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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 GROUP'S INDEPENDENTLY DEVELOPED, BLOCKBUSTER, GLOBALLY INNOVATIVE RADIONUCLIDE-DRUG CONJUGATE, GPN01530, HAS BEEN APPROVED FOR CLINICAL TRIALS IN THE UNITED STATES

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 GPN01530, a globally innovative radionuclide-drug conjugate ("**RDC**") independently developed by the Group, has recently been approved by the United States Food and Drug Administration ("**FDA**") to conduct a Phase I/II clinical study for the diagnosis of solid tumors. It marks another solid step forward in the Group's global strategy for nuclear medicine anti-tumor diagnosis and treatment. As the Group's first self-developed RDC product that receives FDA approval for clinical trials, the successful approval of the GPN01530 clinical trial provides an important paradigm for the international development of the Group's nuclear medicine product pipeline. It is a significant milestone in the Group's global R&D and registration process for nuclear medicine anti-tumor diagnosis and treatment segment, fully demonstrating the Group's comprehensive strength in the construction of cutting-edge nuclear medicine technology platforms, international clinical development, and registration applications, etc. The Group will continue to advance the global R&D and registration of GPN01530 by relying on the international registration route of "dual filings in China and the United States". Based on this, the Group will further deepen the globalization development strategy of this segment, actively promote the international clinical research and registration application of more independently developed innovative nuclear medicine products, and continuously enhance the Group's core competitiveness and international influence in the field of nuclear medicine anti-tumor diagnosis and treatment.

GPN01530 is a small molecule RDC drug that targets fibroblast activating protein ("**FAP**"). FAP is one of the important markers of cancer-associated fibroblasts ("**CAFs**"), participating in processes such as extracellular matrix remodeling, regulation of tumor cell proliferation, and tumor immunosuppression, thus promoting tumor growth and invasion. It is a novel and specific target for tumor diagnosis and treatment. Studies have shown that FAP is not expressed

or is expressed at low levels in normal tissues, but is highly expressed in 90% of epithelial tumor tissues and CAFs in various tumor microenvironments. Specifically targeting FAP, GPN01530 offers new possibilities for the diagnosis and treatment of various malignant tumors. The most commonly used PET/CT imaging agent in clinical practice is 18F-fluorodeoxyglucose ("**^{18}F-FDG**"), which makes corresponding judgments and assessments of the disease by measuring the level of glucose metabolism in the lesion. But its sensitivity is relatively low (40%~68%), and its value in the early diagnosis of tumors is limited. While imaging agents targeting FAP have the characteristics of broad application in solid tumors and high sensitivity, and have become one of the popular targets in radiopharmaceutical research. GPN01530 that independently developed by the Group optimizes the structure of the FAP ligand, improving its uptake in tumor tissues, while reducing its uptake in normal tissues. Preclinical studies have shown that this product, compared to other FAP-targeted ligands, exhibits rapid tumor targeting, higher tumor uptake, and superior pharmacokinetic properties. Furthermore, ongoing IIT human studies have demonstrated a favorable safety profile, rapid background clearance, strong and sustained lesion uptake, and superior clinical image contrast and accurate detection rate of positive lesions compared to ^{18}F-FDG. Based on these preclinical and clinical results, this product significantly improves the diagnostic efficacy of FAP-targeted RDC drugs, and provide a brand-new tumor diagnosis solution for a large number of solid tumor patients.

The early research of the GPN01530 project was entirely independently developed by the Group based on its radiochemical labeling platform and animal molecular imaging platform at the Chengdu Radiopharmaceutical Base. The integrated approach completed the labeling process development and animal imaging studies, and enabled the production and inspection and release of the registration batch using a production line compliant with Good Manufacturing Practices ("**GMP**"). This project is also the first independently developed product that entered the FDA clinical trial stage since the Chengdu Radiopharmaceutical Base began operations in June of this year, demonstrating the excellent preclinical development and international registration capabilities of this technology platform.

Cancer is one of the leading causes of death worldwide. According to data from GLOBOCAN, there were approximately 20 million new cancer cases and 9.7 million cancer deaths globally in 2022, and the number is projected to approach 24 million new cases and 12 million deaths by 2030. In the foreseeable future, cancer will remain a major public health threat to human health. Currently, accurate diagnosis and treatment are widely considered crucial for cancer prognosis. Therefore, radiopharmaceuticals with the potential for integrated diagnosis and treatment have become a hot research area. Statistics show that the global radiopharmaceutical market size is expected to grow from USD5 billion in 2018 to USD9.7 billion in 2024, representing a compound annual growth rate ("**CAGR**") of 11.7%. The market is projected to climb to USD57.3 billion by 2035, with a CAGR of 17.5% between 2024 and 2035. During the same period, the Chinese market grew from RMB3.6 billion in 2018 to RMB7.4 billion in 2024, with a CAGR of 13.0%. By 2035, it is expected to reach RMB75.8 billion, with a CAGR of 23.5% between 2024 and 2035. Continued advancements in imaging technology and radioligand therapy, along with an aging population, will fuel the sustained rapid growth of the radiopharmaceutical market. In the future, if the development of GPN01530 proceeds smoothly, the product is expected to become a major breakthrough in overcoming the challenges of solid tumor diagnosis. With its significant product advantages, it is poised to reshape the landscape of solid tumor diagnosis, seize a leading global market position, and bring new hope to patients worldwide.

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 Pharmaceuticals Limited (ASX: TLX; NASDAQ: TLX) 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 received early formal approval in the United States for a new indicationused 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 5 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, 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-variety, large-scale production, truly achieving complete self-reliance and control over the entire industrial chain of innovative radiopharmaceutical product research and development, production, and sales. 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 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, 17 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*