



Tioga Pharmaceuticals' Asimadoline Demonstrates Positive Results in a Phase 2b Clinical Trial for the Treatment of Irritable Bowel Syndrome

Statistically Significant Reduction of IBS Pain and Normalizing Motility Effect Observed

SAN DIEGO, Calif., May 20, 2008 /PRNewswire – Tioga Pharmaceuticals, Inc. today announced the results of a recent Phase 2b study of its oral kappa opioid receptor agonist, asimadoline, which demonstrated statistically significant results in the treatment of Irritable Bowel Syndrome (IBS). Asimadoline produced significant improvement in diarrhea-predominant (D-IBS) and alternating (A-IBS) patients across multiple parameters including the primary endpoint of pain, as well as secondary endpoints of urgency, frequency and bloating in both males and females. In D-IBS patients, 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 involving 596 subjects. These data were featured today in a late-breaking oral presentation session at the Digestive Disease Week 2008 Annual Meeting.

Study Results

Of the 596 patients randomized in the trial, approximately 33 percent were characterized as D-IBS, 37 percent constipation predominant (C-IBS) and 31 percent alternating between diarrhea and constipation (A-IBS).

- In the overall patient group, patients with at least moderate pain achieved a 17 percent improvement in percent number of months with adequate relief of IBS pain compared to placebo (40 percent vs. 23 percent) with both the 0.5 mg (p=0.006) and the 1.0 mg (p=0.005) dose of asimadoline.
 - Evaluation by IBS subtype revealed benefit in D-IBS and A-IBS patients.
 - Benefit in C-IBS patients was not observed.
 - The rate of adverse events was similar in asimadoline and placebo treated subjects.

- Patients with D-IBS with at least moderate pain achieved a 27 percent improvement in the percent number of months with adequate relief of IBS pain compared to placebo (47 percent vs. 20 percent, p=0.011) with the 0.5mg dose of asimadoline.
 - A 25 percent increase in pain free days was seen with 0.5 mg asimadoline as compared with placebo (p=0.001) during the 12-week dosing period. This represents an increase of approximately 20 pain free days over that seen with placebo.
 - Statistically significant (p<0.05) improvement in pain was seen by week three and persisted for the duration of treatment.
 - Statistically significant improvements were also seen in D-IBS patients receiving the 0.5 mg dose of asimadoline in all of the following secondary endpoints: urgency, adequate relief of IBS symptoms, stool frequency, bloating and daily pain. Statistically significant improvement was also seen in urgency, adequate relief of IBS symptoms, bloating and daily pain in patients receiving the 1.0 mg dose.
 - Benefit was seen in female and male patients.

- Patients with A-IBS with at least moderate pain achieved a 23 percent improvement in the percent number of months with adequate relief of IBS pain compared to placebo (50 percent vs. 27 percent, $p=0.022$) with a 1.0 mg dose of asimadoline.
 - Statistically significant benefit was also seen in the secondary endpoint of adequate relief of IBS symptoms in patients receiving the 1.0 mg dose of asimadoline compared to placebo (57 percent vs. 33 percent, $p=0.032$).
 - Benefit was seen in female and male patients.

Study Design

D-IBS, C-IBS, and A-IBS patients were recruited. Patients underwent a two-week screening, a 12-week treatment and a four-week follow-up period, and they received identical appearing placebo, 0.15 mg, 0.5 mg or 1.0 mg tablets of asimadoline twice daily for the treatment period. Throughout the trial, patients entered data daily by IVRS (interactive voice response system). The primary endpoint was number of months a patient was a responder for adequate relief of pain, where the primary measure was the question, “In the past 7 days have you had adequate relief of your IBS pain or discomfort?” asked once every 7 days. A monthly responder replied “yes” at least three weeks per month. The secondary endpoints were abdominal pain, stool frequency and consistency, urgency, bloating, adequate relief of IBS symptoms and straining. Secondary endpoints were also collected using IVRS. Adverse events, labs and echocardiograms were also collected.

About Irritable Bowel Syndrome

Irritable bowel syndrome is a common, chronic gastrointestinal disorder characterized by abdominal pain and discomfort associated with alterations in bowel habits. The bowel abnormalities may manifest as diarrhea-predominant disease, constipation-predominant disease, or alternation between diarrhea and constipation. IBS is estimated to afflict approximately 12 percent of the adult population in the United States and Europe, with roughly equal prevalence of each subtype. For reasons that remain unknown, IBS is a female-predominant disorder, with two-thirds to three-quarters of the subjects being female.

Lotronex (alosetron), a selective 5-HT₃ receptor antagonist, is the only drug currently approved by the FDA for the treatment of D-IBS; however, due to safety concerns, Lotronex was removed from the market in 2001 and re-launched in 2002 under a strict risk management program. No treatment is currently approved by the FDA for A-IBS. There is, therefore, an urgent unmet clinical need for a safe and effective treatment for the 20 million Americans who suffer from D-IBS and A-IBS.

About Asimadoline

Asimadoline is an orally administered small molecule that is a highly selective kappa opioid receptor agonist. Kappa opioid receptors are found in the digestive tract and are believed to play an important role in control of visceral pain and bowel motility. Asimadoline was originally discovered by Merck KGaA of Darmstadt, Germany. In 2005, Tioga purchased asimadoline from Merck and acquired by assignment all worldwide rights. Asimadoline has been tested in over 1100 subjects and has demonstrated a promising safety profile.

About Tioga

Tioga Pharmaceuticals, Inc. is a pharmaceutical company headquartered in San Diego, CA focused on developing novel treatments for gastrointestinal diseases. Tioga is currently planning Phase 3 development of asimadoline for the treatment of D-IBS and A-IBS and a Phase 2b trial of asimadoline for the treatment of functional dyspepsia. Both disorders represent a large unmet medical need and a substantial market opportunity. For more information, please visit www.tiogapharma.com.

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