



Incyte and Maruho Announce Strategic Alliance Agreement for Ruxolitinib Cream in Japan

April 28, 2022

WILMINGTON, Del. & OSAKA, Japan--(BUSINESS WIRE)--Apr. 28, 2022-- Incyte (NASDAQ:INCY) and Maruho Co., Ltd. today announced that the companies have entered into a Strategic Alliance Agreement for the development, manufacturing and exclusive commercialization of ruxolitinib cream, a novel cream formulation of Incyte's selective JAK2 inhibitor ruxolitinib, for treatment of autoimmune and inflammatory dermatology indications in Japan.

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20220428005807/en/>

Under the terms of the agreement, Maruho will make an upfront payment to Incyte and Incyte is eligible to receive additional potential development, regulatory and commercial milestones and royalties on net sales of the licensed product in Japan.

Maruho will receive the rights to develop, manufacture and exclusively commercialize ruxolitinib cream, and other potential future topical formulations of ruxolitinib, in autoimmune and inflammatory dermatologic diseases, including vitiligo and atopic dermatitis, in Japan.

"Having successfully launched Opzelura™ (ruxolitinib cream) in atopic dermatitis in the United States, and with a regulatory decision for ruxolitinib cream in the U.S. and regulatory feedback in Europe expected this year for vitiligo, we are eager to begin our collaboration with Maruho, a company specialized in dermatology in Japan," said Hervé Hoppenot, Chief Executive Officer, Incyte. "There remains a significant unmet need among patients living with immune-mediated dermatologic diseases and we believe Maruho's expertise makes them an outstanding partner to support the development of ruxolitinib cream and, if approved, help patients and healthcare providers in Japan access this innovative therapy."

Maruho President and CEO, Atsushi Sugita said, "Incyte has successfully launched ruxolitinib cream in the U.S. and provided a new treatment for patients suffering from atopic dermatitis. As a specialty pharmaceutical company in dermatology aimed at improving the lives of patients, supporting the development of ruxolitinib cream has great significance for Maruho. Leveraging our strengths, we will support the development of ruxolitinib cream in Japan and work to provide a new treatment option to patients suffering from immune mediated dermatologic diseases beginning with atopic dermatitis as soon as possible."

The transaction is effective immediately upon the execution of the Strategic Alliance Agreement.

About Ruxolitinib Cream (Opzelura™)

Ruxolitinib cream (Opzelura™), 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 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 Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants, such as azathioprine or cyclosporine, is not recommended.

In October 2021, Incyte announced the validation of the European Marketing Authorization Application (MAA) for ruxolitinib cream as a potential treatment for adolescents and adults (age ≥12 years) with non-segmental vitiligo with facial involvement. Additionally, in December 2021, Incyte announced the acceptance and priority review of the supplemental New Drug Application (sNDA) for ruxolitinib cream as a potential treatment for adolescents and adults (age ≥12 years) with vitiligo.

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.

About Incyte Dermatology

Incyte's science-first approach and expertise in immunology has formed the foundation of the company. In Dermatology, the Company's research and development efforts are focused on leveraging our knowledge of the JAK-STAT pathway to identify and develop topical and oral therapies with the potential to modulate immune pathways driving uncontrolled inflammation and help restore normal immune function.

Currently, Incyte is exploring the potential of JAK inhibition for additional immune-mediated dermatologic conditions with a high unmet medical need, including hidradenitis suppurativa. To learn more, visit the [Dermatology section of Incyte.com](#).

About Incyte

Incyte is a Wilmington, Delaware-based, global biopharmaceutical company focused on finding solutions for serious unmet medical needs through the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit [incyte.com](https://www.incyte.com) and follow [@Incyte](#).

About Maruho

Maruho Co., Ltd. has its headquarters in Osaka and leads Japan in research and development, manufacturing and commercialization of dermatological products. Founded in 1915, Maruho has 1,546 employees (as of the end of September 2021), and net sales were approximately 87.03 billion yen in its fiscal year ended September 30, 2021. Pursuing its long-term corporate vision of "Excellence in Dermatology," Maruho is striving to improve the health and quality of life of people all over the world.

For more information, please visit <https://www.maruho.co.jp/english/>

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 ruxolitinib cream will be approved for use in Japan or elsewhere; whether and when Maruho will bring ruxolitinib cream to market in Japan; the potential of ruxolitinib cream to treat patients with atopic dermatitis, vitiligo or for any other indication; the potential for Incyte to receive royalties and payments from Maruho for development, regulatory 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 the Company'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; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain, other third-party providers and development and discovery operations; determinations made by regulatory authorities; the Company's dependence on its relationships with its collaboration partners; the efficacy or safety of the Company's products and the products of the Company's collaboration partners; the acceptance of the Company's products and the products of the Company's collaboration partners in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report for the year ended December 31, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20220428005807/en/): <https://www.businesswire.com/news/home/20220428005807/en/>

Incyte

Media

Catalina Loveman

+1 302 498 6171

cloveman@incyte.com

Investors

Christine Chiou

+1 302 274 4773

cchiou@incyte.com

Maruho

Media

Corporate Planning Dept. Public Relations Group

+81-(0)6-6371-8831

kouhou@mii.maruho.co.jp

Source: Incyte