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
ACHIEVEMENT OF PRE-SET PRIMARY CLINICAL ENDPOINT IN THE RCT OF BIOHEART® BIORESORBABLE CORONARY RAPAMYCIN-ELUTING SCAFFOLD IN PATIENTS WITH CORONARY HEART DISEASE (BIOHEART-II)

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.

Reference is made to the Company's prospectus published on December 13, 2021 (the "**Prospectus**") and the announcement of the Company dated February 16, 2022 (the "**Announcement**"). Unless otherwise specified, capitalised terms used herein shall have the same meanings as defined in the Prospectus and the Announcement.

The board of directors of the Company (the "**Board**") is pleased to announce that the RCT of the Company's Bioheart® bioresorbable coronary rapamycin-eluting scaffold in patients with coronary heart disease ("**BIOHEART-II**") has recently achieved its pre-set primary clinical endpoint.

BIOHEART-II is a forward-looking, multi-center, and randomized controlled clinical study with the control group receiving treatment using Abbott's marketed Xience everolimus-eluting coronary scaffold. The study aims to evaluate the safety and efficacy of the Company's Bioheart® bioabsorbable coronary rapamycin-eluting scaffold in coronary revascularization. A total of 431 subjects was enrolled in the study. The study showed that the primary clinical endpoint of in-segment late lumen loss at 12 months after the procedures in the test group achieved the primary clinical endpoint of efficacy and was not inferior to that in the control group. In this study, the safety of patients using the Bioheart® bioabsorbable coronary rapamycin-eluting scaffold was similar to that of patients using the control scaffold, with no increased risk of adverse events such as myocardial infarction and death, and no stent thrombosis events.

As of the date of this announcement, only two BRS products were commercialized in China, each of which was a first-generation BRS product with a strut thickness of over 150 μm. We are one of only four domestic players in China with second-generation BRS products at clinical trial stage. Since we completed the patient enrollment of the RCT earlier than the other competitors in China, Bioheart® is expected to be the world's first second-generation BRS system receiving regulatory approval based on multi-center RCT results. Bioheart® was recognized as an "innovative medical device" by the NMPA in February 2017 and is therefore eligible for an expedited approval process. Looking ahead, the Company will carry on its ongoing clinical and registration application programs and will actively prepare for pre-commercialization to bring Bioheart® to the market. The Company will continue to strengthen its in-house research and development capabilities and bring innovation to clinical care.

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 Bioheart® 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, August 16, 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 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.