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.

Fusen Pharmaceutical Company Limited
福森藥業有限公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 1652)

VOLUNTARY ANNOUNCEMENT APPLICATION FOR CONSISTENCY EVALUATION OF "NICARDIPINE HYDROCHLORIDE INJECTION" BEING ACCEPTED

The board of directors (the "**Board**") of Fusen Pharmaceutical Company Limited (the "**Company**" together with its subsidiaries, the "**Group**") announced that the application for quality and efficacy consistency evaluation of generic drugs of the self-developed "Nicardipine Hydrochloride Injection", developed by the Group's wholly-owned subsidiary, Henan Fusen Pharmaceutical Company Limited, has been submitted to and accepted by the National Medical Products Administration of the PRC. The indications for Nicardipine Hydrochloride Injection are the emergency management of perioperative hypertension and hypertensive emergencies.

According to data from IMS, the annual sales volume of Nicardipine Hydrochloride Injection in the U.S. market was approximately USD32 million in 2023, with sales remaining relatively stable in recent years. Data from Menet reveals that the sales volume of this product in Chinese public healthcare institutions exceeded RMB500 million in 2023, representing a year-on-year increase of 16.14%.

Nicardipine Hydrochloride is a new-generation dihydropyridine calcium channel blocker that selectively dilates arteries, enabling rapid and stable control of hypertensive emergencies. It is recommended as a first-line intravenous antihypertensive drug for a broad range of conditions according to the "Guidelines for Diagnosis and Treatment of Hypertensive Emergencies in the PRC (中國高血壓急症診療規範)."

Nicardipine Hydrochloride Injection offers several advantages, including rapid onset, stable blood pressure reduction, comprehensive target organ protection, non-toxic metabolites, safety in use, stronger vascular selectivity, no impact on heart rhythm, improved myocardial safety, and balanced infusion for blood pressure control. The 5ml:5mg specification of Nicardipine Hydrochloride Injection developed by the Group has been sold in the domestic market in China for several years and enjoys a high level of market recognition. The specifications in this application are 2ml:2mg and 10ml:10mg. Once approved, Fusen Pharmaceutical will become one of the companies in China with the most comprehensive range of specifications for this product, meeting different treatment needs of patients. The consistency evaluation applications for all three specifications have been accepted by the Center for Drug Evaluation of the National Medical Products Administration of the PRC (Acceptance numbers: CYHB2450518, CYHB2450517, and CYHB2450519). Upon approval, the quality and efficacy of Fusen Pharmaceutical's Nicardipine Hydrochloride Injection will align with the reference formulation, making it a viable alternative to the original drug in clinical use. Nicardipine Hydrochloride Injection has demonstrated a promising prospect in the emergency management of perioperative hypertension and hypertensive emergencies.

Nicardipine Hydrochloride Injection is a key product for the Group, and the approval of the new specifications and consistency evaluation will provide more treatment options for patients with perioperative hypertension during surgery and hypertensive emergencies.

By Order of the Board
Fusen Pharmaceutical Company Limited
Mr. Cao Changcheng
Chairman and Executive Director

Hong Kong, 15 October 2024

As at the date of this announcement, the Board of the Company comprises Mr. Cao Changcheng (Chairman), Mr. Hou Taisheng, Mr. Chi Yongsheng, Ms. Meng Qingfen and Mr. Cao Zhiming (formerly known as Mr. Cao Dudu) as Executive Directors, and Mr. Sze Wing Chun, Mr. Lee Kwok Tung Louis and Dr. To Kit Wa as independent non-executive Directors.