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 Add to the Istaroxime Patent Estate and Provide Intellectual Property Protection Until Late 2039

WARRINGTON, Pa., Oct. 25, 2022 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology company focused on advancing multiple late-stage interventions for acute cardiovascular disorders, today reported that 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.

Istaroxime is an investigational drug candidate being studied in early cardiogenic shock and acute heart failure. It has a novel dual mechanism of action that increases both systolic contraction and diastolic relaxation (the latter by uniquely addressing heart failure associated SERCA2a dysfunction). SERCA2a activation facilitates sequestration of calcium during diastole, favoring relaxation and making more calcium available for the next contraction, further improving cardiac ventricular function. Phase 2a and Phase 2b studies in acute heart failure have demonstrated significant improvements in cardiac function as well as increasing blood pressure and preserving or increasing renal function.

The U.S. Patent, titled: “Istaroxime-Containing Intravenous Formulation for the Treatment of Acute Heart Failure (AHF)”, is a continuing patent application of the expedited U.S. Track One filing by Windtree, which resulted in U.S. Patent No. 11,197,869 B2 that issued December 14, 2021. The claims cover longer infusion durations of istaroxime for improved outcomes in treatment of acute heart failure. In particular, the claims are directed to an improvement in diastolic heart function following administration of istaroxime by intravenous infusion for 6 hours or more, which Windtree attributes to the SERCA2a mechanism of action of istaroxime and its metabolites.

“We are pleased with this notice of allowance for a new patent that will continue to strengthen the istaroxime patent estate,” said Craig Fraser, President and Chief Executive Officer of Windtree. “Cardiogenic shock and acute heart failure are areas that need innovation for patients and through three Phase 2 studies, istaroxime has consistently demonstrated a unique and we believe, a highly attractive profile. We look forward to continued progress in development as well as building upon our patent estate for both programs.”

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 complimentary 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 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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