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

Oncologic Drugs Advisory Committee (ODAC) Meeting
April 12, 2024

AGENDA

The Committee will discuss the use of minimal residual disease (MRD) as an endpoint in multiple myeloma clinical trials, including considerations regarding timing of assessment, patient populations, and trial design for future studies that intend to use MRD to support accelerated approval of a new product or a new indication.

9:00 a.m.	Call to Order and Introduction of Committee	**Grzegorz (Greg) S. Nowakowski, MD, FASCO** Acting Chairperson, ODAC
9:05 a.m.	Conflict of Interest Statement	**Takyiah Stevenson, PharmD** Acting Designated Federal Officer, ODAC
9:10 a.m.	FDA Introductory Remarks	
	Oncology Endpoint Development	**Nicole Gormley, MD** Associate Director of Oncology Endpoint Development Oncology Center of Excellence (OCE) Director, Division of Hematologic Malignancies II (DHM II) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
	Multiple Myeloma - Minimal Residual Disease (MRD)	**Bindu Kanapuru, MD** Associate Director of Therapeutic Review DHM II, OOD, OND, CDER, FDA
9:40 a.m.	**INDUSTRY PRESENTATIONS**	**Sylvester Comprehensive Cancer Center, University of Miami**
	Introduction	**C. Ola Landgren, MD, PhD** Professor of Medicine Chief, Division of Myeloma, Department of Medicine Director, Sylvester Myeloma Institute Co-Leader, Translational and Clinical Oncology Program Paul J. DiMare Endowed Chair in Immunotherapy Sylvester Comprehensive Cancer Center University of Miami
	Multiple Myeloma, Unmet Medical Need, and Role of MRD	**C. Ola Landgren, MD, PhD**
	Data, Methodology, and Results	**Sean Devlin, PhD** Associate Professor of Biostatistics Associate Attending Biostatistician Department of Biostatistics Memorial Sloan Kettering Cancer Center

AGENDA (cont.)

	INDUSTRY PRESENTATIONS (CONT.)	
	Summary and Clinical Conclusions	**C. Ola Landgren, MD, PhD**
10:10 a.m.	**INDUSTRY PRESENTATIONS**	**International Independent Team for Endpoint Approval of Myeloma Minimal Residual Disease (I2TEAMM)**
	Introduction	**Brian G. M. Durie, MD** Cedars-Sinai Comprehensive Cancer Center Los Angeles, California
	The Need for MRD Assessment	**Bruno Paiva, PhD** Director of Flow Cytometry Department of Hematology and Immunology CIMA Laboratory Diagnostics University of Navara, SPAIN
	Meta-Analyses and Key Results	**Qian Shi, PhD** Professor of Biostatistics and Oncology Department of Quantitative Health Sciences Mayo Clinic Rochester, Minnesota
	Conclusions	**Kenneth C. Anderson, MD** Kraft Family Professor of Medicine Dana-Farber Cancer Institute and Harvard Medical School Boston, Massacheusettes
10:40 a.m.	**FDA PRESENTATIONS**	
	MRD to Support Accelerated Approval	**Rachel Ershler, MD, MHS** Clinical reviewer DHM II, OOD, OND, CDER, FDA
		Jing Zhang, PhD Statistical Reviewer Division of Biometrics IX Office of Biostatistics Office of Translational Sciences, CDER, FDA
11:10 a.m.	**BREAK**	

AGENDA (cont.)

11:25 a.m.	Clarifying Questions
12:15 p.m.	**LUNCH**
1:15 p.m.	**OPEN PUBLIC HEARING**
2:15 p.m.	Questions to the Committee/ Committee Discussion
4:00 p.m.	**ADJOURNMENT**