

NATIONAL INSTITUTES OF HEALTH (NIH)
RECOMBINANT DNA ADVISORY COMMITTEE (RAC)
141ST MEETING
BETHESDA, MD
BUILDING 35, CONFERENCE ROOM 620/630
MARCH 10, 2015
AGENDA

Tuesday, March 10, 2015

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

Donald Kohn, M.D., RAC Chair

Tab 2818 For Your Information
 Notice of Meeting
 Conflict of Interest Guidance

8:05 AM **Minutes**

Tab 2819 Minutes of the December 11, 2014, RAC Meeting

RAC Reviewers: Rebecca Dresser, J.D.
 Patrick Hearing, Ph.D.

8:10 AM **Discussion on Human Gene Transfer Protocol #1412-1364 titled: *Phase I Study of Intracranial Injection of T cells Expressing HER2-Specific Chimeric Antigen Receptors (CAR) in Subjects with Glioblastoma (iCAR)***

PI: Nabil Ahmed, M.D., M.P.H., Texas Children's Hospital,
 Houston, TX

RAC Reviewers: Michael Atkins, M.D.
 William Curry, M.D.
 Rebecca Dresser, J.D.

Tab 2820 Protocol

Tab 2821 OBA Summary

OBA Letter to PI on In-Depth RAC Review and
Public Discussion

(continued) Tuesday, March 10, 2015

Reviews from Drs. Atkins, Curry, and Professor
Dresser
PI's Response

9:30 AM **Public Comments**

9:35 AM **Discussion on Human Gene Transfer Protocol #1501-1378 titled: *A Phase I/II Open Label Clinical Trial Evaluating the Safety and Efficacy of MAGE-A10^{c796}T in Patients with Advanced Breast Cancer***

PI: Edith Perez, M.D., Mayo Clinic, Jacksonville, FL

Sponsor: Marcia Gaido, Ph.D., RAC, Adaptimmune, LLC

RAC Reviewers: Paula Cannon, Ph.D.
 Hans-Peter Kiem, M.D., Ph.D.
 Lainie Ross M.D., Ph.D.

Tab 2822 Protocol

Tab 2823 OBA Summary
 OBA Letter to PI on In-depth RAC Review and
 Public Discussion
 Reviews from Drs. Cannon, Kiem, and Ross
 PI's Response

10:50 AM **Public Comments**

10:55 AM **BREAK**

11:05 AM **Discussion on Human Gene Transfer Protocol #1411-1357 titled: *Phase I, Randomized, Open-Label, Active Controlled, Dose Escalation Study to Evaluate the Safety, Tolerability, and Immunogenicity of INO-1800 Alone or in Combination with INO-9112 Delivered IM Followed by Electroporation in Select Nucleos(t)ide Analogue-Treated, HBeAg Positive, Chronic Hepatitis B Patients***

PI: Douglas T. Dieterich, M.D., Mount Sinai, New York, NY

Sponsor: Ami Shah Brown, Ph.D., M.P.H., Inovio Pharmaceuticals,
 Plymouth Meeting, PA

RAC Reviewers: Donald Kohn, M.D.
 Lainie Ross, M.D., Ph.D.
 Richard Whitley, M.D.

Ad Hoc Reviewer: Marc Ghany, M.D., M.H.Sc.

(continued) Tuesday, March 10, 2015

Tab 2824 Protocol

Tab 2825 OBA Summary

OBA Letter to PI on In-depth RAC Review and
Public Discussion

Reviews from Drs. Ghany, Kohn, Ross, and Whitley
PI's Response

11:40 PM Public Comments

12:30 PM Gene Transfer Safety Assessment Board Report

RAC Reviewers: Michael Atkins, M.D.
William Curry, M.D.
Kevin Donahue, M.D.
Howard Kaufman, M.D.
Hans-Peter Kiem, M.D., Ph.D.
Donald Kohn, M.D.
Joseph Pilewski, M.D.
Michel Sadelain, M.D., Ph.D.
Richard Whitley, M.D.

Tab 2830 Responses to M-I-C-1
Protocol List
Protocols Not Selected for In-Depth Review and
Public Discussion

12:40 PM Proposed updates to the NIH Informed Consent Guidance for Human Gene Transfer Trials subject to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*: Follow-up to December 11, 2014 RAC Discussions

1:00 PM Discussion on Human Gene Transfer Protocol #1411-1360 titled: *Chimeric Antigen Receptor MUC1 T Cell Immunotherapy for Metastatic Breast Cancer*

PI: Stewart A. Sharp, M.D., Harrington Cancer Center, Amarillo,
TX

RAC Reviewers: Hans-Peter Kiem, M.D., Ph.D.
Joseph Pilewski, M.D.
Laurie Zoloth, Ph.D.

Tab 2826 Protocol

Tab 2827 OBA Summary

OBA Letter to PI on In-depth RAC Review and
Public Discussion
Reviews from Drs. Kiem, Pilewski and Zoloth
PI's Response

2:30 PM Public Comments

2:40 PM BREAK

**2:45 PM Discussion on Human Gene Transfer Protocol #1501-1372 titled: A
*Phase I Clinical Trial to Evaluate the Safety and Immunogenicity of a
Personalized Polyepitope DNA Vaccine Strategy in Breast Cancer Patients
with Persistent Triple-Negative Disease Following Neoadjuvant
Chemotherapy***

PI: William E. Gillanders, M.D., Washington University School of
Medicine, St. Louis, MO

RAC Reviewers: Marie-Louise Hammar sjöld, M.D., Ph.D.
Angelica Hardison, M.B.A.
Howard Kaufman, M.D., F.A.C.S.

Tab 2828 Protocol

Tab 2829 OBA Summary

OBA Letter to PI on In-depth RAC Review and
Public Discussion
Reviews from Drs. Hammar sjöld, Kaufman, and Ms.
Hardison
PI's Response

4:15 PM Public Comments

4:30 PM ADJOURN