Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Participates in Virtual Investor “What This Means” Segment

February 4, 2025

Dr. Jennifer Kissner, SVP Clinical Development, discusses the 12-week safety and efficacy results for NORSE EIGHT clinical trial

Watch the “What This Means” segment here

ISELIN, N.J., Feb. 04, 2025 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company that achieved regulatory approval in the European Union (EU) and the United Kingdom (UK) for the first authorized use of an ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD), today announced that Jennifer Kissner, Ph.D., SVP Clinical Development of Outlook Therapeutics participated in a Virtual Investor “What This Means” segment .

As part of the segment, Dr. Kissner discusses the complete 12-week safety and efficacy results for NORSE EIGHT, the second of two adequate and well controlled clinical trials evaluating ONS-5010 in wet AMD patients and the Company’s planned Biologics License Application (BLA) resubmission of ONS-5010 in the first quarter of calendar 2025.

The Virtual Investor “What This Means” segment featuring Outlook Therapeutics is now available here.

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,” “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, Outlook Therapeutics’ ability to remediate or otherwise resolve deficiencies identified in the CRL issued by the FDA, plans to resubmit the BLA for ONS-5010 and the timing thereof, Outlook Therapeutics’ plans for commercial launch of LYTENAVA™ in the UK and EU and timing thereof, expectations concerning the therapeutic potential of LYTENAVA™ as a treatment of wet AMD Outlook Therapeutics’ commercialization strategy, 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, 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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