Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Presents NORSE TWO Phase 3 Pivotal Safety and Efficacy Data for ONS-5010 / LYTENAVA™ (bevacizumab-vikg) at the Retina Subspecialty Day, American Academy of Ophthalmology (AAO) 2021 Annual Conference

November 13, 2021

- NORSE TWO showed highly statistically significant, clinically relevant results consistent with historical ophthalmic bevacizumab data

- Data support planned BLA submission with U.S. FDA in Q12022

ISELIN, N.J., Nov. 13, 2021 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to develop and launch the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, today presented pivotal safety and efficacy data from the Phase 3 NORSE TWO trial for ONS-5010, an investigational ophthalmic formulation of bevacizumab for use in wet age-related macular degeneration (wet AMD) and other retinal indications, at the Retinal Subspecialty Day, AAO 2021 Annual Conference.

The data presentation "*Safety and Efficacy Results of ONS-5010, as Ophthalmic Bevacizumab, Phase 3 Pivotal Study of Monthly Intravitreal OS-5010 in Subjects with Wet AMD (NORSE TWO)"* was given during Section X: Late Breaking Developments, Part II by Firas M. Rahhal, MD, Retina-Vitreous Associates Medical Group, Assoc. Clinical Professor of Ophthalmology, UCLA School of Medicine.

"If approved by the FDA, ONS-5010 will become the first and only on-label ophthalmic bevacizumab, which is very significant for thousands of patients needing anti-VEGF treatments to control their wet AMD," said Dr. Rahhal. "It will be great for patients and their doctors to have more FDA-approved anti-VEGF options that are prepared specifically for intraocular use."

The NORSE TWO Phase 3 pivotal trial enrolled a total of 228 wet AMD patients at 39 clinical trial sites in the United States. NORSE TWO was a superiority trial comparing the safety and efficacy of ONS-5010 ophthalmic bevacizumab dosed monthly against ranibizumab (LUCENTIS®) dosed according to the PIER regimen in the Lucentis labeling. Participants in the trial were treated for 12 months, with the primary endpoint at Month 11 being the difference in proportion of patients who gained at least 15 letters (3 lines) in best corrected visual acuity (BCVA). The key secondary endpoint was the mean change in BCVA from baseline to Month 11. NORSE TWO data showed a strong safety profile, results consistent with previously reported safety data for ONS-5010, and similar to safety levels reported in prior research for bevacizumab used off-label in ophthalmology.

The NORSE TWO pivotal data met both primary and secondary endpoints with statistically significant and clinically relevant results:

- 41.7% (p = 0.0052) ONS-5010 subjects gained ≥ 15 letters of vision
- 56.5% (p = 0.0016) ONS-5010 subjects gained ≥ 10 letters of vision
- 68.5% (p = 0.0116) ONS-5010 subjects gained ≥ 5 letters of vision
- ONS-5010 subjects gained 11.2 letters (p = 0.0043) in BCVA

Results from NORSE TWO also demonstrated that ONS-5010 ophthalmic bevacizumab has a strong safety profile. In findings that are consistent with historical bevacizumab data reported in prior research, in all three ONS-5010 registration trials there was only one ocular inflammatory adverse event, which was treated topically and resolved without sequelae. The safety findings continue to support minimal ocular inflammation and safety signals consistent with what was previously reported in the 2011 CATT trial (National Eye Institute) and other large bevacizumab-controlled ophthalmic studies.

"With the positive results from NORSE TWO, we are confident that, if approved, ONS-5010 has the potential to become a valuable new tool in the armamentarium of therapies for wet AMD. If approved as the first on-label ophthalmic formulation of bevacizumab, ONS-5010 will enable patients to benefit from wider access and provide an attractive alternative for anti-VEGF treatment of wet AMD," added C. Russell Trenary III, President and CEO of Outlook Therapeutics. "We are moving ahead with our plans to submit our BLA for wet AMD with the FDA in the first quarter of calendar 2022 and working with other global regulatory authorities to bring this important therapy to market."

Outlook Therapeutics' clinical program investigating ONS-5010 ophthalmic bevacizumab to treat wet AMD consists of three clinical trials – NORSE ONE, NORSE TWO, and NORSE THREE – all of which have now been completed. Based on the strong data from this clinical program, Outlook Therapeutics plans to submit a new BLA under the Public Health Service Act (PHSA) 351(a) regulatory pathway in the first quarter of calendar 2022. If the BLA is approved, it is expected to result in 12 years of marketing exclusivity in the US for ONS-5010 as the first and only ophthalmic formulation of bevacizumab approved by the FDA to treat wet AMD.

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 pharmacies, products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010 can replace the need to use unapproved repackaged IV bevacizumab from compounding pharmacies for the treatment of wet AMD.

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 abnormal new blood vessels and promotes leakage from these vessels, leading to retinal edema and hemorrhage. With wet AMD, abnormally high levels of VEGF are secreted in the eye and lead to loss of vision. Anti-VEGF injection therapy treats the vision-threatening leakage and hemorrhage as well as blocks the growth of the abnormal blood vessels. 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 biopharmaceutical company working to develop and launch 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 submit ONS-5010 ophthalmic bevacizumab to the U.S. FDA as a 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 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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