Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Doses First Subject in NORSE EIGHT

January 31, 2024

- **NORSE EIGHT clinical trial is being conducted under Special Protocol Assessment (SPA) from FDA to support expected resubmission of the ONS-5010 Biologics License Application (BLA) by the end of CY2024, if successful**

ISELIN, N.J., Jan. 31, 2024 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to achieve FDA approval for the first ophthalmic formulation of bevacizumab for the treatment of retinal diseases, today announced that the first subject has been dosed in the NORSE EIGHT clinical trial evaluating ONS-5010 in neovascular age-related macular degeneration (wet AMD) patients.

The NORSE EIGHT study is a randomized, controlled, parallel-group, masked, non-inferiority study of approximately 400 treatment naive, wet AMD subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010 or 0.5 mg ranibizumab intravitreal injections. Subjects will receive injections at Day 0 (randomization), Week 4, and Week 8 visits. The primary endpoint will be mean change in Best Corrected Visual Acuity (BCVA) from baseline to Week 8. Outlook Therapeutics expects NORSE EIGHT topline results and resubmission of the ONS-5010 BLA by the end of calendar year 2024.

"We are pleased with the continued progress of our ONS-5010 development pathway forward. The start of patient enrollment in NORSE EIGHT represents an important step toward potential FDA approval and launch of ONS-5010. Our team remains focused on the successful execution of the study," commented Russell Trenary, President and Chief Executive Officer.

Earlier this month, Outlook Therapeutics announced that it received written agreement from the FDA under an SPA for NORSE EIGHT. The FDA has reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA. If the NORSE EIGHT trial is successful, it would satisfy the FDA's requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the Complete Response Letter (CRL). In addition, through a Type A meeting and additional interactions, Outlook Therapeutics has identified the approaches needed to resolve the Chemistry, Manufacturing and Controls (CMC) comments in the CRL. Outlook Therapeutics is working to address the open CMC items in the CRL and expects to resolve these comments prior to the expected completion of NORSE EIGHT.

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

About ONS-5010 / LYTENAVA™ (bevacizumab-vikg)

ONS-5010 is an investigational ophthalmic formulation of bevacizumab under development as an intravitreal injection for the treatment of wet AMD and other retinal diseases. Because no FDA-approved ophthalmic formulations of bevacizumab are available currently, clinicians wishing to treat retinal patients with bevacizumab have had to use unapproved repackaged IV bevacizumab provided by compounding pharmacies—products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010 would provide an FDA-approved option for physicians that currently prescribe unapproved repackaged oncologic IV bevacizumab from compounding pharmacies for the treatment of wet AMD.

Bevacizumab-vikg 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-vikg 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 working to achieve FDA approval for the launch of ONS-5010/ LYTENAVA ™ (bevacizumab-vikg) as the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010 ophthalmic bevacizumab is approved, Outlook Therapeutics expects to commercialize it as the first and only FDA-approved ophthalmic formulation of bevacizumab for use in treating retinal diseases in the United States, United Kingdom, Europe, Japan, and other markets. As part of Outlook Therapeutics' multi-year commercial planning process, Outlook Therapeutics and Cencora entered into a strategic commercialization agreement to expand Outlook Therapeutics' reach for connecting to retina specialists and their patients. Cencora will provide third-party logistics (3PL) services and distribution, as well as pharmacovigilance services and other services in the United States. For more information, please visit www.outlooktherapeutics.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 "continue," "expect," "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, statements about ONS-5010's potential as the first FDA-approved ophthalmic formulation of bevacizumab-vikg, expectations concerning Outlook Therapeutics' ability to remediate or otherwise resolve deficiencies identified in the CRL issued by the FDA, including with respect to an additional clinical trial and CMC issues, expectations concerning the NORSE EIGHT trial design, 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, plans for potential commercial launch of ONS-5010, expectations concerning the relationship with Cencora and the benefits and potential expansion 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 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 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 conflict, 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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