Ardelyx Provides Update on Increasing Commercial Momentum and 2025 Strategic Priorities

January 13, 2025

Company achieved significant commercial progress in 2024, finishing with total U.S. net product sales revenue of approximately $319 million (unaudited)

Company reaffirms peak U.S. net IBSRELA sales revenue of greater than $1 Billion

Company announces peak U.S. net XPHOZAH sales revenue of $750 million

Company finishes 2024 with approximately $250 million in cash, cash equivalents and investments (unaudited)

WALTHAM, Mass., Jan. 13, 2025 (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 2024 and initial expectations for 2025.

"In 2024, Ardelyx delivered another year of sustained growth and exceptional performance. The growing demand for IBSRELA and XPHOZAH, both important, first-in-class medicines, has demonstrated that there is a clear unmet need among patients for differentiated therapeutic options," said Mike Raab, president and chief executive officer. "It is an incredibly exciting time for our company with tremendous opportunities in front of us. As you saw in the performance during the fourth quarter, the team is delivering on the promise of IBSRELA. This performance reaffirms our expectation that IBSRELA can achieve greater than $1 billion in annual sales at peak. In 2024, XPHOZAH's performance demonstrated its critical role in the treatment of hyperphosphatemia where there continues to be a high unmet need among patients. It is evident that there is a significant opportunity for XPHOZAH and we expect this product will achieve $750 million in annual sales at peak."

Raab continued, "In 2025, we will be focused on our strategic priorities: Maintaining our growth momentum, building a pipeline and delivering a strong financial performance. We remain steadfast in our commitment to operational excellence and to making decisions in the best interest of patients and our shareholders."

IBSRELA® (tenapanor) records approximately $158 million in net product sales revenue in 2024
U.S. net product sales revenue for IBSRELA during the fourth quarter is expected to be approximately $54 million, with full year net product sales revenue totaling approximately $158 million, subject to adjustment in connection with preparation of audited financial statements. IBSRELA performance demonstrated consistent quarter-over-quarter growth throughout the year, accelerating in the fourth quarter following the completion of the company's field-based sales team expansion. In 2025, the company will focus on continued commercial execution to maintain the strong momentum for IBSRELA.

Ardelyx currently expects full-year 2025 U.S. net product sales revenue for IBSRELA to be between $240.0 and $250.0 million. Ardelyx continues to expect 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.

Strong XPHOZAH® (tenapanor) performance continues, recording approximately $161 million net product sales revenue during 2024
XPHOZAH demonstrated an exceptional launch and finished its first full year of commercialization with 2024 U.S. net product sales revenue of approximately $161 million, including approximately $57 million in net product sales during the fourth quarter, subject to adjustment in connection with preparation of audited financial statements. The strong response from the prescribing community to XPHOZAH continued throughout the year, with feedback reflecting positive patient experiences and outcomes. XPHOZAH saw continued, quarter-over-quarter growth across all key indicators.

At peak, Ardelyx currently expects XPHOZAH to achieve $750 million in annual U.S. net product sales revenue before patent term expiration.

Coverage for oral only therapies, including XPHOZAH, is no longer available under Medicare Part D as of January 1, 2025. Access to XPHOZAH remains through a prescription written by a qualifying healthcare provider sent to Transition Pharmacy, the ArdelyxAssist specialty pharmacy partner. Patients who do not have affordable access will be evaluated for eligibility to receive XPHOZAH through the Ardelyx patient assistance program.

Strong Cash Position
As of December 31, 2024, the company had total cash, cash equivalents and short-term investments of approximately $250 million (unaudited). Ardelyx had approximately 238 million shares outstanding as of December 31, 2024.

Company Presentation at 42nd Annual J.P. Morgan Healthcare Conference
The company will present and provide a business update at the 42nd Annual J.P. Morgan Healthcare Conference on Wednesday, January 15, 2025 at 7:30pm ET / 4:30pm PT. A webcast of the presentation 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). 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 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 currents expectations regarding: opportunities for continued adoption of IBSRELA and XPHOZAH, the annual U.S. net product sales revenue for IBSRELA at peak; the annual U.S. net product sales revenue for XPHOZAH at peak; net product sales revenue for IBSRELA for full year 2024 and the fourth quarter ended December 31, 2024; net product sales revenue for IBSRELA for full year 2025; the potential market share for IBSRELA at peak; net product sales revenue for XPHOZAH for the full year 2024 and the fourth quarter ended December 31, 2024; and its cash position at December 31, 2024. 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, 2024, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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Source: Ardelyx, Inc.