Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Reports Positive Safety Profile from NORSE THREE Open-Label Safety Study for ONS-5010 / LYTENAVA™ (bevacizumab-vikg)

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- **Positive safety profile in NORSE THREE open-label safety study reinforces previously reported safety data for ONS-5010 / LYTENAVA ™, an investigational ophthalmic formulation of bevacizumab-vikg for the treatment of wet AMD**

- **Topline efficacy and safety data from pivotal Phase 3 NORSE TWO study on target to report in calendar Q3 2021, followed by BLA submission by end of 2021**

MONMOUTH JUNCTION, N.J., March 31, 2021 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a late clinical-stage biopharmaceutical company developing the first FDA-approved ophthalmic formulation of bevacizumab-vikg for use in retinal indications, today announced positive topline results from its NORSE THREE open-label safety study evaluating ONS-5010 / LYTENAVA™ (bevacizumab-vikg) to treat retinal diseases.

Topline results from the open-label safety study demonstrated that ONS-5010 showed no unexpected safety trends and had a safety profile consistent with that of prior published data on the use of bevacizumab for ophthalmic conditions, such as the 2011 CATT study undertaken by the National Eye Institute. The safety endpoints for NORSE THREE were the frequency and incidence of treatment-emergent adverse events and an evaluation of changes in safety parameters. In the study, 20 out of 197 patients (10%) experienced an adverse event in the study eye that were most commonly associated with the injection procedure and not ONS-5010. There were no serious adverse events associated with treatment. Notably, there were zero cases of ocular inflammation, a concern that has emerged for other anti-VEGF (Vascular Endothelial Growth Factor) therapies to treat retinal conditions.

“The additional validation of the ONS-5010 safety profile seen in the results of this study, which match up favorably with historical data from prior studies of bevacizumab in ophthalmology, is very encouraging. ONS-5010 has the potential to be a valuable therapeutic addition to the clinical practice of retina physicians. I look forward to the topline data readout from the pivotal safety and efficacy study later this year,” said Mark Humayun, MD, PhD, Medical Advisor to Outlook Therapeutics.

NORSE THREE was conducted to ensure that an adequate number of patient exposures to ONS-5010 / LYTENAVA ™ are available for Outlook Therapeutics’ data package for its planned 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 age-related macular degeneration (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 / LYTENAVA ™ .

Following the data readout of the pivotal safety and efficacy study (NORSE TWO) later this year, Outlook Therapeutics plans to submit a new BLA filing under the PHSA 351(a) regulatory pathway in the fourth quarter of calendar 2021. If the BLA is approved, it will result in 12 years of marketing exclusivity for ONS-5010 / LYTENAVA™ as the first and only FDA-approved ophthalmic formulation of bevacizumab-vikg to treat wet AMD.

Commercial launch planning for ONS-5010 has begun, including manufacturing, distribution, physician and patient outreach, and engagement with key opinion leaders and the payor community. With potential for an enhanced safety and cost-effectiveness profile, ONS-5010, if approved, is well positioned to become the first-line drug of choice in the United States for retinal indications and to be widely adopted by payors and clinicians worldwide in the $13.1 billion global anti-VEGF market.

“We are very pleased with the positive safety profile demonstrated by ONS-5010 in this open-label safety study. This study provided us with the necessary number of patient exposures to ONS-5010 to complete our planned BLA submission for wet AMD later this year,” said Lawrence A. Kenyon, President, CEO and CFO of Outlook Therapeutics. “These results reinforce the positive safety profile seen in our earlier clinical experience trial. Moving forward, our team is now laser-focused on successfully completing our pivotal trial, NORSE TWO, and preparing the BLA after the data readout expected in the third quarter of this calendar year. On behalf of the Outlook Therapeutics team, we would like to thank the clinicians and patients who participated in this study, despite the disruptions of the pandemic.”

In addition to the clinical development plan evaluating ONS-5010 for wet AMD, Outlook Therapeutics has received agreements from the FDA on three Special Protocol Assessments (SPAs) for three additional registration clinical trials. These SPAs cover the protocols for a planned registration clinical trial evaluating ONS-5010 to treat BRVO (NORSE FOUR), and two planned registration clinical trials evaluating ONS-5010 for the treatment of DME (NORSE FIVE and NORSE SIX). Outlook Therapeutics expects to initiate registration clinical trials for ONS-5010 for DME and BRVO later in 2021.

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

ONS-5010 / LYTENAVA ™ (bevacizumab-vikg) is an investigational ophthalmic formulation of bevacizumab-vikg under development to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. ONS-5010 is currently being evaluated in a pivotal registration clinical trial for wet AMD (NORSE TWO) and, if successful, is expected to be submitted to the FDA as a new BLA for this ophthalmic indication under the 351(a) regulatory pathway. Because no currently approved ophthalmic formulations of bevacizumab are available, clinicians wishing to treat retinal patients with bevacizumab use unapproved repackaged IV bevacizumab provided by compounding pharmacists, products that have known risks of contamination and inconsistent potency and availability.

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 new abnormal blood vessels. With wet AMD, abnormally high levels of VEGF are secreted in the eye and can lead to vision loss. Anti-VEGF injection therapy blocks this growth. Since the advent of anti-VEGF therapy, it

has become the standard-of-care treatment option within the retina community globally.

If approved, ONS-5010 will be the first and only FDA-approved ophthalmic formulation of bevacizumab-vikg to treat retinal diseases. Outlook Therapeutics currently intends to initiate registration trials for diabetic macular edema (DME) and branch retinal vein occlusion (BRVO) and to commercialize ONS-5010 in both vials and single-use pre-filled syringes.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a late clinical-stage biopharmaceutical company working to develop ONS-5010 / LYTENAVA™ (bevacizumab-vikg) as the first FDA-approved ophthalmic formulation of bevacizumab-vikg for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010 is approved, Outlook Therapeutics expects to commercialize it as the first and only FDA-approved ophthalmic formulation of bevacizumab-vikg for use in treating retinal diseases in the United States, United Kingdom, Europe, Japan and other markets. Outlook Therapeutics expects to file ONS-5010 with 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 statements about the timing of completion of, and pivotal safety and efficacy data from, NORSE 2, ONS-5010's potential as the first FDA-approved ophthalmic formulation of bevacizumab-vikg, including benefits therefrom to patients, payors and physicians, the timing of BLA submission and commercial launch of ONS-5010, and plans for regulatory approvals in other markets. 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, 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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