Windtree Therapeutics Announces License Agreement with Lee's Pharmaceuticals to Develop and Commercialize Istaroxime, Dual Mechanism SERCA2a Activators and Rostafuroxin for Greater China / Asia Pacific Region

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Windtree to receive potential future milestones up to $138MM plus up to low double digit royalties and full coverage for all development, manufacturing, regulatory and commercialization costs for products in the licensed territory

Lee's plans to initiate and fund Phase 3 for istaroxime in acute heart failure in Greater China while Windtree executes a global cardiogenic shock program

WARRINGTON, Pa., Jan. 17, 2024 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. ("Windtree" or the "Company") (NasdaqCM: WINT), a biotechnology company focused on advancing late-stage interventions for critical cardiovascular disorders, today announced it has entered into a license agreement with Lee's Pharmaceutical (HK) Limited ("Lee's") for the development and commercialization of Windtree's product candidate istaroxime in Greater China, including for acute heart failure and cardiogenic shock. In addition to istaroxime, the agreement also licenses Windtree's preclinical next-generation SERCA2a activators, known as dual mechanism SERCA2a activators, and rostafuroxin, a Phase 2 product candidate for hypertension associated with specific genotypes.

"We believe Windtree's pipeline has great potential and we expect this license agreement will progress development in the treatment of heart failure. We see the agreement as validation of the significant heart failure market opportunity for istaroxime and, when coupled with the unique profile and our positive clinical results to date, demonstrates the potential for istaroxime to provide meaningful benefit in heart failure and cardiogenic shock patients. Greater China holds a significant, if not the largest, heart failure patient population. Windtree already studied istaroxime in heart failure patients in China and the results of the Company's positive Phase 2b study have been presented and published. Lee's intends to start Phase 3 for istaroxime in acute heart failure while Windtree continues to advance its global cardiogenic shock program," said Craig Fraser, Windtree's Chief Executive Officer. "Importantly, the agreement also provides support for development of one or more fast follow-on products from our next generation dual mechanism SERCA2a activators that have potential for oral formulation for treatment of chronic heart failure."

Lee's will receive a license to develop and commercialize istaroxime, the dual mechanism SERCA2a activators and rostafuroxin in the Greater China region for which Windtree is entitled to receive up to $138.1 million in payments upon the achievement of certain milestones (approximately $100 million of which relate the heart failure platform of assets) plus up to low double-digit royalties. Lee's will be responsible for funding all development, manufacturing, regulatory and commercial costs for the covered products in the licensed region. This financial support will apply to all indications studied in the region as well as the portion of global clinical trials, such as the cardiogenic shock trial, which take place in the licensed region. The agreement also establishes a joint steering committee and a joint development committee to oversee the regional development (with Windtree retaining final decision rights over clinical protocols) and a joint commercialization committee.

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

About Rostafuroxin
Rostafuroxin is a novel product candidate for the treatment of hypertension in patients with a specific genetic profile.

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 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; the economic and social consequences of the COVID-19 pandemic 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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