SMi presents their sixth annual

Biomarkers Summit

Innovations in stratified medicine

Wednesday 16th and Thursday 17th January 2013,
Copthorne Tara Hotel, London, UK

KEY SPEAKERS INCLUDE:

Chris Chamberlain
Medical Director, Personalised Medicines
AstraZeneca

Andrew Warren
Director, PK/PD/Immunogenicity Bioanalysis, Novartis

Adam Platt
Diagnostic Development Director
AstraZeneca

Christopher Foley
Imaging Manager
GlaxoSmithKline

Mirella Lazarov
Senior Director Biology, Head of Biomarkers
Gilead Sciences

Yi Yang
Associate Research Investigator
Abbott

Yasmina Bauer
Senior Lab Head Translational Science
Actelion

Nicholas Buss
Toxicology Project Leader
MedImmune

WHY YOU SHOULD ATTEND THIS CONFERENCE:

• Overcome challenges in biomarker and diagnostic drug development
• Utilise biomarkers for effective clinical development
• Improve translatability in clinical studies
• Integrate imaging into clinical studies
• Utilise bioinformatics to elucidate targets implicated in disease or pharmacogenetic effects

PLUS TWO INTERACTIVE PRE–CONFERENCE WORKSHOPS

Tuesday 15th January 2013, Copthorne Tara Hotel, London, UK

A: The design and analysis of clinical trial design with a focus on biomarkers
   Workshop Leader: Aiden Flynn, Managing Director, Exploristics
   8.30am - 12.40pm

B: Exosomes as novel diagnostic tool in cancer: potentials and challenges
   Workshop Leader: Dr Natasa Zarovni, Head, Research & Development, Exosomics Siena
   1.30pm - 5.40pm

www.biomarkers-summit.com

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Who should attend:
Chief Executive Officers, Chief Scientific Officers, Chief Medical Officers, Managing Directors, Vice Presidents, Directors, Partners, Heads and Managers in:

- Biopharmaceuticals
- Specialty Chemicals
- Medical Devices
- Diagnostics
- Clinical Pharmacology
- Preclinical development
- Oncology/Cancer Cell Biology
- Inflammatory Diseases
- Toxicology
- Preclinical safety
- Immunogenicity
- Strategic Alliances
- Business Development
- ADMET

1.30 Translational biomarkers in drug development
- Challenges and risk management in the development of new medicines
- Strategic development and use of biomarkers in translational medicine
- Case study: the TLR7 drug development programme
Speaker to be confirmed

2.10 Renal safety biomarkers
- Overview challenges and opportunities
- Urinary biomarker qualification efforts
- Current regulatory status
- Validation and implementation of urinary biomarkers
Yi Yang, Research Investigator Investigative Toxicology, Abbott

2.50 The use of safety biomarkers for risk assessment of investigative drugs entering first-in-human studies
- The principles of biomarkers for both safety and efficacy in regulatory toxicology studies for both small and large molecules to support FIH studies
- The importance of pharmacodynamic biomarkers used in toxicology studies to support FIH studies
- Brief overview of classical and emerging biomarkers used in regulatory toxicology studies to support FIH studies
Nicholas Buss, Toxicology Project Leader, Medimmune

3.30 Afternoon Tea

3.50 Understanding the mechanisms involved in immune responses to therapeutic proteins
- Development of immune responses directed against protein therapeutics
- Antigen presentation and T-dependent responses
- Models for predicting immunogenicity
- Reducing immunogenicity by design
Matthew Baker, Chief Scientific Officer, Antitope

4.30 On setting the first dose in man: quantitating biotherapeutic drug-target binding through pharmacokinetic and pharmacodynamic models
- Delivering safe starting and therapeutically relevant escalation doses for human studies
- Target-mediated drug disposition
- Assaying captured drug-target complexes
Andrew Warren, Director, PK/PD/Immunogenicity Bioanalysis, Novartis

8.30 Registration and Coffee

9.00 Chairman’s Opening Remarks
Andrew Warren, Director, PK/PD/Immunogenicity Bioanalysis, Novartis

9.10 KEYNOTE ADDRESS
Biomarkers: discovery strategies and technologies
- Strategies for providing truly personalised predictive biomarkers and drugs in use and in development
- Review of some emerging new technologies for generating sophisticated readouts directly informative on drug action
- Predictions of drug responsiveness
Peter Parker, Professor of Cancer Cell Biology, King’s College London

9.50 Pharmacogenomic biomarkers - an update
- Progress in identifying gene regions coding for drug targets
- Results from genome-wide association studies
- Meeting the technical challenges of stratified medicine and companion diagnostics
Mark Caulfield, Director, William Harvey Research Institute, Barts and The London School of Medicine and Dentistry

10.30 Morning Coffee

10.50 How to do it: pharmacogenetics and biomarkers - clinical study and statistical design
- Design and analysis considerations
- Association analysis
- Design options
- Case studies and applications
Aiden Flynn, Managing Director, Exploristics

11.30 CASE STUDY: Translational value of the bleomycin rat model for the treatment of patients with idiopathic pulmonary fibrosis (IPF)
- Whole-genome data collected from an IPF animal model time-course experiment
- Comparison of animal model data from IPF patient-derived lung biopsies
- New possibilities to evaluate efficacy of novel therapeutics in preclinical models and human clinical trials
Yasmina Bauer, Senior Lab Head Translational Science, Actelion

12.10 Networking Lunch

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

9.00 Chairman’s Opening Remarks
Chris Chamberlain, Medical Director, Personalised Medicines, AstraZeneca

9.10 OPENING ADDRESS
The challenges of Biomarkers and diagnostics in drug development
• Identifying patient subpopulations and applying to clinical development
• The utility of biomarkers to aid drug development
• Adapting development strategies to deliver companion diagnostics
• The development of targeted therapies requires new skill sets and processes
Adam Platt, Diagnostic Development Director, AstraZeneca

9.50 Membrane proteins as personalized biomarkers
• The role of membrane receptors and transporters in diseases
• Membrane biomarkers in hematological diseases and cancer
• Membrane biomarkers predicting drug treatment response and resistance
• The red cell membrane proteins as potential biomarkers
Balázs Sarkadi, Head, Biomembrane Department, Institute of Molecular Pharmacology, Research Centre for Natural Sciences, Hungarian Academy of Sciences

10.30 Morning Coffee

10.50 Opportunities for the development of stratified medicine in the UK
• Description of the Technology Strategy Board’s Stratified Medicine Innovation Platform
• Joining up academia, diagnostic and therapeutic development and driving product uptake
• Encouraging wide collaboration from biomarker discovery to product launch
• Current and future focus for public funding
Graham Bell, Lead Specialist Stratified Medicine, Technology Strategy Board

11.30 Employing biomarkers for effective clinical development
• Current regulatory guidelines and challenges
• Establishing biomarker testing infrastructure
• Innovative examples of using biomarkers to enable faster development decision making
Mirella Lazarov, Senior Director Biology, Head of Biomarkers, Gilead Sciences

12.10 Networking Lunch

1.30 Evaluating the cost-effectiveness of diagnostics: the NICE diagnostics assessment programme
• Explaining the structure and purpose of the diagnostics assessment programme
• Evaluating the cost-effectiveness of a diagnostic test
• Explaining how the diagnostics industry can engage with the programme
Nick Crabb, Associate Director, Diagnostics Assessment Programme, NICE

2.10 CASE STUDY: Molecular identification of solid tumours to aid stratified medicine
• Improving diagnostic strategies to facilitate personalised therapeutic interventions
• BRAF V600 mutation testing for malignant melanoma
• KRAS mutation testing for patients with colorectal cancer
Lisa Thompson, Laboratory & Clinical Scientist, The Royal Marsden NHS Foundation Trust

2.50 Exosomes as source for novel cancer biomarkers
• Biology of exosomes
• Detection of specific biomarkers in exosomes
• Clinical validation of assay platforms for cancer diagnosis and staging
Wolfgang Fecke, Project Leader, Hansabimed

3.00 Afternoon Tea

3.30 Imaging in Oncology

3.50 Multi-centre imaging in the context of clinical trials
• Managing multi-centre clinical trials and their associated challenges in oncology
• Examples of best practice in imaging models
• Notable trends gleaned from such studies
Chris Foley, Imaging Manager, GlaxoSmithKline

4.30 Imaging biomarkers of cancer progression
• Noninvasive Measurement of tumor blood flow and interstitial fluid pressure
• Tumor adaptations to ensure nutrient delivery
• Assessing metastatic potential
Simon Walker-Samuel, Senior Research Associate, Centre for Advanced Biomedical Imaging, University College London

5.10 Chairman’s Closing Remarks and Close of Day Two

**SMi’s Pharmaceutical Forward Planner 2012**

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<td>Pharmaceutical Orphan Drugs</td>
<td>Cold Chain Distribution</td>
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<td>22-23</td>
<td>COPD: Novel Therapeutics and Management Strategies</td>
<td>All conferences take place in central London, UK – unless indicated otherwise in brackets</td>
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<td>24-25</td>
<td>Point of Care Diagnostics - Market Opportunities and Technology Trends</td>
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<td>29-30</td>
<td>European Pharmaceutical Pricing &amp; Reimbursement</td>
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**Want to know how you can get involved? Interested in promoting your pharmaceutical services to this market?**
Contact Kellee Halliburton, SMi Marketing on +44 (0) 207 827 6194, or email khalliburton@smi-online.co.uk
Overview of workshop:
The workshop will cover the key statistical considerations for optimising the design and analysis of studies comprising biomarkers. The workshop will be very interactive. Computer simulation will be used to place the audience in realistic clinical development scenarios and participants will be able to work through real challenges in biomarker studies. At the end of the workshop, participants will understand and be able to apply the principles of study design and analysis to other biomarker studies.

- Understand the application of biomarkers in stratified medicine
- Understand the utility of statistics and modeling in optimizing study design
- Understand the challenges in biomarker research by participating in realistic scenarios
- Be able to apply this knowledge

Workshop Agenda:
8.30 Registration and coffee
9.00 Introduction to biomarkers, study design and statistics
   • The utility of biomarkers in stratified medicine
   • The application of statistics and modeling in study design
   • Optimising the design of stratified medicine studies
10.00 Interactive scenario 1
   • Challenges in identifying biomarkers during clinical development
   • How can we improve the likelihood of success of biomarker identification?
   • The importance of disparate sources of information
11.00 Coffee break
11.20 Interactive scenario 2
   • Building on the identification of biomarkers
   • Prospectively designing studies using biomarkers
   • Optimising biomarker research in development programs
12.00 Discussion and conclusions
12.40 End of workshop

About the workshop host
Aiden Flynn has worked for more than 18 years in the development and application statistics and modeling to drug discovery and development. After seven years as a Lecturer at University College London, he spent ten years at GlaxoSmithKline as Director of statistical support for biomarker studies across research and development. Currently, he is Managing Director of Exploristics, the innovative analysis group, with specific interests in study design and optimisation as applied to Personalised Medicine.

About Exploristics
Exploristics provides innovative analysis solutions to maximize the information derived from clinical data. This includes unique expertise in the exploratory analysis and clinical application of biomarkers, pharmacogenomics, imaging and observational data.

Exploristics also develop and distribute computer simulation tools to optimise the design of clinical studies. These include tools for designing personalised medicine research, diagnostics studies and benefit risk studies.
Overview of workshop:
Despite numerous candidates for cancer molecular diagnostics identified in proteomic and histopathological studies of tumor tissues, reliable peripheral biomarkers remain elusive for the majority of solid tumors. The workshop will address the potential of exosome based approaches to surmount common pitfalls of peripheral biomarker detection. Employment of exosome displayed molecules as diagnostic sensors is still an object of technological developments and pilot validation studies of novel solutions for early diagnosis and personalized medicine.

Why should you attend this workshop:
What attendees are expected to gain from this workshop:
• An understanding of the problems and challenges correlated with development of reliable cancer biomarkers and incorporated assays for non-invasive and accurate solid tumor screening and monitoring
• Overview of advantages and complementarities of methods for analysis of exosome associated protein and genomic markers
• Overview of technical issues (advances and pitfalls) regarding the practical employment of exosomes in diagnostics of cancer

Workshop Agenda:
1.30 Registration and coffee
2.00 Introduction into the current status of solid tumor biomarkers in research and clinic
   • False negatives, false positives – challenges of early diagnosis
   • Prognostic and theranostic potential: quest for surrogate markers and personalized medicine
   • Old suspects under the new light: Novel approaches to develop novel and improve traditional cancer markers
30.00 Coffee break
3.20 Case study: Exosomes as privileged targets in –omics approaches
4.20 Coffee break
4.40 Case study: Exosome - associated biomarkers in prostate cancer
5.40 End of workshop

About the workshop host:
Natasa Zarovni is a molecular biologist and physiologist with a PhD in molecular medicine obtained at San Raffaele Research Institute in Milan. As a postdoctoral fellow at Bicocca University in Milan, she gained significant experience in different biomedical fields comprising tumor biology, gene delivery, and functional genomics of stem cells. In 2008 she left her academic career for a position as a scientific officer at Arisla in Milan before joining Hansabioimed (HBM) in 2010 as a team leader. She is currently the Head of R&D of both HBM and Exosomics Siena, a subsidiary company focused on the validation of exosome targeted immunometric assays for diagnostic tumor applications. She is also a member of the editorial board of the journal ‘Exosomics’.

About Exploristics
HBM and its subsidiary Exosomics Siena develop a proprietary methodology that couples the specific capture of exosomes from complex biological fluids with the detection of multiple exosome associated markers (proteins and RNAs), providing a platform for the assessment of cellular state and function. The company is already present on the market with exosome-based research products and has strategic collaborations with academic, clinical and industrial partners worldwide.
BIOMARKERS SUMMIT
Conference: Wednesday 16th and Thursday 17th January 2013, Copthorne Tara Hotel, London, UK
Workshops: Tuesday 15th January 2013, London

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Payment: If payment is not made at the time of booking, then an invoice will be issued and must be paid immediately and prior to the start of the event. If payment has not been received then credit card details will be requested and payment taken before entry to the event. Bookings within 7 days of event require payment on booking. Access to the Document Portal will not be given until payment has been received.

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