



Tioga Pharmaceuticals Receives Special Protocol Assessment Agreement from FDA for Phase 3 Trials of Asimadoline in Irritable Bowel Syndrome

SAN DIEGO, Calif. – April 5, 2010 – Tioga Pharmaceuticals, Inc. announced today that the company has reached agreement with the U.S. Food and Drug Administration (FDA) on Special Protocol Assessments (SPAs) for the Phase 3 efficacy protocols for its product candidate, asimadoline, for the treatment of patients with diarrhea-predominant irritable bowel syndrome (D-IBS). The SPAs represent agreement with FDA on the design, execution and analysis of the two planned Phase 3 trials required for product registration. Tioga and FDA agreed upon the patient population to study; dosage; primary and secondary endpoints and their analyses; inclusion and exclusion criteria; study duration; and evaluations to be performed during the studies, among other items.

“We are very pleased with the agreement reached with FDA for the SPAs and believe it represents a significant step forward for both Tioga as well as the field of IBS,” said Allen Mangel, M.D., Ph.D., consulting Chief Medical Officer for Tioga.

Currently there is only one drug approved in the U.S. for D-IBS patients, but due to safety concerns its use is restricted to female patients with severe cases and it is administered under a risk management program. Tioga’s goal is to develop a safe and effective therapy for the nine million patients suffering from this condition in the U.S.

Tioga plans to initiate the first of two registration trials required for U.S. approval later this month at 120 sites in the U.S. Each trial will be a 600-subject, randomized, double-blind, placebo-controlled, single-dose clinical study to evaluate the safety and efficacy of asimadoline for the treatment of patients with D-IBS.

About Special Protocol Assessments

An SPA is a binding written agreement between the sponsor and the FDA on the design, execution and analysis for a clinical trial that is to form the basis of a new drug application. Final marketing approval depends on the results of efficacy, safety profile, and an evaluation of the risk/benefit of treatment in the Phase 3 program.

About Asimadoline

Asimadoline is an orally administered small molecule that is a highly selective, peripherally restricted, kappa opioid receptor agonist. In a 596-subject Phase 2b clinical trial asimadoline demonstrated statistically significant results in the treatment of D-IBS patients with at least moderate pain across multiple parameters including endpoints of pain, urgency, frequency and bloating in both males and females. A therapeutic benefit was observed within the first month of treatment and was sustained for the three month duration of the trial. Asimadoline appeared to be well tolerated with no adverse events occurring in a dose-dependent manner throughout the randomized, double-blind, placebo-controlled, dose-ranging clinical trial.

About Tioga Pharmaceuticals

Tioga Pharmaceuticals, Inc. is a pharmaceutical company headquartered in San Diego, CA focused on developing novel treatments for gastrointestinal diseases. For more information, please visit www.tiogapharma.com.

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