October 1, 2020

CymaBay Therapeutics to Present Data from its Phase 2 Study of Seladelpar in Patients with NASH at The Liver Meeting® 2020

NEWARK, Calif., Oct. 01, 2020 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ: CBAY), a biopharmaceutical company focused on developing and providing access to innovative therapies for patients with liver and other chronic diseases, today announced that data from a Phase 2 study of seladelpar in nonalcoholic steatohepatitis (NASH) will be delivered during The Liver Meeting Digital Experience™ 2020 (TLMdX) of the American Association for the Study of Liver Diseases (AASLD) which will be held online November 13th – 16th.

The presentation titled “A 52-Week Multi-Center Double-Blind Randomized Phase 2 Study of Seladelpar, a potent and selective peroxisome proliferator-activated receptor delta (PPAR-delta) agonist, in Patients with Nonalcoholic Steatohepatitis (NASH),” [1] will be delivered by Dr. Stephen A. Harrison, MD, Medical Director of Pinnacle Clinical Research. This electronic poster presentation has been selected by AASLD for special recognition as a “Poster of Distinction” and will highlight the effects of seladelpar on liver fat, liver enzymes, and key histologic endpoints recognized by regulators for registration including NASH resolution and reduction in fibrosis.

Dr. Stephen Harrison, MD, commented, “Given that NASH is a multifactorial and complex disease, evaluating combination therapies incorporating different mechanisms of action is an important next step to addressing the unmet need that exists for patients with NASH. I am looking forward to sharing additional data highlighting the effects of seladelpar on NASH and believe these data along with the observed overall safety and tolerability profile position seladelpar to be an ideal agent to be used in combination with other mechanisms of action to provide the greatest clinical benefit.”

Sujal Shah, CEO of CymaBay Therapeutics, commented, “We are excited to have the opportunity to share our first presentation of final data from our Phase 2 study of seladelpar in patients with NASH. These data further reveal the distinctive characteristics of seladelpar impacting lipid metabolism, inflammation and fibrosis in patients with NASH. On behalf of my colleagues at CymaBay, I would like to thank the patients, the investigators, and the clinical research team members who have participated in our study.”

Poster Presentation

[1]“A 52-Week Multi-Center Double-Blind Randomized Phase 2 Study of Seladelpar, a potent and selective peroxisome proliferator-activated receptor delta (PPAR-delta) agonist, in Patients with Nonalcoholic Steatohepatitis (NASH)”
Stephen A. Harrison, Nadege T.Gunn, Arun Khazanchi, Cynthia Guy, Elizabeth Brunt, Sam

Moussa, Seth Baum, Juan Frias, James Trotter, Donald Lazas, Anita Kohli, Bradley Vander Veen, Ziad Younes, Ann Moore, Jason Huffman, John Poulos, Pol Boudes, Stephen Rossi, Yun-Jung Choi, Alexandra Steinberg, Sujal Shah, Klara Dickinson, Charles McWherter

Publication Number: 1710
Session Title: NAFLD and Non Alcoholic Steatohepatitis - Clinical

Congress attendees can visit CymaBay throughout the meeting at the CymaBay booth in the Exhibitors section of the TLMdX homepage.

A full list of presentations can be found on The Liver Meeting Digital Experience™ 2020 website

The presentations will also be made available on the CymaBay website.

About NASH
Nonalcoholic steatohepatitis (NASH) involves the development of a fatty liver that, in patients at risk, triggers inflammation and hepatocellular injury with or without liver fibrosis. The prevalence of nonalcoholic fatty liver disease is increasing, with estimates ranging from 20% to 40% of adults in countries adopting a western diet. Ten to 20% of patients with fatty liver disease progress to NASH. Patients with NASH are at increased risk of cirrhosis and hepatocellular carcinoma, and NASH is projected in the coming years to be the leading reason for liver transplant. Further, most patients with NASH have coexisting obesity, insulin resistance with or without type 2 diabetes, hypertension, and dyslipidemia manifested by high serum cholesterol and triglycerides levels.

About Seladelpar
Seladelpar is a potent, selective, orally active PPARδ agonist that has been 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 (FDA) and the European Medicine Agency (EMA). Seladelpar also received Breakthrough Therapy Designation from the FDA and PRIority MEdicine status from the EMA for PBC.

About CymaBay
CymaBay Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet medical need.

Cautionary Statements
The statements in this press release regarding the potential for seladelpar to treat NASH or PBC, the potential benefits to patients, CymaBay's expectations and plans regarding its current and future clinical trials and CymaBay's ability to fund current and planned 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 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; 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 or to potentially restart clinical trials. 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 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.

Public Relations Contact:

Glenn Silver
Lazar-FINN Partners
(973) 818-8198
Glenn.silver@finnpartners.com

Investor Relations Contact:

Hans Vitzthum
LifeSci Advisors, LLC
(617) 430-7578
Hans@LifeSciAdvisors.com

Source: CymaBay Therapeutics, Inc.