

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

***Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting***  
March 22, 2023

**AGENDA**

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*The committee will discuss new drug application (NDA) 215887, for tofersen (BIIB067) intrathecal injection, submitted by Biogen Inc., for the treatment of amyotrophic lateral sclerosis (ALS) associated with a mutation in the superoxide dismutase 1 (SOD1) gene.*

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9:15 a.m.	Call to Order	<b>Thomas Montine, MD</b> Chairperson, PCNS
9:20 a.m.	Introduction of Committee and Conflict of Interest Statement	<b>Jessica Seo, PharmD, MPH</b> Designated Federal Officer, PCNS
9:30 a.m.	FDA Introductory Comments	<b>Teresa Buracchio, MD</b> Director (Acting) Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
9:45 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Biogen, Inc.</b>
	Introduction	<b>Toby Ferguson, MD, PhD</b> Vice President, Head of Neuromuscular Development Unit Biogen
	Disease Background & Unmet Need	<b>Timothy M. Miller, MD, PhD</b> David Clayson Professor of Neurology Washington University
	Efficacy	<b>Stephanie Fradette, PharmD</b> Clinical Development Lead and ALS Portfolio Head Biogen
	Safety	<b>Laura Fanning, MD</b> Executive Medical Director, Global Medical Safety Biogen
	Clinical Perspective	<b>Timothy M. Miller, MD, PhD</b>
	Conclusion	<b>Stephanie Fradette, PharmD</b>

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**AGENDA (cont.)**

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11:15 a.m. Clarifying Questions to the Applicant

11:35 a.m. **LUNCH**

12:05 p.m. **FDA PRESENTATIONS**

FDA Summary Presentations

**Emily Freilich, MD**  
Cross-Discipline Team Lead  
Deputy Director (Acting)  
Division of Neurology 1 (DN1)  
ON, OND, CDER, FDA

**Tristan Massie, PhD**  
Biostatistics Reviewer  
Division of Biostatistics 1  
Office of Biostatistics  
Office of Translational Sciences (OTS), CDER, FDA

**Xiaohan Cai, PhD**  
Clinical Pharmacology Reviewer  
Division of Neuropsychiatric Pharmacology  
Office of Clinical Pharmacology (OCP)  
OTS, CDER, FDA

**Vishnu Sharma, PhD**  
Pharmacometrics Reviewer  
Division of Pharmacometrics  
OCP, OTS, CDER, FDA

1:35 p.m. Clarifying Questions to FDA

1:55 p.m. **BREAK**

2:10 p.m. **OPEN PUBLIC HEARING**

3:40 pm **BREAK**

3:55 p.m. Questions to the Committee/Committee Discussion

6:00 p.m. **ADJOURNMENT**