Eidos Therapeutics Reports Fourth Quarter and Year-End 2019 Financial Results and Business Update

February 26, 2020

SAN FRANCISCO, Feb. 26, 2020 (GLOBE NEWSWIRE) -- Eidos Therapeutics, Inc. (Eidos) (Nasdaq:EIDX), today reported its financial results for the fourth quarter and full year ended December 31, 2019 and provided an update on the company's recent achievements.

"2019 marked another year of significant scientific, clinical, and corporate progress at Eidos. We presented positive data from the ongoing phase 2 open label extension study suggesting long-term tolerability of AG10 and stabilization of transthyretin amyloid cardiomyopathy disease measures," said Neil Kumar PhD, chief executive officer of Eidos. "We believe the data support the hypothesis that increasing stabilization may lead to improved outcomes for ATTR patients."

2019 Highlights

- Presented interim analysis of the ongoing Phase 2 open label extension study of AG10 in patients with TTR amyloid cardiomyopathy at the AHA 2019 Scientific Sessions in a Late-Breaking Featured Science Oral Presentation. Rates of mortality and cardiovascular hospitalization observed in exploratory analysis were lower than rates observed in placebo-treated participants in the ATTR-ACT study. Serum TTR levels, a prognostic indicator of survival, were elevated and maintained in the normal range throughout the study duration.
- Initiated and continued enrollment of 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.
- Published Phase 1 data of AG10 in healthy volunteers in Clinical Pharmacology in Drug Development.
- Granted Alexion Pharmaceuticals, Inc. an exclusive license to develop and commercialize AG10 in Japan for an upfront payment of $25.0 million and an equity investment of $25.0 million.
- Appointed Uma Sinha, Chief Scientific Officer, to the Board of Directors.
- Plan to initiate Phase 3 study of AG10 in ATTR-PN (ATTRibute-PN) in the first half of 2020.

Fourth Quarter and Full-Year 2019 Financial and Operating Results

Cash and cash equivalents totaled $191.2 million at December 31, 2019 compared with $157.1 million at December 31, 2018.

Eidos reported a net loss attributable to common stockholders of approximately $37.8 million or $1.03 per common share, for the full year 2019, as compared to a net loss attributable to common stockholders of $39.8 million or $1.86 per common share, for the prior year. The Company reported a net loss attributable to common stockholders of $19.0 million or $0.51 per common share, for the fourth quarter of 2019, as compared to a net loss attributable to common stockholders of $9.9 million or $0.27 per common share, for the fourth 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 full year 2019 were $46.9 million, as compared to $28.5 million for the prior year. Research and development expenses for the fourth quarter of 2019 were $13.9 million, as compared to $8.3 million for the same period in the prior year. Research and development expenses for the fourth quarter included costs related to contract manufacturing and the preparation for and conduct of clinical trials of AG10.

General and administrative expenses for the full year 2019 were $17.8 million, as compared to $9.2 million for the prior year. General and administrative expenses for the fourth quarter of 2019 were $5.5 million, as compared to $2.4 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 TTR amyloidosis, or ATTR. In a randomized, placebo-controlled Phase 2 clinical trial in patients with symptomatic ATTR-CM, AG10 was generally well tolerated, demonstrated greater than 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. The open label extension of this Phase 2 clinical trial, or the Phase 2 OLE, identified no safety signals of potential clinical concern associated with administration of AG10 15 months after study initiation. In an exploratory analysis, lower rates of all-cause mortality (including death and cardiac transplantation) and cardiovascular hospitalizations were observed in study participants than in placebo-treated ATTR-CM patients in the ATTR-ACT study. Cardiac

biomarkers and echocardiographic parameters were stable in the AG10 Phase 2 OLE.

AG10 is currently being studied in a Phase 3 clinical trial in patients with ATTR-CM (ATTRibute-CM), and we expect to initiate a Phase 3 clinical trial of AG10 in patients with ATTR-PN in the first half of 2020.

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)

There is significant medical need in ATTR given the large patient population and limited 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 for untreated patients. 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, our ability to enroll patients in and conduct the ATTRibute-CM trial and to initiate and conduct our planned Phase 3 clinical trial of AG10 in ATTR-PN 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 our ongoing and planned clinical trials, 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 Annual Report on Form 10-K for the year ended December 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 December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
License revenue	$ -	$ -	$ 26,691	$ -
Operating expenses*:				
Cost of license revenue	-	-	2,500	-
Research and development	13,858	8,323	46,891	28,539
General and administrative	5,466	2,382	17,751	9,240
Total operating expenses	19,324	10,705	67,142	37,779
Loss from operations	(19,324)	(10,705)	(40,451)	(37,779)
Interest expense	(327)	-	(327)	(1,011)
Other income (expense), net	671	851	2,943	(1,935)
Net and comprehensive loss	(18,980)	(9,854)	(37,835)	(40,725)

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	$ (18,980)	$ (9,854)	$ (37,835)	$ (39,812)
Net loss per share attributable to common stockholders	$ (0.51)	$ (0.27)	$ (1.03)	$ (1.86)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	37,277,751	36,128,132	36,624,692	21,366,995
*** Includes stock-based compensation as follows**				
Research and development	$ 683	$ 456	$ 2,313	$ 1,325
General and administrative	965	372	3,060	1,201
Total stock-based compensation expense	$ 1,648	$ 828	$ 5,373	$ 2,526

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

	December 31, 2019	December 31, 2018
Assets		
Current assets:		
Cash	$ 191,157	$ 157,147
Related party receivable	85	34
Prepaid expenses and other current assets	4,678	1,789
Total current assets	195,920	158,970
Property and equipment, net	1,259	209
Operating lease, right of use asset	4,010	-
Other assets	2,631	933
Total assets	$ 203,820	$ 160,112
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,151	$ 1,956
Related party payable	316	256
Lease liabilities	554	
Accrued expenses and other current liabilities	6,409	2,577
Total current liabilities	10,430	4,789
Debt, non-current	16,112	-
Lease liabilities, non-current	4,591	-
Embedded Derivative	1,165	-
Other liabilities	95	316
Total liabilities	32,393	5,105
Stockholders' equity (deficit):		
Common stock	38	37
Additional paid-in capital	274,494	220,240
Accumulated deficit	(103,105)	(65,270)
Total stockholders' equity	171,427	155,007
Total liabilities and stockholders' equity	$ 203,820	$ 160,112

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