

Stealth Peptides Inc. Completes Initial Phase I Clinical Trial Cohort with Bendavia™, a Mitochondrial Targeted Therapy for Ischemia Reperfusion Injury

14 June 2010 , ROCKVILLE, Md.--(BUSINESS WIRE)--Stealth Peptides Inc. (Stealth), a privately held biopharmaceutical company developing innovative therapies, announced today that it concluded its initial Phase I clinical trial cohort of a first-in-humans study with Bendavia™, a compound that targets mitochondria to treat ischemia reperfusion injury. The Investigational New Drug (IND) application for Bendavia was approved by the U.S. Food and Drug Administration (FDA) during May 2010.

The current Phase I clinical trial is a placebo-controlled, ascending single-dose design study of healthy volunteers to evaluate the clinical safety, tolerability and pharmacokinetics of Bendavia. An independent Safety Review Board (SRB) has closely evaluated the safety data from the initial cohort of volunteers and recommended that the observed safety profile supports continuation of the Phase I clinical trial. The SRB also agreed on starting the planned second cohort of a higher dose for Bendavia by June 15, 2010.

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. Standard animal models for AMI clearly demonstrate that Bendavia offers cardioprotective effects and confirm the importance of Stealth's 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 with AMI patients. These features of the compound hold promise for Bendavia as a paradigm shifting therapy for multiple therapeutic areas. The relationship among mitochondria and ischemia reperfusion injury has gained a remarkable amount of interest recently after several prominent journals, including the New England Journal of Medicine, reported on the mitochondrion's role within myriad areas of unmet medical need.

Stealth CMO, Dr. Richard Straube, commented that "we are extremely pleased with our choice of a Phase I clinical trial partner, Clinical Pharmacology of Miami, particularly given our partner's ability to recruit a volunteer group that includes a diverse range of ages. The current clinical trial enables us to evaluate safety within a meaningful AMI population as opposed to only studying younger Phase I volunteers.

Our aim for Phase II trials is to evaluate the efficacy of Bendavia with AMI patients. Thus, it is important for us to understand Bendavia's safety profile within an older volunteer population.”

“The successful completion of our initial Phase I trial cohort with Bendavia represents an important developmental milestone for us,” remarked Stealth CEO, Travis Wilson. “The unique features of Bendavia along with its strong preclinical safety profile and the ongoing Phase I trial are creating a great deal of interest within the clinical and pharmaceutical communities for AMI and beyond. The preclinical and clinical assessments of Bendavia offer us tremendous encouragement for continuing to develop our additional programs with Bendavia including those for metabolic, neurologic and ophthalmic diseases where mitochondrial function is critical.”

More information regarding Stealth and the Phase I clinical trial for Bendavia is available at www.clinicaltrials.gov.

About Acute Myocardial Infarction and Bendavia™

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 every type of cancer. The degree of infarcted heart tissue is a major determinant of mortality and morbidity with AMI. Bendavia has shown the ability to reduce infarct sizes by more than 35% across several standard AMI models, including large animal models, when administered prior to the onset of reperfusion as defined by the reestablishment of coronary blood flow.

About Stealth Peptides

Stealth Peptides was founded during 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 also incredibly 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.