Catabasis Pharmaceuticals Reports Fourth Quarter and Full Year 2019 Financial Results and Reviews Business Progress

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

-- Conference Call and Webcast Today at 8:30am ET --

BOSTON, Mass., March 10, 2020 – Catabasis Pharmaceuticals, Inc. (NASDAQ:CATB), a clinical-stage biopharmaceutical company, today reported financial results for the fourth quarter and full year ended December 31, 2019 and reviewed recent business progress.

"We made excellent progress with our edasalonexent program in 2019 and are in a great place coming into 2020 with the Phase 3 PolarisDMD trial in Duchenne fully enrolled. We also strengthened our financial position. We are preparing for top-line Phase 3 results in the fourth quarter and a subsequent NDA filing in 2021 and have initial commercialization and supply chain preparations underway," said Jill C. Milne, Ph.D., Chief Executive Officer of Catabasis. "We are also building for the future with our partnership with Duchenne UK to explore edasalonexent in non-ambulatory Duchenne patients and our ongoing preclinical research to explore the potential for broad benefits of edasalonexent in Duchenne and also in additional neuromuscular diseases."

Recent and Upcoming Corporate Highlights

- Phase 3 PolarisDMD trial of edasalonexent in Duchenne muscular dystrophy (DMD) on track to report top-line results in Q4 2020.
    - Patient enrollment is complete and has exceeded the enrollment target with 131 boys enrolled. Patients are enrolled across all 8 countries where the trial is active.
    - The Phase 3 trial is intended to support a new drug application (NDA) for commercial registration of edasalonexent in 2021.
- An analysis of the baseline characteristics of the patients enrolled in the Phase 3 PolarisDMD trial was performed compared to the patients enrolled in the previous Phase 2 MoveDMD trial and found overall similar characteristics in the patient populations in the two trials.
    - 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 who had not been on steroids for the previous 6 months.
    - 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 the Phase 3 and Phase 2 trials and there were no significant differences in these baseline characteristics between the two trials.

    - These findings are believed to support the assumptions on which the Phase 3 trial was powered.
- 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 exploratory Phase 2 trial is planned to assess safety, pharmacokinetics and exploratory measures of function including cardiac, skeletal muscle and pulmonary function in non-ambulatory DMD patients.
- 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.

Fourth Quarter and Full Year 2019 Financial Results

Cash Position: As of December 31, 2019, Catabasis had cash, cash equivalents and short-term investments of $36.2 million, compared to $40.6 million as of September 30, 2019. Following December 31, 2019, Catabasis raised an additional $27.6 million from equity financings for $25.6 million in net proceeds. 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 December 31, 2019 was $7.8 million, compared to $5.3 million for the three months ended December 31, 2018. Net cash used in operating activities for the full year 2019 was $26.6 million, compared to $23.5 million for the full year 2018.

R&D Expenses: Research and development expenses were $4.3 million for the three months ended December 31, 2019, compared to $3.7 million for the three months ended December 31, 2018 and $18.3 million for the full year 2019, compared to $17.0 million for the full year 2018.

G&A Expenses: General and administrative expenses were $2.5 million for the three months ended December 31, 2019, compared to $2.4 million for the three months ended December 31, 2018 and $8.8 million for the full year 2019, compared to $9.3 million for the full year 2018.

Operating Loss: Loss from operations was $6.7 million for the three months ended December 31, 2019, compared to $6.1 million for the three months ended December 31, 2018 and $27.1 million for the full year 2019, compared to $26.4 million for the full year 2018.

Net Loss: Net loss was $6.6 million, or $0.55 per share, for the three months ended December 31, 2019, compared to a net loss of $6.1 million, or $0.85 per share, for the three months ended December 31, 2018 and $26.3 million for the full year 2019, compared to $25.9 million for the full year 2018.

Conference Call and Webcast

Catabasis will host a conference call and webcast at 8:30am ET today to provide an update on corporate developments and to discuss fourth quarter and full year 2019 financial results.

Participant Toll-Free Dial-In Number:	(877) 388-2733
Participant International Dial-In Number:	(541) 797-2984
Pass Code:	3621269

Please specify to the operator that you would like to join the “Catabasis Fourth Quarter and Full Year 2019 Results Call.”

Interested parties may access a live audio webcast of the conference call via the investor section of the Catabasis website, www.catabasis.com. Please connect to the Catabasis website several minutes prior to the start of the broadcast to ensure adequate time for any software download that may be necessary. The webcast will be archived for 90 days.

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 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 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: 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-K for the year ended December 31, 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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Catabasis Pharmaceuticals, Inc.
Consolidated Statements of Operations
(In thousands, except share and per share data)
(Audited)

	Year Ended December 31,	
	2019	**2018**
Operating expenses:		
Research and development	18,317	17,042
General and administrative	8,771	9,329
Total operating expenses	27,088	26,371
Loss from operations	(27,088)	(26,371)
Other income (expense):		
Interest expense	-	(100)
Interest and investment income	845	425
Other (expense) income, net	(50)	176
Total other income, net	795	501
Net loss	$ (26,293)	$ (25,870)
Net loss per share - basic and diluted	$ (2.35)	$ (5.12)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	11,199,057	5,054,823

Catabasis Pharmaceuticals, Inc.
Selected Consolidated Balance Sheets Data
(In thousands)
(Audited)

	December 31, 2019	December 31, 2018
Assets		
Cash and cash equivalents	$ 9,899	$ 15,294
Short-term investments	26,345	22,276
Right-of-use asset	2,349	-
Other current and long-term assets	3,187	1,599
Total assets	41,780	39,169
Liabilities and stockholders' equity		
Current portion of operating lease liabilities	1,225	-
Long-term portion of operating lease liabilities	1,028	-
Other current and long-term liabilities	3,807	4,227
Total liabilities	6,060	4,227
Total stockholders' equity	$ 35,720	$ 34,942

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

	Year Ended December 31,	
	2019	**2018**
Net cash used in operating activities	$ (26,569)	$ (23,465)
Net cash used in investing activities	(4,082)	(21,905)
Net cash provided by financing activities	25,620	44,295
Net decrease in cash, cash equivalents and restricted cash	$ (5,031)	$ (1,075)