# FDA-AACR Workshop to Examine Under-representation of African Americans in Multiple Myeloma Clinical Trials

**February 13, 2020**

**Washington Marriott Wardman Park | Washington, DC**

**Workshop Cochairs:**

**U.S. Food and Drug Administration:**

**Lola A. Fashoyin-Aje, MD, MPH,** Acting Deputy Director, Division of Oncology 3, Office of Oncologic Diseases, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

**Nicole Gormley, MD,** Acting Director, Division of Hematologic Malignancies 1, Office of Oncologic Diseases, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

**Paul G. Kluetz, MD,** Deputy Director, Oncology Center of Excellence, U.S. Food and Drug Administration

**American Association for Cancer Research:**

**Kenneth C. Anderson, MD, FAACR,** Program Director, Jerome Lipper Multiple Myeloma Center and LeBow Institute for Myeloma Therapeutics, Dana-Farber Cancer Institute; Kraft Family Professor of Medicine, Harvard Medical School

## AGENDA

### INTRODUCTION

**8:00 AM** **Welcome**
**Margaret Foti, PhD, MD (hc),** American Association for Cancer Research

**8:05 AM** **Introduction**
**Kenneth C. Anderson, MD, FAACR,** Dana-Farber Cancer Institute

### SESSION I: STATE OF THE SCIENCE & CLINICAL IMPLICATIONS
### SESSION CHAIR: KENNETH C. ANDERSON, MD

**8:15 AM** **Overview of "FDA-AACR Workshop to Examine Under-representation of African Americans in Multiple Myeloma Clinical Trials"**
**Lola A. Fashoyin-Aje, MD, MPH, & Nicole Gormley, MD,** U.S. Food and Drug Administration

**8:35 AM** **FDA analysis of multiple myeloma trials supporting approval**
**Laura Fernandes, PhD, & Bindu Kanapuru, MD,** U.S. Food and Drug Administration

**8:55 AM** **Evaluation of characteristics and outcomes of multiple myeloma patients from an EHR-derived database**
**Kathleen Maignan, MSN, NP,** Flatiron Health

**9:15 AM** **Scope of the issue: Discovery science, differences in clinical features, prognostic factors, differential outcomes**
**Nikhil C. Munshi, MD,** Dana-Farber Cancer Institute

**9:35 AM** **Biology and genomic differences of multiple myeloma**
**Shaji K. Kumar, MD,** Mayo Clinic Cancer Center

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| **9:55 AM** | **Increasing minority accrual in myeloma clinical trials: Emory experience and lessons learned**<br>**Ajay K. Nooka, MD,** Winship Cancer Institute of Emory University |
| **10:15 AM** | **BREAK** |
| | **SESSION II: APPROACHES TO IMPROVE DATA ON OUTCOMES IN RACIAL AND ETHNIC MINORITIES PRIOR TO DRUG APPROVAL**<br>**SESSION CHAIR: CRAIG E. COLE, MD** |
| **10:35 AM** | **Overview of Working Group 1 Recommendations**<br>**Craig E. Cole, MD,** Michigan State University Breslin Cancer Center |
| **10:50 AM** | **PANEL DISCUSSION AND AUDIENCE INPUT** |
| **Moderator:** | **Craig E. Cole, MD,** Michigan State University Breslin Cancer Center |
| **Panelists:** | **Vishal Bhatnagar, MD,** U.S. Food and Drug Administration<br>**Ruemu E. Birhiray, MD,** Hematology Oncology of Indiana<br>**Yelak Biru,** Patient Advocate<br>**Mihaela Popa McKiver, MD, PhD,** Bristol-Myers Squibb<br>**Khalid Mezzi, MD, MBA,** Amgen |
| **11:50 AM** | **LUNCH BREAK (ON YOUR OWN)** |
| | **SESSION III: APPROACHES TO USING POSTAPPROVAL CLINICAL TRIAL DATA TO BETTER UNDERSTAND EFFECTIVENESS AND SAFETY OF THERAPIES IN RACIAL AND ETHNIC MINORITIES**<br>**SESSION CHAIR: RICHARD F. LITTLE, MD** |
| **12:55 PM** | **Overview of Working Group 2 Recommendations**<br>**Richard F. Little, MD,** National Cancer Institute |
| **1:10 PM** | **PANEL DISCUSSION AND AUDIENCE INPUT** |
| **Moderator:** | **Richard F. Little, MD,** National Cancer Institute |
| **Panelists:** | **Bindu Kanapuru, MD,** U.S. Food and Drug Administration<br>**Sikander Ailawadhi, MD,** Mayo Clinic Cancer Center Jacksonville<br>**Wan-Jen Hong, MD,** Genentech<br>**Rachel Kobos, MD,** Janssen Pharmaceuticals<br>**Shaji K. Kumar, MD,** Mayo Clinic Cancer Center<br>**Angela X. Qu, MD, PhD,** Parexel<br>**Tiffany H. Williams,** Patient Advocate |
| **2:10 PM** | **BREAK** |
| | **SESSION IV: APPROACHES TO UTILIZE REAL-WORLD DATA TO UNDERSTAND OUTCOMES WITH SPECIFIC THERAPIES IN RACIAL AND ETHNIC MINORITIES**<br>**SESSION CHAIR: JOSEPH M. UNGER, PHD, MS** |
| **2:30 PM** | **Overview of Working Group 3 Recommendations**<br>**Joseph M. Unger, PhD, MS,** Fred Hutchinson Cancer Research Center |

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| **2:45 PM** | **PANEL DISCUSSION AND AUDIENCE INPUT** |
| **Moderator:** | **Joseph M. Unger, PhD, MS,** Fred Hutchinson Cancer Research Center |
| **Panelists:** | **Kunthel By, PhD,** U.S. Food and Drug Administration |
| | **Daniel Auclair, PhD,** Multiple Myeloma Research Foundation |
| | **Ruthanna Davi, PhD,** Acorn AI |
| | **Irene M. Ghobrial, MD,** Dana-Farber Cancer Institute |
| | **Kathleen Maignan, MSN, NP,** Flatiron Health |
| | **William A. Wood, MD,** UNC Lineberger Comprehensive Cancer Center |

**SESSION V: CONCLUSIONS & FUTURE DIRECTIONS**

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| **3:45 PM** | **PANEL DISCUSSION AND AUDIENCE INPUT** |
| **Moderator:** | **Kenneth C. Anderson, MD, FAACR,** Dana-Farber Cancer Institute |
| **Panelists:** | **Lola A. Fashoyin-Aje, MD, MPH,** U.S. Food and Drug Administration |
| | **Nicole Gormley, MD,** U.S. Food and Drug Administration |
| | **Irene M. Ghobrial, MD,** Dana-Farber Cancer Institute |
| | **Mihaela Popa McKiver, MD, PhD,** Bristol-Myers Squibb |
| | **Joseph Mikhael, MD, MEd, FRCPC, FACP,** International Myeloma Foundation; TGen |
| | **Edith P. Mitchell, MD, MACP, FCCP,** Sidney Kimmel Cancer Center at Thomas Jefferson University |
| | **Tiffany H. Williams,** Patient Advocate |
| **4:45 PM** | **Summary** |
| | **Kenneth C. Anderson, MD, FAACR,** Dana-Farber Cancer Institute |
| **4:55 PM** | **Closing Remarks** |
| | **Paul G. Kluetz, MD,** U.S. Food and Drug Administration |
| **5:00 PM** | **ADJOURN** |