FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee

AGENDA

September 13, 2005

8:00 a.m.	Call to Order Introduction of Committee	Silvana Martino Chair, ODAC
	Conflict of Interest Statement	

The committee will discuss New Drug Application (NDA) 21-491, proposed trade name Xinlay™(astrasentan hydrochloride) capsules, Abbott Laboratories, proposed indication for the treatment of men with metastatic hormone-refractory prostate cancer.

8:10 a.m.	Opening Remarks	Richard Pazdur, M.D., Director Division of Oncology Drug Products, FDA
8:15 a.m.	<u>Sponsor Presentation</u>	<u>Abbott Laboratories</u>
	Introduction	Gary Gordon, M.D. Oncology Vice President
	Unmet Need & Mechanistic Rationale	Joel B. Nelson, M.D., Chairman of Urology University of Pittsburgh
	Efficacy	Darryl J. Sleep, M.D., FCS Oncology Global Project Head
	Safety	Gary Gordon, M.D.
	Places in Therapy	Howard Scher, M.D. Chief of Genitourinary Oncology Memorial Sloan-Kettering Cancer Center
9:00 a.m.	<u>FDA Presentation</u>	
	Xinlay (atrasentan) FDA Review	Amna Ibrahim, M.D. Medical Officer, Division of Drug Oncology Products, FDA and Shenghui Tang Ph.D. Statistical Reviewer, Division of Drug Oncology Products, FDA Ralph B. D'Agostino, Ph.D.
9:45 a.m.	*Questions from the Committee*	
10:00	Break	
10:15 a.m.	Open Public Hearing	

September 13, 2005 Agenda, Continued

10:45 a.m. *Committee Discussion*

12:00 p.m. *Lunch*

The committee will discuss NDA 21-743, S003, Tarceva ™(erlotinib) Tablets, OSI Pharmaceuticals, Inc, proposed indication for the first line treatment, in combination with gemcitabine, of patients with locally advanced, unresectable or metastatic pancreatic cancer.

12:45 Sponsor Presentation

Tarceva (erlotinib) Tablets Pancreatic Cancer	Pablo J. Cagnoni, MD Vice President Medical Affairs & Translational Research OSI Pharmaceuticals, Inc.
Background of Pancreatic Cancer & NCIC PA.3 Study Design	Malcolm Moore, MD Professor of Medicine and Pharmacology Princess Margaret Hospital University of Toronto Chair, NCIC Clinical Trials Group—GI Committee
Clinical Efficacy Data Review of Study NCIC PA.3	Gary M. Clark, PhD Vice President Biostatistics and Data Management OSI Pharmaceuticals, Inc.
Clinical Safety Data Review of Study NCIC PA.3	Karsten Witt, MD Vice President Drug Safety and Medical Writing OSI Pharmaceuticals, Inc.
Tarceva® (erlotinib) Tablets Concluding Remarks and Risk/Benefit Summary	Mace Rothenberg, MD Associate Professor of Medical Oncology Vanderbilt University

1:30 p.m. FDA Presentation

Tarceva (erlotinib) FDA review	Adrian Senderowicz, M.D. Medical Officer, Division of Drug Oncology Products, FDA

2:15 p.m. Open Public Hearing

3:15 p.m. Break

5:00 p.m. Adjourn

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8:00 a.m.	Call to Order Introduction of Committee	Silvana Martino Chair, ODAC
	Conflict of Interest Statement	Johanna Clifford, M.S., RN Executive Secretary, ODAC

The committee will discuss New Drug Application (NDA) 21-880, proposed trade name Revlimid ® (lenalidomide), Celgene Corporation, proposed indication for the treatment of patients with transfusion-dependent anemia due to low-or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cyogenetic abnormalities.

8:10 a.m.	Opening Remarks	Richard Pazdur, M.D., Director Division of Oncology Drug Products, FDA
8:15 a.m.	<u>Sponsor Presentation</u> Introduction	<u>Celgene Corporation</u> Graham Burton, M.D. Senior Vice President, Regulatory Affairs, Drug Safety and Project Management
	Lenalidomide Nonclinical Overview	David Stirling, Ph.D. Chief Scientific Officer
	MDS Classification and Prognosis	John M. Bennett, M.D., Hematomorphologist University of Rochester Medical Center Chair, MDS Foundation
	Lenalidomide Efficacy	Alan List, M.D. Professor of Medicine and Oncology Chief, Division of Malignant Hematolgy H. Lee Moffitt Cancer Center & Research Institute University of South Florida College of Medicine
	Lenalidomide Safety Assessment	Robert Knight, M.D. Vice President, Clinical Research – Oncology
	Conclusions	Graham Burton, M.D.
9:00 a.m.	<u>FDA Presentation</u>	
	Revlimid (lenalidomide) FDA review	Maitreyee Hazarika, M.D. Medical Officer, Division of Drug Oncology Products, FDA & Kimberly Benson, Ph,D. Pharmacology/Toxicology Reviewer Division of Drug Oncology Products, FDA & Edvardas Kaminskas, M.D. Medical Officer, Division of Drug Oncology Products, FDA

September 14, 2005, Continued

9:45 a.m. *Questions from the Committee*

10:00 Break

10:15 a.m. Open Public Hearing

10:45 a.m. *Committee Discussion*

12:00 p.m. *Lunch*

The committee will discuss NDA 21-877, proposed trade name Arranon ® (nelarabine) Injection, GlaxoSmithKline, proposed indication for the treatment of patients with T-cell acute lymphoblastic leukemia (T-ALL) and T-cell lymphoblastic lymphoma (T-LBL) whose disease has not responded to or has relapsed with at least two chemotherapy regimens.

12:45	<u>Sponsor Presentation</u>	<u>GlaxoSmithKline</u>
	Disease Overview	Stephen Sallan, M.D. Professor of Pediatrics, Harvard Chief of Staff, Dana-Farber
	Efficacy Summary	Richard Larson, M.D. Professor of Medicine, University of Chicago Chair, Leukemia Committee, CALGB
	Role in Treatment	William Carroll, M.D. Director, Pediatric Oncology, NYU Chair, ALL Committee, COG
1:30 p.m.	<u>FDA Presentation</u> Arranon (nelarabine) FDA review	Martin Cohen, M.D. Medical Officer, Division of Drug Oncology Products, FDA

2:15 p.m. Open Public Hearing

3:15 p.m. Break

5:00 p.m. Adjourn