

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

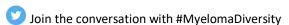
American Association for Cancer Research:

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

	Remeth C. Anderson, MD, FAACK, 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 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 Al

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