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 Additional Indication Atopic Dermatitis (AD) for Ruxolitinib Phosphate Cream Lumirix® Approved in China

China Medical System Holdings Limited (the "Company", together with its subsidiaries, the "Group") is pleased to announce that its subsidiary, Dermavon Holdings Limited (together with its subsidiaries, "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 the approval from the National Medical Products Administration of China (NMPA) for the New Drug Application (NDA) of ruxolitinib phosphate cream Lumirix® ("Lumirix®" or the "Product") for the treatment of mild to moderate atopic dermatitis ("AD") on 2 September 2026. The drug registration certificate was obtained on 3 September 2026. The Product is indicated for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 2 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. The NDA for indication AD has been approved for inclusion in the Priority Review List by the Center for Drug Evaluation (CDE) of the NMPA based on its qualification as a "new variety, dosage form and specification of pediatric drug that conforms to the physiological characteristics of children", which effectively shortened the Product's review process and accelerated the approval for marketing approval in the AD indication.

In January 2026, Lumirix® was approved for marketing by the NMPA, becoming the first topical JAK inhibitor approved in China for the treatment of vitiligo. The approval of this

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NDA for the additional indication of AD marks a key milestone in the Product's expansion into a second therapeutic area, offering a novel treatment option for pediatric patients 2 years of age and older, adolescent and adult AD patients, with safety and efficacy supported by clinical data.

For AD, Dermavon has developed a comprehensive “treatment + care” solution, including the topical formulation Lumirix® for mild-to-moderate AD, the injectable biological agent Comekibart Injection (MG-K10) for moderate-to-severe AD, the oral small molecule targeted drug CMS-D001 for moderate-to-severe AD, and the Heling Soothing Product Series for daily repair, to meet the management needs of AD patients from treatment to daily care.

Ruxolitinib phosphate cream, a novel cream formulation of the selective JAK1/JAK2 inhibitor ruxolitinib developed by Incyte. Lumirix® successfully met its primary endpoint in a randomized, double-blind, placebo-controlled phase III clinical trial in China for mild to moderate AD. The study results demonstrated that a significantly higher proportion of patients treated with Lumirix® achieved IGA (Investigator's Global Assessment) of 0 or 1 with at least two grades of reduction from baseline at week 8, compared with placebo (63.0% vs 9.2%, $P < 0.001$). For the key secondary endpoint, the proportion of subjects achieving at least a 75% improvement from baseline in the Eczema Area and Severity Index score (EASI 75) of treatment with Lumirix® was also significantly higher than that of the placebo group, at week 8 (78.0% vs 15.4%, $P < 0.001$). In terms of safety, the severity of treatment-emergent adverse events (TEAE) during the treatment period was mostly mild or moderate, with no TEAEs leading to discontinuation of the study drug. Overall, Lumirix® was safe and well-tolerated.

AD is a chronic, recurrent and inflammatory dermatologic disease, with the main clinical manifestations of dry skin, chronic eczema-like lesions and obvious itching or pruritus, which may seriously affect the quality of life of patients. It is estimated that there were over 54 million AD patients in China as of 2024. Based on SCORAD scores, mild to moderate AD accounts for 98% of these cases, representing over 52.5 million patients. Topical drugs are the most basic treatment for AD. Traditional topical medications such as topical corticosteroids (TCS) and topical calcineurin inhibitors (TCIs) have clinical pain points with long-term adverse reactions or limited efficacy, therefore novel treatments are urgently needed.

Following the approval of Lumirix® for vitiligo, the approval of the NDA for the AD indication will further broaden the product's clinical utility. Simultaneously, this will strengthen Dermavon’s strategic layout in the field of skin treatments and create synergies with its 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 market competitiveness and brand influence in the field of skin health.

The Group, through 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. Dermavon has sublicensed the relevant rights for the Product outside of Mainland China to the Group (excluding Dermavon).

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. In the U.S., ruxolitinib phosphate cream is the first topical JAK inhibitor approved by the U.S. Food and Drug Administration (FDA) for the topical treatment of non-segmental vitiligo in adult and pediatric patients 12 years of age and older, and for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adult and pediatric patients 2 years of age and older whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. 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, as well as the treatment of moderate atopic dermatitis in adult patients for whom topical corticosteroids and topical calcineurin inhibitors are inadequate or inappropriate.

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, 3 September 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, Mr. Fung Ching Simon and Mr. Lee Sien Liang, Joseph as independent non-executive directors.