Ardelyx Provides Update on Growing Commercial Momentum and 2024 Strategic Priorities

January 8, 2024

Company achieved significant commercial progress in 2023

IBSRELA® now expected to generate greater than $1.0 billion in annual U.S. net product sales revenue at peak

Webcast scheduled for 7:00 PM ET / 4:00 PM PT to discuss IBS-C Market

WALTHAM, Mass., Jan. 08, 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 provided an update on the company's progress in 2023 and initial expectations for 2024.

"2023 was a landmark year for Ardelyx, marking our first full year as a commercial entity and the approval and launch of our second first-in-class product. XPHOZAH® joins IBSRELA in our portfolio of important treatment options for patients with unmet needs," said Mike Raab, president and chief executive officer. "We consistently grew sales of IBSRELA quarter-over-quarter and finished 2023 with strong revenue performance. We are poised to continue with a growth trend in 2024. At the same time, we are seeing a positive initial response to XPHOZAH and are focused on driving awareness and adoption of this important, new medication and establishing its role within the hyperphosphatemia treatment paradigm."

Raab continued, "2024 will be a year when we further our efforts to shape the future of Ardelyx. We will continue to prioritize growing sales of our marketed therapies, while we also seek to advance our business through investments in internal research & development programs, international expansion and external partnerships. We demonstrated in 2023 that we can deliver strong results, and expect to do the same in 2024."

IBSRELA® (tenapanor) Preliminary 2023 Revenue, 2024 Guidance and Revised Peak Sales Expectations
U.S. net product sales revenue for the first full calendar year of commercialization of IBSRELA is expected to be approximately $80 million, subject to adjustment in connection with preparation of audited financial statements, following consistent quarter-over-quarter growth and strong performance across all key indicators, including new and repeat writers and new and refill prescriptions. Ardelyx expects IBSRELA to achieve greater than ten percent market share at peak and generate more than $1.0 billion in annual U.S. net product sales revenue before patent term expiration. In 2024, the company will continue to invest to support future realization of the full potential for IBSRELA, including the expansion of the IBSRELA sales team, additional promotional programming and omnichannel digital capabilities, increased sampling availability, and expanded support provided by the ArdelyxAssist™ patient services program.

Ardelyx currently expects full-year 2024 U.S. net product sales revenue for IBSRELA to be between $140.0 and $150.0 million.

XPHOZAH® (tenapanor) Launch Progress and Preliminary 2023 Revenue
Following approval by the U.S. Food and Drug Administration of XPHOZAH in October 2023 and launch in November 2023, Ardelyx has seen a strong initial response from the nephrology community. U.S. net product sales revenue for the first quarter of commercialization of XPHOZAH is expected to be approximately $2.5 million, subject to adjustment in connection with preparation of audited financial statements.

Strong Cash Position
As of December 31, 2023, the company had total cash, cash equivalents and short-term investments of approximately $184 million (unaudited). Ardelyx had approximately 232 million shares outstanding as of December 31, 2023.

Webcast Details
The company will host a live event and webcast today, January 8, 2024, at 7:00 p.m. ET / 4:00 p.m. PT. The event will include a management update on IBSRELA, 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, MD, MS Ed, MSc, Chief (Emeritus) of the Gastroenterology Section at the John D. Dingell VA Medical Center in Detroit, Mich. The webcast can be accessed by visiting the Investor page of the company's website, www.ardelyx.com, and will be available on the website for at least 30 days following the call.

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.

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, 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.

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 Reform Act of 1995, including Ardelyx's expectation regarding opportunities for continued IBSRELA adoption, the potential market share for IBSRELA and annual U.S. net product sales revenue at peak; Ardelyx's current expectation for net product sales revenue for IBSRELA for full year 2023; projected net product sales revenue for IBSRELA for full year 2024; Ardelyx's current expectation for net product sales revenue for XPHOZAH for the fourth quarter 2023; and Ardelyx's current expectation regarding its cash position at December 31, 2023. Such forward-looking statements involve substantial risks and uncertainties that could cause Ardelyx's future results, performance or achievements to differ significantly 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. 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 October 31, 2023, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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