May 13, 2021

CymaBay Reports First Quarter 2021 Financial Results and Provides Corporate Update

Highly experienced executives, Dr. Dennis Kim as Chief Medical Officer and Lewis Stuart as Chief Commercial Officer, strengthen the management team

Biopharma leaders, Thomas Wiggans and Janet Dorling, appointed to the Board of Directors

Actively recruiting patients in two global, clinical studies evaluating seladelpar in primary biliary cholangitis (PBC):

- *RESPONSE, a 52-week, randomized, placebo-controlled, Phase 3 registrational study*
- *ASSURE, an open-label, long-term study*

Two pipeline programs also in clinical development:

- *Phase 2a study of MBX-2982, a GPR119 agonist, for the prevention of diabetic hypoglycemia*
- *Phase 1 pharmacokinetic study of CB-0406, a non-agonist ligand of PPARγ, for inflammation and fibrosis*

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

NEWARK, Calif., May 13, 2021 (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, 2021.

In May 2021, CymaBay strengthened its management team with the additions of Dr. Dennis Kim as Chief Medical Officer and Lewis Stuart as Chief Commercial Officer. CymaBay also continued to make significant progress conducting the development program for seladelpar in primary biliary cholangitis (PBC). With clinical sites activated in North America and Europe, patient recruitment is underway in **RESPONSE**, a global Phase 3 registrational study evaluating seladelpar in patients with PBC. In addition, CymaBay continued to conduct enrollment activities for **ASSURE**, an open-label, long-term study of seladelpar in patients with PBC intended to collect additional safety data to support registration.

Sujal Shah, President and CEO of CymaBay, stated, “I’m excited to announce the addition of two key executives to our management team, Dr. Dennis Kim as Chief Medical Officer and Lewis Stuart as Chief Commercial Officer. Dennis and Lewis are both experienced biopharma industry executives who will further complement our team and provide leadership in our growing clinical and commercial organizations. We also continued to make progress with **RESPONSE**, our registrational study designed to evaluate the efficacy and safety of seladelpar in patients with PBC. In addition to our core focus in PBC, we are excited about

other early-stage pipeline candidates, with more updates to share in the coming months."

Recent Corporate Highlights

- Hired Dr. Dennis Kim as Chief Medical Officer. Dr. Kim is a physician-scientist trained in endocrinology who brings significant clinical development and executive experience in emerging biotech environments from companies such as Amylin, Orexigen and Zafgen. Dr. Kim is well suited to articulate the science, medicine, and opportunities of our programs to broad audiences including medical experts, investigators, patient groups, investors, and analysts. Dr. Kim will lead all clinical-related functions including development, clinical operations, biometrics, and medical affairs.

- Hired 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. Mr. Stuart brings more than 25 years of experience leading the marketing, sales, market access, and other commercial functions at successful biotech companies and has launched new therapies in women's health, oncology, metabolic, and rare diseases. Mr. Stuart will lead all aspects of CymaBay's commercial operations, including marketing and sales.

- Appointed Thomas Wiggans to the Board. Mr. Wiggans is a biopharma industry veteran, who brings extensive experience and insight having previously served as CEO and leading companies such as Dermira, Peplin, and Connectics from development through commercialization.

- Appointed Janet Dorling to the Board. Ms. Dorling is a senior commercial executive at Gilead, who previously served as Chief Commercial Officer at CymaBay and Achaogen and held prior executive and senior leadership positions in the commercial organization at Roche/Genentech.

- Conducted enrollment activities for **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.

- Conducted enrollment activities for **ASSURE**, an open-label, long-term study of seladelpar in patients with PBC intended to collect additional long-term safety data to support registration.

- Initiated 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 (T1D). The study is being conducted by the AdventHealth Translational

Research Institute (TRI) in Orlando, Florida and fully funded by The Leona M. and Harry B. Helmsley Charitable Trust with CymaBay retaining full rights to MBX-2982.

- Continued executing a single and multiple ascending dose pharmacokinetic study of CB-0406 in healthy subjects to establish its pharmacokinetics, safety, and maximum tolerated dose. CB-0406 is a non-agonist ligand of PPARg that attenuates the expression of inflammatory genes.

- Held $125.5 million in cash, cash equivalents and short-term investments as of March 31, 2021. We believe that cash and investments are sufficient to fund CymaBay's current operating plan into mid-2022.

- Due to the ongoing effects of the global coronavirus pandemic, CymaBay continues to conduct its operations remotely for all employees, which has allowed business activities to continue as seamlessly as possible. CymaBay continues to closely monitor pandemic developments and their associated risks to the business, including the conduct of its clinical development of seladelpar, and will continue to take actions to mitigate them where possible. Further, all CymaBay's actions will continue to be guided by a commitment to ensuring the health and safety of its employees as well as patients enrolled in its clinical studies.

First Quarter Ended March 31, 2021 Financial Results

- Research and development expenses for the three months ended March 31, 2021 and 2020 were $12.4 million and $9.5 million, respectively. Research and development expenses in the three months ended March 31, 2021 were higher than the corresponding periods in 2020 primarily due to an increase in clinical trial activities following our resumption of clinical development of seladelpar in PBC in late 2020. In particular, cost increases were primarily driven by the enrollment activities associated with RESPONSE and ASSURE, our two new global late-stage clinical trials in PBC. In the three months ended March 31, 2020, costs incurred were primarily associated with the termination and shutdown of our Phase 3 PBC, Phase 2b NASH, and Phase 2 PSC clinical trials, and other studies, after the seladelpar development program was placed on hold from November 2019 through July 2020.

- General and administrative expenses for the three months ended March 31, 2021 and 2020 were $5.2 million and $4.4 million, respectively. General and administrative expenses in the three months ended March 31, 2021 were higher than the corresponding period in 2020 due to higher employee compensation associated with the hiring of additional personnel upon resumption of development of seladelpar in the second half of 2020.

- Net loss for the three months ended March 31, 2021 and 2020 was $17.6 million and $13.1 million, or ($0.25) and ($0.19) 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 2021 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 first quarter 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# 13718350. 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, CymaBay's ability to fund current and planned clinical trials and 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; 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.

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

	Quarter Ended March 31,	
	2021	**2020**
	(unaudited)	**(unaudited)**
Operating expenses:		
Research and development	$ 12,382	$ 9,509
General and administrative	5,236	4,418
Total operating expenses	17,618	13,927
Loss from operations	(17,618)	(13,927)
Interest income	67	839
Net loss	$ (17,551)	$ (13,088)
Basic and diluted net loss per common share	$ (0.25)	$ (0.19)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	68,946,092	68,882,459

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

	March 31, 2021	**December 31, 2020**
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 125,458	$ 146,323
Working capital	125,364	141,728
Total assets	136,682	153,825
Total liabilities	9,036	11,119
Common stock and additional paid-in capital	822,061	819,556
Total stockholders' equity	127,646	142,706

Source: CymaBay Therapeutics, Inc.