Ironwood Pharmaceuticals to Highlight Clinical and Preclinical Data for Praliciguat at the American Diabetes Association's 78th Scientific Sessions

June 20, 2018

-Praliciguat Phase IIa data to be featured in an oral presentation -

CAMBRIDGE, Mass.--(BUSINESS WIRE)--Jun. 20, 2018-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD), a commercial biotechnology company, today announced that the company will present clinical and preclinical data for the company's soluble guanylate cyclase (sGC) stimulator praliciguat (IW-1973) during the American Diabetes Association's (ADA) 78 th Scientific Sessions in Orlando, Fla., June 22 through June 26, 2018. Praliciguat is currently being studied in Phase II clinical trials in patients with diabetic nephropathy and in patients with heart failure with preserved ejection fraction (HFpEF).

Data from a Phase IIa 14-day study of praliciguat in patients with diabetes and hypertension will be featured as an oral presentation during the Emerging Targets for Diabetes Treatment session, presented by John P. Hanrahan, M.D., M.P.H., of Ironwood. In addition, a Phase IIa rapid dose escalation study of praliciguat in patients with diabetes and hypertension will be presented during a poster session. Finally, new data will be presented in a moderated poster discussion on praliciguat's effect on glucose tolerance, insulin sensitivity and triglycerides in a preclinical diet-induced obesity model.

sGC plays an important role in regulating many critical physiological processes; therefore dysregulation of sGC may play a role in multiple serious diseases. Ironwood's sGC stimulators, including praliciguat, are believed to harness the nitric oxide/sGC/cyclic guanosine monophosphate (NO/sGC /cGMP) pathway by working synergistically with NO to improve blood flow and metabolism and decrease inflammation and fibrosis. Praliciguat has the potential to address the underlying causes of devastating diseases such as diabetic nephropathy and HFpEF by improving NO signaling, which may improve vascular and metabolic function and decrease the inflammatory and fibrotic consequences associated with these diseases.

The data will be presented as follows:

Oral Presentation

- *Fourteen-Day Study of Praliciguat, a Soluble Guanylate Cyclase Stimulator, in Patients with Diabetes and Hypertension* (oral presentation 74-OR), by John P. Hanrahan, M.D., M.P.H., Ironwood Pharmaceuticals, Inc., Cambridge, MA, will be presented during the Emerging Targets for Diabetes Treatment session on Saturday, June 23, 8:30 a.m. to 8:45 a.m., in Room W304E-H of the Orange County Convention Center.

Poster Sessions

- *Praliciguat, a Clinical-Stage sGC Stimulator, Improved Glucose Tolerance and Insulin Sensitivity and Lowered Triglycerides in a Mouse Diet-Induced Obesity Model* (moderated poster discussion and poster session 1886-P), by Chad Schwartzkopf M.S., Ironwood Pharmaceuticals, Inc., Cambridge, MA, will be presented at the Integrated Physiology of Macronutrient Metabolism and Food Intake session on Saturday, June 23, 12:30 to 1:30 p.m., in the poster hall of the Orange County Convention Center and at the General Poster Session on Monday, June 25, noon to 1:00 p.m., in the poster hall of the Orange County Convention Center.
- *Rapid Dose Escalation Study of Praliciguat, a Soluble Guanylate Cyclase Stimulator, in Patients with Diabetes and Hypertension* (poster session 1207-P), by Albert Profy, Ph.D., Ironwood Pharmaceuticals, Inc., Cambridge, MA, will be presented at the General Poster Session on Sunday, June 24, noon to 1:00 p.m., in the poster hall of the Orange County Convention Center.

About Praliciguat

Praliciguat (IW-1973), an oral, once-daily soluble guanylate cyclase (sGC) stimulator, is being studied in patients with diabetic nephropathy and in patients with heart failure with preserved ejection fraction (HFpEF). Diabetic nephropathy affects an estimated eight million Americans and 20 to 40 percent of all diabetic patients worldwide. It is the leading cause of end-stage renal disease. Currently available products do not treat the underlying pathophysiology of the disease or fully address the needs of this patient population. HFpEF affects an estimated three million Americans and 40 to 70 percent of heart failure patients worldwide. It is a highly symptomatic condition with high rates of morbidity and mortality that can cause insufficient delivery of oxygen to the tissues, fluid in the lungs and edema of the extremities, causing patients to be short of breath and have compromised exercise tolerance. There are no approved therapies to treat HFpEF.

Currently in Phase II development for diabetic nephropathy and for HFpEF, praliciguat has the potential to address the underlying causes of these devastating diseases by improving nitric oxide (NO) signaling, which may improve vascular and metabolic function and decrease the inflammatory and fibrotic consequences associated with these diseases.

About Ironwood's sGC Program

As a pioneering expert in cyclic GMP (cGMP), Ironwood is building on its success with linaclotide, which stimulates guanylate cyclase-C in the intestine, to develop a pipeline of soluble guanylate cyclase (sGC) stimulators. sGC plays an important role in regulating diverse physiological processes; dysregulation of sGC may play a role in multiple serious diseases. Ironwood's sGC stimulators are believed to harness the nitric oxide (NO)/sGC/cGMP pathway by working synergistically with NO to improve blood flow and metabolism and decrease inflammation and fibrosis.

Ironwood is advancing praliciguat (IW-1973) for the potential treatment of diabetic nephropathy and of heart failure with preserved ejection fraction (HFpEF). Olinciguat (IW-1701) is being developed for the potential treatment of achalasia and of sickle cell disease. In addition, Ironwood has a pipeline of other sGC stimulators in pre-clinical development.

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 Ironwood's sGC program and the clinical program for praliciguat; the mechanism of action of praliciguat; prevalence; and praliciguat as a potential treatment for diabetic nephropathy and HFpEF. 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 those related to preclinical and clinical development, manufacturing and formulation development; the risk that future clinical studies need to be discontinued for any reason, including safety, tolerability, enrollment, manufacturing or economic reasons; the risk that findings from our completed nonclinical and clinical studies may not be replicated in later studies; efficacy, safety and tolerability of praliciguat; the risk that the therapeutic opportunities for praliciguat are not as we expect;decisions by regulatory authorities; the risk that we may never get sufficient patent protection for praliciguat or that we are not able to successfully protect such patents; the outcomes in legal proceedings to protect or enforce the patents relating to praliciguat; 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 business or the praliciguat program; and those 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.

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