



## Ironwood and Forest to Present Linaclotide Data at Digestive Disease Week® 2013

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® 2013 in Orlando, Fla., May 18 through May 21, 2013. Among the data highlighted will be two oral presentations: one providing insight into the GC-C/cGMP pathway in patients with IBS-C and another describing the effects of linaclotide on inhibiting visceral pain, both based on nonclinical studies.

The oral presentation titled "*Mechanisms Underlying Linaclotide Induced Inhibition of Colonic Nociception*" (abstract #1602418) will be presented at 2:45 p.m. ET on Monday, May 20, 2013, in room 104A 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.

The oral presentation titled "*Alterations in the Guanylate Cyclase-C Receptor/cGMP Pathway in Patients with Constipation Predominant Irritable Bowel Syndrome*" (abstract #1602470) will also be presented by Dr. Brierley at 8:45 a.m. ET on Sunday, May 19, 2013 in room 314A.

Also being presented are the following poster presentations:

### **Clinical Posters**

*Assessing Abdominal and Bowel Symptoms Using Adequate Relief Based Thresholds: Results from 2 Phase 3 Trials of Linaclotide in Patients with Irritable Bowel Syndrome with Constipation* (abstract #1598133) on Monday, May 20, 2013, 8 a.m. — 5 p.m. in Hall WA1, presented by Michael Camilleri, M.D., Professor of Pharmacology, Physiology, and Medicine, Department of Gastroenterology and Hepatology, Mayo Clinic

*Determining the Minimum Duration for Initial Treatment with Linaclotide in IBS-C Patients: Results from Pooled Phase 3 Trials* (abstract #1596597) on Sunday, May 19, 2013, 8 a.m. — 5 p.m. in Hall WA1, presented by William Chey, M.D., Professor of Medicine, Director of the Gastrointestinal Physiology Laboratory and Co-Director of the Michigan Bowel Control Program at the University of Michigan

*The Effect of Linaclotide on IBS-QOL Sexual Subscale Scores in Patients with Irritable Bowel Syndrome with Constipation: Results from a Post hoc Analysis of 2 Phase 3 Trials of Linaclotide* (abstract #1598793), on Tuesday, May 21, 2013, 8 a.m. — 5 p.m. in Hall WA1, presented by Mark Currie, Ph.D., Senior Vice President, Chief Scientific Officer and President of R&D, Ironwood Pharmaceuticals Inc.

### **Health Economic & Outcomes Research Poster**

*Longitudinal Direct Medical Costs Associated with Irritable Bowel Syndrome-Constipation and Chronic Idiopathic Constipation in a Population-Based Sample over a 10-Year Period* (abstract #1581789), on Sunday, May 19, 2013, 8 a.m. — 5 p.m. in Hall WA1, presented by Linda Herrick, Ph.D., Associate Dean of Undergraduate Nursing, South Dakota State University

All data are embargoed until the time of presentation.

### 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 transit and a reduction in visceral pain, which is thought to be mediated by decreased activity of pain-sensing nerves. The clinical relevance of the effect on pain fibers in 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 was also approved by the European Commission for the treatment of adults in the European Union with IBS-C and is marketed under the brand name Constella® through a license agreement between Ironwood and Almirall, S.A. Ironwood also has partnered with Astellas Pharma

Inc. for development and commercialization of linaclotide in Japan, and with AstraZeneca for development and commercialization of linaclotide in China.

## Important Safety Information

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### 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.**

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### 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](http://www.frx.com/pi/linzess_pi.pdf).

### About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is committed to the art and science of making medicines, from discovery through commercialization. We're focused on three goals: transforming knowledge into medicines that make a difference for patients, creating value that will inspire the continued support of our fellow shareholders, and building a team that passionately pursues excellence. Our first product, linaclotide, is approved in the United States and Europe. Our pipeline priorities include exploring further opportunities for linaclotide, leveraging our deep expertise in functional gastrointestinal disorders, and advancing programs in other areas such as allergic conditions, cardiovascular disease, central nervous system disorders and other conditions defined by patient symptoms. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. Connect with us at [www.ironwoodpharma.com](http://www.ironwoodpharma.com) or on Twitter at [www.twitter.com/ironwoodpharma](http://www.twitter.com/ironwoodpharma) to learn more about Ironwood. Information that may be important to investors will be routinely posted in both these locations.

### About Forest Laboratories, Inc.

Forest Laboratories' (NYSE: FRX) longstanding global partnerships and track record developing and marketing pharmaceutical products in the United States have yielded its well-established central nervous system and cardiovascular franchises and innovations in anti-infective and respiratory, gastrointestinal, and pain management medicine. The Company's pipeline, the most robust in its history, includes product candidates in all stages of development across a wide range of therapeutic areas. The Company is headquartered in New York, NY. To learn more, visit [www.FRX.com](http://www.FRX.com).

#### 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 18 — 21, 2013, at the Orange County Convention Center, FL. 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](http://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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