Food and Drug Administration Center for Biologics Evaluation and Research

BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE

Meeting #34, February 28, 2003 Holiday Inn, Silver Spring, Maryland

Executive Secretary

Gail Dapolito Scientific Advisors & Consultants Staff Center for Biologics Evaluation and Research Food and Drug Administration (HFM-71)

1401 Rockville Pike

Rockville, MD 20852-1448

Phone: (301) 827-1289 Fax: (301) 827-0294

E-mail: dapolito@cber.fda.gov

Committee Management Specialist

Rosanna L. Harvey
Scientific Advisors & Consultants Staff
Center for Biologics Evaluation and Research
Food and Drug Administration (HFM-71)
1401 Rockville Pike

Rockville, MD 20852-1448

Phone: (301) 827-1297 Fax: (301) 827-0294 E-mail: harvey@cber.fda.gov

MEMBERS

CHAIR

Daniel R. Salomon, M.D. 03/31/03 Associate Professor Department of Molecular and Experimental Medicine The Scripps Research Institute 10550 N. Torrey Pines Road, MEM 55 La Jolla, CA 92037

Bruce R. Blazar, M.D. 03/31/05⁺ Professor
Division of Pediatric Bone Marrow
Transplantation/Oncology
University of Minnesota
420 Delaware Street, SE, Box 109
Minneapolis, MN 55455

Katherine A. High, M.D. 03/31/05 William H. Bennett Professor of Pediatrics University of Pennsylvania Children's Hospital of Philadelphia 310 Abramson Research Center 3615 Civic Center Boulevard Philadelphia, PA 19104 Jonathan S. Allan, D.V.M. 03/31/06 Scientist Department of Virology and Immunology Southwest Foundation for Biomedical Research 7620 N.W. Loop 410 at Military Drive San Antonio, TX 77030

David M. Harlan, M.D. 03/31/06 Head Transplantation and Autoimmunity Branch National Institute of Diabetes and Digestive and Kidney Disease, NIH 10 Center Drive, Building 10, Room 11S210 Bethesda, MD 20892

Joanne Kurtzberg, M.D. 03/31/04 Professor of Pediatrics Pediatric Bone Marrow and Stem Cell Program Duke University Medical Center Box 3350 2400 Pratt Street Durham, NC 27710

BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE Meeting #34, February 28, 2003

MEMBERS (Cont'd)

Alison F. Lawton*
Senior Vice President
Regulatory Affairs
Genzyme Corporation
One Kendall Square
Cambridge, MA 02139

Richard C. Mulligan, Ph.D. 03/31/04 Mallinckrodt Professor of Genetics Harvard Medical School Children's Hospital Department of Molecular Medicine 320 Longwood Avenue Boston, MA 02115

Mahendra S. Rao, M.D., Ph.D. 03/31/05 Chief, Stem Cell Biology Section Laboratory of Neurosciences, 4B17 Gerontology Research Center National Institute on Aging, NIH 5600 Nathan Shock Dr. Baltimore, MD 21224

03/31/05

Anastasios A. Tsiatis, Ph.D. 03/31/06 Professor Department of Statistics North Carolina State University Box 8203 2501 Founders Drive Raleigh, NC 27695

Alice J. Wolfson, J.D. ** 03/31/04 Bourhis, Wolfson and Schlichtmann 1050 Battery Street San Francisco, CA 94111 * - Industry Representative ** - Consumer Representative

+ - Not Attending

++ - Patient Representative

TEMPORARY VOTING MEMBERS

Ms. Barbara Ballard⁺⁺
President
SCID Alliance
Immune Deficiency Foundation
Clifton, VA 20124

John Coffin, Ph.D.
Professor of Molecular Biology
Department of Molecular Biology and Microbiology
Tufts University School of Medicine
136 Harrison Avenue
Boston, MA 02111

Kenneth Cornetta, M.D.
Chairman and Professor
Department of Medical and Molecular Genetics
Indiana University
975 W. Walnut Street, Room 130
Indianapolis, IN 46202

John E. French, Ph.D.
Group and Discipline Leader
Laboratory of Experimental Carcinogenesis and
Mutagenesis
National Institute of Environmental Health Sciences
National Institutes of Health
4401 T.W. Alexander Drive
Research Triangle Park, NC 27709

BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE Meeting #34, February 28, 2003

TEMPORARY VOTING MEMBERS (Cont'd)

Warren Leonard, M.D. Chief Laboratory of Molecular Immunology National Heart, Lung and Blood Institute National Institutes of Health 10 Center Drive, Room 7N252 Bethesda, MD 20892

Abbey S. Meyers President and Executive Director National Organization for Rare Disorders Fairwood Professional Building P.O. Box 8923 New Fairfield, CT 06812

Stuart H. Orkin, M.D.
David G. Nathan Professor of Pediatrics
Department of Pediatric Oncology
Harvard Medical School
Dana Farber Cancer Institute
44 Binney Street
Boston, MA 02115

Linda Wolff, Ph.D.
Chief, Leukemogenesis Section
Laboratory of Cellular Oncology
National Cancer Institute
National Institutes of Health
Building 37, Room 4124A
37 Convent Drive, MSC 4255
Bethesda, MD 20892

Crystal Mackall, M.D. Head, Immunology Section Pediatric Oncology Branch National Cancer Institute National Institutes of Health 10 Center Drive, Room 13N240 Bethesda, MD 20892

Thomas Murray, Ph.D. President The Hastings Center 21 Malcolm Gordon Road Garrison, NY 10524

Bruce E. Torbett, Ph.D.
Associate Professor
Department of Molecular and
Experimental Medicine, MEM 55
The Scripps Research Institute
10550 North Torrey Pines Road
La Jolla, CA 92037

BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE Meeting #34, February 28, 2003

GUEST SPEAKERS

Claudio Bordignon, M.D. Professor of Hematology Scientific Director Istituto Scientifico HS Raffaele Via Olgettina 58 20132 Milan ITALY Marina Cavazzana-Calvo, M.D., Ph.D. Professor in Hematology Director, Biotherapy Department INSERM U429 Hopital Necker-Enfants Malades 149 rue de Sevres 75015 Paris FRANCE

Adrian Thrasher, M.D., Ph.D.
Professor of Paediatric Immunology
Centre for Gene Therapy of Childhood Disease
Molecular Immunology Unit
Institute of Child Health
30 Guilford Street
London WC1N EH

NIH REPRESENTATIVES

Amy Patterson, M.D. Director Office of Biotechnology Activities National Institutes of Health 6705 Rockledge Drive Suite 750, MSC 7985 Bethesda, MD 20892 Stephen M. Rose, Ph.D.
Deputy Director, Recombinant DNA Program
Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive
Suite 750, MSC 7985
Bethesda, MD 20892

FDA PARTICIPANTS

Philip D. Noguchi, M.D. Acting Director Office of Cellular, Tissue and Gene Therapies Center for Biologics Evaluation and Research Food and Drug Administration 1401 Rockville Pike, HFM-515 Rockville, MD 20852 Raj K. Puri, M.D., Ph.D. Acting Director Division of Cellular and Gene Therapies, OCTGT Center for Biologics Evaluation and Research Food and Drug Administration 1401 Rockville Pike, HFM-500 Rockville, MD 20852

Carolyn A.Wilson, Ph.D.
Senior Investigator
Laboratory of Molecular Tumor Biology
DCGT/OCTGT/CBER
Food and Drug Administration
1401 Rockville Pike, HFM-518
Rockville, MD 20852

Cynthia A. Rask
Acting Chief
Clinical Review Branch
Division of Clinical Evaluation and
Pharmacology/Toxicology, OCTGT, CBER
1401 Rockville Pike, HFM-576
Rockville, MD 20852

BRMAC #33 CBER Working Group

OCTGT

Dr. Philip Noguchi

Dr. Joyce Frey-Vasconcells Dr. Raj Puri

Dr. Carolyn Wilson

Dr. Cynthia Rask

Ms. Mercedes Serabian

Dr. Stephanie Simek

Ms. Tina Moulton

Dr. Daniel Takefman

Dr. Anne Pilaro