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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 PUBLICATION OF THE RESULT OF IBERIS-HTN STUDY IN CIRCULATION

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 the publication of the result of Iberis-HTN study titled “Efficacy and safety of catheter-based radiofrequency renal denervation in Chinese patients with uncontrolled hypertension: the randomized, sham-controlled, multi-center Iberis-HTN trial” in *Circulation*. Iberis-HTN study is the pivotal trial for our RDN product candidate Iberis Renal Denervation System in China.

Renal denervation (“**RDN**”) can lower blood pressure (“**BP**”) in patients with hypertension in the presence and absence of medication. Iberis-HTN is a sham-controlled trial conducted in China to evaluate the safety and efficacy of a novel multi electrode radiofrequency RDN catheter system in patients with uncontrolled hypertension despite a standardized triple pharmacotherapy. This study showed that in this trial of Chinese patients with uncontrolled hypertension on a standardized triple pharmacotherapy, RDN was safe and reduced ambulatory and office BP at 6 months compared with sham.

Professor Xiongjing Jiang and Professor Felix Mahfoud contributed equally to this work and are joint first co-authors. Academician Runlin Gao is the corresponding author. Full text can be found at <https://doi.org/10.1161/CIRCULATIONAHA.124.069215>.

The founder and chief executive officer of the Company, Philip Li WANG, pointed out: “I am delighted to see that our Iberis-HTN trial result has been published in *Circulation*. This is also the first published trial that included Renal denervation procedure via transradial approach (“**TRA**”). TRA makes RDN safer, more effective, and cheaper. Our ultimate goal is to bring outpatient renal denervation procedures to patients around the world.”

ABOUT THE AUTHORS

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Professor Xiongjing Jiang, MD, Fuwai Hospital, Peking Union Medical College & Chinese Academy of Medical Sciences. He is also the co-principal investigator for IBERIS-HTN.

Professor Felix Mahfoud, a Professor of Cardiology at the University of Basel and Chairman of the Department of Cardiology at University Hospital Basel, Switzerland. He chairs the ESC Communication Committee and the Scientific Documents Committee of the EAPCI. He is also the principal investigator for RADIUS-HTN.

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Academician Runlin Gao, MD, Fuwai Hospital, Peking Union Medical College & Chinese Academy of Medical Sciences, and academician of Chinese Academy of Engineering. He is also the principal investigator for IBERIS-HTN.

ABOUT *Circulation*

Circulation is a prestigious international journal dedicated to cardiovascular field, published by the American Heart Association (AHA). Established in 1950, the journal is published weekly and covers a wide range of topics in cardiovascular disease, including coronary artery disease, heart failure, stroke, peripheral vascular disease, atherosclerosis, and cardiovascular surgery.

As one of the most influential journals in the field of cardiovascular medicine, *Circulation* aims to advance scientific knowledge and clinical practices by publishing cutting-edge research, clinical studies, and reviews. The journal features original research articles, expert commentaries, clinical guidelines, and technical reports, all subject to a rigorous peer-review process to ensure academic integrity and scholarly rigor. *Circulation* has maintained a high impact factor over the years, with its 2023 impact factor reaching 35.5.

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 RADIUS-HTN

The Renal Artery Denervation Using Radial Access in Uncontrolled Hypertension (RADIUS-HTN) (the “**RADIUS-HTN Trial**”) is designed to evaluate the Company’s Iberis® 2nd RDN system in patients with uncontrolled hypertension. The RADIUS-HTN Trial will compare the effectiveness of renal denervation performed via TRA and transfemoral arterial access (“**TFA**”). The principal investigator for the RADIUS-HTN Trial is Professor Felix Mahfoud, a Professor of Cardiology at the University of Basel and Chairman of the Department of Cardiology at University Hospital Basel, Switzerland and the chair of ESC Communication Committee and the Scientific Documents Committee of the EAPCI. 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.

Warning under Rule 18A.05 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, November 28, 2024

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.