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 Complement - mediated Kidney Disease Indication of Innovative Drug Complement Factor B Inhibitor CMS-D017

China Medical System Holdings Limited (the "Company", together with its subsidiaries, the "Group") is pleased to announce that innovative drug CMS-D017 capsules ("CMS-D017" or the "Product") self-developed by the Group, has obtained the Drug Clinical Trial Approval Notice issued by National Medical Products Administration ("NMPA") on 3 February 2026. The NMPA has approved the Group to conduct clinical trials in healthy participants in China to evaluate the safety, tolerability, pharmacokinetic, and pharmacodynamic characteristics of CMS-D017.

CMS-D017 is a novel selective small-molecule inhibitor of complement factor B. The complement system, a vital component of the innate immune system, exerts its biological functions through activation via the classical, lectin, or alternative pathways. Complement factor B, a specific serine protease primarily synthesized in the liver, acts as the "core switch" and "amplifier" of the alternative complement pathway, with its activity directly determining the intensity of complement responses. By targeting and inhibiting complement factor B, CMS-D017 blocks abnormal activation of the alternative complement pathway, reduces damage to target tissues and organs caused by the membrane attack complex, and slows the progression of complement dysregulation-related diseases. CMS-D017 has demonstrated excellent efficacy and safety in preclinical studies. It is being developed for clinical use in the treatment of complement-mediated kidney diseases, including but not limited to IgA nephropathy, idiopathic membranous nephropathy, lupus nephritis, and C3 glomerulopathy.

**For identification purpose only*

Previously, CMS-D017, intended for the treatment of paroxysmal nocturnal hemoglobinuria, was approved by NMPA of drug clinical trials on 30 January 2026. Future development plans for CMS-D017 also include the treatment of age-related macular degeneration, myasthenia gravis and other complement - mediated conditions.

Complement-mediated kidney disease (CMKD) refers to a spectrum of renal disorders directly or indirectly mediated by abnormal activation of the complement system, encompassing various primary and secondary glomerular diseases. Based on pathogenesis, CMKD can be divided into two major groups: (1) Diseases directly mediated by abnormal complement activation, including C3 glomerulopathy (C3G), atypical hemolytic uremic syndrome, and immune complex–mediated membranoproliferative glomerulonephritis; (2) Nephropathies involving complement system participation, such as IgA nephropathy (IgAN), idiopathic membranous nephropathy (IMN), and lupus nephritis (LN). Among these, IgAN and IMN are primary glomerular diseases with a relatively high incidence in China, while LN is a common secondary immune-mediated glomerular disease. Current clinical treatments for these conditions—such as corticosteroids and immunosuppressants—have limitations, including suboptimal efficacy, considerable side effects, and unfavorable prognosis, which result in multiple unmet clinical needs. With the deepening understanding of CMKD pathogenesis, targeted inhibition of complement factor B has emerged as an effective therapeutic strategy for the treatment of CMKD. Given its favorable clinical profile, CMS-D017 may offer patients an improved treatment option.

Upon approval for marketing, CMS-D017 will significantly enhance the Group's capabilities in the field of nephrology. It will synergize with the marketed innovative drug Velphoro (Sucroferric Oxyhydroxide Chewable Tablets, indicated for CKD hyperphosphatemia) and the new drug Desidustat Tablets (indicated for renal anemia, currently undergoing regulatory review for market approval) in expert networks and market resources, collectively elevating the Group's competitiveness and market position in this field.

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 and aims to inform potential investors and shareholders of the Company of the latest business developments of the Group. 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, 3 February 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.