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MONDAY-TUESDAY AUGUST 27-28	TUESDAY-WEDNESDAY AUGUST 28-29	THURSDAY-FRIDAY AUGUST 30-31
Immunomodulatory Therapeutic Antibodies for Cancer	Bispecific Antibodies for Cancer Immunotherapy	Emerging Immuno-Oncology Targets
Rational Combination Cancer Immunotherapy	Preclinical and Translational Immuno-Oncology	Personalized Cancer Vaccines
Immuno-Oncology Biomarkers 1: Quantitative Immune Profiling and Immune Monitoring	**Immuno-Oncology Biomarkers 2:** Predictive Biomarkers and Companion Diagnostics	Neoantigen Targeted Therapies
Oncolytic Virus Immunotherapy	Adoptive T Cell Therapy 1: Discovery	Adoptive T Cell Therapy 2: Development
Training Seminar 1: CAR-T Engineering for Protein Scientists	Training Seminar 2: Immunology for Drug Discovery Scientists	Immuno-Oncology Investing and Partnering Forum

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- Develop new collaborations by networking with industry decision makers and leading academic researchers
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- Focus on your agenda by track hopping between concurrent tracks
- Showcase your research by presenting a scientific poster

WHAT'S NEW IN 2018?

- New track on Bispecific Antibodies completes a 5-day offering on immunotherapy engineering
- IO Biomarkers coverage expanded to 3 days to cover predictive biomarkers, companion diagnostics and immune profiling
- Coverage of Adoptive T-Cell Therapy expanded to 3 days to span discovery and development
- New track on Neoantigen Targeted Therapies highlights personalized immunotherapy approaches
- New Partnering Forum highlights emerging companies and investment opportunities
- Exhibit hall is expanded to accommodate increasing demand to showcase solution providers and posters
- Training seminar and dinner course offering expanded

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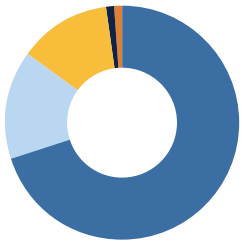

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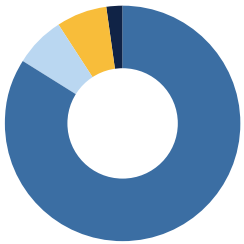

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Professor, Immunology, University of Minnesota

Even Walseng, PhD,
Staff Scientist, Experimental Immunology Branch, National Cancer Institute, National Institutes of Health; Department of Immunology, Hospital Radiumhospitalet, Institute for Cancer Research, University of Oslo

Allison Betof Warner, MD, PhD,
Medical Oncology Fellow, Medicine, Memorial Sloan Kettering Cancer Center

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Andrew Weinberg, PhD,
Chief, Laboratory of Basic Immunology, Providence Health & Services

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Research, Sound Biologics

Niranjan Yanamandra, PhD,
Scientific Director, Translational Research, Immuno-Oncology & Combinations DPU, Oncology R&D, GlaxoSmithKline

Timothy Yap, MD, PhD,
Associate Professor, Department of Investigational Cancer Therapeutics, The University of Texas MD Anderson Cancer Center

Hua Eleanor Yu, PhD,
Professor & Co-Chair, Immuno-Oncology, City of Hope

Xingxing Zang, PhD,
Professor and Louis Goldstein Swan Endowed Chair, Microbiology and Immunology & Medicine, Albert Einstein College of Medicine

Gus Zeiner, PhD,
CSO, Chimera Bioengineering

Litao Zhang, PhD,
Vice President, Leads Discovery and Optimization, Bristol-Myers Squibb

Lei Zheng, MD, PhD,
Associate Professor, Oncology and Surgery, Johns Hopkins University School of Medicine

Ilan Zipkin, PhD,
Vice President, Business Development, Parker Institute for Cancer Immunotherapy

Conference Programs

- Immunomodulatory Therapeutic Antibodies for Cancer
- Rational Combination Cancer Immunotherapy
- Immuno-Oncology Biomarkers 1: Quantitative Immune Profiling and Immune Monitoring
- Oncolytic Virus Immunotherapy
- Bispecific Antibodies for Cancer Immunotherapy
- Preclinical and Translational Immuno-Oncology
- Immuno-Oncology Biomarkers 2: Predictive Biomarkers and Companion Diagnostics
- Adoptive T Cell Therapy 1: Discovery
- Emerging Immuno-Oncology Targets
- Personalized Cancer Vaccines
- Neoantigen Targeted Therapies
- Adoptive T Cell Therapy 2: Development
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Plenary Keynotes

TUESDAY | AUGUST 28

4:20 pm CAR-T Therapy for B Cell Malignancies

Jennifer Brogdon, PhD, Director, Exploratory Immuno-Oncology, Novartis

4:55 Walking on the Moon: Reflections on the Work of the Cancer Moonshot and the Future of the Biden Cancer Initiative

Gregory C. Simon, JD, President, Biden Cancer Initiative

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SC Dinner Short Courses — TUESDAY & WEDNESDAY

TUESDAY, AUGUST 28, 6:30-9:00 PM

Dinner Short Course (SC1)

Bioinformatics for Immuno-Oncology and Translational Research

Instructor:
Yuriy Gusev, PhD, Associate Professor, Innovation Center for Biomedical Informatics (ICBI), Georgetown University

In this course, we cover major applications of Big Data, bioinformatics and systems biology for immuno-oncology research and development with major focus on translational research. We provide a User's Guide to open access online resources and tools as well as overview of state-of-the-art methodologies and approaches to leveraging and integrating of a vast amount of information available through genome-wide molecular profiling, next-generation sequencing, etc. for the immuno-oncology applications. Several important immuno-oncology focus areas will be discussed in detail, such as computational immunophenotyping of tumor samples, HLA typing based on sequencing data, as well as computational methodologies for immunotherapy selection. Several case studies and brief live demos with hands-on exercises will be presented to illustrate the importance and added value of integrative bioinformatics analysis for immuno-oncology.

Course Level: Intermediate difficulty (201 level); some knowledge of genomics technologies and molecular profiling data types (i.e., gene expression, RNAseq) is expected.

Who Should Attend: Targeted audience: PhD/MD-level biomedical researchers, oncologists, graduate students, etc. No computational background is required.

Topics to be Covered in the Course Include:

1. Overview of major applications of bioinformatics methodologies in immuno-oncology.
2. Open access bioinformatics databases and tools that are available for immuno-oncology research – a User's Guide.
3. Case study examples for multi-omics integrative analysis in human cancers with immunology implications.
4. Short live demo of online resources and tools with hands-on examples.
5. Future directions for computational immuno-oncology.

TUESDAY, AUGUST 28, 6:30-9:00 PM

Dinner Short Course (SC2)

Next-Generation Immunotherapies: Part 1

Please join us for a two-part dinner workshop series featuring presentations on the latest immunotherapy technologies from emerging companies. Learn about engineering the next-generation immunotherapies coming down the pipeline, including bi-specific and multi-specific antibody constructs, fully recombinant antibody prodrugs, innovative multivalent therapeutics, immunotherapeutic fusion proteins, antibody-drug conjugates, and other innovative approaches.

Unbiased Functional Screening of Large Bispecific Antibody Panels to Unlock Novel Biology

Mark Throsby, PhD, Executive Vice President & CSO, Merus NV

The bispecific antibody format represents an emerging therapeutic modality. We have developed a set of robust and validated technologies that permits unbiased in-format functional screening to identify human full-length IgG bispecific antibodies candidates with superior therapeutic properties. Two case studies will be presented where this approach has been successful employed to discovery lead candidates with differentiating properties that are now in clinical development.

Development of MabPair Technology, a Novel Platform for Developing Bifunctional Antibody Products

Wei Yan, PhD, CEO, Research, Sound Biologics

We have developed a novel technology that enables the production of two full length IgG molecules from a single production cell line. This was achieved by using a molecular engineering approach from which we can precisely control the correct pairing of antibody heavy chains and light chains during the assembly of two antibodies in the same cell line. This technology platform, which has been designated as MabPair, can be applied for the development of therapeutic antibody products that contain a mixture of two antibodies. MabPair products can offer significant advantages and flexibility over those of bispecific antibodies when addressing multiple targets. We will describe the development of PSB205, our lead MabPair product candidate, that targets two immune checkpoint pathways, and its potential in cancer immunotherapy.

ProTIA – Bispecific T Cell Engagers That Combine Tumor Antigen Binding, Local Protease Activation, and Polymer Exclusion from Normal Tissues

Volker Schellenberger, PhD, President & CEO, Amunix

ProTIAs are highly potent bispecific T cell engagers. ProTIAs are administered to patients as inactive long half-life prodrugs. Activation by tumor-associated proteases occurs within tumor tissue. The released active form has a short circulation half-life, which minimizes the risk of systemic exposure. Amunix's proprietary XTEN™ protein polymer provides half-life modulation, masking of binding sites, and facilitates manufacturing of ProTIA prodrugs.

Probody Therapeutics: Antibody Pro-Drugs Designed for Safer and More Effective Cancer Therapies

W. Michael Kavanaugh, MD, CSO, Head, Research and Non-Clinical Development, Cytomx Therapeutics

Probody™ therapeutics are fully recombinant antibody prodrugs that are converted to active antibodies by tumor-associated proteases. They are designed to protect normal tissues while concentrating active antibody in tumors, thereby widening the therapeutic index. Examples of the application of Probody technology to multiple antibody-based therapies will be presented, including checkpoint blocking naked antibodies directed against PD-(L)1 and CTLA-4, antibody-drug conjugates, and T cell-engaging bispecific antibodies.

Conference Programs

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SC Dinner Short Courses — TUESDAY & WEDNESDAY

ADAPTIR Bispecific Proteins: Stable, Manufacturable Therapeutics for Cancer Immunotherapy

Michael Comeau, Principal Scientist, Immunobiology, Aptevo Therapeutics

The presentation will highlight the activity, stability and manufacturability of ADAPTIR bispecifics and will include recent data for a lead preclinical candidate, APVO436, which targets CD123 and CD3. APVO436 has shown potent biological activity in preclinical studies and is rapidly advancing toward first-in-human clinical trials.

WEDNESDAY, AUGUST 29, 6:00-9:00 PM

Dinner Short Course (SC3)

Next-Generation Immunotherapies: Part 2

Please join us for a two-part dinner workshop series featuring presentations on the latest immunotherapy technologies from emerging companies. Learn about engineering the next-generation immunotherapies coming down the pipeline, including bi-specific and multi-specific antibody constructs, fully recombinant antibody prodrugs, innovative multivalent therapeutics, immunotherapeutic fusion proteins, antibody-drug conjugates, and other innovative approaches.

Targeted VH Humabodies as Novel Multifunctional Immunotherapies

Phil Bland-Ward, PhD, CSO, Crescendo Biologics

Crescendo Biologics is developing multifunctional Humabody therapeutics, with particular focus on novel mechanisms that simultaneously target tumours and activate tumour-specific T cells. Originating from the proprietary Crescendo Mouse platform, Humabody VH domains represent functional building blocks that Crescendo optimally configures to create innovative multivalent therapeutics. These include dual-checkpoint blockade, biparatopic tumour antigen targeting, and Humabody Drug Conjugate (HDC) biologics with outstanding therapeutic potential in cancer.

KAHR Medical Dual Signaling Proteins (DSP) Platform – The Next Generation of Cancer Immunotherapy

Adam Foley-Comer, MD, CMO, KAHR Medical, Ltd.

KAHR Medical is developing a novel drug platform based on bi-functional, immunotherapeutic fusion proteins. KAHR's proprietary technology enables the construction of targeted biological drugs with two functional ends, which can simultaneously block and/or activate two reinforcing biological signals resulting in a synergistic outcome. This platform represents a new generation of ultra-active immunotherapeutic biological drugs rationally designed for the treatment of multiple cancer indications.

Hexavalent TNFR-SF Agonists: A Unique Class of Biologics for Cancer Immunotherapy

Christian Gieffers, PhD, Vice President, Analytics/ Protein Chemistry, Apogenix

The technology platform developed by Apogenix is based on trivalent but single-chain molecular mimics of the TNF-SF Receptor binding domains (scTNFSF-RBDs) fused to a dimerization scaffold. This drug concept was successfully translated to CD40L, CD27L and GITRL. Being hexavalent by design, these fusion proteins are potent agonists on their own. They co-stimulate distinct immune cell types involved in the anti-tumor immune reaction thereby enabling exciting opportunities for combination treatment with other I-O drugs.

Optimization of a Bispecific Anti-CD3 Antibody-Small Molecule Conjugate for the Treatment of Ovarian Cancer

Harun Rashid, PhD, Principal Scientist, Molecular Technology, Ambrx

Bispecific antibodies, which simultaneously target CD3 on T cells and tumor-associated antigens (TAAs) to recruit cytotoxic T cells to cancer cells, are a promising new approach for the treatment of various liquid and solid tumors. We recently described the synthesis of a chemically defined anti-CD3 Fab-folate conjugate that targets cytotoxic T cells to folate receptor positive (FR+) tumors. Here, we report further optimization of the anti-CD3 Fab-folate conjugate for optimal efficacy, reduced toxicity and optimal pharmacokinetic (PK) properties. To strike an optimal balance between efficacy and toxicity due to cytokine release syndrome (CRS), we fine-tuned the affinity of the anti-CD3 antibody as well as optimized the TAA binding. To increase the *in vivo* half-life (T1/2), we simultaneously conjugated both folate and PEG molecules of various sizes by the use of bi-functional linkers. The optimized conjugates showed potent and selective *in vitro* activity, good serum half-life, and potent *in vivo* activity in xenograft mouse models. This semisynthetic approach is likely to be applicable to the generation of additional anti-CD3 bispecific agents using small molecule ligands selective for other TAAs.

Enhancement of Anti-Tumor Immunity via Targeted Alteration of the Microbiome

Bruce Roberts, PhD, CSO, Vedanta Biosciences

Recent clinical data suggests a link between the microbiome and efficacy of checkpoint inhibitors. These observations suggest alteration of the microbiome via administration of live bacterial consortia may have beneficial effects. Vedanta has characterized immunostimulatory commensal compositions capable of inducing CD8 T cells in germ free mice. Results will be presented illustrating these T cell stimulatory consortia enhance anti-tumor efficacy when used in combination with checkpoint inhibitors in animal models.

Talk Title to be Announced

Marnix Bosch, PhD, Chief Technical Officer, Northwest Biotherapeutics

Separate registration required

Conference Programs

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MONDAY-TUESDAY | AUGUST 27-28

Immunomodulatory Therapeutic Antibodies for Cancer

Emerging Targets, Combinations, and Antibody Engineering for Next-Generation Immunotherapy

MONDAY, AUGUST 27

7:30 am Registration & Morning Coffee

THERAPEUTIC STRATEGIES TO OVERCOME IMMUNE EVASION AND RESISTANCE TO CHECKPOINT INHIBITORS

8:25 Chairperson's Opening Remarks
Osama Rahma, MD, Assistant Professor, Medicine, Harvard Medical School; Center for Immuno-Oncology, Dana-Farber Cancer Institute

8:30 Overcoming Resistance to PD-1 Inhibition in Pancreatic Cancer
Osama Rahma, MD, Assistant Professor, Medicine, Harvard Medical School; Center for Immuno-Oncology, Dana-Farber Cancer Institute

Pancreatic cancer doesn't respond traditionally to immunotherapy including PD-1 inhibitors. This is due to the immune suppressive microenvironment and the lack of tumor infiltrating lymphocytes making pancreatic cancer known as an "immune desert." We are currently investigating multiple strategies to overcome pancreatic cancer resistance to immunotherapy including combinational approaches of immunotherapies, radiation and chemotherapy.

9:00 Tumor-Mediated Modulation of Immunometabolism as a Mechanism of Immunotherapy Resistance: Implications for Combination Immunotherapy Development
Brent Hanks, MD, PhD, Assistant Professor, Cancer Immunology/Immunotherapy, Duke Cancer Institute, Duke University School of Medicine

We will discuss recently identified mechanisms by which tumors evade the host immune response by metabolically reprogramming the local immune microenvironment. This will include a discussion of novel pharmacologic strategies capable of reversing these pathways and enhancing the effectiveness of checkpoint inhibitor immunotherapy.

9:30 Tgfβ Attenuates Tumour Response to PD-L1 Blockade by Contributing to Exclusion of T Cells
Alessandra Castiglioni, PhD, Senior Scientific Researcher, Cancer Immunology, Genentech

CD8+ T-effector cell phenotype and high tumor mutation burden are predictors of good responses to therapy with atezolizumab in patients with metastatic urothelial cancer. Lack of response is associated with TGFβ signaling in fibroblasts, especially in patients with an immune-excluded phenotype. Combining TGFβ blockade with anti-PD-L1 antibody in mouse models with the same phenotype increases the anti-tumor efficacy of the therapy, reduced TGFβ signaling in stromal cells and facilitated T-cell penetration into the tumors.

10:00 Coffee Break

10:30 Strategies to Enhance Tumor Antigen Presentation and Interferon Response in Cancer: Implications for Immuno-Molecular Combinations
Justin Balko, PharmD, PhD, Assistant Professor, Medicine, Vanderbilt University Medical Center

Immunotherapies have changed the landscape of cancer treatment in a variety of tumor types. However, many tumors do not respond to the first generation of therapeutic antibodies targeting the immune system, such as anti-PD-1. While a variety of mechanisms may underlie acquired and intrinsic resistance to immunotherapy, anti-tumor immunity can be thwarted by ineffective antigen presentation by MHC-I and MHC-II and poor interferon responsiveness. Preclinical therapeutic strategies to overcome these factors and their translation to clinical trials will be discussed.

11:00 Therapeutic Manipulation of Tumor Microenvironment to Improve Immune Response in Tumors
Allison Betof Warner, MD, PhD, Medical Oncology Fellow, Medicine, Memorial Sloan Kettering Cancer Center

Tumors are not simply collections of cancer cells that arise in a vacuum; they are instead complex structures composed of blood vessels, immune cells, and other supporting structures that interact, consume oxygen and other nutrients, and produce waste. Tumor microenvironment has long been viewed as a therapeutic target. I will discuss recent data on how microenvironmental factors, including changes in angiogenesis, metabolism, and exercise, influence immunobiology and our group's approach to harness these interactions to improve therapeutic outcomes using murine models.

11:30 Long Term Time-Course Monitoring of NK Cell-Mediated ADCC Using the Celigo Image Cytometer

Sponsored by Nexcelom Bioscience

Leo Chan, Technology Research & Development Manager, Nexcelom Bioscience LLC

The traditional release assays for ADCC is inaccurate due to indirect measurement of supernatant for 4 hours. We demonstrated time-course monitoring of NK-mediated ADCC of A375 cells for 76 hours, and showed ADCC killing with decrease in ZsGreen cells. This can better characterize the effects of target antibodies on ADCC.

11:45 Sponsored Presentation *(Opportunity Available)*

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Session Break

EMERGING IMMUNE CHECKPOINT TARGETS

1:25 Chairperson's Remarks
Xingxing Zang, PhD, Professor and Louis Goldstein Swan Endowed Chair, Microbiology and Immunology & Medicine, Albert Einstein College of Medicine

1:30 FEATURED PRESENTATION: New Immune Checkpoints for Human Cancer Immunotherapy
Xingxing Zang, PhD, Professor and Louis Goldstein Swan Endowed Chair, Microbiology and Immunology & Medicine, Albert Einstein College of Medicine

Dr. Zang will discuss expression, function, structure, and immunotherapy of immune checkpoints HHLA2, TMIGD2, B7x, B7-H3, ICOS, and Tim-3.

2:00 Understanding Immune Checkpoint TIM-3 Biology and Implications for Targeting TIM-3 for Cancer Immunotherapy
Xiaomo Jiang, PhD, Investigator, Immuno-Oncology, Novartis Institutes for BioMedical Research

TIM-3 has critical roles in tumor-induced immune suppression on a multitude of cell types. TIM-3 blockade to activate immune response and control

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Immunomodulatory Therapeutic Antibodies for Cancer, *continued*

tumor growth could reflect the combined effects on modulating not only the functional phenotype of dysfunctional effector T cells, but also inhibiting the suppressive activity of various suppressor cells.

2:30 Targeting the CD200 Checkpoint Blockade: A New Avenue for Immunotherapy
Michael Olin, PhD, Assistant Professor, Pediatrics, University of Minnesota; CSO, OX2 Therapeutics
The CD200 immune checkpoint interferes with tumor-immune interactions through multiple mechanisms: i) CD200 is secreted from tumors to the graining lymph nodes where it induces an immunosuppressive environment, ii) CD200 is upregulated in tumor-associated vascular endothelial cells, creating an immunological barrier around the tumor microenvironment, and iii) CD200 within tumor-derived vaccines suppresses an antitumor response. To combat the suppressive mechanisms of CD200, we synthesized inhibitors of the CD200 checkpoint.

3:00 Breakout Discussion Groups and Refreshment Break
This session features discussion groups that are led by a moderator who ensures focused conversations around the key issues listed. Attendees choose to join a specific group, and the small, informal setting facilitates sharing of ideas and active networking. Details on the topics and moderators are available on the conference website.

4:15 FEATURED PRESENTATION: The Development of Agonist OX40 Monoclonal Antibody for Cancer Immunotherapy – Navigating the Bench to Bedside Journey
Niranjan Yanamandra, PhD, Scientific Director, Translational Research, Immuno-Oncology & Combinations DPU, Oncology R&D, GlaxoSmithKline
OX40 is a member of the tumor necrosis factor receptor (TNFR) superfamily and a co-stimulatory molecule expressed on the surface of activated CD4+ and CD8+ T cells. OX40 agonism stimulates both immune effector and memory functions while attenuating the function of immunosupressive regulatory T cells (Tregs). GSK317998, a humanized IgG1 agonistic anti-OX40 monoclonal antibody (mAb) is currently in Phase I clinical development. This presentation will review preclinical and translational research data to support OX40 clinical development.

4:45 Anti-OX40 Treatment in Humans Increases the Frequency of Tumor Ag-Specific T Cells
Andrew Weinberg, PhD, Chief, Laboratory of Basic Immunology, Providence Health & Services
Our group has been able to easily identify/enrich for tumor Ag-specific CD8 T cells from several different tumor types. In a recent neoadjuvant anti-OX40 clinical trial, we were able to obtain pre- and post-treatment biopsies and assess these samples by flow cytometry. We found that some patients showed a dramatic increase in the tumor Ag-specific CD8 T cells, and this correlated with tumor destruction. This work has implications not only for systemic Ab immunotherapy but also personalized adoptive T cell therapy.

5:15 ATOR-1017 – A Tumor-Directed Fcγ-Receptor Cross-Linking Dependent 4-1BB Agonistic Antibody
Christina Furebring, PhD, Senior Vice President, Research, Alligator Bioscience
ATOR-1017 is an agonistic CD137 IgG4 antibody with a unique functional profile compared to the 4-1BB antibodies currently in clinical development. The functional activity depends on cross-linking mediated by Fcγ receptors, which directs the immune activation to the tumor area and reduces the risk of inducing systemic immune activation and liver toxicity. ATOR-1017 is currently in preclinical development, and clinical trials will start in 2019.

5:45 End of Day

TUESDAY, AUGUST 28

7:30 Morning Coffee

EMERGING TARGETS AND STRATEGIES FOR COMBINATION IMMUNOTHERAPY

8:25 Chairperson's Remarks
Jun Tang, PhD, Senior Research Analyst, Venture Philanthropic Fund and Clinical Accelerator, Cancer Research Institute

8:30 Rational Combinations in an irRational World
Jun Tang, PhD, Senior Research Analyst, Venture Philanthropic Fund and Clinical Accelerator, Cancer Research Institute
We will discuss a number of important and actionable trends in the current IO landscape: a large number of companies developing agents against the same IO targets; a rapid increase in the number of anti-PD-1/L1 combination studies, many of which are testing the same combinations and following inefficient patterns; and a significant increase in the number of small, investigator-initiated studies. For each of the findings, we speculate the causes and discuss a few initiatives that aim to address some of these challenges.

9:00 Novel Clinical Trial Designs to Explore Immunotherapy Combinations
Hila Barak, PhD, Senior Clinical Scientist, Cancer Immunotherapy, Genentech

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

10:55 Chairperson's Remarks
Jun Tang, PhD, Senior Research Analyst, Venture Philanthropic Fund and Clinical Accelerator, Cancer Research Institute

11:00 EOS884448, a higG1 mAb Anti-TIGIT, Induces T Cell Mediated Anti-Tumor Immune Response and Demonstrates Strong Anti-Tumor Immunity in Monotherapy
Xavier Leroy, PhD, Director, Drug Discovery, iTeos Therapeutics
EOS884448 anti-TIGIT mAb displays a strong affinity to recombinant human TIGIT and to native TIGIT expressed on human primary T cells. It competes with CD155 for binding to human TIGIT and shows potency to restore cytokine production when human primary T cells are suppressed in presence of CD155. In addition, when produced in mammalian system on human IgG1 isotype, it shows preferential Treg depletion over conventional CD4+ and CD8+ T cells.

11:30 Smac Mimetics Can Trigger Immunogenic Cell Death in Cancer Cells
Jürgen Moll, PhD, Director, Pharmacology and Translational Research, Boehringer Ingelheim

12:00 pm Close of Immunodulatory Therapeutic Antibodies for Cancer

Conference Programs

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MONDAY-TUESDAY | AUGUST 27-28

Rational Combination Cancer Immunotherapy

Data Drives Combinatorial Strategies and Successes

MONDAY, AUGUST 27

7:30 am Registration & Morning Coffee

DATA INFORMS IMMUNOTHERAPY COMBINATIONS

8:25 Chairperson's Opening Remarks
Lei Zheng, MD, PhD, Associate Professor, Oncology and Surgery, Johns Hopkins University School of Medicine

8:30 FEATURED PRESENTATION: Rational Combination of Immunotherapy, It Is Science, Not Logic
Samir N. Khleif, MD, Director, The Loop Immuno-Oncology Lab, Lombardi Comprehensive Cancer Center, Georgetown University Medical Center
Combination immunotherapy is becoming the cornerstone of therapeutic approaches in cancer patients. The tumor microenvironment is a complex biologic system and designing clinical combinations has to take into account the complexity of its biology and the responsiveness of each of its components to the parts of the combination. Proper design is crucial for the success of the therapy. We have identified certain biologic trends in rational combination and in what can work and why certain combinations.

9:00 Hypomethylating Agents in Combination with Immune Checkpoint Inhibitors in Acute Myeloid Leukemia and Myelodysplastic Syndromes
Naval Daver, MD, Associate Professor, Leukemia Department, MD Anderson Cancer Center
Immune checkpoint inhibitors have shown modest clinical efficacy in treating acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS). Hypomethylating agents (HMAs) such as azacitidine dampen immune response. Immune checkpoint molecule upregulation may be an important mechanism of azacitidine resistance. These findings have resulted in clinical trials combining HMAs with immune checkpoint blockade. Clinical trial data have shown encouraging response rates. We discuss preclinical and clinical trials investigating HMA-immune checkpoint inhibitor combinations in AML/MDS.

9:30 Rational Combination of PD-L1/PD1 Targeting and Natural Killer Cells: Hepatocellular Carcinoma Preclinical Study
Siu Tim Cheung, PhD, Associate Professor, Department of Surgery, The Chinese University of Hong Kong
Natural killer cells are increasingly used in the treatment of hematologic malignancy but vague efficacy in solid tumors. The present study provides data to improve the treatment response of PD-L1/PD1 targeting, and furthermore, to exploit the potential use of adoptive NK cells in immunotherapy. The data from the present study will facilitate rational design on combination therapy to improve survival outcomes of the aggressive tumors.

10:00 Coffee Break

10:30 Multiple "Immune Defects" in Pancreatic Cancer: How Do We Find the Right Combination of Immunotherapy?
Lei Zheng, MD, PhD, Associate Professor, Oncology and Surgery, Johns Hopkins University School of Medicine
The resistance of pancreatic cancer to immunotherapy could be caused by one or more of the four immune "defects" including lack of "high quality" T cells, stromal barriers to T cells getting access to tumor cells, immunosuppressive cells, and immune checkpoints in the tumor microenvironment of pancreatic cancer. To overcome such a resistance, a rational combination of agents that target multiple immune defects is highly demanded.

11:00 A Novel 3D *ex vivo* Platform of Fresh Patient Tumor Tissue for Immuno-Oncology Drug Development
Sponsored by NILOGEN ONCOSYSTEMS
Soner Altiok, CSO, Nilogen Oncosystems
Nilogen's novel 3D-EXSM drug assay utilizing fresh patient tumor samples with intact immune microenvironment can help facilitate oncology drug development and biomarker discovery. Our preclinical model recapitulates the complexity of tumor immune microenvironment to test the therapeutic potential of immuno-oncology drugs, identify rational combination therapies and develop novel predictive biomarkers.

11:15 Sponsored Presentation *(Opportunity Available)*

11:30 PANEL DISCUSSION: How Do We Find the Right Combination of Immunotherapy?
Moderator: Lei Zheng, MD, PhD, Associate Professor, Oncology and Surgery, Johns Hopkins University School of Medicine
As the discovery of new cancer immunotherapies continues to grow, developers are identifying promising patient-specific neoantigens and finding new ways to modulate the immune response beyond or in combination with checkpoint inhibitors. Panelists discuss what we know and where to go next.

12:00 pm Luncheon Presentation: Insights from Profiling the Tumor Microenvironment of Over 200+ Single Cell Tumor Suspensions
Sponsored by FOLIO CONVERSANT
Shawn Fahl, PhD, Senior Research Associate, Research & Development, Folio Conversant
The cellular composition of the tumor microenvironment differs across indications and patients. The variability observed in immune cell infiltrates can be an important consideration when developing the next-generation of immunotherapies. As a high volume supplier of dissociated tumor cells, we have performed flow cytometric profiling on over 200 unique patient samples across multiple indications. This presentation will cover the insights and trends observed.

12:30 Session Break

LEVERAGING TRANSLATIONAL DATA FROM THERAPY RESPONSE

1:25 Chairperson's Remarks
Sarah Javaid, PhD, Associate Principal Scientist, Genetics and Pharmacogenomics, Merck

1:30 Forward and Reverse Translational Approaches to Augment Response to Anti-PD1 Therapy
Sarah Javaid, PhD, Associate Principal Scientist, Genetics and Pharmacogenomics, Merck
Immune checkpoint blockade therapies are revolutionizing standard cancer treatment. But not all patients respond to immunotherapy, or they often

Conference Programs

- Immunomodulatory Therapeutic Antibodies for Cancer
- Rational Combination Cancer Immunotherapy
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Rational Combination Cancer Immunotherapy, *continued*

experience toxicities. Combination approaches are key to improving clinical response. Novel high-throughput technologies enable us to understand the mechanisms underlying the complex interactions between the immune system and cancer, identify predictive biomarkers for the patients most likely to benefit from current immunotherapies, avoid immune-related adverse events and reduce treatment costs for those unlikely to respond.

2:00 Leveraging Clinical and Preclinical Targeted Therapy Biomarker Data to Inform Combinations with Immunotherapy
Matthew Meyer, PhD, Senior Investigator II, Oncology Pharmacology, Novartis Institutes for BioMedical Research, Inc.

2:30 Sponsored Presentation *(Opportunity Available)*

3:00 Breakout Discussion Groups and Refreshment Break
This session features discussion groups that are led by a moderator who ensures focused conversations around the key issues listed. Attendees choose to join a specific group, and the small, informal setting facilitates sharing of ideas and active networking. Details on the topics and moderators are available on the conference website.

4:15 Precision Cancer Medicine in the Era of Genomics and Immunotherapy
Shumei Kato, MD, Assistant Clinical Professor, Experimental Therapeutics, GI Medical Oncology & Rare Tumor Clinic, Division of Hematology & Oncology and Center for Personalized Cancer Therapy, UC San Diego Moores Cancer Center
Although immunotherapies can demonstrate salutary anti-cancer effect in a portion of patients, unfortunately not all patients benefit. Even in the presence of favorable response markers (e.g., positive PD-L1, MSI-high, high tumor mutation burden), the response rate is about 50-60%. Further, some patients, e.g., some of those with MDM2 or EGFR alterations, may experience hyperprogression. We present our preliminary experience using a customized targeted and immunotherapy approach in cancer patients. Thus, further evaluation of immune biomarkers as well as novel combination strategy are required.

4:45 The Combination of a Non-Toxic Small Molecule IO Drug with Anti-PD1
Floyd Taub, MD, CEO & CMO, AxImmune
AxI 101 dramatically enhances the response of a variety of mouse models to anti-PD1. It modulates a variety of markers in animals, human PBMCs *ex vivo* and people in Phase I/II trials. All non-anergic lymphoma patients met irRECIST criteria for benefit. Markers determining success will be discussed.

5:15 Single Cell Immunoproteomes and AI-Supported Analysis to Predict Response to Immunotherapy
Carsten Krieg, PhD, Assistant Professor of Immunology, Microbiology & Immunology and Dermatology, Medical University of South Carolina
Immunotherapy has revolutionized oncology but not everyone responds to or relapses under therapy. Most likely, a combination of several therapeutics is needed to achieve tumor control. We developed a workflow based on high-dimensional single cell mass cytometry combined with artificial intelligence supported bioinformatics to analyze liquid blood biopsies to predict immune cell biomarkers. The generated "immune instagrams" might help in stratifying patients prior to immunotherapy, choose the right therapeutic combination, and help support clinical trial decisions.

5:45 End of Day

TUESDAY, AUGUST 28

7:30 am Morning Coffee

DECIPHERING CANCER'S DYNAMICS AND IMMUNE RESPONSE

8:25 Chairperson's Remarks
Doron Levy, PhD, Professor, Department of Mathematics, University of Maryland

8:30 Leveraging Systems Biology and Machine Learning to Improve IO Biomarkers and Inform Combination Therapies
Janusz Dutkowski, PhD, CEO, Data4Cure, Inc.
A key challenge in the field of immunotherapy is predicting which patients will respond to IO therapy either as a single agent or in combination with other treatments. Existing clinical and research strategies, while informative, do not fully explain patient responses. Can a systems approach be more effective? How can we start to build a more comprehensive data-driven picture of the tumor-immune interaction system? The talk focuses on new methods, strategies, and platforms that may help in addressing these challenges.

9:00 Translational Immuno-Oncology in the Age of Big Data – A Bioinformatics Perspective
Yuriy Gusev, PhD, Associate Professor, Innovation Center for Biomedical Informatics (ICBI), Georgetown University
A field of Immuno-Oncology is evolving toward utilization of big data generated by genomic technologies. Many companies and academic research centers have started to adapt bioinformatics methods and tools to deal with the sudden influx of large volumes of molecular profiling data such as genomic sequencing and other omics technologies. A broad overview will be presented of bioinformatics resources and trends for Immuno-Oncology applications, with examples of bioinformatics solutions for translational immune-oncology based on recent collaborations at Georgetown Medical Center.

9:30 Clinical Intelligence-Driven Combination Prediction: A Machine Learning Approach
Sponsored by excelra
Nandu Gattu, PhD, Senior Vice President, Pharma Analytics, Excelra Knowledge Solutions
The expansive landscape of cancer immunotherapies presents vast clinical data, however, the challenge is to find comprehensive clinical trial intelligence with granular information to predict clinical outcomes and design studies. In this talk, we will present a case study on identification of potentially successful drug combinations using our proprietary clinical trials platform. The machine learning-based pathway synergy analysis is combined with systems-level biological interpretation to establish the mechanistic role of the combination in cancer immunotherapy.

10:00 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

10:55 Chairperson's Remarks
Doron Levy, PhD, Professor, Department of Mathematics, University of Maryland

Conference Programs

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Rational Combination Cancer Immunotherapy, *continued*

11:00 A Dynamic View of Cancer Dynamics and Drug Resistance

Doron Levy, PhD, Professor, Department of Mathematics, University of Maryland

Cancer can (and should) be viewed as a very complex and heterogeneous dynamical process. A quantitative realization of the dynamics of the disease may assist in effectively combating it. In this talk we describe how mathematical tools can be used to study cancer dynamics and how this knowledge can be quantitatively utilized to design therapies.

11:30 Tumor Analytical Methods: Profiling by Gene Cluster Summary Scores (GCESS)

Jaime F. Modiano, VMD, PhD, Perlman Professor of Oncology and Comparative Medicine, Veterinary Clinical Sciences, College of Veterinary Medicine and Masonic Cancer Center, University of Minnesota

The GCESS method can differentiate tumors of different histologic origins into prognostically significant subtypes. Gene clusters are defined based on statistical correlations, including parameters that define intrinsic tumor behaviors as well as the composition of the microenvironment and the immunological landscape. The pattern of expression for these clusters is highly conserved across species, reflecting the biology of the disease and underscoring its utility for predicting tumor behavior and metastatic propensity.

12:00 pm Close of Rational Combination Cancer Immunotherapy

Conference Programs

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MONDAY-TUESDAY | AUGUST 27-28

Immuno-Oncology Biomarkers 1:

Quantitative Immune Profiling and Immune Monitoring

MONDAY, AUGUST 27

7:30 am Registration & Morning Coffee

TUMOR MICROENVIRONMENT PROFILING FOR PRECISION IMMUNO-ONCOLOGY

8:25 Chairperson's Opening Remarks
Adil Daud, MD, Professor, Hematology/Oncology, University of California, San Francisco; Director, Melanoma Clinical Research, UCSF Helen Diller Family Comprehensive Cancer Center

8:30 Insights from T Cell Profiling in the Tumor Microenvironment
Adil Daud, MD, Professor, Hematology/Oncology, University of California, San Francisco; Director, Melanoma Clinical Research, UCSF Helen Diller Family Comprehensive Cancer Center

We will describe what we know about T cells in the tumor microenvironment and describe our research with flow cytometry of T cells in patients with melanoma and other cancers and the relationship of activated T cells and response to immune checkpoint inhibitors.

9:00 Precision Immunology through Deeper Single-Cell Profiling
Pratip Chattopadhyay, PhD, Associate Professor, Pathology; Director, Precision Immunology Incubator, Isaac and Laura Perlmutter Cancer Center, New York University Langone Medical Center

In recent years, there has been a revolution in medicine's ability to "wake up" the immune system to fight cancer. In parallel, an incredible array of new single cell technologies have been introduced to characterize immune responses. In this talk, I will introduce two relatively new technologies - 30-parameter fluorescence flow cytometry and Integrated Molecular Cytometry Platforms (like CITE-seq) - that allow complete and comprehensive characterization of immune cells in immunotherapy patients. I will demonstrate how we are making these technologies easier, more robust, and valuable. Finally, I will discuss some insights into the tumor-immune microenvironment.

9:30 Immune Infiltrate as a Prognostic Biomarker in Merkel Cell Carcinoma
Michael T. Tetzlaff, MD, PhD, Associate Professor, Pathology, The University of Texas MD Anderson Cancer Center

Merkel cell carcinoma (MCC) is an aggressive cutaneous malignancy with unpredictable response to immune checkpoint blockade. To identify prognostic/predictive immune-related biomarkers for MCC, we quantified the density and composition of the tumor associated lymphoid infiltrate and confirmed associations with survival. Next, we performed T-cell receptor sequencing to determine associations between the T-cell repertoire and survival. Finally, we determined expression of immune checkpoint markers (beyond PD-L1) in MCC. Our findings identify novel immune-related biomarkers in MCC.

10:00 Coffee Break

10:30 The Immune Microenvironment in Special Types of Pancreatic Malignancy
Elizabeth Thompson, MD, PhD, Assistant Professor, Pathology, Johns Hopkins University

The most common pancreatic malignancy, ductal adenocarcinoma, is not thought to be inherently immunogenic. However, the status of the immune response to other types of pancreatic cancer has not been explored. These tumors are difficult to treat and would benefit from the ability to utilize treatment options like immunotherapy. This talk will explore the immune microenvironment of special subtypes of pancreatic carcinoma and evaluate their potential benefit from immunotherapy.

11:00 T Cell Repertoire Heterogeneity in Non-Small Cell Lung Cancer: Implications for Cancer Immunotherapy
Alexandre Reuben, PhD, Assistant Professor, MD Anderson Cancer Center

Responses to immunotherapy are heavily reliant on the T cell response. Here, we studied the T cell repertoire in patients with early stage non-small cell lung cancer (NSCLC). Increased intratumor T cell repertoire heterogeneity was associated with shortened survival. Furthermore, a large proportion of T cells in NSCLC tumors were associated with factors unrelated to the tumor, such as pathogens. A greater proportion and reactivity of these T cells was also associated with shortened overall survival. Our work sheds light on some of the challenges facing the immunotherapeutic targeting of NSCLC.

11:30 Presentation to be Announced

Sponsored by Acro Biosystems

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Session Break

IMPACT OF MICROBIOME ON RESPONSE TO IMMUNOTHERAPY

1:25 Chairperson's Remarks
Theresa Whiteside, PhD, Professor, Pathology, Immunology & Otolaryngology, Hillman Cancer Center, University of Pittsburgh School of Medicine

1:30 The Breast Tissue Microbiome: Associations with Cancer and Cancer Risk
Tina Hieken, MD, Associate Professor, Surgery, Mayo Clinic

Breast tissue contains a complex microenvironment including a mucosal immune system, providing evidence for an intrinsic breast tissue microbiome. Our pilot data from genomic analysis has confirmed the existence of a human breast tissue microbiome, distinct from that of breast skin and other microbial niches, with demonstrable differences in benign and malignant disease states. Further investigation of the microbiome of breast tissue, other body niches and the immune microenvironment may lead to a biome-based approach to individualized breast cancer risk prediction and identify a platform for novel breast cancer prevention strategies.

2:00 Decoding Human Microbiota Metabolism and Its Role in Cancer Initiation and Treatment
Jason Crawford, PhD, Associate Professor, Chemistry and Microbial Pathogenesis, Yale University

The composition of the gut microbiota can dramatically affect cancer formation and treatment outcomes. Indeed, select members of the gut microbiota are known to promote colorectal cancer

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Immuno-Oncology Biomarkers 1, *continued*

formation, whereas others are known to promote favorable environments for cancer immunotherapies. We describe our efforts to characterize the molecular contributions of genotoxic bacteria in the gut and establish strategies to neutralize their pathways for cancer prevention. We also discuss bacterial metabolites that stimulate the innate immune system, which could contribute to therapeutic responses.

2:30 The Gut Microbiome Influences Differential Responses to Anti-Cancer Immunotherapy

Vancheswaran Gopalakrishnan (Deepak), Post-doctoral Fellow, Laboratory of Dr. Jennifer Wargo, Surgical Oncology – Research, UT MD Anderson Cancer Center

3:00 Breakout Discussion Groups and Refreshment Break

This session features discussion groups that are led by a moderator who ensures focused conversations around the key issues listed. Attendees choose to join a specific group, and the small, informal setting facilitates sharing of ideas and active networking. Details on the topics and moderators are available on the conference website.

LIQUID BIOPSY FOR IMMUNO-ONCOLOGY

4:15 Tumor-Derived Exosomes as Potential Biomarkers of Cancer Progression and Immunological Dysfunction in Cancer

Theresa Whiteside, PhD, Professor, Pathology, Immunology & Otolaryngology, Hillman Cancer Center, University of Pittsburgh School of Medicine

Plasma-derived exosomes are emerging as promising non-invasive correlates of cancer progression. In patients with solid tumors or hematological malignancies, plasma exosomes carry a cargo enriched in immunosuppressive proteins. As immune suppression is one of the hallmarks of cancer progression, circulating exosomes rich in inhibitory molecules are implicated in mediating systemic immune suppression. The molecular cargo of plasma-derived exosomes and their effects on immune cell subsets correlate with the disease activity and tumor stage in patients with head neck cancer (HNC) and melanoma.

4:45 FEATURED PRESENTATION: Exosomes and Their Cargo as Tumor Biomarkers

Samir Hanash MD, PhD, Director, McCombs Institute for Cancer Early Detection and Treatment, MD Anderson Cancer Center

Circulating exosomes have the potential to inform about tumor status. Deep profiling of tumor derived exosomes has identified a rich cargo of antigens that induce an immune response in cancer. The contributions of exosomes in immuno-oncology will be presented.

5:15 Macrophage-Like Circulating Tumor Cells for Prognosis of Metastasis

Shulin Li, PhD, Professor, Director, Pediatric Laboratory Research Programs, W.T. and Louise Jarrett Moran Distinguished Chair, Pediatric Oncology, Pediatric Research, MD Anderson Cancer Center

CTC has been heavily investigated but metastasis associated CTCs are not clearly defined. In our recent years reports, our group has discovered cell surface vimentin (CSV) on CTC is closely associated with tumor metastasis. In this presentation, the presenter will reveal a new subclass of CSV positive CTCs with immune cell markers—CSV-positive macrophage-like CTCs (ML-CTCs) and its correlation with metastasis in GIST.

5:45 Assessment of Immunotherapy Response via Circulating Tumor DNA

Abhijit A. Patel, MD, PhD, Associate Professor, Therapeutic Radiology, Yale University School of Medicine

Immunotherapies are known to produce slow changes in radiographic tumor size. We hypothesized that real-time measurement of tumor cell death via ctDNA could enable earlier assessment of immunotherapy response than serial CT scans in patients with lung cancer. This presentation will summarize our findings, showing that down-trending ctDNA levels correlate strongly with radiographic response and predict a longer duration of treatment benefit, as well as superior progression-free survival and overall survival.

6:15 End of Day

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Immuno-Oncology Biomarkers 1, *continued*

TUESDAY, AUGUST 28

7:30 am Morning Coffee

INTEGRATED BIOMARKER ANALYSIS

8:25 Chairperson's Remarks
Lance D. Miller, PhD, Mary Kirkpatrick Associate Professor of Breast Cancer Research, Wake Forest Baptist Comprehensive Cancer Center

8:30 Integrative Analyses of Microbiota, Environment, and Tumor Immunity for Precision Immuno-Oncology
Shuji Ogino, MD, PhD, Chief of Program in MPE Molecular Pathological Epidemiology, Brigham and Women's Hospital (BWH); Professor (Pathology & Epidemiology), BWH, Dana-Farber Cancer Institute, Harvard Medical School, Harvard T.H. Chan School of Public Health; Associate Member, Broad Institute of MIT and Harvard

The integrative field of immunology-MPE (molecular pathological epidemiology) is an emerging paradigm, and can investigate influences of the exposome (dietary, lifestyle, environmental, microbial, pharmacological, and other exposures) on tumor-immune interactions, thereby informing immunotherapy research. Using over 1000 colorectal cancer cases with rich data on immune response, whole exome sequencing (tumor and normal DNA), tumor neoantigens, and clinical outcomes, proof-of-principle immuno-MPE studies have shown great promise for precision prevention and immuno-oncology.

9:00 Strategies for Dissecting Immunological Signatures that Can Inform Precision Therapy
Darrell R. Borger, PhD, Scientific Director, Immuno-Profiling Laboratory; Director, Translational Research/ Biomarker Laboratory, Massachusetts General Hospital Cancer Center

The targeting of immune checkpoints has been a primary focus in the treatment of cancer and has shown great efficacy. However, not all patients will similarly respond. This talk will highlight translational research efforts that combine expression profiling with spacial analysis in patient tissue to inform combination strategies and the development of a new generation of clinical tests that have the potential to deliver precision immunotherapy.

9:30 NGS Solutions across the Oncology Drug Development Continuum: From Biomarker Discovery to IVD
Sponsored by PGDx
John Simmons, PhD, Director, Translational Science and Diagnostics, Personal Genome Diagnostics

10:00 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

10:55 Chairperson's Remarks
Lance D. Miller, PhD, Mary Kirkpatrick Associate Professor of Breast Cancer Research, Wake Forest Baptist Comprehensive Cancer Center

11:00 Immune Gene Signature Dynamics in Breast Cancer Prognosis and Therapy Prediction
Lance D. Miller, PhD, Mary Kirkpatrick Associate Professor of Breast Cancer Research, Wake Forest Baptist Comprehensive Cancer Center

Gene expression signatures, common to many solid tumor types, reflect the relative abundance of tumor-infiltrating leukocyte populations. These immune gene signatures can be leveraged in large-scale tumor expression profiling studies to assess the clinical relevance of tumor-immune interactions. In this talk, I will present evidence that breast cancer survival and treatment responses depend on the quantifiable, intratumoral interplay between cytotoxic lymphocytes, immunosuppressive myeloid cells and tumor mutational burden.

11:30 Presentation to be Announced

12:00 pm Close of Immuno-Oncology Biomarkers 1: Quantitative Immune Profiling and Immune Monitoring

Conference Programs

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MONDAY-TUESDAY | AUGUST 27-28

Oncolytic Virus Immunotherapy

Commercializing the Exciting Potential of Oncolytic Virotherapy

MONDAY, AUGUST 27

7:30 am Registration & Morning Coffee

FUTURE OF ONCOLYTIC VIROTHERAPY

8:25 Chairperson's Opening Remarks
Samuel D. Rabkin, PhD, Professor, Neurosurgery, Massachusetts General Hospital and Harvard Medical School

8:30 FEATURED PRESENTATION: Unlocking the Full Potential of Cancer Immunotherapy
David Kirn, MD, Co-Founder & Executive Chairman, IGNITE Immunotherapy
IGNITE Immunotherapy is working to unlock the full potential of cancer immunotherapy. Our optimized intravenous oncolytic cancer vaccines are designed to complement approved immune checkpoint inhibitors by igniting an immune response to patients' cancers. This presentation will examine the current opportunities and future challenges.

9:00 Multiply Armed HSV-Based Immulytics for the Treatment of Cancer, Both Alone and in Combination with Immune Checkpoint Blockade
Robert Coffin, PhD, Co-Founder and CEO, Replimune
A number of oncolytic viruses have shown single agent clinical activity and evidence of clinical synergy with immune checkpoint blockade. However, not all patients respond, and as yet most of the promising clinical data has been in melanoma. With the objective of maximally vaccinating patients against their own cancer which will then provide maximal synergy with anti-PD1/L1 blockade, Replimune has developed a new oncolytic immunotherapy platform based on HSV. To augment the natural ability of HSV to kill tumors and activate the immune system, all of Replimune's viruses are armed with two to four therapeutic genes.

9:30 Engineering Vaccinia Virus for Intratumoral Delivery to Generate "*in situ* Vaccination" against Cancer
Liang Deng, MD PhD, Associate Member, Associate Attending Physician, Memorial Sloan Kettering Cancer Center
Vaccinia virus is a large cytoplasmic DNA virus. Modified vaccinia virus Ankara (MVA) is a highly attenuated vaccinia virus, an important vaccine vector. I will discuss our published study on the intratumoral delivery of inactivated MVA to induces systemic antitumor immunity and to overcome resistance to immune checkpoint blockade. I

10:00 Coffee Break

10:30 Novel Micro-RNA Attenuated Oncolytic HSV Virus with Combinatorial Immune Payloads for the Treatment of Metastatic Cancer
Christophe Queva, PhD, CSO, Oncorus
Oncorus is developing the next generation HSV-based oncolytic virus with enhanced potency for tumor cell killing and recruitment of the immune system. Our innovative miR-attenuation strategy enables robust viral replication in tumor cells, while preventing replication in healthy tissue. Oncorus' oHSV are armed with multiple immunomodulatory payloads to synergistically increase recruitment and effector function of immune cells, thus harnessing the full potential of OVs to evoke an abscopal immune response.

11:00 Targeted Oncolytic Viruses - Improving OV Potency, Targeting and Efficacy
Gabriella Campadelli-Fiume, Dr, Professor, Microbiology and Molecular Virology, University of Bologna (UNIBO)
Proprietary viruses developed by NousCom are de-targeted from their natural receptors and re-targeted to surface tumor antigens to selectively infect and kill cancer cells, causing immunogenic cell death, recruitment of T cells at the tumor site and reactivation of T cells in the tumor micro-environment. This next generation of oncolytic viruses can be delivered systemically, and as such can be appropriate for multiple solid tumor indications. Additionally, they can be "armed" by encoding immunomodulatory molecules to potentiate the anti-tumor effect.

11:30 Downstream Processing of Shear-Sensitive Oncolytic Viruses
Sponsored by BIA separations
Ales Strancar, Managing Director, BIA Separations
Filtration and chromatography are powerful tools for virus purification but they can impose shear forces that potentially damage the product. Lipid enveloped viruses frequently experience inactivation, sometimes accompanied by removal of the outer envelope. Outer envelope removal is not a concern for non-lipid-enveloped species but some are brittle and also suffer serious loss of function. This presentation will re-cap sources of shear in filtration and chromatography devices and discuss the effects of common process variables.

12:00 pm Luncheon Presentation to be Announced
Sponsored by Oncolys BioPharma
Toshiyoshi Fujiwara, MD, PhD, Professor & Chairman, Gastroenterological Surgery, Okayama University Graduate School of Medicine, Dentistry, and Pharmaceutical Sciences

12:30 Session Break

IMPROVING OV POTENCY, TARGETING AND EFFICACY

1:25 Chairperson's Remarks
Fares Nigim, MD, Massachusetts General Hospital and Harvard Medical School

1:30 A Novel Oncolytic Vaccinia Virus
John Bell, PhD, Senior Scientist, Center for Innovative Cancer Research, Ottawa Hospital Research Institute
Vaccinia virus has a still incompletely understood genome although several strains of this virus are already in clinical development as oncolytics. We designed studies to obtain a more in depth understanding of the genetic elements of vaccinia which could be modulated to improve the oncolytic/therapeutic characteristics of the virus. A novel oncolytic candidate has been bioselected and engineered and the key enhanced therapeutic properties of this virus will be presented.

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Oncolytic Virus Immunotherapy, *continued*

2:00 The T-Stealth Oncolytic Immunotherapy Platform

Matthew Mulvey, PhD, CEO, BeneVir Biopharm, Inc.

BeneVir's oncolytic immunotherapy platform is based on T-Stealth technology, which overcomes a major barrier to clinical success of oncolytic viruses. This barrier is the body's immune system, which is very effective at killing both harmful viruses (like flu) and beneficial viruses (like oncolytic viruses). BeneVir's T-Stealth oncolytic viruses hide from the immune system in order to continue to destroy cancer cells, both directly and through activation of the immune system.

2:30 VSV-GP Oncolytic Virus Therapy Works through Direct Tumor Lysis And Stimulation of an Anti-Tumor Immune Response

Patrik Erlmann, PhD, Head, R&D, ViraTherapeutics

VSV-GP combines the tumour cell killing efficacy of Vesicular Stomatitis Virus (VSV) with an enhanced safety profile and remarkable immune stimulatory properties, making it an excellent candidate for clinical development as treatment option for advanced cancers. We have demonstrated that VSV-GP infects and cures a range of xenograft and syngeneic mouse tumor models. In addition to direct tumor cell killing VSV-GP treatment leads to a strong as well as durable anti-tumor immune response and immunological memory formation.

3:00 Breakout Discussion Groups and Refreshment Break

This session features discussion groups that are led by a moderator who ensures focused conversations around the key issues listed. Attendees choose to join a specific group, and the small, informal setting facilitates sharing of ideas and active networking. Details on the topics and moderators are available on the conference website.

4:15 Profiling Anti-Tumor Activities of Seprehvir and Seprehvec

Robert Allen, Senior Director, Oncolytic Virotherapy, Sorrento Therapeutics

Seprehvir and Seprehvec, as monotherapies or in combination with Sorrento antibodies and cell-based therapeutics, provide a flexible means of directing and enhancing anti-tumor immunity. The Seprehvec platform has been designed to express mediators of anti-tumor immunity following systemic, intratumoral, and local-regional delivery of virus.

4:45 Enadenotucirev: An Adenovirus with Immunotherapeutic Potential in Its Native Form, or as a Vector for Therapeutic Transgenes

Charles Morris, PhD, CDO, Psioxus

Enadenotucirev is a potent, chimeric Ad11p/Ad3 adenovirus with selective oncolytic activity against a range of epithelial cancer cells. An ongoing clinical study is investigating whether this inflammatory infiltrate can lead to clinical efficacy in combination with an immune checkpoint inhibitor in tumors not otherwise likely to respond to such treatment. A number of potential clinical candidate armed viruses have been produced and will be described.

5:15 Progress with Oncolytic Vesicular Stomatitis Viruses

Stephen J. Russell, MD, PhD, CEO, Vyriad, Inc.

Vesicular Stomatitis Virus (VSV) has low seroprevalence, is readily engineered to encode additional transgenes and can easily be manufactured to high titers for systemic administration to human subjects. Vyriad is developing and testing different different VSV designs for the treatment of human cancer. Voyager-V1, a recombinant VSV carrying transgenes coding for interferon-β and the sodium iodide symporter, is currently being evaluated in three Phase 1 clinical trials. Fully retargeted VSVs encoding fusogenic measles virus glycoproteins are also under development. Preclinical and clinical progress with Vyriad's lead clinical and preclinical stage virotherapies will be discussed.

5:45 End of Day

TUESDAY, AUGUST 28

7:30 am Morning Coffee

IMPROVING OV POTENCY, TARGETING AND EFFICACY (CONT.)

8:25 Chairperson's Remarks

Douglas Jolly, PhD, Executive Vice President, R&D, Tocagen, Inc.

8:30 Treatment with Conditionally Lytic Retroviral Replicating Vector Toca 511 Leads to Long Term Survival in Recurrent High Grade Glioma Patients

Douglas Jolly, PhD, Executive Vice President, R&D, Tocagen, Inc.

Toca 511 is a non-lytic retroviral replicating vector encoding an optimized humanized yeast cyosine deaminase, that productively infects tumors with significant specificity. Upon subsequent administration of Toca FC (an extended release formulation of 5---fluorocytosine) about 6 weeks later in recurrent high grade glioma patients undergoing re-resection, tumor regression, durable reponses and extended survival compared to historical controls were observed. These Phase I data provided justification for the ongoing Phase III trial in the same types of patients.

9:00 Gene-Mediated Cytotoxic Immunotherapy and Immune Checkpoint Blockade for Primary Glioblastoma Treatment; A Translational Journey

Sean Lawler, PhD, Assistant Professor, Managing Director, Harvey Cushing Neurooncology Laboratories, Department of Neurosurgery, Brigham and Women's Hospital

Recent clinical trial data showed encouraging results when GMCI was used in primary glioblastoma patients in combination with standard of care (median survival 25 months after total gross resection). We have performed preclinical studies in murine glioblastomas which shows very high cure rates with a combination of GMCI and anti-PD1. This concept has now been moved forward and a multi-institutional clinical trial of the combination of GMCI and anti-PD1 is now underway. The data, challenges and outlook for this approach will be discussed.

9:30 An Integrated Approach to Managing Immunogenicity Risk and Drug Immune Modulation

Sponsored by ProImmune

Emilee Knowlton, Immunology Sales Specialist, Sales, ProImmune, Inc.

ProImmune provides key tools and technologies for studying the mechanisms of cancer immunology at a molecular and cellular level applicable to all areas of cancer immunotherapy. Assays essential in the drug development stage includes Mass Spectrometry

Conference Programs

- Immunomodulatory Therapeutic Antibodies for Cancer
- Rational Combination Cancer Immunotherapy
- Immuno-Oncology Biomarkers 1: Quantitative Immune Profiling and Immune Monitoring
- Oncolytic Virus Immunotherapy
- Bispecific Antibodies for Cancer Immunotherapy
- Preclinical and Translational Immuno-Oncology
- Immuno-Oncology Biomarkers 2: Predictive Biomarkers and Companion Diagnostics
- Adoptive T Cell Therapy 1: Discovery
- Emerging Immuno-Oncology Targets
- Personalized Cancer Vaccines
- Neoantigen Targeted Therapies
- Adoptive T Cell Therapy 2: Development
- Immuno-Oncology Investing and Partnering Forum

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Oncolytic Virus Immunotherapy, *continued*

assay for characterization of antigen presentation, DC-T/T cell proliferation assays for biologic lead selection and an undiluted whole blood cytokine storm assay, while multimers and IFN gamma ELISpots can be used to measure immune responses during clinical trials.

10:00 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

LATE STAGE DEVELOPMENTS AND MANUFACTURING

10:55 Chairperson's Remarks
Douglas Jolly, PhD, Executive Vice President, R&D, Tocagen, Inc.

11:00 Designing Clinical Trials to Elucidate Oncolytic Virus Mechanisms-of-Action
Caroline Breitbach, PhD, Vice President, Translational Development, Turnstone Biologics

Oncolytic viruses have been shown to target tumors by multiple complementary mechanisms-of-action, including direct oncolysis, tumor vascular targeting and induction of anti-tumor immunity. Phase I/II clinical trials can be designed to validate these mechanisms. Development experience of an oncolytic vaccinia virus and a novel rhabdovirus oncolytic vaccine will be summarized.

11:30 Development and Characterization of Novel Micro-RNA Attenuated Oncolytic Herpes Simplex Viruses
Michael Paglia, MSc, Vice President, CMC Operations, Oncorus

Oncorus is developing next generation HSV-based oncolytic virus with enhanced potency for tumor cell killing and recruitment of the immune system. Our innovative miR-attenuation strategy enables robust viral replication in tumor cells, while preventing replication in healthy tissue. The development and characterization of therapeutic oHSV requires thorough product understanding gained through process characterization. Strategies for development and characterization of manufacturing processes centered around a strong organizational infrastructure will be presented.

12:00 pm Close of Oncolytic Virus Immunotherapy

Conference Programs

- Immunomodulatory Therapeutic Antibodies for Cancer
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Training SEMINARS
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Cambridge Healthtech Institute Training Seminars offer real-life case studies, problems encountered and solutions applied, along with extensive coverage of the academic theory and background. Each Training Seminar offers a mix of formal lecture and interactive discussions and activities to maximize the learning experience. These Training Seminars are led by experienced instructors who will focus on content applicable to your current research and provide important guidance those new to their fields.

MONDAY, AUGUST 27 - TUESDAY, AUGUST 28

TRAINING SEMINAR 1: CAR-T Engineering for Protein Scientists

Instructor:
Dina Schneider, PhD, Manager, Cell Biology, Lentigen Technology, Inc.

This course is intended for academic and industry scientists new to the field of CAR T immunotherapy, and it offers an overview of basic concepts, strategies and tools in CAR T development. Topics will include the history of CAR T field, CAR structure and function, approaches to CAR gene delivery, target selection, the impact of CAR linkers and structural domains on function, multi-targeting CAR constructs, and the emerging technologies for temporal and spatial control of CAR T function.

Topics include:

- History of CAR T development
- Principles of CAR T structure and function
- Target identification
- Screening and selection of suitable binding domains
- Role of linkers and structural domains in CAR T function
- Role of tumor antigen expression in regulating CAR T activity
- Molecular boosters of CAR T function
- Approaches for temporal and spatial regulation of CAR T function
- Multi-targeting CAR T strategies to prevent disease escape
- Approaches to gene delivery for CAR T expression
- Future directions

TUESDAY, AUGUST 28 - WEDNESDAY, AUGUST 29

TRAINING SEMINAR 2: Immunology for Drug Discovery Scientists

Instructors:
Masha Fridkis-Hareli, MSc, PhD, Founder and President, ATR, LLC
Tatiana Novobrantseva, PhD, Co-Founder, Head of Research and Development, Verseau Therapeutics

This 1.5-day seminar will cover the fundamentals of human immunology for an audience of scientists across different backgrounds working in pharmaceutical and biotech organizations in programs related to immunotherapy. The course will cover a historical perspective, basic mechanisms, fundamental concepts and practical approaches to developing therapeutics and their combinations to modulate the immune system. Additionally, the class will offer perspectives on how immune responses can be monitored by assessment of biomarkers and modulated through biopharmaceutical intervention. Through group activities, attendees will actively review immunological concepts as well as design functional immunological assays and read-outs.

Topics include:

- Introduction to the immune system
- Innate immunity
- Adaptive immunity
- Infections, inflammation and cancer
- Antigen generation, capture and presentation to lymphocytes
- Effector mechanisms of cellular immunity
- Antibody generation and antibody-mediated cytotoxicity
- History and mechanisms of checkpoint-based therapeutic approaches
- Engineered cellular therapies – CAR-T and dendritic cells
- Cancer vaccines

Each CHI Training Seminar offers 1.5 days of instruction with start and stop times for each day published in the onsite Program & Event Guide. Training Seminars will include morning and afternoon refreshment breaks, as applicable, and lunch will be provided to all registered attendees on the full day of the class.

Each person registered specifically for the Training Seminar will be provided with a hard copy handbook for the seminar in which they are registered. A limited number of additional handbooks will be available for other delegates who wish to attend the seminar, but after these have been distributed no additional books will be available.

Though CHI encourages track hopping between conference programs, we ask that Training Seminars not be disturbed once they have begun. In the interest of maintaining the highest quality learning environment for Training Seminar attendees, and because seminars are conducted differently than conference programming, we ask that attendees commit to attending the entire program, and not engage in track hopping, as to not disturb the hands-on style instruction being offered to the other participants.

Conference Programs

- Immunomodulatory Therapeutic Antibodies for Cancer
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TUESDAY-WEDNESDAY | AUGUST 28-29

Bispecific Antibodies for Cancer Immunotherapy

Engineering Next-Generation Biotherapeutics in Immuno-Oncology

TUESDAY, AUGUST 28

12:00 pm Registration

EMERGING BISPECIFIC BIOTHERAPEUTICS IN IMMUNO-ONCOLOGY

1:25 Chairperson's Opening Remarks
Matthias Klinger, PhD, Principal Scientist, BiTE Immunology, Amgen Research GmbH

1:30 FEATURED PRESENTATION: The Immune Force Awakens with Novel Bispecific Biotherapeutics: Challenges and Opportunities
Rakesh Dixit, PhD, DABT, Vice President, R&D; Global Head, Biologics Safety Assessment, MedImmune
This presentation will cover: 1) MOA-based smart strategies in making decisions about bispecific vs. combination mixtures; 2) novel bispecific strategies in maximizing the potential of combination biologics/targets through a single molecule; 3) smart engineering approaches to optimize valency, potency, avidity and half-life of bispecific IgG like mAbs; 4) minimize toxicity resulting from the simultaneous hit of two targets or redirected effector cells; 5) on and off-target toxicities and PK-PD resulting from the modulation of two targets should be carefully evaluated very early in drug development.

2:00 BiTE® Antibody Constructs beyond Blinatumomab: Overview of Amgen's Early-Stage BiTE® Pipeline
Matthias Klinger, PhD, Principal Scientist, BiTE Immunology, Amgen Research GmbH
In the US, the bispecific T-cell engager (BiTE®) antibody construct blinatumomab has been approved for the treatment of relapsed or refractory B-precursor acute lymphoblastic leukemia and more recently, also in the respective minimal residual disease setting. This talk will focus on Amgen's subsequent BiTE® pipeline in various hematologic malignancies like acute myeloid leukemia and multiple myeloma but also in solid tumor indications.

2:30 Advances with Bispecifics and Multi-Specifics in the Clinic – Lessons Learned
Tariq Ghayur, PhD, Senior Research Fellow, AbbVie
Of the many bi-/multi-specific biologics formats reported to date, some have progressed to clinical and late preclinical stages. Two areas of focus are now: 1) developing approaches to identify/select targets and/or target pairs with "novel" biology that absolutely requires bi-/multi-specific format; i.e., the specific biology cannot be achieved with monoclonal antibody combinations, and 2) to select the right format to achieve desired outcomes.

3:00 Sponsored Presentation *(Opportunity Available)*

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 PLENARY KEYNOTE SESSION
Click here for details

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

5:30 Dinner Short Course Registration*
**Separate registration required, click here for details*

6:30 End of Day

6:30-9:00 pm Dinner Short Course
SC1: Bioinformatics for Immuno-Oncology and Translational Research

6:30-9:00 pm Dinner Short Course
SC2: Next-Generation Immunotherapies: Part 1

WEDNESDAY, AUGUST 29

7:30 am Morning Coffee

T CELL AND TUMOR REDIRECTING BISPECIFIC ANTIBODIES

8:25 Chairperson's Remarks
Bonnie Hammer, PhD, Vice President, Biologics Development, Invenra

8:30 A Novel Multi-Specific Antibody Targeting PD-L1-Overexpressing Cancers That Redirects and Stimulates Antigen-Committed CD8+ T Cells through Concomitant Engagement of a T Cell Costimulatory Receptor
David Urech, PhD, Co-CEO and CSO, R&D, Numab Therapeutics AG

9:00 Selective Blockage of the Innate Immune Checkpoint Receptor CD47 on Mesothelin (MSLN) Positive Solid Tumor Cells via Dual-Targeting Bispecific Antibodies
Stefano Majocchi, PhD, Research Scientist, Research Department, Novimmune SA
Up-regulation of CD47 is an immune evasion mechanism used by different cancers to evade immune surveillance through the delivery of a universal "don't eat me" signal to phagocytes. In order to avoid poor pharmacological properties and potential hematological toxicities linked to the indiscriminate blockage of ubiquitously expressed CD47, we developed a bispecific antibody (NI-1801) capable of selectively inhibiting CD47 on mesothelin-positive tumor cells. Due to the specificity of a targeting approach, NI-1801 retains potent anti-cancer efficacy both *in vitro* and *in vivo* while showing favorable pharmacological and toxicology profiles.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Using B-Body™ Bispecific Antibodies to Modulate Anti-Tumor Immune Responses
Bonnie Hammer, PhD, Vice President, Biologics Development, Invenra
Bispecific antibodies have distinct advantages over monospecific antibodies by enabling more specific targeting and novel mechanisms of action. We have used our B-Body™ bispecific antibody platform to create antibodies allowing for redirected T cell killing, SNIPER™ antibodies that specifically target subsets of cells for elimination, and antibodies with enhanced agonist activity. Using these antibodies, we show the advantages of being able to screen for functional activity in order to select for a desired response.

Conference Programs

- Immunomodulatory Therapeutic Antibodies for Cancer
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Bispecific Antibodies for Cancer Immunotherapy, *continued*

11:15 PM-CD3: A Novel Highly Tumor-Specific T Cell Engaging Bispecific for the Treatment of Solid Tumors
Anika Jäkel, PhD, Director, Preclinical Pharmacology & Cancer Immunology, Glycotope GmbH
Carbohydrates on the surface of cancer cells represent preferable targets for bispecifics due to their unique tumor-specificity with lack or inaccessibility on normal tissues and broad indication coverage. In a platform approach, we designed and screened several T cell engaging bispecific constructs recognizing the highly tumor-specific carbohydrate/protein antigen TA-MUC1 and CD3 that differed in binding valencies and affinities towards both antigens, serum half-life, molecule size, and Fc-functionality and produced them in our human expression platform GlycoExpress®.

11:55 Bispecific Antibodies for Immunotherapy and Radioimmunotherapy
Nai-Kong Cheung, MD, PhD, Enid A. Haupt Endowed Chair in Pediatric Oncology, Memorial Sloan Kettering Cancer Center
Conventional IgG monoclonal antibodies (mAbs) rely on Fc-dependent mechanisms with insufficient potency because of poor therapeutic index and limited effector cell traffic. Bispecific antibodies (BsAb) have the potential to turn circulating polyclonal T cells into tumor-infiltrating cytotoxic T cells without MHC-restriction to overcome the immunosuppressive tumor microenvironment. BsAb can also be exploited to deliver massive doses of beta or alpha radiation in multistep targeting with vastly improved therapeutic indices.

12:15 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:45 Session Break

BISPECIFIC ANTIBODIES FOR COMBINATION THERAPY

1:40 Chairperson's Remarks
John Desjarlais, PhD, Senior Vice President, Research, CSO, Xencor

1:45 FEATURED PRESENTATION: Bispecific Technology for Multiple Avenues of T Cell Activation
John Desjarlais, PhD, Senior Vice President, Research, CSO, Xencor
Xencor has applied its XmAb bispecific technology platform to create multiple novel modalities for T cell derepression and activation. These include dual checkpoint inhibitors such as a PD1 x CTLA4 bispecific antibody, and a CTLA4 x LAG3 bispecific antibody that combines productively with anti-PD1 for triple checkpoint blockade. We have also discovered a highly active PD1 x ICOS bispecific antibody that productively combines checkpoint blockade and costimulation into a single molecule. Finally, we have utilized our heterodimeric Fc domain to create a novel long-acting IL15/IL15Ra-Fc format for immunotherapy.

2:15 FEATURED PRESENTATION: Mechanisms of Action for the Application of BiTE Antibodies in Immunotherapy Combinations
Tara Arvedson, PhD, Director, Oncology Research, Amgen

2:45 Tumor Localized Activation of Costimulatory Pathways
Manuela Duerr, PhD, Project Leader, Immuno-Oncology, Pieris Pharmaceuticals GmbH
This presentation will cover: 1) role of costimulatory pathways in T cell biology; 2) rationale for tumor localized activation of costimulatory receptors; 3) case study: *in vitro* and *in vivo* characterization of the HER2/4-1BB bispecific molecule PRS-343.

3:15 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Combination Strategies to Augment Activity of CD3 Bispecific Antibodies
Teemu Junttila, PhD, Senior Scientist, Genentech
CD3 bispecific antibodies induce rapid activation of T cells leading to degranulation of cytolytic vesicles and apoptosis of target expressing cancer cells. T cell activation results also in feedback inhibition. PD1 up regulation has been described with multiple molecules and shown to inhibit activity of CD3 bispecific antibodies. The role of other co-inhibitory molecules is less clear. Our goal is to systematically characterize induction and functional role of key co-inhibitory and co-stimulatory molecules upon treatment with CD3 bispecific antibodies to identify optimal combination strategies.

4:30 Coordinate Engagement of T-Cell Regulatory Pathways Using Bispecific DART® Molecules
Jon Wigginton, MD, Senior Vice President, Clinical Development & CMO, MacroGenics
Informed by successes achieved using immunotherapeutic approaches including checkpoint inhibitors and CAR T cells, tremendous attention has now focused on further harnessing the inherent power of the immune system to treat cancer using various combination regimens. A diverse range of pathways provide positive and negative signals to regulate the overall function of T cells. To simultaneously target these pathways, antibody combinations have been tested and demonstrated encouraging clinical activity in patients treated with Anti-PD-1 antibodies in combination with antibodies targeting CTLA-4 or LAG-3.

5:00 Orthomab, a Tetravalent Dual-Specific T Cell Costimulator that Elicits Antitumor Immunity
Adam J. Adler, PhD, Professor, Immunology, University of Connecticut
Combination immunotherapies can more effectively control tumors compared to monotherapies, but also have greater potential to elicit adverse events. We developed OrthomAb, a novel combinatorial single-drug biologic comprised of mAb agonists to the TNFR family costimulatory receptors CD134 and CD137 covalently-linked into a heterodimer, that potentiates T cell effector functions and *in vivo* tumor control. Importantly, OrthomAb's tetravalent structure should enable the minimization of adverse events while preserving therapeutic efficacy.

5:30 Dinner Short Course Registration*
**Separate registration required, click here for details*

5:30 Close of Bispecific Antibodies for Cancer Immunotherapy

6:00-9:00 pm Dinner Short Course
SC3: Next-Generation Immunotherapies: Part 2

Conference Programs

- Immunomodulatory Therapeutic Antibodies for Cancer
- Rational Combination Cancer Immunotherapy
- Immuno-Oncology Biomarkers 1: Quantitative Immune Profiling and Immune Monitoring
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TUESDAY-WEDNESDAY | AUGUST 28-29

Preclinical and Translational Immuno-Oncology

Predictive Preclinical Models and Translational Strategies for Cancer Immunotherapy

TUESDAY, AUGUST 28

12:00 pm Registration

3D TUMOR SPHEROIDS AND ORGANOIDS AS *IN VITRO* MODELS FOR IMMUNO-ONCOLOGY

1:25 Chairperson's Opening Remarks
Shane R. Horman, PhD, Research Investigator III, Functional Genomics – Advanced Assays, Genomics Institute of the Novartis Research Foundation

1:30 FEATURED PRESENTATION: 3D Model to Mimic the Microenvironment
Litao Zhang, PhD, Vice President, Leads Discovery and Optimization, Bristol-Myers Squibb

2:00 Enhancing T-Cell-Mediated Tumor Killing
Shane R. Horman, PhD, Research Investigator III, Functional Genomics – Advanced Assays, Genomics Institute of the Novartis Research Foundation

Overcoming tumor-mediated immunosuppression and enhancing cytotoxic T-cell activity within the tumor microenvironment are two central goals of immuno-oncology (IO) drug discovery initiatives. However, exploratory assays involving immune components are often plagued by low-throughput and poor clinical relevance. Here we present a novel *ex vivo* assay platform for interrogating T-cell-mediated killing of 3-dimensional tumor spheroids that yields clinically-relevant data and can be employed kinetically for the discovery of novel IO therapeutic agents.

2:30 Beyond Genomics: Multiplex Protein Profiling for Biomarker Identification
Christoph Sachse, PhD, Site Head Berlin, NMI TT Pharmaservices

Our approach is to employ comprehensive multiplex protein profiling for lead compound characterization, biomarker identification and precision medicine development. Using the DigiWest technology, we analyze up to 800 total and phospho proteins from cell or tissue samples, thus adding considerable value beyond genomics profiling. We will present data from studies on chemotherapy resistance biomarkers and in primary patient-derived 3D tumor organoids (PD3Ds).

3:00 Automation and Decentralization of CAR-T Cell Manufacture
Sponsored by MACS Miltenyi Biotec
Boro Dropulic, PhD, CSO & General Manager, Administration, Lentigen Technology, Inc., A Miltenyi Biotec Company

3:15 Sponsored Presentation *(Opportunity Available)*

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 PLENARY KEYNOTE SESSION
Click here for details

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

5:30 Dinner Short Course Registration*
**Separate registration required, click here for details*

6:30 End of Day

6:30-9:00 pm Dinner Short Course SC1: Bioinformatics for Immuno-Oncology and Translational Research

6:30-9:00 pm Dinner Short Course SC2: Next-Generation Immunotherapies: Part 1

WEDNESDAY, AUGUST 29

7:30 am Morning Coffee

PREDICTIVE PRECLINICAL MODELS FOR IMMUNO-ONCOLOGY

8:25 Chairperson's Remarks
Marcus Bosenberg, MD, PhD, Professor, Dermatology, Pathology, and Immunobiology, Yale University

8:30 FEATURED PRESENTATION: The Role of Genetically Engineered Mouse Models of Cancer in Profiling Novel Immune Targeting Therapies
Elizabeth Hardaker, PhD, Head, Oncology In Vivo Pharmacology, AstraZeneca

Immune oncology targets are expanding to include multiple cell types, including T cells and myeloid cells. Syngeneic models are useful for profiling some novel immune targeting agents; however, there are some targets and combinations that are not relevant in these models. To understand where the models have utility, we need to have a good understanding of the tumor microenvironment. New model systems are also required to effectively profile novel immune oncology therapies and combinations. In this presentation, the kinetics of the immune response within 3 commonly used syngeneic models (CT26, MC38, 4T1) will be described.

9:00 Using Syngeneic Mouse Models for IO Combination Studies
Manfred Kraus, PhD, Director, in vivo Pharmacology, Tumor Cell Biology, Pfizer Oncology

9:30 Mouse Syngeneic Models: Biological Variability in Response to Therapy and Underlying Cellular and Molecular Factors
Sponsored by charles river
Patrick Fadden, Research Director, Charles River

"Mouse Syngeneic Models: Biological Variability in Response to Therapy and Underlying Cellular and Molecular Factors Involved" Syngeneic models have greater animal to animal variability as well as inter-study variability than standard xenograft models. We will discuss potential biological explanations for this, the relationship between gene expression changes and individual animal response and practical implications for study design and interpretation.

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 Using Mouse Models to Dissect Different Components in the Tumor Microenvironment
Zhao Chen, PhD, Investigator III, Exploratory Immuno-Oncology, Novartis Institute of Biomedical Research

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Preclinical and Translational Immuno-Oncology, *continued*

The tumor microenvironment web largely determines the fate of tumor initiation, progression and treatment responses. Faithful *in vivo* analyses are powerful tools to pinpoint the critical nodes in this dynamic network. Further, *in vivo* genetic screens and subsequent target validation using appropriate *in vivo* models are also keys in identifying immune modulatory targets.

11:15 Modeling Dysfunctional T-Cell Immunity of Tumor in Mouse
Hiroshi Nakashima, PhD, Instructor, Neurosurgery, Brigham & Women's Hospital, Harvard Medical School

11:45 Preclinical Testing of Anti-Cancer Immune Therapies
Marcus Bosenberg, MD, PhD, Professor, Dermatology, Pathology, and Immunobiology, Yale University
Efforts to improve immune-oncology therapies in the setting of low response rates or resistant disease would benefit from human-relevant models that accurately predict responses to new and combinatorial immune therapies. The evaluation of anti-cancer immune therapies using cutting-edge immunogenic mouse models will be presented. In addition, future directions in modeling and correlative analyses will be discussed.

12:15 pm Luncheon Presentation: Transforming Translational Research: CANscript™ - A Better Predictive Model for Oncology
Sponsored by MITRA BIOTECH
Mark Paris, PhD, Director, Translational Applications, Biopharma Business Development, Mitra Biotech, Inc.
Mitra Biotech has developed and clinically validated our human ex-vivo tumor platform technology (CANscript™). CANscript uses patient material (tumor, autologous ligands and PBMC) to explore the mechanism of action and predict efficacy for clinically-directed compounds in a modality-agnostic way using phenotypic effects. This talk will explore how CANscript was used to model the effect of checkpoint inhibition in HNSCC to identify predicted clinical responders and uncover mechanisms of resistance.

12:45 Session Break

MECHANISM OF NON-RESPONSE: RESISTANCE, IMMUNE EVASION, OR LACK OF EFFICACY?

1:40 Chairperson's Remarks
Genevieve Boland, MD, PhD, Director, Melanoma Surgery Program, Massachusetts General Hospital; Director, Surgical Oncology Research Laboratories, Massachusetts General Hospital; Assistant Professor, Harvard Medical School; Associate Member, Broad Institute

1:45 Genetic Alterations in CD19 Lead to CD19 Negative Relapse to CAR19 Therapy in Pediatric Acute Lymphoblastic Leukemia
Elena Orlando, PhD, Bioinformatics Investigator, Novartis Institutes for BioMedical Research
Despite remarkable responses following CAR T-cell therapy in ALL, relapse poses a significant threat. We used next-generation sequencing to study the mechanisms of CD19 negative relapse. We found that all CD19 negative relapse patients evaluated acquired genetic alterations that explain their loss of CD19 protein expression. These findings suggest retreatment strategies likely to be most effective in this setting.

2:15 Genomic and Immunologic Changes Associated with Immune Checkpoint Blockade In Melanoma
Genevieve Boland, MD, PhD, Director, Melanoma Surgery Program, Massachusetts General Hospital; Director, Surgical Oncology Research Laboratories, Massachusetts General Hospital; Assistant Professor, Harvard Medical School; Associate Member, Broad Institute
In melanoma, there is extensive experience treating patients with immune checkpoint therapies (ICT). Longitudinal profiling and patient-derived samples have allowed us to identify genomic, transcriptomic, and epigenetic changes associated with response to therapy and distinct immune changes in patients treated with ICT. This presentation will highlight known and emerging tumor and immune changes associated with response and/or resistance to ICT and identify new areas of investigation and approaches to therapy.

2:45 Presentation to be Announced
Sponsored by The Jackson Laboratory

3:15 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 COX2-PGE2-Orchestrated Secondary Suppression in the Course of Immunotherapy
Pawel Kalinski, MD, PhD, Professor, Oncology, Vice-Chair, Translational Research, Roswell Park Cancer Institute
Immune checkpoint blockade (ICB) provided effective treatment option for many types of advanced cancer, but the majority of cancer patients show primary or secondary resistance to ICB. The effectiveness of ICB and other forms of cancer immunotherapy is regulated at the level of tumor microenvironment (TME) by the balance between type-1 effector cells, such as CD8+ cytotoxic T cells (CTLs), Th1 and NK cells and suppressive cells, such as regulatory T cells (Tregs) and myeloid-derived suppressor cells (MDSCs). We observed the activation of CTLs or NK cells in the TME of human cancers results in a strong mobilization of PD-1-independent "secondary" suppression, mediated by activated MDSCs.

4:30 Cross-Talk among Distinct Immune Regulatory and Effector Cells in Cancer in Different Tissues
Jay A. Berzofsky, MD, PhD, Chief, Vaccine Branch, Center for Cancer Research, National Cancer Institute
We found that the same tumor growing in the lung or skin has different immunoregulatory mechanisms that inhibit immunosurveillance, even when both tumors are growing in the same animal. The effector cells that protect when the regulatory cells are removed also cross talk in only one direction, from skin to lung but not vice versa. Thus, even for the same tumor, one must overcome different immunoregulatory mechanisms for immunotherapy in the primary tumor or in lung metastases, which is an important finding for cancer immunotherapy.

5:00 Targeting the DNA Damage Response to Enhance Immunotherapeutics
Timothy Yap, MD, PhD, Associate Professor, Department of Investigational Cancer Therapeutics, The University of Texas MD Anderson Cancer Center
DNA damage response agents, such as PARP inhibitors, are widely used in clinical oncology and exploit deficiencies in tumor DNA repair. Given the expanding role of immune checkpoint inhibitors in cancer medicine, the interaction of tumor DNA damage with the immune system has recently come into focus. It is now clear that the tumor DNA repair landscape has a key role in driving antitumor response to immune checkpoint blockade.

5:30 Dinner Short Course Registration*
**Separate registration required, click here for details*

5:30 Close of Preclinical and Translational Immuno-Oncology

6:00-9:00 pm Dinner Short Course
SC3: Next-Generation Immunotherapies: Part 2

Conference Programs

- Immunomodulatory Therapeutic Antibodies for Cancer
- Rational Combination Cancer Immunotherapy
- Immuno-Oncology Biomarkers 1: Quantitative Immune Profiling and Immune Monitoring
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TUESDAY-WEDNESDAY | AUGUST 28-29

Immuno-Oncology Biomarkers 2:

Predictive Biomarkers and Companion Diagnostics

TUESDAY, AUGUST 28

12:00 pm Registration

BIOMARKERS TO PREDICT RESPONSE TO IMMUNOTHERAPY

1:25 Chairperson's Opening Remarks
George Poste, DVM, PhD, Chief Scientist, Complex Adaptive Systems, Arizona State University

1:30 FEATURED PRESENTATION: Immunophenotyping to Differentiate Responder and Non-Responder Patients in Cancer Immunotherapy
George Poste, DVM, PhD, Chief Scientist, Complex Adaptive Systems, Arizona State University
The clinical benefits of immune checkpoint inhibitors in a variety of malignancies are unprecedented. Unfortunately, the level of positive therapeutic response is not consistent across different tumor classes and even in responsive tumor lineages non-responders still dominate. The need for comprehensive immunophenotyping to identify the mechanisms underlying these differential responses and better predict responder patients is an urgent clinical and economic imperative.

2:00 Molecular Mechanisms and Biomarkers Predictive of Response to Keytruda
Andrey Loboda, PhD, Director, Genetics and Pharmacogenomics, Merck
The talk will address molecular biomarkers of response to pembrolizumab, including the role of tumor antigenicity, as measured by mutational load (ML) and T cell inflamed microenvironment in predicting the response to pembrolizumab. Data will be presented that prospectively validates the utility of both biomarkers as tumor type agnostic and orthogonal measures of response. These findings provide a biomarker framework for development of pembrolizumab as a monotherapy and for characterizing responses to novel immunotherapy regimens.

2:30 Tissue-Based Diagnostic Tests for Immunotherapy
David L. Rimm, MD, PhD, Professor, Pathology, Yale
While it would be great to be able to predict response to immunotherapy without a biopsy, to date, other modalities including circulating tests and imaging approaches cannot match the sensitivity and specificity of tissue-based tests. Here we will take a closer look at the predictive value of PD-L1 by immunohistochemistry including the tumor vs. the immune cell components as well as other protein-based tests.

3:00 Presentation to be Announced
Sponsored by AACD a biotechne brand

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 PLENARY KEYNOTE SESSION
Click here for details

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

5:30 Dinner Short Course Registration*
**Separate registration required, click here for details*

6:30 End of Day

6:30-9:00 pm Dinner Short Course
SC1: Bioinformatics for Immuno-Oncology and Translational Research

6:30-9:00 pm Dinner Short Course
SC2: Next-Generation Immunotherapies: Part 1

WEDNESDAY, AUGUST 29

7:30 am Morning Coffee

TRANSLATING GENOMIC IO BIOMARKERS TO COMPANION DIAGNOSTICS: MISMATCH REPAIR AND TUMOR MUTATIONAL BURDEN

8:25 Chairperson's Remarks
Robert Anders, MD, PhD, Associate Professor, Pathology, Johns Hopkins University

8:30 FEATURED PRESENTATION: Predictive Biomarkers in Colon Cancer and Mismatch Repair Deficient Tumors
Robert Anders, MD, PhD, Associate Professor, Pathology, Johns Hopkins University
Human cancer tissue samples have been and will be an excellent platform to uncover predictive biomarkers to select a patient for immune based chemotherapy. This lecture will focus on looking back at what biomarkers lead to the success of PD-1/L1 blockade in colon cancer and mismatch repair deficient cancers. Emphasis will be on the lessons that were learned from these clinical trials and how those lessons can be applied moving forward.

9:00 The First Biomarker-Defined Tumor Indication: FDA Approval of Pembrolizumab for MSI-High Cancer
Kenneth Emancipator, MD, Executive Medical Director and Head of Companion Diagnostics, Merck & Co.
The program presents an overview of microsatellite instability (MSI) and mismatch repair defect (MMRD), and how it fits into the tumor immunogenicity-inflammation pathway. It reviews the history and clinical evidence for MSI and MMRD as a predictive biomarker for response to pembrolizumab. It discusses the unprecedented – and unorthodox – path to FDA approval of pembrolizumab. Finally, it discusses MSI and MMRD in the broader context of biomarkers in immuno-oncology.

9:30 Future Biomarker-Defined Tumor Indications: Moving Beyond Single Analyte Approaches
Sponsored by OmniSeq
Carl Morrison, MD, DVM, CMO, OmniSeq
The program presents an algorithmic approach to predicting response to FDA-approved checkpoint inhibitors in multiple tumor types, including melanoma and lung cancer. From PD-L1 expression to T-cell infiltrates (hot vs cold tumors), mutational burden, mutational status, and expression of key immune-related genes we will review how these factors can be combined to improve response prediction in various scenarios and how this may impact clinical use of checkpoint inhibitors.

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Immuno-Oncology Biomarkers 2, *continued*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

10:45 The Return of Precision Medicine in Immuno-Oncology

Zhen Su, MD, MBA, Senior Vice President & CMO, NA, EMD Serono, Inc.

With IO therapies rapidly evolving, the question still remains, which patients will respond? IO has changed the treatment landscape significantly; however, the respective biomarkers and diagnostics do not yet provide a clear direction for clinicians to identify the responsive patient sub-populations. From tumor associated PD-L1 expression, to T-cell infiltrates and mutational burden, we will review the current and future trends as well as discuss the challenges for IO biomarker biology.

11:15 Tumor Mutational Burden Testing for Patient Selection: Implementation of TMB Testing in The Real World

George A. Green, IV, PhD, Head, Pharmacodiagnostic Center of Excellence, Bristol-Myers Squibb

Tumor mutational burden (TMB), the frequency of somatic mutations in the tumor, is an emerging biomarker that predicts responses to immunotherapy. Tumors with high TMB may express novel protein sequences leading to the formation of neoantigens, and are believed to make the tumor more visible to the immune system. This may induce tumor-specific T cell responses that can be enhanced by checkpoint inhibitors. TMB is measured using next-generation sequencing, enabling assessment of hundreds of pre-specified genes. Discussion will provide insight into the rationale behind using TMB and practical considerations for its implementation.

11:45 The Cancer Genome's Influence on Immunotherapy

Nadeem Riaz, MD, Associate Director, Immunogenomics and Precision Oncology Platform, Radiation Oncology, Memorial Sloan Kettering Cancer Center

Will review data showing the importance of tumor mutation burden in predicting outcomes to checkpoint blockade therapy. Will subsequently discuss emerging genetic features associated with response to therapy including microsatellite instability, HLA genotype, tumor clonality, and neo-antigen modeling amongst others.

12:15 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:45 Session Break

BIOMARKERS FOR CHECKPOINT INHIBITORS AND COMBINATIONS

1:40 Chairperson's Remarks

Emmett Schmidt, PhD, Distinguished Scientist & Executive Director, Merck Research Labs

1:45 Emerging Biomarker Strategies in the Era of PD-1 Checkpoint Combination Therapies

Emmett Schmidt, PhD, Distinguished Scientist & Executive Director, Merck Research Labs

PD-1 checkpoint inhibition demonstrates unusually broad monotherapy activity across tumor types. Addressing the unmet medical need of patients not responding to checkpoint monotherapy can be achieved by finding highly effective combination therapies, by finding predictive biomarkers or a combination of both strategies. Biomarker strategies will need to evolve to accommodate the emerging landscape of broadly active PD-1 combination therapies.

2:15 Taking Immune-Oncology beyond Checkpoint Blockade

Marc Pelletier, PhD, Investigator II, Translational Immune Oncology, Novartis Institutes for Biomedical Research

Cancer treatment has been revolutionized by the success of checkpoint blockade in the clinic. In order to expand the pool of responsive patients, clinical trials are focused on combining checkpoint blockade with other immune modulating mechanisms. Critical to this success is the elucidation of biomarkers that presage response or highlight potential therapeutic combinations. TGFβ antagonism offers potential combination benefit and biomarker assessment for clinical development of this target will be discussed.

2:45 Presentation to be Announced

Sponsored by illumina

3:15 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Biomarkers to Assess Efficacy and Toxicity of Immune Checkpoint Immunotherapies in Patients with Melanoma

Philip Friedlander, MD, PhD, Assistant Professor, Medicine, Hematology & Medical Oncology; Director, Melanoma Medical Oncology Program, Icahn School of Medicine at Mount Sinai

The use of anti-CTLA-4 and anti-PD-1 inhibitors to treat stage IV melanoma confers survival benefit. Limitations include the development of response in a subset of patients and the development of immune mediated toxicity. Identifying biomarkers' predicting response or toxicity can optimize treatment choice and minimize toxicity risk. Biomarkers may reflect tumor or blood based characteristics. The identification and validation of whole-blood RNA transcript based gene signatures is a potential strategy.

4:30 Applying Next-Generation Sequencing to Assess Immune-Mediated Drug Hypersensitivity

Masahide Yano, PhD, Research Scientist, Center for Drug Evaluation and Research, FDA

Drug hypersensitivity remains a major clinical problem especially due to its unpredictable outcome in preclinical standard toxicity tests, which often causes patients' morbidity. A goal of this study is to understand immunological mechanisms that underlie severe adverse drug reactions. To achieve this, we employed next-generation sequencing technology to identify a defined repertoire of CD8+ T cell receptors that recognize complexes of HLA/peptide/drug, and investigated their biological functions.

5:00 Prognostic and Predictive Markers for Immunotherapy and Combination Therapy

Kathleen M. Mahoney, MD, PhD, Clinical Instructor, Beth Israel Deaconess Medical Center; Research Fellow, Dana-Farber Cancer Institute

5:30 Dinner Short Course Registration*

**Separate registration required, click here for details*

5:30 Close of Immuno-Oncology Biomarkers 2: Predictive Biomarkers and Companion Diagnostics

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6:00-9:00 pm Dinner Short Course SC3: Next-Generation Immunotherapies: Part 2

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TUESDAY-WEDNESDAY | AUGUST 28-29

Adoptive T Cell Therapy 1: Discovery

Engineering Immune Cells for More Effective Immunotherapies

TUESDAY, AUGUST 28

12:00 pm Registration

NEW TECHNIQUES IN T CELL ENGINEERING

1:25 Chairperson's Opening Remarks
David M. Spencer, PhD, CTO, R&D, Bellicum Pharmaceuticals

1:30 Mechanical Modality to Reengineer and Edit Cells for Enabling Cell/Gene Therapies
Steven Banerjee, CEO, Mekonos, Inc.

We are developing a universal scalable cargo delivery platform using silicon semiconductor technology to transport any type of molecular payload to any cell type outside the body to genetically reprogram single cells on a massively parallel scale before transplanting them into the patient. The overall portable system when fully developed will contain an assembly line of chips with independently controlled nanoneedles driven by a control and automation infrastructure.

2:00 Soluporation Vector-Free Intracellular Delivery Method for Engineering Immune Cells
Shirley O'Dea, PhD, CSO, Avectas Ltd.

Non-viral methods of intracellular delivery of various cargo types are attractive candidates as next-generation delivery modalities because of potential benefits for safety, cost, and production. We have developed a novel non-viral method termed 'soluporation' that achieves efficient intracellular delivery through reversible permeabilization of the cell membrane. Here we describe successful engineering of primary human T cells by soluporation and demonstrate high levels of cell viability and functionality in the modified cells.

2:30 Orthogonal 2D Control Of ACT: Not All Switches Are Created Equal
David M. Spencer, PhD, CTO, R&D, Bellicum Pharmaceuticals

Adoptive cell therapies for solid tumors are still limited by numerous efficacy and safety challenges. Non-homogeneous antigen expression, low-level expression on healthy tissue, unpredictable persistence of therapeutic cells and numerous immunosuppressive factors all contribute to inconsistency in these "living drugs". Using chemically induced dimerization (CID) technology, we developed orthogonal on/off switches, permitting simultaneous regulation of T cell activity, persistence and survival *in vivo*, leading to robust anti-tumor efficacy *in vivo*.

3:00 Sponsored Presentation *(Opportunity Available)*

3:30 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 PLENARY KEYNOTE SESSION
Click here for details

5:30 Welcome Reception in the Exhibit Hall with Poster Viewing

5:30 Dinner Short Course Registration*
**Separate registration required, click here for details*

6:30 End of Day

6:30-9:00 pm Dinner Short Course
SC1: Bioinformatics for Immuno-Oncology and Translational Research

6:30-9:00 pm Dinner Short Course
SC2: Next-Generation Immunotherapies: Part 1

WEDNESDAY, AUGUST 29

7:30 am Morning Coffee

INNOVATIONS IN IMMUNOTHERAPIES

8:25 Chairperson's Remarks
Shulin Li, PhD, Professor, Director, Pediatric Laboratory Research Programs, W.T. and Louise Jarrett Moran Distinguished Chair, Pediatric Oncology, Pediatric Research, MD Anderson Cancer

8:30 Detection and Therapeutic Application of HLA/Peptide Complexes
William Hildebrand, PhD, ABHI Diplomate, Chief Scientist, Pure MHC

T cells utilize HLA/peptide complexes to distinguish infected and cancerous cells from healthy cells. We first describe how proteomics can be used to identify HLA/peptide complexes distinct to tumor and infected cells. Next, we illustrate how complementary immunologic methods can be used to validate that select HLA/peptide complexes are indeed distinct to unhealthy cells. Finally, we demonstrate that HLA/peptide complexes successfully transition into immune therapies for infectious disease and cancer.

9:00 Novel Immunomodulatory Strategy of Targeting Glyco-Immune Checkpoints with EAGLE Technology
Li Peng, PhD, Vice President, Biotherapeutics Discovery, Palleon Pharmaceuticals

Tumors exploit a previously unappreciated axis of immunosuppression through alteration of their cell surface glycans, which impairs multiple types of innate and adaptive immune cells critical to the anti-tumor response. We developed an EAGLE (Enzyme-Antibody Glyco-Ligand Editing) technology to modify tumor-specific glycans. Systematic delivery of EAGLE molecule decreased sialic acid levels and increased T cell infiltration and activation in tumors. EAGLE treatment cured most mice of established tumors and led to resistance to rechallenge in syngeneic models.

9:30 Fully Automated Isolation Of Cell Subsets Straightfrom® Blood Products: Whole Blood, Buffy Coat, Leukopak, LRSC
Sponsored by MACS Miltenyi Biotec
Lotta Raety, Product Manager, Cell Separation, Marketing, Miltenyi Biotec

Isolating leukocytes from blood products is a key step in many cell-based assays. The MultiMACS X cell separator together with the StraightFrom MicroBeads offers fully automated isolation of cell subsets directly from your starting material. Eliminating density gradient centrifugation, the combination provides efficient and standardized cell separation from blood products.

9:45 Sponsored Presentation *(Opportunity Available)*

10:00 Coffee Break in the Exhibit Hall with Poster Viewing

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Adoptive T Cell Therapy 1: Discovery, *continued*

10:45 A Unique Approach to Adoptive Cell Therapy: Harnessing Super Immunity
Matthew E. Colpoys, Jr., Co-Founder & CEO, Tactiva Therapeutics

Tactiva's DEACT approach combines "super immune cells" with epigenetic up-regulation of the target antigen to deliver powerful anti-tumor activity and overcome the T cell exhaustion associated with single TCR therapy. The platform includes a unique CD8 construct that includes both an NY-ESO-1 targeting TCR and dominant negative TGF beta, along with HSC cells engineered to differentiate into mature CD4 T cells with a "tumor recognizing" TCR targeting NY-ESO-1. Both TCRs are unique natural clones.

11:15 Simple Therapeutic Approach for Overcoming Solid Tumor Heterogeneity and Boosting T Cell Infiltration/Function
Shulin Li, PhD, Professor, Director, Pediatric Laboratory Research Programs, W.T. and Louise Jarrett Moran Distinguished Chair, Pediatric Oncology, Pediatric Research, MD Anderson Cancer

Major barriers to CAR T cell efficacy in solid tumors include heterogeneity, poor T cell penetration/accumulation in tumors, and an inert tumor microenvironment. A T cell therapy with the capacity to overcome these challenges is urgently needed. TIL therapy is limited to only some melanoma patients because of failed T cell expansion *in vitro*, lost T cell activity, and poor penetration *in vivo* in large percentages of patients. The presenter provides a simple strategy to address these issues.

11:45 Characterizing the Effects of Sex and Estrogen Signaling on the Function of Antigen-Specific T Cells For Immunotherapy
Flor C. Navarro, Research Scientist, Stephanie K. Watkins Laboratory, Biochemistry and Molecular Biology, Loyola University Chicago

I investigate sex-specific differences mediated by sex hormone signaling, specifically estrogen, on the antigen-specific T cell function and anti-tumor immune response. I use hepatocellular (HCC) carcinoma antigen-specific T cells generated from HCC tumor infiltrating lymphocytes. Using these T cells, I studied the effects of sex and estrogen receptor signaling on T cell function including cytokine production and polyfunctionality, as well as the T cell anti-tumor immune response in a HCC mouse model.

12:15 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:45 Session Break

OFF-THE-SHELF IMMUNOTHERAPIES

1:40 Chairperson's Remarks
Bob Valamehr, PhD, MBA, Vice President, Cancer Immunotherapy, Fate Therapeutics

1:45 Synthetic Biology for Cellular Cancer Immunotherapy
Wilson Wong, PhD, Assistant Professor, Biomedical Engineering, Boston University

I present a split, universal, and programmable (SUPRA) CAR system that simultaneously encompasses multiple critical "upgrades", such as the ability to switch targets without re-engineering the T cells, finely tune T cell activation strength, and sense and logically respond to multiple antigens. Furthermore, we extend the orthogonal SUPRA CAR system to regulate different T cell subsets independently, demonstrating a dually inducible CAR system.

2:15 Synthetic Cells as Platforms for Programmed Drug Manufacturing Inside Tumors
Avi Schroeder, PhD, Assistant Professor, Chemical Engineering, Laboratory for Targeted Drug Delivery and Personalized Medicine Technologies, Technion – Israel Institute of Technology

The talk discusses principles for rationale design of remotely activated synthetic cells and their capacity to treat disease. Synthetic cells were evaluated as autonomous systems for producing therapeutic proteins inside tumors. Synthetic cells can exceed certain natural functions, such as producing biologics at large amounts or producing therapeutic proteins that are toxic to living cells. The technological versatility of synthetic cells opens a new door for tailoring personalized medicines to each patient.

2:45 Adaptive Cancer Immunotherapies
Timothy K. Lu, MD, PhD, Associate Professor, Synthetic Biology Group, Research Laboratory of Electronics, Electrical Engineering and Computer Science, Biological Engineering, Massachusetts Institute of Technology

3:15 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 Genome Editing for "Off-the-Shelf" Allogeneic CAR T Cell Products
Julianne Smith, PhD, Vice President, Translational Sciences, Cellectis

Chimeric antigen receptor (CAR)-redirected T cells have given rise to long-term durable remissions and remarkable objective response rates in patients with refractory leukemia, raising hopes that a wider application of CAR technology may lead to a new paradigm in cancer treatment. A limitation of the current autologous approach is that CAR T cells must be manufactured on a "per patient basis". Cellectis has developed a platform for generating chimeric antigen receptor (CAR)-redirected T cells from thirdparty healthy donors using transcription activator-like effector nucleases (TALEN®). Nuclease mediated inactivation of the TCR alpha abrogates the potential for T cells bearing alloreactive TCRs to mediate Graft versus Host Disease (GvHD). Additional gene inactivation events can be incorporated, permitting resistance to lymphodepleting or chemotherapeutic agents, resistance to tumor inhibition or suppression of cross T cell reactions. Such allogeneic "offthe-shelf" CAR T cell products will permit a wider application of CAR technology and potentially lead to a new paradigm in cancer treatment.

4:30 Engineered Natural Killer Cells Expressing Enhanced Fc Receptors for Cancer Cell Killing
Bruce Walcheck, PhD, Professor, Immunology, University of Minnesota

We have engineered NK cells expressing a novel chimeric Fc receptor that binds tumor-targeting mAbs with high affinity and induces robust ADCC. Advantages of this approach is that the engineered NK cells can bind to a broad array of therapeutic mAbs, which serve as diverse targeting elements for various tumor antigens and malignancies.

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Adoptive T Cell Therapy 1: Discovery, *continued*

5:00 Generation of Engineered Pluripotent Cell-Derived T Cells as a Cornerstone Approach for Off-the-Shelf Cancer Immunotherapy

Bob Valamehr, PhD, MBA, Vice President, Cancer Immunotherapy, Fate Therapeutics

Pluripotent stem cell technology represents a unique and powerful approach to make cell-based immunotherapies available to a wide range of patients through the generation of a consistent and renewable "off-the-shelf" source of therapeutic cells. I discuss our progress towards translating a unique and effective strategy to create a renewable source of "off-the-shelf" T cells derived from a single cell–derived engineered master pluripotent cell line.

5:30 Dinner Short Course Registration*

**Separate registration required, click here for details*

5:30 Close of Adoptive T Cell Therapy 1: Discovery

6:00-9:00 pm Dinner Short Course
SC3: Next-Generation Immunotherapies: Part 2

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THURSDAY-FRIDAY | AUGUST 30-31

Emerging Immuno-Oncology Targets

Novel Targets and Pathways for Cancer Immunotherapy and Combinations

THURSDAY, AUGUST 30

7:45 am Registration & Morning Coffee

TARGETING INNATE AND ADAPTIVE IMMUNITY

8:25 Chairperson's Opening Remarks
Steven A. Greenberg, MD, Professor, Neurology, Harvard Medical School; Brigham and Women's Hospital; Abcuro, Inc.

8:30 Targeting the T and NK Cell Co-Inhibitory Receptor KLRG1: Rationale for Clinical Development
Steven A. Greenberg, MD, Professor, Neurology, Harvard Medical School; Brigham and Women's Hospital; Abcuro, Inc.

Targeting of lymphocyte co-inhibitory receptors, such as CTLA-4, PD-1, LAG-3, and TIM-3, has gained intense interest for treatment of cancer. KLRG1 is also a lymphocyte co-inhibitory receptor, expressed predominantly on effector memory CD8+ T cells and NK cells, whose ligands E- and N-cadherin are differentially expressed during epithelial-mesenchymal transition. Targeting of KLRG1 has not previously been pursued in murine cancer studies. Here we demonstrate that anti-KLRG1 neutralizing antibody demonstrates efficacy in inhibiting metastases, reducing primary tumor volume, and improving survival as monotherapy and synergistic combination therapy with anti-PD-1 in syngeneic murine cancer models. Humanized anti-KLRG1 antibodies activate T cells and are a promising new approach for cancer immunotherapy.

9:00 Clinical Development of Entinostat and Checkpoint Inhibitors
Jian Li, MD, Clinical Research & Development, Syndax Pharmaceuticals

9:30 NKG2D Ligands Regulation of Immune Checkpoint Blockade Therapy of Cancer: Efficacy and Toxicity
Jennifer Wu, PhD, Mary and Patrick Scanlan Professor of Urology, Northwestern University and Robert Lurie Comprehensive Cancer Center

Ligands for the immune activation receptor NKG2D are often induced on the surface of tumor cells in response to genotoxic insults. Surface NKG2D ligand can activate the immune surveillance through activating NK cells and co-stimulating effector T cells. Recent studies demonstrate that advanced tumors shed soluble NKG2D ligands that impair response to immune checkpoint blockade therapy and induce colon toxicity. Therapeutic intervention targeting this pathway will be discussed.

10:00 Coffee Break in the Exhibit Hall (Last Chance for Poster Viewing)

10:45 Immunotherapies by Design: A Best in Class A2A Antagonist Tailored for Immuno-Oncology
Michel Detheux, PhD, CEO, iTeos Therapeutics

The adenosine A2A receptor is the main adenosine receptor expressed on immune cells, which promotes immune suppression, leading to tumor evasion. iTeos' best-in-class A2A receptor antagonist, EOS100850, restores T cell activation inhibited by adenosine. EOS100850 promotes anti-tumor efficacy in mouse tumor models in combination with several immune-checkpoint inhibitors, retains high potency in the presence of elevated intratumoral adenosine concentrations, and is non-brain penetrant. EOS100850 is currently being evaluated for safety and efficacy in preclinical models to enter into clinics in 2018.

11:15 eFT508: A Highly Selective Inhibitor of MNK1/2 Enhances Anti-Tumor Immune Response
Kevin Webster, PhD, Senior Vice President, Cancer Biology, eFFECTOR Therapeutics

eFT508 is a highly selective inhibitor of MNK1/2, kinases that promote tumor immune evasion downstream of MAPK signaling. eFT508 enhances anti-tumor immune response by establishing a regulatory program that stimulates antigen presentation and T cell priming, expansion of memory T cells, and prevents T cell exhaustion. eFT508 is currently under evaluation in multiple phase 1/2 clinical trials as both a monotherapy and in combination with checkpoint inhibitors.

11:45 Evaluating the Immuno-Oncology Potential of Compounds and Combinations using Human *in vitro* TME Models

Sponsored by eurofins | Pharma Discovery Services

Alison O'Mahony, PhD, Vice President, Translational Biology, Research & Development, Eurofins Pharma Discovery Services

With less than a third of cancer patients responding to immuno-oncology (IO) therapies, the challenge is to develop better and safer IO candidates and combination strategies to achieve improved clinical outcomes. Recent IDO failures illustrate the critical need for more translational target validation for agents and combination strategies. Here we demonstrate the application of human-based *in vitro* co-culture assays such as the BioMAP® TME phenotypic models, which may prove superior in advancing safer and more effective IO agents than current animal-centric methods.

12:15 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:45 Session Break

NEOANTIGEN TARGETED THERAPIES

1:40 Chairperson's Remarks
Philip Arlen, MD, President & CEO, Precision Biologics

1:45 FEATURED PRESENTATION: T Cells against Tumor Neoantigens: How Many Are Likely Needed for Clinical Efficacy and Can Contemporary Vaccines Get Us There?
Andrew Allen, PhD, CEO & President, Gritstone Oncology

Two key challenges in neoantigen-directed therapeutics are: 1) accurate neoantigen identification from "sea" of tumor mutations (achieved with deep learning approach, trained on human tumors); 2) induction of large numbers of polyfunctional neoantigen-specific T cells. Novel vaccine approaches to problem (2), in combination with checkpoint modulators, can drive extremely high and sustained T cell responses in non-human primates. We can compare these to T cell numbers observed in successful adoptive cell therapy.

Conference Programs

- Immunomodulatory Therapeutic Antibodies for Cancer
- Rational Combination Cancer Immunotherapy
- Immuno-Oncology Biomarkers 1: Quantitative Immune Profiling and Immune Monitoring
- Oncolytic Virus Immunotherapy
- Bispecific Antibodies for Cancer Immunotherapy
- Preclinical and Translational Immuno-Oncology
- Immuno-Oncology Biomarkers 2: Predictive Biomarkers and Companion Diagnostics
- Adoptive T Cell Therapy 1: Discovery
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- Personalized Cancer Vaccines
- Neoantigen Targeted Therapies
- Adoptive T Cell Therapy 2: Development
- Immuno-Oncology Investing and Partnering Forum

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Emerging Immuno-Oncology Targets, *continued*

2:15 The Discovery and Development of Novel Monoclonal Antibodies Targeting Neoantigens

Philip Arlen, MD, President & CEO, Precision Biologics

Immunogenic neoantigens were derived from a membrane preparation of pooled allogeneic colorectal cancer. The membrane was separated into various fractions by molecular weight and screened for immunogenicity. An immunogenic fraction was identified and used as a vaccine in a clinical trial for patients with chemotherapy refractory disease. There was a correlation observed in patients who developed antibody responses to therapy with both antitumor responses as well as prolongation in overall survival. This vaccine was used as a platform to screen monoclonal antibodies as potential therapeutic candidates.

2:45 Sponsored Presentation *(Opportunity Available)*

3:15 Refreshment Break

3:45 Induction of Potent Neoantigen Targeted CD8+ T Cell Responses via Optimized DNA-Based Immunotherapy

Niranjan Y. Sardesai, PhD, COO, Inovio Pharmaceuticals

Tumor neoantigen targeting for the development of patient specific immunotherapies has emerged as a viable approach for cancer immunotherapy. Considerable efforts are being directed towards the accurate identification and prediction of targetable neoantigens for each patient. However equally critical is the platform deployed for the administration of the selected neoantigens to generate patient T cell responses *in vivo*. We will discuss the use of optimized plasmid DNA based approach.

4:15 Advaxis' Lm Technology™

Robert G. Petit, PhD, Executive Vice President & CSO, Advaxis

4:45 Targeting Neoantigens without the Need to Identify Them: Update on the Phase 3 ADAPT Trial with Rocapuldencel-T in Advanced RCC

Charles A. Nicolette, PhD, CSO & Vice President, R&D, Argos Therapeutics, Inc.

Rocapuldencel-T is a dendritic cell-based immunotherapy where the dendritic cells are programmed with total amplified autologous tumor mRNA plus synthetic RNA encoding CD40 ligand. Clinical and immunologic data from the Phase 3 ADAPT trial in advanced RCC will be presented that is consistent with specific targeting of neoantigens.

5:15 End of Day

FRIDAY, AUGUST 31

8:00 am Breakout Discussion Groups with Continental Breakfast

This session features discussion groups that are led by a moderator who ensures focused conversations around the key issues listed. Attendees choose to join a specific group, and the small, informal setting facilitates sharing of ideas and active networking. Details on the topics and moderators are available on the conference website.

EMERGING CYTOKINE TARGETS

9:00 Chairperson's Remarks

Raymond Tesi, MD, President and CEO, Acting CMO, INmune Bio

9:05 Targeting Soluble TNF in Tumor Microenvironment (TME) to Reverse Resistance to Immunotherapy

Raymond Tesi, MD, President and CEO, Acting CMO, INmune Bio

Checkpoint inhibitors do not work in a majority of patients. The most important predictor of resistance to CPI is MDSC in blood and/or TME. MDSC requires TNF to proliferate. Selective elimination of soluble TNF (with preservation of trans-membrane TNF) in blood and TME will reverse the immunologic factors that cause resistance to CPI and other immunotherapies.

9:35 Preclinical Characterization of a Novel STING Agonist, MK-1454

Saso Cemerski, PhD, Principal Scientist, Merck Research Labs

MK-1454, a novel STING agonist, induces potent cytokine responses and activates several immune cell types *in vitro* including MDSCs and M2-macrophages, key suppressive myeloid cells in the TME. MK-1454 induces robust anti-tumor activity in mouse syngeneic tumor models and cytokine production and gene expression changes in *ex vivo*-stimulated human primary tumors. MK-1454 is currently being evaluated in cancer patients both as monotherapy and in combination with Keytruda.

10:05 Novel, High-Potency Sting Agonists Regress Immunotherapy-Resistant Cancers

Michael A. Curran, PhD, Assistant Professor, Immunology, The University of Texas MD Anderson Cancer Center

Working with MD Anderson's Institute for Applied Cancer Science (IACS), we have developed novel, highly potent agonists of the Stimulator of Interferon Genes (STING) pathway. Not only do these STING agonists outperform existing agents in murine syngeneic melanoma models, but they also synergize with T cell immune checkpoint blockade to treat multi-focal pancreatic cancer which responds poorly, if at all, to weaker agonists.

10:35 Coffee Break

11:00 The TNFR2 Immuno-Oncology Target: Elimination through Antibody Antagonism of Infiltrating Tregs and Direct Oncogene Tumor Death

Denise Faustman, MD, PhD, Associate Professor & Director, Immunobiology Lab, Massachusetts General Hospital, Harvard Medical School

Immune checkpoint inhibitors (ICIs) have revolutionized cancer therapy but exhibit variable efficacy and relapse and can induce autoimmunity. Tumor necrosis factor (TNF) receptor 2 (TNFR2) is a signaling molecule found on the surface of a subset of potent regulatory T cells (Tregs) that can activate the proliferation of these cells through nuclear factor kappa B (NF-kB). TNFR2 is also abundantly expressed on the surface of many human tumors. We propose that blocking TNFR2 might target abundant TNFR2+ tumor-infiltrating Tregs and directly kill TNFR2-expressing tumors.

11:30 NKTR-255: Accessing IL-15 Therapeutic Potential through Robust and Sustained Engagement of Innate and Adaptive Immunity

Peiwen Kuo, PhD, Scientist, Nektar Therapeutics

Recognized as a promising immuno-oncology agent, harnessing the full potential of IL-15 has been stymied by poor pharmacokinetics. NKTR-255 overcomes this barrier with dramatically improved bioavailabilty to drive robust proliferation, while supporting function and survival of NK and CD8 T cells. Demonstrating consistent PK, PD and low toxicity in cyno, combined with single and combination efficacy in various preclinical tumor models, NKTR-255 aims to unlock the true potential of IL-15.

12:00 pm Close of Emerging Immuno-Oncology Targets

Conference Programs

- Immunomodulatory Therapeutic Antibodies for Cancer
- Rational Combination Cancer Immunotherapy
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THURSDAY-FRIDAY | AUGUST 30-31

Personalized Cancer Vaccines

Advancing Personalized and Combination Immunotherapy

THURSDAY, AUGUST 30

7:45 am Registration & Morning Coffee

PERSONALIZED CANCER VACCINES

8:25 Chairperson's Opening Remarks
Nathaniel Wang, PhD, Head, Vaccines and Therapeutics, Viral Systems, Synthetic Genomics, Inc.

8:30 FEATURED PRESENTATION: Neoantigen-Based Vaccines for Breast Cancer
Keith Knutson, PhD, Director, Cancer Vaccine & Immune Therapies Program, Mayo Clinic
Breast cancer causes 500,000 deaths each year. Rather than continue to add to the costs of treatment, we should advance promising approaches for prevention such as vaccination. One approach for a breast cancer vaccine is to target aberrantly expressed 'self' antigens. To produce such a vaccine, we're aiming to achieve key milestones, namely identifying peptide epitopes from cancer antigens and identifying systems that induce durable T cell responses.

9:00 *In situ* Vaccination and the Power of Ignorance
Robert Pierce, MD, Scientific Director, Immunopathology Core, Fred Hutchinson Cancer Research Center
The presence of adaptive immune responses directed against tumor-associated antigens (TAAs) is critical for effective therapy with T cell checkpoint therapies, such as anti-PD-1. Many tumors are characterized by a lack of TILs (tumor infiltrating lymphocytes) even though they express potentially immunogenic antigens. We will discuss potential mechanisms of this "immunologic ignorance" phenotype, focusing on dysregulation of antigen presentation and processing machinery. The potential role for intratumoral IL-12 and other *in-situ* vaccination therapies to reverse this PD-1 non-responder phenotype will be discussed.

9:30 Development of a Rapid Personalized Self-Assembling Vaccine for Cancer
Mark C. Poznansky, MD, PhD, Director, Vaccine & Immunotherapy Center, Massachusetts General Hospital; Associate Professor, Harvard Medical School
We have developed a novel personalized self-assembling vaccine (SAV) for cancer that has the potential to be synthesized and delivered to the patient in 20 days. The vaccine consists of a fusion protein containing the broadly immune activating Mycobacterium tuberculosis derived heat shock protein 70 and avidin which self assembles with selected biotinylated immunogenic peptides derived from identified neoantigens. We have demonstrated proof-of-concept that SAV works in the context of generating T cell specific responses to infectious agents and we have begun work to show that this same function can be applied to generate effective T cell antigen specific responses in the context of preclinical murine models of ovarian cancer.

10:00 Coffee Break in the Exhibit Hall (Last Chance for Poster Viewing)

10:45 Vaccibody's Approach to Cost-Effective Personalized Cancer Neoantigen Vaccines Inducing a Unique CD8-Dominated T Cell Response
Agnete Fredriksen, PhD, President and CSO, Vaccibody AS
Vaccibody's technology potentiates vaccines by attracting, activating and delivering antigens to antigen presenting cells which generates a unique CD8-dominated T cell response. By administering the DNA vaccine format of the Vaccibody vaccine, a rapid, cost-effective and robust manufacturing process can be applied which lends itself perfectly to develop commercially viable patient-specific vaccines on demand. A clinical study using targeted Vaccibody neoepitope DNA vaccines in multiple advanced cancer indications is ongoing.

11:15 Agenus' Synthetic Neoantigen Vaccine Platforms, Including Novel Phosphopeptide Tumor Targets
Daniel Levey, PhD, Senior Director Vaccine Research, R&D, Agenus, Inc.
Agenus' vaccine platform of synthetic neoantigens complexed to recombinant heat shock protein 70 (HSC70) and administered along with QS-21 Stimulon® adjuvant elicits an antigen-specific immune response in both mice and humans. Leveraging our *in silico* Agenus Immunogenic Mutation (AIM™) workflow, we are able to generate an optimal immunogenic vaccine blueprint for our AutoSynVax™ vaccines, which are uniquely designed and manufactured for each patient based on NGS profiling of their tumor. Our PhosphoSynVax™ vaccine is an off-the-shelf vaccine targeting a novel class of tumor neoantigens.

11:45 Development of Synthetic Self-Replicating RNA Platforms for Oncology Vaccines and Therapeutics
Sponsored by SYNTHETIC GENOMICS
Nathaniel Wang, PhD, Head, Vaccines and Therapeutics, Viral Systems, Synthetic Genomics, Inc.
RNA as a vaccine and therapeutic modality has become a focus of significant interest. SGI has developed a self-amplifying RNA replicon that overcomes existing limitations and has shown improved protein expression, immunogenicity, and resistance to immune shutdown. This improved RNA replicon is also compatible with formulation technologies, which lower the effective dose required for immunization and improve cellular immunological memory. These engineered advantages enable novel applications of this platform for oncology vaccines and therapeutics.

12:15 pm Luncheon Presentation: Overcoming the Obstacles of Neoantigen Detection for Cancer Vaccine Development
Sponsored by Personalis
Kedar Hastak, PhD, Field Applications Scientist, Personalis, Inc.
Conventional exome assays often have gaps in sequencing coverage, leading to missed neoantigens. Personalis developed the ACE ImmunoID platform to overcome this and other challenges for more comprehensive neoantigen identification. ACE ImmunoID combines augmented exome/transcriptome assays with state-of-the-art bioinformatics, optimized sample preparation, and automated processes to accelerate personalized cancer vaccine development.

12:45 Session Break

Conference Programs

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Personalized Cancer Vaccines, *continued*

PERSONALIZED VACCINES FOR COMBINATION THERAPY

1:40 Chairperson's Remarks
Nathaniel Wang, PhD, Head, Vaccines and Therapeutics, Viral Systems, Synthetic Genomics, Inc.

1:45 FEATURED PRESENTATION: Neoantigen Approaches as Personal and Precision Cancer Therapeutics
Richard Gaynor, MD, President, R&D, Neon Therapeutics

Neoantigens are important targets in directing the anti-tumor immune response and for the mechanism of action of checkpoint inhibitors. Our goal is to utilize multiple therapeutic options to target neoantigens in a variety of human tumors. One program, currently in the clinic, is utilizing a personal neoantigen vaccine in combination with a checkpoint inhibitor to treat patients with high mutation burden tumors in the metastatic setting. A second program is investigating *ex vivo* immunization of autologous T cells with neoantigens to generate both memory and naïve T cell responses that can be used for adoptive T cell therapy. The third program utilizes a precision medicine approach to identify neoantigens that are conserved in specific tumors for either vaccine or T cell based therapeutics. Together these three approaches will address the potential for personal and precision neoantigen-based cancer therapeutics.

2:15 Personalizing Cancer Vaccines Is More Than Just Whole Exome Sequencing
Bernard A. Fox, PhD, Chief, Laboratory of Molecular and Tumor Immunology, Providence Health & Services; CEO, UbiVac

The discovery of neoantigens, as one class of targets which the immune system uses to recognize cancer cells, has led to a flurry of activity around the development of vaccines containing the mutant peptide epitopes unique to a patient's cancer. Some have described the application of this approach as personalized cancer vaccines. It is also well established that overexpressed and abnormally expressed proteins can serve as cancer antigens and these two classes of proteins dominate the National Cancer Institute's list of 75 cancer antigens prioritized for translation. Developing a vaccine that targets all three classes of antigens: neoantigens, overexpressed and abnormally expressed proteins, potentially provides the immune system with greater breadth of immunity. Further, developing a vaccine that activates both T and B cell immunity, provides additional effector mechanisms that may defend against cancers that lose expression of MHC/HLA and escape T cell mediated destruction. However, the generation of a vaccine containing antigens unique to a patient's cancer as well as those abnormally or overexpressed by that cancer, is only the first phase of personalizing a vaccine-based immunotherapy. A truly personalized approach needs to consider the immune "status" of the patient and tailor therapy to addresses defects in that immune status. Our group, in collaboration with partners, are developing a strategy that incorporates these components to develop a personalized cancer vaccine-based immunotherapy. A phase II trial of components of this strategy will be presented and prospects for future trials discussed.

2:45 Presentation to be Announced

Sponsored by MEDGENOME

3:00 Sponsored Presentation *(Opportunity Available)*

3:15 Refreshment Break

3:45 Developing Cancer Vaccines in the Era of Checkpoint Blockade: Avoiding the T Cell Trap
Yared Hailemichael, PhD, Research Instructor, Melanoma Medical Oncology, The UT MD Anderson Cancer Center

One strategy being explored as an avenue to increase T cell immunity is vaccination. Here, we show that a commonly used experimental vaccine formulation causes local inflammation at the vaccination site becoming a trap for anti-CTLA-4 and anti-PD-(L)1 induced tumor-specific T cells. New findings point the way to rational design and selection of cancer vaccine formulations that synergize with checkpoint blockade therapy.

4:15 Improving Checkpoint Blockade by Improving Tumor Antigen Cross-Presentation
Joshua Brody, MD, Assistant Professor, Medicine, Hematology and Medical Oncology, Icahn School of Medicine at Mount Sinai; Director, Lymphoma Immunotherapy Program

Checkpoint blockade therapy of cancer has had tremendous impact, yet only a subset of patients responds. Although increased tumor mutational burden and tumor-associated antigen (TAA) load correlate somewhat with response to checkpoint blockade, we have shown that Hodgkin's lymphoma, despite a high anti-PD1 response rate, has significantly fewer mutations than highly mutated tumors such as lung cancer. This demonstrates that response to checkpoint blockade is determined by factors beyond mutation burden. Our hypothesis is that checkpoint blockade is limited by suboptimal cross-presentation of TAA by suitably activated dendritic cells.

4:45 Th1 Epitopes for Versatile Tumor- and Patient-Tailored Vaccine Combination Therapies (VCT)
William C. Watt, PhD, President & CEO, EpiThany

Th1 epitopes from overexpressed tumor antigens constitute a rich source of active ingredients for cancer vaccine combination therapies (VCTs). Mining the "Th1 epitoire" for flexibility in vaccine antigen selection enables targeting of diverse tumors, patients and settings. EpiThany is incorporating its a priori validated tumor-specific Th1 epitopes into VCTs using multiple delivery platforms and combination agents to treat breast and ovarian cancers at multiple stages of disease.

5:15 End of Day

Conference Programs

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Personalized Cancer Vaccines, *continued*

FRIDAY, AUGUST 31

8:00 am Breakout Discussion Groups with Continental Breakfast

This session features discussion groups that are led by a moderator who ensures focused conversations around the key issues listed. Attendees choose to join a specific group, and the small, informal setting facilitates sharing of ideas and active networking. Details on the topics and moderators are available on the conference website.

NEOANTIGEN IDENTIFICATION AND SELECTION FOR PERSONALIZED IMMUNOTHERAPY

9:00 Chairperson's Remarks

Nathaniel Wang, PhD, Head, Vaccines and Therapeutics, Viral Systems, Synthetic Genomics, Inc.

9:05 An HLA-Agnostic Functional Neoantigen Discovery Platform for Personalized Cancer Vaccines

Stephen Schoenberger, PhD, Co-Director, San Diego Center for Precision Immunotherapy; Professor, La Jolla Institute for Allergy and Immunology

Accurate identification of patient-specific neoantigens (NeoAg) is essential to develop effective personalized cancer vaccines. We have developed WES/RNAseq-guided platform which combines a filtering algorithm based on sequencing metadata, rather than predicted HLA-binding, with *in vitro* functional T cell analysis. We report that >35% of selected expressed mutations can be verified as neoantigens in low mutational burden tumors by CD4+ and CD8+ T cells recognizing common activating mutations in driver oncogenes and numerous patient-specific "passenger" mutations.

9:35 Functional and Unbiased Neoantigen Calling as a Basis for Personalized Vaccines

Ezra Cohen, MD, Professor, Medicine, University of California, San Diego

Cancer presents a unique opportunity for the clinical application of precision immunotherapy due to the frequent expression of somatic mutations that can be recognized as tumor-specific neoantigens (NeoAgs) by a patient's T cells. Meaningful translation of this concept, however, has been hampered by the lack of reliable methods for identifying NeoAgs in cancers of low mutational burden and by the absence of suitable preclinical animal models for evaluating and optimizing the ability of NeoAg-specific T cells to recognize and eradicate autologous tumors. Through a collaborative effort within the San Diego Center for Precision Immunotherapy we have developed a set of novel bioinformatic and cellular tools which allows for the functional validation of NeoAg recognized by both CD4+ and CD8+ T cells at a higher rate than previously reported. This platform has allowed effective identification of NeoAg in solid tumors with low-to-moderate mutational burden through precision immunotherapy which is now being applied as a vaccine using synthetic long peptides.

10:05 Rapid High-Throughput Functional Selection of Neoantigens and Assessment of Their Safety

Dolores Schendel, CEO & CSO, Medigene

Neoantigens are an important class of highly specific target molecules for specific vaccine and TCR-based immunotherapies. Identification of neoantigens by next-generation sequencing and prediction of binding to the HLA allotypes of a patient, still leaves open the issue of actual immunogenicity and safety of neoantigen targets for therapeutic use. Medigene combines high throughput functional screening with sophisticated *in silico* tools to overcome several current limitations in selecting relevant neoantigens.

10:35 Coffee Break

11:00 Harnessing the Innate Immunogenicity of Foreign Viral Antigens to Fight Solid Tumors

David Anderson, PhD, CSO, Research & Development, VBI Vaccines, Inc.

CMV is expressed on over 95% of glioblastoma, medulloblastoma and breast cancers. Like neoantigens, it provides an opportunity to target a non-self antigen that has inherently higher immunogenicity than traditional tumor associated antigens. Recently CMV-specific autologous approaches have demonstrated over a 2X increase in overall survival in glioblastoma. VBI's approach utilizes its eVLP platform to restimulate CMV immunity by preferential uptake and presentation to dendritic cells. It offers an off-the-shelf approach to target CMV+ tumors.

11:30 Validation of Real Neoantigens with Mass Spectrometry

Harpreet Singh, PhD, President & CEO, Immatics US, Inc.

While neoantigens are a promising target class for immunotherapies in some patient populations, many researchers overlook that only a small fraction (presumably less than 1%) of all non-synonymous mutations are actually presented as pMHC targets and can thus act as neoantigens. Most strategies utilizing *in silico* prediction deliver more than 90% false-positive results. Such irrelevant antigens are currently often used in clinical trials and likely will not result in clinical benefit. Here, we show how Immatics' proprietary XPRESIDENT platform, an ultrahigh-sensitivity, high-throughput, high-fidelity mass spectrometry setup allows to validate real neoantigens. Furthermore, data from clinical applications of highly personalized applications is shown underlining the promise of tailored immunotherapies using both neoantigens and shared antigens.

12:00 A New Source of Highly Immunogenic Neoepitopes for Cancer Vaccines

Stephen Albert Johnston, PhD, Director, Center for Innovations in Medicine; Professor, School of Life Sciences, Biodesign Institute, Arizona State University; CEO, Calviri, Inc.

Mistranslation through microsatellites and mis-splicing produce 100x more neoantigens than DNA mutations. Frameshifts (FS) produced by mis-translation and splicing are highly immunogenic. These FS are protective in mouse models; humans and dogs with cancer raise immune responses to these FS, which can be detected using a rapid peptide array. In a mouse model this array-based system can be used to rapidly create a personal vaccine that shows protection.

12:30 pm Close of Personalized Cancer Vaccines

Conference Programs

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THURSDAY-FRIDAY | AUGUST 30-31

Neoantigen Targeted Therapies

Personalized Cancer Immunotherapy in the Genomic Era

THURSDAY, AUGUST 30

7:45 am Registration & Morning Coffee

PERSONALIZED CANCER VACCINES

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Nathaniel Wang, PhD, Head, Vaccines and Therapeutics, Viral Systems, Synthetic Genomics, Inc.

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9:00 *In situ* Vaccination and the Power of Ignorance
Robert Pierce, MD, Scientific Director, Immunopathology Core, Fred Hutchinson Cancer Research Center

9:30 Development of a Rapid Personalized Self-Assembling Vaccine for Cancer
Mark C. Poznansky, MD, PhD, Director, Vaccine & Immunotherapy Center, Massachusetts General Hospital; Associate Professor, Harvard Medical School
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10:00 Coffee Break in the Exhibit Hall (Last Chance for Poster Viewing)

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11:15 Agenus' Synthetic Neoantigen Vaccine Platforms, Including Novel Phosphopeptide Tumor Targets
Daniel Levey, PhD, Senior Director Vaccine Research, R&D, Agenus, Inc.
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11:45 Development of Synthetic Self-Replicating RNA Platforms for Oncology Vaccines and Therapeutics
Sponsored by Synthetic Genomics
Nathaniel Wang, PhD, Head, Vaccines and Therapeutics, Viral Systems, Synthetic Genomics, Inc.
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NEOANTIGEN TARGETED THERAPIES

1:40 Chairperson's Remarks
Philip Arlen, MD, President & CEO, Precision Biologics

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2:45 Sponsored Presentation *(Opportunity Available)*

3:15 Refreshment Break

3:45 Induction of Potent Neoantigen Targeted CD8+ T Cell Responses via Optimized DNA-Based Immunotherapy
Niranjan Y. Sardesai, PhD, COO, Inovio Pharmaceuticals
Tumor neoantigen targeting for the development of patient specific immunotherapies has emerged as a viable approach for cancer immunotherapy. Considerable efforts are being directed towards the accurate identification and prediction of targetable neoantigens for each patient. However equally critical is the platform deployed for the administration of the selected neoantigens to generate patient T cell responses *in vivo*. We will discuss the use of optimized plasmid DNA based approach.

4:15 Advaxis' Lm Technology™
Robert G. Petit, PhD, Executive Vice President & CSO, Advaxis

4:45 Targeting Neoantigens without the Need to Identify Them: Update on the Phase 3 ADAPT Trial with Rocapuldencel-T in Advanced RCC
Charles A. Nicolette, PhD, CSO & Vice President, R&D, Argos Therapeutics, Inc.
Rocapuldencel-T is a dendritic cell-based immunotherapy where the dendritic cells are programmed with total amplified autologous tumor mRNA plus synthetic RNA encoding CD40 ligand. Clinical and immunologic data from the Phase 3 ADAPT trial in advanced RCC will be presented that is consistent with specific targeting of neoantigens.

5:15 End of Day

FRIDAY, AUGUST 31

8:00 am Breakout Discussion Groups with Continental Breakfast
This session features discussion groups that are led by a moderator who ensures focused conversations around the key issues listed. Attendees choose to join a specific group, and the small, informal setting facilitates sharing of ideas and active networking. Details on the topics and moderators are available on the conference website.

NEOANTIGEN IDENTIFICATION AND SELECTION FOR PERSONALIZED IMMUNOTHERAPY

9:00 Chairperson's Remarks
Nathaniel Wang, PhD, Head, Vaccines and Therapeutics, Viral Systems, Synthetic Genomics, Inc.

9:05 An HLA-Agnostic Functional Neoantigen Discovery Platform for Personalized Cancer Vaccines
Stephen Schoenberger, PhD, Co-Director, San Diego Center for Precision Immunotherapy; Professor, La Jolla Institute for Allergy and Immunology
Accurate identification of patient-specific neoantigens (NeoAg) is essential to develop effective personalized cancer vaccines. We have developed WES/RNAseq-guided platform which combines a filtering algorithm based on sequencing metadata, rather than predicted HLA-binding, with *in vitro* functional T cell analysis. We report that >35% of selected expressed mutations can be verified as neoantigens in low mutational burden tumors by CD4+ and CD8+ T cells recognizing common activating mutations in driver oncogenes and numerous patient-specific "passenger" mutations.

9:35 Functional and Unbiased Neoantigen Calling as a Basis for Personalized Vaccines
Ezra Cohen, MD, Professor, Medicine, University of California, San Diego
Cancer presents a unique opportunity for the clinical application of precision immunotherapy due to the frequent expression of somatic mutations that can be recognized as tumor-specific neoantigens (NeoAgs) by a patient's T cells. Meaningful translation of this concept, however, has been hampered by the lack of reliable methods for identifying NeoAgs in cancers of low mutational burden and by the absence of suitable preclinical animal models for evaluating and optimizing the ability of NeoAg-specific T cells to recognize and eradicate autologous tumors. Through a collaborative effort within the San Diego Center for Precision Immunotherapy we have developed a set of novel bioinformatic and cellular tools which allows for the functional validation of NeoAg recognized by both CD4+ and CD8+ T cells at a higher rate than previously reported. This platform has allowed effective identification of NeoAg in solid tumors with low-to-moderate mutational burden through precision immunotherapy which is now being applied as a vaccine using synthetic long peptides.

Conference Programs

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Neoantigen Targeted Therapies, *continued*

10:05 Rapid High-Throughput Functional Selection of Neoantigens and Assessment of Their Safety

Dolores Schendel, CEO & CSO, Medigene

Neoantigens are an important class of highly specific target molecules for specific vaccine and TCR-based immunotherapies. Identification of neoantigens by next-generation sequencing and prediction of binding to the HLA allotypes of a patient, still leaves open the issue of actual immunogenicity and safety of neoantigen targets for therapeutic use. Medigene combines high throughput functional screening with sophisticated *in silico* tools to overcome several current limitations in selecting relevant neoantigens.

10:35 Coffee Break

11:00 Harnessing the Innate Immunogenicity of Foreign Viral Antigens to Fight Solid Tumors

David Anderson, PhD, CSO, Research & Development, VBI Vaccines, Inc.

CMV is expressed on over 95% of glioblastoma, medulloblastoma and breast cancers. Like neoantigens, it provides an opportunity to target a non-self antigen that has inherently higher immunogenicity than traditional tumor associated antigens. Recently CMV-specific autologous approaches have demonstrated over a 2X increase in overall survival in glioblastoma. VBI's approach utilizes its eVLP platform to restimulate CMV immunity by preferential uptake and presentation to dendritic cells. It offers an off-the-shelf approach to target CMV+ tumors.

11:30 Validation of Real Neoantigens with Mass Spectrometry

Harpreet Singh, PhD, President & CEO, Immatics US, Inc.

While neoantigens are a promising target class for immunotherapies in some patient populations, many researchers overlook that only a small fraction (presumably less than 1%) of all non-synonymous mutations are actually presented as pMHC targets and can thus act as neoantigens. Most strategies utilizing *in silico* prediction deliver more than 90% false-positive results. Such irrelevant antigens are currently often used in clinical trials and likely will not result in clinical benefit. Here, we show how Immatics' proprietary XPRESIDENT platform, an ultrahigh-sensitivity, high-throughput, high-fidelity mass spectrometry setup allows to validate real neoantigens. Furthermore, data from clinical applications of highly personalized applications is shown underlining the promise of tailored immunotherapies using both neoantigens and shared antigens.

12:00 pm A New Source of Highly Immunogenic Neoepitopes for Cancer Vaccines

Stephen Albert Johnston, PhD, Director, Center for Innovations in Medicine; Professor, School of Life Sciences, Biodesign Institute, Arizona State University; CEO, Calviri, Inc.

Mistranslation through microsatellites and mis-splicing produce 100x more neoantigens than DNA mutations. Frameshifts (FS) produced by mis-translation and splicing are highly immunogenic. These FS are protective in mouse models; humans and dogs with cancer raise immune responses to these FS, which can be detected using a rapid peptide array. In a mouse model this array-based system can be used to rapidly create a personal vaccine that shows protection.

12:30 Close of Neoantigen Targeted Therapies

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THURSDAY-FRIDAY | AUGUST 30-31

Adoptive T Cell Therapy 2: Development

Case Studies and Clinical Progress of CAR, NK, TCR, and TIL

THURSDAY, AUGUST 30

7:45 am Registration & Morning Coffee

HEMATOLOGIC CANCERS: CLINICAL PROGRESS

8:25 Chairperson's Opening Remarks
Amy Hines, BSN, RN, Director, Collection Network Management, Be The Match BioTherapies

8:30 FEATURED PRESENTATION: A Translational Perspective of Development of Yescarta (Axicabtagene Ciloleucel), a First-in-Class CAR T Cell Product for Diffuse Large B Cell Lymphoma
Adrian Bot, MD, PhD, Vice President, Translational Sciences, Kite, a Gilead Company
Yescarta (Axicabtagene Ciloleucel) is an anti-CD19 CAR T cell therapy that received approval for treatment of relapsing or refractory DLBCL. This presentation describes key elements of the translational program, correlates of toxicities and durable objective response, product characteristics, patient conditioning, and importance of tumor microenvironment. It also showcases major lessons learned and challenges in developing cell-based immunotherapies.

9:00 Presentation to be Announced

9:30 Predictors of Response to CD19-Specific CAR T Therapy in B-CLL
Jun Xu, PhD, Associate Director, Product Development Laboratory, Center for Advanced Cellular Therapeutics, Perelman Center for Advanced Medicine, University of Pennsylvania
To date, it has not been possible to identify patient- or disease-specific factors that predict why some B-CLL patients and not others have such dramatic responses to CAR T cell treatment. We explored the mechanisms associated with clinical response and lack of response to CAR T therapy, providing evidence for intrinsic T cell fitness in mediating durable anti-tumor responses and long-term complete remissions.

10:00 Coffee Break in the Exhibit Hall (Last Chance for Poster Viewing)

10:45 Facing the Challenges of Apheresis Network Management
Amy Hines, BSN, RN, Director, Collection Network Management, Be The Match BioTherapies
For companies working in cell therapies, managing and maintaining your apheresis (cell collection) network is a critical challenge. How do you know which center is best equipped to handle your needs? How do you evaluate their compliance with FDA and international regulations? Hines discusses the key questions to ask and gives you the tools you'll need to evaluate centers, secure your supply chain and advance your cell therapy program.

11:15 Solving the Challenges of Large-Scale GMP T Cell Manufacturing
Steven L. Highfill, PhD, Assistant Director, Product Development and Management, Center for Cellular Engineering, Clinical Center, National Institutes of Health
This presentation covers current, ongoing GMP manufacturing efforts at the NIH. Highlights focus on CAR T cell manufacturing and some of the challenges that we had to overcome specifically when using autologous patient-derived starting material. In addition, I discuss some newer closed-system manufacturing platforms that will make it easier for academic institutes to provide cell therapy options to their patients.

11:45 Sponsored Presentation *(Opportunity Available)*

12:15 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:45 Session Break

NEXT-GENERATION APPROACHES FOR SOLID TUMORS

1:40 Chairperson's Remarks
Adrian Bot, MD, PhD, Vice President, Translational Sciences, Kite, a Gilead Company

1:45 FEATURED PRESENTATION: Stress-Resistant T Cell Therapy for Solid Tumors
Prasad S. Adusumilli, MD, FACS, FCCP, Associate Attending and Deputy Chief, Thoracic Surgery; Head, Solid Tumors Cell Therapy, Cellular Therapeutics Center; Director, Mesothelioma Program, Memorial Sloan Kettering Cancer Center
CAR T cell therapy efficacy in solid tumors is limited by PD-1/PD-L1 pathway. We have shown that exhausted CAR T cells can be rescued by anti-PD1 agents or by a decoy receptor, PD-1 dominant negative receptor cotransduced with CAR T cells to promote functional persistence. The presentation focuses on cell-intrinsic and extrinsic methods in overcoming checkpoint blockade in cellular immunotherapy.

2:15 TRAP CAR T & Related Cell Therapies: Can Local Delivery Solve Efficacy and Safety Challenges in Solid Tumor Immuno-Oncology?
Janet R. Rea, MSPH, RAC, Senior Vice President, Regulatory, Quality & Clinical Affairs, Atossa Genetics
This presentation reviews cell therapy evolution and challenges. It includes considerations of local delivery options using breast cancer as a model.

2:45 Sponsored Presentation *(Opportunity Available)*

3:15 Refreshment Break

3:45 Eutilex's 4-1BB CTL Adoptive T Cell Therapy: Clinically Safe and First Efficacy in Solid Tumors
Agustin de la Calle, PhD, CBO, Eutilex Co., Ltd.
Eutilex's 4-1BB CTL therapy is the autologous T cell therapy proven safe in man without treatment-related toxicity and no CRS. Efficacy in hematological

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Adoptive T Cell Therapy 2: Development, *continued*

cancers and solid tumors: brain, breast, lung, tracheal, pancreatic cancers, CRC and melanoma. Complete remissions were observed in Hodgkin's and NK/T cell lymphomas. Phase I safety accepted single dose in terminal patients but relapsed patients became responsive again to further treatments. Leader in COGS: simple outpatient procedure.

4:15 Engineering NK Cells for Enhanced Potency and Persistence

James B. Trager, PhD, Senior Vice President, R&D, Nkarta, Inc.

NK cells form a first line of defense against cancer, and they can be formidable mediators of cytotoxicity and adaptive immunity. Efforts to maximize their potential as cancer therapeutics are hampered by difficulty in expanding NK cells, relatively short *in vivo* persistence, and the ability of tumor cells to evade NK recognition. We discuss recent progress in overcoming these barriers to successful therapeutic application of NK cells.

4:45 FEATURED PRESENTATION: Tricked-Out CARs: Next-Generation Approaches to Enhance and Optimize CAR T Cell Function

Benjamin Boyerinas, PhD, Senior Scientist, Immunotherapy, bluebird bio

Genetically engineered CAR T cells can be further engineered to survive and overcome immune evasion mechanisms employed by tumors. We have been developing a novel TGF-β signal conversion platform that provides a T cell supportive signal upon exposure to TGF-β within the hostile tumor microenvironment. This approach, combined with other methodologies such as gene editing and drug-regulated activation, have the potential to enhance specific activity within solid tumors.

5:15 End of Day

FRIDAY, AUGUST 31

8:00 am Breakout Discussion Groups with Continental Breakfast

This session features discussion groups that are led by a moderator who ensures focused conversations around the key issues listed. Attendees choose to join a specific group, and the small, informal setting facilitates sharing of ideas and active networking. Details on the topics and moderators are available on the conference website.

CLINICAL PROGRESS OF CAR, NK, TCR, AND TIL

9:00 Chairperson's Remarks

Paul Rennert, PhD, President & CSO, Aleta Biotherapeutics, Inc.

9:05 GOLD: Activation-Induced Payload Delivery for T Cell Therapies

Gus Zeiner, PhD, CSO, Chimera Bioengineering

GOLD is an endogenous post-transcriptional gene regulatory node that couples T cell metabolic states to transgenic payload outputs. Conditional payload expression is induced by signaling through either the native T cell receptor or a CAR. GOLD is payload-agnostic, and enforces low basal payload expression in resting T cells with a wide dynamic range in activated T cells. GOLD-mediated regulation is non-immunogenic, making GOLD-enabled T cell therapeutics compatible with long-term persistence.

9:35 Developing Tumor Infiltrating Lymphocytes for the Treatment of Cancer

Maria Fardis, PhD, President & CEO, Iovance Biotherapeutics

Iovance is developing tumor-infiltrating lymphocytes (TIL), a one-time cell therapy treatment that leverages and enhances the body's natural defenses against certain aggressive solid tumors. TIL is currently under investigation in several multi-center Phase II clinical trials and preliminary results have demonstrated safety and efficacy in melanoma, head and neck and cervical cancer patients with multiple prior therapies which constitutes unmet medical need.

10:05 PM21-NK Cells for Cancer Therapy

Robert Igarashi, PhD, President, CytoSen Therapeutics

CytoSen is advancing NK cell therapy for treatment of cancer. CytoSen's methods for stimulating NK cells with membrane bound (IL21), originally developed by Dr. Dean A. Lee, produces NK cells with high anti-tumor potency and can generate the highest doses. We plan to leverage our particle-based platform, that has logistical advantages, to pursue clinical studies in leukemia.

10:35 Coffee Break

11:00 A TCR-Based Chimeric Antigen Receptor

Even Walseng, PhD, Staff Scientist, Experimental Immunology Branch, National Cancer Institute, National Institutes of Health; Department of Immunology, Hospital Radiumhospitalet, Institute for Cancer Research, University of Oslo

TCRs have the advantage of targeting any peptide resulting from cellular protein degradation. To expand the horizon of TCR use, we have successfully fused a soluble TCR construct to a CAR-signaling tail. We demonstrate that the TCR-CAR redirection is not restricted to T cells and hence opens therapeutic avenues combing the killing efficiency of NK cells with the diversified target recognition of TCRs.

11:30 Hijacking CAR19 T Cells to Address Critical Issues in Cell Therapy: Application to Diverse Indications

Paul Rennert, PhD, President & CSO, Aleta Biotherapeutics, Inc.

The Aleta platform addresses critical issues in cell therapy including CAR persistence, antigen escape and antigen heterogeneity, and provides important solutions for treating both hematologic and solid tumors. The key element of our technology is the use of novel fusion proteins to redirect CAR T specificity. Our lead programs are directed to B cell malignancies, AML and solid tumors.

12:00 pm Close of Adoptive T Cell Therapy 2: Development

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Conference Programs

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THURSDAY, AUGUST 30

Immuno-Oncology Investing & Partnering Forum

Facilitating Partnering, Funding & Investment to Advance Immuno-Oncology Drugs

THURSDAY, AUGUST 30

7:45 am Registration and Morning Coffee

8:30 State of the Industry Keynote Presentation
Ilan Zipkin, PhD, Vice President, Business Development, Parker Institute for Cancer Immunotherapy

9:15 Investing in Immuno-Oncology Panel Discussion
In this panel discussion, private, public and strategic investors will discuss their investment strategies. Potential topics of discussion include: What does it take to get an immuno-oncology company funded? What are the benefits and risks of business models in devices, pharmaceuticals, diagnostics and information technology? What are today's deal terms and valuations? What are the best exit strategies?
Moderator: Margaux Stack-Babich, Program Manager, Immunotherapy Foundation
Panelists: James Healy, General Partner, Sofinnova Ventures
John Gustofson, Managing Director, AbbVie Ventures
Michael Gladstone, Principal, Atlas Venture

10:15 Networking Coffee Break in the Exhibit Hall

11:00 Partnering and Licensing in Immuno-Oncology
Big pharma, biotech and medtech need to act to capitalize new innovations that provide solutions to the global demands in healthcare. This insider panel will discuss their areas of interest for in-licensing novel therapeutics, devices and diagnostics and what they look for in a partner or investment.
Panelists: Claudina Stevenson, PhD, Director, Search and Evaluation, Oncology, AbbVie
Kaan Certel, PhD, Head, Oncology External Innovation, Global Business Development & Licensing, Sanofi
Maude Tessier, Executive Director, Business Development, Boston Innovation Hub, Merck

12:00 pm Enjoy Lunch on Your Own

1:30 Novel Therapeutics in Cancer Immunotherapy
In this session, we will hear from companies on the cutting edge. Novel drugs are being developed and commercialized, and new pathways are being discovered and targeted. Innovative technology is yielding benefits in development of diagnostics and treatments. Hear from leading companies on their approaches.
Panelists: Richard Purcell, Executive Vice President, Research and Development, Generex Biotechnology, Inc.
Robert Ang, MD, CBO, Neon Therapeutics
RJ Tesi, MD, CEO & CMO, INmune Bio

2:30 Networking Refreshment Break in the Exhibit Hall

3:15 Emerging Immuno-Oncology Targets
With record numbers of immunotherapies in active development, the importance of targets such as the tumor microenvironment is becoming clear. How do you determine what to target? Once you have a target, how do you deliver therapies effectively? This session will preview next-generation products and companies.
Panelists: Len Pagliaro, PhD, CEO, Siva Therapeutics, Inc.
Paul Rennert, President & CSO, Aleta Biotherapeutics, Inc.
Andrew Allen, MD, PhD, President & CEO, Gritstone Oncology, Inc.

4:15 Emerging Company Showcase
The inaugural Emerging Company Showcase offers the stage to young immuno-oncology companies to pitch their drug, device, diagnostic, or software to an audience of investors, CEOs, and executives in the field. Please view the event website for a full list of this year's presenters.
Participants: Charles Garvin, CEO, Riptide Bioscience, Inc.
Romain Micol, President, CEO, Co-Founder, Combined Therapeutics
Graham Allaway, PhD, CEO, Sonoval LLC
Michael Olin, PhD, CSO, OX2 Therapeutics
Additional Participants to be Announced

5:15 Networking Reception in the Exhibit Hall

6:30 Close of Immuno-Oncology Investing & Partnering Forum

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TUES, AUG 28 | 6:30 - 9:00PM: SC1: Bioinformatics for Immuno-Oncology and Translational Research
SC2: Next-Generation Immunotherapies: Part 1
WED, AUG 29 | 6:00 - 9:00PM: SC3: Next-Generation Immunotherapies: Part 2

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(Includes access ONLY to the 1-Day Partnering Forum, excludes conferences, short courses, and training seminars)

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Mon-Tue, Aug 27-28, 2018	Tue-Wed, Aug 28-29, 2018	Thu-Fri, Aug 30-31, 2018
C1A: Immunomodulatory Therapeutic Antibodies for Cancer	C1B: Bispecific Antibodies for Cancer Immunotherapy	C1C: Emerging Immuno-Oncology Targets
C2A: Rational Combination Cancer Immunotherapy	C2B: Preclinical and Translational Immuno-Oncology	C2C: Personalized Cancer Vaccines
C3A: Immuno-Oncology Biomarkers 1: Quantitative Immune Profiling and Immune Monitoring	C3B: Immuno-Oncology Biomarkers 2: Predictive Biomarkers and Companion Diagnostics	C3C: Neoantigen Targeted Therapies
C4A: Oncolytic Virus Immunotherapy	C4B: Adoptive T Cell Therapy 1: Discovery	C4C: Adoptive T Cell Therapy 2: Development
TS1: CAR T Engineering for Protein Scientists	TS2: Immunology for Drug Discovery Scientists	C5C: Immuno-Oncology Investing and Partnering Forum (Thursday Only)

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