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

January 2, 2019

CAMBRIDGE, Mass. & DUBLIN--(BUSINESS WIRE)--Jan. 2, 2019-- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) and Allergan plc (NYSE: AGN) announced today that the companies have reached an agreement with Mylan Pharmaceuticals, Inc. (NASDAQ: MYL) resolving patent litigations brought in response to Mylan's abbreviated new drug applications (ANDAs) seeking approval to market generic versions of LINZESS (linaclotide) prior to the expiration of the companies' applicable patents. The settlement with Mylan is the third patent infringement settlement the companies have reached with respect to LINZESS.

Pursuant to the terms of the settlement, Ironwood and Allergan will grant Mylan a license to market its generic version of LINZESS 145 mcg and 290 mcg in the United States beginning February 5, 2030, and its generic version of LINZESS 72 mcg in the United States beginning August 5, 2030 (both 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 ongoing Hatch-Waxman litigations between the companies and Mylan regarding LINZESS patents pending in the U.S. District Court for the Northern District of West Virginia will be dismissed. Additional details regarding the settlement were not disclosed.

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 Allergan and Ironwood 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 2 million unique patients in the United States having filled approximately 10 million linaclotide prescriptions since launch, according to IQVIA. 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 discovered, developed and are commercializing linaclotide, the U.S. branded prescription market leader for adults with irritable bowel syndrome with constipation (IBS-C) or chronic idiopathic constipation (CIC). Our pipeline priorities for linaclotide include a Phase IIIb trial evaluating its efficacy and safety on multiple abdominal symptoms, including abdominal bloating, pain, and discomfort in adult patients with IBS-C, as well as research into a formulation of linaclotide designed to relieve pain across all IBS subtypes.

We are also advancing a pipeline of innovative product candidates in areas of significant unmet need, including persistent gastroesophageal reflux disease, diabetic nephropathy, heart failure with preserved ejection fraction 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 leader. 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.

Allergan's success is powered by our 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. For more information, visit Allergan's website at www.Allergan.com.

Forward-Looking Statements

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 Mylan 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 Mylan Hatch-Waxman litigation regarding LINZESS; and the submission of the settlement agreement to the U.S. Federal Trade Commission and the U.S. Department of Justice for review. 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 5, 2030, 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, 2018, Allergan's Annual Report on Form 10-K for the year ended December 31, 2017 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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