

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

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting
July 18, 2025

AGENDA

The Committee will discuss supplemental New Drug Application (sNDA) 205422/S-012, for REXULTI (brexpiprazole) tablets, submitted by Otsuka Pharmaceutical Company, Ltd., for the proposed indication of treatment of adults with post-traumatic stress disorder (PTSD), in combination with sertraline.

9:00 a.m.	Call to Order and Introduction of Committee	Rajesh Narendran, MD Acting Chairperson, PDAC
9:05 a.m.	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 Senior Vice President Global Regulatory Affairs Otsuka Pharmaceutical Company, Ltd.
	Background and Unmet Need	Arash Javanbakht, MD Founding Director Stress, Trauma, and Anxiety Research Clinic (STARC) Wayne State University School of Medicine
	Efficacy	John Kraus, MD, PhD Executive Vice President and Chief Medical Officer Otsuka Pharmaceutical Company, Ltd. Jason Connor, PhD President & Lead Statistical Scientist ConfluenceStat LLC

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Safety **Thomas Thompson, MD**
Vice President, Global Clinical Development
Therapeutic Head, CNS
Otsuka Pharmaceutical Company, Ltd.

Clinical Perspective **Kathleen Brady, MD, PhD**
Distinguished University Professor
Medical University of South Carolina
Director, South Carolina Clinical and
Translational 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**

Brexipiprazole for the treatment of
posttraumatic stress disorder (PTSD) in
adults, in combination with sertraline **Roberta Rasetti, MD, PhD**
Clinical Reviewer
DP, ON, OND, CDER, FDA

Yiming Chen, PhD
Statistical Reviewer
Division of Biometrics I
Office of Biostatistics
Office of Translational Sciences
CDER, FDA

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**