

October 28, 2015

# Ardelyx Announces Upcoming Presentations for Tenapanor at the American Society of Nephrology's Kidney Week Meeting 2015

FREMONT, Calif., Oct. 28, 2015 /PRNewswire/ -- Ardelyx, Inc. (NASDAQ: ARDX), a clinical-stage biopharmaceutical company focused on gastrointestinal and cardio-renal diseases, today announced nonclinical and clinical data for tenapanor, the Company's lead product candidate which is being evaluated for the treatment of IBS-C and for the control of hyperphosphatemia in CKD patients on dialysis, will be exhibited in an oral presentation and in multiple posters during American Society of Nephrology's (ASN) Kidney Week 2015 in San Diego, California, November 3-8. The scheduled presentations are:



#### **Oral Presentation**

**Title:** *Tenapanor, an NHE3 Inhibitor, Reduces Serum Phosphate in Patients with CKD Stage 5D and Hyperphosphatemia,* by Geoffrey A. Block, David P. Rosenbaum, Maria Leonsson-Zachrisson, Magnus Åstrand, Susanne Johansson, Mikael Knutsson, and Anna Maria Langkilde

Presenter: Geoffrey A. Block, MD, CCRI, Director of Clinical Research at Denver Nephrology

Session: Recent Developments in Phosphate, FGF-23, and Klotho Biology

Abstract Number: TH-OR114

Date: Thursday, November 5, 2015, 6:18pm PST

Location: San Diego Convention Center, Room 6C

#### **Poster Presentations**

**Title:** A Phase 2 Study on the Effect of Tenapanor on Albuminuria in Patients with T2DM and CKD, by Bergur Stefansson, David P. Rosenbaum, Peter J. Greasley, Maria Leonsson-Zachrisson, and Anna Maria Langkilde

Session: CKD Clinical Trials

Poster Number: TH-PO200

Date: Thursday, November 5, 2015, 10:00am-12:00pm PST

**Title:** Prophylactic and Therapeutic Tenapanor are Vascular Protective in a Rat Model of Chronic Kidney Disease, by Ann-Cathrine Jönsson-Rylander, Margareta Behrendt, Craig Plato, Denise Schwabauer, and Peter J. Greasley

Session: Hypertension: Basic

Poster Number: FR-PO724

Date: Friday, November 6, 10:00 am - 12:00pm PST

**Title:** The Pharmacodynamic Effect of Tenapanor Is Most Pronounced when Administered Before Food in Healthy Volunteers, by David P. Rosenbaum, Mikael Knutsson, Maria Leonsson-Zachrisson, and Susanne Johansson

Session: Pharmacokinetics and Pharmacogenomics in CKD

## **About Tenapanor**

Tenapanor is a minimally-absorbed 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. Fourteen clinical trials of tenapanor have been completed, and over 1,000 subjects have been administered tenapanor to date.

Ardelyx reported positive Phase 2b data in October 2014 for the use of tenapanor in patients with IBS-C. At the twice-daily 50 mg dose of tenapanor, the study met the primary efficacy endpoint of an increase in the complete spontaneous bowel movement (CSBM) responder rate (p < 0.001). Most secondary endpoints, including abdominal pain, the overall responder rate and other abdominal and IBS-C symptoms, demonstrated statistically significant and clinically meaningful improvements. The Company plans to begin a Phase 3 clinical program in IBS-C patients in the fourth quarter of 2015.

In February 2015, Ardelyx announced results from a Phase 2b clinical study evaluating tenapanor to manage hyperphosphatemia in patients on dialysis with end stage renal disease, or CKD-5D, demonstrating that tenapanor caused a statistically significant dose-related decrease in serum phosphate levels for tenapanor-treated patients compared to patients receiving placebo (p=0.012). A second Phase 2b study in hyperphosphatemia patients on dialysis is expected to begin in the fourth quarter of 2015 with results expected in the second half of 2016.

## About Ardelyx, Inc.

Ardelyx is a clinical-stage biopharmaceutical company focused on the discovery, development and commercialization of innovative, minimally-systemic, small molecule therapeutics that work exclusively in the gastrointestinal tract to treat gastrointestinal and cardio-renal diseases. Ardelyx 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, which it is evaluating for the treatment of IBS-C and for the control of hyperphosphatemia in CKD patients on dialysis. In addition to tenapanor, Ardelyx is developing RDX022, a non-absorbed polymer for the treatment of hyperkalemia, or high potassium, in kidney and heart disease patients. Ardelyx is also advancing several research programs focused in gastrointestinal and cardio-renal diseases. Ardelyx is located in Fremont, California. For more information, please visit Ardelyx's website at www.ardelyx.com.

## **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 the potential for tenapanor in treating IBS-C and hyperphosphatemia in CKD patients on dialysis, and the potential for RDX022 in treating hyperkalemia in kidney and heart disease patients. 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 research and the clinical development process. 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 August 12, 2015, and its future current and periodic reports to be filed with the Securities and Exchange Commission.

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To view the original version on PR Newswire, visit:<u>http://www.prnewswire.com/news-releases/ardelyx-announces-upcoming-presentations-for-tenapanor-at-the-american-society-of-nephrologys-kidney-week-meeting-2015-300168201.html</u>

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