Ardelyx Presents Positive Data at DDW 2023 on IBSRELA® (tenapanor), a First-In-Class Treatment for IBS-C in Adults

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IBSRELA provides meaningful reduction of multiple abdominal symptoms

Patient-reported outcomes are strongly correlated with IBS-C abdominal symptom score

WALTHAM, Mass., May 09, 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, today announced that a new analysis from IBSRELA Phase 3 trial, T3MPO-2, was presented in a poster presentation at the 2023 Digestive Disease Week Conference (DDW 2023) that is now underway in Chicago, Illinois. IBSRELA, discovered and developed by Ardelyx, is a first-in-class treatment with a novel mechanism and triple action that is approved by the U.S. Food and Drug Administration to treat irritable bowel syndrome with constipation (IBS-C) in adults.

“Abdominal symptoms of IBS-C, including pain, bloating and discomfort, can have an extremely negative impact on patients’ quality of life,” said Brian E. Lacy, M.D., Ph.D., Professor of Medicine, Mayo Clinic. “The data presented in this poster demonstrate that patients treated with IBSRELA experienced significant improvement in abdominal symptoms and that this improvement correlates with patient reports of adequate relief. This data analysis provides further evidence of the important role IBSRELA, with its novel mechanism of action, can play in the treatment of IBS-C.”

Ardelyx Poster #Tu1618, entitled “*Analysis of Patient-Reported Treatment Satisfaction and Abdominal Score in Patients with Irritable Bowel Syndrome with Constipation (IBS-C) with Tenapanor,”* reported results from a post hoc analysis of the T3MPO-2 study of IBSRELA in adult patients with IBS-C to examine the relationship between patient-reported satisfaction (as measured by adequate relief and degree of relief) and improvement in abdominal symptoms. The Phase 3 T3MPO-2 study randomized patients to tenapanor 50 mg twice a day or matched placebo for 26 weeks of treatment. The analysis demonstrated that IBSRELA meaningfully reduced multiple abdominal symptoms in patients with IBS-C, including bloating, discomfort and pain, compared to placebo. The analysis also indicates that patient-reported treatment satisfaction was strongly correlated with the IBS-C abdominal score (AS3, combining mean weekly abdominal pain, bloating and discomfort scores) and could be a useful tool to assess clinically meaningful improvements in adult patients with IBS-C.

Poster presentations are now publicly available and can be accessed on demand HERE.

INDICATION
IBSRELA (tenapanor) 50mg BID is indicated for the treatment of Irritable Bowel Syndrome with Constipation (IBS-C) in adults.

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%).

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's first approved product, IBSRELA® (tenapanor) is available in the United States and Canada. Ardelyx is developing XPHOZAH® (tenapanor), a novel product candidate for the control of serum phosphorus in adult patients with chronic kidney disease (CKD) on dialysis, which has completed three successful Phase 3 trials. Ardelyx has a Phase 2 potassium lowering compound, RDX013, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease and an early-stage program in metabolic acidosis, a serious electrolyte disorder in patients with CKD. Ardelyx has established agreements with Kyowa Kirin in Japan, Fosun Pharma in China and Knight Therapeutics in Canada for the development and commercialization of tenapanor in their respective territories. For more information, please visit https://ardelyx.com/ and connect with us on Twitter, LinkedIn and Facebook.

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