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CSPC

CSPC PHARMACEUTICAL GROUP LIMITED

石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock Code: 1093)

VOLUNTARY ANNOUNCEMENT

NEW DRUG APPROVAL OF THE GROUP'S "LEVOAMLODIPINE MALEATE TABLETS" GRANTED BY THE U.S. FDA

The board of directors (the "**Board**") of CSPC Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that CONJUPRI[®] (levamlodipine maleate) tablets has received marketing approval from the U.S. Food and Drug Administration (FDA) for the treatment of hypertension. Based on our knowledge, this is the first New Drug Application (NDA) ever submitted to the FDA by Chinese pharmaceutical companies, and now granted full approval following a standard review by the FDA.

Levamlodipine is the purified (S)-amlodipine, the pharmacologically active enantiomer in amlodipine (a racemic mixture of (R)- and (S)-amlodipine), for the treatment of hypertension. Amlodipine is a third-generation calcium channel blocker first developed and marketed by Pfizer as NORVASC[®] (amlodipine besylate) tablets in 2.5 mg, 5.0 mg, and 10.0 mg in 1992. The approved CONJUPRI[®] (levamlodipine maleate) tablets come in 1.25 mg, 2.5 mg and 5.0 mg.

Levamlodipine maleate tablets have been marketed by the Group as Xuanning (玄寧) in China since 2003. The clinical development of levamlodipine maleate tablets in the U.S. was based on the safety and efficacy data demonstrated in China and data showing that levamlodipine has less adverse events than amlodipine.

This NDA approval allows the Group to market CONJUPRI[®] in the U.S. and also paves the way for marketing in other parts of the world. As the first levamlodipine approved by the FDA, CONJUPRI[®] is qualified to be the reference standard for drugs with the same active ingredient.

** for identification purpose only*

The NDA approval of levoamlodipine maleate tablets in the U.S. is a manifestation of the Group's commitment to innovation and to bringing the best medicines to patients worldwide.

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

Hong Kong, 20 December 2019

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. LU Hua, Dr. LI Chunlei, Dr. WANG Qingxi and Mr. CHAK Kin Man as executive directors; Mr. LEE Ka Sze, Carmelo as non-executive director; and Mr. CHAN Siu Keung, Leonard, Mr. WANG Bo, Prof. LO Yuk Lam, Dr. YU Jinming and Mr. CHEN Chuan as independent non-executive directors.