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Acotec Scientific Holdings Limited
先瑞達醫療科技控股有限公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 6669)

VOLUNTARY ANNOUNCEMENT
ACOART LITOS® OBTAINED FDA IDE APPROVAL

This announcement is made by Acotec Scientific Holdings Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to provide the shareholders of the Company and potential investors about the latest business updates of the Group.

The board of directors (the “**Board**”) of the Company is pleased to announce that on November 29, 2023, the Group received the approval of IDE (Investigational Device Exemption) application from the US Food and Drug Administration (FDA) for AcoArt Litos® Paclitaxel Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter (the “**AcoArt Litos®**”).

An IDE refers to the exemption of medical devices from certain regulatory controls, such as prohibitions on the sale of unapproved products, in order to conduct clinical trials on medical devices. It is also an important stage in the US FDA’s Premarket Approval (PMA) and 510(k) review of medical devices. The IDE approval means that the clinical research on AcoArt Litos® in the United States will begin after obtaining approval from the Institutional Review Board (IRB). FDA has determined that the Company had provided sufficient data to support initiation of a human clinical study.

AcoArt Litos® is a paclitaxel DCB used to prevent stenosis or occlusion in BTK arteries for the treatment of chronic limb-threatening ischemia with a vascular interventional approach. AcoArt Litos® received the CE Marking in 2014, the US FDA “breakthrough device” designation in 2019 and the National Medical Products Administration approval for market in 2020. According to Frost & Sullivan, AcoArt Litos® is the first domestically manufactured device receiving US FDA “breakthrough device” designation.

By Order of the Board
Acotec Scientific Holdings Limited
Jing LI

*Chairman of the Board, Executive Director and
Chief Executive Officer*

Hong Kong, November 30, 2023

As at the date of this announcement, the executive Directors are Ms. Jing LI and Mr. Silvio Rudolf SCHAFFNER, the non-executive Directors are Mr. Arthur Crosswell BUTCHER and Ms. June CHANG, and the independent non-executive Directors are Dr. Yuqi WANG, Ms. Hong NI and Ms. Kin Yee POON.