

**FOOD AND DRUG ADMINISTRATION (FDA)  
Center for Drug Evaluation and Research (CDER)**

*Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting*  
November 16, 2022

**DRAFT AGENDA**

---

*The committee will discuss new drug application 213931, for tenapanor hydrochloride tablets, submitted by Ardelyx, Inc., for the control of serum phosphorus levels in adults with chronic kidney disease on dialysis. The committee will be asked to comment on whether the size of the treatment effect on serum phosphorus is clinically meaningful and whether tenapanor's benefits outweigh its risks.*

---

9:30 a.m.	Call to Order	<b>Julia B. Lewis, MD</b> Chairperson, CRDAC
9:35 a.m.	Introduction of Committee and Conflict of Interest Statement	<b>LaToya Bonner, PharmD</b> Acting Designated Federal Officer, CRDAC
9:40 a.m.	FDA Opening Remarks	<b>Aliza Thompson, MD, MS</b> Deputy Director Division of Cardiology and Nephrology (DCN) Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN) Office of New Drugs (OND), CDER, FDA
9:45 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Ardelyx, Inc.</b>
	Introduction	<b>Laura A. Williams MD, MPH</b> Chief Medical Officer, Ardelyx
	Unmet Need	<b>Glenn Chertow, MD</b> Norman S. Coplun Satellite Healthcare Professor of Medicine Professor of Epidemiology and Population Health Stanford University School of Medicine
	Study Design Considerations	<b>Jason Conner, PhD</b> President and Lead Statistical Scientist Confluence Stat LLC
	Efficacy and Clinical Meaningfulness	<b>David Spiegel, MD</b> Vice President, Nephrology Ardelyx
	Safety	<b>Laura A. Williams MD, MPH</b>

**FOOD AND DRUG ADMINISTRATION (FDA)  
Center for Drug Evaluation and Research (CDER)**

*Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting*  
November 16, 2022

**DRAFT AGENDA (cont.)**

---

---

**APPLICANT PRESENTATIONS (CONT.)**

Clinical Perspective

**Stuart Sprague, DO**  
Clinical Professor of Medicine  
University of Chicago, Pritzker School of  
Medicine  
Chief, Division of Nephrology and Hypertension  
NorthShore University Health System

10:45 a.m. Clarifying Questions

11:30 a.m. **BREAK**

11:45 a.m. **FDA PRESENTATIONS**

Tenapanor's Efficacy and Safety

**Aliza Thompson, MD, MS**

**Ling-Wan Chen, PhD**

Biometrics Reviewer  
Division of Biometrics II, Office of Biostatistics  
Office of Translational Sciences, CDER, FDA

**Selena DeConti, PharmD, MPH**

Safety Analyst  
DCN, OCHEN, OND, CDER, FDA

12:30 p.m. Clarifying Questions

1:00 p.m. **LUNCH**

2:00 p.m. **OPEN PUBLIC HEARING**

3:00 p.m. Charge to the Committee

**Aliza Thompson, MD, MS**

3:05 p.m. Questions to the Committee/Committee  
Discussion

5:00 p.m. **ADJOURNMENT**