

Prostate Cancer End Points Workshop
June 21-22, 2004
Bethesda Marriott - Bethesda, MD

AGENDA

Monday, June 21, 2004, AM

Introductory Overview: End Points to Measure Therapeutic Efficacy in Prostate Cancer

8:00 – 8:20	Regulatory Perspective	<u>Richard Pazdur</u>
8:20 – 8:55	Relevance of Prostate Cancer Clinical States to End Points and PSA End Point Application Methodologies	<u>Howard Scher</u>
8:55 – 9:10	Statistical Issues in the Validation of Surrogate Endpoints	<u>Stuart Baker</u>
9:10 – 9:20	Prostate Cancer Specific Mortality – Issues in its Use in Surrogate Validation	<u>Peter Albertsen</u>
9:20 – 9:30	Clarification Questions to Presenters	
9:30 – 9:45	Bone Scan – Issues in Application for Disease Assessment	<u>Steve Larson</u>
9:45 – 9:55	Bone Scan – Application Experience in Clinical Trials	<u>Kevin Carroll</u>
9:55 – 10:05	Break	
10:05 – 10:25	Patient Reported Outcomes	<u>Derek Raghavan</u>
10:25 – 10:35	Clarification Questions to Presenters	
10:35 – 11:40	Formal Questions for Discussion	Discussion Leaders: <u>Anthony D'Amico</u> , <u>Howard Scher</u> & <u>Peter Scardino</u>
11:40 – 12:10	Audience Questions	
12:10 – 12:55	Lunch	

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**End Points for Clinical Trials in Primary Treatment
(Neoadjuvant & Adjuvant) of M0 Disease & Hormone Sensitive M1 Disease**

12:55 – 1:10	Hormone Sensitive Disease – Regulatory End Point History of Approved Therapies	<u>George Benson or Donna Griebel</u>
1:10 – 1:30	Early disease: It's Scope & Associated End Point Issues	<u>Peter Scardino</u>
1:30 – 1:50	Increasing PSA after Primary Treatment	<u>Anthony D'Amico</u>
1:50 – 2:00	Clarification Questions to Presenters	
2:00 – 2:20	Examination of End Points – Increasing PSA after Primary Treatment Including Adjuvant	<u>Howard Sandler</u>
2:20 – 2:30	Clarification Questions to Presenter	
2:30 – 2:50	Examination of End Points in the Adjuvant Casodex EPC Trials Experience	<u>Kevin Carroll</u>
2:50 – 3:00	Clarification Questions to Presenter	
3:00 – 3:10	Break	
3:10 – 3:30	Examination of End Points in Advanced Disease (D2) – Casodex Experience	<u>Laurence Collette</u>
3:30 – 3:40	Clarification Questions to Presenter	
3:40 – 3:50	Examination of End Points in the Primary Hormonal Treatment of Advanced Disease (D2) – SWOG Experience	<u>Cathy Tangen</u>
3:50 – 4:00	Clarification Questions to Presenter	
4:00 – 5:15	Formal Questions for Discussion	Discussion Leaders: <u>Mario Eisenberger,</u> <u>Barry Kramer,</u> & <u>Howard Sandler</u>
5:15 – 5:45	Audience Questions	

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Tuesday, June 22, 2004, AM

**Hormone Refractory Disease
(M0 with PSA Rising Post Hormone Therapy and M1)**

8:00 – 8:30	Introductory Comments and Overview of Regulatory End Point History of Approved Therapies	<u>Bhupinder Mann</u>
8:30 – 8:50	End Points and Trial Design for Evaluating Second-Line Chemotherapy – Post Docetaxel	<u>Mario Eisenberger</u>
8:50 – 9:00	Clarification Questions to Presenter	
9:00 – 9:20	Examination of End Point Applications in the Abbott Atrasentan Trials	<u>Perry Nisen</u>
9:20 – 9:40	Examination of End Points in the Aventis Docetaxel Trial	<u>Martin Roessner</u>
9:40 – 10:00	Examination of End Points in the SWOG Docetaxel Trial	<u>Daniel Petrylak</u>
10:00 – 10:20	Clarification Questions to Abbott, Aventis, & SWOG Presenters	
10:20–10:30	Break	
10:30–12:15	Formal Questions for Discussion	Discussion Leaders: <u>Steven George,</u> <u>Philip Kantoff, &</u> <u>Derek Raghavan</u>
12:15–12:45	Audience Questions	
12:45 – 1:30	Lunch	
1:30 – 3:00	Optional Discussion Period: Wrap-Up Topics of Remaining Interest from Workshop Days 1 and 2	
3:00	Adjourn	