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

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).

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

AGENDA (cont.)

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**	