Windtree Is Leveraging Positive Istaroxime Early Cardiogenic Shock Results to Proactively Engage in Licensing Discussions and Explore Strategic Opportunities to Realize Greater Shareholder Value

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Positive Data for Istaroxime in Early Cardiogenic Shock

Brings Notable Interest from Potential Partners

WARRINGTON, Pa., June 29, 2022 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology company focused on advancing late-stage interventions for acute cardiovascular disorders, today provided an update to its strategy and pursuit related to partnerships and transactions.

During the second quarter, Windtree announced positive clinical results for istaroxime in early cardiogenic shock caused by heart failure that were both consistent with and complementary to previous positive acute heart failure studies. The positive data supported the advancement of a unique new development program in cardiogenic shock due to heart failure. The cardiogenic shock market has an estimated value of $1.25 billion and where research has shown both a high need for new and better drug therapies and receptiveness to the novel and attractive profile of istaroxime. Additionally, the Company believes the opportunity has the potential to be addressed in a what we believe can be a relatively fast and less expensive developmental pathway.

“We believe there is significant value in the area of cardiogenic shock. Since announcing the positive Phase 2 results of our SEISMiC study, there has been notable interest in and potential new opportunities for the Company,” said Craig Fraser, President and CEO. “While the program and its development pathway are quite attractive and have resulted in positive scientific and biopharma industry response, we believe the opportunity is under-recognized and under-valued in the current financial markets. Given this, the Company has begun various proactive engagements and discussions with the intent to create and realize greater shareholder value. Our near-term focus will be on this significant opportunity. To move the program forward and to optimize our cash runway, we reduced operating costs and aligned our resources and activities to prioritize the cardiogenic shock program.”

The recent positive results in early cardiogenic shock have increased both outbound and inbound business development interests and have resulted in numerous discussions to explore global and regional licensing and other forms of partnership. These include our heart failure platform including istaroxime for cardiogenic shock and acute heart failure as well as the follow on pre-clinical, oral SERCA2a activator compounds. While there can be no guarantee of positive outcomes from the business development discussions, the Company’s objective is to monetize the assets and accelerate development with non-dilutive program support for the istaroxime cardiogenic shock development program as well as development of istaroxime in acute heart failure. Beyond traditional licensing, the Company is also exploring broader strategic transactions and other opportunities.

Windtree is making this announcement to inform shareholders and the public that in addition to the active execution of the next steps in our cardiogenic shock program outlined in our corporate deck and filings, the Company is also proactively pursuing partnerships and strategic alternatives with the goal of maximizing value for stockholders. There can be no assurances that the process or discussions will result in transaction, nor as to its outcome or timing and the Company has not made any decisions at this point in time.

About Cardiogenic Shock
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, calculated by using cardiogenic shock patient US hospital claims and worldwide prevalence data multiplied by assumed various regional prices of drug treatment.

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) and in early cardiogenic shock demonstrate that istaroxime infused intravenously significantly improves cardiac function and blood pressure while maintaining a favorable renal profile and 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. 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, including statements with respect to the development pathway for istaroxime in cardiogenic shock and the Company's exploration of licensing and business development opportunities and strategic alternatives. 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: risk that the exploration of licensing and business development opportunities and strategic alternatives may not result in any definitive transaction or enhance stockholder value and may create a distraction or uncertainty that may adversely affect the Company's operating results, business or investor perceptions; the diversion of management's attention from the Company's ongoing business and regular business responsibilities; risk that the contemplated development program for istaroxime in cardiogenic shock may not be eligible for an expedited or lower-cost development pathway; 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 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, 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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