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

@FDAOncology    @AACR    @SGO_org

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### 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**

### 10:00 AM
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)**

### 1:00 PM
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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### 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 troubles with control arms, small sample sizes, need for more real world historic controls and single arm studies, vs. small cohorts within randomized trials.

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<th>Time</th>
<th>Topic</th>
<th>Speaker(s)</th>
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<td>2:50 PM</td>
<td>Emerging Opportunities in Rare Gynecologic Cancers</td>
<td>Anil K. Sood, MD, UT MD Anderson Cancer Center</td>
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<td>3:05 PM</td>
<td>The Challenge of Rare Subsets of Rare Cancers: A focus on ESR1 mutations in gynecologic malignancies</td>
<td>Stephanie L. Gaillard, MD, PhD, Johns Hopkins School of Medicine</td>
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<td>3:20 PM</td>
<td>Progress in Drug Development for Rare Epithelial Ovarian Cancers: The NRG Oncology (GOG) Experience</td>
<td>David M. Gershenson, MD, UT MD Anderson Cancer Center</td>
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<td>3:35 PM</td>
<td>PANEL DISCUSSION and AUDIENCE Q&amp;A</td>
<td>Gordon B. Mills, MD, PhD</td>
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<td>Session IV speakers and the following additional panelist(s):</td>
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<td>Amy E. McKee, MD, U.S Food and Drug Administration</td>
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<td>Annie E. Ellis, Patient Advocate</td>
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<td>Stephen Keefe, MD, MSCE, Merck</td>
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<td>4:25 PM</td>
<td>Wrap up: Summary &amp; Future Directions</td>
<td>Robert L. Coleman, MD, FACOG, FACS, UT MD Anderson Cancer Center</td>
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