



Ardelyx to Provide Company Update on IBSRELA® and Host a KOL Discussion on the IBS-C Landscape on Monday, January 8

January 3, 2024

Live event and webcast scheduled for 7:00 p.m. ET / 4:00 p.m. PT

WALTHAM, Mass., Jan. 03, 2024 (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 it will host a live event and webcast on Monday, January 8, 2024, at 7:00 p.m. ET / 4:00 p.m. PT. The event will include a management update on IBSRELA® (tenapanor), the company's FDA approved treatment for irritable bowel syndrome with constipation (IBS-C), as well as a Key Opinion Leader discussion regarding the IBS-C treatment landscape with Philip Schoenfeld, M.D., MS Ed, MSc, Chief (Emeritus) of the Gastroenterology Section at the John D. Dingell VA Medical Center in Detroit, Mich.

The event is being held at Convene, located at 100 Stockton Street, San Francisco, Calif. and will be webcast live. A link to the webcast can be accessed on the Investors section of the company's website at www.ardelyx.com. The webcast will be archived and available for replay for 30 days following the call. To attend the event or submit a question, please contact investor@ardelyx.com.

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 $\geq 2\%$ 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.

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 has two commercial products approved in the United States, IBSRELA® (tenapanor) and XPHOZAH® (tenapanor), as well as early-stage pipeline candidates. Ardelyx has agreements for the development and commercialization of tenapanor outside of the U.S. Kyowa Kirin has received approval for PHOZEVEL® (tenapanor) for hyperphosphatemia in Japan. A New Drug Application for tenapanor for hyperphosphatemia has been submitted 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.