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  Introduction & welcome  
*Kenneth C. Anderson, MD, FAACR,* Dana-Farber Cancer Institute

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

8:05 AM  Overview of FDA-AACR working groups, objectives, regulatory perspective  
*FDA cochair*

8:30 AM  Scope of the issue: Discovery science, differences in clinical features, prognostic factors, differential outcomes  
*Nikhil C. Munshi, MD,* Dana-Farber Cancer Institute

8:50 AM  Biology and genomic differences of multiple myeloma  
*S. Vincent Rajkumar, MD,* Mayo Clinic

9:10 AM  FDA data analysis, FDA presentation  
*FDA staff*

9:25 AM  Lessons Learned  
*TBD*

10:00 AM  BREAK
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<tr>
<th>Time</th>
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| 10:20 AM | SESSION II: APPROACHES TO IMPROVE DATA ON OUTCOMES IN RACIAL AND ETHNIC MINORITIES  
PRIOR TO DRUG APPROVAL  
SESSION CHAIR: CRAIG E. COLE, MD | Overview of Working Group 1 Recommendations  
Craig E. Cole, MD, Michigan State University Breslin Cancer Center | |
| 10:45 AM | PANEL DISCUSSION  
Moderator: Craig E. Cole, MD, Michigan State University Breslin Cancer Center  
Panelists: Ruemu E. Birhiray, MD, Hematology Oncology of Indiana | | |
| 11:45 AM | LUNCH BREAK (ON YOUR OWN) | | |
| 12:45 PM | SESSION III: APPROACHES TO USING POST-APPROVAL CLINICAL TRIAL DATA TO BETTER TO UNDERSTAND EFFECTIVENESS AND SAFETY OF THERAPIES IN RACIAL AND ETHNIC MINORITIES  
SESSION CHAIR: RICHARD F. LITTLE, MD | Overview of Working Group 2 Recommendations  
Richard F. Little, MD, National Cancer Institute | |
| 1:05 PM | PANEL DISCUSSION  
Moderator: Richard F. Little, MD, National Cancer Institute  
Panelists: Sikander Ailawadi, MD, Mayo Clinic Cancer Center Jacksonville  
Bindu Kanaparu, MD, MBBS, U.S. Food and Drug Administration  
Shaji K. Kumar, MD, Mayo Clinic | | |
| 2:05 PM | BREAK | | |
| 2:20 PM | SESSION IV: APPROACHES TO UTILIZE REAL-WORLD DATA TO UNDERSTAND OUTCOMES WITH SPECIFIC THERAPIES IN RACIAL AND ETHNIC MINORITIES  
SESSION CHAIR: JOSEPH M. UNGER, PHD, MS | Overview of Working Group 3 Recommendations  
Joseph M. Unger, PhD, MS, Fred Hutchinson Cancer Research Center | |
| 2:45 PM | PANEL DISCUSSION  
Moderator: Joseph M. Unger, PhD, MS, Fred Hutchinson Cancer Research Center  
Panelists: Daniel Auclair, PhD, Multiple Myeloma Research Foundation  
Irene M. Ghobrial, MD, Dana-Farber Cancer Institute  
William A. Wood, MD, UNC Lineberger Comprehensive Cancer Center | | |
| 3:45 PM | CONCLUSION & FUTURE DIRECTIONS  
Summary of Recommendations  
Kenneth C. Anderson, MD, FAACR, Dana-Farber Cancer Institute | | |
| 4:00 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  
Paul G. Kluetz, MD, U.S. Food and Drug Administration  
Joseph Mikhail, MD, Med, FRCP, FACP, International Myeloma Foundation; TGen  
Edith P. Mitchell, MD, Thomas Jefferson University Kimmel Cancer Center | |
5:00 PM ADJOURN