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 (DOP1), Office of Hematology and Oncology Products (OHOP), Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration
Julia A. Beaver, MD, Director, Division of Oncology Products 1 (DOP1), Office of Hematology and Oncology Products (OHOP), Center for Drug Evaluation and Research (CDER), 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 John Hopkins University
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 Welcome
AACR Cochair

8:05 AM Opening Remarks

8:15 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, get into the biomarker issues seen with immunotherapy.

8:20 AM Immunotherapy Science: Approach- Biomarker Directed, Tissue-agnostic, Targeted
Deborah K. Armstrong, MD, Johns Hopkins Kimmel Comprehensive Cancer Center
8:35 AM  Immunological Aspects of Treatment Resistance
    Dmitry Zamarin, MD, PhD, Memorial Sloan Kettering Cancer Center

8:50 AM  Combination Approaches
    Rebecca Arend, MD, University of Alabama at Birmingham

9:05 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
    Michael Korn, MD, UCSF Helen Diller Family Comprehensive Cancer Center

9:55 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  Immunotherapy Biomarker Development and Rationale for Combinations
    Amir A. Jazaeri, MD, UT MD Anderson Cancer Center

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

10:40 AM  Statistical Considerations for Combination Immuno-Oncology Trials
    William Brady, PhD, Sarah Cannon Development Innovations

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):
    Rajeshwari Sridhara, PhD, U.S. Food and Drug Administration
    Geoffrey S. Kim, MD, AstraZeneca
    Mary J. Scroggins, Patient Advocate

11:55 AM  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 PARPi 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
    TBD

1:30 PM  Rational PARP + X Agents and Design
    Anil K. Sood, MD, 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

### 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.*

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<th>Time</th>
<th>Session Title</th>
<th>Speaker(s)</th>
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<td>2:50 PM</td>
<td>Discussion on Different Subsets and Treatments Within Tumor Types Including Low Grade Serous, Non-epithelial Ovarian, and Small Cell</td>
<td>Gordon B. Mills, MD, PhD, UT MD Anderson Cancer Center</td>
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<td>3:05 PM</td>
<td>Approach to Drug Development for Patients with ESR1 Mutations</td>
<td>Stephanie L. Gaillard, MD, PhD, Johns Hopkins School of Medicine</td>
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<td>3:20 PM</td>
<td>Title TBD</td>
<td>David M. Gershenson, MD, UT MD Anderson Cancer Center</td>
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<td>3:45 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>
<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>4:35 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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