Windtree Therapeutics Announces Publication from Its SEISMiC Pre Cardiogenic Shock Study Comparing Two Doses of Istaroxime

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WARRINGTON, Pa., April 27, 2023 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (“Windtree” or the “Company”) (NasdaqCM: WINT) is a biotechnology company focused on advancing late-stage interventions for acute cardiovascular disorders of acute heart failure and a lead program studying istaroxime in cardiogenic shock. Cardiogenic shock is caused by a failing heart resulting in diminished cardiac output to the body and is characterized by very low blood pressure and hypoperfusion to end-organs. It is a treatment emergency with high morbidity and mortality.

Windtree conducted a study of istaroxime in patients experiencing early cardiogenic shock due to heart failure (the SEISMiC Study) and previously reported the publication of the primary analysis of SEISMiC comparing the combined istaroxime dose groups and placebo. In this study the primary endpoint of systolic blood pressure area under the curve (SBP AUC) over 6 hours was significantly improved by istaroxime compared to the placebo control group, an effect that was maintained throughout the 24 hour infusion. Patients treated with istaroxime experienced a substantial increase in stroke volume (the amount of blood pumped from the heart with each contraction) that contributed to increased cardiac output without increasing heart rate. As also reported, the study met several other secondary endpoint assessments of cardiac function and importantly, demonstrated that renal function did not worsen in the istaroxime treated group.

Today, Windtree announces the publication of “Safety and Efficacy of Istaroxime 1.0 and 1.5 µg/kg/min for Patients with Pre Cardiogenic Shock,” in the Journal of Cardiac Failure. This publication describes additional analysis completed on dosing of istaroxime in the SEISMiC Study and conveys dose related findings on the primary endpoint SBP AUC and on biomarkers and clinical endpoints. This publication describes both doses of istaroxime as increasing SBP, with the 1.0 µg/kg/min dose having a numerically greater SBP AUC change (93.6% vs 39.5% relative increase over the first 6 hours of the infusion) and fewer serious adverse events than the 1.5 µg/kg/min dose. It also notes that echocardiographic assessment of cardiac function was similar between doses with both doses showing improvement.

“This analysis of our SEISMiC Phase 2 study in pre-cardiogenic shock has provided valuable dose related information,” said Dr. Steve Simonson, SVP and Chief Medical Officer of Windtree Therapeutics. “This publication describes the benefit derived from the 1.0 µg/kg/min dose and indicates the desired improvements in cardiac function and blood pressure may be achieved without requiring the administration of higher doses of istaroxime. These findings will guide our future development strategy in cardiogenic shock, including in the extension study to SEISMiC, which focuses on dose optimization and longer infusions.”

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 increasing heart rate or the incidence of cardiac rhythm disturbances.

About Windtree Therapeutics, Inc.
Windtree Therapeutics, Inc. is advancing late-stage interventions for 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 pre-clinical SERCA2a activator assets as well. In pulmonary care, Windtree has focused on facilitating the transfer of the KL4 surfactant platform, to its licensee, Lee’s Pharmaceutical (HK) Ltd. 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 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 of geopolitical tension, including the conflict between Russia and Ukraine, the People’s Republic of China and the Republic of China (Taiwan), and any 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 U.S. Food and Drug Administration 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 its 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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