



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

January 22, 2019

WILMINGTON, Del.--(BUSINESS WIRE)--Jan. 22, 2019-- Incyte Corporation (Nasdaq:INCY) today announced that the first patient has been treated in GRAVITAS-309, a pivotal Phase 3 trial for the first-line treatment of patients with chronic graft-versus-host disease (GVHD). The trial will evaluate the efficacy and safety of itacitinib, Incyte's novel and selective JAK1 inhibitor, in combination with corticosteroids compared to corticosteroids alone as a first-line treatment for moderate or severe chronic GVHD.

"Given the severity of chronic GVHD, we are pleased to announce the initiation of treatment for the first patient in the GRAVITAS-309 trial, as it represents a critical next step in our comprehensive development program aiming to bring important treatment options to market that address the significant unmet needs of GVHD patients across the spectrum of the disease," said Steven Stein, M.D., Chief Medical Officer, Incyte.

GVHD is a condition that can occur after an allogeneic stem cell transplant (the transfer of stem cells from a donor), where the donated cells initiate an immune response and attack the transplant recipients organs, leading to significant morbidity and mortality. There are two forms of GVHD, acute and chronic, which can affect multiple organ systems including the skin, gastrointestinal (digestive) tract and liver.

It is estimated that there are approximately 15,000 new cases of GVHD diagnosed each year in the U.S., Europe and Japan, where approximately 12,000 new cases are acute GVHD and 3,000 de novo cases are chronic GVHD.^{1,2} The prevalence of chronic GVHD in the U.S., Europe and Japan is estimated to be approximately 25,000 patients.³

A Phase 3 study (GRAVITAS-301) of itacitinib for the treatment of patients with acute GVHD is already underway, with results expected in 2019.

About GRAVITAS-309

GRAVITAS-309 (NCT03584516) 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 chronic graft-versus-host disease (cGVHD). The study will enroll approximately 266 patients 18 years or older who have undergone one allogeneic stem cell transplant from any donor and any donor source for a hematologic malignancy or disorder. The primary endpoint of the GRAVITAS-309 study is overall response rate (ORR) at Month 6, defined as the proportion of subjects demonstrating a complete response (CR) or partial response (PR) per National Institutes of Health consensus guideline. Key secondary endpoints include the maximum (Cmax) and minimum (Cmin) observed serum concentration of itacitinib when administered in combination with corticosteroids at Day 28. For more information about the study, please visit <https://clinicaltrials.gov/ct2/show/NCT03584516>.

About Itacitinib

Itacitinib (INCB039110) is a novel and selective JAK1 inhibitor currently in clinical studies for the first-line treatment of patients with acute and chronic GVHD, and for the treatment of patients with non-small cell lung cancer in combination with osimertinib, an EGFR inhibitor.

Itacitinib was discovered at Incyte, and Incyte holds the global development and commercialization rights for itacitinib with the exception of China, where the rights to develop and commercialize itacitinib have been licensed to Innovent Biologics, Inc.

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.

Follow @Incyte on Twitter at <https://twitter.com/Incyte>.

Forward Looking Statements

Except for the historical information set forth herein, the matters set forth in this release contain predictions, estimates and other forward-looking statements, including without limitation statements regarding: the Company's plans and expectations for the GRAVITAS-309 program. 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 September 30, 2018. The Company disclaims any intent or obligation to update these forward-looking statements.

¹ D'Souza A, Fretham C. Current Uses and Outcomes of Hematopoietic Cell Transplantation (HCT): CIBMTR Summary Slides, 2017. Available at: <http://www.cibmtr.org>.

² Data on file. Incyte Corporation. Wilmington, DE.

³ Jones C., et.al. *Journal of Health Economics and Outcomes Research*, 2016; 4(2):113 – 8.

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Source: Incyte Corporation

Media

Catalina Loveman

+1 302 498 6171

cloveman@incyte.com

Investors

Michael Booth, DPhil

+1 302 498 5914

mbooth@incyte.com