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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**

# GLOBAL INNOVATIVE COMBINATION PRODUCT RYALTRIS® NASAL SPRAY IS APPROVED TO BE COMMERCIALIZED IN CHINA

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 Ryaltris® Compound Nasal Spray ("**GSP 301 NS**"), a global innovative drug developed by Glenmark Specialty S.A. ("**Glenmark**"), has been granted Drug Registration Certificate by the National Medical Products Administration of the People's Republic of China ("**NMPA**") for the treatment of allergic rhinitis ("**AR**") in adults and children. The approval was granted with no supplementary filing requirements during the drug review process, achieving a "zero supplementation request" (零發補) approval. This is another significant R&D progress of the Group in the field of respiratory and critical and severe disease. In February 2019, the Group entered into an exclusive license agreement with Glenmark, obtaining the exclusive rights for commercialization for Ryaltris® Compound Nasal Spray in China.

Ryaltris® is a novel antihistamine and corticosteroid combination nasal spray for the treatment of moderate to severe seasonal AR in adult and pediatric patients 6 years of age and older, and moderate to severe perennial AR in adult and pediatric patients 12 years of age and older. As a compound preparation, Ryaltris® 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, demonstrating strong sales performance and significant market potential.

Ryaltris® was approved to conduct Phase III clinical trials ("**GSP 301-308**") by the NMPA in October 2021, successfully met primary endpoint in September 2023, and the New Drug Application (NDA) was submitted and accepted in February 2024. 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 Ryaltris® treatment group and two monomer positive control originator drugs treatment group [Patanase®NS (Olopatadine Hydrochloride Nasal Spray) and Nasonex®NS (Mometasone Furoate Nasal Spray)] at a ratio of 1:1:1, to evaluate the efficacy, safety, tolerability and pharmacokinetics of Ryaltris® treatment. According to clinical results, the efficacy scores of Ryaltris® are better than the monomer originator preparations Patanase®NS and Nasonex®NS. Meanwhile, the safety, tolerability and pharmacokinetic features of Ryaltris® have also met the preset clinical endpoints. The approval of commercialization of Ryaltris® 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 2022 "Chinese Guidelines for Diagnosis and Treatment of Allergic Rhinitis", intranasal antihistamines and intranasal corticosteroids are the first-line therapies for AR. Meta-analysis demonstrates that combination therapy with intranasal antihistamines and intranasal glucocorticoids significantly improves both nasal and ocular symptoms in patients with moderate-to-severe AR, outperforming monotherapy. While the nasal preparations in China are mainly monomer preparations at present, indicating an urgent clinical demand and a huge market prospect.

Respiratory and critical and severe disease segment is one of the Group's core strategic segments. Its products on sale cover a wide range of indications such as rhinitis, bronchitis, pneumonia, asthma, and chronic obstructive pulmonary disease, etc. It has formed a relatively comprehensive product portfolio in the field of respiratory disease treatment. Among which, the core product Qie Nuo an exclusive product in China, and has been clearly recommended by a number of guidelines and expert consensus; Enerzair® Breezhaler® and Atectura® Breezhaler®, the Group's two global innovative compound preparations for the treatment of asthma, were successfully included in the National Medical Insurance Drug Catalog in January 2023, and have now entered into a rapid expansion period; the Group's fluticasone propionate nasal spray for the treatment of allergic rhinitis was approved to commercialized as the first generic product in China. 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 sepsis, treatment of acute respiratory distress syndrome (ARDS), and sinusitis, 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 product pipeline of critical and severe disease, 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 production, sales and contributed profit of aforementioned product is subject to various factors such as market changes with 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, 10 November 2025

*As at the date of this announcement, the Board comprises four executive directors, namely, Dr. Tang Weikun, Mr. Zhou Chao, Mr. Yang Guang and Ms. Lam Chit Yee Jessica, and four independent non-executive directors, namely, Ms. So Tosi Wan, Winnie, Dr. Xing Li Na, Dr. Pei Geng and Mr. Hu Yebi.*

** For identification purpose only*