

Translational Medicine 2006

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FEATURING CASE STUDY-BASED PRESENTATIONS ON KEY ISSUES IN TRANSLATIONAL MEDICINE, INCLUDING:

- Translational medicine - are we making any decisions on it?
- Translational cancer research at the EORTC: new directives
- Translational medicine: a regulator's view
- Using cognitive function assessment to facilitate translational development from volunteers to patients
- Biomarker assay validation

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POST-CONFERENCE WORKSHOP

Old and novel tumour biomarkers

THURSDAY 16TH FEBRUARY 2006

LED BY PROF. DR. MANFRED SCHMITT,
TECHNICAL UNIVERSITY OF MUNICH

LEADING CLINICAL SPEAKERS FROM THE PHARMACEUTICAL INDUSTRY INCLUDE:

- Dr. Thomas Senderovitz, M.D., Vice President, Experimental Medicine, Global Clinical R&D, **FERRING PHARMACEUTICALS**
- Dr Donna Johnstone, Cancer & Infection Discovery Medicine Director, **ASTRAZENECA**
- Dr. Torsten Reum, MD, Dept. of Scientific Service/ Clinical Trials, **BfArM**
- David Muirhead, Clinical Assay Group, **PFIZER**
- Malcolm Mitchell, Senior Clinical Research Physician, **ELI LILLY**
- Christopher Kirkpatrick, Head of Clinical Pharmacology Unit, **ROCHE PRODUCTS LIMITED**
- Johan Luthmann, Head of Neuroscience, **SERONO**
- Jasper Dingemans, PhD, Vice-President and Head of Clinical Pharmacology, **ACTELION PHARMACEUTICALS**

Translational Medicine 2006

DAY ONE - TUESDAY 14TH FEBRUARY 2006

08:30 *Registration and coffee*

09:00 **Opening remarks from the Chair:**

Christopher Kirkpatrick, Head of Clinical Pharmacology Unit, **ROCHE PRODUCTS LIMITED**

STRATEGIC ISSUES – TRANSLATIONAL MEDICINE AS A CONCEPT

09:10 **Keynote Presentation: managing the discovery-development transition**

- Importance of the FDA's Critical Path Initiative
- Experience with early interactions with the FDA: the End-of-Phase 2A Meeting
- Why is it important to focus of an organisational culture to support filling up the early R&D pipeline?
- How to ensure implementation of critical path research initiatives

Dr. Thomas Senderovitz, M.D., Vice President, Experimental Medicine, Global Clinical R&D, FERRING PHARMACEUTICALS

09:55 **Translational medicine - are we making any decisions on it?**

- Translational medicine, translational sciences and discovery medicine – defined
- This work is seen as having great promise within pharmaceutical development in being able to 'identify the winners early'
- But how many of us are truly making decisions using the data generated from these studies?

Dr Donna Johnstone, Cancer & Infection Discovery Medicine Director, ASTRAZENECA

10:40 *Morning refreshments*

11:00 **Translational medicine in the early risk/benefit assessment of drugs: a regulator's view**

- The role of pre-clinical data in early drug development
- From biomarkers to animal models: do we get an applicable image of human diseases?
- SOPs, guidance documents and rapid scientific progress
- Dealing with "individual and isolated cases" - regulator's exception or rule?
- Integral risk/benefit assessment: claims and reality

Dr. Torsten Reum, MD, Dept. of Scientific Service/Clinical Trials, FEDERAL INSTITUTE FOR DRUGS AND MEDICAL DEVICES (BfArM)

CNS AND TRANSLATIONAL MEDICINE

11:45 **Using cognitive function assessment to facilitate translational development from volunteers to patients**

- Cognitive function: what is it and how is it measured?
- The successful implementation of cognitive testing in Phase I
- Phase I models of dementia: validity, sensitivity and predictability
- Case studies of successful prediction from Phase I to patients in Alzheimer's disease, ADHD, depression and schizophrenia
- The value of integrating cognitive assessment with EEG and MRI in Phase I

Professor Keith A. Wesnes, Chief Executive, COGNITIVE DRUG RESEARCH

12:30 *Lunch*

14:00 **Contribution of pre-clinical pharmacology to CNS drug discovery - highlights and limitations**

- Relation between PK and PD as necessary condition for rational drug development
- Target-based vs. indication-based drug discovery - implications for drug development
- How close we can get with animal studies to human diseases ?
- Animal models of CNS diseases - dynamic feedback to knowledge on disease pathomechanisms
- Use of reference agents - how much better should new treatments be?

Professor Wojciech Danysz, Head, In Vivo Pharmacology, MERZ PHARMACEUTICALS

PROJECT MANAGEMENT IN TRANSLATIONAL MEDICINE

14:45 **Emerging issues in outsourcing and clinical pharmacology**

- Knowing why outsourcing is a big market in clinical pharmacology and early phase clinical development
- What criteria are used for the selection of an appropriate partner?
- Why outsourcing saves money and time and can reduce failure in the pipeline
- Why the pharma industry is gaining efficiency at the expense of gaining knowledge

Christopher Kirkpatrick, Head of Clinical Pharmacology Unit, ROCHE PRODUCTS LIMITED

15:30 *Afternoon Refreshments*

15:50 **Managing the move from pre-clinical into clinical**

- Understanding what's involved in the transition from pre-clinical to clinical
- Utilising predictions from the pre-clinical phase to manage the expectations in the move into clinical development
- Measuring success and feeding back into pre-clinical for future phase transitions

Johan Luthmann, Head of Neuroscience, SERONO

16:35 **Volunteers versus patients in clinical development – why this is an important healthcare issue**

- The move towards starting testing on patients as soon as possible – can it fight against disease?
- What extra work has to be done in the pre-clinical stage to ensure the compound is safe and predicted to be efficacious?
- Regulatory situation and current practice
- Does cutting out the traditional Phase I process of testing on healthy subjects have an impact on pharmacology?
- Is the recruitment of patients as opposed to volunteers a political move as opposed to a traditional process?

Hermann Fuder, VP, Clinical Research and Development, NEURO3D

17:00 **Closing Remarks from the Chair and end of day one**

17:15 **Drinks Reception**

Delegates are invited to join the speakers at an informal drinks reception.

Translational Medicine 2006

DAY TWO - WEDNESDAY 15TH FEBRUARY 2006

08:30 *Registration and coffee*

09:00 **Opening remarks from the Chair:**

Dr Andrew Williams, CEO, MARIX

BIOMARKERS AND TRANSLATIONAL MEDICINE

09:10 **Biomarkers for dose selection: how do they increase the probability of technical success?**

- The value of emerging technologies such as imaging or the '-omics' in early phase trials
- How to identify the best biomarkers among many candidates
- Biomarker validation and innovation
- PK/PD models to support the go/no-go decision and dose selection
- Safety margins: joint assessment of efficacy and safety using biomarkers

Francois Vandenhende, Ph.D., Global Statistics, ELI LILLY AND COMPANY

09:55 **Biomarker assay validation issues**

- Assays need to be 'fit-for-purpose' but can there be standardisation within this approach?
- Accuracy is often compromised but this need not be an issue
- The latest guidelines on BM assay validation
- Should the validation approach be influenced by the technology?
- Validation issues arising from assay translation

David Muirhead, Clinical Assay Group, PFIZER

10:40 *Morning refreshments*

CARDIOLOGY AND TRANSLATIONAL MEDICINE

11:00 **Measuring cardiac function in the Phase I unit, an integrated approach**

- Cardiac function: how much can be measured? The possible range of cardiac function measurement in the Phase I Unit
- Special population characteristics which may be utilised
- Non-invasive cardiac function measurement: echo and modern impedance technology/signal averaging techniques
- Case studies of cardiac assessment: e.g. mean atrial fibrillation frequency; acute changes in cardiac function and pulmonary haemodynamics
- Integrating pre-clinical and clinical studies - the 'One Pair of Eyes' approach

Dr Maurice R Cross, Group Medical Director, VEEDA CLINICAL RESEARCH

11:45 **Anxiometry - a new model of anxiolytic drug effects in healthy volunteers**

- Anxiometry
- Modelling anxiolytic drug effects in healthy volunteers
- Heart-rate variability/skin conductance

Martin Siepmann, Senior Lecturer, Institute of Clinical Pharmacology, TECHNICAL UNIVERSITY DRESDEN

12:30 *Lunch*

SCIENTIFIC ASPECTS OF TRANSLATIONAL MEDICINE - CASE STUDIES AND PRACTICAL EXAMPLES

14:00 **Translational cancer research at the EORTC: new directives and tasks**

- New directives have led to the formation of the Network of Core Institutions (NOCI) at the EORTC, representing various clinical centres
- The EORTC data centre designs, runs and evaluates clinical trials in connection with various interested parties
- There is a strong interaction between the disease-oriented clinical groups of the EORTC, the PathoBiology Group, etc
- This interaction allows the EORTC to advise the clinical groups in allocating and securing clinical material from cancer patients enrolled in EORTC trials for the determination of biomarkers
- The EORTC is proactive in setting up and maintaining multi-centric biobanks to allow interactive analysis of biomarkers

Prof. Dr. Manfred Schmitt, Director, Clinical Research Unit, Department of Obstetrics and Gynaecology,

TECHNICAL UNIVERSITY OF MUNICH

14:45 **Early clinical development of a new principle: urotensin-II receptor antagonism**

- How to deal with a completely new mechanism of drug action
- Early clinical development of a urotensin-II receptor antagonist
- How was pre-clinical information used to design Phase I and IIa studies?
- Conduct and results of two proof-of-concept studies - lessons learned

Jasper Dingemans, PhD, Vice-President and Head of Clinical Pharmacology, ACTELION PHARMACEUTICALS

15:30 *Afternoon Refreshments*

15:50 **Safety and QT in early-phase clinical trials**

- Cardiac safety and measurement and the correct usage of ECGs
- What regulatory issues do you have to be aware of when conducting QT studies?
- Using pre-clinical assays to predict changes in QT
- Integrating pre-clinical and clinical QT data

Malcolm Mitchell, Senior Clinical Research Physician, ELI LILLY UK

16:35 **Drug interactions during drug discovery and development**

- Why drug-drug interactions should be a major part of translational medicine
- Understanding why the interacting potential of a new chemical entity should be investigated early during discovery/development
- Important aspects of in-vitro studies on drug-metabolism and drug-interaction
- The role of metabolites in drug-drug interactions

Stefano Persiani, PhD, Director, Department of Drug Metabolism, Pharmacokinetics and Dynamics, Rotta Research Laboratorium, ROTTAPHARM

17:20 **Closing Remarks from the Chair**

17:30 **End of day two and Champagne prize draw**

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Post-conference Workshop

Thursday 16th February 2006

Old and novel tumour biomarkers: hope or already reality?

Clinical features and histomorphological factors have been used traditionally to predict individual cancer patient outcome or direct cancer treatment. With the new concept of "individualised treatment and targeted therapies", tumour-associated biomarkers have been given a new role in the selection of cancer patients for treatment and in cancer patient management.

Tumour biomarkers can give support to cancer patient stratification and risk assessment, treatment response identification, or to identifying those patients who are expected to respond to certain anticancer drugs. Owing to high-throughput technologies, gene-, protein-, and tissue-arrays, we are now faced with various "cancer gene signatures" rather than with single tumour markers. This scenario requires novel methods for the simultaneous assessment of the tumour biomarkers; quality assessment and quality assurance is also an important issue to consider as well as state-of-the-art statistics to evaluate and validate the tumour biomarkers in question.

Therefore, before a new tumour biomarker can be recommended for clinical routine application, well-designed and controlled biomarker studies have to be conducted to allow validation of the prognostic or predictive ability of the tumour biomarkers. Legal implications, patients' rights, and intellectual property rights have to be observed as well.

09:30 Delegate registration and coffee

10:00 Session 1

- Biobanking – fresh-frozen tissue vs. fixed tissue
- Blood-borne and tissue-derived biomarkers
- Established biomarkers as markers of prognosis, etc
- Gene profiling at the DNA- and mRNA-level
- Gene level vs. protein level: genomics or proteomics?

11:10 Morning refreshments

11:25 Session 2

- State-of-the art statistics to explore the potential of biomarkers
- Biomarkers as markers of tumour invasion and metastasis
- The concept of "predictive oncology"
- Quality assurance and quality assessment programs

12:35 Lunch

13:40 Session 3

- Biomarkers and quality of life issues
- Biomarkers and pharmacokinetics
- The role of tumour biomarkers as targets for therapy
- New tools for the detection of biomarkers: aptamers, etc

14:50 Afternoon Refreshments

15:05 Session 4

- Intellectual property laws
- Patients' rights: written informed consent forms, etc
- Different countries, different ethic laws: multi-centre studies
- The European Union as a funding body for cancer research

16:15 Close of Workshop

About Your Workshop Leader

Prof. Manfred Schmitt is Director of the Clinical Research Unit, Department of Obstetrics and Gynecology, Technical University of Munich. After gaining a Ph. D in biochemistry from University of Mainz, Prof. Schmitt then progressed through academia to his current position at the Technical University of Munich, where he has been since 1993. Professor Schmitt has 58 patents/patent applications and is co-editor of four journals, including Thrombosis and Haemostasis; International Journal of Oncology; Cancer Therapy and Critical Reviews in Clinical Laboratory Science. Professor Schmitt is also co-founder of Wilex Biotechnology GmbH (now Wilex AG) and the Chairman and Board member of the EORTC PathoBiology Group. www.tu-muenchen.de

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 All three days (including a £100 discount!) £1898.00 + VAT (£2230.15)

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