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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

Methotrexate Injection, Pre-filled Syringe

Granted an Approval for Drug Clinical Trial

China Medical System Holdings Limited (the “Company”, together with its subsidiaries, the “Group”) is pleased to announce that the innovative drug Methotrexate Injection, Pre-filled Syringe (the “Product”), which was licensed in by the Group on 21 September 2020 from medac Gesellschaft für klinische Spezialpräparate m.b.H (“medac”), has been granted an approval for drug clinical trial issued on 13 August 2021 by the National Medical Products Administration of the People’s Republic of China and agreed to carry out a clinical trial for adult rheumatoid arthritis (RA) indications. The trial is a non-inferiority designed clinical trial comparing with methotrexate oral solid preparation, aiming to evaluate the safety and efficacy of the Product among Chinese RA patients.

The Product is a methotrexate injection with multiple low-dose formulations in a small volume, indicating for the treatment of active RA and other autoimmune diseases in adults, which has been approved for marketing by European Heads of Medicine Agencies (HMA). Methotrexate is internationally recognized as the first-line gold standard medicine for the systemic treatment for RA. Currently, no methotrexate injection (including pre-filled products) for the treatment of RA has been approved for marketing in China. The Product is expected to be the first methotrexate injection for subcutaneous administration for the treatment of RA in China, meeting the medical needs of basic treatment for RA patients.

The Group is currently actively preparing for initiating the clinical trial of the Product.

The announcement is made on a voluntary basis by the Company. Shareholders and investors are advised to exercise caution when 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, 13 August 2021

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. Wu Chi Keung, Mr. Leung Chong Shun and Ms. Luo, Laura Ying as independent non-executive Directors.