

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

***Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting***  
March 30, 2022

**DRAFT AGENDA**

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*The committee will discuss new drug application (NDA) 216660, for sodium phenylbutyrate/taurursodiol (AMX0035) powder for oral suspension, submitted by Amylyx Pharmaceuticals Inc., for the treatment of amyotrophic lateral sclerosis (ALS).*

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10:00 a.m.	Call to Order	<b>Thomas Montine, MD</b> Chairperson, PCNS
10:05 a.m.	Introduction of Committee and Conflict of Interest Statement	<b>Jessica Seo, PharmD, MPH</b> Designated Federal Officer, PCNS
10:15 a.m.	FDA Introductory Remarks	<b>Teresa Buracchio, MD</b> Director Division of Neurology 1 (DN1) Office of Neuroscience (ON) Office of New Drugs (OND) CDER, FDA
10:30 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Amylyx Pharmaceuticals Inc.</b>
	Introduction	<b>Justin Klee and Joshua Cohen</b> Co-CEOs and Co-Founders Amylyx Pharmaceuticals
	Clinical Trials in ALS	<b>Jeremy Shefner, MD, PhD</b> Kemper and Ethel Marley Professor and Chair of Neurology Barrow Neurological Institute
	Benefit / Risk	<b>Jamie Timmons, MD</b> Head of Scientific Communications Amylyx Pharmaceuticals
	Clinical Perspective	<b>Sabrina Paganoni, MD, PhD</b> Co-Director, Neurological Clinical Research Institute and Healey & AMG Center for ALS, Massachusetts General Hospital Associate Professor, Harvard Medical School

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**DRAFT AGENDA (cont.)**

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

11:45 a.m. **BREAK**

11:55 a.m. **FDA PRESENTATIONS**

FDA Summary Presentations

**Emily Freilich, MD**  
Cross Discipline Team Leader  
DN1, ON, OND, CDER, FDA

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

12:40 p.m. Clarifying Questions to FDA

1:10 p.m. **LUNCH**

1:55 p.m. **OPEN PUBLIC HEARING**

3:25 p.m. **BREAK**

3:35 p.m. Questions to the Committee/Committee  
Discussion

5:00 p.m. **ADJOURNMENT**