

Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Provides Update Following Type A Meeting with FDA Regarding ONS-5010/LYTENAVA™ (bevacizumab-vikg)

March 5, 2026

ISELIN, N.J., March 05, 2026 (GLOBE NEWSWIRE) -- [Outlook Therapeutics, Inc.](#) (Nasdaq: OTLK), a biopharmaceutical company focused on enhancing the standard of care for bevacizumab for the treatment of retina diseases, today provided an update following its recent Type A meeting with the U.S. Food and Drug Administration (FDA) to discuss the December 30, 2025 Complete Response Letter (CRL) for the Biologics License Application (BLA) for ONS-5010/LYTENAVA™ (bevacizumab-vikg).

The Type A meeting was conducted to clarify the outstanding issue identified in the CRL regarding substantial evidence of effectiveness and to discuss potential paths forward for regulatory approval.

"We appreciate the FDA's engagement during the Type A meeting and remain committed to working constructively with the Agency," said Bob Jahr, Chief Executive Officer of Outlook Therapeutics. "Our goal is to reach alignment on the confirmatory evidence supporting our application and to identify the most efficient pathway toward potential approval."

The Company expects to continue engaging in discussions with the FDA to further clarify the Agency's views on confirmatory evidence and the appropriate path forward. Outlook Therapeutics is evaluating the available regulatory options to advance ONS-5010/LYTENAVA™ toward potential U.S. approval.

ONS-5010/LYTENAVA™ demonstrated clinically meaningful and statistically significant improvements in visual acuity in the NORSE TWO randomized, double masked, active controlled Phase 3 trial, which met its primary and key secondary endpoints. NORSE EIGHT, along with other information submitted to the BLA, demonstrated confirmatory evidence of efficacy and safety of ONS-5010 supporting the successful NORSE TWO trial, including functional and pharmacodynamic evidence consistent with the anti-VEGF mechanism of action. ONS-5010 also demonstrated a favorable safety profile, with no safety concerns identified by the FDA.

If approved, ONS-5010/LYTENAVA™ would be the first FDA-approved ophthalmic formulation of bevacizumab supported by standardized manufacturing, FDA-approved labeling, and robust pharmacovigilance.

The product candidate is supported by a fully domestic, end-to-end U.S. manufacturing supply chain.

About ONS-5010 / LYTENAVA™ (bevacizumab-vikg, bevacizumab gamma)

ONS-5010/LYTENAVA™ is an ophthalmic formulation of bevacizumab produced in the United States for the treatment of wet AMD. LYTENAVA™ (bevacizumab gamma) is the subject of a centralized Marketing Authorization granted by the European Commission in the EU and Marketing Authorization granted by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK for the treatment of wet AMD. In certain European Union Member States, ONS-5010/LYTENAVA™ must receive pricing and reimbursement approval before it can be sold.

In the United States, ONS-5010/LYTENAVA™ (bevacizumab-vikg) is investigational. If approved, it has the potential to be the first ophthalmic formulation of bevacizumab-vikg approved by the FDA for use in ophthalmology.

Bevacizumab-vikg (bevacizumab gamma in the EU and UK) is a recombinant humanized monoclonal antibody (mAb) that selectively binds with high affinity to all isoforms of human vascular endothelial growth factor (VEGF) and neutralizes VEGF's biologic activity through a steric blocking of the binding of VEGF to its receptors Flt-1 (VEGFR-1) and KDR (VEGFR-2) on the surface of endothelial cells. Following intravitreal injection, the binding of bevacizumab to VEGF prevents the interaction of VEGF with its receptors on the surface of endothelial cells, reducing endothelial cell proliferation, vascular leakage, and new blood vessel formation in the retina.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a biopharmaceutical company focused on the development and commercialization of ONS-5010/LYTENAVA™ (bevacizumab-vikg, bevacizumab gamma) to enhance the standard of care for bevacizumab for the treatment of retina diseases. 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 commenced commercial launch of LYTENAVA™ (bevacizumab gamma) in Germany, Austria, and the UK as a treatment for wet AMD.

In the United States, ONS-5010/LYTENAVA™ (bevacizumab-vikg) is investigational. 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 statements that may or are considered "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," "believe," "continue," "expect," "may," "on track," "plan," "potential," "target," "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 continued engagement with the FDA and the potential to agree on a regulatory pathway for ONS-5010, the potential of ONS-5010/LYTENAVA™ as a treatment for wet AMD, the potential for ONS-5010 to receive approval from the FDA, 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 in obtaining necessary regulatory approvals, the content and timing of decisions by regulatory bodies, 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, 2025, filed with the SEC on December 19, 2025, as supplemented by the Quarterly Report on Form 10-Q for the fiscal quarter ended December 31, 2025 and future 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, tariffs, and trade tensions, fluctuations in interest rates and 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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