April 10, 2014

Ironwood and Forest Launch New Direct-to-Consumer Awareness Campaign For LINZESS®

CAMBRIDGE, Mass. & NEW YORK--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ:IRWD) and Forest Laboratories, Inc. (NYSE:FRX) announced today that they have commenced a new direct-to-consumer (DTC) patient awareness campaign for LINZESS® (linaclotide), a once-daily treatment for adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC). The campaign aims to help adults suffering from IBS-C or CIC recognize the symptoms of these disorders, describe their symptoms to their doctor, and ask their doctor about LINZESS to help proactively manage their disease. The television portion of the campaign premiered last night on ABC.

"Millions of adults suffer from IBS-C or CIC, but many have not been diagnosed. They may not realize that long-lasting or recurrent symptoms such as infrequent or difficult-to-pass stools, not completely emptying the bowels, and - in IBS-C - belly pain, could indicate the presence of a medical condition and warrant discussion with a doctor," said Tom McCourt, chief commercial officer at Ironwood. "Even among patients who are diagnosed with IBS-C or CIC, fewer than 10 percent are aware of LINZESS, so we see a significant need to raise awareness of these disease states and of LINZESS as a possible treatment option."

The consumer awareness campaign is based on research that revealed gaps in the dialogue when and if adult patients with IBS-C or CIC describe their symptoms to their doctor. The comprehensive campaign includes print advertisements in highly visible consumer magazines such as *People*, *Cooking Light* and *Better Homes & Gardens*; television advertising during several Top 10 programs including Modern Family, The Voice and NCIS; online advertising; an updated brand web site (www.linzess.com); and brochures available in doctors' offices and pharmacies.

"Forest has traditionally focused primarily on physician-facing activities rather than DTC, but with LINZESS, we felt we had a unique opportunity to reach patients who were having a difficult time identifying and conveying the symptoms they were experiencing," said Bill Meury, executive vice president, sales and marketing at Forest. "We were struck by market research showing that many IBS-C and CIC sufferers don't fully describe the severity, frequency, and recurring nature of their symptoms to their doctors, sometimes resulting in a misdiagnosis of common, occasional constipation. This campaign is intended to facilitate a more comprehensive conversation between adult patients and physicians, and to raise consumer awareness about these diseases and LINZESS as a treatment option."

LINZESS is the first and only FDA-approved treatment in a new class of medicines for IBS-C and CIC known as GC-C agonists. It became available to adult IBS-C or CIC patients in December 2012, and it has been shown in clinical trials to significantly reduce abdominal pain in IBS-C patients and significantly increase bowel movement frequency in both IBS-C patients and CIC patients. LINZESS is contraindicated in pediatric patients up to 6 years of age. The use of LINZESS in pediatric patients 6 through 17 years of age should be avoided.

The most common side effect of LINZESS is diarrhea.

About LINZESS (linaclotide)

LINZESS is the first and only guanylate cyclase-C (GC-C) agonist approved by the FDA and is indicated for the treatment of both irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC) in adults. LINZESS is a once-daily capsule that helps relieve the abdominal pain and constipation associated with IBS-C, as well as the constipation, infrequent stools, hard stools and incomplete evacuation associated with CIC. The recommended dose is 290 mcg for IBS-C patients and 145 mcg for CIC patients. LINZESS should be taken at least 30 minutes before the first meal of the day.

LINZESS is thought to work in two ways based on nonclinical studies. LINZESS binds to the GC-C receptor locally, within the intestinal epithelium. Activation of GC-C results in increased intestinal fluid secretion and accelerated transit and a decrease in the activity of pain-sensing nerves in the intestine. The clinical relevance of the effect on pain fibers, which is based on nonclinical studies, has not been established.

In placebo-controlled Phase III clinical trials of more than 2,800 adults, LINZESS was shown to reduce abdominal pain in IBS-C patients and increase bowel movement frequency in both IBS-C patients and CIC patients. Improvement in abdominal pain and constipation occurred in the first week of treatment and was maintained throughout the 12-week treatment period. Maximum effect on abdominal pain was seen at weeks 6-9 and maximum effect on constipation occurred during the first week. When a

subset of LINZESS-treated patients in the trials were switched to placebo, they reported their symptoms returned toward pretreatment levels within one week, while placebo-treated patients switched to LINZESS reported symptom improvements. LINZESS is contraindicated in pediatric patients up to 6 years of age. The use of LINZESS in pediatric patients 6 through 17 years of age should be avoided. In nonclinical studies, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths in young juvenile mice. LINZESS has not been studied in pediatric patients. In adults with IBS-C or CIC treated with LINZESS, the most commonly reported adverse event was diarrhea.

Important Safety Information

WARNING: PEDIATRIC RISK

LINZESS is contraindicated in pediatric patients up to 6 years of age. Use should be avoided in pediatric patients 6 through 17 years of age. In nonclinical studies, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths in young juvenile mice.

Contraindications

- LINZESS is contraindicated in pediatric patients up to 6 years of age.
- LINZESS is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions

Pediatric Risk

- LINZESS is contraindicated in pediatric patients up to 6 years of age. In nonclinical studies, deaths occurred within 24 hours in young juvenile mice (1 to 3 week-old mice; approximately equivalent to human pediatric patients less than 2 years of age) following administration of one or two daily oral doses of linaclotide.
- Use of LINZESS should be avoided in pediatric patients 6 through 17 years of age. Linaclotide did not cause deaths in older juvenile mice (approximately equivalent to humans age 12 to 17 years). Although there were no deaths in older juvenile mice, given the deaths in young juvenile mice and the lack of clinical safety and efficacy data in pediatric patients, use of LINZESS should be avoided in pediatric patients 6 through 17 years of age.

Diarrhea

- Diarrhea was the most common adverse reaction of LINZESS-treated patients in the pooled IBS-C and CIC double-blind placebo-controlled trials. Severe diarrhea was reported in 2% of LINZESS-treated patients. The incidence of diarrhea was similar in the IBS-C and CIC populations.
- Patients should be instructed to stop LINZESS if severe diarrhea occurs and to contact their healthcare provider, who should consider dose suspension.

Adverse Reactions

- In IBS-C clinical trials, the most common adverse reactions in LINZESS-treated patients (incidence ≥2% and greater than placebo) were diarrhea (20% vs 3% placebo), abdominal pain (7% vs 5%), flatulence (4% vs 2%), headache (4% vs 3%), viral gastroenteritis (3% vs 1%) and abdominal distension (2% vs 1%).
- In CIC clinical trials, the most common adverse reactions in LINZESS-treated patients (incidence ≥2% and greater than placebo) were diarrhea (16% vs 5% placebo), abdominal pain (7% vs 6%), flatulence (6% vs 5%), upper respiratory tract infection (5% vs 4%), sinusitis (3% vs 2%) and abdominal distension (3% vs 2%).

Please see full Prescribing Information including Boxed Warning: http://www.frx.com/pi/linzess_pi.pdf.

About IBS-C and CIC

While estimates vary, as many as 13 million adults in the U.S. may suffer from IBS-C, and as many as 35 million may suffer from CIC. Results derived from responses to a web based survey commissioned by Forest Pharmaceuticals and Ironwood Pharmaceuticals suggest that only about half of adult IBS-C sufferers are medically diagnosed, and only 12 percent of adult CIC sufferers are medically diagnosed. Hallmark symptoms associated with IBS-C include abdominal pain and constipation. Symptoms associated with CIC may include constipation, hard or lumpy stools, infrequent stools, and incomplete evacuation (not completely emptying the bowels). There are few available prescription treatment options for these conditions.

Ironwood and Forest Laboratories, Inc. are co-promoting LINZESS in the United States. Linaclotide is marketed by Almirall, S.A. for the treatment of adults with moderate to severe IBS-C in Europe under the brand name CONSTELLA®. Ironwood also has partnered with Astellas Pharma Inc. for development and commercialization of linaclotide in Japan and with AstraZeneca for development and commercialization in China.

LINZESS® is a trademark owned by Ironwood Pharmaceuticals, Inc.

About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is focused on creating medicines that make a difference for patients, building value to earn the continued support of our fellow shareholders, and empowering our team to passionately pursue excellence. We discovered, developed and are commercializing linaclotide, which is approved in the United States, the European Union, and a number of other countries. Our pipeline priorities include exploring further opportunities for linaclotide, as well as leveraging our therapeutic expertise in gastrointestinal disorders and our pharmacologic expertise in guanylate cyclases to address patient needs across the upper and lower gastrointestinal tract. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. Connect with us at www.ironwoodpharma.com or on Twitter at www.twitter.com/ironwoodpharma; information that may be important to investors will be routinely posted in both these locations.

About Forest Laboratories, Inc.

Forest Laboratories (NYSE: FRX) is a leading, fully integrated, specialty pharmaceutical company largely focused on the United States market. The Company markets a portfolio of branded drug products and develops new medicines to treat patients suffering from diseases principally in the following therapeutic areas: central nervous system, cardiovascular, gastrointestinal, respiratory, anti-infective, and cystic fibrosis. Our strategy of acquiring product rights for development and commercialization through licensing, collaborative partnerships, and targeted mergers and acquisitions allows us to take advantage of attractive late-stage development and commercial opportunities, thereby managing the risks inherent in drug development. The Company is headquartered in New York, NY. To learn more, 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, including statements about the goals and components of the patient awareness campaign. These statements involve a number of risks and uncertainties, including the risks that the campaign is not as successful as anticipated, components of the campaign need to be either modified or canceled, Forest and Ironwood need to or choose to spend more on the campaign than originally anticipated, or there is less or no increased demand for LINZESS resulting from the campaign, in addition to the risk factors listed from time to time in each of Forest's and Ironwood's Annual Reports on Form 10‐K, Quarterly Reports on Form 10‐Q, and other SEC filings. Neither Forest nor Ironwood undertakes 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.

Photos/Multimedia Gallery Available: http://www.businesswire.com/multimedia/home/20140410005260/en/

Forest Laboratories, Inc.
Media Relations:
Amanda Kaufman, 646-231-7316
amanda.kaufman@frx.com
or
Investor Relations:
Frank J. Murdolo, 212-224-6714,
media.relations@frx.com
or
Ironwood Pharmaceuticals, Inc.
Media Relations:
Trista Morrison, 617-374-5095
tmorrison@ironwoodpharma.com
or
Investor Relations:
Mary Conway, 617-621-8308
mconway@ironwoodpharma.com

Source: Forest Laboratories, Inc. & Ironwood Pharmaceuticals, Inc.