August 12, 2021

CymaBay Reports Second Quarter and Six Months Ended June 30, 2021 Financial Results and Provides Corporate Update

Secured up to $100 million of additional development funding through a non-dilutive financing transaction with Abingworth

- *Funds the Phase 3 development program for seladelpar in primary biliary cholangitis (PBC), including the Phase 3 RESPONSE clinical trial*

Actively recruiting patients in two global, clinical studies evaluating seladelpar in PBC

- *RESPONSE, a 52-week, randomized, placebo-controlled, Phase 3 registrational study*
- *ASSURE, an open-label, long-term study*

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

NEWARK, Calif., Aug. 12, 2021 (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 ended June 30, 2021.

In July 2021, CymaBay announced a development funding agreement with Abingworth, pursuant to which CymaBay will receive up to $100 million of funding for seladelpar development costs, of which $75 million will be received in three installments over approximately six months. CymaBay has an option to receive an additional $25 million within approximately two months of the completion of enrollment of CymaBay's Phase 3 **RESPONSE** clinical trial. In exchange, CymaBay will make fixed payments spread over a six-year period based on regulatory approval in the U.S. or the E.U. after the first such regulatory approval is obtained, as well as pay fixed and capped sales milestones based on U.S. product sales. CymaBay has the ability to accelerate payment at a reduced amount upon regulatory approval and in the event of a change of control of CymaBay. CymaBay retains upside potential for seladelpar in the U.S. along with full worldwide commercial rights.

CymaBay also continued to make progress conducting the development program for seladelpar in primary biliary cholangitis (PBC). Additional clinical sites were activated in North America and Europe during the second quarter in **RESPONSE**, a global Phase 3 registrational study evaluating seladelpar in patients with PBC, and in **ASSURE**, an open-label, long-term study of seladelpar in patients with PBC intended to collect additional safety data to support registration. Enrollment of patients in both of these studies continued through the second quarter and is expected to increase as more sites are activated through the rest of 2021.

Sujal Shah, President and CEO of CymaBay, stated, "In addition to adding experienced

talent across the functional areas vital to getting seladelpar to patients, we were thrilled to have secured the additional funding needed to complete Phase 3 development of seladelpar in PBC through a non-dilutive, risk-sharing funding agreement with Abingworth. Abingworth has had a long history of funding innovative companies in life sciences and shares our belief that seladelpar has the opportunity to meaningfully improve the care of patients with PBC. This strategic funding agreement further strengthens our balance sheet and allows us to maintain our dedicated focus on completing development of seladelpar to deliver value to patients and shareholders."

Recent Corporate Highlights

- Executed a non-dilutive financing transaction with Abingworth for the development of seladelpar in PBC. Under the terms of the agreement, CymaBay will receive up to $100 million of funding for seladelpar development costs, of which $75 million will be received in three installments over approximately six months. CymaBay has an option to receive an additional $25 million within approximately two months of the completion of enrollment of CymaBay's Phase 3 **RESPONSE** clinical trial.

- Conducted enrollment activities for **RESPONSE**, a 52-week, placebo-controlled, randomized, global, Phase 3 registrational study evaluating the safety and efficacy of seladelpar in patients with PBC. This study is targeting enrollment of 180 patients who have an inadequate response to, or intolerance to, ursodeoxycholic acid, in a 2:1 randomization to oral, once daily seladelpar 10 mg or placebo. The primary outcome measure is the responder rate at 52 weeks. A responder is defined as a patient who achieves an alkaline phosphatase level < 1.67 times the upper limit of normal with at least a 15% decrease from baseline and has a normal level of total bilirubin. Additional key outcomes of efficacy will compare the rate of normalization of alkaline phosphatase at 52 weeks and the level of pruritus at 6-months for patients with moderate to severe pruritus at baseline assessed by a numerical rating scale recorded with an electronic diary.

- Conducted enrollment activities for **ASSURE**, an open-label, long-term study of seladelpar in patients with PBC intended to collect additional long-term safety data to support registration.

- Initiated enrollment in a Phase 2a proof-of-pharmacology study to evaluate the potential for MBX-2982, a GPR119 agonist, to prevent hypoglycemia in patients with type 1 diabetes (T1D). The study is being conducted by the AdventHealth Translational Research Institute in Orlando, Florida and fully funded by The Leona M. and Harry B. Helmsley Charitable Trust with CymaBay retaining full rights to MBX-2982.

- Completed a Phase 1 single ascending dose and multiple asending dose study of CB-0406, a non-agonist ligand of PPARg that attenuates the expression of inflammatory genes. While the study showed CB-0406 had improved pharmacokinetics versus those historically achieved with the pro-drug arhalofenate, CB-0406's safety profile did not support continued development as a result of the occurrence of a small number of reversible cases of thrombocytopenia at higher doses.

- Held $106.1 million in cash, cash equivalents and short-term investments as of June 30, 2021. We believe that cash and investments, along with the initial $75 million

funding raised through the development funding agreement with Abingworth in July 2021 are sufficient to fund CymaBay's current operating plan into 2023.

- 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. The recent emergence of the Delta variant has led to uncertainty regarding the duration and effects that the pandemic will have on future operating milestones. CymaBay continues to closely monitor pandemic developments and their associated risks to the business, including the conduct of its clinical development of seladelpar, and will continue to take actions to mitigate them where possible. Further, all CymaBay's actions will continue to be guided by a commitment to ensuring the health and safety of its employees as well as patients enrolled in its clinical studies.

Second Quarter and Six Months Ended June 30, 2021 Financial Results

- Research and development expenses for the three months ended June 30, 2021 and 2020 were $16.7 million and $7.9 million, respectively. Research and development expenses for the six months ended June 30, 2021 and 2020 were $29.1 million and $17.5 million, respectively. Research and development expenses in the three and six months ended June 30, 2021 were higher than the corresponding periods in 2020 primarily due to an increase in clinical trial activities following our resumption of clinical development of seladelpar in PBC in late 2020. In particular, cost increases were primarily driven by the enrollment activities associated with RESPONSE and ASSURE, our two active global late-stage clinical trials in PBC. In the three and six months ended June 30, 2020, costs incurred were primarily associated with the termination and shutdown of our Phase 3 PBC, Phase 2b NASH, and Phase 2 PSC clinical trials, and other studies, after the seladelpar development program was placed on hold from November 2019 through July 2020.

- General and administrative expenses for the three months ended June 30, 2021 and 2020 were $6.5 million and $3.2 million, respectively. General and administrative expenses for the six months ended June 30, 2021 and 2020 were $11.8 million and $7.6 million, respectively. General and administrative expenses in the three and six months ended June 30, 2021 were higher than the corresponding periods in 2020 due to higher employee compensation associated with the hiring of additional personnel and an increase in consulting and other expenses upon resumption of development of seladelpar in the second half of 2020.

- Net loss for the three months ended June 30, 2021 and 2020 was $23.2 million and $10.7 million, or ($0.34) and ($0.16) per diluted share, respectively. Net loss for the six months ended June 30, 2021 and 2020 was $40.8 million and $23.8 million, or ($0.59) and ($0.35) per diluted share, respectively. Net loss was higher largely due to increases in clinical operating expenses, which were incurred following the resumption of our clinical development of seladelpar in PBC during the second half of 2020. We expect our operating expenses to increase in 2021 as we continue to execute on our clinical development plans.

Conference Call Details

CymaBay will host a conference call today at 4:30 p.m. ET to discuss second quarter 2021 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# 13720877. 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 improving the lives of people with liver and other chronic diseases that have high unmet medical need through a pipeline of innovative therapies. Our deep understanding of the underlying mechanisms of liver inflammation and fibrosis, and the unique targets that play a role in their progression, have helped us receive breakthrough therapy designation (U.S. Food and Drug Administration), PRIority MEdicines status (European Medicines Agency) and orphan drug status (U.S. and Europe) for seladelpar, a first-in-class treatment for people with primary biliary cholangitis (PBC). Our evidence-based decision-making and commitment to the highest quality standards reflect our relentless dedication to the people, families and communities we serve. To learn more, visit www.cymabay.com and follow us on Twitter and Linkedin.

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 current and future clinical trials, including the timing of enrollment in RESPONSE, the impact of the COVID pandemic on the enrollment timeline for CymaBay's clinical trials, CymaBay's ability to fund current and planned clinical trials, the funding expected to be provided by Abingworth and payment schedule, as well as CymaBay's anticipated cash runway 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; the potential termination of the agreement with Abingworth; the ability of CymaBay to meet its obligations under the agreement with Abingworth; the potential emergence of other COVID variants 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, its Quarterly Reports on Form 10-Q 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.

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

	Quarter Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Operating expenses:				
Research and development	$ 16,745	$ 7,942	$ 29,127	$ 17,451
General and administrative	6,521	3,210	11,757	7,628
Total operating expenses	23,266	11,152	40,884	25,079
Loss from operations	(23,266)	(11,152)	(40,884)	(25,079)
Interest income	44	426	111	1,265
Net loss	$ (23,222)	$ (10,726)	$ (40,773)	$ (23,814)
Basic and diluted net loss per common share	$ (0.34)	$ (0.16)	$ (0.59)	$ (0.35)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	68,985,461	68,885,108	68,965,885	68,883,783

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

	June 30, 2021	December 31, 2020
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 106,134	$ 146,323
Working capital	104,854	141,728
Total assets	117,041	153,825
Total liabilities	9,947	11,119
Common stock and additional paid-in capital	824,724	819,556
Total stockholders' equity	107,094	142,706

Source: CymaBay Therapeutics, Inc.