Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Requests Type A Meeting With FDA

September 29, 2023

ISELIN, N.J., Sept. 29, 2023 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to achieve FDA approval for the first ophthalmic formulation of bevacizumab for the treatment of retinal diseases, today announced that a Type A Meeting request has been submitted to the U.S. Food and Drug Administration (FDA) to discuss the Complete Response Letter (CRL) dated August 29, 2023 regarding the Biologics License Application (BLA) for ONS-5010, an investigational ophthalmic formulation of bevacizumab under development to treat wet AMD.

In the FDA's recently issued CRL, although the Agency acknowledged the NORSE TWO pivotal trial met its safety and efficacy endpoints, it concluded it could not approve the BLA during this review cycle due to several CMC issues, open observations from pre-approval manufacturing inspections, and a lack of substantial evidence. The Company is committed to working with the FDA to address its concerns.

"Our belief remains unwavering that the retina community needs an FDA-approved ophthalmic bevacizumab to deliver an alternative on-label bevacizumab option for patients with wet AMD. We look forward to a productive meeting with FDA to discuss the CRL with the goal of obtaining a clear understanding of the items that need to be addressed to resubmit our BLA for ONS-5010 at the earliest opportunity," said Russell Trenary, President and CEO of Outlook Therapeutics.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a biopharmaceutical company working to achieve FDA approval for the launch of 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. The FDA accepted Outlook Therapeutics' BLA submission for ONS-5010 to treat wet AMD with an initial PDUFA goal date of August 29, 2023; FDA did not approve the BLA during this review cycle and the Company is working with the FDA to address the issues that have been raised so that the BLA may be re-submitted. The submission is supported by Outlook Therapeutics' wet AMD clinical program, which consists of three clinical trials: NORSE ONE, NORSE TWO, and NORSE THREE. 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. As part of the Company's multi-year commercial planning process, Outlook Therapeutics and Cencora, formerly AmerisourceBergen, entered into a strategic commercialization agreement to expand the Company's reach for connecting to retina specialists and their patients. Cencora will provide third-party logistics (3PL) services and distribution, as well as pharmacovigilance services and other services in the United States. 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," "believe," "continue," "could," "estimate," "expect," "may," "might," "intend," "potential," "predict," "should," or "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, expectations concerning discussions at a Type A Meeting with the FDA and the results thereof, expectations concerning the ability to remediate or otherwise resolve deficiencies identified in the CRL, expectations concerning decisions of regulatory bodies, including the FDA, and the timing thereof, expectations concerning the relationship with Cencora and the benefits and potential expansion thereof 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, the content and timing of the expected Type A Meeting with the FDA, the content and timing of decisions by the FDA, 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, 2022 as supplemented by the Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, in each case as filed with the SEC and future quarterly reports to be filed with the SEC, which include the uncertainty of future impacts related to macroeconomic factors, including as a result of the ongoing conflict between Russia and Ukraine, high interest rates, inflation and potential future bank failures on the global business environment. 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 Therap

eutics 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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