Oncologic Drugs Advisory Committee Meeting September 6, 2006

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Committee Members in Attendance

Acting Chair

Maha H. A. Hussain, M.D., FACP

Professor of Medicine and Urology Department of Internal Medicine and Urology Division of Hematology/Oncology University of Michigan 7314 CGCG, 1500 E. Medical Center Drive Ann Arbor, MI 48109-0946

Ronald M. Bukowski, M.D.

Director
Experimental Therapeutics Program
The Cleveland Clinic Foundation
One Clinic Center

9500 Euclid Avenue Cleveland, OH 44195

**Antonio J. Grillo-Lopez, M.D.

Retired P.O. Box 3797 Rancho Sante Fe, CA 92067-3797

David Harrington, Ph.D.

Expertise: Statistics
Term: 03/08/06 – 06/30/09
Department of Biostatistics and
Computational Biology
Dana-Farber Cancer Institute
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*Pamela J. Haylock, RN

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Alexandra M. Levine, M.D.

Medical Director USC/ Norris Cancer Hospital Division of Hematology 1441 Eastlake Avenue Los Angeles, CA 90033

Michael C. Perry, M.D.

Director
Division of Hematology/Medical Oncology
University of Missouri
Ellis Fischel Cancer Center
115 Business Loop 70 West
Columbia, MO 65203

Maria Rodriguez, M.D.

Chairman, Ad-Interim M.D. Anderson Cancer Center Department of Lymphoma/Myeloma 1515 Holcombe, Box 429 Houston, TX 77030

* Consumer Representative

** Industry Representative (non-voting)

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Consultants (voting):

Stephen George, Ph.D.

Professor of Biostatistics Director, Biostatistics and Information Systems Duke University Medical Center 2424 Erwin Road, Room 8037 Durham, NC 27705

William Hiatt, M.D.

Member, Cardio-Renal Advisory Committee Professor of Medicine Division of Geriatrics, Section of Vascular Medicine University of Colorado Health Sciences Center 4200 East Ninth Avenue P.O. Box B-179 Denver, CO 80262

Patient Representative (voting):

Karl Schwartz, Staten Island, NY

Michael Link, M.D.

The Lydia J. Lee Professor of Medicine Chief, Division of Hematology/Oncology Stanford University School of Medicine Mail Code 5798 1000 Welch Road, Suite 300 Palo Alto, CA 94304

Gary Lyman, M.D.

Professor of Medicine and Oncology University of Rochester School of Medicine and Dentisty Director, Health Services & Outcomes Research James P. Wilmot Cancer Center University of Rochester Medical Center 601 Elmwood Avenue, Box 704 Rochester, NY 14642

FDA Center for Drug Evaluation and Research Participants (non-voting):

Richard Pazdur, M.D., Director, Office of Oncology Drug Products, CDER, FDA

Rafel Rieves, M.D., Deputy Director, Division of Medical Imaging and Hematology Products, OODP, CDER, FDA

Andrew Dmytrijuk, M.D., Medical Officer, Division of Medical Imaging and Hematology Products, OODP, CDER, FDA

Jyoti Zalkikar, Ph.D., Statistical Team Leader, Division of Biometrics V, Office of Biostatistics, CDER, FDA