January 26, 2017

U.S. Food and Drug Administration Approves 72 mcg Dose of LINZESS® (linaclotide) for Adults with Chronic Idiopathic Constipation

-- LINZESS Now FDA-Approved in Three Dosage Strengths: 72 mcg and 145 mcg for CIC; 290 mcg for IBS-C --
-- New Dosage Strength Expected to be Available in First Quarter of 2017 --

CAMBRIDGE, Mass. and DUBLIN, Jan. 26, 2017 /PRNewswire/ -- Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) and Allergan plc (NYSE: AGN) announced today that the U.S. Food and Drug Administration (FDA) has approved a 72 mcg dose of LINZESS®(linaclotide) for the treatment of chronic idiopathic constipation (CIC) in adult patients.

The newly approved dose will provide physicians with dosing flexibility based on individual presentation or tolerability, in treating the large and heterogenous population of adult CIC patients. The new dose is expected to be available in the first quarter of 2017.

LINZESS is now FDA-approved in three dosage strengths: 290 mcg for adult patients with irritable bowel syndrome with constipation (IBS-C), and 145 mcg and a new 72 mcg for the treatment of adults with CIC.

Since the launch of LINZESS in December of 2012, nearly 1.5 million unique patients have filled nearly 7 million prescriptions, according to IMS Health data.[1]

"LINZESS is the branded prescription market leader in the treatment of adult patients with IBS-C or CIC, and we believe the availability of a 72 mcg dose will enhance the product's utility to physicians in treating patients across the broad CIC patient population, which encompasses up to 35 million adult Americans," said Tom McCourt, Chief Commercial Officer at Ironwood.

Bill Meury, Chief Commercial Officer at Allergan, said, "This approval is testimony to the ongoing commitment of our organizations to continue to innovate with LINZESS and to enhance patient care and refine the treatment of gastrointestinal disorders such as CIC."

The approval of LINZESS 72 mcg is based on results from a Phase III clinical trial of 1,223 adults with CIC. As previously reported, this trial met its primary endpoint; the 72mcg dose demonstrated statistically significant improvement in Complete Spontaneous Bowel Movements compared to placebo over 12 weeks. The most common adverse event was diarrhea; the rates of diarrhea and of discontinuations due to diarrhea were numerically lower for the 72 mcg dose than the 145 mcg dose in this trial. LINZESS has met all primary endpoints in each of its five pivotal U.S. Phase III trials, spanning three doses and two indications.

About Chronic Idiopathic Constipation
Chronic idiopathic constipation (CIC) is a functional gastrointestinal disorder estimated to impact as many as 35 million adult Americans. CIC is generally characterized by infrequent bowel movements (less than three times per week), but symptoms vary across this broad and heterogeneous patient population and may also include recurrent straining, lumpy or hard stools, and/or a sensation that the bowels are not fully empty. There are few available prescription treatment options for this condition.

About LINZESS (linaclotide)
LINZESS® is the #1 prescribed brand for the treatment of irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC), based on IMS Health data. Since its FDA approval in August of 2012 and subsequent launch in December 2012, nearly 1.5 million unique patients have filled nearly 7 million prescriptions for LINZESS, according to IMS Health.[1]

LINZESS is a once-daily capsule that helps relieve the abdominal pain and constipation associated with IBS-C, as well as the constipation, infrequent stools, hard stools and incomplete evacuation associated with CIC. The recommended dose is 290 mcg for IBS-C patients and 145 mcg for CIC patients, with a 72 mcg dose approved for use in CIC depending on individual

patient presentation or tolerability. LINZESS should be taken at least 30 minutes before the first meal of the day.

LINZESS is contraindicated in pediatric patients less than 6 years of age. The safety and effectiveness of LINZESS in pediatric patients less than 18 years of age have not been established. In neonatal mice, linaclotide increased fluid secretion as a consequence of GC-C agonism resulting in mortality within the first 24 hours due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years if age and older to develop severe diarrhea and its potentially serious consequences. In adults with IBS-C or CIC treated with LINZESS, the most commonly reported adverse event was diarrhea.

LINZESS is not a laxative; it is the first medicine approved by the FDA in a class called guanylate cyclase-C (GC-C) agonists. LINZESS contains a peptide called linaclotide that is structurally related to the naturally occurring peptides guanylin and uroguanylin, which activate the GC-C receptor in the intestine. Activation of GC-C is thought to result in two important outcomes, based on nonclinical studies. Linaclotide's activation of GC-C is thought to result in increased intestinal fluid secretion and accelerated transit and also to result in a decrease in the activity of pain-sensing nerves in the intestine.

Ironwood and Allergan plc are co-promoting LINZESS in the United States and Mexico. Linaclotide is marketed by Allergan for the treatment of adults with moderate to severe IBS-C in Europe and Canada under the brand name CONSTELLA®. Ironwood's partner Astellas received approval of linaclotide in Japan 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.

INDICATIONS AND USAGE
LINZESS (linaclotide) is indicated in adults for the treatment of both irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC).

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS

LINZESS is contraindicated in patients less than 6 years of age. In nonclinical studies in neonatal mice, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths due to dehydration. Use of LINZESS should be avoided in patients 6 years to less than 18 years of age. The safety and effectiveness of LINZESS has not been established in patients less than 18 years of age.

Contraindications

- LINZESS is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.

- LINZESS is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions

Pediatric Risk

- LINZESS is contraindicated in patients less than 6 years of age. The safety and effectiveness of LINZESS in patients less than 18 years of age have not been established. In neonatal mice, linaclotide increased fluid secretion as a consequence of GC-C agonism resulting in mortality within the first 24 hours due to dehydration. Due to increased intestinal expression of GC-C, patients less than 6 years of age may be more likely than patients 6 years of age and older to develop severe diarrhea and its potentially serious consequences.

- Use of LINZESS should be avoided in pediatric patients 6 to less than 18 years of age. Although there were no deaths in older juvenile mice, given the deaths in young juvenile mice and the lack of clinical safety and efficacy data in pediatric patients, use of LINZESS should be avoided in pediatric patients 6 years to less than 18 years of age.

Diarrhea

- Diarrhea was the most common adverse reaction in LINZESS-treated patients in the pooled IBS-C

and CIC double-blind placebo-controlled trials. The incidence of diarrhea was similar in the IBS-C and CIC populations. Severe diarrhea was reported in 2% of 145 mcg and 290 mcg LINZESS-treated patients, and in <1% of 72 mcg LINZESS-treated CIC patients. If severe diarrhea occurs, dosing should be suspended and the patient rehydrated.

Common Adverse Reactions (incidence ≥2% and greater than placebo)

- In IBS-C clinical trials: diarrhea (20% vs 3% placebo), abdominal pain (7% vs 5%), flatulence (4% vs 2%), headache (4% vs 3%), viral gastroenteritis (3% vs 1%) and abdominal distension (2% vs 1%).

- In CIC trials of a 145 mcg dose: diarrhea (16% vs 5% placebo), abdominal pain (7% vs 6%), flatulence (6% vs 5%), upper respiratory tract infection (5% vs 4%), sinusitis (3% vs 2%) and abdominal distension (3% vs 2%). In a CIC clinical trial of a 72 mcg dose: diarrhea (19% vs 7% placebo) and abdominal distension (2% vs <1%).

Please see full Prescribing Information: http://www.allergan.com/assets/pdf/linzess_pi

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) for the treatment of hyperuricemia associated with uncontrolled gout. We are also advancing a pipeline of internally and externally generated innovative product candidates in areas of significant unmet need, including uncontrolled gastroesophageal reflux disease and vascular and fibrotic diseases. 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 pharmaceuticals, devices and biologic 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, the Company's R&D model, which defines our approach to identifying and developing game-changing ideas and innovation for better patient care. This approach has led to Allergan building one of the broadest development pipelines in the pharmaceutical industry with 65+ mid-to-late stage pipeline programs in development.

Our Company's success is powered by our more than 16,000 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.

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 availability of the 72 mcg dose of linaclotide and the timing thereof, the potential benefits of the 72 mcg dose of linaclotide and its ability to help treat individual patients' needs, LINZESS's position in the market as the #1 prescribed brand for the treatment of IBS-C and CIC, and prevalence and unmet need. 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 preclinical and clinical development, manufacturing and formulation development; the effectiveness of commercialization efforts by Ironwood and Allergan; efficacy, safety and tolerability of linaclotide; decisions by regulatory authorities; the risk that we may never get sufficient patent protection for linaclotide and our product candidates or that we are not able to successfully

protect such patents; developments in the intellectual property landscape; challenges from and rights of competitors or potential competitors; 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, 2016, Allergan's Annual Report on Form 10-K for the year ended December 31, 2015 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.

1. Data on file, Ironwood Pharmaceuticals/Allergan

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