Ironwood and Forest Announce FDA Has Extended the Review Period for Linaclotide to September 2012

CAMBRIDGE, Mass. & NEW YORK--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) and Forest Laboratories, Inc. (NYSE: FRX) today announced that the U.S. Food and Drug Administration (FDA) notified the companies that it will require a three-month extension to complete its review of the data supporting the New Drug Application (NDA) for linaclotide for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC).

An additional analysis of existing data was recently requested by the FDA to further characterize the relative effect of the two doses of linaclotide that were studied in the Phase 3 CC clinical trials. Since this analysis was submitted to the FDA within three months of the user fee goal date, the date has been extended by three months, in accordance with applicable regulation. No new data have been requested by the agency to complete the review. FDA action is now expected by September 2012. Ironwood and Forest continue to plan for a 2012 launch.

The efficacy and safety of linaclotide was studied in a clinical trial program of more than 2,800 patients for the treatment of IBS-C and CC. Additionally, over 3,200 patients were enrolled in ongoing open-label safety trials and more than 2,000 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 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.

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. Forest's pipeline, the most robust in its history, includes product candidates in all stages of development across a wide range of therapeutic areas. Forest is headquartered in New York, NY. To learn more, visit 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 potential that the FDA recommends modifications to the proposed label for linaclotide, the risk that the FDA issues a complete response letter for linaclotide or does not approve linaclotide for either or both of the IBS-C and CC indications, the difficulty in predicting the acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, the variability in 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 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.

Forest Laboratories, Inc.
Frank J. Murdolo, 212.224.6714
Vice President - Investor Relations
media.relations@frx.com
or
Ironwood Pharmaceuticals, Inc.
Meredith Kaya, 617.374.5082
Investor Relations
mkaya@ironwoodpharma.com

Source: Forest Laboratories, Inc. & Ironwood Pharmaceuticals, Inc.