

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

Cardiovascular and Renal Drugs Advisory Committee (CRDAC) Meeting
December 15, 2020

AGENDA

The committee will discuss supplemental new drug application (sNDA) 207620-S18, for the angiotensin receptor-neprilysin inhibitor, ENTRESTO (sacubitril and valsartan) tablets, submitted by Novartis Pharmaceuticals Corp., for the proposed indication of heart failure with preserved ejection fraction (HFpEF).

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.	APPLICANT PRESENTATIONS	Novartis Pharmaceuticals Corporation
	Introduction	David Soergel, MD Global Head, Cardiovascular, Renal & Metabolism Development Novartis Pharmaceuticals Corporation
	Heart Failure with Preserved Ejection Fraction (HFpEF)	John McMurray, MD Professor, Institute of Cardiovascular & Medical Sciences British Heart Foundation Cardiovascular Research Centre University of Glasgow & Queen Elizabeth University Hospital in Glasgow
	Sacubitril/Valsartan Efficacy and Safety in HFpEF	Scott Solomon, MD Professor, Harvard Medical School Brigham and Women's Hospital
	PARAGON-HF: Clinical Implications	John McMurray, MD
	Closing Remarks	David Soergel, MD
10:45 a.m.	Clarifying Questions	

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AGENDA (cont.)

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

11:25 a.m. **FDA PRESENTATIONS**

Entresto (sacubitril and valsartan) for the
Proposed Indication of Heart Failure with
Preserved Ejection Fraction

Charu Gandotra, MD
Clinical Reviewer
DCN, OCHEN, OND, CDER, FDA

Jennifer Clark, PhD
Statistical Reviewer
Division of Biometrics II (DB-II)
Office of Biostatistics (OB)
Office of Translational Sciences (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. Questions to the Committee/Committee
Discussion

4:00 p.m. **BREAK**

4:15 p.m. Questions to the Committee/Committee
Discussion (cont.)

5:00 p.m. **ADJOURNMENT**