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

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

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

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, 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**