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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

Additional Chronic Obstructive Pulmonary Disease Indication of

Class 1 Innovative Drug MG-K10 Humanized Monoclonal Antibody Injection

China Medical System Holdings Limited (the “Company”, together with its subsidiaries, the “Group”) is pleased to announce that the Class 1 innovative drug anti-IL-4R α MG-K10 humanized monoclonal antibody injection (“MG-K10” or the “Product”) , for which the Group holds co-development rights (except for atopic dermatitis (AD)) and exclusive commercialization rights, has obtained the Drug Clinical Trial Approval Notice issued by National Medical Products Administration (“NMPA”) on 29 September 2025. The NMPA has agreed to conduct the clinical trial of MG-K10 for the treatment of Chronic Obstructive Pulmonary Disease (COPD).

MG-K10

MG-K10 is an innovative long-acting anti-IL-4R α humanized monoclonal antibody that simultaneously blocks the signaling of key type 2 inflammatory cytokines IL-4 and IL-13, for the treatment of type 2 inflammatory diseases. Currently marketed anti-IL-4R α drugs require biweekly dosing, while MG-K10 has a longer half-life, enabling a four-week dosing frequency. It is expected to become the world's first long-acting anti-IL-4R α monoclonal antibody to be launched on the market, and has the potential to become the Best-in-Class (BIC).

The Group and Hunan Mabgeek Biotech Co., Ltd. (“Mabgeek Biotech”) are actively preparing to initiate the relevant clinical trials. MG-K10 has also achieved positive results in a randomized, double-blind, placebo-controlled Phase III clinical study in adults with moderate-to-severe AD, meeting the primary research endpoint as designed. Asthma, prurigo nodularis, and seasonal allergic rhinitis have all entered the Phase III clinical trial stage in China. In the previously completed Phase II clinical trial for adult patients with moderate-to-severe asthma, MG-K10 also demonstrated good efficacy and safety. MG-K10 has also obtained IND approvals for the indications of chronic spontaneous urticaria (CSU), eosinophilic esophagitis and chronic rhinosinusitis with nasal polyps in China.

Chronic Obstructive Pulmonary Disease (COPD)

COPD is a common chronic airway disease characterized by persistent respiratory symptoms and airflow limitation, including chronic cough, sputum production, and progressive dyspnea. According to *The Lancet Respiratory Medicine*, COPD affects more than 400 million people, and continues to be the third cause of death worldwide, posing significant socioeconomic and health burdens. In China, COPD is one of the chronic respiratory diseases of high national concern and has been included as a key prevention and management project in the "Healthy China 2030" initiative. Estimates indicate that the number of COPD patients in China was approximately 104.4 million in 2019, rising to 107.1 million in 2023. Due to exposure to risk factors and an aging population, the incidence of COPD is expected to increase over the coming decades. By 2032, the number is projected to reach 111.4 million. Traditional COPD treatments primarily rely on bronchodilators and corticosteroids, but it still fails to fully meet the treatment needs of patients. Some patients still face challenges such as frequent acute exacerbations and progressive decline in lung function. Currently, innovative treatment options for COPD patients in China are limited, with Dupilumab being the only approved innovative therapy for COPD in China.

MG-K10 has the potential to become Best-in-Class. The addition of new indication for COPD will further enhance the Product’s competitiveness. With a long-acting formulation administered once every four weeks dosing, MG-K10 is expected to provide COPD patients with a new, effective, and safe treatment option. Upon approval for marketing, the product will drive a strategic expansion of the Group's business scope into the respiratory therapeutics sector. Building upon the existing asthma-focused pipeline, this initiative will extend the Group's reach into additional respiratory disease areas, accelerating the development and strategic deployment of a diversified respiratory product portfolio. These efforts will deepen market penetration and therapeutic expertise in this field, substantially strengthening the Group's core competitiveness in respiratory medicine. MG-K10 will provide differentiated treatment options for patients in China, addressing the clinical need for therapies that deliver

robust efficacy, favorable safety, and improved treatment adherence, ultimately bringing meaningful value to patients.

On 24 January 2025, the Group through subsidiaries of the Company entered into a Collaboration Agreement (“Agreement”) with Mabgeek Biotech and its subsidiary for MG-K10. In accordance with the Agreement and supplementary agreements, the Group has obtained the co-development rights (excluding AD) and exclusive commercialization rights for the Product in Mainland China, Hong Kong Special Administrative Region, Macao Special Administrative Region, Taiwan Region and Singapore; its subsidiary Dermavon Holdings Limited has obtained, through its subsidiary, the co-development rights (excluding AD) and exclusive commercialization rights for the Product in the field of dermatological indications in Mainland China.

This announcement is made on a voluntary basis by the Company. 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 September 2025

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.