Oncobiologics Advances ONS-5010 into wet AMD Clinical Trial

November 6, 2018

Receives commitment for $20 million in proceeds from equity private placement

Restructures and extends maturity on $13.5 million of outstanding senior secured notes

CRANBURY, N.J., Nov. 06, 2018 (GLOBE NEWSWIRE) -- Oncobiologics, Inc. (NASDAQ:ONS) today announced that it has begun dosing patients in its first clinical trial for ONS-5010, a proprietary ophthalmic bevacizumab product candidate, in patients with wet age related macular degeneration (wet AMD).

This first clinical study for ONS-5010, the Company's lead product candidate, is being conducted outside of the United States and is designed to serve as the first of two adequate and well controlled studies for wet AMD. The U.S. portion of the second study is scheduled to begin in early 2019 upon the submission of an investigational new drug (IND) application. The Company's wet AMD clinical program was reviewed at a successful end of Phase 2 meeting held with the U.S. Food and Drug Administration (FDA) conducted earlier in 2018. If the program is successful, it will support the Company's plans to submit for regulatory approval in multiple markets in 2020. The Company is developing ONS-5010 as an innovative therapy and not using the biosimilar drug development pathway.

"The commencement of the ONS-5010 clinical program targeting ophthalmic indications is a major achievement and I am extremely proud of the team for reaching this key milestone so quickly," said Lawrence A. Kenyon, President, CEO and CFO. "We were able to enter the clinic in less than 12 months from the start of the project. ONS-5010 presents an exciting opportunity to meet the need for affordable critical therapeutic options for patients and we are planning to build on the progress achieved to date."

Capital Financing and Debt Restructuring

Oncobiologics also announced today that it has received an equity financing commitment for $20 million and restructured and extended the maturity of its senior secured notes that were previously scheduled to mature on December 22, 2018. In combination with these improvements to its balance sheet, the Company has committed to reduce expenses, sell or license the rights to some or all of its clinical stage biosimilar assets and to explore strategic options for its manufacturing plant.

On November 5, 2018, Oncobiologics entered into a purchase agreement with BioLexis Pte. Limited (formerly known as "GMS Tenshi Holdings Pte. Limited"), the Company's strategic business partner and largest investor, providing for the private placement of $20.0 million of shares of its common stock at $0.9327 per share, the Nasdaq "minimum price" on that date. The closing of the sale of the first tranche of this private placement for an aggregate of 8,577,248 shares of Oncobiologics' common stock for aggregate cash proceeds of $8.0 million is expected to occur on or about November 7, 2018, subject to customary closing conditions. The remaining $12.0 will fund in three equal tranches on each of December 3, 2018, January 3, 2019 and February 1, 2019, as set forth in the purchase agreement. Oncobiologics intends to use the net proceeds from the private placement primarily for clinical trials for its lead product candidate, ONS-5010, and for working capital and general corporate purposes, including the agreed repayments on the senior secured notes.

Also on November 5, 2018, Oncobiologics reached an agreement with the holders of its senior secured notes to extend the maturity of the senior secured notes, which have a face value of $13.5 million, up to 12 months, or until December 22, 2019, in exchange for making several payments of principal and interest through August 31, 2019, subject to meeting additional capital raising commitments, with an initial payment of $2.2 million payable upon initial closing of sale of shares to BioLexis. In addition, Oncobiologics agreed to make the senior secured notes convertible into common stock at a price of 1.11924 per share (120% of the price per share paid by BioLexis under the purchase agreement) and reduced the strike price of the warrants held by such holders to $1.50 and extended the expiration of these warrants by three years. Oppenheimer & Co. Inc. acted as financial advisor to Oncobiologics in connection with the restructuring of its senior secured notes.

Oncobiologics also undertook to take such steps as may be reasonably necessary to amend the exercise price to $1.50 and further extend the expiration date of its outstanding Series A warrants (NASDAQ: ONSIW) by three years.

"We appreciate the expanded investment by our partner, BioLexis, and the continued engagement by our long term senior secured note investors to improve and extend our ability to fund and advance the ONS-5010 program," continued Mr. Kenyon. "This capital commitment and debt restructuring are important steps towards our goal to remove all debt from our balance sheet by the end of 2019. We are also exploring all possible opportunities to monetize past investments to support future growth at Oncobiologics."

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 any 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 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 which 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. Previously, this product candidate met the primary and secondary endpoints in a 3-arm single-dose pharmacokinetic (PK) Phase 1 clinical trial. All of the PK endpoints met the bioequivalency criteria of the geometric mean ratios within 90%

confidence interval of 80-125% when compared to both U.S.- and EU-sourced Avastin® reference products.

About AMD and wet AMD
Age related macular degeneration, AMD, is a common eye condition and a leading cause of vision loss among people age 50 and older. Wet AMD is a form of "late stage" AMD, and is also called neovascular AMD. In wet AMD, abnormal blood vessels grow underneath the retina. These vessels can leak fluid and blood, which may lead to swelling and damage of the macula causing vision loss. With wet AMD, abnormally high levels of vascular endothelial growth factor (VEGF) are secreted in the eyes. 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. Wet AMD is a significant disease worldwide, with over 1.8 million patients diagnosed in the United States, top five European countries and Japan alone in 2016 (GlobalData). Revenue from anti-VEGFs (Avastin™, Lucentis™, Eylea™ and Macugen™) exceeds $8 billion annually in those ophthalmic markets in 2016 (GlobalData). Although not currently FDA-approved for use in treating wet AMD, it is believed that bevacizumab accounts for approximately 50% of all wet AMD prescriptions in the United States.

About BioLexis Pte. Limited
BioLexis is a Singapore based joint-venture between Tenshi Life Sciences Private Limited, and GMS Holdings, a private investment company owning a portfolio of diversified businesses globally. Together with Strides Shasun and Tenshi Life Sciences, GMS Holdings is a strategic investor in Stelis Biopharma.

About Oncobiologics, Inc. and its BioSymphony™ Platform
Oncobiologics is a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex monoclonal antibody (mAb) therapeutics. Oncobiologics has advanced three product candidates into clinical development. By leveraging its proprietary BioSymphony™ Platform, Oncobiologics is able to produce high-quality innovative and biosimilar mAb candidates in an efficient and cost-effective manner. The BioSymphony engine is particularly suitable for developing technically challenging and commercially attractive mAbs to meet the need for clinically important yet affordable drugs. Led by a team of biopharmaceutical experts, Oncobiologics operates from a state-of-the-art fully integrated research, development, and manufacturing facility in Cranbury, New Jersey. For more information, please visit www.oncobiologics.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 planned clinical trials for ONS-5010, the ability to successfully conduct such clinical trials, and plans for seeking regulatory approval for ONS-5010, as well as statements about the Company's ability to reduce expenses, monetize its product candidate portfolio and other assets, achieve the necessary milestones to obtain the committed funding from BioLexis, raise additional capital, and amend its Series A warrants. Although Oncobiologics 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 risks associated with raising capital and further restructuring its business, along with those risks detailed in Oncobiologics' 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. Oncobiologics 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.

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