Epizyme Reports Business Progress and First Quarter 2020 Financial Results

May 4, 2020

TAZVERIK™ Successfully Launched for First Approved Indication; PDUFA Date of June 18, 2020 for sNDA for Follicular Lymphoma Indication

Business Continuity Plans in Place in Response to COVID-19

Conference Call to be Held Today, May 4 at 9:00 a.m. ET

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 4, 2020-- Epizyme, (Nasdaq: EPZM), a fully integrated, commercial-stage biopharmaceutical company developing novel epigenetic therapies, today provided business and pipeline updates and reported first quarter 2020 financial results.

"The first quarter of 2020 was significant for Epizyme, marked by the FDA approval of TAZVERIK™ in eligible patients with epithelioid sarcoma and our transition to a commercial-stage company," said Robert Bazemore, president and chief executive officer of Epizyme. "Despite the global challenges as a result of the COVID-19 pandemic, and the continued uncertainties in the recovery process, we know that patients with cancer still need better treatments, and we remain committed to advancing innovative medicines on their behalf. In addition to continuing our commercialization of TAZVERIK for epithelioid sarcoma, a critical activity for our organization, we are preparing to launch in follicular lymphoma, should TAZVERIK be approved for that indication. We believe strongly in TAZVERIK's potential to make a meaningful impact in the lives of patients."

COVID-19 Response
In response to the ongoing COVID-19 pandemic, Epizyme has activated business continuity plans to allow for the continued advancement of TAZVERIK commercialization, tazemetostat clinical development expansion and the company's early pipeline, which are designed to minimize disruptions and protect the safety of its employees. Epizyme continues to assess the situation and any potential impact it may have on its operations, financial guidance and plans, and will provide updates accordingly. Measures implemented to date that address challenges resulting from the global pandemic include:

- **Employee Safety and Remote Operations**: A remote operating model for in-house and field-based employees was implemented in early March, with the exception of a small number of employees to continue critical lab and information technology operations.
- **Patient Access to TAZVERIK**: Epizyme is leveraging a specialty pharmacy and specialty distributors to support seamless patient access, and currently expects to be able to provide an uninterrupted supply of TAZVERIK for commercial use and the company's ongoing clinical trials.
- **U.S. Commercialization:** Epizyme is leveraging virtual personal and non-personal approaches to engage and reach customers.
- **Supporting Ongoing Clinical Trials:** Epizyme is working with clinical trial sites and clinical research organizations to implement virtual capabilities for site initiations and trial monitoring, as well as alternative methods to assist with patient participation.

Recent Progress

- **TAZVERIK Commercially Available in U.S. for Epithelioid Sarcoma (ES):** Epizyme successfully made TAZVERIK commercially available in the U.S. on February 1, 2020, following its accelerated approval on January 23, 2020, for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced ES not eligible for complete resection. Within one week from approval, the first prescriptions were filled, and the company saw continued traction in the first quarter, with physicians incorporating TAZVERIK into their treatment practices.
- **Follicular Lymphoma (FL) U.S. Commercial Launch Readiness Nearly Complete:** The U.S. Food and Drug Administration (FDA) granted Priority Review to Epizyme's supplemental New Drug Application (sNDA) filing with a PDUFA target action date of June 18, 2020 for the accelerated approval of TAZVERIK for a proposed indication of patients with relapsed or refractory FL who have received at least two prior lines of systemic therapy. To support a potential FDA approval, the company has concluded the hiring and training of its salesforce and is completing its FL launch readiness activities, which will utilize both direct and virtual approaches to physician education.
- **Company-sponsored Trials in ES, FL and Prostate Cancer Underway:** Epizyme expects to complete the ongoing safety run-in portions and begin the efficacy expansion portions of the following clinical trials in 2020:
    - Global, randomized, controlled confirmatory Phase 1b/3 trial assessing the combination of TAZVERIK plus doxorubicin compared with doxorubicin plus placebo as a front-line treatment for ES patients;
    - Global randomized, controlled confirmatory Phase 1b/3 trial assessing TAZVERIK in combination with "R^2" (Revlimid® plus rituximab) compared with R^2 plus placebo in the second-line FL treatment setting; and

- Global randomized, controlled Phase 1b/2 clinical trial in chemo-naïve patients with metastatic castration-resistant prostate cancer, assessing tazemetostat with enzalutamide or with abiraterone, standard treatments for this patient population.
- **Additional Investigator-Sponsored Trials Advancing**: Epizyme is supporting a number of investigator-sponsored studies assessing tazemetostat in multiple combinations, including in front-line and relapsed/refractory treatment settings for FL**.**

Financial Guidance

Based on its current operating plans, Epizyme continues to believe that its existing cash, cash equivalents and marketable securities will fund the company's operations into at least 2022. The company expects its non-GAAP adjusted operating expenses for 2020 will be between $235 and $255 million, which excludes any milestone payments paid by the company and non-cash items, such as stock-based compensation and amortization or depreciation of intangibles.

First Quarter 2020 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were $376.5 million as of March 31, 2020, as compared to $381.1 million as of December 31, 2019.
- **Revenue:** Total revenue for the first quarter of 2020 was $1.4 million, comprised of $1.3 million in net sales of TAZVERIK in the U.S. from the first two months of commercialization following its launch in January 2020 and $0.1 million in collaboration revenue, compared to $4.3 million in collaboration revenue for the fourth quarter of 2019, which was primarily due to revenue associated with services performed under the company's multi-target research collaboration with Boehringer Ingelheim.
- **Operating Expenses:** Total GAAP operating expenses were $52.7 million for first quarter of 2020, compared to $61.8 million for the fourth quarter of 2019. Total non-GAAP adjusted cash operating expenses, were $45.7 million for the first quarter of 2020, compared to $45.2 million for the fourth quarter of 2019.
  - **R&D expenses:** GAAP R&D expenses were $25.2 million for the first quarter of 2020, compared to $38.3 million for the fourth quarter of 2019, while non-GAAP adjusted R&D expenses were $22.9 million for the first quarter of 2020, compared to $25.8 million for the fourth quarter of 2019. The decrease was primarily due to one-time expenses related to the company's Oncology Drug Advisory Committee (ODAC) meeting and FL NDA submission in the fourth quarter of 2020.
  - **SG&A expenses:** GAAP SG&A expenses were $26.9 million for the first quarter of 2020, compared to $23.5 million for the fourth quarter of 2019, while non-GAAP SG&A adjusted expenses were $22.5 million for the first quarter of 2020, compared to $19.4 million for the fourth quarter of 2019. The increase was primarily due to expenses related to the company's buildout of its salesforce and infrastructure to support its commercial launch of TAZVERIK for the ES indication and expansion of its infrastructure to support a potential launch in FL.
- **Net Loss (GAAP):** Net loss attributable to common stockholders was $50.9 million, or $0.51 per share, for the first quarter of 2020, compared to $56.4 million, or $0.59 per share, for the fourth quarter of 2019.

A reconciliation of non-GAAP financial measures directly comparable to GAAP financial measures is presented in the table attached to this press release.

Conference Call Information

Epizyme will host a conference call today, May 4, at 9:00 a.m. ET. To participate in the conference call, please dial (877) 844-6886 (domestic) or (970) 315-0315 (international) and refer to conference ID 1329067. A webcast will be available in the investor section of the company's website at www.epizyme.com, and will be archived for 60 days following the call.

About Non-GAAP Financial Measures

In addition to financial information prepared in accordance with the U.S. generally accepted accounting principles (GAAP), this press release includes the following non-GAAP financial measures: total non-GAAP adjusted operating expenses on a historical and projected basis, non-GAAP R&D expenses on a historical basis and non-GAAP G&A expenses on a historical basis. Epizyme derives these non-GAAP financial measures by excluding certain expenses and other items from the respective GAAP financial measure, that is most directly comparable to each non-GAAP financial measure. Specifically, the non-GAAP financial measures exclude stock-based compensation expense, amortization or depreciation of intangibles and milestone payments related to TAZVERIK, which are payable under the company's collaboration agreement with Eisai Pharmaceuticals. The company's management believes that these non-GAAP financial measures are useful to both management and investors in analyzing its ongoing business and operating performance. Management does not intend the presentation of these non-GAAP financial measures to be considered in isolation or as a substitute for results prepared in accordance with GAAP, but as a complement to provide greater transparency. In addition, these non-GAAP financial measures may differ from similarly named measures used by other companies. A quantitative reconciliation of projected non-GAAP adjusted operating expenses to total operating expenses is not available without unreasonable effort primarily due to the company's inability to predict with reasonable certainty the amount of future stock-based compensation expense.

About TAZVERIK

TAZVERIK™ (tazemetostat) is the first EZH2 inhibitor approved by the U.S. Food and Drug Administration (FDA). TAZVERIK™ is an enhancer of zeste homolog 2 (EZH2) methyltransferase inhibitor indicated for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma who are not eligible for complete resection. TAZVERIK is generally well tolerated. The most common adverse reactions (≥20%) were pain, fatigue, nausea, decreased appetite, vomiting and constipation. Serious adverse reactions occurred in 37% of patients receiving TAZVERIK. Serious adverse reactions in ≥3% of patients who received TAZVERIK were hemorrhage, pleural effusion, skin infection, dyspnea, pain and respiratory distress.

This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this

indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). For more information, visit TAZVERIK.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 who are not eligible for complete resection. A supplemental New Drug Application is under Priority Review by the U.S. FDA for TAZVERIK for the treatment of patients with relapsed or refractory follicular lymphoma who have received at least two prior lines of systemic therapy. 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. 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 tazemetostat will receive marketing approval for epithelioid sarcoma in other jurisdictions, full approval in the United States or approval in any other indication on a timely basis or at all, including approval of the company's sNDA for FL; uncertainties related to the impact on the company's business of the COVID-19 pandemic, including the commercial launch of TAZVERIK, ongoing and planned clinical trials and commercial and clinical supply of TAZVERIK; 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; expectations for regulatory approvals, including accelerated approval, 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 success of tazemetostat or the company's therapeutic candidates; and other factors discussed in the "Risk Factors" section of the company's most recent Form 10-K 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.

TAZVERIK™ is a trademark of Epizyme, Inc.

EPIZYME, INC.
CONSOLIDATED BALANCE SHEET DATA (UNAUDITED)
(Amounts in thousands)

	March 31, 2020	December 31, 2019
Consolidated Balance Sheet Data:		
Cash and cash equivalents	$ 179,261	$ 139,482
Marketable securities	197,199	241,605
Intangible assets, net	24,702	—
Total assets	451,637	424,589
Total current liabilities	27,183	34,386
Deferred revenue	3,806	3,806
Long-term debt, net of debt discount	48,381	23,309
Liability related to sale of future royalties	13,087	12,793
Total stockholders' equity	$ 340,317	$ 331,137

EPIZYME, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS (UNAUDITED)
(Amounts in thousands except per share data)

	Three Months Ended March 31		Three Months Ended December 31
	2020	2019	2019
Revenues			
Product revenue, net	$ 1,284	$ -	$ -
Collaboration revenue	70	7,891	4,294
Total revenue	1,354	7,891	4,294
Operating expenses			

Cost of product revenue	614	-	-
Research and development	25,163	26,896	38,257
Selling, general and administrative	26,927	11,986	23,530
Total operating expenses	52,704	38,882	61,787
Operating loss	(51,350)	(30,991)	(57,493)
Other income, net:			
Interest income, net	756	1,658	1,320
Other (expense) income, net	(48)	(6)	21
Non-cash interest expense related to sale of future royalties	(295)	-	(192)
Other income, net:	413	1,652	1,149
Loss before income taxes	(50,937)	(29,339)	(56,344)
Income tax provision	-	-	(58)
Net loss	$ (50,937)	$ (29,339)	$ (56,402)

Reconciliation of net loss to net loss attributable to common stockholders			
Net loss	$ (50,937)	$ (29,339)	$ (56,402)
Accretion of convertible preferred stock		(2,940)	
Net loss attributable to common stockholders	$ (50,937)	$ (32,279)	$ (56,402)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.51)	$ (0.39)	$ (0.59)
Weighted-average common shares outstanding used in net loss per share attributable to common stockholders - basic and diluted	99,616	82,424	95,074

EPIZYME, INC.
Reconciliation of Selected GAAP Measures to Non-GAAP Measures (UNAUDITED)
(Amounts in thousands)

	Three Months Ended March 31		Three Months Ended December 31
Reconciliation of GAAP to Non-GAAP Cost of Product Revenue	**2020**	**2019**	**2019**
GAAP Cost of Product Revenue	$ 614	$ -	$ -
Less: Depreciation and Amortization	(298)	-	-
Non-GAAP Cost of Product Revenue	$ 316	$ -	$ -
Reconciliation of GAAP to Non-GAAP Research and Development			
GAAP Research and Development	$ 25,163	$ 26,896	$ 38,257
Less: Stock-Based Compensation Expenses	(2,162)	(1,165)	(2,294)
Less: Depreciation and Amortization	(138)	(158)	(146)
Less: Eisai R&D Milestone Expense	-	-	(10,000)
Non-GAAP Research and Development	22,863	$ 25,573	$ 25,817
Reconciliation of GAAP to Non-GAAP Selling, General and Administrative:			
GAAP Selling, General and Administrative	$ 26,927	$ 11,986	$ 23,530
Less: Stock-Based Compensation Expenses	(4,348)	(2,046)	(4,106)
Less: Depreciation and Amortization	(93)	(49)	(68)
Non-GAAP Selling, General and Administrative	$ 22,486	$ 9,891	$ 19,356
Reconciliation of GAAP to Non-GAAP Operating Expenses			
GAAP Operating Expenses	$ 52,704	$ 38,882	$ 61,787
Less: Stock-Based Compensation Expenses	(6,510)	(3,211)	(6,400)
Less: Depreciation and Amortization	(529)	(207)	(214)
Less: Eisai R&D Milestone Expense	-	-	(10,000)
Non-GAAP Operating Expenses	$ 45,665	$ 35,464	$ 45,173

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