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Rainmed Medical Limited
潤邁德醫療有限公司
(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2297)

VOLUNTARY ANNOUNCEMENT
NMPA APPROVAL FOR REGISTRATION APPLICATION OF CAIMR SYSTEM

This announcement is made by Rainmed Medical Limited (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to provide the shareholders and potential investors of the Company with the latest information about the business and new product development progress of the Group.

The board (the "**Board** ") of directors (the "**Directors**") of the Company is pleased to announce that the Group has recently received approval from the National Medical Products Administration（國家藥品監督管理局）(the "**NMPA**") for the registration application of our coronary artery function measurement system ("**caIMR System**"), making it the second core product of the Group approved by the NMPA.

Index of microvascular resistance ("**IMR**") is a quantitative method to assess the microvascular function of blood vessels, and is used to identify effective adjunctive treatment to reduce microcirculatory dysfunction and improve future prognosis after percutaneous coronary intervention ("**PCI**"). IMR can guide the diagnosis and management of patients with coronary artery diseases ("**CAD**"). Multiple authoritative studies globally have indicated a significant correlation between IMR value and risk for cardiac death or readmission due to heart failure: patients with IMR ≥25 showed significantly higher risk for cardiac death or readmission due to heart failure than those with IMR <25. In addition, as fractional flow reserve ("**FFR**") measures the macro-circulation of epicardial arteries which account for 5% of all arteries and IMR measures the microcirculation of pre-arterioles, arterioles and capillaries, which account for 95% of all arteries, therefore, using a combination of IMR and FFR can provide a comprehensive evaluation on coronary circulation status of CAD patients. According to China Insights Industry Consultancy Limited, an independent market research and consultancy firm principally engaged in the provision of market research and consultancy services, up to 70% of patients receiving coronary angiography have microvascular dysfunction, and thus are in need of IMR measurement. However, it has been impossible to obtain a precise measurement of IMR without invasive procedures thus far, which makes IMR measurement time-consuming and inconvenient for clinical use due to the complexity of the operation.

Our caIMR System is an innovative product in the field of interventional precision diagnosis and treatment that is designed to address these shortcomings in the diagnosis of microcirculation disorders. It achieved a high evaluation accuracy of 93.8% in the confirmatory clinical trial. Compared to the wire-based IMR measurement which needs 40 to 60 minutes, our caIMR System is able to significantly reduce the measurement time of IMR and diagnosis of coronary microvascular diseases to less than five minutes on average. In April 2022, our caIMR System was certified to be eligible for the Special Review Procedure for Innovative Medical Devices (創新醫療器械特別審查程序) promulgated by the NMPA. In December 2022, our coronary angiography-derived fractional flow reserve system ("**caFFR System**") and caIMR System were included into the Chinese Expert Consensus on Computation of Coronary Physiological Assessment Technology (《中國計算冠狀動脈生理學檢測技術專家共識》) (the "**Expert Consensus**"). The Expert Consensus will fill the gap of the lack of guidance and norm in the clinical application of physiological indicators calculation in the intervention of coronary heart disease in China, and will provide a basis for its standardized application and expansion of the scope of application. We have recently received official approval from the NMPA for the registration application of our caIMR System.

The approval of our caIMR System indicates that the Group is able to provide a comprehensive assessment of coronary artery blood flow in CAD patients. With our caFFR System and caIMR System as the core and key diagnostic modules, our ultimate mission is to manufacture industry-leading vascular interventional surgical robots with full-suite functionalities of angiography imaging, functional precision diagnosis, operation navigation and intervention treatment for various vascular diseases including coronary artery and hypertension.

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
Rainmed Medical Limited
Huo Yunfei
Chairman of the Board and Executive Director

Hong Kong, April 24, 2023

As at the date of this announcement, the Board comprises Mr. Huo Yunfei, Mr. Lyu Yonghui, Mr. Zhang Liang and Ms. Gu Yang as executive directors, Mr. Wang Lin and Mr. Heng Lei as non-executive directors, and Mr. Liu Shuen Kong, Mr. Li Ho Man and Mr. Lau Tsz Ho Tony as independent non-executive directors.