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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 GROUP'S GLOBAL INNOVATIVE PRODUCT STC3141 COMPLETED THE ENROLLMENT AND DOSING OF ALL PATIENTS IN THE PHASE Ib CLINICAL TRIAL FOR THE TREATMENT OF SEPSIS IN AUSTRALIA AND BELGIUM

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 global innovative drug STC3141 in the field of severe disease anti-infection, 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 successfully completed the enrollment of all patients in the Phase Ib clinical trial (“**REFINE**”) for the treatment of sepsis in Australia and Belgium recently, and has successfully completed 72 hours of continuous intravenous dosing for the test patients. The clinical research report is expected to be completed within the next 4 months. It is another important R&D progress of the Group in the field of severe disease anti-infection. As a blockbuster product of which the Group owns its global rights, STC3141 has been strategically planned its patents in 12 countries or regions around the world.

REFINE is an open-label, multi-center, dose-escalation Phase Ib clinical study that was granted approval to conduct in Australia and Belgium since April 2020 and April 2022, respectively. The study enrolled 26 patients with sepsis that requiring treatment in intensive care unit (“**ICU**”) to research and evaluate safety, drug metabolism characteristics and preliminary effectiveness of STC3141 by dose-escalation method in the treatment of sepsis patients with different degrees of renal impairment in ICU. Previously, STC3141 has completed the Phase Ia clinical study in healthy volunteers in Australia, which preliminary determined the safety and metabolic properties of the drug in healthy humans. The Phase Ib clinical study this time aims to further evaluate the safety of the drug in patients with sepsis and the influence of different renal impairments on drug metabolism, providing more information for later clinical trials and development directions, to accelerate the product’s global development process.

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, in addition to the Phase Ib clinical research for the treatment of patients with sepsis conducted in Australia and Belgium, the product was granted approval by the National Medical Products Administration of the People’s Republic of China (NMPA) to conduct Phase Ib clinical research in patients with ARDS, and achieved the clinical endpoint in October 2022. It was also granted approval to conduct Phase IIa clinical trials for the treatment of severe SARS-CoV-2 infection (“**COVID-19**”) in Belgium, Poland and the UK in April, September and October 2021 respectively, and has achieved the clinical endpoint in July 2022. The success of STC3141 in the clinical research on the treatment of 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. At present, the project has received seven clinical approvals for four indications that including sepsis, ARDS, severe COVID-19, and ARDS caused by COVID-19 in five countries on three continents, namely China, Australia, Belgium, the UK, and Poland. The comprehensive promotion of multi-center clinical practice demonstrates the continuous improvement of the Group’s global innovation and R&D capabilities. The progress of the project being approved for Phase Ib clinical trials in Australia and Belgium is also another important milestone in the Group’s overseas clinical research process.

In addition, another product in the field of severe anti-infection of the Group, GS221, an oral small molecule 3CL protease (3-chymotrypsin-like protease, 3CLpro) inhibitor against COVID-19, has also conducted clinical study in China successfully. The results of clinical trials that have been completed so far showed favorable safety and tolerance in the subjects, and no adverse events that were serious or led to discontinuation were observed. Meanwhile, it showed trends of improvement of clinical symptoms, shortening time for negative nucleic acid test, and rapid decline of viral load, indicating that GS221 has potential clinical benefits for the patients. GS221 and STC3141 are expected to achieve coverage of treatment of mild, moderate and severe COVID-19 patients, providing more treatment services to the patients for unmet clinical needs.

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, 8 February 2023

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

** For identification purpose only*