Food and Drug Administration
Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

73rd Meeting

Holiday Inn
8170 Wisconsin Avenue
Bethesda, Maryland

Agenda — December 17-18, 2002

12:30	Call to Order and Opening Remarks	Donna Przepiorka, M.D., Ph.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
12:45	Open Public Hearing	

BL STN 125011/0, Bexxar®, Tositumomab (Anti-B1) and Iodine^{131}-Tositumomab, Corixa Corporation

- indicated for the treatment of patients with relapsed or refractory low-grade, follicular or transformed low-grade, B-cell non-Hodgkin's lymphoma (NHL) including patients with rituximab refractory follicular non-Hodgkin's lymphoma

1:15	Introduction to Tositumomab Therapeutic Regimen	Terrye G. Zaremba, Ph.D. BLA Committee Chairperson CBER, FDA
1:30	**Sponsor Presentation**	**Corixa Corporation**
	Disease Outcome and Therapy for Low-Grade and Transformed NHL	Richard Fisher, M.D. University of Rochester
	Efficacy and Safety Overview: Basis for Approval	Cindy Jacobs, Ph.D., M.D. Senior Vice-President, Clinical Research
	Risk/Benefit Assessment	James Armitage, M.D. University of Nebraska
2:30	Break	
2:45	**FDA Presentation**	Center for Biologics Evaluation and Research
		Stephen Litwin, M.D. Medical Reviewer, FDA
3:45	Questions from the Committee	
4:15	Open Public Hearing	
4:30	Committee Discussion and Vote	
	ODAC Discussants	James Bridges, M.D. CBER Consultant
		James Krook, M.D. CDER Consultant
5:30	Estimated Time of Adjournment	

December 18, 2002

8:00	Call to Order and Opening Remarks	Donna Przepiorka, M.D., Ph.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
8:15	Open Public Hearing	

NDA 20-498, S012, CASODEX® (150 mg bicalutamide), AstraZeneca Pharmaceuticals LP

- indicated as (1) adjuvant therapy to radical prostatectomy and radiotherapy of curative intent in patients with locally advanced non-metastatic prostate cancer who have a high risk for disease recurrence or (2) immediate treatment of localized non-metastatic prostate cancer in patients for whom therapy of curative intent is not indicated

8:45	**Sponsor Presentation**	**AstraZeneca Pharmaceuticals LP**
	Introduction and Regulatory History	Gerard T. Kennealey, M.D.
	Need for CASODEX® in Early Prostate Cancer	Howard I. Scher, M.D. Memorial Sloan-Kettering Cancer Center
	EPC Trial Program: Efficacy and Safety	William A. See, M.D. Medical College of Wisconsin
	Relevance to Clinical Practice	Mark S. Soloway, M.D. University of Miami School of Medicine
	Summary and Conclusions	Gerard T. Kennealey, M.D.
9:45	Break	
10:00	**FDA Presentation**	
	Background and Review Issues	Daniel Shames, M.D. Director, Division of Reproductive and Urologic Drug Products, FDA
	Medical Review Findings	Scott Monroe, M.D. Medical Reviewer, FDA
	Summary and Introduction of Questions	Daniel Shames, M.D.
11:00	Questions from the Committee	
11:45	Open Public Hearing	
12:00	Lunch	
1:00	Committee Discussion and Vote	
3:00	Estimated Time of Adjournment	