March 27, 2019

CymaBay Therapeutics Announces Multiple Presentations During The International Liver Conference™ 2019

Oral presentation will feature clinical data for seladelpar in primary biliary cholangitis (PBC) patients with cirrhosis

NEWARK, Calif., March 27, 2019 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), today announced that multiple seladelpar presentations will be delivered during The International Liver Congress™ of the European Association for the Study of Liver (EASL) in Vienna, Austria from April 10th – 14th. Seladelpar is a potent and selective peroxisome proliferator-activated receptor delta (PPARδ) agonist currently in development for PBC and nonalcoholic steatohepatitis (NASH).

The oral presentation titled "Seladelpar for the treatment of primary biliary cholangitis: experience with 25 cirrhotic patients"[1] will be delivered by Dr. Marlyn Mayo, MD, Associate Professor and Liver Disease Specialist, University of Texas Southwestern Medical Center. This presentation will highlight the efficacy and safety of seladelpar in a subset of PBC patients with cirrhosis from an ongoing long-term Phase 2 study. After 52 weeks of treatment, the mean percent changes in alkaline phosphatase (AP) from baseline were -36% and -43% in the 5/10 mg (dose escalation) and 10 mg groups respectively. In addition, the safety and tolerability profiles of cirrhotic and noncirrhotic patients were similar. These data support that seladelpar maintained its anti-cholestatic effect over 52 weeks and appeared safe and well tolerated in PBC patients with cirrhosis.

"These results are very encouraging and support the further investigation of seladelpar in cirrhotic PBC patients. This is particularly important given the high unmet need that exists within this patient population who are at a greater risk of clinical decompensation," said Dr. Marlyn Mayo, MD.

A second clinical presentation[2] demonstrates that single dose oral administration of seladelpar appeared 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 challenging population. A third presentation[3] using the validated GLOBE score to model PBC clinical progression suggested that seladelpar treatment was associated with a long-term improvement in disease progression.

In addition, a preclinical presentation[4] highlights that seladelpar demonstrates substantial anti-fibrotic and anti-steatotic activity in an obese mouse model of NASH.

Dr. Pol Boudes, Chief Medical Officer of CymaBay Therapeutics, commented, "We are excited to share additional data that further demonstrates that seladelpar retains efficacy and was well tolerated in PBC patients with compensated cirrhosis through 52 weeks. We believe these latest results from our Phase 2 program further de-risk the seladelpar ENHANCE Phase 3 global registration study that is currently recruiting and enrolling patients. We once again want to thank all the patients participating in our clinical studies, as well as their families, their physicians and the clinical research team members that tirelessly support them."

Oral Presentation

April 12th 16:15 - 16:30

PS-122:

[1]"Seladelpar for the treatment of primary biliary cholangitis: experience with 25 cirrhotic patients"
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

Clinical Poster Presentations

April 12th 9:00 - 17:00

FRI-041:
[2]**"Pharmacokinetics, safety, and tolerability of seladelpar in subjects with hepatic impairment"**

Lily Mao, Robert Martin, Alexandra Steinberg, Patricia Rohane, Jaidyn Nguyen, Mary Standen, Pol Boudes

FRI-045:
[3]**"Treatment of patients with primary biliary cholangitis with seladelpar for 52 weeks improves predicted transplant-free survival"**
Carla Fiorella Murillo Perez, Pol Boudes, Alexandra Steinberg, Monika Varga, Yun-Jung Choi, Aliya Gulamhusein, Gideon Hirschfield, Bettina Hansen

Preclinical Poster Presentation

April 12th 9:00 - 17:00

FRI-329:
[4]**"Comparison of seladelpar and combinations with liraglutide or selonsertib for improvement of fibrosis and NASH in a diet-induced and biopsy-confirmed mouse model of NASH"**
Yun-Jung Choi, Jiangao Song, Jeff D. Johnson, Marc K. Hellerstein, Charles McWherter

Congress attendees can visit CymaBay throughout the meeting at booth 253. A full list of presentations can be found on The International Liver Congress ™ 2019 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 NASH
Nonalcoholic steatohepatitis 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 nonalcoholic steatohepatitis. Patients with nonalcoholic steatohepatitis are at increased risk of cirrhosis and hepatocellular carcinoma, and nonalcoholic steatohepatitis is projected in the coming years to be the leading reason for liver transplant. Further, most patients with nonalcoholic steatohepatitis 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 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 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 PPARδ agonist currently in development for the treatment of patients with primary biliary cholangitis (PBC), an autoimmune liver disease, and with nonalcoholic steatohepatitis (NASH). Two Phase 2 studies of seladelpar established proof-of-concept in PBC. CymaBay is currently enrolling patients in a global, Phase 3 registration study of seladelpar for PBC. This study is a 52-week, plac**E**bo-co**N**trolled, randomized, p**HA**se 3 study to evaluate the safety a**N**d effi**C**acy of s**E**ladelpar (ENHANCE) in patients with PBC. CymaBay is also conducting a Phase 2b proof-of-concept study of seladelpar in patients with NASH.

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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