December 9, 2014

Ironwood Pharmaceuticals Initiates Phase IIa Clinical Study of IW-9179 in Diabetic Gastroparesis

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) announced today that dosing has begun in a Phase IIa clinical study evaluating whether its investigational guanylate cyclase-C (GC-C) agonist, IW-9179, can provide symptomatic relief to patients with diabetic gastroparesis. Data are expected in the first half of 2016.

"Gastroparesis symptoms, such as nausea and vomiting, are reported by approximately five to 12 percent of diabetic patients. With few treatment options available, diabetic gastroparesis represents a significant unmet need," said Dr. Michael Hall, senior vice president, clinical development of Ironwood. "The Ironwood team has pioneered research in GC-C agonist pharmacology, and we utilized this experience as well as our expertise in gastrointestinal disorders to create IW-9179. We look forward to evaluating its potential to help diabetic gastroparesis sufferers."

The randomized, double-blind, placebo-controlled, multi-site Phase IIa clinical study is expected to enroll approximately 80 adult patients with diabetic gastroparesis. Patients will be randomized to receive IW-9179 or placebo orally once or twice daily for four weeks. The study design includes multiple exploratory endpoints, including patient-reported daily severity assessments of diabetic gastroparesis symptoms.

About IW-9179

IW-9179 is an investigational guanylate cyclase-C (GC-C) agonist. GC-C is a receptor found mainly on the surface of the intestine and is recognized to be a potential therapeutic target in certain gastrointestinal diseases. Although GC-C is found throughout the gastrointestinal tract, IW-9179 is designed to act primarily in the upper gastrointestinal tract. Ironwood is investigating IW-9179 for the treatment of gastroparesis, with an initial focus on diabetic gastroparesis, and for functional dyspepsia, both of which are upper gastrointestinal disorders characterized by upper abdominal pain, bloating, fullness and nausea, among other symptoms. Data from a Phase I study indicate IW-9179 is minimally absorbed and generally well-tolerated, and initial data from a 10-patient Phase IIa study in which enrollment was limited by stringent inclusion criteria suggest IW-9179 may have applicability in patients with functional dyspepsia. Ironwood is working with gastrointestinal experts and regulatory authorities to define a path forward for IW-9179 in functional dyspepsia. The most common adverse event in both studies was diarrhea. Ironwood has an issued composition of matter patent in the U.S. covering IW-9179, which expires in 2031, and additional patents are allowed and pending in the U.S. and throughout the world.

About Gastroparesis

Gastroparesis is an upper gastrointestinal disorder in which the muscles and/or nerves of the stomach do not function properly, which disrupts the functional activities of the stomach. Common symptoms of gastroparesis include nausea, vomiting, bloating, upper abdominal pain and feelings of fullness after eating just a few bites of food. Gastroparesis can also result in weight loss and malnutrition. Diabetic gastroparesis, which is the focus of the current Phase IIa study, is a condition in which symptoms of gastroparesis occur in patients with type 1 or type 2 diabetes, and has additional harmful effects on glycemic control, as well as secondary effects on organs, which may lead to increased mortality. Gastroparesis symptoms are reported by approximately five to 12 percent of diabetic patients. There are limited treatment options for gastroparesis available.

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 and scope of the clinical program for IW-9179; the design of the Phase IIa study in diabetic gastroparesis, the number of patients expected to be enrolled, endpoints and the data to be generated, including the impact on symptoms of diabetic gastroparesis; the completion of the Phase IIa clinical study and the date on which the data from the study is expected to be available; the study's impact on future development plans; the design and potential impact of IW-9179; symptoms, outcomes, available treatments, unmet need, and IW-9179 as a potential treatment for gastroparesis and functional dyspepsia; the applicability of IW-9179 in patients with, and Ironwood's efforts to define a path forward for IW-9179 in, functional dyspepsia; the strength of the intellectual property for IW-9179; and the percent of diabetic patients reporting symptoms of gastroparesis. 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 on the same timeline as we currently anticipate or are otherwise unable to effectively execute on our clinical program for IW-9179; the risk that the 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; the risk that the data from such clinical study are not available when we currently anticipate them or do not demonstrate efficacy; the risk that the patient population and the percent of diabetic patients reporting symptoms of gastroparesis are not as we presently estimate; the risk that the data from non-clinical studies do not support the data from our clinical study; those related to decisions made by the U.S. Patent and Trademark Office and its foreign counterparts, intellectual property rights of competitors or potential competitors, and the risk that we may never get sufficient patent protection for IW-9179; 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 September 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.

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