

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

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting
FDA White Oak Campus, 10903 New Hampshire Avenue, Building 31 Conference Center
The Great Room (Rm. 1503), Silver Spring, Maryland
March 29, 2016

AGENDA

The committee will discuss the specific risk-benefit profile for new drug application (NDA) 207318, NUPLAZID (pimavanserin) 17 milligram (mg) immediate-release, film-coated oral tablets, submitted by Acadia Pharmaceuticals Inc., for the proposed treatment of psychosis associated with Parkinson's disease.

8:00 a.m.	Call to Order and Introduction of Committee	David A. Brent, MD Chairperson, PDAC
	Conflict of Interest Statement	Kalyani Bhatt, BS, MS Designated Federal Officer, PDAC
8:10 a.m.	FDA Opening Remarks	Mitchell Mathis, MD Director Division of Psychiatry Products (DPP) Office of Drug Evaluation I (ODE-I) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	APPLICANT PRESENTATIONS	ACADIA Pharmaceuticals Inc.
	Introduction	Michael Monahan, MBA, RAC Director, Regulatory Affairs ACADIA Pharmaceuticals Inc.
	Burden of PD Psychosis and Need for Additional Treatment Options	Stuart Isaacson, MD Director, Parkinson's Disease and Movement Disorders Center of Boca Raton Boca Raton, Florida
	Efficacy of Pimavanserin	Serge Stankovic, MD, MSPH Executive Vice President, Research and Development ACADIA Pharmaceuticals Inc.
	Safety of Pimavanserin	George Demos, MD Executive Director, Drug Safety and Pharmacovigilance ACADIA Pharmaceuticals Inc.
	Benefit/Risk Profile	Serge Stankovic, MD, MSPH
	Clinician Perspective	Clive Ballard, MD Institute of Psychiatry King's College London London, United Kingdom
9:45 a.m.	Clarifying Questions to Applicant	

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AGENDA (cont.)

10:00 a.m. **BREAK**

10:15 a.m. **FDA PRESENTATIONS**

Clinical Review of Pimavanserin for the
Treatment of Psychosis Associated with
Parkinson's Disease

Paul Andreason, MD
Clinical Reviewer
DPP, ODE-I, OND, CDER, FDA

Mortality and Antipsychotic Drug Use in
Dementia

Marc Stone, MD
Deputy Director of Safety
DPP, ODE-I, OND, CDER, FDA

11:45 a.m. Clarifying Questions to FDA

12:00 p.m. **LUNCH**

1:00 p.m. **OPEN PUBLIC HEARING**

2:00 p.m. Questions to the Committee/Committee Discussion

3:30 p.m. **BREAK**

3:45 p.m. Questions to the Committee/Committee Discussion

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