Catabasis Pharmaceuticals Announces Phase 3 PolarisDMD Trial Enrolled Expected Patient Population

-- Analysis Shows Patients Enrolled in Phase 2 MoveDMD and Phase 3 PolarisDMD Trials of Edasalonexent in Duchenne Muscular Dystrophy Have Similar Baseline Characteristics --

BOSTON, Mass., December 16, 2019 – Catabasis Pharmaceuticals, Inc. (NASDAQ:CATB), a clinical-stage biopharmaceutical company, today announced the results from an analysis of the baseline characteristics of the Phase 3 PolarisDMD trial of edasalonexent in Duchenne muscular dystrophy (DMD). The analysis shows that overall the patients enrolled in the Phase 3 trial have similar characteristics to the patients that enrolled in the previous Phase 2 MoveDMD trial. Top-line results from the Phase 3 PolarisDMD trial are expected in the fourth quarter of 2020 and the trial is anticipated to support an NDA filing in 2021.

Both the Phase 3 PolarisDMD trial and the Phase 2 MoveDMD trial enrolled boys affected by DMD ages 4 to 7 (up to 8th birthday) with any mutation type whom had not been on steroids for the previous 6 months. The Phase 3 trial enrolled 131 boys at 37 sites in the United States, Canada, Europe, Israel and Australia and 98% were steroid-naïve. The Phase 2 trial enrolled 31 boys in the United States, all of whom were steroid-naïve. A comparison was made between the populations at the baseline of each trial. Baseline age, North Star Ambulatory Assessment (NSAA) score and timed function test values (time to stand, 4-stair climb, and 10-meter walk/run) were similar in both trials; there were no significant differences in these baseline characteristics between the two trials. Distribution of baseline NSAA and timed function tests was less variable in the Phase 3 trial than in the Phase 2 trial. These findings support the assumptions on which the Phase 3 trial was powered. Boys in the Phase 3 trial had an elevated heart rate and elevated muscle enzyme levels at baseline, which was also consistent with the Phase 2 trial population.

Mean ± sd	**PolarisDMD (n=131)**	**MoveDMD (n=23)**
Age (years)	5.7 ± 1.0	6.0 ± 1.1
Percent enrolled patients that had not taken steroids	98%	100%
NSAA score	20.8 ± 4.7	20.1 ± 5.5
10-meter walk/run speed (1/s)	0.181 ± 0.037	0.168 ± 0.045
4-stair climb speed (1/s)	0.265 ± 0.097	0.254 ± 0.110
Time to stand speed (1/s)	0.212 ± 0.070	0.193 ± 0.080

“We are pleased to see that as expected, the patient population enrolled in our Phase 3 PolarisDMD trial is consistent with the patient population enrolled in the Phase 2 MoveDMD trial, which supports our design for the Phase 3 trial. The overwhelming positive interest from physicians and families and the rapid enrollment of the trial reinforces the strong demand for a well-tolerated treatment like edasalonexent with the potential to slow disease progression and preserve muscle function,” said Joanne Donovan, M.D., Ph.D., Chief Medical Officer of Catabasis. “We look forward to sharing results from the trial next year and are dedicated to bringing hope and life changing therapies to patients and their families.”

“The baseline age and functional abilities of the boys enrolled in the Phase 3 trial confirm that we have enrolled the expected patient population and also that this patient population is similar to published natural history studies of boys in this age range who are not on steroids,” said Richard Finkel, M.D., Chief, Division of Neurology, Department of Pediatrics at Nemours Children’s Health System and a Principal Investigator for the Phase 2 and Phase 3 trials with edasalonexent. “There is a clear need for a therapy that could benefit all patients affected by Duchenne, regardless of mutation type, by slowing disease progression while being well tolerated. I am pleased to be participating in this important Phase 3 trial of edasalonexent.”

In the earlier MoveDMD trial and open-label extension, edasalonexent preserved muscle function and substantially slowed disease progression compared to rates of change in the off-treatment control period, significantly improved biomarkers of muscle health and inflammation and was well-tolerated. In more than 60 cumulative patient years of exposure, the majority of adverse events were mild in nature, and the most common treatment-related adverse event was diarrhea, generally mild and transient. There were no serious adverse events observed on treatment, and no adverse trends in chemistry, hematology, or measures of adrenal function.

About Edasalonexent (CAT-1004)

Edasalonexent (CAT-1004) is an investigational oral small molecule designed to inhibit NF-kB that is being developed as a potential foundational therapy for all patients affected by DMD, regardless of their underlying mutation. In DMD the loss of dystrophin leads to chronic activation of NF-kB, which is a key driver of skeletal and cardiac muscle disease progression. Our ongoing global Phase 3 PolarisDMD trial is evaluating the efficacy and safety of edasalonexent for registration purposes. Edasalonexent is also being dosed in the open-label extension trial GalaxyDMD. In our MoveDMD Phase 2 trial and open-label extension, we observed that edasalonexent preserved muscle function and substantially slowed disease progression compared to rates of change in a control period, and significantly improved biomarkers of muscle health and inflammation. 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. For a summary of clinical results, please visit www.catabasis.com.

About Phase 3 PolarisDMD Trial

The global Phase 3 PolarisDMD trial is a one-year, randomized, double-blind, placebo-controlled trial evaluating the efficacy and safety of edasalonexent in patients with DMD. The trial enrolled

patients ages 4 to 7 (up to 8th birthday) regardless of mutation type who had not been on steroids for at least 6 months. Boys on a stable dose of eteplirsen were also eligible to enroll. The primary efficacy endpoint is change in the North Star Ambulatory Assessment score after 12 months of treatment with edasalonexent compared to placebo. Key secondary endpoints include the age-appropriate timed function tests: time to stand, 4-stair climb and 10-meter walk/run. Assessments of growth, cardiac and bone health are also included as important potential areas of differentiation. For each boy that receives placebo, two boys are receiving 100 mg/kg/day of edasalonexent and after 12 months, all boys are expected to receive edasalonexent in the open-label extension study GalaxyDMD. The PolarisDMD trial design was informed by discussions with regulators as well as input from treating physicians, patient organizations and families of boys affected by Duchenne. Top-line results from the Phase 3 PolarisDMD trial are expected in the fourth quarter of 2020. More information about the Phase 3 PolarisDMD clinical trial is available on clinicaltrials.gov.

About Catabasis

At Catabasis Pharmaceuticals, our mission is to bring hope and life-changing therapies to patients and their families. Our lead program is edasalonexent, an NF-kB inhibitor in Phase 3 development for the treatment of Duchenne muscular dystrophy. For more information on edasalonexent and our Phase 3 PolarisDMD trial, 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 including, among other things, statements about the Company's global Phase 3 PolarisDMD trial in DMD to evaluate the efficacy and safety of edasalonexent for registration purposes and the open-label extension trial GalaxyDMD, including the anticipated timing for top-line results, the potential timing for the filing of an NDA, the Company's cash expectations, the Company's planned transition to a commercial-stage organization 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; 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 Annual Report on Form 10-Q for the year ended September 30, 2019, 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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