Ardelyx Announces Publication of Positive Results from T3MPO-3 Long-Term Open-Label Safety Trial of Tenapanor for IBS-C in the Journal of Neurogastroenterology and Motility

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WALTHAM, Mass., Sept. 28, 2023 (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 the publication of results from the T3MPO-3 long-term open-label safety trial of IBSRELA® (tenapanor) for irritable bowel syndrome with constipation (IBS-C) in the *Journal of Neurogastroenterology and Motility* (JNM). The paper, titled "Long-term safety of tenapanor in patients with irritable bowel syndrome with constipation in the T3MPO-3 study," can be accessed in the current online edition of the publication. IBSRELA, discovered and developed by Ardelyx, has a first-in-class mechanism of action and is approved by the U.S. Food and Drug Administration to treat IBS-C in adults.

In this long-term open-label safety study, tenapanor showed acceptable tolerability with a safety profile consistent with that reported in the prior studies.

"The T3MPO-3 results provide important data on IBSRELA's safety profile in a longer-term setting," said David Rosenbaum, Ph.D., chief development officer of Ardelyx. "We are pleased by the publication of these results in this distinguished gastroenterology journal as we continue to grow awareness of IBSRELA as another option for people with IBS-C."

Anthony Lembo, M.D., Director of Research for Cleveland Clinic's Digestive Disease & Surgery Institute, added, "These long-term results provide further support for IBSRELA as a valuable treatment option for people with IBS-C. Adults with IBS-C frequently suffer from constipation, abdominal pain, bloating and other symptoms, which has a significant impact on their quality of life. IBSRELA, with its differentiated mechanism of action and clinically validated efficacy and tolerability, provides an important option for these patients seeking relief from their symptoms."

Patients who completed T3MPO-1 or T3MPO-2, the two Phase 3 trials of tenapanor for IBS-C, were eligible for enrollment in T3MPO-3. The T3MPO-3 trial enrolled a total of 312 patients of which 262 patients completed treatment. Patients received open-label tenapanor 50 mg twice a day for up to an additional 39 (T3MPO-1) or 26 (T3MPO-2) weeks. Ninety patients received ≥52 weeks of tenapanor. Treatment-emergent adverse events (TEAEs) were reported in 117 of the 312 (37.5%) patients in the entire T3MPO-3 population and in 52 of the 90 (57.8%) patients who received ≥52 weeks of tenapanor. Overall, 10.6% of patients experienced diarrhea. TEAEs led to limited discontinuations (13 patients/4.2%) in the entire T3MPO-3 safety population, (11 patients/3.5%) due to diarrhea, (1.7%/1 patient) due to flatulence and abnormal GI sounds. Tenapanor was generally well tolerated with diarrhea being the most commonly reported adverse event.

The article is available online and can be accessed here.

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 12 million people in the U.S. 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 and Canada. Ardelyx is developing XPHOZAH® (tenapanor), a novel product candidate for the control of serum phosphate in adult patients with chronic kidney disease (CKD) on dialysis who have an inadequate response or intolerance to a phosphate binder therapy, which has completed three successful Phase 3 trials and an additional two Phase 4 open-label trials. Ardelyx has a Phase 2 potassium lowering compound, RDX013, for the potential treatment of elevated serum potassium, or hyperkalemia, a problem among certain patients with kidney and/or heart disease and 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. For more information, please visit https://ardelyx.com/ and connect with us on X (formerly Twitter), LinkedIn and Facebook.

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Source: Ardelyx, Inc.