

May 8, 2019

CymaBay Therapeutics Announces Multiple Presentations at DDW 2019

NEWARK, Calif., May 08, 2019 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ: CBAY), today announced that multiple abstracts related to its seladelpar clinical development program for the treatment of primary biliary cholangitis (PBC) will be presented in poster sessions at Digestive Disease Week® (DDW) in San Diego, California from May 18 – 21, 2019. Seladelpar is a potent and selective peroxisome proliferator-activated receptor delta (PPAR δ) agonist currently in development for PBC and nonalcoholic steatohepatitis (NASH).

The presentations will include new data¹ from a qualitative study in collaboration with the PBCers Organization, the Canadian PBC Society, and Evidera highlighting itch (pruritus) as a significant symptom for PBC patients with multiple impacts. A second clinical presentation² demonstrates that seladelpar maintained its anti-cholestatic effect over 52 weeks and appeared safe and well tolerated in PBC patients with cirrhosis. In addition, a third presentation³ highlights that single dose oral administration of seladelpar appears well tolerated and safe in subjects with varying degrees of hepatic impairment (Child-Pugh A-C) and provided important information on seladelpar pharmacokinetic exposure in this difficult population.

“Itch (pruritus) is a common symptom in PBC patients and may be exacerbated by currently approved PBC treatment,” said Dr. Pol Boudes, Chief Medical Officer of CymaBay Therapeutics. “We are excited to collaborate with patient organizations and to share data that highlight the impact of itch (pruritus) on PBC patients. We hope these findings provide the medical community with a greater understanding of this debilitating symptom and highlight the most relevant tools to assess itch from the patient’s perspective. In addition, we will be presenting data from our Phase 2 PBC program, which we believe further de-risk the seladelpar ENHANCE Phase 3 global registration study that is currently recruiting and enrolling patients.”

Presentations at DDW 2019 include:

Clinical Poster Presentations

Monday, May 20th 12:00 pm – 2:00 pm, Halls C-E

1“Capturing the Experience and Impact of Itch in Patients with Primary Biliary Cholangitis (PBC)” (Mo1486) Anne Skalicky, Milenka Jean-Baptiste, Pol Boudes, Klara Dickinson, Chuck McWherter, Alexandra Steinberg, Harinder Chera, Yun-Jung Choi, Cathy Mumford, Gail Wright, Margaret Vernon

Monday, May 20th 12:00 pm – 2:00 pm, Halls C-E

2“Seladelpar for the treatment of primary biliary cholangitis: experience with 25 cirrhotic patients” (Mo1473) Marlyn Mayo, Christopher Bowlus, Michael Galambos, Guy

Neff, Palak Trivedi, Aparna Goel, Joseph Odin, Bruce Bacon, Brian Borg, Stuart Gordon, Aliya Gulamhusein, Stephen Harrison, Cynthia Levy, Carmen Stanca, John Vierling, Alexandra Steinberg, Monika Varga, Jaidyn Nguyen, Sandrin Bergheanu, Yun-Jung Choi, Mary Standen, Pol Boudes

Monday, May 20th 12:00 pm – 2:00 pm, Halls C-E

3“Pharmacokinetics, safety, and tolerability of seladelpar in subjects with hepatic impairment” (Mo1476) *Lily Mao, Robert Martin, Alexandra Steinberg, Patricia Rohane, Jaidyn Nguyen, Mary Standen, Pol Boudes*

A full list of presentations can be found on the Digestive Disease Week @[website](#).

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 lives with PBC.

About Seladelpar

Seladelpar is a potent, selective, orally active PPAR δ agonist that is in development for the treatment of the liver diseases PBC and 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 ENHANCE

ENHANCE (NCT03602560) is a 52-week, placebo-controlled, randomized, Phase 3 study to evaluate the safety and efficacy of seladelpar. It will be conducted in more than 20 countries over five continents (North America, South America, Europe, Australasia and Asia). Approximately 240 PBC patients will be randomized to seladelpar 10 mg/day, seladelpar 5/10 mg/day (starting treatment at 5 mg with the possibility to escalate dose to 10 mg after 6 months), or placebo. Patients must experience an inadequate response to UDCA (defined as a serum alkaline phosphatase level $\geq 1.67 \times$ the upper limit of normal after at least 12 months of treatment) or an intolerance to UDCA to be eligible for the study. Patients who are inadequate responders to UDCA will continue their treatment during the study, and UDCA will be provided free of charge. The primary outcome measure is the responder rate after 52 weeks. A responder is defined as a patient who achieves an alkaline phosphatase level $< 1.67 \times$ the upper limit of normal with at least a 15% decrease from baseline and has a normal level of total bilirubin. Additional key outcomes of efficacy will compare the rate of normalization of alkaline phosphatase at 52 weeks and the level of pruritus at 6-months assessed by a numerical rating scale recorded with an electronic diary. Additional information can be found at <https://www.clinicaltrials.gov/ct2/show/NCT03602560?term=seladelpar&rank=2>. After completing the study, patients will be offered to continue treatment in an open label extension study. Patients on placebo will be offered to start seladelpar in the extension study.

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. CymaBay's lead development candidate, seladelpar, is a potent, selective and orally active PPAR δ agonist currently in development for the treatment of patients with primary biliary cholangitis (PBC), an autoimmune liver disease, and with nonalcoholic steatohepatitis (NASH). CymaBay is currently enrolling patients in ENHANCE, a global, Phase 3 registration study of seladelpar for PBC. CymaBay is also conducting a Phase 2b proof-of-concept study of seladelpar in patients with NASH.

About Digestive Disease Week

Digestive Disease Week® (DDW) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 18-21, 2019, at the San Diego Convention Center. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

Cautionary Statements

The statements in this press release regarding the potential for seladelpar to treat PBC and NASH, the potential benefits to patients, CymaBay's expectations and plans regarding 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. 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.

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Source: CymaBay Therapeutics, Inc.