CymaBay Reports Fourth Quarter and Full Year 2015 Financial Results

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

NEWARK, Calif., March 29, 2016 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), a clinical-stage biopharmaceutical company focused on developing therapies to treat metabolic diseases with high unmet medical need, today provided recent corporate highlights and announced financial results for the quarter and year ended December 31, 2015.

"We have made significant progress during the last quarter in advancing the development of our two key clinical assets," said Harold Van Wart, President and Chief Executive Officer of CymaBay. "Earlier in March, we reported some encouraging top-line data from our pilot Phase 2 study in patients with homozygous familial hypercholesterolemia. Analysis of the data showed that MBX-8025 demonstrated the ability to lower LDL-Cholesterol in a majority of patients, despite raising PCSK9 levels. We are evaluating the feasibility of conducting a second pilot study in combination with a PCSK9 inhibitor to assess whether the reductions in LDL-C can be amplified by neutralizing PCSK9."

"Last quarter, we also initiated a 12 week, placebo-controlled, dose ranging Phase 2 study of MBX-8025 in 75 patients with primary biliary cholangitis," said Dr. Van Wart. "We have consistently observed reductions in markers of cholestasis in clinical studies in other populations that we hope will be replicated in this study."

"For arhalofenate, our drug candidate for the treatment of gout, we have completed our Endof-Phase 2 discussions with the FDA and now have clear direction as to how to conduct a Phase 3 program that could capture the dual benefits of arhalofenate," continued Dr. Van Wart. "Our goal is to sign one or more partnerships in order to initiate the Phase 3 program before the end of 2016."

Recent Business Highlights

MBX-8025 for Rare, Orphan Diseases

MBX-8025 is an oral, potent and selective PPARδ agonist with an anti-atherogenic profile that may be useful in the treatment of a variety of rare and orphan diseases currently under evaluation.

 In March 2016, CymaBay announced results from a pilot Phase 2 clinical study that demonstrated efficacy of MBX-8025 in patients with homozygous familial hypercholesterolemia (HoFH, an autosomal genetic disease characterized by loss-offunction mutations in both alleles of the LDL receptor gene. The results showed that MBX-8025 provided a clinically meaningful reduction in low-density lipoprotein cholesterol (LDL-C) for a subset of patients. A responder analysis showed that 7 subjects (or 58%) exhibited a greater than or equal to 15% decrease in LDL-C, including one patient that was LDL receptor negative. The overall mean change in LDL-C for all subjects was a decrease of 10%. Eight subjects exhibited a decrease in LDL-C with a group mean of 16%, including 3 that showed a greater than or equal to 20% decrease. Mean PCSK9 levels, associated with causing LDL-C to rise, increased significantly during treatment by a mean of 43%. CymaBay is now evaluating the feasibility of conducting a second pilot Phase 2 clinical study to further understand the potential benefits of MBX-8025 in patients with HoFH that are currently being treated with a PCSK9 inhibitor.

- CymaBay also expanded the development of MBX-8025 in 2015 with the initiation of a Phase 2 study in patients with primary biliary cholangitis (PBC) in the fourth quarter of 2015. This double-blind, placebo controlled study intended to enroll approximately 75 patients is expected to be completed in the fourth quarter of 2016.
- The Food and Drug Administration (FDA) granted CymaBay orphan drug designation for MBX-8025 to treat HoFH and severe hypertriglyceridemia in 2015.

Arhalofenate for Gout

Arhalofenate is an oral, once-daily dual-acting drug candidate for gout that both lowers serum uric acid through a uricosuric effect and has an anti-inflammatory activity that suppresses flares.

- In March 2016, CymaBay announced the publication of a paper reporting the results from its Phase 2b gout flare study of arhalofenate in the journal Arthritis & Rheumatology.
- In January 2016, CymaBay announced the successful completion of the end-of-phase 2 meeting discussions with the FDA and the agreement with the agency on all of the key elements of the planned Phase 3 program, including the co-primary endpoints of sUA responder rate and flare rate. The program will consist of two Phase 3 studies of arhalofenate in combination with febuxostat in patients with chronic gout and a third study in patients with tophaceous gout.
- In 2015, CymaBay completed the Phase 2 development of arhalofenate, announcing results from two studies demonstrating key features of arhalofenate as the first potential compound in a new class of potential gout therapy that it refers to as Urate Lowering Anti-Flare Therapy (ULAFT).
- CymaBay is in ongoing discussions with potential partners with the intended goal of signing a partnership agreement that would enable the initiation of Phase 3 development for arhalofenate in 2016.

Corporate Highlights

• In March 2016, announced the appointments of Dr. Evan Stein, Paul Truex and Robert Weiland to its Board of Directors. Dr. Evan Stein, M.D., Ph.D., is a world-renowned expert in the area of lipid metabolism with a particular focus on the development of

therapies to treat HoFH. Paul Truex is currently President and Chief Executive Officer of Anthera Pharmaceuticals, Inc. (NASDAQ:ANTH) and has more than 20 years of experience in senior operational positions in the biotechnology and pharmaceutical industries. Robert Weiland last served as Vice President for Strategy and International Business Development at Baxter International and also brings more than 20 years of experience in business and product commercialization strategy in the pharmaceutical industry.

- In October 2015, appointed Robert J. Wills, a pharmaceutical veteran with more than 25 years of senior leadership experience at Johnson & Johnson and Hoffmann-La Roche, as Chairman of the Board.
- In July 2015, CymaBay successfully completed an offering of 8.2 million shares of its common stock. The net proceeds to CymaBay were approximately \$21 million, after deducting the underwriting discount and offering expenses.
- In April 2015, appointed Kirk Rosemark to Vice President of Regulatory Affairs and Quality Assurance.

Fourth Quarter and Full Year 2015 Financial Results

- Cash, cash equivalents and short-term investments as of December 31, 2015, were \$41.5 million compared to \$34.8 million as of December 31, 2014. CymaBay believes that its current cash, cash equivalents and short-term investments are sufficient to fund operations and capital expenditures associated with the company's current operating plan through at least the second quarter of 2017.
- Research and development expense for the three and twelve months ended December 31, 2015, was \$4.1 million and \$17.0 million, respectively. R&D expense for the three and twelve months ended December 31, 2014 was \$5.3 million and \$15.8 million, respectively. The increase in R&D expense for the full year was primarily related to the increased spending associated with the initiation and conduct of two Phase 2 studies of MBX-8025, one in HoFH and another in PBC, during 2015.
- General and administrative expense for the three and twelve months ended December 31, 2015, was \$1.8 million and \$8.9 million, respectively. G&A expense for the three and twelve months ended December 31, 2014 was \$2.3 million and \$8.2 million, respectively. The small increase in G&A expense in 2015 compared to 2014 was primarily related to an increase in personnel costs to support the company's expanded clinical development program of MBX-8025.
- Net loss for the three and twelve months ended December 31, 2015, was \$6.0 million and \$15.5 million, respectively. Net loss for the three and twelve months ended December 31, 2014, was \$12.7 million and \$31.9 million, respectively. The decrease in net loss for both periods was primarily due to non-cash gains of \$0.1 million and \$11.1 million for the three and twelve months ended December 31, 2015, respectively, from the mark to market valuation of the company's warrant liability. For the three and twelve months ended December 31, 2014, the mark to market valuation of the

company's warrant liability resulted in non-cash losses of \$4.9 million and \$7.2 million, respectively. The 2015 non-cash gains more than offset the small increases in R&D and G&A expenses in 2015 versus 2014.

Conference Call

CymaBay management will host a conference call today at 4:30 p.m. ET to discuss fourth quarter and year-end 2015 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. The conference I.D. is 13632479. 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. A replay of the webcast will be available on the company's website for 14 days following the live event.

About CymaBay

CymaBay Therapeutics, Inc. (CBAY) is a clinical-stage biopharmaceutical company developing therapies to treat metabolic diseases with high unmet medical need, including serious rare and orphan disorders. MBX-8025 is a potent, selective, orally active PPARō agonist. A Phase 2 study of MBX-8025 in patients with mixed dyslipidemia established that it has an anti-atherogenic lipid profile. CymaBay has completed a pilot Phase 2 study of MBX-8025 in patients with homozygous familial hypercholesterolemia and has an ongoing Phase 2 study in patients with primary biliary cholangitis. Arhalofenate, CymaBay's other product candidate, is a potential Urate-Lowering Anti-Flare Therapy that has completed five Phase 2 studies in gout patients. Arhalofenate has been found to reduce painful flares in joints while at the same time 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.

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 MBX-8025 to treat homozygous familial hypercholesterolemia or primary biliary cholangitis, 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 of MBX-8025 and arhalofenate; 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 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<u>www.cymabay.com</u>.

CymaBay Therapeutics, Inc. Unaudited Condensed Statements of Operations Data

(in thousands, except share and per share data)

	Three Months Ended December 31,				Year Ended December 31,			
		2015		2014		2015		2014
Operating expenses:								•
Research and development	\$	4,051	\$	5,277	\$	17,026	\$	15,823
General and administrative		1,796		2,332		8,871		8,185
Total operating expenses		5,847		7,609		25,897		24,008
Loss from operations Other income (expense):		(5,847)		(7,609)		(25,897)		(24,008)
Interest income		61		26		160		74
Interest expense		(329)		(191)		(913)		(755)
Other income (expense), net		136	_	(4,948)		11,121		(7,228)
Net loss	\$	(5,979)	\$	(12,722)	\$	(15,529)	\$	(31,917)
Basic net loss per common share	\$	(0.26)	\$	(0.87)	\$	(0.82)	\$	(2.65)
Diluted net loss per common share	\$	(0.26)	\$	(0.87)	\$	(0.83)	\$	(2.65)
Weighted average common shares outstanding used to calculate basic net loss per common share	23,447,003		14,688,324		18,900,473		12,048,985	
Weighted average common shares outstanding used to calculate diluted net loss per common share	23,447,003		14,688,324		18,917,213		12,048,985	

CymaBay Therapeutics, Inc. Unaudited Condensed Balance Sheet Data (in thousands)

Dec	2015	December 31, 2014		
\$	41,480	\$	34,795	
	36,648		16,770	
	43,079		37,474	
	9,381		4,542	
	1,220		13,596	
	14,964		23,624	
	424,424		394,623	
	28,115		13,850	
		\$ 41,480 36,648 43,079 9,381 1,220 14,964 424,424	\$ 41,480 \$ 36,648 43,079 9,381 1,220 14,964 424,424	

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Source: CymaBay Therapeutics, Inc.