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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
FDA White Oak Campus, Building 31 Conference Center (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
January 17, 2019

AGENDA

The committee will discuss new drug application 210934 for sotagliflozin oral tablet, sponsored by sanofi-aventis U.S., LLC, for the proposed indication: Adjunct to insulin therapy to improve glycemic control in adults with type 1 diabetes mellitus.

8:00 a.m.	Call to Order and Introduction of Committee	**Peter Wilson, 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	**Lisa Yanoff, MD** Director (Acting) 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**	**sanofi-aventis, U.S., LLC**
	Introduction	**Rene Belder, MD** Vice President Diabetes and Cardiovascular Clinical Development Sanofi
	Unmet Medical Needs in Adults with Type 1 Diabetes	**Steven Edelman, MD** Clinical Professor of Medicine University of California San Diego School of Medicine
	Clinical Efficacy Results	**Pablo Lapuerta, MD** Executive Vice President and Chief Medical Officer Lexicon Pharmaceuticals
	Clinical Safety Results	**Klaus Jensen, MD** Head of Diabetes, Cardiovascular and Metabolism Development Sanofi
	Clinical Perspective	**Juan Pablo Frias, MD** Medical Director and Principal Investigator National Research Institute
	Benefit / Risk	**Rene Belder, MD**

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AGENDA (cont.)

9:50 a.m.	Clarifying Questions to Applicant	
10:05 a.m.	**BREAK**	
10:20 a.m.	**FDA PRESENTATIONS**	
	Overview of the Clinical Pharmacology and Development Program for Sotagliflozin	**Mitra Rauschecker, MD** Acting Team Leader DMEP, ODE-II, OND, CDER, FDA
	Statistical Assessment of Sotagliflozin Efficacy	**Kiya Hamilton, PhD** Statistical Reviewer Division of Biometrics II, Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	Diabetic Ketoacidosis in the Sotagliflozin Clinical Development Program	**Mitra Rauschecker, MD**
	Diabetic Ketoacidosis in Type 1 Diabetes Mellitus Patients Using a Sodium-glucose Co-transporter 2 Inhibitor: Postmarketing Experience	**Christine Chamberlain, PharmD, CDE** Safety Evaluator Division of Pharmacovigilance I Office of Pharmacovigilance and Epidemiology (OPE) Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Sentinel Analysis of SGLT2 Inhibitor Use in Patients with Type 1 Diabetes Mellitus and Rates of Diabetic Ketoacidosis	**Christian Hampp, PhD, FISPE** Master Reviewer Epidemiologist Division of Epidemiology I OPE, OSE, CDER, FDA
	Summary of FDA Findings for Sotagliflozin	**Mitra Rauschecker, 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**	