



Contact: Ralph Barry, Chief Business Officer
Aegis Therapeutics LLC
1-858-618-1400 Ext. 102
Email: rbarry@aegisthera.com

Aegis Therapeutics Files First Drug Master File with the FDA

SAN DIEGO, CA August 8, 2005 / BusinessWire /-- Aegis Therapeutics LLC today announced that it has filed its first Drug Master File (DMF) for Intravail™ with the U.S. Food and Drug Administration (FDA) as part of its goal of broadly enabling intranasal delivery of peptide and protein drugs across a wide spectrum of disease categories for the world's current and future leading pharmaceutical and biopharmaceutical companies.

Aegis' Intravail™ absorption enhancement agents are mild and non-irritating to mucosal membranes, providing exceptionally high and unmatched bioavailability performance, comparable in efficiency to subcutaneous injection via the intranasal, ocular and other mucosal membrane administration routes. These agents help deliver potent peptide, protein, and other small and large molecule drugs that currently can be delivered only by injection. To date, Aegis has licensed Intravail™ for beta-interferon, low molecular weight heparin, and for three undisclosed pediatric drugs. Several feasibility studies for additional drugs have been recently completed or are underway.

A DMF provides key confidential, detailed regulatory and scientific information about the facilities, processes, and entities used in the proprietary manufacturing, processing, packaging and storage of Aegis' patented Intravail™ absorption enhancement agents intended for use in humans. The information contained in the DMF will be used to support future Investigational New Drug Applications (INDs) or a New Drug Applications (NDAs), an Abbreviated New Drug Application (ANDA), another DMF, an Export Application, or amendments to any of these. The contents of a DMF are reviewed in connection with the review of an application to the FDA such as an IND or NDA.

According to Aegis' CEO, Dr. Edward T. Maggio, "DMFs provide a strategic advantage by allowing the FDA to access Aegis' confidential regulatory and scientific material without disclosing that information privately or publicly to other parties. Pharmaceutical company licensees of Intravail™ will receive reference authorization to our DMFs in support of their submissions to the FDA."

About Aegis Therapeutics

Aegis Therapeutics LLC is a specialty pharmaceutical company commercializing its patented Intravail™ drug delivery technology that 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 are mild and non-irritating to mucosal membranes. They provide exceptionally high and unmatched bioavailability performance, comparable in efficiency to subcutaneous injection, via the intranasal and other mucosal membrane administration routes. Intravail™ also provides for rapid drug absorption and onset of action, controlled transient permeation of the nasal mucosal barrier, avoidance of gastric hydrolysis and "first pass effect" elimination by the liver, greater patient convenience and compliance, elimination of needle-stick injuries and associated transmission of blood borne pathogens, compatibility with current nasal delivery devices, and ease of formulation, scale-up, and production. For more information about Aegis, please visit the Aegis website at:

<http://www.aegisthera.com>.

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