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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 Ib CLINICAL TRIAL OF THE GLOBAL INNOVATIVE PRODUCT
STC3141 OF THE GROUP FOR THE TREATMENT OF SEPSIS IN AUSTRALIA
AND BELGIUM REACHED THE CLINICAL ENDPOINT**

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 Ib clinical trial (“**REFINE**”) 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) in the field of severe disease anti-infection, for the treatment of sepsis in Australia and Belgium has successfully reached the clinical research endpoint. It is another significant R&D progress of the Group in the field of severe disease anti-infection.

REFINE is an open-label, multi-center, dose-escalation Phase Ib clinical study that aims to study and evaluate the safety, tolerability, drug metabolism characteristics and preliminary effectiveness of STC3141 in the treatment of sepsis patients with different degrees of renal impairment in intensive care unit (“**ICU**”). The study was approved in Australia and Belgium in April 2020 and January 2022, respectively. It completed the dosing for all subjects in February this year, and has already completed all follow-up and data analysis. The study enrolled 26 evaluable subjects, all of whom have received standard ICU supportive treatment and care that appropriate to their condition, adopting the principle of group dosing for continuous 72 hours intravenous dosing and dose escalation. Subjects in each group were continuously observed until the 28th day after receiving treatment. According to the data analysis of the clinical trial, STC3141 showed favorable safety and was well tolerated in general in the primary endpoint of this study. At the same time, in the secondary endpoint analysis 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. In addition, the application of Phase II clinical study of STC3141 for the treatment of sepsis has been officially accepted by the National Medical Products

Administration of the People’s Republic of China (“NMPA”). The research results of REFINE will provide a solid foundation for the further clinical study of STC3141 conducted in China.

The field of severe 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, acute respiratory distress syndrome (“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. 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 at present; the Phase Ib clinical study conducted in patients with ARDS was approved by NMPA in March 2021, and has successfully reached clinical endpoint in October 2022; 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 successfully reached the clinical endpoint in July 2022. The success of STC3141 in multiple clinical research on the treatment of sepsis, ARDS and severe COVID-19 reveals the favorable safety and the potential trend of clinical benefit of this product in the treatment of patients with 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 practice also demonstrates the continuous improvement of the Group’s global innovation and R&D capabilities. It is another important milestone in the clinical research history of the Group’s innovative drugs that the Phase Ib clinical trial for the treatment of sepsis conducted in Australia and Belgium for this project has successfully reached the clinical research endpoint.

In addition, the Group’s another global innovative product for the treatment of sepsis APAD was approved by NMPA to conduct a Phase I clinical research in healthy volunteers in China in March 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. STC3141 and APAD complement each other in their mechanism and can form a favorable synergistic effect 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. 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, 15 June 2023

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

** For identification purpose only*