Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Announces Initiation of Supplemental Open-Label Safety Study for ONS-5010 / LYTENAVA™ (bevacizumab-vikg)

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- **First subjects have been enrolled in supplemental open-label safety study**
- **Study being conducted to ensure the requisite number of patient exposures to ONS-5010 to support new BLA filing to the FDA in 2021**
- **ONS-5010, an investigational ophthalmic formulation of bevacizumab-vikg for the treatment of wet AMD and other retinal diseases, on track to report pivotal data in mid-2021 from ongoing, fully enrolled Phase 3 registration trial**

MONMOUTH JUNCTION, N.J., Oct. 13, 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-vikg for use in retinal indications, today announced the initiation and enrollment of the first patients in its planned supplemental open-label safety study evaluating ONS-5010 / LYTENAVA™ (bevacizumab-vikg) for the treatment of wet age-related macular degeneration (AMD) (NORSE THREE).

The open-label safety study is being conducted to ensure that an adequate number of safety exposures to ONS-5010 / LYTENAVA ™ (bevacizumab-vikg) are available to support Outlook Therapeutics' initial Biologics License Application (BLA) filing for wet AMD with the U.S. Food and Drug Administration (FDA). In total, approximately 180 patients with a wide range of different retinal diseases for which an anti-VEGF drug can be used as a therapeutic option, including wet AMD, diabetic macular edema (DME) and branch retinal vein occlusion (BRVO), are expected to be enrolled. Patients in the safety study will receive three doses of ONS-5010 over a three-month period.

"The initiation of this open-label safety study, the third clinical trial in our wet AMD program, is an important step in our overall development plan for ONS-5010. This study is intended to ensure that enough patients have been treated with ONS-5010 in our streamlined clinical program to support submission for a new BLA," said Lawrence Kenyon, President, CEO and CFO of Outlook Therapeutics. "With both this supplemental safety study and our fully enrolled pivotal Phase 3 trial moving towards completion in the first half of 2021, we remain on track to report the full complement of data needed for our new BLA filing for wet AMD in the third quarter of 2021."

The data from this supplemental safety study, the results from a previously completed clinical experience trial, which demonstrated anticipated safety and efficacy as well as positive proof-of-concept, and the data from the ongoing, fully enrolled pivotal Phase 3 trial will form the complete data set required for a potential new BLA filing for the treatment of wet AMD in the second half of 2021.

While unapproved repackaged IV bevacizumab from compounding pharmacies is already widely used in treating retinal diseases, ONS-5010, if approved, will be the first on-label injectable ophthalmic formulation of bevacizumab-vikg for the treatment of wet AMD and other retinal diseases; it will offer a new approved anti-VEGF treatment option across the spectrum of retinal care, currently estimated to be over $13 billion globally for anti-VEGF therapies. In addition to working towards a new BLA filing under the 351(a) PHSA regulatory pathway, Outlook Therapeutics is also engaged with regulatory authorities in Europe and other major markets for anticipated approvals in those markets. In addition to seeking regulatory approval for treating wet AMD, Outlook Therapeutics intends to initiate registration clinical trials for ONS-5010 for DME and BRVO.

Commercial launch planning for ONS-5010 is ongoing, including distribution, physician and patient outreach, key opinion leader support and payor community engagement. With an enhanced safety and cost-effectiveness profile, Outlook Therapeutics expects ONS-5010 to be widely adopted by payors and clinicians worldwide and to become the first-line drug of choice for payor-mandated "step edit" in the United States for retinal indications. Outlook Therapeutics is also engaged with several life sciences companies that could result in a strategic partnership and definitive agreement for ONS-5010 as soon as the end of 2020.

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 a Phase 3 clinical trial for wet AMD and, if successful, is expected to be filed with 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 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 (or 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.

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 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, the pivotal Phase 3 trial, 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 sufficiency of exposures to support such submission, statements about commercial launch of ONS-5010, the timing of entry into a strategic partnership and definitive agreement with a global ophthalmic company, including its ability to do so, 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, risks in obtaining necessary regulatory approvals, and risks of negotiating strategic partnership agreements, 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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