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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 GLOBAL INNOVATIVE RDC DRUG OF THE GROUP ITM-11 OBTAINED IMPLIED APPROVAL FROM NMPA TO CONDUCT PHASE I CLINICAL STUDY

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 ITM-11, a global innovative radionuclide-drug conjugate ("**RDC**") of the Group for the treatment of gastroenteropancreatic neuroendocrine tumors, has obtained implied approval from the National Medical Products Administration of the People's Republic of China ("**NMPA**") recently to conduct Phase I clinical study in China. The study is a single-armed and open-labeled Phase I clinical study that plans to enroll up to 20 patients with well-differentiated neuroendocrine tumors of gastrointestinal or pancreatic origin ("**GEP-NETs**") that is non-operable, progressive, and somatostatin receptor-positive (SSTR+), to evaluate the safety, radiation dosimetry, and initial efficacy of ITM-11 in patients with GEP-NETs. The approval of this Phase I clinical study is another significant R&D progress of the Group in the field of nuclear medicine anti-tumor diagnosis and treatment.

ITM-11 is a therapeutic RDC drug based on radionuclide conjugated technology that targets GEP-NETs. It conjugates no-carrier-added ^{177}Lu with somatostatin analogs, and targeted killing of tumor cells by binding to the somatostatin receptor (SSTR) that highly expressed on the surface of GEP-NETs. Compared with the commonly used carrier-added ^{177}Lu radioisotope products, the no-carrier-added ^{177}Lu has higher specific activity and purity, and produces less long half-life impurities during the production process and has less radioactive pollution. The product has been granted orphan drug designation by the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA). According to data from Frost & Sullivan, there were 71,300 newly diagnosed cases of GEP-NETs in China in 2020, and the incidence rate is increasing year by year. The "Guidelines of Chinese Society of Clinical Oncology (CSCO) for Neuroendocrine Neoplasms (2021)" indicated that peptide receptor radionuclide therapy based on ^{177}Lu is superior to the high-dose octreotide (somatostatin analogue) that is currently used in the first-line clinical treatment in terms of progression-free

survival time (PFS) and objective response rate (ORR), and it could bring significant benefits to the patients. ITM-11 together with TOCscan®, another RDC product of the Group for the diagnosis of GEP-NETs, can form a product group to realize the integration of the diagnosis and treatment of GEP-NETs, and is expected to provide a new diagnosis and treatment option for the patients with GEP-NETs in China.

By adhering to the treatment concept of integrated oncology diagnosis and treatment, the Group has reserved 13 innovative products in its nuclear medicine anti-tumor diagnosis and treatment segment, including 6 radionuclides including ^{68}Ga, ^{177}Lu, ^{131}I, ^{90}Y, ^{89}Zr and ^{99m}Tc and covering 8 cancers including liver cancer, prostate 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.

The core product of the Group's nuclear medicine anti-tumor diagnosis and treatment segment YiGanTai (易甘泰®) Yttrium-90 resin microsphere injections ("**YiGanTai**") has been granted approval for commercialization by the NMPA in January 2022. The product provides a new and effective treatment modality for patients with liver malignancies in China, offering the opportunity for translational therapy and further surgical resection to achieve clinical cure, bridging the gap in the local treatment of liver metastases from colorectal cancer, improving the long-term treatment outcome of the Chinese patient population with liver cancer, and marking the arrival of a new international precision interventional treatment option in the field of liver malignancies in China. Since the official commercialization of YiGanTai in May 2022, more than 50 hospitals have completed the nuclide transfer procedures, its official surgeries have been carried out in more than 30 hospitals in 17 provinces and cities in China. The follow-up results showed that the overall response of patients who take YiGanTai surgery was satisfactory, and most patients achieved favorable clinical therapeutic effect and prolonged survival. At present, 5 patients have successfully achieved liver cancer tumor downstaging transform and took liver cancer resection, achieving clinical cure. Among patients who could be followed up for 3 months or more, the objective response rate of YiGanTai for liver cancer was over 50%, and more than half of the patients had achieved tumor size remission. Among them, the symptoms of 5 patients were completely relieved with no resection required, and the disease control rate of the follow-up patients exceeded 95%, showing a remarkable therapeutic effect. In order to speed up the implementation and popularization of YiGanTai microsphere precise interventional therapy in China, the Group relied on the high-quality reputation and practical experience accumulated overseas for the product over the years, assisted domestic doctors in conducting multiple personalized practical trainings by well-known overseas clinical experts. At present, it has trained more than 300 doctors in 70 hospitals on the theory or skills of YiGanTai surgery, nearly 20 experts have obtained the operation qualification of independent surgery through strict one-to-one training by overseas experts, and many of them will soon obtain the qualification of training instructor, which will further accelerate the clinical popularization of YiGanTai radioactive interventional operation.

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) 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 more than 400 employees, with more than 40% of them holding master's

degrees and doctoral degrees, 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) to jointly carry out R&D in RDC drugs on the basis of radionuclide research by the Laboratory Nuclear Medicine Research Institute (實驗核醫學研究所) of Shandong University.

The Group is advancing the construction of Class A qualification nuclide production platform in an orderly manner. In the future, the Group will continue to strengthen its R&D and investment in the nuclear medicine anti-tumor diagnosis and treatment segment, enrich and improve the product pipeline and industrial layout, strive to achieve 10 nuclide products entering the clinical stage in the next 3 years, and realize the pipeline layout of more than twenty-five nuclear medicine anti-tumor diagnosis and treatment products, to form a nuclear medicine anti-tumor diagnosis and treatment product cluster with the core of YiGanTai, continuously consolidating 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 approval of commercialization, manufacturing and sale of above products in China is subject to various factors 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 May 2023

As at the date of this announcement, the Board comprises four executive directors, namely, Dr. Tang Weikun, Dr. Shao Yan, Dr. Niu Zhanqi and Dr. Shi Lin, and three independent nonexecutive directors, namely, Ms. So Tosi Wan, Winnie, Dr. Pei Geng and Mr. Hu Yebi.

** For identification purpose only*