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

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
December 8, 2021

AGENDA

The committee will discuss new drug application 215484, for the Nrf2 activator, bardoxolone methyl capsules, submitted by Reata Pharmaceuticals, Inc. The proposed indication is to slow the progression of chronic kidney disease caused by Alport syndrome in patients 12 years of age and older.

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	**Moon Hee V. Choi, 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**	**Reata Pharmaceuticals, Inc.**
	Bardoxolone Methyl Capsules for Treatment of Alport Syndrome	**Melanie Chin, PhD** Vice President, Product Strategy Reata Pharmaceuticals
	Alport Syndrome and Need for Therapies	**Bradley Warady, MD** Director, Division of Nephrology, Director of Dialysis and Transplantation Children's Mercy Kansas City Professor of Pediatrics University of Missouri Kansas City School of Medicine
	Alport Syndrome Phase 3 Study Design	**Colin Meyer, MD** Chief Research and Development Officer Reata Pharmaceuticals
		Nathan Teuscher, PhD Vice President Integrated Drug Development Consulting Certara

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Clinical Efficacy of Bardoxolone Methyl	**Colin Meyer, MD**
	Clinical Safety of Bardoxolone Methyl	**Colin Meyer, MD**
	Benefit/Risk Assessment	**Glenn Chertow, MD, MPH** Professor of Medicine (Nephrology) and (by courtesy) Professor of Epidemiology and Population Health Stanford University School of Medicine
	Conclusion	**Colin Meyer, MD**
11:15 a.m.	Clarifying Questions	
11:45 a.m.	**BREAK**	
11:55 a.m.	**FDA PRESENTATIONS**	
	Bardoxolone Efficacy and Safety	**Lars Johannesen, PhD** Clinical Analyst DCN, OCHEN, OND, CDER, FDA **Dali Zhou, PhD** Biometrics Reviewer Division of Biometrics II, Office of Biostatistics Office of Translational Sciences, CDER, FDA
1:00 p.m.	Clarifying Questions	
1:30 p.m.	**LUNCH**	
2:15 p.m.	**OPEN PUBLIC HEARING**	
3:30 p.m.	Charge to the Committee	**Aliza Thompson, MD, MS**
3:35 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	