Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Announces UK MHRA Marketing Authorization of LYTENAVA™ (bevacizumab gamma) for the Treatment of Wet AMD

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- **UK MHRA marketing authorization follows recent European Commission Marketing Authorization for LYTENAVA ™ (bevacizumab gamma) in the EU for the treatment of wet AMD**
- **Initial commercial launches of LYTENAVA™ (bevacizumab gamma) in the EU and UK anticipated in calendar Q1 2025**
- **Strategic partnership with Cencora (formerly AmerisourceBergen) to support the planned commercial launches of LYTENAVA in UK and EU**

ISELIN, N.J., July 08, 2024 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company focused on development and commercialization of ONS-5010/LYTENAVA™ (bevacizumab-vikg; bevacizumab gamma) for the treatment of retina diseases, today announced that the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA) has granted marketing authorization for LYTENAVA™ (bevacizumab gamma), an ophthalmic formulation of bevacizumab for the treatment of wet AMD in the UK. LYTENAVA™ (bevacizumab gamma) is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in the EU and UK.

Professor Tim Jackson, PhD, FRCOphth, Consultant Ophthalmic Surgeon, King's College Hospital and Professor of Retinal Research, King's College London, commented, "We have waited a long time for a brand of bevacizumab that is authorized for eye use, and it is good news that LYTENAVA ™ has now entered the market. This occurs subsequent to Outlook Therapeutic's clinical trial meeting its endpoint. To date, many ophthalmologists have been hesitant to use an off-label bevacizumab, when licensed products are available. We value being able to utilize products that meet the standards required for marketing authorization. Additionally, a well-controlled pharmaceutical manufacturing operation will allay concerns that compounding pharmacies increase the risk of rare but potentially devastating endophthalmitis."

This approval comes after Outlook Therapeutics was recently granted Marketing Authorization for LYTENAVA ™ (bevacizumab gamma) by the European Commission for the same therapeutic indication. The Marketing Authorization Application (MAA) submission to the MHRA was completed under the new International Recognition Procedure (IRP), which allows the MHRA to rely on a positive opinion by the European Medicines Agency's CHMP concerning an application for granting marketing authorization for the same product in the EU in the MHRA's authorization decision.

"We are pleased to receive UK approval on the heels of marketing authorization in the EU for LYTENAVA™ (bevacizumab gamma). This milestone achievement is the final regulatory step towards our expected commercial launch in the EU and UK in the first calendar quarter of 2025. Our team continues to make a concerted effort to bring to the UK market the first and only authorized ophthalmic bevacizumab for the treatment of wet AMD. We are grateful to all the patients, researchers, clinical sites and the MHRA 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, "MHRA approval represents a very important milestone for Outlook in the execution of our commercial launch plans for LYTENAVA™ (bevacizumab gamma) in the UK. Our team continues to work hand in hand with our commercialization partner, Cencora, to support our launches in the EU and UK anticipated in the first calendar quarter of 2025, and we are looking forward to an exciting year ahead."

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

Cencora will provide comprehensive launch support in the EU and the UK including pharmacovigilance, regulatory affairs, quality management, market access support, importation, third-party logistics (3PL), distribution and field solutions. 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.

"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 the UK and the EU," said Cencora's John W. Arena, interim president of Global Pharma Services and senior vice president of Enterprise Strategy & Solutions. "We will continue to leverage our infrastructure and pharmaceutical services to support a successful commercial launch of LYTENAVA™ 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 and Marketing Authorization granted by the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK) for the treatment of wet age-related macular degeneration (wet AMD).

In the United States, ONS-5010/LYTENAVA™ (bevacizumab-vikg) is investigational and is 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 development and commercialization of ONS-5010/LYTENAVA ™ (bevacizumab-vikg; bevacizumab gamma), for the treatment of retina diseases, including wet AMD. LYTENAVA™ (bevacizumab gamma) is the first ophthalmic formulation of bevacizumab to receive European Commission and United Kingdom Marketing Authorization for the treatment of wet AMD. Outlook Therapeutics is working to initiate its commercial launch of LYTENAVA™ (bevacizumab gamma) in the EU and the UK as a treatment for wet AMD in the first calendar quarter of 2025. In the United States, ONS-5010/LYTENAVA ™ is investigational, 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 approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD.

About Cencora

Cencora is a leading global pharmaceutical solutions organization centered on improving the lives of people and animals around the world. Cencora partners with pharmaceutical innovators across the value chain to facilitate and optimize market access to therapies. Care providers depend on Cencora for the secure, reliable delivery of pharmaceuticals, healthcare products, and solutions. Cencora's 46,000+ worldwide team members contribute to positive health outcomes through the power of its purpose: Cencora is united in its responsibility to create healthier futures. Cencora is ranked #10 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," "expect," "may," "plan," "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 development and commercial launches of ONS-5010/LYTENAVA™ (bevacizumab gamma) in the EU and UK and the timing thereof, expectations concerning the relationship with Cencora, the benefits thereof and the services to be provided thereunder, 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 NORSE EIGHT and the timing for completion of NORSE EIGHT and resubmission of the BLA for ONS-5010, expectations concerning decisions of the FDA and the timing 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 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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