Ironwood Pharmaceuticals to Highlight Clinical Data for IW-3718 in Persistent Gastroesophageal Reflux Disease (GERD) at Digestive Disease Week® 2018

May 23, 2018

- IW-3718 Phase IIb Data Selected for the Distinguished Abstract Plenary Session -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--May 23, 2018-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD), a commercial biotechnology company, today announced that the company in collaboration with researchers will present clinical data for IW-3718 during Digestive Disease Week (DDW) in Washington D.C., June 2 through June 5, 2018.

One of the abstracts will be presented at the Distinguished Abstract Plenary Session. During this session, Michael Vaezi, Ph.D., M.D., of Vanderbilt University will share Phase IIb data on the effect of IW-3718 on heartburn and regurgitation – the two most frequent and bothersome symptoms of gastroesophageal reflux disease (GERD)[1] – in patients with persistent GERD despite treatment with proton pump inhibitors (PPIs).In addition, data will be presented in poster sessions highlighting the role of bile acid in persistent GERD; characteristics of patients who use PPIs and have satisfactory or unsatisfactory control of their GERD symptoms; and the ex vivo effect of the bile acid sequestrant colesevelam on the contractile activity of lower esophageal sphincter muscle, dysfunction of which is believed to be the most common cause of GERD.[2]

IW-3718 is being evaluated for the treatment of persistent GERD, with Phase III trials expected to initiate in the third quarter of 2018. Persistent GERD is a condition affecting an estimated 10 million Americans who continue to suffer from heartburn and regurgitation despite receiving treatment with PPIs, the current standard of care. Bile acids, which are produced in the intestine and play an important role in the digestive process, have been implicated in contributing to GERD symptoms.[3,4] The improvement of GERD symptoms observed in the Phase IIb trial indicates that reflux of intestinal bile acid from the stomach into the esophagus plays a key role in the ongoing symptoms of persistent GERD. IW-3718 is a novel formulation of colesevelam, a bile acid sequestrant designed to release in the stomach over an extended period of time where it is positioned to intercept bile before it reaches the esophagus.

The data will be presented as follows:

Distinguished Abstract Plenary Session

Effect of IW-3718 on Heartburn and Regurgitation Symptoms in Patients with Persistent GERD

- *IW-3718, a novel gastric-retentive bile acid sequestrant, improved heartburn and regurgitation symptoms in patients with persistent GERD despite PPI treatment: A double-blind, placebo-controlled study* (distinguished abstract plenary presentation #875), by Michael Vaezi, Ph.D., M.D., Vanderbilt University Medical Center, Nashville, TN, will be presented at the Esophageal, Gastric & Duodenal Disorders (EGD) session on Tuesday, June 5, 10:06 a.m. to 10:20 a.m., in Room 201 of the Washington Convention Center.

Poster Presentations

Role of Bile Acid in GERD

- *Presence of bile acids detected in human saliva using a novel sensitive bioanalytical method: A comparative study in patients with persistent or controlled GERD symptoms and healthy subjects* (poster session Su1089), by Nisha Perez, Ironwood Pharmaceuticals, Inc., Cambridge, MA, will be presented at the GERD: Diagnostic Testing session on Sunday, June 3, Noon to 2:00 p.m., in Hall C of the Washington Convention Center.
- *Bile acid sequestrant shows effects on the contractile activity of ex-vivo lower esophageal sphincter muscle* (poster session Mo1515), by Sarah Jacobson, Ironwood Pharmaceuticals, Inc., Cambridge, MA, will be presented at the Esophageal Motility and Dysmotility session on Monday, June 4, Noon to 2:00 p.m., in Hall C of the Washington Convention Center.

Characteristics of GERD Patients with Satisfactory or Unsatisfactory Symptom Control

- *Gastroesophageal reflux disease (GERD) patients taking proton pump inhibitors: Characteristics of those with satisfactory or unsatisfactory control of their condition* (poster session Sa1097), by Colin Howden, M.D., The University of Tennessee Health Science Center, Memphis, TN, will be presented at the GERD: Medical, Surgical and Endoscopic Therapies session on Saturday, June 2, Noon to 2:00 p.m., in Hall C of the Washington Convention Center.

About IW-3718

IW-3718 is a novel, gastric retentive formulation of colesevelam, a bile acid sequestrant, developed by Ironwood using the proprietary Acuform® 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 plays a key role in the ongoing symptoms of persistent GERD. FDA-approved treatment options for these patients are limited.

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 are commercializing two innovative primary care products: linaclotide, the U.S. branded prescription market leader for adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC), and lesinurad, which is approved to be taken with a xanthine oxidase inhibitor (XOI), or as a fixed-dose combination with allopurinol, for the treatment of hyperuricemia associated with gout. 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, achalasia and sickle cell disease. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. For more information, please visit www.ironwoodpharma.com or www.twitter.com/ironwoodpharma; information that may be important to investors will be routinely posted in both these locations.

Forward-Looking Statements

This press release contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about prevalence of persistent GERD; the anticipated timing of initiation of the persistent GERD Phase III trial; and the expected period of patent coverage for IW-3718. Applicable risks and uncertainties include those related to preclinical and clinical development, manufacturing and formulation development; the risk that findings from our completed nonclinical and clinical studies may not be replicated in later studies; efficacy, safety and tolerability of IW-3718; decisions by regulatory and judicial authorities; the risk that we are unable to successfully commercialize IW-3718, if approved; the risk that we may never get sufficient patent protection for IW-3718 or that we are not able to successfully protect such patents; the outcomes in legal proceedings to protect or enforce the patents relating to our products and product candidates; developments in the intellectual property landscape; challenges from and rights of competitors or potential competitors; the risk that our planned investments do not have the anticipated effect on our company revenues, products or product candidates; the risk that we are unable to manage our operating expenses or cash use for operations, or are unable to commercialize our products, within the guided ranges or otherwise as expected; and the risks listed under the heading "Risk Factors" and elsewhere in Ironwood's Quarterly Report on Form 10-Q for the quarter ended March 31, 2018, and in our subsequent SEC filings. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and Ironwood undertakes no obligation to update these forward-looking statements.

[1] Vakil, N., Stelwagon M., Shea E.P., & Miller S. (2015). Symptom Burden and Consulting Behavior in Patients with Overlapping Functional Disorders in the US Population. United European Gastroenterology Journal, 4(3), 412-422.

[2] Mitre, M. C., & Katzka, D. A. (2004). Pathophysiology of GERD: Lower Esophageal Sphincter defects. Practical Gastroenterology, 28(5), 44-58.

[3] Bachir G. S., Leigh-Collis J., Wilson P., & Pollak E. W. (1981). Diagnosis of incipient reflux esophagitis: a new test. Southern Medical Journal, 74(9), 1072-4.

[4] Vaezi M. F., & Richter J. E. (1998). Contribution of acid and duodenogastro-oesophageal reflux to oesophageal mucosal injury and symptoms in partial gastrectomy patients. Gut, 41, 297-302.

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Source: Ironwood Pharmaceuticals, Inc.

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