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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

New Drug Application of Ruxolitinib Phosphate Cream Approved in China

The First and Only Targeted Drug Approved in China for Vitiligo

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 published by the Company on 22 April 2025 for details) received approval from the National Medical Products Administration of China (NMPA) on 30 January 2026 for the New Drug Application (NDA) of ruxolitinib phosphate cream (the “Product”) for the treatment of non-segmental vitiligo with facial involvement in children aged 12 years and older and adult patients. It is the first and only targeted drug approved in China for vitiligo, addressing a significant unmet clinical need.

About Ruxolitinib Phosphate Cream

Ruxolitinib phosphate cream (Opzelura®), a novel cream formulation of the selective JAK1/JAK2 inhibitor ruxolitinib developed by Incyte, is the first and only drug approved for the repigmentation of non-segmental vitiligo by the U.S. Food and Drug Administration (FDA). In the U.S., ruxolitinib phosphate cream is indicated for the topical treatment of nonsegmental vitiligo in adult and patients aged 12 years and older, and for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (AD) in patients aged 2 years and older without immunodeficiency. In Europe, ruxolitinib phosphate cream is approved for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

Vitiligo is a chronic autoimmune disease characterized by depigmentation of the skin, which results from the loss of pigment-producing cells known as melanocytes. It is estimated that there are approximately 10.3 million vitiligo patients in China and non-segmental vitiligo patients account for approximately 8.2 million. Existing therapies, such as topical corticosteroids (TCS) and topical calcineurin inhibitors (TCIs), have clinical limitations, with adverse reactions or limited efficacy with long-term use. The NDA approval of ruxolitinib phosphate cream successfully fills the gap in targeted drug treatment for vitiligo and is of great landmark significance.

Prior to receiving formal NDA approval, the Group benefited from the “Early and Pilot Implementation” policy granted to the Hainan Free Trade Port and Lecheng Pilot Zone (“Lecheng Pilot Zone”), the “Hong Kong and Macau Medicine and Equipment Connect” policy, and the clinically urgently needed imported drug policies of the Beijing and Tianjin Free Trade Zones, and had already initiated the pilot application of ruxolitinib phosphate cream. Currently, Boao Super Hospital has prescribed ruxolitinib phosphate cream to over 7,000 patients with non-segmental vitiligo, and more than twenty hospitals in Guangzhou, Shenzhen, Dongguan, Foshan, Zhongshan, Zhuhai, Jiangmen, Huizhou, Beijing and Tianjin have provided prescription services for the Product.

In two identical Phase III double-blind, randomized, placebo-controlled studies (TRuE-V1 and TRuE-V2) conducted overseas, the proportion of patients achieving the primary efficacy endpoint of at least 75% improvement in the Facial Vitiligo Area Score Index (F-VASI 75) after 24 weeks of treatment with ruxolitinib phosphate cream was 29.9% in both studies, significantly higher than the 7.5% and 12.9% in the placebo groups, respectively. Continued use up to 52 weeks showed sustained repigmentation. In accordance with the relevant regulations of the Lecheng Pilot Zone's real-world data application pilot project, ruxolitinib phosphate cream underwent real-world study in China, demonstrating positive efficacy consistent with the results of overseas pivotal clinical studies. All secondary efficacy endpoints in both domestic and overseas clinical studies showed a benefit trend consistent with the primary efficacy endpoint, and the treatment effect for vitiligo continued to improve with prolonged treatment. Furthermore, according to safety monitoring data from the Lecheng Pilot Zone, no new safety event was identified, no adverse event (AE) leading to discontinuation or withdrawal of treatment occurred, and no study drug-related serious adverse event (SAE) occurred.

The approval for marketing in China of the Product for vitiligo will further enrich Dermavon's product portfolio in the field of skin treatment, potentially synergizing with

Dermavon's commercialized innovative drug ILUMETRI (tildrakizumab injection), commercialized exclusive drug Hirudoid (mucopolysaccharide polysulfate cream), and a series of innovative drugs under development and dermatological skin care products, in terms of expert network and market resources, thereby potentially enhancing Dermavon's position in the field of skin health. Furthermore, the Phase III clinical trial in China of ruxolitinib phosphate cream for the treatment of mild to moderate AD has achieved positive results. Currently, the Group is actively advancing the NDA for ruxolitinib phosphate cream for the treatment of AD in China.

The Group, through a subsidiary of Dermavon entered into a Collaboration and License Agreement with Incyte for ruxolitinib phosphate cream on 2 December 2022, obtaining an exclusive license to develop, register and commercialize the Product in Mainland China, Hong Kong Special Administrative Region, Macau Special Administrative Region, Taiwan Region and eleven Southeast Asian countries (the "Territory") and a non-exclusive license to manufacture the Product in the Territory. The subsidiary of Dermavon has sublicensed the relevant rights for the Product outside Mainland China to the Group (excluding Dermavon and its subsidiary).

Incyte has worldwide rights for the development and commercialization of ruxolitinib phosphate cream, marketed in the United States and Europe as Opzelura[®]. Opzelura[®] and the Opzelura[®] logo are registered trademarks of Incyte.

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