

PULMOTECT

Pulmotect Provides Results from Two Randomized, Placebo Controlled Phase-2 Trials of PUL-042 Against COVID-19

- Positive Efficacy Signals from Trials of Prevention and Treatment of COVID-19-*
- Improvement of Respiratory Symptoms and Fewer Intensive Care Admissions from Previously Reported Trial in Patients with COVID-19-*
- Potential Activity Against All SARS-CoV-2 Variants-*

Houston, TX (November 30, 2021) – Pulmotect, Inc., a clinical-stage biotechnology company, announced results from the second of two Phase 2 clinical trials undertaken in the United States with the support of the U.S. Department of Defense (DOD) to evaluate PUL-042 against COVID-19. Results from these trials support the potential of PUL-042 in reducing the severity of COVID-19.

Inhaled PUL-042 stimulates the lung's powerful immune system to protect against a wide range of respiratory pathogens in multiple animal models. In the two Phase 2 trials, PUL-042 was evaluated in one trial as preemptive treatment in patients with early, symptomatic infection and in a second trial in the prophylactic settings in subjects with known exposure to SARS-CoV-2.

"We now have data from over 200 subjects treated with PUL-042," said Dr. Colin Broom, CEO of Pulmotect. "Based on these data and the remarkable activity of PUL-042 in animal models we believe that PUL-042 has potential for treatment of COVID-19

irrespective of future SARS-CoV-2 variants and supports the clinical proof-of-concept for protection against respiratory pathogens in other patient populations.”

The most recent trial 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” randomized 217 subjects with exposure to SARS-CoV-2 who were asymptomatic and not known to be infected at the time of enrollment. PUL-042 was administered as a single dose on Days 1, 3, 6, and 10 of the trial and was well tolerated through 28 days of subject follow up. Subjects were tested for SARS-CoV-2 using a nasopharyngeal PCR test at study enrollment and again after 15 and 28 days. Assessments were made at regular intervals using the Ordinal Scale for Clinical Improvement (OSCI), a nine-point scale proposed by the World Health Organization and symptom scores. In total, 12 subjects were found to be positive for SARS-CoV-2 during the trial:

- Six subjects were positive at study entry; three subjects in each treatment arm. All three PUL-042 treated subjects cleared virus by Day 15 of the trial compared to none of the three placebo treated subjects.
- Six subjects became positive during the trial, three in each treatment group.

There was no statistically significant difference between treatment groups in the primary endpoint of change in OSCI although in the prospectively defined subgroup of males there was a significant difference in favor of PUL-042 ($p=0.04$).

A previously reported trial entitled “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” randomized 101 patients with early, symptomatic disease. PUL-042 was administered as a single dose on Days 1, 3 and 6 of

the trial and was well tolerated over 28 days of patient follow up. Few patients deteriorated based on assessment of OSCI however, three patients were hospitalized for progression of COVID-19. Two hospitalized patients in the placebo arm both required intensive care compared to the one hospitalized patient in the PUL-042 arm, who had received a single dose of PUL-042 and did not require intensive care.

Prospectively defined endpoints and analyses in that trial included evaluation of the cardinal symptoms of COVID-19: cough, shortness of breath, respiratory symptoms (cough and shortness of breath) and fatigue. There was a statistically significant difference in time to improvement of respiratory symptoms ($p=0.0227$) using a log-rank comparison of time to symptom improvement. The median time to improvement of respiratory symptoms was 6 days for PUL-042 and 9 days for placebo. Time to complete resolution of respiratory symptoms also trended in favor of PUL-042.

PUL-042 was well tolerated with a low incidence of adverse effects with no drug related serious adverse events reported in either trial and no deaths.

About PUL-042

PUL-042, a first in class, synergistic combination of two toll-like receptor agonists, activates the lungs' surface innate immune system to inhibit and kill a wide range of respiratory pathogens. 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) that are released by epithelial cells. Activation of the innate immune system also triggers a response from the adaptive immune system. 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 shown against multiple pathogens, even in models with immunocompromised animals, and favorable tolerability demonstrated in clinical trials to date, PUL-042 could offer a broad-spectrum therapy for responding to epidemics

and pandemics including current and future SARS-CoV-2 variants and has potential use for multiple other indications.

The Phase 2 studies of PUL-042 for COVID-19 are 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 has an immunomodulatory platform technology and 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 28 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), other funding agencies, and the Fannin Innovation Studio. For more information, visit www.pulmotect.com.

About Fannin Innovation Studio

Houston-based Fannin Innovation Studio is an early-stage life sciences development group focused exclusively on commercializing biotech and medtech technologies. Fannin creates and manages startups to develop internal and in-licensed programs. Fannin has over a dozen active programs, including three in clinical development. For more information, visit www.FanninInnovation.com, come by the Studio at 3900 Essex Lane -- Suite 575 in Houston, or email us at innovate@fannininnovation.com.

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