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DNA- and RNA-Based
Vaccines

Advances in Vaccine
Technologies

Short Course

Vaccine Adjuvants

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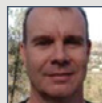
FEATURED SPEAKERS:



Shan Lu,
Professor, University
of Massachusetts



Simon Delagrave,
Senior Director & Head,
Virology Research,
Sanofi Pasteur



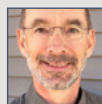
Laurent Humeau,
Vice President, R&D,
Inovio Pharmaceuticals



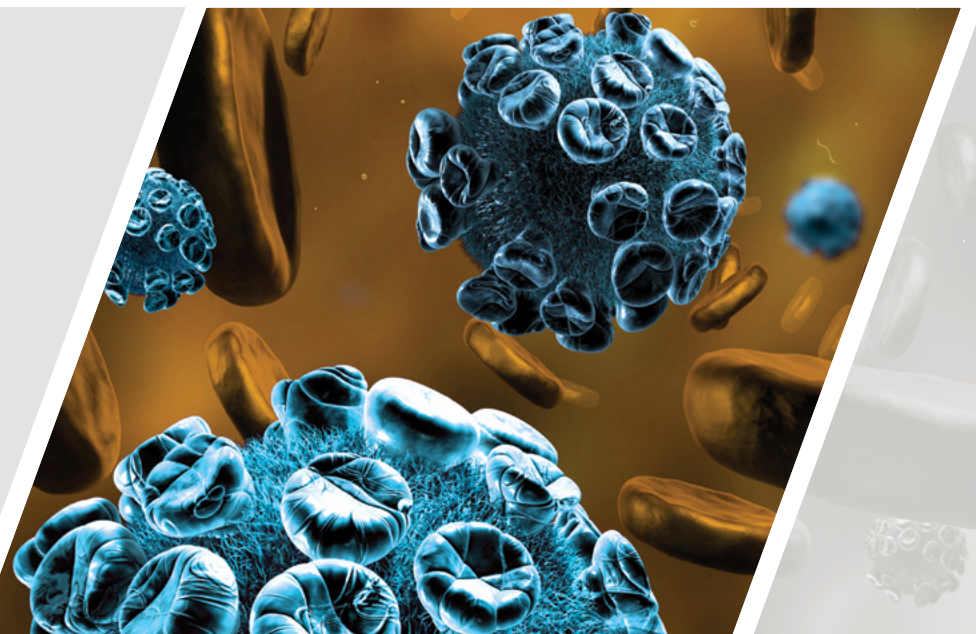
Nicholas Jackson,
Vice President,
Head of Research,
Sanofi Pasteur



Derek O'Hagan,
Head, Global
Discovery Support &
New Technologies,
GlaxoSmithKline Vaccines



Jeffrey Ulmer,
Head, Preclinical R&D,
GlaxoSmithKline
Vaccines



CONFERENCE TRACKS:

DECEMBER 6



Pre-Conference
Symposium:
**DNA- and RNA-
Based Vaccines**

DECEMBER 7 - 8



Track 1:
**Advances
in Vaccine
Technologies**

DECEMBER 8 - 9



Track 2:
**Vaccine
Adjuvants**

RECOMMENDED SHORT COURSE: Dinner Expert ThinkTank: Zika Vaccine Development

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DECEMBER 6 | Pre-Conference Symposium:

DNA- and RNA-Based Vaccines

TUESDAY, DECEMBER 6

8:00 am Symposium Registration and Morning Coffee

Improving Efficacy and Maximizing Immunogenicity of DNA Vaccines

8:25 Chairperson's Remarks

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

8:30 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 demonstrate that DNA immunization can take advantage of recently identified intracellular mechanisms involved in both acquired and innate immune response pathways.

9:00 Improving the Potency of DNA-Based Cancer Vaccines Using SynCon® Technology

Jian Yan, Ph.D., Associate Director, Antigen Discovery and Design, Inovio Pharmaceuticals
Inovio synthetic consensus (SynCon®) technology is a multi-phase DNA vaccine design strategy. Breaking tolerance remains a challenge for cancer vaccine development. Instead of using germline sequences, we incorporated SynCon® design strategy into our cancer vaccine design. Our data showed that SynCon® antigens exhibited stronger ability to break tolerance and induced robust cellular immune responses in both murine and non-human primate models. In a tumor challenge model, we demonstrated that the SynCon® antigen was able to slow tumor growth compared to animals vaccinated with the germline cancer antigen.

9:30 Adjuvant Strategies for Maximizing Immunogenicity of Protein, Polysaccharide and DNA Vaccines

Nikolai Petrovsky, MBBS, Ph.D., Chairman & Research Director, Vaxine; Professor, Flinders University

Highly adaptable pathogens including influenza, tuberculosis and HIV continue to circumvent attempts to control them using traditional vaccine approaches. Hence new advances and technologies are needed to overcome such challenges. In addition to novel computational approaches to intelligent antigen design, novel approaches including polysaccharide, lipid, DNA-encoded and RNA-encoded antigens, and alternative intranasal, intrapulmonary and transdermal vaccine delivery approaches, are all designed to induce stronger immunity at the right geographical locations. Whilst adjuvants have proved indispensable for enhancing the immunogenicity of traditional intramuscularly delivered protein vaccines, far less is known about optimal adjuvant strategies for use with these novel vaccine technologies. This talk will discuss how adjuvanting strategies can be tailored to a broad range of different antigen types and vaccine delivery approaches.

10:00 Coffee Break

Case Studies of DNA Vaccines

10:30 DNA-Launched Live Attenuated Vaccines

Peter Pushko, Ph.D., President & CSO, Medigen, Inc.

A novel DNA vaccine platform (iDNA®) uses plasmid DNA to launch live-attenuated RNA virus vaccines *in vivo*. After administration, the DNA synthesizes the full-length viral genomic RNA and initiates limited replication of live-attenuated virus in the tissues of the vaccine recipient, thereby inducing a protective immune response. With this technology, the field of DNA vaccines is expanded to include a novel type of DNA vaccine that launches live-attenuated viruses.

11:00 A DNA Vaccine to Prevent Congenital Cytomegalovirus Infections

Michael McVoy, Ph.D., Professor, Pediatrics, Virginia Commonwealth University

Development of a congenital cytomegalovirus vaccine is a public health priority. DNA vaccines expressing cytomegalovirus glycoprotein B (gB) or pentameric complex subunits UL128, UL130, or UL131A were evaluated in mice and rabbits. The gB vaccine induced complement-dependent fibroblast and epithelial entry neutralizing responses that were comparable to those induced by natural infection. Thus, a gB-expressing DNA may be an important component of a vaccine for prevention of congenital cytomegalovirus infections.

11:30 Th1 Epitope Selection Unlocks the Potential of Plasmid DNA Vaccines for Cancer

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

Cancer vaccines have travelled an arduous route towards efficacy, and the most promising approaches entering clinical development years ago continue to fall short in later studies. Many approaches have not improved the vaccine antigen component substantially, focusing instead on vector and administration. The EpiThany vaccine platform mines Th1-selective epitopes from tumor antigens, unlocking the true potential of the plasmid DNA vector to show consistent anti-tumor immunogenicity in the clinic.

12:00 pm Retinaldehyde Dehydrogenase 2 as a Molecular Adjuvant for Enhancement of Mucosal Immunity during DNA Vaccination

Kenneth Bagley, Ph.D., Head, Adjuvant Discovery & Development, Profectus BioSciences

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

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DECEMBER 6 | Pre-Conference Symposium:

DNA- and RNA-Based Vaccines

RNA-Based Vaccines

1:55 Chairperson's Remarks

Jeffrey Ulmer, Ph.D., Head, Preclinical R&D US, GSK Vaccines

2:00 Self-Amplifying mRNA Vaccines

Jeffrey Ulmer, Ph.D., Head, Preclinical R&D US, GSK Vaccines

Recent advancements have demonstrated that vaccines based on self-amplifying mRNA have the potential to combine the positive attributes of other types of vaccines without their limitations. Although the mRNA vaccine field is in its infancy, the prospects are promising. The broad utility and rapid response potential of this novel vaccine technology may enable a new generation of vaccines able to address the health challenges of the 21st century.

2:30 Sponsored Presentation (Opportunity Available)

3:00 RNA-Encoded Synthetic Gene Circuits for Tissue-Specific Expression and Small Molecule-Based Dosage Control of Therapeutic Proteins

Ron Weiss, Ph.D., Professor, Biological Engineering, MIT

RNA therapeutics are an attractive alternative to traditional DNA-based therapies, providing transient expression with minimal risk of genomic integration. However, the majority of current applications, ranging from vaccination to genetic reprogramming, rely solely upon constitutive expression. We have employed synthetic biology to expand the potential of RNA expression platforms to include cell-type specific expression and small molecule mediated dose control of therapeutic proteins. Synthetic biology aims to create and characterize libraries of highly predictable and modular genetic parts that can be combined to produce genetic circuits. To this end, we establish a collection of RNA-based parts that can modulate translation. We demonstrate that RNA-based circuits can be regulated using either exogenous siRNAs or endogenous miRNAs. Finally, we couple our genetic parts with small molecule responsive elements to form an RNA-only circuit platform that can dynamically control expression of multiple therapeutic proteins using external inputs.

3:30 Characterizing mRNA-Based Vaccines: From Single Molecules to the Whole Body

Phillip Santangelo, Ph.D., Associate Professor, Biomedical Engineering, Georgia Tech
mRNA-based vaccines present enormous opportunities but also many challenges. In my talk, I'll discuss cutting edge techniques for characterizing mRNA delivery, mRNA trafficking and innate immune responses from the single cell level to the level of the whole organism, using visible and near-IR fluorescence and techniques as well as PET/CT.

4:00 Evaluating Lipid Nanoparticles for mRNA Vaccine Delivery

Matthias Oberli, Ph.D., Research Associate, Langer Lab, David H. Koch Institute for Integrative Cancer Research, MIT

4:30 Close of Symposium

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DECEMBER 7 - 8 | Track 1:

Advances in Vaccine Technologies

WEDNESDAY, DECEMBER 7

7:15 am Registration Open and Morning Coffee

8:15 Welcome Remarks from Conference Director

Advancing Vaccines for Infectious Diseases and Emerging Threats

8:20 Chairperson's Opening Remarks

Harry Kleanthous, Ph.D., Associate Vice President, Head, Research (North America), Sanofi Pasteur

8:30 Novel Antigen Design and Functional Immune Assessments

Nicholas Jackson, Ph.D., Vice President, Head of Research, Sanofi Pasteur

9:00 Advances in DNA Vaccines for Infectious Diseases

Laurent M. Humeau, Ph.D., Vice President, Research & Development, Inovio Pharmaceuticals

Inovio is revolutionizing vaccines to prevent and treat today's cancers and challenging infectious diseases. Its SynCon® vaccines, in combination with its proprietary electroporation delivery, are generating best-in-class immune responses, with therapeutic T-cell responses exceeding other technologies in terms of magnitude, breadth, and response rate. Human data to date have shown a favorable safety profile.

9:30 Technologies for Malaria Vaccine Development

Annie Mo, Ph.D., Program Officer, National Institute of Allergy and Infectious Diseases, National Institutes of Health

Malaria is a devastating disease that affects hundreds of millions of people around the world. Vaccine development becomes critical for the prevention of and the ultimate elimination of malaria and to combat any potential drug resistant parasites. Although the first generation of malaria vaccine RTS,S/AS01 with moderate vaccine efficacy of around 30-40% in children with a 3-dose regimen by 48 months post immunization is on its way to licensure, development of a second generation of vaccine with an improved and prolonged efficacy became imperative. Current advances in malaria vaccine R&D and applicable new technologies to address malaria vaccinology and immunology issues will be presented.

10:00 Use of Systems Serology to Define How Genetic Adjuvants Modify an Antibody Response Generated by a DNA Prime/Subunit Boost Protocol

Kenneth Bagley, Ph.D., Head, Adjuvant Discovery & Development, Profectus BioSciences

Genetic-based adjuvants can enhance an immune response to a DNA vaccine quite dramatically. We utilized systems serology to understand how different genetic adjuvants can modify an antibody response to protect or not against

a heterologous SIV challenge. Exploiting multivariate analysis, we are able to predict which animals received which adjuvant. This approach can be used to potentially predict immune regimens that could be protective in clinical trials.

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

Virus-Like Particle and Nanoparticle Vaccines

11:00 Nanoparticle Vaccines

Takashi K. Kishimoto, Ph.D., CSO, Selecta Biosciences

We have created tolerogenic vaccines using synthetic, self-assembling, biodegradable poly(lactide-co-glycolide) (PLGA) nanoparticles containing rapamycin to induce antigen-specific immune tolerance. Co-administration of these synthetic vaccine particles (SVP) with biologic drugs mitigates the formation of anti-drug antibodies, a common cause for treatment failure and adverse events associated with biologic therapies. SEL-212, our SVP combined with pegylated uricase, is currently being evaluated in Phase I clinical trials in patients with hyperuricemia.

11:30 Enveloped Virus-Like Particles

Adam Buckley, MBA, Vice President, 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 virus like particle 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 Phase I CMV vaccine candidate.

12:00 pm Advancements in Cell Culture-Produced Influenza Vaccines

Amine Kamen, Ph.D., Professor, Bioengineering, McGill University

Over the last decade, public health authorities invested massively to support the development of rapid responses to influenza pandemic threats. Two cell culture-based novel influenza vaccines have been approved. Other advanced vaccination approaches rely on virus-like particle (VLP) strategies. Progresses in influenza vaccine cell-culture manufacturing technologies will be presented and discussed. Influenza VLP produced in insect cells by baculovirus infection and HEK-293 cells by plasmid transfection will be compared from a process standpoint.

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

1:15 Session Break

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DECEMBER 7 - 8 | Track 1:

Advances in Vaccine Technologies

Vaccine Delivery Technologies

2:10 Chairperson's Remarks

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

2:15 NanoStat™ Technology Enables Intranasal Vaccine to Induce Immunity against Infection by and Transmission of Respiratory and Sexually Transmitted Viral or Bacterial Pathogens

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

Two major reasons why the field of mucosal immunity is lagging behind are: i) lack of suitable delivery and adjuvants, and ii) difficulty in defining surrogate markers for protection. NanoStat™ technology, a unique nanoemulsion (NE) was shown to efficiently deliver vaccines intranasally (IN), and trigger a balanced systemic and mucosal immunity. Our data with HSV2, pertussis, and flu demonstrate this technology is well-suited for developing vaccines to protect against disease, prevent carriage, and eliminate transmission.

2:45 Can Skin Vaccination Eliminate MNT in Developing Countries?

Ioanna Skountzou, M.D., Ph.D., Associate Professor, Microbiology and Immunology, Emory University School of Medicine

Microneedle patches may improve vaccination coverage in developing countries. Advantages include ease of supply and delivery, and superior protective immunity.

3:15 Vaccine Delivery and Packaging Technologies for Low Resource Settings

Darin Zehrung, Program Advisor, Vaccine & Pharmaceutical Technologies, PATH

Mr. Zehrung will provide an overview of program requirements for vaccine delivery in low-resource settings as well as examples of current challenges that are faced in low- and middle-income countries (LMICs). Examples of active research that are occurring in the development and use of alternative delivery and packaging technologies in LMICs will also be discussed.

3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

4:15 Sponsored Presentation (Opportunity Available)

4:45 Panel Discussion with the Speakers: The Future of Vaccine Technologies

Moderator: Simon Delagrave, Ph.D., Senior Director, Head of Virology Research North America, Sanofi Pasteur

- What innovative technologies will keep us ahead of emerging threats?
- What is the role of nanoparticle and VLP technology in next-generation vaccines?
- How will new vaccine delivery technologies improve overall response?

5:45-6:45 Welcome Reception in the Exhibit Hall with Poster Viewing

6:30 Dinner Expert ThinkTank: Zika Vaccine Development*

*Separate registration required. See page 6 for details.

THURSDAY, DECEMBER 8

7:15 am Morning Coffee

Universal Influenza Vaccine Design

8:00 Chairperson's Remarks

Nikolai Petrovsky, MBBS, Ph.D., Chairman & Research Director, Vaxine; Professor, Flinders University

8:05 Novel Vaccines that Elicit Broadly Protective Immune Responses against Influenza

Simon Delagrave, Ph.D., Senior Director, Head of Virology Research North America, Sanofi Pasteur

Annual vaccination against seasonal influenza A and B virus subtypes with a well-matched inactivated virus vaccine is highly effective against influenza infection and disease. However, selective immune pressure on viral hemagglutinin (HA) results in antigenic drift of influenza strains. The development of a broadly protective influenza vaccine that can protect against matched and drifted mismatched strains through induction of broadly cross-protective functional antibody responses would provide significant improvement over the current standard of care. This presentation will show how Sanofi Pasteur is studying antibodies elicited by commercial vaccine to understand broadly cross-protective antibodies and, using Computationally Optimized Broadly Reactive Antigens (COBRAs), working to develop novel vaccines that elicit broadly protective immune responses against influenza. Studies funded by Sanofi Pasteur.

8:35 Design of a Universal Influenza Vaccine

Nikolai Petrovsky, MBBS, Ph.D., Chairman & Research Director, Vaxine; Professor, Flinders University

Highly adaptable viruses including influenza continue to circumvent attempts to control them using traditional vaccine approaches. To overcome such challenges and design a universal influenza vaccine, better understanding is needed of viral antigenic structures and their evolution along with better understanding of protective adaptive immunity. Computer structural models identify features that can then be incorporated into synthetic antigens to build a universal influenza vaccine. High-throughput *in silico* screening approaches identify immune-modulators for fine-tuning of the vaccine response. These tools enable design of vaccines that induce broadly cross-neutralizing and long-lasting B and T cell responses. This heralds an era of intelligent vaccine design, allowing accelerated design of vaccines against rapidly evolving viral targets.

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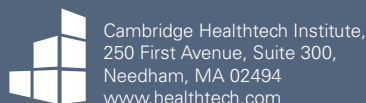
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DECEMBER 7 - 8 | Track 1:

Advances in Vaccine Technologies

9:05 Development of Universal Influenza Vaccine Targeting Conserved Domains

Yawei Ni, Ph.D., President & CSO, KJ Biosciences

Targeting conserved domains for cross protection is essential to development of a universal influenza vaccine. We are developing two complimentary approaches toward this goal. One is novel antigen constructs with a self-assembling nanoparticle carrier which allows combination of conserved domains for enhanced protection. The other is low-pH treatment under proper conditions of influenza antigens to enhance immune responses against conserved domains, which could improve current inactivated vaccines for broader protection.

9:35 Sponsored Presentation (Opportunity Available)

10:05 Coffee Break in the Exhibit Hall with Poster Viewing

Translating Technology to Trials

10:35 Cytomegalovirus Vaccine V160: Translating Experimental Findings to Clinical Trials

Dai Wang, Ph.D., Senior Scientist, Merck

Cytomegalovirus (CMV) causes significant morbidity and mortality in neonates and severely immunocompromised individuals. To address the unmet medical need, we have developed a conditionally replication defective vaccine, termed V160. The candidate is currently under clinical evaluation. This presentation will discuss the scientific premise, preclinical properties and latest progress of V160.

11:05 Talk Title to be Announced

Sonia Trepanier, Ph.D., Senior Director, Clinical Studies, Medicago

11:35 Close of Conference

Short Course

December 7, 6:30-9:30 pm

Dinner Expert ThinkTank: Zika Vaccine Development*

The recent outbreak of Zika virus infection has prompted an urgent response from the global community, and several companies have begun developing vaccines. Although the process can be lengthy, researchers may be able to use platforms from other flaviviruses as a starting point. Still, the biology of the virus must be understood and challenges to advancing new strategies overcome. The ThinkTank will include presentations and a panel discussion with experts in the field, including a company whose candidate is already in clinical trials.

6:30-8:00 Dinner and Presentations Zika Virus Subunit Vaccine Based on VADEX Technology

Ming-Chung Kan, Ph.D., CEO, Vaxsia Biomedical

Human Antibody Responses after Dengue Virus Infection Are Highly Cross-Reactive to Zika Virus

Jens Wrämmert, Ph.D., Assistant Professor, Microbiology & Immunology, Emory University School of Medicine

8:00-9:30 Panel Discussion

Panelists:

Laurent M. Humeau, Ph.D., Vice President, Research & Development, Inovio Pharmaceuticals
Ming-Chung Kan, Ph.D., CEO, Vaxsia Biomedical
Mario Skiadopoulos, Ph.D., Senior Director, Non-Clinical Development, Emergent BioSolutions
Jens Wrämmert, Ph.D., Assistant Professor, Microbiology & Immunology, Emory University School of Medicine
Haritha Adhikarla, Ph.D., Associate Research Scientist, Albert Ko Laboratory, Yale School of Public Health

**Separate registration required*

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DECEMBER 8 - 9 | Track 2:

Vaccine Adjuvants

THURSDAY, DECEMBER 8

12:00 pm Conference Registration

Innovations in Liposomal Adjuvants

12:55 Chairperson's Opening Remarks

Manmohan Singh, Ph.D., Senior Director, Drug Product Development, Takeda Vaccines

1:00 Liposomes as Human Vaccine Adjuvants

Carl Alving, M.D., Chief, Laboratory of Adjuvant & Antigen Research, U.S. Military HIV Research Program, Walter Reed Army Institute of Research

Liposomes are components of two of six types of adjuvants present in licensed vaccines, and research in this field continues to be innovative. The potential for new types of vaccines with liposome adjuvants will be discussed.

1:30 Cationic Liposomes (CAF01) - Mode of Action and Potential for Vaccination Strategies Targeting the Mucosa

Dennis Christensen, Ph.D., Senior Scientist & Head, Vaccine Adjuvant Research Group, Infectious Disease Immunology, Division of Vaccines, Statens Serum Institute
CAF01 liposomes containing glycolipids from the outer cell wall of mycobacteria, signal through the C type lectin receptor Mincle and are efficient vaccine adjuvants for both CMI (TH1/Th17) and humoral immune responses. I will discuss recent data that demonstrate that the TH17 component of the response can be efficiently utilized to target the immune response to the mucosal surfaces resulting in tissue resident memory T cells and high levels of IgA.

2:00 Semi-Synthetic Archaeosome Adjuvants for Induction of Cell-Mediated Immunity

Lakshmi Krishnan, Ph.D., Director, Immunobiology & Program Leader, Vaccines and Immunotherapeutics, National Research Council-Human Health Therapeutics, Canada

Archaeosomes are self-adjuvanting liposomal vesicles, traditionally composed of total polar or semi-synthetic ether glycerolipids unique to the domain of Archaea. A novel iteration of archaeosomes comprises a sulfated disaccharide group covalently linked to the free sn-1 hydroxyl backbone of an archaeal core lipid (sulfated S-lactosylarchaeol, SLA). SLA individually or mixed with uncharged glycolipid (lactosylarchaeol, LA) constitutes vesicles that are simple to formulate and retain robust adjuvant activity for multiple antigens. A key feature of archaeosomes is the ability to induce antigen-specific CD8+ T cells in murine models. This talk will outline the archaeosome technology, potent vaccine delivery systems for cell-mediated immunity.

2:30 Sponsored Presentation (Opportunity Available)

3:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Next-Generation Adjuvants

3:30 Designing and Building the Next Generation of Vaccine Adjuvants

Derek O'Hagan, Ph.D., Head, Global Discovery Support & New Technologies, GlaxoSmithKline 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 which commonly use insoluble aluminium salts as adjuvants. 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. A phosphonate group has been chemically linked to the compounds to enable adsorption to aluminium hydroxide and here we present extensive formulation characterization, and an overview of the *in vitro* and *in vivo* performance of the new generation adjuvants.

4:00 Influenza Vaccine Improvements: Adjuvants, Cell and Beyond

Ethan Settembre, Ph.D., Head, Research, Seqirus

I will talk about how improvements in the current system involve the generation of adjuvanted influenza vaccines (of which Flud is a representative), potentially better matched vaccines and RNA-based technologies. For MF59 adjuvanted vaccines, we have human data supporting the benefits of breadth and magnitude of response, both of which are key for improved flu vaccines.

4:30 Precision Adjuvants: Employing Human *in vitro* Modeling, High Throughput Screening and Systems Biology to Develop Adjuvants Tailored to Vulnerable Populations

Ofer Levy, M.D., Ph.D., Director, Precision Vaccines Program, Boston Children's Hospital; Associate Professor, Pediatrics, Harvard Medical School

Vaccine adjuvants may be most helpful for immunization of high risk populations, such as the very young and the elderly that express distinct immunity. The Precision Vaccines Program at Boston Children's Hospital is leveraging age-specific human *in vitro* modeling, high throughput screening and systems biology to develop adjuvanted vaccine formulations tailored to such distinct and vulnerable populations.

5:00 Development of Novel Immune NIR Laser and MTBhsp70 Based Immune Adjuvants for Cancer and Infectious Diseases Vaccines

Mark Poznansky, M.D., Ph.D., Associate Professor, Medicine, Harvard Medical School; Director, Vaccine & Immunotherapy Center, Massachusetts General Hospital

The Vaccine and Immunotherapy Center at MGH sets as one of its missions the accelerated development of new, safe, efficacious and broadly applicable immune adjuvants for both infectious diseases and cancer vaccines. This talk will describe the latest developments in the studies of two novel adjuvants: 1) a non-tissue damaging near infrared laser, and 2) a mycobacterial heat shock protein-based broadly immune-activating adjuvant.

5:30 End of Day

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DECEMBER 8 - 9 | Track 2:

Vaccine Adjuvants

FRIDAY, DECEMBER 9

8:00 am Morning Coffee

TLR Agonist Adjuvants

8:25 Chairperson's Remarks

Lee M. Wetzler, M.D., Co-Director for Research, Section of Infectious Diseases, Professor of Medicine and Microbiology, Boston University School of Medicine

8:30 Activity of TLR Agonists

Dennis Klinman, M.D., Ph.D., Senior Investigator, Cancer and Inflammation Program, NCI, NIH

The ability of tumor-specific cytotoxic T cells and natural killer cells to eliminate cancers is hindered by the immunosuppressive cells present in the tumor microenvironment. Monocytic myeloid-derived suppressor cells (mMDSC) constitute the most active of these tumor-infiltrating leukocytes and are key contributors to the immunosuppressive milieu. mMDSC arise in the bone marrow from myeloid progenitors and are present at high frequency in patients with cancer. Murine mMDSC express TLR9 and respond to stimulation with CpG oligonucleotides (TLR9 agonists) by differentiating into tumoricidal macrophages. *In vivo* administration of CpG ODN slows/prevents the growth of tumors in mice, an outcome linked to the increased activity of tumoricidal T cells. Human mMDSC express TLRs 2, 7 and 8 (but not 9) and are induced to differentiate into macrophage when stimulated via the relevant toll-like receptors. Agonists targeting TLR 1/2 (such as PAM3) induce mMDSC to mature into immunosuppressive M2-like macrophages whereas agonists targeting TLR 7/8 (such as R848) cause the same precursors to mature into tumoricidal M1-like macrophages. My presentation will focus on the protective activity of TLR agonists alone and in combination with cancer vaccines.

9:00 Induction of Robust and Diverse T Cell Responses by the TLR2 Ligand-Based Adjuvant, Meningococcal PorB

Lee M. Wetzler, M.D., Co-Director for Research, Section of Infectious Diseases, Professor of Medicine and Microbiology, Boston University School of Medicine

There is an unmet clinical need for vaccine adjuvants that induce T cell responses to achieve protection against malignancies and intracellular pathogens such as HIV, TB and Hepatitis C virus where a humoral response alone is not adequate. We have shown that meningococcal PorB, a TLR2 ligand-based adjuvant, has broad and potent adjuvant activity, with induction of robust germinal center and T cell responses, including high levels of Th1 and Th2 type cytokines and antigen specific Th1, Th2, TC2 and TC1 cells. The functionality of the induced CD8 T cells was demonstrated by protection in a *Listeria* mouse model. PorB is a potent new adjuvant, which is able to induce both a humoral response and strong diverse T cell response.

9:30 Evaluation of the Antibody Threshold of Protection Conferred by a Next-Generation Anthrax Vaccine Candidate Adjuvanted with the Immunostimulatory CPG 7909 TLR9 Agonist

Mario Skiadopoulos, Ph.D., Senior Director, Non-Clinical Development, Emergent BioSolutions

The anthrax vaccine candidate AV7909, is comprised of the Biothrax® (Anthrax Vaccine Adsorbed, AVA) drug substance and the adjuvant CPG 7909, a TLR9 agonist, and is being developed as a next-generation anthrax vaccine candidate for post-exposure prophylaxis that would confer protection earlier and would require fewer immunizations than AVA. AV7909 protected animals against lethal challenge with *Bacillus anthracis* spores in a dose-dependent manner. Analysis of the TNA threshold associated with protection in AVA or AV7909 immunized guinea pigs and cynomolgus macaques revealed that addition of the CPG 7909 adjuvant to AVA not only improved the kinetics and magnitude of the immune response, but also resulted in a lower TNA level that was required to confer protection, as compared to AVA alone.

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

Regulatory Challenges

10:30 Regulatory Challenges in the Evaluation of Vaccine Adjuvants

Richard Siggers, Ph.D., Senior Scientific Regulator, Health Canada

11:00 Developing Adjuvants: Challenges and Opportunities

Robert Johnson, Ph.D., Director, Office of Regulatory Affairs, Acting Director, Office of Clinical Research Resources, DMID/NIAID/NIH

11:30 Sponsored Presentation (Opportunity Available)

12:00 pm Enjoy Lunch on Your Own

Mode of Action of Vaccine Adjuvants

1:30 Chairperson's Remarks

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

1:35 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.

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DECEMBER 8 - 9 | Track 2:

Vaccine Adjuvants

2:05 Uncovering Innate Immune Pathways that Contribute to the Efficacy of Lipid Nanoparticle-Based Vaccine Formulations

Gokul Swaminathan, Ph.D., Senior Scientist, Infectious Diseases & Vaccines, Merck Research Laboratories, Merck & Co., Inc.

Emerging evidence suggests that bioengineered nanoparticles can be used as immunomodulatory agents. We have identified novel cationic lipid nanoparticles (LNPs) that significantly enhance antigen-specific B-cell, CD4+T cell, and most notably, CD8+ T-cell responses. Importantly, we found that LNP-containing vaccine formulations resulted in protective efficacy in a virus challenge model, as well as, in syngeneic murine tumor models. By employing *in vitro* systems, transgenic mice models, and *in vivo* imaging, we have uncovered innate immune pathways that contribute to LNP-based vaccines. Such detailed understanding of its mechanism of action will significantly influence the future design of LNPs for vaccines and immune-oncology applications.

2:35 Formulation Development and Biological Activity of Isoprenoid-Based Nanoemulsion Adjuvants

Karina Smolyar, Formulation Development, Infectious Disease Research Institute

Squalene oil-in-water nanoemulsions have been shown to be effective and safe adjuvants, providing increased immunogenicity to co-delivered vaccine antigens. There is ongoing interest in evaluating suitable raw material alternatives to squalene, specifically in stability and bioactivity profiles. Such studies may elucidate non-animal sources for raw materials as well as begin to shed light on potential structure-function relationships of isoprenoid-based nanoemulsion adjuvants.

3:05 Close of Conference

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Uma Patel | Business Development Manager | 781-972-1349 | upatel@healthtech.com

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