Catabasis Pharmaceuticals Announces Top-Line Results for the Phase 3 PolarisDMD Trial of Edasalonexent in Duchenne Muscular Dystrophy

October 26, 2020

-- PolarisDMD Trial Did Not Achieve Primary or Secondary Endpoints --

BOSTON--(BUSINESS WIRE)--Oct. 26, 2020-- Catabasis Pharmaceuticals, Inc. (NASDAQ:CATB), a clinical-stage biopharmaceutical company, today announced that the Phase 3 PolarisDMD trial of edasalonexent in Duchenne muscular dystrophy (DMD) did not meet the primary endpoint, which was a change from baseline in the North Star Ambulatory Assessment (NSAA) over one year of edasalonexent compared to placebo. The secondary endpoint timed function tests (time to stand, 10-meter walk/run and 4-stair climb) also did not show statistically significant improvements. Edasalonexent was observed to be generally safe and well-tolerated in this trial. Catabasis is stopping activities related to the development of edasalonexent including the ongoing GalaxyDMD open-label extension trial. The Company plans to work with external advisors to explore and evaluate strategic options going forward.

“We are deeply saddened and disappointed by the results of our Phase 3 PolarisDMD trial,” said Jill C. Milne, Ph.D., Chief Executive Officer of Catabasis. “I want to sincerely thank all of the boys, their families and caregivers, investigators and the trial sites that participated in and enabled this program. The entire Catabasis team has worked tirelessly to find a treatment for this progressive disease. We hope that our data and work to date can be used to benefit ongoing and future research in DMD.”

The Phase 3 trial was a one-year placebo-controlled trial designed to evaluate the safety and efficacy of edasalonexent in boys ages 4-7 (up to 8th birthday) with DMD. The global trial enrolled 131 boys across eight countries, with any mutation type, who were not on steroids. Edasalonexent was well-tolerated, consistent with the safety profile seen to date. The majority of adverse events were mild in nature and the most common treatment-related adverse events were diarrhea, vomiting, abdominal pain and rash. There were no treatment-related serious adverse events and no dose reductions. The global COVID-19 pandemic had no meaningful impact on the trial or its results. Data from the PolarisDMD trial will be further analyzed and are expected to be presented at an upcoming scientific conference and published.

“These results are disheartening for the Duchenne community, and specifically for the boys who participated in this trial and their families. However, the results contribute to the natural history data of Duchenne and add to the knowledge base that will one day produce a foundational, long-term therapy for this disease,” said Pat Furlong, Founding President and Chief Executive Officer of Parent Project Muscular Dystrophy (PPMD). “The continued advancement of research and the development of possible treatment options will remain of critical importance to our community. We appreciate Catabasis’ efforts and commitment to every family that is or has ever been affected by Duchenne.”

The Company expects to report Q3 2020 financials in November of 2020. As of September 30, 2020, Catabasis had cash and cash equivalents of approximately $52.9 million.

About Catabasis

Catabasis Pharmaceuticals is a clinical-stage biopharmaceutical company. Our mission is to bring hope and life-changing therapies to patients and their families.

Forward Looking Statements

Any statements in this press release about future expectations, plans and prospects for the Company, including statements about its exploration and evaluation of strategic options, the termination of activities related to the edasalonexent program, including the ongoing GalaxyDMD open-label extension trial, and plans to publish data from the Phase 3 PolarisDMD trial, and other statements containing the words “believes,” “anticipates,” “plans,” “hopes,” “expects,” and similar expressions, constitute forward-looking statements within the meaning of applicable securities laws and regulations. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including risks and uncertainties related to: the impact of the COVID-19 pandemic and the effectiveness of the steps we have implemented to address the pandemic; the availability of funding sufficient for the Company’s foreseeable and unforeseeable operating expenses and capital expenditure requirements; unexpected costs or expenses that arise during the termination of activities related to the edasalonexent program; risks inherent in the Company’s exploration, evaluation and implementation of its review of strategic options; and general market and economic conditions; and other factors discussed in the “Risk Factors” section of the Company’s Quarterly Report on Form 10-Q for the period ended June 30, 2020, 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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