Incyte Announces Decision to Discontinue JANUS Studies of Ruxolitinib plus Capecitabine in Patients with Advanced or Metastatic Pancreatic Cancer

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WILMINGTON, Del.--(BUSINESS WIRE)--Feb. 11, 2016-- Incyte Corporation (Nasdaq: INCY) announced today its decision to discontinue the Phase 3 study (JANUS 1) of ruxolitinib or placebo in combination with capecitabine for the second-line treatment of patients with advanced or metastatic pancreatic cancer. The decision to stop the study was made after a planned interim analysis of JANUS 1 demonstrated that ruxolitinib plus capecitabine did not show a sufficient level of efficacy to warrant continuation.

Following these results, and the previously announced interim analysis of the Phase 2 sub-study of ruxolitinib or placebo in combination with regorafinib in patients with metastatic colorectal cancer and high C-reactive protein (CRP), ongoing Incyte-sponsored trials of ruxolitinib in solid tumors will be discontinued, including the Phase 3 JANUS 2 study in pancreatic cancer, the Phase 2 sub-study in patients with metastatic colorectal cancer and low CRP and the Phase 2 studies in breast and lung cancer. Incyte's dose finding study of INCB39110 (a selective JAK1 inhibitor) as first-line treatment for metastatic pancreatic cancer, will also be discontinued. Incyte will work with investigators to appropriately conclude these studies in a manner consistent with the best interest of each patient. Data from these studies will be analyzed and shared with the scientific community over the coming months.

Ongoing studies of ruxolitinib and selective JAK1 inhibitors in hematology indications will continue. Ongoing studies of selective JAK1 inhibition in solid tumor indications that are based on different hypotheses will also continue. These include a series of studies evaluating INCB39110 in combination with either pembrolizumab (anti-PD-1 antibody), epacadostat (Incyte's IDO1 inhibitor), or INCB50465 (Incyte's PI3Kδ inhibitor) to assess the therapeutic utility of JAK1 inhibition based on its effects on the tumor microenvironment. Additionally, the potential impact of JAK1 inhibition on improving the benefit of targeted therapies will be investigated via a Phase 1/2 study of INCB39110 plus osimertinib, AstraZeneca's next generation EGFR inhibitor.

"The hypothesis to evaluate the therapeutic utility of JAK inhibition in patients with solid tumors and high levels of systemic inflammation was initially supported by a subgroup analysis of the randomized, double-blind Phase 2 RECAP study, which suggested a survival benefit in patients with high levels of CRP. As a result, we and the broader scientific community believed further study in pancreatic cancer and other solid tumors with evidence of systemic inflammation was warranted. Unfortunately, the larger studies did not confirm this hypothesis," said Rich Levy, M.D., Chief Drug Development Officer of Incyte. "Moving forward, we remain focused on our strategy to invest in innovation and in our broad development portfolio, as we seek to deliver new medicines to patients with cancer and other diseases."

About JANUS 1

JANUS 1 (INCB 18424-362) was a randomized, double-blind, Phase 3 study of ruxolitinib or placebo in combination with capecitabine in patients with advanced or metastatic pancreatic cancer who had failed or were intolerant of first-line chemotherapy.

The primary objective of the study was to evaluate and compare the overall survival of patients treated with ruxolitinib in combination with capecitabine versus capecitabine alone. Secondary objectives evaluated and compared the efficacy of the two treatment groups with respect to progression-free survival, overall tumor response and duration of response, as well as safety and tolerability.

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 pancreatic cancer.

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

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

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. 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, including without limitation statements regarding: the manner in which these solid tumor studies will be stopped and the plans to present data from the stopped solid tumor studies; the potential success of the studies of ruxolitinib and selective JAK1 inhibitors in hematology indications; the potential success of selective JAK1 inhibitions in solid tumors and in targeted therapies in various combination studies; and plans, expectations and timelines regarding the Company's product pipeline and strategy.

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 Jakafi, the acceptance of Jakafi in the

marketplace, risks related to market competition, the results of and risks associated with further research and development, risks and uncertainties associated with sales, marketing and distribution requirements, risks that results of clinical trials may be unsuccessful or insufficient to meet applicable regulatory standards or warrant continued development, 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, greater than expected expenses, unanticipated or unpredictable expenses relating to litigation or strategic activities, our ability to obtain additional capital when needed, risks related to obtaining effective patent coverage for our products 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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