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## IRONWOOD AND FOREST TO PRESENT POSITIVE DATA FROM LINACLOTIDE PHASE 2B IBS-C STUDY AT ACG ANNUAL SCIENTIFIC CONFERENCE

— Comprehensive Phase 3 Clinical Program Initiated —

*CAMBRIDGE, MASS. and NEW YORK, September 23, 2008* — Ironwood Pharmaceuticals (formerly Microbia) and Forest Laboratories, Inc. (NYSE: FRX) today announced they will present results of a Phase 2b study investigating linaclotide's safety and efficacy in 419 patients with irritable bowel syndrome with constipation (IBS-C) in a plenary session at the American College of Gastroenterology (ACG) 2008 Annual Scientific Meeting in Orlando, Fla. on October 7, 2008. Analysis of these data indicated that the study met its primary endpoint. Linaclotide is a first-in-class investigational compound being evaluated for its potential to treat IBS-C, chronic constipation (CC), and other gastrointestinal disorders.

Ironwood and Forest also announced that they have initiated a comprehensive Phase 3 clinical program to evaluate linaclotide's safety and efficacy in patients with either IBS-C or CC. The program will include two pivotal trials in IBS-C patients and two pivotal trials in CC patients, enrolling over 2,500 patients at approximately 250 clinical centers. The companies recently began patient dosing in the first CC trial and expect to initiate the second CC trial by the end of September, 2008. The companies expect to initiate both IBS-C trials by January, 2009.

### IBS-C Phase 2b Study

This U.S. and Canada based, twelve-week, randomized, double-blind, placebo-controlled Phase 2b study was designed to assess the safety, efficacy, and dose-response of linaclotide in patients with IBS-C. Patients were randomized to receive placebo or linaclotide once-daily in the morning at doses of 75 mcg, 150 mcg, 300 mcg or 600 mcg. The companies released an interim analysis of the study results in March. The completed results to be presented at the ACG conference affirm this earlier analysis. In this study, the change from baseline vs. placebo for complete spontaneous bowel movement (CSBM) frequency — the study's primary endpoint — was significant at all linaclotide dose levels. Notably, abdominal pain was clinically and statistically significantly reduced in all linaclotide treatment groups compared to placebo. Linaclotide-treated patients also experienced improvements in all other top-line efficacy

endpoints—spontaneous bowel movement (SBM) frequency, stool consistency, bloating, abdominal discomfort, adequate relief, and IBS-C symptom severity—and these improvements were statistically significant for at least three of the four linaclotide dose groups for each endpoint. Linaclotide was well tolerated at all doses. The most common adverse event was diarrhea; however, there were no associated dehydration or electrolyte abnormalities, and discontinuations due to diarrhea were infrequent.

### **About Linaclotide**

Linaclotide is a first-in-class compound currently being evaluated for the treatment of IBS-C, CC, and other gastrointestinal disorders. In Phase 2b studies in patients with IBS-C, linaclotide reduced abdominal pain and relieved constipation—the hallmarks of the condition—throughout the 12-week treatment period. Patients with CC who received linaclotide in Phase 2b studies experienced a significant improvement in bowel function as well. Linaclotide was well tolerated at all doses, with the most common adverse event being diarrhea. Positive results from a linaclotide Phase 2b study in 310 patients with CC were detailed in May 2008 at the Digestive Disease Week conference in San Diego. Linaclotide was designed to exert its effect on the intestine with minimal systemic exposure. Linaclotide is an agonist of guanylate cyclase type-C, a receptor found on the lining of the intestine. In preclinical testing, linaclotide was shown to decrease visceral pain, increase fluid secretion into the intestine, and accelerate intestinal transit. A United States patent covering linaclotide composition of matter expires in 2025. In September 2007, Ironwood and Forest Laboratories entered into a 50/50 collaboration to co-develop and co-promote linaclotide in the United States. Ironwood retains exclusive rights to linaclotide outside of North America.

### **About Irritable Bowel Syndrome (IBS)**

One out of six adults in developed countries suffers from IBS, a chronic condition marked by abdominal pain and disturbed bowel function. IBS accounts for 12% of adult visits to primary care physicians and is the most common disorder diagnosed by gastroenterologists. Healthcare costs associated with IBS exceed \$25 billion annually. IBS patients fall largely into three subgroups—constipation-predominant (IBS-C), diarrhea-predominant (IBS-D), and mixed IBS (IBS-M)—and 30% to 40% of these patients suffer from IBS-C. There are currently few available therapies to treat the nine million U.S. patients diagnosed with IBS-C.

### **About Chronic Constipation (CC)**

As many as 26 million Americans suffer from CC. 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 of CC significantly affects patients' quality of life by impairing their ability to work and participate in typical daily activities.

### **About Ironwood Pharmaceuticals**

Ironwood Pharmaceuticals (formerly Microbia) ([www.ironwoodpharma.com](http://www.ironwoodpharma.com)) is an entrepreneurial pharmaceutical company dedicated to the science and art of great drugmaking. The Company is advancing several clinical candidates—linaclotide for the treatment of irritable bowel syndrome with constipation, chronic constipation, and other functional gastrointestinal

disorders; and novel, next-generation cholesterol absorption inhibitors for the treatment of hypercholesterolemia. Ironwood also has a growing pipeline of additional drug candidates in earlier stages of development. Microbia Precision Engineering, Inc., 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 \$231 million in private equity financing and is located in Cambridge, Massachusetts.

### **About Forest Laboratories Inc. and Its Products**

Forest Laboratories (NYSE: FRX) is a US-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](http://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 Reports on Form 10-Q, and any subsequent SEC filings.

*Sources: Ironwood Pharmaceuticals and Forest Laboratories, Inc.*

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