Outlook Therapeutics, Inc. Logo

Leading Ophthalmology Organization Launches Podcast Video with Firas Rahhal, MD, to Explore the Genesis and Promise of Outlook Therapeutics' ONS-5010/LYTENAVA™ (bevacizumab-vikg)

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- **Leading retina clinician Dr. Rahhal discusses the market need for an FDA-approved ophthalmic bevacizumab for treating wet AMD and other retinal diseases**
- **Terry Dagnon, COO, and Jeff Evanson, CCO, of Outlook Therapeutics share the clinical rationale and regulatory framework for developing ONS-5010 as an investigational ophthalmic formulation of bevacizumab for retinal disease**
- **Podcast video from Ophthalmology Innovation Summit is available here.**

MONMOUTH JUNCTION, N.J., Jan. 12, 2021 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a late clinical-stage biopharmaceutical company working to develop the first FDA-approved ophthalmic formulation of bevacizumab-vikg for use in retinal indications, announces the release of a podcast video produced by the Ophthalmology Innovation Summit (OIS) featuring Firas Rahhal, MD, a partner at Retina-Vitreous Associates Medical Group and Associate Clinical Professor of Ophthalmology at the UCLA School of Medicine and two members of Outlook Therapeutics' management team, Terry Dagnon, Chief Operating Officer, and Jeff Evanson, Chief Commercial Officer. The interview, led by Dr. Rahhal, discusses how and why Outlook Therapeutics is advancing its investigational compound ONS-5010, now in Phase 3 clinical trials, towards filing with the Food and Drug Administration (FDA) as the first approved and cGMP-manufactured ophthalmic formulation of bevacizumab designed to meet the needs of the retina community.

The clinical value of bevacizumab in treating retinal disease is already well established, based on prior research and nearly 15 years of clinical use. However, to date clinicians who wish to use it as a less expensive alternative to the costly approved drugs, EYLEA®, LUCENTIS® and BEOVU®, must use off-label repackaged IV bevacizumab (Avastin®) from compounding pharmacies because no FDA-approved ophthalmic formulation of bevacizumab is currently available.

"There is a real clinical and market need for an approved bevacizumab that is manufactured in a cGMP facility and falls within the regular drug supply chain. In my practice we currently use off-label repackaged IV bevacizumab for approximately half my wet AMD patients, which makes me very interested to learn more about the development of an FDA-approved ophthalmic bevacizumab such as ONS-5010 that I could use," said Dr. Rahhal. "It was great to hear from seasoned biopharma industry professionals about the strategy behind their clinical development program for such a noteworthy product."

In the podcast video, Mr. Dagnon and Mr. Evanson explain how Outlook Therapeutics intends to meet this clinical and market need with ONS-5010, which if approved will offer clinicians and their retina patients a safe and efficacious, cGMP-produced bevacizumab in the estimated $13 billion global market for anti-VEGF retina therapies. Outlook Therapeutics expects to commercialize ONS-5010, if approved, under a responsible pricing policy, bringing a win-win-win to clinicians, patients and payors. Outlook Therapeutics' initial BLA filing with the FDA will be for treatment of wet AMD, expected in the second half of this year. Additional clinical trials are planned for indications in diabetic macular edema (DME) and branch retinal vein occlusion (BRVO).

"On behalf of Outlook Therapeutics, Jeff and I want to thank OIS and Dr. Rahhal for spearheading this insightful podcast on our clinical development program for ONS-5010," said Terry Dagnon, COO of Outlook Therapeutics. "We are tremendously excited by the opportunity to have a significant positive impact on retina patients' lives around the world and to work with retina thought leaders like Dr. Rahhal and OIS to raise awareness of this potential new therapy in the retina community."

The full podcast video is available on the OIS Website here.

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

ONS-5010 / LYTENAVA™ (bevacizumab-vikg) 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 pharmacists, products that have known risks of contamination and inconsistent potency and availability. If approved, ONS-5010 will reduce the need for use of unapproved repackaged IV bevacizumab from compounding pharmacists for retinal disease.

ONS-5010 is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody (mAb) that inhibits VEGF and associated angiogenic activity. VEGF is a protein that promotes the growth of new abnormal blood vessels. With wet AMD, abnormally high levels of VEGF are secreted in the eye and lead to loss of vision. Anti-VEGF injection therapy blocks this growth. Since the advent of anti-VEGF therapy, it has become the standard-of-care treatment option within the retina community globally.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a late clinical-stage biopharmaceutical company working to develop ONS-5010/LYTENAVA™ (bevacizumab-vikg) as the first FDA-approved ophthalmic formulation of bevacizumab-vikg for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010 is approved, Outlook Therapeutics expects to commercialize it as the first and only FDA-approved ophthalmic formulation of bevacizumab-vikg for use in treating a range of retinal diseases in the United States, United Kingdom, Europe, Japan, China and other markets. Outlook Therapeutics expects to file ONS-5010 with the U.S. FDA as a new BLA under the PHSA 351(a) regulatory pathway, initially for wet AMD. For more information, please visit www.outlooktherapeutics.com.

Forward-Looking Statements

This press release and the podcast video to which it relates contain 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 “intend,” “will,” “potential,” “may,” “might,” “should,” “expect,” “plan,” “anticipate,” “project,” “believe,” “estimate,” “predict” or “continue,” the negative of terms like these or other comparable terminology, and other words or terms of similar meaning. These include statements about ONS-5010’s ability to meet a clinical and market need, ONS-5010’s potential as the first FDA-approved ophthalmic formulation of bevacizumab-vikg, commercialization and pricing of ONS-5010 if approved, the timing of BLA submission, clinical trials in other indications, , and plans for regulatory approvals in other markets. 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, risks in obtaining necessary regulatory approvals, and risks of funding such ongoing development, as well as those risks detailed in Outlook Therapeutics’ filings with the Securities and Exchange Commission, 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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