

*Hong Kong Exchanges and Clearing Limited, The Stock Exchange of Hong Kong Limited and Singapore Exchange Securities Trading 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)*

**(Hong Kong Stock Code: 867)**

**(Singapore Stock Code: 8A8)**

### **Voluntary and Business Update Announcement**

#### **Approval of Drug Clinical Trials for Ulcerative Colitis and Crohn’s Disease 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 22 May 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 was obtained on 25 May 2026. The NMPA grants consent to conduct clinical trials evaluating the safety and efficacy of CMS-D001 for the treatment of ulcerative colitis and Crohn’s disease.

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 procession of autoimmune diseases. CMS-D001 can reduce the impact on other JAK family kinases and reduce adverse effects while maintaining efficacy.

Ulcerative colitis (UC) is a chronic, non-specific inflammatory bowel disease that primarily affects the colonic mucosa. Patients often present with symptoms such as abdominal pain, diarrhea, mucopurulent bloody stools, and tenesmus. The disease course is prolonged and recurrent, which impacts patients’ quality of life. According to a Frost & Sullivan report, the

number of UC patients in China has been increasing year by year, from approximately 279,000 in 2015 to about 400,000 in 2019, and is expected to reach 918,000 by 2030.

Crohn's disease (CD) is a chronic, granulomatous, inflammatory disease that can involve the entire digestive tract. Common clinical manifestations include abdominal pain, diarrhea, weight loss, intestinal fistula, and intestinal obstruction. CD often presents at a young age, follows a prolonged and recurrent disease course, is associated with a high disability rate, and is currently incurable. These factors severely affect patients' quality of life and prognosis. According to Research Progress on the Epidemiology of Inflammatory Bowel Disease in China, the incidence of CD has been increasing globally in recent years. In China, the prevalence rate of CD is approximately 1.4 - 3.0 per 100,000 population, with an annual incidence of about 0.5 - 1.0 per 100,000. It is estimated that there are currently approximately 20,000 to 45,000 existing patients nationwide. Due to underdiagnosis and misdiagnosis, the actual number of patients may be higher.

UC and CD are the two primary subtypes of inflammatory bowel disease (IBD). Currently, the main drugs for treating mild to moderate IBD in clinical practice are aminosalicylates and glucocorticoids. For moderate to severe IBD, the primary medications include biologics and small-molecule targeted drugs, among which JAK inhibitors have demonstrated the best therapeutic efficacy in clinical settings. However, the highest clinical remission rate remains only 30-40%, highlighting the urgent need to develop novel therapeutic agents for IBD. CMS-D001 exhibits enhanced precision in targeting key pathogenic mechanisms of IBD through specific inhibition of TYK2 activation. This targeted approach minimizes off-target effects on other JAK kinase-mediated signaling pathways, thereby offering a superior safety profile compared to other JAK inhibitors. Therefore, TYK2 inhibitors have become an emerging target for IBD and are expected to be developed into new oral drugs for IBD.

If approved for marketing, CMS-D001 will synergize with the Group's marketed products such as Salofalk (Mesalazine, indicated for UC and CD) and the exclusive product Bioflor (*Saccharomyces boulardii* sachets, for the treatment of diarrhoea in adults and children), strengthening whole-cycle, whole-disease-course management of patients with intestinal diseases, effectively enhancing the Group's capabilities in the digestive therapeutic area. CMS-D001 will also synergize in terms of team, expert network and market resources, 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, together with its subsidiaries ("Dermavon"). CMS-D001 was granted approval for drug clinical trials for the indications of psoriasis on 18 January 2024 and for atopic dermatitis on

11 July 2025. The Phase I study in healthy subjects for CMS-D001 has been completed, and Phase II clinical trials for psoriasis and atopic dermatitis are currently ongoing, with the first subject having been enrolled. The Product will also form pipeline synergies with the Dermavon's products in the skin health field, such as the innovative drug under development, long-acting anti-IL-4R $\alpha$  monoclonal antibody MG-K10, the marketed innovative drug ruxolitinib phosphate cream, and the dermatology-grade skincare products of the Heling soothing product series. Dermavon has exclusively licensed the relevant rights for IBD to the Group (excluding Dermavon). CMS-D001 is also planned to be developed for the treatment of autoimmune diseases such as systemic lupus erythematosus in the future.

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

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, 26 May 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 and Mr. Fung Ching Simon as independent non-executive directors.*