



Catabasis Pharmaceuticals Reports First Quarter 2019 Financial Results and Reviews Business Progress

-- Edasalonexent Phase 3 PolarisDMD Trial in Duchenne Muscular Dystrophy Enrolling Boys Globally --

-- Sustained Slowing of DMD Disease Progression with Edasalonexent Reinforced by Long Term MoveDMD MRI Data --

CAMBRIDGE, Mass., May 14, 2019 – [Catabasis Pharmaceuticals, Inc.](#) (NASDAQ:CATB), a clinical-stage biopharmaceutical company, today reported financial results for the first quarter ended March 31, 2019, and reviewed recent business progress.

“We are making strong progress with enrollment in our Phase 3 PolarisDMD trial for edasalonexent, and the trial is now enrolling patients in seven countries. There has been significant interest from families and enthusiasm from investigators globally, and we believe that approximately 90% of the patients have been identified. We anticipate all patients will be identified in the coming weeks and expect all participating sites to be open for enrollment within a month, which will further support scheduling the remaining families. Based on our current projections, we expect to have top-line results from the study in the second half of 2020, which are anticipated to support an NDA filing in early 2021,” said Jill C. Milne, Ph.D., Chief Executive Officer of Catabasis. “In addition, we continue to be encouraged by the long-term MoveDMD muscle function, biomarker and growth data that reinforce edasalonexent’s potential as a therapy for all affected by Duchenne, regardless of mutation type.”

Recent and Upcoming Corporate Highlights

- The Phase 3 PolarisDMD clinical trial evaluating edasalonexent in boys affected by Duchenne muscular dystrophy (DMD) is enrolling patients at clinical trial sites in seven countries.
 - All patients are expected to be identified in the coming weeks and all participating clinical trial sites are expected to be open for enrollment within a month.
 - Top-line results from the Phase 3 PolarisDMD trial are expected in the second half of 2020, and the trial is intended to support an application for commercial registration of edasalonexent in early 2021.
- The GalaxyDMD trial has been initiated and is enrolling boys from the MoveDMD open-label extension and their eligible siblings. Boys who complete the PolarisDMD trial as well as their eligible siblings will also have the opportunity to participate in the GalaxyDMD open-label extension trial.

- Sustained slowing of DMD disease progression with edasalonexent treatment was reinforced by recent MoveDMD trial open-label extension data.
 - Improvements in lower leg composite MRI T2 were observed through 72 weeks of edasalonexent treatment compared to the off-treatment control period in the Phase 2 MoveDMD trial and open-label extension. These data were presented last week at the 2019 American Academy of Neurology Annual Meeting in Philadelphia, PA. The lower leg composite MRI T2 is highly correlated with functional abilities in boys with DMD in the ImagingDMD natural history database.
 - The improvements in MRI T2 are consistent with the slowing of disease progression and preserved muscle function observed in all assessments of muscle function (the North Star Ambulatory Assessment, 4-stair climb, time to stand and 10-meter walk/run) through 72 weeks of edasalonexent treatment compared to the off-treatment control period.
 - Encouraging growth data from the MoveDMD trial also showed that boys treated with edasalonexent grew age-appropriately in both height and weight, resulting in decreased BMI that approached the average BMI for boys not affected by DMD.

First Quarter 2019 Financial Results

Cash Position: As of March 31, 2019, Catabasis had cash, cash equivalents and short-term investments of \$51.7 million, compared to \$37.6 million as of December 31, 2018. Based on the Company's current operating plan, Catabasis expects that it has sufficient cash to fund operations through top-line Phase 3 results and into the fourth quarter of 2020. Net cash used in operating activities for the three months ended March 31, 2019 was \$6.6 million, compared to \$6.8 million for the three months ended March 31, 2018.

R&D Expenses: Research and development expenses were \$4.2 million for the three months ended March 31, 2019, compared to \$5.2 million for the three months ended March 31, 2018.

G&A Expenses: General and administrative expenses were \$2.1 million for the three months ended March 31, 2019, compared to \$2.4 million for the three months ended March 31, 2018.

Operating Loss: Loss from operations was \$6.3 million for the three months ended March 31, 2019, compared to \$7.6 million for the three months ended March 31, 2018.

Net Loss: Net loss was \$6.0 million, or \$0.62 per share, for the three months ended March 31, 2019, compared to a net loss of \$7.7 million, or \$2.88 per share, for the three months ended March 31, 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 first quarter 2019 financial results.

Participant Toll-Free Dial-In Number: (877) 388-2733

Participant International Dial-In Number: (541) 797-2984
Pass Code: 3195905

Please specify to the operator that you would like to join the “Catabasis First Quarter 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 that is being developed as a potential therapy for all patients affected by DMD, regardless of their underlying mutation. Edasalonexent inhibits NF-kB, which is a key link between loss of dystrophin and disease progression in DMD. NF-kB has a fundamental role in skeletal and cardiac muscle disease in DMD. We are currently enrolling our global Phase 3 PolarisDMD trial to evaluate 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 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 development for the treatment of Duchenne muscular dystrophy. Our global Phase 3 PolarisDMD trial is currently enrolling boys affected by Duchenne. 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, including the anticipated timing for completion of enrollment and 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 March 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)
(Unaudited)

	Three Months Ended March 31,	
	2019	2018
Operating expenses:		
Research and development	4,197	5,247
General and administrative	2,137	2,392
Total operating expenses	6,334	7,639
Loss from operations	(6,334)	(7,639)
Other income (expense):		
Interest expense	-	(57)
Interest and investment income	226	32
Other income, net	70	12
Total other income (expense), net	296	(13)
Net loss	\$ (6,038)	\$ (7,652)
Net loss per share - basic and diluted	\$ (0.62)	\$ (2.88)
Weighted-average common shares outstanding used in net	9,686,224	2,655,584

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

	March 31,	December 31,
	2019	2018
Assets		
Cash and cash equivalents	\$ 11,652	\$ 15,294
Short-term investments	40,012	22,276
Right-of-use asset	1,577	-
Other current and long-term assets	1,256	1,599
Total assets	54,497	39,169
Liabilities and stockholders' equity		
Current portion of operating lease liabilities	1,259	-
Long-term portion of operating lease liabilities	330	-
Other current and long-term liabilities	3,039	4,227
Total liabilities	4,628	4,227
Total stockholders' equity	\$ 49,869	\$ 34,942

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

	Three Months Ended March 31,	
	2019	2018
Net cash used in operating activities	\$ (6,587)	\$ (6,819)
Net cash used in investing activities	(17,738)	-
Net cash provided by financing activities	20,683	7,480
Net (decrease) increase in cash, cash equivalents and restricted cash	\$ (3,642)	\$ 661