Ardelyx Announces Publication of a Review Article Demonstrating Rapid and Meaningful Symptom Relief with Tenapanor in IBS-C

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Post hoc analysis supports a reduction of time to first bowel movement and a consistent improvement in abdominal symptoms, including pain, discomfort, and bloating, during 12 weeks of treatment

WALTHAM, Mass., March 09, 2026 (GLOBE NEWSWIRE) -- Ardelyx, Inc. (Nasdaq: ARDX), a biopharmaceutical company focused on the development and commercialization of innovative medicines that meet significant unmet medical needs, today announced the publication of data from its IBS-C clinical development program, "Tenapanor is associated with earlier and sustained symptom relief in IBS-C: a post hoc analysis" in *Therapeutic Advances in Gastroenterology*, an international, peer-reviewed, open-access journal focused on advancing clinical practice and research in digestive diseases. Tenapanor, branded as IBSRELA® (tenapanor), is a first-in-class retainagogue that is approved by the U.S. Food and Drug Administration to treat irritable bowel syndrome with constipation (IBS-C) in adults.

The post-hoc analysis consisting of pooled data from three clinical trials (one Phase 2b and two Phase 3 studies), supports that tenapanor provides both rapid and sustained relief for adults living with IBS-C, a chronic condition that can disrupt daily life. Patients taking tenapanor reported improvements in bowel movement frequency as early as two weeks, and meaningful relief from abdominal symptoms including pain, discomfort, and bloating within 4–5 weeks.

Continued therapy through 12 weeks increased the likelihood of reporting meaningful symptom improvement and maintenance of benefits across multiple symptoms, highlighting the importance of patients remaining on therapy for an adequate amount of time to fully evaluate their individual benefit potential.

"Tenapanor has been shown to provide meaningful symptom relief for patients with IBS-C, but healthcare providers and patients often want to understand how quickly they can expect to see improvements and whether continued treatment will make a difference," said Brian E. Lacy, M.D., Ph. D., Professor of Medicine, Mayo Clinic and the lead author of the publication. "This post-hoc analysis offers practical, week-by-week insights into the timing and durability of tenapanor's effects, helping healthcare providers set realistic expectations, support patients in achieving sustained improvement across multiple symptoms, and integrate tenapanor into routine clinical care."

This research shows that tenapanor delivers a sustained response for some adults with IBS-C, providing both a clear view of symptom improvement and practical insights for clinicians. The analysis demonstrates "sustained response," defined as improvement maintained over consecutive weeks, may be achieved by some patients and supports that patients who continued therapy were more likely to achieve meaningful improvements across both bowel and abdominal symptoms. There were no new or unexpected safety findings in this post-hoc analysis, and tenapanor was generally well tolerated, with transient, mild-to-moderate diarrhea as the most common adverse event. These findings offer actionable guidance for healthcare providers, helping them tailor treatment plans, educate patients on symptom response over time, and set realistic expectations.

The article is available online and can be accessed 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.

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 Ardelyx
Ardelyx is a commercial-stage biopharmaceutical company focused on the development and commercialization of innovative medicines that meet significant unmet medical needs. Ardelyx has two commercial products approved in the United States, IBSRELA® (tenapanor) and XPHOZAH® (tenapanor). The company's pipeline includes the Phase 3 development of tenapanor for chronic idiopathic constipation (CIC) and RDX10531, a next-generation NHE3 inhibitor with potential application across multiple therapeutic areas. 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.