Windtree Therapeutics Announces New Istaroxime Expedited Review Filing of Patent

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Company Continues to Leverage Data to Strengthen the Istaroxime Patent Estate

WARRINGTON, Pa., April 19, 2021 /PRNewswire/ -- Windtree Therapeutics, Inc. (NasdaqCM: WINT) ("Windtree" or the "Company"), a biotechnology and medical device company focused on advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders, today announced it has filed a Track One prioritized application with the United States Patent and Trademark Office (USPTO) for a patent stemming from an application it filed previously under the Patent Cooperation Treaty (PCT). Under this USPTO program, the new istaroxime patent is expected to receive examination and final disposition within one year of priority status being granted, rather than the customary three years of examination anticipated by the USPTO for non-prioritized examinations.

Windtree is taking steps to strengthen the istaroxime patent estate since it is the Company's lead pipeline asset. "With such high unmet need for patients in the disease areas we are studying istaroxime, we are focusing on ensuring our patent estate has the most protection possible. If we are successful in our clinical studies and eventually gain regulatory approval, our plan is for istaroxime to be well prepared and protected in the commercialization stage," said Craig Fraser, CEO and President of Windtree. Istaroxime is currently being developed in early cardiogenic shock and in acute heart failure (AHF).

Early cardiogenic shock is a life-threatening state of lack of heart function and blood flow to vital organs that is associated with high risk of mortality, despite intensive monitoring and current treatments. Based on the need in this area, regulatory precedent exists for an approval in shock settings based upon improvements in blood pressure with an acceptable safety profile. The Company is currently executing an international randomized double blind placebo controlled study to assess the effect of istaroxime in patients with early cardiogenic shock due to heart failure. This study will include 60 patients (30 assigned to istaroxime and 30 assigned to placebo) receiving study drug infusion over 24 hours. The primary endpoint will evaluate systolic blood pressure over six hours after initiating the infusion. Secondary endpoints will include characterization of blood pressure changes over 24 hours, the number of patients requiring rescue therapy (vasopressors, inotropes or mechanical devices), assessment of renal function and measures associated with safety and tolerability.

After successfully completing positive phase 2a and phase 2b studies in acute heart failure, the next steps in development are focused on optimizing therapy and employing study enrichment strategies to create a strong phase 3 and partnership position. With adequate resources, we plan to conduct an additional phase 2b clinical trial that will enroll approximately 300 patients globally. The trial will focus on enrolling acute heart failure patients with low blood pressure and those who are diuretic resistant, two of the specific patient populations that we believe could particularly benefit from the unique profile and potential ability of istaroxime to increase cardiac function, increase blood pressure and improve renal function. This trial has been designed to collect data on measures that may serve as primary endpoints in a phase 3 clinical trial, and will potentially extend the infusion time beyond 24 hours. The company is currently preparing for the trial start and to secure full clinical funding for the trial with a focus on business development and partnership.

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," "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 or disruption in supply chain; the success and advancement of the clinical development programs for istaroxime, AEROSURF®, 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, 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 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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