Outlook Therapeutics, Inc. Logo

# Outlook Therapeutics Announces Formal Dispute Resolution Request for ONS-5010/LYTENAVA ™ (bevacizumab-vikg) Accepted by FDA

April 7, 2026

ISELIN, N.J., April 07, 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 submitted a formal dispute resolution request (FDRR) to the U.S. Food and Drug Administration (FDA) as a follow-up to its recent Type A meeting regarding the December 30, 2025 Complete Response Letter (CRL) for the Biologics License Application (BLA) for ONS-5010/LYTENAVA ™ (bevacizumab-vikg) for the treatment of neovascular age-related macular degeneration. The FDA has accepted the FDRR and has granted a meeting with the deciding official to be conducted in April 2026.

Subsequent to receiving the CRL in December 2025, Outlook Therapeutics has engaged with the FDA on multiple occasions, including a formal Type A meeting on March 2, 2026, which led to the submission of the FDRR and associated meeting.

"We look forward to our discussions with the FDA and remain committed to our position that data on safety and efficacy for LYTENAVA demonstrated in NORSE TWO and NORSE EIGHT provide sufficient evidence to support approval and bring a much-needed FDA approved option for patients," said Bob Jahr, Chief Executive Officer of Outlook Therapeutics.

The Company's submission includes a comprehensive presentation of the existing clinical, functional, and pharmacodynamic data, and safety findings, which Outlook Therapeutics believes collectively support the efficacy and safety of ONS-5010/LYTENAVA™ for the treatment of neovascular age-related macular degeneration.

Outlook Therapeutics will continue to work collaboratively with the FDA throughout the formal dispute resolution process and will provide updates as appropriate.

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. Additional evidence from NORSE EIGHT and other data submitted in the BLA further support the efficacy and safety profile of ONS-5010, consistent with its anti-VEGF mechanism of action. No safety concerns have been raised 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.

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