Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Receives FDA Agreement for Three Special Protocol Assessments for Additional Planned Clinical Trials of ONS-5010

December 3, 2019

- **ONS-5010, an investigational ophthalmic formulation of bevacizumab for retinal indications, is currently in two clinical trials to treat wet age-related macular degeneration (wet AMD – NORSE 1 and 2).**

- **SPAs for clinical trial protocols for NORSE 4 for branch retinal vein occlusion ("BRVO") and NORSE 5 and NORSE 6 for diabetic macular edema ("DME") indicate FDA agreement on overall protocol design (entry criteria, dose selection, endpoints and planned analyses).**

CRANBURY, N.J., Dec. 03, 2019 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (NASDAQ: OTLK) (the "Company"), a late clinical-stage biopharmaceutical company working to develop the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, today announced that it has received agreement from the U.S. Food and Drug Administration ("FDA") on three Special Protocol Assessments ("SPAs") for three additional registration clinical trials for its ongoing Phase 3 program for ONS-5010, an investigational ophthalmic formulation of bevacizumab. The agreements reached with the FDA on these SPAs cover the protocols for NORSE 4, a registration clinical trial to treat BRVO, and NORSE 5 and NORSE 6, two registration clinical trials to treat DME. Outlook Therapeutics intends to initiate NORSE 4, 5 and 6 in 2020.

"We are very pleased to reach these agreements with the FDA so that we can continue to build clinical data for additional retinal indications beyond wet AMD for ONS-5010," said Lawrence A. Kenyon, President, Chief Executive Officer and Chief Financial Officer. "Anti-VEGF therapy has been the standard of care for years within the retinal community for wet AMD, DME and BRVO, and we hope that ONS-5010 will become the first FDA-approved bevacizumab indicated for these diseases. An on-label bevacizumab would enable clinicians to treat their retinal patients with a well-established therapy, and FDA approval would ensure sterility, potency and accurate, safe syringes for intravitreal injections."

"The Outlook Therapeutics team truly cares about improving the clinical landscape for retinal patients, and I want to commend our clinical team for the tremendous dedication they have shown in advancing our Phase 3 program for ONS-5010," added Terry J. Dagnon, Chief Operating Officer. "ONS-5010, if approved, has the potential to help address the unmet medical needs of patients for a responsibly priced, FDA-approved ophthalmic formulation of bevacizumab to treat retinal diseases."

Study initiation and patient recruitment for NORSE 4, 5 and 6 will begin after enrollment has been completed in the ongoing NORSE 2 clinical trial in wet AMD patients. NORSE 2 is being conducted at 40 clinical sites in the United States and is the second of two required registration clinical trials necessary to support a Biologics License Application ("BLA") for the treatment of wet AMD. If these trials are successful and ONS-5010 receives FDA approval, the commercial launch of ONS-5010 as the first and only on-label ophthalmic formulation of bevacizumab is being planned for 2022.

The NORSE 4, 5 and 6 clinical trials are designed to support Outlook Therapeutics' plans to also submit a BLA for the use of ONS-5010 in the treatment of DME and BRVO. If the ONS-5010 clinical program is successful, it will support Outlook Therapeutics' plan to submit for regulatory approvals in the United States, France, United Kingdom, Italy, Germany, Spain and Japan. If approved, ONS-5010 would be the first and only on-label ophthalmic formulation of bevacizumab for treating retinal diseases in these countries.

About Special Protocol Assessment (SPA)

SPA is a process in which sponsors may request that FDA fully review their study protocols in order to reach agreement on the design and size of certain clinical trials, clinical studies or animal studies to determine if they adequately address scientific and regulatory requirements for a study that could support marketing approval. An SPA agreement indicates concurrence by FDA with the adequacy and acceptability of specific critical elements of overall protocol design (e.g., entry criteria, dose selection, endpoints and planned analyses) for a study intended to support a future marketing application. These elements are critical to ensuring that the trial conducted under the protocol can be considered an adequate and well-controlled study that can support marketing approval. However, an SPA agreement does not indicate FDA concurrence on every protocol detail, does not guarantee approval and may be rescinded.

About ONS-5010

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. ONS-5010 is currently being evaluated in two adequate and well-controlled registration clinical trials for wet AMD (NORSE 1 and 2) and, if successful, is expected to be submitted to the FDA as a new BLA for this ophthalmic indication. If approved, ONS-5010 would be the first and only FDA-approved ophthalmic formulation of bevacizumab to treat retinal diseases. The Company currently intends to commercialize ONS-5010 in both vials and single-use pre-filled syringes.

Bevacizumab is a full-length, humanized anti-VEGF (Vascular Endothelial Growth Factor) recombinant monoclonal antibody (or mAb) that inhibits VEGF and associated angiogenic activity. With wet AMD, abnormally high levels of VEGF are secreted in the eye. VEGF is a protein that promotes the growth of new abnormal blood vessels. 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 the first FDA-approved ophthalmic formulation of bevacizumab for use in retinal indications, including wet AMD, DME and BRVO. If ONS-5010, its investigational ophthalmic formulation of bevacizumab, is approved, Outlook Therapeutics expects to commercialize it as the first and only on-label approved ophthalmic formulation of bevacizumab for use in treating retinal diseases in the United States, Europe, Japan and other markets. Outlook Therapeutics is listed on the Nasdaq Capital Market (NASDAQ: OTLK). 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 statements about the Company’s ability to build clinical data for ONS-5010, plans for seeking regulatory approval for ONS-5010, the timing of clinical trials for ONS-5010, the outcome of clinical trials for ONS-5010 and FDA approval, the timing of commercial launch, the ability of ONS-5010 to provide benefits to patients, payors and physicians, and the benefits of having an FDA approved bevacizumab. Although the Company believes that it has a reasonable basis for forward-looking statements contained herein, they are based on current expectations about future events affecting the Company 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 the Company’s filings with the Securities and Exchange Commission. 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. The Company 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.

For additional details on the Company’s financial performance during the quarter, please see the Company’s filings with the Securities and Exchange Commission.

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