November 6, 2018

CymaBay Reports Third Quarter 2018 Financial Results and Provides Corporate Update

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

NEWARK, Calif., Nov. 06, 2018 (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 financial results and a corporate update for the quarter and nine months ended September 30, 2018.

“We continue to make excellent progress advancing our lead candidate, seladelpar, in two indications -- primary biliary cholangitis (PBC) and nonalcoholic steatohepatitis (NASH),” said Sujal Shah, President and CEO of CymaBay. “Last week we announced the initiation of ENHANCE, a global Phase 3 registration study of seladelpar for patients with PBC. In addition, 52- and 26-week results from our Phase 2 PBC study will be featured in two late-breaking presentations at The Liver Meeting® on November 12. We believe these data support the potential for seladelpar to offer patients with PBC improved efficacy and better tolerability than existing second line treatment while also significantly de-risking the ongoing Phase 3 study. Enrollment in our ongoing Phase 2b study of seladelpar for patients with NASH has been progressing well. We now expect to complete enrollment in the first quarter of 2019, one quarter ahead of our previous guidance. As the only highly selective and potent PPARδ agonist in development for liver disease, we think it may be particularly well suited to treat NASH because of its beneficial effects on lipid, glucose, and sterol metabolism, as well as its effects on inflammation and fibrogenesis. As we approach the end of 2018, our entire team remains committed to these core programs for which we look forward to providing further updates in 2019.”

Third Quarter 2018 and Recent Business Highlights

- Initiated ENHANCE, a global Phase 3 registration study evaluating 5 and 10 mg of seladelpar versus placebo for the treatment of PBC in patients that are inadequate responders to or are intolerant to ursodeoxycholic acid (UDCA)
    - The study is designed to support the submission of a global registration dossier with Health Authorities to obtain approval of seladelpar in PBC
- Two late-breaking presentations featuring positive data from an ongoing Phase 2 study of seladelpar in PBC will be featured during The Liver Meeting® hosted by the American Association for the Study of Liver Diseases (AASLD) in San Francisco, November 9-13, 2018
    - The 52-week composite responder rates in the ongoing Phase 2 study for the 5 mg / 5 mg to 10 mg titration and 10 mg seladelpar groups were 59% and 71%, respectively
    - Results suggest that seladelpar is not associated with drug-induced pruritus and

may support the hypothesis that seladelpar decreases pruritus in PBC patients
    - This is the third consecutive year that data on seladelpar in PBC will be highlighted in a late-breaking presentation at The Liver Meeting®
- Patient recruitment in the placebo-controlled Phase 2b proof-of-concept study investigating seladelpar at three doses in biopsy-proven NASH is one quarter ahead of schedule and is now expected to be fully enrolled in the first quarter of 2019
    - The primary efficacy outcome is the change from baseline in liver fat content at 12 weeks as measured by magnetic resonance imaging using the proton density fat fraction method (MRI-PDFF)
    - The study also includes a second biopsy at 52 weeks to examine its activity on NASH and fibrosis
- Appointed key individuals to expand and strengthen the development organization to execute the seladelpar Phase 3 program and deliver a high-quality registration package
    - Dr. Patricia Rohane, M.D., appointed Vice President, Clinical Development
    - Dr. Stephen Rossi, Pharm. D., appointed Vice President, Early Clinical Development
    - Kamal Sigel, M.S., appointed Vice President, Quality
- Held $198.1 million in cash, cash equivalents and marketable securities at September 30, 2018. Existing cash is expected to fund the current operating plan into 2021.

Third Quarter 2018 Financial Results

- Research and development expenses were $17.9 million in the third quarter of 2018 as compared to $4.2 million in the same period of 2017. The increase was primarily driven by increases in seladelpar-related clinical trial expenses from the expansion and extension of our PBC Phase 2 study, start-up activities related to our PBC Phase 3 study, the ongoing enrollment of our NASH Phase 2b study, and the execution of other NDA-enabling studies.
- General and administrative expenses were $3.3 million in the third quarter of 2018 as compared to $2.2 million in the same period of 2017. The increase was driven primarily by employee compensation expense as we hired additional personnel to support our expanding operations.
- Net loss was $18.6 million, or ($0.34) per diluted share in the third quarter of 2018, as compared to $8.2 million, or ($0.21) per diluted share in the same period of 2017. Net loss was higher primarily due to increased research and development expenses, partially offset by non-cash gains on the revaluation and extinguishment of our warrant liability.

Nine Months Ended September 30, 2018 Financial Results

- No collaboration revenue was recognized in the nine months ended September 30, 2018. Collaboration revenue from Kowa Pharmaceuticals America, Inc. totaling $4.8 million was recognized in the same period of 2017.
- Research and development expenses were $41.7 million in the nine months ended September 30, 2018 as compared to $12.3 million in the same period of 2017. The increase was primarily driven by increases in seladelpar-related clinical trial expenses from the expansion and extension of our PBC Phase 2 study, start-up activities related to our PBC Phase 3 study, the ongoing enrollment of our NASH Phase 2b study, and

the execution of other NDA-enabling studies.

- General and administrative expenses were $10.2 million in the nine months ended September 30, 2018, as compared to $9.5 million in the same period of 2017. The increase was driven primarily by higher compensation and consulting expenses, partially offset by decreases in severance and legal fees.
- Net loss was $53.1 million, or ($0.93) per diluted share in the nine months ended September 30, 2018, as compared to $22.5 million, or ($0.71) per diluted share in the same period of 2017. Net loss was higher primarily due to increased research and development expenses and lower collaboration revenue.

Conference Call Details

CymaBay management will host a conference call today at 4:30 p.m. ET to discuss third quarter 2018 financial results and provide a business update. To access the live conference call, please dial 877-407-0784 from the U.S. and Canada, or 201-689-8560 internationally, Conference ID# 13683385. 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 Seladelpar

Seladelpar is a potent, selective, orally active PPARδ agonist that is in development for the treatment of the liver diseases PBC and NASH. For PBC, seladelpar has received an orphan designation from the US Food and Drug Administration and the European Medicine Agency. Seladelpar also received the ***PRI***ority ***ME***dicine (PRIME) status from the European Medicine Agency.

About CymaBay

CymaBay Therapeutics, Inc. (CBAY) is a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet medical need. Seladelpar is a potent, selective, orally active PPARδ agonist, currently in development for the treatment of patients with primary biliary cholangitis (PBC), an autoimmune liver disease, and with nonalcoholic steatohepatitis (NASH). Two Phase 2 studies of seladelpar established proof-of-concept in PBC. CymaBay is currently conducting a Phase 3 study of seladelpar for PBC and a Phase 2b study of seladelpar for NASH.

Cautionary Statements

The statements in this press release regarding the potential for seladelpar to treat PBC and NASH, the potential benefits to patients, 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. 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:
Hans Vitzthum
LifeSci Advisors, LLC
212-915-2568
Hans@LifeSciAdvisors.com

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	**2017**	**2018**	**2017**
Collaboration revenue	$ -	$ -	$ -	$ 4,793
Operating expenses:				
Research and development	17,853	4,184	41,727	12,269
General and administrative	3,276	2,210	10,223	9,493
Total operating expenses	21,129	6,394	51,950	21,762
Loss from operations	(21,129)	(6,394)	(51,950)	(16,969)
Other income (expense):				
Interest income	1,113	216	2,882	297
Interest expense	-	(258)	(336)	(846)
Loss on extinguishment of debt	-	-	(407)	-
Other income (expense), net	1,453	(1,798)	(3,288)	(4,996)
Total other income (expense)	2,566	(1,840)	(1,149)	(5,545)
Net loss	$ (18,563)	$ (8,234)	$ (53,099)	$ (22,514)
Basic net loss per common share	$ (0.31)	$ (0.21)	$ (0.93)	$ (0.71)
Diluted net loss per common share	$ (0.34)	$ (0.21)	$ (0.93)	$ (0.71)
Weighted average common shares outstanding used to calculate basic net loss per common share	59,121,600	40,035,690	57,255,666	31,848,536
Weighted average common shares outstanding used to calculate diluted net loss per common share	59,387,780	40,035,690	57,298,105	31,848,536

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

	September 30, 2018 (unaudited)	December 31, 2017
Cash, cash equivalents and short-term investments	$ 198,145	$ 97,210
Working Capital	188,615	87,234
Total assets	203,708	104,247
Facility loan	-	6,098
Warrant liability	-	6,091
Total liabilities	15,577	19,300
Common stock and additional paid-in capital	691,777	535,507
Total stockholders' equity	188,131	84,947

Source: CymaBay Therapeutics, Inc.