

New drug halves death rate in those with severe COVID, maker claims

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An experimental medication for critically ill COVID-19 patients appears



to work so well that the drug's maker announced Monday it has stopped its clinical trial early and will apply for emergency use authorization.

The medication, <u>sabizabulin</u>, halved the death rate in COVID-19 patients who were receiving <u>supplemental oxygen</u> and were at high risk of serious lung disease and death; the trial was halted last Friday upon the advice of independent safety monitors because it worked so well, Veru Inc. officials said.

"This study represents a <u>significant milestone</u> in the global fight against COVID-19 as sabizabulin is the first drug to demonstrate a clinically and statistically meaningful reduction in deaths in hospitalized patients with moderate to severe COVID-19," Dr. Mitchell Steiner, chairman, president and CEO of Veru, said in a <u>statement</u>.

"We strongly believe that sabizabulin, with its dual antiviral and <u>anti-inflammatory properties</u> which demonstrated positive efficacy and safety results in the Phase 3 COVID-19 study, can be that greatly needed oral therapy for hospitalized moderate to severe COVID-19 patients," Steiner added.

Gary Barnette, chief scientific officer of Veru, said, "What makes these findings more relevant is that the pharmacological activity of sabizabulin is independent of COVID-19 variant type. Pending upcoming discussion with FDA, this <u>treatment option</u> may be made available soon so we can be ready for when the next clinically important wave of COVID infections comes."

Among the trial participants were 98 people who received the drug and 52 who were given a placebo in addition to regular care. About half of those who received the placebo died within 60 days. By comparison, 20% of those given sabizabulin for 21 days died—and 80% lived—even though they were also severely ill.



The drug was given in a 9-milligram pill that was taken once a day. It doesn't require refrigeration, and the capsule can be given by mouth or opened and added to a feeding tube. It is only for hospital use at this point, so dispensing it will be simpler than distributing it to pharmacies and educating doctors on how to use it.

Sabizabulin interferes with the movement of the coronavirus through microtubules in cells. "It disrupts these 'highways' and breaks them down, so the virus can't get from point A to point B," Steiner told *The New York Times*. The disruption also interferes with the movement of the body's cytokines, which works to tamp down inflammation, he added.

The results have not yet been published in a medical journal or reviewed by outside experts. No safety concerns were found during the trial, according to company officials.

Veru officials said they plan to meet with the U.S. Food and Drug Administration later this month and will apply for emergency use authorization for the drug, which was given <u>fast-track status</u> by the FDA in January, Steiner said. That status is meant to encourage fast development and review of treatments for serious or life-threatening conditions that are not being met already.

An FDA spokeswoman would not comment on a pending application, the *Times* reported.

Nearly 1 million Americans have died from the disease in over two years and 570 are still dying each day, on average, the latest CDC data shows.

More information: The U.S. COVID-19 website has more on the <u>coronavirus</u>.



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