



PULMOTECT

Pulmotect Reports Positive Topline Results from Randomized, Placebo Controlled Phase-2 Trial of PUL-042 against COVID-19

*-Statistically significant reduction in time to improvement of respiratory symptoms-
-Fewer hospitalizations and intensive care admissions-*

Houston, TX (September 21, 2021) – Pulmotect, Inc., a clinical-stage biotechnology company, announced positive topline results from the first of two Phase-2 clinical trials undertaken with the support of the US Department of Defense (DOD) to evaluate PUL-042 against COVID-19. Patients treated with inhaled PUL-042 had a statistically significant reduction in the time to improvement of the combined respiratory symptoms of cough and shortness of breath. Inhaled PUL-042 stimulates the lung's innate immune system with the potential to protect against a wide variety of respiratory pathogens. PUL-042 could be directed against all existing and future variants of the SARS-CoV-2 virus, as well as future pandemics. Based on the promising results from this trial and remarkable activity in pre-clinical models, PUL-042 also has potential for use in other patient populations.

"I am excited about the topline results with PUL-042 and the shortening of time to symptoms improvement for patients with early COVID-19, which could have significant health and economic benefits as the global pandemic continues to unfold," said Dr. Colin Broom, CEO of Pulmotect. "As an easily administered inhaled therapy, PUL-042 could have value in reducing the impact of COVID-19 irrespective of the development

of further variants and has potential utility for other patient populations which we plan to explore including immunosuppressed cancer patients.”

The 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 disease in the United States. PUL-042 was well tolerated when administered as a single dose on Day 1, Day 3 and Day 6 of the trial with 28 days of patient follow up. Two patients were hospitalized with a deterioration from pre-treatment of 2 or more points on the Ordinal Scale for Clinical Improvement, a nine-point scale proposed by the World Health Organization, one in each of the treatment arms. In total, three patients were hospitalized for progression of COVID-19, two in the placebo arm who both required intensive care treatment for 5 days and 9 days and one patient in the PUL-042 arm who was hospitalized for four days having received a single dose of PUL-042 and did not require intensive care.

Prospectively defined endpoints and analyses included evaluation of the cardinal symptoms of COVID-19: cough, shortness of breath, respiratory symptoms (cough and shortness of breath) and fatigue. Each individual symptom was scored as 0 (absent), 1 (mild), 2 (moderate) and 3 (severe). 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. There was also a positive effect on time to improvement of cough ($p=0.0547$). The median time to improvement of cough was 7 days for PUL-042 and 11 days for placebo.

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

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's (JPEO-CBRND) Joint Project Manager for Chemical, Biological, Radiological and Nuclear Medical (JPM CBRN Medical), 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 27 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 start-ups 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.

For More Information – Investor Relations/Questions:

Brenton Scott

bscott@pulmotect.com

713-579-9226