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.