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

Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) Meeting
May 24, 2024

AGENDA

The Committee will discuss the safety and efficacy of biologics license application (BLA) 761326 for NNC0148-0287 injection (insulin icodec), a long-acting insulin analog product, submitted by Novo Nordisk. The proposed indication is to improve glycemic control in adults with diabetes mellitus.

9:00 a.m.	Call to Order	**Cecilia 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	**Michael Nguyen, MD** Cross Discipline Team Leader 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**	**Novo Nordisk**
	Introduction	**Shawn Hoskin, MS** Executive Director, Regulatory Affairs Novo Nordisk
	Unmet Need for Basal Insulin Treatment	**Ildiko Lingvay, MD, MPH, MSCS** Professor of Medicine Department of Internal Medicine/Endocrinology UT Southwestern Medical Center
	ONWARDS Development Program and Icodec Dosing	**Stephen Gough, MD, FRCP** Global Chief Medical Officer Senior Vice President Novo Nordisk
	Safety of Once-Weekly Injection of Insulin Icodec	**Roman Cailleteau, MD** Senior Medical Director Novo Nordisk
	Efficacy and Hypoglycemia in People with Type 2 Diabetes	**Roman Cailleteau, MD**
	Efficacy and Hypoglycemia in People with Type 1 Diabetes	**Stephen Gough, MD, FRCP**

	APPLICANT PRESENTATIONS (CONT.)	
	Clinical Perspective	**Ildiko Lingvay, MD, MPH, MSCS**
	Conclusion	**Stephen Gough, MD, FRCP**
10:35 a.m.	Clarifying Questions to Applicant	
11:00 a.m.	**BREAK**	
11:10 a.m.	**FDA PRESENTATIONS**	
	Clinical Pharmacology Assessment of Insulin Icodec	**Leslie Kenna, PhD** Clinical Pharmacology Reviewer Division of Cardiometabolic and Endocrine Pharmacology (DCEP) Office of Clinical Pharmacology (OCP) Office of Translational Sciences (OTS) CDER, FDA
	ONWARDS 6: Study Design	**Frank Pucino, PharmD, MPH** Clinical Reviewer DDLO, OCHEN, OND, CDER, FDA
	ONWARDS 6: Summary of Efficacy	**Roberto Crackel, PhD** Statistical Reviewer Division of Biometrics II (DB-II) Office of Biostatistics (OB) OTS, CDER, FDA
	ONWARDS 6: Safety Review	**Frank Pucino, PharmD, MPH**
	Exploratory Analysis of Percent Coefficient of Variation (%CV) Subgroup	**Jaejoon Song, PhD** Safety Statistical Reviewer Division of Biometrics VII (DB-VII) OB, OTS, CDER, FDA
	Pharmacometric Modeling of Alternative Dose Titration Strategies	**Elyes Dahmane, PhD** Pharmacometrics Reviewer Division of Pharmacometrics (DPM) OCP, OTS, CDER, FDA
	ONWARDS 6: Benefit-Risk Summary	**Frank Pucino, PharmD, MPH**
12:10 p.m.	Clarifying Questions to FDA	

AGENDA (cont.)

12:35 p.m.	**LUNCH**
1:15 p.m.	**OPEN PUBLIC HEARING**
2:15 p.m.	**BREAK**
2:30 p.m.	Questions to the Committee/Committee Discussion
4:00 p.m.	**ADJOURNMENT**