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 CLINICAL STUDY FOR THE TREATMENT OF HCC CONDUCTED IN THE UNITED STATES OF THE GROUP'S GLOBALLY INNOVATIVE RADIOACTIVE PRODUCT SIR-SPHERES® Y-90 MICROSPHERE INJECTION HAS REACHED ITS CLINICAL ENDPOINT

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 clinical trial ("**DOORwaY90**") conducted in the United States for the treatment of unresectable hepatocellular carcinoma ("**HCC**") of SIR-Spheres® Y-90 resin microsphere injection of Sirtex Medical Pty Ltd, an associate company of the Group, has successfully met its clinical endpoint recently. Previously, the United States Food and Drug Administration ("**FDA**") had officially approved SIR-Spheres® Y-90 microsphere injection for a new indication of unresectable HCC based on breakthrough interim data from the DOORwaY90 clinical trial. The successful completion of the DOORwaY90 study, which reached its clinical endpoint, not only marks the successful conclusion of this clinical research, but also provides solid clinical evidence for Y-90 radioembolization therapy as a definitive treatment option for unresectable HCC that is both highly effective and hepatoprotective. SIR-Spheres® Y-90 microsphere injection is the world's first and only FDA-approved selective internal radiotherapy product for the dual indications of unresectable HCC and colorectal cancer liver metastases. The relevant clinical data will also provide strong support for the expansion of indications in China; at the same time, this achievement demonstrates the Group's excellent overseas clinical registration capabilities and lays an important foundation for the overseas R&D and registration of subsequent self-developed innovative radiopharmaceutical products.

SIR-Spheres® Y-90 resin microsphere injection is a selective internal radiotherapy product for liver malignant tumors. It uses the world's leading interventional technology to inject Y-90 resin microspheres into liver tumor blood vessels, releasing high-energy β radiation to kill tumor cells. It has the dual advantages of radioactive drugs and precise interventional treatment.

The DOORwaY90 study conducted in the United States was the first pivotal, prospective, multicenter clinical study of Y-90 selective internal radiation therapy (SIRT) using partition dosimetry in patients with unresectable HCC in the United States. The study data shows that this research has successfully met its prespecified co-primary endpoints: demonstrating a 90% complete response (CR) rate and a best overall response rate (ORR) of 99%, as assessed by blinded independent central review; all evaluable patients responded to treatment, resulting in 100% local tumor control - one of the highest reported response outcomes in Y-90 therapy. In addition, the responses of SIR-Spheres® Y-90 microsphere injection were durable, with 75% lasting beyond 6 months and a median duration of 295 days, and over 95% of patients maintained stable liver function at 12 months. These excellent clinical results fully demonstrate that the personalized dosimetry of SIR-Spheres® Y-90 microsphere injection can achieve significant tumor response without damaging liver reserve function. At the same time, it also signifies that the SIR-Spheres personalized dosimetry treatment mode not only surpasses the traditional treatment option, but also further expands the application space of liver-directed therapy for patients with unresectable HCC.

The product was approved for commercialization by the FDA and the European Medicines Agency in 2002, and was approved for commercialization by the National Medical Products Administration of the People's Republic of China (NMPA) in 2022 for the treatment of patients with unresectable colorectal cancer liver metastases. Over the past 20 years since its commercialization, the product has been used by more than 150,000 people in more than 50 countries and regions around the world, and its safety and effectiveness have been widely recognized in clinical practice. It is also recommended in the treatment guidelines issued by different international authoritative organizations such as Barcelona Clinic Liver Cancer Guidelines (BCLC), National Comprehensive Cancer Network (NCCN), European Society for Medical Oncology (ESMO) Clinical Practice Guideline for diagnosis, treatment and follow-up of Hepatocellular carcinoma (2025), European Association for the Study of the Liver (EASL) Clinical Practice Guidelines for Hepatocellular Carcinoma (2025), National Institute for Health and Care Excellence (NICE), and has been included in several authoritative clinical practice guidelines in China, including *Guidelines for Diagnosis and Treatment of Primary Liver Cancer (2026 edition)* (《原發性肝癌診療指南(2026年版)》), *Guideline for diagnosis and comprehensive treatment of colorectal liver metastases (2025 edition)*, *Guidelines for Diagnosis and Treatment of Primary Liver Cancer (2024 edition)* of Chinese Society of Clinical Oncology (CSCO), *Chinese clinical practice guidelines on liver transplantation for hepatocellular carcinoma (2021 edition)*.

According to the data from GLOBOCAN 2022, there are approximately 870,000 new cases of liver cancer worldwide, ranking sixth among tumors; and approximately 760,000 deaths, ranking third. The 2024 National Cancer Report of the National Cancer Center of China shows that in 2022, there were approximately 370,000 new cases of liver cancer in China (accounting for 42.5% of the world), ranking fourth among tumors; there were approximately 320,000 deaths (accounting for 42.1% of the world), ranking second; and the proportions ranked first in the world. HCC is the most common primary liver cancer, accounting for 85%-90%. Surgical resection is the preferred method for treating early HCC, but because liver cancer is insidious, early symptoms are not obvious or typical, its early diagnosis is difficult, less than 30% of liver cancer patients are suitable for radical treatment at the initial diagnosis, and treatment is difficult, so the prognosis is poor, and the ratio of morbidity to mortality is as high as 1: (0.8-0.9); even with radical resection, the 5-year tumor recurrence and metastasis rate after liver cancer resection is as high as 50% to 70%; the 5-year survival rate in North American countries.

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 1000 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. In 2025, the Group's nuclear medicine anti-tumor diagnosis and treatment segment recorded revenue of approximately HK$950 million, representing an increase of approximately 61.0% on an annual basis. Core product SIR-Spheres® Y-90 microsphere injection has continued to grow rapidly. This segment has achieved revenue growth of approximately fifteen times over four years.

The Group has established 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, SIR-Spheres® Y-90 microsphere injection was successfully launched in January 2022 for the treatment of liver metastases from colorectal cancer, and it received approval from the NMPA to conduct a Phase II registrational clinical trial for the treatment of unresectable HCC in May 2025; 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 August 2025, further promote the full coverage of the product in the treatment of unresectable liver cancer and achieve market expansion at a strategic level; 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, of which 1 has entered the NDA stage, and 4 have 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). In addition, 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 Group's 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.

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 end-to-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 SIR-Spheres® 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 production, sales and contributed profit of aforementioned product is subject to various factors such as market changes with uncertainty. 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, 13 April 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*