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 for Additional RA Indication of Methotrexate Injection Accepted in China

China Medical System Holdings Limited (the "Company", together with its subsidiaries, the "Group") is pleased to announce that on 4 December 2023, the New Drug Application (NDA) for an additional indication of Methotrexate Injection (the "Product") has been accepted by the National Medical Products Administration of China (NMPA). The Product is a small-volume methotrexate injection with various strengths, which is intended to be used to treat active rheumatoid arthritis (RA) in adult patients.

Methotrexate is recognized internationally as the first choice first-line and anchor drug for RA. The Product is expected to become the first methotrexate prefilled injection to treat RA by subcutaneous administration in China, providing a safer, more effective, more convenient and more accurate administration scheme for active RA adult patients.

According to the communication with NMPA, the bridge clinical trial of the Product in China (the "Study") aims to compare the changes of DAS28-ESR score of patients with RA treated by methotrexate injection and methotrexate tablets compared with the baseline, and to judge whether the non-inferiority is established. The Study reached the preset main endpoint, and the experimental group (given the Product) was not inferior to the control group (given methotrexate tablets). In addition, the results of secondary efficacy indicators suggest that the efficacy of the Product is significantly better than that of methotrexate tablets or there is a

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trend of better. The results also show that some of the curative effects that can be observed in the early stage of the Product are more obvious than those of methotrexate tablets, suggesting that the curative effect of the Product appears earlier. The Product has some advantages over methotrexate tablets in gastrointestinal safety, and no new safety risks have been found in the Study.

In March 2023, the Product was approved for marketing in China for the treatment of severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, and retinoids. The Product was also announced as a Reference Listed Drug by NMPA in July 2021.

The Product has been approved by the European Heads of Medicines Agencies (HMA). At present, the Product has been approved for marketing in more than 40 countries and regions around the world, including the European Union, Australia, China, etc.

The Group obtained a long-term effective and exclusive license for the Product from medac Gesellschaft für klinische Spezialpräparate m.b.H on 21 September 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, 4 December 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.