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10th ANNUAL WORLD adc SAN DIEGO 2019

October 8-11, 2019 | San Diego, CA

600+ ATTENDEES

230+ COMPANIES

88+ SPEAKERS

CMC DAY NEW

The Longest Standing & Most Comprehensive Antibody-Drug Conjugate Conference

Richard Gregory
Chief Scientific Officer
ImmunoGen

Bill Boyle
Chief of Preclinical Research
BioAtla

Andrew Phillips
Director, Next Generation Antibody Drug Conjugates
AbbVie

Melanie Smitt
Medical Director
Genentech

Amy Han
Director of Research & Development
Regeneron

Firelli Alonso
Senior Director, External Supply
Pfizer

Tim Lowringer
Chief Scientific Officer
Mersana

Jay Harper
Associate Director
AstraZeneca

Chris Leamon
Vice President, Research
Endocyte

Greg Thurber
Assistant Professor
University of Michigan

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Welcome to the 10th World ADC San Diego

A Letter from our Chairman

Dear Colleagues,

It is with great pleasure and enthusiasm that I invite you to join me at the 10th Annual World ADC San Diego. With 83 ADCs in clinical development there is a continuing need for a comprehensive meeting for the whole of the ADC field to converge at. This Hanson Wade event brings together drug developers across all stages of development resulting in a must attend event for the ADC community to advance the next 12 months of ADC development. Whether you are involved in early discovery, manufacturing, running a clinical trial or characterizing an ADC, this is the event for you.

For the insights at this event to be useful, they need to be delivered to people actively involved in making the decisions that matter. That's why for the 2019 meeting I'm particularly looking forward to hearing from key academic groups, new companies in the field as well as the pharma and biotech companies at the forefront of progress in this field.

I am looking forward to hearing an update on some exciting programs such as Daiichi Sankyo's DS-8201 and to hear an update on Regeneron's ADC that sits outside of oncology; as this field grows and starts to address other unmet needs.

Within recent months we have seen many collaborations forged in the ADC space which goes to show the importance of building relationships and learning about novel approaches to this exciting field. If you are or want to become a player in the ADC arena, this is the conference you should attend. You will both learn and make valuable connections that will help drive your ADC development forward and help turn the promise of these therapeutics into a reality for patients.

I look forward to seeing many faces, old and new at this year's meeting as we enjoy thought-provoking and inspiring presentations. See you in October.

Sincerely,

Rich Gregory

ImmunoGen

Chairman of World ADC San Diego

Contents

"World ADC maintains its status as the premier scientific conference for ADC-related research. There is broad coverage of topics relevant to all aspects of ADCs including efficacy, safety, manufacturability, novel chemistry and conjugation, and new applications for ADCs. **World ADC really is a one-stop shop for obtaining the crucial updates from the ADC field**"

MedImmune

Attend World ADC San Diego to Maximize the Clinical Therapeutic Window of Your ADC

October 8-11, 2019
San Diego, CA

Celebrating its 10th year, World ADC San Diego continues to be the **industry's longest standing and most comprehensive antibody drug conjugate conference**. Whether you're a newcomer to the field or an ADC veteran World ADC San Diego is your most important event of 2019.

As the world's largest gathering of ADC stakeholders, World ADC San Diego is where investment, development and partnership decisions are made. Join over 600 drug developers from 230 active ADC organizations and **define your 2020 ADC development strategy**. Designed with thought-leaders at Seattle Genetics, AstraZeneca and ImmunoGen this industry defining event will share the pioneering advances with next generation ADC technologies, in depth development case studies with supporting data and learnings from our clinical failures. Attend this conference to **maximize the clinical therapeutic window of your ADC candidate**.

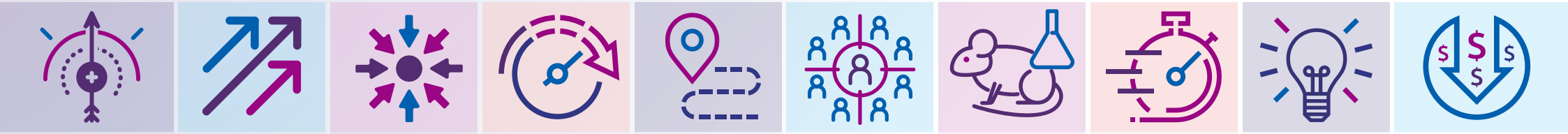
Across four packed days, World ADC San Diego will **cover every element of ADC drug development** providing you with an unparalleled breadth and depth of insight, making it your **most important learning experience of 2019.**

> "Great speakers! Perfect size to meet everyone and feel comfortable engaging others"
>
> NOVARTIS

> "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

> "An effective forum to network and learn the most recent progress on several areas"
>
> AstraZeneca

Attend World ADC San Diego to:



1. **Increase the efficacy of your ADC candidate with improved understanding of** the relationship between your payload, linker and antibody
2. **Get one step ahead in the race to IND** with insight on ADME considerations and bioanalytical support strategies
3. **Identify and manage the primary reference materials for a FIH ADC** to reflect on ADC reference standard management and setting specifications
4. **Improve operational running of clinical trials** by discussing biomarker measurements of surrogate endpoints and mechanistic models
5. **Enhance the potential of ADCs in combination** by navigating the clinical landscape and clinical considerations of a combination trial
6. **Enhance PK/PD strategy** from discovery to the clinic and improve your therapeutic window
7. **Mitigate toxicities and advance preclinical development** to decipher strategies to tailor molecular design
8. **Simplify manufacturing timelines** to overcome challenges of finetuning process development, scale-up and GMP manufacturing of a novel ADC technology platform
9. **Discover innovative frontiers in ADC discovery** as we explore IO payloads, radio-conjugates and ADCs outside of oncology
10. **Minimize ADC manufacturing costs** by developing efficient, scalable, ADC manufacturing processes

What's New for 2019

The 1st CMC Day

As more ADCs enter the clinic the complexity of Chemistry Manufacturing and Controls comes ever more abundant. Focussed from Phase II through to commercial scale manufacturing, the inaugural CMC Seminar Day will enable you to effectively scale up your manufacturing operation. With presentations delving into formulation and fill finish challenges, insights for overcoming manufacturing roadblocks and analytical lessons learned from commercial manufacturing for FDA approved ADCs, the inaugural CMC Day enables you to manufacture your ADC at large scale.

ADC & Combinations

One of the hottest topics currently in the ADC field; the use of ADCs in combination. Based on your feedback this year we wanted to broaden the scope to all combination approaches to allow you to review the landscape of ADCs in combination and its true potential. Whether it's addressing the challenges of running a combination trial or discussing an ADC in combination with chemotherapy, radiation or a checkpoint modulator – we want to discuss all the options that could enhance the clinical therapeutic window of ADCs.

Scientific Poster Session

Growing through popular demand, the Poster Session is often a conference highlight, so we have dedicated a one and a half hour slot in the agenda to highlight the most recent projects and breaking findings in ADC development. Share your work with the pioneers of ADC development, bring a poster and gain feedback on your latest research with this expert community.

Celebrating 10 Years of World ADC San Diego

Join your friends for an evening of celebration. This event will put the spotlight on the last ten years of ADC drug development, as well as look to what the future holds for ADCs. Welcoming everyone from ADC veterans to newcomers this celebration will show how ADCs are fighting the war against cancer and impacting the lives of patients.

Clinical Operations Stream

As the clinical progress of ADCs evolves rapidly, so do the clinical challenges. To reflect this the clinical stream will have more focus on the operational and practical challenges of running a clinical trial. Data will be shared in this stream to support how practical challenges such as biomarker development strategies, patient stratification methods and managing delayed toxicity can be overcome to ensure endpoints are met and trials are smoothly run.

Your 2019 Highlights

Key Talks You Cannot Miss

Andrew Phillips
Director, Next Generation Antibody Drug Conjugates
AbbVie

Andy will be discussing the first-in-class BCL-XL inhibitorADC. ABBV-155 targets B7H3 expressing cancer cells and delivers a potent and specific BCL-XL inhibitor.

Melanie Smitt
Associate Director- Group Medical
Genentech

Earlier this year the FDA granted Kadcyla breakthrough therapy designation for HER2-positive early breast cancer. Melanie will be discussing Genetech's plan for this expansion.

Jeremy Duvall
Associate Director
Mersana

Jeremy will be revealing Mersana's novel ADC platform employing an immunostimulatory payload. Combining IO and ADCs is a heavily discussed topic and this presentation will highlight the considerations and benefits of combining I/O payloads with an ADC approach.

88+ Expert Speakers

Presentations Revealing the Latest Scientific Advances in ADC Science

Regeneron will be providing an update on Regeneron's non-cytotoxic ADC that has the potential to treat atherosclerosis

REGENERON

Endocyte has developed a radioconjugate that utilizes a high affinity targeting ligand to direct potent radiotherapy to prostate cancer cells

ENDOCYTE

3 Seminar Days

Leading ADC Companies Presenting at World ADC San Diego for the First Time

gsk

MENARINI group

zymeworks BUILDING BETTER BIOLOGICS

Lessons Learned From Our Failure & Experiences

Lessons Learned from "Back-to-Back" Regulatory Submissions for Two ADC Products

Pfizer

Lessons Learned from Combination Therapy with Telisotuzumab Vedotin, an MMAE ADC Target c-Met, in NSCLC

abbvie

Challenges & Lessons Learned in ADC CMC Development & Outsourcing

NOVARTIS

10 Workshops

Agenda-at-a-Glance

October 8-11, 2019
San Diego, CA

Workshop Day
Tuesday October, 8

Introduction to ADCs	Modelling & Simulation of ADC in Drug Dev	Workshop A	Workshop C	Workshop E	Workshop G

Lunch & Networking

Introduction to ADCs *continued*	Modelling & Simulation of ADC in Drug Dev *continued*	Workshop B	Workshop D	Workshop F

This is an eye-opening conference that has brought together the greatest minds in antibody-drug conjugates
Genentech

Seminar Day
Wednesday October, 9

1st CMC Day NEW	4th Analytical & Bioanalytical Day	3rd ADC Combo Day

Lunch & Networking

1st CMC Day *continued* NEW	4th Analytical & Bioanalytical Day *continued*	3rd ADC Combo Day *continued*

Scientific Program Day 1
Thursday October, 10

Plenary Stream

Clinical Stream	CMC Stream	Discovery Stream	Translational Stream

Lunch & Networking
Lunch Seminar sartorius stedim biotech

Clinical Stream	CMC Stream	Discovery Stream	Translational Stream

Scientific Poster Session & Networking

Plenary Stream

Scientific Program Day 2
Friday October, 11

Breakfast Briefing
CARBOGEN AMCIS
Plenary Stream

Clinical Stream	CMC Stream	Discovery Stream	Translational Stream

Lunch & Networking
Lunch Seminar cerbios

Plenary Stream

Excellent talks by all the speakers with a transparent and frank attitude to share good and bad experiences gained in the challenging world of ADCs in oncology. A deep and valuable analysis of the state of the art of ADCs with a focus on solid tumors potential. A lot of new technologies, still to be clinically validated, aiming to overcome the "TW Issue" presented
Menarini Ricerche

Your 88 Expert Speakers

Amy Han
Director of Research & Development
Regeneron

Andrew Phillips
Director, Next Generation Antibody Drug Conjugates
AbbVie

Anton Rosenbaum
Translational Sciences Group Leader
AstraZeneca

Antonio Triolo
Head of the Laboratory of Analytical Chemistry for Development & Research & Development
Menarini

Arturo Molina
Chief Medical Officer
Sutro Biopharma

Bill Boyle
Chief of Preclinical Research
BioAtla

Brian Mendelsohn
Director
Ajinomoto Biopharma Services

Brian O'Mara
Associate Director - Downstream Process Development
Ambrx

Cexiong Fu
Principle Scientist
Shire

Chee Ng
Associate Professor
University of Kentucky

Chris Leamon
Vice President, Research
Endocyte

Christian Rolff
Chief Executive Officer
Oxford Biotherapeutics

Christoph Rader
Professor, Department of Immunology and Microbiology
The Scripps Research Institute

Damon Meyer
Associate Director, Conjugation Process Development
Seattle Genetics

Daniel Milano
Senior Engineer, Conjugation Process Development
ImmunoGen

David Bramhill
President
Bramhill Biological Consulting

Dhaval Shah
Associate Professor
Buffalo University

Divya Samineni
Clinical Pharmacologist
Genentech

Ed Ha
Founding Principal Scientist
Angiex, Inc

Engin Ayturk
Director, CMC Process Engineering & BioConjugation
Mersana

Eric Lacoste
Head of Bio-Organic Team & Chemistry, Manufacturing, Control & Project Manager
Sanofi

Firelli Alonso
Senior Director, External Supply
Pfizer

Gail Lewis Phillips
Senior Scientist - Translational Oncology
Genentech

Gary Ren
Scientist
Lawrence Berkley National Labs

Your 88 Expert Speakers

Giorgio Salciarni
Senior Manager - Technical Business Development
BSP

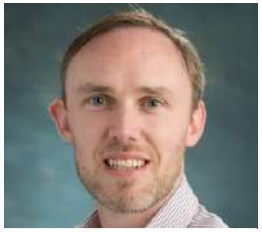
Greg Thurber
Associate Professor
University of Michigan

Hans Georg Lerchen
Chief Scientist - Medicinal Chemistry
Bayer

Hillary Schuessler
Investigator
GSK

Ian Schwartz
Global Bioconjugation Technology Consultant
Sartorius Stedium Biotech

Jacob Roth
Research Fellow
National Center for Advancing Translational Sciences



James Purcell
Project Director – Oncology Discovery
AbbVie

Jay Harper
Associate Director
AstraZeneca

Jens Lohrman
Head of Disease Area, Oncology & Technical Development
Novartis

Jeremy Duvall
Associate Director
Mersana

Jian Wang
Senior Principal Scientist/LC-MS Technical Integration Lead
Bristol-Myers Squibb

John Lambert
Executive Vice President, Emeritus & Distinguished Fellow
ImmunoGen

John Vallerie Douglas
Associate Director
Seattle Genetics

Jun Tang
Senior Manager
Cancer Research Institute

Kate Mikulka
Technical Services Antibody-Drug Conjugate Operations Manager
Pfizer

Kathryn Pugh
Analytical Chemist
Spirogen

Keiji Furuuchi
Associate Director & Head of Immunotherapy & Preclinical Development
Eisai

Leo Kirkovsky
Director, Clinical Assay Group
Pfizer

Letrishka Anthony
Senior Analyst
Beacon Targeted Therapies

Lisa McDermott
Head of Process & Analytical Development
MilliporeSigma

Louie Naumovski
Senior Medical Director
AbbVie

Marc Nasoff
Chief Scientific Officer
Fortis Therapeutics

Marcus Böhme
Head of Research & Development
BTI

Mark Bilodeau
Chief Scientific Officer
Tarveda

Your 88 Expert Speakers

Mark Frigerio
Director Chemistry
Abzena

Mark Stroh
Clinical Pharmacology
CytomX

Maureen O'Connor
Chief Scientific Officer
Forbius

Melanie Derde
Bioconjugation Analytics Manager
Novasep

Melanie Smitt
Medical Director
Genentech

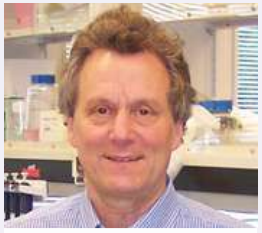
Michael Kaufman
Senior Vice President - Chemistry, Manufacturing & Controls
Mersana

Naresh Jain
President & Chief Executive Officer
NJ Biopharmaceuticals LLC

Nazzareno Dimassi
Associate Director Research & Development
MedImmune

Nick Keen
Chief Scientific Officer
Bicycle Therapeutics

Patrick Dennler
Lab Head / Scientific Specialist
Lonza



Peter Senter
Vice President Chemistry & Distinguished Fellow
Seattle Genetics

Phil Howard
Chief Scientific Officer
Spirogen

Rakesh Dixit
President & Chief Executive Office
BIONAVIGEN, LLC

Randall Morris
Research Professor of Cardiothoracic Surgery &, by courtesy, Medicine & Surgery (Emeritus)
Stanford University School of Medicine

Richard Gregory
Chief Scientific Officer
ImmunoGen

Rick Powers
Independent Consultant

Robert Phillips
Vice President & Global Head of Translational Sciences
Daiichi Sankyo

Sabra Hanspal
Senior Scientist
AbbVie CMO

Scott Henry
Principal Scientist - Analytical Sciences
Seattle Genetics

Scott Miller
Senior Scientific Advisor
CARBOGEN AMCIS

Scott Tagawa
Associate Professor
Cornell University

Seema Kumar
Associate Director
EMD Sereno

Shawn Novick
Independent Consultant

Sri Ghatta
Director & Clinical Scientist
Genmab

Your 88 Expert Speakers

Stuart Hicks
Director, Pipeline Research & Development
ImmunoGen

Subhash Chauhan
Professor
University of Tennessee

Tae Kyo Park
Chief Executive Officer
IntoCell

Thomas Nittoli
Research & Development
Regeneron

Tim Lowringer
Chief Scientific Officer
Mersana

Tony Polverino
Chief Scientific Officer
Zymeworks

Trishna Goswami
Vice President, Clinical Development for Non-Breast Indications
Immunomedics

Vítor Sousa
R&D Biological Senior Manager
Cerbios

Ying Buechler
Vice President, Development
Ambrx

Yutaka Matsuda
ADC Researcher
Ajinomoto Bio-Pharma Services

Zhan Xiao
Principle Scientist
AstraZeneca

Xinfang Li
Vice President - Process Development & Head of Chemistry, Manufacturing & Controls
Mabplex

"World ADC conferences are a key part of the ADC ecosystem, contributing to the growth of knowledge, ideas, and community network"

AstraZeneca

Workshop Day

Tuesday October, 8

Introduction to Discovery & Design of Novel ADCs

9.00-4.00

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, Consultant, **Bramhill Consulting**

Modelling & Simulation of Antibody-Drug Conjugate Pharmacokinetics & Pharmacodynamics (PK/PD) in Drug Development

9.00-4.00

This will be a two-part workshop designed to accommodate both attendees new to modelling and simulation as well as researchers more seasoned in ADC development. The morning session will be geared towards modelling fundamentals while the afternoon will discuss the application and results of simulations specific to ADC preclinical and clinical development. Participants are welcome to attend either or both parts depending on their background and interests. The morning session will introduce basic tenets of antibody drug conjugate PK/PD and how to characterize these aspects using empirical and systems-based mathematical models. These models include systemic PK (plasma clearance, payload deconjugation, target-mediated drug distribution, etc.), tissue distribution (e.g. heterogeneous tumor concentrations), and cellular targeting (internalization, payload release, bystander effects, etc.). Several hands-on modelling examples will be conducted along with strengths and limitations of these approaches.

Join us in the afternoon, where more advanced topics will be introduced towards the application of modelling for preclinical ADC development and clinical translation. This includes integrating the topics covered in the morning session into more comprehensive simulations of ADC PK/PD and what these results can tell us about efficacy and toxicity. Example topics include how the size of ADCs and related drug conjugates, tumor heterogeneity, ADC bystander effects, and antibody co-administration impact the efficacy and therapeutic index of ADCs. Finally, a strategy to translate preclinical efficacy of ADCs into the clinic using PK/PD modelling and simulation will be presented.

Workshop Leader

Greg Thurber, Associate Professor, **University of Michigan**

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

Workshop Day

Tuesday October, 8

Workshop A: Advanced Design of ADCs: Principles & Applications with Next Generation Linkers & Site-Specific Technology

9.00-12.00

Let's explore various ways to improve the therapeutic window of ADCs using a rational approach to improve clinical performance by building a better molecule. By incorporating improvements in solubility as well as attachment stability, great strides can be made. We will discuss various methods for obtaining a defined DAR, and the pros and cons of several key approaches. Also, attention will be given to dual and multi-warhead ADCs, and the various ways to achieve controlled multi-valency on native and engineered proteins. Lastly, with the emergence of Immuno-oncology, dual binding bi-specific antibodies will be discussed as a platform for ADC conjugations.

Agenda Summary:

- Welcome and Introductions
- Background and Defining the Challenge
- Solubilizing the Drug-Linker
- Stabilizing the Linker
- Site-Specific Strategies for Success
- Multi-valency and Dual-Warheads
- Bi-specific constructs as ADC platforms

Workshop Leader

Rick Powers, **Independent Consultant**

Ed Ha, Founding Principal Scientist, **Angiex, Inc**

Workshop C: Next-generation ADC Target Discovery: The New Frontier

9.00-12.00

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.

This workshop will cover:

- Summary of current ADC target landscape at both clinical and preclinical stages with a correlation of the clinical stage targets with the success or failures of their clinical trials
- Lessons learned from the clinical trials: what's the hallmark of a successful ADC target?
- Where do we go from here: how to discover the next-generation of ADC targets?
- Key technologies to enable next-generation ADC target discovery

Workshop Leader

Zhan Xiao, Principle Scientist, **MedImmune**

Workshop E: Building the Bridge from Translation to Discovery - Model-based Forward/Reverse Translational Approach to Guide the Discovery & Development of Therapeutic Monoclonal Antibody

9.00-12.00

Translational science with quantitative modelling and simulation approach plays an important role in moving molecules from discovery to development and eventually to patients. However, translational science is not a miracle tool that will transform junk into gold and the drug developers simply cannot develop the discovered molecules with undesirable properties into drugs for patients. Therefore, in this study, we elucidated a novel concept of reverse translational science by utilizing a model-based approach to transfer the knowledge in reverse direction from development to discovery. FcRn binding affinity profiles and charges have been shown to play an important role in the distribution and elimination of therapeutic monoclonal IgG antibody (TMAb).

Using two case studies, we will demonstrate the utility of using minimal physiologically-based pharmacokinetic (mPBPK) modelling approach to construct detail quantitative relationships between the FcRn binding affinity/charges and the PK parameters of the TMAb. Such relationships are useful to identify the discovery "sweet spot" in designing future generation of TMAb wth desirable biodistribution and elimination properties (Reverse Translational Appraoch). Furthermore, the mPBPK model developed in the preclinical model was useful to predict the PK of the TMAb in adult human subjects (Forward Translational Approach)

Workshop Leader

Chee Meng Ng, Associate Professor of Pharmaceutical Science, **University of Kentucky**

Workshop G: CMO Management; Challenges & Insights for Outsourcing Complex Biologics such as ADCs

9.00-12.00

This workshop will focus on:

- Buy vs. make: Key considerations as an enabler for an effective outsourcing strategy
- Differentiated strategies for "simple" vs "complex" biologics?
- Critical success factors for effective outsourcing
- Scale-up and site transfer of a conjugation process with impact on key product quality attributes: a case study
- Analytical transfers: considerations & lessons learned from a challenging assay transfers
- CDMO or CMO? Outsourcing of overarching development workflows vs. "just" API manufacturing?

Workshop Leader

Jens Lohrman, Head of Disease Area, Oncology & Technical Development, **Novartis**

Workshop Day

Tuesday October, 8

Workshop B: Exploring Novel Mechanism of Actions, Optimizing Payload & Linker Chemistry & Deepening Understanding of Payload Driven Toxicities

1.00-4.00

Discussion will focus on how payload-linker combinations can affect ADC clinical activity and toxicities when attached to antibodies, and how the most appropriate payload-linker combination can be chosen for a particular antibody and/or cancer type.

Attend this workshop to explore the scientific biological rationale for maximizing the synergy of ADC payload- linker combinations.

Join your peers at this workshop to:

- Improve understanding of the most desirable properties of payloads and linkers
- Review current payload-linker combinations which are enhancing the therapeutic window
- We will also cover past strategies to improve and balance: payload potency, impact of homogeneous conjugations on PK/PD, protein/nucleic acid payloads & synergy with I/O
- Explore payload and linker combinations currently at the discovery or development stages
- Learn to develop linker-payloads that will not release prematurely
- Discover important considerations for designing the optimum payload-linker

Workshop Leader

Rick Powers, **Independent Consultant**

Ed Ha, Founding Principal Scientist, **Angiex, Inc**

Workshop D: The Chemistry of Toxins, Conjugations & Linkers for Antibody-drug Conjugates

1.00-4.00

The choice of linker and payload for an ADC is essential for the selection of a successful clinical candidate. This workshop will deepen the understanding of the chemistry behind conjugation technologies and be held by highly experienced leaders in the ADC field who have designed successful candidates from discovery all the way to clinical trials.

Attend this workshop to:

- Understand synthetic challenges, structural features, and stability of toxins
- Chemistry of linkers, linker choice, linker release mechanisms
- Site-specific conjugations vs non-site-specific conjugations
- Stability of ADCs
- Mitigation of aggregation

Workshop Leaders

Thomas Nittoli, Director of R&D Chemistry, **Regeneron Pharmaceuticals, Inc.**

Brian Mendelsohn, Director, **Ajinomoto Bio-Pharma Services**

Naresh Jain, President & CEO, **NJ Biopharmaceuticals LLC**

Workshop F: From FIH to Post-commercial: ADC Reference Standard Management & Setting Specifications

1.00-4.00

This workshop will explore two challenges presented by ADCs during the lifecycle of a product

Identifying and managing the primary reference materials
The reference material for a FIH ADC may be derived from research or development materials, from toxicology lots or from the first GMP lot. However, this material may not be representative of the product later in its lifecycle and/or it may be limited in quantity. We will explore ways to identify and manage reference standard materials and how to bridge references as the product moves towards commercialization and beyond. The primary focus will be on the ADC reference, however the group may explore similar issues as they relate to mAb, drug or linker, impurity standards, and/or assay standards.

Setting and justifying specifications
The specifications for an ADC have been of particular interest for regulators due to the complex and toxic nature of these products. The product profile can be relatively 'simple' (i.e. toxic drug attached to benign targeting mAb) or much more complex – for instance if the mAb has activity, demonstrates differential binding post-conjugation, or stability is an issue. As more is learned about each particular ADC therapeutic product through pre-clinical, clinical and characterization work, identifying CQAs, managing the control strategy, and setting and justifying the specifications becomes an iterative process. As we move from FIH to a commercial product, assays may be fine-tuned or changed and activity assays may be introduced or refined, requiring bridging and specification updates. **This workshop will provide an opportunity for us to discuss how we approach these challenges and meet the expectations of regulators for rigorous justifications regarding our decisions.**

Workshop Leader

Shawn Novick, Independent Consulant

Seminar Day

1st CMC Day

Wednesday October, 9

9.00 Chair's Opening Remarks

Michael Kaufman, Senior Vice President - Chemistry, Manufacturing & Controls, **Mersana**

9.10 Considerations for Scaling Up Your Manufacturing Operations from Phase II & Beyond

- Advantage of applying Ambrx technology to make ADCs
- ARX788 development and manufacturing strategy
- ARX788 comparability strategy and study results addressing process changes

Ying Buechler, Vice President, Development, **Ambrx**

9.40 Using Conjugation Process Purification Capabilities to Support Small-molecule & Bulk Drug Substance Specifications

- Immunogen's approach of using fate/purge studies performed around the conjugation purification process to support small-molecule specification justifications will be discussed
- An overview of worst-case conjugation studies performed to characterize the clearance capacity of the purification process of individual process-related impurities will be given
- A case study for an early stage and late stage program will be presented

Daniel Milano, Senior Engineer, Conjugation Process Development, **ImmunoGen**

10.10 Speed Networking

10.40 Morning Break

11.30 Process Development & Comparison of Analytical Approaches for a Novel Chemical Site-Specific

- Overview of 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.
- Process development for scale-up ADC preparation suitable for GLP toxicological studies
- Comparison of six different analytical techniques to measure DAR
- Proof of site-selectivity using peptide mapping

Yutaka Matsuda, ADC Researcher, **Ajinomoto Bio-Pharma Services**

Solving Formulation & Fill Finish Challenges

12.00 Mastermind Session: ADC Formulation/Fill Finish Development readying for Commercial Scale Manufacturing

More practical and highly interactive breakout roundtables where attendees can crowd-source 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

- Discussing solutions to overcome aggregation challenges
- Case studies on progressive formulation and fill finish methods

12.30 Lunch & Networking

Case Studies: Sharing Insights for Overcoming Manufacturing Roadblocks

1.30 Fine-Tuning Process Development, Scale-up & GMP Manufacturing of a Novel ADC Technology Platform

- Overview of complex supply chain architecture for ADC manufacturing
- QbD-based strategy to process validation of key process intermediates
- Process scale-up Case Studies

Engin Ayturk, Director, CMC Process Engineering & BioConjugation, **Mersana**

2.00 Challenges & Lessons Learned in ADC CMC Development & Outsourcing

- Buy vs. make: considerations and critical success factors
- Scale-up and site transfer of a conjugation process with impact on key product quality attributes: a case study
- Analytical transfers: considerations & lessons learned from a challenging assay transfers

Jens Lohrmann, Head of Disease Area, Oncology & Technical Development Novel Biologic Entities, Senior Manager - Global Program & Translational, **Novartis**

2.30 Panel Discussion: Simplifying Your Global Manufacturing Supply Chain

- What went wrong? Discussing lessons learned from managing late stage manufacturing supply chains
- Effectively managing complex global supply chains
- Exploring opportunities to work with partners in emerging ADC geos such as Asia

Jens Lohrmann, Head of Disease Area, Oncology & Technical Development Novel Biologic Entities, Senior Manager - Global Program & Translational, **Novartis**

Seminar Day

1st CMC Day

Wednesday October, 9

3.00 Afternoon Break & Networking

Analytical Lessons Learned from Commercial Manufacturing for FDA Approved ADCs

4.00 Strategies for Late-stage ADC Product Characterization

- Product characterization: actionable information to enable QBD
- Strategies to address the challenges of ADC charge-variant characterization
- A look to the future: the role of attribute-specific product and process characterization

Scott Henry, Principal Scientist - Analytical Sciences, **Seattle Genetics**

4.30 Lessons Learned from "Back-to-Back" Regulatory Submissions for Two ADC Products

- Learn how to streamline the processes
- Planning ahead – process validation and control strategy
- Effectively and efficiently prepare for PAI

Katherine Mikulka, Manager Technical Services, Oncology Operations, **Pfizer**

5.00 Chair's Closing Remarks

Michael Kaufman, Senior Vice President - Chemistry, Manufacturing & Controls, **Mersana**

"Very well organized meeting with an impressive line-up of industry speakers"

Merck

Seminar Day

4th Analytical & Bioanalytical Day

October 8-11, 2019
San Diego, CA

Wednesday October, 9

8.30 Chair's Opening Remarks

Leo Kirkovsky, Director, Clinical Assay Group, **Pfizer**

8.40 Keynote: 1 Year on – Were the Goals Achieved?

- Introduction to the Analytical and Bioanalytical day
- Lessons learned from previous years
- How the analytical and bioanalytical field has progressed over the last year?

Leo Kirkovsky, Director, Clinical Assay Group, **Pfizer**

9.10 The Evolution & Current Status of Antibody-Drug Conjugate Bioanalysis

- Overcome technical challenges in ADC bioanalysis with advancing technologies and strategies
- Learn how to select and correlate various analytes, technologies and platforms
- Stage specific and continuity of bioanalytical approaches, platforms and strategies at different phrases of ADC development
- Regulatory perspectives along with challenges and strategies of bioanalysis for new conjugate modalities

Jian Wang, Senior Principal Scientist/LC-MS Technical Integration Lead, **Bristol Myers Squibb**

9.40 Analytical Strategies for Accelerated Approval of ADCs

- CQA elucidation from candidate selection to marketing application
- Holistic approach to mAb, DS, and DP comparability
- Lessons learned from an accelerated timeline

Hillary Schuessler, Investigator, **GSK**

10.10 From Deep Characterization to Sub-Ppb Payload Metabolite ID: High-Resolution MS Applications in ADC Analysis

- High-resolution MS-based techniques are widely employed to address a number of complex analytical problems related to the structural characterization of ADCs, their components, formulation excipients and biotransformation products
- Here we present our current approach, in which the information obtained from the MS fragmentation behavior of the molecule under study is used to design highly specific and sensitive characterization methods
- Explore real life examples in different application fields

Antonio Triolo, Head of the Laboratory of Analytical Chemistry for Development & Research & Development, **Menarini**

10.40 Speed Networking

11.10 Morning Break

Adaptations to Characterization Techniques as the Field Evolves

12.00 Streamlining Analytics to Support Research & Early Development of Novel ADC Modalities

- We describe implementation of 2 distinct MS approaches for bottom-up and top-down characterization of ADC quality attributes in a H/T environment. In the bottom up approach, peptide map has been implemented for H/T screening of mAb and ADC PTMs and sequence variants. For top-down ADC characterization, native size exclusion chromatography mass spectrometry (SEC-MS) has been utilized for accurate, quantitative assessments of drug-to-antibody ratio (DAR) and drug-distribution on a diverse portfolio of ADC chemotypes
- These cases highlight a broader strategy at Seattle Genetics whereby we seek to future-proof analytical development activities and timelines by developing chemotype-agnostic, platform H/T approaches. Our vision is to have a suite of MS-based methodologies that sensitively detect and quantitate molecular product quality attributes so that critical process development activities are not delayed unnecessarily by molecule specific analytical method development

John Valliere-Douglass, Associate Director, **Seattle Genetics**

12.30 Single Molecule 3D Image: An Approach to Reveal Antibody Structural Dynamics & Conformational Changes

- Determination of 3D structure of a single protein by individual particle electron tomography (IPET)
- 3D structural dynamics and fluctuation of IgG1 antibody
- Conformational changes and aggregation of antibody by peptide conjugation

Gary Ren, Scientist, **Lawrence Berkeley National Laboratory**

1.00 Lunch & Networking

2.00 Explore Advances in 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 behavior of ADCs and drug intermediates *in vivo*
- Lessons learned from working with PBD-ADCs

Kathryn Pugh, Analytical Chemist, **Spirogen**

Seminar Day

4th Analytical & Bioanalytical Day

Wednesday October, 9

Bioanalytical Support Strategies

2.30 ADME Considerations & Bioanalytical Strategies for Pharmacokinetic Assessments of Antibody-Drug Conjugates

- Overview of structural complexity of ADCs
- Current bioanalytical approaches commonly employed to assess pharmacokinetics of ADCs
- Emerging bioanalytical tools for the assessment of ADC biotransformations

Anton Rosenbaum, Translational Sciences Group Leader, **AstraZeneca**

3.00 Afternoon Break & Networking

Bioanalytical Support Strategies

4.00 A View from the Top: Integrated LC-MS Strategy for Intact ADC/Antibody Analysis

- Novel development of chromatographic column for native ADC separation and online LC-MS analysis
- Top down analysis of antibody/ADC variants
- Establish characterization of conjugation site heterogeneity by LC-MS

Ceixong Fu, Principle Scientist, **Shire**

4.30 Challenges Associated with PK & Immunogenicity Support for Antibody Drug Conjugates

- Quantitative modeling and simulations aid in preclinical to clinical translation of ADC and rely on high-quality bioanalytical (BA) measurements to integrate PK, PD and immunogenicity data
- Changes in BA critical reagents, assay format and/or assay platform across different stages of drug-development may impact observed PK profile/ parameters
- Immunogenicity risk assessment drives ADC immunogenicity testing strategies and mitigation plans
- Highly potent cytotoxic payloads pose challenge in their DMPK assessments
- An integrated bioanalytical and translational strategy should be defined early on for ADC development, keeping in mind that one strategy may not fit all

Seema Kumar, Associate Director, **EMD Sereno**

5.00 Chair's Closing Remarks

Leo Kirkovsky, Director, Clinical Assay Group, **Pfizer**

"World ADC is a very well organized meeting. Every day I was excited to learn new ideas by listening to the great presentations as well as talking to the most talented people. I feel energized after attending the meeting"

Mersana

Seminar Day

3rd ADC & Combinations Day

October 8-11, 2019
San Diego, CA

Wednesday October, 9

9.00 Chair's Opening Remarks

Jay Harper, Associate Director, **AstraZeneca**

Improving Understanding of Various Combination Approaches & the Combination Landscape

9.10 ADC & Checkpoint Landscape Review

- Timeline review of how the clinical combination space had evolved over time
- Analysis of popular checkpoints used in combination
- Insights into clinical trends focused on ADCs and checkpoints

Letrishka Anthony, Senior Analyst, Beacon Targeted Therapies, **Hanson Wade**

9.40 Combining ADCs with..... Evolution of ADC Combinatorial Therapies

- Overview of ADC combination strategies evaluated in the clinic
- Highlights and difficulties with ADC combinations
- Beyond chemo and IO: next wave of ADC combinations

Jay Harper, Associate Director, **AstraZeneca**

10.10 Speed Networking

11.00 Morning Break

Exploring Rational Approaches to Combination Trials

11.30 The Impact of Antibody-Drug Conjugate Distribution on Multiple Mechanisms of Action & Combination Therapy

- Antibody-drug conjugates can work through multiple mechanisms of action (MoA): payload killing, cell signalling blockade, and Fc-effector functions
- The relative contribution of each MoA can be used to increase overall efficacy at tolerable doses, thereby increasing the therapeutic window
- These MoA can be used to improve the efficacy of immuno-oncology agents such as checkpoint inhibitors

Greg Thurber, Associate Professor, **University of Michigan**

12.00 Sharing Clinical Challenges & Considerations for a Combination Trial

- Why should an ADC be combined with an additional drug?
- When should two investigational agents be combined?
- How do you determine relationship of combination agents with adverse events?

Scott Tagawa, Associate Professor in Hematology, Oncology, Clinica l Medicine & Urology, **Weill Cornell - Cornell University**

12.30 Lunch

Counting on Combos: Evaluating Future Development of Combinations

1.30 Rapid Advancements of Oncology Landscape: Where Do ADC Sit in an Immuno-Oncology World?

- The current landscape of IO
- The clinical landscape of IO plus ADC
- How philanthropic investment models could help advance IO combo trials

Jun Tang, Cancer Research Institute

2.00 Combination Therapy with Telisotuzumab Vedotin, an MMAE ADC Targeting c-Met, in NSCLC

- Telisotuzumab vedotin is active agent as a monotherapy in NSCLC
- Telisotuzumab vedotin has acceptable safety profile in NSCLC
- Explore how Telisotuzumab Vedotin can be combined with approved drugs used in treatment of NSCLC

Louie Naumovski, Senior Director – Medical, **AbbVie**

2.30 Afternoon Break

Novel Development for ADCs in Combination

3.30 Discovery of an ADC Platform Employing an Immunostimulatory Payload

- Overview of the considerations and benefits of combining I/O payloads with an ADC approach
- Application of Mersana's modular Synthemer platform technology to create IO ADCs
- Review *in vitro* and *in vivo* characterization of selected examples in relevant model systems

Jeremy Duvall, Associate Director, **Mersana**

4.00 Panel Discussion: Reviewing the Rationale for Combination Studies & Target Selection

- Discuss the approaches of ADC combinations that have been tested in clinic and where available, monotherapy efficacy and safety data for the ADC, the combination partner and the combination
- Review of the various types of combinations and where we see greatest potential
- Summary of the combination day and where to go from here

4.30 Chair's Closing Remarks

Jay Harper, Associate Director, **AstraZeneca**

Scientific Program - Day 1

Thursday October, 10

John Lambert
Executive Vice President, Emeritus & Distinguished Fellow
ImmunoGen

Honorary Chair

Dedicating over 30+ years to ADC drug development and attending every World ADC we're delighted to be welcoming John as our Honorary Chair

Rich Gregory
Chief Scientific Officer
ImmunoGen

8.00 **Chair's Opening Remarks**

John Lambert
Executive Vice President, Emeritus & Distinguished Fellow
ImmunoGen

8.10 **Keynote: Celebrating 10 Years of World ADC- How Far the Field Has Come & Where We Are Going**

- Ten years ago, there was only one marketed ADC, Mylotarg™, that was approved in 2000. However, within one year of the first World ADC meeting, Mylotarg™ was withdrawn from the US and EU markets following a failed phase 3 trial
- However, the approvals of Adcetris™ (in 2011 for HL and ALCL) and Kadcyla™ (in 2013 for HER2+ metastatic breast cancer), two ADCs utilizing potent tubulin agents as payloads, re-ignited enthusiasm for using antibodies for targeted delivery of cytotoxic agents to cancer tissue. In 2017, Mylotarg™ was re-approved for treatment of AML, and another calicheamicin conjugate, Besponsa™, received approval for treating B-ALL
- Today, Kadcyla™ sales exceed $1 billion annually. There are more than 83 different ADCs currently in clinical development. While there are many factors to ensuring the creation on a successful ADC (right target, right antibody, right linker properties and attachment site(s), right payload), getting it right can create ADCs that can become important medicines for treating human disease (especially cancer)

Rakesh Dixit
President & Chief Executive Officer
BIONAVIGEN, LLC

8.40 **Keynote: Learning from Failures & Enabling Innovations in ADCs to Fight Against Deadly Cancers**

- What is common among clinically successful ADCs?
- What went wrong with some clinically unsuccessful ADCs?
- Top five lessons learned from the development of ADCs in the last two decades
- Next Generation ADCs meeting the five rights

9.10 **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.

10.00 **Morning Refreshments**

Scientific Program - Day 1

Thursday October, 10

Clinical Stream

Confirmed Chair:
Sri Ghatta, Director & Clinical Scientist, **Genmab**

Operational Lessons Learned from Phase I Studies & Failures

10.30 Reviewing the ADC Clinical Pipeline

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

Letrishka Anthony, Senior Analyst, Beacon Targeted Therapies, **Hanson Wade**

11.00 Phase 1 Study of ABBV-085, an Antibody-Drug Conjugate Targeting LRRC15, in Sarcomas & Other Advanced Solid Tumors

- LRRC15 target identification and biological relevance in cancer
- ABBV-085, a LRRC15 targeting optimized MMAE (auristatin) ADC
- Phase 1 clinical trial design, escalation and expansion cohort data
- Clinical safety and efficacy observations from the completed Phase 1

James Purcell, Project Director – Oncology Discovery, **AbbVie**

CMC Stream

Confirmed Chair:
Lisa McDermott, Head of Process & Analytical Development, **MilliporeSigma**

Exploring Methods to Improve Scalability & Capacity of Manufacturing Processes

10.30 Key CMC Considerations for Robust ADC Process Development & How to Effectively Manage the CMC Supply Chain

- Delve into the unique technical challenges of ADC process development
- Share experiences on how to confidently manage the complexity in ADC supply chains
- Discuss insights on how to transfer ADC processes to cGMP manufacture

Eric Lacoste, Head of Bio-Organic Team & Chemistry, Manufacturing, Control & Project Manager, **Sanofi**

11.00 TITLE TBC

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

Discovery Stream

Confirmed Chair:
Peter Senter, Vice President & Distinguished Research Fellow, **Seattle Genetics**

Understanding the Relationship Between Payload, Linker & Antibody to Increase Efficacy

10.30 Site-Specific Antibody-Drug Conjugates Carrying Multiple Drugs per Cysteine Conjugation Site

- A novel cysteine-based conjugation platform for the preparation of site-specific high drug load per cysteine conjugation site is presented
- This entails site-specific antibody drug conjugates carrying multiple drugs per cysteine conjugation site

Nazzareno Dimasi, Associate Director Research & Development, **AstraZeneca**

11.00 ThioBridge™ as a Tool for the Design, Optimization & Manufacture of ADCs

- ThioBridge™ conjugation is a flexible approach for producing stable ADCs with defined location and extent of drug loading
- The simple design of ThioBridge™ ADCs means they can easily undergo a systematic determination and optimization of their *in vitro* and *in vivo* biological properties
- ThioBridge™ targets natural disulfides with highly reproducible conjugation profiles at milligram to gram scales
- Abzena's capabilities for design, optimization and manufacturing of ADCs

Mark Frigerio, Director Chemistry, **Abzena**

Translational Stream

Confirmed Chair:
Gail Lewis Phillips, Senior Scientist - Translational Oncology, **Genentech**

Using DMPK Modelling to Mitigate Toxicities

10.30 Discussing Strategies to Tailor the Molecular Design & PKPD Based on Various Properties of the ADC

- Determinants of ADC distribution
- Quantitative systems pharmacology (QSP) and ADC PK/PD
- Rational ADC design via QSP

Mark Stroh, Clinical Pharmacology, **CytomX**

11.00 Assessing Methods To Use For Understanding How You Know Your Drug Is Working

Session Reserved for Iksuda

Scientific Program - Day 1

Thursday October, 10

11.30 Development of AVID100, an Anti-EGFR ADC with a Novel Mechanism for Tumor Selective Cytotoxicity

- AVID100 is being evaluated in Phase 2a dose-expansion cohorts of patients with EGFR-overexpressing SCCHN, sqNSCLC, and TNBC
- AVID100 is highly potent and selectively cytotoxic against EGFR-expressing cancer cells, while sparing normal EGFR-positive keratinocytes
- AVID100 effectively inhibits tumor growth in mouse xenograft studies across a variety of a cancer types
- AVID100 was well-tolerated in a Phase 1a dose-escalation trial in patients with advanced solid tumors with only modest skin toxicity observed

Maureen O'Connor, Chief Scientific Officer, **Forbius**

11.30 Sharing Common Manufacturing & Molecular Misconceptions

- It is important to survey this data for generalizations and guidelines to accelerate development of promising new candidates, oversimplification of experimental findings can lead to misunderstanding that compromises drug development
- In addition, the body of knowledge that has accumulated around ADCs puts us in a position to question portions of the testing paradigm that were put in place in the absence of such data. Some such questions will be posed for discussion

Damon Meyer, Associate Director, Conjugation Process Development, **Seattle Genetics**

11.30 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**

11.30 Analyzing the Clinical Development of STRO-001 & STRO-002

- Review preclinical and IND enabling data for STRO-001 and STRO-002, two novel ADCs generated with cell-free protein synthesis and site-specific conjugation technology
- Provide clinical development update for STRO-001 for treatment of myeloma and B-cell lymphoma
- Deliver clinical development update for STRO-002 for treatment of ovarian cancer

Arturo Molina, Chief Medical Officer, **Sutro Bio**

12.00 Targeting CD205-positive Solid Tumors with a Novel Antibody Drug Conjugate to Reverse Immune Tolerance

- OBT076 includes a fully human antibody targeting CD205, which is overexpressed in subsets of Her2 negative cancer
- In addition to HER2 negative breast cancer, the investigational agent is being developed for a number of other CD205 driven cancers such as gastric cancer, triple-negative metastatic breast cancer, bladder cancer and pancreatic cancers as well as Non-Hodgkin Lymphoma and several other solid and liquid cancers

Christian Rohlff, Chief Executive Officer, **Oxford Biotherapeutics**

12.00 Reviewing Strategies for a Smooth Transfer & Scale-up at a CDMO

- Explore services and methods for smooth ADC transfer and scale-up
- Analytical strategies for ADC development
- Confidently characterize ADC properties

Melanie Derde, Bioconjugation Analytics Manager, **Novasep**

12.00 Exploring an Enhanced Single Molecule PEG for ADC Linker

NOF CORPORATION

12.15 Extended Q&A

12.00 Panel Discussion: Utilising PKPD Studies to Their Full Potential to Confidently Translate into the Clinic

- Discuss which studies are best to use
- How these studies can be utilized to improve preclinical to clinical translation
- Review the lessons learned to enhance confidence in translation

Scientific Program - Day 1

Thursday October, 10

12.30 Lunch & Networking

Ian Schwartz
Global Bioconjugation Technology Consultant
Sartorius Stedium Biotech

12.30 Sartorius Lunch Seminar: Platform Strategies to Accelerate ADC Process Development & De-Risk Manufacturing using Single Use Technologies – Case Studies will be Presented

Operational Challenges in Clinical Trials & Innovations to Overcome This

2.00 Ligand Targeted Cancer Therapy: A Tactical Swing from Chemo to Radiotherapy

- Brief development history of small molecule drug conjugates (SMDCs)
- Comparison of targeted chemo vs. radioligand therapy
- Overview of 177Lu-PSMA-617 and next generation RLTs

Chris Leamon, Vice President, Research, **Endocyte**

2.30 Therapeutic Targeting of Prostate-Specific Membrane Antigen (PSMA)

- Differences in radionuclide vs drug payloads
- Differences in targeting vehicles: antibody vs small molecules
- Is there a need for treatment selection by target expression?

Scott Tagawa, Associate Professor in Hematology, Oncology, Clinical Medicine & Urology, **Weill Cornell - Cornell University**

Ensuring an Efficient Supply Chain Process

2.00 Creating & Sticking to a Time Efficient Supply Chain Process

Sabra Hanspal, Senior Scientist, **AbbVie CMO**

2.30 Aligning the Complex ADC Supply Network to Make Drug Products for Patients

- Strategies for supply network alignment
- Identification of risks in the supply chain

Praveen Prasanna, Director, External Manufacturing, **ImmunoGen**

Delving into Innovative Technologies for Payloads & Linkers

2.00 Discovering Various Payload-Linker Combinations for Optimized Efficacy

- Payload and linker-payload design
- *In vitro* screening of payloads and ADCs
- Confidently assess ADC *in vivo* efficacy

Thomas Nittoli, Research & Development, **Regeneron**

2.30 Homogeneous Antibody Functionalization Via Orthogonally Reactive Lysine & Arginine Residues In One Step & One Pot

- We describe a new blend of chemistry and biology by developing the first site-specific antibody conjugation technology that employs an engineered arginine residue
- The distinctive arginine and lysine residues can be combined in one antibody molecule to afford orthogonal conjugation of two different cargos with high precision and efficiency under mild conditions in a one-step and one-pot reaction

Christoph Rader, Professor, Department of Immunology & Microbiology, **The Scripps Research Institute**

Sharing Strategies to Advance Preclinical Development

2.00 Modifying an Old Platform to Identify New ADC Targets

- Tumor specific human antibodies were identified by panning on tumor cells isolated by laser capture microdissection. Rapidly internalizing antibodies were identified using HCA assays
- Lead candidate antibodies were used to identify a promising new target in mCRPC and Multiple Myeloma
- A vc-MMAE antibody conjugate was developed (FOR46) and patients are currently being dosed at multiple clinical sites

Marc Nasoff, Chief Scientific Officer, **Fortis Therapeutics**

2.30 Innovating Late Stage Pre-Clinical Studies

Session Reserved

Scientific Program - Day 1

Thursday October, 10

3.00 Tisotumab Vedotin: Update from Clinical Study InnovaTV 201

- Tisotumab vedotin`s (TV) early clinical studies
- Data from Cervical cancer cohort of InnovaTV201
- Ocular adverse events mitigation plan and data from InnovaTV201

Sri Ghatta, Director & Clinical Scientist, **GenMab**

3.00 Value Proposition of Integrated, Advanced ADC Manufacturing Processes – Use of Economic Modelling

Session Reserved for ADC Bio

3.00 TrypCo® Technology: A Versatile Enzymatic Tool for Sitespecific Generation of ADC's

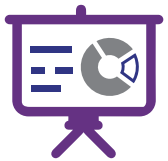
- Introduction into BTI´s novel TrypCo® technology as robust conjugation platform for the enzyme-based generation of sitespecific ADCs
- POC studies for the N- and C-terminal modification of Trastuzumab will be presented
- High flexibility of TrypCo® enables orthogonal dual modification of antibodies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

Andreas Simon, Chief Technology Officer, **BTI**

3.00 Synergistic Combinations of ADCs & Small Molecules that have Potential for Clinical Implementation

- ADCs have failed to meet expectations of single-agent efficacy in clinical settings. To expand their therapeutic index and augment ADC impact, we sought to identify small molecule synergies with ADC payloads to guide strategies in clinical therapy
- Develop a method for *in vitro* high-throughput screening of small molecule combinations in 1,536-well plates. The workflow is amenable to diverse solvents, enabling the future study of bio therapeutics and small molecules
- Screen a 2,400-compound, oncology focused and annotated library in combination with common ADC payloads and identified synergistic pairings determined by the Bliss synergy metric

Jacob Roth, Research Fellow, **National Centre for Advancing Translational Sciences**



3.30 Scientific Poster Session & Afternoon Refreshments

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 60 scientific posters will be presented from novel linker designs to validation of site specific conjugation technologies and more informative *in vivo* models.

Uncovering the Wave of Next Generation Successful ADCs

Patrick Dennler
Lab Head / Scientific Specialist
Lonza

5.00 "Light Path" – Leveraging Lonza's Experience with Timelines & Cost Reduction of Bioconjugate Drug Substance Supply

- Discover Lonza's ADC capabilities and learn about future capacity increases at the manufacturing site in Switzerland
- Roll-out of a novel ADC manufacturing offer/concept for customers: BioConjugates LightPath Development
- Fast generation of ADC drug substance for to support clinical phase I trials. Utilization of Lonza's bioconjugation experience to reduce customer effort to a minimum and accelerate project timelines

Scientific Program - Day 1

Thursday October, 10

Tony Polverino
Chief Scientific Officer
Zymeworks

5.30 **ZW49 A Bispecific HER2-targeted ADC: Next Generation ADC Combining Azymetric & ZymeLink Platforms**

- Discuss ZW49, a biparatopic antibody-drug conjugate armed with our proprietary ZymeLink™ cytotoxic payload
- In vivo efficacy compared to approved and leading clinical-stage HER2-targeted ADCs
- GLP toxicology studies predict an enhanced therapeutic window enabling extended dosing in the clinic

Brian Mendelsohn
Director
Ajinomoto Biopharma Services

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

- The chemical conjugation of antibodies in a site-directed manner remains an area of great interest and active efforts within the ADC community are being made
- Overcome the lack of sensitivity that can be dialled in toward specific residue during the chemical modification
- Analyze 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

Rich Gregory
Chief Scientific Officer
ImmunoGen

6.10 **Chair's Closing Remarks**

"World ADC San Diego is a must-attend event. Not only can you learn from others and network, the presentations are also exhaustive: If it's not presented at World ADC, it's not being researched" Recipharm

Reserve Your Place at the Ceremony from September 23

Join us at the 6th Annual World ADC Awards

Thursday October, 10

WORLD adc AWARDS

Now in its 6th year, the World ADC Awards showcase the innovation, leadership and devotion shown by the best companies, teams and individuals in the industry.

Across 9 categories the Awards will recognise the extraordinary endeavours, teamwork and commercial acumen that has propelled the field to the forefront of cancer research today.

More information can be found at **www.worldadc-usa.com**

2019 World ADC Award Categories

- Best ADC Platform Technology
- Most Promising Clinical Candidate
- Best Contract Manufacturing (CMO)
- Provider Best New Drug Developer
- Best Contract Research (CRO) Provider
- Best Publication 2018
- Individual Input to the Field 2018
- Long Standing Contribution to the Field
- Best Poster 2019

Scientific Program - Day 2

Friday October, 11

Scott Miller Senior Scientific Advisor **CARBOGEN AMCIS**	**7.00**	**Breakfast Briefing**
Rich Gregory Chief Scientific Officer **ImmunoGen**	**8.00**	**Chair's Opening Remarks**
Robert Phillips Vice President & Global Head of Translational Sciences **Daiichi Sankyo**	**8.10**	**Internalization Rate as a Critical Attribute of ADC Design: A Review of HER2 & HER3 ADC's with DXd Linker-Payload Technology**
Peter Senter Vice President Chemistry & Distinguished Research Fellow **Seattle Genetics**	**8.40**	**What Lies Ahead for ADCs?** • What we've learned from past studies • Exciting new developments • Some challenges for the future
Naresh Jain President & Chief Executive Officer **NJ Biopharmaceuticals LLC**	**9.10**	**Protoxins: The Next Generation of Toxins for Antibody-Drug Conjugates** • Reversible and non-reversible Protoxins • • Protoxins of PBD dimers, maytansine, and MMAE • • Improved stability of Protoxin-ADCs
	9.25	**Morning Refreshments & Networking**

"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

Scientific Program - Day 2

Friday October, 11

Mitigating & Managing Toxicity in Clinical Development

11.00 Phase 1 Interim Data of MORAb-202 as Eribulin Conjugated Anti FRA-Targeted ADC

- MORAb-202 is the first ADC which is loaded with HALAVEN® as payload
- HALAVEN® is an approved drug which exhibits unique effects on tumor microenvironment
- The interim data of MORAb-202 Phase 1 study in Japan is to be discussed

Keiiji Furuji, Associate Director & Head of Immunotherapy & Preclinical Development, **Eisai**

11.30 Exploring Biomarker Driven Development Opportunities for Sacituzumab Govitecan

- Discuss Role of TROP-2 in cancer
- Utilizing TROP-2 as a biomarker
- Considerations for development strategies for SG

Trishna Goswami, Vice President, Clinical Development for Non-Breast Indications, **Immunomedics**

Reviewing Strategies to Ensure Robust ADC Manufacturing Processes

11.00 Challenges of Technology Transfer for Early Stage ADC Manufacturing

- A summary of the challenges: tight timelines, multiple CMOs, no platform process
- Strategies to use to overcome the challenges: development and tech transfer in parallel, incremental scale up, detailed tech transfer documents
- Lessons learned from Ambrx ADC programs

Brian O'Mara, Associate Director - Downstream Process Development, **Ambrx**

11.30 Process Understanding & Automated Processing 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?

Lisa McDermott, Head of Process & Analytical Development, **MilliporeSigma**

Innovative Frontiers: Showcasing Alternative ADC Formats

11.00 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 tumor selectivity of ADC metabolism, a tumor associated protease with a unique cleavage sequence is utilized 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**

11.30 A New OHPAS Linker for Phenolic Payload Conjugation

- Structure & Assembly of OHPAS linker: SuFEX (Sulfur Fluorine Exchange) Chemistry
- Stabilities (chemical & biological) and Lability upon Triggering
- Payload Release Mechanisms and Kinetics
- Application to ADCs

Tae Kyo Park, Chief Executive Officer, **IntoCell**

Translating Preclinical Lessons to the Clinic to Enhance Understanding of ADC Safety Profiles

11.00 Development of a 2nd Generation HER2 ADC Comprised of a Novel Antibody Linked to a Reduced Potency PBD Dimer

- The antibody, 7C2, binds domain I and thus does not interfere with trastuzumab, pertuzumab or trastuzuamb emtansine (T-DM1), allowing for combination therapy with these marketed therapeutics
- Reduced potency, mono-alkylating PBD dimers were assessed to allow for higher dose levels and potentially improved TI.
- PBD mono-alkylators were linked to 7C2 using a stable hindered disulfide linker
- Unlike T-DM1, these ADCs exhibit bystander activity
- The PBD-mono-alkylator-ADCs show differential potency compared to T-DM1 both *in vitro* and *in vivo*

Gail Lewis Phillips, Senior Scientist - Translational Oncology, **Genentech**

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 optimize dosing regimen to maximize 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, **State University of New York at Buffalo**

Scientific Program - Day 2

Friday October, 11

12.00 PBPK Modeling to Support DDI Strategy of Polatuzumab Vedotin & Regulatory Implications

- Simcyp is applied for the first time in the prediction of MMAE-DI potential for the two ADCs – brentuximab vedotin and polatuzumab vedotin
- The PBPK model might be sufficient to assess DDI prediction and a dedicated drug interaction study is not required – as a supporting strategy for other vc-MMAE ADCs across the platform
- This model was submitted in the BLA/MAA for polatuzumab vedotin to provide quantitative DI risk assessment without the need of a dedicated clinical DDI study and FDA has accepted our proposed language

Divya Samineni, Clinical Pharmacologist, **Genentech**

12.00 Key Considerations & Best Practices in Externalization of the ADC Supply Chain

- Strategizing the best outsourcing practices for producing and testing ADCs for use in clinical trials
- Establishing guiding principles for externalization to ensure the selection of the right CMOs for ADC outsourcing and technology transfer
- Sizing appropriately of the ADC supply chain to expedite transition from clinical to commercial manufacturing

Firelli Alonso, Senior Director, External Supply, **Pfizer**

12.00 IMGC936: A Novel Antibody-Drug Conjugate Targeting ADAM9-Expressing Solid Tumors

- ADAM9 is a cell surface protein that is overexpressed in multiple solid tumor indications and has been shown to correlate with poor prognosis
- IMGC936 is comprised of a humanized anti-ADAM9 antibody site-specifically conjugated to DM21, a next-generation linker-payload that combines a maytansinoid microtubule-disrupting payload with a stable peptide linker
- IMGC936 shows compelling efficacy in ADAM9-positive xenograft models and was well-tolerated following repeat dosing in cynomolgus monkeys making IMGC936 a promising therapeutic candidate to target a wide range of ADAM9-expressing tumors

Stuart Hicks, Director, Pipeline Research & Development, **ImmunoGen**

12.00 MUC13 mucin, A Novel Candidate for Drug-Antibody Conjugates for GI Cancers

- Learn about MUC13 as a novel target for ADC
- Discussion about novel MUC13 antibodies we have developed
- Learnings regarding our progress on MUC13 antibody drug conjugate project

Subhash Chauhan, Professor, **University of Tennessee**

12.30 Biomarker Measures of Surrogate Endpoints for FDA Qualification of Accelerated ADC Marketing Approvals

- What are the accepted FDA definitions of the contexts of use of biomarkers in clinical trials?
- What is are the regulatory pathways for qualification of biomarker measures for primary surrogate endpoints for accelerated drug marketing approvals by the FDA?
- What are some examples of biomarker measures for primary surrogate endpoints for accelerated drug marketing approvals in oncology that have been approved by the FDA?

Randall Morris, Research Professor of Cardiothoracic Surgery &, by courtesy, Medicine & Surgery (Emeritus), **Stanford University School of Medicine**

12.30 Integrated ADC Development to Production

- What we learnt from the failed ADCs
- What strategy to make a better one
- Does antibody binding affinity influence ADC fate?
- Does conjugation format affect the internalisation?

Xinfang Li, Vice President - Process Development & Head of Chemistry, Manufacturing & Controls, **Mabplex**

12.30 Payload Masking in HSP90 Targeting Miniature Drug Conjugates to Expand the Therapeutic Window

- HSP90 targeting miniature drug conjugates bind to activated HSP90 thus accumulating in tumor xenograft models followed by a prolonged resident time in the tumor compared to normal tissues and sustained release of therapeutic payload
- Masking the payload in HSP90 targeting conjugates significantly reduces the toxicity of the payload while in the intact conjugate in the circulation. The full potency of the payload is realized when the linker cleaves in the tumor
- Optimizing the linker cleavage kinetics with the differential tumor to normal exposure and the payload masking results in complete and sustained tumor regressions in multiple xenograft models

Mark Bilodeau, Chief Scientific Officer, **Tarveda**

12.30 Complex Population Quantitative Pharmacology Approach to Investigate the Disposition of Antibody-Drug Conjugate

- Complex distribution, catabolism and elimination processes of ADC are not yet well understood
- It is important to quantify the disposition pathway of the conjugate and the release mechanism of unconjugated toxins into the systemic circulation in order to better understand the complex ADC pharmacology that are related to observed efficacy and toxicity
- The objective of this study was to develop complex population quantitative pharmacology model that can simultaneously describe disposition and elimination of multiple analytes, including total antibody, conjugate, and unconjugated toxins of ADC in cynomolgus monkeys

Chee Ng, Associate Professor, **University of Kentucky**

Scientific Program - Day 2

Friday October, 11

1.00 **Lunch & Networking**

Vítor Sousa
R&D Biological Senior Manager
Cerbios

1.00 **Cerbios Lunch Seminar**

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Fostering Value through Innovation®

Looking at Future & Current Pioneering Scientific Developments

Melanie Smitt
Medical Director
Genentech

2.30 **Expanding Kadcyla to Move into Early Breast Cancer (EBC)**
- Kadcyla EBC development plan
- Neoadjuvant Kadcyla: KRISTINE results
- Adjuvant Kadcyla for patients with residual disease: KATHERINE results

Bill Boyle
Chief of Preclinical Research
BioAtla

3.00 **CAB ADCs: Reducing On-target Toxicity & Enabling Potent Combination ADC Therapies**
- Reversible ADC activation by the tumor microenvironment for higher therapeutic Index
- Early clinic experiences with CAB-ADCs
- Scrutinize the increasing importance of combination therapies for achieving greater efficacy

Timothy Lowinger
Chief Scientific Officer
Mersana

3.30 **The DolaLock-based ADC Platforms: Dolaflexin & Dolasynthen**
- Update on the clinical evaluation of XMT-1536, a NaPi2b targeted Dolaflexin ADC
- Overview of Dolasynthen, a fully homogeneous, highly versatile ADC platform which allows for precise DAR ranging from 2-24
- Applications of Dolasynthen to identify optimal ADCs for clinical development

4.00 **Afternoon Refreshments & Networking**

Scientific Program - Day 2

Friday October, 11

Advancing ADCs That Sit Outside of Oncology

Amy Han
Director, Chemistry
Regeneron

4.45 ADC as a Targeted Therapy for Cancer & Beyond
- Cytotoxic ADCs targeting tubulin
- Non-cytotoxic ADCs targeting glucocorticoid receptor and Liver X receptor
- Approaches to discover site-specific ADCs using novel linkers

Nick Keen
Chief Scientific Officer
Bicycle Therapeutics

5.15 Bicycle® Toxin Conjugates – A New Approach to Tumor Targeted Delivery
- Bicycles® are fully synthetic short peptides constrained to form two loops which stabilize their structural geometry. This constraint is designed to confer high affinity and selectivity, and the relatively large surface area presented by the molecule allows targets to be drugged that have historically been intractable to non-biological approaches. Bicycles represent a unique therapeutic class, combining the pharmacological properties normally associated with a biologic with the manufacturing and pharmacokinetic advantages of a small molecule, yet with no signs of immunogenicity
- Bicycle Toxin Conjugates (BTCs) have properties ideal for tumour delivery – they penetrate tumors extensively and rapidly, but are renally eliminated maximizing tumor exposure and minimizing systemic exposure.
- Bicycle has three BTC molecules either in the clinic or undergoing IND enabling studies: BT1718, targeting MT1-MMP expressing tumors is in Phase 1 clinical evaluation with Cancer Research UK, BT5528 targeting EphA2 expressing tumous and BT8009 targeting Nectin-4 expressing tumors. In this presentation we will provide an overview of the properties and data emerging from these programs

Andrew Phillips
Director, Next Generation Antibody-Drug Conjugates
AbbVie

5.45 The Development of ABBV-155, a First-in-class BCL-XL Inhibitor ADC
- This talk will highlight the preclinical data outlining the development of ABBV-155
- ABBV-155 targets B7H3 expressing cancer cells and delivers a potent and specific BCL-XL inhibitor
- The used of a targeted warhead offers the potential of synergistic mechanism-based combinations with both chemotherapy and other targeted therapeutics

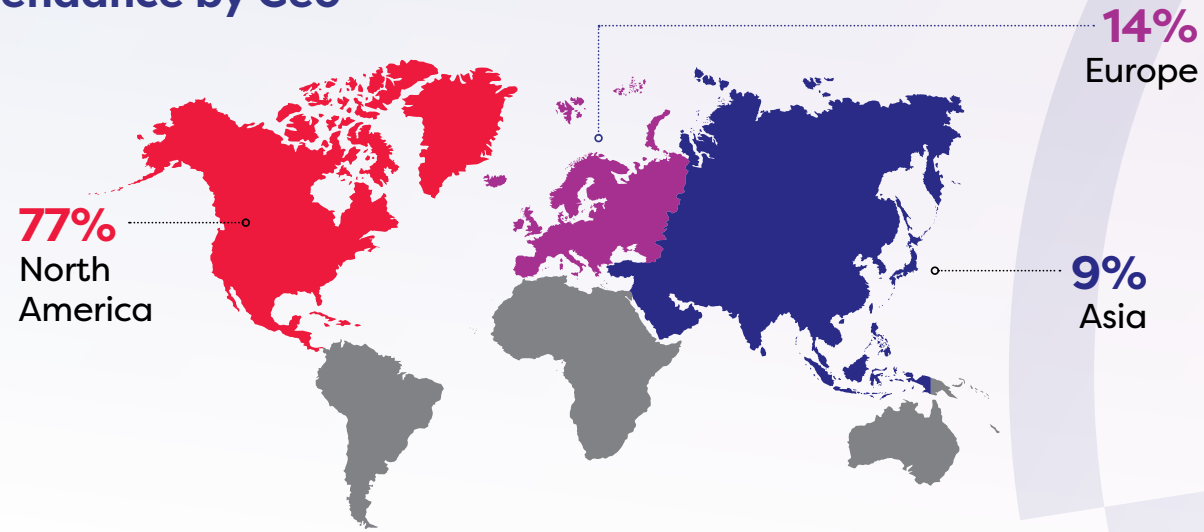
Rich Gregory
Chief Scientific Officer
ImmunoGen

6.15 Chair's Closing Remarks

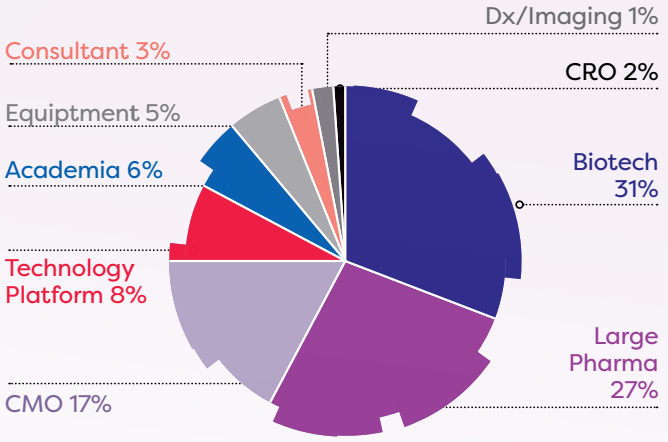
Who You'll Meet

> World ADC meeting has always been the best conference that I attend each year. I have been attending World ADC Meetings every year since it's inception in 2010. It is like a one stop shop for all antibody-drug conjugate (ADC) related activities where we can meet and share mutual scientific interests with colleagues from all over the world. This conference thrives to showcase next generation oncology therapeutics to help cancer patients **Cellerant Therapeutics**

Attendance by Geo



Company Type



Your World ADC Experience

100+ Presentations

60+ Posters

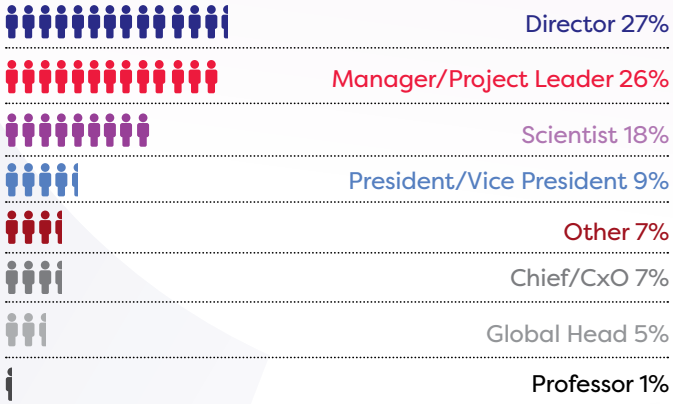
10 Workshops

60%
Made up of key decision makers

58%
Drug Developers

51%
New companies in 2018

Seniority



Your 2019 Networking Planner

Whether you're a veteran or a newcomer to the ADC field, World ADC San Diego offers you plenty of opportunities to build new relationships and catch up with familiar faces.

Workshop Day

Join the Workshops to build relationships with like minded peers and take a deep dive into the hottest topics within ADCs.

Seminar Day

Attend the seminar day to immerse yourself in a dedicated full-day's worth of presentations on three of the hottest ADC topics. Surround yourself with delegates with similar goals and interests to you.

Scientific Program Day 1

Speed Networking

Your chance to meet and network with a cross-section of who's attending. Speed Networking will help you meet and identify who you want to follow up during the conference.

Scientific Program Day 2

Networking Breaks

Throughout your World ADC experience there will be numerous, dedicated, networking breaks for you to meet fellow attendees and have in-depth discussions.

Celebrating 10 years of world ADC San Diego

At the end of the Seminar Day join us for a relaxed evening of celebration. Join at this informal evening to catch up with familiar faces and friends.

World ADC Awards

Meet the individuals, teams and companies at the forefront of ADC research. This will be your opportunity to network with the experts pushing ADCs to the forefront of cancer research.

Poster Session

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 50 scientific posters will be presented, this is a perfect opportunity to continue learning and networking whilst getting an in depth understanding into the work of others.

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Partner with Us

Partnering with the World ADC San Diego is a proven way to attract the attention of key decision makers and influence their choices at a critical time; this is your fastest route to organizations prioritizing ADC development.

This year 600 stakeholders and influencers across the supply chain of ADCs, from discovery through to commercial, will attend World ADC San Diego. This is your annual opportunity to elevate your company's standing and influence industry thinking.

Your brand, your message, your reputation, showcased to the ADC community. This could involve presenting on the agenda, hosting networking sessions, exhibiting, or brand exposure. But our focus and reach is much wider. From being fully integrated across a multi channel global communication strategy, to targeted introductions to the right individuals in your target market, we have opportunities that offer it all.

This leading annual forum is a unique opportunity for you to demonstrate how your company can enable drug developers to overcome the barriers in maximising the clinical therapeutic window of ADCs.

Contact us today to find out how we can help you achieve your business goals faster.

Rob Keast
Commercial Director
Tel: +44 (0)20 3141 8700
Email: adc@hansonwade.com

Our World ADC Partners 2019

Partners

Exhibitors

Ready to Register?

Top 3 Reasons to Attend

1. **SAVE** valuable time and resources by learning your peers are maximizing the clinical therapeutic index of next generation ADCs
2. **GAIN** first-hand insights from the BioAtla, CytomX and Sutro Bio, some of the most exciting biotechs driving innovation for ADCs
3. **FORM** lasting connections by engaging directly with 600+ colleagues from 230+ of the leading pharma and biotech companies actively developing ADCs

3 Easy Ways To Book

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Team Discounts*

- 10% discount – 3 delegates
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> A great event to learn all about latest ADC developments and meet lots of KOL and main players in the field
>
> XenTech

Package Details	Register & Pay by Friday August, 23	Standard Rate
Full Access Pass: Workshop Day + Seminar Day + Scientific Program	$4347 **(save $1350)**	$4547 **(save $1150)**
Conference Pass: Workshop Day or Seminar Day + Scientific Program	$3698 **(save $600)**	$3898 **(save $400)**
Scientific Program Only	$2699 **(save $200)**	$2,899
Seminar Day or Workshop Day	$1399	

Not for profit rates are available - email adc@hansonwade.com

Venue

Manchester Grand Hyatt, San Diego
1 Market Pl, San Diego, CA 92101, USA

For further information or assistance

Click here to visit the website

Please note: Overnight accommodation and travel are not included in the registration fee

Book Your Accommodation by September 17 to Secure a Discounted Rate

TERMS & CONDITIONS

Full payment is due on registration. Cancellation and Substitution Policy: Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

Changes to Conference & Agenda: Hanson Wade reserves the right to postpone or cancel an event, to change the location or alter the advertised speakers. Hanson Wade is not responsible for any loss or damage or costs incurred as a result of substitution, alteration, postponement or cancellation of an event for any reason and including causes beyond its control including without limitation, acts of God, natural disasters, sabotage, accident, trade or industrial disputes, terrorism or hostilities.

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