November 10, 2021

CymaBay Reports Third Quarter and Nine Months Ended September 30, 2021 Financial Results and Provides Corporate Update

Over 100 clinical sites now activated in RESPONSE Phase 3 registration study of seladelpar for patients with primary biliary cholangitis (PBC)

Additional data from prior studies of seladelpar in patients with PBC to be featured at The Liver Meeting® November 12-15, 2021 held by the American Association for the Study of Liver Diseases (AASLD)

CymaBay to host Post-AASLD KOL call on November 15 at 4:30pm ET

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

NEWARK, Calif., Nov. 10, 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 third quarter ended September 30, 2021.

Sujal Shah, President and CEO of CymaBay, stated, “The third quarter of 2021 included key accomplishments that position CymaBay for long-term success. The non-dilutive, risk-sharing development financing agreement signed with Abingworth in July supports the completion of our ongoing phase 3 program for seladelpar in PBC. We now have over 100 sites activated across over 20 countries in our global registration study, **RESPONSE**, and expect these efforts to continue and ultimately drive the completion of enrollment in the first half of 2022. We are excited to also share additional data from our prior studies in PBC at The Liver Meeting® 2021 that demonstrate improved benefit of seladelpar between one to two years of treatment and differentiation from other existing treatments in a population of patients with more advanced disease.”

“As we approach the end of 2021, we are well positioned to deliver on our central focus of improving the lives of patients with PBC. Although the pandemic has presented our entire industry with evolving challenges, I am confident we have assembled talent across the organization that will allow us to achieve both our near term goals and our vision of establishing a pipeline of opportunities for patients with unmet need. I’m also proud of the relationships we have established with patient communities, the medical community and high quality investors that all support the work we are dedicated to day in and day out.”

Upcoming and Recent Corporate Highlights

- An oral presentation titled “Long-Term Safety and Efficacy of Seladelpar in Patients with Primary Biliary Cholangitis” will be delivered by Dr. Marlyn J. Mayo, MD, Professor and Liver Disease Specialist, University of Texas Southwestern Medical Center. This presentation will highlight the efficacy and safety of seladelpar during 2 years of treatment in patients with primary biliary cholangitis (PBC). The mean percent change in alkaline phosphatase (ALP) from baseline was -42% and -50% after 1 and 2 years, respectively. Over 2 years, there were sustained reductions in ALT, AST, and GGT. Total bilirubin and platelet levels remained stable. Seladelpar appeared safe and well-tolerated. These data support that long-term treatment with seladelpar resulted in continued improvement in markers of cholestasis after 1 year.

- A clinical presentation titled “Efficacy and Safety of Seladelpar in Patients with Compensated Cirrhosis and Evidence of Portal Hypertension due to Primary Biliary Cholangitis” will be delivered by Dr. Cynthia Levy, MD, Professor of Medicine, University of Miami. This electronic poster presentation will highlight the treatment effects of seladelpar in compensated cirrhotic patients with portal hypertension after 3 months, which led to ALP changes of -30% in the 5 mg and -45% in the 10 mg groups. Total bilirubin, platelets, albumin, and INR either improved or remained stable. Seladelpar appeared safe and well-tolerated. Efficacy, safety, and tolerability in patients with compensated cirrhosis and portal hypertension was comparable to that of non-cirrhotic patients.

- CymaBay will host a Post-AASLD KOL Call on seladelpar in PBC on Monday, November 15, at 4:30pm ET. The webinar will feature presentations by Dr. Marlyn J. Mayo, MD, and Dr. Cynthia Levy, MD, who will be reviewing the seladelpar abstracts presented at The Liver Meeting® 2021. Dr. Dennis Kim, MD, Chief Medical Officer of CymaBay, will also discuss progress developing seladelpar for patients with PBC. The live and archived webcast will be accessible through this **webcast link** or through the **Events** section of the CymaBay website.

- Continued enrollment in **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.

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

- Supported enrollment efforts 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. 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.

- Executed a non-dilutive financing transaction with Abingworth LLP 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. The first installment of $25 million was received in August and the second installment of $25 million was received in early November. CymaBay expects to receive the third $25 million installment in early February 2022 and 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.

- Held $113.8 million in cash, cash equivalents and short-term investments as of September 30, 2021. We believe that cash and investments on hand, together with additional funding amounts we expect to receive through the development financing agreement with Abingworth are sufficient to fund CymaBay's 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 and other variants 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.

Third Quarter and Nine Months Ended September 30, 2021 Financial Results

- Research and development expenses for the three months ended September 30, 2021 and 2020 were $17.0 million and $7.7 million, respectively. Research and development expenses for the nine months ended September 30, 2021 and 2020 were $46.1 million and $25.2 million, respectively. Research and development expenses in the three and nine months ended September 30, 2021 were higher than the corresponding periods in 2020 primarily due to an increase in clinical trial activities associated with the development of seladelpar in PBC. In particular, cost increases were primarily driven by an expansion of our site activation, patient enrollment, and other clinical trial activities associated with RESPONSE and ASSURE, our two active global late-stage clinical trials in PBC. In the three and nine months ended September 30, 2020, costs incurred were primarily associated with startup activities for RESPONSE and ASSURE as well as costs to shutdown 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 September 30, 2021 and 2020 were $5.2 million and $3.9 million, respectively. General and administrative

expenses for the nine months ended September 30, 2021 and 2020 were $16.9 million and $11.5 million, respectively. General and administrative expenses in the three and nine months ended September 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. In addition, general and administrative expenses during the three and nine months ended September 30, 2020, included restructuring charges of $0.6 million and $0.7 million, respectively, and no similar restructuring charges were incurred during the three and nine months ended September 30, 2021.

- Net loss for the three months ended September 30, 2021 and 2020 was $22.7 million and $11.4 million, or ($0.33) and ($0.17) per diluted share, respectively. Net loss for the nine months ended September 30, 2021 and 2020 was $63.5 million and $35.2 million, or ($0.92) and ($0.51) 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 the future 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 third 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# 13723498. 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 September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
	(unaudited)	**(unaudited)**	**(unaudited)**	**(unaudited)**
Operating expenses:				
Research and development	$ 17,010	$ 7,743	$ 46,137	$ 25,194
General and administrative	5,179	3,907	16,936	11,535

Total operating expenses	22,189	11,650	63,073	36,729
Loss from operations	(22,189)	(11,650)	(63,073)	(36,729)
Other income (expense), net:				
Interest income	29	229	140	1,494
Interest expense	(522)	-	(522)	-
Total other income (expense), net	(493)	229	(382)	1,494
Net loss	$ (22,682)	$ (11,421)	$ (63,455)	$ (35,235)
Basic and diluted net loss per common share	$ (0.33)	$ (0.17)	$ (0.92)	$ (0.51)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	69,022,937	68,887,092	68,985,112	68,884,894

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

	September 30, 2021 (unaudited)	December 31, 2020
Cash, cash equivalents and marketable securities	$ 113,788 *	$ 146,323
Working capital	107,835	141,728
Total assets	122,902	153,825
Total liabilities	35,844	11,119
Common stock and additional paid-in capital	827,372	819,556
Total stockholders' equity	87,058	142,706

* Does not include $25 million received from Abingworth on November 5, 2021.

Source: CymaBay Therapeutics, Inc.