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SMi present their inaugural conference on...

# IMMUNOGENICITY

Assessing Early Risks, Clinical Implications, Outcomes  
and Tolerance of Immunological Response

Holiday Inn Regents Park, London, UK

14th - 15th  
**JULY**  
**2014**

## Conference Chairs:

- **Matthew Baker**, Chief Scientific Officer, **Antitope**
- **Martin Lechmann**, Development DMPK Project Leader, **Roche**

## Key Speakers Include:

- **Robert Dodge**, Associate Director, **BMS**
- **Thomas Lee**, Scientific Investigator, Clinical Immunology, **GSK**
- **Takashi Kei Kishimoto**, Chief Scientific Officer, **Selecta Biosciences Inc.**
- **Ronit Mazor**, Research Fellow, National Cancer Institute, **National Institutes of Health**
- **Anne De Groot**, CEO/CSO, **EpiVax Inc**
- **Daniel Kramer**, Associate Director, Project Representative NBE, **Merck Serono**

## BUSINESS BENEFITS FOR 2014:

- **Grasp** an understanding of Immunogenicity and gain an insight into assessing early risks
- **Hear** case studies on the tools for consideration being utilised for the determination of immunogenicity
- **Assess** major hurdles in clinical development and the implications in design of biologic therapeutics
- **Enhance** your understanding on how to best evaluate read outs for immune response

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**PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS**  
Wednesday 16th July, Holiday Inn Regents Park, London, UK

## A: Clinical Impact of Immunogenicity and Predictive Tools

Workshop Leader:

**Melody Sauerborn**, Senior Expert Immunogenicity, **TNO Triskelion**

8.30am - 12.30pm

## B: Immunogenicity of Biosimilars

Workshop Leaders:

**John Chappell**, Head of Immunoassay, **CPR Pharma Services**

**Bracha Timan**, Head of Global Bioassays and Technology,  
**Teva Pharmaceuticals Ltd**

1.30pm - 5.30pm

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8.30 Registration & Coffee

9.00 **Chairman's Opening Remarks**  
**Matthew Baker**, Chief Scientific Officer, **Antitope**

## ASSESSING EARLY RISKS IN IMMUNOGENICITY

### OPENING ADDRESS

9.10 **Understanding Immunogenicity!**

- Defining immunogenicity and what it's all about
- Immunogenicity from an immunological point of view
- Immunological tolerance and how to break it
- Evaluating immunological response and the reasons for immunogenicity
- Assessing the factors affecting immunogenicity – Where do we go from here?

**Melody Sauerborn**, Senior Expert Immunogenicity, **TNO Triskelion**

9.50 **Practical considerations in the evaluation & implementation of immunogenicity cut-points for clinical trials**

- Cut-point evaluations during method validation entail some important assumptions & challenges
- These include sample selection, quality controls, outliers, variability differences, method robustness, population extensions, etc
- Simpler and robust evaluation process is proposed, ways to verify assumptions, adaptively changing sampling design and evaluation, etc

**Viswanath Devanarayan**, Global Head, Exploratory Statistics, **AbbVie Inc.**

10.30 Morning Coffee

11.00 **Tregitopes an Immunomodulation Powerhouse: Regulating Immune Responses to Biologics**

- Modulation of T cell responses in the context of protein therapy and inflammation may contribute to the design of improved biologic therapeutics for a wide range of clinical conditions.
- A critical flaw in most predictions of immunogenicity is the failure to factor regulatory T cell epitopes (Tregitopes) into the assessment
- The presenter will provide several case studies that validate the critical importance of Tregitopes to biologics, including but not limited to protein replacement therapies, blood factor replacement therapies, monoclonal antibodies as well as mitigation of auto-inflammatory and autoimmune responses

**Anne De Groot**, CEO/CSO, **EpiVax Inc**

11.40 **Inducing immunological tolerance – reviewing the flip side**

- Reviewing the problem of immunogenicity and asking why a protein is immunogenic in certain individuals and not others?
- What do we understand about immunological tolerance?
- Can proteins be modified to become less immunogenic?
- Designing peptides that switch off immune responses and promote tolerance

**David Wraith**, Professor of Experimental Pathology, **University of Bristol**

12.20 Networking Lunch and Poster Presentation Session

## TOOLS FOR CONSIDERATION AND DESIGN OF BIOLOGIC THERAPEUTICS

1.30 **Human In Vitro models to assess Immunogenicity**

- The application of human In Vitro models during early drug development
- Technical challenges and standardisation of In Vitro models
- Relevance of In Vitro models

**Chloe Ackaert**, Scientific Researcher, **University of Salsburg**

2.10 **Identifying and removing T cell epitopes in immunotoxins**

- Immunotoxins are therapeutic proteins that are used to treat cancer. Immunogenicity is their main stumbling block in the clinic
- Assessing comprehensive experimental methods to identify and eliminate the T cell epitopes in the immunotoxin
- Designing a new immunotoxin that has significantly diminished T cell immunogenicity and yet an excellent anti-tumor effect

**Ronit Mazor**, Research Fellow, **National Cancer Institute, National Institutes of Health**

2.50 **Generation of non-immunogenic proteins with full biological activity**

- Many factors either associated with the product, patient, route of delivery or formulation etc. can contribute to immunogenicity but CD4+ T cell epitopes are the principal drivers of immunogenicity in vivo
- Frequency of CD4+ T cell response in ex vivo human T cell assays such as EpiScreen™ gives good correlation with clinical-stage ADA thus providing an important tool for protein engineering
- Deimmunisation of antibodies and proteins focuses on removal of peptide binding to human MHC class II; can be supplemented by other strategies
- CD4+ T cell epitopes can be successfully removed from complex non-human proteins whilst minimising loss of activity

**Matthew Baker**, Chief Scientific Officer, **Antitope**

3.30 **Afternoon Tea**

**Topic: What are the fundamental aspects of the mechanisms of tolerance?**

ROUND TABLE DISCUSSION

4.00 **Nanoparticles for the Induction of Immunological Tolerance**

Selecta has developed biodegradable nanoparticles capable of inducing antigen-specific immune tolerance

- We have demonstrated inhibition of anti-drug antibodies to biologic therapies, such as Factor VIII and adalimumab, resulting in improved efficacy and safety in animal models
- Tolerogenic nanoparticle technology can be applied to existing biologic drugs as part of a lifecycle management strategy to maintain or enhance market share and to novel drugs in development to improve probability of success and differentiate from competitors

**Takashi Kei Kishimoto**, Chief Scientific Officer, **Selecta Biosciences Inc.**

4.40 **Chairman's Closing Remarks and Close of Day One**

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**Antitope** is a leading provider of solutions to enable the development of better biopharmaceuticals. Our mission is to apply these technologies as a comprehensive service for the preclinical prediction of immunogenicity, and for the generation of non-immunogenic fully humanized antibodies, non-immunogenic therapeutic proteins and high yielding manufacturing cell lines. To date, we have entered into multiple agreements with pharmaceutical and biotechnology companies worldwide to apply our technologies for the development of improved biologics. Following its recent merger with PolyTherics Ltd., we now provide an extensive suite of technologies for development of more homogeneous and stable antibody drug conjugates (ADCs) through ThioBridge™, site-specific PEGylation and low viscosity polymers.

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8.30 Registration & Coffee

9.00 Chairpersons Opening Remarks  
**Martin Lechmann**, Development DMPK Project Leader, **Roche**

### CLINICAL IMPLICATIONS AND OUTCOMES

#### OPENING ADDRESS

9.10 **Case Studies on Pre-Existing Antibodies**

- Pre-existing antibodies in treatment-naïve subjects have been often detected during clinical ADA assessments. However, limited information on prevalence, physiological effect, and impact on post-treatment ADA induction is available
- This talk will address pre-existing antibody characterization and implications for immunogenicity management and strategies during clinical studies

**Thomas Lee**, Scientific Investigator, Clinical Immunology, **GSK**

#### KEYNOTE ADDRESS

9.50 **Case Study: Immunogenicity testing for Biosimilars - One assay versus two assays**

- Assessing the implications of screening of early compounds
- Evaluating the consequences of immunogenicity in clinical development testing
- Assessing strategies and considerations for clinical trial design

**Robert Dodge**, Associate Director, **BMS**

10.30 Morning Coffee

### IMMUNOGENICITY OF BIOSIMILARS

11.00 **Immunogenicity testing for Biosimilars - One assay versus two assays - A case study**

- Immunogenicity is one major hurdle in the development of Biosimilars
- There is an ongoing debate about if one has to develop and validate dedicated immunogenicity assays for the Originator and the Biosimilar or if one assay can be employed
- The talk will present the approach Merck Serono is currently using for their Biosimilar program

**Daniel Kramer**, Associate Director, Project Representative NBE, **Merck Serono**

11.40 **Immunogenicity Analytical considerations when supporting Biosimilar Drug Development**

- Presentation will assess what Immunogenicity assays that need to be developed in support of Biosimilar Clinical Development
- Some of the considerations include choice of methodology, Development of 1 Assay v 2 Assays, Positive controls, Neutralising Assays
- Presentation will include case study data

**John Chappell**, Head of Immunoassay, **CPR Pharma Services**

12.20 Networking Lunch and Poster Presentation Session

### IMMUNOGENICITY DEVELOPMENTS

#### KEYNOTE ADDRESS

1.30 **Insight into the development of Biologic Therapeutics**

- Understanding the principles of immunogenicity testing during product development
- Reviewing the pharmacokinetic and efficacy effects of biologic therapeutics

**Martin Lechmann**, Development DMPK Project Leader, **Roche**

PART 2

2.10 **Novel Methods to Induce Tolerance for Adverse Immune Reactions**

- Immune tolerance mechanisms versus reducing immunogenicity
- Application of B cell presentation for tolerance
- Fc fusion proteins and the role of IgG epitopes
- Application of specific T regulatory cells to control immune responses

**David Scott**, Professor and Vice Chair for Research, **Uniformed Services University of Health Science**

2.50 **Afternoon Tea**  
**Topic: Do you fight antibodies with antibodies?**

ROUND TABLE DISCUSSION

3.20 **Predictive/preclinical Immunogenicity Risk Mitigation: Sense and non-sense**

- Unwanted immunogenicity is a critical hurdle during drug development
- Assessing immunogenicity at an early stage can significantly reduce the risk of failure later on
- Standardisation and regulation of early assessment tools

**Philippe Stas**, Consultant, **BLA Consult**

4.00 **Predictability using pre-clinical tools**

- What is classed as important in the decision making process?
- Is the replacement of animals a way of assessing immunogenicity?
- How important are cell based assays when assessing neutralisation of ligand binding assays?
- Evaluating the translation value and whether a minimal approach should be utilised up until phase II/III

**Chloe Ackaert**, Scientific Researcher, **University of Salsburg**  
**Ronit Mazor**, Research Fellow, **National Cancer Institute, National Institutes of Health**  
**David Scott**, Professor and Vice Chair for Research, **Uniformed Services University of Health Science**

PANEL DISCUSSION

4.40 Chairman's Closing Remarks and Close of Day Two

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## HALF-DAY POST-CONFERENCE WORKSHOP A

Wednesday 16th July 2014 | 8.30am – 12.30pm  
Holiday Inn Regents Park, London, UK

### Clinical Impact of Immunogenicity and Predictive Tools

Workshop Leader:

**Melody Sauerborn**, Senior Expert Immunogenicity,  
TNO Triskelion

#### Overview of workshop:

This workshop will focus on the clinical impacts of immunogenicity on safety and efficacy with example cases. In addition, Immunogenicity strategies during clinical stages will be discussed including the risk-assessment of biologics. A short intro into bioassays and the importance to measure neutralizing antibodies will be presented. Last, but not least current overview of predictive immunogenicity tools will be given and the question, "What translational value do the data from preclinics have to the clinical situation?" will be discussed.

#### Key Benefits of Attending:

This workshop will bring all of the aspects of immunogenicity learned during the conference in perspective with a focus on clinical impacts of immunogenicity.

#### Programme:

- 8.30 Registration and coffee
- 9.00 Immunogenicity: Overview Clinical Impacts
- 9.30 The tiered approach
- 10.30 Coffee Break
- 11.00 The risk assessment approach and what that means for each clinical phase
- 11.30 Translational value of preclinical data
- 12.30 Close of Workshop

#### About the workshop host:



Dr. Sauerborn spent most of her undergrad years in well-known institutes such as the Centers for Disease Control and Prevention in Atlanta to widen her knowledge in immunology. After acquiring her Masters in Science she joined the lab of Prof. Schellekens and Prof. Jiskoot, two experts in immunogenicity of protein drugs, to shed more light on the immunological aspects of antibody formation against aggregated protein therapeutics. After obtaining her PhD she started a spin-off, ADA InVivo BV, a biotech CRO in the field of drug safety. Currently she is a project leader, trainer and senior expert in immunogenicity at the bioanalysis and immunogenicity department at TNO Triskelion BV, a Dutch CRO.

**Immunogenicity of Biosimilars**

Workshop Leader:  
**John Chappell**, Head of Immunoassay,  
CPR Pharma Services

**Overview of workshop:**

The workshop will explore the analytical requirements for developing and validating assays in support of Preclinical and Clinical Biosimilar Drug Development. The main focus will be on the Immunogenicity assay requirements but the requirements for PK and Biomarker assays will also be discussed. This will be detailed analysis of both the regulatory and clinical requirements for immunogenicity assessment. The workshop will present Case studies on how assays have been developed and validated in support of Biosimilar drug Development.

**Why you should attend:**

- To get an understanding of the clinical and regulatory considerations for immunogenicity assessments
- To get an understanding on how immunogenicity assays can be developed and validated for Biosimilar Drug development
- See data from actual Case Studies

**Programme:**

- 1.30 Registration and coffee**
- 2.00 Importance of immunogenicity Assessments**
  - Clinical Considerations
- 2.30 Immunogenicity Rates for the originator**
  - PK Profile
  - Disease populations
  - Risk Based strategy
- 3.00 Afternoon Tea**
- 3.30 Regulatory Guidances and White Papers**
  - EMA and FDA Guidances
  - Industry White Papers
  - AAPS Biosimilar APC committee
- In-vitro Immune Stimulation Assays**
- Screening and Confirmatory Assays**
  - What Assays to use
  - Development of 1 Assays v 2 Assays
  - Positive Control Selection
  - Calculation of Cut Points
  - Statistical Requirements (do you need a Biostatistician?)
  - Drug Tolerance
  - Sensitivity
  - Stability
- Neutralising Assays**
  - Choice of Assays
  - Functional Assays v Competition Ligand Binding
- 4.30 PK Assays in support of Biosimilar Development**
  - Biomarker Assays in support of Biosimilar Development
- 5.30 Close of Workshop**

**About the workshop host:**

Prior to joining CPR Pharma Services, John Chappell worked for more than 20 years with leading CROs in both, Europe and North America. As a leading expert in ligand binding assay development, validation and implementation, John is a member of the AAPS Committee that is preparing white papers on biosimilar bioanalytical support, including pharmacokinetic analysis and immunogenicity assessments.

A highly experienced professional, John leads a team of analytical scientists providing a ligand binding assay service for biomarkers, monoclonal antibodies, biosimilars and biologics in early and late phase clinical trials.

# IMMUNOGENICITY

CONFERENCE: 14TH – 15TH JULY 2014, HOLIDAY INN REGENTS PARK, LONDON, UK | WORKSHOPS: 16TH JULY 2014, LONDON

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