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Ironwood Pharmaceuticals Announces Filing by Astellas of New Drug Application in Japan with Linaclotide for the Treatment of Adults with IBS-C

-Filing Triggers $15 Million Milestone Payment to Ironwood from Astellas-

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) today announced that a new drug application (NDA) seeking approval of linaclotide for the treatment of adults with irritable bowel syndrome with constipation (IBS-C) in Japan was filed with the Japanese Ministry of Health, Labor and Welfare by Astellas Pharma Inc., Ironwood's partner for linaclotide in Japan.

Linaclotide is a guanylate cyclase-C (GC-C) receptor agonist currently approved, and is the branded prescription market leader, for the treatment of adults with IBS-C or chronic idiopathic constipation (CIC) in the United States, where more than 40 million patients are estimated to suffer from these conditions. To date, more than 1 million unique U.S. patients have filled a linaclotide prescription since its launch in December 2012, according to IMS Health. Linaclotide is also approved for adults with IBS-C or CIC in more than 30 other countries.

"Today's filing for regulatory approval in Japan by our partner Astellas, and our recent filing for regulatory approval in China with our partner AstraZeneca, are important achievements by Ironwood and our global partners toward bringing linaclotide to appropriate patients around the world," said Mark Currie, Ph.D., chief scientific officer and president of research and development at Ironwood. "In Japan, 2.9 percent of adults are estimated to suffer from IBS-C, with no prescription medicines currently approved for this disease. We hope to help address this unmet need, and we continue to explore further innovation with linaclotide across a broad spectrum of patient needs."

The NDA submission in Japan is based mainly on the results obtained from the double-blind, placebo-controlled, parallel-group comparative Phase III study conducted in Japan in adults with IBS-C, which demonstrated linaclotide's clinical efficacy and safety profile, and which were announced by the companies in November 2015.

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 and a $15 million development milestone payment upon enrollment of the first patient in the Phase III IBS-C trial. These payments are in addition to the $15 million milestone payment earned by Ironwood upon the NDA submission announced today. The agreement also includes an additional $15 million milestone payment for Ironwood upon receipt of approval of linaclotide by the Japan regulatory authority. The agreement also provides for Ironwood to receive royalties, which escalate based on sales volume, if linaclotide is approved in Japan.

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 Allergan plc 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), with more than 1 million unique patients in the United States having filled more than 4 million linaclotide prescriptions since launch, according to IMS Health. Linaclotide is marketed by Allergan for the treatment of adults with moderate to severe IBS-C in Europe under the brand name CONSTELLA®. Ironwood also has partnered with Astellas for development and commercialization of linaclotide in Japan and with AstraZeneca for development and commercialization in China, Hong Kong and Macau.

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 ironwoodpharma.com or follow @ironwoodpharma on Twitter; 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 achievement of milestones and the payment of royalties under our license agreement with Astellas, and the amount and timing thereof; the design and possible benefits of linaclotide and its potential as a treatment for adult IBS-C patients in Japan; the ability of Ironwood and its partners to bring linaclotide to appropriate patients in Japan and around the world; IBS-C prevalence and unmet need; and Astellas' plans with respect to the development of linaclotide in Japan. 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 the risk that Astellas is unable to effectively execute on its linaclotide development plan in Japan, including obtaining regulatory approval for linaclotide as a treatment for adult IBS-C patients; those related to decisions made by regulatory authorities; 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; those related to competition and challenges from and rights of competitors or potential competitors; 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, 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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