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Aegis Therapeutics' ProTek™ Formulation Technology Increases Stability and Reduces Immunogenicity of Protein and Peptide Therapeutics

SAN DIEGO, CA July 10, 2006/BusinessWire/-- Aegis Therapeutics announces the availability for product-specific licensure of its proprietary ProTek™ formulation technology employing proprietary non-toxic excipients that maintain physical stability and physiological activity of protein and peptide therapeutics. ProTek™ permits the generation of easily manufacturable homogeneous and stable aqueous or lyophilized dosage forms of peptide and protein drugs. ProTek™ is applicable to all modes of administration including the injectable, intranasal, pulmonary, oral, oral cavity, and other transmucosal routes.

In accelerated stability studies using elevated temperatures and constant agitation for a period of three weeks, designed to stress the normal stability of a number of the most important and commonly used protein drugs, ProTek™ increased the stability of human growth hormone by more than 5-fold and increased the stability of human insulin by approximately 20-fold - in each case with no sign of decreased stability at the conclusion of the study. Independent tests of ProTek™ with a novel peptide therapeutic currently slated for Phase II clinical trials have demonstrated similar results and in recent weeks have led to the first compound-specific license to be granted for ProTek™.

Protein aggregation, a particularly troublesome form of instability, may arise during the manufacturing process where peptides or proteins are often manipulated at high concentrations, or simply upon extended storage, and is increasingly being identified as a source of multiple deleterious effects for peptide and protein therapeutics. These effects may include loss of efficacy, altered pharmacokinetics, reduced stability resulting in shortened product shelf-life or more stringent "cold chain" handling requirements, and unwanted immunogenicity. Protein immunogenicity is receiving increasing scrutiny by the FDA and other regulatory agencies as evidence mounts concerning potential adverse reactions to the resulting antibodies that arise in some patients.

Don Grimm, Chairman of Aegis Therapeutics, said, "We believe that superior formulation stability for protein and peptide therapeutics will be a significant market differentiator. A ten percent positive shift in market share could translate into a billion dollars or more over a product's normal life cycle." Mr. Grimm further commented, "The prospect of a room-temperature stable insulin for use in insulin pumps could improve consistency and reduce the frequency with which the insulin cartridges must be replaced, or simply improve reliability and convenience of the current injectable insulins."

Protein therapeutics for which ProTek™ is expected to be particularly useful include insulin, human growth hormone, erythropoietin, interferon, Factor VIII, and a growing number of monoclonal antibody therapies.

Aegis licenses its technology on a product-by-product exclusive basis. Companies seeking solutions for manufacturing or formulation problems related to loss of biological activity, aggregation, or unwanted immunogenicity, should contact Ralph Barry, Chief Business Officer for further information.

About Aegis Therapeutics

Aegis Therapeutics LLC is a drug delivery technology company commercializing its patented or proprietary 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 macromolecular therapeutics that can currently only be administered by injection. Aegis' Intravail™ absorption enhancement agents provide exceptionally high and unmatched bioavailability performance, comparable in efficiency to subcutaneous injection, via the intranasal and other mucosal membrane administration routes. Our ProTek™ technology allows creation of proprietary, easily manufacturable, and stable aqueous or lyophilized dosage forms that maintain the physical stability and physiological activity of protein and peptide therapeutics. ProTek™ technology is applicable to injectable, intranasal, and other dosage forms of peptide or protein therapeutics.

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

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