



Pulmotect receives Department of Defense funding for Phase-2 trials of PUL-042 against COVID-19

Up to \$6 million to fund completion of two clinical trials

Houston, TX (January 27, 2021) – Pulmotect, Inc., a clinical-stage biotechnology company, has received funding from the Department of Defense (DOD) to complete two ongoing COVID-19 Phase-2 clinical trials of its innate immune-stimulating drug PUL-042.

“We are delighted to receive funding from the Department of Defense to complete these clinical trials, both of which are enrolling participants at clinical sites in the U.S.,” said Dr. Colin Broom, CEO of Pulmotect. “We appreciate the support to evaluate PUL-042, which not only has the potential to be effective against SARS-CoV-2 but also has potential for use against other pathogens that infect the respiratory tract.” In the first study, PUL-042 or placebo are being administered to 200 participants by inhalation over a 10-day period to evaluate the prevention of infection and reduction in severity of COVID-19. In the second study, 100 participants with early symptoms of COVID-19 are receiving PUL-042 or placebo administered over a six-day period.

Dr. Broom continued, “When delivered by inhalation, PUL-042 activates the innate immune system, the front-line of infection defense, to fight off a wide range of respiratory pathogens. We have a development program to evaluate the effect of PUL-042 in the treatment and prevention of respiratory complications in cancer patients; however, given the current pandemic we have mobilized our resources towards evaluating the effect of PUL-042 against SARS-CoV-2 infection.”

PUL-042, a synergistic combination of two toll-like receptor agonists, activates the lungs' surface immune system. As microbes, including viruses, land on the epithelial cells of the lung lining, they are destroyed on-contact by antimicrobial peptides and reactive oxygen species (ROS), including superoxides, that are released by epithelial cells. PUL-042 has demonstrated protection against a broad range of respiratory pathogens in pre-clinical models, including the coronaviruses that cause MERS and SARS. With robust pre-clinical protection already shown against multiple pathogens and favorable tolerability demonstrated in clinical trials to date, PUL-042 could offer a broad-spectrum therapy for future epidemics or pandemics, bioterror attacks, and other potential indications.

The two clinical trials are entitled:

- A Phase 2 Multiple Dose Study to Evaluate the Efficacy and Safety of PUL-042 Inhalation Solution in Reducing the Infection Rate and Progression to COVID-19 in Adults Exposed to SARS-CoV-2
- A Phase 2 Multiple Dose Study to Evaluate the Efficacy and Safety of PUL-042 Inhalation Solution in Reducing the Severity of COVID-19 in Adults Positive for SARS-CoV-2 Infection

This project is funded in part with federal funds from the DOD's Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense (JPEO-CBRND), through the U.S. Army Contracting Command - New Jersey, under an Other Transaction Agreement (W15QKN-16-9-1002, Project #MCDC 2006-002) awarded to the Medical CBRN Defense Consortium and Pulmotect Inc.

About Pulmotect

Pulmotect is developing PUL-042, a clinical stage, first-in-class, inhaled immunomodulatory agent, a synergistic agonist that amplifies the innate immune defenses of the lung epithelial mucosa to provide broad-spectrum, pathogen-agnostic protection against respiratory infections. Invented at UT MD Anderson Cancer Center/Texas A&M University, PUL-042 has patents issued in 10 countries, both as a stand-alone composition of matter product and in combination with antivirals. PUL-042 R&D has been supported by the National Institutes of Health (NIAID, NIGMS), the Cancer Prevention and Research Institute of Texas (CPRIT), and other funding agencies. For more information, visit www.pulmotect.com.

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