Ardelyx Announces Publication of a Review Article Exploring the Patient Burden and Therapeutic Landscape of IBS-C in the U.S. in Clinical and Experimental Gastroenterology

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WALTHAM, Mass., Oct. 09, 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 the recent publication of a review article, titled “Review of the Patient Burden and Therapeutic Landscape of Irritable Bowel Syndrome With Constipation in the United States” in *Clinical and Experimental Gastroenterology,* an international, peer reviewed, open access journal focusing on all aspects of gastroenterology research, as well as clinical results in human, animal and in vitro studies that shed light on disease processes and potential new therapies.

The article provides an overview of treatment options and disease management for irritable bowel syndrome with constipation (IBS-C) from a U.S. perspective and discusses the importance of the relationship between patient and health care provider in diagnosis and treatment. It recommends a positive diagnostic strategy for IBS-C, based on clinical history, physical examination, and minimal laboratory tests.

“IBS-C patients often experience a high level of disease burden across a variety of factors which extend beyond the physical symptoms associated with the condition. Patients often report negative economic, social and mental health impacts due to IBS-C, which makes even daily activities challenging,” said Morgan Allyn Sendzischew Shane, MD, Division of Gastroenterology and Digestive Disease, University of Miami and lead author of the article. “It’s critical that the larger healthcare community understands the full patient experience, especially as we see how important the patient and healthcare provider relationship is in regard to diagnosis and treatment.”

The authors review the substantial societal burden in terms of health care costs, opportunity costs and decreased quality of life that comes with IBS-C. The article also reviews the treatment journey a patient with IBS-C may experience, beginning with lifestyle interventions and nonpharmacologic options, with progression to a U.S. FDA-approved therapy. IBSRELA® (tenapanor) is identified as one of the currently approved therapies, with data from the T3MPO-1 and T3MPO-2 studies included within the review. IBSRELA is a first-in-class treatment for IBS-C in adults that is approved by the U.S. Food and Drug Administration.

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. Please see full Prescribing Information, including Boxed Warning, for additional risk information.

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 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.

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Source: Ardelyx, Inc.