

Ovarian Cancer End Points Workshop
April 26, 2006
Bethesda North Marriott Hotel and Conference Center
5701 Marinelli Road, Bethesda, MD

Presented by the U.S. Food and Drug Administration and the American Society of Clinical Oncology
Co-sponsored by the American Association for Cancer Research

AGENDA

7:30 – 7:35	Welcome and Introduction	<u>Richard Pazdur</u>
7:35 – 7:55	Regulatory Background	<u>Lee Pai-Scherf</u>
7:55 – 8:30	Design Issues in Clinical Trials of Ovarian Cancer	<u>Tate Thigpen</u>
	<u>Regulatory Use of CA-125 in Ovarian Cancer</u>	
8:30 – 9:00	Use of CA-125 for Response Evaluation in Ovarian Cancer	<u>Robert Bast & Gordon Rustin</u>
9:00 – 9:10	FDA perspective: Analytical aspects of CA-125 tests	<u>Robert Becker</u>
9:10 – 10:00	Questions/Discussion	
10:00 – 10:15	<i>Break</i>	
	<u>Regulatory Endpoints for First-Line Therapy</u>	
10:15 – 11:00	Is PFS a “Valid” Surrogate for OS in Advanced Ovarian Cancer? A Meta-Analysis	<u>Marc Buyse</u>
	Clinical Trial Endpoints for Regulatory Approval: First-Line Therapy for Advanced Ovarian Cancer	<u>Elizabeth Eisenhauer</u>
	First-Line therapy in Ovarian Cancer: Surrogate endpoints for accelerated approval	<u>Mark Brady</u>
11:00 – 11:30	Questions/Discussion	
11:30 – 11:45	Audience Questions/Comments	
11:45 – 12:30	<i>Lunch</i>	
	<u>Regulatory Endpoints for Maintenance Therapy</u>	
12:30 – 12:50	Maintenance Therapy in Ovarian Cancer: PFS and OS as Endpoints of Therapeutic Clinical Trials	<u>Robert Ozols & David Spriggs</u>
12:50 – 1:15	Discussion	
	<u>Regulatory Endpoints for Subsequent Therapies</u>	
1:15 – 1:45	Endpoints in Platinum Sensitive Ovarian Cancer	<u>David Spriggs</u>
	Evaluation Of Chemotherapy Efficacy In Platinum Resistant Ovarian Cancer	<u>Peter Rose</u>
1:45 – 2:15	Discussion	

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2:15 – 2:30	Audience Questions/Comments	
	<u>Patient Reported Outcomes</u>	
2:30 – 2:50	Patient Reported Outcomes: End Points for Ovarian Cancer	<u>Lari Wenzel & Karen Basen-Engquist</u>
2:50 - 3:15	Discussion	
3:15 – 3:30	<i>Break</i>	
3:30 – 3:45	Audience Questions/Comments	
3:45 – 4:45	<u>Biomarker & Endpoint Research Priorities</u>	<u>Edward Trimble</u>
4:45 – 5:00	Workshop Summary/Conclusions	<u>Stacey Nerenstone & Ralph Freedman</u>
5:00	Adjournment	