Oncobiologics announces completion of clinical dosing for bevacizumab (Avastin® biosimilar) candidate

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Oncobiologics, Inc.,a biotherapeutics company focused on developing and commercializing biosimilars, today announced that clinical development for ONS-1045, an Avastin®/bevacizumab biosimilar candidate, is underway with dosing completed in its pivotal pharmacokinetic (PK) study. This study is currently being conducted at the Center for Human Drug Research (CHDR) in Leiden, The Netherlands.

ONS-1045 is being studied in a 3-arm single-dose PK study in healthy male volunteers to compare it against both the US- and EU-sourced Avastin® reference products, and the two reference products to each other. This 3-way PK assessment, designed to assess PK, safety and tolerability, is the first step in the global clinical development program for Oncobiologics' second of eleven biosimilar candidates.

Avastin is a monoclonal antibody that binds to the vascular endothelial growth factor (VEGF) and is approved in multiple markets for the treatment of various cancers including metastatic colorectal and non-squamous non-small cell lung cancers.

"The ONS-1045 PK study is our second clinical study start in less than one year. This is an important demonstration of Oncobiologics' development capabilities, as the company continues to advance its multi-asset biosimilar pipeline," commented Oncobiologics Founder & CEO, Pankaj Mohan, Ph.D.

The company has begun preparing for the global Phase III program and expects the PK study results to be available in time to enable initiation of a Phase III study in Q4 2015.