Ardelyx Presents Additional Data at the 2024 Digestive Disease Week Conference on IBSRELA® (tenapanor), a First-In-Class Treatment for IBS-C in Adults

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WALTHAM, Mass., May 21, 2024 (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 data supporting additional positive clinical observations of IBSRELA® (tenapanor) was presented at the 2024 Digestive Disease Week Conference (DDW), currently taking place in Washington, D.C. IBSRELA is a first-in-class treatment that is approved by the U.S. Food and Drug Administration to treat irritable bowel syndrome with constipation (IBS-C) in adults.

"We are thrilled to share new data on the safety and efficacy of IBSRELA in adults with IBS-C at this year's DDW Conference as we seek to continually elucidate its potential benefit in this patient population. These data provide additional information for both patients and prescribers as they consider IBSRELA as a potential new treatment option when symptoms of IBS-C persist despite current therapies," said Laura Williams, MD MPH, chief medical officer of Ardelyx. "These analyses provide further evidence of the role IBSRELA could play, with its novel mechanism of action, in the treatment of IBS-C."

Poster # Tu1658, entitled "*Efficacy of Tenapanor in Patients with Irritable Bowel Syndrome with Constipation (IBS-C): A Post Hoc Analysis of Patients with and Without Prior Use of Other IBS-C Prescription Medications from The Phase 3 T3MPO-1 and T3MPO-2 Studies,*" reported results from a post hoc analysis of the T3MPO-1 and T3MPO-2 studies of tenapanor in adult patients with IBS-C to examine if there was a difference in efficacy between patients who had prior use of other IBS-C prescription medications and those without. A clinically meaningful response to tenapanor – defined as a complete spontaneous bowel movement response and an abdominal pain response in the same week for ≥6 of the first 12 treatment weeks – was observed among adults with IBS-C regardless of prior IBS-C prescription medication use.

Poster # Tu1663, entitled "*Comparing the Efficacy of Tenapanor in Irritable Bowel Syndrome with Constipation in Hispanic vs Non-Hispanic Patients: A Posthoc Analysis of Patients in the Phase 3 T3MPO-1 and T3MPO-2 Studies,*" reported results from a pooled analysis of the T3MPO-1 and
T3MPO-2 studies of tenapanor in adult patients with IBS-C to examine the relationship between the efficacy of tenapanor and patients of Hispanic ethnicity. Per the analysis, efficacy of tenapanor was comparable, or more pronounced, in Hispanic patients than in non-Hispanic patients.

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

About IBSRELA® (tenapanor)
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 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.

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
- 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 Ardelyx
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). Ardelyx has agreements for the development and commercialization of tenapanor outside of the U.S. Kyowa Kirin commercializes 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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Source: Ardelyx, Inc.