Incyte Announces First Patient Treated in Phase 3 Clinical Trial of Itacitinib for Acute Graft-Versus-Host Disease

July 20, 2017

WILMINGTON, Del.--(BUSINESS WIRE)--Jul. 20, 2017-- Incyte Corporation (Nasdaq:INCY) today announced that the first patient has been treated in GRAVITAS-301, a pivotal Phase 3 trial for the first-line treatment of patients with acute graft-versus-host disease (GVHD). The trial will evaluate the efficacy and safety of itacitinib, Incyte's novel, potent, and selective JAK1 inhibitor, in combination with corticosteroids compared to placebo plus corticosteroids in patients with acute GVHD.

"Today, there are no approved treatment options for acute GVHD, a severe and life-threatening condition that can lead to tissue damage, organ failure, and death in certain transplant recipients," said Steven Stein, M.D., Incyte's Chief Medical Officer. "The initiation of the GRAVITAS-301 trial represents an important milestone for Incyte as we continue to progress our clinical development portfolio, and we look forward to further evaluating the potential of itacinitib to address the unmet needs of patients with this potentially devastating condition."

GVHD is a condition that might occur after an allogeneic transplant (the transfer of genetically dissimilar stem cells or tissue), whereby the donated bone marrow or peripheral blood stem cells view the recipient's body as foreign and attack the body. GVHD can be acute or chronic, and is a significant cause of morbidity and mortality in transplant recipients. The skin, gastrointestinal (digestive) tract, and liver are the most commonly affected organs in patients with acute GVHD.

About GRAVITAS-301

GRAVITAS-301 (NCT03139604) is a randomized, double-blind, placebo-controlled pivotal Phase 3 study evaluating itacitinib or placebo in combination with corticosteroids as a first-line treatment for patients with acute GVHD. The study will enroll approximately 430 patients 18 years or older who have undergone one allogeneic transplant from any donor and any donor source for a hematologic malignancy or disorders. The primary endpoint of the GRAVITAS-301 study is overall response rate (ORR) at Day 28, defined as the proportion of subjects demonstrating a complete response, very good partial response, or partial response. Key secondary endpoints include non-relapse mortality at Month 6, defined as the proportion of subjects who died due to causes other than malignancy relapse, duration of response, and ORR at Day 14, 56, and 100. For more information about the study, please visit https://clinicaltrials.gov/ct2/show/NCT03139604?term=gravitas&rank=2.

About Itacitinib

Itacitinib (INCB039110) is a novel, potent, and selective JAK1 inhibitor currently in clinical studies for the treatment of treatment naïve GVHD and non-small cell lung cancer.

Global development and commercialization rights for itacitinib are wholly-owned by Incyte.

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.

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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 plans and expectations for the GRAVITAS-301 program, 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 and the risks related to the efficacy or safety of the Company's development pipeline, the results of further research and development, the high degree of risk and uncertainty associated with drug development, clinical trials and regulatory approval processes, other market or economic factors and competitive and technological advances; 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 March 31, 2017. Incyte disclaims any intent or obligation to update these forward-looking statements.

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