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

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) and the Drug Safety and Risk Management (DSaRM) Advisory Committee
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
February 12, 2019

AGENDA

The committees will discuss efficacy, safety and risk-benefit profile of new drug application (NDA) 211243, esketamine 28 mg single-use nasal spray device, submitted by Janssen Pharmaceuticals, Inc., for the treatment of treatment-resistant depression.

8:00 a.m.	Call to Order and Introduction of Committee	**Raj Narendran, MD** Chairperson, PDAC
8:05 a.m.	Conflict of Interest Statement	**Kalyani Bhatt, BS, MS** Designated Federal Officer, PDAC
8:10 a.m.	FDA Opening Remarks	**Tiffany R. Farchione, MD** Director (Acting) 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**	**Janssen Pharmaceuticals, Inc.**
	Introduction	**David Hough, MD** Esketamine Compound Development Team Leader Janssen Research and Development, LLC
	Unmet Medical Need	**A. John Rush, MD** CEO Curbstone Consultant LLC Professor Emeritus Duke NUS Santa Fe, New Mexico
	Clinical Development Program Efficacy	**Jaskaran Singh, MD** Senior Director, Clinical Development Janssen Research and Development, LLC
	Clinical Safety	**Vanina Popova, MD** Director, Clinical Development Janssen Research and Development, LLC
	Abuse Potential	**Andrew Krystal, MD** Ray and Dagmar Dolby Distinguished Professor of Psychiatry University of California San Francisco

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Risk Mitigation	**David Hough, MD** Esketamine Compound Development Team Leader Janssen Research and Development, LLC
	Benefit Risk Assessment	**David Hough, MD** Esketamine Compound Development Team Leader Janssen Research and Development, LLC
	Clinician's Perspective	**Madhukar Trivedi, MD** Professor of Psychiatry University of Texas Southwestern Medical Center
9:45 a.m.	Clarifying Questions to Applicant	
10:15 a.m.	**BREAK**	
10:30 a.m.	**FDA PRESENTATIONS**	
	Clinical Overview: Efficacy	**Jean Kim, MD, MA** Clinical Reviewer DPP, ODE I, OND, CDER, FDA **Andrew Potter, PhD** Statistical Reviewer Division of Biometrics I Office of Biostatistics Office of Translational Sciences, CDER, FDA
	Clincial Overview: Safety	**Qi Chen, MD, MPH** Safety Reviewer DPP, ODE I, OND, CDER, FDA
	Risk Management for Esketamine	**Somya Dunn, MD** Commander, United States Public Health Service Risk Management Analyst Division of Risk Management Office of Surveillance and Epidemiology CDER, FDA
12:00 p.m.	Clarifying Questions to FDA	

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12:15 p.m.	**LUNCH**	
1:15 p.m.	**OPEN PUBLIC HEARING**	
2:15 p.m.	Charge to Committee	**Tiffany R. Farchione, MD**
2:25 p.m.	Questions to the Committee/Committee Discussion	
3:20 p.m.	**BREAK**	
3:30 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	