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ACTIVE IMMUNOTHERAPEUTICS FORUM:

- Dr Mitchell H. Gold**, President & CEO, Dendreon Corporation
- Dr Axel Hoos**, Medical Lead, Immunology/Oncology, Bristol-Myers Squibb
- Dr Helen Sabzevari**, Global Head of Oncology-Immunotherapy, Merck Serono
- Dr Samir N. Khleif**, Head, Cancer Vaccine Section, NCI
- Dr Steve Gracheck**, Executive Director, Vaccine Research - La Jolla, Pfizer Global R&D
- Wim Tiest**, Director, Head, Portfolio Strategy & Business Operations, Immunotherapeutics Business Unit, GlaxoSmithKline Biologicals
- Dr Thomas Hinz**, Department of Immunology, Paul-Ehrlich-Institute
- Dr Thomas A. Davis**, CMO & Senior Vice President, Clinical Development, Celldex Therapeutics
- Dr Susan W. Barnett**, Senior Director, Senior Project Leader, Viral Vaccine Research, Novartis Vaccines and Diagnostics, Inc
- Dr Hideki Garren**, Co-founder & Vice President of Research, Bayhill Therapeutics, Inc
- Jens-Peter Marschner, MD**, Head, Immunological Programs, Global Early & Clinical Development Units Oncology, Merck KGaA
- Dr Philippe Pouletty**, Co-Founder & General Partner, Life Sciences, Truffle Capital
- Poul Sorensen, PhD**, Vice President, Global Research, ALK
- Dr David L. Urdal**, CSO, Dendreon Corporation
- Fernando Ulloa-Montoya, PhD**, Head of Molecular Biology Technology Group, Cancer Immunotherapy, GlaxoSmithKline Biologicals
- Markus Muenz**, Group Leader, EpCAM Research, Micromet AG
- Charles A. Nicolette, PhD**, Chief Scientific Officer, Vice President, R&D, Argos Therapeutics, Inc
- Neil L. Berinstein MD**, Chief Scientific Officer, IRX Therapeutics
- Daniel L. Levey, PhD**, Senior Director, Business Development, Antigenics Inc
- Professor Alexander Von Gabain**, Strategic Advisor to the Board, Intercell AG
- Dr Jean-Yves Bonnefoy**, Vice President, R&D, Transgene SA
- Dr Martin Bachmann**, CSO, Cytos Biotechnology AG
- Professor Dr C. J. M. Melief**, Professor of Immunology, Department of Immunohaematology & Blood Transfusion, Leiden University Medical Center
- Dr Harpreet Singh**, CSO, immatics biotechnologies GmbH
- Reiner Laus, MD**, President & Chief Executive Officer, BN ImmunoTherapeutics
- Dr Joyce Frey-Vasconcellis**, Executive Director, PharmaNet Consulting, PharmaNet Development Group
- Philippe Moingeon, PhD**, Vice President, R&D, Stallergenes SA

- Carlos F. Santos, PhD**, Director of Regulatory Affairs & Product Development, Accentia Biopharmaceuticals / Biovest International
- Professor Angus Dalgleish**, Professor of Oncology, St George's, University of London
- Dr Joseph Sinkule**, Founder, Director, & CSO, Aphera, Inc
- Judith Quinlan**, Vice President, Adaptive Trials, Cytel
- Pierre Vandepapelière, MD, PhD**, Chief Medical Officer, Neovacs
- Dr Habib Fakhrai**, Executive Vice Chairman of the Board & CSO, NovarX
- Dr Ulrich Granzer**, Granzer Regulatory Consulting & Services
- Dr Ronald W. Ellis**, Senior Vice President & Chief Technology Officer, NasVax Ltd, Israel
- Dr Ingólfur Johannessen**, Clinical Lecturer in Virology, College of Medicine & Veterinary Medicine, University of Edinburgh & Royal Infirmary of Edinburgh

BARCELONA VACCINE FORUM:

- Dr Marie-Paule Kiény**, Director, Initiative for Vaccine Research, World Health Organization
- Dr David Salisbury**, Director of Immunisation, UK Department of Health
- Dr Rino Rappuoli**, Global Head, Vaccines Research, Novartis Vaccines & Diagnostics
- Dr Robin Robinson**, Director & Deputy Assistant Secretary, 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**, Vice President, Corporate Development, sanofi pasteur
- Dr Beth P. Bell**, Associate Director for Science, National Center for Immunization & Respiratory Diseases, CDC
- Dr Udit Batra**, Head, Global Public Health & Market Access, Novartis Vaccines & Diagnostics
- Dr N. Regina Rabinovich**, Director, Infectious Diseases Development, The Bill & Melinda Gates Foundation
- Yves Leurquin**, Executive Vice President, International & Government Affairs, Crucell NV
- Theresa Finn, PhD**, Associate Director for Regulatory Policy, OVR, CBER, US Food & Drug Administration
- Dr Norbert Hehme**, Vice President, Global External Relations GIO, GlaxoSmithKline Biologicals & Chair, IFPMA Influenza Vaccine Supply International Task Force
- Dr Peter Richardson**, Head of Biologicals, Quality of Medicines Unit, European Medicines Agency
- Dr Shen Xinliang**, Director-General, National Vaccine & Serum Institute & National Engineering Research Center for Novel Vaccines, China
- Dr Ernst C. Soethout**, Senior Research Scientist, Netherlands Vaccine Institute
- Dr Derek O'Hagan**, Vice President, Global Head, Vaccine Delivery Research, Novartis Vaccines & Diagnostics

- Dr John W. Shiver**, Vice President, Global Vaccines Discovery & Basic Research, Merck Research Laboratories
- Dr Ted Bianco**, Director - Technology Transfer, The Wellcome Trust
- Dr Andrew Baum**, Managing Director, Equity Research, Morgan Stanley
- Una S. Ryan, OBE, PhD**, President & CEO, Diagnostics For All
- Dr Rahul Singhvi**, President & CEO, Novavax, Inc
- Dr Antoon Gijssens**, Policy Officer, Unit SANCO C3 - Health Threats, European Commission
- Jan Reid**, Senior Director, Vaccines Licensing, Pfizer R&D Business Development
- Peter Welford, CFA**, Director, European Healthcare Equity Research, Jefferies International Limited
- Dr Philippe Pouletty**, Co-Founder & General Partner, Life Sciences, Truffle Capital
- Dr Sanjay Singh**, CEO, Gennova Biopharmaceuticals Limited
- Dr Marco Cavaleri**, Head of Anti-Infectives & Vaccines, Safety & Efficacy of Medicines Unit, European Medicines Agency
- Dr Alan Shaw**, President & Chief Executive Officer, VaxInnate
- W. Neil Palmer**, President & Principal Consultant, PDCl Market Access
- Professor Alexander Von Gabain**, Strategic Advisor to the Board, Intercell AG
- Staph Leavenworth Bakali**, CEO, Genocoe Biosciences
- Dr Tyler Martin**, Chief Medical Officer, DynaVax Corporation
- Dr Germie van den Dobbelsteen**, Program Manager, Bacterial Vaccines, Netherlands Vaccine Institute
- Dr Susan W. Barnett**, Senior Director, Senior Project Leader, Viral Vaccine Research, Novartis Vaccines and Diagnostics, Inc
- Dr Anne De Groot**, CSO & CEO, EpiVax, Inc
- Dr Katherine Cohen**, Senior Vice President, Global Head of Corporate & Business Development, Intercell AG
- Dr Alexandra Löw-Baselli**, Director of Clinical Development, Vaccines, Baxter BioScience
- Professor Nikolai Petrovsky**, CSO, Vaxine Pty Ltd
- Dr Frank Vandendriessche**, Director, Regulatory Affairs, Europe, MSD Europe
- Dr Wilfried A. M. Bakker**, Senior Research Scientist, Netherlands Vaccine Institute
- Dr Manon Cox**, COO, Protein Sciences Corporation
- Dr Ronald W. Ellis**, Senior Vice President & Chief Technology Officer, NasVax Ltd, Israel
- Katharina Hartmann, MScPharm**, Head of Pharmacovigilance, Crucell Switzerland AG
- Professor Angus Dalgleish**, Professor of Oncology, St George's, University of London
- Dr Jennifer R. Hanneschlagler**, Principal, Tiber Creek Partners, LLC
- Dr David Kirke**, Associate Director, ERA Consulting

Your choice of 2 morning plenary sessions

Barcelona Vaccine Forum

Morning plenary session

How did we do and what have we learnt? Multiple stakeholder 'debrief' on preparations for, and the response to, the 2009/10 H1N1 influenza pandemic

9.00 Chair's introductory overview
Assessing the 5 years of preparation which led up to the 2009/10 pandemic:
What were the major public policy decisions through this period and how did they impact the eventual response to the pandemic?
Dr David Salisbury, Director of Immunisation, UK Department of Health

WHO & CDC perspectives

- How did the processes for identifying/setting up the seed strain and increasing speed-to-market of the vaccines themselves perform, and how could efficiencies be built in to these processes in future? What novel technologies might help in this regard?
- How stable and secure was the vaccine supply on a global basis?
- How did we do at catering for high-risk members of populations, such as the elderly, on a global basis?
- Comparing the roll-out of vaccines in the Northern and Southern Hemispheres: What effect (if any) did they have on the epidemiology of H1N1?
- What is our current opinion on the feasibility and viability of a universal influenza vaccine? How much money could be saved if it becomes a reality? Will the 'one size fits all' approach be the successful model moving forwards, or will there need to be different vaccines for different populations?

9.20 WHO perspective
Global production of H1N1 pandemic vaccine and availability in developing countries

- Survey of estimates of global pandemic vaccine production capacity, June 2009
- Analysis of the quantity of pandemic vaccine produced since May 2009
- Objectives and status of the WHO pandemic vaccine deployment initiative

Dr Marie-Paule Kieny, Director, Initiative for Vaccine Research, World Health Organization

9.40 CDC perspective
2009 H1N1 influenza vaccination: Policy and programme in the United States

- United States vaccination policy and how it was developed
 - Objectives of the programme and its various components - how it worked and what was achieved
- Dr Beth P. Bell**, Associate Director for Science, National Center for Immunization & Respiratory Diseases, CDC

10.00 Questions & discussion

Regulators' review: Comparing and contrasting FDA and EMEA legislation, guidelines, procedures and performance in response to the H1N1 pandemic

10.10 Presentations...
EU regulatory experiences on preparation, response and review of (H1N1) pandemic influenza

- Pandemic preparedness and the EU Mock-up licence approach
- Regulator interactions and operation of EU Network
- Review of safety and efficacy data and CHMP decision making
- Current situation regarding pandemic
- Implementation of lessons learned

Dr Peter Richardson, Head of Biologicals, Quality of Medicines Unit, European Medicines Agency

Pandemic influenza vaccines: US regulatory perspective

- H1N1 2009 vaccine: Lessons learned
 - Preparing for the next pandemic
- Theresa Finn, PhD**, Associate Director for Regulatory Policy, OVR, CBER, US Food & Drug Administration

10.50 ...and panel discussion

- What were/are the similarities and differences between US and European regulatory approaches? How significant were these differences?
- How effectively have Western hemisphere regulators dovetailed with the wider global regulatory environment?
- What will be the consequences for industry in terms of the regulation of novel technologies in future?

11.10 Morning coffee in the exhibition area

Updates from key US and European Government stakeholders

11.50 European Commission perspective
The public health response to pandemic H1N1 influenza: Cooperation and coordination at EU level

- How did the EU support the EU Member States during the pandemic?
- What was the added value of the cooperation and coordination at EU level?
- Despite the cooperation and coordination at EU level, why did the EU Member States take different policy decisions?
- What lessons can be learnt and what improvements can be made?

Dr Antoon Gijssens, Policy Officer, Unit SANCO C3 - Health Threats, European Commission

12.10 US HHS perspective

- Expanding domestic pandemic vaccine manufacturing infrastructure
- Development of next generation influenza vaccines and antiviral drugs
- Reinventing the countermeasure enterprise

Dr Robin Robinson, Director & Deputy Assistant Secretary, 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

12.40 Roundtable discussion

How well did all of the stakeholders interact (Government public health agencies and funding bodies, regulators, WHO/CDC, NGOs, industry)?

- What lessons can be learnt for each stakeholder and the vaccine community at large? Where can improvements be made?
- How well did we manage the immunization of mass populations and the management of public concern?
- How were issues of 'over-supply' addressed and what lessons can we take forward
- Addressing the challenges in providing developing world access to pandemic influenza vaccines
 - To what extent were the poorest countries of the world catered for?
 - How well did mechanisms designed to supply these populations with pandemic influenza vaccines work?
 - How were decisions made by Western Governments in term of honouring commitments to supplying doses to the developing world versus making sure that everyone at high risk in their own populations received vaccines
 - What NGO funding opportunities are available on an ongoing basis for developers of novel influenza vaccine technologies?
- How did the pandemic affect the seasonal influenza vaccine market/seasonal vaccine uptake?
 - Discussing the recommendation for inclusion of H1N1 with the seasonal influenza vaccine for 2010/11
 - Will H1N1 help improve seasonal vaccine uptake on a global basis? To what extent will the threat of further pandemics change recommendations for seasonal 'flu immunisation in future?

Panellists:

Dr N. Regina Rabinovich, Director, Infectious Diseases Development, The Bill & Melinda Gates Foundation
Dr Norbert Hehme, Vice President, Global External Relations GIO, GlaxoSmithKline Biologicals & Chair, IFPMA Influenza Vaccine Supply International Task Force
Dr Udit Batra, Head, Global Public Health & Market Access, Novartis Vaccines & Diagnostics
Dr Ernst C. Soethout, Senior Research Scientist, Netherlands Vaccine Institute

1.30 Buffet lunch in the exhibition area

Continued on next page. Choose from any of the 4 sessions »

Active Immunotherapeutics Forum

Morning plenary session

Learning strategic lessons from imminent AI product launch(es)

- How do development and commercialisation pathways need to differ from traditional cytotoxic drug development?

9.00 Chair's introduction

Wim Tiest, Director, Head, Portfolio Strategy & Business Operations, Immunotherapeutics Business Unit, GlaxoSmithKline Biologicals

9.05 Keynote address

Dendreon as a test case

- A new clinical paradigm: How has the strategy for development differed from that of traditional cytotoxic drugs?
- What data has had greatest influence throughout the regulatory approval process?
- What is the marketing and reimbursement pathway for a cancer vaccine?
- Persuading oncologists to go outside their comfort zone and adopt new modalities
 - How to displace, combine with or integrate the standard of care?
- Next steps - reigniting the platform to get other candidates into the clinic - what's the rationale moving forward?

Dr Mitchell H. Gold, President & CEO, Dendreon Corporation

9.35 Questions & discussion

9.40 Financial markets perspective

- How will Dendreon and other successful phase III trials impact the market for AI products?
- How might the cancer vaccine market evolve?
 - What has been learned from failures to date?
- What business models are most likely to succeed in AI?
- What is the investment community's influence on choice of indication for AI registration?
- What next after cancer vaccines - AI for chronic infectious diseases, allergy, autoimmune diseases?

Dr Philippe Pouletty, Co-Founder & General Partner, Life Sciences, Truffle Capital

10.05 Questions & discussion

10.10 Payor perspective

- How will Provenge™ be reimbursed? What impact will it have on CPT codes?
- When and how should companies start dialogue with payor, physician and patient groups to assess reimbursability of AI products?
- What is the likely requirement for outcomes research / health economics assessment with these new products?
- How will reimbursement decisions be made?
 - How will value be assessed?
- How should these technically complex AI products be positioned?

Dr Ulrich Granzer, Granzer Regulatory Consulting & Services

10.35 Panel discussion

Understanding what the business model needs to look like for AI products

- What are the critical components for building a business model to best fit the disease focus, technology, or potential investment group/partner?
 - How is it different from the traditional drug model?
- The global reimbursement landscape for AI products: What are major differences to be aware of in US/Europe and beyond?
 - How is it different from the traditional model?
- Demonstrating value to the prime influencers: What can industry do to make the field enticing and attractive to physicians and patient advocacy groups?
- Commercial scale-up of AI: What does it need to look like to achieve
 - A markedly increased patient volume?
 - The process being removed from a hospital/clinic environment?

11.10 Morning coffee in the exhibition area

Your choice of 2 parallel sessions

Both Forums

Workshop

Please note: This workshop focuses on Active Immunotherapy examples until lunch. After lunch, the case studies focus on prophylactic vaccines

Optimising the time, money and effort spent on preclinical development: Pushing for early translation into human trials

- Indicative *in vivo* and *in vitro* safety and efficacy models
- How translatable is proof of mechanism and proof of concept?
- How to get to phase I cost effectively: Preparing the regulatory package and clinical setting for prophylactic vaccines and AI

11.50 Moderator's introduction

Dr Helen Sabzevari, Global Head of Oncology-Immunotherapy, Merck Serono

12.00 Using an alternative animal model for toxicology of a novel Alzheimer's Disease immunotherapeutic

- Overview of the AD product candidate
- Preclinical rationale for animal models
- What are the alternative models for AD vaccines and immunotherapeutics?
- Do we need to be more open-minded regarding safety testing in other species?
- How do we allow for differences in immune systems and markers?

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

12.25 Questions & discussion

12.30 State of the art in vitro systems: What novel approaches to predictivity are being adopted in AI?

- The XPRESIDENT platform: Pre-clinical identification, selection and validation of relevant tumour antigens for cancer immunotherapy
- Identification and selection of clinically relevant antigens using human tumours as source material
- Predicting and benchmarking immunogenicity in vitro by an artificial APC approach
- Validation of immunogenicity in early clinical trials
- Validation of clinical relevance of antigens in mid-stage clinical trials

Dr Harpreet Singh, CSO, immatics biotechnologies GmbH

12.55 Questions & discussion

Continued on next page »

Active Immunotherapeutics Forum

Focus session

Early application of statistical methods, flexible approaches and adaptive design in order to better inform pivotal and phase III studies in AI

- With no off the shelf clinical packages available for targeted therapies, how can we avoid trials taking so long?
- How can novel statistical approaches help? What is state of the art in the field and how can it be applied to AI?

11.50 Chair's introduction

Dr Ulrich Granzer, Granzer Regulatory Consulting & Services

Application of adaptive and Bayesian trial designs in AI

12.00 Case study

Early application of statistical methods, flexible approaches and adaptive design; Phase II and Phase III choices

- Adaptive statistical methods in Phase II to predict Phase III outcomes
- Use of adaptive design to take a "snap-shot" of emerging data
- How can novel statistical approaches help? ... or do they?

Dr Joseph Sinkule, Founder, Director, & CSO, Aphera, Inc

12.25 Questions & discussion

12.30 Case study - adaptive trial design for AI

Judith Quinlan, Vice President, Adaptive Trials, Cytel

12.55 Questions & discussion

Managing risk through a smarter phase II/III approach in AI

Continued on next page »

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Barcelona Vaccine Forum

Focus session

How have seasonal and pandemic influenza vaccine markets - and the regulatory environment - evolved over the past year, and how must the industry respond to ensure future success?

Chair:
Dr Antoon Gijssens, Policy Officer, Unit SANCO C3 - Health Threats, European Commission

Industry perspectives
What's in the influenza vaccine market long-term for both large and small vaccine companies?

2.40 Big pharma perspective
H1N1 pandemic: Decision-making under highly uncertain conditions

- Evolving assessment of public health risk
- Impact of this risk on the demand and supply balance
- Importance of execution - key processes and discipline

Dr Udit Batra, Head, Global Public Health & Market Access, Novartis Vaccines & Diagnostics

3.00 Questions & discussion

3.05 Biotech perspective
Can H1N1 pandemic 'flu provide opportunities for emerging companies to develop sustainable commercial models?

Presentation reserved

3.25 Questions & discussion

3.30 Clinical development update
What is the latest progress in universal 'flu vaccine R&D and what key challenges remain?

- Dr M2e
- Cleavage Fragment
- Transition state
- T-cell targets

Dr Alan Shaw, President & Chief Executive Officer, VaxInnate

3.50 Questions & discussion

3.55 Afternoon tea in the exhibition area

4.30 Panel discussion
Looking to the future of the global influenza vaccine market and beyond

- What will be the impact on pricing and reimbursement for seasonal influenza vaccines of increasing manufacturing capacity on a global basis?
- How will this affect various vaccine company business models? (eg. a US/European vaccine manufacturer versus one from India or China)?

- How can coverage be improved on a global basis to help maintain prices?
- What lessons can be taken from the recent pandemic to help accelerate the development of novel vaccines in general?
- How do you put a value on a technology for in-licensing that is aimed at a pandemic outbreak?

Panellist:

Dr Jennifer R. Hanneschlager, Principal, Tiber Creek Partners, LLC

4.55 Chair's closing summary

5.00 Close of session

Workshop

Delivering biotech corporate development and fund-raising strategies to beat the economic downturn

2.40 Moderator's introduction
Analyst's perspective: How is big pharma re-investing in vaccines as they adopt Pharma 2.0 model?

- Monetizing emerging markets
- Oversupply and H1N1
- FDA and novel adjuvants

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

3.00 Questions & discussion

3.05 VC update
Is there still a viable VC model in light of the scarcity of vaccine company IPOs over recent years?

- Where do small companies go as a result?
- What is the model that will succeed in this environment?

Dr Philippe Pouletty, Co-Founder & General Partner, Life Sciences, Truffle Capital

3.25 Questions & discussion

3.30 Fundraising in a difficult environment - a biotech example

- Funding environment - past 12-18 months and now
- Alternative funding sources
- Elements needed for successful fundraising

Staph Leavenworth Bakali, CEO, Genocea Biosciences

3.50 Questions & discussion

3.55 Afternoon tea in the exhibition area

4.30 Case study: A recent pharma entry in the vaccine space

- Challenges and opportunities for new vaccine development
- What opportunities are there for small vaccine companies seeking partners/buyers?
- What are the keys to attracting pharma companies?

Jan Reid, Senior Director, Vaccines Licensing, Pfizer R&D Business Development

4.50 Questions & discussion

4.55 Moderator's closing summary

5.00 Close of session



Both Forums

Workshop continued

1.00 Case studies: Immune interventions for chronic viral diseases - examples of CMV and HIV

- New antigenic targets, vaccine deliveries and immunologic endpoints
- Preclinical proof of concept - inferences from orthologous animal model systems
- Immune-based therapies and combined therapies to improve upon standard of care
- Considerations for the regulatory package moving forward

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

1.25 Questions & discussion

1.30 Buffet lunch in the exhibition area

After lunch, the case studies focus on prophylactic vaccines

2.40 Case study - prophylactic vaccine
Establishing your preclinical rationale for animal models: To what extent can you trust mouse data?

- Identifying and utilising alternative animal models for preclinical efficacy in the prophylactic vaccine setting

Dr Gertie van den Dobbelsteen, Program Manager, Bacterial Vaccines, Netherlands Vaccine Institute

3.00 Questions & discussion

Revisiting the hardest targets - how are recent technological and scientific advances enabling fresh attempts to tackle major, long-standing unmet medical needs?

3.05 Case study - prophylactic vaccine - challenges for an RSV vaccine

- Attenuated virus vs. subunit vaccines
- Circumventing the effect of maternal antibodies against developing an immune response
- Approaches for avoiding potential immune pathologies associated with immunization

Dr John W. Shiver, Vice President, Global Vaccines Discovery & Basic Research, Merck Research Laboratories

3.25 Questions & discussion

3.30 Case study - prophylactic vaccine - HIV

Dr Anne De Groot, CSO & CEO, EpiVax, Inc

3.50 Questions & discussion

3.55 Afternoon tea in the exhibition area

4.30 Panel discussion
Reaching a common understanding of which - and how much - data you need to do to get into the clinic: Is there a consensus?

- Clarifying regulatory uncertainty: What is their latest stance?
- How to get regulatory buy in earlier
- At what point do you have to try your active immunotherapeutic product in a human because preclinical can't give you any more clarity?

4.55 Moderator's closing summary

5.00 Close of session

Active Immunotherapeutics Forum

Focus session continued

1.00 Case study
Generating a well-supported phase III hypothesis in cancer immunotherapy studies: The importance of randomized, controlled phase II studies

- Size, structure and controls of cancer immunotherapy phase II studies
- Relevant surrogate endpoints and biomarkers - are there any?
- Examples of successful trial designs

Reiner Laus, MD, President & Chief Executive Officer, BN ImmunoTherapeutics

1.25 Questions & discussion

1.30 Buffet lunch in the exhibition area

2.40 Case study
How to minimize risk and time to approval of immunotherapeutics: The case of incorporating tumour stem cells in therapeutic vaccines

- Adaptive trial designs vs group sequential
- How many interim stages without jeopardizing the final statistics?
- Comparative studies in phase I-III
- Independent Data Monitoring Committees:
 - Stopping rules for futility
 - Early termination of the trial for efficacy
- Primary and secondary objectives
- Surrogate endpoints

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

3.00 Questions & discussion

3.05 Clinical development of AI combination therapies: Creative and accelerated trial design

- Designing early stage human trials for immunologic evaluation and initial activity assessment when combining experimental agents - chemo / biotherapy / immunotherapy
- Getting to combination phase II without multiple trials - phase 0/I - what's the prevailing opinion on trial design?
- What should the control arm be for combination therapies: How to analyze the survival curve?
- Limitations in evaluating small cohorts and Bayesian design to achieve meaningful decision points for combination therapies involving AI
- Working with regulators to get early buy in for new combination studies

Dr Thomas A. Davis, CMO & Senior Vice President, Clinical Development, Celldex Therapeutics

3.25 Panel discussion

Debating the pros and cons of classical vs

adaptive, flexible trial approaches for AI

- In what circumstances is adaptive design likely to be most effective and when is it likely to be over complicated?
 - What are the knock-on effects in terms of ramping up patient numbers to power up the study?
- How can industry and regulators alike work to advance these data evaluation approaches to clinical development design?
- Comparing the experiences in oncology and other fields using AI

3.50 Chair's closing summary

3.55 Afternoon tea in the exhibition area

Your choice of 2 afternoon plenary sessions

Barcelona Vaccine Forum

Getting ready for the next influenza pandemic: How are recent experiences informing ongoing preparedness strategies?

5.05 Roundtable discussion

- What are the potential strains now circulating for the next Northern Hemisphere 'flu season?
 - What is the latest data regarding the potential resurfacing of H5N1?
- Assuming the next pandemic strain is a more virulent one...
 - What learnings can we take from our experiences with H1N1 and what will be the key differences in technical and regulatory terms? (Eg. in the event that a novel adjuvant is a requirement for an effective vaccine)
 - What would we do in future if we had less time from the point where the pandemic strain was identified to the time by which we needed a vaccine? Are the right technologies in place? If not, what's missing?
 - Are we ready in terms of global capacity? What role for developed and developing world manufacturers alike?
 - In light of the past year's events, what is the role of emerging biotech in emergency situations such as a pandemic moving forward? Simply to demonstrate new technologies, or to actually play a role in supplying vaccines?
 - How should we prepare given our current experience of the potential for reassortment of H1N1/H5N1?
- Examining ongoing studies in maternal immunization for influenza - how could it impact uptake in the long term?
- How can we improve society's acceptance of pandemic influenza vaccination moving forwards?
 - How could public and private sectors alike develop their communications policies and procedures to enable such an improvement?

Panellists:

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

Dr Beth P. Bell, Associate Director for Science, National Center for Immunization & Respiratory Diseases, CDC

Dr N. Regina Rabinovich, Director, Infectious Diseases Development, The Bill & Melinda Gates Foundation

Dr Peter Richardson, Head of Biologicals, Quality of Medicines Unit, European Medicines Agency

Theresa Finn, PhD, Associate Director for Regulatory Policy, OVR, CBER, US Food & Drug Administration

Dr Rahul Singhvi, President & CEO, Novavax, Inc

Dr Antoon Gijssens, Policy Officer, Unit SANCO C3 - Health Threats, European Commission

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

Active Immunotherapeutics Forum

What is big pharma's current view of the viability and promise of the AI business model?

4.35 Chair's introduction

Reiner Laus, MD, President & Chief Executive Officer, BN ImmunoTherapeutics

4.40 Keynote presentation

How to develop the strategy and evaluate the key issues in development of AIs

- How does AI fit into the strategic plans for the business portfolio?
- Which applications are of greatest interest and why? How is their potential value assessed?
- How to make these expensive therapies more affordable and accessible by reducing cost of goods in any way possible - role of biosimilars
 - Small molecule immunotherapeutics - will they be disruptive and replace biologics in AI? Will they drive down costs? Eg those targeting JAK-STAT pathways

Dr Helen Sabzevari, Global Head of Oncology-Immunotherapy, Merck Serono

5.05 Panel discussion

What is the extent of big pharma's current involvement in AI and what form does it take?

- How does big pharma evaluate, assess and process novel AI products?
- What are they looking for from AI biotechs?
 - How should biotechs prepare for due diligence?

- Changing expectations - partnering / collaborating rather than going for a deal from the outset - enabling big pharma to gain confidence in the technology first

- How are they helping with regulatory / clinical development paths for AI products?
- Have we hit the inflection point yet: Are we spending enough money in the area to have success?
 - Are there enough biotechs involved?
- What are the differences between doing deals with big pharma with classical vaccine franchise versus those that don't
- How are AI programs being integrated at big pharma?

Panellists:

Wim Tiest, Director, Head, Portfolio Strategy & Business Operations, Immunotherapeutics Business Unit, GlaxoSmithKline Biologicals

Dr Axel Hoos, Medical Lead, Immunology/Oncology, Bristol-Myers Squibb

Dr Steve Gracheck, Executive Director, Vaccine Research - La Jolla, Pfizer Global R&D

Jens-Peter Marschner, MD, Head, Immunological Programs, Global Early Development Unit, Oncology, Merck KGaA

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

Your choice of 2 morning plenary sessions

Barcelona Vaccine Forum

Morning plenary session

How are innovative partnering models and funding opportunities enabling vaccine market development on a global scale?

9.00 Chair's introduction

Una S. Ryan, OBE, PhD, President & CEO, Diagnostics For All

9.05 Emerging models for accelerating vaccine R&D for neglected diseases

- How to find the balancing point between vaccine discovery and vaccine development?

Dr N. Regina Rabinovich, Director, Infectious Diseases Development, The Bill & Melinda Gates Foundation

9.25 Questions & discussion

9.30 Presentation to be announced

9.50 Questions & discussion

9.55 Making the business case for developing world vaccine R&D: Comparing and contrasting innovative partnering/corporate models aimed at developing novel vaccines and vaccine markets on a global scale - how will these initiatives impact R&D/commercial models and opportunities for each partner?

Dr Ted Bianco, Director - Technology Transfer, The Wellcome Trust

10.15 Questions & discussion

10.20 Biotech case study

Ixiaro: Moving a novel JEV vaccine to global markets for travelers and endemic population

- Features of a novel attenuated, inactivated and Vero-cell based JEV vaccine
- Registration and manufacturing strategies for different customers
- Commercialisation through partnership selection

Professor Alexander Von Gabain, Strategic Advisor to the Board, Intercell AG

10.35 Questions & discussion

10.40 Roundtable discussion

Assessing ongoing and future funding and delivery solutions for developing world vaccines

- What is the latest clinical progress of leading malaria and TB vaccine candidates? What role are PPPs playing in making these projects financially viable?
- Can we sustain the funding of GAVI in its present form? How should GAVI be replenished? Where should the money come from? How should GAVI conduct its business in future? (Eg. One vaccine at a time, or with multiple projects ongoing?)
- With the potential for a number of novel vaccines for primarily developing world diseases to be approved for the market over the coming decade, how will GAVI and others get the funding and build the infrastructure roll them out globally? How will the logistical challenges in the supply chain be addressed?
- How to deliver developing world vaccines that aren't currently on the paediatric schedule, such as typhoid and cholera? What alternatives are there if they don't fit in with current schedules?
- How will the community address issues derived from the actual physical route of delivery to ensure that those populations who need vaccines the most receive them? (Eg. the potential loss of efficacy of oral vaccines in the developing world where malnutrition has an impact)
- How might companion diagnostics dovetail with vaccines and global health moving forward?
- Assuming that poliomyelitis is eradicated in the coming few years, what happens next? What will be the path forward for developing and delivering the doses that will still be required post-eradication?

Panelist:

Dr Wilfried A. M. Bakker, Senior Research Scientist, Netherlands Vaccine Institute

11.30 Morning coffee in the exhibition area



Active Immunotherapeutics Forum

Morning plenary session

Preparing for registration: Generating high quality mid- to late-stage efficacy data to guarantee a robust registration package

- Industry and regulatory collaboration on developing the new clinical development paradigm for AI products

9.00 Chair's introduction

Dr David L. Urdal, CSO, Dendreon Corporation

Case studies from companies approaching registration

- What is required for registration trials? Ensuring you have high quality mid to late stage data in the package to support
 - Efficacy
 - Mechanism of action
 - Potency assays
 - Choice of end point
- What are the specific registration challenges for phase III combination trials?
- Highlighting the differences between registration in US / EU
- For those that have failed registration trials, what would they do differently?

9.05 Getting ready for registration of immunotherapeutics: Not really a drug, and not really a vaccine....

- The how-to of registration trials: Design, endpoints, number
 - Demonstrating product consistency
 - Interacting with the regulators
 - Global development serving worldwide registration
- Wim Tiest**, Director, Head, Portfolio Strategy & Business Operations, Immunotherapeutics Business Unit, GlaxoSmithKline Biologicals

9.25 Questions & discussion

9.30 Characterization of Oncophage, an autologous, protein based therapeutic cancer vaccine: Development challenges and solutions

- Development of a cutting edge cancer vaccine in absence of focused regulatory guidelines (Phase 3 trials through submission of MAA)
- Reconciling Oncophage's unique product attributes with ICH driven characterization requirements
- Challenges associated with demonstration of process consistency
- Consequences of process evolution during Oncophage clinical development

Daniel L. Levey, PhD, Senior Director, Business Development, Antigenics Inc

9.50 Questions & discussion

9.55 BiovaxID: Personalised lymphoma vaccine

- The impact of Phase 2 clinical study design on mid-to-late-stage development
- Lessons learned from a tightly-coupled Phase 2/3 development plan

- Adapting to standard-of-care advances during mid-to-late stage development
- Managing the regulatory pathway for an AI therapeutic vaccine across multiple jurisdictions

Carlos F. Santos, PhD, Director of Regulatory Affairs & Product Development, Accentia Biopharmaceuticals / Biovest International

10.15 Questions & discussion

10.20 StimuvaxR, a therapeutic cancer vaccine targeting MUC1: Strategic considerations

- Reviewing pre-clinical and clinical data
- Detailing the pivotal trial
- How has contact with regulatory authorities been managed?
- Thoughts about the application of biomarkers and exploratory medicine

Jens-Peter Marschner, MD, Head, Immunologicals Programs, Global Early & Clinical Development Units Oncology, Merck KGaA

10.40 Regulatory perspectives: Presentation followed by panel discussion

- How have Dendreon and late stage companies helped to change the regulatory paradigm? In what ways does trial design for AI need to be different from traditional cytotoxic drugs?
- As we enter year 2 of the application of the new Advanced Therapies Regulations, what impact has it had from a regulatory decision-making point of view and also in terms of industry decision-making?
- What is the feedback so far?
- How are companies progressing and what might need updating in the guidelines?
- What are the areas for clarification?
- Feedback from the Draft Guidance for Industry: Clinical Considerations for Therapeutic Cancer Vaccines
 - How might it lead to a redefinition of endpoints and efficacy parameters?
- What are the latest decisions on use of TLRs in AI?
- Minimal residual disease trials: Are they the best venue for cancer immunotherapy? How can lead times be reduced?

Speaker:

Dr Thomas Hinz, Paul-Ehrlich-Institut

Panelists:

Dr Samir N. Khleif, Head, Cancer Vaccine Section, NCI

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

11.30 Morning coffee in the exhibition area

Your choice of 4 parallel sessions

Barcelona Vaccine Forum

Focus session

Where next for novel cell culture and other bioprocessing technologies in the wake of the H1N1 pandemic?

12.10 Chair's introduction

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

Case studies: Update on novel vaccine technologies and platforms that have been developed for the influenza market

- How did they perform in the H1N1 pandemic and what were the lessons learnt?
- How will they impact flu vaccine market economics in the long run? How will they be developed further?

12.20 Second generation cell culture technology

Dr Alexandra Löw-Baselli, Director of Clinical Development, Vaccines, Baxter BioScience

12.45 Questions & discussion

12.50 FluBlok - made in insect cells

- Update FDA licensing process
- VRBPAC meeting experience
- BARDA contract activities

Dr Manon Cox, COO, Protein Sciences Corporation

1.10 Questions & discussion

1.15 Buffet lunch in the exhibition area

Continued on next page »

Workshop

What will be the successful business model for capitalising on R&D and commercial opportunities in the 'BRIC nations'? (Brazil, Russia, India, China)

12.10 Moderator's introductory overview

How will BRIC nation vaccine markets develop over the coming decade and beyond?

- How has the global economic crisis impacted the vaccine environment in the BRIC nations?
 - Has it damaged the appeal of these nations, or further enhanced it?
- Assessing emerging infectious diseases endemic in these nations and the potential markets for vaccine companies
- What will be the impact on the traveller's vaccine market if the middle classes continue to grow as expected in the BRIC nations?

Peter Welford, CFA, Director, European Healthcare Equity Research, Jefferies International Limited

Case studies: Examining recent deals and partnerships between Western big pharma and biotech companies and counterparts from the BRIC nations

- What were the drivers behind the deals in each case?
- How do such deals impact prices and the development of markets in these developing countries?

12.30 sanofi pasteur - Shantha Biotech

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

12.50 VaxInnate - BiologicalE

- How can densely populated countries cope with the next pandemic?
- Can a novel flu vaccine be made and tested in this context?
- How do you structure a tech-transfer relationship to achieve this goal?

Dr Alan Shaw, President & Chief Executive Officer, VaxInnate

1.10 Questions & discussion

Continued on next page »

Active Immunotherapeutics Forum

Focus session

Identifying, validating and applying predictive biomarkers to improve targeting, decision-making and - ultimately - success in cancer vaccines

12.10 Chair's introduction

Defining how biomarkers are being applied to AI products throughout their lifecycle

- What progress is being made with the identification and validation of biomarkers in cancer vaccines?
 - For genetic pre-selection of patients? (responders versus non-responders)
 - For developing diagnostic tests?
 - For labelling?
- What are the latest tools and analytical strategies that are being adopted to really show the statistical significance of clinical data in different populations?

Dr Samir N. Khleif, Head, Cancer Vaccine Section, NCI

12.25 Case study Identifying the right biomarkers

- Broad versus specific biomarkers
 - Increasing trend for inflammatory biomarkers
- Professor Angus Dalglish**, Professor of Oncology, St George's, University of London

12.45 Questions & discussion

12.50 Case study

Validating potential biomarkers for use in the clinic

- How to correlate biomarkers and clinical end points?
- What data is needed and when? What studies are needed?
- What is there beyond overall survival that will tell you what's happening in AI?

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

1.10 Questions & discussion

1.15 Buffet lunch in the exhibition area

Continued on next page »

Workshop

Chronic infectious diseases: How is AI driving innovation and progress in this sector, and what translational opportunities are there for other disease areas?

12.00 Moderator's introduction

Can AI be applied to any chronic infections that can't be addressed by traditional vaccine approaches?

- How is immunosuppression being applied in this field of AI?
- Importance of T reg cells against viral diseases
- AI for viral diseases resulting from transplant / autoimmune disorders

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

12.20 Questions & discussion

Case studies focusing on progress with AI for specific chronic infectious diseases

12.25 Immunotherapy of high-risk HPV infections

- Which immune response is needed?
- What is the mode of action of this therapeutic vaccine?
- What are the clinical benefits?
- Apart from patients with VIN 3 which other patients can benefit?

Professor Dr C. J. M. Melief, Professor of Immunology, Department of Immunohaematology & Blood Transfusion, Leiden University Medical Center

12.45 Questions & discussion

12.50 An autologous AI approach to treating HIV infection

- Defining the unmet medical need
 - Considerations for engineering of the product
 - Challenges to efficacy testing in the ART drug era
 - Trial design and clinical/immunologic endpoints
- Charles A. Nicolette, PhD**, Chief Scientific Officer, Vice President, R&D, Argos Therapeutics, Inc

Continued on next page »

Indicates a highly interactive session for a maximum of 30 participants. Register today to guarantee you place in these sessions

Barcelona Vaccine Forum

Focus session continued

2.25 Recombinant vaccine

- Discuss case study of Novavax H1N1 VLP vaccine candidate
- Lead time for vaccine manufacturing including release testing
- Surge capacity considerations
- Clinical testing and registration of product not under "strain change" pathway
- Commercial production of recombinant vaccine

Dr Rahul Singhvi, President & CEO, Novavax, Inc

2.45 Questions & discussion

2.50 What has been the real impact of disposables on the process economy and what will be their role moving forward?
Presentation reserved

3.10 Questions & discussion

3.15 Panel discussion

- Regulator/industry perspectives: What were the hurdles that prevented technologies from achieving licensure during the H1N1 pandemic and how might they be overcome next time?
 - How will the processes by which novel manufacturing technologies were tested and approved (or otherwise) during the H1N1 pandemic impact the future development of vaccines and vaccine technologies in general?
- What is influenza doing for the vaccine sector as a whole?
 - What impact will the new manufacturing / processing technologies that have largely grown out of the pandemic preparedness effort have on the vaccine sector in general?
 - What are the pros and cons of these platforms in terms of how easily they might be employed in both developed and developing worlds for flu and also for other types of vaccine? How could these technologies be utilised to impact global unmet needs?

Panellists:
Dr Peter Richardson, Head of Biologicals, Quality of Medicines Unit, European Medicines Agency
Theresa Finn, PhD, Associate Director for Regulatory Policy, OVR, CBER, US Food & Drug Administration

3.45 Chair's closing summary

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

Workshop continued

1.15 Buffet lunch in the exhibition area

2.25 Case study
How does global alliance strategy help the biotech to grow and prosper?
Dr Katherine Cohen, Senior Vice President, Global Head of Corporate & Business Development, Intercell AG

How are Chinese and Indian vaccine companies reacting to the expansion plans of Western pharma and biotech?

- What are their current and planned activities in vaccine research, development and manufacturing, and also deal-making?

2.45 Indian perspective: New paradigm in vaccine development

- India as a major supplier of vaccines in developing countries
- A global approach: Gennova and MVI PATH partnership in malaria vaccine development

Dr Sanjay Singh, CEO, Gennova Biopharmaceuticals Limited

3.05 Chinese perspective
Dr Shen Xinliang, Director-General, National Vaccine & Serum Institute & National Engineering Research Center for Novel Vaccines, China

3.25 Questions for the speakers & panel discussion

- What are the drivers behind the re-balancing of developed and developing world manufacturing capacity, and what does it mean for the vaccine sector as a whole?
- Do global partnering opportunities offer more chance of a 'win-win' situation for Western biotechs than traditional deals with big pharma? Do they create more incentive for both parties than traditional big pharma-biotech deals?

3.45 Moderator's closing summary

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

Active Immunotherapeutics Forum

Focus session continued

2.25 Case study
Discovery and application of predictive biomarkers for mAGE-a3 cancer immunotherapy

- Biomarker discovery in early stage trials with MAGE-A3 antigen specific cancer immunotherapy
- Biological significance of the MAGE-A3 ASCI predictive gene signature
- Challenges for predictive biomarker implementation in late stage clinical studies

Fernando Ulloa-Montoya, PhD, Head of Molecular Biology Technology Group, Cancer Immunotherapy, GlaxoSmithKline Biologicals

2.45 Questions & discussion

2.50 Case study
Recent advancements in the role of imaging for biomarker identification and validation

- Imaging and immune response: How are the correlates looking?
- What are the recent advancements in its application?

Speaker to be announced

3.10 Panel discussion
Comparing experiences with EMEA / FDA development procedures for validating biomarkers: What are the similarities / differences in approach?

Panellist:
Dr Thomas Hinz, Paul-Ehrlich-Institut

3.35 Chair's closing summary

3.40 Close of session, followed by afternoon tea in the exhibition area

Workshop continued

1.10 Questions & discussion

1.15 Buffet lunch in the exhibition area

2.25 The need for a new HCV treatment: Towards a therapeutic vaccine

- HCV and today's standard of care (SoC)
- The pivotal role of T-cells
- Improvement of a T-cell vaccine with a TLR agonist
- Perspectives to combine the vaccine with novel small molecule treatment(s)

Professor Alexander Von Gabain, Strategic Advisor to the Board, Intercell AG

2.45 Questions & discussion

2.50 Creation of 'T bodies' against Epstein-Barr Virus (EBV) tumour targets

- What are the main issues regarding immunotherapy for EBV-associated tumours?
- What are the current approaches to such treatment?
- What may the future hold for EBV immunotherapy?

Dr Ingólfur Johannessen, Clinical Lecturer in Virology, College of Medicine & Veterinary Medicine, University of Edinburgh & Royal Infirmary of Edinburgh

3.10 Panel discussion
What are the translational opportunities between AI for cancer and infectious diseases?

- What are the T cell response system similarities between cancer and chronic infectious diseases?

3.35 Moderator's closing summary

3.40 Close of session, followed by afternoon tea in the exhibition area



Your choice of 2 afternoon plenary sessions

Barcelona Vaccine Forum

HIV vaccines: Dissecting recent clinical data to deliver pathways forward

4.30 Short presentations & roundtable discussion

- Reassessing the STEP and Thai HIV vaccine clinical trial data
 - What is the significance of these data in the final analysis and what pointers do they provide in terms of future directions for R&D? What should and what shouldn't we assume in designing future R&D projects?
 - Did cell mediated immunity (CMI) really not deliver on its promises or did the field look at a too narrow set of biomarkers?
- Can we map a credible path forward for T cell vaccines? Will increased breadth and depth of T cell responses and/or polyfunctionality drive progress with HIV vaccines, or is immunodominance and immune escape too formidable an obstacle?
- What role could emerging technology platforms play in addressing some of the remaining challenges in HIV vaccine R&D?
 - Optimizing adjuvants and deliveries for improved functional and protective Ab responses

- Antibody-guided vaccine design
- Electroporation
- Mucosal vaccine technologies
- Virosomes

Chair:
Dr Anne De Groot, CSO & CEO, EpiVax, Inc
Panellists:
Dr John W. Shiver, Vice President, Global Vaccines Discovery & Basic Research, Merck Research Laboratories
Dr Susan W. Barnett, Senior Director, Senior Project Leader, Viral Vaccine Research, Novartis Vaccines and Diagnostics, Inc
Professor Angus Dalgleish, Professor of Oncology, St George's, University of London

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

Active Immunotherapeutics Forum

Planning your combination strategies: Synergistic effects or completely the contrary?

- Making the right business decisions about how and when to consider combinations and with what

4.20 Chair's introduction

Neil L. Berinstein MD, Chief Scientific Officer, IRX Therapeutics

4.25 Regulatory perspective
FDA / EMEA approaches to combination investigations: How well defined and harmonised are the regulatory mechanisms?

- If both agents are unapproved how do you move forward, especially when 2 different companies are involved?

Dr Thomas Hinz, Paul-Ehrlich-Institut
Dr Joyce Frey-Vasconcellos, Executive Director, PharmaNet Consulting, PharmaNet Development Group

4.55 Panel discussion
From a business development perspective, how can we overcome the strategic development concerns with AI combination therapies?

- What are the best commercial strategies for combination?
 - What evidence is there from the cancer, infectious diseases, allergy and autoimmune fields?
- Timing issues: How to combine 2 or more products when none or only 1 is approved?
 - Who will take the risk of development and at what stage?
- Stacking royalties: To what extent can they compromise the commercial viability of an AI combination product?

- Recognising when combination approaches might have synergistic effects or completely the contrary eg with
 - General immunomodulation
 - Chemo
 - Anti-angiogenesis drugs
 - Small molecules: Should you seek or avoid them as combinations?
- Moving to earlier stage combinations: Is this the future?
 - How to be confident that you have the right approach?

Panellists:
Charles A. Nicolette, PhD, Chief Scientific Officer, Vice President, R&D, Argos Therapeutics, Inc
Dr Harpreet Singh, CSO, immatics biotechnologies GmbH
Dr Thomas A. Davis, CMO & Senior Vice President, Clinical Development, CellDex Therapeutics
Dr Joseph Sinkule, Founder, Director, & CSO, Aphera, Inc

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

Media partners



"An inspiring conference with ample opportunity to mix with people with other areas of expertise. Thanks Phacilitate for pulling it off again!"

Professor Ben van der Zeijst, Scientific Director, Netherlands Vaccine Institute

"Great content and venue. High quality of participants and presenters, and great diversity of topics"

Aline Seilly, Field Marketing Manager, EU, Millipore

"Very good meeting overall - a broad spectrum of topics was covered and brilliant speakers were present. Very well organised"

Hedwig Kresse, Senior Analyst, Infectious Diseases, Datamonitor plc

"I found this a really interesting mix of topics and speakers, giving a very broad perspective. The speakers were present and accessible!"

Dr Robert Burns, CEO, Alvos Oncology

Your choice of 2 morning plenary sessions

Barcelona Vaccine Forum

Morning plenary session

Assessing the value and feasibility of emerging vaccine targets and markets in an evolving healthcare environment

- What lessons can be learned from pneumococcal and HPV vaccine success stories to inform both R&D and market development strategies for potential future blockbusters?

9.00 Chair's introduction

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

9.10 What will be the impact of healthcare reform and increasing reliance on HTA for the vaccines world?

- Update and implications of healthcare reform in the US and other markets on the vaccines industry
- Overview and outlook regarding how Health Technology Assessment (HTA) agencies assess the clinical and cost effectiveness of vaccines

W. Neil Palmer, President & Principal Consultant, PDCI Market Access

9.30 Questions & discussion

How could paediatric schedules be changed to incorporate new vaccines such as Men. B in the developed world, and e.Coli and Japanese Encephalitis in the developing world?

9.35 Evolving vaccination schedules and unmet needs: CDC perspective

- Status of US schedule
- Current context and environment
- Looking forward to the future

Dr Beth P. Bell, Associate Director for Science, National Center for Immunization & Respiratory Diseases, CDC

9.55 Questions & discussion

10.00 Industry perspective Expanding opportunities to deliver vaccines for paediatric populations on a global basis

Yves Leurquin, Executive Vice President, International & Government Affairs, Crucell NV

10.20 Questions & discussion

10.25 Morning coffee in the exhibition area

Short presentations & roundtable discussions

11.05 Current blockbusters: How to continue developing the marketplace to maintain growth?

- What is the future of pneumococcal vaccines? Where do they go from here? (What is the potential to further increase valency for both paediatric and adult markets? How realistic a target is a universal pneumococcal vaccine?)
- HPV update
 - How will recent decisions with regard to HPV vaccination recommendation (eg. for males) impact the market?
 - How are therapeutic vaccine approaches developing?
 - What is the future for multivalent HPV vaccines?
 - What new markets and targets might HPV vaccines open up, particularly in terms of other STDs?

Future blockbusters: What are the most attractive targets in terms of potential market value and biological/technical feasibility?

- Meningitis B
- Nosocomial infections (Staph. aureus, C. difficile, Pseudomonas aeruginosa)
- Herpes simplex V2

Panellists:

Dr Rino Rappuoli, Global Head, Vaccines Research, Novartis Vaccines & Diagnostics
Staph Leavenworth Bakali, CEO, Genocera Biosciences

Dr John W. Shiver, Vice President, Global Vaccines Discovery & Basic Research, Merck Research Laboratories

Dr Anne De Groot, CSO & CEO, EpiVax, Inc

12.40 Lunch

Active Immunotherapeutics Forum

Morning plenary session

How do you properly modulate the immune system? Tackling its multiple components and mechanisms of action to overcome the biological challenges

9.00 Chair's introduction

Dr Harpreet Singh, CSO, Immatix biotechnologies GmbH

9.05 Keynote address

Improving the efficacy of active immunotherapy: How can we make it work?

- What is the latest thinking on underlying biology for a better understanding of AI efficacy?
 - eg T reg cells: How do you turn around immunosuppression?
- Do we need to combine immunostimulants with vaccines?
- Relating clinical efficacy to immunologic activity: Is immunologic activity a prerequisite for efficacy?
 - How do you measure this in cancer patients where immunologic reactivity may already be compromised?
- Traditional vaccine approaches are now coming to active immunotherapeutics: What are their future roles?

Dr Axel Hoos, Medical Lead, Immunology/Oncology, Bristol-Myers Squibb

9.25 Questions & discussion

9.30 Short presentations & panel discussion

What are the recent advances in B cell and antibody approaches to AI, and how are they being used to inform decisions in different disease areas?

- Optimising antibody response: How to get high enough levels in certain indications
 - Alzheimer's - Crohn's disease
 - Arthritis - Substance abuse - Cancer
- Dosing issues
- Application of biomarkers
- Regulatory interaction
- To what extent is there a blurring of boundaries between AI and passive immunotherapeutics / MaBs?

Panellists:

Hideki Garren, MD, PhD, Executive Vice President, COO, CSO & Co-Founder, Bayhill Therapeutics

Dr Martin Bachmann, CSO, Cytos Biotechnology AG

10.25 Morning coffee in the exhibition area

11.05 BiTE: Marrying antibody and T cell therapy of cancer

- BiTE: A unique T-cell engaging antibody format
- Clinical proof of concept achieved in NHL and ALL with CD19-specific BiTE antibody blinatumomab
- EpCAM-specific BiTE antibody MT110 in clinical trial with solid tumour patients
- Emerging pipeline of BiTE antibodies in collaboration with strong pharma partners

- Well understood mode of BiTE action
 - Activity of cetuximab-based BiTE antibody against KRAS and BRAF mutated colorectal cancer cells
- Markus Muenz**, Group Leader, EpCAM Research, Micromet AG

11.25 Questions & discussion

11.30 Overcoming immune inhibitory pathways with cancer vaccine approaches

- Identification of dominant inhibitory pathways may provide rationale for selecting the most appropriate immune-modulator - these may be cancer and cancer-stage specific
- Using biomarkers of immune inhibition to increase the likelihood of generating meaningful anti-tumour response through combination of strategies to present tumour antigen to the immune system and appropriate immune modulation
- Multiple immune modulators can be considered but need to be selected rationally based upon disease and stage of disease
- Optimal clinical strategies to evaluate combination therapies and to maximize likelihood of success

Neil L. Berinstein MD, Chief Scientific Officer, IRX Therapeutics

11.50 Questions & discussion

11.55 Panel discussion Adjuvants and other agents: Do you need them?

- AIs have not reached maximum efficacy yet - would novel adjuvants be the answer? Or is the answer to find out how to fight active immunosuppression?
- What are the various mechanisms of action and how might they be applied in AI? eg
 - Anti CTLA4 - Anti-PD1 - Anti-41BB
- Striving for better biomarkers to understand how adjuvants drive the immune system
- What is the regulatory viewpoint on adjuvants for AIs - what is the risk:benefit?
- Many of these adjuvants and other agents have been in clinic for a while: Will they have utility on their own?
- What can you do locally and combine with systemic immunity?
 - How to combine early to optimise utility
- What examples are there of adjuvants / other agenda to supplement / complement AI approaches: Applications in cancer vaccines, infectious diseases and elsewhere

Panellists:

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

Pierre Vandepapelière, MD, PhD, Chief Medical Officer, Neovacs

12.40 Lunch



Your choice of 4 parallel sessions

Barcelona Vaccine Forum

Focus session

Are novel adjuvants realising their potential in influenza and other vaccine target areas?

- Addressing remaining R&D and regulatory challenges

1.40 Chair's introduction

What initiatives are underway to improve our understanding of the Mechanism of Action of adjuvants?

- How do adjuvants work - do we know enough?
- Can we predict safety from preclinical studies?
- Can we develop safe and effective novel adjuvants?

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

2.00 Analysing the latest clinical data from both novel- and alum-adjuvanted pandemic influenza vaccines

- Is the HI assay effective for determining vaccine efficacy?
- Can a background cross-specific immune response be effectively induced by (adjuvanted) vaccines?
- In light of this data, how critical a role should novel adjuvants play in the future of both seasonal and pandemic influenza preparedness?

Dr Ernst C. Soethout, Senior Research Scientist, Netherlands Vaccine Institute

2.20 Questions & discussion

Continued on next page »



Workshop

European regulatory update: Clarifying recent and novel guidelines, and delivering the keys to successful and efficient navigation

1.40 Moderator's introduction How can small biotechs make themselves more attractive to potential big pharma partners and add value to their assets by adopting a global regulatory strategy?

- How to differentiate yourself from competitors? The importance of a global regulatory strategy
- Leveraging opportunities in the regulatory framework to add value
- The importance of interactions with the regulatory authorities: Validate your product development plan
- The importance of regulatory intelligence and how this can add value
- Preparing for due diligence and maximising the value of your data package

Dr David Kirke, Associate Director, ERA Consulting

2.00 Questions & discussion

2.05 Update on assessment of vaccines by the centralised procedure

- Issues on recent assessment of vaccines
 - Considerations on PIPs and RMPs for vaccines
- Dr Marco Cavaleri**, Head of Anti-Infectives & Vaccines, Safety & Efficacy of Medicines Unit, European Medicines Agency

2.25 Questions & discussion

Continued on next page »

Active Immunotherapeutics Forum

Focus session

Methodologies to measure the potency of AI candidates and remove this major obstacle to the progression of products in pivotal trials

- Immune monitoring for clinical efficacy
- Potency assays for product characterisation

12.10 Chair's introduction

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

Case studies

Immune monitoring for clinical efficacy: How do you measure and monitor the potency of AI response in the clinic?

- What are the secondary measures to prove that AI is having an effect (eg other than tumour shrinkage in cancer vaccines)?

1.45 Case study

- How might the data collected in early clinical trials guide optimal regimen for later stage clinical trials?
- What evidence is there that immune response correlates to clinical benefit: Immune related response criteria is the holy grail
- What is the impact of potency assays on patient stratification and dosing?
- What assays and methods have been found to work? - ex vivo assays

Dr Steve Gracheck, Executive Director, Vaccine Research - La Jolla, Pfizer Global R&D

2.05 Questions & discussion

2.10 Active immunotherapeutics against self (cytokines: TNF α and IFN α) and non-self (infectious (HBV) antigens)

- How might the data collected in early clinical trials guide optimal regimen, for later stage clinical trials, and support registration?
- What evidence is there that immune response correlates to clinical benefit: are immune related response criteria the holy grail or should we develop other tools?

Continued on next page »

Workshop

Active immunosuppression: How might progress in the autoimmune and allergy fields inform AI candidates for cancer and infectious diseases?

12.00 Chair's introduction

Charles A. Nicolette, PhD, Chief Scientific Officer, Vice President, R&D, Argos Therapeutics, Inc

How are emerging technologies and approaches - in particular T reg cells - enabling the move into these new therapeutic targets?

1.45 Case study

Advances in DNA vaccines for autoimmune diseases: Clinical results

- Promising results from two clinical trials with DNA vaccines
 - BHT-3021 for type 1 diabetes
 - BHT-3009 for multiple sclerosis
 - Is there evidence for T reg induction by DNA vaccines?
 - Applicability to other disease areas
- Hideki Garren, MD, PhD**, Executive Vice President, COO, CSO & Co-Founder, Bayhill Therapeutics

2.05 Questions & discussion

2.10 Case study

Vaccination against type II diabetes

- Anti-II-1b vaccination
- Preclinical and first clinical data
- Cytokine neutralisation

Dr Martin Bachmann, CSO, Cytos Biotechnology AG

2.30 Questions & discussion

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Barcelona Vaccine Forum

Focus session continued

- 2.25 Challenges in developing adjuvanted seasonal and pandemic influenza vaccines**
 - Recombinant antigen technologies will soon replace traditional inactivated influenza vaccines
 - Adjuvants offer major benefits for both pandemic and seasonal vaccines but consumer opposition needs strong
 - Pandemic requirements are fast moving so only those manufacturers with extensive infrastructure are able to benefit
 - Governments prefer to contract large pharma manufacturers for pandemic supply rather than risk deals with smaller biotechs
 - Vaccine stability and potency are paramount to avoid recall of pandemic vaccine where speed of delivery precludes extensive testing before release

Professor Nikolai Petrovsky, CSO, Vaxine Pty Ltd
- 2.45 Questions & discussion**
- 2.50 Case study**
What is the latest clinical data for adjuvanted vaccines aimed at elderly and immunosuppressed populations?
 - How do adjuvants work in impaired populations?
 - Can we develop safe and effective adjuvants in impaired populations?
 - What adjuvants have demonstrated safety and effectiveness in these populations?
 - What is the future for adjuvants in these populations?

Dr Tyler Martin, Chief Medical Officer, Dynavax Corporation
- 3.10 Questions & discussion**
- 3.15 Panel discussion**
What do we know, and what do we need to know, to help risk-averse health policy makers feel more comfortable about the safety of novel adjuvants?
- 3.40 Chair's closing summary**
- 3.45 Close of conference followed by afternoon tea**

Workshop continued

- Paediatric Investigation Plans (PIPs): Exploring first experiences and lessons learned**
- 2.30 Case study**
Overview of adopted PIP's - learnings from HPV PIP's
 - Topline overview of adopted Art. 7 & Art. 8 PIP's
 - A glance at PIP's adopted for HPV vaccines
 - Challenges and learnings from navigating HPV PIP
 - Do/did the resources spent on vaccine PIP's benefit the pediatric patients?

Dr Frank Vandendriessche, Director, Regulatory Affairs, Europe, MSD Europe
- 2.50 Questions & panel discussion**
 - What is the PIP really impacting? Has it made any difference to timelines, costs and success rates for the paediatric vaccine regulation process?
 - Comparing and contrasting the PIP and PREAs in the US - what are the key similarities and differences?
- 3.05 How are novel risk management guidelines evolving in the vaccine space in Europe?**
 - Have they/will they changed the environment?
 - Should you adapt your R&D and business/commercial models to accommodate them and, if so, how?

Katharina Hartmann, MScPharm, Head of Pharmacovigilance, Crucell Switzerland AG
- 3.25 Questions & discussion**
- 3.30 Panel discussion**
Identifying and addressing key areas of disharmony with US FDA regulations: What are the next steps along the path to harmonisation?
- 3.40 Moderator's closing summary**
- 3.45 Close of conference followed by afternoon tea**

Active Immunotherapeutics Forum

Focus session continued

- What assays and methods have been found to work?
 - *ex vivo* assays - Genotype assays
 - Phenotype assays - Beyond elispot

Pierre Vandepapelière, MD, PhD, Chief Medical Officer, Neovacs
- 2.30 Questions & discussion**
- 2.35 Developing a potency assay for a variable component of the autologous, protein-based therapeutic cancer vaccine, Oncophage: What potency is required for release of the product?**
 - Challenges of developing cancer vaccine potency assays when immune correlates of clinical responses are not known
 - How can requirements for quantitative information on active ingredient be reconciled with inherent variability in the active ingredient?
 - How does one define a correlation between cancer vaccine potency and clinical effect in absence of focused regulatory guidelines?

Daniel L. Levey, PhD, Senior Director, Business Development, Antigenics Inc
- 2.55 Questions & discussion**
- 3.00 Case study**
Developing a well characterised product candidate that optimises potency: Ensuring that potency assays are comparable across trials
 - Lessons learned from the development of sipuleucel-T for men with castrate-resistant prostate cancer
 - Characterization of the product and development of the potency assay
 - Correlation of product parameters with laboratory and clinical outcomes

Dr David L. Urdal, CSO, Dendreon Corporation
- 3.05 Panel discussion**
Regulatory guidance: What is the latest from FDA and EMEA on the acceptance of immune monitoring and requirements for potency assays for AI?
 - What degree of harmonisation is there between regulatory bodies?
 - Drawing lessons from infectious diseases and cancer vaccines together
- 3.40 Chair's closing summary**
- 3.45 Close of conference followed by afternoon tea**

Workshop continued

- AI for allergy: What breakthroughs and barriers has this group encountered and what are their next steps?**
- 2.35 Case study**
Advances in sublingual immunotherapy of respiratory allergies
 - Antigen-specific tolerance induction in humans
 - Specifics of the oral immune system
 - Comparison between the subcutaneous and the sublingual routes of immunotherapy
 - Tolerance induction beyond regulatory T cells - adjuvants and vector systems for the sublingual route

Philippe Moingeon PhD, Vice President, R&D, Stallergenes SA
- 2.55 Questions & discussion**
- 3.00 Case study**
Next generation vaccines in allergic disorders
 - Translational research based identification of new biomarkers for allergic disease and clinical efficacy
 - Rational vaccine design with well characterised mode-of-action and improved immunisation schedules and dosage
 - Primary prevention of asthma and expanded use to new unmet needs

Poul Sorensen, PhD, Vice President, Global Research, ALK
- 3.20 Panel discussion**
How can a greater understanding of mechanism of action in these fields be used to inform R&D in the cancer and infectious disease areas?
- 3.40 Moderator's closing summary**
- 3.45 Close of conference followed by afternoon tea**



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