Windtree Completes Enrollment in Its Phase 2 Study of Lucinactant (KL4 Surfactant) for COVID-19 Associated Lung Injury and Acute Respiratory Distress Syndrome

February 1, 2022

Data anticipated in first quarter 2022

WARRINGTON, Pa., Feb. 01, 2022 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology company focused on advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders, today announced it has completed enrollment in its Phase 2 study of lucinactant (KL4 surfactant) for patients with COVID-19 associated lung injury and acute respiratory distress syndrome (ARDS). Data is anticipated in the first quarter of 2022.

The Phase 2 trial is a multicenter, single-treatment study in 20 patients designed to evaluate the safety and tolerability of lucinactant delivered as a liquid via the endotracheal tube in patients who are mechanically ventilated as a result of COVID-19 associated acute lung injury. Functional changes in gas exchange and lung compliance are also being measured.

“COVID-19 infection can cause serious lung injury resulting in acute respiratory distress syndrome (ARDS) where surfactant destruction and abnormalities may be a contributing factor. This initial pilot study is to determine if we can safely administer lucinactant as a surfactant replacement in these severely ill patients and to learn about potential dosing and respiratory benefits,” said Steve Simonson, MD, Chief Medical Officer of Windtree Therapeutics. "We are pleased to have completed enrollment and look forward to data from this trial in this first quarter of 2022.”

About Lucinactant
Lucinactant is a synthetic surfactant that is structurally similar to human pulmonary surfactant and contains a proprietary synthetic peptide KL4 (sinapultide), a 21-amino acid peptide that is designed to imitate the essential attributes of the human surfactant protein B (SP-B). SP-B is one of four known surfactant proteins and is the most important for proper functioning of the respiratory system. Surfactant is a natural lubricant produced by specialized cells in the lung called alveolar Type 2 cells and is critical for proper lung function. Surfactant helps keep the lungs from collapsing when exhaling and also improves oxygen transfer to the blood. Windtree’s lucinactant can be given either through an endotracheal tube or via a proprietary aerosolized delivery system. It has the potential to mitigate surfactant deficiency and inactivation that can occur as a result of infectious diseases that affect the lung, such as COVID-19. Preclinical data demonstrated that lucinactant may possess other beneficial properties, including modulation of the inflammatory process, antimicrobial properties, and lack of immunogenicity.

About Windtree Therapeutics
Windtree Therapeutics, Inc. is advancing multiple late-stage interventions for acute cardiovascular and acute pulmonary disorders to treat patients in moments of crisis. Using new scientific and 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 for early cardiogenic shock. Windtree’s heart failure platform includes follow-on oral pre-clinical SERCA2a activator assets as well. In pulmonary care, Windtree has focused on facilitating the transfer of the clinical development of AEROSURF®, to its licensee in Asia, Lee's HK. Windtree is also evaluating KL4 surfactant for the treatment of acute respiratory distress syndrome in COVID-19 patients. Included in Windtree’s portfolio is rostafuroxin, a novel precision drug product targeting hypertensive patients with certain genetic profiles.

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," "intends," "may," "could," "might," "will," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Such statements are based on information available to the Company as of the date of this press release and are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially from the Company's current expectations. Examples of such risks and uncertainties include: risks and uncertainties associated with the ongoing economic and social consequences of the COVID-19 pandemic, including any adverse impact on the Company's clinical trials, clinical trial timelines or disruption in supply chain; the success and advancement of the clinical development programs for istaroxime, KL4 surfactant and the Company's other product candidates; the Company's ability to secure significant additional capital as and when needed; the Company's ability to access the debt or equity markets; the Company's ability to manage costs and execute on its operational and budget plans; the results, cost and timing of the Company's clinical development programs, including any delays to such clinical trials relating to enrollment or site initiation; risks related to technology transfers to contract manufacturers and manufacturing development activities; delays encountered by the Company, contract manufacturers or suppliers in manufacturing drug products, drug substances, aerosol delivery systems (ADS) and other materials on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including that: (i) the FDA or other regulatory authorities may not agree with the Company on matters raised during regulatory reviews, may require significant additional activities, may not accept or may withhold or delay consideration of applications, or may not approve or may limit approval of the Company's product candidates, and (ii) changes in the national or international political and regulatory environment may make it more difficult to gain regulatory approvals and risks related to the Company's efforts to maintain and protect the patents and licenses related to its product candidates; risks that the Company may never realize the value of its intangible assets and have to incur future impairment charges; risks related to the size and growth potential of the markets for the Company's product candidates, and the Company's ability to service those markets; the Company's ability to develop sales and marketing capabilities, whether alone or with potential future collaborators; and the rate and degree of market acceptance of the Company's product candidates, if approved. These and other risks are described in the Company's periodic reports, including the annual report on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, filed with or furnished to the Securities and Exchange Commission and available at www.sec.gov. Any forward-looking statements that the Company makes in this press release speak only as of the date of this press release. The Company assumes no obligation to update forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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