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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 Methotrexate Injection Approved in China

China Medical System Holdings Limited (the “Company”, together with its subsidiaries, the “Group”) is pleased to announce that on 24 March 2023, the New Drug Application (NDA) of Methotrexate Injection (the “Product”) has been approved by the National Medical Products Administration of China (NMPA). The Product is indicated for the treatment of severe recalcitrant disabling psoriasis, which is not adequately responsive to other forms of therapy such as phototherapy, PUVA, and retinoids. In January 2022, the NDA was granted a priority review procedure as it complied with the “shortage of products with urgent clinical need” in China.

Methotrexate (MTX) has anti-inflammatory, anti-proliferative and immunomodulatory effects, and is currently one of the most effective traditional drugs for the treatment of psoriasis. However, oral MTX has poor patient compliance due to relatively large gastrointestinal side effects. The Product is administered subcutaneously (this form of administration was recommended by domestic and foreign guidelines), which can increase bioavailability, has lower side effects than oral MTX, in particular less adverse reactions in the gastrointestinal tract, and can improve patient treatment compliance and achieve a greater balance among efficacy, good safety tolerance and compliance. At the same time, the Product is available in a variety of small-capacity strengths, which are easy to use, allowing patients to self-administer medication at home under the judgment and guidance of a doctor to facilitate long-term disease management. The Product can provide a safer, more effective, more convenient, and more

** For identification purpose only*

accurate methotrexate dosing regimen for patients and can meet the drug needs of psoriasis patients for systemic treatment. The Product has patents on uses, formulations and methods in Europe and America. The incidence of psoriasis in China is about 0.47%, and the number of patients exceeds 7 million, of which more than 30% of patients have developed into moderate-to-severe disease.

In addition, for rheumatoid arthritis (RA), MTX is recognized internationally as the first choice first-line and anchor drug. The Product is expected to become the first methotrexate prefilled injection for the treatment of RA by subcutaneous administration in China. The Group continues to advance the bridging clinical trial of the Product for adult RA in China. This study is a randomized, open-label, positive-controlled, multi-center phase III clinical trial, aiming to compare efficacy and safety between methotrexate injection and methotrexate tablets in the treatment of adult RA patients.

The Product has been approved by the EU Heads of Medicines Agencies (HMA) and globally marketed in more than 20 countries, including Germany, Sweden, the United Kingdom, France and etc. The Product is also the Reference Drug announced by NMPA.

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. The Group is promoting the commercialization of the Product in an orderly manner to benefit psoriasis patients at an early date.

The announcement is made on a voluntary basis. 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, 27 March 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.