Epizyme Announces Executive Appointment and Provides Tazemetostat Clinical Update

March 15, 2022

Appointment of Jerald Korn as Chief Operating Officer

First Patient Dosed in the Randomized Portion of SYMPHONY-1 (EZH-302), Epizyme's Phase 1b/3 Confirmatory Study of Tazemetostat in Combination with R^2

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Mar. 15, 2022-- Epizyme (Nasdaq: EPZM), a fully integrated, commercial-stage biopharmaceutical company developing and delivering transformative therapies for cancer patients against novel epigenetic targets, today announced a clinical update as well as the appointment of Jerald Korn as Chief Operating Officer, reporting to President and Chief Executive Officer, Grant Bogle.

"We are excited to welcome Jerald to Epizyme at a pivotal time for the organization," said Mr. Bogle. "Jerald's breadth of experience leading a wide range of functions and working in biotech companies at our stage of development will be a welcomed addition to our senior executive team as we look to drive growth for TAZVERIK® (tazemetostat) as a monotherapy, as well as advance the tazemetostat clinical development program across both hematologic and solid tumor malignancies."

"I am thrilled to be joining Epizyme at such an important time for the company," said Mr. Korn. "I have a passion for working in the oncology space and am excited by the opportunity to help execute on the continued launch of TAZVERIK and to fulfill Epizyme's vision of developing transformative epigenetic medicines. I look forward to working alongside this incredible team as we focus on the strategic priorities where we believe we can make a meaningful impact for people living with cancer."

With more than 15 years in the biotech industry, Mr. Korn most recently served as the Chief Operating Officer and General Counsel at Kaleido Biosciences, where he oversaw legal, human resources, program management, quality, regulatory and other operations, as well as supporting the company with corporate strategy, including two financings, a pipeline prioritization and transition to a new laboratory and manufacturing facility. Prior to Kaleido, Mr. Korn held several leadership positions at TESARO, as well as senior positions at Cubist Pharmaceuticals, Millennium Pharmaceuticals (part of Takeda) and AMAG Pharmaceuticals. Mr. Korn began his career as an associate at the law firm Ropes & Gray and holds a bachelor's degree with honors in economics from Harvard University and a J.D. with honors from Boston University School of Law.

SYMPHONY-1 Clinical Update

Epizyme also reported today that the first patient has been dosed in the Phase 3 portion of the SYMPHONY-1 (EZH-302) study, a confirmatory study assessing tazemetostat in combination with rituximab + lenalidomide (R^2) compared with R^2 plus placebo in patients with relapsed or refractory follicular lymphoma (R/R FL) previously treated with at least one systemic therapy, including those who are rituximab-refractory and/or have experienced progression of disease within two years.

"Dosing the first patient in the Phase 3 portion of the SYMPHONY-1 study is an important milestone for Epizyme and our clinical development of tazemetostat in R/R FL," said Dr. Shefali Agarwal, Executive Vice President and Chief Medical and Development Officer at Epizyme. "As we enroll patients in the Phase 3 randomized portion of the study, we plan to continue to report longer term follow-up data from the Phase 1b safety run-in portion of the study as well as data from other combination studies of tazemetostat in both hematological and solid tumor malignancies that we are conducting."

Epizyme previously announced the completion of the 30-day waiting period for its protocol amendment submitted to the U.S. Food and Drug Administration in December 2021 with 800 mg twice-daily as the recommended Phase 3 dose. The Company is now engaged in global start-up activities, including sites in greater China with its collaboration partner HUTCHMED. The latest results of the Phase 1b safety run-in portion of the study were presented at the American Society of Hematology (ASH) Annual Meeting in December 2021 and can be accessed here.

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 is contingent upon verification and description of clinical benefit in confirmatory studies.

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 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 or will increase to the levels anticipated or at all; whether the prioritization of the company's development activities and cost reductions will achieve the company's objectives or forecasted cost savings; 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; 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 of the company's product candidates will be predictive of the results of future trials, such as the ongoing confirmatory trials of TAZVERIK; 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; whether the company's collaborations and licensing agreements with third parties will be successful; uncertainties as to 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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