August 10, 2020

CymaBay Reports Second Quarter 2020 Financial Results and Provides Corporate Update

FDA lifts all clinical holds on seladelpar

Positive topline data announced from ENHANCE

Company to reinitiate clinical development of seladelpar for patients with PBC

Cash sufficient to fund current operating plan into 2022

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

NEWARK, Calif., Aug. 10, 2020 (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 corporate updates and financial results for the second quarter and six months ended June 30, 2020.

Specifically, in the second quarter and through early August 2020, CymaBay achieved significant progress in its ongoing efforts to review its strategic options, one of which included completing a scientific investigation and working with the FDA to lift the clinical holds on the seladelpar INDs in nonalcoholic steatohepatitis (NASH), primary biliary cholangitis (PBC) and primary sclerosing cholangitis (PSC), the three liver diseases in which CymaBay had terminated clinical studies late last year.

Sujal Shah, President and CEO of CymaBay, stated, “We are thrilled with the significant progress made to date in our efforts to conduct a review of strategic options, one of which was to pursue the reinstatement of our seladelpar program. Specifically, in May, we convened a panel of expert liver pathologists and hepatologists that unanimously concluded after a thorough, independent investigation, that there was no clinical, biochemical, or histological evidence of seladelpar-induced liver injury for patients enrolled in our Phase 2b NASH study. We discussed the panel’s findings and related information with the FDA and submitted complete responses to the agency, and in July, the FDA notified us that all clinical holds on seladelpar were lifted. In addition to this favorable outcome, we evaluated and announced last week positive topline results from our ENHANCE study of seladelpar in PBC which, despite being terminated early, provided sufficient data which appear to support seladelpar’s efficacy and tolerability in this patient population. After receiving notification from the FDA, and reviewing the latest clinical data from the ENHANCE study, we stopped our review of strategic options having decided to focus on reinstating the clinical development program for seladelpar in PBC and to continue to evaluate seladelpar for other indications. We have also been very successfully at minimizing our operating expenses through the first half of the year and expect our cash to fund our current operating plan into 2022.”

Recent Corporate Highlights

- In May 2020, a panel of eight of the world's foremost expert liver pathologists and hepatologists, whose collective experience relevant to CymaBay's investigation includes drug-induced liver injury, NASH and cholestatic liver diseases, completed a four-day independent review analyzing findings from CymaBay's NASH Phase 2b study, and the results of independent pathologist's reviews of the study biopsies, which included a blinded unpaired review and a paired review blinded to chronologic order of the biopsies. The panel unanimously supported lifting the clinical hold for seladelpar and re-initiation of clinical development pending approval by the FDA. In June 2020, CymaBay discussed the data and the panel's conclusions with the FDA and submitted complete responses to the agency. In July 2020, the FDA lifted clinical holds on seladelpar in all indications with open INDs (NASH, PBC and PSC).

- In August 2020, CymaBay announced positive topline results from ENHANCE for seladelpar in patients with PBC. Topline data for patients through 3 and 6 months demonstrated anti-cholestatic, anti-inflammatory, and anti-pruritic activity. Notably, 78.2% of patients on seladelpar 10 mg versus 12.5% on placebo achieved the primary composite outcome after only 3 months ($p<0.0001$). In addition, 27.3% of patients on seladelpar 10 mg versus zero on placebo experienced normalization of ALP by 3 months ($p<0.0001$). Treatment with seladelpar 10 mg also resulted in a statistically significant improvement in pruritus ($p<0.05$) for patients with moderate-to-severe itch versus placebo. Overall, seladelpar appeared to be safe and well-tolerated in this study.

- CymaBay intends to reinitiate the long-term study, a Phase 3 study and other NDA-enabling studies to confirm the potential of seladelpar to be a best-in-class treatment for patients with PBC and to further evaluate suitable strategies to advance seladelpar in other indications.

- CymaBay held $168.9 million in cash, cash equivalents and short-term investments as of June 30, 2020 and had no outstanding debt. Cash and investments are deemed sufficient to fund CymaBay's current operating plan into 2022.

- Due to the ongoing effects of the global coronavirus pandemic, CymaBay continues to conduct its operations remotely for all employees, which has allowed business activities to continue as seamlessly as possible. To date, these developments have not had a significant impact on CymaBay's financial condition or its ability to execute its business plan. CymaBay will continue to closely monitor pandemic developments and their associated risks to the business, including plans to restart clinical development of seladelpar, and will continue to take actions available to mitigate them where possible. Further, all CymaBay's actions will be guided by a commitment to taking all steps possible to ensure the health and safety of its employees as well as patients enrolled in its clinical studies.

Second Quarter and Six Months Ended June 30, 2020 Financial Results

- Research and development expenses for the three months ended June 30, 2020 were $7.9 million, compared to $21.1 million for the three months ended June 30, 2019.

Research and development expenses for the six months ended June 30, 2020 were $17.5 million, compared to $39.7 million for the six months ended June 30, 2019. Research and development expense in the three and six months of 2020 was significantly lower than the corresponding periods in 2019 primarily due to declining clinical trial activities related to the Phase 3 PBC, Phase 2b NASH, and Phase 2 PSC clinical trials, and other studies, as efforts continued to shut down these studies which were early-terminated as a result of the FDA's clinical holds that were placed on the seladelpar program in the fourth quarter of 2019.

- General and administrative expenses for the three months ended June 30, 2020 were $3.4 million, compared to $4.5 million for the three months ended June 30, 2019. General and administrative expenses for the six months ended June 30, 2020 were $7.7 million, compared to $10.2 million for the six months ended June 30, 2019. General and administrative expenses in the three and six months of 2020 were lower than the corresponding periods in 2019 due to lower employee compensation and other administrative expenses incurred as a result of a December 2019 reduction-in-force and restructuring effort that was undertaken to reduce costs in response to the FDA's clinical holds on the seladelpar program.

- Net loss for the three months ended June 30, 2020 was $10.7 million, or ($0.16) per diluted share, compared to a net loss of $24.0 million, or ($0.35) per diluted share in the three months ended June 30, 2019. Net loss for the six months ended June 30, 2020 was $23.8 million, or ($0.35) per diluted share, compared to a net loss of $47.1 million, or ($0.72) per diluted share in the six months ended June 30, 2019. Net loss was lower in the three and six months of 2020 compared to the corresponding periods in 2019 primarily due to a decrease in operating expenses, including clinical trial and labor related expenses, as a result of the early-termination of our seladelpar studies and our cost reduction efforts undertaken in response to the FDA's clinical holds that were placed on the seladelpar program in the fourth quarter of 2019.

Conference Call Details

CymaBay will host a conference call today at 4:30 p.m. ET to discuss second quarter 2020 financial results and provide a corporate 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# 13706143. 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 is developing seladelpar, a potent, selective, orally active PPARδ agonist for patients with primary biliary cholangitis (PBC). Seladelpar has received an orphan designation from the US Food and Drug administration (FDA) and the European Medicine Agency (EMA). Seladelpar also received Breakthrough Therapy Designation from the FDA and PRIority MEdicines status from the EMA for PBC.

Cautionary Statements

Any statements made in this press release and accompanying conference call regarding the potential for seladelpar to treat PBC and potentially improve clinical symptoms of the disease, the potential benefits to patients, CymaBay's expectations and plans regarding its intended future interactions with the FDA, its 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 or to potentially restart clinical trials. 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.

Public Relations Contact:

Glenn Silver
Lazar-FINN Partners
(973) 818-8198
Glenn.silver@finnpartners.com

Investor Relations Contact:

Hans Vitzthum
LifeSci Advisors, LLC
(617) 430-7578
Hans@LifeSciAdvisors.com

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

	Quarter Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Operating expenses:				
Research and development	$ 7,942	$ 21,119	$ 17,451	$ 39,707
General and administrative	3,398	4,529	7,745	10,192
Restructuring charges	(188)	-	(117)	-
Total operating expenses	11,152	25,648	25,079	49,899
Loss from operations	(11,152)	(25,648)	(25,079)	(49,899)
Other income:				
Interest income	426	1,610	1,265	2,786
Total other income	426	1,610	1,265	2,786
Net loss	$ (10,726)	$ (24,038)	$ (23,814)	$ (47,113)
Basic net loss per common share	$ (0.16)	$ (0.35)	$ (0.35)	$ (0.72)
Diluted net loss per common share	$ (0.16)	$ (0.35)	$ (0.35)	$ (0.72)
Weighted average common shares outstanding used to calculate basic net loss per common share	68,885,108	68,697,735	68,883,783	65,312,988
Weighted average common shares outstanding used to calculate diluted net loss per common share	68,885,108	68,697,735	68,883,783	65,312,988

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

	June 30, 2020	December 31, 2019
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 168,907	$ 190,945
Working capital	164,624	185,287
Total assets	176,597	205,727
Total liabilities	10,989	19,379
Common stock and additional paid-in capital	815,108	812,140
Total stockholders' equity	165,608	186,348

Source: CymaBay Therapeutics, Inc.