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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 I 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 I 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-controlled, and dose-escalating Phase I clinical trial, planning to enroll 40 healthy subjects to evaluate the safety, tolerability and pharmacokinetic features of GPN00884 eye drops in healthy subjects after single and multiple dosing.

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, no 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.

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, 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 2020, the overall myopia rate of children and adolescents in China was 52.7%. 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”, and 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.

As one of the major Eye, Nose & Throat (“ENT”) drug R&D, production and sales integrated enterprises in China, the number of the Group’s products on sale ranks among the top of the industry. Its treatment areas covering diseases in multiple departments including ophthalmology, otolaryngology, and stomatology, covering chemical preparations, Chinese drug preparations and health products, including prescription drugs, OTC drugs, medical devices, consumer goods and other major categories, covering both channel of inside and outside hospital, create a “great ENT ecosystem” by integrating “prevention + treatment + health care”. In terms of innovation and R&D, the Group has reserved a few world-wide innovative products for the treatment of “myopia”, “dry eye”, “pterygium”, “anti-inflammatory and analgesic after ophthalmology surgery”, and “Demodex blepharitis” and “meibomian gland disease with Demodex mites”, and have made multiple significant research and development progresses. Among them, the innovative product CBT-001 for the treatment of pterygium was approved to conduct Phase III clinical study in China in March 2023; GPN00136 (BRM421), a small molecule peptide drug for the treatment of dry eye, was approved to conduct Phase II clinical study in China in April 2023; GPN00833, a hormone nanosuspension eye drops for anti-inflammatory and analgesic, has completed first patient’s enrollment and dosing in Phase III clinical trial in China in October 2023. In terms of overseas registration, the product was approved for commercialization by the FDA in March 2024; TP-03, a global innovative ophthalmic preparation for the potential treatment of Demodex blepharitis and Meibomian Gland Disease (MGD) in patients with Demodex mites, has completed Phase III clinical study conducted in China. In terms of overseas registration, the product was approved for commercialization by the FDA in July 2023. It is the first and only drug approved by the FDA for Demodex blepharitis. In the future, the field will adhere to the development strategy of “Chinese and Western combination” and “treatment with both medicines and devices”, continuously strengthen the influence of the industry, and achieve new breakthroughs in the business 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. The approval of commercialization, manufacturing and sale of such product is subject to various factors with uncertainty. Shareholders and prospective investors of the Company are advised to exercise caution when dealing in the securities of the Company.

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

Hong Kong, 11 June 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 non-executive directors, namely, Ms. So Tosi Wan, Winnie, Dr. Pei Geng and Mr. Hu Yebi.

** For identification purpose only*