FESTIVAL OF BIOLOGICS USA

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AMERICAS ANTIBODY CONGRESS 2019

Americas Antibody Congress

Americas Antibody Congress Speakers

Advisory board:

Andrew Korytko, Research Advisor, Group Leader Protein Engineering, **Eli Lilly and Company**
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Partha Chowdhury, Senior Director and Head, Antibody Discovery, **Sanofi**
Scott Glaser, Director, Antibody Therapeutics, **GNF**

Confirmed speakers:

Alexey Berezhnoy, Scientist II, **MacroGenics**
Andreas Katopodis, CEO, **Anaveon**
Andreas Laustsen, Associate Professor, **Technical University of Denmark**
Andres Perez Bay, Senior Staff Scientist, **Regeneron**
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Cory Brooks, Assistant Professor, **Fresno State**
Dana Filoti, Senior Scientist II, NBE Analytical R&D**, AbbVie**
Daniel Weaver, Solutions Architect, **Perkin Elmer, Inc**
Daryl Drummond, Senior Vice President and Head of Research, **Merrimack Pharmaceuticals**
David Shen, SVP and Head of Biologics Research and CMC, **NGM Biopharmaceuticals**
Deryk Loo, Director, Targeted Therapeutics and Site Operations, **Macrogenics**
Elisabeth Nyakatura, Research Assistant Professor, **Albert Einstein College of Medicine**
Elizabeth Gibson, Senior Director of Operations, **CLSA**
Eva-Maria Strauch, Assistant Professor, Dept. of Pharmaceutical and Biomedical Sciences, **University of Georgia**
Feng Wang, Professor and Principal Investigator, **Chinese Academy of Sciences**
Gary Starling, Associate Vice President, Protein Science, **Merck**
Han Xiao, Assistant Professor, Chemistry Biosciences and Bioengineering, **Rice University**
Heidi Chokeir, Managing Director, **Canale Communications**
Hiraoki Suga, Professor, Department of Chemistry, **University of Tokyo**
Ho Cho, VP, Biotherapeutics, **Celgene**
Ivan Mascanfroni, Senior Scientist, Immunology Biologics, **Abbvie Bioresearch Centre**
Jae Sly, Director, Stretegic Bisiness Development, **AcroBiosystems**
James Breitmeyer, President & CEO, **Oncternal Therapeutics**
Jeffrey Froude, Military Deputy Division Chief, **DTRA RD-CBM**
Jill O'Donnell-Tormey, CEO and Director of Scientific Affairs, **Cancer Research Institute**
John Delaney, Executive Director, **Amgen**
John Karanicolas, Associate Professor, **Fox Chase Cancer Centre**
Joseph Jardine, Head of Antibody Discovery, **Institute of Protein Innovation**
Julia Frei, Scientist, **Paul Scherrer Institute**

Jun Zhang, Senior Scientist, **Amgen**
Kevin Heyries, Co-Founder, Business Development and Strategy Lead, **AbCellera**
Kevin Johnson, General Partner, **Medicxi**
Kristen Picha, Sr. Director of Strategy & Operations, DPDS**, Janssen R&D**
Krzysztof Masternak, Head of Biology, **NovImmune**
Lawrence Lum, Professor of Oncology, **University of Virginia**
Leo Kirkovsky, Director, Clinical Assay Group, **Pfizer**
Line Ledsgaard, Research Assistant, **Technical University of Denmark**
Marc Nasoff, Biologics, Chief Scientific Officer, **Centre of Innovation (COI)**
Marilyn Kehry, Vice President, Cell and Functional Biology, **AnaptysBio**
Matt Levengood, Senior Scientist, **Seattle Genetics**
Matthew Tirrell, Pritzker Director, Professor and Dean of the Faculty, **University of Chicago**
Michael Schopperle, Chief Executive Officer, **CureMeta**
Mihriban Tuna, Vice President, Drug Discovery, **F-Star**
Neelie Zacharias, Scientific Researcher, **Genentech**
Partha Chowdhury, Senior Director and Head, Antibody Discovery, **Sanofi**
Patrick Burke, Associate Director, **Seattle Genetics**
Qing Chai, Principal Scientist, **Eli Lilly and Company**
Ramana Doppalapudi, Director of Chemistry, **Avidity Biosciences**
Ren Liu, Associate Principal Scientist, **Merck**
Richard Ding, Director, Downstream Process Development, **AnaptysBio**
Roger Beerli, CSO, **NBE Therapeutics**
Roland Dunbrack, Professor, **Fox Chase Cancer Centre**
Ryan Stafford, Director, Protein Engineering – Discovery, **Sutro Biopharma**
Scott Glaser, Director, Antibody Therapeutics**, GNF**
Stanley Krystek, Research Fellow, **Bristol Myers-Squibb**
Stefan Dübel, Director, **Technische Universität Braunschweig**
Stephen Demarest, Senior Research Fellow, **Eli Lilly and Company**
Stuart Collinson, Partner, **Forward Ventures**
Susan Cellitti, Associate Director, Biotherapeutics, **GNF**
Sven Lee, Vice President, **Abzena**
Teemu Junttila, Senior Scientist, Translational Oncology, **Genentech**
Thomas Keating, Director of Biochemistry, **Immunogen**
Tim Jacobs, Co-founder, **Dualogics**
Travis Young, Vice President, Biologics, **Calibr, a division of Scripps Research**
Vadim Klyushnichenko, VP of Pharmaceutical Development & Quality, **Calibr, a division of Scripps Research**
Vera Molkenthin, Chief Scientist, **AbCheck**
Yanay Ofran, Founder and CEO, **Biolojic Design**
Yoshiko Akamatsu, Senior Principal Research Scientist, Oncology Biologics, **AbbVie**
Zachary Bornholdt, Director, Antibody Discovery, **Mapp Biopharmaceutical, Inc**

Americas Antibody Congress - Sunday 3rd March – Workshop Day	
12:00	Registration
13:00	**AI for antibody drug discovery and development** • An overview of how AI is currently used for in silico antibody discovery and development • Real life examples of how this is currently used, with challenges and case studies • Workshop on how AI can be implemented into the antibody industry **Stanley Krystek,** Senior Principal Scientist, **Bristol Myers-Squibb** (CONFIRMED) **Dana Filoti,** Senior Scientist II, NBE Analytical R&D**, AbbVie** (CONFIRMED) **Qing Chai,** Principal Scientist, **Eli Lilly and Company** (CONFIRMED)
13:45	**Current approaches and future trends in antibody discovery** • Immunization-dependent and -independent Approaches to Ab Discovery • Strategies for Early Screening and Assessment of Antibody Candidates • Format and Developability Considerations in the Antibody Discovery Process • Brainstorming Discovery Approaches for Complex Targets **Anusuya Ramasubramanian,** Scientist, **Sanofi** (CONFIRMED)
14:30	**Women in Science – panel discussion** • Experiences that have influenced thinking around gender in the workplace • How companies are promoting diversity in the workplace • How can we advocate change, successes and challenges? • How can male advocates help? Chaired by: **Elizabeth Gibson,** Senior Director of Operations, **CLSA** (CONFIRMED) **Marilyn Kehry,** Vice President, Cell and Functional Biology, **AnaptysBio** (CONFIRMED) **Jill O'Donnell-Tormey,** CEO and Director of Scientific Affairs, **Cancer Research Institute** (CONFIRMED) **Stephen Demarest,** Senior Research Fellow, **Eli Lilly and Company** (CONFIRMED) **Line Ledsgaard,** PhD Student, **Technical University of Denmark** (CONFIRMED) **Heidi Chokeir,** Managing Director, **Canale Communications** (CONFIRMED)
15:15	**Investment in antibody therapeutics panel** • Panel session lead by senior investors, actively investing within the biologics industry • What do investors look out for in start-ups? • What are the current trends for biologics? • Where do we see the industry moving to in the next 5-10 years? • How can you gain investment? Moderated by: **Stuart Collinson,** Partner, **Forward Ventures** (CONFIRMED) **Kevin Johnson,** General Partner, **Medicxi** (CONFIRMED) **Bruce Steel,** Managing Director, **BioMed Ventures** (CONFIRMED) **Marc Nasoff,** Biologics, Chief Scientific Officer, **Centre of Innovation (COI)** (CONFIRMED)
16:00	End of pre-conference workshop day

Americas Antibody Congress - Monday 4th March – Day 1	
08:00	Registration opens

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08:40	Conference doors open		
	Opening keynotes (Plenary) Chaired by: **Partha Chowdhury,** Senior Director and Head, Antibody Discovery, **Sanofi** (CONFIRMED)		
09:00	Welcome from Terrapinn **Joan Shutt,** Project Manager, **Festival of Biologics 2019**		
09:05	Chair's opening remarks **Partha Chowdhury,** Senior Director and Head, Antibody Discovery, **Sanofi** (CONFIRMED)		
09:15	**Evolution and advancements in cancer immunotherapy** • An accidental beginning and the lag phase • Checkpoint modulators and establishment of a new treatment paradigm: the growth phase and growth pain • Understanding the pitfalls and road blocks: future efforts leading to a new horizon **Partha Chowdhury,** Senior Director and Head, Antibody Discovery, **Sanofi** (CONFIRMED)		
09:40	**Does origin of antibody matter in clinical success?** • Analysis of ab origin and success in clinic • Why origin of ab matters • Biophysical attributes related to clinical success of mAbs **Kristen Picha,** Sr. Director of Strategy & Operations, DPDS**, Janssen R&D** (CONFIRMED)		
10:05	**Discovery of GDF15 receptor (GFRAL/RET) and its novel biological pathway that controls body weight and its clinical applications** • Identified GDF15 as a potent hormone for potentially treating diabetes and weight loss. GDF15 regulates food intake, energy expenditure and body weight in response to metabolic and toxin-induced stresses • Overview of isolation of GDF15 receptor, mechanistic identification and gaining insight of molecular interactions. • Identification of antagonistic antibodies, and co-crystal antibody structures leading to successfully generated antibodies intended for preventing weight loss in cancer cachexia • Presently GDF15 for treating diabetes and weight loss is in development by Merck through licensing, and antibody for GFRAL is in phase 1 clinical study by NGM **David Shen**, SVP and Head of Biologics Research and CMC, **NGM Biopharmaceuticals** (CONFIRMED)		
10:30	Morning networking break		
11:30	**Roundtable session** (Plenary) 12 senior level tables hosted by thought leaders on key challenges and opportunities in antibody drug discovery and development. Participants are invited to join the group discussions on a topic of importance to them. The round table session will have two rotations, each lasting 40 minutes.		
	TABLE 1 **Protein engineering** **Andrew Korytko,** Research Advisor, Group Leader, Protein Engineering, **Eli Lilly and Company** (CONFIRMED)	TABLE 2 **Recent advances in bispecific/multispecific antibodies and their clinical applications** **Stephen Demarest,** Senior Research Fellow, **Eli Lilly and Company** (CONFIRMED)	TABLE 3 **Strategies for generating antibodies to challenging targets** **Scott Glaser,** Director, Antibody Therapeutics**, GNF** (CONFIRMED)
	TABLE 4 **Clinical assay development for ADCs** **Leo Kirkovsky,** Director, Clinical Assay Group, **Pfizer** (CONFIRMED)	TABLE 5 **ADC's in an Immuno-Oncology world – What is the opportunity?** **Ho Cho,** VP, Biotherapeutics, **Celgene** (CONFIRMED)	TABLE 6 **Evolving landscape of antibody discovery platform** **Partha Chowdhury,** Senior Director and Head, Antibody Discovery, **Sanofi** (CONFIRMED)
	TABLE 7 **HTS crossroads, higher throughput or great physiological relevance**	TABLE 8 **Nanobodies** **Cory Brooks,** Assistant Professor, **Fresno State** (CONFIRMED)	TABLE 9 **Manufacture and production of antibodies** **John Delaney,** Executive Director, **Amgen** (CONFIRMED)

	Jae Sly, Director, Strategic Business Development, **AcroBiosystems** (CONFIRMED)		
12:50	Networking Lunch		
	Track 1 **Armed antibodies** Chaired by: **Roger Beerli,** CSO, **NBE Therapeutics** (CONFIRMED)	Track 2 **Bispecifics** Chaired by: **John Delaney,** Executive Director, **Amgen** (CONFIRMED)	Track 3 **mAbs and novel modalities** Chaired by: **John Karanicolas,** Associate Professor, **Fox Chase Cancer Centre** (CONFIRMED)
14:20	**Developing Antibody-Directed Nanotherapeutics (ADNs): A novel strategy for arming antibodies** • Approach to engineering ADNs • An improved therapeutic window with ADNs • Diagnostic strategies for developing ADNs **Daryl Drummond,** Senior Vice President and Head of Research, **Merrimack Pharmaceuticals** (CONFIRMED)	**SILAC-based screen to select potential ADC targets** • Rapid constitutive lysosomal internalization of PRLR is the mechanism behind PRLR ADC efficacy • Bridging HER2 with high turnover proteins (PRLR or APLP2) using bispecific antibodies, triggers HER2 lysosomal degradation and improves HER2 ADC efficacy • High turnover proteins could be exploited to develop more potent ADCs **Andres Perez Bay,** Senior Staff Scientist, **Regeneron** (CONFIRMED)	**Antibody discovery for autoimmune/inflammatory disease** • Agonist anti-checkpoint antibodies may augment endogenous T cell inhibitory signals for treatment of T-cell driven autoimmune and inflammatory diseases • Checkpoint agonist antibody discovery and optimization **Marilyn Kehry,** Vice President, Cell and Functional Biology, **AnaptysBio** (CONFIRMED)
14:40	**Turbocharging antibodies with pClick technology** • Antibody conjugate • Proximity effect, Site-specific conjugation • No antibody engineering **Han Xiao,** Assistant Professor, Chemistry Biosciences and Bioengineering, **Rice University** (CONFIRMED)	**Optimization of preclinical safety and efficacy of anti-HER2/CD3 TDB** • We have investigated how affinity to HER2 and CD3 impacts anti-tumour efficacy, distribution and pre-clinical safety of anti-HER2/CD3 TDB and describe that affinity has a major impact on preclinical tolerability. • Strategies aiming to increase tolerability of anti-HER2/CD3 TDB are discussed **Teemu Junttila,** Senior Scientist, Translational Oncology, **Genentech** (CONFIRMED)	**High-throughput single-cell screening for deep mining of natural immune repertoires** • High-throughput single-cell screening enables the discovery of unique antibodies from natural immune systems • Complex selection assays allow for the identification of antibodies against challenging targets • AbCellera' s pipeline integrates a dynamic, interactive visualization bioinformatic tools enable the exploration of large panels of antibodies and select lead candidates **Kevin Heyries,** Co-Founder, Business Development and Strategy Lead, **AbCellera** (CONFIRMED)
15:00	**NBE-002, a site-specifically conjugated, ROR1-specific anthracycline-ADC with potent immune-stimulatory functions** • We present a novel ADC based on site-specific conjugation of a derivative of the anthracycline PNU-159682 using the transpeptidase Sortase A • The use of a non-cleavable peptide linker provides exquisite stability, whereas the anthracycline payload	**Agonist bispecific antibodies delivering the next immune-oncology breakthrough** • Targeting T cells via TNFRSF costimulatory pathways has the potential to strongly activate the immune system due to broad expression across multiple immune cells • FcγR-mediated crosslinking is often required for optimal activity, limiting clinical efficiency, due to low affinity	**High quality antibodies for therapeutic applications** • AbCheck discovers and optimizes human antibodies for therapeutic applications leveraging several proprietary platforms including in vitro and in vivo technologies • In this talk, AbCheck will present new technological developments regarding its versatile human

	endows the ADC with superior potency combined with attractive immune-oncology properties intrinsic to this class of payloads • Validating data obtained in numerous PDX models, as well as in immunocompetent syngeneic models, will be presented **Roger Beerli,** CSO, **NBE Therapeutics** (CONFIRMED)	of Fc:FcγR interactions and ADCC-mediated T cell depletion • We present novel bispecific programmes that do not bind to FcγR, but instead crosslink their two targets, resulting in a potent and controlled T cell activation **Mihriban Tuna,** SVP Drug Discovery, **F-Star** (CONFIRMED)	antibody discovery and optimization platform with a focus on Rabbit Mass Humanization and AbAccel™ • Both technologies can be combined with AbCheck's yeast display platform AbSieve™ and deliver high quality leads with sub nanomolar affinities and good stabilities which are compatible with different antibody designs including bispecifics **Vera Molkenthin,** Chief Scientist, **AbCheck** (CONFIRMED)
15:20	**Recombinant snakebite antivenom based on human oligoclonal antibodies** • Experimental antivenom against black mamba venom • The first discovery of human monoclonal IgG antibodies against animal toxins • The first use of oligoclonal antibodies against experimental snakebite envenoming **Andreas Laustsen,** Associate Professor, **Technical University of Denmark** (CONFIRMED)	**Bispecific antibodies for conditional activation of immune cells** • How the formats makes a difference for conditional activation • How to control toxicity of immune agonists by design **Yoshiko Akamatsu,** Senior Principal Research Scientist, Oncology Biologics, **AbbVie** (CONFIRMED)	**Development of monoclonal antibodies as an integrated and layered medical countermeasure** • A DoD approach to the use of next generation antibody formats as a medical countermeasure • Standalone therapy vs. an Integrated Layered Defence for the development of Biologics. • Application of novel formats and the utility of effector function to optimize ADME properties **Jeffrey Froude,** Military Deputy Division Chief, **DTRA RD-CBM** (CONFIRMED)
15:40	Afternoon networking break		
	Track 1 **Armed antibodies** Chaired by: **Roger Beerli,** CSO, **NBE Therapeutics** (CONFIRMED)	Track 2 **Bispecifics** Chaired by: **John Delaney,** Executive Director, **Amgen** (CONFIRMED)	Track 3 **mAbs and novel modalities** Chaired by: **John Karanicolas,** Associate Professor, **Fox Chase Cancer Centre** (CONFIRMED)
16:40	**Impact of analogue selection, linker chemistry, and conjugation site on antibody-tubulysin conjugate properties** • ADCs bearing tubulysin payloads are active in MDR+ and bystander activity models • Payload stability in vivo can be modulated through selection of conjugation site and linker composition • Stabilized antibody-tubulysin conjugates are active in xenograft models at well-tolerated doses **Patrick Burke,** Associate Director, **Seattle Genetics** (CONFIRMED)	**Combinatorial immune checkpoint blockade using bispecific DART© molecules: concepts and applications** • Selection and format optimization of PD-1 x CTLA-4 DART molecules (MGD019) for simultaneous blockade of two checkpoint pathways • MGD019 pharmacology and IND enabling studies • Additional applications of bispecific DART and TRIDENT molecules for tumour immunotherapy **Alexey Berezhnoy,** Scientist II, **MacroGenics** (CONFIRMED)	**New ways for human antibodies - from intracellular applications to switchable affinity** • How to target intracellular antigens with antibodies • How to regulate antigen binding affinity of different antibodies with a universal effector **Stefan Dübel,** Director, **Technische Universität Braunschweig** (CONFIRMED)

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17:00	**New technology leading to better antibody-drug conjugates** • New payloads offering improved efficacy and stability • Advantages of a cross-reactive in vivo model system • Optimizing DAR & dosing of ADCs **Thomas Keating,** Director of Biochemistry, **Immunogen** (CONFIRMED)	**Development of a bispecific antibody therapy for Type I Diabetes** • Introduction to Dualogics, a North Carolina based biotech company focused on bispecific antibody therapies • Development of OrthoMab, a next-generation bispecific antibody platform • Progress on the development of DLA001, a bispecific antibody therapy for the treatment of Type I Diabetes **Tim Jacobs,** Co-founder, **Dualogics** (CONFIRMED)	**Understanding amino acid contributions to monoclonal antibody drug design success** • New ideas on how to objectively assess biologics candidate assets and liabilities • Propose a more efficient process that allows scientists to more easily align their antibodies, analyse CDR regions without extracting them, and directly correlate specific amino acids with desirable characteristics • Examples, including those showing surface plasmon resonance, of how humans are more efficient at analysing visual representations of information rather than textual ones • Suggest a new method that can drive biologic therapeutic development much more quickly, efficiently, and accurately **Daniel Weaver,** Solutions Architect, **Perkin Elmer, Inc** (CONFIRMED)
17:20	**Antibody oligonucleotide conjugates for the treatment of muscle disorders** • Targeted delivery of oligonucleotides • Non-hepatic delivery of oligonucleotides using antibody oligonucleotide conjugates • Avidity's plans to develop antibody oligonucleotide conjugate drug candidates for multiple disease indications **Ramana Doppalapudi,** Director of Chemistry, **Avidity Biosciences** (CONFIRMED)	**Pharmacokinetics and disposition of immunocytokines** • Multifunctionality of the next generation scaffolds introduce novel drug disposition. • Disposition of multifunctional protein therapeutics may be driven by single domains or a combination of the various targeting domains • Characterization of drug disposition is a critical step to understanding the PK/PD relationship • Early ADME/PK studies are essential to guide the design and selection of optimal clinical candidates **Cinthia Pastuskovas,** Senior Scientist, **Amgen** (CONFIRMED)	**Advancing a potent Conditionally Active Biologic (CAB) CTLA4 antibody to reduce toxicities associated with single agent and combination IO treatments** • Increasing the therapeutic index for anti-CTLA4 antibodies allowing for greater efficacy and safety • Preclinical evaluation of a CAB CTLA4 and marketed CTLA4 antibodies in mouse efficacy models and in toxicity models in non-human primates • Enabling and advancing combination immuno-oncology therapies for more effective therapies **Bill Boyle,** Head of Preclinical Development, **BioAtla** (CONFIRMED)
17:40	**Development of antibody conjugates for targeted delivery of siRNA** • Preparation and characterization of well-defined antibody-siRNA conjugates • Demonstration of in vitro and in vivo activities • PK analysis of antibody-siRNA conjugates	**Targeting solid tumours with bispecific antibody armed activated T cells (BATs)** • Bispecific antibodies can be used to retarget effector T cells to tumour antigens • Clinical targeting of solid tumours induces adaptive cellular and humoral immunity • Targeting of tumours induces Th1 cytokines in patients	**Modulating antibody activity through chemical biology** • Systemic administration of antibodies can lead to dose-limiting on-target toxicities • We therefore sought to design small-molecule control into existing antibodies, to allow for precise spatial and temporal activation

	Jun Zhang, Senior Scientist, **Amgen** (CONFIRMED)	• Immunotherapy with BATs is non-toxic and may improve survival in metastatic breast and pancreatic cancer patients **Lawrence Lum,** Professor of Oncology, **University of Virginia** (CONFIRMED)	• By incorporating a specific mutation in the heavy chain - light chain interface, we have created antibodies that require an exogenous small-molecule for antigen binding • Because of the conservation at this site, the same mutation/activator pair can be transferred and used in other antibodies **John Karanicolas,** Associate Professor, **Fox Chase Cancer Centre** (CONFIRMED)
18:00	Networking drinks and poster presentation		

Americas Antibody Congress - Tuesday 5th March – Day 2			
08:00	Registration opens		
08:40	Conference doors open		
	Track 1 **Armed antibodies**	Track 2 **Bispecifics**	Track 3

	Chaired by: **Jae Sly,** Director, Strategic Business Development, **AcroBiosystems** (CONFIRMED)	Chaired by: **Partha Chowdhury,** Senior Director and Head, Antibody Discovery, **Sanofi** (CONFIRMED)	**CMC, developability and manufacturing** Chaired by: **Richard Ding**, Director, Downstream Process Development, **AnaptysBio** (CONFIRMED)
09:00	**Increasing the potency of antiviral immunotherapeutics via engineered Fc regions** • Teaching potent neutralizing mAbs, to haemorrhagic fever viruses' new tricks • Second-generation ebolavirus cocktail, MBP134, with optimized Fc effector functions enhances protection • A single 25-mg/kg dose of MBP134 protects non-human primates challenged with EBOV, SUDV, and BDBV **Zachary Bornholdt,** Director, Antibody Discovery, **Mapp Biopharmaceutical, Inc** (CONFIRMED)	**Engineering of a T-cell dependent bispecific to broaden the therapeutic index for solid tumours** • Engineering and fine-tuning of the bispecific to achieve selective binding to tumour cells • Data demonstrating improved TI in in vitro and in vivo tumour models • Preclinical safety studies supporting tolerability **Christoph Spiess,** Senior Scientist, **Genentech** (CONFIRMED)	**Automation enabled high throughput cell line development** • Cell line development demands high throughput workflow • High throughput clone passaging • High throughput fed batch production • High throughput clone selection workflow for perfusion process • Comparing high throughput workflow to traditional shake flask process **Ren Liu,** Associate Principal Scientist, **Merck** (CONFIRMED)
09:20	**MGC018: A duocarmycin-based antibody drug conjugate targeting B7-H3** • Introduction of duocarmycin-based linker payload • Antibody discovery and target validation • Preclinical profiling of MGC018 **Deryk Loo,** Director, Targeted Therapeutics and Site Operations, **MacroGenics** (CONFIRMED)	**Targeted bispecific for treatment of inflammatory diseases** • Improving therapeutic potential of bio-therapeutics by increasing drug concentrations to target tissues and limiting systemic exposure • A case study using a preclinical model of arthritis will be presented • Proteogenomic analysis of inflamed tissues for new targets and biomarkers identification **Ivan Mascanfroni,** Senior Scientist, Immunology Biologics, **AbbVie Bioresearch Centre** (CONFIRMED)	**Engineering HIV broadly neutralizing antibodies (ebnAbs) for improved neutralization breadth, potency and developability** • Interdisciplinary design approach that combines yeast display, deep sequencing, structure-based prediction and antibody lineage analysis to create new antibody variants • Diverse panels of HIV Env used to select antibody variants with globally increased affinity • High-throughput expression and characterization used to screen for reduced polyspecificity and improved biochemical stability **Joseph Jardine,** Head of Antibody Discovery, **Institute of Protein Innovation** (CONFIRMED)
09:40	**Engineering STRO-002: A SARbody™ conjugate targeting folate receptor alpha** • STRO-002 is a homogeneous, site-specific ADC targeting folate receptor alpha which is widely expressed in ovarian and endometrial cancers • STRO-002 contains an antibody engineered using Fab-based ribosome display conjugated to a tubulin-targeting 3-aminophenyl	**Bispecific antibodies as immunotherapies for emerging viruses** • Bispecific antibodies (bsAbs) are a promising platform for development of novel immunotherapies • Ebola virus and other emerging viruses are suitable targets for blabs • We will discuss design and evaluation of bsAbs as candidate immunotherapies for Ebola virus and other emerging pathogens	**Strategic CMC approaches for mAb purification process development and manufacturing** • Platform and/or case-by-case based approach for process development and manufacturing will be applied. • New Technologies, methods and equipment are essential. • A robust, scalable, reproducible, flexible, controllable, and cost-

	hemiasterlin warhead via a cleavable linker • DAR, warhead, linker, and conjugation sites were optimized using Sutro's Xpress CF+ platform to yield a potent ADC with a favourable pharmacological profile **Ryan Stafford,** Director, Protein Engineering – Discovery, **Sutro Biopharma** (CONFIRMED)	**Elisabeth Nyakatura,** Research Assistant Professor, **Albert Einstein College of Medicine** (CONFIRMED)	effective process is designed and executed. • Challenges from biological complexity, impurity removal, adventitious agent control and manufacture facility fit will be discussed **Richard Ding**, Director, Downstream Process Development, **AnaptysBio** (CONFIRMED)
10:00	**Development of antibody drug conjugates to novel embryonic targets in metastatic cancers** • Our drug development strategy is driven by the concept that aggressive/metastatic cancers originate from primitive malignant cells created by cellular reprogramming • Our platform generates highly specific antibodies to novel cancer targets not expressed in normal tissues • CureMeta develops novel therapeutic antibody-drug-conjugates to treat patients with aggressive and metastatic cancers **Michael Schopperle,** Chief Executive Officer, **CureMeta** (CONFIRMED)	**Extended Q&A and networking**	**Development of modern biologics through global CMOs** • Process development and GMP manufacturing • Dealing with CMOs – how to select the best • CMO selection and due diligence process • Process development strategy **Vadim Klyushnichenko,** VP of Pharmaceutical Development & Quality, **Calibr, a division of Scripps Research** (CONFIRMED)
10:20	Morning networking break		
	Track 1 **Armed antibodies** Chaired by: **Jae Sly,** Director, Strategic Business Development, **AcroBiosystems** (CONFIRMED)	Track 2 **Bispecifics** Chaired by: **Partha Chowdhury,** Senior Director and Head, Antibody Discovery, **Sanofi** (CONFIRMED)	
11:20	**Amunix XTEN® polypeptides and THIOMAB™ antibodies to enable site-specific high-DAR ADCs with acceptable pharmacokinetics and efficacy** • Conjugation and analytics development for THIOMAB™ antibody-XTEN®-drug conjugates (TXCs) • In vitro and in vivo validation of high-DAR TXC platform **Neelie Zacharias,** Scientific Researcher, **Genentech** (CONFIRMED)	**IgM as highly potent, cross-linking antibodies for T cell engagement or as agonists of TNF family receptors** • IgM as a platform for high avidity, bi-specific and strong agonist antibodies • Low expression and difficult targets accessed by IgM • Potent and safer bispecific anti-CD20xCD3 IgM for relapsed or refractory lymphoma treatment • IgM for cross-linking of DR5 for enhanced apoptosis **Bruce Keyt,** Chief Scientific Officer, **IGM Biosciences** (CONFIRMED)	
11:40	**Engineering antibody conjugates for delivery of novel payload classes** • Antibody and linker design considerations for novel payload classes • Challenges to capturing complex MoA in vitro • In vivo payload target validation in tumour models **Susan Cellitti,** Associate Director, Biotherapeutics, **GNF** (CONFIRMED)	**Bispecific antibodies for tumor-directed blockade of CD47, the antiphagocytic "don't-eat-me" signal** • To evade anti-tumour immunity cancer cells, overexpress CD47, a ubiquitous phagocytosis inhibitor and immune checkpoint. • We have generated bispecific antibodies that allow selective targeting of CD47 in cancer cells expressing a tumour associated antigen, CD19 or mesothelin.	

		• These dual-targeting kappa-lambda bodies are fully human immunoglobulins of the IgG1 subtype. As such, they induce strong Fc-mediated tumour cell killing in vitro and in vivo. • They also promote T cell mediated anti-tumour immunity through the enhancement of antibody-directed tumour cell phagocytosis and antigen cross-presentation by professional APCs. **Krzysztof Masternak,** Head of Biology, **NovImmune** (CONFIRMED)
12:00	**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 **Julia Frei,** Scientist, **Paul Scherrer Institute** (CONFIRMED)	**Repurposing an imaging agent ligand for prostate cancer I/O** • Calibr has developed a small molecule antibody conjugate that functions as a bispecific antibody. • The molecule has the structure of an antibody drug conjugate and the function of a T cell recruiting bispecific antibody. • Through use of the Fab format, the molecule has excellent stability and favourable exposure in vivo. • Complete elimination of tumours in both xenograft and primary, patient derived models. **Travis Young,** Vice President, Biologics, **Calibr, a division of Scripps Research** (CONFIRMED)
12:20	**Developability assessment: Selecting the best product candidate for manufacture** • Understand the latest series of in silico computational models, analytics, in vitro and ex vivo experiments used in developability assessment • Characterise a molecules Specificity, Immunogenicity, Safety, Functionality and Manufacturability • Data generated informs sequence, structural, formulation and process refinements to select the best candidate for manufacture **Sven Lee,** Vice President, **Abzena** (CONFIRMED)	**Tumor targeted immune checkpoint inhibitor** • New strategy to generate bispecific antibodies targeting both immune checkpoint and tumor associated antigen • A versatile of bispecific antibody constructs that retain binding affinities to both targets • Tumor-targeted immune checkpoint blocking could translate into a therapeutic advantage in a mouse model **Feng Wang,** Professor and Principal Investigator, **Chinese Academy of Sciences** (CONFIRMED)
12:40	Networking lunch	
	Track 1 **Non-antibody approaches and small peptide formats** Chaired by: **Matt Levengood**, Senior Scientist, **Seattle Genetics**	Track 2 **Computational tools for antibody engineering and characterisation** Chaired by: **Stanley Krystek,** Senior Principal Scientist, **Bristol Myers-Squibb**
14:10	**Coiled coil antibody masking domains: A modular approach towards selective activation** • Self-associating coiled-coil peptides were used to impede antibody binding when fused to the antibody N-termini • The same peptides could be readily applied to multiple antibodies • Inclusion of a protease-cleavable sequence allows for reversible control of antibody function • Coiled-coil masked antibodies and antibody-drug conjugates were tested in multiple in vivo models and shown to have improved pharmacologic and activity profiles	**Predictive tools for developability assessment of antibody therapeutics** • Protein therapeutics is the fastest-growing class of pharmaceutical agents • Exploring the application of computational tools for the optimization and development of biologics • Identification of manufacturability hot-spots and mitigation via protein engineering solutions that enhance the protein's properties, such as its activity, affinity, specificity, and stability • Approaches that examine protein aggregation and estimate physical stability of proteins, and identify intrinsic liabilities regarding safety, efficacy, and manufacturability

	Matt Levengood, Senior Scientist, **Seattle Genetics** (CONFIRMED)	**Stanley Krystek,** Senior Principal Scientist, **Bristol Myers-Squibb** (CONFIRMED)
14:30	**From constrained peptides to biologics** • Highly potent macrocyclic peptides against various targets selected by an in vitro display system • Dimerization of macrocyclic peptides making them with antibody-like potency • Converting them into another modality **Hiroaki Suga,** Professor, Department of Chemistry, **University of Tokyo** (CONFIRMED)	**Exploration of small protein folds and their defining features** • We developed a computational platform that enables us to efficiently sample and design any given topologies with high structural diversity to serve as new scaffolding proteins, guide future design efforts and help our general understanding of stability • Using a high-throughput stability screen, we evaluated 45,000 of 9 topologies designed with our new pipeline and derived stability prediction models using machine learning algorithms **Eva-Maria Strauch,** Assistant Professor, Dept. of Pharmaceutical and Biomedical Sciences, **University of Georgia** (CONFIRMED)
14:50	**Protein analogous micelles: versatile, modular nanoparticles** • Peptides are functional modules of protein macromolecules that can be displayed apart from the whole protein to create bio functional surfaces and interfaces, or can be re-assembled in new ways to create synthetic mimics of protein structures • This is what we call protein analogous micelles • Examples of work from our laboratory in this area using peptide-lipid or peptide-polycation conjugate molecules (peptide amphiphiles) include: multi-bio-functional surfaces, DNA-binding peptide assemblies, synthetic vaccines, and protein analogous micelles for cancer and cardiovascular therapeutics **Matthew Tirrell,** Pritzker Director, Professor and Dean of the Faculty, **University of Chicago** (CONFIRMED)	**Computational design of functional, multi-specific and epitope-specific antibodies** • We use AI to design and engineer antibodies that bind to a predetermined epitope • These antibodies can be Multi-specific binding more than one epitope on more than one target, while maintaining fully human, natural format • The approach can be used to improve characteristics of existing antibodies: refine specificity and affinity, thermo-stability and developability **Yanay Ofran,** Founder and CEO, **Biolojic Design** (CONFIRMED)
15:10	**Extended Q&A and networking**	**RosettaAntibodyDesign (RAbD): a general framework for computational antibody design** • RAbD samples CDR conformations from structural clusters of CDRs • Sequence design based on the CDR sequence profiles and structural refinement is performed in Rosetta • RAbD is highly tailorable for different antibody optimization problems • RAbD was computationally benchmarked on redesigning 60 antibodies and tested experimentally on two antibody/antigen systems **Roland Dunbrack,** Professor, Molecular Therapeutics Program, **Fox Chase Cancer Centre** (CONFIRMED)
15:30	Afternoon networking break	
	Closing keynotes (Plenary) **Combination therapies and IO formats** Chaired by: **Gary Starling**, Associate Vice President, Protein Science, **Merck** (CONFIRMED)	
16:30	**Adding to the efficacy of PD-1 based therapies** • Immune checkpoint inhibition has been transformational in the treatment of cancer • Despite the success, many patients and tumour types do not respond to current marketed immunotherapies	

	• Patient selection strategies and combining therapeutic approaches have important roles in enhancing the reach of PD-1-based immunotherapy **Gary Starling**, Associate Vice President, Protein Science, **Merck** (CONFIRMED)
16:55	**T-SIGn viruses: systemic delivery of localized combination immuno-gene therapy within the tumour microenvironment** • T-SIGn platform: transgene-bearing genetically modified variants of enadenotucirev, an oncolytic chimeric group B adenovirus with clinical data demonstrating virus delivery to tumours following systemic dosing • Up to 4 different transgenes have been encoded in a single virus, enabling the design of candidates expressing combinations of biological agents for targeted immunotherapy • Local production of therapeutic combinations by tumour cells infected with the T-SIGn virus enables high local production for increased activity while minimizing systemic exposure for improved safety **Brian Champion,** Chief Scientific Officer, **PsiOxus Therapeutics** (CONFIRMED)
17:20	**Combining antibody and targeted therapies: Cirmtuzumab and ibrutinib - novel synergistic combination for CLL and mantle cell lymphoma** • Cirmtuzumab targets ROR1, an oncofoetal antigen expressed on both liquid and solid tumours • Cirmtuzumab inhibits Wnt5a signalling and reverses stemness in CLL • The ROR1 pathway is not inhibited by BTK inhibitors such as ibrutinib • Cirmtuzumab and ibrutinib are synergistic for CLL and MCL, and a clinical trial of the combination is under way **James Breitmeyer,** President & CEO, **Oncternal Therapeutics** (CONFIRMED)
17:45	**Closing remarks**
18:00	End of conference

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WORLD IMMUNOTHERAPY CONGRESS USA 2019

World Immunotherapy Congress USA

World Immunotherapy Congress USA Speakers

Johanna Mercier, President and Head of U.S., France, Germany and Japan Markets, **Bristol-Myers Squibb**
Robert Rickert, Senior Vice President, Chief Scientific Officer - Cancer Immunology Discovery, **Pfizer**
Christine Brown, Associate Research Professor, **City of Hope**
Jim Caggiano, CEO, **Dendreon**
William Chou, Vice President, Global Commercial Head, Cell and Gene Therapy, **Novartis**
Mark Lowdell, Director of Cellular Therapy, **UCL,** CSO and Founder, **InMuneBio**
Karin Jooss, Executive Vice President of Research, Chief Scientific Officer, **Gritstone Oncology**
Peter Emtage, Global Head of Cell Therapy Research**, Kite**
Steffan Ho, Vice President and Head of Translational Oncology**, Pfizer**
David Sourdive, Co-founder, Executive Vice President - Technical Operations, **Cellectis**
Eric Halioua, President & CEO, **PDC* Line Pharma**
Ho Cho, Vice President, Biotherapeutics, **Celgene**
Keith Knutson, Professor of Immunology, Director of Cancer Center for Immunology and Immunotherapy Program, **Mayo Clinic**
Alain Vertes, Managing Director, **NxR Biotechnologies**
Fred Ramsdell, SVP, Research, **Parker Institute**
Edward Ballesteros, Director Supply Chain, **Bellicum**
Christina Yi, Chief Operations Officer, **Dendreon**
Raymond Tesi, Chief Executive Officer, **INmune Bio**
Kate Broderick, Vice President, **Inovio Pharmaceuticals**
James Breitmeyer, Chief Executive Officer, **Oncternal Therapeutics**
Gary Starling, Associate Vice President, Protein Science, **Merck**
James Legg, SVP Research and Development, **Crescendo Biologics**
Brian Champion, Chief Scientific Officer, **PsiOxus Therapeutics**
Frédéric Triebel, Chief Scientific Officer, Chief Medical Officer, **Immutep**
Mark Poznansky, Director, Vaccine and Immunotherapy Center**, Massachusetts General Hospital**
Hans Klingemann, VP, Research and Development**, NantKwest**
Sari Pesonen, VP, Scientific and Clinical Development, Co-Founder, **Valo Therapeutics**
Stephen Schoenberger, Professor and Co-Director, **La Jolla Institute for Allergy and Immunology and San Diego Center for Precision Immunotherapy**
Ezra Cohen, Associate Director of Moores Cancer Center, **U.C. San Diego Moores Cancer Center**
Douglas Jolly, Executive Vice President, Research and Pharmaceutical Development, **Tocagen**
Bob Valamehr, Vice President, Cancer Immunotherapy, **Fate Therapeutics**
Sandip Patel, Medical Oncologist, Associate Professor of Medicine, **UCSD**

Christopher Jewell, Associate Professor and Associate Chair, **University of Maryland**
Maksim Mamonkin, Assistant Professor**, Baylor College of medicine**
Rob Knight, Faculty Director, Center for Microbiome Innovation, **UCSD**
Anish Suri, CSO**, Cue Biopharma**
Thomas Lane, Chief Medical Officer, **Persimmune**
Travis Young, VP, Biologics, **Calibr**
Shahram Lavasani, CEO, **Immune Biotech**
Alex Kelly, US Business Development Manager, **Retrogenix Limited**
Mario Ehlers, Senior Medical Director, **Eli Lilly**
Deepak Khatry, Science Associate Director and Team Leader, PHC, Biostatistics, **MedImmune**
Nicolas Poirier, Chief Scientific Officer, **OSE Immuno Therapeutics**
Jyoti Mayadev, Associate Professor, Chief, Gynecology Oncology Radiation Services, **UCSD**
Sonia Sharma, Assistant Professor, Director Division Cell Biology, **La Jolla Institute for Immunology**
Elaine Eng, Senior Regulatory Advisor, **UCSD**
Andrew Sharabi, Assistant Professor, **UCSD**
Margaux Stack-Babich, Program Manager, **Immunotherapy Foundation**
Kedar Hastak, Application Scientist, **Personalis**
Samuel Williams, Vice President of Research, **Immuntics**
David Pyrce, Senior Vice President, Innovation & Chief Commercial Officer, **NantKewst**
Lingbing Zhang, Founder and CEO, **Yinuoke**
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World Immunotherapy Congress – Sunday 3rd March – Workshop Day	
12:00	**Registration opens**
13:00	**Progress and challenges in the design and clinical development of microbial therapies** • Influence of the gut microbiome on autoimmunity • Gut microbes and immunotherapy responses • Leaky Gut Syndrome in autoimmune diseases – a potential target for therapy • Success in a probiotic trial in Irritable Bowel Syndrome – a new therapeutic perspective targeting the dysbiosis and beyond • Designing multi-targeted bacterial therapy – what tools do we need? **Shahram Lavasani**, CEO, I**mmuneBiotech (**CONFIRMED)
14:00	**San Diego Center for Precision Immunotherapy (SDCPI)** A series of short presentations by members of the SDCPI Chaired by **Ezra Cohen,** Associate Director, **U.C. San Diego Moores Cancer Center** (CONFIRMED) **Immunotherapy for cervical cancer clinical trials: what we know, and what we are still searching for** • Rationale for immunotherapy in cervical cancer • Review of clinical trial outcomes • National clinical trial ongoing design • Rationale for immunotherapy biomarkers and early response prediction **Jyoti Mayadev,** Associate Professor, Chief, Gynecology Oncology Radiation Services, **UCSD** (CONFIRMED) **Small molecule biomarkers and modulators of immune related adverse events during immune checkpoint blocker therapy** • Review of immune related adverse events and immune checkpoint blockers • Discovery based technologies for HT small molecule profiling • Preliminary results of a multi cohort analysis **Sonia Sharma,** Assistant Professor, Director Division Cell Biology, **La Jolla Institute for Immunology** (CONFIRMED) **Demystifying the IND: regulatory pathways to accelerate patient care** • Learn about the "nuts and bolts" of an IND • Learn about expedited regulatory development pathways • Discuss regulatory strategies to optimize timelines **Elaine Eng,** Senior Regulatory Advisor, **UCSD** (CONFIRMED) **Clinical trials combining Radiation with Immunotherapy** • Goals and future directions **Andrew Sharabi,** Assistant Professor, **UCSD** (CONFIRMED)
16:00	**End of workshop day**

World Immunotherapy Congress USA – Monday 4th March – Day 1	
08:00	**Registration opens**

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08:40	**Conference doors open**		
	Immunotherapy keynotes: current and future trends in immunotherapy		
09:00	**Welcome from Terrapinn**		
09:05	**Chair's opening remarks** **Mark Poznansky,** Director, Vaccine and Immunotherapy Center, **Massachusetts General Hospital**		
09:10	**Precision immunotherapy: the San Diego perspective** **Stephen Schoenberger,** Professor and Co-Director, **La Jolla Institute for Allergy and Immunology and San Diego Center for Precision Immunotherapy** (CONFIRMED)		
09:35	**Keynote panel discussion: the future of immunotherapy - what are the advances that need to be made?** **Chair: Mark Poznansky,** Director, Vaccine and Immunotherapy Center, **Massachusetts General Hospital** (CONFIRMED) **Ho Cho,** Vice President, Biotherapeutics, **Celgene** (CONFIRMED) **Robert Rickert,** Senior Vice President, Chief Scientific Officer - Cancer Immunology Discovery, **Pfizer** (CONFIRMED) **Stephen Schoenberger,** Professor and Co-Director, **La Jolla Institute for Allergy and Immunology and San Diego Center for Precision Immunotherapy** (CONFIRMED) **Douglas Jolly,** Executive Vice President, Research and Pharmaceutical Development, **Tocagen** (CONFIRMED)		
10:25	**Networking break**		
11:30	**Roundtable discussion session** 6 senior level tables hosted by thought leaders on key challenges and opportunities in immunotherapy discovery and development. Participants are invited to join the group discussions on a topic of importance to them. The round table session will have two rotations, each lasting 40 minutes		
	TABLE 1 **ROI for IO Biomarkers** **Steffan Ho**, Vice President and Head of Translational Oncology, **Pfizer** (CONFIRMED)	TABLE 2 **Novel Antibody Platforms for Immunotherapy** **Kate Broderick,** Vice President, **Inovio Pharmaceuticals** (CONFIRMED)	TABLE 3 **Accelerating the bench to bedside timeline in drug development** **Margaux Stack-Babich,** Program Manager, **Immunotherapy Foundation** (CONFIRMED)
	TABLE 4 **Clinical Biomarker Development Considerations for Immunotherapy** **Deepak Khatry,** Science Associate Director and Team Leader, PHC, Biostatistics, **MedImmune** (CONFIRMED)	TABLE 5 **Directly administered viral vectors as immunotherapies** **Douglas Jolly,** Executive Vice President, Research and Pharmaceutical Development, **Tocagen** (CONFIRMED)	
12:50	**Networking lunch**		
	Track 1 **Cell Therapy**	Track 2 **Cancer vaccines**	
	Chair: Bob Valamehr, Vice President, Cancer Immunotherapy, **Fate Therapeutics**	**Chair: Brian Champion,** Chief Scientific Officer, **PsiOxus Therapeutics** (CONFIRMED)	
14:40	**Pluripotent cell-derived off-the-shelf TCR-less CAR-targeted cytotoxic T Cell Therapeutic for the allogeneic treatment of B cell malignancies** • Several obstacles hamper the range of CAR-T application to a wide patient base • FT819 is a first-of-kind off-the-shelf human induced pluripotent stem cell (hiPSC)-derived CAR-T cell product • Preclinical studies suggest that FT819 can be effectively and safely used in the treatment of B cell malignancies in allogeneic setting **Bob Valamehr,** Vice President, Cancer Immunotherapy, **Fate Therapeutics** (CONFIRMED)	**Driving high T-cell titers to neoantigens in tumors – harnessing immunogenic viral vectors with immune check point modulators** • Neoantigen prediction • Viral vectors as vaccine delivery platform(s) • Cancer vaccines in combination with immune checkpoint modulators **Karin Jooss,** Executive Vice President of Research, Chief Scientific Officer, **Gritstone Oncology** (CONFIRMED)	
15:00	**NK-92®: a proven, versatile platform for target-specific NK cell immunotherapy** • NK-92® cells scientifically and clinically developed by NantKwest	**PDC*line Pharma semi-allogeneic cancer vaccine: how abortive allogeneic immune response can prime and boost the induction of specific anti-tumor T cells?**	

	• Allows for virus independent genetic manipulation • In addition to the parental NK-92 (aNK™), IL-2-independent, antibody targeted CD16 expressing haNK® cells are in clinical trials • Various CAR expressing variants (taNK®) for clinical application **Hans Klingemann,** Vice President of Research & Development, **NantKwest** (CONFIRMED)	• PDC*line is a new potent and scalable therapeutic cancer vaccines based on a proprietary allogeneic cell line of Plasmacytoid Dendritic Cells • PDC*line is much more potent to prime and boost antitumor antigen, including neoantigens, specific cytotoxic T-cells than conventional vaccines and improves the response to checkpoint inhibitors • The technology can be applied for any cancer **Eric Halioua**, President & CEO, **PDC* Line Pharma** (CONFIRMED)
15:20	**Tumor-specific pathways to NK cell activation and how they can be used in the clinic** • NK cells have complex activation pathways which differ following ligation by different tumor cells • Conventional cytokine activated NK cells are not optimally primed to kill tumour cells • Knowledege of NK cell activation pathways can be translated to better cancer therapies **Mark Lowdell,** Director of Cellular Therapy, **UCL,** CSO and Founder, **InMuneBio** (CONFIRMED)	**Vaccine for early breast lesions** • Developing T cell-based vaccines targeting a wide variety of tumor antigens, including HER2, CEA, FRa and IGFBP • Demonstrating that once administered systemically, the oncolytic virus Reolysin associates with both peripheral blood mononuclear and polymorphonuclear cells to avoid neutralization by antibody **Keith Knutson**, Professor of Immunology, Director of Cancer Center for Immunology and Immunotherapy Program, **Mayo Clinic** (CONFIRMED)
15:40	**Advancing CAR T cell therapy for brain tumors** • Expanding the repertoire of immunologic targets for brain tumors • Advantages of locoregional delivery of CAR T cells for brain tumors • Combining CAR T cells with anti-PD-1 checkpoint inhibition • Lessons learned from on-going clinical trials **Christine Brown,** Associate Research Professor, **City of Hope** (CONFIRMED)	**Advancing novel combination vaccines and immunotherapies for cancer** • Novel cancer vaccines and immunotherapies • Novel combination immunotherapy and maximizing efficacy • Choosing the safest and most effective immunotherapy and vaccine for the right cancer **Mark Poznansky,** Director, Vaccine and Immunotherapy Center, **Massachusetts General Hospital** (CONFIRMED)
16:00	**Afternoon refreshments**	
	Cell Therapy	**Precision Immunotherapy and the Microbiome**
	Chair: Bob Valamehr, Vice President, Cancer Immunotherapy, **Fate Therapeutics**	**Chair: Ezra Cohen,** Associate Director of Moores Cancer Center, **U.C. San Diego Moores Cancer Center**
16:50	**ROR1 targeted CAR-T** • ROR1 is an oncofetal antigen expressed on both liquid and solid tumors • ROR1 expression is associated with poor outcomes across many cancers • ROR1 is a marker of stemness and a de-differentiated state, making it an excellent target • CAR-T are being developed to treat both liquid and solid tumors **James Breitmeyer,** Chief Executive Officer, **Oncternal Therapeutics** (CONFIRMD)	**Shaping our dynamic microbiomes for lifelong health** • Through the American Gut Project, we now know about the microbiomes of many types of people, from the healthiest (student-athletes, centenarians) to the sickest (cancer patients, ICU patients, those with depression, those with C. diff) • Amazingly, diet has an especially profound effect on our microbiomes, often outweighing the effects of disease or medications. • This raises the prospect of a system for real-time analysis of our microbiomes that helps guide our daily decisions in a way that optimizes our microbiomes for extending our healthspan **Rob Knight**, Faculty Director, Center for Microbiome Innovation, **UCSD** (CONFIRMED)
17:10	**A new approach to cancer immunotherapy** • Late stage cancer induces severe immune system disorder (TID) which brings damage to patient body	**The microbiome in cancer** • Review of the current understanding of how the microbiome influences response to immune checkpoint blockade in cancer

	• TID impacts efficacy of immunotherapeutics aiming to induce anti-tumor immune response • A new direction to develop cancer immunotherapy for terminal stage cancer by targeting TID **Lingbing Zhang,** Founder and CEO, **Yinuoke** (CONFIRMD)	• A summary of potential mechanisms of microbial pathogenesis in cancer • Highlighting the future directions for microbiome science in cancer immunotherapy **Sandip Patel,** Medical Oncologist, Associate Professor of Medicine, **UCSD** (CONFIRMED)
17:30	**Switchable CAR-T cell therapy** • Calibr's unique switchable CAR-T cell platform affords dose-titratable control over activity • Temporal control over activation enables in vivo formation and recall of memory CAR-T cells • The switchable CAR-T cell platform is universal; redirection to multiple targets allows a robust response against antigen loss in preclinical models **Travis Young,** VP, Biologics, **Calibr** (CONFIRMED)	**Designing ultimate microbial therapeutics** • Leaky Gut Syndrome in autoimmunity – a potential target for therapy • Successful bacterial treatment for Irritable Bowel Syndrome (IBS) – a new therapeutic perspective targeting the dysbiosis and beyond • Designing multi-targeted therapeutic microbial consortium what tools do we need? • New generation of probiotic products designed to boost the immunotherapy treatments **Shahram Lavasani**, CEO, **Immune Biotech** (CONFIRMED)
17:50	**Developing and evaluating CAR-T therapies for T-cell malignancies** • Strategies to overcome fratricide of CAR T cells specific to T-cell antigens • Limiting off-tumor toxicity in patients • Current results and future directions **Maksim Mamonkin,** Assistant Professor, **Baylor College of medicine** (CONFIRMED)	**Harnessing nanotechnology to program immune function** • Use of nanotechnology and engineered materials to understand immune processes • Programmable activation of combinations of immune pathways for synergistic potency • Generation of antigen-specific tolerance to combat multiple sclerosis and type 1 diabetes **Christopher Jewell,** Associate Professor and Associate Chair, **University of Maryland** (CONFIRMED)
18:15	**Drinks reception**	

World Immunotherapy Congress – Tuesday 5th March – Day 2	
08:00	Registration opens
08:30	Conference doors open
	Track 1 **Morning keynotes: commercial updates on approved products**
	Chair: Alain Vertes, Managing Director, **NxR Biotechnologies** (CONFIRMED)
09:00	**Taking CAR-T from theory to reality - the Novartis experience** • CTL019 development history • Kymriah trial experience • Global commercialization – update and key learnings • Looking ahead **William Chou**, Vice President, Global Commercial Head, Cell and Gene Therapy, **Novartis** (CONFIRMED)
09:25	**PROVENGE®: Hits and Misses, Now Success** • Navigating the transition from clinical promise to commercial success • Marketplace challenges facing PROVENGE • Orchestrating a successful turnaround • What PROVENGE has taught us about the promise of immunotherapy **Jim Caggiano**, CEO, **Dendreon** (CONFIRMED)
09:50	**Panel discussion: Commercial strategies in immunotherapy** • High level pharma companies come together to discuss their strategies for tackling cancer **Moderator: Alain Vertes,** Managing Director**, NxR Biotechnologies** (CONFIRMED)

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	Johanna Mercier, President and Head of U.S., France, Germany and Japan Markets, **Bristol-Myers Squibb** (CONFIRMED) **Jim Caggiano**, CEO, **Dendreon** (CONFIRMED) **David Pyrce,** Senior Vice President, Innovation & Chief Commercial Officer, **NantKewst** (CONFIRMED)	
10:35	**Networking break**	
	Track 1 **Checkpoint inhibitors**	**Track 2** **Manufacturing and logistics**
	Chair: Fred Ramsdell, SVP, Research, **Parker Institute**	**Chair: David Sourdive,** Co-founder, Executive Vice President - Technical Operations, **Cellectis**
11:40	**The TESLA consortium: Relevant parameters for neoepitope selection** • TESLA integrates multiple, independent computational pipelines and tests the predictions using several validation assays • Differences and common features are apparent • This community-based approach may act as a paradigm for shared progress in cancer therapy **Fred Ramsdell,** SVP, Research, **Parker Institute** (CONFIRMED)	11:40 **Cell therapy supply chain management, logistics and scale-out** • Shipper suitability, features and options • Maintaining chain of custody for starting material and product • Logistics reliability and options • Supply chain sustainability and scale-out **Edward Ballesteros,** Director Supply Chain, **Bellicum**
12:00	**Inactivating Treg cells in tumor microenvironment to improve efficacy of checkpoint inhibitors** • Treg play an important role in intratumoral resistance to checkpoint inhibitors • Bifunctional antibodies can deliver intratumoral cytokines with Treg modulating function while inhibiting immune checkpoints • Bifunctional checkpoint inhibitors powerfully resume exhausted T cell responses **Nicolas Poirier,** Chief Scientific Officer, **OSE Immuno Therapeutics** (CONFIRMED)	12:00 **Deploying gene editing in the manufacturing of clinical "off-the-shelf" engineered allogeneic CAR-T therapies** • Lessons learned in taking gene-edited T-cell product candidates to the clinic • Specificities of manufacturing allogeneic CAR-T products • Perspective on how gene editing is transforming cell therapy and enables synthetic biology to become a reality **David Sourdive,** Co-founder, Executive Vice President – Technical Operations, **Cellectis**
12:20	**Identifying critical receptors and screening for target specificity using human cell microarray technology** • A powerful approach to identify primary receptors for phenotypic antibodies and immune checkpoint ligands • Efficient off-target profiling of biotherapeutics (antibodies, ADCs, scFvs) and cell therapies (including CAR T) **Alex Kelly,** US Business Development Manager, **Retrogenix Limited** (CONFIRMED)	12:25 **Delivering PROVENGE® – An operational success story** • Logistical challenges of delivering an autologous cell therapy • Building blocks for operational success • Developing an integrated system **Christina Yi,** Chief Operations Officer, **Dendreon**
12:40	**CB307: A novel CD137/4-1BB agonist Humabody Therapeutic for PSMA positive Tumours** • The talk will describe the identification, mechanism of action and preclinical characterisation of CB307 • CB307 is a novel bispecific Humabody VH targeting CD137 (4-1BB) and prostate specific membrane antigen (PSMA) • The benefits of using the modular Humabody VH platform, rather than an IgG format to develop this molecule will be discussed, including optimal (monovalent) engagement of both targets with small VH domains and the avoidance of Fc receptor interactions • The unique design of CB307 enables highly potent and tumour selective T-cell co-stimulation	

	James Legg, SVP R&D, **Crescendo Biologics** (CONFIRMED)	
13:00	**Networking lunch**	
	Checkpoint Inhibitors	**Neoantigens**
	Chair: Fred Ramsdell, SVP, Research, **Parker Institute**	**Chair: Alain Vertes,** Managing Director, **NxR Biotechnologies**
14:00	**ImmunoSTATs: a novel biologics therapeutic platform for antigen-specific immunotherapy** • Platform enables selective and antigen-specific modulation of T cells in immuno-oncology, autoimmune diseases and chronic infectious diseases • Modularity and flexibility of the platform allows for incorporation of different antigens, HLA alleles and diverse co-stimulatory/regulatory signals to tackle diverse diseases **Saso Cemerski,** Senior Director of Translational Immunology, **Cue Biopharma** (CONFIRMED)	**Identifying neoantigens for patients** • Identifying the neoantigens expressed in murine and human tumors and optimizing methods for their specific targeting by various targeted vaccines or through adoptive cellular therapy (ACT) with neoantigen-specific T cells • Our discovery that a patient's tumor cells can be converted to cancer stem cells that retain expression of the neoantigens identified in the original cancer and which can form tumors in immunodeficient mice. **Stephen Schoenberger,** Professor and Co-Director, **La Jolla Institute for Allergy and Immunology and San Diego Center for Precision Immunotherapy** (CONFIRMED)
14:20	**Targeting Myeloid deprived suppressor cells (MDSC) to improve efficacy of checkpoint inhibitors** • Cancer causes chronic inflammation which promotes the development of MDSC • MDSC are the "Queen Bee" of the TME and a major cause of resistance to CPI • Eliminating MDSC should improve the response to CPI and eliminate one of the major resistance factors **Raymond Tesi,** CEO**, INmune Bio** (CONFIRMED)	**Comprehensive Immunogenomics for Biomarker Discovery from a Single Sample** • While the success of checkpoint blockade has been promising, it's increasingly apparent that predicting patient response to immunotherapies requires a more robust approach to tumor immunogenomics. • By combining highly sensitive, exome-scale DNA and RNA sequencing with advanced analytics, ImmunoID NeXT provides a multidimensional view of the tumor and the tumor microenvironment (TME) from a single sample preparation. • In this presentation, we'll discuss the benefits of this unique, innovative design for immuno-oncology translational research including mastering challenging samples, utilizing optimized algorithms, and obtaining accurate genomic data for identifying novel biomarker signatures **Kedar Hastak**, Application Scientist, **Personalis** (CONFIRMED)
14:40	**Blockade of the novel TIM-3 ligand galectin-3 induces immune-mediated tumor control** • Identification of a novel binding partner for TIM-3, Galectin-3 • Discovery of antibodies that block the binding of Galectin-3 to TIM-3 • Demonstration of immune-activation by blockade of Galectin-3 TIM-3 binding • Demonstration of anti-tumor activity of Galectin-3 TIM-3 blocking antibody IMT001 **Samuel Williams,** Vice President of Research, **Immuntics**	**Personalized adoptive cellular therapy targeting myelodysplastic syndrome (MDS) stem cell neoantigens (PACTN)** • Development of a personalized, neoantigen-based adoptive T cell immunotherapy for cancer • Goals, issues and rationale in the design of PersImmune's phase 1 clinical trial • Early results of the current phase 1 clinical trial in MDS **Thomas Lane,** Chief Medical Officer, **Persimmune** (CONFIRMED)
15:00	**Two ACTive Immunotherapies (TACTI): Results of a Phase I trial with metastatic melanoma patients** • LAG-3/MHC class II interactions and their modulation in both cancer and auto-immune diseases	**An HLA-agnostic, mutation-burden independent, personalized neoantigen vaccine strategy** • We developed an HLA-agnostic methodology that does not depend on *in silico* prediction models

	• Combination therapy with eftilagimod alpha (LAG-3Ig) and chemotherapy or anti-PD-1 mAb • Highlighting in vitro and in vivo preclinical data along with emerging clinical data **Frédéric Triebel,** Chief Scientific Officer, Chief Medical Officer, **Immutep** (CONFIRMED)	• This novel method reliably and consistently finds neoantigens for both Class I and II MHC presentation • We have started a personalized synthetic long peptide vaccine clinical trial in patients with advanced solid tumors to validate this approach and test the immunogenicity of a vaccine in combination with PD1 blockade **Ezra Cohen,** Associate Director of Moores Cancer Center, **U.C. San Diego Moores Cancer Center** (CONFIRMED)
15:20	**Afternoon refreshments**	
	Closing Keynotes **Combination therapy** Chaired by: **Gary Starling**, Associate Vice President, Protein Science, **Merck** (CONFIRMED)	
	Chair: Gary Starling, Associate Vice President, Protein Science, **Merck**	
16:30	**Adding to the efficacy of PD-1 based therapies** • Immune checkpoint inhibition has been transformational in the treatment of cancer • Despite the success, many patients and tumor types do not respond to current marketed immunotherapies • Patient selection strategies and combining therapeutic approaches have important roles in enhancing the reach of PD-1-based immunotherapy **Gary Starling**, Associate Vice President, Protein Science, **Merck** (CONFIRMED)	
16:55	**T-SIGn Viruses: systemic delivery of localized combination immuno-gene therapy within the tumor microenvironment** • T-SIGn platform: transgene-bearing genetically modified variants of enadenotucirev, an oncolytic chimeric group B adenovirus with clinical data demonstrating virus delivery to tumors following systemic dosing • Up to 4 different transgenes have been encoded in a single virus, enabling the design of candidates expressing combinations of biological agents for targeted immunotherapy • Local production of therapeutic combinations by tumor cells infected with the T-SIGn virus enables high local production for increased activity while minimizing systemic exposure for improved safety **Brian Champion,** Chief Scientific Officer, **PsiOxus Therapeutics** (CONFIRMED)	
17:20	**Combining antibody and targeted therapies: Cirmtuzumab and ibrutinib - novel synergistic combination for CLL and mantle cell lymphoma** • Cirmtuzumab targets ROR1, an oncofetal antigen expressed on both liquid and solid tumors • Cirmtuzumab inhibits Wnt5a signalling and reverses stemness in CLL • The ROR1 pathway is not inhibited by BTK inhibitors such as ibrutinib • Cirmtuzumab and ibrutinib are synergistic for CLL and MCL, and a clinical trial of the combination is under way **James Breitmeyer,** President & CEO, **Oncternal Therapeutics** (CONFIRMED)	
17:45	**Chair's closing remarks**	
18:00	**End of conference**	

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World Biosimilar Congress USA

World Biosimilar Congress USA Speakers

Adam Levysohn, Sr Director Market Access Biosimilar, **Biogen**
Alain Vertès, Managing Director, **NxR Biotechnologies GmbH**
Alvin Luk, Senior Vice President and Chief Medical Officer, **Shanghai Henlius**
Andreu Soldevila, Chief Executive Officer (CEO), **Syna Therapeutics**
Annick de Vries, Director Bioanalysis, **Sanquin Diagnostic Services**
Bradley J. Scott, Senior Clinical Evaluator, Clinical Evaluation Division - Haematology / Oncology, HPFB, **Health Canada**
Bruce Leicher, Attorney and Former Senior Vice President and General Counsel, **Momenta Pharmaceuticals**
Bryan Kim, Vice President, Business Development, **Samsung Bioepis**
Cheryl Koehn, President, **Arthritis Consumer Experts**
Daniel Alvarez, Senior Director- Asset Lead Biosimilars Research Development Unit, **Pfizer**
Dinesh Kundu, GM, Strategy, BD & Program Management, **QbD Biosciences**
Eric Lun, Executive Director, Drug Intelligence, Optimization, Outcomes, and Strategy, Pharmaceutical Services Division, **BC Ministry of Health**
Gareth Powell, Business Development Officer, **NIHR Clinical Research Network (CRN)**
Gerry Hoehn, Medical Director, Oncology, **Teva**
Hubert Chen, Scientific & Medical Advisor, **Pfenex**
Jonathan Sheffield, CEO, **NIHR**
Joseph Fuhr, Adjunct Professor of Pharmaceutical & Healthcare Business, **Widener University**
Julio Baez, Bioengineering Industrial Advisor, **UCSD**
Kalveer Flora, Lead Rheumatology and Biosimilars Specialist Pharmacist, **London North West Healthcare NHS Trust**
Katherine Ruby, Medical Science Liaison, **Sandoz**
Klaas Ehrig, Regulatory Affairs Manager, **Sandoz**

Klemen Spaninger, Director Project Management, **Polpharma Biologics**
Louis Boon, CSO, **Bioceros**
Maggie Dolan, Associate Director market Access EU Biosimilars, **Biogen**
Megan Keaney, Principle Medical Advisor, **Australian Government Department of Health**
Mourad Farouk Rezk, Senior Director, Global Head Medical Affairs Biosimilars, **Biogen**
Nacer E. Hedroug, Former Director, QA Ops Injectable Vertical & Tech Transfer, **Mylan**
Nathan Lewis, Associate Professor, Department of Pediatrics and Bioengineering, **UCSD**
Parastoo Azadi, Technical Director, Analytical Services, **Complex Carbohydrate Research Center**
Sarfaraz Niazi, Chairman, Professor, **Karyo Biologics/University of Illinois**
Sheila Frame, Vice President and Head of Biopharmaceuticals, **Sandoz**
Sian Estdale, Global Scientific Head, **Covance Chemistry Solutions**
Steve Lehrer, Managing Director, **SBLehrer LLC**
Dorthe Bartels, Strategic Adviser, **AMGROS**
Brian Lehman, Strategic Consultant, Pharmacy Professional Affairs, **Sandoz**
Ted Mathias, Partner, **Axinn**
Stacie L. Ropka, Partner, **Axinn**
Len Arsenault, Vice President, Policy, Medical, and External Engagement, **Sandoz**
Tim Shea, Director, **Sterne Kessler Goldstein And Fox Plc**

World Biosimilar Congress USA - Sunday 3rd March – Workshop Day	
12:00	Registration
12:00	Networking Lunch
13:00	**Innovation in Technology and Analytics for the production of biosimilars is needed as:** • Use of biopharmaceutical is hindered by cost and distribution • Novel Analytical tools can be used to better define the product and impurities • Alternate expression systems to bacterial and mammalian systems and downstream technologies can reduce costs while delivering the required productivity and product quality **Julio Baez**, Bioengineering Industrial Advisor, **UCSD**
13:45	**WHAT can the US derive from policy and strategy across Europe in promoting biosimilar uptake?** • Who are the stakeholders and what benefits are to be gained from a positive approach to biosimilars? • How have professional healthcare bodies help deliver the biosimilar agenda in Europe? • What policy approaches across Europe have driven market uptake? • What are the barriers and how can they be overcome • Are there any strategic difference in the delivery of healthcare in the US that need to be considered by biologic companies **Chair: Maggie Dolan,** Associate Director market Access EU Biosimilars, **Biogen** **Adam Levysohn**, Sr Director Market Access Biosimilar, **Biogen** **Alain Vertès**, Managing Director, **NxR Biotechnologies GmbH** **Kalveer Flora**, Specialist Pharmacist Rheumatology and Biosimilars, **London North West University Healthcare NHS Trust**
14:30	**Implementing modern Cell engineering and Process development approaches for affordable and sustainable biosimilar manufacturing** • General Overview of Biosimilars/ Biologics and opportunities for the Biopharma players • Implementation of Gene editing tools CRISPR and TALENS for cell line engineering and production improvement • Modern approaches for high producer cell line and robust upstream process development • Use of cutting-edge technologies to improve biosimilar development and manufacturing • Factors influences protein expression and critical quality attributes including glycosylation of monoclonal antibodies • mAb glycosylation and its overall Impact on biosimilarity and product performance • Case studies on titre and quality improvement at clone and process level for affordable biosimilar development **Nathan Lewis**, Associate Professor, Department of Pediatrics and Bioengineering, **UCSD** (TBC)
15:15	**Networking**
16:00	End of pre-conference workshop day

FESTIVAL OF BIOLOGICS USA

World Biosimilar Congress USA – Monday 4th March – Day 1			
	Registration and refreshments		
08:00	**Registration opens**		
08:40	**Conference doors open**		
	Biosimilar Keynotes		
09:00	Terrapinn opening remarks: **Jessica Robinson**, Project Director, **World Biosimilar Congress USA**		
09:10	**Chair's opening remarks: Maggie Dolan,** Associate Director market Access EU Biosimilars, **Biogen**		
09:15	**Case study on the development and regulatory strategy of PF708, a biosimilar candidate to Forteo** • Comparing/contrasting biosimilars vs. 505(b)(2) regulatory pathway for recombinant peptides in the US • Development of PF708, a therapeutic equivalent/biosimilar candidate to Forteo • Comparative nonclinical and clinical results between PF708 and Forteo **Hubert Chen**, Scientific & Medical Advisor, **Pfenex**		
09:40 10:10	**International stakeholders panel discussion: What can the US derive from policy and strategy across Europe in promoting biosimilar uptake?** *Consisting of industry panellists, physicians, pharmacists, patient advocacy groups, payers, regulators and health authorities, the 360° Perspective Panel allows the whole industry to come together to discuss and debate the sector's most pertinent topics of the day.* • Who are the stakeholders and what benefits are to be gained from a positive approach to biosimilars? • How have professional healthcare bodies help deliver the biosimilar agenda in Europe? • What policy approaches across Europe have driven market uptake? • What are the barriers and how can they be overcome • Are there any strategic difference in the delivery of healthcare in the US that need to be considered by biologic companies Chair: **Maggie Dolan,** Associate Director market Access EU Biosimilars, **Biogen** Health Authority: **Jonathan Sheffield,** CEO, **NIHR** Government: **Megan Keaney,** Principle Medical Advisor, **Australian Government Department of Health** Regulatory: **Bradley J. Scott**, Senior Clinical Evaluator, Clinical Evaluation Division - Haematology / Oncology, HPFB, **Health Canada** Pharmacist: **Kalveer Flora**, Lead Rheumatology and Biosimilars Specialist Pharmacist, **London North West University Healthcare NHS Trust** Patient representative: **Cheryl Koehn**, President, **Arthritis Consumer Experts**		
10:30	**Networking refreshment break**		
11:30	**Roundtable discussion session** *6 senior level tables hosted by thought leaders on key challenges and opportunities in biosimilar development, manufacturing and market access. Participants are invited to join the group discussions on a topic of importance to them. The round table session will have two rotations, each lasting 40 minutes*		
	ROUNDTABLE 1 **Tackling IP and Legal challenges** **Stacie L. Ropka**, Partner, **Axinn**	**ROUNDTABLE 2** **Dealing with competition in the biosimilar industry** **Alain Vertès**, Managing Director, **NxR Biotechnologies GmbH**	**ROUNDTABLE 3** **Market access** **Margaret (Maggie) Dolan**, Associate Director Market Access EU Biosimilars, **Biogen**
	ROUNDTABLE 4 **Agency expectations – Coping with increased quality expectations** **Dinesh Kundu,** GM, Strategy, BD & Program Management, **QbD Biosciences**	**ROUNDTABLE 5** **Global reference product in biosimilar development** **Klaas Ehrig**, Regulatory Affairs Manager, **Sandoz**	**ROUNDTABLE 6** **Development and manufacturing** **Julio Baez**, Bioengineering Industrial Advisor, **UCSD**
12:50	**Networking Lunch**		
	Commercialisation	**Development and Manufacturing**	
	Pricing, reimbursement and market access	**Development and Manufacturing**	
Chair:	**Adam Levysohn**, Sr Director Market Access Biosimilar, **Biogen**	**Julio Baez**, Bioengineering Industrial Advisor, **UCSD**	

14:20	**Unlocking the value of biosimilars in Europe- experience with the anti-tnfs** **Adam Levysohn**, Sr Director Market Access Biosimilar, **Biogen**	**Real world evidence strategies** **Mourad Farouk Rezk**, Senior Director, Global Head Medical Affairs Biosimilars, **Biogen**
14:40	**The phenomenal uptake of biosimilars in Denmark. What's the secret?** • The uptake in Denmark of biosimilars has so far not only been very high but also extremely quick. No doubt this will also be the case for the next biosimilars on the verge of entering the market • A large number of stakeholders have played a very important part. Who are they, what are their respective roles and how exactly did each of them contribute to the result? • Is this only a success story or are there any clouds on the horizon? What can anybody learn from Denmark and what will prove more difficult to copy? Will the Danish market be sustainable in the coming years? **Dorthe Bartels**, Strategic Adviser, **AMGROS**	**Employing systems biology and big data analytics for cell line development and manufacturing of biopharmaceuticals** • We have mapped out the pathways producing recombinant proteins and their glycosylation • Comprehensive omics data have been generated to detail the whole-cell impact of glycoengineering in CHO cells. • A computational model was developed that predicts how to change glycosylation to obtain innovator products **Nathan Lewis**, Associate Professor, Department of Pediatrics and Bioengineering, **UCSD**
15:00	**Achieving broad and sustainable access to biologic medicines through biosimilars** • Market opportunities • Pricing strategies • Patient discount programs • Potential Gains from Competition **Joseph Fuhr**, Adjunct Professor of Pharmaceutical & Healthcare Business, **Widener University**	**Multi-attribute monitoring for biosimilar development** • Learn about requirements for successful biosimilar development • Understand how to build an effective CMC biosimilar strategy • Discover forced degradation approaches to challenge CMC methodologies appropriate for the whole of your biosimilar development **Sian Estdale**, Global Scientific Head, **Covance Chemistry Solutions**
15:20	**Panel Discussion: How can we sustain the value proposition of biosimilars in the future as an industry?** **Chair: Adam Levysohn**, Sr Director Market Access Biosimilar, **Biogen** **Dorthe Bartels**, Strategic Adviser, **AMGROS** **Joseph Fuhr**, Adjunct Professor of Pharmaceutical & Healthcare Business, **Widener University**	**Optimization project timelines and costs of biosimilar development** • Decision on the development of biosimilar candidate development is based on timelines assessed, needed for the development, and costs associated with the development. On top of this all this is driving the business case. • Optimization can be done on different levels of development, cell line development, where you can influence the titre, process development, influencing total yield, clinical strategy in order to optimize number of trials and number of subjects. **Klemen Spaninger**, Director Project Management, **Polpharma Biologics**
15:40	Networking Break	
	Commercialisation	**Development and manufacturing**
	IP and Legal requirements	**Development and manufacturing**
Chair:	**Bruce Leicher,** Attorney and Former Senior Vice President and General Counsel, **Momenta Pharmaceuticals**	**Julio Baez**, Bioengineering Industrial Advisor, **UCSD**

16:40	**Anti-competitive deterrents to market access for biosimilars** • Regulatory Barriers to Market Entry • IP Barriers to Market Entry • Misinformation Barriers to Market Entry • Restricted Access to Reference Product • Distribution, Rebate and Contract Barriers **Bruce Leicher,** Attorney and Former Senior Vice President and General Counsel, **Momenta Pharmaceuticals**	**How improved analytical techniques and outsourcing manufacturing needs help drive the accuracy in our data** • What technologies will help us learn more about the structural features of biosimilar products? • Weighing the benefits of improved analytical techniques such as HR-MS to detect minor protein modifications • Evaluating the potentials of outsourcing analytical and manufacturing needs for faster and more accurate analytical data **Parastoo Azadi**, Technical Director, Analytical Services, **Complex Carbohydrate Research Centre**
17:00	**Patent Dancing in 2019** • Recent court decisions interpreting the BPCIA • How these decisions impact patent dance strategies • What to expect in 2019 and beyond **Ted Mathias**, Partner, **Axinn**	**Case study: CMC and manufacturing biosimilars for checkpoints inhibitors** • Modulating the upstream process to get biosimilarity without losing productivity • Achieving successful quality modulation • Novel SPOT technology to increase productivity • The dangers of higher cell densities, clarification and increasing specific productivity **Louis Boon**, CSO, **Bioceros**
17:20	**A year to review: 2018, more decisions, more launches, more unanswered questions** **Tim Shea**, Director, **Sterne Kessler Goldstein And Fox Plc**	**Expression systems for the production of affordable biosimilars** • Understanding expression systems to reduce costs while delivering the required productivity and product quality • Implementing diverse expression systems to meet needs of different regions • Integrating bioanalytic and bioprocessing with diverse expression systems to achieve the required quality **Julio Baez**, Bioengineering Industrial Advisor, **UCSD**
17:40	**Discussion on IP and market access strategies for the future of biosimilars** **Bruce Leicher,** Attorney and Former Senior Vice President and General Counsel, **Momenta Pharmaceuticals** **Joseph Fuhr**, Adjunct Professor of Pharmaceutical & Healthcare Business, **Widener University** **Ted Mathias**, Partner, **Axinn**	**Panel discussion: Critical attributes to consider when choosing an appropriate CDMO to manufacture your products** • Critical Attributes to Consider When Choosing an Appropriate CDMO • Regulatory and Quality Challenges • Effective International Sourcing and how to work with Partners? • Why culture and flexibility is important for biosimilars? **Chair: Julio Baez**, Bioengineering Industrial Advisor, **UCSD** **Parastoo Azadi**, Technical Director, Analytical Services, **Complex Carbohydrate Research Center** **Louis Boon**, CSO, **Bioceros**
18:15	**Networking drinks reception**	

FESTIVAL OF BIOLOGICS USA

World Biosimilar Congress USA – Tuesday 5th March – Day 2		
08:00	**Registration and refreshments**	
08:50	**Conference doors open**	
09:00	**Intro from chair, recap of day 1 Joseph Fuhr**, Adjunct Professor of Pharmaceutical & Healthcare Business, **Widener University**	
	Opening Keynotes: approval and post-approval of Biosimilars	
09:00	**The New FDA Biosimilars Action Plan—What to Expect?** • Time to revisit the scientific rationale for approving generics and biosimilars—breaking out from tradition and rote practice • Encouraging fast to market approaches—a challenge for both developers and FDA • Making "what is clinically meaningful" truly meaningful-- a new class of substitutable biosimilars and compliant generics **Sarfaraz Niazi**, Chairman, Professor, **Karyo Biologics/University of Illinois**	
09:20	**Ensuring biosimilar sustainability and market access in the USA and in EU** • How the US and EU biosimilar market conditions compare • Key takeaways the US market can learn from the latest years and from the EU to increase adoption of biosimilars • The outlook for biosimilars in the US **Sheila Frame**, Vice President and Head of Biopharmaceuticals, **Sandoz**	
09:40	**Biosimilars: state of clinical and regulatory science** **Bradley J. Scott**, Senior Clinical Evaluator, Clinical Evaluation Division - Haematology / Oncology, HPFB, **Health Canada**	
10:00	**Tackling regulatory and market access hurdles for biosimilars in the USA** • Barriers to Entry • FDA approval • Litigation Issues • Originator's Response • Return on Investment **Joseph Fuhr**, Adjunct Professor of Pharmaceutical & Healthcare Business, **Widener University**	
10:20	**Networking Refreshment Break**	
	Commercialisation	**Development and manufacturing**
	Regulation, reimbursement and market access	**Clinical trials and real-world evidence**
Chair:	**Steve Lehrer**, Managing Director, **SBLehrer LLC**	**Julio Baez**, Bioengineering Industrial Advisor, **UCSD**
11:20	**Hurdles on Blocking Biosimilar Development** • FDA/EMA/WHO/NMPA Guidelines on Biosimilar Development • Current Trends in Biosimilars **Alvin Luk,** Senior Vice President and Chief Medical Officer, **Shanghai Henlius**	**Exploring the need for additional clinical trial experience (post-marketing and/or ISS) and real-world data to establish clinical confidence among US HCPs** • Exploring components that are necessary to establish clinical confidence in biosimilar products • What additional clinical information is needed to help establish clinical confidence among US HCPs? • Implementation of strategies to disseminate clinical data on biosimilars for awareness and familiarization of HCPs **Gerry Hoehn**, Medical Director, Oncology, **Teva**
11:45	**Increasing the use of Biosimilars- the Australian experience**	**Case Study: Zarxio, how to improve access for patients and the value proposition of biosimilar products**

	• The Australian government's Pharmaceutical Benefits Scheme provides all Australians with access to safe, effective and cost-effective medicines • The long-term sustainability of the PBS relies on access to and uptake of generic and biosimilar medicines • Regulatory, pricing and behavioural levers are being used to increase the uptake of biosimilars • It will take some time to evaluate the success of these strategies which continue to evolve **Megan Keaney,** Principal Medical Advisor, **Australian Government Department of Health**	• Key factors that contributed to Zarxio becoming the only biosimilar to surpass its reference biologic in the US market and the impact on patient access • How real-world evidence is vital to building the biosimilar value proposition • The ways in which clinical research and RWE can substantiate biosimilars in the US **Len Arsenault**, Vice President, Policy, Medical, and External Engagement, **Sandoz**
12:10	**Biosimilars: Current requirements and experience with regulatory approvals** *Panel Discussion on regulation followed by questions from the audience* **Bradley J. Scott**, Senior Clinical Evaluator Clinical Evaluation Division - Haematology / Oncology, HPFB, **Health Canada** **Klaas Ehrig**, Regulatory Affairs Manager, **Sandoz** **Megan Keaney,** Principal Medical Advisor, **Australian Government Department of Health**	**Biosimilars in the UK's National Health Service: Trials, Access, Uptake** • Developing the nation's capacity and capability to deliver biosimilar clinical trials • Case study: Steering clear of the usual suspects • Accelerating uptake by developing clinical confidence • Case study: Spotlight on cost savings **Gareth Powell**, Business Development Officer, **NIHR Clinical Research Network (CRN)**
12:30		**Support biosimilar acceptance by giving clinician and patient control using routine diagnostics** **Serum concentrations measurements for biologics/biosimilars- real life data** • Experience from routine diagnostics on concentration and ADA measurements • One dose/ multitude of serum levels; impact of immunogenicity on PK • Validation of PK/ADA assays for originators for biosimilars; routine diagnostics vs. FDA/EMA registration **Annick de Vries**, Director Bioanalysis, **Sanquin Diagnostic Services**
12:55	**Audience Q & A**	**Audience Q & A**
13:00	**Networking Lunch**	
	Commercialisation	**Development and manufacturing**
	Emerging markets	**Development and manufacturing**
Chair:	**Steve Lehrer**, Managing Director, **SBLehrer LLC**	**Julio Baez**, Bioengineering Industrial Advisor, **UCSD**
14:00	**Small companies and Biosimilars: keys to success** • Cost effective cmc development programs with high titre and yield • Manufacture with low COGS and FTO systems • Smart cmc development • Smart (non) clinical program • Regulation evolution for Biosimilars for clinical trials **Andreu Soldevila,** Chief Executive Officer (CEO), **Syna Therapeutics**	**QA Controls and Operations: Validation Qualification & Regulatory** **Nacer E. Hedroug**, Former Director, QA Ops Injectable Vertical & Tech Transfer, **Mylan**

14:20	**Developing biosimilars in global markets challenges and opportunities** Review recent efforts to harmonize across global markets with an emphasize on increasing access to the critical medicines **Steve Lehrer**, Managing Director, **SBLehrer LLC**	**Audience Q & A**
14:40	**Panel discussion: Clinical trials – do we need them to get biosimilars approved?** • Clinical trials vs pharmacology studies, what does the current FDA and EU guidance say? • Clinical pharmacology studies: efficacy & safety • Future possibilities • Q + A with the audience Chair: **Steve Lehrer**, Managing Director, **SBLehrer LLC** **Gerry Hoehn**, Medical Director, Oncology, **Teva** **Gareth Powell**, Business Development Officer, **NIHR Clinical Research Network (CRN)**	
15:20	**Networking Break**	
	Understanding patient perspective and education of healthcare professionals	
Chair:	**Nacer E. Hedroug**, Former Director, QA Ops Injectable Vertical & Tech Transfer, **Mylan**	
15:50	**Implementation and administration of biosimilars in the clinic** **Kalveer Flora**, Lead Rheumatology and Biosimilars Specialist Pharmacist, **London North West University Healthcare NHS Trust**	
16:10	**Multi-stakeholder biosimilar reimbursement policy development: A societal benefit approach** *Biologic biosimilars offer public and private drug plans the opportunity to realize significant cost savings on off-patent biologic originators, maintain quality continuum of care and deliver societal benefit. This presentation will review the process for developing biosimilar public drug plan policy in the Canadian provincial context.* • Review the most recent biosimilar transition studies and real-world experience of transitioning from North America and Europe; • How to meaningfully engage stakeholders in the development of biosimilar reimbursement policy (perspectives and process); • Communication strategies to avoid nocebo effect* associated with transitioning patients from biologic originators to biologic biosimilars **Cheryl Koehn**, President, **Arthritis Consumer Experts** **Eric Lun**, Executive Director, Drug Intelligence, Optimization, Outcomes, and Strategy, Pharmaceutical Services Division, **BC Ministry of Health**	
16:50	**Panel discussion: Providing balanced and consistent information to patients and healthcare professionals** • Understanding how to collaborate with payers and PBMs to create greater patient access • Evaluating appropriate avenues that will enable us to continue providing balanced and consistent information to patients and providers • The importance of patient advocacy groups as a vehicle to translate information and portray a balanced message to patients • Exploring innovative approaches to market the benefits of biosimilars to the healthcare industries **Moderator: Nacer E. Hedroug**, Former Director, QA Ops Injectable Vertical & Tech Transfer, **Mylan** **Panellists:** **Cheryl Koehn**, President, **Arthritis Consumer Experts** **Eric Lun**, Executive Director, Drug Intelligence, Optimization, Outcomes, and Strategy, Pharmaceutical Services Division, **BC Ministry of Health** **Katherine Ruby,** Medical Science Liaison, **Sandoz**	
17:30	**Closing remarks from the chair**	
17:45	**Close of conference – Thank you for coming! See you in 2020!**	

FESTIVAL OF BIOLOGICS USA

CLINICAL TRIALS | AMERICAS 2019

Clinical Trials Americas

Clinical Trials Americas Speakers

Emmanuel Fombu, Global commercial strategy and Digital Innovation, **Johnson & Johnson**
Andrea Perrone, Associate Vice President, Clinical Imaging Translational Medicine, **Merck**
Christopher Boone, Vice President, Head of Real World Data and Analytics Center, **Pfizer**
Denise Steckel, Technical Alliance Manager, **Genentech**
Elise Felicione, Senior Director, R&D Operations, Innovation, **Janssen**
Mark Milberg, Senior Director, Clinical Procurement and Outsourcing, **Ultragenyx**
Matthew Bryant, Head, Clinical Technology & Experience Lab, **Amgen**
Alex Sverdlov, Director of Data, **Novartis**
Jean Claude Zenklusen, Director, The Cancer Genome Atlas, **NCI/NIH**
Rhonda Pisk, Clinical Trials Program Director, **Stanford**
Ken Wilson, Director, Sourcing Operations, **Pfizer**
Jan Davidson, Director, Clinical Development and Research, **Macrogenics**
Laura Galuchie, Transcelerate Lead, **Merck**
Neda Rashti, Group Lead, Clinical Program Management**, Pfizer**
Kyle Holen, Head, Development Design Center, **Abbvie**
Cathy Carfagno, Associate Director, IT Business Lead, Global Clinical Trials Operations, **Merck**
Adama Ibrahim, Senior Clinical Operations Lead, **Biogen** (TBC)
Jzaneen Lalani, Chief Operations Officer, **Curemark**
Mitch Herndon, Associate Director, Patient Engagement & Recruitment, **UCB**
Elizabeth Manning, Patient Engagement Strategy**, UCB**
Brenda Hann, Director, Clinical Trials Operations, **Stanford Medicine**
Mark Mamula, Professor of Medicine Rheumatology, **Yale University**
Francis Kalush, Health Program Coordinator, Center for Drug Evaluation and Research, **FDA**
Sumithra Mandrekar, Professor of Biostatistics and Oncology, **Mayo Clinic**
Jay Mandrekar, Professor of Biostatistics and Neurology, **Mayo Clinic**
Robert Metz, Sr. Vice President, Global Business Operations and External Affairs**, Horizon Pharma**
Hailey McDaniels, Administrative Director, Clinical Trials, **UC San Diego Moores Cancer Center**
Nancy Lutz Paynter, Former Director, Learning and Clinical Integration, **Genentech**
Douglas Reichgott, Director, Research Financial and Regulatory Operations, **Tufts Medical Centre**
Ian Popoff, Former Senior Director, Strategic Advisory Leader, Clinical Drug Development, Portfolio & Project Management, **Pfizer**
Jonathan Sheffield, CEO, **NIHR Clinical Research Network**
Laura Pearce, Head Clinical Alliances, **Cancer Research Institute**
Smita Asare, Executive Director, **I-SPY Trials**
Oriol Serra Ortiz, Global Head Site Intelligence**, Pfizer**
Bryan Souder, Director, TMF Head, **Merck**
Beth Zaharoff, Sr. Director, Patient Focused Engagement and Partnerships, **Tesaro**
Sheryl Lapidus, Director, Corporate Affairs and Patient Advocacy, **Tesaro**
Deepak Khatry, Science Associate Director and Team Leader, PHC, Biostatistics, **MedImmune**
Mark Cobbold, Associate Professor of Medicine, **Massachusetts General Hospital**
John Neal, Founder and Chairman of **PCRS Network, LLC**.Vice Chairman, **ACRP**

Mary Banach, Project manager, **CTSpedia – Vanderbilt Dept of Biostatistics**
Deborah Jezior, Director of Clinical Operations, **Oncternal Therapeutics**

Clinical Trials America – Sunday 3rd March - Workshop Day	
12:00	**Registration opens** **Networking lunch**
13:00	**Partnering with patient advocacy organizations to bring the patient voice into the development of clinical trials** • Strategies for determining which advocacy organizations to partner with • Tactics for bringing in the patient voice early and often • Getting buy-in from Sr. leadership on the importance of advocacy relationships and inclusion of patient voice **Beth Zaharoff,** Sr. Director, Patient Focused Engagement and Partnerships, **Tesaro** (CONFIRMED) **Sheryl Lapidus,** Director, Corporate Affairs and Patient Advocacy**, Tesaro** (CONFIRMED)
14:00	**Complex innovative designs in clinical trials** • Design, implementation, and oversight of innovative clinical trials • Benefits and challenges • What makes them more innovative than sequential designs? • What can you do now that you couldn't before? **Smita Asare**, Executive Director, **I-SPY Trials** (CONFIRMED)
16:00	**End of workshop day**

Clinical Trials Americas – Monday 4th March – Day 1	
08:00	**Registration opens**
08:30	**Conference doors open**
	Clinical Trials keynotes
09:00	**Welcome from Terrapinn**
09:05	**Chair's opening remarks** **Chiar: Smita Asare,** Executive Director, **I-SPY Trials** (CONFIRMED)
09:10	**Navigating new terrains in clinical research** • Personalisation of research • Embracing the digital revolution • Research in non-healthcare settings **Jonathan Sheffield,** CEO, **NIHR Clinical Research Network** (CONFIRMED)
09:30	**Title TBC** **Smita Asare,** Executive Director, **I-SPY Trials** (CONFIRMED)
09:50	**Keynote panel discussion: addressing the key challenges of biologics clinical trials** **Moderator: Smita Asare,** Executive Director**, I-SPY Trials** **Rhonda Pisk,** Clinical Trials Program Director, **Stanford** (CONFIRMED) **Hailey McDaniels**, Administrative Director, Clinical Trials, **UC San Diego Moores Cancer Center** (CONFIRMED) **Denise Steckel,** Technical Alliance Manager, **Genentech** (CONFIRMED)
10:30	**Networking break**
11:30	**Roundtable discussion session**

FESTIVAL OF BIOLOGICS USA

	6 senior level tables hosted by thought leaders on key challenges and opportunities in clinical trials. Participants are invited to join the group discussions on a topic of importance to them. The round table session will have two rotations, each lasting 40 minutes		
	TABLE 1 **Real world data** **Jan Davidson,** Director, Clinical Development and Research, **Macrogenics** (CONFIRMED)	TABLE 2 **Trial set up & feasibility** **Douglas Reichgott,** Director, Research Financial and Regulatory Operations, **Tufts Medical Centre** (CONFIRMED)	TABLE 3 **Optimizing clinical trial design in early research** **Robert Metz,** Sr. Vice President, Global Business Operations, **Horizon Pharma** (CONFIRMED)
	TABLE 4 **Challenges and solutions in ovarian cancer trial enrollment** **Hillary Theakston,** Exectuive Director, **Clearity Foundation** (CONFIRMED)	TABLE 5 **Managing change in your organization** **Cathy Carfagno,** Associate Director, IT Business Lead, Global Clinical Trials Operations, **Merck** (CONFIRMED) **Bryan Souder,** Director, TMF Head, **Merck** (CONFIRMED)	TABLE 6 **AI in clinical development** **Ian Popoff,** Former Senior Director, Strategic Advisory Leader, **Pfizer** (CONFIRMED)
12:50	**Networking lunch**		
	Track 1 **Patient engagement and enrolment**	Track 2 **Trial design and adaptability**	
	Chiar: John Neal, Founder and Chairman of **PCRS Network, LLC.**Vice Chairman, **ACRP**	**Chair: Sumithra Mandrekar,** Professor of Biostatistics and Oncology, **Mayo Clinic**	
14:40	**Raising awareness of clinical trials with patients and healthcare providers** • Dispelling the "guinea pig" myth by enhancing the image of the profession • Enhancing referrals from healthcare providers not usually involved in trials • Integrating clinical research into clinical practice **John Neal,** Founder and Chairman of **PCRS Network, LLC**.Vice Chairman, **ACRP**	**14:40 Clinical trial designs for personalized medicine in oncology** • The fundamentals of the personalized medicine design strategies • Underlying statistical framework • Logistical barriers for implementation of some of these designs • The interpretation of the trial results, using NCI precision medicine trials, and other Phase I, II and III trials as examples **Sumithra Mandrekar**, Professor of Biostatistics and Oncology, **Mayo Clinic** (CONFIRMED)	

15:00	**Operationalizing a clinical trial at an academic site**
	• Successful patient enrolment
	• Study feasibility review
	  ○ Accrual goals
	  ○ Special equipment/procedure
	  ○ Department feedback
	  ○ Resourcing
	• Clinical Research Group Review
	  ○ Faculty review and group approval
	• Submission of clinical research protocol for review and approvals IRB/SRC/Finance
	Brenda Hann, Director, Clinical Trials Operations, **Stanford Medicine**
		15:05 Comparative oncology: spontaneous canine cancer as models for human therapy
		• Detail the similar tumor pathology and mechanisms between canine and human cancer
		• Summarize ongoing therapeutic trials in canine cancer
		• Introduce data from tumor vaccination and immunotherapy in canine cancer
		Mark Mamula, Professor of Medicine Rheumatology, **Yale University**	

15:20	**Advancing clinical research using data analytics to improve patient engagement and experience** • How one can use novel data analytic techniques such as exploratory factor analysis and logistic		

	regression for improving patient participation, engagement and experience in clinical research studies **Jay Mandrekar,** Professor of Biostatistics and Neurology, **Mayo Clinic** (CONFIRMED)	**15:30 Improving standardization efforts in clinical development with The Clinical Development Design (CDD) framework** • CDISC standards, protocol templates, and government registries share what trials are run, data collected, and standardized submissions. Information on how clinical research is designed tends to be captured ad-hoc, making it difficult to find not just externally, but even within organizations • Proposal for a clinical development design information model • Merits for capturing design thinking in a structured manner • Past and current projects ongoing to establish a clinical development design information model, and framework **Mary Banach,** Project manager, **CTSpedia – Vanderbilt Dept of Biostatistics**
15:40	**Partnering with CROs, IRBs and study sites to drive patient recruitment** • Once a study has launched, all eyes (and pressure) focus on the patient recruitment team • To be effective, the team has to build critical relationships well before study launch and partner with key influencers, including advocacy groups, the IRB and CRO, all while developing a meaningful, comprehensive and sustainable recruitment package • This presentation will discuss ways to create an early framework for recruiting, develop important partnerships and leverage already available resources to enable the recruitment team to maximize their time and budget **Jzaneen Lalani,** Chief Operations Officer, **Curemark**	
16:00	**Afternoon refreshments**	
	Patient engagement and enrolment	**Outsourcing strategies: Site/CRO Selection and monitoring**
	Chair: John Neal, Vice Chairman, **ACRP**	**Oriol Sierra Ortiz,** Global Head Site Intelligence**, Pfizer**
17:00	**Patient partnering in clinical development: partner, learn and evolve** • Patient Value Strategy of UCB, a global biopharmaceutical company • UCB's quest of achieving patient-preferred clinical studies • Examples offering successes, challenges and learnings across UCB's clinical development programs **Elizabeth Manning,** Patient Engagement Strategy**, UCB** (CONFIRMED) **Mitch Herndon,** Associate Director, Patient Engagement & Recruitment, **UCB** (CONFIRMED)	**Evidence based site selection tactics & tools driving right site/first time** • Databases and software available which aggregates site data to enable better decision-making • How to effectively utilize data to create an ideal site profile based on feasibility, study start-up data and site experience • How can data improve transparency and reduce study start-up time and overall successful trial execution? **Oriol Sierra Ortiz,** Global Head Site Intelligence**, Pfizer** (CONFIRMED)

17:20	**Panel discussion: transforming clinical trials with patient partnerships and collaboration** • The crucial role patients play in improving the drug development process • Optimization of relationships and collaborations between sponsors, patient organizations, CROs and others • Tangible examples of patient engagement challenges and successes • How can we continue the momentum **Moderator: John Neal,** Vice Chairman, **ACRP** **Elizabeth Manning,** Patient Engagement Strategy**, UCB** (CONFIRMED) **Mitch Herndon,** Associate Director, Patient Engagement & Recruitment, **UCB** (CONFIRMED) **Robert Metz,** Sr. Vice President, Global Business Operations and External Affairs**, Horizon Pharma** (CONFIRMED)	**Panel discussion: choosing and working with CROs - how much should you take on?** • Multiple vs singular CRO input • Finding the balance between expertise and ethos • Pros and cons of different approaches • How do we measure performance? **Chair: Oriol Sierra Ortiz,** Global Head Site Intelligence**, Pfizer** **Kenneth Wilson**, Director, Sourcing Operations, **Pfizer** (CONFIRMED) **Neda Rashti,** Group Lead, Clinical Program Management**, Pfizer** (CONFIRMED) **Mark Milberg,** Senior Director, Clinical Procurement and Outsourcing, **Ultragenyx** (CONFIRMED) **Deborah Jezior,** Director of Clinical Operations, **Oncternal Therapeutics** (CONFIRMED)
18:00	Chair's end of day 1 remarks	Chair's end of day 1 remarks
	Drinks reception	

Clinical Trials Americas – Tuesday 5th March – Day 2	
08:00	Registration opens
08:30	Conference doors open
	Track 1 **Innovation in clinical technology**
09:00	**Day 2 opening remarks** **Chair: Kyle Holen**, Head, Development Design Center, **Abbvie**
09:10	**Reprogramming tumor antigenicity** **Mark Cobbold,** Associate Professor of Medicine, **Massachusetts General Hospital** (CONFIRMED)
09:35	**Panel discussion: what's slowing down uptake of technology in clinical development?** **Moderator: Kyle Holen**, Head, Development Design Center**, Abbvie** **Nancy Lutz Paynter,** FORMER Director, Learning and Clinical Integration, **Genentech** (CONFIRMED) **Mark Cobbold,** Associate Professor of Medicine, **Massachusetts General Hospital** (CONFIRMED) **Christopher Boone,** Vice President, Head of Real World Data and Analytics Center, **Pfizer** (CONFIRMED)
10:20	**Networking break**
	Data and Analytics **Real World Data**
	Mark Cobbold, Associate Professor of Medicine**, Massachusetts General Hospital**
11:30	**Genomics and clinical trials: an opportunity for precision medicine** • Genomic science is mature enough to include in patient treatment • Old style randomized clinical trials in oncology are very difficult to justify • A new era of open data collaboration between clinicians and molecular biology must be envisioned **Jean Claude Zenklusen**, Director, The Cancer Genome Atlas, **NCI/NIH** (CONFIRMED)
11:50	**Planning biomarker-enriched clinical trials and evidence synthesis to improve precision medicine practice** • Successful personalization of medicines requires unbiased data collection from prospectively planned biomarker-enriched clinical studies, objective evidence synthesis utilizing pre-specified statistical analyses, and practical presentation and communication of such evidence

	• In this presentation, I will illustrate how such clinical studies can be planned to optimize probability of trial success and to generate evidence of both therapeutic clinical efficacy and probability of meaningful clinical benefits to individual patients • Such well-considered planning will allow efficient development of precision medicines to satisfy multiple stakeholders including regulators, prescribers, payers and, ultimately, to benefit individual patients **Deepak Khatry**, Science Associate Director and Team Leader, PHC, Biostatistics, **MedImmune** (CONFIRMED)
12:10	**Using big data to help design and execute efficient, innovative clinical trials** • Demonstration of how the use of big data can help you find the right patients and decrease the timeline to your endpoints • Presentation of a case example of how big data directly influence the overall design of the clinical program • Using data sources to collect prospective, external control cohorts for non-randomized studies **Kyle Holen,** Head, Development Design Center, **Abbvie** (CONFIRMED)
12:30	**Transforming clinical trials using RWD** • Trial design • Lessons learned • Regulatory perspective **Christopher Boone,** Vice President, Head of Real World Data and Analytics Center, **Pfizer** (CONFIRMED)
12:50	**Networking lunch**
	Closing keynotes: Industry collaboration and data sharing
	Chair: Laura Galuchie, Transcelerate Lead, **Merck**
14:00	**Rationale for developing imaging criteria for immunotherapy** • Key concepts of iRECIST • The need for industry-wide image data collection **Andrea Perrone,** Associate Vice President, Clinical Imaging Translational Medicine, **Merck** (CONFIRMED)
14:20	**Non-profit-academic-industry collaboration: accelerating research for patients** • Landscape context for need to collaborate on clinical trials and translational research and to unite leading experts • Need for more efficient collaborative clinical trials, especially basket and umbrella platforms, to efficiently evaluate emerging novel therapies that will hopefully lead to faster approval of better treatments • Pros and cons to collaboration (for both industry and academia) • Challenges to and key factors in successful collaboration & partnership, including role of non-profits in fostering and facilitating collaboration **Laura Pearce,** Head Clinical Alliances, **Cancer Research Institute** (CONFIRMED)
14:40	**Case Study: working with collaborators in combination studies – CIT and beyond** • Looking at combination studies – CIT and beyond • Working with collaborators in order to optimize performance • Highlighting the key factors in making all collaborations successful **Denise Steckel,** Technical Alliance Manager, **Genentech** (CONFIRMED)
15:00	**Panel discussion: industry collaboration** • Bridging the gap between industry and academia • How can we encourage collaboration and data sharing in the industry? Chair: **Mark Lowdell**, CSO, **Inmune Bio** (CONFIRMED) **Laura Galuchie,** Transcelerate Lead, **Merck** (CONFIRMED) **Brenda Hann,** Director, Clinical Trials Operations, **Stanford Medicine** (CONFIRMED) **Elise Felicione,** Senior Director, R&D Operations**,** Innovation, **Janssen** (CONFIRMED)
15:40	**Chair's closing remarks**
15:45	**End of Conference** ***Please feel free to join the Immunotherapy and Antibody joint plenary on Combination Therapies or the Biosimilars closing plenary on Patiemt Perpective at 4pm***