Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Provides Update on Biologics License Application (BLA) Submission for ONS-5010 as a Treatment for Wet AMD

May 31, 2022

ISELIN, N.J., May 31, 2022 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a pre-commercial biopharmaceutical company working to develop and launch the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, today announced that the U.S. Food and Drug Administration (FDA) has requested additional information in order to complete the filing of the Company's Biologics License Application (BLA) for ONS-5010/ LYTENAVA™ (bevacizumab-vikg) for the treatment of wet age-related macular degeneration (wetAMD). Outlook Therapeutics has voluntarily withdrawn its BLA for ONS-5010 and is actively working to respond to the FDA's request. The Company plans to re-submit a revised BLA by September 2022.

Russell Trenary, President and Chief Executive Officer of Outlook Therapeutics, commented, "We remain confident in ONS-5010 and its potential to be the first FDA-approved ophthalmic formulation of bevacizumab that avoids the public health risk to patients of off-label treatment of bevacizumab that was never approved for any ophthalmic indications. We are continuing to have productive discussions with the FDA and are committed to providing the additional information necessary to support the application. We look forward to a successful resubmission and ultimately the potential approval of ONS-5010 for the treatment of wet AMD. We also look forward to a future where virtually all retina patients treated with bevacizumab are receiving an FDA-approved ophthalmic therapy."

Based on a compilation of the data from its previously completed clinical trials – NORSE ONE, NORSE TWO and NORSE THREE – Outlook Therapeutics submitted the BLA to the FDA in March 2022. NORSE ONE, a proof-of-concept and clinical experience trial, helped validate the protocols and approach for NORSE TWO, the pivotal safety and efficacy trial. The NORSE TWO data were statistically significant and clinically relevant for the primary and all secondary endpoints. NORSE THREE was an open-label supplementary safety trial conducted to ensure that a sufficient number of patients had been dosed with ONS-5010 ophthalmic bevacizumab to support the regulatory submission.

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 must 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.

Bevacizumab-vikg is a recombinant humanized monoclonal antibody (mAb) that selectively binds with high affinity to all isoforms of human vascular endothelial growth factor (VEGF) and neutralizes VEGF's biologic activity through a steric blocking of the binding of VEGF to its receptors Flt-1 (VEGFR-1) and KDR (VEGFR-2) on the surface of endothelial cells. Following intravitreal injection, the binding of bevacizumab-vikg to VEGF prevents the interaction of VEGF with its receptors on the surface of endothelial cells, reducing endothelial cell proliferation, vascular leakage, and new blood vessel formation in the retina. 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. 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 pre-commercial 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. 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 "anticipate," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "will," 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, our ongoing discussions with the FDA, our ability to provide adequate information to the FDA to support a successful resubmission of the BLA, the timing of a resubmission of the BLA 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, 2021 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.

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.