Conference: 1st - 2nd February 2011
Workshops: 31st January 2011
Venue: Ramada Frankfurt Messe, Frankfurt, Germany

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VACCINE INNOVATION 2011

Optimise your vaccine R&D pipeline to deliver business growth

Your Vaccine Innovation speakers include:

Dr Alexander von Gabain, Strategic Advisor to the Management and Supervisory board, **Intercell AG**

Dr Raafat Fahim, President and CEO, **Nabi Biopharmaceuticals**

Dr Jon Heinrichs, Director, **Merck & Co**

Dr Jeffrey Ulmer, Global Head, External Research, **Novartis Vaccines & Diagnostics**

Dr Jeffrey Almond, Vice President, Discovery Research and External R&D, **sanofi pasteur**

Dr Christian Moser, DVM, Head Research, **Pevion Biotech**

Dr Anja Seubert, Laboratory Head, Department of Immunology, **Novartis Research Center**

Prof Angus Dalgleish, Consultant Medical Oncologist, **St. George's University of London**

Dr Marion F. Gruber, Deputy Director, Office of Vaccines Research & Review, **FDA/CBER**

Dr Jean-Yves Bonnefoy, Vice President, Research and Development, **Transgene**

Dr Philip Krause, Deputy Director, Division of Viral Products, **FDA**

Dr Edward Mocarski, Distinguished Fellow, **MedImmune Vaccines**

- The global **regulatory landscape** is changing rapidly. **Hear from the FDA** on the best approaches to keep your company ahead of the game
- Hear **clinical case studies** on the latest vaccines to market: universal **influenza** vaccine, **dengue fever, RSV, *vulvovaginal candidiasis*** and **recombinant HA** based vaccines
- Learn how to **develop** your **R&D approaches** to **deliver more innovative vaccines into the clinic**
- Partnering is at the forefront of vaccine market expansion. Understand the challenges of **collaborations** and **funding:** How to achieve a **win-win** situation
- Learn the latest developments in **vaccine delivery** and **manufacturing** to aid pipeline success
- Hear about the **new technologies** for improved vaccine development to help **decrease your time to market**
- Learn new ways to identify and validate **new adjuvants** for enhanced immune response

Dr Kingston Mills, Professor of Experimental Immunology, Head School of Biochemistry and Immunology, Director Immunology Research Centre, **Trinity College Dublin**

Dr Alfredo Nicosia, Chief Scientific Officer, **Okairos**

Dr Joe Santangelo, Chief Operating Officer, **Inviragen**

Dr Karl-Josef Kallen, CSO, **CureVac**

Prof Dr Vidadi Yusibov, Executive Director, **Fraunhofer Centre for Molecular Biotechnology**

Dr Christel Gremion-Viatte, Project Manager, **Pevion**

Preconference workshops

January 31st 2011

Workshop A
Overcome the challenge of operating a vaccine business in emerging countries
Lead by: **Klaus Hermansen** Senior Specialist, Consulting, MSc Bio Engineering, **NNE Pharmaplan**

Workshop B
Formulation of stable adjuvant containing vaccines
Prof Dr Tudor Arvinte, Chairman, CEO, Biozentrum, **University of Basel and Therapeomic AG**
Dr Martinus Capelle, Scientist, **University of Basel and Therapeomic AG**

Programme Partner:

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VACCINE INNOVATION 2011

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Your opportunity to learn from the innovators driving the growth and investment in the vaccine market to help generate new revenue streams

Dwindling pipelines and the lack of blockbuster drugs has made the importance of new innovative products more vital than ever. Innovative new vaccines and related technologies offer a fantastic opportunity to bolster pipelines and deliver improved vaccine development to your company.

Are you up to date with the latest developments in **adjuvants, delivery, regulation, process development** and the newest vaccines in the clinic? Attend this meeting and secure your company's position in the vaccine market.

Innovation is driven through learning. Over two days you will have the opportunity to meet and network with international scientists and research leaders from the vaccine industry. Ranging from Directors and Heads of Vaccine R&D, Chief Executives to Scientific Officers and Heads of Commercialisation. Across the industry companies are looking for answers. Share lessons learned, meet and interact with the leading organisations including **Merck & Co, Novartis, sanofi pasteur, Medimmune, Pevion, FDA** and **Intercell** to name a few.

ATTEND THIS MEETING TO:

- Hear from the **FDA** on the best approaches to keep up to date with the rapidly changing global regulatory landscape that's making vaccine development more challenging
- Experience is key, especially in such a competitive market. Take this opportunity to understand the lessons learned from **sanofi pasteur** on developing their vaccines **R&D pipeline**
- **Partnering** is very much at the forefront of **vaccine pipeline development.** Understand Intercell's approach to biotech partnering strategies to make **vaccines globally available**
- Debate with **Pevion Biotech** the advantages and challenges in development and manufacturing of **VLP-based vaccines** and how you could utilise this technology in your developments
- Hear how **Transgene** are developing **Viral based therapeutic vaccines** and their synergy with other cancer vaccines
- Learn from **Merck & Co** the future trends in **pneumococcal vaccine** research and how this could be a possibility for your pipeline development
- Understand the mechanism of action of **vaccine adjuvants Alum** and **MF59** with **Novartis Research Centre**
- Discuss new technologies for **improved vaccines** with representatives from **Novartis Research and Diagnostics, Okairos, Trinity College Dublin, Baxter** and **Inviragen**

Programme Partner:

CureVac is a biopharmaceutical company pioneering the direct therapeutic application of messenger RNA (mRNA) the biomolecule that physically transfers genetic information from the nucleus to the cellular protein production machinery. By making mRNA available for therapeutic purposes, **CureVac** seeks to introduce a novel class of drugs into today's medicine. Building on a unique body of knowledge in RNA research, design and cGMP production, the Company has established a range of proprietary technologies. These include: **RNActive®** for the design of modified and formulated mRNA targeting a broad range of therapeutic applications, **RNAdjuvant®** for the use of RNA as an immune stimulant, PUREmessenger® for the GMP-production of long-chain mRNA up to 15.000 nt. Based on these technologies, the Company is building a growing pipeline of innovative product candidates.

Who Should Attend

Vaccine Innovation is a leading meeting of international scientists and research leaders from the vaccine industry ranging from academia, biotech companies, research institutes and pharmaceutical companies. **Directors and Heads of Vaccine R&D, Chief Executives, Scientific Officers and Heads of Commercialisation** will have the opportunity to debate and discuss the key issues concerning vaccine research and development.

Display and Discuss your Work

As part of the Biorbis mission to accelerate progress and facilitate open discussion, we encourage attendees to present a poster.

There is no additional charge for registered delegates. The only thing we ask is that poster displays are not used for sales or marketing purposes and all poster abstracts are subject to approval by the conference organizers. If you're interested in taking up this great opportunity, simply indicate on your registration form and send your poster title and abstract to:

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Sponsoring Vaccine Innovation 2011 puts you in front of potential new clients in the vaccine industry from companies looking to outsource research, clinical trials, manufacturing through to identification of new technologies to aid the speed of development, along with potential consultation opportunities. Potential clients looking for your expertise at the very time when they are selecting solutions for their business needs. Solutions you can offer.

Contact **Miles Harley** on
miles.harley@hansonwade.com
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CONFERENCE DAY ONE: 1st February 2011

08.00 Registration and morning coffee

09.00 **Chair's opening remarks**
Dr Alexander von Gaba\in, Strategic Advisor to the Management and Supervisory board, **Intercell AG**

KEY FACTORS DRIVING VACCINE DEVELOPMENT

09.15 **Keynote address: Developing a vaccines R&D pipeline**
- Overcoming the barriers in development
- 5/10 year forecast

Dr Jeffrey Almond, Vice President, Discovery Research and External R&D, **sanofi pasteur**

09.45 **Speed networking**
Connect with speakers and other attendees early in the meeting and maximize the benefit of networking time

10.45 Coffee

11.15 **Towards global registration of a novel inactivated and adjuvanted JEV vaccine with a high safety profile**
- The need for improved and novel Flavi-virus vaccines
- A novel vero-cell based inactivated and adjuvant JEV vaccine with a very promising efficacy and safety profile
- Moving into the pediatric indication
- A biotech partnering strategy to make the vaccine globally available

Dr Alexander von Gabain, Strategic Advisor to the Management and Supervisory board, **Intercell AG**

REGULATION AND INNOVATION

11.45 **Vaccine manufacturing & development: A US FDA regulatory perspective**
- Organisation of the Center for Biologic Evaluation & Research (CBER)
- Laws and Regulations
- Vaccine development process
  - Manufacture
  - Clinical development
- Approaches to expedite vaccine development
- Vaccines against global infectious disease
- Global collaboration

Dr Marion F. Gruber, Deputy Director, Office of Vaccines Research & Review, **FDA/CBER**

12.15 Lunch

COLLABORATION AND FUNDING - THE KEY TO SUCCESSFUL VACCINE INNOVATION

13.15 **Collaboration and funding: How to achieve a win-win situation**
NicVAX and option and license agreement between Nabi and GSK
- NicVAX and smoking cessation
- Choosing the right fit for the product
- The NicVAX option and license agreement

Dr Raafat Fahim, President and CEO, **Nabi Biopharmaceuticals**

IDENTIFICATION, DEVELOPMENT AND DELIVERY: NEW DEVELOPMENTS FOR VACCINE INNOVATION

13.45 **Case study: Virus like particles (VLP) and virosomes as adjuvant and carrier**
- VLP systems used for vaccines on the market and in clinical development
- Advantages and challenges in development and manufacturing of VLP-based vaccines
- The virosome as a carrier/adjuvant system
- Mode of action of virosomes

Dr Christian Moser, DVM, Head Research, **Pevion Biotech**

14.15 **Case study: Viral based therapeutic vaccines**
- Scientific rationale
- Biomarkers signature
- Clinical results
- Synergy with other cancer treatments

Dr Jean-Yves Bonnefoy, Vice President Research and Development, **Transgene**

14.45 Coffee

15.15 **Case study: Enhancing the efficacy of vaccine adjuvants**
- Obstacle to therapeutic vaccination
- Suppression of anti-tumor immunity by regulatory T cells
- Novel adjuvant formulation to overcome Treg cell induction
- Dendritic cell vaccines for cancer

Dr Kingston Mills, Professor of Experimental Immunology, Head School of Biochemistry and Immunology, Director Immunology Research Centre, **Trinity College Dublin**

15.45 **Preclinical evaluation of pneumococcal conjugate vaccines with expanded strain coverage**
- Development of a global pneumococcal vaccine to address serotype replacement
- Evaluation of candidate vaccines in rabbit and infant monkey models
- Future trends in pneumococcal vaccine research

Dr Jon Heinrichs, Director, **Merck & Co**

16.15 **Mechanism of action of vaccine adjuvants alum and MF59**
- Adjuvant classification based on mechanism of action
  - Antigen delivery systems
  - Immune potentiating functions
- Alum: Introduction and overview
- MF59: Introduction and overview
- Impact of adjuvant injection on innate immune responses in the injection site
- Complex cross-talk between innate and adaptive immunity
- Contribution of single target cells and signaling pathways to adjuvanticity
- Outlook: New combination adjuvants

Dr Anja Seubert, Laboratory Head, Department of Immunology, **Novartis Research Center**

16.45 **Understanding how Baxter have approached vaccine innovation and development**
- Case study update
- Latest developments

Dr Laura Pérez-Burgos, Research Scientist, Downstream Processing I, **Baxter Innovations GmbH**

THE FUTURE OF VACCINES

17.15 **Panel session: What is the future of vaccines?**
- Overcoming the barriers in development
- 5/10 year forecast

Dr Jeffrey Almond Vice President, Discovery Research and External R&D, **sanofi pasteur**
Dr Jon Heinrichs, Director, **Merck & Co**
Dr Christian Moser, DVM, PhD, Head Research, **Pevion Biotech**

17.45 Close of Day One

19.30 Optional Networking Dinner

CONFERENCE DAY TWO: 2nd February 2011

08.30 Registration

09.00 **Chair's opening remarks**
Dr Alexander von Gabain, Strategic Advisor to the Management and Supervisory board, **Intercell AG**

CONSIDERATIONS IN A GLOBAL VACCINE MARKET

09.15 **Keynote address: Vaccine development in a global market place**
- Technology expansion and innovation
- Implications of global vaccine market

Dr Philip Krause, Deputy Director, Division of Viral Products, **FDA**

NEXT GENERATION VACCINES

09.45 **Case study: Universal influenza vaccine**
- Role for T cell response in preventing Flu disease
- Suitable antigens for universal Influenza vaccine
- Clinically validated vaccine vectors for universal influenza vaccine delivery
- Pre-clinical development of a novel gene-based universal vaccine candidate
- Path toward early clinical POC

Dr Alfredo Nicosia, Chief Scientific Officer, **Okairos**

10.15 **Case study: Dengue vaccine program**
- Developments
- Needle free delivery method
- Clinical results

Dr Joe Santangelo, Chief Operating Officer, **Inviragen**

10.45 Coffee

11.15 **New technologies for improved vaccines**
- Antigen discovery technologies
- Rational approaches to antigen development and optimisation
- Novel adjuvants and delivery systems
- Synergistic effects of heterologous prime-boost strategies

Dr Jeffrey Ulmer, Global Head, External Research, **Novartis Vaccines & Diagnostics**

CANCER VACCINES

11.45 **CureVac's RNActive technology; a new approach to vaccinate against cancer and infections - first clinical data**
Dr Karl-Josef Kallen, MD, CSO, **CureVac**

12.15 Lunch

13.30 **Why so few phase III cancer vaccine trials reproduce good phase II data; the need to identify non responders**
- Phase II patients are selected at specialist centres
- Phase III patients include many patients who would not be accepted on a phase II in spite of extensive inclusion/exclusion criteria
- Non responders have an inflammatory phenotype which may benefit from alternative or additional treatment first
- Ideally need to target TLRs to activate tumours and to inhibit Treg and MDSC activity which can be acheived with appropriate chemotherapy
- The importance of integrating vaccines at the right stage and with other appropriate modalities

Prof Angus Dalgleish, Consultant Medical Oncologist, **St. George's University of London**

THE FUTURE OF VACCINES - CLINICAL UPDATE

14.10 **Case study: Medimmune's development of RSV**
- MEDI-559 is an intranasal, recombinant, live attenuated, temperature sensitive respiratory syncytial virus (RSV)
- Vaccine being developed, in conjunction with the National Institute of Allergy and Infectious Disease (NIAID)
- Prevention of lower respiratory tract disease caused by RSV

Dr Edward Mocarski, Distinguished Fellow, **MedImmune Vaccines**

14.50 **Case study: Recombinant HA-based vaccine against influenza**
- Need for new approaches to manufacture influenza vaccines
- Recombinant subunit influenza vaccines
- Plant cells as a substrate for manufacturing subunit influenza vaccines
- Immunogenicity of plant-produced influenza vaccines (pre-clinical and clinical development).

Prof Dr Vidadi Yusibov, Executive Director, **Fraunhofer Centre for Molecular Biotechnology**

15.30 Coffee

16.00 **Case study: Update on the phase I clinical study of PEV7, a novel virosomal vaccine against vulvovaginal candidiasis**
- 5 to 8% of women experiencing an attack of vulvovaginal candidiasis remain chronically infected and suffer from recurrent episodes until the menopause (RVVC); these women are treated during months with antimycotics, eliminating symptoms but not preventing recurrency
- PEV7, the potential solution for these women, is a monovalent virosome-based subunit vaccine against recurrent VVC caused by pathogenic form of Candida albicans
- PEV7 has entered clinical testing. The Phase I study initiated in Q1 2010 is assessing safety & tolerability of i.m. and intravaginal forms of PEV7 in healthy adults
- An overview of the preclinical development as well as first safety and immunogenicity data for the i.m form of PEV7 will be presented

Dr Christel Gremion-Viatte, Project Manager, **Pevion**

16.40 **Panel session: Considerations in vaccine development**
- Lessons learned over the two days
- Where is the industry going?

Dr Marion F. Gruber, Deputy Director, Office of Vaccines Research & Review, **FDA/CBER**
Dr Christel Gremion-Viatte, Project Manager, **Pevion**
Prof Dr Vidadi Yusibov, Executive Director, **Fraunhofer Centre for Molecular Biotechnology**
Dr Edward Mocarski, Distinguished Fellow, **MedImmune Vaccines**

17.10 Close of conference

"It's a great place to get the latest information and networking"
Pfizer

"An excellent opportunity to find out what other pharma are doing and what's emerging. Very valuable"
AstraZeneca

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PRE CONFERENCE WORKSHOPS 31st January 2011

WORKSHOP A — 10.30am-1.30pm

Overcome the challenge of operating a vaccine business in emerging countries

There is a strong focus on the vaccine business in the emerging countries. Based on a number of business cases, this workshop will cover a number of the challenges that you have to overcome in order to run a successful business in emerging countries. It will give you an introduction to the regulatory challenges and it will bring you some tools and ideas you can use if you want to deliver/bring more affordable vaccines to the market.

Topics to be covered include:

- Regulatory overview with focus on emerging countries
- How does cGMP impact your business in emerging countries?
- Business challenges by operating in emerging countries and how to overcome them
- How to bring more affordable vaccines to the emerging markets
- How to get successful local supply of vaccines in emerging countries

Benefits of attending:

- Excellent overview of the regulatory climate for doing vaccine business in emerging countries
- Answers to many of the obvious challenges you will have by operating in emerging countries
- Tools and ideas for improving operation in emerging countries
- Answers and ideas of how to lower the cost of vaccines manufactured in emerging countries

Workshop leader:
Klaus Hermansen, Senior Process Consultant - Head of Vaccine Design, NNE Pharmaplan

Mr. Klaus Hermansen is Senior Process Specialist for Consulting in NNE Pharmaplan, a global engineering and consulting company providing projects and services for biotech and pharmaceutical companies worldwide. He holds a Master degree in Biotechnology from the Technical University of Denmark where he graduated in 1982 and has been working in the Bio-pharmaceutical industry since then. He started his carrier at Novo Nordisk where he was in charge of Manufacturing. Later he moved into the Vaccine business – also here being responsible for Vaccine Manufacturing in various positions in Denmark, The Netherlands and in UK. Since 2005 he has been based in Denmark working for NNe pharmaplan.
Mr. Hermansen has been engaged in several Biotech projects regarding Multi-product facilities and the use of Single Use technology and he is an expert within the area of Vaccine Manufacturing, Containment and SU technology.

WORKSHOP B — 2.30pm -5.30pm

Formulation of stable adjuvant containing vaccines

The workshop will present vaccine formulation approaches and novel analytical methods to study the antigen binding and interaction with the adjuvant

Topics to be covered include:

- Methods permit the characterisation of conformation, aggregation and colloidal properties of proteins adsorbed to aluminum adjuvants without separation
- The non-invasive analytical methods that were applied for optimising protein – adjuvant formulations include absorbance and fluorescence spectroscopy (fluorescence emission, fluorescence lifetime and anisotropy), circular dichroism, infrared spectroscopy, light scattering and ultrasound velocity
- Centrifugation techniques will also be presented for the determination of binding curves as well as analytical centrifugation with the LUMiSizer to study sedimentation profiles and colloidal properties of the antigen-adjuvant mixtures
- Different case studies will be presented on anti-idiotypic antibody vaccines, virosomes, virus-like particles and influenza vaccines
- The physical and chemical properties of different formulated vaccines are correlated to the immune responses in animal models. Based on these in vivo- in vitro correlations, protein adjuvant vaccines can be optimised that promote a stronger immune response

Benefits of attending:

- This workshop will guide attendees through the development of a stable protein – adjuvant vaccine with advice on the available analytical technologies and their applications
- Answers and ideas of adjuvant vaccine development

Prof Dr Tudor Arvinte, Chairman, CEO, Biozentrum and University of Basel

Tudor Arvinte, Ph.D. was born in Romania in 1956, received his academic training in physics at the University of Jassy, Romania, and his Ph.D. in biophysics from the University of Düsseldorf, Germany. He performed his doctoral work and postdoctoral stage at the Max-Planck-Institute West Germany and held numerous research positions in Europe and the USA: at C.N.R.S., Orléans, France, at Cornell University, New York, at Texas A&M University, and at the Biophor Corporation, College Station, Texas, USA. Since 2001 he is Invited Professor at the School of Pharmacy, University of Geneva, Switzerland where he is teaching a post-graduate course on "Formulation and delivery of protein biopharmaceuticals". In 2003 T. Arvinte co-founded Therapeomic, Inc., biotech company that was spun out from Novartis focused on: i) developing formulations for biopharmaceuticals in collaborations with pharmaceutical companies; and ii) developing therapies based on TGF- 3.

Dr Martinus Capelle, Scientist, Therapeomic AG and University of Basel

Martinus Capelle, who is of Dutch origin, obtained his pharmacist diploma from Utrecht University in 2001. Between 2002 and 2006 he did his PhD at the University of Geneva under the supervision of Prof. Robert Gurny and Prof. Tudor Arvinte. His PhD thesis was entitled: "High Throughput Formulation of Biopharmaceuticals". During his thesis, he developed novel high throughput and spectroscopic methods to characterise a variety of protein formulations, including stable liquids, lyophilized forms, drug delivery systems and protein-adjuvant vaccines. He received from the society of Swiss industrial pharmacists (GSIA) an award for best PhD in Switzerland.

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