CymaBay Therapeutics Presents Poster at EULAR 2015

Phase 2 Data Show That Arhalofenate Has the Potential to Be Used in Combination With Febuxostat to Provide Clinically Meaningful Lowering of Serum Uric Acid in Patients With Gout

NEWARK, CA -- (Marketwired) -- 06/12/15 -- CymaBay Therapeutics, Inc.(NASDAQ: CBAY), a clinical-stage biopharmaceutical company developing therapies to treat metabolic diseases with high unmet medical need, today announced that data from its Phase 2 clinical study of arhalofenate in combination with febuxostat were presented today at the Annual European Congress of Rheumatology (EULAR 2015) in Rome, Italy. The data show that the combination was very effective in decreasing serum uric acid (sUA), which is one of the main treatment goals in the management of gout patients. Arhalofenate treatment also reversed low Fractional Excretion of Uric Acid (FEUA), a common characteristic of gout, into the normal range.

Arhalofenate is an oral, once-daily dual-acting drug candidate for the treatment of gout. It lowers serum uric acid by 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). Preliminary data from this Phase 2 trial were announced by Cymabay in January 2015.

Current treatment guidelines for gout recommend the use of urate lowering drugs 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. Reducing sUA values to below 5 or 4 mg/dL is particularly desirable for patients with advanced disease in order to eliminate urate deposits (known as tophi) within a practical timeframe. Many patients treated with currently marketed xanthine oxidase inhibitors (allopurinol or febuxostat) alone do not reach these goals.

Arhalofenate works 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 (uricosuria) and provides additional sUA lowering when used in combination with xanthine oxidase inhibitors.

Arhalofenate is currently in development as a monotherapy and in combination therapy for the treatment of gout. The potent uric acid lowering activity of arhalofenate, as well as its demonstrated anti-flare effect in gout patients will serve as the basis to design the upcoming Phase 3 program

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

**Abstract:** FRI0329

**Authors:** A. Steinberg, B. Vince, Y.-J. Choi, R. Martin, C. McWerther, P. Boudes

**Date/Time:** Friday, June 12, 2015 at 12:00 pm CET

This was an open label Phase 2 study (NCT02252835) at a single center with two cohorts of gout patients (n = 16 each). The results demonstrated the potent uric acid lowering activity of arhalofenate when combined with febuxostat (Uloric). The combination of febuxostat with arhalofenate was well tolerated, appeared safe and was more efficacious in decreasing sUA than febuxostat alone. On arhalofenate alone, sUA slowly decreased over 2 weeks with small intraday variations in both sUA and FEUA. Low FEUA, a common characteristic of gout, was restored toward normal levels. These data are consistent with the long half-life of arhalofenate (~50 hours).

**Publication:** Evaluation of creatine kinase in gout subjects. A systematic evaluation.

**Abstract:** AB0929

**Authors:** Y.-J. Cho, A. Steinberg, P. Boudes

This analysis consisted of a systematic evaluation of creatine phosphokinase (CK) levels in subjects with gout compared to subjects with type 2 diabetes. These data were collected during the screening period of the large Phase 2 arhalofenate program. The results showed that a clinically significant proportion of gout patients screened
for the Phase 2 program had abnormally elevated CK. Abnormally elevated CK in a gout subject could be due to concomitant medications frequently prescribed in this group (such as colchicine or statins) or recreational (exercise-induced). The possibility that CK elevation could be due to tendinous/muscular deposition of uric acid, while suggested by some case-reports in the literature, remains a hypothesis that needs to be further tested. By performing this analysis, CymaBay is proud to contribute to the scientific dialogue within the medical community.

About EULAR

The European League Against Rheumatism, EULAR, was founded in 1947 as the umbrella organization representing the patient, health professional and scientific societies for rheumatology across the European Union (EU). The 2015 EULAR Annual European Congress of Rheumatology is taking place at the Fiera Roma, in Rome, and is set to be the biggest rheumatology event in Europe with around 14,000 scientists, physicians, allied health professionals and related audiences in attendance from more than 120 countries. The aim of the EULAR Annual Congress is to provide a forum of the highest standard for scientific (both clinical and basic), educational and social exchange between professionals involved in rheumatology, to liaise with patient organizations, in order to achieve progress in the clinical care of patients with rheumatic diseases. For more information go to http://www.congress.eular.org.

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 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 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 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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