CHINA MEDICAL SYSTEM HOLDINGS LIMITED
康哲藥業控股有限公司*
(Incorporated in the Cayman Islands with Limited Liability)
(Hong Kong Stock Code: 867)
(Singapore Stock Code: 8A8)

Voluntary and Business Update Announcement
Approval of Drug Clinical Trials for Systemic Lupus Erythematosus of Innovative Drug Highly Selective TYK2 Inhibitor CMS-D001

China Medical System Holdings Limited (the "Company", together with its subsidiaries, the "Group") is pleased to announce that, on 11 September 2026, the innovative drug CMS-D001 Tablets ("CMS-D001" or the "Product") has been granted the Drug Clinical Trial Approval Notice by the National Medical Products Administration of the People's Republic of China ("NMPA"). The approval notice was obtained on 14 September 2026. The NMPA grants consent to conduct clinical trials evaluating the safety and efficacy of CMS-D001 for the treatment of systemic lupus erythematosus.

CMS-D001 is a highly selective TYK2 (tyrosine kinase 2) inhibitor. TYK2 is a member of the JAK kinase family, which is an important component in immune cell signaling. CMS-D001 specifically inhibits the activation of TYK2 and blocks cell signal transduction mediated by inflammatory cytokines such as IL-23, IL-12 and Type I interferons, thereby inhibiting the pathological process of autoimmune diseases. CMS-D001 can reduce the impact on other JAK family kinases and reduce adverse effects while maintaining efficacy.

Systemic lupus erythematosus ("SLE") is a chronic autoimmune disease that can affect multiple organs, including the skin, joints, kidneys, blood and nervous system. The disease alternates between remission and relapse and can cause irreversible damage to vital organs. According to the China Systemic Lupus Erythematosus Development Report 2020 and the 2009–2019 registry study of the Chinese SLE Treatment and Research Group, there are approximately one million people with SLE in the Chinese mainland, with nearly 200,000

**For identification purpose only*

new cases annually. Moderate to severe cases account for 32.6% of patients, and the 25- to 30-year survival rate is below 30%. Currently available treatments for SLE include glucocorticoids, antimalarial drugs (such as hydroxychloroquine), conventional immunosuppressants (such as cyclophosphamide) and biologics (such as belimumab). However, disease relapse, cumulative organ damage and the risk of infection remain major challenges, underscoring the urgent clinical need for safer and more effective treatment options.

As a highly selective TYK2 inhibitor, CMS-D001 has less impact on other JAK family kinases than pan-JAK inhibitors, allowing it to maintain efficacy in long-term disease control while reducing related safety risks. Compared with marketed injectable biologics, orally administered CMS-D001 offers the advantages of better patient adherence and no risk of anti-drug antibody formation. If approved for marketing, CMS-D001 will provide a new treatment option for patients with SLE in China. It will also synergize with the Group's marketed products, such as the innovative drug Metoject (Methotrexate Injection), by leveraging the Group's existing expert network and market resources in rheumatology and autoimmune diseases, collectively enhancing the Group's competitiveness and market position in this field.

CMS-D001 is self-developed by the Group's subsidiary, Dermavon Holdings Limited ("Dermavon"). CMS-D001 was granted approval for drug clinical trials for the indications of psoriasis, atopic dermatitis, ulcerative colitis and Crohn's disease. Phase II clinical trials for the psoriasis and atopic dermatitis indications are currently ongoing. Dermavon has exclusively licensed the relevant rights relating to SLE and inflammatory bowel disease (including but not limited to the ulcerative colitis and Crohn's disease indications) to the Group (excluding Dermavon).

The Group is actively preparing to initiate relevant clinical trials and strives to launch the Product as soon as possible.

This 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, 14 September 2026

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