

Incyte Announces New Findings from a Randomized Phase 2 Study of Ruxolitinib Cream in Patients with Vitiligo

April 23, 2021

- Presentations will be available on demand as part of the American Academy of Dermatology Virtual Meeting Experience 2021 (AAD VMX)

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced findings from two analyses of its randomized, dose-ranging, vehicle-controlled Phase 2 study evaluating ruxolitinib cream, an investigational nonsteroidal, anti-inflammatory, JAK inhibitor therapy, in adult patients with vitiligo. These presentations (Poster #27535 and #27568) will be available on demand as part of the American Academy of Dermatology Virtual Meeting Experience 2021 (AAD VMX), held virtually from April 23–25, 2021.

As previously announced, the Phase 2 study met its primary endpoint, demonstrating that significantly more patients treated with ruxolitinib cream for 24 weeks achieved a ≥ 50 percent improvement from baseline in the facial vitiligo area scoring index (F-VASI50) score compared to patients treated with a vehicle control (non-medicated cream). Fifty-two-week results were also [previously reported](#).

Updated results at Week 104 (Poster #27535) continue to show improvements in facial repigmentation, measured by F-VASI50 score, and total body repigmentation, measured by the proportion of patients achieving a ≥ 50 percent improvement from baseline in the total vitiligo area scoring index (T-VASI50), a key secondary endpoint, with 1.5% ruxolitinib cream administered twice daily. The results also add to previous findings indicating that a longer duration of therapy was associated with greater repigmentation, as assessed using the F-VASI and T-VASI responses at Weeks 24, 52 and 104.

Key 104-week results include:

	Week 24 n/N (%)	Week 52 n/N (%)	Week 104 n/N (%)
F-VASI Response			
F-VASI50	38/94 (40.4)	47/94 (50.0)	46/55 (83.6)
F-VASI75	20/94 (21.3)	35/94 (37.2)	36/55 (65.5)
F-VASI90	11/94 (11.7)	21/94 (22.3)	29/55 (52.7)
T-VASI response			
T-VASI50	13/94 (13.8)	29/94 (30.9)	32/55 (58.2)
T-VASI75	2/94 (2.1)	9/94 (9.6)	15/55 (27.3)
F-PhGVA of clear or almost clear	10/94 (10.6)	17/79 (21.5)	24/55 (43.6)
PaGIC-V of very much or much improved	23/87 (26.4)	33/78 (42.3)	30/54 (55.6)
BID, twice daily; F-PhGVA, facial Physician's Global Vitiligo Assessment; F-VASI, facial Vitiligo Area Scoring Index; F-VASI50/75/90, $\geq 50\%/ \geq 75\%/ \geq 90\%$ improvement in F-VASI; PaGIC-V, Patient Global Impression of Change for Vitiligo; T-VASI, total Vitiligo Area Scoring Index; T-VASI50/75, $\geq 50\%/ \geq 75\%$ improvement in T-VASI.			

"Vitiligo is a chronic autoimmune disease associated with significant quality of life impairments that currently has no FDA approved treatments available," said Jim Lee, M.D., Ph.D., Group Vice President, Inflammation & Autoimmunity, Incyte. "These findings continue to point to the potential of ruxolitinib cream to provide meaningful facial and total body repigmentation that continues to improve over time for patients who seek treatment for vitiligo. We look forward to further evaluating ruxolitinib cream in this patient population and to sharing results of our Phase 3 TRuE-V studies later this year."

Separately, an exploratory analysis evaluated the maintenance of repigmentation among patients in the Phase 2 study who responded to ruxolitinib cream and then discontinued treatment after 104 weeks (Poster #27568). The findings suggest that the repigmentation seen with ruxolitinib cream may be maintained after treatment discontinuation. Specifically:

- Twelve of 16 patients (75.0%) maintained total body repigmentation and 13 patients (81.3%) maintained facial repigmentation during follow-up duration of one to six months.
- No patients initially randomized to 1.5% ruxolitinib cream twice daily (n=3; with 2 years' exposure) experienced loss of repigmentation at Week 104 versus previous follow-up.

Across both analyses, the overall safety profile of ruxolitinib cream was consistent with previously reported data, and no new safety signals were observed.

"As a physician who treats serious dermatologic conditions like vitiligo, I aim to offer my patients treatments that may help them achieve their goals," said David Rosmarin, M.D., Vice Chair of Research and Education, Dermatology Department at Tufts Medical Center. "I am encouraged by the ruxolitinib cream vitiligo data presented at AAD VMX, including the continued improvement in outcomes and duration of results that were observed in the analyses, and look forward to seeing more from the ongoing evaluation of this potential topical treatment in patients with vitiligo who currently have limited options for skin repigmentation."

These presentations are available on demand on the AAD VMX website at <https://eposters.aad.org/categories>, and can be accessed until July 12, 2021.

About Vitiligo

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 percent to 2.0 percent of the population globally¹ and there are no U.S. Food and Drug Administration (FDA) or European Medicines Agency (EMA)-approved drug therapies for the treatment of vitiligo. It can occur at any age, although many patients with vitiligo will experience initial symptoms before the age of 20².

About the Phase 2 Study (NCT03099304)

This randomized, dose-ranging, vehicle-controlled, Phase 2 study is evaluating the safety and efficacy of ruxolitinib cream for adult patients with vitiligo.

The first part of the study spanned 24 weeks and enrolled 157 adults (aged 18-75 years) diagnosed with vitiligo and with depigmented areas of at least 0.5 percent of the body surface area (BSA) on the face and at least 3 percent of the total BSA on non-facial areas. Patients were equally randomized across five treatment arms, including: ruxolitinib cream 1.5 percent, 0.5 percent or 0.15 percent administered QD; ruxolitinib cream 1.5 percent administered BID; or vehicle control for 24 weeks.

The second part of the study spanned an additional 28 weeks (52 weeks total) and included patients enrolled in the first part of the study. Patients receiving vehicle control or those patients who achieved <25 percent improvement in F-VASI at Week 24 on ruxolitinib cream 0.15 percent were rerandomized to receive ruxolitinib cream 1.5 percent BID, 1.5 percent QD or 0.5 percent QD. After Week 52, patients who completed baseline, Week 24 and Week 52 assessments could continue to receive open-label treatment with 1.5% ruxolitinib cream BID for an additional 104 weeks.

The primary efficacy endpoint was the percentage of patients treated with ruxolitinib cream who achieved a F-VASI50 score at Week 24, compared to patients treated with vehicle control. Key secondary endpoints included the proportion of patients who achieved a F-PhGVA score of 0 or 1 at Week 24, the proportion of patients who achieved T-VASI50 at Week 52 and the safety and tolerability of ruxolitinib cream.

For more information about the study, please visit: <https://clinicaltrials.gov/ct2/show/NCT03099304>

About Ruxolitinib Cream

Ruxolitinib cream is a proprietary formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib that has been designed for topical application. Ruxolitinib cream is currently in Phase 3 development for the treatment of atopic dermatitis (TRuE-AD) and for the treatment of adolescents and adults with vitiligo (TRuE-V). Incyte has worldwide rights for the development and commercialization of ruxolitinib cream.

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 atopic dermatitis, vitiligo and 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](#).

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding the presentation of data from the Company's ongoing clinical development program for ruxolitinib cream and the Company's vitiligo program generally, its clinical development pipeline and whether or when ruxolitinib cream or any development compounds will be approved or commercially available for use in the United States or elsewhere for vitiligo or any other indication, its presentation plans for the upcoming AAD VMX meeting and its goal of improving the lives of patients, 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; 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; greater than expected expenses; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2020. 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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