



Incyte Announces Results of Phase 3 Study of Itacitinib in Patients with Treatment-Naïve Acute Graft-Versus-Host Disease

January 2, 2020

- GRAVITAS-301 results show that treatment with itacitinib in combination with corticosteroids did not statistically improve overall response rate or non-relapse mortality compared to placebo plus corticosteroids

- Conference call scheduled today at 5:00 p.m. ET

WILMINGTON, Del.--(BUSINESS WIRE)--Jan. 2, 2020-- Incyte Corporation (Nasdaq:INCY) today announced that the pivotal Phase 3 GRAVITAS-301 study evaluating itacitinib in combination with corticosteroids in patients with treatment-naïve acute graft-versus-host disease (GVHD) did not meet the primary endpoint of improving overall response rate (ORR) at Day 28 compared to placebo plus corticosteroids (74.0 percent vs. 66.4 percent, $p=0.08$, respectively). Itacitinib added to corticosteroids improved the overall response rate in patients with treatment-naïve acute GVHD; however, the difference versus placebo plus corticosteroids was not statistically significant. In addition, there was no difference observed in non-relapse mortality (NRM) at Month 6, the study's key secondary endpoint, between the treatment and placebo arms.

The safety profile observed in GRAVITAS-301 was consistent with that observed in previously reported studies of itacitinib in combination with corticosteroids. The most common adverse events were thrombocytopenia (34.9 percent for itacitinib and 34.7 percent for placebo) and anemia (29.8 percent for itacitinib and 25.0 percent for placebo).

"The result of this study is disappointing. However, we remain committed to building on the success of the REACH program for ruxolitinib, which showed positive results in steroid refractory acute GVHD. Additionally we will continue to study the role of JAK inhibition in chronic GVHD and in the prophylactic setting, as we seek to develop treatments for patients with this debilitating and often fatal disease," said Steven Stein, M.D., Chief Medical Officer, Incyte.

Incyte will inform investigators of the results and work with them to appropriately conclude the study in a manner consistent with the best interest of each patient. Data from this study will be submitted for presentation at an upcoming scientific meeting.

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 primary endpoint 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. The key secondary endpoint is non-relapse mortality at Month 6, defined as the proportion of subjects who died due to causes other than malignancy relapse. Other secondary endpoints include duration of response. 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 and selective JAK1 inhibitor currently in clinical studies for the first-line treatment of patients with acute and chronic GVHD.

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.

Conference Call Information

Incyte will host a conference call at 5:00 p.m. ET on January 2, 2020. To access the conference call, please dial 877-407-3042 for domestic callers or 201-389-0864 for international callers. When prompted, provide the conference identification number, 13697736.

If you are unable to participate, a replay of the conference call will be available for 30 days. The replay dial-in number for the United States is 877-660-6853 and the dial-in number for international callers is 201-612-7415. To access the replay you will need the conference identification number, 13697736.

The conference call will also be webcast live and can be accessed at www.incyte.com in the Investors section under "Events and Presentations."

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 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 presentation of data from the Company's ongoing clinical development program for itacitinib, development plans for ruxolitinib and further development in GVHD, 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; 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; expenses relating to litigation or strategic activities; 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, 2019. The Company disclaims any intent or obligation to update these forward-looking statements.

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