Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Doses First Patient in the Second Phase 3 Clinical Trial for ONS-5010 in Wet AMD

July 16, 2019

Full enrollment expected to occur in calendar Q4 2019

CRANBURY, N.J., July 16, 2019 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (NASDAQ: OTLK) (the "Company"), a late clinical-stage biopharmaceutical company focused on developing ONS-5010, a proprietary ophthalmic bevacizumab product candidate for the treatment of wet age related macular degeneration (wet AMD) and other retina diseases, today announced that it has dosed the first patient in the ONS-5010-002 Phase 3 clinical trial.

"We are pleased to begin dosing patients in the ONS-5010-002 study, our second Phase 3 clinical trial for ONS-5010. This represents the achievement of another important milestone in our streamlined clinical and regulatory strategy, which is designed to support a Biologics License Application, or BLA, submission for ONS-5010 in wet AMD by the end of 2020," said Lawrence A. Kenyon, President, Chief Executive Officer and Chief Financial Officer.

ONS-5010-002 is the second of the Company's two required adequate and well controlled Phase 3 clinical trials evaluating ONS-5010 against ranibizumab (Lucentis®) for wet AMD. The study is expected to enroll a total of at least 220 patients at sites in the United States. Patients enrolled in the ONS-5010-002 study will be treated for 11 months. The endpoint for the study is a mean increase in baseline visual acuity of at least five letters at 11 months for ONS-5010 dosed on a monthly basis compared to ranibizumab dosed using the approved alternative dosing regimen of three monthly doses followed by quarterly dosing. Full enrollment for ONS-5010-002 is expected in the fourth quarter of calendar 2019.

"The ophthalmic community is well aware of the benefits of bevacizumab in the treatment of wet AMD. ONS-5010 is an exciting product because, if approved, it has the potential to meet the needs of wet AMD patients by offering an FDA approved bevacizumab and, by doing so, potentially overcoming some of the limitations that are encountered with using compounded bevacizumab," added Mark Humayun, M.D., Ph.D., Medical Advisor to Outlook Therapeutics, Inc. and a principal of MTTR LLC, the Company's strategic partner for the ONS-5010 program.

If the ONS-5010 clinical program is successful, it will support the Company's plan to submit for regulatory approval in multiple markets in 2020. If approved, ONS-5010 has potential to mitigate risks associated with off-label use of Avastin or other drugs. Off label use of Avastin is currently estimated to account for at least 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.

About Outlook Therapeutics, Inc.
Outlook Therapeutics is a late clinical-stage biopharmaceutical company focused on developing 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 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 Company's plans for seeking regulatory approval for ONS-5010, including submission of a BLA, timing of completion of enrollment in ONS-5010-002, the outcome of such clinical trial and the ability of ONS-5010 to meet the needs of patients with wet AMD, and mitigate risks associated with off-label use of Avastin. 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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Source: Outlook Therapeutics, Inc.