

FDA-AACR-SGO Workshop on Drug Development in Gynecologic Malignancies

June 14, 2018

FDA White Oak Campus | Silver Spring, MD

Workshop Cochairs:

U.S. Food and Drug Administration:

Sanjeeve Bala, MD, MPH, Clinical Team Leader Gynecologic Malignancies Group, Division of Oncology Products 1, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

Julia A. Beaver, MD, Director, Division of Oncology Products 1, Office of Hematology and Oncology Products, Center for Drug Evaluation and Research, U.S. Food and Drug Administration

American Association for Cancer Research:

Deborah K. Armstrong, MD, Director, Breast and Ovarian Surveillance Service; Professor of Oncology; Professor of Gynecology & Obstetrics, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center

Gordon B. Mills, MD, PhD, Co-Director, Zayed Institute for Personalized Cancer Therapy, Department of Systems Biology 1, Division of Cancer Medicine, UT MD Anderson Cancer Center

Society of Gynecologic Oncology:

Rebecca Arend, MD, Assistant Professor of Obstetrics & Gynecology, University of Alabama at Birmingham

Robert L. Coleman, MD, FACOG, FACS, Vice Chair, Clinical Research, Department of Gynecologic Oncology and Reproductive Medicine, UT MD Anderson Cancer Center

Thomas Herzog, MD, Deputy Director & Professor of Obstetrics & Gynecology, University of Cincinnati Cancer Institute

AGENDA

INTRODUCTION

8:00 AM Introduction & Objectives
Julia A. Beaver, MD, U.S. Food and Drug Administration

SESSION I: DEVELOPMENT OF IMMUNOTHERAPY IN GYNECOLOGICAL MALIGNANCIES – PART 1 SESSION COCHAIRS: SANJEEVE BALA, MD, MPH, & THOMAS HERZOG, MD

Description: To discuss the science behind why immunotherapy would work in GYN malignancies and biomarker issues associated with immunotherapy.

8:10 AM Immunotherapy for Gynecologic Cancers: What is the Biological Rationale for, and Challenge of Immunotherapy for Gynecologic Cancer?
Dmitriy Zamarin, MD, PhD, Memorial Sloan Kettering Cancer Center

8:30 AM Efficacy/Safety of Single Agent Immunotherapy/Immune Checkpoint Inhibitors in Gynecologic Cancer
Deborah K. Armstrong, MD, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center



8:45 AM **Strategy, Efficacy, and Safety of Combination Regimens Using Immunotherapy**
Rebecca Arend, MD, University of Alabama at Birmingham

9:00 AM **PANEL DISCUSSION and AUDIENCE Q&A**

Moderators **Sanjeeve Bala, MD, MPH, & Thomas Herzog, MD**
Session I speakers and the following additional panelist(s):
Amreen Husain, MD, Genentech
W. Michael Korn, MD, UCSF Helen Diller Family Comprehensive Cancer Center

9:50 AM **BREAK**

SESSION II: DEVELOPMENT OF IMMUNOTHERAPY IN GYNECOLOGICAL MALIGNANCIES – PART 2
SESSION COCHAIRS: JULIA A. BEAVER, MD, & REBECCA AREND, MD

Description: To discuss innovative study design ideas to examine contribution of effect of novel immunotherapy combinations in GYN malignancies.

10:10 AM **Novel Immunotherapy Approaches and Cellular-based Therapy for Gynecologic Oncology Patients**
Amir A. Jazaeri, MD, UT MD Anderson Cancer Center

10:25 AM **Innovations in Immuno-oncology Clinical Trial Designs**
Robert L. Coleman, MD, FACOG, FACS, UT MD Anderson Cancer Center

10:40 AM **Statistical Considerations for Immuno-oncology Trials**
Rajeshwari Sridhara, PhD, U.S. Food and Drug Administration

10:55 AM **PANEL DISCUSSION and AUDIENCE Q&A**

Moderators **Julia A. Beaver, MD, & Rebecca Arend, MD**
Session II speakers and the following additional panelist(s):
Geoffrey S. Kim, MD, AstraZeneca
Mary J. Scroggins, MA, Patient Advocate

11:55 PM **LUNCH BREAK (ON YOUR OWN)**

SESSION III: BIOMARKER DEVELOPMENT AND PARP INHIBITORS
SESSION COCHAIRS: DEBORAH K. ARMSTRONG, MD, & ROBERT L. COLEMAN, MD, FACOG, FACS

Description: Given the recent approvals of PARP inhibitors in the BRCA unselected patients, how can we better predict who will respond to these drugs since only a small percentage of BRCA negative group will do so? How can we identify that group?

1:00 PM **FDA Perspective**
Gwynn Ison, MD, U.S Food and Drug Administration

1:15 PM **PARP Resistance Mechanisms**
Alan D'Andrea, MD, Dana-Farber Cancer Institute

1:30 PM **Rational Drug Combinations with PARP Inhibitors**
Gordon B. Mills, MD, PhD, UT MD Anderson Cancer Center

1:45 PM **PANEL DISCUSSION and AUDIENCE Q&A**

Moderators **Deborah K. Armstrong, MD, & Robert L. Coleman, MD, FACOG, FACS**
Session III speakers and the following additional panelist:
Hisani Madison, PhD, MPH, U.S Food and Drug Administration

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2:35 PM BREAK

**SESSION IV: DEVELOPMENT OF DRUGS FOR RARE GYNECOLOGICAL MALIGNANCIES
SESSION COCHAIR: GORDON B. MILLS, MD, PHD**

Description: Development of drugs for rare GYN malignancy subset (e.g. clear cell ovarian cancer); this session will explore trouble with control arms, small sample sizes, need for more real world historic controls and single arm studies, vs. small cohorts within randomized trials.

**2:50 PM Emerging Opportunities in Rare Gynecologic Cancers
Anil K. Sood, MD, UT MD Anderson Cancer Center**

**3:05 PM The Challenge of Rare Subsets of Rare Cancers: A focus on *ESR1* mutations in gynecologic malignancies
Stephanie L. Gaillard, MD, PhD, Johns Hopkins School of Medicine**

**3:20 PM Progress in Drug Development for Rare Epithelial Ovarian Cancers: The NRG Oncology (GOG) Experience
David M. Gershenson, MD, UT MD Anderson Cancer Center**

3:35 PM PANEL DISCUSSION and AUDIENCE Q&A

Moderator Gordon B. Mills, MD, PhD
Session IV speakers and the following additional panelist(s):
Amy E. McKee, MD, U.S Food and Drug Administration
Annie E. Ellis, Patient Advocate
Stephen Keefe, MD, MSCE, Merck

**4:25 PM Wrap up: Summary & Future Directions
Robert L. Coleman, MD, FACOG, FACS, UT MD Anderson Cancer Center**

4:30 PM ADJOURN

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