Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Receives FDA Agreement Under Special Protocol Assessment (SPA) for 90 Day Non-Inferiority Study, NORSE EIGHT, and Announces Private Placement of Up to $172 Million to Advance ONS-5010

January 23, 2024

- Obtained clarity from U.S. Food and Drug Administration (FDA) on next steps to advance ONS-5010
- NORSE EIGHT expected to commence in the first quarter of CY2024, enabling potential resubmission of the ONS-5010 Biologics License Application (BLA) by the end of CY2024
- Private placements to top tier institutional investors and insiders include up to $65 million in common stock and up to an additional $107 million upon cash exercise of warrants, subject to closing conditions
- Aggregate financing, subject to achievement of milestones, is expected to be sufficient to take ONS-5010 through potential FDA approval and fund commercial launch

ISELIN, N.J., Jan. 23, 2024 (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 received written agreement from the FDA under an SPA for the NORSE EIGHT clinical trial protocol evaluating ONS-5010 in neovascular age-related macular degeneration (AMD) subjects. Additionally, Outlook Therapeutics entered into securities purchase agreements with certain institutional and accredited investors for up to $172 million in gross proceeds to fund the advancement of ONS-5010.

“The SPA increases our confidence that ONS-5010, if approved, will more effectively meet the needs of retina surgeons, patients and payers in the $9.5 billion ophthalmic anti-VEGF market in the United States, and the financing represents a significant commitment by our new and existing stockholders to advance this important development program,” commented Russell Trenary, President and Chief Executive Officer. “We believe that the funds we expect to receive in this financing will position Outlook Therapeutics to support the ONS-5010 development pathway through potential FDA approval and launch.”

The FDA has reviewed and agreed upon the NORSE EIGHT trial protocol pursuant to the SPA. If the NORSE EIGHT trial is successful, it would satisfy the FDA’s requirement for a second adequate and well-controlled clinical trial to address fully the clinical deficiency identified in the Complete Response Letter (CRL).

NORSE EIGHT will be a randomized, controlled, parallel-group, masked, non-inferiority study of approximately 400 newly diagnosed, wet AMD subjects randomized in a 1:1 ratio to receive 1.25 mg ONS-5010 or 0.5 mg ranibizumab intravitreal injections. Subjects will receive injections at Day 0 (randomization), Week 4, and Week 8 visits. The primary endpoint will be mean change in BCVA from baseline to week 8. Outlook Therapeutics expects NORSE EIGHT topline results and resubmission of the ONS-5010 BLA by the end of calendar year 2024. In addition, through a Type A meeting and additional interactions, Outlook Therapeutics has identified the approaches needed to resolve the chemistry, manufacturing and controls comments in the CRL. Outlook Therapeutics is working to address the open items and expects to resolve these comments prior to the expected completion of NORSE EIGHT.

Private Placements

Additionally, Outlook Therapeutics announced that it has entered into a definitive securities purchase agreement with certain institutional and accredited investors to purchase shares of common stock and accompanying warrants in a private placement, the closing of which is conditioned upon stockholder approval of the transaction and certain other corporate actions, expected in the first quarter of 2024. The private placement is expected to provide up to $60 million in gross proceeds at closing, before deducting placement agent fees and offering expenses. In addition, Outlook Therapeutics will have the potential to receive additional gross proceeds of up to $99 million upon the full cash exercise of the warrants being issued in the private placement, before deducting placement agent fees and offering expenses. The warrants include a feature that allows Outlook Therapeutics to require cash exercise if certain stock price and milestone conditions are met.

At the 2024 annual meeting, Outlook Therapeutics’ stockholders will be asked to approve, among other items, (i) an authorized share capital increase and (ii) a reverse stock split, each of which must be implemented prior to closing of the private placement, as well as (iii) approval of the private placement under for Nasdaq Rule 5635(d). GMS Ventures and Syntone Ventures, Outlook Therapeutics’ largest stockholders, as well as its directors, have entered into support agreements pursuant to which they have agreed to vote in favor of these proposals.

The private placement is being led by Great Point Partners, LLC, with participation from existing investor GMS Ventures as well as new investors Altium Capital, Armistice Capital, Caligan Partners LP, Schonfeld Strategic Advisors, Sphera Healthcare, Velan Capital, Woodline Partners LP, and an undisclosed life sciences dedicated investor.

BofA Securities and BTIG are acting as co-placement agents in connection with the financing.

Outlook Therapeutics also entered into a securities purchase agreement with Syntone Ventures, another existing stockholder, to purchase $5 million in shares of common stock and warrants on the same terms as the private placement, subject to receipt of requisite approvals in addition to the necessary corporate action items described above.

Outlook Therapeutics intends to use the net proceeds from the financings to fund its ONS-5010 clinical development programs, including to initiate and fund the planned NORSE EIGHT clinical trial, and for working capital and other general corporate purposes.

Convertible Note Extension

In addition, on January 22, 2024, Outlook Therapeutics reached an agreement with the holder of its outstanding convertible promissory note to extend the maturity until July 1, 2025, subject to certain conditions, including receipt of at least $25.0 million of proceeds from an equity offering and reduction of the conversion price on $15.0 million aggregate principal amount of the note.

The offer and sale of the foregoing securities are being made by Outlook Therapeutics in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the Act), and/or Regulation D promulgated thereunder, and such securities have not been registered under the Act or applicable state securities laws. Accordingly, such securities may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Act and such applicable state securities laws.

This press release shall not constitute an offer to sell or a solicitation of an offer to buy these securities, nor shall there be any sale of these securities in any state or other jurisdiction in which such offer, solicitation or sale would be unlawful prior to the registration or qualification under the securities laws of any such state or other jurisdiction.

About ONS-5010 / LYTENAVA™ (bevacizumab-vikg)

ONS-5010 is an investigational ophthalmic formulation of bevacizumab under development as an intravitreal injection for the treatment of wet AMD and other retinal diseases. Because no FDA-approved ophthalmic formulations of bevacizumab are available currently, clinicians wishing to treat retinal patients with bevacizumab have had to 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 would provide an FDA-approved option for physicians that currently prescribe unapproved repackaged oncologic 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.

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 Outlook Therapeutics 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 Outlook Therapeutics' multi-year commercial planning process, Outlook Therapeutics and Cencora entered into a strategic commercialization agreement to expand the Outlook Therapeutics' 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," "estimate," "expect," "intend," "may," "optimistic," "plan," "potential," "target," "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 Outlook Therapeutics' 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, expectations concerning the NORSE EIGHT trial design, the timing for initiation and completion of NORSE EIGHT and resubmission of the BLA for ONS-5010, the private placement, including expected proceeds from the issuance of the shares of common stock and exercise of the warrants, satisfaction of closing conditions, including receipt of necessary stockholder approvals, and uses of proceeds, the sufficiency of Outlook Therapeutics' resources, including funds from the financing, to fund its operations through various milestones, expectations concerning decisions of regulatory bodies, including the FDA and EMA, 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, 2023, filed with the SEC on December 22, 2023, and future quarterly reports Outlook Therapeutics files with the SEC, which include uncertainty of market conditions and 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.

Investor Inquiries:
Jenene Thomas
Chief Executive Officer
JTC Team, LLC
T: 833.475.8247

OTLK@jtcir.com

Source: Outlook Therapeutics, Inc.