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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

FIRST PATIENT ENROLLMENT IN JAPAN FOR THE CLINICAL TRIAL OF A SIROLIMUS DCB PRODUCT CANDIDATE

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 that on March 27, 2025, the Company’s SAKURA-SCB trial for ischemic heart disease in Japan has successfully enrolled its first patient in Tokyo. The trial is a single-blind, multicenter comparative study to evaluate the efficacy and safety of the Company’s sirolimus drug coated balloon (“**DCB**”) product candidate. The procedure was conducted at The Cardiovascular Institute located in Tokyo.

INFORMATION ABOUT DCB PRODUCT CANDIDATE

The Company’s newly developed DCB is a sirolimus drug coated balloon catheter designed mainly for the treatment of denovo small vessel and in-stent restenosis. The drug coating contains sirolimus, amphipathic liposomes, biodegradable polymers and dispersants in a certain ratio to achieve efficient transfer and durable release of the drug coating. By encapsulating sirolimus in biodegradable nanoparticles to form nano drug-loaded microspheres, this method achieves along release of approximately 90 days in the target vessel tissue.

As of the date of this announcement, DCB products currently available in the Japan market all use paclitaxel-based drug coating. Compared with paclitaxel, sirolimus has anti-inflammatory effects, and its unique cytostatic effect potentially allows it to have higher safety, wider therapeutic window, and reduced restenosis.

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 the DCB product candidate 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, March 28, 2025

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.