



Ironwood and Forest to Present Linaclotide Data at Digestive Disease Week® 2014

CAMBRIDGE, Mass. & NEW YORK--(BUSINESS WIRE)-- [Ironwood Pharmaceuticals, Inc.](#) (NASDAQ:IRWD) and [Forest Laboratories, Inc.](#) (NYSE:FRX) announced today they will present linaclotide-related data during Digestive Disease Week® 2014 in Chicago, May 3 through May 6, 2014. The data will be presented through the following poster presentations:

Clinical Posters

Efficacy and Safety of Linaclotide in Chronic Idiopathic Constipation Patients With Abdominal Bloating: Phase 3b Trial Results (abstract #Sa2008) on Saturday, May 3, 2014, 8 a.m. - 5 p.m. in the South Hall, presented by Brian Lacy, M.D., Ph.D., Section Chief, Gastroenterology and Hepatology, Associate Professor of Medicine, Geisel School of Medicine, Dartmouth-Hitchcock Medical Center.

The Relationship Between Chronic Constipation Symptoms and Health-Related Quality of Life: Results From 2 Phase 3 Trials (abstract #Sa1076) on Saturday, May 3, 2014, 8 a.m. - 5 p.m. in the South Hall, presented by Doug Taylor, Director, Health Economics & Outcomes Research, Ironwood Pharmaceuticals, Inc.

Preclinical Posters

Extracellular Cyclic GMP (cGMP), the Downstream Mediator Released in Response to Linaclotide-Induced Activation of Guanylate Cyclase-C (GC-C), Reduces Excitability of Murine and Human Dorsal Root Ganglion (DRG) Neurons (abstract #Mo2029) on Monday, May 5, 2014, 8 a.m. - 5 p.m. in the South Hall, presented by Stuart Brierley, Ph.D., NHMRC Career Development Fellow and Head of the Visceral Pain Research Group, Nerve-Gut Research Laboratory, Discipline of Medicine at the University of Adelaide.

Distinct Alterations in the Guanylate Cyclase-C (GC-C)/cyclic GMP (cGMP) Pathway Are Evident Across Different Subtypes of Irritable Bowel Syndrome (IBS) Patients (abstract #Su2066) on Sunday, May 4, 2014, 8 a.m. - 5 p.m. in the South Hall, also presented by Dr. Brierley.

Linaclotide Induces Endocytosis of the Sodium/Hydrogen Exchanger 3 (NHE3) and Inhibits Sodium Absorption (abstract #Mo1752) on Monday, May 5, 2014, 8 a.m. - 5 p.m. in the South Hall, presented by Nadia Ameen, MBBS, Associate Professor of Pediatrics (Gastroenterology) and of Cellular and Molecular Physiology at Yale School of Medicine.

Health Economic & Outcomes Research Poster

Irritable Bowel Syndrome With Constipation (IBS-C), Chronic Idiopathic Constipation (CIC), Functional Dyspepsia (FD), and Gastroesophageal Reflux Disease (GERD) Commonly Overlap: Results of a Cross-Sectional Population-Based Survey (abstract #Sa1065) on Saturday, May 3, 2014, 8 a.m. - 5 p.m. in the South Hall, presented by Nimish Vakil, M.D., Clinical Professor of Medicine at the University of Wisconsin School of Medicine and Public Health.

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 Forest 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). Linaclotide is marketed by Almirall, S.A. for the treatment of adults with moderate to severe IBS-C in Europe under the brand name CONSTELLA®. Ironwood also has partnered with Astellas Pharma Inc. for development and commercialization of linaclotide in Japan and with AstraZeneca for development and commercialization in China.

LINZESS® and CONSTELLA® are trademarks owned by Ironwood Pharmaceuticals, Inc. Any other trademarks referred to in this press release are the property of their respective owners. All rights reserved.

Important Safety Information

WARNING: PEDIATRIC RISK

LINZESS is contraindicated in pediatric patients up to 6 years of age. Use should be avoided in pediatric patients 6 through 17 years of age.

In nonclinical studies, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths in young juvenile mice.

Contraindications

- LINZESS is contraindicated in pediatric patients up to 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 pediatric patients up to 6 years of age. In nonclinical studies, deaths occurred within 24 hours in young juvenile mice (1 to 3 week-old mice; approximately equivalent to human pediatric patients less than 2 years of age) following administration of one or two daily oral doses of linaclotide.
- Use of LINZESS should be avoided in pediatric patients 6 through 17 years of age. Linaclotide did not cause deaths in older juvenile mice (approximately equivalent to humans age 12 to 17 years). 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, who should consider dose suspension.

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.

About IBS-C and CIC

While estimates vary, as many as 13 million adults in the U.S. may suffer from IBS-C, and as many as 35 million may suffer from CIC. Results derived from responses to a web based survey commissioned by Forest Pharmaceuticals and Ironwood Pharmaceuticals suggest that only about half of adult IBS-C sufferers are medically diagnosed, and only 12 percent of adult CIC sufferers are medically diagnosed. Hallmark symptoms associated with IBS-C include abdominal pain and constipation. Symptoms associated with CIC may include constipation, hard or lumpy stools, infrequent stools, and incomplete evacuation (not completely emptying the bowels). There are few available prescription treatment options for these conditions.

About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ:IRWD) is focused on creating medicines that make a difference for patients, building value to earn the continued support of our fellow shareholders, and empowering our team to passionately pursue excellence. We discovered, developed and are commercializing linaclotide, which is approved in the United States and a number of other

countries. Our pipeline priorities include exploring further opportunities for linaclotide, as well as leveraging our therapeutic expertise in gastrointestinal disorders and our pharmacologic expertise in guanylate cyclases to address patient needs across the upper and lower gastrointestinal tract. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. Connect with us at www.ironwoodpharma.com or on Twitter at www.twitter.com/ironwoodpharma; information that may be important to investors will be routinely posted in both these locations.

About Forest Laboratories, Inc.

Forest Laboratories (NYSE:FRX) is a leading, fully integrated, specialty pharmaceutical company largely focused on the United States market. Forest markets a portfolio of branded drug products and develops new medicines to treat patients suffering from diseases principally in five therapeutic areas: central nervous system, cardiovascular, gastrointestinal, respiratory, and anti-infective. Forest's strategy of acquiring product rights for development and commercialization through licensing, collaborative partnerships and targeted mergers and acquisitions allows Forest to take advantage of attractive late-stage development and commercial opportunities, thereby managing the risks inherent in drug development. In January 2014, Forest acquired Aptalis Pharmaceuticals for \$2.9 billion in cash in order to gain access to its GI and Cystic Fibrosis products, including treatments for Ulcerative Proctitis, Duodenal Ulcers, H. Pylori, Anal Fissures, and Pancreatic Insufficiency. In February 2014, Forest and Actavis plc announced an agreement where Forest would be acquired for about \$25 billion in cash and stock. The acquisition of Forest by Actavis is contingent upon regulatory and shareholder approvals.

Forest is headquartered in New York, NY.

About Digestive Disease Week (DDW)

Digestive Disease Week® (DDW®) is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 3 - 6, 2014, at McCormick Place, Chicago, IL. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

Except for the historical information contained herein, this release contains forward - looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements involve a number of risks and uncertainties, including the potential that the presentations identified above are not given at all or at the times or locations specified, in addition to the risk factors listed from time to time in each of Forest's and Ironwood's Annual Reports on Form 10 - K, Quarterly Reports on Form 10 - Q, and other SEC filings. Neither Forest nor Ironwood undertakes any obligation to update these forward-looking statements to reflect events or circumstances occurring after this press release. These forward-looking statements speak only as of the date of this press release. All forward - looking statements are qualified in their entirety by this cautionary statement.

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