



Incyte Announces Decision to Stop Phase 2 Sub-study of Ruxolitinib Plus Regorafenib in Patients with Metastatic Colorectal Cancer and High CRP

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WILMINGTON, Del.--(BUSINESS WIRE)--Jan. 27, 2016-- Incyte Corporation (Nasdaq: INCY) announced today that the Phase 2 sub-study of ruxolitinib or placebo in combination with regorafenib in patients with relapsed or refractory metastatic colorectal cancer (CRC) and high C-reactive protein (CRP) will be stopped early. The decision to stop the sub-study was made after a planned interim analysis of the high CRP subgroup demonstrated that ruxolitinib plus regorafenib did not show a sufficient level of efficacy to warrant continuation.

"We are disappointed at the outcome from this interim analysis and deeply grateful for the support and commitment of the patients participating in the study, their families, and the study investigators," said Steven Stein, M.D., Chief Medical Officer of Incyte.

About the Study

This Phase 2 randomized, double-blind study (INCB 18424-267) of patients with relapsed or refractory metastatic CRC included an open-label, safety run-in, to confirm the safety of the ruxolitinib plus regorafenib combination in subjects with relapsed or refractory metastatic CRC as well as a randomized phase of the study. The randomized phase of the study included 2 sub-studies targeting separate populations of patients with CRC based on levels of systemic inflammation, as measured by the modified Glasgow Prognostic Score (sub-study 1 CRP >10 mg/L and sub-study 2 CRP ≤ 10 mg/L). Patients in each sub-study were randomized 1:1 to receive ruxolitinib plus regorafenib or regorafenib plus placebo.

About Ruxolitinib (Jakafi®)

Ruxolitinib (Jakafi) is a first-in-class JAK1/JAK2 inhibitor approved by the U.S. Food and Drug Administration for treatment of people with polycythemia vera (PV) who have had an inadequate response to or are intolerant of hydroxyurea. Jakafi is also indicated for treatment of people with intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF, and post-essential thrombocythemia MF.

Ruxolitinib is not approved anywhere in the world as treatment for metastatic colorectal cancer.

Full Prescribing Information, including a more complete discussion of the risks associated with Jakafi, is available at www.jakafi.com.

Jakafi is marketed by Incyte in the United States and by Novartis as Jakavi® (ruxolitinib) outside the United States.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics, primarily for oncology. For additional information on Incyte, please visit the Company's website at www.incyte.com.

Forward Looking Statements

Except for the historical information set forth herein, the matters set forth in this press release 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 the efficacy or safety of any of the product candidates in the Company's development portfolio, the results of further research and development, the high degree of risk and uncertainty associated with drug development, clinical trials and regulatory approval processes, the risks that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards, the ability to enroll sufficient numbers of subjects in clinical trials, other market, economic or strategic factors and technological advances, unanticipated delays, the ability of the Company to compete against parties with greater financial or other resources, risks associated with the Company's dependence on its relationships with its collaboration partners, and other risks detailed from time to time in the Company's reports filed with the Securities and Exchange Commission, including its Form 10-Q for the quarter ended September 30, 2015. The Company disclaims any intent or obligation to update these forward-looking statements.



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