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CymaBay Therapeutics Presents Data at Digestive Disease Week 2020 Online Education

Data from previously completed open-label phase 2 study supports potential for seladelpar to improve pruritus (itching) in patients with PBC

Improvements in other quality-of-life parameters also observed

NEWARK, Calif., June 19, 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 new data from a previously completed open-label Phase 2 study of seladelpar in patients with primary biliary cholangitis (PBC). These data were made available as an electronic presentation through the Digestive Disease Week® (DDW®) 2020 Online Education program. Seladelpar is a potent and selective peroxisome proliferator-activated receptor delta (PPARδ) that has demonstrated anti-cholestatic and anti-inflammatory effects in clinical studies for PBC.

The electronic presentation titled "Effects on Pruritus and Sleep Disturbance in Patients with Primary Biliary Cholangitis (PBC) after 1 year of Treatment with Seladelpar, a Peroxisome Proliferator-Activated Receptor Delta Agonist: Results of an Open-Label Phase 2 Study," highlights the effect of seladelpar treatment over one year (1yr) on key patient reported measures of pruritus (itching) and quality of life (QoL). PBC patients with an incomplete response or intolerance to ursodeoxycholic acid (alkaline phosphatase ≥ 1.67 x upper limit of normal) were randomized in this study to either seladelpar 2 mg, 5/10 mg (initial 5 mg with an option to adjust to 10 mg) or 10 mg groups (with no placebo) and treated for 1yr. Pruritus and QoL measures were evaluated at baseline (BL) through 1yr for patients in the 5/10 mg (n = 49) and 10 mg (n = 52) groups using visual analogue scale (VAS: 0-100), 5D-itch scale (5 domains: 1-5 each) and PBC-40 questionnaires. Substantial improvement in pruritus (VAS ≥ 20-point decrease) at 1yr in patients with moderate to severe pruritus (VAS ≥ 40 at BL) was seen in 58% and 93% of patients in the 5/10 mg and 10 mg groups, respectively. About half of the patients experienced BL sleep disturbance due to itch as measured by the 5-D itch score. Of these patients, improvement in sleep disturbance at 1yr was observed in 81% (5/10 mg) and 78% (10 mg) of patients. A consistent pattern of improvements in PBC-40 itch, sleep and fatigue were noted.

Dr. Andreas E. Kremer, MD, PhD, MHBA, from Friedrich-Alexander-University of Erlangen-Nürnberg, presented these data and commented, “Itching is one of the most common and troublesome clinical symptoms in PBC. Many PBC patients I’ve treated describe itching as being relentless with tormenting physical and emotional consequences in their lives. I was
impressed by the consistency of response to seladelpar seen in patients using different measures of pruritus, including effects on sleep quality. These effects are promising for patients but need to be confirmed in a placebo-controlled study.”

DDW® 2020 Online Education
The abstract (#686) and online presentation is available by searching for the term “seladelpar” at the following DDW® 2020 link:
https://ddw.apprisor.org/epsSearchDDW.cfm

The presentation from DDW® 2020 will also be made available on the CymaBay website at:
https://ir.cymabay.com/presentations.

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 PPARδ agonist that has been in development for the treatment of the liver diseases 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. All development programs for seladelpar are on clinical hold pending the FDA’s review of a complete response submission currently being planned.

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.

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), 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 potentially improve clinical symptoms of the disease, the potential benefits to patients, CymaBay’s expectations and plans regarding its intended future interactions with the FDA, 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 seladelpar histological findings that have not yet been submitted to the FDA, and there is no guarantee as to how or when the FDA will respond; 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.

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