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Ironwood Pharmaceuticals Initiates Phase IIb Clinical Trial of IW-3718 in Refractory Gastroesophageal Reflux Disease

-Demonstrates progress executing strategy to advance at least three new medicines addressing significant unmet needs into later-stage development by 2017/2018-

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) today announced that it initiated a Phase IIb clinical trial of IW-3718 in patients with refractory gastroesophageal reflux disease (GERD). Refractory GERD is a chronic condition in which patients continue to suffer from symptoms such as heartburn and regurgitation despite receiving treatment with a proton pump inhibitor (PPI). Data from this trial are expected in 2017.

"There is a significant unmet medical need among the estimated 10 million patients in the U.S. with refractory GERD," said Mark Currie, Ph.D., chief scientific officer and president of research and development at Ironwood. "For these patients, PPIs are not enough to control their heartburn and regurgitation. They continue to suffer from frequent and bothersome symptoms, and there is a dearth of approved prescription medicines for this condition. For these reasons, the advancement of IW-3718 is a top priority for Ironwood."

The randomized, double-blind, placebo-controlled, dose-ranging Phase IIb clinical trial is designed to evaluate the safety, efficacy, and dose-response relationship of IW-3718. The trial is expected to enroll approximately 260 adult patients who have been diagnosed with GERD and report experiencing heartburn or regurgitation at least four days per week during the previous eight weeks despite ongoing PPI treatment. The study design calls for eligible patients to continue taking their daily PPI therapy and to be randomized to receive additional treatment with placebo or one of three doses of IW-3718, twice-daily for eight weeks. The primary efficacy endpoint is change from baseline in heartburn severity.

Ironwood previously reported positive data from its randomized, double-blind, placebo-controlled Phase IIa study of IW-3718 for refractory GERD. Data from that study showed that IW-3718 improved heartburn severity in the intent-to-treat population. IW-3718 was generally well-tolerated with the most common adverse event being constipation.

About Refractory Gastroesophageal Reflux Disease
An estimated 45 million Americans have gastroesophageal reflux disease (GERD), an estimated 10 million of whom are thought to suffer from the refractory form of the condition, meaning they continue to experience symptoms such as heartburn and regurgitation despite receiving the current standard of care treatment with a proton pump inhibitor (PPI). While PPIs suppress production of stomach acid, research suggests reflux of bile from the intestine into the stomach and esophagus may play a role in the ongoing symptoms of refractory GERD. There are few FDA-approved treatment options for these patients. If left untreated, refractory GERD can lead to serious complications including Barrett's esophagus and, in rare instances, esophageal cancer.

About IW-3718
IW-3718 is a novel, investigational gastric retentive formulation of a bile acid sequestrant, developed by Ironwood using the proprietary Acuform® drug delivery technology licensed from Depomed, Inc. IW-3718 is designed to remain in the stomach and duodenum (upper small intestine) over an extended period of time and to work in combination with a PPI to reduce the detrimental effects of bile and acid on the esophagus.

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, but not limited to, statements about the clinical program for IW-3718, including the design, size and scope of the Phase IIb study and the completion thereof, the size of the potential patient population, the data to be generated from the Phase IIb study, the timing that these data are expected to be available, and the cause of the symptoms suffered by the potential patient population. 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, but are not limited to, the risk that we are unable to enroll as many patients in the clinical study or complete the Phase IIb study on the same timeline as we currently anticipate; the risk that the data from the study may not be available when we currently anticipate them or do not demonstrate the results we expect, including with respect to safety and efficacy; the risk that the Phase IIb study needs to be discontinued for any reason, including safety, enrollment, manufacturing or economic reasons; the risk that the data from non-clinical or previous clinical studies do not support the data from our clinical study; the patient population is not as large as we presently estimate; and the 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, 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. 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 to reflect events or circumstances occurring after this press release. All forward-looking statements are qualified in their entirety by this cautionary statement.

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