# Windtree Announces Notice of Allowance from the US Patent and Trademark Office for a New Istaroxime Patent

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**Anticipated New Patent Will Provide Intellectual Property Protection Until Late 2039**

WARRINGTON, Pa., Oct. 25, 2021 (GLOBE NEWSWIRE) -- 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 the United States Patent and Trademark Office (USPTO) has issued a Notice of Allowance of new patent claims for istaroxime administration. A notice of allowance is issued by the USPTO to indicate that the application has passed examination. When the patent is issued by the USPTO in the near future, it will provide new intellectual property protection for istaroxime until late 2039.

The istaroxime patent application is entitled, “Istaroxime-Containing Intravenous Formulation for the Treatment of Acute Heart Failure (AHF),” and was the result of an expedited US Track One filing by Windtree in April 2021. The claims cover longer infusion durations of istaroxime for improved outcomes in treatment of acute heart failure. Istaroxime is an investigational drug candidate being studied in acute heart failure and also in early cardiogenic shock. Phase 2a and Phase 2b studies in acute heart failure have demonstrated significant improvements in cardiac function as well as preserving or increasing blood pressure and renal function.

“We continue to strengthen the istaroxime patent estate and look forward to the anticipated issuance of this patent from the USPTO,” said Craig Fraser, President and CEO of Windtree Therapeutics. “The istaroxime patent estate is a priority for Windtree and we plan to add additional elements to it as data is obtained in our clinical studies.”

Windtree plans to start the next acute heart failure study by mid-2022. This study will target AHF patients with normal to low blood pressure and look to optimize istaroxime dosing by employing a longer infusion duration. The primary endpoint will be echocardiographic assessment of cardiac function (similar to the 2b study). It will also include as secondary endpoints, assessments that could potentially become primary pivotal endpoints in the Phase 3 program and thus put the program in what the company believes will be a good Phase 3 ready and partnership position. In the meantime, the company is also conducting a Phase 2 study in early cardiogenic shock patients with results expected in the first quarter of 2022.

**About Istaroxime**
Istaroxime is a first-in-class dual mechanism therapy designed to improve both systolic and diastolic cardiac function. Istaroxime is a positive inotropic agent that increases myocardial contractility through inhibition of Na+/K+- ATPase with a complementary mechanism that facilitates myocardial relaxation through activation of the SERCA2a calcium pump on the sarcoplasmic reticulum enhancing calcium reuptake from the cytoplasm. Data from multiple Phase 2 studies in patients with acute heart failure (AHF) demonstrate that istaroxime infused intravenously significantly improves cardiac function and blood pressure without causing heart rate increases or rhythm disturbances.

**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 developing AEROSURF®, a drug-device combination, to deliver its synthetic KL4 surfactant non-invasively to premature infants with respiratory distress syndrome, and is facilitating transfer of 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. Also 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 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, 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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