Windtree Announces Expansion of Patents with Issuance of Istaroxime Patent for Hong Kong

November 4, 2024

Supports Licensing Partner's Phase 3 Activities in Acute Heart Failure

WARRINGTON, Pa., Nov. 04, 2024 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. ("Windtree" or the "Company") (NasdaqCM: WINT), a biotechnology company focused on advancing early and late-stage innovative therapies for critical conditions and diseases, today announced the issuance of an istaroxime patent for Hong Kong. The patent is entitled, "Istaroxime-containing intravenous formulation for the treatment of heart failure (AHF)." The claims are directed formulations comprising istaroxime, pharmaceutically acceptable salts thereof, and methods of use, alone, or in combination with other agents useful for the treatment and management of AHF. The application number is 62021023600.1. The Notice of Publication of the Registration and Grant has a date of October 9, 2024 and will expire in 2039. The patent for mainland China was granted earlier this year (patent number ZL201980003356.1).

Windtree's licensing partner, Lee's Pharmaceutical (HK) Ltd. ("Lee's"), is planning a Phase 3 program in acute heart failure for its Greater China territory. In alignment with the licensing agreement, Lee's is funding all trials and development conducted in their region. Windtree is collaborating with Lee's on the Phase 3 program and has final signing authority on the protocol. Acute heart failure is the #1 cause of hospitalization in patients >65 years of age in many regions of the world and as Windtree advances its cardiogenic shock program globally, Lee's is progressing the acute heart failure intended indication.

Istaroxime is a novel, first-in-class investigational therapy that is intended to improve systolic contraction and diastolic relaxation of the heart while also increasing blood pressure and maintaining renal function with a generally favorable safety profile. Istaroxime has been studied in four positive Phase 2 trials enrolling patients with acute heart failure and early cardiogenic shock due to heart failure.

"Acute heart failure is responsible for millions of hospitalizations annually throughout the world and there is a high need for innovation in drug treatment," said Craig Fraser, Chairman and CEO of Windtree. "Expansion of our patent estate helps support our Greater China regional licensing agreement with Lee's, through which Windtree may receive up to $138 million in potential milestones and low double digit royalties. We will continue to support our partner with patent and other development work."

About Istaroxime
Istaroxime is a first-in-class dual-mechanism therapy designed to improve both systolic and diastolic cardiac function. Istaroxime is designed as 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 have demonstrated 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 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 2 candidate with SERCA2a activating properties for acute heart failure and associated cardiogenic shock, preclinical SERCA2a activators for heart failure and preclinical 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 statements related to the potential clinical effects of istaroxime; the potential benefits and safety of istaroxime; the clinical development of istaroxime; and our research and development program for treating patients in early cardiogenic shock due to heart failure. Such statements constitute 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, among other things: the Company's ability to secure significant additional capital as and when needed; the Company's ability to achieve the intended benefits of the aPKCi asset acquisition with Varian Biopharmaceuticals, Inc.; the Company's risks and uncertainties associated with the success and advancement of the clinical development programs for istaroxime and the Company's other product candidates, including preclinical oncology candidates; 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 the Middle East, 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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Source: Windtree Therapeutics