Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Reports Completion of Patient Dosing in the ONS-5010 Pivotal Phase 3 NORSE TWO Trial

June 8, 2021

- **Topline readout of data from NORSE TWO targeted for calendar Q3 2021**
- **New Biologics License Application (BLA) filing anticipated in calendar Q1 2022**

ISELIN, N.J., June 08, 2021 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a late clinical-stage biopharmaceutical company working to develop the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, reported today that it has administered the final dose to the last patient enrolled in its pivotal NORSE TWO safety and efficacy study evaluating ONS-5010 (bevacizumab-vikg) for treatment of wet age-related macular degeneration (wet AMD). Topline data are expected to be reported for NORSE TWO in the third calendar quarter of 2021.

The NORSE TWO pivotal Phase 3 clinical trial enrolled a total of 228 wet AMD patients at 39 clinical trial sites in the United States. Patients in the trial are being treated for 12 months. The primary endpoint for the study is the difference in proportion of patients who gain at least 15 letters in the best corrected visual acuity (BCVA) at 11 months for ONS-5010 dosed on a monthly basis, compared to LUCENTIS®, which is being dosed quarterly per the PIER regimen.

"We are very pleased to have completed patient dosing and take another step forward in completing our wet AMD clinical program for ONS-5010. On behalf of the Outlook Therapeutics team, I would like to thank the clinicians and participants in the study, whose dedication has made it possible," said Lawrence A. Kenyon, President, CEO and CFO, Outlook Therapeutics. "We remain on track to report topline data in the third quarter and continue to execute against our plan to advance this much-needed ophthalmic formulation of bevacizumab to market. Following the upcoming data readout, we look forward to our planned new BLA submission for wet AMD in the first quarter of calendar 2022."

ONS-5010 (bevacizumab-vikg) registration clinical trial program

The clinical program for the planned ONS-5010 wet AMD BLA consists of three clinical trials: NORSE ONE, a proof-of-concept clinical experience trial in wet AMD patients; NORSE TWO, the pivotal Phase 3 wet AMD trial powered for statistical significance; and NORSE THREE, a supplemental safety study in patients with wet AMD and other retina diseases undertaken to ensure that a sufficient number of patients have been dosed with ONS-5010 to support the BLA filing. Results from NORSE ONE and NORSE THREE demonstrated positive proof-of-concept and a safety profile consistent with that of prior published research on bevacizumab for ophthalmic use.

Following the data readout for NORSE TWO expected next quarter, Outlook Therapeutics plans to submit a new BLA filing under the PHSA 351(a) regulatory pathway in the first quarter of calendar 2022. If the BLA is approved, it will 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.

Pre-commercialization planning underway

In anticipation of potential FDA marketing approval in 2022 for ONS-5010, Outlook Therapeutics has begun commercial launch planning, including distribution, sales force planning, physician and patient outreach, key opinion leader support and payor community engagement. To bring ONS-5010 to market in a way that benefits all stakeholders – clinicians, patients and payors – Outlook Therapeutics intends to work collaboratively with payors and the retina community. Outlook Therapeutics expects ONS-5010, if approved, to be a safe and cost-effective choice for payors and clinicians worldwide and to become a first-line drug of choice for retinal indications.

Outlook Therapeutics is also developing registration documents on a parallel path for approvals in Europe and expects to submit them shortly after completing the filing to the FDA. While Outlook Therapeutics continues to target potential strategic commercialization partners, particularly for European markets, it is preparing to launch ONS-5010 in the United States by itself, pending FDA approval.

In addition to the clinical development program 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 branch retinal vein occlusion (BRVO, NORSE FOUR), and two planned registration clinical trials evaluating the drug candidate for the treatment of diabetic macular edema (DME, NORSE FIVE and NORSE SIX). Outlook Therapeutics expects to initiate registration clinical trials for ONS-5010 for DME and BRVO later in calendar 2021 or in early calendar 2022.

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 pharmacists, products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010 will reduce the need for use of unapproved repackaged IV bevacizumab from compounding pharmacists for retinal disease.

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 lead to loss of vision. 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.

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 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 file ONS-5010 ophthalmic bevacizumab 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, among others, 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, including expectations of market exclusivity, 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, 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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