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

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting
June 17, 2022

DRAFT AGENDA

The committee will discuss supplemental new drug applications (sNDAs) 210793-s008 and 207318-s011, efficacy supplement resubmission for NUPLAZID (pimavanserin) tablets, submitted by Acadia Pharmaceuticals Inc., for the proposed treatment of hallucinations and delusions associated with Alzheimer's disease psychosis.

8:45 a.m.	Call to Order	**Rajesh Narendran, MD** Chairperson, PDAC
8:50 a.m.	Introduction of Committee/ Conflict of Interest Statement	**Joyce Frimpong, PharmD** Designated Federal Officer, PDAC
9:00 a.m.	FDA Opening Remarks	**Tiffany R. Farchione, MD** Director Division of Psychiatry (DP) Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
9:10 a.m.	**APPLICANT PRESENTATIONS**	**Acadia Pharmaceuticals Inc.**
	Introduction	**Daryl DeKarske, MPH** Sr. Vice President, Global Head of Regulatory Affairs and Translational Sciences Acadia Pharmaceuticals Inc.
	Unmet Need	**Pierre Tariot, MD** Director, Banner Alzheimer's Institute Research Professor of Psychiatry University of Arizona College of Medicine
	Efficacy	**Clive Ballard, MD** Pro-Vice Chancellor and Executive Dean Professor of Age-related Diseases College of Medicine and Health University of Exeter United Kingdom **Suzanne Hendrix, PhD** President and CEO, Pentara Corporation
	Overview of Safety	**Mary Ellen Turner, MD, MPH** Sr. Vice President, Pharmacovigilance and Corporate Safety Officer Acadia Pharmaceuticals Inc.

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DRAFT AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Benefit-Risk	**Serge Stankovic, MD** President Acadia Pharmaceuticals Inc.
10:40 a.m.	Clarifying Questions to Applicant	
11:10 a.m.	**BREAK**	
11:20 a.m.	**FDA PRESENTATIONS**	
	Pimavanserin (NUPLAZID) for the treatment of hallucinations and delusions associated with Alzheimer's disease psychosis	**Paul Bossie, MD** Clinical Reviewer DP, ON, OND, CDER, FDA **Xiang Ling, PhD** Statistical Reviewer Division of Biometrics I (DBI) Office of Biostatistics (OB) Office of Translational Sciences (OTS) CDER, FDA
12:50 p.m.	Clarifying Questions to FDA	
1:20 p.m.	**LUNCH**	
2:00 p.m.	**OPEN PUBLIC HEARING**	
3:00 p.m.	Questions to the Committee/Committee Discussion	
4:30 p.m.	**ADJOURNMENT**	