March 9, 2015

Exact Sciences and Ironwood Pharmaceuticals Enter Co-Promotion Agreement for Cologuard®

MADISON, Wis., & CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Exact Sciences Corp. (NASDAQ: EXAS) and Ironwood Pharmaceuticals, Inc. (NASDAQ: IRWD) announced today an agreement to co-promote Exact Sciences' Cologuard®, the first and only FDA-approved noninvasive stool DNA screening test for colorectal cancer. The agreement provides for the near-term expansion of Cologuard promotional efforts through the use of Ironwood's clinical sales specialists to more than double the number of physicians reached in the United States. The non-exclusive co-promotion agreement covers an initial one-year term with the opportunity for extension.

Ironwood's clinical sales specialists are expected to begin Cologuard promotional efforts in the second quarter of 2015, educating health care practitioners to whom they currently detail LINZESS® (linaclotide). LINZESS is the first and only approved therapy in a class of drugs that works differently to treat irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC) in adults. The agreement augments Exact Sciences' 140 sales representatives with Ironwood's team of approximately 160 sales representatives.

"As we continue growing the Cologuard business and providing world-class service, this agreement offers an opportunity to broaden our reach among primary care physicians and gastroenterologists by engaging with them through sales calls and medical education," said Maneesh Arora, chief operating officer of Exact Sciences. "Ironwood's brand and the expertise of their proven sales force complement the early success of our sales team and strong physician interest in Cologuard."

"We at Ironwood are committed to innovation in gastrointestinal health, and we look forward to expanding our conversations with health care providers to include the importance of colon cancer screening," said Tom McCourt, chief commercial officer of Ironwood. "Primary care physicians and gastroenterologists place a high priority on cancer screening and diagnostics. We have built strong relationships with many of these physicians through our discussions about LINZESS for the treatment of adult IBS-C or CIC patients, and we believe introducing Cologuard to these physicians has the potential to enable millions of average risk patients unwilling to undergo a screening colonoscopy to be screened for colon cancer."

Under the terms of the deal, Ironwood will be compensated from the net sales generated from the physicians on whom they call. LINZESS will remain the first-position product for the Ironwood sales team. Exact Sciences will maintain responsibility for all other aspects of commercialization of Cologuard. The companies will also collaborate on medical education initiatives to support more in-depth understanding of Cologuard and the importance of colorectal cancer screening.

About Cologuard

Cologuard is the first and only FDA approved noninvasive stool DNA screening test for colorectal cancer. Cologuard offers people 50 years and older who are at average risk for colorectal cancer an easy-to-use screening test. Cologuard is intended for the qualitative detection of colorectal neoplasia associated DNA markers and for the presence of occult hemoglobin in human stool. Cologuard found 92 percent of colorectal cancers with 87 percent specificity in a cross-sectional study that included 10,000 average risk patients. Cologuard does not require medication, dietary restrictions or bowel preparation prior to taking the test. Both false positives and false negatives do occur. Any positive result should be followed by a diagnostic colonoscopy. A negative Cologuard test result does not guarantee absence of cancer or advanced adenoma. Following a negative result, patients should continue participating in a screening program at an interval and with a method appropriate for the individual patient. Cologuard performance when used for repeat testing has not been evaluated or established. Available by prescription only, Cologuard is not right for everyone. Ask your doctor or visit www.CologuardTest.com for more information.

About LINZESS (linaclotide)

LINZESS® is the first and only guanylate cyclase-C (GC-C) agonist approved by the FDA and is indicated for the treatment of both irritable bowel syndrome with constipation (IBS-C) and chronic idiopathic constipation (CIC) in adults. 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. LINZESS should be taken at least 30 minutes before the first meal of the day.

LINZESS is thought to work in two ways based on nonclinical studies. LINZESS binds to the GC-C receptor locally, within the intestinal epithelium. Activation of GC-C results in increased intestinal fluid secretion and accelerated transit and a decrease in the activity of pain-sensing nerves in the intestine. The clinical relevance of the effect on pain fibers, which is based on nonclinical studies, has not been established.

In placebo-controlled Phase III clinical trials of more than 2,800 adults, LINZESS was shown to reduce abdominal pain in IBS-C patients and increase bowel movement frequency in both IBS-C patients and CIC patients. Improvement in abdominal pain and constipation occurred in the first week of treatment and was maintained throughout the 12-week treatment period. Maximum effect on abdominal pain was seen at weeks 6-9 and maximum effect on constipation occurred during the first week. When a subset of LINZESS-treated patients in the trials were switched to placebo, they reported their symptoms returned toward pretreatment levels within one week, while placebo-treated patients switched to LINZESS reported symptom improvements. LINZESS is contraindicated in pediatric patients under 6 years of age. The use of LINZESS in pediatric patients 6 through 17 years of age should be avoided. In nonclinical studies, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths due to dehydration in young juvenile mice. The safety and efficacy of LINZESS in pediatric patients under 18 years of age have not been established. In adults with IBS-C or CIC treated with LINZESS, the most commonly reported adverse event was diarrhea.

Ironwood and Actavis plc are co-promoting LINZESS in the United States. Linaclotide is marketed by Almirall, S.A. for the treatment of adults with moderate to severe IBS-C in Europe under the brand name CONSTELLA®. Ironwood also has partnered with Astellas Pharma Inc. for development and commercialization of linaclotide in Japan and with AstraZeneca AB for development and commercialization in China.

LINZESS Important Safety Information

WARNING: PEDIATRIC RISK
LINZESS is contraindicated in pediatric patients under 6 years of age. In nonclinical studies, administration of a single, clinically relevant adult oral dose of linaclotide caused deaths due to dehydration in young juvenile mice. Use of LINZESS should be avoided in pediatric patients 6 through 17 years of age. The safety and efficacy of LINZESS has not been established in pediatric patients under 18 years of age.

Contraindications

- LINZESS is contraindicated in pediatric patients under 6 years of age.
- LINZESS is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

Warnings and Precautions

Pediatric Risk

- LINZESS is contraindicated in children under 6 years of age. The safety and effectiveness of LINZESS in pediatric patients under 18 years of age have not been established. In neonatal mice, increased fluid secretion as a consequence of GC-C agonism resulted in mortality within the first 24 hours due to dehydration. Due to increased intestinal expression of GC-C, children under 6 years of age may be more likely than older children and adults to develop significant diarrhea and its potentially serious consequences.
- Use of LINZESS should be avoided in pediatric patients 6 through 17 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 through 17 years of age.

Diarrhea

- Diarrhea was the most common adverse reaction of LINZESS-treated patients in the pooled IBS-C and CIC double-blind placebo-controlled trials. Severe diarrhea was reported in 2% of LINZESS-treated patients. The incidence of diarrhea was similar in the IBS-C and CIC populations.
- Patients should be instructed to stop LINZESS if severe diarrhea occurs and to contact their healthcare provider. The healthcare provider should consider dose suspension and rehydration.

Adverse Reactions

- In IBS-C clinical trials, the most common adverse reactions in LINZESS-treated patients (incidence ≥2% and greater than

placebo) were 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 clinical trials, the most common adverse reactions in LINZESS-treated patients (incidence ≥2% and greater than placebo) were 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%).

Please see full Prescribing Information including Boxed Warning: http://www.frx.com/pi/linzess_pi.pdf

About Ironwood Pharmaceuticals

Ironwood Pharmaceuticals (NASDAQ: IRWD) is focused on creating medicines that make a difference for patients, building value to earn the continued support of our fellow shareholders, and empowering our team to passionately pursue excellence. We discovered, developed and are commercializing linaclotide, which is approved in the United States and a number of other countries. Our pipeline priorities include exploring further opportunities for linaclotide, as well as leveraging our therapeutic expertise in gastrointestinal disorders and our pharmacologic expertise in guanylate cyclases to address patient needs across the upper and lower gastrointestinal tract. Ironwood was founded in 1998 and is headquartered in Cambridge, Mass. Connect with us at www.ironwoodpharma.com or on Twitter at www.twitter.com/ironwoodpharma; information that may be important to investors will be routinely posted in both these locations.

About Exact Sciences

Exact Sciences Corp. (NASDAQ: EXAS) is a molecular diagnostics company focused on the early detection and prevention of colorectal cancer. The company has exclusive intellectual property protecting its noninvasive, molecular screening technology for the detection of colorectal cancer. Cologuard is included in the colorectal cancer screening guidelines of the American Cancer Society and stool DNA is included in the U.S. Multi-Society Task Force on Colorectal Cancer. For more information, please visit the company's website at www.exactsciences.com, follow us on Twitter @ExactSciences or find us on Facebook.

This press release contains forward-looking statements. Investors of Ironwood Pharmaceuticals, Inc. or Exact Sciences Corp. are cautioned not to place undue reliance on these forward-looking statements, including, but not limited to, the promotional efforts and success of Ironwood's clinical sales specialists with respect to Cologuard and LINZESS. 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, but are not limited to, the potential that Ironwood may not effectively promote Cologuard. Applicable risks also include those that are listed under the heading "Risk Factors" and elsewhere in each of Exact Sciences' and Ironwood's Annual Report on Form 10-K for the year ended December 31, 2014, in addition to the risk factors that are listed from time to time in each of Exact Sciences' and Ironwood's Annual Reports on Form 10‐K, Quarterly Reports on Form 10‐Q and any other subsequent SEC filings. Neither Exact Sciences nor Ironwood undertakes any obligation to update these forward-looking statements to reflect events or circumstances occurring after this press release. Except as otherwise noted, 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.

Photos/Multimedia Gallery Available: http://www.businesswire.com/multimedia/home/20150309005899/en/

Ironwood Pharmaceuticals, Inc.
Media Relations:
Trista Morrison, 617-374-5095
tmorrison@ironwoodpharma.com
or
Investor Relations:
Meredith Kaya, 617-374-5082
mkaya@ironwoodpharma.com
or
Exact Sciences Corp.
Media and Investor Relations:
J.P. Fielder, 202-746-6352
jfielder@exactsciences.com

Source: Ironwood Pharmaceuticals, Inc. and Exact Sciences Corp.