Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® and AmerisourceBergen Announce Strategic Commercialization Agreement for ONS-5010 for the Treatment of Wet AMD

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ISELIN, N.J. and CONSHOHOCKEN, Pa., Sept. 27, 2022 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a pre-commercial biopharmaceutical company working to develop and launch the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, and AmerisourceBergen (NYSE: ABC), a global healthcare company and leader in specialty pharmaceutical distribution and services, announced today that they have entered into a strategic relationship in preparation for the anticipated commercial launch in the United States of ONS-5010 / LYTENAVA™ (bevacizumab-vikg), if approved by the U.S. Food and Drug Administration (FDA).

AmerisourceBergen will provide third-party logistics (3PL) services and distribution, as well as medical information and pharmacovigilance services in the United States. As Outlook Therapeutics moves toward a potential launch in the United States, and if ONS-5010 is approved by FDA, AmerisourceBergen's commercialization support will expand to include additional services, such as patient services and field solutions.

"Following our recent Biologics License Application (BLA) submission, entering a relationship with AmerisourceBergen for ONS-5010 is a critical step in the next phase of our pre-commercial strategy execution," commented C. Russell Trenary, III, President and CEO of Outlook Therapeutics. "AmerisourceBergen is the preeminent leader in specialty pharma distribution, which will provide expansive reach and access to the vast majority of anti-VEGF providers. This is expected to significantly enhance our commercial reach. Together, we believe we will be in a position to significantly upgrade treatment options for people living with wet AMD."

"We are thrilled to support Outlook Therapeutics for their pre-commercial launch preparations and, pending FDA approval, plan to leverage our portfolio of commercialization solutions to help them maximize commercial success and increase patient access," said Willis Chandler, President of Global Pharma Services at AmerisourceBergen. "We are uniquely positioned to deliver support across the product lifecycle to meet our partners' specific needs and help them achieve the outcomes they desire. We look forward to continuing to expand our support—both in the U.S. and key markets worldwide—over time."

As the exclusive distribution partner to more than 65,000 community practices nationwide, AmerisourceBergen distributes specialty care products to community practices, such as retinal, eye surgery and ophthalmology practices. If ONS-5010 receives approval, AmerisourceBergen's Besse Medical, one of the largest specialty pharmaceutical distributors to retina specialists, will work to ensure providers across the United States have efficient access to the product. As part of the agreement, AmerisourceBergen's ICS affiliate, a leader in outsourced logistics and distribution services, will provide distribution support, including cold chain storage, via its network of facilities nationwide. Innomar Strategies, a leading service provider for biopharma companies in Canada and a part of AmerisourceBergen, will deliver pharmacovigilance and medical information services for ONS-5010 in the United States.

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.

Outlook Therapeutics is also exploring a relationship with AmerisourceBergen to support the launch of ONS-5010 in international markets. AmerisourceBergen expanded its global distribution capabilities in 2021 with the acquisition of Alliance Healthcare, a leading wholesaler of healthcare products in Europe.

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 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), an investigational therapy, as the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO. Outlook Therapeutics has submitted its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for ONS-5010 to treat wet AMD. The submission is supported by Outlook Therapeutics' wet AMD registration 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. For more information, please visit www.outlooktherapeutics.com.

About AmerisourceBergen

AmerisourceBergen fosters a positive impact on the health of people and communities around the world by advancing the development and delivery of pharmaceuticals and healthcare products. As a leading global healthcare company, with a foundation in pharmaceutical distribution and solutions for

manufacturers, pharmacies, and providers, we create unparalleled access, efficiency, and reliability for human and animal health. Our 42,000 global team members power our purpose: We are united in our responsibility to create healthier futures. AmerisourceBergen is ranked #10 on the Fortune 500 with more than $200 billion in annual revenue. Learn more at https://amerisourcebergen.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," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "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, Outlook's partnership with AmerisourceBergen, the services to be provided thereunder and the anticipated benefits thereof, potential future partnerships with AmerisourceBergen, Outlook's expected commercial reach, market access and distribution network, the timing of a commercial launch of ONS-5010, potential launch in international 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, including the Annual Report on Form 10-K for the fiscal year ended September 30, 2021, as supplemented by its Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, 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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