Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Announces Creation of Global Retina Advisory Council

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- **Advisory Council to collaborate on outreach to retinal clinicians to support development and commercialization of ONS-5010, an investigational ophthalmic formulation of bevacizumab**

MONMOUTH JUNCTION, N.J., Nov. 19, 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, today announced the creation of its Global Retina Advisory Council. Mark Humayun, MD, PhD, has agreed to act as Chairman of the Advisory Council and Firas Rahhal, MD, has agreed to join him as an inaugural member.

The Global Retina Advisory Council is being established by Outlook Therapeutics to ensure that it has access to guidance and advice on all relevant topics from a group of pre-eminent global specialists in retinal medicine. Outlook Therapeutics intends to include additional expert advisors from around the world as it advances its ongoing clinical program and pre-commercialization planning for ONS-5010/LYTENAVA™ (bevacizumab-vikg), an investigational ophthalmic formulation of bevacizumab for treatment of wet age-related macular degeneration (wet AMD) and other retinal diseases.

"As we expand our pre-commercialization activities in anticipation of our planned BLA filing for ONS-5010 to treat wet AMD in mid-2021, collaborating with leading experts in the retinal field will be critical to lay the groundwork for the eventual adoption by the clinical community," said Lawrence Kenyon, President, CEO and CFO of Outlook Therapeutics. "We thank Drs. Humayun and Rahhal for agreeing to join us to help bring the first approved ophthalmic formulation of bevacizumab to market. We anticipate that ONS-5010, if approved, will address the potential issues that retinal clinicians and their patients currently experience with unapproved repackaged IV bevacizumab from compounding pharmacists."

Mark Humayun, MD, PhD, is Medical Advisor at Outlook Therapeutics and a recognized retinal specialist worldwide, with over 250 publications and more than 125 issued patents. Over the course of his career, Dr. Humayun has received several research awards, including the 2005 Innovator of the Year award (*R&D* magazine) and more recently the 2020 Medal for Innovations in Healthcare Technology (Institute of Electrical and Electronics Engineers). He also has been recognized for his clinical work, voted by *U.S. News and World Report* as one of the top 1% of Ophthalmologists in America. Most notably, in 2016 Dr. Humayun received the National Medal of Technology and Innovation from President Barack Obama for his innovative work on bioengineered implants including the development of the Argus II, the world's first FDA-approved artificial retinal prosthesis.

Firas Rahhal, MD, is a partner at Retina-Vitreous Associates Medical Group in Los Angeles and is an Associate Clinical Professor of Ophthalmology at the UCLA School of Medicine – Jules Stein Eye Institute. He has published dozens of scientific papers and is a frequent presenter at major international scientific meetings. He has extensive expertise in advancing clinical development programs, having been an investigator in over 100 national or international trials, many of which led to novel therapies for vitreo-retinal diseases. Dr. Rahhal has been consistently named "Top Doctor" by his physician peers in the *Los Angeles Magazine* annual review. He is Board Certified by the American Board of Ophthalmology and is a member of the American Academy of Ophthalmology, the American Society of Retina Specialists, and The Retina Society. He is Co-Director of the RVA-USC Joint Vitreoretinal Fellowship training program.

"I am honored to be the Chairman of the Global Retina Advisory Council and look forward to working closely with Dr. Rahhal and the Outlook Therapeutics management team to advance Outlook Therapeutics' clinical program for ONS-5010 for the treatment of retina indications. The potential for an FDA-approved ophthalmic formulation of bevacizumab would be a significant addition to the retinal treatment armamentarium, and is anticipated to provide physicians a safe, approved formulation of a drug they are already using off-label in more than 50% of all wet AMD cases," added Dr. Humayun.

Outlook Therapeutics' clinical program for ONS-5010 is on track to report pivotal Phase 3 data in mid-2021, with an expected new Biologics License Application (BLA) to be submitted to the U.S. Food and Drug Administration (FDA) for treatment of wet AMD in the second half of next year. If all goes as planned, Outlook Therapeutics anticipates FDA approval for ONS-5010 in mid-2022 as the first and only approved bevacizumab to treat wet AMD. In addition to the planned BLA filing in the United States, Outlook Therapeutics is also engaged with regulatory authorities in Europe and other major markets for anticipated approvals in those markets. Outlook Therapeutics also intends to initiate registration clinical trials for ONS-5010 for DME and BRVO.

With an enhanced safety and cost-effectiveness profile, Outlook Therapeutics expects ONS-5010, if approved, to be widely adopted by payors and clinicians worldwide and to become the first-line drug of choice for payor-mandated "step edit" in the United States for retinal indications. Outlook Therapeutics is also engaged with several life sciences companies that could result in a strategic partnership and definitive agreement for ONS-5010 as soon as the end of 2020.

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 potential benefits of establishing the Global Retina Advisory Council, 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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