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Running concurrently with the **Cell & Gene Therapy Forum 2010**

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EVENT

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VACCINE FORUM
WASHINGTON 2010

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Driving Progress

Learn from - and network with - numerous senior level representatives of vaccine companies, governments, key NGOs and the finance community. The 60+ speakers confirmed to date include:

- **Vas Narasimhan MD**, Head, Vaccines North America, President, Vaccines USA, Novartis Vaccines & Diagnostics Inc
- **Dr Robin Robinson**, Director, Biomedical Advanced Research & Development Authority (BARDA), Office of the Assistant Secretary for Preparedness & Response (ASPR), US Department of Health & Human Services
- **Dr Anthony Ford-Hutchinson**, Senior Vice President & Franchise Head, Vaccines & Infectious Diseases, Merck Research Laboratories
- **Nelson L. Michael, MD, PhD**, Colonel, Medical Corps, United States Army, Director, Division of Retrovirology, Walter Reed Army Institute of Research, US Military HIV Research Program (MHRP)
- **Allan Saul PhD**, CEO, Novartis Vaccines Institute for Global Health
- **Dr Norman W. Baylor**, Director, Office of Vaccines Research & Review (OVR), CBER, US Food & Drug Administration
- **Dr Thomas Breuer**, Senior Vice President, Head, Global Clinical R&D & Chief Medical Officer, GlaxoSmithKline Biologicals
- **Dr John Purves**, Head of Sector, Quality of Medicines, European Medicines Agency (EMA)
- **Melinda Wharton, MD MPH**, Acting Director of National Centre for Immunization & Respiratory Diseases, Centers for Disease Control & Prevention
- **Dr Steve G. Reed**, CEO, Immune Design & Founder, IDRI
- **Dr Allan P. Jarvis**, Vice President, Corporate Development, sanofi pasteur
- **Dr Jon Andrus**, Senior Technical Advisor in Immunizations, Pan American Health Organization (PAHO)
- **Dr John W. Shiver**, Vice President, Worldwide Basic Research Franchise Head, Vaccines, Merck Research Laboratories
- **Dr Heather L. Davis**, Executive Director & Ottawa Site Head, Vaccines Research, Pfizer
- **Dr Gary J. Nabel**, Director, Vaccine Research Center, National Institute of Allergy & Infectious Diseases (NIAID), NIH
- **Dr Hartmut Ehrlich**, Vice President, Global R&D, Baxter BioScience
- **Seth Rudnick**, Venture Partner, Canaan Partners
- **Dr Bruce G. Gellin**, Director, National Vaccine Program Office, Office of Public Health & Science, Office of the Assistant Secretary for Health, US Department of Health & Human Services
- **Dr Joe Cohen**, Vice President, Emerging Diseases & HIV Vaccines, Research & Development, GlaxoSmithKline Biologicals
- **Dr John Boslego**, Director, Vaccine Development Global Program, PATH
- **Gregg C. Sylvester, MD, MPH**, Head of Adult & Adolescent Vaccines for Medical Affairs & Policy, Merck Vaccines & Infectious Diseases
- **Robert V. House, PhD**, President, DynPort Vaccine Company LLC, A CSC Company
- **Dr Shou-Bai Chao**, Vice President, Vaccines Manufacturing, MedImmune, Inc
- **Dr Michael V. Callahan**, Program Manager, Rapid Vaccine Assessment, Defense Advanced Research Projects Agency (DARPA)
- **Stephen L. Hoffman, MD**, Chief Executive & Scientific Officer, Sanaria Inc
- **Dr W. James Jackson**, Chief Scientific Officer, Emergent Biosolutions
- **Dr Melinda Moree**, Interim CEO, BIO Ventures for Global Health
- **Professor Alexander von Gabain**, CSO, Intercell AG
- **Dr Linda Lambert**, Chief, Respiratory Diseases Branch, Division of Microbiology & Infectious Diseases, NIAID
- **Dr Mitchell Gold**, President & CEO, Dendreon Corporation
- **Philip R. Dormitzer, MD, PhD**, Senior Director, Senior Project Leader, Viral Vaccine Research, Novartis Vaccines and Diagnostics
- **Vic Schmitt**, Venture Partner, Bay City Capital
- **Dr Michael Perdue**, Director - Influenza & Emerging Diseases Program, Biomedical Advanced Research & Development Authority, Office of the Assistant Secretary for Preparedness & Response, US Department of Health & Human Services
- **Dr Rahul Singhvi**, President & CEO, Novavax, Inc
- **Michael Greenberg, MD, MPH**, Director of Clinical Development, Vaccines, CSL
- **M. Juliana McElrath, MD, PhD**, Member, FHCRC, & Professor of Medicine, University of Washington
- **Isabelle Claxton**, Director, Public Policy & Advocacy, GlaxoSmithKline Vaccines
- **Christian Loucq, MD**, Director, The PATH Malaria Vaccine Initiative
- **Dr Alan Shaw**, President & CEO, VaxInnate Corporation
- **Eric Rosenthal, MD, MPH, FAAP**, Clinical Assistant Professor of Medicine & of Health Policy, George Washington University Medical Center, Medical Director, Municipal & Regional Affairs, Child Health Advocacy Institute, Senior Clinical Associate, Emergency Department, Children's National Medical Center
- **Jose Ochoa**, Vice President, Business Development, Emergent BioSolutions Inc
- **Nicholas A. Kartsonis, MD**, Senior Director, Clinical Research - Infectious Diseases/Vaccines, Merck & Co, Inc
- **Paul J. Giannasca, PhD**, Program Leader, C. difficile, Sanofi Pasteur Biologics Co
- **Dr Alfredo Nicosia**, Chief Scientific Officer, Okairos
- **Susan Ano, PhD**, Chief, Infectious Diseases & Medical Engineering Branch Office of Technology Transfer, National Institutes of Health
- **David Apelian MD, PhD, MBA**, Senior Vice President of Research & Development & Chief Medical Officer, Globelmmune, Inc
- **Dr Alain Rolland**, Senior Vice President, Product Development, Vical
- **Dr Beth-Ann Collier**, Senior Vice President for Research & Development, Hawaii Biotech, Inc
- **Paula Bryant, PhD**, Senior S&T Manager - Pretreatments, Chemical & Biological Technologies Directorate, Joint Science & Technology Office, Defense Threat Reduction Agency, US Department of Defense
- **Harriet L. Robinson, PhD**, Senior Vice President, Research & Development, GeoVax Inc
- **John Clerici**, Partner, McKenna Long & Aldridge
- **Fabio Bagnoli, PhD**, Associate Project Leader, Novartis Vaccines & Diagnostics
- **Michael J. Werner**, Partner, Holland & Knight
- **Drew Hannaman**, Vice President, R&D, Ichor Medical Systems, Inc
- **Dr Vidadi Yusibov**, Executive Director, Fraunhofer USA Center for Molecular Biotechnology
- **Dr Robert F. Bargatz**, CSO & Executive Vice President, LigoClyte Pharmaceuticals
- **Eric Faulkner**, Senior Director, US Market Access & Reimbursement, RTI Health Solutions
- **Dr Ronald W. Ellis**, Senior Vice President & Chief Technology Officer, NasVax Ltd, Israel
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MORNING PLENARY SESSION

How are we doing with pandemic planning?

- Are we making the right decisions on vaccine strategy and funding to rapidly deal with outbreaks of new strains

9.00 Chair's introduction

Review of the spread and impact of pandemic H1N1 influenza to date

- Brief review of the epidemiology of the pandemic
- PAHO's response in the Region of the Americas
- Challenges and opportunities, including equity and access to vaccines

Dr Jon Andrus, Senior Technical Advisor in Immunizations, Pan American Health Organization (PAHO)

9.20 Questions & discussion

9.25 Australia as a retrospective case study: Dealing with the realities of pandemic H1N1 influenza

- How did it pan out with normal seasonal influenza about to hit?
- What was the epidemiology of the pandemic - which population groups were most susceptible?
- Was prior exposure a factor? What role did vaccines play?
- How have government and industry worked together to rapidly develop new products?

Michael Greenberg, MD, MPH, Director of Clinical Development, Vaccines, CSL

9.45 Questions & discussion

9.50 Panel discussion Improving surveillance: How do we ensure rapid response strategy, infrastructure and technology are in place for tracking new infectious strains?

- How has the response to pandemic H1N1 influenza gone?
 - How effective have the plans and preparations been in the face of a real pandemic threat?
- What lessons were learned from SARS and H5N1, and how have these translated into improved global surveillance systems?
 - Could the Mexican situation have been detected earlier?

- Examining the linkage between surveillance, rapid response and vaccine manufacture
- Should capacity be expanded further?
- What have we learned from H1N1 and H5N1 about the potential for reassortment
 - What should we be doing to pre-empt the next one?
- What models do DARPA use for their very aggressive identification of pathogens and for rapid vaccine development?

Panelists:
Melinda Wharton, MD MPH, Acting Director of National Centre for Immunization & Respiratory Diseases, Centers for Disease Control & Prevention
Dr Michael V. Callahan, Program Manager, Rapid Vaccine Assessment, Defense Advanced Research Projects Agency (DARPA)

10.30 Keynote vaccine manufacturer's perspective How responsive can manufacturers be to sudden demand without assurance of a market for an "emergency" product?

- How should a facility handle scheduling of annual and pandemic strains?
- Will there be a more modular approach to production capacity?
- How are vaccine manufacturers responding to the stability and ease of administration requirements of a vaccine stockpiling strategy?

Vas Narasimhan MD, Head, Vaccines North America, President, Vaccines USA Novartis Vaccines & Diagnostics Inc

10.50 Questions & discussion

10.55 Morning coffee in the exhibition area

11.35 Presentation reserved

11.55 Questions & discussion

What government funding mechanisms and procurement strategies are in place to accelerate vaccine development, and promote agile manufacturing infrastructure for future pandemic strains and emerging infectious diseases?

- What problems has the recent pandemic highlighted in terms of infrastructure and how are they being addressed through renewed funding, procurement and licensing strategies?
- What is best way to prepare for pandemic? Drugs versus vaccines or both?
- What role will stock-piling versus pre-pandemic vaccine play? What have we learned from the H5N1 and H1N1 experiences?
- What new funding is being made available to stimulate agile manufacturing infrastructure to respond to changes in virus strain or new outbreaks of infectious disease? Is there room for both classic and novel manufacturing techniques?
- What new funding is being made available to drive R&D for biosecurity and emerging infectious diseases? What are the main areas of focus?
- What new products have been ordered?

12.00 BARDA/HHS

Dr Robin Robinson, Director, Biomedical Advanced Research & Development Authority (BARDA), Office of the Assistant Secretary for Preparedness & Response (ASPR), US Department of Health & Human Services

12.20 Questions & discussion

12.25 NIAID/NIH

Linda C. Lambert, PhD, Chief, Respiratory Diseases Branch, Division of Microbiology & Infectious Diseases, NIAID

12.45 Questions & discussion

12.50 Buffet lunch in the exhibition area

FOLLOWED BY YOUR CHOICE OF 3 PARALLEL BREAKOUT SESSIONS:

FOCUS SESSION 1

Clinical trial strategy and regulatory pathways for pandemic influenza vaccines

Please note: The exact content of this session will be adjusted depending on the situation at the time of the event.

2.00 Chair's introduction

2.05 The epidemiologist's perspective on the recent pandemic: Are there any clues to the timing of a new pandemic, and is it really possible to prepare for new strains in advance?

- How did the change of season affect the spread of the disease?
- What are the parallels, if any, between behaviour of H1N1 and 1918 Spanish flu?
- Which population segments have proved to be most resistant / susceptible?
 - What does this indicate in terms of who should be vaccinated first?
- Assuming that the 2009/2010 influenza season will be bad, then statistically can we sit back for another 25 years?

Melinda Wharton, MD MPH, Acting Director of National Centre for Immunization & Respiratory Diseases, Centers for Disease Control & Prevention

2.25 Questions & discussion

2.30 What has been licensed for pandemic influenza over the past few months? How do the regulatory pathways compare to those for H5N1 candidates?

- EMEA / FDA approaches: What are the scenarios for accelerating the approval of a new pandemic vaccine other than H5N1?
- Is there a pathway for accelerated approval based on post-licensure effectiveness?
- How do the regulatory pathways differ for pandemic and seasonal vaccines?
 - Can you put a pandemic vaccine into a seasonal license?
- In the absence of adequate animal models, what pre-clinical and clinical studies might be undertaken to convince the regulator that a new technology (eg DNA vaccine) could be used for pandemic?
- WHO recommendations for the Northern Hemisphere seasonal vaccine 2010-2011: The consequences for manufacturers and regulators
- Can a trivalent vaccine be made quadrivalent?

Dr Norman W. Baylor, Director, Office of Vaccines Research & Review (OVR), CBER, US Food & Drug Administration

Dr John Purves, Head of Sector, Quality of Medicines, European Medicines Agency (EMA)

3.10 Questions & discussion

A comparison of the human data from pandemic influenza candidate vaccines available by January 2010

- Use of adjuvants / ability to dose spare
- Need for 2 doses
- Data by specific age groups
- Safety / efficacy / effectiveness
- How do the different approaches compare
- How might vaccine developers strategize to keep their clinical trials rolling by taking advantage of different seasons on a global basis?

3.15 Case study

Dr Hartmut Ehrlich, Vice President, Global R&D, Baxter BioScience

3.35 Afternoon tea in the exhibition area

4.15 Case study

Michael Greenberg, MD, MPH, Director of Clinical Development, Vaccines, CSL

4.35 Case study

Speaker to be announced

4.55 Questions & discussion

5.00 Chair's closing summary

5.05 Close of session followed by afternoon plenary session

OR | FOCUS SESSION 2

Optimizing your value proposition and positioning strategy for new vaccines

- Case studies of recent launches

2.00 Chair's introduction

Dr Ronald W. Ellis, Senior Vice President & Chief Technology Officer, NasVax Ltd, Israel

HPV vaccine positioning strategies: How is uptake and effectiveness in the field panning out? What data is coming from post-marketing surveillance?

- How do you position different vaccines based on immunogenicity and efficacy?
- How should the data be interpreted?
- Is it possible to translate higher response rates into longer lasting protection?
- What progress is being made with type 6 and 11 in particular?
- How will this be positioned in the market?
- How will the male data be used in terms of positioning strategy and value?
- How have vaccination rates impacted the incidence of other STDs?
- What is the potential for cross protection?
- How will new types be added to the current vaccines?

2.05 Cervarix

Dr Thomas Breuer, Senior Vice President, Head, Global Clinical R&D & Chief Medical Officer, GlaxoSmithKline Biologicals

2.25 Gardasil: Past, present & future

- Understanding the HPV disease burden
- Merck's clinical trials
- Young women, adult women and young men
- Post-marketing
- Second generation vaccine for HPV

Gregg C. Sylvester, MD, MPH, Head of Adult & Adolescent Vaccines for Medical Affairs & Policy, Merck Vaccines & Infectious Diseases

2.45 Presentation & discussion

- A study of initial uptake of the HPV vaccine under Washington, DC's mandatory vaccine law
- How do payers and physicians make their product choice decisions? How do they assess value? What can industry learn?

Panelists:

Eric Faulkner, Senior Director, US Market Access & Reimbursement, RTI Health Solutions
Eric Rosenthal, MD, MPH, FAAP, Clinical Assistant Professor of Medicine & of Health Policy, George Washington University Medical Center, Medical Director, Municipal & Regional Affairs, Child Health Advocacy Institute, Senior Clinical Associate, Emergency Department, Children's National Medical Center

3.15 Pneumococcal conjugate vaccine update

- Prevnar 13: How will it be used in practice, and how will it be positioned?
- What are implications of this model?
 - Is it useful for other disease areas?
- How will other conjugate vaccines be introduced, and how can they compete?

Speaker to be announced

3.35 Afternoon tea in the exhibition area

4.15 Panel discussion

What have been the unexpected outcomes from the introduction of new vaccines, and how might they influence positioning strategies as well as inform R&D paths to licensure for future products?

- Demonstrating ancillary impacts and benefits
 - How to demonstrate the value of vaccines in antimicrobial resistance via epidemiological studies
 - Cross protection potential
 - Can you expect herd immunity from vaccines other than respiratory?
 - The impact of vaccines on healthcare burden
- How is the concept of Patient Reported Outcomes being applied to vaccines - and with what effect?
- How might the evaluation of a new vaccine go beyond its direct impact especially when looking at vaccines for adults / elderly populations?

5.00 Chair's closing summary

5.05 Close of session followed by afternoon plenary session

OR | WORKSHOP

Vaccines for major public health needs: Analyzing the latest clinical results for nosocomial infections

2.00 Moderator's introduction

Dr John W. Shiver, Vice President, Worldwide Basic Research Franchise Head, Vaccines, Merck Research Laboratories

Case studies from those furthest advanced highlighting

- Translation from non-human to human trials
- Regulatory interaction and pathways

2.05 The pursuit of a S. aureus vaccine: A review of Merck's V710 program

- Highlighting the medical need for a S. aureus vaccine (against MSSA and MRSA) and specific patient targets under active discussion
- Emphasizing Merck's general thinking into the identification of a proper target for a vaccine and the rationale for the chosen target in its V710 program
- Sharing the encouraging preclinical data with V710, thereby justifying the rationale for moving forward into clinical development with V710
- Summarizing the available clinical data for V710 from the Phase I program
- Providing the rationale for the chosen patient population for evaluation in the Phase II setting

Nicholas A. Kartsonis, MD, Senior Director, Clinical Research - Infectious Diseases/Vaccines, Merck & Co, Inc

2.30 Questions & discussion

2.35 Development of a broadly protective vaccine against Staphylococcus aureus

- Overview of the reverse vaccinology process
- Novartis' strategy to develop the S. aureus vaccine
- Preclinical results obtained with the Novartis staphylococcal vaccine
- Moving forward: Clinical trials

Fabio Bagnoli, PhD, Associate Project Leader, Novartis Vaccines & Diagnostics

3.00 Questions & discussion

3.05 ACAM-CDIFF™: An active vaccine against C. difficile infection (CDI)

- The evolving CDI landscape
- Inadequacy of current standard of care treatments
- Prevention as a key approach to disease management
- Justification for a vaccine against CDI
- Rationale for targeting toxins A & B
- Current status of clinical development

Paul J. Giannasca, PhD, Program Leader, C. difficile, Sanofi Pasteur Biologics Co

3.30 Questions & discussion

3.35 Afternoon tea in the exhibition area

4.15 Case study

Preventing the spread of Norovirus infection

- Impact of Norovirus in public health settings
- Development status of Norovirus vaccines
- Human challenge studies to evaluate vaccine effectiveness

Dr Robert F. Bargatze, CSO & Executive Vice President, LigoCyte Pharmaceuticals

4.35 Questions & discussion

4.40 Panel discussion

What evidence is there that vaccines and monoclonal / anti-infective antibodies might be used in combination, or in sequence, or competition with each other, to fight nosocomial infections?

5.00 Moderator's closing summary

5.05 Close of session followed by afternoon plenary session

 Indicates a highly interactive workshop for a maximum of 30 participants

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THEN | AFTERNOON PLENARY SESSION

How will pandemic influenza change the technology, manufacturing and economic landscape of the vaccine industry?

Please note: The exact content of this session will be adjusted depending on the situation at the time of the event.

5.10 Panel discussion

- What impact will the substantial increase in influenza vaccine capacity have on the industry?
- How will the economics of the industry change if and when cell manufacturing techniques come on-stream?
 - How will the price/volume relationship relative to manufacturing capacity evolve?

- If cell culture vaccine does not have a promotable advantage for sales in the face of higher costs, how do manufacturers justify it?

Panelists:

Dr Ronald W. Ellis, Senior Vice President & Chief Technology Officer, NasVax Ltd, Israel
Dr W. James Jackson, Chief Scientific Officer, Emergent Biosolutions

5.40 End of day 1 followed by a themed cocktail reception in the exhibition area

7.30 Registration & buffet breakfast in the exhibition area

MORNING PLENARY SESSION

Defining the business models that are most likely to deliver affordable vaccines for major global unmet needs

9.00 Chair's introduction
Dr Allan P. Jarvis, Vice President, Corporate Development, sanofi pasteur

9.05 Keynote address
Innovative approaches to accelerate vaccine development for low-resource countries

- The rich landscape of organizations and efforts
- How are we balancing efforts across low-resource countries?
- How are we prioritizing and selecting our investments in new vaccines?
- How can we leverage and coordinate among disparate efforts?
- What incentives and innovative policies can help us attract new investments and share risks?

Dr John Boslego, Director, Vaccine Development Global Program, PATH

9.30 Questions & discussion

Business models in action: Case studies of NGO, public and private sector investment in vaccines for global public health needs

9.35 Pneumococcal vaccine AMC: Is it the right type of mechanism to incentivize industry to supply the developing world, and if so, what other vaccines might it make sense for?

- What has been the response from global and local manufacturers?
- How are smaller biotechs being incentivized financially to get involved?
- How are risks being managed for manufacturers?

Melinda Moree, PhD, Interim CEO, BIO Ventures for Global Health

10.00 Questions & discussion

10.05 Emerging partners for emerging markets: Including non-western institutions in your vaccine business development strategy

- Introduction to NIH licensing practices and policies
- Identification of potential business development partners
- Case study: Human-bovine rotavirus vaccine technology transfer
- Latest developments on the rotavirus story
- Further applications

Susan Ano, PhD, Chief, Infectious Diseases & Medical Engineering Branch Office of Technology Transfer, National Institutes of Health

10.30 Questions & discussion

10.35 Morning coffee in the exhibition area

11.25 Merck - Wellcome Trust joint venture and other approaches to challenges in developing and emerging vaccine markets

- Specifics of the joint venture – objectives / structure / roll out strategy

- Understanding what it takes to get into the emerging and developing markets eg being able to distinguish between private and tender markets
- Being torn in 2 different directions: What manufacturing technologies / policies are needed to enable vaccines to be distributed through WHO as well as being sold to the west?

Dr Anthony Ford-Hutchinson, Senior Vice President & Franchise Head, Vaccines & Infectious Diseases, Merck Research Laboratories

11.50 Questions & discussion

11.55 Developing vaccines primarily aimed at neglected diseases of developing countries

- Most vaccines for developing countries were first made for Western markets: How do we reverse this paradigm for bulk of the global infectious disease burden for which there is no significant Western market?
- What are the gaps in the development path to vaccines for neglected disease?
- How can these be overcome?

Allan Saul PhD, CEO, Novartis Vaccines Institute for Global Health

12.15 Questions & discussion

12.20 Panel discussion
Realizing the potential of the structures that have been established to deliver vaccines to the developing world

Panelist:
Jose Ochoa, Vice President, Business Development, Emergent BioSolutions Inc

1.00 Buffet lunch in the exhibition area

FOLLOWED BY YOUR CHOICE OF 3 PARALLEL BREAKOUT SESSIONS:

FOCUS SESSION 1

Prophylactic and therapeutic vaccines for chronic viral infectious diseases: Where are the breakthroughs in terms of understanding of immunity?

2.10 Moderator's introduction
Findings from the HIV vaccine Step Trial: Lessons learned and the path forward:

- Long-term perspective on the data: What can be interpreted in terms of breakthroughs in understanding of immunity?
- What indications are there that we are closer to success than 10 years ago?
- How might companies re-orient in this space following that trial?

M. Juliana McElrath, MD, PhD, Member, FHCRC, & Professor of Medicine, University of Washington

2.30 Case study
World's largest HIV vaccine trial: Latest results from the RV144 Phase III trials in Thailand

Nelson L. Michael, MD, PhD, Colonel, Medical Corps, United States Army, Director, Division of Retrovirology, Walter Reed Army Institute of Research, US Military HIV Research Program (MHRP)

2.50 Questions & discussion

2.55 Panel discussion
What do we now think a prophylactic / therapeutic for HIV would look like? What is state of the art in the field?

- What characteristics are required?
- What might the route to licensure look like?

- How would it be positioned in the market?
 - Would it compete with or complement ARVs?
- What are the latest advancements with respect to
 - Potential breakthroughs in pre-clinical: Can a T cell vaccine work in HIV animal models?
 - What is the potential for using live vector delivery systems?
 - Therapeutic vaccines - how to cope with viral escape
 - Prophylactic vaccines - can non-neutralizing activities of Ab contribute to protection?
- How significant a role might mucosal delivery have?
- The role of passive immunity for HIV: In the absence of an effective vaccine could this be an option?

Panelists:
Harriet L. Robinson, PhD, Senior Vice President, Research & Development, GeoVax Inc
Dr Gary J. Nabel, Director, Vaccine Research Center, National Institute of Allergy & Infectious Diseases (NIAID), NIH
Drew Hannaman, Vice President, R&D, Ichor Medical Systems, Inc

3.35 Afternoon tea in the exhibition area

4.15 What does a therapeutic Hep C vaccine have to do to get approved and compete with best in class drugs?

- How to develop an HCV vaccine in the context of current IFN-based therapies and evolving antivirals
- Clinical end-points required to get approval
- Case studies of trial design
- What is the latest data? What impact on viral load?
- How might it be used in combination with drugs?
- The role of passive immunity for chronic viral infections: If structural biology is not leading you towards immunogenicity then could this be an option?

David Apelian MD, PhD, MBA, Senior Vice President of Research & Development & Chief Medical Officer, Globelimmune, Inc

4.30 Questions & discussion

4.35 Panel discussion

- What can all these areas of research, combined with cancer vaccine research, learn from each other in terms of immune intervention and the common denominators that may help us identify vaccine approaches that are more broadly applicable?
- How much synergy is there between prophylactic and therapeutic vaccines in terms of going after difficult, intractable viruses?
 - How are larger companies capitalizing on their infrastructure to access the different capabilities required?
 - Leveraging across technologies on the vaccine / biologics side, and commercial weight on the pharma side

4.55 Chair's closing summary

5.00 Close of session followed by afternoon plenary session

OR | FOCUS SESSION 2

What evidence is now available showing commercial promise for cell culture manufacturing?

2.10 Chair's introduction
How is HHS enabling manufacturers to develop cell culture and incentivizing them to make the switch?

- How necessary is it to have a large capacity for cell culture?
- What is a healthy balance between egg and cell culture for long-term supply?

Dr Michael Perdue, Director - Influenza & Emerging Diseases Program, Biomedical Advanced Research & Development Authority, Office of the Assistant Secretary for Preparedness & Response, US Department of Health & Human Services

Case studies
Hurdles and benefits to switching strategy from egg to cell based manufacture: How are they being overcome and realized?

- Fully realizing the potential of flu cell culture requires multi-institution cooperation to generate and test cell-derived influenza virus vaccine seeds
- The response to H1N1v pandemic influenza highlighted advantages of cell based manufacture
- Cell based manufacture is a starting point for future improvements

2.20 Case study
Philip R. Dormitzer, MD, PhD, Senior Director, Senior Project Leader, Viral Vaccine Research, Novartis Vaccines and Diagnostics

2.40 Questions & discussion

2.45 Case study
Dr Shou-Bai Chao, Vice President, Vaccines Manufacturing, MedImmune, Inc

3.05 Questions & discussion

3.10 Presentation reserved

3.30 Questions & discussion

3.35 Afternoon tea in the exhibition area

4.15 Fast tracking the development of - and path to licensure for - a novel manufacturing platform by utilizing it in pandemic influenza efforts

Dr Rahul Singhvi, President & CEO, Novavax, Inc

4.35 Panel discussion
Examining the process economics of biotherapeutics manufacture, and how to apply them to vaccines

- The biotech industry has already developed robust cell-based manufacturing technologies that should be able to pave the way for vaccine industry to piggy-back - why then has progress been so slow?
- What can be adopted from the regulatory processes and pathways already in place?
- What examples are there of crossover technologies to help vaccines which come out of the drug / device / diagnostic / clean-tech fields?

4.55 Chair's closing summary

5.00 Close of session followed by afternoon plenary session

REGISTER NOW AND TAKE THE OPPORTUNITY TO PROPOSE A TOPIC FOR A WORKING LUNCH SESSION



OR | WORKSHOP

How are translational science and biomarkers being applied to development pathways for novel adjuvants and delivery systems?

- What is the regulatory response?

2.10 Moderator's introduction
Translation applications in prophylactic and therapeutic vaccines: What tools are available to better characterize and test the toxicity of novel adjuvants at an early stage?

- Using biomarkers and microarrays to identify patterns and profiling
- Assessment of adjuvants using memory B-cell microarrays
 - Has this approach proven itself to date, or is it still theoretical?
- Are there specific in vitro technologies that can be used to screen/evaluate vaccine antigen/adjuvant candidates in large numbers prior to animal model testing for more rapid vaccine development?

Dr Steve G. Reed, CEO, Immune Design & Founder, IDRI

Case studies of novel adjuvants: What has translated and what have we yet to find? Translating from mice / non-primates into humans

- How efficacious will they be in specific vaccine formulations with an antigen?
- What translational and clinical data backs this up?
- How are biomarkers being used?
- What does the development pathway look like?

2.25 Vaccine adjuvants comprising combinations of TLR agonists and/or delivery systems

Dr Heather L. Davis, Executive Director and Ottawa Site Head, Vaccines Research, Pfizer

2.45 Question & discussion

2.50 Mice do not always lie - translating preclinical results into novel vaccines

- How to identify protective antigens
- To adjuvant or not to adjuvant – that is the question
- How to find the proper formulation?
- How to decide on surrogate markers predicting efficacy in an early stage

Professor Alexander von Gabain, CSO, Intercell AG

3.10 Question & discussion

3.15 Designing smarter viral vector delivery of vaccines: What has translated successfully to humans?

- How can adenovirus delivery proceed at this time given the bad result with HIV?
- Can animal studies predict the immunogenicity of different adenovirus vectors in humans?
- Is there a better alternative to the currently used cell substrates for adenovirus vector production?
- Are there better vector combinations for vaccine delivery?

Dr Alfredo Nicosia, Chief Scientific Officer, Okairo

3.35 Afternoon tea in the exhibition area

4.15 Panel discussion
Addressing regulatory concerns for licensing new adjuvants and delivery combinations: What impact are translational science and biomarkers having?

- Comparing EU/US approaches to benefit:risk
 - How do the regulatory pathways compare for adjuvants and combination products?
- What are the concerns around mechanism of action / systemic response / chronic inflammation/ long-term effects?
 - How can they be mitigated at an early stage?
- How is it influencing big pharma's interest in novel adjuvants and delivery mechanisms?

Panelists:
Dr Norman W. Baylor, Director, Office of Vaccines Research & Review (OVR), CBER, US Food & Drug Administration
Dr John Purves, Head of Sector, Quality of Medicines, European Medicines Agency (EMA)

4.55 Moderator's closing summary

5.00 Close of session followed by afternoon plenary session

i Indicates a highly interactive workshop for a maximum of 30 participants



VACCINE FORUM WASHINGTON 2010

Driving Progress

THEN | AFTERNOON PLENARY SESSION

Therapeutic cancer vaccines: Now that licensure is a reality, how will these products be commercialized, and what does this mean for the vaccines sector as a whole?

5.05 Chair's introduction
Dendreon: Where are we and what have we learned?

- Why has Provenge worked when so many have failed?
- Does this success give any clear signals that we have broken through the issues that have caused cancer vaccines to fail so far?
- Can we extrapolate from this autologous vaccine to other cancer vaccine types?
- What are we learning regarding commercializing personalized therapies?
 - What are the pricing, reimbursement and positioning strategies?

Dr Mitchell Gold, President & CEO, Dendreon Corporation

5.25 Panel discussion
Examining the commercial potential of therapeutic cancer vaccines

- What are the next promising candidates and what stage have they reached?
- From a commercial standpoint what are the pros and cons of cancer vaccines versus other treatment modalities?

- How is big pharma assessing opportunities in the field: What are they looking for next?
- If cancer vaccines must be used in combination with other therapies, how will this impact trial design, regulatory pathways, and the ability to raise capital?
- Raising capital for the development of cancer vaccines: If survival is the endpoint then very few VCs will have the capital required for long clinical studies - how will the gap be filled?

Panelists:
Dr Allan P. Jarvis, Vice President, Corporate Development, sanofi pasteur
Dr Joyce Frey-Vasconcellis, Executive Director, PharmaNet
M. Juliana McElrath, MD, PhD, Member, FHCRC, & Professor of Medicine, University of Washington

5.50 End of day 1 followed by a themed cocktail reception in the exhibition area

7.30 Registration & buffet breakfast in the exhibition area

MORNING PLENARY SESSION

Analyzing the impact of the Obama administration's healthcare regime on the evolution of priorities for vaccines

9.00 Chair's introduction
Gregg C. Sylvester, MD, MPH, Head of Adult & Adolescent Vaccines for Medical Affairs & Policy, Merck Vaccines & Infectious Diseases

9.05 An update on universal healthcare legislation and its possible effects on the pharmaceutical industry, and vaccine R&D specifically

- Public funding and pricing strategies for new vaccine programs as part of a refocus on prevention and wellness in healthcare
- Will this create a new wave of opportunity for vaccine R&D based on non-traditional, non-routine-use targets?
 - If so what are the funding, reimbursement and commercialization models?
- What is the impact of new health delivery systems? What is their impact on innovation of new products?
Michael J. Werner, Partner, Holland & Knight

9.25 Questions & discussion

9.30 CDC update: What changes are afoot on the back of the healthcare reform package?

- How is the immunization schedule being impacted by the new administration?
- Are we moving towards real recommendations and vaccine schedules for the adolescent vaccine sector? If so, which diseases?
 - HPV has opened the door for this new age group – what's next?
 - Potential booster strategies for meningitis, varicella and pertussis
 - Potential demand for innovation in combination products
- Given the ageing population, what role could and should vaccines play in reducing the healthcare burden in this target group?
- How will the increasingly crowded vaccine schedule be managed?
 - What might be the impact on vaccine manufacturers?

Melinda Wharton, MD, MPH, Acting Director of National Centre for Immunization & Respiratory Diseases, Centers for Disease Control & Prevention

9.50 Questions & discussion

9.55 Update on the National Vaccine Plan

- Neglected diseases / tropical diseases are in the spotlight as a result of the stimulus package
 - How will the funds be allocated – what are the targets?
 - Will the funding open the door for truly neglected diseases, eg Dengue fever?
 - Which targets are feasible yet under-funded?
- What is needed on the technical side to effectively utilize the increase in funding?
- Should there be a list of prioritized vaccines?
Dr Bruce G. Gellin, Director, National Vaccine Program Office, Office of Public Health & Science, Office of the Assistant Secretary for Health, US Department of Health & Human Services

10.15 Questions & discussion

10.20 Vaccine programs for the adult market: Putting the infrastructure in place

- What incentives need to be put in place to stimulate demand for uptake of adult vaccines?
 - Performance measures across healthcare
 - Rewarding physicians for immunizing this age group
- How are discussions in the US progressing on the creation of an adult vaccine entitlement?
 - How to build the infrastructure with insurers
- Quantifying the health economic value of vaccines for 18+

- What data is available on lifetime value and price?
Isabelle Claxton, Director, Public Policy & Advocacy, GlaxoSmithKline Vaccines

10.40 Questions & discussion

10.45 Never assume anything: Successfully developing vaccines for US government customers

- Requirements vs. expectations, risks vs. benefits
- Building a successful team that includes the USG
- Managing risks in medical countermeasure development (where Murphy's Law reigns)
- Laying the groundwork for future success
Robert V. House, PhD, President, DynPort Vaccine Company LLC, A CSC Company

11.05 Panel discussion
What other vaccines are being prioritized?

- Making sure the vaccine pipeline addresses diseases for older populations: Clinical design and reformulation for pneumococcus, influenza, pertussis, RSV, nosocomial infections
- What are the Department of Defense's short and longer-term requirements?
 - What delivery systems and combination vaccines are they focusing on next?
- Are there any vaccine priorities besides influenza that are 'stockpileable'?
 Panellist:
Paula Bryant, PhD, Senior S&T Manager –Pretreatments, Chemical & Biological Technologies Directorate, Joint Science & Technology Office, Defense Threat Reduction Agency, US Department of Defense

11.30 Morning coffee in the exhibition area

FOLLOWED BY YOUR CHOICE OF 3 PARALLEL BREAKOUT SESSIONS:

FOCUS SESSION 1

Evaluating progress in influenza vaccine R&D: Advancing 2nd generation DNA vaccines, and striving for cross protection and the universal vaccine

12.10 Chair's introduction
What are the government's requirements for cross protection?

- How are we helping industry reach the holy grail of universal protection? What role do we see DNA vaccines playing?
Dr Michael Perdue, Director - Influenza & Emerging Diseases Program, Biomedical Advanced Research & Development Authority, Office of the Assistant Secretary for Preparedness & Response, US Department of Health & Human Services

Case studies of second-generation DNA vaccines

- What are the data that say that DNA vaccines work well enough in the clinic to become licensed products?
- How much promise do they hold for reducing development time versus traditional antigen-based vaccines?
- How might new delivery technologies help to ensure that the DNA vaccine is delivered properly in the right place to control dosage?
- Electroporation
- How is industry rallying against the perceived safety issues with DNA vaccines?
- What role might recombinant DNA vaccines have in the development of the universal flu vaccines?

12.30 Electroporation mediated DNA vaccination for influenza: Assessing the feasibility of seasonal, pandemic, and universal immunization strategies

- Characterization of cellular and humoral immunogenicity in animal models
- Synergy with conventional immunization modalities
- Analysis of protection against influenza challenge
- Issues associated with clinical implementation
Drew Hannaman, Vice President, R&D, Ichor Medical Systems, Inc

12.50 Questions & discussion

12.55 Delivery systems and adjuvants for DNA-based vaccines: Development of prophylactic and therapeutic vaccines

- Non-clinical development of a therapeutic poloxamer-formulated CMV DNA vaccine, TransVax™
- Interim Phase 2 clinical data of TransVax™ in hematopoietic stem cell transplant patients
- Non-clinical development of Vaxfectin®-adjuvanted pandemic influenza DNA vaccines
- Phase 1 clinical data of pandemic influenza vaccine
Dr Alain Rolland, Executive Vice President, Product Development, Vical

1.15 Questions & discussion

1.20 Buffet lunch in the exhibition area

Case studies: Universal influenza vaccine – the holy grail

- What's in the pipeline? What human data is available? Why do these companies feel they will succeed where others have failed?
- What do you target? How do you choose the strain? How do you neutralize a virus whose neutralization target is changing every day?
- What are the pros and cons of different approaches? How confident are they of finding correlates of protection of immunity? Can the response ever be too good?
- What are the issues around safety, and what are the potential regulatory pathways?

2.30 Challenges and the potential promise for universal influenza vaccines

- What is the potential of conserved epitopes for inducing broadly neutralizing antibodies?
- Is antibody-dependent cytotoxicity (the basis for M2-directed protection in animals) relevant to human disease?
- Can a vaccine based on inducing T cell immunity provide sufficient protection without an HA-inducing antibody component?
- What is the potential role for a vaccine that is effective against more severe disease but less so against moderate disease?
Dr John W. Shiver, Vice President, Worldwide Basic Research Franchise Head, Vaccines, Merck Research Laboratories

2.50 Questions & discussion

2.55 rDNA (protein based) HA vaccine

- How can we break out of the "flu virus grown in eggs" paradigm that has dominated thinking for 60 years?
- What kinds of data will be required to support a new approach based on HA?
- How has the swine flu pandemic revealed the weaknesses in the current system?
- If a global supply of flu vaccine was available, how would we distribute it?
Dr Alan Shaw, President & CEO, Vaxinnate

3.15 Panel discussion

- Can the universal influenza vaccine really slow down transmission and prevent infection or does it just ameliorate disease? In which case is it simply a therapy for the individual rather than resulting in herd protection?
- Is combination with the seasonal vaccine the ultimate answer?
- Could the universal influenza vaccine be used as a model for other viruses?
- The role of antibodies for treatment of pandemic influenza: How viable a concept is it in terms of both scientific principle and health economics?

3.35 Chair's closing summary

3.40 Close of session and of the Phacilitate Vaccine Forum Washington 2010, followed by afternoon tea

OR | FOCUS SESSION 2

How close are malaria and flavivirus vaccines to the market?

- Analyzing the latest clinical data for breakthroughs and next steps

12.10 Chair's introduction
How is the incidence of malaria evolving, both in the endemic areas and in the west?

- How is the call for elimination and eradication influencing the portfolio?
Christian Loucq, MD, Director, The PATH Malaria Vaccine Initiative

Malaria vaccines: Case studies from those furthest ahead in R&D

- What is the commercial promise and what is the latest clinical data?
- Regulatory and clinical pathway for novel adjuvants: What can be learned from the malaria vaccine trials?
- What is the regulatory pathway for T-cell mediated vaccines?
- What are the issues around how widespread the protection would be?

12.30 The RTS,S malaria vaccine candidate: Getting closer to the goal

- A synthesis of salient phase 2 data
- The ongoing phase 3 trial: design, status and expectations
- The regulatory pathway and strategy leading to licensure
- Getting ready for implementation: what needs to be done?
 - Demand forecast and commercial manufacturing
 - Policy decisions at the global and national public health levels
- Planning for vaccine procurement
 - On-the-ground readiness

Dr Joe Cohen, Vice President, Emerging Diseases & HIV Vaccines, Research & Development, GlaxoSmithKline Biologicals

12.50 Questions & discussion

12.55 Progress toward development of an attenuated sporozoite (whole organism) malaria vaccine

- What is the profile of a vaccine that could be used to eliminate infection from a geographic area?
- What are the challenges to developing such a vaccine?
- Making progress with a metabolically active, non-replicating malaria vaccine – addressing:
 - The manufacturing challenges
 - The logistical delivery challenges
 - The vaccine administration challenges

Stephen L. Hoffman, MD, Chief Executive & Scientific Officer, Sanaria Inc

1.15 Questions & discussion

1.20 Buffet lunch in the exhibition area

Flavivirus vaccines: Case studies from those furthest ahead in R&D

- Latest results from the clinic
- What are the pros and cons of the different vaccine technologies adopted?
- Use of chimerization as a means of generating live attenuated viral vaccines

2.30 Development of recombinant subunit vaccines for Flaviviruses

- Challenges in flavivirus vaccine development
- Application of recombinant subunit approaches to address challenges
- Update on recombinant subunit vaccines in development
 - West Nile virus
 - Dengue
 - Tick-borne encephalitis virus

Dr Beth-Ann Coller, Senior Vice President for Research & Development, Hawaii Biotech, Inc

2.50 Questions & discussion

2.55 Dengue
 Speaker to be announced

3.20 Panel discussion
Working with the regulatory requirements for toxicity testing for live attenuated viral vaccines that don't replicate effectively in animals: How are companies responding?

3.35 Chair's closing summary

3.40 Close of session and of the Phacilitate Vaccine Forum Washington 2010, followed by afternoon tea

OR | WORKSHOP

Financing and partnerships to bring novel enabling technologies to market for developed and developing world vaccine needs

12.10 Moderator's introduction
Are biotechs being bought for their platform technologies or their vaccine programs?
Seth Rudnick, Venture Partner, Canaan Partners

12.20 Panel discussion

- How are vaccine biotechs faring in the current economic downturn?
 - Do VCs and private equity view them differently from biotech working in other modalities?
 - How are the risks weighed up?
- What are VCs / private equity looking for in a company / technology and at what point do they find something compelling enough to provide seed or expanded funding?
- How attractive are biotechs with a business based on potential pandemic outbreak?
 - How do you put a value on any vaccine enabling technology aimed at pandemic?

Panellists:
Vic Schmitt, Venture Partner, Bay City Capital
John Clerici, Partner, McKenna Long & Aldridge

Small company / big company interplay: How does it all connect around manufacturing, supply chain, and the need for dose sparing?

- To what extent are big pharma really interested in working with smaller companies: What are they looking for?
- How much product variation are big pharma looking for in their pipelines?
 - To service 1st, and 3rd world needs – particularly for adjuvants and delivery systems
 - How much are big companies dependent on dose sparing – do they see a real need for it?
- When and how should they work together? How are goals aligned?
- Building sustainable partnerships for global pandemic and seasonal influenza vaccine needs
- What are the potential knock-on effects to be aware of when products are licensed to multiple partners?

12.55 Case study
Dr Rahul Singhvi, President & CEO, Novavax, Inc

1.15 Questions & discussion

1.20 Buffet lunch in the exhibition area

2.30 Case study
Eric Victory, Senior Director, Business Development, MedImmune

2.50 Questions & discussion

2.55 Case study
Development of a novel technology with worldwide manufacturing capabilities
Dr Vidadi Yusibov, Executive Director, Fraunhofer USA Center for Molecular Biotechnology

3.15 Panel discussion

3.35 Moderator's closing summary

3.40 Close of session and of the Phacilitate Vaccine Forum Washington 2010, followed by afternoon tea

Indicates a highly interactive workshop for a maximum of 30 participants



This is the full program as it stands on the date of printing. However, the agenda will continue to evolve as we approach the event, ensuring that only the most current and relevant topics are addressed in Washington this coming January. **Please visit www.phacilitate.co.uk/wv at any time to get updated with the latest developments.**

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We are offering a strictly limited number of sponsorship and exhibition opportunities to companies seeking to raise their profile with this uniquely influential audience.

The exhibition at the 2009 Washington meeting sold out weeks before the event for the third year in a row. We are already well on the way to replicating that success, with optimal booth spaces running short. To receive more information on exhibiting, or to find out about available sponsorship options (ranging from full event, workshop and cocktail reception packages to minor sponsorships, such as documentation memory sticks, program booklets and conference room drops), please don't hesitate to contact

David McCall
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AND REMEMBER! As an exhibitor at this meeting, you will have equal access to delegates and speakers at both the Washington Vaccine Forum 2010 and the co-located Cell & Gene Therapy Forum 2010 - over 500 senior life science executives with the authority to impact your business!

Comments from recent participants included:

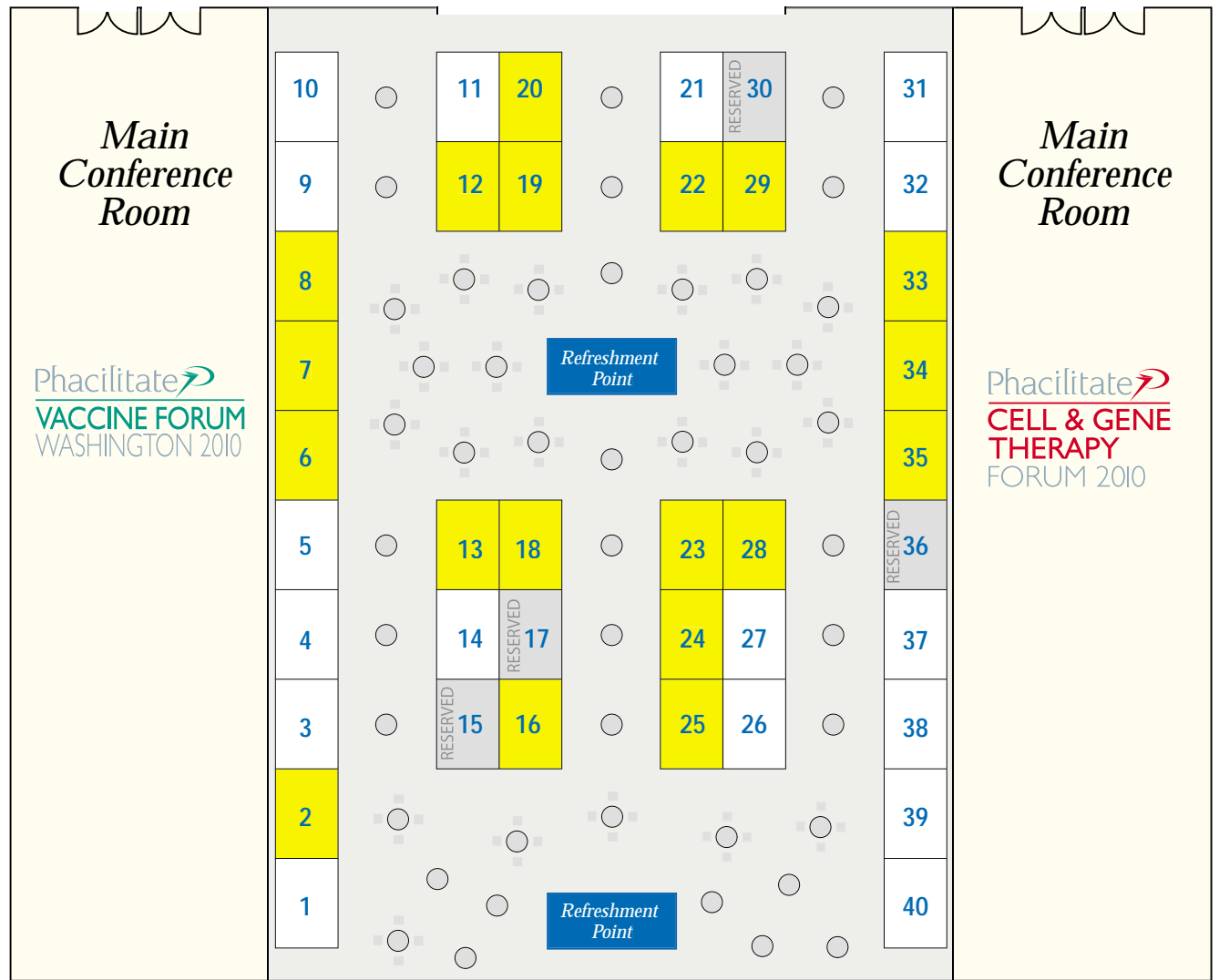
"I continue to find Phacilitate vaccine meetings to have strong speakers and agendas on a range of very timely topics"

Dr Ronald W. Ellis, Senior Vice President & Chief Technical Officer, NasVax Inc, United States (a subsidiary of NasVax Ltd, Israel)

"Excellent opportunity to connect with the vaccine industry's key players"

Dr Silke Fetzer, Head of Product Management, Cell Culture & Vaccine Operational Marketing, GE Healthcare

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- | | | | |
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| Booth 7 | PharmaNet Development Group | Booth 24 | BioLife Solutions, Inc |
| Booth 8 | Fisher Bioservices | Booth 25 | Beardsworth Consulting Group |
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Chrissie DeCesare, Marketing/Client Relations, VGXI Inc

"It really was a great event. I look forward to exhibiting again next year. Very informative and in a great setting that encouraged open dialogue and networking"

Megan Barth, Director of Sales, Pharmaceutical & Biotechnology, Sterigenics