Ardelyx Completes Enrollment in Phase 3 ACCEL Clinical Trial of IBSRELA® (tenapanor) in Adults with Chronic Idiopathic Constipation

November 3, 2026

Trial fully enrolled ahead of schedule

Topline data expected in the second half of 2027

WALTHAM, Mass., Nov. 03, 2026 (GLOBE NEWSWIRE) -- Ardelyx, Inc. (Nasdaq: ARDX), ("Ardelyx" or the "Company") a commercial-stage biopharmaceutical company focused on the development and commercialization of innovative medicines that meet significant unmet medical needs, today announced that it has fully enrolled ahead of schedule all patients in the Phase 3 ACCEL clinical trial evaluating the safety and efficacy of IBSRELA® (tenapanor) for the treatment of chronic idiopathic constipation (CIC) in adults. Topline data is expected in the second half of 2027.

"Completing enrollment ahead of schedule in our Phase 3 clinical trial marks an important milestone for the Company," said Michael Raab, President and Chief Executive Officer of Ardelyx. "The interest and pace of enrollment in the trial underscores the enthusiasm on the part of treating physicians for a new option for their patients experiencing the significant burden of CIC. We are grateful to the patients, the clinical teams and investigators at our trial sites whose commitment made this milestone possible. We look forward to sharing topline results in 2027."

"Many CIC patients continue to experience symptoms despite available therapies, indicating the need for additional treatment options that provide sustained, meaningful relief," said Rajani Dinavahi, M.D., Chief Medical Officer of Ardelyx. "Evaluating the use of IBSRELA for patients with CIC is an important objective for Ardelyx. CIC can impose a substantial burden on daily life, particularly after cycling through multiple over the counter and prescription treatments."

ACCEL is a multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trial designed to assess the safety and efficacy of IBSRELA for the treatment of CIC in adults when administered twice daily for 26 consecutive weeks. The primary endpoint will assess the durable efficacy of tenapanor in relieving constipation. The Phase 3 ACCEL clinical trial in CIC is part of Ardelyx's efforts to evaluate the potential of IBSRELA and its differentiated mechanism of action in a broader population of adult patients with constipation-related disorders. IBSRELA is currently approved in the United States for the treatment of irritable bowel syndrome with constipation (IBS-C) in adults. IBSRELA is not approved for the treatment of CIC.

Ardelyx recently presented the design and rationale for ACCEL at the American College of Gastroenterology (ACG) Annual Scientific Meeting. The presentation highlighted post hoc analyses of two Phase 3 studies of tenapanor in adults with IBS-C that, together with the recognized symptom continuum between CIC and IBS-C, supported further evaluation of tenapanor in adults with CIC.

About Chronic Idiopathic Constipation

CIC can impose a substantial burden on daily life, which is often the motivation for patients to seek care. Symptoms extend beyond infrequent bowel movements and can include discomfort, straining and bloating –which thought leaders in gastroenterology express as the most difficult symptom to treat. Patients often cycle through multiple over-the-counter treatments before seeking clinical care from their healthcare providers. Some patients continue to experience symptoms despite available therapies, indicating that there remains a need for additional treatment options that provide sustained, meaningful relief with acceptable tolerability. IBSRELA's mechanism of action is being investigated now to understand the impact this therapy can have for individuals living with this condition.

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 that is primarily responsible for the absorption of dietary sodium. By inhibiting NHE3, tenapanor reduces the absorption of sodium from the small intestine and colon, retaining luminal water content, accelerating intestinal transit time and resulting in a softer stool consistency. IBSRELA has also been shown to reduce abdominal pain by decreasing visceral hypersensitivity and intestinal permeability in animal models. 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 ≥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 Ardelyx

Ardelyx is a commercial-stage biopharmaceutical company focused on the development and commercialization of innovative medicines that meet significant unmet medical needs. Ardelyx has two commercial products approved in the United States, IBSRELA® (tenapanor) and XPHOZAH® (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 works with its partners to develop and commercialize its products outside of the United States. For more information, please visit https://ardelyx.com/ and connect with us on X (formerly known as Twitter), LinkedIn and Facebook.

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 Litigation Reform Act of 1995, including Ardelyx's current expectations regarding: the timing of topline data from the Phase 3 ACCEL clinical trial; and the potential of IBSRELA (tenapanor) to treat CIC and expand the patient population who may benefit from IBSRELA, subject to regulatory approval. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that are, in some cases, beyond our control and that could cause actual outcomes or results to differ materially from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, uncertainties associated with the development of, regulatory process for, and commercialization of drugs in the U.S. and internationally; the risk of delays in clinical trial completion, data analysis or reporting; the risk that clinical trial results may not establish sufficient safety and efficacy to support regulatory approval, including for CIC; and the risk that prior clinical results or post hoc analyses in IBS-C may not be predictive of results in CIC. 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 August 6, 2026, and its future current and periodic reports to be filed with the Securities and Exchange Commission

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