



## Ardelyx Receives New Patent for Tenapanor

February 3, 2026

### New patent covers IBSRELA® and XPHOZAH® and expires in 2042

WALTHAM, Mass., Feb. 03, 2026 (GLOBE NEWSWIRE) -- 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 the United States Patent and Trademark Office (USPTO) has issued U.S. Patent No. 12,539,299 titled "Oral Formulations of Tenapanor" with an expiration date of November 26, 2042. The patent relates to the formulation of tenapanor and covers the commercial formulations of IBSRELA® (tenapanor) and XPHOZAH® (tenapanor). The patent will be submitted to the Food and Drug Administration for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) for both products.

"We are pleased to have been granted this patent for IBSRELA and XPHOZAH, which expires in fall of 2042," said Mike Raab, president and chief executive officer of Ardelyx. "This is an important step in extending protections for our portfolio of first-in-class medicines in therapeutic areas where there continues to be significant unmet patient need. We are committed to executing a comprehensive intellectual property strategy that enables us to continue driving meaningful impacts for patients and creating lasting value for our shareholders."

The expiration date of November 26, 2042 for this patent is an update from information previously communicated by the Company, and reflects a Patent Term Adjustment resulting from USPTO delays.

#### About IBSRELA® (tenapanor)

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 XPHOZAH® (tenapanor)

XPHOZAH, discovered and developed by Ardelyx, is a first-in-class, phosphate absorption inhibitor with a differentiated mechanism of action that acts locally in the gut to inhibit the sodium hydrogen exchanger 3 (NHE3), thereby reducing phosphate absorption through the paracellular pathway, the primary pathway of phosphate absorption. XPHOZAH is a single tablet, taken twice daily. Diarrhea was the most common side effect experienced by patients taking XPHOZAH in clinical trials. Please see additional full Prescribing Information.

#### IMPORTANT SAFETY INFORMATION (IBSRELA)

##### **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  $\geq 2\%$  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.**

## IMPORTANT SAFETY INFORMATION (XPHOZAH)

### CONTRAINDICATIONS

XPHOZAH is contraindicated in:

- Pediatric patients under 6 years of age
- Patients with known or suspected mechanical gastrointestinal obstruction

### WARNINGS AND PRECAUTIONS

#### Diarrhea

Patients may experience severe diarrhea. Treatment with XPHOZAH should be discontinued in patients who develop severe diarrhea.

### MOST COMMON ADVERSE REACTIONS

Diarrhea, which occurred in 43-53% of patients, was the only adverse reaction reported in at least 5% of XPHOZAH-treated patients with CKD on dialysis across trials. The majority of diarrhea events in the XPHOZAH-treated patients were reported to be mild-to-moderate in severity and resolved over time, or with dose reduction. Diarrhea was typically reported soon after initiation but could occur at any time during treatment with XPHOZAH. Severe diarrhea was reported in 5% of XPHOZAH-treated patients in these trials.

### INDICATION

XPHOZAH (tenapanor), 30 mg BID, is indicated to reduce serum phosphorus in adults with chronic kidney disease (CKD) on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy.

For additional safety information, please see full Prescribing Information.

### About Ardelyx

Ardelyx was founded with a mission to discover, develop and commercialize innovative, first-in-class medicines that meet significant unmet medical needs. Ardelyx has two commercial products approved in the United States, IBSRELA<sup>®</sup> (tenapanor) and XPHOZAH<sup>®</sup> (tenapanor). The company's pipeline includes the Phase 3 development of IBSRELA for chronic idiopathic constipation (CIC) and RDX10531, a next-generation NHE3 inhibitor with potential application across multiple therapeutic areas. Ardelyx has agreements for the development and commercialization of tenapanor outside of the U.S. Kyowa Kirin commercializes PHOZEVEL<sup>®</sup> (tenapanor) for hyperphosphatemia in Japan. A New Drug Application for tenapanor for hyperphosphatemia has been approved in China with Fosun Pharma. Knight Therapeutics commercializes IBSRELA in Canada. For more information, please visit <https://ardelyx.com/> and connect with us on [X \(formerly known as Twitter\)](#), [LinkedIn](#) and [Facebook](#).

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Source: Ardelyx, Inc.