Outlook Therapeutics, Inc. Logo

Oncobiologics announces strategic partnership with GMS Tenshi Holdings Pte. Limited

September 8, 2017

Up to $50 million in combination of equity, warrants and license fees

CRANBURY, N.J., Sept. 08, 2017 (GLOBE NEWSWIRE) -- Oncobiologics, Inc. (NASDAQ:ONS) today announced that it entered into a Purchase Agreement on September 7, 2017 with GMS Tenshi Holdings Pte. Limited ("GMS Tenshi"), providing for the private placement of up to $25.0 million of Oncobiologics' Series A Convertible Preferred Stock ("Series A"), as well as warrants to acquire up to an additional 16,750,000 shares of its common stock (the "Warrants") having an aggregate exercise price of approximately $15 million.

In connection with the entry into the Purchase Agreement, Oncobiologics and GMS Tenshi also entered into a Joint Development and License Agreement (the "License"), providing for the license to GMS Tenshi of rights to ONS-3010 (HUMIRA® biosimilar) and ONS-1045 (AVASTIN® biosimilar) in emerging markets, excluding China, India and Mexico. The License supersedes and replaces a previous strategic license agreement entered into on July 25, 2017 with GMS Tenshi, which licensed only ONS-1045, and which resulted in payments totaling $2.5 million in up-front and milestone fees to Oncobiologics. The License includes an aggregate $2.5 million of additional upfront payments due in part at signing and upon initial closing of the sale of Series A under the Purchase Agreement, as well as potential additional milestones of up to $5.0 million and a net profit share.

Oncobiologics has also entered into an agreement with an existing investor and holder of senior secured notes of Oncobiologics to exchange $1.5 million of its senior secured notes for non-voting Series B Convertible Preferred Stock and forgive the unpaid interest on such exchanged notes.

Oncobiologics Chairman and CEO, Pankaj Mohan, Ph.D., commented, "This investment by GMS Tenshi represents the culmination of our efforts to align with a strategic financial partner with a global strategy to accelerate commercialization of our biosimilar candidates and enhance our partnering and licensing capabilities. The principals of GMS Tenshi are internationally known biopharma entrepreneurs with the know-how to rapidly deliver critically needed biosimilars to emerging markets around the globe. We believe that we now have a partner with the necessary financial and global commercial pharmaceutical expertise that, when combined with our unique BioSymphony™ Platform, will allow us to realize our vision to bring affordable biologic drugs to patients in need around the world."

Oncobiologics intends to use the net proceeds from the private placement primarily for the initiation of Phase 3 clinical trials for its lead biosimilar candidate, ONS-3010, and for working capital and general corporate purposes. ONS-3010 has successfully completed Phase 1 clinical trials and is preparing to enter Phase 3 in 2018. Oncobiologics is developing ONS-3010 as a differentiated HUMIRA® biosimilar with a unique formulation and an innovative Phase 3 clinical program designed to prove biosimilarity to, and interchangeability with, HUMIRA® in a single study population.

GMS Tenshi is a Singapore based joint-venture between Tenshi Life Sciences Private Limited – the private investment vehicle of Arun Kumar, and GMS Holdings, a private investment company headquartered in Amman, Jordan owning a portfolio of diversified businesses globally. Arun Kumar is the founder of the Strides Group of companies, including India-based pharmaceutical company Strides Arcolab Limited (currently Strides Shasun Limited) and Stelis Biopharma Limited, a company engaged in the development of biotherapeutic drugs (including biosimilars). GMS Holdings is a founder and major shareholder in MS Pharma, a leading branded generics company in the Middle East and North Africa region. In the United States, GMS Holdings was a co-founder of and majority shareholder in Alvogen, Inc. a specialty generic pharmaceutical company, which it sold in 2014. Together with Strides Shasun and Tenshi Life Sciences, GMS Holdings is a strategic investor in Stelis Biopharma.

A statement issued by GMS Tenshi noted, "We believe that bringing affordable biosimilars to emerging markets where they are so desperately needed is of critical importance to global healthcare. As pharma specialists, we also recognize the technical challenges in developing and manufacturing complex biologics, and we saw that the Oncobiologics team and its BioSymphony™ Platform offered the scientific and engineering capabilities required to accomplish this. GMS Tenshi is excited to invest in Oncobiologics to accelerate the commercialization of its flagship biosimilar product candidates (namely ONS-3010 and ONS-1045), as well as other pipeline and new product candidates. Our objective is to help Oncobiologics prepare ONS-3010 so that it can be launched alongside other first-wave HUMIRA® biosimilars with potentially improved tolerability compared to the originator product as reported in the successful Phase 1 trial."

Under the Purchase Agreement, Oncobiologics will initially sell 32,628 shares of its Series A to GMS Tenshi for approximately $3.3 million of cash upon satisfaction of certain initial closing conditions, and enter into an Investor Rights Agreement in connection therewith. Under the Investor Rights Agreement, Oncobiologics will grant GMS Tenshi certain registration rights with respect to the shares of its common stock issuable upon conversion of the Series A and exercise of the Warrants. Effective upon the closing of the initial sale of Series A to GMS Tenshi, Oncobiologics' Board also will elect Faisal G. Sukhtian and Joe Thomas, each of whom will be designated by GMS Tenshi under the Investor Rights Agreement, to its Board of Directors, which individuals will fill vacancies on the Board created by the resignations of Robin Smith Hoke and Donald J. Griffith, which will also be effective as of the closing of the initial sale of Series A to GMS Tenshi. Oncobiologics also entered into an Exchange and Purchase Agreement on September 7, 2017 with an existing investor and agreed to exchange $1.5 million aggregate principal amount of the outstanding senior secured notes held by such investor for 1,500,000 of Oncobiologics' non-voting, Series B Convertible Preferred Stock ("Series B") concurrent with the issuance of the remaining 217,372 shares of Series A. Oncobiologics and the holders of its senior secured notes also agreed to amend the terms of such notes to extend the maturity date by 12 months, among other items.

The closing of the sale of the additional 217,372 remaining shares of Series A and the Warrants is subject to a number of additional closing conditions, including receipt of stockholder approval and other customary closing conditions. Under the Investor Rights Agreement, GMS Tenshi will have the right to designate up to two additional directors in connection with the closing of the sale of such remaining securities. Oncobiologics will also grant GMS Tenshi certain information rights, a right of first offer over certain future issuances of securities, as well as a right of participation in certain future securities issuances. In the event that the final closing does not occur, Oncobiologics has agreed to pay GMS Tenshi, under certain circumstances, $12.5 million in liquidated damages in addition to other expenses, and GMS Tenshi will have a right to put all of the Series A purchased at the initial closing to Oncobiologics.

Oncobiologics intends to file a proxy statement with the U.S. Securities and Exchange Commission for its Annual Meeting of Stockholders, pursuant to which it will seek stockholder approval of the issuance of the Series A and Warrants to GMS Tenshi, change of control of Oncobiologics, along with election of directors and other items to be set forth therein.

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 Oncobiologics, Inc. and its BioSymphony™ Platform

Oncobiologics is a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex biosimilar therapeutics. Its current focus is on technically challenging and commercially attractive monoclonal antibodies (mAbs) in the disease areas of immunology and oncology. Oncobiologics is advancing its pipeline of biosimilar products, two of which are currently in clinical development. Led by a team of biopharmaceutical experts, Oncobiologics operates from an in-house state-of-the-art fully integrated research and development, and manufacturing facility in Cranbury, New Jersey. Oncobiologics employs its BioSymphony™ Platform to address the challenges of biosimilar development and commercialization by developing high quality mAb biosimilars in an efficient and cost-effective manner on an accelerated timeline. 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 whether or not the closing of the sale of the Series A and Warrants to GMS Tenshi will occur, our ability to receive potential additional upfront and milestone payments under the License Agreement, the effects of partnering with GMS Tenshi on our ability to continue development of, and potentially commercialize, our biosimilar product candidates, and the exchange of senior secured notes for Series B, among others. Although we believe that we have a reasonable basis for forward-looking statements contained herein, we caution you that they are based on current expectations about future events affecting us and are subject to risks, uncertainties and factors relating to our operations and business environment, all of which are difficult to predict and many of which are beyond our control. Therefore, they may cause our actual results to differ materially from those expressed or implied by forward-looking statements in this presentation. 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. We do 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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