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

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

DRAFT 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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DRAFT 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**	
	Brexpiprazole 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**	