APSGB/HESI
Joint International Workshop

CHALLENGES FOR INHALED DRUG DISCOVERY AND DEVELOPMENT: INDUCED ALVEOLAR MACROPHAGE RESPONSES

DATE:  Tuesday 30th October – Wednesday 31st October 2012
LOCATION:  GlaxoSmithKline R & D
           Stevenage
           United Kingdom

DAY 1

08:30  Registration & Coffee

09:15  Opening remarks: aim of symposium
       Ben Forbes (Academy of Pharmaceutical Sciences Great Britain) and
       Raegan O’Lone (Health and Environmental Sciences Institute)

09:30  SAFETY CHALLENGES FOR INHALED MEDICINES

1  Causes of attrition for inhaled pharmaceuticals
   Speaker:  Ian Robinson, AstraZeneca

2  The biology of induced alveolar macrophage responses
   Speaker:  Louise Donnelly, Imperial College London, UK

10:30  Discussion & Coffee

11:00  BREAKOUT SESSION ONE: UNDERSTANDING MACROPHAGE-RELATED RESPONSES TO INHALED MEDICINES

12:30  Lunch
13:30  ALVEOLAR MACROPHAGE RESPONSES: ASSESSING & MANAGING RISK

3  Interpreting the significance of increased alveolar macrophages in rodents following inhalation of pharmaceutical materials
   Speaker: Kristen Nikula, Seventh Wave Laboratories, USA (on behalf of the STP working group)

4  Drug-induced macrophages: A Clinical Perspective
   Speaker: TBD

14:30  BREAKOUT SESSION TWO: PREDICTING AND MONITORING ADVERSE EFFECTS

16:00  Coffee

16:30  Report-back

17:00  Close
DAY 2

09:00  CONSENSUS FEEDBACK & REVIEW: Breakout sessions
       Speaker: TBD

09:30  ALVEOLAR MACROPHAGE RESPONSES: ASSESSING RISK

5  What is the scientific community doing to better understand alveolar macrophage effects?: Case studies (30 min each)

   (9:30-10:50)
   • *Can Rodent Pulmonary Findings be De-Risked? A Case Study with a Non-Clinical Solution*
     Speaker: Joseph Dybowski, Pfizer
   • *Case Study: Alveolar Macrophage Changes Induced by Inhaled Oligonucleotides in Preclinical Toxicology Studies*
     Speaker: Joel D. Parry, GlaxoSmithKline (& Inhalation Oligonucleotide Subcommittee of the OSWG)
   • *In vitro macrophage assays for selection of drug candidates for preclinical development*
     Speaker: Philippa Allen, GlaxoSmithKline

10:50-11:10  Break

   (11:10-12:30)
   • *Modeling particulate lung burden to aid the interpretation of adverse lung findings*
     Speaker: Rhys Jones, Pfizer
   • *Investing the lung response to inhaled drugs using FFPE samples*
     Speaker: Deon Hildebrand, GlaxoSmithKline
   • *Preclinical Functional and Biochemical Parameter Assessments to Support R&D of Pharmaceuticals that Induce a Pulmonary Macrophage Response: Case Studies with Inhaled Dextrans and the Monoclonal Antibody anti-avB6*
     Speaker: Matt Reed, Lovelace Respiratory Research Institute

12:30 Lunch

14:00  ALVEOLAR MACROPHAGE RESPONSES: THE WAY FORWARD

6  Challenges in nonclinical characterizations and safety evaluations of inhaled pharmaceuticals
       Speaker: Timothy McGovern, SciLucent LLC
14:30 PANEL DISCUSSION: Perspectives on drug-induced alveolar macrophage responses and path forward

15:30 Closing remarks
   Speaker: Jan Klapwijk, GlaxoSmithKline

16:00 Depart