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

@FDAOncology @AACR

Join the conversation with #MyelomaDiversity
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 Ailawadhi, 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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| 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 |
| 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, FRCP, FACP, International Myeloma Foundation; TGen  
Edith P. Mitchell, MD, MACP, FCPP, 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                                  |                                                                 |