

May 8, 2019

# CymaBay Reports First Quarter 2019 Financial Results and Provides Corporate Update

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

NEWARK, Calif., May 08, 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 March 31, 2019.

“The first quarter of 2019 was highlighted by significant clinical and regulatory accomplishments that continue to accelerate and support the development of seladelpar in PBC and NASH,” said Sujal Shah, President and CEO of CymaBay. “In February, we completed enrollment one quarter ahead of schedule in our 52-week, dose-ranging Phase 2b study of seladelpar in patients with NASH, putting us in a position to announce topline data for changes in liver fat, lipids and transaminases at week 12 before the end of the second quarter. Also in February, we announced the FDA granted seladelpar Breakthrough Therapy Designation for patients with early stage PBC. Our progress supported a successful capital raise in March that will now allow us to advance clinical development of seladelpar into a third inflammatory liver disease, primary sclerosing cholangitis (PSC) in the second half of this year. We could not be more pleased with the progress we have made to date and the depth of our overall development program for seladelpar.”

## First Quarter Business Highlights

- Enrollment was completed in a Phase 2b dose-ranging, paired liver biopsy study of seladelpar for the treatment of nonalcoholic steatohepatitis (NASH).
  - A total of 181 patients enrolled with elevated liver fat and biopsy-confirmed NASH.
  - Topline data on the primary efficacy outcome, 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) as well as changes from baseline to 12 weeks in alanine aminotransferase (ALT), low-density lipoprotein C (LDL-C) and triglycerides are expected before the end of 2Q 2019.
- The U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for seladelpar for the treatment of early stage primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adult patients with an inadequate response to UDCA, or as monotherapy in adults unable to tolerate UDCA.
- Continued enrollment of ENHANCE, a global, Phase 3 registration study of seladelpar for the treatment of primary biliary cholangitis (PBC).
  - ENHANCE is being conducted in more than 150 centers in over 20 countries. The study is intended to establish the efficacy and safety of seladelpar for the treatment of PBC to support the submission of a global registration dossier with

- health authorities to obtain approval.
- The study is expected to be fully enrolled by the end of 2019 with the 52-week treatment period targeted to be completed by the end of 2020 and top-line data in 2021.
- Data from an ongoing Phase 2 study of seladelpar in PBC and certain preclinical studies were presented at the International Liver Congress™ 2019 hosted by the European Association for the Study of the Liver in Vienna, Austria.
  - An interim analysis of data from the ongoing Phase 2 study in PBC highlighted comparable anti-cholestatic and anti-inflammatory effects as well as comparable safety and tolerability for seladelpar in non-cirrhotic PBC patients and those with Child-Pugh A cirrhosis.

## **First Quarter Ended March 31, 2019 Financial Highlights & Results**

- Raised \$107.7 million in net proceeds through our March public offering of common stock.
- Held \$264.8 million in cash, cash equivalents and marketable securities at March 31, 2019. Existing cash is expected to fund the current operating plan into 2021.
- Research and development expenses were \$18.6 million in the first quarter of 2019 as compared to \$9.5 million in the same period of 2018. The increase was primarily driven by increases in seladelpar-related clinical trial expenses including:
  - start-up and enrollment activities related to our ENHANCE PBC Phase 3 clinical study
  - ongoing treatment of patients in our NASH Phase 2b clinical study
  - continued treatment of patients in our PBC Phase 2 clinical study
  - execution of other NDA-enabling studies
- General and administrative expenses were \$5.7 million in the first quarter of 2019 as compared to \$3.4 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 \$23.1 million, or (\$0.37) per diluted share in the first quarter of 2019, as compared to \$17.0 million, or (\$0.32) 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 first 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# 13688866. 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 PPAR $\delta$  agonist currently in development for the treatment of patients with primary biliary cholangitis (PBC), an autoimmune liver disease, and with nonalcoholic steatohepatitis (NASH). CymaBay is currently enrolling patients in placebo-controlled, randomized, phase

3 study to evaluate the safety and efficacy of seladelpar (ENHANCE), a global, Phase 3 registration study of seladelpar for PBC. Seladelpar received orphan designation for PBC from the U.S. Food and Drug Administration (FDA) and the European Medicine Agency (EMA). Seladelpar also received Breakthrough Therapy Designation for PBC from the FDA and Priority Medicine status from the EMA. CymaBay is also conducting a Phase 2b proof-of-concept study of seladelpar for patients with NASH.

For additional information about CymaBay visit [www.cymabay.com](http://www.cymabay.com).

### **Cautionary Statements**

The statements in this press release regarding the potential for seladelpar to treat PBC and NASH, the potential benefits to patients, the timing of clinical trials and release of clinical results, 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](http://www.cymabay.com).

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

	<b>Quarter Ended March 31,</b>	
	<b>2019</b>	<b>2018</b>
	<b>(unaudited)</b>	<b>(unaudited)</b>
Operating expenses:		
Research and development	\$ 18,588	\$ 9,477
General and administrative	5,663	3,373
Total operating expenses	<u>24,251</u>	<u>12,850</u>
Loss from operations	(24,251 )	(12,850 )
Other income (expense):		
Interest income	1,176	708
Interest expense	-	(208 )
Other expense, net	-	(4,655 )
Total other income (expense)	<u>1,176</u>	<u>(4,155 )</u>
Net loss	<u><u>\$ (23,075 )</u></u>	<u><u>\$ (17,005 )</u></u>
Basic net loss per common share	\$ (0.37 )	\$ (0.32 )
Diluted net loss per common share	\$ (0.37 )	\$ (0.32 )
Weighted average common shares outstanding used to calculate basic net loss per common share	61,890,632	53,752,753
Weighted average common shares outstanding used to calculate diluted net loss per common share	61,890,632	53,752,753

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

	<b>March 31, 2019</b>	<b>December 31, 2018</b>
	<b>(unaudited)</b>	
Cash, cash equivalents and marketable securities	\$ 264,756	\$ 178,664
Working capital	255,591	167,147
Total assets	274,157	186,747
Total liabilities	16,526	16,329
Common stock and additional paid-in capital	803,725	693,540
Total stockholders' equity	257,631	170,418



Source: CymaBay Therapeutics, Inc.