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- Immunomodulatory Antibodies
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- Adoptive T Cell Therapy
- Oncolytic Virus Immunotherapy
- Personalized Immunotherapy
- Biomarkers for Immuno-Oncology
- Training Seminar: Immunology for Drug Discovery Scientists
- Preclinical & Translational Immuno-Oncology
- Clinical Trials for Cancer Immunotherapy

Plenary Keynote Speakers

Edward Fritsch
Ph.D., Chief Technology Officer, Neon Therapeutics, Inc

Michael Rosenzweig
Ph.D., Executive Director, Biology-Discovery, IMR Early Discovery, Merck Research Laboratories

Morganna Freeman
D.O., Associate Director, Melanoma & Cutaneous Oncology Program, The Angeles Clinic and Research Institute

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IO Immuno-Oncology SUMMIT

MEET THOUGHT LEADERS IN CANCER IMMUNOTHERAPY AT THE PREMIER ANNUAL IO EVENT

As our understanding of tumor immunology has advanced, immuno-oncology has made unprecedented progress in improving the outcomes for cancer patients. Still, with the field in its infancy, the full curative potential of IO has yet to be realized. CHI's 4th Annual Immuno-Oncology Summit has been designed to support a coordinated effort by industry players to bring commercial immunotherapies and immunotherapy combinations through clinical development and into the market. This weeklong, nine-meeting set will include topics ranging from early discovery through clinical development as well as emerging areas such as oncolytic virus immunotherapy. Overall, this event will provide a focused look at how researchers are applying new science and technology in the development of the next generation of effective and safe immunotherapies.

Who Will Attend?

Scientific leaders, C-level executives, professors, site directors and researchers from pharma, biotech, academia, and government working in the areas of immuno-oncology, immunotherapy, antibody and protein engineering, biomarker discovery, immunology, cell and gene therapy, and preclinical and clinical development.

CONFERENCE AT-A-GLANCE

MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY
Immunomodulatory Antibodies		Combination Immunotherapy	Adoptive T Cell Therapy	
Oncolytic Virus Immunotherapy		Personalized Immunotherapy	Biomarkers for Immuno-Oncology	
Training Seminar: Immunology for Drug Discovery Scientists		Preclinical & Translational Immuno-Oncology	Clinical Trials for Cancer Immunotherapy	

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Plenary Keynotes

TUESDAY | AUGUST 30

4:00 Personalized, Neoantigen-Based Immunotherapy

Edward Fritsch, Ph.D., Chief Technology Officer, Neon Therapeutics, Inc.

Multiple lines of evidence have demonstrated the critical role that Neoantigens have in the immune response to cancer and the availability of next-generation sequencing to identify personal, neoantigen-creating mutations has opened the door to directly enhance the power and breadth of host immunity to overcome this deadly disease.

4:30 Emerging Innate Immune Targets for Enhancing Adaptive Anti-Tumor Responses

Michael Rosenzweig, Ph.D., Executive Director, Biology-Discovery, IMR Early Discovery, Merck Research Laboratories

Novel cancer immunotherapies targeting T cell checkpoint proteins have emerged as powerful tools to induce profound, durable regression and remission of many types of cancer. Despite these advances, multiple studies have demonstrated that not all patients respond to these therapies, and the ability to predict which patients may respond is limited. Harnessing the innate immune system to augment the adaptive anti-tumor response represents an attractive target for therapy, which has the potential to enhance both the percentage and rate of response to checkpoint blockade.

5:00 Reading Tea Leaves: The Dilemma of Prediction and Prognosis in Immunotherapy

Morganna Freeman, D.O., Associate Director, Melanoma & Cutaneous Oncology Program, The Angeles Clinic and Research Institute

With the rapid expansion of immunotherapeutics in oncology, scientifically significant advances have been made with both the depth and duration of antitumor responses. However, not all patients benefit, or quickly relapse, thus much scientific inquiry has been devoted to appropriate patient selection and how such obstacles might be overcome. While more is known about potential biomarkers, accurate prognostication persists as a knowledge gap, and efforts to bridge it will be discussed here.

Track Keynotes

Prasad S. Adusumuilli, *M.D., FACS, Deputy Chief of Translational & Clinical Research, Thoracic Surgery, Memorial Sloan-Kettering Cancer Center*

Roy D. Baynes, *M.D., Ph.D., Senior Vice President and Head, Global Clinical Development, Merck Research Laboratories*

Edward Cha, *M.D., Ph.D., Associate Medical Director, Cancer Immunotherapy Franchise, Genentech*

Robert Coffin, *Ph.D., CEO, Replimmune*

Jakob Dupont, *M.D., Senior Vice President & CMO, OncoMed Pharmaceuticals*

Kenneth Emancipator, *M.D., Executive Medical Director, Companion Diagnostics, Merck & Co.*

Ronald Herbst, *Ph.D., Vice President, R&D; Head, Oncology Research, MedImmune*

Robert Iannone, *M.D., Senior Vice President & Head, Immuno-Oncology, Global Medicines Development, AstraZeneca*

Ella Ioffe, *Ph.D., Associate Director, Immune-Oncology, Regeneron Pharmaceuticals*

David M. Kranz, *Ph.D., Phillip A. Sharp Professor of Biochemistry, University of Illinois*

Laszlo Radvanyi, *Ph.D., Senior Vice President and Head, ImmunoOncology Translational Innovation Platform (TIP) EMD Serono*

Zhen Su, *M.D., MBA, Senior Vice President, Global Head of Medical Affairs Oncology, EMD Serono*

James E. Wooldridge, *M.D., CSO, Immuno-Oncology Clinical Development, Eli Lilly and Company*

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Distinguished Faculty

Adam J. Adler
Ph.D., Professor, Immunology, University of Connecticut

Prasad S. Adusumilli
M.D., FACS, Deputy Chief of Translational & Clinical, Research, Thoracic Surgery, Memorial Sloan-Kettering Cancer Center

Omar Ali
Ph.D., Staff Scientist, Wyss Institute for Biologically Inspired Engineering, Harvard University

Robert Anders
M.D., Ph.D., Associate Professor, Pathology, Johns Hopkins University

Philip M. Arlen
M.D., President & CEO, Precision Biologics, Inc.

Roy D. Baynes
M.D., Ph.D., Senior Vice President and Head, Global Clinical Development, Merck Research Laboratories

Stephen Beers
Ph.D., Associate Professor, Cancer Immunology and Immunotherapy, University of Southampton

John Bell
Ph.D., Senior Scientist, Centre for Innovative Cancer Research, Ottawa Hospital Research Institute, Professor, Departments of Medicine and Biochemistry, Microbiology & Immunology, University of Ottawa

Kevin Bonham
Ph.D., Curriculum Fellow, Microbiology and Immunobiology Department, Harvard Medical School

Chris Boshoff
M.D., Ph.D., Vice President and Head, Early, Development, Translational and Immuno-Oncology, Pfizer

Adrian Bot
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Caroline Breitbach
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Joshua Brody
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Tullia Bruno
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MD, Investigator, Experimental Transplantation and Immunology Branch, Lasker Clinical Research Scholar, NIH

Mark J. Federspiel
Ph.D., Professor and Director, Viral Vector Production Laboratory, Mayo Clinic

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Short Courses

Tuesday & Thursday Dinner Short Courses

TUESDAY, AUGUST 30

6:30-9:00 pm SC1: Targeting the Cancer Mutanome

Laszlo Radvanyi, Ph.D., Senior Vice President; Head of Immuno-Oncology Translational Innovation Platform (TIP), EMD Serono

Luis M. Vence, Ph.D., Scientific Manager, Immunology, MD Anderson Cancer Center

Alena Gros Vidal, Ph.D., Research Fellow, Surgery Branch, National Cancer Institute

Suchit Jhunjhunwala, Ph.D., Scientist, Bioinformatics, Genentech

Emerging sequencing and bioinformatics technologies are now giving researchers new perspectives on the mutations in patient specific antigens, now collectively known as the cancer mutanome. Our dinner short course offers academic and industry perspectives on the analytical and computational methods used to identify neo-epitopes within a mutanome that are candidates for therapeutic intervention – and the potential applications of this knowledge in patient diagnostics and immunotherapy. An open discussion format will allow those working in this space to share insights and experiences on how to advance this new field into clinical practice.

6:30-9:00 pm SC2: Bispecific Antibody Development for Immunotherapy

Sanja Gauthier, M.D., Senior Medical Director, Medical Safety Evaluation, Pharmacovigilance and Patient Safety, AbbVie

Cris Kamperschroer, Ph.D., Associate Research Fellow, Drug Safety R&D, Pfizer

Bispecific molecules designed to recruit T cells and induce them to kill tumor cells are showing promise as cancer immunotherapies. There are challenges to developing these molecules, including safety concerns related to the intended pharmacology of T cell activation. This presentation will cover the nonclinical development of a specific T cell targeting bispecific molecule, its key safety concerns, and approaches to mitigate the concerns.

This short course will address:

- Nonclinical development of a T cell targeting bispecific molecule
- Benefit/risk of bifunctional antibodies in oncology clinical development

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Showcase your solutions to a guaranteed, targeted audience through a 15- or 30-minute presentation during a specific conference program, breakfast, lunch, or separate from the main agenda within a pre-conference workshop. Package includes exhibit space, on-site branding, and access to cooperative marketing efforts by CHI. For the luncheon option, lunches are delivered to attendees who are already seated in the main session room. Presentations will sell out quickly, so sign on early to secure your talk!

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Select your top prospects from the pre-conference registration list. CHI will reach out to your prospects and arrange the meeting for you. A minimum number of meetings will be guaranteed, depending on your marketing objectives and needs. A very limited number of these packages will be sold.

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- Web Symposia
- Custom Market Research Surveys
- Podcasts

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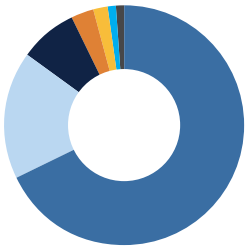
Demographics for CHI Immuno-Oncology Conferences



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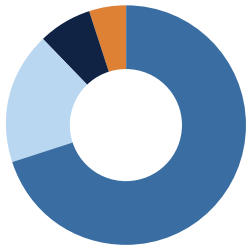
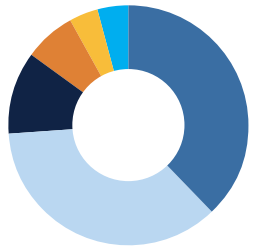
Commercial (Biotech + Pharma)	68%
Academic	17%
Healthcare	8%
Financial	3%
Government	2%
Services/Societies	1%
Other (CRO + Press)	1%



GEOGRAPHIC LOCATION

USA	70%
US Breakdown	
East Coast	60%
West Coast	30%
Midwest	10%
Europe	18%
Asia	7%
Rest of World	5%



DELEGATE TITLE

Scientist/Technologist	38%
Executive + Director	36%
Professor	11%
Manager	7%
Sales & Marketing	4%
Other	4%

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Immunology for Drug Discovery Scientists

TRAINING SEMINAR: IMMUNOLOGY FOR DRUG DISCOVERY SCIENTISTS

Instructors: Kevin Bonham, Ph.D., Lecturer, Microbiology and Immunobiology, Harvard Medical School and Matthew Woodruff, Ph.D., Postdoctoral Fellow, Emory University

In order to detect the presence of potential pathogens, the immune system must interact with every body system and circulate through every tissue. The weight of the microbial threat has led to the evolution of a unique biological skill set that make the immune system incredibly powerful, but also incredibly dangerous. These unique skills and systemic reach mean that the immune system touches almost every human disease, either causally or as an avenue for therapy. In this course, we will explore therapeutic approaches that harness our knowledge of the immune system to treat human disease. From vaccines to cancer (not to mention cancer vaccines!) and diabetes to IBD, we will explore how the immune system can be shaped, engineered, and harnessed by exploring specific examples of current and future therapeutics, and the immunology behind them.

TOPICS INCLUDE:

Introduction to the Unique Biology of the Immune System Pathogen Detection and Inflammation (Innate Immunity)
- Cell-intrinsic detection and response
- Local detection, paracrine signaling
- Systemic responses

Cellular Immunity, Cytotoxicity
- NK-cells
- CD8+ T-cells
- Macrophages
- CD4+ T-cells

Antibodies
- B-cell biology
- Diversity of antibody function
- Complement fixation

Immune System Interactions (The Big Picture)
- Lymphocyte development
- Antigen presentation (B-cell/T-cell, APC/T-cell, DC/B-cell)
- CD4+ T-cell redux

Engineering Immunity – Monoclonal Antibody Therapies

MAB #1 - TGN1412
- Anti-CD28 monoclonal therapy - intended to activate Treg cells
- Actually activated all T-cells, caused cytokine storm in healthy volunteers, severe, permanent damage

MAB #2 - Natilizumab
- Anti α4 integrin -blocks T-cells from entering brain, highly effective treatment for MS
- Great example of rationally-designed therapy, minimal side effects
- Fewer side-effects than most anti-inflammatory drugs, increased risk for PML

Receptor/Fc Hybrids - CD4-Fc anti-HIV

MAB Summary
- Good for inhibiting things, sometimes can activate
- Target must be cell-extrinsic

Engineering Immunity #2 - CAR-T Cells

The Trouble with Neoantigens

How Many Treatments Does it Take to Cure Melanoma?

Molding Immunity - Vaccines
- History of vaccine approaches - mostly antibodies
- Vaccine approaches - better adjuvants/better antigens
- Vaccine approaches - prime and pull
- Vaccine approaches - skip the vaccine (gene therapy)

Harnessing Immunity - Anti-Cancer Approaches

Checkpoint Blockade Therapies
- History
- Targets

Cancer Vaccines

Limitations (Neoantigens, Autoimmunity)

Each CHI Training Seminar offers 1.5 days of instruction with start and stop times for each day shown above and on the Event-at-a-Glance 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.

Dr. Kevin Bonham is a Curriculum Fellow for the Microbiology and Immunobiology Department at Harvard Medical School, and the principal instructor for the Masters of Medical Sciences program in Immunology. He received his Ph.D. from Harvard in the lab of Jonathan Kagan, where he studied the cell biology and biochemistry of Toll-like Receptor signaling and innate immune pattern recognition.

Matthew Woodruff graduated from the Rochester Institute of Technology with a bachelor's degree in biotechnology, and received his Ph.D in Immunology from Harvard in 2014. He now works as a postdoctoral fellow in Dr. Bali Pulendran's lab at the Emory Vaccine Center with a focus on the basic mechanisms of vaccination. He has published on lymphatic dynamics and flow, lymph node structure and function, and the early phases of vaccine response. Outside of bench work, he is interested in the use of creative design and non-traditional presentation methods to make complex immunological concepts relatable to a broad audience.

Immunomodulatory Therapeutic Antibodies for Cancer

Exploring the Evolution of Novel Immunotherapies Based on Checkpoint Inhibitors, Costimulatory Agonists and Emerging Targets

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Recommended Dinner Short Course*
Targeting the Cancer Mutanome
*Separate registration required, please see Short Courses for details

MONDAY, AUGUST 29

7:30 am Registration & Morning Coffee

8:25 Chairperson's Opening Remarks
Tariq Ghayur, Ph.D., Distinguished Research Fellow, AbbVie Bioresearch Center

8:30 OPENING KEYNOTE PRESENTATION: IMMUNOTHERAPY FOR CANCER: THE PROMISE AND CHALLENGES AHEAD
Ronald Herbst, Ph.D., Vice President, R&D; Head, Oncology Research, MedImmune
Immune-evasion is a hallmark of cancer and enhancement of the anti-cancer immune response by targeting checkpoint pathways, such as CTLA-4 and PD-1/PD-L1, is showing significant promise. However, a subset of patients fails to benefit from immune therapy. Going forward it will be key to better understand the immunologic diversity within and across indications, and to identify markers of response (or no response) to therapy to further increase the benefit to patients.

UNDERSTANDING THE MECHANISMS OF ACTION FOR IMMUNOMODULATORY ANTIBODIES

9:00 Lessons Learned from Studies of Checkpoint Blockade Toxicity
Geoffrey T. Gibney, M.D., Medical Oncologist, Georgetown-Lombardi Comprehensive Cancer Center
Recent developments in targeted immune checkpoint blockade have revolutionized treatment approaches in patients with advanced malignancies. While durable responses are seen, checkpoint therapies are associated with a range of immune-related toxicities that can complicate patient care. Combination strategies so far have led to even higher rates of immune events. Most severe toxicities are manageable with corticosteroids and other immunomodulatory agents. The current data on checkpoint blockade toxicities will be reviewed.

9:30 Coffee Break

10:00 Anti-Hypoxia-A2-Adenosinergic Co-Adjuvants to Enable the Full Anti-Tumor Capacities of T- and Natural Killer Cells During Immunotherapies of Cancer
Stephen Hatfield, Ph.D., Research Scientist, New England Inflammation and Tissue Protection Institute, Northeastern University
The presentation introduces the adenosine-generating CD73 ecto-enzyme as a potential drug target and biomarker of the most resistant human tumors. In addition, oxygenation agents join antagonists of A2A Adenosine Receptors as novel checkpoint inhibitors that reprogram the TME away from immunosuppression and have promise if used in combination with existing cancer immunotherapies.

10:30 The Role of Immune Biomarkers in Offering a Standardized Way of Evaluating the *in vivo* Behavior of Cancer Immunotherapies
Susan R. Slovin, M.D., Ph.D., Medical Oncologist, Genitourinary Oncology Service, Memorial Sloan Kettering Cancer Center
Major initiatives are ongoing to establish and validate in clinical trials a platform of biomarkers that can be used to assess biologic changes and treatment responses in solid tumors treated with novel immune drugs. The identification and relevance of biomarkers in trials with immunologic agents can vary with the drug used. How to incorporate the metrics of biomarkers into immunotherapy trials and their validation is a major focus of trial design.

11:00 Tumor-Localized Costimulatory T Cell Engagement with Bispecific CD137-Agonists
Sponsored by: pieris PHARMACEUTICALS
Louis Matis, M.D., Senior Vice President, Chief Development Officer, Pieris Pharmaceuticals, Inc.
We describe the generation and characterization of the CD137/HER2 and CD137/GPC-3 bispecifics designed to promote CD137 clustering in the tumor microenvironment by bridging CD137- positive T cells with target positive tumor cells, thereby providing a potent costimulatory signal to tumor antigen-specific T cells.

11:15 Transforming Antibody Discovery with the Benchling Platform
Sponsored by: Benchling
Sajith Wickramasekara, CEO, Benchling
For most antibody discovery R&D, the discovery process is a work in progress. Keeping track of experimental results of just antibody leads, much less managing the entire antibody discovery workflow, can prove difficult. Existing software solutions force users to engage with disparate pieces of software and require time-consuming and error-prone manual input. Benchling unifies experiment workflows in a single, collaborative research platform that was co-developed with scientists, ensuring that cutting-edge science is never held back by archaic software. In this talk we will describe how we work with scientists in antibody discovery to empower them to design, register and optimize antibodies on a single platform.

11:30 am End of Morning Session *(Delegates may attend session of parallel meeting)*

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

12:30 Session Break

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EMERGING TARGETS AND STRATEGIES FOR CANCER IMMUNOTHERAPY

1:25 Chairperson's Remarks
Adam J. Adler, Ph.D., Professor, Immunology, University of Connecticut

1:30 Bi- and Multi-Specific Biologics for Cancer Immunotherapy: Selecting Target Combinations and Designing Biologics to Modulate Anti-Tumor T Cell Functions
Tariq Ghayur, Ph.D., Distinguished Research Fellow, AbbVie Bioresearch Center
The presentation will discuss how high throughput functional bioassays have been used to select combinations of mAbs to either the same target (different epitopes) or different targets for generating dual-specific DVD-Ig molecules with additive and/or synergistic activity. The talk will also describe the application of new multi-specific formats in understanding the biology of T cell activation by co-ligating CD3 and co-receptors and to design molecules to address specific unmet needs.

2:00 T Cell Activation and Pre-Clinical Anti-Tumor Efficacy of Anti-Lag3 Mabs Is Independent of their Lag-3-Mhc Class II Blocking Capacity
Saso Cemerski, Ph.D., Associate Principal Scientist, Merck Research Laboratories
LAG-3 is a MHC-II-interacting receptor that hampers T cell activation. We assessed the relationship between anti-LAG-3 antibody-induced efficacy and the ability to block LAG-3-MHCII interactions. We compared the bioactivity of two distinct anti-mLAG-3 antibodies that differ in their ability to block LAG-3-MHCII interactions. We demonstrated that anti-LAG-3 antibody efficacy is not associated with their ability to disrupt LAG-3-MHCII interaction, suggesting they could enhance both CD4+ and CD8+ T cell function.

2:30 Pathways and Mechanisms Engaged by OX40 Plus 4-1BB Dual Costimulation Immunotherapy
Adam J. Adler, Ph.D., Professor, Immunology, University of Connecticut
Dual costimulation with CD134 plus CD137 agonists elicits powerful therapeutic tumor immunity by priming robust CD8+ CTL, and CD4 T cells that are cytotoxic and provide both antigen-linked and non-linked help. Further, dual costimulated T cells can be triggered to elaborate effector functions not only by antigen, but also TCR-independently through cytokine combinations such as IL-12 or IL-2 plus either of the IL-1 family members IL-33 or IL-36.

3:00 Refreshment Break

3:30 High Dimensional Cell Analysis of Early Lung Tumor Immune Contexture
Miriam Merad, M.D., Ph.D., Chair, Cancer Immunology, Oncological Sciences, Tisch Cancer Institute, Mount Sinai Hospital
Despite unprecedented clinical response of advanced NSLC to checkpoint blockade, a comprehensive understanding of the immune microenvironment of early stage NSLC has not been done. Here we will present high dimensional single-cell analysis of immune changes that occurs in the vicinity of early lung NSCLC. Our results provide a rationale for testing whether modulation of the lung tumor immune microenvironment can promote anti-tumor immunity, prevent tumor relapse and transform the outcome of patients with early lung cancer.

4:00 Inducing Neo-Antigen Specific T Cells from the Naïve Repertoire
Marit van Buuren, Ph. D., Scientist, Immunology, Neon Therapeutics
The recognition of neo-antigens on human cancer has strongly been connected to the clinical success of immune therapies. Neon Therapeutics Inc. aims to generate neo-antigen specific vaccines and T cell therapies that are tailored for each individual patient. Here we will present the platform that Neon has developed to generate a neo-antigen specific T cell product for the use of adoptive cell transfer.

4:30 Targeting TIM-3 and LAG-3
Jeffrey Hanke, Ph.D., CSO, Tesaro
Strategies to activate exhausted tumor-specific T cells, including the use of monoclonal antibodies (mAb) that block the negative costimulatory receptors CTLA-4 and PD-1/PDL1, are proving effective in a number of cancer types. However, only a subset of patients respond to these therapies, and resistance is increasingly observed. The role of TIM3 and LAG3 will be discussed.

5:00 End of Day

TUESDAY, AUGUST 30

8:00 am Morning Coffee

PROTEIN ENGINEERING FOR CANCER IMMUNOTHERAPIES

8:25 Chairperson's Opening Remarks
John Desjarlais, Ph.D., CSO, Xencor

8:30 The Role of Antibody Isotype and Fc Receptor Interactions in Engineering Cancer Immunotherapies
Stephen Beers, Ph.D., Associate Professor, Cancer Immunology and Immunotherapy, University of Southampton
Exciting clinical results with checkpoint-blocking mAb have revived the belief that the immune system holds the key to controlling cancer. Here we show that immunostimulatory mAb can employ multiple mechanisms in tumors, and that the mechanism used depends on mAb isotype and FcγR availability. These data have broad implications for selecting tumor immune targets and engineering immunomodulatory mAb; illustrating the necessity to determine all potential mechanisms of action to maximize activity and potential clinical utility.

9:00 Immune Checkpoint Inhibition by High-Affinity Receptor Decoys: Good Things Come in Small Packages
Aaron Ring, M.D., Ph.D., Assistant Professor, Immunobiology, Yale University School of Medicine
Immune checkpoints have largely been therapeutically targeted using monoclonal antibodies. However, non-antibody biologics may offer potential advantages in the context of tumor immunotherapy. This talk will highlight two engineered ultra high-affinity decoys of PD-1 and SIRPα—checkpoints of the adaptive and innate immune systems, respectively. These agents illustrate the potential for small protein therapeutics as immunotherapeutics, components of cell-based therapies, and diagnostic agents of immune function and tumor immunogenicity.

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9:30 Targeting Fc Effector Functions to Tumor-Expressed Integrins for Synergistic Innate and Adaptive Immunotherapy

K. Dane Wittrup, Ph.D., Carbon P. Dubbs Professor, Chemical Engineering and Biological Engineering, Massachusetts Institute of Technology

Anti-tumor antibodies combined with extended-PK IL-2 leads to significant immunotherapeutic responses in large established syngeneic tumors in mice. In order to extend this approach to tumor types for which specific antibodies are not available, we have constructed an Fc fusion to a small knottin protein with broad binding specificity to RGD-binding integrins. This pseudo-mAb exhibits strong efficacy in preclinical models and generates a T-cell dependent protective adaptive immune response.

10:00 Discussion with Session Speakers

10:30 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Tumor-Specific Antibodies Engineered to Bind NKG2D Activate both NK and T-Cells

Kyle Landgraf, Ph.D., Senior Scientist, Discovery Research, AvidBiotics

NK and T-cells utilize the NKG2D receptor to destroy cancer cells expressing stress ligands. However, tumors deploy strategies to evade this surveillance pathway. Using structure-guided phage display, NKG2D stress ligands have been engineered as effector domains to convert tumor-specific antibodies into dual NK/T-cell activators through NKG2D engagement. These antibodies can stimulate IFNγ production and degranulation of NK and T-cells, providing rationale for their use in combination with checkpoint therapies.

11:45 Bispecific Antibodies for T Cell Recruitment and Dual Checkpoint Blockade

John Desjarlais, Ph.D., CSO, Xencor

We have optimized a plug-and-play, Fc-containing bispecific antibody platform with high stability, efficient production, and antibody-like pharmacokinetics. This optimized bispecific format resembles a standard monoclonal antibody, with one of the Fab arms replaced by a stability-optimized single-chain Fv (scFv) (scFv-Fab-Fc). We will present application of the platform to generate a broad pipeline of CD3 bispecifics for T cell redirection and dual checkpoint blockade bispecifics for T cell activation.

12:15 pm Close of Immunomodulatory Therapeutic Antibodies for Cancer

PRESENT A POSTER AND SAVE $50!

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Oncolytic Virus Immunotherapy

Unlocking Oncolytic Virotherapies: From Science to Commercialization

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Targeting the Cancer Mutanome
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MONDAY, AUGUST 29

7:30 am Registration & Morning Coffee

REALIZING THE POTENTIAL OF ONCOLYTIC VIRUS IMMUNOTHERAPY

8:25 Chairperson's Opening Remarks
Brian Champion, Ph.D., Senior Vice President, R&D, PsiOxus Therapeutics Ltd

8:30 T-Vec: From Market Approval to Future Plans
Jennifer Gansert, Ph.D., Executive Director, Global Development Lead, Amgen, Inc.
Talimogene laherparepvec (T-VEC) is a modified herpes simplex virus type -1 designed to selectively replicate in tumors and to promote an anti-tumor immune response. T-VEC is approved for metastatic melanoma based on a randomized phase III trial; T VEC significantly improved durable response rate vs GM-CSF. Data from the pivotal trial and combination studies with checkpoint inhibitors will be presented.

9:00 Oncolytic Virotherapies as a Single Shot Cure?
Stephen J. Russell, M.D, Ph.D., Professor, Mayo Clinic
Oncolytic virotherapy is increasingly used as a cancer immunotherapy. However, certain oncolytic viruses can also mediate wholesale tumor destruction independently of an antitumor immune response. This is the oncolytic paradigm, where a cytolytic virus with preferential tumor tropism spreads extensively at sites of tumor growth and directly kills the majority of the tumor cells in the body leaving only a few uninfected tumor cells to be controlled by the concomitant antitumor immune response.

9:30 Coffee Break

UNDERSTANDING MECHANISMS OF ACTION

9:55 Chairperson's Remarks
Fares Nigim, M.D., Massachusetts General Hospital and Harvard Medical School

10:00 Designing Clinical Trials to Elucidate Oncolytic Virus Mechanisms-of-Action
Caroline Breitbach, Ph.D., 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.

10:30 T-Stealth Technology Mitigates Antagonism between Oncolytic Viruses and the Immune System through Viral Evasion of Anti-Viral T-Cells
Matthew Mulvey, Ph.D., CEO, BeneVir
Simultaneous combination of OV and immune checkpoint inhibitors (ICI) are antagonistic because ICI enhance anti-viral T-cell effector activity and speed OV clearance. BeneVir's T-StealthTM armed OV mitigate antagonism between OV and ICI because they evade anti-viral T-cells. This allows OV and ICI to be administered simultaneously over several treatment cycles to maximize the likelihood of a synergistic clinical response

11:00 Improving Oncolysis and Therapy with Pharmacologic Modulation
Antonio Chiocca, Professor & Chairman, Department of Neurosurgery , Brigham & Women's Hospital/ Harvard Medical School

11:30 Moving Toward Multi-Functionality in Poxvirus-Based Oncolytic Virotherapy
Sponsored by: transgene
Eric Quemeneur, Ph.D., Pharm.D., Executive VP and CSO, Transgene
Poxviruses are powerful immunotherapeutics and tumor-targeting platforms. We recently expanded Transgene's portfolio of armed oncolytic Vaccinia Viruses (oVV) by engineering a vector that targets anti-PD1 IgG expression into the tumor. Local concentration of virus-encoded antibody was ~10-50 times higher than the reference mAb, leading to significant improvement of survival in a sarcoma preclinical model. Such results announce the next-generation oVVs, combining immunogenic oncolysis with the capacity to deliver complex therapeutic modalities in the tumor micro-environment.

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

12:30 Session Break

BIOMARKERS AND IMPROVING VIRUS ACTIVITY

1:25 Chairperson's Remarks
David Kirn, M.D., CEO & Co-Founder, 4D Molecular Therapeutics & Adjunct Professor of Bioengineering, UC Berkeley

1:30 New Biomarkers that Predict Response to Oncolytic Virus Immunotherapy
Howard L. Kaufman, M.D., FACS, Associate Director, Clinical Sciences, Rutgers Cancer Institute of New Jersey; Professor and Chief, Division of Surgical Oncology, Rutgers Robert Wood Johnson Medical School
T-VEC is the first oncolytic virus approved for the treatment of melanoma, and will soon enter clinical trials for treatment of other cancers. Further studies using T-VEC in combination with T cell checkpoint inhibitors are underway and showing promising early results. The identification of predictive biomarkers of response would be helpful for improving patient selection and optimizing therapeutic outcomes. We have recently focused on HSV-1 entry receptors and oncogenic signaling pathways within cancer cells as potential biomarkers of T-VEC response.

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2:00 Therapeutic Viral Vector Evolution: A Robust Platform for the Discovery of Optimized Vectors

David Kirn, M.D., CEO & Co-Founder, 4D Molecular Therapeutics; Adjunct Professor, Bioengineering, University of California, Berkeley

Therapeutic virus vectors hold great promise for cancer gene and immunotherapy. However, novel vectors with improved efficacy are needed. Therapeutic Vector Evolution is a discovery platform from which optimized and proprietary viral vectors can be identified with beneficial characteristics of interest.

2:30 Enhancing Oncolytic Virus Activity by Engineering of Artificial MicroRNAs

John Bell, Ph.D., Senior Scientist, Centre for Innovative Cancer Research, Ottawa Hospital Research Institute, Professor, Departments of Medicine and Biochemistry, Microbiology & Immunology, University of Ottawa

We have devised a novel strategy to enhance the ability of oncolytic viruses to infect malignant cells by expressing artificial microRNAs (amiRNAs) from the oncolytic virus genome. We have screened a variety of amiRNAs and identified a number that enhance virus replication within tumour but not normal cells. The characterization of these miRNAs and their targets will be discussed.

3:00 Refreshment Break

3:30 Immuno-Oncolytic Viruses as Cancer Therapies

Stephen Thorne, Ph.D., Professor and Scientific Advisor, Inventor, Western Oncolytics

Oncolytic viruses primarily act as immunotherapies, yet most vectors still rely on the virus' inherent immune activation, often coupled to single cytokine transgene expression. However, for optimal activity they will need to overcome the tumor¹s immunosuppressive microenvironment, to raise anti-tumor CTL and allow repeated systemic delivery. Approaches to achieve all of these activities in a single vector are being developed.

4:00 Arming the Oncolytic Virus Enadenotucirev to Develop Tumor-Localized Combination Immunotherapeutics

Brian Champion, Ph.D., Senior Vice President, R&D, PsiOxus Therapeutics Ltd.

We have developed a systemically deliverable, oncolytic adenoviral platform for directing efficient and selective local production of a combination of biotherapeutic agents selectively within the tumor. This has the potential for enhanced efficacy while reducing side effects by limiting systemic exposure. Up to three separate biomolecules can be encoded in the same virus without affecting oncolytic properties of the virus.

4:30 PANEL DISCUSSION: ONCOLYTIC IMMUNOTHERAPY IN THE ERA OF CHECKPOINT BLOCKADE

Robert Coffin, Ph.D., CEO, Replimmune Ltd

- Is there a future for single agent oncolytic immunotherapy, if so in what clinical context?
- Is clinically effective intravenous dosing with oncolytic immunotherapies, as single agent or in combination, achievable?
- What is next for the development of the next generation of oncolytic immunotherapies?

5:00 End of Day

TUESDAY, AUGUST 30

8:00 am Morning Coffee

TRANSLATIONAL AND CLINICAL UPDATES

8:25 Chairperson's Opening Remarks

8:30 Phase I of Intravenous Vcn-01 in Patients with Advanced Cancer: Update on Clinical & Biologic Data

Manel Cascallo, Ph.D., Co-Founder, President and CEO, VCN Biosciences

A first-in-human Phase I dose escalation study of intravenous administration of VCN-01 (an oncolytic adenovirus with RB tumour-targeting properties and expressing hyaluronidase) with or without gemcitabine and Abraxane is ongoing for patients with advanced solid tumours including pancreatic cancer. Dose dependent tolerability data and VCN-01 levels in different biological samples (including blood and tumour biopsies) are available.

9:00 Reolsyin: A Clinical Update of a Directed Cytotoxic Agent and Immune Modulator

Brad Thompson, Ph.D., CEO, Oncolytics Biotech

REOLYSIN was initially investigated for its potential as a selective cytotoxin. However, recent research shows that it also functions as an immune modulator. This dual mechanism of action for a single viral agent suggests that the potential of viral therapies may be broader than previously anticipated.

9:30 Retroviral Replicating Vectors for Cancer-Selective Immuno/Gene Therapy: Translational and Clinical Update

Noriyuki Kasahara, M.D., Ph.D., Professor, Departments of Cell Biology and Pathology, Co-Leader, Viral Oncology Program, University of Miami

Pro-drug activator gene therapy with retroviral replicating vectors is tumor-selective, and can lead to development of anti-tumor immunity. Ascending dose Phase I trials by Tocagen Inc. in recurrent high-grade glioma demonstrated favorable safety and tolerability, intratumoral virus spread, radiographic responses, and survival surpassing historical benchmarks. Based on these results, a randomized controlled Phase II/III trial is now underway.

10:00 Seprehvir, an Icp34.5 Deleted OHSV with Both Direct and Covert Modes of Action

Joe Conner, Ph.D., CSO, Virttu Biologics

Seprehvir, an oncolytic HSV, is a complex biologic with multi-mechanistic modes of action. Lytic cytotoxicity, induction of Th1 cytokines/chemokine responses, recruitment of innate and adaptive immune cells and changes in the tumor microenvironment can enhance therapeutic efficacy in combination with other anti-cancer agents. How these modes of action intersect with PD-1 checkpoint inhibitors, CAR T cells and small molecule targeted therapies will be discussed.

10:30 Grand Opening Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Virus Manufacturing Comes of Age: Turning Bugs into Features

Anthony Davies, Ph.D., COO, 4D Molecular Therapeutics

Viruses destroy the host in which you're trying to produce them and then must be separated from all components of those cells. Many solutions to these challenges have been invented since the earliest production of viral vaccines in primary cells obtained directly form animals. But few have proven amenable to cost-effective, compliant and scaleable operation.

11:45 Manufacturing Large Enveloped Oncolytic Viruses for Human Clinical Trials

Mark J. Federspiel, Ph.D., Professor and Director, Viral Vector Production Laboratory, Mayo Clinic

The large-scale production and purification of larger enveloped oncolytic viruses are particularly challenging. We have developed enveloped virus GMP production processes using suspension cells in combination with gentle but effective purification using hollow fiber tangential flow filtration that result in greater than 99.5% removal of contaminants and greater than 100-fold increases in final infectious virus titers.

12:15 pm Close of Oncolytic Virus Immunotherapy

Rational Combination Cancer Immunotherapy

A Forward-Looking View of the Science and Strategies that Will Inform the Discovery and Development of Effective Immunotherapy Combinations

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Targeting the Cancer Mutanome
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TUESDAY, AUGUST 30

12:00 pm Registration

1:15 Chairperson's Opening Remarks
Arthur M. Krieg, M.D. CEO, Checkmate Pharmaceuticals

1:20 KEYNOTE PRESENTATION: SELECTING PD-L1/PD-1 IMMUNOTHERAPY COMBINATIONS
Edward Cha, M.D., Ph.D., Associate Medical Director, Cancer Immunotherapy Franchise, Genentech
Although targeted inhibition of the PD-L1 pathway enhances anti-tumor immunity, not all patients achieve benefit from single-agent immunotherapies. Determining and prioritizing effective combinations will rely on further understanding of the mechanisms that drive immune resistance across indications and individual patients.

CONSIDERATIONS IN DESIGNING IMMUNOTHERAPY COMBINATIONS

1:50 Rational Combination Immunotherapy Development Stratified by the Presence or Absence of the T Cell-Inflamed Tumor Microenvironment
Jason J. Luke, M.D., FACP, Assistant Professor, Medicine, Melanoma and Developmental Therapeutics Clinics, University of Chicago Medical Center
Tumors can be categorized by gene expression based on the presence or absence of a T cell-inflamed tumor microenvironment, and this correlates with either response or lack of response to immune-checkpoint blockade. Categorization of these biologically distinct subsets suggests rational immunotherapy combinations directed toward either a T cell-inflamed or non-T cell-inflamed tumor microenvironment. This approach also facilitates a framework for interrogating molecular mechanism of immune exclusion mediating non-inflamed tumors.

2:20 Programming DCs *in situ* for Cancer Vaccination
Omar Ali, Ph.D., Staff Scientist, Wyss Institute for Biologically Inspired Engineering, Harvard University
The innate components required to mediate effective vaccination against weak tumor-associated antigens remain unclear. We utilize three-dimensional and macroporous, polymeric cancer vaccines incorporating different classes of TLR adjuvants to induce tumor regression and protection in order to identify dendritic cell subsets and cytokines critical to this efficacy. Vaccine-induced tumor regression correlated to local CD8(+) DC and pDC numbers, IL-12, and G-CSF concentrations regardless of the incorporated adjuvant.

2:50 Discussion with Session Speakers

3:20 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 PLENARY KEYNOTE SESSION
See Keynotes for details.

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

5:30 Dinner Short Course Registration*
*Separate registration required, please see Short Courses for details

WEDNESDAY, AUGUST 31

8:00 am Morning Coffee

CLINICAL UPDATES

8:25 Chairperson's Remarks
Christopher R. Heery, M.D., Director, Clinical Trials Group, Laboratory of Tumor Immunology, Center for Cancer Research

8:30 Breaking the Suppressive Myeloid Barrier to Overcome Checkpoint Blockade Resistance
Michael A. Curran, Ph.D., Assistant Professor, Immunology; Scientific Director, ORBIT Platform MD Anderson Cancer Center
While blockade of T cell immune checkpoint molecules such as CTLA-4 and PD-1 has dramatically improved therapeutic outcomes in metastatic melanoma and lung cancer, many other cancers such as those of the pancreas, prostate, and colon (MSI-low) fail to respond. We find that suppressive myeloid cells play a critical role in mediating this resistance, and that through their disruption these cancers can be sensitized to checkpoint blockade.

9:00 Novel Combinations of Immunotherapeutics Based on Preclinical Modeling and Clinical Biomarker Analysis
Christopher R. Heery, M.D., Director, Clinical Trials Group, Laboratory of Tumor Immunology, Center for Cancer Research
This talk will discuss examples of clinical trial design based on integration of preclinical modeling and pharmacokinetic and pharmacodynamic analysis of early stage trials. The focus will be on integration of new findings as an iterative process toward optimal trial design to achieve maximal clinical benefit.

9:30 FEATURED PRESENTATION: SUMMARY OF KEY CLINICAL COMBINATION TRIALS PRESENTED AT ASCO
Paul Rennert, Ph.D., President & CSO, Aleta Biotherapeutics Inc.
ASCO 2016 will give us new insights into diverse and interesting advances in oncology therapeutics. I will report on the top studies of interest in the following areas: novel immune checkpoints and checkpoint combinations; immune checkpoint combinations with other therapies, targets in the tumor microenvironment, CAR T and TCR therapies, and other studies that enrich our understanding of immuno-oncology as a broad-based discipline for cancer therapy.

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10:00 Enhancement of Immune Responses with a Well-Tolerated Selective TLR3 Agonist and Potential for I-O Combination

Christopher F. Nicodemus, M.D., FACP, President & CSO, AIT Strategies

Despite dramatic advances with checkpoint inhibitors, the majority of cancer patients fail monotherapy. Rintatolimod is a selective TLR3 agonist with >900 patient dosing experience. Evidence will be reviewed that rintatolimod:

- Modulates the human tumor microenvironment
- Restores cellular immune responses
- Synergizes with checkpoint inhibition in animal tumor models
- Has monotherapy activity in melanoma and renal cell carcinoma
- Currently in human cancers trials as a component of immunotherapy
- IP protection to 2028

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:15 Cancer Immunotherapy: Immunomodulatory Approaches Beyond PD-1

Andrea van Elsas, Ph.D., CSO, Aduro Biotech Europe, The Netherlands

T cell checkpoint inhibitors set a clinical paradigm providing significant benefit to patients diagnosed with advanced cancer. Despite success, the majority of patients do not respond to PD-1, PD-L1 or CTLA-4 blockade. Raising the number of patients benefiting from cancer immunotherapy requires novel therapeutic approaches aimed at these non-responders, for instance using novel immunomodulatory antibodies and combination with active immunization.

11:45 Panel Discussion: Best Practices for Organizations and Academic Labs Entering the Cancer Immunotherapy Space

Moderator: Llew Keltner, M.D., Ph.D., CEO, EPISTAT

The scientific potential of immunotherapy combinations is vast, and the clinical successes in this space have attracted significant numbers of large and small players to the field. Our panel will dissect the most important scientific and strategic considerations for those wanting to participate in these collaborations and offer audience members the opportunity for focused feedback from experts in business, regulatory, scientific, healthcare and dealmaking functions.

Panelists:

Konstantin M. Linnik, Ph.D., Partner, Intellectual Property, Nutter, McClennen & Fish, LLP

Kuldeep Neote, Ph.D., Senior Director, New Ventures, J&J Innovation Center Boston

Taylor Schreiber, M.D., Ph.D., CSO, Heat Biologics, Inc.

Elena Spanjaard, Ph.D., Director, Worldwide Research & Development, Regulatory Affairs, Pfizer

12:45 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

1:15 Session Break

IMMUNOTHERAPY COMBINATION STRATEGIES

1:55 Chairperson's Remarks

Paul Rennert, Ph.D., President & CSO, Aleta Biotherapeutics Inc.

2:00 Next-Generation Biomarkers for the Era of Combination Cancer Immunotherapy

David Kaufman, Ph.D., Executive Director, Clinical Oncology, Merck Research Laboratories

A variety of other agents may have additive or synergistic activity in combination with PD-1 checkpoint blockade. As such regimens advance, it will be critically important to understand how to direct the right combinations to patients who stand to benefit most from them. Next-generation biomarkers are beginning to provide insight into fundamental aspects of tumor cell and immune biology that are relevant for a precision medicine approach to cancer immunotherapy combinations.

2:30 Inhibition of Immune Checkpoints and Vascular Endothelial Growth Factor as Combination Therapy for Metastatic Melanoma

Patrick Alexander Ott, M.D., Ph.D., Assistant Professor, Medicine, Dana-Farber Cancer Institute

Emerging evidence indicates that immunotherapy can lead to immune-mediated vasculopathy in the tumor. While the inhibition of angiogenesis through targeting of vascular endothelial growth factor (VEGF) has been used successfully for the treatment of cancer the mechanisms of its anti-tumor activity remain poorly understood. Initial studies of the complex relationship between angiogenesis, VEGF signaling and the immune system suggest that the combination of immune checkpoint blockade with angiogenesis inhibition has potential.

3:00 Rationale for Combinatorial Immunotherapy Approaches

Alex Morozov, M.D., Ph.D., Senior Medical Director and Global Clinical Lead, Pfizer

Immunotherapy is poised to become an integral part of the cancer treatment paradigm. Cytotoxics, TKIs, other small molecules, and non-IO large molecules like ADCs will remain important treatment modalities. Understanding how these could be combined or sequenced with immunotherapy to transform cancer care is crucial. Pfizer's immunotherapies in the clinic include those targeting PD-1, PD-L1, CTLA-4, OX-40, CD137, CCR2, and MSCF. The rationale for combinatorial strategies will be discussed.

3:30 Refreshment Break with Exhibit and Poster Viewing

4:15 Immunotherapy in Combination with Novel Tumor Vaccines

Craig L. Slingluff, Jr., M.D., Professor, Surgery, University of Virginia School of Medicine

New approaches to cancer vaccines may use neoantigens, novel antigen formulations, or modified delivery systems. Promising findings support vaccines targeting CD4+ helper T cells, and new approaches to in situ vaccination show promise. Novel vaccine adjuvants may augment T cell responses, and combinations with a range of checkpoint blockade molecules or other systemic therapy agents may favorably modulate immune responses to vaccines and to human cancers.

4:45 Novel Combination Immunotherapy Strategies to Optimize T Cell Responses Against Cancer

Howard L. Kaufman, M.D., FACS, Associate Director, Clinical Science, Chief Surgical Officer, Rutgers Cancer Institute of New Jersey

The remarkable success of T cell checkpoint inhibitors has highlighted the importance of promoting activation and preventing suppression of T cells for the treatment of cancer. This presentation will discuss the central importance of T cells within the tumor microenvironment, highlight some of the more promising combinations in development and provide recommendations for how to select the most promising immunotherapy agents for combination regimens.

5:15 Enhancing the Efficacy of Checkpoint Inhibition with a TLR9 Agonist Delivered in a Virus-Like Particle

Arthur M. Krieg, M.D. CEO, Checkmate Pharmaceuticals

Checkpoint inhibitors can induce durable remissions in patients with advanced malignancies that are immunologically "hot" (have a type I IFN signature and CD8 T cell infiltrates) but they are rarely effective in the treatment of immunologically "cold" tumors. Intratumoral injection of a TLR9 agonist CpG-A oligonucleotide is expected to convert "cold", checkpoint-unresponsive tumors into "hot" tumors, resulting in an increased response rate to combination therapy.

5:45 Close of Rational Combination Cancer Immunotherapy

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Personalized Immunotherapy

Personalized Oncology in the Genomic Era: Expanding the Druggable Space

Recommended Dinner Short Course*
Bispecific Antibody Development for Immunotherapy
*Separate registration required, please see Short Courses for details

TUESDAY, AUGUST 30

12:00 pm Registration

TUMOR NEOANTIGENS FOR PERSONALIZED IMMUNOTHERAPY

1:15 Chairperson's Opening Remarks
Pramod K. Srivastava, M.D., Ph.D., Professor, Immunology and Medicine, Director, Carole and Ray Neag Comprehensive Cancer Center, University of Connecticut School of Medicine

1:20 Basics of Personalized Immunotherapy: What Is a Good Antigen?
Pramod K. Srivastava, M.D., Ph.D., Professor, Immunology and Medicine, Director, Carole and Ray Neag Comprehensive Cancer Center, University of Connecticut School of Medicine
The definition of host-protective immunogenic antigen(s) of any human cancer of non-viral origin is still an enigma. New approaches in cancer genomics and bioinformatics are now offering a plethora of candidate antigens, whose role in cancer immunity, and specifically in host-protective cancer immunity, is under extensive testing. Outlines of some broad rules are emerging and some of these shall be discussed.

1:50 Novel Antibodies against Immunogenic Neoantigens
Philip M. Arlen, M.D., President & CEO, Precision Biologics, Inc.
Two novel antibodies, NEO-102 (ensituximab) and NEO-201, were developed from an allogeneic colorectal cancer vaccine that had previously shown activity in patients with metastatic colorectal cancer This vaccine was derived from an immunogenic component of the cell membrane from pooled surgical specimens from both primary and metastatic colon cancer. Patients who benefited from the vaccine in the prior clinical trial produced and sustained high levels of serum IgG against the vaccine. Several thousand candidate antibodies were screened against this vaccine and NEO-102 and NEO-201 were candidates that demonstrated the ability to bind to colon cancer vs. normal tissue.

2:20 PD-1 Blockade in Tumors with Mismatch-Repair Deficiency
Luis Alberto Diaz, M.D., Associate Professor, Oncology, Johns Hopkins Sidney Kimmel Comprehensive Cancer Center
Somatic mutations have the potential to encode "non-self" immunogenic antigens. Tumors with a large number of somatic mutations due to mismatch-repair defects appear to be highly susceptible to immune checkpoint blockade. This presentation will summarize the clinical and genomic data of using mutations as neoantigens.

2:50 *In situ* Vaccination for Lymphoma
Joshua Brody, M.D., Director, Lymphoma Immunotherapy Program, Icahn School of Medicine at Mount Sinai
Prior *ex vivo* combinations of dendritic cells (DC) with tumor antigens have yielded immunologic and clinical responses. Intratumoral immunomodulation may bypass the need for *ex vivo* production of vaccine. *In situ* vaccination combines: intratumoral Flt3L to recruit DC, low dose radiotherapy to load DC with tumor antigens, and intratumoral TLR agonist to activate tumor-antigen-loaded DC. Preliminary results demonstrate DC recruitment and activation, systemic tumor regressions, and induction of neoantigen specific CD8 T cell responses after vaccination.

3:20 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 PLENARY KEYNOTE SESSION
See Keynotes for details.

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

5:30 Dinner Short Course Registration*
*Separate registration required, please see Short Courses for details

WEDNESDAY, AUGUST 31

8:00 am Morning Coffee

PERSONALIZED IMMUNOTHERAPY WITH CANCER VACCINES

8:25 Chairperson's Remarks
Ravi Madan, M.D., Clinical Director, Genitourinary Malignancies Branch, National Cancer Institute, National Institutes of Health

8:30 Presentation to be Announced

9:00 Developing Therapeutic Cancer Vaccine Strategies for Prostate Cancer
Ravi Madan, M.D., Clinical Director, Genitourinary Malignancies Branch, National Cancer Institute, National Institutes of Health
The development of immunotherapy strategies has become the primary focus in oncology. This lecture will provide prostate cancer as a template to demonstrate synergies between immune-based therapies and chemotherapy, radiopharmaceuticals and hormonal therapies.

9:30 Getting Very Personal: Fully Individualized Tumor Neoantigen-Based Vaccine Approaches to Cancer Therapy
Karin Jooss, Ph.D., CSO, Gritstone Oncology
Genetic instability in tumors generates tumor-specific neoantigens which have been identified as the targets of new T cells in patients responding to checkpoint inhibitor therapy. Predicting neoantigens by sequencing routine clinical biopsy material, and then incorporating them into therapeutic cancer vaccines is an attractive concept being developed by Gritstone Oncology. The complexities of neoantigen prediction will be discussed, together with insights into how vaccine vectors are selected and designed.

10:00 Approaches to Assess Tumor Mutation Load for Selecting Patients for Cancer Immunotherapy
Sponsored by: PGD
John Simmons, Ph.D., Manager, Research Services, Personal Genome Diagnostics
Tests to identify patients who are most likely to benefit from cancer immunotherapies are urgently needed. Here we discuss PGDx approaches to assess tumor mutation load as a potential predictor of clinical benefit for checkpoint inhibitors in multiple cancer types.

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

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11:15 eVLP Delivery of Novel Foreign Antigens Elicits Polyvalent Anti-Tumor Immunity
Adam Buckley, Vice President, Business Development, VBI Vaccines

11:45 Immunotherapy Using Ad5 [E1-, E2b-] Vector Vaccines in the Cancer MoonShot 2020 Program
Frank R. Jones, Ph.D., Chairman & CEO, Etubics Corporation
The Cancer MoonShot 2020 project intends to design, initiate and complete randomized clinical trials at all stages of cancer in up to 20 tumor types in as many as 20,000 patients by the year 2020. Etubics is participating in the Cancer MoonShot 2020 program by providing its proprietary viral platform, known as Ad5 [E1-, E2b-] as a treatment agent in several of the program's immunotherapeutic vaccination initiatives and trials.

12:15 pm Sponsored Presentations
(Opportunities Available)

12:45 Luncheon Presentation to be Announced
Sponsored by: ADVAXIS IMMUNOTHERAPIES™
Robert G. Petit, Ph.D., Executive Vice President & CSO, Advaxis Immunotherapies

1:15 Session Break

PERSONALIZED CELL THERAPY

1:55 Chairperson's Remarks
Andrew M. Evens, D.O., Professor and Chief, Hematology/Oncology, Tufts University School of Medicine; Director, Tufts Cancer Center

2:00 Integration of Natural Killer-Based Therapy into the Treatment of Lymphoma
Andrew M. Evens, D.O., Professor and Chief, Hematology/Oncology, Tufts University School of Medicine; Director, Tufts Cancer Center
Targeting signaling pathways or epitopes with small molecules and antibody-based immunotherapeutic agents is a leading strategy for cancer therapy. Promising immunotherapy agents being examined for the treatment of lymphoma include monoclonal antibodies, immunomodulatory agents, PD-1 inhibitors, chimeric antigen receptor (CAR) T-cells, and NK-based therapies. The optimum combinations or sequences of these therapeutics continue to be defined. Additionally, understanding tumor and patient/host heterogeneity is desired in order to optimize personalized medicine.

2:30 Dendritic Cells: Personalized Cancer Vaccines and Inducers of Multi-Epitope-Specific T Cells for Adoptive Cell Therapy
Pawel Kalinski, M.D., Ph.D., Professor, Surgery, Immunology, and Bioengineering, University of Pittsburgh School of Medicine, University of Pittsburgh Cancer Institute
Conditions of dendritic cell (DC) maturation affect their ability to cross-present cancer cell-derived antigens and induce clonal expansion and effector functions of responding T cells. We will discuss the pathways of DC maturation which promote their preferential interaction with naïve, memory and effector T cells, cross-presentation of antigens from dead cancer cells, and induction of large numbers of type-1 CD4+ and CD8+ T cells specific for multiple tumor-associated antigens *ex vivo* and *in vivo*.

3:00 Mesothelin-Targeted CAR T-Cell Therapy for Solid Tumors
Prasad S. Adusumilli, M.D., FACS, Deputy Chief of Translational & Clinical Research, Thoracic Surgery, Memorial Sloan-Kettering Cancer Center
Mesothelin, a cell-surface antigen, provides an exciting prospect based on its higher expression in a majority of solid tumors (estimated annual incidence of 340,000 and prevalence of 2 million patients in the U.S.), limited expression in normal tissues and its association with tumor aggressiveness. CAR T-cell therapy with second generation mesothelin-targeted CARs has been translated to clinical trials targeting mesothelioma, non-small cell lung cancer, triple-negative breast cancer, and other solid tumors.

3:30 Refreshment Break with Exhibit and Poster Viewing

4:15 Synthetic Regulation of T Cell Therapies Adds Safety and Enhanced Efficacy to Previously Unpredicted Therapies
David M. Spencer, Ph.D., CSO, Bellicum Pharmaceuticals
CAR- and TCR-based T cell therapies have had some spectacular successes in a handful of malignancies, but safety and efficacy concerns still impede broader adoption of these new technologies.
Bellicum Pharmaceuticals has developed a suite of synthetic ligand-inducible switches to rapidly and rigorously regulate T cell therapies.
These potent switches address both safety and anti-tumor efficacy and promise to further expand the reach of immunotherapy.

4:45 Long-Term Relapse-Free Survival of Patients with Acute Myeloid Leukemia (AML) Receiving a Telomerase- Engineered Dendritic Cell Immunotherapy
Jane Lebkowski, Ph.D., President & CSO, Research and Development, Asterias Biotherapeutics
There are few treatment options for patients with intermediate and high risk AML, and remission and relapse rates are dismal, especially in patients ≥ 60 years old. A Phase II clinical trial was conducted in subjects with AML to assess a dendritic cell immunotherapy (ASTVAC1) engineered to express a modified form of telomerase that is processed through both the MHC Class I and II antigen presentation pathways. The results suggest that immunotherapy with AST-VAC1 is safe, can stimulate immune responses to telomerase, and may extend relapse-free survival even in patients with high risk AML.

5:15 Activated and Exhausted Tumor Infiltrating B Cells in Non-Small Cell Lung Cancer Patients Present Antigen and Influence the Phenotype of CD4 Tumor Infiltrating T Cells
Tullia Bruno, Ph.D., Research Assistant Professor, Immunology, University of Pittsburgh
The focus of immunotherapy has been on subsets of CD8 and CD4 tumor infiltrating lymphocytes (TILs), however, tumor infiltrating B cells (TIL-Bs) have been reported in tertiary lymphoid structures (TLS) with CD4 TILs, and both TIL-Bs and TLS correlate with NSCLC patient survival. While TIL-Bs have been identified in NSCLC patients, their function in the tumor microenvironment has been understudied with no focus on their role as antigen presenting cells (APCs) and their influence on CD8 and CD4 TILs. Here, we demonstrate that TIL-Bs can efficiently present antigen to CD4 TILs and influence CD4 TIL phenotype depending on their exhaustion profile.

5:45 Close of Personalized Immunotherapy Conference

Preclinical & Translational Immuno-Oncology

Predictive Preclinical Models for Cancer Immunotherapy

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Bispecific Antibody Development for Immunotherapy
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TUESDAY, AUGUST 30

12:00 pm Registration

PRECLINICAL MODELS FOR IMMUNO-ONCOLOGY

1:15 Chairperson's Opening Remarks
Douglas Linn, Ph.D., Senior Scientist, In Vivo Pharmacology, Merck

1:20 Development of Therapeutic Antibodies to Immune Checkpoint Receptors and Their Validation in Humanized Mice
Ella Ioffe, Ph.D., Associate Director, Immune-Oncology, Regeneron Pharmaceuticals
PD-1 and LAG-3 are immune checkpoint receptors on effector T cells, which when activated can allow tumors to escape immunosurveillance. Regeneron has generated fully human monoclonal antibodies that block (human) PD-1 and LAG-3 function. However, since these antibodies do not block murine proteins, we engineered mice expressing humanized ectodomains of PD-1 and LAG-3 from the murine loci, to allow *in vivo* testing of these clinical antibodies. Robust anti-tumor efficacy of anti-PD-1 (REGN2810) and anti-LAG-3 in humanized mice supports their clinical development in combination cancer immunotherapy.

1:50 Applying Preclinical Immuno-Oncology Mouse Models to Guide Decisions in the Clinic
Douglas Linn, Ph.D., Senior Scientist, In Vivo Pharmacology, Merck
The success of immunotherapies such as checkpoint inhibitors has changed the way cancers are being treated. Preclinical immuno-oncology mouse models provide tremendous value to shaping clinical strategies given that countless potential combinations exist with other immunotherapies, radiation, and/or standards of care. This talk will provide an overview of how immuno-oncology mouse models serve a critical role in guiding treatment options at the bedside.

2:20 Understanding the Tumor Microenvironment: Insights from Studying Mouse Tumor Models
Zhao Chen, Ph.D., Investigator III, Exploratory Immuno-Oncology, Novartis Institutes for BioMedical Research
The success of cancer immunotherapy brings our attention to the non-tumor components of cancer. The cross-talks between different cell populations within the tumor microenvironment (TME) likely dictate the efficiency and efficacy of anti-tumor immune response. Yet, what governs the immune system status within a given tumor remains unclear. Using mouse cancer models, we are able to address specific questions including the roles of tumor genotypes and tumor location in shaping up TME.

2:50 Preclinical Models of Immuno-Oncology: How Do They Translate?
Karuppiah Kannan, Ph.D., Associate Director, Cancer Pharmacology, Takeda Pharmaceuticals International

3:20 Refreshment Break in the Exhibit Hall with Poster Viewing

4:00 PLENARY KEYNOTE SESSION
See Keynotes for details

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

5:30 Dinner Short Course Registration*
*Separate registration required, please see Short Courses for details

WEDNESDAY, AUGUST 31

8:00 am Morning Coffee

TRANSLATIONAL RESEARCH ON COMBINATIONAL IMMUNOTHERAPY

8:25 Chairperson's Remarks
Oliver Ghobrial, Ph.D., Principal Scientist, Translational Informatics, Sanofi

8:30 Augmenting Anti-Tumor Immune Response by Targeting the Notch or Wnt Pathways in Combination with PD1 Axis Blockade
Jakob Dupont, M.D., Senior Vice President & CMO, OncoMed Pharmaceuticals

9:00 Value of QSP (Quantitative Systems Pharmacology) *in silico* Physiological Models in Drug Discovery and Development
Oliver Ghobrial, Ph.D.

9:30 A Modified Developmental and Reproductive Toxicity Testing Strategy for Cancer Immunotherapy
Rodney Prell, Ph.D., DABT, Principal Scientist/ Toxicologist, Safety Assessment, Genentech
The tumor microenvironment establishes several inhibitory pathways that lead to suppression of the local immune response, which is permissive for growth. Similar pathways have also evolved during pregnancy as a way to protect the fetus from immune-mediated rejection. Therefore, cancer immunotherapies designed to enhance the immune response against the tumor may have the undesired effect of increasing immune responses to allo-antigens expressed by the fetus. Reproductive toxicity studies are meant to reveal any potential effects on mammalian reproduction at various stages and are used to inform the potential risk to women that are or may become pregnant, while receiving treatment.

10:00 Understanding the Impact of Animal Vendors and the Microbiome—in Tumor Progression and Treatment—in a Model of Metastatic Breast Cancer
Sponsored by: mdbiosciences.
Britnie James, Ph.D., Lead Scientist, Research & Development, MD Biosciences
Dysbiosis can correlate with the predisposition and progression of cancer. Animal vendor differences in the microbiome can impact immunological and cellular functions. We have examined whether animals from different vendors, with discrete microbiomes, would present with different disease progression and therapy responses in a murine model of metastatic breast cancer.

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

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NOVEL *IN VITRO* MODELS FOR IMMUNOTHERAPY DISCOVERY

11:15 Testing Efficacy of Immunotherapy *in vitro*: Primary 3D Co-Cultures of Tumor Cells and T Lymphocytes

Christian Schmees, Ph.D., Head of Tumor Biology, Molecular Biology Department, NMI Natural and Medical Sciences Institute at the University of Tübingen

The development of more efficient approaches in cancer immunotherapy necessitates the application of cellular models closely resembling patient tumors. In my talk, I will present data derived from a patient-derived model system involving the co-culture of 3D tumor spheroids and T lymphocytes. Imaging-based analyses of these models allow for the evaluation of T lymphocyte infiltration as well as T cell induced cytotoxicity in the spheroids in response to antigen stimulation and/or compound treatment.

11:45 Tipping the Balance: Overriding Phosphatidylserine-Mediated Tumor Immune Suppression to Enhance Immune Checkpoint Therapies

Bruce Freimark, Ph.D., Research Director, Preclinical Oncology, Peregrine Pharmaceuticals

Phosphatidylserine (PS) exposure in tumors induces non-inflammatory signals which contribute to an immunosuppressive environment. Antibody blockade of PS activates immune responses by promoting M1 macrophages, maturation of dendritic cells and inducing adaptive T-cell responses. PS targeting antibodies enhance the anti-tumor activity and survival of checkpoint antibodies in preclinical tumor models by increasing activated cytotoxic T-cell infiltrates and immune stimulatory mediators.

12:15 pm Enjoy Lunch on Your Own

NEW TARGETS FOR CHECKPOINT INHIBITORS

1:55 Chairperson's Remarks

Xingxing Zang, Ph.D., Associate Professor, Microbiology and Immunology & Medicine, Albert Einstein College of Medicine

2:00 Tumor Associated Myeloid Cells Can Be Rendered Dysfunctional by the Tumor Microenvironment through Expression of TIM-3: Implications for TIM-3 Blockade in Cancer

Pushpa Jayaraman, Ph.D., Investigator II, Exploratory Immuno-Oncology, Novartis Institutes for BioMedical Research

TIM-3, a T cell exhaustion marker, is more dominant on myeloid cells than on T cells in murine syngeneic tumor models and in renal cell carcinoma (RCC) treatment-naive patients. We present data that TIM-3+ myeloid cells are dysfunctional, and that TIM-3 blockade rescues myeloid pro-inflammatory function. The pathophysiological role of the TIM-3 pathway in innate immunity might have important consequences on T cell function and TIM-3 blockade in cancer.

2:30 New Targets for Human Cancer Immunotherapy

Xingxing Zang, Ph.D., Associate Professor, Microbiology and Immunology & Medicine, Albert Einstein College of Medicine

CTLA-4 and the PD-1/PD-L1 pathway are current focuses for cancer immunotherapy. This presentation will discuss other new immune checkpoints for future human cancer immunotherapy.

3:00 Modulating Interferon-Gamma Induced PD-L1 Expression in Medulloblastoma

Alex Yee-Chen Huang, M.D., Ph.D., Associate Professor, Pediatrics, Pathology & Biomedical Engineering, Case Western Reserve University School of Medicine

Tumors up-regulate immune checkpoint molecules, including PD-L1, in response to immune effector cytokines such as interferon-gamma. Recent data have revealed new molecular target(s), the interference of which can modulate PD-L1 expression by medulloblastoma in response to interferon-gamma, and can result in efficient tumor elimination by normal host immune response. These exciting findings and their clinical implications will be discussed.

3:30 Refreshment Break with Exhibit and Poster Viewing

PATHWAY DISCOVERY FOR COMBINATION THERAPY

4:15 Immune Modulation: Targets beyond CTLA-4/PD-1 Axes

Catherine Sabatos-Peyton, Ph.D., Senior Investigator, Novartis Institutes for BioMedical Research

With the proven clinical efficacy of PD-1/PD-L1 and CTLA-4 agents in multiple cancer indications, immunotherapy has come to the forefront as a way to modulate an anti-tumor response. Beyond the PD-1/PD-L1 axis, multiple other checkpoint inhibitors, including LAG-3 and TIM-3, have moved into the clinic and distinct modalities may lead to synergistic anti-tumor effects with PD-1 pathway co-blockade. Coordinated modulation of the tumor microenvironment by relieving suppressive pathways to favor CD8+ effector T cell activation may open avenues to broader applicability of immunotherapy in cancer.

4:45 Of Mice and Men: Translating the Immune Oncology Mechanism of Action of NKTR-214

Jonathan Zalevsky, Ph.D., Vice President, Biology & Preclinical Development, Nektar Therapeutics

NKTR-214, a CD122-biased immune-stimulatory cytokine, is designed to expand the numbers and activity of tumor-killing lymphocytes and has shown promising preclinical results as a single agent and in combination with checkpoint inhibitors, cell-therapies, and vaccines. In the Phase I/II clinical study, translational research will assess the immunologic effect of NKTR-214 on tumor-infiltrating lymphocytes (TILs) and other immune cells in both blood and serial tumor biopsies to identify potential biomarkers.

5:15 Discussion with Session Speakers

5:45 Close of Preclinical and Translational Immuno-Oncology Conference

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Adoptive T Cell Therapy

Delivering CAR, TCR, and TIL from Research to Reality

THURSDAY, SEPTEMBER 1

7:45 am Registration & Morning Coffee

PRINCIPALS OF ENGINEERED RECEPTOR DESIGN

8:25 Chairperson's Opening Remarks
Adrian Bot, M.D., Ph.D., Vice President, Translational Sciences, R&D, Kite Pharma Inc.

8:30 KEYNOTE PRESENTATION: NEW APPROACHES TO OVERCOME TUMOR IMMUNE SUPPRESSION FOR T-CELL THERAPY
Laszlo Radvanyi, Ph.D., Senior Vice President and Head, Immuno-Oncology Translational Innovation Platform (TIP), EMD Serono
Adoptive T-cell transfer therapies have made tremendous progress for treating cancer, with successes emerging especially in hematologic malignancies. Although, these cell therapies offer new ways of genetically reprogramming T cells through altered specificities and redirecting T-cell signaling pathways, immune suppressive mechanisms in the tumor microenvironment, such as PD-1-PD-L1 axis, TGF-beta, and an insufficient Th1 response, still raise great challenges to success in solid tumors. Some key agents aimed at overcoming these issues being developed at EMD Serono will be presented.

9:00 Engineering Better T Cells
Daniel Williams, Head, UK Research Operations, Adaptimmune
Adaptimmune is a clinical-stage biopharmaceutical company developing engineered TCRs for adoptive T cell therapy. Engineering TCRs specific for tumor antigens which are self-antigens, requires balancing the need for increasing affinity to the target peptide to allow recognition of immune-selected tumors, with the risk of cross-reactivity, which increases at higher affinities. Target identification and validation, together with a broad and robust preclinical safety testing strategy are critical in the development of safe and efficacious affinity-enhanced TCRs.

9:30 Development of an Anti-BCMA Specific CAR with Potent Anti-Multiple Myeloma Activity
Richard A. Morgan, Vice President, Immunotherapy, bluebird bio
B cell maturation antigen (BCMA) is expressed on most multiple myeloma (MM) cells, yet normal tissue expression is limited to plasma and some B cells. Here we demonstrate that a potent, antigen-dependent, memory-like BCMA CAR T cells can be produced with a scalable manufacturing process that mediated robust tumor regressions in animal models. A Phase I clinical trial to test this approach in patients with relapse refractor MM is underway.

10:00 Coffee Break with Exhibit and Poster Viewing

TARGETS FOR T CELL INTERVENTIONS

10:45 CD19 as a Prototypic B Cell Lineage Target for CAR T Cells
Adrian Bot, M.D., Ph.D., Vice President, Translational Sciences, R&D, Kite Pharma Inc.
Anti-CD19 CAR T cells could be the first marketed products in this space. Prolonged B cell deficiency may not be desirable since B cells are required to combat major pathogens. Product candidates capable to mediate rapid and profound tumor debulking, can yield durable clinical responses without persisting B cell deficiency. Novel evidence will be presented, linking product characteristics, conditioning, and biomarkers, to the clinical outcome afforded by CAR T cells.

11:15 CAR-T Cells for Hematological Malignancies: Exploring Alternative Targets
Gianpietro Dotti, M.D., Professor, Microbiology and Immunology, University of North Carolina
Adoptive transfer of CD19-specific CAR-T cells showed remarkable anti-tumor activity in patients with B-cell derived acute lymphoblastic leukemia and lymphomas. Alternative targets have been explored in Phase I studies in hematological malignancies. Specifically, in the effort to reduce the B cell aplasia associated with effective and long-term persisting CD19-specific CAR T cells, we implemented at Baylor College of Medicine a Phase I study with CAR-T cells targeting the k-light chain of human immunoglobulin to selectively eliminate k+ tumors whilst sparing normal l+ B lymphocytes. To target Hodgkin's Lymphoma and other CD30+ lymphomas, we also implemented a Phase I study with CAR-T cells targeting the CD30 antigen. Outcome of these studies and future directions will be reported.

11:45 PANEL: CAR T Cell Therapy: Target Antigen Discovery and Clinical Translation
Panelists: Adrian Bot, M.D., Ph.D., Vice President, Translational Sciences, R&D, Kite Pharma Inc.
Gianpietro Dotti, M.D., Professor, Microbiology and Immunology, University of North Carolina
Richard A. Morgan, Vice President, Immunotherapy, bluebird bio
- Market potential of anti-CD19 CAR T Cells
- The latest clinical results
- Scalability and manufacturing challenges
- Future directions for CAR therapies

12:15 pm Sponsored Presentations
(Opportunities Available)

12:45 Luncheon Presentation
(Sponsorship Opportunity Available)
or Enjoy Lunch on Your Own

1:15 Session Break

2:00 Chairperson's Remarks
Adrian Bot, M.D., Ph.D., Vice President, Translational Sciences, R&D, Kite Pharma Inc.

2:05 Human Papillomavirus (HPV)-Targeted T Cells for HPV-Associated Cancers
Christian S. Hinrichs, M.D., Investigator, Experimental Transplantation and Immunology Branch, Lasker Clinical Research Scholar, NIH
Human papillomavirus (HPV) causes cancers of the uterine cervix, oropharynx, anus, vulva, vagina and penis. These cancers express the HPV E6 and E7 oncoproteins, which are attractive immunotherapeutic targets. Recent work has sought to target these antigens using tumor-infiltrating lymphocytes and genetically engineered T cells.

2:35 XPRESIDENT®-Guided Target Identification and Profiling of On-and Off-Target Toxicity for Safer Adoptive Cell Therapy
Steffen Walter, Ph.D., CSO, Immatics Biotechnologies GmbH

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A major constraint for the broad and safe application of Adoptive Cellular Therapy is the limited number of validated tumor targets and TCRs. We used a proprietary target discovery engine (XPRESIDENT®) combining highly sensitive quantitative mass spectrometry, transcriptomics, immunology and bioinformatics to characterize the immunopeptidome directly on human normal and tumor tissues. We show how this approach can be used to predict on- and off-target toxicities in TCR-based immunotherapies.

3:05 Engineering Designer T Cells for Immunotherapy

Wolfgang Uckert, Associate Professor, Department of Cell Biology and Gene Therapy, Humboldt University Berlin

Successful immunotherapy using T cell receptor (TCR) gene-modified T cells to treat cancer, viral infections or autoimmune diseases is depending on the careful selection of: (i) the target antigen, (ii) a TCR with optimal affinity, (iii) an efficient gene delivery system, and (iv) a safety switch to interrupt therapy in case of severe adverse side effects. Examples of these different areas to generate designer T cells for successful TCR gene therapy are given and discussed.

3:35 Refreshment Break

4:05 KEYNOTE PRESENTATION: A COMPARISON OF TCRS AND CARS: SENSITIVITIES AND SPECIFICITIES

David M. Kranz, Phillip A. Sharp Professor, Biochemistry, University of Illinois, Urbana-Champaign

T cells, via their T-cell receptors (TCRs), evolved to target intracellular peptides as low-density, cell-surface complexes with MHC products. Synthetic constructs known as chimeric antigen receptors (CARs) contain an anti-tumor antigen scFv and recognize higher density antigens. We have designed high-affinity human TCRs in conventional heterodimer format and in CAR-like formats to directly compare features of both systems. These features include T cell surface levels, antigen sensitivities and other properties.

4:35 PANEL: Designing T Cells for Immunotherapies

Panelists:

Christian S. Hinrichs, M.D., Investigator, Experimental Transplantation and Immunology Branch, Lasker Clinical Research Scholar, NIH

Steffen Walter, Ph.D., CSO, Immatics Biotechnologies GmbH

Wolfgang Uckert, Ph.D., Associate Professor, Cell Biology and Gene Therapy, Humboldt University Berlin

David M. Kranz, Phillip A. Sharp Professor, Biochemistry, Biochemistry, University of Illinois

- Strategies for antigen selection and targeting
- Increasing sensitivity and specificities
- Utilizing efficient gene delivery systems
- Dealing with toxicities

5:05 End of Day

FRIDAY, SEPTEMBER 2

8:00 am Morning Coffee

TARGETING SOLID TUMORS

8:25 Chairperson's Opening Remarks

Jonathan Gilbert, Director, Strategic Scientific Partnerships, SQZ Biotech

8:30 Vector-Free Engineering of Immune Cells for Enhanced Antigen Presentation

Jonathan Gilbert, Director, Strategic Scientific Partnerships, SQZ Biotech

Robust engineering of immune cell function is critical to realizing the therapeutic potential of cell therapies in cancer. Our vector-free CellSqueeze technology has demonstrated novel capabilities in diverse areas including engineering antigen presentation to drive powerful and significant T-cell responses. We will present recent developments in our cell-based immunotherapy programs aimed at using patient-derived antigens to target a variety of cancer indications, including solid tumors.

9:00 Design of a Highly Efficacious CAR Targeting Mesothelin in Solid Tumors

Boris Engels, Ph.D., Investigator, Exploratory Immuno-Oncology, Novartis Institutes for Biomedical Research

The treatment of solid tumors with CAR T cells remains challenging. We describe the design of a human CAR targeting mesothelin, a tumor associated antigen overexpressed in many cancers. A pooled screen identified scFvs, which show enhanced efficacy, superior to the CARs currently used in the clinic. We performed in-depth characterization of the scFvs and CARs to gain insight into structure-activity relationships, which may influence CAR efficacy and future design

9:30 Overcoming CAR T Cell Checkpoint Blockade in Solid Tumors

Prasad S. Adusumilli, M.D., FACS, FCCP, Deputy Chief, Translational and Clinical Research, Thoracic Surgery; Associate Attending, Thoracic Surgery; Member, Center for Cell Engineering, Memorial Sloan-Kettering Cancer Center

CAR T-cell therapy for solid tumors is prone to the checkpoint blockade inhibition similar to innate tumor-infiltrating lymphocytes. Strategies to overcome this 'Adaptive Resistance' of infused CAR T cells can promote their anti-tumor efficacy and functional persistence. Understanding solid tumor type-specific immune microenvironment can guide both cell-intrinsic and extrinsic strategies that can modulate the solid tumor microenvironment in addition to promoting CAR T-cell efficiency.

10:00 Coffee Break

MANUFACTURE AND SCALE-UP

10:30 Challenges and Opportunities for Scale-up of CAR T Cells

Máire Quigley,Ph.D., Research Investigator I, Cell and Gene Therapies Unit, Novartis

The response rates of autologous CAR T cell therapies in early clinical trials give hope that these treatments can be developed and widely distributed to patients with unmet need. To successfully evolve from small scale production to commercial manufacturing, multiple challenges must be overcome. Lessons learned from the process scale up of CD19 CAR T cell production will be discussed.

11:00 Cell Therapy: Quality and Good Manufacturing Practices

Yeong "Christopher" Choi, Ph.D., Director, TCPF and Assistant Professor, Oncology, Center for Immunotherapy, Roswell Park Cancer Institute

To bring ground breaking new cell therapies into the clinic, a massive amount of infrastructure is needed. One of the key components is a drug manufacturing facility, which is compliant with US FDA GMP regulations. One of the major challenges of operating a cell therapy cGMP facility, is maintaining a robust Quality Management System. Fortunately, there are a number of voluntary accrediting organizations to promote excellence in the laboratory.

11:30 Manufacturing of Cellectis' Allogeneic UCART Product Candidates

Arjan Roozen, Vice President, GMP Solutions & Manufacturing, Cellectis

This talk will provide an introduction of the concept of Cellectis' allogeneic UCART product candidates and our technological platform. It will describe and explain the challenges during the process of bringing allogeneic UCART product candidates from R&D development phase to the GMP manufacturing phase, in order to have CTM (clinical trial material) available for clinical studies, and afterwards to plan commercial manufacturing of Cellectis' allogeneic UCART GMP cellular gene therapy products.

12:00 pm Close of Adoptive T Cell Therapy

Biomarkers for Immuno-Oncology

Predictive Biomarkers and Companion Diagnostics to Guide Cancer Immunotherapy

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THURSDAY, SEPTEMBER 1

7:45 am Registration & Morning Coffee

COMPANION DIAGNOSTICS FOR IMMUNOTHERAPY

8:25 Chairperson's Opening Remarks

Kenneth Emancipator, M.D., Executive Medical Director, Companion Diagnostics, Merck & Co.

8:30 Developing an Immunohistochemistry Test for Programmed Cell Death Ligand 1 (PD-L1) as a Companion Diagnostic for Pembrolizumab

Kenneth Emancipator, M.D., Executive Medical Director, Companion Diagnostics, Merck & Co.

Tumors express PD-L1 to contribute to escape from immunosurveillance. Pembrolizumab blocks this escape mechanism and thus effectively treats a number of cancers. The rapid clinical development of pembrolizumab required rapid development of an immunohistochemistry assay for PD-L1. Merck developed the assay initially to determine whether or not PD-L1 is a predictive biomarker, then to enrich clinical trials, and ultimately partnered with a diagnostics company to develop the assay as a companion diagnostic.

9:00 Diagnostic Strategies for Cancer Immune Therapy Combinations

Andy Williams, Ph.D., Companion Diagnostics Group Leader, Cancer Immune Therapies, Genentech

Current and future diagnostic opportunities for cancer immune therapies will be covered. This will include companion diagnostics and other informative tests.

9:30 Integration of Cancer Immunotherapy into Precision Medicine

Zhen Su, M.D., MBA, Senior Vice President, Global Head of Medical Affairs Oncology, EMD Serono

10:00 Coffee Break with Exhibit and Poster Viewing

BIOMARKERS TO GUIDE IMMUNOTHERAPY

10:45 Regulatory Considerations for Diagnostics to Guide Cancer Immunotherapy

Janaki Veeraraghavan, Ph.D., Biologist, Office of In Vitro Diagnostics and Radiological Health, Center for Devices and Radiological Health, FDA

11:15 Novel T Cell Biomarkers for Response to PD-1 and PD-1/CTLA4 Immunotherapy

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

Immunotherapy with checkpoint inhibitors has revolutionized the treatment of many cancers. However, even with these agents, 40-60% of patients with advanced melanoma, 50-80% of patients with NSCLC, and even higher proportions of patients in other cancers do not respond. While earlier studies had examined PDL-1 as a marker for response, a deeper understanding is now emerging integrating several tumor and host factors; these include tumor neo-antigens and mutational burden, T cell and APC activation as well as host factors such as the presence or absence of certain metastatic locations which can determine success with immunotherapy.

11:45 Immuno-Oncological Biomarkers in Hematological and Solid Tumors

Scott Rodig, M.D., Ph.D., Associate Professor, Pathology, Harvard Medical School; Associate Pathologist, Pathology, Brigham & Women's Hospital

Clinical response to immune checkpoint inhibitors is associated, in part, to tumor-specific expression of the PD-1 ligands (PDLs) PD-L1 and PD-L2. PDLs are upregulated on tumor cells by cell autonomous and microenvironmental mechanisms. I will speak about a genetic basis for PD-L1 and PD-L2 expression found in a subset of hematological malignancies and a subset of solid tumors. The correlations between genetics, tumor phenotype, and patient response to chemotherapy and immune therapy will be discussed.

12:15 pm Multiscalar Systems Modeling to Design Rational Cancer Immunotherapy Combinations

Sponsored by: Systems Imagination

Spyro Mousses, Ph.D., President, Systems Imagination, Inc.

This case study will describe the mining and modeling of disparate types of information ranging from WGS data to deep clinical phenotype data including pathological and radiological images. Results identified hidden insights that can be leveraged to design safer and more effective drug combinations for cancer immunotherapy.

12:30 Sponsored Presentation
(Opportunity Available)

12:45 Luncheon Presentation: Precision Proteomics—Enabling Solutions for the Field of Immuno-Oncology

Sponsored by: OLINK BIOSCIENCE

Ida Grundberg, Ph.D., Olink Proteomics

Seunghee Kim-Schulze, Assistant Professor of Medicine, Hess Center for Science and Medicine, Human Immune Monitoring Core Facility (HIMC), Mount Sinai School of Medicine

Proseek® panels from Olink Proteomics are powerful tools for targeted protein biomarker discovery. A new panel of 92 protein biomarkers focusing on immuno-oncology is designed to facilitate a better understanding of the interplay between the immune system and tumors, evaluate therapeutic efficacy and provide the foundation for patient stratification. Our innovative Proximity Extension Assay (PEA) technology enables high-multiplex immunoassays without comprising data quality. A recent customer case study will be presented.

1:15 Session Break

BIOMARKER DEVELOPMENT FOR PERSONALIZED IMMUNOTHERAPY

2:00 Chairperson's Remarks

Chan Whiting, Ph.D., Director, Immune Monitoring/ Biomarker Development, Aduro Biotech

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2:05 Emerging Biomarkers and Novel High-Throughput Technologies for Personalized Cancer Immunotherapy

Jianda Yuan, M.D., Ph.D., Director, Translational Immuno-Oncology Research, Merck Research Labs

There is a growing need to identify predictive and prognostic biomarkers that enhance our understanding of the mechanisms underlying the complex interactions between the immune system and cancer. We (SITC Biomarker Task Force Working Group 2 with international experts from academia and industry) assemble to identify and discuss promising technologies for biomarker discovery and validation. We review the current status of emerging biomarkers for immune checkpoint blockade therapy and discuss novel technologies as well as high dimensional data analysis platforms that will be pivotal for future biomarker research.

2:35 High-Dimensional Single Cell Analyses in Tumor Tissues

Sacha Gnjatic, Ph.D., Associate Professor, Tisch Cancer Institute, Hematology/Oncology, Immunology, Icahn School of Medicine at Mount Sinai

The density and distribution of immune cells at the tumor site can be useful as a prognostic or predictive marker of clinical response in many different cancers. New high-dimensional analysis tools for both fresh and preserved tissues are now available to assess the phenotypic and functional tumor immune microenvironment with unprecedented depth and complexity. These studies are poised to help better define local immunocompetence in individual patients, and correlate it with peripheral immune markers and predicted outcome, to improve patient stratification to immunotherapies or other interventions.

3:05 B Cell-Related Biomarkers in Cancer

Sam Hanash, M.D., Ph.D., McCombs Institute for the Early Detection and Treatment of Cancer

3:35 Refreshment Break

4:05 Human Tissue as a Platform for Developing Predictive Biomarkers: A Case Study in PD-L1

Robert Anders, M.D., Ph.D., Associate Professor, Pathology, Johns Hopkins University

Pathologic examination of human tissue has long served as a prognostic biomarker. Increasingly, human tissue is being used to develop predictive biomarkers in the form of immunohistochemistry-based companion or complementary diagnostic tests. However, the evaluation of immunohistochemical studies must be considered in the context of i) tumor type, ii) immune microenvironment, iii) relationship to treatment, and iv) limitations of immunohistochemical staining.

4:35 NanoFACS: Extracellular Vesicle Subset Sorting and Analysis for Personalized Medicine

Jennifer C. Jones, M.D., Ph.D., Assistant Clinical Investigator, Molecular Immunogenetics & Vaccine Research Section, Vaccine Branch, National Cancer Institute, National Institutes of Health

5:05 Biomarkers for Cancer Immunotherapy Using Live-Attenuated *Listeria monocytogenes*

Chan Whiting, Ph.D., Director, Immune Monitoring/ Biomarker Development, Aduro Biotech

A live-attenuated double deleted Lm (LADD) immunotherapy induces systemic cytokines, reprograms the tumor microenvironment and provides clinical benefit. A description of Listeria-based immunotherapy of clinical studies in mesothelioma, pancreatic cancers including comprehensive immune monitoring and biomarker development efforts in these settings will be discussed.

5:35 End of Day

FRIDAY, SEPTEMBER 2

8:00 am Morning Coffee

CLINICAL IMMUNO-ONCOLOGY COMBINATIONS

8:25 Chairperson's Opening Remarks

Jan ter Meulen, M.D., Dr.habil., DTM&H, CSO, Immune Design

8:30 Clinical Immuno-Oncology Combinations

Kevin Horgan, Ph.D., Vice President, Immuno-Oncology Global Medicines Development, AstraZeneca

9:00 Cancer Immunotherapy and Biomarker Strategies for Combination Studies

Jeffrey Wallin, Ph.D., Group Leader, Early Stage Oncology Biomarker Development, Genentech

The activation of anti-tumor immunity by immune checkpoint blockade has demonstrated efficacy in a variety of cancers. Although durable responses have been observed, combination approaches will be required to extend this benefit beyond a subset of patients. Combinations for cancer immunotherapy involve promotion of one or more steps of the cancer-immunity cycle and biomarkers can provide valuable diagnostic and mechanistic information for cancer immunotherapy clinical trials.

9:30 Checkpoint Inhibitors in Combination: Novartis Enters the Clinic

Jennifer Mataraza, Ph.D., Senior Investigator, Immune Oncology, Novartis Institutes for BioMedical Research

This presentation will cover: (1) the role of checkpoint inhibitors in the context of a broader immuno-oncology strategy; (2) an outline of the status of the Novartis checkpoint pipeline; (3) approaches to the discovery of novel CPIs and overcoming resistance.

10:00 Coffee Break

10:30 Novel Approaches for Combination Immunotherapy of Cancer: Lessons Learned and Future Opportunities

Jon Wigginton, M.D., CMO & Senior Vice President, Clinical Development, MacroGenics

There has been tremendous progress in the field of cancer immunotherapy as it has moved recently into the mainstream for the treatment of many cancers. A broad range of non-clinical studies, and more recently, powerful new clinical data from studies combining anti-PD-1 (nivolumab) and anti-CTLA-4 (ipilimumab) for the treatment of patients with melanoma, have focused considerable attention on the potential promise of combination cancer immunotherapy. This presentation will provide an overview of current progress, lessons learned, and future prospects for the combination immunotherapy of cancer.

11:00 Combined Il-15-Based Cytokine Therapy with PD-1 Immune Checkpoint Blockade in Advanced Non-Small Cell Lung Cancer

John Wrangle, M.D., Assistant Professor, Medicine, Hematology/Oncology, Medical University of South Carolina

11:30 Inducing Local and Systemic Anti-Tumor Responses through *in situ* Vaccination: Synergy of the TLR4 Agonist G100 with Localized Radiation Therapy

Jan ter Meulen, M.D., Dr.habil., DTM&H, CSO, Immune Design

The immunosuppressive tumor microenvironment (TME) is a main obstacle to successful cancer immunotherapy. Intratumoral injection of the TLR4 agonist Glucopyranosyl Lipid A in stable emulsion (G100) induces in a pro-inflammatory state of the TME that promotes local and systemic immune responses and tumor control via CD8 T cells. Focal irradiation of tumors enhances G100-mediated tumor control, especially of non-treated lesions (abscopal effect), and supports clinical development as a combination therapy.

12:00 pm Close of Biomarkers for Immuno-Oncology Conference

Clinical Trials for Cancer Immunotherapy

Strategies to Accelerate Immuno-Oncology Clinical Development

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10:00 Coffee Break with Exhibit and Poster Viewing

IMMUNO-ONCOLOGY CLINICAL DEVELOPMENT STRATEGIES

10:45 PD-1 Antibody Has the Potential to Be a Broad Spectrum Antineoplastic Therapy

Roy D. Baynes, M.D., Ph.D., Senior Vice President and Head, Global Clinical Development, Merck Research Laboratories

PD-1 antibody blocks ligands PDL-1 and PDL-2 binding to PD-1 receptor, and activates cytotoxic killer cells, revealing innate immunity to cancer. Big data sets evaluating PDL-1 expression and mutational burden were interrogated to accelerate development. This enabled early approvals in malignant melanoma and NSCLC along with a companion diagnostic. More than 20 different responsive cancers have been identified. Precision medicine approaches identify patients for whom monotherapy is most appropriate and those for whom additional therapies should be considered.

11:15 The Combination Conundrum

James E. Wooldridge, M.D., CSO, Immuno-Oncology Clinical Development, Eli Lilly and Company

11:45 Cancer Immunotherapy: Triumphs and Challenges

Joseph Pearlberg, M.D., Ph.D., Senior Medical Director, Infinity Pharmaceuticals

12:15 pm Enjoy Lunch on Your Own

CLINICAL DEVELOPMENT FOR CHECKPOINT INHIBITORS

2:00 Chairperson's Remarks

Vassiliki Karantza, M.D., Ph.D., Director, Clinical Research Oncology, Merck Research Laboratories

2:05 PD-1 Inhibition by Pembrolizumab for Breast Cancer Treatment

Vassiliki Karantza, M.D., Ph.D., Senior Director, Clinical Research Oncology, Merck Research Laboratories

The PD-1 receptor-ligand pathway is used by tumors to evade immune surveillance. Pembrolizumab is a humanized anti–PD-1 monoclonal antibody that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thus reactivating the immune system to eradicate tumors. Pembrolizumab has shown robust antitumor activity against several advanced malignancies. The safety and efficacy of pembrolizumab in patients with PD-L1-positive advanced breast cancer (triple-negative and ER-positive/HER2-negative) will be discussed.

2:35 The Role of Immune-Checkpoint Therapy in Cancers with Deficient Mismatch Repair

Michael J. Overman, M.D., Associate Professor, Gastrointestinal Medical Oncology, University of Texas MD Anderson Cancer Center

Initial investigations of immune-checkpoint therapy targeting PD1/PDL1 in unselected colorectal cancer (CRC) have demonstrated limited to no activity. However, a subset of CRC, characterized by mismatch deficiency or microsatellite instability (MSI-high), has demonstrated robust early signals of anti-tumor activity with PD1 targeting. It is now clear that MSI-high cancers represent a unique molecular and immunological tumor subset. This talk will discuss the current and ongoing clinical trials investigating immune therapy in this disease subset.

3:05 Attend concurrent session

3:35 Refreshment Break

4:05 Checkpoint Inhibitors for Gliomas

Michael Lim, M.D., Associate Professor, Neurosurgery, Oncology and Radiation Oncology, Johns Hopkins University School of Medicine

The poor prognosis of patients with glioblastoma mandates new approaches. Checkpoint inhibitors are an exciting class of immune-based strategies that have been shown to improve survival in solid tumors such as melanoma, lung cancers, and renal cell cancers. We will discuss the state of checkpoint inhibitors in glioblastoma. We will specifically focus on the existing preclinical data, current clinical trials, and future combination approaches with checkpoint inhibitors for glioblastoma.

4:35 Clinical Biomarkers of a STAT3 Antisense Oligonucleotide, AZD9150

Patricia McCoon, Ph.D., Principal Scientist, Oncology IMED Translational Science, AstraZeneca Pharmaceuticals

AZD9150 is a therapeutic antisense oligonucleotide targeting STAT3 that has shown clinical

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safety and efficacy in two Phase I clinical trials. Clinical biomarker analysis demonstrated STAT3 knockdown in immune cells, and additional gene expression changes associated with better response to immune checkpoint blockade. Addition of mouse STAT3 ASO to anti-PDL1 treatment showed benefit in preclinical syngeneic tumor models. Based on these data, Phase Ib/2 clinical trials have been initiated testing AZD9150 + durvalumab.

5:05 Attend Concurrent Session

5:35 End of Day

FRIDAY, SEPTEMBER 2

8:00 am Morning Coffee

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12:00 pm Close of Clinical Trials for Cancer Immunotherapy Conference

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