UM Tests Anti-Inflammatory Drug Aviptadil to Treat COVID-19-Induced Respiratory Distress

Infectious disease experts with the University of Miami Health System and the Miller School of Medicine have begun a clinical trial using Aviptadil to treat Acute Respiratory Distress Syndrome (ARDS) in patients with COVID-19.

COVID-19-related death is primarily caused by ARDS, in which severe inflammation causes the lungs to fill with fluid and even mechanical ventilation is unable to maintain life. The syndrome is caused by a cytokine storm unleashed by viral particles. Aviptadil (VIP) is known to have potent anti-cytokine effects in numerous animal models and in Phase 1 and Phase 2 human studies.

The trial will enroll patients who are already on mechanical ventilation in the hopes that Aviptadil can decrease mortality in this condition and help to improve the ability of the patient’s lung to transfer oxygen to the body.
“We are so fortunate to have widespread support and collaboration across our institution. We managed to get this study started in a record time due to this,” said Dushyantha Jayaweera, M.D., professor of medicine and principal investigator for the UM study site. “As we follow rigorous scientific standards, we are cautious and do not wish to create any therapeutic misconceptions. This is a placebo-controlled study that may give us useful information on VIP use in patients with COVID-19-related ARDS.”

VIP is a naturally synthesized peptide, which is 40 percent concentrated in the lungs and has been shown to have a potent anti-cytokine activity in numerous animal models of respiratory distress, acute lung injury, and inflammation. The drug has a 20-year history of safe use in human beings in multiple human trials for sarcoidosis, pulmonary fibrosis, and pulmonary hypertension, and is marketed in Europe as a local injection to treat erectile dysfunction.

The study’s co-principal investigators at UM are Daniel H. Kett, M.D., professor of medicine, and Daniel Dante Yeh, M.D., associate professor of surgery. The team will also collaborate with colleagues at the UM Interdisciplinary Stem Cell Institute.

The trial is being led by Relief Therapeutics’ U.S. partner, NeuroRx, Inc., under the U.S. Food and Drug Administration Investigational New Drug clearance – part of the Corona Treatment Acceleration Program (CTAP).

“In a previous trial of VIP for ARDS in patients with sepsis, seven of eight patients on mechanical ventilation showed substantial improvement and six ultimately left the hospital
“alive,” said NeuroRx CEO Jonathan Javitt, M.D., M.P.H. “Patients on ventilators for COVID-19 have only a 50 to 65 percent chance of survival. If the early results can be replicated in ARDS caused by COVID-19, this treatment may have a major impact both on COVID-19 survival and on the availability of ventilators for those in desperate need.”

Relief Therapeutics holds FDA and EU orphan drug designations for the use of VIP to treat ARDS, pulmonary hypertension, and sarcoidosis. Relief also holds a U.S. patent for Aviptadil and proprietary manufacturing processes for its synthesis.