Outlook Therapeutics, Inc. Logo

Outlook Therapeutics CEO, Bob Jahr, Discusses FDA Approval and Commercial Opportunity for LYTENAVA™ in Virtual Investor CEO Connect Segment

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Access the segment here

ISELIN, N.J., Sept. 10, 2026 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company focused on the development and commercialization of LYTENAVA ™ (bevacizumab-vikg, bevacizumab gamma) for the treatment of retinal diseases, today announced that Bob Jahr, Chief Executive Officer, recently participated in a Virtual Investor CEO Connect segment discussing the significance of the FDA approval of LYTENAVA and the Company's plans for its U.S. commercial launch.

During the segment, Mr. Jahr discusses the potential of LYTENAVA to address the significant U.S. retina market by providing physicians with the only FDA-approved ophthalmic formulation of bevacizumab for wet AMD. He also discusses the Company's potential to shift existing off-label use to LYTENAVA and its opportunity to achieve more than $500 million in annual U.S. sales by 2030.

The segment also highlights Outlook Therapeutics' commercial readiness efforts ahead of its planned U.S. launch before the end of 2026, including manufacturing, distribution, market access, reimbursement, and physician education, as well as key learnings from the Company's commercialization efforts in Europe.

"FDA approval of LYTENAVA marks an important transformation for Outlook Therapeutics as we move into our next phase as a commercial-stage company," said Bob Jahr. "We believe LYTENAVA has the potential to make a meaningful impact for retina physicians and patients while addressing a significant market opportunity. We are focused on executing our U.S. launch strategy and building on the experience gained through our European commercialization efforts."

The Virtual Investor CEO Connect segment is available to watch here.

About LYTENAVA™ (bevacizumab-vikg, bevacizumab gamma)

LYTENAVA ™ is an ophthalmic formulation of bevacizumab produced in the United States for the treatment of wet AMD. In theUnited States, LYTENAVA (bevacizumab-vikg) is the only ophthalmic formulation approved by the FDA. LYTENAVA (bevacizumab gamma) is also 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, 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 IgG1 monoclonal antibody specific to human vascular endothelial growth factor (VEGF). Bevacizumab binds VEGF and prevents the interaction of VEGF to its receptors (Flt-1 and KDR) on the surface of endothelial cells. LYTENAVA binds to all isoforms of VEGF-A, thereby preventing interaction with receptors VEGFR-1 and VEGFR-2. By inhibiting VEGF-A, LYTENAVA suppresses endothelial cell proliferation, neovascularization, and vascular permeability. Inhibition of such activity targets a pathophysiologic process that contributes to vision loss.

Important Safety Information and Indication

LYTENAVA (bevacizumab-vikg) is a vascular endothelial growth factor (VEGF) inhibitor indicated for the treatment of patients with neovascular (wet) age-related macular degeneration (nAMD).

Contraindications

LYTENAVA is contraindicated in patients with ocular or periocular infections, in patients with active intraocular inflammation, and in patients with a known hypersensitivity to bevacizumab products or any of the ingredients in LYTENAVA. Hypersensitivity reactions may manifest as severe intraocular inflammation.

Warnings and Precautions

Intravitreal injections have been associated with endophthalmitis and retinal detachments. Proper aseptic injection technique must always be used when administering LYTENAVA. In addition, patients should be monitored following the injection to permit early treatment should an infection occur.

Increases in intraocular pressure have been noted post-injection (up to 60 minutes) while being treated with LYTENAVA. Monitor intraocular pressure prior to and following intravitreal injection with LYTENAVA and manage appropriately.

Although there was a low rate of arterial thromboembolic events (ATEs) observed in the LYTENAVA clinical trials, there is a potential risk of ATEs following intravitreal use of VEGF inhibitors. ATEs are defined as nonfatal stroke, nonfatal myocardial infarction, or vascular death (including deaths of unknown cause).

Adverse Reactions

The most common adverse reaction (≥1%) reported in patients receiving LYTENAVA was conjunctival hemorrhage (4%), eye pain (2%), and vitreous floaters (2%). These are not all the possible side effects of LYTENAVA.

You are encouraged to report side effects of prescription drugs to the FDA.

Visit www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report side effects to Outlook Therapeutics at 1-833-999-OTLK (6855).

Please see the full U.S. Prescribing Information for LYTENAVA here.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a biopharmaceutical company focused on the development and commercialization of LYTENAVA (bevacizumab-vikg (U.S.), bevacizumab gamma (E.U.)). LYTENAVA is the only ophthalmic formulation of bevacizumab to receive U.S. FDA approval and 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 “anticipate,” “believe,” “can,” “could,” “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, express or implied discussions regarding the Company’s planned launch of LYTENAVA in the United States and other jurisdictions and the timing thereof; expectations concerning potential revenue generation from sales of LYTENAVA; expectations surrounding market adoption of LYTENAVA; expectations regarding the potential impact of LYTENAVA in the retina community; Outlook Therapeutics’ development or future revenue plans for LYTENAVA generally; 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 Current Report on Form 8-K filed with the SEC on August 12, 2026 and the Quarterly Report on Form 10-Q for the quarter ended June 30, 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 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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