

DRAFT AGENDA

BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE

Meeting #26

Holiday Inn, Bethesda, MD

March 20, 2000

9:00 a.m. Welcome & Introduction
9:05 Conflict of Interest Statement

Topic I - Islet Transplantation

9:10 FDA Introduction
Philip Noguchi, M.D.
Division of Cellular and Gene Therapies, CBER

9:20 Rationale for islet cell transplantation as an alternative to whole organ pancreas transplants
Camillo Ricordi, M.D.
Diabetes Research Institute
University of Miami School of Medicine

9:50 Allogeneic islet transplantation
A.M. James Shapiro, MD FRCS(C)
Clinical Islet and Pancreas Transplant Programs
University of Alberta, Edmonton

10:20 Lessons from the International Islet Transplantation Registry (ITR) and recommended quality standards for islet preparations
Bernhard J. Hering, M.D.
Diabetes Institute for Immunology and Transplantation
University of Minnesota

10:50 Break

11:05 NIDDK Presentation
Joan Harmon, M.D.
Division of Diabetes, Endocrinology and Metabolic Diseases

11:20 JDF Presentation
Robert Goldstein, M.D.

11:35 Lunch

BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE

**Meeting #26
Agenda - Page 2**

March 20, 2000 (Cont'd)

12:35 p.m. Application of FDA regulatory framework to procurement, processing and characterization of human pancreatic islets
Darin Weber, Ph.D.
Division of Cellular and Gene Therapies, CBER

1:05 p.m. Open Public Hearing

1:35 Committee Discussion - CMC Questions

2:00 Break

2:15 Committee Discussion (Cont'd)

5:00 Break

Topic II - Report of the January 13, 2000 meeting of the Biological Response Modifiers Advisory Subcommittee on Xenotransplantation

5:05 Subcommittee Report
Hugh Auchincloss, Jr., M.D.
Chair, FDA Xenotransplantation Subcommittee

5:30 Committee Discussion

6:00 Adjourn

March 21, 2000

8:00 a.m. BRMAC Administrative Update
Jay P. Siegel, M.D.

Topic III - Update CBER Research Programs

8:15 Division of Cellular and Gene Therapies
Philip Noguchi, M.D.
Director, DCGT

8:20 Donald Fink, Ph.D.
Laboratory of Cell Biology

Meeting #26
Agenda - Page 3

March 21, 2000 (Cont'd)

- 8:25** Division of Therapeutic Proteins
Amy Rosenberg, M.D.
Acting Director, DTP
- 8:35 a.m.** Gibbes Johnson, Ph.D.
Laboratory of Cell Biology
- 8:40** Raymond Donnelly, Ph.D.
Laboratory of Cytokine Research
- 8:45** Emanuel Petricoin, III, Ph.D.
Laboratory of Cytokine Research
- 8:50** Kathryn Zoon, Ph.D.
Laboratory of Chemistry
- 8:55 Closed Session**
- 9:50** Break
- Open Session**
Topic I (Cont'd) - Islet Transplantation/Pre-Clinical Animal Models
- 10:00** Welcome
- 10:05** FDA Introduction
Karen Weiss, M.D.
Division of Clinical Trial Design and Analysis, CBER
- 10:10** Open Public Hearing
- 10:40 a.m.** FDA Perspective, Pre-Clinical Issues
Lauren Black, Ph.D.
Division of Clinical Trial Design and Analysis, CBER
- 10:55** Animal Models of Islet Transplantation
John O'Neil
Joslin Diabetes Center
Harvard University Medical School
- 11:25** Norma Sue Kenyon, Ph.D.
Diabetes Research Institute
University of Miami School of Medicine

BIOLOGICAL RESPONSE MODIFIERS ADVISORY COMMITTEE

Meeting #26

Agenda - Page 4

March 21, 2000 (Cont'd)

- | | |
|-------------------|--|
| 11:45 a.m. | FDA Perspective, Clinical Issues
Thomas L. Eggerman, M.D., Ph.D.
Division of Cellular and Gene Therapies, CBER |
| 12:00 | Lunch |
| 1:-00 p.m. | Committee Discussion - Preclinical/Clinical Issues |
| 2:30 | Break |
| 2:45 | Committee Discussion (Cont'd) |
| 5:00 | Adjourn |