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
ACHIEVEMENT OF PRIMARY CLINICAL ENDPOINT IN THE IBERIS-HTN

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.

References are made to the Company's prospectus published on December 13, 2021 (the "**Prospectus**") and the announcement of the Company dated January 26, 2022 (the "**Announcement**"). Unless otherwise specified, capitalized terms used herein shall have the same meanings as defined in the Prospectus and the Announcement.

The board of directors of the Company (the "**Board**") is pleased to announce that the RCT of the Company's Iberis® 2nd Multi-Electrode Renal Artery Radiofrequency Ablation Catheter System in patients with Essential Hypertension ("**Iberis-HTN**") has achieved its primary clinical endpoint according to the Statistical Report that the Company has just received. The Company will continue its efforts to obtain the clinical research report as soon as possible for the submission of product registration application.

ABOUT Iberis-HTN

Iberis-HTN is a prospective, multicenter, blinded, randomized controlled trial to evaluate the safety and efficacy of the Iberis® Multi-Electrode Renal Artery Radiofrequency Ablation Catheter 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 Company's Iberis® 2nd Multi-Electrode Renal Artery Radiofrequency Ablation Catheter 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® 2nd 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.

ABOUT RDN & Iberis® 2nd

RDN is one of the few device therapies with proven clinical efficacy to treat uncontrolled hypertension and resistant hypertension and is considered by many industry experts as having the potential to transform the treatment paradigm of hypertension. According to Frost and Sullivan (Beijing) Inc., Shanghai Branch Co. ("**Frost & Sullivan**"), Iberis® 2nd is expected to be the first approved multi-electrode RDN product in China. As compared with single-electrode RDN product candidates, our multi-electrode Iberis® 2nd can effectively reduce the duration of the procedure and radiation exposure of patients and physicians. In addition, Iberis® 2nd is the only multi-electrode RDN product candidate in China that enables combined ablation of the main renal artery and its branches. We believe that, as compared with product candidates that can only ablate the main renal artery, Iberis® 2nd is able to improve the blood pressure lowering efficacy of the RDN procedure, which Frost & Sullivan concurs. Iberis® 2nd was recognized as an "innovative medical device" by the National Medical Products Administration in November 2016 and is therefore eligible for an expedited approval process. Furthermore, we are the only company in the world to have RDN catheters that can be used for both transradial arterial access ("**TRA**") and transfemoral arterial access ("**TFA**") to treat high blood pressure. The TRA approach to vascular interventions is preferred by physicians and patients. Compared to TFA, TRA interventions reduce access site complications and shorten the duration of hospital stay with a reduction in procedural costs and increased patient gratification.

Warning under Rule 18A.08(3) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited: There is no assurance that Iberis® 2nd will ultimately be successfully developed and marketed by the Company. 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, April 11, 2023

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, 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.