Don't Miss Your Last Chance to Join - Register Now

9th ANNUAL WORLD adc LONDON 2019

4th-6th March, 2019

Europe's Longest Standing & Most Comprehensive Antibody Drug Conjugate Conference

Maximise the Clinical Therapeutic Window of Your Antibody Drug Conjugate

54 Expert Speakers

Dhaval Shah
Associate Professor, Pharmaceutical Sciences
State University of New York at Buffalo

Gregory Adams
Chief Scientific Officer
Sesen Bio

Greg Thurber
Assistant Professor
University of Michigan

Hadi Falahatpisheh
Head, Toxicology
AbbVie Stemcentrx

Hong Wang
Associate Director & Senior Scientist, Development Toxicology
Genentech

Nancy Levin
Vice President, Development
Triphase

Steve Coats
Vice President, Research & Development
MedImmune

William Olson
Vice President, Therapeutic Proteins
Regeneron

Douglas Leipold
Principal Researcher
Genentech

320 ATTENDEES

140 ORGANISATIONS

54 EXPERT SPEAKERS

9 HOURS OF NETWORKING

To find out more visit: **www.worldadc-europe.com**

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Welcome to the 9th World ADC London

Now in its 9th year, **World ADC** is making its London debut in 2019. As Europe's largest gathering of ADC stakeholders you'll have the opportunity to **network with 320 drug developers from 140 active ADC organisations**. You'll be able to build new connections, further cement partnerships and catch up with peers.

This definitive ADC conference will bring together expert speakers from **ImmunoGen, Seattle Genetics, Mersana Therapeutics** and other leading ADC organisations who will be presenting novel research, cutting edge science and updates from the last 12 months of ADC development. You will leave World ADC London with the latest thinking on the **discovery of novel non-cytotoxic payloads, effectively and confidently translating into the clinic** and **improving your product manufacturability**.

With a sole focus on antibody drug conjugates, three parallel streams and seven workshops, World ADC covers every aspect of ADC drug development enabling you to **maximise the therapeutic window of your ADC pipeline.**

Join your peers at this comprehensive forum to exchange transformative insight, gather lessons learned and network to develop new partnerships. **Don't miss your opportunity to be part of the force accelerating the next 12 months of ADC research**.

Contents

Attend World ADC to:

- Discover new era payloads with differentiated mechanisms of action for **warhead optimisation**
- Learn discovery and validation approaches of targets for ADC therapy to **minimise off-target toxicities**
- Share lessons learned to effectively translate preclinical science to the clinic to **optimise dosing**
- Improve **clinical and non-clinical translation of safety issues** with DNA damaging agents
- Review the **scientific rationale for combining ADCs** with other cancer fighting agents
- Learn the **analytical and bioanalytical requirements** for development and commercialisation of ADCs
- **Predict efficacy and toxicity** through modelling of ADC distribution and biotransformation
- Evaluate the safety and efficacy of clinical ADC's with **novel preclinical strategies**
- Enhance PK/PD strategy from discovery to the clinic and **improve your therapeutic window**
- **Minimise ADC manufacturing costs** by developing efficient, scalable, ADC manufacturing processes

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Why You Should Attend World ADC London

"World ADC was an opportunity to have face time with the industry leaders in ADCs and converse in a cooperative, sharing and constructive environment"

Genentech
A Member of the Roche Group

"Well organised, great list of speakers, nice variety of activities. Perfect size to meet everyone and feel comfortable engaging others"

NOVARTIS

"This conference is the pre-eminent ADC conference where the top companies come to present their data and share their experiences"

Ambrx

"The World ADC meeting was again an awesome event. It was in particular great to see the dynamics and potential of ADC - IO combination therapies unfold"

Boehringer Ingelheim

"This conference is an unique opportunity to talk about ADCs deeply. It was really fruitful"

Daiichi-Sankyo

"A thoroughly engaging and intellectually stimulating experience, World ADC has been packed with new ideas, techniques & friends. The possibilities for new breakthroughs and collaborations based on my time here has made it even more motivating to get back to the lab"

Scripps Research

"One of the best learning experiences. This meeting has solved several questions I did not know how to solve prior. Furthermore, I have thought of a new ADC project that might be useful for our own company and for future patients"

Eisai

"World ADC Conference is THE event to attend to catch up with most recent developments in the field"

Lonza

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Maximise Your Onsite Experience:

Pre-conference Workshop Day
Monday 4th March

3rd Analytical & Bioanalytical Day	Primer Course: Introduction to the Design, Discovery & Development of ADCs	Workshop B	Workshop D	Workshop F
Lunch & Networking				
3rd Analytical & Bioanalytical Day	Primer Course: Introduction to the Design, Discovery & Development of ADCs	Workshop C	Workshop E	Workshop G

3 Parallel Streams

We have separated the main challenges into three key areas; discovery, translation and CMC. Feel free to follow a track or switch between different steams. The best way to maximise your team's learning opportunity at this conference is to send a team, this means that you can make sure that between you and your colleagues, you benefit from all of the topics in different streams.

Scientific Programme - Day 1
Tuesday 5th March

Plenary Stream		
Speed Networking		
Discovery Stream	Translational Stream	CMC Stream
Lunch & Networking		
Discovery Stream	Translational Stream	CMC Stream
Plenary Stream		
Scientific Poster Session		

Speed Networking

Your opportunity to make valuable new contacts in a short space of time. This fast paced session allows you to meet every other person in the room. It's a great opportunity to introduce yourself to attendees that you would like more in depth conversations with and establish meaningful business relationships.

7 Workshops

30 minutes can only provide you with so much detail on the topic at hand, these three hour workshop sessions are led by experts in their field who can delve deeper into a particular session in a more intimate and focussed environment. Interact, discuss and debate to get your questions answered so you have real tangible actions to take back your organisation.

Scientific Poster Session

Share your research with pioneers of the ADC field and gain feedback on your latest research. This popular learning and networking session allows you to connect with your peers in a more relaxed setting whilst exploring the latest developments in the ADC field.

Scientific Programme - Day 2
Wednesday 6th March

Plenary Stream		
Discovery Stream	Translational Stream	CMC Stream
Lunch & Networking		
Discovery Stream	Translational Stream	CMC Stream
Plenary Stream		

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54 Expert Speakers

Alain Beck
Senior Director, Biologics CMC & Developability
Pierre Fabre

Andreas Hald
Research Associate
Copenhagen University Hospital

Andrew Huang
Chief Scientific Officer
MabPlex

Antony Bigot
Section Head
Sanofi

Arnaud Delobel
Director, Research & Development
Quality Assistance

Arnaud Tiberghien
Scientist, Medicinal Chemistry
Spirogen

Brian Mendelsohn
Director, Process Development & Tech Transfer
Ajinomoto

Camille Martin
External R&D Director
McSAF

Cathy Zhang
Senior Principal Scientist
Pfizer

Charles Dumontet
Professor of Hematology & Team Leader
Cancer Research Centre of Lyon

Conor Barry
Analytical Group
Spirogen

David Bramhill
President
Bramhill Biological Consulting

Brian Clark
Principal Consultant
GMP Operations Consulting

Dhaval Shah
Associate Professor, Pharmaceutical Sciences
State University of New York at Buffalo

Douglas Leipold
Principal Researcher
Genentech

Earl Albone
Director, Biochemistry Discovery
Morphotek

Eric Lacoste
Head, Bio-Organic, Chemistry Team
Sanofi

Gavin Bennet
Director, Project Leader
Bicycle Therapeutics

Giorgio Salciarini
Technical Business Development Manager
BSP Pharmaceuticals

Greg Thurber
Assistant Professor
University of Michigan

Gregory Adams
Chief Scientific Officer
Sesen Bio

Hadi Falahatpisheh
Head, Toxicology
AbbVie Stemcentrx

Hans-Georg Lerchen
Chief Scientist, Medicinal Chemistry
Bayer

Hong Wang
Associate Director & Senior Scientist, Development Toxicology
Genentech

Ian Schwartz
Process Development Consultant
Sartorius Stedim

Iontcho Vlahov
Vice President
Endocyte

Jonas Helma
Project Leader, Biology
Ludwig Maximilian University

Justin Mason-Home
Director
HPAPI Project Services Limited

Jutta Wanner
Chief Scientific Officer
Blink Bio

Karan Shah
Development, Analytical Chemistry
ImmunoGen

Thomas Kofoed
CEO and Co-Founder
Alphalyse

Letrishka Anthony
Senior Analyst, Beacon
Hanson Wade

Lisa McDermott
Principal Scientist, Process and Analytical Development
Merck

Ling Xu
Principal Scientist
Mersana Therapeutics

Mark Frigerio
Director of Chemistry, UK
Abzena

Mary Robinette
Principal Project Engineer
Merck

Matthias Winzer
Associate Director, Parenteral Development
Merck KGaA

Melanie Derde
Head, Analytical, Bioconjugation
Novasep

Marcus Bohme
Head of Research & Development
BTI

Nancy Levin
Vice President, Development
Triphase

Nomalie Jaya
Principal Scientist
Seattle Genetics

Norbert Sewald
Professor
University of Bielefeld

Pedro Cal
Post-Doctoral Fellow
University of Cambridge

Philip Howard
Chief Scientific Officer
Spirogen

Proveo
Speaker TBC

Rakesh Dixit
Vice President & Global Head, Biologics
MedImmune

Rebecca Mosher
Executive Director, Translational Medicine
Mersana Therapeutics

Reza Safaei
Head of Global Medial Affairs
Nordic Nanovector

Scott Miller
Senior Scientific Advisor
Carbogen Amics

Steve Coats
Vice President, Research & Development
MedImmune

Sylvain Huille
Senior Scientist, BioDevelopment
Sanofi

Ulf Grawunder
Chief Executive Officer
NBE Therapeutics

William Goundry
Associate Principle Scientist
AstraZeneca

William Olson
Vice President, Therapeutic Proteins
Regeneron

Yiqing Feng
Senior Research Fellow
Eli Lilly

3rd Analytical & Bioanalytical Day | Monday 4th March

Alain Beck
Senior Director, Biologics CMC & Developability
Pierre Fabre

8.30 Chair's Opening Remarks

Alain Beck
Senior Director, Biologics CMC & Developability
Pierre Fabre

8.40 Moving Beyond the Simplistic; Novel Analytical Methods for ADC Characterisation & Assessment

- Discussing evolution of analytical methods for ADC characterisation
- Assessing novel analytical methods for analytical characterisation of next-generation ADCs
- Reviewing application of optimised analytical methods for ADC research

Integrating a Robust Bioanalytical Support Strategy

Ling Xu
Principal Scientist
Mersana Therapeutics

9.10 Strategies & Challenges for Developing Total Antibody & Antibody Conjugated Drug 2-in-1 Method for Dolaflexin Antibody Drug Conjugates

- High throughput 96-well sample preparation approach
- Total antibody and antibody conjugated drug in one assay
- Non-clinical and clinical assays

9.40 Speed Networking

10.40 Morning Refreshments

Selection of Expert Panelists

11.30 Panel: Predicting Efficacy/Tox Relationships through Modelling of ADC Distribution & Biotransformation

- Quantification and characterisation of intact ADC and intermediates, predicticting toxicities and efficacies
- Process chemistry changes in mAb vs conjugation vs small molecule
- What are the gaps in our analytical capability?

12.00 Think Tank Roundtable Sessions

More practical and highly interactive breakout roundtables where attendees can crowdsource solutions and share opinions around pre-assigned topic areas. A valuable chance for attendees to unite around hot topics and debate best practice. No more sitting quietly, this is a dedicated opportunity for you to voice your experiences and identify unique solutions. There will be two 45 minute sessions with the opportunity to change groups halfway through.

13.00 Lunch & Networking

What Happens When it Gets Tricky?

Nomalie Jaya
Principal Scientist
Seattle Genetics

14.00 Leveraging Prior Knowledge to Gain Efficiencies During Product Characterisation of Antibody Drug Conjugates

- Seattle Genetics has developed a deep product understanding of Antibody Drug Conjugates
- As we continue to build our pipeline, accommodate an ever increasing need for speed to clinic and market, we continue to explore opportunities to gain efficiencies. Leveraging prior knowledge gained from multiple product characterization efforts can help realize some of these efficiencies
- This presentation will show a comparison of size & charge variant characterization results for multiple ADCs to highlight common modifications and structural variants across ADCs. Based on this data we propose a streamlined and targeted approach to product characterization that takes advantage of prior knowledge

Karan Shah
Development, Analytical Chemistry
ImmunoGen

14.30 What are the Best Tools to Implement in Robust Characterisation of CQAs

- Developing analytical strategies that account for product variability
- Reviewing how antibody variants can impact the quality attributes of ADCs
- Appropriate analytical strategies are needed to monitor the variants of antibodies and their corresponding immunoconjugates in order to assure consistent product quality

Conor Barry
Analytical Group
Spirogen

15.00 Preclinical Analytical Strategies

- PK of ADCs are more complex than that of antibody and cytotoxic drug alone
- Novel assays are required to truly understand the behaviour of ADCs and drug intermediates *in vivo*
- Lessons learned from working with PBD-ADCs

Alain Beck
Senior Director, Biologics CMC & Developability
Pierre Fabre

15.30 Chair's Closing Remarks:

Pre-Conference Workshops | Monday 4th March

Workshop A: Primer Course: Introduction to the Design, Discovery & Development of ADCs (FULL DAY)

Time: 9.00-16.00

This workshop will offer a one-day intense learning environment to **establish core skills and understanding in the critical areas of ADC research** and **development.**

Designed for new entrants to the ADC field it will deliver critical knowledge in a number of the key problem areas that hinder antibody drug conjugate programs.

Covering essential elements in ADC discovery and early development, this workshop will enable you to:

- Gain an overview of the development process for ADCs
- Improve payload and linker design chemistry
- Understand the impact of conjugation site selection on your ADC
- Choose/choice of optimum "antibody" format
- Select the most appropriate ADC target which is easily accessible
- Learn about cellular assays
- Review the advantages and disadvantages of different preclinical animal models
- Develop early stage assays and learn how to effectively interpret the data

Workshop Leader

David Bramhill
President
Bramhill Biological Consulting

"World ADC is the largest conference with an exclusive focus on ADC. It is an excellent chance to assess the field's direction and meet with other ADC companies"

Tanabe Research Laboratories

"This was the best pragmatic development conference that I have been to"

Biogen

Choose From

Workshop B: Conjugate Diversity: Past, Present & Future

Time: 9.00-12.00

Driven by payload toxicity and resistance there is a huge drive in the ADC field to discover new payloads with differentiated mechanisms of action. Join this workshop to **explore novel payload classes**, as well as to discuss the current challenges and how to overcome these.

Attend this workshop to discuss:

- Diversity of conjugates, one of the struggles with ADCs is finding conjugates with different mechanisms of action
- Going from classic cytotoxic chemotherapy to bacterial toxins which has raised immunogenicity issues
- Chemical and functional diversities of conjugates and different developments
- How to overcome toxicity and drug resistance

Workshop Leader

Charles Dumontet
Professor of Hematology & Team Leader
Cancer Research Centre of Lyon

OR

Workshop D: Designing Effective ADCs through Pharmacokinetic Modelling and PK/PD Experiments

Time: 9.00-12.00

The PK of ADCs are more complex than that of the antibody and cytotoxic drug alone. This two-part, all day workshop focuses on all aspects of pharmacokinetic modelling and PK/PD experiments, the focus of the morning workshop is for the **early stages of ADC development.**

Attend this workshop to:

- Cover mechanistic and multi-scale modelling of biologics such as antibodies and contrast these with small molecules
- Outline how computational models can be integrated with experimental data for a more complete picture of effector-site PK/PD within a tumour
- Discuss strategies to tailor the molecular design to a specific target and patient population based on the antibody, linker, payload and target properties

Workshop Leader

Greg Thurber
Assistant Professor
University of Michigan

OR

Workshop F: Scale Up, Outsourcing & Managing Complex Supply Chains

Time: 9.00-12.00

In an environment of limited capacity for manufacturing, decisions must be made early on in consideration of how to source different components of the ADC supply chain. This workshop will **explore the key criteria for successful clinical and commercial manufacturing of ADCs.** It will also touch upon developing reliable cold shipping lanes.

This workshop will cover:

- CMO Selection
- Criteria for consideration
- Integrated manufacturing vs distributed
- Logistics considerations
- Start Up Phase
- Key elements of agreements
- Assay and process transfer and scale-up
- Operational Phase
- Relationship management
- Oversight and governance

Workshop Leader

Brian Clark
Principal Consultant
GMP Operations Consulting

Workshop C: Discussing Next Generation ADC Targets

Time: 13.00-16.00

With antibody drug conjugates, much attention focuses on the physical properties of the antibody, drug and linker components. However, the characteristics of the target cell and antigen are perhaps the most critical parameters in ADC design. In the context of developing a commercial successful ADC, this workshop will share insights and **discuss the considerations for you to choose the right target for your ADC candidate.**

Join this workshop to:

- Deepen your understanding of tumour heterogeneity
- Discuss the attributes of the target cell and antigen that make for safe and effective ADC targets
- Explore methods for target discovery and validation
- Comprehensively review the current ADC target landscape

Workshop Leader TBC

OR

Workshop E: PK/PD Based Strategies to Improve the Therapeutic Index of ADCs

Time: 13.00-16.00

Following the morning workshop with Greg Thurber, the afternoon workshop focuses on aspects of pharmacokinetic modelling and PK/PD experiments for **later stage development and maximisation of the therapeutic window of ADCs.**

This workshop will:

- Introduce basic tenets of ADC PK/PD, and how to characterise them using empirical and system based mathematical models
- A strategy to translate preclinical efficacy of ADCs into the clinic using PK/PD modelling and simulation will be explained
- How the size of ADC (e.g. FDCs), heterogeneity of tumour, ADC bystander effect, and antibody co-administration may affect the efficacy and therapeutic index of ADCs will be highlighted

Workshop Leader

Dhaval Shah
Associate Professor,
Pharmaceutical Sciences
State University of New York at Buffalo

OR

Workshop G: Occupational Health & Safety in Delivering ADC Projects

Time: 13.00-16.00

Establishing and maintaining safe working environments when handling ADC components is imperative. Some ADC payloads are some of the most occupationally potent and toxic materials ever handled in the biopharmaceutical sector. This workshop will explore the practical H&S elements involved in **pragmatic roll-out of ADC projects.**

Attend this workshop to learn about scientific and systematic, **business-focussed integration and delivery of H&S in ADC projects**, including:

- Strategic business matters, project planning, project elements and costs
- Conceptual and detailed design steps
- Deciding on control and containment
- Dealing with A&E firms and containment equipment vendors
- HPAPI H&S management systems

Workshop Leader

Justin Mason-Home
Director
HPAPI Project Services Limited

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Scientific Programme - Day 1 | Tuesday 5th March

Alain Beck
Senior Director, Biologics CMC & Developability
Pierre Fabre

8.00 Chair's Opening Remarks

Alain Beck
Senior Director, Biologics CMC & Developability
Pierre Fabre

8.10 Riding the ADC Rollercoaster: In-Depth Review of Current ADC Field, as well as Insights on Hotspots of Innovation

- Reviewing the last 12 months of ADC research; lessons learned and current priorities for drug developers in ADC research
- Discuss strategies to select the best target antigens, as well as suitable cytotoxic drugs; the design of optimised linkers; the discovery of biorthogonal conjugation chemistries and cytotoxic issues
- Increasing homogeneity and stability through selection and engineering of antibodies for site-specific drug conjugation
- Exploring novel payload chemistries with differentiated mechanisms of action

Michael Pehl
Chief Executive Officer
Immunomedics

8.40 Keynote: Making Sacituzumab Govitecan Foundational Therapy for High Unmet Need Indications

- Focusing on unmet need indications
- Sacituzumab Govitecan as a lead asset representing a highly differentiated ADC platform (unique MOA)
- Potential beyond mTNBC and development plans in ER+ mBC, Urothelial Cancer, NSCLC including combination therapies
- Commercial considerations

9.10 Session Reserved for Late Breaking Abstract

Listen to this talk to remain at the forefront of the ADC field. Continuing to bring you the very latest data this session will be revealing unpublished data, for the first time.

9.40 Speed Networking

This session is a great opportunity to introduce yourself to the attendees that you would like to have more in depth conversations with. This session is the ideal opportunity to get face-to-face time with many of the brightest minds working in the ADC field and establish meaningful business relationships.

10.30 Morning Refreshments

Discovery Stream

Chair: **Gavin Bennet**, Director, Project Leader, **Bicycle Therapeutics**

Discovering New Era Payloads with Differentiated Mechanisms of Action

11.00 **Exploring Novel Lower Potency PBD Payloads**

- Next generation PBD payloads
- Warhead optimisation
- Exploring the effect of N10 Capping groups

Philip Howard, Chief Scientific Officer, **Spirogen**

Translational Development Stream

Chair: **Hong Wang**, Associate Director & Senior Scientist, Development Toxicology, **Genentech**

Solving the Mystery: ADC Internalisation & Trafficking

11.00 **Minimising Off Target Toxicity of ADCs**

- Mechanisms of off-target toxicity of ADCs
- Approaches to minimise off-target toxicities
- Innovative models to assist preclinical safety evaluation

Hong Wang, Associate Director & Senior Scientist, Development Toxicology, **Genentech**

CMC Stream

Chair: **Mary Robinette**, Principal Project Engineer, **Merck**

Reviewing Strategies & Technologies to Minimise ADC Manufacturing Costs

11.00 **Optimisation of Analytical & Process Development for Bioconjugation**

- Analytical optimisation
- Services and methods
- Analytical development
- ADCs characterisation
- Process development case study

Melanie Derde, Head, Analytical, Bioconjugation, **Novasep**

11.30 **Session reserved for Blink Bio**

Jutta Wanner, Chief Scientific Officer, **Blink Bio**

11.30 **Quantitative Evaluation & Critical Analysis of ADC Bystander Effect**

- This presentation will provide quantitative perspective on in vitro and in vivo bystander effect of ADCs
- It will highlight how one can optimise dosing regimen to maximise the bystander effect of ADCs
- The presentation will also demonstrate how an ADC with the bystander effect behaves differently when it comes to antibody co-administration strategy to overcome the binding-site barrier for ADCs

Dhaval Shah, Associate Professor, Pharmaceutical Sciences, **State University of New York at Buffalo**

11.30 **Scale-up Synthesis of the PBD Drug-Linker Tesirine**

- How challenges arising during the 34 steps synthesis of tesirine were overcome
- Why investing in a robust supply chain is key to a successful delivery
- Remaining challenges and opportunities
- How these synthetic and supply chains improvements can be translated to the delivery of future payloads

Arnaud Tiberghien, Scientist, Medicinal Chemistry, **Spirogen**

12.00 **Targeting uPARAP in Sarcoma & Glioblastoma with ADCs Carrying a Site-Specific PBD Payload**

- The physiological function and structure of uPARAP
- Expression pattern of uPARAP allows highly specific targeting using ADCs in several cancer forms
- Production and humanisation of anti-uPARAP antibodies, and optimisation of anti-uPARAP based ADCs and their effect on cancer cells

Andreas Hald, Research Associate, **Copenhagen University Hospital**

12.00 **Analytical Methods: Key Considerations to Efficiently Bring ADCs to the Market**

- Panel of analytical methods to be used for characterisation and QC release
- Expectations of the regulatory authorities for intermediates (toxin and mAb), DS and DP
- Strategy for method validation depending on the development phase
- Notions of data integrity

Arnaud Delobel, Director, Research & Development, **Quality Assistance**

12.15 **Extended Q & A**

12.00 **Conjugation & Fill Finish: How to Secure the Supply Chain of ADCs**

- Overview of the supply chain
- Driving a clinical product to the BLA
- Setting a robust commercial supply

Giorgio Salciarini, Technical Business Development Manager, **BSP Pharmaceuticals**

12.30 **Lunch & Networking**

Thomas Kofoed
CEO and Co-Founder
Alphalyse

12.30 **Lunch Seminar: Fast, Easy and Accurate DAR Measurement using SCIEX X500B QTOF System and BioPharmaView™ Software**

- High resolution molecular weight (MW) determination
- Fast and detailed report generation
- Easy to operate X500B Mass Spectrometer

Sharing Innovations in Linker Chemistry

14.00 **Tubulis® – A novel Platform for Next-Gen ADC Development**

- ADCs are fascinating multi-component drugs consisting of a biological entity and a chemical small molecule entity
- However, despite great potential to enable targeted chemotherapy, ADCs struggle to translate to the clinics
- Tubulis® aims to provide a novel platform solution to catalyze successful ADC development

Jonas Helma, Project Leader, Biology, **Ludwig Maximillan University**

Sharing Preclinical Lessons Learned to Confidently Translate into the Clinic

14.00 **Practical Aspects of Applying Preclinical Data to Clinical Biomarker Planning**

- Discussing types of preclinical work that can inform development planning
- A focus on immunohistochemistry assay development/threshold setting
- Practical applications of preclinical data to plan for clinical development

Rebecca Mosher, Executive Director, Translational Medicine, **Mersana Therapeutics**

Unravelling the Complexity of ADC Manufacturing: Global Supply Chains

14.00 **Platforming Antibody Drug Conjugate Process Development & Manufacturing Using Single Use Technologies**

- Single-use manufacturing technologies allow companies to quickly bring cGMP manufacturing capability online with less capital investment.
- Here we describe a robust and scalable platform for ADC process development and manufacturing that uses single-use technologies to accelerate development timelines and increase manufacturing predictability while decreasing scale up risks.
- In addition, chemical compatibility of the materials described in the platform to solvents typically used in ADC process will be discussed.

Ian Schwartz, Process Development Consultant, **Sartorius Stedim**

14.30 **Novel Immune-Stimmulatory ADCs (iADCs) for Effective Targeting of Solid Tumours**

- Exploring site-specific conjugates with ultra-potent anthracycline toxins
- Discovering immune-oncology function of NBE's iADCs
- Reviewing Preclinical validation of a ROR1 targeting iADC

Ulf Grawunder, Chief Executive Officer, **NBE Therapeutics**

14.30 **Clinical & Non-clinical Translational of Dose-limiting Toxicities Associated with DNA Damaging Conjugates**

- Clinical landscape of DNA damaging conjugates
- Review of preclinical translation for major dose-limiting toxicities associated with DNA damaging
- Mylotarg case example – preclinical model for hepatic Veno-Occlusive Disease (VOD) and thrombocytopenia

Hadi Falahatpisheh, Research Fellow, **AbbVie-Stemcentrx**

14.30 **Key CMC Considerations for Robust ADC Process Development & to Effectively Manage the CMC Supply Chain**

- Delving into the unique technical challenges that ADCs create which require careful CMC considerations
- Discussing insights on how to develop transferrable ADC processes
- Sharing experiences on how to confidently manage the complexity in ADC supply chains

Eric Lacoste, Head, Bio-Organic, Chemistry Team, **Sanofi**

15.00 **Pro-PBDs: Novel Warheads for Targeted Therapies of Cancer**

- Conceptual design of next generation PBD-based prodrugs for targeted therapies of cancer
- Explore Endocyte's next generation latent warheads – the utility of oxime ethers in pro-PBD formats
- Learn strategies for efficient synthesis of novel pro-PBDs and their conjugates
- Review the selection of the clinical candidate EC2629: the first-in-class pro-PBD-based conjugate

Iontcho Vlahov, Vice President, **Endocyte**

15.00 **Panel: Filling the Gaps with ADC Technology**

- An overview of the ADC technology available
- How this can be used to enhance translation into the clinic
- How the technology can be used to 'fill the gaps'

15.00 **Working with a CMO in the ADC field – From Selection & Technology Transfer to Scale-up and GMP Manufacture**

- Typical challenges faced by companies searching for a CMO. What to consider when comparing options available on the market.
- Process knowledge transfer to your chosen CMO. Common pitfalls and how to avoid them.
- Managing all the moving pieces to bring your ADC to the clinic. What does developing an ADC have in common with a small molecule process and what is unique?
- Models of typical conjugation processes will be included to illustrate the topics being presented

Scott Miller, Senior Scientific Advisor, **Carbogen Amics**

15.30 **Original Rebridging Technology Giving Access to Optimised ADCs Exemplified In HER2+ Model**

- Synthesis and characterisation of McSAF's conjugates
- Evaluation in a HER2+ model
- Optimised ADC compared favourably to Kadcyla®

Camille Martin, External R&D Director, **McSAF**

15.30 **Afternoon Refreshments & Networking**

Mitigating Toxicities to Maximise the Therapeutic Index of ADCs

Rakesh Dixit
Vice President & Global Head of Biologics
MedImmune

16.00 **Keynote: Lessons Learned from the Successful & Failed ADCs in Cancer Treatment: Moving Forward & Creating the Best Magic Bullets**

- Maximising the therapeutic index of ADCs has proven challenging because of the complexity of the molecules. This Keynote will review lessons learned from both clinically successful and unsuccessful ADCs
- Addressing the challenges which are preventing the development of magic bullets
- Learning novel approaches and technologies to move ADC forward

Brian Mendelsohn
Director, Process Development & Tech Transfer
Ajinomoto

16.30 Development of a Novel Chemical Site-Specific ADC Conjugation Platform with Enhanced Therapeutic Window

- One of the difficulties often encountered during the chemical modification of native non-engineered antibodies is the lack of selectivity that can be dialed in toward a specific residue.
- We describe a new platform for the site-selective conjugation of antibodies through the use of a novel class of IgG Fc-affinity peptide reagents to install payload-compatible linkers to well-defined amino acid residues.
- The activity of these resulting DAR2 ADCs will be reviewed and assessed compared to the state-of-the-art.

Douglas Leipold
Principal Researcher
Genentech

17.00 Preclinical Pharmacokinetics & Pharmacodynamics of DCLL9718A: an Antibody Drug Conjugate for the Treatment of Acute Myeloid Leukaemia

- Explore the development of a novel ADC - DCLL9718A is an antibody-drug conjugate that targets C-type lectin-like molecule-1 (CLL-1)
- Reviewing data the characterisation of the in vitro and in vivo stability, the pharmacokinetics (PK) and pharmacodynamics (PD) of DCLL9718A and MCLL0517A in rodents and cynomolgus monkeys
- Discussing key PK analytes to measure to deepen understanding of ADC in vivo behaviour

Alain Beck
Senior Director, Biologics CMC & Developability
Pierre Fabre

17.30 Chair's Closing Remarks

17.40 Scientific Poster Session

After the formal presentations have finished, the learning and networking carries on. The Poster Session is an informal part of the conference agenda, allowing you to connect with your peers in a relaxed atmosphere and continue to forge new and existing relationships. During this session over 25 scientific posters will be presented from novel linker designs to validation of site specific conjugation technologies and more informative *in vivo* models.

"Strong programme, great speakers and a genuine focus on identifying solutions"

Novartis

Scientific Programme - Day 2 | Wednesday 6th March

Alain Beck
Senior Director, Biologics CMC & Developability
Pierre Fabre

8.50 Chair's Opening Remarks

Revealing Next Generation ADC Technologies

Pedro Cal
Post-Doctoral Fellow
University of Cambridge

9.00 Exploring Site Directed Mutations on Native Antibodies to Allow Payload Conjugation

- Novel reagents for protein modification
- Site-selective lysine and cysteine modifications
- Protein microenvironment importance for bioconjugation.

William Olson
Vice President, Therapeutic Proteins
Regeneron

9.30 Cytotoxic & Steroid ADCs for Cancer & Inflammation

- Cytotoxic ADCs targeting tubulin
- Non-cytotoxic ADCs targeting the glucocorticoid receptor
- Approaches to discovery and validation of targets for ADC therapy

10.00 Morning Refreshments & Networking

Discovery Stream

Chair: **Gavin Bennet**, Director, Project Leader, **Bicycle Therapeutics**

Exploring New Frontiers in ADC Research

11.00 **TrypCo® Technology: A versatile enzymatic tool for site-specific generation of ADC's**

- Introduction into BTI´s novel TrypCo® technology as robust conjugation platform for the enzyme-based generation of site-specific ADC´s
- POC studies for the N- and C-terminal modification of Trastuzumab will be presented
- High flexibility of TrypCo® enables orthogonal dual modification of antibodies and their fragments

Marcus Bohme, Head of Research & Development, **BTI**

Translational Development Stream

Chair: **Hong Wang**, Associate Director & Senior Scientist, Development Toxicology, **Genentech**

Clinical Considerations for Developing Disease Modifying ADCs

11.00 **Applying Mechanistic Models to Better Predict Clinical Pharmacology of ADCs**

- ABBV-085 in Sarcoma
- LRRC15 target biology
- ABBV-085 preclinical efficacy and safety
- Phase 1 design and preliminary findings

James Purcell, Senior Scientist & Program Director, Oncology Discovery, **AbbVie**

CMC Stream

Chair: **William Goundry**,Principle Scientist, **AstraZeneca**

Manufacturing Next Generation ADC Technologies: Optimising Processes & Technical Operations

11.00 **Process Understanding and Automated Processing in Development to Ensure First Pass Manufacturing Success of ADCs**

- Studies needed for clinical supplies and for commercial readiness with the goal of providing evidence of process consistency.
- Use of automated systems for gathering information for early phase process transfers to manufacturing.
- DOEs that ensure appropriate ranges are evaluated and ensure deep process understanding.

Mary Robinette, Principal Project Engineer, **Merck**

Lisa McDermott, Principal Scientist, Process and Analytical Development, **Merck**

11.30 **BT5528: A Bicycle Toxin Conjugate Targeting EphA2 for the Treatment of Solid Tumours**

- BT5528 comprises a Bicyclic peptide binder of EphA2 linked to the cleavable linker & toxin vcMMAE
- The small size and hydrophilicity of Bicycle Toxin Conjugates offers rapid and complete tumour penetration, efficient delivery of toxin and rapid renal elimination of unbound drug
- BT5528 offers profound efficacy across a range of EphA2-expressing tumour models, including large heterogeneous PDX models, without the profound toxicity seen with previous antibody conjugate approaches

Gavin Bennet, Director, Project Leader, **Bicycle Therapeutics**

11.30 **Challenges & Opportunities in Developing ADCs**

- Main challenge in developing ADCs is the therapeutic index
- Innovative clinical trials to decrease toxicity and improve efficacy
- Patient selection strategies that incorporate genomic markers of ADC sensitivity
- Novel combination approaches that increase the activity of the ADC and reduce toxicities

Steve Coats, Vice President, Research & Development, **MedImmune**

11.30 **Structural & Dynamic Reporters of the Aggregation of ADCs**

- In ADCs, the drug and the distribution of its attachment points to the antibody affect the folding, the stability, and interactions between these macro-molecules
- Advanced characterization techniques applied to study the onset of aggregation
- Using these could help deciphering whether non-specific interaction is important or whether a subpopulation in the formulation is more prone to aggregation
- Guiding CMC development for better stability and allow for elaborating a formulation platform for ADCs

Sylvain Huille, Senior Scientist, BioDevelopment, **Sanofi**

12.00 **ThioBridge™ as a tool for the design, optimisation and manufacture of ADCs**

- Bullets TBC

Mark Frigerio, Director Chemistry UK, **Abzena**

12.00 **MORAb-202 – a Potent Human Folate Receptor Alpha-Targeting ADC that Utilises the Anti-tubulin Agent Eribulin as Payload**

- MORAb-202 is a cleavable cysteine-based conjugate of farletuzumab, a humanised anti-human folate receptor alpha antibody in Phase II clinical trials, and eribulin, an anti-tubulin agent approved for the treatment of certain metastatic breast cancers
- MORAb-202 exhibits clear bystander effects on the tumour microenvironment, in addition to its direct cytotoxic effects on folate receptor-positive tumour cells
- MORAb-202 is currently in a Phase I clinical trial in Japan

Earl Albone, Director, Biochemistry Discovery, **Morphotek**

12.00 **Title to be Confirmed**

- More details to follow

PROVEO Speaker

12.30 **Lunch & Networking**

Optimising Payload-Linker Combinations

14.00 **Novel Linker Payload Combination**

- MET is over-expressed in many human tumors
- MET-ADC is a novel ADC with optimized linker-payload combination and is highly potent in killing a variety of tumor cells *in vitro*
- MET-ADC demonstrated profound in vivo efficacy in pre-clinical models therefore is a promising agent to treat many types of cancer

Yiqing Feng, Senior Research Fellow, **Eli Lilly**

Bullseye: Validating Novel Formats, Engineering Antibodies & Discovering Appropriate Targets

14.00 **Dosing Optimisation & Mechanism Assessment of CD33-ADC Antibodies in AML Disease Models: Translating Preclinical Science to the Clinic**

- Exploring the dosing options of CD33-ADC preclinical models
- Ensuring smooth transition into the clinic
- Assessing the mechanism of action of CD33-ADC

Cathy Zhang, Senior Principal Scientist, **Pfizer**

Simplifying Process Development to Efficiently Manufacture ADCs

14.00 **Scalable Synthesis of aza-Cryptophycin, a Highly Active Payload for ADCs**

- Evaluated as stand alone agent, but dropped due to tox reason in 2002, Cryptophycin regains attention as highly potent payload for ADCs
- Synthesis of Cryptophycin and its aza analogues have been hampered by poor overall yield
- We will describe in this talk a highly efficient synthesis that provided access to multigram of the compound, in order to provide material for tox evaluation
- In particular, this talk will demonstrate an efficient answer to the 20 + year-old problem of the epoxide introduction

Antony Bigot, Section Head, **Sanofi**

14.30 **Exploring a Next Generation ADC: TRPH-CD22**

- TRPH-222 is a CD22-directed ADC, constructed via a novel, site-specific (SMARTagTM) conjugation approach, resulting in highly controlled and reproducible drug loading
- The molecule was very well-tolerated in IND-enabling studies in the non-human primate at repeat doses up to 50 mg/kg administered IV, and demonstrated superior pharmacokinetics relative to ADCs using conventional conjugation approaches
- TRPH-222 is currently being studied in relapsed and/or refractory B-cell lymphoma patients in a phase 1 clinical trial (NCT03682796)

Nancy Levin, Vice President Development, **Triphase**

14.30 **Vicinium: An anti-EpCAM scFV/Pseudomonas Exotoxin A Fusion Protein in Advanced Development for the Treatment of Non-Muscle Invasive Bladder Cancer**

- Vicinium has been designed for local-regional treatment of cancer, providing the opportunity to both localize the therapeutic agent at the site of disease and reduce the potential for systemic toxicity
- Ongoing results of the phase 3 VISTA trial evaluating Vicinium in the setting of non-muscle invasive bladder cancer will be presented
- The ability of Vicinium to mediate immunogenic cell death potentially initiating host anti-tumor immune responses will be discussed

Gregory Adams, Chief Scientific Officer, **Sesen Bio**

14.30 **Strategies for Scaling-Up ADC Payload Production**

- How challenges arising during the 34 steps synthesis of tesirine were overcome
- An overview of what to consider when scaling-up the synthesis of ADC payloads
- The importance of route design linker to safety and cost
- Case study 1: Tubulysin
- Case study 2: Tesirine

William Goundry, ssociate Principal Scientist, **AstraZeneca**

15.00 **ADCs with Novel Kinesin Spindle Protein Inhibitor Payloads & a Tailor-Made Linker Chemistry**

- Inhibitors of kinesin spindle protein (KSPi) have been developed as a novel payload class in antibody drug conjugates
- To increase tumour selectivity of ADC metabolism, a tumour associated protease with a unique cleavage sequence is utilised for lysosomal ADC cleavage and release of active metabolites with an appropriate profile matching the KSPi mode of action

Hans-Georg Lerchen, Chief Scientist, Medicinal Chemistry, **Bayer**

15.00 **Betalutin® - An Antibody-radionuclide-conjugate (ARC) for the Treatment of Relapsed Non-Hodgkin's Lymphoma**

- Introduction to Nordic Nanovector ASA
- Introduction to Betalutin
- Summary of clinical data and development program of Betalutin

Dr. Reza Safaei, Head, Medical Affairs, **Nordic Nanovector**

15.00 **Stability Investigations on ADCs Model Compounds with Defined Hydrophobicity Levels**

- Identifying representative model compounds for formulation and process development studies
- Property alterations upon conjugation
- Impact of payload hydrophobicity on stability and stress tolerance

Matthias Winzer, Associate Director, Parenteral Development, **Merck KGaA**

15.30 **Afternoon Refreshments & Networking**

Driving Synergy: Assessing ADCs as a Combination Therapies

Letrishka Anthony
Senior Analyst, Beacon
Hanson Wade

16.00 **Review of the ADC Clinical Pipeline**

- Update on the key movements in the clinic
- Insight into the rapidly evolving pipeline
- Analysis of novel clinical ADCs

Greg Thurber
Assistant Professor
University of Michigan

16.30 **Single-Cell Pharmacokinetics & Pharmacodynamics of Biologics: Designing Effective Antibody Drug Conjugates & Checkpoint Inhibitors**

- Biologics have unique distribution in the body that can impede or enhance efficacy depending on the particular drug and target
- Measuring the single-cell delivery and efficacy of these agents can help design more effective therapeutics and delivery strategies
- The local degradation of these agents in the tumour microenvironment can result in counter-intuitive results, but these can be leveraged to improve therapy as illustrated with several examples

Alain Beck
Senior Director, Biologics CMC & Developability
Pierre Fabre

17.00 **Chair's Closing Remarks**

Who You'll Meet

One of the most valuable features of this comprehensive meeting is the networking sessions and the way they are structured – to maximise your time at World ADC London.

With over **320 attendees** and **9 hours of networking**, World ADC London is your opportunity to engage and interact with ADC experts from all levels of drug development. It's the ideal opportunity to meet face-to-face with many of the **brightest minds working in the ADC field** and establish meaningful business relationships.

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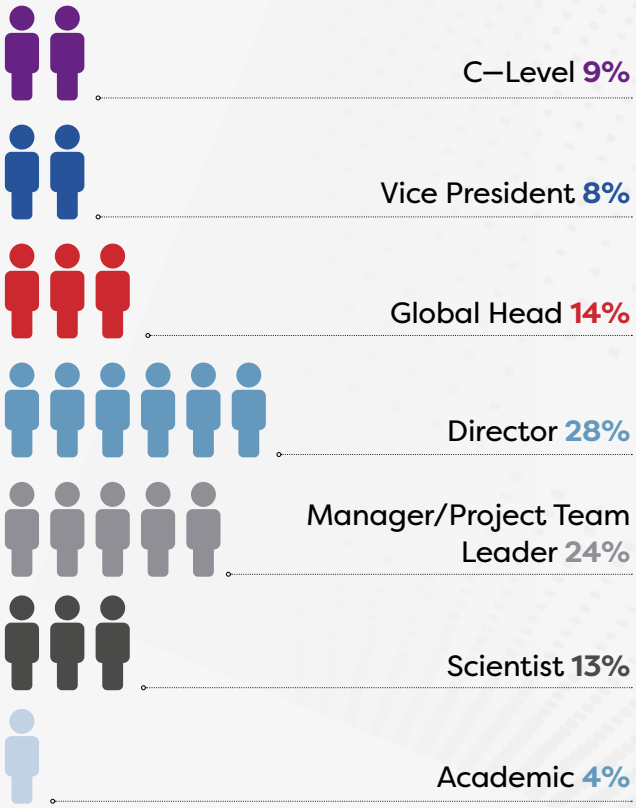

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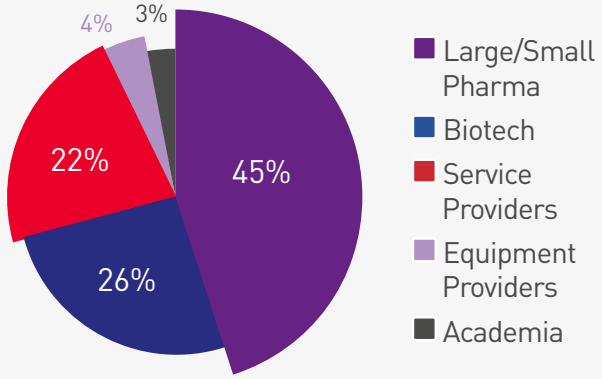
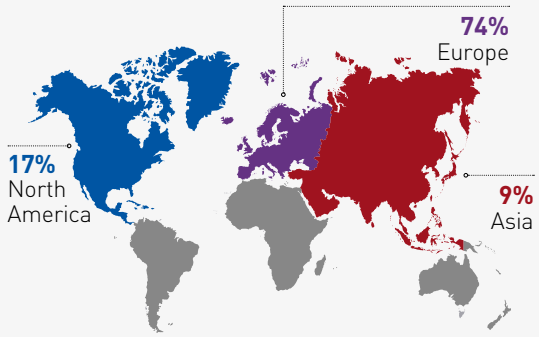


84% of Audience are Drug Developers

54% New Companies in 2018

Attendance by Geo



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