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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 Phase III Drug Clinical Trials for

Additional Chronic Spontaneous Urticaria 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 its subsidiary, Dermavon Holdings Limited (“Dermavon”, an innovative pharmaceutical company specialized in skin health which is applying for a separate listing on the Main Board of The Stock Exchange of Hong Kong Limited, please refer to the announcement of the Company on 22 April 2025 for details) together with its subsidiaries holding the co-development rights (except for atopic dermatitis (AD)) and the exclusive commercialization rights of Class 1 innovative drug anti-IL-4R α MG-K10 humanized monoclonal antibody injection (“MG-K10” or the “Product”) received the drug clinical trial approval notice issued by National Medical Products Administration (“NMPA”) on 28 September 2025. The NMPA has agreed to conduct a Phase III clinical trial of MG-K10 for chronic spontaneous urticaria (CSU).

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 Biotechnology Co., Ltd. (“Mabgeek Biotechnology”) 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 approval for eosinophilic esophagitis, chronic rhinosinusitis with nasal polyps in China.

Chronic Spontaneous Urticaria (CSU)

CSU is a common chronic inflammatory skin disease characterized by recurrent episodes of urticaria (wheals) and/or angioedema (swelling) lasting six weeks or longer, without identifiable external triggers. According to a report by China Insights Consultancy, the number of CSU patients in China reached approximately 10.2 million in 2023. The characteristics of CSU can significantly impact patients' quality of life, and its treatment remains challenging due to its unknown etiology. Antihistamines are the standard treatment for CSU. However, many patients still experience ineffective disease control despite antihistamines, and alternative treatment options are limited. Anti-IL-4R α monoclonal antibodies have demonstrated efficacy in the treatment of CSU and a favorable overall safety profile, offering a new treatment option, particularly for patients who have had an inadequate response to or intolerance to traditional treatments. However, as of now, there are no IL-4R α monoclonal antibodies have been approved for the treatment of CSU in China.

MG-K10 has the potential to become Best-in-Class. The addition of new indication for CSU will further enhance the product's competitiveness. With a long-acting formulation administered once every four weeks, it will provide CSU patients with a new effective and safe treatment option. If approved for marketing, MG-K10 will further enrich the Group's product portfolio, offer differentiated medication choices for patients in China, meet the clinical demand for drugs with good efficacy, safety and patient compliance, and ultimately benefit patients. In the field of dermatological treatment, the Product will synergy with Dermavon's commercialized innovative drug ILUMETRI (tildrakizumab injection), exclusive drug Hirudoid (mucopolysaccharide polysulfate cream) and a series of innovative drugs under development and dermatological skincare products in terms of expert networks and market resources.

On 24 January 2025, the Group through subsidiaries of the Company entered into a Collaboration Agreement with Mabgeek Biotechnology for MG-K10. In accordance with the agreement and supplementary agreements, the Group has obtained the co-development right as stipulated in the agreement and exclusive commercialization right to the Product in Mainland China, Hong Kong Special Administrative Region, Macao Special Administrative Region, Taiwan Region and Singapore; its subsidiary Dermavon 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, 28 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.