**ONS-3010 (Humira®/adalimumab biosimilar) meets primary endpoints in first clinical study**

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**Cranbury, NJ – February 12, 2015** — Oncobiologics, Inc.,a biotherapeutics company focused on developing and commercializing biosimilars,announced today that ONS-3010, its adalimumab (Humira®) biosimilar candidate met the primary endpoints in its first clinical study.

A 3-arm single-dose pharmacokinetic (PK) study was performed in healthy volunteers to compare ONS-3010 to both the US- and EU-sourced Humira® reference products, and the two reference products to each other. All of the PK endpoints met the bioequivalency criteria of the geometric mean ratios within 90% confidence interval of 80-125%. These included: maximum serum concentration (Cmax), area under the time-concentration curve from first time point extrapolated to infinity (AUC0-inf), and area under the time-concentration curve from first to last time point measured (AUC0-t). Safety and immunogenicity were similar across the three arms. An exploratory *ex vivo* pharmacodynamic study also showed encouraging results between ONS-3010 and the reference products on TNF-α blockade and the induction of specific inflammatory responses. This first-in-human study was conducted by the Centre for Human Drug Research (CHDR) in Leiden, The Netherlands.

ONS-3010 is being developed as a biosimilar to adalimumab, an anti-TNF-α monoclonal antibody, which is approved in many countries for the treatment of multiple inflammatory diseases that include rheumatoid arthritis, plaque psoriasis, polyarticular juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease and ulcerative colitis, as well as several pediatric indications. ONS-3010 has the same amino acid sequence, pharmaceutical dosage form, and strength but contains a formulation of different composition.

“The clinical PK similarity study is a required regulatory milestone for biosimilar development. We are excited to report that ONS-3010 has met the PK endpoints, which strengthens our confidence in achieving the global development of ONS-3010 as a biosimilar to Humira®,” stated Claude Nicaise, M.D., Chief Medical Officer at Oncobiologics.

“These clinical results are further validation of our unique BioSymphony platform. Our internal R&D, manufacturing, regulatory and clinical teams, and our strategic partners, CHDR and inVentiv Health, have worked exceptionally well together to achieve this important milestone. We look forward to executing the next clinical phase for ONS-3010, as well as the advancement of the remaining assets in our biosimilar pipeline.” commented Oncobiologics Founder & CEO, Pankaj Mohan, Ph.D.

**About Oncobiologics, Inc. and the BioSymphony™ Model**

Oncobiologics is a privately-held biopharmaceutical company focused on the advancement of its pipeline of 11 biosimilar products, two of which are currently in clinical development. Led by a team of biopharmaceutical experts, Oncobiologics operates from a state-of-the-art 40,000 sq. ft. fully-integrated R&D and manufacturing facility in Cranbury, NJ. The company employs its BioSymphony business model 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 global patients who so urgently need them. The aggregate market value at time of patent expiry for the molecules in Oncobiologics’ pipeline is projected to be in excess of $80 Billion.