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
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
SESSION CHAIR: CRAIG E. COLE, MD

10:35 AM  Overview of Working Group 1 Recommendations
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
Ruemu E. Birhiray, MD, Hematology Oncology of Indiana
Yelak Biru, Patient Advocate
Mihaela Popa Mckiver, MD, PhD, Bristol-Myers Squibb
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
SESSION CHAIR: RICHARD F. LITTLE, MD

12:55 PM  Overview of Working Group 2 Recommendations
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
Sikander Ailawadi, MD, Mayo Clinic Cancer Center Jacksonville
Wan-Jen Hong, MD, Genentech
Rachel Kobos, MD, Janssen Pharmaceuticals
Shaji K. Kumar, MD, Mayo Clinic Cancer Center
Angela X. Qu, MD, PhD, Parexel
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
SESSION CHAIR: JOSEPH M. UNGER, PHD, MS

2:30 PM  Overview of Working Group 3 Recommendations
Joseph M. Unger, PhD, MS, Fred Hutchinson Cancer Research Center

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<th>Time</th>
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<th>Moderator</th>
<th>Panelists</th>
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<td>2:45 PM</td>
<td>PANEL DISCUSSION AND AUDIENCE INPUT</td>
<td>Joseph M. Unger, PhD, MS, Fred Hutchinson Cancer Research Center</td>
<td>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</td>
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<td>3:45 PM</td>
<td>PANEL DISCUSSION AND AUDIENCE INPUT</td>
<td>Kenneth C. Anderson, MD, FAACR, Dana-Farber Cancer Institute</td>
<td>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</td>
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<td>4:45 PM</td>
<td>Summary</td>
<td>Kenneth C. Anderson, MD, FAACR, Dana-Farber Cancer Institute</td>
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<td>4:55 PM</td>
<td>Closing Remarks</td>
<td>Paul G. Kluetz, MD, U.S. Food and Drug Administration</td>
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