



## Ironwood Pharmaceuticals Announces Alignment of Workforce with Priority Growth Platforms

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Ironwood Pharmaceuticals, Inc.](#) (NASDAQ: IRWD) announced today that it is reducing headcount by approximately 10 percent to align its workforce with its strategy to grow a leading gastrointestinal (GI) therapeutics company.

As detailed at Ironwood's [Investor Day](#) in December 2013, the Company's strategy is driven by four priority growth platforms: 1) maximizing the potential of LINZESS<sup>®</sup> (linaclotide), both by building on its successful launch for adult patients with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC) and by exploring the potential utility of linaclotide in additional indications and populations where there exists large unmet need; 2) leveraging Ironwood's commercial capabilities; 3) advancing a pipeline of multiple GI and guanylate cyclase clinical development programs; and 4) continuing to operate productively and efficiently by prioritizing investments in key value drivers. As maximizing LINZESS is core to Ironwood's strategy, Ironwood's field-based sales force and medical science liaison team are excluded from the workforce reduction.

"We are grateful to all of our employees for their passion and hard work in bringing LINZESS to adult patients; we've now developed significant expertise in gastrointestinal diseases and in guanylate cyclase pharmacology, providing us with a strong foundation and promising path forward as we continue to build a leading GI company," said Peter Hecht, chief executive officer of Ironwood. "While it is difficult to part with any of our talented colleagues, we believe this action effectively aligns our resources with our strategy and positions us to maximize value both for patients and for our fellow shareholders."

Ironwood estimates that it will incur aggregate charges of approximately \$4.0 million to \$4.5 million for severance and benefit costs in connection with its reduction in workforce, of which approximately 85 percent to 95 percent are expected to result in cash expenditures. The reduction in workforce is expected to be complete during the first quarter of 2014. The Company continues to focus on driving growth through productive and efficient operations, and expects continued reductions in net cash used in operating activities in 2014 through continued revenue growth and expense management. More information regarding the reduction in workforce is available in the Form 8-K Ironwood filed today with the Securities and Exchange Commission (SEC). The archived webcast of Ironwood's December 2013 Investor Day is available for replay on Ironwood's website until March 12, 2014.

### About LINZESS (linaclotide)

LINZESS is the first and only guanylate cyclase-C (GC-C) agonist approved by the FDA 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.

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<sup>®</sup>. 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.

## 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 and Europe. 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](http://www.ironwoodpharma.com) or on Twitter at [www.twitter.com/ironwoodpharma](http://www.twitter.com/ironwoodpharma); information that may be important to investors will be routinely posted in both these locations.

LINZESS<sup>®</sup> and CONSTELLA<sup>®</sup> are trademarks owned by Ironwood Pharmaceuticals, Inc.

## 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  $\geq 2\%$  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  $\geq 2\%$  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](http://www.frx.com/pi/linzess_pi.pdf).

*This press release contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including, but not limited to, statements about Ironwood's business strategy, structure and operations; the cause, size, timing and impact of Ironwood's reduction in workforce and related activities; the functional source within Ironwood of the positions eliminated in such reduction; the estimated charges and costs expected to be incurred in connection with such reduction; the percent of such charges expected to result in cash expenditures; and Ironwood's financial performance and results, including its growth, revenues and anticipated increased operating efficiencies. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include, without limitation, the difficulties in and effect of implementing Ironwood's business strategy and investments, such as the risk that Ironwood's planned investments do not have their anticipated effect; the difficulties in and effect of implementing Ironwood's reduction in workforce, such as claims arising out of the reduction; the risks related to the difficulty of predicting the financial impact or timing of Ironwood's reduction in workforce, including the risk that the actual financial and other impacts of the reduction could vary materially from the outcomes anticipated; the risk that Ironwood's strategy and planned investments do not have the anticipated effect on LINZESS or Ironwood's revenues; the risk that Ironwood and its partner, Forest Laboratories, Inc., are unable to successfully commercialize LINZESS; and the risk that Ironwood is unable to effectively reduce its operating expenses to a sufficient magnitude or for a sufficient period of time. Applicable risks also include those listed under the heading "Risk Factors" and elsewhere in Ironwood's Quarterly Report on Form 10-Q for the quarter ended September 30, 2013, in addition to the risk factors that are listed from time to time in Ironwood's Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and any subsequent SEC filings. Ironwood undertakes no obligation to update these forward-looking statements to reflect events or circumstances occurring after this press release. Except as otherwise noted, 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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