November 14, 2022

CymaBay Reports Third Quarter and Nine Months Ended September 30, 2022 Financial Results and Provides Corporate Update

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

NEWARK, Calif., Nov. 14, 2022 (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, 2022.

Sujal Shah, President and CEO of CymaBay, stated, “Early in the third quarter we completed enrollment in RESPONSE, our global registration study of seladelpar in patients with PBC. This achievement was a direct result of the tireless efforts of our teams and the relationships we have been fortunate to leverage among partners, health care providers and patient advocacy groups around the world. In addition to clinical presentations highlighting some of the important benefits of seladelpar for patients, we connected with all of these groups at The Liver Meeting® last week and are aligned, coordinated and energized to deliver on transformational catalysts that lie ahead of us in 2023. With over 300 patients with PBC taking seladelpar daily across our active clinical studies, we continue to execute on what we believe is the most robust development program in PBC being conducted today. Our focus at CymaBay is clear and will remain so as we drive towards sharing top-line data from RESPONSE in the third quarter of 2023.”

Recent Corporate Highlights

- Enrollment was completed in the **RESPONSE** study, a 52-week, placebo-controlled, randomized, global, Phase 3 registrational study evaluating the safety and efficacy of seladelpar in patients with PBC. This study has enrolled 193 patients who have an inadequate response or intolerance to ursodeoxycholic acid in a 2:1 ratio to receive once daily oral 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 as assessed by a validated numerical rating scale recorded with an electronic diary.

- Continued strong enrollment in **ASSURE**, the restarted open-label, long-term study of seladelpar in patients with PBC intended to collect additional long-term safety and efficacy data to support registration. There are now over 180 patients in this study

taking seladelpar daily. After completing the **RESPONSE** study, eligible patients will be able to roll over into **ASSURE**.

- Data presented at The Liver Meeting® of the American Association for the Study of Liver Diseases, in Washington, DC. The clinical presentations featured:

    - A poster presentation titled “Seladelpar Improved the Lipid Profile of Patients with Primary Biliary Cholangitis (PBC): Results from Phase 2 and 3 Clinical Studies” delivered by Christopher L. Bowlus MD, the chief of the Division of Gastroenterology and Hepatology at the University of California Davis. This poster highlighted the results of a pooled analysis of the improvements in lipids observed over 6 months from an open-label phase 2 study and a placebo (Pbo) controlled phase 3 study (ENHANCE) assessing seladelpar at a daily dose of 5 mg or 10 mg in PBC patients. This analysis found that of the 373 patients analyzed, total cholesterol, LDL-cholesterol and triglyceride levels were elevated in 77%, 54% and 21% of patients at baseline, respectively. Treatment with seladelpar through 6 months resulted in significant improvements in all three of these parameters. Interestingly, a comparison of lipid lowering in patients with and without background lipid therapy revealed that seladelpar achieved similar treatment effects. Confirmation of the effects of seladelpar treatment on lipid profiles in the RESPONSE and ASSURE studies is of interest given that dyslipidemia is a common feature in patients with PBC.

    - A second poster presenting clinical data titled “Seladelpar, a PPAR-delta Agonist, Improves Inflammatory Lipid Mediators in the Serum Metabolome in Patients with Primary Biliary Cholangitis (PBC)” examined changes from baseline to 3 months in the serum metabolome of 160 patients in the ENHANCE study dosed daily with placebo, seladelpar 5 mg and seladelpar 10 mg. Seladelpar dose-dependently increased serum markers of mitochondrial and peroxisomal fatty acid oxidation and significantly reduced levels of inflammatory lipid mediators. This study of 1,474 untargeted global serum metabolites provided mechanistic insight into metabolic pathways altered by seladelpar treatment of patients with PBC. These results suggest novel aspects by which the action of seladelpar may improve cholestasis and liver function in patients with PBC.

- Held virtual analyst day featuring a presentation from a hepatology key opinion leader, Kris Kowdley, MD, FACP, FACG, AGAF, FAASLD, Director of Liver Institute Northwest and Professor of Medicine at Washington State University, who discussed the current treatment landscape and future goals for treating patients with PBC.

- Announced the promotion of Dr. Charles McWherter to President of Research and Development, in addition to his continuing role as Chief Scientific Officer since 2013. Dr. McWherter’s extensive experience in the pharmaceutical industry as an executive focused on discovery, research and development and the depth of knowledge he has attained in our therapeutic areas of focus make him a perfect fit to serve in this expanded capacity.

- Planning and execution progressed in our manufacturing and supply chain functions to support NDA submission and post-approval launch. Pre-commercial market analysis

and planning became an increasing focus to support our planned product launch.

- Held $153.4 million in cash, cash equivalents and investments as of September 30, 2022. We believe that cash and investments on hand are sufficient to fund CymaBay's operating plan through 2023.

Third Quarter and Nine Months Ended September 30, 2022, Financial Results

- Research and development expenses for the three months ended September 30, 2022, and 2021 were $15.5 million and $17.0 million, respectively. Research and development expenses for the nine months ended September 30, 2022, and 2021 were $51.8 million and $46.1 million, respectively. Research and development expenses in the three months ended September 30, 2022 were lower than the corresponding period in 2021 primarily due to the completion of enrollment of our **RESPONSE** trial in July 2022. Research and development expenses in the nine months ended September 30, 2022 were higher than the corresponding period in 2021 primarily due to the hiring of additional personnel and an expansion of clinical trial activities associated with the ongoing late-stage development of seladelpar in PBC. Specifically, higher costs were primarily driven by site activation, patient enrollment, and other clinical trial activities associated with **RESPONSE** and **ASSURE**, our two active global late-stage clinical trials in PBC.

- General and administrative expenses for the three months ended September 30, 2022 and 2021 were $5.9 million and $5.2 million, respectively. General and administrative expenses for the nine months ended September 30, 2022 and 2021 were $17.9 million and $16.9 million, respectively. General and administrative expenses in the three months ended September 30, 2022 were higher than the corresponding period in 2021 due to the hiring of additional personnel to support our corporate growth. General and administrative expenses in the nine months ended September 30, 2022 were higher than the corresponding period in 2021 due to the hiring of additional personnel, partially offset by a reduction in legal and consulting expenses.

- Net loss for the three months ended September 30, 2022 and 2021 was $24.5 million and $22.7 million, or ($0.28) and ($0.33) per share, respectively. Net loss for the nine months ended September 30, 2022, and 2021 was $79.4 million and $63.5 million, or ($0.90) and ($0.92) per share, respectively. Net loss in the three months ended September 30, 2022 was higher than the corresponding period in 2021 due primarily to an increase in interest expense accretion related to the Abingworth development financing agreement, partially offset by a decline in research and development expense. Net loss in the nine months ended September 30, 2022 was higher than the corresponding period in 2021 due primarily to an increase in interest expense accretion and to a lesser extent, an increase in research and development and other operating expenses associated with the ongoing late-stage development of seladelpar in PBC. Overall, we expect operating expenses to increase in the future as we continue to execute on our development plans for seladelpar in PBC.

Conference Call Details

CymaBay will host a conference call today at 4:30 p.m. ET to discuss third quarter financial results and provide a business update. To access the live conference call, please dial 855-

327-6837 from the U.S. and Canada, or 631-891-4304 internationally, Conference ID #10020554. 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 regarding the potential for seladelpar to treat PBC and potentially improve clinical symptoms of the disease, the potential benefits to patients and the anticipated timing of the release of clinical data 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; and effects observed in trials to date that may not be repeated in the future. 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.

For additional information about CymaBay, visit www.cymabay.com.

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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,	
	2022	2021	2022	2021
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Operating expenses:				
Research and development	$ 15,459	$ 17,010	$ 51,765	$ 46,137
General and administrative	5,904	5,179	17,869	16,936
Total operating expenses	21,363	22,189	69,634	63,073
Loss from operations	(21,363)	(22,189)	(69,634)	(63,073)
Other income (expense), net:				
Interest income	677	29	1,098	140
Interest expense	(3,819)	(522)	(10,832)	(522)
Total other income (expense), net	(3,142)	(493)	(9,734)	(382)
Net loss	$ (24,505)	$ (22,682)	$ (79,368)	$ (63,455)
Basic and diluted net loss per common share	$ (0.28)	$ (0.33)	$ (0.90)	$ (0.92)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	87,804,272	69,022,937	87,803,388	68,985,112

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

	September 30, 2022	December 31, 2021
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 153,415	$ 194,602
Working capital	142,413	172,733
Total assets	159,247	202,318
Total liabilities	99,069	69,381
Common stock and additional paid-in capital	906,976	899,806
Total stockholders' equity	60,178	132,937

Source: CymaBay Therapeutics, Inc.