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Epizyme Announces Fast Track Designation for Tazemetostat in DLBCL and Provides Solid Tumor Program Update

FDA Grants Tazemetostat Fast Track Designation for DLBCL with EZH2 Activating Mutations

Company Focuses Phase 2 Solid Tumor Study on INI1-Negative Tumors and Expands Epithelioid Sarcoma Cohort

CAMBRIDGE, Mass., Nov. 28, 2016 (GLOBE NEWSWIRE) -- Epizyme, Inc. (NASDAQ:EPZM), a clinical-stage biopharmaceutical company creating novel epigenetic therapies, today announced advancements in the Company's clinical programs evaluating tazemetostat, its first-in-class EZH2 inhibitor. The U.S. Food and Drug Administration (FDA) has granted tazemetostat Fast Track designation in patients with diffuse large B-cell lymphoma (DLBCL) with EZH2 activating mutations. Additionally, Epizyme is focusing its Phase 2 registration-enabling study in adult patients with genetically-defined solid tumors on those cancers marked by loss of INI1, and has expanded enrollment in the epithelioid sarcoma cohort of the study based on encouraging early activity in this patient population.

"We are very proud of the continued advancement of our tazemetostat clinical program in both non-Hodgkin lymphoma and genetically-defined solid tumors, important areas of unmet medical need for patients with cancer," said Robert Bazemore, president and chief executive officer, Epizyme. "These developments reflect the execution of our strategy to identify the patient groups who may benefit most from tazemetostat, and our efforts to bring this investigational medicine to patients as quickly as possible."

NHL Program Update: Fast Track Designation for DLBCL Subtype
The FDA has granted Fast Track designation for the investigation of tazemetostat for the treatment of patients with relapsed or refractory DLBCL whose tumors carry an EZH2 activating mutation. Tazemetostat inhibits EZH2, a histone methyltransferase that is increasingly understood to play a role in the growth and proliferation of a number of cancers, including DLBCL, the most commonly diagnosed form of NHL.

The FDA Fast Track program is designed to facilitate the development of important new drugs and to provide patients access to those drugs more quickly. The designation enables early and frequent communication between FDA and a product sponsor throughout the drug development and review process. Through the Fast Track program, a product may be eligible for priority review at the time of a new drug application (NDA) filing and may also be eligible to submit completed sections of the NDA on a rolling basis before the complete application is submitted. These expedited processes can potentially reduce development time and cost associated with bringing a drug to market.

Genetically Defined Solid Tumor Program Update: Focus on INI1-Negative Tumors
Following review by the Independent Data Monitoring Committee, Epizyme has expanded the epithelioid sarcoma cohort of its ongoing Phase 2 trial in adult patients with INI1-negative solid tumors. This expansion is based on encouraging early activity seen, including confirmed objective responses, in the cohort. The company plans to enroll an additional 30 patients with epithelioid sarcoma, bringing the cohort to a total of 60 patients. This study represents the largest trial conducted to date in this rare tumor type. Epithelioid sarcoma is a soft tissue sarcoma characterized by loss of INI1. There are currently no approved systemic therapies for the treatment of patients with epithelioid sarcoma, and outcomes are extremely poor.

The synovial sarcoma arm of the Phase 2 trial has been fully enrolled. Although some patients remain on treatment, Epizyme has concluded that the activity of tazemetostat in this cohort is insufficient to continue further investigation of tazemetostat as a monotherapy. Unlike the cancers in the other four arms of the study, synovial sarcoma is characterized by a functional dysregulation of INI1, rather than by a complete loss of INI1.

Epizyme is now focusing its efforts on the four cohorts of INI1-negative tumors in its study, including the epithelioid sarcoma cohort. Enrollment continues in these cohorts and Epizyme plans to present data from the Phase 2 trial in the first half of 2017.

"The early clinical activity observed in the epithelioid sarcoma arm provides encouraging evidence of the effectiveness of

EZH2 inhibition with tazemetostat in patients with INI1-negative tumors," added Peter Ho., M.D., Ph.D., chief medical officer, Epizyme. "The clinical experience observed so far in both the epithelioid sarcoma and synovial sarcoma cohorts is consistent with our Phase 1 experience for these cancers. We look forward to assessing clinical activity in the Phase 2 study and reporting data in the first half of 2017."

About the Tazemetostat Clinical Program
Tazemetostat, a first-in-class EZH2 inhibitor, is being evaluated as a monotherapy and in combination with other agents in multiple cancer indications. Phase 2 studies of tazemetostat as a monotherapy are currently ongoing in patients with non-Hodgkin lymphoma; in adults with INI1-negative tumors and children with certain genetically defined solid tumors, including INI1-negative tumors and synovial sarcoma; and in patients with mesothelioma characterized by BAP1 loss-of-function.

Additionally, tazemetostat is being evaluated in two combination studies in patients with DLBCL. A Phase 1b/2 trial of tazemetostat in combination with R-CHOP, an immuno-chemotherapy regimen consisting of rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone, is being conducted as a front-line treatment for patients with DLBCL as part of Epizyme's collaboration with the Lymphoma Study Association. A Phase 1b study evaluating tazemetostat in combination with Tecentriq® (atezolizumab), an anti-PD-L1 cancer immunotherapy approved by the U.S. Food and Drug Administration, is being conducted as part of a collaboration with Genentech, a member of the Roche Group, in relapsed and refractory patients with DLBCL. For more information on tazemetostat clinical trials, please visit www.epizymeclinicaltrials.com.

About Epizyme, Inc.
Epizyme, Inc. is a clinical stage biopharmaceutical company creating novel epigenetic therapeutics for cancer patients. Epizyme has built a proprietary product platform that the Company uses to create small molecule inhibitors of a 96-member class of enzymes known as histone methyltransferases, or HMTs. HMTs 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 HMTs, making them oncogenic (cancer-causing). By focusing on the genetic drivers of cancers, Epizyme's targeted science seeks to match the right medicines with the right patients. 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 such as the early data referenced in this release 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; whether a fast track designation will lead to a faster development or regulatory review or approval process; 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.

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