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# 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 FIRST PATIENT ENROLLMENT IN THE RADIUS-HTN TRIAL

Reference is made to the voluntary announcements of Shanghai Bio-heart Biological Technology Co., Ltd. (the "**Company**") dated December 29, 2021 and May 19, 2022 in relation to the RADIUS-HTN clinical trial (the "**Announcements**"). Unless otherwise specified, capitalized terms used herein shall have the same meanings as those defined in the Announcements. This announcement is made by the Company 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 Renal Artery Denervation Using Radial Access in Uncontrolled Hypertension (RADIUS-HTN) (the "**RADIUS-HTN Trial**") is designed to evaluate the Company's Iberis<sup>®</sup> 2nd 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 the chairman of the Arterial Hypertension Working Group of the German Cardiac Society. The CERC is conducting the RADIUS-HTN Trial in Europe as our contract research organization.

The founder and chief executive officer of the Company, Philip Li WANG, pointed out: "We firmly believe that transradial approach for renal denervation procedure is the right direction. It is a safer, more effective, and cheaper procedure. Our ultimate goal is to bring outpatient renal denervation procedures to patients around the world."

The Board is pleased to announce that on March 27, 2023, the first patient was enrolled in Bordeaux, France. The procedure was performed by a team led by Dr. Antoine Cremer at the Centre Hospitalier Universitaire de Bordeaux. There were no reported complications or adverse events.

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 shorten 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 RADIUS-HTN

On May 19, 2022, we announced that at EuroPCR 2022, which is an official annual meeting of the European Association of Percutaneous Cardiovascular Interventions, we finalized plans with clinical trial investigators on the RADIUS-HTN Trial. The CERC will conduct the RADIUS-HTN Trial and evaluate the Company's Iberis<sup>®</sup> 2nd transradial renal denervation (RDN) system in patients with uncontrolled hypertension.

#### **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, March 27, 2023

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.