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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)

(Stock Code: 867)

Voluntary and Business Update Announcement

Approval to Conduct a Phase 3 Clinical Trial Investigating Ruxolitinib Cream in Vitiligo in China

China Medical System Holdings Limited (the “Company”, together with its subsidiaries, the “Group”) is pleased to announce that the National Medical Products Administration (NMPA) has approved the application to conduct a clinical trial evaluating the safety and efficacy of Ruxolitinib Cream (the “Product”) for the treatment of non-segmental vitiligo on 11 December 2023.

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 and 6.5 million vitiligo patients in China and the eleven Southeast Asian countries, respectively. Non-segmental vitiligo patients account for approximately 85% of them. If approved in Greater China and Southeast Asia, it may bring a novel therapeutic option to patients with non-segmental vitiligo in the area and satisfy the clinical need of topical drugs combining safety and efficacy.

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 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 China.

On 2 December 2022, through a subsidiary of the Company, a dermatology medical aesthetic company (“CMS Aesthetics”), the Group entered into Collaboration and License Agreements (the “License Agreements”) with Incyte Corporation (Nasdaq: INCY) (“Incyte”) for topical formulations of ruxolitinib for the treatment of autoimmune and inflammatory dermatology diseases. In accordance with the License Agreements, the Group through CMS Aesthetics gained an exclusive license to develop, register and commercialize the Product in Mainland China, Hong Kong Special Administrative Region, Macao 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 Agreements 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 Agreements may be renewed for a period of ten years thereafter (the “Initial Extended Royalty Term”) as per certain conditions defined in the License Agreements. Upon the expiration of the Initial Extended Royalty Term, the License Agreements may be extended for a period otherwise agreed by both sides as per certain conditions defined in the License Agreements.

The Product, a novel cream formulation of Incyte’s selective JAK1/JAK2 inhibitor ruxolitinib, is the first and only topical JAK inhibitor approved for use in the United States, 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. 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 (age >12 years) with non-segmental vitiligo with facial involvement.

Incyte has worldwide rights for the development and commercialization of ruxolitinib cream, marketed in the United States as Opzelura. Opzelura is a trademark 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, 12 December 2023

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.