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

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

June 10, 2024

AGENDA

The Committee will discuss biologics license application (BLA) 761248, for donanemab solution for intravenous infusion, submitted by Eli Lilly and Company, for the treatment of early symptomatic Alzheimer's disease.

9:00 a.m.	Call to Order and Introduction of Committee	**Thomas Montine, MD, PhD** Chairperson, PCNS
9:10 a.m.	Conflict of Interest Statement	**Jessica Seo, PharmD, MPH** Designated Federal Officer, PCNS
9:15 a.m.	FDA Introductory Comments	**Teresa Buracchio, MD** Director Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
9:30 a.m.	**APPLICANT PRESENTATIONS**	**Eli Lilly and Company**
	Introduction	**David Hyman, MD** Group Vice President Chief Medical Officer Eli Lilly and Company
	Donanemab Clinical Program	**Mark Mintun, MD** Group Vice President, Neuroscience R&D Eli Lilly and Company
	Efficacy Results	**John Sims, MD** Head of Medical-Donanemab Eli Lilly and Company
	Safety Results	**Melissa Veenhuizen, DVM, MS** Vice President, Global Patient Safety Eli Lilly and Company
	Treating Early Alzheimer's Disease	**Reisa Sperling, MD** Brigham and Women's Hospital Massachusetts General Hospital Harvard Medical School

AGENDA (cont.)

10:30 a.m.	Clarifying Questions to the Applicant	
11:00 a.m.	**BREAK**	
11:15 a.m.	**FDA PRESENTATIONS**	
	Clinical Overview of Efficacy	**Kevin Krudys, PhD** Clinical Efficacy Reviewer Associate Director ON, OND, CDER, FDA
	Clinical Overview of Safety	**Natalie Branagan, MD** Clinical Safety Reviewer Division of Neurology 1 (DN1) ON, OND, CDER, FDA
12:15 p.m.	Clarifying Questions to FDA	
12:45 p.m.	**LUNCH**	
1:30 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	**BREAK**	
2:45 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	