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

March 3, 2005

Meeting Participants

Consultants (voting), March 3, 2005

For Combidex:

Marco Amendola, M.D. Professor of Radiology University of Miami, School of Medicine P.O. Box 016960 Miami, FL 33101

William Bradley, M.D., Ph.D. Professor & Chairman University of California, San Diego Department of Radiology 200 West Arbor Drive San Diego, CA 92103-8224

Marion Couch, M.D., Ph.D. Assistant Professor University of North Carolina School of Medicine Dept of Otolaryngology 101 Manning Drive Neurosciences Building – G0412 Chapel Hill, NC 27599

Ralph D'Agostino, Ph.D. Professor of Mathematics/Statistics Boston University Mathematics Department 111 Cummington Street Boston, MA 02215 Mark Dykewicz, M.D. Associate Professor of Internal Medicine St. Louis School of Medicine 1402 South Grand Blvd.

Armando Giuliano, M.D. Chief of Surgical Oncology John Wayne Cancer Institute 2200 Santa Monica Boulevard Santa Monica, CA 90404

Saint Louis, MO 63104

Dennis Ownby, M.D.
Professor of Pediatrics and Medicine
Section of Allergy-Immunology, BG 1019
Medical College of Georgia
Augusta, GA 30912-3790

Dana Smetherman, M.D.
Senior Physician & Section Head of Breast
Imaging & Pediatric Imaging
Alton Oschner Medical Foundation
Department of Radiology
1514 Jefferson Highway
New Orleans, LA 70121

For Prostate Cancer Endpoints:

Gerald Andriole, Jr., M.D Professor and Chief Washington University School of Med. Division of Urologic Surgery 4960 Children's Place St. Louis, MO 63110

Ralph D'Agostino, Ph.D.

Anthony D'Amico, M.D. Chief of Genitourinary Radiation Oncology Brigham and Women's Hospital Dana Farber Cancer Institute 75 Francis Street Boston, MA 02215

Consultants (voting) March 3, 2005 Cont'd

Prostate Cancer Endpoints

Victor DeGruttola, Sc.D. Professor Department of Biostatistics Harvard School of Public Health 677 Huntington Avenue Boston, MA 02115-6096

Mario Eisenberger, M.D. R. Dale Hughes Professor of Onc. The Johns Hopkins University Sidney Kimmel Comprehensive Cancer Ctr. 1650 Orleans Street Baltimore, MD 21231-1000

Eric Klein, M.D. Head, Section of Urologic Oncology Cleveland Clinic Foundation 9500 Euclid Avenue Cleveland, OH 44195

Lisa McShane, Ph.D. Mathematical Statistician National Cancer Institute, NIH 6310 Executive Blvd., Room 8126 Bethesda, MD 20892-7434 Derek Raghavan, M.D., Ph.D. Chairman & Director Cleveland Clinic Taussig Cancer Ctr. Cleveland Clinic Foundation 9500 Euclid Avenue, Desk R35 Cleveland, OH 44195

Howard Sandler, M.D. Professor, Radiation Oncology University of Michigan Med. Ctr. 1500 E. Medical Ctr. Drive Ann Arbor, MI 48109-0010

Howard Scher, M.D. Chief, Genitourinary Oncology Service Memorial Sloan Kettering Cancer Center 1275 York Avenue New York, NY 10021-6094

Patient Representatives (voting):

Eugene Kaczmierak – for Combidex and Prostate Cancer Endpoints

Food and Drug Administration Center for Drug Evaluation and Research

Oncologic Drugs Advisory Committee Meeting

March 4, 2005

Meeting Participants

Consultants (voting)March 4, 2005:

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

Michael Proschan, Ph.D. Mathematical Statistician Office of Biostatistics Research National Heart Lung and Blood Institute Bethesda, MD 20892

Patient Representatives (voting):

Sheila Ross, Washington, DC – For Iressa