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Ironwood Earns $15 Million Milestone from Astellas upon Initiation of Enrollment in Linaclotide Phase III IBS-C Clinical Trial in Japan

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) announced today that it has earned a $15 million development milestone payment from Astellas Pharma Inc., its partner for linaclotide in Japan. This milestone was triggered by Astellas's enrollment of the first patient in a randomized, double-blind, placebo-controlled Phase III clinical trial of linaclotide in adult patients with irritable bowel syndrome with constipation (IBS-C) in Japan. Astellas expects to complete the Phase III trial in 2016.

Ironwood and Astellas entered into a licensing agreement in 2009 to develop and commercialize linaclotide in Japan for the treatment of IBS-C, chronic constipation and other gastrointestinal conditions. Per the agreement, Astellas paid Ironwood a $30 million upfront licensing fee. In addition to the $15 million development milestone payment upon enrollment of the first patient in the Phase III trial, the agreement also includes additional development milestone payments that could total up to $30 million, consisting of $15 million upon filing for regulatory approval in Japan and $15 million upon receipt of approval. The agreement also provides for Ironwood to receive royalties which escalate based on sales volume.

Astellas also plans to expand its development of linaclotide in Japan and is entering into a Phase II clinical trial with linaclotide in adults with chronic constipation. If approved, the same royalty terms would apply.

About Linaclotide

Linaclotide is a guanylate cyclase‑C (GC‑C) agonist that is thought to work in two ways based on nonclinical studies. Linaclotide binds to the GC-C receptor locally, within the intestinal epithelium. Activation of GC-C results in increased intestinal fluid secretion and accelerated transit and a decrease in the activity of pain-sensing nerves in the intestine. The clinical relevance of the effect on pain fibers, which is based on nonclinical studies, has not been established. Linaclotide is marketed by Ironwood and Actavis in the United States as LINZESS® and is indicated for the treatment of adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC). Linaclotide is marketed by Almirall, S.A. for the treatment of adults with moderate to severe IBS-C in Europe under the brand name CONSTELLA®. Ironwood also has partnered with Astellas Pharma Inc. for development and commercialization of linaclotide in Japan and with AstraZeneca for development and commercialization in China.

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 achievement of milestones and the payment of royalties under our license agreement with Astellas, and the amount and timing thereof; the completion of the Phase III clinical study in adult IBS-C patients for Japan and the timing thereof; and Astellas' plans with respect to the development of linaclotide in Japan, and any expansion thereof, including the Phase II clinical trial in adults with chronic constipation. 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 Astellas is unable to enroll as many patients in its clinical studies or on the same timeline as it currently anticipates or is otherwise unable to effectively execute on its linaclotide clinical programs in IBS-C or chronic constipation in Japan; the risk that clinical studies

need 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 studies is not available when currently anticipated or does not demonstrate efficacy; those related to competition in disease states and the commercial potential of linaclotide in Japan; the risks related to pricing and reimbursement, and their impact on potential royalty revenues; and those risks related to competition and future business decisions made by Ironwood or Astellas and their 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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