



FOR IMMEDIATE RELEASE

Ironwood Contact:

Susan Brady
Corporate Communications
617.621.8304
sbrady@ironwoodpharma.com

Forest Contact:

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

IRONWOOD AND FOREST PRESENT POSITIVE LINACLOTIDE RESULTS FROM TWO PIVOTAL PHASE 3 TRIALS IN PATIENTS WITH CHRONIC CONSTIPATION

— Data Presented at DDW Demonstrate Trials Met Primary and All Secondary Endpoints —

CAMBRIDGE, Mass. and New York, May 3, 2010 — Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) and Forest Laboratories, Inc. (NYSE: FRX) today presented Phase 3 clinical trial results assessing the efficacy and safety of the investigational drug linaclotide in patients with chronic constipation (CC). Linaclotide is a guanylate cyclase type C (GC-C) agonist in Phase 3 clinical development for the treatment of irritable bowel syndrome with constipation (IBS-C) and CC. The data presented demonstrate that statistical significance versus placebo was achieved for the primary endpoint of 12-week complete spontaneous bowel movement (CSBM) overall responder for each of the two doses studied in each trial. Statistical significance was also achieved for all secondary endpoints versus placebo, which included measures of bloating, abdominal discomfort, weekly spontaneous bowel movements (SBMs), and weekly CSBMs. Treatment responses occurred within one week and were sustained over the 12-week treatment period. Additional analyses demonstrate that in patients who were switched from linaclotide to placebo during the four-week randomized withdrawal period, constipation symptoms returned toward pretreatment levels, without evidence of worsening compared to baseline (*i.e.*, rebound constipation).

Results were presented today at the Digestive Disease Week (DDW) conference being held in New Orleans from May 1 through May 5, 2010. Top-line results from these trials were previously announced by Ironwood and Forest in a press release on November 2, 2009.

“As many as 34 million people in the U.S.ⁱ suffer from chronic constipation and many patients are not fully satisfied with currently available treatments.”ⁱⁱ I am encouraged by the results from these Phase 3 trials which show that linaclotide statistically significantly improved each of the constipation and abdominal symptoms measured,” stated investigator Anthony Lembo, M.D., Director, GI Motility Center, Beth Israel Deaconess Medical Center, Boston. “The results of these

trials suggest that linaclotide may provide an attractive option for millions of patients suffering from chronic constipation.”

Phase 3 Linaclotide Chronic Constipation Trials

A total of 1,276 patients who met modified Rome II criteria for CC were randomized to receive oral once-daily dosing of linaclotide (133 mcg or 266 mcg) or placebo for 12 weeks in two similarly designed double-blind Phase 3 trials (Trials 01 and 303). Trial 303 also included an additional four-week placebo-controlled randomized withdrawal period, which will be presented as a poster at DDW on Tuesday, May 4, 2010. The average age of the patients was 48 years, 89 percent were female, and 76 percent were Caucasian.

For both trials, the primary endpoint, CSBM overall responder, was defined as a patient achieving three or more CSBMs per week and an increase of at least one CSBM per week from baseline for at least nine of the 12 weeks in the trial. Secondary endpoints were change from baseline in weekly frequency of CSBMs and SBMs, as well as assessments of stool consistency, severity of straining, constipation severity, abdominal discomfort, and bloating. Safety and tolerability were also assessed.

After 12 weeks of treatment, statistically significantly more linaclotide patients met the primary endpoint in each trial compared to placebo. In Trial 01, 16.0 percent of patients receiving 133 mcg of linaclotide and 21.3 percent of patients receiving 266 mcg of linaclotide met the primary endpoint compared to 6.0 percent in the placebo group ($p=0.0012$ and $p<0.0001$, respectively). In Trial 303, 21.2 and 19.4 percent of linaclotide patients were CSBM overall responders compared to 3.3 percent in the placebo group ($p<0.0001$ for each dose). SBM frequency was a key secondary endpoint. Patients reported an overall average of 1.9 SBMs per week at baseline in Trial 01 and 2.1 SBMs per week at baseline in Trial 303; these rates increased to 5.3 and 5.6 SBMs per week on average over the 12-week treatment period in patients receiving 133 mcg and 266 mcg linaclotide, respectively, in Trial 01 compared to 3.0 SBMs per week in patients receiving placebo ($p<0.0001$ for each dose); and to 5.2 and 5.1 SBMs per week in patients receiving 133 mcg and 266 mcg linaclotide, respectively, in Trial 303 compared to 3.2 SBMs per week in patients receiving placebo ($p<0.0001$ for each dose). Statistically significant improvements in all other secondary endpoints were also seen across both Phase 3 trials in patients treated with linaclotide ($p<0.01$ for all).

A total of 538 of the 642 patients who received linaclotide in one of the 12-week Phase 3 trials (Trial 303) participated in a four-week randomized double-blind withdrawal period. The linaclotide patients were re-randomized either to continue on the same dose of linaclotide (133 mcg or 266 mcg) or switch to placebo; and the placebo patients were allocated to receive 266 mcg of linaclotide daily. Patients on linaclotide during the treatment period who were re-randomized to placebo experienced a return of their constipation symptoms toward baseline levels without evidence of rebound CC symptoms or an increase in adverse events (AEs). Patients on placebo during the treatment period who were switched to linaclotide treatment had improvement in bowel symptoms, abdominal symptoms, and global assessments; patients who continued linaclotide treatment showed sustained improvements in these symptoms.

Across the treatment periods of both trials, the most common AEs were diarrhea, flatulence, and abdominal pain. The only dose-related AE was diarrhea (16.0 percent of patients receiving 133 mcg linaclotide and 14.2 percent of patients receiving 266 mcg linaclotide versus 4.7 percent of patients receiving placebo). Diarrhea was also the most common AE leading to discontinuation (4.4 percent of patients receiving 133 mcg linaclotide and 3.8 percent of patients receiving 266 mcg linaclotide versus 0.5 percent of patients receiving placebo). Across the treatment periods of both trials, there were six (1.4 percent) and 11 (2.6 percent) patients receiving 133 mcg and 266 mcg linaclotide, respectively, who experienced serious adverse events (SAEs) compared to nine (2.1 percent) patients receiving placebo. During the randomized withdrawal period of Trial 303, two patients, both receiving placebo, experienced SAEs.

Glossary of Terms

- Complete spontaneous bowel movement (CSBM): A spontaneous bowel movement that is accompanied by the patient self-reporting a feeling of complete emptying of the bowel. CSBM is considered a more clinically meaningful endpoint than SBM because it integrates the objective, quantitative symptom of bowel movement frequency unassisted by laxatives, enemas or suppositories and the subjective, qualitative symptom of sensation of complete emptying of stool from the bowels.ⁱⁱⁱ
- Spontaneous bowel movement (SBM): A bowel movement that occurs in the absence of laxative, enema, or suppository usage within the preceding 24 hours.
- Modified Rome II chronic constipation criteria: A system developed by the Rome Committee to classify chronic constipation, as well as other functional gastrointestinal disorders (FGIDs), which is based on clinical symptoms that cannot be explained by the presence of structural or tissue abnormality.

About Linaclotide

Linaclotide, an investigational drug, is an agonist of guanylate cyclase type-C (GC-C), a receptor found on epithelial cells lining the intestine. In preclinical models, this activation of GC-C leads to increases in cyclic guanosine monophosphate (cGMP), anion secretion, fluid secretion, and intestinal transit. In addition, both linaclotide and cGMP demonstrated anti-nociceptive effects in several preclinical models of visceral pain. Linaclotide is an orally delivered peptide that acts locally in the gut with no detectable systemic exposure at therapeutic doses and is intended for once-daily administration. Linaclotide is in Phase 3 clinical development for the treatment of IBS-C and CC. In a Phase 2b study in patients with IBS-C, linaclotide statistically significantly reduced abdominal pain, abdominal discomfort, bloating, and severity of straining, and increased complete spontaneous bowel movement frequency, throughout the 12-week treatment period versus placebo. In two Phase 3 trials in patients with CC, statistical significance versus placebo was achieved for the primary endpoint—increasing complete spontaneous bowel movements—and all secondary endpoints, which included measures of straining severity, stool hardness, bloating, and abdominal discomfort. In Phase 2 IBS-C and Phase 3 CC trials, diarrhea was the most common adverse

event, and occurred more commonly in linaclotide-treated patients than placebo-treated. Although most events of diarrhea were reported as mild to moderate, diarrhea was the most common cause for discontinuation. Data from the Phase 3 IBS-C trials are expected in the second half of 2010. 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. Ironwood has out-licensed linaclotide to Almirall for European development and commercialization, and to Astellas Pharma for development and commercialization in Japan and other Asian countries.

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 discomfort and bloating. This condition significantly affects patients' quality of life by impairing their ability to work and participate in typical daily activities. Half of patients are not satisfied with currently available treatments.

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, and as many as 11 million people in the U.S. suffer from it. There are currently few available therapies to treat this disorder and there is a high rate of dissatisfaction with available therapies. Patients suffering from IBS-C can be affected physically, psychologically, socially, and economically.

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 1–5, 2010, at the Ernest N. Morial Convention Center, New Orleans. 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 (NASDAQ: IRWD) is an entrepreneurial pharmaceutical company dedicated to the art and science of great drugmaking. Linaclotide, Ironwood's GC-C agonist, is being evaluated in a confirmatory Phase 3 program for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic constipation. Ironwood also has a growing pipeline of additional drug candidates in earlier stages of development. Ironwood is located in Cambridge, Mass. To learn more about Ironwood Pharmaceuticals, visit www.ironwoodpharma.com.

About Forest Laboratories, Inc.

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.

SOURCE: Forest Laboratories, Inc.; Ironwood Pharmaceuticals, Inc.

CONTACT

Forest Laboratories, Inc.
Frank J. Murdolo, Vice President - Investor Relations
212-224-6714
frank.murdolo@frx.com

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

###

- i. Stewart W, "Epidemiology of constipation (EPOC) study in the United States: relation of clinical subtypes to sociodemographic features" *American Journal of Gastroenterology* (1999) 94, 3530–3540; doi:10.1111/j.1572-0241.1999.01642.x.
- ii. Johanson, J.F., & Kralstein, J. "Chronic constipation: a survey of the patient perspective." *Aliment Pharmacol Ther.* 2007; 25:599-608.
- iii. Johanson J.F., "Pilot Study on the Effect of Linaclotide in Patients with Chronic Constipation" *American Journal of Gastroenterology* 2009; 104:125 – 132.