Ardelyx Announces Three Abstracts Accepted for Poster Presentations at Digestive Disease Week 2025 Conference

April 24, 2025

WALTHAM, Mass., April 24, 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 will present 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 upcoming Digestive Disease Week Conference (DDW), to be held May 3-6, 2025, 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.

Title: **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**
Authors: Thomas Wallach, Mihaela Ringheanu, Ana Roig Cantisano, Yang Yang, Karishma Raju, Jocelyn Tabora, Susan Edelstein
Poster Number: Sa1643
Date/Time: May 3, 2025, from 12:30 PM to 1:30 PM PDT

Title: **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**
Authors: Darren Brenner, Karishma Raju, Kenji Kozuka,Yang Yang, Suling Zhao, Susan Edelstein
Poster Number: Sa1673
Date/Time: May 3, 2025, from 12:30 PM to 1:30 PM PDT

Title: **Patient-Reported IBS-C Symptom Severity Correlates Positively With Financial Burden: Results From the IBS in America 2024 Real-World Survey**
Authors: Eric Shah, Luisa Scott, Johannah Ruddy, Elizabeth Stremke, Laura Williams, Baharak Moshiree
Poster Number: Mo1257
Date/Time: May 5, 2025, from 12:30 PM to 1:30 PM PDT

In addition to the poster presentations during DDW, Ardelyx is sponsoring a Product Theater titled: ***"Integrating a Different Mechanism of Action, a different Class of Therapy, Into the Treatment of Adults with IBS-C,"*** on May 4, 2025, from 12:50-1:35 PM PDT, where Satish Rao, MD, and Christina Hanson, NP, will share important clinical considerations in managing adult patients with IBS-C. The presentation will include interactive patient case studies, along with efficacy and safety data from two Phase 3 clinical trials.

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.