

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

Slides Presented

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.

Advanced Magnetics, Inc.

Combixd, Introduction and Indication

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Mark C. Roessel

Vice President Regulatory Affairs
Advanced Magnetics, Inc.

Mechanism of Action, Combixd

Appearance on MR Images

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Mukesh Harisinghani, M.D.

Department of Radiology
Massachusetts General Hospital

Efficacy Data from Phase III Clinical Studies

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William Goeckeler, Ph.D.

Senior Vice President Development
Cytogen Corporation

Safety Data from Clinical Trial

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Gerald Faich, M.D.

President Pharmaceutical Safety Associates

Clinical Utility of Combixd and Various Cancers

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Jelle O. Barentsz, M.D.

Professor of Radiology
University Hospital Nijmegen, Netherlands

FDA Presentation

Efficacy & Safety of Combixd (NDA 21-115)

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Zili Li, M.D., MPH, Medical Team Leader

Division of Medical Imaging and Radiopharmaceutical Drug
Products, FDA

Open Public Hearing Speakers

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10:45 a.m. *Committee Discussion*

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

A Regulatory Perspective of End Points to Measure Safety and Efficacy of Drugs:

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Bhupinder Mann, MBBS, Medical Officer
Division of Oncology Drug Products, FDA
Hormone Refractory Prostate Cancer

Towards a Consensus in Measuring Outcomes in New Agents for Prostate Cancer

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Derek Raghavan, M.D., Ph.D.
Chairman, Department of Hematology and Medical Oncology
Cleveland Clinic Taussig Cancer Center

NCI Prostate Cancer Treatment Trial Portfolio

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Alison Martin, M.D.
Clinical Investigations Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment & Diagnosis, National Cancer Institute, National Institutes of Health

Toward an Endpoint for Accelerated Approval for Clinical Trials in Castration Resistant/Hormone Refractory Prostate Cancer

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Howard Scher, M.D., Chief, Genitourinary Onc. Service
Sidney Kimmel Center for Prostate and Urologic Cancers
Memorial Sloan Kettering Cancer Center

Design of Clinical Trials for Select Patients With a Rising PSA Following Primary Therapy

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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

Open Public Hearing Speakers

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Committee Discussion

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