Eidos Therapeutics Reports First Quarter 2019 Financial Results

May 7, 2019

SAN FRANCISCO, May 07, 2019 (GLOBE NEWSWIRE) -- Eidos Therapeutics, Inc. (Eidos) (Nasdaq:EIDX), today reported its financial results for the first quarter ended March 31, 2019 and provided an update on the company's recent achievements.

"The initiation of our Phase 3 ATTRibute-CM study in the first quarter of 2019 marks another key milestone in our focused effort to make AG10 available for the significant unmet need in transthyretin (TTR) amyloidosis (ATTR)," said Neil Kumar PhD, chief executive officer of Eidos. "In our prior clinical studies, AG10 demonstrated near-complete stabilization of TTR and significantly increased serum TTR, a biomarker associated with survival in ATTR-CM patients. Based on these data, we believe AG10 may demonstrate a meaningful benefit in this patient population."

Recent Achievements and Upcoming Milestones

- Initiated Phase 3 study of AG10 in ATTR-CM (ATTRibute-CM)
- Published Phase 2 data of AG10 in ATTR-CM in the Journal of the American College of Cardiology (JACC)
- Presented sub-group analysis of Phase 2 data in ATTR-CM at American College of Cardiology (ACC) Scientific Sessions
- Plan to initiate Phase 3 study of AG10 in ATTR-PN (ATTRibute-PN) in the second half of 2019
- Plan to present data from the open label extension of the Phase 2 study of AG10 in ATTR-CM in the fourth quarter of 2019

First Quarter Financial and Operating Results

Cash and cash equivalents totaled $147.1 million at March 31, 2019 compared with $157.1 million at December 31, 2018.

Eidos reported a net loss attributable to common stockholders of $11.7 million or $0.32 per common share, for the first quarter of 2019, as compared to a net loss attributable to common stockholders of $8.0 million or $1.81 per common share for the first quarter of 2018. The increase in net loss attributable to common stockholders was driven primarily by research and development expenses related to AG10 clinical trials and other pre-clinical studies, and general and administrative expenses for operations.

Research and development expenses for the first quarter of 2019 were $8.5 million, as compared to $5.7 million for the same period in the prior year. Research and development expenses for the first quarter included costs related to contract manufacturing, the preparation for and conduct of AG10 clinical trials.

General and administrative expenses for the first quarter of 2019 were $4.0 million, as compared to $2.3 million for the same period in the prior year. The increase in general and administrative expense in these periods was due primarily to an increase in professional service fees, salaries and employee-related expense primarily due to an increase in headcount to support the growth of our operations, and other administrative expenses.

About AG10

AG10 is an investigational, orally-administered small molecule designed to potently stabilize tetrameric transthyretin, or TTR, thereby halting at its outset the series of molecular events that give rise to amyloidosis, or ATTR. In a Phase 2 clinical trial in subjects with symptomatic ATTR-CM, AG10 was generally well tolerated, demonstrated >90% average TTR stabilization at day 28, and increased serum TTR concentrations, a prognostic indicator of survival in a retrospective study of ATTR-CM patients, in a dose-dependent manner. AG10 is currently being studied in an open-label extension of a Phase 2 clinical trial in patients with ATTR-CM, and patient enrollment has begun for a Phase 3 clinical trial of AG10 in patients with ATTR-CM (ATTRibute-CM).

AG10 was designed to mimic a naturally-occurring variant of the TTR gene (T119M) that is considered a rescue mutation because co-inheritance has been shown to prevent ATTR in individuals also inheriting a pathogenic, or disease-causing, mutation in the TTR gene. To our knowledge, AG10 is the only TTR stabilizer in development that has been observed to mimic the stabilizing structure of this rescue mutation.

About transthyretin amyloidosis (ATTR)

ATTR represents a significant unmet medical need with a large patient population and an inadequate current standard of care. ATTR is caused by the destabilization of TTR due to inherited mutations or aging and is commonly divided into three distinct categories: wild-type ATTR cardiomyopathy (ATTRwt-CM), mutant ATTR cardiomyopathy (ATTRm-CM), and ATTR polyneuropathy (ATTR-PN). The worldwide prevalence of each disease is approximately 400,000 patients, 40,000 patients and 10,000 patients, respectively.

All three forms of ATTR are progressive and fatal. For patients with ATTRwt-CM and ATTRm-CM, symptoms usually manifest later in life (age 50+), with median survival of three to five years from diagnosis. ATTR-PN either presents in a patient's early 30s or later (age 50+), and results in a median life expectancy of five to ten years from diagnosis. Progression of all forms of ATTR causes significant morbidity, impacts productivity and quality of life, and creates a significant economic burden due to the costs associated with progressively greater patient needs for supportive care.

About Eidos Therapeutics

Eidos Therapeutics is a clinical stage biopharmaceutical company focused on addressing the large and growing unmet need in diseases caused by transthyretin (TTR) amyloidosis (ATTR). Eidos is developing AG10, a potentially disease-modifying therapy for the treatment of ATTR. For more information, please visit www.eidostx.com.

Forward-Looking Statements

This release includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act. All statements other than statements of historical facts, including the statements about the potential therapeutic and clinical benefits of AG10, the potential to accelerate the development and registration of AG10, the design of the ATTRibute-CM trial, our ability to enroll patients in and conduct the ATTRibute-CM trial in accordance with our plans, future clinical and regulatory milestones of AG10, the timing of these events, the indications we intend to pursue and our possible clinical or other business strategies, and our ability to fund our clinical development plans, are forward-looking statements. Forward-looking statements can be identified by terms such as "believes," "expects," "plans," "potential," "would" or similar expressions and the negative of those terms. These forward-looking statements are based on our management's current beliefs and assumptions about future events and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks include, but are not limited to, risks and uncertainties related to: our limited operating history and historical losses, our liquidity to fund the development of AG10 through current and future milestones, our ability to raise additional funding to complete the development of AG10, our dependence on the success of AG10, our ability to enroll patients in the ATTRibute-CM trial, results from our clinical trials and pre-clinical studies and those of third parties working in the same area as our product candidate, our ability to advance AG10 in clinical development in accordance with our plans, and our dependence on third parties in connection with our manufacturing, clinical trials and pre-clinical studies. Additional risks and uncertainties that could affect our future results are included in the section titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2019, to be filed with the Securities and Exchange Commission concurrently herewith. Additional information on potential risks will be made available in other filings that we make from time to time with the SEC. In addition, any forward-looking statements contained in this press release are based on assumptions that we believe to be reasonable as of this date. Except as required by law, we assume no obligation to update these forward-looking statements, or to update the reasons if actual results differ materially from those anticipated in the forward-looking statements.

EIDOS THERAPEUTICS, INC.
Condensed Statements of Operations
(Unaudited)
(In thousands, except share and per share data)

	Three months ended March 31,	
	2019	**2018**
Operating expenses*:		
Research and development	$ 8,549	$ 5,652
General and administrative	4,035	2,345
Total operating expenses	12,584	7,997
Loss from operations	(12,584)	(7,997)
Other income (expense), net	851	(879)
Net and comprehensive loss	(11,733)	(8,876)
Deemed dividend related to redemption feature embedded in Convertible Promissory Notes payable to stockholders	-	(6,523)
Gain on extinguishment of Convertible Promissory Notes payable to stockholders	-	7,436
Net loss attributable to common stockholders	$ (11,733)	$ (7,963)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.32)	$ (1.81)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	36,175,523	4,392,435
*** Includes stock-based compensation as follows**		
Research and development	$ 452	$ 178
General and administrative	512	210
Total stock-based compensation expense	$ 964	$ 388

EIDOS THERAPEUTICS, INC.
Condensed Balance Sheets
(Unaudited)
(In thousands)

	March 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 147,064	$ 157,147
Related party receivable	72	34
Prepaid expenses and other current assets	2,160	1,789
Total current assets	149,296	158,970
Property and equipment, net	196	209
Operating lease, right of use asset	1,053	-
Other assets	2,652	933
Total assets	$ 153,197	$ 160,112
Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,212	$ 1,956
Related party payable	407	256
Lease liabilities	269	-
Accrued expenses and other current liabilities	3,953	2,577
Total current liabilities	7,841	4,789
Other liabilities	201	316
Lease liabilities, non-current	854	-
Total liabilities	8,896	5,105
Stockholders' equity:		
Preferred stock	-	-
Common stock	37	37
Additional paid-in capital	221,267	220,240
Accumulated deficit	(77,003)	(65,270)
Total stockholders' equity	144,301	155,007
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 153,197	$ 160,112

Media Contact:

Carolyn Hawley, Canale Communications, (619) 849-5382, carolyn@canalecomm.com

For Investors

Alex Gray, Burns McClellan, (212) 213-0006, agray@burnsmc.com

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