



## **Ironwood and Forest to Present Linaclotide Results from Phase 2B and Phase 3 Trials in Patients with Irritable Bowel Syndrome with Constipation or Chronic Constipation**

### **Data to be presented at ACG 2011 Annual Scientific Meeting**

CAMBRIDGE, Mass. & NEW YORK--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) and Forest Laboratories, Inc. (NYSE: FRX) today announced they will be presenting additional linaclotide results from four pivotal Phase 3 trials and one Phase 2b study in patients with either irritable bowel syndrome with constipation (IBS-C) or chronic constipation (CC) at the American College of Gastroenterology (ACG) 2011 Annual Scientific Meeting being held in Washington, DC from October 29, 2011 to November 2, 2011. Linaclotide is an investigational guanylate cyclase type-C (GC-C) agonist for the treatment of IBS-C and CC. Positive results from each of these trials have been reported previously.

The linaclotide results will be presented in three poster presentations as follows:

- Poster P765 describes a pooled analysis from the two pivotal Phase 3 IBS-C trials. This poster is authored by Dr. William D. Chey and will be presented on Monday, October 31 from 10:30 a.m. — 4:30 p.m. (Eastern Time).
- Poster P764 describes a pooled analysis of patients with at least moderate bloating from the two pivotal Phase 3 CC trials. This poster is authored by Dr. Anthony Lembo and will be presented on Monday, October 31 from 10:30 a.m. — 4:30 p.m. (Eastern Time).
- Poster P1170 provides an assessment of endpoints used in evaluating treatments for IBS-C and is based on the Phase 2b IBS-C clinical study of linaclotide. This poster is authored by Dr. Jeff Johnston and will be presented on Tuesday, November 1 from 10:30 a.m. — 4:30 p.m. (Eastern Time).

### **About Linaclotide**

Linaclotide, an investigational drug, is an agonist of the guanylate cyclase type-C (GC-C) receptor located on the luminal surface of the intestine. In preclinical models, linaclotide reduced visceral hypersensitivity, increased fluid secretion, and accelerated intestinal transit. The effects on secretion and transit are mediated through cyclic guanosine monophosphate (cGMP), which is also believed to modulate the activity of local nerves to reduce pain. Linaclotide is an orally delivered peptide that acts locally in the gut with no measurable systemic exposure at therapeutic doses and is intended for once-daily administration. An issued composition of matter patent for linaclotide provides protection to 2025 in the United States. Ironwood and Forest plan to co-promote linaclotide in the U.S. Ironwood has out-licensed linaclotide to Almirall for European development and commercialization, and to Astellas Pharma Inc. for development and commercialization in Japan, Indonesia, Korea, the Philippines, Taiwan, and Thailand.

### **About Irritable Bowel Syndrome with Constipation (IBS-C)**

IBS-C is a chronic functional gastrointestinal disorder characterized by abdominal pain, abdominal discomfort, and bloating associated with altered bowel habits, and as many as 11 million people in the U.S. suffer from it. IBS-C can have a negative impact on daily living. There are currently few available therapies to treat this disorder.

### **About Chronic Constipation (CC)**

As many as 34 million Americans suffer from symptoms associated with CC and 8.5 million patients have sought treatment. Patients with CC often experience hard and lumpy stools, straining during defecation, a sensation of incomplete evacuation, and fewer than three bowel movements per week, as well as abdominal discomfort and bloating. There is a high rate of dissatisfaction with currently available treatments for CC.

### **About Ironwood Pharmaceuticals**

Ironwood Pharmaceuticals (NASDAQ: IRWD) is an entrepreneurial pharmaceutical company dedicated to the art and science of great drugmaking. Linaclotide, Ironwood's GC-C agonist, is an investigational drug for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC). The efficacy portion of linaclotide's development program has been

completed and supports the recently submitted NDA submission for both indications, as well as the MAA submission in Europe for the IBS-C indication. Ironwood also has a growing pipeline of additional drug candidates in earlier stages of development. Ironwood is located in Cambridge, Mass. To learn more, visit [www.ironwoodpharma.com](http://www.ironwoodpharma.com).

#### **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 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).

*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 difficulty of predicting FDA approvals, the acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the timely development and launch of new products, and 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 (and neither intends 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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