Windtree Therapeutics Announces Issuance of New Pure SERCA2a Activator Patent

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This class of SERCA2a Activators selectively activates SERCA2a and may lead to novel therapies for heart failure beyond the Company's current lead program

WARRINGTON, Pa., Nov. 16, 2023 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. ("Windtree" or the "Company") (NasdaqCM: WINT), a biotechnology company focused on advancing late-stage interventions for cardiovascular disorders, today announced that the European Patent Office has granted Patent No. 3805243, providing composition of matter patent coverage for the pure SERCA2a Activator class of drug candidates. The pure SERCA2a Activators are one of two families of preclinical drug candidates that act on SERCA2a in the Company's pipeline. The pure SERCA2a Activators are devoid of action on the Na+/K+ pump while activating SERCA2a. The new European patent, titled: "ANDROSTANE DERIVATIVES WITH ACTIVITY AS PURE OR PREDOMINANTLY PURE STIMULATORS OF SERCA2A FOR THE TREATMENT OF Heart Failure," provides patent protection until October 9, 2039 for the family of compounds with the pure SERCA2a mechanism of action. The other family of SERCA2a Activators is the dual mechanism of action (inhibition of the Na+/K+ pump and activation of SERCA2a) which the Company previously announced had received composition of matter patents from the European Patent Office and the U.S. Patent and Trademark Office.

The pure SERCA2a Activators have SERCA2a stimulatory activity, are intended to have oral and intravenous administration and would potentially be developed for use in the chronic out-patient heart failure market as well as the acute setting. In the U.S., approximately 6 million people (nearly 2% of the adult population) have heart failure and approximately half of these patients are expected to die within five years of diagnosis; and in the combined U.S., EU and Japan markets, there are more than 18 million patients suffering from heart failure. Heart failure is the leading cause of hospitalization in patients aged 65 years and older.

"SERCA2a activity is decreased in heart failure. Windtree believes activation of SERCA2a represents a potentially important advancement in heart failure treatment for patients," said Craig Fraser, CEO of Windtree Therapeutics. "Heart failure with preserved ejection fraction (HFpEF) is a condition in which the heart's main pumping chamber (left ventricle) becomes stiff and unable to fill properly. SERCA2a activation has the potential to be beneficial in this type of heart failure that accounts for nearly one-half of the chronic heart failure patients. Given the potential for oral (tablet) use, it could be utilized in both the chronic out-patient and hospital markets."

About Pure SERCA2a Activators
These compounds activate SERCA2a without activity on the Na+/K+ pump. Windtree Therapeutic's research program is evaluating these preclinical product candidates in heart failure.

About Dual Mechanism SERCA2a Activators
Dual Mechanism SERCA2a Activators activate SERCA2a and inhibit the Na+/K+ pump. Windtree Therapeutic's research program is evaluating these preclinical product candidates in heart failure.

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 pre-clinical heart failure platform includes follow-on, potentially oral, 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 and the evolving events in Israel and Gaza, 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 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; the rate

and degree of market acceptance of the Company's product candidates, if approved; and 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 the evolving events in Israel and Gaza, 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. 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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