Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Strengthens Medical Affairs and Commercial Expertise with Appointments of Surendra Sharma, MD, Senior Vice President of Medical Affairs and Glen Olsheim, Executive Director of Commercial Excellence

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Dr. Sharma and Mr. Olsheim bring more than 30 years of combined experience in the global pharmaceutical and biotechnology industry from their various roles launching and commercializing ophthalmic products

ISELIN, N.J., Jan. 19, 2023 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to develop and launch the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, today announced the appointments of Surendra Sharma, MD, as Senior Vice President, Medical Affairs, and Glen Olsheim as Executive Director, Commercial Excellence.

"Outlook Therapeutics is very happy to welcome Surendra and Glen to our growing executive leadership team. Their respective backgrounds in directing the medical affairs of an ophthalmic portfolio and of driving the successful launch and commercialization of ophthalmic products will be tremendously valuable as we move towards the commercial launch of ONS-5010 ophthalmic bevacizumab, pending its approval by the U.S. FDA," said Russell Trenary, President and Chief Executive Officer of Outlook Therapeutics.

Dr. Sharma has more than 15 years of experience in the pharmaceutical and biotechnology industries leading corporate alliances among R&D, commercial, marketing and business stakeholders. Most recently, he was Senior Medical Director, Cornea, Dry Eye and Retina, Global Medical Affairs at Santen Pharmaceuticals, Ltd. Over the course of his career at companies including Spark Therapeutics, Inc., Biogen Inc., Alcon Laboratories, Inc. and Regeneron Pharmaceuticals, Inc., he led global scientific communications strategies designed to align and meet the needs of key stakeholders in the North American and global markets. Dr. Sharma's ability to create and maintain key relationships between the Company and key opinion leaders, the medical and scientific community, patients and advocacy groups, health authorities, and regulatory agencies will be instrumental for Outlook Therapeutics' potential launch and commercialization of ONS-5010 ophthalmic bevacizumab. In his new role as SVP of Medical Affairs, Dr. Sharma will report to Russ Trenary, President and Chief Executive Officer of Outlook Therapeutics.

Dr. Sharma commented, "I am excited to join Outlook Therapeutics at this important inflection point in the Company's development of ONS-5010, which I anticipate will offer an important new therapeutic bevacizumab option to retina patients, that is designed to actually meet standards required for ophthalmic approval. I look forward to leading an integrated effort that aligns the interests of both internal and external stakeholders to create a win-win for Outlook Therapeutics and its stakeholders."

Mr. Olsheim brings to Outlook Therapeutics more than 15 years of product commercialization experience in ophthalmology. Prior to joining Outlook Therapeutics, in his role as the VP of Business and New Product Development at Fagron Sterile Services, he focused on driving revenue, profit and value in repackaging IV bevacizumab for ophthalmic use in retina indications. His familiarity with marketing these off-label products for sale to ophthalmologists brings specific focus to his strong network of industry contacts from major eye institutes and hospitals. His experience and networks will be important for the potential launch and commercialization of ONS-5010 ophthalmic bevacizumab. In his new role as Executive Director of Commercial Excellence, Mr. Olsheim will report to Jeff Evanson, Chief Commercial Officer of Outlook Therapeutics, to help deliver an industry-leading customer experience.

"I am delighted to join the growing Outlook Therapeutics team that includes a group of dynamic industry veterans looking to enhance the standard of care in the anti-VEGF space," said Mr. Olsheim. "I believe my familiarity with the processes for repackaging IV bevacizumab for retinal use complemented by my experience in launching ophthalmic products and commercializing them at scale is well-aligned with Outlook Therapeutics' needs as it moves toward the potential commercial launch of ONS-5010."

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

ONS-5010 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 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 oncologic 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 biopharmaceutical company working to develop and launch ONS-5010/ LYTENAVA™ (bevacizumab-vikg) as the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO. The FDA accepted Outlook Therapeutics' BLA submission for ONS-5010 to treat wet AMD with a PDUFA goal date of August 29, 2023. The submission is supported by Outlook Therapeutics' wet AMD 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. As part of the Company's multi-year commercial planning process, and in anticipation of potential FDA approval in August 2023, Outlook Therapeutics and AmerisourceBergen have entered into a strategic commercialization agreement to expand the Company's reach for connecting to retina specialists and their patients. AmerisourceBergen will provide third-party logistics (3PL) services and distribution, as well as pharmacovigilance 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,” “expect,” “look forward,” “plan,” “potential,” “will,” 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, the services to be provided under Outlook’s partnership with AmerisourceBergen and the anticipated benefits thereof, expectations regarding a commercial launch of ONS-5010, 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, 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, 2022, which include the uncertainty of future impacts related to the ongoing COVID-19 pandemic and other macroeconomic factors. 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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