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OrbusNeich Medical Group Holdings Limited

業聚醫療集團控股有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 6929)

VOLUNTARY ANNOUNCEMENT
FIRST PATIENT ENROLLMENT IN JAPAN CLINICAL TRIAL FOR
ITS PROPRIETARY DRUG-COATED BALLOON

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

The board (the “**Board**”) of directors (the “**Directors**”) of the Company is pleased to announce the successful enrollment of the first patient in its pivotal Japanese clinical trial (OM-0031). This trial will evaluate the Group’s proprietary coronary paclitaxel drug-coated balloon (the “**DCB**”), marking a significant step forward for the Group in further consolidating its leading position in Japan’s interventional cardiology market through its diversified product portfolio.

Built upon the Group’s well-established balloon platform, the innovative drug-coated balloon is engineered for outstanding deliverability, allowing interventionalists to easily navigate complex and severely stenotic lesions. The device also adopts the Group’s proprietary drug-coating technology, which enables the highly efficient and uniform paclitaxel transfer onto the arterial wall. This thoughtful technical pairing ensures precise therapeutic dosing and supports favorable vascular healing while maintaining robust trackability and crossability. By delivering anti-proliferative medicine non-invasively without leaving a permanent implant, the device addresses critical clinical needs in modern interventional cardiology.

The OM-0031 clinical trial is a prospective, multi-center study designed to rigorously evaluate the safety and efficacy of the DCB. The trial targets patients suffering from coronary artery disease, with a particular focus on the treatment of de novo lesions in both small and large vessels and in-stent restenosis (ISR). The primary endpoint of the study will evaluate target lesion failure (TLF) at the six-month follow-up.

Patient enrollment of OM-0031 is expected to continue across 25 leading cardiovascular centers throughout Japan, with the goal of completing patient enrollment by the end of 2027. Following the follow-up period and data analysis, the Company plans to use the clinical data to support its regulatory submission to Japan's Pharmaceuticals and Medical Devices Agency (PMDA), with the aim of bringing this advanced treatment option to the Japanese market as swiftly as possible. Commercializing the product in this strategic market is expected to create new growth opportunities and deliver long-term value to shareholders.

Shareholders of the Company and potential investors are advised to exercise caution when dealing in the shares of the Company.

By order of the Board
OrbusNeich Medical Group Holdings Limited
Mr. David CHIEN
Chairman, Executive Director and Chief Executive Officer

Hong Kong, July 22, 2026

As of the date of this announcement, the Board comprises Mr. David CHIEN, Ms. Kwai Ching Denise LAU and Mr. Wing Shing CHEN as Executive Directors; Mr. Ting San Peter Lionel LEUNG as Non-executive Director; and Mr. Yip Keung CHAN, Mr. Ka Keung LAU BBS, MH, JP and Dr. Lai Fan Gloria TAM as Independent Non-executive Directors.