FDA Authorizes Emergency Use of Gilead Drug Remdesivir for Covid-19 Patients

Action comes after research shows the drug shortened recovery times in patients

By Michelle Hackman and Thomas M Burton
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Caption: Remdesivir is among the most closely watched experimental treatments for Covid-19. Here, empty vials of remdesivir are washed at a Gilead facility.
Photo: gilead sciences/Reuters

WASHINGTON—The Food and Drug Administration authorized the emergency use of the drug remdesivir in Covid-19 patients after researchers reported that it shortened the recovery times in people who have fallen ill from the new coronavirus.

The FDA action limits the use of the drug, produced by Gilead Sciences Inc., for only through the duration of the pandemic, but health regulators could grant full approval if more benefits emerge from a large study by the National Institute of Allergy and Infectious Diseases and other clinical trials under way.

The institute said that a preliminary analysis of its study showed that hospitalized Covid-19 patients taking remdesivir had a speedier recovery than patients taking a placebo—though the reported benefit was moderate, with remdesivir patients recovering in 11 days, or four days faster than the placebo group.

Remdesivir, an antiviral drug administered intravenously and previously tested as a treatment for Ebola, is among the most closely watched experimental treatments for Covid-19, and is being studied in multiple clinical trials around the world. The drug is the first to show a benefit in treating Covid-19 in a major clinical trial.

President Trump, speaking in the Oval Office Friday next to Gilead Chief Executive Daniel O'Day, called the drug "the hot thing" and "an important treatment for hospitalized coronavirus patients."

The president has said he had urged the FDA to grant the drug emergency approval.

"We feel a tremendous responsibility—we're humbled by this being an important first step for hospitalized patients," Mr. O'Day said.

With emergency approval granted, Gilead can work with the government to directly ship the drug to hospitals with the greatest need, Mr. O'Day told *The Wall Street Journal* earlier this week.

Gilead expects to manufacture 1.5 million doses by the end of May, or up to 210,000 treatment courses, assuming that most patients are treated for five days, and more than one million treatment courses by the end of this year.

The company has pledged to donate the 1.5 million doses to hospitals free of charge but has declined to say how much it will charge for remdesivir that it manufactures beginning in June. Some of the donated supply will be distributed internationally.

In the U.S., the federal government will decide where to distribute the donated drug supply, based on epidemiological data showing the cities in most need, Gilead spokesman Chris Ridley said on Friday.

The FDA's standards for an emergency-use authorization aren't as high as they are for its typical drug approvals. Emergency authorizations provide speedy access to treatments for serious diseases during a health crisis. So far, remdesivir's use for Covid-19 has been limited to patients in clinical trials or for those whose doctors were able to make the case for its compassionate use.

Anthony S. Fauci, the Institute's director and the government's leading infectious-disease doctor, said in an interview that the reduction in time to recovery was "highly statistically significant." A data safety and monitoring board analyzed the trial data on Monday and shared its findings with the investigators in the study.

Preliminary analysis of 468 recovered patients showed that patients on remdesivir took a median time of 11 days to recover from their disease, whereas those on placebo took 15 days, a difference of 31%. Recovery, defined as a patient being well enough to leave the hospital or to return to normal activity, is a standard measure in flu studies, the NIAID said in its discussion of the research.

The results so far also pointed in a positive direction regarding the death rate. Among the roughly 1,060 patients enrolled in the study, there was an 8.0% death rate among the remdesivir patients, versus 11.6% in the placebo group. The results weren't considered robust enough to be clinically significant, but data from the full study will continue to be analyzed. About 485 patients in the study are still being evaluated because they haven't recovered or died yet.

The study is headed by Andre Kalil, a professor of internal medicine at the University of Nebraska Medical Center. It encompasses 68 sites, of which 47 are in the U.S. and 21 in European and Asian countries. Full results, including rates of adverse events, haven't yet been published.

The research demonstrates, Dr. Kalil said in an interview, "not only that high-quality science can be done in the middle of a pandemic, but also that new therapies can be successfully discovered to treat patients severely affected by Covid-19."

Two antimalaria drug, chloroquine and hydroxychloroquine, already have emergency-use authorizations from the FDA, though the evidence supporting their expanded access was thinner. Both drugs are also undergoing clinical study.

Mr. Trump and members of his administration initially touted their use in Covid-19 treatment, but the FDA last month issued a warning against their use in nonhospital settings after they were linked to serious heart problems.

The NIAID study of remdesivir was a large randomized, controlled trial, the gold standard in drug research, lending it added prominence for U.S. health regulators. A separate recent study in China posted negative results for the drug, but that study's researchers urged more testing because their trial was stopped early due to problems recruiting subjects as the pandemic slowed there.

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