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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**

#### **Gaining Exclusive License for Oral Small-molecule JAK1 Inhibitor Povorcitinib for the Treatment of Vitiligo and Hidradenitis Suppurativa and Other Indications**

China Medical System Holdings Limited (the “Company”, together with its subsidiaries, the “Group”) is pleased to announce that on 31 March 2024, the Group through a wholly-owned subsidiary of the Company – a dermatology medical aesthetic company (“CMS Skinhealth”) entered into a Collaboration and License Agreement (the “License Agreement”) with Incyte (Nasdaq:INCY) (“Incyte”), a global biopharmaceutical company, for selective oral small-molecule JAK1 inhibitor povorcitinib (the “Product”) for the treatment of non-segmental vitiligo, hidradenitis suppurativa (HS), prurigo nodularis (PN) and asthma and chronic spontaneous urticaria.

In accordance with the License Agreement, the Group through CMS Skinhealth gained an exclusive license to research, 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 Agreement will commence on its effective date and has a royalty term of twelve 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. The Group will make an upfront payment to Incyte and Incyte is eligible to receive additional potential development and commercial milestones and royalties on net sales of the Product in the Territory.

## **POVORCITINIB**

Povorcitinib is a selective oral small-molecule JAK1 inhibitor, with compound and use patents in certain countries/regions in the Territory. Currently, povorcitinib is in Phase 3 clinical trials for non-segmental vitiligo and HS in multiple countries outside of China. Additionally, Phase 2 clinical studies of povorcitinib for PN, asthma and chronic spontaneous urticaria are also ongoing.

In March 2023, Incyte announced that povorcitinib had met the primary endpoint in a global multi-center Phase 2b clinical trial for non-segmental vitiligo. Results showed that after 24 weeks of treatment, compared with vehicle, total body repigmentation of patients treated with povorcitinib once daily was significantly improved. Furthermore, according to the open-label extension period of this Phase 2b study, longer-term use of povorcitinib demonstrated further improvement in total body and facial repigmentation with a favorable tolerability profile.

Previously, in September 2022, povorcitinib also met the primary endpoint in a global multi-center Phase 2 clinical trial for HS. After 16 weeks of treatment, compared with vehicle, the count of abscesses and inflammatory nodules (AN) of patients treated with povorcitinib once daily was a significant reduction. Results from the open-label extension period of this Phase 2 clinical trial showed that povorcitinib 75mg produced sustained efficacy across all treatment groups and was well tolerated.

Vitiligo is a chronic autoimmune disease characterized by depigmentation of the skin, which results from the loss of pigment-producing cells known as melanocytes. Overactivity of the JAK signaling pathway is believed to drive inflammation involved in the pathogenesis and progression of vitiligo. It is estimated that there are approximately 14 million vitiligo patients in China and 6.5 million in the eleven Southeast Asian countries respectively. Non-segmental vitiligo patients account for approximately 85% of them. Vitiligo can occur at any age, although many patients with vitiligo will experience initial onset before the age of 30. Currently, therapeutic options for vitiligo are limited, and the condition is difficult to treat,

especially for patients with moderate to severe extensive vitiligo. Povorcitinib offers a potential oral option for patients with non-segmental vitiligo, particularly those suffering from moderate to severe vitiligo.

HS is a chronic recurrent inflammatory skin condition characterized by the presence of painful inflammatory nodules, abscesses, ruptures, as well as the formation of sinus tracts and scarring. Overactivity of the JAK signaling pathway is believed to drive inflammation involved in the pathogenesis and progression of HS. It is estimated that there are approximately 470 thousand HS patients in China, about 75% of whom are moderate to severe patients. Additionally, it is estimated that there are approximately 13 thousand HS patients in the six Southeast Asian countries, comprising Thailand, Singapore, Malaysia, Philippines, Vietnam and Indonesia. HS has been included in the second batch of the Rare Disease List in China. Given the debilitating nature of condition, it can have a profoundly negative effect on patients' quality of life. However, currently in China, there are no biologics or small molecule medicines approved by the National Medical Products Administration for the treatment of HS, creating an urgent need for effective therapeutic options.

## **INCYTE**

A global biopharmaceutical company on a mission to Solve On., Incyte follows the science to find solutions for patients with unmet medical needs. Through the discovery, development and commercialization of proprietary therapeutics, Incyte has established a portfolio of first-in-class medicines for patients and a strong pipeline of products in Oncology and Inflammation & Autoimmunity. Headquartered in Wilmington, Delaware, Incyte has operations in North America, Europe and Asia.

For additional information on Incyte, please visit [Incyte.com](http://Incyte.com) or follow Incyte on social media: LinkedIn, X, Instagram, Facebook, YouTube.

## **REASONS FOR AND BENEFITS OF ENTERING INTO THE LICENSE AGREEMENT**

The introduction of the selective oral small molecule JAK1 inhibitor povorcitinib is another important collaboration between the Group and Incyte in Dermatology following the Companies' collaboration for ruxolitinib cream (the first and only topical JAK inhibitor approved by the U.S. FDA and the European EMA for repigmentation in vitiligo). Neither the Product nor ruxolitinib cream are approved by the National Medical Products Administration of China (NMPA) for any indication in Mainland of China. If approved in China, topical

ruxolitinib cream and oral povorcitinib may provide differentiated treatment options for non-segmental vitiligo patients and are expected to further enhance CMS Skinhealth's strength in the field of vitiligo treatment. Should povorcitinib be approved and launched in China, it will synergize with the innovative drugs in the commercialization stage including ILUMETRI (tildrakizumab injection), Hirudoid (mucopolysaccharide polysulfate cream) and Aethoxysklerol (polidocanol injection) in terms of expert network and market resources, helping the Product to quickly realize its clinical and commercial value.

Leveraging its strong clinical development and commercialization advantages, the Group hopes to realize the commercialization of povorcitinib in the Territory as soon as possible upon approval to meet the clinical needs of oral vitiligo drugs combining safety and efficacy and benefit relevant patients.

After having considered the above, the Directors believe that the License Agreement is on normal commercial terms and such terms are fair and reasonable and that the License Agreement is in the interests of the Company and its shareholders as a whole.

#### **LISTING RULES IMPLICATIONS**

To the best of the Directors' knowledge, information and belief after having made all reasonable enquiries, Incyte is a third party independent of the Company and its connected persons (as defined in the Rules Governing the Listing of the Securities on The Stock Exchange of Hong Kong Limited (the "Listing Rules")). Therefore, this transaction does not constitute a connected transaction of the Company under Chapter 14A of the Listing Rules. As all relevant applicable percentage ratios (as defined in the Listing Rules) of this transaction are less than 5%, this transaction does not constitute a notifiable transaction of the Company under Chapter 14 of the Listing Rules.

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.

By order of the Board  
China Medical System Holdings Limited  
**Lam Kong**  
*Chairman*

Hong Kong, 1 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.*