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Gilead receives FDA approval for COVID-19 drug remdesivir

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Veklury is the first treatment for COVID-19 to receive FDA approval

The US Food and Drug Administration has approved the antiviral drug Veklury (remdesivir) for use in adult and paediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalisation. Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. Veklury is the first treatment for COVID-19 to receive FDA approval.

This approval does not include the entire population that had been authorised to use Veklury under an Emergency Use Authorisation (EUA) originally issued on May 1, 2020. In order to ensure continued access to the paediatric population previously covered under the EUA, the FDA revised the EUA for Veklury to authorise the drug's use for treatment of suspected or laboratory confirmed COVID-19 in hospitalised paediatric patients weighing 3.5 kg to less than 40 kg or hospitalised paediatric patients less than 12 years of age weighing at least 3.5 kg.

“This approval is supported by data from multiple clinical trials that the agency has rigorously assessed and represents an important scientific milestone in the COVID-19 pandemic,” said Stephen M Hahn, Commissioner, FDA.

The approval of Veklury was supported by the agency's analysis of data from three randomised, controlled clinical trials that included patients hospitalised with mild-to-severe COVID-19.

Important information about using Veklury to treat COVID-19 for its approved use is available in the prescribing information which includes dosing instructions, potential side effects and drug interactions. Possible side effects include: increased levels of liver enzymes, which may be a sign of liver injury; and allergic reactions, which may include changes in blood pressure and heart rate, low blood oxygen level, fever, shortness of breath, wheezing, swelling (e.g., lips, around eyes, under the skin), rash, nausea, sweating or shivering.

The FDA granted this application Fast Track and Priority Review designations. The Agency also granted this application a Material Threat Medical Countermeasure Priority Review Voucher, which provides additional incentives for certain medical products intended to treat or prevent harm from specific chemical, biological, radiological and nuclear threats.