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CymaBay Therapeutics Announces an Oral Presentation Describing the Efficacy of MBX-8025 in a Preclinical Model of NASH at the AASLD 2016 Liver Meeting

NEWARK, Calif., Oct. 06, 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 an abstract describing results from a study evaluating the activity of MBX-8025 in reversing non-alcoholic steatohepatitis (NASH) in diabetic obese mice has been accepted for an oral presentation 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 "PPAR-δ agonist MBX-8025 Abolishes Lipotoxicity and Reverses NASH in Diabetic Obese Mice" was published on the AASLD website at www.aasld.org. It has been scheduled as an oral presentation on November 14 by Fahrettin Haczeyni from the Liver Research Group, The Australian National University Medical School, Canberra, Australia. The senior author, Professor Geoffrey C. Farrell, commented, "In these atherogenic diet-fed diabetic foz/foz mice, the selective PPAR-δ agonist MBX-8025 reverses all of the key components of NASH including insulin resistance, inflammation, lipotoxicity and fibrosis and potentially represents a novel therapeutic agent to treat NASH."

About MBX-8025

MBX-8025 is a potent and selective agonist of PPAR-δ, 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. CymaBay has also completed a pilot Phase 2 clinical study 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 NASH

NASH is a severe type of non-alcoholic fatty liver disease (NAFLD) that is associated with obesity, insulin resistance and type-2 diabetes and is characterized by the accumulation of fat in the liver. NASH occurs when the accumulation of liver fat is accompanied by inflammation and cellular damage. The inflammation can lead to fibrosis (scarring) of the liver and eventually progress to cirrhosis, portal hypertension, liver cancer and eventual liver failure. Once the disease advances beyond NASH to these life-threatening conditions, liver transplantation is the only alternative.

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 NASH 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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