Ardelyx Shares Preliminary Data on Use of IBSRELA® (tenapanor) in Pediatric IBS-C Patients at NASPGHAN 2023

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WALTHAM, Mass., Oct. 04, 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 shared data on the investigational use of IBSRELA® (tenapanor) in pediatric patients via two poster presentations presented at the 2023 North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) Annual Meeting, currently being held in San Diego, California. IBSRELA, discovered and developed by Ardelyx, is a first-in-class treatment with a differentiated mechanism of action that is currently approved by the U.S. Food and Drug Administration to treat irritable bowel syndrome with constipation (IBS-C) in adults. The safety and effectiveness of IBSRELA have not been established in patients less than 18 years of age and IBSRELA is contraindicated in patients less than 6 years of age.

“IBSRELA has already shown that its mechanism of action can bring clinically meaningful and significant improvements on constipation and abdominal symptoms for adults living with IBS-C and we are further evaluating the efficacy and safety of IBSRELA in certain pediatric IBS-C patients,” said Laura Williams, MD, MPH, chief medical officer of Ardelyx. “With nearly 6% of adolescents believed to have IBS, and IBS-C being the predominant subtype, we know there is a real need for safe and effective treatments for a condition that can significantly affect quality of life for these young people. The data presented at NASPGHAN, while preliminary and blinded to treatment assignment, is an important step towards assessing the safety and efficacy of IBSRELA among pediatric populations.”

The first poster presented, **Trial In Progress: R-Ally, A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Tenapanor in Pediatric Patients with IBS-C,** details the design and methods of the ongoing R-Ally Phase 3 Trial aimed at assessing the safety, tolerability and efficacy, of tenapanor in patients ages 12 to 17 with IBS-C. Patients enrolled in the study will be administered either tenapanor (25mg or 50mg) or placebo for 12 consecutive weeks. The primary endpoint for the study is an increase in spontaneous bowel movements of ≥ 2 and a ≥ 30% reduction in abdominal pain from baseline, both during the same week, for ≥ 6 out of 12 weeks. The study was launched in November 2022.

The second poster shown at NASPGHAN, **Preliminary Blinded Safety Data from R-Ally, A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Tenapanor in Pediatric Patients with IBS-C,** shared preliminary blinded safety data from an ongoing investigational study designed to assess the safety, tolerability and efficacy of tenapanor (25mg and 50mg) compared to placebo in pediatric patients between the ages of 12 and 17 with IBS-C. The study expects to enroll approximately 180 pediatric patients with IBS-C who meet the entry criteria during a two-week screening period at up to 60 US sites. The poster presentation detailed that as of May 2023, 42 pediatric patients had been screened, 23 had been included in the randomized trial and begun treatment and three have completed the study. Among these, there were no serious treatment-emergent adverse events, and all that were reported were resolved and considered unrelated to the study drug, except for diarrhea. This blinded data is consistent with safety results seen in previous pivotal studies of adult patients with IBS-C and, to date, there have been no unexpected safety concerns observed.

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.

Investor and Media Contacts:
Caitlin Lowie
clowie@ardelyx.com

Kimia Keshtbod
kkeshtbod@ardelyx.com

Source: Ardelyx, Inc.