Epizyme Provides Update Regarding Tazemetostat Clinical Program

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CAMBRIDGE, Mass., April 23, 2018 (GLOBE NEWSWIRE) -- Epizyme, Inc. (NASDAQ:EPZM), a clinical-stage company developing novel epigenetic therapies, today announced that U.S.-based enrollment of new patients into tazemetostat clinical trials is temporarily on hold. Following a safety report of a pediatric patient who developed a secondary lymphoma, the U.S. Food and Drug Administration (FDA) issued a partial clinical hold affecting new enrollment of patients with genetically defined solid tumors and hematologic malignancies, while the company updates the informed consent, investigator’s brochure and study protocols. Patients on study who have not experienced disease progression may continue to receive tazemetostat. Epizyme has begun developing the modifications to address the partial clinical hold, and will need to confirm alignment with the FDA in order to resume U.S. enrollment.

The partial clinical hold was initiated following a safety report, submitted by Epizyme to the FDA and other regulatory authorities, regarding a patient with advanced poorly differentiated chordoma in the company’s Phase 1 pediatric study who developed a secondary T-cell lymphoma. Doses explored in this study are higher than those in the company’s Phase 2 adult studies, an approach not uncommon to drug development in aggressive, difficult-to-treat pediatric cancers. At the time of the safety report, the patient had been on study for approximately 15 months and had achieved a confirmed partial response. This patient has now discontinued tazemetostat and is being treated for T-cell lymphoma.

Secondary malignancies are known to be potential adverse events associated with many cancer therapies, including chemotherapy and radiation treatment. T-cell lymphoma has been identified as a potential adverse event in tazemetostat study protocols and is included in the investigator’s brochure and the informed consent. More than 750 patients have been treated with tazemetostat to date, and this is the only case of secondary lymphoma that has been observed across the tazemetostat clinical program.

“Patient safety is of the utmost importance to Epizyme. We are working expeditiously with clinical trial investigators and regulatory authorities to initiate the appropriate steps to resume enrollment,” said Robert Bazemore, president and chief executive officer of Epizyme. “Epizyme, along with our global investigator community, has been very encouraged by the clinical responses and tolerability of tazemetostat observed in pediatric and adult patients with hematological malignancies and solid tumors enrolled in our trials. We remain encouraged by the potential of tazemetostat to address the unmet needs of many patients living with cancer.”

About the Tazemetostat Clinical Trial Program
Tazemetostat, a first-in-class EZH2 inhibitor, is currently being studied as a monotherapy in ongoing Phase 1 and 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 NHL; mesothelioma; and combination studies in DLBCL and non-small cell lung cancer (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 with its next development candidate, EZM8266, which 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 relating to the Company's ability to resume enrollment in its tazemetostat trials and the timing of such resumption, and the impact of the safety finding on enrollment of patients in ongoing and future trials of tazemetostat following the lifting of the partial clinical hold and the resumption of enrollment; 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 Designation 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.

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