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CymaBay Therapeutics Announces that the Recommended International Nonproprietary Name for MBX-8025 is Seladelpar

NEWARK, Calif., Dec. 06, 2016 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), a clinical-stage biopharmaceutical company developing therapies to treat indications with high unmet medical need, today announced that the World Health Organization (WHO) has recommended seladelpar as the designated international nonproprietary name for MBX-8025.

As part of its International Nonproprietary Names (INN) program, the WHO assigns a unique nonproprietary name, commonly referred to as the generic name, to pharmacological substances. The name may contain common stems that recognize that the drug belongs to a group of substances that have similar pharmacological activity. The name seladelpar reflects the high selectivity of MBX-8025 toward PPARδ and differentiates it from substances that interact with the other two members of the PPAR family - PPARα and PPARγ.

“I am very pleased that the WHO has recommended seladelpar as the international nonproprietary name for MBX-8025 as it recognizes its uniquely selective PPAR delta agonist profile,” said Harold Van Wart, Chief Executive Officer of CymaBay Therapeutics. “This differentiates seladelpar from compounds that interact with other PPAR receptors such as the fibrates. We believe that the pharmacological properties of seladelpar are uniquely suited to treat liver diseases such as primary biliary cholangitis and nonalcoholic steatohepatitis.”

About Seladelpar
Seladelpar (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, seladelpar decreased LDL-C, triglycerides and high sensitivity CRP, a biomarker of inflammation. Seladelpar 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), seladelpar decreased markers of cholestasis and inflammation without appearing to cause pruritus while also lowering LDL-C. In a diabetic obese model of nonalcoholic steatohepatitis (NASH), seladelpar reversed NASH and inhibited fibrosis suggesting it may have potential for the treatment of this condition. The U.S. Food and Drug Administration (FDA) has granted CymaBay orphan drug designation for seladelpar as a treatment for PBC. In addition, seladelpar has been granted the PRIority MEdicines (PRIME) Designation for the treatment of PBC by the European Medicines Agency. CymaBay has also completed a pilot Phase 2 clinical study showing that seladelpar lowers LDL-C in patients with homozygous familial hypercholesterolemia (HoFH). The FDA has also granted CymaBay orphan drug designation for seladelpar as a treatment for HoFH and Fredrickson types I and V hyperlipoproteinemias.

About CymaBay
CymaBay Therapeutics, Inc. (CBAY) is a clinical-stage biopharmaceutical company developing therapies to treat diseases with high unmet medical need, including serious rare and orphan disorders. Seladelpar is a potent, selective, orally active PPARδ agonist. CymaBay has recently completed a Phase 2 study of seladelpar in patients with primary biliary cholangitis as well as a pilot Phase 2 study in patients with homozygous familial hypercholesterolemia, establishing proof-of-concept in both indications. Previously, a Phase 2 study of seladelpar in patients with mixed dyslipidemia established that it has an anti-atherogenic lipid profile. Arhalofenate, CymaBay’s other product candidate, is a potential Urate-Lowering Anti-Flare Therapy that has completed five Phase 2 studies in gout patients. Arhalofenate has been found to reduce painful flares in joints while at the same time 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 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

seladelpar 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 visitwww.cymabay.com.

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