Ironwood Announces FDA Advisory Committee Meeting Will Not Be Scheduled in Connection with New Drug Application for Linaclotide

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) announced that it was informed this evening that the U.S. Food and Drug Administration (FDA) will not schedule an advisory committee meeting in connection with the its review of the New Drug Application (NDA) for linaclotide proposed for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC). On August 9, 2011, Ironwood, along with its partner Forest Laboratories, announced that they submitted the NDA for linaclotide to the FDA. Under the FDA's Prescription Drug User Fee Act (PDUFA), the companies anticipate action by the FDA in June 2012, approximately 10 months from the submission date.

Ironwood and Forest submitted the NDA for linaclotide for the treatment of IBS-C and CC based upon efficacy and safety results 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 clinical trials: two trials in patients with IBS-C and two trials in patients with CC. Additionally, over 3,200 patients have 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 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.

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 possibility that the advisory committee meeting gets rescheduled to a later date, the potential the FDA convenes an advisory committee that does not recommend approval of linaclotide or that recommends modifications to the proposed label for linaclotide, the risk that the FDA issues a complete response letter for linaclotide, the difficulty of predicting FDA approvals, the

acceptance and demand for new pharmaceutical products, the impact of competitive products and pricing, and the timely development and launch of new products, as well as the risk factors listed from time to time in Ironwood's Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, and other SEC filings. Ironwood undertakes no 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.

Ironwood Pharmaceuticals, Inc.
Susan Brady, 617-621-8304
Corporate Communications
sbrady@ironwoodpharma.com

Source: Ironwood Pharmaceuticals, Inc.