Windtree Announces Istaroxime Presentation By Cardiogenic Shock Thought Leader At Cardiovascular Clinical Trials Conference

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WARRINGTON, Pa., Dec. 16, 2024 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (“Windtree” or the “Company”) (NasdaqCM: WINT), a biotechnology company focused on advancing early and late-stage innovative therapies for critical conditions and diseases, today announced that Alexandre Mebazaa, MD, one of the world’s recognized leaders in cardiogenic shock, gave a well-received presentation highlighting the data on istaroxime from the recently completed Phase 2b SEISMiC B study in early cardiogenic shock due to heart failure. The presentation was given at the Cardiovascular Clinical Trials Conference in Washington, DC.

Dr. Alexandre Mebazaa is Professor of Medicine at Université Paris Cité (France), Chair of Department of Anesthesia & Critical Care and an expert in heart failure and cardiogenic shock. He is part of the task force that wrote the 2021 ESC/HFA Guidelines of Heart Failure and the 2023 addendum.

Early cardiogenic shock is characterized by low blood pressure, leaving the patient at risk of developing inadequate blood flow to vital organs leading to high morbidity and mortality. Istaroxime is a novel first-in-class investigational therapy that is intended to improve cardiac function and increase blood pressure to reverse the condition. Istaroxime maintains renal function and has a generally favorable safety profile. Istaroxime has been studied in four positive Phase 2 trials enrolling patients with acute heart failure and early cardiogenic shock due to heart failure.

“We are pleased that istaroxime is receiving positive attention based on the recent clinical trial results in treating patients with early cardiogenic shock. We believe that pharmacologic innovation is needed in treating patients with cardiogenic shock,” said Dr. Steve Simonson, CMO and SVP of Windtree. “Currently available drugs can have unwanted side effects and poor outcomes. There have been two positive istaroxime Phase 2 studies in early cardiogenic shock. Both have demonstrated the unique characteristics of rapidly and significantly increasing systolic blood pressure and improving cardiac output without increasing heart rate. Additionally, we have not seen an increase in clinically significant arrhythmias and istaroxime has maintained or improved renal function. We look forward to progressing istaroxime toward Phase 3 in cardiogenic shock.”

About Istaroxime
Istaroxime is a first-in-class dual-mechanism therapy designed to improve both systolic and diastolic cardiac function. Istaroxime is designed as 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 early cardiogenic shock or acute decompensated heart failure have demonstrated 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 a biotechnology company focused on advancing early and late-stage innovative therapies for critical conditions and diseases. Windtree’s portfolio of product candidates includes istaroxime, a Phase 2 candidate with SERCA2a activating properties for acute heart failure and associated cardiogenic shock, preclinical SERCA2a activators for heart failure and preclinical precision aPKCi inhibitors that are being developed for potential in rare and broad oncology applications. Windtree also has a licensing business model with partnership out-licenses currently in place.

Forward Looking Statements
This press release contains statements related to the potential clinical effects of istaroxime; the potential benefits and safety of istaroxime; the clinical development of istaroxime; and our research and development program for treating patients in early cardiogenic shock due to heart failure. Such statements constitute 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, among other things: the Company’s ability to secure significant additional capital as and when needed; the Company’s ability to achieve the intended benefits of the aPKCi asset acquisition with Varian Biopharmaceuticals, Inc.; the Company’s risks and uncertainties associated with the success and advancement of the clinical development programs for istaroxime and the Company’s other product candidates, including preclinical oncology candidates; the Company’s ability to access the debt or equity markets; the Company’s ability to secure and successfully complete an out-licensing or asset acquisition transaction; 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; the rate and degree of market acceptance of the Company’s product candidates, if approved; the economic and

social consequences of the COVID-19 pandemic and 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 the evolving events in the Middle East, 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. 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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