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 II CLINICAL TRIAL IN CHINA OF THE GROUP'S CLASS 1 INNOVATIVE TRADITIONAL CHINESE MEDICINE GPN01360 SUCCESSFULLY REACHES THE 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 innovative traditional Chinese medicine ("**TCM**") GPN01360 for the treatment of depression successfully reached its clinical endpoint in Phase II clinical trials conducted in China recently. The success of the clinical trial marks a significant milestone for the Group in the direction of Chinese patent medicine in the field of the ENT (Ear, Nose, and Throat) segment.

This study was a randomized, double-blind, placebo-controlled, multicenter phase II clinical trial that enrolled 148 patients with depression. Patients received oral administration for 8 weeks. It aims to preliminarily evaluate the efficacy and safety of GPN01360 compared to placebo in treating depression (liver stagnation and spleen deficiency syndrome). The primary clinical endpoint was the change in the total score of the Hamilton Depression Rating Scale ("**HAMD-17**") from baseline at week 8; secondary endpoints included efficacy and safety metrics such as the change in the total score of the Montgomery-Asberg Depression Rating Scale ("**MADRS**") from baseline at week 8, the HAMD-17 remission rate and response rate at week 8, the change in the Pittsburgh Sleep Quality Index ("**PSQI**") score from baseline at week 8, the changes in the Clinical Global Impression Scale-Disease Severity (CGI-S) and Clinical Global Impression Scale-Overall Improvement (CGI-I) scores from baseline, and the incidence of adverse events.

The results showed that after 8 weeks of treatment, the primary efficacy endpoint, HAMD-17, showed a significant change from baseline compared to placebo ($P=0.0006<0.05$); secondary efficacy endpoints such as MADRS, TCM syndrome score, HAMD-17 remission rate and efficacy, and Hamilton Anxiety Scale (HAMA) all showed significant differences compared to placebo after 8 weeks of treatment ($P<0.05$); PSQI showed an obvious treatment trend.

Furthermore, GPN01360 demonstrated favorable safety and tolerability, with no significant toxic side effects observed throughout the trial. These results indicate that GPN01360 has favorable safety and efficacy in the treatment of depression, and also shows significant improvement in symptoms such as depression accompanied by anxiety and insomnia.

GPN01360 is a Class 1.1 innovative TCM for the treatment of depression (liver stagnation and spleen deficiency syndrome). Based on the ancient classic formula "Xiaoyaosan(逍遙散)", it was developed and optimized through modern pharmacological and clinical research. The prescription consists of 12 TCM herbs, including Bupleurum, Turmeric Root Tuber, and Finger Citron, with the effects of soothing the liver and strengthening the spleen, relieving depression, and calming the mind. This TCM is mainly used to treat depression of the liver stagnation and spleen deficiency type, of which the typical symptoms include low mood, slow thinking, decreased willpower, irritability, anxiety, insomnia, forgetfulness, poor appetite, and fatigue. Preliminary human clinical studies involving nearly 100 people have shown that GPN01360 demonstrates favorable efficacy and safety in improving depressive symptoms, relieving anxiety and insomnia, and regulating spleen and stomach function.

Depression, also known as depressive disorder, is a common mental disorder that can affect a patient's work, study, and social life. In severe cases, it can lead to suicide, and the relapse rate is as high as 75%-90%. It is a lifelong illness and the leading cause of the global mental health burden, representing a major global public health problem. According to the latest statistics from the World Health Organization (WHO), approximately 332 million people worldwide suffer from depression, with an overall prevalence of about 4.0%, of which the prevalence in adults reaches 5.7%. Depression is the second leading cause of years lived with disability ("**YLDs**") globally, and the leading cause of YLDs in the 15-29 age group. It places a huge burden on global social productivity, with depression and anxiety resulting in 12 billion lost workdays and nearly USD 1 trillion in economic losses annually. The China Mental Health Survey shows that the prevalence of depression among adults in China is 6.8%, which is higher than the global average, with a total of over 90 million people affected. Currently, the clinical cure rate for depression is less than 30%, and clinical treatment still faces several bottlenecks. For example, the delayed efficacy of commonly used antidepressants lead to the suicide risk cannot be controlled quickly, and adverse drug reactions can affect patient adherence. Therefore, there remains a significant unmet clinical need for the treatment of depression, and the Group's GPN01360 is expected to provide a novel clinical treatment option.

As one of the major ENT drug R&D, production and sales integrated enterprises in China, the Group ranks among the top in the industry in terms of the number of product pipelines. Its treatment areas include diseases in multiple fields such as 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. It has established a professional marketing team and formed a nationwide marketing network. Chinese patent medicine is a key direction in the field of the Group's ENT segment. Leveraging the core advantages of TCM in chronic disease treatment, the Group continues to cultivate the Chinese patent medicine market. While consolidating and improving its ENT product matrix, the Group has successfully expanded its business into the treatment of cerebro-cardiovascular chronic diseases and neurology by strategically developing several TCM with significant competitive advantages, such as Maixuekang series products, Danzhen Headache Capsules, and Lishukang Capsules. This has enabled the Group to achieve a strategic transformation of its Chinese patent medicine business from a single-focus area of ENT to a comprehensive chronic disease treatment approach. Leveraging the powerful synergistic

effects of its "carrier-cluster" product pipeline, the Group not only continues to expand its leading advantage in the existing ENT field, but also actively explores new chronic disease treatment areas such as cardiology and neurology, aiming to systematically broaden the treatment boundaries of chronic disease management and open up new growth avenues.

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: 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, 8 December 2025

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*