

**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	Julia B. Lewis, MD Chairperson, CRDAC
9:35 a.m.	Introduction of Committee and Conflict of Interest Statement	LaToya Bonner, PharmD Acting Designated Federal Officer, CRDAC
9:40 a.m.	FDA Opening Remarks	Aliza Thompson, MD, MS 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.	APPLICANT PRESENTATIONS	
	Introduction	Ardelyx, Inc.
	Unmet Need	Laura A. Williams MD, MPH Chief Medical Officer, Ardelyx
	Study Design Considerations	Glenn Chertow, MD Norman S. Coplon Satellite Healthcare Professor of Medicine Professor of Epidemiology and Population Health Stanford University School of Medicine
	Efficacy and Clinical Meaningfulness	Jason Conner, PhD President and Lead Statistical Scientist Confluence Stat LLC
	Safety	David Spiegel, MD Vice President, Nephrology Ardelyx
	Laura A. Williams MD, MPH	

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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**