Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Bolsters Commercialization Expertise with Appointment of Alicia Tozier as Senior Vice President of Marketing and Market Access

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- ***Ms. Tozier has held commercial leadership positions across the full product lifecycle and exceeded goals for 14 launches across 70-plus global markets, with deep experience in ophthalmology and leadership for launching wet AMD/DME therapies.***

ISELIN, N.J., March 03, 2022 (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 that Alicia Tozier has been appointed as Senior Vice President, Marketing and Market Access.

"We are pleased to strengthen our commercialization expertise with the addition of Alicia to our leadership team, bringing another seasoned ophthalmic marketer to guide and support our commercialization efforts. Of particular note, her successful track record with spearheading the introductions of two wet AMD therapies makes her an ideal addition to help us maximize the effectiveness of our potential ONS-5010 ophthalmic bevacizumab launch, if approved by the FDA for marketing," said Jeff Evanson, Chief Commercial Officer of Outlook Therapeutics.

Ms. Tozier is a proven global commercialization leader with expertise across nine ophthalmology disease areas, and she has launched combination products spanning multiple modalities including medical devices, digital therapeutics and pharmaceuticals. Over the course of her career, she has led and scaled 60-plus person commercial launch teams and made significant contributions at leading companies such as Genentech, Astellas and Baxter. Most recently, she oversaw commercialization launch efforts for two wet AMD therapies.

"Ms. Tozier's background in combination products is not only mission-critical for our efforts with ONS-5010, but also for our anticipated development of a pre-filled syringe delivery system for ONS-5010, and for any future products we may consider," added Mr. Evanson. "She will be responsible for leading the global commercial strategy, including marketing and market access, to ensure launch readiness across customers and channels." In her role as SVP, Marketing and Market Access at Outlook Therapeutics, Ms. Tozier will report directly to Chief Commercial Officer Mr. Evanson and work cross-functionally with the leadership team.

"I'm excited for the opportunity to leverage my extensive experience in retina and wet AMD, long-standing relationships in the retinal community, and ophthalmology launch success to build a commercial pathway for the first potential approved ophthalmic bevacizumab," said Ms. Tozier. "With the upcoming potential launch of ONS-5010, I am delighted to become part of the team. Outlook Therapeutics has done the work to support the submission of the BLA and, if ONS-5010 is approved, I believe it will become an important therapeutic option for retina physicians and their patients worldwide."

Outlook Therapeutics expects to submit a Biologics License Application (BLA) for ONS-5010 ophthalmic bevacizumab with the U.S. Food and Drug Administration (FDA) during the first quarter of 2022. In anticipation of potential FDA marketing approval in late 2022 or early 2023, Outlook Therapeutics' commercial launch planning includes manufacturing with drug substance manufacturer FUJIFILM Diosynth Biotechnologies and best-in-class drug product manufacturer Aji Biopharma Services, distribution, sales force planning, physician and payor advisory board outreach, key opinion leader support and payor community engagement.

To bring ONS-5010 to market in a way that benefits all stakeholders – patients, clinicians and payors – Outlook Therapeutics is in collaborative discussions with payors and the retina community. Outlook Therapeutics is also developing registration documents on a parallel path for approvals in Europe and expects to submit them in the fourth quarter of 2022. Outlook Therapeutics continues to explore potential strategic commercialization partners, such as Syntone Biopharma JV in China. Outlook Therapeutics expects ONS-5010, if approved, to be a safe and cost-effective on-label choice for patients, clinicians and payors worldwide for retinal indications.

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 may replace the need to use unapproved repackaged IV bevacizumab from compounding pharmacies for the treatment of wet AMD.

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 abnormal new blood vessels and promotes leakage from these vessels, leading to retinal edema and hemorrhage. With wet AMD, abnormally high levels of VEGF are secreted in the eye and lead to loss of vision. Anti-VEGF injection therapy treats the vision-threatening leakage and hemorrhage as well as blocks the growth of abnormal blood vessels. 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 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. 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. Outlook Therapeutics expects to submit ONS-5010 ophthalmic bevacizumab to the U.S. FDA as a BLA under the PHSA 351(a) regulatory pathway. 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 benefits therefrom to patients, payors and physicians, the timing of BLA submission, potential approval and commercial launch of ONS-5010, potential strategic partners, plans for regulatory approvals in other markets 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 (the “SEC”), including the Annual Report on Form 10-K for the fiscal year ended September 30, 2021 filed with the SEC and future quarterly reports we file with the SEC, 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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