6th ANNUAL WORLD adc

SAN DIEGO 2015

October 19th-22nd

65 sessions to participate in

Evidence-Based Design Decisions

Ensure Product & Process Robustness

Maximize Clinical Benefit

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@world_adc #WorldADC Antibody Drug Conjugates

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Dear Colleagues

I invite you with great enthusiasm to join me at World ADC 2015, in sunny San Diego, where we will share the latest innovations in ADC science.

As I look back at the years spent on ADC research, the quote from Charles Dickens comes to mind - "It was the best of times, it was the worst of times; it was the age of wisdom, it was the age of foolishness …".

I'm sure that resonates with many of you. Kadcyla and Adcetris paved the way to our ADC successes; however, sizeable work remains to be done to broaden their therapeutic window. World ADC will expand our horizons in understanding the ways to achieve this therapeutic window clinically. This conference presents exciting talks, from world experts, addressing clinically critical aspects of ADC development. Learn about linker and payload selection, facets of site-specific ADCs and their potential benefits, analytical and bioanalytical support strategies, and discover new pathways to success.

More than this, World ADC offers you the opportunity to meet colleagues, collaborators, and make new connections. It provides a platform where all ADC researchers come together and share invaluable insights into where the field is moving in the future.

So, join me to chart the future of ADC drug discovery and development and deliver effective medicines for cancer treatment. I look forward to seeing you all and having a fantastic conference.

Warm Regards,
Chetana Rao
Associate Director
BMS

"Eye-opening experience to see the depth and breadth of ADC research and development"

Merck

Contents

Benefits of Attending

1. Leverage new design insights to **make validated decisions in linker and payload selection**
2. **Minimize cost and complexity of manufacturing** by appreciating the strides made in containment technology and supply chain coordination
3. **Strengthen your characterization strategy** by hearing about emerging approaches to perform ADC analysis and bioanalysis with greater sensitivity
4. **Guarantee clinical success** through use of better predictive techniques for assessment of ADC tolerability and efficacy
5. **Reduce preclinical attrition and speed development** by adopting new PK and ADME profiling tools

Poster Session

Share your work with pioneers of the ADC field. Bring a scientific poster to World ADC and gain feedback on your latest research as well as disseminating your findings to the community.

Back by popular demand, we're aspiring to host an even bigger session dedicated to highlighting new chemistries, compounds and creative research. Open to all, this is a valuable opportunity to join over 50 poster presenters in an exciting and data rich session.

All posters are subject to approval by the organizers.

Please send abstracts to adc@hansonwade.com by October 2nd to be eligible.

Top Speakers

Hans Peter Gerber
VP, Bioconjugates
Pfizer

Hear a powerful overview of the evolution of the calicheamicin payload platform. Highlighting lessons learned from over a decade of compounds tested by Pfizer, this is your chance to understand the iterative improvements in their conjugation.

Scott Dylla
CSO
Stemcentrx

For the first time, Stemcentrx reveal the progress of candidates in their pipeline. Discover new paradigms in target discovery and learn about empirical approaches to predict clinical success.

Peter Senter
VP, Chemistry
Seattle Genetics

Winner of the *2014 World ADC Award for Outstanding Contribution to the Field*, Peter Senter will share his views on the critical challenges in advancing ADCs. Evidence-based design decision making will be detailed in a review of chemical optimizations.

Site Tour

Visit the Althea Manufacturing Facility While in San Diego.

Join us for a welcome reception on Monday October 19th. Learn more about Althea's ADC offering, meet the team and tour the new building.

More details and how to sign up can be found on the website.

The site tour runs from 4.45pm-7.00pm and RSVP is required to participate.

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Agenda at a Glance

Monday October 19th

Workshop A: Challenges, Opportunities & New Approaches for the Synthesis of Well-Defined ADCs

Workshop C: Entering the Crowded IP ADC Technology Landscape & Seeking Protections for New Products

Clinical Day: Successful ADC Therapy in Solid Tumors

LUNCH

Workshop B: Selection of the Optimal Antibody or Scaffold Format to Deliver Potent Warheads

Workshop D: Assess Payload Selection Options & Design the Most Efficacious Drug Conjugates

Clinical Day: Treating Hematological Malignancies with Targeted Therapies

Tuesday October 20th

Plenary: Two Decades of ADC Experience

Discovery Stream	Development Stream	Manufacturing Stream
Validating Linker Design Decisions	Strategies for Improved Targeting	Developing Robust & Scalable Processes

LUNCH

Optimizing Linker-Payload Compatibility	Improving Success of Preclinical-Clinical Translation	Advanced Purification & Formulation Techniques

Plenary: Approaches for Maximizing Therapeutic Index & Improving ADC Candidates

Poster Session & Drinks Reception

Wednesday October 21st

Plenary: Advancing Development Strategy for ADCs

Discovery Stream	Development Stream	Manufacturing Stream
Matching Target Biology to Chemical Design	Characterizing ADC Structure & Function	Improving Product Quality & Ensuring Safe Production

LUNCH

Advances in Drug-Conjugate Design	Characterizing ADC Structure & Function	Managing Complex Supply Chain Networks

Plenary: Pioneering New Developments to Fuel the ADCs of the Future

Thursday October 22nd

Workshop E: Utilizing PK/PD Modeling & Simulation to Create a Translational Framework for Development of Better ADCs

Full Day Workshop G: ADC Outsourcing, Technology Transfer & CMO-Client Relationships

LUNCH

Workshop F: Preclinical & Clinical Assay Development for Improving ADC Understanding

Workshop G: Continued

Pre-conference Sessions - Monday October 19th

Workshop A:

Pick **A** or **C**

9am-12pm Challenges, Opportunities & New Approaches for the Synthesis of Well-defined ADCs

In addition to tumor-selective antigen-binding, ADCs must also bear a potent drug connected to the antibody via a suitable linker. The processes for both the drug connection (conjugation) and disconnection (linker cleavage) need to be carefully engineered and controlled to yield a well-defined ADC with desired biological activity.

In this workshop, we will provide case studies around the themes of conjugation and linker cleavage with an emphasis on analytical/chemistry challenges in the former and proteolytic cleavage of peptide linkers in the latter.

Attendees will learn about:

- Chemistry challenges/solutions in site-specific cysteine conjugation
- Analytical characterization of site-specific cysteine conjugates
- Techniques to generate homogeneous DAR preparations (from 1 to many) with both thiol & lysine chemistries
- Modifications of ADCs in plasma, serum & by intracellular proteases

Workshop Leaders:

Jack Sadowsky, Scientist, Genentech

Richard Vandlen, Staff Scientist, Genentech

Workshop C:

Or

9am-12pm Entering the Crowded IP ADC Technology Landscape & Seeking Protections for New Products

In this workshop, legal and business factors to consider for strategically creating, protecting and using proprietary rights to develop ADC products will be considered. In addition to interactive discussions around patented or potentially patentable aspects of a new ADC product, you will learn how data generated during R&D can be used to support or broaden patent claims to a new product.

Attendees will learn about:

- Which aspects of ADC products, the development process, manufacturing & use may be the subject of a patent claim
- At what point in the project should new patents be filed
- At what point is it necessary to license rights to IP of third parties
- How licensing or new IP creation might affect the length of term of exclusivity for a new ADC product

Workshop Leader:

Meg Baker, Registered Patent Agent, Independent Consultant

Clinical Day:

9.00 **Chair's Opening Remarks**
Alan Rigby, VP, Eli Lilly

9.15 **ADCs in Clinical Trials: What Does the Global Landscape Look Like?**
James Eslea-MacDonald, Community Director, Hanson Wade

Successful ADC Therapy in Solid Tumors

9.50 **Early Clinical Development Update on SYD985, a Duocarmycin-Based HER2-Targeting ADC**
Norbert Koper, VP, Clinical, Synthon

10.25 **Morning Refreshments**

11.00 **Advancing Mirvetuximab Soravtansine Through Clinical Development**
Charles Morris, CDO, ImmunoGen

11.35 **Solid Tumor Therapy with Sacituzumab Govitecan, an Anti-TROP2 Targeted SN-38 Conjugated ADC**
David Goldenberg, CSO, Immunomedics

12:10 **Lunch**

Pre-conference Sessions - Monday October 19th

Pick **B** or **D**

Workshop B:

1pm-4pm Selection of the Optimal Antibody or Scaffold Format to Deliver Potent Warheads

This workshop addresses the growing evidence indicating that antibody formats or scaffolds smaller than full IgG can be effective in delivering conjugated potent cytotoxic drugs to target cells/tissues in animal models.

Attendees will learn about:

- Effects of size & format of antibody or scaffold on delivery of conjugated drugs
- How size affects therapeutic window
- Potential for fragments & scaffolds to be more flexible for bispecific formats – e.g. for specificity of an ADC
- How rapidly various potent drugs kill cells
- What is required for half-life when using a small scaffold or fragment
- Half-life extension vs retaining small size of scaffold
- Options to modulate half-life of small proteins

Workshop Leader:

David Bramhill, Consultant,
Bramhill Biological Consulting, LLC

Workshop D:

1pm-4pm Assess Payload Selection Options & Design the Most Efficacious Drug Conjugates

The last decade of ADC research has honed our understanding of which payload mechanisms are most effective and what modifications are required to maximize their clinical effectiveness. But the field continues to evolve and advance.

This workshop will review the distinct classes of payload in current use such as auristatins, PBDs, maytansines, amantins, spliceosome inhibitors and older chemotherapeutic agents. Case studies will focus on advantages and disadvantages of each payload type with thoughts on how these can be optimally applied. Learn how payload choice has broad ranging implications for DAR, post conjugation modifications and dosing. Consideration will also be given to what future opportunities there are for payload innovation.

Attendees will learn about:

- What the most important payload properties are
- How to best optimize them within an ADC construct
- Ways to select the most appropriate payload for a given target biology
- Where new payload opportunities will arise & how to take advantage of these

Workshop Leader:

Ed Ha, Scientist, **Solstice Biologics**

Or

Clinical Day:

Treating Hematological Malignancies with Targeted Therapies

1.10 **Clinical Development Update on ADC Programs at Seattle Genetics**
Jonathan Drachman, CMO, **Seattle Genetics**

1.45 **Translating Preclinical Experiences with Tissue Factor-ADC into Clinical Development**
David Satijn, Director, **Genmab**

2.20 **Afternoon Refreshments**

2.55 **ADCs: A Targeted Chemotherapy Approach for the Treatment of Cancer**
Cecile Combeau, Project Director, **Sanofi**

3.30 **Panel Discussion: What Have we Learned About ADC Development?**

Gain an understanding of how to improve your clinical strategy by hearing from those who have been there and done it before. As the field continues to advance and generate new insights future considerations will be mooted.

- What is the importance of patient selection?
- What can we do about common toxicities?
- Where is the unmet medical need?

Moderator: Alan Rigby, VP, **Eli Lilly**
Charles Morris, CDO, **ImmunoGen**
Norbert Koper, VP, Clinical, **Synthon**

4.15 **Chair's Closing Remarks**

Day One – Tuesday October 20th

7.45	**Chair's Opening Remarks**		**Chetana Rao,** Associate Director, **BMS**
8.00	**Keynote: Evolutionary Improvements in Calicheamicin-ADC Design** • Iterative optimization of conjugation technology • Translating target biology into clinical responses		**Hans Peter Gerber,** VP, Bioconjugates, **Pfizer**
8.30	**New Horizons: ADC Paradigms Challenged** • Not all tumor cells are equal; it matters which cells are targeted • There is no one recipe for what constitutes a good ADC target • Empirical approaches executed *in vivo* with patient-derived xenografts best predict clinical success		**Scott Dylla**, CSO, **Stemcentrx**
9.00	**Morning Refreshments & Speed Networking**		

Discovery Stream
Validating Linker Design Decisions

10.00 Novel Site-Specific Conjugation Tools & Control of DAR
- N-terminal serine modification for antibody conjugation: SeriMabs
- *in vitro* activity is maintained or enhanced through site-specific conjugation
- Site-specific conjugates are efficacious *in vivo*

Thomas Keating, Director, Biochemistry, **ImmunoGen**

10.30 Site-Specific ADC Generation Using SMARTag™ Technology
- Enabling precise & programmable site-specific chemical protein modification against a number of different antigens/targets
- Novel conjugation chemistry for ADCs with enhanced stability & increased DAR
- Linker chemistry that optimizes the potency of the cytotoxic payload

David Rabuka, Global Head of R&D, Chemical Biology, **Catalent**

Development Stream
Strategies for Improved Targeting

10.00 Probody™ Drug Conjugates (PDCs): Redefining the Therapeutic Profile of Drug Conjugates
- PDCs are designed to not require highly differential expression between normal & tumor tissues
- PDCs enable targeting of antigens with broad, persistent & very high expression in cancer: a broader target set than for ADCs
- CytomX PDC targets show >70% prevalence at 3+ expression in many cancer types
- Proof of concept will be shown for safety, efficacy & developability for multiple PDCs

Jon Terrett, VP, Oncology, **CytomX**

10.30 BAY 1187982, a Novel ADC Targeting All Isoforms of FGFR2 with Potent Anti-Tumor Activity
- BAY 1187982 is an ADC comprised of a unique FGFR2 binding antibody (BAY 1179470) & a novel auristatin
- BAY 1187982 shows anti-tumor efficacy *in vivo* in FGFR2-positive tumor cell line-derived as well as PDX models of gastric, ovarian & breast cancer
- A Phase I trial is currently ongoing

Anette Sommer, Principal Scientist, **Bayer**

Manufacturing Stream
Developing Robust & Scalable Processes

10.00 Delivering the Future of Oncology – Manufacturing Next Generation Bioconjugates & Combination Therapies
- *More details to follow*

Andreas Weiler, Head, Emerging Technologies, **Lonza**

10.30 Challenges & Lessons Learned in ADC CMC Development & Outsourcing
- Buy vs. make: considerations & critical success factors from the perspective of a new kid on the ADC block
- Scale-up & site transfer of a conjugation process with impact on key product quality attributes: a case study
- Analytical transfers: considerations & lessons learned from challenging assay transfers

Jens Lohrmann, Technical Project Leader, **Novartis**

11.00 **Achieving Stable, Site-Selective Conjugation to THIOMAB™ Antibodies**
- Challenges & solutions in conjugating payloads to engineered cysteines
- Modulating stability through tandem linker design & conjugation optimization
- Tuning *in vitro* & *in vivo* potency through linker modification

Jack Sadowsky, Scientist, **Genentech**

11.30 **Producing Better ADCs Using ThioBridge™ Conjugation**
- Disulfide re-bridging conjugation to reduce ADC heterogeneity
- ThioBridge™ linkers provide stable conjugation
- PK profiles of ThioBridge™ ADCs vs maleimide conjugation
- Development of more efficacious ADCs

Antony Godwin, VP, Chemistry, **PolyTherics**

11.00 **Position Reserved**

11.30 **Leveraging Multispecificity in Targeting of ADCs**
- Understand how bispecific ADCs can hold the key to enhancing functionality
- Exploiting both bispecificity & biparatopism to improve physico-chemical properties
- Case study data exemplifying these strategies

Robert Hollingsworth, Senior Director, **MedImmune**

11.00 **Streamlining ADC Development & Production**
- How to overcome common supply chain issues
- Approaches for efficient integration of mAb production, conjugation & sterile fill activities
- Case study demonstrating benefits of supply chain integration

Mark Wright, Site Head, **Piramal**

11.30 **Extended Q&A**

12.00 **Lunch**

Optimizing Linker-Payload Compatibility

1.30 **Using the dPEG® as a Framework to Load & Protect Payloads in an ADC Format**
- Introducing new constructs for how the single molecule dPEG® offers a broad range of design options in ADCs, including loading density & a theranostic option
- New PK, BD, *in vivo* activity & ELISA data with Sidewinder™ dPEG® constructs on a whole antibody, as a control format for optimal design in various applications

Paul Davis, CEO, **Quanta BioDesign**

2.00 **Improving Potency & Stability of Antibody Drug Conjugates**
- Overcoming the limitations of heterogeneous conjugation
- Utilizing transglutaminase-based site-specific drug conjugation to generate high loaded ADCs
- Unlocking improved stability, manufacturing & therapeutic index

Pavel Strop, Associate Research Fellow, **Pfizer**

Increasing Success of Preclinical-Clinical Translation

1.30 **Key Considerations for Preclinical Safety Assessment of ADCs**
- ADCs are complex drugs that require consideration of several elements when assessing safety
- The target antigen as well as other components of the ADC can impact the design of the preclinical safety program
- Case study highlighting these concepts will be discussed

Anu Connor, Senior Research Investigator, **Novartis**

2.00 **Nonclinical Safety Considerations for Novel Warheads**
- Warhead properties that impact safety of ADCs
- The relationship between normal tissue expression & on/off target toxicity of novel warheads
- The translatability of traditional nonclinical safety studies to clinical toxicity

Mary Jane Hinrichs, Senior Toxicologist, **MedImmune**

Advanced Purification & Formulation Techniques

1.30 **Conjugation & Fill/Finish at the Same Site, an Innovative Approach to the Supply of ADCs**
- *More details to follow*

Maria Elena Guadagno, Business Director, **BSP Pharmaceuticals**

2.00 **Design, Development & Stability of ADCs & a BMS Case Study**
- Overview & emerging trends in ADC molecular design considerations
- Analytical toolkit for ADC characterization & stability assessment: challenges & opportunities
- Formulation & conjugation strategies to overcome key product challenges

Mary Krause, Research Investigator, **BMS**

2.30 **GlycoConnect™ Expands the Therapeutic Index of ADCs without the Need for Antibody or Cell Line Engineering**
- Native-glycan is the most stable & efficacious position for antibody conjugation
- Compatible with any IgG & all payload classes
- Coupled with HydraSpace™ payload-enhancing linker technology accommodates highly hydrophobic payloads & dual-warhead ADCs
- Linear scalability to multi-gram scale

Floris van Delft, CSO, **SynAffix**

2.30 **Understanding how Target Pharmacology Impacts Success in Development**
- Appreciate target selection criteria behind programs in development at Novartis
- Why quality of expression is more important than quantity

Tinya Abrams, Research Investigator, **Novartis**

2.30 **Case Study: Impact of CMC & Biological Properties on the Developability of ADCs**
- Optimize your approach & strategies in ADC formulation – challenges & lessons learned
- Detect the impact of conjugation chemistries & target identification for development of ADCs
- Focus on recent developments in ADC technology that assist in smooth antibody delivery
- Examine the problems associated with ADCs from formulation to patient delivery

Neil Mody, Scientist, **MedImmune**

3.00 **Preclinical Development of Potent & Selective alpha-Amanitin-Antibody Conjugates**
- alpha-Amanitin SAR
- Conjugation compatibility & challenges in DAR determination
- Platform validation using multiple cancer targets & alpha-amanitin-ADCs with non-cleavable linkers

Brian Mendelsohn, Senior Scientist, **Agensys**

3.00 **Extended Q&A**

3.00 **Development of Stable ADC Products – An In-Depth Look at Liquid & Lyophilized Formulations**
- Pre-formulation assessment & preliminary solution screening
- Tools & techniques for determination of ADC stability
- Considerations for phased product development e.g. liquid for Phase 1 with potential for lyophilization
- Freeze-dry cycle development

Wendy Saffell-Clemmer, Director, Research, **Baxter**

3.30 **Afternoon Refreshments**

Approaches for Maximizing Therapeutic Index & Improving ADC Candidates

4.00 **Preclinical Development of Superior ADCs Incorporating Novel Linker & Warhead Designs**
- Robustness of screening panel from antibody to ADC leads in 2 months, from target to IND within 2 years
- Preclinical studies of several ADC products showing superior PK, PD & toxicity profiles
- Promise of multifunctional ADCs

David Miao, SVP, **Sorrento Therapeutics**

4.30 **Developing Potent ADC Payloads with Non-DNA Targeting Mechanisms of Action**
- Using site-specific conjugation technology to improve the safety profile of amanitin-ADCs
- Preclinical evaluation with relevant animal models
- Assessing potential biomarkers for patient stratification

Andreas Pahl, CSO, **Heidelberg Pharma**

5.00 **Contextualizing Chemical Optimization in the Quest for Next Generation ADCs**
- Issues & challenges observed across an industry
- Assessing the impact of physico-chemistry on cellular biology
- Innovations supporting preclinical development

Peter Senter, VP, Chemistry, **Seattle Genetics**

5.30 **Chair's Closing Remarks**

5.45 **Poster Session & Drinks Reception**

Hosted by: Lonza

Day Two – Wednesday October 21st

7.00	**What's in Your Toolbox? Choosing the Right Analytical Methods & Instrumentation for Defining In-Process Controls & Characterizing Your ADC**	Breakfast Briefing	**Mike Bienkowski**, Manager, Process & Analytical Development, **SAFC** **Lisa McDermott,** Principal Scientist, Process & Analytical Development, **SAFC**
8.45	**Chair's Opening Remarks**		 **Chetana Rao,** Associate Director, **BMS**
9.00	**A Global Overview of Analytical Requirements & New Techniques for ADC Characterization** • Analytical & structural toolbox for Cys & Lys based ADCs • What are FDA & EMA expectations? • Insights from chromatography, electrophoresis & mass spectrometry including top-down, middle-up & down, bottom-up MS approaches		 **Alain Beck**, Senior Director, Antibody Physico-Chemistry, **Pierre Fabre**
9.30	**Routine Use of Liquid Chromatography with Mass Spectrometry (LC/MS) to Determine Key Quality Attributes** • Appreciate the use of LC/MS to determine DAR, conjugation quality, site of conjugation & biotransformation • Both qualitative & quantitative aspects will be shown • New software tools will be shared that simplify data analysis		 **John Gebler**, Director, Biopharma Business Development, **Waters**
10.00	**Lock-Release – A New Paradigm for ADC Development & Manufacturing** • Lock-Release enhances ADC quality & yield & can reduce process complexity & increase plant productivity • Application of Lock-Release to stochastic & site-specific conjugation with a range of toxin classes including auristatin, maytansine, PBD dimers & duocarmycins • Case study demonstrating scalability of Lock-Release		 **Colin McKee**, Head, Technical Projects, **ADC Biotechnology**
10.30	**Morning Refreshments**		

Discovery Stream
Matching Target Biology to Chemical Design

11.00 **Development of an ADC Targeting TIM-1 for the Treatment of Ovarian & Renal Cell Carcinoma**
- Hear first-hand how CDX-014 was produced with a fully human anti-TIM-1 antibody covalently linked to MMAE
- Data showing potent anti-tumor activity in preclinical models & IND-enabling studies for CDX-014 are on-going with clinical development planned for early 2016

Lawrence Thomas, Senior Director, Preclinical Development, **Celldex Therapeutics**

Development Stream
Characterizing ADC Structure & Function

11.00 **Analytical & Bioanalytical Strategy for ADC Drug Products**
- *More details to follow*

Peter Lemaire, Analytical Team Lead, **BMS**

Manufacturing Stream
Improving Product Quality & Ensuring Safe Production

11.00 **Challenges for ADC Development & Manufacturing in an Existing Multi-Product Facility**
- Set-up of closed processing from conjugation to filling of drug substance
- Handling of toxic containing solutions in an existing multi-product manufacturing suite: minimizing the risk
- Containment design choices to ensure personnel & environmental protection
- Defining the quality standards with which disposable technologies should comply: robustness, integrity testing, particulates

Miriam Monge, Director, Integrated Solutions & Process Development Team, **Sartorius**
Berthold Boedeker, Chief Scientist, **Bayer**

11.30 **ConjuAll™ Site-Specific Homogenous ADC Platform with a Novel Linker Chemistry**
- ADCs with DAR of exactly 2.0 or 4.0 from site-specific enzymatic conjugation platform called ConjuAll™
- Rapid process suitable for testing various linkers & toxins
- Proprietary linker chemistry enabling ADC long-term stability & superb PK profile *in vivo* in rat & monkey without DAR change
- Superior *in vivo* efficacy of Herceptin ADC with either DAR=2.0 or 4.0, compared to Kadcyla®

Jeiwook Chae, CBO, **LegoChem Biosciences**

11.30 **Characterizing ADME Properties of ADCs**
- See how factors affecting the ADC stability & efficiency of tumor delivery impact the efficacy & therapeutic window
- ADME properties play a key role in determining the efficacy/toxicity profile for new ADCs
- Hear how *in vitro* & *in vivo* studies are used to characterize the ADME properties

Dan Rock, Scientific Director, **Amgen**

11.30 **Talk Title to be Approved**
- More details to follow

Amar Prashad, Principal Scientist, **Pfizer**

12.00 **A Novel FRET Assay Reveals the Intracellular Activity of Antibody Drug Conjugates**
- Discover a robust & facile method of evaluating ADC intracellular processing
- Case study data showing the intracellular processing of a cathepsin cleavable-linker in a HER2 cell line is similar to that of T-DM1
- Lysosomal efflux of catabolites are different in SKBR3 & PC3 cells, suggesting the lysosomal efflux is cell-dependent

Byoung-Chul Lee, Scientist, **Genentech**

12.00 **Bioanalytical Challenges in Tracing the Biotransformation of ADCs**
- Optimize your approach & strategies in ADC formulation – challenges & lessons learned
- Detect the impact of conjugation chemistries & target identification for development of ADCs
- Focus on recent developments in ADC technology that assist in smooth antibody delivery
- Examine the problems associated with ADCs from formulation to patient delivery

Vangipuram Rangan, Senior Director, **BMS**

12.00 **Case Study of Lysine Conjugation Routes**
- 1-Step vs 2-Step conjugation pros & cons
- Collaborative approach to the ADC market
- Combining large molecule & small molecule expertise

Andreas Karau, Director, Strategic Innovation Management, **Evonik**

12.30 **Lunch**

Advances in Drug Conjugate Design

2.00 **Programmable Linkers for pH-Triggered Release**
- New molecular architecture for pH-sensitive cleavable linkers
- Importance of drug type on release kinetics
- Tunability of release kinetics & stability achieved by slight structural adjustments

Cindy Choy, Post-Doctoral Researcher, **WSU**

Characterizing ADC Structure & Function

2.00 **Talk Title to be Approved**
- More details to follow

Gillian Payne, Senior Director, **ImmunoGen**

Managing Complex Supply Chain Networks

2.00 **Novasep: Integrated Solutions for the Development & Manufacture of ADCs**
- Flexible services to support clinical development, validation & commercial launch
- Focus on Novasep's purification technologies developed for payload & mAb
- Design considerations for a new ADC conjugation facility

Vincent Monchois, Director, Strategic Projects, **Novasep**

2.30 **Novel Targeted Thorium Conjugates: Radio-Immunoconjugates Using High-Energy Alpha-Particles**
- Development of novel Targeted Thorium Conjugates (TTCs), which comprise monoclonal antibodies conjugated to a chelator for the efficient delivery of high-energy alpha-particles
- Preclinical data from *in vitro* assays & *in vivo* models demonstrates specificity & potency
- The data presented are supportive of the further investigation of TTCs in clinical trials

Urs Hagemann, Project Manager, **Bayer**

2.30 **Targeting Solid Cancers Using HuMax-Axl-ADC: Clinical Candidate Selection & Preclinical Efficacy Studies**
- Axl as a novel ADC target
- Clinical candidate selection
- Characterization of HuMax-Axl-ADC *in vitro* & *in vivo*

Esther Breij, Assistant Director, **Genmab**

2.30 **Establishing a Robust Commercial ADC Supply Chain via Partnerships with CMOs**
- ADCETRIS® supply chain: establishment & building robustness
- Trends in the quest to integrate ADC manufacturing
- Addressing challenges with integration of manufacturing services

Todd Allen, Director, Commercial Manufacturing, **Seattle Genetics**

3.00 **Afternoon Refreshments**

Pioneering New Developments to Fuel the ADCs of the Future

3.30 **Fleximer ADCs: Advancing the Platforms Towards the Clinic**
- Establishing preclinical therapeutic index
- Progressing the pipeline
- Exploring new classes of payloads & mechanisms

Timothy Lowinger, CSO, **Mersana**

4.00 **Designing an ADC with a DNA-alkylating Payload: A Focus on Therapeutic Index**
- Why do we need payload alternatives to potent tubulin-acting agents?
- Challenges in developing DNA-targeting payloads for ADCs
- Exploiting linker chemistry to improve therapeutic index
- IMGN779 – advancing towards clinical evaluation

John Lambert, Distinguished Research Fellow, **ImmunoGen**

4.30 **Lessons Learned from ADCs so Far**
- What does existing preclinical & clinical data tell us about what makes ADCs successful?
- Encouraging evidence-based design decision making: why did we make it this way?
- Appreciate lessons learned & hear myths debunked

Paul Polakis, Director, **Genentech**

5.00 **Chair's Closing Remarks**

2nd World ADC Awards

Join your peers in recognizing ADC excellence at the 2nd Annual World ADC Awards. Reflect on the progress made across the industry in the previous 12 months and hope your company comes out on top. The Judges will present awards across six categories rewarding individual, organizational and industry achievements.

Attendance is limited and places will be made available in September.

www.worldadc-awards.com

Post-conference Sessions - Thursday October 22nd

Pick **E & F** or **G**

Workshop E:

9am-12pm Utilizing PK/PD Modeling & Simulation to Create a Translational Framework for Development of Better ADCs

Minimize expense in development by successfully predicting what compounds will be clinically efficacious and which are destined to fail. This workshop will introduce invaluable modeling tools, on three levels, to improve the robustness of your ADC development. Gain an understanding of the critical decision criteria to be made at target, compound and clinical stages.

Attendees will learn about:

- Essential target selection criteria: how to integrate internalization, recycling, receptor expression & affinity data to test target feasibility
- What are the best ADC designs to hit a given target & how to elucidate *in vivo* pharmacology of your compound
- Mechanistic techniques to model tumor penetration & what clinical regimen will be most effective

In this workshop attendees will learn how to use modeling and simulation techniques to integrate knowledge and experimental data to guide decision making and selection of the right target, the right ADC and the right dose (and regimen).

Workshop Leader:

Alison Betts, Associate Research Fellow, **Pfizer**

Workshop G:

9am-5pm ADC Outsourcing, Technology Transfer & CMO-Client Relationships

A large part of biopharmaceutical companies now rely on outsourcing partners for the development and manufacture of biological drug substance and drug product for clinical studies and commercial supply.

For ADCs, the supply chain is further complicated since more components need to be sourced:

- Monoclonal antibody
- Linker
- Payload

In addition, outsourcing of the conjugation process to produce drug substance, and of the formulation and filling processes to manufacture drug product. This is further challenged by finding the right CMO that can handle cytotoxic materials and containment.

The CMC section of a biopharmaceutical project is typically on a time critical path and this can prove a challenge for both the Client (contract giver) and the CMO (contract acceptor). To ensure a successful collaboration and outcome, client expectations must be aligned with the contracted CMO. A mutual understanding of risk is a prerequisite for designing the right development and manufacturing program. In addition, a sense of "co-ownership" of the project adds value in facilitating a seamless contract execution and completion.

What is World ADC like?

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

Tanabe

Post-conference Sessions - Thursday October 22nd

Pick **E & F** or **G**

Workshop F:

1pm-4pm Preclinical & Clinical Assay Development for Improving ADC Understanding

The complex nature of ADCs requires a robust understanding of the interplay of each component and their interactions *in vivo*. Advance your knowledge of the latest bioanalytical tools for both small and large molecule elements of your ADC and accurately assess safety/efficacy relationships.

This workshop will focus on the development and validation of a battery of assays to fully support ADC development e.g. binding, cytotoxicity, release and stability.

Attendees will learn about:

- Preclinically & clinically relevant tools to understand ADC function, not just structure
- The critical role assays play in elucidating effector function, free drug interactions & overall ADC mechanism of action
- Mass spectrometry (LC-MS) as a further assay for characterizing intact ADC & additional payload components
- Where these tools need to be applied to support on-going clinical development

Workshop leader:

Leo Kirkovsky, Director, **Pfizer**

Workshop G: Continued

Wear the "Hat" of a Big Pharma Sponsor in a safe, educational and entertaining environment, allowing you to explore key outsourcing situations in one day, which normally takes years to develop.

- This workshop will discuss the lessons learned from a broad range of biopharmaceutical projects developed successfully by the workshop instructors, who represent both the Client & the CMO sides
- The focus of the workshop will be on the key elements to develop a partnership between the parties, covering all phases, from the CMO selection activity, technology transfer of processes & test methods, to production, testing & delivery of clinical trial materials
- Additionally, the workshop will include an interactive case study, offering the participants hands-on experience with different CMO selection, risk assessment & mitigation, as well as vendor management tools developed to facilitate cost-effective & successful transfer & development of biopharmaceuticals in partnership between the Client & the CMO

Workshop leaders:

Firelli Alonso-Caplen, Senior Director, **Pfizer**
Jon Crate, CTO, **FAI Testing Services**
Kim Hejnaes, Partner, **Invest4biotech**
Morten Munk, Senior Technology Partner, **NNE Pharmaplan**

> "High end global summit in ADC field, held in a beautiful city. A great gathering of elite people and companies"
>
> **Thode Labs**

Tinya Abrams
Research Investigator
Novartis

Todd Allen
Director, Commercial Manufacturing
Seattle Genetics

Firelli Alonso-Caplen
Senior Director
Pfizer

Meg Baker
Registered Patent Agent
Independent Consultant

Alain Beck
Senior Director, Antibody Physico-Chemistry
Pierre Fabre

Alison Betts
Associate Research Fellow
Pfizer

Mike Bienkowski
Manager, Process & Analytical Development
SAFC

Berthold Boedeker
Chief Scientist
Bayer

David Bramhill
Consultant
Bramhill Biological Consulting, LLC

Esther Breij
Assistant Director
Genmab

Jeiwook Chae
CBO
LegoChem Biosciences

Cindy Choy
Post-Doctoral Researcher
WSU

Cecile Combeau
Project Director
Sanofi

Anu Connor
Senior Research Investigator
Novartis

Jon Crate
CTO
FAI Testing Services

Paul Davis
CEO
Quanta BioDesign

Floris van Delft
CSO
SynAffix

Jonathan Drachman
CMO
Seattle Genetics

Scott Dylla
CSO
Stemcentrx

John Gebler
Director, Biopharma Business Development
Waters

Hans Peter Gerber
VP, Bioconjugates
Pfizer

Antony Godwin
VP, Chemistry
PolyTherics

David Goldenberg
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Immunomedics

Maria Elena Guadagno
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Ed Ha
Scientist
Solstice Biologics

Urs Hagemann
Project Manager
Bayer

Kim Hejnaes
Partner
Invest4biotech

Mary Jane Hinrichs
Senior Toxicologist
MedImmune

Robert Hollingsworth
Senior Director
MedImmune

Andreas Karau
Director, Strategic Innovation Management
Evonik

Thomas Keating
Director, Biochemistry
ImmunoGen

Leo Kirkovsky
Director
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Norbert Koper
VP, Clinical
Synthon

Mary Krause
Research Investigator
BMS

John Lambert
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ImmunoGen

Byoung-Chul Lee
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Peter Lemaire
Analytical Team Lead
BMS

Jens Lohrmann
Technical Project Leader
Novartis

Timothy Lowinger
CSO
Mersana

Lisa McDermott
Principal Scientist, Process & Analytical Development
SAFC

Colin McKee
Head, Technical Projects
ADC Biotechnology

Brian Mendelsohn
Senior Scientist
Agensys

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SVP
Sorrento Therapeutics

Neil Mody
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Director, Strategic Projects
Novasep

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Director, Integrated Solutions & Process Development Team
Sartorius

Charles Morris
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ImmunoGen

Morten Munk
Senior Technology Partner
NNE Pharmaplan

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Heidelberg Pharma

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Principal Scientist
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ImmunoGen

Paul Polakis
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Genentech

Andreas Weiler
Head, Emerging Technologies
Lonza

Mark Wright
Site Head
Piramal

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Celgene

Jagath Junutula
VP
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David Meininger
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www.worldadc-awards.com

Nominate your finalists

Nominations open June 29th

www.worldadc-awards.com

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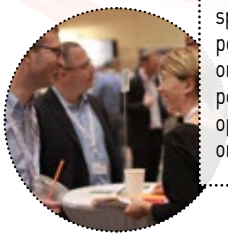
Onsite at World ADC San Diego

Exhibition Pavilion
Meet with partners and peers in between sessions. Assess new technologies and services that can enhance your research at each booth.

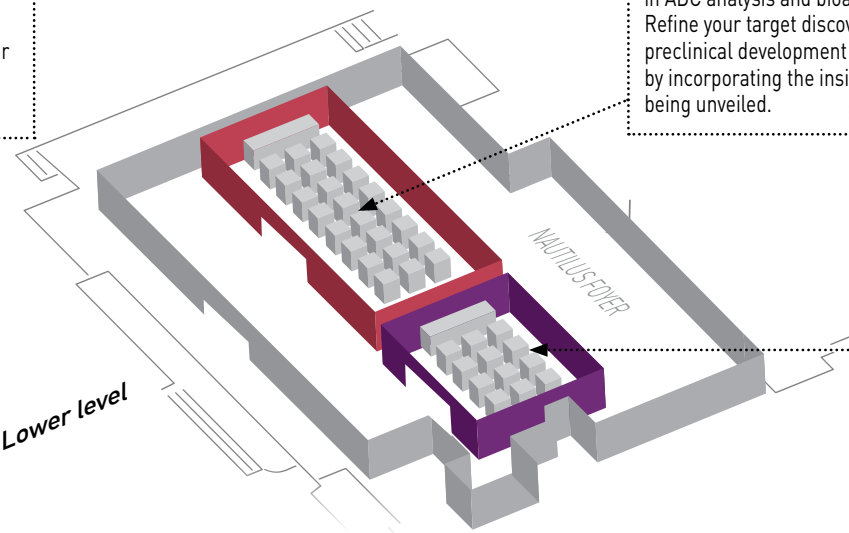
Main Stage
Hear visionary keynotes in the plenary sessions and technical case studies on linker and payload optimization during the Discovery Stream.



Breakout
Participate in our "famous" speed networking and meet potential collaborators early on day one. Join us for the poster session - an excellent opportunity to get feedback on your work.

Interactive Workshops
Dive into detailed discussions on the most important areas of ADC development. Have more time to ask questions, solve your technical headaches and leave with practical tips.

Development Stream
Learn about the latest research in ADC analysis and bioanalysis. Refine your target discovery and preclinical development strategy by incorporating the insights being unveiled.



Manufacturing Stream
ADC manufacturing takes center stage here with talks debating plans for improving yield, conjugation efficiency, drug product integrity and supply chain coordination.

Venue

Sheraton San Diego Hotel & Marina
1380 Harbor Island Drive
San Diego, California, 92101
United States

www.sheratonsandiegohotel.com

Overnight accommodation is not included in the registration fee, however accommodation options will be sent out with your confirmation email upon registering.

Prices & Discounts

PACKAGE PRICES	Register & Pay before July 24th	Register & Pay before September 4th	Standard prices
GOLD PACKAGE Conference + 2 additional days	$4997 **(save $400)**	$5097 **(save $300)**	$5197 **(save $200)**
SILVER PACKAGE Conference + 1 additional day	$3698 **(save $300)**	$3798 **(save $200)**	$3898 **(save $100)**
BRONZE PACKAGE Conference only	$2399 **(save $200)**	$2499 **(save $100)**	$2599
Additional day only	$1399		
CUSTOMIZE YOUR IDEAL WORLD ADC EXPERIENCE	**October 19th**		
	Workshop A ☐ or Workshop B ☐	Workshop C ☐ or Workshop D ☐	
	Clinical Day ☐		
	October 22nd		
	Workshop E ☐ and Workshop F ☐		
	Full Day Workshop G ☐		

Additional Discounts

1. Not for profit are available for those from academic and government institutions
2. Tiered group rates apply when three or more attendees book and pay at one time
3. Corporate rates can be applicable if you are planning on sending multiple attendees from different sites and departments.

Find out more at: www.worldadc-usa.com/pricing-discounts

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If you require any further information on the event, or would like us to assist you in making your booking, please contact Hanson Wade via the contact details below.

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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 four-teenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

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