First Patient Dosed in ACCEL: Phase 3 Chronic Idiopathic Constipation Study of IBSRELA

January 28, 2026

WALTHAM, Mass., Jan. 28, 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 first patient has been dosed in ACCEL (ten-03-301), a Phase 3 clinical trial designed to assess the safety and efficacy of IBSRELA® (tenapanor) for the treatment of chronic idiopathic constipation (CIC) in adults.

ACCEL is a multicenter, randomized, double-blind, placebo-controlled study to assess the safety and efficacy of tenapanor for the treatment of CIC in adults when administered twice daily for 26 consecutive weeks. The Phase 3 clinical trial is designed to enroll approximately 700 patients with CIC. The primary endpoint will evaluate patient-reported outcomes in constipation. Enrollment in ACCEL is expected throughout 2026, with topline data read out in the second half of 2027.

“Today marks an important milestone for our team and the patients we are committed to serving,” said Laura Williams, M.D., M.P.H, chief patient officer and interim chief medical officer of Ardelyx. “We are pleased to announce that the first patient has been dosed in the ACCEL Phase 3 clinical trial, an integral step to bringing IBSRELA and its differentiated mechanism of action to patients with chronic idiopathic constipation. This achievement reflects the dedication of our investigators, clinical staff, internal team, and most importantly, the patients and families who entrust us with their care. We remain focused on conducting this study with the highest standards of safety, integrity and scientific rigor, and we look forward to the insights it will provide for the future health of our patients.”

The Phase 3 ACCEL clinical trial represents important progress in Ardelyx’s goal of expanding the patient population who may benefit from IBSRELA, beyond its lead indication for irritable bowel syndrome with constipation, which demonstrated safety, efficacy and tolerability in a comprehensive clinical development plan.

CIC is characterized by difficult, infrequent or incomplete bowel movements, and is associated with significantly impaired quality of life, disrupted productivity and high healthcare-related costs. CIC is estimated to affect more than 34 million Americans[1].

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 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® (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 has agreements for the development and commercialization of tenapanor outside of the U.S. Kyowa Kirin commercializes PHOZEVEL® (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.

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. Forward-looking statements include, but are not limited to, Ardelyx's current expectations regarding the timing for completion of enrollment of the CIC Phase 3 clinical trial; the timing for the release of topline data from the CIC Phase 3 clinical trial; and the expansion of the patient population who may benefit from IBSRELA. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that are in some cases beyond our control, 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, risks related to clinical development and regulatory approval; commercialization, market acceptance and payer coverage. Ardelyx undertakes no obligation to update or revise any forward-looking statements, except as required by law. 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 October 30, 2025, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

Investor and Media Contacts:
Caitlin Lowie
clowie@ardelyx.com

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[1] NIH: CIC affects about 10-17% of the world population. https://pmc.ncbi.nlm.nih.gov/articles/PMC8547593/ Current U.S. population as of Dec 7, 2025 (https://www.census.gov/popclock/): 342,939,118. 10% of U.S. Population: 34,293,911.

Source: Ardelyx, Inc.