Incyte Announces U.S. FDA Has Extended the Supplemental New Drug Application Review Period for Ruxolitinib Cream (Opzelura™) for the Treatment of Vitiligo

March 14, 2022

WILMINGTON, Del.--(BUSINESS WIRE)--Mar. 14, 2022-- Incyte Corporation (Nasdaq:INCY) announced today that the U.S. Food and Drug Administration (FDA) has extended the review period for the supplemental New Drug Application (sNDA) for ruxolitinib cream (Opzelura™) for the treatment of vitiligo. The Prescription Drug User Fee Act (PDUFA) action date has been extended by three months to July 18, 2022.

The FDA extended the PDUFA action date to allow time to review additional data from the ongoing Phase 3 studies submitted by Incyte in response to the FDA's information request. The submission of the additional information has been determined by the FDA to constitute a Major Amendment to the sNDA, resulting in an extension of the PDUFA goal date.

"We are confident in the data from the TRuE-V clinical trial program which supports our sNDA submission for ruxolitinib cream in vitiligo, and we look forward to bringing this innovative topical treatment to patients with vitiligo in the United States for whom there are no approved therapies that address repigmentation," said Steven Stein M.D., Chief Medical Officer, Incyte.

The pivotal Phase 3 TRuE-V clinical trial program (TRuE-V1 and TRuE-V2) is evaluating the safety and efficacy of ruxolitinib cream versus vehicle in more than 600 adolescent and adult patients (age 12 and older) with non-segmental vitiligo.

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.

On October 28, 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

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 Company's ongoing clinical development program for ruxolitinib cream as well as its dermatology program generally, and whether and when ruxolitinib cream will be approved for use in the U.S. or elsewhere for vitiligo or any additional indications, 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 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; 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 for the year ending December 31, 2022. The Company disclaims any intent or obligation to update these forward-looking statements.

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