



Tioga Pharmaceuticals Begins Phase 3 Trial of Asimadoline in Irritable Bowel Syndrome

SAN DIEGO, Calif. – June 3, 2010 – Tioga Pharmaceuticals, Inc. announced today that the company has dosed its first subject in a Phase 3 clinical trial to evaluate asimadoline for the treatment of patients with diarrhea-predominant irritable bowel syndrome (D-IBS). The trial, referred to as ASMP3001, is the first of two Phase 3 trials being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) for U.S. registration. This first trial will be conducted at 120 sites in the U.S.

ASMP3001 will enroll 600 D-IBS patients to evaluate the safety and efficacy of twice daily treatment of 0.5 milligrams of asimadoline or placebo. The primary endpoint of the randomized, double-blind clinical study is a responder analysis measuring pain relief and improved motility. The secondary endpoints of ASMP3001 include additional measurements of abdominal pain, stool frequency, urgency and stool consistency. The trial protocol, as designed under the SPA, is consistent with FDA's recent Guidance for Clinical Evaluation of IBS Products.

“In the Phase 2b study, asimadoline was shown to significantly improve both pain and abnormal motility in D-IBS patients with at least moderate pain,” said Allen Mangel, M.D., Ph.D., consulting Chief Medical Officer for Tioga Pharmaceuticals. “The millions of patients suffering from this condition in the U.S. have very limited therapeutic options, illustrating a high unmet medical need Tioga is seeking to address.”

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 patients with severe cases and it is administered under a risk management program.

For information about Tioga Pharmaceuticals' Phase 3 asimadoline in D-IBS trial, visit www.clinicaltrials.gov and use the search term “Tioga.”

About Irritable Bowel Syndrome

Irritable bowel syndrome (IBS) is a common, chronic gastrointestinal disorder characterized by recurrent episodes of abdominal pain or discomfort associated with a change in bowel pattern, such as loose or more frequent bowel movements, diarrhea and/or constipation. While the exact etiology of IBS is unknown, it is believed to be due to a disturbance in the interaction between the intestines, the brain and the autonomic nervous system that alters regulation of bowel motility or sensory function. IBS patients fall into different subtypes based on their predominant symptoms: IBS with diarrhea (D-IBS), IBS with constipation (C-IBS) and IBS with alternating diarrhea and constipation (A-IBS). IBS afflicts an estimated 60 million patients in the U.S. and Europe, with roughly equal prevalence of each subtype, and it is the most common diagnosis made by gastroenterologists.

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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