Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Announces FDA Acceptance of Resubmitted Biologics License Application for ONS-5010/LYTENAVA™ (bevacizumab-vikg) as a Treatment for Wet AMD

June 16, 2026

Prescription Drug User Fee Act (PDUFA) goal date of July 29, 2026

ISELIN, N.J., June 16, 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 the U.S. Food and Drug Administration (FDA) has acknowledged receipt of the resubmission of the Biologics License Application (BLA) for ONS-5010/LYTENAVA™ for the treatment of neovascular age-related macular degeneration (nAMD), or wet AMD. The Company has been informed that the resubmission is a Class 1 review, with a PDUFA target action date of July 29, 2026.

"We are very pleased that the FDA has accepted our resubmitted BLA to review the labelling as part of the final step toward potential approval," said Bob Jahr, Chief Executive Officer of Outlook Therapeutics. "This is great news for Outlook and the LYTENAVA ™ team, patients and the retina community. We look forward to collaborating with the FDA over the coming weeks. We are incredibly grateful to our teams, partners, and KOLs for their resilience and dedication."

When approved, ONS-5010/LYTENAVA™ will be the first and only FDA-approved ophthalmic formulation of bevacizumab supported by standardized manufacturing, FDA-approved labeling, and robust pharmacovigilance. Outlook Therapeutics has initiated pre-launch activities in anticipation of the pending BLA approval.

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. When approved, it will be the first ophthalmic formulation approved by the FDA.

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). 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.

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 "can," "potential," "target," when, 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 its Annual Report on Form 10-K for the fiscal year ended September 30, 2025, filed with the SEC on December 19, 2025, as updated by the Outlook Therapeutics' subsequent filings, which include uncertainty of market conditions and future impacts related to macroeconomic factors, including as a result of global geopolitical conflict, 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.

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