10TH ANNUAL

IMVACS IMMUNOTHERAPY & VACCINE SUMMIT

Clinical Advancement through Technology & Innovation

AUGUST 24-28, 2015 • MARRIOTT LONG WHARF HOTEL • BOSTON, MA

PLENARY KEYNOTE ADDRESS:

Dangerous Thoughts on Immunotherapy

Polly C. Matzinger, Ph.D.
Senior Investigator, Ghost Lab, Laboratory of Immunogenetics, NAID/NIH

TRACK KEYNOTES:

Nathalie Garçon, Ph.D.
PharmD, CSO, Bioaster

Michael B. Atkins, M.D.
Deputy Director, Lombardi Comprehensive Cancer Center, Georgetown University Medical Center

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

Michael C. Jensen, M.D.
University of Washington School of Medicine; Seattle Children's Research Institute; Fred Hutchinson Cancer Research Center

Derek O'Hagan, Ph.D.
Global Head, Vaccine Chemistry and Formulation Research, Novartis Vaccines

Rodger Novak, M.D., Ph.D.
CEO & Founder, CRISPR Therapeutics

Register by **June 5** and Save up to **$400!**

CONFERENCE TRACKS:

AUGUST 24-25

- Immunomodulatory Therapeutic Antibodies for Cancer
- Novel Vaccines Part I: Adjuvants

AUGUST 25-26

- Rational Combination Cancer Immunotherapy
- Novel Vaccines Part II: Emerging Technologies

AUGUST 27-28

- Target Discovery for T Cell Therapy
- Gene Editing for Immunotherapy

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IMVACS IMMUNOTHERAPY & VACCINE SUMMIT

Cambridge Healthtech Institute is pleased to bring you the Tenth Annual ImVacS: Immunotherapy and Vaccine Summit, which will showcase clinical advancement of immune therapies through technology and innovation. The 2015 event has been expanded to five days spanning immunotherapies, vaccines, and gene editing with particular focus on case studies and unpublished data in each field.

Kicking off the week are the **Immunomodulatory Therapeutic Antibodies for Cancer** and the **Novel Vaccines: Adjuvants** conference tracks. Immunomodulatory Antibodies for Cancer will explore developments in mainstream and emerging targets in this space, review progress in the application of immunotherapy for difficult to treat cancers and consider different concepts for developing multifunctional antibody immunotherapies. The Adjuvants event will cover the latest advances in a range of adjuvants, from archaeosomes to TLRs, present case studies of successful formulations against challenging diseases, and address issues related to regulatory approval and understanding mode of action.

The middle section of the meeting will bring coverage of **Rational Combination Cancer Immunotherapy**, which will review strategies for combining immune-modulating antibodies with traditional and experimental therapeutics for improved clinical benefit to patients. Additionally, the **Novel Vaccines: Emerging Technologies** conference will examine the latest advancements and applications of vaccine technology, and a look forward to overcoming current challenges.

Finally, to close the week, attendees will have the option to attend the **Target Discovery for T Cell Therapy** or the **Gene Editing for Immunotherapy** events. At Target Discovery, experts will share strategies around T cell receptors (TCR) and tumor infiltrating lymphocytes (TIL), and special attention will be given to chimeric antigen receptors (CAR). Gene editing will showcase emerging gene editing techniques using CRISPR and CAS9 as well as next-generation sequencing in support of immunotherapies. On the final day, these two conference tracks will combine to showcase personalized immunotherapy approaches and the technologies and techniques needed to make immunotherapies a reality.

New to this year's event is a plenary keynote session that will bring together over 300 conference attendees in one session. The plenary address will be given by Dr. Polly Matzinger of the NIH and will focus on different predictions from the various models of immunity and show how they influence how researchers approach immune therapies.

Overall, ImVacS 2015 promises to be a must-attend event for commercial and academic entities to continue advancing immunotherapies and vaccines through technology and innovation.

We hope to see you this August in Boston!

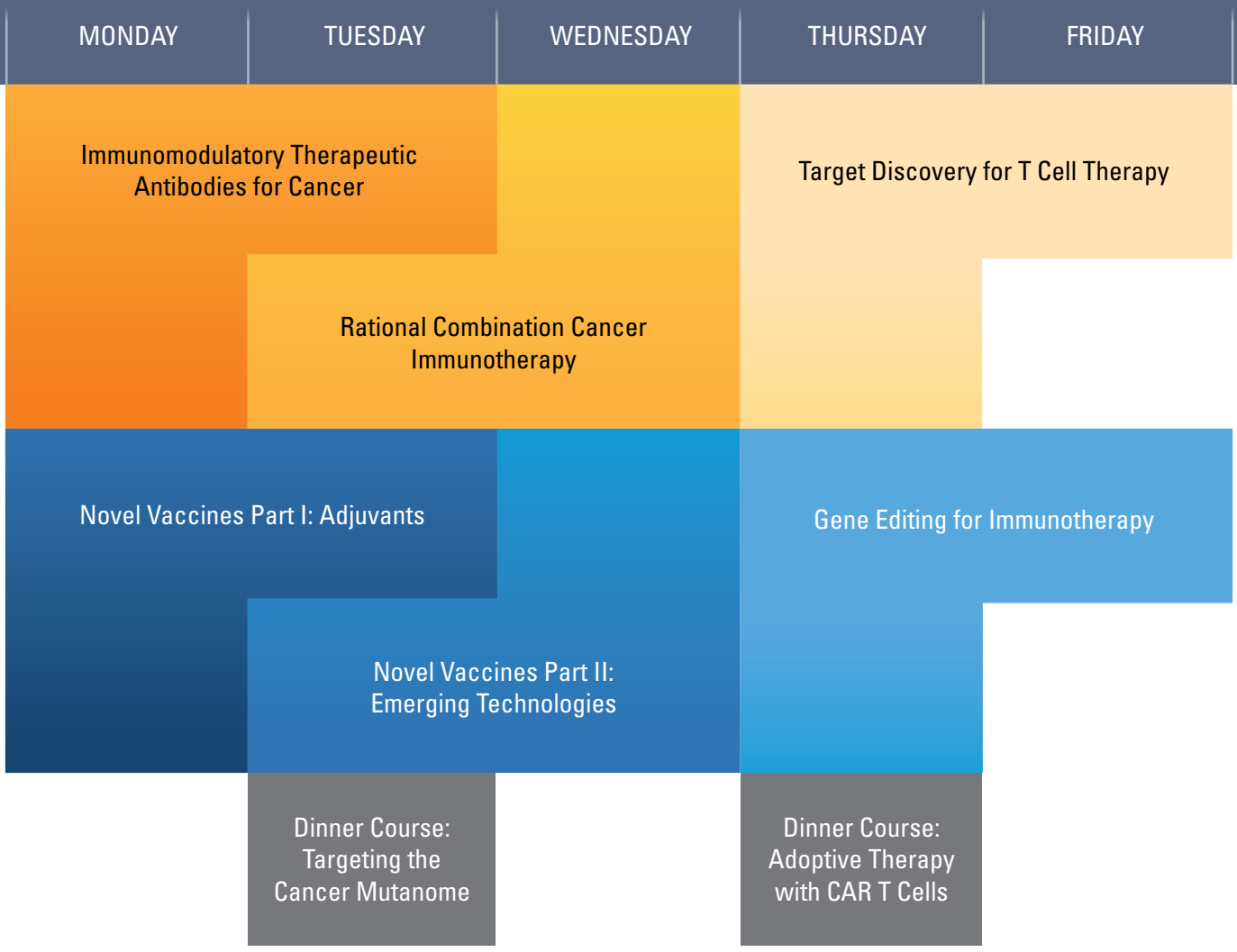
Sincerely,
The ImVacS Team

Samantha Lewis
Conference Producer

Kent Simmons
Senior Conference Director

Virginia Maxwell
Associate Conference Producer

CONFERENCE AT-A-GLANCE



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PLENARY **KEYNOTE:**

TUESDAY, AUGUST 25

11:15 Dangerous Thoughts on Immunotherapy

Polly C. Matzinger, Ph.D., Senior Investigator, Ghost Lab, Laboratory of Immunogenetics, NAID/NIH

What we think influences what we do. If we continue to view the immune system through the old fashioned self-non-self model, the likelihood of finding truly effective immunotherapies is vanishingly small, whether those therapies are for autoimmunity, cancer or transplantation. I will delineate the different predictions from the various models of immunity and show how they influence how we approach immunotherapy.

12:15 pm Luncheon Presentation *(Sponsorship Opportunity Available)*

TRACK **KEYNOTES:**

PD-1 Blockade: Current Status and Future Opportunities

Michael B. Atkins, M.D., Deputy Director, Lombardi Comprehensive Cancer Center, Georgetown University Medical Center

Vaccines and Innovative Technologies: A Millennium Story

Nathalie Garçon, Ph.D., Pharm.D., CSO, Bioaster

Enhancing the Synthetic IQ of CAR T Cells

Michael C. Jensen, M.D., Janet & Jim Sinegal Endowed Professor, Pediatrics; Adjunct Professor, Bioengineering, University of Washington School of Medicine; Joint Member, Program in Immunology, Fred Hutchinson Cancer Research Center

Politics and Realities of IO Combination Trial Design

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

The Next Generation of Vaccine Adjuvants

Derek O'Hagan, Ph.D., Global Head, Vaccine Chemistry and Formulation Research, Novartis Vaccines

Gene Editing on the Cusp of Exciting Opportunities for Human Therapeutics

Rodger Novak, M.D., Ph.D., CEO & Founder, CRISPR Therapeutics

DINNER SHORT COURSES*

6:30 - 9:00 pm

TUESDAY, AUGUST 25

Targeting the Cancer Mutanome

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.

Background and Update on Current Science

Course Leader: Laszlo Radvanyi, Ph.D., Chief Scientific Officer, Lion Biotechnologies

An overview on the emerging field of neo-antigen (mutanome) targeting will be presented. This overview will summarize the current approaches used to deduce cancer neo-antigen epitopes for immunological targeting, specific examples of how neo-antigen targeting is being used already in cancer immunotherapy, some of the obstacles being faced in the field, and the impact of neo-antigen targeting will have in the future of immunotherapy.

Neo-antigens in Cancer Immunotherapy

Lelia Delamarre, Ph.D., Scientist, Cancer Immunology, Genentech (Confirmed)

Tumors accumulate mutations, which can be recognized as foreign and induce immune responses. We developed a novel strategy to identify neo-epitopes by combining whole-exome sequencing and mass spectrometry analysis, along with structural prediction for discovery of immunogenic antigens. This information can be used for the immuno-monitoring of cancer patients, and help identify which patients will benefit from immunotherapy. Finally this knowledge could be exploited for the design of personalized vaccines.

Identifying Suitable Neoepitopes – Seeing Through the Fog of Suppression

Pramod Srivastava, M.D., Ph.D., Professor, Immunology and Medicine, University of Connecticut School of Medicine; Director, Carole and Ray Neag Comprehensive Cancer Center (Confirmed)

Results of experiments, which do or do not eliminate the effect of immune suppression, while screening for immunogenic protective neoepitopes, shall be presented and discussed.

What T Cells See on Human Cancer

Marit van Buuren, MSc, Ph.D. Student, Cancer Immunology, Netherlands Cancer Institute (Confirmed; Unpublished data)

Human tumors are characterized by large numbers of mutations, of which many hundreds can be contained within expressed genes, resulting in so-called "neo-antigens". The immune recognition of these antigens is hypothesized to be of significant importance to the activity of clinically used immunotherapeutics in melanoma. With the use of in-house developed technologies to monitor T cell reactivity, we have shown that the T cell recognition of neo-antigens is a common feature in human melanoma.

6:00 - 9:00 pm

THURSDAY, AUGUST 27

Adoptive Therapy with CAR T Cells

Ben Boyerinas, Ph.D., Scientist II, Cellular and Molecular Immunotherapy, bluebird bio

Adoptive cell therapy (ACT) is causing a great deal of excitement in the research community given its ability to use a patient's immune system to recognize and attack disease cells. The current frontrunner for ACT is chimeric antigen receptor (CAR) T cells, which allows for more potency than has been seen in many other immunotherapies. At this short course, researchers working with CAR T cells will address:

- Genetically modified T cells from immunology to immunotherapy
- Managing toxicity-related side-effects
- Improving platforms and processes
- Novel CAR T cell designs

**Separate registration required.*

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- Focus group
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- Plated dinner with specific conversation focus

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For more information, please contact:
Katelin Fitzgerald, Sr. Manager, Business Development
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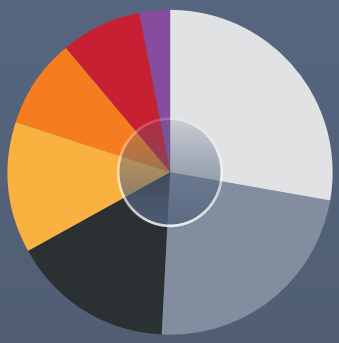
IMVACS ATTENDEE PROFILE

RECORD ATTENDANCE IN 2014!

To view a sample of last year's attendees please visit ImVacS.com

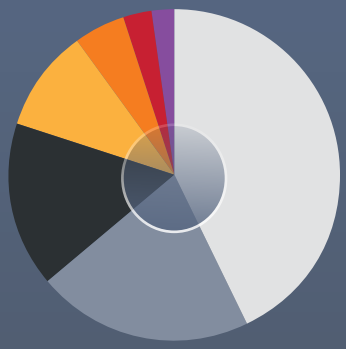
ImVacS 2014 hosted over 300 delegates hailing from 25 countries.

WHO ATTENDS IMVACS?



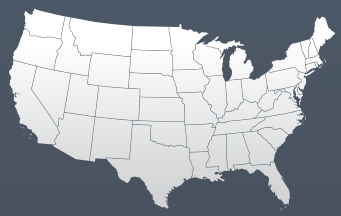
Scientist/Technologist	28%
Executive	23%
Director	16%
Professor	13%
Sales & Marketing	9%
Manager	8%
Other	3%

ATTENDEES BY COMPANY TYPE



Biotechnology	43%
Pharma	21%
Academic	16%
Healthcare/Hospital	10%
Other	5%
Services/Societies	3%
Government	2%

ATTENDEES BY GEOGRAPHIC LOCATION



USA **75%**

EUROPE **11%**

ASIA **9%**

OTHER **5%**

CS Case Study UD Unpublished Data

AUGUST 24-25

Immunomodulatory Therapeutic Antibodies for Cancer

Recommended Dinner Short Course*
Targeting the Cancer Mutanome
**Separate registration required, please see page 4 for details.*

MONDAY, AUGUST 24

7:15 am Registration & Morning Coffee

PD-1 PATHWAY INHIBITORS

8:10 Chairperson's Opening Remarks
Tariq Ghayur, Ph.D., Distinguished Research Fellow, AbbVie Bioresearch Center

» 8:15 KEYNOTE PRESENTATION: PD-1 BLOCKADE: CURRENT STATUS AND FUTURE OPPORTUNITIES
Michael B. Atkins, M.D., Deputy Director, Lombardi Comprehensive Cancer Center, Georgetown University Medical Center

9:00 Current Insights on the PD-1/PD-L1 Axis as a Therapeutic Target in Oncology: A Biomarker Perspective
UD *Kurt Schalper, M.D., Ph.D., Associate Research Scientist, Pathology, Yale University School of Medicine*

Monoclonal antibodies targeting the co-inhibitory immune checkpoint PD-1 or its primary ligand PD-L1 are well tolerated and can induce lasting clinical responses in patients with advanced malignancies. However, the majority of patients treated with such agents do not receive clear benefit, highlighting the need for companion biomarkers to select subjects with the highest potential of benefit. Current status and recent developments in biomarkers for PD-1/PD-L1 axis therapies will be discussed.

9:30 Coffee Break

10:00 Intellectual Property Review of Major Immunotherapy Targets: Non Composition of Matter Approaches to Developing Unique IP in Cancer Immunotherapy
Konstantin M. Linnik, Ph.D., Partner, Intellectual Property, Nutter, McClennen & Fish, LLP

Immunoncology IP is crowded – the number of drugs in R&D far exceeds the number of targets. Navigating the IP around major targets is critical but, more importantly, every drug developer faces challenges in protecting its own intellectually property. What are the patenting approaches that allow entry into this crowded IP space, while preserving the broadest scope of protection?

EMERGING INDICATIONS

10:30 New and Noteworthy Solid Tumor Indications for Checkpoint Inhibitors
Amit Mahipal, M.D., Medical Director, Clinical Research Unit; Assistant Member, H. Lee Moffitt Cancer Center & Research Institute

Immune checkpoint inhibitors have demonstrated high response rates and prolonged survival in selected tumor types and have been approved for treatment of melanoma. Checkpoint inhibitors are currently being evaluated in phase III trials for treatment of non small cell lung cancer, renal cell carcinoma and other cancers. Remarkable response rates and durable responses are also seen in other tumors including bladder cancer, gastric cancer and head and neck cancers that would be focus of this talk.

11:00 Targeting Immune Suppressive Microenvironment by Immune Checkpoint Blockade in Multiple Myeloma
UD *Güllü Topal Görgün, Ph.D., Senior Research Scientist, Dana-Farber Cancer Institute*

PD1/PD-L1-signaling promotes tumor growth while inhibiting anti-tumor immune responses. Here we assessed the impact of single and dual blockade of PD1/PD-L1, alone or in combination with lenalidomide, on accessory and immune cell function as well as multiple myeloma (MM) cell growth in the immune suppressive BM milieu. We demonstrated that checkpoint signaling plays an important role in providing the tumor-promoting, immune-suppressive microenvironment in MM, and that blockade of PD1/PD-L1-signaling induces anti-MM immune responses that can be enhanced by lenalidomide.

11:30 Sponsored Presentation *(Opportunity Available)*

12:00 pm Luncheon Presentation: Breaking Down the Barriers to Immune Infiltration in the Tumor Microenvironment by Neutralization of Semaphorin 4D

Sponsored by VACCINEX

Elizabeth Evans, Ph.D., Director, Oncology Research, Vaccinex Inc.

The tumor stroma creates an immunosuppressive microenvironment that restricts immune-mediated tumor rejection. Semaphorin 4D represents a novel target with a unique mechanism for immunomodulation. SEMA4D is highly expressed at the invasive tumor margin and acts as a guidance molecule, restricting movement of tumoricidal immune cells into the TME. Antibody neutralization of the SEMA4D barrier enhances penetration of activated monocytes and T cells that serves to inhibit syngeneic tumor growth and can enhance activity of other immunomodulatory therapies.

EMERGING TARGETS, PATHWAYS AND MECHANISMS

1:25 Chairperson's Remarks
Paul D. Rennert, Founder & Principal, SugarCone Biotech Consultants LLC

1:30 Tumor Associated Macrophages and CD4 T Cells Have Non-redundant Roles in the Suppression of CD8 T Cell Infiltration into Melanoma

Susan Kaech, Ph.D., Associate Professor, Immunobiology, Yale University School of Medicine

In melanoma patients, ~60% of patients have Braf-V600E mutation and Braf-V600E selective inhibitor, PLX4720, has been shown to trigger melanoma regression. We analyzed the composition and activities of tumor-infiltrating immune cells in an inducible melanoma model based on Cre-mediated Braf-V600E activation and Pten inactivation. Our results suggest that modulation of Braf activity in tumors and possibly also immune cells promotes anti-tumor immune responses and reveals the importance of CD40L-CD40 interaction in PLX4720-mediated antitumor response.

2:00 Building a Robust Translational Sciences Platform for Tumor Immunotherapy: From Identification of New Targets to Patient Enrichment Strategies

Sriram Sathy, Ph.D., Director, Translational Sciences, Jounce Therapeutics

Jounce is focused on developing cancer immunotherapies that are geared to provide durable clinical responses through identification of optimal targets for specific indications and for certain subsets, patients within those indications. Towards this goal we have developed a robust translational platform that allows for both target identification as well as patient/indication selection in an unbiased fashion. This approach relies on the fundamental principle of defining the immune system content and characteristics via a comprehensive multiple parameters approach.

2:30 Local Endothelial Complement Activation Reverses Endothelial Anergy and Enables Effective T Cell Tumor Infiltration and Immunotherapy

UD *Andrea Facciabene, Ph.D., Research Assistant Professor, Obstetrics and Gynecology, University of Pennsylvania School of Medicine*

Cancer immune therapy depends on the ability of T cells to infiltrate tumors through the tumor endothelium. We demonstrated tumor infiltration by antitumor T cells *in vivo* requires local endothelial complement activation and anaphylatoxin release. Th1 cytokines, released by tumor-reactive T cells, induce endothelial C3 expression, local complement activation, and C5a anaphylatoxin release. This promotes the upregulation of ICAM-1 and VCAM-1 and T cell adhesion to the endothelium, circumventing the endothelial barrier *in vivo* and *in vitro*.

3:00 Refreshment Break

3:30 Anti-Tumor Function of an Anti-iNKT TCR Monoclonal Antibody

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

Invariant natural killer T (iNKT) cells are potent anti-tumor T cells. Anti-tumor clinical trials using the iNKT cell ligand, α-galactosylceramide (α-GalCer) have had limited success and one major limitation of α-GalCer-based therapies is the bioavailability of lipid drugs. We have engineered a murine iNKT TCR-targeting monoclonal antibody (NKT14m) and investigated its in-vivo anti-tumor function. We detected a synergistic anti-tumor function of the NKT14m antibody when administered in combination with IL-12.

4:00 The Next Generation of TIL Therapy using Immune Modulator Combinations

CS UD *Laszlo Radvanyi, Ph.D., CSO, Lion Biotechnologies*

The use of autologous tumor-infiltrating lymphocytes (TIL) has made significant advances recently, with commercial efforts underway towards regulatory approval as a potent cell therapy for melanoma and other solid tumors. I will discuss progress towards this goal, including development of biomarkers for patient selection, optimized cytokine therapy after TIL infusion, approaches to improve TIL manufacturing methods, and current efforts to combine TIL therapy with immunomodulators such as T-cell checkpoint blockade.

4:30 Immunomodulatory Antibody Targets in the Tumor Microenvironment

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

CTLA-4 and PD-1/PD-L1 antagonists target T cell immune checkpoint pathways. Novel immune modulatory targets have been identified in the Immunoglobulin superfamily, the TNFR superfamily, and on NK and other cells. Moreover, many inhibitory factors are expressed by or secreted by myeloid and stromal cells within the tumor microenvironment: it is here that we find critical metabolic, growth factor and chemokine receptor targets that control immunosuppression and are important therapeutic targets.

5:00 End of Day

TUESDAY, AUGUST 25

7:25 am Morning Coffee

MULTIFUNCTIONAL ANTIBODY IMMUNOTHERAPIES

7:55 Chairperson's Opening Remarks

John Haurum, M.D., D.Phil., CEO, F-star GmbH & F-star Biotechnology Ltd.

8:00 Design and Construction of Tri- and Tetra-Specific Ig Molecules to Regulate T Cell Functions and Immune Responses

CS UD *Tariq Ghayur, Ph.D., Distinguished Research Fellow, AbbVie Bioresearch Center*

Four dual-variable-domain – Ig (DVD-Ig™) molecules are in clinical development for autoimmune and oncology indications. Now we have extended the DVD-Ig concept to design & construct tri- and tetra-specific (multi-specific) molecules to address additional unmet needs. In this presentation we will describe: (1) some basic functional and stability features of these molecules and; (2) how these molecules can be used to fine tune T cell functions within the context of re-directed toxicity against tumor cells.

8:30 Multivalent Antibody Therapeutics for Cancer Immunotherapy

UD *Charles L. Sentman, Ph.D., Professor, Microbiology and Immunology; Director, Center for Synthetic Immunity, Geisel School of Medicine, Dartmouth College*

Natural killer (NK) cells have the ability to recognize a wide variety of tumor types. We have developed a series of bispecific antibody-like proteins based on NK cell receptor recognition for use in cancer immunotherapy. This presentation will describe the potential of these novel reagents to treat cancer and promote host anti-tumor immunity.

9:00 Immunomodulatory Bispecific Antibodies

Barbara Swanson, Ph.D., Director, Research, Sorrento Therapeutics, Inc.

Using chemical and molecular biology techniques, Sorrento has developed new approaches to generate bispecific antibodies (BsAbs). Both the chemical method, involving specific hetero-dimerization of two half antibodies using bio-orthogonal chemistry, and the molecular biology approach will be discussed. BsAbs utilizing an immunomodulatory antibody paired with a second antibody targeting cancer-associated antigens have been produced, and results from the biochemical and biophysical characterization and cell-based functional assays will be presented.

9:30 Bispecific Antibodies Targeting Checkpoint Inhibitors

UD *Mark Throsby, Ph.D., CSO, Merus*

The Biclonics® platform is a robust and validated technology suite for the development of human full-length IgG bispecific antibodies. In this presentation, we will outline how the technology has been applied to generate lead bispecific antibodies against combinations of checkpoint inhibitory molecules that effectively target and activate 'exhausted'/anergic T cells.

10:00 *In vivo* Efficacy of a Bispecific Molecule Targeting CTLA-4 and EGFR

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

A bispecific antibody was generated by engineering the constant region against EGFR and combining with the variable domain of CTLA-4. The ensuing EGFR/CTLA-4 bispecific showed efficacy in an *in vivo* model compared to either EGFR or CTLA-4 alone. Efficacy of the bispecific in the mouse model did not correlate with Treg depletion, suggestive of a novel biology.

10:15 Sponsored Presentation *(Opportunity Available)*

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

11:15 PLENARY KEYNOTE (See page 4 for details.)

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

12:45 Close of Immunomodulatory Therapeutic Antibodies for Cancer

CS Case Study UD Unpublished Data

AUGUST 24-25

Novel Vaccines Part I: Adjuvants

Recommended Dinner Short Course*
Targeting the Cancer Mutanome
**Separate registration required, please see page 4 for details.*

MONDAY, AUGUST 24

7:15 am Registration & Morning Coffee

NEXT-GENERATION ADJUVANTS

8:10 Chairperson's Opening Remarks
Nathalie Garçon, Ph.D., Pharm.D., CSO, Bioaster

» 8:15 KEYNOTE PRESENTATION: THE NEXT GENERATION OF VACCINE ADJUVANTS
Derek O'Hagan, Ph.D., Global Head, Vaccine Chemistry and Formulation Research, Novartis Vaccines
Rapid progress in molecular immunology has advanced vaccine adjuvant discovery efforts, enabling the use of cellular and target-based assays to screen large collections of chemical compounds for potential use as immune potentiators. However, the question remains as to how to safely and effectively deliver these new adjuvant compounds, particularly for use in existing vaccines. Here we describe a novel approach to enable recently discovered adjuvant active compounds called Small Molecule Immune Potentiators (SMIPs) to adsorb to aluminum hydroxide adjuvant via the mechanism of ligand exchange.

9:00 Novel Archaeal Lipid-Based Semi-Synthetic Adjuvants for Induction of Cell-Mediated Immunity
Lakshmi Krishnan, Ph.D., Team Leader, Human Health Therapeutics, National Research Council, Canada
Archaeosomes, prepared from isoprenoid lipids extracted from archaea, have immuno-modulator and antigen carrier properties. Semi-synthetic archaeosome adjuvants comprise an archaeal core lipid precursor from which a series of glyco-archaeol and phospho-archaeol adjuvants are derived. Adjuvant formulations can be selected to induce a potent antibody, cell-mediated (Th1/CD8 T cells) and/or mucosal immunity. Archaeosomes act through a TLR-independent receptor mediated activation of dendritic cells, thus representing safe and potent novel adjuvants.

9:30 Coffee Break

NEXT-GENERATION ADJUVANTS (CONT'D)

10:00 The Use of a Novel Nanoemulsion Adjuvant for Both Prophylactic and Therapeutic Intranasal Vaccination
Ali Fattom, Ph.D., Senior Vice President, Vaccine R&D, NanoBio
Nanoemulsion (NE) adjuvanted gD2/gB2 was prepared and tested intranasally (IN) in a guinea pig model for both prophylactic and therapeutic vaccination. In the prophylactic study, the IN NE-gD2/gB2 vaccine showed greater protection than the IM MPL/Alum gD2 control and prevented virus latency in 11 out of 12 animals vaccinated. In the therapeutic study, the IN NE-gD2/gB2 vaccine reduced the mean cumulative recurrent lesion scores by 64% compared to the non-vaccinated control group (p=0.006). These studies indicate the possibility of using an IN NE vaccine as both a prophylactic and therapeutic vaccine against genital herpes.

10:30 Novel and Effective Adjuvants for Vaccines against Viruses or Tumors
UD *Jung Huang, Ph.D., Professor, Biochemistry and Molecular Biology, Saint Louis University School of Medicine*
Alum adjuvant has very limited value in the development of many potential vaccines against viruses or tumors. Lymphatic entry of immune cells is known to be an important rate-limiting step in primary immunity to viruses or tumor cells. We have developed novel peptide adjuvants which promote vaccine potency by inducing opening of lymphatic-intercellular junctions and enhancing migration or transit of immune cells from the interstitial space into lymphatic vessels and lymph nodes. Novel adjuvants we developed potentiate efficacy of commercially available vaccines and herpes simplex virus type 2 (HSV-2) experimental vaccine.

11:00 FDA Perspective: Regulatory Considerations in the Safety Assessment of Vaccine Adjuvants and Adjuvanted Vaccines
Carmen M. Collazo-Custodio, Ph.D., Microbiology & Primary Reviewer, Vaccines & Related Product Applications, CBER, FDA
The Office of Vaccines Research and Review (OVRR) is responsible for the regulatory review of Investigational New Drug Applications and Biologics License Applications for preventive and therapeutic vaccines for infectious disease indications. This presentation will provide an overview of key components in the nonclinical (product characterization as well as pharmacology and toxicology evaluation) and the clinical safety assessment of investigational vaccines regulated by OVRR, with a focus on vaccines with novel adjuvants.

11:30 Sponsored Presentation *(Opportunity Available)*

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

ADVANCES IN DNA VACCINES, TLRS AND COMBINATION ADJUVANTS

1:25 Chairperson's Remarks
Lynda Tussey, Ph.D., Vice President, R&D, VaxInnate

1:30 DNA Vaccination at the Crossroads of Acquired and Innate Immunities
Shan Lu, M.D., Ph.D., Professor, Medicine, University of Massachusetts Medical School
The use of DNA immunization to elicit high quality antibody responses is receiving more attention. DNA prime-protein boost is highly effective in eliciting cross-subtype binding and functional antibodies in both animal and human studies. New data

demonstrated that DNA immunization can take advantage of recently identified intracellular mechanisms involved in both acquired and innate immune response pathways.

2:00 Engineered Forms of the TLR5 Agonist, Flagellin, Support Highly Immunogenic Subunit Vaccines

Lynda Tussey, Ph.D., Vice President, R&D, VaxInnate

VaxInnate's vaccine platform supports potent vaccines that can be produced rapidly at low cost and high volume. The platform is based on the genetic fusion of flagellin, a Toll-Like Receptor 5 agonist, to an antigen of choice. The chimeric proteins produced comprise the signals necessary for the induction of robust adaptive immune responses. We have developed a library of engineered forms of flagellin with demonstrated enhanced performance in the clinic. The potential mechanisms underlying these improvements will be discussed along with applications of the platform to our dengue and influenza vaccine programs.

2:30 Nanoliposome Combination Adjuvant Containing QS-21 and a Synthetic TLR4 Ligand

Susan Lin, Process Development Associate IV, Infectious Disease Research Institute

QS-21 is purified from *Quillaja saponaria* and has been demonstrated to have potent adjuvant properties when formulated appropriately. However, the purification process and hemolytic activity of unformulated QS-21 are some of the challenges in making it available for vaccine applications. We successfully purified and incorporated QS-21 into a stable liposomal formulation containing a synthetic TLR4 ligand. We developed a method of producing a proprietary formulation of the adjuvant and demonstrated its potent immunogenicity when combined with recombinant vaccine antigens in various preclinical models. This combination adjuvant has now been produced at IDRI under cGMP conditions for use in Phase I clinical trials.

3:00 Refreshment Break

UNDERSTANDING MODE OF ACTION AND DE-RISKING DESIGN

3:30 Mode of Action of Adjuvant System AS01

Arnaud Didierlaurent, Ph.D., Director, Translational Research & Adjuvant, GlaxoSmithKline Vaccines

The mode of action of Adjuvant System AS01, a liposome-based vaccine adjuvant containing both monophosphoryl lipid A (MPL) and the saponin QS-21, will be described. AS01 is used in several candidate vaccines including the RTS,S malaria and zoster candidate vaccines.

4:00 Effect of Formulation and Particle Size on Stability and Immunogenicity of Oil-in-Water Emulsion Adjuvants

CS *Vidyashankara Iyer, Ph.D., Scientist, Formulation Sciences, MedImmune*

4:30 De-Risking Formulation Design

Roger H. Brookes, Ph.D., Bioprocess R&D, Sanofi Pasteur

Understanding the relevant biological activity of any pharmaceutical formulation destined for human use is crucial. For vaccine-based formulations, activity must reflect the expected immune response, while for non-vaccine therapeutic agents, such as monoclonal antibodies, a lack of immune response to the formulation is desired. The following presentation discusses the human whole blood (hWB) approach as a valuable new tool to de-risk manufacture, formulation design, and clinical progression.

5:00 End of Day

TUESDAY, AUGUST 25

7:25 am Morning Coffee

ADDRESSING UNMET VACCINE NEEDS

7:55 Chairperson's Opening Remarks

Ali Fattom, Ph.D., Senior Vice President, Vaccine R&D, NanoBio

8:00 A Replication Defective Human Cytomegalovirus (CMV) Vaccine

CS UD *Tong-Ming Fu, Ph.D., Senior Investigator, Merck*

Congenital CMV infection is one of the leading causes of birth defects; developing a prophylactic vaccine is an unmet medical need. We constructed a replication defective CMV using genetic/chemical switch, by which the functions of two viral proteins essential for viral replication can be regulated by a synthetic molecule. Vaccine virus cannot replicate without the chemical but can induce neutralizing Abs and CD4/8 T cell responses in rhesus monkeys. The vaccine is under Phase I evaluation.

8:30 Preventing RSV Disease in Young Infants

Deborah Higgins, Ph.D., Scientific Director, RSV Vaccine Project, PATH

An overview of RSV vaccine development focused on protecting the youngest infants from severe disease.

9:00 Elimination of the Cold-Chain Dependence of a Nanoemulsion Adjuvanted Vaccine against Tuberculosis by Lyophilization

Ryan M. Kramer, Ph.D., Scientist II, Characterization and Product Development Manager, Infectious Disease Research Institute

Next-generation rationally-designed vaccine adjuvants represent a significant breakthrough to enable development of vaccines against challenging diseases. New vaccine candidates often require maintenance of a cold-chain process to ensure long-term stability and separate vials to enable bedside mixing of antigen and adjuvant. This presents a significant barrier to worldwide implementation of such vaccines. Herein we describe the development and characterization of a tuberculosis vaccine comprised of both antigen and adjuvant components that are stable in a single vial at sustained elevated temperatures.

9:30 NKT Cell Adjuvanted Glycolipid-Peptide Vaccines

Gavin Painter, Ph.D., Science Team Leader, The Ferrier Research Institute, Victoria University of Wellington

9:45 PANEL DISCUSSION: What is the Future of Vaccine Adjuvant Development?

This panel discussion will address the following topics: progress in developing next-generation adjuvants, issues in addressing unmet vaccine needs, and effective adjuvants for vaccines against viruses and tumor cells.

Moderator: Jung Huang, Ph.D., Professor, Biochemistry and Molecular Biology, Saint Louis University School of Medicine

Panelists:Roger H. Brookes, Ph.D., Bioprocess R&D, Sanofi Pasteur

Arnaud Didierlaurent, Ph.D., Director, Translational Research & Adjuvant, GlaxoSmithKline Vaccines

Vidyashankara Iyer, Ph.D., Scientist, Formulation Sciences, MedImmune

Lakshmi Krishnan, Ph.D., Team Leader, Human Health Therapeutics, National Research Council, Canada

10:00 Sponsored Presentation *(Opportunity Available)*

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

11:15 PLENARY KEYNOTE (See page 4 for details.)

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

12:45 Close of Novel Vaccines Part I: Adjuvants

CS Case Study UD Unpublished Data

AUGUST 25-26

Rational Combination Cancer Immunotherapy

Recommended Dinner Short Course*
Targeting the Cancer Mutanome
**Separate registration required, please see page 4 for details.*

TUESDAY, AUGUST 25

11:15 PLENARY KEYNOTE (See page 3 for details.)

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

12:45 Session Break

1:30 Chairperson's Opening Remarks
Omid Hamid, M.D., Director, Melanoma Center, Angeles Clinic and Research Institute

» 1:35 KEYNOTE PRESENTATION: POLITICS AND REALITIES OF IO COMBINATION TRIAL DESIGN

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

An acute concern of both biotechs and KOLs in IO is getting access to anti-PD-1/PD-L1 from pharma for combination trials. The current state of combination IO trials will be reviewed. The different policies of pharma companies with clinical-stage/marketed anti-PD-1/anti-PD-L1 about access to their compounds for combination trials will be compared. Trial designs and indications that might have decent luck in getting the cooperation of these companies will be suggested.

BIOMARKERS TO SUPPORT COMBINATION IMMUNOTHERAPY

2:20 Biomarkers in Melanoma – Right Patient: Right Trial
Omid Hamid, M.D., Director, Melanoma Center, Angeles Clinic and Research Institute

2:50 Sponsored Presentation *(Opportunity Available)*

3:05 Refreshment Break in the Exhibit Hall with Poster Viewing

3:35 Defining a True Tumor-Specific Epitope for Effective Cancer Immunotherapy

UD *Pramod Srivastava, M.D., Ph.D., Professor, Immunology and Medicine, University of Connecticut School of Medicine; Director, Carole and Ray Neag Comprehensive Cancer Center*

High-throughput genomics and bioinformatics have opened the floodgates for identification of neoepitopes of cancers. A vast majority of these are however ineffective in eliciting host-protective anti-tumor immune response. How does one identify the needle in this haystack?

4:05 Biomarkers to Support the Development and Clinical Application of Immunotherapy Combinations
Jelveh Lameh, Ph.D., Executive Director, Head BioPharma Services Laboratory, Genoptix Medical Laboratory Inc., a Novartis Company

Biomarkers have successfully been applied to multiple aspects of cancer therapy. Up until now, biomarkers have been applied to various aspects of therapies that were targeted directly at the tumor cells. With the recent advances in immunotherapy, the rationale for combination therapies to circumvent resistance has emerged. Thus, application of biomarkers for such combination therapies is expected to improve patient outcomes.

4:35 Prognostic and Predictive Markers for Immunotherapy and Combination Therapy
Kathleen M. Mahoney, M.D., Ph.D., Clinical Instructor, Beth Israel Deaconess Medical Center; Research Fellow, Dana Farber Cancer Institute

Tumor expression of PD-L1 has received much attention as a potential biomarker for PD-1/PD-L1 directed therapy. However it is an inappropriate exclusive biomarker, since "PD-L1 negative" tumors may respond to PD-1 pathway blockade. Emerging data suggests multivariate models including PD-L1 expression and the immune infiltrate within the tumor microenvironment may direct immunotherapy decisions. Incorporating the tumor's mutational landscape, in addition to immunohistochemistry and gene expression signatures, may improve these platforms.

5:05 Welcome Reception in the Exhibit Hall with Poster Viewing

6:00 Dinner Short Course Registration*
*See page 4 for details.

WEDNESDAY, AUGUST 26

8:00 am Morning Coffee

COMBINATION IMMUNOTHERAPY STRATEGIES

8:25 Chairperson's Opening Remarks
Jeff T. Hutchins, Ph.D., Vice President, Preclinical Research, Peregrine Pharmaceuticals

8:30 Immune Checkpoint Modulation: Rational Design of Combination Strategies

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

The immune system can be manipulated to enhance antitumor immunity. Efficacy has been demonstrated by approaches that block immune checkpoints, but not all patients benefit from treatment and improved outcomes are needed. Therapeutic approaches combining multiple immune checkpoint inhibitors with standard anticancer agents (radiotherapy, targeted therapy, and chemotherapy) are of great interest. Current approaches and a framework for the future will be discussed.

9:00 Expansion and Activation of T Cells via the Targeting of the Immunosuppressive Ligand Phosphatidylserine (PS): Combination Strategy with Conventional, Targeted, and Checkpoint Inhibitor Therapy

UD *Jeff T. Hutchins, Ph.D., Vice President, Preclinical Research, Peregrine Pharmaceuticals*

The underlying cause for the failure of current therapies is the persistent and multifocal immune suppression in the tumor microenvironment that drives the absence of pre-existing antitumor T cells. Bavituximab blocks PS-mediated immunosuppression (decreasing MDSCs) by reprograming immune cells in the tumor microenvironment to enhance anticancer activity. Pre-clinical, translational, and clinical results using bavituximab with conventional and immunotherapy combinations promotes a robust, anti-tumor T cell mediated response to enhance cancer therapy.

9:30 Distinct Immunologic Changes *In Vivo* Following Combination Versus Individual PD-1 or CTLA-4 Checkpoint Blockade in Human Cancer

Kavita Dhodapkar, MBBS, Associate Professor of Pediatrics, Yale School of Medicine

10:00 Sponsored Presentation *(Opportunity Available)*

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

11:00 Cancer Vaccine/Immune Checkpoint Combinations

Marc Mansour, Ph.D., COO, ImmunoVaccine, Canada

Combining T cell activating therapies with other immune modulating strategies targeting the tumor microenvironment hold a lot of promise for cancer therapy. Our data show that combining antigen directed T cell activation with cyclophosphamide as an immune modulator enhances systemic immunity and T cell activity in the tumor. The further addition of a checkpoint inhibitor causes additional changes in the tumor microenvironment leading to enhanced anti-tumor activity. The rationale for combining immunotherapies to manage advanced disease will be discussed.

11:30 The TAM Receptor Tyrosine Kinase Family and Their Potential to Modulate Macrophage and Dendritic Cell Function Create Opportunities to Combine with T Cell Checkpoint Drugs

Jerry McMahon, Ph.D., President & CEO, Kolltan Pharmaceuticals

TAM receptor tyrosine kinases and their cognate ligands play a key role in immune homeostasis through signaling in macrophage and dendritic cells and regulating the adaptive immune response. Modulation of the activation of these receptors may up- or down-regulate immune homeostasis for the treatment of cancer and other diseases. Inhibition of Axl and MerTK are under investigation to potentiate the effectiveness of biologic agents that interfere with T cell checkpoints in tumor immunology.

12:00 pm Sponsored Presentation *(Opportunity Available)*

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

1:55 Chairperson's Remarks

Ravi Madan, M.D., Clinical Director, Genitourinary Malignancies Branch, National Cancer Institute

2:00 Enhanced Efficacy of IL-15-based ALT-803 Superagonist Complex in Combination with Immune Checkpoint Inhibitors

UD *Hing C. Wong, Ph.D., President and CEO, Altor Bioscience*

ALT-803 is an IL-15 superagonist:IL-15Rα-Fc complex with improved pharmacokinetics, biodistribution, and efficacy compared to native IL-15. It was shown that ALT-803 induces both innate effector-like and adaptive T cell antitumor activity, suggesting that ALT-803 complements the activity of checkpoint inhibitors to block tumor immune evasion. In murine models, ALT-803+anti-PD-L1+anti-CTLA-4 mAb treatment provided greater survival of tumor-bearing mice compared to treatment with vehicle or ALT-803 alone or the IL-15+anti-PD-L1+anti-CTLA-4 mAb combination.

MODELING AND SYSTEMS BIOLOGY

2:30 Interactome Networks and Human Disease: Potential Applications for Cancer Immunotherapy

UD *David E. Hill, Ph.D., Associate Director, Center for Cancer Systems Biology (CCSB); Principal Scientist, Department of Cancer Biology, Dana-Farber Cancer Institute*

Complex systems formed by interactions among genes and gene products underlie cellular functions. Basic concepts of network biology emphasize why cellular networks are important to consider. To generate the information necessary to address how complex networks relate to biology, we have developed at proteome scale an integrated approach for modeling protein-protein interaction networks. Our main questions are: How are interactome networks organized; how can we uncover features underlying this organization; and how are interactome networks modified in human disease, such as cancer?

3:00 Phase i Trials in Melanoma: A Framework to Translate Preclinical Findings to the Clinic

UD *Alexander Anderson, Ph.D., Chair, Integrated Mathematical Oncology Program, Moffitt Cancer Center*

We present a computational framework to implement phase i trials (virtual/imaginary yet informed clinical trials) in cancer. Using an experimentally calibrated mathematical model, comprising a system of ordinary differential equations, we predict the dynamics of melanoma cells under different mono and combination therapies. We then implement a phase i trial in melanoma and show that we can readily capture observed heterogeneous clinical outcomes and predict optimal future clinical trial design.

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

CLINICAL STUDY OF IMMUNOTHERAPY COMBINATIONS

4:15 Regulatory Challenges in Development of Novel Cancer Combinations

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

The growing demand for combination cancer therapies presents complex regulatory challenges that require modality-specific approaches. Current FDA guidance provides a framework for early development of investigational compounds intended for use in combination. Regulatory concepts that address development of novel biologic combinations, bifunctionals and antibody-drug conjugates will be reviewed, and key considerations for nonclinical and clinical phases of development will be highlighted for each modality.

4:45 Clinical Experience with Immune Combinations in Prostate Cancer

Ravi Madan, M.D., Clinical Director, Genitourinary Malignancies Branch, National Cancer Institute

There is strong rationale for immune-based combinations in the treatment of prostate cancer and clinical data is emerging. These combinations, which include anti-androgen therapies, radiation, chemotherapy and other immune-based treatments, have relevance across multiple tumor types. Perhaps most importantly, the potential for immune-based therapies to generate personalized anti-tumor immune responses is also being developed.

5:15 Close of Rational Combination Cancer Immunotherapy

CS Case Study UD Unpublished Data

AUGUST 25-26

Novel Vaccines Part II: Emerging Technologies

TUESDAY, AUGUST 25

11:15 PLENARY KEYNOTE (See page 3 for details.)

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

12:45 Session Break

NEXT-GENERATION VACCINES AND TECHNOLOGIES

1:30 Chairperson's Opening Remarks
Manmohan Singh, Ph.D., Head, Translational Research, Drug Product and Analytical Development, Novartis Influenza Vaccines

» 1:35 KEYNOTE PRESENTATION: VACCINES AND INNOVATIVE TECHNOLOGIES: A MILLENNIUM STORY
Nathalie Garçon, Ph.D., Pharm.D., CSO, Bioaster

2:20 Direct Intra Lymph Node Injections Enable Superior Immunity
David A. Zarling, Ph.D., CEO, Colby Pharmaceuticals
Direct Intra Lymph Node Injection (ILNI) enables superior immunization for (1) tumor immunity and tumor regression; (2) infectious disease immunity and resistance to challenge infection; and (3) allergy desensitization. ILNI is simple to perform, rapid, painless, safe, effective, and generates durable immune responses via co-localization of antigens and cells within lymphoid organs. Compared to subcutaneous or intradermal injections, intranodal injections enables much higher antigen doses to reach lymph nodes.

2:50 Sponsored Presentation *(Opportunity Available)*

3:05 Refreshment Break in the Exhibit Hall with Poster Viewing

NEXT-GENERATION VACCINES AND TECHNOLOGIES (CONT'D)

3:35 Novel Vaccine Delivery Technologies for Prophylactic Immunization
Manmohan Singh, Ph.D., Head, Translational Research, Drug Product and Analytical Development, Novartis Influenza Vaccines
Traditional routes of immunization for vaccines often lead to patient compliance issues. Many patients dread the use of a needle for routine vaccinations. Recent advances in epidermal delivery of vaccines through a painless and needle-free patch technology has led to many groups working in moving this technology through clinical progression. The talk will focus on one such patch technology to deliver vaccines for prophylactic use.

4:05 New Concepts in HIV Vaccine Development
Kathryn Stephenson, M.D., MPH, Instructor, Medicine, Center for Virology and Vaccine Research/BIDMC, Harvard Medical School
Prevention of HIV remains a public health priority, even in an era of widespread antiretroviral treatment. Experience with subunit vaccines and non-replicating vectors has been disappointing, with failure to show benefit in several efficacy trials. A trial of a canarypox vector plus gp120 showed modest protection in Thailand, but the effect was transient. This talk will focus on new approaches to HIV vaccine design and delivery, including mosaic HIV antigens and novel replicating vectors.

4:35 Tolerogenic Synthetic Nanoparticles for the Treatment of Autoimmune Diseases
UD *Takashi K. Kishimoto, Ph.D., CSO, Selecta Biosciences*
Selecta Biosciences is a clinical stage company that has developed a novel platform of Synthetic Vaccine Particles (SVP) to induce durable antigen-specific immune tolerance. Here we illustrate two potential applications of tolerogenic SVP for the treatment of autoimmune disease: 1) immune tolerance induction directed against a pathogenic autoantigen in experimental autoimmune encephalomyelitis, and 2) tolerance induction directed against an immunogenic biologic therapy (anti-TNFα monoclonal antibody) used in the treatment of arthritis.

5:05 Welcome Reception in the Exhibit Hall with Poster Viewing

6:00 Dinner Short Course Registration*
*See page 4 for details.

WEDNESDAY, AUGUST 26

8:00 am Morning Coffee

DEVELOPMENT OF DNA- AND RNA-BASED VACCINES

8:25 Chairperson's Opening Remarks
Daniel J. Wattendorf, M.D., Col., USAF, MC, Program Manager, Biological Technologies Office, Defense Advanced Research Projects Agency (DARPA)

8:30 Novel Nucleic Acid-Based Immunoprophylaxis Technologies
Daniel J. Wattendorf, M.D., Col., USAF, MC, Program Manager, Biological Technologies Office, Defense Advanced Research Projects Agency (DARPA)
DARPA is investing in novel immunoprophylaxis technologies, including RNA vaccines and DNA- and RNA-based passive gene transfer of antibodies. RNA-based vaccines encoding an antigen have been shown to enhance the robustness of the immune response. Additionally, RNA and DNA platforms for passive gene transfer of antibodies have the potential to bypass the adaptive immune response by establishing immediate but temporary protection. These platforms represent advancement in rapid design and manufacturing of immunoprophylaxis therapies for infectious disease prevention.

9:00 Development of Potent Influenza DNA Vaccines that Can Elicit Broad Cross-Protective Anti-Hemaggultination Responses against Diverse Viral Isolates Using Syncon® Technology

UD *Jian Yan, Ph.D., Antigen Design Lead, Inovio Pharmaceuticals*

An ideal Universal Influenza vaccine should be able to drive cross-protective immune responses against diverse viral isolates using a single vaccine formulation. However, the induction of cross-reactive neutralizing antibodies through vaccination has been historically difficult to achieve. Here, we showed that microconsensus-based HA DNA vaccines designed by SynCon® technology were able to generate cross-protective anti-hemaggultination responses against diverse H1N1 isolates. Furthermore, we extended this novel design to cover the newly emerged H7N9 viruses.

9:30 A Step-Change in Epitope Design Enables a Pipeline of Multi-Antigen DNA Tumor Vaccines

William Watt, Ph.D., CEO & Co-Founder, EpiThany, Inc.; University of Washington Tumor Vaccine Group

New cancer immunotherapies mark progress in our understanding of tumor biology and harnessing the immune system's management of self. However, protein- and peptide-based vaccines are not yet consistently efficacious. Our work uncovers principles governing the genesis of T helper type-restrictive immunity to self-antigens elicited by vaccine epitopes, enabling the design of DNA vaccines to skew immunogenicity from tolerogenic Type II (Th2) to inflammatory Type I (Th1) T cells, and invigorating this cancer immunotherapeutic approach.

10:00 Sponsored Presentation *(Opportunity Available)*

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

NGS IN VACCINE DISCOVERY AND DEVELOPMENT

11:00 Statistical Phylogenetic Analysis of Post-Immunization Clonal Dynamics

UD *Thomas B. Kepler, Ph.D., Professor, Microbiology, Professor, Mathematics and Statistics, Boston University School of Medicine*

The character of the post-vaccination humoral response is determined by competition among B-cell clones and affinity maturation within them. Ig repertoire sequencing promises to substantially deepen our understanding of these processes and the interactions between them. I will describe statistical phylogenetic methods we have developed for partitioning repertoire data into clones and analyzing the inter- and intra-clonal dynamics and will illustrate their use in a study of repeated immunization to anthrax vaccine.

11:30 Whole Genome and Transcriptome Sequencing of Cotton Rat to Assist RSV Vaccine Research

I-Ming Wang, Ph.D., Principal Scientist, Genetics and Pharmacogenomics, Merck Research Labs

12:00 pm Immunogenomics of Non-Human Primates for Ig Repertoire Studies

Akshaya Ramesh, Kepler Lab, Genetics and Genomics, Boston University School of Medicine

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

VACCINES FOR GLOBAL HEALTH

1:55 Chairperson's Remarks

Deborah Higgins, Ph.D., Scientific Director, RSV Vaccine Project, PATH

2:00 The Road to an Ebola Vaccine

Nancy Sullivan, Ph.D., Chief, Biodefense Research Section, Vaccine Research Center, NIH

Ebola virus has been identified as the cause of several highly lethal outbreaks of hemorrhagic fever. The Biodefense Research Section is developing critically important vaccine strategies.

2:30 Approaches to Estimate the Potential Impact of Novel *Neiserial meningitidis* Serogroup B Vaccines Prior to Implementation

Annaliesa Anderson, Ph.D., Senior Director, Vaccine Research and Early Development, Pfizer

Factor H binding protein (fHBP) is a meningococcal virulence factor that is a shared component of two recently licensed vaccines for the prevention of meningococcal serogroup B (MnB) disease. FHBP is ubiquitous to MnB isolates; however, there is antigenic diversity associated within the protein family. Approaches to estimate the impact of fHBP-based vaccines may have on MnB disease and carriage will be presented.

3:00 Development of a Human Vaccine and Therapy Post-Exposure Prophylaxis against Hendra and Nipah Viral Infections

Timothy Fouts, Ph.D., Senior Director, Virology, Profectus BioSciences

Nipah virus (NiV) and Hendra virus (HeV) are enveloped negative-sense RNA viruses causing systemic and fatal diseases in a variety of animal hosts and in humans. They are listed as Category C biothreat agents by the NIH and CDC and Overlap Select Agents by HHS and USDA. There is no approved human vaccine or therapeutic against either NiV or HeV. Profectus BioSciences, Inc. is developing HeV-sG, the ectodomain of HeV attachment glycoprotein, as a human vaccine and m102.4, an antiviral antibody, as a post-exposure therapy.

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

VIRUS-LIKE PARTICLES

4:15 Broad Immune Response Induced by Plant-Made Influenza VLP Vaccines

UD *Sonia Trépanier, Ph.D., Senior Director, Clinical Studies, Medicago*

Poor effectiveness reported for seasonal influenza vaccines reinforces the need for newer technologies such as Medicago's plant-made virus-like particles (VLPs) to provide better vaccines that match circulating strains. Medicago's VLP clinical trials showed immunogenicity responses meeting licensure criteria and induction of cross-reactive T cells, important in protection against antigenic drift. Plant-made influenza VLPs have the potential to provide better and broader immune response that could translate into better efficacy, especially in the elderly population.

4:45 Enveloped Virus-Like Particles – A Novel and Immunogenic Expression Platform

Adam Buckley, MBA, Vice President, Business Development, VBI Vaccines, Inc.

In the past decade, virus-like particles have emerged as a powerful method for antigen presentation and a tremendous commercial success. VBI Vaccines, Inc. has created a next-generation antigen presentation platform capable of expressing envelope proteins within a lipid membrane – a true natural mimic for enveloped viruses. VBI will present data demonstrating the unique properties of this platform, including potency and commercial relevance of the platform by case study of its CMV vaccine.

5:15 Close of Novel Vaccines Part II: Emerging Technologies

CS Case Study UD Unpublished Data

AUGUST 26-27

Target Discovery for T Cell Therapy

Recommended Dinner Short Course*
Adoptive Therapy with CAR T Cells
**Separate registration required, please see page 4 for details.*

THURSDAY, AUGUST 27

7:30 am Registration & Morning Coffee

CHIMERIC ANTIGEN RECEPTORS

8:10 Chairperson's Opening Remarks
Nancy Parenteau, Ph.D., President and CSO, Verik Bio

» 8:15 KEYNOTE PRESENTATION: ENHANCING THE SYNTHETIC IQ OF CAR T CELLS
Michael C. Jensen, M.D., Janet & Jim Sinegal Endowed Professor, Pediatrics; Adjunct Professor, Bioengineering, University of Washington School of Medicine; Joint Member, Program in Immunology, Fred Hutchinson Cancer Research Center
Dr. Jensen's laboratory's work focuses on T cell genetic modification for re-directing antigen specificity to tumors utilizing recent advances not only in the composition and specificity of receptor antigen recognition domains, but also the evolution of multifunctional cytoplasmic signaling domains developed for these chimeric antigen receptors (CARs) that provide dual activation and co-stimulatory signaling. His group is also investigating the context of adoptive transfer with respect to the conditioning of the recipient for enhanced T cell engraftment and expansion, the grafting of CARs on to central memory T cells having endogenous TCR specificities for viral epitopes to which the host has robust immunity, and, the provision tumor microenvironment survival capabilities.

9:00 GoCAR-T™ and CIDeCAR™-enabled T Cell Immunotherapy: An Evolution to Gas Pedal- AND Brake-Based Approaches
David M. Spencer, Ph.D., CSO, Bellicum Pharmaceuticals, Inc.
CAR-T cell approaches have seen some spectacular successes in a subset of B cell malignancies, but efficacy in solid tumors has lagged. We have developed a highly effective, novel costimulatory element, MyD88/CD40 (MC) that can be deployed with CARs as a switch (in GoCAR-T) or in the presence of our clinically validated, Caspase-9-based suicide gene, CaspaCIDe® (in CIDeCAR). This has led to durable tumor control in solid tumor models while allowing for control of toxicity. Recent data and applications will be discussed.

9:30 CAR T Cell Therapy: Target Antigen Discovery and Clinical Translation
Richard Morgan, Ph.D., Vice President, Immunotherapy, bluebird bio
The remarkable success from a number of sites using chimeric antigen receptors (CARs) to target the B cell malignancy antigen CD19 has resulted in an enormous interest in CAR-based therapies. This talk will give a brief introduction to the field with a focus on the critical aspect of tumor antigen choice and the application CAR therapies to target solid cancers.

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

10:45 Durable Clinical Responses upon Treatment with Chimeric Antigen Receptor (CAR)-Engineered T Cells
Adrian Bot, M.D., Ph.D., Vice President, Translational Medicine, Kite Pharma, Inc.
Genetic reprogramming of T cells for adoptive cell therapy showed some tantalizing clinical successes in phase 1 trials. To date, T cells genetically engineered with second generation CARs comprising CD28 or 4-1BB as co-stimulatory domains, showed high objective responses in B-cell acute lymphoblastic leukemia (B-ALL). CAR T cells can also be very effective in large cell, follicular lymphomas or chronic lymphocytic leukemia, as demonstrated by an anti-CD19 CAR product comprising a CD28 endodomain. Upon infusion, these CAR T cells expand dramatically and then decay and clear within months, thereby allowing the recovery of endogenous B cells. Thus, a major question relates to the durability of clinical responses afforded by CAR T cells. With an increasing number of patients treated and years of follow up, evidence is mounting in support of long-lasting clinical responses upon single or double treatment with CAR T cells. In addition, these accumulating data shed light on biomarkers with clinical predictive value.

11:15 A Multidrug Resistant Engineered CAR T Cell for Allogeneic Combination Immunotherapy
CS *Julien Valton, Ph.D., R&D Project Leader, Cellectis*
When allogeneic CAR T cell infusion is considered, host versus graft and graft versus host reactions must be avoided to elicit successful antitumor activity *in vivo*. We propose to address these requirements through the development of multidrug resistant TCRαβ-deficient CAR T cells. We demonstrate that these engineered T cells displayed efficient antitumor activity and proliferated in the presence of drugs, currently used in clinic as preconditioning lymphodepleting regimens.

11:45 Next-Generation Chimeric Antigen Receptor-Engineered T Cells Directed at Novel Cancer Antigens
Hinrich Abken, Ph.D., Professor, Cancer Genetics, Internal Medicine, University Hospital of Cologne
The specificity of CAR-mediated T cell recognition is defined by the antibody domain, is independent of MHC presentation and can be extended to any target for which an antibody is available.We discuss the advantages and limitations of MHC-independent T cell targeting by an engineered CAR in comparison toTCR modified T cells and the impact of the CAR activation threshold on redirected T cell activation. Finally we review most significant progress recently made in early stage clinical trials to treat cancer.

12:15 pm Identification and Targeting of HLA/Peptide Targets Distinct to Cancerous Tissue
Sponsored by pureMHC
William Hildebrand, Ph.D., Chief Scientist, Pure MHC, LLC
The immune system naturally recognizes cancer cells via human leukocyte antigen (HLA)/peptide complexes. We use a powerful HLA cancer ligand database to interrogate cancerous tissue and to identify HLA peptide complexes distinct to cancer. Our monoclonal antibodies to these HLA/cancer targets then provide a platform for the development of immunotherapies.

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

1:00 Session Break

T CELL RECEPTOR TARGETS AND PRODUCTS

2:00 Chairperson's Remarks
Michael Bethune, Ph.D., Postdoctoral Fellow, Laboratory of David Baltimore, Division of Biology and Biological Engineering, Caltech

2:05 ImmTACs: Bispecific TCR-anti-CD3 Fusions for Potent Re-Directed Killing of Cancer Cells – IMCgp100 in a Phase I/IIa Study against Malignant Melanoma
CS *Luise U. Weigand, Ph.D., Team Leader, Cell Biology, Immunocore Ltd.*
ImmTACs are bispecific 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 to date, IMCgp100, is well-tolerated in melanoma patients and induces T cell mobilization and durable T cell responses in metastatic diseases. Here we present the ImmTAC platform and discuss our preclinical approach and progress with IMCgp100.

2:35 Discovery of Prostate Cancer-Reactive T Cell Receptors (TCR) for TCR Gene Therapy
UD *Michael Bethune, Ph.D., Postdoctoral Fellow, Laboratory of David Baltimore, Division of Biology and Biological Engineering, Caltech*
T cell receptor (TCR) gene therapy requires carefully selected antigenic targets and cognate TCRs. New platforms for target discovery and TCR isolation will facilitate expansion of this promising therapy to a broader array of cancers. This presentation will describe a novel platform for cloning tumor-reactive TCRs from tumor-infiltrating lymphocytes and identifying their antigenic targets through molecular display. Focus will be on prostate cancer, but the approach is general.

3:05 Presentation to be Announced

Sponsored by
Beckman Coulter Life Sciences

3:35 Refreshment Break

TUMOR INFILTRATING LYMPHOCYTES

4:05 Talk Title to be Announced
Chantale Bernatchez, Ph.D., Assistant Professor, Melanoma Medical Oncology, MD Anderson

4:35 Identification of Anti-Cancer Antibodies and Antigens by Massively Parallel Sequencing of Tumor Infiltrating Lymphocytes
UD *Adrian W. Briggs, Ph.D., Director, Molecular Biology R&D, AbVitro*
Natural immune responses to cancer may hold the key to finding novel therapeutic targets. Our next generation immune sequencing platform recovers natively paired receptor genes from tumor infiltrating lymphocytes at unprecedented resolution. Using this technology we have isolated patient antibodies that strongly and selectively bind cancer tissue and kill cancer cells when presented as an antibody-drug conjugate. Work is underway to identify their target antigens.

5:05 End of Day

5:00 Dinner Short Course Registration*
*See page 4 for details.

FRIDAY, AUGUST 28

8:00 am Morning Coffee

PERSONALIZED IMMUNOTHERAPY APPROACHES

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

8:30 PANEL: Characterizing T Cell Therapies in the Clinic
- Mechanistics aspects of adoptive cell therapy
- On-treatment and predictive immunotherapy biomarkers
- Relationships between clinical and immunological response

Moderator: Adrian Bot, M.D., Ph.D., Vice President, Translational Medicine, Kite Pharma, Inc.
Panelists: Chantale Bernatchez, Ph.D., Assistant Professor, Melanoma Medical Oncology, MD Anderson
Julien Valton, Ph.D., R&D Project Leader, Cellectis
Luise U. Weigand, Ph.D., Team Leader, Cell Biology, Immunocore Ltd.

» 9:00 FEATURED PRESENTATION: PERSONALIZED CELLULAR IMMUNOTHERAPY AGAINST NOVEL CANCER TARGETS
UD *Harpreet Singh, Ph.D., CSO and Managing Director, immatics biotechnologies GmbH*

9:30 Engaging Macrophages as Effectors of Cancer Immunotherapy
UD *Kipp A. Weiskopf, Ph.D., Research Scientist, Institute for Stem Cell Biology and Regenerative Medicine, Stanford University School of Medicine*
Macrophages are innate immune cells that possess immense potential as effectors of cancer immunotherapy. Their ability to attack cancer can be unleashed by disrupting the CD47-SIRPa interaction, which acts as a myeloid-specific immune checkpoint. CD47-blocking therapies synergize with monoclonal antibody therapies, and their combination could yield personalized immunotherapeutic regimens that could be tailored to individual patients or tumor subtypes.

10:00 Coffee Break

10:30 Engineering T Cells for One and All
CS *Harjeet Singh, Ph.D., Research Investigator, Pediatrics, MD Anderson Cancer Center*
This talk will reveal how the Sleeping Beauty (SB) system can be adapted and used to stably express CARs and TCRs to improve the therapeutic potential of clinical grade T cells. These clinical data serve as a foundation for additional genetic engineering to co-express transgenes to improve persistence as well as provide the opportunity for genome editing to eliminate undesired endogenous genes to improve T cell potency and broaden their distribution and application.

11:00 Developing Potent Cancer Therapies Targeting Cancer Germline and Mutated Antigens
Paul F. Robbins, Ph.D., Staff Scientist, Surgery Branch, Center for Cancer Research, National Cancer Institute
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.

11:30 Close of Target Discovery for T Cell Therapy

CS Case Study UD Unpublished Data

AUGUST 26-27

Gene Editing for Immunotherapy

Recommended Dinner Short Course*
Adoptive Therapy with CAR T Cells
**Separate registration required, please see page 4 for details.*

THURSDAY, AUGUST 27

7:30 am Registration & Morning Coffee

EMERGING GENE EDITING TECHNOLOGIES

8:10 Chairperson's Opening Remarks
Gary K. Lee, Ph.D., Associate Director, Genome Editing, Sangamo BioSciences

» 8:15 KEYNOTE PRESENTATION: GENE EDITING ON THE CUSP OF EXCITING OPPORTUNITIES FOR HUMAN THERAPEUTICS
CS *Rodger Novak, M.D., Ph.D., CEO & Founder, CRISPR Therapeutics*
Within less than two years after its inception the CRISPR-Cas system has truly democratized genome editing with many areas of research being transformed due to ease of use and broad applicability of the technology. With such an enormous impact on many areas of life science the translation of the CRISRP-Cas technology into human therapeutics seems to be a logical consequence. However, besides many exciting opportunities a number of challenges will have to be addressed; some of them more obvious than others.

9:00 Characterization of Cas9-Mediated Genome Editing in Human T Cells
G. Grant Welstead, Ph.D., Scientist II, Editas Medicine
Genome editing via CRISPR/Cas9 promises to provide a novel class of therapies for a variety of human diseases. To better understand the utility of Cas9-mediated gene editing for engineering human T cells, we surveyed a variety of delivery modalities and assessed the functionality of different Cas9 variants in human T cells. Data from this work will be presented.

9:30 Late-Breaking Presentation
Given the continual and rapid evolution of gene editing technologies and applications, this slot will be held for a speaker who will present the latest developments in the field.

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

10:45 *In vivo* Genome Editing using *Staphylococcus aureus* Cas9
Fei Ann Ran, Ph.D., Post-Doctoral Fellow, Laboratory of Dr. Feng Zhang, Broad Institute; Junior Fellow, Harvard Society of Fellows
The Cas9 nuclease from the bacterial CRISPR (clustered regularly interspaced short palindromic repeats) adaptive immune system is a powerful tool for facilitating targeted genome editing in a number of eukaryotic species. Cas9 can be programmed by short guide RNAs to induce multiplexed gene knockout or homology-directed repair with high efficiency. Recently, we have identified an additional small Cas9 nuclease from Staphylococcus aureus that can be packaged, along with its guide RNA, into a single adeno-associated virus (AAV). We demonstrate the use of this system for effective gene modification in adult animals and further expand the Cas9 toolbox for *in vivo* genome editing.

11:15 Zinc Finger Nuclease Driven Gene Modification of T Cells
Gary K. Lee, Ph.D., Associate Director, Genome Editing, Sangamo BioSciences
The ability to engineer the precise genetic modification of human cells to extend their potential therapeutic application is now being realized via the use of zinc finger nucleases (ZFNs). ZFNs are customizable, sequence-specific endonucleases that can be designed to introduce a discrete cleavage event at any user-chosen location within the genome. This talk will describe recent applications of this technology to genetically modify T cells.

11:45 PANEL: Advantages and Disadvantages of Different Gene Editing Technologies
- Current and future therapeutic applications
- Generating knock-outs
- Checking for off-target effects
- Future and emerging gene editing techniques and technologies

Moderator: to be Announced
Panelists:
Rodger Novak, M.D., Ph.D., CEO & Founder, CRISPR Therapeutics
Fei Ann Ran, Ph.D., Post-Doctoral Fellow, Laboratory of Dr. Feng Zhang, Broad Institute and Junior Fellow, Harvard Society of Fellows
Gary K. Lee, Ph.D., Associate Director, Genome Editing, Sangamo BioSciences
André Choulika, Ph.D., CEO, Cellectis

12:15 pm Sponsored Presentation *(Opportunity Available)*

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

1:00 Session Break

MERGING GENE EDITING AND IMMUNOTHERAPY

2:00 Chairperson's Remarks
Alexander Marson, M.D., Ph.D., UCSF Sandler Faculty Fellow, Medicine and Diabetes Center, University of California San Francisco

2:05 Gene Editing in T Cells for Enhanced Adoptive Immunotherapies
Andrew M. Scharenberg, M.D., Professor, Pediatrics; Adjunct Professor, Immunology, University of Washington School of Medicine; Co-Director, Program for Cell and Gene Therapy, Seattle Children's Hospital
Adoptive transfer of engineered autologous primary human T cells has emerged as a potentially transformational approach to therapy of cancer and immunologic diseases. Rare cleaving nuclease technologies are an important enabling technology for achieving the promise of adoptive T cell therapies, as they allow for precise engineering of targeting, function, and control mechanisms. This talk will cover translational application of rare cleaving nuclease technologies using newly developed methods to facilitate high efficiency recombination and multiplex genomic modifications.

2:35 Engineering Human T Cell Circuitry

CS *Alexander Marson, M.D., Ph.D., UCSF Sandler Faculty Fellow, Medicine and Diabetes Center, University of California San Francisco*

T cell genome engineering holds great promise for cancer immunotherapies. We have overcome the poor efficiency of CRISPR/Cas9 genome engineering in primary human T cells using Cas9:single-guide RNA ribonucleoproteins (Cas9 RNPs). Cas9 RNPs can promote targeted genome sequence replacement in primary T cells by homology-directed repair (HDR), which was previously unattainable. This provides technology for diverse experimental and therapeutic applications.

3:05 Sponsored Presentation *(Opportunity Available)*

3:35 Refreshment Break

SEQUENCING IN SUPPORT OF CELL THERAPIES

4:05 Engineering T Cells through Genome Editing

Matthew Porteus, M.D., Ph.D., Associate Professor, Pediatrics, Cancer Biology, Stanford University School of Medicine

T-cells are one of the most potent therapeutic cell types in the body because they can mediate beneficial effects through the elimination of infections and cancers but also can mediate pathologic effects through inflammation and auto-immunity. Moreover, they are also the primary pathologic target for HIV infection. We have been using nuclease-mediated genome editing to engineer T-cellls that contain multiple genetic blocks to HIV infection. In this talk, I will discuss the advances we have made in using engineered nucleases, particularly the CRISPR-Cas9 system using modified synthetic single-guide RNAs, as a method to efficiently edit the genome of T-cells.

4:35 Discovery of Novel Targets for Genetic Engineering of Tumor-Specific T Cells

Kai W. Wucherpfennig, M.D., Ph.D., Professor, Dana-Farber Cancer Institute and Harvard Medical School

A key challenge in the cancer immunology field is the discovery of the most suitable targets for therapeutic intervention. We recently reported a novel RNA-interference (RNAi)-based approach for systematic discovery of such targets in the tumor microenvironment *in vivo* utilizing pooled shRNA libraries as a screening tool. I will discuss how this unbiased method can be used to develop innovative cancer therapeutics.

5:05 End of Day

5:00 Dinner Short Course Registration*

*See page 4 for details.

FRIDAY, AUGUST 28

8:00 am Morning Coffee

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11:30 Close of Gene Editing for Immunotherapy

PRICING & REGISTRATION

SHORT COURSES

	Commercial	Academic, Government, Hospital-affiliated
One short course	$699	$399
Two short courses	$999	$699

SHORT COURSE SELECTION:
Targeting the Cancer Mutanome
Adoptive Therapy with CAR T Cells

CONFERENCE PRICING

PREMIUM PACKAGE (Includes access to all conferences Monday – Friday. Excludes Short Courses)		
Special Early Bird Registration until May 8, 2015	$2,699	$1,199
Early Registration until June 5, 2015	$2,899	$1,399
Advance Registration until July 24, 2015	$3,099	$1,629
Registration after July 24, 2015	$3,299	$1,729
STANDARD PACKAGE (Includes access to two conferences. Excludes Short Courses)		
Special Early Bird Registration until May 8, 2015	$2,249	$1,029
Early Registration until June 5, 2015	$2,449	$1,229
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Special Early Bird Registration until May 8, 2015	$1,329	$629
Early Registration until June 5, 2015	$1,529	$829
Advance Registration until July 24, 2015	$1,699	$899
Registration after July 24, 2015	$1,849	$929

REQUIRED - Conference Selection
Premium Package - Choose 1 from each column (I + II + III)
Standard Package - Choose 1 from 2 columns (I + II, or II + III)
Basic Package - Choose 1 from 1 column (I, II, or III)

August 24-25, 2015

☐ Immunomodulatory Therapeutic Antibodies for Cancer

☐ Novel Vaccines Part I: Adjuvants

August 25-26, 2015

☐ Rational Combination Cancer Immunotherapy

☐ Novel Vaccines Part II: Emerging Technologies

August 26-27, 2015

☐ Target Discovery for T Cell Therapy

☐ Gene Editing for Immunotherapy

Poster Submission - **Discount ($50 Off)**: Poster abstracts are due by July 24, 2015. 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.

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

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