

**NATIONAL INSTITUTES OF HEALTH (NIH)
RECOMBINANT DNA ADVISORY COMMITTEE (RAC)**

127TH MEETING

**ROCKVILLE HILTON & EXECUTIVE MEETING CENTER
DECEMBER 13-14, 2011**

AGENDA

Tuesday, December 13, 2011

2:00 PM **Call to Order and Opening Remarks**

Yuman Fong, M.D., RAC Chair

Tab 2682 For Your Information
Notice of Meeting
Conflict of Interest Guidance

2:05 PM **Minutes**

Tab 2683 Minutes of RAC Meeting September 13-14, 2011

RAC Reviewers: E. Antonio Chiocca, M.D., Ph.D.
David Ornelles, Ph.D.

2:10 PM

Review and Discussion of Human Gene Protocol #1108-1122 titled:
*Phase I Trial of the Safety and Immunogenicity of a DNA Plasmid Based
Vaccine Encoding the Amino Acids 1-163 of Insulin-Like Growth Factor
Binding Protein-2 (IGFBP-2) in Patients with Advanced Ovarian Cancer*

PI: Mary Disis, M.D., University of Washington, Seattle,
WA

RAC Reviewers: Rebecca Dresser, J.D.
Yuman Fong, M.D.
Marshall Strome, M.D., M.S.

Tab 2684 Protocol

Tab 2685 OBA Summary
OBA Letter to PI on In-Depth RAC Review and
Public Discussion
Reviews from Drs. Fong, Strome and Professor
Dresser
PI's Response

Tuesday, December 13, 2011

3:35 PM **Public Comments**

3:45 PM **Break**

3:50 PM **Review and Discussion of Human Gene Protocol #1110-1133 titled: *A Phase I Clinical Trial of mTOR Inhibition with Sirolimus for Enhancing ALVAC(2)-NY-ESO-1(M)/TRICOM Vaccine Induced Anti-Tumor Immunity In Ovarian, Fallopian Tube and Primary Peritoneal Cancer***

PI: Kunle Odunsi, M.D., Ph.D., Roswell Park Cancer Institute, Buffalo, NY

Sponsor: Roswell Park Cancer Institute

RAC Reviewers: Saswati Chatterjee, Ph.D.
Anna Mastroianni, J.D., M.P.H.
Marcella Sarzotti-Kelsoe, Ph.D.

Tab 2686 Protocol

Tab 2687 OBA Summary
OBA Letter to PI on In-Depth RAC Review and Public Discussion
Reviews from Drs. Chatterjee, Sarzotti-Kelsoe, and Professor Mastroianni
PI's Response

5:15 PM **Public Comments**

5:20 PM **Gene Transfer Safety Assessment Board Report**

Tab 2688 Responses to M-I-C-1
Protocol List
Protocols Not Selected for In-Depth Review and Public Discussion

RAC Reviewers: Andrew Badley, M.D.
E. Antonio Chiocca, M.D., Ph.D.
Yuman Fong, M.D.
Hans-Peter Kiem, M.D., Ph.D.
Donald Kohn, M.D.
Marshall Strome, M.D., M.S.
James Yankaskas, M.D., M.S.

5:30 PM **Adjournment**

Wednesday, December 14, 2011

8:15 AM **Call to Order and Opening Remarks**

Yuman Fong, M.D., RAC Chair

8:20 AM **In-depth Review and Discussion of Protocol #1110-1130 titled: *An Adaptive Phase I/II Study of the Safety of CD4⁺ T Lymphocytes and CD34⁺ Hematopoietic Stem/Progenitor Cells Transduced with CAL-1, A Dual anti-HIV Gene Transfer Construct, in Busulfan Conditioned HIV-Infected Adults previously exposed to ART***

PI: Ronald Mitsuyasu, M.D., University of California, Los Angeles, Los Angeles, CA

Sponsor: Calimmune, Inc.

RAC Reviewers: Andrew Badley, M.D.
Marie-Louise Hammarskjöld, M.D., Ph.D.
Susan Ross, Ph.D.

Tab 2689 Protocol

Tab 2690 OBA Summary
OBA Letter to PI on In-Depth RAC Review and Public Discussion
Reviews from Drs. Badley, Hammarskjöld, and Ross
PI's Response

9:45 AM **Public Comments**

9:55 AM **BREAK**

10:10 AM **Update Discussion of Recent Results on Protocol 793 titled: *Pilot Study of Redirected Autologous T Cells Engineered to Contain Anti-CD19 Attached to TCR ζ and 4-1 BB Signaling Domains in Patients with Chemotherapy Resistant or Refractory CD19⁺ Leukemia and Lymphoma***

Presenter: Carl June, M.D., University of Pennsylvania, Philadelphia, PA

TAB 2691 Background Material

10:50 AM **Public Comments**

Wednesday, December 14, 2011

11:00 AM **Review and Discussion of Protocol # 1110-1127 titled:** *Pilot Clinical Trial of Autologous Met Redirected T cells Administered Intratumorally and Intravenously in Patients with Operable Triple Negative Breast Cancer*

PI: Julia C. Tchou, M.D., Ph.D., University of Pennsylvania, Philadelphia, PA

Sponsor: Carl June, M.D., University of Pennsylvania, Philadelphia, PA

RAC Reviewers: Norman Fost, M.D., M.P.H.
 Hans-Peter Kiem, M.D., Ph.D.
 James Yankaskas, M.D., M.S.

Ad hoc: Larry Norton, M.D., Memorial Sloan-Kettering Cancer Center, New York, NY (*by teleconference*)

Tab 2692 Protocol

Tab 2693 OBA Summary
 OBA Letter to PI on In-Depth RAC Review and Public Discussion
 Reviews from Drs. Fost, Kiem, and Yankaskas
 PI's Response

12:40 PM **Public Comments**

12:50 PM **Lunch**

1:50 PM **Update on T-Cell Immunotherapy Targeting Human Cancer Antigens**

Presenter: Steven Rosenberg, M.D., Ph.D., National Cancer Institute, National Institutes of Health, Bethesda, MD

2:30 PM **Public Comments**

2:40 PM **Discussion of a Serious Adverse Event on Protocol # 937 titled:** *Vaccination with Lethally Irradiated Autologous Myeloblast Admixed with Granulocyte Macrophage-colony Stimulating Factor Secreting K562 cells (GM-K562) in Patients with Advanced MDS or AML after Allogeneic Hematopoietic Stem Cell Transplantation*

Sponsor: Glen Dranoff, M.D., Dana-Farber Cancer Institute, Boston, MA

Wednesday, December 14, 2011

Ad hocs: Cynthia Dunbar, M.D., National Heart, Lung, and
Blood Institute, National Institutes of Health,
Bethesda, MD
and
Amy Klion, M.D., National Institute of Allergy and
Infectious Diseases, National Institutes of Health,
Bethesda, MD

3:50 PM **Public Comments**

4:00 PM **Break**

4:10 PM **Update on Discussions Regarding IBC Review of Low Risk Protocols**

Presenter: Jacqueline Corrigan-Curay, J.D., M.D.,
Office of Biotechnology Activities, National
Institutes of Health, Bethesda, MD

4:20 PM **Adjourn**