Vaccine delivery systems for the future

Friday, 17 May 2013
The Stevenage Bioscience Catalyst
Gunnels Wood Road, Stevenage , Hertfordshire, United Kingdom

This conference provides a platform for researchers, physicians and enterprisers to discuss and learn about all the important breakthrough developments in vaccine delivery and on new therapeutics and know what the new trend of the vaccine (drug) delivery technologies is in future and how these technologies can be developed, realized and commercialized. It also provides scientist the opportunity to present their cutting-edge researches in the area of vaccination, drug delivery, gene delivery, immunotherapy and nanotechnology. Throughout the course of the 1-day conference, you will have the opportunity to both expanding the network and hear leaders from the pharmaceutical, academic and clinical communities.

This event is part of the 2013 ***Euroscicon BioTherapeutics Week***,
to find out more see www.biotherapeutics2013.com

This event has CPD accreditation

Meeting chair: *Dr Lan Chen*, Department of Chemical Engineering and Biotechnology University of Cambridge

Who Should Attend
Biotech and Pharma Industry: CEOs, Chief Scientists, Group Heads, Senior and Junior Scientists, Research

Academic and Research Institutes: Group and Lab Heads, Postdoctoral Scientists and Research Students

9:00 – 9:45 Registration

9:45 – 10:00 **Introduction by the Chairs**: *Dr Lan Chen*, Department of Chemical Engineering and Biotechnology University of Cambridge

10:00 – 10:30 **Non-Replicating Viral Vaccines and Novel Antigen Delivery System**
Professor Polly Roy, London School of Hygiene & Tropical Medicine, UK

10:30 – 11:00 **Development of Novel Antibody-Inducing Vaccines against Human Malaria**
Dr Simon Draper, The Jenner Institute, University of Oxford
The human malaria parasite Plasmodium falciparum continues to exert a huge burden on global public health, whilst the development of a highly efficacious vaccine has proved extremely challenging. The disease-causing blood-stage of the parasite's life-cycle is known to be susceptible to antibodies. However, the field has faced significant hurdles in translating this knowledge into efficacious clinical subunit vaccine products. This talk will focus on the development of new approaches to vaccine antigen identification and delivery in the context of human malaria, and will summarise experience to date of these new strategies in Phase I/IIa clinical trials.

11:00 – 11:30 **Speakers' photo then mid-morning break and trade show**
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11:30 – 12:00 **Novel generation of bacteriophage-derived platform technologies for vaccine delivery**
Dr Amin Hajitou, Imperial College Faculty of Medicine Division of Brain Sciences, Hammersmith Hospital, United Kingdom

12:00 – 12:30 **Multifunctional Nanoparticle - new platform for vaccine delivery**
Dr Lan Chen, Department of Chemical Engineering and Biotechnology University of Cambridge
Great advances have been made in the past decades on the development of vaccine delivery but the dilemma between immunogenicity, safety and tolerability has remained a major challenge and not been well overcome. Therefore, it needs to develop smarter delivery solutions to overcome this weakness. A smart drug delivery system is the system that can act accurately only in targeted tissue and make diagnosis and provide therapy during the same time. To achieve these functions, a custom made nano-platform will firstly be built. Then, various therapy cargos will be loaded onto the platform according to requirement, where the cargos are not only chemical substances but any active components, like fluorescent tags, antibodies, peptides and DNA. Eventually, healthcare delivery at low cost, low side-effect, high efficacy and long-lasting manners will be achieved.

12:30 – 13:30 **Lunch and trade show**

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13:30 – 14:00 **Assessment of a newly developed medical device for intradermal vaccination: results of a phase 1 trial in 102 healthy volunteers**

Dr Vanessa Vankerckhoven, VAXINFECTIO (Vaccine & Infectious Disease Institute), University of Antwerp, Belgium
To date, the vast majority of vaccines are administered into the muscle (intramuscular) using needle and syringe. The past years renewed interest has been shown in intradermal vaccination due to its advantages. However, devices to accurately deliver vaccines in the dermal layer of the skin are scarce. The project approach with a distinct university-SME collaboration ultimately led to the development of a prototype device, entitled VAX-ID®. Results of a Phase 1 trial in which intramuscular and intradermal vaccination was compared in 102 healthy volunteers will be discussed.

14:00 – 14:30 **Nanoparticle Tracking Analysis: Visualizing, sizing and counting viruses in liquid suspension.**

Ben Owen, Product Specialist, Nanosight, UK
A laser-based nanoparticle tracking analysis system is now available which allows nanoscale particles such as viruses and virus aggregates to be directly and individually visualised in liquids in real-time, from which high-resolution particle size distribution profiles can be obtained. The technique is fast, robust, accurate and low cost representing an attractive alternative or complement to existing methods of nanoparticle analysis such as Dynamic Light Scattering (DLS), Photon Correlation Spectroscopy (PCS) or Electron Microscopy (EM).

14:30 – 15:00 Afternoon Tea/Coffee and trade show

15:00– 15:30 **Ensuring Sterilising Filtration of Advanced Vaccine Formulations**

Dr Annelies Onraedt, Pall Europe, UK
Advanced vaccine formulations, typically associated with new delivery systems such as adjuvanted vaccines or virus-like-particles can present major challenges to sterilising filtration. In order to comply with cGMP, these challenges and the associated risks have to be understood and mitigated early in process development so that marketing applications to, and product approvals by regulatory authorities are not unnecessarily delayed. In this presentation an overview of the challenges and risks are presented whilst some corrective approaches are proposed.

15:30 - 16:00 **Approaches to T cell vaccines for HIV**

Dr Steven Patterson, Imperial College at Chelsea and Westminster Hospital, UK
An effective HIV vaccine is thought to require T cell responses. T cell immune responses induced by acute infection or a vaccine are usually limited to recognition of a small number of immunodominant or subdominant epitopes. This presents a major hurdle in the development of a T cell vaccine for HIV since a high mutation rate enables the virus to quickly escape immune recognition. Vaccine strategies designed to induce responses to multiple T cell epitopes and overcome the problem of immune escape will be described.

16: 00 - 17:00 **Question and Answer Session**

Delegates will be asked to submit questions to a panel of experts. Questions can be submitted before the event or on the day

17:00 Chairman's summing up

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This meeting was organised by Euroscicon (www.euroscicon.com), a team of dedicated professionals working for the continuous improvement of technical knowledge transfer to all scientists. Euroscicon believe that they can make a positive difference to the quality of science by providing cutting edge information on new technological advancements to the scientific community. This is provided via our exceptional services to individual scientists, research institutions and industry.

About the Speakers

Polly Roy began her education in Calcutta, India but won a fellowship to New York University for her PhD under the supervision of the renowned molecular biologist, Sol Spiegleman. A 3-year postdoctoral position in virology at the Waksman Institute, Rutgers University, followed after which she joined the University of Alabama at Birmingham to establish her own virology research group where she became a full Professor in 1986. In 1987 she received a senior International Fogarty fellowship to study at the University of Oxford where she gradually established a UK-based research group. In 1997, she became Professor at the University of Oxford and in 2001 took the chair of Virology at the London School of Hygiene and Tropical Medicine. Her studies have contributed in many areas of virology, notably virus structure, assembly, RNA replication and vaccine development. Roy was the first to demonstrate the assembly of virus-like particles (VLPs), a technology which has been applied since to many other viruses including for successful vaccine development for Human Papillomavirus, Influenza and SARS. Recently Roy pioneered the synthesis of infectious virus solely from synthetic genes, a major achievement which opens a new window of opportunity for the development of new therapies in the longer term. She has supervised over 140 post-doctoral and post-graduate researchers, published over 300 research papers and has served on various international scientific organizations, committees and boards. She has organized several highly successful international conferences, particularly on the subject of virus assembly and in 2006 was elected a Fellow of the Academy of Medical Sciences. This year Roy has received a Gold Medal for her contribution to science and technology from the Indian Prime Minister during the Annual Indian Science Congress (2012), along with three Nobel laureates. She is also one of the three BBSRC Scientific Innovators of the year.

Ben Owen's background is in biomedical science, with an expertise in diagnostic markets. Ben has specialised in pharmacology and biochemistry, and holds an honours degree from Cardiff University. After several years working in drug development for GlaxoSmithKline and Johnson and Johnson, Ben began working on the development of gold and silver nanoparticles for the diagnostic markets as a senior research scientist at British Biocell International. Ben has been working in the field of nanotechnology for the last 5 years; he is currently a product specialist and business development manager for Nanosight, responsible for sales and scientific support in southern UK, Denmark, Norway and Sweden.

Simon Draper's group is based at the Jenner Institute, University of Oxford. His research interests include studies of vaccine-induced malaria immunity as well as the optimisation of antibody induction by subunit vaccines against blood-stage malaria infection. In recent years, his group has developed novel vaccines targeting blood-stage antigens from the human malaria parasite Plasmodium falciparum, and these have been translated into Phase I/IIa clinical trials. His group are also focusing on the identification of new antigen combinations that may prove to be more successful in inducing protective efficacy against malaria by subunit vaccination in humans.

Steven Patterson is based in the Immunology Department at Imperial College's Chelsea and Westminster Campus where the main research focus of department is HIV. His main research interests are in HIV pathogenesis, vaccines and human dendritic cell biology. Since the mid 1980s his group have investigated the role of dendritic cells in HIV pathogenesis and but in the last six years they have been funded by the Bill and Melinda Gates Foundation to develop a T cell vaccine for HIV that will overcome the problem of virus escape from immune recognition.

Vanessa Vankerckhoven is currently appointed as Research & Innovation Manager of the Vaccine and Infectious Disease Institute at the University of Antwerp. She obtained a master degree in Biomedical Sciences and a PhD in Medical Sciences at the University of Antwerp, Belgium. Her main research interests are in vaccines as well as medical device development such as injection devices and point of care diagnostics. She has been working on the development of an injection device suited for intradermal vaccination. As an R&I manager she is also responsible for assessing technology transfer and valorisation opportunities including patent filing and spin-off creation.

Annelies Onraedt, PhD, is Global Market Manager for Vaccines at Pall Life Sciences, a Total Solutions provider for the Biopharmaceutical industry. She obtained a PhD in Bioscience Engineering from Ghent University, Belgium, for her study in the field of Industrial Microbiology and Biocatalysis. She then joined Pall as a Biopurification Specialist and has several years of experience in optimizing downstream processing technologies for the vaccine industry, including chromatography, tangential and direct flow filtration. In her current position as vaccine market manager, she is in frequent contact with the vaccine industry worldwide. She is involved in the development of integrated manufacturing solutions, new technology platforms and strategic collaboration programs. She is a frequent speaker at conferences and seminars on latest market and technology trends.

Keywords: Malaria; Vaccine; Antibody; Immunology,Vaccine delivery; Immunotherapy; Nanoparticles, Drug-delivery; Gene-Delivery, HIV, vaccine, T cells , Medical device, human volunteers, vaccines, university-industry collaboration, intradermal vaccination, Nanoparticle: charactersation; technique; size; count

POSTERS

ASSESSMENT OF A NEWLY DEVELOPED MEDICAL DEVICE FOR INTRADERMAL VACCINATION: RESULTS OF A PHASE 1 TRIAL IN 102 HEALTHY VOLUNTEERS

Vanessa Vankerckhoven[1,2], Stijn Verwulgen[2,3], Koen Beyers[2,4], Timothi Van Mulder[1], Ruben Camerlynck[3], Charlotte Reypens[5], Alex Vorsters[1,2], and Pierre Van Damme[1,2]

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To date, the vast majority of vaccines are administered into the muscle (intramuscular) using needle and syringe. The unique immunological properties of the skin make the epidermis and dermis attractive sites for prophylactic as well as therapeutic vaccination. The past years renewed interest has been shown in intradermal vaccination due to its advantages, including dose-sparing, improved immunity, improved safety and simpler logistics of delivery. However, devices to accurately deliver vaccines in the dermal layer of the skin are scarce. Our project aimed to develop a new device suited for e.g. injections of vaccines (prophylactic as well as therapeutic) in the intradermal layer of the skin and clinically evaluate the device in healthy volunteers.

A multidisciplinary team consisting of medical scientists, product developers and economists of the University of Antwerp and Artesis University College closely collaborated with VOXDALE BVBA, a design and engineering company based in Antwerp. Furthermore, the Belgian Industrial Research & Development Fund granted funding for 3 master theses (Applied Economics, Nursing and Midwifery, Product Development) supporting the development of a prototype device, development of a business model and clinical evaluation of the device in healthy volunteers. The project approach with a distinct university-SME collaboration ultimately led to the development of a prototype device, entitled VAX-ID®, for which a UK patent application has been filed and PCT filing is ongoing. The prototype device meets technological challenging requirements in terms of safety, waste management, ease of use, use by untrained medical staff, suitability for use in elderly and children and at anatomic sites other than the deltoid region, next to assembly and production requirements.

Next, the device was evaluated with saline content for its usability and acceptability in 102 healthy volunteers, when administered in the deltoid region and the forearm: intradermal (ID) injection using VAX-ID® was compared to intramuscular (IM) injection. Compared to IM injection, ID injection was perceived as non-painful by the vaccinees and remarkably less anxiety upon contact with the VAX-ID® device was reported. Based on 5-day diary, there were no reports of systemic effects. Local reactions were uncommon, except for local redness which was significantly more reported for ID versus IM, whereas pain at the injection site was significantly more reported for IM compared to ID ($P<0.05$). Additionally, usage was optimized through a usability study with the vaccinators.

In conclusion, the multidisciplinary approach allowed conception, construction and evaluation of the VAX-ID® prototype device in a short time span. Based on the developed business model and the assessment of the market potential for the VAX-ID device, a University of Antwerp spin-off company has been created, Novosanis NV, to allow for further development, commercialization and marketing of VAX-ID®. Furthermore, additional clinical studies will now be set-up to assess clinical immunogenicity and safety with vaccine antigen in larger cohorts of adults, children and elderly.

REMOTE-CONTROLLED HYDROGELS FOR SCHEDULING VACCINE ADMINISTRATION

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Vaccination represents a highly efficacious and efficient strategy to reduce worldwide morbidity and mortality saving millions of lives per year. However, most vaccination regimes require multiple injections inherently associated with a risk of infection as well as with the requirement of medical personnel and a functional supply chain management. We present a novel vaccine depot that is triggered to release its cargo and to induce protective immunity by the simple intake of an orally available small molecule thus replacing repeated injections by oral medication. To this aim, we designed a depot exclusively synthesized from compounds routinely used in human therapy. Responsiveness of the depot to a specific small-molecule stimulus was conferred by the grafting of protein-small molecule interactions on polyethylene glycol (PEG). We demonstrate the functionality of this biohybrid depot by the incorporation and stimulus-inducible release of vaccines. Upon implantation of the vaccine-loaded depot into mice, we were able to release the vaccine in a time-controlled manner by the oral administration of the small-molecule stimulus finally resulting in successful immunoprotection. Additionally, good tissue compatibility of the vaccine depot was demonstrated by fine histological analysis. This study represents the first application of a pharmacologically controlled biohybrid material for the scheduled induction of immunization and might represent a feasible strategy for the simplified administration of numerous vaccines and pharmaceuticals.