March 16, 2023

CymaBay Reports Fourth Quarter and Year Ended December 31, 2022 Financial Results and Provides Corporate Update

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

NEWARK, Calif., March 16, 2023 (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 year and fourth quarter ended December 31, 2022.

Sujal Shah, President and CEO of CymaBay, stated, “We are off to a fast start in 2023 after making significant progress in 2022 in our development program evaluating seladelpar for patients with primary biliary cholangitis (PBC). Since completing enrollment in RESPONSE, our global phase 3 registration study, in July 2022, we presented data at The Liver Meeting^{Ò}, licensed rights to develop and commercialize seladelpar for patients with PBC in Japan to Kaken and secured additional funding that extends our runway through the third quarter of 2024. These accomplishments set up the remainder of 2023, during which we intend to manufacture commercial supplies, complete our plans for launch and marketing, and finish clinical development, which we expect to provide major catalysts in the second half of the year.”

2022 and Recent Corporate Highlights

Clinical Development:

- Enrollment was completed in **RESPONSE**, a 52-week, placebo-controlled, randomized, global, Phase 3 registration 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 (UDCA) in a 2:1 ratio to receive once daily oral seladelpar 10 mg or placebo. The primary outcome measure is the composite biochemical responder rate at 52 weeks. A responder is defined as a patient who achieves an alkaline phosphatase (ALP) 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 ALP at 52 weeks and the change from baseline in 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. We expect to release top line data for RESPONSE in the third quarter of 2023.

- Continued 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 200 patients in this study taking seladelpar

daily, including those from our prior studies of seladelpar and patients completing RESPONSE.

- Enrollment continues 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 is fully funded by The Leona M. and Harry B. Helmsley Charitable Trust with CymaBay retaining full rights to MBX-2982.

Presentations and Publications:

- Presented data at The Liver Meeting® 2022 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.
    - 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)”.
- Presented data 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 and predicted transplant-free survival following seladelpar treatment over two years. The GLOBE score is a validated risk-assessment tool providing an estimate of transplant-free survival for patients with PBC. An oral presentation was made during the AALSD Presidential Plenary session of DDW titled “Seladelpar Treatment of Patients With Primary Biliary Cholangitis (PBC) For 2 Years Improves the GLOBE PBC Score and Predicts Improved Transplant-Free Survival” by Dr. Bettina Hansen, PhD.
- Published results from a 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.

Corporate Updates and Business Development:

- Expanded the Board of Directors to include Dr. Éric Lefebvre, the Chief Medical Officer of Pliant Therapeutics.
- Announced the promotion of Dr. Charles McWherter to President of Research and Development, in addition to his continuing role as Chief Scientific Officer.
- Entered into a collaboration and license agreement with Kaken Pharmaceutical Co., Ltd. (“Kaken”) in January 2023 for the development and commercialization in Japan of CymaBay’s investigational drug seladelpar for the treatment of PBC.

- Pursuant to the terms of the agreement, Kaken received an exclusive license to develop, commercialize and market seladelpar in Japan for PBC.
- In exchange, CymaBay received an upfront payment of $34.2 million in January 2023, and is eligible to receive additional potential milestone payments up to ¥17.0 billion (approximately $128.0 million at contract inception) upon Kaken's achievement of certain regulatory and sales milestones.
- CymaBay is eligible to receive 20+% net effective royalties on future sales.
- There are currently no approved second line treatments for PBC in Japan, representing a significant unmet medical need for PBC patients in Japan.

Financial Updates:

- Completed a public equity offering in January 2023, in which we sold 11,821,428 shares of common stock at $7.00 per share and pre-funded warrants to purchase 2,142,857 shares of common stock at $6.9999 per share. Net proceeds of the offering were $92.4 million, after deducting underwriting commissions and other offering expenses.

- Held $135.5 million in cash, cash equivalents and investments as of December 31, 2022. We believe that cash and investments on hand, together with the upfront payment of $34.2 million received from Kaken and $92.4 million of net proceeds received in connection with our January 2023 public equity offering, are sufficient to fund CymaBay's operating plan through the third quarter of 2024.

Fourth Quarter and Year Ended December 31, 2022, Financial Results

- Research and development expenses for the three months ended December 31, 2022, and 2021 were $16.2 million and $18.4 million, respectively. Research and development expenses for the year ended December 31, 2022, and 2021 were $68.0 million and $64.5 million, respectively. Research and development expenses for the three months ended December 31, 2022 were lower than the corresponding period in 2021 primarily due to the completion of enrollment of our **RESPONSE** trial in July 2022 and lower spending in other Phase 1 NDA enabling clinical studies. Research and development expenses for the year ended December 31, 2022 were higher than the corresponding period in 2021 due primarily to an increase in clinical and other research personnel to support our late-stage development of seladelpar in PBC.

- General and administrative expenses for the three months ended December 31, 2022 and 2021 were $7.2 million and $6.1 million, respectively. General and administrative expenses for the year ended December 31, 2022 and 2021 were $25.1 million and $23.0 million, respectively. General and administrative expenses for the three months and year ended December 31, 2022 were higher than the corresponding periods in 2021 due to the hiring of additional personnel to support our corporate growth.

- Net loss for the three months ended December 31, 2022 and 2021 was $26.6 million and $26.5 million, or ($0.30) and ($0.34) per share, respectively. Net loss for the year ended December 31, 2022 and 2021 was $106.0 million and $90.0 million, or ($1.21) and ($1.27) per share, respectively. Net loss in the year ended December 31, 2022 was higher than the corresponding period in 2021 due primarily to an increase in

research and development and general and administrative expenses, as well as an increase in net interest expense related to the Abingworth development financing agreement. 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 877-407-0784 from the U.S. and Canada, or 201-689-8560 internationally, Conference ID # 13736281. 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, manufacturing and commercial plans, and the timing of the release of seladelpar clinical data are forward-looking statements that are subject to risks and uncertainties. Actual outcomes and results and the timing of events 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 product development activities; 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 product candidates; and the ability to obtain sufficient financing to complete development, regulatory approval and commercialization of product candidates. 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 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.

Public Relations Contact:

Glenn Silver
Lazar-FINN Partners
(973) 818-8198
Glenn.silver@finnpartners.com

Investor Relations Contact:

Hans Vitzthum
LifeSci Advisors, LLC
(617) 430-7578
Hans@LifeSciAdvisors.com

CymaBay Therapeutics, Inc.
Financial Results
(In thousands, except share and per share information)

	Quarter Ended December 31,		Year Ended December 31,	
	2022	**2021**	**2022**	**2021**
	(unaudited)	**(unaudited)**		
Operating expenses:				
Research and development	$ 16,230	$ 18,405	$ 67,995	$ 64,542
General and administrative	7,247	6,104	25,116	23,040
Total operating expenses	23,477	24,509	93,111	87,582
Loss from operations	(23,477)	(24,509)	(93,111)	(87,582)
Interest expense, net:				
Interest income	919	27	2,017	167
Interest expense	(4,075)	(2,061)	(14,907)	(2,583)
Total interest expense, net	(3,156)	(2,034)	(12,890)	(2,416)
Net loss	$ (26,633)	$ (26,543)	$ (106,001)	$ (89,998)
Basic and diluted net loss per common share	$ (0.30)	$ (0.34)	$ (1.21)	$ (1.27)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	87,806,063	77,198,483	87,804,063	71,055,331

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

	December 31, 2022	December 31, 2021
Cash, cash equivalents and marketable securities	$ 135,485 *	$ 194,602
Working capital	122,632	172,733
Total assets	141,852	202,318
Total liabilities	105,698	69,381
Common stock and additional paid-in capital	909,337	899,806
Total stockholders' equity	36,154	132,937

* Does not include net proceeds of $92.4 million received from our January 2023 equity financing and a $34.2 million upfront license payment received from the Kaken collaboration agreement.

Source: CymaBay Therapeutics, Inc.