FESTIVAL OF BIOLOGICS

Monday March 2nd – Wednesday March 4th, 2020

Loews Coronado Bay Resort, San Diego, California

Presents

AMERICAS ANTIBODY CONGRESS 2020

WORLD IMMUNOTHERAPY CONGRESS USA 2020

WORLD BIOSIMILAR CONGRESS USA 2020

FESTIVAL OF BIOLOGICS USA

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Americas Antibody Congress 2020

Advisory board

Marilyn Kehry, Vice President, Cell and Functional Biology, **AnaptysBio**
Jeffrey Froude, Major, Stm, Vaccines and Therapeutics Division, **Defence Threat Reduction Agency**
Partha Chowdhury, Senior Director and Head, Antibody Discovery, **Sanofi Genzyme**
John Delaney, Executive Director, Amgen Biologics Discovery, **Amgen**
Andrew Korytko, Research Advisor, Group Leader, Protein Engineering, **Eli Lilly and Company**
Vaughn Smider, Professor, **The Applied Biomedical Science Institute**
Jae Sly, Chief Business Officer, **LigaTrap Technologies LLC**

Speakers

***Aaron Sato,** Chief Scientific Officer, **Twist Bioscience**
Al Tsang, Chief Scientific Officer, **Precision Biologics**
Alexey Berezhnoy, Scientist II, **MacroGenics**
Amrik Basran, Chief Scientific Officer, **Avacta**
Amy Jenkins, Programme Manager, **DARPA**
Andres Perez Bay, Senior Staff Scientist, **Regeneron**
Andrew Korytko, Research Advisor, Group Leader, Protein Engineering, **Eli Lilly and Company**
Andrew Polson, Principal Scientist, **Genentech**
Andrew Tsourkas, Professor of Bioengineering, **University of Pennsylvania**
Anthony Mire-Sluis, Head of Global Quality, **AstraZeneca**

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Anton Rosenbaum, Senior Scientist, Clinical Immunology & Bioanalysis, **AstraZeneca**
Andrea Ferrante, Principal Research Scientist, **Eli Lilly and Company**
Ariel Wirchnianski, PostDoc, **Albert Einstein College of Medicine**
Arunan Kaliyaperumal, Research Fellow, **Eli Lilly and Company**
Bellos Hadjivassiliou, Senior Scientist, **Bristol-Myers Squibb**
Bob DuBridge, Senior Vice President of Research Discovery, **Maverick Therapeutics**
Brandon Dekosky, Assistant Professor, **The University of Kansas**
Brandon Ruotolo, Professor, Chemistry, **University of Michigan**
Brian Kay, Professor, Department of Biological Sciences, LAS Distinguished Professor & University Scholar, **University of Illinois at Chicago**
Bronwyn Gunn, Professor, **Harvard University**
Bruce Keyt, CSO, **IGM Biosciences**
C. Russell Cruz, Director, Translational Research Laboratories, **Centre for Emerging Technologies in Immune Cell Therapy, Children's National Hospital**
Chad Swanson, Senior Director, Neurology Business Group, **Eisai**
Christopher Bahl, Head of Protein Design, **Institute for Protein Innovation**
Cory Brooks, Associate Professor, **Fresno State University**
David Boucher, Chief, Antivirals & Antitoxins, **Biomedical Advanced Research and Development Authority (BARDA)**
David Busch, Senior Scientist, **Merck**
David Dornan, Senior Vice President of Research, **Bolt Biotherapeutics**
David Fontana, Head Strategic Alliance & JCAR017 Program Lead, **Juno Therapeutics**
Derek Wilson, Director, Wilson Lab, **York University**
Denise Haslwanter, Research Fellow, **Albert Einstein College of Medicine**
Dian Su, Scientist, **Genentech**
Elisabeth Nyakatura, Research Assistant Professor, **Albert Einstein College of Medicine**
Elizabeth Brunk, Postdoc Fellow, **UCSD Moores Cancer Center**
Erica Ollmann Saphire, Professor, **La Jolla Institute for Immunology**
Ethan Laudermilch, Post-Doc, **Albert Einstein College of Medicine**
Eugene Zhukovsky, Chief Scientific Officer, **BIOMUNEX Pharmaceuticals**
Ezio Bonvini, Chief Scientific Officer, **MacroGenics**
Fabiana Zappala, PhD Student, **University of Pennsylvania**
Feng Wang, Associate Director, Principal Investigator, **Institute of Biophysics, Chinese Academy of Sciences**
Francisco Ylera, R&D Team Leader, New Technologies, **Bio-Rad Laboratories**
Frank Walsh, Founder and Chief Executive Officer, **Ossianix**
Gary Starling, Associate Vice President, Protein Science, **Merck**
Greg Babcock, Vice President, Research, **Visterra Inc**
Gregory Weiss, Professor, **University of California Irvine**
Gunnar Kaufmann, Chief Scientific Officer, **Oncternal Therapeutics**
Haruki Hasegawa, Principal Scientist, Department of Therapeutic Discovery, **Amgen**
Harun Rashid, Senior Principal Scientist, Molecular Technology, **Ambrx**
Hiroaki Suga, Professor, **The University of Tokyo**
Ian Wilson, Hansen Professor of Structural Biology, Skaggs Institute for Chemical Biology, **The Scripps Research Institute**
Isabelle Turbica, Associate Professor, **Paris-Sud University**
Itay Levin, Director of Antibody Engineering, **Biolojic Design**
Ivan Mascanfroni, Senior Scientist III, Immunology Biologics, **Abbvie Bioresearch Centre**
Jack Ragheb, Senior Medical Fellow, Immunology, **Eli Lilly & Company**
Jae Sly, Chief Business Officer, **LigaTrap Technologies LLC**
James Legg, Vice President, Research & Development, **Crescendo Biologics**
Jared Delmar, Scientist I, **AstraZeneca**
Javier Chaparro-Riggers, Executive Director, **Pfizer**
Jeffrey Froude, Major, Stm, Vaccines and Therapeutics Division, **Defence Threat Reduction Agency**
Jintang He, Scientist, **Genentech**
Joan Shen, Head of Research and Development, **I-Mab Biopharma**
Jon Strauss, Director of CMC, **Calibr, a division of Scripps Research**
Johannes Brozy, Senior Associate Scientist, Bite Technology, **Amgen**
John Delaney, Executive Director, Amgen Biologics Discovery, **Amgen**
John Hood, Chairman, **Endeavour Biomedicines**
John Lambert, Consultant, Honorary Professor, **Queen's University, Belfast,** Former CSO, **ImmunoGen**
Jonathan Davis, Head of Discovery, **Invenra**
Kartik Chandran, Associate Professor, Department of Microbiology & Immunology, **Albert Einstein College of Medicine**
Kevin Johnson, Partner, **Medixci**

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Krzysztof Masternak, Head of Discovery, **Light Chain Bioscience – a brand of Novimmune SA**
Liviu Movileanu, Professor, Department of Physics, **Syracuse University**
Lu Shan, Scientist II, ADPE, **MedImmune**
Marc Nasoff, Chief Scientific Officer, **Fortis Therapeutics**
Marilyn Kehry, Vice President, Cell and Functional Biology, **AnaptysBio**
Marjorie Shapiro, Supervisory Biologics Office of Biotechnology Products, **CDER, FDA**
Mark Chiu, Associate Director, Multispecific Biologics Engineering, **Janssen Research and Development**
Mark Throsby, CSO, **Merus**
Markku Saloheimo, Senior Principal Scientist, V**TT Technical Research Centre of Finland**
Martin Naradikian, Postdoctoral Fellow, **La Jolla Institute for Immunology**
Michael Yellin, Vice President of Clinical Science, **Celldex Therapeutics**
Michaela Lantz, Scientist, **Sanofi**
Mike Schopperle, Chief Scientific Officer, **CureMeta**
Nathan Trinklein, Chief Technology Officer, **Teneobio**
Nicholas Agard, Scientist, **Genentech**
Nina Prak, Professor of Pathology and Laboratory Medicine, **Perelman School of Medicine, University of Pennsylvania**
Ning Ding, Group Leader, Immunology Discovery Group, **Genentech**
Partha Chowdhury, Senior Director and Head, Antibody Discovery, **Sanofi Genzyme**
Pascal Touchon, President and CEO, **Atara Biotherapeutics**
Patrick Wilson, Professor, Department of Medicine/Rheumatology, **The University of Chicago**
Petra Verdino, Principal Scientist, **Eli Lilly and Company**
Philip Tagari, Vice President, Research, **Amgen**
Philipp Spycher, Founder Fellow, **Paul Scherrer Institut**
Philippe Billiald, Full Professor, **University Paris-Saclay,** Scientific Advisor and Co-Founder, **Acticor Biotech**
Qiang (Shawn) Chan, Professor, **The Biodesign Institute and School of Life Sciences, Arizona State University**
Qun Du, Scientist I, **AstraZeneca**
Rachel Overman, Deputy Join Product Manager, BIO 2, **JPM CBRN Medical**
Raja Ghosh, Professor, Chemical Engineering, **McMaster University**
Rajesh Krishnan, Senior Vice President, CMC and Manufacturing Operations, **Oncternal Therapeutics**
Ramana Doppalapudi, Director of Chemistry, **Avidity BioSciences**
Richard Ding, Director of Downstream Purification and Manufacturing, **AnaptysBio**
Richard Vachet, Department Head, Professor in Chemistry, **University of Massachusetts Amherst**
Romesh Rao, Research Associate III, **Seattle Genetics**
Roy Baynes, Senior Vice President and Head Global Clinical Development, Chief Medical Officer, **Merck Research Laboratories**
Sandeep Kumar, Senior Research Fellow, Biotherapeutics, **Boehringer Ingelheim**
Sebastian Meyer, COO, **Numab Innovation AG**
Sebastian Stolzenberg, PostDoc Project Leader, **Free University of Berlin**
Senior Representative, **Abveris**
Senior Representative, **Abzena**
Senior Representative, **Abcellera**
Senior Representative*, **ACROBiosystems
Senior Representative, **Alivamab and Ablexis**
Senior Representative, **Applied BioMath**
Senior Representative, **Biocytogen**
Senior Representative, **Schrödinger**
Stan Fleming, Founding Managing Partner, **Forward Ventures**
Stefan Duebel, Director, **Technical University Braunschweig**
Steven Deitcher, President, CEO and Board Member, **RadImmune Therapeutics**
Susan Sharfstein, Professor of Nanobioscience, College of Nanoscale Science and Engineering, **SUNY Polytechnic Institute**
Tarik Dabdoubi, Team Leader, In Vivo Antibody Discovery, **Sanofi**
Tawnya Flick, Principal Scientist, **Amgen**
Thomas Weber, Application Team Leader USA, **Dynamic Biosensors**
Tony Polverino, Chief Scientific Officer, **Zymeworks**
Torbjörn Gräslund, Professor, Medical Protein Technology, **KTH Royal Institute of Technology**
Toshimitsu Uenaka, President, Epochal Precision Anti-Cancer Therapeutics (EPAT), **Eisai**
Vadim Klyushnichenko, VP of Pharmaceutical Development & Quality, **Calibr, a division of Scripps Research**

Vaughn Smider, Professor, **The Applied Biomedical Science Institute**
Vinodh Kurella, Senior Scientist, **Voyager Therapeutics**
Vu Truong, Founder, Chief Executive Officer and Director, **Aridis Pharmaceuticals**
Weifeng Liu, Senior Scientist, **Pfizer**
Werner Meier, CSO, **Revitope Oncology**
Yanay Ofran, Founder and Chief Executive Officer, **Biolojic Design**
Yeku Olapado, Assistant Clinical Attending, **Massachusetts General Hospital**
Yongku Cho, Assistant Professor, **University of Connecticut**
(132/150)

Workshop moderators
Andrea Ferrante, Principal Research Scientist, **Eli Lilly and Company**
Arunan Kalitaperumal, Research Fellow, Director, **Eli Lilly and Company**
Brenda Hann, Director, Clinical Trials Operations, **Stanford Medicine**
Eve Bukowski, Vice President, Patient Advocacy, Education & Outreach, **California Life Sciences Association (CLSA)**
Jack Ragheb, Senior Medical Fellow, Immunology, **Eli Lilly & Company**
Julie Gerberding, Executive Vice President, Communications, Global Policy, and Population Health & Chief Patient Officer**, Merck**
Kevin Johnson, Partner, **Medixci**
Larry Lum, Professor, Director of Cellular Therapy, Scientific Director of Bone Marrow Transplant, **University of Virginia**
Marc Nasoff, Chief Scientific Officer, **Fortis Therapeutics**
Steven Corn, Founder and CEO, **Metis Advocacy**
Stan Fleming, Founding Managing Partner, **Forward Ventures**

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Day 1 – Monday March 2nd 2020			
7:30am	Registration opens		
8:30am	Doors open		
	Opening keynotes Next generation antibody formats		
9:00am	Opening remarks from Terrapinn		
9:05am	Chair's opening remarks		
9:10am	Title TBA **Philip Tagari,** Vice President, Research, **Amgen** (CONFIRMED)		
9:30am	Title TBA **Erica Ollmann Saphire,** Professor, **La Jolla Institute for Immunology** (CONFIRMED)		
9:50am	**Bispecific antibody innovations to transform the standard of care in HER2-expressing cancers** • Leading the next wave of biotech breakthroughs in oncology through bispecific, multifunctional antibodies and ADCs • Azymetric and ZymeLink: innovative bispecific therapeutic platforms • ZW25: a HER2-targeted bispecific antibody that offers unique mechanisms of action and is rapidly advancing in the clinic for patients with gastric and breast cancer • ZW49: a bispecific antibody-drug conjugate with improved efficacy and tolerability compared with leading HER2-targeted ADCs **Tony Polverino,** Chief Scientific Officer, **Zymeworks** (CONFIRMED)		
10:10am	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*		
10:30am	Morning networking break		
11:30am	**Plenary roundtable session** 15 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 35 minutes.		
	TABLE 1	TABLE 2 **Choosing the right CMO to manufacture your product, balancing cost, time and quality** **Vadim Klyushnichenko,** VP of Pharmaceutical Development & Quality, **Calibr, a division of Scripps Research** (CONFIRMED)	TABLE 3 **Third generation antibody discovery and engineering platforms- Microfluidics and computational discovery** **Partha Chowdhury,** Senior Director and Head, Antibody Discovery, **Sanofi Genzyme** (CONFIRMED)
	TABLE 4 **Nanobodies** **Cory Brooks,** Associate Professor, **Fresno State University** (CONFIRMED)	TABLE 5 **Trends in protein engineering and molecule design** **Andrew Korytko,** Research Advisor, Group Leader, Protein Engineering, **Eli Lilly and Company** (CONFIRMED)	TABLE 6 **Generating assay reagents through phage-display** **Brian Kay,** Professor, Department of Biological Sciences, LAS Distinguished Professor & University

			Scholar, **University of Illinois at Chicago** (CONFIRMED)
	TABLE 7	TABLE 8	TABLE 9
	TABLE 10 *Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)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 (0)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 (0)207 092 1297*
12:40pm	Networking lunch		
Workshop: 12:35 – 1:20	**Identifying early stage assets in academia** • Technology Transfer databases – Identifying Potential Drug Discovery Programs • In-licensing expectations • Academic advisory roles • Establishing a firewall for intellectual property rights **Marc Nasoff**, Chief Scientific Officer, **Fortis Therapeutics** (CONFIRMED)	**Comparing strategies and challenges of bispecific antibody infusion** **Larry Lum,** Professor, Director of Cellular Therapy, Scientific Director of Bone Marrow Transplant, **University of Virginia** (CONFIRMED)	
Workshop: 1:25pm – 1:55pm	**AI for antibody drug discovery and development** **Sandeep Kumar,** Senior Research Fellow, Biotherapeutics, **Boehringer Ingelheim** (reserved) **Bojana Popovic,** Senior Research Scientist, **MedImmune** (invited)		
	Protein engineering Chaired by: **Jae Sly,** Chief Business Officer, **LigaTrap Technologies LLC** (CONFIRMED)	Bispecifics discovery Chaired by: **John Delaney,** Executive Director, Amgen Biologics Discovery, **Amgen** (CONFIRMED)	Armed antibodies Chaired by: **John Lambert,** Consultant, Honorary Professor, **Queen's University Belfast,** Former CSO, **ImmunoGen** (CONFIRMED)	mAbs and novel formats Chaired by: **Gary Starling,** Associate Vice President, Protein Science, **Merck** (CONFIRMED)	Technology showcase
2:00pm	Title TBA *Senior Representative,* **Abcellera** (CONFIRMED)	**COBRA – A new class of conditionally active, T-cell engaging bispecifics for the treatment of solid tumors** • Bispecific T cell engagers have demonstrated high potency and good efficacy in the treatment of certain heme malignancies • The use of this class of therapeutics to treat solid tumors has been more challenging	**Designing effective antibody-drug conjugates: What have we learned in twenty years, since the first approval of Mylotarg®?** • Twenty years ago, the first ADC (Mylotarg®)was approved and marked for treating AML; however 10 years later (2010), it was withdrawn from the US and EU markets following a failed phase 3 trial • The approvals of Adcetris® in 2011 for treating HL and ALCL, and Kadcyla® in 2013	**Discovery of a PD-1 checkpoint agonist antibody for autoimmune/inflammatory disease** • An anti-PD-1 antibody that mimics activity of natural checkpoint ligands and down-modulates T-cell responses has the potential to restore and maintain immune balance in autoimmune	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

		• Maverick has developed a new type of conditionally active T cell engager • Data will be presented outlining the potency and conditionality of these molecules **Bob DuBridge,** Senior Vice President of Research Discovery, **Maverick Therapeutics** (CONFIRMED)	for treating HER2+ metastatic breast cancer, rejuvenated widespread interest in the field. • While there are many factors involved in creating an effective ADC (right target, right antibody, right linker properties and attachment site(s), right payload, right patients), getting the factors right can create ADCs that can become important medicines for treating cancer and other diseases. **John Lambert,** Consultant, Honorary Professor, **Queen's University, Belfast,** Former CSO, **ImmunoGen** (CONFIRMED)	and inflammatory diseases • ANB030 is a humanized IgG1/κ anti-PD-1 agonist antibody that is non-blocking for PD-L1 binding and requires Fcγ receptor engagement for its functional inhibitory activity in solution • Signalling mechanism studies show similar effects for ANB030 and PD-L1-Fc **Marilyn Kehry,** Vice President, Cell and Functional Biology, **AnaptysBio** (CONFIRMED)	
2:20pm	**Assembling antibodies from modules using protein ligation: a new versatile engineering toolbox** • Antibody assembly by protein ligation • Site-specific antibody labeling • Multiplex by Fc switching • Antibody engineering toolbox **Francisco Ylera,** R&D Team Leader, New Technologies, **Bio-Rad Laboratories** (CONFIRMED)	**Optimization of a bispecific anti-CD3 antibody-folate bio-conjugate for the treatment of ovarian cancer** • We report the optimization of an anti-CD3 Fab-Folate bio-conjugate that targets cytotoxic T cells to folate receptor positive (FR+) tumor cells for optimal efficacy, reduced toxicity and optimal pharmacokinetic (PK) properties • The optimized bio-conjugates showed potent and selective in vitro activity, improved serum	Title TBA **Mike Schopperle,** Chief Scientific Officer, **CureMeta** (CONFIRMED)	Title TBA *Senior Representative,* **Biocytogen** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

		half-life, and potent in vivo activity in xenograft mouse models. • This semi-synthetic approach is likely to be applicable for the generation of additional anti-CD3 bispecific bio-conjugate agents using small molecule ligands selective for other TAAs **Harun Rashid,** Senior Principal Scientist, Molecular Technology, **Ambrx** (CONFIRMED)			
2:40pm	**Novel monomeric Fc platform – engineering and applications** • Monovalent fusion proteins are often a necessary drug format for optimal structure and activity profiles • We present our novel monovalent fusion platform in target validation, lead discovery, and structure insights **Lu Shan,** Scientist II, ADPE, **MedImmune** (CONFIRMED)	**Biophysical analysis of bispecific binders with dual-signal biosensors** • Interactions of bispecific binders with two different antigens • Analysis of binding kinetics and avidity • Implications for the engineering of binding selectivity **Thomas Weber,** Application Team Leader USA, **Dynamic Biosensors** (CONFIRMED)	**Overcoming limitations of current Antibody-Drug Conjugates (ADCs) by a novel linker technology** • Introduction of novel linker technology for antibody-drug conjugates (ADCs) • Efficient site-specific payload attachment to native antibodies (no engineering, DAR2, DAR4) will be shown • Comprehensive in-vitro and in-vivo data will be presented **Philipp Spycher,** Founder Fellow, **Paul Scherrer Institut** (CONFIRMED)	Title TBA **Tarik Dabdoubi,** Team Leader, In Vivo Antibody Discovery, **Sanofi** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*
3:00pm	**Engineering proteins therapeutics and antibodies to enable efficient cytosolic delivery with cationic lipids**	**Host- and virus-directed bispecific antibodies as broad-spectrum anti-Ebola therapeutics**	**The bumblebee cannot fly** • Extracellular deposits of intracellular antigens make	**Anti-ROR1 mAb Cirmtuzumab - Novel Synergistic Combinations For**	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at*

	• Photoreactive antibody-binding domains enable the site-specific attachment of anionic polypeptides to nearly any off-the-shelf antibody • Protein therapeutics and antibodies that are fused or conjugated to anionic polypeptides can be complexed with cationic lipids • Cationic lipids facilitate the efficient escape of proteins and antibodies from endosomes/lysosomes and enable their delivery to the cytosol **Andrew Tsourkas,** Professor of Bioengineering, **University of Pennsylvania** (CONFIRMED)	• Multiple members of the filovirus family are associated with human disease • Human monoclonal antibodies have shown therapeutic promise but display only clade-specific activity • We describe multiple bispecific antibody-based approaches with potent and broad anti-filovirus activity • At least one strategy affords unprecedented pan-filovirus neutralization **Kartik Chandran,** Associate Professor, Department of Microbiology & Immunology, **Albert Einstein College of Medicine** (CONFIRMED)	attractive targets for antibody-targeted radiation therapy • Alpha particle emitters may be optimal for the treatment of rapidly progressive cancers • Liquid radiation may be synergistic with checkpoint inhibitors **Steven Deitcher,** President, CEO and Board Member, **RadImmune Therapeutics** (CONFIRMED)	**Hematological Malignancies and Solid Tumors** • Cirmtuzumab targets ROR1, an oncofetal antigen expressed on both liquid and solid tumors • Cirmtuzumab inhibits Wnt5a signalling and reverses cancer stemness • Cirmtuzumab and chemotherapy can act synergistically clinical trial of the combination is underway • Clinical trials using combination therapy are underway **Gunnar Kaufmann,** Chief Scientific Officer, **Oncternal Therapeutics** (CONFIRMED)	*derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*
3:20pm	Networking break				
Workshop: 3:30pm – 4:00pm	**Overview of therapeutic protein immunogenicity workshop** **Jack Ragheb,** Senior Medical Fellow, Immunology, **Eli Lilly & Company** (CONFIRMED) **Andrea Ferrante,** Principal Research Scientist**, Eli Lilly and Company** (CONFIRMED) **Arunan Kaliyaperumal,** Research Fellow, **Eli Lilly and Company** (CONFIRMED)				
	Protein engineering Chaired by: **Jae Sly,** Chief Business Officer, **LigaTrap Technologies LLC** (CONFIRMED)	Bispecifics discovery Chaired by: **Jonathan Davis,** Head of Discovery, **Invenra** (CONFIRMED)	Armed antibodies	mAbs and novel formats Chaired by: **Vaughn Smider,** Professor, **The Applied Biomedical Science Institute** (CONFIRMED)	Technology showcase
4:10pm	**IgMs as therapeutic agonists** • IgMs have 10 or 12 binding subunits and a unique 'mushroom' shape that	**From constrained peptides to neobiologics**	**CD46 – A novel immunomodulatory target for late stage mCRPC and multiple myeloma**	Title TBA	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	defines the arrangement of cell-surface bound ligands • We show this multivalent engagement agonizes clinical targets not addressable by simple IgGs • Further engineering and characterization of IgMs helps define their suitability across multiple therapeutic spaces **Nicholas Agard,** Scientist, **Genentech** (CONFIRMED)	• A novel approach to generate multi-specific biologics/antibodies • Maintaining the bivalency of antibodies • A simply and robust technology **Hiroaki Suga,** Professor, **The University of Tokyo** (CONFIRMED)	• FOR46 is an ADC targeting a novel immune modulatory tumor target (CD46) for the treatment of metastatic Prostate Cancer (mCRPC) and Multiple Myeloma (MM) • Discovery of the target • Preclinical efficacy in mCRPC and MM • Development of the FOR46 drug product • 2 separate Phase 1 clinical trials initiated **Marc Nasoff,** Chief Scientific Officer, **Fortis Therapeutics** (CONFIRMED)	*Senior Representative,* **Alivamab and Ablexis** (CONFIRMED)	
4:30pm	**de novo design of G protein mimetics: generalizable tools for allosteric control of G protein-coupled receptors** • We leverage high-throughput laboratory automation to accelerate protein production and antibody engineering. We are particularly interested in G protein coupled receptors (GPCRs) • Here, I describe the computational de novo design and testing of protein affinity reagents that enable generalized control over GPCR conformation	**Delivery of neurotrophin receptor agonist antibodies to the CNS using VNARs to the transferrin receptor** • Bispecific agonist antibodies to TrkB and TrkC were produced with VNARs to the transferrin receptor • The bispecifics accumulate at therapeutic levels in the CNS when injected IV and retain agonist activity • Neurotrophin specific patterns of gene expression were found in the CNS of injected animals	**MORAb-202, a folate receptor alpha-targeted antibody-drug conjugate, loaded with HALAVEN® (eribulin) as payload** • MORAb-202 is the first ADC which is loaded with HALAVEN® (eribulin) as payload • HALAVEN® is an approved drug which exhibits unique effects on tumor microenvironment • The preclinical and clinical Phase 1 interim data of MORAb-202 are discussed **Toshimitsu Uenaka,** President, Epochal Precision Anti-Cancer	**Biology and applications of long CDR3 antibodies** **Vaughn Smider,** Professor, **The Applied Biomedical Science Institute** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	• These de novo G protein mimetics will enable us to rapidly engineer functional antibodies for GPCRs **Christopher Bahl,** Head of Protein Design, **Institute for Protein Innovation** (CONFIRMED)	**Frank Walsh,** Founder and Chief Executive Officer, **Ossianix** (CONFIRMED)	Therapeutics (EPAT), **Eisai** (CONFIRMED)		
4:50pm	**Antibodies with affinity switches** • Allosteric module to regulate antibody affinity • Works under physiological conditions • Demonstrated for different antibodies **Stefan Duebel,** Director, **Technical University Braunschweig** (CONFIRMED)	**BiTE® antibody constructs in oncology and antiviral applications** • This presentation will give an update on Amgen's BiTE pipeline at the discovery, translational, and early clinical stage of development • We will also showcase antiviral activity of BiTE antibody constructs in research **Johannes Brozy,** Senior Associate Scientist, Bite Technology, **Amgen** (CONFIRMED)	**Bispecific antibody-drug conjugates (ADCs) exploit the tumour-specificity of HER2 and the trafficking properties of APLP2 to improve on HER2-ADC efficacy** • Intracellular trafficking of antibody-drug conjugates (ADCs) is essential for ADC antitumor effect • APLP2xHER2 bispecific antibodies were generated, that used the HER2 arm for surface binding and the low affinity APLP2 arm for internalization/degradation • Two APLP2xHER2-ADCs outperformed T-DM1 in IHC2+ models in vitro and in vivo and showed acceptable PK profile in APLP2 humanized mice **Andres Perez Bay,** Senior Staff Scientist, **Regeneron** (CONFIRMED)	Title TBA *Senior Representative,* **Abzena** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*
5:10pm	**Drug conjugates based on engineered affibody molecules**	Title TBA	Title TBA	**Plant-produced mAbs with improved Fc effector function**	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at*

	• Affibody molecules are small engineered alternative scaffold affinity proteins, which may be designed to bind to receptors over-expressed on different tumor cells • Affibody molecules can be site specifically loaded with the cytotoxic drug DM1, creating homogenous conjugates with a desired drug-to-affibody ratio • HER2-specific affibody drug conjugates slow tumor growth and increases survival in an animal model of ovarian cancer **Torbjörn Gräslund,** Professor, Medical Protein Technology, **KTH Royal Institute of Technology** (CONFIRMED)	**Jonathan Davis,** Head of Discovery, **Invenra** (CONFIRMED)	**Ramana Doppalapudi,** Director of Chemistry, **Avidity BioSciences** (CONFIRMED)	• Plant can produce mAb rapidly via transient expression • Glycoengineering of plants allows the production of mAb with tailor-made glycosylation on demand • Plant-made mAbs with homogenous human glycans have enhanced effector function and efficacy against cancer and viral infection **Qiang (Shawn) Chan,** Professor, **The Biodesign Institute and School of Life Sciences, Arizona State University** (CONFIRMED)	*derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*
5:30pm	Offsite drinks reception				

FESTIVAL OF BIOLOGICS USA

Day 2 – Tuesday March 3rd 2020	
8:00am	Registration opens
8:30am	Doors open
	Day 2 opening keynotes Combination therapies in antibodies and immunotherapy
9:00am	Chair's opening remarks
9:05am	**PD-1 antibodies are transforming cancer treatment both as monotherapy and in combination** • Monotherapy activity has been established and is transforming treatment across a number of major cancers • Precision medicine has been deployed to identify patients most likely to respond and those for whom a combination approach might be preferred • Precision medicine has enabled prediction of potentially important combination therapies • Combination therapies are now beginning to transform treatment across a number of cancers • PD-1 antibodies have become foundational in cancer therapy **Roy Baynes,** Senior Vice President and Head Global Clinical Development, Chief Medical Officer, **Merck Research Laboratories** (CONFIRMED)
9:25am	**Building a leading off-the-shelf, allogeneic T-Cell immunotherapy company** • Epstein-Barr virus (EBV) is associated with a wide range of cancers and multiple sclerosis (MS) • Tab-cel® (tabelecleucel) is an off-the-shelf, allogeneic EBV T-cell immunotherapy in Phase 3 development for patients with EBV+ post-transplant lymphoma as well as other serious EBV-associated ultra-rare diseases • ATA188 is an off-the-shelf, allogeneic T-cell immunotherapy that targets EBV-infected B cells believed to play a role in the pathogenesis of MS • EBV T cells also have potential application as an off-the-shelf, allogeneic CAR T platform • ATA2271/ATA3271 are novel mesothelin-targeted CAR T programs incorporating next-generation technologies for patients with advanced solid tumors • Atara's platform is supported by state-of-the-art T-cell manufacturing that is commissioned and qualified to support clinical development **Pascal Touchon,** President and CEO, **Atara Biotherapeutics** (CONFIRMED)
9:45am	**Strategies for combination therapies with CD19 CARTs in NHL - lessons learned and future directions** • CD19 CAR Ts have demonstrated notable activity in DLBCL, CLL, FL, pALL and other hematological malignancies with high overall response rates and durable CRs • However, a portion of patients either do not respond or their responses are not durable • Learnings from non-responders or CAR-T relapses are providing data into the multitude of potential resistance/suppression mechanisms • This presentation will review combination approaches being evaluated to overcoming resistance in CAR T to improve outcomes in NHL and provide insights for solid tumor approaches and the next wave of targets **David Fontana,** Head Strategic Alliance & JCAR017 Program Lead, **Juno Therapeutics** (CONFIRMED)
10:05am	Title TBA *Senior Representative,* **Applied BioMath** (CONFIRMED)
10:25am	Morning networking break

	Protein engineering	Bispecifics discovery/development	Novel indications for therapeutic antibodies	Armed antibodies	Antibodies for immunotherapy Chaired by: **Jae Sly,** Chief Business Officer, **LigaTrap Technologies LLC** (CONFIRMED)	Technology showcase
11:25am	**Phi – a parameter for quantifying the specificity of post-translational modification site targeting antibodies** • A parameter termed phi that quantifies the fraction of specific binding signal in antibodies • A robust flow cytometry assay for measuring phi. • Application of the assay to measure the specificity of phospho-tau antibodies • Validation results for 7 widely used phospho-tau antibodies **Yongku Cho,** Assistant Professor, **University of Connecticut** (CONFIRMED)	**Applying empirical screening to the discovery of tumor-targeted and immunomodulatory bispecific antibodies** • The attributes of Merus's enabling Biclonics technology • The role of unbiased functional screening in unlocking novel biology • Case studies of clinical stage programs discovered using a functional screening approach **Mark Throsby,** CSO, **Merus** (CONFIRMED)	Title TBA **Chad Swanson,** Senior Director, Neurology Business Group, **Eisai** (CONFIRMED)	**ADME Considerations & Bioanalytical Strategies for Pharmacokinetic Assessments of Antibody-Drug Conjugates** • Overview of structural complexity of ADCs • Current bioanalytical approaches commonly employed to assess pharmacokinetics of ADCs • Emerging bioanalytical tools for the assessment of ADC biotransformations **Anton Rosenbaum,** Senior Scientist, Clinical Immunology & Bioanalysis, **AstraZeneca** (CONFIRMED)	Title TBA **Bruce Keyt,** CSO, **IGM Biosciences** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*
11:45am	Title TBA *Senior Representative,* **Abveris** (CONFIRMED)	**Generating novel, differentiated multi-functional biologics using Humabody VH**	**WISP1 is a therapeutic target for liver fibrosis** • WISP1 as well as MRTF activation are	**Pave the road to drug the "undruggable": Understanding the complex biotransformation of**	**CDX-1140, a unique agonist anti-CD40 mAb for cancer immunotherapy**	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

		• Crescendo has a proprietary transgenic mouse platform for generation of fully human VH domains (Humabody VH) with excellent biophysical properties • This platform is well suited to the generation of formatted multispecific therapeutics for Immuno oncology and other therapeutic areas • The talk will describe recent case studies and how different discovery cascades have been used to identify the most potent formatted molecules • Different approaches will be described and compared including isolation of panels of single VH using display, NGS and early to format approaches • Case studies will be described	hallmarks of liver cirrhosis • WISP1 is an extracellular inducer of MRTF signaling and myofibroblast motility • WISP1 deficient mice are protected against established liver fibrosis progression • A novel WISP1 neutralizing antibody halts established liver fibrosis progression and promotes resolution by inhibiting WISP1-MRTF axis in a chronic liver injury model **Ning Ding,** Group Leader, Immunology Discovery Group, **Genentech** (CONFIRMED)	**antibody-drug conjugates** • Complex biotransfromations of next-generation ADCs • Advanced strategies, technologies and applications in ADC biotransformation • Case study: novel and complex biotransformations of CBI ADCs and their impact **Dian Su,** Scientist, **Genentech** (CONFIRMED)	• CD40 plays key roles in innate and adaptive immune responses, and targeting CD40 can promote tumor regression via multiple mechanisms • CDX-1140 is a fully human IgG2 agonist anti-CD40 mAb selected based on a linear dose response and hypothesized to achieve good systemic exposure and tumor penetration without dose-limiting toxicity observed with other potent agonist anti-CD40 mAbs • CDX1140-01 is a Phase 1 dose-escalation study with tumor specific expansion cohorts of CDX-1140 alone or in combination with CDX-301, a potent dendritic cell growth factor, in patients with advanced cancer; preliminary data from the study will be presented	

		• Beyond bispecific into trispecific **James Legg,** Vice President, Research & Development, **Crescendo Biologics** (CONFIRMED)			**Michael Yellin**, Vice President of Clinical Science, **Celldex Therapeutics** (CONFIRMED)	
12:05pm	Title TBA **Elizabeth Brunk,** Postdoc Fellow, **UCSD Moores Cancer Center** (CONFIRMED)	Title TBA **Ezio Bonvini,** Chief Scientific Officer, **MacroGenics** (CONFIRMED)	Title TBA **Vu Truong,** Founder, Chief Executive Officer and Director, **Aridis Pharmaceuticals** (CONFIRMED)	**ADCs with novel linker drugs** **Andrew Polson,** Principal Scientist, **Genentech** (CONFIRMED)	**T cell redirecting antibody circuits: Bispecifics with a unique "AND" gate to enhance tumor specificity** • Harnessing the Immune System, in particular redirected T-cells to kill tumor cells has revolutionized cancer treatment. However, on and off-target toxicity limit the therapeutic potential of these approaches • Revitope is developing T cell redirecting antibody circuits that use dual-targeting to deliver split anti-CD3 paratopes to the tumor. Reconstitution is only permitted after protease cleavage in the tumor microenvironment to remove the	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

					stabilizing dummy domain. This approach is designed to initiate and focus T cell mediated cytotoxic immunity accurately on the tumor sparing normal tissues • We will discuss protein engineering considerations, in vitro and in vivo activity measurements, half-life and the use of quantitative systems pharmacology modelling approaches to aid mechanistic understanding **Werner Meier,** CSO, **Revitope Oncology** (CONFIRMED)	
12:25am	**Structure of the 4-1BB/4-1BBL complex and distinct binding and functional properties of utomilumab and urelumab** • 4-1BBL:4-1BB complex displays a classical 3:3 structural organization with unique features. • Utomilumab and Urelumab recognize	**A versatile Plug-and-Play tetra-Fab antibody platform, BiXAb, for development of next generation bispecific antibodies with diverse set of mechanisms of action** • BiXAb® possesses excellent drug-like properties	Title TBA **Cory Brooks,** Associate Professor, **Fresno State University** (CONFIRMED)	Title and speaker TBA Referral from Joseph Eschweiler	**Engineered antibody-secreting T cells** • Brief historical overview of antibody-secreting T cell technology • Antibodies engineered to mediate ADCC can be secreted by T cells	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	different epitopes of 4-1BB • Utomilumab is a milder agonist than Urelumab **Weifeng Liu,** Senior Scientist, **Pfizer** (CONFIRMED)	• Two platform showcases: • BMX-002 for targeting of solid tumors • BMX-101: for targeting of hematological malignancies and other cancers **Eugene Zhukovsky,** Chief Scientific Officer, **Biomunex Pharmaceuticals** (CONFIRMED)			• Results in HIV suggest platform linking innate and adaptive components via antibodies is feasible **C. Russell Cruz,** Director, Translational Research Laboratories, **Centre for Emerging Technologies in Immune Cell Therapy, Children's National Hospital** (CONFIRMED)	
12:45am	Networking lunch					
Workshop: 12:50pm – 1:20pm	**Biologics investor clinic** **Kevin Johnson,** Partner, **Medixci** (CONFIRMED) **John Hood,** Chairman, **Endeavour Biomedicines** (CONFIRMED) **Stan Fleming,** Founding Managing Partner, **Forward Ventures** (CONFIRMED)					
	Protein engineering	Bispecifics development	Novel indications for therapeutic antibodies	CMC, developability and manufacturability Chaired by: **Rajesh Krishnan,** Senior Vice President, CMC and Manufacturing Operations, **Oncternal Therapeutics** (CONFIRMED)	Antibodies for immunotherapy Chaired by: **Jae Sly,** Chief Business Officer, **LigaTrap Technologies LLC** (CONFIRMED)	Technology Showcase
2:00pm	**Design of an antibody with multiple specificity for two antigens** • Will demonstrate the properties of a multibody we designed: a natural	**Affimer therapeutics: a versatile platform for the generation of bispecific immunotherapies** • An introduction to the human Affimer scaffold as a	**Antibody Fc effector function engineering and analysis** **Bronwyn Gunn,** Professor, **Harvard University** (CONFIRMED)	Title TBA **Mark Chiu,** Associate Director, Multispecific Biologics Engineering, **Janssen Research and**	**Structure-guided design of an IL-2-based therapeutic that selectively activates regulatory T cells** • Several novel IL-2 mutations that	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	human IgG that specifically binds two unrelated antigens • Will review challenges and opportunities in engineering of multiple specific antibody • Will discuss protein engineering approaches for design, selection, and assessment of multiple specific antibodies **Itay Levin,** Director of Antibody Engineering, **Biolojic Design** (CONFIRMED)	therapeutic platform for the generation of potent antagonists of check point inhibitors such as PD-L1 and LAG-3. • With our anti-PDL1 and LAG-3 Affimer proteins, we have generated high affinity bispecific formats against both human and mouse checkpoints. The Affimer molecules have been formatted as Fc and in-line fusions. • Using cell-based assays, we have shown that the combination of PD-L1 and LAG-3 blockade showed an increase in cytokine release compared to monovalent blockade alone. **Amrik Basran,** Chief Scientific Officer, **Avacta** (CONFIRMED)		**Development** (CONFIRMED)	enhance selectivity of IL-2 for Tregs will be discussed • Enhanced half-life of the IL-2 muteins in vivo • Selective expansion of Tregs in vivo, with modest to no activation of NK cells or Th cells • Efficacy in disease models of autoimmunity **Greg Babcock,** Vice President, Research, **Visterra Inc** (CONFIRMED)	
2:20pm	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**Selection of abBispecific modality for optimal tumor-anchored immune co-stimulation** • Proof-of-concept studies demonstrate	Title TBA **Elisabeth Nyakatura,** Research Assistant Professor, **Albert Einstein**	**Effective CMC strategies for downstream process development and manufacturing under an accelerated timeline**	**T cell engaging bispecific antibodies: Comparing Pfizer's platforms** • T-cell engaging bispecific antibodies are a promising	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

		tumor-cell conditional activation of the CD137 pathway by various TAA x CD137 DART® and TRIDENTTM proteins, including 5T4 x CD137, HER2 x CD137 and PD-L1 x CD137 • The TRIDENT format, bearing monovalent tumor targeting and bivalent CD137 binding, provides an optimal framework for tumor antigen-anchored CD137 bispecifics • PD-L1 x CD137 offers the ability to also simultaneously block a checkpoint in addition to CD137 costimulation • TAA x CD137 bispecific molecules enhance the anti-tumor activity of CD3-based bispecific DART molecules and Fc-optimized therapeutic mAbs **Alexey Berezhnoy,** Scientist II, **MacroGenics** (CONFIRMED)	**College of Medicine** (CONFIRMED)	• Future CMC perspectives for mAb developability from early to late stage clinical trials • A Technical Case Study • What was the problem? • What was technical resolution? • What was the outcome (with Measure – impact on product quality, Operational efficiency etc.)? **Richard Ding,** Director of Downstream Purification and Manufacturing, **AnaptysBio** (CONFIRMED)	therapeutic approach for the treatment of multiple cancer types. • Pfizer has developed several Fc-containing T-cell engaging bispecific antibody platforms, which increase the half-life and allows for conventional dosing. These platforms are currently evaluated in the clinic. • We will compare these platforms and the challenges and opportunities of each platform will be highlighted **Javier Chaparro-Riggers,** Executive Director, **Pfizer** (CONFIRMED)	

2:40pm	Title TBA **Petra Verdino,** Principal Scientist, **Eli Lilly and Company** (CONFIRMED)	Title TBA **Bellos Hadjivassiliou,** Senior Scientist, **Bristol-Myers Squibb** (CONFIRMED)	**Targeted and conditional bispecific for the treatment of fibrosis** • Targeted and conditional bispecifics: Local accumulation and activation of pro-drugs. Improving therapeutic potential of bio-therapeutics by increasing drug concentrations to target tissues and limiting systemic exposure • Antibody engineering, screening and in vivo study using a preclinical model of fibrosis will be presented showing the potential of this technology • Novel technology for new targets and biomarkers discovery **Ivan Mascanfroni,** Senior Scientist III, Immunology Biologics, **Abbvie Bioresearch Centre** (CONFIRMED)	**Early consideration in the design, expression and purification of therapeutic humanized antibody fragments for a successful pharmaceutical development** • Humanization of antibody fragments: Do it with the end in mind • Early assessment of microbial and mammalian host cells is advantageous for successful USP • Protein L is a gold standard for successful DSP but requires special tailoring during the antibody humanization process **Philippe Billiald,** Full Professor, **University Paris-Saclay,** Scientific Advisor and Co-Founder, **Acticor Biotech** (CONFIRMED)	**Development of NM21-1480 a trispecific anti-PD-L1x4-1BBxhSA antibody fragment** • NM21-1480 is a novel trispecific antibody fragment fusion protein directed against PD-L1 and 4-1BB • The molecule is designed to block PD-1/PD-L1 signalling and elicit an intratumorally restricted CD8+ T cell activation, promising a favorable benefit-to-risk profile • In vivo experiments have shown efficacy and tolerability and the molecule is expected to enter clinical testing in Q3/2020 **Sebastian Meyer,** COO, **Numab Innovation AG** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*
3:00pm	Title TBA **Eric Hampton,** Associate Director, Protein Engineering, **Calibr, a**	**A novel T cell engaging bispecific antibody induces specific and efficacious lysis of small cell lung cancer cells in**	**Structure based design of vaccines and therapeutics against Influenza virus** • Broadly neutralizing antibodies to	**Uncovering undesirable properties of mAb clones from overexpression-induced cell phenotypes**	**Tumor-targeted Immune-stimulating antibody conjugates** • Immune-stimulating antibody conjugates	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	division of Scripps Research (invited) **Protein Repurposing off-the-shelf antihelix antibodies for enabling structural biology** **Shohei Koide,** Professor, **New York University** (invited) **Protein engineering and particulate display of B-cell epitopes to facilitate development of novel vaccines** **Daniel Kulp,** Professor, **The Wistar Institute** (invited)	**vitro and potent T cell re-directed anti-tumor activity in vivo** **Paul Adam,** Executive Director, Cancer Immunology and Biotherapeutics Discovery, **Boehringer Ingelheim** (invited)	influenza hemagglutinin have defined major sites of vulnerability • More universal vaccines are being designed based on the conserved neutralizing epitopes • Multidomain antibodies, small proteins, peptides and small molecules have been designed as therapeutic candidates **Ian Wilson,** Hansen Professor of Structural Biology, Skaggs Institute for Chemical Biology, **The Scripps Research Institute** (CONFIRMED)	**by using the ER as a physiological test tube** • Condensation-prone IgGs can induce at least three different types of prominent intracellular inclusion bodies in the ER during mAb overexpression in mammalian cells • Apparent correlations between protein condensation events in the ER and solution behaviours in vitro can be leveraged to identify mAb clones that are not suitable for high-level production and high concentration liquid formulation • This cell phenotype screening assay enables a pre-emptive elimination of unfavourable mAb clones from a large panel of lead candidates at an early stage of antibody discovery program **Haruki Hasegawa,** Principal Scientist,	(ISACs) are tumor-targeting antibodies conjugated with powerful innate immune stimulants • ISACs are capable of invoking potent myeloid cell activation and the production of pro-inflammatory cytokines that favor a productive anti-tumor immune response • ISACs are active in preclinical in vivo models of cancer and are highly efficacious by enhancing ADCP, promoting antigen presentation, immunological memory, and epitope spreading **David Dornan,** Senior Vice President and Head of Research, **Bolt Biotherapeutics** (CONFIRMED)	

				Department of Therapeutic Discovery, **Amgen** (CONFIRMED)		
3:20pm	Afternoon networking break					
	Payers panel Chaired by **Jeffrey Froude,** Major, Stm, Vaccines and Therapeutics Division, **Defence Threat Reduction Agency**	Bispecifics development	Novel indications for therapeutic antibodies	CMC, developability and manufacturability Chaired by: **Rajesh Krishnan,** Senior Vice President, CMC and Manufacturing Operations, **Oncternal Therapeutics** (CONFIRMED)	Antibodies for immunotherapy	Technology Showcase
4:00pm	**Payers panel** Moderator: **Jeffrey Froude,** Major, Stm, Vaccines and Therapeutics Division, **Defence Threat Reduction Agency** Panellists: **Amy Jenkins,** Programme Manager, **DARPA** (CONFIRMED) **David Boucher,** Chief, Antivirals & Antitoxins, **Biomedical Advanced Research and Development Authority (BARDA)** (CONFIRMED) **Rachel Overman,** Deputy Join Product Manager, BIO 2, **JPM CBRN Medical** (CONFIRMED) **Rick Sciotti,** Tx Lead, **NIAID** (invited)	**Preclinical safety and efficacy of a tumor-directed T cell activating 4-1BB x 5T4 ADAPTIR™ bispecific antibody** **Sara Fritzell,** Senior Scientist, **Alligator Bioscience** (invited) **Multivalent agonists** **Jacob Gano,** Scientist and Group Leader, Antibody Engineering, **InhibRx** (invited)	**Human antibody responses to influenza in context** • Influenza virus infection and vaccination in various contexts drives unique antibody responses that inform on antibody-mediated control of the virus • The antibody repertoire induced is driven by immune history • Overcoming biases in B cell/antibody responses is a major obstacle to improved influenza vaccination and therapy **Patrick Wilson,** Professor, Department of Medicine/Rheumatology,	**Developability assessment to select well-behaved mAbs for clinical development** • Monoclonal antibodies are often administered as subcutaneous injections where favorable solution behavior is necessary to enable highly concentrated mAb formulations • Prior to clinical development well-behaved mAbs must be selected for over those that pose challenges to achieving differentiated dosage forms • Developability assessments	**Mechanisms of action of a neoantigen-targeting antibody NEO-201** • This study demonstrates that NEO-201 has several mechanisms of action. NEO-201 is able to mediate both ADCC and CDC. • In addition, NEO-201 can block the interaction between tumor cell CEACAM5 and NK cell CEACAM1 to reverse CEACAM1-dependent inhibition of NK cytotoxicity. • These results suggest that NEO-201 may potentially reverse CEACAM1-dependent immunosuppression	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

			The University of Chicago (CONFIRMED)	incorporating well-characterized predictive methods enable the selection of well-behaved mAbs **Michaela Lantz,** Scientist, **Sanofi** (CONFIRMED)	of NK cells in patients whose tumors express the NEO-201-reactive variant of CEACAM5. • NEO-201 can also target and eliminate human immunosuppressive regulatory T cells (Tregs). • Additional mechanisms are under investigation **Al Tsang,** Chief Scientific Officer, **Precision Biologics** (CONFIRMED)	
4:20pm	Payers panel continued	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**Tissue-based B-cell subsets and clonal networks** • Tissue-based B cell subsets • Clonal networks of influenza-binding B cells • How influenza-binding B cells partition into different B-cell subsets • Implications for immunologic memory and vaccine design **Nina Prak,** Professor of Pathology and Laboratory	**Efficient and scalable membrane devices for biologics purification** • New designs for membrane separation devices • Fast, scalable, high-resolution purification • Comparison with currently used devices • Biologics purification case studies including mAbs purification **Raja Ghosh,** Professor, Chemical Engineering,	**Bispecific antibodies for guided inhibition of CD47** • CD47-SIRPa axis, a phagocytosis checkpoint, is a promising target for cancer immunotherapy. Yet, therapeutic inhibition of CD47 on tumor cells is hindered by ubiquitous expression of the target in healthy tissue • Undesirable on-target/off-tumor effects typically	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

			Medicine, **Perelman School of Medicine, University of Pennsylvania** (CONFIRMED)	**McMaster University** (CONFIRMED)	observed with CD47 blocking monoclonal antibodies can be largely mitigated with a bispecific antibody, which enable guided (i.e., selective) inhibition of CD47 on cancer cells • Such CD47-blocking bispecific antibodies show potent anti-tumor activity associated with favorable pharmacokinetics and safety profiles **Krzysztof Masternak,** Head of Discovery, **Light Chain Bioscience – a brand of Novimmune SA** (CONFIRMED)	
4:40pm	Payers panel continued	Speaker TBA	**High-throughput single-cell approaches to determine antibody genes and functional features** • High-throughput single cell heavy:light sequencing enables natively paired antibody yeast display • Immortalized human yeast display libraries are screened to	**Optimisation of single cell cloning and CHO cell characterisation during biologics production** • Improvements in single cell cloning recovery • Integration of platform production processes with clone screening methods. • Characterization of cellular trafficking events induced	**A novel platform for T-cell redirection that elicits efficient tumour lysis with minimal cytokine release in multiple tumour types** • Discovery of novel CD3 binding antibodies • Unique functional activity based on novel epitope and affinity	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

			identify antigen, epitope, and affinity • Several case studies including HIV naturally infected and ZIKV convalescent patients • Comprehensive mutational analysis reveals unique pathways for antibody improvement **Brandon Dekosky,** Assistant Professor, **The University of Kansas** (CONFIRMED)	during batch and perfusion production **David Busch,** Senior Scientist, **Merck** (CONFIRMED)	• T-cell redirecting bispecific antibodies that efficiently lyse tumors with low levels of cytokine release • TNB-383B lead molecule currently in phase 1 clinical development **Nathan Trinklein,** Chief Technology Officer, **Teneobio** (CONFIRMED)	
5:00pm	Payers panel continued	Title and speaker TBA	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**Understanding the factors that affect cell line selection** • Differences in expression between high and low productivity clones were analysed using proteomics, transcriptomics, phosphoproteomics and DNA methylation analysis • Differential transcription factor binding correlates with increased productivity	**Mucin (MUC)16-directed immunotherapeutic strategies for ovarian cancer** • Immunotherapy has not been as effective in ovarian cancer compared with other solid tumor cancers such as melanoma • Selection of an appropriate tumor-restricted antigen and the presence of a highly immunosuppressive tumor microenvironment have limited	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

				• Cell machinery responds to increased gene expression by upregulating energetic and protein processing pathways **Susan Sharfstein,** Professor of Nanobioscience, College of Nanoscale Science and Engineering, **SUNY Polytechnic Institute** (CONFIRMED)	therapeutic efficacy in this disease • One approach to this problem lies in chimeric antigen receptor (CAR) T-cells which do not require T-cell receptor (TCR)-based recognition for efficacy • Another approach is the use of bi-specific T-cell engagers, which could potentially induce antigen spreading beyond the targeted tumor-associated antigen **Yeku Olapado,** Assistant Clinical Attending, **Massachusetts General Hospital** (CONFIRMED)	
5:20pm	Networking drinks and poster presentation session					

FESTIVAL OF BIOLOGICS USA

Day 3 – Wednesday March 4th 2020				
8:30am	Registration opens			
	New technology in screening and analytics	Immunogenicity and QA/QC	CMC, developability and manufacturability	Research hub
9:00am	**A reagent-independent, targeted 2D-LC-MS/MS method enabling quantification of monoclonal antibodies and biomarkers in the pg/mL range in serum** • Mass spectrometry has emerged as a powerful analytical tool for assessment of pharmacokinetics and biomarkers during the drug development process • Compared with ligand binding assays, a major limitation of mass spectrometry-based assays is their lower sensitivity • To address the sensitivity issue, we have developed a reagent-independent, targeted 2D-LC-MS/MS method which enabled 100X improvement in assay sensitivity compared with conventional LC-MS/MS • A major advantage of this method over ligand binding assays is that it is independent of high quality capture or detection reagent **Jintang He,** Scientist, **Genentech** (CONFIRMED)	**MAb immunogenicity 101** • What are the factors that contribute to immunogenicity? • Can immunogenicity be predicted? • Can immunogenicity be mitigated? **Jack Ragheb,** Senior Medical Fellow, Immunology, **Eli Lilly & Company** (CONFIRMED)	Title TBA **Tawnya Flick,** Principal Scientist, **Amgen** (CONFIRMED)	**Personalized T cell recruiting bispecific autoantibodies for treating cancer** • Strategy to overcome tumor antigen loss and heterogeneity • Tumor-specific targeting for tumors without validated antigens • Antibody conjugation method for site-specific, covalent modification with nearly any antibody • T cell recruiting bispecific autoantibodies using our production method function as expected in vitro and in vivo **Fabiana Zappala,** PhD Student, **University of Pennsylvania** (CONFIRMED)

9:20am	**The pathway to the analytical/QC laboratory of the future - A digital world awaits** • Digitalization of the laboratory will transform the way we develop, transfer, execute and analyze assays and their data • Use of automation, cognitive computing and artificial intelligence allows for speed in assay screening, assay development and improves data reliability • Virtual reality improves in assay design, training and analytical technology transfer • Paperless laboratories reduce human error and allow analysts to focus on science and big data analytics drives assay data understanding **Anthony Mire-Sluis,** Head of Global Quality, **AstraZeneca** (CONFIRMED)	**Immunogenicity of bioproducts: cellular models to evaluate the impact of therapeutic antibody aggregates** • Optimization of in vitro methods to evaluate the potential of aggregated therapeutic antibodies to induce early adaptive immune responses that could drive ADA development • Predictive assays that can monitor DC maturation, in order to determine whether different antibody aggregate types have direct DC stimulatory capabilities • Original co-culture model to assess the potential of oligomeric and subvisible antibody aggregates stimulated DC to drive T lymphocyte cells activation and polarization **Isabelle Turbica,** Associate Professor, **Paris-Sud University** (CONFIRMED)	**Overcome liquid-liquid phase separation (LLPS) caused manufacturing challenges for a therapeutic monoclonal antibody** • LLPS caused problems for the downstream manufacturability of a therapeutic mAb. Process parameter optimization partially mitigated the LLPS, however limitations remained for large-scale manufacturing • We carried out a systematic investigation to gain mechanistic insight into LLPS behavior and developed mitigation strategies • Protein engineering disrupting inter-molecule electrostatic interactions resulted in LLPS free mAb with improved developability **Qun Du,** Scientist I, **AstraZeneca** (CONFIRMED)	Title TBA **Ethan Laudermilch,** Post-Doc, **Albert Einstein College of Medicine** (CONFIRMED)
9:40am	**Collision induced unfolding: Rapid stability analyses for monoclonal antibodies and biosimilars** • Ion mobility-mass spectrometry (IM-MS) is a versatile tool for quickly assessing the higher-order structure (HOS) of mAb samples • Collision induced unfolding (CIU) is a gas-phase analogue of calorimetry measurements routinely taken to assess protein therapeutics, capable of rapid	**Biologics and its immunogenicity in the early clinical development** • Biologics and the immunogenicity • The impact on the efficacy and safety • How to detect and manage immunogenicity during the development **Joan Shen,** Head of Research and Development, **I-Mab Biopharma** (CONFIRMED)	**Concentration does matter for analytical method transfer for bispecifics** • Review the driver for requiring the need for transfer of product specific methods and the timeline • Review the challenges that occurred during method transfer and the work arounds • Recommendations for improvements for CMC management of method transfer	**Identification and characterization of KRAS G12V-specific CD4 T cells from the blood of a pancreatic cancer patient** • We have developed a novel HLA-agnostic approach to neoantigen identification which combines genomic sequencing, bioinformatic analysis, and functional assays • We identified eleven dominant CD4 T clones from the blood of a pancreatic cancer patient and

	(~5 sec / sample) mAb analysis using small amounts of unpurified samples • CIU can rapidly differentiate mAb samples based on HOS differences caused by sequence, stress, disulfide bonding pattern, glycosylation, and conjugation state (for antibody-drug conjugates). • CIU screening can differentiate biosimilars from innovator mAbs, enabled by multi-state classifiers built upon machine learning algorithms developed in the Ruotolo lab. **Brandon Ruotolo,** Professor, Chemistry, **University of Michigan** (CONFIRMED)		**Jon Strauss,** Director of CMC, **Calibr, a division of Scripps Research** (CONFIRMED)	confirmed specificity, restriction, minimal epitopes, and avidity • These KRAS G12V-specific CD4 TCRs could be of therapeutic value to patients with the same driver mutation and HLA haplotype **Martin Naradikian**, Postdoctoral Fellow, **La Jolla Institute for Immunology** (CONFIRMED)
10:00am	**Epitope-targeted antibody screening** • A new approach to selection of antibodies binding to the targeted epitope in the antigen. • By one- or two-round of panning against phage display libraries, hits binding to the target epitope can be enriched and identified • Hits identified by this approach are not biased to their initial affinities and retain high level of sequence diversity. **Feng Wang,** Associate Director, Principal Investigator, **Institute of**	**Molecular Insights into key mechanistic steps of an adaptive immune response** • Computational methods: Molecular dynamics simulations, Markov State Modelling, a deep learning • Allosteric couplings found in simulated Peptide-MHCII complexes • Protein immunogenicity prediction **Sebastian Stolzenberg**, PostDoc Project Leader, **Free University of Berlin** (CONFIRMED)	**Development of the filamentous fungus Myceliophthora thermophila C1 into a next-generation therapeutic protein production system** • Myceliophthora thermophila C1 is a highly potent protein production host exploited for industrial enzyme production. We aim to utilize its vast production potential in production of biologics • The host protease activity limits production of therapeutic and vaccine proteins. We have characterized them and generated multiple protease gene deficient production strains • Superb production levels have been obtained, e.g. up to 22 g/l of Mabs,	Title and tba **Ariel Wirchnianski,** PostDoc, **Albert Einstein College of Medicine** (CONFIRMED)

	Biophysics, Chinese Academy of Sciences (CONFIRMED)		up to 13 g/l of Fc-fusion proteins in a 6-7 day bioprocess. Many difficult-to-express proteins have been produced successfully • We work to humanize the C1 glycosylation machinery by deleting native sugar transferases and expressing components of animal glycosylation pathways in the fungus **Markku Saloheimo,** Senior Principal Scientist, **VTT Technical Research Centre of Finland** (CONFIRMED)	
10:20am	**Generating pairs of recombinant affinity reagents for sandwich assays through MegaSTAR** • Millions of pair-wise combinations created and tested in a single tube • Inherently biased towards identification of non-overlapping binding pairs • Extensive epitope coverage • Suitable for generating monospecific reagents to members of protein families that are challenging targets due to high sequence identity **Brian Kay,** Professor, Department of Biological Sciences, LAS Distinguished Professor & University Scholar, **University of Illinois at Chicago** (CONFIRMED)	Title and speaker TBA	Stabilising proteins at room temperature – translating biostasis into medicine Tristan McClure-Begley, Program Manager, Biologics Technologies Office (BTO), Defense Advanced Research Projects Agency (DEFRA) (invited) Continuous Biopharmaceutical Manufacturing Seongkyu Yoon, Department of Chemical Engineering, University of Massachusetts Lowell (invited) Emerging biomaterials for downstream manufacturing of therapeutic proteins Xuankuo Xu, Senior Scientist, Bristol-Myers Squibb (invited) Single-step Protein A and Protein G avidity purification methods to support bispecific antibody discovery and development	Title and speaker TBA

			Stanislas Blein, Head, Antibody Engineering, Glenmark Pharmaceuticals (invited) Economic Analysis of Batch and Continuous Biopharmaceutical Antibody Production: a Review Maen Qadan, Research Advisor, Eli Lilly and Company (invited) Cation exchange chromatography performed in overloaded mode is effective in removing viruses during the manufacturing of monoclonal antibodies Yumiko Masuda, Daiichi Sankyo Co. (invited) Title TBA Chien-Hung Chen, Staff Scientist, Structural Biology & Biophysics, Takeda (invited)	
10:40am	Morning networking break			
	New technology in screening and analytics	Computational discovery and development Chaired by: **Partha Chowdhury,** Senior Director and Head, Antibody Discovery, **Sanofi Genzyme** (CONFIRMED)	CMC, developability and manufacturability	Research hub
11:15am	**Single-molecule detection of proteins using membrane protein engineering** • A generic strategy for single-molecule detection of protein biomarkers in a complex biofluid will be discussed	**Using big data and computations to guide the design of better antibodies** • We present a discovery and design platform that is based on a combination of computational and biochemical tools. • We show how it is used to design and produce		**Comprehensive analysis of neutralizing antibodies raised against the yellow fever virus vaccine** • First comprehensive analysis of antibody response to yellow fever vaccine

	• We have manufactured a selective sensor is like a fishing rod with three parts: a tethered protein receptor in the form of a hook, a hexapeptide tether, which is similar to a short, flexible line, and a signal transducer, functioning like an angling rod • The transducer forms a membrane protein nanopore that facilitates a uniform electrical current • When a free protein ligand in solution is reversibly bound by the tethered protein receptor, transient capture and release events are measured as current deflections between two substates of the nanopore • Our highly specific sensor could be extended to emerging areas of molecular diagnostics or might be adapted to develop tools in high-throughput protein profiling and drug discovery **Liviu Movileanu,** Professor, Department of Physics, **Syracuse University** (CONFIRMED)	• Antibodies that surgically bind to functional epitopes, thus leading to the desired mechanism of action. • Multibodies: Antibodies that maintain the natural IgG format but can bind two different epitopes on two different targets. • Sub nanomolar affinity binding • Good developability profile • We will show experimental results from biological studies of our antibodies **Yanay Ofran,** Founder and Chief Executive Officer, **Biolojic Design** (CONFIRMED)		• Emergence of highly potent neutralizing antibodies after vaccination over time • Insights into the capacity of the vaccine to protect against the emerging yellow fever virus strain in Brazil **Denise Haslwanter,** Research Fellow, **Albert Einstein College of Medicine** (CONFIRMED)
11:35am	**Higher order structural analysis of protein therapeutics using mass spectrometry** • Reliable, structurally informative, and rapid higher-order structural analysis of protein therapeutics is	Title TBA Senior representative, **Schrödinger** (CONFIRMED)		Title and speaker TBA

	important for ensuring their safety and efficacy • A method based on covalent labeling and mass spectrometry has been developed to identify protein aggregation sites and specific protein regions that undergo subtle structural changes upon mishandling or stress • Covalent labeling with mass spectrometry can provide residue specific structural information under a wide variety of conditions much more rapidly than existing high resolution techniques, such as NMR • When used together with hydrogen/deuterium exchange, covalent labeling mass spectrometry can provide unprecedented structural information for protein therapeutics **Richard Vachet,** Department Head, Professor in Chemistry, **University of Massachusetts Amherst** (CONFIRMED)			
11:55am	**Higher order structure and molecular mechanism of action analysis for accelerated drug design** • Will introduce mass spectrometry and nuclear magnetic resonance technologies for characterizing	**Machine learning enables accurate prediction of deamidation probability and rate** • Deamidation is a major pathway of protein degradation and has been shown to negatively affect both in vitro stability and in vivo		Title and speaker TBA

	higher order structure and molecular mechanism of action • 'Real world' examples of HOS and MoA accelerated biopharmaceuticals development in cancer, neurodegenerative disease and vaccine development • Will introduce concept of 'dynamics-guided drug design' **Derek Wilson,** Director, Wilson Lab, **York University** (CONFIRMED)	biological function of diverse classes of proteins • During protein therapeutics development, deamidation liabilities that are overlooked necessitate expensive and time-consuming remediation strategies, sometimes leading to termination of the project • We applied machine learning to create computational models for antibody asparagine deamidation with nearly 5% increased accuracy over the best currently available models. Surprisingly, our model also paces or outperforms advanced and conventional models on non-antibody proteins • In addition to deamidation probability, we are able to accurately predict deamidation rate, a capability with no peer in current models **Jared Delmar,** Scientist I, **AstraZeneca** (CONFIRMED)		
12:05pm	**Characterization of mAb and ADC charge variants** **Romesh Rao,** Research Associate III, **Seattle Genetics** (CONFIRMED)	Title TBA **Sandeep Kumar,** Senior Research Fellow, Biotherapeutics, **Boehringer Ingelheim** (CONFIRMED)		Title and speaker TBA
12:25pm	**Using mechanical energy to drive protein purification, folding, and antibody discovery** • A vortex fluidic device (VFD) inputs mechanical energy into solutions to drive chemical	**In-silico Immunogenicity Predictions** **Vinodh Kurella,** Senior Scientist, **Voyager Therapeutics** (CONFIRMED)		Title and speaker TBA

	transformations — including protein folding and purification • The VFD offers a simple, efficient, and rapid approach to immobilize and purify proteins in a VFD reactor • Recent results applying this system to molecular evolution and selections with antibody fragment libraries and other applications will be presented **Gregory Weiss,** Professor, **University of California Irvine** (CONFIRMED)			
12:45pm	Networking lunch			
	Americas Antibody Congress – Closing plenary			
1:45pm	**Regulatory updates for antibody therapeutics** **Marjorie Shapiro,** Supervisory Biologics Office of Biotechnology Products, **CDER, FDA** (CONFIRMED)			
2:05pm	Title TBA **Partha Chowdhury,** Senior Director and Head, Antibody Discovery, **Sanofi Genzyme** (CONFIRMED)			
2:25pm	Title and speaker TBA			
2:45pm	Chair's closing remarks			
2:55pm	Closing remarks from Terrapinn			
3:00pm	End of conference			

FESTIVAL OF BIOLOGICS USA

Presents

WORLD IMMUNOTHERAPY CONGRESS USA 2020

World Immunotherapy Congress USA 2019

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Stephen Schoenberger, Professor, **La Jolla Institute for Immunology**
Roy Baynes, Senior Vice President and Head Global Clinical Development, Chief Medical Officer, **Merck**

Speakers

Roy Baynes, Senior Vice President and Head Global Clinical Development, Chief Medical Officer, **Merck**
Andrew Allen, President & Chief Executive Officer, **Gritstone Therapeutics**
Ira Mellman, Vice President, Cancer Immunology**, Genentech**
Bob Valamehr, Chief Development Officer, **Fate Therapeutics**
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Shahram Salek-Ardakani, Senior Director, Cancer Immunology, **Pfizer**
Jeffrey Miller, Professor of Medicine, **University of Minnesota,** Deputy Director, **University of Minnesota Masonic Comprehensive Cancer Center**
Yeku Olapado, Assistant Clinical Attending, **Massachusetts General Hospital**
Michael Yellin, VP, Clinical Science, **Celldex Therapeutics**
Larry Lum, Professor, Director of Cellular Therapy, Scientific Director of Bone Marrow Transplant, **University of Virginia**
Frédéric Triebel, Chief Scientific Officer, Chief Medical Officer, **Immutep**
James Legg, SVP Research and Development, **Crescendo Biologics**
Stephen Schoenberger, Professor, La **Jolla Institute for Immunology**
Ezra Cohen, Associate Director, **U.C. San Diego Moores Cancer Center**
Nicolas Poirier, Chief Scientific Officer, **OSE Immunotherapeutics**
Denise Steckel, Head, Clinical Collaborations Management, **Genentech**
Jay Mandrekar, Professor of Biostatistics and Neurology, **Mayo Clinic**
Saso Cemerski, Senior Director of Translational Immunology, **Cue Biopharma**
Sari Pesonen, VP, Scientific and Clinical Development, Co-Founder, **Valo Therapeutics**
Laurent Humeau, CSO, EVP of Research, Engineering and Clinical Developments, **Inovio Pharmaceuticals**
Kate Broderick, Vice President, **Inovio Pharmaceuticals**
Giedre Krenciute Assistant Member, **St. Jude Children's Research Hospital**
Steven Feldman, Director of Manufacturing and Process Development, **Stanford Center for Cell Therapy**
Jim Heath, President and Professor, **Institute for Systems Biology**
Nate Root, Associate Director, Clinical Disclosure & Transparency, **Ionis Pharmaceuticals**
Bill Monteith, Executive Vice President, Technical Operations, **Cellectis**
Keri Schadler, Assistant Professor**, MD Anderson Cancer Center**
Christina Yi, Chief Operations Officer, **Dendreon**
Loui Madakamutil, SVP, Head of Biology and Preclinical Development, **Nektar Therapeutics**
Steven Jonas, Researcher, **UCLA**
Justin Eyquem, Principal Investigator - Parker Fellow**, UCSF**
Kelly Coulbourne, Associate Director, Clinical Trial Data Registries, **Allergan**
Brian Champion, CSO**, PsiOxus Therapeutics**
Dan Kaufman, Professor of Medicine, Director of Cell Therapy, **UCSD**
Eric Halioua, President and Chief Executive Officer, **PDC*line Pharma**
Christopher Thanos, CEO, **Actym Therapeutics**
Jonathan Pachter, CSO, **Verastem Oncology**
Christophe Quéva, CSO, **Oncorus**
Mohamed Ladha, Vice President and Head, Commercial, **Tocagen**
Robert Wild, Chief Scientific Officer, **Dracen pharmaceuticals**
Kanti Thirumoorthy, Executive Director, Operations Team Lead, Process Development, **Kite Pharma**
Caroline Breitbach, VP R&D Programs and Strategy, **Turnstone Biologics**
Joanne Tan, Research Fellow/Associate Director, **Arcus Biosciences**
Theodore Roth, Research Fellow, **UCSF**
C. Russell Cruz, Director, Translational Research Laboratories, Centre for Emerging Technologies in Immune Cell Therapy, **Children's National Hospital**
David Dornan, Senior Vice President of Research, **Bolt Biotherapeutics**
Sebastian Meyer, COO, **Numab Innovation AG**
Javier Chaparro-Riggers, Executive Director, **Pfizer**
Greg Babcock, Vice President, Research, **Visterra Inc**
Werner Meier, CSO, **Revitope Oncology**
Bruce Keyt, CSO, **IGM Biosciences**
Karsten Sauer, Vice President, Immunology**, Torque Therapeutics**
Robert Coffin, CEO, **Replimmune**
Miguel Garcia-Guzman, Chief Scientific Officer, **Rakuten Medical**
John Bell, Professor of Medicine, **Ottawa Health Research Institute**
Farshad Guirakhoo, CSO, **GeoVax**
Sharareh (Sherri) Gholamin, Researcher, **Caltech**
Nathan Trinklein, Chief Technology Officer, **Teneobio**
Cliona Rooney, Professor, Department of Pediatrics, Section of Hematology-Oncology**, Baylor College of Medicine**
Care - Blood and Marrow Transplant Unit
Anne Cunniffe Marcy, Clinical Research Coordinator**, Stanford University School of Medicine - Cancer Clinical Trials Office**
Scott Carmer, CEO, **NexImmune**

Maksim Mamonkin, Assistant Professor, **Baylor College of Medicine**
RJ Tesi, CEO/CMO, **InMune Bio**
M**ark Lowdell,** CSO, **InMune Bio**
Linda Liu, SVP, Research, **NextCure**
Darya Alizadeh, Assistant Research Professor, **City of Hope**
Niranjan Y. Sardesai, Co-Founder, President and CEO, **Geneos Therapeutics**
Agnete Fredriksen, Co-Founder, President and CSO, **Vaccibody**
Deepak Khatry, Science Associate Director, Oncology Biometrics, **AstraZeneca**
Marit van Buuren, Lab Head, Scientist II, Immunology, **Neon Therapeutics**
Lobelia Samavati, Associate Professor of Molecular Medicine and Genetics, **Center for Molecular Medicine and genetics**
David Reardon, Clinical Director, Center for Neuro-Oncology, **Dana-Farber Cancer Institute**
Philip Arlen, President & CEO, **Precision Biologics**
Shawn Fahl, Director, Flow Cytometry Services, **Discovery Life Sciences**
Vassiliki Papadimitrakopoulou, Professor of Medicine in the Department of Thoracic/Head and Neck Medical Oncology, **MD Anderson Cancer Center**
Joann Peters, Vice President Clinical Operations**, Geneos Therapeutics**
Cathy Carfagno, Associate Director, **Merck**
Jessica Baker Flechtner, CSO, **Genocea**
Christina Annunziata, Head, Translational Genomics Section, **NIH**
Sujith Joseph, Senior Scientist, **Baylor College of Medicine**
Corey Carter, CEO, **EpicentRx INC**
AJ Joshi, SVP, Chief Medical Officer, **Atara Biotherapeutics**
Al Tsang, CSO, **Precision Biologics**
Krzysztof Masternak, Head of Discovery, **Light Chain Bioscience – a brand of Novimmune SA**
Brent Rice, Vice President, Global Market Access**, Autolus**
Amrik Basran, Chief Scientific Officer, **Avacta**
Marina Udier, CEO, **Nouscon**
Christopher (CJ) Barnum, Director of Neuroscience and Translational Medicine, **INmune Bio**
Lelisa Gemta, Associate Scientist, **Regeneron Pharmaceuticals**
Matteo Levisetti, Chief Development Officer, **DNAtrix**
Wenfeng Xu, Vice President of Research, **Hengenix**
Sandhya Girish, Senior Director, Global head Oncology, **Genentech**
Barbara Hickingbottom, Vice President, Clinical Development, **Xencor**
Kefeng (Kevin) Hua, Senior Manager, AI/Machine Learning Development, **Bayer**
Alvin Luk, Senior Vice President & Chief Medical Officer, **Shanghai Henlius Biotech**
Su Xiao, CEO**, Neuropth**
Rajesh Krishnan, Senior Vice President, Process Development and Manufacturing, **Oncternal Therapeutics**
Tam Soden, Senior Director**, Kite Pharma**
Rajita Pappu, Senior Scientist, **Genentech**
Fabiana Zappala, PhD Student, **University of Pennsylvania**
Shannon Turley, Staff Scientist and Group Leader in Cancer Immunology Discovery, **Genentech**
Angelica Loskog, CEO, **Lokon Pharma**
Alfonso Quintas, Chief Medical Officer, **TCR2 Therapeutics**
Ethan Laudermilch, Post-Doc, **Albert Einstein College of Medicine**
Martin Naradikian, Postdoc, **La Jolla Institute for Immunology**
Denise Haslwanter, Research Fellow, **Albert Einstein College of Medicine**
Ariel Wirchnianski, PostDoc, **Albert Einstein College of Medicine**
Senior Representative, **Applied BioMath**
Hanspeter Gerber, SVP & CSO, **3T Biosciences**
Simon Lacey, Director, The Center for Cellular Immunotherapies, **University of Pennsylvania**
Roman Yelensky, EVP & Chief Technology Officer**, Gritstone Oncology**
Kathryn Austgen, Associate Director**, BlueRock Therapeutics**

Workshop hosts:

Julie Gerberding, Executive Vice President, Communications, Global Policy, and Population Health & Chief Patient Officer**, Merck**
Eve Bukowski, Vice President, Patient Advocacy, Education & Outreach**, California Life Sciences Association (CLSA)**
Brenda Hann, Director, Clinical Trials Operations, **Stanford Medicine**

Janet McDowell, Clinical Research Manager, **Stanford University School of Medicine - Cancer Clinical Trials Office**
Theresa Latchford, Oncology Clinical Nurse Specialist, **Stanford Health**
Amrit Takhar, GP Partner and Clinical Lead, **Wansford surgery – NHS**

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Day 1 – Monday March 2nd 2020			
7:30am	Registration opens		
	Opening keynotes		
9:00am	Opening remarks from Terrapinn		
9:05am	Chair's opening remarks		
9:10am	**Mechanistic basis of cancer immunotherapy: checkpoints@10** • Checkpoint inhibition has revolutionized both cancer biology and cancer care. • However, only a minority of patients receive substantial benefit, and no new immunomodulators have been approved outside of the PD-l1/PD-1 axis. Why? • Progress can be made, but will require a deeper and more accurate understanding of the mechanisms of tumor immunity, even our understanding of how checkpoint inhibitors work may be fundamentally flawed **Ira Melmann,** Vice President, Cancer Immunology, **Genentech** (CONFIRMED)		
9:30am	**Title TBA** **Rich Murray,** CEO, **Jounce Therapeutics** (CONFIRMED)		
9:50am	**NK cell Therapy: individualized products to off-the-shelf strategies** • Understand the biologic concept of adaptive NK cells with properties of immune memory • Understand how the CD16 activating receptor can be repurposed to make NK cells antigen specific • Understand concepts of off-the-shelf induced pluripotent derived NK cells **Jeffrey Miller,** Professor of Medicine, Division of Hematology, Oncology and Transplantation, **University of Minnesota** (CONFIRMED)		
10:10am	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*		
10:30am	**Morning networking break**		
11:30am	**Plenary roundtable session** 15 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 35 minutes.		
	TABLE 1 **Novel modalities in immunotherapy** **Gary Starling,** Associate Vice President, **Merck** (CONFIRMED)	TABLE 2 **Product management models** **Kanti Thirumoorthy,** Executive Director, Operations Team Lead, Process Development, **Kite Pharma** (CONFIRMED)	TABLE 3 **Title TBA** **RJ Tesi,** CEO/CMO, **InMune Bio** (CONFIRMED)
	TABLE 4 **Change management** **Cathy Carfagno,** Associate Director, **Merck** (CONFIRMED)	TABLE 5 **Current and future reimbursement challenges for CAR-T cell therapies** **Brent Rice,** Vice President, Global Market Access, **Autolus** (CONFIRMED)	TABLE 6 **Challenges facing bispecific antibodies for immunotherapy** **Wenfeng Xu,** Vice President of Research, **Hengenix** (CONFIRMED)

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	TABLE 7 **Immune checkpoints inhibitors in combination with targeted biosimilars** **Alvin Luk,** Senior Vice President & Chief Medical Officer, **Shanghai Henlius Biotech** (CONFIRMED)		TABLE 8 **Evolving immuno-oncology landscape** **Roy Baynes,** Senior Vice President and Head Global Clinical Development, Chief Medical Officer, **Merck** (CONFIRMED)		TABLE 9 **Roundtable available**
	TABLE 10		TABLE 11		TABLE 12
	TABLE 13 *Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*		TABLE 14 *Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*		TABLE 15 *Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*
12:40pm	**Networking lunch**				
12:45-1:20pm	**WORKSHOP: Comparing strategies and challenges of bispecific antibody infusion** **Larry Lum,** Professor, Director of Cellular Therapy, Scientific Director of Bone Marrow Transplant, **University of Virginia** (CONFIRMED)				
	Cell Therapy	**Cancer Vaccines**	**Tumor Microenvironment**	**Solid Tumours**	**Technology showcase**
			Chair: RJ Tesi, CEO/CMO, **InMune Bio**		
2:00pm	**Off-the-Shelf Cell-based Cancer Immunotherapy: A Master Pluripotent Cell Platform for Mass Production of Allogeneic CAR-T and -NK cell Products** • Using iPSCs to create single cell derived engineered master cell lines with multiplexed functionality • Creating renewable master cell banks to achieve continuous production of engineered NK and T cells • Delivering cost effective, consistent and homogenous cell	**Tumor neoantigens delivered as solid tumor immunotherapeutics – what are the early clinical data telling us?** • Mutation-derived neoantigens are key tumor cell targets for the adaptive immune system, but are rare, and their accurate identification is challenging but necessary • Delivered within potent vaccine vectors, neoantigens may be able to drive therapeutic immune responses	**Immunologic effects of Duvelisib (PI3K-delta/gamma inhibitor) and Defactinib (FAK inhibitor)** • Effects of PI3K-delta and PI3K-gamma inhibition on immune cells in the tumor microenvironment • Effects of FAK inhibition on immunosuppressive cells and stromal density in the tumor microenvironment • Efficacy in combination with checkpoint or co-stimulatory antibodies **Jonathan Pachter,** CSO, **Verastem Oncology** (CONFIRMED)	**Promoting the survival of adoptively transferred tumor-specific T-cells in the solid tumor environment** • T-cells require 3 signals for expansion and survival; lacking in the TME • Tumor-specific T-cells must survive multiple inhibitory signals • Can T-cells be modified to thrive in this environment? **Cliona Rooney,** Professor, Department of Pediatrics, Section of Hematology-Oncology**, Baylor College of Medicine** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	therapeutics on demand and off-the-shelf **Bob Valamehr,** Chief Development Officer, **Fate Therapeutics** (CONFIRMED)	• Clinical trials of neoantigen immunotherapies are underway and early data will be instructive as to how they may be best deployed in the solid tumor immunotherapy context **Andrew Allen,** President & Chief Executive Officer, **Gritstone Therapeutics** (CONFIRMED)			
2:20pm	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**New class of Ag-specific cancer active immunotherapies based on an off-the-shelf antigen presenting cell line (PDC*line)** • 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	**Exercise as a novel method to improve tumor vascular function** • Moderate aerobic exercise remodels solid tumor vasculature, improving blood delivery and decreasing blood flow • In mice, exercise increases efficacy of chemotherapy by enhancing drug delivery • Reduced tumor hypoxia due to exercise-induced vascular remodeling has implications for radiation therapy and immunotherapy **Keri Schadler,** Assistant Professor**, MD Anderson Cancer Center** (CONFIRMED)	**Novel, cleaner targets for solid tumor targeting with high potency modalities** • Conventional cell surface antigens with high expression across tumors are commonly expressed on normal tissues, creating potential for on-target, off-tumor toxicities when targeted by high-potency oncology compounds. • Recent clinical trial data from patients with solid tumors that were treated with immune checkpoint inhibitors demonstrate that CD8+ T cells can mediate deep and durable responses in solid tumors. • How to identify TCRs and pMHC targets involved in mediating complete responses following ICI treatment ? • The most promising approaches to identify pMHC targets and their	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

		• The technology can be applied for any cancer **Eric Halioua,** President and Chief Executive Officer, **PDC*line Pharma** (CONFIRMED)		corresponding TCRs will be discussed **Hanspeter Gerber,** SVP & CSO, **3T Biosciences** (CONFIRMED)	
2:40pm	**TRuCs, a novel engineered T cell approach to the treatment of solid tumors** **Alfonso Quintas,** Chief Medical Officer, **TCR2 Therapeutics** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**Precision engineering to advance adoptive T cell therapies** • Advantages of targeting CAR and TCR transgene into the TRAC locus • Scaling up the TRAC-CAR T cells GMP manufacturing • An Immunocompetent mouse model to study Allogeneic CAR T cells **Justin Eyquem,** Principal Investigator - Parker Fellow**, UCSF** (CONFIRMED)	**Potentiating the NK cell response to solid tumours to overcome the TME** • Induction of NK cell hyporesponsiveness by tumor cells • Role of Treg and MDSC in suppression of intra-tumoral NK responses • The effect of hypoxia on NK cell reactivity M**ark Lowdell,** CSO, **InMune Bio** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*
3:00pm	**Improved cancer therapy using engineered human pluripotent stem cells** • Efficient Development of natural killer (NK) cells from human pluripotent stem cells • Strategies to use human pluripotent stem cells as a platform to produce human NK cells with improved anti-tumor activity • Clinical translation of human pluripotent stem cell-derived NK cells	**Synthetic DNA-based immunotherapies for cancer treatments** • Synthetic DNA with Active Adaptive Electroporation have come of age as a leading immunotherapy platform • Inovio's immunotherapies function exclusively in vivo, generating antigen-specific cellular responses against targeted diseases	**Role of endogenous immune cells in glioma microenvironment during CAR T cell therapy** • Our team is clinically evaluating IL13Rα2-targeted CAR-T cells for the treatment of recurrent IL13Rα2-positive MGs [NCT02208362] • We have established a syngeneic immunocompetent glioma model, which recapitulates the tumor microenvironment (TME) of patients	**Title TBA** **Steven Kelly**, CEO, **Carisma Therapeutics** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	Dan Kaufman, Professor of Medicine, Director of Cell Therapy, **UCSD** (CONFIRMED)	demonstrated in clinical trials • Versatility of the platform allows for complex formulations co-delivering Synthetic DNA encoding for TAAs, genetic adjuvants, mAb and bispecifics **Laurent Humeau**, CSO, EVP of Research, Engineering and Clinical Developments, **Inovio Pharmaceuticals** (CONFIRMED)	• Murine IL13Rα2-CAR-T cells mediate potent antitumor activity against IL13Rα2-engineered KR158, a highly invasive murine glioma model • Characterization of the tumor microenvironment post-CAR-T therapy indicates activation of endogenous cytotoxic CD8 T and myeloid cells, and decrease in the frequency of T regulatory cells. Further analyses reveal that tumor-associated macrophages (TAMs) may be reprogrammed during CAR-T therapy to exhibit tumoricidal activity and may promote the activation of endogenous T cells (CD4/CD8 T cells) resulting in enhanced antitumor activity. • Our data strongly suggest that CAR-T therapy has the potential to reshape the glioma microenvironment creating a context permissible to elicit effective endogenous antitumor immunity. **Darya Alizadeh,** Assistant Research Professor, **City of Hope** (CONFIRMED)		
3:20pm	**Networking break**				

	Cell Therapy	Cancer Vaccines	Tumor Microenvironment	Solid Tumours	Technology showcase
4:10pm	**Arming T cells to target solid tumors** • Arming ex vivo expanded T cells with bispecific antibodies creates an army of anti-tumor CTLs • Infusions have produced encouraging clinical results in breast and pancreatic cancer • Infusion of targeted T cells leads to in situ immunization of the patients endogenous immune system to produce a long-term anti-tumor effect **Larry Lum,** Professor, Director of Cellular Therapy, Scientific Director of Bone Marrow Transplant, **University of Virginia** (CONFIRMED)	**Supercharging the tumor microenvironment with the engineered cytokines NKTR-214 and NKTR-255** • Cytokines are powerful agents that can provide expansion and differentiation for effector cells. In their native state they are poor medicines. • Engineered cytokines can more effectively stimulate cytokine receptor pathways, while controlling adverse events. • The combination of NKTR-214 with Opdivo has demonstrated powerful anti-tumor effects and profoundly alters the tumor microenvironment, increasing effector T-cell counts, increasing PD-1 expression on tumor T-cells, and converting PD-L1 negative tumors to positive, while maintaining a more tolerable AE profile than traditional cytokine therapies • NKTR-255 is an immune cytokine that can	**Targeting sTNF to manipulate the TME in Breast Cancer** • Local mechanisms of resistance to immunotherapy • Role of MUC4 in resistance to trastuzumab in HER2+ breast cancer • Targeting soluble TNF to prevent MUC4 expression and reverse resistance to trastuzumab **RJ Tesi,** CEO/CMO, **InMune Bio** (CONFIRMED)	**A novel therapeutic platform that delivers immunomodulatory payloads to tumor-resident myeloid cells after IV dosing and demonstrates potent anti-tumor efficacy in preclinical studies** • Many experimental therapies developed to promote proper T-cell infiltration in immune-excluded tumors are too toxic for systemic administration, which will be required in a metastatic disease setting. • We have engineered a highly attenuated, microbial-based immunotherapy platform called STACT (S. Typhimurium Attenuated Cancer Therapy). Upon IV administration, the microbe traffics to and enriches in the tumor microenvironment. There, it is specifically phagocytosed and lysed by tumor-resident myeloid cells, enabling efficient delivery of plasmids encoding immunomodulatory payloads	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

		selectively grow NK cells and CD8 memory T cells in the patient's body. This allows for the potential to combine NKTR-255 with ADCC mabs and to induce long term survival of CAR-Ts **Loui Madakamutil,** SVP, Head of Biology and Preclinical Development, **Nektar Therapeutics** (COFIRMED)		• Using our proprietary platform, we have generated multiple systemically-administered therapies that target several well-characterized, yet intractable immune pathways. Characterization of STACT microbes encoding constitutively active STING variants (STACT-STING) and IL-2 (STACT-IL2) are provided as examples **Christopher Thanos,** CEO, **Actym Therapeutics** (CONFIRMED)	
4:30pm	**Deep Primed™ T cell therapy leverages natural biology for superior efficacy against solid tumors** • Success of T cell therapies against solid tumors has been limited • Torque has developed its Deep Primed™ T Cell Immunotherapy platform. Here, the patient's own T cells are first primed and expanded by autologous dendritic cells presenting multiple shared or viral tumor antigens. Next, the resulting multi-targeted T cells (MTC) are loaded with nanoparticles whose payloads are designed to	**Tedopi: neo-epitope cancer vaccine to tackle resistance to immune checkpoint inhibitors** • Tedopi®is a mature multiple neoepitope cancer vaccine with ongoing phase III clinical trial in NSCLC after anti-PD(L)1 failure and phase II in PDAC in combination with the anti-PD1 Opdivo • A precision medicine cancer vaccine for HLA-A2+ patients fighting tumor antigens heterogeneity by covering different tumor antigens	**Title TBA** **Shannon Turley,** Staff Scientist and Group Leader in Cancer Immunology Discovery, **Genentech** (CONFIRMED)	**Cell-Based therapies for solid tumors** • Brief historical overview of cell therapies for solid tumors • CNMC experience: NK cell based approaches for solid tumors • CNMC experience: T cell based approaches for solid tumors **C. Russell Cruz,** Director, Translational Research Laboratories, Centre for Emerging Technologies in Immune Cell Therapy, **Children's National Hospital** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	overcome the above bottlenecks to efficacy. Finally, these Deep Primed™ MTC are infused back into the patient in a multi-dosing regimen. They home to TME and tumor draining lymph nodes, where they release their payloads in a controlled manner. This maximizes efficacy at the target organs and limits systemic exposure. • Deep Primed™ T cell therapy leverages broad and natural repertoires of antigens and T cells for superior efficacy, does not require T cell genetic engineering, and utilizes powerful immunomodulating payloads whose systemic administration is toxic. These benefits are produced at a fraction of the cost of CAR-T and TCR-T cell therapies. • In my talk, I will introduce this groundbreaking technology, present key data demonstrating its extraordinary safety and efficacy, and highlight underlying mechanisms	• An Off-the-Shelf and Ready-to-Use emulsion of a proprietary combination of 10 neoepitopes • Breaking self-tolerance by rational design of fixed-anchor and heteroclitic neoepitopes increasing MHC/TCR affinities and inducing antigen-specific cytotoxicity **Nicolas Poirier,** Chief Scientific Officer, **OSE Immuno Therapeutics** (CONFIRMED)			

	Karsten Sauer, Vice President, Immunology, **Torque Therapeutics** (CONFIRMED)				
4:50pm	**Multi-antigen specific endogenous T cell therapy consisting of stem cell and central memory T cells with potent anti-tumor activity for the treatment of hematologic malignancies** • Company sponsored P1/2 trials in AML and MM • NexImmune's AIM expanded T cell products include populations of primed antigen-specific CD8+ T cells directed at multiple tumor relevant antigen targets • T cell products with high proportion of stem cell and central memory T cell subtypes are associated with long-term T cell persistence and durable anti-tumor activity • NexImmune's proprietary T cell products may address key limitations observed with genttically modified T cell products; specifically, tumor escape through single target down-regulation and tumor relapse due to	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**Metabolism** **Targeting immunometabolism as a novel strategy to fight cancer** • Metabolism and function of cancer cells and immune cells are altered in the context of a tumor and tumor microenvironment leading to tumor immune evasion • Altered immunometabolism pathways provide a rich opportunity for pharmacological intervention • Targeting glutamine metabolism has been identified as a promising approach and a potential new treatment paradigm with broad application for many cancer types **Robert Wild,** Chief Scientific Officer, **Dracen pharmaceuticals** (CONFIRMED)	**Title TBA** **Christine Brown,** Associate Research Professor, **City of Hope** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	diminished T cell persistence **Scott Carmer,** CEO, **NexImmune** (CONFIRMED)				
5:10pm	**Development of off-the-shelf therapeutic T-cells resistant to host immune rejection and superior anti-tumor activity** • Alloimmune defense receptors (ADRs) enable T-cells to recognize and eliminate activated pathogenic T- and NK-cells • ADR T-cells resist immune rejection by allogeneic T- and NK-cells in vitro and in vivo • T-cells co-expressing ADR and CAR evade immune rejection and promote long-term anti-tumor activity in mouse models of "off-the-shelf" cell therapy **Maksim Mamonkin,** Assistant Professor, **Baylor College of Medicine** (CONFIRMED)	**Utilizing a live modified Vaccinia Ankara virus to deliver tumor associated antigen MUC1 on the surface of virus like particles** • Design of a MVA-MUC1 VLP • In vitro characterization of production of hypo glycosylated MUC1 in infected cells • Therapeutic Efficacy of MVA-VLP-MUC1 vaccine in Human MUC1 transgenic mice **Farshad Guirakhoo,** CSO, **GeoVax** (CONFIRMED)	Presentation available	**Differential response of mouse glioma models to immunotherapeutics: understanding the underlying mechanism** • CAR T cell therapy and PD1-blockade in treatment of "hot" and "cold" mouse GBMs • Propose strategies to overcome tumor resistance **Sharareh (Sherri) Gholamin,** Researcher, **Caltech** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*
5:30pm	**Offsite drinks reception**				

FESTIVAL OF BIOLOGICS USA

Day 2 – Tuesday March 3rd 2020	
8:00am	Registration opens
8:30am	Doors open
	Day 2 opening keynotes **Combination Therapies in Antibodies and Immunotherapy**
9:00am	Chair's opening remarks
9:05am	**PD-1 antibodies are transforming cancer treatment both as monotherapy and in combination** • Monotherapy activity has been established and is transforming treatment across a number of major cancers • Precision medicine has been deployed to identify patients most likely to respond and those for whom a combination approach might be preferred • Precision medicine has enabled prediction of potentially important combination therapies • Combination therapies are now beginning to transform treatment across a number of cancers • PD-1 antibodies have become foundational in cancer therapy **Roy Baynes,** Senior Vice President and Head Global Clinical Development, Chief Medical Officer, **Merck** (CONFIRMED)
9:25am	**Building a leading off-the-shelf, allogeneic T-Cell immunotherapy company** • Epstein-Barr virus (EBV) is associated with a wide range of cancers and multiple sclerosis (MS) • Tab-cel® (tabelecleucel) is an off-the-shelf, allogeneic EBV T-cell immunotherapy in Phase 3 development for patients with EBV+ post-transplant lymphoma as well as other serious EBV-associated ultra-rare diseases • ATA188 is an off-the-shelf, allogeneic T-cell immunotherapy that targets EBV-infected B cells believed to play a role in the pathogenesis of MS • EBV T cells also have potential application as an off-the-shelf, allogeneic CAR T platform • ATA2271/ATA3271 are novel mesothelin-targeted CAR T programs incorporating next-generation technologies for patients with advanced solid tumors • Atara's platform is supported by state-of-the-art T-cell manufacturing that is commissioned and qualified to support clinical development **Pascal Touchon,** President and CEO, **Atara Biotherapeutics** (CONFIRMED)
9:45am	**Strategies for combination therapies with CD19 CARTs in NHL - lessons learned and future directions** • CD19 CAR Ts have demonstrated notable activity in DLBCL, CLL, FL, pALL and other hematological malignancies with high overall response rates and durable CRs • However, a portion of patients either do not respond or their responses are not durable • Learnings from non-responders or CAR-T relapses are providing data into the multitude of potential resistance/suppression mechanisms • This presentation will review combination approaches being evaluated to overcoming resistance in CAR T to improve outcomes in NHL and provide insights for solid tumor approaches and the next wave of targets **David Fontana,** Head Strategic Alliance & JCAR017 Program Lead, **Juno Therapeutics** (CONFIRMED)
10:05am	Title TBA *Senior Representative,* **Applied BioMath** (CONFIRMED)
10:25am	**Morning networking break**
10:30-11:15am	**WORKSHOP: Operationalizing pediatric and adult cell therapy trials** **Brenda Hann,** Director, Clinical Trials Operations, **Stanford Medicine** (CONFIRMED) **Janet McDowell,** Clinical Research Manager, **Stanford University School of Medicine - Cancer Clinical Trials Office** (CONFIRMED) **Theresa Latchford,** Oncology Clinical Nurse Specialist, **Stanford Health Care - Blood and Marrow Transplant Unit** (CONFIRMED)

	Anne Cunniffe Marcy, Clinical Research Coordinator, **Stanford University School of Medicine - Cancer Clinical Trials Office** (CONFIRMED)					
	Checkpoint Inhibitors	**Commercialization and Market Access**	**Gene Therapy and CRISPR**	**Clinical Trials**	**Antibodies in Immunotherapy**	**Technology showcase**
11:25am	**Checkpoint Inhibitors in Head and Neck Squamous Cell Carcinoma"** • review current data for anti-PD1 therapy in HNSCC • define current research approaches to improve efficacy • determine strategies to treat anti-PD1 refractory patients **Ezra Cohen,** Associate Director, **U.C. San Diego Moores Cancer Center** (CONFIRMED)	**Kite Pharma experience in the global commercial launch of a CAR-T product** • Preparation for commercial launch in the US and globally • Special considerations for qualification of medical centers • Rapid manufacturing, release and distribution present challenges **Prentice Curry**, Senior Vice President Quality and Compliance, **Kite Pharma** (CONFIRMED)	**Tumor-specific immunogene therapy with T-SIGn viruses** • T-SIGn is a broad cancer-targeted gene therapy platform for delivery and local expression of combinations of genes for the treatment of solid tumors. T-SIGn utilizes enadenotucirev (EnAd), a first generation oncolytic virus with demonstrated intravenous delivery, as a gene delivery vector for up to five transgenes, providing simultaneous expression of combinations of biotherapeutics locally within the tumor microenvironment, while minimizing systemic exposure	**Being the collaborator of choice for combination studies** • Reviewing how this all started • Exploring how work has evolved and what does that mean • Working with collaborators in order to optimize performance • Highlighting key factors in making all collaborations succe ssful • Presenting advantages, challenges & lessons learned **Denise Steckel,** Head, Clinical Collaborations Management, **Genentech** (CONFIRMED)	**Title TBA** **Bruce Keyt,** CSO, **IGM Biosciences** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

			to these same agents • T-SIGn viruses are administered intravenously to reach both primary and metastatic tumor tissue. The transgenes are encoded under the control of the virus major late promoter such that during selective virus replication in tumors the payload biotherapeutic proteins are produced to fight the cancer locally • A variety of viruses encoding different immunomodulatory agents have been generated and functionally characterized, with three progressing into clinical trials: NG-348 (membrane anti-CD3 and CD80), NG-350A (agonist anti-CD40 antibody) and NG-641 (FAP-targeted T-cell activating bispecific antibody plus			

			CXCL9, CXCL10 and IFNa) • Properties of the T-SIGn platform, including clinical experience with the unarmed parental EnAd virus, and activity data from specific virus candidates will be discussed **Brian Champion**, CSO, **PsiOxus Therapeutics** (CONFRMED)			
11:45am	**TACTI-002 phase II trial: a soluble LAG-3 protein (eftilagimod alpha) combined with an anti-PD-1 antibody (pembrolizumab) in three different indications** • Eftilagimod alpha (LAG-3Ig or "efti"), a powerful APC activator targeting MHC II molecules • Stepping on the accelerator (APC activation by efti) while releasing the brake (pembrolizumab) on the T cells: a new combination in immuno-oncology.	**Launch and Commercialization Insights for Gene and Cellular Therapy Products** • How should you think about the market: traditional GTM strategy versus Customized GTM • How to think about market access strategy • LCM is key component to this lifeline of the product in this space **Mohamed Ladha,** Vice President and Head, Commercial, **Tocagen** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)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 (0)207 092 1297*	**CDX-1140, a unique Agonist Anti-CD40 mAb for cancer Immunotherapy** • CD40 plays key roles in innate and adaptive immune responses, and targeting CD40 can promote tumor regression via multiple mechanisms • CDX-1140 is a fully human IgG2 agonist anti-CD40 mAb selected based on a linear dose response and hypothesized to achieve good systemic exposure and tumor penetration without	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	• TACTI-002 phase II trial (109 patients): metastatic NSCLC first or second line and HNSCC **Frédéric Triebel,** Chief Scientific Officer, Chief Medical Officer, **Immutep** (CONFIRMED)				dose-limiting toxicity observed with other potent agonist anti-CD40 mAbs • CDX1140-01 is a Phase 1 dose-escalation study with tumor specific expansion cohorts of CDX-1140 alone or in combination with CDX-301, a potent dendritic cell growth factor, in patients with advanced cancer; preliminary data from the study will be presented **Michael Yellin**, VP, Clinical Science, **Celldex Therapeutics** (CONFIRMED)	
12:05pm	**CUE-101, a novel Fc fusion protein for selective targeting and expansion of anti-tumor T cells for treatment of HPV-driven malignancies** • CUE BioPharma's ImmunoSTATs are proprietary biologics that incorporate, in a single molecular framework, the	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**Title TBA** **Douglas Jolly,** Executive Vice President, Research and Pharmaceutical Development, **Tocagen** (CONFIRMED)	**Using data analytics to overcome challenges with clinical trials data** • Conducting clinical trials can be challenging. • Challenges can include setting up databases, recruitment of participants, missing data issues on key variables of interest etc.	**T cell redirecting antibody circuits: Bispecifics with a unique "AND" gate to enhance tumor specificity** • Harnessing the Immune System, in particular redirected T-cells to kill tumor cells has revolutionized cancer treatment. However, on and off-target toxicity	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	key signals needed to selectively modulate antigen-specific T cells: namely, the HLA-peptide complex to target the TCR along with relevant co-stimulatory/co-inhibitory signals, dependent upon the disease indication. • The protein framework of ImmunoSTATs is based on an Ab Fc backbone and is extremely modular and flexible, which permits for targeting of diverse patient populations and different diseases. • The lead clinical candidate CUE-101 is comprised of HLA-A*0201 bound to a peptide epitope derived from the HPV16 E7 protein (amino acid residues 11-20) along with affinity-			• Ideas for overcoming these challenges using novel data analytic techniques will be discussed from a Data Scientist's perspective **Jay Mandrekar,** Professor of Biostatistics and Neurology, **Mayo Clinic** (CONFIRMED)	limit the therapeutic potential of these approaches • Revitope is developing T cell redirecting antibody circuits that use dual-targeting to deliver split anti-CD3 paratopes to the tumor. Reconstitution is only permitted after protease cleavage in the tumor microenvironment to remove the stabilizing dummy domain. This approach is designed to initiate and focus T cell mediated cytotoxic immunity accurately on the tumor sparing normal tissues • We will discuss protein engineering considerations, in vitro and in vivo activity measurements, half-life and the use of quantitative systems pharmacology modelling approaches to aid	

	attenuated human interleukin-2 (IL-2) to selectively activate and expand HPV16 $E7_{11-20}$-specific $CD8^+$ T cells for HPV-driven malignancies, such as head and neck cancer and cervical cancer **Saso Cemerski,** Senior Director of Translational Immunology, **Cue Biopharma** (CONFIRMED)				mechanistic understanding **Werner Meier,** CSO, **Revitope Oncology** (CONFIRMED)	
12:25pm	**CB213: A second generation checkpoint inhibitor optimally configured for therapeutic efficacy** • The identification and characterisation of CB213 a tetravalent trispecific therapeutic delivering dual checkpoint blockade through dual inhibition of PD-1 and Lag3	**Title TBA** **Jean-Pierre Latere,** COO, **Celyad** (CONFIRMED)	**Engineering T cells for the immunotherapy of pediatric brain tumors** • Immunotherapy challenges for brain tumors • Genetic engineering approaches to improve CAR T cells **Giedre Krenciute**, Assistant Member, **St. Jude Children's Research Hospital** (CONFIRMED)	**Planning biomarker-enriched clinical trials and evidence synthesis to improve precision medicine practice** • Successful personalization of medicines requires unbiased data collection from prospectively planned biomarker-enriched clinical studies, objective evidence synthesis utilizing pre-specified statistical analyses, and	**Engineered antibody-secreting T cells** • Brief historical overview of antibody-secreting T cell technology • Antibodies engineered to mediate ADCC can be secreted by T cells • Results in HIV suggest platform linking innate and adaptive components via	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	• The case study will describe the approach taken to select a novel asymmetric format on the basis of optimal target engagement and activity using the modular Humabody format • Data will be presented showing that this molecule is able to reverse the dysfunctional phenotype of patient derived human T-cells which are non-responsive to clinical PD1 antibodies **James Legg,** SVP Research and Development, **Crescendo Biologics** (CONFIRMED)			practical presentation and communication of such evidence • In this presentation, I will illustrate how such clinical studies can be planned to optimize probability of trial success and to generate evidence of both therapeutic clinical efficacy and probability of meaningful clinical benefits to individual patients • Such well-considered planning will allow efficient development of precision medicines to satisfy multiple stakeholders including regulators, prescribers, payers and, ultimately, to benefit individual patients **Deepak Khatry**, Science Associate Director, Oncology Biometrics, **AstraZeneca** (CONFIRMED)	antibodies is feasible **C. Russell Cruz,** Director, Translational Research Laboratories, **Centre for Emerging Technologies in Immune Cell Therapy, Children's National Hospital** (CONFIRMED)	
12:45pm		Networking lunch				

12:50-1:20pm	**WORKSHOP: Panel discussion - patients as partners in clinical development** • How can we collaborate more with patients? • Improving transparency • Public awareness of clinical trials **Moderator: Julie Gerberding,** Executive Vice President, Communications, Global Policy, and Population Health & Chief Patient Officer**, Merck** (CONFIRMED) **Eve Bukowski,** Vice President, Patient Advocacy, Education & Outreach, **California Life Sciences Association (CLSA)** (CONFIRMED) **Joann Peters,** Vice President Clinical Operations, **Geneos Therapeutics** (CONFIRMED)					
	Checkpoint Inhibitors	**Commercialisation and Market Access**	**Gene Therapy and CRISPR**	**Clinical Trials**	**Antibodies in Immunotherapy**	**Technology showcase**
2:00pm	**Targeting Siglec-15 for cancer immunotherapy** • The development and characterization of NC318, a novel therapeutic antibody targeting Siglec-15 • Brief updates on NC318 Phase I clinical trial • The case study will describe the approach taken to select novel targets derived from NextCure's FIND-IO™ platform **Linda Liu,** SVP, Research, **NextCure** (CONFIRMED)	Presentation available	**Nanotechnology-Enabled Assembly Lines for Gene and Stem Cell-Based Therapies** • The capability to mass produce populations of engineered cells to serve as cellular therapies remains a considerable translational challenge. New intracellular delivery technologies that can simultaneously satisfy universal cargo delivery economically with high efficiency, high processing throughputs, scalability, and minimal cell toxicity are needed • Ideas inspired by microfluidics,	**Early phase development of biomarker-specific agents** • Balancing inclusion criteria, safety monitoring, biomarker expression • Incorporating companion diagnostics, dose escalation or expansion phase? • Strategies for moving from first-in-human study to accelerated approval **Christina Annunziata,** Head, Translational Genomics Section, **NIH** (CONFIRMED)	**Structure-guided design of an IL-2-based therapeutic that selectively activates regulatory T cells** • Several novel IL-2 mutations that enhance selectivity of IL-2 for Tregs will be discussed • Enhanced half-life of the IL-2 muteins in vivo • Selective expansion of Tregs in vivo, with modest to no activation of NK cells or Th cells • Efficacy in disease models of autoimmunity **Greg Babcock,** Vice President, Research, **Visterra Inc** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

			nanolithography, and nanorobotics are combined with gene editing to generate broadly applicable and translatable methods to enable rapid, safe, cost effective, and efficient delivery of biomolecular cargo • Solutions that enable the controlled and temporary permeabilization of the processed cells *via* either i) physical penetration of cellular membranes by precision-engineered nanostructures or ii) mechanical manipulation of cellular membranes are promising alternative strategies to existing viral and non-viral vector-based approaches **Steven Jonas,** Researcher, **UCLA** (CONFIRMED)			

2:20pm	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**Michael DeRidder**, VP, Medicine Commercialization Leader, Oncology Cell Therapy, **GSK** (invited)	**Presentation available**	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**T cell engaging bispecific antibodies: Comparing Pfizer's platforms** • T-cell engaging bispecific antibodies are a promising therapeutic approach for the treatment of multiple cancer types. • Pfizer has developed several Fc-containing T-cell engaging bispecific antibody platforms, which increase the half-life and allows for conventional dosing. These platforms are currently evaluated in the clinic. • We will compare these platforms and the challenges and opportunities of each platform will be highlighted **Javier Chaparro-Riggers,** Executive Director, **Pfizer** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*
2:40pm	**Defining T Cell states associated with response to combination immunotherapy**	**Panel discussion: from clinical trials to commercial manufacturing**	**Engineered T cells for sarcoma** • Autologous T cells engineered to express chimeric	**Clinical trial disclosure and transparency – managing the ever-changing global**	**Development of NM21-1480 a trispecific anti-PD-L1x4-1BBxhSA antibody fragment**	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	Shahram Salek-Ardakani, Senior Director, Cancer Immunology, **Pfizer** (CONFIRMED)	• How to achieve commercial capacity • Overcoming the lack of mature CROs • Technical operations – scaling up • Engaging with regulators • Supply chain challenges • Cost and resources **David Sourdive**, Co-founder, Executive Vice President - Technical Operations, **Cellectis** **Prentice Curry,** Senior Vice President Quality and Compliance, **Kite Pharma** **Bob Valamehr,** Vice President, Cancer Immunotherapy, **Fate Therapeutics** **Christina Yi,** Chief Operations Officer, **Dendreon** (CONFIRMED)	antigen receptors (CARs) are safe and may provide clinical benefits in patients with metastatic sarcoma • Responses following CAR T cell therapy may include involvement of endogenous immune system resulting in tumor clearance. • Introducing engineered signal receptors or gene knockouts can improve CAR T cell function and persistence **Sujith Joseph,** Senior Scientist, **Baylor College of Medicine** (CONFIRMED)	**regulations and requirements** • Global Clinical Trial Registration and Results Disclosure • Public Release of Clinical Information (Health Canada, EMA, FDA) • Drafting documents with the "end" in mind **Nate Root,** Associate Director, Clinical Disclosure & Transparency, **Ionis Pharmaceuticals** (CONFIRMED) **Kelly Coulbourne,** Associate Director, Clinical Trial Data Registries, **Allergan** (CONFIRMED)	• NM21-1480 is a novel trispecific antibody fragment fusion protein directed against PD-L1 and 4-1BB • The molecule is designed to block PD-1/PD-L1 signalling and elicit an intratumorally restricted CD8+ T cell activation, promising a favorable benefit-to-risk profile • In vivo experiments have shown efficacy and tolerability and the molecule is expected to enter clinical testing in Q3/2020 **Sebastian Meyer,** COO, **Numab Innovation AG** (CONFIRMED)	
3:00pm	**Bispecific anti-PD1 checkpoint inhibitors to address cancer immunotherapy resistance mechanisms** • Second generation of PD-x inhibitors will extend the spectrum of patients		*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*		**Tumor-targeted immune-stimulating antibody conjugates** • 3-4 bullet points covering the scope of your talk • Immune-stimulating antibody conjugates (ISACs) are tumor-targeting antibodies conjugated with	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	responding to immunotherapies by addressing untapped immune evasion mechanisms. • BiCKI® is a proprietary bispefic fusion protein platform built on an engineered key backbone anti-PD1 and targeting innovative targets. • The BiCKI® platform strives to inhibit key immune checkpoints while simulfe taneously delivering intratumoral cytokines with Treg modulating function and/or increasing exhausted T cells responses. • The BiCKI® platform can also delivers costimulatory signals to rewire anti-tumoral T-cell activities or other modalities reinstating, among				powerful innate immune stimulants • ISACs are capable of invoking potent myeloid cell activation and the production of pro-inflammatory cytokines that favor a productive anti-tumor immune response • ISACs are active in preclinical in vivo models of cancer and are highly efficacious by enhancing ADCP, promoting antigen presentation, immunological memory, and epitope spreading **David Dornan,** Senior Vice President of Research, **Bolt Biotherapeutics** (CONFIRMED)	

	others, macrophage polarization and phagocytic functions **Nicolas Poirier,** Chief Scientific Officer, **OSE Immuno Therapeutics** (CONFIRMED)					
3:20pm		Afternoon networking break				
	Checkpoint Inhibitors	**Precision Immunotherapy and Biomarkers**	**Gene Therapy and CRISPR**	**Clinical Trials**	**Antibodies in Immunotherapy**	**Technology showcase**
4:00pm	**Evolving field of Eat Me and Don't Eat Me Science** • Review of Macrophage Interactions with Tumors • Review of Therapies targeting CD-47 and SIRP alpha • Current clinical trials targeting CD-47 and SIRP alpha **Corey Carter,** CEO, **EpicentRx INC** (CONFIRMED)	**Photoimmunotherapy, a new tumor targeted approach that activates immune anti-cancer responses and reduces cellular tumor immunosuppression** • Photoimmunotherapy is a new cancer platform that enables the rapid destruction of cellular components within the tumor. • Photoimmunotherapy targeting of cancer cells induces innate and adaptive immune responses that are synergistic with immune checkpoint inhibitors.	**Non-viral engineering of immune cell specificity and function** • Non-viral genome targeting is a new, simple method for targeted integration of new genetic information in primary human T cells • Targeted replacement of the endogenous T cell receptor with a cancer antigen targeting TCR showed specific anti-tumor function *in vitro* and *in vivo* • Pooled knock-in screening based on non-viral genome targeting enabled	**Clinical trial designs** **Barbara Hickingbottom,** Vice President, Clinical Development, **Xencor** (CONFIRMED)	**Mechanisms of action of a neoantigen-targeting antibody NEO-201** • This study demonstrates that NEO-201 has several mechanisms of action. NEO-201 is able to mediate both ADCC and CDC. • In addition, NEO-201 can block the interaction between tumor cell CEACAM5 and NK cell CEACAM1 to reverse CEACAM1-dependent inhibition of NK cytotoxicity. • These results suggest that NEO-201 may potentially reverse CEACAM1-	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

		• Targeted depletion of tumor immunosuppressive components with Photoimmunotherapy, such as T-regs, induces rapid and sustained anti-cancer immune responses with strong synergy with immune checkpoint inhibitors **Miguel Garcia-Guzman,** Chief Scientific Officer, **Rakuten Medical** (CONFIRMED)	rapid discovery of synthetic DNA sequences that along with a new TCR specificity enhanced T cell function *in vivo*. **Theodore Roth,** Research Fellow, **UCSF** (CONFIRMED)		dependent immunosuppression of NK cells in patients whose tumors express the NEO-201-reactive variant of CEACAM5. • NEO-201 can also target and eliminate human immunosuppressive regulatory T cells (Tregs). • Additional mechanisms are under investigation **Al Tsang,** CSO, **Precision Biologics** (CONFIRMED)	
4:20pm	**Multiparametric flow cytometry analysis of immunomodulatory receptors in dissociated tumour and matched blood biospecimens** • Discussion of the limitations of IHC and sequencing for IMR discovery that can be alleviated by multiparametric flow cytometry analysis • Discussion of the optimization of flow cytometer	**Use of biomarkers for precision immunotherapy** **Vassiliki Papadimitrakopoulou,** Professor of Medicine in the Department of Thoracic/Head and Neck Medical Oncology, **MD Anderson Cancer Center** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**The importance of dose optimization in the development and approval of immunooncology drugs** **Sandhya Girish,** Senior Director, Global head Oncology, **Genentech** (CONFIRMED)	**Bispecific antibodies for guided inhibition of CD47** • CD47-SIRPa axis, a phagocytosis checkpoint, is a promising target for cancer immunotherapy. Yet, therapeutic inhibition of CD47 on tumor cells is hindered by ubiquitous expression of the target in healthy tissue • Undesirable on-target/off-tumor	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	instrument settings and gating analysis strategies for dissociate tumours vs blood samples • Exploration of IMR expression at the single-cell level across cellular subsets present in matched tumour and blood samples • Advanced analysis using high dimensional flow cytometry data **Shawn Fahl,** Director, Flow Cytometry Services, **Discovery Life Sciences** (CONFIRMED)				effects typically observed with CD47 blocking monoclonal antibodies can be largely mitigated with a bispecific antibody, which enable guided (i.e., selective) inhibition of CD47 on cancer cells • Such CD47-blocking bispecific antibodies show potent anti-tumor activity associated with favorable pharmacokinetics and safety profiles **Krzysztof Masternak,** Head of Discovery, **Light Chain Bioscience – a brand of Novimmune SA** (CONFIRMED)	
4:40pm	**Affimer therapeutics: generation of checkpoint inhibitor antagonists with broad applications** • The Affimer platform is based on the human protease inhibitor, Stefin A, where we have introduced 2x9 aa loops into the backbone to generate large	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**Clinical experience with T cells expressing NY-ESO-1 TCR and CRISPR edited to eliminate endogenous TCR and PD-1** • NY-ESO-1 is a cancer testis antigen with aberrant expression in myelomas, sarcomas, and melanomas. • This talk will present updated data from a	**Panel discussion: clinical trial opportunities and designs for cell therapies** • What's the definition of personalised medicine? • Ethical considerations • Keeping the patient engaged during long vaccine	**A novel platform for T-cell redirection that elicits efficient tumour lysis with minimal cytokine release in multiple tumour types** • Discovery of novel CD3 binding antibodies • Unique functional activity based on novel epitope and affinity	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

	phage display libraries. Using phage display we have generated a range of antagonists and agonists with nM affinities to targets that are central to the modulation of the immune system in the tumour microenvironment • With our anti-PDL1 Affimer Fc we have demonstrated total tumour regression in mouse syngeneic models in combination with an iDASH inhibitor and immunity to rechallenge with tumour cells, showing that we have achieved an immune memory response. We have expanded the use of our anti-PDL1 Affimer therapeutics by encoding them into DNA and have shown that they		phase 1 pilot clinical trial (NCT03399448) enrolling patients with advanced MM and sarcoma. • This trial evaluates a first-in-human engineered cell therapy of T cells expressing a TCR recognizing a HLA-A201 restricted NY-ESO-1/LAGE-1 epitope (SLLMWITQC), and with CRISPR/Cas9 edited TCRα, TCRβ, and PDCD1 genes **Simon Lacey**, Director, The Center for Cellular Immunotherapies, **University of Pennsylvania** (CONFIRMED)	manufacturing times **Joann Peters,** Vice President Clinical Operations, **Geneos Therapeutics** (CONFIRMED) **Barbara Hickingbottom,** Vice President, Clinical Development, **Xencor** (CONFIRMED) **Archana Sah,** Therapeutic Leader, **Genentech** (invited)	• T-cell redirecting bispecific antibodies that efficiently lyse tumors with low levels of cytokine release • TNB-383B lead molecule currently in phase 1 clinical development **Nathan Trinklein,** Chief Technology Officer, **Teneobio** (CONFIRMED)	

	can be expressed at high levels as function proteins from primary human cells. • With our anti-PDL1 and LAG-3 Affimer proteins, we have generated high affinity bispecific formats with affinities in the double/triple digit pM range. Using primary human cell based assays we have shown that the combination of PD-L1 and LAG-3 blockade showed a significant increase in cytokine release compared to monovalent blockade alone **Amrik Basran,** Chief Scientific Officer, **Avacta** (CONFIRMED)					
5:00pm	**Presentation available**	**Identification of Neoantigens for cancer immunotherapy** **Roman Yelensky,** EVP & Chief Technology Officer,	**Presentation available**		**Mucin (MUC)16-directed Immunotherapeutic strategies for ovarian cancer**	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*

		Gritstone Oncology (CONFIRMED)			• Use of bi-specific T-cell engagers, which could potentially induce antigen spreading beyond the targeted tumor-associated antigen **Yeku Olapado,** Assistant Clinical Attending, **Massachusetts General Hospital** (CONFIRMED)	
5:20pm		Networking drinks and poster presentation session				

FESTIVAL OF BIOLOGICS USA

Day 3 – Wednesday March 4th 2020					
8:30am	Registration opens				
9:00am	Doors open				
	Neoantigens	**Oncolytic Viruses**	**Non-Oncology Immunotherapy**	**Manufacture and Supply Chain**	**Research Hub**
				Chair: Rajesh Krishnan, Senior Vice President, Process Development and Manufacturing, **Oncternal Therapeutics**	
9:00am	**Going natural with Neoantigens** • The success of neoantigen vaccination will rely of accurately target natural ligands that appear on tumor cells/APC, and coordination of both CD4+ and CD8 T cell subsets • We have developed a novel HLA-agnostic platform that functionally identifies CD4+ and CD8+ T cell neoantigens across all tumor types analyzed, regardless of mutational burden • Vaccination with a single peptide comprising CD4+ and CD8+ target neoantigens identified by our method can lead to eradication of large established tumors in a preclinical model	**ONCR-177, a Novel Micro-RNA Attenuated Oncolytic HSV Virus with Combinatorial Immune Payloads for the Treatment of Metastatic Cancer** • Oncolytic virus with a dual mode of action, cancer cell killing and stimulation of antitumor immunity are promising therapeutic approaches for checkpoint irresponsive tumors • ONCR-177 expresses five transgenes (IL-12, CCL4, FLT3L and PD-1 and CTLA-4 antagonists) for potent immune stimulation • ONCR-177 tumor selectivity is enabled by the differential expression of microRNA **Christophe Quéva,** CSO, **Oncorus** (CONFIRMED)	**Synthetic DNA-based immunotherapies for emerging infectious diseases** **Kate Broderick,** Vice President, **Inovio Pharmaceuticals** (CONFIRMED)	**Cellular immunotherapy supply chain management, logistics and scale-out** • Vendor qualification • Maintaining chain of custody for starting material and product • Shipper suitability, features and options • Material sourcing, receipt and testing • Supply chain sustainability and scale-out considerations **Alan K. Smith**, Executive Vice President, Technical Operations, **Bellicum** (CONFIRMED)	Title TBA **Fabiana Zappala,** PhD Student, **University of Pennsylvania** (CONFIRMED)

	Stephen Schoenberger, Professor, **La Jolla Institute for Immunology** (CONFIRMED)				
9:20am	**Harnessing the power of patient T cell responses: ATLAS™ platform** • Personalized immune response profiling drives validation of antigens of proven and pre-existing $CD4^+$ and $CD8^+$ T cell responses • Anti-tumor and inhibitory (pro-tumor) neoantigens are identified • Comprehensive and flexible system: For any patient, any antigen type, any cancer and both $CD8^+$ and $CD4^+$ T cells • Generating unprecedented clinical immune response through novel neoantigen vaccine **Jessica Baker Flechtner,** CSO, **Genocea** (CONFIRMED)	**Engineering viruses to deliver their maximal potential: Two examples from the Turnstone portfolio** **Caroline Breitbach,** VP R&D Programs and Strategy, **Turnstone Biologics** (CONFIRMED)	**Development of single dose vaccines for emerging infection diseases using a novel MVA plug and Play platform** • Design of MVA-VLP and non-VLP vaccines for Zika, Ebola, Marburg and Lassa fever viruses • In vitro characterizations of production of Research Viruses • Efficacy studies in rodent and non-human primate challenge models **Farshad Guirakhoo,** CSO, **GeoVax** (CONFIRMED)	**Automated CAR T cell manufacturing platform for hematologic and solid cancers** • Manufacture of CAR T cells in support of Phase I clinical trials using anti-CD19/22 bispecific CAR • Development of an automated closed retroviral vector transduction process for solid cancer **Steven Feldman,** Director of Manufacturing and Process Development, **Stanford Center for Cell Therapy** (CONFIRMED)	**Title TBA** **Ethan Laudermilch**, Post-Doc, **Albert Einstein College of Medicine** (CONFIRMED)
9:40am	**Title TBA** **Marina Udier,** CEO, **Nouscon** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**Approaching Alzheimer's disease as an immunological disease: role of biomarkers** • Innate immune dysregulation causes chronic inflammation and development of Alzheimer's disease	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**Identification and characterization of KRAS G12V-specific CD4 T cells from the blood of a pancreatic cancer patient** • We have developed a novel HLA-agnostic approach to neoantigen

			• Approaching AD as an immunologic disease changes the clinical strategy in many ways but perhaps none more important than access to biomarkers • We have developed a suite of biomarkers (both invasive and non-invasive) that extent beyond classical blood inflammatory measures to identify the right patients and track target engagement and treatment response **Christopher (CJ) Barnum,** Director of Neuroscience and Translational Medicine, **INmune Bio** (CONFIRMED)		identification which combines genomic sequencing, bioinformatic analysis, and functional assays • We identified eleven dominant CD4 T clones from the blood of a pancreatic cancer patient and confirmed specificity, restriction, minimal epitopes, and avidity • These KRAS G12V-specific CD4 TCRs could be of therapeutic value to patients with the same driver mutation and HLA haplotype **Martin Naradikian,** Postdoctoral Fellow, **La Jolla Institute for Immunology** (CONFIRMED)
10:00am	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**Oncolytic adenovirus and Anti-PD-1 combination therapy for glioblastoma** • Phase 2 trial update • Mechanisms of immune activation **Matteo Levisetti,** Chief Development Officer, **DNAtrix** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**Title TBA** **Mayo Pujols,** VP, Head of Global Cell & Gene Technical Development & Manufacturing, **Novartis** (TBC)	**Title TBA** **Ariel Wirchnianski,** PostDoc, **Albert Einstein College of Medicine** (CONFIRMED)

10:20am	**Overview of Neon's approach to the development of personalized cancer immunotherapies** • The recognition of neo-antigens on human cancer has strongly been connected to the clinical success of immune therapies NEON Therapeutics aims to generate neo-antigen specific vaccines and T cell therapies that are tailored for each individual patient. Here we will present the platform that NEON has developed to generate such personal neoantigen-specific T cell therapies **Marit van Buuren,** Lab Head, Scientist II, Immunology, **Neon Therapeutics** (CONFIRMED)	**Replimune's oncolytic immuno-gene therapy: A potent and versatile approach to patient-specific anti-tumor vaccination and therapy** • Replimune is developing its Imulytic family of oncolytic immuno-gene therapy agents (RP1-RP3), each of which is in or being prepared for clinical trials alone in combination PD1 blockade • The core backbone virus (RP1) has been designed to maximize tumor killing, the amount of tumor antigen released for vaccination purposes, and the immunogenicity of tumor cell death • This is then further armed to deliver potent immune stimulatory protein encoding genes directly to the sites of immune response generation, intended to further augment the systemic anti-tumor immune response generated **Robert Coffin,** CEO, **Replimmune** (CONFIRMED)	**Off-the-shelf, allogeneic T-Cell immunotherapy for patients with progressive Multiple Sclerosis (MS)** • Growing evidence that EBV has a major role in the pathogenesis of MS • Loss of EBV CD8+ T cell function correlates with MS disease progression • ATA188 is a novel off-the-shelf, allogeneic T-cell immunotherapy targeting EBV-infected B cells for patients with progressive MS **AJ Joshi,** SVP, Chief Medical Officer , **Atara Biotherapeutics** (CONFIRMED)	Presentation available	Presentation available
10:40am	**Morning networking break**				
	Neoantigens	**Oncolytic Viruses**	**Non-Oncology Immunotherapy**	**Research Hub**	

11:15am	**Expanded neoantigenic payloads and rapid biopsy to treatment personalized immunotherapy** • DNA based GT-EPIC™ platform addresses the three key needs for effectively targeting neoantigens: • Ability to drive potent and broad T cell immune responses; • Ability to target a larger number of neoantigens in a single formulation; • Short manufacturing turnaround time • Discuss leveraging platform regulatory and manufacturing advantages to facilitate clinical translation **Niranjan Y. Sardesai,** Co-Founder, President and CEO, **Geneos Therapeutics** (CONFIRMED)	**Realizing the full potential of multi-faceted oncolytic viruses** • Oncolytic viruses are safe and selective tumour lysing therapeutics • Vaccinia based viruses have tremendous coding capacity to express multiple therapeutic payloads • Oncolytic Viruses can be engineered to exploit exosome biology **John Bell,** Professor of Medicine, **Ottawa Health Research Institute** (CONFIRMED)	**T cell therapies for HIV** **James Riley**, Associate Professor of Microbiology, **University of Pennsylvania** (CONFIRMED)	**Comprehensive analysis of neutralizing antibodies raised against the yellow fever virus vaccine** • First comprehensive analysis of antibody response to yellow fever vaccine • Emergence of highly potent neutralizing antibodies after vaccination over time • Insights into the capacity of the vaccine to protect against the emerging yellow fever virus strain in Brazil **Denise Haslwanter,** PostDoc, **Albert Einstein College of Medicine** (CONFIRMED)
11:35am	**Update from Vaccibody's clinical trial with the personalized cancer neoantigen vaccine, VB10.NEO; insight into parameters correlating with improved clinical responses** • Inducing a unique CD8-dominated T cell response by targeting antigens to APC • Clinical updates on the phase I/IIa VB N-01 trial in multiple indications • The link between high quality neoepitopes and anti-tumour efficacy	**PeptiCRAd - a novel oncolytic virus based therapeutic cancer vaccine for the treatment of solid tumors** • PeptiCRAd technology uses highly immunogenic, next generation oncolytic adenoviruses as powerful peptide vaccine delivery system to specifically target and treat solid tumors • Rapidly adaptable platform-based delivery can accommodate shared tumor antigens or patient-specific neoantigens	**Safety and efficacy results from large-scale gene Therapy trial in patients with Leber's Hereditary Optic Neuropathy (LHON)** • Reported are two Investigator-Initiated rAAV2-ND4 gene therapy Trials conducted in 2011 and 2018. Combined are largest-scale and longest-term gene therapy study for LHON patients. • Eight-year follow-up data on 9 patients from IIT#1 demonstrated long-term safety and durability of gene therapy. • In IIT#2, 63.21% of 106 patients who reached 12 month follow-up	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297* Presentation available

	Agnete Fredriksen, Co-Founder, President and CSO, **Vaccibody (**CONFIRMD)	• First-in-human clinical trial of PeptiCRAd in combination with checkpoint inhibitor will be started during 2020 **Sari Pesonen**, VP, Scientific and Clinical Development, Co-Founder, **Valo Therapeutics** (CONFIRMED)	had significant BCVA improvement and there were no SAEs. **Su Xiao,** CEO**, Neuropth** (CONFIRMED)	
11:55am	**Engineering tools for cancer immunotherapy** • Discussion of robust, sensitive methods and bioengineered constructs for identifying tumor-antigen-specific T cell populations from patient blood • Discussion of high throughput tools for pairing the antigen-specificity of a T cell with the T cell receptor gene • Discussion of new immunotherapy strategies that enabled by these tools **Jim Heath,** President and Professor, **Institute for Systems Biology** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*	**IL-33 in pulmonary inflammation** • IL33 is a key regulator of type 2 cytokines • I IL33 can regulate non-type 2 pathways • Blockade of IL33 has effects on type 2 and non-type 2 pathways in mouse models of lung disease **Rajita Pappu,** Senior Scientist, **Genentech** (CONFIRMED)	Presentation available
12:05pm	**Title TBA** **David Reardon**, Clinical Director, Center for Neuro-Oncology, **Dana-Farber Cancer Institute** (CONFIRMED)	**Virotherapy activating the CD40/4-1BB pathway in pancreatic cancer – interim clinical data** • Shaping the tumor microenvironment by CD40/4-1BB activating virotherapy (preclinical) • Increasing immune activity using local immune stimulation in pancreatic cancer patients • Interim clinical response data using LOAd703 in pancreatic cancer	**Title TBA** **Kathryn Austgen**, Associate Director**, BlueRock Therapeutics** (CONFIRMED)	Presentation available

		Angelica Loskog, CEO, **Lokon Pharma** (CONFIRMED)		
12:25pm	**Discovery of novel mAbs targeting Solid Tumor Neoantigens** • An immunogenic cancer vaccine demonstrating clinical activity was utilized as a platoform • Antibodies were screened for tumor sensitivity and specificity, as well as anti-tumor activity • Selected antibodies were utilized to identify tumor Neoantigens **Philip Arlen,** President & CEO, **Precision Biologics** (CONFIRMED)	Presentation available	Presentation available	Presentation available
12:45pm	**Networking lunch**			
	Closing plenary **AI and Machine Learning in Immuno-Oncology**			
1:45pm	**Song Qinghua,** Head of Artificial Intelligence & Analytical Innovation, **Kite Pharma** (invited)			
2:05pm	*Reserved for supporting partner. If you are interested in being involved, please contact Derek Cavanagh at derek.cavanagh@terrapinn.com or +44 (0)207 092 1297*			
2:25pm	**AI applications for drug discovery and development** **Kefeng (Kevin) Hua,** Senior Manager, AI/Machine Learning Development, **Bayer** (CONFIRMED)			
2:45pm	Presentation available			
3:05pm	Chair's closing remarks			
3:10pm	Closing remarks from Terrapinn			
3:15pm	**End of conference**			

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Michael Hongwei Xie, Executive Director of Bioassay and Analytical Development, **Shanghai Henlius Biotech Inc.**
Molly Burich, Director, Public Policy: Biosimilars and Reimbursement, **Boehringer Ingelheim**
Mourad Farouk-Rezk, Global Head of Medical (Biosimilars), **Biogen**
Nacer E Hedroug, Director of Quality Improvement**, Mylan**
Nathan Lewis, Associate Professor, Dept Pediatrics and Bioengineering, **USCD**
Ned Pojskic, Leader, Pharmacy & Health Provider Relations, **Green Shield Canada**
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Sameer Awsare, Associate Executive Director, **The Permanente Medical Group**
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Sue Naeyaert, Independent Consultant/Former VP Global Government Affairs, Policy and Pharmacoeconomics Biosimilars, **Fresenius-Kabi SwissBioSim**
Sundar Ramanan, Vice President & Head, Global Regulatory Affairs, **Biocon**
Timothy Chiu, Pharmacist Evidence Analyst & Strategist in Drug Information Services, **Kaiser Permanente**

Wayne Winegarden, Senior Fellow, **Pacific Research Institute**
William Han, Former Assistant General Counsel (Patents), **GSK**

Workshop speakers

Steven Corn, Founder and CEO, **Metis Advocacy**
Marjorie Shapiro, Chief, Laboratory of Molecular and Developmental Immunology, Division of Biotechnology Products Research and Review, **FDA**
Mona Chitre, Chief Pharmacy Officer & VP Integrated Clinical Strategy, **Excellus BlueCross BlueShield**

FESTIVAL OF BIOLOGICS USA

<table>
<tr><th colspan="4">Day 1 – Monday, March 2nd 2020</th></tr>
<tr><td>7:30am</td><td colspan="3">Registration opens</td></tr>
<tr><td>8:30am</td><td colspan="3">Conference doors open</td></tr>
<tr><td>9:00am</td><td colspan="3">Opening remarks from Terrapinn</td></tr>
<tr><td colspan="4">Opening keynotes
Recent policy and the biosimilars industry</td></tr>
<tr><td>9:05am</td><td colspan="3">Chair’s opening remarks
Anna Rose Welch, Chief Editor, Biosimilar Development (CONFIRMED)</td></tr>
<tr><td>9:10am</td><td colspan="3">Erika Satterwhite, Head of Global Biosimilars Policy, Mylan (CONFIRMED)</td></tr>
<tr><td>9:30am</td><td colspan="3">An Amgen sponsored fireside chat
Leah Christl, Executive Director, Global Regulatory and R&D Policy, Amgen (CONFIRMED)</td></tr>
<tr><td>9:50am</td><td colspan="3">Panel discussion: The FDA’s current position on biosimilars and how the industry in the U.S. will move forward

Senior representative, Axinn (CONFIRMED)
Christine Simmon, Executive Director/Senior Vice President, Policy & Strategic Alliances, Biosimilars Council/Association of Accessible Medicines (CONFIRMED)
Sameer Awsare, Associate Executive Director, The Permanente Medical Group (CONFIRMED)
Senior Representative, Amgen (CONFIRMED)
Congressman Scott Peters, Representative for California, U.S. House of Representatives (INVITED)

Moderator: Steve Lehrer, Managing Director, SBLehrer LLC (CONFIRMED)</td></tr>
<tr><td>10:30am</td><td colspan="3">Networking break</td></tr>
<tr><td rowspan="4">11:30am</td><td colspan="3">Plenary roundtable session
6 senior level tables hosted by thought leaders on key issues in the biosimilars industry. Participants are invited to join discussions relevant to their work and the contribute to those that tackle most challenging topics. There will be two rotations and therefore opportunity to join two sessions, each lasting 35 minutes.</td></tr>
<tr><td>TABLE 1

Roundtable available</td><td>TABLE 2
Educating stakeholders on biosimilars, focussing on HCPs and patients

Dorthe Bartels, Strategic Advisor, AMGROS (CONFIRMED)</td><td>TABLE 3
Opportunities for biosimilars in emerging markets

Roman Drai, Research & Development Director, GEROPHARM (CONFIRMED)</td></tr>
<tr><td>TABLE 4
How stakeholders can improve patient access to biosimilars

Pam Traxel, Senior VP, Alliance Development and Philanthropy, American Cancer Society Cancer Action Network (CONFIRMED)</td><td>TABLE 5
Economics benefits of biosimilars (full title TBC)

Ivo Abraham, Professor, Pharmacy Practice and Science, The University of Arizona Health Sciences (CONFIRMED)</td><td>TABLE 6

Roundtable available</td></tr>
<tr><td>TABLE 7
Reserved for supporting partner. If you are interested in being involved, please contact Sam Bohan at sam.bohan@terrapinn.com or +44 (0)20 7 092 1040</td><td>TABLE 8
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<tr><td>12:40pm</td><td colspan="3">Networking lunch</td></tr>
<tr><td>1:25pm – 1:55pm</td><td colspan="3"><u>WORKSHOP SESSION</u>
Transitioning to biosimilars: overview from the health plans</td></tr>
</table>

	Moderator: **Mona Chitre**, Chief Pharmacy Officer & VP Integrated Clinical Strategy, **Excellus BlueCross BlueShield** (CONFIRMED)	
	Track 1 **Market access**	**Track 2** **Biosimilars in healthcare policy**
	Chair: Ross Day, Former Director, Pharmacy Contracting, **Vizient Inc.** (CONFIRMED)	**Chair: Anna Rose Welch**, Chief Editor, **Biosimilar Development** (CONFIRMED)
2:00pm	**Successful uptake of biosimilars in Kaiser Permanente** • Kaiser Permanente experience with biosimilars • How clinician and patient education and awareness of biosimilars can continue evolving and contribute to uptake • Future implications for biosimilar market in the US **Sameer Awsare**, Associate Executive Director, **The Permanente Medical Group** and **Timothy Chiu**, Pharmacist Evidence Analyst & Strategist in Drug Information Services, **Kaiser Permanente** (CONFIRMED)	**Clinical trials and testing of biosimilars: New FDA approaches** • Two levels of testing: in healthy subjects and in patients – in silico approach to extension of clinical efficacy • FDA admission that efficacy studies do not assure biosimilarity determination. Extrapolation of indications negates the clinical efficacy equivalence model • Ultimately biosimilars will be approved with no studies in patients. Dilemma for approval of interchangeable products administered only once? **Sarfaraz Niazi**, Adj. Professor of Pharmaceutical Sciences/CEO, **University of Illinois/PharmSci** (CONFIRMED)
2:20pm	*Reserved for supporting partner. If you are interested in being involved, please contact Sam Bohan at sam.bohan@terrapinn.com or +44 (0)20 7 092 1040*	**Effects of new legislature on biosimilars** **Christine Simmon**, Executive Director/Senior Vice President, Policy & Strategic Alliances, **Biosimilars Council/Association of Accessible Medicines** (CONFIRMED)
2:40pm	**Trends in biosimilar approvals in the EMA/FDA and effects of biosimilars on US biologic prices** • Describing the effect of biosimilar competition on biologic prices in the US, • Discussing how biosimilar competition reduces the growth in prices of reference biologics, and • Presenting trends in biologic and biosimilar products authorizations in the US and the European Union **Enrique Seoane-Vazquez**, Professor, **Chapman University School of Pharmacy & Economics Science Institute** (CONFIRMED)	**Biosimilars: the Canadian experience** • Biosimilars have been approved in Canada since 2014, yet the adoption by clinicians and payers continues to lag behind expectations • Recent initiatives to prefer biosimilars by provincial government are starting to take effect, albeit slowly • This session will explore the experiences of one Canadian private insurer and the unique approach it took to driving biosimilar adoption. The results of a mandatory biosimilar transition policy for patients on etanercept and infliximab will be discussed **Ned Pojskic**, Leader, Pharmacy & Health Provider Relations, **Green Shield Canada** (CONFIRMED)
3:00pm	**Anti-competitive deterrents to investment and innovation in biosimilars and interchangeable biologics**	**Interchangeability designation in the U.S., from law to regulatory to program design guidance via science**

	• What are the barriers? • Is regulatory policy mitigating or creating barriers to market access? • Are incumbent market practices that deter access being addressed? • What has changed in the last 12 months? **Bruce Leicher**, Attorney and Former Senior VP and General Counsel, **Momenta Pharmaceuticals** (CONFIRMED)	• Discuss the intent and purpose of the interchangeability designation in the U.S. • Discuss how the FDA guidance integrates the science to comply with the U.S. statute • Discuss alternatives to clinical development to attain the interchangeability designation in the U.S. **Daniel Alvarez**, Senior Director, Immunology and Inflammation Development Lead, Biosimilars, **Pfizer** (CONFIRMED)
3:20pm	**Afternoon refreshments**	
3:30pm – 4:00pm	**<u>WORKSHOP SESSION</u>** **Draft guidance development of therapeutic protein biosimilars: comparative analytical assessment and other quality-related considerations** **Marjorie Shapiro**, Chief, Laboratory of Molecular and Developmental Immunology, Division of Biotechnology Products Research and Review, **FDA** (CONFIRMED)	
4:10pm	**The biosimilars strategy in Denmark's healthcare system; how the U.S. can learn from this journey** • Learnings from the first biosimilar introduction in Denmark • Set-up of a biosimilar task force **Dorthe Bartels**, Strategic Advisor, **AMGROS** (CONFIRMED)	**Favourable changes in biosimilar policy** **Sue Naeyaert**, Independent Consultant/Former VP Global Government Affairs, Policy and Pharmacoeconomics Biosimilars, **Fresenius-Kabi SwissBioSim** (CONFIRMED)
4:30pm	**An overview on Canadian cross-province experiences implementing a biosimilar strategy** **Sang Mi Lee**, Senior Manager, **pan-Canadian Pharmaceutical Alliance Office** and **Scott Gavura**, Director, Provincial Drug Reimbursement Programs, **Cancer Care Ontario** (INVITED)	**Interchangeability – an industry perspective on the role and value for stakeholders** • Existing interchangeability requirements • Understanding the role of interchangeability and automatic substitution, and how this could impact biosimilar uptake • Assessing the value of interchangeability by key stakeholder **Molly Burich,** Director, Public Policy: Biosimilars and Reimbursement, **Boehringer Ingelheim** (CONFIRMED)
4:50pm	**Key considerations to achieving biosimilar success in emerging markets: affordability and access; regional systemic complexities; and awareness** • Developing low-cost approaches to reducing costs; innovating payment structures; choosing the right portfolio (studying payer, patient and physician needs); and participating in policy making to develop infrastructure and support • Partnering locally for commercialization (from manufacturing to sales) – custom approaches required for each market/sub-market	**Panel discussion: What do policymakers need to address for biosimilars to become more accessible?** **Katie Verb**, Director, Policy and Research, **PhRMA** (CONFIRMED) **Kevin Knopf**, Assistant Clinical Professor Medicine/Chairman Hemotology & Oncology, **University of California/Highland Hospital** (CONFIRMED) **Leah Christl**, Executive Director, Global Regulatory and R&D Policy, **Amgen** (CONFIRMED)

	• Patient and physician awareness – both about biologics and switching to biosimilars – needs to be handled carefully **Steve Lehrer**, Managing Director, **SBLehrer LLC** (CONFIRMED)	**Ned Pojskic**, Leader, Pharmacy & Health Provider Relations, **Green Shield Canada** (CONFIRMED) **Steven Corn**, Founder and CEO, **Metis Advocacy** (CONFIRMED) *Moderator:* **Philip Schneider,** International Advisory Board Chair, **Alliance for Safe Biologic Medicines** (CONFIRMED)
5:10pm	**The first Trastuzumab biosimilar manufactured in China and developed for global approval** • Comparison of NMPA and EMA guidelines for the development of biosimilars • Choice of sourcing the reference product • Summary of the Trastuzumab biosimilar, HLX02 – analytical characterization, non-clinical and clinical studies • Post-marketing pharmacovigilance requirements between NMPA and EMA **Alvin Luk**, CMO and SVP Global Clinical and Medical Affairs, **Shanghai Henlius** (CONFIRMED)	
5:30pm	**Offsite drinks reception**	

Day 2 – Tuesday, March 3rd 2020	
8:00am	Registration opens
8:30am	Conference doors open
Day 2 keynotes **Building a sustainable biosimilar industry**	
8:45am	Chair's opening remarks **Maggie Dolan**, Associate Director Market Access EU Biosimilars, **Biogen** (CONFIRMED)
8:50am	**The evolution of the US biosimilars market** • Approval vs launches, and gradual market uptake of the different marketed biosimilars • Changing perceptions of physicians and payers • Opportunities to support the US biosimilars market **Sheila Frame**, Vice President and Head of Biopharmaceuticals, North America, **Sandoz** (CONFIRMED)
9:10am	*Reserved for supporting partner. If you are interested in being involved, please contact Sam Bohan at sam.bohan@terrapinn.com or +44 (0)20 7 092 1040*
9:30am	**Michael Soldan**, Executive Vice President, Head of Biosimilars, **Fresenius Kabi** (INVITED)
9:50am	**Panel discussion: How to build a sustainable biosimilar market** • How to achieve sustainable uptake (a European perspective) • How successful has biosimilar uptake been so far in the U.S.? • How can we ensure this market is sustainable in the future? **Chad Pettit**, Executive Director, Global Value Access & Policy, Biosimilars, **Amgen** (CONFIRMED) **Fabio Kellett**, Director of Biosimilars, **Napp Pharmaceuticals** (CONFIRMED) **Sheila Frame**, VP and Head, North America, Biopharmaceuticals, **Sandoz** (CONFIRMED) **Elizabeth Jex**, Attorney Advisor, Office of Policy Planning, **Federal Trade Commission** (INVITED) *Moderator:* **Maggie Dolan**, Associate Director Market Access EU Biosimilars, **Biogen** (CONFIRMED)
10:25am	**Networking break**

10:30am – 11:15am	**WORKSHOP SESSION** **What the industry can do to make the patient healthcare experience better** • Results from patient survey on healthcare in the U.S. • Impact on rising healthcare costs that biologics cause **Steven Corn**, Founder and CEO, **Metis Advocacy** (CONFIRMED)	
	Track 1 **The clinical environment and real-world evidence**	**Track 2** **Biosimilars in healthcare policy**
	Chair: Hillel Cohen, Executive Director, Scientific Affairs, **Sandoz** (CONFIRMED)	**Chair: Philip Schneider,** International Advisory Board Chair, **Alliance for Safe Biologic Medicines** (CONFIRMED)
11:25am	**Current state of biosimilars in the U.S. and the role of real-world evidence in overcoming barriers to utilization** • The current status of biosimilar availability and utilization in the U.S. • The barriers to access and utilization of biosimilars in the U.S. from multiple stakeholder perspectives, including patients, healthcare providers, payers, and health systems • Define real-world evidence and discuss how it may be interpreted and used in making treatment and coverage decisions **Cate Lockhart**, Executive Director, **Biologics and Biosimilar Collective Intelligence Consortium** (CONFIRMED)	**Do biosimilars create real competition?** (final title TBC) **Alex Brill**, Resident Fellow, **American Enterprise Institute** (CONFIRMED)
11:45am	**Supporting biosimilar acceptance by giving clinicians and patients control using routine diagnostic serum concentration measurements for biologics/biosimilars – real-world data** • Experience from routine diagnostics on concentration and ADA measurements • One dose/ multitude of serum levels; impact of immunogenicity on PK • Validation of PK/ADA assays for originators for biosimilars; routine diagnostics vs. FDA/EMA registration **Annick De Vries**, Director Bioanalysis, **Sanquin** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Sam Bohan at sam.bohan@terrapinn.com or +44 (0)20 7 092 1040*
12:05pm	**Real-world evidence for benefit-risk decision making: quality and acceptability criteria for different stakeholders** • How do you evaluate and demonstrate real-world data and evidence quality? • How can you select appropriate real-world data sources? • What are important aspects of real-world data relevancy and quality for regulatory-grade decision making?	**Reimbursement in biosimilars** • Current reimbursement landscape for biosimilars • Why not to throw in the towel in biosimilars creating competition • The road ahead for biosimilars and reimbursement **Katie Verb**, Director, Policy and Research, **PhRMA** (CONFIRMED)

	Michael Forstner, Chairman of the Pharmacovigilance Working Group, **Medicines for Europe** (CONFIRMED)	
12:25pm	**The role of biosimilars in addressing unmet medical needs in immune mediated inflammatory diseases (IMID):** • Immune mediated inflammatory diseases are generally undertreated • Biosimilars have already helped the healthcare systems to realize major savings and hence offered headroom for funding innovation • On top of the cost savings, anti-TNFs biosimilars should be leveraged to advance the management of IMID with an earlier, optimized and sustainable control **Mourad Farouk-Rezk**, Global Head of Medical (Biosimilars), **Biogen** (CONFIRMED)	**Originator and biosimilar: getting the balance right** • The U.S. biologics sector is excelling at creating new originator biologic medicines that provide patients with new innovative medicines. Developing a robust competitive market via biosimilars is a different story • Biosimilars offer a tremendous savings opportunity by fostering this needed competitive market. Addressing key market and policy obstacles can help create a more robust and viable competitive market saving the U.S. health care sector billions of dollars **Wayne Winegarden**, Senior Fellow, **Pacific Research Institute** (CONFIRMED)
12:45pm	**Networking lunch**	
1:25pm – 1:55pm	**WORKSHOP SESSION** **How can employers promote biosimilar adoption?** • Biosimilars from an employer's perspective • Employer strategies to promote biosimilars **Matthew Harman**, Senior Director of Pharmacy, **Employers Health** (CONFIRMED)	
	Track 1 **The clinical environment and real-world evidence**	**Track 2** **Commercialization and sustainability**
	Chair: Hillel Cohen, Executive Director, Scientific Affairs, **Sandoz** (CONFIRMED)	**Chair: Blake Leitch**, Global Head Marketing Biosimilars, **Biogen** (CONFIRMED)
2:00pm	**Importance of successful commercialization of biosimilars to hospitals** • Hospitals have experienced unusual pharmaceutical price increases since 2014 • Explosive growth has been observed in treatments for hep-C, MS, diabetes and cancer which require specialty pharmaceuticals, pharmacies and distributors, accounting for ~50% of a typical hospital's spend • Very few life-cycle opportunities in the small molecule environment compared to 2011-2012 and the impact of life-cycle opportunities in the large molecule environment of today are limited **Ross Day**, Former Director, Pharmacy Contracting, **Vizient Inc.** (CONFIRMED)	**Final title TBC** **Ravi Pherwani**, Head of U.S. Oncology Biosimilars, **Pfizer** (CONFIRMED)

2:20pm	*Reserved for supporting partner. If you are interested in being involved, please contact Sam Bohan at sam.bohan@terrapinn.com or +44 (0)20 7 092 1040*	**Sustainability of biosimilars in Europe, with a focus on four EU countries** • What is supposed to be the role of biosimilars? • The European reality of biosimilars • Successful measures to increase the use of biosimilars • The role of biosimilars in the sustainability of health systems **Maria-ceu Machado**, Former President, **INFARMED** (CONFIRMED) and **Sofia Oliveira Martins**, Professor/Former Board Member, **Lisbon University Faculty of Pharmacy/INFARMED** (CONFIRMED)
2:40pm	**Application in the U.S. healthcare system market: introducing biosimilars to the formulary** • A pharmacist's look at the biosimilar product • The health system's look at placing biosimilars • Collaboration to incorporate biosimilar agents **Charles E. Daniels** BSPharm, PhD, Associate Dean and Chief Pharmacy Officer, **University of California San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Sam Bohan at sam.bohan@terrapinn.com or +44 (0)20 7 092 1040*
3:00pm	**Social media influence over patients in the biologic/biosimilar market** • Patient "influencers" sponsored by various companies and organizations appeal to patients on social media platforms • This can be encouraging or discouraging, hurting the promotion of biosimilars, one example is a GI group that fights hard against Infliximab, a biosimilar of Remicade **Elizabeth Johnson**, Biologics Coordinator, **Allergy Partners P.A.** (CONFIRMED)	**Affordability of biosimilars** (final title TBC) **Scott Liu**, CEO, **Shanhai Henlius** (CONFIRMED)
3:20pm	**Afternoon refreshments**	
4:00pm	**Cost savings by use of biosimilars at a county hospital** • Cancer care economics in the public/not-for-profit sector is a proper use case for cost-effectiveness to ensure health equity and quality of care • A program of 100% switching to biosimilars in our public hospital was implemented and resulted in significant cost savings • This approach can be scaled to other public/county hospitals	**Challenges and opportunities for biosimilar businesses in emerging markets** • The main challenges in emerging markets • Cooperative synergy makes long-term opportunities • New environment and opportunities in the Chinese market **Huiguo (Forrest) Hu**, General Manager, International Business, **3SBio** (CONFIRMED)

	Kevin Knopf, Assistant Clinical Professor Medicine/Chairman Hemotology & Oncology, **University of California/Highland Hospital** (CONFIRMED)	
4:20pm	**Value-based treatment pathways in rheumatoid arthritis** • Understand clinical and contracting barriers to the use of biosimilar agents in rheumatology • Review the utility of a value-based treatment pathway for RA • Understand how treatment pathways can be leveraged by providers to increase access to biosimilar agents in rheumatology **Colin C. Edgerton, MD, FACP, FACR,** Executive Chairman, **Articularis Rheumatology Network** (CONFIRMED)	**Heather Wall**, Chief Commercial Officer, **CivicaRx** (CONFIRMED)
4:40pm	**Panel discussion: Clinical trials and RWE. How important is RWE in differentiating between competing biosimilars? How does real-world data influence physicians?** **Charles Daniels**, Associate Dean and Chief Pharmacy Officer, **University of California San Diego, Skaggs School of Pharmacy and Pharmaceutical Sciences** (CONFIRMED) **Elizabeth Johnson**, Biologics Coordinator, **Allergy Partners P.A.** (CONFIRMED)	**Orphan drug biosimilars: when a copy could cost more than the innovator** • Different roles of original drugs and biosimilars on the market • Clinical development programs of originator vs biosimilar. What's the difference? • Problems for orphan drug biosimilars • Ways of overcoming obstacles **Roman Drai**, Research & Development Director, **GEROPHARM** (CONFIRMED)
5:00pm	**Kevin Knopf**, Assistant Clinical Professor Medicine/Chairman Hemotology & Oncology, **University of California/Highland Hospital** (CONFIRMED) **Pradeep Nair**, Associate Director, Oncology and Biosimilars, **Teva Canada Innovation** (INVITED) **John Kelton**, Medical Director - Oncology Biosimilars, **Pfizer** (INVITED) *Moderator:* **Cate Lockhart**, Executive Director, **Biologics and Biosimilar Collective Intelligence Consortium** (CONFIRMED)	**The value and affordability of orphan drugs** • Evaluating the value of orphan drugs • How we can pay for orphan drugs and whether it's feasible for biosimilar producers to improve their affordability **Omar Dabbous**, Vice President Global HEOR and RWE, **AveXis** (CONFIRMED)
5:20pm	**Networking drinks and poster presentation session**	

Day 3 – Wednesday, March 4th 2020		
8:30am	Registration opens	
9:00am	Conference doors open	
	Track 1 **Development, manufacturing and analysis**	**Track 2** **IP and legal challenges**

	Chair: Julio Baez, Bioengineering Industrial Advisor, **UCSD** (CONFIRMED)	**Chair: Bruce Leicher**, Independent Strategic Legal Advisor/Former Senior Vice President and General Counsel, **Momenta Pharmaceuticals** (CONFIRMED)
9:05am	**A case study on utilizing an existing molecule** (full title TBC) **Martin Brenner**, Senior Vice President, CSO, **Pfenex** (CONFIRMED)	**Proposed and pending federal legislation affecting biosimilars** • Improvements to the "patent dance" • Expanding anti- "product hopping" proposals to biosimilars • Patent listing in the Purple Book • Presumptive patent term disclaimer **Hans Sauer**, Deputy General Counsel, Vice President for Intellectual Property, **Biotechnology Innovation Organization** (CONFIRMED)
9:25am	**The pitfalls of biosimilar characterization and how to overcome them** • What are the issues with excipients? • Lot numbers of innovator products • Pros and cons of methodologies such as NMR and MS, and validation of methods and time frame **Parastoo Azadi**, Technical Director of Analytical Services, Senior Research Scientist**, Complex Carbohydrate Research Center, University of Georgia** (CONFIRMED)	***Reserved for Axinn***
09:45am	*Reserved for supporting partner. If you are interested in being involved, please contact Sam Bohan at sam.bohan@terrapinn.com or +44 (0)20 7 092 1040*	**William Han**, Former Assistant General Counsel (Patents), **GSK** (CONFIRMED)
10:05am	**Biosimilarity assessment using functional and binding assays – challenges and insights** • Challenges in defining product Critical Quality Attributes (CQA) to determine the Quality Target Product Profile (QTPP) • Statistical approaches for similarity assessments – how many reference product lots should be sufficient • Similarity assessment of monoclonal therapeutic drug using functional and binding attributes – challenges and insights **Bracha Timan**, Senior Director, Global Bioassays & Technology, **Teva** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Sam Bohan at sam.bohan@terrapinn.com or +44 (0)20 7 092 1040*
10:25am	**Difficult to express antibodies – problems and resolutions** • NeuClone biosimilar development – delivering high-quality, low-cost biosimilars at scale with a pure focus on biosimilar monoclonal antibody development	**Michael Penn**, Principal Counsel, Intellectual Property & Litigation, **Amgen** (INVITED)

	• Over 25 biosimilar monoclonal antibodies in active development
	  ○ Difficult to express antibodies – expression vector constructs
	  ○ Difficult to express antibodies - expression in CHO-K1 vs. CHO-S
	  ○ Difficult to express antibodies – transfection protocols
	
	Noelle Sunstrom, CEO & Founder, **NeuClone** (CONFIRMED)	

10:45am	**Networking break**	
	Track 1 **Development, manufacturing and analysis**	**Track 2** **IP and legal challenges**
	Chair: Julio Baez, Bioengineering Industrial Advisor, **UCSD** (CONFIRMED)	**Chair: Bruce Leicher**, Independent Strategic Legal Advisor/Former Senior Vice President and General Counsel, **Momenta Pharmaceuticals** (CONFIRMED)
11:15am	**Title TBC** **Senior Representative**, **Prestige Biopharma** (CONFIRMED)	*Presentation slot available*
11:35am	**Next generation biosimilars** **Senior Representative**, **Biocon** (CONFIRMED)	*Reserved for supporting partner. If you are interested in being involved, please contact Sam Bohan at sam.bohan@terrapinn.com or +44 (0)20 7 092 1040*
11:55am	*Reserved for supporting partner. If you are interested in being involved, please contact Sam Bohan at sam.bohan@terrapinn.com or +44 (0)20 7 092 1040*	**Diane Retallack**, Senior Director, Upstream Processing and Intellectual Property, **Pfenex** (INVITED)
12:05pm	**Lowering the cost of biosimilars with new technology** • Contribution of clone and process (R&D) on lowering manufacturing costs • Continuous evaluation and implementation of novel technologies both in R&D and manufacturing • Strategy for developing manufacturing capabilities to save running costs • Role of automation and QbD approach to developing affordable biosimilars **Sanjeev Gupta,** Senior General Manager & Head of Advanced Biotechnology, **IPCA** (CONFIRMED)	**Panel discussion: Would the U.S. biosimilars industry benefit from reforms to intellectual property law?** **Diane Retallack**, Senior Director, Upstream Processing and Intellectual Property, **Pfenex** (INVITED) **Hans Sauer**, Deputy General Counsel, Vice President for Intellectual Property, **Biotechnology Innovation Organization** (INVITED) *Moderator:* **Joe Fuhr**, Adjunct Professor of Pharmaceutical & Healthcare Business, **Widener University** (CONFIRMED)

12:25pm	**Big data and predictive glycoengineering** • Glycosylation is complex and difficult to control on biologics • Development of big data analytics has been achieved to understand factors associated with glycosylation • Models and algorithms predict how one may achieve desired glycosylation **Nathan Lewis**, Associate Professor, Dept Pediatrics and Bioengineering, **USCD** (CONFIRMED)	
12:45pm	**Networking lunch**	
	Track 1 **Development, manufacturing and analysis**	**Track 2** **Insulin biosimilars**
	Chair: Julio Baez, Bioengineering Industrial Advisor, **UCSD** (CONFIRMED)	**Chair: Ann Kempski**, Strategic Advisor, **National Coalition on Healthcare** (INVITED)
1:40pm	**Streamlining process development to achieve maximum efficiency with minimum cost and time** • Lineally scalable equipment during scale-up helps to maintain CQAs • Having the right clone (that gives biosimilar products) improves process efficiency • Methods to control process-borne enzymes, such as proteases, sialidases and deglycosylases help to prevent target-product modifications **Rustom Mody**, Senior Vice President and Head of Research & Development, **Lupin** (CONFIRMED)	**Comparing the regulatory challenges for insulin biosimilars between China and the US/EU** • Looking at China through new eyes • Major differences in registering in China, US, EU • Recent changes in China regulatory approaches **Lawrence Hill**, CEO, **Gan & Lee USA** (CONFIRMED)
2:00pm	**Analytical similarity studies and the first biosimilar monoclonal antibody in China** • QbD-based quality study and determination of critical quality attributes (CQAs) of biosimilar mAbs following a developed quality study platform at Henlius and analytical similarity study of biosimilar mAbs and the corresponding regulatory requirements in China and abroad • Presentation of some major results of analytical similarity study on the 1st China biosimilar mAb Hanlikang® (Henlius rituximab biosimilar HLX01 to the MabThera®) • Presentation and discussion of some major analytical similarity study points for Henlius biosimilar HLX02 (a trastuzumab biosimilar to Herceptin®), made both NMPA NDA and EMA MAA filings in 2019 **Michael Hongwei Xie**, Executive Director of Bioassay and Analytical Development, **Shanghai Henlius Biotech Inc.** (CONFIRMED)	**Insulin biosimilars** (full title TBC) **Chrys Kokino**, Head, Global Biologics, **Mylan** (CONFIRMED) and **Abhijit Barve**, Head, Global Clinical Research, **Mylan** (CONFIRMED)

2:20pm	**QA controls and operations: Validation qualification and regulatory** **Nacer E Hedroug**, Director of Quality Improvement**, Mylan** (CONFIRMED)	**Panel discussion: Insulin biosimilars and how they can improve access for diabetes patients** **Lawrence Hill**, CEO, **Gan & Lee USA** (CONFIRMED) **Mona Chitre**, Chief Pharmacy Officer & VP Integrated Clinical Strategy, **Excellus BlueCross BlueShield** (CONFIRMED) **Sarfaraz Niazi**, Adj. Professor of Pharmaceutical Sciences/CEO, **University of Illinois/PharmSci** (CONFIRMED) **Sundar Ramanan**, Vice President & Head, Global Regulatory Affairs, **Biocon** (CONFIRMED) **Chrys Kokino**, Head Global Biologics, **Mylan** (INVITED) **Krista Maier**, Vice President of Public Policy & Strategic Alliances, **American Diabetes Association** (INVITED) *Moderator:* **TBC**
2:40pm	**Progress in expression systems to reduce cost and improve product quality** • Use of improved performance expression systems to reduce costs and development time while improving productivity and product quality • The implementation of novel and improved performance expression systems to meet needs of different regions • Integrated progress in bioanalytics and downstream processing to implement improved performance expression systems **Julio Baez**, Bioengineering Industrial Advisor, **UCSD** (CONFIRMED)	
3:00pm	**Closing remarks from the chairs**	**Closing remarks from the chairs**
3:10pm	**Closing remarks from Terrapinn**	**Closing remarks from Terrapinn**
3:15pm	**End of conference**	

FESTIVAL OF BIOLOGICS USA

AMERICAS ANTIBODY CONGRESS 2020 | WORLD IMMUNOTHERAPY CONGRESS USA 2020 | WORLD BIOSIMILAR CONGRESS USA 2020

Festival of Biologics USA - Workshop agenda

Day 1 - Monday March 2nd 2020		
Conference sessions		
12:45pm – 1:20pm	**Identifying early stage assets in academia** • Technology Transfer databases – Identifying Potential Drug Discovery Programs • In-licensing expectations • Academic advisory roles • Establishing a firewall for intellectual property rights **Marc Nasoff,** Chief Scientific Officer, **Fortis Therapeutics** (CONFIRMED)	**ANTIBODIES: Comparing strategies and challenges of bispecific antibody infusion** **Larry Lum,** Professor, Director of Cellular Therapy, Scientific Director of Bone Marrow Transplant, **University of Virginia** (CONFIRMED)
1:25pm – 1:55pm	**ANTIBODIES: 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,** Research Fellow, **Bristol Myers-Squibb** (invited) **Bojana Popovic,** Senior Research Scientist, **MedImmune** (invited)	**BIOSIMILARS: Transitioning to biosimilars. Overview from payers.** **Mona Chitre**, Chief Pharmacy Officer & VP Integrated Clinical Strategy, **Excellus BlueCross BlueShield** (CONFIRMED) **Senior Representative, pan-Canadian Pharmaceutical Alliance Office** (INVITED) **Senior Representative, Dean Health Plan** (INVITED) **Senior Representative, UnitedHealth Group** (INVITED)

Conference sessions		
3:30pm – 4:00pm	**ANTIBODIES: Overview of therapeutic protein immunogenicity workshop** **Jack Ragheb,** Senior Medical Fellow, Immunology, **Eli Lilly & Company** (CONFIRMED) **Andrea Ferrante,** Principal Research Scientist, **Eli Lilly and Company** (CONFIRMED) **Arunan Kaliyaperumal,** Research Fellow, **Eli Lilly and Company** (CONFIRMED)	**BIOSIMILARS. Draft guidance development of therapeutic protein biosimilars: comparative analytical assessment and other quality-related considerations** **Marjorie Shapiro**, Chief, Laboratory of Molecular and Developmental Immunology, Division of Biotechnology Products Research and Review, **FDA** (CONFIRMED)
Conference sessions		
Day 2 - Tuesday March 3rd 2020		
Conference sessions		
10:30am – 11:15am	**BIOSIMILARS: What the industry can do to make the patient healthcare experience better** • Results from patient survey on healthcare in the US • Impact of biologics on rising healthcare costs **Steven Corn**, Founder and CEO, **Metis Advocacy** (CONFIRMED)	**CLINICAL TRIALS: Operationalizing pediatric and adult cell therapy trials** **Brenda Hann,** Director, Clinical Trials Operations, **Stanford Medicine** (CONFIRMED) **Janet McDowell,** Clinical Research Manager, **Stanford University School of Medicine - Cancer Clinical Trials Office** (CONFIRMED) **Theresa Latchford,** Oncology Clinical Nurse Specialist, **Stanford Health Care - Blood and Marrow Transplant Unit** (CONFIRMED) **Anne Cunniffe Marcy,** Clinical Research Coordinator, **Stanford University School of Medicine - Cancer Clinical Trials Office** (CONFIRMED)
Conference sessions		
12:50pm – 1:20pm	**Biologics investor clinic** • Workshop focusing on investing in biologics • Which biologics are hot now, what are people investing in? • What makes a biologic investable? **Kevin Johnson,** Partner, **Medixci** (CONFIRMED) **John Hood,** Chairman, **Endeavour Biomedicines** (CONFIRMED) **Stan Fleming,** Founding Managing Partner, **Forward Ventures** (CONFIRMED)	**CLINICAL TRIALS: Panel discussion: patients as partners in clinical development** • How can we collaborate more with patients? • Improving transparency • Public awareness of clinical trials **Moderator: Julie Gerberding,** Executive Vice President, Communications, Global Policy, and Population Health & Chief Patient Officer**, Merck** (CONFIRMED) **Eve Bukowski,** Vice President, Patient Advocacy, Education & Outreach, **California Life Sciences Association (CLSA)** (CONFIRMED) Other speakers TBA
1:25pm – 1:55pm	**BIOSIMILARS: How can employers promote biosimilar adoption?** • Biosimilars from an employer's perspective • Employer strategies to promote biosimilars **Matthew Harman**, Senior Director of Pharmacy, **Employers Health** (CONFIRMED)	
Conference sessions		
3:25pm – 3:55pm	Workshop TBA	**CLINICAL TRIALS: Title TBA** **Amrit Takhar,** GP Partner and Clinical Lead, **Wansford surgery – NHS** (CONFIRMED)