



Ironwood And Forest Present Additional Positive Phase 2b Study Results For Linaclotide In Patients With Irritable Bowel Syndrome With Constipation

Data Presented Today at DDW Demonstrate Linaclotide Provided Early Onset of Abdominal Pain Relief and Improved Bowel Habits

CAMBRIDGE, Mass. and New York, May 31, 2009 - Ironwood Pharmaceuticals, Inc. and Forest Laboratories, Inc. (NYSE: FRX) today announced results from additional analyses of their Phase 2b study assessing the safety and efficacy of the novel, first-in-class agent linaclotide in 419 patients with irritable bowel syndrome with constipation (IBS-C). Previous analyses of these data indicated that once-daily oral dosing with linaclotide, across a range of doses, significantly improved abdominal symptoms, bowel habits, and global assessments over the 12-week treatment period. These additional analyses demonstrated that patients treated with linaclotide experienced a statistically significant improvement in abdominal symptoms, bowel habits, and global assessments within the first week of treatment. Results were presented today at the Digestive Disease Week (DDW) conference being held in Chicago from May 30 through June 4, 2009. The companies also will present additional data throughout the week from studies of linaclotide in patients with IBS-C or chronic constipation (CC).

The data presented today in an oral presentation (*Abstract 157: Effect of Linaclotide on IBS-C Symptoms in the First Week of Treatment: Results from a Phase 2b Study*) by investigator Anthony Lembo, M.D., Director, GI Motility Center, Beth Israel Deaconess Medical Center, Boston, indicated that within the first week of treatment, linaclotide significantly improved abdominal symptoms, bowel habits, and global assessments. A statistically significant percentage of patients (48 to 64 percent) experienced a clinically meaningful reduction (≥ 0.5 on a five-point severity scale) in abdominal pain, abdominal discomfort, and bloating in the first week of treatment, compared with 25 to 37 percent of placebo patients ($p < 0.05$ for each pairwise comparison of a linaclotide dose group to the placebo group). For patients receiving the Phase 3 linaclotide dose, 300 ug daily, 60 percent showed this level of improvement in the first week ($p < 0.005$). There was also significant improvement in stool frequency, stool consistency, straining, adequate relief, and global relief during the first week of linaclotide treatment ($p < 0.05$ for all dose groups and $p < 0.001$ for the 300 ug dose group). These levels of improvement were sustained throughout the 12 weeks of treatment. Linaclotide was well tolerated at all doses with no treatment-related serious adverse events. The most common adverse event was diarrhea; however, there were no associated dehydration or electrolyte abnormalities. Study discontinuations due to diarrhea ranged from 1 to 7 percent of patients in the four linaclotide dose groups; no placebo-treated patients discontinued due to diarrhea.

"Management of abdominal pain, discomfort, and bloating, in addition to constipation, is important for patients suffering from IBS-C because these symptoms can be debilitating," said Anthony Lembo, M.D. "The results of this Phase 2b study suggest treatment with linaclotide may reduce symptoms in patients within a week of starting treatment."

The additional linaclotide presentations being made this week at DDW will be:

- Abstract 236: Global Endpoints in IBS Clinical Trials: Results from a Phase 2b Study of Linaclotide, an oral presentation by Jeffrey Johnston, M.D., F.A.C.P., F.A.C.G. on Sunday, May 31 at 2:30 p.m. CT; McCormick Place, Room E352
- Abstract 418: Effect of Linaclotide on Quality of Life in Adults with Chronic Constipation: Results from a Phase 2b Study, an oral presentation by Bernard J. Lavins, M.D. on Monday, June 1 at 2:15 p.m. CT; McCormick Place, Room S406A
- Abstract 1273: Time to Onset of Linaclotide Effect on the Bowel Habits in Patients with Chronic Constipation: Results from a Phase 2b Study, a poster presentation by Jeffrey Johnston, M.D., F.A.C.P., F.A.C.G. on Tuesday, June 2 from 8:00 a.m. to 5:00 p.m. CT; McCormick Place, South Hall

Ironwood and Forest presented the initial analyses from both the IBS-C and CC studies last year.

IBS-C Phase 2b Study Design

This North American-based, randomized, multi-center, double-blind, placebo-controlled, dose-range-finding, parallel-group Phase 2b study was designed to assess the safety, efficacy, and dose response of linaclotide in patients with IBS-C. The primary efficacy endpoint was change from baseline in complete spontaneous bowel movement (CSBM) frequency. The study evaluated the effects of 75, 150, 300, or 600 ug linaclotide or placebo administered orally once daily to adults meeting modified Rome II criteria for IBS-C. Participants underwent a two-week pretreatment (baseline) period before undergoing the 12-week

treatment period, followed by a two-week post-treatment period. Daily assessments of bowel habits and symptom severity, and weekly global assessments were performed using an interactive voice response system. During the baseline period patients had to demonstrate <3 CSBM/week and mean daily abdominal pain of at least mild severity. Treatment effects in the intent-to-treat population were estimated using an analysis of covariance and the Cochran-Mantel Haenszel test.

About Linaclotide

Linaclotide is a first-in-class compound in Phase 3 clinical development for the treatment of IBS C and CC. Linaclotide demonstrated proof of concept in a comprehensive Phase 2b program, comprised of two clinical studies in over 700 patients with either IBS-C or CC. In patients with IBS-C, linaclotide significantly reduced abdominal pain, discomfort, and bloating and improved bowel function throughout the 12-week treatment period. In patients with CC, linaclotide reduced constipation, abdominal discomfort, and bloating throughout the 4-week treatment period. Across both studies, the most common adverse event in the linaclotide-treated groups was diarrhea, and diarrhea was the most common adverse event leading to discontinuation. Linaclotide is a once daily, orally delivered peptide that acts locally in the gut with no detectable systemic exposure at therapeutic doses. Linaclotide is an agonist of guanylate cyclase type-C, a receptor found on the lining of the intestine. An issued composition of matter patent for linaclotide provides protection to 2025. In September 2007, Ironwood and Forest entered into a 50/50 collaboration to co-develop and co-promote linaclotide in the United States. In April 2009, Ironwood licensed to Almirall the European rights to develop and commercialize linaclotide.

About Irritable Bowel Syndrome with Constipation (IBS-C)

IBS-C is a chronic functional gastrointestinal disorder characterized by abdominal pain, discomfort, and bloating associated with altered bowel habits. There are currently few available therapies to treat this disorder. Nine million U.S. patients have been diagnosed with IBS-C, and as many as 15 million people in the U.S. suffer from it. Patients suffering from IBS-C can be affected physically, psychologically, socially, and economically.

About Chronic Constipation (CC)

As many as 23 million Americans suffer from CC and 12 million patients have sought treatment and been diagnosed. 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. The discomfort and bloating of CC significantly affects patients' quality of life by impairing their ability to work and participate in typical daily activities.

About Digestive Disease Week (DDW)

DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy, and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases, the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy, and the Society for Surgery of the Alimentary Tract, DDW takes place May 30 - June 4, 2009, at McCormick Place, Chicago, IL. The meeting showcases approximately 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine, and technology. For more information, visit www.ddw.org.

About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (www.ironwoodpharma.com) is an entrepreneurial pharmaceutical company dedicated to the science and art of great drugmaking. Linaclotide, the Company's first-in-class compound, is being evaluated in a comprehensive Phase 3 program for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation (CC). Ironwood also has a growing pipeline of additional drug candidates in earlier stages of development. Microbia, Inc. (formerly Microbia Precision Engineering), a majority-owned subsidiary of Ironwood, is an industrial biotechnology company developing and commercializing novel bioprocesses for the production of specialty chemicals. Ironwood has raised \$281 million in private equity financing and is located in Cambridge, Massachusetts.

About Forest Laboratories, Inc. and Its Products

Forest Laboratories (NYSE: FRX) is a U.S.-based pharmaceutical company with a long track record of building partnerships and developing and marketing products that make a positive difference in people's lives. In addition to its well-established franchises in therapeutic areas of the central nervous and cardiovascular systems, Forest's current pipeline includes product candidates in all stages of development and across a wide range of therapeutic areas. The company is headquartered in New York, NY. To learn more about Forest Laboratories, 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 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 Forest Laboratories' Annual Report on

Form 10-K, Quarterly Report on Form 10-Q, and any subsequent SEC filings.

Ironwood Contact:

Susan Brady
Corporate Communications
617.621.8304
sbrady@ironwoodpharma.com

Forest Contact:

Frank Murdolo
Vice President, Investor Relations
212.224.6714
frank.murdolo@frx.com