

Examining the commercial potential of

# Stem Cell Technologies

for use in drug discovery and regenerative medicine

14<sup>th</sup> & 15<sup>th</sup> June 2001, Jarvis International Regent's Park, London

As you know, the study of regenerative medicine has taken off in recent years and now there are a great many therapeutic and drug discovery products in development that make use of stem cells and related technologies. Many of these technologies are in Phase II and III and should be of interest to pharmaceutical companies looking for the next big revolution in therapy for in-licensing. Also, as the companies developing these therapies are ripe for investment, they should be of interest to venture capitalists too. This meeting brings together ten of the leading companies in this field with a speaker panel that includes Professor Lord Robert Winston (subject to availability), Dr Evan Snyder and Crispin Kirkman of the UK BioIndustry Association. I think you will agree that there will be few business conference programmes that are as eminent and comprehensive. If you are interested in regenerative medicine then this is an event you cannot afford to miss!

## HEAR UPDATES ON THE KEY COMPANIES AND PRODUCTS IN REGENERATIVE MEDICINE!

We know that you will be interested in hearing from those companies developing stem cell products so we have put together an unrivalled programme of company profiles:

**RENEURON • DIACRIN INC • TRISTEM CORPORATION LIMITED •  
NEURONOVA AB • NEUROTECH S.A. • GERON CORPORATION • NOVO  
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## READ WHAT PAST DELEGATES HAVE SAID ABOUT IIR'S BIOTECHNOLOGY EVENTS

*'Good Opportunity to update on competitors products'*

Dr Joanna Horobin, Exec VP Commercial Development,  
ENTREMED INC

*'Good speakers, good chairman, good topics'*

Dr Marco Sardina, Medical Director, Italfarmaco SpA

*'Good presentations with case studies and plenty of time for discussion'*

Pamela Sanderson, Clinical Pharmacologist,  
AVENTIS PHARMA (HOECHST)

*'Enlightenment, networking, good material'*

Helen Hartley, Research Physician, GLAXOWELLCOME

*'Very impressive range of speakers'*

Dr Neerja Bhatnagar, Head of Automated Synthesis and New Technologies, HOECHST MARION ROUSSEL

*'Good professional contacts and exchange of experience'*

Dr Gerben Visser, Departmental Head, Medicinal Chemistry,  
SOLVAY PHARMACEUTICALS

*'Good organisation, enough time for discussion, more good than bad presentations'*

Professor Hugo Kubinyi, Head of Combinatorial Chemistry and Molecular Modelling, BASF AG

## WHO SHOULD ATTEND

This programme is intended for pharmaceutical and biotech professionals who are concerned with the research and development of stem cell products. Those who are interested in finding out more about the products currently in clinical trials are urged to attend, including **Heads of Scientific/Biological Licensing, Heads of CNS, Heads of Research, Heads of Drug Discovery/ Innovation...**

**...in addition** this programme should also appeal to the financial sector with potential delegates including **Pharmaceutical Analysts** and **Venture Capitalists** who may be interested in the opportunity to network with the key players in one of the hottest areas of biotechnology.

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# Examining the commercial potential of Stem Cell Technologies for use in drug discovery and regenerative medicine

Thursday 14th and Friday 15th June 2001, Jarvis International Regent's Park, London

CQ1791

# Evaluating strategies to move towards the manufacture of living cell biopharmaceuticals

Wednesday 13th June 2001, Jarvis International Regent's Park, London

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### Conference & Workshop

13th-15th June 2001  
Jarvis International Regent's Park  
18 Lodge Road  
London NW8 7JT  
Tel: +44 (0) 20 7722 7722 Fax: +44 (0) 20 7483 2408

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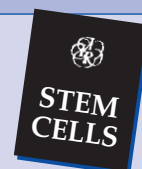
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Examining the commercial potential of

# Stem Cell Technologies

for use in drug discovery and regenerative medicine

*14<sup>th</sup> & 15<sup>th</sup> June 2001, Jarvis International Regent's Park, London*

- **Understand** the scope for the commercial exploitation of Stem cell research
- **Spotlight** on key companies working on stem cells and related technologies
- **Focus** on methods for the xenotransplantation of porcine stem cells
- **Evaluate** transformed cell lines for use in drug discovery and therapeutic applications
- **Assess** innovative techniques to produce stem cells from adult tissue through retro-differentiation

## Featuring key presentations from:

**Professor Lord Robert Winston**  
(subject to availability) *Chairman*  
**HOUSE OF LORDS SELECT  
COMMITTEE ON SCIENCE  
AND TECHNOLOGY**

**Crispin Kirkman**  
*Chief Executive*  
**BIOINDUSTRY ASSOCIATION**

**Dr Evan Snyder**  
*Assistant Professor of Neurology*  
**BOSTON CHILDREN'S HOSPITAL**

*...and essential updates on fields of  
research and the products in development  
from the following companies:*

- GENZYME CORPORATION
- RENEURON • DIACRIN INC
- TRISTEM CORPORATION LIMITED
- NEURONOVA AB • NEUROTECH S.A.
- GERON CORPORATION • NOVO  
NORDISK • MODEX THERAPEUTICS
- LAYTON BIOSCIENCES INC

**PLUS  
DON'T  
MISS**

Pre-conference Workshop

*Evaluating strategies to move towards the*  
**manufacture of living cell biopharmaceuticals**

*Wednesday 13<sup>th</sup> June 2001 at The Jarvis International Regent's Park, London*

Led by: **Professor David Onions**, *Director*, Q-ONE BIOTECH Ltd

Researched and  
Arranged by IIR Limited



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**Plus exclusive  
coverage of TEN  
key companies in  
regenerative  
medicine!!**

# Examining the commercial potential of Stem Cell Technology

14<sup>th</sup> & 15<sup>th</sup> June 2001, Jarvis In

## DAY ONE: THURSDAY 14<sup>TH</sup> JUNE 2001

09:00 Registration and Coffee

### 09:30 Opening remarks from the Chair

**Dr Peter Hóngeard Andersen**  
*Divisional Director of Biology*  
LUNDBECK A/S

### 09:40 **Heralding a revolution in the political and social climate for medical research into neural transplants, tissue repair and stem cells**

- Keeping pace with scientific developments to ensure balanced and informed appraisal of medical need, commercial considerations and ethical objections
- Reviewing recent legislative moves in the UK parliament to permit regulated embryonic stem cell research and therapeutic cloning
- Maintaining open lines of communication between government, medical research and industry so that the legislative environment can adjust to medical advances without expensive delays
- Facilitating education and appropriate informed debate of complex scientific issues to bridge the understanding gap between the biotech industry and the public

**Professor Lord Robert Winston** (*subject to availability*)  
*Chairman*

HOUSE OF LORDS SELECT COMMITTEE ON SCIENCE AND TECHNOLOGY

### 10:20 **Surveying the performance of companies developing technologies for tissue repair and regenerative medicine**

- Bridging the understanding gap to facilitate a market that is supported by public opinion
- Analysing the startups, biotechnology companies and pharmaceutical companies developing technologies and products for regenerative medicine
- Detailing licensing and partnership deals to market and distribute cell-based therapies
- Projecting timelines and predicting sales for the leading products

**Crispin Kirkman**  
*Chief Executive*

BIOINDUSTRY ASSOCIATION

11:00 Morning Coffee

### 11:30 **Examining the range of stem cell sources and their potential for commercial development**

- Comparing stem cells from a variety of sources:
  - Xenotransplants ■ Human embryo derived stem cells ■ Human adult derived stem cells ■ Genetically modified stem cells
- Evaluating these stem cells for their:
  - Comparison of technical capacities ■ Application to therapeutic uses ■ Anticipation of risk factors
- Identification of the ethical concerns of activists and the general public

**Daniel Dornbusch**

*Director, Business Development*

GENZYME CORPORATION

### 12:10 **The successful development and marketing of cell based therapies: are biologicals different?**

- Setting out the basics on how to develop and market a commercial product
- Understanding the essential similarity between most pharmaceuticals and biologicals as commercial products
- Addressing the key commercial issues while the product is in development
- Considering potential commercial partners and evaluating overtures to licensing deals to ensure win-win partnerships
- Assuring the product meets customer needs which will justify pricing and ensure commercial viability

**Dr Trevor Flanagan**

*Director*

PREMARK SERVICES

12:50 Lunch

### 14:00 **Finding novel genes and looking for gene expression using stem cells for Drug Discovery**

COMPANY PROFILE

- Generating stem cells by 'conditional immortalisation' of cell lines extracted from foetal brain tissue
- Introducing a temperature-controlled oncogene into the cell line that causes cells to proliferate in lab conditions but deactivates at body temperature to ensure there is no risk of tumour-genesis in therapeutic uses
- Discovering novel genes associated with stem cell function
- Chipping neural stem cells and setting up arrays to screen for gene expression when exposed to drug candidates in early development
- Appreciating the potential of human stem cell lines as high throughput toxicology screens reducing the requirement for animal testing

**John Sinden**

*Chief Scientific Officer*

RENEURON

### 14:40 **Diacrin's clinical development programmes in cell transplantation.**

COMPANY PROFILE

- Harvesting porcine and human cells for therapeutic uses: understanding the concepts and technologies involved
- Reviewing regulatory issues associated with cell transplantation
- Reviewing ongoing clinical trials using porcine cells for neurological disorders including Parkinson's and Huntington's disease, stroke, epilepsy, pain and spinal cord repair
- Reviewing ongoing clinical trials using human cells, including hepatic failure and cardiac disease
- Anticipating developments with stem cells in therapeutic interventions

**E. Michael Egan**

*Chief Operating Officer*

DIACRIN, INC

15:20 Afternoon Tea

### 16:00 **Producing stem cells from adult blood peripheral cells by retro-differentiation: a new clinical treatment for disorders of the haematopoietic system**

COMPANY PROFILE

- Understanding the concepts involved in 'retro-differentiation' where stem cells can be derived from adult lymphocytes
- Describing the process of how stem cells are derived in vitro from a patient's blood
- Developing haematopoietic therapies using retro-differentiated stem cells in blood disorders such as leukaemia

**Dr Ilham Abuljadayel**

*Chief Scientific Officer*

TRISTEM CORPORATION LIMITED

### 16:40 **Focussing on NeuroNova's development of adult neural stem cells for research and clinical use**

COMPANY PROFILE

- Assessing the potential for using adult stem cells for therapeutic and research purposes
- Understanding the processes for producing neural stem cells from adult sources
- Gauging whether adult stem cells will be able to compete in the market place with cells of embryonic or fetal origin
- Evaluating stimulation of neurogenesis as an alternative to direct cell transplantation

**Dr Anders Haegerstrand**

*President and C.E.O.*

NEURONOVA AB

17:20 Closing remarks from the chair and end of Day One

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# Technologies for use in drug discovery and regenerative medicine

International Regent's Park, London

## DAY TWO: FRIDAY 15<sup>TH</sup> JUNE 2001

09:00 Registration and coffee

12:50 Lunch

### 09:30 Opening remarks from the Chair

**Dr Philippe Truffinet**  
*Director, Clinical Development CNS*  
AVENTIS PHARMA, FRANCE

### 09:40 Reviewing eye and CNS applications of encapsulated and non-encapsulated immortalised lines

- Maintaining photoreceptor function with immortalised retinal cell transplants
- Developing an ophthalmic protein delivery system using encapsulated immortalised retinal cells
- Successfully preventing retinal degeneration in large animal models
- Employing immunotherapy for glioblastoma using xenogenic endothelial cells

**Dr Tom Shepherd**  
*President and Chief Executive Officer*  
NEUROTECH S.A.

### 10:20 Developing human embryonic stem cells, telomerase and nuclear transfer for regenerative medicine and drug discovery

- Discussing human embryonic stem cells (hESCs): An immortal and totipotent human tissue source
- hESCs: Exponentially scalable in serum-free and feeder-free conditions
- hESC differentiation: Treatment of neurodegenerative diseases, spinal cord injury, heart failure and chronic liver diseases
- hESC-derived cells: Drug screens, toxicity testing and disease modelling
- Telomerase: Immortalisation of somatic cells ex vivo for drug discovery, biologics production and cell therapies
- Telomerase gene therapy: Regenerative medicine in vivo

**Dr Calvin Harley**  
*Chief Scientific Officer*  
GERON CORPORATION

11:00 Morning Coffee

### 11:30 Using stem cell derived beta-cells for the treatment of diabetes

- Understanding the process by which pancreatic stem cells develop into insulin-producing beta cells and the importance this has for diabetic therapy
- Focussing on the autoimmune aspects of diabetes
- Evaluating the potential of allo versus auto transplantation for diabetes to minimise the risk of tissue rejection
- Analysing future directions in the research programme

**Dr Ole Madsen**  
*Director of Hagedorn Research Institute*  
NOVO NORDISK

### 12:10 Using cell based regenerative approaches for skin replacement and drug delivery of proteins

- Using Outer Root Sheath cells extracted from hair shafts that produce fully functional skin cells to develop cell patches for skin repair of chronic ulceration
- Immortalising human fibroblasts with hTERT (the protein component of human telomerase) to produce a protein delivery system with all the properties of a primary cell but without the risk of tumorigenesis
- Looking towards future developments in cell-based therapies for regenerative medicine at Modex

**Dr Ed Baetge**  
*Chief Scientific Officer*  
MODEX THERAPEUTICS

### 14:00 Capitalising on the fast advancing science of neural stem cells and their potential application in brain repair

- Understanding the versatility inherent in neural stem cells and their suitability for transplant technologies in the pediatric and adult brain damaged by stroke
- Extracting neural stem cells from the nervous system and growing them under laboratory conditions for reimplantation in paediatric or adult brains
- Evaluating animal models of stem cell based neural repair and preclinical trials of stem cell therapies currently under development
- Gearing up for clinical trials and estimating timelines to compelling proof of efficacy across a range of disorders

**Dr Evan Snyder**  
*Assistant Professor of Neurology*  
BOSTON CHILDREN'S HOSPITAL

### 14:40 Repairing brain damage in chronic stroke with LBS-Neurons™ - transplants of transformed immortalised human neural cell lines

- Drawing on animal models of neurodegenerative disorders and brain injury to get a handle on the potential for neural transplants to repair damaged brain tissue
- Growing progenitor cells derived from a teratocarcinoma in vitro and treating them in a patented manner so that they differentiate into immature human neuronal cells that can be cryogenically frozen and used for surgical implants
- Implanting cells in and around the area of neural damage in order to reactivate host cells and provide additional cellular architecture
- Describing results from safety and feasibility trials in chronic stroke patients showing a trend toward efficacy in restoring lost motor function
- Focussing on a recently acquired neural stem cell line which might provide a route to treat different types of diseases or disorders using two different cell types

**Gary Snable**  
*Chief Executive Officer*  
LAYTON BIOSCIENCES INC

### 15:20 PANEL DISCUSSION:

**Anticipating a future where stem cell technology and regenerative medicine is an accepted part of the treatment regimes for a number of diseases**

16:00 Closing remarks from Chair and End of Conference

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# Evaluating strategies to move towards the manufacture of living cell biopharmaceuticals

Led by: **Professor David Onions, Director, Q-ONE BIOTECH**

Wednesday 13th June 2001, Jarvis International Regent's Park, London

## ABOUT YOUR WORKSHOP

The potential of stem cell therapies for the treatment of a wide range of pathologies has created a huge amount of interest in pharmaceutical and biotechnological circles. But many people raise the concern that if these technologies are to be exploited commercially, then companies are going to have to find out ways to manufacture cell-based therapies on a large enough scale to meet demand.

This obviously presents unique problems when dealing with living cell therapies. How can you safely manufacture the volume of cells necessary for a marketed therapy? How do you go about scaling up for production? How can

you facilitate smooth technology transfer? What are the regulatory requirements for live cell production? What are the safety issues relating to viral contamination?

This workshop will address these issues giving you the tools to plan strategically for the future manufacture of your living cell therapy. The content will be appropriate for professionals in scientific, licensing, manufacturing and other senior roles in the pharma and biotech industries with an interest in exploring and strategically planning their manufacturing options.

## WORKSHOP AGENDA

09:00 Registration and coffee

09:30 **Introduction to the workshop**

09:40 **SESSION ONE: Laying down the basics for a strategic manufacturing plan for living cell therapies**

- Process development and scale-up
- Timescales for production and characterisation of cell banks
- Selection, testing and quarantine of raw materials
- Validation strategies

11:00 Morning Coffee

11:30 **SESSION TWO: Understanding the principals of Good Manufacturing Practice and clarifying the regulatory requirements**

- Overview of cGMP in relation to production of biotech products
- The importance of adequate staff training to maintain cGMP compliance
- Facility design considerations – the importance of getting it right from the start

12:50 Lunch

14:00 **SESSION THREE: Viral safety issues affecting the development of xenotransplantation**

- Discussion of the level of maintenance required for high health status donor species
- Specific concerns raised by the presence of Porcine Endogenous Retrovirus (PERV) in pig organs
- The importance of monitoring patient and donor health, including the development of methods to detect zoonoses

15:20 Afternoon Tea

15:50 **SESSION FOUR: Strategies for viral safety evaluation of cell based therapies with limited shelf life**

- Discover the unique safety problems relating to the use of stem cells.
- Requirements for the testing of reagents and starting materials
- The development of a product qualification process

17:00 Close of workshop

## ABOUT YOUR WORKSHOP LEADER

**Professor David Onions** is the cofounder and a director of *Q-One Biotech Ltd.* which was recently described by Europe's largest venture capital company 3i plc, as Scotland's most successful biotechnology start up. Initiated in 1990 it has grown from 4 persons to 170 staff involved in the safety evaluation and contract production of biotechnology products. The company is fully GLP compliant and GMP accredited for the production of recombinant products, virus vaccines and vectors.

Professor Onions is or has been a member of the advisory boards of Baxter Health Care International, Transgene, Cantab Pharmaceuticals plc, Genetic Therapy Inc and Medeva plc. He is the chairman of the safety advisory board

of the Novartis subsidiary, Imutran Ltd a leading company involved in the development of xenotransplantation. In addition Professor Onions is a consultant to the vaccine company Intervet International. He has also acted as a consultant to many leading pharmaceutical and vaccine companies on the virological safety of biotechnology products.

He is a member or, former member, of several regulatory groups including the UK Advisory Committee on Release of GMOs Into the Environment (ACRE), the FDA Xenotransplantation Advisory Committee and The World Health Organisations Expert Advisory Panel on Biological Standardisation.

## ASSISTING THE WORKSHOP LEADER

**Director of BioManufacturing: Conor O'Dea**

A graduate from University College Galway with an M.Sc. in Biotechnology. Conor has nine years experience in the development and production of clinical grade biotechnology products in the U.S.A. and Ireland. He has developed downstream purification processes, overseen biotechnology production processes and has helped in the design of multi-use and custom designed production facilities.

**Senior Manager - Virology: Daniel Galbraith**

A graduate of the University of Glasgow in Microbiology, Daniel attained a Masters in Forensic Science. After completion of his Ph.D., he gained post-doctoral research experience in a Health Service Regional Virus Laboratory. He was responsible for a team developing, sequencing and analysing PCR products as diagnostic tools for detecting a range of viruses. Current responsibilities include advising on viral safety testing strategies.

## ABOUT Q-ONE BIOTECHNOLOGY

**Q-One Biotech Ltd** provides GMP contract manufacturing, specialist safety testing and process validation services to the biopharmaceutical industry. We have extensive experience of technology transfer and scaling up for a wide range of innovative biotechnology products including viral vectors, cell therapy products, cell banks, plasmid DNA and vaccines. We also undertake validation studies for processes designed to remove/inactivate viral, DNA, mycoplasma and scrapie/BSE contaminants. Our services include GLP accredited safety testing of biopharmaceuticals, human blood products, vaccines, transgenes,

xenotransplants and gene therapy products. Q-One Biotech has devised over 500 study protocols to test cell lines, biological material and final products to fulfil the regulatory requirements of the FDA, EMEA and ICH. Q-One's purpose built facilities are located in Glasgow, Scotland, UK and Worcester, MA, USA and operate in full compliance with GMP and GLP standards. Both our facilities operate to the same high standards of service and provide consistency in terms of quality systems, study protocols and technical and regulatory support.

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