Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Submits IND Application for ONS-5010 to the FDA

March 1, 2019

CRANBURY, N.J., March 01, 2019 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (NASDAQ:OTLK) (the “Company”) announced today the submission of its Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for ONS-5010. ONS-5010 is an innovative monoclonal antibody (mAb) therapeutic product candidate being developed for wet age related macular degeneration (wet AMD), diabetic macular edema (DME) and branch retinal vein occlusion (BRVO). Once effective, the IND will allow the Company to begin enrolling patients in the U.S. portion of its ONS-5010-002 Phase 3 clinical trial in patients with wet AMD.

ONS-5010-002 is the second of two adequate and well controlled Phase 3 clinical trials evaluating ONS-5010 against ranibizumab (Lucentis®) for wet AMD. ONS-5010-002 was recently initiated in Australia and is expected to begin enrolling patients in Australia and New Zealand in March 2019 and in the United States (once the IND is effective) in April 2019 for a total of at least 180 patients. Enrollment in ONS-5010-001, the first of the two Phase 3 wet AMD clinical trials for ONS-5010, is being conducted in Australia and is expected to complete enrollment in March 2019 with a total of at least 60 patients.

“Submitting this IND represents the achievement of a major milestone for Outlook Therapeutics and our ONS-5010 program,” said Lawrence A. Kenyon, President, Chief Executive Officer and Chief Financial Officer. “The implementation of our innovative development strategy for ONS-5010 continues to advance quickly across our two Phase 3 clinical trials. We look forward to completing enrollment in the ONS-5010-001 study and beginning enrollment in ONS-5010-002 over the next several weeks. We remain on track with our plan to submit ONS-5010 for regulatory approval in multiple markets in 2020.”

If approved by regulators, ONS-5010 has the potential to mitigate the risks associated with off-label use of Avastin® or other drugs. Off label use of Avastin® is currently estimated to account for approximately 50% of all wet AMD prescriptions in the United States.

About ONS-5010
ONS-5010 is a proprietary ophthalmic formulation of bevacizumab to be administered as an intravitreal injection for the treatment of wet AMD and other retina diseases. Bevacizumab is a full length humanized anti-VEGF (Vascular Endothelial Growth Factor) antibody that inhibits VEGF and associated angiogenic activity. The Company’s proprietary ophthalmic bevacizumab product candidate is an anti-VEGF recombinant humanized monoclonal antibody (or mAb) formulated as a single use vial for IVT injection. By inhibiting the VEGF receptor from binding, bevacizumab prevents the growth and maintenance of tumor blood vessels. Previously, this product candidate met the primary and secondary endpoints in a 3-arm single-dose pharmacokinetic (PK) Phase 1 clinical trial. All of the PK endpoints met the bioequivalency criteria of the geometric mean ratios within 90% confidence interval of 80-125% when compared to both U.S.- and EU-sourced Avastin® reference products.

About Outlook Therapeutics, Inc.
Outlook Therapeutics is a clinical-stage biopharmaceutical company focused on developing its lead clinical program, ONS-5010, a proprietary ophthalmic bevacizumab product candidate for the treatment of wet age related macular degeneration (wet AMD) and other retina diseases. ONS-5010 is currently in Phase 3 clinical trials outside the United States for patients suffering from 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 “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 effectiveness of the Company’s IND for ONS-5010, its ongoing and planned Phase 3 clinical trials for ONS-5010, enrollment in such trials, and the outcome of such clinical trials and plans for seeking regulatory approval for ONS-5010. 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.

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