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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 APPLICATION FOR THE GROUP'S GLOBAL INNOVATIVE RDC TLX591 TO JOIN AN INTERNATIONAL MULTICENTER PHASE III CLINICAL TRIAL OBTAINS IMPLIED APPROVAL FROM 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 application for the Group's global innovative investigational radionuclide-drug conjugate ("**RDC**") TLX591 (^{177}Lu-rosopatamab tetraxetan) for the treatment of prostate cancer to join an international multicenter Phase III clinical trial has obtained implied approval from 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 and regions, including China, the United States, Australia, New Zealand and in Europe. 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 entered into a product strategic cooperation agreement with Telix Pharmaceuticals Limited (ASX: TLX, NASDAQ: TLX, together with its subsidiaries worldwide, "**Telix**") in November 2020, through which the Group obtained the exclusive rights of multiple innovative RDC products developed by Telix, including TLX591, TLX591-CDx and TLX250-CDx, in Greater China (Mainland China, Hong Kong Special Administrative Region of China, Macau Special Administrative Region of China, and Taiwan Region of 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 directly to tumor sites while significantly reducing off-target organ exposure. Compared to existing PSMA-targeted radioligand therapy ("**RLT**") that can comprise 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, markedly improving patient compliance and convenience. This breakthrough dosing regimen and trial 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 potential for improved safety profile compared with existing RLT approaches. 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 demonstrating potential to improve 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 properties, 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.

In addition, the global innovative RDC product for prostate cancer diagnosis and companion diagnostic to TLX591, TLX591-CDx, completed the first patient dosing in its Phase III clinical trial in China in August 2023, and completed enrollment and dosing of all patients in May 2025. At present, this product has already been registered and commercialized by Telix in the United States, Australia, Canada, Brazil, the United Kingdom, France, Germany, Italy 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.

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 5 innovative RDC drugs that have been approved to conduct registered clinical research in the nuclear medicine anti-tumor diagnosis and treatment segment, 4 of which have entered the Phase III clinical stage: TLX591-CDx, an investigational product for the diagnosis of prostate cancer, has completed enrollment and dosing of all patients in May 2025; TLX250-CDx, a product for diagnosis of clear cell renal cell carcinoma, has completed the first patient enrollment and dosing in November 2024; 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; and TLX591, a product for the treatment of prostate cancer, has been approved to join an international multicenter Phase III clinical trial recently. In addition, the Group's globally innovative radioactive product sir-Spheres® Y-90 resin microsphere injection ("**YiGanTai®**") officially approved by the United States Food and Drug Administration ("**FDA**") ahead of schedule for a new indication for the treatment of unresectable hepatocellular carcinoma ("**HCC**") in July 2025, marking SIR-Spheres® Y-90 resin microsphere injection the world's first and only selective internal radiation therapy product approved by the FDA for dual indications of both unresectable HCC and colorectal cancer liver metastases (CRLM). And relevant clinical data will also provide strong support for the expansion of its indications in China. At the same time, it demonstrates the Group's excellent overseas clinical registration capabilities, and provides significant guarantees for the subsequent overseas development of self-developed innovative nuclear medicine products; global innovative diagnostic radiopharmaceutical GPN02006, which targets glypican-3 ("**GPC-3**") based on radionuclide-antibody conjugation technology, has achieved a milestone breakthrough in the investigator-initiated clinical study (IIT clinical study) conducted in China earlier, and granted an oral presentation at the 2025 Annual Meeting of the Society of Nuclear Medicine and Molecular Imaging (SNMMI); clinical research data showed that GPN02006 exhibited excellent safety and imaging efficacy: all subjects did not report any drug-related adverse reactions after administration, and the safety and tolerability performance was excellent; high-quality imaging can be achieved 30 minutes after administration, fully meeting the clinical rapid diagnosis needs of hepatocellular carcinoma. GPN02006 has great potential and is expected to become the world's first hepatocellular carcinoma (HCC) diagnostic RDC product targeting the GPC-3 target. 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 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's world-leading nuclear medicine R&D and production base located in Wenjiang District, Chengdu has obtained a Class A "Radiation Safety License" issued by the Ministry of Ecology and Environment of the People's Republic of China in May 2025, and has officially commenced operations in June this year. As the world's first closed-loop platform for the entire nuclear medicine industry chain, the R&D and production base has a total planned investment of more than RMB 3 billion, focusing on core areas such as isotope process development and preparation, nuclear medicine coupling technology, and automated labeling technology. It covers the one-stop full life cycle management of nuclear medicine early research, process development, quality research, non-clinical research, intelligent production and precise distribution, establishing a world-class R&D, production, quality and operation system. The base has 14 production lines that meet the requirements of Good Manufacturing Practice (GMP) for pharmaceutical production, and has built a full-chain AI operation system and intelligent manufacturing system, which can realize the independent production of multiple isotopes and multiple nuclear medicine preparations. At the same time, a production line for α-nuclide drugs is reserved, which is one of the smart factories with the most complete types of nuclides and the highest degree of automation in the world. It can fully meet the Group's needs for multivariety and large-scale preparation of therapeutic and diagnostic nuclear medicines. The nuclear medicine R&D and production base has ten highlights and technological breakthroughs: (1) It has the Belgian IBA cyclotron and the ability to independently produce key nuclides, solving the problem that China's scarce isotopes mainly rely on imports; (2) Fully automated production of nuclides, with production capacity stability raised to the international leading level; (3) Building an intelligent manufacturing system, with automated synthesizers to build a precisely controlled "molecular factory", greatly improving experimental and production stability; (4) Establish a fully automatic filling system to achieve "zero contact" in the entire process; (5) Automated ligand production lines enable the parallel development of multiple types of nuclear medicines and reduce production costs; (6) Build a full-link interconnection system, increase production efficiency by 300%; (7) Realize full-link AI intelligent operation, greatly improve operational efficiency; (8) Equipped with the highest international standard radioactive operation hot room to completely block the leakage path of radioactive materials; (9) Create the world's first full-process radiation monitoring system in the field of radioactive drugs to achieve "zero external discharge" and "zero exceeding standards"; (10) The "four-inone" of "ligand + nuclide + technology platform + intelligent production" breaks the international monopoly. These highlights and technological breakthroughs not only meet the standards of the International Atomic Energy Agency (IAEA), but also set a new safety benchmark for the nuclear medicine industry. The full operation of the base marks that the Group has successfully built a closed-loop system covering the entire industry chain of "R&D production-sales", which not only opens up the key links in the global strategic plan of nuclear medicine, but also achieves a strategic leap from laboratory R&D to industrial mass production. Relying on an independent and controllable industrial ecosystem, the Group has formed a nuclear medicine innovation matrix covering integrated diagnosis and treatment with domestic and international dual circulation, providing the driving force for the Group's development in the nuclear medicine field. 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.

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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, 22 July 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*