May 19, 2011

Metabolex Initiates Phase 2 Trial of Arhalofenate

Potential Best-in-Class Uricosuric Agent for the Treatment of Gout

HAYWARD, Calif., May 19, 2011 /PRNewswire/ -- Metabolex, Inc., a biopharmaceutical company focused on the discovery and development of proprietary new medicines for the treatment of metabolic diseases, announced today that it has initiated a Phase 2 clinical trial of arhalofenate (MBX-102), its product candidate for the management of hyperuricemia in patients with gout.

This randomized, double-blind, placebo-controlled study will evaluate the safety and urate-lowering activity of 400 and 600 mg of arhalofenate in 60 patients with hyperuricemia and a diagnosis of gout. The primary endpoint of the study is the percent reduction in serum uric acid levels from baseline following four weeks of treatment. As part of its broader Phase 2 program, Metabolex will also be initiating a combination study with allopurinol in patients refractory to allopurinol and a combination study with febuxostat (Uloric®, Takeda Pharmaceutical Company Limited; Adenuric®, Ipsen and Menarini).

Arhalofenate is a novel, orally administered, small molecule uricosuric agent that was previously under development by Metabolex for Type 2 diabetes. Arhalofenate has completed eight Phase 1 and four Phase 2 studies which demonstrate that it has excellent safety and tolerability in more than 550 patients for up to six months of treatment. During this development program, it was observed that once daily dosing with arhalofenate not only lowers glucose and triglycerides, but also results in robust, dose-dependent reductions in serum uric acid through its uricosuric activity. The uric acid reductions were fully retained in patients with mild-to-moderate renal insufficiency. Thus, arhalofenate is a potential best-in-class uricosuric agent that not only corrects the hyperuricemia associated with gout, but also addresses other aspects of metabolic syndrome seen in patients with gout.

"We are excited about initiating our gout trials. Our Phase 2 program is designed to show that arhalofenate has a broad clinical profile for the treatment of hyperuricemia and gout including first-line use and, for patients not reaching treatment goals, in combination with allopurinol or febuxostat," said Harold Van Wart, President and CEO of Metabolex. "Advancing the development of arhalofenate has the potential to significantly improve the lives of patients suffering from gout."

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 eight million have progressed to a gout diagnosis.

About Metabolex

Metabolex is a privately-held biopharmaceutical company focused on the discovery and development of proprietary new medicines for the treatment of metabolic diseases. The company has three clinical-stage compounds: Arhalofenate, which has completed four Phase 2 trials and is currently enrolling patients in a Phase 2 trial for gout; MBX-2982, which has recently completed a Phase 2a trial in Type 2 diabetics; and MBX-8025, which has completed a Phase 2 trial in patients with dyslipidemia.

For additional information about Metabolex and its development pipeline, visit www.metabolex.com.

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