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Incyte Announces Positive Results from a Phase 2 Study of Ruxolitinib Cream in Patients with Vitiligo

June 15, 2019

- *24-week results demonstrate significant improvement in repigmentation of facial vitiligo lesions after treatment with ruxolitinib cream*
- *Data presented at the World Congress of Dermatology support the planned initiation of a pivotal Phase 3 program, for which preparations are currently underway*
- *Investor conference call and webcast scheduled for Monday, June 17 at 8 a.m. EDT*

WILMINGTON, Del.--(BUSINESS WIRE)--Jun. 15, 2019-- Incyte (Nasdaq:INCY) today announces 24-week results from its randomized, double-blind, dose-ranging, vehicle-controlled, Phase 2 study evaluating ruxolitinib cream, a nonsteroidal, anti-inflammatory, JAK inhibitor therapy, in adult patients (18 to 75 years of age) with vitiligo. 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). F-VASI50 response was most notably achieved with ruxolitinib cream 1.5 percent administered once daily (QD) and twice daily (BID) vs. vehicle control (50 percent and 45 percent vs. 3 percent, respectively; $P < 0.001$).

These results are being presented at the 24th World Congress of Dermatology (WCD) in Milan, Italy, during a late-breaking research session today, June 15, 2019, from 9:25 a.m. CET to 9:35 a.m. CET (3:25 a.m. EDT to 3:35 a.m. EDT). (Location: Room Yellow 3).

"The positive 24-week data presented at the World Congress of Dermatology support the potential of ruxolitinib cream to offer a novel treatment option for patients with this chronic autoimmune disease," said Steven Stein, M.D., Chief Medical Officer, Incyte. "For patients who choose to seek treatment for their vitiligo, current options are often limited by inadequate efficacy or potential side effects. We look forward to advancing ruxolitinib cream into Phase 3 development for vitiligo in the hope that it may become the first approved treatment for what can be a life-altering disease."

Key 24-week results include:

- Significantly more patients achieved F-VASI50 after 24 weeks of treatment with all ruxolitinib cream regimens compared to the vehicle control. The highest F-VASI50 response was achieved with ruxolitinib cream 1.5 percent QD and BID compared to vehicle control (50 percent and 45 percent vs. 3 percent, respectively; $P < 0.001$).
- A ≥ 75 percent improvement from baseline in the facial vitiligo area severity index score was achieved by 17 percent, 30 percent, and 0 patients treated with ruxolitinib cream 1.5 percent QD, BID, and vehicle cream, respectively.
- Facial Physician Global Vitiligo Assessment (F-PhGVA) scores of clear (no signs of vitiligo) or almost clear (only specks of depigmentation present) skin were achieved by 13 percent, 9 percent, and 0 patients receiving ruxolitinib cream 1.5 percent QD, BID, and vehicle cream, respectively.
- Ruxolitinib cream was generally well-tolerated at all dosage strengths.

Over-activity of the JAK signaling pathway has been shown to drive inflammation involved in the pathogenesis and progression of vitiligo. These data on ruxolitinib cream, a JAK inhibitor, support the planned initiation of pivotal Phase 3 development later in 2019, for which preparations are already underway.

"As a physician, I am looking for safe and effective options that may help my patients achieve their treatment goals," said David Rosmarin, M.D., Assistant Professor at the Tufts University School of Medicine. "I am encouraged by these clinical trial results and the potential of ruxolitinib cream to become an important treatment option for the repigmentation of vitiligo lesions."

About Vitiligo

Vitiligo is a chronic, immune-mediated skin disease that is estimated to affect between 2 and 3 million people in the U.S. and for which there is no known cure. It can occur at any age, although many people experience vitiligo symptoms before the age of 20.

Vitiligo is characterized by the progressive loss of pigmentation in patches of skin across the body, causing the skin to appear lighter. This occurs when pigment-producing cells known as melanocytes are destroyed or stop functioning. Vitiligo can affect any area of skin on the body and may also affect hair, eyes or the inside of the mouth. The exact cause of vitiligo is unknown, though recent research suggests that changes in the immune system may be responsible for the disease.

About the Study

The safety and efficacy of ruxolitinib cream were evaluated in an Incyte-sponsored randomized, double-blind, dose-ranging, vehicle-controlled, Phase 2 study (NCT03099304), which began in April 2017. The Phase 2 study program is comprised of three parts spanning 104 weeks. The first part of the study – the findings for which are being presented at the 24th WCD – 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 primary efficacy endpoint was the percentage of patients treated with ruxolitinib cream who achieved 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 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 results expected in the first half of 2020, and is expected to enter Phase 3 development for the treatment of certain patients with vitiligo (TRuE-V) in the second half of 2019. Incyte has worldwide rights for the development and commercialization of ruxolitinib cream.

Conference Call Information

Incyte will host an investor conference call and webcast at 8:00 a.m. EDT on Monday, June 17, 2019—the call and webcast can be accessed via the Events and Presentations tab of the Investor section of www.incyte.com.

To access the conference call on Monday, June 17, 2019, please dial 877-407-3042 for domestic callers or +1-201-389-0864 for international callers. When prompted, provide the conference identification number, 13689599.

If you are unable to participate, a replay of the conference call will be available for 30 days. The replay dial-in number for the United States is 877-660-6853 and the dial-in number for international callers is +1-201-612-7415. To access the replay you will need the conference identification number, 13689599.

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 plans to initiate a Phase 3 program for ruxolitinib cream in vitiligo, the 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 March 31, 2019. Incyte disclaims any intent or obligation to update these forward-looking statements.



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