FOR IMMEDIATE RELEASE

Incyte Announces Swissmedic approval of Opzelura® (ruxolitinib) Cream 15mg/g for the Treatment of Non-Segmental Vitiligo

- *Opzelura is the first approved treatment in Switzerland to address repigmentation in non-segmental vitiligo.*
- *Phase 3 data supporting the approval show that treatment with Opzelura resulted in improved facial and total body repigmentation, sustained and continued improvements with longer duration of treatment.*

MORGES, Switzerland – January 31, 2025 – Incyte (NASDAQ:INCY) today announced that the Swiss Agency for Therapeutic Products (Swissmedic) has granted approval for Opzelura® (ruxolitinib) cream 15mg/g for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age, when non-therapeutic measures are not sufficient or when they are not well tolerated. Opzelura is the first and only approved treatment in Switzerland to offer eligible patients with non-segmental vitiligo support for repigmentation.

"Today's approval marks a significant milestone for people living with vitiligo and their healthcare providers across Switzerland," said Lee Heeson, Executive Vice President and Head of Incyte International, Incyte. "This approval reflects our deep commitment to strengthening our presence and addressing the needs of Dermatology patients in Switzerland. We look forward to continuing our collaboration with the Swiss authorities to ensure that eligible patients gain timely access to Opzelura."

The Swissmedic decision is based on data from two pivotal Phase 3 clinical trials (TRuE-V1 [NCT04052425] and TRuE-V2 [NCT04057573]), evaluating the efficacy and safety of ruxolitinib cream versus vehicle (non-medicated cream) in more than 600 patients with non-segmental vitiligo, aged 12 and older[i]. Results from the TRuE-V program showed that treatment with ruxolitinib cream resulted in significant improvements in facial and total body repigmentation versus vehicle as shown by the number of patients reaching the facial and total body Vitiligo Area Scoring Index (F-VASI & T-VASI) endpoints at Week 24 compared to vehicle and in an open-label extension at Week 52[i].

Results at Week 24, which were consistent across both studies, showed that 29.8% and 30.9% of patients treated with ruxolitinib cream achieved ≥75% improvement from baseline in the facial Vitiligo Area Scoring Index (F-VASI75), the primary endpoint, compared to 7.4% and 11.4% of patients treated with vehicle in TRuE-V1 and TRuE-V2, respectively. At Week 52, approximately one in two patients treated with ruxolitinib cream achieved F-VASI75[i].

Additionally, at Week 24, more than 15% of patients treated with ruxolitinib cream achieved ≥90% improvement from baseline in F-VASI (F-VASI90), compared to approximately 2% of patients treated with vehicle. At Week 52, approximately one in three ruxolitinib cream-treated patients achieved F-VASI90[i].

In clinical trials, the most common adverse effects (all causalities) (incidence ≥ 1%) were application site acne, application site pruritus, application site erythema, application site rash, pyrexia, application site exfoliation, nasopharyngitis, upper respiratory tract infection, flu, urinary tract infection, headache, and elevated liver enzymes[i].

For further safety information, see the "Warnings and Precautions" and "Adverse Reactions"[i,ii] section of the Opzelura Professional and Patient Information

"The data underpinning the Swissmedic approval clearly demonstrate Opzelura's efficacy in achieving repigmentation both on the face and across the entire body," said Antonios Kolios, M.D., Department of Dermatology, University Hospital, Zurich, Switzerland. "This is particularly encouraging, given the limited treatment options available for our patients in the past."

Vitiligo is a chronic autoimmune disease in which areas of skin depigment due the progressive destruction of pigment-producing cells known as melanocytes.[iii] Over-activity of the JAK signaling pathway is believed to drive inflammation involved in the pathogenesis and progression of vitiligo. Vitiligo can occur at any age, although many patients with vitiligo will experience initial onset before the age of 30[iii], and has a significant impact on people living with the condition.[iv]

"For people affected by vitiligo, there are currently only very limited treatment options," says Dominic Bühler, board member of the Swiss Psoriasis and Vitiligo Society. "Any improvement of this situation, whether through expanded treatment options or new medications, is highly welcomed by us as a patient organization on behalf of the vitiligo patients we represent."

About Opzelura® (ruxolitinib) Cream

Opzelura, a novel formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib, is the first and only topical JAK inhibitor approved for use in Switzerland for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age, when non-therapeutic measures are not sufficient or when they are not well tolerated.

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

Opzelura and its logo are registered trademarks of Incyte.

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 several immune-mediated dermatologic conditions with a high unmet medical need, including atopic dermatitis, vitiligo, hidradenitis suppurativa and prurigo nodularis.

To learn more, visit the Dermatology section of Incyte.com.

About Incyte

A global biopharmaceutical company on a mission to *Solve On.*, Incyte follows the science to find solutions for patients with unmet medical needs. Through the discovery, development and commercialization of proprietary therapeutics, Incyte has established a portfolio of first-in-class medicines for patients and a strong pipeline of products in Oncology and Inflammation & Autoimmunity. Headquartered in Wilmington, Delaware, Incyte has operations in North America, Europe and Asia.

For additional information on Incyte, please visit Incyte.com or follow us on social media: LinkedIn, X, Instagram, Facebook, YouTube.

Forward-Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release, including statements regarding whether Opzelura might provide a successful treatment option for patients with vitiligo, 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 and the ability to enroll subjects in accordance with planned schedules, supply chain and other third-party providers and development and discovery operations; determinations made by Swissmedic; 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 U.S. Securities and Exchange Commission, including our annual report on Form 10-K and our quarterly report on Form 10-Q for the quarter ended September 30, 2024. The Company disclaims any intent or obligation to update these forward-looking statements.

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[i] Opzelura. Product information for human medicinal products for professionals. Incyte; June 2024 [INSERT HYPERLINK TO PI VIA VEEVA PROMOMATS]

[ii] Opzelura. Product information for human medicinal products for patients. Incyte; June 2024 [INSERT HYPERLINK TO PI VIA VEEVA PROMOMATS]

[iii] Frisoli M, et al. Vitiligo: mechanisms of pathogenesis and treatment. *Annual. Review of Immunology.* 2020; 38(1):621-648.

[iv] Bibeau K, et al. Maui Derm for Dermatologists 2022. ePoster on Diagnosis and Management of Vitiligo from the Perspectives of Patients and Healthcare Professionals: Findings from the Global VALIANT Study.