Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Submits Type A Meeting Request to FDA Following Complete Response Letter

February 11, 2026

ISELIN, N.J., Feb. 11, 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 announced that it has submitted a Type A meeting request to the U.S. Food and Drug Administration (FDA) following receipt of a Complete Response Letter (CRL) dated December 30, 2025, regarding the Company's Biologics License Application (BLA) for ONS-5010/LYTENAVA ™ (bevacizumab-vikg) for the treatment of wet age-related macular degeneration (wet AMD).

The CRL identified a single deficiency based on a purported lack of substantial evidence of effectiveness, and recommended submission of additional confirmatory evidence. Outlook Therapeutics believes this determination is inconsistent with the totality of evidence submitted in the BLA, including data from an adequate and well-controlled study and confirmatory evidence of effectiveness. Based on prior discussions with the FDA in September 2025, during which Outlook Therapeutics understood that it had aligned with FDA on the requirements for resubmission of the BLA, the issuance of an additional CRL was unexpected. Prior to submitting the Type A meeting request, Outlook Therapeutics conducted informal meetings with the FDA to discuss the CRL.

"Outlook Therapeutics remains confident in the strength of the clinical evidence supporting ONS-5010 and firmly believes the totality of data meets the FDA's substantial evidence standard," said Bob Jahr, Chief Executive Officer of Outlook Therapeutics. "We are committed to working constructively with the FDA to resolve these issues and to bringing this important therapy to patients with wet AMD in the United States."

The BLA for ONS-5010 is supported by clinically meaningful data, including results from NORSE TWO, a single adequate and well-controlled Phase 3 trial that demonstrated statistically significant and clinically relevant improvements in visual acuity at 12 months. NORSE TWO met its primary endpoint - patients gaining three lines (15 letters) of visual acuity - and a key secondary endpoint of mean change from baseline in visual acuity. Additional secondary endpoints, including gains of one line, two lines, and preservation of vision (loss of fewer than three lines), further reinforce the robustness and consistency of the treatment effect.

At FDA's request, Outlook Therapeutics also conducted NORSE EIGHT, a second adequate and well-controlled Phase 3 study. While NORSE EIGHT did not meet its primary endpoint at 8 weeks, the study demonstrated a positive trajectory consistent with NORSE TWO through 12 weeks of treatment and provided important functional and mechanistic/pharmacodynamic evidence of efficacy. Specifically, NORSE EIGHT showed consistent gains in best-corrected visual acuity across all measured timepoints, low variability, and results aligned with the established anti-VEGF mechanism of action.

In addition to NORSE TWO and NORSE EIGHT, Outlook Therapeutics submitted a comprehensive package of confirmatory evidence, including mechanistic and pharmacodynamic data demonstrating VEGF inhibition and natural history data showing that the observed improvements with ONS-5010 represent a clear departure from the expected progression of untreated wet AMD. Outlook Therapeutics believes the resubmitted BLA fully satisfied the substantial evidence standard for demonstrating effectiveness, and intends to continue to work with the FDA on a path forward for resolving the FDA's request for additional confirmatory evidence.

ONS-5010 also demonstrated a favorable safety profile, with ocular adverse reactions consistent with both the control arm (ranibizumab) and with intravitreal injections generally and the FDA has never expressed any safety concerns with ONS-5010. The availability of an FDA-approved bevacizumab product for wet AMD would provide patients and physicians with a consistent, high-quality, commercially manufactured option supported by FDA-approved labeling, standardized manufacturing, and robust pharmacovigilance.

ONS-5010/LYTENAVA™ (bevacizumab-vikg) is supported by a fully domestic, end-to-end U.S. manufacturing supply chain, enhancing reliability of supply and aligning with long-term public health and national resilience objectives.

As previously announced, LYTENAVA ™ (bevacizumab gamma) was granted Marketing Authorization by the European Commission in the EU and Marketing Authorization by the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK for the treatment of wet AMD. In June 2025, LYTENAVA ™ (bevacizumab gamma) became commercially available in Germany and the UK for the treatment of wet AMD. In addition to current plans to expand its commercial presence in select countries in Europe, Outlook Therapeutics continues to speak with and explore collaborations with potential commercial and distribution partners in additional European countries, as well as outside of Europe. LYTENAVA™ (bevacizumab gamma) is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in adults in the European Union and UK.

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 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 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, expectations concerning Outlook Therapeutics' plans to conduct a Type A meeting with the FDA and the ability to remediate or otherwise resolve the deficiency identified in the CRL, expectations concerning decisions of regulatory bodies and the timing thereof, the potential to receive approval from the FDA, the potential of ONS-5010/LYTENAVA™ as a treatment for

wet AMD and to mitigate certain risks associated with the current off-label use of repackaged bevacizumab, 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 Outlook Therapeutics is not able to provide sufficient evidence to support the approval 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, 2025, filed with the SEC on December 19, 2025, and in 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

Source: Outlook Therapeutics, Inc.