

Pooled Results from Incyte's TRuE-AD1 and TRuE-AD2 Atopic Dermatitis Studies of Ruxolitinib Cream Show Clinically Meaningful Improvements in Patient-Reported Quality of Life Assessments

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- Results reinforce that ruxolitinib cream treatment results in a rapid, substantial and sustained reduction in itch

-Results also demonstrate improvement in patient-reported perceptions of sleep quality, sleep depth and restoration associated with sleep as measured by the PROMIS® Short Form-Sleep Disturbance (8b) questionnaire

-Oral presentation will be available on-demand as part of the 29th EADV Virtual Congress

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced efficacy and safety results from a pooled analysis of two randomized, double-blind, vehicle-controlled Phase 3 studies – TRuE-AD1 and TRuE-AD2 – evaluating ruxolitinib cream for the treatment of patients with mild-to-moderate atopic dermatitis (AD). The presentation (FC08.08) will be available on-demand as part of the 29th European Academy of Dermatology and Venereology (EADV) Congress, held virtually from October 29-31, 2020.

Key findings from the individual TRuE-AD1 and TRuE-AD2 studies were [previously reported](#).

The new, pooled data reinforce that treatment with ruxolitinib cream resulted in a rapid, substantial and sustained reduction in itch; and improved the extent and severity of AD as measured by the Eczema Area Severity Index (EASI) and Scoring Atopic Dermatitis (SCORAD) assessment tools.

In addition, treatment with ruxolitinib cream resulted in notable improvements in quality of life measures such as the PROMIS (Patient-Reported Outcomes Measurement Information System)¹ sleep disturbance (8b)² score. PROMIS is a set of well-accepted patient-reported outcome measurement tools that are psychometrically supported.¹ In the TRuE-AD trials, the PROMIS Short Form-Sleep Disturbance (8b) questionnaire was used to assess patients' self-reported perceptions of sleep quality, sleep depth and restoration associated with sleep.

Key results from the pooled analysis include:

	Ruxolitinib cream 0.75% BID	Ruxolitinib cream 1.5% BID	Vehicle
Primary endpoint			
IGA-TS, responders	n=483	n=481	n=244
	44.7%*	52.6%*	11.5%
Key secondary endpoints			
EASI-75, responders	n=483	n=481	n=244
	53.8%*	62.0%*	19.7%
Itch NRS (≥4-point improvement) [†] , responders	n=313	n=307	n=158
	41.5%*	51.5%*	15.8%
PROMIS Short Form-Sleep Disturbance (8b) (≥6-point improvement) [‡] , responders	n=446	n=449	n=226
	20.9%**	23.8%**	14.2%
Secondary endpoint			
SCORAD, mean change from baseline	n=483	n=481	n=244
	-62.9%*	-67.3%*	-30.4%
Additional efficacy analysis			
Daily Itch NRS Score, mean change from baseline within 12 hours	n=483	n=481	n=244
	-0.4***	-0.5***	-0.1
IGA-TS: Investigator's Global Assessment (IGA)-Treatment Success defined as an IGA score of 0 (clear) or 1 (almost clear) with ≥2-point improvement from baseline at Week 8; BID: twice daily; EASI-75: ≥75% improvement from baseline at Week 8 in the Eczema Area and Severity Index (EASI) score; NRS: Numerical Rating Scale; PROMIS: Patient-Reported Outcomes Measurement Information System; SCORAD: Scoring Atopic Dermatitis.			
[†] Patients included in the analysis had an Itch NRS score ≥4 at baseline; [‡] Patients included in the analysis had a PROMIS Short Form-Sleep Disturbance (8b) score of ≥6 at baseline.			
*P<0.0001 vs. vehicle at Week 8; **P<0.05 vs. vehicle at Week 8; ***P<0.02 vs. vehicle.			

The overall safety profile of ruxolitinib cream was consistent with [previously reported](#) data, with no new safety signals observed in this pooled analysis.

"Atopic dermatitis is a chronic inflammatory skin condition that may result in decreased quality of life for patients; attributable in part to sleep disturbances resulting from intense and persistent itch," said Jim Lee, M.D., Ph.D., Group Vice President, Inflammation & Autoimmunity, Incyte. "Pooled results from the TRuE-AD studies reinforce the potential of ruxolitinib cream to become an important antipruritic and anti-inflammatory treatment option for patients with atopic dermatitis and we are on track to submit a New Drug Application (NDA) to the U.S. Food and Drug Administration at the end of this year."

About Atopic Dermatitis

Atopic dermatitis (AD) is a common chronic and intensely pruritic disease characterized by inflammation of the skin. AD affects more than 30 million individuals in the United States and 80-90% of patients have mild-to-moderate disease. 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/NCT03745638> and <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 patients with mild-to-moderate 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 about the potential of ruxolitinib cream to provide a meaningful treatment for patients with atopic dermatitis, the TRuE-AD clinical program, the Company's Dermatology program, the safety and efficacy of ruxolitinib cream in patients with atopic dermatitis, and expected timing of the filing of the NDA for ruxolitinib cream for the treatment of atopic dermatitis, 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 efficacy or safety of the Company's products; 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 Form 10-Q for the quarter ended June 30, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

PROMIS® is a registered trademark of the U.S. Department of Health and Human Services.

References:

1. PROMIS. HealthMeasures. Available at: <https://www.healthmeasures.net/explore-measurement-systems/promis>. Accessed on October 28, 2020.
2. Buysse DJ, et. al. Development and validation of patient-reported outcome measures for sleep disturbance and sleep-related impairments. *Sleep* 2010; 33:781-792.



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Media

Catalina Loveman, +1 302 498 6171

cloveman@incyte.com

Nupur Patel, PharmD, +1 302 498 5822

npatel@incyte.com

Investors

Michael Booth, DPhil, +1 302 498 5914

mbooth@incyte.com

Christine Chiou, +1 302 274 4773

cchiou@incyte.com

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