FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

AGENDA

March 13, 2006

8:00 a.m.	Call to Order Introduction of Committee	Silvana Martino, D.O. Chair, ODAC
	Conflict of Interest Statement	Johanna Clifford, M.Sc., RN
8:10 a.m.	Opening Remarks	Richard Pazdur, M.D., Director Division of Oncology Drug Products, FDA

The Committee will discuss pre-clinical requirements and phase 1 trial design issues for the development of oncologic drug products.

8:15 a.m.	Preclinical Safety Data for First in Human (FIH) Clinical Trials in Healthy Volunteer Subjects	David Jacobson-Kram, Ph.D., D.A.B.T. Associate Director for Pharmacology & Toxicology Office of New Drugs, FDA
8:30 a.m.	Nonclinical Perspective on Initiating Phase I Studies for Small Molecular Weight Compounds	John Leighton, Ph.D. Pharmacology/Toxicology Team Leader Division of Oncology Drug Products, FDA
8:50 a.m.	Industry Perspective: Preclinical Development Considerations for Biologics – Oncology Focus	James Green, Ph.D. Vice President, Biogenidec Cambridge, MA
9:20 a.m.	Nonclinical Perspective on Initiating Studies For Biological Oncology Products	Martin D. Green, Ph.D. Supervisory Pharmacologist DBOP, OND, CDER
		&
	Nonclinical Perspective on Initiating Phase 1 Studies for Biological Oncology Products - Case Studies	Ann Pilaro, Ph.D. Expert Toxicologist DBOP, OND, CDER
9:40 a.m.	Non-Clinical Studies for Initiating Phase I studies in Oncology: Small Molecules vs. Biologics	David Ross, M.D., Ph.D. Medical Officer Office of Oncology Drug Products, FDA
10: a.m.	*Break*	
10:15 a.m.	Open Public Hearing	
10:45 a.m.	Questions from the Committee	

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AGENDA Continued

11:00 a.m.	Questions to the Committee & Committee Discussion	
12:00 p.m.	*Lunch*	
1:00 p.m.	Call to Order Introduction of Committee	Silvana Martino, D.O. Chair, ODAC
	Conflict of Interest Statement	Johanna Clifford, M.S., RN Executive Secretary, ODAC
1:10 p.m.	Opening Remarks	Richard Pazdur, M.D., Director Office of Oncology Drug Products, FDA
1:15 p.m.	Sponsor Presentation	Eli Lilly & Co.
	Introduction and Objectives	Richard Gaynor, M.D.
	Management of Ovarian Cancer	Robert Ozols, M.D.
	Clinical Efficacy of Gemzar/Carboplatin	Allen Melemed, M.D.
	Safety Results and Patient Benefit	Richard Gralla, M.D.
	Robustness of Efficacy Results	Daniel Sargent, Ph.D.
	Risk/Benefit Overview	Tate Thigpen, M.D.
2:00 p.m.	FDA Presentation Gemzar Review	Martin Cohen, M.D. Medical Officer, Office of Oncology Drug Products & John R. Johnson, M.D. Medical Officer, Office of Oncolgy Drug Products FDA
2:45 p.m.	The Role of Covariates in Clinical Trials	Ralph D'Agostino, Ph.D. Boston University Boston, MA
3:00 p.m.	*Break*	
3:15 p.m.	*Open Public Hearing*	
3:45 p.m.	Questions to the Committee and Committee Discussion	
5:00 p.m.	Adjourn.	