**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

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

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**DRAFT 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**<br>Cross-Discipline Team Lead<br>Deputy Director (Acting)<br>Division of Neurology 1 (DN1)<br>ON, OND, CDER, FDA<br><br>**Tristan Massie, PhD**<br>Biostatistics Reviewer<br>Division of Biostatistics 1<br>Office of Biostatistics<br>Office of Translational Sciences (OTS), CDER, FDA<br><br>**Xiaohan Cai, PhD**<br>Clinical Pharmacology Reviewer<br>Division of Neuropsychiatric Pharmacology<br>Office of Clinical Pharmacology (OCP)<br>OTS, CDER, FDA<br><br>**Vishnu Sharma, PhD**<br>Pharmacometrics Reviewer<br>Division of Pharmacometrics<br>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** | |