Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Reports Financial Results for Fiscal Year 2021 and Provides Corporate Update

December 22, 2021

- **Positive clinical data reported for ONS-5010 / LYTENAVA ™ (bevacizumab-vikg) in 2021 from multiple clinical trials, including statistically significant top-line efficacy and safety data from pivotal Phase 3 NORSE TWO trial for wet age-related macular degeneration (wet AMD)**

- **Recent financing activities expected to provide funding through the anticipated approval of the ONS-5010 biologics license application (BLA) expected in the first calendar quarter of 2023**

- **Pre-launch commercial planning underway in anticipation of ONS-5010 approval**

ISELIN, N.J., Dec. 22, 2021 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to develop and launch the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, today announced recent corporate highlights and financial results for its fiscal year ended September 30, 2021.

Outlook Therapeutics also provided a clinical development and pre-commercialization update on ONS-5010 / LYTENAVA ™ (bevacizumab-vikg), its investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD) and other retinal indications.

Recent Corporate Highlights

- Closed a $57.5 million gross proceeds equity offering, including full exercise of underwriter's option to purchase additional shares;
- Presented data at scientific conferences including the Retina Subspecialty Day, American Academy of Ophthalmology (AAO) 2021 Annual Conference, the Eyecelerator@AAO 2021 Conference Retina Showcases, the 2021 American Society of Retina Specialists (ASRS) Annual Meeting, the Ophthalmology Innovation Summit (OIS) Retina Innovation Showcase, and the EURETINA Virtual 2021 Medical Conference;
- Reported new positive 12-month safety data from pivotal Phase 3 NORSE TWO trial, which reinforce strong safety profile consistent with previous trials of ONS-5010 and with prior published data on ophthalmic use of bevacizumab; and
- Announced positive top-line results from pivotal Phase 3 NORSE TWO safety and efficacy trial evaluating ONS-5010 for treatment of wet AMD.

"The past year has been truly transformational for Outlook Therapeutics. Our goal was to successfully complete the registration clinical trials for ONS-5010, and we have not only accomplished that but also reported statistically significant and clinically relevant data that bolster our confidence as we progress toward our BLA submission and potential FDA approval. I am incredibly proud of this team and the solid execution on the strategic path toward potential approval. ONS-5010 has the opportunity to address a significant unmet need among the retina community in the multi-billion dollar U.S. market for treating wet AMD. This is truly an exciting time, as we believe we are positioning ourselves for success and remain dedicated to advancing this program and building shareholder value as we head into 2022," commented Mr. C. Russell Trenary III, President and Chief Executive Officer of Outlook Therapeutics. "We designed ONS-5010 to meet stringent standards associated with pH levels, osmolarity, drug concentration, stability, shelf life, endotoxin levels, lack of particulates, and sterility that have been established by the FDA for approved ophthalmic drugs. If approved, ONS-5010 would represent a unique form of bevacizumab for use in ophthalmology."

ONS-5010 (bevacizumab-vikg) Clinical Program Overview

Outlook Therapeutics' wet AMD ONS-5010 clinical program for the planned BLA submission consists of three clinical trials, NORSE ONE, NORSE TWO, and NORSE THREE, all of which have now been completed. In early August, Outlook Therapeutics reported positive top-line data from its NORSE TWO pivotal Phase 3 clinical trial. In NORSE TWO, ONS-5010 achieved statistically significant and clinically relevant primary (p = 0.0052) and key secondary (p = 0.0043) efficacy endpoints with 41.7% of subjects gaining at least 15 letters of BVCA. In November 2021, positive results were also reported at the AAO 2021 Annual Conference for the remaining secondary endpoints, with 56.5% (p = 0.0016) of ONS-5010 subjects gaining ≥ 10 letters of vision and 68.5% (p = 0.0116) of ONS-5010 subjects gaining ≥ 5 letters of vision. ONS-5010 was also found to be safe and well tolerated in the NORSE TWO trial.

With the registration clinical trials now completed, Outlook Therapeutics plans to submit a new BLA under the Public Health Service Act (PHSA) 351(a) regulatory pathway in the first quarter of calendar 2022. If the BLA is approved as planned in the first quarter of calendar 2023, it is expected to result in 12 years of marketing exclusivity for ONS-5010 as the first and only ophthalmic formulation of bevacizumab approved by the FDA to treat wet AMD.

As previously announced, if ONS-5010 receives FDA approval, Outlook Therapeutics plans to file a supplementary application for approval to provide the product in a pre-filled, silicone-free syringe that meets the strict specifications for ophthalmic use. In anticipation of potential approval, Outlook Therapeutics is conducting NORSE SEVEN to compare the safety of ONS-5010 in vials versus pre-filled syringes. NORSE SEVEN will enroll ~120 subjects with visual impairment due to retinal disorders. Patients will be treated for three months and the enrollment of patients in the arm of the study receiving ONS-5010 in vials has been completed.

Pre-Commercialization Planning Underway

Per the National Eye Institute (NEI), use of unapproved repackaged IV bevacizumab from compounding pharmacies is estimated to account for at

least 50% of all wet AMD prescriptions in the United States each year. Globally, the nine major markets account for an estimated $13.1 billion market for anti-VEGF drugs to treat retina diseases.

In anticipation of potential FDA marketing approval in 2022 for ONS-5010, Outlook Therapeutics has begun commercial launch planning, including manufacturing with drug substance manufacturer FUJIFILM Diosynth Biotechnologies and best-in-class drug product manufacturer Aji Biopharma Services, distribution, sales force planning, physician and payor advisory board outreach, key opinion leader support and payor community engagement.

To bring ONS-5010 to market in a way that benefits all stakeholders – patients, clinicians and payors – Outlook Therapeutics has already commenced collaborative discussions with payors and the retina community. Outlook Therapeutics is also developing registration documents on a parallel path for approvals in Europe and expects to submit them shortly after completing the submission to the FDA. Outlook Therapeutics continues to explore potential strategic commercialization partners, such as Syntone Biopharma JV in China. Outlook Therapeutics expects ONS-5010, if approved, to be a safe and cost-effective choice for patients, clinicians and payors worldwide for retinal indications.

In addition to the clinical development program evaluating ONS-5010 for wet AMD, Outlook Therapeutics has received agreements from the FDA on three Special Protocol Assessments (SPAs) for three additional registration clinical trials. These SPAs cover the protocols for a planned registration clinical trial evaluating ONS-5010 to treat branch retinal vein occlusion (BRVO, NORSE FOUR) and two planned registration clinical trials evaluating the drug candidate for the treatment of diabetic macular edema (DME, NORSE FIVE and NORSE SIX). Outlook Therapeutics currently expects to initiate registration clinical trials for ONS-5010 for DME and BRVO in 2023 if FDA approval is received for the wet AMD indication.

Financial Highlights for the 2021 Fiscal Year Ended September 30, 2021

For the fiscal year ended September 30, 2021, Outlook Therapeutics reported a net loss attributable to common stockholders of $53.2 million, or $0.35 per basic and diluted share, compared to a net loss attributable to common stockholders of $48.9 million, or $0.67 per basic and diluted share, for fiscal 2020.

At September 30, 2021, Outlook Therapeutics had cash and cash equivalents of $14.5 million.

Subsequent to fiscal year 2021, Outlook Therapeutics closed a $57.5 million gross proceeds equity offering, including full exercise of underwriter's option to purchase additional shares, which is expected to provide funding to the anticipated approval of the ONS-5010 biologics license application (BLA) expected in the first calendar quarter of 2023.

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

ONS-5010 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 pharmacies, products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010 may replace the need to use unapproved repackaged IV bevacizumab from compounding pharmacies for the treatment of wet AMD.

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 abnormal new blood vessels and promotes leakage from these vessels, leading to retinal edema and hemorrhage. With wet AMD, abnormally high levels of VEGF are secreted in the eye and lead to loss of vision. Anti-VEGF injection therapy treats the vision-threatening leakage and hemorrhage as well as blocks the growth of the abnormal blood vessels. 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 biopharmaceutical company working to develop and launch 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. 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. Outlook Therapeutics expects to submit ONS-5010 ophthalmic bevacizumab to the U.S. FDA as a BLA under the PHSA 351(a) regulatory pathway. 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 "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," 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, including benefits therefrom to patients, payors and physicians, including expectations of market exclusivity, the timing of BLA submission, potential approval and commercial launch of ONS-5010, plans for and the timing of potential future clinical trials, potential strategic partners, 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 and risks in obtaining necessary regulatory approvals, 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, 2021 to be filed with the SEC and future quarterly reports we file with the SEC, 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.

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Outlook Therapeutics, Inc.
Consolidated Statements of Operations
(Amounts in thousands, except per share data)

	Year ended September 30,	
	2021	**2020**
Operating expenses:		
Research and development	$ 38,958	$ 26,342
General and administrative	12,769	9,971
Impairment of property and equipment	-	528
	51,727	36,841
Loss from operations	(51,727)	(36,841)
Loss on equity method investment	46	-
Interest expense, net	936	1,756
Loss on extinguishment of debt	-	1,896
Change in fair value of redemption feature	-	(1,797)
Change in fair value of warrant liability	452	(185)
Loss before income taxes	(53,161)	(38,511)
Income tax expense (benefit)	2	(3,272)
Net loss	(53,163)	(35,239)
Series A-1 convertible preferred stock dividends and related settlement	-	(166)
Deemed dividend upon modification of warrants	-	(3,140)
Deemed dividend upon amendment of the terms of the Series A-1 convertible preferred stock	-	(10,328)
Net loss attributable to common stockholders	$ (53,163)	$ (48,873)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (0.35)	$ (0.67)
Weighted average shares outstanding, basic and diluted	152,676	72,556

Consolidated Balance Sheet Data
(Amounts in thousands)

	September 30,	
	2021	**2020**
Cash and cash equivalents	$ 14,477	$ 12,536
Total assets	$ 22,811	$ 19,733
Current liabilities	$ 6,752	$ 15,889
Total stockholders' equity	$ 4,607	$ 2,826

Source: Outlook Therapeutics, Inc.