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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 III CLINICAL TRIAL IN CHINA OF THE GROUP'S GLOBAL INNOVATIVE OPHTHALMIC DRUG GPN00833 HAS COMPLETED THE FIRST PATIENT ENROLLMENT AND DOSING

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 III clinical trial of GPN00833, an anti-inflammatory and analgesic hormone nanosuspension eye drop of the Group, has completed first patient's enrollment and dosing recently. The clinical study is a multi-center, randomized, double-blinded, placebo-controlled, and parallel-grouped Phase III clinical study, planning to enroll 252 patients who underwent cataract surgery to evaluate the efficacy and safety of GPN00833 for the treatment of inflammation and pain after cataract surgery in Chinese population. It is a significant R&D progress of the Group in the field of ophthalmic disease treatment.

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 New Drug Application (NDA) of the product has been submitted to the United States Food and Drug Administration (FDA) in the first half of this year.

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, was approved to conduct Phase II clinical study in China in April this year. 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. 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, 24 October 2023

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