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AEGIS' PROTEK® EXCIPIENTS PROVIDE A SUPERIOR ALTERNATIVE TO POLYSORBATES IN PREVENTING PROTEIN AGGREGATION AND UNWANTED OXIDATIVE DAMAGE AND IMMUNOGENICITY

SAN DIEGO, CA March 23, 2016 -- Biotherapeutics incorporating alkylglucosides rather than polysorbates are likely to achieve substantial commercial benefits and a strong and differentiable market franchise for innovator biotherapeutics and biosimilars. Aggregation-induced neutralizing antibodies and anaphylactic reactions sometimes associated with polysorbates are serious and growing concerns of both the FDA and the European Medicines Agency (EMA). This will have significant and growing impact on development and regulatory approval of both biosimilar and innovator biotherapeutics. Because immunogenicity can reduce or eliminate a protein drug's efficacy upon subsequent administration — and may even neutralize a patient's corresponding residual biological activity — it would be difficult if not unethical to justify using a product demonstrated to be immunogenic over one with less or no immunogenicity. Incorporating alkylglucosides in place of polysorbates for innovator or biosimilar biotherapeutics currently in development could provide clinically superior products. A complete discussion may be found in the March issue of BioProcess International at the following link:

<http://www.bioprocessintl.com/manufacturing/antibody-non-antibody/alkyl-mono-and-di-glucosides-highly-effective-nonionic-surfactant-replacements-for-polysorbates-in-biotherapeutics-a-review/>

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.

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