



April 25, 2017

## **Epizyme Announces Tazemetostat Fast Track Designation for Follicular Lymphoma and Plenary Session on Phase 2 NHL Data at ICML**

*Interim Efficacy and Safety Data from Ongoing Phase 2 Study in Follicular Lymphoma and DLBCL Selected for Plenary Presentation at the International Conference on Malignant Lymphoma*

*Management to Host Conference Call on June 14 at 10:30 a.m. ET*

CAMBRIDGE, Mass., April 25, 2017 (GLOBE NEWSWIRE) -- Epizyme, Inc. (NASDAQ:EPZM), a clinical-stage biopharmaceutical company creating novel epigenetic therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to tazemetostat, the Company's first-in-class EZH2 inhibitor, for the treatment of patients with relapsed or refractory follicular lymphoma, either wild type EZH2 or with EZH2 activating mutations. Fast Track designation is intended to provide expedited processes for the development and FDA review of drugs that may reduce development time and costs associated with bringing a drug to market.

Epizyme also announced that interim efficacy and safety data from all five study cohorts in its ongoing Phase 2 study of tazemetostat in patients with relapsed or refractory follicular lymphoma and diffuse large B-cell lymphoma (DLBCL) has been selected for a plenary session on Wednesday, June 14, 2017 at 2:00 p.m. CET at the International Conference on Malignant Lymphoma (ICML) in Lugano, Switzerland. In addition, results from a biomarker study of tazemetostat in patients with NHL will be presented in a poster session during ICML. The Company plans to hold a conference call to discuss these clinical findings on Wednesday, June 14 at 10:30 a.m. ET.

"This is an important milestone for our NHL program, with tazemetostat now having FDA Fast Track designation for relapsed or refractory diffuse large B-cell lymphoma with EZH2 activating mutations and for relapsed or refractory follicular lymphoma, regardless of EZH2 mutation," said Robert Bazemore, president and chief executive officer, Epizyme. "In addition to this regulatory recognition of tazemetostat's therapeutic potential, the selection of interim Phase 2 data for the opening plenary session underscores the lymphoma community's enthusiasm for our lead product candidate. Our development goal is to bring tazemetostat to patients as quickly as possible and we look forward to advancing this study throughout 2017."

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.

### **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 genetically defined solid tumors, including INI1-negative and SMARCA4-negative tumors and synovial sarcoma; 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 both relapsed/refractory follicular lymphoma with or without an EZH2 activating mutation and DLBCL with EZH2 activating mutations, as well as Orphan Drug designation for malignant rhabdoid tumors.

### **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](http://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 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-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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