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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 8-K**

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**CURRENT REPORT**  
Pursuant to Section 13 or 15(d)  
of the Securities Exchange Act of 1934

**Date of Report (Date of earliest event reported): February 9, 2015**

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**ARDELYX, INC.**  
(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-36485**  
(Commission  
File Number)

**26-1303944**  
(IRS Employer  
Identification Number)

**34175 Ardenwood Blvd.**  
**Fremont, CA 94555**  
(Address of principal executive offices, including Zip Code)

**Registrant's telephone number, including area code: (510) 745-1700**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
  - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
  - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
  - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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**Item 7.01 Regulation FD Disclosure.**

Attached hereto as Exhibit 99.1 is a corporate presentation of Ardelyx, Inc. (the “Company”) incorporated by reference herein.

The information furnished under this Item 7.01 shall not be considered “filed” under the Securities Exchange Act of 1934, as amended, nor shall it be incorporated into any future filing under the Securities Act of 1933, as amended, or under the Securities Exchange Act of 1934, as amended, unless the Company expressly sets forth in such future filing that such information is to be considered “filed” or incorporated by reference therein.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits.**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate presentation of Ardelyx, Inc.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: February 9, 2015

ARDELYX, INC.

By: /s/ Mark Kaufmann  
Mark Kaufmann  
Chief Financial Officer

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**EXHIBIT INDEX**

<u>Exhibit No.</u>	<u>Description</u>
99.1	Corporate presentation of Ardelyx, Inc.

ARDELYX<sup>®</sup>

Investor Presentation

Mike Raab  
CEO

FEBRUARY  
2015

## Forward Looking Statements and Further Information



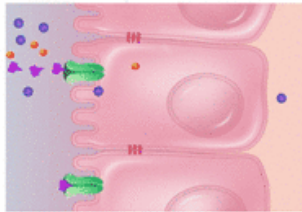
### Special Note Regarding Forward-Looking Statements

To the extent that statements contained in this presentation 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 potential of tenapanor in treating the renal indications for which it is currently being evaluated, the potential for tenapanor in treating IBS-C patients, the availability and timing of data from ongoing tenapanor clinical trials, potential milestone payments from our collaboration partners, 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's reliance upon Sanofi for the discovery and development under the licensed NaP2b inhibitor program, and the uncertainties inherent in the research and discovery 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 third quarter report filed with the Securities and Exchange Commission on November 7, 2014.



## Clinical-Stage Biopharmaceutical Company

Oral, Small Molecule,  
Non-Systemic, First-in-Class Drugs



Rapid, Efficient Drug Discovery  
& Design Platform Provides  
Broad Drug Candidates

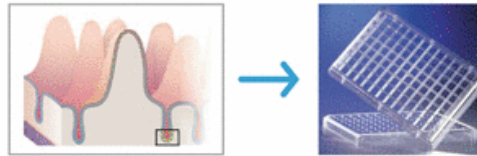


Fig 1



History of Capital Efficiency



Balanced Portfolio of Early to Mid-  
Stage Candidates Across Partnered &  
Proprietary Programs



Figure 1 from Sato T and Clevers H., "Growing self-organizing mini-guts from a single intestinal stem cell: mechanism and applications." Science. 2013 Jun 7;340(6137):1190-4





# A History of Rapid, Capital Efficient Development



## DEVELOPMENT



## FINANCINGS

\$26M Series A  
NEA & CMEA

\$30M Series B  
NEA & CMEA  
Amgen Ventures

\$69M IPO  
\$61.2M net

## LICENSES



AstraZeneca

\$35M  
Upfront

\$15M  
Development  
Milestone

\$25M  
Development  
Milestone

Up to \$870M for Tenapanor

SANOFI

Up to \$198M for NaP2b

# Proven Management Team



MIKE RAAB	President & Chief Executive Officer	NEA	genzyme	Bristol-Myers Squibb
JEREMY CALDWELL, PhD	EVP & Chief Scientific Officer	THIRD ROCK	MERCK Research Laboratories	Genomics Institute of the Novartis Research Foundation
MARK KAUFMANN	Chief Financial Officer	MedImmune	CELMEID	nexia
DAVID ROSENBAUM, PhD	SVP Drug Development	Geltex PHARMACEUTICALS, INC.	Trine PHARMACEUTICALS	Arthur D Little
ELIZABETH GRAMMER	VP and General Counsel	genzyme	Geltex PHARMACEUTICALS, INC.	EDWARDS ANGELL PALMERS DODGE
JEFF JACOBS, PhD	VP Chemistry	sunesis	gsk GlaxoSmithKline	AFFYMAX
NARANI ARASARATNAM	VP Corporate Controller	CONNOR GROUP	EY	ARTHUR ANDERSEN
GEORGE JUE	VP Operations	HYPERION PHARMACEUTICALS	PDL BioPharma	Genentech
ROB BLANKS	VP Regulatory Affairs and QA	Idenix PHARMACEUTICALS	Geltex PHARMACEUTICALS, INC.	Repligen Corporation
ANDY SPENCER, PhD	VP R&D Alliance Management	ALVINE PHARMACEUTICALS, INC.	PDL BioPharma	Mirus

# Investment Highlights



## PROPRIETARY PLATFORM

Discovery and Design of Non-Systemic, Small Molecule Therapeutics

## 2 VALIDATED PROGRAMS

Tenapanor: AstraZeneca Collaboration; Phase 2 in Three Indications

NaP2b Inhibition: Sanofi Collaboration

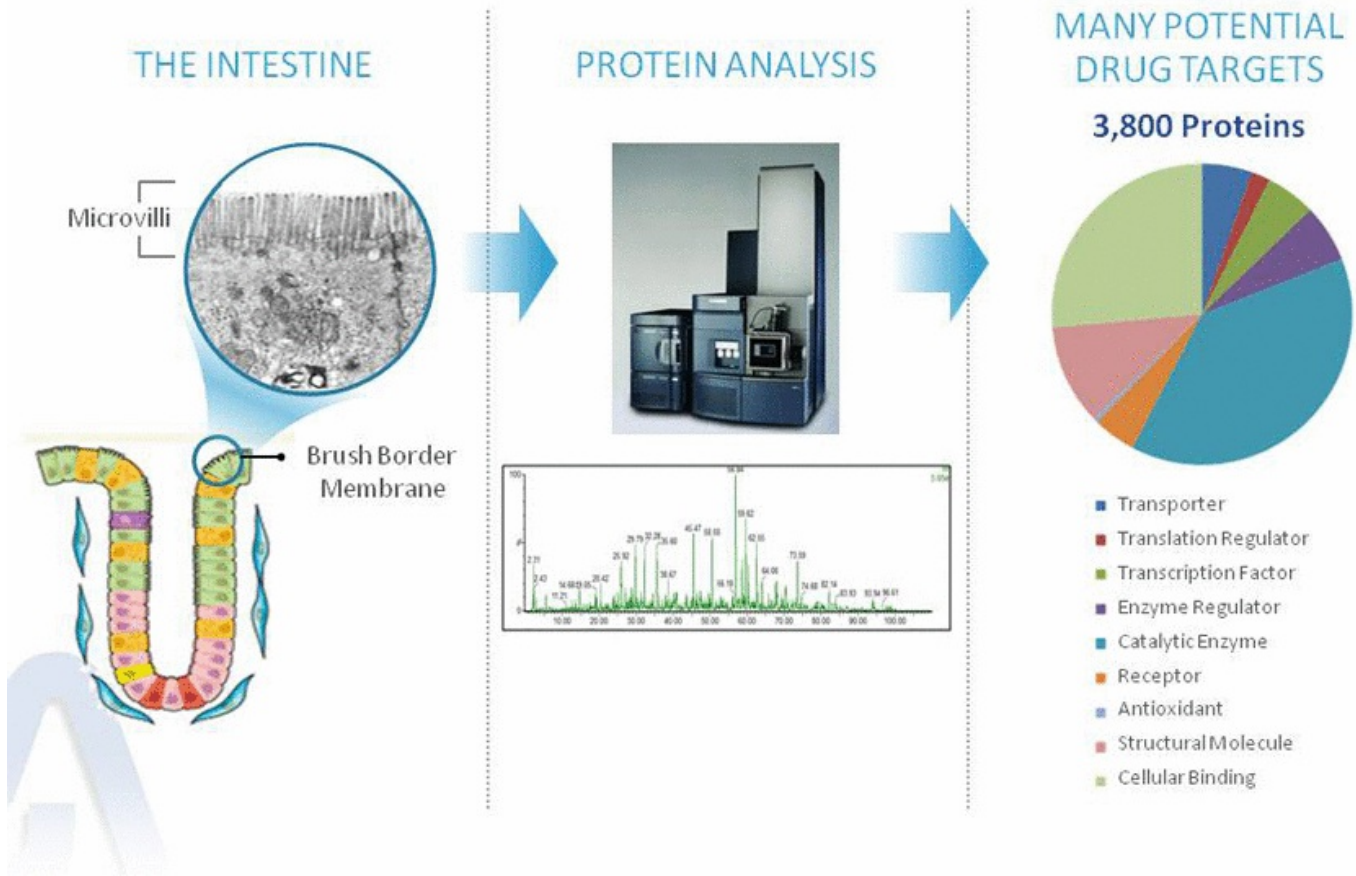
## WHOLLY-OWNED PIPELINE

Enhanced Drug Discovery Capabilities with Rapid, Proprietary Screening Process

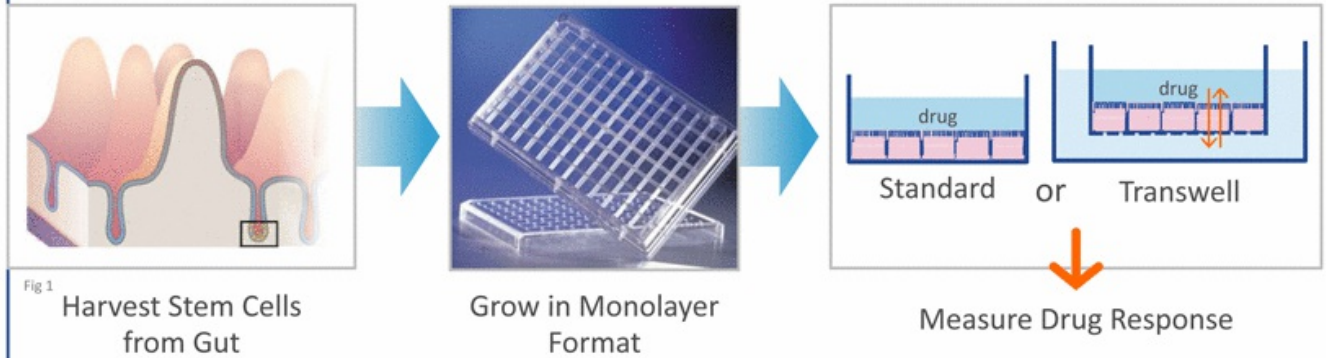
## PROVEN MANAGEMENT TEAM

Deep Domain Expertise

# Intestinal Epithelium Is Rich with Potential Targets



## Ardelyx Primary Enterocyte and Colonocyte Culture System



### THE BENEFITS

- **Discovery:** Rapid Screening of Drugs
- **Translation to Humans:** Simulate Relevant Gut Cell Physiology
- **Powerful Tool:** Mechanisms, Targets, Phenotypic Screening

Figure 1 from Sato T and Clevers H., "Growing self-organizing mini-guts from a single intestinal stem cell: mechanism and applications." Science. 2013 Jun 7;340(6137):1190-4

## Investment Highlights



### PROPRIETARY PLATFORM

Discovery and Design of Non-Systemic, Small Molecule Therapeutics

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NaP2b Inhibition: Sanofi Collaboration

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### PROVEN MANAGEMENT TEAM

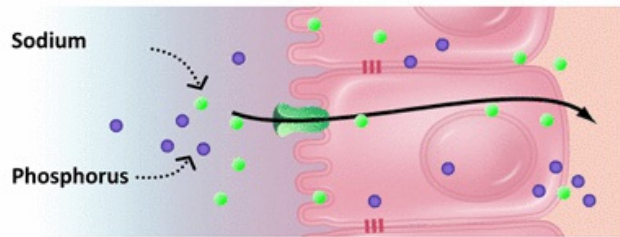
Deep Domain Expertise

# Tenapanor Reduces Sodium and Phosphorus Absorption



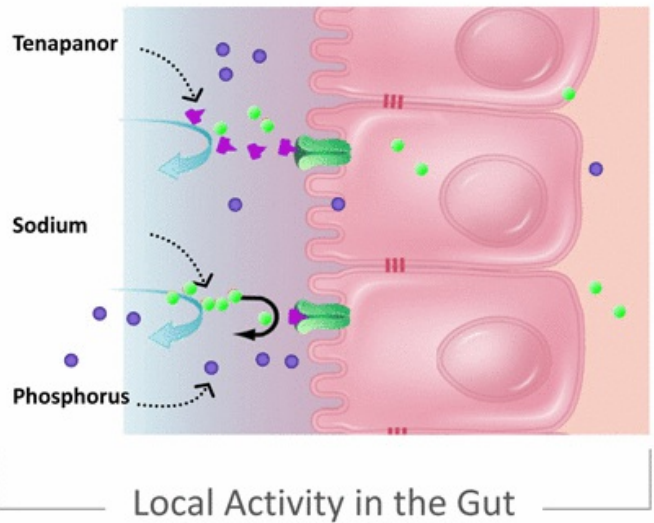
## WITHOUT TENAPANOR

Dietary Sodium/Phosphorus Passes Into Circulation

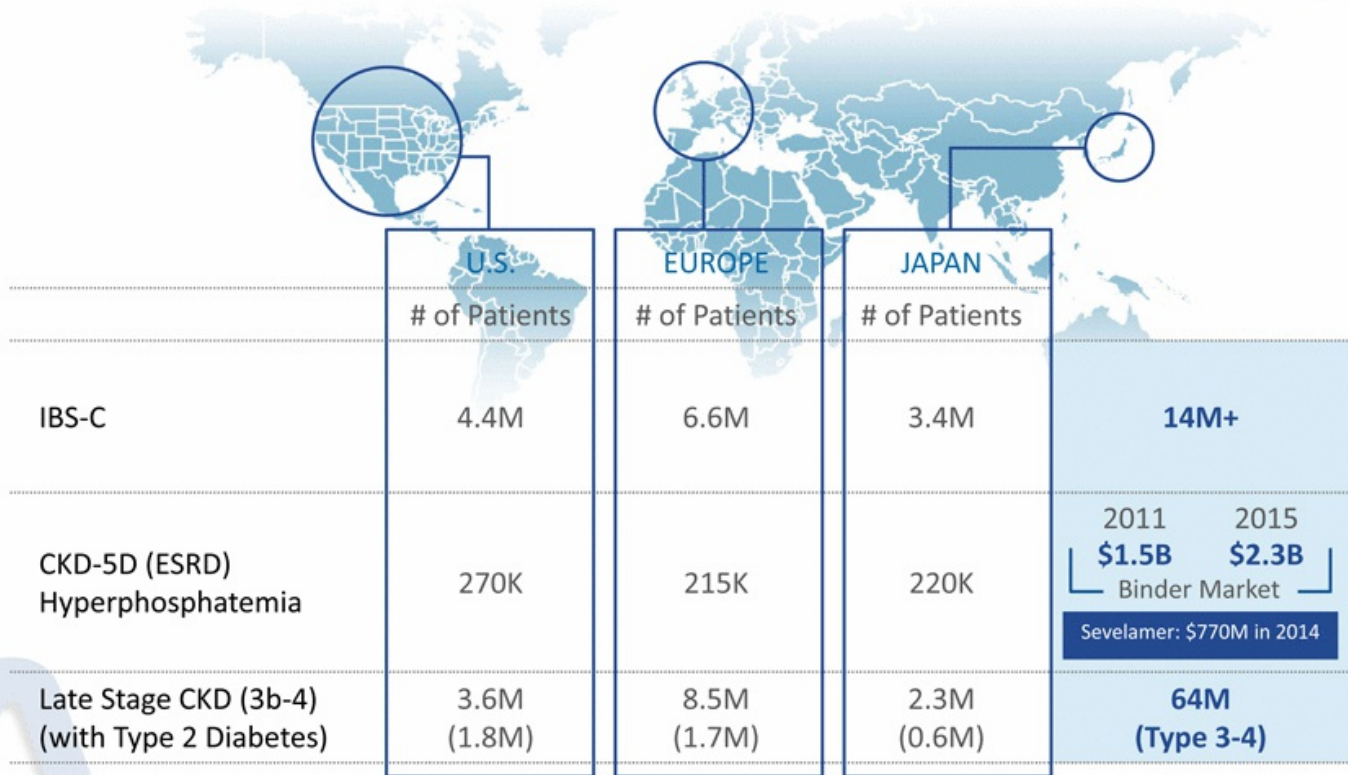


## WITH TENAPANOR

Diverts Sodium/Phosphorus from Circulation



# Significant Market Opportunity for Tenapanor



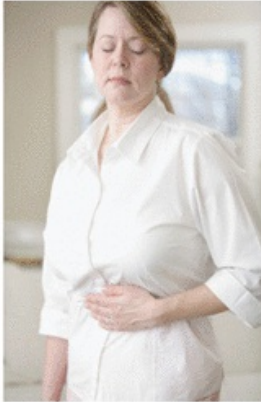
Sources: Technavio Insights: Global Hyperphosphatemia Drugs Market 2011-2015, USRDS 2013 Atlas of CKD & ESRD, Dialysis Outcomes and Practice Patterns Study (DOPPS), Am J Kidney Dis. 2012 Jul, European ERA-EDTA Registry Annual report 2011, Ther Apher Dial. 2010 Dec, JAMA. 2007 Nov, J Chin Med Assoc. 2010 Oct, BioTrends TreatmentTrends 2013, Patient Prefer Adherence 2008, Clin Gastroenterol Hepatol. 2012, Aliment Pharmacol Ther. 2005, Aliment Pharmacol Ther. 2003; Sanofi press release



# Extensive Clinical Experience with Tenapanor in Multiple Indications



## 14 Clinical Trials



### Constipation-Predominant Irritable Bowel (IBS-C) n=417

- Phase 2b clinical trial met primary endpoint at 50 mg BID
- Most secondary endpoints met
- Dose response observed



### CKD-5D Hyperphosphatemia n= 178

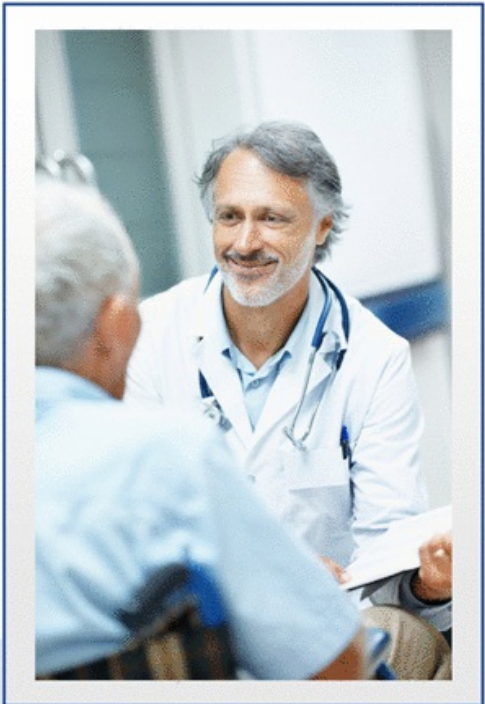
- Phase 2b clinical trial met primary endpoint
- Decreased serum phosphate levels
- Higher rates of diarrhea observed than in previous trials



### CKD Na & Fluid Overload n=77

- Data expected 2Q2015, earlier than previously reported (2H2015)

## Tenapanor Generally Well-Tolerated



- >1,000 individuals exposed to drug
- Single Dose Up to 900 mg
- 3 Months Up to 100 mg/Day
- Non-Systemic: >99.3% of All Tested Serum Samples Had No Detectable Levels of Tenapanor (>3,000 samples)
- Most AE's Due to Exaggerated Pharmacology of Drug (e.g. Loose Stools/Diarrhea)



GI Disorder:  
Constipation and  
Abdominal Pain

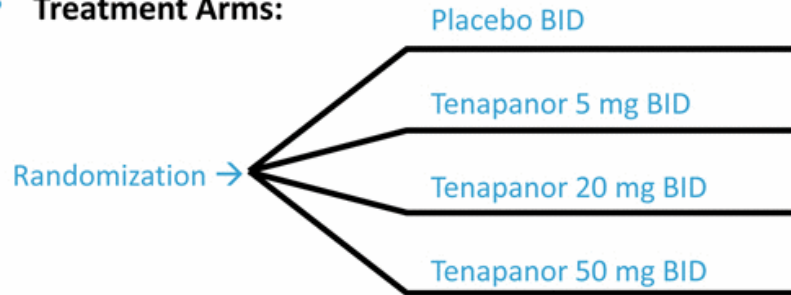
### LIMITATIONS OF CURRENT TREATMENTS

- OTC Drugs Inexpensive but Not Very Effective in Moderate to Severe Cases
- Amitiza® and Linzess® Fall Short:
  - Achieve Endpoint in Only 7% to 20% of Patients
  - Side Effects (e.g., Diarrhea)
- Medical Need for Improved Therapies with Better Efficacy, Excellent Safety and Tolerability

## IBS-C Phase 2b Protocol



- **Design:** Double-blind, placebo-controlled, randomized 1:1:1:1 into three treatment arms, 1 placebo arm (approximately 93 patients/group) for a total of 371 patients; 12 weeks treatment, 4 weeks follow-up
- **Primary Endpoint:** Percent complete spontaneous bowel movement (CSBM)\* responders (patient needs to have an increase of at least one CSBM from baseline for 6 of the 12 treatment weeks)
- **Secondary Endpoints:** Overall Responder Rate, Abdominal Pain and Abdominal and IBS-C Symptoms
- **Treatment Arms:**

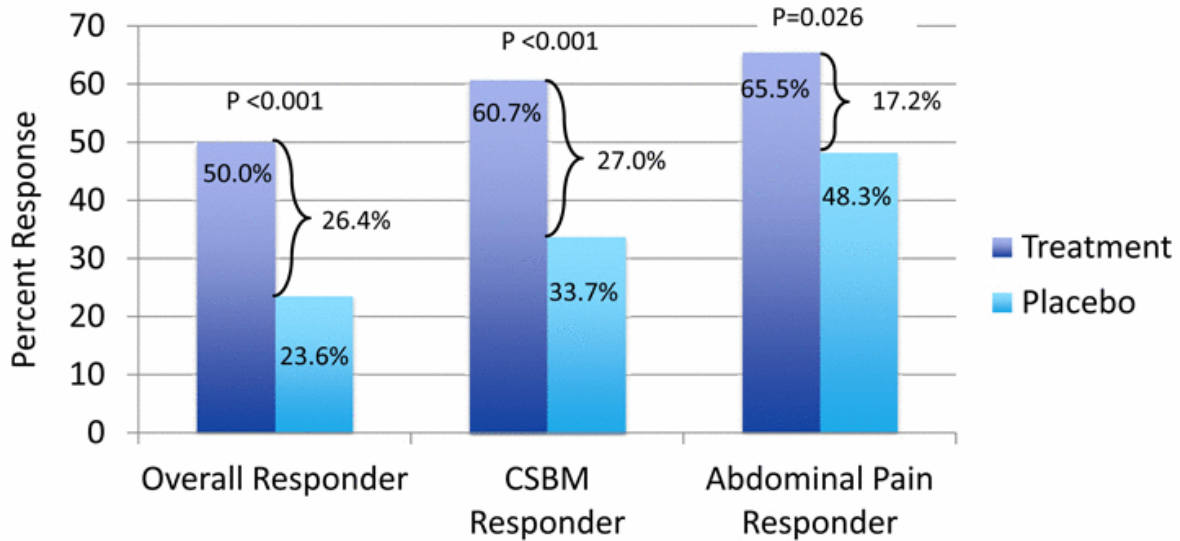


\*CSBM defined as a spontaneous bowel movement that feels complete and is not aided by the use of any other medication, like a laxative

# Phase 2b IBS-C Results: Responder Rates for 50 mg BID Dose (6 of 12 weeks)



Trial Met Primary Efficacy Endpoint At 50 Mg BID Dose  
Complete Spontaneous Bowel Movement (CSBM) Responder

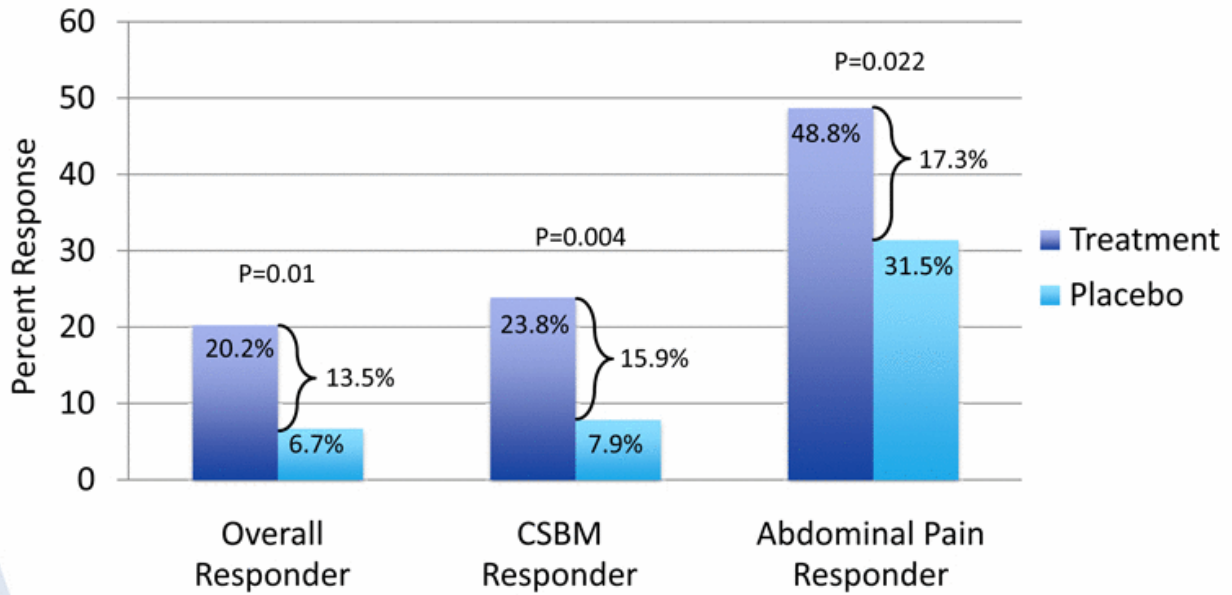


- Overall Responder = dual composite endpoint of CSBM and abdominal pain responders, which is the primary regulatory endpoint in Europe and US (EMA draft guidance 2013, FDA guidance 2012)

# Phase 2b IBS-C Results: Responder Rates for 50 mg BID Dose (9 of 12 weeks)



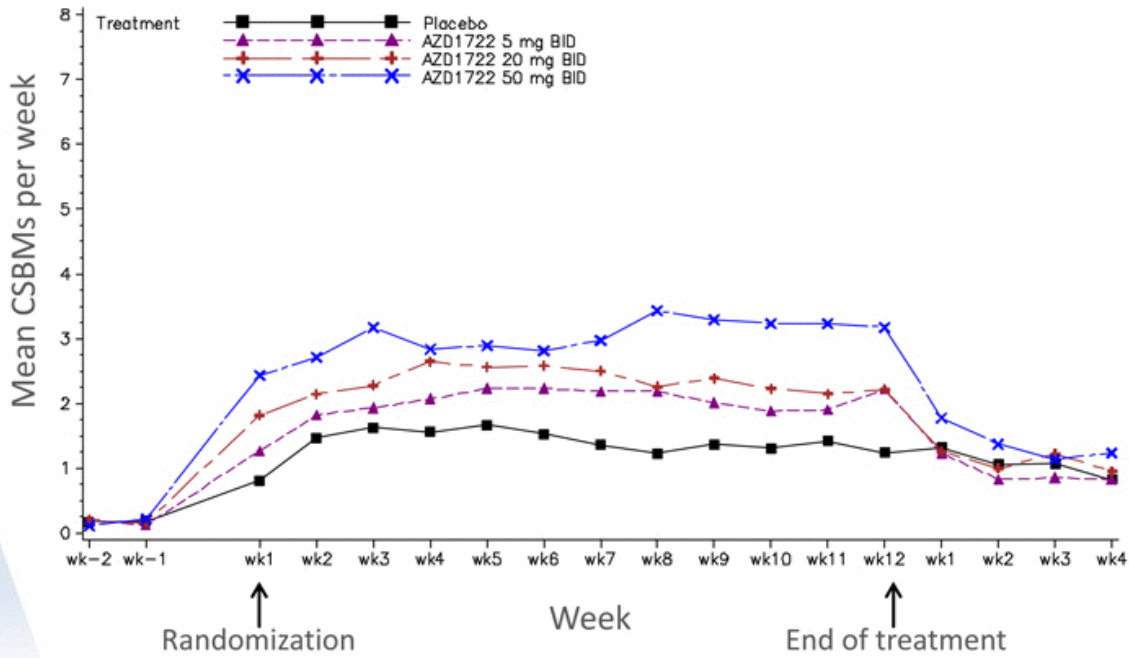
Responder Endpoint Is More Stringent  
+ $\geq 1$  mean CSBM/week from baseline and  $\geq 3$  CSBM/week for 9 of 12 weeks



# Results: Dose Response Relationship



Dose response relationship was observed in the primary endpoint, as well as in most other secondary endpoints, although statistical significance was not achieved at the 5 mg or 20 mg BID doses; activity of tenapanor was maintained throughout entire 12-week treatment period



## Tenapanor in IBS-C Phase 2b Results: Efficacy



- Adequate relief of IBS symptoms was statistically significant ( $p=0.002$ ) for tenapanor 50 mg BID (63.1%) versus placebo (39.3%) at the endpoint week (week 12 or last valid week)
- Based on the treatment satisfaction patient scale questionnaire, more subjects receiving 50 mg BID responded that they were “quite satisfied” or “very satisfied” with tenapanor\* versus placebo (65% vs. 38% placebo;  $p<0.001$ )



\* “Quite” and “very” are 4 and 5 respectively, on a 5-point scale



- Tenapanor well-tolerated across all treatment arms and there were no drug-related serious adverse events.
- The most common adverse events at 50 mg BID ( $\geq 5\%$ ) that occurred more frequently in tenapanor-treated patients compared to placebo-treated patients were diarrhea 11.2 percent vs. 0 percent and urinary tract infections 5.6 percent vs. 4.4 percent
- Overall rates of discontinuation due to adverse events were 4.5 percent for the tenapanor-treated patients (50 mg BID) and 3.3 percent for the placebo-treated patients.
- Based on the analysis of plasma samples tested as part of the study, the minimally systemic nature of tenapanor was confirmed



# Tenapanor for Hyperphosphatemia in CKD-5D



## LIMITATIONS OF PHOSPHATE BINDERS:

### Pill Burden

- CKD-5D Patients Take 10-14 Oral Medications Daily
- Prescribed Binder Doses Intolerable for Many Patients; Water Intake Limited
- Non-Compliance Often Results in Reduced Efficacy

### Safety and Tolerability

- Long-Term Vascular Calcification with Calcium-Based Binders
- Gastrointestinal Side Effects

## PILL BURDEN: TENAPANOR VS. BINDERS

	BREAKFAST	LUNCH	DINNER
<b>BINDERS</b>			
<b>Calcium-Based Binders: Ca Acetate/PhosLo</b> Common Dose: 1-2.5 Grams Each Meal			
<b>Sevelamer/Renagel/Renvela</b> Common Dose: 0.8-2.4 Grams Each Meal			
<b>Lanthanum/Fosrenol</b> Common Dose: 0.5-1.5 Grams of Elemental Lanthanum Each Meal			
<b>Ferric Citrate/Auryxia</b> Common Dose: 2-4g of ferric citrate each meal, Which is Equivalent to 1.3 to 2.5g of Elemental Iron per Day			
<b>TENAPANOR</b>			
<b>Tenapanor – Targeted Daily Dose</b> Targeted Dose: ≤10mg Twice Daily (30mg Twice Daily Used for Illustration Purposes to Right)			

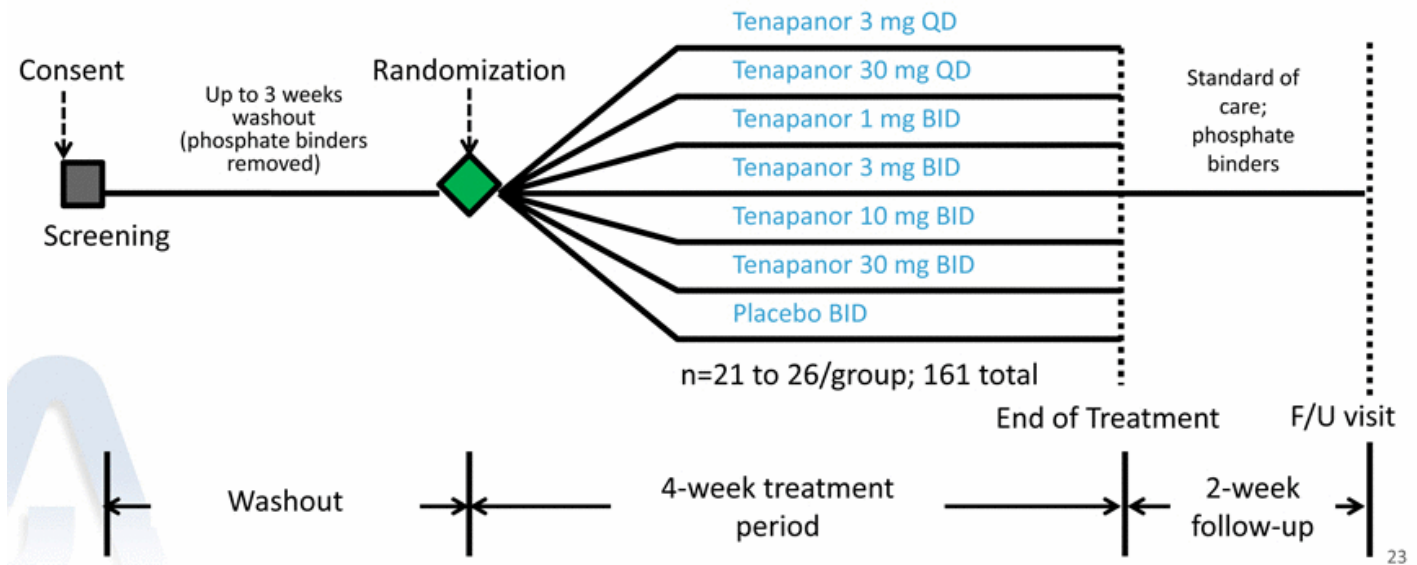
Not Actual Size; However, Relative Sizes Are to Scale

# Phase 2b Design for Tenapanor in CKD-5D Hyperphosphatemia



## CKD-5D Hyperphosphatemia Phase 2b Protocol

- **Design:** Randomized, double blind, placebo-controlled, multi-center, international study
- **Key Inclusion Criteria:**  $\geq 1.5$  mg/dL increase in S-phosphate from screening to end of washout and a S-phosphate  $\geq 6.0$  mg/d at randomization
- **Primary Endpoint:** Change from baseline of S-phosphate levels to end of treatment. Analysed using an ANCOVA with treatment group as a fixed factor, and baseline as a covariate.



# CKD-5D Hyperphosphatemia Phase 2b Study: Effects on Serum Phosphate



Tenapanor Produced A Statistically Significant Dose-related Decrease in Serum Phosphate Levels (P=0.012)

Group	n	LSMean*	95% CI
1 mg BID	23	-0.47	( -1.18, 0.24)
3 mg BID	21	-1.18	(-1.93, -0.44)
10 mg BID	23	-1.70	(-2.41, -0.99)
30 mg BID	24	-1.98	(-2.67, -1.28)
3 mg QD	22	-0.56	(-1.28, 0.17)
30 mg QD	21	-1.11	(-1.85, -0.37)
Placebo	26	-0.54	(-1.21, 0.13)

\*LSMean = Least square mean. Change from Baseline at End of Treatment (mg/dL)



## Adverse Events: Gastrointestinal Disorders\*



Preferred Term	1 mg BID	3 mg BID	10 mg BID	30 mg BID	3 mg QD	30 mg QD	Placebo
n/group	23	21	23	25	22	21	26
Abdominal Distension		1					
Abdominal Pain				2	1		1
Abdominal Pain Upper			1				
Diarrhea	6	6	11	17	4	11	3
Diverticulum	1						
Dyspepsia		1					
Fecal Incontinence		1	2				2
Feces Soft		1					
GI Hypermotility					1		
GI Sounds Abnormal			1				
Hemorrhoids						1	
Nausea		1	1	1	2	1	1
Rectal Prolapse				1			
Steatorrhea			1				
Vomiting		1			1	2	

\*Number of patients who had at least 1 AE in system organ class of gastrointestinal disorders

## Adverse Events Leading to Discontinuations



Discontinuation rate due to diarrhea was higher than expected in 30 mg groups

Adverse Event Term	1 mg BID	3 mg BID	10 mg BID	30 mg BID	3 mg QD	30 mg QD	Placebo
n/group	23	21	23	25	22	21	26
Discontinuations due to AE/group**	3	3	3	9	1	7	2
Abdominal Pain				1			
Diarrhea*	2	3	3	8		6	
Nausea						1	
Vomiting						1	
Serum Calcium Decrease					1		
Hyperphosphatemia	1				1		2
Dizziness						1	
Atherosclerosis		1					

\*The term "diarrhea" also includes similar changes in stool form or bowel habits

\*\*There may be multiple reasons for a single discontinuation

## Approved Therapies for Hyperphosphatemia in CKD-5D Patients



### AE's Due To GI Disorders Are Common In Phosphate Binders

Adverse Events*	Renvela®#	Fosrenol®**	Auryxia®
Abdominal Pain	9%	5%	
Constipation	8%		8%
Diarrhea	19%		21%
Nausea	20%	11%	11%
Vomiting	22%	9%	7%

\* Data from package inserts

# Label warning: Serious cases of dysphagia, bowel obstruction, and perforation have been associated with sevelamer use, some requiring hospitalization and surgery

\*\*Label warning: Serious cases of GI obstruction, ileus and fecal impaction





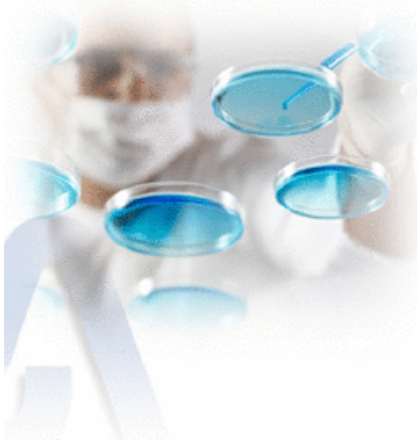
Sodium and  
Fluid Overload

### LIMITATIONS OF CURRENT TREATMENTS TO DELAY CKD PROGRESSION

- Poor Compliance with Low Sodium Diets
- Diuretics Lose Efficacy and Cause Electrolyte Disorders
- ACE Inhibitors Reduce Blood Pressure but Hyperkalemia Limits Widespread Use in CKD Patients



### *CKD Phase 2a Protocol*

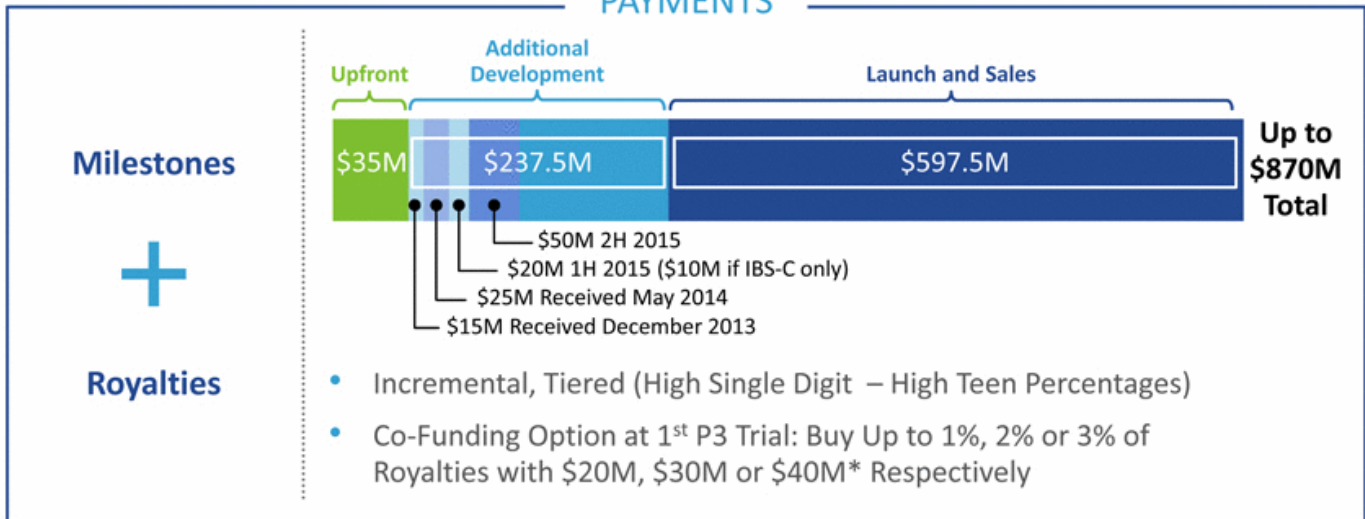


- **Design:** Double-Blind, 12 Weeks of Treatment, Targeted n=140 (70 Active/70 Placebo); 154 enrolled
- **Objective:** Safety, Tolerability, and Pharmacodynamics of Tenapanor in CKD Patients with Type 2 Diabetes Mellitus and Albuminuria
- **Primary Endpoint:** Changes in Urine Albumin to Creatinine Ratio (UACR), Baseline to Week 12
- **Other Endpoints:** Pharmacodynamic Effects of Tenapanor on Urinary Na Excretion; Mean Weekly Stool Consistency and Stool Frequency
- **Doses:** 5, 15, 30, or 60 mg Capsules. Starting Dose is 15 mg BID Orally for 12 Weeks
- **Status:** Enrollment Completed, Data Expected Q2 2015

# The AstraZeneca/Tenapanor Collaboration



## PAYMENTS



## OTHER TERMS

<b>AstraZeneca Responsibilities:</b>	<ul style="list-style-type: none"> <li>• All R&amp;D and Commercialization Expenses**</li> </ul>
<b>Ardelyx Rights:</b>	<ul style="list-style-type: none"> <li>• Right to Co-Promote in the US</li> </ul>

\*Exercisable Within 60 Days After Decision to Proceed to P3 Clinical for the First Indication for Tenapanor  
 \*\*Subject to cap on obligation for IBS-C reimbursement

## RDX002: NaP2b and Our Collaboration with Sanofi



### PROPRIETARY PLATFORM

Discovery and Design of Non-Systemic, Small Molecule Therapeutics

### 2 VALIDATED PROGRAMS

Tenapanor: AstraZeneca Collaboration;  
Phase 2 in Three Indications

RDX002 NaP2b Inhibition: Sanofi Collaboration

### WHOLLY-OWNED PIPELINE

Enhanced Drug Discovery Capabilities with Rapid, Proprietary Screening Process

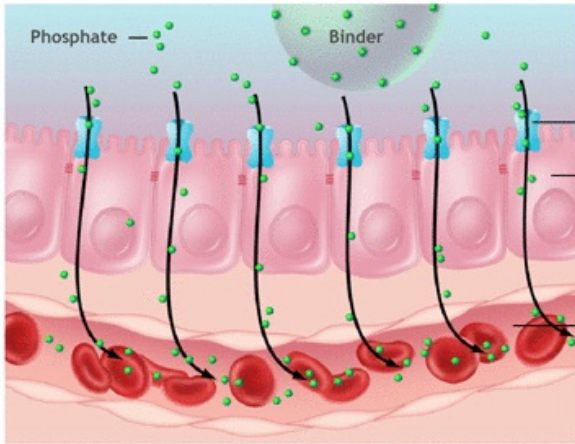
### PROVEN MANAGEMENT TEAM

Deep Domain Expertise

# Phosphate Binder vs. Phosphate Transport Inhibitor

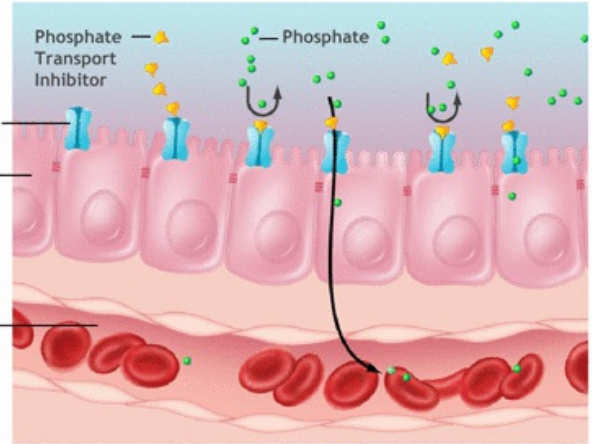


## Binder



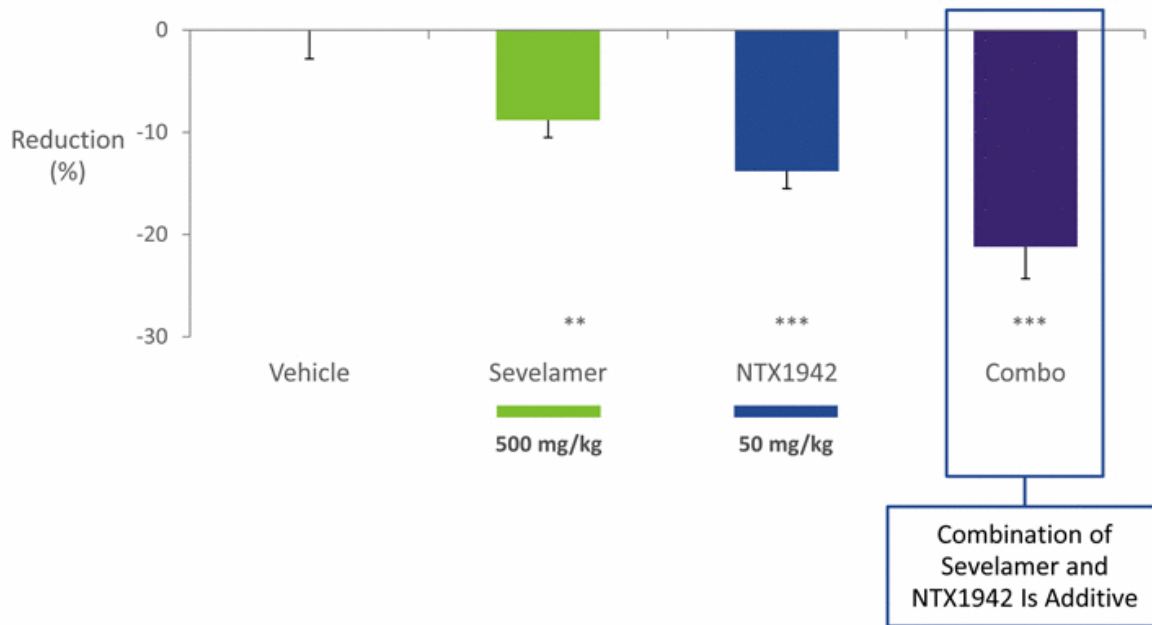
- GI-Upset/Pill-Burden
- Increased Calcium Load with Calcium Based Binders
- Concerns of Metal Accumulation with Metal Based Binders

## Phosphate Transport Inhibitor



- Potential for Dramatically Reduced Pill-Burden
- Potential for Use in Combination with Phosphate Binders

# RDX002: NTX1942 Reduces Urine Phosphorus Levels in Normal Rats and Is Additive to Sevelamer



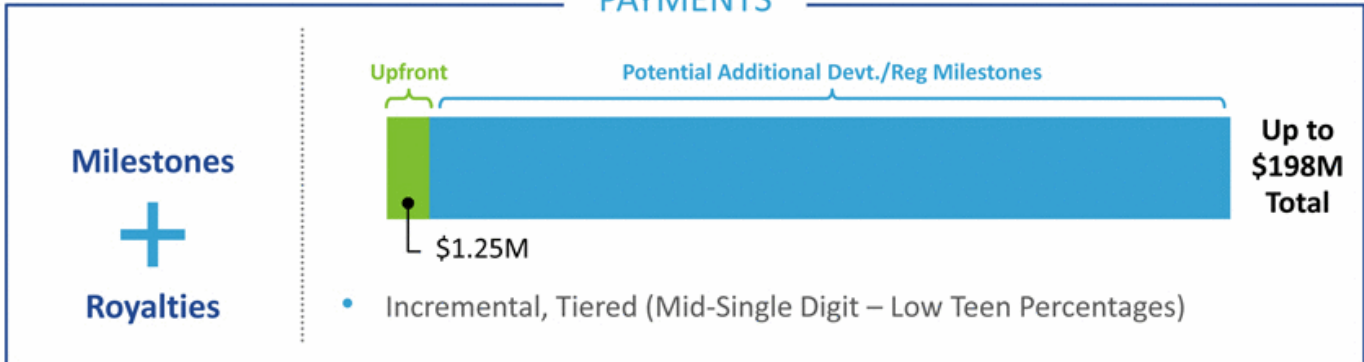
**NTX1942 Response Is Superior to Sevelamer at  $\approx 1/10$  of the Dose**

Data Shown is the Mean  $\pm$  SEM; \*\* = p<0.01; \*\*\* =p<0.001, by one-way ANOVA, n= 12

# The Sanofi/NaP2b Collaboration



## PAYMENTS



- Licensed Technology**
- NaP2b Patent Portfolio and Related Know-how for Research to Complete Activities under Preclinical Development Plan
  - Option to Obtain Exclusive License to Develop, Manufacture and Commercialize NaP2b Inhibitors
- Other Terms**
- Sanofi Responsible for Completing Pre-Clinical Development Plan, and if It Exercises the Option, for All Development and Commercialization at Its Expense
  - Ardelyx Has the Right to Co-Promote in the US

# Investment Highlights



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## PROVEN MANAGEMENT TEAM

Deep Domain Expertise

# RDX009: TGR5 Agonists for Inflammatory Bowel Disease (IBD), Short Bowel or NASH



## TGR5 STIMULATION

- Enhances GLP1 and GLP2 (Incretins) Secretion Directly to the GI Mucosa
- Anti-Inflammation and Mucosal Healing Effects
- Gattex® = GLP2 approved for Short Bowel Syndrome – Studied in Crohn’s
  - Daily Injections
- Intercept and Exelixis/BMS Both Have Systemic TGR5 Agonists
  - Gallbladder Emptying Issues
  - Short Lasting Incretin Secretion

## ARDELYX TGR5 AGONISTS + DPP4 INHIBITOR

- No Gallbladder Issues
- Long Lasting Incretin Secretion
- Significantly Improves Mucosal Damage In Mouse Model of IBD



### THE CHALLENGE

- All Potassium Binders (e.g. Patiromer) Have Limited Efficacy on per Gram Basis
- Therapeutic Dose for Kayexelate, Patiromer or ZS-9 Substantially the Same (15-30 g/day)
- The Limiting Factor in Efficacy is Not Binder Capacity but Availability of Potassium in the Colon

### ARDELYX POTASSIUM “SECRETAGOGUE”

- To Move Potassium into Colon and Increase Fecal Excretion
- Used as a Stand Alone or in Combination with Potassium Binder
- Augment Patient Compliance
- Maintain Normal Serum Potassium with Optimal Dosing of Antihypertensives (RAAS Blockade Drugs)

# Financial Overview



\$ MILLIONS

<b>Cash and Cash Equivalents</b>	\$112.0M (as of 9/30/14)
<b>Annualized Operating Expenses*</b>	\$16.2M (Based on 9 Months Ended 9/30/14)
<b>Debt</b>	\$0

### Capital Raised

<p><b>Series A \$26M</b></p>  <p>2008</p>	<p><b>Series B \$30M</b></p>  <p>2011</p>	<p><b>IPO \$69M</b></p> <p><b>Nasdaq: ARDX</b></p> <p>2014</p> 
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\* From Ardelyx's third quarter 10Q: \$22,915 total operating expenses for the 9 months ended September 30, 2014 (p3), less \$10,744 (p15 "AstraZeneca collaboration development expense" for the 9 months ended September 30, 2014) = \$12,171 \* 12 month/9 months = \$16.2M

## Investment Highlights



### PROPRIETARY PLATFORM

Discovery and Design of Non-Systemic, Small Molecule Therapeutics

### 2 VALIDATED PROGRAMS

Tenapanor: AstraZeneca Collaboration; Phase 2 in Three Indications

NaP2b Inhibition: Sanofi Collaboration

### WHOLLY-OWNED PIPELINE

Enhanced Drug Discovery Capabilities with Rapid, Proprietary Screening Process

### PROVEN MANAGEMENT TEAM

Deep Domain Expertise

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**ARDELYX<sup>®</sup>**

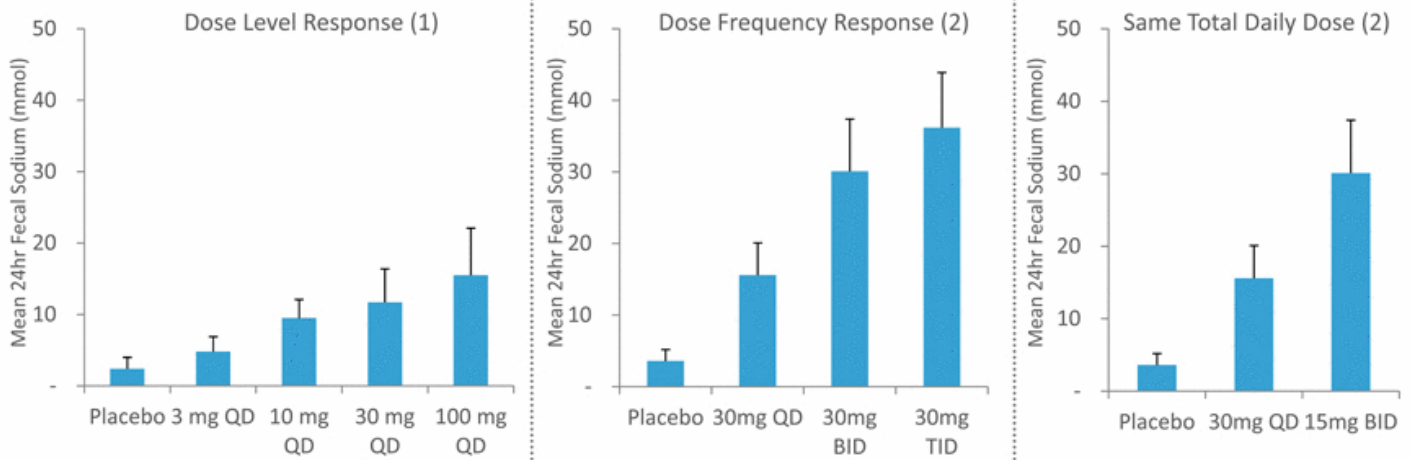
APPENDIX



# Tenapanor Demonstrates Dose Level and Dose Frequency Response<sup>1</sup>



## PHASE 1 IN HEALTHY ADULT VOLUNTEERS



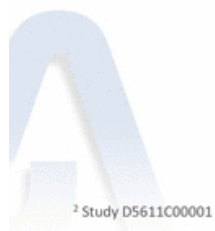
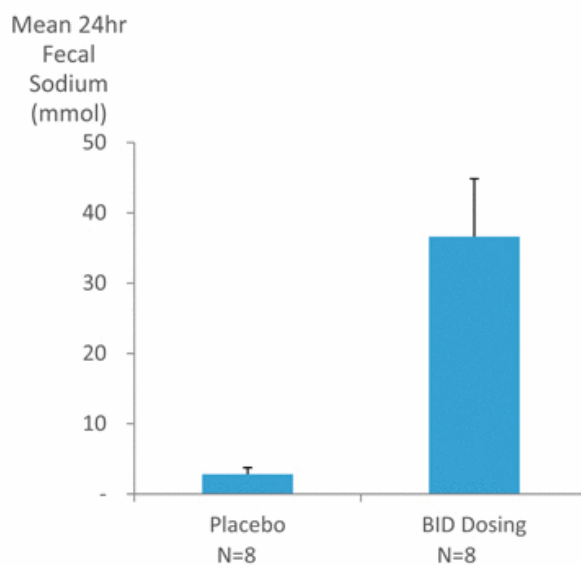
<sup>1</sup> RDX5791-101

<sup>2</sup> RDX5791-102; some data published in Spencer et al *Sci Transl Med* 6, 227ra36 (2014)

# Tenapanor Diverts Dietary Sodium to the Feces CKD-5D Patients



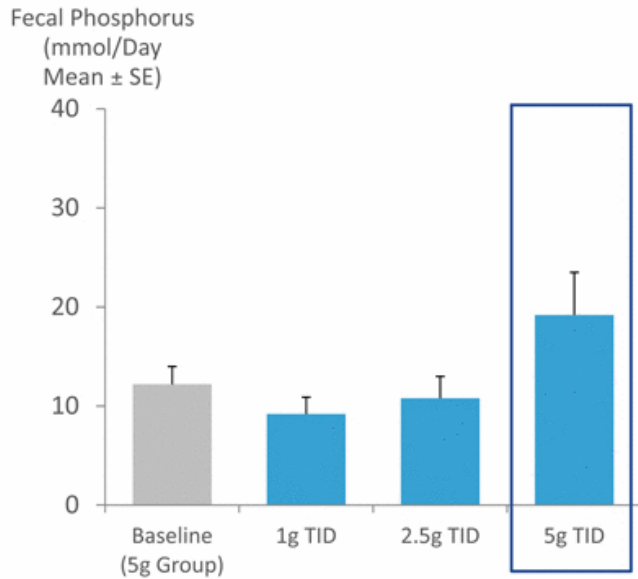
## PHASE 2a FLUID IN SUBSET OF CKD-5D PATIENTS<sup>2</sup>



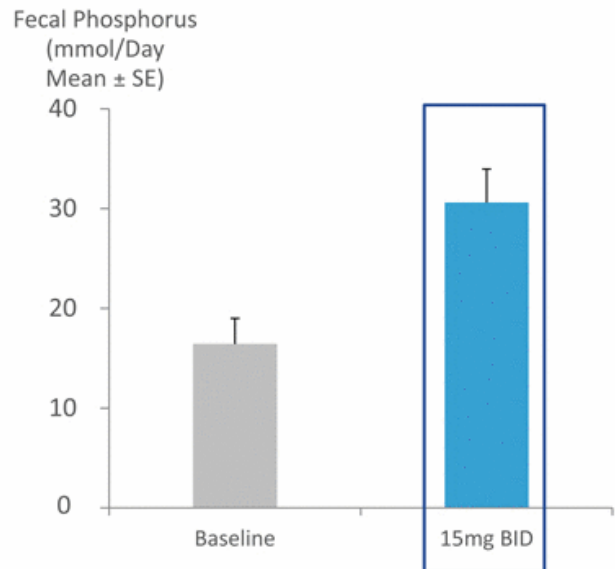
# Comparative Human Response: Sevelamer vs. Tenapanor in Healthy Adult Volunteers



## SEVELAMER<sup>1</sup>



## TENAPANOR<sup>2</sup>



Dose 15,000 mg/Day

30 mg/Day

Similar Results,  
But **1/500<sup>th</sup>** the Dose

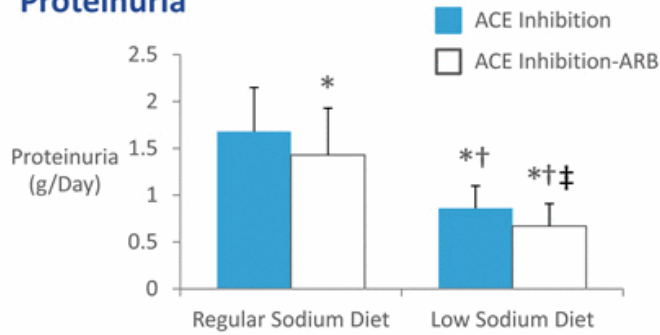
<sup>1</sup> Burke et al. 1997; <sup>2</sup> Study D5611C00002

# Studies Support Impact of Treating Elevated Sodium and Phosphorus

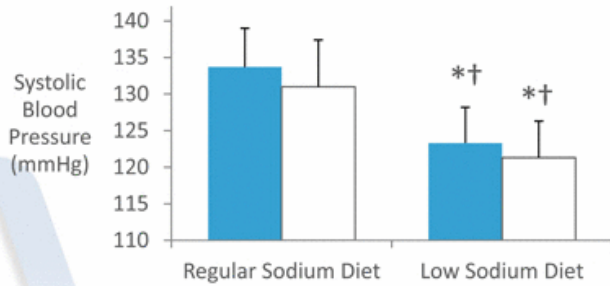


## SODIUM<sup>1</sup>

### Proteinuria

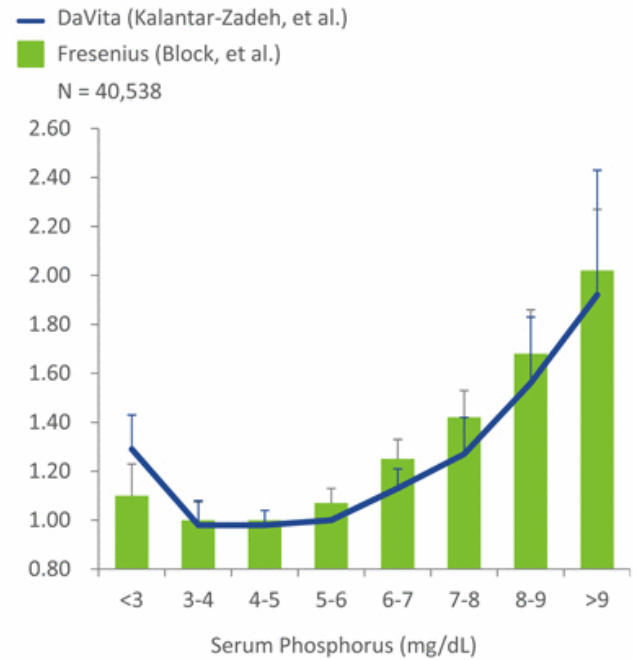


### Systolic Blood Pressure



## PHOSPHORUS<sup>2</sup>

### Relative Risk of Death\*



\*Not adjusted for active vitamin D intake; serum phosphorus 4-5 mg/dL was normalized to 1.0

1. Slagman, et al., *BMJ* (2011) 343:d4366; 2. Block, et al. *JASN* (2004) 15:2208-2218; 3. Kalantar-Zadeh, et al. *KJ* (2006) 70:771-780  
 \*P<0.05 v ACE inhibition on regular sodium diet. †P<0.05 v ACE inhibition plus ARB on regular sodium diet. ‡P<0.05 v ACE inhibition on low sodium diet

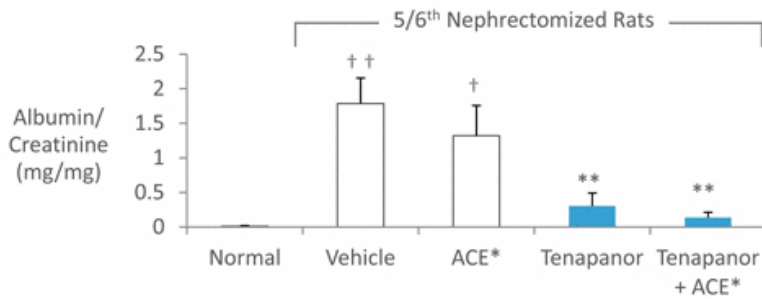


# Beneficial Effects of Tenapanor on Sodium and Phosphorus in CKD Models

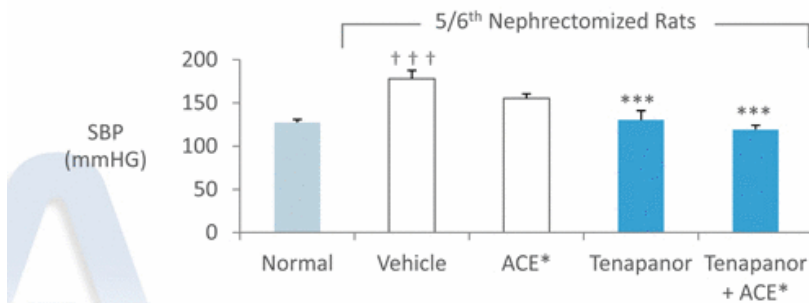


## SODIUM

### Urinary Albumin/Creatinine



### Systolic Blood Pressure



\*ACE = Enalapril ; One way Anova, followed by Dunnett's test;  
 \*\* p<0.01; \*\*\* p<0.001 vs. vehicle; † p<0.05; † †; p<0.01; † † † p<0.001 vs. sham; N=12/group

## PHOSPHORUS

### Aortic Mineral Content

