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CymaBay Therapeutics Presents Positive Results from its Ongoing Phase 2 Study of Seladelpar in Patients with PBC at The Liver Meeting® 2018

- *Sustained anti-cholestatic and anti-inflammatory effects observed with no worsening of pruritus through 52 weeks*
- *Results highlight the potential for seladelpar to offer patients an efficacious and safe second line treatment option*
- *Efficacy and tolerability were retained in a subset of patients with compensated cirrhosis*
- *Global 52-week Phase 3 Study (ENHANCE) initiated to support registration*

NEWARK, Calif., Nov. 13, 2018 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ: CBAY) presented data from its ongoing Phase 2 study of seladelpar in patients with primary biliary cholangitis (PBC). Presentations were delivered during two late-breaking presentations yesterday at The Liver Meeting® 2018 hosted by the American Association for the Study of Liver Diseases, as well as multiple additional clinical and pre-clinical presentations. Seladelpar is an orally administered, potent and selective peroxisome proliferator-activated receptor delta (PPARδ) agonist currently in development for PBC and nonalcoholic steatohepatitis (NASH).

Professor Chris Bowlus, MD, Division Chief of Gastroenterology and Hepatology, University of California at Davis Health, presented efficacy data on the first set of patients treated for 52 weeks and safety data on patients that received at least one dose of seladelpar in the ongoing open label Phase 2 PBC study. Eligible PBC patients with either an inadequate response, defined as alkaline phosphatase (AP) greater than 1.67 times the upper limit of normal (ULN), or intolerance to ursodeoxycholic acid (UDCA) were randomized to daily seladelpar at 5 or 10 mg. After 12 weeks, patients on 5 mg could escalate to 10 mg if their AP treatment goal was not met (5/10 mg group). The primary efficacy outcome was the AP % change from baseline. At 52 weeks, the mean decreases in AP were -47% and -46% in the 5/10 and 10 mg groups, respectively. A key secondary outcome was the composite responder rate measured at week 52 where a responder was defined as a patient with AP <1.67 x ULN, ≥15% decrease in AP, and total bilirubin ≤ULN. At 52 weeks, 59% and 71% of patients met the composite endpoint in the 5/10 and 10 mg groups, respectively. This composite responder rate is the primary endpoint in the global ENHANCE Phase 3 registration study that was recently initiated. The anti-cholestatic effect of seladelpar was further substantiated with normalization of AP levels at 52 weeks in 24% and 29% of patients in the 5/10 and 10 mg groups, respectively. Treatment with

seladelpar also demonstrated a robust anti-inflammatory activity with median transaminase decreases of -31% and -33% in the 5/10 and 10 mg groups, respectively. Seladelpar appeared safe and well tolerated. Of the 119 patients that received at least one dose of seladelpar, 11 serious adverse events were documented and none were considered related to seladelpar. Three patients discontinued seladelpar, of which only one discontinuation, for a grade 1 gastroesophageal reflux, was deemed related to seladelpar. There was no transaminase safety signal, and importantly, there was no indication that seladelpar was associated with drug-induced pruritus.

In a second late-breaking presentation, Dr. Andreas Kremer, MD, PhD, MHBA, Hepatology Department, Friedrich-Alexander-University of Erlangen-Nürnberg, Erlangen, Germany, shared a 26-week analysis from the study on the effect of seladelpar on pruritus. Pruritus is a common clinical symptom of PBC that adversely effects a patient's quality of life. Twenty-six weeks represents the time point used to evaluate pruritus as a key secondary outcome in the upcoming ENHANCE Phase 3 registration study. After 26 weeks, the median changes in the pruritus visual analog scale (VAS) was -50% and -55% in the 5 /10 and 10 mg groups, respectively. These data suggest that seladelpar is not associated with drug-induced pruritus and support further evaluation of seladelpar's potential benefit on pruritus.

Other presentations demonstrated that seladelpar retained efficacy and was well tolerated in patients with compensated cirrhosis and that seladelpar, using an accepted predictive model, was associated with an improvement in clinical outcomes.

Dr. Pol Boudes, Chief Medical Officer of CymaBay Therapeutics commented, "We are very encouraged by the clinically meaningful anti-cholestatic and anti-inflammatory effects we continue to see in PBC patients, now with treatment extended through 52 weeks. We believe these results help to de-risk the seladelpar ENHANCE Phase 3 registration study. We once again want to thank all the patients participating in our clinical studies, as well as their families, their physicians and the clinical research team members that tirelessly support them."

CymaBay's late-breaking presentations and additional abstracts from The Liver Meeting® 2018 can be found at: https://ir.cymabay.com/presentations.

About PBC
Primary biliary cholangitis (PBC) is a serious and potentially life-threatening autoimmune disease of the liver characterized by impaired bile flow (cholestasis) and accumulation of toxic bile acids. There is an accompanying inflammation and destruction of the intrahepatic bile ducts, which can progress to fibrosis, cirrhosis and liver failure. Other clinical symptoms of PBC include fatigue and pruritus, which can be quite disabling in some patients. PBC is primarily a disease of women: 1 in 1000 women over the age of 40 lives with PBC.

About Seladelpar
Seladelpar is a potent, selective, orally active PPARδ agonist that is in development for the treatment of the liver diseases PBC and NASH. For PBC, seladelpar has received an orphan designation from the US Food and Drug Administration and the European Medicine Agency. Seladelpar also received the PRIority MEdicine (PRIME) status from the

European Medicine Agency.

About CymaBay
CymaBay Therapeutics, Inc. (CBAY) is a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet medical need. Seladelpar is a potent, selective, orally active PPARδ agonist, currently in development for the treatment of patients with primary biliary cholangitis (PBC), an autoimmune liver disease, and with nonalcoholic steatohepatitis (NASH). Two Phase 2 studies of seladelpar established proof-of-concept in PBC. CymaBay is currently conducting a Phase 3 study of seladelpar for PBC and a Phase 2b study of seladelpar for NASH.

Cautionary Statements
The statements in this press release regarding the potential for seladelpar to treat PBC and NASH, the potential benefits to patients, CymaBay's expectations and plans regarding current and future 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; 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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