CHINA MEDICAL SYSTEM HOLDINGS LIMITED
康哲藥業控股有限公司*

(Incorporated in the Cayman Islands with Limited Liability)

(Stock Code: 867)

Voluntary and Business Update Announcement
New Drug Application for Vitiligo Indication of Ruxolitinib Phosphate Cream Accepted in China

China Medical System Holdings Limited (the "Company", together with its subsidiaries, the "Group") is pleased to announce that on 24 September 2024, the New Drug Application (NDA) for vitiligo indication of ruxolitinib phosphate cream (the "ruxolitinib cream" or the "Product") has been accepted by the National Medical Products Administration of China (NMPA).

Ruxolitinib cream achieved positive results in Chinese Real-World Study. The primary efficacy endpoint was the proportion of patients in the treatment group who achieved F-VASI 75 response at week 24, which was 49.5%, significantly higher than the target value of 14.1% ($p<0.0001$). The study met its primary endpoint, demonstrating that ruxolitinib cream is effective in treating patients with nonsegmental vitiligo, reducing the area of the lesions, and repigmenting the skin. All secondary efficacy endpoints showed a trend of benefit consistent with the primary efficacy endpoint, and the treatment effect for vitiligo continued to improve with longer treatment duration. Adverse events mostly had severity levels of grade 1 or 2. No AEs leading to discontinuation or withdrawal, and no SAEs related to the study drug occurred.

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 14 million vitiligo patients and 6.5 million in the eleven Southeast

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Asian countries. Non-segmental vitiligo patients account for approximately 85% of them. Topical corticosteroids (TCS) and calcineurin inhibitors (CI) are used off-label for non-segmental vitiligo, however, these therapies have clinical deficiencies with long-term adverse reactions of long-term treatment or limited efficacy.

About Ruxolitinib Cream

Ruxolitinib cream (Opzelura), a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, is approved by the U.S. Food & Drug Administration for the topical treatment of nonsegmental vitiligo in patients 12 years of age and older, and is the first and only treatment for repigmentation approved for use in the United States. Ruxolitinib cream (Opzelura) is also approved in the U.S. for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (AD) in non-immunocompromised patients 12 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 cream (Opzelura) is approved for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

The transfer of ruxolitinib cream from overseas production to domestic production (localization technology transfer) is being orderly promoted by the Contract Development Manufacturing Outsourcing Organization (CDMO), and the lab-scale and pilot trial studies have been completed and under scale-up production. The Group strives to complete the localization study as soon as possible, register in Mainland China and obtain marketing approval, so as to enable the Chinese patients with vitiligo to use the innovative product.

The Product is not approved by the NMPA for any indication in China. However, on 12 August 2023, the Product was approved by Hainan Medical Products Administration for Urgent Clinical Import, and officially became available to applicable patients in the Hainan Boao Lecheng International Medical Tourism Pilot Zone (the "Pilot Zone") on August 18, for the topical treatment of non-segmental vitiligo in adults and adolescents aged 12 and above with facial involvement. Benefiting from the Early and Pilot Implementation Policy granted by the state to Hainan Free Trade Port and the Pilot Zone, patients with vitiligo in China can apply for the Product in Boao Super Hospital first and receive treatment from the expert team. In addition, ruxolitinib cream was approved by the Pharmaceutical Administration Bureau (ISAF) of Macau on 11 April 2024 for the topical treatment of non-segmental vitiligo with facial involvement in adult and adolescents form 12 years of age.

On 2 December 2022, the Group through a subsidiary of the Company, a dermatology medical aesthetic company ("CMS Skinhealth") entered into a Collaboration and License

Agreement (the "License Agreement") with Incyte for topical formulations of ruxolitinib for the treatment of autoimmune and inflammatory dermatology diseases. In accordance with the License Agreement, the Group through CMS Skinhealth received 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 (Indonesia, Philippines, Vietnam, Thailand, Myanmar, Malaysia, Cambodia, Laos, Singapore, Timor-Leste and Brunei Darussalam) (the "Territory") and a non-exclusive license to manufacture the Product in the Territory. The License Agreement commenced on its effective date and has a royalty term of ten years from the date of the commercial sale of the Product in the Territory (the "Royalty Term"). Upon the expiration of the Royalty Term, the License Agreement may be renewed for a period of ten years thereafter (the "Initial Extended Royalty Term") as per certain conditions defined in the License Agreement. Upon the expiration of the Initial Extended Royalty Term, the License Agreement may be extended for a period otherwise agreed by both sides as per certain conditions defined in the License Agreement.

Incyte has worldwide rights for the development and commercialization of ruxolitinib 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, 24 September 2024

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. Chen Hongbing as non-executive director; and (iii) Mr. Leung Chong Shun, Ms. Luo Laura Ying and Mr. Fung Ching Simon as independent non-executive directors.