FESTIVAL OF BIOLOGICS USA

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AMERICAS ANTIBODY CONGRESS 2019

Americas Antibody Congress

Americas Antibody Congress Speakers

Advisory board:

Alexey Rak, Head of Bio Structure and Biophysics, **Sanofi**
Hans Klingemann, Vice President, Research & Development, **NantKwest**
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Marilyn Kehry, Vice President, Cell and Functional Biology, **AnaptysBio**
Michael DeRidder, Head of Commercial Strategy, Oncology Cell Therapy, **GSK**
Partha Chowdhury, Senior Director and Head, Antibody Discovery, **Sanofi**
Scott Glaser, Director, Antibody Therapeutics, **GNF**

Confirmed speakers:

Adrian Guthals, Bioinformatics Scientist, **MappBio**
Alec Gross, Group Leader, Protein Engineering and Antibody Technology, **EMD Serono**
Alexey Berezhnoy, Scientist II, **MacroGenics**
Alexey Rak, Head of Bio Structure and Biophysics, **Sanofi**
Andreas Katopodis, CEO, **Anaveon**
Andrew Korytko, Research Advisor, Group Leader Protein Engineering, **Eli Lilly and Company**
Bijan Zakeri, Senior Scientist, Protein Engineering and Antibody Technologies, **EMD Serono**
Brian Champion, Chief Scientific Officer, **PsiOxus Therapeutics**
Bruce Keyt, Chief Scientific Officer, **Igm Biosciences**
Cinthia Pastuskovas, Senior Scientist, **Amgen**
Chawita (Jelly) Netirojjanakul, Senior Scientist, **Amgen**
Christoph Speiss, Senior Scientist, **Genentech**
Cory Brooks, Assistant Professor, **Fresno State**
Dana Filoti, Senior Scientist II, NBE Analytical R&D**, AbbVie**
Daryl Drummond, Senior Vice President and Head of Research, **Merrimack Pharmaceuticals**
Deryk Loo, Director, Targeted Therapeutics and Site Operations, **Macrogenics**
Eva-Maria Strauch, Assistant Professor, Dept. of Pharmaceutical and Biomedical Sciences, **University of Georgia**
Feng Wang, Professor and Principal Investigator, **Chinese Academy of Sciences**
John Karanicolas, Associate Professor, **Fox Chase Cancer Centre**
Gary Starling, Vice President, Protein Science, **Merck**
Hiraoki Suga, Professor, Department of Chemistry, **University of Tokyo**
Ho Cho, VP, Biotherapeutics, **Celgene**
Ivan Mascanfroni, Senior Scientist, Immunology Biologics, **Abbvie Bioresearch Centre**
Jack Sadowsky, Scientist, Protein Chemistry, **Genentech**
James Breitmeyer, President & CEO, **Oncternal Therapeutics**
Jay Short, Chairman, CEO, President and Co-founder, **BioAtla**
Jeffrey Froude, Military Deputy Division Chief, **DTRA RD-CBM**
Jill O'Donnell-Tormey, CEO and Director of Scientific Affairs, **Cancer Research Institute**
Jon Lai, Associate Professor, Biochemistry, **Albert Einstein College of Medicine**

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Julian Andreev, Senior Staff Scientist, **Regeneron**
Karthik Viswanathan, Director, Research, **Visterra**
Kevin Johnson, General Partner, **Medicxi**
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**
Marilyn Kehry, Vice President, Cell and Functional Biology, **AnaptysBio**
Martin Hangler, CMC Project Manager, **Genmab**
Matt Levengood, Senior Scientist, **Seattle Genetics**
Matthew Tirrell, Pritzker Director, Professor and Dean of the Faculty, **University of Chicago**
Mihriban Tuna, Vice President, Drug Discovery, **F-Star**
Partha Chowdhury, Senior Director and Head, Antibody Discovery, **Sanofi**
Patrick Burke, Associate Director, **Seattle Genetics**
Philip Newton, Scientist II, **MedImmune**
Philipp Spycher, PSI Founder Fellow, **Paul Scherrer Institut**
Qing Chai, Principal Scientist, **Eli Lilly and Company**
Rakesh Dixit, Vice President, R&D, Global Head Biologics Safety Assessment, **MedImmune**
Ramana Doppalapudi, Director of Chemistry, **Avidity Biosciences**
Richard Ding, Director, Downstream Process Development, **AnaptysBio**
Roger Beerli, CSO, **NBE Therapeutics**
Ryan Stafford, Director, Protein Engineering – Discovery, **Sutro Biopharma**
Sandeep Kumar, Senior Research Fellow, (Biotherapeutics) and Group Leader**, Boehringer Ingelheim**
Sanjaya Singh, Vice President & Global Head, **Janssen BioTherapeutics**
Scott Glaser, Director, Antibody Therapeutics**, GNF**
Senior representative, **AbCellera**
Senior representative, **AcroBiosystems**
Senior representative, **Fujifilm Diosynth Biotechnologies**
Standish Fleming, Managing Member, Owner, **Forward Ventures**
Stanley Krystek, Senior Principal Scientist, **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**
Teemu Junttila, Senior Scientist, Translational Oncology, **Genentech**
Thomas Keating, Director of Biochemistry, **Immunogen**
Thomas Pillow, Senior Scientist, Discovery Chemistry, **Genentech**
Tim Jacobs, Co-founder, **Dualogics**
Travis Young, Vice President, Biologics, **Calibr**
Vadim Klyushnichenko, VP of Pharmaceutical Development & Quality, **California Institute for Biomedical Research (Calibr)**
Yoshiko Akamatsu, Senior Principal Research Scientist, Oncology Biologics, **Abbvie**
(70/80)

Reserved:
John Reed, Head of Global R&D, **Sanofi**
Mark Throsby, EVP, and CSO, **Merus**
Yong Ben, Chief Medical Officer, **BioAtla**

Americas Antibody Congress - Sunday 3rd March 2019 –Workshop Day	
11:00	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) **Sandeep Kumar,** Senior Research Fellow, (Biotherapeutics) and Group Leader**, Boehringer Ingelheim** (CONFIRMED)
13:45	**Title to be announced** *Senior representative,* **Fujifilm Diosynth Biotechnologies** (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? **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,** Research Assistant, **Technical University of Denmark** (CONFIRMED) **Kristen Harrington-Smith,** VP and Head, CAR-T, **Novartis Oncology** (invited) **Sara Radcliffe,** President and CEO, **California Life Science Association (CLSA)** (invited) **Johanna Mercier,** President and Head of US Commercial, **Bristol Myers-Squibb** (invited) **Maureen Kelly,** Group Medical Director, **AbbVie** (invited)
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) **Standish Fleming,** Managing Member, Owner, **Forward Ventures** (CONFIRMED) **Jean-Francois Formela,** MD, Partner, **Atlas Venture** (invited)
16:00	End of pre-conference workshop day

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<table>
<tr><th colspan="4">Americas Antibody Congress - Monday 4th March 2019 – Day 1</th></tr>
<tr><td>07:00</td><td colspan="3">Registration opens</td></tr>
<tr><td>08:00</td><td colspan="3">Conference doors open</td></tr>
<tr><td></td><td colspan="3">Opening keynotes</td></tr>
<tr><td>09:00</td><td colspan="3">Welcome from Terrapinn
Joan Shutt, Project Manager, Festival of Biologics 2019</td></tr>
<tr><td>09:05</td><td colspan="3">Chair’s opening remarks</td></tr>
<tr><td>09:10</td><td colspan="3">Multispecific antibodies to treat HIV
Gary Nabel, Chief Scientific Officer, Sanofi (invited)</td></tr>
<tr><td>09:30</td><td colspan="3">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

Sanjaya Singh, Vice President & Global Head, Janssen BioTherapeutics (CONFIRMED)</td></tr>
<tr><td>09:50</td><td colspan="3">Advancements in antibody drug conjugates: therapeutic challenges of safety and efficacy
• Next generation ADCs with improved antibodies, payload, linkers, conjugation technology
• Lessons learned from the clinical development of ADCs
• Maximizing efficacy while minimizing toxicities
• ADC disposition, PK-PD challenges
• Translational challenges to ADC development
• Looking at the future of ADCs

Rakesh Dixit, Vice President, R&D, Global Head Biologics Safety Assessment, MedImmune (CONFIRMED)</td></tr>
<tr><td>10:10</td><td colspan="3">Title to be announced
Reserved for Fujifilm Diosynth Biotechnologies</td></tr>
<tr><td>10:30</td><td colspan="3">Morning networking break</td></tr>
<tr><td>11:30</td><td colspan="3">Plenary roundtable session
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 30 minutes.</td></tr>
<tr><td></td><td>TABLE 1
Protein engineering

Andrew Korytko, Research Advisor, Group Leader, Protein Engineering, Eli Lilly and Company (CONFIRMED)</td><td>TABLE 2
Recent advances in bispecific/multispecific antibodies and their clinical applications

Stephen Demarest, Senior Research Fellow, Eli Lilly and Company (CONFIRMED)</td><td>TABLE 3
Strategies for generating antibodies to challenging targets

Scott Glaser, Director, Antibody Therapeutics, GNF (CONFIRMED)</td></tr>
<tr><td></td><td>TABLE 4
Clinical assay development for ADCs

Leo Kirkovsky, Director, Clinical Assay Group, Pfizer (CONFIRMED)</td><td>TABLE 5
ADC’s in an Immuno-Oncology world – What is the opportunity?

Ho Cho, VP, Biotherapeutics, Celgene (CONFIRMED)</td><td>TABLE 6
Advancement in ADCs

Rakesh Dixit, Vice President, R&D, Global Head Biologics Safety Assessment, MedImmune (CONFIRMED)</td></tr>
<tr><td></td><td>TABLE 7
Just-in-time production of antibodies

Bijan Zakeri, Senior Scientist, Protein Engineering and Antibody Technologies, EMD Serono (CONFIRMED)
Alec Gross, Group Leader, Protein Engineering and Antibody Technology, EMD Serono (CONFIRMED)</td><td>TABLE 8
Nanobodies

Cory Brooks, Assistant Professor, Fresno State (CONFIRMED)</td><td>TABLE 9
Developing bispecifics

Moderator to be announced</td></tr>
</table>

	TABLE 10 Reserved for supporting partner *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	TABLE 11 Reserved for supporting partner *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	TABLE 12 Reserved for supporting partner *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*
12:30	**Speed networking** A fun, exciting and effective way to make a lot of initial connections (in a very different environment from the standard business networking meetings).		
12:50	Networking Lunch		
	Armed antibodies	**Bispecifics**	**mAbs and novel modalities**
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 proteomics screen to select potential ADC targets** • Rapid constitutive lysosomal internalization of Prolactin Receptor (PRLR) is the mechanism behind PRLR ADC efficacy. • By bridging PRLR, or another high turnover protein, Amyloid Precursor-like Protein 2 (APLP2), with surface tumor target HER2 using bispecific antibodies, HER2 lysosomal degradation can be triggered, and HER2 ADC efficacy can be significantly improved. • Our study opens up a possibility to exploit high turnover proteins such as PRLR and APLP2 in combination with bispecific antibodies to enhance efficacy of ADCs **Julian Andreev**, Senior Staff Scientist, **Regeneron** (CONFIRMED)	**Revolutionizing antibody cancer therapy- Conditionally Active Biologics (CABs)** • Increasing the therapeutic window for biologics for greater efficacy and safety • Expanding the number of druggable targets by shifting selectivity from the target to the drug • Discovering, engineering and evolving antibodies for their untapped selective and reversible activation in disease microenvironments, while minimizing the risk of immunogenicity • Enabling and advancing combination immuno-oncology therapies for more effective therapies **Jay Short,** Chairman, CEO, President and Co-founder, **BioAtla** (CONFIRMED)
14:40	**Evolution and advancements in cancer immunotherapy** **Partha Chowdhury,** Senior Director and Head, Antibody Discovery, **Sanofi** (CONFIRMED)	**Title TBC** **Teemu Junttila,** Senior Scientist, Translational Oncology, **Genentech** (CONFIRMED)	Reserved for **AbCellera**
15:00	**Preclinical Validation of 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 endows the ADC with superior	**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 of Fc:FcγR interactions and ADCC-mediated T cell depletion	**Application of homogeneous time resolved fluorescence in antibody discovery and protein engineering: A case study** • Successful biochemical and mechanistic characterisation of a lead antibody molecule using HTRF • Implementation of high throughput HTRF epitope competition assays as a surrogate affinity screen

	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)	• 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)	• Novel application of HTRF in the reengineering of a lead antibody to address target mediated antibody clearance in vivo **Philip Newton,** Scientist II, **MedImmune** (CONFIRMED)
15:20	*Reserved for supporting partner* *If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*	**Bispecific antibodies for conditional activation of immune cells** • How the formats makes differences for conditional activation • How to control toxicity of immune agonists by design • How affinity of agonist antibody impact efficacy and toxicity in mouse models **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 Defense for the development of Biologics. • Application of novel formats and the utility of effector function in order to optimize ADME properties **Jeffrey Froude,** Military Deputy Division Chief, **DTRA RD-CBM** (CONFIRMED)
15:40	Afternoon networking break		
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)
17:00	*Reserved for supporting partner* *If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*	**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	**Identifying unique disease targets and design and engineer effective therapeutics** **Karthik Viswanathan,** Director, Research, **Visterra**

		• Progess on the development of DLA001, a bispecific antibody therapy for the treatment of Type I Diabetes **Tim Jacobs,** Co-founder, **Dualogics** (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 candiates for multiple disease indications **Ramana Doppalapudi,** Director of Chemistry, **Avidity Bioscences** (CONFIRMED)	**Title TBC** **Cinthia Pastuskovas,** Senior Scientist, **Amgen** (CONFIRMED)	**Antibody discovery and pre-clinical development for autoimmune/inflammatory disease** • Immune checkpoint molecules on T cells function to down regulate antigen-specific immune responses • Agonist anti-checkpoint antibodies are anticipated to augment endogenous inhibitory signals and be efficacious for treatment of T-cell driven autoimmune and inflammatory diseases • Checkpoint agonist antibody discovery, affinity maturation and functional requirements will be presented • Optimization of biophysical characteristics of candidates prior to pre-clinical development will be presented, including thermal stabilization and high concentration pre-formulation **Marilyn Kehry,** Vice President, Cell and Functional Biology, **AnaptysBio** (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 **Chawita (Jelly) Netirojjanakul,** Senior Scientist, **Amgen** (CONFIRMED)	**Targeting solid tumors with bispecific antibody armed activated T cells (BATs)** • Bispecific antibodies can be used to retarget effector T cells to tumor antigens • Clinical targeting of solid tumors induces adaptive cellular and humoral immunity • Targeting of tumors induces Th1 cytokines in patients • 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)	**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 • 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		

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Americas Antibody Congress - Tuesday 5th March – Day 2			
08:00	Registration opens		
08:30	Conference doors open		
	Armed antibodies	**Bispecifics**	**CMC, developability and manufacturing**
09:00	**New payloads for antibody-drug conjugates** • Exploring drugs with novel mechanisms of action and learning the requirements for effective ADC payloads • Impact of drug load on ADC activity • The importance of payload metabolism and how to avoid using antibody or small molecule engineering **Thomas Pillow**, Senior Scientist, Discovery Chemistry, **Genentech** (CONFIRMED)	**Engineering of a T-cell dependent bispecific to broaden the therapeutic index for solid tumors** • Engineering and fine-tuning of the bispecific to achieve selective binding to tumor cells • Data demonstrating improved TI in in vitro and in vivo tumor models • Preclinical safety studies supporting tolerability **Christoph Speiss,** Senior Scientist, **Genentech** (CONFIRMED)	Title to be announced
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)	**Just-in-time production of bispecific antibodies and other IgG scaffolds for rapid screening** • Modular and rapid assembly of antibody scaffolds • Bispecific, IgG-like, and ADC formats • Enabling faster screening and concept validation studies **Bijan Zakeri,** Senior Scientist, Protein Engineering and Antibody Technologies, **EMD Serono** (CONFIRMED)	*Reserved for supporting partner* *If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*
09:40	**Payload considerations for IMGN632, a CD123-targeting ADC for acute myeloid leukemia** **Thomas Keating,** Director of Biochemistry, **Immunogen** (CONFIRMED)	**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 **Jon Lai**, Associate Professor, Biochemistry, **Albert Einstein College of Medicine** (CONFIRMED)	**Integrating new biophysical and structural biology methods to improve Biologics** • New low protein consuming, high throughput biophysical methods for mAbs, ADCs, multi-specific Biologics • Computational biophysics to predict biologics long terms stability • Structural biology for Ab-Ag affinity modulation, biologics stability optimization **Alexey Rak,** Head of Bio Structure and Biophysics, **Sanofi** (CONFIRMED)
10:00	*Reserved for supporting partner* *If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*	**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	*Reserved for supporting partner* *If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*

		• Proteogenomic analysis of inflamed tissues for new targets and biomarkers identification **Ivan Mascanfroni,** Senior Scientist, Immunology Biologics, **Abbvie Bioresearch Centre** (CONFIRMED)		
10:20	Morning networking break			
	Armed antibodies	**Bispecifics**	**CMC, developability and manufacturing**	**Technology showcase**
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 **Jack Sadowsky,** Scientist, Protein Chemistry, **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 • oLow 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)	**Effective CMC Development for Bispecific Antibodies: DuoBody technology: A versatile platform for generating bispecific antibodies** • Platform-based approaches for development and manufacture of Bispecifics • Highlighting streamlined approach from DNA to FIH GMP manufacturing processes • Case studies detailing recent CMC approaches in the development of a range of bispecific therapeutics **Martin Hangler,** CMC Project Manager, **Genmab** (CONFIRMED)	Reserved for **BioDuro**
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 tumor 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-tumor 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 tumor associated antigen, CD19 or mesothelin. • These dual-targeting kappa-lambda bodies are fully human immunoglobulins of the	Title to be announced	Reserved for **Avacta**

		IgG1 subtype. As such, they induce strong Fc-mediated tumor cell killing in vitro and in vivo. • They also promote T cell mediated anti-tumor immunity through the enhancement of antibody-directed tumor 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 **Philipp Spycher,** PSI Founder Fellow, **Paul Scherrer Institut** (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 favorable exposure in vivo. • Complete elimination of tumors in both xenograft and primary, patient derived models. **Travis Young,** Vice President, Biologics, **Calibr** (CONFIRMED)	**Development of modern biologics through global CMOs** • Process developmend 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, **California Institute for Biomedical Research (Calibr)** (CONFIRMED)	*Reserved for supporting partner* *If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*
12:20	**Engineering STRO-002: A SARbodyTM 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-	**New scaffold of bispecific antibodies and their applications** • A new platform of generating bispecific antibodies • Using a heterodimeric bispecific antibody to recruit T cells against tumor **Feng Wang,** Professor and Principal Investigator, **Chinese**	*Reserved for supporting partner If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*	*Reserved for supporting partner* *If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*

	aminophenyl 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 favorable pharmacological profile **Ryan Stafford,** Director, Protein Engineering – Discovery, **Sutro Biopharma** (CONFIRMED)	**Academy of Sciences** (CONFIRMED)		
12:40	Networking lunch			
	Computational tools for antibody engineering and characterisation	**Non-antibody approaches and small peptide formats**	**CMC, developability and manufacturing**	**Technology showcase**
14:10	**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 with regard to safety, efficacy, and manufacturability **Stanley Krystek,** Senior Principal Scientist, **Bristol Myers-Squibb** (CONFIRMED)	**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 **Matt Levengood**, Senior Scientist, **Seattle Genetics** (CONFIRMED)	**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-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)	*Reserved for supporting partner* *If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*
14:30	**Exploration of small protein folds and their defining features** • We developed a computational platform that enables us to efficiently sample and	**From constrained peptides to biologics** • Highly potent macrocyclic peptides against various targets selected by an in vitro display system	*Reserved for supporting partner* *If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*	*Reserved for supporting partner* *If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*

	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)	• Dimerization of macrocyclic peptides making them with antibody-like potency • Converting them into another modality **Hiraoki Suga,** Professor, Department of Chemistry, **University of Tokyo** (CONFIRMED)		
14:50	*Reserved for supporting partner* *If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*	**Protein analogous micelles: versatile, modular nanoparticles** • Peptides are functional modules of protein macromolecules that can be displayed apart from the whole protein to create biofunctional 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	Title to be announced	*Reserved for supporting partner* *If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*

		of the Faculty, **University of Chicago** (CONFIRMED)		
15:10	**e Novo MS/MS sequencing of native human antibodies** **Adrian Guthals,** Bioinformatics Scientist, **MappBio**	**Modulating antibody structure and function through directed mutations and chemical rescue**	Title to be announced **Jonny Finlay,** CEO, **Ultrahuman** (invited)	*Reserved for supporting partner* *If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297*
15:30	Afternoon networking break			
	Closing keynotes **Combination therapies and IO formats**			
16:30	Title to be announced **John Reed,** Head of Global R&D, **Sanofi** (invited)			
16:50	**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**, Vice President, Protein Science, **Merck** (CONFIRMED)			
17:10	**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)			
17:30	**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)			
17:50	**Closing remarks**			
18:00	End of conference			

FESTIVAL OF BIOLOGICS USA

WORLD IMMUNOTHERAPY CONGRESS USA 2019

World Immunotherapy Congress USA

World Immunotherapy Congress USA Speakers

Johanna Mercier, President and Head, U.S. Commercial, **Bristol-Myers Squibb**
Christine Brown, Associate Research Professor, **City of Hope**
Jim Caggiano, CEO, **Dendreon**
Mark Lowdell, Director of Cellular Therapy, **UCL,** CSO and Founder, **InMuneBio**
Karin Jooss, Executive Vice President of Research, Chief Scientific Officer, **Gritstone Oncology**
Franz-Josef Obermair, Chief Executive Officer**, Tepthera**
Peter Emtage, Global Head of Cell Therapy Research**, Kite**
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**
Michael DeRidder, Head of Commercial Strategy, Oncology Cell Therapy**, GSK**
Fred Ramsdell, SVP, Research, **Parker Institute**
Alan K. Smith, Executive Vice President, Technical Operations, **Bellicum**
Christina Yi, Chief Operations Officer, **Dendreon**
Raymond Tesi, Chief Executive Officer, **INmune Bio**
James Breitmeyer, Chief Executive Officemanur, **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**
Matthew Hewitt, Director, Tumour Immunology & Microenvironment**, Bellicum Pharmaceuticals**
Hans Klingemann, VP, Research and Development**, NantKwest**
Martin Treder, Chief Scientific Officer, **Affimed Therapeutics**
Sari Pesonen, VP, Scientific and Clinical Development, Co-Founder, **Valo Therapeutics**
Angie Park, Sr. Director of Immunotherapy and Stem Cells, **OncoMed Pharmaceuticals**
Steven Deitcher, Former Chief Executive Officer, **Medeor Therapeutics**
Rafael Vargas, Director, LATAM Biomarker & Diagnostics Leader**, Merck**
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, Assistant Professor of Medicine, **UCSD**
Christopher Jewell, Assistant Professor & Associate Chair for Research, **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**
Bernard Vanhove, Chief Operating Officer, **OSE Immuno Therapeutics**
(48/60)

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	**SDCPI workshop** • A series of short presentations by members of the **San Diego Center for Precision Immunotherapy** Chaired by **Ezra Cohen,** Associate Director, **U.C. San Diego Moores Cancer Center** **Speakers TBC**
16:00	**End of workshop day**

FESTIVAL OF BIOLOGICS USA

World Immunotherapy Congress USA – Monday 4th March – Day 1			
07:30	**Registration opens**		
08:30	**Conference doors open**		
	Immunotherapy keynotes		
08:55	**Welcome from Terrapinn**		
09:00	**Chair's opening remarks**		
09:10	**Sara Kenkare-Mitra,** Senior Vice President, Development Sciences, **Genentech** (invited)		
09:30	**Reserved for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*		
09:50	**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) **Peter Emtage**, Global Head of Cell Therapy Research**, Kite** (CONFIRMED) **Matthew Hewitt,** Director, Tumour Immunology & Microenvironment**, Bellicum Pharmaceuticals** (CONFIRMED)		
10:30	**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 30 minutes		
	TABLE 1 **ROI for IO Biomarkers** **Steffan Ho**, Vice President and Head of Translational Oncology, **Pfizer** (CONFIRMED)	TABLE 2 **Individualized therapeutic cancer vaccines – How to select for immunogenic neoantigens?** **Franz-Josef Obermair,** CEO, **Tepthera** (TBC)	TABLE 3 **Non-oncology: personalised cellular immunotherapies to improve outcomes in organ transplant recipients** **Steven Deitcher,** Former Chief Executive Officer, **Medeor Therapeutics** (CONFIRMED)
	TABLE 4 **Autoimmune side effects of cancer immunotherapy** **Mario Ehlers,** Senior Medical Director, **Eli Lilly** (CONFIRMED)	TABLE 5 **Title to be announced** **Deepak Khatry,** Science Associate Director and Team Leader, PHC, Biostatistics, **MedImmune** (CONFIRMED)	TABLE 6 **Title to be announced**
	TABLE 7 **Reserved for sponsor** *If interested, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	TABLE 8 **Reserved for sponsor** *If interested, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	TABLE 9 **Reserved for sponsor** *If interested, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*
12:30	**Speed networking** A fun, exciting and effective way to make a lot of initial connections (in a very different environment from the standard business networking meetings).		
12:50	**Networking lunch**		
	Track 1 **Cell Therapy**	Track 2 **Cancer vaccines**	
	Chair: **Matthew Hewitt,** Director, Tumour Immunology & Microenvironment**, Bellicum Pharmaceuticals**		
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	**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	

	• 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)	**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 • 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 Pharma semi-allogeneic cancer vaccine: how abortive allogeneic immune response can prime and boost the induction of specific anti-tumor T cells?** • 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**
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	**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.

	James Breitmeyer, Chief Executive Officer, **Oncternal Therapeutics** (CONFIRMD)	• 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	**Therapeutic strategies based on Innate Immunity and Affimed's ROCK® platform** • Harnessing innate immunity by immune cell engagement is a promising approach for the therapy of cancer patients • Affimed has developed a differentiated modular antibody platform, ROCK® (redirected optimized cell killing), which enables the development of high affinity engagers of innate immune effector cells (NK cells and macrophages) and targeting specific receptors on cancer cells • Promising clinical efficacy and safety data as single agents and in combination with the checkpoint inhibitor pembrolizumab will be discussed in addition to further combination of ROCK®-based bispecific antibodies with other IO agents **Martin Treder,** Chief Scientific Officer, **Affimed Therapeutics** (CONFIRMED)	**The microbiome in cancer** • Review of the current understanding of how the microbiome influences response to immune checkpoint blockade in cancer • A summary of potential mechanisms of microbial pathogenesis in cancer • Highlighting the future directions for microbiome science in cancer immunotherapy **Sandip Patel,** Medical Oncologist, Assistant 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)	**Reserved for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*
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,** Assistant Professor & Associate Chair for Research, **University of Maryland** (CONFIRMED)
18:15	**Offsite drinks reception**	

FESTIVAL OF BIOLOGICS USA

World Immunotherapy Congress – Tuesday 5th March – Day 2		
08:00	Registration opens	
09:00	Conference doors open	
	Track 1 **Morning keynotes: commercial updates on approved products**	
09:00	**Case study: Kymriah** **Pascal Touchon**, SVP and Global Head Cell and Gene, **Novartis** (TBC)	
09:20	**Reserved for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	
09:40	**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)	
10:00	**Panel discussion: Commercial strategies in immunotherapy** • High level pharma companies come together to discuss their strategies for tackling cancer **Chair: Alain Vertes,** Managing Director**, NxR Biotechnologies** (CONFIRMED) **Michael DeRidder,** Head of Commercial Strategy, Oncology Cell Therapy, **GSK** (CONFIRMED) **Johanna Mercier**, President and Head, U.S. Commercial, **Bristol-Myers Squibb** (CONFIRMED) **Jim Caggiano**, CEO, **Dendreon** (CONFIRMED) **Puja Sapra,** Vice President and Chief Scientific Officer, Targeted Therapeutics Discovery, Oncology R&D, **Pfizer** (invited) **Michael Kalos,** Vice President, **Johnson & Johnson** (invited)	
10:40	**Networking break**	
	Track 1 **Checkpoint inhibitors**	**Track 2** **Manufacturing and logistics**
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, **Fred Parker Institute** (CONFIRMED)	**Logistics and supply chain management for cell therapy** • Shipper suitability, features and options • Maintaining chain of custody for starting material and product • Logistics reliability and options • Supply chain sustainability and scale-out **Alan K. Smith,** Executive Vice President, Technical Operations, **Bellicum** (CONFIRMED)
12:00	**Title TBC** **Bernard Vanhove,** Chief Operating Officer, **OSE Immuno Therapeutics** (CONFIRMED)	**Reserved for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*
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)	**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** (CONFIRMED)

12:40	**Targeting Immune Checkpoints with Humabody VH Therapeutics** • Crescendo Biologics develops Humabody VH products, small highly adaptable and flexible proteins which can be developed into differentiated therapeutics • Crescendo's approach to developing differentiated Immuno oncology therapeutics **James Legg**, SVP R&D, **Crescendo Biologics** (CONFIRMED)	**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** (CONFIRMED)
13:00	**Networking lunch**	
	Checkpoint Inhibitors	**Neoantigens**
14:00	**Preclinical Evaluation of an Agonist GITR Ligand** • A linker-less GITRL trimer-Fc fusion protein was generated by OncoMed's TNF superfamily ligand engineering platform • GITRL demonstrated a robust preclinical anti-tumor activity in syngenic mouse tumor models • GITRL also showed anti-tumor activity in aging mice **Angie Park**, Sr. Director of Immunotherapy and Stem Cells, **OncoMed Pharmaceuticals** (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)	**Reserved for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*
14:40	**Reserved for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	**Personalized adoptive cellular therapy targeting myelodysplastic syndrome (MDS) stem cell neoantigens (PACTN)** • Scientific rationale and approach to personalized, neoantigen-driven adoptive immunotherapy • Evidence for neoantigen-reactive T cell specificity for MDS stem cells • Feasibility of the PACTN approach in a phase 1 clinical trial **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 • 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	**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 • 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

	Frédéric Triebel, Chief Scientific Officer, Chief Medical Officer, **Immutep** (CONFIRMED)	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**	
16:30	**Title TBC** **John Reed,** Head of Global R&D, **Sanofi** (invited)	
16:50	**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)	
17:10	**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)	
17:30	**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)	
17:50	**Chair's closing remarks**	
18:00	**End of conference - on site drinks reception**	

World Biosimilar Congress USA

World Biosimilar Congress USA Speakers

Adam Levysohn, Sr Director Market Access Biosimilar, **Biogen**
Adnan Sabir, Assoc. Director, QA, **Kowa Pharmaceuticals America, Inc.**
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**
Bernd Liedert, Senior Clinical Director, TA Biosimilars, **Boehringer Ingelheim**
Bruce Leicher, Attorney and Former Senior Vice President and General Counsel, **Momenta Pharmaceuticals**
Bryan Kim, Vice President, Business Development, **Samsung Bioepis**
Cecil Nick, Vice President, Biotechnology, **PAREXEL**
Cheryl Koehn, President, **Arthritis Consumer Experts**
Chrys Kokino, Head of Global Biologics & Insulins Commercial, **Mylan**
Dinesh Kundu, GM, Strategy, BD & Program Management, **Intas Biopharmaceuticals**
Don Stewart, CEO, **Plantform Corporation**
Florian Turk, Head Global Payor Marketing, Sales and Relations, **Sandoz Biopharmaceuticals**
Gerry Hoehn, Medical Director, Oncology, **Teva**
HoUng Kim, Head of Strategy & Operations Division, **Celltrion**
Hubert Chen, Chief Medical & Scientific Officer, **Pfenex**
Ian Henshaw, Global Head of Biogen's Biosimilars Unit**, Biogen**
Jonathan Sheffield, CEO, **NIHR**
Julio Baez, Former Head Technology, **Cipla Biotech**
Kalveer Flora, Specialist Pharmacist Rheumatology and Biosimilars, **London North West Healthcare NHS Trust**
Kevin Choi, Director of Marketing Department, **Celltrion Healthcare**
Klemen Spaninger, Director Project Management, **Polpharma Biologics**
Larry LaMotte, Principal Consultant, **Advocacy Options, LLC**
Maggie Dolan, Associate Director market Access EU Biosimilars, **Biogen**
Mareike Ostertag, Director Science & Regulatory policy, **Novartis**
Matt Cooper, Business Development & Marketing Director**, NIHR**
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**
Parastoo Azadi, Technical Director, Analytical Services, **Complex Carbohydrate Research Center**

Peg Ford, Co-Founder/ President, **Ovarian Cancer Alliance of San Diego**
Peter Jørgensen, CEO, **Danish Generic and Biosimilar Medicines Industry Association (IGL)**
Racho Jordanov, CEO, **JHL Biotech Inc.**
Roman Drai, Director, Clinical Development, **GEROPHARM**
Ruediger Jankowsky, Managing Director, **Cinfa Biotech**
Shubhadeep Sinha, Senior Vice- President, Dept. of Clinical Development & Medical Affairs (CD&MA), **Hetero Labs Limited**
Vanessa Schiavo, Head of Regulatory Affairs and CMC, **Libbs Farmacêutica**
Vimal Gandhi, Director, Global Biosimilar Operations and Strategy, **AstraZeneca**
Sarfaraz Niazi, Chairman, Professor, **Karyo Biologics/University of Illinois**
TBC: Julie Ann Rosenberg, Development Asset Lead Oncology Biosimilars, **Pfizer Essential Health**
TBC: Tiffany Mccaslin, Senior Policy Analyst**, National Business Group on Health**
TBC: Maria-ceu Machado, President, **INFARMED**
TBC: Bradley J. Scott, Senior Clinical Evaluator, Clinical Evaluation Division - Hematology / Oncology, HPFB, **Health Canada**
TBC: Francis Rienzo, Interim CEO, **Medicaid Plans of America**
TBC: Katherine Ruby, Medical Science Liason, Biosimilars, **Sandoz**
(48/50)

World Biosimilar Congress USA - Sunday 3rd March – Workshop Day	
11:00	Registration
12:00	Networking Lunch
13:00	**Analytics and innovation –** The role it plays in the current and future state of biosimilars **Julio Baez**, Former Head of Technology, **Cipla BioTec** (confirmed) **Marie Smith**, Regional Account Manager Integrated Managed Health Care, **Abbvie** (invited) **Yi Du**, Director, Strategic Alliances, **Huahai Pharma** (invited)
13:45	**Panel Discussion: How can we sustain the value proposition of biosimilars in the future as an industry?** **Chair: Ian Henshaw**, Global Head of Biogen's Biosimilars Unit, **Biogen** **Erin Federman,** VP, Head of Biologics, **Mylan** (invited) **Florian Turk**, Head Global Payor Marketing, Sales and Relations, **Sandoz Biopharmaceuticals** (confirmed) **Alain Vertès**, Managing Director, **NxR Biotechnologies GmbH** (confirmed)
14:30	**Payer, physician and patient education –** How can we ensure that industry message is aligned, and stakeholders are well informed? **James Kent**, Regional Medicine Procurement Specialist, East of England, **NHS England** (invited) **Maria Nishi**, Director, **Merck** (invited) **JC Rozendaal**, Director, **Sterne, Kessler, Goldstein & Fox P.L.L.C.** (invited) **Mark Prygoda**, Group Product Manager, **Genentech** (invited) **Orian Regnier**, Short Acting Insulin biosimilar Lead, **Sanofi-Aventis Groupe** (invited) **Katherine Ruby**, Medical Science Liaison, Biosimilars, **Sandoz** (invited)
15:15	End of pre-conference workshop day

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World Biosimilar Congress USA – Monday 4th March – Day 1			
	Registration and refreshments		
07:00	**Registration opens**		
09:00	**Conference doors open**		
	Biosimilar Keynotes		
09:10	**Chair's opening remarks:**		
09:15	**Keynote interview: Balancing biosimilars, biobetters and new molecular entities – discussing Pfenex's next moveHow past experiences play a vital role in the current and future state of biosimilar products** • How recent advances in regulatory science and guidance are influencing the development of biosimilars and complex generics: case study with teriparatide • How Pfenex looks to drive its current pipeline and evolve its resources to enter new avenues • How to maintain the right balance between adding more novel proteins and maintaining a presence in biosimilars/complex generics space **Hubert Chen**, Chief Medical and Scientific Officer, **Pfenex** (CONFIRMED)		
09:35 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** (CONFIRMED) Patient advocate: **Peg Ford**, Co-Founder/ President, **Ovarian Cancer Alliance of San Diego** (CONFIRMED) Health Authority: **Jonathan Sheffield,** CEO, **NIHR** (CONFIRMED) Government: **Megan Keaney,** Principle Medical Advisor, **Australian Government Department of Health** (CONFIRMED) Payer: **Francis Rienzo,** Interim CEO, **Medicaid Plans of America** (invited) Regulatory: **Bradley J. Scott**, Senior Clinical Evaluator, Clinical Evaluation Division - Hematology / Oncology, HPFB, **Health Canada** (invited) **Maria-ceu Machado**, President, **INFARMED** (invited) Health Authority: **Tiffany Mccaslin**, Senior Policy Analyst**, National Business Group on Health** (invited)		
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 30 minutes*		
	ROUNDTABLE 1 **Tackling IP and Legal challenges** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	**ROUNDTABLE 2** **Dealing with competition in the biosimilar industry** **Alain Vertès**, Managing Director, **NxR Biotechnologies GmbH** (CONFIRMED)	**ROUNDTABLE 3** **Optimizing Biosimilars´ Studies from a ClinOps Perspective** **Bernd Liedert**, Senior Clinical Director, TA Biosimilars, **Boehringer Ingelheim** (CONFIRMED)
	ROUNDTABLE 4 **Market access** **Margaret (Maggie) Dolan**, Associate Director Market Access EU Biosimilars, **Biogen** (CONFIRMED)	**ROUNDTABLE 5** **Agency expectations – Coping with increased quality expectations** **Dinesh Kundu,** GM, Strategy, BD & Program Management, **Intas Biopharmaceuticals** (CONFIRMED)	**ROUNDTABLE 6** **Global reference product in biosimilar development** **Mareike Ostertag**, Director Science & Regulatory policy, **Novartis** (CONFIRMED)

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	ROUNDTABLE 7 **Development and manufacturing** **Julio Baez**, Former Biotechnology Leader, **Cipla BioTec** (CONFIRMED)		
12:30	**Speed Networking -** *A fun, exciting and effective way to make a lot of initial connections (in a very different environment from the standard business networking meetings)*		
13:00	**Networking Lunch**		
	Commercialisation	**Development and Manufacturing**	
	Pricing and reimbursement	**Development and Manufacturing**	
Chair:	To be announced	To be announced	
14:20	**Re-visiting Benefits of Biosimilars in the Era of Value-based Care** • Improving patient access • Biologics in earlier stage • Impact of biosimilars in oncology • Value addition **HoUng Kim**, Head of Strategy & Operations Division, **Celltrion** (CONFIRMED)	**Navigating the development journey - from choosing the right cell line to entering commercialization** • From cell line to commercialization – understanding the questions of which molecules, which markets, how and when • Analysing product development - cell lines vs cell lines with process; in-house vs outsourced or combination; case studies/examples from the biosimilar world • Increasing quality expectations from Agencies for both analytical & clinical – how small companies cope with that • Leveraging the external expertise to help take your products to commercialization quicker – decrease the timeline to commercialization **Racho Jordanov**, CEO, **JHL Biotech Inc.** (CONFIRMED)	
14:40	**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** (CONFIRMED)	**Case Study: Developing biosimilars with a tobacco plant expression system** • Pros and cons of alternative expression systems for biosimilars • Expression and post-translational modification in plant systems • Approaches to large scale cGMP manufacturing with plant systems **Don Stewart**, CEO, **Plantform Corporation** (CONFIRMED)	
15:00	**Achieving broad and sustainable access to biologic medicines through biosimilars** **Florian Turk**, Head Global Payor Marketing, Sales and Relations, **Sandoz Biopharmaceuticals** (CONFIRMED)	**Using synergistic antibody screening to develop Herceptin biosimilars** **SPEAKING OPPORTUNITY AVAILABLE** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	
15:20	***A year to review: 2018, more decisions, more launches, more unanswered questions*** **SPEAKING OPPORTUNITY AVAILABLE** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	**How your biosimilars development strategies are translated into a full program management** **Klemen Spaninger**, Director Project Management, **Polpharma Biologics** (CONFIRMED)	

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15:40	Networking Break	
	Commercialisation	**Development and manufacturing**
	IP and Legal requirements	**Analytics and CDMO Selection**
Chair:	To be announced	To be announced
16:40	**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? **Peter Jørgensen**, CEO, **Danish Generic and Biosimilar Medicines Industry Association (IGL)** (CONFIRMED)	**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** (CONFIRMED)
17:00	**Sponsored IP & Litigation session - Opportunity available for lawyers to educate the audience on how industry can best navigate the patent/IP landscape** **SPEAKING OPPORTUNITY AVAILABLE** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	**Leveraging technologies during the early development stages to dictate your cost effectiveness in the later stages** • What factors will help us avoid repeated safety and efficacy studies throughout the product lifecycle? • Adopting modern manufacturing methods to produce your drugs efficiently and economically • Ensuring efficient plant utilization to provide a reasonable cost advantage in the long term **Annick de Vries**, Director Bioanalysis, **Sanquin Diagnostic Services** (CONFIRMED)
17:20	**Understanding the main barriers to approval and market entry and analyzing partnerships that will help us address them** • Delays in market entry – Addressing where we are today and analyzing current affairs • Reviewing new guidelines, current pipelines and the patent landscape • What kinds of partnerships will help us speed up approval and market entry? **Chrys Kokino**, Head of Global Biologics & Insulins Commercial, **Mylan** (CONFIRMED)	**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? **Vimal Gandhi**, Director, Global Biosimilar Operations and Strategy, **AstraZeneca** (CONFIRMED) **Parastoo Azadi**, Technical Director, Analytical Services, **Complex Carbohydrate Research Center** (CONFIRMED) **Racho Jordanov**, CEO, **JHL Biotech Inc.** (CONFIRMED)
18:00	**Offsite networking drinks reception**	

FESTIVAL OF BIOLOGICS USA

World Biosimilar Congress USA – Tuesday 4th March – Day 2		
08:00	**Registration and refreshments**	
08:50	**Conference doors open**	
09:00	**Intro from chair, recap of day 1**	
	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** (CONFIRMED)	
09:20	**An FDA Perspective on the Quality of Module 3 in 351k BLA Applications** • Areas that have been problems in 351k applications • Update on guidance document commitments (including Interchangeability and Statistical Approaches to Evaluate Analytical Similarity) • BSUFA II **Marjorie A. Shapiro**, Chief, Laboratory of Molecular and Developmental Immunology, Division of Biotechnology Products Research and Review I, **OBP/OPQ/CDER/FDA** (invited)	
09:40	**Biosimilars: Current requirements and experience with regulatory approvals** *Panel Discussion on regulation followed by questions from the audience* **Mareike Ostertag**, Director Science & Regulatory policy, **Novartis** (CONFIRMED) **Bradley J. Scott**, Senior Clinical Evaluator Clinical Evaluation Division - Hematology / Oncology, HPFB, **Health Canada** (invited) **Maria-ceu Machado**, President, **INFARMED** (invited)	
10:00	**Biosimilars: state of clinical and regulatory science** **Bradley J. Scott**, Senior Clinical Evaluator Clinical Evaluation Division - Hematology / Oncology, HPFB, **Health Canada** (invited)	
10:20	**Networking Refreshment Break**	
	Commercialisation	**Development and manufacturing**
	Regulation, reimbursement and market access	**Clinical trials and real-world evidence**
Chair:	To be announced	To be announced
11:20	**Switching, Interchangeability and Substitution in the in the US and in Europe** • Two years of experience with the draft FDA Guidance on Demonstrating Interchangeability • Acceptance of switching and substitution in countries of the European Community • Multiple switching and hypothetical implications for clinical performance • VOLTAIRE-X, a study designed to support the claim of interchangeability **Bernd Liedert**, Senior Clinical Director, TA Biosimilars, **Boehringer Ingelheim** (CONFIRMED)	**Clinical development of biosimilars - the importance of making your clinical trials as specific, consistent and sensitive as possible** • Case study example of pegfilgrastim biosimilar clinical trial design • Understanding how we can build a bridge between the originator and biosimilar product using a specific, consistent and tailor-made approach • The importance of study population, study design, endpoints and statistics • Collaborating with regulatory affairs and making clinical studies as sensitive to differences as possible **Ruediger Jankowsky**, Managing Director, **Cinfa Biotech** (CONFIRMED)

11:40	**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** (CONFIRMED)	**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** (CONFIRMED)
12:00	**Perceptual evolution through evidence-based approach** • Biosimilar Development – the case of the world first mAb biosimilar • Perceptual Evolution on Biosimilars – lesson learned from Europe • US Challenges to Overcome **Kevin Choi**, Director of Marketing Department, **Celltrion Healthcare**	**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 **Gerry Hoehn**, Medical Director, Oncology, **Teva** (CONFIRMED) **Ruediger Jankowsky,** Managing Director, **Cinfa Biotech** (CONFIRMED)
12:40		
13:00	**Networking Lunch**	
	Commercialisation	**Development and manufacturing**
	Emerging markets	**Immunogenicity, analytics and CDMO selection**
Chair:	To be announced	To be announced
14:00	**Case Study: Biosimilar development in Russia and EuroAsian Union** **Roman Drai**, Director, Clinical Development, **GEROPHARM** (CONFIRMED)	**How unsafe are the new biosimilars really?** • From theory to practice • The evolving evidence base • Closing the gap • Incremental risk vs expected risk **Uwe Gudat**, Head of Clinical Safety & Pharmacovigilance, **Fresenius Kabi SwissBioSim GmbH** (invited)
14:20	**Brazilian Experience in development of biosimilar products** • Regulatory overview and pathways and Safety • Challenges to the Tech Transfer • Public Policy and Market Access **Vanessa Schiavo**, Head of Regulatory Affairs and CMC, **Libbs Farmacêutica** (CONFIRMED)	**Improving the eventual chances of success in the clinic by evaluating the doses and affinities required for engaging tissue-embedded targets during the pre-clinical stages of development** **SPEAKING OPPORTUNITY AVAILABLE** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*
14:40	**Biosimilar regulations in non- US/ Non- EU/ Non- Japan, ROW markets** • Pharmacovigilance in Biosimilar development and post marketing • Clinical Development of Biosimilars	**QA Controls and Operations: Validation Qualification & Regulatory** **Nacer E. Hedroug**, Former Director, QA Ops Injectable Vertical & Tech Transfer, **Mylan** (CONFIRMED)

	Shubhadeep Sinha, Senior Vice- President, Dept. of Clinical Development & Medical Affairs (CD&MA), **Hetero Labs Limited** (CONFIRMED)	
15:00	**Case study: Spanish biosimilar developer** **Andreu Soldevila,** Chief Executive Officer (CEO), **Syna Therapeutics (**CONFIRMED)	**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**, Former Biotechnology Leader, **Cipla BioTec** (CONFIRMED)
15:20	**Networking Break**	
	Understanding patient perspective and education of healthcare professionals	
Chair:	To be announced	
15:50	**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** (CONFIRMED) **Eric Lun**, Executive Director, Drug Intelligence, Optimization, Outcomes, and Strategy, Pharmaceutical Services Division, **BC Ministry of Health** (invited)	
16:10	**Implementation and administration of biosimilars in the clinic** **Kalveer Flora**, Specialist Pharmacist Rheumatology and Biosimilars, **London North West Healthcare NHS Trust** (CONFIRMED)	
16:30	**Anti-biosimilars or pro-safety? Addressing the truth about ensuring cost savings <u>and</u> patient safety** • Cost savings vs patient safety – How can we sustain a balance between the two? • Understanding the need for robust and comprehensive post-market tracking and reporting systems • Incorporating the patient voice into the development of biosimilar drugs to ensure a promising future **Larry LaMotte**, Principal Consultant, **Advocacy Options** (CONFIRMED)	
16:50	**Patient advocacy panel – 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 **<u>Moderator:</u> TBC**	

	<u>Panellists:</u> **Peg Ford**, Co-Founder/ President, **Ovarian Cancer Alliance of San Diego** (CONFIRMED) **Cheryl Koehn**, President, **Arthritis Consumer Experts** (CONFIRMED) **Larry LaMotte**, Principal Consultant, **Advocacy Options, LLC** (CONFIRMED) **Jennifer Day**, Coordinator, Emerging Therapeutics Strategy Program, **Kaiser Permanente** (invited) **Chad Woods**, Head, Patient Access, **Sandoz** (invited)
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

Rob Scott, VP Development and Chief Medical Officer, **Abbvie**
Andrea Perrone, Associate Vice President, Clinical Imaging Translational Medicine, **Merck**
Michelle Shogran, Head of Innovation – Portfolio and Operations, **Bayer**
Christopher Boone, Vice President, Head of Real World Data and Analytics Center, **Pfizer**
Nancy Lutz Paynter, Director, Learning and Clinical Integration, **Genentech**
Mark Milberg, 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**
Kimberly Tableman, Head, Digital Clinical Trials, **GSK** (TBC)
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**
Jim Kremidas, Executive Director, **ACRP**
Cathy Carfagno, Associate Director, IT Business Lead, Global Clinical Trials Operations, **Merck**
Adama Ibrahim, Senior Clinical Operations Lead, **Biogen**
Shree Patel, Director Clinical Operations, **Achilles Therapeutics**
Jzaneen Lalani, Chief Operations Officer, **Curemark** (TBC)
Mitch Herndon, Associate Director Patient Recruitment, **UCB**
Elizabeth Manning, Patient Engagement Strategy**, UCB**
Brenda Hann, Head of Clinical Trials, **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, **Mayo Clinic**
Robert Metz, Sr. Vice President, Global Business Operations and External Affairs**, Horizon Pharma**
Hailey Tipton, Administrative Director, Clinical Trials, **UC San Diego Moores Cancer Center**
Julie Dietrich, Director, Clinical Development, **Amgen**
Douglas Reichgott, Director, Research Financial and Regulatory Operations, **Tufts Medical Centre**
Ian Popoff, 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**
Laszlo Vasko, Senior Director, Business Technology Leader - Clinical Operations and Innovation, **Janssen**
Andreas Koester, VP Clinical Innovation, **Janssen**
Bryan Souder, Director, TMF Head, **Merck**

Scott Martin, Chair of the Steering Committee, **CDSR**
Beth Zaharoff, Director, patient Focused Drug Development, **Tesaro**
Sheryl Lapidus, Director, Corporate Affairs and Patient Advocacy, **Tesaro**
Deepak Khatry, Science Associate Director and Team Leader, PHC, Biostatistics, **MedImmune**
Emmanuel Fombu, Director, Digital Medicines, **Novartis**
Phill Wallis, Director, Digital Clinical Trials, Clinical Operations**, GSK**
Basker Gummadi, Deputy Director of Digital Innovation**, Bayer**
(48/60)

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<table>
<tr><th colspan="5">Clinical Trials Americas – Monday 4th March – Day 1</th></tr>
<tr><td>07:30</td><td colspan="4">Registration opens</td></tr>
<tr><td>08:30</td><td colspan="4">Conference doors open</td></tr>
<tr><td></td><td colspan="4">Clinical Trials keynotes</td></tr>
<tr><td>08:55</td><td colspan="4">Welcome from Terrapinn</td></tr>
<tr><td>09:00</td><td colspan="4">Chair’s opening remarks</td></tr>
<tr><td>09:10</td><td colspan="4">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)</td></tr>
<tr><td>09:30</td><td colspan="4">Reserved for sponsor
If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 207 092 1297</td></tr>
<tr><td>09:50</td><td colspan="4">Keynote panel discussion: addressing the key challenges of biologics clinical trials
Rhonda Pisk, Clinical Trials Program Director, Stanford (CONFIRMED)
Hailey Tipton, Administrative Director, Clinical Trials, UC San Diego Moores Cancer Center (CONFIRMED)
Jill Loftiss, Head, Clinical Operations, Oncology, MedImmune/AstraZeneca (invited)
Andy Lee, SVP, Head of Global Clinical Trial Operations, MSD (invited)</td></tr>
<tr><td>10:30</td><td colspan="4">Networking break</td></tr>
<tr><td>11:40</td><td colspan="4">Roundtable discussion session</td></tr>
<tr><td></td><td>TABLE 1
Reserved for sponsor
If you are interested in being involved, please contact Derek Cavanagh at</td><td>TABLE 2
Trial set up & feasibility
Douglas Reichgott, Director, Research Financial and Regulatory Operations, Tufts Medical Centre (CONFIRMED)</td><td>TABLE 3
Julie Dietrich, Director, Clinical Development, Amgen (CONFIMRED)</td><td>TABLE 4
Optimizing clinical trial design in early research
Robert Metz, Sr. Vice President, Global Business Operations, Horizon Pharma (CONFIRMED)</td></tr>
<tr><td></td><td>TABLE 5
Patient engagement
Francis Kalush, Health Program Coordinator, FDA (CONFIMRED)</td><td>TABLE 6
Managing change in your organization
Cathy Carfagno, Associate Director, IT Business Lead, Global Clinical Trials Operations, Merck (CONFIRMED)
Bryan Souder, Director, TMF Head, Merck</td><td>TABLE 7
AI in clinical development
Ian Popoff, Senior Director, Strategic Advisory Leader, Pfizer (CONFIRMED)</td><td>TABLE 8
Real world data
Jan Davidson, Director, Clinical Development and Research, Macrogenics (CONFIRMED)</td></tr>
<tr><td>12:40</td><td colspan="4">Speed networking</td></tr>
<tr><td>13:00</td><td colspan="4">Networking lunch</td></tr>
<tr><td></td><td colspan="2">Track 1
Patient engagement and enrolment</td><td colspan="2">Track 2
Trial design and adaptability</td></tr>
<tr><td>14:40</td><td colspan="2">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
Jim Kremidas, Executive Director, ACRP (CONFIRMED)</td><td colspan="2">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)</td></tr>
<tr><td>15:00</td><td colspan="2">Brenda Hann, Head of Clinical Trials, Stanford Medicine (CONFIRMED)</td><td colspan="2">Comparative oncology: spontaneous canine cancer as models for human therapy</td></tr>
</table>

		• 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** (CONFIRMED
15:20	**Identifying patient populations using AI** **Reserved for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com	**Implementing unequal randomization in clinical trials with heterogeneous treatment costs** • Optimal allocation designs minimizing total study cost under statistical efficiency constraints • State-of-the-art restricted randomization procedures to implement optimal allocation in practice • Statistical inference following these procedures, using population-based and randomization-based approaches **Alex Sverdlov**, Director of Data, **Novartis** (CONFIRMED)
15:40	**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, **Mayo Clinic** (CONFIRMED)	**Standardization efforts in clinical development focused on the "what" and not the "how"** • 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 **Laszlo Vasko,** Senior Director, Business Technology Leader - Clinical Operations and Innovation, **Janssen** (CONFIRMED)
16:00	**Afternoon refreshments**	
	Patient engagement and enrolment	**Outsourcing strategies:** **Site/CRO Selection and monitoring**
17:00	**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	**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)

	Jzaneen Lalani, Chief Operations Officer, **Curemark** (CONFIRMED)	
17:20	**Patient partnering in clinical development: a UCB case study** • Patient Value Strategy of UCB, a global biopharmaceutical company • UCB's quest of achieving patient-preferred clinical studies • Case study offering successes, challenges and learnings within one of UCB's clinical development programs **Elizabeth Manning,** Patient Engagement Strategy**, UCB** (CONFIRMED) **Mitch Herndon,** Associate Director Patient Recruitment, **UCB** (CONFIRMED)	**Reserved for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*
17:40	**Panel discussion: transforming clinical trials with patient partnerships and collaboration** • The crucial role patients play in improving the clinical trial enterprise • Barriers to successful engagement • Collaboration between patient groups and trial sponsors **Elizabeth Manning,** Patient Engagement Strategy**, UCB** (CONFIRMED) **Mitch Herndon,** Associate Director Patient 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 **Kenneth Wilson**, Director, Sourcing Operations, **Pfizer** (CONFIRMED) **Neda Rashti,** Group Lead, Clinical Program Management**, Pfizer** (CONFIRMED) **Mark Milberg,** Director, Clinical Procurement and Outsourcing, **Ultragenyx** (CONFIRMED) **Panel space available for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com
18:15	Chair's end of day 1 remarks	
	Offsite drinks reception	

FESTIVAL OF BIOLOGICS USA

Clinical Trials Americas – Tuesday 4th March – Day 2		
08:00	Registration opens	
09:00	Conference doors open	
	Track 1 **Innovations in clinical technology**	
09:00	**Digital innovation in clinical development: adopt or die** **Rob Scott,** VP Development and Chief Medical Officer, **Abbvie** (CONFIRMED)	
09:20	**AI for tumour profiling** Reserved for sponsor *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	
09:40	**Title TBC** **Basker Gummadi,** Deputy Director of Digital Innovation, **Bayer** (CONFIRMED)	
10:00	**Panel discussion: what's slowing down uptake of technology in clinical development?** **Nancy Lutz Paynter,** Director, Learning and Clinical Integration, **Genentech** (CONFIRMED) **Rob Scott,** VP Development and Chief Medical Officer, **Abbvie** (CONFIRMED) **Basker Gummadi,** Deputy Director of Digital Innovation, **Bayer** (CONFIRMED) **John Cai,** Executive Director, Real World Data Analytics & Innovation**, Merck** *(invited)* **Peter Bergethon**, MD, Vice President, Quantitative Medicine and Clinical Technologies, **Biogen** *(invited)* **Craig Lipset,** Head of Clinical Innovation, **Pfizer** *(invited)*	
10:40	**Networking break**	
	Track 1 **Real world evidence**	**Track 2** **Innovation in Clinical Technology**
11:40	**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)	**Integrating clinical and operational data to improve workflow** **Phill Wallis,** Director, Digital Clinical Trials, Clinical Operations, **GSK** (CONFIRMED)
12:00	**Evidence-based decisions in developing next generation immunotherapies** **Emmanuel Fombu,** Director, Digital Medicines, **Novartis** (CONFIRMED)	**Reserved for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*
12:20	**Reserved for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	**Panel discussion: How can Blockchain can Transform the Pharmaceutical and Healthcare Industry?** **Adama Ibrahim,** Senior Clinical Operations Lead, **Biogen** (CONFIRMED) **Disa Lee Choun,** Director, Head of Data Acquisition, **UCB** *(invited)* **Vahan Simonyan, R**&D Director of Bioinformatics, **FDA** *(invited)* **Munther Baara,** Head of New Clinical Paradigm, **Pfizer** *(invited)* **Verner De Biasi,** Head Emerging Platforms, **GSK** *(invited)*
12:40	**How can real world data address questions that trials can't?** **Matthew Moyer,** Director, Clinical Supply Technology, **Merck** (TBC)	
13:00	**Networking lunch**	
	Data and analytics	**Regulation, safety and efficacy**
14:00	**The Cancer Genome Atlas: molecular characterisation of tumours** **Jean Claude Zenklusen,** Director, The Cancer Genome Atlas, **NCI/NIH** (CONFIRMED)	**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)

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14:20	**Biomarker-stratified clinical trial designs** **Deepak Khatry,** Science Associate Director and Team Leader, PHC, Biostatistics, **MedImmune** (CONFIRMED)	**Reserved for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*
14:40	**Working with specific data management provider Reserved for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	**FDA panel discussion: Regulatory considerations and means to accelerate approval** **Rhonda Pisk,** Clinical Trials Program Director, **Stanford** (CONFIRMED) **Francis Kalush,** Health Program Coordinator, Center for Drug Evaluation and Research, **FDA** (invited)
15:00	**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)	
15:20	**Afternoon refreshments**	
	Track 1 **Closing keynotes: Industry collaboration and data sharing**	
15:50	**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)	
16:10	**Reserved for sponsor** *If you are interested in being involved, please contact Derek Cavanagh* at derek.cavanagh@terrapinn.com *or +44 207 092 1297*	
16:30	**Clinical data sharing by industry and academia** • Purpose and history • Methods • Results and challenges **Scott Martin,** Chair of the Steering Committee, **CDSR** (CONFIRMED)	
16:50	**Panel discussion: industry collaboration** • Bridging the gap between industry and academia Chair: **Mark Lowdell**, CSO, **Inmune Bio** (CONFIRMED) **Laura Galuchie,** Transcelerate Lead, **Merck** (CONFIRMED) **Brenda Hann,** Head of Clinical Trials, **Stanford Medicine** (CONFIRMED) **Andreas Koester,** VP Clinical Innovation, **Janssen** (CONFIRMED)	
17:30	**Chair's closing remarks**	
17:45	**On site drinks reception**	