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First FDA-approved treatment for COVID-19 includes use in adolescents

by from the Food and Drug Administration's Office of Pediatric Therapeutics and Center for Drug Evaluation and Research, Division of Pediatric and Maternal Health and Division of Antivirals

The Food and Drug Administration (FDA) has approved the antiviral Veklury (remdesivir) for treatment of COVID-19 requiring hospitalization in adults and pediatric patients 12 years of age and older who weigh at least 40 kilograms (kg).

Veklury is a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor. It is administered by intravenous infusion as a single loading dose on day 1 followed by once-daily maintenance dosing beginning on day 2 for five to 10 days, depending on clinical severity and response.

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The approval of Veklury was supported by the FDA's analysis of data from three randomized, controlled trials in patients hospitalized with mild to severe COVID-19.

In one randomized, double-blind, placebo-controlled clinical trial, the FDA concluded that remdesivir treatment resulted in faster recovery (median 10 days) compared to placebo (median 15 days). The major safety issues identified were hepatotoxicity and hypersensitivity reactions, including infusion-related and anaphylactic reactions.

Pediatric approval was based on the following:

- extrapolation of efficacy data from adults because COVID-19 and the response to remdesivir therapy in adolescents is likely to be similar to adults;
- pharmacokinetic modeling and simulation demonstrating the dosing regimen in adults is expected to result in comparable exposures in pediatric patients 12 years and older weighing at least 40 kg;
- the safety profile in adults weighing 40-50 kg was comparable to adults weighing more than 50 kg; and
- data from 39 pediatric patients 12 years and older weighing at least 40 kg who received remdesivir in a compassionate use program.

An ongoing trial is evaluating the safety, tolerability, pharmacokinetics and treatment response of remdesivir in pediatric patients with COVID-19, including term and preterm neonates (https://clinicaltrials.gov/ct2/show/NCT04431453).

To ensure continued access to the pediatric population previously covered under the emergency use authorization (EUA), the FDA revised the EUA for Veklury to authorize treatment of suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized patients younger than 12 years weighing at least 3.5 kg.

Resources

- Veklury prescribing information
- Information on FDA's approval of Veklury
- Additional information on FDA's approval of Veklury
- FDA's summary review of Veklury
- Coronavirus Treatment Acceleration Program
- Additional FDA Update columns