Ardelyx Presents Data Supporting IBSRELA® (tenapanor) at Digestive Disease Week 2025 Conference

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Analysis of IBS in America 2024 Real-World Survey Demonstrates that severity of IBS-C correlates with financial hardship and distress

WALTHAM, Mass., May 06, 2025 (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 the company presented data supporting the company's first-in-class retainagogue, IBSRELA ® (tenapanor), as well as results from the IBS in America 2024 supplemental survey, at the Digestive Disease Week Conference (DDW), now underway in San Diego. IBSRELA is approved by the U.S. Food and Drug Administration to treat irritable bowel syndrome with constipation (IBS-C) in adults.

"Ardelyx is committed to continuing to grow our understanding both of the IBS patient experience and the possible impact that our first-in-class retainagogue, IBSRELA, can have on different patient populations," said Laura Williams, Chief Patient Officer. "We are especially pleased to continue our partnership with the IBS in America Real-World Survey which helps unveil new insights into the lived experience of patients with IBS, especially as it relates to quality of life. We are also pleased to be able to share data we continue to collect on the safety and tolerability of IBSRELA in other important patient groups."

Poster # Mo1257, entitled *"Patient-Reported IBS-C Symptom Severity Correlates Positively With Financial Burden: Results From the IBS in America 2024 Real-World Survey,"* demonstrated that greater IBS-C symptom severity is associated with greater financial hardship and distress, or financial toxicity. Based on data from the IBS in America 2024 Real-World supplemental survey, the Functional Assessment of Chronic Illness Therapy Measure of Financial Toxicity (FACIT-COST®) and Patient-Reported Outcomes Measurement Information System® (PROMIS®) gastrointestinal (GI) symptom scales were used to assess financial toxicity and symptoms, respectively.

Poster #Sa1643, entitled *"Safety and Tolerability of Tenapanor in Pediatric Patients With Irritable Bowel Syndrome With Constipation: An Analysis of Blinded Safety Data from a Phase 3 Study and its Open-Label Extension,"* reports interim, blinded safety results from the Phase 3 R-ALLY study of tenapanor in pediatric patients aged ≥12 to <18 years-old with IBS-C, and its open-label safety extension study. No serious adverse events or unexpected safety signals were reported as part of either study. Diarrhea was the only adverse event related to study drug, which is consistent with tenapanor's mechanism of action.

Poster #Sa1673, entitled *"Neither Tenapanor nor its Major Metabolite Were Detected in the Breast Milk of Healthy Lactating Females After 4 Days of Dosing: A Phase 1, Open-Label, Pharmacokinetic Study,"* presents data from a four-day study that was conducted to assess the pharmacokinetics of tenapanor and its primary metabolite, M1, in breast milk, as well as the safety and tolerability of tenapanor in healthy lactating females. The results of the study showed that tenapanor was not present at detectable levels in the breast milk of healthy lactating females after repeated oral administration. Tenapanor and M1 were below the limit of quantitation at all concentrations and all time points, and no unexpected treatment-emergent adverse events were reported.

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 approved 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.