

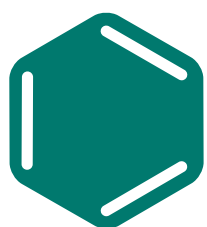


Register by July 25 and SAVE up to \$200!

August 11-14, 2014

Marriott Long Wharf Hotel
Boston, MA

Ninth Annual



ImVacS

The Immunotherapies and Vaccine Summit

Conference Tracks



**Novel Vaccines Part One:
Adjuvants, TLRs & DNA
Vaccines**



**Novel Vaccines Part Two:
Emerging Vaccine
Technologies**



**Immunomodulatory
Therapeutic Antibodies
for Cancer**



**Combination Cancer
Immunotherapy**



**Target Discovery for
T Cell Therapy**

Keynote Speakers



Norman W. Baylor, Ph.D.
*President and CEO, Biologics
Consulting Group, Inc.*



Bolyn Hubby, Ph.D.
*Senior Director, Head, Vaccine
and Phage R&D, Synthetic
Genomics Vaccines, Inc.*



Michael A. Postow, M.D.
*Assistant Attending Physician, Melanoma
and Immunotherapeutics Service,
Memorial Sloan-Kettering Cancer Center*

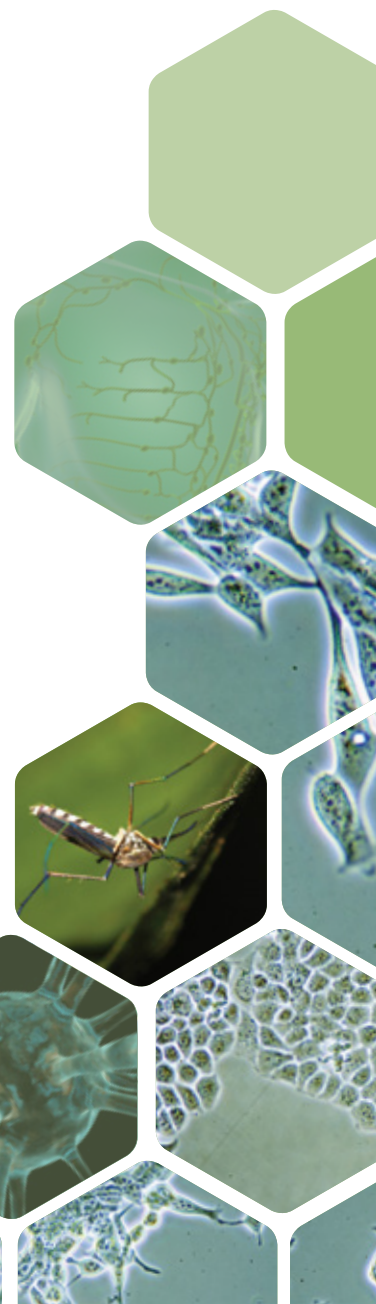


Omid Hamid, M.D.
*Director, Melanoma Center,
Angeles Clinic and Research Institute*



Zelig Eshhar, Ph.D.
*Professor, Immunology,
The Weizmann Institute of Science*

ImVacS.com



About the Conference

The Immunotherapies and Vaccine Summit

ImVacS, The Immunotherapies and Vaccine Summit, brings together a global audience of vaccine researchers and developers of cancer immunotherapies for five focused meetings that explore the frontiers of immunology as the basis for patient treatment.

Part 1 of the 9th annual "Novel Vaccines" meeting addresses "Adjuvants, TLRs and DNA Vaccines," while Part 2 explores "Emerging Vaccine Technologies." The 2nd annual "Immunomodulatory Therapeutic Antibodies for Cancer" meeting examines developments in the models and tools used in developing these emerging drug products, while the inaugural "Combination Cancer Immunotherapy" meeting focuses on the application of these antibody programs in combination with other treatment modalities. The Target Discovery for T Cell Therapy Symposium will bring together leading academic and industry researchers to discuss how to find and validate suitable targets and antigens for T cell therapies.

Conference at-a-Glance

Monday,
August 11

Novel Vaccines Part One: Adjuvants,
TLRs & DNA Vaccines

Immunomodulatory Therapeutic
Antibodies for Cancer

Tuesday,
August 12

**Dinner Short Course - Vaccine Production
& Manufacturing**

**Dinner Short Course - Cancer Vaccines:
Clinical Updates, New Technologies and Challenges**

Wednesday,
August 13

Novel Vaccines Part Two: Emerging
Vaccine Technologies

Combination Cancer Immunotherapy

Thursday,
August 14

Target Discovery for T Cell Therapy

Corporate Sponsors



Life Sciences



Dinner Short Courses*

Tuesday, August 12 | 6:30 to 9:00pm

Vaccine Production & Manufacturing **CANCELED**

Instructors:

Robert Boulanger, Ph.D., Technology Manager, Core Team, Protein Sciences

José Manuel Otero, Ph.D., Director, Engineering, Upstream Process Development, Merck

Peter Latham, President, Latham BioPharm Group

This course provides an excellent overview of vaccine manufacturing with an emphasis on new technologies. Current manufacturing trends that are influencing vaccine production include cell culture-based manufacturing, disposables, aseptic operations, and rational process development. New vaccine production trends will be discussed by those in the field, including how new approaches to production are affecting the way vaccines function.

Overcoming challenges will be addressed, such as optimizing processes for large-scale production including cell line development and manufacture of novel modes of delivery, such as virus-like particles (VLPs).

Additional topics include risk-based studies, Quality by Design, and lifecycle approach to process validation and control. Finally, the globalization of supply will be explored, including its influence on process scale, facility design, product image and regulatory expectations.

- Disposable/single-use technologies
- Cell culture-based production
- QbD
- Rational process development
- Lifecycle approach to process validation and control
- Large-scale production
- Supply management
- Regulatory expectations

Cancer Vaccines: Clinical Updates, New Technologies and Challenges **CANCELED**

Instructors:

Jianping Yuan, Ph.D., BM, Research Associate, Vaccine and

Immunotherapy Center, Massachusetts General Hosp

Eric von Hofe, Ph.D., President, Antigen Express, Inc.

The recent clinical successes of immune-modulating therapeutic antibodies have renewed interest in immunotherapy as a means of combating or responding to cancers. This course surveys exciting new science and clinical results for prophylactic and therapeutic vaccines used both alone and in combination with other traditional and emerging forms of immunotherapy.

- Updates of recent clinical trials
- Application as monotherapies
- Application in immunotherapy combinations
- Adjuvants
- Emerging targets and technologies
- Regulatory considerations

*Separate registration is required.

Keynote Presentations



The Regulatory Outlook for Future Vaccine Adjuvants

Norman W. Baylor, Ph.D., President and CEO, Biologics Consulting Group, Inc.

There continues to be a need for the development of effective vaccines against emerging and neglected infectious diseases. Many vaccines under development against these diseases are recombinant molecules or subunits of pathogenic organisms. Many of these antigens do not elicit adequate immune responses, and require the incorporation of adjuvants. The development of safe and potent immunologic adjuvants and delivery systems that can enhance and direct vaccine-specific immunity is needed. In this presentation I will discuss the regulatory outlook and considerations for evaluating future vaccine adjuvants.



Putting Cancer in Check with Novel Immunomodulatory Strategies

Michael A. Postow, M.D., Assistant Attending Physician, Melanoma and Immunotherapeutics Service, Memorial Sloan-Kettering Cancer Center

Immunomodulatory antibodies that enhance T cell mediated immunity continue to demonstrate remarkable clinical success for patients with a variety of cancers. Antagonistic antibodies increase T cell function through blockade of negative regulatory circuits, and agonistic antibodies directly augment T cell function through engagement of various co-stimulatory receptors. Ongoing research seeks to identify why some patients have dramatic benefits to these approaches and to investigate whether combining these immunomodulatory antibodies with other cancer treatments improves outcomes.



Synthetic Genomics to Address Emerging Threats and Global Supply Challenges

Bolyan Hubby, Ph.D., Senior Director, Head, Vaccine and Phage R&D, Synthetic Genomics Vaccines, Inc.

The potential of synthetic biology is being realized in the vaccine space. This presentation will describe the application of synthetic genomics tools, coupled with automation, to produce synthetic vaccine candidates across a variety of targets. SGVI and partners have applied this technology to improve response to emerging threats and the lead influenza program has advanced through initial clinical testing. Converting digital sequence information into DNA, RNA, and protein in an automated fashion enables distributed manufacturing to address vaccine supply challenges.



Update from 2014 ASCO Meeting: Clinical Trials for Immunotherapy Combinations

Omid Hamid, M.D., Director, Melanoma Center, Angeles Clinic and Research

After significant success in the field of Immuno-Oncology in multiple solid tumors, focus has shifted to combinations of immunotherapies. A combinatorial approach with each other or with other therapeutic modalities could potentially lead to enhanced efficacy, improved response rate, progression-free survival and overall survival. Despite this enthusiasm, initial trials have been fraught with toxicity. This presentation will focus on recent data on state-of-the-art combinations with discussion on efficacy, outcome, dosing and applicability across many tumor types.



CART Cells from the Mouse Cage to the Patients' Health

Zelig Eshhar, Ph.D., Professor, Immunology, The Weizmann Institute of Science

This presentation will be a brief chronicle description of the pioneering of the CAR strategy and its emergence and evolution for adoptive cell treatment of cancer. It will focus on experimental models for cancer in experimental settings and summarize the lessons learned from such models. The potential and challenges for cancer therapy in patients will also be discussed. Finally, the pioneering of the CAR strategy and its emergence and evolution for adoptive cell treatment of cancer will be outlined.



AUGUST 11-12, 2014

Novel Vaccines Part One: *Adjuvants, TLRs & DNA Vaccine*

Recommended Dinner Short Course* **Vaccine Production & Manufacturing**

*Separate registration required, please see page 16 for details

MONDAY, AUGUST 11

7:30 am Conference Registration & Morning Coffee

ADJUVANTS

8:35 Chairperson's Opening Remarks

Nathalie Garçon, Ph.D., PharmD., Vice President, Head, Global Vaccine Centre for Adjuvants and Technology Innovation, GlaxoSmithKline

» 8:45 OPENING KEYNOTE PRESENTATION:

The Regulatory Outlook for Future Vaccine Adjuvants



Norman W. Baylor, Ph.D., President and CEO, Biologics Consulting Group, Inc.

There continues to be a need for the development of effective vaccines against emerging and neglected infectious diseases. Many vaccines under development against these diseases are recombinant molecules or subunits of pathogenic organisms. Many of these antigens do not elicit adequate immune

responses, and require the incorporation of adjuvants. The development of safe and potent immunologic adjuvants and delivery systems that can enhance and direct vaccine-specific immunity is needed. In this presentation I will discuss the regulatory outlook and considerations for evaluating future vaccine adjuvants.

9:30 Vaccine Adjuvants: Where We Are Today and What Is Needed for the Future

Nathalie Garçon, Ph.D., PharmD., Vice President, Head, Global Vaccine Centre for Adjuvants and Technology Innovation, GlaxoSmithKline

10:00 Coffee Break

10:30 Novel Use of an NIR Laser to Adjuvant Vaccines

Mark C. Poznansky, M.D., Ph.D., Associate Professor, Medicine, Harvard Medical School, and Director, Vaccine and Immunotherapy Center, Infectious Diseases Medicine, Massachusetts General Hospital

There is a critical unmet need for safe and efficacious vaccines. The team at the Vaccine and Immunotherapy Center (VIC) at MGH has discovered that a non-tissue damaging near infrared laser when delivered to an intradermal vaccination site can elicit a balanced, Th1 and Th2, immune response and increase the efficacy of a vaccine to influenza in a mouse lethal challenge model. We have begun to explore the mechanism of action of the laser in the skin. We will present published and preliminary data that supports the further exploration of this approach for human vaccination.

11:00 Development of an Adjuvanted Recombinant Subunit Vaccine against Dengue

Daniilo R. Casimiro, Ph.D., Executive Director, Vaccine Research, Merck & Co.

Preclinical studies of a recombinant subunit vaccine have been conducted in non-human primates to evaluate the immunogenicity and efficacy of tetravalent formulations. These preclinical studies have shown the capacity of the recombinant proteins to induce balanced tetravalent immune responses and protect against dengue virus infection. Data from these preclinical non-human primate studies will be presented along with results of a vaccine candidate being tested in a Phase 1 clinical trial in healthy, flavivirus-naïve, adults. An update on clinical trial status will also be provided.

11:30 Antiviral and Adjuvant Activities of RIG-I Agonists

John Hiscott, Ph.D., Program Director, Vaccine & Gene Therapy Institute of Florida

RIG-I is a cytosolic sensor critically involved in the recognition of viral RNA and activation of the innate immune response to RNA virus infection. We evaluated the antiviral and adjuvant properties of small RNA-based RIG-I agonists on the replication of influenza virus, as well as two emerging arthropod-borne viral pathogens - dengue and chikungunya virus. An optimized 5'triphosphorylated RNA generated an antiviral response that inhibited multiplication of these viruses and served as an effective adjuvant *in vivo* in combination with H5N1 VLPs. Our studies highlight the therapeutic potential of RIG-I agonists as versatile antiviral agents.

12:00 pm Sponsored Presentation (Opportunity Available)

12:30 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

RNA- & DNA-BASED VACCINES

1:55 Chairperson's Remarks

Luis Brito, Ph.D., Head, Formulation Science, Novartis Vaccines & Diagnostics, Inc.

2:00 RNA: The New Revolution in Nucleic Acid Vaccines

Luis Brito, Ph.D., Head, Formulation Science, Novartis Vaccines & Diagnostics, Inc.

At Novartis we have reinvented the gene vaccine by creating a synthetic self-amplifying mRNA vaccine platform. The Platform takes advantage of cell-free mRNA production from a transcription reaction and delivery with a synthetic delivery system. The broad utility of this novel vaccine technology has been demonstrated with genes encoding antigens from several pathogens and found to elicit broad and potent protective immune responses. Responses are comparable to a viral delivery technology, but without the inherent limitations of viral vectors.

2:30 Monitoring B Cell Development and Ig Gene Usage for Vaccine Development

Shan Lu, M.D., Ph.D., Professor, University of Massachusetts Medical School

Traditionally, serum antibody levels were the main measurements of general antibody responses to vaccination. Given the importance of B cell development in controlling the level and quality of antibody responses, it becomes increasingly significant to determine B cell responses in immunized hosts. Rapidly evolving technologies such as B cell ELISPOT and deep gene sequencing can provide useful information on the development and longevity of antigen-specific B cell responses as well as Ig gene usage from fresh or frozen PBMCs.

3:00 Synthetic DNA Vaccines for Difficult Targets

David B. Weiner, Ph.D., Professor, Pathology and Laboratory Medicine, Chair, Gene Therapy and Vaccine Program, CAMB, University of Pennsylvania Perelman School of Medicine

Through multiple improvements including synthetic plasmid optimization, genetic adjuvant technology further combined with enhanced EP delivery, we now report a platform for vaccine/immune therapeutic development with major relevance to human disease settings. These combined DNA approaches drive immune responses similar or superior to live viral vector protocols in important model systems including HIV, HPV therapy, Influenza among others. We will present data that illuminate specific features of these synthetic DNA vaccines and benchmark their performance in animal models and in human studies.

3:30 Refreshment Break

INFLUENZA

4:00 Synthetic Influenza Vaccine Viruses

Philip R. Dormitzer, M.D., Ph.D., Head of US Research, Global Head of Virology, and Vice President at Novartis Vaccines

Reliance on antiquated egg-based technology impairs influenza vaccine match to circulating strains and slows pandemic responses. H7N9 influenza emerged in China in March, 2013. Novartis and its partners at the J Craig Venter Institute used a new synthetic virus generation process to synthesize a H7N9 vaccine virus several days after it was posted by the Chinese CDC. Novartis produced clinical trial lots using the synthetic virus and mammalian cell culture technology, began trials in August, and initiated large-scale vaccine production.

4:30 Development of an Inactivated Nasal Influenza Vaccine

Anna-Karin Maltais, Ph.D., CSO, Eurocine Vaccines AB

Eurocine Vaccines is a publicly listed, clinical-stage company developing nasal vaccines. Dr. Maltais will present Eurocine Vaccines' lead development program, Immunose™ FLU, an influenza vaccine candidate primarily targeting children. Young children are a risk group for severe influenza infection but the vaccines approved for use in children from 6 months have limited protective effect. The presentation will also discuss Endocine™, the adjuvant/delivery system used to enable nasal vaccination and a key component of Immunose™ FLU.

5:00 Development of a Second Generation Recombinant Influenza Vaccine Having Room Temperature Stability

Kathy Holtz, Ph.D., Formulation Development Scientist, Protein Sciences Corporation

Recombinant hemagglutinin (rHA) proteins are the active component in a newly approved influenza vaccine produced using the Baculovirus Expression Vector System (BEVS). Chemical changes occur during storage of the drug substance that affect tertiary, quaternary, and higher order structures of the rHA protein, and reduce the apparent potency. A strategy will be presented that addresses potency loss to reduce the cost of vaccine production, and confers room temperature stability to the drug substance thus offering the potential to bypass the cold chain for vaccine storage.

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

6:30 Close of Day

TUESDAY, AUGUST 12

7:45 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

PERTUSSIS

8:25 Chairperson's Remarks

William M. Egan, Ph.D., Senior Expert, Novartis Vaccines & Diagnostics

8:30 FEATURED PRESENTATION: The Host Response to Pertussis Infection and Vaccination in the Baboon

Tod Merkel, Ph.D., Principle Investigator, Laboratory of Respiratory and Special Pathogens, Center for Biologics Evaluation and Research (CBER), FDA

Pertussis rates in the US have been steadily rising over the last thirty years despite nationwide vaccination coverage in children in excess of 95%. The US is now experiencing levels of pertussis not observed since the 1950s. We developed a baboon model of pertussis to examine host responses to pertussis

infection and vaccination with acellular and whole-cell pertussis vaccines. Our results identify key differences in vaccine and infection-induced immunity that suggest possible strategies for the development of next-generation pertussis vaccines.

9:00 Pertussis Resurgence – 2014: Facts, Fiction, Myths and Misconceptions

James D. Cherry, M.D., M.Sc., Distinguished Research Professor, Pediatrics, David Geffen School of Medicine, UCLA, and Attending Physician, Pediatric Infectious Diseases, Mattel Children's Hospital

The resurgence of reported pertussis in the US began in 1984. The magnitude of this resurgence dramatically increased during the last decade. The causes of this resurgence include: greater awareness, better diagnostic tests, less efficacious vaccines (DTP vs DTaP) and genetic changes in *Bordetella pertussis*. Today, however, the rate of pertussis is still ~20 fold less than in the prevaccine era and illness in vaccine failures is less severe than illness in nonvaccinated children.

9:30 Host Response to Bordetella Adenylate Cyclase Toxin: Should This Antigen Be Added to Acellular Pertussis Vaccines?

Erik L. Hewlett, M.D., Professor, Medicine and of Microbiology, Immunology and Cancer Biology, University of Virginia School of Medicine

Adenylate cyclase toxin (ACT) is an essential virulence factor of *Bordetella pertussis* and a known protective antigen. It is not in acellular pertussis vaccines, however, because it was not available when these vaccines were developed. We are characterizing the host response to ACT and are mapping the epitopes to which convalescent sera react, in order to identify the appropriate domain/s of the toxin to use as an immunogen.

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

TOLL-LIKE RECEPTORS

10:45 Systematic Analysis of Responses Induced by a TLR2 Ligand Immune Adjuvant

Lee M. Wetzler, M.D., Associate Program Director for Research, Infectious Diseases, Professor, Medicine, and Associate Professor, Microbiology, Boston University School of Medicine

The Neisserial major outer membrane protein PorB, has significant immune activating activity, can act as a potent vaccine adjuvant and that the mechanism of this activity is mediated by its interaction with TLR2 and TLR1. New data shall be presented demonstrating its ability to enhance antigen uptake and antigen presenting cell migration. Finally we shall show that PorB induces specific genes and gene sets, highlighted by increased expression of cell cycle related genes and microRNAs, all associated with B cell proliferation and germinal center formation.

11:15 In vitro Modeling Identifies TLR8 Agonists that Are Effective Vaccine Adjuvants in vivo

Ofer Levy, M.D., Ph.D., Senior Associate Physician in Medicine, Boston Children's Hospital, and Professor, Pediatrics, Harvard Medical School

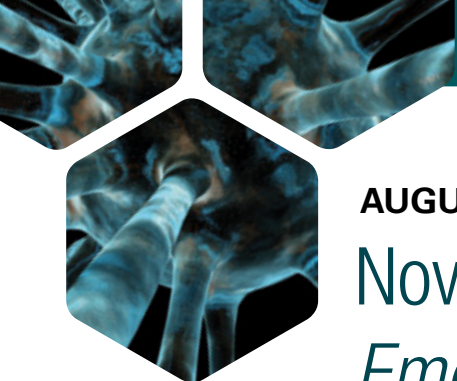
Vaccine adjuvants act via species-specific signaling mechanisms, yet biopharmaceutical development continues to employ rodent and other models that are not predictive of human responses. In this context, to enhance vaccine development, we have developed novel human *in vitro* models, including whole blood assays, dendritic cell arrays and microphysiologic tissue constructs that allow autonomous monocyte-derived dendritic cell development, to characterize species and age-specific responses to vaccine adjuvants. We have identified several Toll-like receptor-8 (TLR8) agonists as having unique immunostimulatory activity toward human newborn, infant and adult leukocytes and have now verified that such adjuvants dramatically increase antigen-specific antibody responses *in vivo*.

This proof of concept suggests that our novel platforms are predictive of *in vivo* responses, thereby representing a disruptive innovation that may accelerate and de-risk vaccine development.

11:45 Sponsored Presentation (Opportunity Available)

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

12:30 Close of Conference



AUGUST 12-13, 2014

Novel Vaccines Part Two: *Emerging Vaccine Technologies*

Recommended Dinner Short Course*

Vaccine Production & Manufacturing

*Separate registration required, please see page 16 for details

TUESDAY, AUGUST 12

12:30 Conference Registration

1:55 pm Chairperson's Opening Remarks

SYNTHETIC BIOLOGY AND *IN SILICO* TOOLS

» 2:00 KEYNOTE PRESENTATION:

Synthetic Genomics to Address Emerging Threats and Global Supply Challenges



Bolyn Hubby, Ph.D., Senior Director, Head, Vaccine and Phage R&D, Synthetic Genomics Vaccines, Inc.

The potential of synthetic biology is being realized in the vaccine space. This presentation will describe the application of synthetic genomics tools, coupled with automation, to produce synthetic vaccine candidates across a variety of targets. SGVI and partners have applied this technology to improve response to emerging threats and the lead influenza program has advanced through initial clinical testing. Converting digital sequence information into DNA, RNA, and protein in an automated fashion enables distributed manufacturing to address vaccine supply challenges.

2:45 Databases and *in silico* Tools for Vaccine Design

Yongqun (Oliver) He, D.V.M., Ph.D., Associate Professor, Microbiology and Immunology, Affiliated Member, Center for Computational Medicine and Biology (CCMB), Member, Comprehensive Cancer Center, University of Michigan

Many databases and tools are available to support rational vaccine design. The Protegen protective antigen database, VirMugenDB "virmugen" database, and Vaxign vaccine design tool are parts of the integrative VIOLIN vaccine database and analysis system (<http://www.violinet.org>). The analyses of Protegen and VirMugen data allow prediction of genes for subunit and live attenuated vaccine development. Vaxign is the first Web-based vaccine design program based on reverse vaccinology. New vaccine design methods are being developed based on the community-based Vaccine Ontology (VO).

3:15 Sponsored Presentation (Opportunity Available)

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

NEXT-GENERATION VACCINE TECHNOLOGIES

4:15 Engineering Cancer Immunotherapy One (DNA) Sequence at a Time

Mark Bagarazzi, M.D., CMO, Inovio Pharmaceuticals

Inovio is developing cancer immunotherapeutics by targeting both viral oncogenes (HPV E6, E7) as well as self proteins associated with cancer progression and metastases (PSA, PSMA, hTERT). Our common approach involves enhancing the delivery of optimized DNA sequences with the use of our proprietary *in vivo* electroporation system. We will share both preclinical and clinical data regarding several cancer indications.

4:45 Deep Profiling of HIV-Specific T Cell Responses by Mass Cytometry

Damien Soghoian, Ph.D., Researcher, Virology, Harvard University

HIV-specific T cell responses play an important role in the antiviral immune response and will likely be critical for an HIV vaccine. However, the functional and phenotypic features of these cells that are most beneficial remain unclear. Mass cytometry, or cytometry by time of flight (CyTOF), affords the ability to obtain an unprecedented level of information on single cells. This presentation will describe the highly multiparametric profiling of HIV-specific T cells by CyTOF and how insights gained from this analysis may inform HIV vaccine development.

5:15 Robust Induction of Cytotoxic T Lymphocyte (CTL) Response through Low-Frequency Sonophoresis Assisted Transcutaneous Immunization

Diviya Sinha, Ph.D., Technical Instructor, Biology, Massachusetts Institute of Technology (MIT)

Traditional vaccinations have had limitations at inducing a potent CTL response; essential for protection against intra-cellular infections and effective cancer vaccine development. Here, we demonstrate that a needleless skin vaccination strategy based on low-frequency sonophoresis (LFS) is able to induce long-lived antigen specific CTLs in the absence of any external adjuvants. Innate adjuvancy associated with LFS skin pretreatment is hypothesized to result in the observed induction of CTLs, which respond rapidly against a viral LCMV challenge months following a single immunization.

5:45 End of Day

WEDNESDAY, AUGUST 13

7:45 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

PREDICTING & ENHANCING HUMAN RESPONSE

8:25 Chairperson's Opening Remarks

Mark Bagarazzi, M.D., CMO, Inovio Pharmaceuticals

8:30 Genomic Analysis of Vaccine Response in Humans

W. Nicholas Haining, B.M., B.Ch., Assistant Professor of Pediatrics, Harvard Medical School, and Scientific Co-Leader, HSCT Program, Pediatric Oncology, Dana-Farber Cancer Institute Children's Hospital, and Associate Member, Broad Institute of Harvard and MIT

Vaccination is one of the most effective methods of preventing human disease. However, many vaccines are not universally protective and even widely used vaccines fail to achieve protective immunity. This presentation will discuss advances in genomic approaches to identify the biological features of the early vaccine response that predict the subsequent development of vaccine immunity.

9:00 Identification of Novel Vaccine Candidates Using a Robust Immunogen Optimization System

Sean Du, Ph.D., COO, Altravax, Inc.

Altravax has developed a robust Immunogen Optimization System™ (IOS) that can be applied to a variety of vaccine candidates for the improvement of overall immunogenicity, antibody cross-reactivity, potent T-cell responses, manufacturing efficiency, and product stability. Using IOS, we have developed a preclinical vaccine pipeline including a novel preventive dengue vaccine, based on a single-component VLP that can induce tetravalent immunity capable of neutralizing all four dengue serotypes, and a first-in-class therapeutic vaccine for chronic hepatitis B infection.

9:30 Innovative Preclinical Models for Developing *Staphylococcus aureus* Vaccines

Fabio Bagnoli, Ph.D., Project Leader, Novartis Vaccines and Diagnostics

Staphylococcus aureus is a major human pathogen and current antibiotics are not efficacious against emerging multidrug resistant strains. Unfortunately, *S. aureus* vaccine development is hindered by the lack of known correlates of protection. Three-dimensional organotypic human tissue models may represent a valid alternative to animal infection models. This talk will present data on a novel *S. aureus* vaccine formulation as well as research to develop innovative preclinical models for predicting vaccine efficacy in humans.

10:00 Sponsored Presentation (Opportunity Available)

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Genomics of TB and HIV Disease Progression in African Children

Graeme Mardon, Ph.D., Professor, Developmental Biology & Pathology, Baylor College of Medicine

The Collaborative African Genomics Network (CAfGEN) seeks to integrate genetic and genomics technologies to identify host factors that are important to the progression of HIV and HIV-TB infection in sub-Saharan African children. This will include recruitment of cohorts of HIV and HIV-TB infected children, whole-exome and RNA sequencing, and SNP genotyping of patients at the extremes of HIV and TB disease progression. These projects will provide important mechanistic insights to pediatric HIV and HIV-TB disease progression.

11:30 T Cell Crossreactivity, Heterologous Immunity, and Viruses

Liisa K. Selin, M.D., Ph.D., Professor, Pathology, University of Massachusetts Medical School

Heterologous immunity occurring as a consequence of T cell crossreactivity between unrelated pathogens has been shown by us with animal models to contribute to reduced (beneficial) or enhanced viral loads, and remarkably altered immunopathology (detrimental). Our objective is to determine how crossreactive T cells impact T cell selection and function, and influence disease outcome as the host is exposed to subsequent acute or persistent infections. Insights on these issues are necessary for the intelligent design of effective modern vaccines without unwanted side effects.

12:00 pm Development of a Robust, Defined, Animal-Free Virus Production Medium Optimized for Microcarrier Culture

Mark Szczypka, Ph.D., Senior Director, Applications and New Product Development, Pall Life Sciences

Sponsored by
 Pall Life Sciences

12:30 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

INNOVATIONS FOR CONQUERING DISEASE & INFECTIONS

1:55 Chairperson's Remarks

Sean Du, Ph.D., COO, Altravax, Inc.

2:00 Nanosponge Toxoid for Safe and Effective Vaccination

Liangfang Zhang, Ph.D., Associate Professor, Nanoengineering and Moores Cancer Center, University of California, San Diego

Toxoid vaccines are routinely used to promote antitoxin immunity for the treatment and prevention of bacterial infections. A novel toxin-detainment strategy is disclosed that employs a unique toxin nanosponge to arrest and deliver non-disrupted pore-forming toxins for immune processing. Mice vaccinated with the resulting nanosponge toxoid show superior toxin-specific humoral response and protective immunity against both systemic and subcutaneous toxin challenges. These results indicate that the immunogenicity and efficacy of toxoid vaccines can be enhanced by the non-disruptive detoxification approach.

2:30 Exploring the Role of Size and Shape Impact on Immune Response through PRINT Technology

Michele Stone, Ph.D., PMP, Director, Vaccines, Liquidia Technologies

Particle technology is becoming increasingly prominent as a vaccine delivery system. PRINT technology allows for independent manipulation of particle, size, shape, charge, hydrophobicity, and composition. A variety of particles ranging from 80 to 10,000 nm were produced to explore controlled delivery of antigens and immunostimulants. Using a broad range of matrix materials formulated with active antigens and adjuvants, PRINT technology has defined specific sizes and shapes that appear to have superior effects on B cell and T cell immune responses.

3:00 An Ultra-Low Dose Live-Attenuated Influenza Vaccine – An Opportunity to Overcome Current Manufacturing Bottlenecks

J. Robert Coleman, Ph.D., MBA, Co-Founder, Executive Vice President, Vaccine Development, Codagenix, Inc.

Using our SAVE vaccine platform, we have developed a clinically relevant H1N1 live-attenuated Influenza vaccine strain against the 2009 pandemic virus that is highly immunogenic in ferrets. The vaccine has efficacy at ultra-low doses, doses 1,000-FOLD lower than current vaccines. Due to its low dose requirement, our vaccine technology could overcome critical bottlenecks in the influenza vaccine manufacturing process as well as provide a seasonal vaccine that is antigenically identical in all segments to the target strains with high efficacy.

3:30 Refreshment Break

VACCINE DELIVERY INNOVATIONS

3:45 Interbilayer-Crosslinked Multilamellar Vesicles: A System for Co-Delivery of Antigen and Adjuvant

Adrienne V. Li, Ph.D., Senior Scientist, Vedantra Pharmaceuticals, Inc.

Vedantra Pharmaceuticals has been developing a 'toughened' liposome for enhancing vaccine delivery. Our technology, Interbilayer-Crosslinked Multilamellar Vesicles (ICMVs), is formed by crosslinking of adjacent lipid bilayers within a liposome. ICMVs show enhanced protein antigen loading and extended drug release kinetics allowing efficient vaccine delivery. When the malaria antigen VMP001 is loaded into ICMVs, immunized animals generated higher titer, higher avidity, and more durable antibody response with broader epitope recognition by immune sera, compared to animals that received the soluble VMP001 protein.

4:15 Tuning the Direction and Magnitude of the Immune Response with New Nanomaterial-Based Vaccines

Tarek Fahmy, Ph.D., Associate Professor, Biomedical Engineering, Engineering & Applied Science, Yale University

Vaccine development has progressed significantly since Jenner and Pasteur, moving from whole microorganisms towards subunit vaccines containing only their antigenic proteins. Nanoparticulate-based vaccines have tunable physical properties, allowing for encapsulation and controlled delivery of multivalent antigen, immunostimulatory factors and incorporation of pathogen associated molecular patterns (PAMPs) targeting dendritic cells. Overall, immune responses can both quantitatively and qualitatively, be tuned efficiently using such systems. Here we discuss advances in both immunology and nanomaterials that have brought particulate-based vaccines to clinical applications.

4:45 Close of Conference

AUGUST 11-12, 2014

Immunomodulatory Therapeutic Antibodies for Cancer

Discovery and Development of the Next Wave of Checkpoint Inhibitors

Recommended Dinner Short Course*

Cancer Vaccines: Clinical Updates, New Technologies and Challenges

*Separate registration required, please see page 16 for details

MONDAY, AUGUST 11

7:30 am Conference Registration & Morning Coffee

8:35 Chairperson's Opening Remarks

Laszlo Radvanyi, Ph.D., Chief Scientific Officer, Lion Biotechnologies

» 8:45 KEYNOTE PRESENTATION: Putting Cancer in Check with Novel Immunomodulatory Strategies



Michael A. Postow, M.D., Assistant Attending Physician, Melanoma and Immunotherapeutics Service, Memorial Sloan-Kettering Cancer Center

Immunomodulatory antibodies that enhance T cell mediated immunity continue to demonstrate remarkable clinical success for patients with a variety of cancers. Antagonistic antibodies increase T cell function through blockade of negative regulatory circuits, and agonistic antibodies directly augment T cell function through engagement of various co-stimulatory receptors. Ongoing research seeks to identify why some patients have dramatic benefits to these approaches and to investigate whether combining these immunomodulatory antibodies with other cancer treatments improves outcomes.

RESEARCH & DEVELOPMENT

9:30 Tim-3 and Other Checkpoint Inhibitors that Induce T Cell Exhaustion and Tolerance

Vijay K. Kuchroo, DVM, Ph.D., Samuel L. Wasserstrom Professor of Neurology, Harvard Medical School

We have now identified cytokines and transcription factors that induce Tim-3 expression in naïve T cells and marks these T cells for dysfunction. This signaling axis is crucial for induction of Tim-3 and other genes including Lag3 and IL-10, that are coordinately expressed to induce T cell dysfunction in vivo. We are beginning to identify at a genomic level the modules that control the expression of Tim-3 with other checkpoint blockers and mechanisms by which these inhibitory receptors are co-regulated in exhausted/dysfunctional T cells.

10:00 Coffee Break

10:30 Humanized Mice as Preclinical *in vivo* Models For NKT Cell-Based Cancer Immunotherapy

Weiming Yuan, Ph.D., Assistant Professor, Molecular Microbiology and Immunology, Keck School of Medicine, University of Southern California

Despite overall conservation, subtle but important differences exist between CD1d/Natural Killer T (NKT) lipid presentation systems in humans and mice. We recently published the first hCD1d knock-in (hCD1d-KI) mouse. Now we further introduced human iNKT cell TCR into these mice. These humanized mice will allow more accurate *in vivo* modeling of human NKT cell responses to lipid drugs and facilitate preclinical assessment of lipid drugs for NKT cell-based immunotherapies.

11:00 Identification of Novel Immune Checkpoints as Targets for Cancer Immunotherapy

John Hunter, Ph.D., Site Head and Vice President, Antibody R&D, Compugen USA Inc.

Utilizing a predictive discovery platform, Compugen has identified nine target proteins predicted as immune checkpoints. Here we present results obtained for a novel immune checkpoint, CGEN-15049. CGEN-15049 inhibits the activity of NK cells and CTLs. The CGEN-15049 fusion protein displays robust inhibition of T cell activation and enhances iTregs differentiation. CGEN-15049 is expressed in tumor cells of numerous types of cancers and in tumor infiltrating immune cells. Based on its immunomodulatory activities and its expression pattern, CGEN-15049 may serve as mAb target for cancer immunotherapy.

11:30 Immunotherapy of Ovarian Cancer with Combination Enhanced Antigen Modulating Antibodies: Clinical Progress

Madi R. Madiyalakan, CEO, Quest PharmaTech

Quest uses specific antibody to enhance immunity to the target tumor antigen and associated tumor. We are using our lead product oregovomab to optimize combinations of chemotherapy and immune modulators in human clinical trials. Our randomized phase II confirming the effects of carboplatin paclitaxel in front line chemo-immunotherapy of ovarian cancer is pending analysis. We also are evaluating effects of TLR3 stimulation with Hiltonol in this setting, and the combination with Gemcitabine and radiation therapy in pancreatic cancer.

12:00 pm Phosphatidylserine (PS) Targeting Antibodies Enhances Activity of Immune Checkpoint Inhibitors by Repolarizing Immunosuppressive Immune Cells Populating the Tumor Microenvironment

Jeff Hutchins, Ph.D., Vice President, Pre-Clinical Development, Peregrine Pharmaceuticals

PS is a phospholipid normally residing in the inner leaflet of the plasma membrane and becomes exposed on cells of the tumor microenvironment, promoting an immunosuppressive microenvironment (MDSCs, immature dendritic cells, M2 macrophages, anti-inflammatory cytokines). Bavituximab, a PS-targeting antibody, repolarizes this microenvironment, enhancing innate and adaptive anti-tumor immunity. We demonstrate PS targeting antibodies enhance anti-tumor activity of multiple forms of standard therapy, including anti-CTLA-4 and anti-PD-1 checkpoint inhibitor antibodies without the side-effects of systemic immune activation.

12:30 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

IMMUNE MODULATORY TARGETS FOR ANTIBODY THERAPEUTICS

1:55 Chairperson's Remarks

Dmitry I. Gabrilovich, M.D., Ph.D., Christopher M. Davis Professor, Professor, Translational Tumor Immunology, Wistar Institute

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2:00 The Next Wave of Immune Checkpoint Modulator Targets

Paul D. Rennert, Founder & Principal, SugarCone Biotech Consultants LLC

Immuno-oncology therapy covers diverse approaches including immune checkpoint modulators, cytotoxic antibodies & ADCs, and bispecific modalities. To further improve cancer care we must understand how best to match therapeutics with specific patients. We must understand how to combine these therapies with genetically engineered T cells, diverse cancer vaccine approaches and targeted drugs. Further, we must discover the next generation of immune checkpoint, ADC and other therapeutic targets.

2:30 Emerging T Cell Checkpoint Regulators

Ana Carrizosa Anderson, Ph.D., Assistant Professor, Neurology, Harvard Medical School

The field of cancer immunotherapy has seen an explosion in therapies targeting the checkpoint receptors CTLA-4 and PD-1. While therapies that interfere with these receptor signaling pathways have been very promising in the clinic, a significant fraction of treated patients remain unresponsive to these therapies. This has prompted investigation into the possibility of targeting other immune checkpoints for the treatment of cancer. Data on emerging checkpoint targets will be discussed.

3:00 Myeloid-Derived Suppressor Cells – Emerging Regulators of Immune Responses

Dmitry I. Gabrilovich, M.D., Ph.D., Christopher M. Davis Professor, Professor, Translational Tumor Immunology, Wistar Institute

Myeloid-derived suppressor cells (MDSC) is a major factor responsible for tumor escape. These cells accumulate in large numbers in tumor-bearing hosts and are characterized by their myeloid origin, immature state, and, most importantly, by their potent ability to suppress different aspects of immune responses, primarily T-cell proliferation and cytokine production. These cells were found to correlate with clinical outcome of the diseases. Their targeting represents an attractive therapeutic opportunity.

3:30 Refreshment Break

4:00 Humanized Monoclonal Antibodies as Agonists for GITR or OX40 Signaling

Robert B. Stein, M.D., Ph.D., CSO, Agenus

We now know that there are many checkpoints in addition to CTLA-4 and PD-1. A new category of CPMs includes agonist antibodies targeting other checkpoint proteins, such as the receptors on T-lymphocytes called GITR and OX40. They stimulate anti-tumor immune responses and may play major roles in treating patients with a broad range of cancers. They can be developed as single agents and in optimized combinations, possibly including combinations with anti-cancer vaccines and other agents.

4:30 Costimulatory Pathways to Enhance Melanoma Adoptive T-Cell Therapy

Laszlo Radvanyi, Ph.D., Chief Scientific Officer, Lion Biotechnologies

The infusion of expanded tumor-infiltrating lymphocytes (TIL), initially expanded from small 3-5 mm² tumor fragments with IL-2, is a powerful therapy option for metastatic melanoma. This talk will present work on how we are beginning to manipulate T-cell costimulatory pathways in the tumor microenvironment in these early tumor fragment cultures, as well as at later stages of cell expansion, to generate TIL with enhanced survival and anti-tumor potential.

5:00 Comparative T Cell Costimulation by Targeting OX40, 4-1BB And TNFRSF25

Taylor Schreiber, M.D., Ph.D., Chairman, Scientific Advisory Board, Pelican Therapeutics

OX40 and 4-1BB are well accepted T cell costimulators that diverge in their specificity for CD4+ or CD8+ T cells. TNFRSF25 is a highly related receptor with similar expression by T cells that has potent costimulatory activity of both CD8+ T cells and T regulatory cells. Here we will present a systematic comparison of the activity of each of these molecules during both primary and memory T cell mediated immune responses and in the context of therapeutic treatment of multiple murine tumor models.

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

6:30 Close of Day

TUESDAY, AUGUST 12

7:45 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

BIOMARKERS AND SURROGATE ENDPOINTS

8:25 Chairperson's Opening Remarks

Llew Keltner, MD, PhD, CEO, EPISTAT

8:30 Challenges and Current Status of Developing Biomarkers for Cancer Immunotherapy

Janice Mehnert, M.D., Medical Oncologist, Cancer Institute of New Jersey

9:00 New Clinical Endpoint Concepts for Immunomodulatory Therapies

Llew Keltner, MD, PhD, CEO, EPISTAT

The promise of cancer immunotherapy for patients will only be realized if the most optimal combination immunotherapies are brought forward, as combinations. As a result, new models for combined regulatory and payer approval must be enabled in the clinical phases of drug development, and new clinical endpoints must be designed and validated. The FDA has strongly signaled that sponsors should work early and openly with the agency to build trials that can provide reasonable assurance of efficacy and safety, but can bring promising immunotherapies to market very rapidly. CMS and private payers are balking at mounting new-entity costs

EMERGING SCIENCE AND TARGETS

9:30 Novel Method for Suppression of Human Regulatory T Cells (Tregs) via Tnfr2 Antagonism

Denise Faustman, M.D., Ph.D., Director, Immunobiology; Associate Professor, Medicine, Immunobiology, Massachusetts General Hospital & Harvard Medical School

In cancer, overabundant Treg activity inhibits host defenses. Inhibiting Treg activity is a cancer approach. The recently discovered restricted tissue distribution of TNFR2 on human Tregs makes this receptor a possible therapeutic target. The generation of human directed TNFR2 monoclonal antibodies uncovered antagonists that inhibited Treg proliferation, signaling and function. Selective inhibition of Tregs through tissue restricted TNFR2 receptor allows the development of in vivo therapeutic regimens with decreased toxicity.

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

10:45 Preclinical and Clinical Evidence for Immune Checkpoint Modulation by ARGX-110, an Antibody Targeting CD70

Torsten Dreier, Ph.D., Chief Development Officer, arGEN-X BV, The Netherlands

11:15 Empowering Therapeutic Monoclonal Antibodies with a Biologic Payload for Cancers

Sanjay Khare, Ph.D., CEO, ImmunGene

We empower therapeutic antibodies by fusing them with IFN-alpha, thereby combining the targeting specificity of antibodies with the cytotoxic effects of IFN-alpha, which results in biologically pay-loaded antibodies that are more potent than native antibodies or soluble IFN-alpha. Data showing our molecules selectively targeting tumor cells while reducing the systemic toxicity of the payload and demonstrating considerably increased therapeutic index will be presented.

11:45 Modular Antibody Technology™ to Create Bispecific mAb2™

Jacqueline Doody, Vice President, Immunology, F-star Biotechnology Ltd

F-star creates unique Fcab™s by engineering the constant region of antibodies against a single target, which can be developed as a mono-therapeutic agent or combined with the variable regions of differing antibodies to create a bispecific. F-star's mAb2™ bispecific antibodies retain antibody properties such as Fc-mediated effector function, manufacturability, stability, and PK.

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

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AUGUST 12-13, 2014

Combination Cancer Immunotherapy

Strategies for Increasing the Efficacy of Cancer Immunotherapy by Combining Emerging Antibody Therapeutics with Classic and Novel Biotherapeutics

Recommended Dinner Short Course*

Cancer Vaccines: Clinical Updates, New Technologies and Challenges

*Separate registration required, please see page 16 for details

TUESDAY, AUGUST 12

12:30 Conference Registration

1:55 pm Chairperson's Opening Remarks

Peter P. Lee, M.D., Billy and Audrey L. Wilder Endowed Professor, Chair, Department of Cancer Immunotherapeutics & Tumor Immunology, City of Hope Comprehensive Cancer Center

» 2:00 KEYNOTE PRESENTATION:

Update from 2014 ASCO Meeting: Clinical Trials for Immunotherapy Combinations



Omid Hamid, M.D., Director, Melanoma Center, Angeles Clinic and Research Institute

After significant success in the field of Immuno-Oncology in multiple solid tumors, focus has shifted to combinations of immunotherapies. A combinatorial approach with each other or with other therapeutic modalities could potentially lead to enhanced efficacy, improved response rate, progression-free survival and overall survival. Despite this

enthusiasm, initial trials have been fraught with toxicity. This presentation will focus on recent data on state-of-the-art combinations with discussion on efficacy, outcome, dosing and applicability across many tumor types.

ADVANCES IN CANCER IMMUNOLOGY THAT IMPACT COMBINATION THERAPY

2:45 Restoring and Enhancing Host Immune Function in Cancer

Peter P. Lee, M.D., Billy and Audrey L. Wilder Endowed Professor, Chair, Department of Cancer Immunotherapeutics & Tumor Immunology, City of Hope Comprehensive Cancer Center

Host anti-tumor immune responses play an important role in achieving durable clinical responses even with chemotherapy, leading to the novel concept of immunogenic cell death. Successful treatment of patients with advanced metastatic disease will be crucially dependent on synergistic drug combinations able to effectively modulate immunogenic cell death and restore/enhance anti-tumor immune responses. We will report on our recent results in identifying synergistic drug combinations that can induce immunogenic cell death and restore/enhance immune function.

3:15 Sponsored Presentation (Opportunity Available)

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

4:15 Defining T Cell Pathways Engaged by Combination Checkpoint Blockade Immunotherapy

Ryan Teague, Ph.D., Assistant Professor, Molecular Microbiology & Immunology, Saint Louis University School of Medicine

Blockade of T cell inhibitory signaling pathways is being pursued for immunotherapy in cancer patients, but the biochemical pathways being targeted in responding T cells are not well characterized, particularly for combination treatments. To achieve the promise of immunotherapy it is vital to define molecules key to a clinically successful response. Our work strives to define the operative T cell mechanisms elicited during checkpoint blockade, providing translational insight for the treatment of patients with cancer.

4:45 Immune Corrective Strategies

Samir Khleif, M.D., Director, GRU Cancer Center; Professor of Medicine, Medical College of Georgia

SPECIAL PRESENTATION

5:15 Lifting the Curve & Raising the Bar: The Impact of Immunotherapy on the Cancer Therapeutics Market

Seamus Fernandez, Managing Director, Leerink Partners

Curing cancer has been an elusive goal. Today, with ipilimumab and PD1/PDL1 antibodies "lifting the curve" and data suggesting combinations will achieve even broader and deeper responses, the market must prepare for this goal to become a reality. Given the economic cost of drug development and expected pressures on payer reimbursement it is critical to understand the role of a backbone therapy, the importance of biomarker-based patient selection, and the implications of a raised bar for existing and future cancer therapy.

5:45 End of Day

WEDNESDAY, AUGUST 13

7:45 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

8:25 Chairperson's Opening Remarks

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

STRATEGIES FOR COMBINATION IMMUNOTHERAPY

8:30 Strategies for Combining Immunotherapy with Radiation Therapy

James W. Welsh, M.D., Assistant Professor, Radiation Oncology, Division of Radiation Oncology, The University of Texas MD Anderson Cancer Center

The biological premise behind such a strategy is that the tumor antigen release achieved by localized radiation will promote specific adaptive immune system targeting, which can be augmented further by systemic immune-stimulating agents. Clinicians hope to induce a phenomenon known as the abscopal effect, where localized radiation results in immune-mediated tumor regression in disease sites well outside of the radiation field. I present a review of the early clinical and pre-clinical evidence behind this approach, with emphasis on treatment of non-small cell lung cancer.

9:00 Genomic Determinants of Sensitivity to Immunotherapeutics

Peter Hammerman M.D., Ph.D. Assistant Professor of Medicine, Department of Molecular and Cellular Oncology, Harvard Medical School

Genomic discovery efforts performed across multiple tumor types have identified key molecular alterations involved in tumorigenesis. A surprising

result from these studies is that many tumor types harbor somatic alterations in genes which have an impact on immunity. Here, I will describe somatic alterations in key immunomodulatory genes in cancer, genomic studies of tumors and the microenvironment which have suggested particular vulnerabilities to immunotherapies and the use of transgenic animals with intact immune systems and relevant mutational profiles to study immunotherapies pre-clinically.

9:30 Combination of Immune Therapies in Preclinical Models

Li-Fen Lee, Ph.D., Senior Principal Scientist, Rinat, Pfizer

From a drug development and clinical care perspective, the activity observed with anti-PD-1 is clear. Robust single agent activity was observed and for durable and persisted without off-target toxicity. However, as we learn from the clinical trial data to date, the majority of patients will not respond or will have incomplete response to anti-PD-1. Because other immune regulation mechanisms of immunosuppression that work together or in parallel with PD-1 we explore different combinations in different tumor syngeneic animal models. We focus on tumors that are resistant to single agent treatment. The detailed efficacy and mechanisms will be discussed.

10:00 Sponsored Presentation (Opportunity Available)

10:15 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Targeting Antigen-Loss Tumor Variants through CD134 Plus CD137 Agonist Combination Therapy

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

Costimulatory receptor agonists can elicit T cell-mediated anti-tumor immunity. Further, combining different agonists can enhance therapeutic efficacy. In particular, dual costimulation through CD134 (OX40) plus CD137 (4-1BB) engages multiple immune cells with tumoricidal potential that include cytotoxic CD8+ T cells and, surprisingly, cytotoxic CD4 Th1 cells. In addition to directly targeting tumors, dual-costimulated cytotoxic CD4 Th1 cells also orchestrate a bystander helper response that can target antigen-loss tumor variants.

11:30 Prospects for Combination Immunotherapy for Hepatobiliary and Pancreatic Cancers

Neeharika Srivastava, M.D., Clinical Fellow in Medicine, Beth Israel Deaconess Medical Center

Hepatobiliary and pancreatic cancers are notoriously difficult to treat, largely due to high recurrence rates and resistance to traditional chemotherapies. Several clinical trials of immune therapy in these malignancies have demonstrated promising results, although none have produced a survival benefit. Combination immunotherapy may boost efficacy. Current avenues of research are discussed and potential opportunities are explored.

12:00 pm Immune Modulation and Combined Immunotherapies Using Gold Nanoparticles

Aaron Foster, Ph.D., Director, Product Discovery, Bellicum Pharmaceuticals

Gold represents a flexible and inert material to design nanoshells for thermal ablation of tumors, or to functionalize with molecules to modulate immunity for use as a single cancer therapy or in combination with other immunotherapies such as adoptive T cell transfer and vaccines. Our work examines how to use gold nanoparticles as an adjuvant to stimulate tumor-specific T cell responses and to disrupt immune suppressor cells to enhance immunotherapy.

12:30 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

CLINICAL UPDATES OF COMBINATION IMMUNOTHERAPIES

1:55 Chairperson's Remarks

Marc Mansour, Ph.D., COO, ImmunoVaccine

2:00 Key Issues in the Clinical Development of Immunotherapy Combinations

Jason J. Luke, M.D., Instructor, Medicine, Harvard Medical School

Immunotherapy is on the verge of relevancy in many cancers and combinations with other modalities (immuno-, chemo/targeted therapies and radiation) are

imminent. Beyond a strong preclinical rationale for combinations, careful selection of endpoints in clinical trials will be important. Historically, response rate and progression-free survival were considered useful surrogate endpoints however immunotherapy may not fit this model. Further, the toxicities of combinations will need to be considered closely within different cancers and patient populations.

2:30 Integrating Cancer Immunotherapy – Evaluating Options for New Combination Therapies

Margaret K. Callahan, M.D., Ph.D., Associate Professor, Medicine, Immunotherapy Clinical Core, Memorial Sloan-Kettering Cancer Center

RAF inhibitors selectively block extracellular signal-regulated kinase (ERK) signaling in BRAF-mutant melanomas and have defined a genotype-guided approach to care. RAF inhibitors have the opposite effect in BRAF wild-type tumor cells, where they cause hyperactivation of ERK signaling. We provide clear evidence that RAF inhibitors potentiate T cell activation *in vitro* and *in vivo*. Paradoxical activation of ERK signaling in T cells offers one mechanism to explain the enhanced antitumor activity seen when RAF inhibitors are combined with CTLA-4 blockade in preclinical models.

3:00 Combined Treatment Using Adoptive Cell Therapy, IL-2, and Tumor-Specific Antibodies

Taha Merghoub, Ph.D., Associate Biologist, Memorial Sloan Kettering Cancer Center

IL-2 is frequently given alongside other immunotherapies to enhance immune response. The protein, however, has poor pharmacokinetic properties and negative side effects. Our pre-clinical work combines a persistent form of IL-2 with adoptive cell transfer and a tumor-targeting antibody, resulting in tumor regression and, in some cases, complete cures with immunological memory. These results show adjuvants such as extended pharmacokinetic IL-2 can potentially improve the clinical outcomes of other targeted immunotherapies.

3:30 Refreshment Break

3:45 What Can We Expect Immunologically and Clinically from Combining an Immune Modulator with the Survivin Targeting Vaccine DPX-Survivac?

Marc Mansour, Ph.D., COO, ImmunoVaccine

DPX-Survivac is a depot based cancer vaccine designed to generate robust CD8 T cells against survivin, a therapeutic target associated with solid tumors and blood cancers. Combining DPX-Survivac with metronomic cyclophosphamide has demonstrated significantly increased its immunogenicity in advanced cancer patients. We have additional data to suggest that combination therapy diminishes the immune suppression at the tumor level to enhance the activity of the treatment. Grouping of this therapy with checkpoint inhibitors can further drive tumor specific immune responses.

4:15 Combinations with CRS-207, a Live-Attenuated Listeria Monocytogenes Expressing Mesothelin

Dirk Brockstedt, Ph.D., Senior Vice President, Research & Development, Aduro Biotech, Inc.

Aduro BioTech recently completed a Phase 2 trial of the combination of CRS-207 and GVAX Pancreas immunotherapies in patients with advanced-stage metastatic pancreatic cancer. This is the first randomized study to show that immunotherapy is effective in pancreatic cancer, and Aduro has initiated the follow-on Phase 2b ECLIPSE trial. Aduro is also conducting an ongoing Phase 1 trial of CRS-207 in combination with chemotherapy in patients with malignant pleural mesothelioma.

4:45 Applications of Systems Biology for Characterizing Mechanism of Action and Biomarker Discovery in Cancer

Craig Meagher, Ph.D., Senior Scientist, Research, Dendreon Corporation

Better characterization of the immunological mechanism of action against tumors and the identification of predictive and pharmacodynamic biomarkers of clinical outcome are important needs for cancer immunotherapies. We are using various high-content platforms to address such needs for sipuleucel-T, an autologous cellular immunotherapy for the treatment of asymptomatic or minimally symptomatic, metastatic castration-resistant prostate cancer. Results from some of these investigations will be presented. Such approaches may be broadly applicable for other cancer immunotherapies and may assist in assessing immunotherapy combinations in cancer.

AUGUST 14, 2014

Target Discovery for T Cell Therapy

Next Step to Advance Immunotherapies

THURSDAY, AUGUST 14

8:00 am Symposium Registration & Morning Coffee

8:25 Chairperson's Opening Remarks

Adrian Bot, M.D., Ph.D., Vice President, Translational Medicine, Kite Pharma, Inc.

CHIMERIC ANTIGEN RECEPTORS (CARs)

» 8:30 KEYNOTE PRESENTATION

CART Cells from the Mouse Cage to the Patients' Health



Zelig Eshhar, Ph.D., Professor, Immunology, The Weizmann Institute of Science

This presentation will be a brief chronicle description of the pioneering of the CAR strategy and its emergence and evolution for adoptive cell treatment of cancer. It will focus on experimental models for cancer in experimental settings and summarize the lessons learned from such models. The potential and challenges for cancer therapy

in patients will also be discussed. Finally, the pioneering of the CAR strategy and its emergence and evolution for adoptive cell treatment of cancer will be outlined.

9:00 CART Cell Therapy: Target Antigen Discovery and Clinical Translation

Richard Morgan, Ph.D., Vice President, Immunotherapy, Bluebird Bio

This talk will emphasize the importance of tumor antigen discovery in the selection of targets in CART cell therapy. As examples, I will compare and contrast Her2/neu and EGFRvIII as solid tumor targets. I will also discuss the clinical translation of these two CAR-based therapies.

9:30 Clinical Responses in Patients Infused with T Lymphocytes Redirected to Target K-Light Immunoglobulin Chain

Carlos A. Ramos, M.D., Assistant Professor, Medicine, Section of Hematology-Oncology, Baylor College of Medicine

T cells expressing chimeric antigen receptors (CARs) targeting B-cell malignancies show remarkable clinical efficacy but their long term persistence causes depletion of normal B cells and hypogammaglobulinemia because the antigens targeted do not discriminate tumor from normal B cells. Since B-cell malignancies express either a κ or a λ -light immunoglobulin we generated a CAR (κ -CAR) specific for κ -light chain to selectively target κ + lymphoma/leukemia cells, while sparing the normal B cells expressing the non-targeted λ -light chain. We present results of a phase I clinical of T cells express

10:00 Coffee Break

T CELL RECEPTORS (TCRS)

10:30 Expression of Cancer Testis Antigens in Human BRCA-Associated Breast Cancers: Potential Targets for Immunoprevention

Achim A. Jungbluth, M.D., Ph.D., Director, Immunohistochemistry, Pathology, Memorial Sloan-Kettering Cancer Center

Novel breast cancer risk-reducing strategies for individuals with germline mutations of the BRCA1 and/or BRCA2 genes are urgently needed. Identification of antigenic targets that are expressed in early cancers, but absent in normal breast epithelium of these high-risk individuals, could provide the basis for the development of effective immunoprophylactic strategies. Cancer testis (CT) antigens are potential candidates because their expression is restricted to tumors, and accumulating data suggest that they play important roles in cellular proliferation, stem cell function, and carcinogenesis.

11:00 Target Discovery for TCR-Mediated Immunotherapy of Cancer with ImmTACs

Emma Hickman, Ph.D., Head, Target Validation, Immunocore

ImmTACs are bi-specific, pico-Molar affinity T cell Receptors fused to an anti-CD3 specific scFv that re-directs a potent T cell response towards its target. The most advanced ImmTAC reagent to-date, IMCgp100, is well tolerated in melanoma patients and induces T cell mobilisation and tumour shrinkage in clinical trials. Here we discuss our approach to target identification and target profiling for the ImmTAC platform.

11:30 Fine-Tuning TCR-Antigen Specificity and Predicting Potential Off-Target Reactivity

Joanna E. Brewer, Ph.D., Group Leader, Cellular Biology, Adaptimmune Ltd.

Adoptive T cell therapy (ACT) with gene-modified T cells is emerging as a highly promising strategy for the treatment of many types of cancer. Mutating T cell receptors, to improve their affinity for tumour specific epitopes, provides the needed potency for efficacy but may present safety concerns for off-target recognition as TCRs effectively bypass thymic selection. A combination of peptide bioinformatics and primary cell screening offers a robust delineation of any possible peptide epitopes that can be recognised by an individual TCR.

12:00 pm Sponsored Presentation (Opportunity Available)

12:30 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

TUMOR-INFILTRATING LYMPHOCYTE (TIL) THERAPY

1:30 Emerging Biomarker Approaches to Predict Response in Melanoma T Cell Therapy

Laszlo Radvanyi, Ph.D., Professor, Melanoma Medical Oncology, University of Texas, MD Anderson Cancer Center

The high clinical response rates (up to 50%) in melanoma patients receiving autologous tumor-infiltrating lymphocyte (TIL) therapy offers us an unprecedented opportunity to identify both on-treatment and predictive immunotherapy biomarkers. This talk will present our work on a comprehensive systems biology platform identifying biomarkers of response and resistance in a diverse array of specimen types from patients receiving TIL therapy. A number of TIL phenotypic markers and genomic markers in tumors predictive of response and improved survival after therapy have been identified; these markers also beginning to shed light on the mechanisms underlying therapy resistance.

2:00 Developing Potent Cancer Therapies Targeting Cancer Germline and Mutated Antigens

Paul F. Robbins, Ph.D., Head, DNA Sequencing and FACS Cores, Surgery Branch; Staff Scientist, Center for Cancer Research, National Cancer Institute

Current cancer gene therapy trials have focused on transducing autologous T cells with T cell receptors (TCRs) that recognize tumor antigens with limited or no normal tissues expression, as severe toxicities were observed in clinical trials targeting differentiation antigens. In a recent trial utilizing a TCR directed against the cancer germline antigen NY-ESO-1, whose expression is limited to the normal testis, objective clinical response rates of 58 and 56% were observed in patients with melanoma and synovial cell sarcoma, respectively, but no normal tissue toxicities attributed to the transferred T cells were observed. Additional strategies are also being developed to target mutated epitopes that are generally limited in their expression to a single patient but that may represent particularly potent targets for therapy.

2:30 Immune Profiling during Pre-Clinical Development and in Phase I/II Clinical Trials

Yoav Peretz, Ph.D., Scientific Director, Immunology, ImmuneCarta, Caprion

Immune monitoring of patients enrolled in clinical trials has become crucial to help guide the development of immunotherapies and reveal potential relationships between the clinical and immunological response. The lack of protective signatures is partly explained by the realization that monoparametric evaluations fail to capture the phenotypic and functional heterogeneity of the immune response. Therefore, multiparametric flow cytometry has become the tool of choice given its ability to simultaneously analyze the relative distribution of cellular phenotypes and functions in complex mixtures of cells such as in peripheral blood and tissues.

In the case-reports presented, we will describe the tools used to comprehensively monitor cellular responses and evaluate the immunostimulatory and suppressive compartments. Use of these analytical tools to evaluate changes in the phenotype and function of cellular subsets during disease and after treatment enables the identification of correlates and predictive biomarkers of immune protection.

3:00 Refreshment Break

NEW METHODS TO DISCOVER NOVEL TARGETS

3:15 High-Throughput Mass-Spectrometry-Based Identification and Selection of Novel Targets for Cancer Immunotherapies

Harpreet Singh, Ph.D., Managing Director, CSO, Co-Founder, Immatics Biotechnologies GmbH

The XPRESIDENT® antigen discovery platform (also known as the Tuebingen Approach) allows the rapid identification, selection and validation of novel T cell targets which have been discovered with a combination of mass-spectrometry based quantitative peptidomics, transcriptomics, T cell immunology and bioinformatics. Also data from several clinical trials conducted with these targets as vaccines in several hundreds of patients and their suitability for adoptive cellular therapy will be discussed.

3:45 In vivo Discovery of Targets for Cancer Immunotherapy

Kai W. Wucherpfennig, M.D., Ph.D., Cancer Immunology & AIDS, Dana-Farber Cancer Institute; Professor of Neurology at Harvard Medical School

A novel pooled shRNA screen has been developed to discover genes that represent key negative regulators of cytotoxic T cell function in tumors. shRNAs that target such negative regulators greatly enhance T cell accumulation in tumors and improve T cell function. This approach enables systematic target discovery in relevant tissue microenvironments.

4:15 Chairperson's Closing Remarks

Adrian Bot, M.D., Ph.D., Vice President, Translational Medicine, Kite Pharma, Inc.

4:30 Close of Symposium

“Target Discovery for T Cell Therapy parallels the rapidly increasing interest in this therapeutic modality that is showing tantalizing evidence of clinical efficacy. This meeting gathers leaders from academia and industry actively engaged in discovery and translation of novel targets for T cell immunotherapy.”

Dr. Adrian Bot, Vice President, Translational Medicine, Kite Pharma, Inc.

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Co-locate your user group meeting or custom event. CHI will help market the event, manage logistical operations, develop the agenda, and more. CHI can handle the entirety of the meeting or select aspects.

Exhibit

Exhibitors will enjoy facilitated networking opportunities with qualified delegates, making it the perfect platform to launch a new product, collect feedback, and generate new leads. Exhibit space sells out quickly, so reserve yours today!

Additional branding and promotional opportunities are available, including:

- Conference Tote Bags
- Literature Distribution (Tote Bag Insert or Chair Drop)
- Badge Lanyards
- Program Guide Advertisement
- Padfolios and More...

Advertising opportunities such as marketing and promotional emails are also available

Additional branding and sponsorship opportunities available!
Reserve Exhibit Space by May 1, 2014 to Save \$300



Stay Connected



#IMVACS14

For sponsorship and exhibit information, please contact:

Katelin Fitzgerald

Business Development Manager

781-972-5458 | kfitzgerald@healthtech.com

Hotel & Travel Information

Conference Venue and Host Hotel:

Marriott Boston Long Wharf
296 State Street

Boston, MA 02109 Room Rate: **\$269 s/d**
Tel: 617-227-0800 Res Cutoff: **July 14, 2014**

To make a reservation, please visit the [Hotel & Travel](#) page of our website or call the hotel directly to reserve your sleeping accommodations. You will need to identify yourself as a Cambridge Healthtech Institute conference attendee to receive the discounted room rate with the host hotel. Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space-and-rate-availability basis. Rooms are limited, so please book early.

Why Stay at the Marriott Long Wharf?

- Just four miles from Boston's Logan International Airport
- Complimentary wireless internet access in guest rooms
- Walk to some of Boston's finest attractions - to name a few: Faneuil Hall, Quincy Market, Boston Common, The Boston Tea Party ship, and the New England Aquarium. Or, take a sunset cruise – just steps away!
- Minutes from Boston's finest restaurants and shops

We understand that you have many choices when making your travel arrangements. Please understand that reserving your room in the CHI room block allows you to take full advantage of the conference sessions, events and networking opportunities, and ensures that our staff will be available to help should you have any issues with your accommodations.

Flight Discounts:

Special discounts have been established with American Airlines. Please use one of the following methods:

- Call 1-800-433-1790 and use Conference code 2984AA
- Go online to www.aa.com/group and enter Conference code 7654AA in promotion discount box
- Contact our designated travel agent, Rona Meizler at 1-617-559-3735 or rona.meizler@protravelinc.com.

Car Rental Discounts:

Special discount rentals have been established with Hertz for this conference. Please use one of the following methods:

- Visit hertz.com to make your reservation and use Hertz Convention Number (CV) 04KL0005
- Call Hertz directly at 800-654-3131 and reference our Hertz Convention Number 04KL0005

If you are driving, visit boston.bestparking.com for information on finding nearby parking lots and the rates in and around the city

Pricing and Registration Information

SHORT COURSES

	Commercial	Academic, Government, Hospital-affiliated
One Short Course	\$699	\$399

SHORT COURSE SELECTION:

Tuesday, August 12 6:30 to 9:00 pm
Vaccine Production & Manufacturing

Tuesday, August 12 6:30 to 9:00 pm
Cancer Vaccines: Clinical Updates, New Technologies and Challenges

SYMPOsia PRICING

Register for a Symposia + Conference and SAVE! See online pricing for details.

Thursday, August 14

Target Discovery for T-Cell Therapy

Advance Registration Discount until July 25	\$1099
Registration after July 25 and onsite	\$1299

SUMMIT PRICING

(Includes access to two conferences, excludes Short Courses)

Advance Registration Discount until July 25	\$2299	\$1129
Registration after July 25 and onsite	\$2499	\$1199

BASIC CONFERENCE PRICING

(Includes access to one conference, excludes Short Courses)

Advance Registration Discount until July 25	\$1699	\$799
Registration after July 25 and onsite	\$1899	\$899

REQUIRED - Conference Selection

Based on your pricing option please select the conference(s) you will attend
Summit Pricing - Select TWO (one from each column)
Basic Pricing - Select ONE (one from either column)

POSTER DISCOUNT (\$50 OFF)

Poster abstracts are due by July 18, 2014. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com.

* CHI reserves the right to publish your poster title and abstract in various marketing materials and products.

August 11-12, 2014

- ☐ Novel Vaccines - Part One: Adjuvants, TLRs & DNA Vaccines
☐ Immunomodulatory Therapeutic Antibodies for Cancer

August 12-13, 2014

- ☐ Novel Vaccines - Part Two: Emerging Vaccine Technologies
☐ Combination Cancer Immunotherapy

ALUMNI DISCOUNT: Cambridge Healthtech Institute (CHI) appreciates your past participation at ImVacS. As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate. Please note: Our records must indicate you were an attendee of ImVacS in the past in order to qualify.

Group Discounts are Available!

Special rates are available for multiple attendees from the same organization. For more information on group discounts contact David Cunningham at 781-972-5472

*Alumni, Twitter, LinkedIn, Facebook or any other promotional discounts cannot be combined. Discounts not applicable on Event Short Courses.

If you are unable to attend but would like to purchase the Event Proceedings CD for \$750 (plus shipping), please visit ImVacS.com.
Massachusetts delivery will include sales tax.



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ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

**To view our Substitutions/
Cancellations Policy, go to
<http://www.healthtech.com/regdetails>**

Video and/or audio recording of any kind is prohibited onsite at all CHI events.

How to Register: ImVacS.com

reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode
IMT F
when registering!

Please refer to the Registration Code below: