Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Announces SMC Recommendation of LYTENAVA™ (bevacizumab gamma) for the Treatment of Wet AMD

June 10, 2025

ISELIN, N.J., June 10, 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 the Scottish Medicines Consortium (SMC) acceptance of LYTENAVA ™ (bevacizumab gamma) for use within NHS Scotland for the treatment of wet age-related macular degeneration (wet AMD). LYTENAVA™ (bevacizumab gamma) is the first and only licensed ophthalmic formulation of bevacizumab for use in treating wet AMD in adults in the United Kingdom (UK) and has an initial 10 years of market exclusivity from the date of initial marketing authorization from the Medicines and Healthcare products Regulatory Agency.

"Receiving the SMC recommendation of LYTENAVA™ (bevacizumab gamma) for patients with wet AMD is a significant milestone for our company and a testament to our commitment to improving patient outcomes," commented Jedd Comiskey, Senior Vice President, Head of Europe, Outlook Therapeutics. "This acceptance will allow patients in Scotland to have access to an additional important treatment option. Our focus now is to work closely with healthcare providers to ensure a smooth rollout and to continue our mission of advancing healthcare solutions that make a real difference in people's lives."

The SMC acceptance follows the news from Outlook Therapeutics earlier this month that LYTENAVA™ is now commercially available in the UK for the treatment of wet AMD. The recommendation was based on the results from Outlook Therapeutics' wet AMD clinical program for ONS-5010 / LYTENAVA™, which consists of three completed registration clinical trials - NORSE ONE, NORSE TWO and NORSE THREE, as well as studies and peer reviewed literature substituting or supporting certain tests and studies.

Dr. Manjit Mehat, Senior Clinical Lecturer at The University of Edinburgh, NHS Consultant Ophthalmologist, and Vision Scotland Eye Surgeon noted, "This decision marks a significant step forward in ongoing efforts to provide the best possible care for patients needing licensed anti-VEGF treatments to control their wet AMD."

Outlook Therapeutics has entered into a strategic collaboration with Cencora (formerly AmerisourceBergen) to support the commercial launch of LYTENAVA™ globally following regulatory approvals. The collaboration and integrated approach is designed to support market access and efficient distribution of LYTENAVA ™ to benefit all stakeholders, including retina specialists, providers and patients in the European Union and UK and, if approved, in the United States.

About LYTENAVA™ (bevacizumab gamma)

ONS-5010 / LYTENAVA™ is an ophthalmic formulation of bevacizumab 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 ™ is investigational, and a BLA has been resubmitted to the FDA. 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," "may," "plan," "potential," "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, expectations concerning the therapeutic potential of ONS-5010/LYTENAVA™ as a treatment of wet AMD, expectations concerning the relationship with Cencora and the benefits and potential expansion thereof, Outlook Therapeutics' plans for commercial launch of LYTENAVA ™ in additional countries in the EU, Outlook Therapeutics' commercialization strategy, the market opportunity for ONS-5010/LYTENAVA™, expectations concerning decisions of regulatory bodies and the timing thereof, ONS-5010/LYTENAVA™'s potential as the first FDA-approved ophthalmic formulation of bevacizumab for use in treating retinal indications, including wet AMD, in the United States 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, the content and timing of decisions by regulatory bodies, the sufficiency of Outlook Therapeutics' resources, unanticipated or greater than anticipated impacts or delays due to macroeconomic and geopolitical conditions (including the long-term impacts of ongoing overseas conflicts, tariffs and trade tensions, fluctuations in inflation and interest rates and other economic uncertainty), as well as those risks detailed in Outlook Therapeutics' filings with the Securities and Exchange Commission (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, the Quarterly Report on Form 10-Q for fiscal quarter ended March 31, 2025 and future quarterly reports Outlook Therapeutics files with the SEC. 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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