November 5, 2019

CymaBay Reports Third Quarter 2019 Financial Results and Provides Corporate Update

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

NEWARK, Calif., Nov. 05, 2019 (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 ended September 30, 2019.

“The third quarter marked one of our most productive periods, culminating in reaching target enrollment in ENHANCE, our global, Phase 3 registration study of seladelpar in PBC, earlier than originally projected,” said Sujal Shah, President and CEO of CymaBay. “We expect to complete enrollment in ENHANCE by the end of November and remain on track to report topline data from this 52-week study in early 2021. We also made significant progress in our efforts to expand development of seladelpar into a second rare, cholestatic liver disease with the initiation of our Phase 2 dose-ranging study in PSC. As our development activities advance in the coming months, we look forward to topline data from our completed open-label Phase 2 study in PBC, and topline 52-week biopsy data from our Phase 2b study in NASH, in the first and second quarters of 2020, respectively.”

Third Quarter and Recent Business Highlights

- Reached target enrollment of 240 patients in ENHANCE, our global, Phase 3 registration study of seladelpar for the treatment of primary biliary cholangitis (PBC).
    - The study is expected to be fully enrolled by the end of November 2019 with topline data release anticipated in early 2021.
- Initiated a Phase 2 clinical study of seladelpar in primary sclerosing cholangitis (PSC).
    - The Phase 2 study is a randomized, placebo-controlled, dose-ranging study that will enroll approximately 100 patients at 60 sites globally.
    - Patients will be randomized to placebo or seladelpar 5, 10 or 25 mg in a 1:1:1:1 randomization.
    - The study includes an interim assessment of safety and efficacy after approximately 10 patients in each dose group reach 12 weeks of treatment.
- Confirmed additional pharmacodynamic effects in the 12-Week interim analysis of the Phase 2b dose-ranging study in NASH.
    - Dose-dependent decreases of plasma C4 of up to 55% at 50 mg, a key mechanistic marker of hepatocellular bile acid synthesis.
    - Dose-dependent increases in carnitine and short-chain acyl carnitines of over 35% considered to be plasma markers of increased lipid metabolism.
    - No significant effects were observed using the ELF panel, a plasma-based marker of fibrosis, or in corrected-T1, an exploratory magnetic resonance imaging method being developed to identify inflammation associated with NASH.

These measures will be assessed at additional timepoints as the study continues.
    - The study remains blinded until the 52-week liver histology endpoint, expected in 2Q 2020.
- Announced acceptance of two abstracts for presentation at The Liver Meeting® hosted by the American Association for the Study of Liver Diseases (AASLD) in Boston, MA (November 8-12, 2019).
    - “Pharmacokinetics of Seladelpar in Patients with Primary Biliary Cholangitis, with or without Cirrhosis” (Publication #1328)
    - “Structural and Biophysical Characterization of the Origins of the Selectivity of Seladelpar and Elafibranor, Peroxisomal Proliferator Activated Receptor (PPAR) Agonists Targeting Inflammatory Liver Diseases” (Publication #2253)

Third Quarter Financial Highlights & Results

- Held $218.6 million in cash, cash equivalents and marketable securities at September 30, 2019. Existing cash is expected to fund the current operating plan into 2021.
- Research and development expenses were $23.2 million in the third quarter of 2019 as compared to $17.9 million in the same period of 2018. The increase was primarily driven by higher manufacturing costs incurred to support our ongoing clinical trials and registration batches as well as a severance expense incurred due to the departure of an executive.
- General and administrative expenses were $4.5 million in the third quarter of 2019 as compared to $3.3 million in the same period of 2018. The increase was driven primarily by higher employee compensation and other administrative expenses as we hired additional personnel to support our expanding operations.
- Net loss was $26.3 million, or ($0.38) per diluted share in the third quarter of 2019, as compared to $18.6 million, or ($0.34) per diluted share in the same period of 2018. Net loss was higher primarily due to increased research and development expenses.

Nine Months Ended September 30, 2019 Financial Highlights & Results

- Raised $107.7 million in net proceeds through our March public offering of common stock.
- Research and development expenses were $62.9 million in the nine months ended September 30, 2019 as compared to $41.7 million in the same period of 2018. The increase was primarily driven by increases in seladelpar-related clinical trial expenses including enrollment activities related to our ENHANCE PBC Phase 3 clinical study, start-up and enrollment activities related to our PSC Phase 2 clinical study, higher manufacturing costs incurred to support our ongoing clinical trials and registration batches, and execution of other NDA-enabling studies.
- General and administrative expenses were $14.7 million in the nine months ended September 30, 2019 as compared to $10.2 million in the same period of 2018. The increase was driven primarily by higher employee compensation expense and other administrative expenses as we hired additional personnel to support our expanding operations.
- Net loss was $73.4 million, or ($1.10) per diluted share in the nine months ended September 30, 2019 as compared to $53.1 million, or ($0.93) per diluted share in the same period of 2018. Net loss was higher primarily due to increased research and development expenses.

Conference Call Details
CymaBay management will host a conference call today at 4:30 p.m. ET to discuss third quarter 2019 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# 13694084. 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. CymaBay's lead development candidate, seladelpar, is a potent, selective and orally active PPARδ agonist currently in development for the treatment of patients with primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC), and nonalcoholic steatohepatitis (NASH). CymaBay is evaluating seladelpar in a global, Phase 3 registration study in PBC, a Phase 2 dose-ranging study in PSC and a Phase 2b dose-ranging study in NASH.

For additional information about CymaBay visitwww.cymabay.com.

Cautionary Statements
The statements in this press release regarding the potential for seladelpar to treat PBC, PSC and NASH, the potential benefits to patients, the success, timing and progress of clinical trials and timing of the release of clinical results, CymaBay's expectations and plans regarding current and future clinical trials, anticipated cash runway, 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 visitwww.cymabay.com.

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

	Quarter Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Operating expenses:				
Research and development	$ 23,193	$ 17,853	$ 62,900	$ 41,727
General and administrative	4,514	3,276	14,706	10,223
Total operating expenses	27,707	21,129	77,606	51,950
Loss from operations	(27,707)	(21,129)	(77,606)	(51,950)
Other income (expense):				
Interest income	1,425	1,113	4,211	2,882
Interest expense	-	-	-	(336)
Loss on extinguishment of debt	-	-	-	(407)
Other income (expense), net	-	1,453	-	(3,288)
Total other income (expense)	1,425	2,566	4,211	(1,149)
Net loss	$ (26,282)	$ (18,563)	$ (73,395)	$ (53,099)
Basic net loss per common share	$ (0.38)	$ (0.31)	$ (1.10)	$ (0.93)
Diluted net loss per common share	$ (0.38)	$ (0.34)	$ (1.10)	$ (0.93)
Weighted average common shares outstanding used to calculate basic net loss per common share	68,701,043	59,121,600	66,454,750	57,255,666
Weighted average common shares outstanding used to calculate diluted net loss per common share	68,701,043	59,387,780	66,454,750	57,298,105

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

	September 30, 2019	December 31, 2018
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 218,594	$ 178,664
Working capital	210,413	167,147
Total assets	231,800	186,747
Total liabilities	19,209	16,329
Common stock and additional paid-in capital	808,873	693,540
Total stockholders' equity	212,591	170,418

Source: CymaBay Therapeutics, Inc.