# CymaBay Therapeutics Announces Presentations During The International Liver Congress™ 2021

NEWARK, Calif., June 09, 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 multiple seladelpar presentations will be delivered during The International Liver Congress  $^{\text{TM}}$  2021 of the European Association for the Study of Liver (EASL) which will be held online June  $23^{\text{rd}} - 26^{\text{th}}$ .

- A presentation will be made highlighting the efficacy, safety and tolerability of seladelpar in the important subset of patients having compensated liver cirrhosis due to PBC.
- A second clinical presentation<sup>2</sup> examines the efficacy of seladelpar in PBC patients who were previously treated with obeticholic acid (Ocaliva) or fibrates.
- A third presentation<sup>3</sup> will focus on adjudication of suspected drug-induced liver injury (DILI) in NASH patients using independent blinded review by a panel of pathologists and hepatologists.
- A preclinical presentation<sup>4</sup> will highlight the effect of seladelpar and CB-0406 combination therapy on obesity, liver fibrosis and steatosis in an obese mouse model in NASH.

Dr. Dennis Kim, Chief Medical Officer of CymaBay Therapeutics, commented, "We are pleased to have the opportunity to present a wide range of abstracts at this year's International Liver Congress™. The clinical results highlight the potential for seladelpar to offer PBC patients an efficacious and safe treatment option. We continue to advance clinical development activities with a focus on the seladelpar RESPONSE Phase 3 global pivotal study in PBC that is currently recruiting and enrolling patients."

Presentations at The International Liver Congress™ 2021 include:

<sup>1</sup>"Efficacy, safety, and tolerability of seladelpar in patients with compensated liver cirrhosis due to primary biliary cholangitis (PBC): a pooled analysis of phase 2 and phase 3 studies" (Abstract #1809)

Stuart C Gordon, Palak Trivedi, Christopher Bowlus, Michael Galambos, Aparna Goel, Aliya Gulamhusein, Cynthia Levy, Guy Neff, Carmen Stanca, Douglas Thorburn, Bruce Bacon, Brian Borg, Yvonne Doerffel, Lisa Forman, Bradley Freilich, Liana Gheorghe, María Saraí González, Stephen Harrison, Jonathan Huang, Sook-Hyang Jeong, Seung Up Kim, John Lake, Joseph Odin, Won Young Tak, Hillel Tobias, John M. Vierling, Ke Yang, Alexandra (Sasha) Steinberg, Yun-Jung Choi, Charles McWherter, Marlyn J. Mayo

<sup>&</sup>lt;sup>2</sup>"Treatment with seladelpar in patients with primary biliary cholangitis (PBC) and

# prior experience with obeticholic acid (OCA) or fibrates" (Abstract #2120)

Aliya Gulamhusein, Guy Neff, Aparna Goel, Marlyn J. Mayo, Carmen Stanca, Christopher Bowlus, Lisa Forman, Pietro Invernizzi, Frederik Nevens, Ehud Zigmond, Eli Zuckerman, Ke Yang, Yun-Jung Choi, Alexandra (Sasha) Steinberg, Charles McWherter, Kris V. Kowdley

<sup>3</sup>"An independent blinded review of suspected drug-induced liver injury (DILI) in nonalcoholic steatohepatitis (NASH) patients by a panel of pathologists and hepatologists: lessons learned from the seladelpar hepatoxicity review committee (SHRC)" (Abstract # 1504)

Paul Watkins, David E Kleiner, Pierre Bedossa, Zack Goodman, Neil Kaplowitz, Willis Maddrey, John M. Vierling, Michael Charlton, Cynthia Guy, Elizabeth Brunt, Stephen Harrison, Edward Cable, Yun-Jung Choi, Sujal Shah, Klara Dickinson, Charles McWherter

<sup>4</sup>"Effect of seladelpar and CB-0406 combination therapy on obesity, liver fibrosis and steatosis in a diet-induced obese (DIO) mouse model of biopsy-confirmed non-alcoholic steatohepatitis (NASH) with fibrosis" (Abstract #1797)

Yun-Jung Choi, Jeffrey Stebbins, Ed Cable, Jiangao Song, Jeff Johnson, Charles McWherter

Congress attendees can visit CymaBay throughout the virtual meeting at the CymaBay microsite. A full list of presentations can be found on The International Liver Congress ™ 2021 website. The presentations will also be made available later this month on the <a href="CymaBay website">CymaBay website</a>.

# **About Seladelpar**

Seladelpar is a potent, selective, orally active PPAR $\delta$  agonist that has been in development for the treatment of the liver diseases primary biliary cholangitis (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 for early stage PBC and PRIority MEdicine status from the EMA.

# **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 <a href="https://www.cymabay.com">www.cymabay.com</a> and follow us on <a href="https://www.cymabay.com">Twitter</a> and Linkedin.

## **Cautionary Statements**

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

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