SMi present their 2nd annual conference on Biomarkers in Clinical Trials

Monday 20th & Tuesday 21st September 2010
Hilton London Kensington Hotel, London, UK

This conference will feature presentations from a combination of senior industry professionals and academic experts. Attendees will benefit from a unique event exploring practical issues relating to the use of biomarkers in clinical development.

KEY SPEAKERS INCLUDE:

Mike Lau
Principal Clinical Development Scientist, Oncology
GlaxoSmithKline

Mark Fidock
Senior Principle Scientist, Biomarkers and Translational Biology
Pfizer

Chris Harbron
Technical Lead Statistician, Discovery Statistics
AstraZeneca

Shawnmarie Mayrand-Chung
National Institutes of Health Programme Director
Biomarkers Consortium

David Dow
Group Leader, Molecular and Cellular Technologies
GlaxoSmithKline

Dominic Williams
Senior Lecturer, MRC Centre for Drug Safety Science
University of Liverpool

Russell D. Petty
Clinical Senior Lecturer in Medical Oncology
University of Aberdeen

KEY TOPICS:
- Preclinical biomarker discovery and translation for clinical utility
- Using molecular biomarkers to identify patient populations
- Multimodality cancer biomarker discovery and development
- Next-generation sequencing technologies
- Miniaturised multiplexed immunoassays

PLUS A HALF-DAY POST-CONFERENCE WORKSHOP
Wednesday 22nd September 2010, Hilton London Kensington Hotel
Commercialisation of Biomarkers for Personalised Medicine

To attend, contact Zain Philbey on Tel +44 (0) 20 7827 6722, Fax +44 (0) 20 7827 6723, email zphilbey@smi-online.co.uk or visit www.smi-online.co.uk/ts07.asp to register online
Biomarkers in Clinical Trials
Day One / Monday 20th September 2010
www.smi-online.co.uk/ts07.asp

8.30 Registration & Coffee
9.00 Chairman’s Opening Remarks
Russell D. Petty, Clinical Senior Lecturer in Medical Oncology, University of Aberdeen
9.10 Translational Biomarkers
• Preclinical Biomarker discovery and translation for clinical utility
• Biomarker tool box – enabling PK/PD
• Case studies in the area of inflammation and infectious diseases
• Biomarker use for decision making in clinical studies
Mark Fidock, Senior Principle Scientist, Biomarkers and Translational Biology, Pfizer
9.50 Improved Detection of Nephrotoxicity through Novel Kidney Biomarkers
• Performance of novel kidney biomarkers in animal models of acute and sub-chronic kidney injury
• Strengths and limitations of these biomarkers
• Implications for translation into the clinic
Angela Mally, Senior Scientist, Department of Toxicology, University of Würzburg
10.30 Using Preclinical Data to Optimise the Value of Biomarkers in the Clinic
• Using molecular biomarkers to identify patient populations
• The use of preclinical data from in-vitro systems and samples from undosed volunteers
• Increasing the likelihood of robust identification of patients who would benefit from treatment
• Reproducibility, robustness, evaluability, translation and interpretability
• Implications for clinical development processes
Chris Harbron, Technical Lead Statistician, Discovery Statistics, AstraZeneca
11.00 Morning Coffee
11.30 Translating Biomarkers into Companion Diagnostics
• Drug and diagnostic co-development – key drivers
• Lessons learned in companion diagnostic development
• Companion diagnostic development models
• IVD and clinical trial assays
Carol Berry, Vice President, Pharmacogenomic Services, Asuragen
12.10 Translating Lymphoma Gene Expression Signatures intoRoutine Clinical Biomarkers
• Identification of patients who are not responsive to current therapy
• The need for co-development of biomarkers and novel therapies
• Reassessment of biomarker utility in response to evolving gold standard therapy
• The importance of reagents and techniques that enable specific and reproducible biomarker detection
Alison Banham, Senior Scientist, Nuffield Department of Clinical Laboratory Sciences, University of Oxford
12.50 Networking Lunch
1.50 Cerebrospinal Fluid Biomarkers in Neurodegeneration and NeuroInflammation
• From basic research to clinical trials
• Alzheimer’s disease
• Multiple sclerosis
• Niemann-Pick disease
Niklas Mattsson, Senior Physician, Institute of Neuroscience and Physiology, Clinical Neurochemistry Laboratory, Sahlgrenska University Hospital, Mölndal
2.30 Automating Biomarker Discovery and Qualification – Capturing Hypothesis, Analysis and Intellectual Property
• Solutions to empower scientists to seamlessly use and integrate clinical, genomic and image data
• Automatically annotating genomic data using internal, public and third party sources
• Using E-WorkBook: steps and decision points of the experimental set-up, data capture and analysis
• Reports can be automatically generated and the burden of validation reduced
Jonathan Sheldon, Director, Translational Medicine, IDBS
3.10 Afternoon Tea
3.30 Multimodality Cancer Biomarker Discovery and Development: Optimising the use of Biospecimens and Patients
• Complex clinical phenotypes in cancer patients
• Combining clinical, imaging and tissue biomarkers
• Combined hypothesis generating and hypothesis driven approaches
• Clinical implementation of combined biomarker modality approaches
Russell D. Petty, Clinical Senior Lecturer in Medical Oncology, University of Aberdeen
4.10 An Overview of Next-Generation Sequencing Technologies
• Technology overview
• Recent advances
• Potential applications in biomarker research
• Future developments
David Dow, Group Leader, Molecular and Cellular Technologies, GlaxoSmithKline
4.50 Discovery, Evaluation and Validation of Novel, Low Abundance Protein Biomarkers in Human Plasma
• Analytical requirements for antibody-free plasma protein biomarker discovery
• Study design and technology considerations for the discovery and verification stages
• Bridging the gap between discovery and clinical implementation
• Case study: Unbiased discovery and development of novel plasma protein biomarkers in the field of heart failure
How Davies, Business Development Director, Pronota
5.30 Chairman’s Closing Remarks & Close of Day One

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Supported by
Chairman's Opening Remarks
Dominic Williams, Senior Lecturer, MRC Centre for Drug Safety Science, University of Liverpool

The Advantages of Efficacy Biomarkers in Exploratory Development
• Determining which efficacy biomarkers are appropriate
• Validation of Phase I efficacy biomarkers
• Assessing whether a drug is on target
• Regulatory authorities and efficacy biomarkers
Shetnah Morgan, Senior Clinical Research Scientist, AstraZeneca

Translational Biomarkers in Drug Induced Liver Injury
• Role of metabolism in drug-induced liver injury
• Mechanistic biomarkers of cell damage
• Involvement of the innate immune system during hepatic stress
• A chronic infusion model of paracetamol hepatotoxicity
Dominic Williams, Senior Lecturer, MRC Centre for Drug Safety Science, University of Liverpool

Assessing Response to Cancer Treatments Using Magnetic Resonance
• Introduction to magnetic resonance in assessing novel treatments
• DCE-MRI as a measure of vascular impact
• DWI-MRI to assess cellular change
• Metabolic read-outs with MR – current and future
Martin Leach, Professor of Physics as Applied to Medicine, The Institute of Cancer Research

MicroRNA as Biomarkers of Disease and Drug Efficacy
• Introduction to microRNAs
• Approaches and considerations in microRNA profiling for biomarker discovery
• Clinical progress of microRNA biomarker assays
• Emerging evidence on invasive and non-invasive microRNA signature utility in diagnostics and theranostics
Stergios Moschos, Principle Scientist, Pfizer

Miniaturised Multiplexed Immunoassays
• Technologies and applications
• Capabilities and limitations of multiplexed immunoassays
• Multiplexed immunoassays for biomarker discovery
Thomas Joos, Head of Biochemistry, Natural and Medical Sciences Institute, University of Tübingen

Networking Lunch

Innovative and New Ways of Conducting Clinical Trials in Biomarkers
• Navigating the landscape to design and conduct effective, efficient and regulatory acceptable trials
• Biomarkers and adaptive trial designs: shortening the time it takes to discover and prove that a new drug or medical procedure is effective
• Modelling and monitoring the effectiveness of personalised treatment in real time
• Safety biomarkers: collaborative efforts for moving forward at a faster pace
Shawnmarie Mayrand-Chung, National Institutes of Health Program Director, Biomarkers Consortium

Discovery, Development and Launch of Personalised Healthcare Therapies
• Challenges across the value chain
• Delivering personalised medicine globally
• Learnings from AstraZeneca case studies
Ansar Jawaid, Global Diagnostics Brand Manager, AstraZeneca

Biomarkers in Clinical Trials
Day Two | Tuesday 21st September 2010

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ABOUT THE SMI PHARMACEUTICAL TEAM
SMi have been involved in the pharmaceutical industry since 1993 and have developed a series of informative and niche events, covering the latest issues and developments surrounding the industry. Events bring together senior industry professionals and serving companies who have a focus on being at the forefront of developments in this area. SMi aim to generate informed and topical discussion through the medium of both conferences and executive briefings. Our pharmaceutical events are research-based and content driven with regular contact with major industry personnel and cover a wide range of industry sectors. For more information, please visit www.smi-online.co.uk/pharma.asp
Overview

The commercialisation of biomarkers is the final and often most daunting part of the biomarker process. It is crucial that the correct path is taken to ensure your biomarker has the greatest chance of commercial success. In this half-day workshop, various approaches, examples and case studies will be presented and participants will also have the opportunity to raise specific issues and problems that they face or expect to face from their own biomarker commercialisation strategies.

Key Topics

• Clinical and scientific validation of biomarkers
• Practical considerations when commercialising biomarkers
• Case studies illustrating the benefits and risks of different approaches
• The impact of successful biomarker commercialisation
• Reimbursement strategies

8.30  Registration & coffee

9.00  Introduction to biomarker commercialisation for personalised medicine

9.15  Clinical and scientific validation of biomarkers

10.15  Regulatory aspects

10.45  Coffee

11.15  Reimbursement strategies

11.45  Case studies of successful biomarker commercialisations

12.15  Group discussion and Q&A

12.45  Close of workshop

About the Workshop Leader:

James Clark is the founder and director of the life science consultancy Permedx, specialising in the development of personalised and translational medicine. He has over fifteen years of experience in project management, including senior and executive roles in pharmaceutical and biotechnology companies. He has initiated a number of translational medicine strategies resulting in the successful development of biomarkers and companion diagnostics. He has developed successful CE marking personalised medicine tests and reimbursement strategies for both UK and European healthcare markets.

About the Organisation:

Permedx was established to satisfy a growing need for specialist advice for the development and commercialisation of translational and personalised medicine diagnostics. Permedx consulting offers services from early biomarker validation and discovery, through to strategic planning for commercialisation, reimbursement and CE marking of biomarkers diagnostics. www.permedx.co.uk
PHARMACEUTICAL FORWARD PLANNER

May 2010
10/11 Generics, Supergenerics & Patient Strategies
17/18 Clinical Trial Logistics

June 2010
07/08 Pain Therapeutics
23/24 Global Protein Summit
28/29 RNAi, siRNA & miRNA
28/29 Pharmaceutical Portfolio & Product Lifecycle Management
30/01 KOL Europe*

July 2010
05/06 Clinical Trials in Cancer
07/08 ADMET
12/13 In Vitro Diagnostics

September 2010
20/21 Biomarkers in Clinical Trials
22/23 Biosimilars & Biobetters
29/30 KOL Knowledge Leaders

October 2010
04/05 Managing Partnerships with CROs
11/12 Personalised Medicine
25/26 Nutraceuticals & Functional Foods
25/26 Point of Care Diagnostics
27/28 European Pharmaceutical Pricing & Reimbursement*

November 2010
10/11 Metabolic Diseases
15/16 Clinical Trials in CNS
17/18 COPD*
22/23 Cell Based Assay

December 2010
01/02 Cold Chain Distribution

* These conferences will take place in mainland Europe

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Contact Kiran Sharma, SMi Marketing on +44 (0) 207 827 6050, or email ksharma@smi-online.co.uk
BIOMARKERS CLINICAL TRIALS
Workshop: 22nd September 2010, London

4 WAYS TO REGISTER

ONLINE at www.smi-online.co.uk/ts07.asp

POST your booking form to: Events Team, SMi Group Ltd, Great Guildford Business Square, 30 Great Guildford Street London, SE1 0HS, UK

PHONE on +44 (0) 20 7827 6722

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EARLY BIRD □ Book by 28th May 2010 to receive a £300 early bird discount
□ Book by 30th June 2010 to receive a £100 early bird discount

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I would like to attend: (Please tick as appropriate) Fee Total
□ Conference and Half-Day Workshop £1998.00 + VAT £2347.65
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□ Distribution of your company’s promotional literature to all conference attendees £999.00 + VAT £1173.83

GROUP DISCOUNTS AVAILABLE

The Conference fee includes refreshments, lunch, conference papers and CD ROM containing all of the presentations.

VENUE

Hilton London Kensington Hotel, 179-199 Holland Park Avenue, London, W11 4UL

□ Please contact me to book my hotel
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