Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Announces Commercial Launch of LYTENAVA™ (bevacizumab gamma) in Germany and the UK for the Treatment of Wet AMD

June 2, 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)**
- **2.8 million injections of repackaged off-label bevacizumab in Europe each year[1]**

ISELIN, N.J., June 02, 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 that LYTENAVA™ (bevacizumab gamma) is now commercially available in Germany and the UK for the treatment of wet age-related macular degeneration (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 European Union and UK.

"We are excited to have launched LYTENAVA™ (bevacizumab gamma) for patients with wet AMD in Germany and the UK. I would like to extend sincere gratitude to the Outlook team and our partners for their commitment and dedication that helped to get us to this major milestone. Going forward, we remain laser focused on ensuring success in Germany and the UK as well as preparing for additional launches across the region later this year and throughout 2026," commented Jedd Comiskey, Senior Vice President, Head of Europe at Outlook Therapeutics.

Off-label repackaged bevacizumab is one of the most frequently used first-line anti-VEGF treatments in Europe (approximately 2.8 million injections annually) and the United States (approximately 2.7 million injections annually) for the treatment of retinal diseases. ONS-5010/LYTENAVA ™ has potential to mitigate certain risks associated with the current off-label use of repackaged bevacizumab.

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 certain European markets and, if approved, in the United States.

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 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, the success of Outlook Therapeutics' commercial launch of LYTENAVA™ in Germany and the UK, 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 the therapeutic potential of LYTENAVA™ as a treatment of wet AMD, expectations concerning the relationship with Cencora and the benefits and potential expansion thereof, 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, 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.

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[1] (Citeline (2023), Global Data (2023) and Market Scope (2022); ASRS 2024 Membership Survey Presented at ASRS NY 2022; Market Scope 2024 US Retina Quarterly Updates; GlobalData: Age-Related Macular Degeneration: Global Drug Forecast and Market Analysis to 2028 (April 2020)

Source: Outlook Therapeutics, Inc.