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Epizyme Announces Tazemetostat to be Evaluated in NCI's Recently Initiated NCI-COG Pediatric MATCH Trial

CAMBRIDGE, Mass., July 24, 2017 (GLOBE NEWSWIRE) -- Epizyme, Inc. (NASDAQ:EPZM), a clinical-stage biopharmaceutical company creating novel epigenetic therapies, today announced that the National Cancer Institute (NCI), part of the National Institutes of Health, has initiated its NCI-COG Pediatric MATCH study, which includes a phase 2 evaluation of tazemetostat as one of its treatment arms. Conducted under Epizyme's Cooperative Research and Development Agreement (CRADA) executed with NCI in 2016, this multi-institutional study will evaluate tazemetostat as a monotherapy for pediatric patients with advanced solid tumors, including CNS tumors, non-Hodgkin lymphoma or histiocytic disorders that harbor gain of function mutations in EZH2, or loss of function mutations in the SWI/SNF complex subunits SMARCB1 or SMARCA4. The Pediatric MATCH study, which will be operationalized by the Children's Oncology Group (COG), aims to match targeted agents, such as tazemetostat, with specific molecular changes identified through genomic sequencing of refractory/recurrent tumors from children and adolescents with cancer.

"We are very pleased to be participating in the Pediatric MATCH trial as it will allow us to extend our exploration of tazemetostat's potential clinical utility in the treatment of molecularly targeted tumors," said Peter Ho, M.D., Ph.D., chief medical officer of Epizyme. "We look forward to working with the NCI and COG investigators to advance our understanding of tazemetostat's potential against these devastating cancers in children and adolescents."

"This trial would not have been possible without the enthusiastic support of the partnering pharmaceutical companies, as evidenced by their willingness to provide targeted agents for this trial," said NCI study co-chair Nita Seibel, M.D., of NCI's Division of Cancer Treatment and Diagnosis.

As part of the CRADA executed between Epizyme and NCI in 2016, NCI has agreed to collaborate with Epizyme on clinical trials to evaluate the safety and efficacy of tazemetostat in both adult and pediatric patients with hematologic malignancies and solid tumors. As part of the agreement, NCI will fund and sponsor all clinical trials conducted under this collaboration.

About the Tazemetostat Clinical Trial Program
Tazemetostat, a first-in-class EZH2 inhibitor, is currently being studied in ongoing Phase 2 programs in both follicular lymphoma and diffuse large B-cell lymphoma (DLBCL) forms of non-Hodgkin lymphoma; certain molecularly defined solid tumors, including epithelioid sarcoma and other INI1-negative tumors; and mesothelioma, as well as in combination studies in DLBCL. Tazemetostat has been granted Fast Track designation by the U.S. Food and Drug Administration for follicular lymphoma regardless of EZH2 mutation and for DLBCL with EZH2-activating mutations, as well as Orphan Drug designation for soft tissue sarcoma and malignant rhabdoid tumors.

About the NCI-COG Pediatric MATCH Trial[1]
Pediatric MATCH is a precision medicine cancer treatment clinical trial that analyzes patients' tumors to determine whether they contain genetic abnormalities for which a targeted drug exists (that is, "actionable mutations") and assigns treatment based on the abnormality. This trial seeks to determine whether treating cancers according to their molecular abnormalities will show evidence of effectiveness.

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 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 results from preclinical studies or earlier clinical studies will be predictive of the results of future studies; whether interim data from clinical studies will be indicative of the final results of the study; whether results from clinical studies will warrant meetings with regulatory authorities or submissions for regulatory approval; whether submissions for regulatory approval will be made when anticipated or at all and whether these submissions will be reviewed under the accelerated approval framework; whether the Company will receive regulatory approvals to conduct trials or to market products; whether the Company's collaborations such as the collaboration with NCI reported in this release will be successful; 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.

[1] 1. The National Cancer Institute: http://www.cancer.gov/about-cancer/treatment/clinical-trials/nci-supported/pediatric-match

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