Food and Drug Administration Center for Drug Evaluation and Research Oncologic Drugs Advisory Committee Meeting

March 13, 2006

Meeting Participants

Consultants (voting), September 13, 2006

Session 1: Preclinical Study Design for Oncology Drug Products

Susan Bates, M.D.
Head, Molcular Therapeutics Section
National Institutes of Health
Medical Oncology Branch
Building 10, Room 12N226
10 Center Drive
Bethesda, MD 20892

Ralph D'Agostino, Ph.D.
Professor of Mathematics/Statistics
Boston University
Mathematics Department
111 Cummington Street
Boston, MA 02215

Tito Fojo, M.D., Ph.D.
Head, Experimental Therapeutics Section
National Institutes of Health
Medical Oncology Branch
Building 10, Room 12C103
10 Center Drive
Bethesda, MD 20892

Patient Representative (voting)

Martha Solanche, New York

Guest Speakers (non-voting)

James Green, Ph.D.
Senior Vice President of Preclinical & Clinical Development Sciences
Biogen Idec, Inc.
4 Kato Summit
Sudbury, MA 01776

Eric Kodish, MD F. J. O'Neill Professor and Chair Department of Bioethics - JJ60 Cleveland Clinic 9500 Euclid Avenue Cleveland, OH 44195-0001

Chris H. Takimoto, MD, PhD, FACP Director of Pharmacology Zachry Chair of Translational Research Institute for Drug Development Cancer Therapy and Research Center Alice P. McDermott Building 14960 Omicron Drive San Antonio, TX 78245-3217

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Meeting Participants Continued

Afternoon Session: Gemzar (gemcitabine hydrochloride), Eli Lilly & Co.

Ralph D'Agostino, Ph.D. Professor of Mathematics/Statistics Boston University Mathematics Department 111 Cummington Street Boston, MA 02215

Harry Long, M.D. Associate Professor of Oncology Mayo Clinic College of Medicine Division of Medical Oncology 200 1st Street SW Rochester, MN 55905-0001

Stacy Nerenstone, M.D. Senior Physician & Associate Clinical Professor Department of Medicine University of Connecticut Hartford, CT 06106-2527

Patient Representative (voting):

Martha Solonche, New York