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CymaBay Therapeutics Reaches Target Enrollment in the ENHANCE Global Phase 3 Study Evaluating Seladelpar for Primary Biliary Cholangitis

ENHANCE on track to complete full enrollment earlier than projected

NEWARK, Calif., Nov. 04, 2019 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ: CBAY), a clinical-stage biopharmaceutical company focused on developing and providing access to innovative therapies for patients with liver and other chronic diseases with a high unmet medical need, today announced achievement of the targeted 240 patient enrollment goal for ENHANCE, a global Phase 3 study evaluating seladelpar for patients with Primary Biliary Cholangitis (PBC). CymaBay is on track to complete full enrollment by the end of November.

With more than 240 patients enrolled, ENHANCE is CymaBay's lead regulatory registration study evaluating the safety and efficacy of its investigational drug, seladelpar, for patients already diagnosed with PBC who have been using ursodeoxycholic acid (also known as UDCA or ursodiol), but have not achieved the recommended treatment goal or cannot tolerate UDCA. ENHANCE is a 52-week, placebo-controlled, randomized study conducted in over 20 countries.

"We thank our investigators, their staff, and patients worldwide for their support in achieving today's milestone for this landmark study in PBC. Reaching the recruitment goal of our Phase 3 study ahead of schedule underscores the enormous unmet need for new treatment options in this serious, chronic liver disease," stated Sujal Shah, President and Chief Executive Officer of CymaBay Therapeutics. "I am proud of our team's efforts, which are focused every day on delivering for patients and their families. Through ENHANCE, our goal is to find a new treatment alternative to help people living with PBC."

Later this week, CymaBay will be presenting data from its Phase 2 clinical study (publication #1328) and a preclinical study (publication #2253) for seladelpar at The Liver Meeting® hosted by the American Association for the Study of Liver Diseases (AASLD) in Boston, MA (November 8-12, 2019). For additional information, visit www.cymabay.com.

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's lead development candidate, seladelpar, is a potent, selective and orally active PPARδ agonist currently in development for the treatment of patients with primary biliary cholangitis (PBC), primary sclerosing cholangitis (PSC), and nonalcoholic steatohepatitis (NASH). CymaBay is evaluating seladelpar in a global, Phase 3 registration study in PBC, a Phase 2 dose ranging study in PSC and a Phase 2b dose ranging study in NASH.

About Seladelpar
Seladelpar is a potent, selective, orally active PPARδ agonist that is in development for the treatment of the liver diseases PBC, PSC and NASH. 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 MEdicine status from the EMA.

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.

Cautionary Statements
The statements in this press release regarding the potential for seladelpar to treat PBC, PSC and NASH, the potential benefits to patients, CymaBay's expectations and plans regarding clinical trials, including the timing of trials and the release of data in regard thereto, 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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