Ardelyx Presents Data that Continues to Support the Benefits of IBSRELA® (tenapanor) at the American College of Gastroenterology's 2025 Annual Meeting

October 28, 2025

IBSRELA patients reported treatment satisfaction in real-world survey

Post-hoc analysis of T3MPO-1 and T3MPO-2 studies demonstrates effectiveness of IBSRELA in reducing abdominal bloating for patients with IBS-C

Analysis of electronic health records suggests IBSRELA may reduce burden to healthcare system

WALTHAM, Mass., Oct. 28, 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) at the American College of Gastroenterology's (ACG) Annual Scientific Meeting, now underway in Phoenix. IBSRELA is approved by the U.S. Food and Drug Administration to treat irritable bowel syndrome with constipation (IBS-C) in adults.

"At Ardelyx, we remain deeply committed to advancing our understanding of the impact IBS-C has on patients and the potential for IBSRELA to address the symptoms of the condition and support an improved quality of life for patients," said Edward Conner, MD, Chief Medical Officer. "The data we presented at ACG highlights three important aspects of IBS-C that affect patients: That there are gaps in treatment satisfaction, that abdominal bloating is one of the most bothersome symptoms, and that frequent visits to healthcare professionals can be burdensome. Results from these data build on the established efficacy, safety and tolerability profile of IBSRELA and highlight the continued value in helping patients manage the burden of IBS-C."

Poster # P5062, entitled *"Treatment Satisfaction With Tenapanor (IBSRELA): Real-World Survey of Patients With Irritable Bowel Syndrome With Constipation,"* reports data from a real-world survey of patients receiving tenapanor for the treatment of IBS-C. The survey was conducted to assess treatment satisfaction, IBS-C symptom resolution and improvement in quality of life. Overall, the findings support the effectiveness of tenapanor in the management of IBS-C, with a majority of patients reporting treatment satisfaction (88%) and improvements in constipation (95%), bloating (75%), and abdominal pain (84%). More than 70% of patients reported improved ability to participate in daily activities including work, social activities and exercise. Overall, 76% of participants expressed that tenapanor is better than other IBS-C medications they have used.

Poster # P0809, entitled *"Tenapanor Improves Abdominal Bloating Symptoms in Patients With IBS-C Experiencing Moderate to Severe Bloating,"* demonstrates, based on the Phase 3 T3MPO-1 and T3MPO-2 studies, that tenapanor may be effective in reducing bloating for patients with IBS-C and that a clinically meaningful reduction in bloating can be experienced as early as week one of treatment onset and sustained through the duration of treatment. Abdominal bloating is one of the most bothersome symptoms of IBS-C, yet it is not a typical primary endpoint in clinical trials.

Poster # P0787, entitled *"Reduction in Gastrointestinal Visits and Portal Messaging Following Tenapanor (IBSRELA) Initiation for Community Gastrointestinal Patients,"* reports data from an ongoing electronic health record study to understand real-world use and outcomes of IBS-C medications in community gastrointestinal (GI) practices. The preliminary findings indicate that GI-related clinical encounters and patient portal message activity substantially decreased after tenapanor initiation among patients with high pre-tenapanor healthcare resource utilization (HCRU). This suggests that tenapanor may reduce burden on the healthcare system and patients with IBS-C by reducing high HCRU, potentially leading to cost savings.

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.

Investor and Media Contacts:
Lindsey Manuel
lmanuel@ardelyx.com

Source: Ardelyx, Inc.