Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Receives European Commission Marketing Authorization for LYTENAVA ™ (bevacizumab gamma) for the Treatment of Wet AMD

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- **LYTENAVA™ (bevacizumab gamma) becomes first ophthalmic formulation of bevacizumab to receive European Commission Marketing Authorization for the treatment of wet AMD**
- **European Commission decision applies automatically to all 27 EU Member States and, within 30 days, also to Iceland, Norway and Liechtenstein**
- **LYTENAVA™ (bevacizumab gamma) receives ten years of market exclusivity in EU**
- **Advancing toward commercial launch of LYTENAVA™ (bevacizumab gamma) in EU expected in calendar Q1 2025**
- **Strategic partnership with Cencora (formerly AmerisourceBergen) to support the planned commercial launches of LYTENAVA in EU**

ISELIN, N.J., May 28, 2024 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company focused on the commercialization and development of ONS-5010/LYTENAVA™ (bevacizumab-vikg; bevacizumab gamma), for the treatment of retina diseases, today announced that the European Commission has granted Marketing Authorization for LYTENAVA™ (bevacizumab gamma), an ophthalmic formulation of bevacizumab for the treatment of wet AMD in the EU. LYTENAVA™ (bevacizumab gamma) is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in the EU.

The application for European Commission Marketing Authorization of LYTENAVA™ (bevacizumab gamma) is a mixed application grounded on Article 8.3 of Directive 2001/83/EC and is based on the results from Outlook's wet AMD clinical program, 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. This decision applies automatically in all 27 EU Member States and, within 30 days, also to Iceland, Norway and Liechtenstein. Additionally, the Marketing Authorization grants Outlook an initial ten years of market exclusivity in the EU for LYTENAVA™ (bevacizumab gamma).

"This is a landmark milestone for us. We are extremely pleased to receive Marketing Authorization for LYTENAVA™ (bevacizumab gamma) in the EU and are moving toward our potential first commercial launch in an EU Member State in the first calendar quarter of 2025. The EU represents the second largest wet AMD market in the world, and we look forward to continuing our efforts to bring to the EU market the first and only on-label, ophthalmic bevacizumab for the treatment of wet AMD. We are incredibly grateful to all the patients, researchers, clinical sites and the European Medicines Agency for the research, drug development, and regulatory efforts that led to this approval," commented Russell Trenary, President and Chief Executive Officer of Outlook Therapeutics.

Jedd Comiskey, Senior VP – Head of Europe for Outlook Therapeutics, added, "We believe that LYTENAVA ™ (bevacizumab gamma) has the potential to be a meaningful treatment option in the ophthalmology landscape in the EU and are thrilled to focus efforts toward our potential initial launch in the European region. Our team is working hand in hand with our commercialization partner, Cencora, to support our EU launch anticipated in the first calendar quarter of 2025. We look forward to further solidifying our global launch strategy and to an exciting year ahead."

As part of the Company's multi-year planning process, Outlook Therapeutics entered a strategic collaboration with Cencora (formerly AmerisourceBergen) to support the commercial launch of LYTENAVA globally following regulatory approvals.

Cencora will provide comprehensive launch support in Europe including pharmacovigilance, regulatory affairs, quality management, market access support, importation, third-party logistics (3PL), distribution and field solutions. The collaboration and integrated approach will support market access and efficient distribution of LYTENAVA in a way that benefits all stakeholders, including retina specialists, providers and patients that will have efficient access to the product.

"We have been working closely with Outlook Therapeutics to develop and execute a global launch strategy and are thrilled to help them bring this therapy to market in Europe," said John W. Arena, senior vice president of Enterprise Strategy & Solutions on Cencora's Global Pharma Services team. "We will deliver the integrated solutions needed to support a successful commercial launch and ensure healthcare providers have timely and reliable access to the therapy."

About ONS-5010 / LYTENAVA™ (bevacizumab-vikg; 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. Outlook has also submitted its Marketing Authorization Application (MAA) to the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK) seeking authorization of ONS-5010/LYTENAVA ™ (bevacizumab gamma) for the treatment of wet age-related macular degeneration (wet AMD). The submission was completed under the new International Recognition Procedure (IRP). The IRP is available for new UK MAAs of a medicinal product (having the same qualitative and quantitative composition, and the same pharmaceutical form) that has previously been authorized by a Reference Regulator (RR). In this case this is the European Medicines Agency (EMA) Committee on Human Medicinal Products (CHMP). The IRP allows the MHRA to rely on a positive opinion by the CHMP concerning an application for grant of Marketing Authorization for the same product in the EU.

In the United States, ONS-5010/LYTENAVA™ is currently being evaluated in an ongoing non-inferiority study for the treatment of wet AMD.

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 commercialization and development of ONS-5010/LYTENAVA ™ (bevacizumab-vikg; bevacizumab gamma), for the treatment of retina diseases, including wet AMD, DME and BRVO. LYTENAVA ™ (bevacizumab gamma) is the first ophthalmic formulation of bevacizumab to receive European Commission Marketing Authorization for the treatment of wet AMD. Outlook is working to initiate its commercial launch of LYTENAVA™ (bevacizumab gamma) in the EU and has also filed a MAA for ONS-5010 as a treatment for wet AMD in the UK. In the United States, ONS-5010/LYTENAVA™ is being evaluated in an ongoing non-inferiority study for the treatment of wet AMD and if successful, the data may be sufficient for Outlook to resubmit a BLA application to the FDA in the United States. If approved in the United States, ONS-5010/LYTENAVA™, would be the first ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO.

About Cencora

Cencora is a leading global pharmaceutical solutions organization centered on improving the lives of people and animals around the world. We partner with pharmaceutical innovators across the value chain to facilitate and optimize market access to therapies. Care providers depend on us for the secure, reliable delivery of pharmaceuticals, healthcare products, and solutions. Our 46,000+ worldwide team members contribute to positive health outcomes through the power of our purpose: We are united in our responsibility to create healthier futures. Cencora is ranked #11 on the Fortune 500 and #24 on the Global Fortune 500 with more than $250 billion in annual revenue. Learn more at investor.cencora.com

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,” “expect,” “may,” “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, expectations concerning commercial launch of ONS-5010/LYTENAVA™ in the EU and the timing thereof, expectations concerning decisions of regulatory bodies, including the MHRA and the FDA, and the timing thereof, ONS-5010’s potential as the first and only FDA-approved ophthalmic formulation of bevacizumab for use in treating retinal diseases in the United States, expectations concerning Outlook’s ability to remediate or otherwise resolve deficiencies identified in the CRL issued by the FDA, including with respect to an additional clinical trial and CMC issues, expectations concerning NORSE EIGHT and the timing for completion of NORSE EIGHT and resubmission of the BLA for ONS-5010, plans for potential commercial launch of ONS-5010 in other jurisdictions, expectations concerning the relationship with Cencora and the benefits and potential expansion thereof, and other statements that are not historical fact. Although Outlook 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 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 pharmaceutical product candidates, risks of conducting clinical trials and risks in obtaining necessary regulatory approvals, the content and timing of decisions by the MHRA and FDA, as well as those risks detailed in Outlook’s filings with the Securities and Exchange Commission (the SEC), including the Annual Report on Form 10-K for the fiscal year ended September 30, 2023, filed with the SEC on December 22, 2023, and future quarterly reports Outlook 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, high interest rates, 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 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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