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# CymaBay Therapeutics to Host Post-AASLD Key Opinion Leader Webinar on Seladelpar for Primary Biliary Cholangitis

**Webinar on Monday, November 15th, @ 4:30pm EST**

NEWARK, Calif., Nov. 11, 2021 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ: CBAY), a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet need, today announced that it will host a Key Opinion Leader (KOL) webinar on seladelpar for primary biliary cholangitis (PBC) on Monday, November 15, at 4:30pm EST.

The webinar will feature presentations by Professor Marlyn J. Mayo, M.D. (University of Texas Southwestern Medical Center) and Professor Cynthia Levy, M.D. (University of Miami) who will both discuss the abstracts that were presented at The Liver Meeting Digital Experience™ 2021 (TLMdX) of the American Association for the Study of Liver Diseases (AASLD). Dr. Mayo will discuss the efficacy and safety of seladelpar during 2 years of treatment in patients with primary biliary cholangitis (PBC) and Dr. Levy will highlight the treatment effects of seladelpar in compensated cirrhotic patients with portal hypertension after 3 months, which led to ALP changes of -30% in the 5 mg and -45% in the 10 mg groups.

Dennis Kim, M.D., Chief Medical Officer of CymaBay, will also discuss the company's progress developing seladelpar for patients with PBC. Seladelpar (MBX-8025) is a potent, selective, orally active peroxisome proliferator-activated receptor  $\delta$  (PPAR $\delta$ ) agonist in development for the treatment of patients with the autoimmune liver disease, primary biliary cholangitis (PBC). Backed by an extensive body of clinical evidence and global patient experience through its Phase 2 and Phase 3 (ENHANCE) studies of seladelpar in Primary Biliary Cholangitis (PBC), CymaBay initiated an international pivotal Phase 3 study (RESPONSE) in early 2021.

To register for the webinar, please click [here](#).

Marlyn J. Mayo, M.D. is a Professor of Internal Medicine, Division of Digestive and Liver Diseases at the University of Texas Southwestern, in Dallas, Texas. Dr. Mayo obtained her B.A. from Northwestern University in Evanston, Illinois in 1986 and her M.D. from Baylor College of Medicine in Houston, Texas in 1990. After her internship and residency in Internal Medicine at University of California, Irvine, she completed a fellowship in Gastroenterology & Hepatology at UT Southwestern. Dr. Mayo became interested in primary biliary cholangitis (PBC) because of her interest in autoimmune diseases. Dr. Mayo went to UT Southwestern to conduct research and work on the largest PBC trial at the time with Burton Combes, M.D., a pioneer in liver disease who started the premier journal of the American Association for the Study of Liver Diseases, Hepatology, and founded the American Liver Foundation. She studied immunology under Peter Lipsky, M.D, former Director of the Intramural Research

Program & the Autoimmunity Branch of NIAMS at the NIH. She has held numerous grants and published widely in the field of PBC. She is a devoted mentor who has won awards for her teaching and served as the Gastroenterology Fellowship Program director. Currently, she maintains a clinical practice focused on cholestatic and autoimmune diseases, teaches medical students, interns, residents and fellows; and serves as principal investigator for multiple clinical trials in PBC.

Cynthia Levy, M.D. is a native of Brazil, where she graduated from medical school at Universidade Federal do Rio de Janeiro. She completed residency in Internal Medicine first at her home institution and then at University of Miami/Jackson Memorial Hospital. Dr. Levy undertook training in Gastroenterology at Mayo Clinic Rochester, MN, and subsequently went to University of Florida, Gainesville, for a Transplant Hepatology Fellowship, later joining their staff. In 2010 she returned to the University of Miami as an Associate Professor of Medicine.

Dr. Levy currently serves as the Assistant Director for the Schiff Center for Liver Diseases and is the Program Director for the Transplant Hepatology Fellowship. She has a strong research interest in autoimmune and cholestatic liver diseases and runs both investigator-initiated and industry-sponsored studies. Dr Levy is also the UM principal investigator for the NIH Porphyria Consortium. She is an American Gastroenterology Association Fellow and a Fellow of the American Association for the Study of Liver Diseases. She has over 60 peer-reviewed publications, including original papers, editorials, reviews and book chapters.

### **About PBC**

PBC is a rare, chronic inflammatory liver disease primarily affecting women (1 in 1,000) over the age of 40. PBC is characterized by impaired bile flow (known as cholestasis) and the accumulation of toxic bile acids in the liver, leading to inflammation and destruction of the bile ducts within the liver and causing increased levels of alkaline phosphatase (ALP) and total bilirubin. The most common early symptoms of PBC are itching (pruritus) and fatigue, which can be very debilitating for some patients. Progression of PBC is associated with an increased risk of liver cancer and liver-related mortality.

### **About Seladelpar**

Seladelpar is a first-in-class oral, selective PPAR $\delta$  agonist shown to regulate critical metabolic and liver disease pathways in indications with high unmet medical need. Preclinical and clinical data support its ability to regulate genes involved in bile acids synthesis, inflammation, fibrosis and lipid metabolism, storage and transport.

### **About CymaBay**

CymaBay Therapeutics, Inc. is a clinical-stage biopharmaceutical company focused on improving the lives of people with liver and other chronic diseases that have high unmet medical need through a pipeline of innovative therapies. Our deep understanding of the underlying mechanisms of liver inflammation and fibrosis, and the unique targets that play a role in their progression, have helped us receive breakthrough therapy designation (U.S. Food and Drug Administration), PRiority MEdicines status (European Medicines Agency) and orphan drug status (U.S. and Europe) for seladelpar, a first-in-class treatment for people with primary biliary cholangitis (PBC). Our evidence-based decision-making and commitment to the highest quality standards reflect our relentless dedication to the people, families and communities we serve. To learn more, visit [www.cymabay.com](http://www.cymabay.com) and follow us on [Twitter](#) and [LinkedIn](#).

## **Cautionary Statements**

Any statements made in this press release and the accompanying webinar 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 current and future clinical trials, including the timing of full enrollment in RESPONSE, the impact of the COVID pandemic on the enrollment timeline for CymaBay's 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 enroll clinical trials or 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, its Quarterly Reports on Form 10-Q 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](http://www.cymabay.com).

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