Outlook Therapeutics, Inc. Logo

Outlook Therapeutics to Participate in Retina World Congress 2022

May 10, 2022

ISELIN, N.J., May 10, 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, today announced that Terry Dagnon, Chief Operations Officer of Outlook Therapeutics, will be a panelist at the Retina World Congress 2022 taking place May 12-15, 2022 in Fort Lauderdale, Florida.

Details for the panel are as follows:

Session: Retina Unplugged
Title: Biosimilars (and other VEGFs)
Panelist: Terry Dagnon, Chief Operations Officer, Outlook Therapeutics
Date and time: Thursday, May 12, 2022, 8:05 AM EDT

As part of the panel, Mr. Dagnon will discuss Outlook Therapeutics' ONS-5010 / LYTENAVA ™ (bevacizumab-vikg), 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. In March 2022, Outlook Therapeutics announced the submission to the U.S. Food and Drug Administration (FDA) of its new Biologics License Application (BLA) for ONS-5010 under the Public Health Service Act (PHSA) 351(a) regulatory pathway. If the BLA is approved, it is expected to result in 12 years of marketing exclusivity for ONS-5010 as the first and only ophthalmic formulation of bevacizumab approved by the FDA to treat wet AMD.

"While off-label repackaged IV bevacizumab is widely used for retina diseases, it is not currently formulated or approved for ophthalmic use and these repackaged versions are widely known to be associated with public health concerns due to FDA compliance and safety issues," commented Terry Dagnon, Chief Operations Officer of Outlook Therapeutics. "Our ophthalmic formulation, ONS-5010, is the first bevacizumab molecule specifically formulated and optimized to meet FDA standards for ophthalmic intravitreal injection. Over the course of its development, there has been some misperception within the retina community as to whether ONS-5010 is a biosimilar to Avastin® (bevacizumab); however, with no FDA-approved ophthalmic indications for Avastin®, a biosimilar regulatory pathway is not legally possible. The ONS-5010 BLA was submitted on March 30, 2022 to FDA as a PHSA 351(a) new Biologics License Application (BLA)."

For more information about the 2022 Retina World Congress, please visit the event website here.

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 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 pre-commercial 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 under the PHSA 351(a) regulatory pathway. 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.

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 "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "potential," "intend" or "continue," 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, including expectations of market exclusivity, and plans for the commercialization of ONS-5010. 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, and subsequent Quarterly Reports on Form 10-Q, 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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