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

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
December 13, 2022

DRAFT AGENDA

The committee will discuss new drug application 216401, for omecamtiv mecarbil tablets, submitted by Cytokinetics, Inc. The proposed indication is to reduce the risk of cardiovascular death and heart failure events in patients with symptomatic chronic heart failure with reduced ejection fraction. The committee will discuss whether the phase 3 trial (GALACTIC-HF) establishes substantial evidence of effectiveness of omecamtiv mecarbil and whether the benefits of omecamtiv mecarbil outweigh the risks when used according to the applicant's proposed dosing regimen.

9:00 a.m.	Call to Order and Introduction of Committee	**Julia B. Lewis, MD** Chairperson, CRDAC
9:05 a.m.	Conflict of Interest Statement	**Rhea Bhatt, MS** Designated Federal Officer, CRDAC
9:10 a.m.	FDA Opening Remarks	**Norman Stockbridge, MD, PhD** Director Division of Cardiology and Nephrology (DCN) Office of Cardiology, Hematology, Endocrinology and Nephrology (OCHEN) Office of New Drugs (OND), CDER, FDA
9:15 a.m.	**APPLICANT PRESENTATIONS**	**Cytokinetics, Inc.**
	Introduction	**Rachel E. Melman, MBS, RAC** Senior Director, Regulatory Affairs Cytokinetics
	Unmet Needs in Heart Failure with Reduced Ejection Fraction (HRreF)	**G. Michael Felker, MD, MHS, FACC, FAHA, FHFSA** Vice-Chief of Cardiology Director of Cardiovasccular Research Professor of Medicine Duke University School of Medicine
	Efficacy of Omecamtiv Mecarbil in HRrEF	**Fady Malik, MD, PhD, FACC, FHFA** Executive Vice President, Research & Development Cytokinetics
	Safety of Omecamtiv Mecarbil in HRrEF	**Stuart Kupfer, MD** Senior Vice President, Chief Medical Officer Cytokinetics

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DRAFT AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Dosing Strategy	**Stuart Kupfer, MD**
	Benefit/Risk	**Scott D. Solomon, MD** Professor of Medicine, Harvard Medical School Brigham and Women's Hospital
	Conclusion	**Fady Malik, MD, PhD, FACC, FHFA**
10:45 a.m.	Clarifying Questions	
11:15 a.m.	**BREAK**	
11:25 a.m.	**FDA PRESENTATIONS**	
	Omecamtiv Mecarbil Efficacy and Safety	**Tzu-Yun McDowell, PhD** Clinical Reviewer DCN, OCHEN, OND, CDER, FDA **William Koh, PhD** Statistical Reviewer Division of Biometrics II Office of Biostatistics Office of Translational Sciences (OTS) CDER, FDA **Li Wang, PhD** Clinical Pharmacology Reviewer Division of Cardiometabolic & Endocrine Pharmacology Office of Clinical Pharmacology OTS, CDER, FDA
12:30 p.m.	Clarifying Questions	
1:00 p.m.	**LUNCH**	
2:00 p.m.	**OPEN PUBLIC HEARING**	
3:00 p.m.	Charge to Committee	**Norman Stockbridge, MD, PhD**

DRAFT AGENDA (cont.)

3:10 p.m.	Questions to the Committee/Committee Discussion
4:05 p.m.	**BREAK**
4:15 p.m.	Questions to the Committee/Committee Discussion (cont.)
5:00 p.m.	**ADJOURNMENT**