FDA Authorizes Drug Combination for Treatment of COVID-19

Arthritis drug Olumiant (baricitinib) can be used in combination with remdesivir.

November 20, 2020 By Food and Drug Administration (FDA)

Today [November 19], the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the drug baricitinib, in combination with remdesivir, for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients two years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

In a clinical trial of hospitalized patients with COVID-19, baricitinib, in combination with remdesivir, was shown to reduce time to recovery within 29 days after initiating treatment compared to patients who received a placebo with remdesivir. The safety and effectiveness of this investigational therapy for use in the treatment of COVID-19 continues to be evaluated. Baricitinib is not authorized or approved as a stand-alone treatment for COVID-19.

“Today’s action demonstrates the FDA’s steadfast efforts to make potential COVID-19 treatments available in a timely manner, where appropriate, while continuing to support research to further evaluate whether they are safe and effective,” said FDA Commissioner Stephen M. Hahn, MD. “As part of our Coronavirus Treatment Acceleration Program, the FDA continues to use every possible avenue to facilitate new treatments for patients as quickly as possible to combat COVID-19.”

Baricitinib is a janus kinase inhibitor, which blocks the activity of one or more of a specific family of enzymes, interfering with the pathway that leads to inflammation. Baricitinib is a prescription oral tablet medication that is FDA-approved (and sold under the brand name Olumiant) for the treatment of moderately to severely active rheumatoid arthritis. Under today’s EUA, the FDA is authorizing the emergency use of baricitinib, in combination with remdesivir, for the treatment of certain hospitalized patients with suspected or laboratory-confirmed COVID-19.

Remdesivir is an FDA-approved (and sold under the brand name Veklury) intravenous antiviral drug for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization. Remdesivir also remains authorized for emergency use for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg (about 7.7 pounds) to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg.

“The FDA’s emergency authorization of this combination therapy represents an incremental step forward in the treatment of COVID-19 in hospitalized patients, and FDA’s first authorization of a drug that acts on the inflammation pathway,” said Patrizia Cavazzoni, MD, acting director of the FDA’s Center for Drug Evaluation and Research. “Despite advances in the management of COVID-19 infection since the onset of the pandemic, we need more therapies to accelerate recovery and additional clinical research will be essential to identifying therapies that slow disease progression and lower mortality in the sicker patients.”

The issuance of an EUA is different than an FDA approval. In determining whether to issue an EUA, the FDA evaluates the totality of available scientific evidence and carefully balances any known or potential risks with any known or potential benefits of the product for use during an emergency. Based on the FDA’s review of the totality of the scientific evidence available, the agency has 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. There are no adequate, approved and available alternative treatments to baricitinib, when used in combination with remdesivir, for the treatment of suspected or laboratory confirmed COVID-19 in hospitalized adults and pediatric patients two years of age or older requiring supplemental oxygen, invasive mechanical ventilation, or ECMO.

The data supporting this EUA for baricitinib combined with remdesivir are based on a randomized, double-blind, placebo-controlled clinical trial (ACTT-2), which was conducted by the National Institute of Allergy and Infectious Diseases (NIAID). This clinical trial evaluated whether baricitinib impacted how long it took for subjects who were also taking remdesivir to recover from COVID-19. The trial followed patients for 29 days and included 1,033 patients with moderate or severe COVID-19; 515 patients received baricitinib plus remdesivir, and 518 patients received placebo plus remdesivir. Recovery was defined as either being discharged from the hospital or being hospitalized but not requiring supplemental oxygen and no longer requiring ongoing medical care. The median time to recovery from COVID-19 was seven days for baricitinib plus remdesivir and eight days for placebo plus remdesivir. The odds of a patient’s condition progressing to death or being ventilated at day 29 was lower in the baricitinib plus remdesivir group versus the placebo plus remdesivir group. The odds of clinical improvement at day 15 was higher in the baricitinib plus remdesivir group versus the placebo plus remdesivir group. For all of these endpoints, the effects were statistically significant.

Under the EUA, fact sheets that provide important information about using baricitinib in combination with remdesivir in treating COVID-19 as authorized must be made available to health care providers and to patients and caregivers. These fact sheets include dosing instructions, potential side effects and drug interactions. Possible side effects of baricitinib in combination with remdesivir include serious infections, blood clots, changes in certain lab test results and allergic reactions.

The EUA was issued to Eli Lilly and Company.

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