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FDA issues EUA to Gilead's Remdesivir for COVID-19 treatment

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Authorization Enables Broader Use of Remdesivir to Treat Hospitalized Patients with Severe COVID-19 Disease in the United States

Gilead Sciences, Inc. has announced that the U.S. Food and Drug Administration (FDA) has granted emergency use authorization (EUA) for the investigational antiviral remdesivir to treat COVID-19.

The EUA will facilitate broader use of remdesivir to treat hospitalized patients with severe COVID-19 disease, enabling access to remdesivir at additional hospitals across the country.

Allocation of the currently limited available supply of remdesivir will be made based on guiding principles that aim to maximize access for appropriate patients in urgent need of treatment, with direction from and in collaboration with the government.

Remdesivir is authorized for the treatment of hospitalized patients with severe COVID-19 disease. The optimal duration of treatment is still being studied in ongoing clinical trials. Under the EUA, both 5-day and 10-day treatment durations are suggested, based on the severity of disease.

The authorization is temporary and does not take the place of the formal new drug application submission, review and approval process. The EUA allows for the distribution and emergency use of remdesivir only for the treatment of COVID-19; remdesivir remains an investigational drug and has not been approved by FDA.

The U.S. government will coordinate the donation and distribution of remdesivir to hospitals in cities most heavily impacted by COVID-19. Given the severity of illness of patients appropriate for remdesivir treatment and the limited availability of drug supply, hospitals with intensive care units and other hospitals that the government deems most in need will receive priority in the distribution of remdesivir. Gilead is working with the U.S. government on the logistics of remdesivir distribution and will provide more information when the company begins shipping the drug under the EUA.