

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

Joint Meeting of the Psychopharmacologic Drugs Advisory Committee and the Peripheral and Central Nervous System Drugs Advisory Committee Meeting

April 14, 2023

DRAFT AGENDA

The committees will discuss supplemental new drug application (sNDA) 205422 s009, efficacy supplement for REXULTI (brexpiprazole) tablets, submitted by Otsuka Pharmaceutical Company, Ltd., and Lundbeck, Inc., for the proposed treatment of agitation associated with Alzheimer's dementia.

9:00 a.m.	Call to Order	Rajesh Narendran, MD Chairperson, PDAC
9:05 a.m.	Introduction of Committee/Conflict of Interest Statement	Joyce Frimpong, PharmD Designated Federal Officer, PDAC
9:15 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
9:25 a.m.	APPLICANT PRESENTATIONS	Otsuka Pharmaceutical Company, Ltd.
	Introduction	Mary Hobart, PhD Vice President Global Regulatory Affairs Otsuka Pharmaceutical Company, Ltd.
	Unmet Need in Agitation Associated with Alzheimer's Dementia	Zahinoor Ismail, MD, FRCPC Professor Hotchkiss Brain Institute & O'Brien Institute for Public Health University of Calgary
	Efficacy	Robert McQuade, PhD Executive Vice President and Chief Strategy Officer Otsuka Pharmaceutical Company, Ltd.
	Safety	John Kraus, MD, PhD Executive Vice President and Chief Medical Officer Otsuka Pharmaceutical Company, Ltd.

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Clinical Perspective

Alireza Atri, MD, PhD

Director

Banner Sun Health Research Institute

Benefit/Risk Summary

Mary Hobart, PhD

10:25 a.m. Clarifying Questions to Applicant

10:55 a.m. **BREAK**

11:05 a.m. **FDA PRESENTATIONS**

Shamir N. Kalaria, PharmD, PhD

Clinical Reviewer

DP, ON, OND, CDER, FDA

Efficacy

Safety

12:05 p.m. Clarifying Questions to FDA

12:35 p.m. **LUNCH**

1:30 p.m. **OPEN PUBLIC HEARING**

2:30 p.m. Questions to the Committee/Committee Discussion

4:00 p.m. **ADJOURNMENT**