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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 WORLD-LEADING NUCLEAR MEDICINE R&D AND PRODUCTION BASE OBTAINS A CLASS A "RADIATION SAFETY LICENSE" AND IS ABOUT TO BE PUT INTO OPERATION

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 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 recently, and will officially start operations in June this year. This base was signed at the end of 2022, the environmental impact assessment was fully conducted in April 2023, the construction permit was obtained and the official groundbreaking ceremony was held in November of the same year. The main structure was completed in just five months, breaking the industry construction record with a two-year cycle. The base will help the Group improve its global footprint in nuclear medicine and build a new independent and controllable ecosystem. It is another important milestone in the Group's strategic plan of building the entire industry chain in the field of nuclear medicine anti-tumor diagnosis and treatment.

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 multi-variety 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 of China's reliance on imports of scarce isotopes; (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-in-one" 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.

This time, it is the Chengdu Wenjiang Nuclear Medicine R&D and Production Base obtained the Class A "Radiation Safety License" that marks the Group's nuclear medicine intelligent factory will soon be put into operation, and a core leap for the Group to implement the "Global Nuclear Medicine Leader" strategy. This breakthrough indicates 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. By accelerating the industrialization of radiopharmaceuticals, the Group has completed the last part in its global nuclear medicine strategy. Relying on an independent and controllable industrial ecosystem, the Group has formed a nuclear medicine innovation matrix covering integrated diagnosis and treatment, and domestic and international dual circulation, providing the driving force for the Group's development in the nuclear medicine field. The base will also be built together with the Group's Boston R&D Center in the United States, Grand Pharma-Shandong University Radiopharmaceutical Research Institute, etc. to form its global nuclear medicine R&D center network, providing the global market with radiopharmaceutical solutions with completely independent intellectual property rights. At the same time, the base has filled the gap in international radiopharmaceutical industrial standards with "Intelligent Manufacturing in China", promoted the upgrading of the global nuclear medicine industry, and made important contributions to the development of the nuclear medicine field in China and the world. With the base being put into operation, the implementation of the Group's global innovative nuclear medicine pipeline will enter a new stage, which will not only help the Group cultivate more high-value blockbuster nuclear medicine varieties, but will also further consolidate the Group's steps forward in the global development of the nuclear medicine industry. 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.

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 ⁶⁸Ga, ¹⁷⁷Lu, ¹³¹I, ⁹⁰Y and ⁸⁹Zr, 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 radionuclide-drug conjugate ("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, an investigational product for the diagnosis of prostate cancer, has completed the enrollment and dosing of all patients recently; 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 multi-center COMPOSE trial in March 2025. In addition, the application for an international multi-center Phase III clinical study of the Group's innovative RDC product candidate TLX591 for the treatment of prostate cancer has been accepted in China; global innovative diagnostic radiopharmaceutical GPN02006, which targets glypican-3 ("GPC-3") based on radionuclideantibody conjugation technology, has achieved a milestone breakthrough in the investigatorinitiated 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 Pharmaceuticals Limited (ASX: TLX, NASDAQ: 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 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:

Whether this project construction 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, 18 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