

Outlook Therapeutics Provides COVID-19 Impact Update on Ongoing Clinical Trials NORSE 1 and NORSE 2

April 14, 2020

- **Company reports no anticipated COVID-19 impact on NORSE 1, its first registration clinical trial evaluating ONS-5010, an investigational ophthalmic formulation of bevacizumab, to treat wet AMD**
- **Risk mitigation strategies being developed for possible one- to three-month delay related to COVID-19 for NORSE 2, the Company's second registration clinical trial for ONS-5010 to treat wet AMD, depending on local emergency conditions**

CRANBURY, N.J., April 14, 2020 (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 provided a clinical update on the impact of the COVID-19 pandemic on the status of NORSE 1 and NORSE 2, its ongoing registration clinical trials for ONS-5010 / LYTENAVA™ (bevacizumab-vikg), an investigational ophthalmic formulation of bevacizumab.

All clinical and chemistry, manufacturing and control (CMC) activities are currently active for both NORSE 1 and NORSE 2, registration clinical trials evaluating ONS-5010 for treatment of wet age-related macular degeneration (wet AMD). The Company has confirmed with the Ophthalmic Division of the U.S. Food and Drug Administration (FDA) that it considers both approved and investigational treatments for sight-threatening conditions such as wet AMD not to be elective, and that as such they should continue during the COVID-19 restrictions.

NORSE 1 completed enrollment in August 2019 and is on pace to meet its schedule as expected. The Company anticipates reporting data during the third calendar quarter of 2020. At this time, COVID-19 is not expected to affect the completion of NORSE 1 and anticipated data readout date.

NORSE 2, which commenced enrollment in July 2019 and is being conducted in the United States, continues to screen, enroll and treat patients, subject to additional COVID-19 safety protocols for both patients and staff at trial sites. Due to these additional safety protocols, some sites have temporarily shut down and patient enrollment has slowed. Outlook estimates that final enrollment could be delayed by one to three months, depending on local conditions, which have varying degrees of "shelter-in-place" and other type of executive orders mandating various restrictions.

"In these unprecedented times across the globe, the safety of the patients and medical staff engaged in our NORSE 1 and NORSE 2 clinical trials is our top priority. We are fortunate enough not to expect any delay in our NORSE 1 clinical trial and anticipate reporting data from the study in August of this year, as planned. We want to share our deepest appreciation to all medical staff and patients for their ongoing participation in this important clinical work," said Lawrence A. Kenyon, President, CEO and CFO, Outlook Therapeutics. "While the full impact of COVID-19 remains uncertain, we are confident that the statistical analysis plans we have built into the NORSE 2 clinical trial will mitigate potential missed visits and the slower pace of enrollment we are currently experiencing. Our team remains dedicated to advancing the program efficiently while minimizing delays as much as possible."

About ONS-5010 / LYTENAVA™

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

ONS-5010 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 age-related macular degeneration (wet AMD), diabetic macular edema (DME) and branch retinal vein occlusion (BRVO). If ONS-5010 / LYTENAVA™ (bevacizumab-vikg), its investigational ophthalmic formulation of bevacizumab, is approved, Outlook Therapeutics expects to commercialize it as the first and only approved ophthalmic formulation of bevacizumab for use in treating approved retinal diseases in the United States, Europe, Japan and other markets. 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 its plans for filing a BLA for ONS-5010 / LYTENAVA™ (bevacizumab-vikg), its commercialization plans for ONS-5010, expected data read-out dates for NORSE 1, and the impact of the COVID-19 pandemic on its ongoing ONS-5010 clinical trials. 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, the uncertainty regarding the COVID-19 pandemic and its duration, 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](#).

CONTACTS:

Outlook Therapeutics:

Lawrence A. Kenyon

LawrenceKenyon@outlooktherapeutics.com

Media Inquiries:

Emmie Twombly

Media Relations Specialist

LaVoie Health Science

M: 857.389.6042

etwombly@lavoiehealthscience.com

Investor Inquiries:

Jenene Thomas

Chief Executive Officer

JTC Team, LLC

T: 833.475.8247

OTLK@itcir.com



Source: Outlook Therapeutics, Inc.