

**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

**DRAFT 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	<b>Thomas Montine, MD, PhD</b> Chairperson, PCNS
9:05 a.m.	Conflict of Interest Statement	<b>Jessica Seo, PharmD, MPH</b> Designated Federal Officer, PCNS
9:15 a.m.	FDA Introductory Comments	<b>Teresa Buracchio, MD</b> Director Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
9:30 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Eli Lilly and Company</b>
	Introduction	<b>David Hyman, MD</b> Group Vice President Chief Medical Officer Eli Lilly and Company
	Donanemab Clinical Program	<b>Mark Mintun, MD</b> Group Vice President, Neuroscience R&D Eli Lilly and Company
	Efficacy Results	<b>John Sims, MD</b> Head of Medical-Donanemab Eli Lilly and Company
	Safety Results	<b>Melissa Veenhuizen, DVM, MS</b> Vice President, Global Patient Safety Eli Lilly and Company
	Treating Early Alzheimer's Disease	<b>Reisa Sperling, MD</b> Brigham and Women's Hospital Massachusetts General Hospital Harvard Medical School

**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

**DRAFT 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**