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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 INTERNATIONAL MULTI-CENTER PHASE III CLINICAL TRIAL FOR THE TREATMENT OF PTERYGIUM OF THE GROUP'S GLOBAL INNOVATIVE OPHTHALMIC DRUG CBT-001 HAS REACHED ITS PRIMARY 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 international multi-center Phase III clinical trial of the Group's global innovative ophthalmic drug CBT-001 (GPN00153) for the treatment of Pterygium has reached its primary clincial endpoint recently. Both doses of CBT-001 demonstrated statistically significant improvements versus vehicle in conjunctival hyperemia at Month 3 and pterygium lesion length at Month 12. The findings mark the first time a drug has demonstrated therapeutic effects in pterygium through a statistically significant improvement in hyperemia and lesion size. Additional analyses are ongoing.

Key data highlights:

- Conjunctival hyperemia: This study directly targeted the most prominent symptom of ocular surface hyperemia in patients with pterygium, which aimed at objectively verifying the rapid effect of the drug in alleviating local inflammation and redness. The clinical data from this study showed that at Month 3, both dose groups of CBT-001 (0.1% and 0.2%, administered twice daily) demonstrated a highly statistically significant improvement in conjunctival hyperemia as compared with the control group ($p<0.001$). An even more encouraging signal is that this clinical improvement was observable as early as Week 2 after administration and persisted throughout the entire 12-month follow-up cycle. These results are consistent with those of the Phase II clinical trial.

- Pterygium lesion length: This indicator is designed to assess the drug's capacity to inhibit the continued expansion of the lesion towards the cornea. As shown by the preliminary results from the Phase III Study in this publication, at Month 12, both dose groups demonstrated a statistically significant reduction in pterygium lesion length as compared with the control group ($p<0.001$). In terms of lesion size, the benefit in the treatment group compared with the vehicle was approximately 10% of the baseline value. Notably, at Month 12, the observed treatment effect had not yet plateaued.

- Safety: Superficial punctate keratitis was the most commonly reported adverse event in the CBT-001 0.1% group (20% versus 8% in the vehicle group), and the majority of events resolved after treatment with artificial tears. Other individual adverse events occurred in fewer than 10% of patients in the 0.1% group. Similar adverse events were reported with the 0.2% dose at a moderately higher rate.

Cloudbreak Pharma Inc. is conducting additional analyses of the Phase III results, including secondary endpoints and subgroup analyses, and intends to meet with the FDA to review the study findings and discuss potential next steps for the CBT-001 development programme, including the clinical and regulatory implications of the results.

This clinical trial [CS-301 (NCT05456425)] is an international, multi-center, randomized, double-blinded, vehicle-controlled Phase III trial, aiming to evaluate the efficacy of two doses of CBT-001 ophthalmic emulsion (0.1%, 0.2%) compared to a vehicle in patients with pterygium, with two doses daily for 24 months. The primary efficacy endpoints include reduction in conjunctival hyperemia related to the vascularized pterygium lesion at 3 months and prevention of pterygium progression at 12 months. The study protocol also includes a 12-month extension for an additional 12 months of safety data. The enrollment began in the United States in June 2022, and expanded to China, New Zealand, Australia, and India. The topline results summary covers 659 patients.

Pterygium is a common chronic inflammation and proliferative ocular surface disease. It usually occurs at corner of the conjunctiva and may gradually affect cornea, leading to astigmatism or covering the pupil, resulting in diminished vision or even blindness. According to the data of the *World report on vision* of the World Health Organization, the global prevalence of pterygium is 10.2%, and it is as high as 33% in rural areas of China. According to relevant literature, the prevalence of people aged 40 and above in China is 13.4%, and it shows a continuous upward trend with increasing age. Currently, there are no medications specifically indicated for the treatment of pterygium. In cases accompanied by significant inflammation, preservative-free artificial tears may be used topically to lubricate the ocular surface, or low-concentration corticosteroid eye drops may be used for a short period to reduce congestion and edema. Existing therapeutic drugs have not demonstrated definitive efficacy and carry safety risks associated with long-term use. Severe cases can be treated with surgery, but the recurrence rate after sclerectomy for pterygium is as high as 31-83%. Recurrent episodes can lead to serious complications, such as symblepharon, narrowing of the conjunctival sac, restricted ocular motility, strabismus, and diplopia. It is evident that there remains a significant unmet clinical need in the treatment of pterygium.

CBT-001 is a novel multi-kinase inhibitor (MKI) eye drop independently developed by Cloudbreak Pharma Inc. (HKEX: 2592). It is an innovative, improved formulation of nintedanib, the core active ingredient in OFEV, a drug already approved for the treatment of pulmonary fibrosis. By inhibiting multiple kinase receptor pathways, the drug blocks neovascularization and tissue fibrosis. It addresses the pathological root cause of pterygium, fibrovascular proliferation, rather than merely alleviating clinical symptoms. Previous, Phase II clinical trials for CBT-001 in the United States have demonstrated its ability to significantly and persistently inhibit both neovascularization and ocular hyperemia associated with pterygium, while maintaining a favorable safety profile. The product is indicated for all stages of pterygium, including mild, moderate, and severe, and may also be used to prevent recurrence following pterygium surgery. The Group has obtained exclusive rights for the manufacturing (including technology transfer) and commercialization of CBT-001 in Mainland China, the Hong Kong Special Administrative Region of China, the Macao Special Administrative Region of China, and Taiwan Region of China. If approved for commercialization, CBT-001 would become the world's first therapeutic drug product for pterygium. It has the potential to fundamentally transform the current clinical landscape, which relies primarily on surgery and palliative care, and to establish a differentiated competitive advantage for the Group in the field of ophthalmic anti-inflammatory and anti-proliferative treatments.

The Group always regards the field of ophthalmology as one of its important strategic development directions, continuously focuses on ophthalmic drug innovation, adheres to the path of professional development, to improve its industry position and market competitiveness constantly. At present, by employing a strategy that combines cooperative introduction with independent research and development, the Group 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 is expected to offer patients a broader range of treatment options and improve their quality of life. Simultaneously, the Group continues to strengthen the development of its products' clinical evidence-based medical framework and its professional academic promotion system, providing clinicians with comprehensive disease management solutions and tailored product-related services. Moving forward, this segment will remain deeply committed to cutting-edge innovation, continuously enhancing its industry influence and achieving new breakthroughs in its field.

In the ophthalmology segment, Xingterun® (varenicline tartrate nasal spray, OC-01) for the treatment of dry eye disease is 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. The product was approved for commercialization in the United States in October 2021, approved for commercialization by the National Medical Products Administration of the People's Republic of China ("**NMPA**") in November 2024, and achieved its first commercial prescription since its commercialization in Mainland China in July 2025; the global innovative ophthalmic product Manmu'an® (lotilaner ophthalmic solution 0.25%, TP-03) for the treatment of *Demodex* blepharitis was approved for commercialization by the Pharmaceutical Administration Bureau of Macao Special Administrative Region of China in May 2025, was approved for commercialization by the NMPA in March 2026; and achieved its first batch of commercial prescriptions issued in Mainland China in October of the same year. GPN00833, hormone nanosuspension eye drops for anti-inflammatory and analgesic, completed the Phase III clinical trial in China and met the primary endpoint in November 2024; GPN00884, a global innovative ophthalmic drug used to delay the progression of myopia in children, completed the first patient enrollment in the Phase IIa clinical study conducted in China in October 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, 5 November 2026

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*