Connecting the Immunotherapy Community to Drive Innovation and Collaboration

CAMBRIDGE HEALTHTECH INSTITUTE'S 9TH ANNUAL

Immuno-Oncology SUMMIT

IN-PERSON • VIRTUAL
FLEXIBLE REGISTRATION

October 4-6, 2021
WESTIN COPLEY PLACE | BOSTON, MA
& ONLINE (EDT)

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- Preclinical and Translational Immuno-Oncology
- Oncolytic Virus Immunotherapy

REGISTER EARLY FOR MAXIMUM SAVINGS!

Plenary Keynote Presenters

Zhen Su
CEO
Marengo Therapeutics

Kristen Hege
SVP, Early Clinical Development
Bristol-Myers Squibb

Keynote Speakers

Roy Baynes
SVP & Head, Global Clinical Development, CMO, Merck

Adrian Bot
VP & Global Head, Translational Medicine, Kite Pharma

Joshua Tan
Chief, Antibody Biology Unit
NAID, NIH

Stephen Pastores
Professor, Medicine
Memorial Sloan Kettering Cancer Center

David Rimm
Professor & Director, Pathology
Yale University School of Medicine

Stephen Russell
CEO, Vyriad

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About the Event

Over the past 9 years, CHI's Immuno-Oncology Summit has become the leading annual meeting focusing on the latest applied research, providing comprehensive and in-depth coverage across all modalities and stages in the pipeline. Every year, we assemble an international mix of thought leaders and decision makers from industry and academia to bring you the latest developments in immuno-oncology, while providing access to a comprehensive 3-day program and extensive networking opportunities that CHI's IO Summit provides.

2 Ways to Attend, 1 Shared Experience

Your safety and comfort are our priority.

To provide maximum flexibility to match your needs, CHI will provide this event live in-person and virtually. We feel this combination will bring about one truly unique event experience. This hybrid format will fuse the best of our traditional onsite events with the expanded benefits of a virtual conference. Bringing together the life sciences community is what CHI does, and we look forward to bringing our community together with this new offering.

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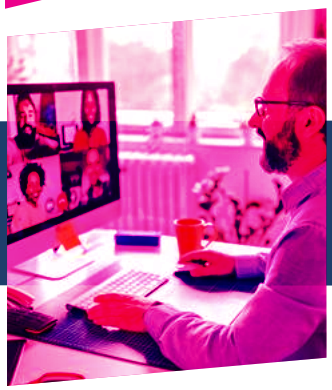
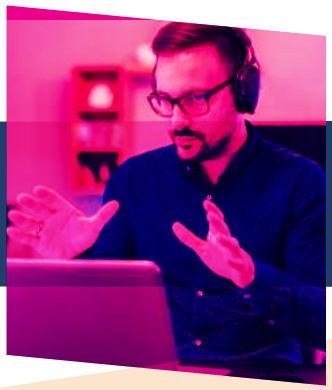

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- Recapture the power of serendipitous face-to-face connections with colleagues and technology providers who share similar interests and challenges
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Plenary Keynote Session

TUESDAY, OCTOBER 5

Advancing Precision Immuno-Oncology

4:20 pm Plenary Keynote Introduction

Benjamin G. Neel, MD, PhD, Professor, Medicine, NYU Grossman School of Medicine; Director, Laura and Isaac Perlmutter Cancer Center, NYU Langone Health

4:25 KEYNOTE PRESENTATION: The Rapid Evolution of Precision IO: The Future Role of Biomarkers in IO Development in Clinical Utilization

Zhen Su, MD, MBA, CEO, Marengo Therapeutics

As we turn the corner into a new decade, scientific and technological advances are helping to achieve a more precision approach for immunotherapy. While PD-L1 staining offers enrichment, mutation burden, microsatellite instability, and other immune biomarkers may be able to advance the precision approach. Evolution and real-world adaptation of testing tools, such as companion diagnostic capabilities, will become the new focal point to advance patient care.

4:55 KEYNOTE PRESENTATION: Lessons Learned from BCMA and CD19 CAR T Trials

Kristen M. Hege, MD, Senior Vice President, Early Clinical Development, Hematology/Oncology and Cell Therapy, Bristol-Myers Squibb

Dr. Hege will discuss drawing correlations between patient and product characteristics and clinical outcomes for iterative improvement; identifying variables associated with CAR T expansion and persistence; understanding mechanisms and predictors of non-response, durable response and tumor escape; and new directions for cell therapy.

MONDAY, OCTOBER 4

7:30 am Registration and Morning Coffee

BISPECIFIC CAR T CELLS

8:25 Chairperson's Remarks
Alison Crawford, PhD, Senior Staff Scientist, Oncology & Angiogenesis, Regeneron Pharmaceuticals

8:30 New Shark and Camel Nanobody-Based CAR T Cells Targeting PD-L1 and B7-H3
Mitchell Ho, PhD, Senior Investigator; Deputy Chief, Laboratory of Molecular Biology; Director, Antibody Engineering Program, National Cancer Institute (NCI), NIH
Our laboratory has constructed the V_HH and V_{NAR} single domain antibody phage display libraries from camels (Camelus dromedarius) and sharks (Ginglymostoma cirratum). In my talk, I will discuss (i) isolation of camel V_HHs and shark $V_{NAR}s$ against PD-L1 and B7-H3, (ii) characterization of CAR T cells derived from these single domain antibodies for treating solid tumors, and (iii) mechanisms of action related to NFkB and NFAT signaling pathways.

9:00 Bispecific Anti-CD20, Anti-CD19 CAR T Cells for Relapsed B Cell Malignancies
Nirav N. Shah, MD, Associate Professor, Hematology, Medical College of Wisconsin
Bispecific anti-CD20, anti-CD19 CAR T cells are being explored as a potential second generation cell therapy treatment for B-cell non-Hodgkin lymphoma. Unique to our program is utilization of a point-of-care CAR T cell manufacturing process with the Prodigy CliniMACS device and exploration of a fresh (non-cryopreserved) infusion of CAR T cells. We will review clinical outcomes of this vector, manufacturing platform, benefits of a fresh infusion, and future directions.

9:30 KEYNOTE PRESENTATION: Bispecific Antibodies Potently Neutralize SARS-CoV-2 Variants of Concern
Joshua Tan, PhD, Chief, Antibody Biology Unit, National Institute of Allergy and Infectious Diseases, National Institutes of Health
The emergence of SARS-CoV-2 variants of concern underscores the need for antibody-based tools that target multiple sites of the spike protein. We isolated 216 monoclonal antibodies and designed several bispecific antibodies that potently neutralize authentic SARS-CoV-2. Notably, two of nine bispecific antibodies neutralized the Alpha, Beta, Gamma and Delta variants and the wild-type virus with comparable potency. Thus, bispecific antibodies represent a promising next-generation countermeasure against SARS-CoV-2 variants of concern.

10:00 Session Break

COSTIMULATORY BISPECIFICS

10:30 Investigating CD3 Bispecific Treatment of Solid Tumors Using PSMAxCD3
Alison Crawford, PhD, Senior Staff Scientist, Oncology & Angiogenesis, Regeneron Pharmaceuticals
We generated a bispecific antibody that targets both the prostate tumor–specific antigen PSMA and CD3 (PMSAxCD3). Mice expressing the human CD3 and PSMA were generated to examine antitumor efficacy in the presence of an immune system. Although PSMAxCD3 showed antitumor efficacy in mice with low tumor burden, efficacy was less substantial against larger solid tumors. Addition of 4-1BB costimulation boosted efficacy against larger tumors, leading to durable antitumor responses.

11:00 Immunotherapy Combinations with Bispecific T Cell Engager Molecules Elicit Anti-Solid Tumor Regression in Immune 'Cold' Syngeneic Models Refractory to CTLA4/PD1 Checkpoint Blockade
Olivier P. Nolan-Stevaux, PhD, Senior Principal Scientist, Oncology, Amgen Inc.
Using immunocompetent mice and surrogate T cell engager (TCE) molecules, we demonstrate that pre-treatment tumor T cell density is critical to TCE anti-tumor efficacy, characterize the CD8+ T cell-polarized response to TCE therapy *in vivo*, uncover dual roles of CD4+ T cells in TCE efficacy, and identify therapeutic combinations that cause the regression of poorly T cell-infiltrated cold solid tumors refractory to immune checkpoint blockade therapy.

11:30 Preclinical Efficacy and Safety Screening of T Cell Engagers *In Vivo*
BIOCYTOGEN
Jenna Frame, Manager, Scientific Communications & Marketing, Marketing, Biocytogen
Mice expressing human immune checkpoints can serve as powerful preclinical models to evaluate the *in vivo* efficacy of anti-human antibody candidates for immuno-oncology targets. To ensure immunocompetence, knock-in humanized mouse models are carefully designed and subjected to rigorous validation. This session will highlight the use of humanized CD3E and CD3EDG models for broader targeting of the entire CD3 complex with novel mono- and bispecific antibody therapeutics.

12:10 pm Immunophenotyping of TCR and BCR clonotypes
CELLECTA
Alex Chenchik, President and Chief Scientific Officer, Cellecta, Inc.
TCR/BCR repertoire profiling holds great potential for understanding disease mechanisms. We introduce a novel technology for profiling of all human TCR and BCR variable regions and phenotypic characterization of immune cells in bulk and at the single-cell level in PBMCs and immune cell fractions. Preliminary data shows that TCR/BCR clonotype analysis combined with targeted expression profiling of immune cells can be applied for large-scale discovery in several immune-responsive model systems.

CONDITIONAL ACTIVATION

1:05 Direct Control of CAR T Cells through Small Molecule-Regulated Antibodies
Javier Chaparro-Riggers, PhD, Executive Director, BioMedicine Design, Pfizer
We develop conditionally activated CARs to improve the safety profile of CAR T cells. The tumor antigen recognition is directly modulated by an FDA-approved small molecule drug. The resulting CAR T cells demonstrate specific cytotoxicity of tumor cells comparable to that of traditional CARs, but the cytotoxicity is reversibly attenuated by the addition of the small molecule.

1:35 Conditionally Active T Cell Engager Engineered for the Treatment of Solid Tumors
Danielle Dettling, Senior Director, Research and Development, Maverick Therapeutics/Takeda Pharmaceuticals
Maverick has developed a novel recombinant bsAb platform called COBRA (Conditional Bispecific Redirected Activation). COBRAs are engineered to enable targeting of more widely expressed and validated tumor cell surface antigens by focusing T cell engagement within the tumor microenvironment. Maverick has (2) initial leads currently in clinical development, TAK-186 (EGFR-targeted COBRA), and TAK-280 (B7H3-targeted COBRA), which combined have the potential to treat a wide variety of solid tumor indications.

2:05 Humanized mouse model choices for immuno-oncology drug efficacy and toxicity evaluation
GemPharmatech models to defy impossible
Juan Liang, Scientist, Research and Development Department, GemPharmatech Co., Ltd.

The humanized mice capable of evaluation of tumor microenvironment *in vivo* have provided a unique platform for immuno-oncology drug tests. Genetically engineering mice and human immune system reconstituted mice show different features to facilitate drug evaluation, and model types related to efficacy and toxicity results. We'll present the pre-clinical model choice based on drug design exemplified by Fc dependent antibody and T cell engager and showing toxicity evaluation data.

2:20 Sponsored Presentation *(Opportunity Available)*

2:35 Exhibit Hall with Poster Viewing

SAFETY AND DMPK FOR BISPECIFIC ANTIBODIES

3:25 Anti-CD79b/CD3 T Cell Dependent Bispecific (TDB) for the Treatments of B Cell Malignancies: Impact Antibody Binding Properties on Pharmacokinetics and Pharmacodynamics

Rajbharan Yadav, PhD, Scientist, Development Sciences, Genentech

Preclinical studies demonstrated potency of anti-CD79b/CD3 TDB can be enhanced with increased binding affinity of either the anti-CD79b arm or the anti-CD3 arm. This evaluates the effect of CD3 binding affinities on PK and how it relates to the PD and safety. Anti-cynoCD79b/CD3 TDB was well tolerated, exhibited nonlinear PK consistent with target-mediated clearance (CL_{Total} range: 42-315 mL/day/kg) and resulted in dose-dependent B cell depletion.

3:55 Development of Bispecific Antibodies against Solid Tumors Using DDS and Molecular Imaging

Masahiro Yasunaga, MD, PhD, Chief, Division of Developmental Therapeutics, National Cancer Center, Japan

In vivo imaging revealed three types of phenotypes: (1) good accumulation of both antibodies and T cells, (2) good antibody delivery but suppressed T cell migration, and (3) suppression of both antibodies and T cells. In solid tumors, (2) and (3) were predominant. Moreover, exhausted T cells could attenuate BsAb efficacy. We are developing BsAb therapy combined with immunoregulation to overcome T cell deserts and exhaustion in the tumor microenvironment.

4:25 Close of Day

TUESDAY, OCTOBER 5

8:00 am Registration and Morning Coffee

EMERGING BI- AND MULTI-SPECIFIC PLATFORMS AND FORMATS

8:30 PM-IL15: A Novel IL-15-Based Immunocytokine with Unique Tumor Targeting Properties via Glycoepitope Recognition

Anika Jäkel, PhD, Director, Preclinical Pharmacology and Cancer Immunology, Glycotope, Germany

Glycoepitopes are potent targets for tumor therapeutics due to their unique tumor-specificity and broad indication coverage. We developed an IL-15-based immunocytokine (PM-IL15) targeting a conformational induced glycosylation/protein combined epitope (glycoepitope) on MUC1. PM-IL15 is designed to induce anti-tumor responses directly within the tumor microenvironment. It has high potential for the treatment of solid tumors either as monotherapeutic agent or as valuable combination partner for different anti-cancer drugs.

9:00 Augmented Bispecific Antibody-Based Anticancer Therapeutics Boost Neutrophil Cytotoxicity

Marjolein van Egmond, PhD, Professor, Oncology and Inflammation, Amsterdam UMC, The Netherlands

IgG mAbs eliminate tumor cells through NK cell-mediated ADCC and macrophage-mediated antibody-dependent phagocytosis. IgG, however, ineffectively recruits neutrophils as effector cells. By contrast, IgA mAbs induce neutrophil migration and activation through the IgA Fc receptor (FcaRI), but do not activate NK cells and have poorer half-life. We combined the agonistic activity of IgG mAbs and FcaRI targeting in a bispecific antibody, and results with this novel molecule will be discussed.

9:30 Sponsored Presentation *(Opportunity Available)*

10:00 Exhibit Hall with Poster Viewing

10:40 Tumor-Localizing Bispecific Antibodies

Peter Ellmark, PhD, Vice President, Discovery, Alligator Bioscience AB

Bispecific antibodies have the potential to provide new options in indications where checkpoint inhibitors fail. A new promising class of tumor associated antigen (TAA) conditionally active agonistic bispecific antibodies that targets CD40 and 4-1BB has recently emerged as a promising approach to enhance T cell priming and activity in immuno-oncology. Alligator develops bsAbs targeting both TAA x CD40/TAA x 4-1BB and data from these programs will be presented.

11:10 Molecular Mechanism of HER2 Rapid Internalization and Redirected Trafficking Induced by Anti-HER2 Biparatopic Antibody

Inna Vainshtein, PhD, Senior Director, Bioanalytics, Exelixis

Receptor-mediated internalization is an essential part of MOA for antibody-drug conjugates (ADC). A bispecific format of ADC may affect its internalization properties. Contrary to parental arm antibodies a biparatopic anti-HER2 antibody (anti-HER2-Bs), targeting two non-overlapping epitopes on HER2, induced rapid internalization and efficient degradation of receptors. Our study investigated the molecular mechanism of rapid internalization and redirected trafficking providing insights in drug MOA and rational design of bispecific molecules.

11:40 CD38-CD3 Bionics in AML Treatment

Flavia Pichiorri, PhD, Associate Professor, Hematologic Malignancies Translational Science, Briskin Center for Multiple Myeloma Research, City of Hope

On the basis of technology developed at City of Hope, we have developed CD38-CD3 Biologics Nested Inside Chains (BIONICS), which comprise a CD38 nanobody linked to an anti-CD3 antibody via a short peptide linker. Our data show that CD38-CD3 BIONICS induces remarkable T cell activation and can eradicate acute myelogenous leukemia (AML) cells not only *in vitro* but also *ex vivo* in autologous patient setting and *in vivo* animal models.

12:10 pm Close of Bispecific Antibodies for Cancer Immunotherapy

MONDAY, OCTOBER 4

7:30 am Registration and Morning Coffee

ADVANCING PRECISION MEDICINE WITH LIQUID BIOPSY

8:25 Chairperson's Opening Remarks

Sam Hanash, MD, PhD, Director, Red & Charline McCombs Institute; Evelyn & Sol Rubenstein Distinguished Chair, Cancer Prevention; Professor, Clinical Cancer Prevention-Research, Translational Molecular Pathology, University of Texas MD Anderson Cancer Center

8:30 Circulating Exosomes and Their Cargo as Immuno-Oncology Biomarkers

Sam Hanash, MD, PhD, Director, Red & Charline McCombs Institute; Evelyn & Sol Rubenstein Distinguished Chair, Cancer Prevention; Professor, Clinical Cancer Prevention-Research, Translational Molecular Pathology, University of Texas MD Anderson Cancer Center

There is currently substantial interest in liquid biopsy approaches to profile tumors. Profiling of the exosome surfaceome and cargo has yielded immuno-oncology biomarkers that inform about tumor status and potential response to immunotherapy.

9:00 Small Extracellular Vesicles (sEV) in Plasma of Cancer Patients as Contributors to Liquid Tumor Biopsy

Theresa L. Whiteside, PhD, Professor, Pathology, Immunology & Otolaryngology, University of Pittsburgh

Exosomes, a subset of small EVs, are emerging as key components of liquid tumor biopsy and as biomarkers of immune competence. Plasma-derived exosomes can be separated by immune capture into tumor cell-derived and T cell-derived fractions. Each fraction carries information about the tumor or immune competence of the cancer patient. Simultaneous real-time molecular profiling of the tumor and host immune status by plasma-derived exosomes suggest that sEVs are promising biomarkers.

9:30 Liquid Biopsy to Guide Immunotherapy

Catherine Alix-Panabières, PhD, Associate Professor and Director, Laboratory of Rare Human Circulating Cells (LCCRH), University Medical Center of Montpellier, France

The emergence of immunotherapy in oncology requires the discovery, validation and adoption of robust, sensitive and specific predictive and prognostic biomarkers for daily practice. The use of a liquid biopsy could provide an important complementary or alternative added value to PD-L1 detection in tissue biopsy. I will discuss how liquid biopsy could be used in the field of immuno-oncology to predict response or relapse for patients undergoing immune-checkpoint inhibitor therapy.

10:00 Accelerating The Next Generation Of Immune Medicine With Cellular Proteomics isoplexis

Michael Brenan, Proteomics Specialist, IsoPlexis

10:15 Session Break

PREDICTING CLINICAL OUTCOME

10:30 Analysis of Peripheral Blood Markers in Patients Receiving Checkpoint Blockade: Pretreatment Characteristics and On-Treatment Pharmacodynamics

Margaret K. Callahan, MD, PhD, Medical Oncologist, Memorial Sloan Kettering Cancer Center

Using data generated from immune profiling of peripheral blood samples collected from ICB-treated patients, we applied a novel supervised statistical learning approach to classify phenotypes and determine their association with survival and treatment response. We will describe how baseline characteristics of T cells in the peripheral blood associate with clinical outcomes.

11:00 Activated Natural Killer Cells Predict Poor Clinical Prognosis in High-Risk B- and T-Cell Acute Lymphoblastic Leukemia

Caroline Duault, PharmD, PhD, Research Scientist, Institute for Immunity, Transplantation and Infection, Stanford School of Medicine

B- and T- cell acute lymphoblastic leukemia (B/T-ALL) may be refractory or recur after therapy by suppressing host anti-cancer immune surveillance mediated specifically by natural killer (NK) cells. The comprehensive analysis of the NK cell phenotype and functions in ALL patients highlighted the relevance of developing NK cells as diagnostic and prognostic tool to predict clinical outcome and underscore the clinical potential of allogeneic NK infusions to prevent ALL recurrence.

11:30 The Spatial Relationship of TiME in an era of Digital Pathology ULTIVUE

Keith Wharton, MD PhD FCAP, Vice President, Medical Director, Ultivue

Utility of multiplex immunohistochemistry/immunofluorescence (mIHC/IF) highlights the spatial distribution of infiltrating immune cells within the tumor immune microenvironment that allow a detailed characterization of specific cell phenotypes defined by co- or lack of expression of multiple markers that may help in predicting clinical responses and mechanisms of resistance to therapy. In this presentation we will show a unique workflow supporting whole slide imaging of a high-plex mIF and traditional same slide H&E for comprehensive tissue immunophenotyping analysis.

12:00 pm Session Break

12:10 Immunophenotyping of TCR and BCR clonotypes CELLECTA

Alex Chenchik, President and Chief Scientific Officer, Cellecta, Inc.

TCR/BCR repertoire profiling holds great potential for understanding disease mechanisms. We introduce a novel technology for profiling of all human TCR and BCR variable regions and phenotypic characterization of immune cells in bulk and at the single-cell level in PBMCs and immune cell fractions. Preliminary data shows that TCR/BCR clonotype analysis combined with targeted expression profiling of immune cells can be applied for large-scale discovery in several immune-responsive model systems.

BIOMARKER STRATEGIES IN CANCER IMMUNOTHERAPY

12:45 Chairperson's Remarks

Alain Algazi, MD, Associate Professor, Medicine, University of California, San Francisco

12:50 Translational Research Insights Leveraging Predictive Biomarkers of Response to Anti-PD-1 Therapy

Terri K. McClanahan, PhD, Executive Director, Molecular Discovery Biologics, Merck Research Labs

Pan-cancer molecular biomarkers of immunotherapy response can identify patients likely to derive benefit from PD-1/PD-L1-directed monotherapy. Clinical genomic data has also illuminated mechanisms of resistance to immunotherapy which can be leveraged to drive rational combinations and novel drug discovery. Data will be presented showing key determinants of response to pembrolizumab across multiple tumor types, as well as emerging resistance signatures, which provide a framework for novel approaches to cancer therapy.

1:20 Dissecting Mechanisms of Resistance to PD-1/PD-L1 Blockade in Bladder Cancer

Matthew D. Galsky, MD, Division of Hematology and Medical Oncology, Professor of Medicine, Icahn School of Medicine at Mount Sinai; Associate Director, Translational Research, Tisch Cancer Institute

Several biomarkers associated with response and resistance to immune checkpoint blockade in urothelial cancer have been described. However, how these different cancer cell, stromal, and immune cell features are interrelated, and which are independently associated with outcomes, are not well defined. Approaches to identify independent features associated with immune checkpoint blockade outcomes for prioritization as biomarkers and therapeutic targets will be described.

1:50 Biomarker Strategies in Cancer Immunotherapy PRECISION for medicine

Darren Davis, Senior Vice President, Precision for Medicine

Tumor biopsies and advanced multiplex immunofluorescence enable quantification of immune cell subsets including their precise placement within the tumor microenvironment—yet getting samples can put patients at risk. Liquid biopsies are less invasive and enable monitoring of circulating biomarkers. In this presentation, we will show an innovative strategy utilizing liquid biopsies to assess biomarkers in both circulating tumor cells (CTCs) and peripheral immune cells from the same patient sample.

2:05 Diagnostic Tests for Prediction of Response to Immune Checkpoint Inhibitors in Lung Cancer biodesix

Robert Georgantas, PhD, Senior Vice President of Research and Translational Science, Biodesix

AI and Machine Learning (AI/ML) have enabled the development of diagnostic tests using unbiased -omics level data. In this presentation, we focus on the use of unbiased liquid biopsy-based proteomics for the development of diagnostic tests that predict response of lung cancer patients to immune checkpoint inhibitors (ICIs). Finally, we will introduce methods in translational science to examine the biologic underpinnings that drive test outcomes.

2:35 Exhibit Hall with Poster Viewing

INFORMING CLINICAL DEVELOPMENT

3:25 Evaluating Biomarkers of JTX-8064 (Anti-LILRB2/ILT4 mAb) to Inform Clinical Development

Johan Baeck, MD, Senior Vice President, Clinical Development and Medical Affairs, Jounce Therapeutics

JTX-8064 is a LILRB2/ILT4 antagonist mAb that may relieve myeloid cell immunosuppression by shifting macrophages to an M1-like state and activating T cells. Using histoculture, pharmacodynamic (PD) responses to JTX-8064 can be measured preclinically in a human *ex vivo* tumor system. *Ex vivo* evaluation of human tumors identified hypotheses for both predictive and pharmacodynamic markers that can be evaluated in the clinical development of JTX-8064.

3:55 Durable Responses and Immune Activation with Intratumoral Electroporation of pIL-12 Plus Pembrolizumab in Actively Progressing Anti-PD-1 Refractory Advanced Melanoma: KEYNOTE 695 Interim Data

Alain Algazi, MD, Associate Professor, Medicine, University of California, San Francisco

In patients with rigorously defined anti-PD-1 refractory advanced melanoma, we show that increasing intratumoral IL-12 through plasmid electroporation induced deep, durable, systemic responses including regression of visceral lesions with nominal systemic toxicity. This work represents the final stage of translation of our earlier biomarker findings using an approach that adds negligible toxicity to standard-of-care checkpoint inhibitor therapy.

4:25 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page for a complete listing of topics and descriptions.

Immuno-Oncology Biomarkers

Interactive Discussion: Immuno-Oncology Biomarkers

Tullia C. Bruno, PhD, Assistant Professor, Immunology, University of Pittsburgh & Hillman Cancer Center

5:15 Close of Day

TUESDAY, OCTOBER 5

8:00 am Registration and Morning Coffee

PREDICTING RESPONSE AND RESISTANCE TO IMMUNOTHERAPY

8:25 Chairperson's Remarks

Evisa Gjini, PhD, MBA, Director, Solid Tumors Oncology, Translational Medicine, Bristol-Myers Squibb

8:30 KEYNOTE PRESENTATION: Current and Future Methods of Predicting Response to Immunotherapy

David L. Rimm, MD, PhD, Professor, Pathology and Medicine (Oncology); Director, Translational Pathology, Yale University School of Medicine

Companion diagnostics for immunotherapy are not very sensitive or specific, but sufficient to enrich the population of responders to immunotherapy. This session will take a closer look at the only FDA approved methods (IHC and TMB) and then examine some data on potential future methods.

9:00 Mechanistic Basis of Response to PD-1 Blockade

Adil Daud, MD, Professor, Hematology/Oncology, University of California, San Francisco; Director, Melanoma Clinical Research, UCSF Helen Diller Family Comprehensive Cancer Center

The use of checkpoint inhibitors for cancer has revolutionized immunotherapy. Certain features of immunotherapy are clear: tissue type, obesity, age, gender, tissue of origin, tumor mutation burden and most importantly the presence of tumor-directed T cells in the tumor microenvironment are critical features. I explore recent publications showing T cell replacement and replenishment as a critical feature and the interesting data from tumor models that informs immunotherapy.

9:30 Measurement of Activity of Signal Transduction Pathways in Individual Patient Tissue and Blood Samples to Quantify Innate and Adaptive Immune Response and Predict Response to Immunotherapy PHILIPS

Anja van de Stolpe, Chief Scientific Officer, Philips Molecular Pathway Diagnostics

Signal transduction pathways control the functional state of the different immune cell types. OncoSignal RT-qPCR tests quantify the activity of signaling pathways in immune cells from blood or tissue samples. Tests can be used to assess activation

of the innate and adaptive immune response, enabling use to predict and monitor response to immunotherapy. OncoSignal-based companion diagnostics will be commercialized in a partnership with QIAGEN.

10:00 Exhibit Hall with Poster Viewing

10:40 Understanding Mechanisms of Resistance to Therapy in Prostate Cancer

Evisa Gjini, PhD, MBA, Director, Solid Tumors Oncology, Translational Medicine, Bristol-Myers Squibb

Prostate cancer (PCa) is primarily driven by androgen receptor signaling, with treatment dominated by androgen depravation therapies. Although the prognosis for low-grade localized PCa is favorable, about half of patients with high-grade localized disease develop metastatic castration resistant PCa. We have identified a subset of high-grade PCa patients who relapse under SOC that may benefit from the addition of adjuvant immune checkpoint blockade to SOC to overcome immune suppression.

11:10 Multimodality Assessment of Melanoma Immunotherapy Response and Resistance

Genevieve Boland, MD, PhD, Assistant Professor, Surgery; Director, Melanoma Surgery Program, Massachusetts General Hospital

Despite progress in melanoma treatment with immunotherapy, many patients develop resistance and succumb to their disease. Analysis of patient-derived tumors and blood samples have allowed us to understand mechanisms of therapeutic response and resistance. We are using multi-omic strategies to identify novel therapeutic targets and biomarkers to assist in risk stratification and disease management.

11:40 Use of Machine Learning in Predicting Immune Therapy Response

Iman Osman, MD, Rudolf L. Baer Professor of Dermatology, Professor, Medicine & Urology, New York University Langone Medical Center

Several biomarkers of response to immune checkpoint inhibitors show potential but are not yet scalable to the clinic. We developed a pipeline that integrates deep learning on histology specimens with clinical data to predict ICI response in melanoma. We built a multivariable classifier that predicted response with AUC 0.80. With prospective validation, we believe our approach has potential for integration into clinical practice.

12:10 pm Close of Immuno-Oncology Biomarkers

MONDAY, OCTOBER 4

7:30 am Registration and Morning Coffee

RECENT ADVANCES IN CELL-BASED THERAPY

8:25 Chairperson's Opening Remarks
Paul D. Rennert, PhD, President & CSO, Aleta Biotherapeutics

8:30 Development of First-in-Class Genetically Engineered T Cells: Lessons Learned
Adrian Bot, PhD, Vice President and Global Head, Translational Medicine, Kite Pharma, a Gilead Company
CAR T cell therapy against CD19 showed considerable promise in B cell malignancies. In Non-Hodgkin's lymphoma, evidence to date points to a subset of ≈40% of patients showing durable complete response years post-treatment, with evidence of normal B cell recovery. Detailed translational analysis uncovered product and tumor related features that may determine durable efficacy, with impact on next generation interventions.

TARGETING SOLID TUMORS

9:00 Cell Therapy for Solid Tumors
Sabina Adhikary, PhD, Principal Scientist, Translational Medicine, Kite Pharma, A Gilead Company
T cell receptor engineered T cells are attracting tremendous interest in the treatment of epithelial cancers. Their ability to target intracellular proteome can be directed against shared tumor associated antigens, such as cancer testes antigens and viral oncoproteins. Emerging data point to clinical activity of these engineered T cells in various epithelial cancers, as well as potential mechanisms of treatment evasion that may help inform on future treatment optimizations.

9:30 Development of TAC-T Cells for Treatment of Solid Tumors
Sabine Chlosta, MD, PhD, CMO, Triumvira Immunologics
Triumvira develops autologous and allogeneic T cell therapies engineered with the T cell Antigen Coupler (TAC) receptor that redirects T cells to the respective antigen on tumor cells and activates T cells by co-opting the endogenous T cell receptor complex independently of MHC. Preclinical models have shown tumor clearance with minimal toxicity. A Phase I/II trial with TAC01-HER2 for patients with solid tumors is ongoing.

10:00 Session Break

10:30 How to Build CARs that Run Over Tumors–Recipes for Successful Cell Therapy
Paul D. Rennert, PhD, President & CSO, Aleta Biotherapeutics
Much attention has been on the potential for allogeneic cell therapeutics yet other fundamental issues remain. These include cell fitness, cell expansion and persistence, tumor heterogeneity and immunosuppression. The solutions I will discuss confront these critical issues to drive cell therapy to succeed in more hematologic cancer patients and to break through to meaningfully treat solid tumor indications.

11:00 Chimeric Antigen Receptor Macrophages for Cancer Immunotherapy
Michael Klichinsky, PharmD, PhD, Co-Founder & Vice President, Discovery, Carisma Therapeutics
While immunotherapies have had a revolutionary impact on cancer care, adoptive cell therapy has thus far been limited in the solid tumor space. In this talk, Carisma Therapeutics' proprietary CAR-M (chimeric antigen receptor macrophage) cell therapy platform will be reviewed, with a focus on preclinical solid tumor data and a discussion of the ongoing first-in-class, first-in-human CAR-M clinical trial evaluating CT-0508 for HER2+ solid tumor patients.

11:30 Cellular Analysis Workflows and Tools for Development and Manufacturing of Immunotherapies
Agilent Trusted Answers
Yama A. Abassi, Head of Business and Assay Development, Cell Analysis, Agilent Technologies
The intersection of cell biology and engineering and biomedical sciences is giving rise to next generation immunotherapies with transformative impact on cancer treatment. These approaches require analytical tool which could analyze critical functional aspects of these therapies during development and manufacturing. Agilent Technologies is well poised to support the growing number of immunotherapy workflows from early discovery to production. We will discuss these workflows, measurement modalities and new standards to inform, validate and qualify every step of the process.

12:00 pm Session Break

12:10 Immunophenotyping of TCR and BCR clonotypes
CELLECTA
Alex Chenchik, President and Chief Scientific Officer, Cellecta, Inc.
TCR/BCR repertoire profiling holds great potential for understanding disease mechanisms. We introduce a novel technology for profiling of all human TCR and BCR variable regions and phenotypic characterization of immune cells in bulk and at the single-cell level in PBMCs and immune cell fractions. Preliminary data shows that TCR/BCR clonotype analysis combined with targeted expression profiling of immune cells can be applied for large-scale discovery in several immune-responsive model systems.

ADVANCING NK-CELL THERAPY

1:00 Chairperson's Remarks
Bruce J. McCreedy, PhD, CSO, Myeloid Therapeutics

1:05 NK Cell-Cancer Immunity Cycle and Advances in NK Cell Targeting and CAR NK Cells
Nicholas Huntington, PhD, Co-Founder and CSO, oNKo-Innate Pty Ltd.
Emerging data show a role for intratumoural NK cells in driving immunotherapy response and, accordingly, there have been renewed efforts to further elucidate and target the pathways controlling NK cell antitumour function. I discuss how the role of NK cells evolves with tumour progression, presenting new opportunities to target NK cell function to enhance cancer immunotherapy response rates across a more diverse range of cancers.

1:35 Development of Engineered Natural Killer Cells as Off-the-Shelf Cancer Therapies
James B. Trager, PhD, CSO, Nkarta Inc.
Natural Killer (NK) cells are innate immune cells that can eliminate target cells in an antigen-independent fashion. NK cells can be engineered to express chimeric antigen receptors (CARs), armored to exhaustion, and expanded under optimized conditions, and gene edited to further enhance cytotoxicity, selectivity, and persistence. Nkarta is developing off-the-shelf CAR NK cells that maximize the therapeutic potential of allogeneic NK cells alone or in combination with other agents.

2:05 Cellular Avidity to Tumor Cells is a Key Driver for the Functioning of Engineered T Cells
LUMICKS
Will Singleterry, PhD, Commercial Director - Immuno-Oncology at LUMICKS, LUMICKS
Recent studies have revealed that CARs and TCRs do not need highest affinity for best performance. Instead, CAR-T cells require suboptimal cell avidity while TCR-T cells do best having high avidity to their target. Here, we'll present the first CAR-T cell studies revealing correlation between avidity and *in vivo* tumor reduction and cell function, and discuss how avidity can become the key quality attribute used for cell product release to patients.

2:35 Exhibit Hall with Poster Viewing

LATEST ADVANCES IN MYELOID CELLS, TILs

3:25 ATAK Engineered Myeloid Cells for the Treatment of Solid Tumors

Bruce J. McCreedy, PhD, CSO, Myeloid Therapeutics

The immunosuppressive tumor microenvironment (TME) of solid tumors is a barrier to cellular and immunotherapies. Myeloid cell-derived tumor associated macrophages (TAMs) accumulate in tumors but frequently are co-opted by tumors cells into supporting tumor growth. We developed the Activate, Target, Attack & Kill (ATAK) myeloid cell platform to engineer myeloid cells to recognize and phagocytize tumor cells as well as orchestrate a broad anti-tumor immune response against solid tumors.

3:55 Toward Commercializing Tumor Infiltrating Lymphocyte Cell Therapy for Treatment of Solid Tumors

Madan H. Jagasia, Senior Vice President, Medical Affairs, Iovance Biotherapeutics

Iovance is currently conducting pivotal studies in patients with metastatic melanoma and advanced cervical cancer. In addition, the company's TIL therapies are being investigated for the treatment of patients with locally advanced, recurrent or metastatic cancers including head and neck and non-small cell lung cancer.

4:25 Interactive Discussions

Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around topics related to the conference program.

5:15 Close of Day

TUESDAY, OCTOBER 5

8:00 am Registration and Morning Coffee

ADVANCES IN SOLID TUMORS, ALLOGENEIC THERAPY

8:25 Chairperson's Remarks

Dongfang Liu, PhD, Associate Professor, Director Immunoassay Development, Pathology & Immunology & Lab Medicine, Rutgers University

8:30 A Novel Multi-Specific CD4+ CTL Therapy for B Cell Malignancies: Preclinical and Translational Studies

Baochun Zhang, PhD, Assistant Professor, Medical Oncology, Dana Farber Cancer Institute

CD8+ CTL-based therapies, including CD19-targeted CAR T cell therapy, have seen substantial limitations in B cell malignancies, producing durable remissions only in less than one-half of treated patients. Here, we present a novel form of immunotherapy for B cell malignancies using multi-specific CD4+ CTLs with superior ability for *in vivo* persistence, and discuss results from preclinical and translational studies.

9:00 CAR-NK for Solid Tumor

Dongfang Liu, PhD, Associate Professor, Director Immunoassay Development, Pathology & Immunology & Lab Medicine, Rutgers University

We are developing a novel immunotherapy for hepatocellular carcinoma (HCC), the most common type of liver cancer. Our approach is to re-engineer Natural Killer (NK) cells – which are native to the human immune system – to target the specific cancer cell marker CD147, and thereby kill the cancer cells more effectively and safely than existing treatments.

9:30 Utilizing point of care processing for adoptive cell therapy orgenesis

Eyal Neria, Scientific Director Immuno-Oncology & Viral Disease, Orgenesis INC

Orgenesis' point of care platform (POCare) is a decentralized processing approach for cell and gene therapies. Advantages include simplified logistics, scalability, rapid response to patient needs and reduced cost. We will present our strategy incorporating mobile processing solutions to minimize physical infrastructure with integrated closed automated processing systems. We will present a case study of an adoptive cell therapy with tumor infiltrating lymphocytes for solid cancers in adult and pediatric indications.

10:00 Exhibit Hall with Poster Viewing

PRECLINICAL AND CLINICAL UPDATES

10:40 Double-Blind Randomized Clinical Trial Demonstrates Therapeutic Evidence of RFS/OS Benefit of Gemogenovatucel-T (Vigil), a Triple Function Immunotherapy in Advanced Ovarian Cancer Treatment

John J. Nemunaitis, Co-Founder & CSO, Medical Affairs, Gradalis. Inc.

Phase I/II trial results of Vigil involving 233 cancer patients and 1433 doses demonstrate safety, mechanism and optimization of dose schedule. Results of Phase 2a/2b trials validate improved RFS and OS in advanced OC patients with BRCA wild-type (BRCA-wt) molecular profile and enhanced response in homologous recombination proficient (HRP) subset population. Combination therapy with atezolizumab and/or BRCA-wt/HRP subset with TP53 mutation support broad treatment application involving solid tumor malignancies.

11:10 Cancer & COVID-19: Cellular Therapeutic Interventions for an Immunological Paradigm

Yan Leyfman, MD, Director, Immunology Division, Global COVID-19 Taskforce

Due to their immunocompromised status, cancer patients are at an increased risk for severe SARS-CoV-2 infection, which causes systemic injury through IL-6-mediated inflammation. We present a model to explain the mechanistic interplay between both conditions with clinical evidence. We also evaluate the efficacy of novel therapies in clinical trials, including a promising cellular therapy that received FDA fast track designation.

11:40 Close of Cell-Based Immunotherapies

TUESDAY, OCTOBER 5

12:30 pm Registration

IMPROVING IMMUNOTHERAPY SPECIFICITY AND SAFETY

1:25 Chairperson's Remarks

Tony R. Arulanandam, DVM, PhD, Consultant, Immuno-Oncology and Co-Founder NextPoint Therapeutics

1:30 KEYNOTE PRESENTATION: Toxicities Associated with Immunotherapy and Approach to Cardiotoxicity with Novel Cancer Therapies

Stephen M. Pastores, MD, Professor, Medicine, Memorial Sloan Kettering Cancer Center

The recent advent of targeted agents and immunotherapies (immune checkpoint inhibitors [ICIs] and chimeric antigen receptor [CAR] T cell therapy) have led to improved quality of life and survival rates in many patients with cancer. This presentation will focus on the clinical features and grading and management of toxicities associated with ICIs and CAR T cell therapy in the critical care setting.

2:00 Immune Checkpoint Inhibitor Toxicities: Systems-Based Approaches to Improve Patient Care and Research

Douglas B. Johnson, MD, Assistant Professor, Medicine, Ingram Cancer Center, Vanderbilt University Medical Center

Immune checkpoint inhibitors are transforming cancer care, but also cause immune-related adverse events (irAEs). A robust clinical and research framework is critical to developing effective institutional strategies for patient management, defining evidence-based management strategies, and uncovering mechanistic insights into irAEs. Here, we will present insights as we have implemented these systematic approaches, as well as clinical and translational findings gained within this framework.

2:30 Engineering Considerations for Antibody Subclass Selection

Andrew Crowley, Researcher, Engineering, Dartmouth College

Altering the subclass of an otherwise identical monoclonal IgG lineage can significantly impact the half-life, receptor binding affinity, and effector function potential of the antibody. To date however, only a small part of the raw material that occurs naturally as IgG subclass and allotype has been used for engineering therapeutic antibodies. These allelic variants potentially offer a means of finely tuning IgG for a range of clinically desirable properties.

3:00 Accelerating Immunotherapy Drug Development with Simple Cell-Based Assays for Immune Checkpoint Receptors

Jennifer Lin-Jones, Senior Group Leader, Assay Development, Eurofins DiscoverX

The development of immunotherapy drugs as an effective strategy for combating cancer is an area of intense research with the need for assays for testing biologics and small molecules that modulate immune checkpoint receptors. Here we will highlight easy-to-use, cell-based assays as an effective tool for screening and characterizing candidate therapeutics for clinically relevant inhibitory and co-stimulatory checkpoint receptor targets – SIRPα and PD-1.

3:30 Exhibit Hall with Poster Viewing

4:10 Transition to Plenary Keynote

PLENARY KEYNOTE SESSION: ADVANCING PRECISION IMMUNO-ONCOLOGY

4:20 Plenary Keynote Introduction

Benjamin G. Neel, MD, PhD, Professor, Medicine, NYU Grossman School of Medicine; Director, Laura and Isaac Perlmutter Cancer Center, NYU Langone Health

4:25 KEYNOTE PRESENTATION: The Rapid Evolution of Precision IO: The Future Role of Biomarkers in IO Development and Clinical Utilization

Zhen Su, MD, MBA, CEO, Marengo Therapeutics

As we turn the corner into a new decade, scientific and technological advances are helping to achieve a more precision approach for immunotherapy. While PD-L1 staining offers enrichment, mutation burden, microsatellite instability, and other immune biomarkers may be able to advance the precision approach. Evolution and real-world adaptation of testing tools, such as companion diagnostic capabilities, will become the new focal point to advance patient care.

4:55 KEYNOTE PRESENTATION: Lessons Learned from BCMA and CD19 CAR T Trials

Kristen M. Hege, MD, Senior Vice President, Early Clinical Development, Hematology/Oncology and Cell Therapy, Bristol-Myers Squibb

Dr. Hege will discuss drawing correlations between patient and product characteristics and clinical outcomes for iterative improvement; identifying variables associated with CAR T expansion and persistence; understanding mechanisms and predictors of non-response, durable response and tumor escape; and new directions for cell therapy.

5:25 Immuno-Oncology Summit Connects

Explore new products and services in our Exhibit Hall, engage with poster presenters, schedule 1-on-1 meetings, and build your research community during this open networking period.

6:25 Close of Day

WEDNESDAY, OCTOBER 6

8:00 am Registration and Morning Coffee

EMERGING CHECKPOINT INHIBITOR TARGETS AND PATHWAYS

8:25 Chairperson's Remarks

Zhiqiang An, PhD, Professor, Molecular Medicine, University of Texas Health Science Center at Houston

8:30 ILT3 (LILRB4) Promotes the Immunosuppressive Function of Tumor-Educated Human Monocytic Myeloid-Derived Suppressor Cells

Latika Singh, PhD, Senior Scientist, Discovery Oncology/Immunology, Merck Research Laboratories

Myeloid-derived suppressor cells (MDSC) are immature myeloid cells that dampen antitumor immune responses. We characterized the phenotype and function of cancer cell line educated monocytic MDSCs (M-MDSC). M-MDSCs expressed higher cell surface levels of immunoglobulin-like transcript 3 (ILT3 or LILRB4) compared with monocytes. Treatment with an anti-ILT3 antibody reduced the capacity of M-MDSCs to cause T cell suppression. Thus, antagonism of ILT3 may enhance the efficacy of immune checkpoint inhibitors.

9:00 Antibodies Targeting the LILRB Family of Receptors for Cancer Therapy

Zhiqiang An, PhD, Professor, Molecular Medicine, University of Texas Health Science Center at Houston

LILRB family of receptors transduce signals via ITIMs that lead to negative regulation of immune cell activation. The activation of LILRBs on immune cells may contribute to cancer immune evasion. Some LILRBs expressed by tumor cells may regulate cancer development. LILRBs thus have dual concordant roles in cancer – as immune checkpoint molecules and as tumor-sustaining factors. LILRBs thus represents a novel class of targets for cancer antibody therapy.

9:30 KIR3DL3 Is a T and NK Cell Immunoinhibitory Receptor for HHLA2 and Mediates an Alternative Inhibitory Pathway to PD-1: Proof-of-Concept Checkpoint Blockade with KIR3DL3 and HHLA2 Antibodies

Tony R. Arulanandam, DVM, PhD, Consultant, Immuno-Oncology and Co-Founder NextPoint Therapeutics

HHLA-2 (B7H7) is a member of the B7 family of ligands and mediates both co-stimulatory (via TMIGD2/CD28H) and inhibitory effects on T cells. Through a HHLA2-Fc receptor screen we identified KIR3DL3 as an inhibitory receptor expressed in T and NK cells. Given the high expression of HHLA2 in PD-L1 negative tumors we developed ligand blocking KIR3DL3 and HHLA2 antibodies and showed checkpoint inhibition in T and NK cells.

10:00 Sponsored Presentation *(Opportunity Available)*

10:30 Exhibit Hall & Last Chance for Poster Viewing

GLYCAN-SENSING RECEPTORS

11:20 Glycan-Dependent T Cell Recruiter Technology: A Novel Immunotherapy for Cancer

Michael Demetriou, MD, PhD, Professor, Neurology, University of California, Irvine

We have developed novel immunotherapeutic bi-specific proteins that target abnormal N-glycans expressed by many diverse cancer types, termed "Glycan-dependent T cell Recruiter" or GlyTR. GlyTR1 bi-specific proteins specifically bind to human CD3 and targeted glycans, robustly activate T cells only in the presence of cancer cells, induce T cell dependent killing of many diverse cancer cells, and markedly inhibit *in vivo* growth of cancer xenografts in humanized NSG mice.

11:50 Unlocking the Therapeutic Potential of Glycobiology

Li Peng, PhD, Senior Vice President, Research & Early Product Development, Palleon Pharmaceuticals

Sialoglycans have emerged as a critical glyco-immune checkpoint that impairs antitumor response but are undruggable using conventional therapeutic approaches due to their structure heterogeneity and promiscuous ligand-receptor interactions. We have developed an engineered human sialidase-based EAGLE platform to overcome this hurdle by enzymatically cleaving the critical moiety, terminal sialic acids, and off sialoglycans. EAGLEs have demonstrated single-agent activity and a wide safety margin in preclinical models.

12:20 pm Sialic Acid Ligands of CD28 Block Costimulation of T Cells

Landon Edgar, PhD, Assistant Professor, Pharmacology and Toxicology, University of Toronto, Canada

Removal of monosaccharides called sialic acids from the surface of either T cells or APCs increases activation of the former. We have discovered the molecular basis for this effect; CD28, the most common co-stimulatory receptor on T cells, is a sialic acid binding protein and ligation of sialic acids prevents CD28 from associating with its activatory proteinaceous ligands CD80/86. Importantly, removal of sialic acids is synergistic with PD-1 blockade.

12:50 Enjoy Lunch on Your Own

NOVEL TARGETING STRATEGIES

1:55 Optimizing TNFR2 Antagonism for Immunotherapy with Tumor Microenvironment Specificity

Denise L. Faustman, MD, PhD, Associate Professor & Director, Immunobiology Labs, Massachusetts General Hospital

Creation of TNF receptor superfamily agonistic and antagonistic antibodies for cancer and autoimmunity is desired. We have focused on TNFR2 as an attractive target for Treg expansion and depletion. Many therapeutic antibodies need involvement of the Fc-receptor for signal strength. It is now possible to create new classes of antibodies independent of Fc receptor binding. Fc-receptors can facilitate cross-linking and signal strength but it also creates *in vivo* toxicity problems.

2:25 Macrophage Repolarization Is a Potent Mechanism for Inflaming Tumor Microenvironment

Igor Feldman, PhD, Co-Founder and Chief Analytics Officer, Verseau

Tumors evolve the ability to induce and maintain a microenvironment capable of shielding it from immune surveillance. Macrophage repolarization is capable of shifting the polarity of the tumor microenvironment away from tolerance and toward an immune attack. Given the prevalence of human tumors highly infiltrated with tolerogenic macrophages, targeting them is a potent strategy to broaden the clinical reach of what was possible with T cell checkpoint inhibitors.

2:55 Session Break

3:10 Discovery of Novel Therapeutic Targets from the Native Immune Response

Edward (Ned) Patz, PhD, CEO, Grid Therapeutics; Professor, Radiology, Duke University

An understanding of the native human immune response to cancer has the potential to yield novel therapeutic strategies for cancer. We suggest that anti-tumor immunity can be initiated by tumor specific antibodies derived from select patients, which can be used to promote tumor cell death and an adaptive immune response.

3:40 Dual Endothelin-1/VEGFsignal-peptide Receptor (DESpR): Therapeutic Target on TANs and CSCs

Victoria Herrera, MD, Professor of Medicine, Boston University School of Medicine; Co-Chair, Scientific Advisory Board, NControl Therapeutics

Cumulative research implicates TANs in immune-suppression and CSCs in immune-evasion. Inhibition of the dual endothelin-1/VEGF-signal peptide receptor (DEspR) using a humanized anti-DEspR IgG4^{S228P}-antibody, hu6g8, induces apoptosis in DEspR+ neutrophils and CSCs. This mode-of-action differentiates a therapeutic paradigm to block neutrophil/CSC-mediated resistance to immune checkpoint-inhibitors and pro-metastatic functions. Prevalence of DEspR-expression in solid tumors and emerging safety profile of hu6g8 in hyperinflammatory states delineate a rational profile for synergistic therapeutic combinations.

4:10 Close of Summit

TUESDAY, OCTOBER 5

12:30 pm Registration

KEYNOTE PRESENTATION

1:25 Chairperson's Remarks

Oliver Jonas, Scientific Founder, Kibur Medical; and Assistant Professor in Radiology, Harvard Medical School, Kibur Medical

1:30 Precision Medicine in Immuno-Oncology: Selecting for Monotherapy, Understanding Resistance Biology, and Informing Combination Therapies

Roy Baynes, MD, PhD, Senior Vice President & Head, Global Clinical Development; CMO, Merck, Sharp and Dohme

Precision medicine tools have enabled PD-1 antibody therapy to transform cancer care in a number of major tumor types. They have also provided insights to resistance biology and potential logical choices for combination therapies. Combination therapies with PD-1 antibodies as the backbone are beginning to impact many therapeutic choices.

PK/PD MODELS FOR IMMUNO-ONCOLOGY

2:00 Evaluating Strategies for Overcoming Rituximab Resistance Using a Quantitative Systems Pharmacology Model of Antibody-Dependent Cell-Mediated Cytotoxicity and Phagocytosis

Dean Bottino, PhD, Senior Scientific Director, Clinical Translational Modeling & Simulation Leader, Takeda

Given that antibody dependent cell mediated cytotoxicity (ADCC) and phagocytosis (ADCP) are thought to be the major mechanisms of action of Rituximab (R), increasing the activation levels of natural killer (NK) and macrophage (MP) cells may be one strategy for overcoming R resistance. We have developed and calibrated to ex-vivo literature data a quantitative systems pharmacology (QSP) model of ADCC/ADCP

2:30 Leveraging PK/PD Modeling to Speed Up the Path to Proof-of-Concept in Immuno-Oncology

Arijit Chakravarty, PhD, CEO, Fractal Therapeutics

The lack of translational relevance for preclinical *in vivo* efficacy models supporting immuno-oncology represents a significant (and often underappreciated) challenge for drug development in this field. In the absence of translational efficacy models, how do you rationally plan and execute a preclinical-to-clinical translation strategy? In this talk, we will discuss how to make that happen, relying in particular on *ex vivo* assays, PK/PD modeling, and Bayesian trial design.

3:00 Implantable Microdevices: Changing the Game for *in vivo* Pharmacology Studies

Oliver Jonas, Scientific Founder, Kibur Medical; and Assistant Professor in Radiology, Harvard Medical School, Kibur Medical

The implantable microdevice (IMD) is a translational tool that allows us to systematically screen many individual and combination therapies in a small cohort of study animals.

This session explains how IMDs work, and how we use them to facilitate the collection of robust data for numerous applications, including:

- Combination screening
- Testing of compounds that have no PK or toxicology data
- Candidate comparison
- Specific biology, e.g., candidate interaction with TME
- Clinical translation

3:30 Exhibit Hall with Poster Viewing

4:10 Transition to Plenary Keynote

PLENARY KEYNOTE SESSION: ADVANCING PRECISION IMMUNO-ONCOLOGY

4:20 Plenary Keynote Introduction

Benjamin G. Neel, MD, PhD, Professor, Medicine, NYU Grossman School of Medicine; Director, Laura and Isaac Perlmutter Cancer Center, NYU Langone Health

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6:25 Close of Day

WEDNESDAY, OCTOBER 6

8:00 am Registration and Morning Coffee

MODELS AND STRATEGIES FOR CANCER IMMUNOTHERAPY

8:25 Chairperson's Remarks

Russell Jenkins, MD, PhD, Center for Cancer Research, Massachusetts General Hospital

8:30 Mouse Models to Test Therapeutic Bispecific Antibodies

Gavin Thurston, PhD, Senior Vice President, Oncology Research, Regeneron Pharmaceuticals

9:00 Novel Preclinical Models to Evaluate Immune Oncology Therapeutics

Vish Muthusamy, PhD, Executive Director, Center for Precision Cancer Modeling, Yale School of Medicine

9:30 Overcoming Resistance to Anti-BCMA Bispecific Antibody in a Syngeneic Mouse Model of Multiple Myeloma through Combination Therapy

Marta Chesi, PhD, Associate Professor, Medicine, Mayo Clinic

Anti-BCMA bispecific antibodies are very effective against relapse/refractory myeloma. However, patients inevitably relapse. Using the immunocompetent Vk*MYC mouse model of myeloma, we found tumor burden and T cell exhaustion limit the efficacy of anti-BCMA/CD3 antibody. The addition of an IMiD only transiently deepened the response, but further exacerbated T cell exhaustion. Surprisingly, concurrent treatment with anti-BCMA/CD3 and cyclophosphamide proved very effective, prevented exhaustion and provided immunological protection against tumor reoccurrence.

10:00 High-Definition Spatial Proteomics for Characterizing the Tumor Microenvironment

Jason Ptacek, Associate Director, Research Services, Ionpath

Dr. Ptacek will provide an overview of how high-definition spatial proteomics, enabled by Multiplexed Ion Beam Imaging (MIBI), can be used to explore the tumor microenvironment with unprecedented depth. Examples of quantitative single-cell phenotype mapping in tissue analysis applications and the ability to generate actionable insights from this highly multiplexed, spatial proteomic data will be presented.

10:30 Exhibit Hall & Last Chance for Poster Viewing

ORGANOID AND SPHEROID MODELS

11:20 Exploiting Genetically Defined, Organoid-Based Models of High-Grade Serous Ovarian Cancer

Benjamin G. Neel, MD, PhD, Professor, Medicine, NYU Grossman School of Medicine; Director, Laura and Isaac Perlmutter Cancer Center, NYU Langone Health

Current therapies, including conventional chemotherapy, targeted therapy, and immune therapy are typically tested in different types of preclinical models. Immune-therapies have been tested primarily in "syngeneic tumor models" of unclear cell-of-origin and "irrelevant" genetics. Using mouse fallopian tube organoids, we engineered a suite of new, genetically defined models of high-grade serous ovarian cancer. I will discuss the use of these models to derive combination therapies for this deadly disease.

11:50 *In vitro* Models for Cancer Immunity and Immunotherapy

Shay Soker, PhD, Professor, Wake Forest Institute for Regenerative Medicine; Director, Wake Forest Organoid Research Center

3D human tissue organoids replicate native tissue structure and function and can be studied *in vitro* for several weeks to allow intensive investigations. We used human tissue organoids to study cancer progression, metastasis and response to therapy. Patient-specific tumor organoids, consisting of tumor and stromal cells could replicate the patient's own treatment response. We have recently improved the tumor organoids' capabilities by adding immune cells to create immune-responsive tumor organoids.

12:20 pm *Ex vivo* Profiling of Novel Cancer Therapies Using Organotypic Tumor Spheroids

Russell Jenkins, MD, PhD, Center for Cancer Research, Massachusetts General Hospital

Preclinical models that translate to human immunity are needed to assess novel cancer immunotherapy combinations. New approaches and model systems are needed to deprioritize ineffective strategies and to better understand mechanisms of response and resistance to promising approaches. To address this need, we have developed a system for *ex vivo* profiling of novel immunotherapy combinations using 3D microfluidic culture of murine- and patient-derived organotypic tumor spheroids (MDOTS/PDOTS).

12:50 Enjoy Lunch on Your Own

MECHANISMS AND TARGETS IN IMMUNO-ONCOLOGY

1:50 Chairperson's Remarks

Katherine Seidl, PhD, Head, Oncology Drug Discovery Unit, Takeda Pharmaceuticals International Co.

1:55 Decoding Immune Signatures to Guide Therapeutic Design

Katherine Seidl, PhD, Head, Oncology Drug Discovery Unit, Takeda Pharmaceuticals International Co.

Innovative immuno-oncology therapeutics require focus on various underexplored mechanisms in the cancer immunity cycle. We are building a framework to identify the key determinant mechanisms and parameters that can be used to link patients with therapies. Allogeneic cell therapy platforms will be discussed in this context as an example with application to other therapeutic approaches. Attributes regarding patient population, cell platform, targets, and armoring options are taken into account.

2:25 ImmunoPerturbomics: New Targets, Mechanisms and Modalities in Immuno-Oncology

Shashank Patel, PhD, Director, R&D Immunology, NextCure

CRISPR-Cas9 cell engineering is making great strides in driving novel immuno-medicines to the clinic. This talk will focus on how this technology is uncovering the mechanisms of immune resistance to checkpoint therapies and identifying next-generation IO targets and modalities.

2:55 Session Break

3:10 Neoantigens and Inhibigens Selected with the ATLAS Bioassay Have Differential Impacts on Tumor Immunotherapy: Preclinical and Clinical Results

Jessica Baker Flechtner, PhD, CSO, Genocea Biosciences

3:40 Preclinical Development of an Anti-PD-1-GITR-L Agonist Bispecific for Immuno-Oncology

Hamsell M. Alvarez, PhD, Associate Director, Oncology Discovery, AbbVie

Since PD-1 and GITR are co-expressed on recently activated antigen-specific T cells and on memory cells, a bispecific that targets both specificities is warranted. Anti-PD-1-GITR-L is a bispecific molecule that overcomes immune escape to PD-(L)1 blockade by enhancing and sustaining the activation, proliferation, and memory differentiation of primed antigen-specific T cells by inducing a PD-1 mediated GITR clustering. The MoA is independent of FcγR-mediated cross-linking, and ADCC-mediated Treg depletion.

4:10 CD24 Signaling through Macrophage Siglec-10 Is a Target for Cancer Immunotherapy by Macrophages

Amira Barkal, MD, PhD, Resident Physician, Internal Medicine, Brigham & Women's Hospital, Harvard Medical School

Cancer cells evade clearance by macrophages through the overexpression of anti-phagocytic surface proteins called 'don't eat me' signals. Here we report that CD24 is the dominant 'don't eat me' signal in multiple solid tumors. In preclinical models, CD24 blockade leads to a macrophage-dependent reduction in tumor growth and extension of survival. Collectively, these data support the therapeutic potential for targeting CD24.

4:40 Close of Summit

TUESDAY, OCTOBER 5

12:30 pm Registration

1:25 Chairperson's Opening Remarks
Samuel D. Rabkin, PhD, Professor, Neurosurgery, Massachusetts General Hospital and Harvard Medical School

CLINICAL SUCCESSES AND DEVELOPMENTS

1:30 KEYNOTE PRESENTATION: The Current Clinical Landscape of Oncolytic Virus Therapy
Howard L. Kaufman, MD, Head, R&D, Immuneering Corporation; Clinical Associate, Division of Surgical Oncology, Massachusetts General Hospital
We conducted a literature search of OV clinical studies over 20 years and identified 97 trials representing 3,233 patients. We report the most common viruses, transgenes, indications, routes, and correlative biomarker analyses used. Only a limited number of viruses and payloads have entered the clinic. There is an opportunity to optimize clinical OV study designs to improve OV therapy.

ANTI-TUMOR IMMUNITY, BIOMARKERS

2:00 Oncolytic Viruses: Balancing Anti-Viral and Anti-Tumor Immunity
Dmitriy Zamarin, MD, PhD, Medical Oncologist, Gynecologic Medical Oncology & Immunotherapeutics, Memorial Sloan Kettering Cancer Center
Tumor immune heterogeneity represents one of the key impediments to immunotherapy efficacy. Using oncolytic Newcastle Disease Virus (NDV) as a model, we find that intratumoral NDV therapy increases TCR repertoire overlap and elicits distinct T cell phenotypes across the treated and distant tumor sites. Understanding of the interplay between the virus-specific and tumor-specific T cells will be key to development of engineered oncolytic viruses with maximal immunotherapeutic potential.

2:30 IFNγ Pathway Defects Leads to Oncolytic Virus Sensitivity in Melanoma
Ian Watson, PhD, Assistant Professor, Department of Biochemistry, McGill University
Mutations in the IFNγ response pathway is one of the best-established mechanisms of immune checkpoint inhibitor (ICI) resistance. Disablement of the anti-viral IFNγ response should render melanomas sensitive to oncolytic viruses (OVs). Our study provides mechanistic evidence supporting OVs as a precision-medicine strategy to treat ICI-resistant and treatment-naïve melanomas with defects in the IFNγ pathway, and also demonstrates the potential clinical utility of JAK inhibitor-OV combination as a melanoma therapy.

3:00 Interactive Discussions
Interactive Discussions are informal, moderated discussions, allowing participants to exchange ideas and experiences and develop future collaborations around a focused topic. Each discussion will be led by a facilitator who keeps the discussion on track and the group engaged. For in-person events, the facilitator will lead from the front of the room while attendees remain seated to promote social distancing. For virtual attendees, the format will be in a Zoom room. To get the most out of this format, please come prepared to share examples from your work, be a part of a collective, problem-solving session, and participate in active idea sharing. Please visit the Interactive Discussion page for a complete listing of topics and descriptions.

Development of Oncolytic Viruses
Howard L. Kaufman, MD, Head, R&D, Immuneering Corporation; Clinical Associate, Division of Surgical Oncology, Massachusetts General Hospital

3:30 Exhibit Hall with Poster Viewing

4:10 Transition to Plenary Keynote

PLENARY KEYNOTE SESSION: ADVANCING PRECISION IMMUNO-ONCOLOGY

4:20 Plenary Keynote Introduction
Benjamin G. Neel, MD, PhD, Professor, Medicine, NYU Grossman School of Medicine; Director, Laura and Isaac Perlmutter Cancer Center, NYU Langone Health

4:25 KEYNOTE PRESENTATION: The Rapid Evolution of Precision IO: The Future Role of Biomarkers in IO Development and Clinical Utilization
Zhen Su, MD, MBA, CEO, Marengo Therapeutics
As we turn the corner into a new decade, scientific and technological advances are helping to achieve a more precision approach for immunotherapy. While PD-L1 staining offers enrichment, mutation burden, microsatellite instability, and other immune biomarkers may be able to advance the precision approach. Evolution and real-world adaptation of testing tools, such as companion diagnostic capabilities, will become the new focal point to advance patient care.

4:55 KEYNOTE PRESENTATION: Lessons Learned from BCMA and CD19 CAR T Trials
Kristen M. Hege, MD, Senior Vice President, Early Clinical Development, Hematology/Oncology and Cell Therapy, Bristol-Myers Squibb
Dr. Hege will discuss drawing correlations between patient and product characteristics and clinical outcomes for iterative improvement; identifying variables associated with CAR T expansion and persistence; understanding mechanisms and predictors of non-response, durable response and tumor escape; and new directions for cell therapy.

5:25 Immuno-Oncology Summit Connects
Explore new products and services in our Exhibit Hall, engage with poster presenters, schedule 1-on-1 meetings, and build your research community during this open networking period.

6:25 Close of Day

WEDNESDAY, OCTOBER 6

8:00 am Registration and Morning Coffee

ADVANCING ONCOLYTIC VIRUS IMMUNOTHERAPIES

8:25 Chairperson's Remarks
Paola Grandi, PhD, CSO, CG Oncology, Inc.

8:30 Oncolytics in an Era of Combination Therapies
Samuel D. Rabkin, PhD, Professor, Neurosurgery, Massachusetts General Hospital and Harvard Medical School
Oncolytic herpes simplex virus (oHSV) is both directly cytotoxic and immunotherapeutic. Combination therapies, including arming oHSV with therapeutic transgenes or systemic administration of pharmacological agents, can enhance efficacy, especially when they alter the tumor microenvironment. We will discuss preclinical combination studies with oHSV expressing IL-12 that impacted immunological outcomes beneficially and adversely.

9:00 Redesigning Viruses as Potent Precision Cancer Therapies
Clodagh C. O'Shea, PhD, Professor, Molecular and Cell Biology Laboratory, Salk Institute for Biological Studies

9:30 Hydrogel-Based Sustained Delivery Systems Enhance the Potency and Safety of Oncolytic Virotherapy

Chae-Ok Yun, PhD, Professor, Biotechnology, Hanyang University

Intratumoral administration of oncolytic viruses (OV) is preferred in clinical environment, but inadequate intratumoral retainment and shedding of OVs to normal tissues limit the potency and safety of virotherapy. To address this challenge, we have developed several different hydrogel systems to prolong the antitumor activity of OV, as well as inhibiting nonspecific shedding of virions to normal tissues to improve its safety profile.

10:00 Novel Oncolytic Viral Immunotherapies for Solid Tumors

Paul Peter Tak, President & Chief Executive Officer, Candel Therapeutics, Inc.

Candel Therapeutics is a clinical stage biopharmaceutical company developing oncolytic viral immunotherapies. Its engineered adenoviral and herpes simplex virus gene constructs are designed to induce cell death in cancer cells in a pro-inflammatory tumor microenvironment, resulting in a specific immune response against the injected tumor and uninjected metastases. Candel's clinical pipeline is focused on lung cancer, high-grade glioma, pancreatic cancer, and prostate cancer. The Candel discovery platform is based on HSV.

10:30 Exhibit Hall & Last Chance for Poster Viewing

IMPROVING POTENCY AND ENGINEERING

11:20 Next Generation Oncolytic Immunotherapy

Robert Coffin, PhD, CEO & Founder, Replimune Ltd.

Replimune is developing a series of multiply armed oncolytic immunotherapies based on a high potency clinical strain of HSV, designed to provide sequentially potent local tumor destruction and systemic immune activation to provide patient-specific immunization against the patient's particular complement of tumor antigens. Compelling clinical safety and efficacy data has been generated with RP1 (expresses GALV-GP R- and GM-CSF) and RP2 (additionally expresses anti-CTLA-4), including in combination with anti-PD1 therapy.

11:50 Resurgence of the Oncolytic Measles Platform: Armed, Resurfaced and Precision Targeted

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

Measles is a highly promising oncolytic virotherapy platform. Clinical trials confirm its anti-tumor activity after systemic administration, only in patients lacking anti-measles antibodies. We engineered a new generation of systemically deliverable oncolytic measles viruses that evade neutralization by anti-measles antibodies present in the blood of vaccinated individuals, which are fully re-targeted so attachment and entry into targeted cancer cells is fully reprogrammed by single chain antibodies displayed on virus surfaces.

12:20 pm Retroviral Replicating Vectors: Lessons Learned from Clinical Trials and New Vector Systems to Enhance Therapeutic Efficacy

Noriyuki Kasahara, MD, PhD, Professor & Alvera L. Kan Endowed Chair, Neurological Surgery & Radiation Oncology, University of California, San Francisco (UCSF)

Clinical evaluation of retroviral replicating vectors for prodrug-activator virotherapy has been pursued for over a decade, and early phase trials for recurrent glioma showed therapeutic benefit. A recent Phase III trial did not meet overall endpoints, but prodrug dosing was inadequate, and subsequent analysis revealed highly significant survival in specific subgroups. Further clinical investigation is on-going, and next-generation vectors with enhanced cytotoxicity and activation of anti-tumor immunity are being developed.

12:50 Enjoy Lunch on Your Own

PRECLINICAL AND CLINICAL UPDATES

1:50 Chairperson's Remarks

Fares Nigim, MD, PhD, Clinical Fellow, Neuro-Oncology, Massachusetts General Hospital, Dana Farber Cancer Institute, Harvard Medical School

1:55 Preclinical Development of CG0070

Paola Grandi, PhD, CSO, CG Oncology, Inc.

Oncolytic immunotherapy is a form of cancer treatment that uses genetically modified viruses to preferentially kill cancer cells and generate anti-tumor immune responses. Our agent, CG0070, is at the forefront of this field, leading a two-pronged attack against cancer through both direct and indirect killing.

2:25 CG0070 for the Treatment of Non-Muscle Invasive Bladder Cancer and Other Solid Tumors

James M. Burke, MD, CMO, CG Oncology, Inc.

CG0070 is a cancer selective, GM-CSF expressing serotype 5 human adenovirus engineered to selectively replicate in cells with retinoblastoma tumor suppressor gene pathway defects. Clinical efficacy and safety have been demonstrated across 2 clinical trials targeting non-muscle invasive bladder cancer. The status of clinical development of CG0070 including an ongoing phase 3 registration study will be reviewed.

2:55 Session Break

3:10 Development of Synthetic Oncolytic Viral Immunotherapies for Repeat Systemic Treatment of Cancer

Lorena Lerner, PhD, Vice President, Molecular Biology and Virology, Oncorus, Inc.

Oncorus innovative Synthetic RNA virus platform is designed to enable repeat intravenous administration of viral immunotherapy. Synthetic RNA viruses are comprised of viral RNA genomes encapsulated in lipid nanoparticles that by-pass virus neutralizing antibodies. Synthetic RNA viruses selectively replicate and produce infectious virions within tumor cells, promoting immune cell infiltration and response to checkpoint inhibitors. They are well tolerated and demonstrate potent and durable anti-tumor activity.

3:40 Extracellular Matrix Hyaluronan as a Therapeutic Target in Oncolytic Virus Therapy of Glioblastoma

Hiroaki Wakimoto, MD, PhD, Assoc Prof, Neurosurgery, Massachusetts General Hospital

Extracellular matrix (ECM) in the tumor microenvironment (TME) promotes malignant phenotypes of cancers, but how ECM impacts virus immunotherapy of cancer remained largely unknown. We show that tumor hyaluronan degradation by hyaluronidase-armed oncolytic adenovirus ICOVIR17 increased immune cell infiltration and PD-L1 levels in murine glioblastoma. Combination therapy of ICOVIR17 and PD-1 blockade induced long-term survivals, revealing hyaluronan in the TME as a previously underappreciated therapeutic target in oncolytic virus immunotherapy.

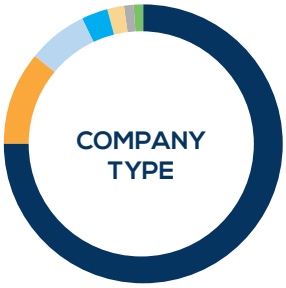
4:10 Viral Backbone Engineering to Achieve a Systemically Deliverable Oncolytic Virus Platform

Stephen H. Thorne, PhD, CSO, Kalivir

This presentation will discuss: Next-generation oncolytic virus therapies will ideally be delivered intravenously; modifications of the viral backbone can increase systemic delivery, even in the face of pre-existing anti-viral immunity; and the addition of therapeutic trans gene and transgender combinations can result in a platform of potent systemic therapies.

4:40 Close of Summit

2020 Attendee Demographics



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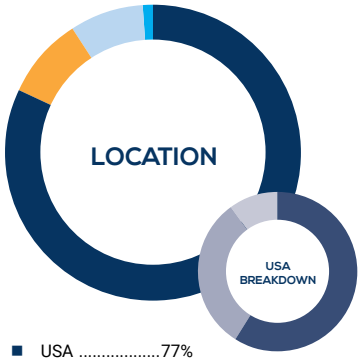

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