



Ardelyx to Present Additional Data Supporting First-In-Class IBSRELA® (tenapanor) for Adults with Irritable Bowel Syndrome with Constipation at the 2024 Digestive Disease Week Conference

May 7, 2024

WALTHAM, Mass., May 07, 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 additional data supporting IBSRELA® (tenapanor) will be presented at the 2024 Digestive Disease Week Conference (DDW), to be held May 18-21, 2024, in Washington, D.C. IBSRELA is approved by the U.S. Food and Drug Administration to treat irritable bowel syndrome with constipation (IBS-C) in adults.

Title: **Efficacy of Tenapanor in Patients with Irritable Bowel Syndrome With Constipation (IBS-C): A Posthoc Analysis of Patients With and Without Prior Use of Other IBS-C Prescription Medications From the Phase 3 T3MPO-1 and T3MPO-2 Studies**

Authors: Eric Shah, Brian Lacy, Yang Yang, Susan Edelstein, David Rosenbaum

Poster Number: Tu1658

Date/Time: May 21, 2024, from 12:30 PM to 1:30 PM EDT (UTC -4)

Title: **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**

Authors: Rosita Frazier, William Hasler, Yang Yang, Susan Edelstein, David Rosenbaum

Poster Number: Tu1663

Date/Time: May 21, 2024, from 12:30 PM to 1:30 PM EDT (UTC -4)

In addition to the poster presentations during DDW, Ardelyx is sponsoring a Product Theater titled: “**Discover IBSRELA: a Different Mechanism of Action to Treat Adults With IBS-C: A Case-Based Discussion,**” on May 19, 2024, from 2:30-3:15 PM EDT, where Brooks Cash, MD, will lead an engaging discussion about important clinical considerations for managing IBS-C in adult patients. The presentation will include interactive patient case studies, along with IBSRELA efficacy and safety data from the Phase 3 clinical trial program.

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 $\geq 2\%$ 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) as well as early-stage pipeline candidates. 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](#).

Investor and Media Contacts:

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Source: Ardelyx, Inc.