

Outlook Therapeutics, Inc. Logo

Outlook Therapeutics Announces \$16.0 Million Private Placement to Advance the Development of ONS-5010 / LYTENAVA™ (bevacizumab-vikg)

May 26, 2020

- **Strategic investment at a premium enhances Company's ongoing development activities of ONS-5010 / LYTENAVA™ (bevacizumab-vikg), an investigational ophthalmic formulation of bevacizumab to treat wet AMD, toward FDA approval**
- **Syntone and Outlook to form joint venture to develop and commercialize ONS-5010 / LYTENAVA™ (bevacizumab-vikg) in greater China**

MONMOUTH JUNCTION, N.J., May 26, 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 it has entered into a Stock Purchase Agreement with Syntone Ventures LLC for a private placement of \$16.0 million of common stock at a price of \$1.00 per share. In addition, Outlook Therapeutics entered into a joint venture agreement with Syntone Technologies Group Co. Ltd. ("Syntone") to form a PRC joint venture to develop and commercialize [ONS-5010 / LYTENAVA™](#) (bevacizumab-vikg) in China pursuant to a license agreement to be entered into between Outlook Therapeutics and the joint venture. Outlook Therapeutics will use \$0.9 million of the private placement proceeds to fund its initial capital contribution to the PRC joint venture.

"We are pleased to enter into this strategic opportunity to further advance the development of ONS-5010. This partnership provides many advantages, including the ability to leverage Syntone's presence in, and knowledge of, the Chinese market," commented Lawrence A. Kenyon, President, CEO and CFO of the Company. "While our primary focus for the development and commercialization of ONS-5010 remains on the seven major global markets, we saw this as an opportunity to bring capital into the Company at a premium with a motivated strategic investor, and to enhance the potential commercialization of ONS-5010 in an additional market with unique characteristics."

"Syntone's businesses to date have focused on creating energy production and critical living materials for society," added Syntone's Chairman Zheng Zongmei. "Because health problems are also a common issue for humanity, Syntone has been looking for opportunities to put our ideals into action in healthcare and we believe Outlook Therapeutics is the ideal partner. We want to help Outlook Therapeutics bring LYTENAVA™ to those in need, not only in previously targeted markets, but also in China."

The closing of the sale of the shares is expected to occur on or about June 1, 2020, subject to the satisfaction of customary closing conditions. Outlook Therapeutics intends to use the net proceeds from the financing for working capital and general corporate purposes, including in support of its ONS-5010 development program, with approximately \$0.9 million of the proceeds being used to fund its initial capital contribution to the planned PRC joint venture. An additional capital contribution from Outlook Therapeutics of approximately \$2.1 million will be required within the next 4 years. The planned PRC joint venture will be 80% owned by Syntone and 20% owned by Outlook Therapeutics and is intended to focus on the development and commercialization of ONS-5010 in the greater China market, which includes Hong Kong, Taiwan and Macau. Outlook Therapeutics has agreed to enter into a license agreement providing for the license to the PRC joint venture of rights to ONS-5010 in greater China.

The securities in the private placement are being offered in a private placement under Section 4(a)(2) of the Securities Act of 1933, as amended (the "Act") and/or Regulation D promulgated thereunder, and such securities have not been registered under the Act or applicable state securities laws. Accordingly, such securities may not be offered or sold in the United States except pursuant to an effective registration statement or an applicable exemption from the registration requirements of the Act and such applicable state securities laws.

This news release shall not constitute an offer to sell or a solicitation of an offer to buy, nor shall there be any sale of these securities in any state or jurisdiction in which such offer, solicitation or sale would be unlawful, prior to registration or qualification under the securities laws of any such state or jurisdiction.

About Syntone Technologies Group Co. Ltd.

Syntone Technologies Group Co. Ltd., based in Hebei, China, is part of a larger group of enterprises which have significant operations in China concentrated in oil and gas but also including real estate and emerging technology. These enterprises have experience investing outside of China, including in the United States. Syntone has identified biotechnology as an area of interest for investment to provide an opportunity for Chinese patients to experience the benefits provided by these therapies. Syntone Ventures LLC is a wholly-owned U.S.-based subsidiary of Syntone Technologies Group Co. Ltd.

About ONS-5010 / LYTENAVA™ (bevacizumab-vikg)

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 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, ONS-5010 will be the first and only FDA-approved ophthalmic formulation of bevacizumab to treat 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 (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 ONS-5010 / LYTENATM (bevacizumab vkg), 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. Outlook Therapeutics expects to file ONS-5010 with the U.S. FDA as a new BLA under the PHS 351(a) regulatory pathway. 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 closing of the private placement, the expected benefits of the Syntone relationship and PRC joint venture, as well as the effects of such relationship on the planned commercialization of ONS-5010. Although the Company believes that it has a reasonable basis for the 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, which include the uncertainty of future impacts related to the ongoing COVID-19 pandemic. 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

Investor Inquiries:

Jenene Thomas

Chief Executive Officer

JTC Team, LLC

T: 833.475.8247

OTLK@jtcir.com

Media Inquiries:

Emmie Twombly

Media Relations Specialist

LaVoie Health Science

M: 857.389.6042

etwombly@lavoiehealthscience.com



Source: Outlook Therapeutics, Inc.