Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.

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
BIO-HEART ANNOUNCES UPCOMING RADIUS-HTN TRIAL IN EUROPE FOR TRANSRADIAL ACCESS FOR THE TREATMENT OF UNCONTROLLED HYPERTENSION AND RESISTANT HYPERTENSION

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

The board of directors of the Company (the "**Board**") is pleased to announce that the Company has contracted with the European Cardiovascular Research Center ("**CERC**") to conduct a European clinical trial evaluating the Company's Iberis® 2nd transradial renal denervation (RDN) system. Iberis® 2nd is our self-developed second-generation RDN system, and it is the world's only RDN product candidate that provides both the transfemoral and transradial intervention (TRI) approaches to physicians and patients. CERC is a prestigious contract research organization focusing on cardiovascular device clinical trials. The principal investigator for the study is Professor Felix Mahfoud, MD from Saarland University Hospital, Homburg/Saar and chairman of the Arterial Hypertension Working Group of the German Cardiac Society.

Despite the availability of antihypertensive medications, many patients fail to control their hypertension, a dangerous condition that can lead to heart attack and death. The availability of a system that provides TRI approach is a major advancement in the RDN field. The TRI approach which accesses the radial artery through the forearm, has been shown to reduce many complications associated with conventional access through the femoral artery in the leg. Numerous clinical trials have shown a reduction in major adverse events and bleeding complications when the radial artery approach is used for catheter-based interventions. TRI also reduces the cost of procedures and allows many patients to return home the day of their procedure.

The Company's Iberis® 2nd for RDN is a device-based, minimally invasive procedure for the treatment of high blood pressure. During the brief procedure, the Iberis® 2nd catheter is placed in the renal artery. Low level radiofrequency energy is delivered to the artery to denervate the renal nerves and cause a reduction in sympathetic nervous system activity, which can result in lower blood pressure.

Recently, the European Society of Hypertension (the "**Society**") published an updated position paper stating that RDN "is effective in reducing or interrupting the sympathetic signals to the kidneys and decreasing whole body sympathetic activity". The Society noted that five independent sham-controlled randomized clinical trials provide "conclusive evidence" that RDN can lower ambulatory and office blood pressure both in patients with and without concomitant antihypertensive medication. A panel of U.S. hypertension experts has also noted that the clinical trials showed that RDN could provide consistent reduction in blood pressure within a 24-hour interval.

Hypertension is one of the most common risk factors leading to disease burden worldwide. According to Frost and Sullivan (Beijing) Inc., Shanghai Branch Co., the total number of hypertension patients in China in 2019 was approximately 317.4 million, leading to increased cardiovascular morbidity and mortality, impaired quality of life, and increased cost to health systems. Based on meta-analyses of randomized trials using pharmacological treatments, a decrease of 10 mmHg in office systolic blood pressure is estimated to lower the incidence of cardiovascular events by 20%. Despite the broad availability of antihypertensive medications, access to drugs and adherence remain challenging for patients and physicians.

Iberis® 2nd is approved for sale in the European Union and bears a CE mark. Enrollment of patients in China in a randomized sham-controlled clinical trial of the device is ongoing and will be completed in early 2022.

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.

Information about the Company

The Company, headquartered in Shanghai, China, is a leading innovative interventional cardiovascular device company in China, with a current focus on the treatment of uncontrolled hypertension and resistant hypertension, the leading cardiovascular risk factor in the world. With Iberis® 2nd, the Company has pioneered the minimally invasive use of transradial access for RDN to treat patients with uncontrolled hypertension and resistant hypertension.

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, December 29, 2021

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 as executive director, Ms. Li CAI, Mr. Quan ZHOU, Mr. Ji CHEN and Mr. Jie YIN as non-executive directors, and Mr. Charles Sheung Wai CHAN, Mr. Xubo LU and Mr. George Chien Cheng LIN as independent non-executive directors.