

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
December 17, 2019

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Lauren Tesh Hotaki, PharmD, BCPS, BCIDP

Division of Advisory Committee and Consultant Management
Office of Executive Programs, CDER, FDA

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Massimo Cristofanilli, MD, FACP

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

Christian S. Hinrichs, MD

Investigator & Lasker Clinical Research Scholar
Experimental Transplantation and Immunology
Branch
National Cancer Institute
National Institutes of Health (NIH)
Bethesda, Maryland

Philip Hoffman, MD

(Chairperson)
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

Anthony D. Sung, MD

(Morning Session Only)
Assistant Professor of Medicine
Duke University School of Medicine
Duke Adult Blood and Marrow Transplant Clinic
Durham, North Carolina

Thomas S. Uldrick, MD, MS

Deputy Head, Global Oncology
Associate Member, Vaccine and Infectious Disease
Division
Associate Member, Clinical Research Division
Fred Hutchinson Cancer Research Center
Seattle, Washington

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MEETING ROSTER (cont.)

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

Albert L. Kraus, PhD

(Industry Representative (alternate))

Global Regulatory Portfolio Lead, Oncology
Pfizer, Inc.
Guilford, Connecticut

TEMPORARY MEMBERS (Voting)

Piyush Agarwal, MD

(Afternoon Session Only)

Professor of Surgery and Urology
Director, Bladder Cancer Program
Fellowship Director, Urologic Oncology
Comprehensive Cancer Research Center
University of Chicago
Chicago, Illinois

Dawn Aldrich, PhD

(Patient Representative; Morning Session Only)

New Rochelle, New York

Andrea B. Apolo, MD

(Afternoon Session Only)

Clinical Investigator
Genitourinary Malignancies Branch
National Cancer Institute, NIH
Bethesda, Maryland

Randy W. Hawkins, MD

(Acting Consumer Representative)

Department of Internal Medicine
Internal Medicine/Pulmonary & Critical Care
Charles R. Drew University of Medicine and Science
Los Angeles, California

Colette Johnston

(Patient Representative; Afternoon Session Only)

Moab, Utah

Matthew H. Kulke, MD

(Morning Session Only)

Zoltan Kohn Professor
Department of Medicine
Boston University School of Medicine
Co-Director, Boston University-Boston Medical
Center Cancer Center
Boston, Massachusetts

Diane Reidy Lagunes, MD

(Morning Session Only)

Medical Oncologist
Division of Gastrointestinal Oncology
Memorial Sloan Kettering Cancer Center
New York, New York

Jonah Murdock, MD, PhD, FACS

(Afternoon Session Only)

Chief, Section of Urology
Washington DC Veterans Affairs Medical Center
Washington, District of Columbia

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Christian P. Pavlovich, MD

(Afternoon Session Only)

Professor of Urology and Oncology
Director of Urologic Oncology Fellowship
James Buchanan Brady Urological Institute
Johns Hopkins University School of Medicine
Baltimore, Maryland

Hanna K. Sanoff, MD, MPH

(Morning Session Only)

Associate Professor
Department of Medicine, Division of
Hematology/Oncology
University of North Carolina (UNC)
Clinic Medical Director, UNC North Carolina
Cancer Hospital
Chapel Hill, North Carolina

Mohammad Minhaj Siddiqui, MD FACS

(Afternoon Session Only)

Director, Urologic Oncology
Associate Professor of Surgery
University of Maryland School of Medicine
Chief of Urology
Veterans Affairs Maryland Healthcare System
Baltimore, Maryland

FDA PARTICIPANTS (Non-Voting)

Richard Pazdur, MD

Director, Oncology Center of Excellence (OCE),
FDA
Acting Director, Office of Oncologic Disease (OOD)
Office of New Drugs (OND), CDER, FDA

Steven Lemery, MD

(Morning Session Only)
Acting Director
Division of Oncology 3 (DO3)
OOD, OND, CDER, FDA

Lola Fashoyin-Aje, MD MPH

(Morning Session Only)

Acting Deputy Director
DO3, OOD, OND, CDER, FDA

Martha Donoghue, MD

(Morning Session Only)

Cross-Discipline Team Leader
Gastrointestinal Cancers Team
DO3, OOD, OND, CDER, FDA

Naomi Horiba, MD, MPH

(Morning Session Only)

Clinical Reviewer
Gastrointestinal Cancers Team
DO3, OOD, OND, CDER, FDA

Julia Beaver, MD

(Afternoon Session Only)

Director
Division of Oncology 1 (DO1)
OOD, OND, CDER, FDA

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MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting) (cont.)

Daniel Suzman, MD

(Afternoon Session Only)

Acting Clinical Team Leader

Genitourinary Team 2

DO1, OOD, OND, CDER, FDA

Jamie Brewer, MD

(Afternoon Session Only)

Clinical Reviewer

Genitourinary Team 2

DO1, OOD, OND, CDER, FDA

Joyce Cheng, PhD

(Afternoon Session Only)

Statistical Reviewer

Division of Biometrics V (DBV)

Office of Biostatistics (OB)

Office of Translational Science (OTS), CDER, FDA