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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 GROUP'S GLOBAL INNOVATIVE HEARTLIGHT X3 LASER ABLATION PLATFORM SUCCESSFULLY COMPLETED THE FIRST CHARTERED ACCESS AF LASER ABLATION OPERATION IN CHINA IN RUIJIN-HAINAN HOSPITAL

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 Heartlight X3 laser ablation platform, the Group’s innovative medical device for the treatment of atrial fibrillation (“**AF**”), has successfully completed the first chartered access AF laser ablation clinical treatment in China in Ruijin-Hainan Hospital Shanghai Jiao Tong University School of Medicine Boao Research Hospital (“**Ruijin-Hainan Hospital**”) recently. It is another major progress of the Group in cerebro-cardiovascular precision interventional diagnosis and treatment, and also marks the field of AF treatment in China has ushered in a new international precision treatment method.

AF is an arrhythmia phenomenon caused by dysfunction of the atrial electrophysiological system, and is the most common form of persistent arrhythmia. The prevalence of AF has significantly positive correlation with age. According to the statistics, the prevalence of AF among Chinese adults is approximately 1.6%, with significant geographic variation. At present, there are about 20 million patients with AF in China. Given that the population ageing rapidly in China, it is expected that the number of patients with arrhythmia and AF will continue to grow rapidly in the future, and the prevention and treatment of AF will become a social concern.

AF is a progressive disease, and the current treatment methods are mainly drug therapy and non-drug therapy. Drug therapy usually can only control the heart rhythm to a certain extent, requires long-term medication, and is accompanied by side effects. In contrast, transcatheter ablation interventional treatment of AF can better cover patients who do not respond well to drug therapy or who are not suitable for drug therapy. It completes the ablation of the pulmonary veins through catheter intervention to block the disordered electrical signal conduction and achieve the effect of inhibiting AF, that is, pulmonary vein isolation (“**PVI**”),

which is the cornerstone of transcatheter ablation of AF. “Current Knowledge and Management Recommendations of Atrial Fibrillation: 2018” and “European Heart Journal (2020)” both recommend catheter ablation as the first-line treatment for patients with AF who are not well controlled by drugs.

HeartLight X3 is the only product in the world that can achieve circumferential ablation by laser in the treatment of AF. It was approved for commercialization by the United States Food and Drug Administration (FDA) in May 2020, and its first and second generation systems have achieved mature applications around the world and completed more than 15,000 cases of clinical treatment. Utilizing the unique RAPID mode, Heartlight X3 laser ablation platform adopts the patented cardiac endoscopic technology for direct tissue visualization, adjustable laser energy and ultra-compliant balloon technology to achieve accurate and continuous energy delivery, thereby reducing the manual overlap processing of individual lesions, and more confidently performing complete pulmonary vein isolation. HeartLight X3 laser ablation platform has the point-to-point adjustable energy precise ablation characteristics of traditional radiofrequency catheter ablation, and at the same time has the characteristics of simple operation and short procedure time of cryoablation, greatly reducing the dependence on the operator. Overseas studies have shown that HeartLight X3 can quickly and automatically conduct PVI. It only takes approximately 3 minutes to isolate a pulmonary vein, and the total operation time is only about 73.7 minutes. At the same time, HeartLight X3 enables clinicians to complete the operation with very few X-rays exposure, with a total radiation exposure time of only about 4 minutes. Compared with radiofrequency ablation, the therapeutic effect and safety of laser ablation are comparable, but the laser ablation group has a similar one-year no AF recurrence rate (about 70%) in high-experience centers and low-experience centers, while the one-year no AF recurrence rate of the radiofrequency ablation group was greatly influenced by the operator’s experience (71% in high-experience centers vs. 58% in low-experience centers), indicating that the learning threshold of the laser ablation system may be lower than that of radiofrequency ablation. Long-term research data show that the four-year PVI success rate of patients treated with the laser ablation system is still as high as approximately 75%. HeartLight X3 is expected to provide a new treatment option for the vast number of patients with AF in China.

The field of cerebro-cardiovascular precision interventional diagnosis and treatment is one of the core strategic areas of the Group. The Group adheres to the treatment concept of “interventional without implantation” and conducts comprehensive layout in three directions, namely channel management, structural heart disease, electrophysiology and heart failure, to build a high-end medical device product cluster. At present, the segment has reserved 16 products, of which 3 products in vascular intervention have been approved for commercialization in China. The new drug application for NOVASIGHT Hybrid in China was submitted and accepted in June 2022, and the NDA for HeartLight X3 laser ablation platform was submitted at present, while other products are also being actively promoted for the clinical registrations in China, in order to achieve the stage-by-stage commercialization for innovative products in the coming years, driving the business in this segment to achieve leapfrog growth.

The Group has completed the comprehensive construction of the “active + passive” innovative device platform in this segment, and formed the R&D and production layout of two centers in China and multiple overseas bases. Among them, the Active Equipment R&D and Production Base in Optics Valley, Wuhan and the Passive Equipment R&D and Production Base in Changzhou have been put into use. The establishment of overseas R&D centers in Minnesota, the United States, and the construction of R&D bases in Germany, Canada, Italy, etc. are also

progressing in an orderly manner. In the future, the Group will commence the construction of the Shanghai R&D Center, which will mainly focus on the innovation and R&D of structural heart disease product line, and is planning for the construction of the Beijing R&D Center, which will mainly focus on the research of the technology of biodegradable recycled materials platform, and gradually apply to the channel field of artificial blood vessels. At present, the Group has carried out technology cooperation with clinical centers or R&D platforms in the United States, Canada, Germany, Italy and Switzerland, and gradually started a new process of globalized R&D. The segment has more than 200 employees and more than 50 R&D teams, with over 50% of them holding master's degrees and doctoral degrees. With a comprehensive background in medicine, pharmacy, materials, machinery, electronics, etc., it helps to achieve stable and long-term development in R&D and innovation. The Group is committed to developing this segment into a leading "cerebro-cardiovascular precision interventional therapy platform" in China and the globe.

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 aforementioned product is still in the R&D stage. The approval of commercialization, manufacturing and sale of such product 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.

By order of the Board
Grand Pharmaceutical Group Limited
Chairman
Dr. Tang Weikun

Hong Kong, 14 February 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*