



## **Tioga Pharmaceuticals, Inc. and Ono Pharmaceutical Co. Announce Agreement to Develop and Commercialize Asimadoline in Japan**

SAN DIEGO, Calif. – September 1, 2009 – Tioga Pharmaceuticals, Inc. and Ono Pharmaceutical Co, Ltd. Osaka, Japan today announced an exclusive license agreement under which Ono has licensed rights to develop and commercialize asimadoline in Japan, South Korea and Taiwan. Tioga retains all other rights to asimadoline.

Under the terms of the agreement, Ono is responsible for developing and commercializing asimadoline in Japan, South Korea and Taiwan. Ono's initial development of asimadoline will focus on diarrhea predominant irritable bowel syndrome (D-IBS). Tioga will receive an upfront payment and development and commercial milestone payments. Ono will also pay Tioga a royalty on the sales of asimadoline in Japan, South Korea and Taiwan.

"We are delighted to collaborate with Ono Pharmaceutical to develop asimadoline in Japan, South Korea and Taiwan for the millions of patients suffering from D-IBS. There is a large medical need for a safe and effective therapy, and asimadoline has great promise for these patients and others around the world," said Stuart Collinson, Ph.D., Tioga's Chairman and CEO.

"We are pleased to gain rights to develop and commercialize asimadoline in Japan, South Korea and Taiwan from Tioga, a bio-pharmaceutical company focusing on developing novel treatments for gastrointestinal diseases. The medical needs of D-IBS patients currently are not well satisfied. Asimadoline is expected to provide features that are not offered by existing therapies as it has demonstrated efficacy particularly in abdominal pain and discomfort with good safety profiles in clinical testing to date. We will expeditiously promote the clinical development of asimadoline in Japan, and do our best to make the drug available for the D-IBS patients as quickly as possible," said Gyo Sagara, Ono's President, Representative Director and CEO.

Tioga plans to initiate Phase III development of asimadoline for D-IBS in the United States in the first quarter of 2010, and Ono plans to start Phase I studies in Japan during the first half of 2010. In a recent 596 subject placebo controlled Phase IIb trial, asimadoline demonstrated a clinically meaningful and statistically significant treatment effect on multiple D-IBS symptoms, including abdominal pain, stool frequency, urgency and a global assessment of IBS symptoms in male and female D-IBS subjects experiencing moderate to severe baseline abdominal pain. Asimadoline was well tolerated with no adverse events occurring in a dose dependent manner.

### **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. In 2005, Tioga purchased asimadoline from Merck and acquired by assignment all worldwide rights. Asimadoline has been tested in over 1,100 subjects to date 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. For more information, please visit [www.tiogapharma.com](http://www.tiogapharma.com).

###

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