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 of Ruxolitinib Cream Approved in Macau

China Medical System Holdings Limited (the "Company", together with its subsidiaries, the "Group") is pleased to announce that the Pharmaceutical Administration Bureau (ISAF) of the Macau Special Administrative Region of the People's Republic of China ("Macau") has approved the new drug application of Ruxolitinib Cream (the "Product") on 11 April 2024. The drug registration certificate was obtained on 16 April 2024. The Product is approved for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

Ruxolitinib cream, a novel cream formulation of Incyte's (NASDAQ:INCY) selective JAK1/JAK2 inhibitor ruxolitinib, is the first and only topical JAK inhibitor approved for use in the United States. Ruxolitinib cream is indicated for the topical treatment of nonsegmental 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 (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. The Product is the first and only product approved by the U.S. Food and Drug Administration (FDA) for vitiligo patient repigmentation. Use of the Product in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants, such as azathioprine or cyclosporine, is not recommended. The Product is also approved in Europe for the treatment of adolescents and adults from 12 years of age with non-segmental vitiligo with facial involvement. Two pivotal multi-regional clinical trials (including the US and European sites) showed that after 24 weeks of treatment, compared with vehicle (non-medicated cream), the

* *For identification purpose only*

facial and total body repigmentation of patients treated with ruxolitinib cream was significantly improved, and 52-week data showed continuous improvement in repigmentation with the extension of treatment. The most common adverse reaction reported in the clinical trials was application site acne.

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 6,700 vitiligo patients in Macau. Non-segmental vitiligo patients account for approximately 85% of them.

The Product is not approved by the National Medical Products Administration of China (NMPA) for any indication in Mainland of 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 18 August, for the topical treatment of non-segmental vitiligo in adolescents and adults 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. The Group will also cooperate with Boao Super Hospital to collect the Real World Research (RWS) for the Product, which could support the registration and launching of the Product in Mainland of China.

NMPA has approved (i) the application to conduct a clinical trial evaluating the safety and efficacy of the Product for the treatment of non-segmental vitiligo on 11 December 2023 and (ii) the application to conduct a clinical trial evaluating the safety and efficacy of the Product for the treatment of mild to moderate atopic dermatitis (AD) on 18 March 2024.

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 gained 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 Products' first commercialization 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 is a trademark of Incyte.

The Group is promoting the commercialization of ruxolitinib cream in Macau in an orderly manner to benefit vitiligo patients at an early date.

The announcement is made on a voluntary basis. 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,16 April 2024

As at the date of the announcement, the directors of the Company comprise (i) Mr. Lam Kong, Mr. Chen Hongbing and Ms. Chen Yanling as executive directors; and (ii) Mr. Leung Chong Shun, Ms. Luo Laura Ying and Mr. Fung Ching Simon as independent non-executive directors.