Multiple Abstracts from Incyte's Growing Dermatology Portfolio Featured at American Academy of Dermatology (AAD) Annual Meeting

March 6, 2023

- *Three late-breaking presentations in vitiligo highlight new long-term data from the Phase 3 TRuE-V trials for Opzelura® (ruxolitinib) cream and results from a Phase 2b study with povorcitinib (INCB54707), an oral JAK1 inhibitor*
- *Incyte to host an in-person analyst and investor event on Saturday, March 18, 2023, from 5:30-7:00 p.m. CT to discuss key vitiligo data presentations*

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 6, 2023-- Incyte (Nasdaq:INCY) today announced that multiple abstracts featuring data from its dermatology portfolio will be presented at the upcoming 2023 American Academy of Dermatology (AAD) Annual Meeting, held March 17-21, 2023, in New Orleans.

New data from the Phase 3 TRuE-V clinical trial program evaluating the durability and long-term response (up to 104 weeks) of Opzelura® (ruxolitinib) cream in patients (age ≥12 years) with vitiligo will be presented in two late-breaking oral presentations, building on the previously announced positive 24- and 52-week results from the TRuE-V1 and TRuE-V2 studies. Additionally, safety and efficacy data from a Phase 2b study of povorcitinib, an investigational oral small-molecule JAK1 inhibitor, in patients with vitiligo will be presented as an oral presentation during a late-breaking abstract session.

"The research being featured at this year's AAD Annual Meeting highlights the potential of Incyte therapies to meet the needs of patients living with vitiligo and other serious skin conditions," said Jim Lee, M.D., Ph.D., Group Vice President, Inflammation & Autoimmunity, Incyte. "Collectively, these data are representative of our science-first approach and the continued progress of our portfolio as we seek to discover and develop innovative dermatology treatments for patients."

Key abstracts include:

Late-Breaking Oral Presentations

Vitiligo

Relapse and Maintenance of Clinical Response in the Randomized Withdrawal Arm of the TRuE-V Long-Term Extension Phase 3 Study of Ruxolitinib Cream in Vitiligo (Session: S025 – Late-Breaking Research: Session 1. Saturday, March 18, 9:20 a.m. CT)

Facial and Total Vitiligo Area Scoring Index Response Shift During 104 Weeks of Ruxolitinib Cream Treatment for Vitiligo: Results from the Open-Label Arm of the TRuE-V Long-Term Extension Phase 3 Study (Session: S025 – Late-Breaking Research: Session 1. Saturday, March 18, 9:30 a.m. CT)

Efficacy and Safety of Povorcitinib in Vitiligo: Results from a Phase 2, Placebo-Controlled, Dose Ranging Study (Session: S042 – Late-Breaking Research: Session 2. Saturday, March 18, 2:30 p.m. CT)

Posters with Oral Presentation

Atopic Dermatitis

Ruxolitinib Cream Monotherapy Use Demonstrates Maintenance of Disease and Symptom Control with Use as Needed in Adults and Adolescents with Atopic Dermatitis: Pooled Analysis from the Long-Term Safety Periods of Two Phase 3 Studies (Abstract #44103. Session: Atopic Dermatitis. Friday, March 17, 2023, 3:20 p.m. – 3:25 p.m. CT)

Hidradenitis Suppurativa

Changes in Draining Tunnel (dT) Counts in the Randomized, Placebo-Controlled, Phase 2 Study of Povorcitinib (INCB054707) in Patients with Hidradenitis Suppurativa (HS) (Abstract #44062. Session: Immunodermatology & Blistering Disorders. Saturday, March 18, 2023, 10:40 a.m. – 10:45 a.m. CT)

Vitiligo

Vitiligo Noticeability Scale Score Maintenance or Shift During 52 Weeks of Ruxolitinib Cream Treatment for Vitiligo: Pooled Analysis of the TRuE-V Phase 3 Studies (Abstract #43959. Session: Pigmentary Disorders & Vitiligo. Saturday, March 18, 2023, 5:50 p.m. – 5:55 p.m. CT)

Facial Vitiligo Area Scoring Index Response Maintenance or Shift During 52 Weeks of Ruxolitinib Cream Treatment for Vitiligo: Pooled Analysis of the TRuE-V Phase 3 Studies (Abstract #43912. Session: Pigmentary Disorders & Vitiligo. Saturday, March 18, 2023, 5:35 p.m. – 5:40 p.m. CT)

e-Poster Exhibits

For e-Poster exhibits, abstract content will be available in the online viewing portal and on-site at the viewing stations. They will also be published online via the *Journal of the American Academy of Dermatology (JAAD)* supplement in Fall 2023.

Graft-Versus-Host Disease (GVHD)

Oral Ruxolitinib Treatment for Patients with Dermatologic Manifestations of Acute or Chronic Graft-Versus-Host Disease: A Post Hoc Analysis of the Phase 3 REACH2 and REACH3 Studies (Session: Immunodermatology & Blistering Disorders.)

Vitiligo

Total Vitiligo Area Scoring Index Response Maintenance or Shift During 52 Weeks of Ruxolitinib Cream Treatment for Vitiligo: Pooled Analysis of the TRuE-V Phase 3 Studies (Abstract #43938. Session: Pigmentary Disorders & Vitiligo.)

Treatment-Emergent Adverse Events of Interest for Janus Kinase Inhibitors: Pooled Analysis of the 52-Week TRuE-V Phase 3 Studies of Ruxolitinib Cream Treatment for Vitiligo (Abstract #43978. Session: Pigmentary Disorders & Vitiligo.)

Understanding the Patient Perspective in Living with and Treating Vitiligo (Abstract #43040. Session: Pigmentary Disorders & Vitiligo.)

More information regarding the 2023 AAD Annual Meeting can be found at https://www.aad.org/member/meetings-education/am23.

In-Person Event and Webcast

Incyte will host an in-person analyst and investor event on Saturday, March 18, 2023, from 5:30-7:30 p.m. CT, to discuss the key vitiligo data presentations at AAD. The event will be webcasted and can be accessed via the Events and Presentations tab of the Investor section of Incyte.com and it will be available for replay for 90 days.

Conference call details will be provided on our website.

About Opzelura® (ruxolitinib) Cream

Opzelura® (ruxolitinib) cream, a novel cream formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, approved by the U.S. Food & Drug Administration for the topical treatment of nonsegmental vitiligo in patients 12 years of age and older, is the first and only treatment for repigmentation approved for use in the United States. Opzelura is also approved in the U.S. 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.

Incyte has worldwide rights for the development and commercialization of ruxolitinib cream, marketed in the United States as Opzelura. In April 2022, Incyte entered into a strategic alliance agreement with Maruho Co., Ltd. for the development, manufacturing and exclusive commercialization of ruxolitinib cream for treatment of autoimmune and inflammatory dermatology indications in Japan.

Opzelura is a registered trademark of Incyte.

About Povorcitinib (INCB54707)

Povorcitinib (INCB54707) is an oral small-molecule JAK1 inhibitor currently in Phase 2 clinical trials for hidradenitis suppurativa (HS), vitiligo and prurigo nodularis. A Phase 3 study in HS is also ongoing.

About Jakafi® (ruxolitinib)

Jakafi® (ruxolitinib) is a JAK1/JAK2 inhibitor approved by the U.S. FDA for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea; intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults; steroid-refractory acute GVHD in adult and pediatric patients 12 years and older; and chronic GVHD after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.[1]

Jakafi is marketed by Incyte in the United States and by Novartis as Jakavi® (ruxolitinib) outside the United States. Jakafi is a registered trademark of Incyte Corporation. Jakavi is a registered trademark of Novartis AG in countries outside the United States.

About Incyte Dermatology

Incyte's science-first approach and expertise in immunology has formed the foundation of the company. Today, we are building on this legacy as we discover and develop innovative dermatology treatments to bring solutions to patients in need.

Our research and development efforts in dermatology are initially focused on leveraging our knowledge of the JAK-STAT pathway. We are exploring the potential of JAK inhibition for a number of immune-mediated dermatologic conditions with a high unmet medical need, including atopic dermatitis, vitiligo, lichen planus, lichen sclerosus and prurigo nodularis.

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 Incyte's dermatology portfolio, the presentation of clinical data for that portfolio, whether or when any products, development compounds, or combinations in that portfolio will be approved or commercially available for use in humans anywhere in the world (beyond those products already approved for certain indications in specific regions), whether and when approved products from Incyte's dermatology portfolio will provide successful treatment options for dermatology patients, along with Incyte's goal of improving the lives of patients, contain predictions, estimates and other forward-looking statements.

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 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 Incyte and its partners' clinical trials, supply chain, other third-party providers and development and discovery operations; determinations made by the U.S. FDA and other regulatory authorities outside of the United States; the efficacy or safety of Incyte and its partners' products; the acceptance of Incyte and its partners' products in the marketplace; market competition; sales, marketing, manufacturing and distribution requirements; and other risks detailed from time to time in Incyte's reports filed with the Securities and Exchange Commission, including its annual report for the year ended December 31, 2022. Incyte disclaims any intent or obligation to update these forward-looking statements.

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[1] Jakafi (ruxolitinib) tablets: Prescribing Information. U.S. Food and Drug Administration

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