



Ironwood Announces Linaclotide European Regulatory Submission for the Treatment of Irritable Bowel Syndrome with Constipation

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) today announced that its European partner Almirall, S.A. submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) for linaclotide, a guanylate cyclase type-C (GC-C) agonist, for the treatment of irritable bowel syndrome with constipation (IBS-C). The submission includes efficacy and safety data from a Phase 3 program comprising two double-blind placebo-controlled trials measured against the endpoints required by the EMA and two open-label long term safety studies. A total of more than 1,600 patients with IBS-C received a once-daily dose of either linaclotide or placebo across the two Phase 3 clinical trials. In these trials, statistically significant improvements in abdominal and bowel symptoms were achieved for linaclotide-treated patients versus placebo-treated patients for the co-primary and secondary endpoints.

Safety data collected across the two Phase 3 IBS-C clinical trials demonstrated that diarrhea was the most commonly reported adverse event and led to study discontinuation in 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 2,000 of those patients have received linaclotide for at least 12 months.

The trials were designed to support regulatory submissions for linaclotide in both Europe and the U.S. In August 2011, Ironwood and its U.S. partner Forest Laboratories, Inc. submitted a New Drug Application for linaclotide to the U.S. Food and Drug Administration.

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 in Europe to 2024. 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 much as 4 percent of the European population suffers from it. IBS-C can have an impact on daily living. There are currently few available therapies to treat this disorder.

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. The efficacy portion of linaclotide's development program has been completed and supports the recent 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.

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 or EMA 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 Ironwood's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, and other SEC filings. Ironwood does not undertake 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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