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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 NDA OF THE GROUP'S GLOBAL INNOVATIVE RDC TLX591-CDx 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 new drug application ("**NDA**") of TLX591-CDx (Illuccix®, gallium Ga 68 PSMA-11), the Group's innovative investigational radionuclide-drug conjugate ("**RDC**") for the diagnosis of prostate cancer, has recently been submitted to the National Medical Products Administration of the People's Republic of China ("**NMPA**") and has been accepted. This is a significant R&D advancement of the Group in the field of nuclear medicine anti-tumor diagnosis and treatment. In addition, the Group's RDC product candidate TLX591 for the treatment of prostate cancer has been approved to conduct an international multi-center Phase III clinical study in China. In the future, the combination of the two therapeutic and diagnostic products builds up a head of steam, and are expected to bring more accurate and efficient diagnosis and treatment solutions to patients with prostate cancer in China.

The NDA submission includes data from the TLX591-CDx clinical study in China, which reported positive top-line results in December 2025.The study is a single-arm, open-label Phase III clinical study evaluating TLX591-CDx Positron Emission Tomography / Computed Tomography (PET/CT) or Positron Emission Tomography / Magnetic Resonance Imaging (PET/MRI) detection in more than 100 patients with biochemically recurrent prostate cancer, to determine the diagnostic effectiveness of the product candidate, and at the same time, to evaluate the safety and tolerability profile in the Chinese population. According to top-line clinical results, the overall positive predictive value ("**PPV**") was 94.8% for detection of tumors with TLX591-CDx (confidence intervals, CI: 85.9%-98.2%). This confirmed that the clinical experience of TLX591-CDx imaging in Chinese patients is comparable to studies in non-Chinese patients. The high PPV was consistent even in patients with very low prostate-specific antigen (PSA) values, and across differing metastatic locations.

In addition, more than two-thirds (67.2%) of patients experienced a change in their treatment plan following TLX591-CDx PET/CT or PET/MRI compared with the initial plan at baseline. This indicates that PET imaging with TLX591-CDx had a meaningful impact on clinical decision-making, potentially leading to improved treatment strategies for participants with biochemical recurrence (BCR).

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 to 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-CDx is a globally innovative, radionuclide-small molecule based diagnostic radiopharmaceutical targeting prostate-specific membrane antigen ("**PSMA**"), suitable for the diagnosis of newly diagnosed and recurrent prostate cancer. The targeting agent PSMA-11 in TLX591-CDx can specifically bind to PSMA in prostate cancer in a high-affinity manner. Based on available published data, it has five major characteristics, including internalization into cells, stable biological activity, short circulation half-life in vivo, good permeability to tumor parenchyma, and rapid clearance by non-targeted tissues.

TLX591-CDx was approved for commercialization in Australia in November 2021, and, in December of the same year, it was approved for commercialization in the United States; was approved for commercialization in Canada in October 2022; was approved for an expanded indication in the United States in March 2023 for the screening of patients with prostate cancer for PSMA-targeted radionuclide therapy, and was subsequently approved for this indication in Australia and Canada in October 2024. In 2025, TLX591-CDx has been approved for commercialization in Austria, Belgium, Brazil, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden and the United Kingdom. The product achieved sales of approximately USD517 million in 2024; sales of approximately USD461 million in the first three quarters of 2025, representing an increase of more than 25% over the same period last year.

In the nuclear medicine anti-tumor diagnosis and treatment segment, the Group has achieved a comprehensive layout in the fields of R&D, production, distribution, and sales, with over 900 employees worldwide. The Group has established a global nuclear medicine industry chain layout based on its R&D centers in Boston and Chengdu, production facilities in Boston, Frankfurt, Singapore, and Chengdu, and a sales network covering over 50 countries and regions worldwide.

The Group, together with Sirtex Medical Pty Ltd, cooperated with Telix and ITM Isotope Technologies Munich SE ("**ITM SE**") to establish a world-class tumor intervention technology platform and a RDC technology platform. The Group adheres to the treatment concept of integrated oncology diagnosis and treatment. Currently, the Group has 16 innovative products in the pipeline at the R&D registration stage, covering 5 radionuclides including ^{68}Ga, ^{177}Lu, ^{131}I, ^{90}Y, ^{89}Zr as well as 7 cancers including liver cancer, prostate cancer and brain cancer. The early stages of R&D focused primarily on RDC drugs, with a product pipeline now comprising more than 10 products. In terms of product types, it covers two types of radionuclide drugs for diagnosis and therapy, providing patients with global leading anti-tumor solutions with multi-indication treatment options, multi-means and integrated diagnosis and treatment.

Global R&D efforts for innovative products within the segment are progressing smoothly. In China, YiGanTai® Y-90 microsphere injection was successfully launched in January 2022 for the treatment of liver metastases from colorectal cancer, and in May 2025, it received approval from the NMPA to conduct a Phase II registrational clinical trial for the treatment of unresectable hepatocellular carcinoma (HCC); The global innovative temperature-sensitive embolization agent GPN00289 completed all patients' enrollment in its registrational clinical study in October 2025. Overseas registration-wise, SIR-Spheres® Y-90 microsphere injection was formally approved in the United States for a new indication, used to treat unresectable HCC, marking SIR-Spheres® Y-90 resin microsphere injection as the first and only FDA-approved selective internal radiation therapy for the dual indications of unresectable HCC and colorectal liver metastases; granted CE Mark approval in Europe for multiple liver cancer indications in September 2025, further promote the full coverage of the product in the treatment of unresectable liver cancer and achieve market expansion at a strategic level, meanwhile, it demonstrates the Group's excellent overseas clinical registration capabilities and commercial operation capabilities, providing significant safeguards for the subsequent global development of self-developed innovative nuclear medicine products, at the same time, relevant overseas clinical data will also provide key support for the expansion of liver cancer-related indications of the product in China; in addition, the Group is also actively collaborating with Chinese and international experts to develop other indications for SIR-Spheres® Y-90 resin microsphere injection. The Group will adopt an international registration pathway involving "dual filings in China and the United States" to facilitate global market expansion for the product.

At present, the Group has 6 RDC drugs approved to conduct registered clinical research in the nuclear medicine anti-tumor diagnosis and treatment segment, with 4 of them having entered the Phase III clinical stage, including TLX591-CDx for diagnosing prostate cancer, TLX591 for treating prostate cancer, TLX250-CDx for diagnosing clear cell renal cell carcinoma, and ITM-11 for treating gastroenteropancreatic neuroendocrine tumors (GEP-NETs). Recently, GPN01530, a globally innovative small molecule RDC independently developed by the Group that targets fibroblast activating protein (FAP), has recently been approved by the FDA to conduct a Phase I/II clinical study for the diagnosis of solid tumors. It is the Group's first self-developed RDC product that receives FDA approval for clinical trials, the successful approval of its clinical trial provides an important paradigm for the international development of the Group's nuclear medicine product pipeline. At the same time, it demonstrates the excellent preclinical development and international registration capabilities of the Group's radiopharmaceutical technology platform, and is a significant milestone in the Group's global R&D and registration process for nuclear medicine anti-tumor diagnosis and treatment segment; the New Drug Application (NDA) for ITM-11 submitted by the Group's partner ITM SE in the United States has been officially accepted by the FDA; in addition, 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). The product 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.

Grand Pharma's Radiopharmaceutical R&D and Production Base (遠大醫藥放射性藥物研發及生產基地), located in Wenjiang District, Chengdu, Sichuan Province, China, was completed and accepted in April 2025, obtained a Class A Radiation Safety Licence issued by the Ministry of Ecology and Environment in May, and officially commenced operations at the end of June. This facility is the world's first fully integrated closed-loop nuclear medicine supply chain platform, covering the entire value chain from "isotope production – nuclear medicine R&D – manufacturing – clinical trials – commercialization". It has established endto-end management capabilities spanning the entire lifecycle from early-stage R&D to clinical translation to commercialization, with R&D efficiency leading globally. It addresses the 'bottleneck' challenges in nuclear medicine, achieving 100% domestic production to break free from reliance on imports. Fourteen high-standard GMP production lines meet the demand for multi-product, large-scale production. Established a fully intelligent management system, featuring nuclear-grade safety and unmanned intelligent manufacturing, achieving "zero radiation leakage", "zero pollution discharge", and "zero occupational exposure exceeding standards", meeting the standards of the world's top nuclear facilities. We have established a world-class research, production, quality, and operational system, making it one of the most comprehensive and highly automated intelligent factories in the world in terms of isotope variety and automation levels. This R&D and production base will further solidify the foundation of the Group's nuclear pharmaceutical industry, accelerate the implementation of global innovative R&D pipelines, drive the Group's high-quality development in the nuclear pharmaceutical sector, cultivate high-value blockbuster products, and lay a solid foundation for the domestic production of the Group's radioactive drugs. In the future, the Group will continue to strengthen the R&D in and establishment of the nuclear medicine anti-tumor diagnosis and treatment segment, as well as enrich and improve the product pipeline and industrial layout, forming a nuclear medicine anti-tumor diagnosis and treatment product cluster with the core of YiGanTai® Y-90 resin microsphere injections, which continuously consolidates 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 final clinical trial results may vary from the top-line results, but this does not affect the fact that this trial has reached the primary clinical endpoint. 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, 19 January 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*