Catabasis Pharmaceuticals Announces the Phase 3 PolarisDMD Trial of Edasalonexent in Duchenne Muscular Dystrophy has Exceeded Target Enrollment

-- Top-line Results Expected Fourth Quarter of 2020 --

CAMBRIDGE, MA, September 30, 2019 – Catabasis Pharmaceuticals, Inc. (NASDAQ:CATB), a clinical-stage biopharmaceutical company, announced today the completion of enrollment for the Phase 3 PolarisDMD trial of edasalonexent in Duchenne muscular dystrophy (DMD). The target enrollment of 125 boys was exceeded due to strong interest from our 40 clinical sites in 8 countries and the support of patient advocacy organizations. 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.

"We are thrilled to reach this important milestone. The interest and feedback from families and trial sites has been overwhelmingly positive. At a time when there are multiple trials for Duchenne, we are very pleased that physicians and families chose the Phase 3 PolarisDMD trial for edasalonexent," said Joanne Donovan, M.D., Ph.D., Chief Medical Officer of Catabasis. "Edasalonexent has the potential to be a foundational therapy, providing benefit to boys, regardless of their underlying mutation, with the potential to benefit muscle function, as well as cardiac function and bone health. We look forward to completing the trial next year and are working diligently toward the goal of making edasalonexent available to patients."

The PolarisDMD trial enrolled 130 boys ages 4 to 7 (up to 8th birthday) with any mutation type and who had not been on steroids for the past 6 months. The trial is a randomized, double-blind, placebo-controlled trial with 2 to 1 randomization such that two boys receive edasalonexent for each boy that receives placebo. At the completion of 52 weeks, all boys and their eligible siblings are expected to have the option to enroll in GalaxyDMD, an open-label extension study designed to assess the long-term safety of edasalonexent. Boys can begin or continue treatment with an approved exon skipping therapy in the GalaxyDMD trial, which has a streamlined schedule with visits to trial sites every six months.

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 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, including the anticipated timing for top-line results, potential timing for the filing of an NDA, 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 preclinical or 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 quarterly period ended June 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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