Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Completes Patient Enrollment for NORSE 2 Study of ONS-5010 / LYTENAVA ™ (bevacizumab-vikg)

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- **Pivotal NORSE 2 safety and efficacy data expected to be reported in the third calendar quarter of 2021**
- **ONS-5010 / LYTENAVA ™ (bevacizumab-vikg) has the potential to be the first FDA-approved ophthalmic formulation of bevacizumab for use in multiple retinal indications**

MONMOUTH JUNCTION, N.J., July 07, 2020 (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, today announced the completion of patient enrollment in its NORSE 2 clinical trial for ONS-5010 / LYTENAVA ™ (bevacizumab-vikg), an investigational ophthalmic formulation of bevacizumab for use in retinal indications.

"We are extremely grateful to the patients and medical staff who continue to take part in this study, even amidst the effects of the COVID-19 pandemic. The hard work and dedication shown by these individuals have made it possible for us to achieve this important milestone, which now starts the clock to the completion of the study and to our reporting of pivotal data, expected in the third calendar quarter of 2021," commented Lawrence A. Kenyon, President, CEO and CFO of Outlook Therapeutics.

The NORSE 2 clinical trial commenced patient enrollment in July 2019. Due to the number of patients in screening at the time of achieving the trial's stated goal of enrolling 220 patients in the study, Outlook Therapeutics has enrolled 227 patients at 39 clinical trial sites in the United States. Patients in the trial are being treated for 12 months. The primary endpoint for NORSE 2 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. Outlook Therapeutics expects to report pivotal safety and efficacy data in the third calendar quarter of 2021.

"Within the retina community, the use of anti-VEGF therapy continues to be the standard of care for many ophthalmic diseases. Given the high cost of the present FDA-approved anti-VEGF therapies, many physicians have turned to off-label repackaged bevacizumab supplied by compounding pharmacists. There is significant unmet patient need for an FDA-approved bevacizumab for use in treating retinal diseases. I believe that LYTENAVA™, if approved, will offer clinicians an important new safe and effective, on-label anti-VEGF therapy option across the spectrum of retinal care," commented Mark Humayun M.D., Medical Advisor for Outlook Therapeutics.

Outlook Therapeutics intends to complete development of ONS-5010 for submission to the FDA as a new BLA under the 351(a) PHSA regulatory pathway for the treatment of wet AMD and also has plans to submit for regulatory approvals in Europe and Japan, as well as other countries.

If approved, ONS-5010 will be the first and only on-label ophthalmic formulation of bevacizumab for treating retinal diseases and has the potential to address a $9.1 billion anti-VEGF market.

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

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) 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. ONS-5010 is currently being evaluated in two adequate and well-controlled registration clinical trials for wet AMD (NORSE 1 and NORSE 2) 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. If approved, ONS-5010 will be the first and only FDA-approved ophthalmic formulation of bevacizumab to treat retinal diseases. Outlook Therapeutics currently intends to commercialize ONS-5010 in both vials and single-use pre-filled syringes.

ONS-5010 is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody (mAb) that inhibits VEGF and associated angiogenic activity. With wet AMD, abnormally high levels of VEGF are secreted in the eye. VEGF is a protein that promotes the growth of new abnormal blood vessels. 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 the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010 / LYTENAVA™ (bevacizumab-vikg), its investigational ophthalmic formulation of bevacizumab, is approved, Outlook Therapeutics expects to commercialize it as the first and only approved ophthalmic formulation of bevacizumab for use in treating approved retinal diseases in the United States, 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, 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.

For additional details on Outlook Therapeutics' financial performance during the quarter, please see the Outlook Therapeutics filings with the Securities and Exchange Commission.

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