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

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

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, Conflict of Interest Statement, and Statement on Formal Dispute Resolution Request	**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**	**Ardelyx, Inc.**
	Introduction	**Laura A. Williams MD, MPH** Chief Medical Officer, Ardelyx
	Unmet Need	**Glenn Chertow, MD** Norman S. Coplon Satellite Healthcare Professor of Medicine Professor of Epidemiology and Population Health Stanford University School of Medicine
	Study Design Considerations	**Jason Conner, PhD** President and Lead Statistical Scientist Confluence Stat LLC
	Efficacy and Clinical Meaningfulness	**David Spiegel, MD** Vice President, Nephrology Ardelyx
	Safety	**Laura A. Williams MD, MPH**

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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**	