FDA Approved Remdesivir to Treat COVID in People With Kidney Problems, Despite Data Showing Drug Causes Renal Failure

The Food and Drug Administration (FDA) on July 14 approved Veklury, also known as remdesivir, to treat COVID-19 in people with severe renal impairment, including dialysis, despite data showing that the drug increases the risk of kidney failure.

Remdesivir is an antiviral medication that targets the RNA in viruses to prevent replication. The FDA first authorized remdesivir for emergency use in May 2020 to treat people with severe COVID-19. It has since been approved for adults and children as young as 28 days who weigh at least 6.6 pounds.

The U.S. approval follows the European Commission's decision on June 26 to extend the approved use of Veklury to treat COVID-19 in people with severe renal impairment. The updated

prescribing information for remdesivir doesn't require adjusting the dose for renal-impaired patients and also removes the requirement that patients undergo estimated glomerular filtration rate testing—the most reliable way to measure how well the kidneys are working before taking the drug.

"The approval by the FDA of Veklury for the treatment of patients with renal impairment reflects the urgency to make this medicine available to these patients and underscores the established safety profile for Veklury," Anu Osinusi, vice president of Clinical Research for Hepatitis, Respiratory, and Emerging Viruses at Gilead Sciences, said in a statement.

According to the company, the FDA based its approval of remdesivir for use in patients with severe renal impairment on the results of a phase 1 study and a phase 3 randomized, double-blind, placebo-controlled, parallel-group, multicenter study trial that assessed how the drug interacts with the body and its safety profile.

Yet the phase 3 study was terminated prematurely because of "feasibility issues" and because it was "underpowered to assess for efficacy because of lower-than-expected enrollment."

The company stated that its data didn't reveal any new safety signals "associated with increased metabolite levels in patients with severely reduced kidney function." However, data from the phase 3 study show that the rate of serious adverse events was significantly higher for those who had received remdesivir than it was for those who had received the placebo. People who had taken remdesivir were more likely to experience acute kidney injury (AKI), sepsis, COVID-19 pneumonia, sudden death, and heart problems.

"Remdesivir should never have been approved in the first place," Dr. Paul Marik, a critical care physician and author

of more than 500 peer-reviewed journal articles. “Gilead had to cook the data to be approved. The World Health Organization’s own data show it increases the risk of kidney failure twentyfold, so why you would approve it for someone with renal dysfunction is obscene.”

In 2020, the WHO published a bulletin that recommended against using remdesivir to treat COVID-19. The WHO’s recommendations were based on a review of evidence published in The British Medical Journal, which included data from four international trials covering more than 7,000 hospitalized COVID-19 patients. The WHO found no evidence that the treatment helped hospitalized patients recover or improved their outcomes.

Dr. Marik said the National Institutes of Health and Gilead “cooked the first study” that formed the initial basis of the FDA authorization in October 2020 because remdesivir was “so toxic.”

“They committed scientific fraud in a single clinical study that provided data to the FDA, changing the endpoint halfway through the study to try and prove the drug had any benefit,” he said. “The FDA is a proxy for Big Pharma. It has no interest in public health.”

Studies Link Remdesivir to Kidney Problems

In a study published in December 2020 in Clinical Pharmacology and Therapeutics, researchers detected a safety signal for remdesivir and nephrotoxicity—a rapid deterioration of kidney function that’s caused by damage associated with a drug, chemical, or toxin.

Using a combination of the terms “acute renal failure” and “remdesivir” in the WHO’s VigiBase system—which gathers spontaneous reports of suspected adverse drug reactions from

more than 130 countries—a "statistically significant disproportionality signal" was observed in 138 cases instead of the nine expected. The odds ratio of acute renal failure with remdesivir was twentyfold that of comparative drugs.

A March 2022 study in Frontiers—using data from the Vaccine Adverse Event Reporting System—identified a significant association between AKI and remdesivir in COVID-19 patients, especially in older male patients and those aged 65 and older.

A May 2021 pharmacovigilance analysis found that "compared with the use of chloroquine, hydroxychloroquine, dexamethasone, sarilumab, or tocilizumab, the use of remdesivir was associated with an increased reporting of kidney disorders."

As part of the same analysis, researchers assessed 5,532 reports related to COVID-19 patients from the WHO's database and identified 434 cases related to kidney disorders, including 327 reported with remdesivir.

Remdesivir treatment was discontinued shortly after kidney disorder onset, and the median treatment duration was three days. In 316 cases, no other drug was suspected in the onset of kidney disorders. Reactions were serious in 301 cases (92 percent), and 15 patients died. Acute kidney injury presented in 295 cases, with tubular necrosis in eight cases.

"Our findings, based on postmarketing real-life data from [more than] 5,000 COVID-19 patients, support that kidney disorders, almost exclusively AKI, represent a serious, early, and potentially fatal adverse drug reaction of remdesivir," the study reads. "These results are consistent with findings from another group."

Although the researchers said further data were needed to confirm the safety signal, they urged physicians to be aware of the potential risk of kidney problems and, when prescribing remdesivir, to perform "close kidney monitoring"—the very

monitoring that the FDA has removed from its updated prescribing information but is still found on the National Institutes of Health’s website on COVID-19 treatment guidelines.