



## **FDA Grants Fast Track Designation to Tioga Pharmaceuticals' Asimadoline for the Treatment of Diarrhea-Predominant Irritable Bowel Syndrome**

SAN DIEGO, Calif. – June 1, 2011 – Tioga Pharmaceuticals, Inc. announced today that its investigational compound asimadoline has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of patients with diarrhea-predominant irritable bowel syndrome (D-IBS). Tioga is conducting a multi-center Phase 3 clinical trial evaluating asimadoline in D-IBS, conducted under a Special Protocol Assessment agreement with the FDA for U.S. registration.

The Fast Track program is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life threatening conditions and that demonstrate the potential to address unmet medical needs. New drug applications for products in the Fast Track program ordinarily are eligible for priority review.

“The FDA’s granting of Fast Track designation for asimadoline signals the agency recognizes that diarrhea-predominant irritable bowel syndrome is a serious illness and that patients lack a safe and effective therapy,” said Stuart Collinson, Ph.D., Chairman and CEO of Tioga Pharmaceuticals.

For information about Tioga Pharmaceuticals’ Phase 3 D-IBS trial, go to [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

### **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. Asimadoline has been tested in over 1,100 subjects to date and has a positive safety profile.

### **About Tioga Pharmaceuticals**

Tioga Pharmaceuticals, Inc. is a pharmaceutical company headquartered in San Diego, CA focused on developing novel treatments for gastrointestinal diseases. Tioga is developing asimadoline in Phase 3 clinical trials for the treatment of diarrhea-predominant irritable bowel syndrome (D-IBS). Ono Pharmaceutical Co, Ltd. licensed from Tioga exclusive rights to develop and commercialize asimadoline in Japan, where Phase 1 trials are currently underway, as well as South Korea and Taiwan. For more information about Tioga Pharmaceuticals, please visit [www.tiogapharma.com](http://www.tiogapharma.com).

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### **Contacts:**

David Urso  
Tioga Pharmaceuticals, Inc.  
Chief Operating Officer and General Counsel  
Phone: 858-964-5021  
Email: [urso@tiogapharma.com](mailto:urso@tiogapharma.com)

Pam Lord  
Canale Communications  
Phone: 619-849-6003  
Email: [pam@canalecomm.com](mailto:pam@canalecomm.com)