Market Research Finds 99% Of US Clinical Cardiologists Surveyed Report a High Unmet Need for New Innovative Drug Treatments for Early Cardiogenic Shock Patients (ECS) as Windtree Therapeutics Prepares for Clinical Results from its Istaroxime ECS Study

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Cardiogenic Shock Worldwide Total Market Value Is Estimated To Be $1.25 Billion

WARRINGTON, Pa., Oct. 12, 2021 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology and medical device company focused on advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders, today announced the results of a US physician survey and an assessment of worldwide total market value for cardiogenic shock. After two positive istaroxime phase 2 acute heart failure studies provided the rationale, Windtree began clinical development of istaroxime in the second disease state of early cardiogenic shock.

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 considered a medical emergency and should be treated immediately.[1] It has high in-hospital mortality (~30-40%) and substantial morbidity in survivors.[2] A cardiogenic shock classification system has been developed by the Society for Cardiovascular Angiography and Interventions (SCAI). It categorizes patients from Stage A, who are at risk for cardiogenic shock because of an acute event, through Stage E who are in circulatory collapse requiring cardiopulmonary resuscitation and/or devices for support.

Using cardiogenic shock patient US hospital claims and worldwide prevalence data, Windtree estimates the worldwide total market value of cardiogenic shock to be $1.25 billion. This estimate is calculated by multiplying the patient numbers from the largest markets by assumed various regional prices of drug treatment consistent with other acute care therapies of similar incidence rates. The addressable market for istaroxime will be a subset of the total market value of $1.25 billion.

Additionally, Windtree conducted market research to understand how one of its main customer groups views the need for innovation in this disease. The physician market research (conducted for Windtree by Sermo, a leading provider of real time physician insights) asked 100 US based clinical cardiologists who treat cardiogenic shock patients how needed was new drug innovation to treat SCAI class B cardiogenic shock patients (Windtree refers to these patients as early cardiogenic shock patients). 99 out of 100 cardiologists responded that there was high need for pharmacologic (drug) innovation in SCAI class B cardiogenic shock patients. Additionally, 84% of the cardiologists responded they would be likely to extremely likely to use a drug with a profile reflective of istaroxime's clinical profile for early cardiogenic shock patients. The majority of the cardiologists also responded they would position a drug with the profile of istaroxime for utilization before use of other existing classes of therapies such as inotropes and vasopressors.

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 - 30 assigned to istaroxime and 30 assigned to placebo with systolic blood pressures (SBP) between 75-90 mmHg receiving study drug infusion over 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 expects the study to be completed in Q4 2021.

Sources:

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

[2] Kolte D, American Heart Association; 2014 Jan 13

About Istaroxime

Istaroxime is a first-in-class dual mechanism therapy designed to improve both systolic 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 developing AEROSURF®, a drug-device combination, to deliver its synthetic KL4 surfactant non-invasively to premature infants with respiratory distress syndrome, and is facilitating transfer of 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. Also 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 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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