Incyte Announces Positive Topline Results From Phase 3 TRuE-AD Program Evaluating Ruxolitinib Cream in Patients With Atopic Dermatitis

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Primary and secondary endpoints met in both TRuE-AD1 and TRuE-AD2

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 19, 2020-- Incyte (Nasdaq:INCY) today announced that the second randomized, vehicle-controlled, pivotal Phase 3 study from the TRuE-AD clinical trial program has met its primary endpoint.

Building on the previously-reported positive topline results from TRuE-AD2, the results of TRuE-AD1 also show that significantly more patients treated with ruxolitinib cream 0.75% or 1.5% achieved Investigator's Global Assessment Treatment Success (IGA-TS) – defined as an IGA score of 0 (clear) or 1 (almost clear) with at least a two-point improvement from baseline at Week 8 – than patients treated with vehicle control (non-medicated cream). The overall efficacy and safety profile of ruxolitinib cream was consistent with previous data, and no new safety signals were observed.

The TRuE-AD1 and TRuE-AD2 trials both evaluated the safety and efficacy of ruxolitinib cream in adolescent and adult patients (age ≥ 12 years) with mild-to-moderate atopic dermatitis (AD). The long-term safety portion of both studies will continue as planned. Additionally, data from both studies will be further analyzed and submitted for publication and presentation at an upcoming scientific meeting.

"The successful outcomes of both the TRuE-AD1 and TRuE-AD2 studies confirm the potential of ruxolitinib cream as an important, non-steroidal treatment option for the millions of patients suffering from AD," said Jim Lee, M.D., Group Vice President, Inflammation & AutoImmunity, Incyte. "We look forward to working with regulators as we seek approval of ruxolitinib cream as the first topical formulation of a JAK inhibitor for patients with AD."

Key Findings from TRuE-AD1 and TRuE-AD2

Almost 1,250 patients (age ≥ 12 years) diagnosed with AD for at least two years and who are candidates for topical therapy were enrolled in the identically-designed TRuE-AD1 and TRuE-AD2 trials. 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 (BSA) (excluding scalp) were randomized 2:2:1 into one of three treatment arms for eight weeks, including: ruxolitinib cream 0.75% administered twice daily (BID); ruxolitinib cream 1.5% BID; and vehicle (non-medicated cream).

The primary endpoint of both TRuE-AD1 and TRuE-AD2 was IGA-TS at week 8. Secondary endpoints in both trials included the proportion of participants who achieved a ≥75% improvement in Eczema Area and Severity Index (EASI75) score at week 8 and the proportion of participants with a ≥ 4-point improvement in Itch Numerical Rating Scale (NRS4) score at week 8. Key efficacy results include:

TRuE-AD1

- 50.0% of patients treated with ruxolitinib cream 0.75% BID and 53.8% of patients treated with ruxolitinib cream 1.5% BID achieved IGA-TS, compared to 15.1% treated with vehicle control ($p < 0.0001$ and $p < 0.0001$, respectively).
- 56.0% of patients treated with ruxolitinib cream 0.75% BID and 62.1% of patients treated with ruxolitinib cream 1.5% BID achieved at least a 75% improvement in their EASI score from baseline, compared to 24.6% treated with vehicle control ($p < 0.0001$ and $p < 0.0001$, respectively).

TRuE-AD2

- 39.0% of patients treated with ruxolitinib cream 0.75% BID and 51.3% of patients treated with ruxolitinib cream 1.5% BID achieved IGA-TS, compared to 7.6% treated with vehicle control ($p < 0.0001$ and $p < 0.0001$, respectively).
- 51.5% of patients treated with ruxolitinib cream 0.75% BID and 61.8% of patients treated with ruxolitinib cream 1.5% BID achieved at least a 75% improvement in their EASI score from baseline, compared to 14.4% treated with vehicle control ($p < 0.0001$ and $p < 0.0001$, respectively).

In addition, a statistically-significant difference in itch reduction as measured by the NRS4 was observed for both dose strengths compared to vehicle control in both TRuE-AD1 and TRuE-AD2.

In both TRuE-AD1 and TRuE-AD2 after 8 weeks of treatment, the overall rate of treatment emergent adverse events was comparable between the ruxolitinib cream 0.75% BID, ruxolitinib cream 1.5% BID and vehicle control groups (29.4%, 26.3% and 33.6%, respectively). The rate of serious adverse events was 0.8% and 0.6% for ruxolitinib cream 0.75% BID and 1.5% BID, respectively, and 0.8% for vehicle control. Long-term safety is currently being evaluated in the 44-week extension period of both studies.

About Atopic Dermatitis

AD is a common chronic disease characterized by inflammation of the skin. At least 11 million people in the United States have been diagnosed with and are being treated for AD. The majority of these patients have a mild or moderate form of the disease and approximately 80% are adults or adolescents. 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, dose-ranging, 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 (BSA) (excluding scalp) were randomized 2:2:1 into one of three treatment arms for eight weeks, including: ruxolitinib cream 0.75% administered twice daily (BID); ruxolitinib cream 1.5% BID; and vehicle (non-medicated cream). 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% 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. Other key secondary endpoints include: the proportion of patients achieving at least a 75% improvement from baseline in the Eczema Area and Severity Index (EASI75) score – another measurement of the extent and severity of AD, and the proportion of participants with at least a four-point improvement in the itch numerical rating scale (NRS). 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

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 presentation of data from the Company's ongoing clinical development program for ruxolitinib cream, whether and when the Company will file an NDA for ruxolitinib cream, and whether ruxolitinib cream will be approved for use in the U.S. or elsewhere, 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, 2019. The Company disclaims any intent or obligation to update these forward-looking statements.

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