SMi present their 15th annual conference on...

Superbugs & Superdrugs
A Focus on Antibacterials

4th and 5th March 2013, Copthorne Tara Hotel, London

KEY TOPICS FOR 2013:
- The EMA approach to regulating antimicrobials
- Case Studies on mechanisms of action for inhibiting antibiotics
- Strategies for combating bacterial genetic variation influences of infections
- Current Partnerships addressing antimicrobial resistance
- Utility of natural products and alternative approaches to aid drug discovery

PLUS TWO INTERACTIVE HALF-DAY POST-CONFERENCE WORKSHOPS
Wednesday 6th March 2013, Copthorne Tara Hotel, London

A: Licensing of R&D Antibiotics
Workshop Leader: David Scott, Licensing & Business Development Consultant, PharmaConsulting
08.30 – 12.30

B: Nanotechnology’s future for antibiotics
Workshop Leader: Sonia Contera, Co-Director Oxford Nanotechnology, University of Oxford
13.30 – 17.00

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EXPERT SPEAKERS INCLUDE:

Pierre Raboisson
Head of Medicinal Chemistry
Johnson & Johnson

Neil Ryder
Executive Director, Infectious Diseases, Novartis

Line Matthiesen
Head of Infectious Diseases and Public Health Unit
European Commission

Anthony Coates
Professor of Medical Microbiology
St. George’s University
London

Christian Felter
Medical Director
Astellas

Jerome Guillemont
Research Fellow
Johnson & Johnson

William Wiess
Director, Pre-Clinical Services
University of North Texas Health Science Center

Malcolm Page
Head of Biology
Basilea Pharmaceutica

Richard Bergstrom
Director General
EFPIA

Ursula Theuretzbacher
Principal Scientist
CEFAIA
“Very good and engaging speakers” – Merck

08.30 Registration and Coffee
09.00 Chairman’s opening remarks
Richard Bax, Senior Partner, Transcrip Partners

Update on the Current Regulatory Environment

09.10 Update on current R&D and the Regulatory Environment
- Big and Little Pharma activity and progress.
- Report on REACT, B5AC, IDSA, Barda FP7 EU and Innovative Medicines Initiative.
- A developer’s view on the EMA workshop on the development of new antibacterial medicines 25/26th October 2012
- Prospects for the future
Richard Bax, Senior Partner, Transcrip Partners

09.50 The war you cannot win – but survive: How the pharma industry is mobilising to get the pipeline going
- Pooling resources in public-private partnerships with the European Commission (IMI and Horizon 2020)
- Towards reasonable and predictable regulatory requirements
- How to preserve new antibiotics? A global compact for controlled use?
Richard Bergstrom, Director General, EFPIA

10.30 Morning Refreshments

Targeting MDR Gram-Negative Bacteria

11.00 The use of isogenic strains in antimicrobial drug discovery
- Highly characterised isogenic strains
- Uses of isogenic strains in in vivo systems
- PK/PD with isogenic strains
Peter Warn, CSO, Euprotec

11.40 Inhibition of lipopolysaccharide transport to the outer membrane in Pseudomonas aeruginosa by peptidomimetic antibiotics
- Evidence that the peptidomimetics inhibit the LPS transport function of LptD
- Comparison of the effects caused by the antibiotic on the wild-type strain with those caused by depleting LptD in the mutant strain
- Mechanism of action for the peptidomimetic antibiotics that involves inhibition of LPS transport to the cell surface
William Wiess, Director, Pre-Clinical Services, University of North Texas Health Science Center

12.20 Networking Lunch

13.50 Case study: development candidate BAL30072
- Activity of BAL30072 against multi-drug resistant Gram-negative bacteria
- Activity of BAL30072 against Burkholderia pseudomallei and B. mallei
- Combined effects of BAL30072 and carbapenems in vitro
- Enhanced activity of BAL30072 and meropenem in animal infection models
Malcolm Page, Head of Biology, Basilea Pharmaceutica

14.30 The design of a novel class of antibiotics for the treatment of highly resistant gram-negatives
- An exploration of the process to engineer new antibiotics for the worst bacteria
- Overcoming known resistance mechanisms
- Achieving the desired safety window
Erin Duffy, Chief Scientific Officer, Rib-X Pharmaceuticals

15.10 Afternoon Tea

15.40 Discovery of Bedaquiline (TMC207), a new candidate for the treatment of tuberculosis
- Short introduction on the disease / pipeline
- History of DARQs (diarylquinoline class) / SAR
- TMC207, properties / spectrum of activity / in vivo efficacy / MOA
Jerome Guillemont, Research Fellow, Johnson & Johnson

16.20 GC-072: A novel resistance-breaking oxoquinolizinone
- Novel oxoquinolizinone
- Broad-spectrum and potent topoisomerase inhibitor
- Different binding site than quinolones
- Excellent in vitro coverage of Gram-positive and Gram-negative MDR pathogens
- Favorable PK and initial Tox profile
- Active in in vivo infection models, oral and IV
Jutta Heim, Chief Scientific Officer, Evolva

17.00 Antibacterial developments in Tuberculosis research
- New models are needed for anti-bacterial development in TB
- Novel in vitro models which mimic TB persister bacteria
- Considering a new murine model which is more similar to human tuberculosis than current models
Anthony Coates, Professor of Medical Microbiology, St. Georges University London

17.40 Chairman’s Closing Remarks

17.50 Close of Day One
08.30 Re-registration and Coffee

09.00 Chairman’s opening remarks
   William Wiess, Director, Pre-Clinical Services, University of North Texas Health Science Center

09.10 Discovery and development of Simeprevir (TMC435) and TMC647055, two novel direct antiviral agents targeting the Hepatitis C Virus
   • Hepatitis C virus (HCV)-encoded NS3/4A protease and NS5B polymerase are essential for viral replication and represent two attractive targets for therapeutic intervention in HCV-infected patients
   • Both NS3/4A protease and NS5B non-nucleoside inhibitors are able to decrease HCV viremia, either as monotherapy or in addition to the current standard of care therapy
   • Simeprevir (TMC435) and TMC647055 are two potent and selective inhibitors of HCV replication in genotype 1b replicon cells with EC50 values of 8 nM and 82 nM, respectively
   • Combination of these two drug candidates in an interferon-free setting is currently under investigation in the clinic
   Pierre Raboisson, Head of Medicinal Chemistry, Johnson & Johnson

09.50 Invasive Fungal Infections: New approaches
   • Review the evolving epidemiology of invasive fungal infections
   • Analysis of the current treatment landscape
   • What’s next?
   Christian Felter, Medical Director, Astellas

10.30 Morning Coffee

11.00 Fungal Infection; trends and progress in novel therapies
   • Emerging fungal pathogens and the need for new drugs
   • Trends in antifungal drug resistance
   • Recent developments in novel antifungal therapies
   • Targeted approached: do they can they work?
   Neil Ryder, Executive Director, Infectious Diseases, Novartis

11.40 Clinical Evidence for Fabi Antibiotics
   • Scientific rationale for Fabi inhibitors, a new mechanism of action drug class
   • Clinical proof of concept in Phase 2: safety and efficacy
   • Rationale use of a Staph specific spectrum antibiotic in clinical practice
   Barry Hafkin, Chief Medical Officer, Affinium Pharmaceuticals

12.20 Networking Lunch

13.40 Partnering and Working with BARDA
   • Background on BARDA
   • Strategic emphasis of BARDA in addressing antimicrobial resistance
   • Examples of current partnerships
   • How to engage and work effectively with BARDA
   Joseph Larsen, Branch Chief, Biomedical Advanced Research and Development Authority (BARDA)

14.30 New partnerships to combat antimicrobial resistance
   • Meeting the challenges in implementing the European Commission’s Action plan on antimicrobial resistance
   • Partnerships with industry on antimicrobial resistance
   • Partnership among countries on antimicrobial resistance
   • The vision on future research under Horizon 2020
   Line Matthiesen, Head of Infectious Diseases and Public Health Unit, European Commission

15.10 Afternoon Tea

15.40 Publicly funded antibacterial drug development in Europe
   • In an era of increasing antimicrobial resistance and dwindling antibiotic resources, publicly funded drug development projects intend to give much needed impulses to bridge the bottlenecks between discovery and early development and thus, for advancing promising antibacterial R&D concepts into the clinics
   • “Redevelopment” of off-patent antibiotics in academic settings funded by government grants is the only currently viable way forward
   • The urgent need for efficient and innovative concepts for developing novel as well as “redeveloping” old antibiotics demands concerted action based on private and public funding
   Ursula Theuretzbacher, Principal Scientist, CEFAIA

16.20 Novel antibiotics from marine microorganisms
   • The need for novel antibiotics and novel mechanisms of action
   • Diverse chemistry from marine microorganisms
   • Examples of novel antibiotics from marine sources
   • Approaches to optimize discovery of natural product chemistry
   Tim Morley, CSO, Aquapharm

17.00 Chairman’s Closing Remarks

17.10 Close of Day Two

Want to know how to get involved? Interested in promoting your services to this market?
Kellee Halliburton, SMi Marketing on +44 (0) 207 827 6194, or email khalliburton@smi-online.co.uk

fax your registration to +44 (0)870 9090 712 or call +44 (0)870 9090 711
Overview of workshop
A workshop designed to introduce the issues relating to seeking licensing partners for antibiotic compounds in research, with an opportunity to discuss specific issues and share experiences. The unique workshop will be led by licensing expert David Scott and will present attendees with an in-depth view into licensing partnerships.

Why you should attend:
- **Develop** your knowledge of the licensing process
- **Analyse** what Big Pharma is looking for when in-licensing R&D compounds
- **Discover** specific issues relating to Antibiotic compounds
- **Learn** how to prepare an out-licensing dossier for an R&D product
- **Discuss** and network with industry experts on key issues and experiences in the field

Programme

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>08.30</td>
<td>Registration &amp; Coffee</td>
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<tr>
<td>09.00</td>
<td><strong>Welcome &amp; Introductions</strong></td>
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<tr>
<td>09.10</td>
<td>Introduction to the licensing process</td>
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<td>• Activities involved</td>
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<td>• Outline of typical deal structures</td>
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<td>09.45</td>
<td><strong>What Big Pharma is looking for when in-licensing R&amp;D compounds</strong></td>
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<td>• Key factors effecting evaluation</td>
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<td>• Specific issues relating to Antibiotic compounds</td>
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<td>10.30</td>
<td>Morning Coffee</td>
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<tr>
<td>11.00</td>
<td><strong>Preparing an out-licensing dossier for an R&amp;D product</strong></td>
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<td>• Confidential Prospectus</td>
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<td>- section by section review</td>
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<td>• Non-confidential Brochure</td>
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<td>• Presentation</td>
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<tr>
<td>11.50</td>
<td>General discussion on issues and experiences</td>
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<td>12.30</td>
<td>Close of Workshop</td>
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About the Workshop leader:
David Scott is a freelance healthcare consultant and a skilled negotiator who has closed a number of major deals for inward and outward licensing for pharmaceutical products, delivery systems and technologies. He has published widely (he is the author of the best-selling report, Scrip’s Practical Guide to Pharmaceutical Licensing) and also provides licensing training for a number of organizations including C.E.L.forpharma. David has a BSc in Chemistry as well as post-graduate qualifications in marketing and is an accredited Certified Licensing Professional. Following 22 years working in Big Pharma David has spent the past 16 years as a freelance consultant and has provided strategic advice and successfully concluded both inward and outward licensing agreements on behalf of a range of worldwide clients. His client base includes top-ranking global companies, European regional companies, biotech companies, technology start-ups and universities. He currently sits on the boards of two UK-based pharmaceutical businesses.

About PharmaConsulting:
PharmaConsulting is the business organisation for David Scott, a freelance licensing and business development consultant. www.pharmaconsulting.co.uk
Overview:
Led by the expertise of Sonia Contera, Co-Director, Oxford Martin Institute of Nanoscience for Medicine and Oxford University Lecturer, this exciting workshop will discuss the latest developments in nanoscience and will explore how nanotechnology can be used in the field of antimicrobials. Discussing antibacterial nanostructures, nanobiocomposites and drug delivery, this workshop will be a perfect opportunity to develop the use of nanotechnology in antibacterials.

Why you should attend?:
• Consider antibacterial nanostructures; their materials and their mechanisms
• Discuss the future of nanobiocomposites
• Evaluate nanobiotechnology in antimicrobial infection detection
• Discover case studies of antibacterial drug delivery with nanostructures
• Network with key industry experts on developments in this fast-paced field

Topic 1: Antibacterial nanostructures
• Introduction of the materials and their mechanism
• Antibacterial nanostructures. Some examples: Metal and Metal Oxide Nanoparticles, chitosan, C60, carbon nanotubes, nanoemulsions.
• NANOANTIBIOTICS, the future:
  - controllable and relatively uniform distribution in the target tissue,
  - improved solubility,
  - sustained and controlled release,
  - improved patient-compliance,
  - minimized side effects, and
  - enhanced cellular internalization & tackle multiple biological pathways found in broad species of microbes
• Nanotechnology-assisted detection of antimicrobial infection and resistance

Topic 2. Antibacterial drug delivery.
• Introduction to drug delivery with nanostructures. Some examples:
  - Liposomes
  - Solid-lipid combined nanoparticles for antibiotic delivery
  - Polymeric nanoparticles
  - Dendrimers
• Advantages and disadvantages of antimicrobial NPs over free antimicrobial agents.
• Nanotoxicology
• Treatment of drug-resistant bacteria and biofilms using nanotechnology

Programme
13.30 Registration & Coffee
14.00 Welcome & Introductions
14.10 Topic 1: Antimicrobial nanomaterials
14.45 Discussion
15.20 Coffee break
15.50 Topic 2: Targeted drug-delivery of antibiotics using nanotechnology
16.30 Discussion Session
17.00 Close of Workshop

About the workshop host Sonia Contera
Research interests: Linking biological physics with bio/medicine using nanoscience.
• Nanophysics for medicine, (drug-delivery, nanocomposites for tissue engineering, biosensing). Biocompatible functional nanomaterials
• Physics in biology at the nanoscale
• Molecular forces in biology, physicochemical interactions at bionano-interfaces, nanostructure/biomolecule/cells interactions

About The Oxford Martin Institute of Nanoscience for Medicine
The Oxford Martin Institute of Nanoscience for Medicine (http://www.oxfordmartin.ox.ac.uk/institutes/nanoscience) was created in 2008 to work at the interface of biology, physics, chemistry and engineering to create the tools to facilitate novel strategies for new treatments using nanostructures that target disease and promote healing. It is currently directed by Dr. Sonia Contera (physicist) and Dr. Sonia Trigueros (biologist). The Institute is part of the Oxford Martin School, a unique, interdisciplinary research community of over 300 scholars working to address the most pressing global challenges and opportunities of the 21st century.
SUPERBUGS & SUPERDRUGS
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Workshops: Wednesday 6th March 2013, London, UK
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□ £499.00 + VAT £598.80

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