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 KICKS OFF RADIUS-HTN TRIAL AT EUROPCR

Reference is made to the voluntary announcement dated December 29, 2021 in relation to the RADIUS-HTN clinical trial (the "Announcement"). Unless otherwise specified, capitalised terms used herein shall have the same meanings as those defined in the Announcement. This announcement is made by the Company on a voluntary basis to provide the shareholders and potential investors with updated information in relation to the latest business advancement of the Group.

The Board is pleased to announce that at EuroPCR 2022, which is an official annual meeting of the European Association of Percutaneous Cardiovascular Interventions, the Company finalized plans with clinical trial investigators on the European clinical trial on Renal Artery Denervation Using Radial Access in Uncontrolled Hypertension (RADIUS-HTN) (the "RADIUS-HTN Trial"). The European Cardiovascular Research Center ("CERC") will conduct the RADIUS-HTN Trial and evaluate the Company's Iberis® 2nd transradial renal denervation (RDN) system in patients with uncontrolled hypertension. The RADIUS-HTN Trial will compare the effectiveness of renal denervation performed via transradial arterial access (TRA) and transfemoral arterial access (TFA). The principal investigator for the RADIUS-HTN Trial is Professor Felix Mahfoud, MD from Saarland University Hospital, Homburg/Saar and chairman of the Arterial Hypertension Working Group of the German Cardiac Society.

We are the only company in the world to have CE Marking for catheters that can be used for both TRA and 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 shortens the duration of hospital stay with a reduction in procedural costs and increased patient gratification. Iberis<sup>®</sup> 2nd is a device-based, minimally invasive procedure for the treatment of high blood pressure. Clinical trials for Iberis<sup>®</sup> 2nd are conducted in collaboration with Terumo, our strategic business collaborator.

### Information about CERC

CERC is a prestigious contract research organization based in Massy, France, and focuses on cardiovascular device clinical trials. It was founded by experienced physicians whose expertise enabled CERC to build a strong partnership with companies in interventional cardiology.

### Information about Terumo

Terumo is a company listed on the Tokyo Stock Exchange (stock code: 4543) with extensive business portfolios ranging from vascular intervention and cardio-surgical solutions, blood transfusion and cell therapy technology, to medical products essential for daily clinical practice.

#### **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<sup>®</sup> 2nd, the Company has pioneered the minimally invasive use of transradial access for RDN to treat patients with uncontrolled hypertension and resistant hypertension.

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, May 19, 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 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.