Ardelyx to Present Poster Presentations on IBSRELA® (tenapanor) for Adult Patients with IBS-C at the American College of Gastroenterology 2022 Annual Scientific Meeting

October 24, 2022

WALTHAM, Mass., Oct. 24, 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 post-hoc analyses from its Phase 3 T3MPO trials will be presented in two posters at the 2022 American College of Gastroenterology Annual Scientific Meeting (ACG 2022) taking place in Charlotte, North Carolina from October 21-26, 2022 and virtually.

"The Phase 3 studies we conducted in support of IBSRELA's approval are robust and provide extensive data, and at ACG, we are presenting new post-hoc analyses that elucidate additional benefits observed for patients treated with IBSRELA versus placebo," said Laura Williams, chief medical officer of Ardelyx. "In adult patients with IBS-C, IBSRELA was found to improve abdominal symptom scores, which included symptoms such as abdominal pain, discomfort, bloating, fullness and cramping, over the 26-week treatment period. Additionally, IBSRELA treatment significantly improved the complete spontaneous bowel movement durable response. These data add to the potential impact IBSRELA can have for people living with IBS-C."

Ardelyx Poster Presentations:

- **Poster # C0268, entitled "Efficacy of Tenapanor in Improving IBS-C Abdominal Symptoms: A Post Hoc Analysis of Multi-item Abdominal Score From the 26-Week Phase 3 T3MPO-2 Study," to be presented on October 24, 2022, from 3:00pm-5:00pm EDT**
- **Poster # E0264, entitled "Potential of Tenapanor as a Treatment for Chronic Idiopathic Constipation: A Post Hoc Analysis from the Phase 3 T3MPO-1 and T3MPO-2 Studies for Irritable Bowel Syndrome with Constipation in Adults," to be presented on October 25, 2022, from 3:00pm-5:00pm EDT**

In addition to the poster presentations during ACG, Ardelyx is sponsoring a Product Theater titled: An Innovative Approach to the Treatment of Adults with Irritable Bowel Syndrome with Constipation (IBS-C), on Monday, October 24, 2022, from 2:45pm-3:15pm ET. During this Product Theater, Dr. Susan Lucak, MD, will review the multifactorial pathophysiology of IBS-C, the novel mechanism of action of IBSRELA, and safety and efficacy data for IBSRELA from the Phase 3 clinical development program.

Product Theater speaker: Susan L. Lucak, MD, affiliated assistant professor of clinical medicine, Weill Cornell Medicine; special lecturer, Columbia University Medical Center; attending physician, Lenox Hill Hospital New York, NY.

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 and Canada. 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 lowering compound, 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.

Forward Looking Statements

To the extent that statements contained in this press release are not descriptions of historical facts regarding Ardelyx, they are forward-looking statements reflecting the current beliefs and expectations of management made pursuant to the safe harbor of the Private Securities Reform Act of 1995, including the potential for IBSRELA to treat patients with CIC. Such forward-looking statements involve substantial risks and uncertainties that could cause Ardelyx's future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, uncertainties associated with the drug development process and the regulatory approval process. Ardelyx undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Ardelyx's business in general, please refer to Ardelyx's Quarterly Report on Form 10-K filed with the Securities and Exchange Commission on August 4, 2022, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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SOURCE Ardelyx

Investor and Media Contacts: Kimia Keshtbod, kkeshtbod@ardelyx.com, Sylvia Wheeler, Wheelhouse Life Science Advisors, swheeler@wheelhouselsa.com, Alex Santos, Wheelhouse Life Science Advisors, asantos@wheelhouselsa.com