Epizyme Receives Fast Track Designation from U.S. FDA and Announces Initiation of Phase 1/1b Study of its Novel SETD2 Inhibitor, EZM0414

November 4, 2021

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Nov. 4, 2021-- Epizyme, Inc. (Nasdaq: EPZM), a fully integrated, commercial-stage biopharmaceutical company developing and delivering novel epigenetic therapies, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to EZM0414, the Company's novel, first-in-class, oral SETD2 inhibitor, as an investigational agent for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL). In addition, the Company has initiated a Phase 1/1b study to evaluate safety and determine the optimal dose of EZM0414. Following this dose-ranging phase, the study will be expanded to evaluate EZM0414 in three patient cohorts: t(4;14) multiple myeloma, non t(4;14) multiple myeloma, and DLBCL.

"Today we are excited to announce an important milestone for Epizyme, as we prepare to bring another investigational candidate into the clinic with the initiation of this first-in-human clinical trial of our SETD2 inhibitor, EZM0414," said Grant Bogle, President and Chief Executive Officer at Epizyme. "As leaders in pioneering therapies against novel epigenetic targets, bringing EZM0414 to the clinic is an important advancement as we strive to fulfill our vision of making transformative therapies a reality for patients living with cancer."

SETD2 is a histone methyltransferase, similar to EZH2, which plays multiple important roles in oncogenesis. Epizyme recently shared data demonstrating potent preclinical in vitro and in vivo activity for a selective inhibitor of the SETD2 histone methyltransferase at the 2021 European Hematology Association (EHA) meeting. The Company plans to share additional preclinical data and the Phase 1/1b trial design as a trial in progress at an upcoming medical meeting.

"The receipt of Fast Track designation underscores the urgent need for innovative therapies that may significantly improve the lives of patients living with devastating diseases such as DLBCL," said Dr. Shefali Agarwal, Executive Vice President and Chief Medical and Development Officer at Epizyme. "Additionally, through the initiation of our Phase 1/1b study, we look forward to evaluating the safety and efficacy of EZM0414 in both DLBCL and multiple myeloma, including high-risk t(4;14) multiple myeloma. Multiple myeloma patients with this high-risk mutation often have a poorer prognosis and is an area of high unmet medical need. We believe the inhibition of SETD2 may play an important role in treating these patients."

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.

About Epizyme, Inc.

Epizyme, Inc. is a fully integrated, commercial-stage biopharmaceutical company committed to its mission of rewriting treatment for cancer and other serious diseases through novel epigenetic medicines. The Company is focused on creating medicines that are targeted at specific causes of diseases, that are orally administered, tolerable, easy to take and based on a deep understanding of the patients that may benefit from them. The Company aspires to change the standard-of-care for patients and physicians by developing medicines with fundamentally new mechanisms of action. 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: whether commercial sales of TAZVERIK for epithelioid sarcoma and follicular lymphoma in the approved indications will be successful; whether tazemetostat will receive marketing approval for epithelioid sarcoma or follicular lymphoma in other jurisdictions, full approval in the United States or approval in any other indication; whether results from preclinical studies or earlier clinical studies will be predictive of the results of future trials, such as the ongoing confirmatory trials; whether results from clinical studies will warrant meetings with regulatory authorities, submissions for regulatory approval or review by governmental authorities under the accelerated approval process; whether the company will receive regulatory approvals, including accelerated approval, to conduct trials or to market products; the impact of the COVID-19 pandemic on the company's business, results of operations and financial condition; 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 success of tazemetostat; and other factors discussed in the "Risk Factors" section of the company's most recent Form 10-K or 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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