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Fluvoxamine Data Unveiled as Promising Early Treatment in Patients with Mild COVID-19

COVID-19 Early Treatment Fund Urging Businesses, Government and Americans to Provide More Funding to Clinical Trials of Repurposed Drugs

SAN FRANCISCO – Oct. 6, 2020 – The COVID-19 Early Treatment Fund (CETF), which is administered by Rockefeller Philanthropy Advisors, a 501(c)(3) organization created to ensure the rapid and successful completion of outpatient clinical trials of existing drugs that lead to effective early treatments for COVID-19, today announced the results of a recently funded outpatient clinical trial at Washington University in St. Louis that examined the viability of fluvoxamine in patients with mild COVID-19. The trial results indicated that fluvoxamine, if given early in the course of COVID-19, significantly reduced the likelihood of hospitalization.

"Today, with all the focus on vaccines, we are neglecting to adequately fund research on the most promising existing drugs for treating this virus," said Steve Kirsch, CETF founder. "COVID-19 will be with us for a while, so in addition to the vaccine studies, we should be focusing on testing drugs such as fluvoxamine, camostat, GS-441524, and doxazosin. Preventing serious illness and death should be the goal, and repurposed drugs can be rolled out quickly to the benefit of millions worldwide. Virtually all of the funding for these outpatient trials is coming from a very small number of private donors. That needs to change. This trial provides strong evidence that drug repurposing may soon prove to be the fastest and least expensive way to end this pandemic."

Researchers from the Washington University School of Medicine shared the new data today at the International Society for Influenza and Other Respiratory Virus Diseases Antiviral Group virtual conference on Therapeutics for COVID-19. Fluvoxamine — a repurposed drug — has been around since 1983 and could prevent COVID-19 patients from developing more severe symptoms.

Fluvoxamine is a selective serotonin reuptake inhibitor (SSRI), a class of anti-depressants, mostly prescribed for people suffering from an obsessive-compulsive disorder. It was tested in coronavirus patients because fluvoxamine has very 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.

According to Dr. Angela Reiersen, who was part of the study team and presented the findings at today's conference, "In addition to inhibiting serotonin reuptake, fluvoxamine binds to a protein called the sigma-1 receptor. We think fluvoxamine's action at the sigma-1 receptor may prevent the excessive release of cytokines, inflammatory molecules which can contribute to severe lung inflammation and the need for ventilator support."

152 people participated in this trial, all of whom were 18 years or older, were diagnosed with mild forms of COVID-19, and lived in either Missouri or Illinois. As explained by Dr. Reiersen, "The innovative fully-remote, contactless study design enabled patients to participate in the study while self-quarantining at home."

Participants were randomly assigned (1:1) to take either fluvoxamine or a placebo. As this was a remote, 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, as opposed to the six of 72 people who got the placebo and deteriorated. The results suggest that fluvoxamine may mitigate the risk of hospitalization and death. Furthermore, it confirmed an earlier observational study that was done in France that showed a significant association between the use of SSRI antidepressants and a reduction in intubation and deaths due to COVID-19.

The clinical trial was conducted by Dr. Eric Lenze, director of the Healthy Mind Lab at Washington University in St. Louis. Dr. Lenze is a highly cited scientist who has performed more than 250 clinical trials.

“Early-stage clinical trials are urgently needed and woefully underfunded,” said Dr. Lenze. “Funding from our University partners and the COVID-19 Early Treatment Fund was critical to moving the fluvoxamine study forward and helps us get closer to identifying an existing drug that can prevent hospitalization and save lives.”

CETF and the researchers are working rapidly on a larger remote outpatient clinical trial to validate these findings, with a goal to complete the larger trial by the end of the year.

Dr. Robert Siliciano, M.D., Ph.D., chairman of CETF’s Scientific Advisory Board (SAB) and a leading scientist in identifying early treatment for HIV added, “With no treated patient experiencing clinical deterioration, this is a very promising result with a high degree of statistical significance that shows the importance of early treatment on the potential to improve outcomes and reduce hospitalizations.”

CETF’s SAB is a world-class team of independent physician-scientists that thoroughly review every grant proposal to identify repurposed pharmaceuticals to treat COVID-19 symptoms and reduce hospitalizations from COVID-19 by over 75%. COVID-19 Early Treatment Fund is the sole or primary sponsor of several other clinical trials that are 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) 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 and joined by infectious disease expert Dr. Lisa Danzig, 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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