March 17, 2022

# CymaBay Reports Fourth Quarter and Year Ended December 31, 2021 Financial Results and Provides Corporate Update

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

NEWARK, Calif., March 17, 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 fourth quarter and fiscal year ended December 31, 2021.

Sujal Shah, President and CEO of CymaBay, stated, “2021 was a year of growth for CymaBay and included accomplishments that position CymaBay for long-term success. A non-dilutive, risk-sharing development financing agreement of up to $100 million signed with Abingworth in July, together with a $75 million public equity offering in November support the completion of our ongoing Phase 3 program for seladelpar in PBC. We now have over 120 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 have seen a high level of interest in our long-term safety study, ASSURE, where we have enrolled more than 120 patients from our prior studies of seladelpar in PBC. We were also excited to share additional data at The Liver Meeting® 2021 that we believe demonstrate improved benefit of seladelpar between one to two years of treatment, and differentiation from other existing treatments in a population of PBC patients with more advanced disease.”

“Heading into 2022, we are well positioned to deliver on our laser focus of improving the lives of patients with PBC. Although the pandemic and recent global unrest have 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 longer-term vision of establishing a pipeline of opportunities for patients with unmet need. Despite these challenges, we have seen steady progress since re-initiating our development program in PBC in 2021. 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.”

### Recent Corporate Highlights

- 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. To date we have over 120 sites activated across more than 20 countries.

- 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. To date we have enrolled over 120 patients in the study, building our already extensive safety database for seladelpar treated PBC patients.
- 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.
- Announced that results of analyses from two clinical studies of seladelpar were delivered during The Liver Meeting Digital Experience™ 2021 (TLMdX) of the American Association for the Study of Liver Diseases (AASLD), as follows:
    - Oral presentation titled “Long-Term Safety and Efficacy of Seladelpar in Patients with Primary Biliary Cholangitis” delivered by Dr. Marlyn J. Mayo, MD, highlighting the efficacy and safety of seladelpar during 2 years of treatment in patients with primary biliary cholangitis (PBC).
    - A clinical presentation titled “Efficacy and Safety of Seladelpar in Patients with Compensated Cirrhosis and Evidence of Portal Hypertension due to Primary Biliary Cholangitis” delivered by Dr. Cynthia Levy, MD, highlighting 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.
- Continued to grow our team from 40 to 59 employees during the year, including the hiring of two executive officers; Dr. Dennis Kim as Chief Medical Officer, a physician-scientist trained in endocrinology who brings significant clinical development and executive experience and Lewis Stuart as Chief Commercial Officer, an executive who brings a diverse set of experiences launching products in both the pharmaceutical and molecular diagnostics healthcare sectors.
- Expanded the Board of Directors composition by appointing Thomas Wiggans a biopharma industry veteran and Janet Dorling a senior commercial executive at Gilead. Recently appointed Dr. Éric Lefebvre, the Chief Medical Officer of Pliant Therapeutics, to the Board.
- Executed a non-dilutive financing transaction with Abingworth LLP for the development of seladelpar in PBC. CymaBay will receive up to $100 million of funding for seladelpar development costs, of which $75 million has been received to date. CymaBay has an option to receive an additional $25 million after the completion of enrollment of CymaBay’s Phase 3 **RESPONSE** clinical trial.
- Completed public equity offering in November 2021, CymaBay sold 15,625,000 shares of common stock at $4.00 per share and pre-funded warrants to purchase 3,125,000 shares of common stock at $3.9999 per share. After deducting underwriting commissions and other estimated offering expenses, net proceeds of the offering were $70.5 million.
- Held $194.6 million in cash, cash equivalents and short-term investments as of

December 31, 2021. We believe that cash and investments on hand, together with committed capital available through the development financing agreement with Abingworth, is sufficient to fund CymaBay's operating plan through 2023.

**Fourth Quarter and Year Ended December 31, 2021 Financial Results**

- Research and development expenses for the three months ended December 31, 2021 and 2020 were $18.4 million and $10.7 million, respectively. Research and development expenses for the twelve months ended December 31, 2021 and 2020 were $64.5 million and $35.9 million, respectively. Research and development expenses in the three and twelve months ended December 31, 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.
- General and administrative expenses for the three months ended December 31, 2021 and 2020 were $6.1 million and $5.2 million, respectively. General and administrative expenses for the twelve months ended December 31, 2021 and 2020 were $23.0 million and $16.7 million, respectively. General and administrative expenses in the three and twelve months ended December 31, 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 December 31, 2021 and 2020 was $26.5 million and $15.8 million, or ($0.34) and ($0.23) per diluted share, respectively. Net loss for the twelve months ended December 31, 2021 and 2020 was $90.0 million and $51.0 million, or ($1.27) and ($0.74) 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 fourth quarter and fiscal year end 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# 13726915. 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 December 31, | | Year Ended December 31, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| | **(unaudited)** | **(unaudited)** | | |
| Operating expenses: | | | | |
| Research and development | $ 18,405 | $ 10,688 | $ 64,542 | $ 35,882 |
| General and administrative | 6,104 | 5,185 | 23,040 | 16,720 |
| Total operating expenses | 24,509 | 15,873 | 87,582 | 52,602 |
| Loss from operations | (24,509) | (15,873) | (87,582) | (52,602) |
| Other income (expense), net: | | | | |
| Interest income | 27 | 122 | 167 | 1,616 |
| Interest expense | (2,061) | - | (2,583) | - |
| Total other income (expense), net | (2,034) | 122 | (2,416) | 1,616 |
| Net loss | $ (26,543) | $ (15,751) | $ (89,998) | $ (50,986) |
| Basic and diluted net loss per common share | $ (0.34) | $ (0.23) | $ (1.27) | $ (0.74) |
| Weighted average common shares outstanding used to calculate basic and diluted net loss per common share | 77,198,483 | 68,917,646 | 71,055,331 | 68,893,127 |

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

| | **December 31, 2021** | **December 31, 2020** |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 194,602 | * $ 146,323 |
| Working capital | 172,733 | 141,728 |
| Total assets | 202,318 | 153,825 |
| Total liabilities | 69,381 | 11,119 |
| Common stock and additional paid-in capital | 899,806 | 819,556 |
| Total stockholders' equity | 132,937 | 142,706 |

* Does not include $25 million received from Abingworth on January 28, 2022.

Source: CymaBay Therapeutics, Inc.