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CymaBay Therapeutics Presents Positive Final Results From 52-Week Phase 2 Study in Primary Biliary Cholangitis at The Digital International Liver Congress™ 2020

- *Sustained anti-cholestatic and hepatoprotective effects observed in patients with and without cirrhosis*
- *Self-reported pruritus improved at one year for patients in highest categories of baseline itch*
- *Selected for inclusion in the "Best of ILC" presentation*
- *Results mirror recently reported ENHANCE Phase 3 data confirming anti-cholestatic and anti-pruritic effects of seladelpar*

NEWARK, Calif., Aug. 27, 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 final results from a previously completed open-label Phase 2 study of seladelpar in patients with primary biliary cholangitis (PBC). These data will be made available as an electronic presentation through the Digital International Liver Congress™ 2020 of the European Association for the Study of Liver (EASL) which will be held online August 27th – 29th and were selected for inclusion in the "Best of ILC" presentation.

The presentation titled "Durability of treatment response after 1 year of therapy with seladelpar in patients with primary biliary cholangitis (PBC): final results of an international phase 2 study," was delivered by Dr. Cynthia Levy, MD, Professor of Medicine, University of Miami. This electronic presentation highlights the efficacy, safety, and tolerability of seladelpar over 1 year of open-label treatment. Eligible PBC patients with either an inadequate response (alkaline phosphatase [ALP] ≥1.67 x upper limit of normal [ULN]) or intolerance to ursodeoxycholic acid (UDCA) were either sequentially assigned or randomized to daily seladelpar at 2 mg, 5/10 mg (initial 5 mg with an option to adjust to 10 mg) or 10 mg groups and treated for 1 year. At 1 year, the mean decreases in ALP were 41% and 45% in the 5/10 mg and 10 mg groups, respectively. A key secondary endpoint was the composite responder rate measured at 1 year and defined as a patient with ALP <1.67 x ULN, ≥ 15% decrease in ALP, and total bilirubin ≤ULN. At 1 year, 55% and 69% of patients met the composite responder endpoint in the 5/10 mg and 10 mg groups, respectively. Mean decreases in ALT, AST, and GGT were observed in all treatment groups. Normalization of ALP levels at 1 year occurred in 14% and 33% in the 5/10 mg and 10 mg, respectively. Pruritus was evaluated at baseline through 1 year for patients in the 5/10 mg and 10 mg 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 1 year in patients with moderate to severe pruritus (VAS ≥40 at baseline) was seen in 58% and 93% of patients in the 5/10 mg and 10 mg groups, respectively. Seladelpar in doses up to 10 mg appeared safe and well-tolerated in patients with and without cirrhosis. Of the 119

patients that received at least one dose of seladelpar, 14 serious adverse events were documented and none were related to seladelpar. Four patients discontinued the study due to an adverse event. Nine patients had liver biopsies performed during the long-term study after treatment with seladelpar ranging from 15 – 33 months. Post-treatment liver biopsy findings were consistent with expected features of PBC.

“These findings suggest that seladelpar treatment in a high-risk PBC patient population promotes clinically significant improvement in biochemical markers of cholestasis and provides a potential benefit on pruritus. Additionally, seladelpar treatment appeared safe and well-tolerated which is encouraging given the unmet need that exists in this high-risk population,” said Dr. Levy.

Sujal Shah, CEO and President of CymaBay Therapeutics, commented, “We are extremely encouraged by the sustained anti-cholestatic effects and improvement in markers of liver injury observed with seladelpar treatment in this study. We believe the results from this Phase 2 PBC study have now been confirmed in the placebo-controlled ENHANCE study, which demonstrated clinically meaningful and statistically significant differences in anti-cholestatic, hepatoprotective, and anti-pruritic effects from placebo after only 3 months of treatment. These data and data from ENHANCE strengthen our confidence in the potential for seladelpar to be a breakthrough therapy for patients with PBC. We want to thank the patients and investigators who have participated in our clinical studies and look forward to the re-initation of a Phase 3 registration study for seladelpar in PBC.”

CymaBay’s presentations from The Digital International Liver Congress™ will also be made available on the CymaBay website (www.cymabay.com).

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.

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 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 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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