Pulmotect Initiates Landmark Phase 2 Clinical Trial in Immunosuppressed Cancer Patients

Leading oncology centers in the United States engaged to conduct the Phase 2 Antiviral Trial and further advance the development of PUL-042

HOUSTON, TX, UNITED STATES, July 8, 2025 /EINPresswire.com/ -- Pulmotect, Inc., a privately held clinical-stage biotechnology company, today announced that it has begun dosing in their 100 patient Phase 2, double-blind, placebo controlled, clinical trial in immunosuppressed patients with hematologic malignancies. The trial is funded in part by an $8.9 million Product Development Research grant awarded by the Cancer Prevention and Research Institute of Texas (CPRIT, ID#DP230066).

“This clinical trial is a key stepping stone in our development program with PUL-042. The three viruses that we are targeting have no effective treatments and are the most serious and potentially lethal viruses that cause pneumonia in this patient population. It is unheard of for an agent to be clinically effective against multiple different viruses however, PUL-042 activates lung surface immunity to fight off infection and is effective in multiple preclinical models against viruses, bacteria and fungi. The prospect of viral resistance to treatment is non-exsitent due to PUL-042 being a host directed therapy which makes this an exciting and potentially paradigm changing therapeutic. ” said Dr. Colin Broom, CEO of Pulmotect.

“This trial is an example of bringing private and public resources together to address a significant problem facing cancer patients. With funding support from the state of Texas, Fannin Partners and other investors we are able to conduct this trial with the participation of leading cancer centers across the country and their patients.” said Leo Linbeck III, Chairman, Pulmotect Board of Directors and Chairman, Fannin Partners.

The Phase 2 antiviral trial is entitled “A Phase 2 Multiple Dose Study to Evaluate the Efficacy and Safety of PUL-042 Inhalation Solution in Reducing Lower Respiratory Tract Complications in Patients with Hematologic Malignancies and Recipients of Hematopoietic Stem Cell Transplantation (HSCT) with Documented Viral Infections with Parainfluenza Virus (PIV), Human Metapneumovirus (hMPV) or Respiratory Syncytial Virus (RSV).” (NCT06665100). The design of the trial builds upon the experience and results from Pulmotect's previous Phase 2 trials that demonstrated activity of inhaled PUL-042 against SARS-CoV-2 when administered by nebulization following diagnosis of viral infection.

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 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 viral, bacterial and fungal respiratory pathogens in pre-clinical models, including models with immunocompromised animals. Phase 1 and 2 trials to date have demonstrated favorable tolerability in more than 200 subjects that included healthy individuals, COPD patients and subjects infected with SARS-CoV-2 with evidence of antiviral activity. PUL-042 may provide potentially life saving therapy for immunocompromised patients and also offer a broad-spectrum therapy for multiple other populations such as patients with COPD, asthma, seasonal infections and potential utility in future pandemics.

About Pulmotect

Pulmotect has an immunomodulatory platform technology and is developing PUL-042, a clinical-stage, first-in-class, inhaled, immunomodulatory agent. This synergistic agonist 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 Department of Defense (DoD), National Institutes of Health (NIAID, NIGMS), CPRIT, other funding agencies, and private investors including Houston based Fannin Partners, LLC, a life sciences product development company. For more information, visit www.pulmotect.com.

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