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**Cryofocus Medtech (Shanghai) Co., Ltd.**

**康豐生物科技(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: 6922)**

## **VOLUNTARY ANNOUNCEMENT**

### **NMPA APPROVAL FOR KEY COMPONENTS OF ATRIAL FIBRILLATION CRYOABLATION SYSTEM**

This announcement is made by Cryofocus Medtech (Shanghai) Co., Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform shareholders of the Company and potential investors about the latest business development of the Group.

The Company is pleased to announce that, on December 4, 2023, two key components of its Atrial Fibrillation Cryoablation System (心臟冷凍消融系統) (“**AF Cryoablation System**”), namely, the cryoablation equipment (冷凍消融設備) (the “**Cryoablation Equipment**”) and the balloon cryoablation catheter (球囊型冷凍消融導管) (formerly known as AF cryoablation catheter (房顫冷凍消融導管)) (the “**Balloon Cryoablation Catheter**”), were granted approval by the National Medical Products Administration of the People’s Republic of China (國家藥品監督管理局) (the “**NMPA**”).

The Cryoablation Equipment mainly includes a freezing unit and a control system, with a primary function to deliver cryogen to the Balloon Cryoablation Catheter. The Balloon Cryoablation Catheter is a flexible balloon catheter which mainly includes three parts, namely, a device connection part, an operation control part and a blood contact part. The AF Cryoablation System will be used for the treatment of drug-refractory recurrent symptomatic paroxysmal atrial fibrillation.

The Company is the first medical device company to apply cryoballoon with liquid nitrogen as the refrigerant for the treatment of drug-refractory recurrent symptomatic paroxysmal atrial fibrillation. Using liquid nitrogen as the refrigerant, the target tissue is rapidly cooled down by the ultra-low temperature generated by the liquid nitrogen, and the ablation range can be precisely controlled to achieve the therapeutic effect of necrosis of aberrant myocardial cells, which greatly improves the effectiveness and safety of the product. Unlike traditional point-by-point radiofrequency ablation, cryotherapy technology can realize one-time comprehensive ablation, which is safe, effective, convenient and reproducible. The cryoballoon ablation has become one of the standard methods to realize pulmonary vein isolation.

The clinical study results of the AF Cryoablation System have been published in *Journal of the American College of Cardiology* in October 2023 (*JACC: Asia*. 2023 Oct, 3 (5) 805–816).

The Company has overcome many key difficulties in the clinical application of liquid nitrogen cryogen and developed the original liquid nitrogen cryoablation technology in China, which can efficiently isolate pulmonary veins. Combined with ultra-vacuum heat insulation technology, the freezing medium can be transported to a treatment site under low pressure and the balloon temperature can be accurately controlled and monitored in real time, further improving the safety and effectiveness of the AF Cryoablation System. Meanwhile, in contrast to nitrous oxide (N<sub>2</sub>O) as a freezing medium, nitrogen gas is safe, readily available and environmentally friendly, which is better for clinical promotion and application.

**THE COMPANY MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET THE AF CRYOABLATION SYSTEM. SHAREHOLDERS OF THE COMPANY AND THE POTENTIAL INVESTORS ARE ADVISED TO EXERCISE DUE CARE WHEN DEALING IN THE SHARES OF THE COMPANY.**

By Order of the Board  
**Cryofocus Medtech (Shanghai) Co., Ltd.**  
**Mr. LI Kejian**  
*Chairman of the Board*

Hong Kong, December 5, 2023

*As at the date of this announcement, the Board comprises Mr. LI Kejian, Mr. ZHU Jun and Mr. LIU Wei as executive Directors, Mr. LV Shiwen and Mr. ZHAO Chunsheng as non-executive Directors, and Dr. GAO Dayong, Mr. LIANG Hsien Tse Joseph, Dr. QIN Zheng and Dr. HU Henan as independent non-executive Directors.*