Windtree Therapeutics Announces KL4 Surfactant and AEROSURF® Global License Agreement

August 23, 2022

Windtree may receive up to $78.9 million in development, regulatory and commercial milestones plus low double digit royalties
Development and all other costs to be assumed by Lee's Pharmaceutical and Zhaoke Pharmaceutical

WARRINGTON, Pa., Aug. 23, 2022 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology company focused on advancing multiple late-stage interventions for acute cardiovascular disorders, today announced it has entered into a global licensing agreement with Lee's Pharmaceutical (HK) Limited, (Lee's) and its affiliate Zhaoke Pharmaceutical (Hefei) Co. Ltd., (Zhaoke) for the development and commercialization of Windtree's acute pulmonary pipeline treatments KL4 surfactant and drug/device combination, AEROSURF ®, for the treatment of preterm infants with respiratory distress syndrome (RDS) and other potential applications. RDS often occurs in preterm infants when the lung is not fully developed with natural lung surfactant and may require surfactant therapy to sustain life.

"We are excited to announce this global licensing transaction for our KL4 surfactant platform given the value it can provide to the Company, its shareholders and critically ill patients," said Craig Fraser, President and Chief Executive Officer of Windtree. "The out-licensing of the KL4 platform supports our portfolio prioritization and increases non-dilutive resources to progressing istaroxime on the significant opportunity in the major markets of cardiogenic shock and heart failure where recent positive data has created what we believe could be a relatively fast and less expensive developmental pathway in cardiogenic shock. Given the clinical potential of KL4 surfactant and AEROSURF to help preterm infants with RDS, we desired a partner who was capable of fully assuming execution of the platform and could build value. Over the past few years, we have worked with the Lee's and Zhaoke's teams as they invested significantly in building manufacturing, analytical and clinical capabilities to move the KL4 platform into late-stage development. This transaction strengthens Windtree's resources for its core programs and delivers significant potential value to its shareholders on assets we were no longer progressing ourselves."

Under terms of the global license agreement, Lee's and Zhaoke will receive a global license to develop and commercialize Surfaxin ®, lyophilized lucinactant and AEROSURF for any potential indications and applications. Lee's and Zhaoke will be responsible for funding all development, intellectual property, manufacturing, and commercialization activities and provide developmental, regulatory and eventual commercial sales milestones for Windtree of up to $78.9 million plus potential double-digit royalties. Windtree had previously granted a regional license to Lee's and Zhaoke for KL4 and AEROSURF for the territory of Greater China for which Windtree received an upfront payment, and this new agreement expands that territory globally. With the execution of this agreement, Windtree will no longer have ongoing maintenance and operating costs for the KL4 platform.

About Lyophilized Lucinactant and AEROSURF®
Lyophilized lucinactant is an investigational synthetic peptide (KL4 surfactant) containing drug product that is being developed to improve the management of RDS in premature infants who may not have fully developed natural lung surfactant and may require surfactant therapy to sustain life. AEROSURF® (lucinactant for inhalation) is a drug/device combination designed to deliver aerosolized KL4 surfactant noninvasively using our proprietary ADS technology and potentially may meaningfully reduce the use of invasive endotracheal intubation and mechanical ventilation. We believe that AEROSURF, if approved, may meaningfully reduce the number of premature infants who are subjected to invasive surfactant administration, and potentially provide transformative clinical and pharmacoeconomic benefits. The FDA has granted Fast Track designation for AEROSURF to treat RDS and the program has Orphan Drug designation.

About Windtree Therapeutics
Windtree Therapeutics, Inc. is advancing multiple late-stage interventions for acute cardiovascular 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. 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 and the Company's other product candidates; the impacts of political unrest, including as a result geopolitical tension, including escalation in the conflict between Russia and Ukraine, the People's Republic of China and the Republic of China (Taiwan), and any additional resulting sanctions, export controls or other restrictive actions that may be imposed by the United States and/or other countries which could have an adverse impact on the Company's operations, including through disruption in supply chain or access to potential international clinical trial sites, and through disruption, instability and volatility in the global markets, which could have an adverse impact on the Company's ability to access the capital markets; 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, 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, or 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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