

Incyte Announces New Findings from Pooled Analyses of the Phase 3 TRuE-AD Program Evaluating Ruxolitinib Cream in Patients with Atopic Dermatitis

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 three pooled analyses of its randomized, double-blind, vehicle-controlled Phase 3 studies – TRuE-AD1 and TRuE-AD2 – evaluating ruxolitinib cream, an investigational JAK1/JAK2 inhibitor designed for topical application, as a treatment for patients with atopic dermatitis (AD). These presentations (Posters #27716, #27620 and #26887) will be available on demand as part of the American Academy of Dermatology Virtual Meeting Experience 2021 (AAD VMX), held virtually April 23–25, 2021.

Positive topline results from the individual TRuE-AD1 and TRuE-AD2 studies were [previously reported](#). Efficacy and safety results from a pooled analysis of TRuE-AD1 and TRuE-AD2 were also [announced](#) and presented at the 29th European Academy of Dermatology and Venereology (EADV) Congress in October 2020. The primary and secondary endpoints were met in both TRuE-AD1 and TRuE-AD2.

New findings from the analyses being presented at AAD VMX add to the growing body of evidence on ruxolitinib cream as a potential treatment for AD.

One analysis (Poster #27716) assessed patient response to ruxolitinib cream across several clinical characteristics, including baseline Investigator's Global Assessment (IGA) score (2 or 3), Eczema Area Severity Index (EASI) score (≤ 7 or > 7), itch numerical rating scale (NRS) score (< 4 or ≥ 4) and affected Body Surface Area (BSA) ($< 10\%$ or $\geq 10\%$; patients with $\geq 10\%$ BSA are typically classified as having more severe AD).

- Ruxolitinib cream 0.75% applied twice daily (BID) and ruxolitinib cream 1.5% BID both demonstrated greater improvement compared to vehicle in all analyzed efficacy endpoints (i.e., IGA Treatment Success [IGA-TS], the proportion of patients achieving at least a 50%, 75% or 90% improvement from baseline in the EASI score [EASI-50, EASI-75, EASI-90] and the proportion of patients with at least a 4-point improvement in the itch NRS [NRS4]) at Week 8, regardless of clinical characteristic subgroup.
- Higher responses were observed in patients with more severe disease (e.g., baseline BSA $\geq 10\%$).

A subsequent analysis (Poster #27620) looked specifically at patients in TRuE-AD1 and TRuE-AD2 with BSA $\geq 10\%$ and EASI ≥ 16 at baseline, criteria that have been used in clinical studies with systemic therapies to identify patients with more severe AD. It found higher rates of clinical responses with ruxolitinib cream versus vehicle in these patients, and results were similar using different definitions for more severe AD (i.e., IGA=3; IGA=3 and EASI ≥ 16 ; IGA=3, EASI ≥ 16 and BSA $\geq 10\%$; and IGA=3, EASI ≥ 16 , BSA $\geq 10\%$ and itch NRS ≥ 4). Specifically:

- At Week 8, more patients achieved IGA-TS with ruxolitinib cream 0.75% and ruxolitinib cream 1.5% versus vehicle (50.0% and 59.4% versus 0%, respectively).
- More patients who applied ruxolitinib cream 0.75% and ruxolitinib cream 1.5% versus vehicle achieved EASI-50 (80.6% and 78.1% versus 38.5%), EASI-75 (75.0% and 71.9% versus 7.7%), and EASI-90 (52.8% and 46.9% versus 7.7%) at Week 8.
- At Week 8, more patients achieved itch NRS4 with ruxolitinib cream 0.75% and ruxolitinib cream 1.5% versus vehicle (50.0% and 61.1% versus 27.3%).

"We are pleased to have the opportunity to share additional analyses from the TRuE-AD program with the scientific community at AAD VMX as these data provide more insight into the needs of people living with AD and the impact ruxolitinib cream could have across patient subgroups," said Jim Lee, M.D., Ph.D., Group Vice President, Inflammation & Autoimmunity, Incyte. "Specifically, the findings suggest ruxolitinib cream could be an effective treatment option for AD irrespective of patients' pre-treatment characteristics, and may be efficacious among those with more severe disease – potentially delaying or preventing the need for systemic therapy in these patients. We look forward to furthering analyzing data from the TRuE-AD program in the hopes it will lead to a meaningful new option for patients living with this inflammatory skin condition, which can significantly impact patients' quality of life."

Finally, a third pooled analysis (Poster #26887) provided additional context regarding the impact of ruxolitinib cream on sleep quality and related impacts – a key quality of life measure. It showed clinically-relevant improvement in sleep parameters in adolescents and adults with AD who received ruxolitinib cream as demonstrated by mean change from baseline in patient-reported outcomes tools. Specifically:

- At Week 8, more patients with Patient-Reported Outcomes Measurement Information System (PROMIS) sleep-related impairment (8a) and sleep disturbance (8b) scores ≥ 14 at baseline who received ruxolitinib cream 0.75% or ruxolitinib cream 1.5% BID achieved a clinically meaningful ≥ 6 -point improvement versus vehicle (30.3% and 33.9% versus 20.3%; and 26.5% and 30.5% versus 17.9%, respectively).
- More patients who received ruxolitinib cream 0.75% or ruxolitinib cream 1.5% BID reported no nights of disturbed sleep versus vehicle (66.1% and 71.6% versus 44.3%) at Week 8, as assessed by Patient-Oriented Eczema Measure (POEM) item 2 (number of nights of disturbed sleep due to eczema over the past seven days).
- A greater reduction in mean change from baseline in Scoring Atopic Dermatitis (SCORAD) sleeplessness scores (indicating improved sleep quality) was reported in patients who received ruxolitinib cream compared with those who

applied vehicle at Weeks 2, 4 and 8.

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

"There is an urgent need for new treatment options that balance efficacy and tolerability for patients with atopic dermatitis," said Kim Papp, M.D., Ph.D., Founder and President of Probiy Medical Research and the Coordinating Investigator for the TRuE-AD program. "I am thoroughly encouraged by findings from the TRuE-AD program, and the potential ruxolitinib cream could have for patients whose everyday lives are impacted by the itch and inflammation associated with their disease."

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 Atopic Dermatitis

Atopic dermatitis (AD) is a chronic skin disease, affecting more than 21 million people in the United States and is characterized by inflammation and intense itch. Signs and symptoms of AD include irritated and itchy skin that can cause red lesions that may ooze and crust. Patients with AD are also more susceptible to bacterial, viral and fungal infections.

About TRuE-AD

The TRuE-AD clinical trial program consists of two randomized, double-blind, vehicle-controlled Phase 3 studies, TRuE-AD1 (NCT03745638) and TRuE-AD2 (NCT03745651), evaluating the safety and efficacy of ruxolitinib cream compared to vehicle (non-medicated cream) in patients with atopic dermatitis (AD). Both studies enrolled more than 600 patients (age ≥12 years) diagnosed with AD for at least two years and who were candidates for topical therapy.

Patients with an Investigator's Global Assessment (IGA) score of 2 to 3, and with AD on 3% to 20% of their Body Surface Area (excluding scalp) were randomized 2:2:1 into one of three arms for eight weeks: ruxolitinib cream 0.75% applied twice daily (BID); ruxolitinib cream 1.5% applied BID; and vehicle. Participants who successfully completed an assessment at Week 8 were offered participation in the 44-week long-term safety treatment extension period with ruxolitinib cream 0.75% or 1.5% applied BID.

The primary endpoint of the TRuE-AD studies was the proportion of participants achieving an Investigator's Global Assessment Treatment Success (IGA-TS), defined as an IGA score of 0 (clear) or 1 (almost clear) with at least a 2-point improvement from baseline at Week 8. Key secondary endpoints include: the proportion of patients achieving at least a 75% improvement from baseline in the Eczema Area and Severity Index (EASI-75) score, the proportion of participants with at least a 4-point improvement in the itch Numerical Rating Scale, and the proportion of participants with at least a 6-point improvement in the Patient-Reported Outcomes Measurement Information System (PROMIS) Short Form – Sleep Disturbance (8b) 24-hour recall score. Additional secondary endpoints include mean percentage change from baseline in Scoring Atopic Dermatitis (SCORAD) score. The studies have also been tracking the frequency, duration and severity of adverse events associated with the use of ruxolitinib cream.

For more information about the TRuE-AD studies, please visit <http://clinicaltrials.gov/ct2/show/NCT03745651>.

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](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 the presentation of data from the Company's ongoing clinical development program for ruxolitinib cream and the Company's atopic dermatitis 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 atopic dermatitis 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.



View source version on [businesswire.com](https://www.businesswire.com/news/home/20210423005325/en/): <https://www.businesswire.com/news/home/20210423005325/en/>

Media

Catalina Loveman

+1 302 498 6171

cloveman@incyte.com

Jenifer Antonacci

+1 302 498 7036

jantonacci@incyte.com

Investors

Christine Chiou

+1 302 274 4773

cchiou@incyte.com

Source: Incyte