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

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
December 10, 2019

AGENDA

The committee will be asked to discuss new drug application (NDA) 022034, for vernakalant HCl solution, for intravenous injection, submitted by Correvio International Sàrl, for the proposed indication of rapid conversion of recent onset atrial fibrillation to sinus rhythm for non-surgery patients: atrial fibrillation ≤ 7 days duration, and for post-cardiac surgery patients: atrial fibrillation ≤ 3 days duration.

8:00 a.m.	Call to Order and Introduction of Committee	**Julia B. Lewis, MD** Chairperson, CRDAC
8:05 a.m.	Conflict of Interest Statement	**Yinghua Wang, PharmD, MPH, RAC** Acting Designated Federal Officer, CRDAC
8:10 a.m.	FDA Introductory Remarks	**Norman Stockbridge, MD, PhD** Director Division of Cardiovascular and Renal Products (DCaRP), Office of Drug Evaluation I (ODE I) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Correvio International Sàrl**
	Introduction	**Mark Corrigan, MD** Chief Executive Officer Correvio International Sàrl
	Recent Onset AF: High Unmet Need for an Additional Pharmaceutical Treatment	**Peter R. Kowey, MD** Professor Lankenau Institute for Medical Research Lankenau Heart Institute Jefferson Medical College of Thomas Jefferson University
	Nonclinical Pharmacology	**Peter K.S. Siegl, PhD** Nonclinical Pharmacologist Correvio International Sàrl
	Clinical Efficacy	**Andrew Tershakovec, MD, MPH** Clinical Lead Correvio International Sàrl
	Safety	**W. Douglas Weaver, MD** Cardiologist Correvio International Sàrl

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	A Clinical Assessment of Benefit-Risk	**Peter R. Kowey, MD**
	Conclusion	**Mark Corrigan, MD**
9:45 a.m.	Clarifying Questions	
10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATIONS**	
	FDA Overview of Cardiovascular Safety	**Preston M. Dunnmon, MD, MBA, FACP, FACC** Medical Officer DCaRP, ODE I, OND, CDER, FDA
	Safety of Ibutilide and Electrical Cardioversion in Patients with Atrial Fibrillation or Flutter	**Daniel Woronow, MD, FACC** Medical Officer Division of Pharmacovigilance I Office of Pharmacovigilance and Epidemiology Office of Surveillance and Epidemiology CDER, FDA
	FDA Conclusion	**Preston M. Dunnmon, MD, MBA, FACP, FACC**
11:15 a.m.	Clarifying Questions	
11:30 a.m.	**LUNCH**	
12:30 p.m.	Open Public Hearing	
1:30 p.m.	Charge to the Committee	**Norman Stockbridge, MD, PhD**
1:40 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	**BREAK**	
3:15 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	