



Catabasis Pharmaceuticals Receives FDA Fast Track Designation for CAT-1004 for the Treatment of Duchenne Muscular Dystrophy

July 6, 2015

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jul. 6, 2015-- [Catabasis Pharmaceuticals, Inc.](#) (NASDAQ: CATB), a clinical-stage drug development company built on a pathway pharmacology technology platform, today announced that CAT-1004 has received Fast Track designation from the U.S. Food and Drug Administration (FDA) for the treatment of Duchenne muscular dystrophy (DMD). CAT-1004 is designed to inhibit activated NF-kB, which has the potential to reduce muscle inflammation and degeneration, and promote muscle regeneration for patients with DMD regardless of the underlying mutation. DMD is a rare disease that involves progressive muscle degeneration that eventually leads to death and for which there are no approved therapies in the United States.

"Fast Track designation for CAT-1004 highlights its potential to treat a serious, life threatening disease with few treatment options for these young patients," said Jill C. Milne, Ph.D., co-founder and chief executive officer of Catabasis. "By targeting activated NF-kB in pre-clinical studies, CAT-1004 has demonstrated disease-modifying potential for this devastating condition."

The FDA Fast Track process is designed to expedite the development and review of drugs to treat serious or life-threatening conditions and demonstrate the potential to address unmet medical needs. Companies that receive Fast Track designation are allowed to submit New Drug Applications (NDA) on a rolling basis, expediting the FDA review process, and benefiting from more frequent communication with the FDA to discuss all aspects of clinical development. In addition, drugs that receive Fast Track designation are eligible for accelerated approval and priority review if certain criteria are met.

About CAT-1004

CAT-1004 is an oral small molecule that inhibits activated NF-kB, a protein that coordinates cellular response to muscular damage, stress and inflammation and plays an important role in muscle health. In skeletal muscle, activated NF-kB drives muscle degeneration and suppresses muscle regeneration. In animal models of DMD, CAT-1004 inhibited activated NF-kB, reduced muscle inflammation and degeneration and increased muscle regeneration. In Phase 1 clinical trials, CAT-1004 inhibited activated NF-kB and was well-tolerated with no observed safety concerns. The FDA has previously granted CAT-1004 orphan drug designation for the treatment of DMD.

About Catabasis

Catabasis Pharmaceuticals is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics using its proprietary Safely Metabolized And Rationally Targeted, or SMART, linker technology platform. The Company's SMART linker technology platform is based on the concept of treating diseases by simultaneously modulating multiple targets in one or more related disease pathways. The Company engineers bi-functional product candidates that are conjugates of two molecules, or bioactives, each with known pharmacological activity, joined by one of its proprietary SMART linkers. The SMART linker conjugates are designed for enhanced efficacy and improved safety and tolerability. The Company's focus is on treatments for rare diseases. The Company is also developing other product candidates for the treatment of serious lipid disorders. For more information on the Company's technology and pipeline of drug candidates, please visit www.catabasis.com.

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