Outlook Therapeutics, Inc. Logo

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

December 4, 2024

First positive reimbursement decision worldwide for LYTENAVA™; First launch anticipated in H1 2025

LYTENAVA™ is the first and only approved ophthalmic formulation of bevacizumab for the treatment of wet AMD in the European Union (EU) and United Kingdom (UK)

40,000 new wet AMD patients each year in the UK who could benefit from treatment[1]

ISELIN, N.J., Dec. 04, 2024 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company that achieved regulatory approval in the European Union and the United Kingdom earlier this year for LYTENAVA ™ (bevacizumab gamma), the first ophthalmic formulation of bevacizumab authorized for the treatment of wet age-related macular degeneration (wet AMD) in adults, today announced that the National Institute for Health and Care Excellence (NICE) has recommended LYTENAVA™ (bevacizumab gamma), as an option for the treatment of wet AMD. LYTENAVA™ (bevacizumab gamma) is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in adults in the EU and UK and has an initial 10 years of market exclusivity.

"We are very pleased to receive the NICE recommendation of LYTENAVA™ (bevacizumab gamma) for patients with wet AMD. As the first positive reimbursement decision worldwide, this builds on our momentum and bolsters our commercialization strategy moving forward," commented Jedd Comiskey, Senior Vice President, Head of Europe, of Outlook Therapeutics. "We remain committed to providing the UK health system with a cost effective treatment option for treating wet AMD. Looking ahead, our team continues preparations for commercial launch in the UK anticipated in 2025 and continues to work through the pricing and reimbursement processes for EU countries, with launches in the EU anticipated to follow."

NICE is an executive non-departmental public body responsible for providing guidance on the promotion of good health and the prevention and treatment of ill health in the UK, considering clinical effectiveness and value for money. The NICE recommendation applies to England and Wales and follows the recent Marketing Authorization for LYTENAVA ™ (bevacizumab gamma) for the treatment of wet AMD by the United Kingdom (UK) Medicines and Healthcare products Regulatory Agency (MHRA).

Professor Tim Jackson, PhD, FRCOphth, Consultant Ophthalmic Surgeon, King's College Hospital and Professor of Retinal Research, King's College London, commented, "It is good news that bevacizumab gamma will be available for patients in England and Wales on the NHS. LYTENAVA ™ (bevacizumab gamma) is the first licensed ophthalmic formulation of bevacizumab. Despite not previously being approved for ophthalmic use, bevacizumab has been widely used to treat wet-AMD outside the UK and the approval by NICE marks significant progress towards ophthalmologists being able to use licensed bevacizumab for wet AMD in the UK. Importantly, the licensing process puts in place a number of quality controls, and combined with reduced cost, this should provide a welcome, cost-effective treatment option for our patients."

"The approval by NICE makes LYTENAVA™ (bevacizumab gamma) the first and only ophthalmic bevacizumab to be available on the NHS and for Independent Sector Providers, which is a stride in the right direction for the patients needing anti-VEGF treatments to control their wet AMD," said Alexander Silvester, Chief Medical Officer, SpaMedica.

The positive NICE recommendation was based on 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.

As part of a 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. 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.

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 in the European Union (EU) 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 MHRA 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, expected in the first half of calendar 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 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.

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," "continue," "expect," "may," "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, plans for commercial launch of LYTENAVA™ in the UK and EU and timing thereof, Outlook Therapeutics' commercialization strategy, the therapeutic potential of LYTENAVA™ as a treatment of wet AMD, the expected cost effectiveness of LYTENAVA™ in the UK, expectations concerning the relationship with Cencora, the benefits thereof and the services to be provided thereunder, ONS-5010's potential as the first FDA-approved ophthalmic formulation of bevacizumab for use in treating retinal indications, including wet AMD, in the United States, expectations concerning Outlook Therapeutics' ability to remediate or otherwise resolve deficiencies identified in the CRL issued by the FDA, including plans to resubmit the BLA for ONS-5010, expectations concerning decisions of regulatory bodies and the timing thereof, 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, 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, 2023, filed with the SEC on December 22, 2023, and future quarterly 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, 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 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.

Investor Inquiries:
Jenene Thomas
Chief Executive Officer
JTC Team, LLC
T: 908.824.0775
OTLK@jtcir.com

Media Inquiries:
Ellie Blundell
Senior Account Executive
Hanover Communications
T: +44 7738 832195
eblundell@hanovercommunications.com

[1] https://www.linkedin.com/posts/national-institute-for-health-and-care-excellence_nicenews-activity-7257688556624662529-bz5y?utm_source=share&utm_medium=member_desktop

Source: Outlook Therapeutics, Inc.