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US FDA approves Lilly's COVID-19 drug

May 16, 2022 | News

FDA approves Lilly and Incyte's OLUMIANT (baricitinib) for the treatment of certain hospitalized patients with COVID-19



Eli Lilly and Company and Incyte have announced that the U.S. Food and Drug Administration (FDA) has approved OLUMIANT (baricitinib) for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO) with a recommended dose of 4-mg once daily for 14 days or until hospital discharge, whichever comes first.

The FDA's approval is supported by results from two randomized, double-blind, placebo-controlled Phase 3 studies (ACTT-2 and COV-BARRIER, including the COV-BARRIER OS 7 addendum study), announced previously. No new safety signals potentially related to the use of OLUMIANT were identified in the studies.

Baricitinib has been available in the U.S. under Emergency Use Authorization (EUA) since November 2020. An EUA will remain in place for hospitalized pediatric patients 2 to less than 18 years old who require various degrees of oxygen support. The emergency authorization is not an approval and is temporary for the duration where circumstances justify the authorization.

Lilly has submitted applications for regulatory approval or authorization to multiple regulatory agencies around the world and anticipates further regulatory decisions to follow.