



Ironwood Pharmaceuticals to Present Linaclotide Data at Digestive Disease Week® 2016

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Ironwood Pharmaceuticals, Inc.](#) (NASDAQ: IRWD) today announced the presentation of linaclotide-related clinical and preclinical data from the company and its collaborators during Digestive Disease Week® (DDW) 2016 in San Diego, CA, May 21 through May 24, 2016.

The data will be presented via oral and poster presentations as follows:

Insights into GC-C Expression in IBS-C (Oral Presentation):

Guanylate Cyclase-C Expression Is Down-Regulated in Colonic Biopsies From Female Irritable Bowel Syndrome Patients With Constipation (session ID #366), by Stuart Brierley, Ph.D., Associate Professor and Head of the Visceral Pain Group, Discipline of Medicine at the University of Adelaide, et al., will be presented at the Diagnosis and Advances in Understanding and Management of IBS session taking place on Sunday, May 22, 2016, 2:36 p.m. to 2:48 p.m. Pacific Time, in Location 33 of the San Diego Convention Center.

Linaclotide Preclinical Data: Colon and Bladder Potentially Connected Pathways (Oral and Poster Presentations):

Chronic Oral Administration of the Guanylate Cyclase-C Agonist Linaclotide Attenuates Colitis Induced Bladder Afferent Hyperactivity (session ID #561), by Luke A. Grundy, Ph.D., Postdoctoral Fellow, University of Adelaide, et al., will be presented at the Receptors and Enteric Neurosciences session taking place on Monday, May 23, 2016, 8:15 a.m. to 8:30 a.m. Pacific Time, in Location 29 CD of the San Diego Convention Center.

Linaclotide Attenuates Visceral Organ CrossTalk: Importance of Guanylate Cyclase C (GC-C) Activation in Improving Colonic Hyperpermeability Induced by Protamine Sulfate Infusion Into the Bladder (poster ID #Mo1315), by Ehsan Mohammadi, B.Sc., Senior Research Associate, University of Oklahoma College of Medicine, et al., will be presented at the Probiotics/Novel Therapeutics in Intestinal Disease (III) session taking place on Monday, May 23, 2016, 9:30 a.m. to 4 p.m. Pacific Time, in Hall C of the San Diego Convention Center.

Clinical Data on Linaclotide in Patients with IBS-C from China and Japan (Poster Presentations):

Determining an Optimal Dose of Linaclotide in Use in Japanese Patients With Irritable Bowel Syndrome With Constipation: A Phase II Randomized, Double-Blind, Placebo-Controlled Study (poster ID #Mo1626), by Shin Fukudo, Ph.D., Professor and Director of Behavioral Medicine, Tohoku University, et al., will be presented at the IBS: Clinical session taking place on Monday, May 23, 2016, 9:30 a.m. to 4 p.m. Pacific Time, in Hall C of the San Diego Convention Center.

Efficacy and Safety of Linaclotide in Patients with IBS-C: Results from a Phase 3, Randomized, Double-blind, Placebo-controlled Trial in China and Other Regions (poster ID #Mo1646), by Yunsheng Yang, M.D., Ph.D., Professor, Department of Gastroenterology and Hepatology, Chinese PLA General Hospital, et al., will be presented at the IBS: Clinical session taking place on Monday, May 23, 2016, 9:30 a.m. to 4 p.m. Pacific Time, in Hall C of the San Diego Convention Center.

About Linaclotide

Linaclotide is a guanylate cyclase-C (GC-C) agonist that is thought to work in two ways based on nonclinical studies. Linaclotide binds to the GC-C receptor locally, within the intestinal epithelium. Activation of GC-C results in increased intestinal fluid secretion and accelerated transit and a decrease in the activity of pain-sensing nerves in the intestine. The clinical relevance of the effect on pain fibers, which is based on nonclinical studies, has not been established. Linaclotide is marketed by Ironwood and Allergan plc in the United States as LINZESS® and is indicated for the treatment of adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC), with more than 1 million unique patients in the U.S. having filled more than 4.5 million linaclotide prescriptions since launch, according to IMS Health. Linaclotide is marketed by Allergan for the treatment of adults with moderate to severe IBS-C in Europe under the brand name CONSTELLA®. Ironwood also has partnered with Astellas for development and commercialization of linaclotide in Japan and with AstraZeneca for development and commercialization in China.

About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is a commercial biotechnology company focused on creating medicines that make a difference for patients, building value for our fellow shareholders, and empowering our passionate team. We are advancing an innovative pipeline of medicines in multiple areas of significant unmet need, including irritable bowel syndrome with constipation (IBS-C)/chronic idiopathic constipation (CIC), vascular and fibrotic diseases, and refractory gastroesophageal reflux disease, among others. We discovered, developed and are commercializing linaclotide, the U.S. branded prescription market leader in the IBS-C/CIC category, and we are applying our proven R&D and commercial capabilities to advance multiple internally-developed and externally-accessed product opportunities. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. For more information, please visit www.ironwoodpharma.com or www.twitter.com/ironwoodpharma; information that may be important to investors will be routinely posted in both these locations.

LINZESS Important Safety Information

WARNING: PEDIATRIC RISK

LINZESS is contraindicated in pediatric patients under 6 years of age. In nonclinical studies, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths due to dehydration in young juvenile mice. Use of LINZESS should be avoided in pediatric patients 6 through 17 years of age. The safety and efficacy of LINZESS has not been established in pediatric patients under 18 years of age.

Contraindications

- | LINZESS is contraindicated in pediatric patients under 6 years of age.
- | LINZESS is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions

Pediatric Risk

- | LINZESS is contraindicated in children under 6 years of age. The safety and effectiveness of LINZESS in pediatric patients under 18 years of age have not been established. In neonatal mice, increased fluid secretion as a consequence of GC-C agonism resulted in mortality within the first 24 hours due to dehydration. Due to increased intestinal expression of GC-C, children under 6 years of age may be more likely than older children and adults to develop significant diarrhea and its potentially serious consequences.
- | Use of LINZESS should be avoided in pediatric patients 6 through 17 years of age. Although there were no deaths in older juvenile mice, given the deaths in young juvenile mice and the lack of clinical safety and efficacy data in pediatric patients, use of LINZESS should be avoided in pediatric patients 6 through 17 years of age.

Diarrhea

- | Diarrhea was the most common adverse reaction of LINZESS-treated patients in the pooled IBS-C and CIC double-blind placebo-controlled trials. Severe diarrhea was reported in 2% of LINZESS-treated patients. The incidence of diarrhea was similar in the IBS-C and CIC populations.
- | Patients should be instructed to stop LINZESS if severe diarrhea occurs and to contact their healthcare provider. The healthcare provider should consider dose suspension and rehydration.

Adverse Reactions

- | In IBS-C clinical trials, the most common adverse reactions in LINZESS-treated patients (incidence $\geq 2\%$ and greater than placebo) were diarrhea (20% vs 3% placebo), abdominal pain (7% vs 5%), flatulence (4% vs 2%), headache (4% vs 3%), viral gastroenteritis (3% vs 1%) and abdominal distension (2% vs 1%).
- | In CIC clinical trials, the most common adverse reactions in LINZESS-treated patients (incidence $\geq 2\%$ and greater than placebo) were diarrhea (16% vs 5% placebo), abdominal pain (7% vs 6%), flatulence (6% vs 5%), upper respiratory tract infection (5% vs 4%), sinusitis (3% vs 2%) and abdominal distension (3% vs 2%).

Please see full Prescribing Information including Boxed Warning: http://www.frx.com/pi/linzess_pi.pdf.

View source version on [businesswire.com](http://www.businesswire.com): <http://www.businesswire.com/news/home/20160517005213/en/>

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