection group achieved the primary endpoint, compared with 31.3% in the placebo group ($P=0.001$), and clinical efficacy was observed as early as the second week of treatment. The batoclimab subcutaneous injection group also demonstrated statistically significant improvements over placebo in secondary endpoints, including sustained improvement in the Quantitative Myasthenia Gravis (QMG) score, the duration of sustained improvement of at least three points in the MG-ADL score, and the proportion of patients achieving minimal symptom expression (defined as an MG-ADL score of 0 or 1) at any visit. Overall, the treatment was well tolerated.

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

Hong Kong, 23 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.

* *For identification purposes only*