

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



MicroPort CardioFlow Medtech Corporation

微创心通医疗科技有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 2160)

VOLUNTARY ANNOUNCEMENT

ALTAVALVE™ WAS GRANTED THE BREAKTHROUGH DEVICE DESIGNATION BY THE FDA

This announcement is made by MicroPort CardioFlow Medtech Corporation (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business advancement of the Group.

The board of directors of the Company (the “**Board**”) is pleased to announce that, recently, AltaValve™ mitral valve replacement medical device (“**AltaValve™**”), has been granted the breakthrough device designation (the “**Breakthrough Device Designation**”) by the U.S. Food and Drug Administration (the “**FDA**”). AltaValve™ is one TMVR (transcatheter mitral valve replacement) product developed by the Group in collaboration with our business partner, 4C Medical Technologies, Inc. (“**4C Medical**”), for the treatment of (a) moderate-to-severe or severe mitral regurgitation (“**MR**”), and (b) moderate-to-severe or severe MR with moderate/severe mitral annular calcification.

AltaValve™ offers a novel transcatheter therapeutic option to fulfill an unmet clinical need in patients who are unsuitable for surgery or transcatheter edge-to-edge repair. The atrial-only fixation of the technology is designed to minimize the complexities and variabilities associated with anchoring to the mitral annulus, which preserves critical cardiac structures, reducing the risk of left ventricular outflow tract obstruction or damage to the left ventricle.

The Breakthrough Device Designation by the FDA recognizes AltaValve™ as a device that should receive expedited review to provide patients with earlier access. This designation is given to devices that potentially offer more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases. 4C Medical has achieved positive results in the early feasibility study of AltaValve™, and anticipates commencing a global pivotal clinical trial in late 2024 to support its CE mark and FDA approval.

INFORMATION ABOUT 4C MEDICAL

4C Medical is a company incorporated under the laws of the State of Delaware. It is engaged in the research and development of the mitral and tricuspid valve devices in the United States. The Company, along with its wholly-owned subsidiary Derryhill Global Limited, holds approximately 29.6% equity interest in 4C Medical, making it the largest shareholder as of the date of this announcement. The Company enjoys the exclusive commercial rights in relation to AltaValve™ in Mainland China, Hong Kong, Macau and Taiwan.

The Company cannot guarantee that AltaValve™ will be ultimately commercialized successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

By Order of the Board
MicroPort CardioFlow Medtech Corporation
Chen Guoming
Chairman

Shanghai, PRC, May 9, 2024

As of the date of this announcement, the executive Directors are Mr. Jeffrey R Lindstrom, Mr. Zhao Liang and Ms. Yan Luying, the non-executive Directors are Mr. Chen Guoming, Mr. Zhang Junjie and Ms. Wu Xia, and the independent non-executive Directors are Mr. Jonathan H. Chou, Dr. Ding Jiandong and Ms. Sun Zhixiang.