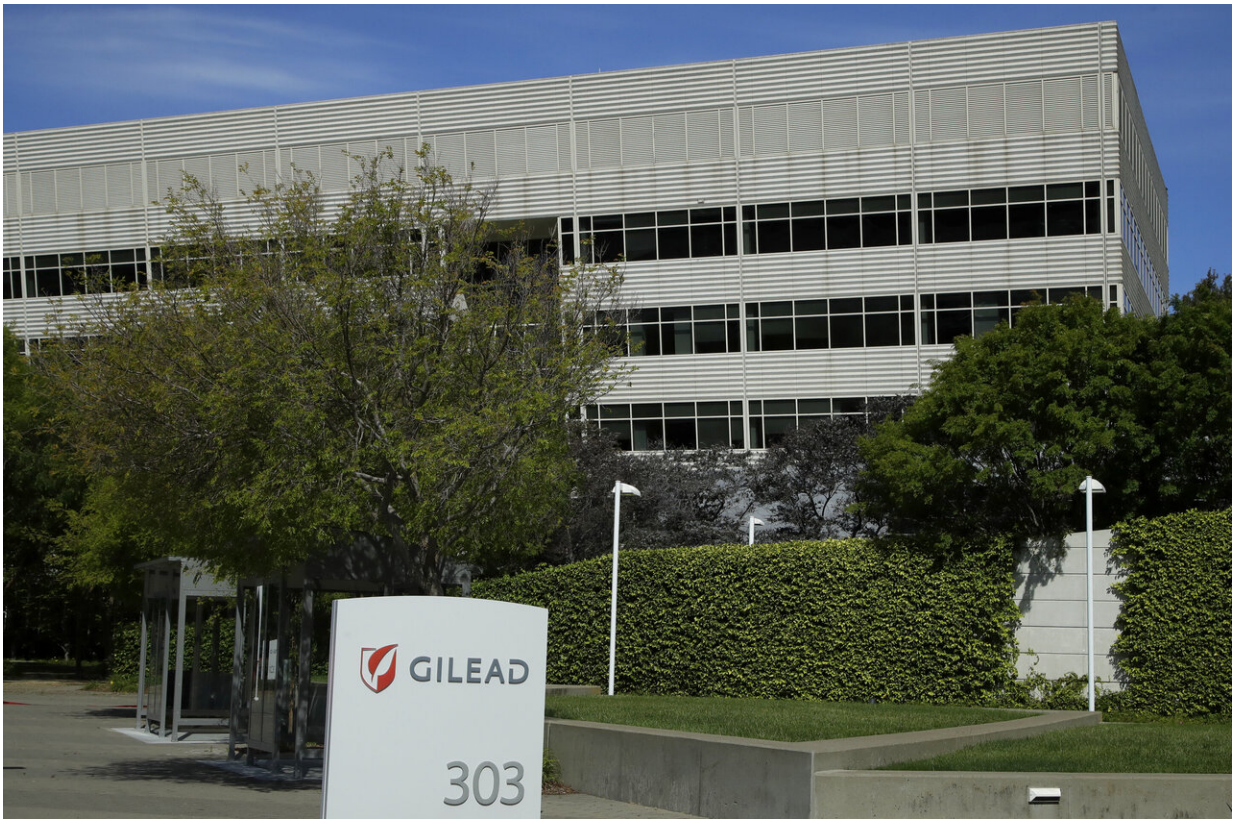
EU regulator starts safety review of coronavirus drug

October 2 2020



This April 30, 2020, file photo shows Gilead Sciences headquarters in Foster City, Calif. The European Medicines Agency says it has started a safety review after some patients taking the coronavirus drug remdesivir reported serious kidney problems. In a statement on Friday, Oct. 2, 2020, the EU regulator said it isn't clear whether remdesivir is causing the "acute kidney injury," but that the issue "warrants further investigation." Remdesivir is one of the few licensed treatments for the coronavirus, in additional to the generic steroid dexamethasone. In July, health experts criticized the U.S. for buying up a

significant portion of the drug, made by Gilead Sciences. (AP Photo/Ben Margot, File)

The European Medicines Agency says it has started a safety review after some patients taking the coronavirus drug remdesivir reported serious kidney problems.

In a statement on Friday, the EU regulator said it isn't clear whether remdesivir was causing the "acute kidney injury," but that the issue "warrants further investigation."

Remdesivir was given a conditional marketing authorization by the EMA on July 3 and can be used to treat people older than age 12 with severe COVID-19 and pneumonia who require oxygen treatment. The approval for the drug was fast-tracked with the understanding that more evidence would be submitted after a license was granted.

"The benefits to these severely ill patients outweigh the risks of making the medicine available despite having less complete data than normally expected," the EMA said.

Remdesivir is one of the few licensed treatments for the coronavirus, in addition to the generic steroid dexamethasone. In July, health experts criticized the United States for buying up a significant portion of the drug, made by Gilead Sciences.

The European Medicines Agency said the potential problem of kidney toxicity caused by remdesivir was evaluated when the conditional approval was given but that analysis was mainly based on animal studies. It noted that kidney injuries can be caused by other factors, including diabetes and the coronavirus itself.

The regulator said recommendations for the use of remdesivir remain unchanged; doctors are already advised to monitor patients for kidney complications prior to starting treatment and not to use the drug in patients with known kidney problems.

The agency said "enhanced safety monitoring" is in place to detect potentially worrying and unexpected side effects from remdesivir through monthly safety reports.

Early studies testing remdesivir in patients hospitalized with COVID-19 found that those who received the treatment recovered quicker than those who didn't.

On Thursday, the EMA said it had begun the process of potentially fast-tracking approval for an experimental COVID-19 vaccine developed by Oxford University and AstraZeneca.