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ASIA EDITION

Lilly reports reduced recovery time in critically ill COVID-19 patients with Baricitinib

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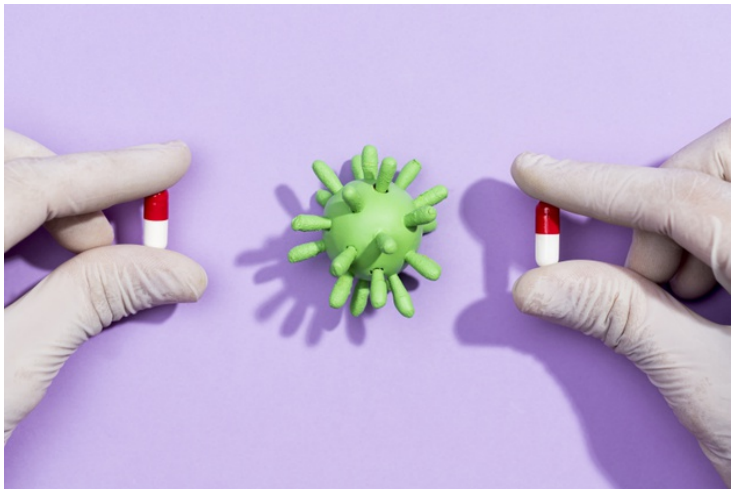
The study demonstrated the efficacy in combination with Remdesivir



US based Eli Lilly and Company and Incyte shared additional data showing baricitinib in combination with remdesivir reduced time to recovery and improved clinical outcomes for patients with COVID-19 infection compared with remdesivir.

This finding was part of additional efficacy and safety data from the Adaptive COVID-19 Treatment Trial (ACTT-2) sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH) presented today by John Beigel, M.D., associate director for clinical research in the Division of Microbiology and Infectious Diseases at NIAID. These data were presented at a special International Society for Influenza and other Respiratory Virus Diseases Antiviral Group (isirv-AVG) Virtual Conference on 'Therapeutics for COVID-19.' The largest benefits were observed in patients requiring supplemental oxygen (grade 5 on the eight-point ordinal scale) and those who required high-flow oxygen/non-invasive ventilation (grade 6) at baseline.

As previously reported, ACTT-2 achieved the primary endpoint, demonstrating that the overall patient population treated with baricitinib in combination with remdesivir improved their median time to recovery from 8 to 7 days in comparison to remdesivir, a 12.5% improvement (incidence rate ratio: 1.16; 95% CI: 1.01, 1.32; p=0.04). The study also met a pre-specified secondary endpoint. Using the ordinal scale that ranged from recovered to death, the odds of improvement in clinical status at Day 15 were 30% greater in patients being treated with baricitinib in combination with remdesivir compared with remdesivir (odds ratio 1.3; 95% CI: 1.0, 1.6; p=0.04).

Lilly is continuing conversations with the U.S. Food and Drug Administration (FDA) around the potential for Emergency Use Authorization (EUA) of baricitinib, a JAK1/JAK2 inhibitor licensed to Lilly from Incyte, to treat hospitalized patients with COVID-19. In the U.S., baricitinib has not been approved by the FDA to treat COVID-19, and the efficacy and safety of baricitinib for the treatment of COVID-19 has not been established.

Indication and Usage for OLUMIANT (baricitinib) tablets (in the United States) for RA patients

OLUMIANT® (baricitinib) 2-mg is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. Limitation of Use: Not recommended for use in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine.