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You will be able to reserve a place at a pre-conference course during the registration process. It is highly advisable to book your places early as they are strictly limited and will be allocated on a first-come-first-served basis.

You must complete and submit the registration form in order to reserve your place at the conference. The registration fee must be paid in full at the time of booking your place. Payment must be received before the start of the conference in order to guarantee admittance.

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**Barcelona Vaccine Forum**

**Shared morning plenary session**

**10.00** Chair’s introduction

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

**10.10** 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 computing licensed & newly approved products. What risk will cost-effectiveness research play and how will this impact the vaccine and active immunotherapy areas?

**10.30** Industry perspective

New vaccines and active immunotherapies from the HTA perspective

- What do we need?
- The required data for a successful reimbursement
- Is there a space for collaboration?

**10.40** Public & private sector stakeholders’ roundtable discussion

Assessing how you should 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 Olivera Sola-Morales, HTA Director, Catalan Agency for Health Technology Assessment & Research (AAGTS)
- Pierre A. Morgon, Vice President, Franchise & Global Marketing Operations, sanofi pasteur

**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?

**11.00** Morning coffee in the exhibition area

Followed by your choice from of the 4 sessions

### Session 1: Understanding the Next Pandemic

**11.30** Chair’s introduction

Dr Marion Gruber, Scientific Officer, Viracor-IBT Laboratories, Inc

**11.40** Food & Drug Administration

- Why did H1N1 pandemic ‘flu vaccine uptake levels vary so widely from region to region?
- What is the relative value of each approach to public health stakeholders focusing on eradication programs?

**11.50** Industry perspective

- 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 the market in the US and other countries?

**12.00** Public & private sector stakeholders’ roundtable discussion

- How are regulatory processes evolving as a consequence of the H1N1 pandemic?
- What is the role of countries in the developing world?

Panelists:

- Dr. Mark W. Schwartz, CEO & President, Aphena

### Session 2: Vaccine, What’s Next?

**12.00** Chair’s introduction

Dr Julianna Lisziewicz, Project Manager, HIV Vaccines, US Army Medical Research and Development Command

**12.10** Industry perspective

- What is the relative value of each approach to public health stakeholders focusing on eradication programs?
- What are the limits of the prophylactic model?
- What is the route to ensure reimbursement issues are resolved prior to licensure?
- How far in advance do you need to plan?

Panellists:

- Dr. Mark W. Schwartz, CEO & President, Aphena

### Session 3: How is Industry responding?

**12.00** Case study

R&D and commercial success in Recombinant human CD83 protein: A first-in-class therapeutic that actively suppresses immune responses

Dr. Mark W. Schwartz, CEO & President, Aphena

**12.10** Case study

Combating a global killer: What’s the role of vaccines in addressing the challenges of HIV/AIDS?

Jerome H. Kim, MD, Deputy Director (Science & Technology), PATH, HIV Vaccines, US Army Medical Material Development Activity

**12.20** Questions & discussion

**12.30** Case study

Developing vaccines for the future: What lessons have we learned from HPV and HCV: Is prevention or treatment the better option?

Dr. Mark W. Schwartz, CEO & President, Aphena

**12.40** Case study

- What is the route to ensure reimbursement issues are resolved prior to licensure?
- How far in advance do you need to plan?

Panellists:

- Dr. Mark W. Schwartz, CEO & President, Aphena

### Session 4: How is Industry responding?

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- How far in advance do you need to plan?

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### Morning coffee in the exhibition area

Followed by your choice from of the 4 sessions

### Morning coffee in the exhibition area

Followed by your choice from of the 4 sessions

*Indicates a highly interactive session for a limited attendance number. Register today to guarantee you place in these sessions.**
Both Forums Focus session continued

**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?**

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

**Biotech perspective**
- Biotech/biopharma partnering between large pharma and small biotech: a growing trend in licensing.
- How does this compare with their therapeutic pipelines?
- Large pharma is becoming more dependent on small biotech to complement their in-house pipelines.
- To improve the chances of success, large pharma have increased their licensing activities significantly.

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

**HPV therapeutic vaccine case study**
- Antidotes to the challenges of vaccine failure: T-cell responses against early proteins E6 and E7 for therapy.
- How to break through: Vaccine (vaccinoprimed) regulatory T cells.
- Disease spectrum for treatment with therapeutic HPV vaccines: pre-malignant diseases, CIN, VIN, AIN, cervical cancer, vulvar cancer; head and neck cancer; oesophageal cancer (squamous).
- Advantages of synthetic vaccines.
- Combination of therapeutic vaccination with other treatment modalities (chemotherapy, monoclonal antibodies).

**HCV therapeutic vaccine case study**
- How will it help inform criteria for target selection going forward: Developing a more systemic and sophisticated approach.
- How can vaccines need to be individualized or not?
- What models would stimulate their interest in AI?
- How should they be positioned?
- What targets would be considered?

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**Panel discussion**
- Examine the fundamentally different financial dynamics of the prophylactic and therapeutic vaccine spaces.
- The regulatory environment - what data to submit?
- What models would stimulate their interest in AI?

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**Chair’s closing summary**

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

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**Panel discussion**
- Examining the pros and cons of paediatric influenza vaccines.
- "Universal" antigen?
- Solutions to this potential issue?

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**Chair’s closing summary**

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

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**Register to guarantee your place in one of the partner working lunch sessions or take the opportunity to propose a topic.**

**Register before 18th February to save €200**
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 are the optimal international expansion models for large and small vaccine industry players alike?

9.00 Chair's introduction
Uma S. Ryan, OBE, PhD, President & CEO, Diagnostics For All

9.05 Analysts' perspective
Dr Michael Perdue, Director - Influenza & Vaccinology & Tropical Medicine, Oxford University

9.20 Global vaccine market: Chinese company's perspective
Dr Samantha Dong, R&D Manager, Sinovac Biotech Ltd

9.35 Tech transfer models for global expansion: Eastern vaccine company perspectives
Pieter Neels, Head, Vaccines & Infectious Diseases, Wellcome Trust Hilleman Laboratories

9.50 Big pharma perspectives: Build vs. Buy vs. Partner - examining the strategic business models for global expansion being employed by major players
Dr Rahul Singhvi, Head, Portfolio Strategy & Licensing, Wellcome Trust Hilleman Laboratories

10.05 Big pharma perspective
Dr Robert Repetto, Director of Strategic & External Affairs, Merck Co, Inc

10.20 Big pharma perspective
Becoming a global vaccine company: A Merck perspective
Dr Jerald Sadoff, Head, Vaccines & Infectious Diseases, VWP (EMA), Federal Agency for Medicinal & Health Products, Belgium

10.35 What are the options available to vaccine makers in terms of global vaccine expansion?
Wim Tiest, Director, Head, Portfolio Strategy & Business Operations, Immunotherapeutics Business Unit, GlaxoSmithKline Biologicals

10.50 Questions & discussion

11.20 Morning coffee in the exhibition area

Active Immunotherapeutics Forum
Morning plenary session

Advanced phase III active immunotherapy programs: I just used well the pre-clinical and early clinical trials to translate?

9.00 Chair's introduction
Dr Dan H. March, President, Advanced Phase III Immunotherapeutics

9.10 Case study
De-risking cancer immunotherapy development: A not-for-profit model
Dr Samir N. Khleif, Head, Vaccines & Infectious Diseases, VWP (EMA), Federal Agency for Medicinal & Health Products, Belgium

9.20 Case study
Vaccinology & Tropical Medicine, Oxford University
Dr Thomas Hinz, Head, Vaccine and Infectious Disease Immunotherapeutics Program, Biomedical Advanced Research & Development Authority, Office of the Assistant Secretary for Preparedness & Response, US Department of Health & Human Services

9.35 Case study
Making a case for a clinical trial: Atherosclerosis, NCI
Dr Donald J. Francis, Chief Medical Officer, Crucell

9.50 Questions & discussion

10.40 Morning coffee in the exhibition area
Day 2 - Thursday, May 12th 2011

Barcelona Vaccine Forum
Focus session continued

1.1.25 Cell culture derived influenza vaccines: Fighting back to licensure and beyond
- Technology update
- Challenges and solutions including safety and efficacy data
- Case studies

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

1.1.28 Questions & discussion

1.1.35 Buffet lunch in the exhibition area

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

2.2.05 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 vaccine strategies

Dr Charles Richards, Executive Vice President of R&D, Lipi, Cyto Pharmaceutical

2.2.10 Questions & discussion

2.2.15 Buffet lunch in the exhibition area

2.2.20 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

Dr Elke Marie Appel, MSc, PhD, Associate Director, Department of Infectious Disease Immunology, Head of Section, TB Vaccine Research, Statens Serum Institut

2.2.25 Case study
Managing 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 - considerate specific to vaccines
- Changes in the manufacturing process of cell based vaccines post-approval - regulatory requirements

Nabilo Thomas, PhD, Regulatory Project Manager, ERA Consulting (UK) Ltd

2.2.30 Questions & discussion

Panel discussion
How can we improve our 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?
- Can we draw contracting timelines from strain selection to final vaccine supply? Are cell-based manufacturing technologies really quicker than the traditional egg-based process?
- Is looking for a manufacturing a viable alternative in the developing world?

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

2.2.35 Chair’s closing summary

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

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

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

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

Aline Seolly, Field Marketing Manager, EU, Amplio

3.1.15 Your choice of 2 afternoon plenary sessions

Barcelona Vaccine Forum

Panelists:
Dr Robert M. F. Fattah, President & CEO, Nabi Biopharmaceuticals
Wille Tintel, Director, Head, Portfolio Strategy & Business Development, Immunotherapeutics Business Unit, Merck (Canada) Ltd
Dr Carlos P. Santos, CSO & Vice President, Product Development, Accentia Biopharmaceuticals / Bielvest International

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

3.2.00 Active Immunotherapeutics Forum
Focus session continued

3.2.05 What is the impact of standard of care in the selection of treatment on the development strategy of active immunotherapeutics?
- Radiation
- Other entities
- Safety
- Regulatory
- Financial and time aspects

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

3.2.10 Questions & discussion

3.2.15 Buffet lunch in the exhibition area

3.2.20 Case study
Integration of peptide-based cancer vaccine MA01 with immunomodulators and TKIs - from preclinical to phase III
- Selection of immunomodulator for phase III
- Data-driven selection of additional immunomodulator for phase II
- Phase I trial with combination partner for phase II
- Practical models and clinical biomarkers/immunomonitoring as vital tool for optimizing combinations
- Developing the combination of the partner candidates in the clinic
- Implications for trial design and regulatory submissions

Dr Harpreet Singh, Founder & CEO, IMS ImmunoPharmaceuticals GmbH

3.2.25 Questions & discussion

3.2.30 Chair’s closing summary

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

3.3.05 "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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www.phacilitate.co.uk/barcelona
Barcelona Vaccine Forum
Monday morning session

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

10.00 Chair's introduction

Keynote industry perspectives

10.10 How will the vaccine R&D model evolve moving forward?

- Identifying the keys to success for large and small companies pursuing strategies to move the remaining development of existing and new technologies forward

- What are the key scientific and technological challenges with the traditionally difficult infectious diseases (e.g. RNA, the Big 3, Man, B)

10.25 Big pharma perspective

Creating an innovative vaccine pipeline

- New technologies enable new solutions - Reverse vaccinology
- Structural vaccinology
- Adjuvants
- Vectored
- Leadership in research

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

10.40 Biotech perspective

Novel platform technologies will lead to important advances

- Non-replicating viral vectors
- Unique capsids
- Adjuvant formulations and presentations

Dr Jerad Sadoff, Chief Medical Officer, CureVac

10.55 Regulatory and industry perspectives on evolving the vaccine preclinical development model

- What is the need for and role of toxicity studies in modern vaccine R&D? How large should vaccine safety studies be? When should preventive toxicity 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 non-modelling technologies advancing, alleviating the death of genuinely predictive animal models by helping us to better understand the immunogenicity/reactivity of vaccines?

Dr Martin Bachmann, CEO, Novartis Vaccines

11.10 how to rationalise vaccine R&D at each step from preclinical through to the marketplace

11.15 Chair's introduction

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

Regulator and industry perspectives on evolving the vaccine preclinical development model

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11.30 Moderator's introduction

Alla A. Lai, PhD, Chief Executive Officer, MIRAXYS, and Trust Helikum Foundation, President

11.35 Effective and affordable vaccines for neglected diseases

- Are vaccines the solution to the growing burden of disease in low and middle income countries?
- What about RVV vaccines, total annual global expenditure on new vaccines for neglected diseases is about the global development of one vaccine for wealth countries
- What needs to be done to make such vaccines affordable?

Dr Julian A. Jackson, Head of Global Village, Institute for Global Health Care

11.50 New vaccine opportunities

- How to improve the cost-effective and efficient vaccine production with Public-Private Partnerships?
- Examining recent successful models

12.05 R&D partnerships between public and private sector, the IAVI experience

- Challenges in HIV vaccine development
- Case studies of successful HIV-RGD partnerships
- Government needs and opportunities

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

12.20 Working with Singapore government and academic agencies for the development of novel flu vaccines

- High explosive outbreaks in high awareness
- Many lessons learned for the next pandemic
- How a preparedness for the military

Dr Martin Bachmann, CEO, Cytos Biotechnology AG

12.35 Questions & discussion

Barcelona Vaccine Forum
Monday平行 session

10.00 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?

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11.05 Questions & discussion

11.20 Capitalising on developing world public sector funding and commercial opportunities for the vaccine industry

- How to develop the value chain and the R&D and corporate/commercial implications for Western pharmaceuticals targeting developing countries which are prevalent in a given region?
- Are there opportunities for public sector organisations in these regions and countries looking for small as well as large Western partners?

Peter Wulf, co-founder & CEO, SENTINELX therapeutics

11.35 Continued on next page

Active Immunotherapeutics Forum
Monday morning session

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

10.00 Chair's introduction

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

10.10 How will the vaccine R&D model evolve moving forward?

- What are the key scientific and technological challenges with the traditionally difficult infectious diseases (e.g. RNA, the Big 3, Man, B)

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Barcelona Vaccine Forum
Focus session continued

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

12.50 Assessing the capabilities of inexpensive diagnostic tests for dramatically reducing costs of clinical trials and streamlining the whole vaccine development process
Dr Afzal A. Lai, PhD, Chief Executive Officer, MSD Welcome Trust Healthcare Laboratories

12.55 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 can we overcome fundamental lack of infrastructure/cold chain compliance issues? What incentives are there to engage industry in this effort?
- Do we need global assessment of vaccine success and/or identification of new emerging strains as a result of the spread and potential resurgence of known strains with vaccines?

13.05 Moderator’s closing summary

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

Active Immunotherapeutics Forum
Focus session continued

12.30 Targeting the micro-environment of the tumour as a whole: Are killer T cells necessarily the key?
- Suppression of type I macrophages
- Suppression of myeloid-derived suppressor cells
- Suppression of ‘bad’ inflammation (anti-TNF, anti-IL-6)
- Suppression of IFN and T cells in place
- Suppression of Stat 3 signaling
- Suppression of angiogenesis

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

12.45 Questions & discussion

12.50 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 vaccinia-like effect?
- What is their potential role in AIDs?
- What is the progress with a combination of virus?
- Why has industry’s interest been reawakened?

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

13.05 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 attain multiple points simultaneously: innate, adaptive, microenvironment?
- Developing a better understanding of how to establish functional immune memory

13.20 Chair’s closing summary

13.25 Close of the Active Immunotherapeutics Forum 2011, followed by lunch.

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Bronze sponsor:

Viracor–IBT Laboratories
L  A  B  O  R  A  T  O  R  I  S
Viracor-IBT Laboratories, BioPharma Services – Accelerates drug and vaccine development from bench to market through providing a comprehensive range of preclinical services to pharmaceutical, biotech, medical device, and vaccine developers. With 27 years serving biopharmaceutical clients and as pioneers in immunology, infectious disease and allergy testing, we are uniquely positioned to provide unparalleled services for custom assay development, viral load testing, immune monitoring, and biomarkers & bioanalytics. www.viracoribt.com

Sponsorship & Exhibition Opportunities

The conference was very well organised and hosted - the topics and presentations focused on the leading edge of the vaccine industry. Excellent and valuable. Worth the cost!”
Kathleen Calender, President, PharMA Inc

Options available to your company include:

Gold, silver and bronze sponsorships, giving you the chance to place a high-level executive in a conference agenda itself. These packages provide the very greatest levels of pre-event and on-site exposure, guaranteeing you significantly increase your organisation’s profile within the target audience of your choice.

Sponsoring a lunch or breakfast workshop, giving you the chance to invite 50 selected attendees to a session hosted by a senior member (or members) of your executive team. Sessions are approx. 70 mins in duration and are available on day 1 and 2 of the event so that you can match your subject matter to that of the appropriate sessions of the main programmes.

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And whichever package you choose, you will be able to use the pre-event on-line partnering system to make contact with individual speakers and delegates – the perfect way to optimise your return on investment in the event by maximising the number of meetings your team can have in place. Plus - take the chance to book complimentary private meeting rooms, ideal for confidential discussions with current or potential clients and/or partners.

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

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Phacilitate are the best conference organisers on clinical development programmes.

“Excellent event to meet sponsors focused on clinical development programmes. Phacilitate are the best conference organisations we have met.”

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“Another excellent conference with high calibre attendees. It exceeded all of our expectations!”

Dr May de las Alas, Business Development Associate, Syneos Clinical Research plc

“Another excellent conference with high calibre attendees, exceeded all of our expectations!”

Dr May de las Alas, Business Development Associate, Syneos Clinical Research plc

“Phacilitate provides not only one of the best conferences of the year in this sector, but also recognises the value of, and supports, the B2B networking that is critical to our ROI for such events.”

Lee Buckley, Marketing Communications, Progenitor Cell Therapy LLC

Day 3 - Friday, May 13th 2011

Active Immunotherapeutics Forum
Focus session 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?

Panelists:
Dr Thomas Hinz, Head of Sector, Therapeutic Vaccines, Paul Ehrlich Institute
Dr Samir N. Khlaif, Head, Cancer Vaccine Section, NCI
Dr Oliver Maria Wilbert, MBA, Senior Director, Immunotherapeutics, Global Product Unit, Oncology Portfolio Development, Merck Serono
Dr Harpreet Singh, Founder & CEO, 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

12.45 Moderators’ closing summary

13.00 Close of the Active Immunotherapeutics Forum 2011, followed by lunch

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

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Ian C. Sellick, Director of Marketing, Pall Life Sciences

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Boy Franzen, Director of Client Services, Syneos Clinical Research plc

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Dr May de las Alas, Business Development Associate, Syneos Clinical Research plc

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