Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Announces UK Submission of Marketing Authorization Application (MAA) for ONS-5010 as a Treatment for Wet AMD

May 13, 2024

- **UK submission for national MAA review follows recently received positive opinion from Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) concerning the authorization of ONS-5010/LYTENAVA™ (bevacizumab gamma)**

ISELIN, N.J., May 13, 2024 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to achieve regulatory approval for the first authorized use of an ophthalmic formulation of bevacizumab for the treatment of retinal diseases in the US and Europe, today announced the submission of its Marketing Authorization Application (MAA) to the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom (UK) seeking authorization of ONS-5010/LYTENAVA™ (bevacizumab gamma) for the treatment of wet age-related macular degeneration (wet AMD).

The submission was completed under the new International Recognition Procedure (IRP), which allows the MHRA to rely on a positive opinion by the European Medicines Agency's CHMP concerning an application for grant of marketing authorization for the same product in the EU. The IRP is available for new UK MAAs of a medicinal product (having the same qualitative and quantitative composition, and the same pharmaceutical form) that has previously been authorized by a Reference Regulator (RR). In this case this is the EMA.

"The submission of our MAA to the MHRA is another step closer to the possibility of offering clinicians and their patients in the UK market the only on-label, ophthalmic bevacizumab to treat wet AMD," said Russell Trenary, President and CEO of Outlook Therapeutics. "On the heels of the recent positive opinion by the CHMP in the EU, we continue to make noteworthy progress toward the potential authorization of ONS-5010/LYTENAVA™ in the UK."

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.

As previously announced, Outlook Therapeutics received a CHMP positive opinion on March 22, 2024 concerning an application for grant of marketing authorization for ONS-5010/LYTENAVA™ in the EU. TheEuropean Commission is expected to make a decision within approximately 67 days following the CHMP opinion. The decision will apply automatically in all 27 EU Member States, and, within 30 days, also to Iceland, Norway and Liechtenstein.

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

ONS-5010/LYTENAVA™ 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 FDA or European Commission approved ophthalmic formulations of bevacizumab are currently available, clinicians wishing to treat retinal patients with bevacizumab have had to use repackaged IV bevacizumab authorized for a different therapeutic indication and provided by compounding pharmacies—products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010/LYTENAVA™ would provide an authorized option for physicians to treat wet AMD inthe United States, EU and the UK.

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 working to achieve FDA, European Commission and MHRA approval for the launch of ONS-5010/LYTENAVA™ (bevacizumab-vikg or bevacizumab gamma) as the first approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010/LYTENAVA™ is approved,Outlook Therapeutics expects to commercialize it as the first and only European Commission, MHRA or FDA approved ophthalmic formulation of bevacizumab for use in treating retinal diseases in the United States, EU, and UK. Authorization may also be sought in other European markets, Japan, and other markets. As part of the Outlook Therapeutics multi-year commercial planning process, Outlook Therapeutics and Cencora have entered into a strategic commercialization agreement to expand Outlook Therapeutics' reach for connecting to retina specialists and their patients. Cencora will provide third-party logistics (3PL) services and distribution, as well as pharmacovigilance services and other services in the United States, EU and UK.

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 "continue," "expect," "may," "plan," "possible," "potential," "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, ONS-5010's potential as the only on-label, ophthalmic bevacizumab to treat wet AMD for patients and clinicians in the UK market, expectations concerning decisions of regulatory bodies, including the European Commission and the MHRA, and the timing thereof, 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 pharmaceutical product candidates, risks of conducting clinical trials and risks in obtaining necessary regulatory

approvals, the content and timing of decisions by the FDA, 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.

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