

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Oncologic Drugs Advisory Committee (ODAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)

10903 New Hampshire Avenue, Silver Spring, Maryland

May 24, 2017

DRAFT MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Lauren Tesh, PharmD, BCPS

Division of Advisory Committee and Consultant Management

Office of Executive Programs, CDER, FDA

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Harold J. Burstein, MD, PhD

Institute Physician

Dana-Farber Cancer Institute

Associate Professor of Medicine

Harvard Medical School

Boston, Massachusetts

Bernard F. Cole, PhD

Professor

Department of Mathematics and Statistics

University of Vermont

Burlington, Vermont

Heidi D. Klepin, MD, MS

Associate Professor of Internal Medicine

Section of Hematology and Oncology

Wake Forest University Health Sciences

Winston Salem, North Carolina

Grzegorz S. Nowakowski, MD

Associate Professor of Medicine and Oncology

Mayo Clinic Rochester

Rochester, Minnesota

Vassiliki A. Papadimitrakopoulou, MD

Professor of Medicine

The University of Texas MD Anderson Cancer
Center

Department of Thoracic Head & Neck Medical
Oncology

Division of Cancer Medicine

Houston, Texas

Courtney J. Preusse, MA

(Consumer Representative)

Research Administrator and Patient Advocate
Clinical Research Division

Fred Hutchinson Cancer Research Center
Seattle, Washington

Gregory J. Riely, MD, PhD

Associate Attending

Memorial Sloan Kettering Cancer Center

Associate Professor, Weill Cornell Medical
College

New York, New York

Brian I. Rini, MD, FACP

(Acting Chairperson)

Professor of Medicine, Lerner College of Medicine
Leader, GU Program

Department of Hematology and Oncology
Cleveland Clinic Taussig Cancer Institute
Cleveland, Ohio

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
May 24, 2017

DRAFT MEETING ROSTER (cont.)

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting) (cont.)

Thomas S. Uldrick, MD, MS

Clinical Director
HIV & AIDS Malignancy Branch
Center for Cancer Research
National Cancer Institute
Bethesda, Maryland

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Non-Voting)

Phuong Khanh (P.K.) Morrow, MD, FACP

Executive Medical Director, Amgen Oncology
Therapeutic Area Head, US Medical Organization
Thousand Oaks, California

TEMPORARY MEMBERS (Voting)

Ralph B. D'Agostino, Sr., PhD

Professor of Mathematics/Statistics, Epidemiology
and Biostatistics
Mathematics and Statistics Department
Boston University
Boston, Massachusetts

Courtney Fitzhugh, MD

(Participation in afternoon session)
Investigator
Laboratory of Early Sickle Mortality Prevention
Sickle Cell Branch, Division of Intramural Research
National Heart, Lung, and Blood Institute
National Institutes of Health (NIH)
Bethesda, Maryland

Stanley Lipkowitz, MD, PhD

(Participation in morning session)
Chief
Women's Malignancy Branch
Center for Cancer Research
National Cancer Institute, NIH
Bethesda, Maryland

Michael E. Menefee, MD

(Participation in afternoon session)
Assistant Professor of Oncology
Division of Hematology and Oncology
Mayo Clinic
Jacksonville, Florida

Shirley H. Miller, BA

(Participation in afternoon session)
(Patient Representative)
Manager, Community Programs
Sickle Cell Disease Program
Carolinas Healthcare System
Charlotte, North Carolina

Lori M. Minasian, MD, FACP

(Participation in morning session)
Deputy Director
Division of Cancer Prevention
Investigator, Women's Malignancy Branch
National Cancer Institute, NIH
Bethesda, Maryland

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
May 24, 2017

DRAFT MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Stacy Nerenstone, MD

(Participation in morning session)
Assistant Clinical Professor of Medicine
University of Connecticut
Senior Physician
Department of Medicine
Medical Staff President
Hartford Hospital
Hartford, Connecticut

Andrew D. Seidman, MD

(Participation in morning session)
Attending Physician
Breast Cancer Medicine Service
Associate Chair, Academic Administration
Department of Medicine
Memorial Sloan Kettering Cancer Center
Professor of Medicine
Weill Cornell Medical College
New York, New York

Patricia A. Spears, BS

(Participation in morning session)
(Patient Representative)
Raleigh, North Carolina

Melanie E. Royce, MD, PhD

(Participation in morning session)
Consultant, Breast Cancer Specialist
Immediate Past Director of the Breast Clinic and
former Professor
University of New Mexico Comprehensive Cancer
Center
Albuquerque, New Mexico

FDA PARTICIPANTS (Non-Voting)

Richard Pazdur, MD

Director
Office of Hematology Oncology Products (OHOP)
Office of New Drugs (OND), CDER, FDA

Julia Beaver, MD

(Participation in morning session)
Acting Director
Division of Oncology Products 1 (DOP1)
OHOP, OND, CDER, FDA

Laleh Amiri-Kordestani, MD

(Participation in morning session)
Medical Team Leader
Breast Cancer Group
DOP1, OHOP, OND, CDER, FDA

Harpreet Singh, MD

(Participation in morning session)
Medical Officer
DOP1, OHOP, OND, CDER, FDA

Amanda Walker, MD

(Participation in morning session)
Medical Officer
DOP1, OHOP, OND, CDER, FDA

Joyce Cheng, PhD

(Participation in morning session)
Statistical Reviewer
Division of Biometrics V (DBV)
Office of Biometrics (OB)
Office of Translational Science (OTS)
CDER, FDA

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
May 24, 2017

DRAFT MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting) (cont.)

Ann Farrell, MD

(Participation in afternoon session)

Director

Division of Hematology Products (DHP)

OHOP, OND, CDER, FDA

Kathy Robie-Suh, MD, PhD

(Participation in afternoon session)

Medical Team Leader

DHP, OHOP, OND, CDER, FDA

Rosanna Setse, MD, MPH, PhD

(Participation in afternoon session)

Medical Officer

DHP, OHOP, OND, CDER, FDA

Che Smith, PhD

(Participation in afternoon session)

Statistical Reviewer

DBV, OB, OTS, CDER, FDA

DRAFT