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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 IIa CLINICAL STUDY CONDUCTED IN CHINA OF THE GROUP'S GLOBAL INNOVATIVE OPHTHALMIC DRUG GPN00884 HAS COMPLETED THE FIRST PATIENT ENROLLMENT

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 IIa clinical study conducted in China of the Group's global innovative ophthalmic drug GPN00884 used to delay the progression of myopia in children, has completed the first patient enrollment recently. This study is a randomized, double-blind, placebo parallel-controlled Phase IIa clinical trial, planning to enroll more than 80 myopic subjects aged 6 to 12 years old. It aims to preliminarily evaluate effectiveness of GPN00884 eye drops in delaying the progression of myopia in children and its safety in children with myopia.

GPN00884 eye drops are an innovative drug with a new mechanism used to delay the progression of myopia in children. Compared with low-concentration atropine eye drops, GPN00884 eye drops have no mydriasis effect, will not cause adverse reactions such as photophobia and decreased accommodation, and the dosing period is not limited, which can improve patient compliance. At present, there is still a lack of drugs with clear efficacy and safety in terms of delaying the progression of myopia in children in China, indicating an unmet clinical need in the field of this disease. GPN00884 eye drops are expected to provide doctors and patients with a new clinical treatment solution for delaying the progression of myopia in children.

Previously, GPN00884 eye drops was approved to conduct Phase I clinical trial in China in March 2024, all patients were enrolled in August of the same year, and Phase I clinical trial was completed in March 2025. The Phase I clinical results showed that GPN00884 has favorable safety and tolerance after single and multiple doses in healthy subjects, with linear pharmacokinetic characteristics. It is another major milestone for the Group in the direction of ophthalmology in the segment of ENT that the first patient in the Phase IIa clinical study of this product was enrolled this time.

Myopia is one of the most severe public health problems worldwide. According to the World Report on Vision issued by the World Health Organization, the number of myopia patients in the world reached 2.6 billion in 2020, of which 312 million were under the age of 19; especially the prevalence of myopia in high-income countries in Asia-Pacific region reached 53.4%, which is much higher than that in Australia, Europe, Americas and other regions. China is the country with the most myopia in the world. According to the survey results of the National Health Commission, the prevalence of myopia among adolescents in China ranked first in the world. In 2022, the overall myopia rate of children and adolescents in China was 51.9%. Frost & Sullivan predicts that by 2030, there will be 190 million people with myopia under the age of 20 in China. Myopia in children and adolescents shows a trend of early age of onset, rapid progression, and deep degree, and the incidence rate is also rising. In 2018, the Ministry of Education and the National Health Commission and other eight departments jointly issued the Implementation Plan for Comprehensive Prevention and Control of Myopia in Children and Adolescents\*(《綜合防控兒童青少年近視實施方案》), and the National Health Commission has also continuously issued notices such as the "14th Five-Year Plan" National Eye Health Plan (2021-2025)\*(《「十四五」全國眼健康規劃(2021-2025年)》) and the Guidelines for Myopia Prevention and Treatment (2024 Edition)\*(《近視防治指南(2024 年版)》). The prevention and control of myopia has become one of the national strategies. Driven by the large number of patients, the clinical and market demand for myopia treatment products will continue to expand.

The Group always regards the field of ophthalmology as one of its important strategic development directions, continuously focus on ophthalmic drug innovation, adheres to the path of professional development, to improve its industry position and market competitiveness constantly. At present, the Group has established a "professional, full-series, multi-variety" innovative drug product system. Through the strategy of combining cooperative introduction with independent research and development, it reserves a variety of global innovative products for the treatment of "dry eye", "Demodex blepharitis", "anti-inflammatory and analgesic after ophthalmology surgery", "pterygium" and "myopia", etc., building differentiated competitive advantages, and has made significant research and development progress. In the next three years, a number of innovative products are expected to be approved for commercialization.

Among them, varenicline tartrate nasal spray (OC-01), currently the world's first and only preservative-free, multi-dose, sterile packaged nasal spray approved for the treatment of mild, moderate and severe dry eye, has been approved for commercialization in the United States in October 2021, has been approved for commercialization by the National Medical Products Administration of the People's Republic of China ("NMPA") in November 2024, and its first batch of commercial prescriptions has been issued in Mainland China in July 2025; GPN00833, a hormone nanosuspension eye drops for anti-inflammatory and analgesic, has completed the Phase III clinical trial in China and successfully met the primary endpoint in November 2024; the global innovative ophthalmic product GPN01768 (TP-03, lotilaner ophthalmic solution, 0.25%) for the treatment of Demodex blepharitis has had its new drug application submitted to the NMPA and was accepted, and was approved for commercialization by the Pharmaceutical Administration Bureau of Macao Special Administrative Region of China in May 2025; and GPN00153 (CBT-001), an innovative and improved new drug for the treatment of pterygium, has completed the first subject enrollment in the Phase III clinical study in China in the international multi-center Phase III clinical study in March 2024, and has completed the enrollment of all subjects in global centers of the international multi-center Phase III clinical study in June 2025.

In the future, the Group will accelerate the comprehensive and differentiated strategic plan of its R&D pipeline, and continuously enrich its innovative product reserves in the ophthalmic segment. In addition, the Group has attracted and trained a group of professionals with both clinical and marketing experience in the field of ophthalmology, and established a professional marketing team that is customer-centric and academic-led, forming a nationwide marketing network. As innovative ophthalmic products continue to be approved, the Group will make full use of its core advantages in this field, continue to explore the cutting-edge innovation track of ophthalmology, further strengthen the professional promotion and brand building of core products, and provide new momentum for the Group's sustainable and healthy development.

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, and whether it can ultimately benefit is still uncertain. Shareholders and prospective investors of the Company are advised to exercise caution when dealing in the securities of the Company.

Note: In this announcement, the Chinese translations of organizations and products are unofficial translations and are for display purposes only.

By order of the Board

Grand Pharmaceutical Group Limited

Chairman

Dr. Tang Weikun

Hong Kong, 26 October 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