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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

NEW INDICATION OF THE GROUP'S GLOBALLY INNOVATIVE RADIOACTIVE PRODUCT SIR-SPHERES® Y-90 RESIN MICROSPHERE INJECTION IS OFFICIALLY APPROVED IN EUROPE

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 SIR-Spheres® Y-90 resin microsphere injection ("**YiGanTai®**") of Sirtex Medical Pty Ltd, an associate company of the Group, has recently received CE Mark approval in Europe for new indications for the treatment of liver cancer patients. The approval of the new indications expands the scope of application of this therapy from unresectable hepatocellular carcinoma ("**HCC**") and unresectable metastatic liver tumors from primary colorectal cancer ("**mCRC**") to multiple indications, including unresectable intrahepatic cholangiocarcinoma ("**ICC**"), hepatic metastases by neuroendocrine tumors ("**mNET**"), or other liver metastases, covering a more comprehensive classification of primary liver cancer and secondary liver metastasis. In addition, the United States Food and Drug Administration ("**FDA**") recently approved SIR-Spheres® Y-90 resin microsphere injection for a new indication treatment in HCC. The registration milestones achieved by SIR-Spheres® Y-90 resin microsphere injection in the European and American markets 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. In addition, relevant overseas clinical data will also provide key support for the expansion of liver cancer-related indications of the product in China. 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. Leveraging its global strategic plan of nuclear medicine and independently controlled industrial ecosystem, the Group has established a nuclear medicine

innovation matrix encompassing diagnosis and treatment integration, and domestic and international dual circulation. It has formed a closed-loop system encompassing the whole industry chain of R&D-production-sales, empowering it to continuously lead the global expansion of nuclear medicine anti-tumor diagnostic and treatment products and consolidate its position as an industry leader.

SIR-Spheres® Y-90 resin microsphere injection was approved for commercialization by the FDA and Europe in 2002, 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, and was approved by the NMPA to conduct a Phase II registrational clinical trial for the treatment of unresectable HCC in May 2025. YiGanTai® Y-90 resin microsphere injection has demonstrated rapid adoption since its approval for commercialization in China, treating nearly 2,000 patients by the end of 2024, and generating approximately HK$500 million in sales in 2024, with a year-on-year increase exceeding 140%. In July 2025, based on the breakthrough interim clinical data from the DOORwaY90 clinical trial, the FDA formally approved SIR-Spheres® Y-90 resin microsphere injection for the indication of unresectable HCC ahead of schedule, without any restrictions on tumor diameter size. The interim results show that SIR-Spheres® Y-90 resin microsphere injection achieves an objective response rate of 98.5% for the treatment of unresectable HCC; all evaluable patients demonstrated treatment response, indicating a 100% local tumor control rate; additionally, the median duration of response exceeded 300 days. The FDA's approval of this new indication marks 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. Combined with the approval in Europe of new indications, these regulatory milestones further demonstrate the international recognition for SIR-Spheres® in the treatment of liver cancer.

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 by 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), European Association for the Study of the Liver (EASL), National Institute for Health and Care Excellence (NICE) and has been included in several authoritative clinical practice guidelines in China, including the "2024 CSCO Guidelines for Diagnosis and Treatment of Primary Liver Cancer" (《二零二四年 CSCO 原發性肝癌診療指南》), the "Guidelines for Diagnosis and Treatment of Primary Liver Cancer (2024 edition)" (《原發性肝癌診療指南(2024 版)》), "Chinese Guidelines for Diagnosis and Comprehensive Treatment of Colorectal Cancer Liver Metastases (2023 edition)" (《中國結直腸癌肝轉移診斷和綜合治療指南(2023 版)》), "Clinical Practice Guidelines for Liver Cancer and Liver Transplantation in China (2021 edition)" (《中國肝癌肝移植臨床實踐指南(2021 版)》).

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. Primary liver cancer mainly includes three different pathological types: HCC, ICC and mixed hepatocellular carcinoma-cholangiocarcinoma, among which HCC is the most common, accounting for approximately 85%, and ICC accounts for more than 10%. Surgical resection is the preferred method for treating early liver cancer, 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 and regions is less than 20%, and it is even lower in China at only 12%. Therefore, liver cancer patients are in urgent need of effective treatment. With the expansion of SIR-Spheres® Y-90 resin microsphere injection's precise interventional treatment into new indications and clinical popularization around the world, the product's accessibility to liver cancer patients will be significantly improved, bringing new treatment options to more liver cancer 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 Pharmaceutical Limited and ITM Isotope Technologies Munich SE to establish a world-class tumor intervention technology platform and a radionuclide-drug conjugate ("**RDC**") technology platform. The Group adheres to the treatment concept of integrated oncology diagnosis and treatment. Currently, the Group has 15 innovative products in the pipeline at the R&D registration stage, covering five radionuclides including ^{68}Ga, ^{177}Lu, ^{131}I, ^{90}Y, ^{89}Zr as well as seven 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 12 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. 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). 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); 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.

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 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 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, 8 September 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*