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
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, Massachusetts

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