Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Reports Final Visit for Last Patient in Open-Label Safety Study for ONS-5010/LYTENAVA™ (bevacizumab-vikg)

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Topline results from open-label safety study (NORSE THREE) on target for Q2 2021

MONMOUTH JUNCTION, N.J., Feb. 11, 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-vikg for use in retinal indications, today announced that the last patient completed their final visit for the ongoing open-label safety study evaluating ONS-5010/LYTENAVA ™ (bevacizumab-vikg) to treat retinal diseases (NORSE THREE).

Two of the three planned clinical trials for the ONS-5010 / LYTENAVA ™ wet age-related macular degeneration (wet AMD)U.S. Biologics License Application (BLA) are now completed. The open-label safety study enrolled 197 subjects, in only 4 weeks, with a range of retinal diseases for which an anti-VEGF drug is a therapeutic option, including wet AMD, diabetic macular edema (DME) and branch retinal vein occlusion (BRVO). Subjects enrolled in the study received three monthly intravitreal (IVT) doses of ONS-5010 / LYTENAVA™. The data from this study is expected to be reported in the second quarter of calendar 2021 and will be included in the complete data package to support the planned BLA for wet AMD, on schedule for submission to the U.S. Food and Drug Administration (FDA) in the fourth quarter of calendar 2021.

"We sincerely thank the clinicians and study participants for their commitment and dedication to completing this safety study in this ongoing pandemic environment. The NORSE THREE study plays a key role in our overall ONS-5010 registration program. With the last patient visit now completed in this study, we are focused on the successful completion and data readout for the pivotal NORSE TWO Phase 3 study of ONS-5010 for the treatment of wet AMD, followed by our planned BLA submission," added Lawrence A. Kenyon, President, CEO and CFO, Outlook Therapeutics.

Following the data readout from both the open-label safety study and the pivotal safety and efficacy study, Outlook Therapeutics plans to submit a new BLA filing to the FDA under the PHSA 351(a) regulatory pathway. If the BLA is approved, it will result in 12 years of marketing exclusivity for ONS-5010.

Commercial launch planning has begun, 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, if approved, 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.

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 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 a range of retinal diseases in the United States, United Kingdom, Europe, Japan, China 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, initially for wet AMD. 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 "intend," "will," "potential," "may," "might," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict" or "continue," the negative of terms like these or other comparable terminology, and other words or terms of similar meaning. These include statements about timing of data from ongoing clinical trials of ONS-5010, timing of BLA submission, expectations regarding marketing exclusivity, market acceptance, ONS-5010's ability to meet a clinical and market need, ONS-5010's potential as the first FDA-approved ophthalmic formulation of bevacizumab-vikg, commercialization if approved, initiation of clinical trials in other indications, 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 funding such ongoing development, as well as those risks detailed in Outlook Therapeutics' filings with the Securities and Exchange Commission. These risks, which include the uncertainty of future impacts related to the ongoing COVID-19 pandemic, 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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