



## **Ironwood and Forest Announce Submission of New Drug Application for Linaclotide for the Treatment of Irritable Bowel Syndrome With Constipation and Chronic Constipation**

*CAMBRIDGE, Mass. and NEW YORK, August 9, 2011 (BUSINESS WIRE)* - Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) and Forest Laboratories, Inc. (NYSE: FRX) today announced they have recently submitted a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for linaclotide, a guanylate cyclase type-C (GC-C) agonist, for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC). The submission includes efficacy and safety data from a Phase 3 program comprising four double-blind placebo-controlled trials and two open-label long term safety studies. A total of more than 2,800 patients received a once-daily dose of either linaclotide or placebo across the four placebo-controlled clinical trials: two trials in patients with IBS-C and two trials in patients with CC. In these trials, statistically significant improvements in abdominal and bowel symptoms were achieved for linaclotide-treated patients versus placebo-treated patients for all primary and secondary endpoints.

Safety data collected across the four placebo-controlled Phase 3 clinical trials demonstrated that diarrhea was the most commonly reported adverse event and led to study discontinuation in 4 percent to 5 percent of linaclotide-treated patients compared to fewer than 1 percent of patients receiving placebo. Additionally, over 3,200 patients have enrolled in ongoing open-label safety studies and more than 1,100 of those patients have received linaclotide for at least 12 months.

### **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. Ironwood and Forest plan to co-promote linaclotide in the United States. Ironwood has out-licensed linaclotide to Almirall, S.A. 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 an 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 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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