Incyte Announces First Presentation of Phase 3 Data from the TRuE-AD Program of Ruxolitinib Cream at the Revolutionizing Atopic Dermatitis Virtual Symposium

April 5, 2020

- Ruxolitinib cream resulted in a rapid and robust clinical response, with significantly more patients achieving Investigator's Global Assessment (IGA) Treatment Success (IGA-TS; primary endpoint), defined as an IGA score of 0 (clear) or 1 (almost clear), and EASI75 (key secondary endpoint), defined as the proportion of patients who achieved a ≥ 75% improvement in the Eczema Area and Severity Index Score

- Treatment with ruxolitinib cream also resulted in a rapid, substantial and sustained reduction in itch, a key quality of life measure for patients with atopic dermatitis

- Data support the planned submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration before the end of 2020

WILMINGTON, Del.--(BUSINESS WIRE)--Apr. 5, 2020-- Incyte (Nasdaq: INCY) today announced the first presentation of Phase 3 data for ruxolitinib cream in atopic dermatitis at the Revolutionizing Atopic Dermatitis Virtual Symposium. The Phase 3 TRuE-AD program, which includes the TRuE-AD1 and TRuE-AD2 studies, is evaluating ruxolitinib cream 0.75% and 1.5% twice daily (BID) for the treatment of patients with mild-to-moderate atopic dermatitis.

"Data that will be presented today during the Revolutionizing Atopic Dermatitis Virtual Symposium show that ruxolitinib cream significantly reduced both the skin inflammation and itch associated with atopic dermatitis. The reduction in itch can potentially improve key disease-related and quality of life outcomes for patients living with atopic dermatitis," said Jim Lee, M.D., Ph.D., Group Vice President, Inflammation & AutoImmunity, Incyte. "We are pleased to share these important data with the dermatology community, as they support the potential of ruxolitinib cream to become an important antipruritic and anti-inflammatory treatment option for patients with atopic dermatitis, and we look forward to submitting a New Drug Application (NDA) to the U.S. Food and Drug Administration later this year."

The primary endpoint for the TRuE-AD1 and TRuE-AD2 studies was the proportion of patients achieving Investigator's Global Assessment (IGA) 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. Key secondary endpoints included the proportion of patients who achieved a ≥ 75% improvement in Eczema Area and Severity Index (EASI75) score at Week 8 and the proportion of patients with a ≥ 4-point improvement in Itch Numerical Rating Scale (NRS4) score at Week 8.

As previously reported, both Phase 3 studies met the primary endpoint. Significantly more patients treated with ruxolitinib cream 0.75% BID [TRuE-AD1: 50.0%; TRuE-AD2: 39.0%] and 1.5% BID [TRuE-AD1: 53.8%; TRuE-AD2: 51.3%] achieved IGA-TS compared to vehicle [non-medicated cream; TRuE-AD1: 15.1%; TRuE-AD2: 7.6%]; $P < 0.0001$. Additionally, a significant proportion of patients treated with ruxolitinib cream 0.75% BID [TRuE-AD1: 56.0%; TRuE-AD2: 51.5%] and 1.5% BID [TRuE-AD1: 62.1% and TRuE-AD2: 61.8%] achieved EASI75 at Week 8 compared to vehicle [TRuE-AD1: 24.6%; TRuE-AD2: 14.4%]; $P < 0.0001$.

Data from both studies also demonstrate that treatment with ruxolitinib cream has a rapid, substantial and sustained impact on itch, a key quality of life measure for patients living with atopic dermatitis:

- Significantly more patients treated with ruxolitinib cream experienced a clinically meaningful reduction in itch (NRS4) than patients given vehicle at Week 8.
    - In TRuE-AD1, 40.4% of patients treated with ruxolitinib cream 0.75% BID and 52.2% of patients treated with ruxolitinib cream 1.5% BID achieved NRS4, compared to 15.4% of patients given vehicle ($P < 0.001$ and $P < 0.0001$, respectively).
    - In TRuE-AD2, 42.7% of patients treated with ruxolitinib cream 0.75% BID and 50.7% of patients treated with ruxolitinib cream 1.5% BID achieved NRS4, compared to 16.3% of patients given vehicle ($P < 0.0001$).
- A rapid reduction in itch was observed with ruxolitinib cream treatment. A significantly greater reduction in the itch Numerical Rating Scale (NRS) was observed within 12 hours of treatment with ruxolitinib cream 1.5% BID compared to vehicle ($P < 0.05$).

The overall safety profile of ruxolitinib cream in atopic dermatitis was consistent with previous study data, with no new safety signals observed. The long-term safety of ruxolitinib cream is currently being evaluated in the 44-week extension period of both studies.

"Atopic dermatitis can have a profound impact on patients and their quality of life. I see a need for more treatment options that can improve itch and other symptoms that can lead to disruption in activities of daily living," said Kim Papp, M.D., Ph.D., Founder and President of Probity Medical Research and the Coordinating Investigator for the TRuE-AD program. "I am encouraged by these data. The potential of ruxolitinib cream to become an important treatment option for patients living with atopic dermatitis is exciting."

These data will be presented as part of the Revolutionizing Atopic Dermatitis Virtual Symposium during the Late Breaking Abstracts session on Sunday, April 5, from 3:56-4:09 p.m. EDT.

About Atopic Dermatitis

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. 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 (NRS4). 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.

Conference Call Information
Incyte will host an investor conference call and webcast at 8:00 a.m. EDT on Monday, April 6, 2020. The webcast will be available via investor.incyte.com.

To access the conference call on Monday, April 6, 2020, please dial 877-407-3042 for domestic callers or +1-201-389-0864 for international callers. When prompted, provide the conference identification number, 13700027.

If you are unable to participate, a replay of the conference call will be available for 30 days. The replay dial-in number for the United States is 877-660-6853 and the dial-in number for international callers is +1-201-612-7415. To access the replay you will need the conference identification number, 13700027.

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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