



Potential Use of Biomarkers of Inflammation and of Early Immunological Events to Assess Vaccine Safety

May 10-11, 2012 - Baltimore, Maryland

Preliminary Program

As of: February 15, 2012

Scientific Committee

Co-chairpersons:

Paul-Henri Lambert, University of Geneva, Switzerland

William Egan, PharmaNet

Ian Gust, University of Melbourne

Rebecca Sheets, NIH/NIAID

- 07:30 **Registration**
- 08:00 **Continental breakfast**
- 08:45 **Opening**
Johannes Löwer, IABS
Paul-Henri Lambert, University of Geneva

Day 1 - Thursday, May 10, 2012

Session I

Molecular monitoring of vaccine reactogenicity in the context of regulatory processes

- 09:00 - 09:30 Understanding inflammation
Eicke Latz, University of Massachusetts
- 09:30 - 09:40 Discussion
- 09:40 - 10:00 Present assessment of local and systemic vaccine reactogenicity
Jeffrey Roberts, CBER
- 10:00 - 10:10 Discussion
- 10:10 - 10:30 Quality control: *in vitro* assessment of vaccines by monocyte activation test (MAT)
Ingo Spreitzer, PEI, Langen
- 10:30 - 10:40 Discussion

10:40 - 11:00 Coffee Break

11:00 - 11:20 Early immunological events triggered by the vaccine adjuvant MF59 in mice
Ennio De Gregorio, Novartis

11:20 - 11:30 Discussion

11:30 - 11:50 Developing a vaccine safety classifier in non-human primates
I-Ming Wang, Merck & Co., Inc.

11:50 - 12:00 Discussion

12:00 - 12:20 Exploring inflammasome and adjuvanticity in clinical studies
Alessandra Mortellaro, Singapore Immunology Network (SIgN)

12:20 - 12:30 Discussion

12:30 Lunch

14:00 - 14:50 **Panel Discussion**
Chairperson: Norman Baylor, BCG, Inc.

Which biomarkers should be considered for measuring vaccine-induced inflammation at local and systemic level?

- Which biomarkers can be used in early clinical trials?
- Validation process?
- Views of regulators & industry

Panelists: Ingo Spreitzer, PEI; **Ennio De Gregorio**, Novartis; **I-Ming Wang**, Merck & Co., Inc.; **Arnaud Didierlaurent**, GSK; **Alessandra Mortellaro**, Singapore Immunology Network; **Jeffrey Roberts**, CBER

Session II

Monitoring of vaccine-induced innate immunity in the context of regulatory processes

14:55 - 15:35 **Keynote lecture**
Biomarkers of innate immunity following vaccination: towards systems vaccinology
Bali Pulendran, Emory University

15:35 - 15:45 Discussion

15:45 - 16:05 Coffee Break

In vitro approaches

16:05 - 16:25 Use of in-vitro models of the human immune system to assess adjuvanted vaccines
William Warren, Sanofi Pasteur

16:25 - 16:35 Discussion

- 16:35 - 16:55 **Animal models**
Influence of vaccine formulations and mode of administration on the kinetics and breadth of APC targeting in the draining lymph nodes
Claire-Anne Siegrist, University of Geneva
- 16:55 - 17:05 Discussion
- 17:05 - 17:25 Assessing innate immunity induced by adjuvant systems
Arnaud Didierlaurent, GSK
- 17:25 - 17:35 Discussion

Day 2 - Friday, May 11, 2012

Session II (continued)

Monitoring of vaccine-induced innate immunity in the context of regulatory processes

- 08:00** Continental breakfast
- 09:00 - 09:20 **Clinical Studies**
Scientific investigations of trivalent influenza vaccine-induced adverse events in the paediatric population: role of innate immunity
Eugene Maraskovsky, CSL
- 09:20 - 09:30 Discussion
- 09:30 - 09:50 Gene expression profiles following live and inactivated influenza vaccines
Wei Zhu, Medimmune
- 09:50 - 10:00 Discussion
- 10:00 - 10:20** Break
- 10:20 - 11:20 **Panel Discussion**
Chairperson: Robert L. Coffman, Dynavax
Should innate immunity be assessed in early vaccine trials in the context of regulatory processes?
- Can biomarkers be used for comparative adjuvant /formulation assessment?
 - Can biomarkers be used to compare vaccine and natural infection?
 - Relative importance of in-vitro and in-vivo preclinical assays.
- Panelists: Pieter Neels**, EMA; **Hana Golding**, FDA; **William Warren**, Sanofi Pasteur; **Nathalie Garçon**, GSK

Session III

Monitoring of vaccine effects on unrelated immune responses

- 11:25 - 11:45 Assessing innate immunity effects in animal models of autoimmune diseases
Willem van Eden, Utrecht University, The Netherlands
- 11:45 - 11:55 Discussion
- 12:00 - 13:30 Lunch**
- 13:30 - 13:50 Can one predict the effects of vaccination in atopic patients?
Patrick Holt, Telethon Institute for Child Health Research, Perth, Australia
- 13:50 - 14:00 Discussion
- 14:00 - 14:20 Assessing bystander immunological activation following vaccination in humans
Gianfranco Di Genova, University of Southampton, UK
- 14:20 - 14:30 Discussion
- 14:30 - 15:00 Can one predict a high risk of autoimmune disease before vaccination?
George Eisenbarth, University of Colorado
- 15:00 - 15:10 Discussion
- 15:10 - 15:30 **Panel Discussion on non-specific immunological effects**
Chairperson: Michel Goldman, IMI, Brussels
- Should early atopy or autoimmune disease risk biomarkers be used in early clinical trials?
 - Should immunological interferences be monitored at pre-clinical or early clinical stages of vaccine development?
- Panelists:** **William Warren**, Sanofi Pasteur; **Willem van Eden**, Utrecht, The Netherlands; **P. Holt**, Telethon Institute for Child Health Research, Perth, Australia; **Gianfranco Di Genova**, University of Southampton, UK; **George Eisenbarth**, University of Colorado; **Norman Baylor**, BCG, Inc.; **Pieter Neels**, EMA
- 15 :30-15 :50 Key conclusions of the meeting
David Lewis, University of Surrey
- 15:50 - 16:00 **Concluding remarks**
William Egan, PharmaNet