

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



CSPC PHARMACEUTICAL GROUP LIMITED

石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1093)

VOLUNTARY ANNOUNCEMENT

USTEKINUMAB INJECTION RECEIVES MARKETING AUTHORISATION FROM 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 Ustekinumab Injection (brand name: Enyike (恩益克®)) (the “**Product**”) developed by the Group has received marketing authorisation from the National Medical Products Administration of the People’s Republic of China (“**NMPA**”).

The Product is a fully human IgG1 κ monoclonal antibody that binds with high affinity and specificity to the p40 protein subunit of human interleukins IL-12 and IL-23. IL-12 and IL-23 are naturally occurring cytokines involved in the inflammatory and immune response processes of plaque psoriasis and Crohn’s disease, playing a central role in their pathogenesis. Ustekinumab disrupts the IL-12- and IL-23-mediated signaling and cytokine cascades by disrupting the interaction of these cytokines with the cell-surface receptor chain, IL-12R β 1, thereby effectively alleviating disease symptoms, continuously improving the condition, and bringing long-term clinical benefits to patients.

The originator drug of the Product, Stelara® (Ustekinumab Injection), was approved for marketing in China in 2017 and has been approved for three indications in China, namely adult plaque psoriasis, paediatric plaque psoriasis and Crohn’s disease. Since its launch, it has consistently remained among the mainstream drugs for the treatment of autoimmune diseases in China, and its efficacy and safety have been widely recognised.

The Product was developed as a Class 3.3 therapeutic biological product and is a biosimilar to the originator drug, Stelara®. It is indicated for the treatment of adult patients with moderate to severe plaque psoriasis who have failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including cyclosporine, methotrexate (MTX) or PUVA (psoralen and ultraviolet A), as well as paediatric patients and adolescents aged 6 years and above (weighing 60 kg to 100 kg) with moderate to severe plaque psoriasis who have an inadequate response to or are intolerant to other systemic therapies or phototherapies.

The development of the Product followed relevant research guidelines for biosimilars. Adhering to a stepwise approach, and on the basis of completing comprehensive pharmaceutical and non-clinical comparative studies, “head-to-head” clinical pharmacokinetic, efficacy and safety comparative trials were conducted against the originator drug, Stelara[®], confirming a high degree of similarity between the Product and Stelara[®] in terms of quality, pharmacokinetics, efficacy and safety. The results of the aforementioned comparative clinical trials on efficacy and safety have been published in the *Journal of the American Academy of Dermatology*, the official journal of the American Academy of Dermatology (AAD), which ranks first in the field of dermatology.

The approval of the Product will further enrich the Group’s product portfolio in the field of autoimmune diseases and is expected to bring more treatment options to patients.

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

Hong Kong, 22 May 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, Mr. WANG Huaiyu, 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.