August 11, 2022

# CymaBay Reports Second Quarter and Six Months Ended June 30, 2022 Financial Results and Provides Corporate Update

*Enrollment completed in RESPONSE with 193 patients enrolled in over 20 countries*

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

NEWARK, Calif., Aug. 11, 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 second quarter ended June 30, 2022.

Sujal Shah, President and CEO of CymaBay, stated, “We are elated to have finished enrollment in RESPONSE, our second, global Phase 3 study of seladelpar for patients with primary biliary cholangitis (PBC). We enrolled 193 patients across more than 20 countries and would like to thank our patients, their families and all of the clinical-site personnel involved for helping us reach this critical milestone. We anticipate releasing topline data for RESPONSE in the third quarter of 2023. Together with the more than 150 patients that are already enrolled in ASSURE, our long-term extension study, we believe our development program for seladelpar is one of the most robust to be conducted in PBC. We were also pleased to present data at EASL this past June, including two-year treatment data with seladelpar showing it improved the GLOBE PBC score and predicted improved transplant-free survival. Finally, we continue to focus on careful management of expenses which has resulted in a strong balance sheet with $170.8 million of cash, cash equivalents and investments as of June 30, 2022.”

**Recent Corporate Highlights**

- Completed 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 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**, an 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 150 patients in this study taking daily seladelpar. After completing the **RESPONSE** study, patients will be able to roll over

into **ASSURE**.

- Supported continued 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. 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.

- Featured results of our studies at The International Liver Congress™ 2022 of the European Association for the Study of Liver (EASL) held in London, UK., including a presentation by Bettina Hansen, PhD, Associate Professor Toronto Centre for Liver Disease, University of Toronto, reporting the improvement in GLOBE score following seladelpar treatment over two years and predicted transplant-free survival. The GLOBE score is a validated risk-assessment tool providing an estimate of transplant-free survival for patients with PBC. The presentation reported:

    - Treatment of 50 patients with oral seladelpar 5 or 10 mg daily for 2 years resulted in a mean (SD) change from baseline in GLOBE score of -0.417 (0.269), resulting in a corresponding hazard ratio of 0.66 for transplantation or death compared to no prior treatment with seladelpar (baseline).
    - The improvement in GLOBE score and predicted survival did not depend on age. However, an analysis of subpopulations of high-risk patients by GLOBE score (> 0.3) revealed that while patients of all ages improved, the younger patients tended to have numerically greater improvements, suggesting a potential benefit of earlier treatment.

- 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 $170.8 million in cash, cash equivalents and investments as of June 30, 2022. We believe that cash and investments on hand are sufficient to fund CymaBay's operating plan through 2023.

**Second Quarter and Six Months Ended June 30, 2022, Financial Results**

- Research and development expenses for the three months ended June 30, 2022, and 2021 were $17.9 million and $16.7 million, respectively. Research and development expenses for the six months ended June 30, 2022, and 2021 were $36.3 million and $29.1 million, respectively. Research and development expenses in the three- and six-month period ended June 30, 2022, were higher than the corresponding periods in 2021 primarily due to an increase in clinical trial activities associated with the ongoing late-stage 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.

- General and administrative expenses for the three months ended June 30, 2022, and

2021 were $5.9 million and $6.5 million, respectively. General and administrative expenses for the six months ended June 30, 2022, and 2021 were $12.0 million and $11.8 million, respectively. General and administrative expenses in the three months ended June 30, 2022, were lower than in the three months ended June 30, 2021, due to a reduction in legal and consulting expenses. General and administrative expenses were higher in the six months ended June 30, 2022, when compared to the six months ended June 30, 2021, due to compensation associated with the hiring of additional personnel, partially offset by a reduction in legal and consulting expenses.

- Net loss for the three months ended June 30, 2022 and 2021 was $27.1 million and $23.2 million, or ($0.31) and ($0.34) per share, respectively. Net loss for the six months ended June 30, 2022, and 2021 was $54.9 million and $40.8 million, or ($0.62) and ($0.59) per share, respectively. Net loss was higher due to an increase in clinical operating expenses, as clinical activity related to our late-stage development of seladelpar in PBC continued to expand, as well as an increase in interest expense accretion related to the Abingworth development financing arrangement. We expect our 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 second quarter 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# 13730902. 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 and the potential benefits to patients, as well as the timing of the release of data from RESPONSE 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2022 | 2021 | 2022 | 2021 |
| | (unaudited) | (unaudited) | (unaudited) | (unaudited) |
| Operating expenses: | | | | |
| Research and development | $ 17,891 | $ 16,745 | $ 36,306 | $ 29,127 |
| General and administrative | 5,878 | 6,521 | 11,965 | 11,757 |
| Total operating expenses | 23,769 | 23,266 | 48,271 | 40,884 |
| Loss from operations | (23,769) | (23,266) | (48,271) | (40,884) |
| Other income (expense), net: | | | | |
| Interest income | 321 | 44 | 419 | 111 |
| Interest expense | (3,648) | - | (7,013) | - |
| Other income | 2 | - | 2 | - |
| Total other income (expense), net | (3,325) | 44 | (6,592) | 111 |
| Net loss | $ (27,094) | $ (23,222) | $ (54,863) | $ (40,773) |
| Basic and diluted net loss per common share | $ (0.31) | $ (0.34) | $ (0.62) | $ (0.59) |
| Weighted average common shares outstanding used to calculate basic and diluted net loss per common share | 87,802,939 | 68,985,461 | 87,802,939 | 68,965,885 |

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

| | June 30, 2022 | December 31, 2021 |
|---|---|---|
| | (unaudited) | |
| Cash, cash equivalents and marketable securities | $ 170,757 | $ 194,602 |
| Working capital | 154,051 | 172,733 |
| Total assets | 177,724 | 202,318 |
| Total liabilities | 95,267 | 69,381 |
| Common stock and additional paid-in capital | 904,617 | 899,806 |
| Total stockholders' equity | 82,457 | 132,937 |

Source: CymaBay Therapeutics, Inc.