# Windtree Announces First Patient Dosed in its Phase 2 Clinical Trial Studying KL4 Surfactant in Acute Lung Injury in Adults with COVID-19

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**The Phase 2 study will evaluate key physiological measures and is expected to be completed in 3-6 months**

WARRINGTON, Pa., Jan. 6, 2021 /PRNewswire/ -- Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology and medical device company focused on advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders, today announced that it has dosed the first patient in its Phase 2 clinical trial studying lucinactant in acute lung injury in adults with COVID-19 associated lung injury and acute respiratory distress syndrome (ARDS). Lucinactant is the Company's synthetic KL4 surfactant that is structurally similar to human pulmonary surfactant.

"With COVID-19 cases continuing to increase across the U.S. and globally there's considerable need to develop effective new treatments for those who develop respiratory failure, particularly therapies that can help reduce the intensity of care in the hospital where the availability of beds, ventilators and ICU space are fast reaching short supply levels," said Steve Simonson, M.D., chief medical officer at Windtree Therapeutics. "We have built a strong body of preclinical evidence supporting the potential use of KL4 surfactant for acute lung injury caused by multiple insults including viral infection and we believe that surfactant therapy could potentially play an important role in supporting COVID-19 patients who develop severe respiratory disease."

The SARS-CoV-2 virus causing COVID-19 uses the angiotensin-converting enzyme 2 (ACE2) receptor for entry into host cells. ACE2 is a surface molecule on alveolar Type 2 cells in the lungs. The Type 2 cells are the source of surfactant production in the lung. Damage or loss of Type 2 cells and the viral pneumonia often associated with COVID-19 may result in impaired surfactant production and increased surfactant degradation. This process can result in decreased lung compliance and impaired gas exchange leading to increased risk for respiratory failure and ARDS requiring mechanical ventilation. There are no approved drug therapies for ARDS, yet surfactant abnormalities are a known characteristic of the condition. The Company believes its synthetic KL4 surfactant may have the potential to mitigate surfactant deficiency, improve respiratory parameters and reduce the time a patient spends on mechanical ventilation and the number of days a patient spends in the intensive care unit.

"As more evidence is generated on the long-term effects of COVID-19 induced lung disease, having effective treatments that can potentially mitigate chronic lung damage will be of great importance. This study complements our many years of research and studies on the effectiveness of KL4 surfactant in treating various acute respiratory syndromes," said Craig Fraser, CEO and president of Windtree Therapeutics. "In working with top investigators and trial sites who are experiencing significant increases in ICU patients being treated for COVID-19, we look forward to generating data that may potentially support the development of a needed, new critical care intervention."

**About Windtree's COVID-19 Phase 2 Study:**
The initial study will evaluate changes in physiological parameters in COVID-19 patients who are intubated and mechanically ventilated for associated lung injury and ARDS. The study will establish the dosing regimen, tolerability, and functional changes in gas exchange and lung compliance after KL4 surfactant administration. The study will include up to 20 patients with COVID-19 and ARDS and on mechanical ventilation from 4-5 U.S. sites. Dosing will be through the endotracheal tube, with repeat dosing based on changes in oxygenation. Planned outcome measures include: physiologic response - Oxygenation Index (OI), lung compliance on the ventilator and clinical parameters including time on mechanical ventilation, days in intensive care unit and mortality (although this first study will not be powered for these measures). Recruitment is expected to take 3-6 months (depending on COVID-19 rates at study sites). If the initial Phase 2 study results demonstrate adequate safety/tolerability and efficacy on physiological variables, Windtree may initiate two additional clinical trials. One study would more fully assess the impact of KL4 surfactant on clinical endpoints such as time on mechanical ventilation, time in the ICU, mortality. The second study would be to utilize the Company's novel and proprietary Aerosolized Delivery System (ADS) to aerosolize and deliver the KL4 surfactant noninvasively in COVID-19 patients that are at high risk of respiratory failure with an intent to avoid mechanical ventilation, a similar strategy to the Company's respiratory distress syndrome studies in preterm infants.

**About Windtree Therapeutics**
Windtree Therapeutics, Inc. is advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders to treat patients in moments of crisis. Using new clinical approaches, Windtree is developing a multi-asset franchise anchored around compounds with an ability to activate SERCA2a, with lead candidate istaroxime being developed as a first-in-class treatment for acute heart failure and early cardiogenic shock in heart failure. Windtree has also focused on developing AEROSURF® as a non-invasive surfactant treatment for premature infants with respiratory distress syndrome, and is facilitating transfer of clinical development of AEROSURF® to its licensee in Asia, Lee's HK, while Windtree evaluates other uses for its synthetic KL4 surfactant for the treatment of acute pulmonary conditions including lung injury due to viral, chemical and radiation induced insults. Also in its portfolio is rostafuroxin, a novel precision drug product targeting hypertensive patients with certain genetic profiles.

For more information, please visit the Company's website at www.windtreetx.com.

**Forward-Looking Statements**
*This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. The Company may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans,"*

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