Ardelyx Presents Data at DDW 2022 on IBSRELA® (tenapanor), a First-In-Class Treatment for IBS-C in Adults

May 24, 2022

Three poster presentations continue to highlight the safety and efficacy of IBSRELA based on data from two Phase 3 trials in adults with irritable bowel syndrome with constipation (IBS-C)

WALTHAM, Mass., May 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 new analyses from IBSRELA Phase 3 trials, T3MPO-1 and T3MPO-2, were presented in three poster presentations at the 2022 Digestive Disease Week Conference (DDW 2022) that is now underway in San Diego, California and virtually.

IBSRELA, discovered, developed and recently launched by Ardelyx, is a first-in-class treatment with a novel mechanism and triple action that is approved by the U.S. Food and Drug Administration (FDA) to treat irritable bowel syndrome with constipation (IBS-C) in adults.

"IBSRELA represents a much-needed novel mechanism approach to treating the many patients who suffer with IBS-C," said Brian E. Lacy, M.D., Ph.D., Professor of Medicine, Mayo Clinic. "I am enthusiastic about having a new therapeutic option, and believe that IBSRELA will make a real difference for many patients."

Ardelyx Poster Presentations:

- **Poster #Mo1396, entitled "*Long Term Treatment with Tenapanor Improves Abdominal Pain and Other Abdominal Symptoms Associated with IBS-C*,"** summarizes data from a Phase 3 study named T3MPO-2. In this 26-week study, treatment with IBSRELA ameliorated a variety of abdominal symptoms associated with IBS-C, with improvements in abdominal pain, bloating, discomfort, cramping, and fullness observed as early as week 1 and sustained for the entire 26 weeks.
- **Poster #Mo1394, entitled "*Effect of Tenapanor on Treatment Satisfaction, Degree of Relief, and Quality of Life for Patients with Irritable Bowel Syndrome with Constipation*,"** reviews data from a treatment satisfaction questionnaire completed monthly by patients in the Phase 3 trials, T3MPO-1 and T3MPO-2, where a significantly higher proportion of IBSRELA-treated patients reported adequate relief of IBS-C symptoms versus placebo each week. Treatment with IBSRELA led to greater relief of symptoms, greater treatment satisfaction, and improved quality of life compared with placebo in patients with IBS-C.
- **Poster #Tu1375, entitled "*Tenapanor has Early Onset of Action in Treating Symptoms of Irritable Bowel Syndrome with Constipation (T3MPO-1 and T3MPO-2 Trials)*,"** presents analyses that evaluated the onset of action for IBSRELA within the first week of treatment in the T3MPO-1 and T3MPO-2 studies. These data demonstrated that IBSRELA provided statistically significant and clinically meaningful improvements in gastrointestinal and pain symptoms compared with placebo in as early as the first week of treatment.

All poster presentations are now publicly available and can be accessed on demand HERE.

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.

Ardelyx 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 make a real difference in the lives of patients with IBS-C. 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, the uncertainties in the drug commercialization 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-Q filed with the Securities and Exchange Commission on May 5, 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