Windtree Announces Issuance of Composition of Matter Patent for Dual Mechanism SERCA2a Activators by the US Patent and Trademark Office

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Patent provides protection through late 2039 for drug candidates with potential to improve cardiac function in heart failure patients

WARRINGTON, Pa., Aug. 23, 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 reported that the United States Patent and Trademark Office (USPTO) has issued US Patent No. 11,730,746 covering the Company’s dual mechanism SERCA2a Activators. The new composition of matter patent, titled: “17BETA-HETEROCYCLYL-DIGITALIS LIKE COMPOUNDS FOR THE TREATMENT OF HEART FAILURE,” provides patent protection through late 2039.

The newly issued patent follows the Company’s announcement in April 2023 that the European Patent Office granted Patent No. 3599243, which also provides patent coverage for the dual mechanism SERCA2a Activator class of drug candidates. Windtree has preclinical drug candidates with dual mechanisms of action (inhibition of the Na+/K+ pump and activation of SERCA2a) as well as pure SERCA2a activators (devoid of action on the Na+/K+ pump).

SERCA2a has been known to play a key role in heart failure and has thus been a much sought after but elusive target for several potential drug therapies. Istaroxime and these follow-on SERCA2a Activators look to deliver on the potential of SERCA2a activation in heart failure. The dual mechanism compounds activate SERCA2a and inhibit the Na+/K+ pump in a manner similar to istaroxime, which is administered intravenously (IV) and is the Company’s lead program for cardiogenic shock and acute decompensated heart failure. These new dual mechanism SERCA2a Activator product candidates are intended to be both oral and IV therapies, which could result in a hospital inpatient therapy for acute decompensated heart failure as well as an outpatient oral therapy for hospital discharge and chronic heart failure treatment.

“We are making steady progress with our IP portfolio strategy for the dual mechanism SERCA2a Activator family of drug candidates,” said Craig Fraser, Chief Executive Officer of Windtree Therapeutics. “We plan to position these new compounds as a ‘fast follow-on’ to istaroxime while offering the potential of oral bioavailability for use as a treatment for chronic heart failure. Much may be accomplished for heart failure patient treatment with this innovation.”

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, including oral and intravenous SERCA2a Activator heart failure compounds.

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 early cardiogenic shock or acute decompensated heart failure demonstrate that istaroxime infused intravenously significantly improves cardiac function and blood pressure without increasing heart rate or the incidence of cardiac rhythm disturbances.

About Windtree Therapeutics, Inc.
Windtree Therapeutics, Inc. is advancing 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 cardiogenic shock and acute decompensated heart failure. Windtree’s heart failure platform includes follow-on 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. and Zhaoke Pharmaceutical (Hefei) Co. 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 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 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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