FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

AGENDA

March 3, 2005:

The committee will discuss New Drug Application (NDA) 21-115 Combidex® (ferumoxtran-10) Advanced Magnetics, Incorporated, proposed indication for intravenous administration as a Magnetic Resonance Imaging (MRI) contrast agent to assist in the differentiation of metastatic and non-metastatic lymph nodes in patients with confirmed primary cancer who are at risk for lymph node metastases.

8:00 a.m.	Call to Order Introduction of Committee	Silvana Martino, D.O., Acting Chair, ODAC
	Conflict of Interest Statement	Johanna Clifford, M.S., RN, Executive Secretary, ODAC
8:10 a.m.	Opening Remarks	George Mills, M.D., Director Division of Medical Imaging and Radiopharmaceutical Drug Products, FDA
8:15 a.m.	Sponsor Presentation	Advanced Magnetics, Inc.
	Combidex, Introduction and Indication	Mark C. Roessel Vice President Regulatory Affairs Advanced Magnetics, Inc.
	Mechanism of Action, Combidex Appearance on MR Images	Mukesh Harisinghani, M.D. Department of Radiology Massachusetts General Hospital
	Efficacy Data from Phase III Clinical Studies	William Goeckeler, Ph.D. Senior Vice President Development Cytogen Corporation
	Safety Data from Clinical Trial	Gerald Faich, M.D. President Pharmaceutical Safety Associates
	Clinical Utility of Combidex and Various Cancers	Jelle O. Barentsz, M.D. Professor of Radiology University Hospital Nijmegen, Netherlands
9:00 a.m.	FDA Presentation	
	Efficacy & Safety of Combidex (NDA 21-115)	Zili Li, M.D., MPH, Medical Team Leader Division of Medical Imaging and Radiopharmaceutical Drug Products, FDA
9:45 a.m.	*Questions from the Committee*	
10:00	Break	

(Agenda Continued)

10:15 a.m. Open Public Hearing

10:45 a.m. *Committee Discussion*

12:00 p.m. *Lunch*

The committee will discuss prostate cancer endpoints as a follow up to the June 2004 FDA Workshop.

12:45 p.m.	Call to Order	Maha Hussain, M.D., Acting Chair, ODAC
	Conflict of Interest Statement	Johanna Clifford, MS, RN, Exec. Sec., ODAC
12:55 p.m.	Opening Remarks	Richard Pazdur, M.D., Director Division of Oncology Drug Products, FDA
1:05 p.m.	A Regulatory Perspective of End Points to Measure Safety and Efficacy of Drugs: Hormone Refractory Prostate Cancer	Bhupinder Mann, MBBS, Medical Officer Division of Oncology Drug Products, FDA
1:20 p.m.	Towards a Consensus in Measuring Outcomes in New Agents for Prostate Cancer	Derek Raghavan, M.D., Ph.D. Chairman, Department of Hematology and Medical Oncology Cleveland Clinic Taussig Cancer Center
1:50 p.m.	NCI Prostate Cancer Treatment Trial Portfolio	Alison Martin, M.D. Clinical Investigations Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment & Diagnosis, National Cancer Institute, National Institutes of Health
2:00 p.m.	Toward an Endpoint for Accelerated Approval for Clinical Trials in Castration Resistant/Hormone Refractory Prostate Cancer	Howard Scher, M.D., Chief, Genitourinary Onc. Service Sidney Kimmel Center for Prostate and Urologic Cancers Memorial Sloan Kettering Cancer Center
2:30 p.m.	Design of Clinical Trials for Select Patients With a Rising PSA Following Primary Therapy	Anthony D'Amico, M.D., Ph.D. Professor and Chair of Genitourinary Radiation Oncology Brigham & Women's Hospital, Dana Farber Cancer Institute Harvard Medical School

3:00 p.m. *Break*

3:15 p.m. Open Public Hearing

3:45 p.m. Committee Discussion

5:00 p.m. Adjourn

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March 4, 2005

The committee will discuss the results of a confirmatory trial for NDA 21-399, IRESSA® (gefitinib) AstraZeneca Pharmaceuticals LP, for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of both platinum-based and docetaxel chemotherapies.

8:00 a.m.	Call to Order Introduction of Committee	Silvana Martino, D.O., Acting Chair, ODAC
	Conflict of Interest Statement	Johanna Clifford, M.S., RN, Executive Secretary, ODAC
8:10 a.m.	Opening Remarks	Richard Pazdur, M.D., Director Division of Oncology Drug Products, FDA
8:20 a.m.	Sponsor Presentation	Astra Zeneca L.P.
	Introduction & Regulatory History	Mark Scott, Ph.D.
	Trial 709	Kevin Carroll, MSc
	Clinical Actions and Implications	Judith Ochs, M.D.
	Summary	Mark Scott, Ph.D.
9:00 a.m.	Open Public Hearing	
9:15 a.m.	Committee Discussion	
10:15 a.m.	Break	

The committee will discuss safety concerns, specifically osteonecrosis of the jaw (ONJ), associated with two bisphosphonates, NDA 21-223, ZOMETA® (zoledronic acid) Injection and AREDIA®, NDA 20-036 (pamidronate disodium for injection), both from Novartis Pharmaceuticals Corp. Zometa is indicated for the treatment of patients with Multiple Myeloma and patients with documented bone metastases from solid tumors, in conjunction with standard antineoplastic therapy. Prostate cancer should have progressed with at least one hormonal therapy. It is also approved for hypercalcemia of malignancy. AREDIA is indicated, in conjunction with standard antineoplastic therapy, for the treatment of osteolytic bone metastases of breast cancer and osteolytic lesions of multiple myeloma. It is also indicated for the treatment of moderate or severe hypercalcemia associated with malignancy, and treatment of patients with moderate to severe Paget's disease of bone.

10:35 a.m.	Call to Order Introduction of Committee	Silvana Martino, D.O., Acting Chair, ODAC
	Conflict of Interest Statement	Johanna Clifford, M.S., RN, Executive Secretary, ODAC
10:40 a.m.	Opening Remarks	Richard Pazdur, M.D., Director Division of Oncology Drug Products, FDA
	FDA Presentation	
10:45 a.m.	Regulatory History of Zometa & Aredia	Nancy Scher, M.D., Medical Officer Division of Oncology Drug Products, FDA
11: 00 a.m.	Post-Marketing Safety Assessment of Osteonecrosis of the Jaw: Pamidronate and Zoledronic Acid	Carol Pamer, R.Ph. Office of Drug Safety, FDA
11:15 a.m.	Osteonecrosis of the Jaws in Myeloma: Time Dependent Correlation with Zometa & Zometa Use	Brian Durie, M.D. Hematology/Oncology Cedars-Sinai Outpatient Cancer Center
11:30 a.m.	Sponsor Presentation	Novartis Pharmaceuticals
	ONJ Reported in Bisphosphonates Treated Patients – An Overview	Diane Young, M.D. Vice President & Global Head Clinical Development - Oncology
	Clinical Benefit of Bisphosphonates in Cancer Patients with Metastatic Bone Disease	James Berenson, M.D. Director, Multiple Myeloma and Bone Metastases Programs Cedars-Sinai Medical Center
12:00 p.m.	Open Public Hearing	
12:15 p.m.	Committee Discussion	
1:15 p.m.	Adjourn	