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## LifeTech Scientific Corporation 先健科技公司

(Incorporated in the Cayman Islands with limited liability)
(Stock code: 1302)

## **VOLUNTARY ANNOUNCEMENT**

## FDA Approved Investigator-initiated Pre-market Clinical Trial of LAmbre<sup>TM</sup> Plus LAA Closure System Obtained Medical Insurance Coverage in the US

This announcement is made by LifeTech Scientific Corporation (the "Company", together with its subsidiaries, the "Group") on a voluntary basis to provide the shareholders and potential investors with updated information in relation to the latest business and new product development of the Group.

The board (the "Board") of directors (the "Directors") of the Company is pleased to announce that on 30 August 2022, the Group's LAmbre<sup>TM</sup> Plus Left Atrial Appendage Closure System ("LAmbre<sup>TM</sup> Plus LAA Closure System" or the "Device") obtained medical insurance coverage in the US of an investigator-initiated clinical trial ("Trial") which has already been approved by the US Food and Drug Administration ("FDA") in the US on 2 March 2022. The Trial was initiated by the investigator, and all patients enrolled will receive full medical coverage. The primary objective of the Trial is to demonstrate the safety and efficacy of the implantation of LAmbre<sup>TM</sup> Plus LAA Occluder in patients with large and/or irregularly shaped appendages with non-valvular atrial fibrillation compared to oral anticoagulation (OAC).

The Trial is a prospective, randomized, multicenter study which enrolls more than 3,000 subjects at up to 75 investigational sites in the US for group-controlled trials with a control group of oral anticoagulants. The Trial is expected to see more than 1,500 implants of the Device at a fee, and a marketing application for the Device will be submitted to the FDA after satisfying certain clinical milestones.

The Device was independently developed by the Company with further structural optimization on the basis of LAmbre<sup>TM</sup> Left Atrial Appendage Closure System ("LAmbre<sup>TM</sup> LAA Closure System"). LAmbre<sup>TM</sup> LAA Closure System is an advanced product in the industry in terms of design and technology which has been widely used in over 40 countries with nearly 20,000 cases in clinical application around the world. This is a major milestone in the process of international development of the Group. The Company is confident that the Device will obtain US pre-market approval (PMA) from the FDA after completing pre-market clinical research in the US.

As the LAmbre<sup>TM</sup> Plus LAA Closure System is still subject to further approval from the FDA, shareholders and potential investors of the Company should exercise caution when dealing in the securities of the Company.

By order of the Board

LifeTech Scientific Corporation

XIE Yuehui

Executive Director, Chairman and Chief Executive Officer

Hong Kong, 5 September 2022

As at the date of this announcement, the Board comprises Mr. XIE Yuehui and Mr. LIU Jianxiong being executive Directors; Mr. JIANG Feng being non-executive Director; and Mr. LIANG Hsien Tse Joseph, Mr. WANG Wansong and Mr. ZHOU Luming being independent non-executive Directors.