



Incyte Announces the Validation of the European Marketing Authorization Application for Ruxolitinib Cream in Vitiligo

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- The MAA seeks approval of ruxolitinib cream for the treatment of adolescent and adult patients with non-segmental vitiligo with facial involvement

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced the validation of the European Marketing Authorization Application (MAA) for ruxolitinib cream, a topical JAK inhibitor, as a potential treatment for adolescents and adults (age >12 years) with non-segmental vitiligo with facial involvement. The validation of the MAA by the European Medicines Agency (EMA) confirms that the submission is ready to enter the formal review process.

"The EMA's validation of the MAA for ruxolitinib cream marks an important milestone for people with vitiligo, for whom there is often a significant impact on everyday life and who currently have limited treatment options," said Jonathan Dickinson, General Manager Europe, Executive Vice President at Incyte. "We are committed to listening to the patient community to understand how we can help fulfill unmet needs and support healthcare providers to better manage this challenging disease. We look forward to working with the regulatory authorities, with the aim to bring this new potential therapy to eligible patients as soon as possible."

The MAA is supported by data from the Phase 3 TRuE-V clinical trial program evaluating the safety and efficacy of ruxolitinib cream in more than 600 people (age >12 years) with vitiligo. Results from the Phase 3 program, recently [presented](#) at the 30th European Academy of Dermatology and Venereology (EADV) congress during a late-breaking research session, showed significant improvements in facial and total body repigmentation at 24 weeks of treatment with ruxolitinib cream in people with vitiligo. In the TRuE-V studies, patients using ruxolitinib cream did not report clinically significant application site reactions, and the overall safety profile was consistent with previous study data.

Vitiligo is a chronic autoimmune disease characterized by depigmentation of skin that results from the loss of pigment-producing cells known as melanocytes. Over-activity of the JAK signaling pathway has been shown to drive inflammation involved in the pathogenesis and progression of vitiligo. It affects approximately 0.5% to 2.0% of the population globally¹ and there are no U.S. Food and Drug Administration (FDA) or EMA-approved drug therapies for repigmentation in vitiligo. The disease can occur at any age, although many patients with vitiligo will experience initial symptoms before the age of 20.²

About TRuE-V

The TRuE-V clinical trial program includes two Phase 3 studies, TRuE-V1 (NCT04052425) and TRuE-V2 (NCT04057573), evaluating the safety and efficacy of ruxolitinib cream in patients with vitiligo.

The studies each enrolled approximately 300 patients (age ≥12 years) who have been diagnosed with non-segmental vitiligo and have depigmented areas including at least 0.5% of the body surface area (BSA) on the face, ≥0.5 facial vitiligo area severity index [F-VASI] score, at least 3% BSA on nonfacial areas, ≥3 total body Vitiligo Area Scoring Index [T-VASI] score and total BSA involvement (facial and nonfacial) of up to 10%. Participants were randomized into two arms: 1.5% ruxolitinib cream twice daily (BID) and vehicle control for the 24-week double-blind period. Patients who successfully completed baseline and Week 24 assessments, including those that received vehicle control during the double-blind phase, were offered treatment extension with 1.5% ruxolitinib cream BID for an additional 28 weeks.

The primary endpoint of both studies in the TRuE-V program is the proportion of patients achieving F-VASI75, defined as at least a 75% improvement from baseline in the F-VASI score at Week 24. Key secondary endpoints include: the percentage change from baseline in facial BSA (F-BSA) at Week 24, the proportion of patients achieving F-VASI50 (at least 50% improvement from baseline in the F-VASI), F-VASI90 (at least 90% improvement from baseline in the F-VASI) and T-VASI50 (at least 50% improvement from baseline in the T-VASI) at Week 24, the proportion of patients achieving F-VASI75, F-VASI90, T-VASI50 and T-VASI75 (at least 75% improvement from baseline in the T-VASI) at Week 52 and the proportion of patients achieving a Vitiligo Noticeability Scale (VNS) score of 4 (a lot less noticeable) or 5 (no longer noticeable) at Week 24. The studies also track the frequency, duration and severity of adverse events associated with the use of ruxolitinib cream.

For more information on the TRuE-V studies, please visit <https://clinicaltrials.gov/ct2/show/NCT04052425> and <https://clinicaltrials.gov/ct2/show/NCT04057573>.

About Ruxolitinib Cream

Ruxolitinib cream is an investigational novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib.

In September 2021, ruxolitinib cream (Opzelura™) was approved for use by the U.S. Food and Drug Administration (FDA) 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.

Additionally, ruxolitinib cream is being investigated for the treatment of adolescents and adults with vitiligo in the Phase 3 TRuE-V clinical trial program. Results from this program were recently [announced](#).

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 a number of immune-mediated dermatologic conditions with a high unmet medical need, including hidradenitis suppurativa. To learn more, visit the [Dermatology section of Incyte.com](https://www.incyte.com/dermatology).

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](https://twitter.com/Incyte).

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding whether or when ruxolitinib cream might provide a successful treatment option for patients with vitiligo, the Company's ongoing clinical development program for ruxolitinib cream and its dermatology program generally, contain predictions, estimates, and other forward-looking statements.

These forward-looking statements are based on the Company's current expectations and 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 and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain and other third-party providers and development and discovery operations; determinations made by the FDA, EMA or other regulatory authorities; the Company's dependence on its relationships with its collaboration partners; the efficacy or safety of the Company's products; the acceptance of the Company's products 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 and its quarterly report on Form 10-Q for the quarter ended June 30, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

¹ Kruger C. A review of the worldwide prevalence of vitiligo in children/adolescents and adults. *Int J Dermatol*. 2012;51(10):1206-1212.

² Rodrigues M. New Discoveries in the pathogenesis and classification of vitiligo. *J Am Acad Dermatol*. 2017; 77:1-13.



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