Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Announces Executive Leadership Transition

December 3, 2024

ISELIN, N.J., Dec. 03, 2024 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company that achieved regulatory approval in the European Union and the United Kingdom earlier this year for LYTENAVA ™ (bevacizumab gamma), the first ophthalmic formulation of bevacizumab authorized for the treatment of wet age-related macular degeneration (wet AMD) in adults, today announced that Russell Trenary has stepped down as the Company's President and Chief Executive Officer (CEO), effective immediately. Lawrence Kenyon, Executive Vice President, Chief Financial Officer and member of the board of directors, has been appointed Interim CEO.

"On behalf of our management team and board, I would like to thank Russ for his dedication and many contributions to the Company and wish him the best in his future endeavors," commented Randy Thurman, the Company's Executive Chairman. "We are pleased to have Larry lead Outlook Therapeutics during this transition period. We remain committed to our plans to resubmit the BLA for ONS-5010 in the first quarter of calendar 2025 and to begin sales of LYTENAVA™ in Europe in the first half of calendar 2025."

Mr. Kenyon has served as the Company's Chief Financial Officer and Secretary since September 2015. He has been a member of Outlook Therapeutics' board of directors since August 2018 and also served as the Company's President and CEO from August 2018 to July 2021.

The Company has engaged an executive search firm to work with the board of directors to identify a permanent CEO.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a biopharmaceutical company focused on the development and commercialization of ONS-5010/LYTENAVA ™ (bevacizumab-vikg; bevacizumab gamma), for the treatment of retina diseases, including wet AMD. LYTENAVA™ (bevacizumab gamma) is the first ophthalmic formulation of bevacizumab to receive European Commission and MHRA Marketing Authorization for the treatment of wet AMD. Outlook Therapeutics is working to initiate its commercial launch of LYTENAVA™ (bevacizumab gamma) in the EU and the UK as a treatment for wet AMD, expected in the first half of calendar 2025. In the United States, ONS-5010/LYTENAVA ™ is investigational, is being evaluated in an ongoing non-inferiority study for the treatment of wet AMD, and if successful, the data may be sufficient for Outlook to resubmit a BLA to the FDA in the United States. If approved in the United States, ONS-5010/LYTENAVA™ would be the first approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD.

Forward-Looking Statements

This press release contains forward-looking statements. All statements other than statements of historical facts are "forward-looking statements," including those relating to future events. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "continue," "expect," "may," "will," or "would" the negative of terms like these or other comparable terminology, and other words or terms of similar meaning. These include, among others, plans for commercial launch of LYTENAVA™ in the UK and EU and timing thereof, Outlook Therapeutics' commercialization strategy, the therapeutic potential of LYTENAVA™ as a treatment of wet AMD, ONS-5010's potential as the first FDA-approved ophthalmic formulation of bevacizumab for use in treating retinal indications, including wet AMD, in the United States, expectations concerning Outlook Therapeutics' ability to remediate or otherwise resolve deficiencies identified in the CRL issued by the FDA, including plans to resubmit the BLA for ONS-5010 and the timing thereof, expectations concerning decisions of regulatory bodies and the timing thereof, and other statements that are not historical fact. Although Outlook Therapeutics believes that it has a reasonable basis for the forward-looking statements contained herein, they are based on current expectations about future events affecting Outlook Therapeutics and are subject to risks, uncertainties and factors relating to its operations and business environment, all of which are difficult to predict and many of which are beyond its control. These risk factors include those risks associated with developing and commercializing pharmaceutical product candidates, risks of conducting clinical trials and risks in obtaining necessary regulatory approvals, including the risk that the data from the NORSE EIGHT trial does not support the resubmission or subsequent filing by the FDA of the ONS-5010 BLA, the content and timing of decisions by regulatory bodies, the sufficiency of Outlook Therapeutics' resources, as well as those risks detailed in Outlook Therapeutics' filings with the Securities and Exchange Commission (the SEC), including the Annual Report on Form 10-K for the fiscal year ended September 30, 2023, filed with the SEC on December 22, 2023, and future quarterly reports Outlook Therapeutics files with the SEC, which include uncertainty of market conditions and future impacts related to macroeconomic factors, including as a result of the ongoing overseas conflicts, high interest rates, inflation and potential future bank failures on the global business environment. These risks may cause actual results to differ materially from those expressed or implied by forward-looking statements in this press release. All forward-looking statements included in this press release are expressly qualified in their entirety by the foregoing cautionary statements. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Outlook Therapeutics does not undertake any obligation to update, amend or clarify these forward-looking statements whether as a result of new information, future events or otherwise, except as may be required under applicable securities law.

Investor Inquiries:
Jenene Thomas
Chief Executive Officer
JTC Team, LLC
T: 908.824.0775
OTLK@jtcir.com

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