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SMi presents their 14th annual conference on...

Asthma & COPD

Improving health outcomes and revolutionising clinical trials with real world studies

COPTHORNE TARA HOTEL, LONDON, UK

WORKSHOP: 10TH
CONFERENCE: 11TH-12TH

APRIL 2018

CHAIR FOR 2018:

- **Wisla Wedzicha**, Professor of Respiratory Medicine and Head of Respiratory Clinical Science, **Imperial College London**

KEYNOTE SPEAKERS INCLUDE:

- **Quan Yang**, Senior Pharmaceutical Assessor, **MHRA**
- **Maria Gerhardsson de Verdier**, Director of Epidemiology, **AstraZeneca**
- **René van der Merwe**, Senior Director Respiratory & Inflammation, **MedImmune**
- **Alison Moore**, Clinical Development Director, **GSK**
- **Peter Barnes**, Head of Respiratory Medicine, **Imperial College London**
- **Jonathan Phillips**, Principal Scientist, Inflammation, **Amgen**
- **Christopher Stevenson**, Venture Leader - COPD, Disease Interception Accelerator, **Janssen**
- **Georg Brauers**, Senior Manager Regulatory Affairs, **Boehringer Ingelheim**

REASONS TO ATTEND:

- **Explore** advancements in the use of Real-World data in clinical trials and drug development
- **Discuss** the use of triple combination therapies and reducing exacerbations in asthma & COPD sufferers
- **Review** health economics and market access for innovative treatments
- **Hear** regulatory updates in bioequivalence and drug-device combinations
- **Discover** novel Asthma and COPD Phenotyping and biomarker application for personalised medicines

PLUS ONE INTERACTIVE HALF-DAY PRE-CONFERENCE WORKSHOP | TUESDAY 10TH APRIL 2018, COPTHORNE TARA HOTEL, LONDON, UK

COPD and Asthma: How do digital solutions provide more effective management of the conditions?

Workshop Leader:

Jaquie Finn, Head of Digital Health, **Cambridge Consultants**

13.30 - 17.00



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Register online or fax your registration to +44 (0) 870 9090 712 or call +44 (0) 870 9090 711

8.30 Registration & Coffee

9.00 Chair's Opening Remarks

Wisla Wedzicha, Professor of Respiratory Medicine and Head of Respiratory Clinical Science, **Imperial College London**

NOVEL THERAPEUTICS APPROACHES TO COPD & ASTHMA

OPENING ADDRESS

9.10 Novel approaches to management and prevention of COPD exacerbations

- COPD exacerbations are important in the natural history of COPD and key outcome measures
- A number of interventions reduce exacerbations and currently there is interest in which combinations of these therapies are optimal in exacerbation prevention
- How does intervention affect differing exacerbation phenotypes both at the acute event and for prevention?

Wisla Wedzicha, Professor of Respiratory Medicine and Head of Respiratory Clinical Science, **Imperial College London**

9.50 Treating severe asthma with novel injectable antibody-based medicines

- Data from clinical trials
- Mechanism of action in the reduction of targeted inflammatory biomarkers
- Position of new biologic asthma drugs in the market

Rene van der Merwe, Senior Director Respiratory & Inflammation, **MedImmune**

10.30 Morning Coffee

11.00 Case study on gaining approval to market triple combination therapeutics

- Data supporting the use of a ICS/LABA/LAMA fixed-dose combination inhaler
- How does this compare to ICS/LABA treatments?
- What are the potential drawbacks of triple combination treatment?

Tim Higenbottam, Senior Pharmaceutical Physician, **Allergy Therapeutics**

ADVANCEMENTS IN INHALATION DEVICE DEVELOPMENT

KEYNOTE ADDRESS

11.40 Regulatory requirements, human factors and usability for inhaled drug-device combination products

- EU regulations and updates for inhalation drug development, including combination considerations
- What are the expectations of the regulatory bodies?
- How does device type affect the development and approval process?
- Usability considerations and lessons learnt
- How best to interact with regulators when applying for approval of a novel device

Quan Yang, Senior Pharmaceutical Assessor, **MHRA**

12.20 Networking Lunch

13.30 How can smart inhalers be utilised to revolutionise the use of inhalers?

- The burden of asthma and COPD remains high despite many new medicines
- A major contributor is poor adherence to maintenance medications
- Smart inhalers are being developed to monitor the way patients use their inhalers
- Can the data from smart inhalers improve patient-clinician communication?
- Can smart inhalers lead to improvements in adherence and health outcomes?

Alison Moore, Clinical Development Director, **GSK**

14.10 Repositioning Andrographolide for Steroid Resistance in COPD: Efficacy and Mechanism

- Steroid resistance is a major therapeutic challenge in COPD management
- Drugs able to enhance steroid efficacy in COPD can be attractive add-on therapies
- Andrographolide is a bioactive molecule widely used for common colds and sore throats
- Andrographolide is able to reverse steroid resistance in COPD models

Fred Wong, Head and Associate Professor, Department of Pharmacology, **National University of Singapore**

14.50 Afternoon Tea

15.20 Assessing bioequivalence of orally inhaled products (OIPs)

- Guidelines for bioequivalence of OIPs around the world (US, Japan, Brazil and EU)
- EMA concept paper on update of OIP guideline
- In vitro in vivo correlation

Georg Bravers, Senior Manager Regulatory Affairs, **Boehringer Ingelheim**

16.00 Lipid mediators as targets for therapy in asthma

- ORMDL3, sphingolipids and asthma- is there a link? Is sphingosine-1-phosphate an answer?
- Leukotrienes – is there a future for anti-leukotriene therapy?
- Prostaglandin D2 – new treatment, old targets

Grzegorz Woszczek, Principal Investigator, MRC & Asthma UK Centre in Allergic Mechanisms of Asthma, **King's College London**

16.40 Chair's Closing Remarks and Close of Day One

Register online at www.asthma-copd.co.uk

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8.30 Registration & Coffee

9.00 Chair's Opening Remarks

Wisla Wedzicha, Professor of Respiratory Medicine and Head of Respiratory Clinical Science, **Imperial College London**

EARLY DETECTION, MOLECULAR PHENOTYPING AND BIOMARKER DEVELOPMENT

OPENING ADDRESS

9.10 Genetic driven drug discovery for respiratory disease

- Learnings/cautions from the first asthma gene: ADAM33
- Recent success with TSLP and IL-33
- Overview COPD genetics
- Identify/prioritize novel COPD drug targets

Jonathan Phillips, Principal Scientist, Inflammation, **Amgen**

KEYNOTE ADDRESS

9.50 New therapeutic targets for COPD

- The need for new treatments in COPD – beyond bronchodilation
- Targeting kinases involved in inflammation
- Targeting oxidative stress
- Targeting accelerated ageing and cellular senescence

Peter Barnes, Head of Respiratory Medicine, **Imperial College London**

10.30 Morning Coffee

REAL WORLD STUDIES AND DISEASE MODIFYING DRUGS

11.00 How can we ensure better treatment for patients with chronic obstructive airway diseases by enhanced multinational observational studies?

- Redefining diseases: Where we are and where we need to go
- A real-world evidence map: Need for comparable data across disease entity, severity and countries
- Development of personalised care: Next steps

Maria Gerhardsen de Verdier, Director of Epidemiology, **AstraZeneca**

11.40 From efficacy to effectiveness, the Salford Lung Study in COPD and now Asthma

- A first in the world, Pragmatic RCT in everyday clinical practice with a pre- license medicine
- Last year COPD was published, now Asthma
- Hear about the operational challenges and solutions
- Learn how this data is being received in the external world

David Leather, Medical Vice President, Global Respiratory Franchise, **GSK**

12.20 Networking Lunch

THE EMERGING ROLE OF SMOOTH MUSCLE IN ASTHMA

13.30 The emerging role of airway smooth muscle in the pathogenesis of severe asthma

- Importance of the non-contractile function of airway smooth muscle in severe asthma
- In vivo evidence supporting a proinflammatory role of airway smooth muscle in asthma
- Evidence showing that the development of steroid resistance in airway smooth muscle can be seen both in vitro and in vivo in patients with severe asthma

Yassine Amrani, Principal Investigator, **NIHR**

14.10 Bronchial smooth muscle hyperresponsiveness, airways hyperresponsiveness and inflammation in asthma: Time to think again

- The role of Calcium Sensing Receptors on airways smooth muscle hyperresponsiveness
- How inflammation amplifies the effects of smooth muscle hyperresponsiveness while conversely the Calcium Sensing Receptor is involved in the activation of certain inflammatory cells
- Inhaled and oral corticosteroids reduce airways inflammation to varying degrees in different asthmatic patients but do not affect smooth muscle hyperresponsiveness
- Drug targets and how Calcium Sensing receptor antagonists delivered topically to the airways, might offer the first opportunity to treat asthma at its root cause

Chris Corrigan, Professor of Asthma, Allergy & Respiratory Science, **King's College London**

14.50 Afternoon Tea

15.20 The COPD - Lung cancer crossover: How can we focus our efforts on treating this disease?

- The link between Lung cancer and COPD
- Can we treat both disorders using the same drug targets?
- Can early treatment of COPD reduce the likelihood of developing lung cancer?

Christopher Stevenson, Venture Leader - COPD, Disease Interception Accelerator, **Janssen**

16.00 Inhalers: Delivering the promise

- Inhalers what we have learned from the past
 - Current situation
 - Outlook for the future and what we have left to achieve
- Dermot Ryan**, Allergy and Respiratory Research Group, Usher Institute of Population Health Sciences and Informatics, **University of Edinburgh**, Clinical Strategic Director, **Optimum Patient Care**

16.40 Chair's Closing Remarks and Close of Day Two

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HALF DAY PRE-CONFERENCE WORKSHOP

Tuesday 10th April 2018,
Cophthorne Tara Hotel, London, UK
13.30 - 17.00

COPD and Asthma: How do digital solutions provide more effective management of the conditions?

Workshop Leader:

Jaquie Finn, Head of Digital Health,
Cambridge Consultants

Workshop overview:

This half day workshop will explore how the treatment of Asthma and COPD is evolving alongside digital therapeutics. The discussion will focus on how data, nudge behaviour and enhanced user experience can improve outcomes through more effective disease management.

The workshop will provide insights on emerging technology trends relevant to the future of respiratory drug delivery devices and highlight the development and validation challenges one might face. Specifically, the workshop will examine the impact that wireless technologies, sensors, wearables and data analytics now have for pharmaceutical companies who need to start developing more holistic treatment solutions that empower

- 1) patients to better manage their disease state and
- 2) healthcare professionals make better clinical decisions throughout treatment.

Reasons to attend:

- You are looking to understand what, why and how you may want to use data from connected devices
- You are looking to build a digital solution around your drug or drug delivery device
- You are looking to gain a holistic view of the competitive space around COPD/Asthma
- You want to understand how best to conduct HF studies that encompass a digital element
- You want an overview of the current regulatory guidelines for digital elements

Programme:

- 13.30 Registration & Coffee**
- 14.00 Opening remarks and introductions**
- 14.10 Session 1- Current gaps in the treatment of COPD and Asthma**
- Compliance
 - Patient outcomes
 - Reimbursement/competitiveness
- 14.50 Session 2- Emerging trends in digital health**
- Delivering better user experience
 - Role of sensors, wearables and digital
 - biomarkers
 - Data analytics and digital services
- 15.30 Afternoon Tea**
- 16.00 Session 3 - The future of COPD and Asthma**
- Evolution of connected drug delivery devices
 - Development and manufacturing
 - Considerations
 - Regulatory considerations
- 16.40 Discussion**
- 17.00 Close of Workshop**

About the Workshop Leader:

Jaquie is Head of Digital Health at Cambridge Consultants and leads the initiative to provide strategic guidance and practical support to clients within the healthcare industry who are looking at transitioning their business model to include a digital element. This includes device connectivity, data science strategies, launch strategy and digital service design. Jaquie has a BSc in Applied Biology, 10 years' experience in Molecular Biology and 15 years' experience of Product Management and Marketing for software, hardware and digital services in medical and life science industries that include immunology, ophthalmology, neuroscience and bioinformatics. Jaquie is a member of the Chartered Institute of Marketing (CIM).

About the organisation:

Cambridge Consultants develops breakthrough products, creates and licenses IP, and provides business consultancy in technology-critical issues for clients worldwide. For more than 50 years, we have been helping clients turn business opportunities into commercial successes, whether they are launching first-to-market products, entering new markets or expanding existing markets through new technologies. Our auto-injector, inhaler and injection device development programmes extend from concept creation through to industrialisation, with a 'quality by design' approach and full compliance with international regulatory standards.

SMI PHARMACEUTICAL EVENT PLANNER 2018

JANUARY 2018

Pre-Filled Syringes Europe

17th - 18th January 2018, London, UK

Pharmaceutical Microbiology

22nd - 23rd January 2018, London, UK

Social Media in the Pharmaceutical Industry

22nd - 23rd January 2018, London, UK

FEBRUARY 2018

Parallel Trade

6th - 7th February 2018, London, UK

3D Cell Culture

21st - 22nd February 2018, London, UK

RNA Therapeutics

21st - 22nd February 2018, London, UK

MARCH 2018

Superbugs & Superdrugs

19th - 20th March 2018, London, UK

Paediatric Clinical Trials

19th - 20th March 2018, London, UK

Drug Discovery

21st - 22nd March 2018, London, UK

Controlled Release Delivery

21st - 22nd March 2018, London, UK

APRIL 2018

Antibodies and Antibody Drug Conjugates

9th - 10th April 2018, London, UK

Adaptive Designs in Clinical Trials

9th - 10th April 2018, London, UK

Asthma & COPD

11th - 12th April 2018, London, UK

Pre-Filled Syringes East Coast

11th - 12th April 2018, Boston, MA

MAY 2018

Pharmaceutical Freeze Drying Technology

8th - 9th May 2018, London, UK

Injectable Drug Delivery

16th - 17th May 2018, London, UK

Pain Therapeutics

21st - 22nd May 2018, London, UK

Highly Potent Active Pharmaceutical Ingredients

21st - 22nd May 2018, London, UK

Drug Safety

23rd - 24th May 2018, London, UK

JUNE 2018

Pre-Filled Syringes West Coast

4th - 5th June 2018, San Diego, CA

Pharmaceutical Microbiology West Coast

7th - 8th June 2018, San Diego, CA

ADMET

11th - 12th June 2018, London, UK

Molecular Diagnostics

13th - 14th June 2018, London, UK

BioBanking

13th - 14th June 2018, London, UK

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Conference: 11th - 12th April 2018, Copthorne Tara Hotel, London, UK Workshop: 10th April 2018, Copthorne Tara Hotel, London, UK

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