Ardelyx Showcased Encouraging Data on Treatment Satisfaction and Efficacy of IBSRELA® (tenapanor) for IBS-C at GHAPP 2023

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WALTHAM, Mass., Sept. 11, 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, shared encouraging data on IBSRELA® (tenapanor) via two poster presentations presented at the 2023 Gastroenterology & Hepatology Advanced Practice Providers (GHAPP) Annual Conference currently being held in National Harbor, Maryland September 7-9. IBSRELA, discovered and developed by Ardelyx, is a first-in-class treatment with a novel mechanism that is approved by the U.S. Food and Drug Administration to treat irritable bowel syndrome with constipation (IBS-C) in adults.

“IBS-C can be incredibly challenging to manage and can significantly disrupt the quality of life for many patients who experience multiple symptoms, including abdominal pain, bloating and discomfort. There is a growing body of data that continues to expand our understanding of IBSRELA and how it works to provide symptomatic relief. These data provide additional evidence of IBSRELA’s safety and efficacy, bringing much needed relief to those living with IBS-C,” said Laura Williams, MD, MPH, chief medical officer of Ardelyx. “The data presented at GHAPP demonstrate that people with IBS-C are experiencing significant improvements in abdominal symptom scores when treated with IBSRELA and that efficacy and durability are consistent across a diverse group of patients. These symptomatic improvements are also manifested in patient reported outcomes of treatment satisfaction.”

The first poster presented, **Analysis of Patient-Reported Treatment Satisfaction and Abdominal Score in Patients with Irritable Bowel Syndrome with Constipation (IBS-C) Treated with Tenapanor,** which was previously presented at the 2023 Digestive Disease Week Conference, reported results from a post hoc analysis of the T3MPO-2 trial 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 trial randomized patients to tenapanor 50 mg twice a day or matched placebo for 26 weeks of treatment. This post hoc analysis found that IBSRELA-treated patients with IBS-C reported a reduction in abdominal symptom scores 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.

The second poster presented at GHAPP, **A Subgroup Efficacy Analysis in Patients with IBS-C from the Tenapanor Phase 3 Studies,** reported results from a pooled analysis from the T3MPO-1 and T3MPO-2 trials of IBRSELA in adult patients with IBS-C which evaluated patients based on baseline characteristics including abdominal pain severity, sex, age and race to better understand efficacy across these subgroups. Patients were randomized to tenapanor 50 mg twice per day or placebo for 12 weeks in T3MPO-1 and for 26 weeks in T3MPO-2. The post hoc pooled analysis found that a higher proportion of patients randomized to tenapanor versus placebo had a durable complete spontaneous bowel movement (CSBM) response. Additionally, for most subgroups, a higher proportion of patients randomized to tenapanor versus a placebo had an early CSBM and spontaneous bowel movement (SBM) response. The analysis also indicated that the results were not affected by a variety of patient characteristics, including age, race, sex and those with differing baseline abdominal pain severity scores.

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'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 phosphate in adult patients with chronic kidney disease (CKD) on dialysis who have had an inadequate response or intolerance to phosphate binder therapy, which has completed three successful Phase 3 trials and an additional two Phase 4 open label 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 X (formerly Twitter), LinkedIn and Facebook.

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