Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Announces LYTENAVA™ (bevacizumab-vikg), Anticipated Brand Name for ONS-5010, If Approved

March 5, 2020

- **Outlook Therapeutics intends to market ONS-5010 as LYTENAVA ™ (bevacizumab-vikg), if approved.**
- **LYTENAVA™ (bevacizumab-vikg), an investigational ophthalmic formulation of bevacizumab for retinal indications, is currently in two registration clinical trials (NORSE 1 and NORSE 2) to treat wet age-related macular degeneration (wet AMD).**

CRANBURY, N.J., March 05, 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 announced that it has received U.S. Food and Drug Administration (FDA) tentative approval of the Tradename for ONS-5010 as LYTENAVA™ (bevacizumab-vikg). The Tradename is conditionally approved by FDA and will be subject to further review at the time of the Company's planned filing of a new biologics license application (BLA) with the FDA for LYTENAVA™ (bevacizumab-vikg) in 2021.

About LYTENAVA™ (bevacizumab-vikg)

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. LYTENAVA ™ (bevacizumab-vikg) is currently being evaluated in two adequate and well-controlled 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, LYTENAVA™ (bevacizumab-vikg) would be the first and only FDA-approved ophthalmic formulation of bevacizumab to treat retinal diseases. The Company currently intends to commercialize LYTENAVA™ (bevacizumab-vikg) in both vials and single-use pre-filled syringes.

LYTENAVA™ (bevacizumab-vikg) 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 LYTENAVA™ (bevacizumab-vikg), 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. 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 plans for filing a BLA for LYTENAVA ™ (bevacizumab-vikg), plans for offering LYTENAVA ™ (bevacizumab-vikg) in unit-dose vials and pre-filled syringes, FDA approval of LYTENAVA ™ (bevacizumab-vikg), 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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