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Incyte Announces Positive 52-Week Results From a Randomized Phase 2 Study of Ruxolitinib Cream in Patients With Vitiligo

October 12, 2019

- Data presented at EADV demonstrate continued improvement in repigmentation of vitiligo lesions upon longer treatment duration with ruxolitinib cream

WILMINGTON, Del.--(BUSINESS WIRE)--Oct. 12, 2019-- Incyte (Nasdaq:INCY) today announces positive 52-week results from its randomized, double-blind, dose-ranging, Phase 2 study evaluating ruxolitinib cream, a nonsteroidal, anti-inflammatory, JAK inhibitor therapy, in adult patients with vitiligo.

As previously announced, the 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 severity index (F-VASI50) score compared to patients treated with a vehicle control (non-medicated cream).

Updated results at week 52 show substantial improvements in total body repigmentation with ruxolitinib cream, measured by the proportion of patients achieving a ≥ 50 percent improvement from baseline in the total vitiligo area severity index (T-VASI50), a key secondary endpoint. In addition, after 52 weeks of treatment with ruxolitinib cream 1.5 percent administered twice daily (BID), 58 percent of patients achieved F-VASI50 and 51 percent of patients achieved a ≥ 75 percent improvement (F-VASI75). F-VASI75 after 24 weeks is the primary outcome measure of both the TRuE-V1 and TRuE-V2 randomized Phase 3 trials that are already underway.

The 52-week results are being shared at the 28th European Academy of Dermatology and Venereology (EADV) congress in Madrid, Spain, during a late-breaking research session today, October 12, 2019, from 11:30 a.m. CEST to 11:45 a.m. CEST (Location: Hall 10 Dalí; Late Breaking News, Abstract #D3T01.1L).

"We are very encouraged about the positive updated data presented at EADV, which demonstrate substantial facial and total body repigmentation of vitiligo lesions in patients treated with ruxolitinib cream, and continued improvements with longer duration of treatment," said Jim Lee, M.D., Group Vice President, Inflammation & Autoimmunity, Incyte. "As we seek to offer a much-needed option for those patients impacted by this life-altering disease, we are excited that the pivotal Phase 3 studies evaluating ruxolitinib cream in patients with vitiligo are underway, with results expected in 2021."

Key 52-week results include:

- A longer duration of therapy, from week 24 to week 52, was associated with greater repigmentation, as objectively assessed using the VASI.
 - The percentage of patients receiving 1.5 percent ruxolitinib cream BID who achieved F-VASI50 increased from Week 24 to Week 52 (45.5 percent to 57.6 percent, respectively).
 - A ≥ 75 percent (F-VASI75) and ≥ 90 percent (F-VASI90) improvement from baseline in F-VASI score was achieved by 51.5 percent and 33.3 percent of patients treated with 1.5 percent ruxolitinib cream BID at 52 weeks, compared to 30 percent and 12 percent of patients at 24 weeks, respectively.
- Among all patients treated with 1.5 percent ruxolitinib cream BID, the proportion of patients achieving T-VASI50 at Week 52 was 36.4 percent. Among patients with a baseline total body surface area of ≤ 20 percent (the body surface area limited for treatment), 45.0 percent receiving the 1.5 percent BID dose achieved a T-VASI50 response at 52 weeks.
- The proportion of patients receiving ruxolitinib cream 1.5 percent BID who achieved Facial Physician Global Vitiligo Assessment (F-PhGVA) scores of clear (no signs of vitiligo) or almost clear (only specks of depigmentation present) skin increased from Week 24 to Week 52 (9.1 percent and 21.2 percent, respectively).
- Ruxolitinib cream was generally well-tolerated at all dosage strengths and no treatment-related serious adverse events were reported.

"Many patients with vitiligo seek treatments that can repigment vitiligo lesions but, unfortunately, current therapeutic options are limited by poor efficacy, burdensome treatment regimens or side-effects," said Amit Pandya, M.D., Clinical Professor at the University of Texas Southwestern Medical Center. "The updated results from this study are encouraging as they demonstrate ruxolitinib cream's potential to become an effective treatment option for individuals with vitiligo."

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 Study

The safety and efficacy of ruxolitinib cream are being evaluated in an Incyte-sponsored randomized, double-blind, dose-ranging, vehicle-controlled,

Phase 2 study (NCT03099304), which began in April 2017.

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 nonfacial 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 party 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. An open-label extension where patients receive treatment with 1.5 percent BID dosing is currently ongoing.

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 patients with mild to moderate atopic dermatitis (TRuE-AD) with initial results expected in the first half of 2020, 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

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company's website at www.incyte.com.

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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 Phase 3 program for ruxolitinib cream in vitiligo, the design, timing and potential results of such a Phase 3 program, the potential for ruxolitinib cream to be an effective treatment option for patients with vitiligo and whether or when ruxolitinib cream will be approved for the treatment of 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 and the risks related to the efficacy or safety of the Company's development pipeline, the results of further research and development, the high degree of risk and uncertainty associated with drug development, clinical trials and regulatory approval processes, other market or economic factors and competitive and technological advances; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ending June 30, 2019. Incyte 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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