Windtree Finds Cardiogenic Shock Has High Cost of US Patient Care and Plans Innovation with the Unique Profile of Istaroxime

March 6, 2023

US Hospital Claims Data Reveals Cardiogenic Shock Patients
Have an Average Hospital Length of Stay of 19.6 Days
Making Its Intensive Patient Care Cost Very High

WARRINGTON, Pa., March 06, 2023 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (“Windtree” or the “Company”) (NasdaqCM: WINT), a biotechnology company focused on advancing late-stage interventions for cardiovascular disorders, is targeting cardiogenic shock as a potential indication for its drug candidate, istaroxime and today announces results of a recently completed market study.

Innovative therapeutic interventions have the potential to decrease the long length of hospital stay associated with cardiogenic shock and its resulting high cost to the health care system. US hospital claims data obtained by Windtree show that in 2020 the US average cardiogenic shock patient length of stay in the hospital was 19.6 days and the median was 10 days. The US average length of stay for any hospitalization was 5.5 days (NIH, Interventions To Decrease Hospital Length of Stay, 2018). Additionally, the resources required to take care of these patients are substantial, frequently requiring ICU or CCU care where costs are high. These patients are at risk to experience clinical worsening that can lead to greater morbidity and mortality. On top of the clinical development plan to demonstrate efficacy and safety in the treatment of cardiogenic shock, Windtree’s development program will also be assessing the potential pharmacoeconomic benefits that a successful therapy can bring in this area.

As previously reported, the SEISMiC Phase 2 study was an international, randomized, double blind, placebo-controlled study that enrolled 60 patients with Society for Cardiovascular Angiography & Interventions (SCAI) Stage B early cardiogenic shock due to severe heart failure with SBP between 75-90 mmHg. The primary endpoint was the difference in SBP area under the curve over six hours after initiating the infusion. The study met its primary endpoint in SBP profile over six hours, with the istaroxime treated group performing significantly better compared to the control group (p =0.017). The improvement persisted through the 24-hour SBP profile measurement, which was also statistically significant (p=0.025).

The Company conducted market research with 100 US based clinical cardiologists who treat cardiogenic shock patients to understand the unmet need. The study revealed that 99% of US Cardiologists surveyed said there is a high need for drug treatment innovation to treat cardiogenic shock patients. When shown a blinded profile of istaroxime, the same cardiologists were asked how likely they would be to use the drug to treat their cardiogenic shock patients and 84% said they would be highly likely or likely to prescribe istaroxime for their patients. The Company considered the market research results encouraging.

“It is not common to see such a high unmet medical need, desirable market value and no competitive drug development,” said Craig Fraser, CEO and President of Windtree Therapeutics. “Additionally, we are encouraged by the positive results of istaroxime’s Phase 2 study in early cardiogenic shock that built upon previous positive results in acute heart failure and demonstrated a unique and attractive therapeutic profile. We believe that istaroxime has the therapeutic effect needed to navigate late-stage development and hopefully address the significant and critical needs of patients in cardiogenic shock. Given the relatively attractive cost and timing of development and, if approved, commercialization by a relatively small team, the program fits well with Windtree’s strategy. We look forward to keeping investors updated on our clinical development progress.”

The Company conducted further research to determine the cardiogenic shock worldwide total market value and estimates it to be $1.25 billion, calculated by using cardiogenic shock patient US hospital claims and worldwide prevalence data multiplied by assumed various regional prices of drug treatment. To the Company’s knowledge, there are no other drug candidates in clinical development for cardiogenic shock at this time.

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 rhythm disturbances.

About Windtree Therapeutics, Inc.
Windtree Therapeutics, Inc. is advancing multiple 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 oral 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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Source: Windtree Therapeutics