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CymaBay Therapeutics Announces an Oral Late-Breaking Presentation of a Phase 2 Proof-of-Concept Study of MBX-8025 in Patients With Primary Biliary Cholangitis at the AASLD 2016 Liver Meeting

NEWARK, Calif., Oct. 20, 2016 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), a clinical-stage biopharmaceutical company focused on developing therapies to treat metabolic diseases with high unmet medical need, today announced that a late-breaking presentation describing results from a phase 2 proof-of-concept study of MBX-8025 in patients with primary biliary cholangitis (PBC) will be delivered at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD) in Boston, November 11-15, 2016. MBX-8025 is an orally administered potent and selective peroxisome proliferator-activated receptor delta (PPARδ) agonist.

The abstract, entitled “A phase 2 proof of concept study of MBX-8025 in patients with Primary Biliary Cholangitis (PBC) who are inadequate responders to ursodeoxycholic acid (UDCA)” is published on the AASLD website at www.aasld.org. The presentation will be made on November 15 by Professor David Jones, Professor of Liver Immunology, Institute of Cellular Medicine, Newcastle University in the U.K.

About MBX-8025

MBX-8025 is a potent and selective agonist of PPARδ, a nuclear receptor important for lipid transport, storage and metabolism in liver and muscle. In a Phase 2 study in subjects with mixed dyslipidemia, MBX-8025 decreased LDL-C, triglycerides and high sensitivity CRP, a biomarker of inflammation. MBX-8025 also decreased alkaline phosphatase and gamma glutamyl transferase, two key markers of cholestasis. In a recently completed Phase 2 study in subjects with primary biliary cholangitis (PBC), MBX-8025 decreased markers of cholestasis and inflammation without appearing to cause pruritus while also lowering LDL-C. The European Medicines Agency has granted CymaBay PRIority MEdicines (PRIME) status for MBX-8025 for the treatment of PBC. A Pilot Phase 2 clinical study has also been completed showing that MBX-8025 lowers LDL-C in patients with homozygous familial hypercholesterolemia (HoFH). The U.S. Food and Drug Administration (FDA) has granted CymaBay orphan drug designation for MBX-8025 as a treatment for HoFH and Fredrickson types I and V hyperlipoproteinemia.

About PBC

Primary biliary cholangitis (PBC), formerly known as primary biliary cirrhosis, 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, afflicting approximately one in 1,000 over the age of 40.

About PRIME

PRIME is a program launched by the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need and have the potential to bring a major therapeutic advantage to patients. The program is voluntary and is designed to offer enhanced interaction and early dialogue with developers of promising medicines, to optimize development plans and speed up evaluation so these medicines can reach patients earlier. Through PRIME, the EMA offers early and proactive support to medicine developers to optimize the generation of robust data on a medicine’s benefits and risks and enable accelerated assessment of medicines applications. The scheme focuses on medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without treatment options. These medicines are considered priority medicines by EMA. To be accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on early clinical data.

About CymaBay

CymaBay Therapeutics, Inc. (CBAY) is a clinical-stage biopharmaceutical company focused on developing therapies to treat metabolic diseases with high unmet medical need, including serious rare and orphan disorders. MBX-8025 is a potent, selective, orally active PPAR-δ agonist. A Phase 2 study of MBX-8025 in patients with mixed dyslipidemia established that it has an anti-atherogenic lipid profile. CymaBay has completed Phase 2 studies for MBX-8025 in subjects with primary biliary cholangitis and homozygous familial hypercholesterolemia, establishing proof-of-concept in both indications. Arhalofenate, CymaBay's other product candidate, is a potential Urate-Lowering Anti-Flare Therapy that has completed five Phase 2 studies in subjects with gout. Arhalofenate 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.

Cautionary Statements

The statements in this press release regarding the potential use of MBX-8025 for the treatment of PBC and the potential future performance of CymaBay's product candidates, are forward looking statements that are subject to risks and uncertainties. Actual results and the timing of events regarding the further development of CymaBay's product candidates 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 of MBX-8025 and arhalofenate; 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 Annual Report on Form 10-K and Quarterly Report on Form 10-Q 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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