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 IS APPROVED TO CONDUCT PHASE III CLINICAL STUDY IN CHINA

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 been approved by the National Medical Products Administration of the People's Republic of China ("**NMPA**") recently to conduct Phase III clinical study ("**COMPOSE Study**", NCT04919226) in China. The COMPOSE Study is a prospective, randomized, controlled, open-label, and international multi-center phase III clinical study. It aims to evaluate the efficacy, safety and patient-reported outcomes of ITM-11 in patients with neuroendocrine tumors of gastrointestinal or pancreatic origin ("**GEP-NETs**") that is Grade 2 and 3 well-differentiated aggressive, and somatostatin receptor-positive (SSTR+). The COMPOSE Study plans to enroll at least 202 patients in 11 countries around the world, including China, the United States, the United Kingdom, France, Germany, and Australia. The approval of this international multi-center Phase III clinical study is another important R&D progress of the Group in the field of nuclear medicine anti-tumor diagnosis and treatment. Including China into the international multi-center clinical practice, on the one hand, will significantly promote the registration and R&D of ITM-11 in China, and on the other hand, further enhance the internationalization of the Group's clinical development 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's nuclear medicine anti-tumor diagnosis and treatment segment has reserved 14 innovative products, 9 of which are innovative RDC drugs, including 6 radionuclides including ^{68}Ga, ^{177}Lu, ^{131}I, ^{90}Y, ^{89}Zr and ^{99m}Tc and covering 7 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. Currently, the Group has 4 innovative RDC drugs that have been approved to conduct clinical research in the nuclear medicine anti-tumor diagnosis and treatment segment, 3 of which have entered the Phase III clinical stage, including TLX591-CDx, for the diagnosis of prostate cancer, TLX250-CDx, for diagnosis of clear cell renal cell carcinoma, and ITM-11, for the treatment of GEP-NETs. 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) 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 600 employees, with approximately 30% 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, 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, 24 March 2024

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

** For identification purpose only*