Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Announces Validation of Marketing Authorization Application by the European Medicines Agency for ONS-5010 as a Treatment for Wet AMD

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- Decision for potential approval expected from European Commission in early 2024
- Submission follows the U.S. FDA acceptance of the ONS-5010 BLA for wet AMD, with a PDUFA date of August 29, 2023

ISELIN, N.J., Dec. 22, 2022 (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 the validation of its Marketing Authorization Application (MAA) by the European Medicines Agency (EMA) for ONS-5010 / LYTENAVA ™ (bevacizumab-vikg), an investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD). The formal review process of the MAA by the EMA's Committee for Medicinal Products for Human Use (CHMP) is now set to begin with an estimated decision date expected in early 2024.

"The validation of our MAA by the EMA is another exciting moment for our team in 2022 and takes us one step closer to offering clinicians and their patients the first and only on-label, ophthalmic bevacizumab to treat wet AMD," said Russell Trenary, President and CEO of Outlook Therapeutics. "In addition to the recent acceptance of our BLA by the U.S. FDA and our continued progress toward commercial launch, pending approval, we believe ONS-5010 is well-positioned to provide a preferred treatment option for the retina community and enhance the standard of care in the anti-VEGF space."

The MAA submission is supported by results from Outlook Therapeutics' wet AMD clinical program for ONS-5010, which consists of three completed registration clinical trials - NORSE ONE, NORSE TWO and NORSE THREE. If approved, an initial eight years of regulatory exclusivity in the European Union (EU) is expected for ONS-5010 in wet AMD. The regulatory exclusivity for ONS-5010 could potentially be increased by an additional two years if Outlook Therapeutics pursues approvals for additional indications. Outlook Therapeutics is assessing both direct commercialization and partnering in Europe on a country-by-country basis

"This is a significant milestone as we continue to execute on our development strategy and position ONS-5010 as a much-needed therapeutic option to treat retinal diseases. We are grateful to the team of European experts with whom we closely collaborated to create what we believe is a high-quality dossier for submission that can be used for further regulatory evaluation processes in other regions globally," added Terry Dagnon, Chief Operations Officer of Outlook Therapeutics. "We look forward to working with the EMA and our team of European experts throughout the review process."

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 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," "estimate," "expect," "intend," "look forward," "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, the timing of potential approval decision by the EMA, expectations concerning market exclusivity, the services to be provided under Outlook's partnership with AmerisourceBergen and the anticipated benefits thereof, expectations regarding a commercial launch of ONS-5010, plans for regulatory submissions and 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 and other macroeconomic factors. 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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