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## **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**

## CLINICAL TRIAL APPLICATION FOR THE CLASS 1.1 INNOVATIVE TRADITIONAL CHINESE MEDICINE 'SY617' HAS BEEN ACCEPTED

The board of directors (the "Board") of Fusen Pharmaceutical Company Limited (the "Company", together with its subsidiaries, the "Group") is pleased to announce that the clinical trial application for "SY617" developed by Jiaheng (Zhuhai Hengqin) Pharmaceutical Technology Company Limited\* (嘉亨(珠海横琴)醫藥科技有限公司), a wholly-owned subsidiary of the Group, has been submitted to and accepted by the National Medical Products Administration of the People's Republic of China. The functions and indications of SY617 are to dispel wind and remove toxin, clear epidemic heat, and eliminate dampness. It is used for the treatment of influenza diagnosed as wind-heat with dampness syndrome. Symptoms include fever, heavy-headedness, pharyngalgia, aversion to wind, cough, sore limbs, chest tightness, epigastric distension, red tongue with white or yellow greasy coating, and a pulse that is soft, slippery, or floating and rapid.

According to data from MENET (米內網), the top three traditional Chinese medicines for respiratory diseases in 2022 are heat-clearing and detoxifying medicines, cough, phlegm and panting-relieving medicines, and cold medicines, with the market size of traditional Chinese cold medicines ranking third. The sales of traditional Chinese cold medicines in hospital channels amounted to approximately RMB8.5 billion in 2022, and exceeded RMB4.5 billion in the first half of 2023.

Influenza (commonly known as flu) is an acute respiratory disease caused by the influenza virus, characterised by high infectivity, high incidence, high variability, and recurrent infections. Currently, the mainstream medicine neuraminidase inhibitors recommended by international Guide and marketed in China have certain limitations and may develop resistance, highlighting the urgent need to find other effective treatments. Traditional Chinese medicine has unique advantages in alleviating flu symptoms, enhancing patients' recovery capabilities, and preventing complications.

SY617 consists of two in-house preparations with many years of usage history from the Affiliated Hospital of Chengdu University of Traditional Chinese Medicine (Sichuan Provincial Hospital of Traditional Chinese Medicine). Under the guidance of traditional Chinese medicine theories and after effective combination and translational research, SY617 was once selected as a major scientific and technological project by the Sichuan Provincial Administration of Traditional Chinese Medicine (四川省中醫藥管理局). This product belongs to Class 1.1 prescription drugs, which are innovative traditional Chinese medicines formulated in accordance with traditional Chinese medical theories and have human usage experience. According to the Special Provisions on the Administration of Traditional Chinese Medicine Registration, Phase I clinical trials of SY617 were not required to be conducted. Therefore, the application for Phase II clinical trials was submitted directly, which has now been accepted by the Centre for Drug Evaluation of the National Medical Products Administration of China (Acceptance No.: CXZL2400038). SY617 has shown very promising prospects in treating influenza diagnosed as wind-heat with dampness syndrome.

SY617 is another blockbuster Chinese medicine anti-flu product following Shuanghuanglian Oral Solution and Shuanghuanglian Injection, which further enriches the Group's product pipeline in the area of anti-flu proprietary Chinese medicine treatment. The launch of this product will provide more treatment options for patients with influenza diagnosed as windheat with dampness syndrome.

By order of the Board

Fusen Pharmaceutical Company Limited

Mr. Cao Changcheng

Chairman and Executive Director

Hong Kong, 12 July 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.

\* For identification purposes only