FDA Approves First COVID-19 Treatment for Young Children

Remdesivir (Veklury) is now approved for kids ages 28 days to 12 years.

April 26, 2022 By Food and Drug Administration (FDA)

Today [April 25], the U.S. Food and Drug Administration expanded the approval of the COVID-19 treatment Veklury (remdesivir) to include pediatric patients 28 days of age and older weighing at least 3 kilograms (about 7 pounds) with positive results of direct SARS-CoV-2 viral testing, who are:

- Hospitalized, or
- Not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

This action makes Veklury the first approved COVID-19 treatment for children less than 12 years of age. As a result of today's approval action, the agency also revoked the emergency use authorization for Veklury that previously covered this pediatric population.

Before now, Veklury was only approved to treat certain adults and pediatric patients (12 years of age and older who weigh at least 40 kilograms, which is about 88 pounds) with COVID-19.

"As COVID-19 can cause severe illness in children, some of whom do not currently have a vaccination option, there continues to be a need for safe and effective COVID-19 treatment options for this population," said Patrizia Cavazzoni, M.D., director of the FDA's Center for Drug Evaluation and Research. "Today's approval of the first COVID-19 therapeutic for this population demonstrates the agency's commitment to that need."

Veklury is not a substitute for vaccination in individuals for whom COVID-19 vaccination and booster doses are recommended. The FDA has approved two vaccines, and three vaccines are available for emergency use, to prevent COVID-19 and the serious clinical outcomes associated with COVID-19, including hospitalization and death. The FDA urges the public to get vaccinated and receive a booster when eligible. Learn more about FDA-approved and authorized COVID-19 vaccines. [Editor's note: COVID-19 vaccines are not yet authorized for children under age 5.]

Given the similar course of COVID-19 disease in adults and pediatric patients, today's approval of

Veklury in certain pediatric patients is supported by efficacy results from Phase III clinical trials in adults.

Information on the trials in adults can be found in the FDA-approved drug labeling for Veklury. This approval is also supported by a Phase II/III, single-arm, open-label clinical study of 53 pediatric patients at least 28 days of age and weighing at least 3 kilograms (about 7 pounds) with confirmed SARS-CoV-2 infection and mild, moderate or severe COVID-19. Patients in this pediatric phase 2/3 trial received Veklury for up to 10 days. The safety and pharmacokinetic results from the phase 2/3 study in pediatric subjects were similar to those in adults.

The only approved dosage form is Veklury for injection.

Possible side effects of using Veklury 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 approval to Gilead Sciences Inc.

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