# Ardelyx Announces US Launch of IBSRELA®, a New First-in-Class Treatment for IBS-C in Adults

April 4, 2022

- *IBSRELA®(tenapanor) is the First and Only NHE3 Inhibitor FDA Approved for the Treatment of IBS-C in Adults*
- *First Novel Mechanism Therapy to Treat IBS-C in a Decade*
- *Product Now Available*

WALTHAM, Mass., April 4, 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 the launch of IBSRELA, the first and only NHE3 inhibitor for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults. IBSRELA is the first FDA-approved product for Ardelyx.

"The commercialization of IBSRELA marks a significant milestone for Ardelyx and for adult patients with IBS-C and their healthcare providers," said Mike Raab, president and chief executive officer of Ardelyx. "It's hugely rewarding to see an idea born from our discovery research translate into a breakthrough medicine for patients. IBSRELA is the first novel mechanism therapy to be introduced for IBS-C in over a decade and offers an important new option to treat the abdominal pain, bloating, and discomfort, along with the constipation associated with this debilitating condition. We have built a world-class commercial team and are entering the market with a highly experienced sales force, a disruptive omnichannel approach, and an innovative and differentiated therapy that meets a significant unmet need."

Anthony Lembo, M.D., director of the GI Motility and Functional Bowel Disorders Program at Beth Israel Deaconess Medical Center and professor of medicine at Harvard Medical School, added, "Innovative, novel therapies are needed in IBS-C due to the heterogeneous nature of the condition and the large proportion of patients who continue to suffer despite treatment. The launch of IBSRELA, a first-in-class NHE3 inhibitor, provides a new treatment option with a novel mechanism of action and impressive efficacy data to address the constipation and multiple abdominal symptoms commonly seen in patients with IBS-C, as demonstrated in the Phase 3 clinical trials. I am excited to have a new treatment option that offers the potential to advance the care of patients who suffer from IBS-C."

The approval of IBSRELA is based on two successful Phase 3 trials involving over 1,200 patients with IBS-C. Both trials met their primary endpoint – significantly more patients treated with IBSRELA vs. placebo were overall responders (experienced a ≥30% improvement in abdominal pain from baseline and an increase in at least one complete spontaneous bowel movement per week from baseline, in the same week for at least 6 of the first 12 weeks of treatment). In T3MP0-2, the Phase 3 long-term trial, improvements from baseline in average weekly bowel movements, abdominal pain, bloating and other abominal symptoms were observed as early as Week 1, with improvement sustained through the end of the 26-week trial. Additionally in the Phase 3 trial T3MP0-2, patients treated with IBSRELA reported a 41% improvement in quality of life score from baseline to end of treatment, and the vast majority of patients reported satisfaction with treatment. The most common side effect in clincial trials was diarrhea, occurring in 16% of patients (4% placebo), and was most commonly mild-to-moderate and transient, resolving in ≤1 week with continued treatment.

## Ardelyx Commitment to Patient Access

As a company dedicated to advancing patient care, Ardelyx is committed not only to setting new standards in product innovation, but also to setting new standards in patient support. To that end, Ardelyx has created ArdelyxAssist ™, an innovative, digitally forward, high touch, patient services program. ArdelyxAssist will provide a broad range of access and affordability support for patients and health care providers, with seamless integration into office work processes, and digital connectivity to patients and providers.

## 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 is also advancing RDX013, a potassium secretagogue, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease and has 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 Ardelyx's expectations regarding the manner in which ArdelyxAssist will operate, and the potential for Ardelyx's product candidates to treat the diseases and conditions for which they are being developed. 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 commercialization of drugs, 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 28, 2022, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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