



## **Ironwood and Allergan Announce Settlement with Aurobindo 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 Aurobindo Pharma Ltd., resolving patent litigation brought in response to Aurobindo 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. The settlement with Aurobindo is the second patent infringement settlement the companies have reached with respect to LINZESS.

Pursuant to the terms of the settlement, Ironwood and Allergan will grant Aurobindo Pharma a license to market a generic version of LINZESS in the United States beginning on August 5, 2030 (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 litigation between the companies and Aurobindo Pharma regarding LINZESS patents will be dismissed. Additional details regarding the settlement were not disclosed.

"LINZESS is the leading branded treatment prescribed in the U.S. for adult sufferers of irritable bowel syndrome with constipation or chronic idiopathic constipation, with more than 10 million prescriptions filled," said Bill Meury, Executive Vice President and Chief Commercial Officer, Allergan. "We are pleased to have resolved the patent litigation with Aurobindo Pharma. Allergan and Ironwood continue to invest in the LINZESS franchise and to be confident in the product's market leadership."

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 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 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](http://www.ironwoodpharma.com) or [www.twitter.com/ironwoodpharma](https://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](http://www.Allergan.com). For more information, visit Allergan's website at [www.Allergan.com](http://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 Aurobindo 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 Aurobindo 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 confidence in the product's market leadership and strength of its growth trajectory. 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 August 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 Annual Report on Form 10-K for the year ended December 31, 2017, 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.

View source version on [businesswire.com](https://www.businesswire.com/news/home/20180503006491/en/): <https://www.businesswire.com/news/home/20180503006491/en/>

Allergan Global Corporate Media Relations

Amy Rose, 862-289-3072

or

Allergan U.S. Product Relations

Fran DeSena, 201-427-8762

or

Allergan Investor Relations

Daphne Karydas, 862-261-7558

or

Ironwood Investor and Media Relations

Meredith Kaya, 617-374-5082

[mkaya@ironwoodpharma.com](mailto:mkaya@ironwoodpharma.com)

Source: Ironwood Pharmaceuticals, Inc.

News Provided by Acquire Media