Stealth Peptides Inc. Announces FDA IND Approval for Conduct of Clinical Studies with Bendavia™, A Mitochondrial Targeted Therapy for Ischemia Reperfusion Injury

17 May 2010, ROCKVILLE, Md.—BUSINESS WIRE--Stealth Peptides Inc. (Stealth), a privately held biopharmaceutical company developing innovative therapies, announced today that the U.S. Food and Drug Administration (FDA) approved its Investigational New Drug (IND) application for Bendavia™. Bendavia is a new chemical entity that targets mitochondria to treat ischemia reperfusion injury, which commonly occurs with many cardiovascular, renal and neurologic insults.

Stealth's lead clinical program is for acute myocardial infarction (AMI), an indication with clear clinical metrics for FDA marketing approvals and demonstrating the beneficial biologic activity of Bendavia.

A focus of Stealth's AMI clinical program is to translate the preclinical efficacy of Bendavia into patient benefit. Statistics from the American Heart Association indicate that more than 600,000 people within the U.S. die from heart disease and AMI each year, which is greater than the combined total from all cancers. The degree of infarcted heart tissue is a major determinant of patient mortality and morbidity with AMI. Bendavia has shown the ability to reduce infarct sizes by more than 35% across several standard AMI animal models, including large animals, when administered prior to the onset of reperfusion as defined by the reestablishment of coronary blood flow.

The IND approval permits Stealth to initiate its first Phase I clinical trial of Bendavia using a placebo–controlled, ascending single–dose design in healthy volunteers. The aims of the Phase I trial are to evaluate the clinical safety, tolerability and pharmacokinetics of Bendavia. Stealth CEO, Travis Wilson, remarked that the company's "AMI animal studies clearly demonstrate that Bendavia has beneficial cardioprotective effects and confirm the significance of our novel target, the mitochondrion, for ischemia reperfusion injury. Bendavia also appears to be a strong renal protectant, which can potentially curtail many of the renal complications seen in AMI patients. These features of the compound, along with a strong preclinical safety profile, hold promise for Bendavia as a paradigm shifting therapy for multiple therapeutic areas where mitochondrial function is critical."

Stealth's Phase I trial is scheduled to enroll its first healthy volunteer later this month.
More information regarding Stealth and the Phase I clinical trial for Bendavia is available at www.clinicaltrials.gov.

About Stealth Peptides

Stealth Peptides was founded in 2006 with technology licensed from Cornell University. Stealth has a rich and promising pipeline of preclinical and clinical compounds from a unique class of short peptides (500–700 Daltons each) that target mitochondria. Published data for these compounds suggest significant *in vitro* and *in vivo* efficacy for cardiovascular, renal, neurologic and metabolic diseases. The intellectual property portfolio around these compounds is exceptionally robust with compositions, including Bendavia, protectable by patent until at least 2026. Stealth integrates deeply experienced consultants and advisors with its core team and facilities from Rockville, Maryland and Boston, Massachusetts to Shanghai, China.

More information regarding Stealth and its pipeline is available at www.stealthpeptide.com.