October 30, 2018

CymaBay Announces the Initiation of the Seladelpar Global Phase 3 Registration Study (ENHANCE) for the Treatment of Primary Biliary Cholangitis and Additional Corporate Updates

- *Phase 3 patient enrollment commenced with multiple investigational sites in the U.S. initiated*
- *Team expanded with key hires focused on delivering a high-quality registration package*

NEWARK, Calif., Oct. 30, 2018 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ: CBAY), today announced that the company has initiated the seladelpar Phase 3 registration study for the treatment of Primary Biliary Cholangitis (PBC). The study is a 52-week, plac**E**bo-co**N**trolled, randomized, p**HA**se 3 study to evaluate the safety a**N**d effi**C**acy of s**E**ladelpar (ENHANCE) that will be conducted in more than 20 countries spanning five continents. The study is intended to establish the efficacy and safety of seladelpar for the treatment of PBC to support the submission of a global registration dossier with health authorities to obtain approval of seladelpar. Seladelpar is a drug candidate for PBC patients who are inadequate responders to ursodeoxycholic acid (UDCA), the first line treatment of PBC, or who are intolerant to UDCA.

Pol Boudes, MD, Chief Medical Officer of CymaBay, commented, “The initiation of this Phase 3 is truly an exciting moment. I want to warmly thank all of the PBC patients who participate in our clinical studies, as well as their families and their medical teams. The data we have collected since the first PBC patient received seladelpar in December 2015 are encouraging and we believe support the potential for seladelpar to significantly improve the lives of patients with PBC. I also want to thank the CymaBay team, our advisers, and the regulators around the world who made this moment possible.”

Organizational Update – Development team expanded with key senior hires
In addition to the initiation of ENHANCE, CymaBay announced the appointment of key individuals to expand and strengthen the development organization in order to execute the seladelpar Phase 3 program and deliver a high-quality registration package.

- Dr. Patricia Rohane, M.D., has joined CymaBay as Vice President, Clinical Development. Patricia brings extensive Phase 3 and global registration experience and will lead the seladelpar clinical team. Patricia is specialized in immunology/allergy and internal medicine and spent more than 15 years at Sanofi-Aventis and Celgene.

- Dr. Stephen Rossi, Pharm. D., joins as Vice President, Early Clinical Development. Steve brings more than 15 years of experience in liver diseases, both in academia and industry. Steve most recently led the development of NGM282 for nonalcoholic steatohepatitis (NASH), primary sclerosing cholangitis (PSC), and PBC at NGM Biopharmaceuticals. He also held leadership roles at Gilead Sciences and Roche.

- Kamal Sigel, M.S., has been named Vice President, Quality. Kamal is a Certified Quality Auditor and brings substantial experience ranging from Phase 3 to commercial in the areas of manufacturing, compliance and quality control. Kamal comes to CymaBay most recently after more than 10 years at Anthera Pharmaceuticals and Hyperion Therapeutics.

Sujal Shah, President and CEO of CymaBay stated, “We are particularly excited to welcome Patricia, Steve, and Kamal to CymaBay as we continue to build the organization to achieve our goal of delivering seladelpar to PBC patients. The initiation of ENHANCE is a transformative event for the company. As we look to take this pivotal step forward in the development of seladelpar for PBC, new results from our ongoing Phase 2 study will be highlighted in two late-breaking presentations on November 12 at The Liver Meeting® 2018 of the American Association for the Study of Liver Diseases. These data give us confidence that we can target a potential label for seladelpar that reflects a strong efficacy profile without drug-induced pruritus.”

Pipeline Update – Kowa returns rights to arhalofenate; resources fully focused on liver programs

On October 24, 2018, Kowa Pharmaceuticals America, Inc. terminated the Exclusive License Agreement for the rights to develop and commercialize arhalofenate in the U.S. Arhalofenate is a Phase 3-ready drug candidate with a dual-acting anti-inflammatory and uricosuric activity. Arhalofenate had been in development as a combination with febuxostat, a xanthine oxidase inhibitor, to deliver greater urate lowering and anti-flare activity for patients with gout.

“We are disappointed in Kowa's decision to end our development and commercialization agreement for arhalofenate for the treatment of gout,” said Sujal Shah. “However, over the past two years, we have been fully committed to redirecting our efforts and resources toward our current focus in liver disease and are extremely proud of the progress we’ve made advancing seladelpar in PBC and NASH. We believe seladelpar has the potential to significantly improve patient care and look forward to providing further updates in the weeks ahead.”

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 is in development for the treatment of the liver diseases PBC and NASH. For PBC, seladelpar has received an orphan designation from the US Food and Drug Administration and the European Medicine Agency. Seladelpar also received the PRIority MEdicine (PRIME) status from the European Medicine Agency.

About ENHANCE
ENHANCE (NCT03602560) is a 52-week, placebo-controlled, randomized, Phase 3 study to evaluate the safety and efficacy of seladelpar. It will be conducted in more than 20 countries over five continents (North America, South America, Europe, Australasia and Asia). Approximately 240 PBC patients will be randomized to seladelpar 10 mg/day, seladelpar 5/10 mg/day (starting treatment at 5 mg with the possibility to escalate dose to 10 mg after 6 months), or placebo. Patients must experience an inadequate response to UDCA (defined as a serum alkaline phosphatase level ≥ 1.67 x the upper limit of normal after at least 12 months of treatment) or an intolerance to UDCA to be eligible for the study. Patients who are inadequate responders to UDCA will continue their treatment during the study, and UDCA will be provided free of charge. The primary outcome measure is the responder rate after 52 weeks. A responder is defined as a patient who achieves an alkaline phosphatase level < 1.67 x the upper limit of normal with at least a 15% decrease from baseline and has a normal level of total bilirubin. Additional key outcomes of efficacy will compare the rate of normalization of alkaline phosphatase at 52 weeks and the level of pruritus at 6-months assessed by a numerical rating scale recorded with an electronic diary. Additional information can be found at https://www.clinicaltrials.gov/ct2/show/NCT03602560?term=seladelpar&rank=2. After completing the study, patients will be offered to continue treatment in an open label extension study. Patients on placebo will be offered to start seladelpar in the extension 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 PPARδ agonist, currently in development for the treatment of patients with primary biliary cholangitis (PBC), an autoimmune liver disease, and with nonalcoholic steatohepatitis (NASH). Two Phase 2 studies of seladelpar established proof-of-concept in PBC. CymaBay is currently conducting a Phase 3 study of seladelpar for PBC and a Phase 2b study of seladelpar for NASH.

Cautionary Statements
The statements in this press release regarding the potential for seladelpar to treat PBC and NASH, the potential for arhalofenate to treat gout, the potential benefits to patients, CymaBay’s expectations and plans regarding 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. 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.

Contact:
Hans Vitzthum
LifeSci Advisors, LLC
212-915-2568
Hans@LifeSciAdvisors.com

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