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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
October 31, 2024

DRAFT AGENDA

The Committee will discuss new drug application 210934, for sotagliflozin oral tablet, submitted by Lexicon Pharmaceuticals, Inc., for the proposed indication, as an adjunct to insulin therapy, to improve glycemic control in adults with type 1 diabetes mellitus and chronic kidney disease.

8:30 a.m.	Call to Order and Introduction of Committee	**Cecilia C. Low Wang, MD** Chairperson, EMDAC
8:35 a.m.	Conflict of Interest Statement	**Joyce Frimpong, PharmD** Acting Designated Federal Officer, EMDAC
8:40 a.m.	FDA Introductory Remarks NDA 210934: Sotagliflozin to Improve Glycemic Control in Adults with Type 1 Diabetes Mellitus and Chronic Kidney Disease (T1D-CKD)	**Patrick Archdeacon, MD** Deputy Director Division of Diabetes, Lipid Disorders, and Obesity (DDLO) Office of Cardiology, Hematology, Endocrinology, and Nephrology (OCHEN) Office of New Drugs (OND), CDER, FDA
8:55 a.m.	**APPLICANT PRESENTATIONS**	**Lexicon Pharmaceuticals, Inc.**
	Introduction: T1D-CKD Indication	**Brian Corrigan** Senior VP Regulatory & Quality Assurance Lexicon Pharmaceuticals, Inc.
	Overview of T1D-CKD Disease, Burden, and Unmet Need	**Steven Edelman, MD** Professor of Medicine Division of Endocrinology, Diabetes & Metabolism University of California, San Diego Founder and Director Taking Control of Your Diabetes 501(c)(3)
	Sotagliflozin Efficacy	**Michael Davies, PhD** Executive Director, Clinical Development Lexicon Pharmaceuticals, Inc.

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APPLICANT PRESENTATIONS (CONT.)

	Sotagliflozin Safety	**Craig Granowitz, MD, PhD** Senior Vice President and Chief Medical Officer Lexicon Pharmaceuticals, Inc.
	T1D-CKD Management, Risk Management, and Education	**Richard Pratley, MD** Medical Director AdventHealth Diabetes Institute Senior Investigator, Diabetes Program Lead AdventHealth Translational Research Institute
	Conclusion	**Craig Granowitz, MD, PhD**
10:10 a.m.	Clarifying Questions to Applicant	
10:30 a.m.	**BREAK**	
10:45 a.m.	**FDA PRESENTATIONS**	
	Overview of Sotagliflozin Development Program	**Mari Suzuki, MD** Clinical Reviewer DDLO, OCHEN, OND, CDER, FDA
	Efficacy Review of Tandem Studies by estimated glomerular filtration rate (eGFR) Subgroup	**Wenda Tu, PhD** Statistical Reviewer Division of Biometrics II (DBII) Office of Biostatistics (OB) Office of Translational Sciences, CDER, FDA
	Major Safety Considerations for Sotagliflozin in Patients with Type 1 Diabetes and Chronic Kidney Disease	**Mari Suzuki, MD**

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FDA PRESENTATIONS (CONT.)

	The Evidence and Uncertainties Regarding Benefits and Risks for Sotagliflozin to Improve Glycemic Control in Adults with Type 1 Diabetes and Chronic Kidney Disease	**Justin Penzenstadler, PharmD** Clinical Team Leader DDLO, OCHEN, OND, CDER, FDA
11:55 p.m.	Clarifying Questions to FDA	
12:15 p.m.	**LUNCH**	
1:15 p.m.	**OPEN PUBLIC HEARING**	
2:15 p.m.	Questions to the Committee/Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	

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