January 3, 2017

# CymaBay Announces Exclusive Licensing Agreement with Kowa Pharmaceuticals America, Inc. for the Development and Commercialization of Arhalofenate in the United States

**— Kowa to fully fund development through NDA approval**
**— CymaBay to receive up to $205M in up-front and milestone payments**
**— Conference call and webcast today at 4:30 pm ET**

NEWARK, Calif., Jan. 03, 2017 (GLOBE NEWSWIRE) -- CymaBay Therapeutics, Inc. (Nasdaq:CBAY), a clinical-stage biopharmaceutical company developing therapies to treat specialty and orphan diseases with high unmet medical need, today announced that it has entered into an exclusive license agreement with Kowa Pharmaceuticals America, Inc. for the development and commercialization of arhalofenate in the United States (U.S.).

Under the terms of the agreement, CymaBay will receive up to $15 million in upfront and near-term milestone payments and is eligible to receive up to an additional $190 million in payments based upon the achievement of specific development, regulatory and sales milestones. CymaBay is also eligible to receive tiered, double digit royalties on future sales of arhalofenate products. Kowa will be responsible for all development and commercialization costs. CymaBay had earlier reached agreement with the Food and Drug Administration (FDA) on the size and scope of the Phase 3 program which is estimated to cost $100 million. CymaBay retains full development and commercialization rights for the rest of the world. Locust Walk served as a transaction advisor to CymaBay.

Kowa Pharmaceuticals America, Inc., a US subsidiary of Kowa Company, Ltd., a privately held, multinational company based in Japan, markets cardiometabolic drugs including LIVALO® (pitavastatin) and Lipofen® (fenofibrate capsules, USP) in the U.S. The company focuses its efforts on the successful commercialization of its current and near term portfolio of pharmaceutical products with an established and growing primary care sales force in the U.S.

“We are extremely pleased to enter into this agreement with Kowa to develop and market arhalofenate in the U.S. Kowa has proven development capabilities as well as the resources to carry out a large Phase 3 development program. They also have an established primary care sales force to market arhalofenate products. As arhalofenate is a potential novel therapy for gout, a disease most often treated by primary care physicians,

it is a very good fit with Kowa's established strength in this area," said Harold Van Wart, Ph.D., President and CEO of CymaBay. "Identifying a partner to complete the Phase 3 development and commercialization of arhalofenate has been a key part of CymaBay's strategy. It enables us to advance arhalofenate to the market while allowing us to focus our internal resources on the rest of our pipeline which addresses serious and rare disorders."

Arhalofenate is an oral, once-daily dual-acting drug candidate for the treatment of gout. In an extensive Phase 2 clinical program in patients with gout, arhalofenate has been shown to decrease serum uric acid while also suppressing gout flares. It is the first compound in a new class of gout therapy that CymaBay refers to as Urate Lowering Anti-Flare Therapy (ULAFT). Arhalofenate is being developed as a combination product with febuxostat. CymaBay has completed end-of-Phase 2 discussions with the FDA and has come to agreement on a Phase 3 program that would provide a very competitive label that can capture the unique dual actions of arhalofenate.

**Conference Call and Webcast**

CymaBay management will host a conference call and webcast today, January 3, 2017 at 4:30 p.m. ET to discuss this licensing agreement and provide a corporate update on the company's strategy. To access the live conference call, please dial (877) 407-0784 from the U.S. and Canada, or (201) 689-8560 internationally. To access the live and subsequently archived webcast of the conference call, go to the Investors section of the company's website at http://ir.cymabay.com/events. A replay of the webcast will be available on the Company's website for 14 days following the live event.

**About CymaBay**

CymaBay Therapeutics, Inc. (CBAY) is a clinical-stage biopharmaceutical company developing therapies to treat specialty and orphan diseases with high unmet medical need. Seladelpar is a potent, selective, orally active PPARδ agonist. CymaBay has recently completed a Phase 2 study of seladelpar in patients with primary biliary cholangitis as well as a pilot Phase 2 study in patients with homozygous familial hypercholesterolemia, establishing proof-of-concept in both indications. Previously, a Phase 2 study of seladelpar in patients with mixed dyslipidemia established that it has an anti-atherogenic lipid profile. 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. Arhalofenate has been licensed to Kowa Pharmaceuticals America, Inc. in the U.S. CymaBay retains full development and commercialization rights for arhalofenate outside the U.S.

**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 gout therapy that CymaBay refers to as Urate Lowering Anti-Flare Therapy (ULAFT). Arhalofenate increases the excretion of uric acid into urine resulting in a

decrease in sUA levels. This is accomplished by its inhibition of the urate transporter URAT1 in the proximal tubules of the kidney. 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. In a Phase 2 study of arhalofenate in combination with the xanthine oxidase inhibitor febuxostat, which works by blocking the production of uric acid, the sUA lowering activity of arhalofenate was complementary and additive to that of febuxostat. The anti-flare activity of arhalofenate is attributable to its suppression of the urate crystal-induced production of IL-1β in gouty joints. The goal of the Phase 3 program is to study the combination of arhalofenate and febuxostat to confirm the urate lowering and anti-flare activity.

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 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.

**Cautionary Statements**

The statements in this press release regarding the potential future performance of CymaBay's product candidates are forward looking statements that are subject to risks and uncertainties. Actual results and the timing of events regarding the further development of CymaBay's product candidates, including but not limited to the expected Phase 3 trial of Arhalofenate and the anticipated resulting label, 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 of seladelpar and arhalofenate; effects observed in trials to date which 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 Quarterly Report on Form 10-Q 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](http://www.cymabay.com).

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