

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

Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting
September 7, 2022

AGENDA

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).

12:00 p.m.	Call to Order and Introduction of Committee	Thomas Montine, MD Chairperson, PCNS
12:05 p.m.	Introduction of Committee and Conflict of Interest Statement	Jessica Seo, PharmD, MPH Designated Federal Officer, PCNS
12:15 p.m.	FDA Introductory Remarks	Billy Dunn, MD Director, Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
12:45 p.m.	APPLICANT PRESENTATIONS	Amylyx Pharmaceuticals Inc.
	Introduction	Tammy Sarnelli, MPAHC Global Head, Regulatory Affairs Amylyx Pharmaceuticals
	Current Landscape in ALS	Sabrina Paganoni, MD, PhD Co-Director, Neurological Clinical Research Institute Sean M. Healey and AMG Center for ALS Massachusetts General Hospital Associate Professor, Harvard Medical School
	Biomarker Data	Lahar Mehta, MD Head of Global Clinical Development Amylyx Pharmaceuticals
	CENTAUR Results and New Overall Survival Analyses	Jamie Timmons, MD Head of Scientific Communications Amylyx Pharmaceuticals
	Clinical Perspective	Merit E. Cudkowicz, MD, MSc Chief, Neurology Department and Director Sean M. Healey and AMG Center for ALS Massachusetts General Hospital Julianne Dorn Professor of Neurology Harvard Medical School
1:45 p.m.	Clarifying Questions to the Applicant	

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

Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting
September 7, 2022

AGENDA (cont.)

2:00 p.m. **BREAK**

2:15 p.m. **FDA PRESENTATIONS**

FDA Overview

Teresa Buracchio, MD
Director
Division of Neurology 1 (DN 1)
ON, OND, CDER, FDA

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

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

3:15 p.m. Clarifying Questions to FDA

3:30 p.m. **OPEN PUBLIC HEARING**

4:30 p.m. **BREAK**

4:45 p.m. Questions to the Committee/Committee
Discussion

6:30 p.m. **ADJOURNMENT**