

Incyte Announces U.S. FDA Has Extended the sNDA Review Period for Ruxolitinib (Jakafi®) in Chronic Graft-Versus-Host Disease (GVHD)

June 8, 2021

WILMINGTON, Del.--(BUSINESS WIRE)-- Incyte (Nasdaq:INCY) today announced that the U.S. Food and Drug Administration (FDA) has extended the review period for the supplemental New Drug Application (sNDA) for ruxolitinib (Jakafi®) for the treatment of adult and pediatric patients 12 years and older with steroid-refractory chronic graft-versus-host disease (GVHD). The new Prescription Drug User Fee Act (PDUFA) target action date is September 22, 2021.

The FDA extended the PDUFA action date to allow time to review additional data 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 by three months.

"We remain confident in the data from the REACH3 trial supporting our sNDA submission for ruxolitinib and look forward to continued dialogue with the FDA throughout the remainder of the review process," said Steven Stein M.D., Chief Medical Officer, Incyte. "We will work closely with the agency and are dedicated to bringing this innovative treatment to patients with steroid-refractory chronic GVHD who urgently need new treatment options."

The sNDA was based on data from REACH3, a Phase 3 randomized, open-label, multicenter study comparing ruxolitinib with best available therapy (BAT) in adult and pediatric patients 12 years and older with steroid-refractory chronic GVHD.

About Jakafi® (ruxolitinib)

Jakafi is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. FDA for the 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, and for the treatment of steroid-refractory acute GVHD in adult and pediatric patients 12 years and older.

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

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](https://www.incyte.com) and follow [@Incyte](https://twitter.com/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, the REACH program and the Company's GVHD program generally, and whether and when ruxolitinib will be approved for use in the U.S. or elsewhere for steroid-refractory chronic GVHD 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 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 FDA; 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; and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its annual report on Form 10-Q for the quarter ended March 31, 2020. The Company disclaims any intent or obligation to update these forward-looking statements.



View source version on [businesswire.com](https://www.businesswire.com/news/home/20210608005435/en/): <https://www.businesswire.com/news/home/20210608005435/en/>

Media

Catalina Loveman

+1 302 498 6171

cloveman@incyte.com

Jenifer Antonacci

+1 302 498 7036

janconacci@incyte.com

Investors

Christine Chiou

+1 302 274 4773

cchiou@incyte.com

Source: Incyte