Food and Drug Administration
Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee
Meeting Agenda
March 12-13, 2003

74th Meeting

Versailles Ballroom
Holiday Inn
Bethesda, MD

March 12, 2003

8:00	Call to Order and Opening Remarks	Donna Przepiorka, M.D., Ph.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest (COI) Statement	Johanna Clifford, M.S.,RN, BSN
8:15	Open Public Hearing	
8:45	Introduction – Accelerated Approval Process	Richard Pazdur, M.D., Director Ramzi Dagher, M.D., Medical Officer Division of Oncology Drug Products Center for Drug Evaluation & Research
9:15	Sponsor Presentation	Steven Hamburger, Ph.D. Johnson & Johnson Pharmaceutical Research & Development, LLC
	NDA 50-718 Doxil (doxorubicin hydrochloride liposome) ***Indication: Treatment of Kaposi's sarcoma in AIDS patients with disease that has progressed on prior combination therapy or in patients who are intolerant to such therapy.***	
9:30	FDA Comments & ODAC Discussion	Bruce Redman, D.O. ODAC Discussant
10:15	*Break*	
	COI Statement & Introduction of New Participants	Johanna Clifford, M.S., RN, BSN
10:30	Sponsor Presentation	Steven Hamburger, Ph.D. Johnson & Johnson Pharmaceutical Research & Development, LLC
	NDA 50-718/S-006 Doxil (doxorubicin hydrochloride liposome) ***Indication: Treatment of metastatic ovarian cancer in patients with disease that is refractory to both paclitaxel and platinum-based chemotherapy regimens.***	
10:45	FDA Comments & ODAC Discussion	Otis Brawley, M.D. ODAC Discussant
11:30	*Lunch*	
12:30	Open Public Hearing	
	COI Statement & Introduction of New Participants	Johanna Clifford, M.S., RN, BSN

1:00	Sponsor Presentation	James L'Italien, M.D. & Gordon Bray, M.D. Ligand Pharmaceuticals, Inc.
	BLA 97-1325/STN 103767 Ontak (denileukin diftitox) ***Indication: Treatment of persistent or recurrent cutaneous T-Cell lymphoma in patients whose maligant cells express the CD25 component of the IL-2 receptor.***	
1:15	FDA Comments & ODAC Discussion	Bruce Cheson, M.D. ODAC Discussant
2:00	*Break*	
	COI Statement & Introduction of New Participants	Johanna Clifford, M.S., RN, BSN
2:15	Sponsor Presentation	James Pluda, M.D. MedImmune Oncology, Inc.
	NDA 20-221/S-002 Ethyol (amifostine) ***Indication: Reduction in cumulative renal toxicity associated with repeated administration of cisplatin in patients with advanced non-small cell lung cancer.***	
2:30	FDA Comments & ODAC Discussion	Douglas Blayney, M.D. ODAC Discussant
3:15	Estimated Time of Adjournment	

March 13, 2003

8:00	Call to Order and Opening Remarks	Donna Przepiorka, M.D., Ph.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Johanna Clifford, M.S., RN, BSN Executive Secretary, ODAC
8:15	Open Public Hearing	
8:45	Sponsor Presentation	Matthew L. Sherman, M.D. Wyeth-Ayerst Laboratories, Inc.
	NDA 21-174 Mylotarg (gemtuzumab ozogamicin) ***Indication: Treatment of CD33 positive acute myeloid leukemia patients in first relapse who are 60 years of age or older and who are not considered candidates for cytotoxic chemotherapy.***	
9:00	FDA Comments & ODAC Discussion	Donna Przepiorka, M.D., Ph.D ODAC Chair
9:45	*Break*	
	COI Statement & Introduction of New Participants	Johanna Clifford, M.S., RN, BSN
10:00	Sponsor Presentation	Stephen Howell, M.D. Skyepharma, Inc.
	NDA 21-041 Depocyt (cytarabine liposomal injection) ***Indication: Intrathecal treatment of lymphomatous meningitis***	
10:15	FDA Comments & ODAC Discussion	Gregory Reaman, M.D. ODAC Discussant
11:00	*Lunch*	

12:00	Open Public Hearing	
	COI Statement & Introduction of New Participants	Johanna Clifford, M.S., RN, BSN
12:30	Sponsor Presentation	Daniel Vlock, M.D. Pharmacia Corporation
	NDA 21-156 Celebrex (celecoxib) ***Indication: Reduction in number of adenomatous colorectal polyps in familial adenomatous polyposis (FAP) patients.***	
12:45	FDA Comments & ODAC Discussion	David Kelsen, M.D. ODAC Discussant
1:30	*Break*	
	COI Statement and Introduction of New Participants	Johanna Clifford, M.S., RN, BSN
1:45	Sponsor Presentation	Craig Tendler, M.D. Schering-Plough Corporation
	NDA 21-029 Temodar (temozolomide) ***Indication: Treatment of refractory anaplastic astrocytoma***	
2:00	FDA Comments & ODAC Discussion	Sarah Taylor, M.D. ODAC Discussant
2:45	Introduction of Questions and Committee Discussion	
4:00	Estimated Time of Adjournment	

Patient Representative (Voting):

Musa Mayer - New York, NY

Consultant (Voting):

Thomas Fleming, Ph.D.
Professor and Chair
Department of Biostatistics
University of Washington
Box 357232
Seattle, WA 98195

Acting Industry Representative (Non-Voting):

George Ohye
3 Heritage Hills Court
Skillman, NJ 08558-2340