

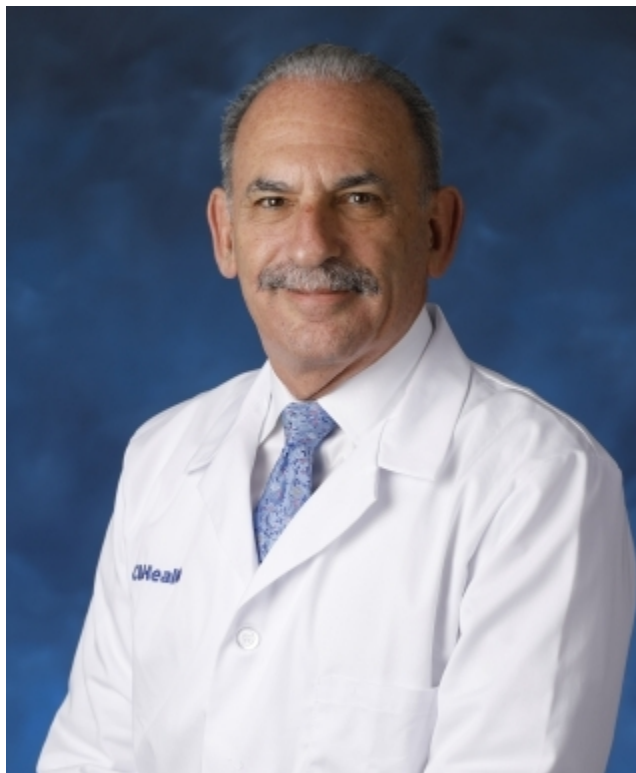
Outlook Therapeutics® Announces Presentation of Efficacy and Safety Results from NORSE EIGHT Clinical Trial Evaluating ONS-5010 for the Treatment of Wet AMD

January 23, 2025

- Data presented at Hawaiian Eye and Retina 2025 Meeting
- Results confirmed that intravitreal ONS-5010 provided early and sustained anatomic improvements, with steady gains in BCVA and reliable, consistent safety
- ONS-5010 demonstrated to be non-inferior to Lucentis at 4 and 12 weeks
- Company on track for anticipated BLA resubmission in calendar Q1 2025

ISELIN, N.J., Jan. 23, 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 the presentation of data from NORSE EIGHT at the [Hawaiian Eye and Retina 2025 Meeting](#) being held January 18-24, 2025 in Kauai, HI.

As part of the meeting, Baruch D. Kuppermann, MD, PhD, of Gavin Herbert Eye Institute, University of California, Irvine, CA presented the abstract titled, “ONS-5010 (bevacizumab-vikg) versus Ranibizumab for Neovascular Age-related Macular Degeneration: Results from the NORSE-EIGHT Noninferiority Randomized Trial,” highlighting the Company's [recently announced](#) 12-week safety and efficacy results for the NORSE EIGHT clinical trial evaluating ONS-5010 in wet AMD patients.



The NORSE EIGHT clinical trial was a randomized, controlled, parallel-group, masked, non-inferiority study of newly diagnosed, wet AMD subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010 or 0.5 mg ranibizumab intravitreal injections. Subjects received injections at day 0 (randomization), week 4, and week 8 visits, and returned for a final study visit at week 12. The primary endpoint was mean change in BCVA from baseline to week 8.

“The NORSE EIGHT results provide additional evidence to the retina community that ONS-5010 meets the expectations for an ophthalmic formulation of bevacizumab, without the challenges that can arise from using repackaged, off-label formulations available today. The reductions in central retinal thickness observed in the trial confirmed that ONS-5010 reduced fluid in the retina on par with ranibizumab, and I've been encouraged with the consistency of this treatment across all NORSE clinical studies,” said Dr. Kuppermann.

Key Highlights

- Mean BCVA at baseline was 58.8 ETDRS letters for the ONS-5010 group and 59.9 letters for the ranibizumab group.
- ONS-5010 demonstrated mean BCVA improvements of +3.3, +4.2 and +5.5 letters at Months 1, 2, and 3 respectively.
- The difference in mean BCVA between ONS-5010 and ranibizumab was -1.009 letters (95% confidence interval, -2.865, 0.848), meeting the noninferiority margin at Month 3 ($p=0.0043$) (applying the statistical parameters from the week 8 primary endpoint with the lower bound of the non-inferiority margin at -3.5 with a 95% confidence interval).

- As previously announced, in the NORSE EIGHT trial, ONS-5010 did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment with the U.S. Food and Drug Administration (FDA).
- Anatomical response was similar between treatments, with a reduction in central retinal thickness of -123.9 microns for ONS-5010 treated eyes and -127.3 microns for the ranibizumab group.
- ONS-5010 was generally well-tolerated with overall ocular adverse event rates comparable to ranibizumab, with no cases of retinal vasculitis reported in either study arm. The most commonly reported adverse event (AE) was conjunctival hemorrhage, which occurred in 5 (2.5%) participants in each group.
- Safety results demonstrated across the full duration of NORSE EIGHT are consistent with previously reported safety results from the NORSE ONE, NORSE TWO, and NORSE THREE clinical trials.

"Based on the data seen to date, we continue to be encouraged by the potential of ONS-5010 for the treatment of wet AMD. We believe that the complete data set from all of our NORSE clinical trials supports the resubmission of our BLA in the United States for the treatment of wet AMD, which we remain on track to complete this quarter," added Lawrence Kenyon, Chief Financial Officer and Interim Chief Executive Officer of Outlook Therapeutics.

Based on the completed analysis of the 12-week results, Outlook Therapeutics plans to resubmit the Biologics License Application (BLA) application for ONS-5010 in the first quarter of calendar 2025.

For more information about the NORSE EIGHT study, visit clinicaltrials.gov and reference identifier NCT06190093.

In the EU and the UK, ONS-5010/LYTENAVA™ (bevacizumab gamma) has already been granted Marketing Authorization. Outlook Therapeutics intends to continue efforts to begin launching in Europe in the first half of calendar 2025.

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 AMD.

In the United States, ONS-5010/LYTENAVA™ (bevacizumab-vikg) is investigational.

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," "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' plans for commercial launch of LYTENAVA™ in the UK and EU and timing thereof, as well as the potential to launch with a partner, expectations concerning the therapeutic potential of LYTENAVA™ as a treatment of wet AMD, 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' 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.

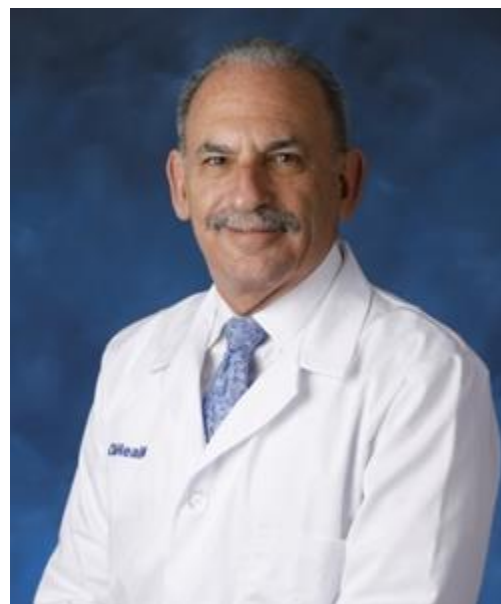
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Source: Outlook Therapeutics, Inc.

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