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SMi presents the 6th Annual Conference on...

Antibodies and Antibody Drug Conjugates

Facilitating commercial success through updates on recent breakthroughs

CONFERENCE: 9TH -10TH
WORKSHOPS: 11TH

APRIL 2018

COPTHORNE TARA HOTEL, LONDON, UK

CHAIRS FOR 2018:

Mahendra Deonarain, Chief Executive and Scientific Officer, **Antikor Biopharma**

Rakesh Dixit, Vice President and Global Head Biologics Safety Assessment, **Medimmune**

KEY SPEAKERS INCLUDE:

- **Robert Lyon,** Senior Director, **Seattle Genetics**
- **Arnaud Tiberghien,** Scientist II, **Spirogen**
- **Alison Betts,** Associate Research Fellow, **Pfizer**
- **Thomas Pillow,** Senior Scientist, **Genentech**
- **Andreas Pahl,** CSO, **Heidelberg Pharma**
- **Carlo Boutton,** Director of Technology, **Ablynx**

HIGHLIGHTS IN 2018:

- Learn about the implementation of superior technologies to develop more effective and efficient **Antibody Drug Conjugates**
- Discover new and novel **payloads,** e.g. **Antibody Targeted Amanitin Conjugates (ATACs)** and **minor-groove binding DNA-interactive molecules as ADC payloads,** to expand the ADC landscape
- Discuss the practicalities of the use of **Highly Potent Active Pharmaceutical Ingredients**
- Refine the practice of using **fragment conjugates** in order to develop a tailored **therapy for solid tumours**
- Design principles for maximising the drug delivery **efficiency** and **therapeutic index**

PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS | WEDNESDAY 11TH APRIL 2018, COPTHORNE TARA HOTEL, LONDON, UK

A: ADCs from early development into first-in-human studies

Workshop Leader:
Peter Bach, Biotechnology Consultant, BioPharmaLogic
08.30 - 12.30

B: Recombinant Antibodies – structure, function and drug development

Workshop Leaders:
Dr Mahendra Deonarain, CEO & CSO, Antikor Biopharma Ltd
Prof Kerry Chester, Professor of Molecular Medicine, UCL
13.30 - 17.30

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Antibodies and Antibody Drug Conjugates

Day One | Monday 9th April 2018

www.adcsummit.com

8.30 Registration & Coffee

9.00 **Chairman's Opening Remarks**

Rakesh Dixit, Vice President, R&D, Global Head, Biologics Safety Assessment, **MedImmune Inc**

PK-PD AND TECHNOLOGICAL ADVANCEMENTS

9.10 **Use of modelling and simulation to compare new generation HER-2 ADCs with Kadcyla™: a focus on PK and efficacy**

- Kadcylaä is a HER-2 ADC approved in 2013 for patients with HER2+ metastatic breast cancer
- Kadcylaä is only efficacious in high HER2 tumors and patients are acquiring resistance
- New generation HER-2 ADCs are being designed to overcome these limitations
- PK/PD methodologies for efficacy and safety differentiation will be presented
- For PK predictions a mechanistic target mediated drug disposition model is proposed accounting for binding to shed HER-2 extracellular domain and variability across patients

Alison Betts, ADC Scientist, **Pfizer**

9.50 **Application of a PK-PD Modeling & Simulation in Antibody-Drug Conjugate Development**

- Preclinical to clinical translation
- Bystander effect of ADCs
- Binding site barrier of ADCs
- Cell-level pharmacokinetics of ADCs

Aman Singh, PK-PD Scientist, **Janssen**

10.30 **Morning Coffee**

11.00 **GlycoConnect™ and HydraSpace™ technologies for superior Antibody-Drug Conjugates**

- Head-to-head comparison demonstrates superiority of Glycan-Conjugated ADCs (GlycoConnect™) versus mainstream technologies
- Readily adaptable HydraSpace™ enables highly hydrophobic payloads, dual warhead ADCs and further expands TI
- Decomposition of Parameters Contributing to the Improved Therapeutic Index
- GlycoConnect™ and HydraSpace™

Sander van Berkel, Director R&D Operations, **Synaffix**

ADC PAYLOADS

11.40 **Antibody Targeted Amanitin Conjugates (ATACs) - Expanding the ADC landscape with a new payload targeting RNA Polymerase II**

- Antigen-Targeted Amanitin-Conjugates (ATACs) represent a new class of ADCs using the payload Amanitin
- This payload introduces a novel mode of action into oncology therapy, the inhibition of RNA polymerase II
- The technology platform includes Amanitin supply, site-specific conjugation, demonstrated safety profile and biomarker
- HDP-101 is the first ATAC directed against BCMA entering Phase I trials by the end of 2018

Andreas Pahl, CSO, **Heidelberg Pharma**

12.20 **Networking Lunch**

13.30 **CBI and PBD dimers as payloads for Antibody-Drug Conjugates**

- Structure-based drug design for ADCs
- Location of linker attachment and immolation can be important for conjugate activity
- Impact of payload and linker on both efficacy and toxicity

Thomas Pillow, Scientist, **Genentech, Inc.**

14.10 **PBDs - update on an efficient and effective payload class**

- A potent and flexible class of ADC payloads and their industrial processing viability
- Whether or not PBDs make better payloads than others
- The clinical progress and current uses of PBDs with case study examples
- New PBD payloads in developments. Consequences on mode of action, efficacy and tolerability

Arnaud Tiberghien, Scientist II, Chemistry, **Spirogen**

14.50 **Afternoon Tea**

15.20 **Minor-groove binding DNA-interactive molecules as ADC Payloads - the impact of sequence-selectivity and mono-alkylation versus cross-linking**

- The impact of mono-alkylation versus intra- and interstrand cross-linking mechanisms of action on the in vitro and in vivo efficacy and toxicity of ADC payloads and ADCs.
- Is there an opportunity to match the sequence-selectivity of DNA-interactive payloads to the genetic profiles of tumour types?
- Is there an opportunity to improve the therapeutic window of ADCs by "tuning" the mechanism of action and sequence-selectivity of the payload?

David E. Thurston, Professor of Drug Discovery, **King's College London**

HIGHLY POTENT INGREDIENTS AND SUPPLY CONSIDERATIONS

16.00 **Highly Potent APIs (HPAPIs) in ADC projects**

- ADC toxicants in the context of pharma HPAPIs
- Other ADC component hazards
- Health and safety project elements in designing and delivering hpapi projects
- Risk assessment, risk communication and risk management

Justin Mason-Home, Director, **HPAPI Project Services Limited**

16.40 **Novasep's integrated solutions for ADCs**

- Simplifying the supply chain through an integrated offer
- Design considerations of a dedicated conjugation facility
- Novasep's strengths for ADCs: case studies

Francois D'Hooge, Head of Bioconjugation, **Novasep S A S**

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

Register online at www.adcsummit.com

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8.30 Registration & Coffee

9.00 Chairman's Opening Remarks

Mahendra Deonarain, Chief Scientific and Operating Officer, **Antikor Biopharma Ltd.**

WARHEADS AND SITE SELECTIVITY

9.10 Guided warhead loaded missiles of ADCs in fight against deadly cancers: challenges and opportunities

- Five Rights of creation of the best optimized fit-for-purpose ADCs
- Target, linker, warhead selection: Dos and Don'ts
- Internalisation of ADCs – how to improve internalization, lysosomal delivery and intracellular target hit
- Increasing the effectiveness of the ADCs by effective tumor targeting minimising the off-target toxicity of ADCs

Rakesh Dixit, Vice President, R&D, Global Head, Biologics Safety Assessment, **MedImmune Inc**

9.50 Site-selective ADCs by disulfide bridging

- Site-selective ADCs offer the prospect of improved Therapeutic Indexes over traditional heterogeneous conjugation approaches, and are likely to form the basis of next generation ADCs
- Can achieve such site-selectivity by targeting the four interchain disulfide bonds (in IgG1s), using bridging reagents which reconnect the two cysteine residues
- We describe the development of Next Generation Maleimide reagents, and the related Pyridazinediones, as optimised platforms for ADCs constructed in this way

Jamie Baker, Chemistry Lecturer, **University College London**

10.30 Morning Coffee

FRAGMENT DRUG CONJUGATES AND THERAPEUTIC WINDOWS

11.00 Antibody Fragment Drug Conjugates (FDCs): A tailored therapy for solid tumours

- Discovery of antibody fragments specifically designed for FDCs
- Manufacture of FDCs and payload screening
- In vivo pharmacokinetics and tumour cure efficacy in gastric cancer models
- Rodent models for toxicology and tolerability

Mahendra Deonarain, Chief Scientific and Operating Officer, **Antikor Biopharma Ltd.**

11.40 Design principles for maximizing the drug delivery efficiency and therapeutic index of ADCs

- The conjugation of drug-linkers to an antibody can result in increased nonspecific uptake and catabolism in healthy tissues
- This phenomenon has two potential negative consequences - unintended delivery of the drug to non-target tissues, and diminished exposure of the tumor to the ADC
- Careful design of the drug-linker can minimize this effect in preclinical models, with demonstrable decreases in drug concentrations in normal tissues paired with maximal delivery to the tumor
- Toxicology and xenograft studies indicate that the optimized design both decreases off-target toxicity and improves antitumor activity, and we are currently planning to evaluate this design clinically with an anti-CD48 antibody for patients with multiple myeloma

Robert Lyon, Senior Director Protein Sciences, **Seattle Genetics Ltd**

12.20 Networking Lunch

IMMUNO-ONCOLOGICAL COMBINATION THERAPIES

13.30 Precision cancer therapy ADCs with novel target, antibody and cancer toxin technologies

- Selection of novel ADC cancer targets in the post-genomics era
- Improved efficacy by optimizing targets to ADC technologies
- Target Selection criteria - how to choose the best target for your specific need

Jim Ackroyd, Therapeutic Target Manager, **Oxford BioTherapeutics Ltd**

14.10 Anthracycline-based antibody drug conjugates with potent immune-stimulatory functions

- Site-specific conjugation using sortase enzyme (SMAC™ Technology), yielding homogenous ADCs
- Highly potent payload, providing access to difficult-to-address targets
- Anthracycline-based payload with attractive IO properties

Roger Beerli, CSO, **NBE Therapeutics**

14.50 Afternoon Tea

15.20 The use of Nanobody formatting to improve immune-oncology therapeutics

- Small Nanobodies® with their modular design are a perfect starting point for generating multivalent and multispecific therapeutics for immune modulation
- The power of the platform and its flexibility to develop optimal drug formats will be demonstrated by a multivalent approach for an agonistic Nanobody against the co-stimulatory immune checkpoint receptor GITR and a multispecific T-cell recruitment format

Carlo Boutton, Director of Technology, **Ablynx**

16.00 The use of bispecific antibodies to modulate anti-tumour immune responses

- Bispecific antibodies: an attractive alternative to cancer treatments combinations
- F-star's approach to create bispecific mAb²
- In vitro and in vivo efficacy of F-star bispecific antibodies targeting oncology pathways

Delphine Buffet, Senior Research Associate, **F-Star**

16.40 Chairman's Closing Remarks and Close of Day Two

HALF DAY POST-CONFERENCE WORKSHOP A

Wednesday 11th April 2018
Copthorne Tara Hotel, London, UK
08.30 - 12.30

ADCs from early development into first-in-human studies

Workshop Leader:
Peter Bach, Biotechnology Consultant, **BioPharmaLogic**

Workshop overview:
ADC development has been the most exciting advance in therapeutic drug development, especially as the concept expanded to include anti-body fragments, peptide analogues and novel linkers and war heads. However, these are a complex development process as targeting molecule, linker and war head all have to be assessed for safety. Success depends on understanding what is possible and using different approaches in find the best options help get the quickest first-time in human study (FTIH) study. The outcome is to provide an agency with a credible CMC package, demonstrable efficacy and safety to support a risk management plan for FTIH. The Workshop aims to cover the most important aspects that should be part of the "big picture" to file an IND and how to risk-manage to reach objectives and deal with the unexpected.

Why you should attend:
This Workshop will provide the top view for all disciplines and functions including discovery, manufacturing, nonclinical, regulatory and clinical to provide each with the challenges faced by the other disciplines.

Who should attend:
Scientists in Discovery, Senior Scientists, Associate and Directors in Discovery, Manufacturing, Nonclinical, Regulatory and Clinical Support. The contents is especially aimed to help small companies developing ADC

Agenda

08.30 **Registration and coffee**
09.00 **Opening remarks and introductions**
09.10 **Session 1: Regulatory Strategy**
- Biology for the regulatory arguments
- CMC for nonclinical development
- Staging the test item supply to speed the development

10.00 **Session 2: Taking the conjugate into the clinic**
- Geographical differences
- Finding clinical leverage
- Global option for FTIH

10.40 **Morning coffee**
11.10 **Session 3: Non-Clinical**
- Models
- Service providers
- Data interpretation
- In vitro and in vivo safety assessments:
  - Literature Based Risk Assessment
  - Immunohistochemistry
  - CRO selection, Study design and CROs management

11.50 **Session 4: Final considerations**
- Bioanalytical considerations
- Agency interactions
- The regulatory package
- Outsourcing strategy – test item supply: matching nonclinical needs to speed the development

12.30 **Closing remarks**

About the Workshop Leader:
Peter Bach trained in chemistry, biochemistry, pharmacology and toxicology. His academic focus contributed to the understanding of target selective injury (and hence human risk assessment), research that attracted support from industry, and national and international research funders. He advised WHO, IPCS, IARC, ILO, IUPAC, EU and other agencies on Chemical Safety. In the CRO sector Peter supported global virtual teams, SMEs and major Pharmaceutical companies to fast-track novel biologicals (including ADCs). He has also worked with NCEs out of discovery, through safety assessment and into first-time-in-human studies and through clinical phase I-III programmes and licensed, following interactions with US, EU and other Regulatory Agencies. In the BioPharma Sector Dr Bach has lead nonclinical strategy and operations, and been responsible for global outsourcing and its implementation, the development of multiple products across a wide range of therapeutic areas and been responsible for post marketing safety stewardship of multiple licensed products. He has developed multiple drug conjugate molecules include a range of drug delivery platforms (antibody to peptide), many linkers and a number of different war heads, the most advanced of which is in Phase III.

About the Organisation:
BioPharmaLogic Ltd works with multidisciplinary teams in the EU, Eastern Europe, US, Canada, Asia, Australia and South Africa to expedite nonclinical development to enable first-time-in-humans and proof of concept. They deliver challenging milestones that supported start-ups, SMEs, mid-Cap and global Biopharmaceutical companies, especially in the development of biosimilars and next generation ADCs.

HALF DAY POST-CONFERENCE WORKSHOP B
Wednesday 11th April 2018
Copthorne Tara Hotel, London, UK
13.30 - 17.30

Recombinant Antibodies – structure, function and drug development

Workshop Leader:
Dr Mahendra Deonarain, CEO & CSO, **Antikor Biopharma Ltd**
Prof Kerry Chester, Professor of Molecular Medicine, **UCL**

Workshop overview:

This workshop will describe some key basic concepts about recombinant antibodies: structure, function, biophysical and biological properties. We will then build upon these concepts to illustrate how antibody-based medicine drug discovery is impacted, using examples from antibody discovery and conjugates.

Why you should attend:

This will provide scientists in the field of biologics drug development an excellent insight into antibodies at all levels and a chance to interact with experts in the field.

Who should attend:

Research & Development Directors/Managers/ Scientists, Senior Scientists, Chief Scientific Officers, Chief Medical Officers, Heads of Clinical Development, Heads of Pre-Clinical Development.

Agenda

13.30 **Registration and coffee**

14.00 **Opening remarks and introductions**

14.10 **Session 1: Antibody structure and function**
- Comparison of the five classes of antibodies and their determined binding specificity
- Analysis of structure-function relationships for antibodies
- Examination of C domains and how these mediate function

14.50 **Session 2: Antibody biophysics**
- Biophysical characterization of antibodies
- Methods for the determination of antibody-antigen binding affinities
- Where is the limit for analysis of antibodies using biophysical methods

15.30 **Afternoon Tea**

16.00 **Session 3: Antibody discovery**
- Analysis of sources (origins) of different antibodies
- Strategies to accelerate antibody discovery
- A look at current and emerging Antibody Discovery Technologies

16.40 **Session 4: Antibody conjugation**
- Methods of Antibody conjugation
- Why is antibody-drug conjugation useful
- The chemistry behind Antibody-Drug Conjugates

17.20 **Closing remarks**

17.30 **End of Workshop**

About the Workshop Leaders:

Dr Deonarain was a Reader in Antibody technology at Imperial College London and a PI for 16 years. He is now CEO and CSO at Antikor Biopharma developing antibody drug conjugates.

Prof Chester is Professor of Molecular Medicine and leads the Recombinant Antibody Therapeutics Group at UCL. She has pioneered the area of antibody fusion proteins and focuses on 'bench to bedside' clinical translation of antibody therapies.

About the Organisation:

Antikor is a, Imperial College spin-out, pre-clinical biotechnology company developing antibody fragment based drug conjugates and is based at the Stevenage Bioscience Catalyst Innovation Hub.

UCL is world-leading research and teaching university, providing innovative teaching to drive entrepreneurial solutions to the world's major problems.

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