Incyte Announces First Patient Treated in Phase 3 Clinical Trial Program for Ruxolitinib Cream in Atopic Dermatitis

December 20, 2018

WILMINGTON, Del.--(BUSINESS WIRE)--Dec. 20, 2018-- Incyte (Nasdaq:INCY) today announced that the first patient has been treated in the Phase 3 TRuE-AD clinical trial program evaluating the long-term safety and efficacy of ruxolitinib cream as monotherapy for adolescent and adult patients (age ≥ 12 years) with atopic dermatitis (AD) who are candidates for topical therapy.

“Atopic dermatitis can have a serious impact on patients’ overall health and quality of life and, unfortunately, the long-term use of prescription topical corticosteroids can lead to significant side effects, underscoring the medical need for new topical therapies to treat this chronic skin disease,” said Steven Stein, M.D., Chief Medical Officer, Incyte. “With the initiation of the Phase 3 program, for ruxolitinib cream, we are moving closer to our goal of providing a safe and effective alternative treatment for adolescent and adult patients living with this chronic, burdensome disease.”

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 percent 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 includes two Phase 3 studies (NCT03745638 and NCT03745651) evaluating the safety and efficacy of ruxolitinib cream in patients with atopic dermatitis (AD).

The studies will each enroll approximately 600 patients (age ≥ 12 years) who have been diagnosed with AD for at least two years, who have an Investigator’s Global Assessment (IGA) score of 2 to 3, a Body Surface Area (BSA) involvement (excluding scalp) of 3% to 20% and who are candidates for topical therapy. Participants will be randomized 2:2:1 into one of three treatment arms.

The primary endpoint of the TRuE-AD studies 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 2-point improvement from baseline at Week 8. Key secondary endpoints include: the proportion of patients achieving at least a 75 percent improvement from baseline in the Eczema Area and Severity Index (EASI) score – a measurement of the extent and severity of AD – or EASI75, and the proportion of participants with at least a four-point improvement in the itch numerical rating scale (NRS). The studies will also track 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 Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company’s website at www.incyte.com.

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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 in patients with atopic dermatitis, and the enrollment, design, timing and results of the TRuE-AD clinical trial program, 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, 2018. The Company disclaims any intent or obligation to update these forward-looking statements.

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Source: Incyte

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