Incyte and CMS Announce Collaboration and License Agreement for Povorcitinib, an Oral JAK1 Inhibitor, in Mainland China, Hong Kong, Macau, Taiwan and Southeast Asia

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Povorcitinib, a selective oral JAK1 inhibitor discovered by Incyte, is an investigational medicine being evaluated for the treatment of non-segmental vitiligo, hidradenitis suppurativa (HS), prurigo nodularis (PN), asthma and chronic spontaneous urticaria

WILMINGTON, Del. and HONG KONG--(BUSINESS WIRE)--Apr. 1, 2024-- Incyte (Nasdaq:INCY) ("Incyte") and China Medical System Holdings Limited ("CMS" or the "Group") are pleased to announce that on March 31, 2024, Incyte and CMS, through a wholly-owned dermatology medical aesthetic subsidiary of the Company ("CMS Skinhealth"), entered into a Collaboration and License Agreement for the development and commercialization of povorcitinib (the "Product"), a selective oral JAK1 inhibitor, to research, develop, register and commercialize the Product in Mainland China, Hong Kong, Macao, Taiwan Region and eleven Southeast Asian countries (the "Territory") and a non-exclusive license to manufacture the Product in CMS' Territory.

Under the terms of the agreement, CMS 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 licensed product in CMS' territory.

CMS will receive an exclusive license to develop and commercialize and a non-exclusive license to manufacture povorcitinib in autoimmune and inflammatory dermatologic diseases, including non-segmental vitiligo, hidradenitis suppurativa (HS), prurigo nodularis (PN), asthma and chronic spontaneous urticaria, for patients in mainland China, Hong Kong, Macau, Taiwan and certain countries in Southeast Asia.

"We are excited to announce the addition of this collaboration for povorcitinib, expanding our relationship with CMS in the Dermatology space beyond ruxolitinib cream, to include two products with the potential to help patients with limited treatment options," said Hervé Hoppenot, Chief Executive Officer, Incyte. "There remains a significant need for new, innovative treatment for vitiligo and other immune-mediated dermatologic conditions, and we look forward to working together with the CMS team to bringing these products to market in China."

Mr. Huang Anjun, the general manager of CMS Skinhealth, stated that, "We expect that this collaboration will enhance CMS Skinhealth's portfolio of potential treatments for vitiligo that, if approved, will provide differentiated treatment options for vitiligo patients in China. Upon approval, povorcitinib is poised to synergize with the innovative drugs in the commercialization stage of our pipeline Ilumetri (tildrakizumab injection), original/drugs including Hirudoid (mucopolysaccharide polysulfate cream) and Aethoxysklerol (polidocanol injection) in terms of our network and market resources, which will help the Product to realize its clinical and commercial value."

The transaction is effective immediately upon the execution of the Collaboration and License Agreement.

About 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.

About Vitiligo

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[1]. Vitiligo can occur at any age, although many patients with vitiligo will experience initial onset before the age of 30[2]. Currently, therapeutic options for vitiligo are limited, and the condition is difficult to treat, especially for patients with moderate to severe extensive vitiligo.

About Hidradenitis Suppurativa (HS)

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[3].

It is estimated that there are approximately 470 thousand HS patients in China, about 75% of whom are moderate to severe patients[4]. Additionally, it is estimated that there are approximately 13 thousand HS patients in the six Southeast Asian countries, comprising Thailand, Singapore, Malaysia, Philippine, 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[5].

About 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 or follow us on social media: LinkedIn, X, Instagram, Facebook, YouTube.

About CMS Skinhealth

CMS's Dermatology and Medical Aesthetic Business "CMS Skinhealth" regards dermatology prescription products as its core, and extends to dermatology-grade skincare products and light medical aesthetic products, continually optimizing full lifecycle skin-health management solutions, and gradually moving toward becoming "the largest and most professional skin-health management company in China ". Relying on its strong clinical development and commercialization advantages, CMS will realize the commercialization of povorcitinib in the Territory as soon as possible to meet the clinical needs of oral vitiligo drugs with efficacy and benefit relevant patients.

About CMS

CMS is a platform company linking pharmaceutical innovation and commercialization with strong product lifecycle management capability, dedicated to providing competitive products and services to meet unmet medical needs.

CMS focuses on the global first-in-class (FIC) and best-in-class (BIC) innovative products, and efficiently promotes the clinical research, development and commercialization of innovative products, enabling the continuous transformation of scientific research into clinical practices to benefit patients.

CMS deeply engages in several specialty therapeutic fields, and has developed proven commercialization capabilities, extensive networks and expert resources, resulting in leading academic and market positions for its major marketed products. CMS continues to promote the in-depth development of its advantageous specialty fields and expand business boundaries. While strengthening the competitiveness of the cardio-cerebrovascular/gastroenterology business, CMS independently operates its dermatology and medical aesthetics business, and ophthalmology business, aiming to gain leading positions in specialty therapeutic fields, whilst enhancing the scale and efficiency. At the same time, CMS has expanded its business territory to the Southeast Asian market, striving to become a "bridgehead" for global pharmaceutical companies to enter the Southeast Asian market, further escorting the sustainable and healthy development of the Group.

Incyte Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding whether and when povorcitinib will be approved for use in mainland China, Hong Kong, Macau, Taiwan or Southeast Asia; whether and when CMS will bring povorcitinib to market in mainland China, Hong Kong, Macau, Taiwan or Southeast Asia; the potential of povorcitinib to treat patients with vitiligo, hidradenitis superativa or for any other indication; the potential for Incyte to receive royalties and payments from CMS for development and commercial milestones; and the potential for Incyte to broaden its ability to bring new medicines to patients in Asia and elsewhere, contain predictions, estimates and other forward-looking statements.

These forward-looking statements are based on Incyte's current expectations and are subject to risks and uncertainties that may cause actual results to differ materially, including unanticipated developments in and risks related to: unanticipated delays; further research and development and the results of clinical trials possibly being unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development; the ability to enroll sufficient numbers of subjects in clinical trials; Incyte's dependence on its relationships with its collaboration partners; the efficacy or safety of Incyte's products and the products of its collaboration partners; the acceptance of Incyte's products and the products of its collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including our quarterly report on Form 10-Q for the quarter ended December 31, 2023. Incyte disclaims any intent or obligation to update these forward-looking statements.

CMS Forward-Looking Statements

This press release is not intended to promote any products to you and is not for advertising purposes. This press release does not recommend any drugs, medical devices and/or indications. If you want to know more about the diagnosis and treatment of specific diseases, please follow the opinions or guidance of your doctor or other medical and health professionals. Any treatment-related decisions made by healthcare professionals should be based on the patient's specific circumstances and in accordance with the drug package insert.

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Certain matters discussed in this press release may contain statements regarding the Group's market opportunity and business prospects that are individually and collectively forward-looking statements. Such forward-looking statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties and assumptions that are difficult to predict. The Group assumes no obligation to update any forward-looking information contained in this press release. Any forward-looking statements and projections made by third parties included in this press release are not adopted by the Group and the Company is not responsible for such third-party statements and projections.

References:

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