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

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting

June 4, 2024

DRAFT AGENDA

The Committee will discuss new drug application 215455, for midomafetamine (MDMA), submitted by Lykos Therapeutics, for the proposed indication of treatment of post-traumatic stress disorder. The Committee will be asked to discuss the overall benefit-risk profile of the product, including the potential public health impact.

8:30 a.m.	Call to Order	**Rajesh Narendran, MD** Chairperson, PDAC
8:35 a.m.	Introduction of Committee/Conflict of Interest Statement	**Joyce Frimpong, PharmD** Designated Federal Officer, PDAC
8:45 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
8:55 a.m.	**APPLICANT PRESENTATIONS**	**Lykos Therapeutics**
	Introduction	**Amy Laverdiere, MBA** Program Lead Lykos Therapeutics
	Unmet Need	**Jerry Rosenbaum, MD** Director Center for the Neuroscience of Psychedelics Massachusetts General Hospital Research Institute Stanley Cobb Professor Psychiatry Harvard Medical School
	Efficacy	**Berra Yazar-Klosinski, PhD** Chief Scientific Officer Lykos Therapeutics
	Safety	**Alia Lilienstein, MD, MPH** Senior Medical Director Lykos Therapeutics

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Clinician Perspective	**Kelley O'Donnell, MD, PhD** Director of Clinical Training NYU Langone Center for Psychedelic Medicine Research Assistant Professor of Psychiatry NYU School of Medicine
	Benefit-Risk	**Berra Yazar-Klosinski, PhD**
10:25 a.m.	Clarifying Questions to Applicant	
10:55 a.m.	**BREAK**	
11:05 a.m.	**FDA PRESENTATIONS**	
	Introduction: Product and Disease Background	**David Millis, MD** Clinical Reviewer DP, ON, OND, CDER, FDA
	Regulatory History and Key Issues	**David Millis, MD**
	Efficacy Analysis	**Olivia Morgan, PhD** Statistical Reviewer Division of Biometrics I (DBI) Office of Biostatistics (OB) Office of Translational Sciences (OTS) CDER, FDA
	Safety Analysis	**David Millis, MD**
	Risk Management for Midomafetamine	**Victoria Sammarco, PharmD, MBA** Risk Management Analyst Division of Risk Management (DRM) Office of Medication Error Prevention and Risk Management (OMEPRM) Office of Surveillance and Epidemiology (OSE) CDER, FDA
12:35 p.m.	Clarifying Questions to FDA	

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DRAFT AGENDA (cont.)

1:05 p.m.	**LUNCH**
2:00 p.m.	**OPEN PUBLIC HEARING**
3:45 p.m.	**BREAK**
3:55 p.m.	Questions to the Committee/Committee Discussion
5:30 p.m.	**ADJOURNMENT**