Windtree Therapeutics

Windtree and Eleison Announce Initial Results of Delivering Inhaled Lipid Cisplatin (ILC) Utilizing Windtree's Drug Delivery Technology

Results Demonstrate Feasibility to Aerosolize ILC for Use in Thoracic Oncology Treatment

WARRINGTON, Pa. and PRINCETON, N.J., June 4, 2019 /PRNewswire/ -- Windtree Therapeutics, Inc. (OTCQB: WINT), a biotechnology and medical device company focused on developing drug product candidates and medical device technologies to address acute cardiovascular and pulmonary diseases, and Eleison Pharmaceuticals LLC, a specialty pharmaceutical company developing life-saving therapeutics for rare cancers, today jointly announced positive results of the feasibility study using Windtree's proprietary Aerosol Delivery System (ADS) aerosolization technology to deliver Eleison's inhaled lipid cisplatin (ILC).

Eleison has an exclusive worldwide license to ILC, a novel, sustained-release formulation of cisplatin in a nanoscale lipid-based complex administered via inhalation or intraperitoneally. ILC, when administered by inhalation, can deliver high levels of sustained release cisplatin targeted to the lung, with minimal systemic-related toxicities. Eleison is developing ILC for lung cancer and completed a phase 2 study of ILC in patients with bone cancer (osteosarcoma) metastatic to the lung.

Windtree has licensed and further developed its ADS utilizing innovative aerosolization technology to deliver pulmonary surfactants (alone or in combination with any other pharmaceutical compound(s)) as an active ingredient for the prevention or treatment of respiratory indications. The ADS has been shown to deliver high aerosol output rates, small and uniform particle size, and consistent aerosol characteristics throughout extended dosing periods, including particularly difficult to aerosolize substances like lipids. The ADS is the technology used in the medical device component of Windtree's AEROSURF® combination drug/device product candidate currently being studied in premature infants with respiratory distress syndrome (RDS).

The feasibility assessment demonstrated that Windtree's ADS technology can effectively aerosolize ILC and at a higher volume compared to conventional nebulizer technology. In the feasibility study, the ADS technology produced in 20 minutes approximately the same volume of aerosolized ILC that required approximately two hours to produce in a phase 2 clinical trial treating osteosarcoma lung metastases with ILC delivered by conventional nebulizer technology. It is expected that a more rapid aerosol delivery rate has the potential to improve the treatment experience for patients receiving ILC. The feasibility study also confirmed the aerosolized drug produced by the ADS technology had the characteristics and particle size appropriate for delivering drug to the lung and was comparable to the aerosolized drug used in the prior ILC clinical trial. Importantly, the cytotoxicity of the aerosolized ILC measured in an appropriate cell line was maintained. The feasibility study also raised the possibility that the ADS technology has the potential to improve the efficiency of dosing and decrease the wasted product inherent in conventional nebulizer technology.

"Combining faster delivery time with our aerosolized ILC and using less volume and having less waste would have the potential to enhance the usability and acceptance of ILC. We are very excited about the prospects of this innovative combination to further differentiate our program and look forward to continued opportunities for collaboration between Eleison and Windtree," stated Edwin Thomas, Eleison's CEO.

"We are very encouraged by this research collaboration to date, which has demonstrated the drug delivery potential of our device technology beyond treating premature infants with RDS," commented Craig Fraser, CEO of Windtree Therapeutics. "The ADS is an innovative platform that we plan to continue to study in our AEROSURF development program and potentially in additional acute care drug delivery uses, starting with this important area of oncology and Eleison's unique product candidate ILC".

About Windtree Therapeutics

Windtree Therapeutics, Inc. is a clinical-stage, biopharmaceutical and medical device company focused on the development of novel therapeutics intended to address significant unmet medical needs in important acute care markets. Windtree has three lead clinical development programs and multiple pre-clinical programs spanning respiratory and cardiovascular disease states, including istaroxime, a novel, dual-acting agent being developed to improve cardiac function in patients with acute heart failure with a potentially improved side effect profile from existing treatments; AEROSURF®, an innovative combination drug/device product candidate that is designed to deliver the Company's proprietary synthetic, peptide-containing surfactant non-invasively to premature infants with respiratory distress syndrome (RDS); and rostafuroxin, a novel precision drug product being developed to target hypertensive patients with certain genetic profiles in the important group of patients with resistant hypertension. Windtree also has multiple pre-clinical products including potential heart failure therapies delivered orally that are based on SERCA2a mechanism of action.

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

About Eleison Pharmaceuticals

Eleison's mission is to acquire, develop, and commercialize clinical stage drug candidates for "orphan" oncology indications, providing new hope for patients with rare life-threatening diseases. The Company has two programs in late-stage development, including ILC, and is also currently conducting a global Phase III clinical trial of glufosfamide in pancreatic cancer. Eleison was founded in 2009 and is headquartered in Princeton, NJ. Additional information about Eleison can be found at the Company's website www.eleison-pharma.com

Forward-Looking Statements

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to certain risks and uncertainties that could cause actual results, including projections of future cash balances and anticipated cash outflows, to differ materially from the statements made. Examples of such risks and uncertainties include: the risk that, as a development company with limited resources and no operating revenues, the Company's ability to continue as a going concern in the near term is highly dependent upon successful and timely advancement of its clinical development programs for

istaroxime and AEROSURF®; risks that Windtree will be unable to secure significant additional capital as and when needed, or to access debt or equity financings, which could result in substantial equity dilution; risks related to Windtree's development programs, which may involve time-consuming and expensive pre-clinical studies and clinical trials and which may be subject to potentially significant delays or regulatory holds, or fail; risks related to technology transfers to contract manufacturers and manufacturing development, and problems or delays encountered by Windtree, 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 Windtree 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 Windtree's products, and (ii) changes in the national or international political and regulatory environment may make it more difficult to gain regulatory approvals; risks related to Windtree's efforts to maintain and protect the patents and licenses related to its products; and other risks and uncertainties described in Windtree's filings with the Securities and Exchange Commission including the most recent reports on Forms 10-K, 10-Q and 8-K, and any amendments thereto.

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