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

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
October 26, 2022

AGENDA

The committee will discuss new drug application (NDA) 216951, for the hypoxia inducible factor prolyl hydroxylase inhibitor, daprodustat tablets, submitted by GlaxoSmithKline, LLC, for the treatment of anemia due to chronic kidney disease in adult patients not on dialysis and on dialysis.

9:00 a.m.	Call to Order	**Julia B. Lewis, MD** Chairperson, CRDAC
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	**Jessica Seo, PharmD, MPH** Acting Designated Federal Officer, CRDAC
9:10 a.m.	FDA Opening Remarks	**Ann Farrell, MD** Director Division of Non-Malignant Hematology (DNH) Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN) Office of New Drugs (OND), CDER, FDA
9:20 a.m.	**APPLICANT PRESENTATIONS**	**GlaxoSmithKline, LLC (GSK)**
	Introduction	**Janet van Adelsberg, MD** Medicines Development Leader, Daprodustat Vice President, GSK
	Unmet Need	**Kirsten Johansen, MD** Professor of Medicine, University of Minnesota Nephrology Division Director Co-Director, Chronic Disease Research Group Hennepin County Medical Center
	Clinical Trial Results	**Alexander Cobitz, MD, PhD** Clinical Development Lead, Daprodustat Senior Medical Director, GSK
	Cardiovascular Safety	**Kaivan Khavandi, MBChB, PhD, MCRP** Vice President Clinical Development, GSK
	Differential Dosing Frequency & On-Treatment Analysis Bias	**Kevin Carroll, PhD** Biostatistics Consultant Chief Statistician, KJC Statistics Ltd
	General Safety	**Heather Stein, MD** Vice President Safety Evaluation and Risk Management Global Safety, GSK

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Clinical Perspective	**Ajay Singh, MBBS, FRCP** Senior Associate Dean for Postgraduate Medical Education Director, Master in Medical Sciences in Clinical Investigation (MMSCI) Program Harvard Medical School Renal Physician, Brigham and Women's Hospital
10:50 a.m.	Clarifying Questions	
11:20 a.m.	**BREAK**	
11:30 a.m.	**FDA PRESENTATIONS**	
	Background and Efficacy of Daprodustat	**Justin Penzenstadler, PharmD** Clinical Reviewer DNH, OCHEN, OND, CDER, FDA
	Daprodustat's Cardiovascular Safety	**Van Tran, PhD** Statistical Reviewer Division of Biometrics VII, Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Daprodustat's General Safety and Summary	**Justin Penzenstadler, PharmD**
12:40 p.m.	Clarifying Questions	
1:10 p.m.	**LUNCH**	
2:10 p.m.	**OPEN PUBLIC HEARING**	
3:10 p.m.	Questions to the Committee/Committee Discussion	
4:10 p.m.	**BREAK**	
4:20 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:15 p.m.	**ADJOURNMENT**	