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

DRAFT 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 Julieanne Dorn Professor of Neurology Harvard Medical School
1:45 p.m.	Clarifying Questions to the Applicant	

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DRAFT 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**	