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9th ANNUAL WORLD adc SAN DIEGO 2018

November 12-15, 2018

The Industry's Longest Standing & Most Comprehensive Antibody-Drug Conjugate Conference

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

John Lambert
Executive Vice President, Emeritus & Distinguished Fellow
ImmunoGen

Robert Iannone
Head of Research & Development, Chief Medical Officer
Immunomedics

Rakesh Dixit
Vice President, Research & Development, Global Head of Biologics Safety Assessment
MedImmune

Bob Lutz
Chief Development Officer
Formation Biologics

Mariya Pavlyuk
Global Clinical Lead
Pierre Fabre

Antoine Yver
Executive Vice President & Global Head of Oncology
Daiichi Sankyo

Scott Dylla
Chief Scientific Officer
AbbVie Stemcentrx

650 Attendees

220 Organizations

92 Expert Speakers

4 Parallel Streams

Senior Partners:

ALTHEA · Heidelberg PHARMA Focused Cancer Therapies · immunogen · Mersana THERAPEUTICS · SeattleGenetics®

Tel: +1 415 735 3289 **Email:** adc@hansonwade.com **www.worldadc-usa.com** @world_adc #WorldADC Antibody Drug Conjugates

hansonwade

Welcome to the 9th World ADC San Diego

A Letter from our Chairman

Dear Colleagues,

We are once again approaching the premier ADC meeting of the year - World ADC San Diego. With a comprehensive agenda covering discovery, clinical development and manufacturing, this Hanson Wade organized event has established itself as the must-attend meeting for the ADC community to learn about new innovations in ADCs and to keep abreast of the tremendous progress in this burgeoning field of targeted therapeutics.

ADCs have been an area of active research for over 20 years, and there is no question that we have all benefited from the pioneering work of the teams that brought forward clinically successful ADCs such as Mylotarg, Adcetris and Kadcyla. Over the past 7+ years that I have been attending World ADC, we have seen significant innovations in the field, many of which I first encountered at this conference. We have had the opportunity to follow many of these approaches and candidates as they have progressed through discovery, preclinical development and manufacturing, and are now in the process of being evaluated in the clinic. World ADC provides an ideal forum to keep up to date with the fast pace of progress and innovation in this exciting area, and to connect with like-minded individuals who share tremendous enthusiasm for all that this therapeutic approach has to offer.

With multiple streams covering discovery, translational medicine, clinical development and manufacturing, World ADC Summit San Diego provides an unparalleled opportunity for delegates to share, learn and discuss various approaches to dealing with the myriad challenges encountered with these complex, promising molecules. I enthusiastically invite you to join us for what I am confident will be another successful, enlightening meeting this fall.

Sincerely,

Tim Lowinger - Mersana

Chairman of World ADC San Diego

"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

Contents

BOOK NOW TO TO SECURE YOUR PLACE

Click here to register

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

Now in its 9th year, World ADC San Diego is the **industry's most comprehensive antibody drug conjugate conference**. Designed with AbbVie Stemcentrx, Seattle Genetics and ImmunoGen this leading forum shares the latest data, insight and lessons learned enabling you to **maximize the clinical therapeutic window of your ADC candidate.**

Across 4 days, 4 streams, World ADC San Diego covers every element of ADC drug development. From construct design to improving preclinical predictability and product manufacturability this event will provide you with an unparalleled breadth and depth of content.

Join over 650 drug developers across 220 active ADC organizations at World ADC **to build new relationships** and **further cement existing partnerships.**

For ADC drug developers, like you, **World ADC San Diego is the ultimate learning and networking experience.**

Attend World ADC to:

01 Navigate clinical toxicities by gaining a detailed understanding of payload specific driven toxicities

02 Discover novel enzymatic linkers to develop more stable ADCs *in vivo*

03 Deepen your understanding of ADC internalization to overcome drug resistance and develop a truly curative candidate

04 Unravel the mechanisms driving on- and off- target toxicities and maximize your candidates therapeutic window

05 Evaluate the development of novel preclinical strategies which better reflect ADC clinical safety and efficacy

06 Draw on clinical learnings from novel, next generation ADCs, currently in Phase I clinical trials

07 Explore the development and execution of a companion diagnostic strategy to better analyze and stratify your patient population to optimize response

08 Realize the scientific rationale and clinical data for the combination of ADCs with IO to treat unmet clinical needs

09 Efficiently choose and work with CMOs with insights from selection, tech transfer to scale-up and GMP manufacture

10 Improve ADC targeting via antibody engineering and application of novel formats for ADCs

11 Effectively translate from Phase II to Phase III clinical development with lessons learned from ADCs in late stage clinical development

12 Review novel analytical techniques to assess batch-to-batch reproducibility

Your World ADC Experience

650 Attendees

220 Organizations

92 Expert Speakers

4 Streams of Learning

14 Workshops

5th Annual World ADC Awards

60+ Posters Presented

CMO Site Tour

Build Your Own Experience

Empowering Your ADC Development with New Industry Intelligence

Dedicated to bring you the **most innovative ADC** science World ADC captures **pioneering data**, **thought-provoking insights** and **practical lessons learned**.

Regardless of your focus here's five talks you cannot afford to miss at this year's event:

REGENERON

Realize the potential of ADCs for indications outside oncology. Learn of the discovery and development of novel non-cytotoxic payloads for the potential treatment of Atherosclerosis

Daiichi-Sankyo

Examine the clinical validation of an ADC design meant to deliver a by-stander effect. Explore the preclinical and clinical story of DS-8201 and U3-1402

Formation Biologics

Discover next generation ADCs. Discuss early clinical findings for AVID100

Pfizer

Gain lessons learned from commercial scale manufacturing of Mylotarg and Besponsa

FDA

Join the FDA as they discuss some examples of issues with ADC-specific product quality attributes identified in pre-INDs and INDs. Gain these learnings to streamline and accelerate your ADC manufacturing

Present Your Research at World ADC

Share your findings with pioneers of the ADC field and gain valuable feedback on your latest research.

Open to all, the Scientific Poster Session is one of the highlights of World ADC San Diego.

After the Seminar Day concludes join your friends, colleagues and clients for a drink at this data rich, science driven session.

This is your opportunity to **showcase your own research as well as review over 60+ scientific posters,** which present the most innovative ADC science.

Don't miss this opportunity to:

- **Communicate** your new results to a vast audience of ADC experts
- **Get feedback** from peers and colleagues in the industry
- **Learn** how others in the field have been tackling similar challenges

All posters are subject to approval by World ADC. Please send your abstract to adc@hansonwade.com by Friday October 26 to be eligible.

Your 2018 World ADC Highlights

Late Breaking Abstracts

Listen to these talks to remain at the forefront of the ADC field. Continuing to bring you the very latest data these sensational sessions will be revealing unpublished data, for the first time. **Join these sessions to hear read outs in real time before they hit the headlines!**

4 Parallel Streams of Learning

Covering the A to Z of ADCs, World ADC is the industry's most comprehensive and detailed learning experience. **Join the community here to access an unparalleled amount of content to enable you to develop more clinically effective ADCs**. Follow one track throughout the full conference or switch it up and jump between sessions you're interested in and tailor your agenda to your needs.

ALTHEA

Explore an ADC Manufacturing Site

Whilst at World ADC, visit Althea's new San Diego facility. **Deepen your understanding of how a facility operates**. Learn more about how Althea can support your ADC development, meet the team and tour their state of the art new building.

5th Annual World ADC Awards

Join your peers to recognize the innovation that has propelled the field to the forefront of cancer research

Now in its 5th year, the World ADC Awards **reward the innovation, leadership, and devotion shown by the best companies, teams, and individuals in the industry**. Across nine categories, the Awards will recognize the extraordinary endeavours, teamwork and commercial acumen that has propelled the field to the forefront of cancer research today.

74% attend workshops

More Focused Workshops

Dedicated to the most exciting or challenging areas of ADCs, the focused workshops are **your opportunity to learn from topic area experts and discuss your challenges with like-minded individuals**. Join these in-depth sessions to interact, discuss and debate to get your questions answered.

You will learn the latest on: the scientific rationale for combining ADCs with immune checkpoint modulators; developing the optimal bioanalytical strategy for next generation ADCs and deepen your understanding on mitigating clinical toxicities.

You will leave with real tangible actions to take back to the office with you.

Agenda-at-a-Glance

Seminar Day 1
Monday, November 12

3rd Analytical & Bioanalytical Day	2nd ADC & IO Combo Day	Introduction to ADCs	Workshop A	Workshop C	Workshop E

Lunch & Networking

3rd Analytical & Bioanalytical Day	2nd ADC & IO Combo Day	Introduction to ADCs	Workshop B	Workshop D	Workshop F

Althea Site Tour

ALTHEA

World ADC Scientific Poster Session

Scientific Program Day 1
Tuesday, November 13

Plenary Stream

Speed Networking

Discovery Stream	Translational Stream	Clinical Stream	Manufacturing Stream

Lunch & Networking

Lunch Seminar sartorius

Discovery Stream	Translational Stream	Clinical Stream	Manufacturing Stream

Plenary Stream

Scientific Program Day 2
Wednesday, November 14

Breakfast Briefing MilliporeSigma

Plenary Stream

Discovery Stream	Translational Stream	Clinical Stream	Manufacturing Stream

Lunch & Networking

Lunch Seminar Baxter

Discovery Stream	Translational Stream	Clinical Stream	Manufacturing Stream

Plenary Stream

Seminar Day 2
Thursday, November 15

Workshop G	Workshop J

Lunch & Networking

Workshop H	Workshop K

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

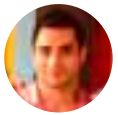
Your 92 Expert Speakers

Ahmed Bassyouni
Independent Consultant


Alex Lazar
Director Analytical & Pharmaceutical Sciences
ImmunoGen


Alexander Staudacher
University of South Australia & University of Adelaide


Alison Armour
Chief Medical Officer
Endocyte


Aman Singh
PKPD Scientist
Janssen Pharmaceuticals


Amy Han
Director, Chemistry
Regeneron Pharmaceuticals


Andreas Pahl
Chief Scientific Officer
Heidelberg Pharma


Antoine Yver
Executive Vice President & Global Head of Oncology
Daiichi Sankyo


April Wheeler
Manager
MilliporeSigma


Armin Storz
Sales Manager
Bausch&Stroebel


Arturo Molina
Chief Medical Officer
Sutro BioPharma

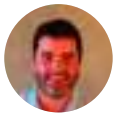

Bethany Powell Gray
Senior Research Associate, Sullenger Lab, Department of Surgery
Duke University Medical Center


Bernhard Stump
Leader, ADC, Research & Development
Lonza


Bob Lutz
Chief Development Officer
Formation Biologics


Brad Stringer
Associate Scientific Fellow, Molecular Pathology
Takeda


Brian Clark
Principal Consultant
GMP Operations Consulting


Brian Mendelsohn
Director, ADC Chemistry
Althea


Cecile Chalouni
Senior Scientist
Genentech


Charlie Johnson
Chief Executive Officer
ADC Biotechnology


Chawita (Jelly) Netirojjanakul
Senior Scientist
Amgen


Chen Fang
Senior Scientist, Bioconjugation Development
Goodwin Biotechnology


Christian Rohlff
Chief Executive Officer
Oxford Biotherapeutics


Dale Miles
Senior Scientist
Genentech


Daryl Drummond
Chief Scientific Officer & Head of Research
Merrimack Pharmaceuticals


David Bramhill
Consultant
Bramhill Consulting


David Lee
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Mersana Therapeutics


David Satijn
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Genmab


David Tice
Director, Research & Development
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Dengfeng Liu
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MedImmune


Dian Su
Scientist
Genentech


Ed Ha
Principal Scientist
AngieX


Edit Tarcsa
Director, DMPK-BA
AbbVie


Eunice Wang
Assistant Professor
Roswell Park Cancer Institute


Francois D'Hooge
Head, Bioconjugation Unit (ADC)
Novasep


Gail Lewis Philips
Senior Scientist
Genentech

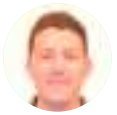

Giorgio Salciarini
Technical Business Development Manager
BSP Pharmaceuticals


Glenn Petrie
Senior Scientific Advisor
EAG Laboratories


Greg Sacha
Senior Research Scientist
Baxter Healthcare


Hirokazu Suzuki
Researcher, Biologics & Immuno-Oncology Laboratories
Daiichi Sankyo


Ian Schwartz
Process Development Consultant
Sartorius Stedim


Jack Sadowsky
Scientist
Genentech

Jennifer Richardson
Vice President, Pharmacology & Toxicology
CytomX

Jian Wang
Senior Principal Scientist, Bioanalytical Sciences
Bristol Myers Squibb

Xun Meng
Chief Executive Officer & Co-Founder
Abmart

John Harlan
Principal Research Scientist
AbbVie

John Lambert
Executive Vice President, Emeritus & Distinguished Fellow
ImmunoGen

Johnny Yin
Principal
Johnny Yin Biotechnology Consulting

Jon Roffey
Senior Group Leader
Cancer Research UK

Jun Tang
Senior Analyst
Cancer Research Institute

Karen Cha
Drug Development Consultant
Sapience Regulatory Consulting

Karim Malek
Medical Director
ImmunoGen

KJ Jeong
Senior Vice President, Head of Research & Development
Alteogen

Laurie Tatalick
Consultant
Laurie Tatalick Consulting

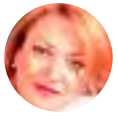
Leo Kirkovsky
Director, Clinical Assay Group
Pfizer

Leslie Sharp
Vice President, Immuno-Oncology
BioAtla

Lisa McDermott
Senior Manager, Process & Analytical Development Group
MilliporeSigma

Luc Desnoyers
Senior Director, Translational Sciences
CytomX

Marc Robillard
Chief Executive Officer
Tagworks Pharmaceuticals



Mariya Pavlyuk
Global Clinical Lead
Pierre Fabre

Mary Robinette
Principal Project Engineer
MilliporeSigma

Matthew Bird
Team Leader
Abzena

Matthew Sung
Senior Scientist
Pfizer

Michael Kaufman
Senior Vice President, CMC
Mersana

Milos Dokmanovic
Biologist
US Food & Drug Administration

Muctarr Sesay
Chief Scientific Officer & Vice President
Goodwin Biotechnology

Nagendra Chemuturi
Senior Investigator
Novartis

Nathan Tumey
Professor, Pharmacy & Pharmaceutical Sciences
Binghamton University

Nazzareno Dimasi
Associate Director, Research & Development
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Phil Howard
Chief Scientific Officer
Spirogen

Philipp Spycher
PSI Founder Fellow
Paul Scherrer Institute

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Tarveda

Rick Powers
Chief Consultant
ADC Consulting

Robert Iannone
Head of Research & Development, Chief Medical Officer
Immunomedics

Samuele Cazzamalli
Research Scientist
Philochem

Scott David Collins
Associate Director, Pharmacology
Mersana

Scott Dylla
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AbbVie-Stemcentrx

Scott Miller
Head of Special Projects
Carbogen Amcis

Shweta Singh
Senior Scientist
CytomX

Shyra Gardai
Director of Immunology
Seattle Genetics

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Timothy Lowinger
Chief Scientific Officer
Mersana Therapeutics

Tinya Abrams
Senior Investigator
Novartis

Tok Han
Director & Team Leader, Oncology Operations
Pfizer

Trevor Hallam
Chief Scientific Officer
Sutro Biopharma

Trish Anthony
Senior Analyst, Beacon
Hanson Wade

Yun Bai
Director
Ambrx

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

Novartis

3rd Analytical & Bioanalytical Day

Monday November 12

8.00 **Chair's Opening Remarks**
Leo Kirkovsky, Director, Clinical Assay Group, **Pfizer**

8.10 **Keynote: Bioanalytical & Regulatory Lessons Learned from Mylotarg**
- Exploring the key bioanalytical lessons learned from Mylotarg
- Understanding of the regulatory pathway involved
- Looking into the future

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

8.40 **Keynote: Continuity of Strategy & Technology in ADC Bioanalysis from Discovery to Submission & Bioanalytical Strategies for New Conjugate Modalities**
- Stage specific and continuity of bioanalytical approaches, platforms and strategies at different phases of ADC development
- Recommended strategy in choosing ADC analytes, assay platforms and assay DAR characteristics
- Discussion on regulatory requirements
- Challenges and strategies of bioanalysis for new conjugate modalities

Jian Wang, Senior Principal Scientist, Bioanalytical Sciences, **Bristol Myers Squibb**

Novel ADCs: Analytical & Bioanalytical Considerations for Diversifying & More Complex ADC Technologies

9.10 **Exposure Assessment of a Probody™ Drug Conjugate**
- Focus on Probody therapeutics, which are masked antibody prodrugs designed to be activated in the tumor microenvironment
- A multi-analyte HPLC-MS/MS approach enables simultaneous quantification of the masked antibody, functional antibody and conjugated payload in plasma
- Discussion of approaches to the assessment of tumor exposure

Jennifer Richardson, Vice President, Pharmacology & Toxicology, **CytomX**

9.40 **Speed Networking**

10.15 **Morning Refreshments**

Novel ADCs: Analytical & Bioanalytical Considerations for Diversifying & More Complex ADC Technologies

10.45 **Session Reserved for SCIEX**

11.15 **Developing Analytical Strategies that Account for Product Variability**
- Review how antibody variants can impact the quality attributes of ADCs e.g. trisulfide variants and unpaired cysteine residues present in antibodies can impact the free drug profile of the ADCs
- Discussion of how the conjugation process can change several quality attributes of the antibodies and creates product variants e.g. variants with different masses and charge profiles
- Appropriate analytical strategies are needed to monitor the variants of antibodies and their corresponding immunoconjugates in order to assure consistent product quality

Alex Lazar, Director Analytical & Pharmaceutical Sciences, **ImmunoGen**

11.45 **Analytical Characterization of Dolaflexin ADCs**
- Review of the use of Dolaflexin, a polymer-drug platform, which enables the generation of ADCs with drug-to-antibody ratios up to 15 while maintaining acceptable pharmacokinetics and drug-like properties
- Address the complex structure of Dolaflexin ADCs
- Describe selected innovative analytical approaches used to characterize these antibody-polymer-drug systems

David Lee, Senior Director, Analytical Chemistry, **Mersana Therapeutics**

12.15 **Exploring ADC Heterogeneity Characterization & Conjugation Dynamics Analysis**
- Analyze ADC conjugation heterogeneity
- Focus on conjugation d ynamics

Dengfeng Liu, Associate Director, **MedImmune**

12.45 **Lunch & Networking**

Analytical & Bioanalytical Requirements for ADC Development & Commercialization

1.45 **Critical Factors for a Successful Potency Assay**
- Cell selection and maintenance
- Data analysis and statistical treatment
- Control of critical reagents
- Phase appropriate validation
- Bioassay life cycle management

Glenn Petrie, Senior Scientific Advisor, **EAG Laboratories**

2.00 **Integration of Key Bioanalytical Measurements into Systems Pharmacokinetic Models to Characterize Translational PK-PD Relationships for ADCs**
- Development of systems PK-PD model for ADCs
- Quantitative characterization of Bystander effect of ADCs
- Preclinical to Clinical translation of ADCs

Aman Singh, PKPD Scientist, **Janssen Pharmaceuticals**

2.30 **Exploring the Ever-Evolving Bioanalytical Strategy for ADCs from Discovery to the Clinic**
- Choosing what is appropriate to support decision making at the various stages of a project and how does one approach this by balancing speed, quality and available reagents
- Key questions to answer during drug discovery (ADC optimization), versus late stage development are usually very different, therefore the analytes and assays appropriate to answer those questions could also be different
- Presenting case studies and a bioanalytical decision tree

Edit Tarcsa, Director, DMPK-BA, **AbbVie**

3.00 **Think Tank Roundtable Sessions**
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.

3.30 **Afternoon Refreshments & Networking**

4.00 **Moderator Feedback & Audience Debate**
Moderators will be assigned to each roundtable to facilitate discussion and collate the findings. Following the roundtables, they will present back to the entire delegation as part of a panel discussion for information dissemination.

Integrating a Robust Bioanalytical Support Strategy

4.30 **Bioanalysis on a Budget: ADC Discovery in a Budget-Constrained Environment**
- Describe bioanalytical workflows and methodology employed in our labs for the study of ADC stability, metabolism, and identity
- These methods, while perhaps not "state of the art", allow for ADC discovery using relatively inexpensive instruments that are commonly found in chemistry labs throughout the country
- The utility of these methods will be illustrated using examples of ADCs being developed in our lab for oncology and autoimmune applications

Nathan Tumey, Professor, Pharmacy & Pharmaceutical Sciences, **Binghamton University**

5.00 **Panel Discussion: ADC Analysis & Bioanalysis**
Moderators will be assigned to each roundtable to facilitate discussion and collate the findings. Following the roundtables, they will present back to the entire delegation as part of a panel discussion for information dissemination.

Supported by PPD

5.30 **Chair's Closing Remarks**
Leo Kirkovsky, Director, Clinical Assay Group, **Pfizer**

"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

2nd ADC & IO Combo Day

Monday November 12

8.00 **Chair's Opening Remarks**
Shyra Gardai, Director of Immunology, **Seattle Genetics**

8.10 **Rapid Advancements of Oncology Landscape: A Review of ADC & Immuno-Oncology**
- The current landscape of IO
- The clinical landscape of IO plus ADC
- How philanthropic investment models could help advance IO combo trials

Jun Tang, Senior Analyst, **Cancer Research Institute**

Improving Understanding of Scientific Rationale for Effective Combination Therapies

8.40 **Mirvetuximab Soravtansine: Where do ADC Sit in an Immuno-Oncology World?**
- Introduction to ImmunoGen and Mirvetuximab Soravtansine
- Exploring antitumor activity of Mirvetuximab Soravtansine as a single agent
- Understanding antitumor activity in combination with Pembrolizumab

Karim Malek, Medical Director, **ImmunoGen**

9.10 **Speed Networking**

10.00 **Morning Refreshments**

Improving Understanding of Scientific Rationale for Effective Combination Therapies

10.30 **Improving Our Understanding of the Scientific Rationale & Mechanisms of Action for ADC & Immuno-Oncology Combination Therapies**
- Non-clinical data to support combinations of ADC and IO agents
- Preclinical models to support ADC and IO combinations
- Selection of ADC targets for IO combination strategies

Leslie Sharp, Vice President, Immuno-Oncology, **BioAtla**

11.00 **Think Tank Roundtable Sessions**
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.

11.30 **Moderator Feedback & Audience Debate**
Following the roundtables, moderators will present back to the entire delegation as part of a panel discussion for information dissemination.

12.00 **Lunch & Networking**

Preclinical & Clinical Learnings of ADC & Immune Checkpoint Modulator Combinations

1.00 **Head-to-head Comparison of Non-Internalizing ADC & SMDC Products, Alone & in Combination with Antibody-IL2 Fusion Proteins**
- Explore experimental evidence that suggests it may be possible to have efficacy with an extracellular release of the toxic drug
- Carbonic Anhydrase IX is a non-internalizing cell membrane-protein overexpressed in tumor hypoxia and in certain malignancies, targeted in patients with radionuclide conjugates and with an ADC product
- Insight into how Acetazolamide exhibits a high binding affinity to CAIX. Acetazolamide based SMDC products may represent an alternative to ADC products for the treatment of CAIX-positive solid tumors, as single agents or in combination with immunocytokines

Samuele Cazzamalli, Research Scientist, **Philochem**

1.30 **Preclinical Update & Clinical Plan of Topoisomerase I Inhibitor, Exatecan Derivative-Based ADCs (DXd-ADC) with IO Combination**
- Overviews of DXd-ADC technology
- Preclinical updates of DXd-ADC franchise
- Clinical plans of DXd-ADC franchise

Hirokazu Suzuki, Researcher, Biologics & Immuno-Oncology Laboratories, **Daiichi Sankyo**

2.00 **Case Study: Bridging Preclinical & Clinical Data for ADC & IO Combo Trials**
- Discuss preclinical data that suggests that Brentuximab vedotin and Ladiratuzumab vedotin drive immunogenic cell death
- Review biomarker data from clinical trials of BV in Hodgkin lymphoma and LV in breast cancer supports the induction of inflammatory cytokines and innate inflammatory responses which are consistent with MMAE-induced ICD
- Insight from how our data supports an additional mechanism of action for BV and LV and provides the rationale for combining our ADCs with immuno-oncology therapies including PD-L1 checkpoint blockade antibodies in ongoing clinical trials

Shyra Gardai, Director of Immunology, **Seattle Genetics**

2.30 **Afternoon Refreshments & Networking**

The Future: Evaluating Future Development of ADC & IO Combinations

3.00 **Investigational ADCs & Combination Regimens for Treatment of B-cell Malignancies**
- Review investigational ADC in clinical testing for non-Hodgkin lymphoma and multiple myeloma
- Review rationale for antigen targeting
- Review rationale for ongoing combination studies

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

3.30 **Panel Discussion: Challenges & Opportunities with ADC & IO Combos**
- Lessons learned from progress in the field so far
- Evaluating opportunities over the next 12 months
- How do different stakeholders need to contribute?

Panellists will be a selection of experts

4.00 **Chair's Closing Remarks**
Shyra Gardai, Director of Immunology, **Seattle Genetics**

"I met a lot of scientists and vendors with whom I will follow-up. I gained a better perspective on where the field is"

RodTargX Therapeutics

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

MedImmune

Workshops

AM | Monday November 12

Primer Course: Introduction to the Design, Discovery & Development of ADCs

CHOOSE FROM

9.00 – 4:00 (Full Day)

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 Biological Consulting**

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

OR

9.00 – 12:00

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
- 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: To be confirmed

Workshop C: Filing a Successful ADC IND - from Discovery to First in Human Study

OR

9.00 – 12:00

This workshop will cover early development needs from product candidate ID to successful initiation of the first-in-human study. Antibody-drug conjugates are complex products requiring additional consideration for successful IND preparation. The CMC requirements for the antibody, additional CMC challenges for analytics and safety considerations for first-in-human studies are covered in this broad overview for filing an initial IND.

Workshop Leader: Karen Cha, Drug Development Consultant, **Sapience Regulatory Consulting**

Workshop E: Preclinical Pharmacology & Mechanistic Modelling of Antibody Drug Conjugates in Support of Human Clinical Trials

9.00 – 12:00

This workshop will discuss the nonclinical methods and strategies to evaluate ADC pharmacology and mitigate the risk to success in the clinic.

You'll learn the tools and insight to successfully submit an investigational new drug (IND) application by robustly demonstrating both reasonable safety for initial use in humans and exhibiting pharmacological activity.

This workshop will also share insight from non-clinical pharmacology studies that have demonstrated utility to identify combination therapies.

Attend this workshop to:

- Improve understanding of antigen density and ADC internalization
- Consider tumor tissue transport and subcellular trafficking
- Enhance pharmacokinetic modelling to robustly predict ADC pharmacology
- Decipher ADC efficacious dose range
- Improve understanding of target-mediated toxicity
- Explore considerations for nonclinical testing beyond antibody-drug conjugate monotherapies

Workshop Leader: Johnny Yin, Principal, **Johnny Yin Biotechnology Consulting**

Workshops

PM | Monday November 12

Primer Course: Introduction to the Design, Discovery & Development of ADCs

9.00 – 4:00 (Full Day)

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 Biological Consulting**

Workshop B: Design of Next Generation Linkers & Site-Specific Conjugation Techniques

CHOOSE FROM

1.00 – 4:00

Let's explore various ways to improve the therapeutic window of ADCs with more soluble and more stable linkers, multi-valency, and the use of site specific conjugation techniques. We will look at ways to have a defined DAR, a stable linkage, and controlled multi-valency on native and engineered proteins.

Workshop Leaders:

Rick Powers, Chief Consultant, **ADC Consulting**

Ed Ha, Principal Scientist, **AngieX**

Workshop D: Revealing Cutting Edge Science for Selecting the Right Antibody Format for Payload Delivery

OR

1.00 – 4:00

Historically, focus has been on the conjugation of cytotoxic small molecules to monoclonal antibodies, which has achieved remarkable clinical success. Since then antibody fragments, domains and even small 'scaffolds' have been explored for targeted payload delivery. This workshop will optimize ADC R&D by assessing in detail different antibody formats, as well as critically evaluating their characteristics and effectiveness.

Attendees will learn about:

- Assessing which antibody format optimises target binding: IgG vs fragment vs scaffold
- Exploring the options for multivalent conjugates
- Deciphering the differing requirements

Workshop Leader: Nazzareno Dimasi, Associate Director, R&D, **MedImmune**

Workshop F: Managing & Mitigating ADC Toxicities in Preclinical & Clinical Development

1.00 – 4:00

This translational session will focus on the mechanisms of clinical and nonclinical safety of novel ADCs with an emphasis on understanding the mechanisms of the observed findings. Emphasis will be placed on discussing ways in which the toxicities can be modified by rationale drug design or mitigating strategies in the clinical setting.

Workshop Leader: Laurie Tatalick, Consultant, **Laurie Tatalick Consulting**

Scientific Program – Day 1

Tuesday November 13

John Lambert,
Executive Vice President, Emeritus & Distinguished Fellow
ImmunoGen

Honorary Chair

- After dedicating over 30+ years to ADC drug development and attending every World ADC we're delighted to welcome John as our Honorary Chair

Timothy Lowinger
Chief Scientific Officer
Mersana Therapeutics

7.30 **Chair's Opening Remarks**

Robert Iannone
Head of Research & Development, Chief Medical Officer
Immunomedics

7.40 **Keynote: 2018-2019: Overcoming Challenges of Maximizing the Clinical Therapeutic Window of Antibody Drug Conjugates (ADCs)**

- Review the last 12 months of ADC drug development
- Discuss the development and latest clinical advances of sacituzumab govitecan

Rakesh Dixit
Vice President, Research & Development, Global Head of Biologics Safety Assessment,
MedImmune

8.10 **Keynote: Strategies for Improving Therapeutic Index & Minimizing On & Off-Target Toxicities of Highly Potent ADCs**

- Overcome warhead challenges in targeting solid tumors and improve the therapeutic index
- The antibody characteristics matter more than realized
- Optimization of warhead potency
- Good and bad of site-specific conjugation and linkers
- Impact of ADC disposition
- Dosing schedule and mitigation of toxicities
- Translational medicine approaches to improve therapeutic index

8.40 **Session Reserved for Late Breaking Abstract**

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**

Discovery Stream

Chair: Ravi Chari, Vice President, Chemistry & Biochemistry, **ImmunoGen**

Optimizing ADC Payload-Linker Chemistry

10.30 **Unveiling Complex & Novel Biotransformations of Antibody Drug Conjugates Bearing CBI Dimer Payloads**

- Complex and novel biotransfromations of CBI ADCs
- Impact of biotranformations on *in vitro* potency, *in vivo* efficacy and bioanalysis of CBI ADCs
- *In vitro* assay for predicting CBI ADC biotransformations
- Means for modulating CBI ADC biotransformations

Dian Su, Scientist, **Genentech**

11.00 **Discovering Novel Next Generation PBD Payloads**

- Why PBDs make good payloads
- Clinical progress of ADCs
- New PBD payloads

Phil Howard, Chief Scientific Officer, **Spirogen**

Translational Stream

Chair: Gail Lewis Philips, Senior Scientist, **Genentech**

Enhancing Understanding of ADC Trafficking, Processing & Resistance

10.30 **Trafficking & Processing of Antibody Drug Conjugates in Cancer Cells**

- Imaging allows us to better understand the cellular mechanisms of ADCs
- Dissect the trafficking and processing of ADCs using FRET technology
- Intracellular trafficking of ADCs can vary upon the structure of the ADC, its antigen and the phenotype of the targeted cell

Cecile Chalouni, Senior Scientist, **Genentech**

11.00 **Antibody Drug Conjugates & Bystander Killing: Is Antigen-Dependent Internalization Required?**

- It is becoming increasingly clear that non-internalizing ADCs with particular drug/linker combinations can be effective in treating cancer through bystander killing
- These ADCs are effective due to extracellular cleavage of the linker or processing by other cell types
- Examine whether ADCs of the antibody APOMAB, which specific targets dead tumor cells, are effective in preclinical cancer models and discover what linker/drug combinations work best

Alexander Staudacher, **University of South Australia & University of Adelaide**

Clinical Stream

Exploring Translational & Clinical Learnings of Phase I ADCs

10.30 **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

Trish Anthony, Senior Analyst, **Beacon, Hanson Wade**

11.00 **Preclinical & Clinical Development of AVID100: An EGFR-Targeting Antibody Drug Conjugate**

- Explore the preclinical development of an ADC to EGFR
- Discuss early clinical findings for AVID100

Bob Lutz, Chief Development Officer, **Formation Biologics**

Manufacturing Stream

Chair: Lisa McDermott, Senior Manager, Process & Analytical Development Group, **MilliporeSigma**

Process Development: Developing Robust & Scalable Processes for Clinical ADCs

10.30 **Novasep's Integrated Solutions for ADCs**

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

Francois D'Hooge, Head, Bioconjugation Unit (ADC), **Novasep**

11.00 **Case Study: Lessons Learned from Developing Processes for Late Stage Clinical Development**

- Evaluate current understanding of the challenges associated with developing reliable processes
- Focus on solving challenges in developing robust and scalable processes for late stage clinical ADCs
- Explore a case study for clinical ADC

Richard Silva, Senior Director, Process Development, CMC, **ImmunoGen**

11.30 **Click Chemistry-Triggered Drug Release from Tumor-Bound ADCs**

- Learn how non-internalizing receptors can become amendable to ADC therapy
- Development of a diabody-based MMAE ADC against non-internalizing TAG72 with a high tumor uptake and low retention in healthy tissues
- Discover how ADC tumor binding and blood clearance is followed by systemic administration of a chemical activator that cleaves the ADC linker, leading to potent antitumor activity in murine tumor models
- Analyze an analogous ADC comprising a protease-cleavable linker that is not effective in these tumor models

Marc Robillard, Chief Executive Officer, **Tagworks Pharmaceuticals**

11.45 **Extended Q&A**

11.30 **Caveolae-Mediated Internalization as a Novel Mechanism of T-DM1 Resistance**

- Learn how T-DM1 resistant N87 cells were generated using an 'on-off' schema to mimic clinic exposure dynamics to chemotherapeutics
- T-DM1 resistant N87 cells retained high expression of HER2 and did not up-regulate drug efflux pumps
- HER2-targeting ADCs with cleavable linkers and membrane permeable payloads overcame T-DM1 resistance *in vitro* and *in vivo*
- Understand the extent of ADC internalization into caveolae correlates with HER2-expressing cell lines' sensitivity to T-DM1

Matthew Sung, Senior Scientist, **Pfizer**

11.30 **W0101 First Antibody Drug Conjugate Targeting IGF1R: From Tumor Growth Inhibition in Preclinical Models to Patients**

- More details to follow

Mariya Pavlyuk, Global Clinical Lead, **Pierre Fabre**

11.30 **Challenges in Scaling Up Process Development from Clinical to Commercial**

- Experiences when moving to higher scales and what is required to maintain process characterization and robustness
- Differences from supporting FIH to pivotal trials
- Ensuring consistency of yields and process integrity during tech transfer

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

12.00 Lunch & Networking

Stefan Luedtke
Project Manager
Baxter Healthcare

Greg Sacha
Senior Research Scientist
Baxter Healthcare

Lunch Seminar: ADC Formulation Development to Full-Scale Manufacturing

- Examining the prediction of stability using HDX-MS
- Comparison of HDX-MS, DLS, and second derivative FTIR
- Manufacturing of oncology agents in Halle, Germany

Discovering Novel Bioconjugation Methods & Payloads

1.30 **Turning Native Antibodies into Homogeneous ADCs Without Antibody Engineering**

- A new site-specific method to generate homogeneous ADCs will be introduced that does not require antibody engineering
- Versatility of method will be shown
- Comprehensive characterization of generated ADCs will be presented

Philipp Spycher, PSI Founder Fellow, **Paul Scherrer Institute**

Advancing Preclinical Development Strategies

1.30 **Overcoming the Complexity of ADC Pharmacology**

- Overview of PDX clinical trials for ADC Development, perspectives from large pharma and biotech
- Focusing on the advantages of outsourcing PDX clinical trials rather than coordinating internally

Scott David Collins, Associate Director, Pharmacology, **Mersana**

Exploring Translational & Clinical Learnings of Phase I ADCs

1.30 **Development of NexMab™-Based Antibody Drug Conjugate for the Treatment of Breast & Gastric Cancers**

- NexMab™ platform-based stable and site-specific conjugation
- Bystander effect and less toxicity with cleavable linker and controlled DAR
- First-in-human phase I trial is underway with metastatic breast cancer patients

KJ Jeong, Senior Vice President, Head of Research & Development, **Alteogen**

Sharing Quality Control Strategies to Optimize Batch-Batch Reproducibility & Meet Regulatory Requirements

1.30 **Development of Novel Drug-Linker Manufacturing Processes**

- Development of polymeric drug-linkers which enable high-DAR ADCs
- Control of product heterogeneity
- Ensuring batch-to-batch reproducibility

Michael Kaufman, Senior Vice President, CMC, **Mersana**

2.00 **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

Matthew Bird, Team Leader, **Abzena**

2.00 **Session Reserved for Mabplex**

- More details to follow

2.00 **Sharing Cutting Edge Insight from Phase I Clinical Trial of Next Generation ADC**

- Patients most likely to benefit from the promise of immunotherapy are patients whose tumors are inflamed
- Learn of the proprietary OGAP® system, which identified a novel membrane cancer target, OX001L
- OX001L shows substantial prevalence of OX001L across multiple tumor types, which are lacking intratumoral PD-1(+) T-cell infiltrate
- Review how a human OX001L antibody conjugated to a DNA alkylating toxin exhibited substantial anti-tumor activity *in vivo*
- OX001L ADC is a distinctive therapeutic molecule, which could act on "cold" tumors, which are unlikely to respond to conventional checkpoint-directed therapy

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

2.00 **Lock-Release: Delivering a Solid Phase Solution to Conjugators**

- An overview of the Lock-Release concept and its benefits to developers and manufacturers
- Examples that demonstrate the range of use, scalability, improvements in quality and its simplicity
- Unexpected benefits of Lock-Release technology
- Discover how to integrate Lock-Release alongside traditional conjugation techniques at GMP scale

Charlie Johnson, Chief Executive Officer, **ADC Biotechnology**

2.30 **Novel Mode of Action Payload Identified Through Phenotypic Screening**

- Discover novel, highly potent, selective and novel series of dual CDK11A/B inhibitor compounds that were identified from a phenotypic screen
- Evaluate how these compounds demonstrated nM anti-proliferative (BrdU), cell-kill (relative cell count) and apoptosis induction (activated caspase-3) activity across a wide panel of cancer cell lines
- Review preliminary data which indicates these compounds have potential as novel warhead molecules for ADC therapies

Jon Roffey, Senior Group Leader, **Cancer Research UK**

2.30 **From Cells to ADCs: A Magnetic Bead-Based Conjugation & High-Throughput Analysis of ADCs**

- Assess automated high throughput screening in large molecule discovery research
- Magnetic bead-based approach for antibody capture and conjugation
- High-throughput MS platform for accurate detection and rapid quantitation of ADCs

Chawita (Jelly) Netirojjanakul, Senior Scientist, **Amgen**

2.30 **From Bench to Bedside & Back Again: The Development of a c-KIT ADC**

- Targeting c-KIT with an ADC was an attractive approach: c-KIT is a genetic driver exhibiting rapid internalization upon ADC binding and the ADC was efficacious at low levels with a safety profile allowing for clinical assessment
- However, hypersensitivity reactions were unexpectedly observed at low ADC dose levels in the initial patients
- Thus, alternative mechanistic approaches were explored in an attempt to mitigate this prohibitive toxicity

Tinya Abrams, Senior Investigator, **Novartis**

2.30 **Analysis of Trends & Case Studies for Antibody Drug Conjugates (ADC) IND Submissions at US Food & Drug Administration: Product Quality Perspective**

- Antibody drug conjugates are a rapidly growing area in drug development, as reflected by a significant increase in IND submissions to the FDA
- Analyze the advances in technologies that have optimized ADC development
- Discuss some examples of issues with ADC-specific product quality attributes identified in pre-INDs and INDs

Milos Dokmanovic, Biologist, **US Food & Drug Administration**

3.00 **Session Reserved for Seattle Genetics**

- More details to follow

3.00 **Process Development & Manufacturing Considerations of Antibody Conjugates**

- An overview of Goodwin Biotechnology bioconjugation capabilities
- Process development and scale-up manufacturing considerations of antibody drug conjugates
- Unique challenges for development and manufacturing of antibody-chelator conjugates for radioimmunotherapy
- Case studies of process development and scale-up manufacturing of antibody conjugates

Muctarr Sesay, Chief Scientific Officer & Vice President, **Goodwin Biotechnology**

Chen Fang, Senior Scientist, Bioconjugation Development, **Goodwin Biotechnology**

3.15 **Extended Q&A**

3.00 **Extended Q&A**

3.00 **Delivering the Next Wave of ADCs to the Patient – From Process Development to Commercial Manufacturing**

- A variety of new concepts including novel payloads, novel linkages to antibodies and completely new bioconjugation concepts for the delivery of active compounds to their targets are emerging
- Discover examples of how processes for the next wave of innovative drugs were optimized for clinical manufacturing
- Deepen understanding of which steps are needed to move towards commercialization

Bernhard Stump, Leader, ADC, Research & Development, **Lonza**

3.30 Afternoon Refreshments & Networking

Developing Next Generation ADCs

4.30 **5 Minute Short-Fire Poster Presentation Talks**

Capturing the scientific highlights of the World ADC San Diego Poster Session.
The Short-Fire Presentation talks will put the spotlight on five exceptional posters.

Andreas Pahl, Chief Scientific officer, **Heidelberg Pharma**

5.00 **Antibody Targeted Amanitin Conjugates (ATACs)**

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

Antoine Yver, Executive Vice President & Global Head of Oncology, **Daiichi Sankyo**

5.30 **Daiichi Sankyo DXd ADC Technology: DS-8201 & U3-1402: Clinical Validation of an ADC Design Meant to Deliver a By-Stander Effect**

- More details to follow

Brian Mendelsohn, Director, ADC Chemistry, **Althea**

6.00 **Development of a Novel Chemical Site-Specific ADC Conjugation Platform**

- The chemical conjugation of antibodies in a site-directed manner remains an area of great interest and active efforts within the ADC community. 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
- Discover a new platform for the site-selective conjugation of antibodies through the use of a class of Fc-affinity compounds to install payload-compatible linkers to well-defined amino acid residues
- The *in vitro* and *in vivo* activity of these resulting ADCs will be reviewed and assessed compared to the state-of-the-art

Tok Han, Director & Team Leader, Oncology Operations, **Pfizer**

6.30 **Lessons Learned from Commercial Scale Manufacturing of Approved ADC**

- Consideration and strategy for process validation
- Importance of control strategy and timing
- Commercial specification challenges
- What to expect during pre-approval inspection (PAI)

Timothy Lowinger Chief Scientific Officer **Mersana Therapeutics**

7.00 **Chair's Closing Remarks**

7.30 **5th Annual World ADC Awards Ceremony**

5th Annual World ADC Awards

Tuesday November 13

Now in its 5th 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

5th WORLD adc AWARDS

2018 World ADC Award Categories

Supported by: Ambrx

- Best ADC Platform Technology
- Best New Drug Developer
- Individual Input to the Field 2017
- Most Promising Clinical Candidate
- Best Contract Research (CRO) Provider
- Long Standing Contribution to the Field
- Best Contract Manufacturing (CMO) Provider
- Best Publication 2017
- Best Poster 2018

In Partnership with: abbvie

Reserve Your Place at the Ceremony
From Monday September 24

Scientific Program – Day 2

Wednesday November 14

Mary Robinette
Principal Project Engineer
MilliporeSigma

April Wheeler
Manager
MilliporeSigma

7.00 **Breakfast Briefing: Complete Single-Use ADC Technology from Development Through Scale-Up**

- How single-use technologies can provide benefits for ADC manufacturing
- Why a solid manufacturing platform is crucial for a successful transfer to GMP production
- How a case study demonstrates the advantages of single-use equipment in a scale-up to GMP production

Timothy Lowinger
Chief Scientific Officer
Mersana Therapeutics

8.00 **Chair's Opening Remarks**

8.10 **Session Reserved for Late Breaking Abstract**

Pioneering Scientific Advances Powering the Development of 4th Generation ADCs

Scott Dylla
Chief Scientific Officer
AbbVie-Stemcentrx

8.40 **Reviewing Advances of AbbVie Stemcentrx Clinical Pipeline**

- Update on the clinical progress of AbbVie Stemcentrx ADC pipeline
- Review clinical results for TRINITY trial

Trevor Hallam
Chief Scientific Officer
Sutro Biopharma

9.10 **Rapid, Precise Design & Systematic Evaluation of Protein SAR to Create Optimized Homogeneous Product Candidates**

- Explore Sutro's two most advanced product candidates derived from a unique design and manufacturing process
- STRO-001, an ADC directed against CD74, for patients with multiple myeloma and NHL. STRO-001 is currently enrolling patients in a Phase 1 trial
- STRO-002, an ADC directed against folate receptor-alpha, or FolRĐ , for patients with ovarian and endometrial cancers. An IND application to the FDA is planned this year
- Discover next-generation conjugate protein therapeutics using advanced precision XpressCF+ Platform

Timothy Lowinger
Chief Scientific Officer
Mersana Therapeutics

9.40 High DAR ADCs with a Controlled Bystander Effect: From Concept to Clinical Experience

- Two Dolaflexin ADCs, targeting Her2 and NaPi2b, are now in clinical trials
- Both have a DAR of 10-15, and utilize a novel auristatin payload designed to have a controlled bystander effect
- How does the clinical experience match with preclinical expectations?
- Dolasynthen – a new platform that provides fully homogeneous ADCs together with optimal DAR and a controlled bystander effect

10.10 Morning Refreshments & Networking

Discovery Stream

Chair: Ravi Chari, Vice President, Chemistry & Biochemistry, **ImmunoGen**

Identifying & Validating New ADC Tumor Targets

11.00 **ADC Target Discovery & Tissue Mapping: Integration of Genomic & Immunohistochemistry Techniques**

- ADC target mapping in tumors for ADC positioning in the clinic
- Mapping potential partner targets for bi-specific ADCs
- Using IHC techniques to compare target expression in tumors vs. normal tissues to select targets with better therapeutic index profiles

Brad Stringer, Associate Scientific Fellow, Molecular Pathology, **Takeda**

Translational Stream

Chair: Gail Lewis Philips, Senior Scientist, **Genentech**

Minimizing Off Target Toxicity: Improving Understanding of ADC PK-PD

11.00 **An AXL-Specific Antibody Drug Conjugate Shows Preclinical Anti-Tumor Activity in Wild-Type & Treatment-Resistant Non-Small Cell Lung Cancer**

- HuMax-AXL-ADC is an antibody drug conjugate composed of an AXL-specific human monoclonal immunoglobulin G1 conjugated via a protease-cleavable valine-citrulline linker to the microtubule disrupting agent monomethyl auristatin E (MMAE)
- AXL is associated with pan-cancer EMT and multidrug resistance across many cancer types
- Preclinical results of HuMax-AXL-ADC in NSCLC provides support for treatment of NSCLC patients, including those with (acquired) resistance to EGFR inhibitors

David Satijn, Vice President, Antibody Products, **Genmab**

Clinical Stream

Rapidly Advancing Clinical Biomarkers & Companion Diagnostics for ADCs

11.00 **Development & Execution of a Diagnostics Strategy for Patient Analyses & Stratification for a Probody Drug Conjugate (PDC)**

- Development of a PDC for CD166, a target expressed in tumor and healthy tissues
- Enabling indication selection
- Development and validation of a diagnostic assay for CD166
- Evaluation of target distribution in a patient population

Luc Desnoyers, Senior Director, Translational Sciences, **CytomX**

Manufacturing Stream

Chair: Michael Kaufman, Senior Vice President, **Mersana**

Building Robust ADC Technical Operations

11.00 **Strategies for Accelerating the Development of Antibody Drug Conjugates in Oncology**

- Overview and highlights of strategies for two key aspects of rapid development of ADCs in oncology: dose selection and material comparability
- Enhance understanding of the important interdependencies that exist between these two development aspects - how exposure/response relationships can influence the material comparability
- Discuss the unique challenges related to establishing material comparability, including considerations related to the ADC payload
- Learn how to better inform material comparability strategies by leveraging platform safety data and establishing ADC mechanism of action in the context of the disease being treated

Dale Miles, Senior Scientist, **Genentech**

11.30 **Cancer Target Atlas for Antibody Drug Conjugates**

- A massively parallel monoclonal antibody array (Human Membrane Proteome MabArray) is developed for measuring thousands of cancer and immune cell surface proteins
- Differential profiling of tumor cell surface proteomes with MabArrayTM enables the discovery of novel cell surface targets for ADC
- Multiple preclinical ADC molecules are currently being developed

Xun Meng, Chief Executive Officer & Co-Founder, **Abmart**

11.30 **Session Reserved for The Jackson Laboratory**

- More details to follow

11.30 **Session Reserved for Seattle Genetics**

- More details to follow

11.30 **Working with a CMO in the ADC field – From Selection & Technology Transfer to Scale-Up & 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, Head of Special Projects, **Carbogen Amcis**

12.00 **Session Reserved for MedImmune**

- More details to follow

David Tice, Director, Research & Development, **MedImmune**

12.00 **Development of a Transferrin Receptor Targeting Probody Drug Conjugate for the Treatment of Solid Tumors**

- ProbodyTM therapeutics are designed to remain largely inactive until proteolytically activated in the tumor microenvironment, enabling the safer and selective targeting of tumor antigens that are highly expressed in both tumor and normal tissue
- Transferrin receptor (CD71) is highly expressed on many cancers but its normal tissue distribution precludes its development as an ADC
- CytomX has designed a CD71 targeting Probody drug conjugate, CX-2029, that demonstrates potent activity in multiple *in vivo* patient derived xenograft models across many indications, whilst establishing a significant therapeutic window over its parental ADC in NHP tolerability studies. CX-2029 is currently enrolling in a (FIH) Phase 1 dose escalation study

Shweta Singh, Senior Scientist, **CytomX**

12.00 **Extended Q&A**

12.00 **Augmenting External Capacity with In-House Investment to Safeguard Timelines in Clinical Scale ADC Production**

- More details to follow

Thomas Lecocq, Associate Director, CMC Project Management, **CytomX**

12.30 Lunch & Networking

Improving ADC Targeting: Antibody Engineering & Application of Novel Formats for ADCs	Practical Lessons Learned from Preclinical ADC Development	Widening the Therapeutic Index: Mitigating Clinical Toxicities	Developing Harmonious Supply Chains
2.00 **Disulfide Re-Bridging with Pyrrolobenzodiazepine Dimers Enable the Formation of Homogeneous, Potent & Differentiated Antibody & Fab Drug Conjugates** • Explore a novel class of homogeneous IgG and Fab drug conjugates with a drug to antibody ratio of one • These ADCs are prepared using novel pyrrolobenzodiazepine dimers that have been engineered to re-bridge two adjacent cysteines at the antibody hinge, at an engineered position in the CH2 domain and at the Fab cysteines forming the intrachain disulphide bond **Nazzareno Dimasi**, Associate Director, Research & Development, **MedImmune**	2.00 **Harnessing Multiscale Modelling to Optimize Design of Antibody Drug Conjugates for Clinical Success** • Mechanistic physiologically-based pharmacokinetic models (PBPK) can be used as a platform to study the impact of various ADC characteristics on their disposition in plasma, tissues and tumor, allowing us to build quantitative relationship between exposure and efficacy • Understand how to select ADCs with an increased likelihood of success • Explore how mathematical simulations can provide an efficient method for exploring the vast permutation and combinations of parameters influencing efficacy and toxicity of these complex molecules **Renu Singh Dhanikula**, Senior Investigator, **Bristol Myers Squibb**	2.00 **Results From the Phase 1 Of PEN-221, a Miniature Drug Conjugate Targeting the Somatostatin Receptor SSTR2** • SSTR2 is over expressed on the surface of various cancers including neuroendocrine cancers and small cell lung cancer • PEN-221 is a miniature drug conjugate containing the potent payload DM1 that binds with high selectivity and affinity to SSTR2 • The results from the Phase 1 study of PEN-221 in patients with SSTR2 expressing tumors have triggered the initiation of Phase 2a **Richard Wooster**, Chief Scientific Officer, **Tarveda**	2.00 **Session Reserved for Seattle Genetics** • More details to follow
2.30 **Tunable Cytotoxic Aptamer-Drug Conjugates for the Treatment of Prostate Cancer** • Review the chemical conjugation of the cancer-specific aptamer E3 to the drugs monomethyl auristatin E (MMAE) and monomethyl auristatin F (MMAF) yields a potent cytotoxic agent that efficiently kills prostate cancer cells *in vitro* but does not affect normal prostate epithelial cells • Importantly, treatment with the MMAF-E3 conjugate significantly inhibits prostate cancer growth in mice, demonstrating the *in vivo* utility of aptamer–drug conjugates. • Additionally, evaluate how the use of antidotes can block E3 aptamer–drug conjugate cytotoxicity, providing a safety switch in the unexpected event of normal cell killing *in vivo* **Bethany Powell Gray**, Senior Research Associate, Sullenger Lab, Department of Surgery, **Duke University Medical Center**	2.30 **Optimizing Understanding of Critical Parameters to Make More Meaningful Predictions** • Confidently analyze preclinical PK/PD to better define the therapeutic window and predict of human pharmacokinetics • Design and implement a strategy for assessing ADME issues • Discuss experiences in preparing regulatory documents to support IND, NDA and BLA filings **Nagendra Chemuturi**, Senior Investigator, **Novartis**	2.30 **Reviewing the Development of Phase II ADC: Expanded Cohort Study for Lutetium-177 PSMA61** • Exploring where SMDCs sits in the targeted-therapy landscape • Sharing learning from a Phase II clinical trial design, with specific focus on dosing frequency • Reviewing and analyzing the latest clinical data **Alison Armour**, Chief Medical Officer, **Endocyte**	2.30 **ARX788 Manufacturing & Comparability Strategy Meeting Regulatory Requirements** • ADC and ARX788 ADC project overview • ARX788 development and manufacturing strategy • ARX788 comparability strategy addressing process changes **Yun Bai**, Director, **Ambrx**

3.00 **Site-Specific Conjugation: Lessons from Cys-Deletion Mutants**

- Conjugation through cysteines involved in inter-chain disulfide bonds is a proven strategy for generation of ADCs using cys-directed chemistries
- However, little is known about how the local environment around each of these cysteines might impact the properties of the resultant ADC
- Systematically examine positional differences in ADC properties using cys-deletion mutants (general properties of unconjugated antibodies, conjugation efficiency and ADC function and stability)

John Harlan, Principal Research Scientist, **AbbVie**

3.00 **Session Reserved for Merrimack Pharmaceuticals**

- More details to follow

Daryl Drummond, Chief Scientific Officer & Head of Research, **Merrimack Pharmaceuticals**

3.00 **Antibody Drug conjugates: Promising Therapies for Hematological Malignancies**

- Novel ADCs in clinical development for blood cancers
- Clinical issues and toxicities
- Future of ADCs in these malignancies

Eunice Wang, Assistant Professor, **Roswell Park Cancer Institute**

3.00 **Extended Q&A**

3.30 Afternoon Refreshments & Networking

Harnessing ADC Learnings to Explore New Frontiers

Amy Han
Director, Chemistry
Regeneron Pharmaceuticals

4.30 **Novel Non-Cytotoxic ADCs for Potential Treatment of Atherosclerosis**

- More details to follow

Jack Sadowsky
Scientist
Genentech

5.00 **Amunix XTEN® Polypeptides & THIOMAB™ Antibodies to Enable Site-Specific High-DAR ADCs with Acceptable Pharmacokinetics & Efficacy**

- Conjugation and analytics development for THIOMAB™ antibody-XTEN®-drug conjugates (TXCs)
- *In vitro* and *in vivo* validation of high-DAR TXC platform

"Very informative. A lot of valuable information"
UCB

Workshops

AM | Thursday November 15

Workshop G: Plunging into a World of Developing Robust & Scalable Processes for Clinical Manufacturing

8.00 – 11:00

The complexity of ADCs means developing robust and scalable manufacturing processes can be very challenging.

As antibody drug conjugates (ADCs) move through clinical development, from phase 1 to pivotal studies, supported by clinical efficacy and appropriate safety, the development of late stage and commercial-ready processes and methods becomes a priority.

Join this working group to discuss the early stage of process development, with a focus on speed, consistency, and quality. For later stage development, additional aspects such as process robustness, cost effectiveness, process and method transferability, and an integrated control strategy as a foundation for the regulatory filing will be reviewed.

Workshop Leader: To be confirmed

CHOOSE FROM

Workshop H: Modularity & Flexibility for Aseptic Processing for ADCs. From Batches for Clinical Trials to Commercial Production

8.00 – 11:00

Sterile fill finish for ADCs or other biological pharmaceutical products are the final dose for the treatment of the patient. This could be during clinical trials or later for commercial production. The workshop will explain how sterile fill finish could be applied even for small start up companies to produce their first clinical batches by themselves and enlarge the installation later with additional modules to launch their product with the VarioSys-Technology.

We will focus on:

- Additional topics during the workshop
- Modularity for different containers like vials and syringes
- Ready to use containers like nested vials
- Aseptic isolator technology
- Cleaning and cross contamination requirements

Workshop Leaders:

Richard Denk, Head, Sales Containment, **SKAN**

Armin Storz, Sales Manager, **Bausch&Stroebel**

AND

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

12.00 – 3:00

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**

OR

Workshop J: Improve Manufacturing Quality Controls

12.00 – 3:00

ADCs are viewed by regulatory agencies as both drug and biological molecules which adds a layer of complexity for characterization, manufacturing process controls, comparability, release, and stability assays. Attend this workshop to improve your manufacturing quality controls and meet the appropriate regulatory requirements for the entire ADC molecule.

This workshop will give an in-depth review of the current:

- Quality Control Standards – what are the expectations?
- Process Development
- Method transfer and validation
- Raw material testing
- In-process testing
- Cleaning and environmental monitoring
- Stability testing
- Application of next generation bioassays

Workshop Leaders: Ahmed Bassyouni, **Independent Consultant**

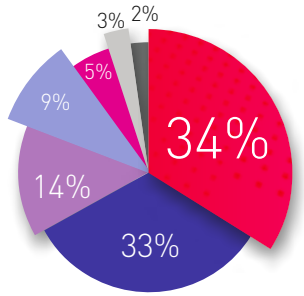
Who You'll Meet

"The World ADC Summit is an opportunity to have face time with the industry leaders in ADCs and converse in a cooperative, sharing, and constructive environment" **Genentech**

Seniority of Attendees

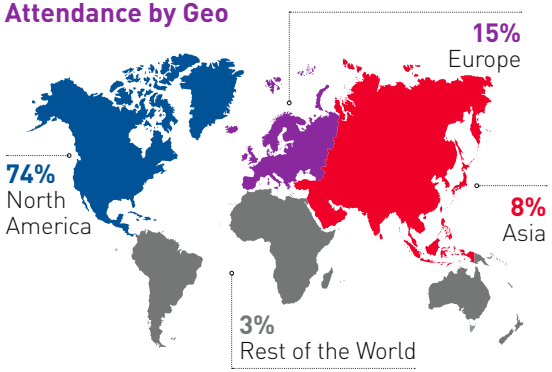
- **9%** C -Level
- **8%** Vice President
- **10%** Global Head
- **26%** Director
- **26%** Manager / Project Leader
- **13%** Principal Scientist / Scientist
- **8%** Academic

Attendance by Company



- Large Drug Developer
- Small & Medium Drug Developer
- CMO
- Academia
- CRO
- Equipment Provider
- Other

Attendance by Geo



84% of Audience are Drug Developers

27% New Companies in 2017

Speed Networking

Specifically designed to connect you with new contacts, the renowned Speed Networking will be one of the most valuable hours you will spend at the conference. This session is the ideal opportunity to meet face-to-face with many of the brightest minds working in the ADC field and establish meaningful business relationships.

Maximize Your Onsite Experience by Attending as a Team

All the scientific content being presented across the 4 parallel streams of learning

Maximize your team's learning opportunity at this conference. Sending a team means that you can make sure that between you, you benefit from all of the topics in different streams.

More effective networking and relationship building

Ensure you've met with all potential new partners, existing collaborators and colleagues.

Value for money

Tiered group rates apply when three or more attendees book and pay at one time. Corporate rates can be applicable if you are planning on sending multiple attendees from different sites and departments.

Team Discounts:

5+ person team: 20% discount
4 person team: 15% discount
3 person team: 10% discount

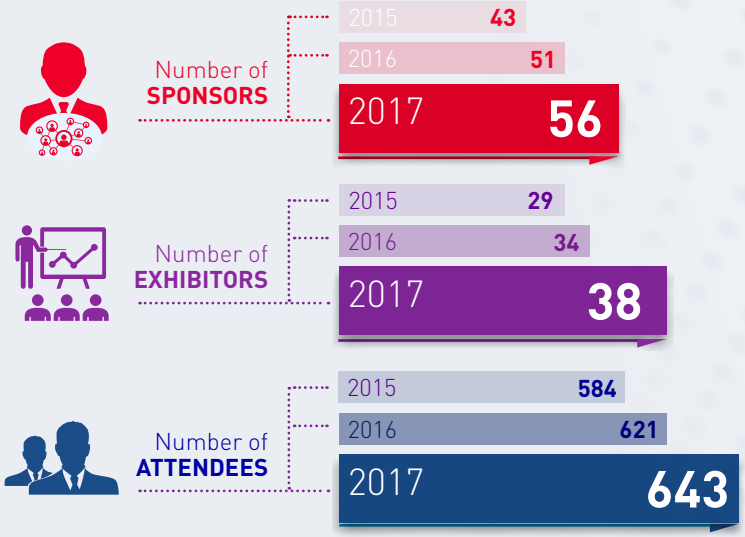
"This 8th conference was the first time I attended. That was really impressive and beneficial! I would like to attend the 9th conference next year. Thank you very much"
Bayer

Partnering with World ADC

World ADC San Diego is your fastest route to organizations prioritizing ADC development.

This year 650 stakeholders and influencers across the supply chain of ADCs, from discovery through to commercial, will attend World ADC. 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.



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

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Email: adc@hansonwade.com

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Workshop Partners






Exhibitors











Venue

Marriott Marquis San Diego

Ideal for both business travellers and vacationers, the hotel is within walking distance to City Walk, the Gaslamp Quarter, Seaport Village and Petco Park. After a busy day at the conference, relax in the spacious accommodations, all offering either scenic city or waterfront views. Take a dip in one of two freeform swimming pools, indulge in an onsite spa treatment, or keep your workout routine in the fitness center. Enjoy award-winning cuisine at Marina Kitchen Restaurant & Bar, or sample inventive Asian-fusion at Roy's.

333 W Harbor Dr, San Diego, CA 92101, USA

www.marriott.co.uk/hotels/travel/sandt-marriott-marquis-san-diego-marina

Book by Thursday October 19 to get a reduced rate

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

Register

Pricing

Packages	Register & Pay before July 6	Register & Pay before August 3	Register & Pay before September 7	Register & Pay before October 5
Full Access Pass Scientific Program plus 2 x Seminar Days	$4,147 **(save $1,450)**	$4,247 **(save $1,350)**	$4,347 **(save $1,250)**	$4,447 **(save $1,150)**
Conference Pass Scientific Program plus 1 x Seminar Day	$3,498 **(save $700)**	$3,598 **(save $600)**	$3,698 **(save $500)**	$3,798 **(save $400)**
Scientific Program Pass	$2,499 **(save $300)**	$2,599 **(save $200)**	$2,699 **(save $100)**	$2,799
Seminar Day Pass	$1,399	$1,399	$1,399	$1,399

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

TEAM DISCOUNTS 5+ person team: 20% Discount | 4 person team: 15% Discount | 3 person team: 10% Discount

When you've made your selections - **secure your place**

Register me now

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"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

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. Data Protection: The personal information shown and/or provided by you will be held in a database. It may be used to keep you up to date with developments in your industry. Sometimes your details may be obtained or made available to third parties for marketing purposes. If you do not wish your details to be used for this purpose, please write to: Database Manager, Hanson Wade, Suite A, 6 Honduras Street, London EC1Y 0TH