Outlook Therapeutics, Inc. Logo

Outlook Therapeutics' Recent Financing Secures Funding to Support ONS-5010 / LYTENAVA ™ (bevacizumab-vikg) Through Planned BLA Submission

February 4, 2021

Overallotment option on recent public offering partially exercised by underwriter

Closed concurrent private placement for $3.0 million gross proceeds

Aggregate gross proceeds of $41.6 million strengthens financial position and provides strategic optionality to maximize stockholder value

MONMOUTH JUNCTION, N.J., Feb. 04, 2021 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a late clinical-stage biopharmaceutical company working to develop the first FDA-approved ophthalmic formulation of bevacizumab-vikg for use in retinal indications, today provided an update on its progress towards potential approval and commercialization of ONS-5010 / LYTENAVA™ (bevacizumab-vikg) for the treatment of wet AMD and other retinal diseases.

This week, Outlook Therapeutics completed a $35.0 million public common stock offering that included participation by GMS Ventures and Investments, an affiliate of Outlook Therapeutics' largest stockholder and strategic partner, BioLexis Pte. Ltd., as well as partial exercise of the underwriter's overallotment option for an additional $3.6 million, which is expected to close today. Outlook Therapeutics also closed the previously announced concurrent private placement of common stock to Syntone Ventures, LLC, its strategic partner in China, for additional gross proceeds of $3.0 million. The combined net proceeds from these stock offerings are expected to provide sufficient capital to fund operations through the expected filing of the Biologics License Application (BLA) for ONS-5010 for wet age-related macular degeneration (wet AMD), which is planned for the end of calendar 2021. This financing also provides Outlook Therapeutics with optionality as it evaluates the best commercialization path for ONS-5010.

"This recent financing provides Outlook Therapeutics with the necessary capital to advance ONS-5010 to BLA filing for wet AMD and to also continue discussions with potential partners as we evaluate the best path forward to commercialize ONS-5010 as LYTENAVA™," commented Lawrence A. Kenyon, President, CEO and CFO of Outlook Therapeutics. "Not only have we secured enough capital to significantly extend our cash runway through important upcoming milestones in 2021, but we have provided ourselves with more time to unlock the greatest value and potential for ONS-5010, the company, and our stockholders. We believe we are now in an improved position that will allow us to both maximize the value of this asset and to provide an FDA-approved ophthalmic formulation of bevacizumab to patients."

Commercial launch planning has begun, including distribution, physician and patient outreach, key opinion leader support and payor community engagement. With an enhanced safety and cost-effectiveness profile, Outlook Therapeutics expects ONS-5010, if approved, to be widely adopted by payors and clinicians worldwide and to become the first-line drug of choice for payor-mandated "step edit" in the United States for retinal indications.

Extensive market research indicates that ONS-5010, if approved, will be a significant therapy in the retinal anti-VEGF market, currently estimated to be in excess of $13 billion worldwide.

Clinical Progress of ONS-5010 On Track

All planned clinical trials for ONS-5010 / LYTENAVA™ (bevacizumab-vikg) for the wet AMD U.S. BLA are now fully enrolled or completed. Outlook Therapeutics completed patient enrollment in its pivotal Phase 3 (NORSE TWO) clinical trial in July 2020, enrolling a total of 227 patients at 39 clinical trial sites in the United States. Outlook Therapeutics expects to report pivotal safety and efficacy data in the third calendar quarter of 2021.

Additionally, in November 2020, Outlook Therapeutics completed enrollment of 195 subjects, ahead of schedule, with a range of retinal diseases for which an anti-VEGF drug is a therapeutic option, including wet age-related macular degeneration (wet AMD), diabetic macular edema (DME) and branch retinal vein occlusion (BRVO), for its open-label safety study (NORSE THREE). The study is being conducted to ensure the adequate number of safety exposures to ONS-5010 are available for the initial regulatory filings.

Following the data readout from both the open-label safety study and the pivotal safety and efficacy study, Outlook Therapeutics plans to submit a new BLA filing to the U.S. Food and Drug Administration (FDA). If the BLA is approved, it will result in 12 years of marketing exclusivity.

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

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) is an investigational ophthalmic formulation of bevacizumab under development to be administered as an intravitreal injection for the treatment of wet AMD and other retinal diseases. Because no currently approved ophthalmic formulations of bevacizumab are available, clinicians wishing to treat retinal patients with bevacizumab have had to use unapproved repackaged IV bevacizumab provided by compounding pharmacists, products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010 will reduce the need for use of unapproved repackaged IV bevacizumab from compounding pharmacists for retinal disease.

ONS-5010 is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody (mAb) that inhibits VEGF and associated angiogenic activity. VEGF is a protein that promotes the growth of new abnormal blood vessels. With wet AMD, abnormally high levels of VEGF are secreted in the eye and lead to loss of vision. Anti-VEGF injection therapy blocks this growth. Since the advent of anti-VEGF therapy, it has become the standard-of-care treatment option within the retina community globally.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a late clinical-stage biopharmaceutical company working to develop ONS-5010/LYTENAVA™ (bevacizumab-vikg) as the first FDA-approved ophthalmic formulation of bevacizumab-vikg for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010 is approved, Outlook Therapeutics expects to commercialize it as the first and only FDA-approved ophthalmic formulation of bevacizumab-vikg for use in treating a range of retinal diseases in the United States, United Kingdom, Europe, Japan, China and other markets. Outlook Therapeutics expects to file ONS-5010 with the U.S. FDA as a new BLA under the PHSA 351(a) regulatory pathway, initially for wet AMD. 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 “potential,” “expect,” “intend,” “will,” “may,” “might,” “should,” “plan,” “anticipate,” “project,” “believe,” “estimate,” “predict” or “continue,” the negative of terms like these or other comparable terminology, and other words or terms of similar meaning. These include statements about the sufficiency of the cash runway, the timing of BLA submission, the expected optionality to evaluate commercialization path, the ability to maximize the value of ONS-5010, the closing of the partial exercise of the over-allotment option, ONS-5010’s ability to meet a clinical and market need, ONS-5010’s potential as the first FDA-approved ophthalmic formulation of bevacizumab-vikg, commercialization and pricing of ONS-5010 if approved, clinical trials in other indications, and plans for regulatory approvals in other markets. 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, risks in obtaining necessary regulatory approvals, and risks of funding such ongoing development, as well as those risks detailed in Outlook Therapeutics’ filings with the Securities and Exchange Commission, which include the uncertainty of future impacts related to the ongoing COVID-19 pandemic. 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.

CONTACTS:

Media Inquiries:
Harriet Ullman
Assistant Vice President
LaVoieHealthScience
T: 617-669-3082
hullman@lavoiehealthscience.com

Investor Inquiries:
Jenene Thomas
Chief Executive Officer
JTC Team, LLC
T: 833.475.8247
OTLK@jtcir.com

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