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

Endocrinologic and Metabolic Drugs Advisory Committee Meeting (EMDAC)
May 27, 2021

DRAFT AGENDA

The committee will discuss the safety and efficacy of biologics license application (BLA) 761183, for teplizumab intravenous infusion, submitted by Provention Bio, Inc. The proposed indication is for the delay of clinical type 1 diabetes mellitus in at-risk individuals.

9:00 a.m.	Call to Order	**Thomas J. Weber, MD** Chairperson, EMDAC
9:05 a.m.	Introduction of Committee and Conflict of Interest Statement	**LaToya Bonner, PharmD** Designated Federal Officer, EMDAC
9:10 a.m.	FDA Introductory Remarks	**Justin Penzenstadler, PharmD, MS** Clinical Reviewer Division of Diabetes, Lipid Disorders, and Obesity (DDLO) Office of Cardiology, Hematology, Endocrinology and Neprology (OCHEN) Office of New Drugs (OND), CDER, FDA
9:20 a.m.	**APPLICANT PRESENTATIONS**	**Provention Bio, Inc.**
	Introduction	**Eleanor Ramos, MD** Chief Medical Officer Provention Bio Inc.
	Unmet Need	**Colin Dayan, MD, PhD** Professor of Clinical Diabetes and Metabolism Cardiff University School of Medicine
	Efficacy and Safety	**Eleanor Ramos, MD**
	Clinical Perspective	**Kevan Herold, MD** Professor of Immunobiology and Endocrinology Yale University School of Medicine
	Target Population for Indication	**Eleanor Ramos, MD**
10:50 a.m.	Clarifying Questions to Applicant	
11:10 a.m.	**BREAK**	

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DRAFT AGENDA (cont.)

11:20 a.m.	**FDA PRESENTATIONS**	
	Overview of the Clinical Development Program for Teplizumab	**Lauren Wood Heickman, MD** Clinical Reviewer DDLO, OCHEN, OND, CDER, FDA
	Statistical Assessment of Teplizumab Efficacy	**Yu Wang, PhD** Statistical Reviewer Division of Biometrics II, Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Clinical Safety of Teplizumab	**Lauren Wood Heickman, MD**
12:30 p.m.	Clarifying Questions to FDA	
12:45 p.m.	**LUNCH**	
1:30 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	Questions to the Committee/Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee/Committee Discussion	
5:30 p.m.	**ADJOURNMENT**	