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FDA broadens EUA for Veklury (remdesivir) for Hospitalized COVID-19 Patients

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Approval based on the encouraging clinical data

The U.S. Food and Drug Administration broadened the scope of the existing emergency use authorization (EUA) for the drug Veklury (remdesivir) to include treating all hospitalized adult and pediatric patients with suspected or laboratory-confirmed COVID-19, irrespective of their severity of the disease. Previously, the drug was only available under the EUA for severe COVID-19 hospitalized cases per the May 2020 EUA authorization.

Based on the Agency's ongoing review of the EUA, including its review of the totality of scientific information now available, the FDA has determined that it is reasonable to believe Veklury may be effective for the treatment of suspected or laboratory-confirmed COVID-19 in all hospitalized adult and pediatric patients. The Agency's review has also concluded that the known and potential benefits of Veklury outweigh the known and potential risks for these uses.

"The FDA continues to make safe and potentially helpful treatments for COVID-19 available as quickly as possible in order to help patients. The data to support today's action are encouraging. The data show that this treatment has the potential to help even more hospitalized patients who are suffering from the effects of this devastating virus," said FDA Commissioner Stephen M. Hahn, M.D. "We are working with drug developers to conduct randomized clinical trials to further study the safety and effectiveness of a number of potential therapies for COVID-19."