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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)

(Hong Kong Stock Code: 867)

(Singapore Stock Code: 8A8)

Voluntary and Business Update Announcement

Approval of Drug Clinical Trials for

Paroxysmal Nocturnal Hemoglobinuria 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 30 January 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 paroxysmal nocturnal hemoglobinuria. Future development plans for CMS-D017 also include the treatment of complement-mediated kidney diseases, age-related macular

degeneration, myasthenia gravis and other conditions.

Paroxysmal nocturnal hemoglobinuria (PNH) is an acquired clonal disorder of hematopoietic stem cells caused by mutations in the PIG-A gene located on the X chromosome. Patients typically present with clinical manifestations such as hemoglobinuria, thrombosis, and pancytopenia. Complement C5 inhibitors currently serve as the first-line treatment for PNH; however, they are effective only against intravascular hemolysis and do not address extravascular hemolysis. Moreover, since complement C5 functions as a common downstream component in all three complement pathways, its inhibition carries a significant risk of infection. Existing C5 inhibitors also require intravenous or subcutaneous administration, which poses challenges for long-term treatment convenience. CMS-D017 inhibits C3 convertase formation by binding to complement factor B upstream in the complement alternative pathway. It thereby targets both extravascular and intravascular hemolysis, while sparing the classical and lectin pathways—a mechanism that may lower infection risk. Its oral formulation further enhances patient compliance, making it a potentially better therapeutic alternative for PNH patients.

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 Velporo (Sucroferric Oxyhydroxide Chewable Tablets, indicated for CKD hyperphosphatemia) and the new drug Oxemia (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, 30 January 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.