



Ironwood and Allergan Announce Settlement with Sun Pharma Resolving LINZESS® (linaclotide) Patent Litigation

CAMBRIDGE, Mass. & DUBLIN--(BUSINESS WIRE)-- [Ironwood Pharmaceuticals, Inc.](#) (NASDAQ: IRWD) and [Allergan plc](#) (NYSE: AGN) announced today that the companies have reached an agreement with wholly-owned subsidiaries of Sun Pharmaceutical Industries Ltd. (Sun Pharma, including its subsidiaries and/or associate companies), resolving patent litigation brought in response to Sun Pharma's abbreviated new drug application (ANDA) seeking approval to market a generic version of LINZESS (linaclotide) prior to the expiration of the companies' applicable patents.

Pursuant to the terms of the settlement, Ironwood and Allergan will grant the wholly-owned subsidiaries of Sun Pharma a license to market a generic version of LINZESS in the United States beginning on February 1, 2031 (subject to U.S. FDA approval), unless certain limited circumstances, customary for settlement agreements of this nature, occur. As a result of the settlement, all Hatch-Waxman litigation between the companies and Sun Pharma regarding LINZESS patents will be dismissed. Additional details regarding the settlement were not disclosed.

"Ironwood and Allergan have established LINZESS as the branded prescription market leader in the IBS-C and CIC category," said Tom McCourt, Chief Commercial Officer, Ironwood. "We are pleased to have resolved this patent litigation with Sun Pharma, as we believe it confirms the strength of our LINZESS intellectual property. Allergan and Ironwood are committed to continuing to grow the LINZESS franchise for many years to come."

As required by law, the companies will submit the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review.

Patent infringement litigations brought by the companies against other parties who have submitted ANDAs to the U.S. FDA seeking approval to market generic versions of LINZESS remain pending in the U.S. District Court for the District of Delaware, where the earliest scheduled trial date is June 17, 2019.

About Linaclotide

Linaclotide is a guanylate cyclase-C (GC-C) agonist that binds to the GC-C receptor locally, within the intestinal epithelium. 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 greater than 1.5 million unique patients in the United States having filled more than 9 million linaclotide prescriptions since launch, according to QuintilesIMS. In Europe, Allergan markets linaclotide under the brand name CONSTELLA® for the treatment of adults with moderate to severe IBS-C. In Japan, Ironwood's partner Astellas markets linaclotide under the brand name LINZESS for the treatment of adults with IBS-C. Ironwood also has partnered with AstraZeneca for development and commercialization of linaclotide in China, Hong Kong and Macau, and with Allergan for development and commercialization of linaclotide in all other territories worldwide.

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 commercializing two innovative primary care products: linaclotide, the U.S. branded prescription market leader for adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC), and lesinurad, which is approved to be taken with a xanthine oxidase inhibitor (XOI), or as a fixed-dose combination with allopurinol, for the treatment of hyperuricemia associated with gout. We are also advancing a pipeline of innovative product candidates in areas of significant unmet need, including uncontrolled gastroesophageal reflux disease, diabetic nephropathy, heart failure with preserved ejection fraction, achalasia and sickle cell disease. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. For more information, please visit www.ironwoodpharma.com or www.twitter.com/ironwoodpharma; information that may be important to investors will be routinely posted in both these locations.

About Allergan plc

Allergan plc (NYSE: AGN), headquartered in Dublin, Ireland, is a bold, global pharmaceutical company and a leader in a new industry model - Growth Pharma. Allergan is focused on developing, manufacturing and commercializing branded pharmaceutical, device, biologic, surgical and regenerative medicine products for patients around the world.

Allergan markets a portfolio of leading brands and best-in-class products for the central nervous system, eye care, medical aesthetics and dermatology, gastroenterology, women's health, urology and anti-infective therapeutic categories.

Allergan is an industry leader in Open Science, a model of research and development, which defines our approach to identifying and developing game-changing ideas and innovation for better patient care. With this approach, Allergan has built one of the broadest development pipelines in the pharmaceutical industry with 55+ mid-to-late stage pipeline programs currently in development.

Allergan's success is powered by our more than 18,000 global colleagues' commitment to being Bold for Life. Together, we build bridges, power ideas, act fast and drive results for our customers and patients around the world by always doing what is right.

With commercial operations in approximately 100 countries, Allergan is committed to working with physicians, healthcare providers and patients to deliver innovative and meaningful treatments that help people around the world live longer, healthier lives every day.

For more information, visit Allergan's website at www.Allergan.com.

LINZESS[®] and CONSTELLA[®] are trademarks of Ironwood Pharmaceuticals, Inc. Any other trademarks referred to in this press release are the property of their respective owners. All rights reserved.

Forward-Looking Statement

This press release contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about the resolution of patent litigation with Sun Pharma and all related settlement terms, including the date of generic entry and the potential for earlier generic entry under certain limited circumstances; the dismissal of all Sun Pharma Hatch-Waxman litigation regarding LINZESS; the submission of the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review; the coverage, strength and extent of the intellectual property covering LINZESS; and our commitment to grow the linaclotide franchise in the future. 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 decisions by regulatory and judicial authorities; competition and future business decisions made by us, as well as our competitors or potential competitors; the risk that we may never get sufficient patent protection for linaclotide or that we are not able to successfully protect such patents; the risk that we lose, or settle on less favorable terms, other linaclotide ANDA litigation, or that other ANDA filers enter the market earlier than February 1, 2031, as well as any other potential settlements; developments in the intellectual property landscape; and the risks listed under the heading "Risk Factors" and elsewhere in Ironwood's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, Allergan's Annual Report on Form 10-K for the year ended December 31, 2016 and in the subsequent SEC filings of each company. These forward-looking statements (except as otherwise noted) speak only as of the date of this press release, and Ironwood and Allergan undertake no obligation to update these forward-looking statements.

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