Outlook Therapeutics, Inc. Logo

Virtual KOL Roundtable Recap: Outlook Therapeutics and Firas Rahhal, MD, Discussed wet AMD Treatment Landscape and ONS-5010/LYTENAVA ™

November 11, 2020

- **Dr. Rahhal, a leading retinal clinician, offered insight on wet AMD treatment and the potential of ONS-5010/LYTENAVA ™ (bevacizumab-vikg), if approved, to improve available treatment options**
- **Outlook Therapeutics detailed ongoing development and pre-commercial planning of ONS-5010/LYTENANA ™**
- **Webcast replay from the event is now available: click here**

MONMOUTH JUNCTION, N.J., Nov. 11, 2020 (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, held its previously announced virtual KOL Roundtable on October 29, 2020 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 Outlook Therapeutics' management team – Lawrence Kenyon, President, CEO and CFO, Terry Dagnon, COO, and Jeff Evanson, CCO.

"Gaining perspective from a practicing clinician who frequently uses available anti-VEGF treatment options for his patients provides invaluable insight as we continue to advance the clinical development of our investigational ophthalmic formulation of bevacizumab, ONS-5010/LYTENAVA ™ . We believe ONS-5010, if approved, is strategically positioned to address many of the shortcomings in the treatment landscape for wet AMD that were discussed during the Roundtable, as it would offer patients and clinicians an approved ophthalmic formulation of a therapeutic that is already widely used. We thank Dr. Rahhal for taking the time to join us for our discussion and believe the retina physician point of view is important when looking at the opportunity Outlook Therapeutics presents," commented Mr. Kenyon.

Treatment Background

The Roundtable opened with a discussion of current treatment options for retinal diseases, including wet age-related macular degeneration (wet AMD), diabetic macular edema (DME) and branch retinal vein occlusion (BRVO). Such retinal diseases are characterized by excessive growth of abnormal blood vessels under the retina, which if untreated leads to vision loss and even blindness. Anti-VEGF medications control this abnormal growth, and for the past 15 years have become the standard of care for treating these diseases.

Bevacizumab is an anti-VEGF drug, but it is not approved for ophthalmic use. Although there are three anti-VEGF drugs currently approved to treat ophthalmic disease, they are extremely expensive. As a result, physicians who wish to treat their retinal patients with a less expensive anti-VEGF drug often use unapproved, repackaged IV bevacizumab from compounding pharmacists. ONS-5010, if approved, will be the first and only on-label ophthalmic formulation of bevacizumab-vikg for the treatment of wet AMD.

Payors have also weighed in on the value of bevacizumab in treating retinal diseases. Many now require use of off-label bevacizumab as a first-line treatment option before they will cover more expensive alternatives. The Centers for Medicare and Medicaid Services has issued guidance to this effect and a few major payors have also mandated its use. If approved, ONS-5010/LYTENAVA ™ will offer a new, approved treatment option for wet-AMD in the estimated $13 billion global market for anti-VEGF retina therapies.

Dr. Rahhal: The Need for an Approved Bevacizumab for Ophthalmic Use

Dr. Rahhal expanded on his personal experience over many years of treating patients with retinal diseases. In his practice, Dr. Rahhal treats approximately 50% of his wet AMD patients with repackaged IV bevacizumab from compounding pharmacists, a percentage which he said he believes is reasonably typical of other U.S. retinal practices.

Although he appreciates the significant cost savings of using off-label bevacizumab, he has at times encountered problems related to inconsistent potency, particulate contamination in the syringes, microbial contamination and syringe malfunctions. Problems can arise, he stated, as a result of variability across batches from different compounding pharmacies and from their storage practices. Additionally, silicone oil droplets can contaminate syringes, which when injected intravitreally, potentially can lead to an accumulation of silicone in patients' eyes, causing vision problems.

"In my experience, there remains an unmet need for an FDA-approved and cGMP-produced bevacizumab that is specifically formulated for ophthalmic use. What the team at Outlook Therapeutics has set out to accomplish with ONS-5010, if approved, would be a valuable addition to the treatment armamentarium," commented Dr. Rahhal. "Additionally, I believe that if Outlook Therapeutics commercializes ONS-5010, if approved, in a silicone-free, pre-filled syringe that meets the strict specifications for ophthalmic use, the product would gain widespread acceptance by the retinal treatment community. I am excited about the potential of ONS-5010 and look forward to the read-out of the pivotal data from the Phase 3 study next year. I believe ONS-5010, if approved, would be a significant improvement over the off-label bevacizumab that many doctors are already using."

Management Update on Outlook Therapeutics' Development Program

The Roundtable concluded with an update from Outlook Therapeutics' management on the current clinical development program and anticipated commercialization strategy for ONS-5010/LYTENAVA™. Management reported that the investigational compound is currently in Phase 3 registration clinical trials, with an expected read-out of pivotal data in mid-2021. Results from these trials will comprise the complete data package that is expected to be submitted to the U.S. Food and Drug Administration (FDA) for a new Biologics License Application (BLA) in the second half of 2021.

Outlook Therapeutics' management emphasized that they intend to commercialize ONS-5010, if approved, at a responsible price, and in both unit-dose vials and pre-filled ophthalmic syringes. In anticipation of a first approval from the FDA in mid-2022, Outlook Therapeutics is engaged in launch planning, including distribution, physician and patient outreach, key opinion leader support and payor community engagement. In addition to the planned BLA filing in the United States, management indicated that they are also engaged with regulatory authorities in Europe and other major markets for anticipated approvals in those markets. Outlook Therapeutics also expects to initiate registration clinical trials for ONS-5010 for DME and

BRVO.

A webcast replay of the KOL roundtable discussion is now available on the Events page of the Investors section of Outlook Therapeutics' website (outlooktherapeutics.com).

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 (or 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 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 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 "potential," "may," "might," "will," "should," "expect," "plan," "anticipate," "project," "believe," "estimate," "predict," "intend" 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 potential as the first FDA-approved ophthalmic formulation of bevacizumab-vikg, including benefits therefrom to patients, payors and physicians, the ability of ONS-5010 to gain widespread acceptance in the retinal treatment community, the timing of completion of, and pivotal safety and efficacy data from, the pivotal Phase 3 trial, the timing of BLA submission and sufficiency of exposures to support such submission, statements about commercial launch of ONS-5010, 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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