Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Wins Appeal Following Formal Dispute Resolution Process for ONS-5010/LYTENAVA™ (bevacizumab-vikg)

May 26, 2026

Company plans to resubmit BLA to the FDA in June 2026

ISELIN, N.J., May 26, 2026 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company focused on the development and commercialization of ONS-5010/LYTENAVA™ (bevacizumab-vikg, bevacizumab gamma) for the treatment of retinal diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted the appeal following completion of the Formal Dispute Resolution (FDR) process with the Office of New Drugs (OND). The FDA concluded that substantial evidence of effectiveness has been established for LYTENAVA™ for the treatment of neovascular age-related macular degeneration (nAMD). As a result, Outlook Therapeutics expects to resubmit the ONS-5010/LYTENAVA™ (bevacizumab-vikg) Biologics License Application (BLA) in June 2026.

The Company engaged in the FDR process after its recent Type A meeting with the Division of Ophthalmology (Division) and Office of Specialty Medicine (OSM) related to the December 30, 2025 Complete Response Letter (CRL) for the BLA for ONS-5010/LYTENAVA ™ .

In its formal response, OND determined that the results of the NORSE TWO trial, together with confirmatory evidence including NORSE EIGHT, natural history, and mechanistic and pharmacodynamic data, establish substantial evidence of effectiveness for LYTENAVA ™ for the treatment of nAMD. The response directs the Division and OSM to work with Outlook Therapeutics to reach an agreement on final labeling. As indicated in the formal decision, it is anticipated that this will be a Class 1 resubmission with a PDUFA date and decision expected within 60 days of FDA's receipt of the resubmission.

"We appreciate the opportunity to engage with the FDA through the FDR process," said Bob Jahr, Chief Executive Officer of Outlook Therapeutics. "The Agency's action on our appeal provides a clear path forward toward U.S. approval."

Mr. Jahr added, "Importantly, we are extremely grateful for the continued support and confidence of our stakeholders throughout this process. I would especially like to thank our team for their tireless efforts, resilience and unwavering commitment throughout what was a rigorous and highly demanding process. Their persistence and professionalism were instrumental in achieving this successful outcome. We have remained resolute that patients deserve additional FDA-approved options for the treatment of nAMD and look forward to receiving an approval decision for ONS-5010/LYTENAVA ™ ."

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

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," "can," "could," "continue," "expect," "look forward," "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 to resubmit the BLA for ONS-5010 and the timing thereof, plans for continued engagement with the FDA, the potential of ONS-5010/LYTENAVA™ as a treatment for wet AMD, the potential for ONS-5010 to receive approval from the FDA 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 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 March 31, 2026 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 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.

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

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