

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*



**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 Tildrakizumab Injection Approved in China**

China Medical System Holdings Limited (the “Company”, together with its subsidiaries, the “Group”) is pleased to announce that on 26 May 2023, the New Drug Application (NDA) of Tildrakizumab Injection under the brand name of ILUMETRI (“ILUMETRI”) has been approved by the National Medical Products Administration of the People’s Republic of China (“China”) (NMPA). ILUMETRI is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. The Company has obtained the drug registration certificate on 30 May 2023.

ILUMETRI is a humanized IgG1/κ monoclonal antibody designed to selectively bind to the p19 subunit of interleukin-23 (IL-23) and inhibit its interaction with the IL-23 receptor, leading to inhibition of the release of pro-inflammatory cytokines and chemokines. ILUMETRI has patents on composition and formulation in China. The results of the extended study of Phase III clinical trial in China demonstrated that the primary efficacy assessment indicator PASI 75 response rate continued to increase over treatment time. The PASI 75 response rate reached a high level after 28 weeks of treatment with ILUMETRI and maintained at 91.3% at week 52, and ILUMETRI showed good long-term safety and tolerance. ILUMETRI only requires 4 administrations per year over maintenance period, which may result in higher patient compliance. ILUMETRI provides adults with moderate-to-severe plaque psoriasis a safe and effective treatment option.

Psoriasis is an autoimmune disease with complex causes, where IL-23 is regarded as one of the important drivers of the pathogenesis of psoriasis. The prevalence of psoriasis in China is

about 0.47%, and the number of patients exceeds 7 million. More than 30% of these patients have developed into moderate-to-severe disease.

ILUMETRI has been approved for marketing in the Hong Kong Special Administrative Region of China in April 2022. Tildrakizumab Injection has also been approved for marketing in the U.S., EU, Japan, UK, Switzerland, Canada, Australia and other countries/regions.

The Group obtained an exclusive license for ILUMETRI from Sun Pharmaceutical Industries Ltd. on 27 June 2019. As one of the Group's most important innovative dermatology products, ILUMETRI will sit alongside our marketed products Hirudoid and Aethoxysklerol and pipeline product ruxolitinib cream to further enhance the comprehensive competitiveness of the Group within the dermatology field. The Group is promoting the commercialization of ILUMETRI in an orderly manner to benefit adults with moderate-to-severe plaque psoriasis at an early date.

The announcement is made on a voluntary basis. 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, 30 May 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.*