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

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

DRAFT 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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DRAFT 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**	