Tuesday, September 23, 2008

08:15 Welcome and Announcements  
Dr. Ian MacKenzie, President of the Safety Pharmacology Society

08:30 President’s Keynote Address  
Dr. Craig January, University of Wisconsin  
Discovery of hERG: Historical Perspectives and Contemporary Concerns

09:30 Break

10:00 A. Translational: Biomarkers (Session Chair Mike Engwall)

  ECG and Blood Pressure as biomarkers - orthostatic hypotension  
  Speaker: Dr. Nancy Poy, Pfizer

  Ultrasound as a biomarker of cardiovascular function: valves, hypertrophy, and vascular  
  Speaker: To be confirmed

  Serum Chemistry Parameters as Cardiovascular Biomarkers  
  Speaker: To be confirmed
B. Emerging Technologies (Session Co-Chairs, Anthony Bahinski/Craig January)

**Stem Cells Session Overview:**
The field of stem cell research has been rapidly accelerating in the last several years. The development of validated human cell-based *in vitro* safety screens has the potential to facilitate earlier attrition of compounds with unacceptable safety profiles. This session will focus on recent efforts to develop a new source of pluripotent stem cells from somatic tissue and on the development of in vitro models using stem cell derived human tissue for drug safety evaluation.

**Stem cells: Emerging Applications in Medicine**
Speaker: To be confirmed

**Stem cells: New Developments in Reprogramming**
Speaker: To be confirmed

**Stem cells Panel Discussion**

C. Integrated Systems Physiology (Session Co-Chairs: Maxim Soloviev, Franz Hock)

**Introduction to Chronobiology**
Speaker: Prof. Dr. med. Dr. h.c. Björn Lemmer Institut für Experimentelle & Klinische Pharmakologie & Toxikologie

**Chronopharmacology: Considerations for Drug Development**
Speaker: Prof. Dr. med. Dr. h.c. Björn Lemmer Institut für Experimentelle & Klinische Pharmakologie & Toxikologie

**Overview of Sleep Apnea**
Speaker: Dr. Gordon Mitchell, University of Wisconsin

**Cardiopulmonary Complications of Apnea**
Speaker: Dr. Barbra Morgan, University of Wisconsin-Madison

12:00 LUNCH Break (Exhibits Hall)

Poster Viewing
2:00  
**A. Invited Oral Communications 1**
1. Presentation selected from submitted abstracts
2:15 PM  
2. Presentation selected from submitted abstracts
2:30 PM  
3. Presentation selected from submitted abstracts
2:45 PM  
4. Presentation selected from submitted abstracts

**B. Invited Oral Communications 2**
1. Presentation selected from submitted abstracts
2:15 PM  
2. Presentation selected from submitted abstracts
2:30 PM  
3. Presentation selected from submitted abstracts
2:45 PM  
4. Presentation selected from submitted abstracts

3:00  
**Break**

3:30  
**A. Translational**  (Session Chair, Ian MacKenzie)

**EEG and relevance in evaluation of sleep and seizure**
Speaker: [Invited] Dr. Joseph Arezzo, Albert Einstein College of Medicine, New York

**Gastrointestinal System: Importance of early screening for ulcer, gastric secretion, and emesis**
Speaker: To be confirmed

**Regulatory and clinical perspective on biomarkers: How much value do they really provide?**
Speaker: To be confirmed
B. Emerging Technologies  (Session Chair, Anthony Bahinski)

Session Overview:
With increasing emphasis on mechanistic studies, the emergence of biotherapeutics and earlier involvement in the drug discovery process, there is an increasing need for novel in vivo models beyond the core battery of safety pharmacology assays. This session will focus on recent efforts to develop a new generation of mice with completely humanized immune systems to evaluate the safety of biologics and the use of RNAi and transgenic animals to provide early insights into target safety.

Novel in-vivo models – Humanized/Transgenic models
Speaker: To be confirmed

Novel in-vivo models - RNAi/ssRNA/naked
Speaker: To be confirmed

DNA therapies, challenges and working methods of administration
Speaker: To be confirmed

C. Integrated Systems Physiology  (Session Chair, Ted Baird)

Neural Regulation of the Gastrointestinal Tract
Speaker: Dr. Gary M. Mawe, University of Vermont

Mechanisms of Visceral/Cardiac Pain Perception
Speaker: Dr. Robert D. Foreman, Department of Physiology, University of Oklahoma Health Sciences Center

5:00  Adjourn Day 1
Wednesday, September 24, 2008

08:00  **A. Translation: Issues in Personalized Medicine** (Session Chair, Dusty Sarazan)

   **A Personal Experience in the Treatment of Depression**
   Speaker: To be confirmed

   **The Science Behind the Story: Individual considerations in treatment**
   Speaker: To be confirmed

   **Aging Populations- From Pediatric to Geriatric: Not Just Healthy Volunteers.**
   Speaker: To be confirmed

**B. Emerging Strategies** (Session Co-Chairs, Alan Bass/Neils-Christian Ganderup)

   **Introduction**
   Speaker: Alan Bass, Schering Plough, Kenilworth, N.J.

   **Beyond hERG**
   Speaker: To be confirmed

   **Beyond QT prolongation**
   Speaker: To be confirmed

   **Industry Consortia: An update**
   Speaker: Neils-Christian Ganderup, Ellegaard Göttingen Minipigs A/S

**C. Integrated Systems Physiology** (Session Chair, Scott Mittelstadt)

   **Thrombosis**
   Speaker: Dr. John Folts, Professor of Medicine, Director, Coronary Thrombosis Research and Prevention Laboratory, University of Wisconsin.

   **Baroreflex in Blood Pressure Regulation**
   Speaker: Jeanne Seagard, PhD, Department of Anesthesiology, Zablocki Department of Veterans Affairs Medical Center, Medical College of Wisconsin

09:30  **Break**
10:00  A. Translational (Session Chair, Dusty Sarazan)

**Population Differences- How Does Gender and Race Influence Personalized Medicine?**
Speaker: Dr. Jon Ruckle, Medical Director Covance, Honolulu, HI

B. Emerging Strategies (Session Chair, Alan Bass)

**Discovery Drug Safety Studies: Select the best candidate to develop**
Speaker: To be confirmed

**Frontloading Safety Pharmacodynamic Testing:**
**Discovery phase exploratory drug safety**
Speaker: To be confirmed

C. Integrated Systems Physiology (Session Chair, Dennis Murphy)

**Ventilatory Control: Carotid Body Plasticity and Pharmacology**
Speaker: Gerald Bisgard, Professor Emeritus Comparative Biosciences, University of Wisconsin

**Effects of Gender and Age on Ventilatory Control**
Speaker: Mary Behan, Professor of Comparative Biosciences, Veterinary Medical School, University of Wisconsin

11:00  Safety Pharmacology Society Annual Meeting & Awards

12:30  LUNCH Break

2:00  A. Invited Oral Communications 3

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2:45 PM  4. Presentation selected from submitted abstracts

3:00  Break

3:30  A. Translation Track (Session Chair, Kristy Bruse)

Predictivity Model/Frame- What are the Tools and How are They Used for Predicting Liability?
Speaker: Dr. Rob Wallis, Pfizer

Case Study- Applying Biomarker tools to predict abuse liability
Speaker: To be confirmed

Panel Discussion - Personalized Medicine
Speakers: To be confirmed

B. Emerging Strategies – Integration of Toxicity and Safety Pharmacology Studies in Risk Assessment (Session Chair, Sharon Rowton/Alfred Botchway)

Single vs. multi dose studies
Speaker: Dr. Wil Redfern

Case studies to answer why you would/or not consider cross discipline assessment
Speaker: To be determined

CV, CNS, Respiratory: How to use established models for combined risk assessment
Speaker: Mary-Jeanne Kallman, Eli Lilly
C. Integrated Systems Physiology (Session Chair, Ted Baird)

Ophthalmology and the Physiology of the Eye
Speaker: To be confirmed

Long-Term Regulation of Blood Pressure: Endocrine and Renal
Speaker: Dr. Kim Hoagland, Merck & Co., Inc., West Point, Pennsylvania, USA.

Drug-Induced Activation of Immune Function: Mechanisms and Potential Adverse Effects
Speaker: Curtis Maier, Director of Immunotoxicology, GlaxoSmithKline Pharmaceuticals

5:00 Adjourn Day 2

Thursday, September 25, 2008

08:15 Introduction to Biologics (Session Chair, Tom Beck)
Speaker: Hugo Vargas, Amgen, Thousand Oaks, CA

This presentation will give an overview of the commonly encountered biologic molecules and touch on potential complexities these types of molecules present for safety pharmacology.

08:45 Point-Counter Point: Integration of Safety Pharmacology Endpoints in Toxicology Studies for Biologics Testing (Session Chair, Tom Beck)
Speakers: To be confirmed

This discussion will present the advantages and disadvantages of incorporation of Safety Pharmacology endpoints into toxicology studies conducted with large molecules. Each speaker will present his or her view and critically evaluate the others views.

09:30 Break

10:00 Biologics and Safety Pharmacology: A regulatory perspective (Session Chair, Alan Bass)
Speaker: [Invited] Scientist from US FDA
11:00  Biologics and Safety Pharmacology: A clinical perspective  
      (Session Chair, Alan Bass)  
      Speaker: Dr. Steve Flach, Medical Director, Covance Madison.

11:45  Closing Remarks

12:00  Annual Meeting Adjourns