

November 5, 2015



CymaBay Therapeutics to Present Results From Two Arhalofenate Phase 2 Studies at the American College of Rheumatology (ACR) Annual Meeting, November 6 - 11

Phase 2 Flare Study Results Demonstrate that Arhalofenate Reduces Flares while Lowering Serum Uric Acid in Gout Patients

Phase 2 Combination Study Results of Arhalofenate-Febuxostat (Uloric™) Revealed Complimentary Actions Enabling Gout Patients to Achieve Their Target Serum Uric Acid Goal

NEWARK, Calif., Nov. 5, 2015 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (NASDAQ:CBAY), a clinical-stage biopharmaceutical company developing therapies to treat metabolic diseases with high unmet medical need, today announced that the results from two Phase 2 studies of arhalofenate will be presented at the American College of Rheumatology Annual Meeting, being held November 6-11, in San Francisco, California.

Date/Time: Monday, November 9, 5:15pm - 5:30pm Pacific Time

Oral

Presentation: "A Study to Evaluate the Efficacy and Safety of Arhalofenate for Preventing Flares and Reducing Serum Uric Acid in Gout Patients"

Session

Type: ACR Concurrent Abstract Session

Abstract: 2111

Authors: Alexandra Steinberg¹, Harinder Chera¹, Yun-Jung Choi¹, Robert Martin¹, Charles McWherter¹, Yunbin Zhang², Pol Boudes¹ on behalf of the Arhalofenate Anti-Flare Therapy Study Group,

¹Cymabay Therapeutics, Newark, CA,

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This was a double-blind, placebo controlled phase 2b (NCT02063997) study which enrolled 239 subjects with gout, hyperuricemia and a history of flares. Patients were assigned (1:2:2:2:2) to treatments with placebo, arhalofenate 600 or 800 mg, allopurinol 300 mg or allopurinol 300 mg administered with colchicine 0.6 mg. The primary efficacy endpoint, a comparison of flare rates between the arhalofenate 800 mg and allopurinol 300 mg groups, was met with arhalofenate showing a 46% reduction ($p = .0056$) in flare rate. Additional key outcomes included a 41% lower flare rate for the arhalofenate 800 mg group compared to placebo ($p = .049$) and reductions in sUA for the arhalofenate 600 and 800 mg groups at 12 weeks vs. placebo that were statistically significant ($p = .021$ and $.0059$, respectively). Arhalofenate was well tolerated and appeared safe.

Date/Time: Tuesday, November 10, 9:00am - 11:00am Pacific Time

Poster
Presentation: "A Study to Evaluate the Pharmacodynamics, Pharmacokinetics and Safety of Arhalofenate in Combination with Febuxostat When Treating Hyperuricemia Associated with Gout"

Session Type: ACR Poster Session C

Abstract: 2351

Authors: Alexandra Steinberg, Yun-Jung Choi, Robert Martin, Charles McWherter and Pol Boudes, CymaBay Therapeutics, Newark, CA

This was a single-center, open label phase 2 (NCT02252835) study that enrolled two cohorts of gout patients with hyperuricemia (mean sUA of 9.4 and 9.2 mg/dL; $n = 16$ each). Cohorts were administered arhalofenate 600 or 800 mg as monotherapy, followed by combination with febuxostat (40 and 80 mg), and finally by febuxostat as monotherapy. The combination of febuxostat (Uloric™) and arhalofenate demonstrated a potent serum uric acid (sUA) lowering activity. For the highest dose combination (arhalofenate 800 mg with febuxostat 80 mg), a 63% reduction from baseline in sUA was observed resulting in 100 and 79% of patients achieving a sUA < 5 and < 4 mg/dL, respectively. There was no significant pharmacodynamic interaction between arhalofenate and febuxostat. The combination of arhalofenate and febuxostat was well tolerated and appeared safe.

About Arhalofenate

Arhalofenate is an oral, once-daily dual-acting drug candidate for the treatment of gout. It lowers serum uric acid (sUA) through a uricosuric effect and also has an anti-inflammatory activity that suppresses flares. It is the first compound in a new class of gout therapy that we refer 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 a renal uric acid transporter called URAT1. This leads to the excretion of uric acid into the urine. The sUA lowering produced by arhalofenate's uricosuric activity 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-1 β 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. Many patients treated with currently marketed xanthine oxidase inhibitors (allopurinol or febuxostat) alone do not reach their sUA goal. In previously published 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 for the first six months or more. The anti-inflammatory activity of arhalofenate has been shown in clinical studies to suppress flares, making it uniquely suited for the treatment of gout.

About the American College of Rheumatology

The American College of Rheumatology is an ethically-driven, professional membership organization committed to improving the care of patients with rheumatic disease and advancing the rheumatology subspecialty. Founded in 1934, it is a not-for-profit, global medical society that serves over 9,500 physicians, health professionals and scientists worldwide. See more at: <http://www.rheumatology.org/about-us>.

About CymaBay

CymaBay Therapeutics, Inc. (NASDAQ: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, CymaBay's lead product candidate, has shown two therapeutic actions in a single drug in multiple Phase 2 gout studies. In gout patients, arhalofenate is intended to prevent painful flares in joints while at the same time promoting excretion of uric acid by the kidney, thereby addressing both the signs and symptoms of gout and the hyperuricemia that is the root cause of the disease. CymaBay's second product candidate, MBX-8025 is a potent, selective, orally active PPAR δ agonist. A Phase 2 study of MBX-8025 in patients with mixed dyslipidemia established that it has an anti-atherogenic lipid profile. CymaBay has initiated a pilot study of MBX-8025 in patients with homozygous familial hypercholesterolemia.

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 and the anticipated timing and 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 possibility that subsequent analyses of the data disclosed above may lead to different (including less favorable) interpretations of the results than the analyses conducted to date or may identify important implications of the Phase 2 study that are not reflected in these statements, or be subject to differing interpretations by any regulatory agency; the success, cost and timing of any of CymaBay's 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; and the market potential for CymaBay's product candidates. Additional risks relating to CymaBay are contained in CymaBay's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on May 11, 2015. 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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