FDA issues EUA to baricitinib plus remdesivir for COVID-19

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(HealthDay)—Emergency use authorization was issued for baricitinib in

combination with remdesivir for hospitalized patients with COVID-19, the U.S. Food and Drug Administration announced Thursday.

The EUA for the combination treatment applies to hospitalized patients ages 2 years and older with suspected or laboratory-confirmed COVID-19 who require supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation. The janus kinase inhibitor baricitinib is currently FDA-approved for treating moderately to severely active rheumatoid arthritis.

Based on the agency's review of the evidence, the FDA "determined that it is reasonable to believe that baricitinib, in combination with remdesivir, may be effective in treating COVID-19 for the authorized population. And, when used under the conditions described in the EUA to treat COVID-19, the known and potential benefits of baricitinib outweigh the known and potential risks for the drug."

The FDA granted the EUA based on data from the ACTT-2 trial, a randomized, double-blind, placebo-controlled clinical trial conducted by the National Institute of Allergy and Infectious Diseases. The trial included 1,033 patients—515 randomly assigned to baricitinib plus remdesivir and 518 randomly assigned to placebo plus remdesivir. Patients were followed for 29 days. Median time to recovery from COVID-19 was seven and eight days for patients receiving baricitinib plus remdesivir and those receiving placebo plus remdesivir, respectively. Patients receiving baricitinib plus remdesivir had significantly lower odds of progressing to death or being ventilated at 29 days and significantly higher odds of clinical improvement at 15 days compared with patients receiving placebo plus remdesivir.

Baricitinib is not authorized or approved as a stand-alone treatment for COVID-19, the FDA notes. Its safety and effectiveness for use in the treatment of COVID-19 continue to be evaluated.

The EUA was issued to Eli Lilly and Company.

More information: More Information