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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
Hilton Washington DC/Rockville Hotel & Executive Meeting Center, Plaza Ballroom
1750 Rockville Pike, Rockville, Maryland
June 28, 2016

AGENDA

The committee will discuss supplemental new drug application (sNDA) 204629, empagliflozin (JARDIANCE) tablets, and sNDA 206111, empagliflozin and metformin hydrochloride (SYNJARDY) tablets. Both sNDAs are sponsored by Boehringer Ingelheim Pharmaceuticals, Inc., for the proposed additional indication in adult patients with type 2 diabetes mellitus and high cardiovascular risk to reduce the risk of all-cause mortality by reducing the incidence of cardiovascular death and to reduce the risk of cardiovascular death or hospitalization for heart failure.

8:00 a.m.	Call to Order and Introduction of Committee	**Robert Smith, MD** Chairperson, EMDAC
8:05 a.m.	Conflict of Interest Statement	**LaToya Bonner, PharmD** Designated Federal Officer, EMDAC
8:10 a.m.	FDA Introductory Remarks	**Jean-Marc Guettier, MDCM** Director Division of Metabolism and Endocrinology Products (DMEP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
8:20 a.m.	**APPLICANT PRESENTATIONS**	**Boehringer Ingelheim Pharmaceuticals, Inc.**
	INTRODUCTION	**Hans-Juergen Woerle, MD** Vice President Therapeutic Area Metabolism Boehringer Ingelheim
	Context and Background	**Prof. Bernard Zinman** Chairman, EMPA-REG OUTCOME Steering Committee Director, Leadership Sinai Centre for Diabetes Professor of Medicine, University of Toronto
		Hans-Juergen Woerle, MD
	Cardiovascular Outcomes	**Uli Broedl, MD** Head of Clinical Development Therapeutic Area Metabolism Boehringer Ingelheim
	Safety, Data Quality and Integrity	**Hans-Juergen Woerle, MD**
	Clinical Perspective	**Prof. Bernard Zinman**

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AGENDA (cont.)

	APPLICANT PRESENTATIONS (cont.)	
	Summary	**Hans-Juergen Woerle, MD**
9:50 a.m.	Clarifying Questions to Applicant	
10:05 a.m.	**BREAK**	
10:20 a.m.	**FDA PRESENTATIONS**	
	The EMPA-REG OUTCOME Trial	**Andreea Lungu, MD** Clinical Reviewer DMEP, ODE-II, OND, CDER, FDA
	Statistical Assessment	**Jennifer Clark, PhD** Mathematical Statistician Division of Biometrics II (DB-II) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER FDA
	Further Assessment of Endpoints and Non-Cardiovascular Safety	**Andreea Lungu, MD**
11:50 a.m.	Clarifying Questions to FDA	
12:05 p.m.	**LUNCH**	
1:05 p.m.	**OPEN PUBLIC HEARING**	
2:05 p.m.	Questions to the Committee/Committee Discussion	
3:45 p.m.	**BREAK**	
4:00 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	

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