Windtree Extends Scientific Collaboration in Heart Failure Studying Its SERCA2a Activators with the University of Milan-Bicocca

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Collaboration to focus on the continued development of chronic heart failure treatment SERCA2a activator compounds adding to Windtree's acute treatment Istaroxime

WARRINGTON, Pa., March 22, 2021 /PRNewswire/ -- Windtree Therapeutics, Inc. (NasdaqCM: WINT), a biotechnology and medical device company focused on advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders, today announced the company is extending its collaboration with the University of Milan-Bicocca for the discovery and development of new SERCA2a compounds for the potential treatment of chronic and acute human heart failure. Over the next 12 months, the program will focus on the further characterization of Windtree's SERCA2a activators and their interaction with SERCA2a and associated regulatory proteins.

"We are delighted to extend our collaboration with the scientific team at the University in Milan-Bicocca as we continue to develop SERCA2a activators and understand their potential in chronic and acute heart failure," said Steve Simonson, M.D., senior vice president and chief medical officer. "The potential role of SERCA2a activation as a treatment in heart failure (including heart failure with preserved ejection fraction, or HFpEF) has been recognized but successful intervention at this target has been elusive. By utilizing a novel approach to SERCA2a activation, Windtree has developed a portfolio of oral (and i.v.) SERCA2a activitors which are progressing through pre-clinical testing and development. This collaboration strengthens and extends the SERCA2a program and will provide important scientific support to Windtree efforts to bring these compounds forward."

Two aspects of SERCA modulation to be explored under the terms of this collaboration include the antiarrhythmic potential and modulation of smooth muscle activity resulting from SERCA2a activation. Ahead of this preclinical research, Windtree is advancing istaroxime, a first-in-class, dual action, luso-inotropic agent for the treatment of acute decompensated heart failure. Istaroxime is currently being assessed in a Phase 2 study in patients experiencing early cardiogenic shock and has been granted Fast Track designation by the FDA based on positive Phase 2a and Phase 2b trial results in patients with acute heart failure. Istaroxime has a dual mechanism of action including inhibition of the sodium-potasium ATPase and activation of SERCA2a.

About Windtree Therapeutics
Windtree Therapeutics, Inc. is advancing multiple late-stage interventions for acute cardiovascular and pulmonary disorders to treat patients in moments of crisis. Using new 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 acute heart failure and early cardiogenic shock in heart failure. Windtree has also focused on developing AEROSURF® as a non-invasive surfactant treatment for premature infants with respiratory distress syndrome, and is facilitating transfer of clinical development of AEROSURF® to its licensee in Asia, Lee's HK, while Windtree evaluates other uses for its synthetic KL4 surfactant for the treatment of acute pulmonary conditions including lung injury due to viral, chemical and radiation induced insults. Also, in its portfolio is rostafuroxin, a novel precision drug product targeting hypertensive patients with certain genetic profiles.

For more information, please visit the Company's website at www.windtreetx.com.

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 ongoing economic and social consequences of the COVID-19 pandemic, including any adverse impact on the Company's clinical trials or disruption in supply chain; the success and advancement of the clinical development programs for istaroxime, KL4 surfactant 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, aerosol delivery systems and other materials on a timely basis and in sufficient amounts; risks relating to rigorous regulatory requirements, including that: (i) the FDA 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 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; and the rate and degree of market acceptance of the Company's product candidates, if approved. These and other risks are described in the Company's periodic reports, including the 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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