Drug Redevelopment and Product Pipeline Enhancement

Focusing on Innovative Strategies and External Partnerships to Boost Productivity and Optimise the Product Pipeline

London, UK

25th and 26th February, 2010

Maximise profits and strengthen your product pipeline by turning to proven re-tasking strategies and effective external collaborations

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Attending This Premier **marcus evans** Conference Will Enable You to:

- **Explore** novel indications for active clinical compounds
- **Optimise** product life-cycle management through risk-adverse strategies
- **Examine** the changing patent scenery in drug-development
- **Cut back** R&D timeframe associated with drug re-development
- **Assess** the latest formulation and regulatory standards on drug re-tasking
- **Expand** product portfolios by re-targeting compounds for novel indications
- **Achieve** effective product differentiation in a highly-competitive pharmaceutical market
- **Speed up** regulatory procedures and increase project approval rates
- **Network** with key industry players from pharma, biotech and drug delivery industries to capture the latest trends and key approaches

Learn from Key Practical Case Studies:

- **Merck Serono International** discuss partnership opportunities and portfolio expansion strategies
- **Transgene** bring in alternative indication routes for active clinical compounds
- **Genzyme Corporation** explore partnering models and their utility in drug development
- **GlaxoSmithKline** strengthen proof of concept while minimising R&D expenditure
- **Acino Pharma** boost profit margins through opportunistic drug development
- **Alligator Bioscience** optimise therapeutic proteins and ward off safety risks by drug redesign

In the Chair Day 1:

Dr. Manuel Heim
Head, Global Portfolio
and Innovation Management
Acino Pharma

In the Chair Day 2:

Dr. Bruce Pratt
Vice President, Science Development
Genzyme Corporation

marcus evans Expert Speaker Panel:

Jutta Reinhard – Rupp Phd.
Head of Innovation and Partnerships,
Medical Science and Innovation
Merck Serono

Dr. Bruce Pratt
Vice President, Science Development
Genzyme Corporation, US

Dr. Andrew Parsons
Vice President, CEED
Head of Preclinical Development
GlaxoSmithKline

Dr. Manuel Heim
Head, Global Portfolio and
Innovation Management
Acino Pharma

Arif Shivji
World Wide Business
Development Principal
Pfizer

Aris Persidis
Ph.D., President
Biovista, Inc.

Lucette Doessegger
Global Head, Safety Licensing and
Early Development
Roche

Sarah Carty
Director of Business Development
Elan Drug Technologies

Dr. Ronald Rooke
Director, Immunopharmacology
Transgene

Pietro Crovetto
Director, Global Business Development
Teva Pharmaceuticals

James McCormik
Associate Director, Regulatory Affairs
Pharmaceutical Product Development (PPD)

Christina Furebring
Director, Research and Development
Alligator BioScience

John Overington
Team Leader, Chemogenomics
The European Molecular Biology
Laboratory (EMBL)

Dr. Nasir Hussain
Partner
Straegy Foresight Partnership LLP

Sponsor:

Biovista
To seek - To know - To act

Day 1

25th February, 2010

08.30 Registration and Coffee

09.00 Opening Address from the Chair

Dr. Manuel Heim
Head, Global Portfolio and Innovation Management
Acino Pharma

PIONEERING STRATEGIES IN DRUG FORMULATION

09.10 Case Study

Drug Redevelopment as a Key Approach to Increase your Product Pipeline and Gain a Competitive Edge

- Exploring the commercial drive behind the repositioning
- Assessing success prospects when expanding product use to new indications
- Safeguard R&D expenditures by strengthening the proof of concept
- Building new business cases by means of repositioning existent compounds

Dr. Andrew Parsons
Vice President, CEED
Head of Preclinical Development
GlaxoSmithKline

09.55 Case Study

Exploring New Indications for Existing Compounds

- Identifying additional targets for active clinical compounds
- Pharmacokinetic frameworks in translational drug research
- Alternatives on improving the candidate selection process
- Benefiting from biomarkers: From clinical practice to drug improvement

Dr. Ronald Rooke
Director, Immunopharmacology
Transgene

10.40 Morning Coffee and Networking Break

11.00 **What Else Can My Drug Do?**

- Seeing drugs as major strategic assets, with market potential beyond the initially targeted indications
- Matching the mechanism of action (MoA) of any drug against the MoA of any of the 8,000 diseases and 12,000 adverse events known to medicine
- Case studies of accelerated and systematic indication expansion
- Highlighting key business signals that show how drug repositioning done systematically is a major emerging tool in pipeline development

Aris Persidis
Ph.D., President
Biovista, Inc

11.45 Case Study

Optimization of Therapeutic Proteins

- Creating medically & commercially viable biopharmaceuticals
- Providing second generation biologics
- Managing safety risks by drug redesign
- Case study : ADC-1004, a potent c5a receptor antagonist

Tina Furebring
Director, Research & Development
Alligator Bioscience

12.30 Lunchon

BOOSTING PROFITS THROUGH ALTERNATIVE COMMERCIALISATION

13.30 Case Study

Increasing Product Pipeline through Reformulation Strategies

- Opportunistic drug development :Expanding profit margins through minimal re-investments
- Going the extra mile: Uncovering the profit potential for in-store compounds
- Innovative mechanisms of re-tergeting compounds for new indications

Dr. Manuel Heim
Head, Global Portfolio and Innovation Management
Acino Pharma

BUILDING A STRONG PRODUCT PIPELINE WITH EXTERNAL PARTNERSHIPS AND COLLABORATIONS

14.15 Case Study

Partnering Your Way to Success – Attracting External Resources and Collaborations to Enhance Your Product Pipeline

- Key drivers to consider for a successful repositioning with an external partner
- Matching technology quests of drug developers with targeted solutions from service providers
- Expanding product portfolios through external collaboration
- Insights in the latest strategies for reaching new markets

Jutta Reinhard–Rupp
Head of Strategy and Organization
Molecular Medicine and Imaging
Merck Serono International

15.00 Afternoon Tea and Networking Break

15.20 Case Study

Creating Opportunities for Pipeline Extension Through Collaborations

- The current imperatives for collaborations and partnering
- A review of partnering models and their utility in drug development and repurposing
- How to find the right partner for drug repurposing – a view from both sides of the table
- How to find the right partner for drug repurposing – a view from both sides of the table

Dr. Bruce Pratt
Vice President, Science Development
Genzyme Corporation

REGULATORY CHALLENGES: THE ROCKY ROAD TO MARKET APPROVAL

16.05 Interactive Panel Discussion

Overcoming Regulatory Setbacks On the Way to Market Approval

- Insights into increasing market approval success rate
- Untangling the regulatory maize maze: Useful shortcuts for project submissions
- Simplifying the market approval process: How can regulators help?
- Aiming for consensus among drug developers and regulators : Balancing cross-interest
- Accessing the data package :challenges entailed by submitting a drug for market authorizsation

Panelists include:

Dr. Manuel Heim
Head, Global Portfolio and Innovation Management
Acino Pharma

James McCormick
Associate Director, Regulatory Affairs
Pharmaceutical Product Development (PPD)

16.50 Closing Comments from the Chair

17.00 End of Day One

Day 2

26th February, 2010

08.30 Registration and Coffee

09.00 Opening Address from the Chair

Dr. Bruce Pratt
Vice President, Science Development
Genzyme Corporation, US

BALANCING THE BENEFITS AND RISKS IN DRUG REDEVELOPMENT

09.10 Case Study

Optimising Life-Cycle Management in Drug Research
- Maximise market value for re-targeted compounds
- Innovative technology platforms for re-purposing old molecules towards novel indications
- Directing drug re-development towards new markets

Sarah Carty
Director of Business Development
Elan Drug Technologies

09.55 Case Study

Adopting Low-Risk Strategies in Drug Redevelopment
- Reducing timeframes in drug re-development: Inside views from specialised service providers
- Effective approaches for minimising R&D expenditures
- Accurate risk evaluation in drug development
- Risks involved in finding the optimum ROI generating approach

Arif Shivji
World Wide Business Development Principal
Pfizer

10.40 Morning Coffee and Networking Break

11.00 Case Study

Addressing Regulatory Challenges Entailed by Compound Repurposing
- Regional Regulatory differences and Complications
- Regional Dossier requirements
- Advertising and labeling regulations
- Solutions to rapid expansion of global market

James McCormick
Associate Director, Regulatory Affairs
Pharmaceutical Product Development (PPD)

KEEPING THE EYE ON THE SAFETY FACTOR

11.45 Case Study

Optimising Risk Assessments in Drug Re-Tasking
- Assessing health and safety measurements
- Novel trends in health and safety risk management protocol
- Drug safety from a pharmacovigilance perspective: Exploring the prevalent challenges
- Tackling the looming threat of counterfeit drugs
- Stumbling on opportunities: How safety assessments may lead to new indication discoveries

Lucette Doessegger
Global Head, Safety Licensing and Early Development
Roche

12.30 Luncheon

13.30 Case Study

Reshaping the Market Landscape of Respiratory Products
- Exploring the market impact of novel delivery devices
- Addressing CFC transition challenges
- How to add value to a franchise opportunity ?
- Tackling re-pricing within the market for respiratory products
- Harmonising regulations with ecological imperatives

Pietro Crovetto
Director, Global Business Development
Teva Pharmaceuticals

ETHICAL CHALLENGES ASSOCIATED WITH REPOSITIONING

14.15 Case Study

Balancing Profits &Principles
- Do ethic principles still count in profit-driven endeavors?
- Assessing the necessity of bio-ethical trainings
- Aiming for ethical consensus among drug developers: Utopia or attainable goal?
- Public availability of data package: Where does lawful access to public data end and where does intellectual trespassing begin?
- Prospecting the need for firmer ethical regulations

Dr. Nasir Hussain
Partner
Strategy Foresight Partnership LLP

15.00 Afternoon Tea and Networking Break

15.20 **The Role of Chemogenomics in Drug Discovery**
- From target identification to drug validation roadmaps for drug re-development
- Bioinformatic insights : mMapping ad and aAnalyzing DNA and protein sequences
- Applications of experimental analysis : A recount on successful cases

John Overington
Team Leader, Chemogenomics
The European Molecular Biology Laboratory

16.05 Closing Comments from the Chair

16.15 End of Conference

Speakers' Profiles

Dr. Bruce Pratt
Vice President, Science Development
Genzyme Corporation ,US

Dr. Bruce M. Pratt is Vice President, Science Development, for Genzyme Corporation, with responsibilities in the identification and evaluation of early stage opportunities (primarily therapeutic products) and proactive, selective outreach activities to the academic, biotechnology and life science sectors. He has worked for Genzyme for 21 years, initially in positions of increasing responsibility in Cell and Protein Therapeutics Research and Development, culminating as Sr. Director of Cell Biology. From 2002 through 2004, he was based in one of Genzyme's European offices, identifying early stage European research and product opportunities as well as developing relationships with biotechnology companies and academic centers of excellence. Following his return to the United States in July 2004, he has continued his role in early stage opportunity identification and outreach to the biotechnology sector. Prior to his work at Genzyme, Dr. Pratt worked at Collagen Corporation and Celtrix Pharmaceuticals in Palo Alto California. He earned his Ph.D. from Michigan State University and was a post-doctoral fellow at Yale University School of Medicine, Department of Pathology.

Dr.Ronald Rooke
Director, Immunopharmacology Department
Transgene

Starting with 2005, Mr. Rooke has been Head of the Immunopharmacology Department. (Transgene, Illkirch, France) Cancer Immunotherapy. Preclinical models, Bio-informatics, bio-analysis and immunomonitoring. Prior to this function, he has been heading the Preclinical Immunology Laboratory (Transgene, Strasbourg, France) being in charge of the preclinical model for cancer immunotherapy. Mr. Rooke's activity at Transgene began in 1997 as Senior Scientist for the immune response to gene therapy vectors. Ronald has finished his PhD in Microbiology and Immunology(AZT-resistance of HIV-1) at McGill University Montreal Canada, adding also a diploma of Post-doctoral Fellow within IGBMC, Strasbourg, France for the paper on "TCR-MHC interaction and lymphocyte survival – Positive selection model".

John Overington
Team Leader, Chemogenomics
The European Molecular Biology Laboratory (EMBL)

John initially studied chemistry at the University of Bath. This introduced him to the application of computers to address chemical problems, this then led to an interest in modelling biological systems. John then studied for a PhD at Birkbeck College, University of London, with Tom Blundell, working on developing software for automated protein modelling, and subsequently sequence-structure comparison methods. John then moved to the laboratories of Pfizer at Sandwich in the United Kingdom, where his interests and responsibilities grew to cover structural biology, molecular modelling and cheminformatics. As the next stage in his career, John took a position at Inpharmatica, a leading London-based informatics company, where he led the chemogenomics technology group. John has led the development of many novel databases and algorithms applied to human health research. Most recently John has moved to the EMBL-EBI to place these databases in the public domain on an open access basis, and to develop data-mining approaches to aid in the target and lead discovery, and lead optimisation processes.

Jutta Reinhard-Rupp, Ph.D.
Head of Innovation & Partnerships
Medical Science and Innovation, Merck Serono

In her current position, Mrs. Rainhard-Rupp is responsible for the implementation of key strategic initiatives at Merck Serono, which are related to their department (MSI), encompassing stratified medicine, innovative therapeutic approaches and public-private partnerships. Jutta studied Biology in Mainz and Tübingen and received her PhD at the Max-Planck Institute Tübingen on „Unconventional myosins in vertebrates".
After postdoctoral training in bone metabolism („Estrogen receptor regulated genes in osteoblasts") at Ciba-Geigy/Novartis, Mrs. Reinhard-Rupp continued as a lab leader at Evotec Biosystems in Hamburg in the assay development group, establishing new cell-based approaches for high-throughput screening. Subseqently, she then joined Aventis (former HoechstMarionRoussel) in 1997 as a project leader and deputy of the Martinsried Genomics Center and in 2000 became Head of Functional Genomics in Frankfurt.
With a group of 35 co-workers, Mrs. Reinhard-Rupp established cutting-edge technologies in the area of gene expression profiling, proteomics and in-vitro validation tools (antisense, RNAi) in order to support target identification and validation in the R&D process. In January 2002,she became Head of Scientific Affairs, with responsibility for external networks and strategic planning. Together with a cross-functional team, Mrs. Reinhard-Rupp developed an integrated disease area strategy for Oncology, which was approved by the Aventis Board in June 2003. This strategy laid the foundation for the initiation of a Pharmacogenomics/-genetics platform in August 2003, where she took the eadership of the science and technology part. In 2005, she moved to the Sanofi-Aventis development department and became project director in the therapeutic indication of Cardiovascular Diseases. Among the three projects that Mrs. Reinhard-Rupp was leading, one was a gene therapy project (NV1FGF in critical limb ischemia), which moved forward into clinical phase III (2007). Since January 2008, Mrs. Jutta Reinhard-Rupp is with Merck Serono in Switzerland (Geneva) in the department of Medical Science and Innovation. Her responsibilities encompass the implementation of key strategic initiatives and the lead of the internal IMI office (European project collaborations.

Aris Persidis Ph.D.
President
Biovista, Inc.

Aris Persidis is President and co-founder of Biovista. He has also served as Senior Vice President at Upstate/Serologicals, Managing Director and President of RHeoGene, and Assistant Director-Medical School Technology Transfer Program – and Assistant Professor (Adjunct) at the Wharton School of Business. Aris Iso was part of the co-founding of Cellzome, in Heidelberg, Germany, and Anadys, in San Diego, CA. Aris is a recipient of the Honeywell European Futurist Award (1986) and has published extensively on bio-business subjects. In 1997-2000 he authored the monthly "Industry Trends" column for the journal Nature Biotechnology. He has published more than 80 papers and book chapters, has lectured at Wharton, the Columbia Business School, George Washington University and the University of Auckland Business School, and is a frequent speaker at major international meetings. Aris holds a First Class B.Sc. Degree in biological chemistry from Essex University, U.K. (1983-1986), and a Ph.D. in biochemistry from the University of Cambridge, U.K. (1986-1989), where he was varsity ballroom dancing champion.

Nasir Hussain, MBA, Phd.
Ex-Head of Formulation
Glide Pharma Ltd

With almost 20 years of working in the pharmaceutical sector, Nasir was most recently the Head of Pharmaceutics at Glide Pharma, responsible for the product development of Glide's needle-free drug delivery system. In between a stint as an academic (Pharmaceutical Technology), he spent several years in the US developing and in-licensing gene therapy technologies.
Nasir is a board-registered pharmacist completing his undergraduate and postgraduate degrees (Doctorate in Nanotechnology) at The University of London.
More recently, Nasir developed at Cass Business School operational frameworks for mitigating risks in drug licensing deals. For this, he was awarded the 2008 Finance Prize by The London Guild of International Bankers for his application of Financial Portfolio Theory in the construction of optimal in-licensed drug portfolios. His principal interests reside in the application of non-quantitative modeling techniques, principally Morphological analysis and Analytic Hierarchy Planning in the Pharma sector. In early 2009, he co-founded the Strategy Foresight Partnership LLP.