August 1, 2017

US Oncology Research and Epizyme Establish Collaboration to Identify Non-Hodgkin Lymphoma Patients with EZH2 Mutations

Eligible Patients to be Directed to Epizyme's Ongoing Phase 2 Clinical Trial of Tazemetostat in Follicular Lymphoma and Diffuse Large B-cell Lymphoma

THE WOODLANDS, Texas and CAMBRIDGE, Mass., Aug. 01, 2017 (GLOBE NEWSWIRE) -- Epizyme, Inc. (NASDAQ:EPZM), a clinical-stage biopharmaceutical company creating novel epigenetic therapies, and US Oncology Research, one of the nation's largest networks of independent, community-based oncology practices dedicated to advancing high-quality treatments through clinical trials, today announced a collaboration to screen and identify relapsed or refractory follicular lymphoma (FL) and diffuse large B-cell lymphoma (DLBCL) patients with EZH2 mutations. Once identified, eligible candidates will be directed to Epizyme's ongoing Phase 2 clinical trial of tazemetostat, the Company's first-in-class EZH2 inhibitor, as a single-agent treatment for relapsed or refractory patients with FL or DLBCL.

"Relapsed follicular lymphoma and DLBCL are difficult diseases for which there is generally poor prognosis and limited treatment options for patients," said Michael Seiden, M.D., Ph.D. chief medical officer, US Oncology Research. "Physicians affiliated with US Oncology Research strive to provide access to the treatment strategies that are best suited to each patient. Given the encouraging clinical activity and favorable safety profile demonstrated by tazemetostat in these patient populations, US Oncology Research is pleased to work with Epizyme to offer this screening process so that appropriate patients being treated by an affiliated physician can be promptly directed to a clinical trial evaluating an investigational therapy that is targeted to their cancer."

USoncology-logo.jpg

US Oncology Research

Under the collaboration, US Oncology Research will implement a separate screening protocol in 68 locations in the U.S. to identify relapsed or refractory FL and DLBCL patients with tumors bearing EZH2 mutations who may be candidates for enrollment in Epizyme's ongoing Phase 2 clinical trial. US Oncology Research will direct identified patients to the tazemetostat Phase 2 clinical trial for protocol screening and potential enrollment into the trial. Sites began screening patients in July 2017.

"We are pleased that US Oncology Research, a program recognized for tremendous success in oncology clinical trials and for providing patients with access to novel treatments, is joining our effort to develop a targeted treatment for lymphoma patients with EZH2 mutations," said Peter Ho , chief medical officer of Epizyme. "This collaboration significantly expands our clinical trial footprint within the United States and is expected to further enhance our enrollment of patients whose tumors harbor an EZH2 mutation for our ongoing Phase 2 study of tazemetostat. We believe that tazemetostat has the potential to play a very important role in the targeted treatment of these patients in the future."

About Follicular Lymphoma (FL) and Diffuse Large B-Cell Lymphoma (DLBCL)
FL, an indolent form of non-Hodgkin lymphoma (NHL), is considered to be incurable with existing treatments and is characterized by cycles of relapse that become increasingly difficult to treat with each disease progression. Approximately 25,000 patients in the U.S. and major European countries are diagnosed with FL every year[1], of which 15 to 20 percent are estimated to have an EZH2 mutation. There are no approved treatments indicated for patients with FL with an EZH2 mutation. In April 2017, the FDA granted Fast Track designation to tazemetostat for FL regardless of EZH2 mutational status.

DLBCL is an aggressive form of NHL that, once diagnosed, typically requires immediate treatment. Approximately 45,000 patients are diagnosed with DLBCL in the U.S. and major European countries every year[2]. Among patients with germinal center DLBCL, an estimated 15 to 20 percent have an EZH2 mutation. Forty to 50 percent of patients will relapse on their first-line treatment, which is most commonly the chemotherapy regimen R-CHOP, and there are few treatment options for

patients who relapse or become refractory to chemotherapy. In November 2016, the FDA granted Fast Track designation to tazemetostat for DLBCL with EZH2 mutations.

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 (FL) 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 FL 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 US Oncology Research
Supported by McKesson Specialty Health and The US Oncology Network, US Oncology Research draws from a network of experienced investigators and dedicated clinical staff who specialize in oncology clinical trials. US Oncology Research serves 60 research sites and 165 locations managing about 350 active trials at any given time. Physicians in the research network have enrolled nearly 68,000 patients in over 1,500 trials since inception in 1992 and have played a role in nearly 70 FDA-approved cancer therapies, approximately one-third of all cancer therapies approved by the FDA to date. For more information visit https://www.usoncology.com/physicians/clinical-trials.

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. (the Company) 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 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 the rate of enrollment in the Company's trials will be increased meaningfully or at all; 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-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] Decision Resources, 2017
[2] Decision Resources, 2017

Contacts

Claire Crye, US Oncology Research

Claire.Crye@usoncology.com

281-825-9927

Cheya Pope, Epizyme, Inc.

media@epizyme.com

617-229-7561

Monique Allaire, THRUST IR

monique@thrustir.com

(617) 895-9511


Primary Logo

Source: Epizyme, Inc.

News Provided by Acquire Media