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# Incyte Announces U.S. FDA Has Extended the New Drug Application Review Period for Ruxolitinib Cream for the Treatment of Atopic Dermatitis

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte Corporation (Nasdaq:INCY) announced today that the U.S. Food and Drug Administration (FDA) has extended the review period for the New Drug Application (NDA) for ruxolitinib cream for the treatment of atopic dermatitis (AD). The Prescription Drug User Fee Act (PDUFA) action date has been extended by three months to September 21, 2021.

The FDA extended the PDUFA action date to allow time to review additional analyses of previously submitted data provided 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 NDA, resulting in an extension of the PDUFA goal date.

"We are confident in the potential of ruxolitinib cream to offer a safe and effective treatment option for atopic dermatitis and will continue to work with the FDA to bring this targeted topical therapy to patients in the U.S. as soon as possible," said Steven Stein, M.D., Chief Medical Officer, Incyte.

## About Ruxolitinib Cream

Ruxolitinib cream is a proprietary formulation of Incyte's selective JAK1/JAK2 inhibitor ruxolitinib that has been designed for topical application. Ruxolitinib cream is currently in Phase 3 development for the treatment of adolescents and adults with atopic dermatitis (TRuE-AD) and vitiligo (TRuE-V). Incyte has worldwide rights for the development and commercialization of ruxolitinib cream.

## 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 atopic dermatitis or any other indication, 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 and its quarterly report on Form 10-Q for the quarter ended March 31, 2021. The Company disclaims any intent or obligation to update these forward-looking statements.

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