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 NDA OF THE GROUP'S GLOBAL INNOVATIVE PRODUCT RYALTRIS® COMPOUND NASAL SPRAY SUBMITTED TO NMPA HAS BEEN ACCEPTED

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 New Drug Application ("**NDA**") of Ryaltris® Compound Nasal Spray ("**GSP 301 NS**"), the Group's global innovation drug for the treatment of allergic rhinitis ("**AR**") in adults and children, that submitted to the National Medical Products Administration of the People's Republic of China ("**NMPA**") has been accepted. This is another significant R&D progress of the Group in the field of respiratory and severe diseases anti-infection.

GSP 301 NS is a novel antihistamine and corticosteroid combination nasal spray for the treatment of AR in adults and children. As a compound preparation, GSP 301 NS can bring more convenient and effective treatment methods to patients with AR, improve patient compliance, and bring new treatment methods to patients with AR in China. The product was approved for commercialization by the U.S. Food and Drug Administration (FDA) in January 2022, in addition, it has also been approved for commercialization in several countries and regions such as Australia, Russia, South Korea, the United Kingdom and the European Union.

GSP 301 NS was approved to conduct Phase III clinical trials ("**GSP 301-308**") by the NMPA in October 2021, and successfully met primary endpoint in September 2023. GSP 301-308 is a randomized, double-blinded, double-simulated, three-arm, multicenter, parallel-controlled Phase III clinical study. It enrolled 535 patients with seasonal AR in total, which were randomly assigned to GSP 301 NS treatment group and two monomer positive control originator drugs treatment group [Patanase®NS (Olopatadine Hydrochloride Nasal Spray) and Nesuna®NS (Mometasone Furoate Nasal Spray)] at a ratio of 1:1:1, to evaluate the efficacy, safety, tolerability and pharmacokinetics of GSP 301 NS treatment. According to clinical results, 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 GSP 301 NS have also met the preset clinical endpoints. The acceptance of NDA of GSP 301 NS 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 AR. For patients with moderate or severe AR, 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; Enerzair® Breezhaler® (indacaterol acetate, glycopyrronium bromide and mometasone furoate powder for inhalation II) and Atectura® Breezhaler® (indacaterol acetate and mometasone furoate powder for inhalation II, III), two global innovative compound preparations of the Group for the treatment of asthma, were successfully included in the National Medical Insurance Drug Catalog in January 2023. 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, treatment of acute respiratory distress syndrome (ARDS), parainfluenza and SARS-CoV-2 infection (COVID-19), etc. 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 approval of aforementioned product's commercialization, manufacturing and sale 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 February 2024

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*