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Incyte Announces Acceptance and Priority Review of NDA for Ruxolitinib Cream for Atopic Dermatitis

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has accepted for Priority Review the New Drug Application (NDA) for ruxolitinib cream, a selective JAK1/JAK2 inhibitor designed for topical application, as a treatment for atopic dermatitis (AD), a type of eczema.

“Incyte’s deep understanding of the pathways involved in immune-mediated skin conditions led us to investigate the potential for ruxolitinib cream to address key factors associated with atopic dermatitis, that is, inflammation of the skin and itch,” said Jim Lee, M.D., Ph.D., Group Vice President, Inflammation & Autoimmunity, Incyte. “We are grateful to the people living with atopic dermatitis whose participation in our clinical trials helped generate the evidence to support this regulatory submission, and we look forward to working with the FDA as we seek to bring forward a new topical treatment for people living with this chronic skin disease.”

The NDA is supported by data from the Phase 3 TRuE-AD clinical trial program, which included more than 1,200 people, age 12 years and older. Primary efficacy and safety results from both **TRuE-AD trials** were presented at the Revolutionizing Atopic Dermatitis Virtual Symposium in April 2020. Additional safety and efficacy data from the 44-week, open-label, long-term extension of both TRuE-AD1 and TRuE-AD2 were included in the NDA.

Incyte submitted a priority review voucher (PRV) along with the NDA application for ruxolitinib cream. The use of the PRV shortens the review period by four months. The Prescription Drug User Fee Act (PDUFA) target action date is June 21, 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.

TRuE-AD **results** presented at the 29th European Academy of Dermatology and Venereology (EADV) Congress in October 2020 examined sleep quality, sleep depth and restoration associated with sleep, key quality of life measures for people with AD.

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 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 as well as its dermatology program generally, and whether and when ruxolitinib cream will be approved for use in the U.S. or elsewhere for atopic dermatitis or any other indication, 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 Form 10-K for the year ended December 31, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.

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