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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 III CLINICAL TRIAL IN CHINA OF THE GROUP'S GLOBAL
INNOVATIVE PRODUCT RYALTRIS COMPOUND NASAL SPRAY HAS
COMPLETED THE ENROLLMENT OF ALL SUBJECTS**

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 multicenter Phase III clinical trial of Ryaltris Compound Nasal Spray (“**GSP 301**”), the group’s global innovation drug for the treatment of seasonal allergic rhinitis (“**SAR**”) for patients aged 12 years and above, recently completed all subjects enrollment in China. The study is a randomized, double-blinded, double-simulated, three-arm, parallel-controlled Phase III clinical study, enrolling more than 535 patients aged 12 and above with symptoms of allergic rhinitis, to evaluate the efficacy, safety, tolerability and pharmacokinetics of GSP301 in the treatment of SAR in Chinese adults and adolescents.

GSP 301 is a novel antihistamine and corticosteroid combination nasal spray consisting of olopatadine hydrochloride and mometasone furoate for the treatment of SAR in adults and adolescents. As a compound preparation, GSP 301 can bring more convenient treatment methods to patients with SAR, improve patient compliance, and bring new treatment methods to patients with SAR. The product was approved for commercialization by the U.S. Food and Drug Administration (FDA) in January 2022, and before that it has been commercialized in several countries and regions such as Australia, South Korea, Russia, the United Kingdom and the European Union. GSP 301 was approved by NMPA in October 2021 to conduct Phase III clinical trials, and the first subject was enrolled in April 2022. The completion of the enrollment of all subjects in the Phase III clinical study for SAR is another important milestone in the implementation of the project in China.

China is one of the countries with the highest incidence of allergic rhinitis in the world. According to the relevant epidemiological survey results in China, the prevalence of allergic rhinitis in Chinese adults is about 17.6%, and the sick population is nearly 250 million. Among them, there are approximately 130 million patients with moderate-severe persistent allergic rhinitis, indicating a huge patient population. According to the “Allergic Rhinitis and Its Influence on Asthma (ARIA)” guideline, nasal antihistamines and nasal corticosteroids are the first choice for SAR. For patients with moderate or severe SAR, it is recommended to use a combination of nasal antihistamines and nasal corticosteroids. While the nasal preparations in China are mainly unilateral preparations at present, indicating an urgent clinical demand and a huge market prospect.

Respiratory and severe disease anti-infection segment is one of the Group’s core strategic segments, with nearly 10 products on sale, covering rhinitis, pharyngitis, bronchitis, pneumonia, asthma and other indications. It has formed a relatively comprehensive product portfolio in the field of respiratory disease treatment. Among which, the group’s star products, Qie Nuo and Jinsang Series Products, are both national exclusive products and have been clearly recommended by a number of guidelines and expert consensus. In terms of products under research, the Group’s innovative strategic plan in research products focuses on the significant unmet clinical needs, with a number of products under research, covering allergic rhinitis, sepsis, acute respiratory distress syndrome (“ARDS”), parainfluenza and COVID-19, etc. Among which, STC3141, a global innovative drug for severe diseases such as sepsis, has received seven clinical approvals in five countries and regions. Both Phase Ib clinical study for ARDS in China and Phase IIa clinical study for severe COVID-19 in Europe have reached clinical endpoints. The Phase Ib clinical trial for the treatment of sepsis approved in Australia and Belgium has completed the enrollment and dosing of all patients, and the clinical study report is expected to be completed in the first half of 2023. The application for Phase II clinical research for the treatment of sepsis submitted in China has been officially accepted by NMPA, and other international multi-center clinical trials are also progressing smoothly. Another global innovative product APAD for the treatment of sepsis has been approved by NMPA to conduct Phase I clinical research. In the future, the Group will continue to adopt the R&D concept of independent R&D and global expansion to create a full-cycle management product cluster for chronic airway diseases and a pipeline of anti-infection products for severe diseases, so as to continuously strengthen the Group’s industry position in this field.

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, and the approval of commercialization, manufacturing and sale in China is subject to various factors, and whether can ultimately contribute benefit also have uncertainty. Shareholders and prospective investors of the Company are advised to exercise caution when dealing in

the securities of the Company.

Note: The English transliteration of the Chinese name(s) in this announcement is included for information purpose only, and should not be regarded as the official English name(s) of such Chinese name(s).

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

Hong Kong, 8 May 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*