

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

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

DRAFT 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
9:15 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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DRAFT 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

10:45 a.m. Clarifying Questions

11:15 a.m. **BREAK**

11:25 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**