ONS-1045 (Avastin®/bevacizumab biosimilar) Meets Primary and Secondary Endpoints in Phase 1 Clinical Trial

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Oncobiologics Announces ONS-1045 (Avastin®/bevacizumab biosimilar)
Meets Primary and Secondary Endpoints in Phase 1 Clinical Trial

Cranbury, NJ – Oct. 5, 2015 — Oncobiologics, Inc. ("Oncobiologics") announced that its bevacizumab (Avastin®) biosimilar candidate, ONS-1045, met the primary and secondary endpoints in a Phase 1 clinical trial.

A 3-arm single-dose pharmacokinetic (PK) study was performed in 135 healthy male volunteers to compare ONS-1045 to both the U.S.- and EU-sourced Avastin® 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 the primary endpoint of area under the time-concentration curve from first time point extrapolated to infinity (AUC0-inf), and the two secondary endpoints: maximum serum concentration (Cmax), and area under the time-concentration curve from first to last time point measured (AUC0-t). Safety and immunogenicity were similar and no neutralizing antibodies were detected across the three arms. This first-in-human study for ONS-1045 was conducted by the Centre for Human Drug Research (CHDR) in Leiden, The Netherlands.

ONS-1045 is being developed as a biosimilar to bevacizumab, an anti-vascular endothelial growth factor-A (VEGF-A) monoclonal antibody ("mAb"), which is approved in many countries for the treatment of a variety of metastatic cancers. Oncobiologics has begun both in-house manufacturing of Phase 3 clinical trial material and clinical site assessment in preparation for the initiation of the global confirmatory Phase 3 clinical trial.

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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 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 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 our plans, objectives, strategies and prospects regarding, among other things, ONS-1045 and the other biosimilar products in our pipeline. 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.