Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Presents Positive NORSE THREE Safety Data for ONS-5010 / LYTENAVA ™ (bevacizumab-vikg) at EURETINA Virtual 2021 Medical Conference

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ISELIN, N.J., Sept. 13, 2021 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to develop and launch the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, today announced the presentation of safety data from the NORSE THREE trial evaluating ONS-5010 / LYTENAVA™ (bevacizumab-vikg) at the EURETINA Virtual 2021 conference on September 12, 2021. The previously announced topline results from the open-label safety study demonstrated that ONS-5010 ophthalmic bevacizumab, under evaluation for the treatment of wet AMD, showed no unexpected safety trends and had a safety profile consistent with that of prior published data undertaken by the National Eye Institute (2011 CATT trial).

"ONS-5010 has the potential to close the gap on a high unmet need for patients and retinal clinicians," said Professor Timothy L. Jackson, PhD, MB ChB FRCOphth, Ophthalmic and Retinal Surgeon and Professor of Retinal Research at King's College London and data presenter at EURETINA. "If approved, ONS-5010 ophthalmic bevacizumab may improve clinical outcomes of patients with wet AMD while potentially avoiding serious adverse events associated with off-label repackaging of IV bevacizumab, including variability in potency, eye infections and loss of sight."

The NORSE THREE study was conducted to ensure an adequate number of patients with wet AMD and other retinal diseases had been dosed with ONS-5010 to support Outlook Therapeutics' planned new biologics license application (BLA) submission in the United States and for other global regulatory filings. The open-label study met its goal of ensuring that a sufficient number of individuals have now been treated with ONS-5010 by enrolling 197 treatment-naïve and previously treated subjects with a range of retinal diseases for which an anti-VEGF drug is a therapeutic option, including wet AMD, diabetic macular edema (DME) and branch retinal vein occlusion (BRVO). Subjects enrolled in the study received three monthly intravitreal doses of ONS-5010 ophthalmic bevacizumab.

"ONS-5010 has been rigorously tested to support our efforts to provide the first approved ophthalmic formulation of bevacizumab," said C. Russell Trenary III, President and Chief Executive Officer, Outlook Therapeutics. "With the trial data and market insight seen to date, we believe ONS-5010 has the potential to become the cornerstone of care for multiple retinal indications and we look forward to working closely with the U.S. Food and Drug Administration and other global regulatory authorities toward our goal of bringing this important therapy to market."

Outlook Therapeutics' wet AMD ONS-5010 clinical program for the planned BLA submission consists of three clinical trials, NORSE ONE, NORSE TWO, and NORSE THREE, all of which have now been completed. Most recently, Outlook Therapeutics reported positive topline data from its NORSE TWO pivotal Phase 3 clinical trial. In NORSE TWO, ONS-5010 achieved statistically significant and clinically relevant primary (p = 0.0052) and key secondary (p = 0.0043) efficacy endpoints with 41% of subjects gaining at least 15 letters of BVCA. ONS-5010 was also found to be safe and well tolerated in the NORSE TWO trial.

With the registration clinical trials now completed, Outlook Therapeutics plans to submit a new BLA under the Public Health Service Act (PHSA) 351(a) regulatory pathway in the first quarter of calendar 2022. If the BLA is approved, it is expected to result in 12 years of marketing exclusivity for ONS-5010 as the first and only ophthalmic formulation of bevacizumab approved by the FDA to treat wet AMD.

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

ONS-5010 is an investigational ophthalmic formulation of bevacizumab under development to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. Because no currently approved ophthalmic formulations of bevacizumab are available, 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 will replace the need to use unapproved repackaged IV bevacizumab from compounding pharmacies for the treatment of wet AMD.

ONS-5010 is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody (mAb) that inhibits VEGF and associated angiogenic activity. VEGF is a protein that promotes the growth of abnormal new blood vessels and promotes leakage from these vessels, leading to retinal edema and hemorrhage. With wet AMD, abnormally high levels of VEGF are secreted in the eye and lead to loss of vision. Anti-VEGF injection therapy treats the vision-threatening leakage and hemorrhage as well as blocks the growth of the abnormal blood vessels. Since the advent of anti-VEGF therapy, it has become the standard-of-care treatment option within the retina community globally.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a biopharmaceutical company working to develop and launch 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. Outlook Therapeutics expects to submit ONS-5010 ophthalmic bevacizumab to the U.S. FDA as a new BLA under the PHSA 351(a) regulatory pathway. 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 "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," 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, including benefits therefrom to patients, payors and physicians, including expectations of market exclusivity, the timing of BLA submission and commercial launch of ONS-5010, plans for regulatory approvals in other markets, and plans for future clinical trials. 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, as well as those risks detailed in Outlook Therapeutics' filings with the Securities and Exchange Commission, including the Annual Report on Form 10-K for the fiscal year ended September 30, 2020, as amended, and subsequent Quarterly Reports on Form 10-Q, which include the uncertainty of future impacts related to the ongoing COVID-19 pandemic. 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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