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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

ACCEPTANCE OF BIOLOGIC LICENSE APPLICATION OF USTEKINUMAB INJECTION

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 biologic license application of Ustekinumab Injection (the “**Product**”) developed by CSPC Megalith Biopharmaceutical Co., Ltd (石藥集團巨石生物製藥有限公司), a subsidiary of the Company, has been accepted by the National Medical Products Administration (NMPA) of the People’s Republic of China.

The Product, a fully human IgG1 κ monoclonal antibody, is an IL-12/IL-23 p40 inhibitor. Ustekinumab binds with specificity to the p40 protein subunit of IL-12 and IL-23 with high affinity, disrupting the interaction of IL-12 and IL-23 with the cell-surface receptor, IL-12R β 1, to disrupt IL-12 and IL-23 mediated signal transduction and cytokine cascades, which in turn inhibits the proliferation of keratinocytes and plays a curative effect in the treatment of psoriasis.

The Product is applied as a Class 3.3 therapeutic biological product for the indication of plaque psoriasis in adults and children. The application is mainly based on a pivotal Phase III clinical trial enrolling adult patients with moderate to severe plaque psoriasis who have not responded to, are contraindicated for, or cannot tolerate any of the systemic therapies, including cyclosporine, methotrexate (MTX), PUVA (psoralen and ultraviolet A), and acitretin capsules. The clinical trial results demonstrated that the Product was highly consistent with the originator drug, Stelara[®], in terms of efficacy for the treatment of subjects with moderate to severe plaque psoriasis, and had good safety profile. The Product has good efficacy in the treatment of plaque psoriasis, with a dosing interval of once every 12 weeks during the stabilisation period, possessing a distinct advantage in clinical application.

By Order of the Board
CSPC Pharmaceutical Group Limited
CAI Dongchen
Chairman

Hong Kong, 26 November 2024

As at the date of this announcement, the Board comprises Mr. CAI Dongchen, Mr. ZHANG Cuilong, Mr. WANG Zhenguo, Mr. PAN Weidong, Mr. WANG Huaiyu, Dr. LI Chunlei, Dr. JIANG Hao, Dr. YAO Bing and Mr. CAI Xin as executive directors; and Mr. WANG Bo, Mr. CHEN Chuan, Prof. WANG Hongguang, Mr. AU Chun Kwok Alan, Mr. LAW Cheuk Kin Stephen as independent non-executive directors.