FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

AGENDA

September 6, 2006

8:00 a.m.	Call to Order Introduction of Committee	**Maha Hussain, M.D.** Acting Chair, ODAC
	Conflict of Interest Statement	**Johanna Clifford, M.Sc., RN** Executive Secretary, ODAC
8:15 a.m.	Opening Remarks	**Richard Pazdur, M.D., Director** Office of Oncology Drug Products (OODP), CDER, FDA

The committee will discuss the following new drug application (NDA) 21-874 proposed trade name Genasense® (oblimersen sodium) Injection, Genta Incorporated, proposed indication for the treatment of patients with chronic lymphocytic leukemia in combination with fludarabine and cyclophosphamide.

	Sponsor Presentation	**Genta Incorporated**
8:25 a.m.	Introduction	Loretta M. Itri, M.D. President, Pharmaceutical Development and Chief Medical Officer
	Relapsed Refractory CLL	Michael Keating, M.D. Professor of Medicine M.D. Anderson Cancer Center
	Clinical Efficacy/Safety	Loretta M. Itri, M.D.
	Risk/Benefit	Susan O'Brien, M.D. Professor of Medicine, Leukemia MD Anderson Cancer Center
	Conclusions	Loretta M. Itri, M.D.
9:10 a.m.	**FDA Presentation** Genasense for the treatment of relapsed/refractory CLL in combination with fludarabine and cyclophosphamide	**NDA 21-874** Robert Kane, M.D., Medical Officer Division of Drug Oncology Products OODP, CDER, FDA
9:45 a.m.	*Questions from the Committee*	
10:15 p.m.	Break	
10:30 p.m.	Open Public Hearing	
11:00 a.m.	*Questions to the ODAC and ODAC Discussion*	
12:00 p.m.	*Lunch*	

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AGENDA CONTINUED

1:00 p.m.	Call to Order Introduction of Committee	**Maha Hussain, M.D.** Acting Chair, ODAC
	Conflict of Interest Statement	**Johanna Clifford, M.Sc., RN** Executive Secretary, ODAC
1:15 p.m.	Opening Remarks	**Richard Pazdur, M.D., Director** Office of Oncology Drug Products, OODP, FDA

The committee will discuss the following new drug application (NDA) 20-287, FRAGMIN® (dalteparin sodium), Pfizer, Incorporated, proposed indication for the extended treatment of symptomatic venous thromboembolism (VTE), proximal deep vein thrombosis (DVT), and/or pulmonary embolism (PE) to reduce the recurrence of VTE in patients with cancer.

	Sponsor Presentation	**Pfizer, Incorporated**
1:25 p.m.	Introduction	Connie Newman, M.D., Therapeutic Area Head CVMED Worldwide Regulatory Affairs and Quality Assurance
	Background on VTE and Cancer	Craig Eagle, M.D., Senior Director Head of Worldwide Medical Oncology
	CLOT Study Design & ITT Results	Agnes Y. Y. Lee, M.D., M.Sc., FRCPC Associate Professor, Medicine, McMaster University Hamilton Health Sciences Henderson Hospital Hamilton, ON
	CLOT Study Further Analyses	Craig Eagle, M.D.
	Summary/Conclusions	Craig Eagle, M.D.
2:10 p.m.	**FDA Presentation** FDA Review of Clinical Data: Fragmin for treatment of VTE in cancer patients	**NDA 21-986** Andrew Dmytrijuk, M.D., Medical Officer Division of Medical Imaging and Hematology Products, OODP, CDER, FDA
2:45 p.m.	*Questions from the Committee*	
3:15 p.m.	Break	
3:30 p.m.	Open Public Hearing	
4:00 a.m.	*Questions to the ODAC and ODAC Discussion*	
5:00 p.m.	*Adjourn*	

FOOD AND DRUG ADMINISTRATION

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AGENDA

September 7, 2006

8:00 a.m.	Call to Order Introduction of Committee	**Maha Hussain, M.D.** Acting Chair, ODAC
	Conflict of Interest Statement	**Johanna Clifford, M.Sc., RN** Executive Secretary, ODAC
8:15 a.m.	Opening Remarks	**Richard Pazdur, M.D., Director** Office of Oncology Drug Products (OODP), FDA

The committee will discuss NDA 21-660, ABRAXANE® (paclitaxel protein-bound particles for injectible suspension) (albumin-bound), Abraxis Bioscience, Inc., including trial design issues for adjuvant treatment of node-positive breast cancer.

	Sponsor Presentation	**Abraxis Bioscience, Inc.**
8:25 a.m.	Abraxane®: Background & PK/Safety Comparisons with Taxol®	Michael J. Hawkins, M.D. Chief Medical Officer
	Results of the Phase 3 Clinical Trials of Abraxane® vs. Taxol® in Metastatic Breast Cancer	William J. Gradishar, M.D., FACP Professor of Medicine Northwestern University
	Perspectives on the use of Abraxane® In Node-positive Breast Cancer	Clifford A. Hudis, M.D. Chief, Breast Cancer Medicine Service Memorial Sloan Cancer Center
9:10 a.m.	**FDA Presentation**	**NDA 21-660**
	Proposal for Abraxane Approval in Adjuvant Breast Cancer	Patricia Cortazar, M.D., Medical Officer Division of Drug Oncology Products, OODP, CDER, FDA
	A Pharmacokinetic Comparison of Abraxane and Taxol	Brian Booth, Ph.D., Clinical Pharmacology Acting Team Leader for Oncology Drugs, Division of Clinical Pharmacology 5, Office of Clinical Pharmacology, CDER, FDA
	Trial Design Considerations	Rajeshwari Sridhara, Ph.D., Statistical Team Leader for Oncology Drugs, Division of Biometrics V, Office of Biostatistics, CDER, FDA
9:45 a.m.	*Questions from the Committee*	
10:15 a.m.	Break	
10:30 a.m.	Open Public Hearing	
11:00 a.m.	*Questions to the ODAC and ODAC Discussion*	
12:00 p.m.	Adjourn	