November 15, 2021

CymaBay Therapeutics Long-term Open Label Study Finds Treatment with Seladelpar for Two Years Improves Key Liver Biomarkers in Patients with PBC

- *Study results presented at The Liver Meeting® 2021 demonstrated continued reductions in biomarkers of cholestasis and hepatocellular injury over two years*
- *Seladelpar generally appeared safe with low rates of discontinuation and no liver-related serious adverse events over two years of treatment*
- *A second clinical presentation found seladelpar treatment in patients with compensated cirrhosis and evidence of portal hypertension resulted in improvements in biomarkers of cholestasis and hepatocellular injury*
- *These results will also be presented during a post-AASLD Key Opinion Leader (KOL) webinar on seladelpar in PBC on Monday, Nov. 15*

NEWARK, Calif., Nov. 15, 2021 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ: CBAY), a biopharmaceutical company focused on developing and providing access to innovative therapies for patients with liver and other chronic diseases, today announced that results of analyses from two clinical studies of seladelpar were delivered during The Liver Meeting Digital Experience™ 2021 (TLMdX) of the American Association for the Study of Liver Diseases (AASLD).

In an oral presentation titled “Long-Term Safety and Efficacy of Seladelpar in Patients with Primary Biliary Cholangitis”[1] Marlyn J. Mayo, MD, Professor and Liver Disease Specialist, University of Texas Southwestern Medical Center presented data from an open label, Long-Term Extension Study, highlighting the efficacy and safety of seladelpar at one and two years of treatment in patients with primary biliary cholangitis (PBC). Eligible PBC patients with either an inadequate response, defined as alkaline phosphatase (ALP) greater than or equal to 1.67 times the upper limit of normal (ULN), or intolerance to ursodeoxycholic acid (UDCA) were randomized to daily seladelpar 5 or 10 mg. The primary endpoint of this analysis was the percent change in ALP from baseline at one and two years. The mean percent change in ALP from baseline was -42% and -50% after one and two years, respectively. Key secondary endpoints of the analysis were a composite response of ALP <1.67x ULN, ALP decrease ≥15% and total bilirubin (TB) ≤ULN at one and two years; ALP normalization at one and two years and markers of hepatocellular injury. The composite endpoint was achieved by 64% and 79% of patients after one and two years, respectively. In addition, ALP normalization was achieved in 24% and 42% in patients at one and two years, respectively. In patients with elevated total bilirubin at baseline, 54% and 43% of patients achieved TB normalization at one and two years, respectively. Over two years, there were sustained reductions in ALT, AST, and GGT and platelet levels remained stable. Seladelpar

appeared safe and well-tolerated. These data support that long-term treatment with seladelpar resulted in continued improvement in markers of cholestasis after one year.

Dr. Dennis Kim, Chief Medical Officer commented, “These results are particularly encouraging as they suggest that seladelpar may provide an effective long-term treatment option for patients with PBC and may signal that the benefits gleaned may be sustained and perhaps even improve over a 2-year period.”

A second clinical presentation titled “Efficacy and Safety of Seladelpar in Patients with Compensated Cirrhosis and Evidence of Portal Hypertension due to Primary Biliary Cholangitis”[2] was presented by Cynthia Levy, MD, Professor of Medicine, University of Miami. The results were from an electronic poster presentation of a pooled analysis of Phase 2 and Phase 3 studies (n=366) highlights the treatment effects of seladelpar in compensated cirrhotic patients with portal hypertension (n=22) after 3 months. In this analysis, 33% and 60% of cirrhotic patients with portal hypertension (PHT) met the composite responder endpoint in the 5 mg and 10 mg groups, respectively. ALP changes of -30% in the 5 mg and -45% in the 10 mg groups were observed and 8% and 40% of cirrhotic patients with PHT achieved ALP normalization in the 5 mg and 10 mg groups, respectively; corresponding changes at 5 and 10 mg in ALT levels were -13% and -26%, respectively. Total bilirubin, platelets, albumin, and INR either improved or remained stable. Seladelpar appeared safe and well-tolerated. Efficacy, safety, and tolerability in patients with compensated cirrhosis and PHT was comparable to that of non-cirrhotic patients.

”Patients with cirrhosis and portal hypertension have more narrow treatment options. Understanding the safety and efficacy of seladelpar in cirrhotic patients with and without portal hypertension will be an ongoing part of the seladelpar program with the goal of understanding if seladelpar is an appropriate treatment option for this currently underserved population,” said Dr. Kim. “We look forward to gathering additional data in cirrhotic and non-cirrhotic patients with PBC in RESPONSE, our Phase 3 global pivotal study of seladelpar, that is currently recruiting and enrolling patients.”

Oral Presentation:
November 14th 1:00 PM EST
106:
[1]“Long-Term Safety and Efficacy of Seladelpar in Patients with Primary Biliary Cholangitis”
Marlyn J. Mayo, John M. Vierling, Christopher L. Bowlus, Guy Neff, Michael R. Galambos, Stuart C. Gordon, Brian Borg, Cynthia Levy, Stephen A. Harrison, Paul J. Thuluvath, Aparna Goel, Mitchell L. Shiffman, Alexandra Steinberg, Emily Xu, Ke Yang, Yun-Jung Choi, Klara Dickinson, Charles McWherter

Clinical Poster Presentation:
November 12th – 15th
1269:
[2]“Efficacy and Safety of Seladelpar in Patients with Compensated Cirrhosis and Evidence of Portal Hypertension due to Primary Biliary Cholangitis”

Cynthia Levy, Joseph A. Odin, Guy Neff, Palak Trivedi, Liliana-Simona Gheorghe, Christopher L. Bowlus, John M. Vierling, Aliya F. Gulamhusein, Sook-Hyang Jeong, Emily

Xu, Ke Yang, Yun-Jung Choi, Elaine Watkins, Charles McWherter

The presentations are available on the CymaBay website.

CymaBay will host a post-AASLD KOL webinar on seladelpar in PBC on Monday, November 15, at 4:30pm EST. The webinar will feature presentations by Dr. Marlyn J. Mayo, MD, and Dr. Cynthia Levy, MD, who will be reviewing their abstracts recently presented at The Liver Meeting® 2021. The company will also discuss its progress developing seladelpar for patients with PBC. The live and archived webcast will be accessible through this **webcast link** or through the **Events** section of the Company's website.

About PBC
PBC is a rare, chronic inflammatory liver disease primarily affecting women (1 in 1,000) over the age of 40. PBC is characterized by impaired bile flow (known as cholestasis) and the accumulation of toxic bile acids in the liver, leading to inflammation and destruction of the bile ducts within the liver and causing increased levels of alkaline phosphatase (ALP) and total bilirubin. The most common early symptoms of PBC are itching (pruritus) and fatigue, which can be very debilitating for some patients. Progression of PBC is associated with an increased risk of liver cancer and liver-related mortality.

About Seladelpar
Seladelpar is a first-in-class oral, selective PPARδ agonist shown to regulate critical metabolic and liver disease pathways in indications with high unmet medical need. Preclinical and clinical data support its ability to regulate genes involved in bile acids synthesis, inflammation, fibrosis and lipid metabolism, storage and transport.

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, CymaBay's expectations and plans regarding its current and future clinical trials, including the timing of enrollment in RESPONSE, the impact of the COVID pandemic on the enrollment timeline for CymaBay's clinical trials and CymaBay's ability to fund current and planned clinical trials 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; the potential emergence of other COVID variants; 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, its Quarterly Reports on Form 10-Q 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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