Ovarian Cancer Workshop Agenda

Presented by FDA, SGO, AACR and ASCO

September 3, 2015 - 8:00 am – 5:00 pm

FDA White Oak campus, Building 31, Great Room "B & C"

8:00 - 8:10	**Welcome and Introduction – Amy McKee, M.D. – FDA**
8:10 - 8:15	**Workshop Rationale - Thomas Herzog, M.D. – University of Cincinnati Cancer Institute** Why we are here? • To review the current state of science of ovarian cancer biology and implications for clinical trial design; to discuss data for pathologic CR and second look surgery; • To discuss and explore emerging measures of treatment effect, including circulating factors, tissue and imaging biomarker; • To discuss relevant endpoints reflective of the diversity of disease and patient populations and how this impacts available trial designs and context for endpoints; • To explore novel treatment designs relative to discovery and regulatory approval.
8:15 - 9:30	**How do we exploit the neoadjuvant platform for discovery and regulatory approval?** **Moderator Robert Coleman, M.D. – University of Texas, MD Anderson Cancer Center** • **Treatment effects from standard of care** **Deborah Armstrong, M.D. – Johns Hopkins School of Medicine** • **Regulatory opportunities and implications of endpoints** **Gwynn Ison, M.D. – FDA** **Panelists:** **David R. Spriggs, M.D. – Memorial Sloan Kettering Cancer Center** **Robert Burger, M.D. – University of Pennsylvania** **Annie Ellis – Patient Advocate**
9:30 – 10:00	**How do we better categorize ovarian cancer patients and enrich patient populations for clinical trials?** • **Clinical Trial Enrichment Strategies for Patients with Newly Diagnosed Ovarian Cancer - Ursula Matulonis, M.D. – Dana Farber Cancer Institute** • **Moving beyond newly diagnosed and platinum sensitive/resistant disease: How can we better classify ovarian cancer patients for clinical trials?** **Ronald Alvarez, M.D. – University of Alabama, Birmingham**
10:00-10:15	**Break**

10:15-11:45	**Biomarkers** **Moderator: Julia Beaver, M.D. – FDA** • **The role of tissue/circulating based biomarkers as clinical trial endpoints** **Michael Birrer, M.D., Ph.D. – Dana-Farber/Harvard Cancer Center** • **The role of tissue/circulating based biomarkers in clinical trials: regulatory perspective** **Julia Beaver, M.D. – FDA** • **The role of image based biomarkers as clinical trial endpoints** **Susanna Lee, M.D., Ph.D. – Massachusetts General Hospital** • **CA125 as a marker of response and progression in clinical trials** **Gottfried Konecny, M.D. – UCLA** • **Regulatory perspective on use of CA-125 as an independent endpoint for accelerated approval** **Geoff Kim, M.D. – FDA** **Panelists:** **Susan Leighton - Patient Advocate** **Peg Ford – Patient Advocate**
11:45 – 12:30	**LUNCH**
12:30 - 1:30	**PANEL: Perils and pitfalls of clinical trials** **Moderator: Bradley Monk, M.D. - St Joseph's Hospital** **Panelists:** **Shenghui Tang, Ph.D. – FDA** **Rajeshwari Sridhara, Ph.D. – FDA** **Mark Brady, Ph.D. – University of Buffalo** **Larry Rubenstein, Ph.D. – NCI** **Daniel Sargent, Ph.D. –Mayo Clinic** • Findings for subgroups that are not pre-specified • Over-interpretation of strata analysis • Sensitivity analyses • Incomplete patient-reported outcome data • Mid-trial amendments (vs SPA)
1:30 – 2:30	**How do we study Immunotherapy?** **Moderator: Sanjeeve Bala, M.D. – FDA** • **Non-Cellular immune-based therapeutic strategies** **Kunle Odunsi, M.D., Ph.D. – Roswell Park Cancer Center**

	• **Cellular immune-based therapeutic strategies** **Daniel Powell, M.D. – University of Pennsylvania** • **Immunotherapy from a regulatory standpoint** **Sanjeeve Bala, M.D. – FDA** **Panelist:** **Annie Ellis - Patient Advocate**
2:30 – 3:00	**FDA Patient Representatives: The Patient's perspective** • **Peg Ford, Patient advocate** • **Annie Ellis, Patient Advocate**
3:00 – 3:15	**BREAK**
3:15 - 4:00	**Innovative clinical design strategies** **Moderator: Amy McKee, M.D. – FDA** • **What are the most efficient ways to study rare ovarian tumors?** **David Gershenson, M.D. – MD Anderson** • **Innovative clinical trial designs** **Rajeshwari Sridhara, Ph.D. – FDA** • **FDA Regulatory Myths** **Amy McKee, M.D. – FDA** **Panelist:** **Susan Leighton – Patient Advocate**
4:00 – 5:00	**Workshop Summary and Conclusions** **Moderators: Thomas Herzog, M.D. – University of Cincinnati Cancer Institute;** **Geoff Kim, M.D. – FDA** **PANEL (All Speakers)** • **Summary slides from each session: CLINICAL Trials Endpoints (GRID)** • **2-3 provocative questions (What are our real knowledge gaps? How do we prioritize and plan the path forward)** o Is the "4th line plus space" still a viable strategy? What are the requisites and what are appropriate trials considered confirmatory for regulatory filing? o How do we study combinations in the platinum-resistant space (do we need to do component assessment in addition to combination)? What if no single agent activity is expected but synergy is expected? o Introduce Grid