



Ironwood Pharmaceuticals Presenting Linaclotide Data at the World Congress of Gastroenterology at ACG 2017

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Ironwood Pharmaceuticals, Inc.](#) (NASDAQ:IRWD), a commercial biotechnology company, today announced that the company and its collaborators are presenting clinical data for linaclotide at the World Congress of Gastroenterology (WCOG) at the American College of Gastroenterology (ACG), on October 13-18, 2017 in Orlando, Florida.

Linaclotide is a guanylate cyclase-C (GC-C) agonist that acts by a mechanism pioneered by Ironwood scientists. Linaclotide is marketed in the United States as LINZESS® and is the U.S. branded prescription market leader for adults with Chronic Idiopathic Constipation (CIC) or Irritable Bowel Syndrome with Constipation (IBS-C). It is also marketed in Japan as LINZESS for the treatment of adults with IBS-C, and in Europe as CONSTELLA® for the treatment of adults with moderate to severe IBS-C. Linaclotide delayed release-1 (DR1) is an investigational drug designed to provide targeted delivery of linaclotide to the distal small intestine and colon, where it is believed that the majority of the abdominal pain associated with IBS-C originates.

Researchers will present analyses of clinical data focusing on the safety and tolerability of linaclotide in the treatment of CIC and IBS-C, and on symptom improvement with linaclotide DR1 in IBS-C. An additional presentation will focus on the effect of stool consistency on bowel movement satisfaction with treatment of patients with IBS-C or CIC. The data will be presented via poster presentations as follows:

Bowel Movement Satisfaction in Patients with IBS-C or CIC:

- | *Impact of Stool Consistency on Bowel Movement Satisfaction in IBS-C or CIC Patients Treated With Linaclotide or Other Medications: Results From the CONTOR Study* (Abstract #P301), by Douglas C.A. Taylor, M.B.A., Director, Health Economics and Outcomes Research, Ironwood Pharmaceuticals, will be presented during a poster session on Sunday, October 15, 3:30 to 7:00 p.m.

Symptom Improvement with Linaclotide DR1 in IBS-C:

- | *Effect of Linaclotide DR1, a Delayed-Release Formulation of Linaclotide, in IBS-C Patients: Analysis of Symptom Improvement Using Responder Radar Plots* (Abstract #P1149), by William D. Chey, M.D., F.A.C.G. Professor of Medicine, Michigan Medicine, University of Michigan, Ann Arbor, Michigan, will be presented during a poster session on Monday, October 16, 10:30 a.m. to 4:00 p.m.

Pooled Analysis of Safety and Tolerability of Linaclotide for the Treatment of CIC and IBS-C:

- | *Safety and Tolerability of Linaclotide for the Treatment of CIC and IBS-C: A Pooled Analysis of Phase 3-3b Placebo-Controlled Trials in North America* (Abstract #P2020), by Judy Nee, M.D., Beth Israel Deaconess Medical Center, Boston, Massachusetts, will be presented during a poster session on Tuesday, October 17, 10:30 a.m. to 4:30 p.m.

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 commercializing two innovative primary care products: linaclotide, the U.S. branded prescription market leader for adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC), and lesinurad, which is approved for the treatment of hyperuricemia associated with gout in patients who have not achieved target serum uric acid (sUA) levels with a medically appropriate daily dose of a xanthine oxidase inhibitor (XOI) alone. We are also advancing a pipeline of internally and externally generated innovative product candidates in areas of significant unmet need, including uncontrolled gastroesophageal reflux disease and vascular and fibrotic diseases. 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.

About Linaclotide

Linaclotide is a guanylate cyclase-C (GC-C) agonist that binds to the GC-C receptor locally, within the intestinal epithelium, and is thought to work in two ways, based on nonclinical studies. Activation of GC-C results in increased intestinal fluid secretion and accelerated transit, as well as 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 greater than 1.5 million unique patients in the United States having filled more than 8 million linaclotide prescriptions since launch, according to QuintilesIMS. In Europe, Allergan markets linaclotide under the brand name CONSTELLA® for the treatment of adults with moderate to severe IBS-C. In Japan, Ironwood's partner Astellas markets linaclotide under the brand name LINZESS for the treatment of adults with IBS-C. Ironwood also has partnered with AstraZeneca for development and commercialization of linaclotide in China, Hong Kong and Macau, and with Allergan for development and commercialization of linaclotide in all other territories worldwide.

LINZESS INDICATIONS AND USAGE

LINZESS (linaclotide) is indicated in adults for the treatment of both irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC).

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

LINZESS is contraindicated in patients less than 6 years of age. In nonclinical studies in neonatal mice, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths due to dehydration. Use of LINZESS should be avoided in patients 6 years to less than 18 years of age. The safety and effectiveness of LINZESS has not been established in patients less than 18 years of age.

Contraindications

LINZESS is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.

LINZESS is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions

Pediatric Risk

LINZESS is contraindicated in patients less than 6 years of age. The safety and effectiveness of LINZESS in patients less than 18 years of age have not been established. In neonatal mice, linaclotide increased fluid secretion as a consequence of GC-C agonism resulting in mortality within the first 24 hours due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years of age and older to develop severe diarrhea and its potentially serious consequences.

Use of LINZESS should be avoided in pediatric patients 6 to less than 18 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 years to less than 18 years of age.

Diarrhea

Diarrhea was the most common adverse reaction in LINZESS-treated patients in the pooled IBS-C and CIC double-blind placebo-controlled trials. The incidence of diarrhea was similar in the IBS-C and CIC populations. Severe diarrhea was reported in 2% of 145 mcg and 290 mcg LINZESS-treated patients, and in < 1% of 72 mcg LINZESS-treated CIC patients. If severe diarrhea occurs, dosing should be suspended and the patient rehydrated.

Common Adverse Reactions (incidence ≥2% and greater than placebo)

In IBS-C clinical trials: 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 trials of a 145 mcg dose: 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%). In a CIC clinical trial of a 72 mcg dose: diarrhea (19% vs 7% placebo) and abdominal distension (2% vs < 1%).

Please see full Prescribing Information: http://www.allergan.com/assets/pdf/linzess_pi

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