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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
Tommy Douglas Conference Center
10000 New Hampshire Avenue, Silver Spring, Maryland
May 10, 2018

AGENDA

The committee will discuss the safety and efficacy of new drug application (NDA) 210645, for volanesorsen solution for subcutaneous injection, submitted by Akcea Therapeutics, Inc. The proposed indication is as an adjunct to diet for the treatment of patients with familial chylomicronemia syndrome.

8:00 a.m.	Call to Order and Introduction of Committee	**Peter Wilson, MD** Chairperson, EMDAC
8:05 a.m.	Conflict of Interest Statement	**LaToya Bonner, PharmD** Designated Federal Officer, EMDAC
8:10 a.m.	FDA Introductory Remarks	**John Sharretts, MD** Clinical Team Lead (acting) Division of Metabolism and Endocrinology Products (DMEP), Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	**APPLICANT PRESENTATIONS**	**Akcea Therapeutics, Inc.**
	Introduction	**Louis St.L. O'Dea, MB BCh BAO. CSPQ. FRCP(C)** Chief Medical Officer, Akcea Therapeutics
	Unmet Need: Disease Background	**Daniel J. Rader, MD** Seymour Gray Professor of Molecular Medicine Perelman School of Medicine University of Pennsylvania
	Pancreatitis	**Steve Freedman, MD, PhD** Professor of Medicine, Harvard Medical School Chief, Division of Translational Research Director, The Pancreas Center Beth Israel Deaconess Medical Center
	Efficacy	**Louis St.L. O'Dea, MB BCh BAO. CSPQ. FRCP(C)**
	Safety	**Walter Singleton, MD** Former Chief Medical Officer, Ionis Pharmaceuticals
	Risk Management	**Michael Stevenson, RPh, PhD** Head of Medical Affairs, Akcea Therapeutics

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Clinical Perspective	**Seth J. Baum, MD, FACC, FACPM, FAHA, FNLA, FASPC** President, American Society of Preventive Cardiology Affiliate Clinical Professor of Medicine Schmidt College of Medicine
9:50 a.m.	Clarifying Questions to Applicant	
10:05 a.m.	**BREAK**	
10:20 a.m.	**FDA PRESENTATIONS**	
	Clinical Review Introduction	**Mary D. Roberts, MD** Clinical Reviewer DMEP, ODE-II, OND, CDER, FDA
	Statistical Review of Efficacy	**Alexander Cambon, PhD** Statistical Reviewer Division of Biometrics II, Office of Biostatistics Office of Translational Sciences (OTS), CDER, FDA
	Clinical Review	**Mary D. Roberts, MD**
	Clinical Pharmacology Review	**Yunzhao Ren, MD, PhD** Clinical Pharmacology Reviewer Division of Clinical Pharmacology II Office of Clinical Pharmacology (OCP) OTS, CDER, FDA
	Risk Evaluation and Mitigation Strategy (REMS) Considerations	**Ingrid N. Chapman, PharmD, BCPS** Risk Management Analyst Division of Risk Management (DRISK) Office of Medication Error and Risk Management (OMEPRM) Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Benefit/Risk Summary	**Mary D. Roberts, MD**
11:50 a.m.	Clarifying Questions to FDA	
12:05 p.m.	**LUNCH**	

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1:05 p.m.	**OPEN PUBLIC HEARING**
2:05 p.m.	Questions to the Committee/Committee Discussion
3:45 p.m.	**BREAK**
4:00 p.m.	Questions to the Committee/Committee Discussion
5:00 p.m.	**ADJOURNMENT**