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 Advisory Committee (DSaRM)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
November 2, 2018

AGENDA

The committees will discuss the efficacy, safety, and benefit-risk profile of new drug application (NDA) 211371, brexanolone 5 mg/mL intravenous injection, submitted by Sage Therapeutics, for the proposed indication of postpartum 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 Farchione, MD** Deputy 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**	**Sage Therapeutics, Inc.**
	Brexanolone for Treatment of Postpartum Depression (PPD)	**Stephen J. Kanes, MD, PhD** Chief Medical Officer Sage Therapeutics, Inc.
	Unmet Need for PPD Treatment	**Samantha Meltzer-Brody, MD** Ray M. Hayworth Distinguished Professor of Mood Disorders Associate Professor, Department of Psychiatry Director, Perinatal Psychiatry Program at Chapel Hill University of North Carolina Center for Women's Mood Disorders
	Brexanolone Clinical Study Design and Efficacy	**Christopher Silber, MD** Senior Vice President, Clinical Development Sage Therapeutics, Inc.
	Brexanolone Safety	**Helen Colquhoun, MD** Vice President, Medical Science Sage Therapeutics, Inc.

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 Advisory Committee (DSaRM)
November 2, 2018

AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Clinical Perspective	**Samantha Meltzer-Brody, MD**
9:45 a.m.	Clarifying Questions	
10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATIONS**	
	Clinical Overview	**Bernard Fischer, MD** Lead Medical Officer DPP, ODE I, OND, CDER, FDA
	Safety Overview - Proposed Risk Evaluation and Mitigation Strategies	**Leah Hart, PharmD** Risk Management Analyst Division of Risk Management Office of Medication Error Prevention and Risk Management Office of Surveillance and Epidemiology, CDER, FDA
11:45 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**OPEN PUBLIC HEARING**	
2:00 p.m.	Questions to the Committee/Committee Discussion	
3:15 p.m.	**BREAK**	
3:30 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	