Food and Drug Administration
Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

66th Meeting

Holiday Inn
Bethesda, Maryland

Proposed Agenda

December 13-14, 2000

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	

NDA 20-726/S-006, Femara® (letrozole) Tablets, Novartis Pharmaceuticals Corporation

- indicated as first-line therapy in postmenopausal women with advanced breast cancer

	Introduction	John Johnson, M.D. Medical Team Leader, FDA
8:45	**Sponsor Presentation**	
9:45	Questions from the Committee	
10:15	Break	
10:30	**FDA Presentation**	Martin Cohen, M.D. FDA Reviewer
11:15	Questions from the Committee	Richard Pazdur, M.D. Director Division of Oncology Drug Products
11:45	Committee Discussion and Vote	
12:30	Lunch	

December 13, 2000 – Afternoon Session

1:30	Open Public Hearing	
	NDA 21-240, histamine hydrochloride injection (1 mg/ml), Maxim Pharmaceuticals, Inc.	
	- indicated for adjunctive use with interleukin-2 (aldesleukin) in the treatment of adult patients with advanced metastatic melanoma that has metastasized to the liver	
	Introduction	Donna Griebel, M.D. Team Leader
2:00	**Sponsor Presentation**	**Maxim Pharmaceuticals, Inc.**
	Overview of Metastatic Melanoma	Michael Atkins, M.D. Harvard University Beth Deaconess Medical Center
	Efficacy and Safety of Histamine Dihydrochloride for Injection as an Adjunct to Interleukin-2 in Patients with Metastatic Melanoma	Kurt R. Gehlson, Ph.D. Senior Vice President Chief Technical Officer
3:00	Questions from the Committee	
3:30	Break	
3:45	**FDA Presentation**	Judy Chiao, M.D. FDA Reviewer
4:15	Questions from the Committee	Richard Pazdur, M.D. Director, DODP
4:45	Committee Discussion and Vote	
5:15	Adjourn	

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BLA 99-0786, Campath®, (alemtuzumab), Millenium and ILEX Partners, LP

- indicated for the treatment of patients with chronic lymphocytic leukemia who have been treated with alkylating agents and who have failed fludarabine therapy

8:30	**Sponsor Presentation**	**Millenium and ILEX Partners, LP**
	Overview of CLL: Need for New Therapeutic Options	Michael J. Keating, M.B., B.S. M.D. Anderson Cancer Center
	Presentation of Clinical Data	Lee R. Brettman, M.D. F.A.C.P. Senior Vice President, Medical Affairs Millenium Pharmaceuticals
9:30	Questions from the Committee	
10:00	Break	
10:15	**FDA Presentation**	Genevieve Schechter, M.D. FDA Reviewer
11:00	Questions from the Committee	
11:30	Committee Discussion and Vote	
12:15	Lunch	

December 14, 2000 – Afternoon Session

1:00	Open Public Hearing	
	Single Patient Exemptions to the Use of Non-approved Oncology Drugs and Biologics	
1:40	Introduction	Grant Williams. M.D. Medical Team Leader, DODP, CDER
2:00	Perspective from Ethicists	Jeremy Sugarman, M.D., M.P.H., M.A. Duke University Medical Center Ruth Linden, Ph.D. Stanford University
2:30	Perspective from Industry	Robert Spiegel, M.D. Schering-Plough Research Institute Gerard T. Kennealey, M.D. Astra-Zeneca Pharmaceuticals
3:00	Break	
3:15	Perspective from Patient Advocates	Carl F. Dixon Kidney Cancer Associaton Robert Erwin Marti Nelson Cancer Research Foundation Jan Platner National Breast Cancer Coalition
3:45	Introduction of the Questions	Richard Pazdur, M.D. Director, DODP, CDER
4:00	Committee Discussion	
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