CymaBay Therapeutics Announces Additional Positive Results from its Ongoing Phase 2 Study of Seladelpar in Patients with PBC will be Presented During the Late-Breaking Session at The Liver Meeting®

- 52-week analysis highlights the potential for seladelpar to offer patients improved efficacy and better tolerability than existing second line treatment.
- Third consecutive year data from the development of seladelpar in PBC will be highlighted in a late-breaking presentation at The Liver Meeting®.

NEWARK, Calif., Oct. 03, 2018 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), today announced that two late-breaking presentations describing new long-term data from its ongoing Phase 2 study of seladelpar in patients with primary biliary cholangitis (PBC) will be featured on November 12, 2018 during The Liver Meeting® hosted by the American Association for the Study of Liver Diseases (AASLD) in San Francisco, CA (November 9-13, 2018). Seladelpar is an orally administered, potent and selective peroxisome proliferator-activated receptor delta (PPARδ) agonist currently in development for PBC and nonalcoholic steatohepatitis (NASH).

The first presentation, abstract LB-3, titled “Efficacy and Safety of Seladelpar, a Selective Peroxisome Proliferator-Activated Receptor Delta Agonist, in Primary Biliary Cholangitis: 52-Week Analysis of an Ongoing International, Randomized, Dose Ranging Phase 2 Study” will be delivered by Professor Chris Bowlus, MD, Division Chief of Gastroenterology and Hepatology, University of California at Davis Health. The 52-week analysis from this ongoing Phase 2 study may provide some insight into the primary efficacy outcome of the upcoming pivotal Phase 3 seladelpar PBC study. The Phase 3 primary efficacy outcome is a composite responder rate measured at 52 weeks that comprises an alkaline phosphatase <1.67 times the upper limit of normal, a decrease of at least 15% in alkaline phosphatase, and a total bilirubin less than or equal to the upper limit of normal. The 52-week composite responder rates in the ongoing Phase 2 study for the 5 mg/10 mg and 10 mg seladelpar groups were 59% and 71%, respectively. These rates suggest seladelpar has the potential to be an improved second line treatment for PBC.

The second presentation, abstract LB-26, titled “Effect of Seladelpar on Pruritus in Primary Biliary Cholangitis: 26-Week Analysis of an Ongoing International, Randomized, Dose Ranging Phase 2 Study” will be delivered by Dr. Andreas Kremer, MD, PhD, MHBA, Hepatology Department, Friedrich-Alexander-University of Erlangen-Nürnberg, Erlangen, Germany. Twenty-six weeks represents the time point that has been selected to evaluate pruritus as a key secondary outcome in the upcoming seladelpar pivotal Phase 3 study. The 26-week analysis from this ongoing Phase 2 study showed that the median changes in pruritus as measured by the visual analog scale (VAS) was -50% and -55% in the 5 mg/10 mg and 10 mg seladelpar groups, respectively. These data suggest that seladelpar is not associated with drug-induced pruritus and may support the hypothesis that seladelpar decreases pruritus in PBC patients. The effects of seladelpar on pruritus will be evaluated in the pivotal Phase 3 study as a key secondary outcome measure.

Dr. Pol Boudes, Chief Medical Officer of CymaBay Therapeutics commented, “We are extremely encouraged to be able to report these impressive 52-week results for the composite regulatory endpoint for both the 5 mg/10 mg and 10 mg dose groups, and we are especially grateful to do so in an oral late-breaking presentation during the The Liver Meeting®.” Dr. Boudes continued, “We believe these results help to significantly de-risk the seladelpar Phase 3 study. In addition, to have a second late-breaking presentation sharing the findings on the effects on pruritus through 26 weeks highlights the importance of including this burdensome patient symptom as a key secondary endpoint in the upcoming Phase 3 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.”

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 planning to advance development of seladelpar into Phase 3 for PBC and commenced a Phase 2 for NASH earlier this year.

**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 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](http://www.cymabay.com).

Contact:

Hans Vitzthum
LifeSci Advisors, LLC
212-915-2568
Hans@LifeSciAdvisors.com

Source: CymaBay Therapeutics, Inc.