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Enrollment Begins in Long-Term Extension Study of Seladelpar in Patients with Primary Biliary Cholangitis

Study allows continued access to long-term treatment with seladelpar in support of the phase 3 registration program
Patients currently enrolling have now completed one year of treatment in the phase 2 low dose study

NEWARK, Calif., Jan. 08, 2018 (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 that the first primary biliary cholangitis (PBC) patients have been successfully enrolled in the seladelpar long-term extension study (NCT03301506). The study entitled “An Open-Label Long-Term Study to Evaluate the Safety and Tolerability of Seladelpar in Subjects with Primary Biliary Cholangitis (PBC)” is an international Phase 2/3 study that is being conducted both in North America and Europe. The study will provide access to long-term seladelpar treatment for patients enrolled in a previous or ongoing study evaluating seladelpar for the treatment of PBC. The objectives of the study are to provide additional long-term safety and efficacy data that will support the seladelpar registration program and to follow patients until registration of seladelpar.

The long-term extension study is currently enrolling patients that complete the Phase 2 low dose seladelpar study (NCT029556022). Positive interim results from this Phase 2 study[1] were shared with the scientific community during a late-breaking presentation on October 23, 2017 in Washington, DC at The Liver Meeting® hosted by the American Association for the Study of Liver Diseases.

“We are very excited to continue to provide seladelpar to PBC patients who enrolled in our clinical development program,” said Pol Boudes, M.D., Chief Medical Officer, CymaBay. Dr. Boudes added, “Our patients and their families have made immense contributions toward building our understanding around the potential for seladelpar to treat PBC and along with our investigators, have helped us advance the program to Phase 3. The long-term extension study also fulfills an important commitment of CymaBay to provide PBC patients who benefit from seladelpar continued and uninterrupted access to the drug.”

1. Hirschfield GM, Bowlus CL, Harrison SA, et al. Treatment efficacy and safety of low dose Seladelpar, a selective PPAR- δ agonist, in patients with primary biliary cholangitis: twelve-week interim analysis of an international, randomized, dose ranging, phase 2 study. LB-4. Hepatology 2017;66(6S):1256A

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 and selective agonist of PPARδ, a nuclear receptor that regulates genes involved in bile acid/sterol, lipid and glucose metabolism and inflammation. Seladelpar is currently in development for the treatment of patients with the autoimmune liver disease, primary biliary cholangitis (PBC) and 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 Phase 2 for NASH. Arhalofenate is a potential urate-lowering anti-flare therapy that has been found to reduce painful flares in joints while at the same time lowering serum uric acid by promoting excretion of uric acid by the kidney. This dual action addresses both the signs and symptoms of gout while managing the underlying pathophysiology of hyperuricemia. Arhalofenate has been licensed in the U.S. to Kowa Pharmaceuticals America, Inc. CymaBay retains full development and commercialization rights for arhalofenate outside the U.S.

Cautionary Statements

The statements in this press release regarding the potential for seladelpar to treat PBC and/or NASH and arhalofenate to treat gout, the potential benefits to patients of these product candidates, the expectations regarding ongoing and future clinical trials, and CymaBay’s ability to provide PBC patients who benefit from seladelpar continued and uninterrupted access to the drug are forward looking statements that are subject to risks and uncertainties. Actual results and the timing of events regarding the further development of seladelpar and arhalofenate 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 continued success of CymaBay’s partnership with Kowa; 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 Quarterly Report on Form 10-Q, 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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