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**LEPU SCIENCOTECH MEDICAL TECHNOLOGY (SHANGHAI) CO., LTD.\***

**樂普心泰醫療科技(上海)股份有限公司**

*(A joint stock company incorporated in the People's Republic of China with limited liability)*

**(Stock Code: 2291)**

## **VOLUNTARY ANNOUNCEMENT**

### **MemoSorb® BIODEGRADABLE PATENT FORAMEN OVALE OCCLUDER PRODUCT OBTAINS MEDICAL DEVICE REGISTRATION CERTIFICATE**

The board of directors (the “**Board**”) of LEPU ScienTech Medical Technology (Shanghai) Co., Ltd.\* (the “**Company**”) is pleased to announce that Shanghai Shape Memory Alloy Co., Ltd.# (上海形狀記憶合金材料有限公司), a wholly-owned subsidiary of the Company, has obtained a medical device registration certificate granted by the National Medical Products Administration of the People’s Republic of China for the MemoSorb® Biodegradable Patent Foramen Ovale Occluder Product (“**MemoSorb® Biodegradable PFO Occluder**”).

Foramen ovale is a structure between the right atrium and left atrium in the heart. In the fetal development stage, foramen ovale is patent for blood circulation in the left and right atrium, and with the completion of development of pulmonary circulation after giving birth, the septum secundum and septum primum of the atrial septum bond together and fuse into a permanent atrial septum. If not fused, patent foramen ovale (“**PFO**”) is formed. Studies have found that the incidence of PFO is 30% in one to 29 year(s) old, 25% in 30~79 years old and 20.2% in over 80 years old, and it is generally believed that the incidence of PFO in adults is approximately 25%. PFO is usually asymptomatic, but severe patent closure may have a variety of clinical manifestations, with cryptogenic stroke and migraine being the most common. According to the Recommendations of Chinese Experts on the Treatment Strategy of Patent Foramen Ovale (《卵圓孔未閉處理策略中國專家建議》), the Consensus of Chinese Experts on the Prophylactic Occlusion Procedure of Patent Foramen Ovale (《卵圓孔未閉預防性封堵術中國專家共識》), the Chinese Expert Guidelines for the Prevention of Patent Foramen Ovale-associated Stroke (《卵圓孔未閉相關卒中預防中國專家指南》) and domestic and overseas research results, PFO is one of the leading causative factors of cryptogenic stroke, and is closely associated with migraine, peripheral arterial embolism, decompression sickness, etc. PFO accounted for approximately 40% in causes of embolic stroke of undetermined source.

PFO occlusion procedure can effectively prevent occurrence of associated strokes and mitigate the symptoms of associated diseases, however the traditional metal PFO occluder accompanies patients for life after implantation, which hinders the intervention path of the left heart system in the later stage, and may also cause complications such as nickel ion precipitation, intracardiac tissue abrasion, thrombosis and atrial arrhythmia. MemoSorb® Biodegradable PFO Occluder, which was

developed by the Company in-house, is made of biomedical polymer materials, which plays the role as a temporary bridge in the human body after implantation, degrades over time into carbon dioxide and water to be excreted from the human body upon completion of autologous tissue biorepair, and achieves “implantation without residue” (植入無殘留) while successful closure of foramen ovale, avoiding the risk of complications that may be caused by metal occluder implanted in the human body for life, effectively lowering the incidence of cardioembolic stroke and mitigating migraine, dizziness and other symptoms. It also leaves a safe pathway for interventional treatments such as transseptal procedure in the future, bringing long-term health benefits and higher quality of life to patients.

In recent years, PFO occlusion procedure has developed rapidly with the support of evidence-based medicine, and the relevant technology has become relatively mature in the field of interventional treatment for structural heart disease, and the relevant standards for its operation and management have been established. In recent years, the number of PFO interventions in China increased rapidly. According to the Annual Report on PFO Intervention (2022) (《卵圓孔未閉介入治療年度報告2022》), in 2022, up to 40,000 patients received PFO treatment (including intervention and surgery) in China, ranking first among all structural heart disease interventions. Currently, there are more than 200 hospitals carrying out and more than 300 physicians involved in PFO interventional treatment.

The successful launch of MemoSorb® Biodegradable PFO Occluder is of great significance for preventing cryptogenic stroke and promoting the development of the “co-treatment of cardiovascular and cerebrovascular diseases” (心腦同治) discipline in China. Looking ahead, with the further development of its clinical application, it will bring more benefits to patients, particularly young patients.

The sales performance of MemoSorb® Biodegradable PFO Occluder will be subject to a number of factors including but not limited to clinical promotion, channel expansion, changes in competitive landscape and macro policies, in which there exist uncertainties of this product on the Company’s financial performance. Shareholders of the Company and potential investors should exercise caution when dealing in the securities of the Company.

By order of the Board

**LEPU ScienTech Medical Technology (Shanghai) Co., Ltd.\***

樂普心泰醫療科技(上海)股份有限公司

**Ms. Chen Juan**

*Chairman of the Board and Executive Director*

Shanghai, the People’s Republic of China  
September 10, 2023

*As at the date of this announcement, the Board comprises Ms. Chen Juan and Ms. Zhang Yuxin as executive Directors, Mr. Fu Shan and Mr. Zheng Guorui as non-executive Directors, and Ms. Chan Ka Lai Vanessa, Mr. Zheng Yufeng, and Mr. Liu Daozhi as independent non-executive Directors.*

\* *The Company is a registered non-Hong Kong company as defined under the Companies Ordinance (Chapter 622 of the Laws of Hong Kong) and it is registered under its Chinese name and under the English name “LEPU ScienTech Medical Technology (Shanghai) Co., Ltd.*

# *For identification purposes only.*