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
New Drug Application for the Seasonal Allergic Rhinitis Indication of Class 1 Innovative Drug MG-K10 Accepted in China

China Medical System Holdings Limited (the "Company", together with its subsidiaries, the "Group") is pleased to announce that the New Drug Application (NDA) in China for the Seasonal Allergic Rhinitis (SAR) indication of MG-K10 (generic name: Comekibart Injection, "MG-K10" or the "Product"), a Class 1 innovative drug anti-IL-4Rα humanized monoclonal antibody injection, for which the Group holds co-development rights (excluding the indication of atopic dermatitis (AD)) and exclusive commercialization rights, was accepted by the National Medical Products Administration of China (NMPA) on 23 April 2026. The Product is proposed for the treatment of adult patients with moderate-to-severe seasonal allergic rhinitis whose symptoms remain inadequately controlled after treatment with intranasal corticosteroids.

MG-K10

MG-K10 is an innovative long-acting anti-IL-4Rα humanized monoclonal antibody that simultaneously blocks the signaling pathways of the key type 2 inflammatory cytokines IL-4 and IL-13, thereby exerting immunomodulatory effects. It is being developed for the treatment of type 2 inflammatory diseases, including seasonal allergic rhinitis, asthma, atopic dermatitis (AD), prurigo nodularis, chronic obstructive pulmonary disease (COPD), chronic spontaneous urticaria (CSU), chronic rhinosinusitis with nasal polyps, and eosinophilic esophagitis. Currently marketed anti-IL-4Rα therapies require administration once every two weeks. MG-K10, with its longer half-life, enabling a once-every-four-weeks dosing regimen.

* *For identification purpose only*

It therefore has the potential to become the first long-acting anti-IL-4Rα monoclonal antibody to be marketed globally, with the potential to be best-in-class. MG-K10 has met the primary endpoint in a multicenter, randomized, double-blind, placebo-controlled Phase III clinical trial in adult patients with moderate-to-severe seasonal allergic rhinitis. The results of the Phase III study demonstrated that the primary endpoint achieved statistical significance, with significantly superior efficacy compared with the placebo group, and a favorable safety profile.

Seasonal Allergic Rhinitis (SAR)

Allergic rhinitis is a chronic inflammatory disease of the nasal mucosa mediated by IgE, with type 2 inflammation as the core pathogenic mechanism. It occurs in susceptible individuals upon exposure to environmental allergens such as pollen and dust mites. In recent years, the prevalence of the disease in China has increased from 11.1% to 17.6%, affecting approximately 250 million people, among whom 52.2% are patients with persistent moderate-to-severe disease. The disease burden is significant and has become an important public health issue. Current standard treatments, including intranasal corticosteroids and antihistamines, have notable limitations. 62% of patients with moderate-to-severe disease remain inadequately controlled. Long-term use of intranasal corticosteroids may lead to adverse reactions such as epistaxis, while antihistamines are often associated with side effects such as drowsiness, indicating significant unmet clinical needs. As a biologic therapy targeting IL-4Rα, MG-K10 can block the type 2 inflammatory pathway at its source. Compared with currently approved biologics targeting the same pathway (which require dosing once every two weeks), MG-K10 achieves a differentiated breakthrough in dosing frequency with its long-acting property allowing administration once every four weeks, thereby significantly extending dosing intervals. This may help improve patient treatment adherence and reduce the time and economic burden associated with frequent hospital visits. The Product has the potential to provide a new treatment option for patients with moderate-to-severe disease who respond poorly to conventional therapies, thereby reducing the individual and socio-economic burden associated with the disease.

The acceptance by the NMPA of the NDA for the Seasonal Allergic Rhinitis indication of MG-K10 represents an important milestone for the Group's ophthalmology business, CMS Vision, as it expands its therapeutic focus from ophthalmology into the field of otolaryngology (ENT). It also marks another significant milestone in the Group's research and development progress in the field of type 2 inflammatory diseases. If the Product is successfully approved for marketing, the Group will leverage its strong academic promotion capabilities and extensive commercialization network to accelerate the commercialization of the Product. It is also expected to further enhance the academic brand influence of CMS

Vision in the relevant specialty areas and provide new momentum for the Group's business growth.

On 24 January 2025, the Group through subsidiaries of the Company entered into a Collaboration Agreement ("Agreement") with Hunan Mabgeek Biotech Co., LTD 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, 23 April 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.