Incyte Provides Statement on NIH Initiated Trial of Baricitinib in Combination with Remdesivir for Patients with COVID-19

WILMINGTON, Del. – May 8, 2020 – The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), has initiated a randomized, controlled trial evaluating the safety and efficacy of baricitinib (Olumiant®) – a JAK1/JAK2 inhibitor discovered by Incyte – plus the investigational antiviral remdesivir, developed by Gilead Sciences, Inc., for adult patients with COVID-19.

This study is part of the NIAID's Adaptive COVID-19 Treatment Trial (ACTT), which is assessing the safety and efficacy of potential treatments for patients with COVID-19. The preliminary analysis of the first phase of the ACTT demonstrated that patients who received remdesivir had a significantly shorter time to recovery compared to patients who received placebo. The second phase (ACTT 2) is designed to examine if adding baricitinib, an agent with multiple biological functions, including anti-inflammatory pharmacological effects, to the remdesivir regimen could provide additional benefit for patients. This trial is expected to enroll more than 1,000 participants across approximately 100 U.S. and international trial sites.

Baricitinib, marketed as Olumiant by Eli Lilly and Company, is approved in more than 65 countries as a treatment for certain patients with moderately to severely active rheumatoid arthritis. This is the first large, randomized, controlled trial assessing the combination of remdesivir and baricitinib in patients with COVID-19, and this treatment regimen is not currently FDA-approved for this use.

About ACTT 2

ACTT 2 is a randomized, controlled clinical trial evaluating the safety and efficacy of remdesivir plus baricitinib for COVID-19 infection.

The study will enroll approximately 1,000 adult patients with confirmed COVID-19 infection with evidence of lung involvement, including a need for supplemental oxygen, abnormal chest X-rays or illness requiring mechanical ventilation. Eligible patients will be randomized 1:1 to receive baricitinib plus remdesivir or placebo plus remdesivir. Baricitinib will be administered as a 4mg oral dose for the duration of hospitalization, for a maximum of 14 days. Remdesivir will be administered as a 200mg intravenous (IV) dose followed by a 100mg once-daily IV dose for the duration of hospitalization, for a maximum of 10 days.

The primary endpoint of the study will be the time to recovery, defined as a participant being well enough for hospital discharge, up until Day 29. Key secondary endpoints include patient outcomes at Day 15 using an ordinal 8-point scale and mortality.

An independent data and safety monitoring board (DSMB) will monitor ongoing results to ensure patient well-being and safety as well as study integrity.

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