Outlook Therapeutics, Inc. Logo

Outlook Therapeutics' Positive NORSE THREE Safety Data Presented at 2021 American Society of Retina Specialists for ONS-5010 Ophthalmic Bevacizumab

October 12, 2021

Strong safety data from NORSE THREE registration trial consistent with other trials for ONS-5010 and in prior published research

ISELIN, N.J., Oct. 12, 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 presented the results from its NORSE THREE supplemental safety study evaluating ONS-5010 / LYTENAVA™ (bevacizumab-vikg) at the 39th Annual Meeting of the American Society of Retina Specialists in San Antonio, Texas. As previously reported, topline data from the NORSE THREE open-label study of ONS-5010 ophthalmic bevacizumab demonstrated no unexpected safety trends and had a safety profile consistent with those of other trials of ONS-5010 as well as prior published data such as that undertaken by the National Eye Institute (*e.g.*, 2011 CATT trial).

Suber Huang, MD, MBA, FASRS, Founder and CEO of the Retina Center of Ohio and presenter at the 39th Annual Meeting of the American Society of Retina Specialists, said "I am excited to see that in the NORSE THREE trial the safety profile of ONS-5010 ophthalmic bevacizumab reinforces what has been previously reported in other studies of ONS-5010 as well as in earlier published research on the use of bevacizumab in ophthalmology. If approved, ONS-5010 will offer retina specialists the first safe and effective, on-label bevacizumab that avoids the potentially serious adverse events associated with off-label repackaged IV bevacizumab from compounding pharmacies. I hope to see it become an important new weapon in our therapeutic armamentarium."

The three-month NORSE THREE safety study, which was conducted to ensure that an adequate number of subjects with retinal disease had been dosed with ONS-5010 to support Outlook Therapeutics' planned BLA submission to the U.S. Food and Drug Administration (FDA), enrolled 197 treatment-naïve and previously treated subjects who suffered from a variety of retinal conditions for which an anti-VEGF therapy is appropriate, such as wet age-related macular degeneration (wet AMD), diabetic macula edema (DME) and branch retinal vein occlusion (BRVO). Participants received three monthly intravitreal doses of ONS-5010 ophthalmic bevacizumab. The study examined the frequency and incidence of adverse events as well as any changes in safety parameters.

Data from NORSE THREE indicated that in this study ONS-5010 showed no intraocular inflammation or vasculitis, and the frequency and incidence of adverse events and ocular adverse events were low. The most common adverse event in the study eye was conjunctival hemorrhage related to injection procedure, not to ONS-5010, and there were no additional serious adverse events associated with these injections. NORSE THREE showed no unanticipated safety signals.

"The strong safety results from NORSE THREE reinforce the safety profile seen across all three NORSE clinical trials for ONS-5010 and reflect the consistent safety observed both in decades of real-world clinical practice and in prior published research on the use of bevacizumab in ophthalmology," said C. Russell Trenary, President and CEO, Outlook Therapeutics. "With our wet AMD clinical program investigating ONS-5010 as the first ophthalmic formulation of bevacizumab to be potentially approved to treat retinal conditions now complete, we are actively preparing our BLA, and we expect to file it with the FDA in early 2022. If approved, we believe ONS-5010 has the potential to make a significant impact in the retina community and to address the need for an approved ophthalmic bevacizumab."

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. In early August, 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.

CONTACTS:
Media Inquiries:
Harriet Ullman
Vice President
LaVoie Health Science
T: 617-669-3082
hullman@lavoiehealthscience.com

Investor Inquiries:
Jenene Thomas
Chief Executive Officer
JTC Team, LLC
T: 833.475.8247
OTLK@jtcir.com

Source: Outlook Therapeutics, Inc.