



## Windtree Announces Issuance of New U.S. Patent Covering Technology on Its Redesigned AEROSURF® Device

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### New patent covers updated aerosol delivery system and design until 2039

WARRINGTON, Pa., Feb. 16, 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 that the United States Patent and Trademark Office (USPTO) has issued U.S. Patent No. 10,874,818, covering features of the aerosol delivery system (ADS) for the Company's AEROSURF® drug delivery device. This patent adds to the robust patent portfolio exclusively licensed to Windtree in the field of aerosolized delivery of pulmonary surfactants, alone or combined with other agents.

Windtree completed design verification of the newly designed ADS platform, which utilizes the same aerosolization technology used during the phase 2 clinical program evaluating AEROSURF in treating preterm infants with Respiratory Distress Syndrome (RDS), but with improved ergonomics, interface, controls, and dose monitoring in a modular design. The new ADS also implements design changes to potentially mitigate the risks of device-related treatment interruptions experienced in the prototype device used in the AEROSURF phase 2b clinical trial. The Company believes the redesigned device may support enhanced clinical outcomes by potentially allowing for reduced time to initial administration of our KL4 surfactant and reduced time intervals between doses compared to the phase 2 prototype. This patent protection covers device elements that will facilitate modification for use in a wider range of patients including adults with respiratory disease or for drug delivery.

The new U.S. Patent covers the ADS, which includes an aerosol delivery unit, the cartridge receiver, assembly, an inductor assembly, capillary tube, and susceptor for the delivery of aerosol from liquid formulation. Additionally, the patent allows for the ADS to include a power control unit and operation interface. The patent extends the Company's device protection until 2039.

"We are pleased to strengthen our intellectual property protection with the addition of the U.S. patent covering a key element in our AEROSURF drug delivery device," said Craig Fraser, CEO and President. "This new in-licensed patent expands our overall IP portfolio surrounding AEROSURF. We are active in strengthening the global patent estate for all of our assets and technology, not just with AEROSURF but also with our cardiovascular portfolio including our lead asset, istaroxime, for acute heart failure."

### 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.windtreetxt.com](http://www.windtreetxt.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, AEROSURF®, 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 (ADS) 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](http://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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