

**FOOD AND DRUG ADMINISTRATION**  
Center for Drug Evaluation and Research  
Oncologic Drugs Advisory Committee  
**Slides Presented**

*March 4, 2005*

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

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**Astra Zeneca L.P.**

Introduction & Regulatory History  
[\[HTML\]](#) [\[PPT\]](#)

Mark Scott, Ph.D.

Trial 709  
[\[HTML\]](#) [\[PPT\]](#)

Kevin Carroll, MSc

Clinical Actions and Implications  
[\[HTML\]](#) [\[PPT\]](#)

Judith Ochs, M.D.

Summary  
[\[HTML\]](#) [\[PPT\]](#)

Mark Scott, Ph.D.

Supporting Slides  
[\[HTML\]](#) [\[PPT\]](#)

Open Public Hearing *Speakers*  
[\[HTML\]](#) [\[PPT\]](#)

Committee Discussion  
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*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.*

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## **FDA Presentation**

Regulatory History of Zometa & Aredia

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Nancy Scher, M.D., Medical Officer

Division of Oncology Drug Products, FDA

Post-Marketing Safety Assessment of  
Osteonecrosis of the Jaw: Pamidronate and  
Zoledronic Acid

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Carol Pamer, R.Ph.

Office of Drug Safety, FDA

Osteonecrosis of the Jaws in Myeloma:  
Time Dependent Correlation with Zometa &  
Zometa Use

[\[HTML\]](#) [\[PPT\]](#)

Brian Durie, M.D.

Hematology/Oncology

Cedars-Sinai Outpatient Cancer Center

## **Novartis Pharmaceuticals Presentation**

ONJ Reported in Bisphosphonates Treated  
Patients – An Overview

[\[HTML\]](#) [\[PPT\]](#)

Diane Young, M.D.

Vice President & Global Head

Clinical Development - Oncology

Clinical Benefit of Bisphosphonates in Cancer  
Patients with Metastatic Bone Disease

[\[HTML\]](#) [\[PPT\]](#)

James Berenson, M.D.

Director, Multiple Myeloma and Bone Metastases Programs

Cedars-Sinai Medical Center

Supporting Slides

[\[HTML\]](#) [\[PPT\]](#)

Open Public Hearing Speakers

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Felice O’Ryan

Kaiser Permanente

Oakland, California

[\[HTML\]](#) [\[PPT\]](#)

Committee Discussion

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