

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

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting

September 13, 2023

DRAFT AGENDA

The committee will discuss supplemental new drug application (sNDA) 210922 s015 for ONPATTRO (patisiran) lipid complex for injection, submitted by Alnylam Pharmaceuticals, Inc., for the proposed treatment of the cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults.

9:00 a.m.	Call to Order	Javed Butler, MD, MPH, MBA Chairperson, CRDAC
9:05 a.m.	Introduction of Committee/ Conflict of Interest Statement	Joyce Frimpong, PharmD Acting Designated Federal Officer, CRDAC
9:15 a.m.	FDA Opening Remarks	Norman Stockbridge, MD, PhD Director Division of Cardiology and Nephrology (DCN) Office of Cardiology, Hematology, Endocrinology, and Nephrology (OCHEN) Office of New Drugs (OND)
9:25 a.m.	APPLICANT PRESENTATIONS	Alnylam Pharmaceuticals, Inc.,
	Introduction	Pushkal P. Garg, MD Chief Medical Officer Alnylam Pharmaceuticals
	Unmet Need	John Berk, MD Professor of Medicine Clinical Director of Amyloidosis Center Boston University
	Efficacy	John Vest, MD Senior Vice President, Clinical Research Alnylam Pharmaceuticals
	Impact of Patisiran on Patient Health Status	John Spertus, MD, MPH Professor, Daniel J. Lauer / Missouri Endowed Chair in Metabolic and Vascular Disease Research University of Missouri-Kansas City

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Safety

Elena Yureneva, MD, MHA
Executive Director, Head of Medical Safety
& Risk Management
Alnylam Pharmaceuticals

Clinical Perspective

Ronald Witteles, MD
Professor of Cardiovascular Medicine
Co-Director, Stanford Amyloid Center
Stanford University School of Medicine

10:25 a.m. Clarifying Questions to Applicant

10:55 a.m. **BREAK**

11:05 a.m. **FDA PRESENTATIONS**

Patisiran Efficacy and Safety

Rosalyn Adigun, MD, PharmD
Clinical Reviewer
DCN, OCHEN, CDER, FDA

12:05 p.m. Clarifying Questions

12:35 p.m. **LUNCH**

1:30 p.m. **OPEN PUBLIC HEARING**

2:30 p.m. Charge to the Committee

Norman Stockbridge, MD, PhD

2:35 p.m. Questions to the Committee/Committee
Discussion

4:00 p.m. **ADJOURNMENT**