

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

AGENDA

December 5, 2007

8:00 a.m.	Call to Order Introduction of Committee	Maha Hussain, M.D. Chair, ODAC
	Conflict of Interest Statement	Nicole Vesely, Pharm.D. Designated Federal Official, ODAC

The committee will discuss supplemental biologics license application (sBLA)125085/91, AVASTIN® (bevacizumab), Genentech, Inc., proposed indication, in combination with paclitaxel for the treatment of patients who have not received chemotherapy for their locally recurrent or metastatic, HER2 negative breast cancer.

8:10 a.m.	Opening Remarks	Richard Pazdur, M.D. Director, Office of Oncology Drug Products (OODP), Office of New Drugs (OND), CDER, FDA
8:25 a.m.	Metastatic Breast Cancer Treatments	Patricia Cortazar, M.D. Medical Officer, Division of Drug Oncology Products (DDOP), OODP, OND, CDER, FDA
8:45 a.m.	<u>Sponsor Presentation</u> Overview	<u>Genentech, Inc</u> David Schenkein, M.D. Sr. Vice President Clinical Hematology & Oncology Genentech, Inc.
	ECOG E2100- Study Design and Efficacy	Kathy Miller, M.D. Associate Professor of Medical Oncology Indiana University School of Medicine
	ECOG E2100- Safety	Barbara Klencke, M.D. Associate Group Medical Director Genentech, Inc.
	Metastatic Breast Cancer and Avastin: Placing ECOG Study 2100 In Context	Eric Winer, M.D. Associate Professor Department of Medicine Harvard Medical School
	Concluding Remarks	Christopher Bowden, M.D. Senior Group Medical Director Genentech, Inc.
9:45 a.m.	<i>Break</i>	

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- 10:00 a.m. **FDA Presentation**
Bevacizumab (Avastin®) plus
Paclitaxel for 1st line Metastatic
Breast Cancer
- sBLA 125085/91**
Lee Pai-Scherf, M.D.
Medical Officer, Division of Biologic Oncology
Products (DBOP), OODP, OND, CDER, FDA
and
Laura Lu, Ph.D.
Statistical Reviewer – Biologic Oncology, Division of
Biostatistics 5, Office of Biostatistics, CDER, FDA
- 11:00 a.m. Open Public Hearing
- 12:00 p.m. *Lunch*
- 1:00 p.m. *Questions from the Committee*
- 2:00 p.m. *Questions to the ODAC and ODAC Discussion*
- 3:00 p.m. *Adjourn*