

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

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
July 15, 2021

AGENDA

The committee will discuss new drug application 213805, for the hypoxia inducible factor prolyl hydroxylase inhibitor, roxadustat tablets, submitted by FibroGen, Inc., for the treatment of anemia due to chronic kidney disease in adult patients not on dialysis and on dialysis.

9:30 a.m.	Call to Order and Introduction of Committee	Julia B. Lewis, MD Chairperson, CRDAC
9:35 a.m.	Conflict of Interest Statement	Joyce Yu, PharmD Designated Federal Officer, CRDAC
9:40 a.m.	FDA Opening Remarks	Ellis F. Unger, MD Director Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN) Office of New Drugs (OND), CDER, FDA
9:45 a.m.	APPLICANT PRESENTATIONS	FibroGen, Inc.
	Introduction	R. Wayne Frost, PharmD, JD Senior Vice President Regulatory Affairs FibroGen, Inc.
	Unmet Need	Roberto Pecoits-Filho, MD, PhD Nephrologist and Senior Research Scientist Arbor Research Collaborative for Health
	Efficacy Results	Lynda Szczech, MD Vice President Clinical Development and Medical Affairs FibroGen, Inc.
	Safety Results	Dustin Little, MD Global Clinical Head AstraZeneca LP
	Clinical Perspective	Steven Fishbane, MD Professor of Medicine Chief, Division of Nephrology Donald and Barbara Zucker School of Medicine
11:15 a.m.	Clarifying Questions	

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AGENDA (cont.)

11:45 a.m. **BREAK**

11:55 a.m. **FDA PRESENTATIONS**

Roxadustat for the Treatment of Anemia
Due to Chronic Kidney Disease in Adult
Patients not on Dialysis and on Dialysis

Saleh Ayache, MD
Clinical Reviewer
Division of Non-Malignant Hematology (DNH)
OCHEN, OND, CDER, FDA

Jae Joon Song, PhD
Statistical Reviewer
Division of Biometrics VII (DB-VII)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS)
CDER, FDA

1:10 p.m. Clarifying Questions

1:30 p.m. **LUNCH**

2:30 p.m. **OPEN PUBLIC HEARING**

3:30 p.m. Questions to the Committee/Committee
Discussion

4:15 p.m. **BREAK**

4:25 p.m. Questions to the Committee/Committee
Discussion (cont.)

5:30 p.m. **ADJOURNMENT**