Ardelyx Launching IBSRELA® Second Quarter of 2022

- *IBSRELA (tenapanor) the first and only NHE3 inhibitor approved for treatment of IBS-C in adults*
- *IBSRELA potential peak net revenue greater than $500 million annually*
- *Large and established IBS-C market in need of new therapeutic options*
- *Small specialty sales organization and focused digital marketing to target high prescribers and dissatisfied patients*
- *Company continues to pursue approval of tenapanor in hyperphosphatemia*
- *Company to host conference call today at 8:00 AM ET*

FREMONT, Calif. and WALTHAM, Mass. November 30, 2021 – Ardelyx, Inc. (Nasdaq: ARDX), a specialty biopharmaceutical company founded with a mission to discover, develop and commercialize innovative first-in-class medicines that meet significant unmet medical needs, today announced plans to launch IBSRELA, the company's approved treatment for irritable bowel syndrome with constipation (IBS-C) in adults, in the second quarter of 2022.

Mike Raab, president and chief executive officer of Ardelyx, stated, "Over the last five years, the IBS-C market has grown to be sizeable and concentrated, with 9,000 high-writing physicians accounting for approximately 50% of the almost five million prescriptions written annually for drugs indicated for the treatment of IBS-C. This market is ripe for the entry of a novel therapeutic option like IBSRELA, as existing therapies do not adequately address all patient treatment needs. Our market research has clearly shown that treating physicians recognize the need for new therapeutic alternatives to address the unmet medical needs of patients currently managed for IBS-C. That same research demonstrates high interest in, and intent to prescribe, IBSRELA for a subset of patients. By capturing even a modest share, in the mid to high single-digit of this large market, IBSRELA has the potential to generate at least $500 million in peak annual net revenue. We will use the next few months to build commercial inventory and prepare the market for a second-quarter 2022 launch. We believe we have a clear line of sight to breakeven and ultimate profitability for the product, which we expect will create significant shareholder value."

William Chey, M.D., Nostrant Professor of Medicine at the University of Michigan School of Medicine, added, "It is now widely recognized that while people with IBS-C present with similar symptoms, it is a disorder of heterogeneous pathogenesis. Therefore, while there has been much improvement in our treatment of patients with IBS-C over the last two decades with the introduction and broad adoption of GC-C agonists, it should be no surprise that many patients continue to suffer. There is a need for innovation. The launch of IBSRELA, as a first-in-class NHE3 inhibitor, is exciting, as it offers a unique mechanism of action with compelling clinical data, providing physicians with an important new tool to advance the care of patients with IBS-C."

“IBSRELA, with its first-in-class mechanism and strong clinical data package, is an important new addition to the IBS-C treatment armamentarium,” said Laura A. Williams, M.D., M.P.H., chief medical officer of Ardelyx. “The approval of IBSRELA was based on two successful Phase 3 trials involving over 1,200 patients with IBS-C. Both trials met their primary and most secondary endpoints. Additionally, in both trials, improvements from baseline in average weekly bowel movements and abdominal pain were observed by Week 1, with improvement sustained through the end of treatment. IBSRELA can play a meaningful role in the treatment of patients suffering from IBS-C.”

“As we work to bring IBSRELA to patients, we remain intent on pursuing approval of tenapanor for hyperphosphatemia through the formal dispute resolution process with the FDA, and as a commercial facing organization, if approved, we will be well-positioned to bring this novel therapy to patients,” said Mike Raab, president and chief executive officer of Ardelyx.

Conference Call Information

The company will host a conference call today, November 30, 2021 at 8:00 AM ET to discuss the plans to launch IBSRELA for the treatment of IBS-C. To participate in the conference call, please call (855) 296-9612 (toll-free) or (920) 663-6277 (toll) and reference call ID number 2977157. A webcast of the call can also be accessed by visiting the Investor page of the company’s website www.ardelyx.com and will be available on the website for 30 days following the call.

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 distention (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, resulting in an increase in luminal water concentration, 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 rat model of colonic hypersensitivity, tenapanor reduced visceral hyperalgesia and normalized colonic sensory neuronal excitability.

About Ardelyx, Inc.

Ardelyx is focused on discovering, developing and commercializing innovative first-in-class medicines to meet significant unmet medical needs. Ardelyx received approval for IBSRELA (tenapanor) with plans to launch in the second quarter of 2022. Ardelyx is developing 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 plans to launch IBSRELA in the second quarter 2022; Ardelyx's expectations regarding peak annual net revenue for IBSRELA; Ardelyx's expectations regarding the percentage of the market that Ardelyx expects to capture with IBSRELA; Ardelyx's expectations regarding its ability to generate revenue sufficient to achieve breakeven and to potentially reach profitability with sales of IBSRELA, and Ardelyx's plans to continue to seek approval for tenapanor for the control of serum phosphorus in patients with chronic kidney disease on dialysis. 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, 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-Q filed with the Securities and Exchange Commission on November 12, 2021, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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