Food and Drug Administration
Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

64th Meeting

Holiday Inn
Bethesda, Maryland

Agenda — December 13-14, 1999

9:00	Call to Order and Opening Remarks	Richard Schilsky, M.D. Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC
	Open Public Hearing	

Barry Kupsch – Barrhead, A.B., Canada
Gaetana Grobluski – Nesconset, New York
Nancy W. Borcherding – Southgate, Kentucky
John H. Carter – Albany, New York
Judy Jones – Mycosis Fungoides Foundation
Carroll D. Cruse – Grayson, Louisiana (letter)
Margaret Russotto – Cranford, New Jersey (letter)
Tim McVoy – Clearwater, Florida (letter)

NDA 21-055, Targretin® (bexarotene) Capsules, 75 mg., Ligand Pharmaceuticals Inc.

- indicated for the treatment of cutaneous manifestations in patients with all clinical stages of CTCL (IA-IVB) in the following categories: patients with early stage CTCL who have not tolerated other therapies, patients with refractory or persistent early stage CTCL, and patients with refractory advanced stage CTCL

9:15	**Sponsor Presentation**	Ligand Pharmaceuticals, Inc.
	Introductions and Background	Howard T. Holden, Ph.D.
	Overview of CTCL	Francine M. Foss, M.D. New England Medical Center
	Targretin Capsules Efficacy Results	Richard C. Yocum, M.D.
	Targretin Capsules Safety Findings	Steven D. Reich, M.D.
	A Clinical Investigator's Perspective	Kenneth B. Hymes, M.D. New York University
		Madeline Duvic, M.D. M.D. Anderson Cancer Center
	Summary and Questions	Howard T. Holden, Ph.D.

10:15	Questions from the Committee	
10:45	Break	
11:00	**FDA Presentation**	Oluwole Odujinrin, M.D. FDA Reviewer
11:30	Questions from the Committee	
12:00	Committee Discussion and Vote	
	ODAC Discussants	Kim A. Margolin, M.D. ODAC Member
		Douglas Blayney, M.D. ODAC Member
12:30	Lunch	

December 13, 1999 – Afternoon Session

1:30 Open Public Hearing

Gaetano Giorno – Alliance for Lung Cancer Advocacy, Support and Education (ALCASE)
Scott Rivers - ALCASE
Randolph W. Urmston – Seattle, Washington (letter)
Charles Ammerman – Rockdale, Texas (letter)
David Tyre – Maysville, North Carolina (letter)

NDA 20-449/S-011 - Taxotere® (docetaxel) for Injection Concentrate,
Rhone-Poulenc Rorer Pharmaceuticals Inc.

- indicated for the treatment of patients with locally advanced or metastatic Non-small Cell Lung Cancer after failure of prior chemotherapy

1:45	**Sponsor Presentation**	Rhone-Poulenc Rorer Pharmaceuticals Inc.
	Introduction	Philip Chaikin, Pharm.D., M.D.
	Overview of NSCLC treatment and Phase 2 Data	Mark Green, M.D. Hollings Cancer Center Medical University of South Carolina
	Pivotal Study TAX317	Frances Shepherd, M.D. Princess Margaret Hospital Toronto, Ontario
	Pivotal Study TAX320	Frances Fossella, M.D. University of Texas M.D. Anderson Cancer Center
	Quality of Life	Richard Gralla, M.D. Alton Ochner Cancer Institute New Orleans, Louisiana

	Benefit/Risk	Mark Green, M.D.
	Safety Profile/Conclusion	Philip Chaikin, Pharm. D., M.D.
2:45	Questions from the Committee	
3:15	Break	
3:30	**FDA Presentation**	Donna Griebel, M.D. FDA Reviewer
4:00	Questions from the Committee	
4:30	Committee Discussion and Vote	
	ODAC Discussants	Richard Schilsky, M.D. ODAC Member
		Derek Raghavan, M.D., Ph.D. ODAC Member
5:00	Adjourn	

December 14, 1999

8:00	Call to Order and Opening Remarks	Derek Raghavan, M.D. Acting Chair, ODAC
	Introduction of Committee	
	Conflict of Interest Statement	Karen M. Templeton-Somers, Ph.D. Executive Secretary, ODAC

Design and Analysis of Active Control Clinical Trials

	Interpretation and Analysis of Active Control Equivalence or Non-inferiority Trials	Robert Temple, M.D. Director, Office of Drug Evaluation I
	Bayesian Design and Analysis of Active Control Clinical Trials	Richard M. Simon, D.Sc ODAC Member
10:00	Break	
10:15	Open Public Hearing	

Abby Meyer – National Organization for Rare Disorders
Jean Marie Baxter – Deer Park, New York
Beth Schreiber – Boynton Beach, Florida
Pat Weidner – Youngstown, Ohio
Leon Wang, Ph.D. – Suffern, New York (letter)
Ronald Fuller – Dallas, Texas (letter)

NDA 21-156, Celebrex ™ (celecoxib), G. D. Searle & Co.

- indicated for the reduction and regression of adenomatous colorectal polyps in Familial Adenomatous Polyposis patients

10:30	**Sponsor Presentation**	G. D. Searle & Co.
	Introduction	Richard Spivey, Pharm.D., Ph.D. Vice-President, Worldwide Regulatory Affairs
	Background	Philip Needleman, Ph.D. Co-President Chief Scientist, Monsanto
		Gary Kelloff, M.D. Chief of Chemopreventive Agent Development, Research Group/NCI – Division of Cancer Prevention
	Pre-Clinical	Jaime L. Masferrer, Ph.D. COX-2 Cancer Project Leader Group Leader Discovery Pharmacology
	Clinical: Familial Adenomatous Polyposis	Bernard Levin, M.D. Vice President for Cancer Prevention M.D. Anderson Cancer Center
	FAP Study: Rationale, Design/Logistics, Efficacy Data	Ernest T. Hawk, M.D., M.P.H. Chief, Gastrointestinal & other Cancer Research Group
		Division of Cancer Prevention, NCI
	FAP Study: Safety Data FAP Follow-up Trial	Gary B. Gordon, M.D., Ph.D. Director, Cancer Prevention/Treatment Clinical Research
	Conclusion/Moderator	Richard N. Spivey, Pharm. D., Ph.D.
		Philip Needleman, Ph.D.
11:30	Questions from the Committee	
12:00	Lunch	
1:00	**FDA Presentation**	Judy Chiao, MD FDA Reviewer
1:30	Questions from the Committee	
2:00	Open Public Hearing	
	Carolyn Aldige – Cancer Research Foundation of America	
2:15	Committee Discussion and Vote	
	ODAC Discussants	Christina Surawicz, M.D. Member, Gastrointestinal Drugs Advisory Committee
		David Kelsen, M.D. ODAC Member

3:15 Adjourn