August 10, 2023

CymaBay Reports Second Quarter and Six Months Ended June 30, 2023 Financial Results and Provides Corporate Update

Top-line data from RESPONSE Phase 3 study in PBC expected by end of September 2023

IDEAL clinical trial actively recruiting

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

NEWARK, Calif., Aug. 10, 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, announced today corporate updates and financial results for the second quarter ended June 30, 2023.

Sujal Shah, President and CEO of CymaBay, stated, “I’m incredibly proud of the progress our teams have made thus far this year as we march towards our key and exciting milestone in the third quarter when we expect to report top-line results from RESPONSE, our global phase 3 registration study of seladelpar in patients with primary biliary cholangitis (PBC). With RESPONSE nearing completion and ASSURE having enrolled over 300 patients to date, we believe the seladelpar development program in PBC is one of the most robust development programs in PBC ever conducted. We continue to believe seladelpar has the potential to be a differentiated second-line treatment option offering patients benefits on markers of disease associated with risk of progression and on symptoms. As announced earlier today, we are now also actively recruiting patients in IDEAL, a study to evaluate seladelpar’s effects on biochemical normalization in PBC patients who only achieve a partial response to first-line treatment. We believe data from IDEAL has the potential to reset expectations for second-line treatment in PBC. In anticipation of a successful data readout in RESPONSE and regulatory acceptance, our organizational build efforts are also underway as we start to put together key components of our commercial and medical affairs infrastructure.”

Corporate Updates:

- Announced the initiation of a 52-week, placebo-controlled, randomized, Phase 3 study **I**ntended to **D**etermine the **E**ffects of seladelpar on normalization of **A**lkaline phosphatase **L**evels in subjects with PBC (**IDEAL**). This study will target enrolling 75 patients, who have an incomplete response or intolerance to ursodeoxychoic acid (UDCA) as well as ALP greater than upper limit of normal (ULN) but less than 1.67xULN, in a 2:1 randomization to oral, once daily seladelpar 10 mg or placebo.

- Featured results of our studies at The International Liver Congress™ 2023 of the European Association for the Study of Liver (EASL). The presentation reported:
    - Treatment with seladelpar was found to be correlated with decreases in pruritus and Interleukin-31 (IL-31) levels in patients with PBC. We believe this to be the

first intervention in PBC to show this correlation. IL-31 is a cytokine known to play a significant role in pruritus in a variety of other diseases.
    - Transcriptomics data produced from two distinct fibrosis models, coupled with a platform capable of searching publicly available databases, revealed new aspects of the action of seladelpar to reduce established fibrosis.
    - An analysis revealing that patients previously treated with UDCA, and having elevated levels of alkaline phosphatase (ALP) that do not currently qualify for second-line treatment, very often had additional factors for risk of disease progression. This highlights the potential for a broader population of patients that may benefit from second-line therapy.

- Enrollment completed 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 fully funded by The Leona M. and Harry B. Helmsley Charitable Trust with CymaBay retaining full rights to MBX-2982. Top-line results expected by year-end 2023.

Financial Updates:

- Recognized $31.0 million of collaboration revenue in the second quarter of 2023 related to the $34.2 million upfront fee received from the collaboration and license agreement with Kaken Pharmaceutical Co., Ltd. in January 2023 for the development and commercialization of seladelpar in Japan.
- Held $213.8 million in cash, cash equivalents and investments as of June 30, 2023. We believe that cash and investments on hand are sufficient to fund CymaBay's operating plan through the third quarter of 2024.

Second Quarter and Six Months Ended June 30, 2023 Financial Results

- Collaboration revenue recognized for the three and six months ended June 30, 2023 was $31.0 million, on completion of the initial technology transfer associated with the license to develop and commercialize seladelpar in Japan. Of the $34.2M upfront payment received from Kaken, $2.7 million remains deferred and will be recognized upon completion of the Company's ongoing clinical data delivery and CMC development performance obligations.
- Research and development expenses for the three months ended June 30, 2023, and 2022 were $19.5 million and $17.9 million, respectively. Research and development expenses for the six months ended June 30, 2023 were $38.1 million and $36.3 million, respectively. Research and development expenses for the three- and six-month periods ended June 30, 2023 increased compared to the corresponding periods in 2022 as we continue to hire additional research and development personnel and engage external contractors to support our clinical studies and potential regulatory submissions.
- General and administrative expenses for the three months ended June 30, 2023 and 2022 were $11.6 million and $5.9 million, respectively. General and administrative expenses for the six months ended June 30, 2023 and 2022 were $19.9 million and $12.0 million, respectively. General and administrative expenses for the three and six months ended June 30, 2023 were higher than the corresponding period in 2022 due to an increase in headcount as we continued to add administrative personnel and expand our infrastructure to support our drug development activities and prepare for

potential commercialization of seladelpar in PBC.

- Net loss for the three months ended June 30, 2023 and 2022 was $0.8 million and $27.1 million, or ($0.01) and ($0.31) per share, respectively. Net loss for the six months ended June 30, 2023 was $29.6 million and $54.9 million, or ($0.30) and ($0.62), respectively. Net loss for the three- and six-month periods ended June 30, 2023 was lower than the corresponding periods in 2022 due primarily to the recognition of $31.0 million of collaboration revenue during the three months ended June 30, 2023 and higher interest income earned on our investments and other income due to refundable tax credits, offset in part by an increase in operating expenses. Overall, we expect operating expenses to increase in the future as we continue to support our ongoing drug development activities and expand on initiatives to plan and prepare for potential commercialization of seladelpar in PBC.

Conference Call Details

CymaBay will host a conference call today at 4:30 p.m. ET to discuss first quarter financial results and provide a business update. To access the live conference call, please dial 1-877-308-2053 from the U.S. and Canada, or 1-212-231-2921 internationally, Conference ID # 22027740. 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 investigational 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 approval, launch and commercialization of seladelpar or timing or plans in regard thereto, including the timing of the release of top-line data from RESPONSE, as well as statements regarding the Company’s expected cash runway, potential benefits of seladelpar, potential of IDEAL to reset expectations for second-line treatment in PBC, completion of ongoing clinical trials and subsequent regulatory submissions 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; 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 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,	
	2023	2022	2023	2022
	(unaudited)	(unaudited)	(unaudited)	(unaudited)
Collaboration revenue	31,016	-	31,016	$ -
Operating expenses:				
Research and development	19,537	17,891	38,088	36,306
General and administrative	11,578	5,878	19,902	11,965
Total operating expenses	31,115	23,769	57,990	48,271
Loss from operations	(99)	(23,769)	(26,974)	(48,271)
Other income (expense), net:				
Interest income	2,627	321	4,640	419
Interest expense	(4,618)	(3,648)	(9,021)	(7,013)
Other income	1,282	2	1,769	2
Total other income (expense), net	(709)	(3,325)	(2,612)	(6,592)
Net loss	$ (808)	$ (27,094)	$ (29,586)	$ (54,863)
Basic and diluted net loss per common share	$ (0.01)	$ (0.31)	$ (0.30)	$ (0.62)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	102,150,390	87,802,939	100,072,281	87,802,939

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

	June 30, 2023	December 31, 2022
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 213,844	$ 135,485
Working capital	206,177	122,632
Total assets	226,650	141,852
Total liabilities	118,242	105,698
Common stock and additional paid-in capital	1,010,975	909,337
Total stockholders' equity	108,408	36,154

Source: CymaBay Therapeutics, Inc.