Ardelyx Announces Additional Data Supporting the Efficacy and Safety of First-In-Class IBSRELA® (tenapanor) for Adults with IBS-C, to be Presented at DDW 2022

May 17, 2022

WALTHAM, Mass., May 17, 2022 /PRNewswire/ -- 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 the efficacy and safety of IBSRELA will be presented in three posters at the 2022 Digestive Disease Week Conference (DDW 2022) to be held May 21-24, 2022, in San Diego, California and virtually.

Ardelyx Poster Presentations:

Title:	**Long Term Treatment with Tenapanor Improves Abdominal Pain and Other Abdominal Symptoms Associated with IBS-C**
Abstract Number:	3693115
Poster Number:	Mo1396
Date/Time:	May 23, 2022, from 12:30 PM to 1:30 PM PDT

Title:	**Effect of Tenapanor on Treatment Satisfaction, Degree of Relief, and Quality of Life for Patients with Irritable Bowel Syndrome with Constipation (IBS-C)**
Abstract Number:	3693709
Poster Number:	Mo1394
Date/Time:	May 23, 2022, from 12:30 PM to 1:30 PM PDT

Title:	**Tenapanor has Early Onset of Action in Treating Symptoms of Irritable Bowel Syndrome with Constipation (IBS-C) (T3MPO-1 and T3MPO-2 Trials)**
Abstract Number:	3693673
Poster Number:	Tu1375
Date/Time:	May 24, 2022, from 12:30 PM to 1:30 PM PDT

In addition to the poster presentations during DDW, Ardelyx is sponsoring a Product Theater titled: *IBSRELA, an Innovative Approach for the Treatment of Irritable Bowel Syndrome with Constipation (IBS-C) in Adults*, on May 23, 2022, from 2:30-3:15pm PT, where thought leading experts Dr. Brooks Cash and Dr. Mark Pimentel, will review the multifactorial pathophysiology of IBS-C, the novel mechanism of action of IBSRELA, and efficacy and safety data of IBSRELA from the Phase 3 clinical trial program.

Product Theater speakers: Brooks D. Cash, MD, FACG, AGAF, FASGE, Dan and Lillie Sterling Professor of Medicine, Chief, Gastroenterology, Hepatology, and Nutrition, UT Health Science Center at Houston McGovern Medical School, and Mark Pimental, MD, FRCP(C), Executive Director, Medically Associated Science and Technology (MAST) Program, Cedars- Sinai Medical Center, Los Angeles, CA.

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 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 11 million people in the US. IBS-C is associated with significantly impaired quality of life, reduced productivity, and substantial economic burden.

About IBSRELA for IBS-C

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 Ardelyx, Inc.

Ardelyx was founded with a mission to discover, develop and commercialize innovative first-in-class medicines that meet significant unmet medical needs. Ardelyx's first approved product, IBSRELA® (tenapanor) is available in the United States. Ardelyx is developing XPHOZAH® (tenapanor), a novel product candidate to control serum phosphorus in adult patients with CKD on dialysis, which has completed three successful Phase 3 trials. Ardelyx has a Phase 2 potassium secretagogue program, RDX013, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease and an early-stage program in metabolic acidosis, a serious electrolyte disorder in patients with CKD. Ardelyx has established agreements with Kyowa Kirin in Japan, Fosun Pharma in China and Knight Therapeutics in Canada for the development and commercialization of tenapanor in their respective territories.

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