

October 23, 2014

# Ardelyx's Tenapanor Selected for Oral and Poster Presentations at the American Society of Nephrology's Kidney Week 2014

FREMONT, Calif., Oct. 23, 2014 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on cardio-renal, gastrointestinal and metabolic diseases, today announced that Ardelyx, together with its development partner, AstraZeneca (NYSE:AZN, LON:AZN), will present tenapanor-related preclinical and clinical results during Kidney Week 2014, the annual meeting of the American Society of Nephrology (ASN). Abstracts of the presentations were published today on the ASN website.



ASN Kidney Week, the world's largest nephrology meeting, will take place November 11 - 16, 2014 in Philadelphia, PA. Oral and poster presentations related to tenapanor are listed below.

# **Tenapanor-Related Oral Abstract Presentations:**

### November 14, 2014, 5:30 p.m. ET

Title: Tenapanor Inhibits Phosphorous Absorption, and Protects Against Vascular Calcification in Nephrectomized Rats (abstract # 425; FR-OR111)

Presenter: Dominique Charmot, Ph.D., Ardelyx Chief Scientific Officer

Session Title: Mineral Disease: Ca/Mg/PO4

Location: Room 119-B

#### November 14, 2014, 5:42 p.m. ET

Title: Tenapanor, a Minimally Absorbed NHE3 Inhibitor, Reduces Dietary Phosphorus Absorption in Healthy Volunteers (abstract #4829; FR-OR112)

Presenter: David Rosenbaum, Ph.D., Ardelyx Vice President Drug Development

Session Title: Mineral Disease: Ca/Mg/PO4

Location: Room 119-B

#### **Tenapanor-Related Poster Presentations:**

November 14, 2014, 10:00 a.m.-12:00 p.m. ET; Location: Exhibit Hall A

Title: Reduction of Sodium and Phosphorus Absorption Provided by Tenapanor is Not Affected by Co-Administration of Sevelamer in Healthy Volunteers (abstract # 903; Poster Board #FR-PO966)

Authors: Susanne Johansson, David Rosenbaum, Maria Leonsson-Zachrisson, Mikael Knutsson, Dennis Ruff

Title: Tenapanor, a Minimally Absorbed Small-Molecule Inhibitor of NHE3, Reduces Absorption of Sodium and Phosphorus in Healthy Japanese Volunteers (abstract # 2498; Poster Board #FR-PO965)

Authors: Susanne Johansson, David Rosenbaum, Mikael Knutsson, Maria Leonsson-Zachrisson

A full list of Ardelyx sessions is available on the ASN website here: http://www.asn-online.org/abstracts

For more information about ASN visit: http://www.asn-online.org/

## **About Tenapanor**

Tenapanor (also known as RDX5791 and AZD1722) is a minimally-systemic small molecule inhibitor of NHE3, a transporter of sodium in the gastrointestinal tract. Orally administered tenapanor has been shown in clinical trials to reduce the intestinal absorption of both dietary sodium and phosphorus. Ardelyx licensed tenapanor to AstraZeneca in October 2012. A total of 12 clinical trials of tenapanor have been completed or are ongoing, including over 830 subjects who have been administered tenapanor to date. Ardelyx and AstraZeneca are evaluating tenapanor in three indications:

- <u>ESRD patients on hemodialysis to treat hyperphosphatemia</u>: Phase 2b randomized, double-blind, placebo-controlled clinical trial in 150 ESRD patients to evaluate the effects of tenapanor on serum phosphorus. Enrollment is ongoing and the results of this clinical trial are expected in the first half of 2015.
- <u>Stage 3 CKD patients with type 2 diabetes mellitus, the presence of the protein albumin in the urine, or albuminuria, and high blood pressure.</u> Phase 2a randomized, double-blind, placebo-controlled clinical trial in 140 patients to evaluate the effects of tenapanor on kidney function and fluid overload. Enrollment is ongoing and the results of this clinical trial are expected in the second half of 2015
- <u>IBS-C patients</u>: Phase 2b randomized, double-blind, placebo-controlled clinical trial in 371 patients to evaluate the effect
  of tenapanor on the frequency of bowel movements versus placebo. Results were announced October 1, 2014. At the 50
  mg dose given twice daily, the study met its primary efficacy endpoint of an increase in the complete spontaneous bowel
  movement (CSBM) responder rate. Most secondary endpoints, including abdominal pain and other abdominal and IBS-C
  symptoms, demonstrated clinically meaningful improvements. Tenapanor was well-tolerated.

# About Ardelyx, Inc.

Ardelyx is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of innovative, non-systemic, small molecule therapeutics that work exclusively in the gastrointestinal tract to treat cardio-renal, gastrointestinal and metabolic diseases. The Company has developed a proprietary drug discovery and design platform enabling it, in a rapid and cost-efficient manner, to discover and design novel drug candidates. Utilizing this platform, Ardelyx has discovered and designed tenapanor.

Ardelyx formed a collaboration with AstraZeneca in October 2012 to develop and commercialize tenapanor. In addition to tenapanor, the Company has discovered small molecule NaP2b inhibitors for the treatment of hyperphosphatemia in ESRD, a program licensed to Sanofi, and independently is advancing several additional research programs focused in cardio-renal, gastrointestinal and metabolic diseases. Ardelyx is located in Fremont, California. For more information, please visit Ardelyx's website at <u>www.ardelyx.com</u>.

# **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 statements regarding the availability and timing of data from ongoing tenapanor clinical trials, and the potential of our drug discovery and design platform. Such forward-looking statements involve substantial risks and uncertainties that could cause the development of tenapanor, or 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, the uncertainties inherent in the clinical development process, Ardelyx's reliance upon AstraZeneca for the development of tenapanor, and AstraZeneca's right under the license agreement to choose which indication or indications for which tenapanor will be developed. 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 second quarter report filed on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2014.

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To view the original version on PR Newswire, visit:<u>http://www.prnewswire.com/news-releases/ardelyxs-tenapanor-selected-for-oral-and-poster-presentations-at-the-american-society-of-nephrologys-kidney-week-2014-951403301.html</u>

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