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CymaBay Initiates Arhalofenate Phase 2b Gout Study

NEWARK, CA -- (Marketwired) -- 03/26/14 -- CymaBay Therapeutics, Inc. (OTCQB: CYMA), a biopharmaceutical company developing therapies addressing unmet medical needs in metabolic disease, today announced that it has randomized the first patient in a Phase 2b clinical trial of arhalofenate (MBX-102). Arhalofenate is a dual acting product candidate for the treatment of gout that is targeted to lower serum uric acid (sUA) and reduce the incidence of flares.

This randomized, double-blind, active comparator- and placebo-controlled study will evaluate the safety, flare prevention and sUA-lowering activity of arhalofenate in approximately 225 patients with a diagnosis of gout, hyperuricemia and a history of 3 or more flares in the last 12 months. The study has 5 arms including placebo, arhalofenate (600 and 800 mg), allopurinol (300 mg) and allopurinol (300 mg) plus colchicine (0.6 mg). The primary endpoint of the study is the flare incidence rate for the arhalofenate (800 mg) arm vs. allopurinol (300 mg) following twelve weeks of treatment. A key secondary endpoint is the sUA responder rate (the percentage of patients that achieve sUA levels below 6 mg/dL) for the treatment arms. The study is designed to assess whether arhalofenate can provide sUA lowering comparable to the most commonly prescribed dose of allopurinol (300 mg) and flare reduction similar to colchicine, the drug most commonly used to prevent sUA-lowering induced flares.

"We are excited about initiating this Phase 2b gout study which can confirm arhalofenate's novel profile of decreasing painful gout flares while at the same time lowering sUA. Importantly, it tests the ability of arhalofenate to avoid flares without the need for co-treatment with colchicine. Arhalofenate's dual mechanism is ideal for patients not reaching treatment goals," said Harold Van Wart, President and CEO of CymaBay. "We are pleased to announce that we have met this important milestone which we projected for the first half of this year."

About Arhalofenate

Arhalofenate was previously in development for the treatment of type 2 diabetes. It was studied in eight Phase 1 and four Phase 2 trials in which it demonstrated good safety and tolerability in more than 550 patients for up to 6 months of treatment. The glucose lowering exhibited by arhalofenate did not meet the desired product profile for the type 2 diabetes indication. However, data from these trials showed that arhalofenate exhibited dose-dependent reductions in sUA. The decreases in sUA are due to a uricosuric effect in which arhalofenate blocks the reabsorption of uric acid from the kidneys mediated by the transporter URAT-1, resulting in increased renal clearance into the urine. These reductions were retained in patients with mild to moderate renal insufficiency. In addition to lowering glucose in patients with type 2 diabetes (but not normals), arhalofenate lowered triglycerides and markers of inflammation, suggesting its ability to address metabolic comorbidities such as insulin resistance and hypertriglyceridemia that are prevalent in the gout patient

population.

On the basis of these findings, CymaBay is now developing arhalofenate for the treatment of gout. The company has conducted three Phase 2a studies (one monotherapy study and one each in combination with febuxostat and allopurinol) confirming the sUA lowering in gout patients. A key and unexpected finding from these studies was that, in contrast to other agents that lower sUA, arhalofenate reduced the incidence and duration of flares. Preclinical studies subsequently revealed the mechanistic basis for this activity. Arhalofenate suppresses the mono sodium urate crystal induced up-regulation of IL-1β in isolated murine macrophages and a rodent model of gouty inflammation. Clinical studies in gout patients with biologic agents that neutralize IL-1β have demonstrated that it is the trigger for gout flares and that blocking its action has an anti-flare effect. Thus, arhalofenate has two activities in the same molecule that are ideally suited to treat gout -- sUA lowering and suppressing the initiation of gout flares. Arhalofenate has completed all preclinical safety studies including the carcinogenicity studies with results that support continued development.

About Hyperuricemia and Gout

Gout is a chronic, progressive rheumatic disease, caused by an inflammatory response to uric acid crystals deposited in joints and soft tissues as a result of excess uric acid in the blood (hyperuricemia). Elevated sUA levels cause urate crystals to form in joints triggering acute arthritic flares, chronic destructive arthropathy and formation of tophi. According to the NHANES (2007-2008) study, the incidence of hyperuricemia in the US is over 45 million and over 8 million have progressed to a gout diagnosis.

About CymaBay

CymaBay Therapeutics is a clinical-stage biopharmaceutical company developing therapies addressing unmet medical needs. Arhalofenate, the company's lead product candidate, has shown two therapeutic actions in a single drug. In gout patients, arhalofenate is intended to prevent painful attacks in joints while at the same time promoting excretion of sUA by the kidney, thereby addressing the hyperuricemia that is the root cause of gout. The company has two other product candidates -- MBX-8025 and MBX-2982. MBX-8025 is a potent, selective, orally active PPAR-δ agonist. A Phase 2 study of MBX-8025 in patients with mixed dyslipidemia has established that it has a strong anti-atherogenic lipid profile that may be useful in the treatment of a wide variety of indications currently under evaluation. MBX-2982 is a GPR-119 agonist that lowers glucose in patients with type 2 diabetes.

This press release contains "forward-looking" statements, including, without limitation, statements related to development plans, the timing of planned clinical trials and result. Any statements contained in this press release that are not statements of historical fact may be deemed to be forward-looking statements. Words such as "planned," "will," "may," "expect," and similar expressions are intended to identify these forward-looking statements. These forward-looking statements are based on CymaBay's current expectations and inherently involve significant 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 these risks and uncertainties, which include, without limitation, the availability of resources to develop CymaBay's product candidates, CymaBay's need for additional capital in the future to sufficiently fund CymaBay's operations and research, the uncertain timing of completion of

and the success of clinical trials, market competition, as well as other risks detailed from time to time in CymaBay's reports filed with the Securities and Exchange Commission, including its Quarterly Report on Form 10-Q for the quarter ended September 30, 2013. CymaBay does not undertake any obligation to update forward-looking statements and expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein.

For additional information about CymaBay visitwww.cymabay.com.

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