Incyte Announces Positive CHMP Opinion for Ruxolitinib Cream (Opzelura™) for the Treatment of Non-segmental Vitiligo in Adults and Adolescents

February 24, 2023

- *At approval, ruxolitinib cream will be the first treatment for repigmentation in non-segmental vitiligo available in the European Union (EU)*
- *In Europe, there are approximately 1.5 million patients diagnosed with vitiligo, a progressive and complex disease with a high unmet need*
- *The positive CHMP opinion is based on Phase 3 data showing treatment with ruxolitinib cream resulted in improvements in facial and total body repigmentation*[1]

WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 24, 2023-- Incyte (Nasdaq:INCY) today announced that the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion recommending the approval of ruxolitinib cream (Opzelura™) for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

“The positive CHMP opinion brings us one step closer to bringing ruxolitinib cream, the first ever treatment for repigmentation in non-segmental vitiligo, to patients and healthcare professionals in the European Union (EU),” said Steven Stein, M.D., Chief Medical Officer, Chief Medical Officer, Incyte. “With no centrally approved treatment option currently available in the EU, this positive opinion marks a significant milestone for the vitiligo community.”

The CHMP opinion recommending the approval of ruxolitinib cream was based on data from two pivotal Phase 3 clinical trials (TRuE-V1 and TRuE-V2) evaluating the safety and efficacy of ruxolitinib cream versus vehicle (non-medicated cream) in more than 600 people with non-segmental vitiligo, age 12 and older[1]. Results from the TRuE-V program, recently published in *The New England Journal of Medicine,* 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, with a higher proportion of patients responding at Week 52[1]. The most common adverse reactions (incidence ≥ 1%) were application site acne, application site pruritus, nasopharyngitis, headache, urinary tract infection, application site erythema, and pyrexia[2].

The CHMP’s opinion is now being reviewed by the European Commission, which has the authority to grant centralized marketing authorizations for medicinal products in the EU. When approved, this will be the first approved vitiligo therapy available in the EU indicated for the treatment of non-segmental vitiligo with facial involvement in adults and adolescents from 12 years of age.

“Given its complex pathogenesis and unpredictable progression, vitiligo can be very challenging for dermatologists to treat,” said Thierry Passeron M.D., Ph.D., Professor and Chair, Department of Dermatology, Université Côte d'Azur in Nice, France and one of the lead investigators of the TRUE-V trials. “I welcome today’s news and look forward to the potential approval of an effective therapy that can address repigmentation, providing a much-needed option for those patients living with vitiligo who are actively seeking treatment, as well as the clinical community dedicated to its treatment.”

About Vitiligo
Vitiligo is a chronic autoimmune disease characterized by depigmentation of skin that results in patchy loss of skin color from the progressive destruction of pigment-producing cells known as melanocytes. Overactivity of the JAK signaling pathway is believed to drive inflammation involved in the pathogenesis and progression of vitiligo. In Europe, approximately 1.5 million patients are diagnosed with vitiligo (0.2 to 0.8% of the population[3,4]), and its overall prevalence is estimated to be less than 1%, with the majority of patients (approximately 8 in 10) suffering from non-segmental vitiligo[5]. Vitiligo can occur at any age, although many patients with vitiligo will experience initial onset before the age of 30[6]. Vitiligo not only impacts physical health but also places a heavy burden on quality of life including employment and psychosocial health such as depression.

About TRuE-V
The TRuE-V clinical trial program includes two Phase 3 studies, TRuE-V1 (NCT04052425) and TRuE-V2 (NCT04057573), evaluating the safety and efficacy of ruxolitinib cream in patients with vitiligo. Each study enrolled approximately 300 patients (age ≥12 years) who have been diagnosed with non-segmental vitiligo.

About Ruxolitinib Cream (Opzelura™)
Ruxolitinib cream (Opzelura™), a novel cream formulation of Incyte’s selective JAK1/JAK2 inhibitor ruxolitinib, approved by theU.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.

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 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 whether and when ruxolitinib cream might be approved in the EU to treat patients with vitiligo, the potential for success of such treatment, Incyte's TRuE-V clinical program 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 and the ability to enroll subjects in accordance with planned schedules; the effects of the COVID-19 pandemic and measures to address the pandemic on the Company's clinical trials, supply chain, and other third-party providers and development and discovery operations; determinations made by the European Commission and other regulatory authorities; 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; and other risks detailed from time to time in the Company's reports filed with the U.S. Securities and Exchange Commission, including its annual report for the year ending December 31, 2022. The Company disclaims any intent or obligation to update these forward-looking statements.

---

[1] Rosmarin D, et al. Two Phase 3 Randomized Controlled Trials of Ruxolitinib Cream for Vitiligo. *New England Journal of Medicine*. 2022; 387:1445-1455.

[2] Opzelura Prescribing Information. Wilmington, DE. Incyte Corporation.

[3] Mohr N, et al. Epidemiology of Vitiligo - A Dual Population-Based Approach. *Clinical Epidemiology*. 2021 May 26;13:373-382.

[4] Bibeau K, et al. Vitiligo prevalence and quality of life among adults in Europe, Japan and the USA. *Journal of the European Academy of Dermatology and Venerology*. 2022 V36(10), P 1831-1844

[5] Gandhi K, et al. Prevalence of Vitiligo Among Adults in the United States. JAMA Dermatol. 2022 Jan 1;158(1):43-50.

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

View source version on businesswire.com: https://www.businesswire.com/news/home/20230223006046/en/

Media
Catalina Loveman
+1 302 498 6171
cloveman@incyte.com

Ela Zawislak
+41 21 343 3113
ezawislak@incyte.com

Investors
Christine Chiou
+1 302 274 4773
cchiou@incyte.com

Source: Incyte Corporation