CSPC PHARMACEUTICAL GROUP LIMITED
石藥集團有限公司

(Incorporated in Hong Kong with limited liability)

(Stock code: 1093)

VOLUNTARY ANNOUNCEMENT

MINGFULE (銘復樂®) (RECOMBINANT HUMAN TNK TISSUE-TYPE PLASMINOGEN ACTIVATOR FOR INJECTION) MET PRIMARY ENDPOINT IN PHASE III STUDY FOR THE TREATMENT OF ACUTE ISCHEMIC STROKE

The board of directors (the "**Board**") of CSPC Pharmaceutical Group Limited (the "**Company**", together with its subsidiaries, the "**Group**") is pleased to announce that Mingfule (銘復樂®) (recombinant human TNK tissue-type plasminogen activator for injection) (rhTNK-tPA) independently developed by CSPC Recomgen Pharmaceutical (Guangzhou) Co., Ltd.* (石藥集團明復樂藥業(廣州)有限公司) ("**CSPC Recomgen**"), a non-wholly owned subsidiary of the Company, has met its predefined primary endpoint in a Phase III clinical study (study code: TRACE II) for the treatment of acute ischemic stroke.

TRACE II is a multi-center, prospective, randomized, open-label, blinded-endpoint and non-inferiority Phase III clinical study to evaluate the efficacy and safety of Mingfule (rhTNK-tPA, 0.25mg/kg) in comparison with standard human recombinant tissue plasminogen activator (alteplase) (rt-PA, 0.9mg/kg) for the treatment of acute ischemic stroke within 4.5 hours of symptoms onset. A total of 1,430 subjects were enrolled in the study on a randomized basis, the results has demonstrated that Mingfule is non-inferior to alteplase in efficacy with the primary endpoint (the proportion of excellent functional outcome defined as a mRS of 0 to 1 at 90 days) fully met and has a trend of enhancement in efficacy. The safety profile of Mingfule in the study was similar to alteplase with respect to all safety endpoints including related bleeding, death and adverse events. It was also consistent with the profile and trend shown in clinical study of foreign products with the same mechanism of action for the same indication, but with a lower 90-day mortality rate.

Based on the study results, the Group has submitted an application for pre-BLA meeting to the National Medical Products Administration ("**NMPA**").

Stroke is currently the predominant cause of disability and death in China. According to the China Stroke Center Report 2020, there were approximately 17.8 million stroke patients, 3.4 million new cases of stroke and 2.3 million stroke-related deaths among people older than 40 years of age in China in 2020. The success of Mingfule for the indication of acute ischemic stroke will offer a better treatment option for patients with such disease in the near future. The Group believes that Mingfule, with the synergy provided by the strong commercialization capabilities of NBP in this field, will be able to achieve rapid sales ramp-up and benefit more patients.

ABOUT MINGFULE (rhTNK-tPA)

Mingfule (rhTNK-tPA), a recombinant protein produced by using mammalian cells and genetic engineering technology, was independently developed by CSPC Recomgen and obtained marketing approval from NMPA in January 2015 for thrombolysis treatment in patients with acute myocardial infarction. Mingfule is a third-generation rt-PA product, being a mutant of rt-PA: asparagine at locus 103 substitutes for threonine ("**T**"), glutamine at locus 117 substitutes for asparagine ("**N**"), and 4 alanines at loci 296-299 substitute for lysine, histidine and 2 arginines ("**K**"), respectively. Compared with conventional rt-PA products, Mingfule is by far the safest and most effective rt-PA thrombolytic drug with a longer half-life period and stronger antagonistic capability of plasminogen activator inhibitor-1 (PAI-1), enhancing the ability and specificity to combine with fibrin. Compared with conventional rt-PA products which are administered by intravenous injection followed by continuous intravenous infusion for 1 hour, Mingfule can be administered by a single bolus intravenous injection within 5-10 seconds, which is convenient and allows patients to complete intravenous thrombolytic treatment in a shorter time, demonstrating significant clinical application advantages.

In order to satisfy the unmet clinical needs of patients with acute ischemic stroke, the clinical study of Mingfule for the treatment of acute large-arterial occlusive stroke of longer time window (4.5-24 hours onset) has been initiated. Based on the characteristics of the mechanism of action and the existing clinical data of Mingfule, the Group plans to continue the development of Mingfule in combination with endovascular therapy in ischemic stroke and other indications including deep vein thrombosis, pulmonary embolism, central retinal artery occlusion.

By order of the Board
CSPC Pharmaceutical Group Limited
Cai Dongchen
Chairman

Hong Kong, 4 August 2022

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. WANG Qingxi, Mr. CHAK Kin Man and Dr. JIANG Hao as executive directors; and Mr. WANG Bo, Mr. CHEN Chuan, Prof. WANG Hongguang, Mr. AU Chun Kwok Alan and Mr. LAW Cheuk Kin Stephen as independent non-executive directors.

** For identification purposes only*