May 12, 2022

CymaBay Reports First Quarter 2022 Financial Results and Provides Corporate Update

Over 150 clinical sites now activated in RESPONSE Phase 3 clinical trial

Results from a 52-week, open-label phase 2 study of seladelpar in patients with PBC published in the Journal of Hepatology

Biopharma leader, Éric Lefebvre, M.D. appointed to the Board of Directors

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

NEWARK, Calif., May 12, 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 first quarter ended March 31, 2022.

Sujal Shah, President and CEO of CymaBay, stated, “Despite facing ongoing external challenges, we have made steady progress over the past few months enrolling patients in RESPONSE, our second, global phase 3 registration study of seladelpar for patients with primary biliary cholangitis (PBC). We now have over 150 clinical sites activated across 26 countries where we have continued to increase our direct site engagement initiatives. As we approach what we project to be the final months of screening, we have greater visibility into monthly metrics and forecast completion of enrollment in the third quarter. We were also excited to have the results of our 52-week, open-label, Phase 2 study of seladelpar in patients with PBC published in the Journal of Hepatology last month. The opportunity to have these data featured in one of the world’s preeminent medical journals for liver diseases elevates seladelpar’s visibility as a differentiated drug candidate for patients with PBC. Finally, we have continued to navigate the difficult market environment with a focus on diligent expense management leaving us with a strong balance sheet after completing two successful financings in 2021. In the first quarter, we received the third $25 million funding tranche from our non-dilutive, clinical funding agreement with Abingworth and ended the quarter with $193 million of cash, cash equivalents and investments.”

Recent Corporate Highlights

- Moving towards completion of 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 150 sites activated across 26 countries.

- Continued strong 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. In April, we successfully rolled over patients completing RESPONSE into ASSURE. Together with patients that entered into ASSURE from prior studies with seladelpar, there are now approximately 140 patients in this study taking daily seladelpar.

- 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.

- Published results from Phase 2, 52-week study of seladelpar in patients with primary biliary cholangitis (PBC) in the Journal of Hepatology. This 52-week, phase 2, dose-ranging, open-label study examined the efficacy and safety of seladelpar in PBC patients who were receiving or intolerant to first-line therapy with ursodeoxycholic acid., The results included:

    - An interim primary efficacy analysis of ALP change from baseline at Week 8 found that seladelpar treatment provided 26%, 33%, and 41% reductions for the 2 mg, 5 mg and 10 mg doses, respectively (all $p<0.005$).
    - Responses were maintained or improved at Week 52, which included dose escalation in 91% and 80% of the 2 mg and 5 mg cohorts, respectively.
    - At Week 52, the composite biochemical response (ALP <1.67×ULN, ≥15% ALP decrease from baseline, and normal total bilirubin) rates were 64%, 53%, and 67%, and ALP normalization rates were 9%, 13%, and 33% in the 2 mg, 5 mg, and 10 mg cohorts, respectively.
    - The pruritus visual analog scale score decreased in the 5 mg and 10 mg cohorts.
    - There were no treatment-related serious adverse events (AEs), and 4 patients discontinued due to AEs.

- Expanded the Board of Directors to include Dr. Éric Lefebvre, the Chief Medical Officer of Pliant Therapeutics. Prior to joining Pliant, Dr. Lefebvre served as the Vice President of Research and Development of Allergan plc and before that was Chief Medical Officer of Tobira Therapeutics, Inc. Dr. Lefebvre also led global clinical development and global medical affairs at Janssen Pharmaceuticals for 10 years prior to starting his pharmaceutical career at GlaxoSmithKline Canada.

- Received $25 million of funding in January 2022 from Abingworth through a non-dilutive financing agreement for the development of seladelpar, which was executed in July 2021. $75 million has been received to date through the financing agreement. CymaBay also has an option to receive an additional $25 million after the completion of

enrollment of the **RESPONSE** clinical trial.

- Held $193.4 million in cash, cash equivalents and investments as of March 31, 2022. 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.

First Quarter Ended March 31, 2022 Financial Results

- Research and development expenses for the three months ended March 31, 2022 and 2021 were $18.4 million and $12.4 million, respectively. Research and development expenses in the three months ended March 31, 2022 were higher than the corresponding period 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 March 31, 2022 and 2021 were $6.1 million and $5.2 million, respectively. General and administrative expenses in the three months ended March 31, 2022 were higher than the corresponding period in 2021 due to higher employee compensation associated with the hiring of additional personnel and an increase in consulting and other expenses to support our late-stage development of seladelpar in PBC.

- Net loss for the three months ended March 31, 2022 and 2021 was $27.8 million and $17.6 million, or ($0.32) and ($0.25) per diluted share, respectively. Net loss was higher largely due to increases in clinical operating expenses, as clinical activity related to our late-stage development of seladelpar in PBC continued to expand and accretion of interest expense related to the Abingworth development financing arrangement. 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# 13728967. 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 and CymaBay's ability to fund current and planned clinical trials 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 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.

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 March 31,	
	2022	**2021**
	(unaudited)	**(unaudited)**
Operating expenses:		
Research and development	$ 18,415	$ 12,382
General and administrative	6,087	5,236
Total operating expenses	24,502	17,618
Loss from operations	(24,502)	(17,618)
Other income (expense), net:		
Interest income	98	67
Interest expense	(3,365)	-
Total other income (expense), net	(3,267)	67
Net loss	$ (27,769)	$ (17,551)
Basic and diluted net loss per common share	$ (0.32)	$ (0.25)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	87,802,939	68,946,092

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

	March 31, 2022	**December 31, 2021**
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 193,444	$ 194,602
Working capital	178,007	172,733
Total assets	200,642	202,318
Total liabilities	93,261	69,381
Common stock and additional paid-in capital	902,225	899,806
Total stockholders' equity	107,381	132,937

Source: CymaBay Therapeutics, Inc.