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## **CSPC PHARMACEUTICAL GROUP LIMITED**

**石藥集團有限公司**

*(Incorporated in Hong Kong under the Companies Ordinance)*

**(Stock Code: 1093)**

### **VOLUNTARY ANNOUNCEMENT**

#### **SUBMISSION OF NDA TO U.S. FDA FOR LEVOAMLODIPINE MALEATE TABLETS**

The board of directors (the “**Board**”) of the CSPC Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) is pleased to announce that the Group has successfully submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (“**U.S. FDA**”) for levoamlodipine maleate tablets (the “**Drug**”) for the treatment of hypertension. Based on our knowledge, this is the first NDA submission to the U.S. FDA by a Chinese pharmaceutical enterprise.

Levoamlodipine 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 by Pfizer and was approved as NORVASC<sup>®</sup> 2.5 mg, 5.0 mg, and 10.0 mg tablets for the treatment of hypertension in the U.S. in 1992. The levoamlodipine maleate tablets for the submission by the Group in U.S. are 1.25 mg, 2.5 mg and 5.0 mg. Levoamlodipine maleate tablets (brand name: “Xuanning 玄寧”) have been marketed in China since 2003.

The clinical development of the Drug in U.S. was based on efficacy data and enhanced safety profile demonstrated in China. Following a Pre-NDA meeting with the U.S. FDA in October 2018 and completion of the pivotal clinical study in December 2018, the NDA for the Drug was successfully submitted. The standard review time for NDA in U.S. is approximately 12 months.

In addition to the Drug, the Group has a portfolio of innovative drug products currently under development in U.S..

By order of the Board  
**CSPC Pharmaceutical Group Limited**  
**CAI Dongchen**  
*Chairman*

Hong Kong, 5 March 2019

*As at the date of this announcement, the Board comprises Mr. CAI Dongchen, Mr. WANG Zhenguo, Mr. PAN Weidong, Mr. WANG Huaiyu, Dr. LU Hua, Dr. LI Chunlei, Mr. ZHANG Cuilong, 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, Professor LO Yuk Lam, Mr. YU Jinming and Mr. CHEN Chuan as independent non-executive directors.*