Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Announces Acceptance of Biologics License Application by U.S. FDA for ONS-5010 as a Treatment for Wet AMD

November 13, 2025

- **Prescription Drug User Fee Act (PDUFA) goal date of December 31, 2025**

ISELIN, N.J., Nov. 13, 2025 (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 the U.S. Food and Drug Administration (FDA) has acknowledged receipt of the resubmission of the Biologics License Application (BLA) for ONS-5010 (bevacizumab-vikg), an investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD). The FDA has advised that it considers the BLA resubmission a complete, Class 1 response to the August 27, 2025 action letter, which results in a 60 day review period from the date of resubmission. As a result, the FDA has set a Prescription Drug User Fee Act (PDUFA) goal date of December 31, 2025. ONS-5010, if approved, will be branded as LYTENAVA™ (bevacizumab-vikg) for the treatment of wet AMD.

"We are pleased that the FDA has accepted our resubmission of the BLA for ONS-5010 (bevacizumab-vikg), marking another important milestone in our effort to bring the first and only FDA-approved ophthalmic formulation of bevacizumab to patients in the United States suffering from wet AMD. Our team has worked diligently to address the feedback from the agency, strengthen the resubmitted BLA and resolve the outstanding issue highlighted in the Complete Response Letter (CRL) from August 2025," commented Bob Jahr, Chief Executive Officer of Outlook Therapeutics.

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 the United States, ONS-5010/LYTENAVA ™ (bevacizumab-vikg) is investigational. In certain European Union Member States ONS-5010/LYTENAVA™ must receive pricing and reimbursement approval before it can be sold.

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 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," "intend," "may," "on track," "plan," "potential," "seek," "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, Outlook Therapeutics' expectations concerning the resubmitted BLA and the sufficiency thereof, including the ability to address the deficiency identified in the CRL, the potential to obtain FDA approval for ONS-5010 and the timing thereof, expectations concerning the potential commercial launch of ONS-5010 in the United States the potential of ONS-5010/LYTENAVA™ as a treatment for wet AMD, 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 the Outlook Therapeutics is unable to address the issues identified in the CRL and ultimately obtain FDA approval, 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, 2024, filed with the SEC on December 27, 2024, as supplemented by the Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 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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