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CymaBay Therapeutics Announces Acceptance of Arhalofenate Phase 2b Gout Study Manuscript in Arthritis and Rheumatology

Accompanying Editorial Cites Need for Novel Therapies to Reduce Gout Flares

NEWARK, Calif., March 28, 2016 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), today announced the online publication of its Phase 2b study of arhalofenate, a novel dual-acting product candidate for the treatment of gout, in *Arthritis and Rheumatology,* an official journal of the American College of Rheumatology. The study, "A Randomized, Double-Blind, Active- and Placebo-Controlled Efficacy and Safety Study of Arhalofenate for Reducing Flare in Patients with Gout", demonstrated the positive effects of treatment with arhalofenate at reducing gout flares and lowering serum uric acid (sUA). The study publication has been accepted for an upcoming print issue of the journal *Arthritis and Rheumatology*, and is accompanied by an editorial describing the need for novel agents such as arhalofenate for the treatment of gout.

Results of the phase 2b clinical study in patients with gout demonstrate that arhalofenate reduces flares in patients with gout. Arhalofenate is the first compound in a new class of investigational therapies that CymaBay refers to as Urate Lowering Anti-Flare Therapy (ULAFT). A summary of the topline results from the Phase 2b study were previously announced by CymaBay in February 2015 and presented at the American College of Rheumatology conference in November 2015.

In an editorial accompanying the publication, Tuhini Neogi, M.D., Ph.D. (Boston University School of Medicine) and Hyon Choi, M.D., Dr. P.H. (Massachusetts General Hospital, Harvard Medical School), described the need for novel new agents to reduce gout flares, as well as the novel mechanism of arhalofenate, its sustained effects over a 24-hour period and its attractive safety profile. Drs. Neogi and Choi note that: "A single agent that can lower both serum urate and the risk of gout attacks…could provide a desirable multifaceted anti-gout option to address these major unmet needs."

They continue, "[This] Phase 2 randomized trial of arhalofenate provides promising results of a novel agent for gout that appears to tackle at least two key aspects of gout management in a single drug: lowering serum urate and providing flare prophylaxis, with the potential for a new class of drug that could be coined "ULAFT": urate-lowering, anti-flare therapy. Results from well-conducted Phase 3 trials are awaited to see how this drug will fit into the relatively small existing gout care armamentarium." The authors also noted the "absence of any potentially concerning safety signal" for arhalofenate.

Following end of Phase 2 discussions with the Food and Drug Administration (FDA) last

year, CymaBay is in ongoing discussions with potential partners with the intended goal of signing a partnership agreement that would enable the initiation of Phase 3 development for arhalofenate.

"Our development of arhalofenate meets a serious medical need for the approximately eight million people in the U.S. who suffer from gout. We estimate that more than 3 million of these patients are currently taking urate lowering therapies (ULT), the majority of whom are inadequately responding or experiencing gout flares," said Harold Van Wart, Chief Executive Officer of CymaBay. "This important publication and the accompanying editorial reinforce the significance of arhalofenate as the first of a new class of investigational agents that both lowers serum uric acid and reduces flares."

Phase 2b Results Overview

The 12-week randomized, double-blind, controlled, study evaluated gout patients who had experienced three or more flares in the previous twelve months. Patients (n=239) were randomized to daily arhalofenate 600 or 800 mg, allopurinol 300 mg, allopurinol 300 mg plus 0.6 mg colchicine or placebo. The study met its primary endpoint and showed a significant reduction of 46 percent in the flare rate for the arhalofenate 800 mg group compared to the allopurinol 300 mg group (0.66 versus 1.24, p = 0.0056). Arhalofenate 800 mg was also significantly better than placebo (p = 0.049) and not significantly different from allopurinol plus colchicine (p = 0.091). In a secondary analysis, arhalofenate 800 mg showed a 41 percent lower flare rate than placebo (p = 0.049). The reductions in sUA for arhalofenate 600 and 800 mg at 12 weeks versus placebo were statistically significant (p = .021 and .0059, respectively), but did not result in a statistically significant number of patients reaching the goal of < 6 mg/dL.

The paper can be accessed online at http://onlinelibrary.wiley.com/doi/10.1002/art.39684/abstract and the editorial can be viewed here http://onlinelibrary.wiley.com/doi/10.1002/art.39687/abstract.

About Arhalofenate

Arhalofenate is an oral, once-daily dual-acting drug candidate for the treatment of gout that both lowers serum uric acid (sUA) and suppresses flares. It is the first compound in a new class of investigational gout therapy that CymaBay refers to as Urate Lowering Anti-Flare Therapy (ULAFT).

Arhalofenate lowers sUA by blocking the reabsorption of uric acid in the proximal tubules of the kidney by inhibiting a renal uric acid transporter called URAT1. This leads to increased excretion of uric acid into the urine with concomitant lowering of sUA. Arhalofenate produces its uricosuric effect gradually and appears to have a favorable overall and renal safety profile in studies completed to date in over 1,100 patients. The sUA lowering of arhalofenate is complementary and additive to that produced by the xanthine oxidase inhibitor febuxostat, which works by blocking the production of uric acid. The anti-flare activity of arhalofenate is attributable to the suppression of the urate crystal-induced production of IL-1β in gouty joints.

Current treatment guidelines for gout recommend the use of urate lowering therapies (ULTs) to reverse hyperuricemia in order to remove deposits of pro-inflammatory urate crystals. The

minimal goal of this treatment is to reduce sUA levels to below 6 mg/dL. The goal for patients with a more advanced form of the disease called tophaceous gout is <5 mg/dL. Many patients treated with currently marketed xanthine oxidase inhibitors (allopurinol or febuxostat) alone do not reach these goals. In previous studies, arhalofenate in combination with febuxostat has been shown to significantly increase the number of patients achieving their sUA goals.

Paradoxically, the initiation of ULT triggers an increased risk of gout flares. The anti-inflammatory activity of arhalofenate has been shown in clinical studies to suppress flares, making it uniquely suited for the potential treatment of gout.

About CymaBay

CymaBay Therapeutics, Inc. (CBAY) is a clinical-stage biopharmaceutical company developing therapies to treat metabolic diseases with high unmet medical need, including serious rare and orphan disorders. Arhalofenate is a potential Urate-Lowering Anti-Flare Therapy that has completed five Phase 2 studies in gout patients. Arhalofenate has been found to reduce painful flares in joints while at the same time promoting excretion of uric acid by the kidney. This dual action addresses both the signs and symptoms of gout while managing the underlying pathophysiology of hyperuricemia. MBX-8025, CymaBay's other product candidate, is a potent, selective, orally active PPARδ agonist. A Phase 2 study of MBX-8025 in patients with mixed dyslipidemia established that it has an anti-atherogenic lipid profile. CymaBay has completed a pilot Phase 2 study of MBX-8025 in patients with homozygous familial hypercholesterolemia and has an ongoing Phase 2 study in patients with primary biliary cholangitis.

Cautionary Statements

The statements in this press release, including those statements regarding the potential of arhalofenate to treat gout, the therapeutic and commercial potential of arhalofenate, the timing of any Phase 3 study of arhalofenate and the anticipated development timing, therapeutic and commercial potential of other product candidates of CymaBay Therapeutics, Inc. are forward looking statements that are subject to risks and uncertainties. Actual results and the timing of events regarding the further development of arhalofenate and other product candidates of CymaBay 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, costs and timing of any Phase 3 study of arhalofenate or identification of a suitable partner for any planned Phase 3 study of arhalofenate, the success, cost and timing of any of CymaBay's other product development activities; any delays or inability to obtain or maintain regulatory approval of CymaBay's product candidates in the United States or worldwide; the ability of CymaBay to attract funding partners or collaborators with development, regulatory and commercialization expertise; 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, including for arhalofenate; and the market potential for CymaBay's product candidates. Additional risks relating to CymaBay are contained in CymaBay's most recent Quarterly Report on Form 10-Q, filed with 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.

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