Shanghai Bio-heart Biological Technology Co., Ltd.
上海百心安生物技術股份有限公司

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

(Stock Code: 2185)

VOLUNTARY ANNOUNCEMENT
A CLINICAL TRIAL OF SIROLIMUS DRUG-ELUTING BALLOON FOR THE TREATMENT OF IN-STENT RESTENOSIS WILL BE CONDUCTED IN JAPAN

This announcement is made by the board (the "**Board**") of directors (the "**Directors**") of Shanghai Bio-heart Biological Technology Co., Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to keep the shareholders of the Company (the "**Shareholders**") and potential investors informed of the latest business development of the Company.

The Board is pleased to inform the Shareholders and potential investors that the Company's recently-developed sirolimus drug-eluting balloon product will conduct clinical trials for the treatment of in-stent restenosis (ISR) in Japan.

The product is a sirolimus drug-eluting balloon catheter. The drug coating contains sirolimus, amphipathic liposomes, biodegradable polymers and dispersants in a certain ratio to achieve efficient transfer and durable release of the drug coating, which is safe and effective. By encapsulating sirolimus in biodegradable nanoparticles to form nano drug-loaded microspheres, this method achieves an ultra-long release of about 90 days in the target vessel tissue. The final microsphere micelles are formed by the self-assembly effect resulting from the amphipathic liposome with the dispersant and the nano drug-loaded microspheres through intermolecular forces. Due to the effect of amphiphilic liposomes, the transfer ability of the microsphere micelles into the target vessel tissue is greatly improved, and finally drug transfer and long release period are achieved. Drug-eluting balloon (DEB) is a kind of drug coated balloon (DCB), which usually has a longer drug release period.

In-stent restenosis is a common complication after Percutaneous Coronary Intervention (PCI) procedures, with over 240,000 PCI procedures per year reported in Japan according to literature reports, and the incidence rate of in-stent restenosis is approximately 10%, and the Drug coated balloon (DCB) market is expected to be broad due to the increase in the number of PCI procedures and the expansion of indications. According to the consensus of Asia-Pacific experts, DCB is currently recommended as the first-line treatment for in-stent restenosis, and the indications are gradually expanded to small vessel disease, bifurcation lesions, etc.

To date, DCB products available in Japan market use paclitaxel-based drug coating. The paclitaxel drug-coated balloon still has a lot of room for improvement due to problems such as the cytotoxic mechanisms of action, long-term embolism caused by shedding of coating particles, and poor performance in calcified blood vessels.

Compared with paclitaxel, sirolimus's unique cytostatic effect makes it have higher safety and wider therapeutic window, and has anti-inflammatory effect. However, due to the low lipophilic nature of sirolimus, low tissue transfer rate and difficulty in coating to the balloon surface, as a coating drug, it is technically difficult and has a higher technical barrier.

Based on the public information available to date, no sirolimus drug-coated balloon products are currently available in Japan market. The Company's product is expected to become the first sirolimus drug-coated balloon approved in Japan. Looking forward, the Company will accelerate the clinical trial execution to achieve the commercialization of the product in Japan as soon as possible. The Company will continue to strengthen its R&D capabilities and bring innovative therapies to patients worldwide.

This announcement is made by the Company on a voluntary basis to provide information to the Shareholders and potential investors of the Company. There is no assurance that the Company will ultimately develop, launch and/or commercialize the product successfully.

Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
Shanghai Bio-heart Biological Technology Co., Ltd.
Philip Li WANG
Chairman and executive Director

Shanghai, the People's Republic of China, November 18, 2022

As at the date of this announcement, the Board of the Company comprises Mr. Philip Li WANG as Chairman and executive Director, Mr. Yunqing WANG and Ms. Peili WANG as executive Directors, Mr. Quan ZHOU and Mr. Ji CHEN as non-executive Directors, and Mr. Charles Sheung Wai CHAN, Mr. Xubo LU and Mr. George Chien Cheng LIN as independent non-executive Directors.