

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 14, 2019

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Jennifer Shepherd, RPh

Division of Advisory Committee and Consultant Management

Office of Executive Programs, CDER, FDA

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Massimo Cristofanilli, MD, FACP

(Morning Session Only)

Associate Director of Translational Research and
Precision Medicine

Robert H. Lurie Comprehensive Cancer Center
Chicago, Illinois

Susan Halabi, PhD

Professor of Biostatistics and Bioinformatics

Duke University Medical Center
Durham, North Carolina

Philip C. Hoffman, MD

Professor of Medicine

The University of Chicago

Section of Hematology/Oncology

Department of Medicine

Chicago, Illinois

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 Nowakowski, MD

Associate Professor of Medicine and Oncology

Division of Hematology

Mayo Clinic Rochester

Rochester, Minnesota

Courtney J. Preusse, MA

(Consumer Representative)

Senior Research Administrator

Clinical Research Division

Fred Hutchinson Cancer Research Center

Seattle, Washington

Brian I. Rini, MD, FACP

(Chairperson)

Professor of Medicine, Lerner College of Medicine

Leader, GU Program

Department of Hematology and Oncology

Cleveland Clinic Taussig Cancer Institute

Cleveland, Ohio

Thomas S. Uldrick, MD, MS

Deputy Head, Global Oncology

Associate Member, Vaccine and Infectious Disease

and Clinical Research Divisions

Fred Hutchinson Cancer Research Center

Associate Professor of Medicine

University of Washington

Seattle, Washington

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MEETING ROSTER (cont.)

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

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

(Industry Representative)

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

TEMPORARY MEMBERS (Voting)

Susan Broyles

(Patient Representative; Morning Session Only)

Aledo, Texas

Karim Anton Calis, PharmD, MPH, FASHP, FCCP

(Morning Session Only)

Director of Clinical Research and Compliance
Office of the Scientific Director
Eunice Kennedy Shriver National Institute of Child
Health and Human Development
National Institutes of Health (NIH)
Bethesda, Maryland

Sally Hunsberger, PhD

Biostatistician
National Institute of Allergy and Infectious
Diseases, NIH
Rockville Maryland

Valerae O. Lewis, MD

(Morning Session Only)

Professor and Chair,
Department of Orthopaedic Oncology
John Murray Professor in Orthopaedic Oncology
The University of Texas M.D. Anderson Cancer
Center
Houston, Texas

A. Michael Lincoff, MD

(Afternoon Session Only)

Professor of Medicine, Case Western Reserve
University
Vice Chair, Department of Cardiovascular
Medicine
Cleveland Clinic
Cleveland, Ohio

Doris Strader, MD

(Morning Session Only)

Professor, Department of Medicine
Department of Gastroenterology & Hepatology
The Robert Larner, MD College of Medicine
University of Vermont
Burlington, Vermont

Anthony D. Sung, MD

(Afternoon Session Only)

Assistant Professor of Medicine
Division of Hematologic Malignancies and
Cellular Therapy
Duke University
Durham, North Carolina

Wayne Taylor

(Patient Representative; Afternoon Session Only)

Hudson, Florida

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Victor M. Villalobos, MD, PhD

(Morning Session Only)

Medical Director, Cancer Clinical Trials Office
Director, Sarcoma Oncology
Director, Molecular Oncology Therapeutics
Assistant Professor of Medicine
University of Colorado Denver - Anschutz Medical
Campus
Aurora, Colorado

Kevin Weinfurt, PhD

(Morning Session Only)

Professor and Vice Chair of Research
Department of Population Health Sciences
Duke University School of Medicine
Durham, North Carolina

FDA PARTICIPANTS (Non-Voting)

Richard Pazdur, MD

Director, Oncology Center of Excellence, FDA
Acting Director, Office of Hematology &
Oncology Products (OHOP)
Office of New Drugs (OND), CDER, FDA

Patricia Keegan, MD

(Morning Session Only)

Director
Division of Oncology Products 2 (DOP2)
OHOP, OND, CDER, FDA

Ashley Ward, MD

(Morning Session Only)

Acting Supervisory Associate Director
DOP2, OHOP, OND, CDER, FDA

Lola Fashoyin-Aje, MD, MPH

(Morning Session Only)

Cross-Discipline Team Leader
DOP2, OHOP, OND, CDER, FDA

Christy Osgood, MD

(Morning Session Only)

Clinical Reviewer
Melanoma/Sarcoma Team
DOP2, OHOP, OND, CDER, FDA

Mallorie Fiero, PhD

(Morning Session Only)

Statistical Reviewer
Division of Biometrics V (DBV)
Office of Biometrics (OB)
Office of Translational Sciences (OTS), CDER, FDA

Ann Farrell, MD

(Afternoon Session Only)

Director
Division of Hematology Products (DHP)
OHOP, OND, CDER, FDA

Albert Deisseroth, MD, PhD

(Afternoon Session Only)

Associate Director
DHP, OHOP, OND, CDER, FDA

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting) (cont.)

Donna Przepiorka, MD, PhD

(Afternoon Session Only)

Cross-Discipline Team Leader
DHP, OHOP, OND, CDER, FDA

Aviva Krauss, MD

(Afternoon Session Only)

Clinical Reviewer
DHP, OHOP, OND, CDER, FDA

Kunthel By, PhD

(Afternoon Session Only)

Statistical Reviewer
DBV, OB, OTS, CDER, FDA