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# CymaBay Therapeutics Announces the Publication of the Seladelpar Proof-of-Concept Study for Primary Biliary Cholangitis in *Lancet Gastroenterology and Hepatology*

NEWARK, Calif., Aug. 15, 2017 (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 the proof-of-concept study of seladelpar, a potent and selective PPAR $\delta$  agonist, for the treatment of primary biliary cholangitis (PBC) was published by *Lancet Gastroenterology and Hepatology*, a prominent peer-reviewed journal featuring clinical advances in liver diseases. The paper titled "Seladelpar (MBX-8025), A Selective PPAR- $\delta$  Agonist, in Patients with Primary Biliary Cholangitis with an Inadequate Response to Ursodeoxycholic Acid: A Double-blind, Randomised, Placebo-controlled, Phase 2, Proof-of-Concept Study<sup>1</sup>" was published as a collaboration involving key international PBC experts.

"The publication of our first PBC study with seladelpar is a very important clinical milestone for CymaBay, the clinical community and patients affected with PBC," said Dr. Pol Boudes, M.D., Chief Medical Officer of CymaBay. Dr. Boudes added, "This study, which evaluated higher doses of seladelpar (50 mg and 200 mg), established the potency of the compound to reverse cholestasis, the prominent pathophysiological mechanism in play in PBC. It also demonstrated seladelpar's activity to decrease bile acid synthesis and inflammation, which are key detrimental consequences of the disease. While we stopped this study because of an alanine aminotransferase (ALT) safety signal, we have recently announced the interim results of our ongoing low dose Phase 2 study in PBC which indicated that seladelpar retains its anti-cholestatic activity at lower doses (5 mg and 10 mg) while also decreasing transaminase levels. Based on these interim results we are further expanding the ongoing low dose Phase 2 study, and starting to plan our Phase 3 program."

Prof. David Jones, University of Newcastle, Newcastle UK, the first author of the publication added, "Seladelpar has the potential to be an improved second-line therapy for primary biliary cholangitis. A study at lower doses is underway and appears to have identified active doses that do not cause ALT elevation. If the risk of ALT elevation can be eliminated while retaining efficacy, the drug offers the potential for liver biochemistry normalization in patients with primary biliary cholangitis."

The paper can be accessed online at:

[http://www.thelancet.com/journals/langas/article/PIIS2468-1253\(17\)30246-7/fulltext](http://www.thelancet.com/journals/langas/article/PIIS2468-1253(17)30246-7/fulltext)

<sup>1</sup> David Jones, Pol F Boudes, Mark G Swain, Christopher L Bowlus, Michael R Galambos, Bruce R Bacon, Yvonne Doerffel, Norman Gitlin, Stuart C Gordon, Joseph A Odin, David

Sheridan, Markus-Alexander Wörns, Virginia Clark, Linsey Corless, Heinz Hartmann, Mark E Jonas, Andreas E Kremer, George F Mells, Peter Buggisch, Bradley L Freilich, Cynthia Levy, John M Vierling, David E Bernstein, Marek Hartleb, Ewa Janczewska, Fedja Rochling, Hemant Shah, Mitchell L Shiffman, John H Smith, Yun-Jung Choi, Alexandra Steinberg, Monika Varga, Harinder Chera, Robert Martin, Charles A McWherter, Gideon M Hirschfield. Seladelpar (MBX-8025), A Selective PPAR- $\delta$  Agonist, in Patients with Primary Biliary Cholangitis with an Inadequate Response to Ursodeoxycholic Acid: A Double-blind, Randomised, Placebo-controlled, Phase 2, Proof-of-Concept Study.

## **About CymaBay**

CymaBay Therapeutics, Inc. (CBAY) is a clinical-stage biopharmaceutical company focused on developing therapies for liver and other chronic diseases with high unmet medical need. Seladelpar is a potent, selective, orally active PPAR $\delta$  agonist currently in development for the treatment of patients with the autoimmune liver disease, primary biliary cholangitis (PBC). A Phase 2 study of seladelpar established proof of concept in PBC. CymaBay is currently conducting a second Phase 2 study of seladelpar in PBC in order to support dose selection for Phase 3.

## **Cautionary Statements**

The statements in this press release, including those statements regarding the structure and conduct of clinical trials, future performance of CymaBay's product candidates, the potential of seladelpar to treat primary biliary cholangitis or nonalcoholic steatohepatitis, the therapeutic and commercial potential of CymaBay's product candidates, and any of the targeted indications for the potential future development or commercialization of CymaBay's product candidates are forward looking statements that are subject to risks and uncertainties. Actual results and the timing of events regarding the further development of CymaBay's product candidates 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 which 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 Quarterly Report on Form 10-Q, 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](http://www.cymabay.com).

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