Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Announces Strategic Organizational Realignment

December 6, 2023

- **Realignment focused on supporting ONS-5010 U.S. and EU regulatory and commercial priorities**
- **Continued progress toward commencement of additional adequate and well-controlled study to support the ONS-5010 Biologics License Application (BLA) in the U.S.**
- **European regulatory efforts and commercial strategy development continue to advance toward expected approval of ONS-5010 in Europe in the first half of 2024**

ISELIN, N.J., Dec. 06, 2023 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to achieve U.S. Food and Drug Administration (FDA) approval for the first ophthalmic formulation of bevacizumab for the treatment of retinal diseases, today announced a realignment of resources.

Effective immediately, Joel Prieve, formerly the Senior Vice President of Commercial Operations, has been appointed to the role of Senior Vice President of Licensing and M&A. In this role, he will be responsible for developing and executing the Company's strategy in the areas of licensing and partnerships, as well as evaluating and executing potential merger and acquisition opportunities. Additionally, Terry Dagnon, formerly Chief Operations Officer, will assume the new role of Senior Advisor. Previously, Outlook Therapeutics announced the addition of Jedd Comiskey as Senior Vice President – Head of Europe to focus on potential commercial launch and commercial partnership opportunities for ONS-5010 in the EU, if approved.

As previously reported, Outlook Therapeutics is working with the FDA to design an additional adequate and well-controlled clinical trial to support the planned ONS-5010 BLA resubmission. Based on the October Type A meeting and ongoing informal discussions with FDA, Outlook Therapeutics has submitted a protocol for a non-inferiority study evaluating ONS-5010 versus ranibizumab in a 3-month study of treatment naïve patients with a primary efficacy endpoint at 2 months. 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 Complete Response Letter (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 and resubmission of the ONS-5010 BLA by the end of calendar year 2024.

Outlook Therapeutics also submitted a Marketing Authorization Application (MAA) in Europe, which was validated for review in December 2022. The formal review process of the MAA by the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) is underway with an estimated decision date expected in the first half of 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 "believe," "continue," "estimate," "expect," "may," "intend," "plan," "potential," "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 CMC 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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