Commercial Translation of Regenerative Medicine

Optimise cell product quality and overcome regulatory, reimbursement and funding challenges within successful clinical trials

London, UK

18th & 19th November 2010

Attending This Premier marcus evans Conference Will Enable You to:

• Evaluate regulatory body approved case studies to achieve clinical success
• Gain insight into global views on pricing and reimbursement issues
• Assess the best methods to enhance cell product quality and delivery
• Update your knowledge on recent regulatory guidelines and meet expectations
• Learn about the latest innovations in regenerative medicine
• Identify the link in translating regenerative medicine products from the lab to the clinic
• Improve your chance of gaining financial backing from investors

Hear Cutting-Edge Industry Case Studies:

• Advanced BioHealing provides insight into achieving product regulatory approval and reimbursement success
• Tigenix examines orthopaedic models used successfully in the clinic and achieving regulatory and reimbursement approval
• CytoKraft outlines the latest technology for cardiovascular repair using cell based therapies
• Avita Medical profiles advancements in autologous skin replacement therapy and its clinical uses
• Athersys reviews the use of stem cells in CNS disease such as multiple sclerosis and spinal cord injury
• Pluristem profiles how to achieve a smooth transition between phase 1 and 2 in a commercialised way

marcus evans Expert Speaker Panel:

Dr. William Haseltine
Chairman
Haseltine Global Health LLC

Geoff MacKay
President and Chief Executive Officer
Organogenesis

Dr. Gil Beyen
Chief Executive Officer
Tigenix

Yosuke Ozawa
President and CEO
Japan Tissue Engineering Co. Ltd (J-TEC)

Dr. Todd McAllister
Chief Executive Officer
CytoKraft

Dr. William Dolphin
Chief Executive Officer
Avita Medical

Dr. Mike Raxworthy
Chief Executive Officer
Neotherix

Dr. Yen Choo
Chief Executive Officer
Plasticell

Dean Tozer
Senior Vice President
Advanced BioHealing

Dr. Robert Deans
Senior Vice President, Regenerative Medicine
Athersys

Dr. Kim Warren
Head of Research and Development, Cell Therapy
Lonza

Dr. Joydeep Goswami
Vice President, Primary and Stem Cell Systems
Life Technologies

Dr. Gary du Moulin
Senior Director, Quality Compliance
Genzyme

Dr. Christian van den Bos
Executive Program Manager, LIFT
Lonza

Dr. Gregory Bonfiglio
Managing Partner
Proteus Venture Partners

Dr. Jean-Francois Deleuze
Head of Regenerative Medicine Platform
Sanofi-Aventis

Dr. Chaya Mazouz
Vice President, Clinical and Regulatory Affairs
Pluristem

Dr. Paul Kemp
Chief Scientific Officer
Intercyte

Dr. John Orsato
Associate Vice President, Strategy and Business Development, Corporate Licenses
Sanofi-Aventis

Dr. Liz Bui
Intellectual Property Counsel and Director of Corporate Development
Viacyte

Dr. Jean-Pierre Latere
Director, Business Development
Cardio3 Biosciences

Dr. Jef Pinxteren
Head of Research and Development
ReGenesys

Dr. Mikael Englund
Site Manager
Cellartis AB

Dr. Kai Pinkernell
Medical Director, Head of Clinical Development
Miltenyi Biotec GmbH

From manufacturing to the clinic: STEPPING STONES to COMMERCIAL cell based therapy SUCCESS

In the Chair:
Prof. Chris Mason
Stem Cell and Regenerative Medicine Bioprocessing Unit
Advanced Centre for Biochemical Engineering
University College London, UK

Preferred Partners:
Lonza

Documentation Sponsor:
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termis.

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Day 1
18th November 2010

08:30 Registration and Coffee

08:50 Opening Address from the Chair
Prof. Chris Mason
Stem Cell and Regenerative Medicine Bioprocessing Unit
Advanced Centre for Biochemical Engineering
University College London, UK

09:00 Keynote Presentation:
Regenerative medicine in 2010 – Advancements and lessons learnt
• Overview of market successes and downturns
• Announcements of new guidelines and feedback
• Examples of mergers and acquisitions
Dr. William Haseltine
Chairman
Haseltine Global Health LLC

09:40 Incorporating the concepts of pharmaceutical quality systems into regenerative medicine products
• Relevance of ICH Q 8,9, and 10 to RM products
• Process understanding vs. process controls
• Determining critical quality attributes and critical process parameters
• Applying risk management principles
• Process analytical technology as it relates to RM products
Dr. Gary du Moulin
Senior Director, Quality Compliance
Genzyme

10:20 Morning Coffee

10:50 Panel Opening Speech:
Dr. Kim Warren
Head of Research and Development, Cell Therapy
Lonza

11:00 Interactive Panel Discussion:
Validatory pathways to optimise cell product quality
Leading industry and regulatory body representatives discuss the current regulations and guidance available for product quality assessment
• Is there a gold standard for potency assays?
• How can you successfully remove particulates?
• How do you control the quality of ancillary products?
• What are the best methods for clean room management?
Dr. Gary du Moulin
Senior Director, Quality Compliance
Genzyme
Dr. Chaya Mazouz
Vice President, Clinical and Regulatory Affairs
Pluristem
Dr. Paul Kemp
Chief Scientific Officer
Intercytex
Dr. Christian van den Bos
Executive Program Manager, LIFT
Lonza

11:40 Challenges in translation
• The meaning of bench to bedside
• Pitfalls in translation
• Regulatory framework and innovation – Focus on autologous approaches
• Cell therapy, regulation and clinical practicability
Dr. Kai Finkenbell
Medical Director, Head of Clinical Development
Miltenyi Biotec GmbH

12:20 The role of cell therapy reagents in ensuring cell product quality
• Understanding the value of GMP reagents
• Xeno free vs. animal origin containing products
• Regulatory certification (S10K etc.)
• Removing undesired cell types
Dr. Joydeep Goswami
Vice President, Primary and Stem Cell Systems
Life Technologies

13:00 Luncheon

14:10 Improved cell product quality through optimised stem cell differentiation
• Use of HTS approaches to:
  – Obtain a more functional phenotype
  – Improve manufacturing yields
  – Reduce regulatory burden
  – Reduce manufacturing costs
Dr. Yen Choo
Chief Executive Officer
Plasticell

14:50 Mini Disease Case Studies:
A series of fast paced, 20 minute presentations focusing on different disease areas in regenerative medicine discussing the latest clinical data, business strategies and future development
Orthopaedics
• Models used successfully in the clinic
• Design of bioactive biomaterials to promote cartilage growth
• Upcoming product platforms to enhance biological repair processes
Dr. Gil Beyen
Chief Executive Officer
Tigenix
Cardiovascular
• Techniques to repair or replace damaged heart tissue
• Strategies to promote blood vessel growth
• Clinical advancements in improving contractile function
Dr. Todd McAllister
Chief Executive Officer
Cytograft

15:30 Afternoon Tea

16:00 Dermatology
• Profile of clinical data available
• Areas of potential use
• Future of manufacturing and distribution
Dr. William Dolphin
Chief Executive Officer
Avita Medical
CNS
• Preserving neuronal function following stroke and spinal cord injury
• Adherent stem cells in treatment of multiple sclerosis
• Brain immune cell cross-talk in CNS injury
Dr. Robert Deans
Senior Vice President, Regenerative Medicine
Athersys

16:40 MultiStem®: An update on research and clinical development of an adult adherent stem cell product
• MultiStem – Adherent adult stem cell platform
• Production process – Master cell bank strategy
• Mechanisms of action – Immunomodulating properties
• Status of clinical trials
• Research programs and future perspectives
Dr. Jef Pinxteren
Head of Research and Development
ReGenesys

17:20 Understanding the challenges involved for hES cell production scale-up
• Factors to consider when up-scaling production for a commercial market
• Solutions for meeting up-scale challenges
Dr. Mikael Englund
Site Manager
Cellartis

18:00 Closing Comments from the Chair

18:05 End of Day 1
Day 2
19th November 2010

8:30 Registration and Coffee

8:50 Opening Address from the Chair

Prof. Chris Mason
Stem Cell and Regenerative Medicine Bioprocessing Unit
Advanced Centre for Biochemical Engineering
University College London, UK

CELL DELIVERY AND DISTRIBUTION CHALLENGES

9:00 Large scale manufacturing and distribution – Maintaining quality and quantity
- Speed of distribution and maintaining shelf life
- Forms of product transportation available for use
- Pressures of cold chain shipping and suitable clinic facilities

Geoff MacKay
President and Chief Executive Officer
Organogenesis

9:40 Myocardial cell delivery – Finding the correct catheter
- Issues when delivering cell based therapies to the myocardium
- Catheterisation technology available
- Imaging approaches to aid delivery
- Successful examples of usage

Dr. Jean-Pierre Latere
Director, Business Development
Cardio3 Biosciences

10:20 Morning Coffee

GLOBAL STRATEGIES FOR PRICING AND REIMBURSEMENT

10:50 Case Study:
Achieving regulatory approval and reimbursement success
- How to work with regulatory bodies such as the FDA
- The journey to achieving approval from research to reimbursement
- Cell product quality assessment and overcoming challenges

Dean Tozer
Senior Vice President
Advanced BioHealing

11:30 KFS and issues in commercialising regenerative medicine in Japan
- JACE (epidermis for burn care) business model
- Conditions for JACE in approval and reimbursement
- Key factors for success and issues
- What’s coming next
- Next step: From J-TEC to G-TEC

Yosuke Ozawa
President and CEO
Japan Tissue Engineering Co. Ltd (J-TEC)

12:10 Interactive Panel Discussion:
Worldwide views on pricing and reimbursement
Key industry representatives from USA, Europe and Asia discuss and compare their countries’ regulations on reimbursement and how this can be utilised within a successful global strategy
- How do you demonstrate the pharmacoeconomic benefit?
- How do you navigate global reimbursement?
- Who are the decision makers involved in the process?
- Legislative reform and its impact on reimbursement

Geoff MacKay
President and Chief Executive Officer
Organogenesis

Yosuke Ozawa
President and CEO
Japan Tissue Engineering Co., Ltd. (J-TEC)

Dean Tozer
Senior Vice President
Advanced BioHealing

12:50 Luncheon

14:00 Case Study:
Transformation during phase 1 into phase 2 in a commercialised way
- Achieving a smooth transition between phase 1 and 2
- Minimising time waste before reaching phase 3
- Areas to improve cost effectiveness

Dr. Chaya Mazouz
Vice President, Clinical and Regulatory Affairs
Pluristem

MEETING THE FUNDING GAP FOR REGENERATIVE MEDICINE

14:40 Interactive Panel Discussion:
Expectations of big pharmaceuticals in regenerative medicine
Leading industry representatives from pharmaceutical and biotech companies discuss the interest from big pharmaceuticals in the field and analyse the potential issues involved
- Meeting the need for increased investment in the field
- Partnering ventures to improve product portfolios
- Key issues limiting pharmaceutical involvement in the field

Dr. John Orsato
Associate Vice President, Strategy and Business Development, Corporate Licenses
Sanofi-Aventis

Dr. Liz Bui
Intellectual Property Counsel and Director of Corporate Development
Viacyte

Dr. Jean-Francois Deleuze
Head of Regenerative Medicine Platform
Sanofi-Aventis

15:20 Afternoon Tea

15:50 Accessing translational funding for RegenMed product development
- Securing public sector funding from the UK Technology Strategy Board
- Opportunities to bridge the translation gap
- Outlook for 2011

Dr. Mike Raxworthy
Chief Executive Officer
Neotherix

16:30 Pitfalls of finding investment – Lessons to be learnt
- Marketing strategies to generate product interest
- Avoiding increasing research costs
- Improved pharmacoeconomic evaluation of products

Dr. Paul Kemp
Chief Scientific Officer
Intercytex

17:10 Closing Comments from the Chair

17:25 End of Conference

Media Partner:

StemCells.net

StemCells.net is the main web information portal dedicated to Stem Cell research and regenerative medicine. Updated on a daily basis, the unique mix of specialist supplier listings, events, news, scientific posters and new products makes this a one-stop-shop for essential information.

www.StemCells.net

Business Development Opportunities:

Does your company have solutions or technologies that the conference delegates would benefit from knowing? If so, you can find out more about the exhibiting, networking and branding opportunities available by contacting:

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CONFERENCE DELEGATE TERMS

Terms & Conditions: marcus evans Ltd. 1. Fees are exclusive of program materials and refreshments.
2. Payment Terms: Following completion and return of the registration form, full payment is required within 5 days from receipt of invoice. A NON-REFUNDABLE payment must be received prior to the conference date. A receipt will be issued on payment. Due to limited conference space, we advise early registration to avoid disappointment.
3. Cancellation/Substitution: Provided the cost has been paid, substitutions at no extra charge up to 14 days before the event are allowed. Substitutions between 14 days and the start of the event will be allowed subject to an administration fee of 10% of the total fee that is to be transferred. Unless all bookings carry a 50% cancellation liability immediately after a signed sales contract has been received by marcus evans. In the event of any force majeure event (including, but not limited to any government restriction) which prevents the conference from being held at the time and place advertised, or at which the conference is to be held at a time or place, or in a manner, or at a cost, or in a format, or under such conditions, or at such prices, or with such guarantees, or with any other arrangement, which is not acceptable to marcus evans or its service provider, the conference may be postponed or cancelled. In such event, the Conference and its organizers shall be entitled to retain any and all sums that have been received by them for the Conference, and whose return to the Client would not be commercially feasible.

WHO SHOULD ATTEND: CEOs, CSOs, Presidents and Directors dealing with the commercial applications of cell and tissue based products from the leading Biotechnology organisations specialising in tissue engineering and regenerative medicine as well as experts in the field from the following institutions:
- Pharmaceutical Companies
- Leading Academic Research
- Regulatory Authorities
- Device Manufacturers
- Consultants
- Contract Manufacturing
- Automation Specialists
- Cell Line Development
- Venture Capital

Regenerative medicine has become the most lucrative area of modern day medicine with an estimated global market value of $500 billion (US Department of Health). It offers companies the potential for substantial growth but to accomplish this requires major funding, research and quality control for translation to the bedside. By understanding how to overcome these challenges and achieve regulatory approval, a company can accelerate its rate of progress and attain unprecedented success.

This 8th annual marcus evans conference will provide invaluable knowledge to develop business strategies to accomodate global pricing and reimbursement challenges and attract funding. Attendees will receive key industry and regulatory insight into improving cell product quality and evaluate the best methods available for cell delivery. This in turn will identify the link to translate your product from research phase into commercial clinical use, developing funding opportunities to excel in this breakthrough market.

If you would like further information about the event or information about how to book, please contact:
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