# Day 1 - Wednesday, May 11th 2011

7.30: Registration & buffet breakfast in the exhibition area

## Barcelona Vaccine Forum
## Active Immunotherapeutics Forum
### Shared morning plenary session

**Vaccines and active immunotherapy at the crossroads: How will R&D portfolios adapt to meet the demands of the evolving marketplace?**

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

**How are healthcare sector practices evolving with regard to the assessment and reimbursement of novel vaccines and active immunotherapies?**
- Understanding cost vs. benefit decision-making criteria for competing licensed & newly approved products: What role will cost effectiveness research play and how will this impact the vaccine and active immunotherapy areas?

**9.05 Industry perspective**
- Historically, R&D priorities for vaccines focused on infectious diseases with most significant disease burden
- Marketplace is rapidly changing – combining with unmet medical needs to shape future R&D priorities
  - Unmet medical needs
    - Novel targets
    - Select populations
    - Therapeutic vaccines
  - Market place realities
    - Introduction of newer vaccines (especially mid-income and developing world markets)
  - Cost of immunization
  - Logistical considerations (cold chain space, reliable transportation)
  - Customer acceptance
- Policymakers and healthcare professionals are increasing their emphasis of these financial and logistical realities. Examples:
  - ACIP decision for infant MCV (Not cost effective)
  - GAVI investment cases
  - Introduction of PCV in the developing world
- Approaches to help R&D decision making
  - Cost of new vaccines
  - Logistical considerations
  - Customer acceptance

**Joseph C. Sullivan**, Executive Director, New Vaccines Product Group, Merck & Co, Inc

**9.25 New vaccines and active immunotherapeutics from the HTA perspective**
- What do we need?
- The required data for a successful reimbursement
- Is there a space for collaboration?

**Dr Oriol Solà-Morales**, HTA Director, Catalan Agency for Health Technology Assessment & Research (AIAQS)

**9.45 Public & private sector stakeholders' roundtable discussion**
**How should you design and conduct pharmacoeconomic studies to support novel vaccines and active immunotherapies in the current healthcare environment?**
- What sort of data, and what degree of benefit, do payers and healthtech evaluators need to see?
- How does this harmonise with regulatory requirements?
- What is the route to ensure reimbursement issues are resolved prior to licensure?
  - How far in advance do you need to plan?

Panellists:
**Dr Karen J. Huebscher**, Head, Europe Public Health & Market Access, Novartis Vaccines
**Dr David L. Urdal**, CSO, Dendreon Corporation

**How is industry responding? Assessing the fundamental choices open to pharma & biotech decision-makers: What are the strategic keys to R&D and commercial success in...**

**10.10 ...driving forward with infectious disease targets?**
**Pierre A. Morgon**, Vice President, Franchise & Global Marketing Operations, sanofi pasteur

**10.30 ...broadening the realm of vaccine technology to incorporate novel therapeutic areas and approaches?**
**Dr Oliver Maria Wilbert, MBA**, Senior Director, Immunotherapies; Global Product Unit Oncology Portfolio Development, Merck Serono

**10.50 Questions for the speakers & panel discussion**
**What are the pros and cons, and implications for the overall business model, of either approach?**
- What is the optimal balance between vaccines and active immunotherapy in the R&D portfolio?

**11.10 Morning coffee in the exhibition area**

Followed by your choice from of the 4 sessions »

## Barcelona Vaccine Forum
### Workshop ⓘ

**Defining key public and private stakeholders' roles in ensuring a healthy influenza vaccine sector moving forward**

**11.50 Chair's introduction**
**Dr Bram Palache**, Global Scientific Communications & Public Affairs Director, Influenza Vaccines, Abbott

**11.55 Working Party A**

**Assessing the ongoing fall-out from the 2009/10 H1N1 pandemic: Learning lessons for the next pandemic**
**Areas for discussion:**
- Is there anything we can do to better predict the next pandemic, and its severity, on a global basis?
- How can we prepare to meet demand more effectively, and in a more timely manner?
  - How are regulatory processes evolving as a consequence?
- Assay development in the influenza vaccine space - how does it need to advance to improve management of 'flu outbreaks?
- Should Asia be taking a greater role in anticipation of/preparing for an avian 'flu outbreak in humans? If so, what form should it take?
- Why did H1N1 pandemic 'flu vaccine uptake levels vary so widely from region to region?
  - What were the keys to success in those countries where uptake levels were high?
- How to improve lines of communication between the various public and private sector stakeholders?
- How should we manage negative public perceptions associated with the H1N1 pandemic?
  - Was there any effect on 'flu vaccine uptake during the 2010/11 season? Has there been an impact on vaccine uptake in general, including paediatric vaccines?

Panellists:
**Dr John Siu Lun Tam**, Scientist, Global Influenza Programme (GIP), Health Security & Environment (HSE), World Health Organization
**Pieter Neels**, Belgian CHMP Member & vice-chair VWP (EMA), Federal Agency for Medicinal & Health Products, Belgium
**Dr Steven Kleiboeker, DVM, PhD**, Chief Scientific Officer, Viracor-IBT Laboratories, Inc
**Dr Marion Gruber**, Deputy Director, Office of Vaccines Research & Review (OVRR), CBER, US Food & Drug Administration
**Dr Suresh Jadhav**, Executive Director, Serum Institute of India Ltd
**Mike Seymour**, International Director, Crisis & Issues Management, Edelman

**1.10 Buffet lunch in the exhibition area**

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## Both Forums
### Focus session 1

**Happy birthday Provenge: Lessons learned from 1 year of experience as an approved product**

**11.50 Chair's introduction**
**Reiner Laus, MD**, President & Chief Executive Officer, BN ImmunoTherapeutics

**11.55 Dendreon's perspective: Leaving no stone unturned**
- Who is using Provenge, how are patients selected, and how are they dealing with capacity restrictions?
- Have there been any side effects?
- What is the outcome of discussions with CMS? How is reimbursement being handled?
- How much better than control does AI need to be for cost-effectiveness?
  - How do you sell agencies, reimbursers, and the public on slight incremental lifespan vs. very high cost?
- Addressing the procurement, logistics, and manufacturing issues
  - Working with blood banks
  - Manufacturing facilities outside US: How is the GSK facility working in practice? What supply goes where?
  - Managing the international shipping of biological products
- Entering international markets: What is the strategy for Europe and RoW?
  - What reimbursement feedback has there been so far from EU?
- With the benefit of hindsight what are the major lessons learned in terms of
  - Risk mitigation
  - Biomarker identification and validation
  - Pre-clinical strategy: What was actually translational?
  - Immune monitoring: What is the true mechanism of action?
  - Clinical design
- Active life cycle management – looking for the next indications
  - What are the good tumour types for AI?
- Combination strategies: What are the next steps to improve survival?

**Dr David L. Urdal**, CSO, Dendreon Corporation
**Heidi Hagen**, Senior Vice President of Operations, Dendreon Corporation
**Michael G. Covington**, CMC Director, Regulatory Affairs, Dendreon Corporation

**1.10 Buffet lunch in the exhibition area**

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## Both Forums
### Focus session 2

**Chronic infectious diseases – HIV, HPV and HCV: Is prevention or therapy the answer?**
- What is the relative value of each approach to public health stakeholders focusing on eradication programs?

**11.50 Chair's introduction**
**Professor Alexander von Gabain**, Strategic Advisor to the Boards, Intercell AG

**HIV: Do recent positive results from prophylactic and therapeutic approaches really signal a renaissance?**
- What are the major opportunities and challenges for prophylactic, active immunotherapeutic and antiviral approaches?
- What's coming out of pre-clinical and clinical that's most promising?
- Can a neutralising anti-HIV antibody be generated by a vaccine or do we need other approaches?

**11.55 Case study – prophylactic**
**Building on the Thai HIV Vaccine Trial: Insights from correlates work, animal models and acute infection**
- Correlates: Summary of progress and promising leads
- Parallels: Vaccine-induced protection in NHP
- Acute HIV infection: Opening the window of opportunity
- Clinical development strategy for HIV vaccines

**Jerome H. Kim, MD**, Deputy Director (Science) & Project Manager, HIV Vaccines, US Army Medical Materiel Development Activity

**12.15 Questions & discussion**

**12.20 Case study**
**DermaVir active immunotherapy for HIV: A technology for induction of Th1 type cellular immunity and clinical results**
- Antigen selection and characterization
- Antigen formulation to "pathogen-like" nanomedicine
- Targeted antigen delivery to lymph node dendritic cells
- Challenges with HIV therapeutic vaccination

**Dr Julianna Lisziewicz**, President & CEO, Genetic Immunity

**12.40 Panel discussion**
**To what extent can you translate data/results from therapeutic to prophylactic spheres?**
- What are the limits of the prophylactic model?
- What are the relevant lessons for infectious disease vaccine developers from novel adjuvant applications in the therapeutic vaccine space?

**1.10 Buffet lunch in the exhibition area**

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## Active Immunotherapeutics Forum
### Workshop ⓘ

**Focusing on autoimmune disease, allergy and asthma: Developing a greater understanding of inflammation and tolerance models to drive the AI field forward**

**11.50 Moderator's introduction**
**Dr. Mark W. Schwartz**, CEO & President, Apthera

**Autoimmunity and inflammation: How is AI achieving targeted suppression of the immune reaction?**
- What interventions are seeing greatest success? What is known about their mechanism of action?
- What progress is being made with the identification and validation of biomarkers?
- Use of stem cells + T cell approaches to switch off chronic inflammation

**11.55 Case study**
**Recombinant human CD83 protein: A first-in-class therapeutic that actively suppresses inflammatory and autoimmune responses**
- Efficacy in animal models of transplantation rejection and inflammatory disease
- Both T cell and B cell responses are specifically blocked
- No requirement for chronic dosing to achieve specific lifelong tolerance without global immunosuppression
- Deciphering the mechanism of tolerance induction by sCD83
- Challenges for clinical development of sCD83

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

**12.15 Questions & discussion**

**12.20 Case study**
Speaker to be announced

**12.40 Panel discussion**
**What are the main areas of overlap / cross talk between autoimmune disease, oncology and chronic viral infectious diseases?**
- How is one area informing advancements in the others?

**1.10 Buffet lunch in the exhibition area**

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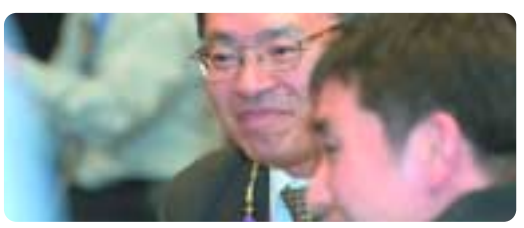

ⓘ Indicates a highly interactive session for a maximum of 30 participants. **Register today to guarantee you place in these sessions**

# Day 1 - Wednesday, May 11th 2011 Continued

## Barcelona Vaccine Forum

### Workshop

**2.20 Working Party B**

**What will the influenza vaccine marketplace look like over the coming few years? How can we drive it forward?**

**Areas for discussion:**

- How much should public and private sector stakeholders continue to invest short-term in 'non-conventional' technology development, and preparedness in general?
- Assessing the risk of over-capacity in the Western hemisphere leading to lower prices and large companies leaving the market - what are the strategic solutions to this potential issue?
- What will be the impact of recent progress with a 'universal' antigen?
- Examining the pros and cons of paediatric influenza vaccination: Is it a realistic proposition moving forward?
- How to make influenza vaccines that work well in adults/the elderly? What is the latest progress?
- What will be the impact of joint procurement agreements in Europe?
  - Will they stretch beyond pandemic influenza to other vaccine areas/targets?
- What impact did the trivalent (incorporating H1N1) vaccine have on epidemiology where it was used? What lessons can we draw from this moving forward?

Panellists:

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

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

**Dr Karen J. Huebscher**, Head, Europe Public Health & Market Access, Novartis Vaccines

**Dr Rahul Singhvi**, President & CEO, Novavax, Inc

**3.25 Conclusions and further action points from both Working Parties in terms of:**

- How to improve global coordination between communication and supply efforts in crisis situations?
- How will the industry build on recent progress in terms of the acceptability of novel adjuvants to the regulators, particularly with regard to developing effective vaccines for poor responders?
- How to keep public health decision makers engaged in pandemic influenza preparedness moving forward?

**A report will be made available to all attendees shortly after the meeting summarising the conclusions and next steps from the working parties**

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

## Both Forums

### Focus session continued

**2.20 Third party perspectives: Regulator, payer and physician feedback on the impact Provenge has had in their field**

**Dr Thomas Hinz**, Head of Section, Therapeutic Vaccines, Paul-Ehrlich-Institut

**Dr Oriol Solà-Morales**, HTA Director, Catalan Agency for Health Technology Assessment & Research (AIAQS)

**3.10 Industry perspectives: Is Provenge an outlier or is the tide really turning?**

- How has the approval of Provenge affected our development strategies and commercial planning?
- How will it help inform criteria for target selection going forward: Developing a more systemic and sophisticated approach
- Do cancer vaccines need to be individualised or not?
- How will companies need to adapt their development and commercialisation strategy now that there is a standard to work against?

Panellists:

**Dr Carlos F. Santos**, CSO & Vice President, Product Development, Accentia Biopharmaceuticals / Biovest International

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

**3.35 Chair's closing summary**

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



## Both Forums

### Focus session continued

**How are we addressing the major challenges faced by the prophylactic model for HPV and HCV?**

**2.20 HPV therapeutic vaccine case study**

- Antibodies to L1 for prophylaxis versus robust T cell responses against Early proteins E6 and E7 for therapy
- Strategies to inactivate therapeutic vaccine-prompted regulatory T cells
- Disease spectrum for treatment with therapeutic HPV16 vaccine: pre-malignant diseases, CIN, VIN, AIN, cervical cancer, vulvar cancer, head and neck cancer, oesophagus cancer (squamous)
- Advantages of synthetic vaccines
- Combination of therapeutic vaccination with other treatment modalities (chemotherapy, monoclonal antibodies)

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

**2.40 Questions & discussion**

**2.45 Development of TG4040 therapeutic vaccine for the treatment of HCV infected patients**

- Scientific rationale
- Preclinical package
- Immunomonitoring
- Clinical plan

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

**3.05 Panel discussion**

**Examining chronic infectious disease eradication programmes and goals: What role for prophylactic and therapeutic interventions alike?**

- What is the relative value of each area to key funders/public health stakeholders?
- How to balance the two basic approaches for key targets including HIV and HPV
- WHO and The Gates Foundation: What role do they see for active immunotherapeutics in global health programmes?
  - What models would stimulate their interest in AI?
  - How should they be positioned?
  - What targets would be considered?

Panellist:

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

**3.35 Chair's closing summary**

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

## Active Immunotherapeutics Forum

### Workshop continued

**Allergy and asthma: State of the art tolerance models and new delivery technologies to improve AI efficacy**

- How to specifically induce tolerance against common allergens?
- Can tolerance models be studied pre-clinically?
- How to polarise dendritic cells to tolerizing mode?
- Novel administration routes
- Progress with the pan-allergy approach: How will it affect the future of the sector?
- The regulatory environment - what data to submit? How long to we have to wait to see if the treatment is truly disease modifying?

**2.20 Case study**

**Targeting plasmacytoid dendritic cells for the treatment of asthma: A phase II study**

- Toll-like receptor 9 ligand packaged into virus-like particles
- Activation of plasmacytoid dendritic cells
- Induction of IFNa and ICOSL
- Shutting down Th2 responses and induction of Tregs

**Dr Martin Bachmann**, CSO, Cytos Biotechnology AG

**2.40 Questions & discussion**

**2.45 Case study**

**Apitopes: Improving treatment of autoimmune and allergic conditions through rational design of peptide epitopes**

- Design of peptide epitopes, the Apitope approach
- Mechanisms of peripheral tolerance
- Use of peptides for induction of peripheral tolerance
- A phase I study of ATX-MS1467 in secondary progressive MS

**Dr Martin Sims**, Research Director, Apitope

**3.05 Panel discussion**

**Comparing and contrasting tolerance versus immune stimulation in a creative way: What can each camp learn from the other?**

**3.35 Moderator's closing summary**

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

## Shared afternoon plenary session

**How to capitalise on evolving licensing & partnering trends and innovative operating models to beat the financial downturn?**

**4.20 Chair's introduction**

**Analyst's perspective**

**Examining big pharma vaccine development pipelines: What percentage of their candidates are in-licensed? How does this compare with their therapeutic pipelines?**

- What are the differences in Present Value of vaccine versus therapeutic product candidates?

**Adrian Howd, PhD**, Analyst, Biotechnology & Pharmaceuticals, Healthcare Research Team, Joh. Berenberg, Gossler & Co. KG

**Industry case studies: Exploring the evolution of big pharma/biotech partnering models: How is the trend for early-stage risk-sharing deals impacting large and small companies alike?**

- Exploring recent deals: What are the key success factors for either party?

**4.30 Big pharma perspective**

**Partnering for success**

- Partnerships are key to the growth of both large and small vaccine companies
- Matching expectations and realities; an essential ingredient
- Ways to mitigate risk in transactions; defining risk and transactional methods to share it
- Management of partnerships for success

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

**4.20 Biotech perspective**

**Risk sharing between large pharma and small biotech; a growing trend in licensing**

- Large pharma is becoming more dependent on small biotech to complement their new product portfolio
- To improve the chances of success, large pharma have increased their licensing activities significantly
- With increasingly limited budgets and increasing licensing activities, large pharma resorted to licensing models that shifted some of the risk to small biotech
- Small biotech, on the other hand, are accepting such models partly due to the limited availability of other financing opportunities in the current equity market

**Dr Raafat E. F. Fahim**, President & CEO, Nabi Biopharmaceuticals

**4.50 Questions & discussion**

**5.00 Roundtable discussion**

**Survival strategies for biotechs in tough financial times**

- What improvements can we expect in investor psyche over the next 6-12 months?
- How to improve cost efficiency?
  - What are the strategic repercussions from, and impact on the decision-making processes of, stripping back biotech portfolios to focus on a single technology platform and/or product candidate?
  - When/how will the 'virtual development' model impact the vaccine/active immunotherapy spaces?
    - Can such models be applied in the vaccine area as they have been in the therapeutic space given the fundamentally different financial dynamics of the vaccine market?
- When should biotech stay private? Will being public help that much in today's commercial environment?

Panellists:

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

**Christopher F. Nicodemus, MD, FACP**, Chairman & Chief Scientific Officer, Advanced Immune Therapeutics, Inc

**Dr Rahul Singhvi**, President & CEO, Novavax, Inc

**Jill O'Donnell-Tormey, PhD**, Executive Director, Cancer Research Institute, member of the Executive Committee of the Cancer Immunotherapy Consortium, member of the Coordinating & Review Committee of the Cancer Vaccine Collaborative

**5.40 Close of day 1, followed by a cocktail reception in the exhibition area**

### Media partners

# Day 2 - Thursday, May 12th 2011

7.30: Registration & buffet breakfast in the exhibition area

## Your choice of 2 morning plenary sessions

### Barcelona Vaccine Forum

#### Morning plenary session

**How will your company stake a claim in the global vaccine sector of the future?**

- What is the optimal international expansion model for large and small vaccine industry players alike?

**9.00 Chair's introduction**

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

**9.05 Analyst's perspective: How important will developing markets be in the context of the global vaccine sector as whole?**

- What are the most interesting geographies to target for vaccine makers looking for regional expansion?
- What are the most promising target indications in emerging markets?
- What are the best market access strategies for vaccine makers in key developing markets?

**Hedwig Kresse**, Head, Vaccines & Infectious Diseases; Regional Head Growth Markets – Asia-Pacific, Datamonitor plc *(provisionally confirmed)*

**Big pharma perspectives: Build vs. Buy vs. Partner - examining the strategic business models for global expansion being employed by major players**

- What are the specific challenges/opportunities inherent in each model, and how are they being capitalised upon/addressed on a region-by-region basis?

**9.20 Big pharma perspective**

**Dr Robert Repetto**, Director of Strategic & External Affairs, Pfizer, Inc *(provisionally confirmed)*

**9.40 Big pharma perspective**

**Becoming a global vaccine company: A Merck perspective**

- Merck has been a major vaccine company for over four decades but has focused primarily on the US and European markets
- Merck recognises the need for strategic partnerships to become a global vaccine company
- A variety of strategic business models will be needed to meet the global vaccine needs

**Michael N. Robertson, MD**, Senior Director, External Scientific Affairs, Merck & Co, Inc

**10.00 What are the options available to vaccine biotechs in terms of global expansion?**

- How to pay for it? What public sector funding opportunities exist in the developing world for biotechs?
  - How to capitalise on them?
- Examining opportunities/business models for partnering with developing world companies
  - What are the strategic concerns? (Eg. Does the loss of commercial rights in a given region impact the potential to partner with big pharma in other regions?
- How can vaccine biotechs overcome the major barrier to global entry of developing multiple processes for multivalent vaccines?

**Professor Alexander von Gabain**, Strategic Advisor to the Boards, Intercell AG

**Eastern vaccine company perspectives**

- What are our commercial and R&D goals moving forward, and what role will partnerships with Western players take in achieving them?
- The 2-way street: Defining the opportunities for large and small Western vaccine companies to partner with developing world companies in order to bring products to Western markets

**10.20 Global vaccine market: Chinese company's perspective**

- Chinese vaccine industry has been developing fast in recent years
- Players in Chinese vaccine industry
- Sinovac's efforts in getting into international vaccine market
- Global vaccine market: Sinovac's strategy

**Dr Samantha Dong**, R&D Manager, Sinovac Biotech Ltd

**10.35 Tech transfer models for global expansion: Indian manufacturer perspective**

- Overview of Indian vaccine industry in purview of strategic business models of build, buy and partner models
- Impact of Indian vaccine industry on global health
- Regulatory pathways
- Global expectations and challenges

**Dr Suresh Jadhav**, Executive Director, Serum Institute of India Ltd

**10.50 Roundtable discussion**

- How to address IP considerations where vaccine development/manufacture is conducted in developing nations? Western and Eastern company perspectives
- How are regulatory pathways for predominantly developing world vaccines evolving on a global basis and which one should you take? (eg. WHO certification vs. Article 58 vs. the US FDA vs. adopting a purely developing world regulatory pathway)
  - What are the strategic repercussions of the restructuring of the WHO prequalification process?
  - What regulatory tactics have been/are being adopted by different companies and why? With what results?
  - Is parallel review between national regulatory authorities a viable solution?
- How will the trend for big pharma companies to make vaccines available for free, or at cost-price, impact the global vaccine marketplace long-term?

Panellists:

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

**Altaf A. Lal, PhD**, Chief Executive Officer, MSD Wellcome Trust Hilleman Laboratories

**Pieter Neels**, Belgian CHMP Member & vice-chair VWP (EMA), Federal Agency for Medicinal & Health Products, Belgium

**Dr Marion Gruber**, Deputy Director, Office of Vaccines Research & Review (OVRR), CBER, US Food & Drug Administration

**11.20 Morning coffee in the exhibition area**

### Active Immunotherapeutics Forum

#### Morning plenary session

**Advanced phase III active immunotherapy programs: Just how well did the pre-clinical and early clinical trials translate?**

**9.00 Chair's introduction**

**With the benefit of hindsight, what are the 3 biggest lessons learned from**

- Pre-clinical
  - What did they see in mice that made them go ahead? Was it translational? What if anything was learned about mechanism of action?
  - What led them to that pre-clinical and clinical design? Were they the right decisions?
  - What can we do pre-clinically to answer questions that are meaningful clinically: How can it be made more predictive? What are the alternative pre-clinical routes for getting into man without tox models?
- Early clinical trials
  - Can you base your business decisions on immunological data? How predictive is it of clinical outcomes?
  - What was discovered about surrogates of immunity? What should the primary indication be in terms of approval of AI products?
  - What wouldn't they have predicted?

**9.05 Case study**

**Clinical and pre-clinical development of BiovaxID autologous idiotype vaccine for Non-Hodgkin's Lymphoma**

**Dr Carlos F. Santos**, CSO & Vice President, Product Development, Accentia Biopharmaceuticals / Biovest International

**9.25 Questions & discussion**

**9.30 Building preclinical and clinical evidence for the big jump - MAGE–A3 ASCI case study**

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

**9.50 Questions & discussion**

**9.55 Case study**

**"Reverse" drug development in allergy and specific immunotherapy**

**Dr Kim Simonsen**, Senior Director, Global Clinical Development, ALK

**10.15 Questions & discussion**

**10.20 Case study**

**De-risking cancer immunotherapy development: A not-for-profit model**

Well designed early-phase clinical trials of cancer immunotherapies can yield critical data on the effect they have on the immune system, and are essential to informing decisions for further clinical development. A coordinated academic clinical trials network (the Cancer Vaccine Collaborative) with a special emphasis on in-depth immunological monitoring represents a powerful rubric for not-for-profit participation with industry partners in the de-risking of investment in cancer immunotherapy development.

**Jill O'Donnell-Tormey, PhD**, Executive Director, Cancer Research Institute, member of the Executive Committee of the Cancer Immunotherapy Consortium, member of the Coordinating & Review Committee of the Cancer Vaccine Collaborative

**10.40 Panel discussion**

**What has been the regulatory reaction to positive immune data? Reflections from EU and US regulators and companies**

- What is the pre-clinical package needed for registration?
- What are the regulators looking for from clinical trials :
  - Were there enough patients?
  - Was the safety data sufficient?
- What's the regulatory guidance on humeral and cell-mediated immune monitoring?
  - Can biological end-points actually play a larger role?
- Will one phase III study be sufficient?
- How to work in an environment where regulators have to be totally reactive
- What criteria might now be considered in order to have confidence that an AI candidate has a high likelihood of clinical success?

Panellists:

**Dr Thomas Hinz**, Head of Section, Therapeutic Vaccines, Paul-Ehrlich-Institut

**Michael G. Covington**, CMC Director, Regulatory Affairs, Dendreon Corporation

**11.20 Morning coffee in the exhibition area**

## Your choice of 4 parallel sessions

### Barcelona Vaccine Forum

#### Focus session

**Driving the adoption of next generation vaccine manufacturing technologies on a global scale**

- What are the strategic keys to enable efficient and commercially feasible technology transfer worldwide?

**12.00 Chair's introduction**

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

**12.05 Addressing quality issues with developing world vaccine manufacture: How do you ensure quality is consistent with developed world standards?**

- Assessing the 'higher quality equals higher cost' conundrum
  - How can this be alleviated to drive novel technologies into developing nations?

**Dr Rahul Singhvi**, President & CEO, Novavax, Inc

**Next-generation cell culture and single-use manufacturing technologies**

- What strategies are companies employing to drive further development/market expansion?

**12.25 Single-use manufacturing technology**

Presentation reserved

**12.45 Questions & discussion**

Continued on next page »

#### Workshop ⓘ

**Light at the end of the tunnel: Are we finally set to address the most pressing global infectious disease threats?**

**12.00 Moderator's introduction**

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

**Case studies**
**Malaria: Updates on the latest clinical trial data for the most advanced vaccine candidates**

**12.05 Case study**

**Dr Didier Leboulleux**, Associate Director, RTS,S Clinical Unit, PATH Malaria Vaccine Initiative (MVI)

**12.25 Case study**

**The role of cellular immunity in protection against liver stage malaria**

- Mouse protection due to CD8 T cells against CS protein
- Protection in human challenge seen with adjuvants and CS that includes targets of cellular immunity
- Human challenge protection in absence of antibody following DNA + Adenovirus immunisation

**Dr Jerald Sadoff**, Chief Medical Officer, Crucell

**12.45 Case study**

**Professor Adrian V. S. Hill**, Wellcome Trust Principal Research Fellow, Centre for Clinical Vaccinology & Tropical Medicine, Oxford University

**1.05 Questions & discussion**

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

### Active Immunotherapeutics Forum

#### Focus session

**Combination science: Which combinatorial strategies are achieving material advancement in active immunotherapeutic efficacy?**

- Optimising dosing and scheduling
- Combination with standard of care and with increasingly targeted new entities

**12.10 Chair's introduction**

**Combinatorial active immune therapy: An overview of where the field is going**

- What are the different categories of combination approach that are making greatest headway?
- What are the new pieces in the jigsaw to alter the environment for AIs to work better?

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

**12.25 Questions & discussion**

**How do you integrate active immunotherapeutics into the standard of care? Proof of concept case studies illustrating:**

- How is dosing and scheduling being optimised?
- What is the mechanism of action?

**12.30 Case study**

**Pick your biological gradient carefully!! Prevention of recurrence vs treatment of metastatic cancer for HER2 1+ and 2+ breast cancer patients**

*The presentation will cover NeuVax for the prevention of recurrence and the rationale and data supporting*:

- Target patient population
- Metastatic vs recurrence, and combination with Standard of Care
- Dose optimization
- Current results and path forward

**Dr Mark W. Schwartz**, CEO & President, Apthera

**12.50 Questions & discussion**

Continued on next page »

#### Workshop ⓘ

**Achieving a valid phase III hypothesis to mitigate risk in active immunotherapy**

- Creative approaches to finding the elusive biomarker
- Investing in randomised phase II trials

**11.40 Chair's introduction**

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

**11.45 Biomarkers brainstorming session: Unveiling mechanism of action - what are the surrogates to demonstrate what the AI does?**

**A report will be made available to all attendees shortly after the meeting outlining the conclusions and next steps from this brainstorming session**

- Approaches to biomarker selection and validation for early efficacy and for patient selection
- What are the predictive biomarkers which might be used as surrogate endpoints?
- Is T cell immune monitoring a good biomarker?
- What are the alternative surrogates of efficacy - antibody markers?
- How to define an immunological phenotype that predisposes candidates to be good or bad patients for your active immunotherapy?
  - Immunoprofiling – how do we get there?
- Is it necessary to run a 5 year patient study before you can do a biomarker study? Or are there creative approaches which could be more efficient?
- Feedback from companies conducting biomarker studies in phase III: Lessons learned for proof of concept studies
- Having found a biomarker, how should it be integrated into phase III to enhance the development of the product?
- What are the practical implications of biomarker development and being more specific – how might they be used commercially?

Continued on next page »

# Day 2 - Thursday, May 12th 2011 Continued

## Barcelona Vaccine Forum

### Focus session continued

**12.50 Cell culture derived influenza vaccines: From bench to licensure and beyond**
- Technology update
- Clinical programs including safety and efficacy data
- Correlate of protection
- Future developments

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

**1.10 Questions & discussion**

**1.15 Buffet lunch in the exhibition area**

**OR Working lunch**
**Is the 'Quality by Design' concept really applicable to biologics?**
(Highly interactive, discussion-based session for a maximum of 12 participants)

**2.25 Technology transfer to emerging country process evolution: Opportunities and challenges**
- Vaccine needs in emerging countries are leading to diverse technology transfer approaches
- Being successful requires a real shared-benefit mindset
- Agility of organisation is also a key success factor
- It is a very significant opportunity for know-how development

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

**2.45 Questions & discussion**

**2.50 Manufacturing process development and change in the development of novel cell based vaccines: The regulatory pathway to licensure in Europe**
- The regulatory path for vaccines in Europe
- CMC considerations in cell based vaccine development
- Illustrating comparability following a change in the manufacturing process - considerations specific to vaccines
- Changes in the manufacturing process of cell based vaccines post-approval - regulatory requirements

**Natalie Thomas, PhD**, Regulatory Affairs Project Manager, ERA Consulting (UK) Ltd

**3.10 Questions & discussion**

**3.15 Panel discussion**
**How can we improve response to the next major global infectious disease outbreak in terms of ensuring equitable/timely supply of vaccines on a worldwide basis?**
- How to make next-generation manufacturing

technologies affordable?
- Comparing and contrasting timelines from strain selection to final vaccine supply: Are cell-based manufacturing technologies really quicker than the traditional egg-based process?
  - Is egg-based manufacturing a viable option in the developing world?

Panellist:
**Dr John Siu Lun Tam**, Scientist, Global Influenza Programme (GIP), Health Security & Environment (HSE), World Health Organization

**3.35 Chair's closing summary**

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

### Workshop continued

**1.15 Buffet lunch in the exhibition area**

**OR Working lunch**
**Is the 'Quality by Design' concept really applicable to biologics?**
(Highly interactive, discussion-based session for a maximum of 12 participants)

**2.25 What is the latest R&D progress with next-generation TB vaccine candidates?**
- Progress in clinical development of novel TB vaccines
- Pre- and post-exposure TB vaccination strategies
- TB vaccine adjuvants

**Else Marie Agger, MSc, PhD**, Associate Director, Department of Infectious Disease Immunology; Head of Section, TB Vaccine Research, Statens Serum Institut

**2.45 Case study**
**Clinical status of Virus Like Particle (VLP) vaccines for norovirus acute gastroenteritis**
- Challenges of vaccine development for norovirus
- Advantages of VLP for vaccine development
- Lessons learned from monovalent VLP vaccine clinical studies
- Multivalent VLP vaccine clinical status

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

**3.05 Panel discussion**
- How can the wider vaccine community 'think out of the box' to identify and address new infectious disease outbreaks as they occur?
- Dengue fever and chikungunya: What sort of public health strategies can/should be employed in developed world nations and what is the market opportunity for the vaccine industry?
  - What is the latest epidemiology/incidence/clinical severity data for these diseases on a global basis?
- Given the recent spread of dengue fever and chikungunya in the US and Southern Europe, does the WHO/CDC foresee the re-emergence of other infectious diseases in the West (eg. malaria)?

**3.35 Moderator's closing summary**

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

**"Very good science, interesting practical down to business debates, good networking"**

Cristina Wilma, Director, Business Development/PreMarketing, Antisense Pharma GmbH

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

Aline Seilly, Field Marketing Manager, EU, Millipore

## Active Immunotherapeutics Forum

### Focus session continued

**12.55 What is the impact of standard of care in anticancer treatment on the development strategy of active immunotherapeutics?**
- Chemotherapies
- Radiation
- Tumor entities
- Safety aspects
- Regulatory aspects
- Financial and time aspects

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

**1.15 Questions & discussion**

**1.20 Buffet lunch in the exhibition area**

**Moving away from conventional combinations into those that are increasingly targeted: What are the practical considerations?**

**2.30 Case study**
**Development of combinatorial cancer vaccines**
- Which questions can/should be addressed preclinically?
- Are preclinical tumor models translational (predicting clinical success)?
- How to justify each component of the combinatorial cancer vaccine

**Dr Karin Jooss**, Research Fellow, Vaccine Research, Pfizer Global R&D

**2.50 Questions & discussion**

**2.55 Case study**
**Combination of peptide-based cancer vaccine IMA901 with immunomodulators and TKIs - from preclinical to phase III**
- Selection of immunomodulator for phase I
- Data-driven selection of additional immunomodulator for phase II
- Data-driven selection of TKI combination partner for phase III
- Preclinical models and clinical biomarkers/immunomonitoring as vital tools for optimising combinations
- Dissecting the contribution of the combination partners in the clinic
- Implications for trial design and regulatory submissions

**Dr Harpreet Singh**, Founder & CSO, immatics biotechnologies GmbH

**3.15 Panel discussion**
**How do you choose the optimal immune modulator?**
- What are the scientific considerations when evaluating which cytokines, chemokines, and co-stimulatory molecules could be combined with your AI candidate?

Panellist:
**Christopher F. Nicodemus, MD FACP**, Chairman & Chief Scientific Officer, Advanced Immune Therapeutics, Inc

**3.45 Chair's closing summary**

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

### Workshop continued

Panellists:
**Dr Harpreet Singh**, Founder & CSO, immatics biotechnologies GmbH
**Dr Karin Jooss**, Research Fellow, Vaccine Research, Pfizer Global R&D
**Dr Carlos F. Santos**, CSO & Vice President, Product Development, Accentia Biopharmaceuticals / Biovest International
**Reiner Laus, MD**, President & Chief Executive Officer, BN ImmunoTherapeutics
**Dr Jean-Yves Bonnefoy**, Vice President, R&D, Transgene SA
**Dr Kim Simonsen**, Senior Director, Global Clinical Development, ALK
**Dr Richard Harrop**, Head of Clinical Analysis, Oxford BioMedica UK Ltd
**Joanne Parker, PhD**, Director of Research & Pharmaceutical Services, Viracor-IBT Laboratories, Inc

**1.20 Buffet lunch in the exhibition area**

**2.30 Case study**
**Identification of markers of efficacy in cancer patients treated with TroVax (MVA-5T4)**
- Active immunotherapeutics are believed to have a delayed therapeutic effect, therefore an early marker of efficacy would be valuable
- Data from a phase III trial of TroVax in renal cancer patients has enabled a detailed investigation of early predictors of treatment benefit
- Antibodies, induced by vaccination, against the tumour antigen 5T4 correlated strongly with enhanced patient survival
- Developing an "immune response surrogate" (IRS) using pre-treatment factors which are readily measured in each patient
  - correlation with the magnitude of the induced 5T4 antibody response and treatment benefit
  - application to an independent dataset comprising patients with renal, colorectal and prostate cancer

**Dr Richard Harrop**, Head of Clinical Analysis, Oxford BioMedica UK Ltd

**2.50 Questions & discussion**

**2.55 Designing randomised phase II trials that will establish a valid phase III hypothesis without breaking the bank**
- Designing clinical trials and supporting assays to give a higher likelihood of discovering a surrogate marker
- Size, structure and controls of cancer immunotherapy phase II studies
- Examples of successful trial designs and lessons for future approaches

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

**3.15 Panel discussion**
**What role can adaptive trial designs and interim sample size reassessments play in establishing the phase III hypothesis?**

**3.45 Moderator's closing summary**

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

## Your choice of 2 afternoon plenary sessions

### Barcelona Vaccine Forum

**Addressing public perception issues and technological challenges to drive vaccination schedule expansion and vaccine uptake in non-paediatric populations**

**4.20 Chair's introduction**
**Mike Seymour**, International Director, Crisis & Issues Management, Edelman

**4.25 Short presentations & roundtable discussion**
- How to accommodate new paediatric vaccines in busy US and European schedules?
  - What would it take to harmonise paediatric schedules on either side of the Atlantic/across Europe?
    - A unified schedule for Europe - is this possible, or even desirable?
  - Should/can we expand into the toddler population and, if so, how?
  - How effective is herd immunity in that age group?
- How can we drive uptake in adolescent and adult vaccine markets?
  - How can we address patient access issues?
  - How can we shorten regimens and improve communication of risk/benefit?
  - What is the role of alternative delivery devices?
- Whose responsibility is vaccine public image/risk communication in Europe?
  - How can we improve this critical aspect to counter anti-vaccine sentiment on a global basis?

Panellists:
**Pierre A. Morgon**, Vice President, Franchise & Global Marketing Operations, sanofi pasteur
**Dr Karen J. Huebscher**, Head, Europe Public Health & Market Access, Novartis Vaccines

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

### Active Immunotherapeutics Forum

**Advanced phase III active immunotherapy programs: So the efficacy is good, but how do you build the infrastructure to support the potential of your product?**

**4.30 Panel discussion**
**Looking ahead: What are the most important infrastructural elements of the equation to put in place to prepare for market?**
- Having the right partners and collaborations in place to facilitate entry to the market
  - Working with clinical leaders
  - Who does what – how much support will small companies get?
- Ensuring access to hospitals / specialists / GPs / patients - is it easy to diagnose?
  - Will there be enrolment and compliance issues?
- How will biomarkers and selection criteria be worked into the commercialisation of the product?
- Putting in place active lifecycle management to generate solid data for marketing and reimbursement, and to look for new and broader indications
- How and when to plan for and put resources into sales force and delivery

Panellists
**Dr Raafat E. F. Fahim**, President & CEO, Nabi Biopharmaceuticals
**Wim Tiest**, Director, Head, Portfolio Strategy & Business Operations, Immunotherapeutics Business Unit, GlaxoSmithKline Biologicals
**Dr Carlos F. Santos**, CSO & Vice President, Product Development, Accentia Biopharmaceuticals / Biovest International
**Dr Charles A. Nicolette**, Chief Scientific Officer, Vice President, R&D, Argos Therapeutics Inc

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

**"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

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# Day 3 - Friday, May 13th 2011

7.30: Registration & buffet breakfast in the exhibition area

## Your choice of 2 morning plenary sessions

### Barcelona Vaccine Forum

#### Morning plenary session

**Revolutionising the vaccine industry R&D model to effectively address existing and future targets**

**9.00 Chair's introduction**

**Keynote industry perspectives**
**How will the vaccine R&D model evolve moving forward?**
- Identifying the keys to success for large and small companies pursuing strategies to solve the remaining commercial, scientific and technological challenges with the traditionally 'difficult' infectious diseases (eg. RSV, the big 3, Men. B)

**9.05 Big pharma perspective**
**Creating an innovative vaccine pipeline**
- New technologies enable new solutions
  - Reverse vaccinology
  - Structural vaccinology
  - Adjuvants
  - Vectors
- Leadership in research

**Dr Christian W. Mandl**, Vice President & Global Head of Virology, Head of Research, US, Novartis Vaccines and Diagnostics, Inc

**9.25 Biotech perspective**
**Novel platform technologies will lead to important vaccines**
- Non-replicating viral vectors
- Unique cell lines
- Adjuvant formulations and presentations

**Dr Jerald Sadoff**, Chief Medical Officer, Crucell

**9.45 How will a more 'rational' approach to vaccine R&D drive the continued development and acceptance of novel adjuvants?**
- How can emerging R&D technologies help alleviate continuing concerns over safety?

**Dr J. Tyler Martin, Sr**, President & Chief Medical Officer, Dynavax Technologies

**10.05 Roundtable discussion**
**Getting away from 'trial and error' methodology in vaccine R&D: How to rationalise choices from discovery onwards?**
- What are next key targets for the vaccine sector and how should we pursue them?
  - Where are the current gaps in the vaccine R&D 'toolbox'?
- How does a recent big pharma entrant to the vaccines space view the R&D model? What changes are required?
- What aspects of the immune system do you need to monitor and why?
  - What is the actual role of immune response in protection?
- Do we believe that there are still diseases out there that can be addressed with a universal vaccine, or are we heading inexorably towards more targeted populations?

**10.30 Morning coffee in the exhibition area**

### Active Immunotherapeutics Forum

#### Morning plenary session

**New horizons: What is the scope of opportunity for the next generation of active immunotherapies?**

**9.00 Chair's introduction**
**Neil L. Berinstein, MD**, Chief Scientific Officer, IRX Therapeutics

**9.05 Based on what we know from the first wave of approvals and phase III successes, what diseases are the best fit for AI?**
- Update on most recent successes and promising candidates in Phase III
- Lessons learnt on therapeutic settings for AIs in oncology
- Key success factors for AIs

**Dr Oliver Maria Wilbert, MBA**, Senior Director, Immunotherapies; Global Product Unit Oncology Portfolio Development, Merck Serono

**9.30 Questions & discussion**

**9.35 Keynote address**
**What does the next generation of active immunotherapies need to do to reach a wider audience?**
- Antigen-Specific Cancer Immunotherapy (ASCI): GSKBio approach to the field
- From tumor specificity to selection of the patients most likely to benefit from ASCI (identification of a predictive gene signature)
- Challenges associated with predictive gene signature identification

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

**10.00 Panel discussion**
**Moving away from trial and error: To what extent is it becoming possible to set objective criteria to say if a disease should be an AI target or not?**
- What can be extrapolated from recent successes and failures that could be useful as a basis for selecting
  - The right disease targets
  - The technology to use to go after it

Panellists:
**Frédéric Triebel, MD, PhD**, Scientific & Medical Director, Immutep SA
**Dr Martin Bachmann, CSO**, Cytos Biotechnology AG

**10.30 Morning coffee in the exhibition area**

## Your choice of 4 parallel sessions

### Barcelona Vaccine Forum

#### Focus session

**How to rationalise vaccine R&D at each step from preclinical through to the marketplace**

**11.10 Chair's introduction**
**Dr Christian W. Mandl**, Vice President & Global Head of Virology, Head of Research, US, Novartis Vaccines and Diagnostics, Inc

**Regulator and industry perspectives on evolving the vaccine preclinical development model**
- What is the need for and role of toxicology studies in modern vaccine R&D? How large should vaccine safety studies be? When should preclinical toxicology studies be completed?
- What are the alternatives to poor animal models in preclinical development? Are there novel ways of modelling vaccine safety studies? What can we learn from marketed vaccines to develop better models?
- How are systems biology tools/techniques alleviating the dearth of genuinely predictive animal models by helping us to better understand the immunogenicity/reactogenicity of vaccines?

**11.15 Regulator's perspective**
**Role of preclinical toxicology studies in vaccine development: A US perspective**
- Current approaches to preclinical toxicology studies
- Applicable guidance (US/EMA/Japan)
- Common current issues and challenges

**Dr Marion Gruber**, Deputy Director, Office of Vaccines Research & Review (OVRR), CBER, US Food & Drug Administration

**11.30 Industry perspective**
Speaker to be announced

**11.45 Questions & discussion**

**11.55 What is the latest progress in developing biomarkers and assays to identify functional immune response?**
- How will assay automation impact the R&D model moving forward?

Presentation reserved

Continued on next page »

#### Workshop ⓘ

**How can NGOs and the public sector best support the global expansion of vaccine R&D and supply?**
- Which Public-Private Partnership initiatives and models have been successful and why?

**11.10 Moderator's introduction**
**Altaf A. Lal, PhD**, Chief Executive Officer, MSD Wellcome Trust Hilleman Laboratories

**11.15 Effective and affordable vaccines for neglected diseases**
- > 30 new vaccines could be justified on the basis of disease burden in low and middle income countries
- Excluding HIV vaccines, total annual global expenditure on new vaccines for neglected diseases is about the cost of developing one vaccine for wealth countries
- We need to:
  - Maximize health benefits return on the limited investment available
  - Improve the sustainability of investing in vaccine development
  - Increase the investment available

**Dr Allan Saul**, CEO, Novartis Vaccines Institute for Global Health

**Case studies**
**How to be more cost-efficient and effective with Public-Private Partnerships? Examining recent successful models**

**11.35 R&D partnerships between public and private sector, the IAVI experience**
- Challenges in HIV vaccine development
- Case studies of successful biotech R&D partnerships
- Current unmet needs and opportunities

**Dr Hansi Dean**, Director, New Alliances, International AIDS Vaccine Initiative (IAVI)

**11.50 Working with Singapore government and academic agencies for the development of novel 'flu vaccines**
- High exposure results in high awareness
- Getting really prepared for the next pandemic
- Is 'flu-preparedness a case for the military?
- Singapore: A dynamic government teams up with dynamic academics

**Dr Martin Bachmann**, CSO, Cytos Biotechnology AG

**12.05 Questions & discussion**

**12.20 Capitalising on developing world public sector funding and commercial opportunities for the vaccine industry**
- How to access this funding and what are the R&D and corporate/commercial implications for Western pharma/biotech of targeting diseases which are only prevalent in a given region?
- Are public health organisations in these regions and countries looking for small as well as large Western industry partners?

**Peter Wulff**, co-Founder & CEO, SENTINEXT therapeutics

Continued on next page »

### Active Immunotherapeutics Forum

#### Focus session

**The X Factor: What are the promising new discoveries and agents that will direct step changes in efficacy in the next generation of cancer AIs?**
- How is a greater understanding of mechanism of action being applied?
- What comes after Ipilumamab?

**11.10 Chair's introduction**
**Dr Vincent Brichard**, Vice President, Cancer Immunotherapeutics, GlaxoSmithKline Biologicals

**11.15 Roundtable**
**As we discover more about the role of key immune cells, what are the most promising immune modulators in development? How targeted can we be?**
- What is a better understanding of the role of these cells telling us? How should they be targeted in active immunotherapy?
  - Macrophages
  - Antigen presenting cell (APC) activators
  - Non-specific immune modulators eg cytokines / chemokines
  - Regulatory T cells: How and when should they be removed? What should the ratios be?
  - Cancer stem cells
- Which promising new molecules are in development?
  - Immune check point inhibition
  - Co-stimulatory molecules
  - Co-inhibitory molecules
  - New TLRs
- How have they proved in vivo mechanism of action?
- What are the considerations for assessing their suitability?
  - How do they complement the vaccine approach?
- How will these new molecules be developed – standalone or in combination?

Panellists:
**Frédéric Triebel, MD, PhD**, Scientific & Medical Director, Immutep SA
**Jens-Peter Marschner, MD**, Head, Immunological Programs, Global Early & Clinical Development Unit, Oncology, Merck KGaA
**Christopher F. Nicodemus, MD FACP**, Chairman & Chief Scientific Officer, Advanced Immune Therapeutics, Inc
**Dr Robert Wilkinson**, Principal Scientist II, Oncology Innovative Medicines (iMED), AstraZeneca

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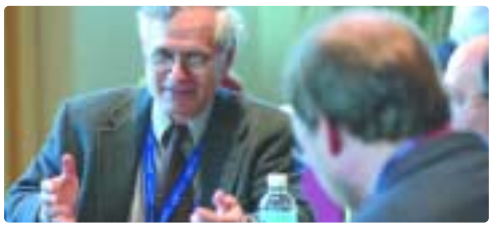

#### Workshop ⓘ

**Combination strategies: The latest regulatory and commercial guidance for active immunotherapies**
- From promise to practice: Registering products that have multiple components
- How do you combine two or more investigational agents?

**11.10 Chair's introduction**
**Jill O'Donnell-Tormey, PhD**, Executive Director, Cancer Research Institute, member of the Executive Committee of the Cancer Immunotherapy Consortium, member of the Coordinating & Review Committee of the Cancer Vaccine Collaborative

**11.15 Working party A**
**Commercial considerations for co-development**
- Using two scenarios:
  - 2 biotechs co-developing their lead products
  - A biotech co-developing their lead product with big pharma
- The major hurdles for co-development will be addressed by a panel of industry and legal experts
  - Data sharing
  - Access to and ownership of assets
  - Intellectual property rights
  - Freedom to operate with the combination component not owned by the developer of the combination product
  - Market access / reimbursement

Panellists:
**Dr Julianna Lisziewicz**, President & CEO, Genetic Immunity
**Dr Mark W. Schwartz**, CEO & President, Apthera
**Neil L. Berinstein, MD**, Chief Scientific Officer, IRX Therapeutics
**Reiner Laus, MD**, President & Chief Executive Officer, BN ImmunoTherapeutics

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

# Day 3 - Friday, May 13th 2011 Continued

## Barcelona Vaccine Forum

### Focus session continued

12.15 **Case study**
**How are adaptive trial designs enabling better decision-making from smaller clinical trials in the vaccine space?**
**Dr Jerald S. Schindler**, Vice President, Biostatistics & Research Decision Sciences - Late Development Statistics, Merck Research Laboratories

12.35 **Assessing the capabilities of inexpensive diagnostic tests for dramatically reducing costs of clinical trials and streamlining the whole vaccine development process**
- Do we need standardised and harmonised biomarkers for vaccine trials?
- Can we reduce the cost of post-marketing trails and assessments with point-of care tests?
- Do we need global assessment of vaccine success and/or identification of new emerging strains as a result of widespread suppression of known strains with vaccines?

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

12.55 **Panel discussion**
- How will the adoption of diagnostics and patient stratification techniques evolve within the vaccine clinical development model, particularly to address safety issues?
  - What are the specific applications and indications where we will see the greatest initial progress in this regard?
- How will we drive the development of
  - Better assays for immune response?
  - Technologies to allow on-the-spot diagnosis of an individual patient's risk profile and/or of disease?
- Is it feasible for small vaccine companies to validate their own biomarkers?
  - What initiatives might help to alleviate this burden?
- Does the sector need and want more targeted vaccines, or are 'personalised vaccines' an inevitability given ongoing trends in healthcare?

1.25 **Chair's closing summary**

1.30 **Close of the Phacilitate Vaccine Forum Barcelona 2011, followed by lunch.**

### Workshop continued

12.40 **Case study**
**Need for effective thermostable vaccines and delivery technologies**
- What are public health benefits in low-resource countries?

**Altaf A. Lal, PhD**, Chief Executive Officer, MSD Wellcome Trust Hilleman Laboratories

1.00 **Panel discussion**
**How will public and private sector players address key logistical challenges to ensure vaccines reach patients in the poorest regions of the world safely and securely?**
- How to overcome fundamental lack of infrastructure/cold chain/compliance issues? What incentives are there to engage industry in this effort?

1.25 **Moderator's closing summary**

1.30 **Close of the Phacilitate Vaccine Forum Barcelona 2011, followed by lunch.**

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## Active Immunotherapeutics Forum

### Focus session continued

12.15 **Targeting the micro-environment of the tumour as a whole: Are killer T cells necessarily the key?**
- Suppression of type II macrophages
- Suppression of myeloid –derived suppressor cells
- Suppression of "bad" inflammation (anti-TNF, anti-IL-6)
- Suppression of TGFbeta and IL-10
- Suppression of Stat 3 signaling
- Suppression of angiogenesis

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

12.35 **Questions & discussion**

12.40 **Taking a second look at oncolytic viruses: How promising are they as another piece in the active immunotherapy equation?**
- How can the immune response they induce be optimised and made more systemic?
- Are they developing a vaccine-like effect?
- What is their potential role in AI?
  - What is the progress with percentage of responders?
- Why has industry's interest been reawakened?

**David H. Kirn, MD**, Founder, President & Chief Executive Officer, Jennerex Biotherapeutics

1.00 **Panel discussion**
**How is a greater understanding of mechanisms of action leading to the evolution of new, less reductionist models of non-classical immunology?**
- How will active immunotherapy approaches evolve to attack at multiple points simultaneously; innate, adaptive, microenvironment?
  - Developing a better understanding of how to establish functional immune memory

1.25 **Chair's closing summary**

1.30 **Close of the Active Immunotherapeutics Forum 2011, followed by lunch**

### Workshop continued

12.20 **Working party B**
**Clinical and regulatory considerations for co-development**
- Update on FDA draft guidance for combining 2 investigational agents
- EMA's stance on co-development pathways
- How much pre-clinical is needed to justify going into different modalities?
- What are the safety risks for each individual agent based on results from combination studies?
- As combinations become more established, how can you predict what your patients will be exposed to? Will you be able to see clear signals in the face of all that's going on?

Panellists:
**Dr Thomas Hinz**, Head of Section, Therapeutic Vaccines, Paul-Ehrlich-Institut
**Dr Samir N. Khleif**, Head, Cancer Vaccine Section, NCI
**Dr Oliver Maria Wilbert**, MBA, Senior Director, Immunotherapies; Global Product Unit, Oncology Portfolio Development, Merck Serono
**Dr Harpreet Singh**, Founder & CSO, immatics biotechnologies GmbH
**Michael G. Covington**, CMC Director, Regulatory Affairs, Dendreon Corporation

**A report will be made available to all attendees shortly after the meeting outlining the conclusions and next steps from the working parties**

1.25 **Moderator's closing summary**

1.30 **Close of the Active Immunotherapeutics Forum 2011, followed by lunch**

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Kathleen Callender, President, PharmaJet Inc

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**For more information please contact Dean Guest at deang@phacilitate.co.uk (Tel: +44 (0)20 7839 6137).**

**Comments from previous sponsors and exhibitors at Phacilitate events include:**

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