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SMi Present the 3rd Annual Conference on...

Immunogenicity

Holiday Inn Kensington Forum, London, UK

13 - 14
JUNE
2016

**Accelerating commercialisation of your
next gen biotherapeutics – adopt advanced
immunogenicity assessments for successful
regulatory approval**

Chairs for 2016:



Annie De Groot,
CEO and CSO,
EpiVax, Inc.



Adnan Khan,
Senior Scientist Immunology/Pharmacology,
UCB

Featured Speakers:

- **Meenu Wadhwa**, Section Leader, Cytokines and Growth Factors, NIBSC, **MHRA**
- **Kei Kishimoto**, Chief Scientific Officer, **Selecta Biosciences**
- **Daniel Sikkema**, Executive Director, Head of Immunogenicity and Clinical Immunology, **GlaxoSmithKline**
- **Jochem Gokemeijer**, Associate Director, **Bristol-Myers Squibb**
- **Tim Hickling**, Immunogenicity Sciences Discipline Lead, **Pfizer**

Key Sessions:

- **MHRA: Towards harmonisation of immunogenicity assays**
- **Integration of immunogenicity risk data to forecast clinical outcomes**
- **A harmonised approach to interpretation and reporting of clinical immunogenicity data**
- **Development and validation of cell based antibody neutralisation assays**

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PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS
Wednesday 15th June 2016, Holiday Inn Kensington Forum, London, UK

A: Approaches to standardising assays for measuring drug levels and anti drug antibodies to biotherapeutics in clinical practice

Workshop Leaders:

Hishani Kirby, Founder and Director, **Hishani Kirby Associates Ltd**
Daniel Sikkema, Executive Director, Head of Immunogenicity
and Clinical Immunology, **GlaxoSmithKline**

08.30 – 12.30

B: Unwanted immunogenicity from bench to bedside

Workshop Leaders:

Arno Kromminga, CEO/CSO, **IPM Biotech**
Sofie Pattijn, Chief Technology Officer, **ImmunXperts**

13.30 – 17.30

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Immunogenicity

Day One | Monday 13th June 2016

08.30 Registration & Coffee

09.00 **Chairman's Opening Remarks**
Annie De Groot, CEO and CSO, **EpiVax, Inc.**

OPENING ADDRESS

09.10 **Improving the efficacy and safety profile of biotherapeutics by addressing product immunogenicity with tolerogenic nanoparticles**

- The development of anti-drug antibodies (ADAs) is a common cause for treatment failure and adverse events associated with biologic therapies.
- Addressing product immunogenicity has the potential to improve efficacy and safety profile of novel biologics; reduce catastrophic late stage clinical failure due to ADAs; provide life cycle management for existing products; and differentiate products from biosimilars.
- Selecta Biosciences is a clinical stage company that has developed a novel platform of Synthetic Vaccine Particles (SVP) to induce durable antigen-specific immune tolerance for the prevention of ADAs

Kei Kishimoto, Chief Scientific Officer, **Selecta Biosciences**

09.50 **Redefining the well-defined: unwanted immune responses**

- What is an unwanted immune response?
- What can we define as tolerance?
- Therapeutic innervation and innovation

Adnan Khan, Senior Scientist Immunology/Pharmacology, **UCB**

10.30 Morning Coffee

EXPLORING IMMUNOGENIC ASSESSMENT TECHNIQUES

11.00 **A harmonised approach to interpretation and reporting of clinical immunogenicity data**

- How can we harmonise data?
- Should we be able to compare trial results that use different ranking methods
- The benefits a harmonised approach can bring to the reporting of clinical immunogenicity data

Daniel Sikkema, Executive Director, Head of Immunogenicity and Clinical Immunology, **GlaxoSmithKline**

KEYNOTE ADDRESS

11.40 **Towards harmonisation of immunogenicity assays**

- Wide variation in ADA incidence and titres often reported for a therapeutic
- Should we produce reference panels or standardise methods to harmonise data?
- Availability of a WHO reference panel for erythropoietin antibody assays

Meenu Wadhwa, Section Leader, Cytokines and Growth Factors, **NIBSC, MHRA**

12.20 Networking Lunch

13.20 **Immunogenicity risk assessment tools for biologics**

- Immunogenicity risk assessment tools to inform biologics development programs
- Utilisation of immunogenicity tools to guide critical quality attributes (CQA) for product attributes
- Challenges in clinical validation of immunogenicity risk assessment

Jochem Gokemeijer, Associate Director, **Bristol-Myers Squibb**

NEXT GENERATION BIOLOGICS

14.00 **Integrating best-in-class in vitro and ex vivo assays to manage immunogenicity risk in biologics**

- Learn how data from cell-based assays, physical MHC-peptide binding assays and mass spectrometry antigen presentation assays can be integrated to characterize immune responses against, or caused by, biotherapeutic drugs
- Mitigate the risk of first infusion reactions using whole-blood cytokine release assay
- Improve decision-making in lead selection, lead characterisation and re-engineering options

Jeremy Fry, Director of Sales, **ProlImmune Ltd.**

14.40 Afternoon Tea

15.10 **Nanobodies, a promising new class of biopharmaceuticals. What about their immunogenicity?**

- Nanobodies originate from camelids, but does their humanisation make sense?
- Different methods for anti-drug antibodies (ADA) assessment towards nanobodies
- In vitro immunogenicity risk assessment of nanobodies

Chloé Ackaert, Postdoctoral Researcher, **Free University of Brussels**

15.50 **Understanding the role of aggregation in the immunogenicity of biotherapeutic proteins**

- Comparison of the immunological responses to immunisation with recombinant biologics in monomeric and aggregated forms in a mouse model
- The results were generally indicative of skewing towards a Th1-type response
- Can HCPs also play a role in modulating the immune response?

Jeremy Derrick, Professor, **University of Manchester**

16.30 **Chairman's Closing Remarks and Close of Day One**
Annie De Groot, CEO and CSO, **EpiVax, Inc.**

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Abzena offers a suite of complementary services and technologies. Its range of technologies include immunogenicity assessment, antibody drug conjugation, protein engineering, PEGylation, cell line development, GMP manufacturing and a range of bespoke assays to enable the development of better biopharmaceuticals which will have a greater chance of reaching the market.

www.abzena.com

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08.30 Registration and Coffee

09.00 **Chairman's Opening Remarks**

Adnan Khan, Senior Scientist Immunology/Pharmacology, **UCB**

OPENING ADDRESS / KEYNOTE ADDRESS

09.10 **Development and validation of cell based antibody neutralisation assays**

- Examples of validation of cell based neutralisation assays
- Their application to release / stability testing of vaccines
- Consideration of the assay life cycle

Sue Charlton, Scientific Lead, Vaccine Research Group, **Public Health England**

09.50 **Integration of immunogenicity risk data to forecast clinical outcomes**

- Immune responses to biologics as a normal response to drug exposure
- Identifying key risk factors for immunogenicity
- Working with protein engineers to reduce immunogenicity of biotherapeutics
- Utilising non-clinical assays for immunogenicity assessment

Tim Hickling, Immunogenicity Sciences Discipline Lead, **Pfizer**

10.30 Morning Coffee

A CLOSER LOOK AT ADAPTIVE T CELLS

11.00 **Influence of aggregates on in vitro T cell responses**

- Immunogenicity of therapeutic protein products can elicit unwanted ADA
- Protein aggregation can result in enhanced immunogenicity
- In vitro methods that measure the impact of these aggregates on enhanced immunogenicity will be useful tools in screening processes to avoid or reduce problems associated with ADA

Mark Fogg, Immunology Group Leader, **Abzena**

11.40 **T-cell amplification assays for immunogenicity prediction: T-cell repertoire and epitopes**

- Why are T cell assays performed to predict immunogenicity?
- What kind of data do they produce?
- Do they have been already confronted to clinical observations?
- Are they really useful as compared to other predictive approaches?

Machteld Tiemessen, Senior Scientist, **Janssen**

12.20 Networking Lunch

INNOVATIONS IN IMMUNOGENICITY

13.20 **Correlation of T-cell responses induced by therapeutic cancer vaccines with clinical responses**

- In premalignant disease caused by high risk HPV, therapeutic vaccination-induced T-cell responses correlate with clinical responses
- In late stage HPV-induced cancer myeloid cell depletion by standard chemotherapy fosters robust vaccine-induced T cell responses
- Therapeutic vaccines works as monotherapy in pre-malignant disease, but treatment of late stage cancer requires combination of vaccination with immunomodulation

Kees Melief, Chief Scientific Officer, **ISA Pharmaceuticals**

Ronald Loggers, Chief Executive Officer, **ISA Pharmaceuticals**

14.00 **A computational pipeline for personalised cancer vaccine development**

- Checkpoint inhibitors are changing cure rates for cancer and generating excitement in the cancer field
- While cure rates are improving, personalised cancer vaccines may improve cure rates even further
- Personalised cancer vaccines are feasible using available computational tools
- Participants will learn how personalised cancer vaccines will move the needle on cancer cures of the future

Annie De Groot, CEO, **EpiVax**

14.40 Afternoon Tea

15.10 **Immunogenicity of biosimilar monoclonal antibodies**

- Unexpected immunogenicity linked to biosimilar monoclonal antibodies
- The challenge of assessing similarity between originator and biosimilar mAb
- Developing a characterisation strategy for proving comparability with biosimilars

Andreas Herrmann, CEO, **Baliopharm AG**

15.50 **Protein aggregates: Why do we need to study them? Quantification and characterisation of sub-visible particles in protein therapeutics**

- Biopharmaceutical and problems never seen with non-protein substances
- Protein aggregates structure and function
- Strategy in analysis and characterization of protein aggregates

Mantas Malisauskas, Manager R&D, **Baxalta**

16.30 **Chairman's Closing Remarks and Close of Day Two**
Adnan Khan, Senior Scientist Immunology/Pharmacology, **UCB**

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**A: Approaches to standardising assays
for measuring drug levels and anti drug
antibodies to biotherapeutics in
clinical practice**

Workshop Leaders:

Hishani Kirby, Founder and Director,
Hishani Kirby Associates Ltd

Daniel Sikkema, Executive Director, Head of Immunogenicity
and Clinical Immunology, **GlaxoSmithKline**

Overview of Workshop:

The assay requirements for rapid decision making with licenced biotherapeutics in clinical practice can be very different from the best practice applied during regulated studies. The growing trend for therapeutic drug monitoring (TDM) with biotherapeutics has highlighted the need for harmonisation of assays and associated data throughout the lifecycle of a given drug.

In this workshop, an overview of historical approaches to validating methods to quantify biopharmaceuticals and to detect, monitor, and characterise anti-drug antibodies will be presented. The current best practices, terminology, and future insights for standardisation of methods and associated technological developments will be discussed.

You will be able to learn about the latest trends and developments for quantifying biotherapeutics and monitoring anti-drug antibodies will be presented in the context of assay harmonisation, associated challenges and possible solutions.

Programme:

08.30	Registration
09.00	Workshop Leaders Introduction
09.10	Overview of historical approaches for drug and ADA measurement: Fit for purpose? • Which format? • What are the parameters? • Constraints and challenges
10.30	Morning Coffee
11.00	Looking beyond – technological developments • Future standardisation of methods • Advanced quantification techniques for biopharmaceuticals and application on immunogenicity • Associated challenges and solutions
12.00	Q&A
12.30	End of Workshop

About the Workshop Leader:

Hishani Kirby, PhD, Founder and Director,
Hishani Kirby Associates Ltd

With over 25years in the biopharmaceutical industry, Hishani has gained wide experience in the development of biopharmaceutical products. This has been mainly with Mab and Mab-based fragments, where she has utilised her extensive protein analytical and bioanalytical expertise, in the characterisation and measurement of complex biotherapeutics. Hishani first established her career at Celltech in Mab therapeutics and then joined UCB, where she was responsible for providing expert guidance on bioanalytical strategy in PK, PD and immunogenicity in support of the company's portfolio from discovery through to post licencing phases of development, as well as leading the team responsible for execution of analytical and bioanalytical services.

More recently, Hishani has formed her own consulting company providing expertise in scientific aspects of bioanalysis, immunogenicity risk assessment and testing strategies, and in regulatory considerations in biopharmaceutical development. Her strengths are in designing and implementing practical/ innovative analytical solutions to enable rapid decision making through development to post license life cycle management.

Daniel Sikkema, Executive Director, Head of Immunogenicity and Clinical Immunology, **GlaxoSmithKline**

Dan joined GlaxoSmithKline (GSK) as Executive Director and Head of the Clinical Immunology group in BioPharm R&D in August 2010. Prior to this, he had held various positions of increasing responsibility at Bristol-Myers Squibb, Wyeth Vaccines, Merck Vaccines and Biologics, and Sanofi Pasteur. Dan has contributed to the clinical immunology and microbiology assessments leading to licensure of Prev(e)nar, Meningitec, Gardasil, Rotavax, ProQuad, and Zostavax, and has worked extensively with the WHO, US Centers for Disease Control, National Institute for Biological Standards and Controls, US FDA, and EMA. Now at GSK he is heading the Immunogenicity and Clinical Immunology group assessing immunogenicity of administered biotherapeutics and the quantitation of target-engaged biomarkers in the clinical setting, as well as leading the Innovative Medicines Initiative (www.abirisk.eu) to further understand the underlying mechanisms and basic biology around induction of immunogenicity to biotherapeutics and their clinical relevance. July 1, 2015, he assumed the Chair Elect position for Division V at American Society for Microbiology.

B: Unwanted immunogenicity from bench to bedside

Workshop Leaders:

Arno Kromminga, CEO/CSO, IPM Biotech
Sofie Pattijn, Chief Technology Officer, ImmunXperts

Overview of Workshop:

This workshop will give an insight on the rapid growing field of unwanted immunogenicity and the science behind it. The immunology of an unwanted immune response will be addressed and discussed. Also, an overview of the tools for early immunogenicity assessment will be given. Finally, the emerging trends and clinical impact of neutralising anti-drug antibodies will be discussed followed by a summary of the lessons learned and future challenges.

Programme:

13.30	Registration
14.00	The immunology of immunogenicity
14.45	Tools for early non-clinical immunogenicity assessment
15.30	Afternoon Tea
16.00	Neutralising anti-drug antibodies: Emerging trends and clinical impact
16.45	Lessons learned and future challenges
17.20	Closing remarks
17.30	Close of workshop

About the Workshop Leaders:

Dr Arno Kromminga is currently CSO of GLP-certified IPM Biotech. In addition, he is a faculty member at the Institute of Immunology at the University of Kiel. He studied Biochemistry and Immunology and has 20+ years experience in assay development, is author of multiple publications in peer-reviewed journals and books and is a co-founder and board member of the European Immunogenicity Platform (EIP). He and his team have developed and validated numerous immunological binding and cellular functional assays for immunogenicity testing and PK/PD analysis for pre-clinical and clinical studies. His major interest besides the validation of assays, is the interpretation of results to obtain clinically meaningful data

Sofie Pattijn (CTO, ImmunXperts) has over 20 years of experience in the field of immunogenicity assessment (vaccines and biotherapeutics). She has extensive hands-on lab experience and has managed and coached several In Vitro teams over the last decade. From 2008 till 2013 she was Head of the In Vitro Immunogenicity group at AlgoNomics (Ghent, Belgium) and Lonza Applied Protein Services (Cambridge, UK). Prior to that, she worked at Innogenetics, Belgium for over 15 years.

IMMUNOGENICITY

Conference: Monday 13th & Tuesday 14th June 2016, Holiday Inn Kensington Forum, London, UK

Workshops: Wednesday 15th June 2016, London, UK

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