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Epizyme Announces Tazemetostat Granted Orphan Drug Designation for the Treatment of Soft Tissue Sarcoma

CAMBRIDGE, Mass., June 21, 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 Orphan Drug designation to tazemetostat, the company's first-in-class EZH2 inhibitor, for the treatment of patients with soft tissue sarcoma (STS).

"This is an important milestone for Epizyme, as we advance tazemetostat through clinical development," said Robert Bazemore, president and chief executive officer, Epizyme. "We are encouraged by the positive regulatory milestones we have achieved for tazemetostat, including this Orphan Drug designation for soft tissue sarcomas. We look forward to our continued engagement with the FDA as we work to bring tazemetostat to patients with both solid tumors and hematological malignancies as quickly as possible."

The Orphan drug status conveys eligibility for certain development incentives and market exclusivity for STS independent from Epizyme's intellectual property protection. The FDA Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases or disorders that affect fewer than 200,000 people in the U.S.

STS is a cancer occurring in muscle, fat, blood vessels, tendons, fibrous tissues and connective tissue, which can arise anywhere in the body at any age. STS is an aggressive and difficult-to-treat cancer with more than 50 subtypes, including epithelioid sarcoma, highlighting the need for effective treatment options. According to the American Cancer Society, approximately 13,000 patients will be diagnosed with STS in the U.S. in 2017.

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 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 orphan drug designation will lead to orphan drug exclusivity or the other potential benefits of orphan drug designation for which the Company is eligible; 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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