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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 APPROVAL FOR SIROLIMUS-COATED CORONARY BALLOON DILATATION CATHETER ACOART CANNA® BY PRC NATIONAL MEDICAL PRODUCTS ADMINISTRATION

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 with updated information in relation to the latest business and new product development progress of the Group.

The board of directors (the "Board") of the Company is pleased to announce that on July 31, 2025, the Group received the registration approval from the PRC National Medical Products Administration for Sirolimus-Coated Coronary Balloon Dilatation Catheter AcoArt Canna®. AcoArt Canna® is indicated for the dilatation treatment of de novo coronary artery bifurcation lesions with a vessel diameter ranging from 2.0mm to 4.0mm. Clinical trial results have demonstrated the efficacy and safety of AcoArt Canna® in clinical applications: the primary endpoint of the clinical trial was the percentage of diameter stenosis (DS, %) in the target lesion branch vessel as shown by angiography at 9 months post-procedure. The treatment group using AcoArt Canna® recorded a D.S. of 30.52% at 9 months post-procedure, while the control group using paclitaxel-coated coronary balloon dilatation catheters showed a D.S. of 33.46% at 9 months post-procedure, with no statistically significant difference between the two groups. Furthermore, based on the analysis of clinical safety data, the treatment group did not demonstrate any abnormal risks or events compared to the control group. The Company will carry out marketing activities in PRC market when appropriate.

THE COMPANY MAY NOT BE ABLE TO ULTIMATELY MARKET SIROLIMUS-COATED CORONARY BALLOON DILATATION CATHETER ACOART CANNA®. SHAREHOLDERS OF THE COMPANY AND POTENTIAL INVESTORS ARE ADVISED TO EXERCISE DUE CARE WHEN DEALING IN THE SHARES OF THE COMPANY.

By Order of the Board

Acotec Scientific Holdings Limited

Jing LI

Chairperson of the Board, Executive Director and Chief Executive Officer

Hong Kong, August 4, 2025

As at the date of this announcement, the executive Director is Ms. Jing LI, the non-executive Directors are Mr. Silvio Rudolf SCHAFFNER, 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.