

ZOMETA[®]
zoledronic acid

Oncologic Drugs Advisory Committee
Bethesda, Maryland
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Introduction

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Oncology Business Unit
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ZOMETA®

Overview

- **ZOMETA belongs to a new class of highly potent bisphosphonates**
- **Treatment of hypercalcemia of malignancy**
 - Approved by FDA in August 2001
 - Approved in over 60 countries
- **Treatment of bone metastases**
 - Filed July 2001 in EU and August 2001 in US and other major countries
 - Dose: Zoledronic acid 4 mg infused over 15 min q 3 to 4 wk
- **Non-oncologic uses under evaluation**
 - Paget's disease, osteoporosis, rheumatoid arthritis

ZOMETA® in Bone Metastases

Proposed Indication

ZOMETA (zoledronic acid) is indicated for the treatment of osteolytic, osteoblastic, and mixed bone metastases of solid tumors and osteolytic lesions of multiple myeloma, in conjunction with standard antineoplastic therapy

ZOMETA® in Bone Metastases

Phase III Trials

Three randomized, international, parallel, double-blind trials

Trial	N	ZOMETA 4 mg and 8 mg versus	Patient population	Duration
010	1,648	Pamidronate	Multiple myeloma Breast cancer	13 mo
039	643	Placebo	Prostate cancer	15 mo
011	773	Placebo	Other solid tumors	9 mo

ZOMETA® in Bone Metastases Clinical Profile (1)

- **ZOMETA is bone specific, not tumor specific;
effective in a broad variety of tumor types
studied**
 - **Breast cancer and multiple myeloma**
 - **Prostate and other solid tumors**
 - **Other bisphosphonates have not
demonstrated efficacy in these tumor
types**

ZOMETA® in Bone Metastases

Clinical Profile (2)

- **First bisphosphonate shown to be effective across a wide variety of solid tumor types in treatment of bone metastases**
- **Safety is comparable with that of i.v. pamidronate**
 - **Overall safety profile is supported by data from over 3,000 patients treated with ZOMETA**

Agenda

Introduction Burkhard Daldrup, PhD

**Pathophysiology of Metastatic Bone Disease
and the Role of Bisphosphonates Prof. Robert Coleman,
MD, FRCP**

**ZOMETA® in Breast Cancer
and Multiple Myeloma James Berenson, MD,
Paul Gallo, PhD**

**ZOMETA® in Prostate Cancer and
Solid Tumors Other Than Prostate Cancer
and Breast Cancer Matthew Smith, MD
Prof. Robert Coleman,
MD, FRCP**

Conclusions David Parkinson, MD

Questions and Answers

Novartis Oncology

Clinical Research and Development . . John Seaman, PharmD

Consultants

Statistics Richard J. Cook, PhD
Thomas R. Fleming, PhD

Clinical Experts

Lung and Other Cancers Pierre P. Major, MD, FRCPC
Radiologic Analysis Joseph F. Simeone, MD, FACR
Renal Advisory Board Raimund R. Hirschberg, MD