



Incyte Announces Positive Data from Phase 2b Trial of Ruxolitinib Cream in Patients with Atopic Dermatitis

September 13, 2018

- *Study met primary and key secondary endpoints, demonstrating significant improvement from baseline in EASI score and reduced itch compared to vehicle*
- *Results presented at EADV support planned initiation of global, pivotal Phase 3 program*

WILMINGTON, Del.--(BUSINESS WIRE)--Sep. 13, 2018-- Incyte Corporation (Nasdaq:INCY) today announced positive results from its randomized, dose-ranging, vehicle- and active-controlled Phase 2b study evaluating ruxolitinib cream in patients with atopic dermatitis (AD) who are candidates for topical therapy. The study, part of the True-AD clinical trial program, met its primary endpoint, demonstrating that ruxolitinib cream 1.5% administered twice daily (BID) significantly improved Eczema Area and Severity Index (EASI) scores – a measurement of the extent and severity of AD – from baseline versus vehicle control (non-medicated cream) at Week 4. Additionally, treatment with ruxolitinib cream 1.5% BID resulted in a rapid and sustained reduction in itch versus vehicle, a key secondary endpoint. These results were shared in an oral presentation today at the 27th European Academy of Dermatology and Venerology (EADV) Congress in Paris, France.

"The positive results of this Phase 2 study demonstrate the potential of ruxolitinib cream to offer a novel, effective non-steroidal topical therapy to the millions of patients suffering from AD," said Steven Stein, M.D., Chief Medical Officer, Incyte. "We look forward to further advancing the True-AD clinical trial program for ruxolitinib cream and initiating Phase 3 registrational trials in this indication to further explore the potential of JAK inhibition to modulate inflammation and itch, and therefore provide much-needed relief to patients with this disease."

Key study results included:

- Significantly improved EASI score in the ruxolitinib cream 1.5% BID arm versus vehicle at Week 4 (71.6 percent vs. 15.5 percent improvement; $P<0.001$), the primary endpoint, and improvement (meeting the criteria for non-inferiority) in EASI score versus the active control, triamcinolone 0.1% cream (a mid-potency topical corticosteroid), at Week 4 (71.6 percent vs. 59.8 percent improvement), a secondary endpoint.
- Significantly improved EASI scores in the ruxolitinib cream 1.5% BID arm versus vehicle at Weeks 2 and 8 (52.7 percent vs. 4.8 percent and 78.5 percent vs. 26.9 percent, respectively; $P<0.001$).
- Significantly greater changes in EASI score in the once daily (QD) ruxolitinib cream 1.5% and 0.5% arms versus vehicle at Week 4 (1.5% QD [67.0 percent vs. 15.5 percent improvement], 0.5% QD [52.2 percent vs. 15.5 percent improvement]; $P<0.001$).
- Significantly more Investigator's Global Assessment (IGA) responders – a measure of disease severity – in the ruxolitinib cream 1.5% BID arm versus vehicle at Week 4 (38.0 percent vs. 7.7 percent; $P<0.001$), and greater IGA response rates across other ruxolitinib arms versus vehicle.
- Rapid and sustained reductions in itch numerical rating scale (NRS) score observed as early as within two days from the initiation of therapy (ruxolitinib cream 1.5% cream BID vs. vehicle, -1.8 vs. -0.2 ; $P<0.0001$), and a more pronounced reduction in itch with ruxolitinib cream 1.5% BID and QD than with triamcinolone cream 0.1% BID.

Ruxolitinib cream was well-tolerated at all dosage strengths and was not associated with clinically-significant application site reactions. All treatment-related adverse events were Grade 1 or Grade 2 in severity.

Ruxolitinib cream is the first JAK1/JAK2 inhibitor to exhibit positive results as a topical monotherapy in the AD patient population. Over-activity of the JAK signaling pathway has been shown to drive inflammation involved in the pathogenesis of AD. These data support the planned initiation of a global, pivotal Phase 3 program, for which preparations are already underway.

"There is no cure for AD, and it continues to be a major therapeutic challenge for patients, primary care providers and specialists. Though topical corticosteroids have been a mainstay in treatment of AD for decades, their utility has been limited due to significant side effects associated with long-term use," said principal investigator of the trial, Brian Kim, M.D., M.T.R., F.A.A.D., Assistant Professor of Dermatology and Co-Director of the Center for the Study of Itch at Washington University School of Medicine in St. Louis, Missouri, USA. "There is an urgent need for new and innovative treatments for patients with this condition, which tends to be chronic. As a physician who treats patients with AD, I am encouraged by the potential of ruxolitinib cream to fill this gap."

About Atopic Dermatitis

Atopic dermatitis (AD) is a common chronic disease characterized by inflammation of the skin. Approximately 11 million people in the United States have been diagnosed with AD, and the majority (10 million) have a mild or moderate form of the disease. Signs and symptoms of AD include skin rash

and dry skin, and it can cause intense itching, scratching and lesions that may ooze or crust. Patients with AD are also more susceptible to bacterial, viral and fungal infections.

About the Study

The safety and efficacy of ruxolitinib cream in adults with atopic dermatitis (AD) were evaluated in an Incyte-sponsored randomized, dose-ranging, vehicle- and active- controlled Phase 2b study (NCT03011892), which began in December 2016 and completed in March 2018. The study, part of the True-AD clinical trial program, enrolled 307 adults (aged 18-70 years) diagnosed with AD for at least two years and who were candidates for topical therapy.

Patients with AD on 3 to 20 percent of their body surface area, with an IGA score of 2 to 3, were equally randomized across six treatment-arms, including: twice daily (BID) ruxolitinib 1.5% cream; once daily (QD) ruxolitinib 0.15%, 0.5% or 1.5% cream; vehicle (non-medicated cream); and active control (triamcinolone 0.1% cream [TAC], a mid-potency topical corticosteroid). All patients received eight weeks of blinded study treatment; the TAC arm received four weeks of TAC followed by four weeks of vehicle; and there was an additional four weeks of open-label ruxolitinib 1.5% cream BID.

The primary efficacy endpoint was mean percentage change from baseline in Eczema Area and Severity Index (EASI score) – a measurement of the extent and severity of AD – at Week 4 in the ruxolitinib 1.5% BID arm versus vehicle. Key secondary endpoints included percent change from baseline in EASI score at Week 4 in the other ruxolitinib cream arms versus vehicle BID and versus triamcinolone 0.1% cream; the proportion of patients achieving an IGA score of 0 (clear) to 1 (almost clear) with at least a 2-point improvement from baseline; the proportion of patients achieving at least a 75 percent improvement from baseline in EASI (EASI75); itch numerical rating scale (NRS); and safety through 12 weeks of dosing.

For more information about the study, please visit <https://clinicaltrials.gov/ct2/show/NCT03011892>.

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 web site 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 release contain predictions, estimates and other forward-looking statements, including statements regarding the potential of ruxolitinib cream to meaningfully improve the outcomes of patients with atopic dermatitis and plans to initiate a pivotal study. These forward-looking statements are based on Incyte's current expectations and subject to risks and uncertainties that may cause actual results to differ materially, including scheduling and related issues with respect to study initiation, unanticipated developments in and risks related to the efficacy or safety of ruxolitinib cream for the treatment of atopic dermatitis, the results of additional data and additional analyses of data from this study, actions taken by regulatory authorities, and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended June 30, 2018. Incyte disclaims any intent or obligation to update these forward-looking statements.

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