

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

Peripheral and Central Nervous System Drugs Advisory Committee Meeting (PCNS)
November 6, 2020

DRAFT AGENDA

The Committee will discuss Biologics License Application (BLA) 761178 for aducanumab solution for intravenous infusion, submitted by Biogen Inc., for the treatment of Alzheimer's disease.

- | | | |
|------------|--|---|
| 10:00 a.m. | Call to Order and Introduction of Committee | Nathan B. Fountain, MD
Chairperson, PCNS |
| 10:10 a.m. | Introduction of Committee and Conflict of Interest Statement | LaToya Bonner, PharmD
Acting Designated Federal Officer, PCNS |
| 10:15 a.m. | FDA Introductory Remarks | Billy Dunn, MD
Director
Office of Neuroscience
Office of New Drugs, CDER, FDA |
| 10:20 a.m. | APPLICANT PRESENTATION

Opening Remarks | Biogen Inc.

Samantha Budd Haerberlein, PhD
Senior Vice President
Head of Neurodegeneration Development Unit
Biogen Inc. |
| 11:00 a.m. | Clarifying Questions to the Applicant | |
| 11:25 a.m. | FDA PRESENTATION

FDA Summary Presentation | Billy Dunn, MD |
| 12:05 p.m. | Clarifying Questions to FDA | |
| 12:30 p.m. | LUNCH | |
| 1:30 p.m. | OPEN PUBLIC HEARING | |
| 2:30 p.m. | Questions to the Committee/Committee Discussion | |
| 4:30 p.m. | ADJOURNMENT | |