CymaBay Reports First Quarter 2017 Financial Results and Provides Corporate Update

Conference call and webcast today, 4:30pm Eastern Time

NEWARK, Calif., May 11, 2017 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), a clinical-stage biopharmaceutical company developing therapies to treat specialty and orphan diseases with high unmet medical need, today announced financial results and a corporate update for the quarter ended March 31, 2017.

"Our primary therapeutic focus at CymaBay today is in liver disease. We believe we are well positioned to advance our lead development candidate, seladelpar, for patients with primary biliary cholangitis (PBC), and to subsequently implement a broader strategy to expand the development of seladelpar in other liver diseases, including nonalcoholic steatohepatitis (NASH)," said Sujal Shah, Interim President and Chief Executive Officer of CymaBay Therapeutics. "Our second Phase 2 dose-ranging study investigating seladelpar in PBC is progressing well, and we look forward to announcing key interim data expected in the third quarter. We view the announcement of these data as a significant milestone for the company and a key event to trigger planning and launch of a Phase 3 program for seladelpar in PBC."

First Quarter 2017 and Recent Business Highlights

Seladelpar - An oral, potent and selective PPARδ agonist currently in an ongoing Phase 2 dose-ranging study in patients with PBC.

- Reached target enrollment of 24 patients for the planned interim analysis of the initial 5 mg and 10 mg dose groups. Interim data analysis expected in Q3 2017.
- The primary efficacy endpoint in the study is the change from baseline in alkaline phosphatase (ALP), a key biomarker for anti-cholestatic activity accepted as part of a composite endpoint for accelerated approval in the U.S. and Europe.
- Presented additional clinical data, including markers of cholesterol absorption, cholesterol synthesis and bile acid synthesis, from a prior Phase 2 proof-of-concept study of seladelpar in PBC at the International Liver Congress™ sponsored by the European Association for the Study of Liver Diseases (EASL) in Amsterdam, The Netherlands.

Arhalofenate - A Phase 3-ready oral, dual-acting drug candidate for gout that lowers serum uric acid (sUA) through a uricosuric effect and has an anti-inflammatory (anti-IL-1 β) activity that suppresses flares.

 Announced an exclusive license agreement with Kowa Pharmaceuticals America, Inc. for the rights to develop and commercialize arhalofenate in the United States and its territories and possessions.

- Received an up-front payment of \$5 million. CymaBay is eligible to receive additional near term milestone payments of \$10 million based on the initiation of specific development activities by Kowa, up to an additional \$190 million in payments based upon the achievement of specific development and sales milestones, and tiered, double-digit royalties on future sales of arhalofenate products.
- Hosted a kick-off meeting with an interdisciplinary team from Kowa and the first Joint Advisory Committee meeting supporting technology transfer of the arhalofenate program.

Corporate Updates

- Announced the promotion of Sujal Shah, to Interim President and Chief Executive Officer.
- Raised \$9.2 million after deducting underwriting discounts, commissions, and other
 offering expenses in a public offering of 5.2 million shares of common stock at a public
 offering price of \$1.93 per share.

First Quarter 2017 Financial Results

- Cash, cash equivalents and marketable securities totaled \$23.4 million at the end of the first quarter of 2017. Management believes it has funds sufficient to fund operations through at least the next 12 months.
- \$4.8 million of collaboration revenue was recognized in the first quarter of 2017 related to the Kowa license and collaboration agreement. No collaboration revenue was reported in the first quarter of 2016.
- Research and development expenses were \$4.0 million in the first quarter of 2017, as compared to \$4.4 million in the first quarter of 2016. R&D expenses in the first quarter of 2017 were largely in line with the prior year period as expenses associated with conducting the second Phase 2 study in PBC were similar to those from the first Phase 2 study in PBC conducted in 2016.
- General and administrative expenses were \$3.7 million in the first quarter of 2017, as compared to \$2.5 million in the first quarter of 2016. The increase in G&A expenses in the first quarter of 2017 as compared to the prior year period was primarily due to severance expenses associated with the announced retirement of the Company's former CEO on March 29, 2017.
- Net loss was \$5.4 million, or (\$0.20) per diluted share in the first quarter of 2017, as compared to \$6.8 million, or (\$0.29) per diluted share in the first quarter of 2016. Net loss in the first quarter of 2017 was \$1.4 million lower as compared to the prior year period primarily due to the recognition of collaboration revenue in 2017, offset by one-time severance related expenses and a non-cash mark-to-market loss on the revaluation of the Company's warrant liability.

Conference Call

CymaBay management will host a conference call today at 4:30 p.m. ET to discuss first quarter 2017 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# 13661044. 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. (CBAY) is a clinical-stage biopharmaceutical company focused on developing therapies for specialty and orphan diseases with high unmet medical need. Seladelpar is a potent, selective, orally active PPARδ agonist currently in development for the treatment of patients with the autoimmune liver disease, primary biliary cholangitis (PBC). A Phase 2 study of seladelpar established proof of concept in PBC. CymaBay is currently conducting a second Phase 2 study of seladelpar in PBC in order to support dose selection for Phase 3. Arhalofenate is a potential urate-lowering anti-flare therapy that has completed five Phase 2 studies in subjects with gout. Arhalofenate has been found to reduce painful flares in joints while at the same time lowering serum uric acid by promoting excretion of uric acid by the kidney. This dual action addresses both the signs and symptoms of gout while managing the underlying pathophysiology of hyperuricemia. Arhalofenate has been licensed in the U.S. to Kowa Pharmaceuticals America, Inc. CymaBay retains full development and commercialization rights for arhalofenate outside the U.S.

Cautionary Statements

The statements in this press release, including those statements regarding the structure and conduct of clinical trials, future performance of CymaBay's product candidates, the potential of seladelpar to treat primary biliary cholangitis or nonalcoholic steatohepatitis, the potential of arhalofenate to treat gout, the therapeutic and commercial potential of CymaBay's product candidates, and any of the targeted indications for the potential future development or commercialization of CymaBay's product candidates are forward looking statements that are subject to risks and uncertainties. Actual results and the timing of events regarding the further development of CymaBay's product candidates 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 which 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 Quarterly Report on Form 10-Q, 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.

CymaBay Therapeutics, Inc. Balance Sheet Data

(In thousands, except share and per share amounts)

	March 31, 2017	December 31, 2016	
	(unaudited)	,	_
Cash, cash equivalents and short-term investments	\$ 23,396	\$	16,994
Working Capital	13,777		9,217
Total assets	25,379		19,359
Facility loan	8,219		8,864
Warrant Liability	3,279		1,145
Total liabilities	16,152		15,422
Common stock and additional paid-in capital	437,539		426,897
Total stockholders' equity	9,227		3,937

CymaBay Therapeutics, Inc. Financial Results

(In thousands, except share and per share information) (unaudited)

	Three Months Ended March 31,			
		2017		2016
Collaboration revenue	\$	4,793	\$	-
Operating expenses:				
Research and development	\$	4,041	\$	4,428
General and administrative		3,701		2,461
Total operating expenses		7,742		6,889
Loss from operations Other income (expense):		(2,949)		(6,889)
Interest income		37		53
Interest expense		(305)		(332)
Other income (expense), net		(2,134)		320
Net loss	\$	(5,351)	\$	(6,848)
			-	
Basic net loss per common share	\$	(0.20)	\$	(0.29)
Diluted net loss per common share	\$	(0.20)	\$	(0.29)
Weighted average common shares outstanding used to calculate basic net loss per common share Weighted average common shares outstanding used to calculate	2	6,609,931	23,447,003	
diluted net loss per common share	2	6,609,931	2	3,447,003

Contacts:

Sujal Shah CymaBay Therapeutics, Inc. (510) 293-8800 sshah@cymabay.com

or

Hans Vitzthum LifeSci Advisors, LLC 212-915-2568 Hans@LifeSciAdvisors.com



Source: CymaBay Therapeutics, Inc.