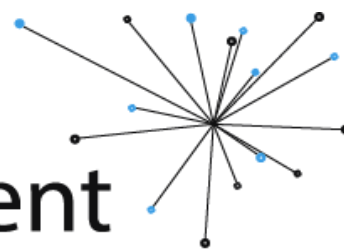


Therapeutic HIV Vaccine Development



Washington, DC | 19-20 September, 2013

Bethesda North Marriott Hotel and Conference Center |
5701 Marinelli Road, North Bethesda, MD 20852

Agenda

Day 1 – Thursday September 19, 2013

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|-------------|--|
| 7:30 - 8:00 | Registration |
| 8:00 - 8:10 | Opening / introductions |
| 8:10 – 8:20 | Goals/objectives of the meeting
<i>Kevin Fisher AVAC</i> |
| 8:20 – 9:00 | The Scientific Rationale behind Therapeutic vaccines.
<i>Yves Levy MD, PhD - ANRS; Vaccine Research Institute</i> |

Roundtable 1: What are the required immunologic responses for therapeutic vaccines?

Moderator: Janet Siliciano

- Which specific t-cell responses are most important?
- Is there a role for antibody?
- Are innate or adaptive responses likely to be more successful?
- Which magnitude or breadth of responses will be more important?
- How might a vaccine deal with viral escape?
- What assays are available for measuring immune response?

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| 9:00 - 9:15: | Induction of innate and adaptive immunity
<i>Galit Alter, PhD - Ragon Institute</i> |
| 9:15 – 9:30: | Is there a role for antibodies?
<i>Vidar Wendel-Hansen, MD, PhD - Bionor</i> |
| 9:30 – 9:45 | Antiviral activity of <i>Cytotoxic T lymphocytes</i>
<i>Lucy Dorrell MD - University of Oxford</i> |
| 9:45 – 10:00 | The role of regulatory T cell function
<i>Mike McCune MD, PhD - UCSF</i> |
| 10:00 – 10:45 | Roundtable Discussion |

10:45 – 11:00 Break

Roundtable 2: What can we learn from therapeutic vaccine studies in NHPs?

Moderator: Veffa Franchini

- Can NHP studies model vaccination in the context of ARV treatment?
- What might efficacy in NHP tell us about efficacy in humans?
- Can immune responses controlling viral replication during chronic infection be translated into prevention of transmission (or vice versa)?
- Can testing in NHP accelerate the therapeutic vaccine development process?

11:00 – 11:15 Models for Testing Therapeutic Vaccines in NHPs.
Jeff Lifson, MD - SAIC-Frederick

11:15 – 11:30 Therapeutic DNA Vaccination in NHPs.
George Pavlakis, MD, PhD - National Cancer Institute

11:30 – 11:45 Therapeutic CMV/SIV Vaccination in NHPs.
Jeff Lifson, MD - SAIC-Frederick

11:45 – 12:15 Roundtable Discussion

12:15 – 1:00 Lunch

Roundtable 3: What can we learn from human clinical trials of therapeutic vaccines?

Moderator: Daniel Kuritzkes

- Which immunologic, virologic and clinical endpoints have been found in therapeutic vaccine trials?
- What level of virologic suppression could be deemed clinically beneficial?
- What are the challenges and opportunities in testing therapeutic vaccines in acute vs. chronically infected patients, or treatment naïve vs. virally suppressed patients?
- What should be the role of analytic treatment interruption and reservoir depletion in study designs?

1:00 - 1:15 Measuring immunologic responses in clinical trials
Nicole Frahm, PhD – Fred Hutchinson Cancer Center

1:15 - 1:30 Autologous Dendritic Cell Vaccines: Lessons for the Field
Felipe Garcia, MD, PhD – Servicio de Infecciones Hospital Clinic

1:30 - 1:45 Autologous Dendritic Cell Vaccines: Lessons for the Field
Jeff Jacobson, MD – Drexel/Argos Therapeutics

1:45 – 2:00 Break

2:00 – 2:15 DNA/Vector vaccines: Lessons for the Field
John Eldridge PhD - Profectus

2:15 - 2:30 Peptide vaccines: Lessons for the Field
Anders Fomsgaard – Statens Serum Institut

2:30 – 3:15 Roundtable Discussion (with *Vidar Wendel-Hansen*)

3:15 – 3:30 Break

Roundtable 4: What is the role for therapeutic vaccines in the Cure scientific agenda?

Moderator: Romas Geleziunas

- How might therapeutic vaccines work to kill newly activated latent cells?
- How might therapeutic vaccine approaches differ for acute vs. chronic patients?
- How might therapeutic vaccines be combined with early treatment options?
- What are the regulatory issues in combination cure approaches?
- What assays are available for measuring functional cure?

3.30 – 4:00 Therapeutic vaccines in the cure scientific agenda
Steve Deeks, MD – UCSF

4:00 – 4:15: Antibody effector mechanisms
Jonathan Karn, Case Western Reserve

4:15 – 4:30: Combining Therapeutic vaccines and latency activators
Lucy Dorrell MD - University of Oxford

4:30 – 4:45 Cure endpoints for therapeutic vaccine development.
*Deborah Persaud, MD- Johns Hopkins University
School of Medicine*

4:45 – 5:30 Roundtable Discussion (with Carol Weiss)

5:30 Break for Day.

Day 2 – Friday September 20 2013

Roundtable 5: What can be learned from testing vaccine candidates as preventive and therapeutic vaccines?

Moderator: Susan Barnett

- What are the differences in immune responses between HIV+ and HIV- populations?
- Are there lessons to be learned about overcoming immune escape?
- Are there strategies for protecting, or limiting induction of, CD4 target cells?
- What are the different regulatory considerations?

8:30 – 8:45 Geovax vaccines: Lessons for the field
Harriet Robinson PhD – Emory/Geovax

8:45 – 9:00 Whole Killed Virus in Preventive and Therapeutic Vaccines
Chil-Yong Kang MD - Sumagen Canada

9:00 – 9:15 Strategies for Protecting HIV target cells
Pablo Tebas MD - U of Pennsylvania

9:30 – 9:45 Regulatory Considerations in Therapeutic Vaccines
Carol Weiss MD, PhD - FDA

9:45 – 10:15 Roundtable Discussion

10:15 – 10:30 Break

Break Out Groups

10:30-12:00

There are four breakout groups in the morning on the second day of the meeting. There will be some overlap between the group discussions but each group will come at these issues from a different perspective. Meeting participants and speakers will be asked to select a breakout group at registration. Each group will have a moderator and will have a rapporteur who can report back for the meeting report. The ultimate goal of the meeting is the development of specific, scientifically based next steps to advance therapeutic vaccine development.

Group One

This Group will focus on scientific gaps in therapeutic vaccine development.

Group Two

This Group will focus on opportunities scientific coordination and synergies between the therapeutic vaccine and the preventive HIV vaccine agendas.

Group Three

This Group will focus on opportunities scientific coordination and synergies between the therapeutic vaccine, the treatment optimization and cure agendas.

Group Four

This Group will focus on ethical and regulatory considerations related to trial design (including ATI), and clinical endpoints in therapeutic vaccine development.

12:00 – 1:00: Report-backs with accompanying lunch

1:00 Meeting ends.

1:00 – 2:00 Meeting of meeting organizers and funders: amfAR, AVAC, BMGF, NIH, GHAVE and TAG.