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Grand Pharmaceutical Group Limited
遠大醫藥集團有限公司*
(Incorporated in Bermuda with limited liability)
(Stock Code: 00512)

VOLUNTARY ANNOUNCEMENT

**THE PHASE II CLINICAL STUDY IN CHINA OF
THE GROUP'S GLOBAL INNOVATIVE PRODUCT STC3141
HAS COMPLETED THE FIRST PATIENT ENROLLMENT AND DOSING**

This announcement is made by the board of directors (the “**Board**”) of Grand Pharmaceutical Group Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis.

The Board is pleased to announce that the Phase II clinical study for the treatment of sepsis in China of the global innovative drug STC3141, which is developed by the Group’s wholly-owned subsidiary Grand Medical Pty Ltd. (an innovative drug R&D center set up by the Group in Australia), has completed first patient’s enrollment and dosing recently. This is another important R&D progress of the Group in the field of respiratory and severe disease anti-infection.

The study is a multi-center, randomized, double-blinded, placebo-controlled Phase II dose-exploring clinical study. It plans to enroll 180 sepsis patients receiving standard treatment and care, with continuous dosing for 5 days by intravenously administration, and follow up to day 28, to evaluate the efficacy, safety and pharmacokinetics of different doses of STC3141 in patients with sepsis. Previously, the Phase Ib clinical study of STC3141 for the treatment of sepsis in Australia and Belgium, and the Phase Ib clinical study of acute respiratory distress syndrome (“**ARDS**”) in China have both indicated favorable safety and tolerability of the product. In terms of effectiveness, STC3141 showed positive signals in terms of helping patients getting off the ventilator and booster drug, and shortening the length of ICU hospitalization, and the efficacy was dose-dependent. The Phase II clinical study of STC3141 this time will provide more data support to later clinical trials and development directions, to accelerate the product’s global development process.

The field of respiratory and severe disease anti-infection is one of the core strategic areas of the Group. STC3141, a global innovative product with a new mechanism, can neutralize extracellular protein and neutrophils trap net to reverse the body organ damage caused by the excessive immune response, and can be used for a variety of severe indications, such as sepsis, ARDS and other diseases with high clinically mortality and lack of effective therapy. The product has a novel mechanism and the results of related preclinical research have been published in the top academic journal “Nature Communications” in February 2020, which has far-reaching academic influence. In terms of clinical research, the product has received 7 clinical approvals for 4 indications that including sepsis, ARDS, severe SARS-CoV-2 infection (“COVID-19”), and ARDS caused by COVID-19 in 5 countries on 3 continents, namely China, Australia, Belgium, the UK, and Poland, and has completed 3 clinical studies on patients. Its Phase Ib clinical study for the treatment of sepsis that approved in Australia and Belgium in April 2020 and January 2022, respectively, has successfully reached the clinical endpoint in June 2023; the Phase Ib clinical study in patients with ARDS conducted in China was approved by the National Medical Products Administration of the People’s Republic of China in March 2021, and has been completed in October 2022 and successfully reached clinical endpoint; the Phase IIa clinical study for the treatment of severe COVID-19 was approved in Belgium, Poland and the UK in April, September and October 2021, respectively, and has been completed in July 2022 and successfully reached the clinical endpoint. At present, the success of STC3141 in multiple clinical research on the treatment of sepsis, ARDS and severe COVID-19 have all revealed the favorable safety, tolerance and the clinical benefit potential of this product in the treatment of severe diseases, and provides positive data support for the subsequent clinical development of this product in the field of severe diseases. The comprehensive promotion of multi-center clinical study practice also demonstrates the continuous improvement of the Group’s global innovation and R&D capabilities. The first patient enrollment and dosing of the Phase II clinical trial for the project is another important milestone in the clinical research history of the Group.

In addition, the Phase I clinical trial in China of APAD, the Group’s another global innovative product for sepsis, has completed the first patient enrollment and dosing in August this year. This product is a small molecule compound with a novel mechanism of action independently developed by the Group. By antagonizing a variety of pathogen-related molecules and inhibiting the excessive activation of immune cells, it is expected to prevent the occurrence and progression of sepsis from the source. These two products complement each other in their mechanism and are expected to form a favorable product portfolio in the treatment of severe diseases such as sepsis.

The Group always puts focus on the R&D of innovative products and advanced technologies. Adhering to a patient-centered and innovation-driven approach, the Group will continue to increase its investment in world-class innovative products and advanced technologies to meet unmet clinical needs and enrich its product pipeline and improve supply chain. The Group adopts the strategy of “global expansion and dual-cycle operation”, forming a new pattern of domestic and international cycles that synergize with each other. In this way, the Group can make full use of its industrial advantages and R&D capabilities, to accelerate the commercialization process for innovative products and provide patients with more advanced and diverse treatment options globally.

Warning:

The aforementioned product is still in the R&D stage. The approval of commercialization, manufacturing and sale of such product is subject to various factors with uncertainty, and whether it can ultimately benefit is still uncertain. Shareholders and prospective investors of the Company are advised to exercise caution when dealing in the securities of the Company.

By order of the Board
Grand Pharmaceutical Group Limited
Chairman
Dr. Tang Weikun

Hong Kong, 27 November 2023

As at the date of this announcement, the Board comprises four executive directors, namely, Dr. Tang Weikun, Mr. Zhou Chao, Dr. Shi Lin and Mr. Yang Guang, and three independent nonexecutive directors, namely, Ms. So Tosi Wan, Winnie, Dr. Pei Geng and Mr. Hu Yebi.

** For identification purpose only*