



## Ironwood Pharmaceuticals Presenting IW-3718 and Linaclotide Data at the American College of Gastroenterology 2018 Annual Scientific Meeting

October 8, 2018

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Oct. 8, 2018-- [Ironwood Pharmaceuticals, Inc.](#) (NASDAQ: IRWD), a commercial biotechnology company, today announced the presentation of clinical data for IW-3718 and linaclotide from the company and its collaborators during the American College of Gastroenterology 2018 Annual Scientific Meeting in Philadelphia, PA, October 5 through October 10, 2018.

IW-3718 is being evaluated in Phase III clinical trials for the treatment of persistent gastroesophageal reflux disease (GERD). Persistent GERD is a condition affecting an estimated 10 million Americans who continue to suffer from heartburn and regurgitation despite receiving treatment with proton pump inhibitors, the current standard of care. Researchers will present analyses of Ironwood's Phase IIb data on the effect of IW-3718 on health-related quality of life in patients with persistent GERD, as well as data on the effect of IW-3718 on esophageal erosions in this patient population.

Linaclotide is a guanylate cyclase-C (GC-C) agonist that acts by a mechanism pioneered by Ironwood scientists. Linaclotide is marketed in the United States as LINZESS<sup>®</sup> and is the U.S. branded prescription market leader for adults with Chronic Idiopathic Constipation (CIC) or Irritable Bowel Syndrome with Constipation (IBS-C). It is also marketed in Japan as LINZESS for the treatment of adults with IBS-C and adults with chronic constipation, and in Europe as CONSTELLA<sup>®</sup> for the treatment of adults with moderate to severe IBS-C. Researchers will present an analysis of clinical data focusing on the impact of linaclotide on constipation symptoms and quality of life in patients with IBS-C or CIC. An additional presentation will focus on treatment patterns in patients with IBS-C or CIC.

The data via poster presentations is as follows:

### Treatment Impact on Patients with IBS-C or CIC

- *Treatment Patterns, Over-the-Counter (OTC) Use, and Outcomes among Patients with Irritable Bowel Syndrome with Constipation or Chronic Idiopathic Constipation: Results from the CONTOR Study* (poster session #P0331), by Douglas C.A. Taylor, MBA, Ironwood Pharmaceuticals, Inc., Cambridge, MA, was presented on Sunday, October 7, 5:15 p.m. to 6:30 p.m., in Exhibit Halls DE of the Pennsylvania Convention Center.
- *Impact of Linaclotide on Patient-Reported Constipation Symptoms and Quality of Life: Results from the CONTOR Study* (poster session #P0332), by Douglas C.A. Taylor, MBA, Ironwood Pharmaceuticals, Inc., Cambridge, MA, was presented on Sunday, October 7, 5:15 p.m. to 6:30 p.m., in Exhibit Halls DE of the Pennsylvania Convention Center.

### Effect of IW-3718 on Patients with Persistent GERD

- *Clinical Response is Associated with Improvement in Health-Related Quality of Life in Patients with Persistent GERD Symptoms* (poster session #P2019), by Hancheng Jiang, M.S., Ironwood Pharmaceuticals, Inc., Cambridge, MA, will be presented on Tuesday, October 9, 1:00 p.m. to 2:15 p.m., in Exhibit Halls DE of the Pennsylvania Convention Center.
- *Effects of a Gastric-Retentive Extended-Release Bile Acid Sequestrant on Esophageal Erosions in Patients with Persistent GERD; Exploratory Analysis from a Phase IIb Study of IW-3718* (poster session #P2026), by Peter Kahrilas, M.D., Northwestern University Feinberg School of Medicine, Chicago, IL, will be presented on Tuesday, October 9, 1:00 p.m. to 2:15 p.m., in Exhibit Halls DE of the Pennsylvania Convention Center.

### About IW-3718

IW-3718 is a novel, gastric retentive formulation of colessevelam, a bile acid sequestrant, developed by Ironwood using the proprietary Acufarm<sup>®</sup> drug delivery formulation technology licensed from Depomed, Inc. IW-3718 is designed to deliver the bile acid sequestrant to the stomach over an extended period of time where it is positioned to intercept bile before it reaches the esophagus. Data from non-clinical and clinical studies collectively support the extended release and gastric-retentive profile of IW-3718. Ironwood has existing patents and pending patent applications for IW-3718 that are expected to provide patent coverage into the mid-2030s.

### About Persistent Gastroesophageal Reflux Disease (GERD)

An estimated 10 million adult Americans and more than 60 million adult patients globally suffer from persistent gastroesophageal reflux disease (GERD), meaning they continue to experience symptoms such as heartburn and regurgitation despite receiving treatment with a proton pump inhibitor (PPI). While PPIs suppress production of stomach acid, Ironwood's clinical research demonstrates that reflux of bile from the intestine into the stomach and esophagus may play a key role in the ongoing symptoms of persistent GERD. FDA-approved treatment options for these patients are limited.

### About Linaclotide

Linaclotide is a guanylate cyclase-C (GC-C) agonist that is thought to work in two ways based on nonclinical studies. Linaclotide 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. Linaclotide is marketed by Ironwood and Allergan plc in the United States as LINZESS and is indicated for the treatment of adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC), with nearly 2 million unique patients in the United States having filled nearly 11 million linaclotide prescriptions since launch, according to IQVIA. Linaclotide is marketed by Allergan for the treatment of adults with moderate to severe IBS-C in Europe under the brand name CONSTELLA. Astellas has the exclusive rights to develop and commercialize linaclotide in Japan. Ironwood also has partnered with AstraZeneca for development and commercialization of linaclotide in China, Hong Kong and Macau.

#### **About Ironwood Pharmaceuticals**

Ironwood Pharmaceuticals (Nasdaq: IRWD) is a commercial biotechnology company focused on creating medicines that make a difference for patients, building value for our fellow shareholders, and empowering our passionate team. We discovered, developed and are commercializing linaclotide, the U.S. branded prescription market leader for adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC). Our pipeline priorities for linaclotide include a Phase IIIb trial evaluating its efficacy and safety on multiple abdominal symptoms, including abdominal bloating, pain, and discomfort in adult patients with IBS-C, as well as research into a formulation of linaclotide designed to relieve pain across all IBS subtypes.

We are also advancing a pipeline of innovative product candidates in areas of significant unmet need, including persistent gastroesophageal reflux disease, diabetic nephropathy, heart failure with preserved ejection fraction and sickle cell disease. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. For more information, please visit [www.ironwoodpharma.com](http://www.ironwoodpharma.com) or [www.twitter.com/ironwoodpharma](https://www.twitter.com/ironwoodpharma); information that may be important to investors will be routinely posted in both these locations.

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