



Contact: Ed Maggio, PhD
Chief Executive Officer
Aegis Therapeutics LLC
1-858-618-1400 Ext. 101
Email: emaggio@aegisthera.com

Aegis Awarded 2nd Patent for Monoclonal Antibody Formulations that Avoid Oxidative Damage Due to Polysorbate Surfactants

SAN DIEGO, CA October 7, 2014/MarketWire-- Aegis Therapeutics LLC announced today that it has been awarded U.S. Patent No. 8,846,044, dramatically broadening its patent franchise to cover all useful alkylsaccharides for stabilizing any or all monoclonal antibody biotherapeutics. The Aegis ProTek® excipients provide reduced immunogenicity while avoiding the oxidative damage caused by contaminating peroxides and reactive aldehydes intrinsic to the polysorbates such as Tween®-20 and 80, a commonly used polysorbate surfactants found in nearly all monoclonal antibody therapeutics. Oxidative damage that can result in protein aggregation and neutralizing antibodies that block drug action is a growing concern throughout the pharma industry and governmental regulatory bodies. The FDA recently issued a "Guidance for Industry" document titled: "Scientific Considerations in Demonstrating Biosimilarity to a Reference Product" highlighting its concerns about immunogenicity in biotherapeutics (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM291128.pdf>).

ProTek® excipients circumvent the problem of oxidative damage to biotherapeutics while achieving superior aggregation prevention – keys to maintaining drug potency and reducing unwanted immunogenicity. Efforts to control the level of residual peroxides in polysorbate-containing solutions, including degassing and filling under nitrogen or inclusion of antioxidants, such as cysteine, glutathione or methionine, are often impractical and have been reported to result in interactions with the protein that cause further degradation or precipitation in some instances. Polysorbate damage to biotherapeutics is discussed at length in a just published review article in the Journal of Excipients and Food Chemicals: <http://ojs.abo.fi/index.php/jefc/article/view/157/154>.

To date, two Top-10 Big Pharma companies have licensed the application of ProTek® excipients to stabilize their proprietary monoclonal antibody biotherapeutics along with selected non-mAb biotherapeutics and two additional Top-10 Big Pharma's are in current negotiations with Aegis for similar licenses. Other issued ProTek® related patents provide for non-invasive delivery and/or stabilization of all GLP-1 analogs, insulin, human growth hormone, parathyroid hormone and analogs, octreotide, and beta-, alpha-, and gamma-interferons, with others pending.

About Aegis Therapeutics

Aegis Therapeutics LLC is a drug delivery technology company commercializing its patented drug delivery and drug formulation technologies through product-specific licenses. Our Intravail® drug delivery technology enables the non-invasive delivery of a broad range of protein, peptide and non-peptide drugs that can currently only be administered by injection, via the oral, buccal, and intranasal administration routes, and with high bioavailability. Our ProTek® excipients stabilize, prevent aggregation, and reduce unwanted immunogenicity of protein and peptide therapeutics while avoiding the oxidative damage caused by polysorbate surfactants currently found in most protein injectable drugs.

For more information about Aegis, please visit: <http://aegisthera.com/>.