



Catabasis Initiates Phase 2 Trial of CAT-2003 in Patients with Hypertriglyceridemia and Hypercholesterolemia

CAMBRIDGE, Mass., Aug. 21, 2013 - [Catabasis Pharmaceuticals Inc.](#) today announced the initiation of PATHWAYS I*, a Phase 2 trial investigating the safety, tolerability and efficacy of CAT-2003, an oral SMART Linker conjugate constructed using the company's proprietary technology. CAT-2003 will be evaluated in patients with hypertriglyceridemia and in combination with statins in patients with hypercholesterolemia.

"We recently announced positive Phase 1 data showing that CAT-2003 significantly reduced fasting and post-prandial triglyceride levels in healthy individuals and produced an improvement in lipid biomarkers such as LDL-C**, ApoB** and PCSK9**," said Joanne Donovan, M.D., Ph.D., chief medical officer of Catabasis. "Because of these promising results, we are advancing CAT-2003 into Phase 2 to evaluate the drug's effects in patients with hypertriglyceridemia and hypercholesterolemia."

Michael Jirousek, Ph.D., co-founder and chief scientific officer of Catabasis, added, "CAT-2003 acts through the intracellular targeting of multiple nodes in the lipid synthesis pathway. One arm of this study will focus on evaluating the effect of CAT-2003 on lipid levels in combination with statins in patients with hypercholesterolemia. As a result of the inhibition of PCSK9 production we have observed with CAT-2003, we may see a synergistic effect with statins in lowering lipids such as LDL."

In the first arm of this randomized, double-blind, placebo-controlled Phase 2 study, 72 patients with moderate hypertriglyceridemia will receive one of three doses of CAT-2003 or placebo for four weeks. Fasting triglycerides and non-HDL-C will be measured and compared to baseline in these patients. In a second arm, 24 patients with hypercholesterolemia on statins will receive either a specified dose of CAT-2003 or placebo once per day for four weeks. Fasting LDL-C levels will be evaluated in this group of patients. Top line data is expected in the fourth quarter of 2013.

For more information on this trial, see clinicaltrials.gov.

* Pilot Study to Assess CAT-2003 in Patients with Hyperlipidemia (PATHWAYS I)

** LDL-C – low density lipoprotein cholesterol; ApoB – apolipoprotein B; PCSK9 - proprotein convertase subtilisin/kexin type 9

About CAT-2003

CAT-2003 is a new chemical entity that is a SMART Linker conjugate. It is being investigated for the treatment of severe hypertriglyceridemia and hypercholesterolemia. In preclinical models of severe hypertriglyceridemia, a significant and dose-dependent reduction in plasma triglycerides

was observed with CAT-2003. In preclinical models of dyslipidemia, CAT-2003 dramatically reduced LDL cholesterol. In combination with a statin, CAT-2003 synergistically lowered LDL cholesterol. In a Phase 1 trial, CAT-2003 demonstrated a significant reduction in fasting and post-prandial triglyceride levels and had positive effects on biomarkers including reductions in LDL, apolipoprotein C-III (ApoC-III), ApoB and PCSK9.

About Catabasis

Catabasis is a clinical-stage company dedicated to the discovery and development of innovative, effective and safe medicines to treat inflammatory and metabolic diseases. The company's drug development programs are rooted in the principles of pathway pharmacology, the treatment of diseases by simultaneously modulating more than one target in a disease pathway. Using its proprietary SMART Linker technology, the company conjugates two drugs that act on different components of a disease pathway to produce new chemical entities with significantly enhanced efficacy and an improved safety and tolerability profile. The company has assembled a team of passionate and experienced scientists who are committed to improving the lives of patients. The company was founded in 2008 and is headquartered in Cambridge, Mass.

Please visit www.catabasis.com for more information.

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