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CymaBay Therapeutics Granted EMA Orphan Drug Designation for Seladelpar for the Treatment of Primary Biliary Cholangitis

NEWARK, Calif., Sept. 11, 2017 (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 European Medicines Agency's (EMA) Committee for Orphan Medicinal Products (COMP) issued a positive opinion on the application for orphan drug designation of seladelpar for treatment of primary biliary cholangitis (PBC), a life-threatening and life-limiting chronic cholestatic liver disease. Seladelpar, an orally administered potent and selective peroxisome proliferator-activated receptor delta (PPARδ) agonist is currently in Phase 2 clinical development for the treatment of PBC.

European 'Orphan' medicinal products are for diagnosing, preventing or treating life-threatening or serious conditions that are rare and affect not more than 5 in 10,000 people in the European Union (EU). The designation potentially qualifies the sponsor for ten years of marketing exclusivity upon approval, as well as fee reduction for various centralized activities, including applications for marketing authorization, inspections and protocol assistance.

Seladelpar previously received orphan drug designation from the U.S. Food and Drug Administration (FDA) and PRIority MEdicine (PRIME) designation by the EMA for the treatment of PBC.

“We believe the EMA’s COMP decision to grant orphan designation to seladelpar for the treatment of PBC further validates the unmet medical need that remains for patients with PBC despite current therapies,” said Sujal Shah, Interim President and Chief Executive Officer of CymaBay. “We remain encouraged by the significant clinical and regulatory progress in our development program and the potential impact these collective regulatory designations may have in making seladelpar accessible to patients with PBC.”

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 live with PBC.

About Seladelpar

Seladelpar is a potent, selective, orally active peroxisome proliferator-activated receptor delta (PPARδ) agonist that is in development for the treatment of the liver diseases primary biliary cholangitis (PBC) and nonalcoholic steatohepatitis (NASH). For PBC, seladelpar has received an orphan designation from the US Food and Drug Administration and the European Medicines Agency (EMA) as well as PRIority MEdicine (PRIME) status from the EMA.

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 NASH, the potential benefits to patients, and the expectations regarding future 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 which 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 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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