

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

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

**AGENDA**

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*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   | <b>Julia B. Lewis, MD</b><br>Chairperson, CRDAC  |
| 9:05 a.m. | Conflict of Interest Statement  | <b>Joyce Yu, PharmD</b><br>Designated Federal Officer, CRDAC   |
| 9:10 a.m. | FDA Opening Remarks   | <b>Norman Stockbridge, MD, PhD</b><br>Director<br>Division of Cardiology and Nephrology (DCN)<br>Office of Cardiology, Hematology,<br>Endocrinology and Nephrology (OCHEN)<br>Office of New Drugs (OND), CDER, FDA |
| 9:15 a.m. | <b>GUEST SPEAKER PRESENTATIONS</b>  |  |
|           | Spironolactone for HF with Preserved Ejection Fraction: Effectiveness and Safety Results      | <b>Martin Rose, MD, JD</b><br>Member, Rose Regulatory Consulting, LLC  |
|           | TOPCAT  | <b>Bertram Pitt, MD</b><br>Professor of Medicine Emeritus<br>University of Michigan School of Medicine<br>Division of Cardiology   |
|           | Treatment Of Preserved Cardiac Function Heart Failure with an Aldosterone anTagonist (TOPCAT) | <b>Marc A. Pfeffer, MD, PhD</b><br>Distinguished DzaU Professor of Medicine<br>Harvard Medical School<br>Senior Physician, Cardiovascular Division<br>Brigham and Women’s Hospital                                 |

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**AGENDA (cont.)**

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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**