Research Finds U.S. Cardiogenic Shock Patients Have High Hospital Inpatient Mortality and Long Length of Stay – Adding to Previously Reported Need for New Pharmacologic Innovation

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Windtree Is Studying Istaroxime in Early Cardiogenic Shock Patients

WARRINGTON, Pa., Nov. 22, 2021 (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 the results of U.S. hospital claims data analysis showing hospital inpatient mortality and length of hospital stay for cardiogenic shock patients.

Cardiogenic shock is a serious condition that occurs when the heart cannot pump enough blood and oxygen to the brain, kidneys, and other vital organs. Cardiogenic shock is a medical emergency and needs to be treated immediately.[1] There is a lack of satisfactory pharmacological intervention to reverse the conditions 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.

U.S. hospital claims data reveals that inpatient mortality for cardiogenic shock patients was 30% in 2020.[2] To help explain the relative severity of cardiogenic shock, the acute myocardial infarction (e.g. “heart attack”) mortality rate in the U.S. was 5% in 2020.[3] The analysis, along with previously reported primary market research with 100 U.S. cardiologists noting a high need for new therapies and their high likelihood of using an agent with istaroxime’s observed clinical profile further reveals the need for improved pharmacologic innovation for cardiogenic shock patients.

Additionally, U.S. hospital claims data was assessed to determine length of stay in the hospital for cardiogenic shock patients. The average length of stay for patients with cardiogenic shock was 19.6 days with a median of 10 days in 2020.[4] According to the Agency for Healthcare Research and Quality (AHRQ), the U.S. national average for a hospital stay of any disease was 4.6 days in 2020.[5]

“We are working to complete our early cardiogenic shock study with istaroxime with the ultimate goal of developing a therapy that can be used earlier to rapidly improve blood pressure and cardiac function without unwanted side effects of many existing, older agents,” said Craig Fraser, CEO and President of Windtree Therapeutics. “In the next few months, we should be in a position to assess the results of this initial early cardiogenic shock study and if positive, will meet with regulatory agencies to discuss the development program and approval requirements and the potential for applying for supportive pathways that could accelerate development timelines.”

The istaroxime phase 2 study in early cardiogenic shock is an international, randomized, double blind, placebo- controlled study. It will include approximately 60 SCAI class B early cardiogenic shock patients with severe heart failure and systolic blood pressures (SBP) between 75-90 mmHg – all will receive standard of care with 30 assigned to istaroxime and 30 assigned to placebo. The patients will receive study drug infusion for 24 hours. The primary endpoint is the difference in SBP area under the curve over six hours after initiating the infusion. Secondary endpoints will include characterization of blood pressure changes over 24 hours, the number of patients requiring rescue therapy (vasopressors, inotropes or mechanical devices), assessment of renal function and measures associated with safety and tolerability. Windtree is targeting topline data results from the study in Q1, 2022.

Sources:

[1] www.nhlbi.nih.gov/health-topics/cardiogenic-shock

[2] Windtree market research, hospital claims data, October 2021

[3] AHRQ Quality Indicators, Inpatient Quality Indicators, v2020, July 2020

[4] Windtree market research, hospital claims data, October 2021

[5] AHRQ, Healthcare cost and utilization project, March 2021

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 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 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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