Incyte Announces that the TRuE-AD2 Pivotal Trial of Ruxolitinib Cream Met its Primary Endpoint in Patients with Atopic Dermatitis

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WILMINGTON, Del.--(BUSINESS WIRE)--Jan. 28, 2020-- Incyte (Nasdaq:INCY) today announced positive topline results from its randomized, vehicle-controlled, pivotal Phase 3 TRuE-AD2 study evaluating the safety and efficacy of ruxolitinib cream in adolescent and adult patients (age ≥ 12 years) with atopic dermatitis (AD).

The study, part of the TRuE-AD clinical trial program, met its primary endpoint. Significantly more patients treated with ruxolitinib cream 0.75% and 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 is consistent with previous data, and no new safety signals were observed. The long-term safety portion of the study will continue as planned.

"This positive topline result reinforces the potential of ruxolitinib cream, if approved, to offer AD patients a much-needed effective, non-steroidal therapy," said Jim Lee, M.D., Group Vice President, Inflammation & AutoImmunity, Incyte. "We look forward to the results of the TRuE-AD1 trial, the second study in the pivotal clinical trial program, later this quarter, and to sharing these data with the medical community as part of our commitment to develop a new first-line treatment option for these patients."

Data from TRuE-AD2 will be submitted for presentation at an upcoming scientific meeting.

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-AD2

TRuE-AD2 (NCT03745651) is an Incyte-sponsored randomized, double-blind, vehicle-controlled Phase 3 study evaluating the safety and efficacy of ruxolitinib cream compared to vehicle (non-medicated cream) in patients with atopic dermatitis (AD). The study enrolled over 600 patients (age ≥ 12 years) diagnosed with AD for at least two years and who are candidates for topical therapy.

Patients with an Investigator's Global Assessment (IGA) score of 2 to 3 (a measure of disease severity), and with AD involving between 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 TRuE-AD2 is 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 two-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 (EASI) score – another measurement of disease extent and severity – or EASI75, and the proportion of participants with at least a four-point improvement in the itch numerical rating scale (NRS). The study is also tracking the frequency, duration and severity of adverse events associated with the use of ruxolitinib cream.

For more information about the study, please visit http://clinicaltrials.gov/ct2/show/NCT03745651.

About TRuE-AD

The TRuE-AD clinical trial program is evaluating ruxolitinib cream in patients with atopic dermatitis (AD) and includes two Phase 3 studies: TRuE-AD1 (NCT03745638) and TRuE-AD2 (NCT03745651). The TRuE-AD1 trial is ongoing with initial results expected in the first quarter of 2020. For more information about TRuE-AD1, please visit http://clinicaltrials.gov/ct2/show/NCT03745638.

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 potential of

ruxolitinib cream to become a first line treatment for patients with atopic dermatitis, the planned submission of the TRuE-AD data to the U.S. FDA, whether and when ruxolitinib cream will be approved by the U.S. FDA and the presentation of data from the Company's ongoing clinical development program for ruxolitinib cream, 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-Q for the quarter ended September 30, 2019. The Company disclaims any intent or obligation to update these forward-looking statements.

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