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VIC CONGRESS

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Gene Therapy

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Wednesday 3 - Thursday 4 December 2014
Sheraton Hotel Brussels, Brussels, Belgium

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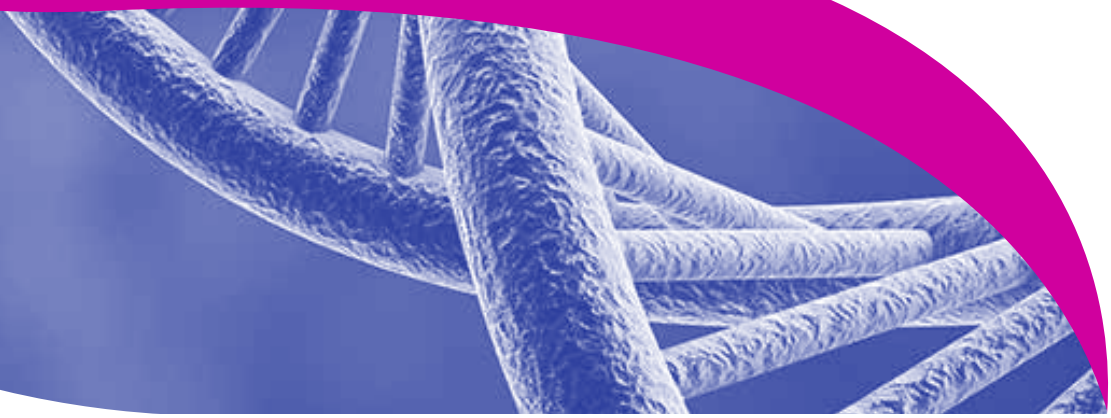

Speakers Include

Dr Peter Nolan
Executive Director
Oxford Biomedica
UK

Dr Mark D. Angelino
VP Pharmaceutical Sciences
Bluebird Bio, USA

Dr Janneka Meulenberg,
CEO, **ORCA Therapeutics**
Former VP of Preclinical and Clinical Development & Director of Project Management at **uniQure.**
The Netherlands

Dr Abraham Scaria,
Senior Scientific Director, Gene Therapy/Opthalmology,
Sanofi-Genzyme R&D Center, USA

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BioPharm SERIES

www.informa-ls.com/genetherapy

Day One: Wednesday 3 December 2014

08.00 Morning Coffee & Registration

08.50 **Opening Remarks from the Chair**

Professor Alan Boyd, *CEO,* **Boyds Consultants, UK**

The Path to Commercialisation - Sanofi-Genzyme, Glybera and Oxford Biomedica

09.00 **Development of a gene therapy for neovascular AMD**

VEGF antagonists are useful for treating neovascular AMD, however currently approved treatments require frequent and chronic intravitreal injections. We are developing an AAV based anti-VEGF gene therapy that could be an alternate method for the long-term treatment of diseases of ocular neovascularisation, without the need for repeated intraocular injections.

Dr Abraham Scaria, *Senior Scientific Director, Gene Therapy/ Opthalmology,* **Sanofi-Genzyme R&D Center, USA**

09.35 **Lessons from Glybera, learning insights for product development of gene and virotherapies**

The path to commercialization of Glybera, the first gene therapy approved in the Western world took 12 years. While moving this product from the bench to registration studies we faced many technical, financial, and strategic challenges. In this presentation, I will give a historical perspective of the development path, the lessons learned, and to what extent the insights are helpful in developing future virus-based products, amongst which the oncolytic adenovirus ORCA-010 for cancer patients.

Dr Janneke Meulenberg, *CEO*, **ORCA Therapeutics, The Netherlands.**
Former VP of Preclinical and Clinical Development & Director of Project Management at **uniQure**.

10.10 **Implementing an effective pricing and reimbursement strategy for gene therapies**

With one approved gene therapy product and a substantial clinical pipeline of others it remains a potential challenge to understand what the reimbursement climate will look like for 'one-shot' therapies in the future. This talk will cover how this risk can be better understood and mitigated.

Dr Peter Nolan, *Executive Director,* **Oxford Biomedica, UK**

10.45 **Morning Break and Poster Session**

11.15 **Discussion Panel – Lessons learnt and future challenges for the commercialisation of gene therapy**

- Understanding the lessons learnt in the field and the implications for future development
- Exploring the key challenges obstructing the progression of gene therapy
- Examining the impact of pricing and reimbursement in industry – how much do the perspectives of developer, payer and consumer impact upon a product's success?

Professor Alan Boyd, *CEO,* **Boyds Consulants,** UK

11.50 **The importance of intellectual property when commercialising a gene therapy product**

Maximising commercial value in a gene therapy medicinal product demands a fresh understanding, and strategic use, of their unique intellectual property and regulatory characteristics. Starting with an up-to-date appraisal of gene patent law and public policy concerns, this talk examines some alternative tactics to securing exclusivity for gene therapy products.

Mr Julian Hitchcock, *Counsel,* **Lawford Davies Denoon, UK**

12.25 **Spotlight Presentation**

These presentations are hosted by leading service providers in the field of gene therapy. If you are interested in hosting a spotlight session please contact Luke Pickering for more information: luke.pickering@informa.com

12.55 **Networking Lunch with VIC Congress Attendees**

Accelerating Preclinical and Clinical Development

14.00 **Understanding the guidelines on the quality, non-clinical and clinical aspects of genetically modified products**

Advanced therapy medicinal products have been included in European regulation since 2007 and since then a number of guidelines have been issued on these products. In this presentation we will review some of these guidelines, identifying key issues and how to navigate the requirements set out through case studies. We will then speculate on the guideline developments that have occurred since the approval of Glybera and the impact that Glybera may have on the regulations surrounding gene therapy medicinal products moving forward.

Sean Russell, *Senior Regulatory Affairs Manager,* **Diamond Pharma Services, UK**

14.35 **Overcoming limitations in animal models in the development of new therapies for neurodegenerative diseases**

The mathematician's quip "All models are wrong, but some are useful" (George E.P. Box) applies to animal models of disease as well. The pitfalls of relying on single models of neurodegenerative disease will be described, and multiple model strategies and emerging tools, such as patient-derived iPS cells, presented as alternatives.

Dr Bill Kaemmerer, *Bakken Fellow,* **Medtronic Neuromodulation, USA**

15.10 **Win-Win: Using synergies in human and animal gene therapy drug development**

Many diseases affect both humans and animals and can successfully be treated by the same approach. Although there are significant differences in human and veterinary drug development including their regulatory pathways, biotech companies can make use of a number of synergies to streamline the development of gene therapy drugs for several species.

Dr Stanislav Plutizki, *Vice President,* **Regulatory and Medical Affairs, GeneQuine, Germany**

15.45 **Afternoon Break**

16.15 **Translational development of GS010, an ocular mitochondrial gene therapy**

GS010 is the first gene therapy product shaped and designed to compensate for the loss of function of ND4, a mitochondrial Complex I protein mutated in patients with Leber Hereditary Optic Neuropathy. We will present the preclinical strategy and early clinical development update of GS010 in the context of a retinal blinding disease.

Dr Didier Pruneau, *CSO,* **GenSight Biologics, France**

16.50 **Clinical development as a foundation for commercial success in rare diseases**

Genable Technologies is a company developing gene based medicines for retinal dystrophies. How we inform and educate patients, their families, physicians and patient organisations, and how we construct & conduct our clinical studies is crucial to the ultimate success of GT038, our therapeutic candidate for retinitis pigments, a rare disease of the eye which results in progressive blindness.

Dr Jason Loveridge, *CEO*, **Genable Technologies, Ireland**

17.25 End of Day One Followed by Networking Drinks with VIC Congress Attendees

18.30 **Evening Seminar: The Clinical Success of Genetically Modified Cell Therapies**

> "Analysts forecast that sales of gene-based therapies could exceed $465 million annually by the year 2015"

Day Two: Thursday 4 December 2014

07:55 **Opening Remarks from the Chair**

Manufacturing Genetically Modified T-Cells

08:00 **Commercialisation of an autologous cell therapy product: Pitfalls and difficulties**

Traditional drugs can be made in bulk and dispersed to several hundred/thousands of individual patients. In contrast, autologous cell therapy products are derived from the patient's own cells which requires a single manufacturing process per patient. Thus, the commercialisation strategy for such products needs to consider several unique issues. This presentation will discuss issues of establishing a large market for an autologous therapy.

Dr Knut Niss, *Senior Technical Project Leader,* **Novartis Pharmaceuticals Corp., USA**

08:30 **CAR-T Discussion Panel**

- Going from academia to industry: What are the unique challenges when developing T-Cell Therapies from academic projects?
- Developing a robust, scalable process
- Problems when manufacturing autologous cell therapies – clinical and commercial supply
- Technology development and vector supply considerations

Dr Knut Niss, *Senior Technical Project Leader,* **Novartis Pharmaceuticals Corp., USA**
Ms Bernadette Keane, *Vice President, Quality,* **Bluebird bio, USA**
Dr Bruce Levine, University of Pennsylvania, USA

Vector Selection and Optimisation

09.00 **Lentiviral vectors: vector system optimisation and development towards commercial scale production**

Oxford BioMedica (OXB) has developed optimised minimal lentiviral vector systems based on the non-primate lentivirus EIAV, and HIV-1. OXB were the first to administer lentiviral vector directly to patients, utilising a platform EIAV process, in four indications. An overview of the vector platforms and scale-up approaches will be provided.

Dr James Miskin, *Head of Manufacturing Development,* **Oxford Biomedica, UK**

09.35 **Case-study: Adeno-Associated virus-based vectors in gene therapy**

For more information please visit our website: **www.informa-ls.com/genetherapy**

Dr Michael Linden, *Director, Gene Therapy Consortium,* **Kings College London, UK**

10.10 **A case-study of a novel AAV based gene therapy treatment for a rare disease.**

Dimension Therapeutics focuses on developing novel adeno-associated virus (AAV) gene therapy treatments for rare diseases. Dimension's partnerships with REGENX Biosciences and the University of Pennsylvania provides exclusive gene therapy intellectual property and access to multiple best-in-class AAV vectors based on REGENX's NAV technology. Dimension has entered a collaboration with Bayer HealthCare for the development and commercialisation of gene therapy products for hemophilia A. This talk will discuss plans to develop and commercialise Dimension's hemophilia products.

Dr Sam Wadsworth, *Chief Scientific Officer,* **Dimension Therapeutics, USA**

10.45 **Morning Break**

11.15 **Engineering a better vector for sustained gene expression**

Adeno-associated virus (AAV) vectors demonstrate extreme clinical promise, this presentation will aim to improve the understanding of how AAV viral vector serotypes selection can optimise preclinical/clinical applications and will also discuss how the application of AAV viral vectors can achieve improved tissue-specific delivery and sustained expression of the transgene whilst reducing the host immune responses and thus the need for repeated dose administration.

Dr Takis Athanasopolous, *Lecturer, Molecular Biotechnology,* **University of Wolverhampton, UK**

11.50 **Newest generation adenoviral vectors for the treatment of osteoarthritis in animals and humans**

GeneQuine Biotherapeutics develops gene therapy drugs for the treatment of osteoarthritis, which is the most prevalent joint disorder and leading cause of disability in people aged over 65 years. Using the latest generation of adenoviral vectors, GeneQuine has demonstrated sustained gene expression in joints and efficient symptomatic and disease-modifying treatment in mouse and equine models of osteoarthritis with its lead product.

Dr Kilian Guse, *CEO & Co-Founder,* **GeneQuine Biotherapeutics, Germany**

12.25 **Discussion Panel – Which vector is right for you?**

- Comprehensive overview of the risks and benefits associated with both AAV and LV vectors
- The future of vectors – will AAV or LV use increase or will we see new methods of delivery emerging?

Proposed panellists:
Dr James Miskin, *Head of Manufacturing Development,* **Oxford Biomedica, UK**
Dr Sam Wadsworth, *Chief Scientific Officer,* **Dimension Therapeutics, USA**

13.00 **Spotlight Session**

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13.30 Networking Lunch with VIC Congress Attendees

Ensuring Quality in Manufacturing

14.30 **Characterising your gene therapy product and ensuring good assay development**

The evaluation of potency plays a key role in defining the quality of gene therapy products including GM cells, and helps enable process changes. The key message of the presentation is that aggressive early investment in a solid potency evaluation strategy can greatly enhance eventual product and mitigate the risk of costly product failure in late-stage development.

Dr Christopher Bravery, *Director,* **Consulting on Advanced Biologicals Ltd, UK**

15.05 **Mitigating risk of process changes in preclinical and clinical development**

Early in gene therapy and cell therapy development, production methods and materials are more suited for research, and must be modified to enable commercial-scale GMP manufacturing. Process changes, however, risk losing the product's critical quality attributes. Comparability studies are essential to mitigate these risks, ensuring the fully developed process yields the desired product.

Dr Scott R. Burger, Advanced Cell & Gene Therapy LLC, USA

15.40 **Afternoon Break and Announcement of Poster Prize Winner**

16.15 **Scaling up manufacturing processes for gene therapy products : case study on AAV9 Vectors**

For more than a decade, gene therapy has shown promising results in patients suffering genetic disorders. To respond to the increasing demands of product quantity and quality for clinical trials with perspectives of commercialisation, major efforts must focus on process scale up and industrialisation. This presentation will describe the complexity and current state of the art of gene therapy vector manufacturing, with a case study on AAV9.

Dr Matthias Hebben, *Head of Bioprocess Development,* **Généthon, France**

16.50 **Preparing your manufacturing facility for a commercial launch**

This talk will examine the industrialisation of both lentiviral vector and cell transduction processes and will discuss the control strategies implemented throughout our supply chain, from plasmids through to the logistics of returning cells back to the subject. This talk will also explore considerations and strategies as ex-vivo, autologous therapies approach commercialisation.

Dr Mark D. Angelino, *VP Pharmaceutical Sciences,* **Bluebird Bio, USA**

17.25 **Chairperson's Closing Remarks and End of Day Two**

Pre-Conference Workshop: Tuesday 2nd December 2014

The Art of Scientific Advice for ATMPs

Registration for this workshop is at 09.30 for a 10.00 start.
The workshop will finish no later than 16.00. Workshop documents, refreshments and lunch will be provided

Workshop Leaders:

Dr Scott Burger, *Principal,*
Advanced Gene & Cell Therapy, USA

Dr Christopher Bravery, *Director,*
Consulting on Advanced biologicals, UK

Although the number of scientific guidelines are increasing, they remain necessarily general and unable to envisage every scenario, but rather attempt to convey the principles. Inevitably during the development of any product a number of issues will arise that are not foreseen within existing guidelines or which do not fit the approaches suggested. It is important to prepare carefully and to frame your questions in a way that will ensure a clear answer.

This workshop will cover the various types of FDA meeting and the various types of EMA and EU national competent authority (NCA) meetings that are open to you. This workshop will cover:

- FDA meetings from pre-pre-IND to pre-BLA
- EMA meetings from ITF to pre-MAA submission
- NCA meetings
- How to prepare briefing documentation
- How to frame questions
- Meeting etiquette

Evening Seminar: Wednesday 3rd December 2014

The Clinical Success of Genetically Modified Cell Therapies

Registration at 18.00 for an 18.15 start. The workshop will finish no later than 20.30.
Seminar documents and an evening networking dinner will be provided

Free Evening Seminar with 4-day Pass

Workshop Leader:

Dr Bruce Levine,
Barbara and Edward Netter Professor in Cancer Gene Therapy
University of Pennsylvania, USA

CAR T cells have been shown to result in significant and durable clinical responses in leukemia in patients who are relapsed or refractory to all other available treatment. This technology recently received Breakthrough Designation from the US FDA. An alliance between the University of Pennsylvania and Novartis has allowed significant expansion of the CAR T cell clinical and research programs in hematologic malignancies and other cancers.

Attend this seminar to explore:

- The clinical successes of genetically modified cell therapies.
- The unique challenges and advantages associated with this approach.
- The future of this field and it's implications for the gene therapy industry

Post-Conference Workshop: Friday 5th December 2014

Clinical Trial Development for Gene Therapy Medicinal Products

Registration at 08.30 for a 09.00 start. The workshop will finish no later than 15.00.
Workshop documents, refreshments and lunch will be provided

Workshop Leader:

Dr Alan Boyd, *CEO*
Boyds Consultants, UK

In order to get a gene based therapy approved, it's safety and efficacy must be demonstrated via appropriate clinical studies. At this workshop the whole process of clinical trial development will be presented and discussed. The emphasis for the workshop will be on how to design the right studies to support the marketing approval, defining the right objectives for the study, the selection of the endpoints and the choice of the appropriate assessments. The problems that may be encountered by poor clinical study designs will also be covered.

This workshop will cover:

- Participant selection for both common and orphan diseases
- Designing adaptive clinical designs based on limited patient populations
- Reducing timelines, white space and quickly gaining proof-of-concept data
- Establishing a risk management plan incorporating clinical monitoring and practical recommendations for long-term patient follow-up.
- Considering the impact of long-term follow-up on cost and commercialisation

Join the Conversation

Join us on LinkedIn:
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VIC CONGRESS

Sponsorship and Exhibition Opportunities

VIC Congress Vital Statistics

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160+ Companies represented

10+ Hours of networking

70+ Industry speakers

4 Conferences – 1 Location

- **Cell Therapy Manufacturing**
- **Gene Therapy** (New for 2014!)
- **Development & Manufacturing of Vaccines**
- **Veterinary Vaccines**

> "This event offered a focused and comprehensive perspective into current manufacturing practices, challenges and emerging solutions, while also providing excellent networking opportunities"
>
> **PCT Cell Therapy Services**

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- Present a service or technology on the conference programme to create market awareness of your expertise
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- Build relationships and meet new customers at the networking drinks reception
- Take full advantage of the pre-event support on offer by hosting a webinar as part of a comprehensive marketing campaign

> "The conference is a great opportunity to meet people dealing with same problems and challenges in the industry"
>
> Torlak Institute

2013 Primary Audience Analysis

C-Level & VPs 21%

Directors & Department Heads 37%

Scientists 32%

Academics 10%

Industry already in attendance

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Commercialising Gene Therapy

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STEP 1 : SELECT YOUR WORKSHOPS

- ☐ Pre-Conference – Scientific Advice for Gene Therapy Products (W)
- ☐ Evening Seminar – Genetically Modified Cell Therapies (S)
- ☐ Post-Conference – The Clinical Success of Genetically Modified Cell Therapies (Y)

STEP 2: SELECT YOUR PACKAGE

Event Selection	Book Before Friday 12th September 2014	SAVE	Book Between Friday 12th September and Friday 31st October 2014	SAVE	Book Before Friday 31st October 2014	SAVE
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☐ Conference + Evening Seminar	☐ £1998 + VAT @ 21% = £2417.58	£200	☐ £2098 + VAT @ 21% = £2538.58	£100	☐ £2198 + VAT @ 21% = £2659.58	-
☐ Conference + Pre or Post Conf Workshop	☐ £2199 + VAT @ 21% = £2660.79	£200	☐ £2299 + VAT @ 21% = £2781.79	£100	☐ £2399 + VAT @ 21% = £2902.79	-
☐ Conference + Pre or Post Conf Workshop + Evening Seminar	☐ £2598 + VAT @ 21% = £3143.58	£300	☐ £2698 + VAT @ 21% = £3264.58	£200	☐ £2798 + VAT @ 21%= £3385.58	£100
☐ FULL Pass: Conference + Pre & Post Conf Workshop + FREE Evening Seminar	☐ £2899 + VAT @ 21% = £3507.79	£700	☐ £2999 + VAT @ 21% = £3628.79	£600	☐ £3099 + VAT @ 21% =£3749.79	£500

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Cancellation date: 18th November 2014

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