

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

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
December 16, 2020

DRAFT AGENDA

The committee will discuss spironolactone for the proposed treatment of heart failure with preserved ejection fraction (HFpEF), a serious and often fatal condition for which no drug is approved to improve outcomes. The data supporting the new indication are post-hoc analyses of the National Heart, Lung, and Blood Institute (NHLBI) sponsored TOPCAT (Treatment of Preserved Cardiac Function Heart Failure With an Aldosterone Antagonist) trial, which nominally failed to meet its primary endpoint. Spironolactone is currently marketed in the US for the treatment of heart failure with reduced ejection fraction, hypertension, primary hyperaldosteronism, and for the management of edema.

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| 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 | Joyce Yu, PharmD
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. | GUEST SPEAKER PRESENTATIONS | |
| | Effectiveness and Safety of Spironolactone in Adults with Heart Failure with Preserved Ejection Fraction in TOPCAT | Martin Rose, MD, JD
Member, Rose Regulatory Consulting, LLC |
| | TOPCAT | Bertram Pitt, MD
Professor of Medicine Emeritus
University of Michigan School of Medicine
Division of Cardiology |
| | Treatment Of Preserved Cardiac Function Heart Failure with an Aldosterone anTagonist (TOPCAT) | Marc A. Pfeffer, MD, PhD
Distinguished Dzaou Professor of Medicine
Harvard Medical School
Senior Physician, Cardiovascular Division
Brigham and Women’s Hospital |

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DRAFT AGENDA (cont.)

10:30 a.m. **FDA PRESENTATION**

TOPCAT: Spironolactone vs. placebo for
the treatment of heart failure with
preserved ejection fraction

Ququan Liu, MD, MS
Mathematical Statistician
Division of Biometrics II (DB-II)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS)
CDER, FDA

10:40 a.m. Clarifying Questions

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

11:30 a.m. **OPEN PUBLIC HEARING**

12:30 p.m. Questions to the Committee/Committee
Discussion

2:00 p.m. **ADJOURNMENT**