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SMi Presents the 3rd Annual Conference on...

Orphan Drugs and Rare Diseases

Review Early Access Initiatives, Enhance Commercialisation Pathways and Develop Patient Engagement

Holiday Inn Regents Park Hotel, London, UK

20TH-21ST OCT 2014

CHAIRS FOR 2014:

Dominic Nutt, Director of Communications, **The Saatchi Cancer Initiative, M&C Saatchi**

Dario DiSimone, Sr. Director, Head of Rare Disease Europe, **Pfizer Inc.**

Fred Marin, CEO, **GMP Orphan SAS**

Deborah O'Neil, Chief Executive Officer, **Novabiotics Ltd**

Keynote Speaker:

- **Ian Hudson,** CEO, **MHRA**

Key Speakers Include:

- **Dr. Günter Harms,** Market Access & Public Affairs Director, **Shire**
- **Bertram Häussler,** Chairman of the Board of Management, **IGES Institut**
- **Josie Godfrey,** Associate Director, Highly Specialised Technologies, **NICE**
- **Chris Hart,** Information Practice Leader, **AstraZeneca**
- **Anthony Hall,** Co-Founder, **Findacure Foundation**

Benefits of attending:

- **Hear** important insights from **Ian Hudson**, CEO, **MHRA** on the **Early Access to Medicines Initiative** and **adaptive licensing**
- **Focus** on enhancing development pathways, with the growth of the commercial pipeline for orphan drugs and rare diseases
- **Assess tools** for consideration to gain early market access and enhance patient recruitment
- **Interactive round table discussion** led by **Dominic Nutt,** Director of Communications, The Saatchi Cancer Initiative, **M&C Saatchi** on creating a culture of innovation in the field of orphan drugs and rare diseases

PLUS THREE INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS

Wednesday 22nd October 2014, Holiday Inn Regents Park Hotel, London, UK

A: Commercial Aspects of Orphan Drugs and Rare Diseases

Workshop Leaders: **Anthony Hall,** Co-Founder, **Findacure Foundation** & **Mark Barrett,** Managing Director, **Orphan Insight Limited**
8.30am - 12.30pm

B: Assessing Regulatory Requirements for Orphan Drugs

Workshop Leader: **Camille Metais,** Associate Director, Regulatory Affairs, **Alexion Pharma International**
8.30am - 12.30pm

C: Developing Novel Biologic Therapies for Rare and Orphan Diseases

Workshop Leader: **Tim Miller,** CEO, **Abeona Therapeutics**
1.00pm - 5.30pm

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8.30 **Registration & Coffee**

9.00 **Chairs Opening Remarks**
Fred Marin, CEO, **GMP Orphan SAS**

REGULATORY INSIGHT & EARLY ACCESS INITIATIVES

OPENING ADDRESS

9.10 **Why are orphan drugs different? – Achieving sustainable access for orphan drugs in Europe**

- EU OMP regulation and importance of national rare disease plans
- Specific Market Access challenges for OMPs
- The challenge of demonstrating value for OMPS
- Shire engagement to address these challenges; Examples

Dr. Günter Harms, Market Access & Public Affairs Director, **Shire**

KEYNOTE ADDRESS

9.50 **Review: The Early Access to Medicines Scheme**

- What's to expect and what's required regarding the EAMS
- Reviewing the first update and how this can be implemented
- Assessing an early indication that a product may be a possible candidate for early access, based on the available clinical data
- EU adaptive licensing pilot and other ways regulators support innovation and success

Ian Hudson, CEO, **MHRA**

10.30 **Morning Coffee**

11.00 **Empower: What led to the Early Access to Medicines Scheme?**

- Why the process of drug regulation is broken and how it can be mended.
- The Empower campaign and the Halpin Protocol: How can we achieve earlier access to medicine for patients without encouraging snake oil salesmen?
- Welcoming the Early Access scheme while encouraging further reform

Professor Sir Peter Lachmann, Emeritus Professor of Immunology, **University of Cambridge**

SPOTLIGHT PRESENTATION

11.40 **Pricing, Policy and Reimbursement of the Health Technology Assessment**

SPOTLIGHT PRESENTATION

- Organisations assessing clinical and cost-effectiveness of new medicines
- Reviewing the budget impact, is the incremental cost affordable?
- Assessing why the acceptance rate for orphan drugs appears to be low?

Josie Godfrey, Associate Director, Highly Specialised Technologies, **NICE**

12.20 **Networking Lunch**

1.20 **Chairs Afternoon Opening Remarks**
Deborah O'Neil, Chief Executive Officer, **Novabiotics Ltd**

1.30 **Orphan Drugs in Germany**

- AMNOG and the overall regulatory and political environment
- Market and Budget Impact
- Moving forward

Bertram Häussler, Chairman of the Board of Management, **IGES Institut**

SPECIFIC DEVELOPMENT PATHWAYS OF ORPHAN INDICATIONS

2.10 **Repurposing of orphan drugs for other orphan indications**

- Important not to overlook the potential of expanding the utility of orphan treatments by repurposing for other, often very different, rare disease indications; numerous orphan drugs will have this potential
- An attractive route to new rare disease therapies that has distinct advantages over repurposing non-orphan molecules and also re-profiling orphan meds for non-orphan indications
- NovaBiotics' Lynovex is one example of a repurposed orphan-orphan therapeutic

Dr Deborah O'Neil, Chief Executive Officer, **Novabiotics Ltd**

CASE STUDY

2.50 **Aspects linked to the development of gene and cell products for rare diseases**

- An explanation of the factors linked to gene and cell therapy
- Assessing the new technologies and how we move forward in the field of rare diseases

Dr Didier Caizergues, Director, Department of International Regulatory Affairs, **Genethon**

> *"Enjoyed the two-day conference; general overview of disease space & interesting talks delivered."*
> **Associate Director, Shire, Attendee from 2013**

3.30 **Afternoon Tea**

4.00 **Early Access to Orphan Drugs – the rationale, challenges and options available**

- Why consider Early Access?
- What are the challenges for Early Access?
- Introduction to the mechanisms, regulatory environment and options for Early Access
- Insight into the potential benefits and risks of Early Access

Mark Corbett, Vice President, Clinigen Global Access Programs (GAP), **Clinigen**

4.40 **Challenges of the setup of large clinical trials for orphan drugs**

- Review of the current Clinical trial regulations worldwide
- Specific challenges for orphan drugs
- Case study/examples
- Is the new Clinical trial regulation expected to improve the current situation?

Camille Metais, Associate Director, Regulatory Affairs, **Alexion Pharma International**

5.20 **Chairs Closing Remarks and Close of Day One**

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8.30 **Registration & Coffee**

9.00 **Chairs Opening Remarks**
Dario DiSimone, Sr. Director, Head of Rare Disease Europe, **Pfizer Inc.**

MARKET ACCESS AND COMMERCIALISATION

OPENING ADDRESS

9.10 **The forecast for 2015 and where will we be ten years from now?**
- Advances in rare disease treatments, what's looking promising?
- Evaluating the benefits of partnerships and patient groups
- Assessing clinical development and future hurdles to access orphan drugs

Tim Miller, President & CEO, **Abeona Therapeutics**

9.50 **Repositioning in the orphan arena, a real life approach**
- What about the patent?
- What about the price?
- What about innovation?

Fred Marin, CEO, **GMP Orphan SAS**

10.30 **Morning Coffee**

KEYNOTE ADDRESS

11.00 **Talking Initiatives, Frameworks and Collaborations in Rare Disease Research**
- Assessing the commercial pipeline for orphan drugs and rare diseases
- Unlocking initiatives to enhance development and collaborative projects
- Reviewing the commercialisation opportunities for development

Dario DiSimone, Sr. Director, Head of Rare Disease Europe, **Pfizer Inc.**

11.40 **New and exciting collaborations in rare disease public health and research**
- European reference network in the field of metabolic diseases
- Rare disease registers successful models and lessons

Samantha Parker, VP RRD Foundation and Director of external affairs and rare disease partnerships, **Orphan Europe**

12.20 **Networking Lunch**

1.20 **Chairs Afternoon Opening Remarks**
Dominic Nutt, Director of Communications, Saatchi Cancer Initiative, **M&C Saatchi**

ROUND TABLE DISCUSSION

1.30 **Creating a Culture of Innovation in the field of Orphan Drugs and Rare Diseases**
- Introduction and Overview
- Reviewing the Medical Innovation Bill going through Parliament to allow doctors to prescribe off-label medicines to patients with no alternative, without fear of prosecution if something goes wrong
- Alleviating the legal responsibility off the Doctor's shoulders when prescribing medicines
- A quick insight into compassionate use programmes and facilitating its approval in the EU

Leader: **Dominic Nutt,** Director of Communications, Saatchi Cancer Initiative, **M&C Saatchi**

PATIENT ENGAGEMENT

2.10 **Patient Zone Case Study**
- What can patient groups achieve with the right collaboration?

PATIENT REPRESENTATION

Emily Crossley, Patient Representative, **Duchene Children's Trust**

2.50 **Clinical trials in a world with social media**
- Monitoring clinical trials and patient recruitment – the promises of social media
- Listening to patients with social media
- Overcoming the challenges of social media

Chris Hart, Information Practice Leader, **AstraZeneca**

3.30 **Afternoon Tea**

4.00 **Non-industry-led drug development for rare diseases**
- Empowering patient groups to lead the drug development process
- Academia-led drug development
- Open access drug development

Anthony Hall, Co-Founder, **Findacure Foundation**

PANEL DEBATE

4.40 **Funding Drug Development**
- Evaluating investment and innovation
- What are investors looking for?
- Forming cross-stakeholder partnerships and strategic partnerships

Leaders:
Anthony Hall, Co-Founder, **Findacure Foundation**
Chris Hart, Information Practice Leader, **AstraZeneca**
Fred Marin, CEO, **GMP Orphan SAS**
Dr. Günter Harms, Market Access & Public Affairs Director, **Shire**

5.20 **Chairs Closing Remarks and Close of Day Two**

Supported by

HALF-DAY POST-CONFERENCE WORKSHOP A

Wednesday 22nd October 2014 I 8.30am – 12.30pm I Holiday Inn Regents Park Hotel, London, UK

Commercial Aspects of Orphan Drugs and Rare Diseases

Workshop Leaders: **Anthony Hall,** Co-Founder, **Findacure Foundation** & **Mark Barrett,** Managing Director, **Orphan Insight Limited**

Overview of workshop:

Looking at the environment for commercialisation of medicines to treat rare diseases it is important to determine the key stakeholders and infrastructures within the healthcare system that will positively support successful product introduction and uptake. The plan for commercialisation will be reviewed from clinical development to market introduction, across a range of stakeholder groups.

Why you should attend:

This workshop will provide you with the opportunity to examine your own perceptions and plans for the introduction of OMPs. It will stimulate some additional thinking with the use of case studies and group discussion with the objective of providing all attendees a broad perspective of the potential challenges and routes to success to optimise market uptake post-approval.

Programme:

8.30 **Registration and Coffee**

9.10 **Assessing the potential challenges and routes to success**

9.50 **How do you optimise market uptake post-approval**

10.30 **Coffee Break**

11.00 **Case study examples**

11.40 **Discussion and Q&A**

12.30 **End of Workshop**

About the workshop hosts:

Anthony Hall, Co-Founder, **Findacure Foundation**
Dr Anthony Hall (Tony) graduated from King's College London with first class joint honours in physiology and pharmacology before going on to study medicine at the Royal Free Hospital. He joined the pharmaceutical industry in 1994 before starting his own company in 2001.

Mark Barrett, Managing Director, **Orphan Insight Limited**
In the last 15 years, Mark has been working in the field of orphan and ultra-orphan medicines in positions within pharma and biotech companies as general manager and managing director, most recently as MD of Alexion Pharma UK where Mark established the company's operations in the UK and Ireland.

About Findacure Foundation:

Findacure is a charity founded with the aim to build a movement and promote the research and development of treatments for fundamental diseases, on behalf of patients and those who care for them. Findacure aims to empower the patient sector to take control of their disease area and help patient groups meet the challenges of medical research and drug development.

About Orphan Insight Limited:

Orphan Insight Ltd utilises specialised knowledge gained by personal experience working within the orphan and ultra-orphan areas to provide expert advice to companies looking to enter the orphan medicines market or companies already operating in this market. This advice covers a broad spectrum of stakeholder mapping and disease specific investigation to develop robust plans for market introduction, including first-hand knowledge of reimbursement mechanisms and engagement activities required for successful commercialisation.

HALF-DAY POST-CONFERENCE WORKSHOP B

Wednesday 22nd October 2014 I 8.30am – 12.30pm I Holiday Inn Regents Park Hotel, London, UK

Assessing Regulatory Requirements for Orphan Drugs

Workshop Leader: **Camille Metais,** Associate Director, Regulatory Affairs, **Alexion Pharma International**

Overview of workshop:

This workshop will present an overview of the different Orphan Drug regulations worldwide. An analysis of the main differences in terms of applications and procedures will be presented. Then a hands-on session will allow the attendees to develop a strategy to prepare an orphan drug designation application for Europe. A review of the typical pitfalls and issues identified during the review will be provided.

Why you should attend:

- To understand the different ODD regulations worldwide
- To delve into the European regulations regarding the ODD application and procedure
- To simulate the preparation of an EU orphan drug designation application
- To anticipate the common issues in the preparation of the ODD application for Europe

About the workshop host:

Camille Métais is Associate Director, Regulatory Affairs in Alexion Pharmaceuticals International, Lausanne, Switzerland. Camille is responsible for the management of projects involving the design and implementation of European and global regulatory strategies for the development, registration, and maintenance of pharmaceutical and biotechnology medicinal products developed by Alexion. Her expertise is in development of regulatory strategies for drugs and biologics, especially including orphan and pediatric diseases.

Programme:

8.30 **Registration and Coffee**

9.00 **Introduction and overview from the workshop host**

9.10 **Overview of the orphan drug regulations worldwide**

9.50 **Focus on the European Orphan Drug Designation (application and procedure)**

10.30 **Coffee Break**

11.00 **Simulation exercise on how to prepare an orphan drug designation application for EMA**

11.40 **Review of the typical issues identified by COMP**

12.20 **Discussion and Q&A**

12.30 **End of Workshop**

About Alexion:

Alexion is a biopharmaceutical company focused on serving patients with severe and rare disorders through the innovation, development and commercialization of life-transforming therapeutic products. Alexion is the global leader in complement inhibition and has developed and markets Soliris® (eculizumab) as a treatment for patients with paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS), two debilitating, ultra-rare and life-threatening disorders caused by chronic uncontrolled complement activation.

HALF-DAY POST-CONFERENCE WORKSHOP C

Wednesday 22nd October 2014 I 1.00pm -5.30pm I Holiday Inn Regents Park Hotel, London, UK

Developing Novel Biologic Therapies for Rare and Orphan Diseases

Workshop Leader: **Tim Miller**, CEO, **Abeona Therapeutics**

Overview of workshop:

There are an estimated 7,000 rare diseases, but only 5% have an approved therapy or one in development. Developing biologics for orphan indications offers accelerated approval and higher probability of regulatory success. This workshop will cover the primary aspects of moving a biologic therapy for rare disease from concept to clinical trials, with a focus on gene therapy strategies and regulatory strategy.

Why you should attend:

- Better understand biologics roadmap to clinical trials for orphan drug products
- Review of important regulations and guidelines
- Identify challenges with biologics manufacturing
- Explore preclinical and clinical development options
- Evaluate how to present the Orphan Disease Business model

Who should attend? VPs, Directors, Managers working within:

- Biologics and Biotechnology
- Biotherapeutics
- Intellectual property
- Regulatory compliance
- R & D
- Manufacturing
- Preclinical/Clinical Product Development
- Marketing & Sales
- Business Development
- Regulatory affairs

Programme:

1.00 Registration and Coffee
1.30 Intro and overview
2.15 Assessing a biologic strategy for rare disease therapy
3.00 Afternoon Tea
3.30 Review of US regulatory pathway for biologics
4.15 Case study – gene therapy for rare disease
5.00 Discussion and Q&A
5.30 End of Workshop

About the workshop host:

Dr. Miller is co-founder, President & CEO of Abeona Therapeutics, a rare-disease focused company. Abeona is developing gene and stem cell based therapies for patients with rare genetic diseases, with initial therapies being developed for patients with Sanfilippo syndromes (MPS III). Dr. Miller has over 20 years of scientific research, product development, clinical operations and business development expertise, with a focus on transitioning novel biotherapeutics through pre-clinical development and into Phase 1 and 2 human clinical trials. Previously with Juventas Therapeutics, SironRX Therapeutics, and Copernicus Therapeutics, Dr. Miller has focused on gene therapy and regenerative medicine. He has raised over $7M for therapies in cystic fibrosis, cardiovascular disease, wound healing, scar prevention, and Sanfilippo syndromes to advance these therapies into clinical trials. As a serial entrepreneur, he has managed all aspects of research and development, manufacturing of biologics, and clinical program start-up from a small company perspective, with direct experience engaging Food and Drug Administration (FDA) and NIH advisory agencies on multiple Investigational New Drug (IND) submissions. During his career, he has contributed to multiple patent applications, managed intellectual property, and published research in several internationally recognized journals.

About the Abeona Therapeutics:

Abeona Therapeutics was formed in early 2013 to help focus the search for a cure for Sanfilippo Syndrome (MPS III) and provide a unifying voice between patient advocate groups, researchers, clinicians and investors. Abeona Therapeutics is the result of collaborative efforts between hospital and multiple international patient advocate groups for developing Sanfilippo therapies. The collaboration has helped focus parents and caregivers on a leading therapy with broad potential to provide long-term benefits to children with Sanfilippo Syndrome, which led to the collaboration receiving the 2013 "Champions of Hope" award for patient advocacy from Global Genes. Abeona received Orphan Drug Designation for Sanfilippo Syndrome type A and B, with clinical trials anticipated to begin in late 2014/early 2015.

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