Outlook Therapeutics, Inc. Logo

Oncobiologics Announces First CTA Approvals for Global Phase 3 Clinical Program for ONS-3010 (Humira® biosimilar)

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Clinical Program Designed to Enable Interchangeability with Humira in U.S.

CRANBURY, N.J., June 16, 2016 (GLOBE NEWSWIRE) -- Oncobiologics, Inc. (NASDAQ:ONS), a clinical-stage biopharmaceutical company focused on identifying, developing, manufacturing and commercializing complex monoclonal antibody (mAb) biosimilar therapeutics, today announced that its Phase 3 clinical plan for ONS-3010 (Humira® biosimilar) has received the first of its European Union (EU) clinical trial authorization (CTA) approvals, including in the United Kingdom, Germany and Spain, for the biosimilarity study portion of the Phase 3 clinical program.

The global Phase 3 clinical program for ONS-3010 is expected to include recruitment and treatment of patients in approximately 20 countries, including the United States and various member states of the EU. The program study design is based on input from multiple Health Authorities including the U.S. Food and Drug Administration (FDA) and European Medicines Agency (EMA), and will include testing intended to enable interchangeability for Humira® in the United States. The Phase 3 program will be conducted in patients with moderate to severe plaque psoriasis and is anticipated to begin dosing patients later in 2016.

“We are excited to move to this final clinical confirmatory stage to demonstrate that ONS-3010 is biosimilar to Humira,” said Kenneth Bahrt, M.D., Chief Medical Officer of Oncobiologics. “This study marks the beginning of our first Phase 3 program and is supported by positive data from our previous Phase 1 study of ONS-3010.”

Oncobiologics Chairman and Chief Executive Officer Pankaj Mohan, Ph.D., added, “These CTA approvals are another important step for Oncobiologics as we move to this final clinical confirmatory stage to demonstrate that ONS-3010 is biosimilar to Humira. It also highlights the unique capabilities of our fully integrated BioSymphony Platform as an in-house engine to develop and manufacture complex mAb biosimilars. In addition, we believe our proprietary formulation, for which we have filed a patent application, is an important differentiator for ONS-3010 that may provide improved tolerability compared to the originator product as reported in our successful Phase 1 trial. Ultimately, our goal is to offer a biosimilar product that provides both economic and therapeutic benefit to payors, buying groups, physicians and, most importantly, patients.”

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 eight 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

The scientific information in this news release related to pipeline products is preliminary and investigative. These potential products are not approved by the U.S. Food and Drug Administration or any other regulatory body, and no conclusions can or should be drawn regarding the safety or effectiveness of the product candidates. Moreover, all statements other than statements of historical facts included in this press release that address activities, events or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. These include statements about the ONS-3010 clinical program, including recruitment, anticipated dosing date, interchangeability and improved tolerability. 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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