



## Catabasis Initiates Phase 1 Trial of CAT-2003 for Treatment of Severe Hypertriglyceridemia

CAMBRIDGE, Mass., March 26, 2013 - [Catabasis Pharmaceuticals Inc.](#), today announced the initiation of a Phase 1 study to investigate the safety and tolerability of CAT-2003 in healthy volunteers and in adults with mildly elevated lipids. CAT-2003 is a conjugate of niacin and eicosapentaenoic acid (EPA), an omega-3 fatty acid, covalently linked using the company's proprietary SMART Linker technology to create a new chemical entity and is being developed for patients with severe hypertriglyceridemia.

"Advancing CAT-2003 into the clinic is another important milestone for Catabasis after recently announcing positive Phase 1 data for CAT-1004 that validated our SMART Linker platform," said Michael Jirousek, Ph.D., chief scientific officer of Catabasis. "In preclinical animal models, CAT-2003 produced robust triglyceride and low density lipoprotein (LDL) cholesterol lowering, and synergistic reductions in LDL cholesterol when CAT-2003 was combined with a statin."

This randomized, double-blind, placebo-controlled Phase 1 study will be conducted in two parts. In the first part, healthy adults will receive a single ascending dose of CAT-2003 or placebo. In the second part, healthy adults or patients with mildly elevated lipids will receive CAT-2003 or placebo daily for 14 days. The study will evaluate safety, tolerability and pharmacokinetics. Triglycerides, LDL cholesterol and biomarkers related to the mechanism of action of CAT-2003 will also be assessed. Data is expected in the second quarter of 2013.

For more information on this trial see [clinicaltrials.gov](#).

### About CAT-2003

CAT-2003 is a new chemical entity that is a conjugate of the B vitamin niacin and eicosapentaenoic acid (EPA), an omega-3 fatty acid, linked using the company's proprietary SMART Linker technology. It is being investigated for the treatment of severe hypertriglyceridemia. In preclinical models of severe hypertriglyceridemia, a significant and dose-dependent reduction in plasma triglycerides was observed with CAT-2003, while a simple combination of niacin and omega-3 had only a marginal effect. In preclinical models of dyslipidemia, CAT-2003 dramatically reduced LDL cholesterol. In combination with a statin, CAT-2003 synergistically lowered LDL cholesterol. Because CAT-2003 is not activated until it is delivered to the target cell, CAT-2003 is not expected to activate the receptor that causes "niacin flush," a side effect characterized by blushing of the skin and a sensation of warmth resulting from blood vessel dilation; this effect can reduce patient compliance.

### About Hypertriglyceridemia

Severe hypertriglyceridemia refers to a condition involving levels of triglycerides equal to or above 500 mg/dL. Severe hypertriglyceridemia is associated with markedly increased risk for cardiovascular disease and pancreatitis, and recent studies have demonstrated that elevated triglyceride levels can be regarded as an independent risk factor for cardiovascular events such

as myocardial infarction, ischemic heart disease and ischemic stroke. The prevalence of hypertriglyceridemia is rapidly increasing in the United States and throughout the world. It is estimated that over four million patients have severe hypertriglyceridemia in the United States. The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol recommends that the first priority for the management of severe hypertriglyceridemia be triglyceride reduction to decrease the risk of pancreatitis. Current treatments include adhering to a low-fat, low-carbohydrate diet, exercise and alcohol abstinence. Medical therapies can include statins to normalize other lipid parameters, fibrates and omega-3 fatty acids.

## 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](http://www.catabasis.com) for more information.

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