WHO-Backed Study Finds No Remdesivir Benefit for Hospitalized Covid-19 Patients

Result adds to debate over medicine’s utility in treating new coronavirus

The U.S. Food and Drug Administration authorized the emergency use of remdesivir in Covid-19 patients in May. PHOTO: SIMA DIABBLOOMBERG NEWS

By Joseph Walker
Updated Oct. 16, 2020 9:14 pm ET

A multicountry study funded by the World Health Organization found that the antiviral drug remdesivir, developed by Gilead Sciences Inc., didn’t reduce deaths from Covid-19 in hospitalized patients, a result that adds to debate over the medicine’s utility in treating the new coronavirus.

The WHO study showed that death rates were about the same in hospitalized patients after 28 days whether they received treatment with remdesivir or standard medical care.
The study compared remdesivir and other drugs each against standard treatment in more than 5,000 hospitalized patients across dozens of countries.

In the study, about 11% of patients taking remdesivir died, versus 11.2% of patients receiving standard treatment, according to a preliminary report published online. The report is a “preprint” version of a scientific paper that hasn’t yet been published in a peer-reviewed journal. Researchers have made increasing use of preprint databases during the coronavirus pandemic to disseminate information to clinicians quickly.

The paper is currently in the peer-review revision process and will soon be published in an academic journal, said WHO Chief Scientist Soumya Swaminathan in an interview.

Treatment with remdesivir also had little or no effect on reducing hospital stays or the need for ventilation, the study found. Its authors say the data, when analyzed in the context of previous trials, “absolutely excludes the suggestion that remdesivir can prevent a substantial fraction of all deaths.”

The WHO study contrasts with an earlier study funded by the U.S. government that found remdesivir, which is sold under the brand name Veklury, significantly sped up hospitalized patients’ recovery compared with a placebo. Based on that study, which was funded by the National Institute of Allergy and Infectious Diseases, remdesivir was granted emergency-use authorization in the U.S. in May.

Antivirals are typically thought to be more effective the earlier they are taken, and remdesivir might still show a benefit in treating patients who aren’t hospitalized, said the WHO’s Dr. Swaminathan. But across “the whole spectrum of hospitalized patients, there’s no benefit in terms of either progression of disease or mortality,” she said.

Gilead, which donated remdesivir supplies for the WHO study, questioned the trial’s conclusions, in part because the study didn’t compare remdesivir to a placebo, a method scientists use to reduce the risk of biasing the results.

“The emerging data appear inconsistent with more robust evidence from multiple randomized, controlled studies published in peer-reviewed journals validating the clinical benefit of Veklury,” Gilead said in a statement. “We are concerned that the data from this open-label global trial have not undergone the rigorous review required to allow
The WHO-backed study, published last week in the New England Journal of Medicine, found that patients taking remdesivir recovered in 10 days on median, compared with a median of 15 days among patients receiving a placebo. About 11.4% of patients taking remdesivir died in the NIAID study after 29 days, compared with 15.2% of placebo patients—a numerical improvement in reducing deaths, though not a statistically significant one. Statistical significance is a measure of the probability that the result of an experiment is due to random chance.

Gilead has said remdesivir did show statistically significant reductions in death in some patients when the data were analyzed according to patients’ disease severity. Those analyses weren’t part of the original clinical-trial design and carry less statistical weight than if they were preplanned.

The WHO study, dubbed the Solidarity trial, is known as a platform trial that evaluates several experimental treatments simultaneously against a single control group to more quickly get trial results and reduce the number of patients who aren’t given a potentially beneficial therapy.

The Solidarity trial evaluated four drugs that were either previously approved or studied for other diseases: remdesivir, which was studied in Ebola; the HIV medication Kaletra; the multiple-sclerosis treatment interferon beta-1a; and the malaria drug hydroxychloroquine. All of the drugs showed little or no effect in reducing deaths in patients with Covid-19, their length of hospital stay or the need for ventilation.

Clinical trials comparing experimental drugs with placebos are considered the most rigorous way to evaluate a medicine’s effectiveness, but the results can sometimes appear
rosier than in real-world settings because patients receive specialized attention from study investigators, said Peter Bach, director of the Center for Health Policy and Outcomes at Memorial Sloan Kettering Cancer Center.

The WHO study likely reflects remdesivir’s benefit in the real-world setting, and the benefit appears to be marginal to nonexistent, said Dr. Bach: “You really have to squint to see any.”

Differences in the way the WHO and NIAID studies were conducted, however, make it difficult to reconcile the results, said Walid Gellad, associate professor of medicine at the University of Pittsburgh. The WHO study, for instance, only counted deaths that occurred in the hospital but not those that might have occurred in patients who were discharged. Differences in the quality of health care in the international locations where the WHO study was conducted might also influence the results, he said.

Dr. Gellad said he continues to view remdesivir as having some benefit for Covid-19 patients, albeit a small one, even when considering the WHO study results. “I would say that it helps people with Covid get better, but it does not cure Covid and it’s not a slam dunk,” said Dr. Gellad. “But I would still want it if I were in the hospital [with Covid], even with what Solidarity is showing.”

Write to Joseph Walker at joseph.walker@wsj.com

Appeared in the October 17, 2020, print edition as ‘Study Adds to Remdesivir Debate.’