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JAMA reports fluvoxamine as potential early treatment for COVID-19

First publication of a placebo-controlled trial to demonstrate that respiratory deterioration can be prevented with medication

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Research News

SAN FRANCISCO - Nov. 12, 2020 - The COVID-19 Early Treatment Fund (CETF), today announced that *JAMA*, *The Journal of the American Medical Association*, published the results of a Washington University School of Medicine in St. Louis double-blind, randomized controlled clinical trial that investigated whether the antidepressant medication fluvoxamine, if taken within seven days of first symptoms of COVID-19, can reduce the risk for respiratory deterioration. The CETF-funded study showed that fluvoxamine was effective: none of the 80 patients who took the drug met the respiratory deterioration criteria compared to an 8.3% rate in the 72 patients who took a placebo.

Dr. Carolyn Machamer, a professor of cell biology at the Johns Hopkins School of Medicine and a member of CETF's scientific advisory board (SAB), who has studied the basic biology of coronaviruses for years noted, "The results of the fluvoxamine trial are encouraging and warrant a further evaluation in a larger study. A treatment that can prevent lung problems in people with mild symptoms of COVID-19 is desperately needed."

Under the leadership of Dr. Eric Lenze, director of the Healthy Mind Lab at Washington University School of Medicine in St. Louis, study researchers tested fluvoxamine, which is typically used to treat patients with obsessive-compulsive disorder, in coronavirus patients because it has strong anti-inflammatory properties. The researchers believed this capability could prevent cytokine storms - the body's massive, sometimes deadly, inflammatory reaction to coronavirus and other infections.

"This placebo-controlled study indicates that fluvoxamine may prevent serious breathing problems in people with mild COVID-19 illness, and is the first in this patient population to be published in a peer-reviewed journal," said Lenze. "These are promising findings, and we look forward to conducting a much larger study in the coming weeks to further evaluate the effectiveness of fluvoxamine."

The 152 trial participants, all of whom were 18 years or older, were diagnosed with mild forms of COVID-19, and lived in either Missouri or Illinois. Participants were randomly assigned (1:1) to take either fluvoxamine or a placebo. In this outpatient clinical trial, there was no face-to-face contact between participants and clinicians; study materials, including the study drug, were delivered to the participants' homes. In this trial, of the 80 participants who received the drug, zero hit the endpoint of clinical deterioration (oxygen saturation of 92% or lower along with difficulty breathing or hospitalization for pneumonia), as opposed to the six of 72 people who got the placebo and experienced deterioration. The results show that fluvoxamine

has the potential to reduce the risk of hospitalization in COVID-19 patients.

"We now have evidence that an inexpensive, safe, and readily available pill can reduce deterioration and hospitalization from COVID-19," said Steve Kirsch, CETF founder. "This trial validates what we have already learned from multiple scientific studies, the greater the sigma-1 activation, the greater the protection."

The study result affirmed a large, multi-center observational study done in France that showed that SSRI drugs significantly reduced the risk of requiring a ventilator or death from COVID-19. The French study showed that the SSRIs with the highest sigma-1 receptor activation had the greatest benefit.

Unaffiliated to this study, David Seftel, M,D., Harvard-educated internist and CEO of Stanford partner lab Enable Biosciences who serves as a Principal Investigator for several NIH projects, opined: "Fluvoxamine might be considered by doctors for off-label use to treat COVID-19 patients early in their disease. Even if vaccines or other therapeutics are used as a first line of defense, fluvoxamine may dramatically decrease the odds that someone will need to be hospitalized."

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CETF will provide additional funding to Washington University School of Medicine in St. Louis to conduct another, larger trial with 880 participants to confirm these promising findings regarding the clinical benefits of fluvoxamine. That trial will be available for participants across the United States to enroll in remotely.

Additionally, CETF is the sole or primary sponsor of several other clinical trials that are reviewed by the CETF SAB, a world-class team of independent physician-scientists who thoroughly review every grant proposal to identify repurposed pharmaceuticals to treat COVID-19 symptoms and reduce hospitalizations from COVID-19 by over 75% and led by leading scientific researchers.

To learn more about CETF's mission, clinical trials or to donate to expedite the fight against COVID-19, visit treatearly.org.

ABOUT THE COVID-19 EARLY TREATMENT FUND

The COVID-19 Early Treatment Fund (CETF), a501(c)(3) organization administered by Rockefeller Philanthropy Advisors, was created to ensure the rapid and successful completion of outpatient clinical trials that lead to effective early treatments for COVID-19, using existing drugs. This bold new approach offers the shortest path to saving lives, by bringing new treatments online within a matter of months. CETF already has several clinical trials ready to go, with dozens more under review. Many of these only need modest funding to get underway. Each proposed trial is rigorously reviewed by a 12-person Scientific Advisory Board, hand-picked for their world-leading expertise in coronaviruses, immunology, and drug development. Only the most well-designed trials with strong scientific rationale are funded, ensuring independent, objective results. CETF goes well beyond just funding and provides a wide range of resources to support the success of the trial including sharing of best practices, assistance in negotiating with drug companies, and assistance with recruitment. Donors can maximum impact in a minimum amount of time. CETF was founded by entrepreneur and philanthropist Steve Kirsch, as a way to expedite the fight against

COVID-19. Early treatment with existing drugs is the fastest, most effective, and lowest cost way to safely reopen the world. CETF aims to reduce COVID-19 hospitalization and death by at least 75%. Once funded, outpatient trials could identify an effective early treatment within just a few months. Help us expedite the fight against COVID-19 by donating now.

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