Windtree Eliminates $15 Million Contingent Liability to Deerfield Management Company

January 25, 2024

WARRINGTON, Pa., Jan. 25, 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 that the Company entered an Exchange and Termination Agreement with affiliates of Deerfield Management Company (collectively, “Deerfield”) pursuant to which Deerfield has agreed to terminate its rights under the Company’s 2017 Exchange and Termination Agreement to receive up to $15,000,000 in development and commercial milestone payments associated with AEROSURF®, an acute pulmonary drug/device combination intended to treat premature infants with respiratory distress syndrome. Windtree out-licensed global rights to AEROSURF® in 2022.

“We appreciate the support of Deerfield in our efforts to strengthen our financial position with the completion of this transaction and the expected elimination the $15 million contingent liability. As a result, we believe we have meaningfully strengthened and simplified our balance sheet,” said Craig Fraser, Windtree's President and Chief Executive Officer. “In addition, our lead asset, istaroxime, is progressing in two ongoing clinical trials in cardiogenic shock and we recently announced a new regional license with Lee’s Pharmaceuticals intended to initiate Phase 3 work in acute heart failure and potentially provide non-dilutive revenue. Along with significantly cutting our cash burn rate since the second half of 2022, I believe we have strengthened the company through recent transactions such as this one. We look forward to keeping our shareholders updated on our progress.”

In exchange for Deerfield terminating its rights to receive any milestone payments, the Company agreed to issue to Deerfield 608,272 shares of the Company’s common stock and to pay Deerfield a $100,000 cash payment upon execution of the agreement. In addition, the Company agreed to pay Deerfield an additional $100,000 on the earlier of (i) January 24, 2025 or (ii) the Company receiving a specified amount of gross proceeds from debt or equity financings occurring on or after the agreement date.

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 Lyophilized Lucinactant and AEROSURF®
Lyophilized lucinactant is an investigational synthetic peptide (KL4 surfactant) containing drug product that is being developed to improve the management of RDS in premature infants who may not have fully developed natural lung surfactant and may require surfactant therapy to sustain life. AEROSURF® (lucinactant for inhalation) is a drug/device combination designed to deliver aerosolized KL4 surfactant noninvasively using our proprietary ADS technology and potentially may meaningfully reduce the use of invasive endotracheal intubation and mechanical ventilation. The KL4 and AEROSURF® program was globally out-licensed to Lee’s Pharmaceutical and Zhaoke Pharmaceutical in 2022.

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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