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 APPLICATION FOR THE GROUP'S GLOBAL INNOVATIVE RDC TLX591 TO JOIN INTERNATIONAL MULTICENTER PHASE III CLINICAL TRIAL IS ACCEPTED BY THE NMPA

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 global innovative radionuclide-drug conjugate ("**RDC**") TLX591 for the treatment of prostate cancer, has recently had its Investigational New Drug (IND) application for inclusion in an international multicenter Phase III clinical trial formally accepted by the the National Medical Products Administration of the People's Republic of China ("**NMPA**"). This represents a significant R&D progress for the Group in the field of nuclear medicine anti-tumor diagnosis and treatment. The Group attaches great importance to the global development strategy of the nuclear medicine industry, actively promotes the global development and registration process of innovative nuclear medicine products, and will continuously deepen the global expansion of the Group's nuclear medicine product pipeline.

The study is a prospective, randomized, controlled, open-label, international multicenter Phase III clinical trial, planning to enroll over 500 patients across multiple countries, including China, the United States, Australia, and New Zealand. It aims to evaluate the efficacy and safety of TLX591 in combination with standard care compared to standard care alone in patients with progressive metastatic castration-resistant prostate cancer (mCRPC) who have progressed after prior treatment with androgen receptor pathway inhibitors (ARPI).

Previously, the Group's global innovative RDC product for prostate cancer diagnosis, TLX591-CDx, completed the first patient dosing in its Phase III clinical trial in China in August 2023, and is expected to complete enrollment of all patients by the second quarter of this year. At present, this product has already been approved for commercialization in the United States, Australia, Canada, Brazil, the United Kingdom, the Czech Republic, France, and multiple European Economic Area member states, achieving sales of AUD 783 million in 2024. The Phase III clinical trials of TLX591 and TLX591-CDx in China are critical to the Group to achieve comprehensive coverage of "integrated diagnosis and treatment" of prostate cancer, which is expected to deliver more precise and effective diagnostic and therapeutic solutions for patients with prostate diseases in China.

TLX591 is a global innovative monoclonal antibody product conjugated with a therapeutic radionuclide, intended for the treatment of prostate-specific membrane antigen ("**PSMA**")-positive mCRPC patients who have progressed after ARPI therapy. Its core technology achieves dual breakthroughs through precise antibody targeting and radionuclide delivery system: the product targets PSMA, utilizing a monoclonal antibody as a highly specific targeting mechanism, delivering the therapeutic radionuclide ^{177}Lu precisely deliver to tumor sites while significantly reducing off-target organ exposure rate. Compared to existing PSMA-targeted radioligand therapy ("**RLT**") that lasts up to six cycles over 30 weeks, TLX591 only requires a two-dose regimen administered approximately 14 days apart, which significantly shortens the treatment cycle and markedly improving patient compliance. This breakthrough design addresses the clinical pain points such as long treatment cycles and heavy patient burden associated with existing therapies. Based on its unique targeted delivery mechanism and pharmacological properties, TLX591 demonstrates significant safety advantages. It is cleared via hepatic metabolism rather than renal pathways, with long-term follow-up showing no significant acute or delayed nephrotoxicity, overcoming the technical bottleneck of renal toxicity in traditional RLT treatments. Additionally, its macromolecular structure results in minimal absorption rate into salivary glands and lacrimal glands, reducing the incidence of common adverse reactions such as xerostomia and dry eye syndrome, thereby improving patients' quality of life. As the prostate cancer treatment field urgently needs solutions with lower radiation exposure, TLX591, with its precise targeting and differentiated pharmacological advantages, has demonstrated clinical potential to surpass existing PSMA-targeted small-peptide RLT molecules. It is expected to redefine the treatment standard for PSMA-positive mCRPC.

By adhering to the treatment concept of integrated oncology diagnosis and treatment, the Group's nuclear medicine anti-tumor diagnosis and treatment segment has reserved 15 innovative products in the R&D registration stage, including 5 radionuclides including ^{68}Ga, ^{177}Lu, ^{131}I, ^{90}Y and ^{89}Zr, and covering 7 cancers including liver cancer, prostate cancer, kidney cancer, and brain cancer. In terms of product types, it covers two types of radionuclide drugs for diagnosis and therapy, providing patients with multi-indication treatment options, multi-methods and integrated diagnosis and treatment of the world's leading anti-tumor solutions. Currently, the Group has 4 innovative RDC drugs that have been approved to conduct registered clinical research in the nuclear medicine anti-tumor diagnosis and treatment segment, 3 of which have entered the Phase III clinical stage: TLX591-CDx, a product for the diagnosis of prostate cancer, is expected to complete enrollment of all patients in the second quarter of this year; TLX250-CDx, a product for diagnosis of clear cell renal cell carcinoma, has completed the first patient enrollment and dosing in November 2024; and ITM-11, a product for the treatment of GEP-NETs, has completed the enrollment and dosing of the first patient in China in its international multicenter COMPOSE trial in March 2025. As for now, the Group has the largest total reserve of innovative diagnostic and therapeutic RDC drugs that have entered Phase III clinical studies in China, and also one of the innovative pharmaceutical companies in the world with the richest product pipeline and integrated diagnosis and treatment strategic plan in the field of nuclear medicine anti-tumor.

The nuclear medicine anti-tumor diagnosis and treatment platform is the Group's high-end technology platform in the field of anti-tumor. The Group has achieved a comprehensive strategic plan in the fields of R&D, production, sales, regulatory qualifications and established a complete industrial chain. The Group, together with Sirtex Medical Pty Limited, cooperated with Telix Pharmaceuticals Limited (ASX: TLX) and ITM Isotope Technologies Munich SE to establish a world-class tumor intervention R&D platform and a radionuclide-drug conjugate R&D platform. It has nearly 800 employees, and is one of the most globalized segments of the Group. At the same time, the Group and Shandong University jointly established Grand Pharma - Shandong University Radiopharmaceutical Research Institute (遠大醫藥-山東大學放射藥物研究院), and with the

institute as the core, the Group gradually completed the establishment of an early R&D platform for nuclear medicine to carry out the independent R&D of RDC drugs. Currently, it has 12 products in the pipeline at the early R&D stage.

The Group is advancing the construction of Class A qualification nuclide production platform in an orderly manner, and will obtain a radiation safety license and start its operations this year. In the future, the Group will continue to strengthen its R&D and contribution in the nuclear medicine anti-tumor diagnosis and treatment segment, enrich and improve the product pipeline and industrial layout, to form a nuclear medicine anti-tumor diagnosis and treatment product cluster with the core of YiGanTai Yttrium-90 microsphere injections, continuously consolidating the Group's global leading position in the field of nuclear medicine anti-tumor diagnosis and treatment.

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, 7 May 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*