

Data from Investigator Initiated Study of Ruxolitinib in Patients with Severe COVID-19 Published in the *Journal of Allergy and Clinical Immunology*

WILMINGTON, Del. – MAY 26, 2020 – Incyte is aware that data from a small, randomized, independent investigator initiated study of ruxolitinib plus standard of care (SoC) versus placebo plus SoC in patients with severe COVID-19 have been published in the *Journal of Allergy and Clinical Immunology*. Data from the study, led by Dr. Jianfeng Zhou from Tongji Hospital, Huazhong University of Science and Technology in Wuhan, China, suggest that ruxolitinib could improve outcomes for patients with severe COVID-19; however, Phase 3 trials are required to confirm the promising activity.

Based on published results, ruxolitinib plus SoC was associated with faster clinical improvement in patients with severe COVID-19 compared to treatment with SoC alone; however, the difference in this small study was not found to be statistically significant. Other encouraging findings include improvement measured by CT at Day 14 in 18 (90%) patients treated with ruxolitinib plus SoC compared to 13 (62%) patients in the control group; and a noted reduction in levels of target cytokines (including IL-6) reported in patients treated with ruxolitinib plus SoC compared to placebo plus SoC. In addition, the study authors did not observe a negative impact of ruxolitinib plus SoC treatment on viral clearance. Ruxolitinib plus SoC was generally well tolerated. In the first 28 days of randomized therapy, 80% of patients in the ruxolitinib plus SoC group and 71% patients in the control group reported adverse events. Total hematological and non-hematological adverse events (any Grade) and chemical laboratory abnormalities were similar between the two groups. No deaths were reported in the ruxolitinib plus SoC group compared to three deaths in the placebo plus SoC aroup.

The results of this independent investigator initiated study represent the first randomized clinical data for ruxolitinib in COVID-19 and add to the clinical rationale and support for the Incyte and Novartis-sponsored global Phase 3 RUXCOVID study; the Incyte-sponsored 369 DEVENT study; and Incyte's Expanded Access Program (EAP) in the United States. The *Journal of Allergy and Clinical Immunology* publication can be accessed online at: https://www.jacionline.org/article/S0091-6749(20)30738-7/abstract.

Currently, there is limited clinical evidence on the safety and efficacy of ruxolitinib for the treatment of COVID-19 associated cytokine storm, and ruxolitinib is not FDA-approved for this use.

For more information about Incyte's response to COVID-19, including information on the RUXCOVID and 369 DEVENT studies and the EAP, visit: Incyte.com/COVID-19.

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 Qlncyte.

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