Windtree Acquires Early-Stage, Novel Oncology Platform and Completes $1.5 Million Convertible Note Bridge Financing

April 8, 2024

WARRINGTON, Pa., April 08, 2024 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. (“Windtree” or the “Company”) (NasdaqCM: WINT), today announced that on April 2, 2024 the Company entered into an asset purchase agreement with Varian Biopharmaceuticals, Inc. (“Varian”) to acquire certain of its assets, including a proprietary atypical protein kinase C iota inhibitor (aPKCi). The Company also completed a $1.5 million convertible note bridge financing.

The acquired Varian asset platform is a novel, potential high-potency, specific, aPKCi with possible broad use in oncology as well as certain rare malignant diseases. The asset platform includes two formulations: VAR-101 (topical) and VAR-102 (oral).

In consideration of the purchase of the Varian assets, on April 2, 2024, the Company issued to certain of Varian’s creditor investors a total of 5,500 shares of Series B Convertible Preferred Stock, par value $0.001 per share (the “Preferred Shares”), that have an initial conversion price of $0.3603, which is subject to adjustment to no lower than $0.0721. Dividends on the Preferred Shares shall accrue at 10.0% per annum, subject to limited exceptions. With successful development, the Company would pay up to $2.3 million in milestone payments upon the achievement of certain regulatory and clinical development milestones relating to the acquired assets with the Company having the option to pay such milestone payments either in cash or the Company’s common stock.

Protein kinase inhibitors are a class of anti-cancer therapeutics that have made a significant impact on the treatment of cancers. Among the kinase targets for further development are the Protein Kinase C (“PKC”) family, which are key components of many signaling pathways that drive the formation of cancer. aPKCi is a promising atypical PKC iota isozyme with defined oncogenic role in multiple signaling pathways, and in the initiation and development of multiple tumor types. GLI-1 is a transcription factor at the terminal end of the Hedgehog (Hh) signaling pathway, and many other important pathways, including RAS-RAF, TGFb, and P14K-AKT-mTOR. In many tumor types, high levels of GLI-1 expression is a negative prognostic marker. Pre-clinical data of the acquired platform showed dose dependent modulation of basal cell carcinoma cell viability and GLI-1 pathway modulation in vitro, as well as dose dependent anti-tumor activity in xenograft mouse models of non-small cell lung cancer and pancreatic ductal carcinoma. The protein kinase inhibitor adds to Windtree’s product candidate portfolio of novel pre-clinical and late-stage clinical product candidates and development programs, including SERCA2a activators and programs in out-licensed partnership.

“Completion of the Varian asset acquisition and the bridge financing represents a potentially transformative next step for Windtree. Adding an innovative protein kinase inhibitor that has what we believe is an exciting pre-clinical data package with two formulations in development to our existing portfolio of product candidates creates an additional opportunity for value creation as we advance and look to partner our late and early-stage SERCA2a activator platform, including istaroxime,” said Craig Fraser, Chief Executive Officer of Windtree. “We see potential application in both rare and more prevalent tumor types, both in monotherapy and in combination with other agents. We believe there will be options for targeted disease selection and differentiation due to the potential for high specificity and topical formulation to treat various skin cancers. In the weeks to come, I look forward to providing updates on the use of this newly acquired capital and plans for our portfolio and programs, including licensing activity for istaroxime and our SERCA2a activators as well as our company strategy to have a stronger balance sheet and opportunities to further leverage our experience to grow the business.”

In addition to the asset purchase, on April 2, 2024, the Company entered into a securities purchase agreement with certain investors whereby the Company agreed to sell to such investors $1.5 million in senior convertible notes (the “Notes”) for aggregate gross proceeds of $1.5 million (the “Notes Offering”). The Notes have an initial conversion price of $0.3603, which is subject to adjustment upon the occurrence of specified events to no lower than $0.0721 (subject to any stock split, stock dividend, stock combination, recapitalization or other similar transaction). The Company may, at its option, redeem the Notes subject to certain conditions and terms in the securities purchase agreement. The Notes may convert in a subsequent financing or will accrue interest at a rate of 10% per annum and mature on January 2, 2025, unless previously converted or redeemed. The Company intends to use the net proceeds from the Notes Offering for general corporate purposes.

The Company agreed to seek stockholder approval for the issuance of all of the Company’s common stock issuable upon conversion of the Notes and the Preferred Shares in accordance with the rules and regulations of the Nasdaq Stock Market.

Additional details are available by reading the Company’s Current Report on Form 8-K relating to the Varian asset acquisition and senior convertible note bridge financing, which was filed with the Securities and Exchange Commission on April 8, 2024.

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 Pure SERCA2a Activators

These compounds activate SERCA2a and Windtree Therapeutics' research and development program is evaluating these preclinical product candidates, including oral and intravenous SERCA2a activator heart failure compounds.

About Windtree Therapeutics, Inc.

Windtree Therapeutics, Inc. is a biotechnology company focused on advancing early and late-stage innovative therapies for critical conditions and diseases. Windtree's portfolio of product candidates includes istaroxime, a Phase II candidate with SERCA2a activating properties for acute heart failure and associated cardiogenic shock, pre-clinical SERCA2a activators for heart failure and VAR-101 and VAR-102, pre-clinical precision aPKCi inhibitors that are being developed for potential in rare and broad oncology applications. Windtree also has a licensing business model with partnership out-licenses currently in place.

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: the Company's ability to secure significant additional capital as and when needed; the Company's ability to obtain approval for the issuance of all of the Company's common stock issuable upon conversion of the Notes and the Preferred Shares; risks and uncertainties associated with the success and advancement of the clinical development programs for istaroxime and the Company's other product candidates, including pre-clinical candidates such as VAR-101 and VAR-102; 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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