

Wednesday, March 10, 2010 (continued)

9:50 AM **Public Comment**

9:55 AM **Break**

10:00 AM **Discussion of Human Gene Transfer Protocol #1001-1020 entitled:**
Administration of EBV-specific Cytotoxic T Cells Expressing HER2 Chimeric Antigen Receptor to Subjects with Advanced Osteosarcoma (ECHO)

PIs: Nabil Ahmed, M.D., M.P.H., Texas Children's Hospital,
Houston, TX
Stephen Gottschalk, M.D., Texas Children's Hospital,
Houston, TX
Lisa Wang, M.D., Texas Children's Hospital, Houston, TX
[Slide Presentation](#)

RAC Reviewers: Yuman Fong, M.D.
Jeffrey Kahn, Ph.D.

Tab 2592 Protocol

Tab 2593 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Reviews from Drs. Fong, and Kahn
PI's Response

11:45 AM **Public Comment**

11:50 AM **LUNCH**

12:20 PM **Discussion of Human Gene Transfer Protocol # 1001-1023 entitled:** *Gene Transfer for Patients with Sickle Cell Disease Using a Gamma Globin Lentivirus Vector: An Open Label Phase I/II Pilot Study*

PI: Punam Malik, M.D., Cincinnati Children's Hospital Medical
Center, Cincinnati, OH [Slide Presentation](#)

RAC Reviewers: Hung Fan, Ph.D.
Eric Kodish, M.D.
Susan Ross, Ph.D.

Ad hoc Reviewer: George Dover, M.D., Johns Hopkins Children's
Center, Baltimore, MD

Wednesday, March 10, 2010 (continued)

Tab 2594 Protocol

Tab 2595 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Reviews from Drs. Fan, Kodish, Ross, and Dover
PI's Response

2:15 PM **Public Comment**

2:20 PM **Break**

2:35 PM **Gene Transfer Safety Assessment Board Report**

Tab 2596 Responses to M-I-C-1
Protocol List
Protocols Not Selected for In-Depth Review and
Public Discussion [Slide Presentation](#)

RAC Reviewers: Howard J. Federoff, M.D., Ph.D.
Scott E. Strome, M.D.
David A. Williams, M.D.
James R. Yankaskas, M.D., M.S.
John A. Zaia, M.D.

2:50 PM **Updates from the Office of Biotechnology Activities**

3:00 PM **Discussion of Biocontainment for University of Wisconsin's Proposed
Research Involving the Cloning of Ebola and Marburg cDNAs into
*E. coli***

Presenters: Joseph Kanabrocki, Ph.D., RAC Member
Gabriele Neumann, Ph.D., University of Wisconsin,
Madison, WI
[Slide Presentation1](#) [Slide Presentation2](#)

Tab 2597 Background Materials

4:00 PM **Public Comment**

Wednesday, March 10, 2010 (continued)

4:10 PM **Discussion of Proposal to Exempt the Mating of Certain Biosafety Level 1 Transgenic Rodents from the Requirements of Section III-E-3 of the *NIH Guidelines***

Presenters: Jane Flint, Ph.D., RAC Member
 James Pickel, Ph.D., National Institute of Mental Health, NIH
 [Slide Presentation](#)

5:10 PM **Public Comment**

5:15 PM **Adjourn**

Thursday, March 11, 2010

8:00 AM **Call to Order and Opening Remarks**

Jeffrey Bartlett, Ph.D., Acting RAC Chair

8:10 AM **Discussion of Human Gene Transfer Protocol #0912-1016 entitled: *A Phase II Study to Determine the Efficacy and Safety of Allogeneic Human Chondrocytes Expressing TGF- β 1 in Patients with Grade 3 Degenerative Joint Disease of the Knee***

PI: Michael A. Mont, M.D., Sinai Hospital of Baltimore, Baltimore, MD

Sponsor: TissueGene, Inc. [Slide Presentation](#)

RAC Reviewers: Jeffrey Bartlett, Ph.D.
 Hildegund Ertl, M.D.
 Anna Mastroianni, J.D.

Ad hoc Reviewer: Robert Carter, M.D., National Institute of Arthritis and Musculoskeletal and Skin Diseases, NIH

Tab 2598 Protocol

Tab 2599 OBA Summary
 OBA Letter to PI on In-Depth RAC Review and Public Discussion
 Reviews from Drs. Bartlett, Ertl, Carter, and Prof. Mastroianni
 PI's Response

10:00 AM **Public Comment**

10:10 AM **Break**

Thursday, March 11, 2010 (continued)

10:20 AM

Discussion of Human Gene Transfer Protocol # 1001-1026 entitled: *A Phase I Neoadjuvant Study of In-situ REIC/Dkk-3 Therapy Followed by Prostatectomy in Patients with High Risk Localized Prostate Cancer*

PI: Simon Hall, M.D., Mount Sinai Medical Center, New York, NY

Sponsor: Momotaro-Gene, Inc. [Slide Presentation](#)

RAC Reviewers: Michael Buchmeier, Ph.D.
Jane Flint, Ph.D.
Jeffrey Kahn, Ph.D.

Ad hoc Reviewer: James Gulley, M.D., Ph.D., F.A.C.P., National Cancer Institute, NIH

Tab 2600 Protocol

Tab 2601 OBA Summary
OBA Letter to PI on In-Depth RAC Review and Public Discussion
Reviews from Drs. Buchmeier, Flint, Kahn, and Gulley
PI's Response

12:25 PM

Public Comment

12:30 PM

Adjourn