Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Reports Financial Results for Second Quarter Fiscal Year 2023 and Provides Corporate Update

May 15, 2023

- **Upcoming Prescription Drug User Fee Act (PDUFA) goal date of August 29, 2023 for ONS-5010, an investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD)**
- **Pre-launch commercial activities continue in preparation for potential approval and launch of ONS-5010**

ISELIN, N.J., May 15, 2023 (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 second quarter ended March 31, 2023.

"We continue to make significant progress in our pre-launch activities as we approach our PDUFA goal date set for August 29, 2023, just three short months away. These initiatives are focused on positioning Outlook Therapeutics as an upcoming leader in the anti-VEGF space by meeting FDA requirements for an ophthalmic approval. The ONS-5010 Biologics License Application (BLA) was submitted and accepted for filing by the FDA as a 351(a) stand-alone BLA. We believe ONS-5010, if approved, has the potential to be the standard of care in the retinal anti-VEGF space and look forward to potentially bringing to market the first FDA-approved ophthalmic formulation of bevacizumab," commented Russell Trenary, President and Chief Executive Officer of Outlook Therapeutics.

Upcoming Anticipated Milestones

- Continued progress with ongoing pre-launch commercial preparations in anticipation of potential approval for ONS-5010 in 2023;
- PDUFA goal date of August 29, 2023;
- Continued evaluation of ONS-5010 in a pre-filled syringe in the NORSE SEVEN clinical trial; and
- Estimated decision date from the EMA's CHMP on the Company's submitted MAA in the EU for ONS-5010 expected in early 2024.

Commercial Planning Underway to Support Potential Approval of the First Ophthalmic Formulation of Bevacizumab for Use in Retinal Indications

According to GlobalData, the use of unapproved repackaged IV bevacizumab from compounding pharmacies is estimated to account for approximately 50% of all wet AMD injections in the United States each year. This represents approximately 3.5 million injections of off-label, repackaged bevacizumab each year in the United States alone. Globally, the nine major markets account for an estimated $13.1 billion market for anti-VEGF drugs to treat retina diseases.

Because patients, physicians and payors rely heavily on bevacizumab as an important option for treating wet AMD, ONS-5010 has been developed to address the potential potency and safety issues that have been reported to be associated with using off-label, repackaged bevacizumab from compounding pharmacies, including:

- As reported in a study published in *JAMA*, 81% of all tested syringes of repackaged bevacizumab received from compounding pharmacies contained suboptimal protein concentrations, which could result in lower clinical efficacy.
- Non-standard materials used to transfer and hold repackaged bevacizumab can potentially add particulates to non-ophthalmic-designed bevacizumab, which in turn may fail to meet the standards FDA requires for ophthalmic compounds.

In August 2022, Outlook Therapeutics submitted a PHSA 351(a) BLA for ONS-5010 as a standalone biologic to potentially become the only approved ophthalmic formulation of bevacizumab. ONS-5010, if approved, cannot qualify as a biosimilar because the PHSA requires a biosimilar to have the same "conditions of use" (e.g., indications) as a reference product. AVASTIN, the currently marketed non-ophthalmic formulation of bevacizumab, is not approved by FDA for the treatment of wet AMD or other retinal diseases.

In the NORSE TWO Phase 3 clinical trial, which compared ONS-5010 (dosed monthly) with LUCENTIS (using the PIER dosing regimen), ONS-5010 showed significantly higher results in improving BCVA by ≥ 15 letters from baseline at 11 months (41.7% compared to 23.1% in LUCENTIS group, $p = 0.0052$). Patients receiving ONS-5010 also demonstrated statistically significant mean change in BCVA of 11.2 letters compared to 5.8 letters in the control arm ($p = 0.0043$). Additionally, the majority of ONS-5010 subjects maintained or gained BCVA during the study (defined as change from baseline in BCVA ≥ 0), with at least 80% of ONS-5010 subjects maintaining BCVA each month. Safety evaluations revealed similar safety profiles of ONS-5010 and the comparator LUCENTIS. In fact, only one serious ocular adverse event occurred in the ONS-5010 arm (increase in intraocular pressure) in 1100 injections.

If approved, ONS-5010 / LYTENAVA™ (bevacizumab-vikg) will be the first ophthalmic formulation of bevacizumab, not a biosimilar.

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Pre-Launch Preparations Proceeding as Planned

In anticipation of potential FDA marketing approval in 2023, Outlook Therapeutics has begun commercial launch planning, including best-in-class partnerships with FUJIFILM Diosynth Biotechnologies for drug substance, and with drug product manufacturer Aji Bio-pharma Services for the finished drug product.

Outlook Therapeutics is actively building out its sales and commercial team, and in September, 2022 Outlook Therapeutics entered into a strategic partnership with AmerisourceBergen in preparation for the anticipated commercial launch in the United States of ONS-5010. As Outlook Therapeutics moves toward a potential launch in the United States, AmerisourceBergen's commercialization support will expand to include additional services. Through the agreement with AmerisourceBergen, Outlook Therapeutics expects to significantly increase market access and efficient distribution of ONS-5010, if approved by the FDA. Moreover, working with AmerisourceBergen will help to provide Outlook Therapeutics with an accelerated pathway to deliver a high-quality customer experience to retina specialists. To bring ONS-5010 to market in a way that benefits all stakeholders – patients, clinicians, and payors – Outlook Therapeutics has also been in collaborative discussions with payors and the retina community.

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 EMA's Committee for Medicinal Products for Human Use (CHMP) is underway with an estimated decision date expected in early 2024. In addition to pursuing potential strategic partnering opportunities in the EU and other regions, such as the current partnership with Syntone Biopharma JV in China, Outlook Therapeutics is also exploring an expanded relationship with AmerisourceBergen to support the launch of ONS-5010 in international markets. AmerisourceBergen increased its global distribution capabilities in 2021 with the acquisition of PharmaLex and Alliance Healthcare, leading wholesalers and specialized service provider of healthcare products in Europe.

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.

Financial Highlights for the Fiscal Second Quarter Ended March 31, 2023

For the fiscal second quarter ended March 31, 2023, Outlook Therapeutics reported a net loss attributable to common stockholders of $6.7 million, or $0.03 per basic and diluted share, compared to a net loss attributable to common stockholders of $19.7 million, or $0.09 per basic and diluted share, for the same period last year.

As of March 31, 2023, Outlook Therapeutics has cash and cash equivalents of $43.7 million, which is expected to be sufficient to fund its operations through the anticipated approval of the BLA for ONS-5010 in the third calendar quarter of 2023, and potentially through the fourth calendar quarter of 2023.

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 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 can replace the need to use 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 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. The FDA accepted Outlook Therapeutics' BLA submission for ONS-5010 to treat wet AMD with a PDUFA goal date of August 29, 2023. The submission is supported by Outlook Therapeutics' wet AMD clinical program, which consists of three clinical trials: NORSE ONE, NORSE TWO, and NORSE THREE. 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, and in anticipation of potential FDA approval in August 2023, Outlook Therapeutics and AmerisourceBergen have entered into a strategic commercialization agreement to expand the Company's reach for connecting to retina specialists and their patients. AmerisourceBergen 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," or "will," 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 potential approval and commercial launch of ONS-5010 and the timing thereof, expectations about the sufficiency of our capital, upcoming anticipated milestones, expectations concerning decisions of regulatory bodies, including the FDA and the EMA, and the timing thereof, our estimated market, expectations concerning our relationship with AmerisourceBergen and the benefits and potential expansion thereof, plans for and the timing of potential future clinical trials, including the expected completion of NORSE SEVEN and the expected commencement of NORSE FOUR, NORSE FIVE and NORSE SIX, potential strategic partners, plans for regulatory submissions, approvals and commercialization of ONS-5010 in other markets 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, 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 March 31, 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 conflict between Russia and Ukraine, the COVID-19 pandemic, 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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Outlook Therapeutics, Inc.
Consolidated Statements of Operations
(Amounts in thousands, except per share data)

	Three months ended March 31,		Six months ended March 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 545	$ 12,220	$ 10,407	$ 22,092
General and administrative	6,293	6,690	12,119	9,967
Loss from operations	(6,838)	(18,910)	(22,526)	(32,059)
Loss (income) on equity method investment	17	6	(5)	30
Interest (income) expense, net	(188)	418	2,261	770
Loss on extinguishment of debt	-	-	578	1,026
Change in fair value of promissory notes	3	344	3	506
Change in fair value of warrant liability	(19)	25	(49)	(225)
Loss before income taxes	(6,651)	(19,703)	(25,314)	(34,166)
Income tax expense	3	2	3	2
Net loss attributable to common stockholders	$ (6,654)	$ (19,705)	$ (25,317)	$ (34,168)
Per share information:				
Net loss per share of common stock, basic and diluted	$ (0.03)	$ (0.09)	$ (0.10)	$ (0.17)
Weighted average shares outstanding, basic and diluted	256,667	219,068	241,878	203,443

Consolidated Balance Sheet Data
(Amounts in thousands)

	March 31, 2023	September 30, 2022
Cash and cash equivalents	$ 43,629	$ 17,397
Total assets	$ 54,024	$ 28,528
Current liabilities	$ 43,528	$ 19,730
Total stockholders' equity	$ 10,488	$ 8,737

Source: Outlook Therapeutics, Inc.