Cancer Drug Development: New Directions and Challenges


Gain an insight from leaders in the field:

- Prof Karol Sikora, Global Clinical Expert – Cancer, AstraZeneca
- Dr Pearl Huang, Director, Oncology, GlaxoSmithKline
- Dr George Blackledge, Vice President, Medical Director, Oncology, AstraZeneca
- Dr Giorgio Massimini, Director, Clinical Oncology, Pharmacia
- Dr Paolo Paololetti, Vice President, Medical – Oncology, ALIMTA Product Team Leader, Lilly
- Dr Paul Quarta, Medical Director, Schering-Plough
- Dr Juergen Hammer, Head, Bioinformatics, Genetics & Genomics, Roche
- Dr Peter Traxler, Senior Scientist, Research Manager, Novartis
- Dr Jonathan Allis, Vice President, Imaging Technology Group, Amersham Health
- Dr Jeffrey Ulmer, Senior Director, Chiron
- Dr Leonard Post, Senior Vice President, Research & Development, Onyx Pharmaceuticals
- Prof Stephen Jackson, Deputy Director, Wellcome Trust / Cancer Research UK Institute
- Prof Ian Judson, Professor, Cancer Pharmacology, Honourary Consultant Medical Oncologist, Institute of Cancer Research / Royal Marsden NHS Trust

Programme Highlights

- TRANSLATIONAL MEDICINE: keep up to date with the latest technology
- REGULATIONS: assess new ways of satisfying requirements
- IMMUNE RESPONSE EXPLOITATION: review the current approaches
- TARGETED DRUGS: focus on the new directions
- NETWORKING: exchange ideas with leaders in the field

PLUS A HALF DAY EXECUTIVE BRIEFING

Novel Immunotherapeutic Vaccine Platform


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8.30 Registration & Coffee

9.00 Chairman’s Opening Remarks
Prof Karol Sikora, Global Clinical Expert – Cancer, AstraZeneca

OPENING ADDRESS

TRANSLATIONAL CANCER RESEARCH

9.10 The key to the future
- The paradigm shift in cancer drug development
- The new order of corporate research organisation
- Bridging the academic – industrial divide
- Harnessing innovation in biomarkers, surrogates and imaging
- Creating diagnostic capability to package with new therapeutics
- Creating centres of excellence in translational research
Prof Karol Sikora, Global Clinical Expert – Cancer, AstraZeneca

REGULATORY MATTERS, CLINICAL TRIALS AND PUBLIC POLICY

WHAT ARE THE CRITERIA?

9.40 Iressa – the first of a new type of cancer medicine
- Clinical benefits
- Results of clinical trials
- Tumour response rates required for regulatory approval
- Convincing controls
- Compassionate use programmes
Dr George Blackledge, Vice President, Medical Director, Oncology, AstraZeneca

MEETING THE CHALLENGE OF PUBLIC POLICY

10.20 Getting it right with NICE
- Mode of action of Caelyx® in fighting cancer
- Patient selection for treatment
- Importance of cost issues
- Benefits of cost issues regarding numbers of patients eligible for treatment
- Efficacy and tolerability factors
- Ease of administration
Dr Paul Quartey, Medical Director, Schering-Plough

11.00 Morning Coffee

NEW APPROACHES TO CLINICAL DEVELOPMENT

11.20 New drugs, new criteria
- Maximum tolerated dose
- Biological effective dose
- Accurate dos:response information
- How significant is shrinkage / no shrinkage?
- Reliability of tumour markers
- Assessment of combination therapy of new drugs with traditional ones
Dr Giorgio Massimini, Director, Clinical Oncology, Pharmacia

NEW ANTICANCER DRUGS

12.00 Impact of changing targets on trial design
- Preclinical aspects of new drug development – developing pharmacodynamic assays as an integral part of the preclinical package
- Recently identified new targets
- Development of mechanism-based clinical trials
- Defining the Optimum Biological Dose – is this a realistic goal?
- Impact of new targets on conventional concepts of Phase I / II trials
- Imatinib in gastrointestinal stromal tumour – lessons for future molecular targeted therapies
- Satisfying the regulatory authorities – are phase II trials ever enough?
Prof Ian Judson, Professor, Cancer Pharmacology, Honorary Consultant Medical Oncologist, Institute of Cancer Research / Royal Marsden NHS Trust

TRANSLATIONAL MEDICINE

HIGH-THROUGHPUT TARGET IDENTIFICATION AND ASSESSMENT

2.00 Benefits of “Process Biology”, a modular target assessment approach
- Need for operational improvements of the target assessment process
- Expression analysis technologies for drug discovery
- Prioritising most likely drug candidates
- Knowledge discovery in an integrated environment
- Integrating traditional and in silico approaches
Dr Juergen Hammer, Head, Bioinformatics, Genetics & Genomics, Roche

IMAGING RESEARCH PROGRAMMES

2.40 Bringing diagnosis and therapy together
- Identifying new molecular diagnostic products
- Acceleration of research decisions
- Imaging technology
- Facilitating early approval of new therapeutics
- Application to treatment of cancer
- Future potential for finding new and powerful diagnostic and therapeutic products
Dr Jonathan Allis, Vice President, Imaging Technology Group, Amersham Health

3.20 Afternoon Tea

ANGIOGENESIS

MULTIPLE MYELOMA AND MYELOPROLIFERATIVE DISORDERS

3.40 The ImiDs
- Thalidomide
- Celgene’s STEPS programme
- Multiple myeloma and myeloproliferative disorders
- Myelofibrosis with myeloid metaplasia
- REVIMID
- ACTIMID
- Future directions
Dr Jerome Zeldis, Chief Medical Officer, Vice President, Medical Affairs, Celgene

INNOVATIVE CANCER THERAPY

4.20 ONCOLYTIC VIRUSES
- Advantages of adenovirus as platform
- Exploiting the abnormal p53 and RB pathways in malignant cells
- Specificities of adenoviruses ONYX-015 and ONYX-411
- Clinical experience : safety and efficacy
- Armed therapeutic viruses : oncolytic adenoviruses as vectors for transgene delivery
Dr Leonard Post, Senior Vice President, Research & Development, Onyx Pharmaceuticals

5.00 Chairman’s Closing Remarks and Close of Day One
8.30 Re-registration & Coffee

9.00 Chairman’s Opening Remarks
Prof Jim Cassidy, Professor, Oncology, Cancer Research UK, Medical Oncology

FUNCTIONAL GENOMIC APPROACH

9.10 Exploiting the commercial potential of the 2001 Nobel Prize in Medicine
Dr Peter Traxler, Product Team Leader, SIGNAL TRANSDUCTION INHIBITION

9.20 Protein kinase inhibitors with broad therapeutic potential
• Mechanism of action at the molecular level
• Rational design – a challenge for a medicinal chemist
• Preclinical profile at the enzymatic, cellular and in vivo level
• Clinical data
• Successes and failures
• Future challenges
Dr Peter Traxler, Senior Scientist, Research Manager, Novartis

9.40 Is the era of cytotoxics over?
• Targeting treatment with cytotoxics
• Have targeted treatments lived up to their expectations?
• Development of new cytostatic targeted treatments
Dr Paolo Paolletti, Vice President, Medical – Oncology, ALIMTA Product Team Leader, Lilly

TARGETED MOLECULAR THERAPY

10.20 DNA REPAIR: NEW TARGETS FOR CANCER THERAPY
Dr Paolo Paolletti, Vice President, Medical – Oncology, ALIMTA

10.40 Radiation sensitivity
• Localisation, repair and targeting of DNA damage
• Biochemical and genetic methods for validating drug targets
• Preclinical and clinical data
• Mechanism of action
• Future challenges
Dr Paolo Paolletti, Vice President, Medical – Oncology, ALIMTA

11.00 Morning Coffee

11.20 Drugs as inhibitors of DNA repair
• Biochemical and genetic methods for validating drug targets
• Detection, signalling and repair of DNA double strand breaks (DSB)
• Targeting the homologous recombination system and the non-homologous end joining (NHEJ) systems
• Inhibiting key enzymes in DNA DSB repair pathways
• Enhancing the efficacy of chemotherapeutic agents and of ionising radiation therapy
• Potential anti-cancer activity of DNA repair inhibitors
Prof Stephen Jackson, Deputy Director, Wellcome Trust / Cancer Research UK Institute

POLYKETIDE DRUG CANDIDATES

11.40 Epothilone D and Geldanamycin as anti-cancer agents
• I. Manipulating the genetic instructions for making polyketides
• II. Production and properties of Epothilone D
• Clinical trials of epothilones
• III. Hsp90 as a drug target
• Geldanamycin analogs as chemo-sensitizers
Prof Dan Santi, Chairman, Chief Executive Officer, Kosan Biosciences

12.00 Epothilone D and Geldanamycin as anti-cancer agents
• Mechanism of action
• Clinical and preclinical data
• Safety and toxicity
• Mechanism of action
• Future challenges
Prof Dan Santi, Chairman, Chief Executive Officer, Kosan Biosciences

12.40 Lunch

MULTIPLE ANTI-CANCER DRUGS WITH NOVEL MECHANISMS OF ACTION
2.00 A clinically validated target, the mitotic spindle
• Role of mitotic kinesins in cell division
• Transcriptional profiling demonstrating the over expression of kinesin spindle proteins (KSP) in cancer
• Biochemical studies of KSP enzymatic inhibition
• Breadth of anti-tumour activity
• Absence of treatment-associated neuropathy
• Preclinical data
Dr Pearl Huang, Director, Oncology, GlaxoSmithKline

EXPLOITING THE IMMUNE RESPONSE

CANCER CELL–SPECIFIC MONOCLONALS WITH TOXIC PAYLOADS
2.40 Toxic drugs
• Mechanism of action
• Traditional use of monoclonal antibodies in cancer treatment
• Technology overview
• Unexpected discovery of therapeutic potential for low dose monoclonal antibodies
• Mechanisms of immune activation by monoclonal antibodies via immune complex formation
• Documented preclinical and clinical proof of principle
• Broad therapeutic potential
Dr Birgit Schultes, Executive Director, Research, AltaRex

3.20 Afternoon Tea

CANCER VACCINE STRATEGIES
3.40 An overview
• Review of vector platforms for therapeutic vaccines
• Autologous vaccines
• Recombinant vaccines
• Natural killer cells
• Radioactive conjugates
• Combination treatments
• Encouraging results in early phase cancer vaccine clinical trials
Dr Jeffrey Ulmer, Senior Director, Chiron

ANTIBODIES TO MODULATE TUMOUR IMMUNITY
4.20 Using tumour antibodies as vaccines
• Technology overview
• Traditional use of monoclonal antibodies in cancer treatment
• Unexpected discovery of therapeutic potential for low dose monoclonal antibodies
• Mechanisms of immune activation by monoclonal antibodies via immune complex formation
• Documented preclinical and clinical proof of principle
• Broad therapeutic potential
Dr Birgit Schultes, Executive Director, Research, AltaRex

5.00 Chairman’s Closing Remarks and Close of Conference

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• 06/07 Vaccines
• 18/19 Wholesale Distribution in the Pharmaceutical Industry
• 19/19 Tissue Engineering

DECEMBER 2002
• 02/03 Clinical Trials in CNS
• 04/06 Dermatological Disorders

JANUARY 2003
• 13/14 Portfolio Management in Pharmaceutical R&D
• 15/16 Nutraceuticals, Functional Foods & Probiotics
• 20/21 Reducing the Attrition Rate in Drug Discovery
• 27/28 Beyond the Genome
• 27/28 Computer Systems Validation in the Pharmaceutical Industry

FEBRUARY 2003
• 10/11 Microarray Technology: Commercial and Technical Issues
• 12/13 Antisense Technologies
• 17/18 Angiogenesis
• 17/18 Obesity and Related Disorders
• 24/25 Drug Design

MARCH 2003
• 05/06 Superbugs & Superdrugs
• 10/11 Cancer Drug Development: New Directions and Challenges
• 17/18 Cosmetics and Healthcare
• 19/20 Asthma Therapeutics

• 26/27 Predictive In Silico Models in Drug Discovery and Development
• 31/3-1/4 Biologics

APRIL 2003
• 7/8 Target Validation
• 9/10 Kinases
• 28/29 Anti-arbitrage Agents
• 30/4-1/5 Supergenerics and Patent Busting

MAY 2003
• 12/13 Drug Discovery
• 19/20 Gynaecological Medicine
• 21/22 Paediatric Medicine

JUNE 2003
• 11/12 Pain Therapeutics
• 23/24 Depression and Anxiety
• 23/24 Outsourcing in the Pharmaceutical Industry
• 25/26 Neurodegenerative Disorders
• 30/6-17 Clinical Trials in Cancer
• 30/6-17 Therapeutic Antibodies

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HALF DAY EXECUTIVE BRIEFING

Novel Immunotherapeutic Vaccine Platform


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About the Briefing

The Briefing will describe two approaches to cancer therapy under development at Biovex. In the first Biovex is developing dendritic cell-mediated anti-cancer vaccines using modified herpes simplex virus (HSV) for antigen delivery. In the second Biovex has developed an enhanced potency “oncolytic” version of HSV (ie it replicates selectively to kill tumour cells) combined with expression of GM-CSF. The background and rationale for each will be discussed, together with results so far.

Briefing Timetable

9.00 Registration & Coffee

9.30 GENERAL INTRODUCTION TO IMMUNOTHERAPY
• Review of approaches to immunotherapy
• Rational behind the use of immunotherapeutic vectors
• Dendritic cell approach
Dr Philip Reay

10.00 CONSTRUCTING A NOVEL IMMUNOTHERAPEUTIC VECTOR PLATFORM
• Challenges of loading dendritic cells with therapeutic antigens
• Optimisation of HSV as a vector
• High efficiency dendritic cell transduction
• Multiple antigen delivery
• Dendritic cell activation
Dr Robert Coffin

10.30 PROGRESS TO DATE
• Choosing therapeutic antigen genes
• The melanoma vaccine construct
• Planned proof-of-principle Phase I/II trials
• Further products for tumour antigen-encoding genes
• Potential additional targets in cancer and infectious disease
Dr Philip Reay

11.00 Morning Coffee

11.20 ONCOLYTIC CANCER THERAPY
• Background and rationale
• The in situ tumour vaccine concept
• OncoVEX GM-CSF: pre-clinical and clinical studies
Dr Robert Coffin

12.00 GENERAL DISCUSSION

Close of Executive Briefing

Pre-registered delegates will be sent materials of interest prior to the Briefing. For this reason delegates are encouraged to register early.

About your Briefing Leaders

Dr Philip Reay joined Biovex in August 2001 as Group Leader, Immunology. Prior to this Dr Reay was a Wellcome Senior Research Fellow in the Nuffield Department of Clinical Medicine and the Molecular Immunology Group at the University of Oxford.

Dr Robert Coffin, Chief Scientific Officer, is a founding scientist and Lecturer in Virology at University College London, and Honorary Senior Lecturer at The Institute of Child Health. Dr Coffin has authored some 40 scientific papers and is an inventor on 13 filed patent applications.

About Biovex

Biovex is a three year old private biotech company that is developing a new class of potent vaccines principally to treat and prevent cancer. The Company is headquartered in Oxford, UK.

The Company has three technology platforms based on the manipulation of the herpes simplex type one virus. The Company has two vaccine platforms: OncoVEX and ImmunoVEX and a functional genomics platform for gene determination in the nervous system (NeurOvEX).

The Company’s lead product OncoVEX GM-CSF is currently undergoing a Phase I/II study in breast cancer, head and neck cancer, gastrointestinal cancer and malignant melanoma.

The Company’s ImmunoVEX vaccine platform stimulates a key class of immune policing (dendritic) cells. The Company’s lead product to treat malignant melanoma is expected to enter the clinic in the third quarter of 2003.
Please register the following delegates for (photocopy for multiple registrations)

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