Outlook Therapeutics, Inc. Logo

Outlook Therapeutics® Adds Global Commercial Expertise with Appointment of Jedd Comiskey as Senior VP - Head of Europe

November 14, 2023

ISELIN, N.J., Nov. 14, 2023 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (Nasdaq: OTLK), a biopharmaceutical company working to achieve FDA approval for the first ophthalmic formulation of bevacizumab for the treatment of retinal diseases, today announced the appointment of Jedd Comiskey as Senior VP – Head of Europe.

Mr. Comiskey has a successful track record in the planning, organization and execution of product launches. Over the course of his career, he has demonstrated innovative, solution-focused results, navigating the highly complex European pharmaceutical landscape.

"We believe in the potential of ONS-5010 to address the global need for an approved bevacizumab that meets ophthalmic standards for the treatment of wet AMD. While continuing our efforts to meet the additional requirements that the FDA is requiring for U.S. approval of ONS-5010, we are working toward the upcoming decision date for our Marketing Authorization Application (MAA) in Europe with the EMA, expected in the first half of 2024. We believe Jedd will play an integral role as we prepare for a potential European partnership in launching ONS-5010," commented Russell Trenary, President and CEO of Outlook Therapeutics.

Mr. Comiskey added, "I am thrilled to join the Outlook Therapeutics team to help solidify the Company's global launch strategy, and I believe ONS-5010 has the potential to be a meaningful treatment option in the ophthalmology landscape in Europe. As the Company continues its work towards potential European launch, I look forward to leveraging the valuable experience and proven approaches I've executed over my career to enable us to hit the ground running."

Prior to joining Outlook Therapeutics, Jedd served as the Senior Brand Director; Ophthalmology at Apellis Switzerland GmbH. As part of his role, Jedd was the commercial lead for the launch of SYFOVRE® (pegcetacoplan), defining regional brand strategy, formulating key market commercialization plans, engaging stakeholders, and supporting affiliates with launch preparations. In addition to his regional role, Jedd was accountable for detailed mapping of the ophthalmology landscape, preparatory stakeholder engagement and formulation of comprehensive commercialization strategy, and infrastructure plans at Apellis. Prior to that, Jedd served as the Franchise Head GI Rare at Takeda Pharmaceuticals International AG where he was responsible for directing the company's commercial launch across Europe and Canada for two treatments indicated for rare gastrointestinal disorders. He also served as the Director of Market Access and Marketing at Takeda Products Ireland Ltd. Additional career appointments include Head of Market Access at Bayer Ltd, Market Access Manager at Takeda Products Ireland Ltd, Product Manager: ADHD at Shire Pharmaceuticals Ireland Ltd, and Cardiovascular Product Manager at Servier Laboratories Ireland Ltd.

Mr. Comiskey holds a Bachelor of Science in Chemistry from the University College Dublin and a PhD in Chemistry from the Royal College of Surgeons in Ireland.

About Outlook Therapeutics, Inc.

Outlook Therapeutics is a biopharmaceutical company working to achieve FDA approval for the launch of 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 an initial PDUFA goal date of August 29, 2023; the FDA did not approve the BLA during this review cycle and the Company is working with the FDA to address the issues that have been raised so that the BLA may be re-submitted. 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, Outlook Therapeutics and Cencora, formerly AmerisourceBergen, entered into a strategic commercialization agreement to expand the Company's reach for connecting to retina specialists and their patients. Cencora will provide third-party logistics (3PL) services and distribution, as well as pharmacovigilance services and other 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," "believe," "continue," "could," "estimate," "expect," "may," "might," "intend," "potential," "predict," "should," or "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, expectations concerning our ability to remediate or otherwise resolve deficiencies identified in the Complete Response Letter issued by the FDA, expectations concerning decisions of regulatory bodies, including the FDA and the EMA, and the timing thereof, plans for potential commercial launch of ONS-5010, expectations concerning our relationship with AmerisourceBergen and the benefits and potential expansion thereof 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, the content and timing of decisions by the FDA, 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, 2022 as supplemented by the Quarterly Report on Form 10-Q for the quarter ended June 30, 2023, in each case as filed with the SEC and future quarterly reports we file with the SEC, which include the uncertainty of future impacts related to macroeconomic factors, including as a result of the ongoing overseas conflict, high interest rates, inflation and potential future bank failures on the global business environment. 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.

CONTACTS:

Media Inquiries:
Harriet Ullman
Vice President
LaVoieHealthScience
T: 617.429.5475
hullman@lavoiehealthscience.com

Investor Inquiries:
Jenene Thomas
Chief Executive Officer
JTC Team, LLC
T: 833.475.8247
OTLK@jtcir.com

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