Epizyme Announces Data from TAZVERIK® (Tazemetostat) Clinical Programs to be Presented During Poster Sessions at 2021 ESMO Virtual Congress

September 14, 2021

- Two Poster Presentations for Tazemetostat, a Methyltransferase Inhibitor, in Metastatic Castration-Resistant Prostate Cancer and in Combinations in Patients with Solid Tumors

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Sep. 14, 2021-- Epizyme, Inc. (Nasdaq: EPZM), a fully integrated, commercial-stage biopharmaceutical company developing and delivering novel epigenetic therapies, today announced that clinical data will be presented at the upcoming 2021 European Society of Medical Oncology (ESMO) Virtual Congress, taking place on September 16-21, 2021.

At the conference there will be two posters on two of the trials examining tazemetostat use in solid tumors. One details updated data from the ongoing safety run-in portion of the EZH-1101 prostate cancer study evaluating tazemetostat in combination with either abiraterone/prednisone or enzalutamide. The second poster describes the ongoing study investigating tazemetostat's use in combination with other agents to treat solid tumors.

"Consistent with the preliminary data we shared during our Next Episode vision call earlier this year, the data presented at ESMO from our EZH-1101 study suggest tazemetostat combinations in prostate cancer led to a subset of patients having durable ≥50% decline in prostate-specific antigen levels (PSA50) with one patient having a radiographic tumor response," said Dr. Shefali Agarwal, Executive Vice President and Chief Medical and Development Officer at Epizyme. "We are encouraged to see the progression free survival data with a follow-up of almost two years in the safety run-in, and this data, while still maturing, will be shown in the poster session. Additionally, the adverse events data with the combination treatment were consistent with the known safety profile of the individual agents with no new safety signals. The randomized portion of the EZH-1101 study is ongoing with more than one-third of patients enrolled to date. This study is one part of our overall program exploring tazemetostat as both monotherapy and in combinations across multiple hematologic and solid tumor cancers."

Details of the presentations are listed below:

ESMO Poster Presentations

Title: Safety of Tazemetostat in Combination With Abiraterone/Prednisone or Enzalutamide in Patients With Metastatic Castration-Resistant Prostate Cancer
Presenters: Wassim Abida, MD, PhD; Daniel Saltzstein, MD
Abstract Code: 586P

Title: Trial in Progress: Tazemetostat in Combination With a PARP Inhibitor or Durvalumab in Patients With Solid Tumors
Presenter: Charles M. Rudin, MD, PhD; Robert L. Coleman, MD
Abstract Code: 1870TiP

The ESMO abstracts are available at https://www.esmo.org/meetings/esmo-congress-2021/abstracts. All oral and poster presentations will be available on the ESMO website on Thursday, September 16, 2021 8:30 a.m. CEST / 2:30 a.m. ET.

About TAZVERIK® (tazemetostat)

TAZVERIK is a methyltransferase inhibitor indicated for the treatment of:

- Adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.
- Adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least two prior systemic therapies.
- Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options.

These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trials.

The most common (≥20%) adverse reactions in patients with epithelioid sarcoma are pain, fatigue, nausea, decreased appetite, vomiting and constipation. The most common (≥20%) adverse reactions in patients with follicular lymphoma are fatigue, upper respiratory tract infection, musculoskeletal pain, nausea and abdominal pain.

View the U.S. Full Prescribing Information here: Epizyme.com

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. In addition to an active research and discovery pipeline, Epizyme has one U.S. FDA approved

product, TAZVERIK® (tazemetostat), for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma (ES) who are not eligible for complete resection; adult patients with relapsed or refractory follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least two prior systemic therapies; and adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options. These indications are approved under accelerated approval based on overall response rate and duration of response. Continued approval for these indications may be contingent upon verification and description of clinical benefit in confirmatory trial(s). The Company is also exploring the treatment potential of tazemetostat in investigational clinical trials in other solid tumors and hematological malignancies, as a monotherapy and combination therapy in both relapsed and front-line disease settings. By focusing on the genetic drivers of disease, Epizyme seeks to match medicines with the patients who need them. For more information, visit www.epizyme.com.

TAZVERIK® is a registered trademark of Epizyme, Inc.

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 the refinement of the company's commercial strategy and cost reductions will achieve the company's objectives; 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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