April 5, 2016

Ironwood Pharmaceuticals Reports Top-Line Data from Exploratory Phase IIa Study of IW-9179 in Diabetic Gastroparesis

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) announced today that top-line data from an exploratory Phase IIa clinical study indicate IW-9179 did not meaningfully reduce the severity of symptoms in patients with diabetic gastroparesis. Based on these data, Ironwood intends to discontinue development of IW-9179 for gastroparesis.

"Our mission is to bring innovative medicines to patients in need, and exploratory trials are designed to help us identify the investigational medicines and appropriate indications with the most potential to help patients," said Mark Currie, Ph.D., chief scientific officer and president of research and development at Ironwood. "While these data indicate IW-9179 does not warrant advancement for gastroparesis, we recognize gastroparesis as a severely underserved disorder, and we want to extend our gratitude to the patients and health care professionals who participated in this study."

The Phase IIa study was a randomized, double-blind, placebo-controlled study of oral IW-9179 administered to 90 patients with diabetic gastroparesis. Patients were randomized to receive IW-9179 or placebo once or twice daily for four weeks. Efficacy was evaluated through multiple patient assessments of cardinal symptoms associated with gastroparesis. Top-line data indicate IW-9179 did not meaningfully improve these symptoms relative to placebo. IW-9179 was generally well-tolerated with the most common adverse event being diarrhea, which was mostly mild to moderate in nature. Ironwood intends to discontinue development of IW-9179 for gastroparesis and focus on ongoing programs in three key franchises: irritable bowel syndrome with constipation/chronic idiopathic constipation, vascular and fibrotic disease, and refractory gastroesophageal reflux disease.

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 advancing an innovative pipeline of medicines in multiple areas of significant unmet need, including irritable bowel syndrome with constipation (IBS-C)/chronic idiopathic constipation (CIC), vascular and fibrotic diseases, and refractory gastroesophageal reflux disease, among others. We discovered, developed and are commercializing linaclotide, the U.S. branded prescription market leader in the IBS-C/CIC category, and we are applying our proven R&D and commercial capabilities to advance multiple internally-developed and externally-accessed product opportunities. 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.

This press release contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about the top-line data from the Phase IIa clinical study of IW-9179 in diabetic gastroparesis; the design of the Phase IIa study and its impact on the results thereof; development plans for IW-9179, including decisions regarding discontinuation of development for gastroparesis and the drivers thereof; and the advancement, development and prioritization of our product candidates. 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 findings from our completed nonclinical and clinical studies may not be replicated in later studies; the risk that analyses of clinical data may not produce the expected findings; the risk that patient populations are not as presently estimated or that there is insufficient commercial opportunity; efficacy, safety and tolerability of linaclotide and our product candidates; decisions by regulatory authorities; the risk that we may never get sufficient patent protection for linaclotide and our 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, linaclotide or our product candidates; and those risks listed under the heading "Risk Factors" and elsewhere in Ironwood's Annual Report on Form 10-K for the year ended December 31, 2015 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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