Epizyme Reports Fourth Quarter and Full Year 2017 Operating Results and 2018 Milestones

March 13, 2018

First Tazemetostat NDA Submission for Epithelioid Sarcoma Targeted for Fourth Quarter of 2018; Second Tazemetostat NDA Submission for Follicular Lymphoma Targeted for 2019

Multiple Phase 2 Study Data Readouts Planned in 2018

Conference Call to be Held Today at 8:30 a.m. ET

CAMBRIDGE, Mass., March 13, 2018 (GLOBE NEWSWIRE) -- Epizyme, Inc. (NASDAQ: EPZM) today reported key pipeline progress and 2018 milestones, as well as operating results for the quarter and year ended December 31, 2017.

“2017 was truly a transformational year for Epizyme as we moved several steps closer to bringing tazemetostat to patients with both solid tumors and hematological malignancies,” said Robert Bazemore, president and chief executive officer of Epizyme. “These efforts have positioned Epizyme for one of the most milestone-rich years in the company’s history. We plan to submit our first NDA for tazemetostat for the treatment of patients with epithelioid sarcoma in the fourth quarter and are targeting a second NDA submission for the treatment of follicular lymphoma in 2019. We plan to present updated data from both of these programs this year, as well as from our studies in mesothelioma, diffuse large B-cell lymphoma, and other adult INI1-negative tumors. In addition, Epizyme will be readying its next product candidate, EZM8266, for the clinic. I am proud of our team’s many accomplishments and am confident in our ability to continue building momentum as we transition into a fully-integrated, commercial organization.”

Pipeline Progress in Recent Months

- Epizyme had a positive interaction with the FDA in the fourth quarter of 2017 regarding its registration strategy for tazemetostat for the treatment of patients with follicular lymphoma, and the company believes that it has an opportunity to submit for accelerated approval. Epizyme is targeting a New Drug Application (NDA) submission in 2019.

- Epizyme reported that a Phase 1b/2 clinical study evaluating tazemetostat in combination with atezolizumab (TECENTRIQ®) for the treatment of metastatic non-small cell lung cancer was opened for enrollment. The study is part of MORPHEUS, Genentech's open-label, multi-center, randomized umbrella study evaluating the efficacy and safety of multiple immunotherapy-based treatment combinations in solid tumors.

- Epizyme presented data from the completed dose-escalation portion of its Phase 1 study of tazemetostat in pediatric patients with INI1-negative solid tumors at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. Objective responses were observed in patients with epithelioid sarcoma (n=1), poorly differentiated chordoma (n=2) and atypical teratoid rhabdoid tumors (n=1) at dose levels ranging from 520 to 900 mg/m^2 twice daily.

- Epizyme reported that its ongoing Phase 2 study designed to evaluate tazemetostat as a treatment for adults with mesothelioma characterized by BAP1 loss-of-function surpassed the futility assessment, achieving the primary endpoint of ≥35 percent disease control rate at 12 weeks.

- Epizyme named its next product candidate, EZM8266, a novel first-in-class G9a inhibitor being developed for the treatment of sickle cell disease (SCD). The company reported preclinical data at the 59th Annual Meeting & Exposition of the American Society of Hematology (ASH) demonstrating the potential of EZM8266 to treat SCD.

Key 2018 Milestones

- **Submit First Tazemetostat NDA for Epithelioid Sarcoma**: Following engagement with the FDA in 2017, Epizyme has identified a path to submit for accelerated approval for tazemetostat for the treatment of patients with epithelioid sarcoma. The company completed enrollment of patients in the expansion cohort of its Phase 2 study in 2017 and plans to present updated data from all patients in the second half of 2018. These data will inform the planned NDA submission for tazemetostat for this indication in the fourth quarter of 2018. In addition, the company is preparing for a confirmatory study

in epithelioid sarcoma to support its registration strategy.

- **Continue Regulatory Engagement on Follicular Lymphoma Program:** Following its initial interaction with the FDA in late 2017, the company plans to continue its engagement with the Agency throughout 2018 to further refine the registration strategy for accelerated approval of tazemetostat for the treatment of follicular lymphoma. Epizyme also plans to initiate a tazemetostat combination study in follicular lymphoma in the second half of 2018, designed to support its registration strategy.

- **Complete Follicular Lymphoma Patient Enrollment and Present Updated Data:**Epizyme plans to complete enrollment in the cohort of patients with relapsed or refractory follicular lymphoma with an EZH2 mutation in its ongoing Phase 2 study of tazemetostat as a monotherapy in 2018; enrollment in the cohort of patients with wild-type EZH2 was completed in early 2017. The company expects to present updated data from the ongoing study at a medical meeting in mid-to-second half of 2018.

- **Complete Phase 2 DLBCL Enrollment and Present Monotherapy and Combination Data:** Epizyme plans to complete enrollment of patients with relapsed or refractory DLBCL with an EZH2 mutation in its ongoing Phase 2 study of tazemetostat as a monotherapy in 2018; enrollment of patients with wild-type EZH2 was completed in early 2017. The company expects to present updated monotherapy data and announce next steps for the program in mid-to-second half of the year. Epizyme also plans to begin reporting initial data on tazemetostat as a combination treatment for DLBCL in 2018.

- **Present Mesothelioma Data and Next Development Steps:** The company plans to present data from its Phase 2 study of tazemetostat in patients with relapsed or refractory mesothelioma at a medical meeting and to communicate next steps for this tumor type in mid-2018.

- **Advance Clinical Studies in Adults and Children with INI1-Negative Tumors:** Epizyme is advancing its ongoing Phase 2 study of tazemetostat in adult patients with INI1-negative tumors. In the second half of 2018, the company plans to present data from cohorts that have surpassed futility, which currently includes epithelioid sarcoma, malignant rhabdoid tumor and other INI1-negative tumor cohorts. The company is also advancing its Phase 1 clinical study in pediatric patients with INI1-negative tumors and expects to complete enrollment in the dose-expansion portion of the study in 2018.

- **Prepare EZM8266 for Clinical Initiation in Early 2019:** Epizyme plans to complete IND-enabling studies for EZM8266, its G9a inhibitor designed to treat patients with sickle cell disease, in 2018 and prepare for a Phase 1 study in early 2019.

Fourth Quarter and Full Year 2017 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities were $276.4 million as of December 31, 2017, as compared to $242.2 million as of December 31, 2016. The increase is primarily the result of the company's public offering of common stock that closed in September 2017, offset by operating expenditures for the year.

- **Revenue:** There was no collaboration revenue for the fourth quarter of 2017 and $10.0 million for the full year ended December 31, 2017, compared to $0.5 million for the fourth quarter of 2016 and $8.0 million for the full year ended December 31, 2016. The increase in annual collaboration revenue is primarily due to greater milestone contribution from the company's agreement with GSK in 2017.

- **R&D Expenses:** Research and development (R&D) expenses were $28.9 million for the fourth quarter of 2017 and $109.7 million for the full year ended December 31, 2017, compared to $28.4 million for the fourth quarter of 2016 and $91.5 million for the full year ended December 31, 2016. The increase is primarily due to higher costs for tazemetostat manufacturing and clinical trial activities in 2017.

- **G&A Expenses**: General and administrative (G&A) expenses were $8.4 million for the fourth quarter of 2017 and $37.2 million for the full year ended December 31, 2017, compared to $7.6 million for the fourth quarter of 2016 and $28.4 million for the full year ended December 31, 2016. The increase is primarily due to increased consulting services and preparations for tazemetostat commercialization.

- **Net Loss:** Net loss was $36.2 million, or $0.52 per share, for the fourth quarter of 2017 and $134.3 million, or $2.18 per share, for the full year ended December 31, 2017, compared to $35.0 million, or $0.60 per share, for the fourth quarter of 2016 and $110.2 million, or $1.93 per share, for the full year ended December 31, 2016.

Financial Guidance

Epizyme continues to expect that its existing cash, cash equivalents and marketable securities as of December 31, 2017 will be sufficient to fund its planned operations into the third quarter of 2019.

Conference Call Reminder
Management will host a conference call and webcast today at 8:30 a.m. ET to discuss the company's fourth quarter and full year 2017 financial results and other business highlights. To participate in the conference call, please dial (877) 844-6886 (domestic) or (970) 315-0315 (international) and refer to conference ID 7299537. A live webcast will be available in the investor section of the company's website at http://www.epizyme.com. The webcast also will be archived on the website for 60 days.

About the Tazemetostat Clinical Trial Program
Tazemetostat, a first-in-class EZH2 inhibitor, is currently being studied as a monotherapy in ongoing Phase 2 programs in certain molecularly defined solid tumors, including epithelioid sarcoma and other INI1-negative tumors; both follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL) forms of non-Hodgkin lymphoma (NHL); mesothelioma; and combination studies in DLBCL and NSCLC.

About Epizyme, Inc.
Epizyme, Inc. is a clinical-stage biopharmaceutical company committed to rewriting treatment for cancer and other serious diseases through novel epigenetic medicines. Epizyme is broadly developing its lead product candidate, tazemetostat, a first-in-class EZH2 inhibitor, with studies underway in both solid tumors and hematological malignancies, as a monotherapy and combination therapy in relapsed and front-line disease. The company is also developing a novel G9a program and its next development candidate, EZM8266, is targeting sickle cell disease. By focusing on the genetic drivers of disease, Epizyme's science seeks to match targeted medicines with the patients who need them. For more information, visit www.epizyme.com.

Cautionary Note on Forward-Looking Statements
Any statements in this press release about future expectations, plans and prospects for Epizyme, Inc. and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," 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 of future clinical studies and in the availability and timing of data from ongoing clinical studies; whether interim results from a clinical trial will be predictive of the final results of the trial; whether results from preclinical studies or earlier clinical studies will be predictive of the results of future trials; whether results from clinical studies will warrant meetings with regulatory authorities, submissions for regulatory approval or review by governmental authorities under the accelerated approval process; whether fast track and orphan drug designations will provide the benefits for which tazemetostat is eligible; expectations for regulatory approvals to conduct trials or to market products; whether the company's cash resources will be sufficient to fund 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 therapeutic candidates; and other factors discussed in the "Risk Factors" section of the company's most recent Form 10-K filed with the SEC and in the company's other filings from time to time with the SEC. In addition, the forward-looking statements included in this press release represent the company's views as of the date hereof and should not be relied upon as representing the company's views as of any date subsequent to the date hereof. 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.

EPIZYME, INC.
CONDENSED CONSOLIDATED BALANCE SHEET DATA (UNAUDITED)
(Amounts in thousands)

	December 31, 2017	December 31, 2016
Cash, cash equivalents, and marketable securities	$ 276,439	$ 242,192
Total assets	289,359	252,441
Deferred revenue, net of current portion	28,809	28,809
Total stockholders' equity	235,371	201,700

EPIZYME, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(Amounts in thousands except per share data)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2017	2016	2017	2016
Collaboration revenue	$ -	$ 478	$ 10,000	$ 8,007
Operating expenses:				
Research and development	28,933	28,383	109,661	91,461
General and administrative	8,431	7,580	37,181	28,372
Total operating expenses	37,364	35,963	146,842	119,833
Loss from operations	(37,364)	(35,485)	(136,842)	(111,826)
Other income, net	862	469	2,197	1,614
Loss before income taxes	(36,502)	(35,016)	(134,645)	(110,212)
Income tax benefit	336	-	336	-
Net loss	$ (36,166)	$ (35,016)	$ (134,309)	$ (110,212)

Loss per share allocable to common stockholders:				
Basic	$ (0.52)	$ (0.60)	$ (2.18)	$ (1.93)
Diluted	$ (0.52)	$ (0.60)	$ (2.18)	$ (1.93)
Weighted average shares outstanding:				
Basic	69,287	58,016	61,471	57,126
Diluted	69,287	58,016	61,471	57,126

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Source: Epizyme, Inc.