

Phacilitate

VACCINE FORUM BARCELONA 2009

NEW FOR '09

Phacilitate

ACTIVE IMMUNOTHERAPEUTICS FORUM 2009

22-24 June, The Fira Palace
Barcelona

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2 conferences together for the first time in '09 - all networking shared!

Over 65 key decision-makers from the global vaccine and active immunotherapy communities are confirmed to speak, including:

Jean Stéphenne, President & General Manager, GlaxoSmithKline Biologicals

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 Allan P. Jarvis, Senior Vice President, Corporate Development, sanofi pasteur

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

Dr Derek O'Hagan, Vice President, Global Head, Vaccine Delivery Research, Novartis Vaccines & Diagnostics

Dr Helen Sabzevari, Global Head of Oncology-Immunotherapy, EMD Serono, Inc

Dr Nathalie Garçon, Vice President, Head of Global Adjuvant Centre for Vaccine Development, GlaxoSmithKline Biologicals

Dr Andrew Baum, Managing Director, Equity Research, Morgan Stanley

Dr Kanwarjit Singh, Senior Program Officer, Policy & Finance, Bill & Melinda Gates Foundation

Dr Samir N. Khleif, Head, Cancer Vaccine Section, NCI & Special Assistant to the Commissioner of the Food and Drug Administration

Heather L. Davis, PhD, Executive Director, Pfizer Global R&D, Vaccines Research; Site Head, Ottawa Laboratories

Dr Raf Lemmens, R&D Vaccine Program Leader, GE Healthcare Life Sciences

Dr Barry C. Buckland, Vice President, Bioprocess R&D, Merck Research Laboratories

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

Drs Ben Machielse, Executive Vice President, Operations, MedImmune, Inc

Professor Christoph Huber, Chairman, Department of Hematology/Oncology, Johannes Gutenberg-University, Mainz, Germany

Jacob Thrane, Equity Analyst (Healthcare), Standard & Poor's

Dr Vincent Brichard, Vice President, Cancer Immunotherapeutics, GlaxoSmithKline Biologicals

Dr René Labatut, Vice President, Global Manufacturing Technology, sanofi pasteur

Jim Self, Executive Director, Business Development, Global Vaccine & Infectious Diseases, Merck & Co, Inc

Dr Martin Friede, Research & Product Development (RPD), Initiative for Vaccine Research (IVR), World Health Organization

Dr Jeff Southerton, Executive Director, Worldwide Business Development, Pfizer Global R&D

Mae Shieh, Head, Business Development & Partnerships, Novartis Vaccines Institute for Global Health Srl (NVGH)

Dr Michael Pfeleiderer, Head of Viral Vaccines Section, Paul-Ehrlich-Institut

Gideon Kersten, Head, Assay Development & Analytical Development, Netherlands Vaccine Institute

Hans Küpper, Partner, Global Life Science Ventures GmbH

Dr Rahul Singhvi, President & CEO, Novavax, Inc

Dr Alan Shaw, President & CEO, VaxInnate Corporation

Dr Eszter Nagy, Vice President of Preclinical Research & Development, Intercell AG

Dr Jean-Yves Bonnefoy, Vice President, R&D, Transgene

Dr Martin Bachmann, CSO, Cytos Biotechnology AG

Dr Susan W. Barnett, Senior Director, Senior Project Leader, Viral Vaccine Research, Novartis Vaccines and Diagnostics, Inc

Dr Steve Chatfield, Director, Centre for Emergency Preparedness & Response, Health Protection Agency

Anders Peter Gram, Executive Vice President, Technical Operations, Bavarian Nordic A/S

Manfred Reiter, Director, R&D Upstream Process Development, Baxter BioScience

Dr Reiner Laus, CEO, BN ImmunoTherapeutics

Dr Habib Fakhrai, Executive Vice Chairman of the Board & CSO, NovaRX

Nicole Provost, PhD, Vice President, Product Development, Dendreon Corporation

Dr Alex Franzusoff, Vice President & Founding Scientist, GlobImmune, Inc

Dr Ted Bianco, Director - Technology Transfer, Wellcome Trust

Professor Angus Dalgleish, Research Director, Onyvox Limited

Dr Michael G. Hanna, Jr, Founder, Chairman & CEO, Vaccinogen, Inc

Alejandra Gurtman, MD, Director, Clinical Research, Wyeth Vaccines Research

Robert L. Coffman, PhD, Vice President & Chief Scientific Officer, Dynavax Technologies

Dr Salomé de Cambra, Senior Consultant, European Pricing & Reimbursement, RTI Health Solutions

Dr Gary Jennings, Vice President, Preclinical Development, Cytos Biotechnology

Dr Pierpaolo Correale, Medical Oncologist, Translational Immunooncology Unit, Medical Oncology Division, Siena University School of Medicine

Michele Pellegrini, MD, Clinical Development, Influenza Vaccines, Global Clinical Research & Development, Novartis Vaccines and Diagnostics

Dr Charles Richardson, Executive Vice President of R&D, LigoCyte Pharmaceuticals

Beth-Ann Collier, PhD, Senior Vice President for Research & Development, Hawaii Biotech, Inc

Dr Joyce Frey-Vasconcelles, Executive Director, PharmaNet Consulting, PharmaNet Development Group

Isabelle Fourthin, MD, General Manager, Genopoletic

Professor Giuseppe Pantaleo, Chief of the Division of Immunology & Allergy, Centre Hospitalier Universitaire Vaudois (CHUV), University of Lausanne, Switzerland

Dr Bernd Eisele, CEO, Vakzine Projekt Management GmbH

Professor Dr Achim Schneeberger, CMO, AFFIRIS GmbH

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

Dr Harpreet Singh, CSO, immatics biotechnologies GmbH

Carlota Dobaño, PhD, Assistant Research Professor, Barcelona Centre for International Health Research (CRESIB)

Dr Rinaldo Zurbriggen, CSO, Pevion Biotech

Julianna Lisziewicz, PhD, President & CEO, Genetic Immunity

Dr Deirdre McIntosh, Senior Regulatory Affairs Project Manager & Scientific Consultant, ERA Consulting (UK) Ltd

Dr R. J. Tesi, President & CEO, Coronado Biosciences

John M. Clerici, Partner, McKenna Long & Aldridge LLP

Frédéric Triebel, MD, PhD, Scientific & Medical Director, Immutep SA

Helen Young PhD, Director of Development, Cambridge Biostability Limited

Dr David Kirke, Senior Regulatory Affairs Project Manager, ERA Consulting Group

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9.00 - 11.10 - Your choice of 2 morning plenary sessions

Barcelona Vaccine Forum

Morning plenary session

Progress reports from industry trailblazers and global/national public health analysts: What are the short and long-term drivers of - and threats to - growth and commercial success?

9.00 Chair's introduction

Market drivers from the public health perspective: The role that the public sector can play in the development of vaccines

- Setting priorities and identifying opportunities
- Capabilities in vaccine development
- Vaccines for uncertain commercial market:
 - Biodefense and emerging disease

Dr Steve Chatfield, Director, Centre for Emergency Preparedness & Response, Health Protection Agency

9.10 Keynote address

HPV vaccine as a trailblazer: Progress made, lessons learned and future opportunities

- What impact has the vaccine had on the disease burden and epidemiology?
 - Has there been a change in nature of immunology?
 - How has it been used in the field?
 - What have been the obstacles to more widespread use?
- Feedback from post licensing studies
- What scope is there for expansion into further population groups?
 - What are the implications of the latest results from males and older women?
- Progress with second generation HPV vaccine
- How might these vaccines help open up new STD opportunities - both viral and bacterial eg Chlamydia and herpes simplex?
- Combined vaccination campaign HBV + HPV in young adults

Jean Stéphenne, President & General Manager, GlaxoSmithKline Biologicals

9.30 Questions & discussion

9.35 Presentation & panel discussion

Analysis of drivers and forecasts for growth in the vaccine sector for the next 5 years

- Progress and opportunities by disease area and by vaccine type - mass market cheap vs new sophisticated expensive targeted vaccines
 - Recombinant protein based
 - Therapeutic
 - Conjugates
 - Bacterial
 - Viral and bacterial vectored
 - Inactivated virus
- Technological breakthroughs - for new, cheaper vaccines and for tough targets - which technologies and peripherals will make greatest headway and impact?

- What pathways are emerging for technology-driven companies to initiate and continue clinical trials?
- Blockbuster vaccines
 - What are forecasts based on?
 - Are they overhyped?
 - Is it realistic to keep the current growth rates going? If so, with what targets?
- Rotavirus vaccine as a global trailblazer
 - What have been the greatest contributors to its global commercial success?
 - What lessons can others learn?

Panelists:

Dr Andrew Baum, Managing Director, Equity Research, Morgan Stanley

Jacob Thrane, Equity Analyst (Healthcare), Standard & Poor's

10.20 Update from the Gates Foundation

- What are the biggest breakthroughs and hurdles to date?
- How is risk:benefit being assessed in the current economic climate?
- How has the appetite for AMCs been affected?
- How are we moving forward globally on protection?

Dr Kanwarjit Singh, Senior Program Officer, Policy & Finance, Bill & Melinda Gates Foundation

10.40 Panel discussion

Sustainable funding for vaccines in the macro economic crisis: How will government and NGO funding be prioritized and allocated?

- How will the current global financial environment impact priorities and coordination of funding of vaccines for public health?
- How will we strive to identify promising new technologies pre proof-of-concept: What are the resourcing issues?
- Gates Foundation grant for highly novel ideas: Has anything promising emerged for vaccines?

Panelists:

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 Ted Bianco, Director - Technology Transfer, Wellcome Trust

11.10 Morning coffee in the exhibition area

Active Immunotherapeutics Forum

Morning plenary session

Learning lessons from experiences to date to make a compelling business case for active immunotherapy moving forward

9.00 Chair's introduction

Dr Allan P. Jarvis, Senior Vice President, Corporate Development, sanofi pasteur

9.10 Opening keynote address

Analysing the key successes and failures in active immunotherapy over the past 10-15 years: What lessons can be learned to inform ongoing R&D strategy?

- What major obstacles remain and how close are we to overcoming them?
 - What are the chief lessons from recent phase III clinical trials in particular?
 - What is the current state of technical understanding and where are the major gaps?

Professor Christoph Huber, Chairman, Department of Hematology/Oncology, Johannes Gutenberg-University, Mainz, Germany

9.30 Questions & discussion

9.35 What lessons can be learned from related therapeutic classes, such as passive immunotherapy, that have already spawned successfully marketed products?

- To what extent, and in what specific applications, can these breakthroughs be adopted as 'Proof of Concept' for the active immunotherapy field?
- In what areas might we see crossover to other indications, as has occurred in the passive immunotherapy field?
 - What would be the chief obstacles to achieving this crossover with a licensed active immunotherapeutic?

Dr Helen Sabzevari, Global Head of Oncology-Immunotherapy, EMD Serono, Inc

9.55 Questions & discussion

10.00 How will active immunotherapeutics fit in to the reimbursement picture?

- What will be the keys to getting your active immunotherapy added to a regimen?
- Dr Salomé de Cambra**, Senior Consultant, European Pricing & Reimbursement, RTI Health Solutions

10.20 Questions & discussion

10.25 Roundtable discussion

- Which indications present the real commercial opportunities moving forwards?
- When can we expect to see the breakthrough 'blockbuster' product that is widely expected from the field?
 - Will it come from a relatively well established technology platform, or will it stem from the next generation of technologies entering the clinic?
- What are the mechanisms of the markets driving the development of active immunotherapeutics, and how might current and future trends influence the R&D portfolio?
- What do you need to achieve in order to make your active immunotherapeutic competitive in applications where a small molecule product is already on the market?
- How should you think about positioning your active immunotherapeutic from the global perspective, both in terms of future clinical development strategy/opportunities and target markets?

11.10 Morning coffee in the exhibition area



11.50 - 3.50 - Your choice of 4 parallel sessions

Barcelona Vaccine Forum

Focus session

Capitalising on flexible, scaleable, multi-purpose manufacturing facilities and disposable, cost-effective manufacturing processes

11.50 Chair's introduction

A perspective on flexible manufacturing of vaccines

- Emerging production scenarios
- Focus on manufacturing efficiency improvements
- Conceptual thoughts - practical solutions

Dr Raf Lemmens, R&D Vaccine Program Leader, GE Healthcare Life Sciences

12.10 Questions & discussion

12.15 What are the key questions to ask as a vaccine manufacturer when considering the switch to flexible and/or disposable manufacturing processes and platforms?

- How to scale-up and down - and how to avoid re-validation each time
 - How to simulate the production process and scale-up procedure as early as possible
 - Integrating multiple use and disposable solutions: What is the decision-making process?
 - Being prepared for regulatory requirements concerning purity, virus clearance and validation of single use processes
 - What are the characterisation limitations still to be overcome?
 - What are the capacity, recovery and yield implications?
 - Impact on capex and opex pressures
- Anders Peter Gram**, Executive Vice President, Technical Operations, Bavarian Nordic A/S

12.35 Questions & discussion

Continued on next page >>

Workshop *i*

Creative approaches to the co-development of biologics: Licensing & partnering, collaboration and IP protection

11.50 Moderator's introduction

Necessity is the mother of invention: Innovative responses to the tough financial climate

- Trends and forecasts: What form is collaboration, licensing and partnering now taking, and how might the situation evolve in the short- and long-term?
- Where do we stand with IPOs at the moment: When are they forecast to come back?
- Exploring untapped, unexplored links between big biotech and the vaccine sector: Capitalising on well developed, innate manufacturing and scale-up capabilities

Jim Self, Executive Director, Business Development, Global Vaccine & Infectious Diseases, Merck & Co, Inc

12.10 Questions & discussion

Case studies of recent deals in the vaccine and active immunotherapy fields

- What were the strategic drivers behind recent investments by big pharma, particularly from newcomers to the area, and what are their ongoing plans for the development of the field?
- Examining big pharma's increasing role as a developer rather than a discoverer: What are they looking for from vaccine or active immunotherapy companies and what are their evaluation criteria?
- Engendering a collaborative / collegiate approach to licensing and partnering
- Ensuring access to, and untangling, IP - in particular for adjuvants and combination products

Continued on next page >>

Active Immunotherapy Forum

Focus session

Selecting and integrating the optimal combination therapy strategy into your oncology clinical development programme

- What are the strategic keys to operating successfully in the adjuvanted setting?

11.50 Chair's introduction

Dr Samir N. Khleif, Head, Cancer Vaccine Section, NCI & Special Assistant to the Commissioner of the Food and Drug Administration

Case studies

Examining the latest clinical strategies, trial designs and data for various combinations in the oncology active immunotherapy space, including combinations with:

- Chemotherapy
- Novel adjuvants
- Anti-CTLA-4
- IFN, IL-2 and other immunostimulants

12.05 How to incorporate the Standard of Care into your clinical development strategy? Speaker to be announced

12.25 Questions & discussion

Continued on next page >>

Workshop *i*

Optimising the value of preclinical R&D to increase the potential for success in the clinic

- What models and technologies can offer the predictive capabilities required to mitigate safety risk later in the R&D cycle?

11.50 Moderator's introduction

Heather L. Davis, PhD, Executive Director, Pfizer Global R&D, Vaccines Research; Site Head, Ottawa Laboratories

12.00 Regulatory perspective

What is the safety package required to progress to first-in-man trials with an active immunotherapeutic, and what types of data can support your animal model work?

- What are the key differences between US and European regulatory approaches/requirements in this area?

Dr Deirdre McIntosh, Senior Regulatory Affairs Project Manager & Scientific Consultant, ERA Consulting (UK) Ltd

12.25 Questions & discussion

12.35 Case study

Examining the pros and cons of animal models in practical application: What is the latest data to support their potential to predict safety issues and/or immunogenicity?

- Transgenic animal models
- Chimeric animal models

Dr Susan W. Barnett, Senior Director, Senior Project Leader, Viral Vaccine Research, Novartis Vaccines and Diagnostics, Inc

12.55 Questions & discussion

Continued on next page >>

Barcelona Vaccine Forum

Focus session continued

How are flexible, disposable manufacturing processes being applied to different vaccines, and how have companies approached:

- Up and down scalability
- Multi-purpose use
- Platform integration
- Validation and regulatory approval
- Performance assessment in terms of cost cutting, speeding time to market, dose sparing, capacity and yield
- Cost implications and impact on cost of goods

12.40 Optimisation of flexible, multipurpose cGMP pilot launch unit using disposable technology

- Process scalability - management by design
- Reducing cost of ownership and increasing efficiency
- Increasing speed to market for new products
- Increasing the potential for portfolio evolution

Dr René Labatut, Vice President, Global Manufacturing Technology, sanofi pasteur

1.00 Questions & discussion

1.05 Buffet lunch in the exhibition area

2.15 Multipurpose production facility: Vero and chicken cell derived vaccine technology platform with multi- and single-use components

- Achieving large scale flexibility
- What are the main areas of cost reduction?
- Experiences to date with a multipurpose vaccine platform

Manfred Reiter, Director R&D Upstream Process Development, Baxter BioScience

2.35 Questions & discussion

2.40 Hepatitis: A vaccine based on disposable bioreactors

- Comparison of disposable bioreactors to stainless steel
- Control of the flow pattern
- Up and down scalability

Dr Barry C. Buckland, Vice President, Bioprocess R&D, Merck Research Laboratories

3.00 Questions & discussion

3.05 Presentation followed by panel discussion

How are VLP based vaccines helping to shape the manufacturing processes of the future? What is the impact on:

- productivity and quality?
- cost of goods and capital expenditure?
- characterisation of products?
- potential for multi product facilities?

Dr Rahul Singhvi, President & CEO, Novavax, Inc

3.45 Chair's closing summary

3.50 Close of session followed by afternoon tea in the exhibition area

Workshop continued

12.15 Big pharma & biotech Acquisition as a growth strategy: The sanofi pasteur / Acambis transaction

- What were the drivers behind the deal?
- What were the evaluation criteria?
- Integrating big and small company cultures: What is the collaboration model?
- How did the biotech align itself for successful assimilation?

Dr Allan P. Jarvis, Senior Vice President, Corporate Development, sanofi pasteur

12.35 Questions & discussion

12.40 Big pharma / biotech deal-making: Pfizer's deals with Coley, Cytos and other examples

- The drivers behind the deals
- Evaluating potential partners
- The challenges of different business/deal models
- Ensuring successful implementation after the deal is done

Dr Jeff Southerton, Executive Director, Worldwide Business Development, Pfizer Global R&D

1.00 Questions & discussion

1.05 Buffet lunch in the exhibition area

2.15 Biotech & biotech

- What were the drivers behind the deal?
- What were the evaluation criteria?
- Integrating company cultures
- What is the collaboration model?
- To what extent has integration been necessary?
- How have the IP issues been resolved?

2.35 Questions & discussion

2.40 Do public-private partnerships provide a sustainable model for achieving global health goals?

- A review of public-private partnerships: what have we learned?
- NVGH, a neglected disease institute within big pharma: A case study in progress

Mae Shieh, Head, Business Development & Partnerships, Novartis Vaccines Institute for Global Health Srl (NVGH)

3.00 Questions & discussion

3.05 Panel discussion How can smaller companies and research institutions ensure that their activities are on the radar screen of big pharma and biotech?

- Demonstrating the market value of your product to potential investors and collaborators
- How to make your ideas and technology scalable
- How to position your technology and your offer
- When is going it alone a viable strategy?

3.45 Moderator's closing summary

3.50 Close of session followed by afternoon tea in the exhibition area

Active Immunotherapy Forum

Focus session continued

12.35 The significance of timing: When should you move from a monotherapy to combination therapy strategy?

- Considerations for developing a combination therapy strategy
- What are suitable surrogates (animal models, endpoints, etc) to support decision-making for combination therapies?
- Adoption of placebo-controlled trials early in clinical development of chemoimmunotherapy combination strategies

Dr Alex Franzusoff, Vice President & Founding Scientist, Globelmmune, Inc

12.55 Questions & discussion

1.05 Buffet lunch in the exhibition area

Case studies

How do you design your phase II trial in order to be able to make a sound decision at the end as to the regimen and combination for your phase III trial?

- How do you decide on the order in which your combination will be administered (eg chemo first and then the active biologic to 'mop up' at the end)?
- What are the pros and cons of the options available?

2.15 Blocking TGF-β in whole tumor cell vaccines: Preserving the response to frontline chemotherapy

- Effects on antigen presenting cells
- Effects on Treg cells
- Effects on immune activation
- Design and results of phase II clinical trials: how to find optimal phase III population?
- Design of phase III clinical trial

Dr Habib Fakhrai, Executive Vice Chairman of the Board & CSO, NovaRX

2.35 Questions & discussion

2.45 Chemoimmunotherapy of colon cancer

Dr Pierpaolo Correale, Medical Oncologist, Translational Immunooncology Unit, Medical Oncology Division, Siena University School of Medicine

3.05 Questions & discussion

3.15 Panel discussion Exploring the development of two or more unlicensed technologies in development as combination therapies

- What are the pros and cons, and what might the regulatory pathway look like?
- What collaboration management and IP issues arise, and how might they be addressed?

3.45 Chair's closing summary

3.50 Close of session followed by afternoon tea in the exhibition area

Workshop continued

1.05 Buffet lunch in the exhibition area

2.15 Case study Which translational medicine techniques and technologies can be utilised in the active immunotherapy space?

- Are they aiding in providing a better understanding of Mechanism of Action early in R&D?

Dr Bernd Eisele, CEO & CSO, Vakzine Projekt Management GmbH

2.35 Questions & discussion

2.45 Case study Viroosomal breast cancer vaccine - how did we successfully proceed to human trials?

- Viroosomal carrier system
- Preclinical data
- Phase I data
- Lessons we learnt

Dr Rinaldo Zurbriggen, CSO, Pevion Biotech

3.05 Questions & discussion

3.15 Panel discussion What more, if anything, can be done in preclinical R&D to predict long-term safety issues with active immunotherapeutics?

- Are there lessons that can be learned from past experiences?

3.45 Moderator's closing summary

3.50 Close of session followed by afternoon tea in the exhibition area

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4.30 - 5.30 - Shared afternoon plenary session

Sustainable funding in the current financial climate:

What are the keys to accessing alternative sources of finance and infrastructure support?

4.30 Roundtable discussion Taking the pulse of the financial markets, the venture capital community, and city states with regard to their expectations for the vaccine and active immunotherapy fields

- VC view - what trends do they see?
 - What do they want to see from vaccine and active immunotherapy companies?
- How might recent phase III 'failures' affect financing levels moving forwards?

- Exploring the potential to secure funding on a global basis. What opportunities are emerging from Asia in particular, and what are the keys to accessing this funding?
- City states and sovereign funds - how attractive is the vaccine/active immunotherapy market to them, how might they be incentivised to invest and what is their funding allocation criteria?
 - Technology transfer requirements - at what cost to public health globally?

Panellists:

- Hans Küpper**, Partner, Global Life Science Ventures GmbH
- John M. Clerici**, Partner, McKenna Long & Aldridge LLP
- Dr Ted Bianco**, Director - Technology Transfer, The Wellcome Trust
- Dr Andrew Baum**, Managing Director, Equity Research, Morgan Stanley

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

Media partners



9.00 - 11.15 - Shared morning plenary session

Great expectations: Advancing our understanding of the immune system to drive the development of next generation products and platform technologies

9.00 Chair's introduction
How is the mode of action of adjuvants driving R&D in vaccines and active immunotherapeutics?
Dr Martin Friede, Research & Product Development (RPD), Initiative for Vaccine Research (IVR), World Health Organization

9.20 Keynote address
The role of adjuvants in vaccine development
 • How might recent observations in biology and chemistry enable the development of safe and effective new vaccine adjuvants and immunotherapeutics?
 • What is an ideal adjuvant? Which vaccine targets will require novel adjuvants?

• Advancing our understanding of the mechanism of action of existing adjuvants to inform progress towards more rational adjuvant design
Dr Derek O'Hagan, Vice President, Global Head, Vaccine Delivery Research, Novartis Vaccines & Diagnostics
9.40 Questions & discussion

9.45 Short presentations followed by panel discussion
Expert review of the TLR field and other signalling receptors: What is the current state of the art and where are the key remaining gaps in our understanding?
 • Which ones to target with the adjuvant – one or multiple?
 - Applying locally and acting globally? – safety considerations

• Exploiting synergies between TR agonists and other signalling receptors that interact with the immune system
 • What are the alternatives to agonists - looking laterally at other receptors
 • Adjuvants for self protein based vaccines
 • Examples from prophylactics and therapeutics

Four speakers will each give a 10 minute review of their technology emphasising their key success so far and their key challenge going forward
 Speakers:
Heather L. Davis, PhD, Executive Director, Pfizer Global R&D, Vaccines Research; Site Head, Ottawa Laboratories
Dr Nathalie Garçon, Vice President, Head of Global Adjuvant Centre for Vaccine Development, GlaxoSmithKline Biologicals

Dr Alan Shaw, President & CEO, VaxInnate Corporation
Dr Eszter Nagy, Vice President of Preclinical Research & Development, Intercell AG

10.50 Next generation adjuvant formulations: Inducing the right immune response in the right place
 • Designing adjuvant molecules with enhanced activity for human cells
 • Designing formulations for intra-dermal delivery
 • Role of adjuvants and formulations for mucosal immunity
Dr Steve G. Reed, CEO, Immune Design & Founder, IDRI

11.10 Questions & discussion

11.15 Morning coffee in the exhibition area

12.05 - 3.50 - Your choice of 4 parallel sessions

Barcelona Vaccine Forum

Focus session

Formulation, delivery and stability: Advancements and opportunities in mucosal targets and other alternative routes of administration

Chair's introduction

12.05 What progress is being made with mucosal vaccine targets: Where do the greatest opportunities, and hurdles, lie?

- What's in the pipeline: Where are we making greatest R&D progress?
 - Gastrointestinal
 - Respiratory
 - Genital
- What are the challenges for formulation, delivery and stability?
- Platforms technologies for different mucosal targets
- What devices are needed to realise the opportunities?
- What forms of collaboration are required?

Drs Ben Machielse, Executive Vice President, Operations, MedImmune, Inc

12.25 Questions & discussion

12.30 Case study

Mucosal prime plus parenteral boost approaches for elicitation of protective immunity against HIV

- Preclinical data and results using recombinant viral vectors and proteins in adjuvant
- Phase 1 clinical results with adjuvanted protein vaccines
- Future directions for induction of protective immunity at mucosal sites

Dr Susan W. Barnett, Senior Director, Senior Project Leader, Viral Vaccine Research, Novartis Vaccines and Diagnostics, Inc

12.50 Questions & discussion

Alternative routes of administration: Case studies highlighting

- Where is the evidence they work? Data from immunogenicity and challenge studies
- Impact on immune response: Does it generate different immunity in different population groups such as infants or elderly populations?
- Strategy for regulatory success: What are the key hurdles remaining?
- How does the delivery route impact formulation?
- Economics of different routes of administration: What impact does it have on ease of distribution, dose sparing capabilities, stability and acceptability

12.55 Transcutaneous immunization with skin patch technology: A novel travellers ETEC vaccine

- Data from immunogenicity and Phase II study
- Impact on immune response and safety
- Strategy for regulatory success: what are the key hurdles remaining?

Dr Eszter Nagy, Vice President of Preclinical Research & Development, Intercell AG

1.15 Questions & discussion

1.20 Buffet lunch in the exhibition area

2.30 Bioneedles as vaccine carriers: A novel platform for needle free delivery of vaccines

- Biodegradable high velocity injectables for parenteral vaccine delivery
- Increased stability: avoiding the cold chain
- Dose sparing possibilities
- Preclinical development status: proof of principle, stability, universal applicability, formulation
- Product development and regulatory issues

Gideon Kersten, Head, Assay Development & Analytical Development, Netherlands Vaccine Institute

2.50 Questions & discussion

Continued on next page »

Workshop

Influenza vaccines: Is industry supplying what government and public health demand?

- Government funding and regulatory update
- Progress with the universal 'flu vaccine
- Improving protection of the elderly with novel adjuvants

12.05 Moderator's introduction

Dr David Kirke, Senior Regulatory Affairs Project Manager, ERA Consulting Group

12.10 Update from BARDA

Pandemic preparedness strategy and implementation: Funding, threat levels and stockpiling strategies

- Latest strategy and implementation progress – pandemic / pre-pandemic
- Funding commitments
- Role of vaccines and active immunotherapy in biological countermeasures
- Acceptability of cell-culture vaccine (cell-lines and substrates)

- Is strengthening pandemic vaccine preparedness leading to an overcapacity issue?
- Readiness of rapid response manufacturing technologies for pandemic 'flu
- What level of baseline protection against pandemic does the seasonal 'flu vaccine create?

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

12.30 Questions & discussion

12.35 Regulatory roundtable Dialogue with US and EU agencies to highlight degrees of harmonisation, and approaches to scientific advice and routes to approval

- Acceptability of new cell lines and substrates: How are authorities making decisions? What degree of harmonization is there?
 - What's the incentive to keep trying to get approval for new cell lines?
- What are the latest views on the value of animal models?
- Immune correlates and endpoints: What are the regulators looking for?
- Acceptability of and regulatory pathways for - New adjuvants
 - New routes of administration to target new segments and/or improve efficacy in 'flu
- Impact of the Vaccine Antigen Master File

Dr Norman W. Baylor, Director, Office of Vaccines Research & Review (OVRR), CBER, US Food & Drug Administration
Dr Michael Pfeleiderer, Head of Viral Vaccines Section, Paul-Ehrlich-Institut

1.20 Buffet lunch in the exhibition area

2.30 Progress with the realisation of the universal 'flu vaccine: What does the data indicate so far?

- Update on M2 (and M3 / M1)
- Demonstrating efficacy for cross protection against a number of serotypes
 - What are the immune correlates?
- What role do animal models play?
- Latest data from early clinical trials
- How will novel adjuvant and vector technologies be deployed?
- Planning ahead for formulation and delivery
- What's the route to licensure?

Dr Alan Shaw, President & CEO, VaxInnate Corporation

2.50 Questions & discussion

Continued on next page »

Active Immunotherapy Forum

Focus session

How can the innovative application of biomarkers and novel endpoints be used to optimise your oncology clinical trial design strategy?

12.05 Chair's introduction

Dr Alex Franzusoff, Vice President & Founding Scientist, GlobelImmune, Inc

Case studies

How is the development and application of novel biomarkers and surrogate endpoints evolving in practice and with what results to date?

- At what stage did we commence biomarker R&D, and how was it integrated into the active immunotherapeutic development programme?
- How are we approaching the challenge of validation? What is the regulatory pathway?

12.15 Therapeutic vaccines against non-small cell lung cancer

- Scientific rationale

- Synergy with other cancer treatments
- Clinical results
- Biomarkers signature

Dr Jean-Yves Bonnefoy, Vice President, R&D, Transgene

12.40 Questions & discussion

12.50 Presentation to be announced

1.10 Questions & discussion

1.20 Buffet lunch in the exhibition area

2.30 Increasing the pool of long-lived Effector-Memory CD8 T cells in patient's blood with IMP321 (LAG-3lg): A reliable endpoint in cancer immunotherapy?

- Long-lived Effector-Memory CD8 T cells versus fully differentiated effector CD8 T cells in patient's blood: A more relevant endpoint
- The immunoadjuvant effect of chemotherapy: New facts
- The immunoadjuvant effect of IMP321 (LAG-3lg): Increase of the long-lived CD28+ Effector-Memory CD8 T cell pool
- Rationale for combination therapy (chemo-immunotherapy)
- The immunoadjuvant effect of IMP321 given the day after paclitaxel as a first-line therapy for metastatic breast cancer

Frédéric Triebel, MD, PhD, Scientific & Medical Director, Immunet SA

2.50 Questions & discussion

2.55 Delayed Cutaneous Hypersensitivity (DCH) is a marker for the demonstration of the functional immunogenicity of the autologous colon tumor cell vaccine, OncoVAX

Dr Michael G. Hanna, Jr, Founder, Chairman & CEO, Vaccinogen, Inc

3.15 Questions & discussion

Continued on next page »



Workshop

Delivering the latest clinical trial designs and data from leading non-oncology active immunotherapeutic candidates in development

- What progress is being made in enhancing both the safety and efficacy of active immunotherapies for emerging indications?

12.05 Moderator's introduction

Professor Angus Dagleish, Research Director, Onyvx Limited

Case studies

Clinical development updates from key application areas outside of the oncology space

- How are the clinical development models developing in step with evolving regulations and the emergence of technological breakthroughs with the potential to deliver validated biomarkers and surrogate endpoints, such as imaging?

12.15 AFFITOPE vaccines for Alzheimer's disease: From concept to clinical testing

- The AFFITOPE concept – why using AFFITOPES of Aβ rather than Aβ itself? Implications for vaccine design, composition, safety and efficacy.
- POC data: Assessing the effect of AFFITOPE vaccines targeting neopeptides of Aβ in animal models of Alzheimer's disease.
- First-in-man studies of AFFITOPE vaccines AD01 and AD02: Early data on their safety, tolerability and immunogenicity in Alzheimer patients.

Professor Dr Achim Schneeberger, CMO, AFFIRIS GmbH

12.40 Questions & discussion

12.50 Vaccination against hypertension: Clinical Proof of Concept

- Virus-like particle
- Chronic disease
- Half-life of clinical efficacy

Dr Martin Bachmann, CSO, Cytos Biotechnology AG

1.10 Questions & discussion

1.20 Buffet lunch in the exhibition area

2.30 HIV

- What progress is being made in understanding and countering regulatory immune responses and drug resistance caused by genetic diversity?

Julianna Lisiewicz, PhD, President & CEO, Genetic Immunity

2.50 Questions & discussion

2.55 Perspectives on immune-based intervention in HIV infection

- HIV chronic infection
- Immune-based intervention
- Role of therapeutic vaccine
- Role of immunoregulatory molecules


Professor Giuseppe Pantaleo, Chief of the Division of Immunology & Allergy, Centre Hospitalier Universitaire Vaudois (CHUV), University of Lausanne, Switzerland

3.15 Questions & discussion

3.20 Panel discussion

3.45 Chair's closing summary

3.50 Close of session followed by afternoon tea in the exhibition area

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Barcelona Vaccine Forum

Focus session continued

2.55 State of the art stability and cold chain avoidance for reformulation of existing vaccines and for novel vaccine technologies

- Effectiveness with different routes of administration
- Quantifying the lifespan expansion of different formulations
- What impact does it have on immunogenicity?
- What are the economic implications?

Helen Young PhD, Director of Development, Cambridge Biostability Limited

3.15 Questions & discussion

3.20 Panel discussion

How are novel adjuvants being used in combination with alternative delivery methods and targets to enhance immunogenicity?

- Broadening and differentiating the response
- What combinations are showing greatest promise for enhancing the response elicited in adult and elderly populations?

3.45 Chair's closing summary

3.50 Close of session followed by afternoon tea in the exhibition area

Workshop continued

2.55 Addressing a major unmet medical need: More efficient influenza vaccines for the elderly

- Impact of influenza in the elderly
- Age-related changes of the immune system and their impact on influenza vaccination
- Expectations from adjuvanted seasonal vaccines - are they efficacious or not in the elderly?
- What data is needed to convince registration authorities and doctors that the adjuvanted vaccine is more effective?

Michele Pellegrini, MD, Clinical Development, Influenza Vaccines, Global Clinical Research & Development, Novartis Vaccines and Diagnostics

3.15 Questions & discussion

3.20 Case study

Highlighting the clinical milestones to date: What progress is being made with respect to immune response in healthy adults?

- What predictive immune responses are you measuring and why?
- Demonstrating proof of concept
- Assessing immune responses - particularly in the most vulnerable target groups Clinical development strategy
- Latest clinical data

Dr Rahul Singhvi, President & CEO, Novavax, Inc

3.40 Questions & discussion

3.45 Moderator's closing summary

3.50 Close of session followed by afternoon tea in the exhibition area

Active Immunotherapy Forum

Focus session continued

3.20 Panel discussion
What is the most reasonable primary endpoint for oncology active immunotherapy?

- How can we tie what we know about the Mechanism of Action of active immunotherapeutics into biomarker development and clinical trial design?
 - What repercussions will this have on the classical oncology clinical development model?
- How can the industry capitalise on the potential of novel imaging technologies to accelerate clinical development of active immunotherapeutics?
 - What are the keys to successfully and efficiently building an imaging component into your clinical trial design?

3.45 Chair's closing summary

3.50 Close of session followed by afternoon tea in the exhibition area

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Hilde de Winter, Medical Director, GENimmune

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Drew Hannaman, Vice President, R&D, Ichor Medical Systems, Inc

"The Phacilitate Vaccine Forum offers a great mix of regulators, industry and academia. Locations are always excellent"

Dr Roeland van Dam, Marketing & Business Development, Netherlands Vaccine Institute

4.30 - 5.30 - Your choice of 2 afternoon plenary sessions

Barcelona Vaccine Forum

Bringing novel adjuvants to market: Gaining clarity on regulatory pathways and clinical data requirements upon which to build the business model

4.30 Chair's opening keynote presentation
Industry perspective: What does/will it take to commercialise a novel adjuvant?

- Lessons learn from existing vaccines on the need for adjuvants in new vaccines
- Demonstrating the value of a new adjuvant preclinically and clinically

- How can we demonstrate safety of new adjuvanted vaccines?

Dr Nathalie Garçon, Vice President, Head of Global Adjuvant Centre for Vaccine Development, GlaxoSmithKline Biologicals

4.50 Questions & discussion

4.55 Regulatory roundtable discussion

- What preclinical models make sense for novel adjuvants?
- What should the safety, reactogenicity and efficacy package look like?
- What are the issues when testing in children and the elderly?
- Where should the balance be between dose sparing, enhanced immunology and other effects?

- Progress on future licensure for standalone adjuvants - and implications for industry
- Progress on fast track regulation: Update on the Priority Review Voucher Scheme and its impact so far
- How might it revolutionise the vaccine and adjuvant approval process?

- What is the economic value of the Vouchers?
- What will it take for the experimental medicine approach to come to adjuvanted vaccines?

Panelists:

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

Dr Martin Friede, Research & Product Development (RPD), Initiative for Vaccine Research (IVR), World Health Organization

Dr David Kirke, Senior Regulatory Affairs Project Manager, ERA Consulting Group

Leave space for one more
Dr Michael Pfeleiderer, Head of Viral Vaccines Section, Paul-Ehrlich-Institut

5.30 End of day 2 followed by a themed cocktail reception in the exhibition area

Active Immunotherapy Forum

Addressing fundamental strategic questions to inform your target selection strategy

4.30 Short presentations and panel discussion

- Active immunotherapy or prophylaxis?
 - How to make the strategic choice of your fundamental approach to a target such as HSV, where either has potential?
- Can one minimise the risk of potential safety

issues caused by the elicitation of an immune response through one's target selection?

- Immunostimulation or suppression?
 - How do you choose the appropriate approach for a new target?
 - What are the pros and cons of each approach in specific fields?
- What are the criteria for selecting the part of the immune system that you wish to engage? (TLRs, T cells, etc)

Chair:

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

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

Dr Jean-Yves Bonnefoy, Vice President, R&D, Transgene

Dr Susan W. Barnett, Senior Director, Senior Project Leader, Viral Vaccine Research, Novartis Vaccines and Diagnostics, Inc

5.30 End of day 2, followed by a cocktail reception in the exhibition area



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The Minister of Health, Welfare and Sports supervises the NVI. The NVI has about 400 employees and an annual turnover of approximately 80 million euros. The NVI collaborates with many (inter)national public and private partners.

The NVI guarantees the supply of vaccines against infectious diseases for the Dutch population. The vaccines are used in the regular national vaccination programs and for emergency vaccination campaigns. More specifically, the tasks of the NVI are:

1. To supply high-quality vaccines for the national vaccination needs in a timely way and at affordable prices. The vaccines are produced in the NVI's own production facilities or they are purchased.
2. To research and develop new vaccines.
3. Maintaining a knowledge base about vaccines and vaccination for the Department of Health.

www.nvi-vaccin.nl

9.00 - 11.25 - Your choice of 2 morning plenary sessions

Barcelona Vaccine Forum

Morning plenary session

Future blockbusters and ongoing tough targets: How are companies steering products through the entire development phase to demonstrate risk:benefit?

9.00 Chair's introduction
Dr Ronald W. Ellis, Senior Vice President & Chief Technology Officer, NasVax Ltd

9.05 13 valent pneumococcal conjugate vaccine

- Licensure criteria
- Overview of phase 3 clinical program
- Key clinical data

Alejandra Gurtman, MD, Director, Clinical Research, Wyeth Vaccines Research

9.25 Questions & discussion

9.30 Development of vaccines to prevent Norovirus Acute Gastroenteritis

- Norovirus epidemiology
- Unique challenges for Norovirus vaccine development
- Formulation development
- Preclinical studies including safety/toxicology
- Clinical development strategy
- Human Norovirus challenge protection studies to assess surrogates of protection

Dr Charles Richardson, Executive Vice President of R&D, LigoCyte Pharmaceuticals

9.50 Questions & discussion

9.55 HEPLISAV™ - Investigational Hepatitis B vaccine adjuvanted with a TLR9 agonist

- Use of a novel adjuvant: 1018 ISS - an agonist for TLR9
- Phase 2 clinical studies - optimisation of 2 dose regimen
- Enhanced responsiveness in older adults.
- Results of the PHAST Trial - a Phase 3 trial of HEPLISAV v Engerix-B
 - Overall safety
 - Immunogenicity

Robert L. Coffman, PhD, Vice President & Chief Scientific Officer, Dynavax Technologies

10.15 Questions & discussion

10.20 Panel discussion
Progressing future blockbusters, improving vaccines that aren't efficacious enough, and developing vaccines for the ageing population: Where should our priorities lie?

- RSV
- CMV
- Zoster
- Pertussis
- Staph aureus and other nosocomial infections

11.25 Morning coffee in the exhibition area

Active Immunotherapeutics Forum

Morning plenary session

How are regulators and industry alike progressing towards a defined regulatory pathway for active immunotherapeutics?

- How are guidelines evolving in Europe and the US, and what are key differences between the two?

9.00 Chair's introduction
Dr Joyce Frey-Vasconcells, Executive Director, PharmaNet Consulting, PharmaNet Development Group

US and European perspectives
How is the regulatory environment for active immunotherapy developing on either side of the Atlantic?

- Examining the impact on the field to date of recent regulatory guidelines and initiatives

9.10 Cancer biomarkers, the Critical Path and immunotherapeutics - where do we stand?

Dr Samir N. Khleif, Head, Cancer Vaccine Section, NCI & Special Assistant to the Commissioner of the Food & Drug Administration

9.30 European regulatory perspective

Dr Michael Pfeleiderer, Head of Viral Vaccines Section, Paul-Ehrlich-Institut

9.50 Questions & discussion

Industry case studies

10.00 Preclinical development of Immunodrugs™ - pathways to the clinic for therapeutic B cell vaccine

- Key safety considerations
- Guidance from regulatory authorities
- Nonclinical testing programmes
- Development strategies

Dr Gary Jennings, Vice President, Preclinical Development, Cytos Biotechnology

10.20 Questions & discussion

10.25 Experiences in achieving trial authorisation with different European national authorities

- How and why did we submit cancer vaccine trial applications to more than 10 European authorities?
- What issues did we encounter with different authorities in Europe and how were they addressed?
- What do we recommend to companies who plan to do multi-national trials in Europe?

Dr Harpreet Singh, CSO, immatics biotechnologies GmbH

10.45 Questions & discussion

10.50 Roundtable discussion

Long-term follow-up requirements for active immunotherapeutics

- How can industry and regulator work together to progress understanding of the reversibility of induced responses and on how well you can control them?
- How much follow-up could be done post-licensure, potentially?

11.25 Morning coffee in the exhibition area

12.05 - 3.50 - Your choice of 3 parallel sessions

Barcelona Vaccine Forum

Plenary session

Progress with vaccines for tropical and/or emerging infectious diseases

- How is migration and climate change impacting the commercial viability of these vaccines?

A series of case studies addressing

- Market size and need
- Impact of global migration / global warming on prevalence in western markets
- Travellers vaccine market: Do you need different vaccines for endemic populations and travellers?
- Risk: benefit assessment in different population segments and age groups
- Pre-clinical safety: Animal models for pathology vs immunology
- Progress in the clinic: Strategy for clinical and regulatory pathways
- Will the Priority Review Voucher program have any impact on these diseases?

12.05 Development of a recombinant subunit vaccine for West Nile Virus

- Overview of epidemiology/disease burden for West Nile virus
- Preclinical safety and efficacy of HBI vaccine candidate
- Preliminary results of Phase 1 clinical trial of HBI candidate
- Development pathways for a West Nile vaccine

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

12.25 Questions & discussion

12.30 Malaria: Understanding protective immunity to malaria during the conduct of a phase III vaccine trial

- Challenges of malaria vaccine development
- Types of malaria vaccines under development
- Past studies addressing mode of action of malaria vaccines
- Plans for studying correlates of immunity of RTS, S/AS01E, a GlaxoSmithKline vaccine candidate

Carlota Dobaño, PhD, Assistant Research Professor, Barcelona Centre for International Health Research (CRESIB)

12.50 Questions & discussion

12.55 Development of a live vaccine (rBCGΔureC::Hly/VPM1002) against tuberculosis

- Unique challenges for rBCG vaccine development
- Project management with a European consortium of partners
- Process development for GMP material
- Preclinical program including challenge, safety and toxicology studies
- Immunogenicity testing in phase I
- Clinical development strategy for endemic areas

Dr Bernd Eisele, CEO & CSO, Vakzine Projekt Management GmbH

1.15 Questions & discussion

1.20 Buffet lunch in the exhibition area

2.30 Title of case study to be announced

Dr Steve Chatfield, Director, Centre for Emergency Preparedness & Response, Health Protection Agency

2.50 Questions & discussion

2.55 Panel discussion
What lessons can be learned regarding the development and commercialisation path for tropical / emerging infectious diseases?

- What can industry learn from changing patterns of disease distribution?
- How is migration and climate change impacting the commercial viability of these vaccines?

3.30 Afternoon tea and close of the Barcelona Vaccine Forum 2009

Active Immunotherapy Forum

Focus session

How are innovative trial designs overcoming the challenges in targeting and accessing the most appropriate patient populations for oncology active immunotherapeutics?

12.05 Chair's introduction

Dr Habib Fakhrai, Executive Vice Chairman of the Board & CSO, NovaRX

12.10 How should one approach the challenge of accessing healthier patients?

- Should we enroll "healthier patients" in clinical trials?
- How do we define "healthier patients"?
- The challenge of designing a trial for "healthier patients"?
- Advantage and peril of using surrogate end-points for trial design

Dr R. J. Tesi, President & CEO, Coronado Biosciences

12.35 Questions & discussion

12.45 Case study

Reaping the benefits of affecting patient immune status prior to dosing

- How to build this strategy into your clinical trial design?
- Professor Angus Dalgleish**, Research Director, Onyx Limited

1.10 Questions & discussion

1.20 Buffet lunch in the exhibition area

Case studies

Patient stratification in active immunotherapy clinical trial design: What has been the impact to date on efficacy?

2.30 Patient selection for Proof of Concept in active immunotherapy

- Selection of target population
- Endpoints
- The place of clinical vs immuno read-outs
- Strategy to get Proof of Concept and Phase III design
- Predictive biomarkers

Dr Vincent Brichard, Vice President, Cancer Immunotherapeutics, GlaxoSmithKline Biologicals

2.50 Questions & discussion

2.55 Clinical trial designs to determine clinical activity of active immunotherapies of prostate cancer

- Biology of prostate cancer immunotherapy
- Endpoints and outcomes of Phase I studies
- Analysis of the outcome of a randomized, placebo-controlled 125 patient study of PROSTVAC™, a therapeutic prostate cancer vaccine
- Implications for designs of pivotal studies

Dr Reiner Laus, CEO, BN Immunotherapeutics

3.15 Questions & discussion

3.20 Panel discussion

What role will active immunotherapy play in driving the evolution of personalised medicine in the oncology field?

- What opportunities are there in reality for developing a treatment regimen based on someone's specific tumour, and how might active immunotherapy fit into the picture?

3.45 Chair's closing summary

3.50 Afternoon tea & close of the Phacillate Active Immunotherapeutics Forum 2009

Workshop

Overcoming the key remaining challenges in the process development and product characterisation of active immunotherapeutics

12.05 Moderator's introduction

Honing your dosing strategy: How do you define a manufacturable dose?

- How should you integrate your chosen dosing strategy with your process development strategy?

12.35 Questions & discussion

12.45 Case study

What constitutes a potency assay for an active immunotherapy? How is a company in Phase III trials addressing this question?

Nicole Provost, PhD, Vice President, Product Development, Dendreon Corporation

1.10 Questions & discussion

1.20 Buffet lunch in the exhibition area

2.30 Delivering strategic solutions to manufacturing and product characterisation challenges with allogeneic therapies

- How do you characterise an allogeneic cell line sufficiently to achieve licensure?
- How can you optimise your definition of Mechanism of Action and potency assay in order to overcome comparability issues, particularly with scale-up?
 - How well can you characterise your product *in vitro* in context of its performance *in vivo*?
 - How do you demonstrate comparability of an allogeneic active immunotherapeutic product without doing a clinical trial every time every time something changes in the manufacturing process?

Dr Joyce Frey-Vasconcells, Executive Director, PharmaNet Consulting, PharmaNet Development Group

2.50 Questions & discussion

3.00 Case study

Delivering strategic solutions to manufacturing and product characterisation challenges with autologous therapies

- How to build and validate a phase III scale GMP manufacturing facility for an autologous cell therapy?
- How do you tackle issues caused by the impact of a patient's existing drug regimen on their cells?
- Defining and addressing the chief CMC challenges in the oncology field

Isabelle Fourthin, MD, General Manager, Genopietic

3.20 Questions & discussion

3.30 Panel discussion

3.45 Moderator's closing summary

3.50 Afternoon tea & close of the Phacillate Active Immunotherapeutics Forum 2009



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