March 12, 2020

CymaBay Reports Fourth Quarter and Fiscal Year End 2019 Financial Results and Provides Corporate Update

Investigating unexpected findings from Phase 2b study of seladelpar in NASH

In parallel, board and management evaluating all potential strategic alternatives to maximize shareholder value and implementing cost containment efforts

Conference call and webcast today at 4:30 p.m. ET

NEWARK, Calif., March 12, 2020 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ: CBAY), a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet need, today announced corporate updates and financial results for the fourth quarter and fiscal year ended December 31, 2019.

“Since announcing the decision to halt the development of seladelpar last November, we have been focused on two parallel initiatives: an investigation of the unexpected histologic findings identified by study pathologists in the Phase 2b study of seladelpar in NASH, and an evaluation of strategic alternatives to maximize shareholder value,” said Sujal Shah, President and CEO of CymaBay. “Our investigation includes several key activities that will be essential for us to understand the nature and significance of the findings and have the requisite follow-up dialogue with the FDA which we are planning for before the end of the second quarter.”

Shah continued, “In parallel to this investigation, our executive team and board have been focused on a comprehensive evaluation of strategic alternatives and cost-cutting initiatives. While we remain committed to completing the investigation, we believe these efforts are prudent in order to make decisions expeditiously once we gain needed clarity on the potential path forward for seladelpar.”

Recent Business Highlights

- The development of seladelpar was halted in all indications after consulting with expert liver pathologists and hepatologists and in consideration of patient safety. The FDA agreed with this decision, formally placed the seladelpar program on clinical hold for all indications, and subsequently provided input on plans to further investigate the situation. Since then, CymaBay has commenced an in-depth review of the Phase 2b NASH findings. This investigation includes three activities intended to confirm and subsequently understand the significance of the findings identified by study pathologists:
    - First, a comprehensive collection and review of data including patient demographics, medical history, concomitant medications and a broad set of biochemical markers.
    - Second, a blinded, independent review of baseline and end of treatment biopsies by several, world-renowned liver pathologists. The independent pathology review will include an accepted pathology scoring framework, known as the Ishak Modified HAI scoring system, to quantitatively characterize features of histology present in our patient population both at baseline and at end-of-treatment. Among these features includes a scoring for the presence and severity of interface hepatitis which is not quantified in the existing framework for scoring NASH pathology.
    - Third, a formal pathology and clinical hepatology review panel meeting that CymaBay anticipates convening in the middle of the second quarter during which experts will review all information gathered to provide a consensus and independent determination of the role of seladelpar in the Phase 2b NASH findings. This panel will allow for a properly informed dialogue with FDA regarding seladelpar development.

- Completed reading of the Phase 2b NASH end-of-treatment biopsies by study pathologists. Preliminary results reported below are for the 152 patients out of the 181 patients enrolled in the study with paired biopsies at entry and end-of-study:

Phase 2b Preliminary Topline Results

Proportion of Patients Achieving Endpoints at End of Study	Placebo (N = 25)	Seladelpar 10 mg (N = 39)	Seladelpar 20 mg (N = 42)	Seladelpar 50 mg (N = 46)
Fibrosis improvement (≥1 stage) with no worsening of NASH	20.0 %	23.1 %	23.8 %	37.0 %
Resolution of NASH with no worsening of fibrosis	8.0 %	10.3 %	19.0 %	26.1 %
Fibrosis improvement and resolution of NASH	8.0 %	5.1 %	11.9 %	19.6 %

* Statistics pending final analysis.

- Resolution of NASH defined as patients having a NAFLD Activity Score (NAS) of 0 or 1 for lobular inflammation and 0 for hepatocellular ballooning.
- Patients that did not have end-of-study biopsies are not included in reported histology endpoints.
- Measured changes from baseline to end-of-treatment in liver enzymes including ALT, AST, GGT and ALP, resembled the pattern of meaningful reductions previously reported at week 12.

- Implemented cost containment and restructuring program following the decision to place the seladelpar program on hold in order to minimize expenses and conserve capital. As part of this program, CymaBay froze hiring, significantly scaled-back future procurement plans, reduced its work force by more than 60% and scaled down or cancelled many existing contracts for goods and services. The size of the Board of Directors has also been decreased from nine to five seats.
    - As a result of these actions, CymaBay recorded a $5.1 million restructuring charge during the fourth quarter which includes $2.9 million of employee severance costs, $0.9 million of non-cash stock-based compensation expense associated with the acceleration of stock options of certain terminated employees, and $1.3 million of charges associated with the termination of certain contract manufacturing agreements.
- Held $190.9 million in cash, cash equivalents and short-term investments at December 31, 2019.

Fourth Quarter and Year Ended December 31, 2019 Financial Results

- Research and development expenses for the three and twelve months ended December 31, 2019 were $20.9 million and $83.8 million, respectively. This compared to R&D expenses of $16.4 million and $58.1 million for the three and twelve months ended December 31, 2018, respectively. Prior to the decision to halt development of seladelpar in November 2019, research and development expenses in the fourth quarter and twelve months ended 2019 were generally higher than in the corresponding periods in 2018 due to expanding clinical trial activities related to the PBC Phase 3 clinical trial, PSC Phase 2 clinical trial, and other NDA-enabling studies.
- General and administrative expenses for the three and twelve months ended December 31, 2019 were $4.5 million and $19.2 million, respectively. This compared to $4.2 million and $14.4 million for the three and twelve months ended December 31, 2018, respectively. Prior to the decision to halt development of seladelpar, G&A expenses in the fourth quarter and twelve months ended 2019 were higher than in the corresponding periods in 2018 as a result of higher labor costs and other administrative expenses necessary to support expanding development activities.
- Net loss for the three and twelve months ended December 31, 2019 was $29.4 million, or ($0.43) per diluted share, and $102.8 million, or ($1.53) per diluted share, respectively. This compared to net loss of $19.4 million, or ($0.32) per diluted share, and $72.5 million, or ($1.26) per diluted share, in the three and twelve months ended December 31, 2018, respectively. Net loss was higher largely due to increases in operating expenses, including restructuring charges.

Conference Call Details

CymaBay will host a conference call today at 4:30 p.m. ET to discuss fourth quarter and fiscal year end 2019 financial results and provide a business update. To access the live conference call, please dial 855-327-6837 from the U.S. and Canada, or 631-891-4304 internationally, Conference ID# 10008868. To access the live and subsequently archived webcast of the conference call, go to the Investors section of the company's website at http://ir.cymabay.com/events.

About CymaBay
CymaBay Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet medical need.

Cautionary Statements
The statements in this press release regarding the timing of completion and outcome of the investigation into the seladepar histological findings, the potential benefits of seladelpar to patients with NASH, CymaBay's expectations and plans regarding current and future clinical trials and CymaBay's ability to fund current and planned clinical trials are forward looking statements that are subject to risks and uncertainties. Actual results and the timing of events regarding the further development of seladelpar could differ materially from those anticipated in such forward-looking statements as a result of risks and uncertainties, which include, without limitation, risks related to: the success, cost and timing of any of CymaBay's product development activities, including clinical trials; effects observed in trials to date that may not be repeated in the future; any delays or inability to obtain or maintain regulatory approval of CymaBay's product candidates in the United States or worldwide; and the ability of CymaBay to obtain sufficient financing to complete development, regulatory approval and commercialization of its product candidates in the United States and worldwide or to potentially restart clinical trials. Additional risks relating to CymaBay are contained in CymaBay's filings with the Securities and Exchange Commission, including without limitation its most recent Annual Report on Form 10-K and other documents subsequently filed with or furnished to the Securities and Exchange Commission. CymaBay disclaims any obligation to update these forward-looking statements except as required by law.

For additional information about CymaBay visit www.cymabay.com.

Contact:
Sloane & Company
Dan Zacchei / Joe Germani, 212-486-9500
Dzacchei@sloanepr.com / JGermani@sloanepr.com

CymaBay Therapeutics, Inc.
Financial Results
(In thousands, except share and per share information)

	Quarter Ended December 31,		Year Ended December 31,	
	2019 (unaudited)	2018 (unaudited)	2019	2018
Operating expenses:				
Research and development	$ 20,937	$ 16,397	$ 83,837	$ 58,124
General and administrative	4,532	4,158	19,238	14,381
Charges on restructuring	5,075	-	5,075	-
Total operating expenses	30,544	20,555	108,150	72,505
Loss from operations	(30,544)	(20,555)	(108,150)	(72,505)
Other income (expense):				
Interest income	1,131	1,106	5,342	3,988
Interest expense	-	-	-	(336)
Loss on extinguishment of debt	-	-	-	(407)
Other expense, net	-	-	-	(3,288)
Total other income (expense)	1,131	1,106	5,342	(43)
Net loss	$ (29,413)	$ (19,449)	$ (102,808)	$ (72,548)
Basic net loss per common share	$ (0.43)	$ (0.32)	$ (1.53)	$ (1.25)
Diluted net loss per common share	$ (0.43)	$ (0.32)	$ (1.53)	$ (1.26)
Weighted average common shares outstanding used to calculate basic net loss per common share	68,749,075	59,448,000	67,033,046	57,808,254
Weighted average common shares				

outstanding used to calculate diluted net loss per common share	68,749,075	59,448,000	67,033,046	57,838,299

CymaBay Therapeutics, Inc.
Balance Sheet Data
(In thousands)

	December 31, 2019	December 31, 2018
Cash, cash equivalents and marketable securities	$ 190,945	$ 178,664
Working capital	185,287	167,147
Total assets	205,727	186,747
Total liabilities	19,379	16,329
Common stock and additional paid-in capital	812,140	693,540
Total stockholders' equity	186,348	170,418

Source: CymaBay Therapeutics, Inc.