Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Reports Financial Results for Fiscal Year 2024 and Provides Corporate Update

December 27, 2024

- **LYTENAVA™ is the first and only approved ophthalmic formulation of bevacizumab for the treatment of wet AMD in the European Union (EU) and United Kingdom (UK); First commercial launch anticipated in H1 CY25**
- **Received NICE recommendation of LYTENAVA™ (bevacizumab gamma) for the treatment of wet AMD**

ISELIN, N.J., Dec. 27, 2024 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company that achieved regulatory approval in the European Union and the United Kingdom earlier this year for the first authorized use of an ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD), today announced financial results for fiscal year 2024 and provided a corporate update.

"Over the course of the past year, our team has continued to execute and progress the development of ONS-5010/LYTENAVA™ in Europe and the United States. Following the receipt of our first positive reimbursement decision worldwide for LYTENAVA™ from NICE in the United Kingdom, our team continues to make preparations for commercial launch in the UK and Germany, which is expected in the first half of calendar 2025," commented Lawrence Kenyon, Chief Financial Officer and Interim Chief Executive Officer of Outlook Therapeutics. "We expect to receive the month 3 NORSE EIGHT efficacy data in January 2025 and are continuing preparations for the planned resubmission of our BLA in the first quarter of calendar 2025. We believe that 2025 holds significant opportunity for Outlook Therapeutics and we remain confident in the potential of ONS-5010/LYTENAVA™ to provide a meaningful impact globally for the treatment of wet AMD."

Upcoming Anticipated Milestones

- Final efficacy data from NORSE EIGHT expected in January 2025;
- Resubmission of the ONS-5010 BLA targeted for Q1 CY2025;
- Initial commercial launches in Europe planned to commence in first half of CY2025; and
- Potential for US FDA approval of ONS-5010 in second half of CY2025.

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) Clinical and Regulatory Update

In May 2024, the European Commission granted Marketing Authorization for LYTENAVA™ (bevacizumab gamma) for the treatment of wet AMD in the EU. Additionally, in July 2024, the UK Medicines and Healthcare products Regulatory Agency (MHRA) granted Marketing Authorization for LYTENAVA ™ (bevacizumab gamma) for the same indication in the UK. In December 2024, the National Institute for Health and Care Excellence (NICE) recommended LYTENAVA™ (bevacizumab gamma) as an option for the treatment of wet AMD. Plans for a potential 2025 launch in the UK and Germany are ongoing. Outlook Therapeutics remains confident that ONS-5010/ LYTENAVA™ is an important therapy for the treatment of wet AMD in place of off-label repackaged bevacizumab that has not received regulatory approval for use in retina diseases such as wet AMD.

Previously, the Company reported that in the NORSE EIGHT trial, ONS-5010 did not meet the pre-specified non-inferiority endpoint at week 8 set forth in the special protocol assessment (SPA) with the U.S. Food and Drug Administration (FDA). However, the preliminary data from the trial demonstrated an improvement in vision and the presence of biologic activity, as well as a continued favorable safety profile for ONS-5010. Analysis of the data is ongoing as the month 3 data from NORSE EIGHT is being collected, which is expected to be available in January 2025. Upon receipt of the full month 3 efficacy and safety results for NORSE EIGHT, Outlook Therapeutics plans to resubmit the BLA for ONS-5010 in the first quarter of calendar 2025.

LYTENAVA™ (bevacizumab gamma) is the first and only authorized ophthalmic formulation of bevacizumab for use in treating wet AMD in adults in the EU and UK and has an initial 10 years of market exclusivity. Authorization may also be sought in other European countries, Japan, and elsewhere. As part of a multi-year planning process, Outlook Therapeutics entered into a strategic collaboration with Cencora (formerly AmerisourceBergen) to support the commercial launch of LYTENAVA ™ globally following regulatory approvals. The collaboration and integrated approach is designed to support market access and efficient distribution of LYTENAVA™ to benefit all stakeholders, including retina specialists, providers and patients.

In the EU and the UK and other regions outside of the US, Outlook Therapeutics is planning to commercialize LYTENAVA™ (bevacizumab gamma) directly and is also assessing potential licensing and partnering options. Additionally, if approved by the FDA, Outlook Therapeutics plans to commercialize ONS-5010/LYTENAVA™ (bevacizumab-vikg) directly in the US.

Financial Highlights for the 2024 Fiscal Year Ended September 30, 2024

For the fiscal year ended September 30, 2024, Outlook Therapeutics reported a net loss of $75.4 million, or $4.06 per basic and diluted share, compared to a net loss of $59.0 million, or $4.72 per basic and diluted share, for the prior fiscal year.

As of September 30, 2024, Outlook Therapeutics had cash and cash equivalents of $14.9 million.

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

ONS-5010/LYTENAVA ™ is an ophthalmic formulation of bevacizumab for the treatment of wet AMD. LYTENAVA ™ (bevacizumab gamma) is the subject of a centralized Marketing Authorization granted by the European Commission in the European Union (EU) and Marketing Authorization granted by the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK) for the treatment of wet age-related macular degeneration (wet AMD).

In the United States, ONS-5010/LYTENAVA™ (bevacizumab-vikg) is investigational and is being evaluated in an ongoing non-inferiority study for the

treatment of wet AMD.

Bevacizumab-vikg (bevacizumab gamma in the EU and UK) 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 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 focused on the development and commercialization of ONS-5010/LYTENAVA ™ (bevacizumab-vikg; bevacizumab gamma), for the treatment of retina diseases, including wet AMD. LYTENAVA™ (bevacizumab gamma) is the first ophthalmic formulation of bevacizumab to receive European Commission and MHRA Marketing Authorization for the treatment of wet AMD. Outlook Therapeutics is working to initiate its commercial launch of LYTENAVA™ (bevacizumab gamma) in the EU and the UK as a treatment for wet AMD, expected in the first half of calendar 2025. In the United States, ONS-5010/LYTENAVA ™ is investigational, is being evaluated in an ongoing non-inferiority study for the treatment of wet AMD, and if successful, the data may be sufficient for Outlook to resubmit a BLA to the FDA in the United States. If approved in the United States, ONS-5010/LYTENAVA™, would be the first approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD.

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," "expect," "may," "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, plans for commercial launch of ONS-5010 in the EU and UK and the timing thereof, including the potential to launch with a partner, plans to continue analyzing data for the NORSE EIGHT trial and the potential to resubmit the BLA for ONS-5010 and the timing thereof, 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 decisions of regulatory bodies and the timing thereof, the potential of ONS-5010/LYTENAVA ™ as a treatment for wet AMD, the market opportunity for 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 and commercializing pharmaceutical product candidates, risks of conducting clinical trials and risks in obtaining necessary regulatory approvals, including the risk that the data from the NORSE EIGHT trial does not support the resubmission or subsequent filing by the FDA of the ONS-5010 BLA, the content and timing of decisions by regulatory bodies, the sufficiency of Outlook Therapeutics' resources, 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 conflicts, 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: 908.824.0775
OTLK@jtcir.com

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

	Year ended September 30,	
	2024	**2023**
Operating expenses:		
Research and development	$ 41,763	$ 26,453
General and administrative	29,940	26,673
Loss from operations	(71,703)	(53,126)
Loss on equity method investment	101	11
Interest income	(906)	(971)
Interest expense	3,157	2,531
Loss on extinguishment of debt	-	578
Change in fair value of promissory notes	2,457	3,756

Warrant related expenses	37,490	-
Change in fair value of warrant liability	(38,638)	(51)
Loss before income taxes	(75,364)	(58,980)
Income tax expense	3	3
Net loss	$ (75,367)	$ (58,983)
Per share information:		
Net loss per share of common stock, basic and diluted	$ (4.06)	$ (4.72)
Weighted average shares outstanding, basic and diluted	18,549	12,509

Consolidated Balance Sheet Data

(Amounts in thousands)

	September 30,	
	2024	**2023**
Cash and cash equivalents	$ 14,928	$ 23,392
Total assets	$ 28,823	$ 32,301
Current liabilities	$ 42,554	$ 46,732
Total stockholders' deficit	$ (73,077)	$ (14,438)

Source: Outlook Therapeutics, Inc.