

**Food and Drug Administration
Center for Drug Evaluation and Research**

Oncologic Drugs Advisory Committee

70th Meeting

Advisors and Consultants Staff Conference Room

5630 Fishers Lane

Rockville, Maryland

Agenda

January 31, 2002

8:30	Call to Order and Opening Remarks	Stacy Nerenstone, M.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
	Open Public Hearing	
	Ann E. Fonfa – The Annie Appleseed Project (letter)	
	sNDA 21-386, Zometa ® (zoledronic acid for injection), Novartis Pharmaceuticals Corporation	
	- indicated for the treatment of bone metastases in patients with multiple myeloma, breast cancer, prostate cancer and other solid tumors	
9:00	Sponsor Presentation	Novartis Pharmaceuticals Corporation
	Introduction	Burkhard Daldrup, Ph.D.
	Pathophysiology of Metastatic Bone Disease and the Role of Bisphosphonates	Robert Coleman, M.D., FRCP
	ZOMETA® in Breast Cancer and Multiple Myeloma	James Berenson, M.D.
10:00	FDA Presentation	
	ZOMETA® in Breast Cancer and Multiple Myeloma (Study 010)	Grant Williams, M.D. Medical Team Leader Division of Oncology Drug Products
10:20	Questions from the Committee	

10:50

Break

11:05	Sponsor Presentation	Novartis Pharmaceuticals Corporation
	ZOMETA® in Prostate Cancer and Solid Tumors Other Than Prostate Cancer and Breast Cancer	Matthew Smith, M.D. Robert Coleman, M.D., FRCP
	Conclusions	David Parkinson, M.D.
11:50	FDA Presentation	
	ZOMETA® in Prostate Cancer and Solid Tumors Other Than Prostate Cancer and Breast Cancer (Studies 039 and 011)	Amna Ibrahim, M.D. Medical Officer Division of Oncology Drug Products
	Safety Review (Studies 010, 011 and 039)	Nancy Scher, M.D. Medical Officer Division of Oncology Drug Products
12:30	Questions from the Committee	
1:00	Lunch	
1:45	Open Public Hearing	
2:15	Introduction to the Issues	Grant Williams, M.D.
	Committee Discussion and Vote	
4:00	Adjourn	