Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Receives European Union Positive CHMP Opinion for ONS-5010 as a Treatment for Wet AMD

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- **Positive opinion serves as a basis for final decision for potential authorization from the European Commission (EC), expected within 67 days**

ISELIN, N.J., March 22, 2024 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to achieve the first approval for an ophthalmic formulation of bevacizumab for the treatment of retinal diseases in the US and the EU, today announced that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has issued a positive opinion concerning the authorization of ONS-5010/LYTENAVA™ (bevacizumab gamma), an investigational ophthalmic formulation of bevacizumab for the treatment of wet age-related macular degeneration (wet AMD) in the EU. Outlook Therapeutics is assessing both direct commercialization of the product and partnering in Europe on a country-by-country basis.

"The CHMP positive opinion for ONS-5010/LYTENAVA ™ represents a significant milestone for Outlook Therapeutics and advancement in the treatment of wet AMD in the EU. We are proud to be one step closer to bringing to the EU market the first and only on-label, ophthalmic bevacizumab for the treatment of wet AMD, if approved," commented Russell Trenary, President and Chief Executive Officer.

The CHMP positive opinion was based on 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 well as studies and bibliographic literature substituting or supporting certain tests and studies. If approved, an initial ten years of market exclusivity in the European Union (EU) is expected for ONS-5010/LYTENAVA ™ .

The CHMP's positive opinion supports the grant of marketing authorization by the European Commission (EC) for Outlook Therapeutics' application for ONS-5010. The EC 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 available currently, clinicians wishing to treat retinal patients with bevacizumab have had to use repackaged IV bevacizumab provided by compounding pharmacies—products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010/LYTENAVA™ would provide an approved option for physicians to treat wet AMD.

Bevacizumab-vikg/bevacizumab gamma 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 achieve FDA and European Commission 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 ophthalmic bevacizumab is approved, Outlook Therapeutics expects to commercialize it as the first and only FDA and/or EC approved ophthalmic formulation of bevacizumab for use in treating retinal diseases in the United States, EU, United Kingdom, Europe, Japan, and other markets. As part of the Outlook Therapeutics' multi-year commercial planning process, Outlook Therapeutics and Cencora entered into a strategic commercialization agreement to expand the 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. 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," "estimate," "expect," "intend," "may," "optimistic," "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, statements about ONS-5010's potential as the first ophthalmic formulation of bevacizumab-vikg for the treatment of retinal diseases in the US and EU, expectations concerning decisions of regulatory bodies, including the EC, and the timing thereof, plans for potential commercial launch of 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 pharmaceutical product candidates, risks of conducting clinical trials and risks in obtaining necessary regulatory approvals, the content and timing of decisions by the EC, 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 conflict, 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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