November 5, 2020

CymaBay Reports Third Quarter 2020 Financial Results and Provides Corporate Update

*CymaBay announces trial design for **RESPONSE**, a global phase 3 registration study for seladelpar in primary biliary cholangitis (PBC)*

*Results from the **ENHANCE** phase 3 study evaluating seladelpar for PBC to be featured in an oral, late-breaking presentation at The Liver Meeting® 2020*

NASH phase 2b data for seladelpar to be presented in a "Poster of Distinction" at The Liver Meeting® 2020

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

NEWARK, Calif., Nov. 05, 2020 (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 third quarter and nine months ended September 30, 2020.

In the third quarter and through early November 2020, CymaBay made significant progress in restarting the development program for seladelpar in primary biliary cholangitis (PBC). Start-up is well underway for **RESPONSE**, a global phase 3 registration study evaluating seladelpar in patients with PBC and is poised for first patient dosed in the first quarter of next year. Results from the **ENHANCE** phase 3 study will be featured on November 16 in the late-breaking session of The Liver Meeting® 2020 sponsored by the American Association for the Study of Liver Diseases (AASLD). This marks the fourth consecutive year in which data from the seladelpar development program in PBC will be featured in an oral, late-breaking presentation at The Liver Meeting®.

Sujal Shah, President and CEO of CymaBay, stated, "We are making great progress towards restarting our seladelpar development program with **RESPONSE** as we drive to completing late-stage development of seladelpar for patients with PBC. Results from our **ENHANCE** study to be presented at The Liver Meeting® 2020 demonstrate the anti-cholestatic, anti-inflammatory and anti-pruritic effects of seladelpar in patients with PBC and we believe highlight the potential for seladelpar to address key unmet needs for patients suffering from this serious, life-threatening disease. In addition to our core focus in PBC, we continue to evaluate seladelpar and our other early-stage clinical assets for other indications and development opportunities."

Recent Corporate Highlights

- Start-up activities initiated for **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 is intended to enroll 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.

- CymaBay has also initiated start-up activities for**ASSURE**, an open-label, long-term study of seladelpar in patients with PBC intended to collect additional safety data to support registration. This study is expected to begin enrolling patients in early 2021. The first subjects will consist of patients who have participated in the Company's prior studies of seladelpar in PBC, including the open-label phase 2 study, ENHANCE and the Company's long-term safety study. As patients complete **RESPONSE**, and potentially other future PBC studies with seladelpar, they may also have the opportunity to enroll in **ASSURE**.

- Announced results from two separate studies of seladelpar in patients with PBC and NASH that will be featured at The Liver Meeting® 2020 sponsored by the American Association for the Study of Liver Diseases to be held virtually November 13th – 16th

    - 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 August 2020, CymaBay announced positive topline results from**ENHANCE** for seladelpar in patients with PBC. Topline data for patients through 3 and 6 months demonstrated anti-cholestatic, anti-inflammatory, and anti-pruritic activity. Notably, 78.2% of patients on seladelpar 10 mg versus 12.5% on placebo achieved the primary composite outcome after only 3 months ($p<0.0001$). In addition, 27.3% of patients on seladelpar 10 mg versus zero on placebo experienced normalization of ALP by 3 months ($p<0.0001$). Treatment with seladelpar 10 mg also resulted in a statistically significant improvement in pruritus ($p<0.05$) for patients with moderate-to-severe itch at baseline versus placebo. Overall, seladelpar appeared to be safe and well-tolerated in this study.

- In November 2020, announced a study to evaluate the potential for MBX-2982, a GPR119 agonist, to prevent hypoglycemia in patients with type 1 diabetes (T1D). Insulin-induced hypoglycemia in diabetes is a significant limiting factor in achieving the desired glucose control and is the cause of significant morbidity. In recent preclinical studies, GPR119 agonists were shown to enhance glucagon secretion in response to

low glucose levels and were able to prevent hypoglycemia in animal models. The Phase 2a proof-of-pharmacology study will assess whether MBX-2982 can enhance glucagon secretion during insulin-induced hypoglycemia in subjects with T1D. The study will be led by the AdventHealth Translational Research Institute in Orlando, Florida and fully funded by The Leona M. and Harry B. Helmsley Charitable Trust. CymaBay retains full rights to MBX-2982.

- CymaBay held $161.3 million in cash, cash equivalents and short-term investments as of September 30, 2020 and had no outstanding debt. We believe that cash and investments are sufficient to fund CymaBay's current operating plan into 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. To date, these developments have not had a significant impact on CymaBay's financial condition or its ability to execute its business plan. CymaBay will continue 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.

Third Quarter and Nine Months Ended September 30, 2020 Financial Results

- Research and development expenses for the three months ended September 30, 2020 were $7.7 million, compared to $23.2 million for the three months ended September 30, 2019. Research and development expenses for the nine months ended September 30, 2020 were $25.2 million, compared to $62.9 million for the nine months ended September 30, 2019. Research and development expenses in the first three and nine months of 2020 were significantly lower than the corresponding periods in 2019 primarily due to declining clinical trial activities related to the phase 3 PBC, phase 2b NASH, and phase 2 PSC clinical trials, and other studies, as efforts continued to shut down these studies, which were early-terminated as a result of the FDA's clinical holds that were placed on the seladelpar program in the fourth quarter of 2019.

- General and administrative expenses for the three months ended September 30, 2020 remained flat at $4.5 million when compared to the three months ended September 30, 2019. General and administrative expenses for the nine months ended September 30, 2020 were $12.2 million, compared to $14.7 million for the nine months ended September 30, 2019. General and administrative expenses in the first nine months of 2020 were lower than the corresponding period in 2019 due to lower employee compensation and other administrative expenses incurred as a result of a December 2019 reduction-in-force and restructuring effort that was undertaken to reduce costs after stopping development of seladelpar, while investigating the findings in the NASH phase 2 study.

- Net loss for the three months ended September 30, 2020 was $11.4 million, or ($0.17) per diluted share, compared to a net loss of $26.3 million, or ($0.38) per diluted share in the three months ended September 30, 2019. Net loss for the nine months ended

September 30, 2020 was $35.2 million, or ($0.51) per diluted share, compared to a net loss of $73.4 million, or ($1.10) per diluted share in the nine months ended September 30, 2019. Net loss was lower in the first three and nine months of 2020 compared to the corresponding periods in 2019 primarily due to a decrease in operating expenses, including clinical trial and labor related expenses, as a result of the early-termination of our seladelpar studies and our cost reduction efforts undertaken after stopping development of seladelpar in the fourth quarter of 2019, while beginning an investigation of the findings in the NASH phase 2 study. Given the FDA's subsequent lifting of the clinical hold and CymaBay's restart of the seladelpar program and further exploration of other clinical development opportunities, losses are expected to increase in the future as the Company continues its restarted clinical development activities.

Conference Call Details

CymaBay will host a conference call today at 4:30 p.m. EST to discuss third quarter 2020 financial results and provide a corporate 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# 13709641. 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). For 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 status from the EMA.

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 or to restart clinical trials. 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 September 30,		Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
	(unaudited)	**(unaudited)**	**(unaudited)**	**(unaudited)**
Operating expenses:				
Research and development	$ 7,743	$ 23,193	$ 25,194	$ 62,900
General and administrative	4,494	4,514	12,239	14,706
Restructuring charges	(587)	-	(704)	-
Total operating expenses	11,650	27,707	36,729	77,606
Loss from operations	(11,650)	(27,707)	(36,729)	(77,606)
Other income:				
Interest income	229	1,425	1,494	4,211
Total other income	229	1,425	1,494	4,211
Net loss	$ (11,421)	$ (26,282)	$ (35,235)	$ (73,395)
Basic and diluted net loss per common share	$ (0.17)	$ (0.38)	$ (0.51)	$ (1.10)
Weighted average common shares outstanding used to calculate basic and diluted net loss per common share	68,887,092	68,701,043	68,884,894	66,454,750

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

	September 30, 2020	**December 31, 2019**
	(unaudited)	
Cash, cash equivalents and marketable securities	$ 161,264	$ 190,945
Working capital	155,667	185,287
Total assets	168,486	205,727
Total liabilities	11,851	19,379
Common stock and additional paid-in capital	817,660	812,140
Total stockholders' equity	156,635	186,348

Source: CymaBay Therapeutics, Inc.