Oncobiologics launches Phase I Clinical Trial for ONS-3010 Biosimilar version of Humira®

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Cranbury, NJ – June 12, 2014 — Oncobiologics, Inc. announced today that it has received approval to initiate a Phase I clinical trial in Europe for its first biosimilar molecule, ONS-3010, a highly biosimilar version of the marketed drug, Humira®.

After reviewing Oncobiologics' Clinical Trial Application, the Centrale Commissie Mensgebonden Onderzoek (CCMO), the Dutch Competent Authority, has provided a Letter of No Objection, and the Independent Ethics Committee of the Foundation "Evaluation of Ethics in Biomedical Research" has approved a Phase I trial to be conducted by the Center for Human Disease Researchin Leiden, The Netherlands. The study is expected to be completed before the end of 2014.

"After a very successful development campaign, we are excited to see our first biosimilar molecule enter thisPhase I study. This represents the culmination of two years of hard work by our team, as well as proof-of-concept for our biosimilars business model, BioSymphony, which integrates our world-class CMC and manufacturing capabilities with the external clinical expertise of inVentiv Health, a top global CRO, and several regionally strong commercial partners around the world," commented Oncobiologics Founder & CEO, Pankaj Mohan, Ph.D.

Aldeyra (NASDAQ:ALDX) CEO Todd C. Brady M.D., Ph.D. added, "As an advisor, I have witnessed the rapid development of Oncobiologics and am thrilled to see the company take this exciting step. Oncobiologics has built a team of respected industry leaders within the framework of an agile startup. It is a testament to that team that Oncobiologics has been able to satisfy the challenging regulatory hurdles surrounding the development of complex mAb biosimilars. I look forward to the successful completion of this trial as well as the continued advancement of other potential products in the Oncobiologics pipeline."

Oncobiologics is developing several additional biosimilars, including a biosimilar version of Avastin®, which will be filed for its first clinical trial later in 2014. Oncobiologics is also pursuing biosimilar versions of Herceptin®, Rituxan® and Erbitux® with plans to initiate studies in 2015 and thereafter.

About Oncobiologics, Inc.
Oncobiologics is a privately-held biopharmaceutical company developing a pipeline of biosimilars and next generation biotherapeutics. Formed by a team of leading industry experts from firms such as Eli Lilly, Bristol-Myers Squibb, Amgen, Genentech, Merck and Pfizer, Oncobiologics operates from a state-of-the-art 35,000 sq. ft. fully integrated R&D and Manufacturing facility in Cranbury, NJ. For more information, please visit www.oncobiologics.com

About the Oncobiologics BioSymphony Model
The BioSymphony™ biosimilars business model is designed to ensure that biosimilar assets meet the stringent requirements of U.S. and European regulators, while also achieving accelerated development and technical excellence in creating affordable medicines for patients who so urgently need them. The model leverages Oncobiologics' in-house CMC, biomanufacturing expertise and infrastructure with subject matter expert partners from around the globe to create a world-class biosimilars commercialization engine. The Oncobiologics R&D function features cell line development, analytical and formulation development, and upstream and downstream process development. The R&D facility is outfitted with a state-of-the-art cGMP single-use manufacturing platform for producing clinical material and is being expanded to handle commercial launch with twin 2000-liter single-use bioreactor lines. Oncobiologics' CMC and Regulatory functions are closely integrated with partner inVentiv Health, a global leader in clinical development. The BioSymphony model is on target to generate three monoclonal antibody products per year from 2017-2018.