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
NMPA APPROVAL FOR REGISTRATION OF IBERIS® RDN SYSTEM

This announcement is made by Shanghai Bio-heart Biological Technology Co., Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to provide the shareholders and potential investors of the Company with updated information in relation to the latest business advancement of the Group.

The board of directors of the Company (the "**Board**") is pleased to announce that on February 26, 2025, Iberis® Multi-Electrode Renal Artery Radiofrequency Ablation Catheter System (including Multi-electrode Renal Artery Radiofrequency Abation Catheter and Multi-Channel Radiofrequency Generator) ("**Iberis® RDN system**") developed by a subsidiary of the Company, Shanghai AngioCare Medical Technology Co., Ltd.* (上海安通醫療科技有限公司) ("**AngioCare**"), has been approved by the National Medical Products Administration of the People's Republic of China (國家藥品監督管理局) ("**NMPA**"), for the adjuvant treatment for resistant hypertension and hypertension patients with drug intolerance.

Detailed result of the pivotal trial ("**Iberis-HTN**") for the Iberis® RDN system has been published in *Circulation*. For further details of the publication of the result of Iberis-HTN study in *Circulation*, please refer to the voluntary announcement of the Company dated November 28, 2024. AngioCare has obtained CE marking for Iberis® RDN system in 2016 in Europe.

ABOUT IBERIS-HTN

Iberis-HTN is a prospective, multicenter, blinded, randomized controlled trial to evaluate the safety and efficacy of the Iberis® RDN system for the treatment of essential hypertension, with the control group in the trial receiving a sham procedure (Renal arteriography). The trial aims to evaluate the safety and efficacy of the Group's Iberis® RDN system for the Treatment of Essential Hypertension. A total of 217 subjects were enrolled in the trial. The results from the trial showed that the primary clinical endpoint of change in mean systolic blood pressure from baseline during 24-hour ambulatory blood pressure at 6 months after the procedures in the test group achieved the primary clinical endpoint of efficacy and was significantly superior to that in the sham control group. In this study, the safety of patients receiving RDN procedures using the Iberis® was similar to that of patients receiving sham procedures, with no increased risk of adverse events, and there were no serious adverse events related to the device trialed.

Warning under Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: The Company cannot guarantee that Iberis® RDN system will be ultimately commercialized successfully. Shareholders and potential investors of the Company are advised to exercise due care 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, February 26, 2025

As at the date of this announcement, the Board comprises Mr. Philip Li WANG as Chairman and executive director, Mr. Yunqing WANG and Ms. Peili WANG as executive directors, and Mr. Yiqing CHEN, Mr. Xubo LU and Mr. Yifei JIANG as independent non-executive directors.

* *For identification purpose only*