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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 NDA OF A GLOBAL INNOVATIVE HORMONE NANOSUSPENSION EYE
DROPS WAS APPROVED BY THE FDA**

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 Formosa Pharmaceuticals, Inc., the Group’s partner in the field of ophthalmology, has announced that the New Drug Application (“**NDA**”) of GPN00833 (APP13007), an anti-inflammatory and analgesic hormone nanosuspension eye drops, has been approved by the United States Food and Drug Administration (“**FDA**”) recently. The Group has the exclusive development and commercialization rights of this product in Mainland China, Hong Kong and Macau. The significant overseas progress of this product this time will further support the registration work in China.

GPN00833 is anti-inflammatory and analgesic hormone nano-suspension eye drops. Its main active ingredient, clobetasol propionate, is a potent glucocorticoid, which has efficient local anti-inflammatory and strong capillary contraction effect. Meanwhile, its unique nano-preparation technique effectively solves the low bioavailability and safety risks caused by low water solubility of hormone products. The overseas Phase II clinical study and two Phase III clinical trials of this product have successfully reached the clinical endpoints. According to clinical results, GPN00833 has significant effectiveness in the treatment of postoperative anti-inflammatory and analgesic ophthalmology with favorable safety. At present, the product has been approved to conduct Phase III clinical research in China in April 2023, and the first patient has been enrolled.

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 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; the Investigational New Drug (IND) application in China of GPN00884, a global innovative ophthalmic drug for the delay of progression of myopia in children, was submitted to the National Medical Products Administration of the People’s Republic of China (NMPA) and has been accepted in December 2023. 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 aforementioned product is still in the R&D stage in China. 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, 7 March 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*