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CHINA MEDICAL SYSTEM HOLDINGS LIMITED

康哲藥業控股有限公司*

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 867)

Voluntary and Business Update Announcement

New Drug Application of Methylthionium Chloride Enteric-coated Sustained-release Tablets Accepted in China

The board (the “Board”) of directors (the “Directors”) of China Medical System Holdings Limited (the “Company”, together with its subsidiaries, the “Group”) is pleased to announce that on 15 February 2023, New Drug Application of the Group’s innovative patented drug methylthionium chloride enteric-coated sustained-release tablets (“Methylthionium Chloride Enteric-coated Sustained-release Tablets” or the “Product”) has been accepted by the National Medical Products Administration of China (NMPA).

Methylthionium Chloride Enteric-coated Sustained-release Tablets is an oral diagnostic drug, being designed to significantly increase the detection rate of non-polypoid colorectal lesions by enhancing the visualization of the colorectal lesions in adult patients undergoing screening or surveillance colonoscopy. The Product obtained positive results of its Phase III clinical trial in China. The primary study endpoint - the detection rate of non-polypoid colorectal lesions, defined as the proportion of subjects with at least one histologically proven nonpolypoid colorectal lesion, was 51% in the test group (the Product was given) and 41.2% in the control group (placebo was given). The difference between the two groups was statistically significant ($P < 0.0001$). The false positive was well controlled.

Methylthioninium Chloride Enteric-coated Sustained-release Tablets has been approved by the European Medicines Agency (EMA) to be commercialized in the European Union under the trade name Lumeblue™ in August 2020.

This announcement is made on a voluntary basis by the Company and aims to inform potential investors and shareholders of the Company of the latest business developments of the Group. Shareholders and investors are advised to exercise caution in dealing in the shares and other securities of the Company.

By order of the Board
China Medical System Holdings Limited
Lam Kong
Chairman

Hong Kong, 15 February 2023

As at the date of the announcement, the directors of the Company comprise (i) Mr. Lam Kong, Mr. Chen Hongbing and Ms. Chen Yanling as executive directors; and (ii) Mr. Leung Chong Shun, Ms. Luo Laura Ying and Mr. Fung Ching Simon as independent non-executive directors.