FDA Takes Actions to Expand Use of Treatment for Outpatients with Mild-to-Moderate COVID-19

Today, the U.S. Food and Drug Administration took two actions to expand the use of the antiviral drug Veklury (remdesivir) to certain non-hospitalized adults and pediatric patients for the treatment of mild-to-moderate COVID-19 disease. This provides another treatment option to reduce the risk of hospitalization in high-risk patients. Previously, the use of Veklury was limited to patients requiring hospitalization.

"On the heels of the FDA's recent authorization of two oral antiviral drugs, today's actions bolster the arsenal of therapeutics to treat COVID-19 and respond to the surge of the omicron variant," said Patrizia Cavazzoni, M.D., director of the FDA's Center for Drug Evaluation and Research. "Today's actions provide adults and pediatric patients, with mild-to-moderate COVID-19 who are at high risk of severe COVID-19, with a treatment option they could receive outside of a traditional inpatient hospital setting, including at skilled nursing facilities, home healthcare settings and outpatient facilities such as infusion centers."

Veklury is not a substitute for vaccination in individuals for whom COVID-19 vaccination and a booster dose are recommended. The FDA has approved one vaccine and authorized others 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 if eligible. Learn more about FDA-approved or -authorized COVID-19 vaccines.

The FDA has expanded the approved indication for Veklury to include its use in adults and pediatric patients (12 years of age and older who weigh at least 40 kilograms, which is about 88 pounds) with positive results of direct SARS-CoV-2 viral testing, and who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.

The agency also revised the Emergency Use Authorization (EUA) for Veklury to additionally authorize the drug for treatment of pediatric patients weighing 3.5 kilograms to less than 40 kilograms or pediatric patients less than 12 years of age weighing at least 3.5 kilograms, with positive results of direct SARS-CoV-2 viral testing, and who are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization of death.

Based on today's actions, these high-risk non-hospitalized patients may receive Veklury via intravenous infusion for a total of three days for the treatment of mild-to-moderate COVID-19 disease.

The approval of Veklury for use in non-hospitalized patients is supported by a randomized, placebo-controlled clinical trial that included 562 non-hospitalized patients with mild-to-moderate COVID-19 who were at high risk for progression to severe COVID-19, including hospitalization or death. The main outcome measured in the trial was whether a patient was hospitalized for any COVID-19 related reason or died from any reason within 28 days of treatment. Overall, 2 of 279 patients who received Veklury (0.7%) required COVID-19 related hospitalization compared to 15 of 283 patients who received a placebo (5.3%). There were no deaths in either group.

Pediatric patients for whom Veklury is authorized will receive doses adjusted for their body weight in order to achieve comparable exposures to adults and pediatric patients receiving the approved dose. Given the similar course of COVID-19 disease, the authorization of Veklury in certain pediatric patients is based on extrapolation of efficacy from adequate and well-controlled studies in adults.

Important details 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. Similar safety information about using Veklury to treat COVID-19 in certain non-hospitalized pediatric patients under the EUA is available in the fact sheets for health care providers and parents/caregivers.

The FDA granted approval and reissued the revised EUA to Gilead Sciences Inc.

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Coronavirus (COVID-19) Update: FDA Authorizes

First COVID-19 Diagnostic Test Using Breath Samples

Test provides results in less than three minutes

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for the first COVID-19 diagnostic test that detects chemical compounds in breath samples associated with a SARS-CoV-2 infection. The test can be performed in environments where the patient specimen is both collected and analyzed, such as doctor's offices, hospitals and mobile testing sites, using an instrument about the size of a piece of carry-on luggage. The test is performed by a qualified, trained operator under the supervision of a health care provider licensed or authorized by state law to prescribe tests and can provide results in less than three minutes.

"Today's authorization is yet another example of the rapid innovation occurring with diagnostic tests for COVID-19," said Jeff Shuren, M.D., J.D., director of the FDA's Center for Devices and Radiological Health. "The FDA continues to support the development of novel COVID-19 tests with the goal of advancing technologies that can help address the current pandemic and better position the U.S. for the next public health emergency."

The performance of the InspectIR COVID-19 Breathalyzer was validated in a large study of 2,409 individuals, including those with and without symptoms. In the study, the test was shown to have 91.2% sensitivity (the percent of positive samples the test correctly identified) and 99.3% specificity (the percent of negative samples the test correctly identified). The study also showed that, in a population with only 4.2% of individuals who are positive for the virus, the test had a negative predictive value of 99.6%, meaning that people who receive a negative test result are likely truly negative in areas of low disease prevalence. The test performed with similar sensitivity in a follow-up clinical study focused on the omicron variant.

The InspectIR COVID-19 Breathalyzer uses a technique called gas chromatography gas mass-spectrometry (GC-MS) to separate and identify chemical mixtures and rapidly detect five Volatile Organic Compounds (VOCs) associated with SARS-CoV-2 infection in exhaled breath. When the InspectIR COVID-19 Breathalyzer detects the presence of VOC markers of SARS-CoV-2, a presumptive (unconfirmed) positive test result is returned and should be confirmed with a molecular test. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, as they do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

InspectIR expects to be able to produce approximately 100 instruments per week, which can each be used to evaluate approximately 160 samples per day. At this level of production, testing capacity using the InspectIR COVID-19 Breathalyzer is expected to increase by approximately 64,000 samples per month.

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Coronavirus (COVID-19) Update: FDA Approves First COVID-19 Treatment for Young Children

Today, 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.

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 3 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 2/3, 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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Source: FDA