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 STUDY IN CHINA OF THE GROUP'S GLOBAL INNOVATIVE PRODUCT RYALTRIS® COMPOUND NASAL SPRAY HAS COMPLETED AND HAS SUCCESSFULLY MET PRIMARY 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 III clinical trial conducted in China of Ryaltris® Compound Nasal Spray ("**GSP 301 NS**") ("**GSP 301-308**"), the group's global innovation drug for the treatment of seasonal allergic rhinitis ("**SAR**") for patients aged 12 years and above, has been completed and successfully met primary endpoint recently. This is another significant progress of the Group in the field of respiratory and severe diseases anti-infection.

GSP 301-308 is a randomized, double-blinded, double-simulated, three-arm, multicenter, parallel-controlled Phase III clinical study. It enrolled 535 patients aged 12 and above with SAR in total, which were randomly assigned to GSP 301 NS treatment group and two monomer positive control originator drugs treatment group [Olopatadine Hydrochloride Nasal Spray ("**Patanase NS**") and Mometasone Furoate Nasal Spray ("**Nesuna®NS**")] at a ratio of 1:1:1. It all were dosed for 14 days and the score information of patients on the improvement of symptoms after medication was collected to evaluate the efficacy, safety, tolerability and pharmacokinetics of GSP 301 NS treatment.

GSP 301-308 curative effect evaluation adopts reflective total nasal symptom score ("**rTNSS**") and instantaneous total nasal symptom score (iTNSS) scoring tables which have been recognized internationally. The higher the score in the score table, the more severe the nasal symptoms of the patient. The decrease of the score after medication indicated the improvement of the patient's symptoms, and the greater the change of the score compared with the baseline (score before medication), the more obvious the improvement of the SAR symptoms of the patient after treatment. The primary observational endpoint of efficacy in this clinical study is:

compared the change from the baseline in the mean of the 12-hour rTNSS in the morning and afternoon of the subjects self-assessed during the 14-day period of GSP 301 NS (the "**test drug**") treatment group with the change value of the two monomer positive control drug treatment groups. It means that the test drug is more effective if the test drug group decreases more than the control group. The clinical results of the study showed that, the least square means of changes from baseline in the average morning and afternoon 12-hour rTNSS self-assessment of subjects in the GSP 301 NS group, Patanase NS group and Nesuna®NS group during the 14 days of treatment were -3.84, -2.58 and -3.35 respectively. According to statistical data, the decrease in rTNSS in the GSP 301 NS group was greater than that in the Patanase NS group and Nesuna®NS group, and the inter-group difference was clinically and statistically significant (GSP 301 NS vs. Patanase NS, P<0.0001; GSP 301 NS vs. Nesona®NS, P=0.0018), proving the efficacy scores of GSP 301 NS are better than the monomer originator preparations Patanase NS and Nesuna®NS. Meanwhile, the safety, tolerability and pharmacokinetic features of the product have also met the preset clinical endpoints.

GSP 301 NS is a novel antihistamine and corticosteroid combination nasal spray for the treatment of SAR in adults and adolescents. As a compound preparation, GSP 301 NS 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 approved for commercialization in several countries and regions such as Australia, South Korea, Russia, the United Kingdom and the European Union. GSP 301 NS was approved by the National Medical Products Administration of the People's Republic of China in October 2021 to conduct Phase III clinical trials, completed the first subject enrollment in April 2022, and completed all subjects' enrollment in May 2023. GSP 301-308 is a registration clinical study of GSP 301 NS in China, and its successful completion 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 monomer 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 SARS-CoV-2 infection ("**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, and

has completed 3 clinical studies on patients. Its Phase Ib clinical study in patients with ARDS conducted in China, the Phase IIa clinical study for the treatment of severe COVID-19 conducted in Europe, and the Phase Ib clinical study for the treatment of sepsis conducted in Australia and Belgium have all met clinical endpoints. And it has been approved to conduct Phase II clinical study for the treatment of sepsis in China. Another global innovative product for the treatment of sepsis APAD has been approved to conduct Phase I clinical study and has completed the first patient enrollment. 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, 13 September 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*