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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
September 21, 2023

DRAFT AGENDA

The Committee will discuss the safety and efficacy of ITCA 650 (exenatide in DUROS device), a drug-device combination product that is the subject of a new drug application (NDA) submitted by Intarcia Therapeutics, (Intarcia) (NDA 209053), for the proposed indication, as an adjunct to diet and exercise, to improve glycemic control in adults with type 2 diabetes mellitus.

9:00 a.m.	Call to Order	**Cecelia Low Wang, 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	**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
9:20 a.m.	**APPLICANT PRESENTATIONS**	**Intarcia Therapeutics (an i2o Business Unit)**
	Introduction	**Kurt Graves** Chairman, President, CEO Intarcia Therapeutics (an i2o Business Unit)
	Clinical Efficacy	**Daniel Drucker, MD, FRS, FRCPC, OC** Senior Scientist Lunenfeld-Tanenbaum Research Institute Mount Sinai Hospital Professor of Medicine University of Toronto
	Clinical Safety	
	CDER's Prioritized Issues	
	1) Acute Kidney Injury (AKI)	**Daniel Drucker, MD, FRS, FRCPC, OC**

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (cont.)

	2) Major Adverse Cardiovascular Events (MACE)	**Philip Sager, MD, FACC, FAHA, FHRS** Adjunct Professor Stanford University School of Medicine Member, Executive Committee Cardiac Safety Research Consortium
	3) Clinical Validation of Device In Vitro Release (IVR)	**Kurt Graves**
	Benefit/Risk & Conclusions	**Kurt Graves**
10:50 a.m.	Clarifying Questions	
11:15 a.m.	**BREAK**	
11:25 a.m.	**FDA PRESENTATIONS**	
	ITCA 650 (exenatide in DUROS) Device Review Conclusions	**David Wolloscheck, PhD** Assistant Director General Hospital Devices Team Center for Devices and Radiological Health (CDRH) FDA
	Clinical Pharmacology Assessment of ITCA 650	**Edwin Chow, PhD** Clinical Pharmacology Team Leader Division of Cardiometabolic and Endocrine Pharmacology (DCEP) Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS), CDER, FDA
	Overview of Sources of Clinical Data for Efficacy and Safety	**Patrick Archdeacon, MD** Deputy Director DDLO, OCHEN, OND, CDER, FDA

DRAFT AGENDA (cont.)

FDA PRESENTATIONS (cont.)

	Efficacy Review of Studies CLP-103 and CLP-105	**Wenda Tu, PhD** Statistical Reviewer Division of Biometrics II (DB-II) Office of Biostatistics (OB), OTS, CDER, FDA
	Clinical Safety and Summary of CDER's Overall Conclusions	**Michelle Carey, MD, MPH** Associate Director for Therapeutic Review DDLO, OCHEN, OND, CDER, FDA
12:55 p.m.	Clarifying Questions	
1:20 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**	
4:10 p.m.	Questions to the Committee/Committee Discussion	
5:30 p.m.	**ADJOURNMENT**	