

Mode of Action of Adjuvants Implications for vaccine safety and design

IABS Meeting and NFID/ACVR Satellite Meeting
April 29-30, 2010 - Bethesda, Maryland, USA

 IABS Human Vaccines

Organizing Committee:

Norman Baylor, FDA

Steve Black, Cincinnati Children's Hospital Medical Center

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Emanuelle Trannoy, Sanofi Pasteur

Kathy Zoon, NIH

Executive Committee:

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Paul-Henri Lambert, University of Geneva

Betty Dodet, Dodet Bioscience

PROVISIONAL PROGRAMME

updated 16 April 2010

SESSION 1 - Update on the adjuvant mode of action

Chairpersons: *Paul-Henri Lambert and Ian Gust*

08:00 **Keynote lecture 1**

Targeting innate immunity with traditional, live attenuated, and adjuvanted subunit vaccines
Steven Reed, Infectious Disease Research Institute, Seattle

08:25 Discussion

08:30 Aluminium-based adjuvants: the role of inflammasome

Mirjam Kool, Erasmus University, Rotterdam

08:50 Discussion

09:00 The mode of action of oil-in-water emulsion adjuvants

Ennio de Gregorio, Novartis Vaccines & Diagnostics, Siena

09:20 Discussion

09:30 Directing and maintaining the immune response by cationic liposomes

Peter Lawætz Andersen, Statens Serum Institute, Copenhagen

09:50 Discussion

10:00 **Break**

10:20 Saponin-based adjuvants

Debbie Drane, CSL Ltd., Melbourne

10:40 Discussion

10:50 TLR agonists as vaccine adjuvants

Dennis Klinman, National Cancer Institute, Bethesda

11:10 Discussion

11:20 TLR4 agonists

Nathalie Garçon, GSK Biologicals, Rixensart

11:40 Discussion

11:50 **Keynote lecture 2**

Adjuvants for HIV vaccines – Which profile in the post-STEP era?

Gary Nabel, National Institute of Allergy and Infectious Diseases, Bethesda

12:10 Discussion

12:20 **Lunch**

13:30 Mucosal adjuvants

Yasmine Belkaid, National Institute of Allergy and Infectious Diseases, Bethesda

13:50 Discussion

SESSION 2 - Correlating the adjuvant mode of action with vaccine design for specific targets

Chairpersons: *Kathryn Zoon and Martin Friede*

14:00 **Keynote lecture 3**

Which target disease vaccine may require an adjuvant?

Paul-Henri Lambert, University of Geneva

14:25 Discussion

14:30 Which challenges for early life vaccine adjuvants?

Claire-Anne Siegrist, University of Geneva

14:50 Discussion

15:00 What can we expect from adjuvants for vaccination in the elderly?

Beatrix Grubeck-Loebenstein, Institute for Biomedical Aging Research, Innsbruck

15:20 Discussion

15:30 Malaria vaccine : a journey into the selection of the adjuvant

Marcelle Van Mechelen, GSK Biologicals, Rixensart

15:50 Discussion

16:00 **Break**

16:20 Adjuvants for tuberculosis vaccines

Stefan Kaufmann, Max Plank Institute, Berlin

16:40 Discussion

16:50 **Round Table 1: First lessons from the H1N1 pandemic**

Chairpersons: *Martin Friede and Rebecca Sheets*

- Role of adjuvants

Albert Osterhaus, Erasmus University, Rotterdam

- Early post-marketing experience with AS03-adjuvanted H1N1 vaccine in the UK – Preliminary assessment of safety issues

Philip Bryan, Medicines and Healthcare products Regulatory Agency, UK

- Adjuvants and breadth of response

Hana Golding, Food and Drug Administration, Bethesda

- Discussants

Norman Baylor, Food and Drug Administration, Bethesda

Giuseppe Del Giudice, Novartis Vaccines & Diagnostics, Siena

Kathryn Edwards, Vanderbilt University, Nashville

Emanuelle Trannoy, Sanofi Pasteur, Lyon

Pieter Neels, Federal Agency for Medicines and Health Products of Belgium

Tom Verstraeten, GSK Biologicals, Rixensart

18:20 End of session

SESSION 3 - Can understanding the adjuvant mode of action help to assess vaccine safety?

Chairpersons: *Norman Baylor and Pieter Neels*

- 08:30 **Keynote lecture 4**
Vaccine adjuvant safety: main issues
Kathryn C. Zoon, National Institute of Allergy and Infectious Diseases, Bethesda
- 08:55 Discussion
- 09:00 Safety issues with mucosal adjuvants
Myron M. Levine, University of Maryland, Baltimore
- 09:20 Discussion
- 09:30 Non-clinical safety assessment of adjuvanted vaccines: are new approaches needed?
Hana Golding, Food and Drug Administration, Bethesda
- 09:50 Discussion
- 10:00 Can animal models of autoimmunity be used to assess the risk of autoimmune responses?
Robert S. Fujinami, University of Utah, Salt Lake City
- 10:20 Discussion
- 10:30 **Break**
- 10:50 Considering essential steps for early assessment of adjuvanted vaccine safety: The point of view from scientists from industry
Coordinated and presented by *Sohail Ahmed, Novartis Vaccines & Diagnostics, Siena*
- 11:10 Discussants
Robert Coffman, Dynavax Technologies Corp., Berkeley
Nathalie Garçon, GSK Biologicals, Rixensart
Emanuelle Trannoy, Sanofi Pasteur, Lyon
Hana Golding, Food and Drug Administration, Bethesda
Pieter Neels, Federal Agency for Medicines and Health Products of Belgium
Steve Reed, Infectious Disease Research Institute, Seattle
- 11:40 **Lunch**

SESSION 3 (continued) - Can understanding the adjuvant mode of action help to assess vaccine safety?

Chairpersons: *Norman Baylor and Pieter Neels*

- 13:40 Toll-like receptor triggering stimulates immunity at the antigen site but suppresses autoimmune and allergic responses when applied systemically
Jean-François Bach, Académie des Sciences, Paris
- 14:00 Discussion
- 14:10 **Round-Table**
How should the mode-of-action shape the design of non-clinical studies and initial clinical trials of adjuvanted vaccines?
Point of view from regulatory authorities
Pieter Neels, Federal Agency for Medicines and Health Products of Belgium
Hana Golding, Food and Drug Administration, Bethesda
Marion Gruber, Food and Drug Administration, Bethesda
Elizabeth Sutkowski, Food and Drug Administration, Bethesda
- Point of view from industry*
Sohail Ahmed, Novartis V&D, Siena
Nathalie Garçon, GSK Biologicals, Rixensart
Emanuelle Trannoy, Sanofi Pasteur, Lyon
Robert Coffman, Dynavax Technologies Corp., Berkeley
- Point of view from academia*
Paul-Henri Lambert, University of Geneva
Myron M. Levine, University of Maryland, Baltimore
Claire-Anne Siegrist, University of Geneva
Steven G. Reed, Infectious Disease Research Institute, Seattle
- 15:40 Summary and concluding remarks
William Egan, PharmaNet, Princeton
- 16:00 **End of the meeting**