March 25, 2021

CymaBay Reports Fourth Quarter and Year End 2020 Financial Results and Provides Corporate Update

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 in 2021:

- *Phase 2a study of MBX-2982, a GPR119 agonist, for the prevention of hypoglycemia in patients with type 1 diabetes*
- *Phase 1 single and multiple ascending dose study of CB-0406, a non-agonist ligand of PPARγ*

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

NEWARK, Calif., March 25, 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 fourth quarter and fiscal year ended December 31, 2020.

In the fourth quarter of 2020 and through early March 2021, CymaBay made significant progress reinitiating the development program for seladelpar in primary biliary cholangitis (PBC). With multiple clinical sites activated, patient recruitment is underway in **RESPONSE**, a global Phase 3 registrational study evaluating seladelpar in patients with PBC. In addition, we have also initiated **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, “One year ago today, our work towards finding novel treatments for patients with chronic, inflammatory and metabolic diseases was on hold as we completed the important work of ensuring patient safety before moving forward. Today we have four active clinical studies ongoing across three programs. We continue to make great progress towards restarting our seladelpar development program with **RESPONSE** as we execute on a focused strategy to complete late-stage development of seladelpar for patients with PBC. Results from our previous Phase 3 study in PBC, **ENHANCE,** presented at The Liver Meeting® 2020, highlighted the anti-cholestatic, anti-inflammatory and anti-pruritic effects of seladelpar in patients with PBC that we believe support the potential for seladelpar to address key unmet needs for patients suffering from this disease. In addition to our core focus in PBC, we continue to evaluate seladelpar for other indications and are excited about our early-stage pipeline maturing in the coming months.”

Recent Corporate Highlights

- Initiated **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 will target enrolling 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.

- Initiated **ASSURE**, an open-label, long-term study of seladelpar in patients with PBC intended to collect additional long-term safety data to support registration. The first subjects will consist of patients who have participated in CymaBay's prior studies of seladelpar in PBC, including the patients who completed the open-label Phase 2 study and enrolled into the previous long-term study and ENHANCE. Patients who complete **RESPONSE**, and potentially other future PBC studies with seladelpar, will also have the opportunity to enroll in **ASSURE**.

- Presented results from two separate studies of seladelpar in patients with PBC and NASH at The Liver Meeting® 2020 as follows:

    - Oral, late-breaking presentation by Professor Gideon Hirschfield, MD, on November 16 highlighting results from **ENHANCE**, a Phase 3 study of seladelpar in patients with PBC
    - "Poster of Distinction" presentation by Dr. Stephen Harrison, MD, featuring results from a Phase 2 paired-liver biopsy study of seladelpar in patients with NASH

- In November 2020, we announced 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. TRI commenced startup activities in early 2021 and topline results are currently anticipated in late 2021.

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

- Held $146.3 million in cash, cash equivalents and short-term investments on December 31, 2020. 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 restarting of its clinical development of seladelpar, and will continue to take actions available 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.

Fourth Quarter and Year Ended December 31, 2020 Financial Results

- Research and development expenses for the three and twelve months ended December 31, 2020 were $10.7 million and $35.9 million, respectively. This compared to R&D expenses of $20.9 million and $83.8 million for the three and twelve months ended December 31, 2019, respectively. Research and development expenses in the three and twelve months ended December 31, 2020 were lower than the corresponding periods in 2019 primarily due to a decline in clinical trial activities related to the termination 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. Clinical development of seladelpar in PBC was resumed in late 2020, and these clinical expense reductions were offset in part by increases in clinical trial costs associated with the commencement of RESPONSE and ASSURE, our two new global late-stage clinical trials in PBC.

- General and administrative expenses for the three and twelve months ended December 31, 2020 were $5.2 million and $17.4 million, respectively. This compared to $4.5 million and $19.2 million for the three and twelve months ended December 31, 2019, respectively. General and administrative expenses in the year 2020 were lower than in 2019 due to lower employee compensation costs following the completion of a reduction-in-force plan in late 2019. General and administrative expenses in the three months ended December 31, 2020 were higher than the corresponding period in 2019 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 and twelve months ended December 31, 2020 was $15.8 million, or ($0.23) per diluted share, and $51.0 million, or ($0.74) per diluted share, respectively. This compared to net loss of $29.4 million, or ($0.43) per diluted share, and $102.8 million, or ($1.53) per diluted share, in the three and twelve months ended December 31, 2019, respectively. Net loss was lower largely due to decreases in clinical operating expenses which resulted from the temporary clinical hold placed on the seladelpar development program. With development of seladelpar restarted 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 fourth quarter and fiscal year end 2020 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# 13715944. 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 developing therapies for liver and other chronic diseases with high unmet medical need. CymaBay is developing seladelpar, a potent, selective, orally active PPARδ agonist for patients with primary biliary cholangitis (PBC). Seladelpar has received an orphan designation from the US Food and Drug administration (FDA) and the European Medicine Agency (EMA). Seladelpar also received Breakthrough Therapy Designation from the FDA for early stage PBC and PRIority MEdicines (PRIME) status from the EMA. CymaBay is currently commencing a global, Phase 3 registration study of seladelpar for PBC. This study is a 52-week, placebo-controlled, randomized, Phase 3 study to evaluate the safety and efficacy of seladelpar (RESPONSE) in patients with PBC. For more information about RESPONSE, please visit: www.pbcstudies.com.

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.

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 December 31,		Year Ended December 31,	
	2020	**2019**	**2020**	**2019**
	(unaudited)	**(unaudited)**		
Operating expenses:				
Research and development	$ 10,688	$ 20,937	$ 35,882	$ 83,837
General and administrative	5,186	4,532	17,425	19,238
Restructuring (benefit) charges	(1)	5,075	(705)	5,075
Total operating expenses	15,873	30,544	52,602	108,150
Loss from operations	(15,873)	(30,544)	(52,602)	(108,150)
Other income:				
Interest income	122	1,131	1,616	5,342
Total other income	122	1,131	1,616	5,342
Net loss	$ (15,751)	$ (29,413)	$ (50,986)	$ (102,808)
Basic and diluted net loss per common share	$ (0.23)	$ (0.43)	$ (0.74)	$ (1.53)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	68,917,646	68,749,075	68,893,127	67,033,046

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

	December 31, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	$ 146,323	$ 190,945
Working capital	141,728	185,287
Total assets	153,825	205,727
Total liabilities	11,119	19,379
Common stock and additional paid-in capital	819,556	812,140
Total stockholders' equity	142,706	186,348

Source: CymaBay Therapeutics, Inc.