Outlook Therapeutics, Inc. Logo

Oncobiologics Announces Presentation of Final Data from Phase 1 Clinical Study of ONS-3010 (HUMIRA® Biosimilar)

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CRANBURY, N.J., Nov. 14, 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 presented final data from the Phase 1 trial evaluating bioequivalence of ONS-3010 (Humira biosimilar) and the US and European originator versions of Humira (adalimumab). The data was presented at the 2016 American College of Rheumatology Annual Scientific Meeting in Washington, DC on November 13, 2016.

The Phase I ONS-3010 trial demonstrated pharmacokinetic (PK) bioequivalence on the primary and secondary endpoints for the biosimilar candidate and the US and EU originator product (Humira). There was no significant difference in immunogenicity or overall safety, except for a reduction in the burning sensation at the ONS-3010 injection site.

“This final Phase 1 data clearly suggests that ONS-3010 is highly biosimilar to the originator adalimumab products,” said Kenneth Bahrt, M.D., FACR, Chief Medical Officer of Oncobiologics. “Of note, is the reduced burning sensation at the injection site, which can be an important differentiator for our biosimilar candidate,” he concluded.

Three randomized, gender-balanced groups of 66 healthy subjects received single subcutaneous doses of 40mg of either ONS-3010 or Humira (EU or US product). Blood samples were collected at regular intervals for PK and immunogenicity testing. Bioequivalence (BE) was assessed using general linear model procedures. Adverse events and serious adverse events were monitored and recorded.

Top line results included:

- The PK profiles for E.U. Humira, U.S. Humira and ONS-3010 were similar in outcome.
- For AUC0-inf and Cmax, the primary endpoints, bioequivalence was demonstrated (i.e., ratio of geometric means ONS-3010/EU Humira [1.03 and 1.00], ONS-3010/US Humira [1.06 and 1.06], EU Humira / US Humira [1.04 and 1.07], for AUC0-inf and Cmax respectively).
- Bioequivalence was also demonstrated for the secondary PK endpoint, $AUC_{0\text{-last}}$.
- Adverse events were evenly divided over treatments, usually mild in severity, and self-limiting.
- A single serious adverse event (bacterial abscess) occurred in the ONS-3010 arm.
- Immunogenicity results showed similar profiles in the three treatment groups for anti-drug and neutralizing antibodies.

Oncobiologics Chairman and Chief Executive Officer Pankaj Mohan, Ph.D., added, “We are pleased with the data on ONS-3010, especially the finding of reduced injection site discomfort using our proprietary formulation. As we prepare for our Phase 3 clinical study, we believe that ONS-3010 can become a new affordable option for patients suffering from rheumatoid arthritis. Ultimately, our goal is to offer a biosimilar product that provides both economic and therapeutic benefits to payors, buying groups, physicians and, most importantly, patients.”

A copy of the presentation poster is available at www.oncobiologics.com/as_acr-poster

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.

HUMIRA® is a registered trademark of AbbVie Biotechnology Ltd.

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