



Ironwood Presents IW-9179 Phase IIa Data at American College of Gastroenterology 2014 Annual Scientific Meeting

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- [Ironwood Pharmaceuticals, Inc.](http://www.ironwoodpharm.com) (NASDAQ:IRWD) announced today the presentation of initial data from a Phase IIa clinical study in functional dyspepsia with IW-9179, an investigational guanylate cyclase-C (GC-C) agonist designed to target the upper gastrointestinal (GI) tract. These data will be presented during the American College of Gastroenterology 2014 Annual Scientific Meeting in Philadelphia, October 17 through October 22, 2014. Ironwood expects to initiate a Phase IIa clinical study evaluating IW-9179 in a second therapeutic area, gastroparesis, before the end of the year. Gastroparesis is an upper GI disorder that impacts an estimated 9 million Americans and is characterized by nausea, vomiting, bloating, early satiety and pain.

"As innovators in the science of guanylate cyclase-C, Ironwood created the first and only FDA-approved GC-C agonist, which is indicated for two lower gastrointestinal disorders. We are encouraged by the initial IW-9179 data and our other recent data indicating GC-C agonists may also have utility in treating upper gastrointestinal disorders," said Dr. Michael Hall, MB, BCh., senior vice president, clinical development of Ironwood. "Common upper GI disorders such as gastroparesis and functional dyspepsia remain areas where millions of suffering patients are in need of effective therapies."

The Phase IIa clinical study of IW-9179 was a randomized, double-blind study in 10 patients (six on IW-9179, four on placebo) with functional dyspepsia (FD). Patients treated with IW-9179 reported a numerically greater improvement from baseline, compared with placebo-treated patients, on six out of seven FD symptoms evaluated, including epigastric pain, epigastric bloating, postprandial fullness, early satiation, nausea and belching. The most common adverse event in IW-9179-treated patients was diarrhea. Enrollment in this study was limited by stringent enrollment criteria that sought to identify patients suffering only from GI symptoms of FD - a difficult task given that FD sufferers frequently also have symptoms of other GI disorders such as gastroesophageal reflux disease (GERD) or irritable bowel syndrome (IBS). In fact, of the 58 patients who initially met the stringent enrollment criteria and completed the 14-day pretreatment period, 78% were not qualified to enter the study treatment period owing to overlapping GI symptoms. These data inform Ironwood's continued work with gastrointestinal experts and regulatory authorities to define the path to bring forward new therapies in FD.

These data will be presented in the poster, *Evaluation of Daily GI Symptoms in a Phase 2a Study of IW-9179 in Functional Dyspepsia* (abstract #P1637) on Tuesday, October 21, 2014, 10:30 a.m. to 4:00 p.m., Eastern Time. Jan Tack, MD, Ph.D., Head of Clinic in the Department of Gastroenterology, and Professor of Internal Medicine at the University of Leuven, Belgium, is the lead investigator and first author.

About Functional Dyspepsia

Functional dyspepsia is an upper gastrointestinal disorder characterized by key symptoms of epigastric pain, epigastric bloating, postprandial fullness, epigastric burning, nausea, belching, and early satiety. It is estimated to impact 35 million Americans, and there are currently no treatment options approved by the Food and Drug Administration.

About Gastroparesis

Gastroparesis is an upper gastrointestinal disorder in which the muscles and/or nerves of the stomach do not function properly, which prevents the stomach from emptying. Common symptoms include nausea, vomiting, bloating, early satiety and pain. Gastroparesis is estimated to impact 9 million Americans, and there are limited treatment options available.

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About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is focused on creating medicines that make a difference for patients, building value to earn the continued support of our fellow shareholders, and empowering our team to passionately pursue excellence. We discovered, developed and are commercializing linaclotide, which is approved in the United States and a number of other countries. Our pipeline priorities include exploring further opportunities for linaclotide, as well as leveraging our therapeutic expertise in gastrointestinal disorders and our pharmacologic expertise in guanylate cyclases to address patient needs across the upper and lower gastrointestinal tract. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. Connect

with us at www.ironwoodpharma.com or on Twitter at 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 size, scope and design of the IW-9179 development program and the associated clinical studies and development plans; the initiation of clinical studies and the timing thereof; the completion of clinical studies, the data generated and the impact of such data on future development plans; functional dyspepsia and gastroparesis symptoms, available treatments and the effectiveness of GC-C agonists to treat these disorders as well as other upper gastrointestinal disorders; the overlap of symptoms across GI disorders; Ironwood's efforts to bring new therapies in functional dyspepsia; the size of potential patient populations; and the timing, location and content of presentations. 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 initiate, enroll, and complete clinical studies on the same timeline as we currently anticipate or otherwise are unable to effectively execute on our IW-9179 development program; the risk that a clinical study needs to be discontinued for any reason, including safety, efficacy, tolerability, enrollment, manufacturing or economic reasons; those related to decisions made by regulatory authorities; those related to our ability to bring new therapies in functional dyspepsia, gastroparesis and other upper gastrointestinal disorders; the risk that the data from clinical studies is not available when we currently anticipate it or does not demonstrate efficacy; the risk that the data from non-clinical studies does not support the data from our clinical studies; the risk that the patient population is not as large as we presently estimate; and those risks related to competition and future business decisions made by Ironwood and its competitors or potential competitors. Applicable risks also include those that are listed under the heading "Risk Factors" and elsewhere in Ironwood's Quarterly Report on Form 10-Q for the quarter ended June 30, 2014, 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 other subsequent SEC filings. Ironwood undertakes no obligation to update these forward-looking statements to reflect events or circumstances occurring after this press release. Except as otherwise noted, these forward-looking statements speak only as of the date of this press release. All forward - looking statements are qualified in their entirety by this cautionary statement.

Ironwood Pharmaceuticals, Inc.

Media Relations

Trista Morrison, 617-374-5095

Director, Corporate Communications

tmorrison@ironwoodpharma.com

or

Investor Relations

Meredith Kaya, 617-374-5082

Director, Investor Relations

mkaya@ironwoodpharma.com

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