# Catabasis Pharmaceuticals Reports First Quarter 2020 Financial Results and Reviews Business Progress

*-- Top-Line Results Expected in Q4 2020 from Fully Enrolled Edasalonexent Global Phase 3 PolarisDMD Trial in Duchenne Muscular Dystrophy --*

**BOSTON, Mass., May 12, 2020 –** Catabasis Pharmaceuticals, Inc. (NASDAQ:CATB), a clinical-stage biopharmaceutical company, today reported financial results for the first quarter ended March 31, 2020 and reviewed recent business progress.

"Our fully enrolled Phase 3 PolarisDMD trial for edasalonexent in Duchenne is progressing well and we are continuing to prepare for top-line Phase 3 results in the fourth quarter of this year and a subsequent NDA filing in 2021. We have initial commercialization and supply chain preparations underway and recently strengthened our financial position," said Jill C. Milne, Ph.D., Chief Executive Officer of Catabasis. "In the current environment, our priorities are focused on the safety of patients as well as maintaining study integrity. Advantages of our Phase 3 trial include that enrollment was completed last year, clinical trial site visits are only every three months, and that patients take the oral study drug at home. Together with our clinical trial sites and consistent with recent regulatory guidance, we have developed contingency plans that we are implementing as needed to enable the continued conduct of the Phase 3 trial as well as the open-label extension GalaxyDMD trial."

**Recent and Upcoming Corporate Highlights**

- The fully enrolled Phase 3 PolarisDMD trial of edasalonexent in Duchenne muscular dystrophy (DMD) is progressing with top-line results expected in Q4 2020.
    - Patient enrollment was completed in 2019 with 131 boys enrolled across 8 countries.
    - The Phase 3 PolarisDMD trial is intended to support a new drug application (NDA) for commercial registration of edasalonexent in 2021.
    - Contingency plans are in place to enable the continued conduct of our Phase 3 PolarisDMD and GalaxyDMD clinical trials. These plans include the delivery of study drug to patients' homes, increased flexibility in the timing of patient visits, and use of telehealth for remote visits to monitor safety and assess patients where in-person visits are not available.
- The open-label extension GalaxyDMD trial continues to enroll boys who have completed treatment in the Phase 3 PolarisDMD trial. Their eligible siblings up to age 12 have the option to enroll as well.
- Catabasis closed a $26.5 million underwritten public offering in February 2020. The proceeds will be used for clinical trial and other research and development activities; initial commercialization preparations; and for working capital and other general corporate

purposes. Based on the Company's current operating plan, Catabasis expects that it has sufficient cash to fund operations through a potential NDA filing and into Q3 2021.

- Catabasis plans to commercialize edasalonexent in the US and we are evaluating our commercialization strategy outside of the US. We are encouraged by the favorable feedback we have received from healthcare providers and payors on the potential profile for edasalonexent and the meaningful role it could play as a foundational therapy for all patients with DMD, regardless of mutation.
- Clinical findings supporting edasalonexent treatment in young boys being associated with age-normative growth and normal adrenal function from the Phase 2 MoveDMD trial and open-label extension were presented at the Muscular Dystrophy Association Virtual Clinical Trials Session by Dr. Erika Finanger, M.D., Division of Neurology at Oregon Health and Science University and a Principal Investigator for the Phase 2 MoveDMD, Phase 3 PolarisDMD, and open-label extension GalaxyDMD trials of edasalonexent in DMD.
- Catabasis and Duchenne UK entered into a partnership to evaluate edasalonexent in a Phase 2 trial in non-ambulatory DMD patients. Duchenne UK granted Catabasis over $600,000 in funding to support patient and clinical trial site costs. This planned Phase 2 trial is designed to assess safety and pharmacokinetics of edasalonexent and exploratory measures of function including cardiac, skeletal muscle and pulmonary function in non-ambulatory DMD patients.

**First Quarter 2020 Financial Results**

**Cash Position:** As of March 31, 2020, Catabasis had cash, cash equivalents and short-term investments of $55.1 million, compared to $36.2 million as of December 31, 2019. Based on the Company's current operating plan, Catabasis expects that it has sufficient cash to fund operations through a potential NDA filing and into Q3 2021. Net cash used in operating activities for the three months ended March 31, 2020 was $7.0 million, compared to $6.6 million for the three months ended March 31, 2019.

**R&D Expenses:** Research and development expenses were $5.3 million for the three months ended March 31, 2020, compared to $4.2 million for the three months ended March 31, 2019.

**G&A Expenses:** General and administrative expenses were $2.8 million for the three months ended March 31, 2020, compared to $2.1 million for the three months ended March 31, 2019.

**Operating Loss:** Loss from operations was $8.0 million for the three months ended March 31, 2020, compared to $6.3 million for the three months ended March 31, 2019.

**Net Loss:** Net loss was $8.0 million, or $0.50 per share, for the three months ended March 31, 2020, compared to a net loss of $6.0 million, or $0.62 per share, for the three months ended March 31, 2019.

**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 evaluated in the GalaxyDMD open-label extension trial. 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 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 the potential impact of the COVID-19 pandemic on the Company's business and operations, statements about future clinical trial plans including, among other things, statements about the potential commencement of the Company's planned Phase 2 trial in non-ambulatory patients, 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, 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: risks and uncertainties related to the impact of the COVID-19 pandemic, 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 Quarterly Report on Form 10-Q for the period ended March 31, 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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## Catabasis Pharmaceuticals, Inc.
## Consolidated Statements of Operations
(In thousands, except share and per share data)
*(Unaudited)*

| | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| Operating expenses: | | |
| Research and development | 5,289 | 4,197 |
| General and administrative | 2,753 | 2,137 |
| Total operating expenses | 8,042 | 6,334 |
| Loss from operations | (8,042) | (6,334) |
| Other income (expense): | | |
| Interest and investment income | 167 | 226 |
| Other (expense) income, net | (77) | 70 |
| Total other income, net | 90 | 296 |
| Net loss | $ (7,952) | $ (6,038) |
| Net loss per share - basic and diluted | $ (0.50) | $ (0.62) |
| Weighted-average common shares outstanding used in net loss per share - basic and diluted | 15,898,664 | 9,686,224 |

## Catabasis Pharmaceuticals, Inc.
## Selected Consolidated Balance Sheets Data
(In thousands)
*(Unaudited)*

| | March 31, 2020 | December 31, 2019 |
|---|---|---|
| **Assets** | | |
| Cash and cash equivalents | $ 13,344 | $ 9,899 |
| Short-term investments | 41,759 | 26,345 |
| Right-of-use asset | 1,799 | 2,349 |
| Other current and long-term assets | 2,274 | 3,187 |
| Total assets | 59,176 | 41,780 |
| **Liabilities and stockholders' equity** | | |
| Current portion of operating lease liabilities | 879 | 1,225 |
| Long-term portion of operating lease liabilities | 875 | 1,028 |
| Other current and long-term liabilities | 3,711 | 3,807 |
| Total liabilities | 5,465 | 6,060 |
| Total stockholders' equity | $ 59,176 | $ 41,780 |

**Catabasis Pharmaceuticals, Inc.**
**Selected Consolidated Statements of Cash Flows Data**
(In thousands)
*(Unaudited)*

| | Three Months Ended March 31, | |
|---|---|---|
| | **2020** | **2019** |
| Net cash used in operating activities | $ (6,989) | $ (6,587) |
| Net cash used in investing activities | (15,432) | (17,738) |
| Net cash provided by financing activities | 25,624 | 20,683 |
| Net increase (decrease) in cash, cash equivalents and restricted cash | $ 3,203 | $ (3,642) |