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

Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting

June 9, 2023

DRAFT AGENDA

The committee will discuss supplemental biologics license application (sBLA) 761269/s-001, for LEQEMBI (lecanemab) solution for intravenous infusion, submitted by Eisai, Inc., for the treatment of Alzheimer's disease, initiated in patients with mild cognitive impairment or mild dementia stage of disease. This product was approved under 21 CFR 314.500 (subpart H, accelerated approval regulations) for the treatment of Alzheimer's disease. Confirmatory studies are studies to verify and describe the clinical benefit of a product after it receives accelerated approval. The committee will discuss the confirmatory study, BAN2401-G000-301, conducted to fulfill post-marketing requirement 4384-1 detailed in the January 6, 2023, approval letter, available at https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2023/761269Orig1s000ltr.pdf.

10:00 a.m.	Call to Order	**Robert C. Alexander, MD** Acting Chairperson, PCNS
10:05 a.m.	Introduction of Committee and Conflict of Interest Statement	**Jessica Seo, PharmD, MPH** Designated Federal Officer, PCNS
10:15 a.m.	FDA Introductory Remarks	**Teresa Buracchio, MD** Director (Acting) Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
10:30 a.m.	**APPLICANT PRESENTATIONS**	**Eisai, Inc.**
	Introduction	**Lynn Kramer, MD, FAAN** Chief Clinical Officer, Alzheimer's Disease and Brain Health (ADBH) Eisai, Inc.
	Study 301 Efficacy	**Michael Irizarry, MD, MPH** Senior Vice President, Deputy Chief Clinical Officer, ADBH Eisai, Inc.
	Robustness of Efficacy Results	**Shobha Dhadda, PhD** Senior Vice President, Biostatistics and Clinical Development Operations, ADBH Eisai, Inc.
	Study 301 Safety	**Michael Irizarry, MD, MPH**
	Clinician's Perspective	**Sharon Cohen, MD, FRCPC** Medical Director

		Toronto Memory Program
	Conclusion	**Lynn Kramer, MD, FAAN**
11:30 a.m.	Clarifying Questions to the Applicant	
11:45 a.m.	**LUNCH**	
12:30 p.m.	**FDA PRESENTATIONS**	
	Clinical Overview of Efficacy	**Kevin Krudys, PhD** Clinical Efficacy Reviewer Associate Director ON, OND, CDER, FDA
	Statistical Overview	**Tristan Massie, PhD** Biostatistics Reviewer Division of Biostatistics 1 (DB1) Office of Biostatistics OND, CDER, FDA
	Clinical Overview of Safety	**Deniz Erten-Lyons, MD** Clinical Safety Reviewer Division of Neurology 1 (DN1) ON, OND, CDER, FDA
	Concluding Remarks	**Teresa Buracchio, MD**
1:30 p.m.	Clarifying Questions to FDA	
1:45 p.m.	**BREAK**	
2:00 p.m.	**OPEN PUBLIC HEARING**	
3:10 p.m.	**BREAK**	
3:20 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	