Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Completes Patient Enrollment of Open-Label Safety Study for ONS-5010/LYTENAVA™ (bevacizumab-vikg)

November 3, 2020

- **Full enrollment of 195 subjects in NORSE THREE achieved in less than one month, significantly ahead of schedule**
- **All planned clinical trials for ONS-5010/LYTENAVA ™BLA for wet AMD now fully enrolled or completed**
- **Pivotal data expected in mid-2021 from ongoing, fully enrolled Phase 3 registration trial for ONS-5010 (NORSE TWO) with new BLA filing expected in second half of 2021**

MONMOUTH JUNCTION, N.J., Nov. 03, 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 completion of patient enrollment for its planned open-label safety study evaluating ONS-5010/LYTENAVA™ (NORSE THREE). Patient enrollment for the study was completed in less than one month, significantly ahead of the planned four-month enrollment schedule.

The open-label safety study enrolled 195 subjects with a range of retinal diseases for which an anti-VEGF drug is a therapeutic option, including wet age-related macular degeneration (AMD), diabetic macular edema (DME) and branch retinal vein occlusion (BRVO). Subjects enrolled in the study are receiving three monthly intravitreal (IVT) doses of ONS-5010/LYTENAVA™. The data from this study will be included in the complete data package to support the planned Biologics License Application (BLA) for wet AMD, on schedule for submission to the United States Food and Drug Administration (FDA) in the second half of 2021.

"I am delighted to see the enthusiasm for ONS-5010 that our clinical trial investigators have shown and their ability to rapidly enroll patients. The expedited manner in which enrollment was completed strengthens our confidence that an FDA-approved ophthalmic formulation of bevacizumab represents a significant unmet need in the ophthalmic community," said Mark Humayun, MD, PhD, Medical Advisor to Outlook Therapeutics.

While unapproved repackaged IV bevacizumab from compounding pharmacies is already widely used in treating retinal diseases, ONS-5010, if approved, will be the first and only on-label ophthalmic formulation of bevacizumab-vikg for the treatment of wet AMD. It will offer a new, approved treatment option for wet-AMD, in the estimated $13 billion global market for anti-VEGF retina therapies.

"On behalf of the entire Outlook Therapeutics team, I would like to express our deep appreciation to the dedicated clinicians conducting this safety study as part of our ONS-5010 registration program," added Lawrence Kenyon, President, CEO and CFO, Outlook Therapeutics. "The speed with which we completed enrollment in this safety study tells us a lot about the confidence of physicians and patients in ONS-5010. We believe that we remain well-positioned to file a new BLA for wet AMD as planned in 2021, now that all three of the planned clinical trials have either been completed or are fully enrolled."

In addition to the planned BLA filing in the United States, Outlook Therapeutics is also engaged with regulatory authorities in Europe and other major markets for anticipated approvals in those markets. Outlook Therapeutics also intends to initiate registration clinical trials for ONS-5010 for DME and BRVO.

Commercial launch planning for ONS-5010, including distribution, physician and patient outreach, key opinion leader support and payor community engagement, remains ongoing. 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 retina 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. 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.

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 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 “expect,” “will,” “could,” “may,” “might,” “should,” “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, the timing of BLA submission, sufficiency of exposures and clinical trials conducted to support such submission, ONS-5010’s potential as the first FDA-approved ophthalmic formulation of bevacizumab-vikg, including benefits therefrom to patients, payors and physicians, 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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