

Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Completes Patient Enrollment for NORSE 1 a Phase 3 Clinical Trial for ONS-5010 in Wet AMD

August 20, 2019

Initial data expected to be announced in calendar Q3 2020

CRANBURY, N.J., Aug. 20, 2019 (GLOBE NEWSWIRE) -- Outlook Therapeutics, Inc. (NASDAQ: OTLK) (the "Company"), a late clinical-stage biopharmaceutical company focused on developing ONS-5010, an ophthalmic bevacizumab product candidate for the treatment of wet age related macular degeneration (wet AMD) and other retina diseases, today announced that it has completed patient enrollment in the NORSE 1 Phase 3 clinical trial, which is evaluating ONS-5010 against ranibizumab (Lucentis®) for wet AMD.

"We are pleased with the building momentum in our two ongoing Phase 3 clinical trials for ONS-5010, including completing enrollment in NORSE 1. Achieving this milestone keeps us on track for our goal to submit ONS-5010 for regulatory approval in the United States in 2020, pending the successful outcome of our trials. I am very proud of our clinical development team's work as we move this program forward in an effort to provide an approved bevacizumab treatment option for wet AMD patients around the world," said Lawrence A. Kenyon, President, Chief Executive Officer and Chief Financial Officer.

NORSE 1 has enrolled a total of 61 patients at 9 sites in Australia. The study is the first of two ongoing, adequate and well controlled Phase 3 clinical trials evaluating ONS-5010 against ranibizumab for wet AMD. The endpoint for the study is a mean change in baseline visual acuity at 11 months for ONS-5010 dosed on a monthly basis compared to ranibizumab dosed using the PIER alternative dosing regimen of three monthly doses followed by quarterly dosing. The Company expects to announce a readout of the topline results from NORSE 1 in the third quarter of calendar 2020.

"The NORSE 1 study design was confirmed in our April 2018FDA meeting to be one of our two adequate and well controlled clinical trials required to support approval of ONS-5010 to treat wet AMD. We are excited to complete each milestone in our effort to bring an approved anti-VEGF therapy to market for potential benefit to patients, payors, and physicians," added Terry J. Dagnon Chief Operating Officer 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 an 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 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, enrollment in clinical trials for ONS-5010, the timing of announcing top line data from such trials, the outcome of such clinical trials, the ability of ONS-5010 to mitigate risks associated with off-label use of Avastin and provide benefits to patients, payors and physicians. 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](http://www.sec.gov).

CONTACTS:

Outlook Therapeutics:

Lawrence A. Kenyon

LawrenceKenyon@outlooktherapeutics.com

Media & Investors:

Jeremy Feffer

Managing Director

LifeSci Advisors, LLC
T: 212.915.2568
jeremy@lifesciadvisors.com



Source: Outlook Therapeutics, Inc.