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

PHASE III STUDY OF GLOBAL INNOVATIVE RDC CANDIDATE TLX591-CDx DOSES FIRST PATIENT 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 the Phase III clinical trial conducted by the Group of TLX591-CDx (Illuccix®, gallium Ga 68 PSMA-11), an innovative radionuclide-drug conjugate ("**RDC**") for the diagnosis of prostate cancer, in China has completed the first patient enrollment and dosing recently. The study is a single-arm, open-label Phase III clinical study. It is planned to use TLX591-CDx and perform Positron Emission Tomography/ Computed Tomography (PET/CT) or Positron Emission Tomography/Magnetic Resonance Imaging (PET/MRI) detection in more than 100 patients with biochemical recurrence after radical prostatectomy and/or radical radiotherapy, to evaluate the diagnostic effectiveness of the product, and at the same time, to evaluate the safety and tolerability of the product in the Chinese population. The Group has exclusive licenses of this product in Mainland China, Hong Kong SAR, Macau SAR and Taiwan, and the first patient enrollment and dosing in this Phase III clinical trial is another important research and development progress of the Group in the field of nuclear medicine anti-tumor diagnosis and treatment.

TLX591-CDx is a globally innovative, radionuclide-small molecule based diagnostic radiopharmaceutical targeting prostate-specific membrane antigen ("PSMA"), suitable for the diagnosis of metastatic and recurrent prostate cancer. The targeting agent PSMA-11 in TLX591-CDx can specifically bind to PSMA in prostate cancer in a high-affinity manner. It has five characteristics, including internalization into cells, stable biological activity, short circulation half-life in vivo, good permeability to tumor parenchyma, and rapid clearance by non-targeted tissues. Previously, this product was approved for commercialization in Australia in November 2021. In December of the same year, it was approved for commercialization in the United States and was specially authorized in Brazil to allow sales prior to the official approval. It was also approved for commercialization in Canada in October 2022. Marketing authorisation applications for this investigational candidate are currently progressing in the

United Kingdom and the European Union. In terms of clinical research, TLX591-CDx completed a Phase I trial in Japan in February 2022, which included 10 subjects. The results of the study showed that TLX591-CDx was safe and well tolerated. No serious adverse events were observed among all subjects, and systemic and organ-specific radiation dosimetry and pharmacokinetic data showed no significant differences between Japanese and Western patients. The first patient enrollment and dosing in this Phase III clinical trial will further accelerate the process of the product's commercialization 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 National Medical Products Administration of the People's Republic of China 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 60 hospitals have completed the nuclide transfer procedures, its official surgeries have been carried out in more than 40 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, more than 10 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 more than 30 patients were completely relieved with no resection required, and the disease control rate of the follow-up patients exceeded 70%, 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 400 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 6 of them have obtained 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 nearly 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 of Shandong University (山東大學實驗核醫學研究所).

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 Yttrium-90 resin microsphere injections, 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, 14 August 2023

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*