# FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Oncologic Drugs Advisory Committee (ODAC) Meeting April 21, 2022

# **MEETING ROSTER**

# **DESIGNATED FEDERAL OFFICER (Non-Voting)**

#### She-Chia Chen, PharmD

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

# **ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)**

### Ranjana H. Advani, MD

Physician Leader, the Lymphoma Clinical Care Program Saul A. Rosenberg Professor of Lymphoma Stanford University Medical Center Stanford, California

### Massimo Cristofanilli, MD, FACP

Chief of Breast Medical Oncology Associate Director of Precision Medicine Meyer Cancer Center (MCC) Scientific Director of the Englander Institute of Precision Medicine Weill Cornell Medicine Division of Hematology-Oncology New York, New York

### Christopher H. Lieu, MD

Associate Professor of Medicine Associate Director for Clinical Research Director, Gastrointestinal Medical Oncology Program University of Colorado Aurora, Colorado

### **David E. Mitchell**

*(Consumer Representative)* Founder, Patients for Affordable Drugs Bethesda, Maryland

### Mark R. Conaway, PhD

Professor and Director of Translational Research Division of Translational Research and Applied Statistics Department of Public Health Sciences University of Virginia Charlottesville, Virginia

## Jorge A. Garcia, MD, FACP

*(Acting Chairperson)* Chair, Division of Solid Tumor Oncology George and Edith Richman Distinguished Scientist Chair Director, GU Oncology Program University Hospitals Seidman Cancer Center Case Comprehensive Cancer Center Case Western Reserve University Cleveland, Ohio

## Ravi A. Madan, MD

Clinical Director Genitourinary Malignancies Branch Center for Cancer Research National Cancer Institute National Institutes of Health Bethesda, Maryland

#### <u>Jorge J. Nieva, MD</u>

Associate Professor of Clinical Medicine Section Head, Solid Tumors University of Southern California (USC) Norris Comprehensive Cancer Center Keck School of Medicine of USC Los Angeles, California

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# **MEETING ROSTER (cont.)**

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

### Anthony D. Sung, MD

Associate Professor of Medicine Duke University School of Medicine Duke Adult Blood and Marrow Transplant Clinic Durham, North Carolina

# **ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)**

### Jonathan D. Cheng, MD

*(Industry Representative)* Senior Vice President Head of Oncology Development Global Drug Development Bristol-Myers Squibb Lawrenceville, New Jersey

# **TEMPORARY MEMBERS (Voting)**

#### Jessie Lai-Sim Au, PharmD, PhD

Director Institute of Quantitative Systems Pharmacology Carlsbad, California Moser Endowed Chair of Pharmaceutical Sciences University of Oklahoma Health Sciences Oklahoma City, Oklahoma Chief Scientific Officer Optimum Therapeutics LLC Carlsbad, California Distinguished University Professor Emeritus The Ohio State University Columbus, Ohio

## Christopher S. Coffey, PhD, MS

Professor, Department of Biostatistics Director, Clinical Trials Statistical & Data Management Center University of Iowa Iowa City, Iowa

#### Andy I. Chen MD, PhD

Associate Professor Knight Cancer Institute Oregon Health & Science University Portland, Oregon

#### Louis F. Diehl, MD

Professor of Medicine Duke University Durham, North Carolina

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# **MEETING ROSTER (cont.)**

# **TEMPORARY MEMBERS (Voting) (cont.)**

### Kieron M. Dunleavy, MD

Director of Hematology Lombardi Comprehensive Cancer Center Medstar Georgetown University Hospital Georgetown University Washington, District of Columbia

### Michele Nadeem-Baker, MS

(Patient Representative) Charlestown, Massachusetts

## FDA PARTICIPANTS (Non-Voting)

#### **Richard Pazdur, MD**

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

#### Nicole Gormley, MD

Director Division of Hematologic Malignancies II (DHM II) OOD, OND, CDER, FDA

<u>Yvette Kasamon, MD</u> Team Leader DHM II, OOD, OND, CDER, FDA

#### Brian Booth, PhD

Director Division of Cancer Pharmacology I Office of Clinical Pharmacology OTS, CDER, FDA

### Walter K. Kraft, MD, MS, FACP

Professor of Pharmacology, Medicine & Surgery Department of Pharmacology and Experimental Therapeutics Thomas Jefferson University Philadelphia, Pennsylvania

### Gita Thanarajasingam, MD

Associate Professor, Division of Hematology Department of Medicine Mayo Clinic Rochester, Minnesota

### Marc R. Theoret, MD

Deputy Center Director, OCE Supervisory Associate Director (Acting) OOD, OND, CDER, FDA

## Nicholas Richardson, DO, MPH

Clinical Team Leader DHM II, OOD, OND, CDER, FDA

#### Thomas Gwise, PhD

Director Division of Biometrics IX Office of Biostatistics Office of Translational Sciences (OTS), CDER, FDA