



Windtree Announces License and Supply Agreement to Become Sourcing Partner for a Small Biotech with an FDA Approved Product

Transaction is part of the Company's new corporate strategy to become a revenue generating biotech

WARRINGTON, Pa., March 20, 2025 (GLOBE NEWSWIRE) -- Windtree Therapeutics, Inc. ("Windtree" or the "Company") (NasdaqCM: WINT), a biotechnology company focused on becoming a revenue generating biotech and advancing early and late-stage innovative therapies for critical conditions and diseases, is pleased to announce that it has entered into a License and Supply Agreement to become the sourcing partner for Evofem Biosciences, Inc. (OTCQB: EVFM) for one of Evofem's FDA-approved products -- PHEXXI® (lactic acid, citric acid and potassium bitartrate). The product is a first-in-class hormone-free, on-demand prescription contraceptive vaginal gel that women control. PHEXXI annual revenues have grown to more than \$19 million with more than 96,000 boxes of 12 pre-filled applicators sold in full year 2024.

Windtree has manufacturing contacts that we believe are capable of reducing pharmaceutical product cost of goods for PHEXXI. Pursuant to the License and Supply Agreement, Windtree will serve as the sourcing partner to Evofem and aims to help generate profitable revenue by contracting with the manufacturer to produce PHEXXI at a cost that is significantly below current levels. Evofem will maintain ownership of the asset and continue to commercialize PHEXXI in the United States and internationally through strategic partnerships.

"Windtree announced our new corporate strategy to become a revenue generating biotech in January 2025," said Jed Latkin, CEO of Windtree. "This License and Supply Agreement with Evofem is a first step in our plan to generate profitable revenue to provide value to our stockholders. Using our extensive contacts across the globe, we have engaged with a pharmaceutical manufacturer on the plan to produce PHEXXI. We look forward to this opportunity. We anticipate that our manufacturing partner will work with us as we do the tech transfer and manufacture the initial batches and the validation batches in line with the FDA requirements."

"Global expansion of PHEXXI has always been a critical mandate for Evofem, but a significant hurdle has been high

manufacturing costs which make commercialization cost-prohibitive in many markets outside of the U.S.," said Sandra Pelletier, CEO of Evofem. "The meaningful decrease in the per-box cost of PHEXXI that we expect to achieve with Windtree's assistance should allow Evofem to take PHEXXI into new, price-sensitive global markets where there is great need for non-hormonal contraceptives that women control. Our goal is to empower women; and to have PHEXXI available in all markets around the world is a big step in that direction."

[Sandra Pelletier is the President and Chief Executive Officer of Evofem, and is Interim Chair of Evofem's board of directors, and also serves on Windtree's board of directors.]

About Windtree Therapeutics, Inc.

Windtree Therapeutics, Inc. is a biotechnology company focused on becoming a revenue generating biotech and 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 Windtree serving as a sourcing partner to Evofem; potential future positive revenue generation; manufacturing capabilities; decreasing the cost of PHEXXI; and Evofem taking PHEXXI into new global markets. 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 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 acquire revenue generating subsidiaries; the market's reaction to potential acquisitions by the Company; 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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