Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Announces Receipt of Type A Meeting Minutes and Reiterates Regulatory Path Forward for ONS-5010

November 27, 2023

- **Resubmission of the ONS-5010 BLA on track for the end of calendar year 2024, pending final agreement on a clinical trial protocol with the FDA and successful completion of the required additional clinical trial**
- **Planned clinical trial expected to be a 3-month non-inferiority study with 60 day efficacy endpoint**

ISELIN, N.J., Nov. 27, 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 the receipt of the official minutes from the Type A meeting with the U.S. Food and Drug Administration (FDA) held in October 2023 regarding the Complete Response Letter (CRL) dated August 29, 2023 for the Biologics License Application (BLA) for ONS-5010, an investigational ophthalmic formulation of bevacizumab under development to treat wet AMD.

As previously reported, the FDA requires an additional adequate and well-controlled study to support the ONS-5010 BLA. The FDA has informed Outlook Therapeutics that it can conduct a non-inferiority study evaluating ONS-5010 versus ranibizumab in a 3-month study of treatment naïve patients with a primary endpoint at 2 months. As recommended by the FDA at the Type A meeting, Outlook Therapeutics has been working with the Division of Ophthalmology to design an appropriate study to satisfy the FDA's requirements. The FDA and Outlook Therapeutics have also identified the approaches needed to resolve the CMC comments in the CRL.

"We are encouraged by the productive discussions we have had with the FDA regarding next steps for our ONS-5010 approval pathway. We continue to believe in the potential of ONS-5010 to address the need here in the United States, as well as globally, for an approved ophthalmic bevacizumab that meets FDA standards for the treatment of wet AMD," commented Russell Trenary, President and CEO of Outlook Therapeutics.

Based on the October Type A meeting and ongoing informal discussions with the FDA, Outlook Therapeutics has submitted a protocol for review at an upcoming Type A meeting with the FDA in December 2023. Upon confirmation of the protocol details with the FDA, Outlook Therapeutics intends to submit a Special Protocol Assessment (SPA) to memorialize the agreement with the FDA on the trial design and confirm that, if successful, this additional study, in combination with the successful completion of the ongoing work related to the CMC requests in the CRL, would support approval of a resubmitted ONS-5010 BLA. Outlook Therapeutics continues to believe that the proposed clinical trial design as included in the Type A meeting request would allow for completion of the study in 2024 and resubmission of the ONS-5010 BLA by the end of calendar year 2024.

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; the 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," "will," or "would" 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 our ability to remediate or otherwise resolve deficiencies identified in the CRL issued by the FDA, including with respect to an additional clinical trial and CMS issues, the timing for completion of an additional clinical trial and resubmission of the BLA for ONS-5010, expectations concerning decisions of regulatory bodies, and the timing thereof, plans for potential commercial launch of ONS-5010, 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 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 we file with the SEC, which include the uncertainty of future impacts related to macroeconomic factors, including as a result of the ongoing overseas conflict, 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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