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Incyte Announces Positive Results from Phase 3 TRuE-V Program Evaluating Ruxolitinib Cream in Patients with Vitiligo

-Primary and key secondary endpoints met in both TRuE-V1 and TRuE-V2 studies

-Data will support planned U.S. and EU regulatory submissions for ruxolitinib cream in vitiligo in the second half of 2021

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced positive topline results from its pivotal Phase 3 TRuE-V clinical trial program evaluating the safety and efficacy of ruxolitinib cream, an investigational, nonsteroidal, anti-inflammatory, JAK inhibitor, topical therapy, in adolescent and adult patients (age ≥12 years) with vitiligo.

Both the TRuE-V1 and TRuE-V2 studies met the primary endpoint ($p<0.0001$ for TRuE-V1; $p<.01$ for TRuE-V2), demonstrating that significantly more patients treated with ruxolitinib cream 1.5% twice daily (BID) achieved a ≥75% improvement from baseline in the facial vitiligo area scoring index (F-VASI75) compared to patients treated with a vehicle control at Week 24.

The studies also met key secondary endpoints including patient reported outcomes. The overall efficacy and safety profile of ruxolitinib cream is consistent with **previously reported Phase 2 data**, and no new safety signals were observed. The long-term efficacy and safety portions of both studies will continue as planned. Additionally, data from both studies will be submitted for publication and presentation at an upcoming scientific meeting in the second half of 2021.

“These positive results – the first Phase 3 data to demonstrate significant improvements in facial and total body repigmentation – confirm the potential of ruxolitinib cream to be a meaningful treatment option for individuals living with and seeking treatment for their vitiligo,” said Jim Lee, M.D., Group Vice President, Inflammation &

Autoimmunity, Incyte. “We look forward to working with regulators to bring this much needed treatment option to patients. If approved, ruxolitinib cream would be the first and only medical treatment for repigmentation in vitiligo.”

Based on these findings, Incyte plans to submit marketing applications for ruxolitinib cream for the treatment of adolescent and adult patients with vitiligo (age ≥12 years) to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) in the second half of 2021. The FDA is currently reviewing a New Drug Application (NDA) for ruxolitinib cream for the treatment of adolescents and adults (age ≥12 years) with atopic dermatitis, a type of eczema.

“Vitiligo is a chronic immune-mediated skin condition that can significantly impact quality of life for those living with, and suffering from, this disease,” said David Rosmarin, M.D., Vice Chair of Research and Education, Dermatology Department at Tufts Medical Center. “As a clinician, I am extremely encouraged by the initial findings from the TRuE-V program and the potential to have ruxolitinib cream as a future topical treatment option for vitiligo patients, who currently have limited therapies available that effectively and safely address repigmentation.”

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% to 2.0% 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 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 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** 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 Company's ongoing clinical development program for ruxolitinib cream in patients with vitiligo, the enrollment, design, timing and results of the TRuE-V clinical trial program, and whether ruxolitinib

cream will become an approved treatment option for patients with vitiligo, 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; 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 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; greater than expected expenses; expenses relating to litigation or strategic activities; 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-Q for the quarter ending March 31, 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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