

Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Provides Update on Type A Meetings with FDA

November 2, 2023

ISELIN, N.J., Nov. 02, 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 it has completed the requested Type A Meetings with 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.

The FDA informed Outlook Therapeutics that an additional adequate and well-controlled clinical trial would be required for the approval of ONS-5010 for the treatment of wet AMD. During the meetings, Outlook Therapeutics reached an agreement in principle with the FDA on a clinical trial design that would most likely allow for the resubmission of the ONS-5010 BLA as early as the end of calendar year 2024, and subsequent approval around mid-2025, pending final agreement on a clinical trial protocol with the FDA and successful completion of the required additional clinical trial. The FDA and Outlook Therapeutics also agreed on the approaches needed to resolve the CMC comments in the CRL and Outlook Therapeutics believes these efforts should be sufficient to support approval.

"We are confident that we can meet the additional requirements that the FDA is requiring for approval of ONS-5010. The retina community of patients, physicians and payers are all in need of an FDA-approved bevacizumab that meets ophthalmic standards for the treatment of wet AMD, and we remain focused on achieving this critical treatment option," 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. 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 the ability to remediate or otherwise resolve deficiencies identified in the CRL, including with respect to the design and completion of a subsequent clinical trial, anticipated timelines for completion of another clinical trial and re-submission of a BLA for ONS-5010, expectations concerning decisions of regulatory bodies, including the FDA, and the timing 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, receiving agreement from the FDA for any clinical trial protocols, 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 overseas conflict between, 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 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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