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Catabasis Pharmaceuticals Announces the Initiation of an Open-Label Extension for the MoveDMD® Trial Studying Edasalonexent (CAT-1004) in Duchenne Muscular Dystrophy

CAMBRIDGE, MA, July 7, 2016 – Catabasis Pharmaceuticals, Inc. (NASDAQ:CATB), a clinical-stage biopharmaceutical company, today announced the initiation of an open-label extension for the Phase 2 portion (Part B) of the MoveDMD trial studying edasalonexent (CAT-1004), an investigational therapy, in boys with Duchenne muscular dystrophy (DMD). The Phase 2 portion of the MoveDMD trial is a randomized, double-blind, placebo-controlled 12-week trial to assess the efficacy and safety of two doses of oral edasalonexent with the primary end point being change in magnetic resonance imaging (MRI). Top-line results are expected late 2016. In the open-label extension, all patients will receive edasalonexent for 36 weeks beyond the 12-week placebo-controlled period. During the open-label extension, safety will be monitored and additional assessments including MRI, timed function tests, muscle strength measures, the North Star Ambulatory Assessment and the pediatric outcomes data collection instrument (PODCI) will be performed. All patients who complete the 12-week Phase 2 portion of the MoveDMD trial will be eligible to enroll in the open-label extension. Catabasis has previously reported favorable safety, tolerability and pharmacokinetics as well as positive biomarker results demonstrating NF-kB target engagement from the initial 7-day dose-ranging portion of the MoveDMD trial.

"We are pleased to extend edasalonexent dosing in the MoveDMD trial based on the acceptable safety and tolerability data seen to date," said Joanne Donovan, M.D., Ph.D., Chief Medical Officer of Catabasis. "The MoveDMD open-label extension is expected to inform on safety and efficacy of edasalonexent when administered for up to 48 weeks, and is important to our overall development strategy. We very much appreciate the support that we have received from the DMD community for the MoveDMD trial."

"I am pleased to see the progress with this clinical trial and to offer additional dosing of this novel investigational therapy to boys affected by Duchenne when they complete the 12-week placebo-controlled portion of the trial," said Erika Finanger, M.D., Assistant Professor, Pediatrics & Neurology, Oregon Health & Sciences University and Consulting Neurologist, Shriners Hospitals for Children and a principal investigator in the MoveDMD trial. "We need therapies that have the potential to make a meaningful difference in boys affected by DMD regardless of the underlying mutation."

In the first portion of the MoveDMD trial (Part A), 17 ambulatory boys between ages 4 and 7 with a genetically confirmed diagnosis of DMD across a range of dystrophin mutations received edasalonexent. The boys were steroid naive or had not used steroids for at least six months prior to the trial. This portion of the trial was conducted at three sites in the U.S., and assessed the

safety, tolerability and pharmacokinetics of edasalonexent in patients at three dosing levels (33 mg/kg/day, 67 mg/kg/day and 100 mg/kg/day) during seven days of dosing. Phase 2 of the MoveDMD trial (Part B) is a randomized, double-blind, placebo-controlled trial to evaluate the safety and efficacy of edasalonexent in DMD over a 12-week period at 5 clinical trial sites in the U.S. at two dosing levels, 67 mg/kg/day and 100 mg/kg/day. The boys that participated in the first part of the MoveDMD trial that remain eligible are asked to participate in Phase 2 and additional participants are expected to be enrolled for a total of approximately 30 boys. The open-label extension (Part C) includes dosing with edasalonexent for 36 weeks beyond the 12-week placebo-controlled portion of the trial and will evaluate longer term safety and efficacy with the same clinical end points. We are currently identifying additional patients who are interested in participating in the Phase 2 trial. Entry criteria are similar to those in the first portion of the trial. The Parent Project Muscular Dystrophy and the Muscular Dystrophy Association are providing funding to support participant travel for the MoveDMD trial.

More information about the MoveDMD trial can be found on the clinical trials page of the Catabasis website and on ClinicalTrials.gov under trial identifier NCT02439216.

About Edasalonexent (CAT-1004)

Edasalonexent (CAT-1004) is an oral small molecule that has the potential to be a disease-modifying therapy for all patients affected by Duchenne muscular dystrophy (DMD or Duchenne), regardless of the underlying mutation. Edasalonexent inhibits NF-kB, a protein that is activated in Duchenne and drives inflammation and fibrosis, muscle degeneration and suppresses muscle regeneration. In animal models of DMD, edasalonexent inhibited NF-kB, reduced muscle degeneration and improved muscle regeneration and function, and beneficial effects were observed in skeletal, diaphragm and cardiac muscle. The FDA has granted orphan drug, fast track and rare pediatric disease designations and the European Commission has granted orphan medicinal product designation to edasalonexent for the treatment of DMD. We have previously reported safety, tolerability and reduction in NF-kB activity in Phase 1 trials in adults. We are currently conducting the MoveDMD® trial of edasalonexent in 4-7 year-old boys affected by Duchenne. From Part A of the MoveDMD trial, we have reported that edasalonexent was generally well tolerated with no safety signals observed and successful NF-kB target engagement. Pharmacokinetic results demonstrated edasalonexent plasma exposure levels consistent with those previously observed in adults at which inhibition of NF-kB was observed.

About MoveDMD®

MoveDMD is a Phase 1 / 2 clinical trial of edasalonexent (CAT-1004) in boys ages 4-7 affected with DMD (any confirmed mutation). The MoveDMD trial is a three-part clinical trial investigating the safety and efficacy of edasalonexent in DMD. Part A of the MoveDMD trial evaluated the safety, tolerability and pharmacokinetics of, and NF-kB target engagement with, edasalonexent and showed positive results. The boys in Part A of the trial are asked to participate, if eligible, in Part B of the trial. Part B of the trial is a Phase 2 trial to evaluate the safety and efficacy of edasalonexent in DMD over a 12-week period and will enroll approximately 30 boys. The primary end point is changes in MRI of the leg muscles, and the secondary end points are age-appropriate timed function tests: 10-meter walk/run, 4-stair climb and time to stand. Additional assessments

include muscle strength, the North Star Ambulatory Assessment and the pediatric outcomes data collection tool (PODCI). Part C is an open-label extension that includes dosing with edasalonexent for 36 weeks beyond the 12-week placebo-controlled portion of the trial and will evaluate longer term safety and efficacy with the same clinical end points as Part B.

About MRI

Magnetic resonance imaging (MRI) is a non-invasive imaging technique that can assess muscle structure and composition and measure disease status in children with DMD. Two MRI measures used in Duchenne to indicate muscle degeneration are T2 and fat fraction. MRI is sensitive to changes in muscle structure and composition induced by disease processes such as the inflammation, edema, muscle damage and fat infiltration that occur in Duchenne. Changes in T2 may be seen in less than 12 weeks while changes in fat fraction may take longer. Changes in these MRI measures have been correlated with longer-term changes in clinically meaningful measures of functional activity. Changes in MRI can show the effects of an investigational therapy on disease progression in Duchenne in an objective and quantifiable manner.

About Catabasis

At Catabasis Pharmaceuticals, our mission is to bring hope and life-changing therapies to patients and their families. Our SMART (Safely Metabolized And Rationally Targeted) linker drug discovery platform enables us to engineer molecules that simultaneously modulate multiple targets in a disease. We are applying our SMART linker platform to build an internal pipeline of product candidates for rare diseases and plan to pursue partnerships to develop additional product candidates. For more information on the Company's drug discovery platform and pipeline of drug candidates, please visit www.catabasis.com.

Forward Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about future clinical trial plans and other statements containing the words “believes,” “anticipates,” “plans,” “expects,” “may” and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: uncertainties inherent in the initiation and completion of preclinical studies and clinical trials and clinical development of the Company’s product candidates; availability and timing of results from preclinical studies and clinical trials; whether interim results from a clinical trial will be predictive of the final results of the trial or the results of future trials; expectations for regulatory approvals to conduct trials or to market products; availability of funding sufficient for the Company’s foreseeable and unforeseeable operating expenses and capital expenditure requirements; other matters that could affect the availability or commercial potential of the Company’s product candidates; and general economic and market conditions and other factors discussed in the “Risk Factors” section of the Company’s Quarterly Report on Form 10-Q for the period ended March 31, 2016, which is on file with the Securities and Exchange Commission, and in other filings that the Company may make with the Securities and Exchange Commission in the future. In addition, the forward-looking statements

included in this press release represent the Company's views as of the date of this press release. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date of this release.

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