March 9, 2017

Epizyme Reports 2016 Financial Results and Provides 2017 Pipeline Goals

Data from Tazemetostat Phase 2 Programs in NHL and Molecularly Defined Solid Tumors Planned for Medical Meetings in Second Quarter

Conference Call to Be Held Today at 8:30 a.m. Eastern Time

CAMBRIDGE, Mass., March 09, 2017 (GLOBE NEWSWIRE) -- Epizyme, Inc. (NASDAQ:EPZM), a clinical-stage biopharmaceutical company creating novel epigenetic therapies, today reported financial results for the fourth quarter and full year 2016. In addition, the Company reviewed recent highlights and provided guidance on its clinical and research pipeline in 2017.

"2016 was a year of tremendous progress across all aspects of Epizyme, which set the stage for 2017 to be a transformational year for the company," said Robert Bazemore, president and chief executive officer of Epizyme. "We have a broad clinical development program with tazemetostat in multiple tumor types and treatment settings. We plan to present data from both our ongoing, global Phase 2 studies in both molecularly defined solid tumors and non-Hodgkin lymphoma in June, and to initiate discussions with regulators to define registration pathways for tazemetostat. We are advancing our ongoing monotherapy and combination studies and plan to announce the next development candidate from our preclinical pipeline this year. As we look ahead, we are on our way to achieving our vision of rewriting cancer treatment through novel epigenetic medicines."

Recent Achievements

- **Tazemetostat Combination with Prednisolone Initiated:** Epizyme has initiated clinical investigation of tazemetostat in combination with prednisolone in relapsed/refractory patients with DLBCL, based on observed preclinical synergy of the agents. This combination regimen is being conducted as the sixth cohort to the ongoing Phase 2 NHL study. Epizyme also anticipates initiating a new combination study in patients with follicular lymphoma in 2017.
- **Enrollment Completed in Three of Five NHL Study Cohorts:** Epizyme has completed enrollment in three of the five cohorts of its ongoing, global Phase 2 study of tazemetostat in patients with relapsed/refractory non-Hodgkin lymphoma (NHL): the two cohorts enrolling patients with diffuse large B-cell lymphoma (DLBCL) with wild-type EZH2 and a third enrolling patients with follicular lymphoma with wild-type EZH2.
- **Follicular Lymphoma Enrollment Initiated in U.S.:** In January 2017, following a positive written response from the U.S. Food and Drug Administration (FDA) to the company's written request, Epizyme opened enrollment to patients with follicular lymphoma in the United States as part of the Company's Phase 2 study in NHL.
- **Fast Track Designation Granted for DLBCL with EZH2 Mutations:** In December 2016, the U.S. FDA granted Fast Track designation to tazemetostat for the treatment of patients with DLBCL whose tumors carry an EZH2 activating mutation. DLBCL is the most common form of NHL. The Fast Track designation provides expedited processes that may reduce development time and costs associated with bringing a drug to market.
- **Epithelioid Sarcoma Cohort Expanded in Phase 2 Solid Tumor Study:** In late 2016, Epizyme expanded the epithelioid sarcoma cohort of its ongoing Phase 2 trial of tazemetostat in adult patients with certain molecularly defined solid tumors, following review by the Independent Data Monitoring Committee. This expansion was based on encouraging early activity, including confirmed objective responses, and surpassing the pre-specified futility hurdle in the cohort. This cohort will enroll up to 60 patients, or double the initial cohort size of 30 patients.
- **Synovial Sarcoma Cohort Completed Enrollment in Phase 2 Solid Tumor Study:** The synovial sarcoma cohort of the Phase 2 trial in patients with molecularly defined solid tumors was fully enrolled in November 2016. This arm surpassed its pre-specified futility hurdle; however, the Company concluded that the activity was insufficient to continue further investigation of tazemetostat as a monotherapy. Epizyme is focusing its efforts on the remaining four cohorts of INI1-negative tumors.

Key 2017 Milestones and Goals

- **Interim Phase 2 Data Presentations Anticipated in the Second Quarter:** Epizyme plans to report efficacy,

safety and biomarker data from all five arms of the ongoing Phase 2 study in NHL, and from the study cohorts that have reached their futility analysis in the ongoing Phase 2 study in molecularly defined solid tumors. Pending abstract approval, the Company plans to present interim solid tumor data at the American Society of Clinical Oncology (ASCO) Annual Meeting. Pending abstract submission and approval, the Company anticipates presenting interim data from all five arms of the ongoing Phase 2 NHL trial at The International Conference on Malignant Lymphoma (ICML).

- **Preparing for Regulatory Engagement beginning Mid-Year:** Epizyme is preparing for regulatory engagement around its Phase 2 studies, beginning with the United States Food and Drug Administration (FDA) in mid-2017 on its molecularly defined solid tumor program. The Company is also preparing for FDA engagement on its NHL program in the second half of the year. These interactions are intended to determine registration paths for tazemetostat in each disease area.
- **Combination Studies Progressing**: The combination studies of tazemetostat in front-line DLBCL with R-CHOP and in relapsed/refractory DLBCL with atezolizumab (Tecentriq™) are continuing to enroll patients globally. Epizyme expects the optimal dose of tazemetostat in these combinations will be established this year, and for enrollment to continue to evaluate the safety and efficacy profile of both combinations.
- **Mesothelioma Study Progressing:** Epizyme is continuing to enroll patients in its global Phase 2 study of tazemetostat in patients with mesothelioma characterized by BAP1 loss-of-function. The Company anticipates completing enrollment in this trial in 2017.
- **Next Development Candidate to be Named:** Epizyme is progressing a pipeline of next-generation small molecules against novel epigenetic targets, and plans to name the next epigenetic development candidate from its pipeline in 2017. This is part of the Company's goal of bringing three new product candidates into the clinic by 2020.

Fourth Quarter and Full-Year 2016 Financial Results

- **Cash Position**: Cash, cash equivalents and marketable securities were $242.2 million as of December 31, 2016, as compared to $208.3 million as of December 31, 2015.
- **Revenue:** Collaboration revenue was $0.5 million for the fourth quarter of 2016 and $8.0 million for the full year ended December 31, 2016, compared to $0.6 million for the fourth quarter of 2015 and $2.6 million for the full year ended December 31, 2015. The year-over-year increase was driven predominantly by the achievement of a $6.0 million milestone under the Company's agreement with GSK during 2016.
- **R&D Expenses:** Research and development (R&D) expenses were $28.4 million for the fourth quarter of 2016 and $91.5 million for the full year ended December 31, 2016, compared to $16.8 million for the fourth quarter of 2015 and $111.2 million for the full year ended December 31, 2015. R&D spending on discovery research programs and tazemetostat clinical development increased in both the quarter ended December 31, 2016 and, excluding the impact of the $40.0 million upfront payment to Eisai in the first quarter of 2015 to acquire worldwide rights, excluding Japan, to tazemetostat, in the year ended December 31, 2016.
- **G&A Expenses**: General and administrative (G&A) expenses were $7.6 million for the fourth quarter of 2016 and $28.4 million for the full year ended December 31, 2016, compared to $6.0 million for the fourth quarter of 2015 and $23.9 million for the full year ended December 31, 2015. The increase was primarily due to higher compensation-related expenses associated with expansion of the senior leadership team in the first half of 2016 to support the Company's operational growth, as well as increased investment in business development activities and tazemetostat-related pre-commercial activities.
- **Net Loss:** Net loss was $35.0 million for the fourth quarter of 2016 and $110.2 million for the full year ended December 31, 2016, compared to $22.2 million for the fourth quarter of 2015 and $132.4 million for the full year ended December 31, 2015.

2017 Guidance

Epizyme believes that its cash, cash equivalents and marketable securities of $242.2 million as of December 31, 2016 will be sufficient to fund the Company's planned operations into at least the third quarter of 2018.

Conference Call Information

Epizyme will host a conference call and audio webcast today at 8:30 a.m. Eastern Time to discuss its fourth quarter and full year 2016 financial results and 2017 pipeline goals. To participate in the conference call, please dial (877) 844-6886 (domestic) or (970) 315-0315 (international) and refer to conference ID 79789689. The webcast can be accessed under "Events and Presentations" in the Investor Relations section of the company's website at www.epizyme.com.

About Epizyme, Inc.

Epizyme, Inc. is a clinical-stage biopharmaceutical company committed to rewriting cancer treatment 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 and in relapsed and front-line disease. Using the Company's proprietary platform, Epizyme has pioneered the identification and development of small molecule inhibitors of histone methyltransferases and other chromatin modifying proteins (CMPs), such as tazemetostat. CMPs are part of the system of gene regulation, referred to as epigenetics, that controls gene expression. Genetic alterations can result in changes to the activity of CMPs, which can allow cancer cells to grow and proliferate. By focusing on the genetic drivers of cancers, Epizyme's science seeks to match targeted medicines with the

specific patients that need it. For more information, visit www.epizyme.com and connect with us on Twitter at @EpizymeRx.

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 or submissions for regulatory approval; 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-Q 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.

Tecentriq™ is a trademark of Genentech, Inc., (South San Francisco, CA, USA), a member of the Roche Group.

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

	December 31, 2016	December 31, 2015
Cash and cash equivalents	$ 77,895	$ 208,323
Marketable securities	164,297	—
Total assets	252,441	217,903
Deferred revenue	28,809	30,709
Total stockholders' equity	201,700	169,532

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,	
	2016	2015	2016	2015
Collaboration revenue	$ 478	$ 555	$ 8,007	$ 2,560
Operating expenses:				
Research and development	28,383	16,819	91,461	111,209
General and administrative	7,580	6,017	28,372	23,900
Total operating expenses	35,963	22,836	119,833	135,109
Operating loss	(35,485)	(22,281)	(111,826)	(132,549)
Other income, net	469	55	1,614	173
Net loss	$ (35,016)	$ (22,226)	$ (110,212)	$ (132,376)
Loss per share allocable to common stockholders:				
Basic	$ (0.60)	$ (0.53)	$ (1.93)	$ (3.32)

Diluted	$ (0.60)	$ (0.53)	$ (1.93)	$ (3.32)
Weighted average shares outstanding:				
Basic	58,016	41,725	57,126	39,839
Diluted	58,016	41,725	57,126	39,839

Contacts:

Monique Allaire, THRUST IR

monique@thrustir.com

(617) 895-9511

Primary Logo

Source: Epizyme, Inc.

News Provided by Acquire Media