Ardelyx Shares Positive Data on Symptom Response During Treatment With IBSRELA® (tenapanor) for IBS-C and hosts IBS-C Product Theater at ACG 2023

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WALTHAM, Mass., Oct. 23, 2023 (GLOBE NEWSWIRE) -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs, announced that they will share positive data on IBSRELA® (tenapanor) via an oral presentation and two posters at the American College of Gastroenterology (ACG) annual meeting, being held October 20 to 25 in Vancouver, Canada. IBSRELA, discovered and developed by Ardelyx, is a first-in-class treatment that is currently approved by the U.S. Food and Drug Administration to treat irritable bowel syndrome with constipation (IBS-C) in adults.

“We are excited to share new data that adds to the robust body of evidence supporting IBSRELA and its differentiated mechanism of action, which is bringing much needed improvement to the lives of people living with IBS-C,” said Laura Williams, MD, MPH, chief medical officer of Ardelyx. “Physicians and other professionals attending ACG 2023 work with IBS-C patients every day and know all too well how challenging this condition can be. We are hopeful that this data increases the enthusiasm we have already seen for this new treatment and the potential it has to reduce the burden of IBS-C symptoms.”

“The findings being presented today on the median time to first response with IBSRELA are particularly meaningful for patients seeking relief from the pain, bloating and discomfort associated with IBS-C and demonstrate how important it is to give patients a fair trial on IBSRELA,” added Brian E. Lacy, M.D., Ph.D., Professor of Medicine, Mayo Clinic. “While a significant proportion of patients will have an early positive response to IBSRELA treatment, patient response rates increase with continued therapy. This finding underscores the importance of maintaining treatment beyond 3-4 weeks, so as not to miss those patients who will improve with time.”

- The oral presentation, titled **Tenapanor Treatment Success for IBS-C Symptoms Increases with Duration of Therapy** led by Dr. Brian E. Lacy, Dr. Yang Yang and Dr. David P. Rosenbaum, will share findings from a pooled analysis of the phase 2b and phase 3 T3MPO studies of IBSRELA in adult patients. These studies looked at the effects of the drug on abdominal pain and other IBS-C symptoms. The new post-hoc data presented today evaluate the time to onset of tenapanor effect on bowel function and abdominal symptoms in adult patients with IBS-C. The researchers concluded that these patients experience a relatively quick onset of symptom relief under tenapanor treatment and that weekly response rates continued to increase with treatment duration.

- The first poster to be presented at the ACG meeting, titled **Tenapanor Can Improve Abdominal Symptoms Independent of Changes in Bowel Movement Frequency in Adult Patients with IBS-C,** also looks at data from the T3MPO studies to examine effects on abdominal pain and abdominal score 3 (AS3), independent of changes in bowel functions over the first 12 weeks of the study. The data showed that tenapanor improved abdominal symptoms regardless of improvement in complete solid bowel movements (CSBMs) in adult patients with IBS-C and that improvement in abdominal symptoms without improvement in CSBMs may be a result of tenapanor’s novel mechanism of action that has been shown to reduce both intestinal permeability and visceral hypersensitivity in nonclinical studies.

- The second poster, **Improvement in Bloating and Overall Complete Spontaneous Bowel Movement Response with Tenapanor Treatment: A Post Hoc Analysis of the IBS-C Clinical Studies,** analyzes data from the T3MPO studies to assess the relationship between improvement in bloating and overall CSBM response in patients treated with tenapanor. This analysis concluded that patients with tenapanor demonstrated a marked improvement in average weekly bloating score, and that patients who had an overall CSBM response had a greater improvement in bloating than those who did not.

These poster presentations are publicly available and can be accessed on demand here.

In addition to the poster presentations during ACG, Ardelyx is sponsoring a Product Theater titled **Discover a Different Mechanism of Action to Treat Adults With IBS-C: A Case Based Discussion** on Monday, October 23, 2023, from 2:30 to 3:00 PM PT at booth 2319 of the exhibit hall. During this Product Theater, Dr. Kavita Kongara, MD and Kimberly Orleck, PA-C, MPH, RD will share important clinical considerations in managing adult patients with IBS-C, including interactive patient case studies, along with efficacy and safety data from Ardelyx’s two phase three clinical trials.

IMPORTANT SAFETY INFORMATION

WARNING: RISK OF SERIOUS DEHYDRATION IN PEDIATRIC PATIENTS
IBSRELA is contraindicated in patients less than 6 years of age; in nonclinical studies in young juvenile rats administration of tenapanor caused deaths presumed to be due to dehydration. Avoid use of IBSRELA in patients 6 years to less than 12 years of age. The safety and effectiveness of IBSRELA have not been established in patients less than 18 years of age.

CONTRAINDICATIONS

- IBSRELA is contraindicated in patients less than 6 years of age due to the risk of serious dehydration.
- IBSRELA is contraindicated in patients with known or suspected mechanical gastrointestinal obstruction.

WARNINGS AND PRECAUTIONS
Risk of Serious Dehydration in Pediatric Patients

- IBSRELA is contraindicated in patients below 6 years of age. The safety and effectiveness of IBSRELA in patients less than 18 years of age have not been established. In young juvenile rats (less than 1 week old; approximate human age equivalent of less than 2 years of age), decreased body weight and deaths occurred, presumed to be due to dehydration, following oral administration of tenapanor. There are no data available in older juvenile rats (human age equivalent 2 years to less than 12 years).
- Avoid the use of IBSRELA in patients 6 years to less than 12 years of age. Although there are no data in older juvenile rats, given the deaths in younger rats and the lack of clinical safety and efficacy data in pediatric patients, avoid the use of IBSRELA in patients 6 years to less than 12 years of age.

Diarrhea
Diarrhea was the most common adverse reaction in two randomized, double-blind, placebo-controlled trials of IBS-C. Severe diarrhea was reported in 2.5% of IBSRELA-treated patients. If severe diarrhea occurs, suspend dosing and rehydrate patient.

MOST COMMON ADVERSE REACTIONS
The most common adverse reactions in IBSRELA-treated patients (incidence ≥2% and greater than placebo) were: diarrhea (16% vs 4% placebo), abdominal distension (3% vs <1%), flatulence (3% vs 1%) and dizziness (2% vs <1%).

INDICATION
IBSRELA (tenapanor) is indicated for the treatment of Irritable Bowel Syndrome with Constipation (IBS-C) in adults.

Please see full Prescribing Information, including Boxed Warning, for additional risk information.

About Irritable Bowel Syndrome with Constipation (IBS-C)
Irritable bowel syndrome with constipation (IBS-C) is a gastrointestinal disorder characterized by both abdominal pain and altered bowel movements, estimated to affect 12 million people in the U.S. IBS-C is associated with significantly impaired quality of life, reduced productivity, and substantial economic burden.

About IBSRELA for IBS-C
IBSRELA (tenapanor) is a locally acting inhibitor of the sodium/hydrogen exchanger 3 (NHE3), an antiporter expressed on the apical surface of the small intestine and colon primarily responsible for the absorption of dietary sodium. By inhibiting NHE3 on the apical surface of the enterocytes, tenapanor reduces absorption of sodium from the small intestine and colon, thus retaining luminal water content, which accelerates intestinal transit time and results in a softer stool consistency. IBSRELA has also been shown to reduce abdominal pain by decreasing visceral hypersensitivity and by decreasing intestinal permeability in animal models. In a rat model of colonic hypersensitivity, tenapanor reduced visceral hyperalgesia and normalized colonic sensory neuronal excitability.

About Ardelyx, Inc.
Ardelyx was founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. Ardelyx has two commercial products approved in the United States, IBSRELA® (tenapanor) and XPHOZAH® (tenapanor) as well as early-stage pipeline candidates. Ardelyx has agreements for the development and commercialization of tenapanor outside of the U.S. Kyowa Kirin has received approval for PHOZEVEL® (tenapanor) for hyperphosphatemia in Japan. A New Drug Application for tenapanor for hyperphosphatemia has been submitted in China with Fosun Pharma. Knight Therapeutics commercializes IBSRELA in Canada. For more information, please visit https://ardelyx.com/ and connect with us on X (formerly known as Twitter), LinkedIn and Facebook.

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