Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Provides a Corporate Update and Business Outlook

January 25, 2022

- **Outlook Therapeutics advancing first ever ophthalmic formulation of bevacizumab towards new U.S. FDA Biologics License Application (BLA) submission, anticipated this quarter**

- **ONS-5010 / LYTENAVA ™ (bevacizumab-vikg) expected to receive, if approved, 12 years of regulatory exclusivity in the U.S. estimated $13 billion global ophthalmic anti-VEGF market**

- **Strong balance sheet to support the Company's expected capital needs through the anticipated approval of the ONS-5010 BLA expected in the first calendar quarter of 2023**

ISELIN, N.J., Jan. 25, 2022 (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 provided a business outlook for 2022.

"The past twelve months have been truly transformational for Outlook Therapeutics. Building off of that momentum, we continue to progress toward our targeted BLA submission this quarter and ultimately potential FDA approval. Now more than ever, we believe that ONS-5010 has the opportunity to address a significant unmet need among the retina community and the potential to provide physicians with a safe, effective, and FDA-approved version of bevacizumab that meets standards required for ophthalmic injections. With the potential for impactful milestones on the horizon, we believe we are positioning ourselves for success and remain dedicated to advancing this program to unlock the full potential of Outlook Therapeutics," commented Mr. C. Russell Trenary III, President and Chief Executive Officer of Outlook Therapeutics. "We look forward to an exciting year for Outlook Therapeutics and our continued efforts to bring ONS-5010 for wet AMD over the finish line."

ONS-5010 / LYTENAVA ™

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 age-related macular degeneration (wet AMD) and other approved retinal diseases. Since no 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 risk of contamination and inconsistent potency and availability. If approved, ONS-5010 will replace the need to use unapproved repackaged IV bevacizumab from compounding pharmacists for the treatment of wet AMD.

With the registration clinical trials now completed, 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 as anticipated in the first quarter of calendar 2023, it is expected to result in 12 years of marketing exclusivity for ONS-5010 as the first and only ophthalmic formulation of bevacizumab approved by the FDA to treat wet AMD.

As previously announced, if ONS-5010 receives FDA approval, Outlook Therapeutics plans to file a supplementary application for approval to provide the product in a pre-filled, silicone oil free syringe that will meet the strict specifications for ophthalmic use. In anticipation of potential approval, Outlook Therapeutics is conducting NORSE SEVEN to compare the safety of ONS-5010 in vials versus pre-filled syringes. NORSE SEVEN will enroll approximately 120 subjects with visual impairment due to retinal disorders. Patients will be treated for three months and the enrollment of patients in the arm of the study receiving ONS-5010 in vials has been completed.

Upcoming Milestones

- Planned submission of new BLA to the FDA in the first calendar quarter of 2022;
- Execution of the NORSE SEVEN study evaluating Outlook Therapeutic's vial delivery system versus a pre-filled syringe of ONS-5010;
- Ongoing pre-launch commercial planning underway in anticipation of potential ONS-5010 approval; and
- Continued progress on preparation for NORSE FOUR (BRVO) and NORSE FIVE AND SIX (DME) evaluating ONS-5010 for additional ophthalmic indications.

"As we advance toward a potential commercial launch of ONS-5010, we are working diligently to build the proper infrastructure to support a launch in the U.S. This includes onboarding our commercial team, expanding our operations team, and collaborating with the retina community to provide education and build awareness. Additionally, we are conducting our NORSE SEVEN study to evaluate our vial delivery systems versus a pre-filled syringe of ONS-5010. While not a gating item in our planned BLA submission or potential approval, we believe that a pre-filled syringe will be a key differentiator in the marketplace, providing a more user-friendly delivery system designed for ophthalmic use," added Mr. Trenary.

Pre-Commercialization Planning Underway

Per the National Eye Institute (NEI), use of unapproved repackaged IV bevacizumab from compounding pharmacies is estimated to account for at least 50% of all wet AMD prescriptions in the United States each year. Globally, the nine major markets account for an estimated $13.1 billion market for anti-VEGF drugs to treat retina diseases.

In anticipation of potential FDA marketing approval in 2022 for ONS-5010, Outlook Therapeutics has begun commercial launch planning, including manufacturing with drug substance manufacturer FUJIFILM Diosynth Biotechnologies and best-in-class drug product manufacturer Aji Biopharma Services, distribution, sales force planning, physician and payor advisory board outreach, key opinion leader support and payor community engagement.

To bring ONS-5010 to market in a way that benefits all stakeholders – patients, clinicians and payors – Outlook Therapeutics has already commenced collaborative discussions with payors and the retina community. Outlook Therapeutics is also developing registration documents on a parallel path for approvals in Europe and expects to submit them shortly after completing the BLA submission. Outlook Therapeutics continues to explore potential strategic commercialization partners, such as Syntone Biopharma JV in China. Outlook Therapeutics expects ONS-5010, if approved, to be a safe and cost-effective choice for patients, clinicians and payors worldwide for retinal indications.

In addition to the clinical development program 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 branch retinal vein occlusion (BRVO, NORSE FOUR) and two planned registration clinical trials evaluating the drug candidate for the treatment of diabetic macular edema (DME, NORSE FIVE and NORSE SIX). Outlook Therapeutics currently expects to initiate registration clinical trials for ONS-5010 for DME and BRVO in 2023 if FDA approval is received for the wet AMD indication.

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 may 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, potential approval and commercial launch of ONS-5010, expectations about the sufficiency of our capital, plans for and the timing of potential future clinical trials, including the expected completion of NORSE SEVEN, potential strategic partners, plans for regulatory approvals in other markets and other statements that are not historical fact. 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 (the "SEC"), including the Annual Report on Form 10-K for the fiscal year ended September 30, 2021 to be filed with the SEC and future quarterly reports we file with the SEC, 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.

CONTACTS:

Media Inquiries:
Harriet Ullman
Vice President
LaVoie Health Science
T: 617-669-3082
hullman@lavoiehealthscience.com

Investor Inquiries:
Jenene Thomas
Chief Executive Officer
JTC Team, LLC
T: 833.475.8247
OTLK@jtcir.com

Source: Outlook Therapeutics, Inc.