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 OVERSEAS PHASE III CLINICAL STUDY OF A GLOBAL INNOVATIVE HORMONE NANOSUSPENSION EYE DROPS SUCCESSFULLY REACHED CLINICAL 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 Group's partner in the field of ophthalmology, Formosa Pharmaceuticals, Inc. has announced that the Phase II clinical study and two Phase III clinical studies of APP13007, an anti-inflammatory and analgesic hormone nanosuspension eye drop, have successfully reached the clinical endpoints. According to clinical results, APP13007 has significant effectiveness in the treatment of postoperative anti-inflammatory and analgesic ophthalmology with favorable safety. It is planning to submit New Drug Application (NDA) to the United States Food and Drug Administration (FDA) in the first half of this year. The Group has the exclusive development and commercialization rights of this product in Mainland China, Hong Kong and Macau.

APP13007 is anti-inflammatory and analgesic hormone nano-suspension eye drops. Its unique nano-preparation technique effectively solves the low bioavailability and safety risks caused by low water solubility of hormone products. The Phase II clinical trial (CPN-201) and two Phase III clinical trials (CPN301 and CPN-302) of APP13007 in the United States are randomized, double-blinded, and placebo-controlled. A total of nearly 900 patients after cataract surgery were enrolled, and the main clinical endpoint was to evaluate the proportion of subjects whose ocular inflammation completely disappeared after cataract surgery and the pain was completely relieved and continued without recurrence. According to the results of the comprehensive statistical analysis of the three clinical studies, in terms of safety, the data of the treatment group and the control group were comparable, and the subjects tolerated APP13007 well; in terms of anti-inflammation, after 14 days of continuous administration, the proportion of the number of front cells (inflammation indicators) in the treatment group and the control group was zero was 58.2% vs 17.3%; in terms of analgesia, the proportion of

subjects in the treatment group and the control group who responded that the pain index was zero on the 4th day was 81.4% vs 47.4%; in terms of drug effect persistence, the proportion of subjects in the treatment group and control group who maintained a pain index of zero from the 4th day to the 15th day was 71.6% vs 27.7%. The above analysis shows that APP13007 is significantly better than the control group in the treatment of anti-inflammatory and analgesic after cataract surgery with favorable safety. In addition, in terms of registration in China, the Group has submitted an Investigational New Drug ("**IND**") application of GPN00833 (APP13007) to the National Medical Products Administration of the People's Republic of China ("**NMPA**") in January this year and has been accepted.

Hormone ophthalmic preparations are one of the most commonly used and effective drugs for the treatment of ocular inflammatory reactions, which can quickly and effectively control the inflammatory response and condition after ophthalmic surgery. However, due to the limitation of ophthalmic preparation technology, the current hormone ophthalmic preparations are dominated by imported products in China. There are no new products on the market in this market segment in the past decade. There is an urgent need for strong hormonal eye drops with high safety in clinic, and APP13007 product is expected to fill the gap in clinical demand.

As one of the major ophthalmic drug R&D, production and sales integrated enterprises in China, the Group has nearly 30 ophthalmic products, mainly focusing on major indications such as dry eye, retinal hemorrhage, glaucoma, cataract, anti-inflammation and myopia, covering chemical preparations, Chinese drug preparations and eye health products, including prescription drugs, OTC drugs, medical devices, consumer goods and other major categories, creating a "public eye care 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" and "anti-inflammatory and analgesic after ophthalmology surgery". Among them, the innovative product CBT-001 for the treatment of pterygium was approved to conduct Phase III clinical study in China in March this year; GPN00136 (BRM421), a small molecule peptide drug for the treatment of dry eye, submitted an IND application to NMPA in January this year and has been accepted. In the future, the field will adhere to the development strategy of "leading by the blockbuster innovative drugs and devices, and based on the products of the public eye care ecosystem", 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 approval of commercialization of above products in China 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.

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, 11 April 2023

As at the date of this announcement, the Board comprises four executive directors, namely, Dr. Tang Weikun, Dr. Shao Yan, Dr. Niu Zhanqi and Dr. Shi Lin, and three independent nonexecutive directors, namely, Ms. So Tosi Wan, Winnie, Dr. Pei Geng and Mr. Hu Yebi.

** For identification purpose only*