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CymaBay Therapeutics Halts Clinical Development of Seladelpar

NEWARK, Calif., Nov. 25, 2019 (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 company was terminating its Phase 2b study of seladelpar in subjects with non-alcoholic steatohepatitis (NASH) and its recently initiated Phase 2 study of seladelpar in subjects with primary sclerosing cholangitis (PSC). In addition, the company is putting on hold all studies of seladelpar in subjects with primary biliary cholangitis (PBC).

The decision to halt development of seladelpar was based on initial histological findings observed in the Phase 2b study of seladelpar in NASH. Planned, blinded histological assessments of the first tranche of liver biopsies in the trial revealed atypical histological findings, including histology characterized as an interface hepatitis presentation, with or without biliary injury. The company has initiated a series of investigative actions to better understand these findings.

“The atypical histological findings in the NASH Phase 2b clinical study of seladelpar were observed in patients who demonstrated on-study improvement or stabilization of their biochemical measures of inflammation and liver injury and no liver-related adverse events after 52 weeks of treatment,” stated Sujal Shah, CEO of CymaBay. “These findings were also unexpected based on our preclinical and clinical experience with seladelpar to date. However, in light of the findings, we have decided to terminate our NASH and PSC studies and place our PBC studies on hold pending further review and follow-up. We are very disappointed in having to halt the development of seladelpar at this time but patient safety and care is paramount. We would like to thank patients and their families, as well as the investigators and site personnel that have participated in these studies.”

Conference Call

CymaBay management will host a conference call today at 4:30 p.m. EST to discuss the company’s decision to terminate its NASH and PSC studies and put its PBC studies on hold. To access the live conference call, please dial 877-407-0784 from the U.S. and Canada, or 201-689-8560 internationally, Conference ID# 13697148. To access the live and subsequently archived webcast of the conference call, go to the Investors section of the company's website at <http://ir.cymabay.com/events>.

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. For additional information about CymaBay visit www.cymabay.com.

Cautionary Statements

The statements in this press release regarding CymaBay’s future plans and potential clinical development are forward looking statements that are subject to risks and uncertainties.

Actual results and the timing of events 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 CymaBay's product development activities, including 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.

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