

Ironwood and AstraZeneca Announce Linaclotide Collaboration for China

CAMBRIDGE, Mass. & LONDON--(BUSINESS WIRE)-- AstraZeneca and Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) announced today an agreement to co-develop and co-commercialize Ironwood's linaclotide in China. Linaclotide is the first and only guanylate cyclase-C (GC-C) agonist approved by the US Food and Drug Administration, in August.

In May, Ironwood filed a clinical trial application with the State Food and Drug Administration in China for a Phase III clinical trial to assess the efficacy and safety of linaclotide in adult patients suffering from irritable bowel syndrome with constipation (IBS-C). IBS-C, which is characterized by symptoms of abdominal pain and constipation, is a chronic and prevalent functional gastrointestinal disorder in China and there are currently few treatment options for this condition.

"China is one of the fastest growing prescription medicines markets in the world and linaclotide represents a valuable opportunity to meet the needs of local patients by providing an innovative new treatment option," said Mark Mallon, Regional Vice-President for Asia Pacific and President, AstraZeneca China. "We are pleased to be partnering with Ironwood for linaclotide in China, which capitalizes on our leadership in the gastrointestinal sector in the emerging markets."

Peter Hecht, Ironwood's Chief Executive Officer, said: "As we continue to advance our efforts to make linaclotide available to patients around the world, we are excited about this opportunity to collaborate in China with AstraZeneca, one of the world's most successful companies in gastrointestinal medicine."

AstraZeneca and Ironwood are jointly responsible for strategic oversight of the development and commercialization of linaclotide in China. AstraZeneca will have primary responsibility for the local operational execution.

Under the terms of the collaboration, AstraZeneca will make an upfront payment of \$25 million to Ironwood and will share the net profits and losses associated with linaclotide in China, with AstraZeneca carrying 55 percent of each until a certain specified milestone is achieved, moving to a 50/50 split thereafter. Ironwood will also be eligible for \$125 million in additional commercial milestone payments contingent on the achievement of certain sales targets.

In addition, the companies also announced today their agreement that Ironwood's sales force of approximately 160 experienced clinical sales specialists will promote AstraZeneca's NEXIUM[®] (esomeprazole magnesium) in the US. This agreement will augment AstraZeneca's existing interactions with gastroenterologists and primary care physicians on behalf of NEXIUM and the patients who need it. It will also provide Ironwood with an opportunity to increase its presence with the key gastrointestinal physicians in the US.

"A large percentage of adult patients who have IBS-C or who have chronic idiopathic constipation, may also suffer from gastroesophageal reflux disease," said Thomas McCourt, Chief Commercial Officer, Senior Vice President, Marketing and Sales, Ironwood Pharmaceuticals. "This agreement provides our experienced clinical sales specialists with the opportunity to bring two different and effective therapies to physicians for managing their patients who have these prevalent and troublesome gastrointestinal disorders."

About Linaclotide

Linaclotide is a guanylate cyclase-C (GC-C) agonist that is provided as an oral capsule intended for once-daily administration.

It binds to guanylate cyclase C locally in the intestine, with no measurable blood plasma concentrations, resulting in an increase in both intracellular and extracellular concentrations of cyclic guanosine monophosphate (cGMP). Elevations in intracellular cGMP are believed to stimulate secretion of intestinal fluid and accelerate gastrointestinal transit resulting in increased frequency of bowel movements. Elevations in extracellular cGMP are believed to decrease activity of pain-sensing nerves, which is thought to be responsible for a reduction in intestinal pain, according to non-clinical models.

About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is an entrepreneurial pharmaceutical company dedicated to the art and science of great drugmaking. Ironwood is located in Cambridge, Mass. To learn more, visit www.ironwoodpharma.com.

This press release contains forward looking statements. Investors are cautioned not to place undue reliance on these forwardlooking statements, including, but not limited to, the development plans for linaclotide in China, the potential for linaclotide to be approved for marketing by the State Food and Drug Administration in China, the commercialization opportunity for linaclotide in China, the potential for Ironwood to receive sales-related milestones, and the opportunity for Ironwood to promote NEXIUM in the United States. 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 the risks that advancements in the linaclotide development program in China do not proceed as expected, the State Food and Drug Administration in China does not agree with the Phase III clinical trial design, Ironwood and AstraZeneca are unable to successfully complete the Phase III clinical trial or to demonstrate the efficacy of linaclotide in patients in China in order to obtain marketing authorization, serious adverse events arise in patients that are deemed to be definitely or probably related to linaclotide treatment, Ironwood and AstraZeneca are unable to effectively commercialize linaclotide in China, Ironwood is unable to successfully co-promote NEXIUM in the U.S., Ironwood or AstraZeneca terminates all or part of the collaboration or co-promotion arrangement, as well as risks related to the difficulty of predicting regulatory approvals and the acceptance of and demand for new pharmaceutical products. Applicable risks also include those that are listed in Ironwood's Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, in addition to the risk factors that are listed from time to time in its Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and any subsequent SEC filings. Ironwood undertakes no obligation to update these forward-looking statements to reflect events or circumstances occurring after this press release. 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.

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialization of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation, oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com.

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