Incyte Announces Multiple Abstracts from its Dermatology Portfolio have been Accepted for Presentation at the 2022 American Academy of Dermatology (AAD) Annual Meeting

March 18, 2022

- *New data on ruxolitinib cream (Opzelura™) in vitiligo and atopic dermatitis will be presented, including 52-week results from the Phase 3 TRuE-V vitiligo program which will be featured as a late-breaking oral presentation*

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 18, 2022-- Incyte (Nasdaq:INCY) today announced that multiple abstracts featuring data from its dermatology portfolio will be presented at the upcoming American Academy of Dermatology (AAD) Annual Meeting, held March 25-29, 2022, in Boston.

New 52-week data from the Phase 3 TRuE-V vitiligo program evaluating the safety and efficacy of ruxolitinib cream in adolescent and adult patients (age ≥12 years) with vitiligo will be presented as an oral presentation in a late-breaking abstract session. Incyte previously announced positive 24-week results from the TRuE-V1 and TRuE-V2 studies.

"We are pleased to convene again at AAD 2022 and present new ruxolitinib cream data which highlights its potential for patients with atopic dermatitis and vitiligo and our commitment to the Dermatology community," said Jim Lee, M.D., Ph.D., Group Vice President, Inflammation & Autoimmunity, Incyte. "We look forward to sharing data from multiple Phase 3 studies highlighting clinical trial data for ruxolitinib cream – notably the 52-week results from the TRuE-V vitiligo program – as well as findings from the VALIANT study which contribute to the scientific understanding of the natural history of vitiligo and its burden on patients in the United States."

Key abstracts include:

Late-Breaking Oral Presentation

Vitiligo

Efficacy and Safety of Ruxolitinib Cream Monotherapy for the Treatment of Vitiligo: Results from Two 52-Week Phase 3 Studies (Session: S026 – Late-Breaking Research: Clinical Trials. Saturday, March 26, 10:40 a.m. ET)

Posters with Oral Presentation

Atopic Dermatitis

Efficacy of Ruxolitinib Cream for the Treatment of Atopic Dermatitis by Anatomic Region: Pooled Analysis From Two Randomized Phase 3 Studies (Category: Atopic Dermatitis)

Vitiligo

Efficacy and Safety of Ruxolitinib Cream for the Treatment of Vitiligo: Week 24 Pooled Analysis of the TRuE-V Phase 3 Studies (Category: Pigmentary Disorders & Vitiligo)

Efficacy and Safety of Ruxolitinib Cream for the Treatment of Vitiligo by Patient Demographics and Baseline Clinical Characteristics: Pooled Subgroup Analysis From Two Randomized Phase 3 Studies (Category: Pigmentary Disorders & Vitiligo)

The Mental Health and Psychosocial Burden Among Patients Living With Vitiligo in the United States: Findings From the VALIANT Study (Category: Pigmentary Disorders & Vitiligo)

Poster Presentations

Atopic Dermatitis

Long-Term Safety and Disease Control of Ruxolitinib Cream Among Black or African American Patients With Atopic Dermatitis: Pooled Results From Two Phase 3 Studies (Abstract #34794. Friday, March 25, 2022 - Sunday, March 27, 2022, 9:00 a.m. – 5:00 p.m. ET; ePoster only)

Ruxolitinib Cream Provided Progressive Improvement in Patients With Atopic Dermatitis Who Did Not Achieve Investigator's Global Assessment Treatment Success at Week 8: Pooled Results From Two Phase 3 Studies (Abstract #35163. Friday, March 25, 2022 - Sunday, March 27, 2022, 9:00 a.m. – 5:00 p.m. ET; ePoster only)

Vitiligo

Exploring the Natural History of Vitiligo in the United States: Findings From the VALIANT Study (Abstract #34612. Friday, March 25, 2022 - Sunday, March 27, 2022, 9:00 a.m. – 5:00 p.m. ET; ePoster only)

Do Patients With Vitiligo and Healthcare Professionals Treating Them Recognize the Burden in Living With the Disease in the United States? Findings From the VALIANT Study (Abstract #34631. Friday, March 25, 2022 - Sunday, March 27, 2022, 9:00 a.m. – 5:00 p.m. ET; ePoster only)

Full abstracts will be available on the AAD website on March 25, 2022. More information regarding the 2022 AAD Annual Meeting can be found at https://www.aad.org/member/meetings-education/am22.

About Ruxolitinib Cream (Opzelura™)

Ruxolitinib cream (Opzelura) a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, is the first and only topical JAK inhibitor approved for use in the United States for the topical short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis (AD) in non-immunocompromised patients 12 years of age and older whose disease is not adequately controlled with topical prescription therapies, or when those therapies are not advisable. Use of Opzelura in combination with therapeutic biologics, other JAK inhibitors, or potent immunosuppressants, such as azathioprine or cyclosporine, is not recommended.

In October 2021, Incyte announced the validation of the European Marketing Authorization Application (MAA) for ruxolitinib cream as a potential treatment for adolescents and adults (age >12 years) with non-segmental vitiligo with facial involvement. Additionally, in December 2021, Incyte announced the acceptance and priority review of the supplemental New Drug Application (sNDA) for ruxolitinib cream as a potential treatment for adolescents and adults (age ≥12 years) with vitiligo.

Incyte has worldwide rights for the development and commercialization of ruxolitinib cream, marketed in the United States as Opzelura.

Opzelura is a trademark of Incyte.

About Incyte Dermatology

Incyte's science-first approach and expertise in immunology has formed the foundation of the company. In Dermatology, the Company's research and development efforts are focused on leveraging our knowledge of the JAK-STAT pathway to identify and develop topical and oral therapies with the potential to modulate immune pathways driving uncontrolled inflammation and help restore normal immune function.

Currently, Incyte is exploring the potential of JAK inhibition for a number of immune-mediated dermatologic conditions with a high unmet medical need, including vitiligo and hidradenitis suppurativa. To learn more, visit the Dermatology section of Incyte.com.

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 Opzelura to provide a successful treatment for atopic dermatitis, whether and when ruxolitinib cream might be approved to treat patients with vitiligo, the potential for success of such treatment, Incyte's clinical trials and Incyte's Dermatology program generally, 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; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain, other third-party providers and development and discovery operations; determinations made by the FDA and other regulatory authorities; the efficacy or safety of the Company's products; the acceptance of the Company's products in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report and its quarterly report on Form 10-Q for the quarter ended December 31, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

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