



Windtree Completes Enrollment of Phase 2 Study of Istaroxime in Early Cardiogenic Shock

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On track for top-line data in April 2022

WARRINGTON, Pa., March 15, 2022 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology company focused on advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders, today announced it has successfully completed enrollment in its phase 2 study of istaroxime in early cardiogenic shock caused by heart failure.

The study is an international, randomized double-blind, placebo-controlled study designed to assess the efficacy and safety of istaroxime and to support an intended pathway for the development in early cardiogenic shock. The study has enrolled 60 Society for Cardiovascular Angiography & Interventions (SCAI) class B early cardiogenic shock patients with severe heart failure (30 assigned to istaroxime and 30 assigned to placebo) and systolic blood pressures (SBP) between 75-90 mmHg. Study drug was administered over 24 hours. The primary endpoint is the SBP profile over the first 6 hours after initiating the infusion. Secondary endpoints will include various assessments of blood pressure changes over 24 hours and measures associated with safety and tolerability. All patients will complete a 30-day follow-up prior to database lock and generation of topline data; as a result, topline data is expected to be announced in April.

"We are very pleased to have completed enrollment in the study of istaroxime in early cardiogenic shock due to heart failure. We are eager to examine the potential of istaroxime in this critical condition. The efforts of participating centers to enroll patients are much appreciated given the challenges of conducting research in hospital cardiac care units during the global pandemic," said Steve Simonson, MD, CMO of Windtree Therapeutics.

Cardiogenic shock is a serious condition that occurs when the heart is failing significantly and cannot pump enough blood and oxygen to the brain, kidneys, and other vital organs. Mortality rates are significant and, depending on severity, range from 7% to 40% in the U.S. There is a lack of satisfactory pharmacological intervention to reverse the condition as available therapies have unwanted side effects such as risk for arrhythmias, decreasing blood pressure, renal dysfunction and even increases in mortality that limit their usefulness and position them as "rescue medicines" for severe cases. Market research revealed 99% of 100 U.S.-based clinical cardiologists interviewed who treat cardiogenic shock patients responded that new drug innovation to treat SCAI class B cardiogenic shock patients is highly needed. The cardiogenic shock worldwide total market value is estimated to be \$1.25 billion.

Craig Fraser, CEO and President of Windtree Therapeutics added, "Early cardiogenic shock patients need new therapies that can be used earlier and more broadly to rapidly improve blood pressure and cardiac function without many of the unwanted side effects of existing, older agents that often cause cardiologists to reserve using them. We look forward to announcing topline data and our continued execution of this program, as well as the larger acute heart failure program, as we move forward in developing istaroxime as an innovative new therapy."

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 two 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 cardiac rhythm disturbances and was generally well tolerated.

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 facilitating the transfer of the 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. 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, KL4 surfactant 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 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 clinical trials and clinical trial timelines, in particular with respect to clinical trial sites in Russia, or disruption in supply chain and 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, 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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